REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: GPF515 / FGE03

Product name(s): Boscalid / Prothioconazole 350 / 200 WG

Chemical active substance(s):

Boscalid, 350 g/kg
Prothioconazole, 200 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(Article 33 application for a new product registration)

Applicant: UPL Holdings Coöperatief U.A.

Submission date: November 2024, updated March 2025, updated May 2025

MS Finalisation date: June 2025, updated October 2025 (initial Core Assessment)

November 2025 (final Core Assessment)

Version history

When	What
November 2024	V0 – Version from applicant for submission to z-RMS Poland in the frame of the PPP Authorization according to Article 33 of Regulation (EC) No 1107/2009.
March 2025	Update version following zRMS questions about the GAP for minor uses
May 2025	Updated version following zRMS comments about the boscalid livestock feedings
June 2025	Initial zRMS assessment The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are ~~struck through~~ and shaded for transparency. Following the evaluation and before sending the document for commenting, all coloured highlighting was removed, from the parts updated by the Applicant, for better legibility.
September 2025	Updated version about the stability data of the study S23-105428
October 2025	Core Assessment updated following the commenting period and adding an assessment of new studies Additional information/assessments included by the zRMS in the report in response to comments received from the cMS and the Applicant are highlighted in yellow. Not agreed or not relevant information are ~~struck through~~ and shaded for transparency.
November 2025	Final report (Core Assessment updated following the commenting period) No additional information or assessments after the commenting period.

Table of Contents

7 Metabolism and residue data (KCA section 6) 5

7.1 Summary and zRMS Conclusion 5
7.1.1 Critical GAP(s) and overall conclusion 5
7.1.2 Summary of the evaluation 9
7.1.2.1 Summary for boscalid 9
7.1.2.2 Summary for prothioconazole 10
7.1.2.3 Summary for FGE03 11
7.2 Boscalid 12
7.2.1 Stability of Residues (KCA 6.1) 12
7.2.1.1 Stability of residues during storage of samples 12
7.2.1.2 Stability of residues in sample extracts (KCA 6.1) 14
7.2.2 Nature of residues in plants, livestock and processed commodities 14
7.2.2.1 Nature of residue in primary crops (KCA 6.2.1) 14
7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1) 15
7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1) 16
7.2.2.4 Conclusion on the nature of residues in commodities of plant origin (KCA 6.7.1) 17
7.2.2.5 Nature of residues in livestock (KCA 6.2.2-6.2.5) 17
7.2.2.6 Conclusion on the nature of residues in commodities of animal origin (KCA 6.7.1) 19
7.2.3 Magnitude of residues in plants (KCA 6.3) 20
7.2.3.1 Summary of European data and new data supporting the intended uses 20
7.2.3.2 Oilseed rape (uses no. 1 and 2) 20
7.2.3.3 Minor oilseeds (uses no. 3 ~~and 4~~) 20
7.2.3.4 Conclusion on the magnitude of residues in plants 22
7.2.4 Magnitude of residues in livestock 23
7.2.4.1 Dietary burden calculation 23
7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3) 24
7.2.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation) (KCA 6.5.2-6.5.3) 29
7.2.5.1 Available data for all crops under consideration 30
7.2.5.2 Conclusion on processing studies 30
7.2.6 Magnitude of residues in representative succeeding crops 31
7.2.6.1 Field rotational crop studies (KCA 6.6.2) 31
7.2.7 Other / special studies (KCA6.10, 6.10.1) 32
7.2.8 Estimation of exposure through diet and other means (KCA 6.9) 32
7.2.8.1 Input values for the consumer risk assessment 33
7.2.8.2 Conclusion on consumer risk assessment 41
7.3 Prothioconazole 44
7.3.1 Stability of Residues (KCA 6.1) 44
7.3.1.1 Stability of residues during storage of samples 44
7.3.1.2 Stability of residues in sample extracts (KCA 6.1) 51
7.3.2 Nature of residues in plants, livestock and processed commodities 52
7.3.2.1 Nature of residue in primary crops (KCA 6.2.1) 52
7.3.2.2 Nature of residue in rotational crops (KCA 6.6.1) 54
7.3.2.3 Nature of residues in processed commodities (KCA 6.5.1) 56
7.3.2.4 Conclusion on the nature of residues in commodities of plant origin (KCA 6.7.1) 57
7.3.2.5 Nature of residues in livestock (KCA 6.2.2-6.2.5) 58
7.3.2.6 Conclusion on the nature of residues in commodities of animal origin (KCA 6.7.1) 61
7.3.3 Magnitude of residues in plants (KCA 6.3) 61

7.3.3.1 Summary of European data and new data supporting the intended uses 61
7.3.3.2 Summary of new data supporting the intended use in oilseed rape 61
7.3.3.3 Conclusion on the magnitude of residues in plants 65
7.3.4 Magnitude of residues in livestock 67
7.3.4.1 Dietary burden calculation 67
7.3.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3) 77
7.3.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation) (KCA 6.5.2-6.5.3) 82
7.3.5.1 Available data for all crops under consideration 82
7.3.5.2 Conclusion on processing studies 83
7.3.6 Magnitude of residues in representative succeeding crops 83
7.3.6.1 Field rotational crop studies (KCA 6.6.2) 84
7.3.7 Other / special studies (KCA 6.10, 6.10.1) 86
7.3.8 Estimation of exposure through diet and other means (KCA 6.9) 87
7.3.8.1 Input values for the consumer risk assessment 87
7.3.8.2 Conclusion on consumer risk assessment 90
7.4 Combined exposure and risk assessment 95
References 97

Appendix 1 Lists of data considered in support of the evaluation 100

Appendix 2 Detailed evaluation of the additional studies relied upon 114

A 2.1 Boscalid 114
A 2.1.1 Stability of residues 114
A 2.1.2 Nature of residues in plants, livestock and processed commodities 115
A 2.1.3 Magnitude of residues in plants 116
A 2.1.4 Magnitude of residues in livestock 126
A 2.1.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation) 126
A 2.1.6 Magnitude of residues in representative succeeding crops 128
A 2.1.7 Other/Special Studies 128
A 2.2 Prothioconazole 131
A 2.2.1 Stability of residues 131
A 2.2.2 Nature of residues in plants, livestock and processed commodities 188
A 2.2.3 Magnitude of residues in plants 191
A 2.2.4 Magnitude of residues in livestock 226
A 2.2.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation) 227
A 2.2.6 Other/Special Studies 227

Appendix 3 Pesticide Residue Intake Model (PRIMo) 234

A 3.1 TMDI calculations 234
A 3.1.1 Boscalid 234
A 3.1.2 Prothioconazole 236
A 3.2 IEDI calculations 237
A 3.3 IESTI calculations - Raw commodities 242
A 3.3.1 Boscalid 242
A 3.3.2 Prothioconazole 242
A 3.4 IESTI calculations - Processed commodities 248
A 3.4.1 Boscalid 248
A 3.4.2 Prothioconazole 248

Appendix 4 Additional information provided by the applicant 254

7 Metabolism and residue data (KCA section 6)

7.1 Summary and zRMS Conclusion

7.1.1 Critical GAP(s) and overall conclusion

Selection of critical uses and justification
The critical GAPs with respect to consumer intake and risk assessment for the preparation FGE03 are presented in Table 7.1-1. They have been selected from the individual GAPs in the Central zone for oilseed rape. A list of all intended uses within Poland is given in Part B, Section 0, which includes two intended uses in oilseed rape (uses no. ~~0~~1 and ~~0~~2).
One critical intended use for oilseed rape (use no. ~~0~~2) was selected based on the highest application rate and the latest application timing (BBCH), which cover intended use no. ~~0~~1.

Overall conclusion
Oilseed rape
The data available for boscalid and prothioconazole are considered sufficient for risk assessment. An exceedance of the current MRLs of 1.00 mg/kg for boscalid and of 0.15 mg/kg for prothioconazole-desthio (sum of isomers) as laid down in Reg. (EU) 396/2005 (Reg. (EU) No. 2022/1324 and Reg. (EU) No ~~2019/552~~ 2024/1318, respectively) for oilseed rape is not expected.
Minor uses
Available results show that the in force MRLs of prothioconazole (Reg. (EU) 2024/1318) on winter turnip rape (0401060-002), mustard (0401080), sunflower (0401050), poppy (0401030), linseed (0401010) will not be exceeded. An exceedance of the current MRLs for prothioconazole as laid down in Reg. (EU) 2024/1318 is expected for gold of pleasure (0401130), hemp (0401140) and borage (0401120). These uses are not accepted.

The chronic and the short-term intakes of boscalid and prothioconazole residues, according to the residue definition for risk assessment are unlikely to present a public health concern.
As far as consumer health protection is concerned, zRMS agrees with the authorization of the intended use(s) without gold of pleasure (0401130), hemp (0401140) and borage (0401120).
According to available data, no specific mitigation measures should apply.

Data gaps
Noticed data gaps are:
- ~~Storage stability study for oilseeds for 1,2,4-T and TA~~

~~This data gap should be filled in as post-registration requirement.~~

The following data gaps were identified during the peer review of the TDM metabolites (EFSA, 2018b, amended 2019) and are applicable to prothioconazole:
• *Storage stability data on 1,2,4-T, TA and TAA in high acid content commodities, on 1,2,4-T in high protein content commodities and on TLA in cereal straw and covering the maximum storage time interval of the residue samples of the residue trials in primary and rotational crops (relevant for the risk assessment to cover the complete group of TDMs).*
• *Poultry and ruminant feeding studies conducted with TLA or, alternatively, metabolism studies performed in accordance with the current recommendations as a surrogate to these feeding studies to determine the magnitude of TLA residues in products of animal origin (relevant for the risk assessment to cover the complete group of TDMs).*
• *Residue trials analysing for all TDMs and compliant with the representative use on cereals (wheat, rye, barley, oats, triticale) and on oilseed rapeseeds and supported by acceptable storage stability data on TDMs.*
• *Rotational crops field residue trials supported by acceptable storage stability data on TDMs.*
These data gaps should be filled in at the renewal of prothioconazole.

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

1	2	3	4	5	6	7		8				9			10	11
GAP number (see part B.0)*	**Crop and/ or situation ****	**Zone**	**Product code**	**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)**	**kg as/hL min max**	**water L/ha min max**	**kg as/ha min max**		
~~01~~	~~Oilseed rape (*Brassica napus*) BRSNN~~	~~CZ, HU, PL~~	~~FGE03~~	~~F~~	~~Sclerotinia (*Sclerotinia sclerotiorum*) SCLESC~~	~~WG~~	~~350 boscalid 200 prothioconazole~~	~~Spray overall~~	~~BBCH 61-69~~	~~a) 1 b) 1~~	~~-~~	~~a) 0.7 b) 0.7~~	~~100-400~~	~~a) 245 boscalid 140 prothioconazole b) 245 boscalid 140 prothioconazole~~	~~35~~	
~~0~~2	Oilseed rape (winter and spring) (*Brassica napus*) BRSNN	CZ, HU, PL	FGE03	F	Sclerotinia (*Sclerotinia sclerotiorum*) SCLESC	WG	350 boscalid 200 prothioconazole	Spray overall	BBCH 61-73	a) 1 b) 2	14	a) 0.7 b) 1.4	100-400	a) 245 boscalid 140 prothioconazole b) 490 boscalid 280 prothioconazole	35	A ~~R~~ ~~See remark below the Table~~
Minor uses according to Article 51 (zonal uses)																
~~03~~	~~gold of pleasure, winter turnip rape, mustard, sunflower, poppy linseed, flax, hemp, borage~~	~~CZ, HU, PL~~	~~FGE03~~	~~F~~	~~Sclerotinia (*Sclerotinia sclerotiorum*) SCLESC~~	~~WG~~	~~350 boscalid 200 prothioconazole~~	~~Spray overall~~	~~BBCH 61-69~~	~~a) 1 b) 1~~	~~-~~	~~a) 0.7 b) 0.7~~	~~100-400~~	~~a) 245 boscalid 140 prothioconazole b) 245 boscalid 140 prothioconazole~~	~~35~~	

~~04~~3	~~gold of pleasure (0401130),~~ winter turnip rape (0401060-002), mustard (0401080), sunflower (0401050), poppy (0401030), linseed (0401010), flax, ~~hemp (0401140), borage (0401120)~~	CZ, HU, PL	FGE03	F	Sclerotinia (*Sclerotinia sclerotiorum*) SCLESC	WG	350 boscalid 200 prothioconazole	Spray overall	BBCH 61-73	a) 1 b) 2	14	a) 0.7 b) 1.4	100-400	a) 245 boscalid 140 prothioconazole b) 490 boscalid 280 prothioconazole	35	N for gold of pleasure (0401130), hemp (0401140), borage (0401120) An exceedance of the current MRLs for PTZ (Reg. (EU) 2024/1318) is expected
																A ~~R~~ for winter turnip rape (0401060-002), mustard (0401080), sunflower (0401050), poppy (0401030), linseed (0401010) ~~See remark below the Table~~ In addition, the use on sunflower (0401050) is accepted before forming of the edible part, before BBCH 65 (BBCH 61-65).

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
** Use also code numbers according to Annex I of Regulation (EU) No 396/2005
*** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

Explanation for Column 11 “Conclusion”

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

~~Remark:~~

- ~~The interval from sampling until extraction for 1,2,4-T and TA in the Bousquet’s study (647-2023; 2023) was longer than the storage stability period for 1,2,4-T and TA in oilseed rape from S. Baxter, B. Phipps study (QG/21/002).~~ ~~**Therefore additional data on storage stability for 1,2,4-T and TA in oilseed rape, winter turnip rape (0401060-002), mustard (0401080), sunflower (0401050), poppy (0401030), linseed (0401010) are required (data gap).**~~

7.1.2 Summary of the evaluation

The preparation FGE03 is a WG formulation composed of boscalid (350 g/kg) and prothioconazole (200 g/L).

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

Reference value	Source	Year	Value	Study relied upon	Safety factor
Boscalid - Parent compound					
ADI	EC	2008	0.04	Rat 2-year oral feed	100
ARfD	EC	2008	Not necessary	Low acute toxicity and lack of developmental toxicity concerns	
Prothioconazole - Parent compound					
ADI	EC	2007	0.05	Rat oncogenicity study	100
ARfD	EC	2007	0.2	Rat developmental study	100
Prothioconazole-desthio					
ADI	EC	2007	0.01	Rat oncogenicity study	100
ARfD	EC	2007	0.01	Rat developmental study	100
1,2,4-triazole (1,2,4-T)					
ADI	EC	2018	0.023	Rat 12-month study	300
ARfD	EC	2018	0.10	Rat developmental study	300
Triazole alanine (TA)					
ADI	EC	2018	0.30	Rabbit developmental study	100
ARfD	EC	2018	0.30	Rabbit developmental study	100
Triazole acetic acid (TAA)					
ADI	EC	2018	1.00	Rat 2-generation and rabbit developmental studies	100
ARfD	EC	2018	1.00	Rat 2-generation and rabbit developmental studies	100
Triazole lactic acid (TLA)					
ADI	EC	2018	0.30	Bridging from triazole alanine (TA)	
ARfD	EC	2018	0.30	Bridging from triazole alanine (TA)	

7.1.2.1 Summary for boscalid

Table 7.1-3: Summary for boscalid

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
~~0~~1, ~~0~~2	Oilseed rape (BRSNN)	Yes	Yes	Yes	Yes	Yes	No	No
~~0~~3~~, 04~~	Minor oilseeds	Yes	Yes	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

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

7.1.2.2 Summary for prothioconazole

Table 7.1-4: Summary for prothioconazole

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?
~~0~~1, ~~0~~2	Oilseed rape (BRSNN)	Yes	Yes	Yes	Yes ~~No for 1,2,4-T and TA~~	Yes	No	No
~~0~~3~~, 04~~	Minor oilseeds	Yes	Yes	Yes	Yes ~~No for 1,2,4-T and TA~~	Yes for winter turnip rape (0401060-002), mustard (0401080), sunflower (0401050), poppy (0401030), linseed (0401010) No for gold of pleasure (0401130), hemp (0401140), borage (0401120)	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

The effects of processing on the nature of prothioconazole residues have been investigated. As residues of prothioconazole do not exceed the trigger values defined in Reg (EU) No 283/2013 (except Triazole Derivative Metabolites - TDMs), there is no need to investigate the effect of industrial and/or household processing on prothioconazole residues except for TDMs.
Regarding TDMs, studies show that they remained stable under the standard hydrolysis conditions. Studies on magnitude of residues in processed commodities in wheat after treatment with prothioconazole were presented in the Triazole Derivate Metabolites Addendum - Confirmatory data (B.7.5.2, UK, 2018).

Residues of prothioconazole residues (except TDMs) 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 exceeding residues in primary crops will be present in succeeding crops.
Regarding TDMs, in the framework of the confirmatory data, several field rotational crop trials have been conducted to investigate the magnitude of TDM residues in rotational crops after the use of triazole active substances. Residues of TA, TLA and TAA were found above 0.01 mg/kg in succeeding crops. These results were considered in the consumer risk assessment performed in the framework of the review of TDMs confirmatory data.

Considering dietary burden and based on the intended uses, no significant modification of the intake was calculated for livestock. Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary.
Regarding TDM arising from prothioconazole uses, as concluded by the UK, “further consideration is not required due to the fact that none of the TDMs were identified” in the available livestock metabolism studies conducted with prothioconazole.

7.1.2.3 Summary for FGE03

Table 7.1-5: Information on FGE03 (KCA 6.8)

Crop	PHI for FGE03 proposed by applicant	PHI/ Withholding period* sufficiently supported for		PHI for FGE03 proposed by zRMS	zRMS Comments (if different PHI proposed)
		Boscalid	Prothioconazole		
Oilseed rape (BRSNN)	35 days	Yes	Yes	35 days	-
Minor oilseeds	35 days	Yes	Yes	35 days	-

NR: not relevant
* Purpose of withholding period to be specified

Table 7.1-6: Waiting periods before planting succeeding crops

Waiting period before planting succeeding crops			Overall waiting period proposed by zRMS for FGE03
Crop group	Led by boscalid	Led by prothioconazole	
Oilseed rape (BRSNN)	~~NR~~ Not needed	~~NR~~ Not needed	~~NR~~ Not needed
Minor oilseeds	~~NR~~ Not needed	~~NR~~ Not needed	~~NR~~ Not needed
All crops	Not needed	Not needed	Not needed

NR: not relevant

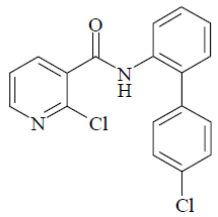
Assessment

To be fulfilled by the zRMS.

7.2 Boscalid

General data on boscalid are summarized in the table below (last updated 2023/05/05)

Table 7.2-1: General information on boscalid

Active substance (ISO Common Name)	Boscalid
IUPAC	2-chloro-N-(4'-chlorobiphenyl-2-yl)nicotinamide
Chemical structure	
Molecular formula	$C_{18}H_{12}Cl_2N_2O$
Molar mass	343.21 g/mol
Chemical group	Pyridine - carboxamides
Mode of action (if available)	C2: carboxamides, Group 7 - SDHI - Succinate DeHydrogenase Inhibitors.
Systemic	No
Company (ies)	BASF AG *
Rapporteur Member State (RMS)	Germany
Approval status	Approved Date of (01/08/2008) and reference to decision (COMMISSION DIRECTIVE 2008/44/EC - REGULATION (EU) No 2023/918).
Restriction	See Approval Directive / Regulation
Review Report	SANCO/3919 /2007-rev. 5, 21/01/2008
Current MRL regulation	Regulation (EC) No 2022/1324
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes**
EFSA Journal: Conclusion on the peer review	No
Current MRL applications on intended uses	None

* Notifier in the EU process to whom the a.s. belong(s)
** EFSA Journal 2014;12(7):3799 - see list of references

7.2.1 Stability of Residues (KCA 6.1)

7.2.1.1 Stability of residues during storage of samples

Available data

The frozen stability of boscalid (formerly named as: nicobifen) storage at < -18°C was determined in representative commodities for high water content (cabbage, peach and pea), high acid content (grape), high oil content (oilseed rape), high starch content (wheat grain), and dry feed item (wheat straw). Data has been generated within the scope of boscalid Annex I inclusion (Germany, 2002) and during the renewal framework, the studies were re-evaluated (Slovakia, 2018).

For animal commodities the frozen stability of boscalid and its metabolite M510F01 at < -18°C was determined in ruminants (muscle, liver, fat and milk) and poultry (egg) over 5-months period (Germany,

2002). Furthermore, during the renewal framework, the studies were re-evaluated and considered as acceptable (Slovakia, 2018).
The summary information on boscalid stability in plant and animal matrices is described below in Table 7.2-2.
One additional storage stability study on honey over a 5-month period is presented in the framework of this application (Flore, 2022, KCA 6.1/01). The detailed assessment of the new study is presented in Appendix 2 (A 2.1.1.1.2.1)
Procedural recoveries in all matrices were acceptable. No residues above the LOQ of 0.02 mg/kg could be detected in the corresponding control samples.

Table 7.2-2: Summary of stability data achieved at ≤ - 18°C

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products – Boscalid, parent only			
Cabbage	High water content	24 months	Germany, 2002
Peach	High water content	24 months	Germany, 2002
Pea	High water content	24 months	Germany, 2002
Grape	High acid content	16 months	Germany, 2002
Oilseed rape	High oil content	24 months	Germany, 2002
Wheat grain	High starch content	24 months	Germany, 2002
Cereal straw	Dry feed item	24 months	Germany, 2002
Animal products – Boscalid and M510F01			
Ruminant (cow)	Muscle	5 months	EFSA, 2014
Ruminant (cow)	Liver	5 months	EFSA, 2014
Ruminant (cow)	Fat	5 months	EFSA, 2014
Ruminant (cow)	Milk	5 months	EFSA, 2014
Poultry (hen)	Egg	5 months	EFSA, 2014
New data			
Animal Products – Boscalid			
Honey	Honey	5 months	Flore S., 2022, report No S22-01684 KCA 6.1/01.

Conclusion on stability of residues during storage

Available data demonstrates that residues of boscalid are stable for up to 24 months in the raw agricultural commodities cabbage, peach, peas, oilseed rape, wheat grain and cereal straw. On grape stability has been demonstrated over a period of 16 months. In animal matrices (ruminants and poultry), the frozen stability of boscalid and its metabolite M510F01 have been demonstrated for up to 5 months.
In addition, the new study has demonstrated stability of boscalid in honey for up to 5 months.
The storage period submitted in the original monograph and the additional study are sufficient to cover the storage period of the intended GAP table for this application.

zRMS comments:
In the EFSA Journal 2014;12(7):3799 it is stated that the potential degradation of residues during storage of the residues trials samples was also assessed. In the framework of the peer review, storage stability of boscalid was demonstrated for a period of 16 months at -18 °C in commodities with high acid content (grape) and 24 months at -18 °C in commodities with high water content (cabbage, peach, pea), high oil content (rape seed), dry commodities (wheat grain) and cereal straw (Germany, 2002).

Studies demonstrated storage stability of boscalid and M510F01 in milk, muscle, fat, liver, kidney and egg for up to 5 months when stored deep frozen (Germany, 2002).

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

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

Available data
Extraction efficiency of the solvents systems was demonstrated. Residue amounts of boscalid extracted from samples of wheat whole plant (high water content matrix), wheat grains (dry matrix) and oilseed rape seeds (high oil content matrix) with incurred residues were compared when extracting with different solvent systems as used in pre and post registration methods and when extracting with different solvent systems as were used in metabolism studies in accordance to the technical guideline on the evaluation of extraction efficiency of residue analytical methods, SANTE/2017/10632, rev. 4.
Extraction efficiency is summarized under dRR part B5 (Rastogi, T. Cross-Validation - Comparing Amounts of Boscalid extracted from Samples of Plant Origin with incurred Residues using three different Solvent Systems, Study Number: S22-00983)
All methods were validated in accordance with SANTE/2020/12830, rev. 2. In none of the extracts investigated was any degradation observed. From the data available, it can be concluded that boscalid is stable in sample extracts or solutions when stored during residue analysis.

Conclusion on stability of residues in sample extracts
Boscalid is stable in all sample extracts and solutions when stored during the residues analysis. The stability of the residue in sample extracts can be considered as covered by available data for the same period as the sample extracts of residue trials.

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

7.2.2 Nature of residues in plants, livestock and processed commodities

7.2.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data
The metabolism of boscalid in primary crops has been assessed in the original monograph (Germany, 2002). Crops belonging to the group of fruit crop (grape), pulse and oilseed (beans) and leafy vegetable (lettuce), were evaluated for the elucidation of the metabolic pathway of boscalid.
Furthermore, metabolism study on root and tuber vegetable (carrot) with seed treatment application[1] was performed to support the framework of the boscalid renewal (Slovakia, 2018). The summary information is described below in Table 7.2-3.
No new data are submitted in the framework of this application.

Table 7.2-3: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G [(a)]	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Fruits and	Grape	U-^{14}C-diphenyl;	F	0.8	3	45	Foliar	Germany,

[1] New data developed by BASF to support the AIR III renewal of boscalid.

fruiting vegetable		3-^{14}C- pyridine					treatment	2002
Pulses and oilseeds	Bean	U-^{14}C-diphenyl; 3-^{14}C- pyridine	G	0.7	3	18	Foliar treatment	Germany, 2002
Leafy vegetables	Lettuce	U-^{14}C-diphenyl; 3-^{14}C- pyridine	G	0.5	3	0, 14, 53[(b)]	Foliar treatment	Germany, 2002
Root and tuber vegetables	Carrot	3-^{14}C -pyridine	G	-	-	-	Seed treatment	Slovakia, 2018

(a): Outdoor/field application (F) or glasshouse/protected/indoor application (G)
(b): whole plant, forage and bean straw, respectively

Summary of plant metabolism studies reported in the EU
Metabolism studies assessed in the original monograph reveal that ^{14}C-boscalid labelled at two positions is metabolised by two key transformation steps, hydroxylation of the aromatic ring system reaction followed by glutathione conjugation on grapes, lettuce and beans.
The relevant residue in grapes consisted of parent boscalid (92.7–96.4% TRR). Boscalid was also the main component in lettuce and in green beans/pods, amounting to 99.3% and 97% of the TRR, respectively. Other metabolites were clearly below 10% TRR.
The metabolism of boscalid in carrot (after seed treatments) was qualitatively and quantitatively comparable with the previously assessed study in fruit crops, pulses and oilseeds and leafy vegetables. Labelled material leads to the conclusion that the residue consists of the parent compound boscalid only.

Conclusion on metabolism in primary crops
The metabolic pathway of boscalid is similar in all crop groups investigated. The residue definition for risk assessment and enforcement was set as parent boscalid only.
The metabolic behaviour of boscalid in primary crops is sufficiently addressed.

zRMS comments:
In EFSA Journal 2014;12(7):3799 it is stated that metabolism of boscalid was investigated for foliar treatment on fruits and fruiting vegetables (grapes), on pulses and oilseeds (beans) and on leafy vegetables (lettuce), using U-^{14}C-diphenyl and 3-^{14}C-pyridine labelled boscalid (Germany, 2002). The metabolism studies showed that the metabolic pathway is similar in all crops.
Information presented by Applicant above are sufficient to support the proposed uses on oilseeds.

Definition:
The residue for enforcement and risk assessment in all plant commodities is defined as boscalid only.
No additional data are required .

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data
During the original monograph of boscalid (Germany, 2002), a confined metabolism study in rotational crops was performed and considered acceptable. Two different labelled forms [U-^{14}C-diphenyl] and [3-^{14}C-pyridine] of boscalid were applied to bare soil followed by planting of rotational crops (radish, lettuce and wheat). The summary information is described below in Table 7.2-4.
No new data are submitted in the framework of this application.

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

Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G *	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks	
EU data								
Leafy vegetables	Lettuce	U-^{14}C-	Bare soil,	2.1	30, 120,	Mature	Bare soil	Germany,

Root and tuber vegetables	Radish	diphenyl; 3-^{14}C-pyridine	G		270, 365	crops	application - Loamy sand	2001
Cereals	Wheat							

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

Summary of plant metabolism studies reported in the EU

The major compound detected in the rotational crop matrices tested was the parent. The TRR in the lettuce leaves ranged from 0.014 to 0.072 mg/kg, on radish roots from 0.009 to 0.09 mg/kg and on wheat grain ≤ 0.028 mg/kg. The highest TRR was found in wheat straw (0.81-7.99 mg/kg), followed by wheat forage (0.19-1.47 mg/kg) and radish leaves (0.09-0.30 mg/kg). The significantly levels detected in these three matrices after plant back intervals (PBIs) of 270 and 365 days indicate that residues of boscalid may occur above the LOQ (0.05 mg/kg) in edible parts of other crops than investigated.

Further investigations were performed on the residue situation of boscalid in rotational crops. Confined study was submitted with the DAR addendum and already evaluated at EU level (Germany, 2006). The field rotational crop study was performed in wheat, and it is summarized under data point KCA 6.6.2.

Conclusion on metabolism in rotational crops

The proposed metabolic pathway in succeeding crops involves hydroxylation and conjugation reactions. The parent compound is therefore the main substance of concern in rotational crops and no metabolites of concern were identified in soil. Consequently, metabolic patterns in primary and rotational crops are found to be similar and a specific residue definition for rotational crops is not deemed necessary. The metabolic behaviour in rotational crops is sufficiently addressed.

zRMS comments:
The metabolism of boscalid in rotational crops was found to be similar to the primary crops and a specific residue definition for rotational crops is not deemed necessary (EFSA, 2014).
The metabolism of boscalid in plants is sufficiently addressed and no additional metabolism studies are necessary to support the proposed uses of the product FGE03 / Patton Boost.

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

The effects of processing nature of boscalid were investigated in the framework of the Annex I inclusion (Germany, 2002). The standard hydrolysis study simulating the effect on the nature of boscalid residues under representative processing conditions of pasteurisation, boiling and sterilisation was assessed. Tested conditions are described below in Table 7.2-5.

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

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

Conditions (Duration, Temperature, pH)	Identified compound(s) (%)	Reference
EU data		
Pasteurisation (20 minutes, 90°C, pH 4)	Parent (99.3%)	Germany, 2002
Baking, boiling, brewing (60 minutes, 100°C, pH 5)	Parent (100.2%)	Germany, 2002
Sterilisation (20 minutes, 120°C, pH 6)	Parent (99.1%)	Germany, 2002

Conclusion on nature of residues in processed commodities

The study demonstrates that food processes such as brewing, cooking, sterilisation or pasteurisation, will not impact on the nature of boscalid residues. No degradation of boscalid was observed under the standard hydrolysis conditions. The relevant residue for enforcement and risk assessment in processed commodities is therefore expected to be the same as for primary crops (Germany, 2002).

zRMS comments:
In EFSA Journal 2014;12(7):3799 it is stated that studies were conducted simulating representative hydrolytic conditions for pasteurisation (20 minutes at 90°C, pH 4), boiling/brewing/baking (60 minutes at 100°C, pH 5) and sterilisation (20 minutes at 120°C, pH 6). From these studies, it was concluded that in processed commodities, boscalid residues were shown to be stable during processing by pasteurisation, baking/brewing/boiling and sterilisation. Boscalid can be regarded as stable to hydrolysis. These processing conditions are not expected to have a significant impact on the composition of residues in matrices of plant origin (Germany, 2002).

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

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

Endpoints	
Plant groups covered	Fruits and fruiting vegetable (Grape) Pulses and oilseeds (Bean) Leafy vegetables (Lettuce) Root and tuber vegetables (Carrot)
Rotational crops covered	Leafy vegetables (Lettuce) Root and tuber vegetables (Radish) Cereals (Wheat)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Boscalid is stable under standard hydrolysis conditions
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes
Plant residue definition for monitoring	Parent only (SANCO/3919 /2007, Reg. (EU) 2022/1324)
Plant residue definition for risk assessment	Parent only (SANCO/3919 /2007)
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

During the original monograph of boscalid, metabolism studies in animals were performed and considered acceptable. Furthermore, during the renewal framework, the studies were re-evaluated and considered as acceptable but not sufficient. There is a lack of information regarding the fate of pyridine moiety in ruminants and poultry liver. Therefore, a new hen metabolism study using 3-^{14}C-pyridine was submitted by the applicant. However, the renewal assessment had already been completed by the RMS (Slovakia, 2018) and the details of the study and evaluation are not available.
The summary information is described below in Table 7.2-7. No new data submitted in the framework of this application.

Table 7.2-7: Summary of animal metabolism studies

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

Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling	
poultry		diphenyl]				Excreta	Daily	2002
						Tissues	At sacrifice	
		3-^{14}C-pyridine	Not given	Not given	Not given	Not given	Not given	Slovakia, 2018
Fish	Rainbow trout	[^{14}C-diphenyl] and pyridine-$_{15}$N, 2-$_{13}$C]	Not informed	20 µg/L; 200 g/L	28	Muscle (edible)	Daily	Germany, 2002
						Viscera (non-edible)	Daily	
						Whole fish	At sacrifice	

Summary of plant metabolism studies reported in the EU

The metabolism and distribution of radioactive labelled boscalid [U-^{14}C-diphenyl] was investigated in lactating goats and laying hens. Most of the radioactivity was excreted after administrated in both animal types showing no accumulation of U-^{14}C-diphenyl-boscalid in goat milk, eggs and tissues.

Boscalid and its metabolite M510F01 were the main residues found in animal tissues and products of hens and goats. Exception for liver (ruminant and pig) where the main component of the residue was the sum of boscalid, its metabolite M510F01 and its bound residues (M510F53 and M510F52), expressed as boscalid. Please note that the residue definition for poultry is still considered as provisional due the absence of data in the second radiolabelling (pyridine moiety) (EFSA, 2014).

No new data are submitted within the scope of this application regarding the fate of pyridine moiety in ruminants and poultry liver. The applicant for this dossier decided to wait for the member state assessment of the study submitted by BASF during the framework of the renewal, to avoid repeating animal studies due to animal welfare concerns.

No metabolism study was performed in pigs, since the metabolite patterns in rodents (rats) and ruminants (goats) did not differ significantly. For details on the rodent's metabolite patterns please refer to the toxicological and metabolism dossier (dRR Part B6).

Furthermore, the metabolism of boscalid in fish (rainbow trout) was assessed according to OECD 305 and SANCO/11187/2013. The results showed a maximum bioaccumulation factor (BCF) of 125 after 28 days in rainbow trout. However, boscalid and its metabolite showed a half-life of 1 day and after 3.3 days the TRR eliminated represent 90%, showing that the risks of bioaccumulation in fish and other aquatic organisms is unlikely due to the rapid excretion of the parent and its metabolite M510F01 and M510F05.

Conclusion on metabolism in livestock

The available studies are valid, but not sufficient to address the metabolism of boscalid in livestock. An additional study performed by BASF to address the fate of pyridine moiety in poultry liver is pending of evaluation.

zRMS comments:

According to the EFSA Journal 2014;12(7):3799 there are available metabolism studies include one study in lactating goats and one study in laying hens, both using [U-^{14}C-diphenyl] labelled boscalid. The metabolism studies on both ruminant and poultry show that parent compound, its hydroxy metabolite M510F01 and its conjugate are the main components of the residue in animal tissues and products, except in liver where the bound residues (measured as M510F53 and M510F52) were found to be the main components of the residue but the actual identity of those bound residues was not elucidated. The general metabolic pathways in rodents and ruminants were found to be comparable; the findings in ruminants can therefore be extrapolated to pigs.

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

enforcement is defined as boscalid in muscle, fat, milk and eggs and as the sum of boscalid and its hydroxy metabolite M510F01 including its conjugates expressed as boscalid in liver and kidney. For risk assessment in liver, bound residues (measured as M510F53 and M510F52, but expressed as boscalid) should also be included, but data is sufficient to derive a conversion factor for ruminant and pig livers only and supplementary data on the nature and magnitude of the bound residues in poultry liver are required. Since log Po/w of boscalid is close to 3 (Germany, 2002) and residues in fat were found to be higher than in muscle, EFSA concludes that the residue in commodities of animal origin is fat soluble.

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

In our opinion the evaluation of new poultry metabolism and the setting residue definition should be carried out at the EU level and the active substance level, not at the level of plant protection product registration in the Central Zone.

Definition:
Enforcement residue definition for animal commodities (Reg. (EU) 2022/1324):
- muscle, fat, milk and eggs: parent boscalid (BAS 510 F);
- kidney, liver: Sum of boscalid and its hydroxy metabolite 2-chloro-N-(4′-chloro-5-hydroxybiphenyl-2-yl)nicotinamide (free and conjugated) expressed as boscalid

Risk assessment residue definition for animal commodities:
- parent boscalid (BAS 510 F);
- liver (poultry) and kidney: sum of parent boscalid (BAS 510 F) and hydroxylation product M510F01 (including its conjugates), expressed as boscalid;
- liver (ruminant and pig): sum of parent boscalid (BAS 510 F) and hydroxylation product M510F01 (including its conjugates) and the bound residues (measured as M510F52 or M510F53), expressed as boscalid.

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

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

	Endpoints
Animals covered	Lactating goats
	Laying hens
	Fish
Time needed to reach a plateau concentration	2-3 days in milk
	6 days in eggs
Animal residue definition for monitoring	muscle, fat, milk and eggs: parent liver and kidney: sum of boscalid and its metabolite M510F01
Animal residue definition for risk assessment	muscle, fat, milk and eggs: parent (Reg. (EU) 2022/1324) kidney: sum of boscalid and its metabolite M510F01 liver: sum of boscalid, its metabolite M510F01 and its bound residues (measured as M510F53 and M510F52). kidney, liver: Sum of boscalid and its hydroxy metabolite 2-chloro-N-(4′-chloro-5-hydroxybiphenyl-2-yl)nicotinamide (free and conjugated) expressed as boscalid (Reg. (EU) 2022/1324)
Conversion factor	Not applicable
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	Yes (log P_{ow}=2.96)

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

The magnitude of residues on oilseed rape is covered by own data performed by the applicant for the framework of this application.

7.2.3.2 Oilseed rape (uses no. 1 and 2)

The intended uses on oilseed rape (winter and spring) are covered by new trials performed with a WG formulation containing boscalid solo (code FGG01) and are summarised in Table 7.2-9.
A total of 8 new trials in NEU were performed during 2022 and 2023 on oilseed rape representative countries north of France, Germany, United Kingdom and Poland. The crops were treated twice with the formulation FGG01 (WG – boscalid 500 g/kg) via foliar application at a dose rate of 250 g boscalid/ha (equivalent to 500 g product/ha). The initial application (A1) was made at least 14±1 day before the second application (A2) to the treated plots at BBCH 61-79. The second application (A2) was performed 35 days before crop harvest and no later than BBCH 81. Moreover, one additional plot was added in two of the new trials performed in 2022 (one each in NEU and SEU), in which an exaggerated dose of 5 N (1250 g boscalid/ha - 2.5 kg product/ha) was applied. From these trials additional samples were generated for the determination of boscalid in the processed fractions. Raw samples were sent to the processing test site for the preparation of the processed fractions, raw oil, press cake and crude oil. The details of the processed phase are described on data point 7.2.5.
Four of the new trials were performed as decline trials and whole plant samples were collected at 0, 7, 14 and 21 days and seed at 35 days after last application (DALA), which represents the normal commercial harvest. The remaining four trials were performed as harvest trials and seed samples were collected at 35 DALA, which represents the intended PHI.
The residue level of boscalid was analysed in the whole plant and seed. Quantification was performed by LC-MS/MS detection. Samples were stored for up to 311 days at < -18°C between sampling and extraction. The limit of quantification was 0.01 mg/kg.
Residues of boscalid in the whole plant ranged from 0.58 to 4.6 mg/kg and residues of boscalid found in treated seed ranged from <LOQ to 0.22 mg/kg. The detailed assessment of the new studies is presented in Appendix 2 (A 2.1.3.1.1 and A 2.1.3.1.2)
According to SANTE 2019/12752, a sufficient number of trials were available to cover the intended uses on oilseed rape. The distribution of the trials is also properly addressed. Therefore, the new trials can be considered sufficient to support the active substance boscalid in oilseed rape (intended uses no. 1 and 2) when applied according to the GAP table of formulation FGE03.
An MRL exceedance above the current value of 1 mg/kg (Reg. (EU) No 520/2011) is not expected since the maximum highest residue (HR) measured in seed was 0.22 mg/kg. The new data was input into the MRL calculator (please refer to the excel spreadsheet named as: KCA_6.3-01_OECD MRL Calculator_FGE03.xlsm) and the calculated EU MRL was 0.4 mg/kg, indicating that no exceedance of the MRL will occur.

7.2.3.3 Minor oilseeds (uses no. 3 ~~and 4~~)

The available data described above in data point 7.2.3.2 used to cover the intended use on oilseed rape can be used to cover the intended use in these minor oilseeds, extrapolation according to SANTE/2019/12752 is possible. The unprotected residue data and the new data performed on oilseed rape are sufficient to cover the intended uses no. 3.
Exceptions – please see zRMS comments below.

Table 7.2-9: Summary of EU reported and new data supporting the intended uses of FGE03 and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded (rounded) OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Oilseed rape	New trials	N-EU	GAP on which assessment is based: 2 x 0.25 kg as/ha, BBCH 61-81, PHI 35d, outdoor E/RA: <LOQ, 0.016, 0.041, 0.074, 0.081, 0.12, 0.16, 0.22	~~0.074~~ 0.078	0.22	0.375 (0.4)	1	Yes

* Source of EU MRL: Reg. (EC) No 2022/1324.

7.2.3.4 Conclusion on the magnitude of residues in plants

The intended uses on oilseed rape are considered acceptable and covered by own data performed by the applicant for the framework of this application. The data considered for this application shows that no exceedance of the MRL will occur (please refer to the excel spreadsheet named as: KCA_6.3-01_OECD MRL Calculator_FGE03.xlsm).

zRMS comments:
Residue Definitions (SANCO/3919 /2007; Reg. (EU) 2022/1324):
Monitoring (Mo): Boscalid
Risk Assessment (RA): Boscalid

Oilseed rape
Oilseed rape is the major crop in northern Europe (SANTE/2019/12752). A minimum of eight trials are required.

Two new magnitude of residue studies were submitted in the framework of this application. Summary is presented below.
Summary:
1. Study S22-01574; North, L., 2023
Four N-EU trials were conducted in accordance with the following GAP: 2 x 250 g a.s. /ha, application interval - 14 days, 2nd application at BBCH 67-81 (outdoor) to determine of the residues of boscalid in oilseed rape specimens: seed and whole plant.

Residues of boscalid in whole plant: 0.97, 1.2 mg/kg
Residues of boscalid in seed: 0.016, 0.074, 0.16; 0.22 mg/kg.

2. Study S23-0004; North, L., 2024
Four N-EU trials were conducted in accordance with the following GAP: 2 x 250 g a.s. /ha, application interval - 14 days, 2nd application at BBCH 69-80 (outdoor) to determine of the residues of boscalid in oilseed rape specimens: seed and whole plant.

Residues of boscalid in whole plant: 0.58, 0.78 mg/kg
Residues of boscalid in seed: <0.01, 0.012, 0.041, 0.081 mg/kg.

Available results show that the in force MRL of boscalid on oilseed rape of 1 mg/kg (Reg. (EU) 2022/1324) will not be exceeded. The current EU MRL for boscalid is sufficient to support the proposed use.
The trials are supported by valid storage stability data and validated analytical methods.

The proposed use on oilseed rape is considered acceptable.

Minor uses: gold of pleasure (0401130), winter turnip rape (0401060-002), mustard (0401080), sunflower (0401050), poppy (0401030), linseed (0401010), flax, hemp (0401140), borage (0401120)

Based on the Technical Guidelines SANTE/2019/12752, rev.01:
- 8 residue trials on oilseed rape (0401060) can be used for extrapolation to linseeds (0401010), poppy seeds (0401030), mustard seeds (0401080) and gold of pleasure seeds (0401130) after forming of the edible part.
- 8 residue trials on oilseed rape (0401060) can be used for extrapolation to Whole group Oilseeds (0401000), except peanuts/groundnuts (0401020) before forming of the edible part (for oilseeds, a significant part of the edible part is present from full blossom (BBCH 65) onwards).

Available results show that the in force MRL of boscalid on oilseed rape (0401060), gold of pleasure (0401130), winter turnip rape (0401060-002), mustard (0401080), sunflower (0401050), poppy (0401030), linseed (0401010), hemp (0401140) and borage (0401120) of 1 mg/kg (Reg. (EU) 2022/1324) will not be exceeded. The current EU MRL for boscalid is sufficient to support the proposed uses.

Taking into account the possibility of extrapolation (SANTE/2019/12752, rev.01) the proposed uses on minor uses: winter turnip rape (0401060-002), linseeds (0401010), poppy seeds (0401030), mustard seeds (0401080) and gold of pleasure seeds (0401130) after forming of the edible part is considered acceptable.
Following minor uses: sunflower (0401050), hemp (0401140) and borage (0401120) are accepted before forming of the edible part, before BBCH 65.

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

A livestock dietary burden calculation was performed considering the primary crops and uptake residues from previously treated soil, the input values derived in the EU Review of boscalid, and the residue levels found in oilseed rape as described above. Processing factors were used for the processed feed commodities when required. The input values for a livestock burden calculation are listed in Table 7.2-10 below. The results of the calculations are reported in Table 7.2-11.

Table 7.2-10: Input values for the dietary burden calculation (considering primary crops and uptake residues from previously treated soil)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment[1]	Input value (mg/kg)	Comment[1]
Boscalid				
Alfalfa forage (green)	0.08	STMR	1.46	Highest residue
Alfalfa, hay (fodder)	0.32	Median residue x PF (4)	5.84	Highest residue x PF (4)
Alfalfa silage	0.08	Median residue x PF (4)	1.46	Highest residue x PF (4)
Barley, straw	15.2	Median residue	33.7	Highest residue
Beet, mangel, fodder	0.05	Median residue	0.84	Highest residue
Beet, sugar, tops	0.05	Median residue	0.84	Highest residue
Cabbage heads, leaves	1.10	Median residue	2.82	Highest residue
Clover (fresh) forage	0.08	Median residue	1.46	Highest residue
Clover, hay	0.32	Median residue x PF (4)	5.84	Highest residue x PF (4)
Clover, silage	0.08	Median residue	1.46	Highest residue
Corn, field, forage/silage	0.21	Median residue	6.80	Highest residue
Grass, forage (fresh)	0.21	Median residue	6.80	Highest residue
Grass, hay	0.84	Median residue x PF (4)	27.20	Highest residue x PF (4)
Grass, silage	0.21	Median residue	6.80	Highest residue
Kale, leaves (forage)	1.10	Median residue	4.10	Highest residue
Wheat, straw	33.7	Median residue	52.7	Highest residue
Oat, straw	15.2	Median residue	33.7	Highest residue
Rye straw	19.6	Median residue	39.5	Highest residue
Rape, forage	0.078	STMR value from residue trials on oilseed rape presented in this application	0.780	Highest residue
Potatoes, culls	0.10	Median residue	0.42	Median residue
Carrot, culls	0.19	Median residue	0.38	Highest residue
Swede	0.05	Median residue	0.37	Highest residue
Turnips	0.14	Median residue	0.65	Highest residue
Barley, oat, grain	1.07	Median residue	1.07	Median residue
Corn, field, grain	0.05	Median residue	0.05	Median residue
Peas (dry)	0.13	Median residue	0.13	Median residue
Beans (dry)	0.13	Median residue	0.13	Median residue
Cotton, undelinted seed	0.05	Median residue	0.05	Median residue

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment[1]	Input value (mg/kg)	Comment[1]
Lupin, seed	0.05	Median residue	0.05	Median residue
Wheat, rye, grain	0.17	Median residue	0.17	Median residue
Apple, pomace, wet	2.52	STMR (0.42) x PF (6)	2.52	Median residue (0.42) x PF (6)
Cotton, meal	0.07	STMR (0.05) x PF (1.3)	0.07	Median residue (0.05) x PF (1.3)
Linseed meal	0.20	STMR (0.1) x PF (2)	0.20	Median residue (0.1) x PF (2)
Grape, pomace, wet	3.55	STMR (1.42) x PF (2.5)	3.55	STMR (1.42) x PF (2.5)
Peanuts meal	0.20	STMR (0.10) x PF (2)	0.20	STMR (0.10) x PF (2)
Rape, meal	0.078	STMR value from residue trials on oilseed rape presented in this application (0.078) x PF (1)	0.078	STMR value from residue trials on oilseed rape presented in this application (0.078) x PF (1)
Soya bean, meal	0.02	STMR (0.1) x PF (0.16)	0.02	STMR (0.1) x PF (0.16)
Sunflower, meal	0.32	STMR (0.16) x PF (2)	0.32	STMR (0.16) x PF (2)
Wheat, bran	0.73	STMR (0.17) x PF (4.32)	0.73	STMR (0.17) x PF (4.32)

[1] Input values from the EFSA Journal (2014);12(7):3799 - primary crops and uptake of residues from previously treated soil, unless stated different.

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)
Boscalid					
Beef cattle*	0.2316	0.335	Wheat, straw	13.97	Y
Dairy cattle*	0.3375	0.504	Wheat, straw	13.09	Y
Ram/ewe	0.5478	0.849	Wheat, straw	25.50	Y
Lamb	0.7036	1.071	Wheat, straw	25.19	Y
Breeding swine	0.048	0.094	Kale, leaves	4.09	Y
Finishing swine*	0.041	0.041	Barley, grain	1.36	Y
Broiler poultry	0.087	0.087	Brewer´s grain	1.23	Y
Layer poultry*	0.355	0.503	Wheat, straw	7.35	Y
Turkey	0.071	0.071	Brewer´s grain	0.99	Y

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

The calculated dietary burdens for all groups of livestock were found to exceed the trigger value of 0.1 mg/kg DM. Further investigation of residues is therefore required in all commodities of animal origin.

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

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Available data

Intended use on oilseed rape is fed to all livestock animals (cattle, sheep, swine and poultry) in the EU according to ENV/JM/MONO (2013).

A feeding study on laying hens was performed in the framework of boscalid for the Annex I inclusion

(DAR addendum, Germany, 2006). The study was performed with four groups, three containing twelve laying hens and one (dosed with the high dose level) containing 20 laying hens of at least 40 weeks old. One group was kept as control; one group was treated with boscalid at level 1 mg/kg food dry weight (equivalent to 0.06 mg/kg/bw), and the other received 5x (medium) and 20x (high) this dose. All treatments were performed during 29 consecutive days. Eggs were taken every 2-4 days from the previous dosed day (-1) up to 38 days after first treatment. The birds were sacrificed within 24h after the last treatment and liver, muscle and fat samples were taken. Residues of boscalid and its metabolite M510 F01 were analysed in all samples.

Analysis of whole egg samples collected through the dosing period showed that no residues of boscalid and its metabolite M510 F01 above the limit of quantification, 0.01 mg/kg and 0.02 mg/kg, respectively were found in egg from the treated hens at 1x and 5x. The highest tested dose (20 mg/kg diet) showed increasing residue level along with the time. It was estimated that a plateau had been reached within the two weeks of dosing. The highest residue level of boscalid was 0.037 mg/kg at the 20 mg/kg dose level tested group.

No residues of boscalid and its metabolite M510 F01 above LOQ were detected in any of the hen matrices (muscle, liver and fat) treated at 1 mg/kg food dry weight. For muscle no residue above LOQ was detected in all treatment. Mean residues of boscalid and its metabolite M510 F01 above LOQ were detected in liver and fat from the mid and high dose groups. For liver, residues ranged from 0.11 to 0.18 mg/kg in the mid-dose group and from 0.14 to 0.20 mg/kg in the high-dose group. For fat, mean residues of 0.009 mg/kg and 0.171 mg/kg were detected in the mid and high dose, respectively.

The dose levels used in the feeding study were sufficient to cover the calculated burdens. Significant residues in edible matrices of poultry, except muscle, are expected and an MRL for poultry products has been derived with the Reg. (EU) no. 2016/156. The existing study on poultry is out of protection and it is still accepted during the framework of the boscalid renewal (Slovakia, 2018 – AIR III). Therefore, it is still reliable to support the framework of this application. No MRL exceedance is expected for poultry products after crop treatments according to the intended GAP table of the product ~~FGG01~~ FGE03.

Two feeding studies in lactating dairy cows were performed to address the magnitude of residues in ruminants. The first study was performed for the framework of boscalid for the Annex I inclusion (DAR, Germany, 2002) and the second was developed for the framework of boscalid renewal (Slovakia, 2018).

The unprotected DAR study tested 14 cows in the ranged weight of 480 - 735 kg. Cows were divided into 4 groups (3 cows/group), one group was kept as control and cows in the other group were fed twice daily with 1.5, 4.5 and 18 mg/kg diet of boscalid for 28±1 days. Two additional cows were fed with the highest dose, one developed mastitis and was discarded from the study and the other was kept on normal diet for another 7 days, for the monitoring of the residue decline after withdrawal of the test compound. Cows were milked twice daily and on the 21st day of the study a larger amount of milk was sampled and separated into skim milk and cream. The cows were sacrificed within 24h after the last treatment and liver, kidney, muscle, and fat samples were taken. Residues of boscalid and its metabolite M510 F01 were analysed in all samples.

No residues of boscalid and its metabolites M510 F01 and M510F 02 were found in milk samples from the control and low dose groups. In a few samples of the group tested at medium dose boscalid was detected above the LOQ (0.01 mg/kg) and no residues of its metabolites (M510 F01 and M510F 02) were detected. Samples from the highest tested dose reveals a regular occurrence of boscalid from the first day onwards, with the plateau been reached within two weeks (0.04-0.05 mg/kg). Analysis of the samples from the withdrawn animal showed that residues are rapidly excreted, since no residues in milk were observed after three days from when the dosing had stopped.

Residues consisting of boscalid and its metabolite M510 F01 and M510F 02 could be quantified only in liver and kidney. In all other matrices boscalid was the only quantifiable residue. In muscle, only one sample from the high dose group showed residues of boscalid above the LOQ (0.0326 mg/kg), all others were < 0.025 mg/kg. In fat, one sample of the low dose group showed residues higher than the LOQ (0.0526 mg/kg) and the samples from the medium and high dose showed residues of boscalid in the range of 0.084 - 0.267 mg/kg. In liver and kidney only metabolites M510F01 and M510F02 were found in samples from the medium dose group. In the high dose group, boscalid as well its metabolites were determined. Additionally, liver was analysed for bound residues by microwave treatment and residues (0.09 mg/kg boscalid) were detected in the high dose group. As residues were detected in milk (skim and cream), fat, liver and kidney at the high dose level tested (18 mg/kg), this study is not considered sufficient to cover the highest dose level calculated from dietary burden for ruminants (25.5 mg/kg DM for raw/ewe).

In order to cover the dose level calculated from dietary burden for ruminants, a new study has been submitted in the framework of boscalid renewal (Slovakia, 2018 – AIR III). A total of 13 cows in the ranged

weight of 500 - 640 kg were divided into three groups, one group (3 cows) was kept as control and the cows in the other groups were fed twice daily with 35 mg/kg diet of boscalid (3 cows) and 105 mg/kg diet of boscalid (7 cows) for 29 days. From the 7 cows treated with the high dose, one has been discarded, 3 were used for the dose assessment and 3 for the monitoring of the residue decline after withdrawal of the test compound. Cows were milked twice daily and on the 22nd, 28th and 42nd day of the study a larger amount of milk was sampled and separated into skim milk and cream. The cows were sacrificed within 24 hours after the last treatment and liver, kidney, muscle, and fat (omental, perirenal and subcutaneous) samples were taken, except for the three animals in the depuration experiment which were terminated, one each on days 36, 39 and 43, of the study to determine residue decline of the test compound.

No residues of boscalid and its metabolites M510 F01 were found in milk samples from the control. For the low dose group residues of boscalid ranged from < 0.01 to 0.023 mg/kg (parent) and was < 0.01 mg/kg for the metabolite (M510 F01). Samples from the highest tested dose reveals a regular occurrence of boscalid from the first day onwards, with a peak on day 7 of the study, with the plateau been reached in the following days. Residues of boscalid were below the LOQ (< 0.01 mg/kg) in skim milk samples from all dosing groups and the maximum residues of boscalid in cream milk were 0.072 and 0.492 mg/kg for the low and high-dose groups, respectively. Analysis of the samples from the withdrawal animal showed that residues are rapidly excreted, since no residues in milk were observed after two days from when the dosing had stopped. Ater 14 days of dosing ceased the residues of boscalid in skim and cream milk (samples from the withdrawal animal) were below the LOQ.

For the cows' tissues, the maximum combined residues (boscalid and metabolite) were 0.11 and 0.24 mg/kg in liver and kidney from the low and high dose groups, respectively. No residues were detected in muscle samples. In fat, the maximum residues of boscalid were found in perirenal fat at 0.22 and 0.25 mg/kg for the low and high dose groups, respectively. From the withdrawal animals, used for the decline assessment, residues of boscalid declined to below the LOQ in all tissue samples after 10 days of dosing ceased.

Feeding studies on pigs are not developed or required since the metabolic pathways in rats and cows (ruminants) are comparable and can be extrapolated to pigs. For details on the rodent's metabolite patterns please refer to the toxicological and metabolism (dRR Part B6).

Although the log of Po/w is 2.9, which is close to 3 (Germany, 2002), the bioconcentration study showed there is no risk of boscalid accumulation in fish or other aquatic organisms due to the rapid excretion of the parent compound and its metabolite. The results showed an elimination of more than 90% of the radioactivity in 3.3 days.

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

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

Commodity	Dietary burden		Results of the livestock feeding study (EFSA, 2014)						Median residue (mg/kg)[a]	Highest residue (mg/kg)[b]	Calculated MRL (mg/kg)[c]	CF for RA
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level (mg/kg bw/d)[a]	No	Result for enforcement		Result for RA[b]					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
EU data EFSA Journal 2014;12(7):3799												
Enforcement residue definition: **- muscle, fat:** boscalid **- kidney, liver**: sum of boscalid and its hydroxy metabolite M510F01 (free and conjugated), expressed as boscalid **Risk assessment residue definition:** **- muscle, fat:** boscalid **- kidney:** sum of boscalid and its hydroxy metabolite M510F01 (free and conjugated), expressed as boscalid **- liver:** sum of boscalid, its hydroxy metabolite M510F01 (free and conjugated) and its bound residue (measured as M510F53 or M510F52), expressed as boscalid												
Pig muscle	0.048	0.094	1.22	3	<0.025	<0.025	<0.025	<0.025	<0.025	<0.025	0.025*	1.0
			3.36	3	<0.025	<0.025	<0.025	<0.025				
Pig fat			1.22	9	0.15	0.22	0.15	0.22	0.01	0.02	0.02	1.0
			3.36	9	0.17	0.25	0.17	0.25				
Pig liver			1.22	3	0.09	0.11	-	-	0.00	0.01	0.01	1.5[h]
			3.36	3	0.20	0.24	-	-				
Pig kidney			1.22	3	0.11	0.11	0.11	0.11	0.01	0.01	0.01	~~1.5~~ 1
			3.36	3	0.18	0.24	0.18	0.24				
Ruminant muscle	0.232	~~0.335~~ 1.071	1.22	3	<0.025	<0.025	<0.025	<0.025	<0.025	<0.025	0.03	1.0
			3.36	3	<0.025	<0.025	<0.025	<0.025				
Ruminant fat			1.22	9	0.15	0.22	0.15	0.22	0.06	0.09	~~1.0~~ ~~0.1~~ 0.2	1.0
			3.36	9	0.17	0.25	0.17	0.25				
Ruminant liver			1.22	3	0.09	0.11	-	-	0.03	0.05	~~0.05~~ 0.1	1.5[h]
			3.36	3	0.20	0.24	-	-				
Ruminant kidney			1.22	3	0.11	0.11	0.11	0.11	0.05	0.07	~~0.05~~ 0.1	1.0
			3.36	3	0.18	0.24	0.18	0.24				
Milk	0.338	0.504	1.22	30	0.01	n.a.	0.01[d]	n.a.	0.00	0.00	0.01	1.0

Commodity	Dietary burden		Results of the livestock feeding study (EFSA, 2014)						Median residue (mg/kg)[a]	Highest residue (mg/kg)[b]	Calculated MRL (mg/kg)[c]	CF for RA
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level (mg/kg bw/d)[a]	No	Result for enforcement		Result for RA[b]					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
			3.36	60	0.05	n.a.	0.05[e]	n.a.				
Enforcement and risk assessment residue definitions: **- muscle, fat, milk**: boscalid **- liver:** sum of boscalid and its hydroxy metabolite M510F01 (free and conjugated), expressed as boscalid												
Poultry muscle	0.335	0.503	0.06	3	<0.025	<0.025	<0.025	<0.025	<0.025	<0.025	0.025*	1.0
			0.32	3	<0.025	<0.025	<0.025	<0.025				
			1.26	3	<0.025	<0.025	<0.025	<0.025				
Poultry fat			0.06	3	<0.025	<0.025	<0.025	<0.025	0.11	0.16	0.2	1.0
			0.32	3	0.06	0.10	0.06	0.10				
			1.26	3	0.14	0.17	0.14	0.17				
Poultry liver			0.06	3	<0.05	0.05	0.08	0.05	0.20	0.28	0.3	1.0
			0.32	3	0.14	0.18	0.14	0.18				
			1.26	3	0.41	0.47	0.41	0.47				
Eggs			0.06	30	<0.01[f]	n.a.	<0.01[f]	n.a.	<0.01	<0.01	0.01	1.0
			0.32	30	<0.01[f]	n.a.	<0.01[f]	n.a.				
			1.26	50	0.02[g]	n.a.	0.02[g]	n.a.				

(*): Indicates that the MRL is set at the limit of analytical quantification
n.a.: Not applicable – only the mean values are considered for calculating MRLs in milk
(a): Median residue value according to the enforcement residue definition, derived by interpolation/extrapolation from the feeding study for the median dietary burden (FAO, 2009).
(b): Highest residue value (tissues, eggs) or mean residue value (milk) according to the enforcement residue definition, derived by interpolation/extrapolation of the maximum dietary burden between the relevant feeding groups of the study (FAO, 2009).
(c): The median conversion factor for enforcement to risk assessment.
(d): Mean residue level from day 1 until day 28 (3 cows, 10 sampling days).
(e): Mean residue level from day 1 until day 28 (6 cows, 10 sampling days).
(f): Mean residue level from day 1 until day 28 (3 hens, 10 sampling days).
(g): Mean residue level from day 1 until day 28 (5 hens, 10 sampling days).
(h): Tentative conversion factor derived from a separate ruminant feeding study.

Conclusion on feeding studies

The existing study on poultry is out of protection and it is still accepted during the framework of the boscalid renewal (Slovakia, 2018 – AIR III), therefore, it is still reliable to support the framework of this application.
The existing study on ruminants from the DAR is out of protection and it is still accepted during the framework of the boscalid renewal (Slovakia, 2018). However, it was not sufficient to cover the highest dose level calculated from dietary burden for ruminants (25.5 mg/kg DM for raw/ewe). The new study described in the renewal dossier (Slovakia, 2018) tested higher doses and are in accordance with the maximum dose level calculated. The applicant of this dossier already considered the necessity of obtain access to the study developed with higher doses by the applicant of the active substance, BASF SE, in order to avoid the study repetition due to animal welfare.
Feeding studies are valid but not sufficient. Further investigations for poultry and ruminants are necessary due to the absence of data in the second radiolabelling (pyridine moiety). Additional data has been requested by EFSA (2014) and Slovakia (2018) to address the fate of the pyridine moiety in animals' commodities.
As a final conclusion, the data-gap mentioned above does not impact the framework of this application, since the requested uses do not modify the theoretical maximum daily intake for animals and, according to the available feeding data, there is no risk for animal MRL to be exceeded.

zRMS comments:
The uses under consideration are well covered by the input levels for rape meal and rape forage, which have been used for calculations of dietary burden for livestock by EFSA (EFSA, 2014).
No new feeding studies have been performed. The Applicant refers to data of active ingredient which the data protection was expired.
A lactating cow feeding study and a laying hen feeding study for boscalid were peer-reviewed during the Annex I inclusion process and were considered to be acceptable. However, as the dose levels were insufficient to cover the calculated dietary burden for ruminants, a new feeding study was submitted during Member State consultation in the context of the Article 12 review of the existing MRLs and evaluated (EFSA, 2014).
Two groups of lactating cows, each consisting of three animals (three additional animals for the highest dose, to conduct a depuration follow-up) were dosed for 28 consecutive days with boscalid at levels of 35.8 and 116.3 mg/kg in the diet (equivalent to 1.22 and 3.36 mg/kg bw). The samples were analysed for boscalid and for M510F01, including its conjugates. In milk, a plateau level was reached after two weeks for ruminants exposed to the highest dose level.
In the Article 12 review, EFSA considered the available data as sufficient for deriving MRLs in livestock.

The studies also cover the feed intake arising from the intended uses of FGE03 / Patton Boost, as the specific input values derived in context of the present dossier are covered by the input values used by EFSA in their assessment.
Considering the input levels for dietary burden calculation of the intended uses with FGE03 / Patton Boost on oilseed rape it could be shown that the use is well covered by already registered boscalid containing products on these crops. Thus, there is no risk for animal MRLs to be exceeded.

Conclusion:
The available feeding studies demonstrate that intakes calculated for all groups of livestock are not expected to result in high amounts of residues.
Based on available feeding data, there is no risk for animal MRLs to be exceeded.

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

Data on processing studies has been generated and reviewed within the scope of boscalid Annex I inclusion (Germany, 2002) and during the renewal process of boscalid (Slovakia, 2018). Processing studies were performed on grapes, peas and oilseed rape and were considered acceptable. According to OECD guideline 508, only procedures for the representatives uses on grapes (wet pomace, juice, must and wine) and oilseed rape (meal and oil) are considered as essential (category 1). Processing procedures for cooked and canned peas were assessed as additional data.
The magnitude of residues in processed commodities of grapes (4 trials) and peas (4 trials) are covered by unprotected data generated within the scope of boscalid Annex I inclusion (Germany, 2002). The formulations code tested in the processing studies performed for Annex I inclusion was BAS 510 01 F, which is a WG formulation which contains 500 g/kg of boscalid. The data protection period of the study reports developed with this formulation submitted in support of the initial approval of boscalid on

08/11/2002 have already expired, in accordance with Article 59(1) of Regulation 1107/2009 (10 years for the initial product authorisation). Trials to assess the procedure of oil production performed for the purpose of the renewal of boscalid are still under protection. Therefore, to address this data package new processing study (North L., 2023) was performed by the applicant for the framework of this application.

7.2.5.1 Available data for all crops under consideration

The intended use on oilseed rape can be covered by new processing study data performed in the framework of this application. The summary information on boscalid processing studies is described below in Table 7.2-12. The detailed assessment of the new study is presented in Appendix 2 (A 2.1.5.2.1).

Table 7.2-13: Overview of the available processing studies

Processed commodity	Number of studies	Median PF *	Median CF	Comments	Reference
EU data					
Residue definition: Boscalid					
Rape seed					
Refined oil	4	1.29	n.a.	-	Slovakia, 2018
Meal (press cake)	4	0.56	n.a.	-	Slovakia, 2018
Oil (crude)	4	1.11	n.a.	-	Slovakia, 2018
New data					
Residue definition: Boscalid					
Rape seed					
Refined oil	2	1.05	n.a.	-	North L., 2023, report No S22-01574
Meal (press cake)	2	0.13	n.a.	-	
Oil (crude)	2	0.98	n.a.	-	

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

7.2.5.2 Conclusion on processing studies

Residue levels in refined oil and crude oil from oilseed rape processed fractions were > 1. Median processing factors of 1.29 and 1.05 were calculated for refined oil in the EU protected study and own study, respectively. And of 1.11 and 0.98 for the crude oil preparation in the EU protected study and own study, respectively. For meal a median processing factor < 1 (0.56 and 0.14) was calculated. Further processing studies are not required, as they are not expected to affect the outcome of the risk assessment.

zRMS comments:
The relevant residue for enforcement and risk assessment in processed commodities is therefore expected to be the same as for primary crops.
New data were submitted in the framework of this application. Two residue trials were conducted on oilseed rape during 2022 for the processing phase. Oilseed rape fields were treated with two foliar applications with Boscalid 500 g/kg WG at a dose rate of 1250 g boscalid/ha (equivalent to 5N dose). The applications targeted a 14±1 day retreatment interval with the second application performed during BBCH 67-81. Specimen was taken at normal commercial harvest (35 DALA) and processed into raw oil, press cake and crude oil.
The same levels of boscalid residue in processed commodities was found in the raw agricultural commodity, generating a processing factor of 1.0 for raw and crude oil.
For meal (press cake) a median processing factor < 1 (0.23 mg/kg and 0.24 mg/kg) was calculated.

Data presented by Applicant in point 7.2.5 have been accepted and are sufficient to support the proposed uses.

7.2.6 Magnitude of residues in representative succeeding crops

Oilseed rape is annual crop and can be grown in rotation. Considering available data dealing with nature of residues (see 0), residues of boscalid may occur in plants due to uptake from soil. Therefore, a study dealing with magnitude of residues in succeeding crops is required.
The existing studies on the magnitude of residues in rotational crops under practical conditions from the DAR (Germany, 2002) and Addendum 1 of the DAR (Germany, 2006), provided in support of the initial Annex I approval of boscalid, are out of protection and are still accepted during the framework of the boscalid renewal (Slovakia, 2018). Moreover, new studies were performed in EU and US with the aim to elucidate the transfer of boscalid residues from soil to succeeding crops.

7.2.6.1 Field rotational crop studies (KCA 6.6.2)

Available data
In addition to the confined rotational crop study referenced in data point 7.2.2.2, two rotational crop field trials were evaluated as part of the peer review (Germany, 2002).
In one trial, a total of 3.8 kg of boscalid was applied over two years to vegetables, during the first year an amount of 2.1 kg was applied to lettuce (2 × 0.3 kg boscalid/ha – 0.75N) and green beans (3 × 0.5 kg boscalid/ha – 1.5N) and during the second year an amount of 1.7 kg applied to carrots (3 × 0.3 kg boscalid/ha – 1.7N) and cabbage -flower (2 × 0.4 kg boscalid/ha – 1N). The following year, spring wheat was sown in the same plot and no treatment with boscalid-containing products were applied to the plots.
In the second trial, boscalid was applied on winter rape (0.5 kg boscalid/ha – 1N) and, 365 days after harvest, wheat was sown on the same plot. Residues levels of boscalid were found in wheat forage and wheat straw after two years of treatment. Although the applied dose was higher than the intended dose, these field studies demonstrate uptake of boscalid residues via roots into succeeding crops.
No new studies for residues in succeeding crops have been submitted by the applicant in the framework of this application.

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

Primary crop	Rate (g a.s./ha) (GS at application or PHI)	Residue levels in succeeding crops			
		Succeeding crop group	Succeeding crop	Sowing intervals (DAT)	Reference / Remarks
EU data					
Lettuce and green beans	2100	Cereals	Spring wheat	365	Germany, 2002
Carrots and cauliflower	1700	Cereals	Spring wheat	365	Germany, 2002
Oilseed rape	250	Cereals	Winter wheat	365	Germany, 2002

Conclusion on rotational crops studies
The available studies on rotational crops clearly indicate that there is a potential for residues in crops grown in rotation. To avoid possible problems with residues in crops which are not treated with plant protection products containing boscalid, both in the monitoring and in the consumer dietary risk assessment, special measures are proposed. A general default MRL of 0.5 mg/kg was proposed in Addendum 1 to the DAR (Germany, 2006) for all rotational crop commodities in order to take into account the soil contamination and for completion with residue legislation in the context of Article 12 (2) of Regulation (EC) No 396/2005. However, the member state suggested a more adjusted approach for different crop groups. Therefore, it is necessary to establish MRLs which are high enough to cover possible residues in most rotational crops.

zRMS comments:
No new data were submitted in the framework of this application.
Crops under evaluation are expected to be grown in rotation. In EFSA Journal 2014;12(7):3799 it is stated that according to the soil degradation studies evaluated in the framework of the peer review, the DT_{90} value of boscalid is expected to exceed one year, which is higher than the trigger value of 100 days (EC, 2008). According to the

European guidelines on rotational crops (EC, 1997b), further investigation of residues in rotational crops is therefore relevant. Moreover, as the DT_{90} value exceeds one year, boscalid is likely to accumulate in soils treated for several consecutive years and particular attention has to be paid to the plateau concentration expected in soil after several years of applications.
It should be noted that the critical GAPs of the uses under consideration are with two applications of 245 g boscalid/ha below the critical EU GAPs with 2 applications of 350 g a.s./ha. Therefore specific plant-back restrictions related to the use of FGE03 / Patton Boost are not required, provided that the product is used according to GAP.
No additional data are required.

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

Oilseed rape is considered as relevant for nectar production and collection by honeybees according to SANTE/11956/2016 rev.9. Although boscalid is a non-systemic active substance with low water solubility, which indicates that transfer from flowers to honey is considered unlikely, intended crops can be treated during the flowering period and boscalid residue levels in the honey must be addressed.
Therefore, in a new study by Knoll (2022), four trials (2 NEU and 2 SEU) were performed to determine the residues levels in honey to support the intended uses on melliferous crops (oilseed rape). Trials were performed in protected oilseed rape located in representative areas of honey production (Germany (2) and Spain (2)) during 2022. Each trial contained one untreated and one treated plot, which were treated according to the GAP table. In order to represent the worst-case scenario, two foliar applications targeted a minimum of 6 days interval with the second application performed during flowering (BBCH 60-69). Honey samples were collected from the combs, ranging from 3 to 27 days after the last application, to cover the critical period.
The residue levels of boscalid were analysed in honey following the validated analytical procedure S22-00776 described in the analytical methods section of this dossier (please refer to study Sahvorost, N., 2002 - summarized in dRR Part B5). Quantification was performed by LC-MS/MS detection. Samples were stored for up to 19 days at < -18°C between sampling and extraction. The limit of quantification was 0.01 mg/kg. Residues of boscalid found in honey ranged from < 0.01 mg/kg (LOQ) to 0.0455 mg/kg. The detailed assessment of the new studies is presented in Appendix 2 (A 2.1.7.1).
An MRL exceedance above the current value for honey of 0.1 mg/kg (Reg. (EC) No 2021/590) is not expected since the maximum highest residue (HR) measured in honey was 0.046 mg/kg. The new data performed was input into the MRL calculator, and the calculated EU MRL was 0.1 mg/kg for honey, indicating that no exceedance of the MRL will occur.
The available data for boscalid sufficiently address aspects of the residue situation that might arise from the use of FGE03. Therefore, other special studies are not needed.

zRMS comments:
Oilseed rape belongs to melliferous crops according to the SANTE/11956/2016 rev. 9, 14 September 2018.
It should be noted that boscalid is a non-systemic active substance, however FGE03 / Patton Boost will be applied during the flowering stage (BBCH 60-69) of oilseeds which is foraged by bees. Therefore, some residues in the honey can be expected after application.
New data were submitted in the framework of this application.
Four residues trials was conducted to determine the magnitude of residues boscalid in honey. Two applications of FGG01 at a dose rate of 500 g boscalid/ha were made with 7±1 day tretreatment interval with the second application performed during the flowering period (BBCH 60-69) of oilseed rape.
Residue levels for boscalid in treated samples ranged between < 0.01 mg/kg to 0.0455 mg/kg.

Available results show that the in force MRL of boscalid on honey of 0.15 mg/kg (Reg. (EU) 2022/1324) will not be exceeded. The current EU MRL for boscalid is sufficient to support the proposed use.
No additional data are required.

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

Toxicological reference values relevant for dietary risk assessment are reported in the summary of the evaluation (see 7.1.2). As ARfD was not deemed necessary, acute risk assessment is not relevant.

7.2.8.1 Input values for the consumer risk assessment

~~The median residue level for raw agricultural commodity derived from the submitted trials and the median residues derived by EFSA in previous assessments (EFSA, 2014, 2015, 2019, 2020) were the values used in the calculation. Input values for the consumer risk assessment are in Table 7.2-14 below.~~

~~**Table 7.2-15: Input values for the consumer risk assessment including uptake of residues from previously treated soil**~~

~~Commodity~~	~~Chronic risk assessment~~	
	~~Input value (mg/kg)~~	~~Comment [a]~~
~~Risk assessment residue definition: Boscalid~~		
~~Citrus fruit~~	~~0.07~~	~~STMR*PeF (EFSA, 2014)~~
~~Almonds~~	~~0.05~~	~~STMR (EFSA, 2014)~~
~~Brazil nuts~~	~~0.05~~	~~STMR (EFSA, 2014)~~
~~Cashew nuts~~	~~0.05~~	~~STMR (EFSA, 2014)~~
~~Chestnuts~~	~~0.05~~	~~STMR (EFSA, 2014)~~
~~Coconuts~~	~~0.05~~	~~STMR (EFSA, 2014)~~
~~Hazelnuts/cobnuts~~	~~0.05~~	~~STMR (EFSA, 2014)~~
~~Macadamia~~	~~0.05~~	~~STMR (EFSA, 2014)~~
~~Pecans~~	~~0.05~~	~~STMR (EFSA, 2014)~~
~~Pine nut kernels~~	~~0.05~~	~~STMR (EFSA, 2014)~~
~~Pistachios~~	~~0.27~~	~~STMR (EFSA, 2014)~~
~~Walnuts~~	~~0.05~~	~~STMR (EFSA, 2014)~~
~~Other tree nuts~~	~~0.05~~	~~STMR (EFSA, 2014)~~
~~Apple~~	~~0.42~~	~~STMR (EFSA, 2014)~~
~~Pear~~	~~0.42~~	~~STMR (EFSA, 2014)~~
~~Quince~~	~~0.42~~	~~STMR (EFSA, 2014)~~
~~Apricots~~	~~0.77~~	~~STMR (EFSA, 2014)~~
~~Cherries (sweet)~~	~~1.51~~	~~STMR (EFSA, 2014)~~
~~Peaches~~	~~0.77~~	~~STMR (EFSA, 2014)~~
~~Plums~~	~~1.21~~	~~STMR (EFSA, 2014)~~
~~Table and wine grapes~~	~~1.42~~	~~STMR (EFSA, 2014)~~
~~Strawberries~~	~~1.95~~	~~STMR (EFSA, 2014)~~
~~Cane fruit~~	~~2.53~~	~~STMR (EFSA, 2014)~~
~~Blueberries~~	~~3.60~~	~~STMR (EFSA, 2014)~~
~~Cranberries~~	~~3.60~~	~~STMR (EFSA, 2014)~~
~~Currants (red, black and white)~~	~~3.60~~	~~STMR (EFSA, 2014)~~
~~Gooseberries (green, red and yellow)~~	~~3.60~~	~~STMR (EFSA, 2014)~~

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment [a]
Mediterranean medlars	3.60	STMR (EFSA, 2014)
Elderberries	3.60	STMR (EFSA, 2014)
Other small fruits and berries	3.60	STMR (EFSA, 2014)
Rose hips	2.60	STMR*PeF (EFSA, 2014)
Mulberries (black and white)	2.60	STMR*PeF (EFSA, 2014)
Azarole/Mediterranean medlar	2.60	STMR*PeF (EFSA, 2014)
Kiwi fruits (green, red, yellow)	0.07	STMR*PeF (EFSA, 2014)
Bananas	0.05	STMR*PeF (EFSA, 2014)
Granate apples/pomegranates	2.00	MRL (EFSA, 2020)
Potatoes	0.31 0.1	STMR (EFSA, 2014)
Root and tuber vegetables except beetroots and Jerusalem artichokes	0.31	STMR (EFSA, 2014)
Beetroots	0.38	STMR (EFSA, 2014)
Jerusalem artichokes	2.0	EU MRL (EFSA, 2020)
Garlic	2.20	STMR (EFSA, 2014)
Onions	2.20	STMR (EFSA, 2014)
Shallots	2.20	STMR (EFSA, 2014)
Spring onions/green onions and Welsh onions	2.30	STMR (EFSA, 2014)
Tomatoes	0.40	STMR (EFSA, 2014)
Sweet peppers/bell peppers	0.57	STMR (EFSA, 2014)
Aubergines/egg plants	0.40	STMR (EFSA, 2014)
Okra/lady's fingers	0.57	STMR (EFSA, 2014)
Other solanaceae	0.57	STMR (EFSA, 2014)
Cucurbits – edible peel	0.73	STMR (EFSA, 2014)
Cucurbits – inedible peel	0.40	STMR (EFSA, 2014)
Flowering brassica and head brassica, except head cabbage	1.52	STMR (EFSA, 2014)
Head cabbage	1.10	STMR (EFSA, 2014)
Leafy brassica	3.65	STMR (EFSA, 2014)
Kohlrabi	1.52	STMR (EFSA, 2014)
Lettuce and other salad plants including Brassicaceae and spinaches	5.60	STMR (EFSA, 2014)
Purslanes, chards/beet leaves, grape leaves and watercress	3.65	STMR (EFSA, 2014)
Witloofs/Belgian endives	8.55	STMR (EFSA, 2014)
Herbs and edible flowers	14.45	STMR (EFSA, 2014)

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment [a]
Beans (with pods)	0.38	STMR[b]
Beans (without pods) [b]	0.50	STMR (EFSA, 2015)
Peas (with pods)	0.38	STMR[b]
Peas (without pods) [b]	0.50	STMR (EFSA, 2015)
Lentils (fresh)	3.00	STMR (EFSA, 2014)
Asparagus	0.10	STMR (EFSA, 2014)
Cardoons	0.10	STMR (EFSA, 2014)
Celeries	2.18	STMR (EFSA, 2014)
Florence fennels	2.18	STMR (EFSA, 2014)
Globe artichokes	1.23	STMR (EFSA, 2014)
Leeks	2.35	STMR (EFSA, 2014)
Rhubarbs	0.10	STMR (EFSA, 2014)
Dry pulses, except lupins/lupini beans	0.13	STMR (EFSA, 2014)
Lupins/lupini beans	0.12	STMR (EFSA, 2014)
Oilseeds, except soyabeans[b]	0.096	STMR[b]
Soyabeans	0.12	STMR (EFSA, 2014)
Barley, oats	1.07	STMR (EFSA, 2014)
Rye, wheat	0.17	STMR (EFSA, 2014)
Buckwheat, maize, millet, rice, sorghum, other cereals	0.05	STMR (EFSA, 2014)
Coffee beans	0.05	STMR (EFSA, 2014)
Herbal infusions from dried flowers and dried leaves	0.05	STMR (EFSA, 2014)
Herbal infusions from dried roots	0.95	STMR (EFSA, 2014)
Hops	24.51	STMR (EFSA, 2014)
Spices	0.05	STMR (EFSA, 2014)
Sugar cane	0.21	STMR (EFSA, 2014)
Swine meat and fat	0.03	STMR (EFSA, 2014)
Ruminants meat	0.05	STMR (EFSA, 2014)
Ruminants fat	0.12	STMR (EFSA, 2014)
Poultry meat and fat	0.03	STMR (EFSA, 2014)
Milk	0.02	STMR (EFSA, 2014)
Bird's eggs	0.01	STMR (EFSA, 2014)
Swine kidney[c]	0.05	STMR (EFSA, 2014)
Ruminants' kidney[c]	0.09	STMR (EFSA, 2014)

~~Commodity~~	~~Chronic risk assessment~~	
	~~Input value (mg/kg)~~	~~Comment [a]~~
~~Poultry liver[c]~~	~~0.06~~	~~STMR (EFSA, 2014)~~
~~Swine liver[d]~~	~~0.08~~	~~STMR (EFSA, 2014)~~
~~Ruminants' liver[d]~~	~~0.11~~	~~STMR (EFSA, 2014)~~
~~Honey and other apiculture products[b]~~	~~0.020~~	~~STMR[b]~~

~~[a] Input values from the EFSA Journal (2014);12(7):3799 – primary crops and uptake of residues from previously treated soil, unless stated different.~~
~~[b] STMR value from residue trials presented in this application~~
~~[c] Risk assessment residue definition for these commodities is as: sum of boscalid and its hydroxy metabolite M510F01 (free and conjugate), expressed as boscalid~~
~~[d] Risk assessment residue definition for these commodities is as follows: sum of boscalid and its hydroxy metabolite M510F01 (free and conjugate) and its bound residue (measured as M510F53 or M510F52), expressed as boscalid.~~

Assessments of the potential chronic dietary consumer risk resulting from exposure to residues of boscalid (BAS 510 F) were performed using the EFSA Pesticide Residues Intake Model (PRIMo) rev. 3.1. The (unrefined) risk assessment (TMDI) was based on the current EU MRLs laid down in Reg. (EU) 2022/1324. Additionally, as a more refined assessment is required (IEDI), STMRs taken from the corresponding EFSA reasoned opinions, instead of the MRLs, are included in the assessment, considering the combined assessment of primary uses and uptake of residues from previously treated soil.

Table 7.2-16: Input values for the consumer risk assessment including uptake of residues from previously treated soil

Commodity	**Chronic risk assessment (IEDI)**	
	Input value (mg/kg)	**Comment MRL – Reg. (EU) 2022/1324**
Risk assessment residue definition: boscalid		
Citrus fruits	0.05	Median Residue (CXL)
Tree nuts except pistachios	0.05*	EU MRL
Pistachios	0.27	Median residue (EFSA, 2014)
Pome fruits, except apples, pears, quinces	0.01*	EU MRL
Apples, pears, quinces	0.42	Median residue (EFSA, 2014)
Stone fruits, except apricots, cherries, peaches, plums	0.01*	EU MRL
Apricots	0.77	Median residue (EFSA, 2014)
Cherries (sweet)	1.51	Median residue (EFSA, 2014)
Peaches	0.77	Median residue (EFSA, 2014)
Plums	0.29	Median residue (EFSA, 2014)
Table and wine grapes	1.42	Median residue (EFSA, 2014)
Strawberries	1.90	Median residue (EFSA, 2014)
Cane fruits	2.47	Median residue (EFSA, 2014)
Other small fruit and berries, except rose hips, mulberries and elderberries	3.60	Median residue (EFSA, 2014)
Rose hips, mulberries and elderberries	2.60	Median residue (EFSA, 2014)
Miscellaneous fruits with edible peel	0.01*	EU MRL
Miscellaneous fruits with inedible peel, small, except kiwi	0.01*	EU MRL
Kiwi fruits (green, red, yellow)	0.08	Median residue × PF (EFSA, 2014)

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment [a]
Miscellaneous fruits with inedible peel, large except bananas, mangoes and granate apples/pomegranates	0.01*	EU MRL
Bananas	0.05	Median residue (EFSA, 2014)
Mangoes	2	EU MRL
Granate apples/pomegranates	0.50	Median residue (EFSA, 2020)
Potatoes	0.1	Median residue (EFSA, 2014)
Tropical root and tuber vegetables except sweet potatoes, yams, arrowroots	2	EU MRL
Sweet potatoes, yams, arrowroots	0.1	Median residue (EFSA, 2014)
Beetroot	0.38	Median residue (EFSA, 2014)
Carrots, horseradish	0.24	Median residue (EFSA, 2014)
Celeriac, turnip rooted celeries	0.39	Median residue (EFSA, 2014)
Jerusalem artichokes	2	EU MRL
Parsnips, parsley root, salsify, turnips	0.14	Median residue (EFSA, 2014)
Radishes	0.33	Median residue (EFSA, 2014)
Other root and tuber vegetables: swedes/rutabaga, others	2	EU MRL
Garlic, onions, shallots	0.20	Median residue (EFSA, 2014)
Spring onions/green onions and welsh onions	2.30	Median residue (EFSA, 2014)
Bulb vegetables, others	0.5	EU MRL
Tomatoes, aubergines (egg plants)	0.40	Median residue (EFSA, 2014)
Sweet peppers/bell peppers	0.56	Median residue (EFSA, 2014)
Okra/lady finger, other Solanaceae	3	EU MRL
Cucurbits with edible peel	0.73	Median residue (EFSA, 2014)
Cucurbits with inedible peel	0.40	Median residue (EFSA, 2014)
Sweet corn	0.05	EU MRL
Other fruiting vegetables	0.9	EU MRL
Broccoli	1.55	Median residue (EFSA, 2014)
Cauliflower	1.55	Median residue (EFSA, 2014)
Other flowering brassica	5	EU MRL
Brussels sprouts	0.30	Median residue (EFSA, 2014)
Head cabbage	1.10	Median residue (EFSA, 2014)
Other head brassica	5	EU MRL
Chinese cabbage	1.10	Median residue (EFSA, 2014)
Kale	1.10	Median residue (EFSA, 2014)
Other leafy brassica	9	EU MRL
Kohlrabi	1.38	STMR related to the MRL (8 mg/kg) proposed within the confirmatory MRL dossier 2018 (Current EU MRL: 5 mg/kg, STMR 0.08 mg/kg (EFSA, 2014))
Lettuce and salad plants	5.60	Median residue (EFSA, 2014) UK model: used for beansprouts
Spinaches	5.60	Median residue (EFSA, 2014)

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment [a]
Purslane	5.60	STMR related to the MRL (50 mg/kg) proposed within the confirmatory MRL dossier 2018 (Current EU MRL: 0.9 mg/kg, STMR 0.05 mg/kg)
Beet leaves (chard)	5.60	STMR related to the MRL (50 mg/kg) proposed within the confirmatory MRL dossier 2018 (Current EU MRL: 30 mg/kg, no STMR given (ESA, 2014))
Other spinach and similar	5.60	STMR related to the MRL (50 mg/kg) proposed within the confirmatory MRL dossier 2018 (Current EU MRL: 0.9 mg/kg, no STMR given (ESA, 2014))
Vine leaves (grape leaves)	0.01*	EU MRL
Water cress	0.01*	EU MRL
Witloofs/Belgian endives	1.16	Median residue (EFSA, 2014)
Herbs and edible flowers, except basil	5.60	Median residue (EFSA, 2014)
Basil	14.5	Median residue (EFSA, 2014)
Beans (with pods)	1.28	STMR related to the MRL (6 mg/kg) proposed within the Annex I renewal (Current EU MRL: 5 mg/kg, STMR 0.66 mg/kg (EFSA, 2015))
Beans (without pods)	0.11	Median residue (EFSA, 2014)
Peas (with pods)	1.28	STMR related to the MRL (6 mg/kg) proposed within the Annex I renewal (Current EU MRL: 5 mg/kg, STMR 0.66 mg/kg (EFSA, 2015))
Peas (without pods)	0.11	Median residue (EFSA, 2014)
Lentils (fresh)	3	EU MRL
Other legume vegetables	0.06	EU MRL
Asparagus	0.10	Median residue (EFSA, 2014)
Cardoons	0.9	EU MRL
Celeries	2.25	STMR related to the MRL (20 mg/kg) proposed within the confirmatory MRL dossier 2018 (Current EU MRL: 9 mg/kg, STMR 0.05 mg/kg (EFSA, 2014))
Florence fennels	2.25	STMR related to the MRL (20 mg/kg) proposed within the confirmatory MRL dossier 2018 (Current EU MRL: 9 mg/kg, STMR 0.05 mg/kg (EFSA, 2014))
Globe artichokes	1.23	Median residue (EFSA, 2014)
Leek	2.35	Median residue (EFSA, 2014)
Rhubarb	0.9	EU MRL
Bamboo shoots	0.01*	EU MRL
Palm hearts	0.01*	EU MRL
Other stem vegetables	0.5	EU MRL
Fungi	0.01*	EU MRL
Algae	0.01*	EU MRL
Beans	0.13	Median residue (EFSA, 2014)

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment [a]
Lentils	0.13	Median residue (EFSA, 2014)
Peas	0.13	Median residue (EFSA, 2014)
Lupins	3	EU MRL
Other pulses	3	EU MRL
Linseeds	0.10	Median residue (EFSA, 2014)
Peanuts/groundnuts	0.10	Median residue (EFSA, 2014)
Poppy seeds	0.10	Median residue (EFSA, 2014)
Sesame seed	1	EU MRL
Sunflower seed	0.16	Median residue (EFSA, 2014)
Rape seed /canola seeds	0.078	Median residue in this submission
Soya beans	0.10	Median residue (EFSA, 2014)
Mustard seed	0.10	Median residue (EFSA, 2014)
Cotton seed	1	EU MRL
Pumpkin seeds	1	EU MRL
Safflower	1	EU MRL
Borage seeds	0.10	Median residue (EFSA, 2014)
Gold of pleasure seeds	0.10	Median residue (EFSA, 2014)
Hemp seed	1	EU MRL
Castor beans	1	EU MRL
Other oilseeds	0.06	EU MRL
Oil fruits	0.01*	EU MRL
Cereals, except barley, oats, wheat, rye grain	0.15	EU MRL
Barley	1.07	Median residue (EFSA, 2014)
Oats	1.07	Median residue (EFSA, 2014)
Wheat	0.17	Median residue (EFSA, 2014)
Rye	0.17	Median residue (EFSA, 2014)
Teas	40	EU MRL
Coffee beans	0.05*	EU MRL
Herbal infusions (from flowers)	0.9	EU MRL
Herbal infusions (from leaves and herbs)	0.9	EU MRL
Herbal infusions (roots)	0.95	Median residue (EFSA, 2014)
Herbal infusions (any other parts of the plant)	0.01*	EU MRL
Cocoa beans	0.01*	EU MRL
Carobs/Saint John's breads)	0.01*	EU MRL
Hops	24.5	Median residue (EFSA, 2014)
Seed spices	0.9	EU MRL
Fruit spices	0.9	EU MRL
Bark spices	0.9	EU MRL

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment [a]
Root and rhizome spices except horseradish	0.4	EU MRL
Horseradish, root spices	2	EU MRL
Spices (bud, flower stigma, aril)	0.9	EU MRL
Sugar beet roots	0.05	Median residue (EFSA, 2014)
Sugar canes	7	EU MRL
Chicory roots	0.4	EU MRL
Other sugar plants	0.5	EU MRL
Swine, muscle	0.01	EU MRL
Swine, fat tissue	0.07	EU MRL
Swine, edible offal	0.07	EU MRL
Other swine products	0.05*	EU MRL
Bovine, muscle	0.01	EU MRL
Bovine, fat tissue	0.3	EU MRL
Bovine, edible offal	0.3	EU MRL
Other bovine products	0.05*	EU MRL
Sheep, muscle	0.01	EU MRL
Sheep, fat tissue	0.3	EU MRL
Sheep, edible offal	0.3	EU MRL
Other sheep products	0.05*	EU MRL
Goat, muscle	0.2	EU MRL
Goat, fat tissue	0.3	EU MRL
Goat, edible offal	0.3	EU MRL
Other goat products	0.05*	EU MRL
Equine, muscle	0.01	EU MRL
Equine, fat tissue	0.3	EU MRL
Equine, edible offal	0.3	EU MRL
Other equine products	0.05*	EU MRL
Poultry, muscle	0.01	EU MRL
Poultry, fat tissue	0.08	EU MRL
Poultry, edible offal	0.15	EU MRL
Other poultry products	0.05*	EU MRL
Other farm animals, muscle	0.01	EU MRL
Other farm animals, fat tissue	0.3	EU MRL
Other farm animals, edible offal	0.3	EU MRL
Other farm animal products, other	0.05*	EU MRL
Milk and cream	0.02	EU MRL
Birds’ eggs	0.01	EU MRL

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment [a]
Honey	0.15	EU MRL
Amphibians and reptiles	0.01*	EU MRL
Snails	0.01*	EU MRL
Other terrestrial animal products	0.01*	EU MRL
Risk assessment residue definition: sum of boscalid and its hydroxy metabolite M510F01 (free and conjugated), expressed as boscalid		
Swine, kidney	0.05*	EU MRL
Bovine, kidney	0.2	EU MRL
Sheep, kidney	0.2	EU MRL
Goat, kidney	0.2	EU MRL
Equine, liver	0.2	EU MRL
Equine, kidney	0.2	EU MRL
Poultry, kidney	0.05*	EU MRL
Poultry, liver	0.15	EU MRL
Other farm animals, liver	0.2	EU MRL
Other farm animals, kidney	0.2	EU MRL
Risk assessment residue definition: sum of boscalid, its hydroxy metabolite M510F01 (free and conjugated) and its bound residue (measured as M510F53 or M510F52), expressed as boscalid		
Swine, liver	0.05*	EU MRL
Bovine, liver	0.2	EU MRL
Sheep, liver	0.2	EU MRL
Goat, liver	0.2	EU MRL

(*) Indicates lower limit of analytical determination

7.2.8.2 Conclusion on consumer risk assessment

~~A first-tier chronic consumer risk assessment was performed for boscalid based on available data described in Table 7.2-14 and using the EFSA PRIMo model rev 3.1.~~
~~With the current EFSA model the chronic risk assessment ranges from 4 to 70% of ADI (see Table 7.2-15 and Appendix 3). The diet with the highest TMDI is "NL toddler" with 70% of ADI. For this diet, the highest contributor are apples with 11% of ADI. The diet with the second highest TMDI is "DE child" with 50% of ADI, in which apples still the major contributor with 13% of ADI.~~
~~According to the presented TMDI calculation a chronic intake of boscalid residues is unlikely to present a public health concern. The proposed uses of boscalid in the formulation 500 g/kg WG do not represent unacceptable chronic risks for the consumer. An extensive calculation sheet is presented in Appendix 3 (A 3.1). The chronic consumer intake for the representative uses is estimated to be below the ADI (= 70%). As an ARfD was not deemed necessary, acute risk assessment is not relevant. Results are listed in table 7.2-15.~~

Table 7.2-17: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo	~~70~~ 400% (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo	72% (based on NL toddler)
IESTI (% ARfD) according to EFSA PRIMo*	-

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

The proposed uses of boscalid in the formulation FGE03 do not represent unacceptable acute and chronic risks for the consumer.

zRMS comments:
The calculation of the TMDI using EFSA model (version 3.1) and all MRLs according to current Reg. (EU) No 2022/1324 led to a utilisation of the ADI of 400% with the NL toddler being the population group with the highest value. For this diet, the highest contributor is spinaches with 90% of the ADI.

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

Boscalid

LOQs (mg/kg) range from:		to:	
Toxicological reference values			
ADI (mg/kg bw/day):	0,04	ARfD (mg/kg bw):	not necessary
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2008	Year of evaluation:	2008

Input values
Details - chronic risk assessment
Supplementary results - chronic risk assessment
Details - acute risk assessment/children
Details - acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : 26

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)
400%	NL toddler	159,85	90%	Spinaches	54%	Apples	31%	Escaroles/broad-leaved endives		
262%	DE child	104,96	62%	Apples	25%	Spinaches	20%	Oranges		
229%	GEMS/Food G11	91,52	34%	Sugar canes	28%	Soyabeans	20%	Potatoes		
227%	GEMS/Food G10	90,63	41%	Lettuces	24%	Soyabeans	23%	Sugar canes		
222%	GEMS/Food G06	88,83	29%	Sugar canes	27%	Tomatoes	14%	Wheat		
219%	NL child	87,62	31%	Spinaches	29%	Apples	17%	Potatoes		
217%	GEMS/Food G08	86,92	28%	Sugar canes	25%	Lettuces	20%	Potatoes		
216%	GEMS/Food G07	86,23	30%	Lettuces	27%	Sugar canes	19%	Potatoes		
199%	IE adult	79,41	18%	Sweet potatoes	16%	Wine grapes	16%	Wine grapes		
189%	GEMS/Food G15	75,57	23%	Sugar canes	18%	Potatoes	14%	Lettuces		
168%	SE general	67,22	50%	Lettuces	21%	Potatoes	8%	Spinaches		
146%	FR child 3 15 yr	58,30	17%	Oranges	14%	Other lettuce and other salad plants	13%	Spinaches		
145%	IT adult	58,02	47%	Lettuces	20%	Other lettuce and other salad plants	12%	Spinaches		
144%	ES adult	57,60	67%	Lettuces	9%	Spinaches	6%	Oranges		
140%	ES child	56,03	52%	Lettuces	11%	Oranges	10%	Spinaches		
134%	NL general	53,43	19%	Spinaches	12%	Escaroles/broad-leaved endives	12%	Potatoes		
132%	RO general	52,70	21%	Wine grapes	19%	Potatoes	18%	Head cabbages		
131%	IT toddler	52,42	36%	Lettuces	14%	Other lettuce and other salad plants	13%	Wheat		
131%	PT general	52,33	31%	Wine grapes	27%	Potatoes	13%	Lettuces		
128%	FR toddler 2 3 yr	51,15	20%	Spinaches	16%	Apples	10%	Beans (with pods)		
124%	DE women 14-50 yr	49,44	14%	Lettuces	13%	Apples	10%	Wine grapes		
122%	FR adult	48,87	29%	Wine grapes	19%	Other lettuce and other salad plants	14%	Tea (dried leaves of Camellia sinens		
119%	DK child	47,50	18%	Lettuces	16%	Cucumbers	12%	Potatoes		
119%	DE general	47,43	12%	Apples	12%	Lettuces	10%	Wine grapes		
112%	FI 3 yr	44,80	24%	Potatoes	10%	Cucumbers	8%	Spinaches		
104%	UK toddler	41,73	17%	Potatoes	10%	Oranges	9%	Apples		
102%	FR infant	40,72	33%	Spinaches	10%	Potatoes	8%	Apples		
93%	UK infant	37,06	16%	Potatoes	8%	Apples	7%	Carrots		
92%	FI 6 yr	36,76	19%	Potatoes	10%	Lettuces	7%	Cucumbers		
87%	UK vegetarian	34,90	18%	Lettuces	10%	Wine grapes	7%	Potatoes		
74%	UK adult	29,41	15%	Lettuces	14%	Wine grapes	7%	Potatoes		
67%	PL general	26,98	17%	Potatoes	10%	Apples	7%	Tomatoes		
66%	DK adult	26,60	12%	Wine grapes	11%	Lettuces	6%	Potatoes		
63%	FI adult	25,07	18%	Lettuces	6%	Potatoes	4%	Tomatoes		
60%	LT adult	23,88	16%	Potatoes	9%	Apples	8%	Lettuces		
18%	IE child	7,33	3%	Potatoes	2%	Wheat	2%	Apples		

Conclusion:
The estimated TMDI/NEDI/IEDI was in the range of 0 % to 399,6 % of the ADI.
For 26 diet(s) the ADI is exceeded.

The refined assessment of chronic risk is required as TMDI calculations exceeded 100% of the ADI. IEDI calculation has been performed with the STMRs values taken from the corresponding EFSA reasoned opinions, instead of the MRLs, are included in the assessment, considering the combined assessment of primary uses and uptake of residues from previously treated soil. The input values are presented in Table 7.3-16, corrected by zRMS. The total chronic intake calculated accounted for 72% of the ADI (NL toddler) with apples (11%) as highest contributing commodity. Therefore the intended uses will not result in a consumer chronic exposure exceeding the ADI.

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Boscalid

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	0,04	ARfD (mg/kg bw):	not necessary
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2008	Year of evaluation:	2008

Input values

Details - chronic risk assessment | Supplementary results - chronic risk assessment | Details - acute risk assessment/children | Details - acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	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)
72%	NL toddler	28,98	11%	Apples	10%	Spinaches	5%	Table grapes		
67%	GEMS/Food G11	26,70	34%	Sugar canes	4%	Tea (dried leaves of Camellia sinensis)	4%	Wine grapes		
65%	IE adult	25,97	18%	Sweet potatoes	13%	Tea (dried leaves of Camellia sinensis)	4%	Wine grapes		
64%	GEMS/Food G06	25,63	29%	Sugar canes	5%	Tea (dried leaves of Camellia sinensis)	4%	Table grapes		
62%	GEMS/Food G07	24,72	27%	Sugar canes	5%	Wine grapes	5%	Tea (dried leaves of Camellia sinens		
60%	GEMS/Food G08	23,91	28%	Sugar canes	4%	Wine grapes	3%	Tea (dried leaves of Camellia sinens		
53%	GEMS/Food G10	21,39	23%	Sugar canes	5%	Lettuces	3%	Tea (dried leaves of Camellia sinens		
51%	GEMS/Food G15	20,39	23%	Sugar canes	4%	Wine grapes	2%	Head cabbages		
46%	DE child	18,38	13%	Apples	5%	Table grapes	3%	Spinaches		
39%	NL child	15,45	6%	Apples	4%	Table grapes	4%	Spinaches		
35%	FR adult	13,82	14%	Tea (dried leaves of Camellia sinensis)	8%	Wine grapes	2%	Other lettuce and other salad plants		
25%	FR child 3 15 yr	10,10	2%	Tea (dried leaves of Camellia sinensis)	2%	Wheat	2%	Apples		
25%	DE women 14-50 yr	9,99	3%	Tea (dried leaves of Camellia sinensis)	3%	Wine grapes	3%	Apples		
25%	DE general	9,83	3%	Tea (dried leaves of Camellia sinensis)	3%	Wine grapes	3%	Apples		
24%	NL general	9,68	4%	Tea (dried leaves of Camellia sinensis)	2%	Spinaches	2%	Wine grapes		
23%	RO general	9,26	6%	Wine grapes	4%	Head cabbages	2%	Wheat		
23%	SE general	9,23	6%	Lettuces	2%	Head cabbages	1%	Wheat		
22%	FR toddler 2 3 yr	8,78	3%	Apples	3%	Beans (with pods)	2%	Spinaches		
21%	IT adult	8,57	5%	Lettuces	2%	Other lettuce and other salad plants	2%	Wheat		
21%	PT general	8,52	9%	Wine grapes	2%	Wheat	1%	Lettuces		
21%	UK infant	8,20	6%	Tea (dried leaves of Camellia sinensis)	2%	Milk: Cattle	2%	Apples		
20%	ES adult	8,09	7%	Lettuces	1%	Wine grapes	1%	Barley		
20%	IT toddler	8,08	4%	Lettuces	3%	Wheat	2%	Other lettuce and other salad plants		
20%	DK child	7,98	3%	Cucumbers	2%	Apples	2%	Rye		
19%	ES child	7,49	6%	Lettuces	2%	Wheat	1%	Apples		
18%	UK toddler	7,14	3%	Tea (dried leaves of Camellia sinensis)	2%	Apples	2%	Wheat		
18%	UK vegetarian	7,09	5%	Tea (dried leaves of Camellia sinensis)	3%	Wine grapes	2%	Lettuces		
17%	FI 3 yr	6,85	2%	Cucumbers	2%	Strawberries	2%	Oat		
17%	UK adult	6,72	5%	Tea (dried leaves of Camellia sinensis)	4%	Wine grapes	2%	Lettuces		
17%	FR infant	6,67	4%	Spinaches	2%	Apples	2%	Beans (with pods)		
13%	FI 6 yr	5,27	1%	Strawberries	1%	Cucumbers	1%	Lettuces		
12%	DK adult	4,97	3%	Wine grapes	1%	Lettuces	1%	Apples		
10%	FI adult	4,06	2%	Lettuces	1%	Wine grapes	0,7%	Coffee beans		
10%	PL general	3,87	2%	Apples	1%	Table grapes	1%	Head cabbages		
9%	LT adult	3,60	2%	Apples	1%	Head cabbages	0,9%	Lettuces		
3%	IE child	1,34	0,5%	Wheat	0,3%	Apples	0,3%	Currants (red, black and white)		

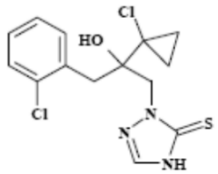
Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Boscalid is unlikely to present a public health concern.

Updated extensive calculation sheets are presented in Appendix 3.
Since the setting of an ARfD was not deemed necessary for boscalid, no acute consumer risk assessment was performed.
The proposed uses of boscalid in the product FGE03/ Patton Boost do not represent unacceptable chronic and acute risks for the consumer.
No further studies are required to support the proposed uses.

7.3 Prothioconazole

General data on prothioconazole are summarized in the table below (last updated 2024/05/16)

Table 7.3-1: General information on prothioconazole

Active substance (ISO Common Name)	Prothioconazole
IUPAC	(RS)-2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-2,4-dihydro-1,2,4-triazole-3-thione
Chemical structure	
Molecular formula	$C_{14}H_{15}Cl_2N_3OS$
Molar mass	344.26 g/mol
Chemical group	Triazolinthione
Mode of action (if available)	G1: C14-demethylase in sterol biosynthesis – DeMethylation Inhibitor (DMI) – SBI class I
Systemic	Yes
Company	Bayer CropScience AG*
Rapporteur Member State (RMS)	Poland (UK was the original RMS)
Approval status	Approved Date of (01/08/2008) and reference to decision (COMMISSION DIRECTIVE 2008/44/EC - REGULATION (EU) No 2023/918)
Restriction	Only uses as a fungicide may be authorised
Review Report	SANCO/3923/07 – final 10/12/2007, revised 26/01/2021
Current MRL regulation	Regulation (EC) No 2024/1318
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes
EFSA Journal: conclusion on the peer review	Yes, Prothioconazole, EFSA Journal 2007, TDMs (confirmatory data) EFSA Journal 2018.
EFSA Journal: conclusion on Article 12	Yes (EFSA Journal 2014 and EFSA Journal 2020**)
Current MRL applications on intended uses	EFSA-Q-2019-00353 (UK) - Oilseed rape Status: Reasoned opinion available (EFSA Journal 2020;18(2):5999)

* Notifier in the EU process to whom the a.s. belong(s)
** EFSA, 2014;12(2):3689, EFSA, 2020;18(2):5999

7.3.1 Stability of Residues (KCA 6.1)

7.3.1.1 Stability of residues during storage of samples

Available data

Prothioconazole

The frozen stability of prothioconazole-desthio storage at < -18°C was determined in representative commodities for high water content (wheat green, spinach, sugar beet, tomato and oilseed pod), high oil content (oilseed rape), high starch content (wheat grain), and dry feed item (wheat straw, oilseed straw and dry pea). Data has been generated within the scope of prothioconazole Annex I inclusion (DAR addendum - United Kingdom, 2007) and during the framework of the article 12 MRL review (EFSA, 2014).

Moreover, in the context of Article 12 confirmatory data assessment, the stability of the hydroxylated metabolites of prothioconazole isomers (prothioconazole-α-hydroxy-desthio, prothioconazole-3-hydroxy-

desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio) were determined in high oil content (oilseed rape and soya bean), high water content (tomato), high starch content (potato) and high acid content (orange) (EFSA, 2020).
Two additional studies on the storage stability study of residues of prothioconazole-desthio and 5 hydroxy prothioconazole-desthio (sum of isomers - PTZ-α-hydroxydesthio, PTZ-3-hydroxydesthio, PTZ-4-hydroxydesthio, PTZ-5-hydroxydesthio, PTZ-6-hydroxydesthio) metabolites is presented in the framework of this application. Stability was assessed in orange, field bean (dried), oilseed rape (seed) and wheat (forage, grain and straw) over a 12-months period (Giancola, D., 2024, study No. QG/21/001 – interim report) and in honey over a period of 13 months (Giancola, D., 2023, study No.: QG/21/007). The detailed assessment of the new studies is presented in Appendix 2 (A 2.2.1.1.1.1 and A 2.2.1.1.2.1, respectively).
The summary information on prothioconazole-desthio and 5 hydroxy prothioconazole-desthio metabolites stability in plants and animal matrices is described below in Table 7.3-1.

TDMs
The frozen stability of the triazole derivate metabolites (TDMs - 1,2,4-triazole, triazole alanine (TA), triazole lactic acid (TLA) and triazole acetic acid (TAA)) was investigated in the framework of peer review (United Kingdom, 2018b; EFSA, 2018). The data is additionally included in the evaluation of confirmatory data following the Article 12 MRL review of prothioconazole (EFSA, 2020).
Moreover, an additional study on the storage stability of TDMs (1,2,4-triazole, triazole alanine (TA), triazole lactic acid (TLA) and triazole acetic acid (TAA)) on honey was performed for the framework of this application. Stability was assessed in honey over a 6-months period (Giancola, D., 2023, study No.: QG/21/007). The detailed assessment of the new study is presented in Appendix 2 (A 2.2.1.1.2.1).
The stability of the TDMs (TA, TLA and TAA) in animal matrices was previously assessed by the TDMG, to avoid the repletion of test on vertebrates a letter of access to access the study ID: 869333 ([redacted], 2020) is provided. The summary information on TDMs stability in plant and animal matrices is described below in Table 7.3-2.

Table 7.3-1: Summary of stability data for prothioconazole-desthio and 5 hydroxy prothioconazole-desthio metabolites achieved at ≤ - 18°C (unless stated otherwise)

Matrix	Characteristics of the matrix according to SANTE/2020/12830, Rev.2	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products			
Wheat green material	High water content	18 months Prothioconazole-desthio (JAU 6476-desthio)	United Kingdom, 2007 (DAR addendum)
Wheat grain	Dry commodity (high starch content)	18 months Prothioconazole-desthio (JAU 6476-desthio)	United Kingdom, 2007 (DAR addendum)
Wheat straw	Dry commodity	18 months Prothioconazole-desthio (JAU 6476-desthio)	United Kingdom, 2007 (DAR addendum)
Spinach	High water content	24 months Prothioconazole-desthio	EFSA, 2014
Sugar beet	High water content	24 months Prothioconazole-desthio	EFSA, 2014
Tomatoes	High water content	24 months Prothioconazole-desthio	EFSA, 2014
Oilseed rape (seed)	High oil content	24 months Prothioconazole-desthio	EFSA, 2014

Matrix	Characteristics of the matrix according to SANTE/2020/12830, Rev.2	Acceptable Maximum Storage duration	Reference
Oilseed rape (straw)	Dry commodity	24 months Prothioconazole-desthio	EFSA, 2014
Oilseed rape (pod)	High water content	24 months Prothioconazole-desthio	EFSA, 2014
Dry peas	Dry commodity (high protein content)	24 months Prothioconazole-desthio	EFSA, 2014
Soya beans Oilseed rape	High oil content	24 months Prothioconazole-α-hydroxy-desthio, Prothioconazole-3-hydroxy-desthio, Prothioconazole-4-hydroxy-desthio, Prothioconazole-5-hydroxy-desthio, Prothioconazole-6-hydroxy-desthio	United Kingdom, 2018a
Tomatoes	High water content	24 months Prothioconazole-α-hydroxy-desthio, Prothioconazole-3-hydroxy-desthio, Prothioconazole-4-hydroxy-desthio, Prothioconazole-5-hydroxy-desthio, Prothioconazole-6-hydroxy-desthio	United Kingdom, 2018a
Potatoes	High starch content	24 months Prothioconazole-α-hydroxy-desthio, Prothioconazole-3-hydroxy-desthio, Prothioconazole-4-hydroxy-desthio, Prothioconazole-5-hydroxy-desthio, Prothioconazole-6-hydroxy-desthio	United Kingdom, 2018a
Oranges	High acid content	24 months Prothioconazole-α-hydroxy-desthio, Prothioconazole-3-hydroxy-desthio, Prothioconazole-4-hydroxy-desthio, Prothioconazole-5-hydroxy-desthio, Prothioconazole-6-hydroxy-desthio	United Kingdom, 2018a
Animal Products			
Ruminant	Liver, kidney, muscle, fat & milk	1 month Prothioconazole-desthio, Prothioconazole-3-hydroxy-desthio (M14), Prothioconazole-4-hydroxy-desthio (M15)	United Kingdom, 2004
New data			
Plant products			
Wheat forage	High water content	24 months Prothioconazole-α-hydroxy-desthio, Prothioconazole-3-hydroxy-desthio, Prothioconazole-4-hydroxy-desthio, Prothioconazole-5-hydroxy-desthio, ~~Prothioconazole-6-hydroxy-desthio~~ 12 months Prothioconazole-6-hydroxy-desthio	Giancola, D., 2024~~3~~5, study No.: QG/21/001 KCA 6.1/02 ~~– interim report~~
Wheat grain	Dry commodity (high starch content)	24 months Prothioconazole-α-hydroxy-desthio Prothioconazole-3-hydroxy-desthio Prothioconazole-4-hydroxy-desthio Prothioconazole-5-hydroxy-desthio ~~Prothioconazole-6-hydroxy-desthio~~ 12 months Prothioconazole-6-hydroxy-desthio	
Wheat straw	Dry commodity	24 months	

Matrix	Characteristics of the matrix according to SANTE/2020/12830, Rev.2	Acceptable Maximum Storage duration	Reference
		Prothioconazole-α-hydroxy-desthio Prothioconazole-3-hydroxy-desthio Prothioconazole-4-hydroxy-desthio Prothioconazole-5-hydroxy-desthio Prothioconazole-6-hydroxy-desthio	
Orange	High acid content	24 months Prothioconazole-α-hydroxy-desthio, Prothioconazole-3-hydroxy-desthio, Prothioconazole-4-hydroxy-desthio, Prothioconazole-5-hydroxy-desthio, Prothioconazole-6-hydroxy-desthio	
Bean (dried)	High protein content	24 months Prothioconazole-desthio ~~Prothioconazole-α-hydroxy-desthio~~ ~~Prothioconazole-3-hydroxy-desthio~~ Prothioconazole-4-hydroxy-desthio Prothioconazole-5-hydroxy-desthio Prothioconazole-6-hydroxy-desthio 12 months Prothioconazole-α-hydroxy-desthio 18 months Prothioconazole-3-hydroxy-desthio	
Oilseed rape seed	High oil content	24 months Prothioconazole-desthio Prothioconazole-α-hydroxy-desthio Prothioconazole-3-hydroxy-desthio ~~Prothioconazole-4-hydroxy-desthio~~ ~~Prothioconazole-5-hydroxy-desthio~~ ~~Prothioconazole-6-hydroxy-desthio~~ 18 months Prothioconazole-4-hydroxy-desthio 12 months Prothioconazole-5-hydroxy-desthio 6 months Prothioconazole-6-hydroxy-desthio	
Animal Products			
Honey	No group	13 months Prothioconazole-desthio Prothioconazole-α-hydroxy-desthio, Prothioconazole-3-hydroxy-desthio, Prothioconazole-4-hydroxy-desthio, Prothioconazole-5-hydroxy-desthio, Prothioconazole-6-hydroxy-desthio	Giancola, D., 2023, study No.: QG/21/007 KCA 6.1/0~~4~~5
No new data were submitted in the framework of this application.			

Table 7.3-2: Summary of stability data for TDMs (1,2,4-triazole, triazole alanine (TA), triazole lactic acid (TLA) and triazole acetic acid (TAA) achieved at) ≤ - 18°C (unless stated otherwise)

Matrix	Characteristics of the matrix according to SANTE/2020/12830, Rev.2	Acceptable Maximum Storage duration (months)				Reference
		1,2,4-Triazole	TA	TAA	TLA	
Data relied on in EU						
Plant products						
Barley, wheat grain	Dry commodity (high starch content)	12	26	26	48	EFSA, 2018
Barley, wheat straw	Dry commodity	12	53	40	48	EFSA, 2018
Soya beans	High oil content	12	26	53	48	EFSA, 2018
Oilseed rape	High oil content	not stable	not stable	53	48	EFSA, 2018
Dry peas, navy beans	Dry commodity (high protein content)	No data	15	25	48	EFSA, 2018
Oranges	High acid content	No data	No data	No data	48	EFSA, 2018
Apples, tomatoes, mustard leaves, wheat forage, radishes tops/roots, turnip roots, sugar beet roots, cabbages, lettuces	High water content	6	53	53	48	EFSA, 2018
Animal Products						
Ruminant	Milk	18	No data	No data	No data	EFSA, 2018
	Eggs	12	No data	No data	No data	
	Liver	12	No data	No data	No data	
	Muscle	12	No data	No data	No data	
	Fat	12	No data	No data	No data	
New data						
Plant Products						
Oilseed rape seed	High oil content commodity	15 days	~~12~~ 15 days	12	12	Baxter, B. Phipps, 2025, KCP 8.1-04 (KCA 6.1/03) – Report No. QG/21/002
Field bean (dried)	Dry commodity (high protein content)	12	~~12~~ 1	12	12	
Wheat grain	Dry commodity (high starch content)	12	~~12~~ 6	12	12	
Wheat straw	-	12	~~12~~ 1	12	12	
Oranges	High acid content commodity	~~12~~ 6	12	12	12	
Wheat forage	High water content commodity	12	12	12	12	
Oilseed rape seed	High oil content commodity	~~Up to~~ 90 days				Sandro Jooß, 2025 Study Code S23-105428 ~~ongoing~~ KCA 6.1/04
Cereal grain	Dry commodity (high starch content)	~~Up to~~ 12 months				Sandro Jooß, 2025 Study Code S23-105428 ~~ongoing~~ KCA 6.1/04
Honey		6	6	6	6	Mealing, H, 2024, study No.: QG/21/006 KCA 6.1/~~05~~06

Matrix	Characteristics of the matrix according to SANTE/2020/12830, Rev.2	Acceptable Maximum Storage duration (months)				Reference
		1,2,4-Triazole	TA	TAA	TLA	
Animal Products						
Matrix not disclosed	Milk	18	6	6	6	[redacted], 2020, study No.: 869333 KCA 6.1/~~06~~07
	Cream	No data	6	6	6	
	Eggs	12	6	6	6	
	Liver	12	6	6	6	
	Kidney	No data	6	6	6	
	Muscle	12	6	6	6	
	Fat	12	6	6	6	

Conclusion on stability of residues during storage

Prothioconazole

Residues of prothioconazole-desthio were shown to be stable in all wheat matrices (green material/forage, grain and straw) over an 18-months period (United Kingdom, 2007). Moreover, the stability of prothioconazole-desthio was determined for high water content (tomato, sugar beet, spinach, oilseed rape pods), in high oil content (oilseed rape seed) and dry commodities (dry pea and oilseed rape straw) for a period of 24 months (EFSA, 2014).
In the context of Article 12 confirmatory data assessment (EFSA, 2020) residues of 5 hydroxylated metabolites were demonstrated to be stable for 24 months when stored at - 18°C in high-water (tomato), high starch (potato), high oil (soya beans, oilseed rape seed) and high acid (orange) commodities.

One of the new storage stability studies shows stability of the 5 hydroxylated metabolites in orange, field bean (dried), oilseed rape (seed) and wheat (forage, grain and straw) under deep freeze storage conditions (≤ -18°C) for at least 24 months. The exceptions - please see zRMS comments below.

The other new storage stability study shows stability of the 5 hydroxylated metabolites in honey under deep freeze storage conditions (≤ -18°C) for at least 13 months. Mean recovery of each analyte at each interval was in the range of 70% to 120%. Therefore, prothioconazole-desthio and the hydroxylated metabolites are stable in honey for up to 13 months.

According to the Draft Assessment Report (United Kingdom, 2004) residues of prothioconazole-desthio, prothioconazole-3-hydroxy-desthio (M14) and prothioconazole-4-hydroxy-desthio (M15) were shown to be stable in ruminants animal matrices (liver, kidney, muscle, fat and milk) for one month.
As samples from the prothio-desthio analyte were stored frozen for a maximum of 631 days for oilseed rape (seed), it is concluded that the residue data is valid with regards to storage stability. Samples which analysed the 5-hydroxy prothio-desthio were stored for 138 days (approximately 5 months) and the maximum storage period covered is 24 months, it is concluded that storage period is supported.
Stability data in plant matrices, to support the use of FGE03 on oilseed rape, is considered to be covered by unprotected ‘data relied on in EU’ and new data.

TDMs

The storage stability of all TDMS (TA, TLA, TAA and 1,2,4-Triazole) was proved in different commodity groups over different period of storage. For details, please refer to Table 7.3-2.
A new storage stability study is submitted (Jooß, S., 2025, Study No S23-105428) by the applicant to confirm the stability of residues of Triazole Derivative Metabolites (TDMs) metabolites stored under deep freeze storage conditions in in oilseed rape (seeds) and cereal (grain) at ≤ 18 °C (target) in the dark over a storage period up to 12 months for cereal (grain) and up to 3 months for oilseed rape (seeds). It should be noted that the CRO performing this study (Eurofins) was the same CRO that performed the analysis of the submitted residue trials 1,2,4-T and TA in oilseed rape seed.

The new storage stability study shows stability of the TDMs in honey under deep freeze storage conditions (≤ -18°C) for at least 6 months. Mean recovery of each analyte at each interval was in the range of 70% to 120%. Therefore, prothioconazole-desthio and the 5 hydroxy prothioconazole-desthio (sum of isomers - PTZ-α-hydroxydesthio, PTZ-3-hydroxydesthio, PTZ-4-hydroxydesthio, PTZ-5-hydroxydesthio, PTZ-6-hydroxydesthio), metabolites are stable in honey for up to 6 months.
Stability of TA, TLA and TAA under deep freeze conditions (< -18°C) was demonstrated for a period of 6 months in milk, milk-cream, eggs, liver, kidney, muscle and fat (study ID: 869333, [redacted], 2020).
Samples from the submitted residue trials were stored frozen a maximum of 884 days for oilseed rape (seed) analysed for the metabolites TLA and TAA, for up to 23 days for the metabolites 1,2,4-Triazole (T) and Triazole alanine (TA), it is concluded that the residue data is valid with regards to storage stability.
Stability data in plant products, to support the use of FGE03 on oilseed rape, is considered to be covered by data relied on in EU and new data.

zRMS comments:
Information given by the Applicant is acceptable and sufficient.
Studies on the storage stability of prothioconazole and its metabolite in crop and animal tissues under frozen conditions were assessed in the framework at the EU level.
Residues of prothioconazole-desthio are stable for 18 months under deep-freeze storage in high water content matrices (wheat green matter), dry commodities (cereal grain) and straw and for 24 months in high oil content (rapeseeds).

Crops
1. Additionally, new study on the storage stability of prothioconazole-desthio and its hydroxy metabolites in crops (Giancola, D., 2024, Study No.: QG/21/001) were submitted in the framework of this application.

The results of the study demonstrate that prothioconazole-desthio in following samples: orange, field bean (dried) and oilseed rape seed, prothioconazole (5) hydroxy metabolites in wheat (grain, forage and straw), orange, field bean (dried) and oilseed rape seed are stable under frozen storage at -18 °C or below for 24 months, except:
- prothioconazole-6-hydroxy-desthio in wheat forage and grain are stable for 12 months,
- prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio and prothioconazole-6-hydroxy-desthio in oilseed rape (seed) are stable for 18, 12 and 6 months, respectively,
- prothioconazole-α-hydroxy-desthio and prothioconazole-3-hydroxy-desthio in field bean (dried) are stable for 12 and 18 months, respectively.
The study was conducted according to the OECD 506 and is acceptable.
More details of this study are provided in Appendix 2.

Remark:
In our opinion the storage stability results for prothioconazole-desthio hydroxy metabolites in some matrices and for some time points are ambiguous / inconclusive and it is difficult to clearly indicate the time point until which the metabolites are stable.
Procedural recoveries at some timepoints are outside of acceptance criteria (70% to 120%) and therefore data were not accepted.
I would like to ask for substantive comments from other cMS regarding the results of this study during the commenting period (please refer to Reporting Table, Part A-B for Patton Boost, 10.2025).

2. The stability of residues of triazole derived metabolites (1,2,4-triazole, triazole alanine, triazole acetic acid and triazole lactic acid) in various crops stored under deep freeze storage conditions (≤-18°C) was investigated in the framework of the peer review of TDMs (UK, 2018b, EFSA, 2018b, amended 2019) and in the evaluation of confirmatory data following the Article 12 MRL review of prothioconazole (EFSA 2020). In the cereals commodities the stability of all TDMs has been demonstrated**. For oilseeds 1,2,4-Triazole and TA are not stable (data gap). Please see comment below.**
New study on the storage stability of TDMs in crops (S. Baxter, B. Phipps 2025, Study No.: QG/21/002) were submitted in the framework of this application.
The results of the study demonstrate that TDMs in following samples: oilseed rape (seed), field bean (dried), orange and wheat (forage, grain and straw) are stable under frozen storage at -18 °C or below for 12 months, except:
- 1,2,4-T and TA in oilseed rape seed are stable for 15 days,
- TA in field bean (dried) and in wheat straw is stable for 1 month and in wheat grain for 6 months,
- 1,2,4-T in oranges is stable for 6 months.

Remark:

The Bousquet's study (647-2023; 2023) on the magnitude of residues of the PTZ-OH-desthio metabolites is not valid with regard to storage stability. The interval from sampling until extraction for 1,2,4-T and TA in this study was longer than the storage stability period for 1,2,4-T and TA in oilseed rape from S. Baxter, B. Phipps study (QG/21/002). **Therefore additional data on storage stability for 1,2,4-T and TA in oilseed rape are required (data gap). Please see comment below.**

Honey
New studies on the storage stability of prothioconazole-desthio and its hydroxy metabolites (Giancola, D., 2023; Study No.: QG/21/007) and triazole derivative metabolites (TDMs): 1,2,4-triazole, triazole alanine, triazole acetic acid and triazole lactic acid (Mealing H., 2024; Study No.: QG/21/006) in honey were submitted in the framework of this application.
Residues of prothioconazole-desthio and 5 hydroxy metabolites: prothioconazole-α-hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio and prothioconazole-6-hydroxy-desthio are considered to be stable in honey when stored frozen (<-18°C) for 13 months. Residues of triazole derivative metabolites (TDMs): 1,2,4-triazole, triazole alanine, triazole acetic acid and triazole lactic acid are considered to be stable in honey when stored frozen (<-18°C) for 6 months.
No significant degradation was demonstrated (<30% of nominal).
The studies were conducted according to the OECD 506 and are acceptable.
More details of these studies are provided in Appendix 2.

Conclusion:
Further storage stability data are required for 1,2,4-Triazole and TA in oilseeds.

The Applicant provided information on an ongoing new study:
Study title: "Storage Stability of the Triazole Derivative Metabolites (TDMs) in Plant Matrices under Deep Frozen Conditions"; Study Code S23-105428. Lab: Eurofins Agroscience Services EAG Laboratories GmbH. Study Director: Sandro Jooß
1,2,4-T, TAA, TLA, TA in oilseed rape seeds (up to 90 days) and cereal grain (up to 12 months).

Commenting period, 10.2025:
The Applicant informs the study is now finalized and the final report is joined during the commenting period.

Conclusion:
Residues of triazole derivative metabolites (TDMs): 1,2,4-triazole, triazole alanine, triazole acetic acid and triazole lactic acid are considered to be stable in oilseed rape (seeds) and cereal (grain) when stored frozen (<-18°C) for 12 months and 90 days, respectively, since no significant degradation was demonstrated (<30% of nominal). The study complies with OECD 506 and is acceptable.
The Bousquet's study (647-2023; 2023) on the magnitude of residues of 1,2,4-Triazole and TA is supported by valid storage stability data (Jooß, 2025).
Further storage stability data are not required for 1,2,4-Triazole and TA in oilseeds.

7.3.1.2 Stability of residues in sample extracts (KCA 6.1)

Available data
The stability of crop sample extracts was checked as part of the field residue studies. The stability of prothioconazole metabolites in the specimen extracts during the analytical procedure was proven for at least 15 days when stored at typically 1-10°C in the dark by the corresponding procedural recovery specimen which were stored under the same conditions together with the field specimens. The results do not indicate any residue decrease within this period of storage and subsequent analytical measurements. For the TDMs, internal isotopically labelled standard was used for quantification and was added directly at the end of the sample extraction procedure. The internal standard is considered to show the same degradation behaviour as the analyte itself so that the stability of the TDM analytes in sample extracts was not investigated.

Conclusion on the stability of residues in sample extracts
The stability of prothioconazole metabolites in the specimen extracts is sufficiently demonstrated in the framework of the available supervised residue trials.

zRMS comments:

Information given by the Applicant is acceptable and sufficient.
No further data are required.

7.3.2 Nature of residues in plants, livestock and processed commodities

7.3.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

The metabolism of prothioconazole in primary crops has been assessed in the original DAR (United Kingdom, 2007 – DAR addendum), as well as to the peer review of the triazole derivative metabolites (TDMs) in the light of confirmatory data submitted (United Kingdom, 2018b and EFSA, 2018).

Crops belonging to the group of cereals (wheat), pulse and oilseed (peanut) and root crop (sugar beet) were treated with foliar application for the elucidation of the metabolic pathway of prothioconazole. The crop group of cereals (spring wheat) was also treated with prothioconazole applied via seed treatment. The summary information is described below in Table 7.3-3.

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

Table 7.3-3: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G [(a)]	Rate (kg a.s./ha)	No (interval in days)	Sampling (DAT)	Remarks	
EU data								
Cereals	Wheat	[U-^{14}C-phenyl] prothioconazole	Foliar treatment, G (spring wheat)	0.20	2	Forage: 6 Hay: 26 Grain and straw: 48	The plants were grown under environmental conditions (sunlight and temperatures). A glass roof protected the plants from rainfall. The soil was surface irrigated	United Kingdom, 2007 (DAR addendum)
		[3,5-^{14}C-triazole] prothioconazole-desthio	Foliar treatment, G (summer wheat)	0.25	2	Forage: 0, 14 Grain and straw: 48	The plants were grown under environmental conditions (sunlight and temperatures). A glass roof protected the plants from rainfall. The soil was surface irrigated	JMPR: FAO, 2008a, 2008b EFSA, 2014
		[3,5-^{14}C-triazole] prothioconazole-desthio	Foliar treatment, F (spring wheat)	0.18; 0.29	2	Forage, hay, grain, straw	1 day after application, the soil tub was moved to the outside of the greenhouse	JMPR: FAO, 2008a, 2008b EFSA, 2014
		[U-^{14}C-phenyl] prothioconazole	Seed, G (spring wheat)	0.02; 0.10 kg a.s./100 kg seeds	1	Forage: 57 Hay: 110 Grain and straw: 153	ca. 220 kg seeds/ha	United Kingdom, 2007 (DAR addendum)
Pulses and oilseeds	Peanut	[U-^{14}C-phenyl] prothioconazole	Foliar, G	0.30	3	14	Hay and nuts without shells	United Kingdom, 2007 (DAR addendum)
		[3,5-^{14}C-triazole] prothioconazole-desthio	Foliar, G	0.30	3	14	Hay and nuts without shells	JMPR: FAO, 2008a, 2008b EFSA, 2014.

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G [(a)]	Rate (kg a.s./ha)	No (interval in days)	Sampling (DAT)	Remarks	
Root crops	Sugar beet	[U-^{14}C-phenyl] prothioconazole	Foliar, G	0.29	4	7	Roots, tops (leaves)	EFSA, 2009
		[3,5-^{14}C-triazole] prothioconazole-desthio	Foliar, G	0.29	4	7	Roots, tops (leaves)	JMPR: FAO, 2008a, 2008b EFSA, 2014

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

Summary of plant metabolism studies reported in the EU

Metabolism studies assessed in the original DAR reveal that the metabolic pattern of prothioconazole and prothioconazole-desthio was shown to be similar with prothioconazole-desthio being the predominant compound of the total residues.

The prothioconazole-desthio with further hydroxylation and glucosidation steps resulted in the formation of triazole derivative metabolites (TDMs), which consist essentially of triazole alanine (TA) and triazole acetic acid (TAA), representing 90% of the TRR. These compounds are common, unspecific metabolites of triazole fungicides. Although the metabolism study in peanut did not use radiolabelling in the triazole ring, it is expected from studies performed with other triazole fungicides that these TDMs are also present as major constituent of the residue in oilseeds.

Summary of new plant metabolism studies

No new plant metabolism studies.

Conclusion on metabolism in primary crops

Based on the metabolic pattern identified in the metabolism studies and hydrolysis studies (described below), the toxicological significance of metabolites and degradation products, the residue definition for primary crops were proposed as 'prothioconazole-desthio (sum of isomers)' for enforcement and for risk assessment is:

1) sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers)
2) Triazole alanine (TA) and triazole lactic acid (TLA)
3) Triazole acetic acid (TAA)
4) 1,2,4-triazole (1,2,4-T).

Both residue definitions are applicable for foliar and seed treatments, to primary crops, rotational crops and processed products.

zRMS comments:

No new plant metabolism studies are provided.
Information given by the Applicant is acceptable and sufficient.

In the framework of the peer review under Directive 91/414/EEC and the Art.12 MRL review (EFSA, 2007, 2014), the metabolism of prothioconazole was investigated by foliar applications on root (sugar beet), pulses/oilseeds (peanut) and cereal/grass (wheat) crop groups and by seed treatment on cereal (wheat) (EFSA, 2007). In addition, the metabolism of prothioconazole-desthio labelled in the triazole moiety was investigated after foliar applications on cereals (EFSA, 2007).

Prothioconazole is extensively metabolised and the metabolic pathway was similar in all crops investigated. Prothioconazole-desthio was the predominant compound of the total residues with further hydroxylation (with the formation of several closely related metabolites) and glucosidation steps, whilst cleavage of the triazole bound of prothioconazole-desthio molecule resulted in the formation of TDMs.

In EFSA Journal 2018;16(7):5376 it is stated that *Primary crops metabolism data are reported for a total of 16 approved triazole compounds, and 2 triazole active substances that are not approved at EU level (bitertanol, flusilazole), on fruit crops, cereals (straw and grain), pulses and oilseeds and root crops.(...) Based on the metabolism data in primary and rotational crops that were compiled from the assessment of the 18 triazole active*

substances the triazole active substances were shown to degrade into the common metabolites 1,2,4-T, TA, TLA and TAA, known as TDMs.

The residue definitions
Taking into account conclusions EFSA regarding residue definitions presented in EFSA Journal 2020;18(2):5999, EFSA Journal 2014;12(5):3689 and EFSA Journal 2018;16(7):5376, based on the metabolic pattern identified in metabolism studies, hydrolysis studies, the toxicological significance of metabolites and degradation products, the residue definitions for plant products were proposed as '**prothioconazole-desthio (sum of isomers)**' for enforcement and, as follows, for the risk assessment:
1) sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers)
2) Triazole alanine (TA) and triazole lactic acid (TLA)
3) Triazole acetic acid (TAA)
4) 1,2,4-triazole (1,2,4-T).

These residue definitions are applicable to primary crops, rotational crops and processed products and for both foliar and seed treatments.
Since all compounds included in the residue definitions are a mixture of enantiomers and since there are no enantiospecific analytical methods, the residue definitions are expressed as "sum of isomers".
Although the residue definition for risk assessment includes consideration of all metabolites containing a common moiety, it is not possible to develop a common moiety method to meet the residue definition for risk assessment. For this reason, all the analytes have to be determined separately. 6 analytes, representing the major portion of the TRR (Total Radioactive Residue) for prothioconazole in the plant metabolism studies, should be determined in residue trials. These are: prothioconazole-desthio, 3-hydroxy-prothioconazole-desthio, 4-hydroxy-prothioconazole-desthio, 5-hydroxy-prothioconazole-desthio, 6-hydroxy-prothioconazole-desthio and alpha-hydroxy-prothioconazole-desthio (including all their acid-hydrolysable conjugates).

No further data are required.

7.3.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data
The metabolism of prothioconazole in rotational crops has been assessed in the original DAR (United Kingdom, 2007 – DAR addendum). Crops belonging to the group of cereals (spring wheat), leafy vegetables (swiss chard) and root and tuber vegetables (turnip) were sown following the treatment of bare soil. Moreover, the metabolism of prothioconazole labelled in triazole ring (TDMs) was investigated in a confined rotational crop developed with the same crops (swiss chards, turnips and spring wheat), following the treatment of bare soil within four applications. The study was assessed by the JMPR (FAO, 2009a, 2009b), reported in the MRL review (EFSA, 2014) and submitted in the framework of the prothioconazole renewal (United Kingdom, 2018a). The summary information is described below in Table 7.3-4.
No new data are submitted in the framework of this application.

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

Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G *	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks	
EU data								
Leafy vegetables	Swiss chard	[U-^{14}C-phenyl] prothioconazole	F Bare soil	1 × 0.58	28, 146, 269	80, 188, 348	-	United Kingdom, 2007 (DAR addendum)
Root and tuber vegetables	Turnip	[U-^{14}C-phenyl] prothioconazole	F Bare soil	1 × 0.58	28, 146, 269	94, 201, 349	Roots and tops	
Cereals	Spring wheat	[U-^{14}C-phenyl] prothioconazole	F Bare soil	1 × 0.58	28, 146, 269	Green material: 73, 178, 327 Hay: 111, 231, 377 Grain and straw: 145, 269, 412	-	

Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G *	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks	
Leafy vegetables	Swiss chard	[3,5-^{14}C-triazole] prothioconazole-desthio	F Bare soil	4 × 0.204	30, 125, 366	77, 169, 406	-	FAO, 2009a FAO, 2009b EFSA, 2014
Root and tuber vegetables	Turnip	[3,5-^{14}C-triazole] prothioconazole-desthio	F Bare soil	4 × 0.204	30, 125, 366	113, 195, 420	-	
Cereals	Wheat	[3,5-^{14}C-triazole] prothioconazole-desthio	F Bare soil	4 × 0.204	30, 125, 366	Green material: 62, 154, 388 Hay: 80, 171, 420 Grain and straw: 121, 209, 450	-	

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

Summary of plant metabolism studies reported in the EU

The confined study performed for the Annex I inclusion showed that residues declined between first and third rotational cycle tested. Significant residues (> 0.1 mg/kg) were only found in wheat straw and hay, with a similar or lower levels than those recorded for the direct treated spring wheat. The metabolism profile in primary treated wheat and wheat grown as rotational crop was found to be very similar. The level of prothioconazole-desthio (M04) in swiss chard was 0.014 mg/kg at the shortest plant back interval of 30 days. No other metabolite was detected. In turnip leaves and turnip roots, no metabolite was present at significant levels (> 0.01 mg/kg).

The study performed for the elucidation of the prothioconazole metabolism labelled in triazole ring indicated the cleavage of triazole linkage to form major metabolites TA, TLA and TAA, whereas parent prothioconazole and prothioconazole-desthio were identified as minor metabolites (EFSA, 2014). No free 1,2,4-triazole was detected in any matrix (FAO, 2009 a, b). During the peer review of the pesticide risk assessment for the TDMs in light of confirmatory data, it was also concluded that the metabolic behaviour of TDMs is similar both in primary and rotational crops (EFSA, 2018). For the proposed uses assessed in this application, no further information is required.

Summary of new plant metabolism studies

No new data submitted in the framework of this application.

Conclusion on metabolism in rotational crops

Residues in rotational crops will not lead to any additional exposure to prothioconazole above that from directly treated crops. Overall, it can be concluded that the metabolism in primary and rotational crops is similar. Therefore, a specific residue definition for rotational crops is not deemed necessary.

The TDMs showed similar metabolic patterns in primary and rotational crops. For details, please refer to the peer review of the pesticide risk assessment for the TDMs in light of confirmatory data submitted (EFSA, 2018).

zRMS comments:

No new plant metabolism studies in rotational crops are provided. Information given by the Applicant is acceptable and sufficient.

In EFSA Journal 2020;18(2):5999 it is stated that *The metabolism of prothioconazole in rotational crops was investigated in the framework of the EU pesticides peer review in Swiss chards, turnips and spring wheat following the treatment of bare soil with prothioconazole at an application rate of 580 g/ha using the compound labelled in the phenyl ring. The main compounds identified were prothioconazole-desthio and its hydroxylated derivative metabolites, either free or conjugated.*

The MRL review concluded that metabolism of prothioconazole in primary and rotational crops was found to be similar and a specific residue definition for rotational crops is not necessary (EFSA, 2014).

The metabolism of prothioconazole labelled in triazole ring was assessed by the JMPR (FAO, 2009a) as reported in the MRL review. The studies indicate the cleavage of triazole linkage to form major metabolites TA, TLA and

TAA (EFSA, 2014). During the peer review of TDMs in light of confirmatory data, the metabolism of various triazole compounds in rotational and primary crops was investigated.
It was concluded that for TDMs similar metabolic patterns were depicted both in primary and rotational crops (EFSA, 2018b).

No further data are required.

7.3.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

The effects of processing nature of prothioconazole and prothioconazole-desthio were investigated in the framework of the MRL review (EFSA, 2014). The standard hydrolysis study simulating the effect on the nature of prothioconazole and prothioconazole-desthio residues under representative processing conditions of pasteurisation, boiling and sterilisation was assessed. A new hydrolysis study (Bloβ, K., 2019, study No. S21-04814) with prothioconazole-desthio is submitted in the framework of this application. The detailed assessment of the new study is presented in Appendix 2 (A 2.2.2.1.3).
Moreover, the nature of the residues in processed commodities labelled in triazole ring (TDMs) was investigated in a standard hydrolysis study. The study was submitted in the framework of the prothioconazole renewal (United Kingdom, 2018a). The summary information is described below in Table 7.3-5.

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

Conditions (Duration, Temperature, pH)	Stable	Identified compound(s) (%)	Reference
EU data (Prothioconazole)			
Pasteurisation (20 minutes, 90°C, pH 4)	**Yes**	Prothioconazole degrades to prothioconazole-desthio under sterilisation process (≤ 11% AR). Prothioconazole-desthio remains stable (99.4 – 99.9% of AR)	EFSA, 2014; EFSA, 2020
Baking, boiling, brewing (60 minutes, 100°C, pH 5)	**Yes**		
Sterilisation (20 minutes, 120°C, pH 6)	**Yes**		
New Data (Prothioconazole-desthio)			
Pasteurisation (20 minutes, 90°C, pH 4)	**Yes**	Prothioconazole-desthio remains stable (98.4 - 100.4% of AR)	Bloβ, K., 2019, Study No. S21-04814 (KCA 6.5.1/01:)
Baking, boiling, brewing (60 minutes, 100°C, pH 5)	**Yes**		
Sterilisation (20 minutes, 120°C, pH 6)	**Yes**		
EU data (TDMs)			
Pasteurisation (20 minutes, 90°C, pH 4)	**Yes**	Triazole-UL-^{14}C labelled triazole alanine, triazole acetic acid, triazole lactic acid and 1,2,4-Triazole; remain stable under sterilisation processes (96.4–100.5% of AR)	United Kingdom, 2018a
Baking, boiling, brewing (60 minutes, 100°C, pH 5)	**Yes**		
Sterilisation (20 minutes, 120°C, pH 6)	**Yes**		

Conclusion on nature of residues in processed commodities

The study demonstrates that food processes such as brewing, cooking, sterilisation or pasteurisation, will not impact on the nature of prothioconazole and prothioconazole-desthio residues. No degradation was observed under the standard hydrolysis conditions. Based on the available data for processed commodities, the residue definition for enforcement and risk assessment derived in primary crops can also apply to the processed commodities.
A new hydrolysis study (Bloβ, K., 2019) shows that [^{14}C] prothioconazole-desthio was stable during all processing conditions (98.4% to 100.4% applied radioactivity (AR)) and no hydrolysis or degradation products were formed under conditions representative for simulating pasteurisation, baking/

brewing/boiling and sterilisation.
The TDMs are stable under hydrolysis studies simulating baking/brewing/boiling, pasteurisation and sterilisation (EFSA, 2018). For details, please refer to the peer review of the pesticide risk assessment for the triazole derivative metabolites in light of confirmatory data submitted (United Kingdom, 2018b; EFSA, 2018).

zRMS comments:
The effect on the nature of prothioconazole and prothioconazole-desthio has not been investigated in the framework of the EU pesticides peer review. EFSA concluded in the MRL review prothioconazole and prothioconazole-desthio remain stable during all processing conditions.
The TDMs are stable under hydrolysis studies simulating baking/brewing/boiling, pasteurisation and sterilisation (EFSA, 2018).

As residues of prothioconazole exceeding 0.1 mg/kg are not expected in the treated crops, there is no need to investigate the effect of industrial and/or household processing.
However, the Applicant submitted additional new hydrolysis study (Bloβ, K., 2019, Study No. S21-04814).

A study concerning the effects of processing on the nature of the residue [^{14}C] Prothioconazole-desthio was performed according to guidelines 7035/VI/95 rev. 5 and OECD 507.
Three different hydrolysis conditions were chosen to simulate normal processing practices: pasteurisation, baking/brewing/boiling and sterilisation.
The results of this study demonstrated that no significant hydrolysis or reaction products were formed under conditions representative of pasteurisation, baking/brewing/boiling and sterilisation.
There was no significant change in the radioactivity content following processing under the three different conditions.
Test Item was stable during all processing conditions and no hydrolysis or degradation products were formed under conditions representative of simulating pasteurisation, baking/brewing/boiling and sterilisation. The study is acceptable.
In our opinion, the study on the nature of residues and the conclusion regarding the residue definition should be evaluated at the EU level, not at the MS level.

No further data are required.

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	Pulses/oilseeds (peanuts) and root crops (sugar beet): foliar application Cereals (wheat): foliar and seed application
Rotational crops covered	Swiss chard (leafy vegetables), turnip (root and tuber vegetables), spring wheat (cereals)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Prothioconazole-desthio is stable under standard hydrolysis conditions TDMs are stable under standard hydrolysis conditions.
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes
Plant residue definition for monitoring	Prothioconazole: prothioconazole-desthio (sum of isomers) (EFSA, 2020; Commission Regulation (EU) ~~2019/552~~ 2024/1318)
Plant residue definition for risk assessment	1) Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chloro-phenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers); 2) TA and TLA (compounds share the same toxicity data);

	3) TAA; 4) 1,2,4-T (EFSA, 2014; EFSA, 2018)
Conversion factor from enforcement to RA	EFSA, 2007: 2 (cereal grain and oilseeds) EFSA, 2014: Tentative conversion factors to account for hydroxy metabolites of prothioconazole-desthio: 2 (cereal grains, pulses, oilseeds, leafy vegetables and tuber vegetables) and 3 in cereal straw. 1 (maize - derived from metabolism study) EFSA, 2020: 2.7 (Root and tuber vegetables (except sugar beet)) A conversion factor of 2 for crops where no data according to the risk assessment residue definition are available and for which a risk management decision is pending: pulses, flowering brassica, Brussels sprouts, head cabbages, shallots, onions, leeks, rye, barley, oats

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

Available data

The metabolism of prothioconazole in poultry and lactating ruminants has been assessed in the original DAR (United Kingdom, 2004 - DAR and United Kingdom, 2007 – DAR addendum). Labelled prothioconazole ([U-14C-phenyl] was tested in laying hens and labelled prothioconazole and prothioconazole-desthio were tested in lactating goats. Moreover, the metabolism of prothioconazole labelled in triazole ring [3,5-14C-triazole] was investigated in laying hens and in lactating ruminants. Studies were assessed by the JPMR (FAO, 2008a and FAO, 2008b).

The summary information is described below in Table 7.3-7. 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								
Laying poultry	Hens	[U-^{14}C-phenyl] prothioconazole	6	10	3	Eggs	Once daily	United Kingdom, 2007 (DAR addendum)
						Excreta	At regular intervals	
						Tissues	At sacrifice (5h after last administration)	
		[3,5-^{14}C-triazole] prothioconazole	6	10	3	Eggs	Once daily	JMPR: FAO, 2008a, 2008b EFSA, 2014
						Excreta	At regular intervals	
						Tissues	At sacrifice (5h after last administration)	
Lactating ruminants	Goat	[U-^{14}C-phenyl] prothioconazole	1	10 (250 mg a.s./kg feed)	3	Milk	Twice daily	United Kingdom, 2007 (DAR addendum)
						Urine and faeces	Daily and at sacrifice	
						Tissues	At sacrifice	

Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling	
		[U-^{14}C-phenyl] prothioconazole-desthio	1	10 (195 mg a.s./kg feed)	3	Milk	Twice daily	United Kingdom, 2007 (DAR addendum)
						Urine and faeces	Daily and at sacrifice	
						Tissues	At sacrifice	
		[3,5-^{14}C-triazole] prothioconazole	1	10	3	Milk	Twice daily	FAO, 2008a, FAO, 2008b
						Urine and faeces	Daily and at sacrifice	
						Tissues	At sacrifice	
Pigs	"Following prothioconazole administration to rats, metabolite 1,2,4-triazole was recovered in urine at minor amounts (2.3 % AR), whilst it was not recovered in goats. Therefore, meanwhile a harmonized approach on how to consider TDMs in the risk assessment, the general metabolic pathways in rodents and ruminants can be considered as comparable, mainly involving various types of hydroxylation affecting the chlorophenyl ring and leading to the formation of metabolites both under their free and glucuronide or sulphate conjugated forms. The metabolic pathway of prothioconazole-desthio depicted in ruminants can therefore be extrapolated to pigs."							EFSA, 2014
Fish	Not required, as residues of prothioconazole > 0.1 mg/kg of the total diet in fish feed (dry weight basis) are not expected.							
New data								
No new data submitted in the framework of this application.								

Summary of plant metabolism studies reported in the EU

The metabolism and distribution of radioactive labelled prothioconazole [U-^{14}C-phenyl] prothioconazole was investigated in laying hens and lactating goats. Additional radioactive prothioconazole labelled at [U-^{14}C-phenyl] prothioconazole-desthio was tested in lactating goats.

Goat metabolism studies showed that prothioconazole is rapidly adsorbed but not extensively metabolised, being largely excreted. Only 0.96% of the total dose was found in tissues after sacrifice and prothioconazole was the major residue. Prothioconazole-desthio is rapidly adsorbed, although there is more extensive metabolism. It is largely excreted in the goat, 1.9 % of the total dose was found in tissues after sacrifice. The main metabolic reactions in the goat were hydroxylation of prothioconazole-desthio resulting in the isomers M14 and M15, followed by oxidation of the chlorophenyl moiety leading to M32 and M36. To greater or lesser extent, there was also conjugation of prothioconazole-desthio and metabolites with glucuronic acid. Although these compounds were found in tissues following dosing at very exaggerated levels, they were mainly associated with the excretory organs and are therefore unlikely to be distributed to other parts of the body. A similar metabolic pathway was observed in poultry.

No metabolism study was performed in pigs, since the metabolite patterns in rodents (rats) and ruminants (goats) did not differ significantly. For details on the rodent's metabolite patterns, please refer to the toxicological and metabolism dossier (dRR Part B6).

Furthermore, the metabolism of prothioconazole in fish (rainbow trout) was not assessed and is not required as residues of prothioconazole > 0.1 mg/kg of the total diet in fish feed is not expected.

However, the available studies indicate similar metabolic patterns for the different compounds and moieties investigated. Additional studies addressing these requirements are therefore not expected to provide different results. It is also noted that no livestock metabolism study was performed with administration of all the metabolites included in the residue definition set for risk assessment in plants. Nevertheless, EFSA assumes that the administration of prothioconazole-desthio only in the livestock metabolism studies is acceptable since no different metabolic route of degradation would be expected if all the metabolites containing the moiety of the residue definition for risk assessment in plants were considered. Therefore, no additional metabolism data are deemed necessary.

TDMs

The metabolism and distribution of radioactive labelled [3,5-^{14}C-triazole] was investigated in laying hens and lactating goats. According to EFSA, 2018: "The compilation of the poultry and ruminant metabolism studies conducted with the triazole pesticide active substances with the ^{14}C labelling on the triazole moiety showed that besides the parent compound that was detected in significant proportions in all animal matrices ranging between 27% and 81% TRR in milk, eggs and tissues, 1,2,4-T was also found to be a predominant compound of the total residues with levels ranging from 31% to 86% TRR in those matrices. TA was identified at very low levels in poultry muscle only (< 10% TRR) and at levels between 22% and 39% TRR in ruminant matrices.

Since TA is a major component in feed items, the potential transfer of this compound in poultry and ruminant matrices was further investigated in a metabolism study conducted with ^{14}C-TA. TA remains the major compound of the total residues in all poultry matrices (84–97.2% TRR) and in ruminant tissues (56–76% TRR) while TA and 1,2,4-T accounted for 8% and 86% TRR, respectively, in milk. TLA and TAA were detected in very low levels in all matrices (< 1% TRR). The potential transfer of TAA, TLA and 1,2,4-T present in feed items to the animal matrices was not further investigated. Although there are indications from the ruminant metabolism study conducted with ^{14}C-TA that there is no accumulation of TAA and TLA (4.2% and < 1% of the total administered dose in urine, respectively), these metabolites were however detected in the ruminant matrices from the feeding study conducted with TA.

Conclusion on metabolism in livestock

Prothioconazole

Based on the overall metabolic pattern of prothioconazole and prothioconazole-desthio in animals, the residue definition for enforcement in animal products is proposed as prothioconazole-desthio (sum of isomers) for all livestock matrices. For risk assessment the residue definition is defined in all commodities of animal origin as the sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers) (EFSA, 2014).

The log Po/w of prothioconazole-desthio equals 3.04 (EFSA, 2007). Since higher prothioconazole-desthio residue levels were found in fat compared to fat free muscle, it was concluded that the residue definition for enforcement in commodities of animal origin is fat soluble (EFSA, 2014).

TDMs

Based on the available data performed with triazole and its metabolite TA and the data on the livestock feeding studies performed with TA and TAA (EFSA, 2018), it was agreed in the following residue definition.

Residue definition for enforcement:

Triazole parent compound only (prothioconazole-desthio - sum of isomers)

Residue definition for risk assessment:

1) Triazole parent compound and any other relevant metabolite exclusively linked to the parent compound (sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers);
2) TA and TLA, since these compounds share the same toxicity;
3) TAA;
4) 1,2,4-triazole

zRMS comments:

Information given by the Applicant is acceptable and sufficient.

In EFSA Journal 2014;12(5):3689 it is stated that *Based on the overall metabolic picture of prothioconazole and prothioconazole-desthio in animals, the residue definition for enforcement in animal products was set as* ***prothioconazole-desthio (sum of isomers)*** *for all the livestock matrices. This compound is fat soluble.*

(…) For risk assessment, the residue was defined in all commodities of animal origin as the ***sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2- chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers).***

According to the EFSA Journal 2018;16(7):5376: *Ruminant and poultry metabolism studies labelled on the triazole ring are available.*
(…) Based on the metabolism studies conducted, respectively, with triazole pesticide active substances and TA and considering the results of the livestock feeding studies carried out with TA and TAA, respectively, the experts agreed on the following residue definitions:

- *Residue definition for enforcement: triazole parent compound only*
- *Residue definition for risk assessment:*
  1. *Triazole parent compound and any other relevant metabolite exclusively linked to the parent compound;*
  2. *TA and TLA, since these compounds share the same toxicity;*
  3. *TAA;*
  4. *1,2,4-triazole.*

No further data are required.

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

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

	Endpoints
Animals covered	Lactating goats
	Laying hens
Time needed to reach a plateau concentration	1-2 days in milk
Animal residue definition for monitoring (prothioconazole)	Prothioconazole-desthio (sum of isomers) (EFSA, 2014, Reg. (EU) 2024/1318)
Animal residue definition for monitoring (TDMs)	Triazole parent compound only (EFSA, 2018)
Animal residue definition for risk assessment (prothioconazole)	Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers) (EFSA, 2014)
Animal residue definition for risk assessment (TDMs)	1) Triazole parent compound and any other relevant metabolite exclusively linked to the parent compound 2) TA and TLA, since these compounds share the same toxicity 3) TAA 4) 1,2,4-triazole (EFSA, 2018)
Conversion factor	EFSA, 2014: 2 (liver); 9 (kidney) not necessary for milk, ruminant muscle and ruminant fat
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	Yes, log P_{OW} for prothioconazole-desthio (JAU 6476-desthio) = 3.04

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

The magnitude of residues on oilseed rape is covered by own data performed by the applicant for the framework of this application.

7.3.3.2 Summary of new data supporting the intended use in oilseed rape

The intended uses on oilseed rape (winter and spring) are covered by 44 new trials (24 NEU and 20 SEU) performed for the framework of this application. Trials were performed during 2020, 2021, 2022 and 2023.

New trials were performed in eight different representative oilseed rape countries. For the northern-zone (24 NEU) the selected countries were, north of France (2), Belgium (3), Denmark (1), Germany (8), the Netherlands (5) and Poland (5). For the southern-zone (20 SEU) countries were, Greece (2), Italy (10), south of France (1) and Spain (7). Crops were treated twice with a plant protection product containing prothioconazole 250 g/L applied via foliar. Forty of the trials tested a DC formulation (other code: FGR06) and 4 trials tested an EC formulation.
Applications were performed at a dose rate of 175 g prothioconazole/ha (equivalent to 0.7 L product/ha). The initial application (A1) was made at least 14±1 day before the second application (A2) to the treated plots at BBCH 67-77. The second application (A2) was performed 35 days before crop harvest and no later than BBCH 80.
Half of the new trials (22) were performed as decline trials and whole plant samples were collected at 0, 7±1, 21±2 and NCH (normally commercial harvest) and seeds at NCH (PHI approx. 35 days). The remaining 22 trials were performed as harvest trials and seed samples were collected at NCH (PHI approx. 35 days).
The detailed assessment of the 44 trials distributed over eight different studies are summarized in the Table 7.3-9 below and described in detail in the Appendix 2 (A 2.2.3.1.1, A 2.2.3.1.2, A 2.2.3.1.3, A 2.2.3.1.4, A 2.2.3.1.5, A 2.2.3.1.6, A 2.2.3.1.7, A 1.1.1.1.1).
The trials quantified different combination of the tested analytes in oilseed rape (plant and seed). Sixteen trials (8 NEU and 8 SEU), summarized in the Appendix 2 (A 2.2.3.1.1, A 2.2.3.1.2, A 2.2.3.1.3 and A 2.2.3.1.4) analysed prothioconazole-desthio and the 5 hydroxy prothioconazole-desthio (sum of isomers - PTZ-α-hydroxydesthio, PTZ-3-hydroxydesthio, PTZ-4-hydroxydesthio, PTZ-5-hydroxydesthio, PTZ-6-hydroxydesthio). The maximum storage interval from sampling to last analysis was 665 days for prothioconazole-desthio and it is covered by the available storage stability data. However, the 5 hydroxy prothioconazole-desthio data exceeded the available storage stability data and was therefore not considered in the framework of this application.

Moreover, sixteen trials (8 NEU and 8 SEU), summarized in the appendix 2 (A 2.2.3.1.5), quantified the 5 hydroxy prothioconazole-desthio (sum of isomers - PTZ-α-hydroxydesthio, PTZ-3-hydroxydesthio, PTZ-4-hydroxydesthio, PTZ-5-hydroxydesthio, PTZ-6-hydroxydesthio) and the triazole derivate metabolites (1,2,4-Triazole (T) and Triazole alanine (TA)). The maximum storage interval from sampling to last analysis was 147 days for the 5 hydroxy prothioconazole-desthio metabolites and 23 days for the TDMs, period is covered by the available storage stability data.
The analytes triazole acetic acid (TAA) and triazole lactic acid (TLA) were analysed in 12 trials (8 NEU and 4 SEU). Trials are summarized in the Appendix 2 (A 2.2.3.1.6, A 2.2.3.1.7, A 2.2.3.1.8). The maximum storage interval was 890 days, and it is covered by the storage stability data for the triazole derivate metabolites (TAA and TLA).
Quantification was performed by LC-MS/MS detection (28 trials – 16 NEU and 12 SEU) or LC-DMS/MS (16 trials – 8 NEU and 8 SEU). The limit of quantification differed between analytes. The limit of quantification for prothioconazole-desthio and the triazole acetic acid (TAA) was 0.005 mg/kg. For the five hydroxy-prothio-desthio metabolites and the other TDMs (1,2,4-Triazole (T), Triazole alanine (TA) and Triazole lactic acid (TLA)) was 0.01 mg/kg.
Residues of prothioconazole-desthio in seed ranged from <0.005 (<LOQ) to 0.074 mg/kg. The residues levels of the 5 hydroxy prothioconazole-desthio (sum of isomers - PTZ-α-hydroxydesthio, PTZ-3-hydroxydesthio, PTZ-4-hydroxydesthio, PTZ-5-hydroxydesthio, PTZ-6-hydroxydesthio) expressed as prothioconazole-desthio in seed ranged from <LOD to 0.05 mg/kg. The sum of the 5 hydroxy prothioconazole-desthio ranged from 0.01 to 0.11 mg/kg. In the overall assessment (Table 7.3-9) residue levels of prothioconazole-desthio data was considered for monitoring data (Mo) purpose and the sum of the sum of the 5 hydroxy prothioconazole-desthio for the risk assessment (Table 7.3-9).
Residues of triazole alanine (TA) in seed ranged from 0.13 to 4.50 mg/kg. The residues levels of the triazole lactic acid (TLA) in seed ranged from <0.01 (<LOQ) to 0.134 mg/kg. The triazole acetic acid (TAA) residue in seed ranged from <0.005 (<LOQ) to 0.0265 mg/kg. No residues of 1,2,4-T was detected. It is noted that significant residue levels of TDMs were often found in untreated control samples of the residue trials suggesting the use of triazole pesticide active substances in previous seasons. However, these trials were considered for risk assessment with the purpose of performing a 'worst case' consumer dietary intake calculation. The results of all TDMS are summarized in the overall table (Table 7.3-9).

The data sets from NEU and SEU zones cannot be combined since are not similar according to the Mann-Whitney U-test, therefore values from each zone are presented separated in the summary table below (Table 7.3-9).

According to SANTE 2019/12752, a sufficient number of trials were available to cover the intended uses on oilseed rape. The distribution of the trials is also properly addressed. Therefore, the new trials can be considered sufficient to support intended uses number 1 and 2 in the GAP for FGE03.

An MRL exceedance above the current value of 0.15 mg/kg (Reg. (EU) No 2024/1318) is not expected since the maximum highest residue (HR) measured in seed was 0.074 mg/kg. The new data was input into the MRL calculator (please refer to the excel spreadsheet named as: KCA_6.3-01_OECD MRL Calculator_FGE03.xlsm) and the calculated MRL for the NEU and SEU were 0.085 and 0.15 mg/kg, respectively, indicating that no exceedance of the MRL will occur.

Table 7.3-9: Summary of new data supporting the intended uses of FGE03 and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded (and rounded) OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Mo: Prothioconazole-desthio (sum of isomers) **RA**: prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-*2H*-1,2,4-triazole moiety expressed as prothioconazole-desthio [(a)] **TA:** Triazole alanine - **TLA:** triazole lactic acid - **TAA:** Triazole acetic acid and - **T:** 1,2,4-triazole								
Oilseed rape	New trials	N-EU	Trials GAP; 2 x 0.175 kg a.s./ha, last application BBCH 80, 14 days interval, PHI 35 days, outdoor. Mo: 2x <0.005, 0.00514, 0.00659, 0.0136, 0.0146, 0.0182, 0.0564 Sum of Prothioconazole-alpha-hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio expressed as prothioconazole-desthio: 8x<0.05 RA: 2x<0.055, 0.05514, 0.05659, 0.0636, 0.0646, 0.0682, 0.1064	E: 0.01 RA: 0.06	E: 0.056 RA: 0.1064	0.085 (0.09)	0.15	Yes
			TA: 0.15, 0.20, 0.22, 0.23, 0.29, 0.52, 0.79, 1.3 TLA: 3x<0.01, 0.0105, 0.0290, 0.0365, 0.0491, 0.131 TAA: 4x <0.005, 0.00576, 0.00896, 0.00928, 0.0265 T: 6x <0.01	0.26 0.01 0.005 0.01	1.3 0.131 0.0265 0.01	-	-	-
	~~New trials~~	~~S-EU~~	~~Trials GAP; 2 x 0.175 kg a.s./ha, last application BBCH 80, 14 days interval, PHI 35 days, outdoor.~~ ~~Mo: 0.00755, 0.0393, 0.0447, 0.0516, 0.0609, 2x 0.0645, 0.0738~~ ~~RA: 0.01, 3x 0.02, 2x 0.0.3, 2x 0.04~~	~~0.056~~	~~0.074~~	~~0.153~~ ~~(0.15)~~	~~0.15~~	~~Yes~~
			~~TA: 0.13, 0.14, 0.23, 0.25, 0.78, 3.2, 3.4, 4.5~~ ~~TLA: 2x <0.01, 0.012, 0.134~~ ~~TAA: 3x <0.005, 0.0174~~ ~~T = 6x <0.01~~	~~0.52~~ ~~0.51~~ ~~0.005~~ ~~0.01~~	~~4.5~~ ~~0.134~~ ~~0.0174~~ ~~0.01~~	~~-~~	~~-~~	~~-~~

* Source of EU MRL: Reg. (EU) No 2024/1318

** Studies not relevant for envisaged GAP uses due to more critical GAP than envisaged.

[(a)]The residue definition for risk assessment is sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-*2H*-1,2,4-triazole moiety expressed as prothioconazole-desthio. The 5 components listed here all contain the moiety of the definition, as does prothioconazole-desthio, results for which have not been repeated in this column.

7.3.3.3 Conclusion on the magnitude of residues in plants

According to the available data, the intended uses on oilseed rape are considered acceptable. No exceedances of the MRLs are envisaged based on the requested uses for FGE03.

zRMS comments:
Residue Definitions (EFSA 2020; Reg EU 2024/1318):
Monitoring (Mo): Prothioconazole-desthio (sum of isomers)
Risk Assessment (RA):
1) Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers) (EFSA, 2014)
2) TDMs (EFSA, 2018), with separate assessment of:
- Triazole alanine (TA) and triazole lactic acid (TLA)
- Triazole acetic acid (TAA)
- 1,2,4-triazole (1,2,4-T)

Oilseed rape
Oilseed rape is the major crop in northern Europe (SANTE/2019/12752). A minimum of eight trials are required.

Sufficient trials on oilseed rape conducted according to the residue definition for monitoring only (trials measuring levels of prothioconazole-desthio only) were previously presented and evaluated (DAR, 2007). There are no data on prothioconazole-hydroxy-desthio in the DAR (2007).

Five new magnitude of residue studies were submitted in the framework of this application. Summary is presented below.
Summary:
1. Study QG22007; Toscano Saes & Coleman 2023
Six N-EU trials were conducted in accordance with the following GAP: 2 x 175 g a.s. /ha, application interval - 14 days, 2nd application at BBCH 80 (outdoor) to determine of the residues of prothioconazole metabolites: PTZ-dethio, PTZ-alpha-OH-desthio, PTZ-3-OH-desthio, PTZ-4-OH-desthio, PTZ-5-OH-desthio, PTZ-6-OH-desthio, in oilseed rape specimens: seed and plant (rest of plant or immature plant).

In the treated seed specimens at harvest, residue levels of PTZ-desthio ranged between <0.005 mg/kg – 0.056 mg/kg.
Residues of hydroxy- derivatives of prothioconazole-desthio in oilseed rape grain at harvest were <0.005 mg/kg.

2. Study NZ/21/002; Toscano Saes & Coleman 2023
Two N-EU trials were conducted in accordance with the following GAP: 2 x 175 g a.s. /ha, application interval - 14 days, 2nd application at BBCH 80 (outdoor) to determine of the residues of prothioconazole metabolites: PTZ-dethio, PTZ-alpha-OH-desthio, PTZ-3-OH-desthio, PTZ-4-OH-desthio, PTZ-5-OH-desthio, PTZ-6-OH-desthio, in oilseed rape specimens: seed and rest of plant.

In the treated seed specimens at harvest, residue levels of PTZ-desthio ranged between <0.005 mg/kg – 0.00659 mg/kg.
Residues of hydroxy- derivatives of prothioconazole-desthio in oilseed rape grain at harvest were <0.005 mg/kg.

3. Study 647-2023; Bousquet 2023
Eight N-EU trial was conducted in accordance with the following GAP: 2 x 175 g a.s. /ha, application interval – 14 days, 2nd application at BBCH 80 (outdoor) to determine of the residues of prothioconazole metabolites: PTZ-alpha-OH-desthio, PTZ-3-OH-desthio, PTZ-4-OH-desthio, PTZ-5-OH-desthio, PTZ-6-OH-desthio and 1,2,4-triazole (T), triazole alanine (TA) in oilseed rape specimens: seed and forage.

Residues of PTZ-alpha-OH-desthio, PTZ-3-OH-desthio, PTZ-4-OH-desthio, PTZ-5-OH-desthio and PTZ-6-OH-desthio, expressed as prothioconazole-desthio, ranged between:
- 0.21 and 0.55 mg/kg (0.21, 0.30, 0.33, 0.55 mg/kg) in forage specimens
- 8x<LOQ in seeds specimens
(LOQ: 0.01 mg/kg for each analyte, 0.05 mg/kg for prothioconazole expressed as prothioconazole desthio as a sum of hydroxy-metabolites)

No residue of 1,2,4-T were detected at any time in seed.

Residues of TA ranged between:
- 0.03 and 0.06 mg/kg (0.03, 2x0.04, 0.06 mg/kg) in forage specimens
- 0.02 and 1.3 mg/kg (0.02, , 0.15, 0.22, 0.23, 0.29, 0.52, 0.79, 1.3 mg/kg) in seeds specimens

4. Study EE/23/007; Phipps 2023
Six N-EU trials were conducted in accordance with the following GAP: 2 x 175 g a.s. /ha, application interval - 14 days, 2nd application at BBCH 80 (outdoor) to determine of the residues of triazole derived metabolites (TDM's) (triazole acetic acid and triazole lactic acid) in oilseed rape specimens: seed, immature plant and rest of plant.

Residues of TAA ranged between:
- <0.005 and 0.00928 mg/kg (3x<0.005, 0.00576, 0.00896, 0.00928mg/kg) in seeds,
- <0.005 and 0.0324 mg/kg (3x<0.005, 0.00548, 0.00660, 0.0324 mg/kg) in rest of plants.

Residues of TLA ranged between:
- <0.01 and 0.0491 mg/kg (2x<0.01, 0.0105, 0.029, 0.0365, 0.0491 mg/kg) in seeds
- <0.01 and 0.0178 mg/kg (3x<0.01, 0.0102, 0.0109, 0.0178 mg/kg) in rest of plants.

5. Study NZ/21/003; Gibson & Toscano Saes, 2022
Two N-EU trials were conducted in accordance with the following GAP: 2 x 175 g a.s. /ha, application interval - 14 days, 2nd application at BBCH 80 (outdoor) to determine of the residues of triazole derived metabolites (TDM's) (triazole acetic acid and triazole lactic acid) in oilseed rape specimens: seed and rest of plant.

Residues of TAA were <LOQ and 0.0265 mg/kg in seeds, and <LOQ in rest of plants.
Residues of TLA were <LOQ and 0.131 mg/kg in seeds, and <0.01 in rest of plants.

Available results show that the in force MRL of prothioconazole on oilseed rape of 0.15 mg/kg (Reg. (EU) 2024/1318) will not be exceeded. The current EU MRL for prothioconazole is sufficient to support the proposed use.
The trials are supported by valid storage stability data and validated analytical methods.

Remark:
The Bousquet's study (647-2023; 2023) on the magnitude of residues of the PTZ-OH-desthio metabolites is valid with regard to storage stability. The interval from sampling until extraction for 1,2,4-T and TA in this study was longer than the storage stability period for 1,2,4-T and TA in oilseed rape from S. Baxter, B. Phipps study (QG/21/002). **Therefore additional data on storage stability for 1,2,4-T and TA in oilseed rape are required (data gap).**
Commenting period, 09.2025:
The Applicant provided new storage stability study (Jooß, 2025; Study Code S23-105428). The Bousquet's study (647-2023; 2023) on the magnitude of residues of 1,2,4-T and TA is supported by new valid storage stability data.

The proposed uses on oilseed rape is considered acceptable.

Minor uses: gold of pleasure (0401130), winter turnip rape (0401060-002), mustard (0401080), sunflower (0401050), poppy (0401030), linseed (0401010), flax, hemp (0401140), borage (0401120)

Based on the Technical Guidelines SANTE/2019/12752, rev.01:
- 8 residue trials on oilseed rape (0401060) can be used for extrapolation to linseeds (0401010), poppy seeds (0401030), mustard seeds (0401080) and gold of pleasure seeds (0401130) after forming of the edible part.
- 8 residue trials on oilseed rape (0401060) can be used for extrapolation to Whole group Oilseeds (0401000), except peanuts/groundnuts (0401020) before forming of the edible part (for oilseeds, a significant part of the edible part is present from full blossom (BBCH 65) onwards).

MRLs values for oilseeds (Reg. (EU) 2024/1318):

400000	OILSEEDS AND OIL FRUITS	
401000	Oilseeds	MRL (mg/kg)
401010	Linseeds	0.09
401020	Peanuts/groundnuts	0.02*
401030	Poppy seeds	0.09
401040	Sesame seeds	0.02*

401050	Sunflower seeds	0.2
401060	Rapeseeds/canola seeds	0.15
401070	Soyabeans	0.2
401080	Mustard seeds	0.09
401090	Cotton seeds	0.3
401100	Pumpkin seeds	0.02*
401110	Safflower seeds	0.02*
401120	Borage seeds	0.02*
401130	Gold of pleasure seeds	0.04
401140	Hemp seeds	0.02*
401150	Castor beans	0.02*
401990	Others (2)	0.02*

Available results show that the in force MRLs of prothioconazole (Reg. (EU) 2024/1318) on oilseed rape (0401060), winter turnip rape (0401060-002), mustard (0401080), sunflower (0401050), poppy (0401030), linseed (0401010) will not be exceeded.
An exceedance of the current MRLs for prothioconazole as laid down in Reg. (EU) 2024/1318 is expected for gold of pleasure (0401130), hemp (0401140) and borage (0401120). These uses are not accepted.

Taking into account the possibility of extrapolation (SANTE/2019/12752, rev.01) the proposed uses on minor crops: winter turnip rape (0401060-002), linseeds (0401010), poppy seeds (0401030), mustard seeds (0401080) after forming of the edible part is considered acceptable.
Minor use on sunflower (0401050) is accepted before forming of the edible part, before BBCH 65.

7.3.4 Magnitude of residues in livestock

Reference is made to the EU peer review of prothioconazole (United Kingdom, 2004 (DAR) and United Kingdom, 2007 (DAR addendum), EFSA, 2007) and to the MRL review and modification for prothioconazole (EFSA, 2014, 2020, 2022 and 2023), as well as to the peer review of the triazole derivative metabolites (TDMs) in the light of confirmatory data submitted (United Kingdom, 2018b and EFSA, 2018). The following data gaps were identified during the assessment of TDMs, relevant for the risk assessment to cover the complete group of triazole derived metabolites: "Poultry and ruminant feeding studies conducted with TLA or, alternatively, metabolism studies performed in accordance with the current recommendations as a surrogate to these feeding studies to determine the magnitude of TLA residues in products of animal origin" (EFSA, 2018). These data gaps for prothioconazole are addressed by two studies performed by the TDMG.

1) 'Determination of the Triazole Derived Metabolites in Eggs and Tissues of Laying Hens following Multiple Oral Administration of Triazole Lactic Acid', [redacted] 2021, Report No. IF19-05004879
2) 'Determination of the Triazole Derived Metabolites in Milk and Tissues of Dairy Cows following Multiple Oral Administration of Triazole Lactic Acid, [redacted] 2021, Report No. IF19-05004884.

A letter of access for both studies is provided, therefore both studies can be used to address the data gaps identified before.

7.3.4.1 Dietary burden calculation

<u>Prothioconazole</u>
The dietary burden calculation made by EFSA in the framework of the Article 12 evaluation is available for prothioconazole (see EFSA, 2014). Prothioconazole is authorised for use on several crops that might be fed to livestock. EFSA calculated the livestock dietary burdens for different groups of livestock using the agreed European methodology (European Commission, 1996). The envisaged GAP uses are covered by this calculation.
In addition, new dietary burden calculations were conducted in EFSA, 2020 and according to EFSA "the new data on carrots, swedes, turnips and wheat were submitted in the framework of the assessment of the

Article 12 confirmatory data application (United Kingdom, 2019). The most recent livestock dietary burden was calculated in the EFSA opinion on the modification of prothioconazole residues in sunflower seeds (EFSA, 2015b), updating the calculation done by the MRL review (EFSA, 2014). However, due to the fact that existing EU MRLs for livestock and for various feed commodities are set on the basis of CXLs, instead of proposals made by the MRL review, the livestock dietary burden was calculated using Animal Model (OECD methodology), considering the actual existing EU MRLs for feed commodities. The input values for rapeseeds and carrots, swedes, turnips were as derived from the current assessment; for remaining feed commodities the input values were corresponding to the existing EU MRLs and were as reported in the MRL review, or in JMPR reports (in particular for cereals, cotton, maize, peanuts and soya beans, since for these crops the existing EU MRLs are set on the basis of CXLs) (FAO, 2009a, 2009b, 2014, 2018) and in previous EFSA reasoned opinions (for sunflower seeds, EFSA, 2015b). Where residue data according to the risk assessment residue definition were not available, default conversion factors for risk assessment as derived by the MRL review, were applied."
Dietary burden calculation using EFSA animal model 2017 was performed. The input values are presented in the table 7.3-10 below. Input values were the same used in the latest exposure calculations for livestock described in EFSA, ~~2020~~2023.

Table 7.3-10: Input values for the dietary burden calculation (considering the uses evaluated in Art. 12 and Art. 6 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: sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers)				
Beet sugar, tops (EFSA, 2023)	0.82	STMR	1.5	HR
Beet sugar, ensiled pulp (EFSA, 2023)	1.08	STMER x PF (18)	1.08	STMR x PF (18)
Beet sugar, molasses (EFSA, 2023)	0.18	STMR x PF (3)	0.18	STMR x PF (3)
Rape seed meal (EFSA, 2020)	0.16	STMR x PF (2)[(a)]	0.16	STMR x PF (2)[(a)]
Sunflower seed meal (EFSA, 2015a,b)	0.04	STMR × CF (2) × PF (2)[(a)]	0.04	STMR × CF (2) × PF (2)[(a)]
Head cabbage (EFSA, 2014)	0.02	STMR × CF	0.12	STMR × CF
Corn silage (EFSA, 2014)	0.01	STMR	0.01	STMR
Corn grain (FAO, 2014); (EFSA, 2014)	0.02	STMR × CF (2)	0.02	STMR × CF (2)
Corn, milled by-products[(b)] (FAO, 2014); (EFSA, 2014)	0.02	STMR × CF (2)	0.02	STMR × CF (2)
Corn, hominy meal[(b)] (FAO, 2014); (EFSA, 2014)	0.02	STMR × CF (2)	0.02	STMR × CF (2)
Corn gluten feed[(b)] (FAO, 2014); (EFSA, 2014)	0.02	STMR × CF (2)	0.02	STMR × CF (2)
Corn gluten meal[(b)] (FAO, 2014); (EFSA, 2014)	0.02	STMR × CF (2)	0.02	STMR × CF (2)
Distiller's grain[(b)] (FAO, 2014); (EFSA, 2014)	0.02	STMR × CF (2)	0.02	STMR × CF (2)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Barley grain (FAO, 2009b); (EFSA, 2014)	0.07	STMR × CF (2)	0.07	STMR × CF (2)
Brewer's grain (FAO, 2009b); (EFSA, 2014); (EFSA, 2020)	0.23	STMR barley grain × CF (2) × PF (3.3)[a]	0.23	STMR barley grain × CF (2) × PF (3.3)[a]
Oat grain (FAO, 2009a); (EFSA, 2014)	0.02	STMR × CF (2)	0.02	STMR × CF (2)
Wheat grain (FAO, 2009c); (EFSA, 2014)	0.04	STMR × CF (2)	0.04	STMR × CF (2)
Wheat gluten meal[b] (FAO, 2009a); (EFSA, 2014)	0.04	STMR wheat grain × CF (2) × PF (1.8)[a]	0.04	STMR wheat grain × CF (2) × PF (1.8)[a]
Wheat milled by-products[b] (FAO, 2009a); (EFSA, 2014)	0.28	STMR wheat grain × CF (2) × PF (7)[a]	0.28	STMR wheat grain × CF (2) × PF (7)[a]
Rye grain (FAO, 2009a); (EFSA, 2014)	0.02	STMR × CF (2)	0.02	STMR × CF (2)
Barley straw (FAO, 2009a); (EFSA, 2014)	1.96	STMR[d] × CF (3)	7.50	HR[d] × CF (3)
Oats straw (EFSA, 2014)	1.26	STMR × CF (3) (EFSA, 2014)	7.50	HR[d] × CF (3) (EFSA, 2014)
Wheat straw (EFSA, 2014)	2.69	STMR x CF (3) (EFSA, 2020)	5.52	HR[d] (EFSA, 2014) × CF (3)
Rye straw (EFSA, 2014)	2.25	STMR[d] × CF (3)	5.52	HR[d] × CF (3)
Cotton seed (FAO, 2018) (EFSA, 2020)	0.10	STMR x CF (2)	0.10	STMR x CF (2) x PF (1.3)[a]
Cotton meal (FAO, 2018); (EFSA, 2020)	0.14	STMR × CF (2) × PF (1.3)[a] STMR x PF	0.14	STMR × CF (2) × PF (1.3)[a] STMR x PF
Beans (dry) (EFSA, 2014)	0.02	STMR × CF (2)	0.02	STMR × CF (2)
Peas, lupins (dry) (FAO, 2009c) (EFSA, 2020)	0.10	STMR × CF (2)	0.10	STMR × CF (2)
Lupin seed meal (FAO, 2009b) (EFSA, 2020)	0.11	STMR x CF (2) x PF (1.1)[a]	0.11	STMR x CF (2) x PF (1.1)[a]
Potatoes (EFSA, 2014)	0.01	STMR	0.01	HR
Potato process waste[b] Potato dried pulp[b] (EFSA, 2014)	0.01	STMR potato × PF (1)[c]	0.01	HR potato × PF (1)[c]
Turnips, swede, carrot culls (EFSA, 2020)	0.08	STMR	0.10	HR
Peanut meal (FAO, 2009)	0.04	STMR × CF (2) × PF (2)	0.04	STMR × CF (2) × PF (2)
Linseed meal (EFSA, 2015 a,b)	0.12	STMR × CF (2) × PF (2)[a]	0.12	STMR × CF (2) × PF (2)[a]
Soybean seed (FAO, 2014)	0.10	STMR × CF (2)	0.10	STMR × CF (2)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Soybean seed meal (EFSA, 2020)	0.13	STMR (FAO, 2014) × CF (2) × PF (1.3)[(a)]	0.13	STMR (FAO, 2014) × CF (2) × PF (1.3)[(a)]
Soybean[(b)] (EFSA, 2020)	1.30	STMR soybean (FAO, 2014) × CF (2) × PF (13)[(a)]	1.30	STMR soybean (FAO, 2014) × CF (2) × PF (13)[(a)]

STMR: supervised trials median residue; HR: highest residue; PF: processing factor; CF: conversion factor for enforcement to risk assessment residue definition.
(a): For rape seed meal/sunflower seed meal, brewer's grain, wheat gluten meal, wheat milled by-products, cotton seed meal, lupin seed meal, soybean meal, lupin seed meal, and soybean hulls in the absence of processing factors supported by data, default processing factors of 2, 3.3, 1.8, 7, 1.3, 1.1, 1.3 and 13 were, respectively, included in the calculation to consider the potential concentration of residues in these commodities.
(b): New commodities (OECD methodology), not considered in MRL review.
(c): Default processing factors were not applied because prothioconazole and its metabolites were below LOQ both in maize and potatoes, indicating no-residue situation. Thus, concentration of residues in these commodities is therefore not expected.
(d): The STMR and HR values derived by the JMPR (FAO, 2009 a,b) are lower than the values derived for cereals straws for the authorised EU uses reported in the MRL review (EFSA, 2014).

Table 7.3-11: Results of the dietary burden calculation for prothioconazole-desthio and 5 hydroxy prothioconazole-desthio

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Risk assessment residue definition: Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers)					
Beef cattle*	0.0513	0.113	Rye	4.71	Y
Dairy cattle*	0.0832	0.181	Rye	4.70	Y
Ram/ewe	0.1180	0.289	Rye	8.70	Y
Lamb	0.1552	0.396	Rye	8.68	Y
Breeding swine	0.048	0.108	Rye	4.66	Y
Finishing swine*	0.018	0.020	Beet, sugar	0.68	Y
Broiler poultry	0.015	0.016	Soybean	0.23	Y
Layer poultry*	0.066	0.152	Rye	2.23	Y
Turkey	0.013	0.015	Swede	0.20	Y

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

The calculated dietary burdens for all groups of livestock were found to exceed the trigger value of 0.1 mg/kg DM. Further investigation of residues is therefore required in all commodities of animal origin. The intake calculations for the maximum dietary burden of livestock demonstrate that residues of prothioconazole (sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers)) are significant in the diets of livestock (> 0.1 mg/kg dry matter in the diet) for all groups of livestock, confirming that further investigation of residues in all commodities of animal origin is required.

<u>TDMs</u>
Livestock dietary intake calculations for TDMs (1,2,4-T, TA, TAA and TLA) was performed during EU peer review of the pesticide risk assessment for the triazole derivative metabolites (United Kingdom, 2018b and EFSA, 2018).

The intended uses on oilseed rape are covered by these calculations as input values are covered by the highest residues found in the previous residue trials. The respective input values are described below on table 7.3-12 and can be found in the confirmatory data assessment of the Triazole Derivate Metabolite (United Kingdom, 2018b).

Table 7.3-12: Comparison of input values for dietary burden calculation from confirmatory data assessment (United Kingdom, 2018b) with values derived from new supplementary primary crop field residue studies

Crop	HR or STMR-P	Residue (mg/kg)				HR or STMR-P	Residue (mg/kg)			
		TA	TLA	TAA	1,2,4-T		TA	TLA	TAA	1,2,4-T
	Residues input values for the median dietary burden calculation (bold in brackets: HR/STMRs derived from new supplementary residue studies)					Residues input values for the max. dietary burden calculation (bold in brackets: HR/STMRs derived from new supplementary residue studies)				
Forages										
Alfalfa forage	STMR	0.16	0.4	0.1	0.05	HR	0.524	1.43	0.434	0.06
Alfalfa hay	HR x default PF (2.5)	0.4	1	0.25	0.3	HR x default PF (2.5)	1.31	3.58	1.085	0.15
Alfalfa meal	HR x default PF (2.5)	0.4	1	0.25	0.3	HR x default PF (2.5)	1.31	3.58	1.085	0.15
Alfalfa silage	HR x default PF (1.1)	0.18	0.44	0.11	0.06	HR x default PF (1.1)	0.576	1.57	0.477	0.06
Beet, mangel fodder,	STMR	0.18	0.05	0.05	0.05	HR	0.239	0.14	0.05	0.12
Beet tops	STMR	0.04	0.05	0.01	0.03	HR	0.218	0.14	0.02	0.12
Cabbage Heads	STMR	0.17	0.01	0.01	0.04	HR	0.5	0.01	0.01	0.113
Clover forage	STMR	0.16	0.4	0.1	0.05	HR	0.524	1.43	0.434	0.06
Clover hay	STMR x default PF (3)	0.48	1.2	0.3	0.15	HR x default PF (3)	1.57	4.29	1.3	0.18
Clover silage	STMR x default PF (1)	0.16	0.4	0.1	0.05	HR x default PF (1)	0.524	1.43	0.434	0.06
Grass forage	STMR	0.16	0.4	0.1	0.05	HR	0.524	1.43	0.434	0.06
Grass hay	STMR x default PF (3.5)	0.56	1.4	0.35	0.18	HR x default PF (3.5)	1.83	5	1.5	0.21
Grass silage	STMR x default PF (1.6)	0.26	0.64	0.16	0.08	HR x default PF (1.6)	0.838	2.3	0.694	0.096
Kale	STMR	0.17	0.01	0.01	0.04	HR	0.5	0.01	0.01	0.11
Rape forage	STMR	0.1	0.04	0.01	0.01	HR	0.913	0.04	0.034	0.023
Cereal straws/stover	STMR	0.12	0.37	0.24	0.12	HR	0.65	1.1	0.78	0.05
Turnip leaves	STMR	0.04	0.05	0.01	0.04	HR	0.218	0.14	0.02	0.12
Roots and Tubers										
Carrot	STMR	0.18	0.02	0.05	0.05	HR	0.239	0.13	0.5	0.06
Potato	STMR	0.18	0.02	0.05	0.05	HR	0.239	0.13	0.5	0.06
Swede	STMR	0.18	0.02	0.05	0.05	HR	0.239	0.13	0.5	0.06
Turnip	STMR	0.18	0.02	0.05	0.05	HR	0.239	0.13	0.5	0.06
Cereal grains / crops										
All cereal grains	STMR	0.79	0.05	0.02	0.621	STMR	0.79	0.05	0.02	0.621
Pulses	STMR	0.17	0.01	0.05	0.05	STMR	0.17	0.01	0.05	0.05
By-products										
Apple pomace	STMR-P	0.17 STMRx PF 0.32x0.52	0.1 STMRx PF 0.04x2.5	0.3 STMRx PF 0.05x0.52	0.3 STMRx default PF (5)	STMR-P	0.17 STMRx PF 0.32x0.52	0.1 STMRx PF 0.04x2.5	0.3 STMRx PF 0.05x0.52	0.3 STMRx default PF (5)
Beet sugar dried pulp	STMR* default PF (18)	3.3	0.38	0.9	0.9	STMR* default PF (18)	3.3	0.38	0.9	0.9
Beet sugar ensiled pulp	STMR* default PF (3)	0.55	0.06	0.15	0.15	STMR* default PF (3)	0.55	0.06	0.15	0.15

Crop	HR or STMR-P	Residue (mg/kg)				HR or STMR-P	Residue (mg/kg)			
		TA	TLA	TAA	1,2,4-T		TA	TLA	TAA	1,2,4-T
	Residues input values for the median dietary burden calculation (bold in brackets: HR/STMRs derived from new supplementary residue studies)					Residues input values for the max. dietary burden calculation (bold in brackets: HR/STMRs derived from new supplementary residue studies)				
Beet, sugar molasses	STMR* default PF (28)	5.1	0.59	1.4	1.4	STMR* default PF (28)	5.1	0.59	1.4	1.4
Brewer's grain	STMR* default PF (3.3)	2	0.073	2.6	0.17	STMR* default PF (3.3)	2	0.073	2.6	0.17
Canola	STMR* PF	1.45 STMRx PF (1.039x1.4)	0.13 STMRx PF 0.065x2	0.24 STMRx PF 0.12x2	0.1 STMRx default PF (2)	STMRx PF	1.45 STMRx PF (1.039x1.4)	0.13 STMRx PF (0.065x2)	0.24 STMRx PF (0.12x2)	0.1 STMRx default PF (2)
Citrus	STMRx P	0.17 STMRx PF (0.32x0.52)	0.1 STMRx PF 0.04x2.5	0.13 STMRx PF 0.05x2.5	0.5 STMR x default PF (10)	STMR-P				
Corn, field milled by-products	STMR x default PF (1)	0.62	0.02	0.79	0.05	STMR x default PF (1)	0.62	0.02	0.79	0.05
Corn, field, hominy meal.	STMR x default PF (6)	3.7	0.13	4.74	0.3	STMR x default PF (6)	3.7	0.13	4.74	0.3
Corn, field gluten feed	STMR x default PF (2.5)	1.6	0.06	1.98	0.13	STMR x default PF (2.5)	1.6	0.06	1.98	0.13
Corn, field, gluten meal	STMR x default PF (1)	0.62	0.02	0.79	0.05	STMR x default PF (1)	0.62	0.02	0.79	0.05
Cotton meal	STMR x PF	1.45 STMR x PF (1.039 x1.4)	0.13 STMR x PF (0.065 x2)	0.24 STMR x PF (0.12 x2)	0.07 STMR x default PF (1.3)	STMR x default PF	1.45 STMR x PF (1.039x1.4)	0.13 STMR x PF (0.065 x2)	0.24 STMR x PF (0.12 x2)	0.07 STMR x default PF (1.3)
Distiller's grain	STMR x default PF (3.3)	2	0.073	2.6	0.17	STMR x default PF (3.3)	2	0.073	2.6	0.17
Flaxseed/linseed meal	STMR x PF	1.45 STMR x PF (1.039 x1.4)	0.13 STMR x PF (0.065 x2)	0.24 STMR x PF (0.12 x2)	0.1 STMR x default PF (2)	STMR x default PF (2)	1.45 STMR x PF (1.039 x1.4)	0.13 STMR x PF (0.065 x2)	0.24 STMR x PF (0.12 x2)	0.1 STMR x default PF (2)
Lupin seed meal	STMR x default PF (1.1)	0.19	0.01	0.06	0.06	STMR x default PF (1.1)	0.19	0.01	0.06	0.06
Potato process waste	STMR x default PF (20)	3.7	0.42	1	1	STMR x default PF (20)	3.7	0.42	1	1
Potato dried pulp	STMR x default PF (38)	6.99	0.8	1.9	1.9	STMR x default PF (38)	6.99	0.8	1.9	1.9
Rape meal	STMR x default PF	1.45 STMR x PF (1.039 x1.4)	0.13 STMR x PF (0.065 x2)	0.24 STMR x PF (0.12 x2)	0.1 STMR x default PF (2)	STMR x default PF	1.45 STMR x PF (1.039 x1.4)	0.13 STMR x PF (0.065 x2)	0.24 STMR x PF (0.12 x2)	0.1 STMR x default PF (2)
Safflower meal	STMR x default PF	1.45 STMR xPF 1.039 x1.4	0.13 STMR x PF (0.065 x2)	0.24 STMR x PF (0.12 x2)	0.1 STMR x default PF (2)	STMR x default PF	1.45 STMR xPF 1.039 x1.4	0.13 STMR x PF (0.065 x2)	0.24 STMR x PF (0.12 x2)	0.1 STMR x default PF (2)
Soybean meal	STMR x default PF	1.45 STMR xPF	0.13 STMR x PF	0.24 STMR x PF	0.07	STMR x default PF	1.45 STMR xPF	0.13 STMR x PF	0.24 STMR x PF	0.07

Crop	HR or STMR-P	Residue (mg/kg)				HR or STMR-P	Residue (mg/kg)			
		TA	TLA	TAA	1,2,4-T		TA	TLA	TAA	1,2,4-T
	Residues input values for the median dietary burden calculation (bold in brackets: HR/STMRs derived from new supplementary residue studies)					Residues input values for the max. dietary burden calculation (bold in brackets: HR/STMRs derived from new supplementary residue studies)				
		1.039 x1.4	(0.065 x2)	(0.12 x2)	STMR x default PF (1.3)		1.039 x1.4	(0.065 x2)	(0.12 x2)	STMR x default PF (1.3)
Soybean hulls	STMR x default PF (13)	13.5	0.85	1.56	0.7	STMR x default PF (13)	13.5	0.85	1.56	0.7
Sugarcane molasses	STMR x default PF (32)	5.89	0.67	1.6	1.6	STMR x default PF (32)	5.89	0.67	1.6	1.6
Sunflower meal	STMR xPF	1.45 STMR xPF 1.039x1.4	0.13 STMR x PF (0.065x2)	0.24 STMR x PF (0.12x2)	0.1 STMR x default PF (2)	STMR xPF	1.45 STMR xPF 1.039x1.4	0.13 STMR x PF (0.065x2)	0.24 STMR x PF (0.12x2)	0.1 STMR x default PF (2)
Wheat gluten	STMR x default PF(1.8)	1.11	0.04	1.42	0.09	STMR x default PF (1.8)	1.11	0.04	1.42	0.09
Wheat milled by-products	STMR x default PF (7)	4.35	0.15	5.53	0.35	STMR x default PF (7)	4.35	0.15	5.53	0.35

The dietary burdens for the TDMs (1,2,4-T, TA, TAA and TLA) according to United Kingdom (2018b) are shown in Table 7.3-13 to Table 7.3-16, respectively.

Table 7.3-13: The median and maximum dietary burden for 1,2,4-Triazole

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Risk assessment residue definition: Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers)					
Cattle (all diets)	0.104	0.109	Potato, waste	3.75	Y
Cattle (dairy only)	0.104	0.109	Potato, waste	2.83	Y
Sheep (all diets)	0.118	0.121	Potato, waste	3.63	Y
Sheep (ewe only)	0.118	0.121	Potato, waste	3.63	Y
Swine (all diets)	0.045	0.047	Potato, waste	2.04	Y
Poultry (all diets)	0.037	0.038	Potato, dried pulp	0.54	Y
Poultry (layer only)	0.029	0.032	Potato, dried pulp	0.46	Y

Table 7.3-14: The median and maximum dietary burden 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)
Risk assessment residue definition: Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers)					
Cattle (all diets)	0.376	0.405	Potato, waste	13.63	Y
Cattle (dairy only)	0.376	0.405	Potato, waste	10.52	Y
Sheep (all diets)	0.425	0.454	Potato, waste	13.63	Y
Sheep (ewe only)	0.425	0.454	Potato, waste	13.63	Y
Swine (all diets)	0.163	0.178	Potato, waste	7.71	Y
Poultry (all diets)	0.158	0.165	Potato, dried pulp	2.34	Y
Poultry (layer only)	0.130	0.149	Potato, dried pulp	2.18	Y

Table 7.3-15: The median and maximum dietary burden 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)
Risk assessment residue definition: Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers)					
Cattle (all diets)	0.118	0.140	Potato, waste	4.29	Y
Cattle (dairy only)	0.118	0.140	Potato, waste	3.63	Y
Sheep (all diets)	0.153	0.170	Wheat, milled by products	4.37	Y
Sheep (ewe only)	0.127	0.146	Potato, waste	4.37	Y
Swine (all diets)	0.108	0.109	Wheat, milled by products	3.76	Y
Poultry (all diets)	0.138	0.140	Wheat, milled by products	2.05	Y
Poultry (layer only)	0.135	0.140	Wheat, milled by products	2.05	Y

Table 7.3-16: The median and maximum dietary burden 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)
Risk assessment residue definition: Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers)					
Cattle (all diets)	0.078	0.177	Grass, forage	4.61	Y
Cattle (dairy only)	0.078	0.177	Grass, forage	4.61	Y
Sheep (all diets)	0.079	0.187	Grass, forage	5.61	Y
Sheep (ewe only)	0.079	0.187	Grass, forage	5.61	Y
Swine (all diets)	0.026	0.055	Grass, forage	2.37	Y
Poultry (all diets)	0.021	0.055	Clover, hay	0.77	Y
Poultry (layer only)	0.021	0.052	Clover, hay	0.77	Y

The calculated dietary burdens for all TDMs (1,2,4-T, TA, TAA and TLA) for all groups of livestock were found to exceed the trigger value of 0.1 mg/kg DM. Further investigation of residues is therefore required in all commodities of animal origin.
The intake calculations for the maximum dietary burden of livestock demonstrate that residues of TDMs are significant in the diets of livestock (> 0.1 mg/kg dry matter in the diet) for all groups of livestock, confirming that further investigation of residues in all commodities of animal origin is required.

zRMS comments:
Information given by the Applicant is acceptable and sufficient.
Prothioconazole
The median and maximum dietary burdens for livestock were estimated for prothioconazole and were calculated using the animal model calculator developed by EFSA (Animal model 2017). The input values presented in the table 7.3-10 were the same used in the latest exposure calculations for livestock described in EFSA Reasoned Opinion (EFSA, 2023).
The calculated dietary burdens for prothioconazole were found to exceed the trigger value of 0.1 mg/kg DM (or 0.004 mg/kg bw/d, respectively) for all livestock groups. Further investigation of residues is therefore required.

TDMs
Livestock dietary burden calculation has been performed respectively for each TDM compound in the addendum – confirmatory data on TDMs performed by UK in 2018 (UK, 2018) using results from residue trials and from rotational crops. Additionally Applicant presented Livestock dietary burden calculation with using the input values used in the EU assessment from TDM confirmatory data (UK, 2018) and the highest value found for TA in oilseed rape seed.

The calculated dietary burdens for 1,2,4-triazole (1,2,4-T) were not found to exceed the trigger value of 0.1 mg/kg DM for all livestock groups.
The calculated dietary burdens for triazole alanine (TA) and triazole acetic acid (TAA) were found to exceed the trigger value of 0.1 mg/kg DM for all livestock groups.
The calculated dietary burdens for triazole lactic acid (TLA) were found to exceed the trigger value of 0.1 mg/kg DM for sheep only.
The feeding studies are required for TA, TAA and TLA.

It should be noted that the results of dietary burdens for TDMs taking into account the intended uses of FGE03 / Patton Boost are covered by the dietary burdens calculated by the UK (2018) for the different groups of livestock.

Remark on residue behaviour in fish (B.7.2.2.5 and B.7.2.4)
According to the new Working Documents on the nature and magnitude of pesticide residues in fish (SANTE/10254/2021, SANTE/10252/2021) as well as on the dietary burden calculator for pesticide residues in fish (SANTE/10250/2021), data on residue behaviour in fish are required when the pesticide use may lead to residues >0.1 mg/kg in the total diet (dry weight basis) and when the active substances and/or metabolites are fat soluble, i.e. have a log Po/w ≥3.
For prothioconazole-desthio the log Po/w is 3.04 and EFSA concluded that prothioconazole-desthio is fat soluble due to higher residue levels found in fat than in fat free muscle. Rape seed meal is used as a fish feeding stuff. However, residues of prothioconazole-desthio ranged from below the LOQ to 0.056 mg/kg rape seeds. Residues above the trigger value of 0.1 mg/kg are therefore not expected. Further data are not required.

7.3.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Available data
The magnitude of prothioconazole residues in livestock was evaluated during EU review (United Kingdom, 2004 and 2007; EFSA, 2007) and during Article 12 MRL review (EFSA, 2014 and EFSA, 2020). Reference to the respective evaluations is considered to be sufficient.
The magnitude of residues in livestock regarding TDMs was evaluated during EU peer review of the pesticide risk assessment for the triazole derivative metabolites (United Kingdom, 2018b and EFSA, 2018) and reference is made to the respective evaluation.
No new data were submitted in the framework of this application.

Available data
Prothioconazole

Table 7.3-17: Overview of livestock feeding studies with prothioconazole-desthio

Group	Species	No of animal	Test item	Application details		Sample details		Reference
				Rate	Duration (days)	Commodity	Time of sampling	
EU Data								
Lactating ruminants	Dairy cow	10	Prothioconazole-desthio	4, 25, 100 mg/kg in the diet (eq. to 0.145, 0.909 and 3.636 mg/kg bw per day)	28	Milk Tissues (liver, kidney, muscle, fat)	24 times during study After sacrifice	United Kingdom, 2004 and 2007 (DAR, DAR addendum) EFSA, 2007

Although the maximum dietary burden for poultry exceeds the threshold of 0.1 mg/kg DM, no appropriate feeding study is available and is required, since based on the metabolism study, no residues above the LOQ are expected in poultry matrices at the calculated dietary burden (EFSA, 2014).
The magnitude of prothioconazole residues in ruminants was investigated in a feeding study with lactating cows (EFSA, 2007; FAO, 2008a, 2008b; United Kingdom, 2004, 2007). Three groups of lactating cows, each consisting of three animals, were dosed for 28 consecutive days with prothioconazole-desthio at levels

of 4, 25, and 100 mg/kg in the diet (equivalent to 0.145, 0.909 and 3.636 mg/kg bw per d, respectively). The samples were analysed for prothioconazole-desthio, M14 (prothioconazole-3-hydroxy-desthio) and M15 (prothioconazole-4-hydroxy-desthio). Results of the ruminant livestock feeding study are summarised in Table 7.3-18. In milk, a plateau level was reached after 1 or 2 days of exposure, according to the dose level group. Since neither the metabolites (free and conjugated) containing the common moiety and included in the residue definition for risk assessment nor the glucuronide conjugates of prothioconazole-desthio were analysed, EFSA reported the residue levels for enforcement only (prothioconazole-desthio) and considered the conversion factors for enforcement to risk assessment of 2 and 9, respectively for liver and kidney based on the goat metabolism study with administration of prothioconazole-desthio. No tentative CF was derived for milk, muscle and fat since the residue levels in these matrices are expected to be negligible (< 0.01 mg/kg) at the calculated dietary burden. However, conversion factors reported above should in principle be covered by a new feeding study to estimate prothioconazole metabolites containing the common moiety in accordance with the residue definition for risk assessment.
Furthermore, in the framework of the reported feeding study, the storage stability of prothioconazole-desthio, M14 and M15 was demonstrated in all matrices for up to 1 month when stored deep frozen and was shown to cover the storage time interval of the residue samples of the feeding study. Degradation of prothioconazole-desthio residues during storage of the feeding study residue samples is therefore not expected.
Consequently, the available data allow deriving tentative MRLs in ruminants and pigs. These MRLs were derived in compliance with the latest recommendations on this matter (FAO, 2009b) and are summarised in Table 7.3-18. Tentative MRLs in all commodities are established at the LOQ, except in liver and kidney of ruminants, where MRLs of 0.05 and 0.02 mg/kg respectively are proposed.
When using the dietary burdens calculated above (considering the uses evaluated in Art. 12 procedure and the uses under consideration, presented in Table 7.3-12), estimated residues at 1N dietary burden in ruminant and pig matrices and in milk do not exceed the current MRLs in the respective commodities as given in Com. Reg. (EU) 2019/552 (Table 7.3-18).
According to EFSA (2020) the following applies with regard to residues in livestock: “The results of the dietary burden calculation demonstrate that the exposure of all livestock species exceeds the trigger value of 0.1 mg/kg DM […]. EFSA notes that since the residue trials on grass (major component of livestock dietary burden) have not been submitted, the EU livestock dietary burden from the existing EU uses including grass could not be properly calculated. However, since the existing EU MRLs for livestock commodities reflect CXLs, which are derived on the basis of significantly higher livestock dietary burdens as calculated by the JMPR in 2017 for cattle and poultry (FAO, 2018), the nature and magnitude of prothioconazole residues in livestock was not investigated¨.

Table 7.3-18: Overview of the values derived from livestock feeding studies

Commodity	Dietary burden		Results of the livestock feeding study (EFSA 2014)						Median residue (mg/kg)[c]	Highest residue (mg/kg)[d]	Calculated MRL (mg/kg)	In-force MRL (mg/kg) Reg. (EU) 2024/1318	CF for RA[e]
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level (mg/kg bw/d)[a]	No	Result for enforcement		Result for RA[b]						
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)					
EU data EFSA 2014													
Enforcement residue definition: prothioconazole-desthio (sum of isomers). **Risk assessment residue definition**: sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers).													
Pig muscle	0.017	~~0.031~~ 0.108	0.15	3	<0.01	<0.01	n.a.	n.a.	<0.01	<0.01	0.01* (tentative)	0.01	1.0
			0.91	3	<0.01	<0.01	n.a.	n.a.					
			3.64	3	<0.01	<0.01	n.a.	n.a.					
Pig fat			0.15	3	<0.01	<0.01	n.a.	n.a.	<0.01	<0.01	0.01* (tentative)	0.02	1.0
			0.91	3	<0.01	0.01	n.a.	n.a.					
			3.64	3	0.02	0.04	n.a.	n.a.					
Pig liver			0.15	3	0.02	0.03	n.a.	n.a.	<0.01	<0.01	~~0.01*~~ 0.03 (tentative)	0.5	2.0
			0.91	3	0.14	0.18	n.a.	n.a.					
			3.64	3	0.68	1.20	n.a.	n.a.					
Pig kidney			0.15	3	<0.01	<0.01	n.a.	n.a.	<0.01	<0.01	0.01* (tentative)	0.5	9.0
			0.91	3	0.03	0.03	n.a.	n.a.					
			3.64	3	0.13	0.24	n.a.	n.a.					
Milk	0.028	~~0.086~~ 0.181	0.15	3	<0.005[f]	N/A	n.a.	n.a.	<0.005	<0.005	0.005* (tentative)	0.01*	1.0
			0.91	3	<0.005[f]	N/A	n.a.	n.a.					
			3.64	3	<0.005[f]	N/A	n.a.	n.a.					
Ruminant muscle	0.069	~~0.208~~ 0.396	0.15	3	<0.01	<0.01	n.a.	n.a.	<0.01	<0.01	0.01* (tentative)	0.01	1.0
			0.91	3	<0.01	<0.01	n.a.	n.a.					
			3.64	3	<0.01	<0.01	n.a.	n.a.					
Ruminant fat			0.15	3	<0.01	<0.01	n.a.	n.a.	<0.01	<0.01	0.01*	0.02	1.0

			0.91	3	<0.01	0.01	n.a.	n.a.			(tentative)		
			3.64	3	0.02	0.04	n.a.	n.a.					
Ruminant liver			0.15	3	0.02	0.03	n.a.	n.a.	0.01	0.042	~~0.05~~ 0.08 (tentative)	0.5	2.0
			0.91	3	0.14	0.18	n.a.	n.a.					
			3.64	3	0.68	1.20	n.a.	n.a.					
Ruminant kidney			0.15	3	<0.01	<0.01	n.a.	n.a.	<0.01	0.012	0.02 (tentative)	0.5	9.0
			0.91	3	0.03	0.03	n.a.	n.a.					
			3.64	3	0.13	0.24	n.a.	n.a.					

N/A: Not applicable.
n.a.: Not analysed.
(a): Based on a 560 kg animal consuming approximately 20 kg feed DM/day.
(b): In the feeding study, residues were not determined according to the residue definition for risk assessment. Indeed, only prothioconazole-desthio, M14 and M15 were analysed.
(c): Median residue value according to the enforcement residue definition, derived by interpolation/extrapolation from the feeding study for the median dietary burden (FAO, 2009b).
(d): Highest residue value (tissues) 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, 2009b).
(e): The tentative conversion factors for enforcement to risk assessment in liver and kidney were derived on the basis of the available metabolism study on ruminants. For muscle, fat and milk, no CF was derived as residue levels are expected at the maximum meat ruminant dietary burden in these matrices are negligible (<0.01 mg/kg).
(f): Mean residue level from day 1 or 4 until day 29 (3 cows, 13 or 14 sampling days).
(*): Indicates that the MRL is set at the limit of analytical quantification

TDMs

The magnitude of residues in livestock regarding TDMs was evaluated during EU peer review of the pesticide risk assessment for the triazole derivative metabolites (United Kingdom, 2018b and EFSA, 2018) and reference is made to the respective evaluation.

EFSA, 2018: "Poultry and ruminants feeding studies were conducted respectively with TA and TAA and analysed for the magnitude of TA, TAA, 1,2,4-T and TLA residues. The poultry feeding study conducted with TA showed that TA remained predominant in all matrices and a slight metabolisation to 1,2,4-T in whole eggs, liver and muscle at the highest dosing level was noted. When the animals were fed with TAA, this compound was detected in eggs, fat and liver with residues of TA in liver only at all dosing levels. From the ruminant feeding study conducted with TA, TA remained predominant in all tissues but with a significant metabolisation of TA into 1,2,4-T in milk and to a minor extent into 1,2,4-T and TAA in tissues. TLA was identified in fat only, but its detection was rather attributed to a contamination as the respective levels were independent from the dosing levels. When ruminants were fed with TAA, this metabolite was only detected at the highest dose level in whole milk and in all tissues whilst TA was identified in liver, muscle and kidney at all the dosing levels. 1,2,4-T and TLA compounds were never detected (< 0.01 mg/kg). Animal tissues, milk and eggs samples were analysed within 30 days of sampling.

Since livestock feeding studies were not conducted to address the potential transfer of 1,2,4-T and TLA in products of animal origin, the experts agreed that transfer factors for TA derived from the feeding studies conducted with TA should be applied to 1,2,4-T, assuming that the absorption and excretion behaviour of TA and 1,2,4-T are similar. Similarly transfer factors for TAA derived from the feeding studies conducted with TAA should be applied to TLA assuming that the absorption and excretion behaviour of TAA and TLA are comparable and because of the similarity of the functional groups. From the available toxicological studies, the absorption and excretion of TA, 1,2,4-T and TAA were shown to be similar, and the experts agreed to estimate the 1,2,4-T residue levels in animal matrices by applying transfer factors for TA derived from the feeding study conducted with TA. A feeding study conducted with 1,2,4-T is therefore not required as no further metabolism of this compound in animal matrices is expected. In contrast and since a similar absorption and excretion behaviour of TLA compared to the other TDMs could not be demonstrated, livestock feeding studies conducted with TLA or metabolism studies performed in accordance with the current recommendations as a surrogate to these feeding studies should be provided (data gap). Meanwhile and provisionally, transfer factors for TAA derived from the feeding study conducted with TAA were applied to estimate the residue levels of TLA in animal commodities. The magnitude of residues of each TDM in animal matrices were therefore estimated by using the approach of a separate dietary burden calculation for each TDM and the application of transfer factors respectively to 1,2,4-Tand to TLA for which feeding studies are not available.

Furthermore, the residues of the TDMs (mainly 1,2,4-T and to a minor extent, TA) arising from the metabolism of triazole pesticide active substances in livestock should also be considered to derive the total residue levels of the individual TDMs in animal matrices. In the framework of these confirmatory data assessments and since feeding studies conducted with the triazole compounds were not available, the residue levels of 1,2,4-T and TA were estimated from the metabolism studies conducted with the triazole compounds when these were available. For any future assessment of triazole pesticide active substances, livestock feeding studies or, alternatively metabolism studies should be conducted with the triazole compounds to carry out a complete livestock exposure assessment."

The data gaps for prothioconazole are addressed by the TDMG studies report No. IF19-05004879 and No. IF19-05004884. A letter of access is provided for both studies, and it can be considered as sufficient.

Conclusion on feeding studies

The intended uses on oilseed rape are covered by the referenced intake calculations for livestock. Regarding available feeding data and evaluations in EFSA 2014, and EFSA, 2020, there is no risk for livestock MRLs of prothioconazole-desthio (sum of isomers) to be exceeded.

zRMS comments:

Information given by the Applicant is acceptable and sufficient.

The livestock feeding studies was investigated during the peer review of prothioconazole. The intended uses do not modify the theoretical maximum daily intake for animals for prothioconazole and TDMs. The residues in animal commodities will not exceed MRLs (Reg. (EU) 2024/1318).

No further data are required to support the intended uses of FGE03 / Patton Boost.

Remark:
It should be noted that EFSA recommended providing a ruminant feeding study to estimate the potential exposure to all the prothioconazole metabolites containing the common moiety in accordance with the residue definition for risk assessment.
Additionally, regarding TDMs EFSA identified livestock exposure assessment as a data gap.

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

Reference is made to the EU peer review of prothioconazole (United Kingdom, 2004 (DAR) and United Kingdom, 2007 (DAR addendum) and EFSA, 2007) and to the MRL review and modification for prothioconazole (EFSA, 2014, 2020, 2022 and 2023), as well as to the peer review of the triazole derivative metabolites (TDMs) in the light of confirmatory data submitted (United Kingdom, 2018b and EFSA, 2018). No new data were submitted in the framework of this application.

7.3.5.1 Available data for all crops under consideration

Data on processing studies was reviewed during the approval of prothioconazole and the peer review of the pesticide risk assessment for the triazole derivative metabolites in light of confirmatory data submitted and were considered acceptable. One processing study of prothioconazole-desthio in sugar beet has been performed (EFSA, 2023) and is not sufficient to derive robust processing factors. Therefore, it is not described here as sugar beet is not an intended use of the current applicant.

Prothioconazole
Studies on the magnitude of residues of prothioconazole (except TDMs) in processed commodities are not required, as residues of the sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers) were ≤ 0.1 mg/kg in oilseed rape seed at commercial harvest. Based on the results of residue trials, significant residue levels will not occur in oilseed rape seed at harvest. Accordingly, processing studies are not required.

TDMs
In oilseed rape, 1,2,4-T and TLA always show residues < 0.1 mg/kg, whereas the trigger of 0.1 is partly exceeded for TA and TAA (HR and STMR exceed 0.1). The contribution of cereals to the IEDIs and IESTIs of the four relevant TDMs is always < 10 % of the ADI and ARfD, respectively. Due to the low residue in the respective commodities and the low contribution to dietary intake, processing studies are not required. However, processing factors for TA, TLA and TAA derived from processing studies with cereals are available and can be used during risk assessments to account for possible residue concentration during processing. The overview of the processing factors is described in Table 7.3-19 and are given for the sake of completeness. No processing factors are available for the metabolite 1,2,4-triazaole. Residues in the animal feed items were < 0.1 mg/kg and consequently the data requirements for processing are not required.

Table 7.3-19: Overview of the available processing studies

Processed commodity	Number of studies	Median PF *	Median CF **	Comments	Reference
EU data					
Triazole alanine (TA)					
Rape seed, meal	1	1.4	1	-	United Kingdom, 2018b
Cereal grain, bran	1	2.2	1	-	United Kingdom, 2018b
Triazole acteic acid (TAA)					
Cereal grain, bran	1	1.3	1	-	United Kingdom, 2018b
Triazole lactic acid (TLA)					

Processed commodity	Number of studies	Median PF *	Median CF **	Comments	Reference
Rape seed, meal	1	2	1	-	United Kingdom, 2018b
New data					
No new data					

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

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

7.3.5.2 Conclusion on processing studies

Based on the results of residue trials, residue levels of prothioconazole metabolites (excluding TDMs) will not occur > 0.1 mg/kg in oilseed rape at harvest. Accordingly, processing studies are not required.
Regarding TDMs, processing factors for TA and TAA derived from processing studies with cereals are available, which can be used during risk assessments to account for possible residue concentration during processing.

zRMS comments:
As residues of prothioconazole exceeding 0.1 mg/kg are not expected in the treated oilseed rape, there is no need to investigate the magnitude of prothioconazole residues in processed commodities.

Regarding TDMs, processing studies on oilseed rape grain have been evaluated in confirmatory data for Triazole Derivate Metabolites (UK, 2018).

Table: Overview of the available processing studies - TDMs

Processed commodity	Individual Processing factors (Median)				Comments	Reference
	1,2,4-T	TA	TAA	TLA		
EU confirmatory data (B.7.5.2, UK, 2018)						
Rapeseed, meal	NC, NC, NC, NC	2.9, 0.52, 0.81, 1.9 (1.35)	>1.2, >2, >2, NC (>2)	NA, >1, >3, >2 (>2)		UK, 2018
Rapeseed, press cake	NC, NC, NC	0.61, 0.78, 1.3 (0.78)	NC, NC, >1	>2, >2, NC (>2)		
Rapeseed, refined oil	NC, NC, NC, NC	<0.02, <0.03, <0.04, <0.03 (<0.03)	NC, NC, NC, NC	NA, NC, NC, NC		

NA not analysed
NC Not calculated since the residues were below the limit of quantification both in the raw agricultural commodity and in the processed fraction, no processing factor could be derived.

Calculated processing factors show concentration of:
- TA, TAA and TLA in rapeseed meal,
- and TLA in rapeseed press cake.

Further data are not required.

7.3.6 Magnitude of residues in representative succeeding crops

Oilseed rape can be grown in rotation. Data dealing with magnitude of residues in succeeding crops are available and are summarized hereafter.

7.3.6.1 Field rotational crop studies (KCA 6.6.2)

Available data

Reference is made to the EU peer review of prothioconazole (United Kingdom, 2004 (DAR) and United Kingdom, 2007 (DAR addendum) and EFSA, 2007) and to the MRL review and modification for prothioconazole (EFSA, 2014, 2020, 2022 and 2023), as well as to the peer review of the triazole derivative metabolites (TDMs) in the light of confirmatory data submitted (United Kingdom, 2018b and EFSA, 2018).

Prothioconazole:

The metabolism of prothioconazole in rotational crops (spring wheat, swiss chard and turnip) was investigated during the first approval (United Kingdon, 2007 (DAR, addendum)). Considering available data dealing with nature of residues in rotational crops (see 0), no study dealing with magnitude of prothioconazole-desthio (sum of isomers) residue in succeeding crops is required.

TDMs:

The metabolism of triazole compounds in rotational crops (turnip, carrot, lettuce and barley) was investigated during the EU peer review in the light of confirmatory data submitted (United Kingdom, 2018b and EFSA, 2018). Four supervised field trials investigated the residues of triazole alanine (TA), triazole lactic acid (TLA), triazole acetic acid (TAA) and 1,2,4-triazole (1,2,4-triazole) in the rotational crops. Bare soils were treated with FS and EC formulations containing 100 g/L and 250 g/L of prothioconazole and three ranges of plant-back intervals (20-35 days, 60-200 days and 270-365 days) was tested to each crop. Part of the trials simulated the crop failure (emergency rotation), bare soil was treated once with the EC formulation at the rate of 630 g a.s./ha of prothioconazole and crops were sown 21-34 days after the application. In the trials simulating a normal rotation, the FS formulation was applied to wheat seed at the rate of 15 g a.s./dt. The seed was sown at a nominal rate of 200 kg seed/ha and the wheat plants received 3 additional treatments via foliar spray at the rate of 200 g a.s./ha with the EC formulation. The treatments were performed at the growth stages BBCH 32, 39 and 65-69, respectively, with intervals of 7-30 days between treatments. At harvest, wheat straw was ploughed in and the plot was left bare until rotational crops were sown. The plant-back intervals were variable depending on the crop and ranged between 56 and 200 days for the short crop rotation and between 277 and 345 days for the annual crop rotation. A summary of the median (STMR) and highest residues (HR) of T, TA, TAA and TLA measured in the rotational crops for emergency and normal rotation is described in table 7.3-21.

However, a data gap regarding the storage stability of the rotational crop field trial samples was identified during the assessment of TDMs. In order to address this data gap, a new study has been planned for the determination of the residue levels of prothioconazole-desthio, prothioconazole-α-hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5- hydroxy-desthio, prothioconazole-6-hydroxy-desthio and the triazole derived metabolites (1,2,4-Triazole, TA. TAA and TLA) in rotational crops. The agricultural commodities, turnip, leaf lettuce and wheat grown as rotational crops were sown in bare soil treated with one application of Prothioconazole 250g g/L EC. The study report No. S22-02433 (Semrau, J., 2022) is being supported by available storage data (analysis of all TDMs is within 6 months of storage). A copy of the study plan is provided, and the final report is expected by middle of 2025.

Table 7.3-20: Summary of available studies in field rotational crops

Primary crop	Rate (kg a.s./ha) (GS at application or PHI)	Residue levels in succeeding crops			
		Succeeding crop group	Succeeding crop	Sowing intervals (DAT)	Reference / Remarks
EU data					
Please refer to data point 7.3.2.2 - table 7.3-4					
New data					
Bare soil	0.630	Root vegetables	Turnip	28 120 355	KCA 6.6.2-01: Semrau, J, 2022, Study No.: S22-

Primary crop	Rate (kg a.s./ha) (GS at application or PHI)	Residue levels in succeeding crops			
		Succeeding crop group	Succeeding crop	Sowing intervals (DAT)	Reference / Remarks
		Leafy vegetables	Lettuce	28 120 355	02433
		Cereals	Wheat	28 120 355	

Table 7.3-21: STMRs and HRs for the triazole derived metabolites in carrot/turnip, lettuce and barley grown as succeeding crops following the use of FS and EC formulations containing 100 g/L and 250 g/L of prothioconazole (United Kingdom, 2018b)

Commodity	No of trials	STMR (mg/kg)				HR (mg/kg)			
		T	TA	TAA	TLA	T	TA	TAA	TLA
Carrot or turnip leaf – bare soil	4	0.01	0.032	0.01	0.057	0.01	0.176	0.01	0.132
Carrot or turnip leaf – normal rotation	7	0.01	0.01	0.01	0.019	0.01	0.039	0.01	0.046
Carrot or turnip root – bare soil	4	0.01	0.076	0.01	0.021	0.01	0.195	0.01	0.131
Carrot or turnip root – normal rotation	7	0.01	0.023	0.01	0.010	0.01	0.041	0.01	0.01
Lettuce – bare soil	4	0.01	0.047	0.022	0.079	0.01	0.091	0.03	0.01
Lettuce – normal rotation	8	0.01	0.011	0.023	0.02	0.01	0.012	0.036	0.048
Barley plant – bare soil	4	0.01	0.068	0.01	0.078	0.01	0.082	0.01	0.165
Barley plant – normal rotation	8	0.01	0.037	0.01	0.032	0.01	0.057	0.01	0.208
Barley straw – bare soil	4	0.01	0.053	0.063	0.113	0.01	0.129	0.288	0.192
Barley straw – normal rotation	8	0.01	0.011	0.019	0.042	0.01	0.023	0.057	0.068
Barley grain – bare soil	4	0.01	0.412	0.144	0.02	0.01	0.455	0.293	0.037
Barley grain – normal rotation	8	0.01	0.075	0.067	0.01	0.01	0.184	0.132	0.031

Note: for the calculation of the STMRs and HRs, the residue values measured in the control samples were taken into account whenever they exceeded the values measured in the corresponding treated samples. The STMRs were calculated based on the highest residue levels from each trial. Separate STMRs and HRs were calculated based on the trials involving soil application and based on the trials with application to a preceding crop, respectively. The worst case STMR and the worst-case HR were then determined by selecting the greater STMR and the greater HR from the two datasets."

Conclusion on rotational crops studies

The available data on the metabolism of prothioconazole in rotational crops is considered sufficient (see7.3.2.2) and no study dealing with magnitude of prothioconazole-desthio (sum of isomers) residue in succeeding crops is required.

The peer review of TDMs (EFSA, 2018) investigated the metabolism of triazole compounds in primary and rotational crops and concluded that for TDMs the metabolic patterns were similar. The identified data gap regarding the storage stability data on TDMs will be covered within the ongoing study (Study No.: S22-02433).

zRMS comments:
Information given by the Applicant is acceptable.
No residues are expected in rotational crops for the intended uses of FGE 03 / Patton Boost, so additional field rotational crop studies are not considered required.

Regarding TDMs, rotational crop studies were considered by the UK in the assessment of confirmatory data on TDMs (the UK, 2018).

The Applicant submitted study plan of a new study, Semrau, J., 2022; Study No. S22-02433, KCA 6.6.2-01.
Applicant statement:
"Unfortunately, the final version of the KCA 6.6.2-01 report is not yet available. However, we can provide the final report as soon as available - it is now expected in January 2026.
Please note that this study was set up as the peer review on the pesticide risk assessment for the TDMs, could not conclude on the magnitude of TDMs in rotational crops following the use of triazole fungicides due to data gaps related to storage stability (EFSA, 2018b). We are of the understanding that such TDM data gaps, which have been identified in this TDM review, will need to be addressed after AIR of prothioconazole."

7.3.7 Other / special studies (KCA 6.10, 6.10.1)

Oilseed rape is considered as relevant for nectar production and collection by honeybees according to SANTE/11956/2016 rev.9. Prothioconazole is a systemic fungicide intended to be applied as a spray during spring (BBCH 30-69), therefore residues in pollen and bee products collected from treated crops are expected and residue levels in the honey must be addressed.
The magnitude of prothioconazole-desthio (sum of isomers) and triazole derivate metabolites (TDMs) in honey was assessed in two different studies performed for the framework of this application.

Prothioconazole
In a new study performed by Andrews and Coleman (2023), four trials (2 NEU and 2 SEU) were performed to determine the residues levels in honey. Trials were performed in protected *Phacelia tanacetifolia* (PHCTA) located in representative areas of honey production (Germany, United Kingdom, South of France and Spain) during 2021. Each trial contained one untreated and one treated plot, which were treated according to the GAP table. In order to represent the worst-case scenario, two foliar applications within 10-14 days interval were performed during flowering (BBCH 60-69). Honey samples were collected from the combs, ranging from 6 to 12 days after the last application, to cover the critical period.
The residue levels were analysed in honey following the validated analytical procedure QG/21/009 described in the analytical methods section of this dossier (for details please refer to study summarized in dRR Part B5). Quantification was performed by LC-MS/MS detection. Samples were stored for up to 391 days at < -18°C between sampling and extraction. The limit of quantification was 0.005 mg/kg and the limit of detection (LOD) of 0.0015 mg/kg. Residues of prothioconazole-desthio (sum of isomers) were 3x<0.005 mg/kg (< LOQ) and 1x0.0123 mg/kg. The detailed assessment of the new studies is presented in Appendix 2 (A 2.2.6).

TDMs
In a new study performed by Lebrun (2023), four trials (2 NEU and 2 SEU) were performed to determine the residues levels in honey. Trials were performed in protected *Phacelia tanacetifolia* (PHCTA) located in representative areas of honey production (Denmark, North of France, Spain and Italy) during 2023. Each trial contained one untreated and one treated plot, which were treated according to the GAP table. In order to represent the worst-case scenario, two foliar applications within 7 ±1 days interval were performed during flowering (BBCH 60-69). Honey samples were collected from the combs, ranging from 6 to 8 days after the last application, to cover the critical period.
The residue levels were analysed in honey following the analytical validation procedure in compliance with SANTE/2020/12380 rev.2 performed with this study (for details please refer to study summarized in dRR Part B5). Quantification was performed by two independent methods, one specific for triazole alanine (TA) and one for 1,2,4-triazole, triazole acetic acid (TAA) and triazole lactic acid (TLA). Detection was done by LC-DMS-MS/MS. Samples were stored for up to 153 days at < -18°C between sampling and extraction. The limit of quantification (LOQ) was 0.01 mg/kg and the limit of detection (LOD) of 0.003 mg/kg. Residues level of the triazole derivate metabolites (TDMs) were < 0.01 mg/kg (< LOQ). The detailed assessment of the new studies is presented in Appendix 2 (A 2.2.6).
An MRL exceedance above the current value for honey of 0.01 mg/kg (Reg. (EU) 2024/1318) is not expected, as no residues of prothioconazole-desthio, 5 hydroxy- prothioconazole-desthio (sum of isomers)

and triazole derivate metabolites (TDMs) will occur in honey, showing that no exceedance of the MRL will occur.
The available data for prothioconazole (sum of prothioconazole-desthio, 5 hydroxy-prothioconazole-desthio and TDMs) sufficiently address aspects of the residue situation that might arise from the use of FGE03. Therefore, other special studies are not needed.

zRMS comments:
Information given by the Applicant is acceptable and sufficient.

The Applicant submitted two studies to determine residues of the magnitude of residues prothioconazole-desthio and hydroxy-prothioconazole-desthio metabolites in honey (Study No.: QG.21.003; Andrews & Coleman 2024 and Study No.: 644-2023; Lebrun, 2024) after two foliar applications of the formulated product FGR06, a DC formulation with a nominal concentration of 250 g/L prothioconazole applied at the target dose rate of 200 g a.s./ha to *Phacelia tanacetifolia* plants.

Residues in honey
Study No.: QG21003:
Residue levels for prothioconazole-desthio in honey samples ranged between <LOQ and 0.0123 mg/kg.
Residue levels for the five prothioconazole-hydroxy-desthio metabolites in honey samples were <LOQ.
Study No.: 644-2023:
No residues of 1,2,4-triazole (T), triazole acetic acid (TAA), triazole alanine (TA) and triazole lactic acid (TLA) were measured above the LOQ in the treated honey.

These studies comply with the requirements of SANTE /11956/2016 rev. 9, so the studies are acceptable.
More details of the residue studies in honey are provided in Appendix 2.

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

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

7.3.8.1 Input values for the consumer risk assessment

Prothioconazole
The consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo). Toxicological reference values relevant for dietary risk assessment are reported in the summary of the evaluation (see 7.1.2).
The median residue level for oilseed rape derived by EFSA (2020) in previous assessment, the current EU-MRLs (last update Reg. (EU) No 2024/1318) for the other commodities and the corresponding conversion factor of 2 for risk assessment were used as input values.

Table 7.3-22: Input values for the consumer risk assessment for prothioconazole-desthio and 5 hydroxy prothioconazole-desthio, expressed as prothioconazole-desthio (sum of isomers)

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Prothioconazole: prothioconazole-desthio (sum of isomers) (F)				
Oilseed rape	EU-MRL x CF(2)	Reg. (EU) 2024/1318 EFSA Journal 2020;18(2):5999	EU-MRL x CF(2)	Reg. (EU) 2024/1318 EFSA Journal 2020;18(2):5999
pulses, flowering brassica, Brussels sprouts, head cabbages, shallots, onions, leeks, rye, barley, oats, oilseeds, wheat	EU-MRL x CF(2)	Reg. (EU) 2024/1318 EFSA Journal 2020;18(2):5999	-	-

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	**Comment**	**Input value (mg/kg)**	**Comment**
root and tuber vegetables (except sugar beet)	EU-MRL x CF(2.7)	Reg. (EU) 2024/1318 EFSA Journal 2020;18(2):5999	-	-
All other plant commodities	EU-MRL	Reg. (EU) 2024/1318	-	-
Prothioconazole: prothioconazole-desthio (sum of isomers) (F)				
Ruminant and pig liver	EU-MRL x CF(2)	Reg. (EU) 2024/1318 EFSA 2014	EU-MRL x CF(2)	Reg. (EU) 2024/1318 EFSA 2014
Ruminant and pig kidney	EU-MRL x CF(9)	Reg. (EU) 2024/1318 EFSA 2014	EU-MRL x CF(9)	Reg. (EU) 2024/1318 EFSA 2014
All other animal commodities	EU-MRL	Reg. (EU) 2024/1318	EU-MRL	Reg. (EU) 2024/1318

Input values for the consumer risk assessment for IESTI calculation:

Commodity	Acute risk assessment	
	Input value (mg/kg)	Comment
Oilsee rape	0.06 (STMR)	New trials
Muscle of swine,bovine, sheep, goat,equine, other farmedanimals	0.01	HR (b) (FAO, 2018)
Fat of swine, bovine,sheep, goat, equine,other farmed animals	0.018	HR (b) (FAO, 2018)
Liver of swine, bovine, sheep, goat, equine,other farmed animals	0.23	HR (b) (FAO, 2009b)
Kidney, edible offal ofswine, bovine, sheep,goat, equine, otherfarmed animals	0.15	HR (b) (FAO, 2009b)
Muscle of poultry	0.0016	HR (b) (FAO, 2018)
Fat of poultry	0.008	HR (b) (FAO, 2018)
Liver, kidney, edibleoffal of poultry	0.071	HR (b) (FAO, 2018)
Milks	0.005	HR (EFSA, 2014)
Eggs	0.01	HR (EFSA, 2014)

TDMs:

The consumer risk assessment for TDMs was performed during evaluation of the pesticide risk assessment for the triazole derivative metabolites in light of confirmatory data to which explicit reference is made (United Kingdom, 2018b and EFSA, 2018). The consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo). This exposure assessment model contains the relevant European food consumption data for different sub-groups of the EU population.

No MRLs have been set for the triazole derivative metabolites at EU-level yet. Therefore, the input values were according to EFSA 2018: "…a 'worst-case' consumer exposure assessment to the TDMs has been carried out in this conclusion taking into consideration the highest residue input values for risk assessment from all the individual residue data sets for plant commodities and the highest residue levels of each TDM

arising in products of animal origin from the triazole active substances and from each of the TDMs. […] The magnitude of the TDMs have been determined in numerous residue trials conducted on crops covering most of the crop categories and for different triazole active substances both in primary and rotational crops. These trials were submitted in the framework of the confirmatory data (United Kingdom, 2015). The submitted residue trials were performed according to specific good agricultural practices (GAPs) authorised for the triazole active substances and residue trials conducted outside Europe were also available. In some cases, these residue trials were compliant with the representative uses of triazole active substances that were approved at EU level. All the residue trials that were used to perform the consumer dietary intake assessment involve only the use of a single triazole active substance, these residue trials do not reflect the situation where several different triazole active substances may be applied on a crop during the same growing season or from treatments with triazole active substances during the previous seasons. However, it is noted that significant residue levels were often found in untreated control samples of residue trials on primary and rotational crops suggesting the use of triazole pesticide active substances in previous seasons. Despite these uncertainties, the experts were of the opinion that these trials should be considered with the purpose of performing a 'worst case' consumer dietary intake calculation. It was, however, emphasised that residue trials analysing all TDMs and compliant with the European authorised uses should be provided in order to conduct a realistic consumer dietary risk assessment and also the need for monitoring data on the occurrence and background levels of all TDMs in plants. For each commodity the input residue values for risk assessment (supervised trials median residues (STMR) and the supervised trials highest residues (HR) were calculated based on all the residue trials conducted with the same active substance on this commodity and for a commodity group, the highest STMR and HR values derived from all the individual data sets have been applied to each crop within the commodity group in order to conduct the 'worst-case' consumer dietary intake calculation." The input values for the TDMs are described in Table 7.3-23, Table 7.3-24, Table 7.3-25 and Table 7.3-26.

Table 7.3-23: Input values for the consumer risk assessment – TDMs (source Triazole Derivative Metabolites February 2018 – Appendices D-F)

Crop group	Residue (mg/kg)							
	T		TA		TAA		TLA	
	STMR	HR	STMR	HR	STMR	HR	STMR	HR
Plants								
Citrus fruit	0.050	0.050	0.320	0.628	0.050	0.100	0.040	0.140
Pome fruit	0.010	0.021	0.039	0.530	0.030	0.060	0.030	0.110
Stone fruit	0.010	0.010	0.320	0.628	0.020	0.034	0.038	0.138
Berries	0.010	0.026	0.060	0.100	0.050	0.100	0.040	0.140
Banana	0.050	0.050	0.050	0.070	0.050	0.050	n.a	n.a
Root & tuber vegetables	0.010	0.016	0.184	0.239	0.010	0.010	0.021	0.131
Bulb vegetables	0.010	0.010	0.060	0.260	0.010	0.010	0.010	0.270
Fruiting vegetables	0.010	0.030	0.210	0.460	0.010	0.020	0.030	0.110
Brassica vegetables	0.039	0.113	0.170	0.500	0.010	0.010	0.010	0.010
Leafy vegetables	0.015	0.020	0.047	0.091	0.023	0.036	0.080	0.140
Legume vegetables	0.010	0.010	0.090	0.340	0.010	0.030	0.010	0.040
Stem vegetables	0.010	0.010	0.090	0.114	0.020	0.030	0.010	0.030
Pulses	0.050	0.050	0.170	3.700	0.050	0.052	0.010	0.060
Oilseeds	0.050	0.100	1.039	2.826	0.120	0.680	0.065	0.192
Oilfruits	0.050	0.100	1.039	2.826	0.120	0.680	0.065	0.192
Cereals	0.050	0.080	0.621	2.200	0.790	1.730	0.022	0.160
Sugar plants	0.050	0.060	0.050	0.078	0.050	0.050	0.010	0.010
Ruminant meat	0.270	0.310	0.460	0.620	0.040	0.040	0.040	0.040
Ruminant fat	0.180	0.240	0.220	0.340	0.050	0.080	0.070	0.100
Ruminant liver	0.310	0.360	1.010	1.360	0.050	0.050	0.040	0.040

Ruminant kidney	0.320	0.340	0.490	0.580	0.150	0.220	0.090	0.130
Ruminant milk	0.300	0.350	0.040	0.040	0.040	0.040	0.040	0.040
Sheep meat	0.290	0.330	0.510	0.680	0.040	0.040	0.040	0.040
Sheep fat	0.190	0.260	0.230	0.380	0.060	0.080	0.070	0.110
Sheet liver	0.340	0.390	1.130	1.800	0.050	0.050	0.040	0.040
Sheep kidney	0.340	0.370	0.550	0.650	0.180	0.250	0.090	0.130
Sheep milk	0.320	0.370	0.040	0.040	0.040	0.040	0.040	0.040
Swine meat	0.130	0.170	0.210	0.270	0.040	0.040	0.040	0.040
Swine fat	0.100	0.130	0.090	0.140	0.040	0.050	0.070	0.080
Swine liver	0.130	0.170	0.500	0.610	0.040	0.050	0.040	0.040
Swine kidney	0.140	0.200	0.220	0.270	0.110	0.140	0.050	0.080
Poultry meat	0.040	0.040	0.110	0.120	0.040	0.040	0.040	0.040
Poultry fat	0.040	0.040	0.010	0.110	0.040	0.040	0.040	0.040
Poultry liver	0.040	0.040	0.270	0.310	0.050	0.050	0.040	0.040
Poultry Eggs	0.040	0.040	0.060	0.060	0.040	0.040	0.040	0.040

7.3.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3. Summary tables for the consumer risk assessment are presented below for the sum of prothioconazole-desthio isomers (Table 7.3-~~27~~24) and the TDMs (Table 7.3-25-7.3-28 ~~7.3-28, Table 7.3-29, Table 7.3-30, Table 7.3-31~~).

<u>Prothioconazole</u>
A first-tier chronic consumer risk assessment was performed for prothioconazole-desthio based on available data described in Table 7.3-22 and using the EFSA PRIMo model rev 3.1. With the current EFSA model the chronic risk assessment ranges from ~~2~~ 4 to ~~30~~ 42% of ADI (see Table 7.3-27 and A 3.1.2). The diet with the highest TMDI is “NL toddler” with ~~30~~ 42% of ADI. For this diet, the highest contributors are ~~maize/corn~~ wheat with ~~7~~8% of ADI. The diet with the second highest TMDI is “GEMS/food G11” with ~~20~~36% of ADI, in which soyabeans are the major contributor with ~~7~~15% of ADI.
According to the presented TMDI calculation a chronic intake of prothioconazole residues is unlikely to present a public health concern. The proposed uses of prothioconazole in the formulation FGE03 do not represent unacceptable chronic risks for the consumer. An extensive calculation sheet is presented in Appendix 3 (A 3.1.2).
The proposed uses of prothioconazole in the formulation FGE03 do not represent unacceptable acute and chronic risks for the consumer with regard to residue of prothio-desthio (sum of isomers).

Table 7.3-~~27~~24: Consumer risk assessment for prothioconazole-desthio and 5 hydroxy prothioconazole-desthio, expressed as prothioconazole-desthio (sum of isomers)

All commodities

TMDI (% ADI) according to EFSA PRIMo	42% (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo	Further refinement not required as TMDI shows no exceedance
IESTI (% ARfD) according to EFSA PRIMo*	Unprocessed commodities Results for children 18.56% Bovine: Liver 10.91% Bovine: Edible offals (other than liver and kidney) 6.21% Milk: Cattle 5.65% Bovine: Kidney 4.50% Swine: Edible offals (other than liver and kidney) 2.82% Swine: Liver 1.90% Swine: Kidney 1.24% Eggs: Chicken 1.21% Swine: Muscle/meat 1.21% Milk: Goat 0.83% Rapeseeds/canola seeds 0.78% Poultry: Liver 0.72% Bovine: Muscle/meat

	0.69% Other farmed animals: Muscle/meat 0.60% Equine: Muscle/meat Results for adults 16.45% Swine: Other products 10.00% Bovine: Other products 9.20% Bovine: Liver 6.44% Sheep: Liver 4.98% Bovine: Edible offals (other than liver and kidney) 3.92% Swine: Edible offals (other than liver and kidney) 3.34% Poultry: Liver 3.30% Swine: Kidney 3.25% Swine: Liver 3.16% Bovine: Kidney 1.93% Milk: Cattle 1.03% Sheep: Edible offals (other than liver and kidney) 0.92% Milk: Goat 0.92% Poultry: Kidney 0.76% Milk: Sheep Processed commodities Results for children 0.4% Rapeseeds / oils Results for adults -
NTMDI (% ADI) **	N/A
NEDI (% ADI)**	N/A
NESTI (% ARfD) **	N/A

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

TDMs

Table 7.3-~~28~~25: Consumer risk assessment for 1,2,4-triazole

TMDI (% ADI) according to EFSA PRIMo	Not applicable, no MRLs set.
IEDI (% ADI) according to EFSA PRIMo	88% (based on NL toddler)
IESTI (% ARfD) according to EFSA PRIMo*	Unprocessed commodities Results for children 37.27% Milk: Cattle 7.25% Milk: Goat 2.90% Bovine: Liver 2.24% Bovine: Muscle/meat 2.06% Swine: Muscle/meat 1.86% Equine: Muscle/meat 1.79% Sheep: Muscle/meat 1.28% Bovine: Kidney 1.14% Milk: Sheep 0.68% Poultry: Muscle/meat 0.50% Bovine: Fat tissue 0.50% Eggs: Chicken 0.25% Swine: Kidney 0.22% Swine: Fat tissue 0.21% Swine: Liver Results for adults 11.57% Milk: Cattle 5.52% Milk: Goat 4.83% Milk: Sheep 1.77% Bovine: Muscle 1.56% Sheep: Muscle/meat 1.49% Equine: Muscle/meat 1.44% Bovine: Liver 1.09% Sheep: Liver 0.82% Swine: Muscle/meat 0.72% Bovine: Kidney

	0.48% Goat: Muscle 0.47% Poultry: Muscle 0.44% Swine: Kidney 0.26% Swine: Fat tissue 0.24% Swine: Liver Processed commodities Results for children 0.0% Rapeseeds / oils Results for adults -
NTMDI (% ADI) **	N/A
NEDI (% ADI)**	N/A
NESTI (% ARfD) **	N/A

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

The proposed uses of prothioconazole in the formulation FGE03 do not represent unacceptable acute and chronic risks for the consumer with regard to residue of 1,2,4-triazole.

Table 7.3-2026: Consumer risk assessment for triazole lactic acid (TLA)

TMDI (% ADI) according to EFSA PRIMo	Not applicable, no MRLs set.
IEDI (% ADI) according to EFSA PRIMo	**Normal Mode** 1% (NL toddler) 1st contributor: 0.6% Milk: Cattle 2nd contributor: 0.1% Apples 3rd contributor: 0.1% Maize/corn
IESTI (% ARfD) according to EFSA PRIMo*	Unprocessed commodities Results for children 1.66% Milk: Cattle 0.32% Milk: Goat 0.23% Poultry: Muscle/meat 0.17% Eggs: Chicken 0.16% Bovine: Kidney 0.16% Swine: Muscle/meat 0.11% Bovine: Liver 0.10% Bovine: Muscle/meat 0.08% Equine: Muscle/meat 0.07% Sheep: Muscle/meat 0.07% Bovine: Fat tissue 0.05% Milk: Sheep 0.05% Swine: Fat tissue 0.03% Swine: Kidney 0.03% Rapeseeds/canola seeds Results for adults 0.51% Milk: Cattle 0.25% Milk: Goat 0.20% Milk: Sheep 0.16% Poultry: Muscle 0.09% Bovine: Kidney 0.08% Bovine: Muscle 0.06% Swine: Muscle/meat 0.06% Equine: Muscle/meat 0.06% Sheep: Muscle/meat 0.06% Poultry: Liver 0.06% Swine: Kidney 0.06% Eggs: Chicken 0.05% Swine: Fat tissue 0.05% Bovine: Liver 0.04% Sheep: Liver Processed commodities Results for children 0.0% Rapeseeds / oils

	Results for adults -
NTMDI (% ADI) **	N/A
NEDI (% ADI)**	N/A
NESTI (% ARfD) **	N/A

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

The proposed uses of prothioconazole in the formulation FGE03 do not represent unacceptable acute and chronic risks for the consumer with regard to residue of triazole lactic acid (TLA).

Table 7.3-~~30~~27: Consumer risk assessment for triazole acetic acid (TAA)

TMDI (% ADI) according to EFSA PRIMo	Not applicable, no MRLs set.
IEDI (% ADI) according to EFSA PRIMo	**Normal Mode** 0.5% (NL toddler) 1st contributor: 0.1% Milk: Cattle 2nd contributor: 0.1% Maize/corn 3rd contributor: 0.0% Apples **Refined mode** 0.5% (NL toddler) 1st contributor: 0.2% Milk: Cattle 2nd contributor: 0.1% Maize/corn 3rd contributor: 0.0% Apples
IESTI (% ARfD) according to EFSA PRIMo*	**Normal Mode** Wheat: 1% (based on unprocessed commodities, children) Rice: 0.7% (based on unprocessed commodities, adults) Sugar beets (roots)/sugar: 0.6% (based on processed commodities, children) Sugar beets (roots)/sugar: 0.2% (based on processed commodities, adults) Unprocessed commodities Results for children 0.50% Milk: Cattle 0.10% Milk: Goat 0.08% Bovine: Kidney 0.07% Poultry: Muscle/meat 0.05% Eggs: Chicken 0.05% Swine: Muscle/meat 0.04% Bovine: Liver 0.03% Bovine: Muscle/meat 0.02% Equine: Muscle/meat 0.02% Sheep: Muscle/meat 0.02% Swine: Kidney 0.02% Bovine: Fat tissue 0.02% Rapeseeds/canola seeds 0.01% Milk: Sheep 0.01% Swine: Fat tissue Results for adults 0.15% Milk: Cattle 0.07% Milk: Goat 0.06% Milk: Sheep 0.05% Poultry: Muscle 0.05% Bovine: Kidney 0.03% Swine: Kidney 0.02% Poultry: Liver 0.02% Bovine: Muscle 0.02% Bovine: Liver 0.02% Swine: Muscle/meat 0.02% Equine: Muscle/meat 0.02% Sheep: Muscle/meat

	0.02% Eggs: Chicken 0.01% Sheep: Liver 0.01% Swine: Fat tissue Processed commodities Results for children 0.0% Rapeseeds / oils Results for adults -
NTMDI (% ADI) **	N/A
NEDI (% ADI)**	N/A
NESTI (% ARfD) **	N/A

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

The proposed uses of prothioconazole in the formulation FGE03 do not represent unacceptable acute and chronic risks for the consumer with regard to residues of triazole acetic acid (TAA).

Table 7.3-~~31~~28: Consumer risk assessment for triazole alanine (TA)

TMDI (% ADI) according to EFSA PRIMo	Not applicable, no MRLs set.
IEDI (% ADI) according to EFSA PRIMo	6% (based on NL toddler)
IESTI (% ARfD) according to EFSA PRIMo*	Unprocessed commodities Results for children 3.66% Bovine: Liver 1.66% Milk: Cattle 1.49% Bovine: Muscle/meat 1.24% Equine: Muscle/meat 1.23% Sheep: Muscle/meat 1.09% Swine: Muscle/meat 0.73% Bovine: Kidney 0.68% Poultry: Muscle/meat 0.48% Rapeseeds/canola seeds 0.32% Milk: Goat 0.25% Swine: Liver 0.25% Eggs: Chicken 0.24% Bovine: Fat tissue 0.11% Swine: Kidney 0.11% Poultry: Liver Results for adults 1.81% Bovine: Liver 1.68% Sheep: Liver 1.18% Bovine: Muscle 1.07% Sheep: Muscle/meat 0.99% Equine: Muscle/meat 0.51% Milk: Cattle 0.49% Poultry: Liver 0.47% Poultry: Muscle 0.44% Swine: Muscle/meat 0.41% Bovine: Kidney 0.32% Goat: Muscle 0.29% Swine: Liver 0.25% Milk: Goat 0.20% Milk: Sheep 0.20% Swine: Kidney Processed commodities Results for children 0.2% Rapeseeds / oils Results for adults -
NTMDI (% ADI) **	N/A
NEDI (% ADI)**	N/A

NESTI (% ARfD) **	N/A

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

The proposed uses of prothioconazole in the formulation FGE03 do not represent unacceptable acute and chronic risks for the consumer with regard to residue of triazole alanine (TA).

The proposed uses of prothioconazole in the formulation FGE03 do not represent unacceptable acute and chronic risks for the consumer with regard to the residue definition.

zRMS comments:
TMDI calculation for prothioconazole was performed using the in-force MRLs (Regulation (EU) 2024/1318) and appropriate conversion factors for enforcement to risk assessment.

Prothioconazole
The calculation of the TMDI using EFSA model (version 3.1) and MRLs values according to the Regulation (EU) 2024/1318 and appropriate conversion factors for enforcement to risk assessment led to a utilisation of the ADI of 42% with the NL toddler being the population group with the highest value. For this diet, the highest contributor is wheat with 8% of the ADI. The intended uses will not result in a consumer chronic exposure exceeding the ADI for prothioconazole-desthio.
An acute consumer risk assessment was performed only for the crops under consideration. IESTI: for children – 18.56% (Bovine: Liver), for adults – 16.45% (Swine: Other products).

TDMs
The dietary risk assessment was calculated using PRIMo rev 3.1 for each TDM. Toxicological reference values and input values from EFSA conclusion on confirmatory data on TDMs (EFSA, 2018) were taken into account.

The data available are considered sufficient for risk assessment. The chronic and the short-term intakes of prothioconazole residues and TDMs are unlikely to present a public health concern.
The intended uses of FGE03/Patton Boost are accepted.

7.4 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.
The product is a mixture of two active substances, but for only one of them has an acute reference dose been allocated. Therefore, combined acute exposure is not considered.

zRMS comment:
The product FGE03 is a mixture of prothioconazole and boscalid. Although no acute reference dose has been allocated to boscalid, acute reference doses were set for the TDMs. Therefore, the risk assessment of combined exposure is relevant.

As first approach, dose-addition of residues of the individual active substances is assumed by making use of the Hazard Index (HI) concept. The Hazard Quotient (HQ) is calculated for all compounds in the PPP that are acutely toxic.
An ARfD has been established for prothioconazole, 1,2,4-T, TA, TAA and TLA. An acute consumer risk assessment from combined exposure can be performed using Hazard Index (HI), calculated with the following formula:

$$HI = \Sigma\ HQ$$

with HQ (Hazard Quotient) = IESTI/ARfD

The Hazard Index for the commodities under consideration is <1. Thus, combined exposure to all residues in FGE03 is not expected to present a consumer risk. No further refinement of the assessment is required.

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United Kingdom, 2019. Evaluation report on the confirmatory data assessment and setting of prothioconazole MRLs in oilseed rape. March, 2019, 71pp.

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
Boscalid					
KCA 6.1/01 (CP 7.2.1)	Flore, S.	2022	Storage Stability of Boscalid in Honey under Deep Frozen Conditions Report no. S22-01684 – UPL/2022/0340 Eurofins Agroscience Services EcoChem GmbH, Germany GLP Unpublished	N	UPL
~~KCA 6.3/01 (CP 7.3.3)~~	~~Davolos, CC.~~	~~2024~~	~~OECD calculator for oilseed rape and honey for the active substance boscalid and prothioconazole based on the use of the FGE03 formulation.~~ ~~File name: OECD Calculator_FGG03_prothioconazole_intended uses~~ ~~Unpublished~~	~~N~~	~~UPL~~
KCA 6.3.1/01; KCA 6.5.2/01 (CP 7.2.3 and (CP 7.2.5)	North, L.	2023	Determination of residues of Boscalid after two applications of Boscalid 500 WG in Oilseed rape and its processed fractions at 4 sites in Northern Europe and 4 sites in Southern Europe 2022 Report no. S22-01574 – UPL/2022/0442 Eurofins Agroscience Services Ltd., United Kingdom GLP Unpublished	N	UPL
KCA 6.3.1/02 (CP 7.2.3)	North, L.	2024	Determination of residues of Boscalid after two applications of Boscalid 500 WG in Oilseed rape at 4 sites in Northern Europe and 4 sites in Southern Europe 2023 Report no. S23-00040 - UPL/2023/0503 Eurofins Agroscience Services Ltd., United Kingdom GLP Unpublished	N	UPL
~~KCA 6.4/01 (CP 7.2.4)~~	~~Davolos, CC.~~	~~2024b~~	~~Animal burden calculation of boscalid based on the use of the FGE03 formulation.~~ ~~File name: boscalid_mrl_guidelines_animal_model_2017~~ ~~Unpublished~~	~~N~~	~~UPL~~
~~KCA 6.9/01 (CP 7.2.8)~~	~~Davolos, CC.~~	~~2024~~	~~Dietary Risk Assessment of boscalid based on the use of the FGE03 formulation.~~ ~~File name: Chronic_EFSA_PRIMo_rev3.1_boscalid~~ ~~Unpublished~~	~~N~~	~~UPL~~

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.10/01 (CP 7.2.7)	Knoll, M.	2022	Boscalid 500 WG: Determination of Residues of Boscalid in Honey after two Applications in Winter Oilseed Rape at Four Sites in Northern and Southern Europe in 2022 Report no. S22-00761 – UPL/2022/0377 Eurofins Agroscience Services EcoChem GmbH, Germany GLP Unpublished	N	UPL
Prothioconazole					
KCA 6.1/02 (CP 7.3.1)	Giancola, D.	2025	Prothioconazole-desthio and 5 hydroxy metabolites: Frozen Storage Stability in Crops ~~– Interim Report~~ Report No.: QG/21/001 Battelle UK, Essex, UK GLP Unpublished	N	UPL Europe Limited Sipcam Oxon S.p.A Barclays Chemicals (R&D) Limited Albaugh Europe Sàrl
KCA 6.1/03	Baxter, B. Phipps	2025	Triazole Derived Metabolites: Frozen Storage Stability in Crops for 12 Months; Study No.: QG/21/002 Battelle UK, Essex, UK GLP Unpublished	N	UPL Europe Limited
KCA 6.1/04 (CP 7.3.1)	Jooß, S.	2025	Storage Stability of the Triazole Derivative Metabolites (TDMs) in Plant Matrices under Deep Frozen Conditions. Study No.: S23-105428 Eurofins Agroscience Services EAG Laboratories GmbH GLP Unpublished	N	UPL Europe Limited
KCA 6.1/05 (CP 7.3.1)	Giancola, D.	2023	Prothioconazole-desthio and 5 hydroxy metabolites: Frozen Storage Stability in Honey Study No.: QG/21/007 Battelle UK, Essex, UK GLP Unpublished	N	UPL Europe Limited Sipcam Oxon S.p.A Barclays Chemicals (R&D) Limited Albaugh Europe Sàrl

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	**Vertebrate study Y/N**	**Owner**
KCA 6.1/0~~4~~6 (CP 7.3.1)	Mealing, H.	2024	Triazole Derivative Metabolites: Frozen Storage Stability in Honey for 6 months Study No.: QG/21/006 Battelle UK, Essex, UK GLP Unpublished	N	UPL Europe Limited Sipcam Oxon S.p.A Barclays Chemicals (R&D) Limited Albaugh Europe Sàrl
KCA 6.1/~~05~~07 (CP 7.3.1)	[redacted]	2020	Storage Stability of Triazole Alanine (TA), Triazole Acetic Acid (TAA) and Triazole Lactic Acid (TLA) in Animal Matrices under Deep Frozen Conditions. Report No. 869333 [redacted] GLP Unpublished	Y	TDMG (LoA to UPL)
~~KCA 6.1/06~~07	~~Baxter, B. Phipps~~	~~2025~~	~~Triazole Derived Metabolites: Frozen Storage Stability in Crops for 12 Months;~~ ~~Study No.: QG/21/002~~ ~~Battelle UK, Essex, UK~~ ~~GLP~~ ~~Unpublished~~	~~N~~	~~UPL Europe Limited~~
KCA 6.5.1/01 (CP 7.3.2.3)	Bloß, K.	2022	[^{14}C] Prothioconazole-desthio Hydrolysis under Typical Conditions (pH, Temperature and Time) of Processing. Report No.: S21-04814 Eurofins Agroscience Services EcoChem GmbH GLP Unpublished	N	UPL Europe Limited
~~KCA 6.3.1/03~~ ~~(CP 7.3.3)~~	~~Hardy, J.;~~ ~~Coleman, H.~~	~~2024~~	~~Magnitude of Residues of Prothioconazole-desthio, Hydroxy-prothioconazole-desthio metabolites, Triazole Lactic Acid and Triazole Acetic Acid Following Two Applications of a 250 g/L EC Formulation to Oilseed Rape in Southern Europe, 2020~~ ~~Report No.: QG20008~~ ~~GLP~~ ~~Unpublished~~	~~N~~	~~UPL Europe Limited~~ ~~Barclays Chemicals (R&D) Limited~~ ~~Albaugh Europe Sàrl~~
KCA 6.3.1/04 (CP 7.3.3)	Toscano-Saes, R.; Coleman, H.	2023	Magnitude of Residues of Prothioconazole-desthio and Hydroxyprothioconazole-desthio Metabolites Following Two Applications of a Prothioconazole 250 g/L DC Formulation to Oilseed Rape in Northern and Southern Europe, 2021 Report No.: NZ/21/002	N	UPL Europe Limited Barclays Chemicals (R&D) Limited

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
			GLP Unpublished		Albaugh Europe Sàrl
~~KCA 6.3.1/05 (CP 7.3.3)~~	~~Toscano-Saes, R.; Coleman, H.~~	~~2023~~	~~Magnitude of Residues of Prothioconazole-desthio and Hydroxyprothioconazole-desthio metabolites Following Two Applications of Prothioconazole 250 g/L DC (FGR06) to Oilseed rape in southern Europe, 2022~~ ~~Report No.: QG22006~~ ~~GLP~~ ~~Unpublished~~	~~N~~	~~UPL Europe Limited~~ ~~Sipcam Oxon S.p.A~~ ~~Barclays Chemicals (R&D) Limited~~ ~~Albaugh Europe Sàrl~~
KCA 6.3.1/06 (CP 7.3.3)	Toscano-Saes, R.; Coleman, H.	2023	Magnitude of Residues of Prothioconazole-desthio and Hydroxyprothiocon-azole-desthio metabolites Following Two Applications of Prothioconazole 250 g/L DC (FGR06) to Oilseed rape in northern Europe, 2022 Report No.: QG22007 GLP Unpublished	N	UPL Europe Limited Sipcam Oxon S.p.A Barclays Chemicals (R&D) Limited Albaugh Europe Sàrl
KCA 6.3.1/07 (CP 7.3.3)	Bousquet, C.	2024	Magnitude of the residue of prothioconazole metabolites in oilseed rape in Northern and Southern Europe – 2023 Report No.: 647-2023 GLP Unpublished	N	UPL Europe Limited Barclays Chemicals (R&D) Limited Albaugh Europe Sàrl
KCA 6.3.1/08 (CP 7.3.3)	Gibson, G.; Toscano-Saes, R.	2022	Magnitude of Residues of Triazole Derived Metabolites (TDM's) (triazole acetic acid and triazole lactic acid) Following Two Applications of Prothioconazole 250 g/L DC (FGR06) to Oilseed Rape in Northern and Southern Europe, 2021 Report No.: NZ/21/003 GLP Unpublished	N	UPL Europe Limited Barclays Chemicals (R&D) Limited Albaugh Europe Sàrl
~~KCA 6.3.1/09 (CP 7.3.3)~~	~~Toscano-Saes, R.~~	~~2023~~	~~Magnitude of Residues of Triazole Derived Metabolites (TDM's) (triazole acetic acid and triazole lactic acid) Following Two Applications of Prothioconazole 250 g/L DC (FGR06) to Oilseed Rape in Southern Europe, 2022~~ ~~Report No.: EE/23/006~~ ~~GLP~~ ~~Unpublished~~	~~N~~	~~UPL Europe Limited~~ ~~Barclays Chemicals (R&D) Limited~~ ~~Albaugh Europe Sàrl~~
KCA 6.3.1/10	Phipps, B.	2023	Magnitude of Residues of Triazole Derived Metabolites (TDM's) (triazole acetic acid and triazole	N	UPL Europe Limited

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
(CP 7.3.3)			lactic acid) in Oilseed Rape Following Two Appli-cations of Prothioconazole 250 g/L DC (FGR06) in Northern Europe, 2022 Report No.: EE/23/007 GLP Unpublished		Barclays Chemicals (R&D) Limited Albaugh Europe Sàrl
~~KCA 6.4/02 (CP 7.3.4)~~	~~Davolos, CC.~~	~~2024~~	~~Animal burden calculation of prothioconazole based on the use of the FGE03 formulation.~~ ~~File name: prothioconazole_mrl_guidelines_animal_model_2017~~ ~~Unpublished~~	~~N~~	~~UPL~~
KCA 6.4.2/01 (CP 7.3.4)	[redacted]	2021	Determination of the Triazole Derived Metabolites in Eggs and Tissues of Laying Hens following Multiple Oral Administration of Triazole Lactic Acid Report No. IF19-05004879 [redacted] GLP Unpublished	Y	TDMG (LoA to UPL)
KCA 6.4.2/02 (CP 7.3.4)	[redacted]	2021	Determination of the Triazole Derived Metabolites in Milk and Tissues of Dairy Cows Multiple Oral Administration of Triazole Lactic Acid Report No. IF19-05004884 [redacted] GLP Unpublished	Y	TDMG (LoA to UPL)
KCA 6.6.2/01 (CP 7.3.6)	Semrau, J.	2022	Determination of residues of prothioconazole metabolites and triazole derivative metabolites in rotational crops (turnip, leaf lettuce, wheat) after one application of Prothioconazole 250g/L EC on bare soil at 2 sites in Northern Europe and 2 sites in Southern Europe 2022-2024. Report No.: S22-02433 (Study Plan) Eurofins Agroscience Services EcoChem GmbH GLP Unpublished	N	UPL Europe Limited
~~KCA 6.9/02 (CP 7.3.8)~~	~~Davolos, CC.~~	~~2024~~	~~Dietary Risk Assessment of prothioconazole based on the use of the FGE03 formulation.~~ ~~File name: Chronic_EFSA_PRIMo_rev3.1_prothioconazole~~ ~~Unpublished~~	~~N~~	~~UPL~~
KCA 6.10/02 (CP 7.3.7)	Andrews, G. Coleman, H.	2023	Magnitude of Residues of Prothioconazole-desthio and Hydroxy prothioconazole-desthio Metabolites in Honey Following Two Tunnel Applications of a Prothioconazole 250 g/L EC Formulation (FF-065) to	N	UPL Europe Limited

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
			Phacelia in Northern and Southern Europe, 2021 Study No.: QG/21/003 Battelle UK, Essex, UK GLP Unpublished		Sipcam Oxon S.p.A Barclays Chemicals (R&D) Limited Albaugh Europe Sàrl
KCA 6.10/03 (CP 7.3.7)	Lebrun, F.	2024	Magnitude of the residue of triazole derivative metabolites in phacelia honey in Northern and Southern Europe – 2023 Study No.: 644-2023 Battelle UK, Essex, UK GLP Unpublished	N	UPL Europe Limited Albaugh Europe Sàrl

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
Boscalid					
KCA 6.1	Funk H., Mackenroth, C.	2001	Investigation of the Stability of Residues of BAS 510 F in Plant Matrices under Storge Conditions. Report No. 2001/1015028; RIP2002-192 GLP Unpublished	N	BASF
KCA 6.2.1	Rabe U., Schlueter H.	2001	Metabolism of 14C-BAS 510 F in grapevine BASF AG Agrarzentrum Limburgerhof; Limburgerhof; Germany Fed.Rep. Report No. 2000/1014860 GLP Unpublished	N	BASF
KCA 6.2.1	Hamm R.T.	1999	BAS 510 F in lettuce Report No. 1999/11240 GLP Unpublished	N	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 6.2.1	Veit P.	2001	Metabolism of 14C-BAS 510 F in beans Report No. 2000/1014861 GLP Unpublished	N	BASF
KCA 6.2.2	[redacted]	2000	The Metabolism of 14C-BAS 510F in Lactating Goat. Report No. 000/1012353; RIP2001-331 GLP Unpublished	Y	BASF
KCA 6.2.2	[redacted]	2000	14C-BAS 510 F- Absorption, Distribution and Excretion after Repeated Oral Administration in Lactating Goats. Report No. BASF DocID: 2000/1017221; RIP2001-330GLP Unpublished	Y	BASF
KCA 6.2.2	[redacted]	2001	Nature of Residues of 14C-BAS 510 F in Laying Hens. Report No. 2000/5154; RIP2001-332 GLP Unpublished	Y	BASF
KCA 6.3.1	Beck, J.	2003	Study on the residue behavior of Boscalid (BAS 510 F) in grapes (wine) after application of BAS 510 01 F under field conditions in Germany, France, Italy and Spain, 2002 Report no. 2003/1001357 GLP Unpublished	N	BASF
KCA 6.3.1	Moreno, S.	2003	Study on the residue behavior of Boscalid (BAS 510 F) in grapes (wine) after application of BAS 510 01 F under field conditions in Spain, 2002 Report no. 2003/1001279 GLP Unpublished	N	BASF
KCA 6.3.1	Schulz, H.	2004	Study on the residue behavior of BAS 510 F in vines after application of BAS 510 01 F under field conditions in France (N & S), Spain, Italy and Germany, 2003 Report no. 2004/1015915 GLP Unpublished	N	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.3.2	Raunft, E.	2001	Study on the residue behavior of BAS 510 F in winter rape after treatment with BAS 510 01 F under field conditions in Germany, Sweden and Great Britain, 2000. Report no. BASF DocID 2000/1014851 GLP Unpublished	N	BASF
KCA 6.3.2	Peny, A.	2001	Residue study in oil seed rape following treatment with the preparation BAS 510 01 F under field conditions in France in 2000. Report no. BASF DocID 2000/1014877 GLP Unpublished	N	BASF
KCA 6.3.2	Schulz, H.	2005	Study on the residue behavior of BAS 510 F in spring rape after treatment with BAS 510 01 F under field conditions in Germany, England and Sweden, 2004 Report no. BASF DocID 2005/1004971 GLP Unpublished	N	BASF
KCA 6.3.2	Oxspring S.,	2007	Study on the residue behaviour of BAS 510 F in spring oilseed rape after treatment with BAS 510 01 F under field conditions in Southern Europe during 2006 Report no. BASF DocID 2007/1007952 GLP Unpublished	N	BASF
KCA 6.3.2	Schaeufele, M.	2009	Residue study (decline) with BAS 664 AS F, BAS 510 01 F and BAS 555 00 F applied to oilseed rape in Germany and Northern France in 2008 Report no. BASF DocID 2008/1074165 GLP Unpublished	N	BASF
KCA 6.3.3	Heck, W.	2000	Study on the residue behavior of BAS 510 F in peas after treatment with BAS 510 01 F under field conditions in Germany, Denmark and Sweden, 1999 Report no. BASF DocID 2000/1014848 GLP Unpublished	N	BASF
KCA 6.3.3	Schulz, H.	2000	Determination of the residue of BAS 510 F in peas following treatment with BAS 510 01 F under field conditions in France 1999 Re port no. BASF DocID 2000/1014879	N	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
			GLP Unpublished		
KCA 6.3.3	Heck W., Mackenroth C.	2001	Study on the residue behavior of BAS 510 F in peas after treatment with BAS 510 01 F under field conditions in Germany, Denmark, France and Sweden, 2000 Report no. BASF DocID 2000/1014852 GLP Unpublished	N	BASF
KCA 6.3.3	Perny, A.	2001	Residue study in green peas following treatment with the preparation BAS 510 01 F under field conditions in France in 2000 Report no. BASF DocID 2000/1014878 GLP Unpublished	N	BASF
KCA 6.3.3	Klaas, P.	2008	Study on the residue behavior of BAS 510 F in green beans after treatment with BAS 510 01 F under field conditions in Germany, the Netherlands, United Kingdom and Northern France, 2007. Report no. BASF DocID 2008/1028266 GLP Unpublished	N	BASF
KCA 6.3.3	Schulz, H.	2011	Study on the residue behavior of Boscalid in green beans after treatment with BAS 510 01 F under field conditions in Germany, the Netherlands, Northern France, Belgium, Southern France, Greece, Italy and Spain, 2009 Report no. BASF DocID 2010/1165744 GLP Unpublished	N	BASF
KCA 6.3.3	Meyer M.,	2011	Study on the residue behaviour of Boscalid in green beans after treatment with BAS 510 01 F under field conditions in Southern Europe (Southern France, Greece, Italy and Spain) and Northern Europe (Belgium), 2010 Report no. BASF DocID 2011/1251203 GLP Unpublished	N	BASF
KCA 6.4.1	[redacted]	2002	A meat and egg magnitude of the residue study with BAS 510 F in laying hens. Report no. 2002/5002466 GLP Unpublished	Y	BASF
KCA 6.4.2	[redacted]	2001	Residues in milk and edible tissues following oral administration of BAS 510 F to lactating dairy cattle. Report no. 2000/1017228 GLP	Y	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
			Unpublished		
KCA 6.4.2	[redacted]	2008	A meat and milk magnitude of the residue study with BAS 510 F in lactating dairy cows Report no. 2008/7015330 GLP Unpublished	Y	BASF
KCA 6.5.1	Scharf J.	1998	Hydrolysis of BAS 510 F at 90°C, 100°C, and 120°C Report no. 1998/10878 GLP Unpublished	N	BASF
KCA 6.5.3	Meumann H. et al.	2000	Study on the residue behaviour of BAS 510 F in grape process fractions after treatment with BAS 510 01 F under field conditions in Germany, 1999 Report no. 2000/1012412 GLP Unpublished	N	BASF
KCA 6.5.3	Scharm M.	2001	Determination of the residue of Reg. no. 300 355 in peas and processed products following treatment with BAS 510 01 F under field conditions in Germany 2000 Report no. 2000/1014885 GLP Unpublished	N	BASF
KCA 6.5.3	Versoi P.L., Abdel-Baky S.	2001	The magnitude of BAS 510 F residues in canola seed processed fractions. Report no. 2001/5001064 GLP Unpublished	N	BASF
KCA 6.6.1	Hamm R.T., Veit P.	2001	Confined rotational crop study with ^{14}C-BAS 510 F Report no. 2000/1014862 GLP Unpublished	N	BASF
KCA 6.6.2	Funk H., Mackenroth C.	2001	Determination of the residues of BAS 510 F in wheat obtained from the trial year 2000 Report no. 2000/1014853, RIP2001-374 GLP Unpublished	N	BASF
KCA 6.6.2	Funk H., Mackenroth C.	2001	Report amendment no. 1 to final report: Determination of the residues of BAS 510 F in wheat obtained from the trial year 2000.	N	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
			Report no. 2001/1000989, RIP2001-375 GLP Unpublished		
KCA 6.6.2	Jeannine M. J,	2002	Cereal Grains and Soybean Field Rotational Study for BAS 510 F, Report no. 2002/5001341 GLP Unpublished	N	BASF
KCA 6.6.2	Jeannine M. J,	2002	Field Rotational Study for BAS 510 F on Grasses, Alfalfa and Clover as Livestock Feed Crops Report no. 2002/5002063 GLP Unpublished	N	BASF
KCA 6.6.2	David W. Haughey, Samy Abdel-Baky	2001	Limited Rotational Crop Study for the Use of BAS 510 F Report no. 2001/5000966 GLP Unpublished	N	BASF
KCA 6.6.2	Versoi, P., Abdel-Baby, S.	2001	Magnitude of the Residue of BAS 510 F in Peas and Beans Planted as Rotational Crops and of BAS 500 F in Peas and Beans When Applied as a Foliar Spray Report no. 2001/5003311 GLP Unpublished	N	BASF
KCA 6.6.2	Raymond C. L.	2002	Sugar Beet, Garden Beet and Turnip Field Rotational Crop Study for BAS 510 02 F Residues. Report no. 2002/5004273 GLP Unpublished	N	BASF
KCA 6.6.2	Beck, J., Lehmann, A. Grote, C., Mackenroth, C.	2003	Study on the residue behaviour of Boscalid (BAS 510 F) on succeeding crops after application of BAS 510 01 F on bare soil and cultivation of potatoes under field conditions in Denmark, France, Germany and Great Britain, 2002 Report no. 2003/1001358 GLP Unpublished	N	BASF
KCA 6.6.2	Schroth E., Martin T.	2008	Study on the residue behaviour of BAS 510 F on the rotational crop: Carrots, after the application to the soil of BAS 510 01 F under field conditions in France (South), Germany, Netherlands and Spain, 2007 Report no. 2008/1036949 GLP Unpublished	N	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 6.6	Hamm, T.R.; Veit, P.	2001	Confined Rotational Crop Study with 14CBAS 510 F. BASF DocID.: 2000/1014862 - RIP2001-373 GLP Unpublished	N	BASF
Prothioconazole					
KCA 6.1	Heinemann, O.	2001	18 months storage stability of residues of JAU 6476 and JAU 6476-desthio during frozen storage in/on wheat matrices Report no. MR-282/00 GLP Unpublished	N	BCS
KCA 6.2	Hass M.; Bornatsch W.	2000	Metabolism of JAU 6476 in sugar beets Report no. 200466 GLP Unpublished	N	BCS
KCA 6.2	Vogeler K.; Sakamoto H.; Brauner A.	1993	Metabolism of SXX 0665 in summer wheat Report no. PF3906 GLP Unpublished	N	BCS
KCA 6.2	Haas M.	2001	Metabolism of JAU 6476 in spring wheat after seed dressing Report no. MR-467/99 GLP Unpublished	N	BCS
KCA 6.2	Haas M.	2001	Extraction efficient testing of the residue method (00647) for the determination of JAU 6476 residues in spring wheat using aged radioactive residues. Report no. MR-467/99 GLP Unpublished	N	
KCA 6.2	[redacted]	2002	[Phenyl-UL-^{14}C]JAU 6476 Absorption, distribution, excretion and metabolism in the lactating goat Report no. MR-092/01 GLP Unpublished	Y	BCS
KCA 6.2	[redacted]	2002	[Phenyl-UL-^{14}C] JAU 6476-desthio Absorption, distribution, excretion, and metabolism in the lactating goat	Y	BCS

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Report no. MR-091/01 GLP Unpublished		
KCA 6.2	[redacted]	2001	[Phenyl-UL-^{14}C]JAU 6476 Absorption, distribution, excretion and metabolism in laying hens Report no. MR-309/01 GLP Unpublished	Y	BCS
KCA 6.4	[redacted]	2001	JAU 6476-desthio – Dairy cattle feeding study Report No.: MR-535/00 GLP Unpublished	Y	BCS
KCA 6.5	Gilges M.	2001	Hydrolysis of JAU 6476 under conditions of processing Report No.: MR-166/00 GLP Unpublished	N	BCS
KCA 6.6	Haas M.	2001	Confined rotational crop study with JAU 6476 Report no. MR-159/00 GLP Unpublished	N	BCS
Triazole Derivate Metabolite (TDMs)					
For the relevant studies please refer to the EU peer review of the triazole derivative metabolites (TDMs) in the light of confirmatory data submitted (UK, 2018b, EFSA, 2018b, amended 2019).					

List of data submitted by the applicant and not relied on

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

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

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

Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1 Boscalid

A 2.1.1 Stability of residues

A 2.1.1.1 Stability of residues during storage of samples

A 2.1.1.1.1 Storage stability of residues in plant products

No additional data.

A 2.1.1.1.2 Storage stability of residues in animal products

A 2.1.1.1.2.1 Study 1

Comments of zRMS:	Residues of boscalid in honey have been shown to be stable under deep freeze storage conditions (≤ -18°C) for 5 months. Sample extraction and determination of residues was performed according to the analytical method of validation study S22-00776. The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg. All method validation data are within the acceptable criteria: mean recovery range of 70-120% and relative standard deviation ≤ 20%. The study was conducted according to the OECD 506 and is acceptable.

Reference:	KCA 6.1/01 (CP 7.2.1)
Report	Storage stability of boscalid in honey under deep frozen conditions, Flore S., 2022, report no. S22-01684, document no. UPL/2022/0340
Guideline(s):	Yes (OECD 506; SANTE/2020/12830, rev.1 and ENV/MC/CHEM(98)17)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods
Honey specimens were homogenized by thoroughly stirring with a spatula and stored at ≤ -18°C in the dark until fortification and extraction. Samples were fortified with boscalid at 0.10 mg/kg (10 x LOQ), and after homogenization they were stored at ≤ -18°C. Fortified samples were analysed after 0 and 30 and 149 days of storage.
The analytical method is based on multi-residue method QuEChERS and involved an extraction of the samples with acetonitrile, followed by addition of water. After centrifugation an aliquot of the extract was cleaned by dispersive SPE with PSA and magnesium sulphate. Final sample extracts were diluted with water:acetonitrile (1:1) and final determination was performed by LC-MS/MS. The primary analytical method was fully validated for honey in the study S22-00776 (Sahvorost, N., 2022 - submitted as KCP 5.2/01) summarized in dRR Part B5, and a partial validation in honey was performed in study S22-00761 (Knoll, M. 2022, submitted as KCA 6.10/01 (CP 7.2.7)).

Results and discussions
The recoveries and stability results are given in Table A 2.1-1 and A 2.1-2.
After 149 days of storage 70% of the initial amount of boscalid in honey was determined indicating that residues are stable for at least 5 months of storage at -18°C.

Table A 2.1-2: Summary of concurrent recoveries of boscalid from honey

Matrix	Spike level (mg/kg)	Storage Interval (days)	Sample size (n)	Individual procedural recoveries (%)	Mean ± std dev
Boscalid					
Honey	0.10	0	2	105, 105	105
	0.10	30	2	91, 97	94 ±3
	0.10	149	2	108, 106	107 ±1

Table A 2.1-3: Stability of boscalid residues in honey following storage at -18°C

Matrix	Spike level (mg/kg)	Storage interval (days)	Individual recovered residues (mg/kg)	Individual recoveries (%)
Boscalid				
Honey	0.10	0	0.105, 0.105	105
	0.10	30	0.091, 0.097	94
	0.10	149	0.108, 0.106	107

Conclusion
According to EC guideline 7032/VI/95, residues can be regarded as stable if the mean recovery at a given storage period does not fall below 70% of the initial value. Results from this study indicate that residues of boscalid are stable in honey for at up 149 days (5 months) of storage at ≤-18°C.

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

A 2.1.2.1 Nature of residue in plants

No additional data.

A 2.1.2.2 Nature of residues in livestock

No additional data.

A 2.1.3 Magnitude of residues in plants

A 2.1.3.1 Oilseed rape

Table A 2.1-3: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (DAR, Germany, 2002 and EFSA, 2014)	1-2	0.25	8-12 days	61-69	35
Intended cGAP (number ~~0~~1 and ~~0~~2)	1-2	0.245	~~n.a.~~ 14 days	~~57-69~~ 61-73	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

Comments of zRMS:	Eight residue trials (4N-EU and 4 S-EU) were conducted on oilseed rape during 2022. Two applications of FGG01 (50% w/w, boscalid) was applied to plot 2 at 250 g ai/ha (target) with a 14±1 day treatment interval at 49 and 35 days before harvest with the second application performed during BBCH 67-81. Samples of whole plant from the treated plots were taken by hand 0, 7, 14 and 21 days after the final application. Samples of seed from the treated plots were taken by hand 35-36 days after the final application (NCH). The analytical method as developed within S22-06799 was used for the analysis of samples within analytical phase. The limit of quantification (LOQ) was 0.01 mg/kg Max. study storage interval between sampling and extraction for boscalid was 311 days. The study on the magnitude of residues is valid with regard to storage stability. <u>Results for N-EU:</u> Residues of boscalid in whole plant: 0.97, 1.2mg/kg Residues of boscalid in seed: 0.016, 0.074, 0.16; 0.22 mg/kg. The study is acceptable.

Reference:	KCA 6.3.1/01 and KCA 6.5.2/01 (CP 7.2.3)
Report	Determination of residues of Boscalid after two applications of Boscalid 500 WG in Oilseed rape and its processed fractions at 4 sites in Northern Europe and 4 sites in Southern Europe 2022, North, L., 2023, report no. S22-01574, document no. UPL/2022/0442.
Guideline(s):	Yes (OECD 506; OECD 508; SANTE/2020/12830, rev.1 and ENV/MC/CHEM(98)17).
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

The objective of the study was to determine the residue level of boscalid in oilseed rape. Eight trials were conducted on field oilseed rape during 2022 in Northern Europe (4 NEU) and Southern Europe (4 SEU). Test sites were in United Kingdom, Germany, Poland, France (2 trials), Italy, Spain and Bulgaria. Half of the trials (4NEU and 4SEU) were performed as decline trials and half as harvest.

Oilseed rape fields were treated with two foliar applications with Boscalid 500 g/Kg WG formulation (code FGG01) at a dose rate of 250 g boscalid/ha (equivalent to 0.5 kg product/ha) and 200-400 L/ha water spray volume. The applications targeted a 14±1 day retreatment interval with the second application performed during BBCH 67-81.
Specimens consisted of oilseed rape whole plant and seed. In the decline trials, specimens were taken at 0 days after last application (DALA), at 7 DALA, 14 DALA, 21 DALA and 35 DALA, which represents the normal commercial harvest. Specimen from the harvest trials was taken at normal commercial harvest (35 DALA).

Results and discussions
Specimens were analysed for residues of boscalid by following the validated analytical procedure developed at Eurofins AgroSciences services described in study no. S22-06799 (see study Rastogi, 2022, summarised in dRR Part B5). Extraction was performed with the mixture of methanol, water and hydrochloric acid (70:25:5). After cleaning, the extract was reconstituted in methanol/water (1:1). Quantification was performed by LC-MS/MS detection. Samples were stored for up to 311 days at < -18°C between sampling and extraction.
The limit of quantification (LOQ) for the analysis of boscalid in oilseed rape was 0.01 mg/kg with a limit of detection (LOD) of 0.003 mg/kg. No residues of boscalid above the limit of detection were found in any of the untreated specimens.
Overall mean recovery efficiencies for boscalid in oilseed rape within this study were within the required range of 70 – 120%. The relative standard deviation was less than 20% at all fortification levels, thus demonstrating sufficient accuracy and precision of the method in accordance with SANTE/2020/12830, rev.1. Calibration curves were established with satisfactory linearity (r > 0.995).
Residues in treated oilseed rape seed samples ranged from 0.016 mg/kg to 0.25 mg/kg. Detailed results are described in Table A 2.1-4.

Table A 2.1-44: Summary of the study no. S22-01574 - 8 trials (4 NEU and 4 SEU)

Reference:	KCA 6.3.1/01		
Report	Determination of residues of Boscalid after two applications of Boscalid 500 WG in Oilseed rape and its processed fractions at 4 sites in Northern Europe and 4 sites in Southern Europe 2022, North, L., 2023, report no. S22-01574, document no UPL/2022/0442		
GLP:	Yes	Sample storage conditions:	Up to 311 days; -18°C
Crop:	Oilseed rape	Analytical method:	S22-06799, validated
Succeeding crop:	-	Limit of Quantification (mg/kg):	0.01 mg/kg
Indoor/Outdoor:	Field	Limit of Detection (mg/kg):	0.003 mg/kg
Formulation:	FGG01	Residues calculated as:	Boscalid
Content of active substance (g/kg or g/L):	500 g/kg		

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						
S22-01574-01 Bickerstaffe, Lancashire, UK	Oilseed rape / Ramses	15 Aug 2021 Not applicable 15 Jul 2022	-	-	-	-	-	Whole plant Seed	< 0.01 < 0.01	0 35	Analytical procedure S22-06799 extracts were analysed within 24 hours
			256 260	307 312	83.4 83.3	27 May 2022 10 Jun 2022	75 79	Whole plant Whole plant Whole plant Whole plant Whole plant Whole plant Whole plant Whole plant Seed	2.3 2.5* 2.4 2.6* 2.4 3.0* 1.2 1.2* 0.22	0 0 7 7 14 14 21 21 35	
S22-01574-02 Bernau, Brandenburg, Germany	Oilseed rape / Ludger	01 Sep 2021 05-28 May 2022 14 Jul 2022	-	-	-	-	-	Whole plant Seed	< 0.01 < 0.01	0 35	Analytical procedure S22-06799 extracts were analysed within 24 hours

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						
Continuation S22-01574-02			247 256	296 307	83.4 83.4	25 May 2022 09 Jun 2022	67-69 79	Whole plant Whole plant Whole plant Whole plant Whole plant Whole plant Whole plant Whole plant Seed	3.1 3.5* 2.4 2.0* 1.8 1.7* 0.84 0.97* 0.16	0 0 7 7 14 14 21 21 35	
S22-01574-03 Obrzycko, Wielkopolskie, Poland	Oilseed rape / Derrick	25 Aug 2021 07-27 May 2022 21 Jul 2022	-	-	-	-	-	Seed	< 0.01	36	Analytical procedure S22-06799 extracts were analysed within 24 hours
			266 258	426 413	62.4 62.5	01 Jun 2022 15 Jun 2022	73 80	Seed	0.074	36	
S22-01574-04 Sermersheim, Bas-Rhin, France	Oilseed rape / Temptation	01 Sep 2021 01-30 Apr 2022 05 Jul 2022	-	-	-	-	-	Seed	< 0.01	35	Analytical procedure S22-06799 extracts were analysed within 24 hours
			256 242	307 290	83.4 83.4	17 May 2022 31 May 2022	77 80	Seed	0.016	35	
~~S22-01574-05~~ ~~Torraba de los Frailes, Aragon, Spain~~	~~Oilseed rape / Implement~~	~~19 Sep 2021~~ ~~Not applicable~~ ~~25 Jul 2022~~	~~-~~	~~-~~	~~-~~	~~-~~	~~-~~	~~Whole plant~~ ~~Seed~~	~~< 0.01~~ ~~< 0.01~~	~~0~~ ~~35~~	~~Analytical procedure S22-06799 extracts were analysed within 24 hours~~

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						
~~Continuation S22-01574-05~~			~~303~~ ~~294~~	~~303~~ ~~294~~	~~83.5~~ ~~83.3~~	~~06 Jun 2022~~ ~~20 Jun 2022~~	~~65-71~~ ~~71-75~~	~~Whole plant~~ ~~Whole plant~~ ~~Whole plant~~ ~~Whole plant~~ ~~Whole plant~~ ~~Whole plant~~ ~~Whole plant~~ ~~Whole plant~~ ~~Seed~~	~~4.5~~ ~~3.3*~~ ~~3.8~~ ~~0.36*~~ ~~2.4~~ ~~2.1*~~ ~~2.7~~ ~~2.7*~~ ~~0.25~~	~~0~~ ~~0~~ ~~7~~ ~~7~~ ~~14~~ ~~14~~ ~~21~~ ~~21~~ ~~35~~	
~~S22-01574-06~~ ~~Villanova Di Castenaso, Emilia-Romagna, Italy~~	~~Oilseed rape / Miranda~~	~~20 Oct 2021~~ ~~16 Apr – 15 May 2022~~ ~~14 Jun 2022~~	~~-~~	~~-~~	~~-~~	~~-~~	~~-~~	~~Whole plant~~ ~~Seed~~	~~< 0.01~~ ~~< 0.01~~	~~0~~ ~~35~~	~~Analytical procedure S22-06799 extracts were analysed within 24 hours~~
			~~258~~ ~~235~~	~~310~~ ~~282~~	~~83.2~~ ~~83.3~~	~~26 Apr 2022~~ ~~10 May 2022~~	~~61-63~~ ~~67~~	~~Whole plant~~ ~~Whole plant~~ ~~Whole plant~~ ~~Whole plant~~ ~~Whole plant~~ ~~Whole plant~~ ~~Whole plant~~ ~~Whole plant~~ ~~Seed~~	~~3.6~~ ~~4.7*~~ ~~2.3~~ ~~2.3*~~ ~~1.7~~ ~~1.7*~~ ~~1.5~~ ~~1.4*~~ ~~0.22~~	~~0~~ ~~0~~ ~~7~~ ~~7~~ ~~14~~ ~~14~~ ~~21~~ ~~21~~ ~~35~~	
~~S22-01574-07~~ ~~Chernyovo, Sofia, Bulgaria~~	~~Oilseed rape / DK Immozta CL~~	~~12 Oct 2021~~ ~~03-15 May 2022~~ ~~13 Jul 2022~~	~~-~~	~~-~~	~~-~~	~~-~~	~~-~~	~~Seed~~	~~< 0.01~~	~~35~~	~~Analytical procedure S22-06799 extracts were analysed within 24 hours~~
			~~259~~ ~~261~~	~~362~~ ~~365~~	~~71.5~~ ~~71.5~~	~~25 May 2022~~ ~~08 Jun 2022~~	~~75~~ ~~79~~	~~Seed~~	~~0.024~~	~~35~~	
~~S22-01574-08~~ ~~Cordes-Tolosannes, Tarn et Garonne, France~~	~~Oilseed rape / Expacito~~	~~02 Sep 2021~~ ~~Not recorded~~ ~~21 Jun 2022~~	~~-~~	~~-~~	~~-~~	~~-~~	~~-~~	~~Seed~~	~~< 0.01~~	~~35~~	~~Analytical procedure S22-06799 extracts were analysed within 24 hours~~
			~~256~~ ~~261~~	~~205~~ ~~209~~	~~125~~ ~~125~~	~~03 May 2022~~ ~~17 May 2022~~	~~79~~ ~~79-81~~	~~Seed~~	~~0.082~~	~~35~~	

A 2.1.3.1.2 Study 2

Comments of zRMS:	Eight residue trials (4N-EU and 4 S-EU) were conducted on oilseed rape during 2023. Two applications of Boscalid 500 WG, FGG01 (50% w/w, boscalid) were applied at 0.5 kg ai/ha (target) at 49 and 35 days before harvest. The applications targeted a 14±1 day treatment interval with the second application performed during BBCH 69-80. From trials S2-00040-01, -02 samples of oilseed rape from the treated plots were taken by hand 0, 7, 14, 21 and 35 days after the final application. From trials S23-00040-03, -04 samples of oilseed rape from the untreated and treated plots were taken by hand 35 days after the final application. Based on analytical method validated in study S22-06799. The limit of quantification (LOQ) was 0.01 mg/kg. Max. study storage interval between sampling and extraction for boscalid was 121 days. The study on the magnitude of residues is valid with regard to storage stability. <u>Results for N-EU:</u> Residues of boscalid in whole plant: 0.58, 0.78 mg/kg Residues of boscalid in seed: <0.01, 0.012, 0.041, 0.081 mg/kg. The study is acceptable.

Reference:	KCA 6.3.1/02 (CP 7.2.3)
Report	Determination of residues of Boscalid after two applications of Boscalid 500 WG in Oilseed rape at 4 sites in Northern Europe and 4 sites in Southern Europe 2023, North, L., 2024, report no. S23-00040, document no. UPL/2023/0503.
Guideline(s):	Yes (OECD 506; OECD 508; SANTE/2020/12830, rev.1 and ENV/MC/CHEM(98)17).
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

The objective of the study was to determine the residue level of boscalid in oilseed rape. Eight trials were conducted on field oilseed rape during 2023 in Northern Europe (4 NEU) and Southern Europe (4 SEU). Test sites were in United Kingdom, Germany, Poland, France (2 trials), Italy, Spain, and Bulgaria. Half of the trials (4NEU and 4SEU) were performed as decline trials and half as harvest.

Oilseed rape fields were treated with two foliar applications with Boscalid 500 g/Kg WG formulation (code FGG01) at a dose rate of 250 g boscalid/ha (equivalent to 0.5 kg product/ha) and 100-400 L/ha water spray volume. The applications targeted a 14±1 day retreatment interval with the second application performed during BBCH 69-80.

Specimens consisted of oilseed rape whole plant and seed. In the decline trials, specimens were taken at 0 days after last application (DALA), at 7 DALA, 14 DALA, 21 DALA and 35 DALA, which represents the normal commercial harvest. Specimen from the harvest trials was taken at normal commercial harvest (35 DALA).

Results and discussions

Specimens were analysed for residues of boscalid by following the validated analytical procedure developed at Eurofins AgroSciences services described in study no. S22-06799 (see study Rastogi, 2022, summarised in dRR Part B5). Extraction was performed with the mixture of methanol, water and hydrochloric acid (70:25:5). After cleaning, the extract was reconstituted in methanol/water (1:1).

Quantification was performed by LC-MS/MS detection. Samples were stored for up to 121 days at < -18°C between sampling and extraction.
The limit of quantification (LOQ) for the analysis of boscalid in oilseed rape was 0.01 mg/kg with a limit of detection (LOD) of 0.003 mg/kg. No residues of boscalid above the limit of detection were found in any of the untreated specimens.
Overall mean recovery efficiencies for boscalid in oilseed rape within this study were within the required range of 70 – 120%. The relative standard deviation was less than 20% at all fortification levels, thus demonstrating sufficient accuracy and precision of the method in accordance with SANTE/2020/12830, rev.1. Calibration curves were established with satisfactory linearity (r > 0.995).
Residues in treated oilseed rape seed samples ranged from <0.01 mg/kg (<LOQ) to 0.78 mg/kg. Detailed results are described in Table A 2.1-5.

Table A 2.1-5: Summary of study no. S23-00040 - 8 trials (4 NEU and 4 SEU)

Reference:	KCA 6.3.1/02		
Report	Determination of residues of Boscalid after two applications of Boscalid 500 WG in Oilseed rape at 4 sites in Northern Europe and 4 sites in Southern Europe 2023, North, L., 2024, report no. S23-00040, document no. UPL/2023/0503		
GLP:	Yes	Sample storage conditions:	Up to 121 days; -18°C
Crop:	Oilseed rape	Analytical method:	S22-06799, validated
Succeeding crop:	-	Limit of Quantification (mg/kg):	0.01 mg/kg
Indoor/Outdoor:	Field	Limit of Detection (mg/kg):	0.003 mg/kg
Formulation:	FGG01	Residues calculated as:	Boscalid
Content of active substance (g/kg or g/L):	500 g/kg		

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						
S23-00040-01 64-530, Obrzycko, Wielkopolskie, Poland	Oilseed rape / Quincy	27 Aug 2022 Not applicable 20 Jul 2023	-	-	-	-	-	Whole plant Seed	< 0.01 < 0.01	0 35	Analytical procedure S22-06799 extracts were analysed within 24 hours
			285 252	228 201	125 125	01 Jun 2023 15 Jun 2023	72 75	Whole plant Whole plant Whole plant Whole plant Seed	3.3 1.2 0.63 0.58 0.081	0 7 14 21 35	
S23-00040-02 LE651SE, Lount, Leicestershire, UK	Oilseed rape / Campus	06 Sep 2022 15 Apr – 22 May 2023 21 Jul 2023	-	-	-	-	-	Whole plant Seed	< 0.01 < 0.01	0 35	Analytical procedure S22-06799 extracts were analysed within 24 hours
			240 242	192 193	125 125	02 Jun 2023 16 Jun 2023	71-73 79-80	Whole plant Whole plant Whole plant Whole plant Seed	4.6 0.74 0.90 0.78 0.041	0 7 14 21 35	
S23-00040-03 45390 Aulney-la-Rivière, Loiret, Northern France	Oilseed rape / LF Aviron	16 Aug 2022 03 Apr – 12 May 2023 28 Jun 2023	-	-	-	-	-	Seed	< 0.01	28	Analytical procedure S22-06799 extracts were analysed within 24 hours

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						
			253 246	202 196	125 125	17 May 2023 31 May 2023	72 78	Seed	0.012	28	
S23-00040-04 21784, Geversdorf, Niedersachsen, Germany	Oilseed rape / PT 303	22 Aug 2022 Not available 02 Aug 2023	-	-	-	-	-	Seed	< 0.01	28	Analytical procedure S22-06799 extracts were analysed within 24 hours
			248 244	297 293	83 83	12 Jun 2023 26 Jun 2023	79 79	Seed	<0.01	28	
~~S23-00040-05~~ ~~40057,~~ ~~Granarolo dell'Emilia~~ ~~Emilia-Romagna,~~ ~~Italy~~	~~Oilseed rape / Expectation (DEKALB)~~	~~20 Sep 2022~~ ~~05-24 Apr~~ ~~12 Jun 2023~~	~~-~~	~~-~~	~~-~~	~~-~~	~~-~~	~~Whole plant~~ ~~Seed~~	~~< 0.01~~ ~~< 0.01~~	~~0~~ ~~35~~	~~Analytical procedure S22-06799 extracts were analysed within 24 hours~~
			~~271~~ ~~240~~	~~325~~ ~~288~~	~~83~~ ~~83~~	~~24 Apr 2023~~ ~~08 May 2023~~	~~69~~ ~~75~~	~~Whole plant~~ ~~Whole plant~~ ~~Whole plant~~ ~~Whole plant~~ ~~Seed~~	~~3.0~~ ~~0.46~~ ~~0.26~~ ~~0.24~~ ~~0.056~~	~~0~~ ~~7~~ ~~14~~ ~~21~~ ~~35~~	
~~S23-00040-06~~ ~~82 290,~~ ~~La Ville-Dieu du Temple,~~ ~~Tarn et Garonne,~~ ~~Southern France~~	~~Oilseed rape / DK expacito~~	~~15 Sep 2022~~ ~~Not applicable~~ ~~28 Jun 2023~~	~~-~~	~~-~~	~~-~~	~~-~~	~~-~~	~~Whole plant~~ ~~Seed~~	~~< 0.01~~ ~~< 0.01~~	~~0~~ ~~35~~	~~Analytical procedure S22-06799 extracts were analysed within 24 hours~~
			~~257~~ ~~254~~	~~205~~ ~~203~~	~~125~~ ~~125~~	~~11 May 2023~~ ~~25 May 2023~~	~~71~~ ~~80~~	~~Whole plant~~ ~~Whole plant~~ ~~Whole plant~~ ~~Whole plant~~ ~~Seed~~	~~7.0~~ ~~4.6~~ ~~6.5~~ ~~4.7~~ ~~0.11~~	~~0~~ ~~7~~ ~~14~~ ~~21~~ ~~35~~	
~~S23-00040-07~~ ~~44492, Allueva,~~ ~~Aragon,~~ ~~Spain~~	~~Oilseed rape / click CL~~	~~20 Feb 2023~~ ~~Not applicable~~ ~~15 Aug 2023~~	~~-~~	~~-~~	~~-~~	~~-~~	~~-~~	~~Seed~~	~~< 0.01~~	~~35~~	~~Analytical procedure S22-06799 extracts were analysed within 24 hours~~
~~Continuation~~ ~~S23-00040-07~~			~~271~~ ~~254~~	~~325~~ ~~325~~	~~83~~ ~~83~~	~~27 Jun 2023~~ ~~11 Jul 2023~~	~~67~~ ~~75~~	~~Seed~~	~~0.78~~	~~35~~	
~~S23-00040-08~~		~~16 Aug 2022~~	~~-~~	~~-~~	~~-~~	~~-~~	~~-~~	~~Seed~~	~~< 0.01~~	~~35~~	

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						
~~2068, Polyantsi, Sofia, Bulgaria~~	~~Oilseed rape / DK immortal CL~~	~~03 Apr – 12 May 2023 28 Jun 2023~~	~~247 227~~	~~346 360~~	~~71 71~~	~~02 Jun 2023 16 Jun 2023~~	~~67-71 75~~	~~Seed~~	~~0.069~~	~~35~~	~~Analytical procedure S22-06799 extracts were analysed within 24 hours~~

A 2.1.4 Magnitude of residues in livestock

A 2.1.4.1 Livestock feeding studies

No additional data

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

A 2.1.5.1 Distribution of the residue in peel/pulp

No additional data

A 2.1.5.2 Processing studies on a core set of representative processes

A 2.1.5.2.1 Study 1

Comments of zRMS:	Two residue trials were conducted on oilseed rape during 2022 for the processing phase. Oilseed rape fields were treated with two foliar applications with Boscalid 500 g/kg WG formulation (code FGG01) at a dose rate of 1250 g boscalid/ha (equivalent to 5N dose). The applications targeted a 14±1 day retreatment interval with the second application performed during BBCH 67-81. Specimen was taken at normal commercial harvest (35 DALA) and processed into raw oil, press cake and crude oil. The analytical method as developed within S22-06799 was used for the analysis of samples within analytical phase. The limit of quantification (LOQ) was 0.01 mg/kg Max. study storage interval between sampling and extraction for boscalid was 273 days. The study on the magnitude of residues is valid with regard to storage stability. The same levels of boscalid residue in processed commodities was found in the raw agricultural commodity, generating a processing factor of 1.0 for raw and crude oil. For meal (press cake) a median processing factor < 1 (0.23 mg/kg and 0.24 mg/kg) was calculated. The study is acceptable.

Reference:	KCA 6.3.1/01 and KCA 6.5.2/01 (CP 7.2.5)
Report	Determination of residues of Boscalid after two applications of Boscalid 500 WG in Oilseed rape and its processed fractions at 4 sites in Northern Europe and 4 sites in Southern Europe 2022, North, L., 2023, report no. S22-01574, document no. UPL/2022/0442.
Guideline(s):	Yes (OECD 506; OECD 508; SANTE/2020/12830, rev.1 and ENV/MC/CHEM(98)17).
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

The objective of the study was to determine the residue level of boscalid in processing fractions of oilseed rape. Two trials were conducted on oilseed rape during 2022 in Northern Europe (Germany) and Southern Europe (North-France).

Oilseed rape fields were treated with two foliar applications with Boscalid 500 g/Kg WG formulation (code FGG01) at a dose rate of 1250 g boscalid/ha (equivalent to 5N dose) and 200-400 L/ha water spray volume. The applications targeted a 14±1 day retreatment interval with the second application performed during

BBCH 67-81. Specimen was taken at normal commercial harvest (35 DALA) and processed into raw oil, press cake and crude oil.

Results and discussions

Specimens were analysed for residues of boscalid by following the validated analytical procedure developed at Eurofins AgroSciences services described in study no. S22-06799 (see study Rastogi, 2022, KCP 5.2/01 summarised in dRR Part B5). Extraction was performed with the mixture of methanol, water and hydrochloric acid (70:25:5). After cleaning, the extract was reconstituted in methanol/water (1:1). Quantification was performed by LC-MS/MS detection. Samples were stored for up to 273 days at < -18°C between sampling and extraction.

The limit of quantification (LOQ) for the analysis of boscalid in oilseed rape was 0.01 mg/kg with a limit of detection (LOD) of 0.003 mg/kg. No residues of boscalid above the limit of detection were found in any of the untreated specimens.

Overall mean recovery efficiencies for boscalid in oilseed rape within this study were within the required range of 70 – 120%. The relative standard deviation was less than 20% at all fortification levels, thus demonstrating sufficient accuracy and precision of the method in accordance with SANTE/2020/12830, rev.1. Calibration curves were established with satisfactory linearity (r > 0.995).

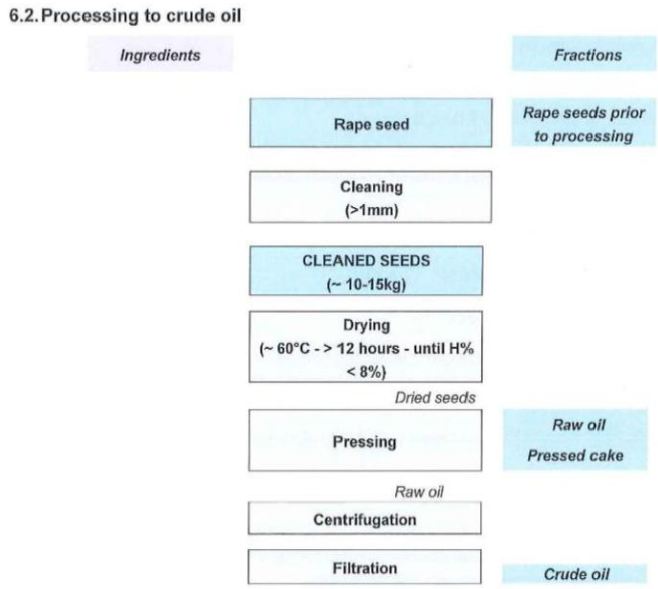
The same levels of boscalid residue in processed commodities was found in the raw agricultural commodity, generating a processing factor of 1.0 for raw and crude oil. Detailed results are described in Table A 2.1-6 and the flowchart is described in Figure A1.

Table A 5: Residue data from Oilseed rape processing study with boscalid

RAC	Residues in RAC (unwashed sample, mg/kg)	PHI (days)	Processed commodity	Residue (mg/kg)	PF*	Comments/ Reference
Oilseed rape	2.4	35	Raw oil Press cake Crude oil	2.5 0.23 2.3	1.0 0.10 0.96	North, L., 2023, report no. S22-01574
	1.4	35	Raw oil Press cake Crude oil	1.6 0.24 1.4	1.1 0.17 1.0	

* processing factor

Figure A 1: Processing flowchart for crude oil



Conclusion

No specific processing factor was determined for the processing of oil seed rape into oil, since the same levels of boscalid residues in processed products (raw and crude oil) was found in the raw agricultural

product. No specific processing factors were used for dietary exposure assessments and no specific MRL was derived for oil.

A 2.1.6 Magnitude of residues in representative succeeding crops

No additional data.

A 2.1.7 Other/Special Studies

A 2.1.7.1 Study 1

Comments of zRMS:	Four independent residues trials was conducted to determine the magnitude of residues boscalid in honey under semi-field conditions at four sites in Northern and Southern Europe. Two applications of FGG01 at a dose rate of 500 g boscalid/ha were made with 7±1 day tretreatment interval with the second application performed during the flowering period (BBCH 60-69) of oilseed rape. The multi-residue method QuEChERS that was previously validated (study S22-00776) according to SANTE/2020/12830, rev. 1 for monitoring for honey with a limit of quantification of 0.01 mg/kg. Samples were stored for up to 19 days at < -18°C between sampling and extraction. This is covered by the storage stability test. Residue levels for boscalid in treated samples ranged between < 0.01 mg/kg to 0.0455 mg/kg. The study is acceptable.

Reference:	KCA 6.10/01 (CP 7.2.7)
Report	Boscalid 500 WG: Determination of residues of boscalid in honey after two applications in winter oilseed rape at four sites in Northern and Southern Europe in 2022, Knoll M., 2022, report no. S22-00761, document no. UPL/2022/0377
Guideline(s):	Yes (OECD 509 (published in June 2021 and SANTE/2020/12830, rev.1)
Deviations:	Yes (without impact)
GLP:	Yes
Acceptability:	Yes

Materials and methods
The objective of the study was to determine the residue level of boscalid in honey. Four trials were conducted on protected oilseed rape during 2022 in Northern Europe (2 NEU) and Southern Europe (2 SEU). Test sites were in Germany and Spain.
Protected oilseed rape was treated with two foliar applications with Boscalid 500 g/Kg WG formulation (code FGG01) at a dose rate of 500 g boscalid/ha (equivalent to 1 kg product/ha) and nominal 300 L/ha water spray volume. The applications targeted a 7±1 day retreatment interval with the second application performed during the flowering period (BBCH 60-69).

Results and discussions
Specimens were analysed for residues of boscalid by following the validated analytical procedure developed at Eurofins AgroSciences services described in study no. S22-00776 (see study Sahvorost, 2022, summarised in dRR Part B5). Extraction was performed with acetonitrile, after addition of water. Cleaning was performed by dispersive SPE with primary/secondary amine (PSA), the extract was reconstituted in methanol/water (1:1) with 0.5% formic acid. Quantification was performed by LC-MS/MS detection. Samples were stored for up to 19 days at < -18°C between sampling and extraction.

The limit of quantification (LOQ) for the analysis of boscalid in honey was 0.01 mg/kg. No residues of boscalid above the limit of detection were found in any of the untreated specimens.
Overall mean recovery efficiencies for boscalid in honey within this study were within the required range of 70 – 120%. The relative standard deviation was less than 20% at all fortification levels, thus demonstrating sufficient accuracy and precision of the method in accordance with SANTE/2020/12830, rev.1. Calibration curves were established with satisfactory linearity (r > 0.995).
Residues in treated honey samples ranged from < 0.01 mg/kg to 0.0455 mg/kg. Detailed results are described in Table A 2.1-7.

Table A 2.1-7: Summary of study no. S22-00761 - 4 trials (2 NEU and 2 SEU)

Reference:	KCA 6.10/01		
Report	Boscalid 500 WG: Determination of residues of boscalid in honey after two applications in winter oilseed rape at four sites in Northern and Southern Europe in 2022, Knoll M., 2022, report no. S22-00761, document no. UPL/2022/0377		
GLP:	Yes	Sample storage conditions:	Up to 19 days; -18°C
Crop:	Honey*	Analytical method:	S22-00776, validated
Succeeding crop:	-	Limit of Quantification (mg/kg):	0.01 mg/kg
Indoor/Outdoor:	Protected – DE and ES	Limit of Detection (mg/kg):	0.003 mg/kg
Formulation:	FGG01	Residues calculated as:	Boscalid
Content of active substance (g/kg or g/L):	500 g/kg		

Location including Postal Code	Commodity / Variety (a)	Date of Sowing or Planting (b)	Application rate per treatment		Dates of treatment (c)	Growth stage at Application (A) and at Sampling		Portion analysed	Residues (mg/kg)	PHI Days (d)	Details on trial (e)
			g a.s./ha	water (L/ha)		A	S		Boscalid		
Eggenstein-Leopoldshafen, Baden-Württemberg, 76344 Germany	Honey*	08 Sep 2021	--	--	Untreated	-	65	Honey*	<0.01	n.a.	Analytical procedure S22-00776 extracts were analysed within 24 hours
			488.5 505.4	293.1 303.2	Treated A1= 13 April 2022 A2= 19 April 2022	63 65	65	Honey*	0.0273	3 DALA	
Pforzheim, Baden-Württemberg, 75177 Germany	Honey*	07 Sep 2021	--	--	Untreated	-	67	Honey*	<0.01	n.a.	
			495.3 492.4	297.2 295.4	Treated A1= 19 April 2022 A2= 27 April 2022	63 65	67	Honey*	0.0455	8 DALA	
Valdeganga, Cestille le Maniche 02150 Spain	Honey*	24 Sep 2021	--	--	Untreated	-	69	Honey*	<0.01	n.a.	
			486.5 471.0	291.9 282.6	Treated A1= 07 Apr 2022 A2= 14 Apr 2022	63 64-65	69	Honey*	0.0133	27 DALA	
Almansa, Albacete, 02640 Spain	Honey*	27 Oct 2021	--	--	Untreated	-	68-69	Honey*	<0.01	n.a.	
			499.3 502.4	299.6 301.4	Treated A1= 15 Apr 2022 A2= 21 Apr 2022	66-70 62-73	68-69	Honey*	<0.01	21 DALA	

DALA = Days After Last Application to the Treated Plot
* The honey was produced by bees with access to a flowering OSR crop only
n.a.: not applicable. Untreated and treated plots samples were collected at the same day

The limit of quantification (LOQ) was 0.01 mg/kg for the analyte.
Sample residues below the validated LOQ are reported as <0.01 mg/kg. All other residues are reported to 4 decimal place.

A 2.2 Prothioconazole

A 2.2.1 Stability of residues

A 2.2.1.1 Stability of residues during storage of samples

A 2.2.1.1.1 Storage stability of residues in plant products

A 2.2.1.1.1.1 Study 1

Comments of zRMS:	The interim report for study KCA 6.1/01 (Giancola, D., 2024, Study No.: QG/21/001) includes 8 –12 months of storage data was evaluated by zRMS-PL in RR for PPP of FHO04 /Patton Supra (January 2025). In our opinion the storage stability results for prothioconazole-desthio hydroxy metabolites in some matrices and for some time points are ambiguous / inconclusive and it is difficult to clearly indicate the time point until which the metabolites are stable. Procedural recoveries at some timepoints are outside of acceptance criteria (70% to 120%) and therefore data were not accepted. **The results of this study should be discussed by other cMS during the commenting period.** The results of the study demonstrate that prothioconazole-desthio in following samples: orange, field bean (dried) and oilseed rape seed, prothioconazole (5) hydroxy metabolites in wheat (grain, forage and straw), orange, field bean (dried) and oilseed rape seed are stable under frozen storage at -18 °C or below for 24 months, except: - prothioconazole-6-hydroxy-desthio in wheat forage and grain are stable for 12 months, - prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio and prothioconazole-6-hydroxy-desthio in oilseed rape (seed) are stable for 18, 12 and 6 months, respectively, - prothioconazole-α-hydroxy-desthio and prothioconazole-3-hydroxy-desthio in field bean (dried) are stable for 12 and 18 months, respectively. Two methods of analysis were used for prothioconazole-desthio (QG/20/011, J. Pearson, 2022) and its (5) hydroxy metabolites (QG/22/001, D. Giancola, 2023). All samples were analysed by liquid chromatography coupled with a tandem mass spectrometer (LC-MS/MS). The LOQ of the methods was 0.005 mg/kg. The mean recoveries over all testing intervals were within 60% - 120% with the relative standard deviations ≤ 20 % for all analytes and matrices. For more details please refer to Part B5. The study was conducted according to the OECD 506 and is acceptable.

Reference:	KCA 6.1/02 (CP 7.3.1)
Report	Prothioconazole-desthio and 5 hydroxy metabolites: Frozen Storage Stability in crops. Giancola, D., Martin, J., 2024. Report No.: QG/21/001
Guideline(s):	Yes (OECD 506, ENV/JM/MONO(2009)31, SANTE/2020/12830)
Deviations:	Deviations from study plan: 1. Test item Prothioconazole-α-hydroxy-desthio batch number 4276-094A18 was used from 26th September onwards. No impact as test item deemed fit for use within study. 2. Samples for field beans matrix due for analysis at 6 months ± 14 days were analysed on the 24th of May (for Prothioconazole-3-hydroxy-desthio, Prothioconazole-4-hydroxy-desthio, Prothioconazole-5-hydroxy-desthio, Prothioconazole-6-hydroxy-desthio) and on the 6th of June (for Prothioconazole-α-hydroxy-desthio).Therefore, samples for field beans matrix were analysed at 7 months ± 14 instead of 6 months. No impact on the study as

all the other timepoints will be carried out as per study plan.
3. The following test items were used that had the same batch number as stated in the study plan, but differing purities and expiry dates: Prothioconazole-3-hydroxy-desthiowith a purity of 99.6% and expiration date of 23 June 2025; Prothioconazole-4-hydroxy-desthio with a purity of 99.6% and expiration date of 23 June 2025, and Prothioconazole-6-hydroxy-desthio with a purity of 98.0% and expiration date of 23
June 2025. No impact on the study as concentrations of solutions and standards used in the study amened accordingly to the test item purity used.
4. In each batch from 1 to 63 a reagent blank, consisting of ACN: H2O 80:20 v/v was analysed alongside control blank, recovery sample and stability samples. No impact as the RB was analysed to check any contamination from the extraction solvent used.
5. GMS 2995 and std 705 onward, were prepared using Prothioconazole-5-hydroxy-desthio batch number 3922-021A4 expiring on 23 June 2025. No impact as the correct test item with the updated expiry date was used.
6. Calculations to generate final result spreadsheets differed from the calculations reported in the Study Plan. No impact as correct calculation used. No impact as correct calculation used.
These deviations have been collectively assessed to have no impact on the study.
7. Procedural recoveries below 70% were accepted for Prothioconazole-α-hydroxy-desthio in batch 48RB, 69RB and 86RD; for Prothioconazole-3-hydroxy-desthio in batch 86RC; for Prothioconazole-5-hydroxy-desthio in batch 32RB and 71RD; for Prothioconazole-6-hydroxy-desthio in batch 56RC. No impact as these data were accepted to allow the comparison with the stability sample data and correctly evaluate a possible residue decline for the analyte.

GLP:	Yes
Acceptability:	Yes

Materials and methods

Samples of orange, field bean (dried) and oilseed rape seed were individually fortified with prothioconazole-desthio and its 5 hydroxy metabolites at a concentration of 0.05 mg/kg (10x LOQ) and stored at nominal temperature of -18°C. Duplicate stability samples were analysed. Samples of wheat (grain, forage and straw) were individually fortified with prothioconazole 5 hydroxy metabolites at a concentration of 0.05 mg/kg (10x LOQ) and stored at nominal temperature of -18°C. Duplicate stability samples were analysed. Wheat (grain, forage and straw), orange, field bean (dried) and oilseed rape seed samples were analysed at 0, 1, 3, 6, 12, 18 and 24 months. The 6-month timepoint was analysed for prothioconazole-desthio (5) hydroxy metabolites in field bean (dried) at 7 months. Additional samples of prothioconazole-6-hydroxy-desthio in wheat grain were analysed at 8 months. For each matrix and each interval, 2 fortified stability samples per analyte and per matrix were weighed along with 2 procedural recovery samples fortified on the day of extraction (at 10x LOQ). For each interval, 1 control sample and 1 reagent blank were also analysed. For each matrix, two additional sets of fortified stability samples were fortified at the start of the study.
Two methods of analysis were used for prothioconazole-desthio and its 5 hydroxy metabolites. Residues of prothioconazole-desthio were extracted from oilseed rape seed, field bean (dried) and orange by dissolving the samples in water and then extracting the analyte with acetonitrile using QuEChERS kits. A portion of the final extract was then taken through the SPE clean-up and then diluted with water 2:3 v/v for final determination by liquid chromatography with tandem mass spectrometry (LC-MS/MS). One ion mass transition (quantitation transition) was monitored for stability samples.
Residues of prothioconazole-desthio and its 5 hydroxy metabolites were extracted from oilseed rape seed, field beans (dried) and orange by shaking in acetonitrile: water (80:20 v/v) followed by filtration through Whatman filter paper. Residues of prothioconazole-desthio and its 5 hydroxy metabolites were extracted from wheat forage, wheat grain and wheat straw with acetonitrile and QuEChERS extraction salts, followed by centrifugation. An aliquot of the acetonitrile phase was then taken and mixed with water. For all matrices, the

extracts were evaporated to the aqueous remainder by rotary evaporation.
The extracts were then adjusted to pH 3-4 using 1M HCl and incubated for hydrolysis at 80°C for one hour. After hydrolysis, the sample extracts were then adjusted to pH 7 using 1M sodium bicarbonate solution. Sample extracts were then cleaned up by liquid/liquid partition using cyclohexane/ethyl acetate (85:15, v/v). The organic layer was then evaporated to dryness under a stream of nitrogen. After reconstitution in acetonitrile and water, a portion of the final extract is taken for final determination by liquid chromatography with tandem mass spectrometry (LC-MS/MS).

The objective of this study was to provide information on the stability of residues of in oilseed rape (seed), field bean (dried) and orange and residues of prothioconazole-desthio (5) hydroxy metabolites in oilseed rape (seed), field bean (dried), orange, wheat forage, wheat grain and wheat straw when stored under deep freeze storage conditions (≤ -18 °C) for up to 24 months.

The wheat (grain, forage and straw), orange, field bean (dried) and oilseed rape seed samples were analysed at nominal intervals of 0, 1, 3, 6, 12, 18 and 24 months. One spare set of samples for prothioconazole-desthio (5) hydroxy metabolites in field bean were analysed at 7 months instead of 6 months. For prothioconazole-6-hydroxy-desthio in wheat grain one spare set of samples was analysed at 8 months. Moreover, for prothioconazole-6-hydroxy-desthio in wheat grain additional set of samples were fortified to allow the repeat analysis of the 12-month timepoint.

The range of temperature during storage was approximately ≤ -18 ºC using average daily records from an immersed probe.

Samples of wheat (grain, forage and straw), orange, field bean (dried) and oilseed rape seed were fortified with and its (5) hydroxy metabolites at a concentration of 0.05 mg/kg (nominal value).

The LOQ of the validated method was 0.005 mg/kg.

Results and discussions
Residues in control samples were less than the LOQ. Recovery efficiency results for prothioconazole-desthio and its 5 hydroxy metabolites in wheat (grain, forage and straw), orange, field bean (dried) and oilseed rape seed are presented in Table A 2.2-1. The mean recovery efficiencies ranged from 70-120%.

Table A 6: Stability of prothioconazole-α-hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio and prothioconazole-6-hydroxy-desthio in wheat forage following storage at ≤-18°C.

Matrix	Analyte	Nominal storage interval (months)	Sample	Fortification level (mg/kg)	Recovery (%)	Amount found (mg/kg)	Mean Stability Samples Recovery (%)	Uncorrected Stability Samples day 0 as 100%	Mean procedural recoveries	Stability samples	Stability Samples Corrected day 0 as 100%
Wheat (forage)	Prothioconazol-desthio	0	1	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
			2	n/a	n/a	n/a					
		1	1	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
			2	n/a	n/a	n/a					
		3	1	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
			2	n/a	n/a	n/a					
		6	1	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
			2	n/a	n/a	n/a					
		12	1	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
			2	n/a	n/a	n/a					
		18	1	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
			2	n/a	n/a	n/a					
		24	1	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
			2	n/a	n/a	n/a					
	Prothioconazol-3-hydroxy-desthio	0	1	0.0495	87	0.043	85	100	85	100	100
			2	0.0495	82	0.0408					
		1	1	0.0488	79	0.0386	81	95	97	83	83
			2	0.0478	82	0.0392					
		3	1	0.0469	71	0.0334	70	83	82	86	86
			2	0.0501	70	0.0348					
		6	1	0.0485	68	0.033	69	81	77	89	90
			2	0.0501	69	0.0347					
		12	1	0.0503	66	0.0334	68	80	76	89	89
			2	0.0483	69	0.0332					

		18	1	0.0472	74	0.0349	71	84	86	83	83
			2	0.0480	68	0.0328					
		24	1	0.0483	69	0.0334	68	80	75	90	91
			2	0.0482	66	0.0318					
	Prothioconazol-4-hydroxy-desthio	0	1	0.0504	100	0.0506	102	100	85	120	100
			2	0.0499	103	0.0513					
		1	1	0.0498	82	0.0408	85	83	93	91	76
			2	0.0486	87	0.0424					
		3	1	0.0487	75	0.0366	75	74	81	93	78
			2	0.047	76	0.0355					
		6	1	0.0486	72	0.035	72	71	74	98	82
			2	0.0476	73	0.0347					
		12	1	0.0476	72	0.0343	72	71	75	96	81
			2	0.0486	72	0.0352					
		18	1	0.0485	77	0.0375	77	76	87	89	74
			2	0.0497	78	0.0385					
		24	1	0.0500	84	0.0418	81	80	91	89	75
			2	0.0478	79	0.0377					
	Prothioconazol-5-hydroxy-desthio	0	1	0.0495	85	0.0422	88	100	73	120	100
			2	0.0489	90	0.044					
		1	1	0.0484	82	0.0398	82	94	92	90	75
			2	0.0478	82	0.0394					
		3	1	0.0482	66	0.032	66	75	76	87	72
			2	0.0491	66	0.0322					
		6	1	0.0497	75	0.0372	72	82	72	100	83
			2	0.0497	69	0.0344					
		12	1	0.0485	72	0.035	71	82	77	93	77
			2	0.05	71	0.0354					
		18	1	0.0485	75	0.0363	78	89	83	94	78

			2	0.0476	81	0.0385					
		24	1	0.0493	84	0.0412	77	88	86	89	74
			2	0.0492	70	0.0344					
	Prothioconazol-6-hydroxy-desthio	0	1	0.0496	76	0.0375	80	100	83	96	100
			2	0.0481	84	0.0402					
		1	1	0.0485	63	0.0305	61	77	88	69	72
			2	0.0485	59	0.0287					
		3	1	0.0502	74	0.0369	72	91	83	87	91
			2	0.0499	71	0.0353					
		6	1	0.0496	68	0.0337	66	83	72	92	96
			2	0.049	65	0.0318					
		12	1	0.05	64	0.032	68	85	83	82	85
			2	0.0486	72	0.035					
		18	1	0.0492	48	0.0236	49	61	87	56	58
			2	0.0478	49	0.0235					
		21	1	0.0493	60	0.0296	63	79	103	61	63
			2	0.0477	65	0.0311					
		24	1	0.0488	120	0.0584	102	128	95	107	112
			2	0.0488	84	0.0410					
	Prothioconazol-α-hydroxy-desthio	0	1	0.0495	74	0.0368	74	100	75	98	100
			2	0.0485	74	0.0364					
		1	1	0.0484	73	0.0351	76	103	90	84	85
			2	0.0502	79	0.0394					
		3	1	0.05	75	0.0373	74	101	85	87	89
			2	0.0475	74	0.0351					
		6	1	0.0488	70	0.0342	66	89	72	91	93
			2	0.0503	61	0.0307					
		12	1	0.0488	72	0.0353	72	97	74	97	98
			2	0.0484	71	0.0342					

		18	1	0.0476	75	0.0357	76	103	83	92	93
			2	0.0473	77	0.0366					
		24	1	0.0477	74	0.0351	75	102	79	95	96
			2	0.0481	76	0.0367					

n/a: analyte not investigated

Table A 7: Stability of prothioconazole-desthio, prothioconazole-α-hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio and prothioconazole-6-hydroxy-desthio in oilseed rape (seed) following storage at ≤-18°C.

Matrix	Analyte	Nominal storage interval (months)	Sample	Fortification level (mg/kg)	Recovery (%)	Amount found (mg/kg)	Mean Stability Samples Recovery (%)	Uncorrected Stability Samples day 0 as 100%	Mean procedural recoveries	Stability samples	Stability Samples Corrected day 0 as 100%
Oilseed rape (seed)	Prothioconazol-desthio	0	1	0.05	95	0.0476	95	100	89	107	100
			2	0.05	94	0.0472					
		1	1	0.05	84	0.0421	84	89	88	96	90
			2	0.05	84	0.0421					
		3	1	0.05	86	0.0432	85	89	87	97	91
			2	0.05	83	0.0415					
		6	1	0.05	95	0.0473	81	86	95	85	80
			2	0.05	68	0.0339					
		12	1	0.05	89	0.0445	91	96	93	98	92
			2	0.05	92	0.0462					
		18	1	0.05	81	0.0407	82	86	87	94	88
			2	0.05	82	0.0411					
		24	1	0.05	81	0.0405	80	84	85	94	88
			2	0.05	78	0.0390					
	Prothioconazol-3-hydroxy-desthio	0	1	0.05	68	0.0338	73	100	82	89	100
			2	0.05	79	0.0396					
		1	1	0.05	69	0.0347	70	95	80	87	98
			2	0.05	70	0.0352					

		3	1	0.05	70	0.035	69	94	79	87	98
			2	0.05	68	0.034					
		6	1	0.05	73	0.0366	71	97	78	91	102
			2	0.05	69	0.0344					
		12	1	0.05	71	0.0355	70	95	79	88	98
			2	0.05	68	0.0341					
		18	1	0.05	78	0.0392	81	110	80	101	113
			2	0.05	83	0.0416					
		24	1	0.05	72	0.0362	72	98	71	101	113
			2	0.05	71	0.0354					
	Prothioconazol-4-hydroxy-desthio	0	1	0.05	78	0.039	77	100	80	96	100
			2	0.05	75	0.0376					
		1	1	0.05	74	0.037	72	94	84	85	89
			2	0.05	69	0.0346					
		3	1	0.05	71	0.0357	71	93	76	94	98
			2	0.05	71	0.0355					
		6	1	0.05	70	0.0349	69	90	80	86	90
			2	0.05	68	0.0338					
		12	1	0.05	66	0.0331	67	87	78	86	90
			2	0.05	68	0.0338					
		18	1	0.05	77	0.0386	79	103	75	105	109
			2	0.05	80	0.0400					
		24	1	0.05	62	0.0312	62	81	72	87	90
			2	0.05	62	0.0312					
	Prothioconazol-5-hydroxy-desthio	0	1	0.05	69	0.0346	72	100	80	90	100
			2	0.05	75	0.0374					
		1	1	0.05	70	0.0348	65	90	79	82	91
			2	0.05	59	0.0297					

		3	1	0.05	71	0.0357	71	99	76	94	104
			2	0.05	71	0.0356					
		6	1	0.05	64	0.0322	67	93	78	86	95
			2	0.05	70	0.0348					
		12	1	0.05	69	0.0346	70	97	73	96	107
			2	0.05	71	0.0354					
		18	1	0.05	69	0.0344	69	96	65	107	119
			2	0.05	70	0.0349					
		24	1	0.05	74	0.0372	73	102	72	102	113
			2	0.05	72	0.0361					
	Prothioconazol-6-hydroxy-desthio	0	1	0.05	83	0.0416	82	100	80	103	100
			2	0.05	82	0.0408					
		1	1	0.05	66	0.0328	66	80	82	81	78
			2	0.05	67	0.0334					
		3	1	0.05	65	0.0324	65	79	89	73	71
			2	0.05	65	0.0326					
		6	1	0.05	61	0.0306	60	73	75	80	78
			2	0.05	59	0.0296					
		12	1	0.05	55	0.0275	55	67	55*	101	98
			2	0.05	56	0.0278					
		18	1	0.05	75	0.0373	75	81	78	96	94
			2	0.05	76	0.0379					
		24	1	0.05	85	0.424	80	98	90	89	87
			2	0.05	76	0.0380					
	Prothioconazol-α-hydroxy-desthio	0	1	0.05	77	0.0385	78	100	77	101	100
			2	0.05	79	0.0395					
		1	1	0.05	70	0.0348	69	89	78	89	88
			2	0.05	69	0.0346					

		3	1	0.05	69	0.0346	69	88	73	94	93
			2	0.05	68	0.034					
		6	1	0.05	71	0.0354	70	89	73	95	94
			2	0.05	68	0.0342					
		12	1	0.05	78	0.0389	75	96	75	100	99
			2	0.05	72	0.036					
		18	1	0.05	78	0.0389	78	100	75	104	103
			2	0.05	78	0.0389					
		24	1	0.05	71	0.0356	71	91	71	100	99
			2	0.05	71	0.0356					

* Mean Procedural recoveries at 12-month timepoint outside of acceptance criteria and therefore data were not accepted. As spare set had previously been used for 6-month timepoint, only one spare set remained, and the analysis was not repeated. However, corrected results seem to indicate stability of Prothioconazole-6-hydroxy-desthio in Oilseed Rape Seed after 12 months. Results at 18 and 24 months confirmed stability of prothioconazole-6-hydroxy-desthio in oilseed rape seed.

Table A 3: Stability of prothioconazole-3-hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio and prothioconazole-6-hydroxy-desthio in wheat (grain) following storage at ≤-18°C.

Matrix	Analyte	Nominal storage interval (months)	Sample	Fortification level (mg/kg)	Recovery (%)	Amount found (mg/kg)	Mean Stability Samples Recovery (%)	Uncorrected Stability Samples day 0 as 100%	Mean procedural recoveries	Stability samples	Stability Samples Corrected day 0 as 100%
Wheat (grain)	Prothioconazol-desthio	0	1	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
			2	n/a	n/a	n/a					
		1	1	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
			2	n/a	n/a	n/a					
		3	1	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
			2	n/a	n/a	n/a					
		6	1	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
			2	n/a	n/a	n/a					
		12	1	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
			2	n/a	n/a	n/a					
		18	1	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a

			2	n/a	n/a	n/a					
		24	1	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
			2	n/a	n/a	n/a					
	Prothioconazol-3-hydroxy-desthio	0	1	0.0498	91	0.0452	93	100	83	112	100
			2	0.05	94	0.0472					
		1	1	0.0485	88	0.0425	88	95	95	92	83
			2	0.049	88	0.0429					
		3	1	0.049	82	0.0404	82	88	83	98	88
			2	0.0499	81	0.0403					
		6	1	0.0501	79	0.0394	78	84	86	91	81
			2	0.0483	77	0.0373					
		12	1	0.0481	78	0.0373	77	83	83	93	83
			2	0.0484	76	0.0368					
		18	1	0.0499	81	0.0405	80	86	90	88	79
			2	0.0500	78	0.0390					
		24	1	0.0481	71	0.0342	73	79	77	95	85
			2	0.0491	75	0.0369					
	Prothioconazol-4-hydroxy-desthio	0	1	0.0498	98	0.049	96	100	79	122	100
			2	0.0499	94	0.0469					
		1	1	0.0488	81	0.0396	82	86	87	95	78
			2	0.0473	84	0.0396					
		3	1	0.0489	81	0.0395	79	82	84	94	77
			2	0.0477	77	0.0368					
		6	1	0.0497	76	0.0379	76	79	81	94	77
			2	0.0501	76	0.0382					
		12	1	0.0496	69	0.0343	73	75	79	92	75
			2	0.0498	76	0.0378					
		18	1	0.0481	80	0.0387	81	84	83	97	80

			2	0.0501	81	0.0405					
		24	1	0.0482	83	0.0399	82	85	83	99	81
			2	0.0496	81	0.0403					
	Prothioconazol-5-hydroxy-desthio	0	1	0.05	83	0.0414	85	100	71	120	100
			2	0.05	87	0.0436					
		1	1	0.0482	88	0.0424	90	106	90	100	84
			2	0.0497	92	0.0457					
		3	1	0.0483	74	0.0356	72	85	74	98	82
			2	0.0503	71	0.0358					
		6	1	0.0495	76	0.0378	78	91	82	95	79
			2	0.0502	79	0.0395					
		12	1	0.0472	84	0.0395	81	95	86	94	79
			2	0.0503	78	0.0394					
		18	1	0.0489	87	0.0426	87	102	82	106	89
			2	0.0467	87	0.0405					
		24	1	0.0469	85	0.0400	83	98	86	87	81
			2	0.0486	81	0.0393					
	Prothioconazol-6-hydroxy-desthio	0	1	0.0497	96	0.0477	95	100	84	113	100
			2	0.0498	94	0.0466					
		1	1	0.0485	98	0.0476	93	98	88	106	94
			2	0.0503	88	0.0443					
		3	1	0.05	73	0.0366	73	77	89	82	73
			2	0.0504	74	0.0371					
		6	1	0.0484	57	0.0277	61	64	109	56	49
			2	0.0487	64	0.0312					
		8	1	0.0494	101	0.0498	100	105	105	95	84
			2	0.0488	99	0.0484					
		12*	1	0.0498	80	0.0396	79	98	85	92	112

			2	0.0499	78	0.0387					
		18	1	0.0494	59	0.0291	60	63	99	61	54
			2	0.0487	61	0.0298					
		24	1	0.0498	85	0.0424	86	91	86	100	89
			2	0.0493	87	0.0428					
	Prothioconazol-α-hydroxy-desthio	0	1	0.0497	79	0.0391	76	100	73	104	100
			2	0.0491	73	0.0357					
		1	1	0.0501	79	0.0398	83	110	88	94	91
			2	0.0499	87	0.0433					
		3	1	0.05	80	0.0401	84	111	87	96	93
			2	0.0473	87	0.0413					
		6	1	0.0502	76	0.0383	79	104	83	95	92
			2	0.0493	82	0.0403					
		12	1	0.0499	78	0.0388	78	103	83	94	90
			2	0.0498	78	0.0388					
		18	1	0.0501	70	0.0353	77	102	80	96	93
			2	0.0481	84	0.0403					
		24	1	0.0498	82	0.0408	80	105	83	96	93
			2	0.0490	78	0.0380					

n/a: analyte not investigated,
*Additional set of samples were fortified at 0-month timepoint (T1C) for the repeat analysis at 12- month timepoint (T5C). Corrected recoveries at T5C are calculated against T1C results.

Table A 4: Stability of prothioconazole-desthio, prothioconazole-α-hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio and prothioconazole-6-hydroxy-desthio in orange following storage at ≤-18°C.

Matrix	Analyte	Nominal storage interval (months)	Sample	Fortification level (mg/kg)	Recovery (%)	Amount found (mg/kg)	Mean Stability Samples Recovery (%)	Uncorrected Stability Samples day 0 as 100%	Mean procedural recoveries	Stability samples	Stability Samples Corrected day 0 as 100%
Orange	Prothioconazol-desthio	0	1	0.05	99	0.0494	98	100	97	101	100
			2	0.05	98	0.0489					
		1	1	0.05	92	0.046	93	94	97	96	94

			2	0.05	93	0.0467					
		3	1	0.05	76	0.0381	87	89	97	90	89
			2	0.05	98	0.0489					
		6	1	0.05	101	0.0507	102	104	89	115	113
			2	0.05	103	0.0515					
		12	1	0.05	93	0.0464	93	95	96	97	96
			2	0.05	94	0.0469					
		18	1	0.05	92	0.0461	91	93	96	95	94
			2	0.05	90	0.0449					
		24	1	0.05	70	0.0349	71	72	105	68	67
			2	0.05	72	0.0360					
	Prothioconazol-3-hydroxy-desthio	0	1	0.05	89	0.0444	90	100	90	100	100
			2	0.05	91	0.0456					
		1	1	0.05	73	0.0367	76	84	80	95	95
			2	0.05	78	0.039					
		3	1	0.05	78	0.0392	80	88	85	94	94
			2	0.05	81	0.0404					
		6	1	0.05	78	0.0392	78	87	81	96	96
			2	0.05	78	0.039					
		12	1	0.05	82	0.0412	84	94	82	103	103
			2	0.05	86	0.0432					
		18	1	0.05	90	0.0448	89	99	88	101	101
			2	0.05	88	0.0440					
		24	1	0.05	82	0.0412	82	91	80	103	103
			2	0.05	82	0.0408					
	Prothioconazol-4-hydroxy-desthio	0	1	0.05	86	0.0432	85	100	87	98	100
			2	0.05	84	0.042					
		1	1	0.05	75	0.0377	61	71	76	80	81
			2	0.05	46	0.0228					

		3	1	0.05	76	0.0382	76	89	82	93	95
			2	0.05	76	0.0378					
		6	1	0.05	78	0.0388	78	91	85	92	94
			2	0.05	78	0.0391					
		12	1	0.05	82	0.0408	81	95	82	98	100
			2	0.05	79	0.0397					
		18	1	0.05	81	0.0404	80	94	81	99	101
			2	0.05	80	0.0400					
		24	1	0.05	80	0.0400	78	92	89	88	90
			2	0.05	77	0.0384					
	Prothioconazol-5-hydroxy-desthio	0	1	0.05	82	0.0412	82	100	84	98	100
			2	0.05	82	0.0412					
		1	1	0.05	72	0.0362	72	87	75	96	98
			2	0.05	71	0.0357					
		3	1	0.05	77	0.0384	78	94	80	97	99
			2	0.05	79	0.0394					
		6	1	0.05	82	0.0408	81	98	84	96	98
			2	0.05	80	0.0399					
		12	1	0.05	82	0.0412	84	102	81	104	106
			2	0.05	86	0.0428					
		18	1	0.05	73	0.0365	75	91	75	100	102
			2	0.05	76	0.0388					
		24	1	0.05	84	0.0420	80	97	85	94	96
			2	0.05	76	0.0379					
	Prothioconazol-6-hydroxy-desthio	0	1	0.05	81	0.0404	82	100	92	89	100
			2	0.05	82	0.0412					
		1	1	0.05	65	0.0327	65	79	76	85	96
			2	0.05	64	0.032					
		3	1	0.05	72	0.0361	73	90	85	86	97

			2	0.05	75	0.0373					
		6	1	0.05	78	0.0388	76	93	79	96	108
			2	0.05	74	0.0369					
		12	1	0.05	72	0.0361	76	93	96	79	89
			2	0.05	80	0.0399					
		18	1	0.05	76	0.0380	72	88	74	97	109
			2	0.05	68	0.0339					
		24	1	0.05	76	0.0382	76	93	107	71	80
			2	0.05	75	0.0376					
	Prothioconazol-α-hydroxy-desthio	0	1	0.05	83	0.0417	81	100	84	97	100
			2	0.05	78	0.0391					
		1	1	0.05	72	0.0358	74	92	77	96	99
			2	0.05	77	0.0383					
		3	1	0.05	73	0.0364	73	90	76	96	99
			2	0.05	73	0.0367					
		6	1	0.05	78	0.0389	78	97	79	99	102
			2	0.05	78	0.0392					
		12	1	0.05	85	0.0424	85	105	80	106	109
			2	0.05	85	0.0427					
		18	1	0.05	87	0.0436	87	108	83	105	108
			2	0.05	87	0.0436					
		24	1	0.05	79	0.0393	77	96	76	102	105
			2	0.05	76	0.0381					

Table A 5: Stability of prothioconazole-3-hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio and prothioconazole-6-hydroxy-desthio in wheat (straw) following storage at ≤-18°C.

Matrix	Analyte	Nominal storage interval (months)	Sample	Fortification level (mg/kg)	Recovery (%)	Amount found (mg/kg)	Mean Stability Samples Recovery (%)	Uncorrected Stability Samples day 0 as 100%	Mean procedural recoveries	Stability samples	Stability Samples Corrected day 0 as 100%
Wheat (straw)	Prothioconazol-desthio	0	1	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
			2	n/a	n/a	n/a					
		1	1	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
			2	n/a	n/a	n/a					
		3	1	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
			2	n/a	n/a	n/a					
		6	1	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
			2	n/a	n/a	n/a					
		12	1	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
			2	n/a	n/a	n/a					
		18	1	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
			2	n/a	n/a	n/a					
		24	1	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
			2	n/a	n/a	n/a					
	Prothioconazol-3-hydroxy-desthio	0	1	0.0503	82	0.0414	82	100	91	91	100
			2	0.0502	82	0.0413					
		1	1	0.0499	89	0.0443	92	111	85	108	119
			2	0.0499	94	0.0471					
		3	1	0.0502	83	0.0418	82	100	85	96	107
			2	0.0496	81	0.04					
		6	1	0.0499	82	0.0407	78	95	71	110	122
			2	0.0502	75	0.0375					
		12	1	0.0498	94	0.0466	90	109	86	105	116
			2	0.05	86	0.0432					

		18	1	0.0495	86	0.0428	84	102	89	84	104
			2	0.0501	82	0.0409					
		24	1	0.0498	87	0.0434	121	147	81	133	147
			2	0.0496	155	0.0770					
	Prothioconazol-4-hydroxy-desthio	0	1	0.05	82	0.0412	79	100	89	89	100
			2	0.0496	76	0.0378					
		1	1	0.0501	85	0.0424	85	107	82	103	116
			2	0.05	85	0.0424					
		3	1	0.0497	81	0.0401	80	101	82	98	110
			2	0.0502	79	0.0399					
		6	1	0.0503	73	0.0366	68	86	70	97	109
			2	0.05	63	0.0315					
		12	1	0.0498	88	0.0438	84	106	82	102	115
			2	0.0496	80	0.0396					
		18	1	0.0499	78	0.0387	80	100	71	112	126
			2	0.0503	82	0.0410					
		24	1	0.0505	77	0.0388	80	101	79	101	114
			2	0.0499	83	0.0415					
	Prothioconazol-5-hydroxy-desthio	0	1	0.0497	84	0.0417	82	100	86	95	100
			2	0.0496	80	0.0396					
		1	1	0.05	75	0.0376	77	94	76	102	107
			2	0.0498	79	0.0395					
		3	1	0.0498	81	0.0402	84	102	89	94	99
			2	0.0503	86	0.0434					
		6	1	0.0499	76	0.038	74	90	74	100	105
			2	0.0501	71	0.0356					
		12	1	0.0496	81	0.04	82	100	78	105	110
			2	0.0498	83	0.0414					
		18	1	0.0502	74	0.0372	73	89	75	87	102

			2	0.0501	72	0.0360					
		24	1	0.0502	91	0.0457	91	111	86	106	111
			2	0.0499	90	0.0451					
	Prothioconazol-6-hydroxy-desthio	0	1	0.0499	80	0.0398	81	100	82	99	100
			2	0.0497	82	0.0409					
		1	1	0.0501	78	0.0392	80	99	81	99	100
			2	0.0498	82	0.0406					
		3	1	0.05	82	0.0408	83	103	82	101	103
			2	0.0497	85	0.0421					
		6	1	0.0497	79	0.0391	74	91	76	97	98
			2	0.0496	68	0.0339					
		12	1	0.0501	77	0.0388	81	100	73	111	112
			2	0.0505	85	0.0428					
		18	1	0.0498	79	0.0392	78	96	80	98	99
			2	0.0496	77	0.0383					
		24	1	0.0502	88	0.0441	84	104	79	107	108
			2	0.0498	81	0.0402					
	Prothioconazol-α-hydroxy-desthio	0	1	0.0502	84	0.042	83	100	86	96	100
			2	0.0504	82	0.0412					
		1	1	0.05	95	0.0474	91	110	86	106	110
			2	0.05	88	0.0438					
		3	1	0.0495	86	0.0427	86	104	88	98	102
			2	0.0496	86	0.0427					
		6	1	0.0498	75	0.0371	75	91	72	104	108
			2	0.0496	75	0.0374					
		12	1	0.0496	89	0.0444	89	108	81	110	114
			2	0.0504	89	0.0446					
		18	1	0.0501	85	0.0426	87	105	78	111	116
			2	0.0495	88	0.0438					

		24	1	0.0497	88	0.0439	92	11	81	113	118
			2	0.0503	95	0.0478					

n/a: analyte not investigated

Table A 6: Stability of prothioconazole-desthio, prothioconazole-α-hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio and prothioconazole-6-hydroxy-desthio in field bean (dried) following storage at ≤-18°C.

Matrix	Analyte	Nominal storage interval (months)	Sample	Fortification level (mg/kg)	Recovery (%)	Amount found (mg/kg)	Mean Stability Samples Recovery (%)	Uncorrected Stability Samples day 0 as 100%	Mean procedural recoveries	Stability samples	Stability Samples Corrected day 0 as 100%
Field bean (dried)	Prothioconazol-desthio	0	1	0.05	96	0.0478	95	100	94	101	100
			2	0.05	95	0.0476					
		1	1	0.05	88	0.0441	88	92	93	95	93
			2	0.05	88	0.0438					
		3	1	0.05	99	0.0497	98	103	98	100	99
			2	0.05	97	0.0486					
		6	1	0.05	94	0.0472	94	98	90	104	102
			2	0.05	93	0.0464					
		12	1	0.05	87	0.0436	88	92	91	97	95
			2	0.05	89	0.0444					
		18	1	0.05	105	0.0524	104	109	104	100	98
			2	0.05	103	0.0515					
		24	1	0.05	83	0.0416	85	89	89	95	94
			2	0.05	87	0.0433					
	Prothioconazol-3-hydroxy-desthio	0	1	0.05	72	0.036	73	100	72	101	100
			2	0.05	74	0.0369					
		1	1	0.05	77	0.0386	73	100	84	86	85
			2	0.05	68	0.0339					
		3	1	0.05	58	0.0288	63	86	76	83	82
			2	0.05	68	0.0339					

		7	1	0.05	73	0.0366	72	99	77	94	93
			2	0.05	71	0.0356					
		12	1	0.05	54	0.0271	63	86	74	85	84
			2	0.05	71	0.0356					
		18	1	0.05	73	0.0365	73	101	74	99	98
			2	0.05	74	0.0368					
		24	1	0.05	65	0.0325	67	91	67	100	98
			2	0.05	68	0.0342					
	Prothioconazol-4-hydroxy-desthio	0	1	0.05	71	0.0356	71	100	74	96	100
			2	0.05	72	0.0358					
		1	1	0.05	73	0.0364	75	105	80	94	97
			2	0.05	77	0.0384					
		3	1	0.05	71	0.0356	71	99	73	97	100
			2	0.05	70	0.035					
		7	1	0.05	65	0.0323	67	93	79	84	87
			2	0.05	69	0.0343					
		12	1	0.05	55	0.0277	64	89	73	87	90
			2	0.05	72	0.0359					
		18	1	0.05	86	0.0428	85	119	78	109	113
			2	0.05	85	0.0424					
		24	1	0.05	81	0.0404	81	113	81	100	103
			2	0.05	81	0.0404					
	Prothioconazol-5-hydroxy-desthio	0	1	0.05	72	0.0362	74	100	75	99	100
			2	0.05	76	0.0378					
		1	1	0.05	73	0.0365	75	102	79	95	97
			2	0.05	78	0.0389					
		3	1	0.05	61	0.0307	55	74	68*	81	82
			2	0.05	48	0.0241					

		7	1	0.05	72	0.0362	74	100	78	95	96
			2	0.05	75	0.0375					
		12	1	0.05	80	0.0399	77	104	76	101	102
			2	0.05	74	0.037					
		18	1	0.05	71	0.0357	78	106	71	111	112
			2	0.05	86	0.0428					
		24	1	0.05	83	0.0416	79	107	76	104	106
			2	0.05	76	0.0378					
	Prothioconazol-6-hydroxy-desthio	0	1	0.05	79	0.0394	76	100	73	105	100
			2	0.05	74	0.037					
		1	1	0.05	77	0.0387	80	105	88	91	87
			2	0.05	83	0.0416					
		3	1	0.05	72	0.0358	71	92	84	84	80
			2	0.05	70	0.0348					
		7	1	0.05	75	0.0375	76	99	81	93	89
			2	0.05	76	0.0382					
		12	1	0.05	86	0.0428	85	111	84	101	96
			2	0.05	84	0.042					
		18	1	0.05	65	0.0327	63	83	92	69	66
			2	0.05	61	0.0304					
		20	1	0.05	78	0.0389	77	101	72	107	102
			2	0.05	76	0.0380					
		24	1	0.05	79	0.0396	78	102	78	100	95
			2	0.05	77	0.0384					
	Prothioconazol-α-hydroxy-desthio	0	1	0.05	72	0.0361	72	100	74	97	100
			2	0.05	72	0.0358					
		1	1	0.05	55	0.0277	55	77	74	75	77
			2	0.05	56	0.0278					

		3	1	0.05	56	0.0281	59	82	72	82	84
			2	0.05	61	0.0307					
		7	1	0.05	62	0.0309	62	86	62**	99	102
			2	0.05	62	0.0308					
		12	1	0.05	67	0.0336	71	99	70	101	104
			2	0.05	74	0.0372					
		18	1	0.05	75	0.0376	75	104	68	110	114
			2	0.05	75	0.0374					
		24	1	0.05	74	0.0371	77	107	68	113	116
			2	0.05	79	0.0394					

* Mean Procedural recoveries at 3 months timepoint failed to meet the acceptance criteria and therefore data were not accepted. The samples were re-extracted using one set of additional samples. Although the procedural recoveries failed to meet the acceptance criteria on the second occasion too, the analysis was no repeated because only one set of spare samples remained. However, data for the following timepoints show Prothioconazole-5-hydroxy-desthio in field bean (dried) to be stable after 12 months.

** *Procedural recoveries at 7 months timepoint outside of acceptance criteria and therefore data were not accepted. However, as stability results for 7-month timepoint consistent with results of procedural recoveries of freshly fortified samples, and results of 12-month timepoint within acceptance criteria, Prothioconazole-α-hydroxy-desthio in field bean (dried) considered to be stable after 12 months as shown by the corrected results.

Conclusion

Prothioconazole-desthio stability samples in orange, field bean (dried) and oilseed rape seed were found to be stable (mean recovery of each analyte at each interval is in the range of 70% to 120%) under deep freeze storage conditions (≤ -18 °C) for up to 24 months.

Prothioconazole (5) hydroxy metabolites stability samples in wheat (grain, forage and straw), orange, field bean (dried) and oilseed rape seed, were found to be stable (mean corrected recovery of each analyte at each interval is in the range of 70% to 120%) under deep freeze storage conditions (≤ -18 °C) for up to 24 months.

However, the following has been observed:

- For prothioconazole-6-hydroxy-desthio in wheat grain the stability samples at the 6-month timepoint and at the 18-month timepoint unexpectedly showed corrected recovery values of 56% and 55%, respectively. In both cases, the corrected recovery values at the subsequent timepoints (95% and 100%, respectively) indicate stability of prothioconazole-6-hydroxy-desthio in wheat grain for up to 24 months.
- For prothioconazole-6-hydroxy-desthio in wheat forage the stability samples at the 18-month timepoint showed a corrected recovery value of 61%. The corrected recovery value at the subsequent timepoint (107%) indicates stability of prothioconazole-6-hydroxy-desthio in wheat forage for up to 24 months.
- For prothioconazole-6-hydroxy-desthio in field bean (dried) the stability samples at the 18-month timepoint showed a corrected recovery value of 69%. The corrected recovery value at the subsequent timepoint (100%) indicates stability of prothioconazole-6-hydroxy-desthio in field bean (dried) for up to 24 months.
- For prothioconazole-3-hydroxy-desthio in wheat straw stability samples at the 24-month timepoint showed corrected recovery value of 133%. This is due an unexpected stability sample recovery of 155%.
- For prothioconazole-4-hydroxy-desthio in wheat grain stability samples at 0-month timepoint showed a corrected recovery value of 122%.
- For prothioconazole-4-hydroxy-desthio in wheat straw stability samples at 18-month timepoint showed a corrected recovery value of 126% (corrected per day 0 as 100%).

A 2.2.1.1.1.2 Study 2

Study 2 – S. Baxter, B. Phipps 2025, Study No.: QG/21/002

Comments of zRMS:	The results of the study demonstrate that TDMs in following samples: oilseed rape (seed), field bean (dried), orange and wheat (forage, grain and straw) are stable under frozen storage at -18 °C or below for 12 months, except: - 1,2,4-T and TA in oilseed rape seed are stable for 15 days (for clarity, stability results are presented below). The mean stability sample recoveries a tor after 15 days intervals was less than 70% therefore 1,2,4-triazole and TA in oilseed rape (seed) can only be considered stable for 15 days.

1,2,4-Triazole stability results in oilseed rape (seed)

Nominal Sampling Interval (months)	Nominal Fortification Level (mg/kg)	Stability Sample Recovery (%)	Mean Stability Sample Recovery (%)	Mean Procedural Recovery (%)	Mean Stability Sample Corrected Recovery (%)*
0	0.0500	73.9	79.4	91.2	100
0	0.0500	84.8			
15 days	0.0500	58.0	55.5	89.2	71.5
15 days	0.0500	53.0			
1	0.0500	50.9	52.5	92.0	65.6
1	0.0500	54.2			
2	0.0500	54.5	50.9	90.4	64.7
2	0.0500	47.3			
3	0.0500	39.8	42.3	78.6	61.8
3	0.0500	44.8			
6	0.0500	45.9	41.2	86.8	54.5
6	0.0500	36.5			

* Corrected for procedural recovery and day 0 stability recovery as 100%

Triazole alanine stability results in oilseed rape (seed)

Nominal Sampling Interval (months)	Nominal Fortification Level (mg/kg)	Stability Sample Recovery (%)*	Mean Stability Sample Recovery (%)*	Mean Procedural Recovery (%)*	Mean Stability Sample Corrected Recovery (%)**
0	1.00	73.9	71.1	80.3	100
0	1.00	68.3			
15 days	1.00	71.7	73.7	88.9	93.6
15 days	1.00	75.7			
1	1.00	57.0	58.7	84.7	78.2
1	1.00	60.3			
2	1.00	58.4	57.2	81.8	78.9
2	1.00	55.9			
3	1.00	60.5	61.1	76.5	90.2
3	1.00	61.7			
6	1.00	62.9	57.3	80.9	80.0
6	1.00	51.8			
12	1.00	55.1	54.1	79.1	77.3
12	1.00	53.1			

* Corrected for control residues >30%LOQ
** Corrected for procedural recovery and day 0 stability recovery as 100%

- TA in field bean (dried) and in wheat straw is stable for 1 month and in wheat grain for 6 months (for clarity, stability results are presented below):

Triazole alanine stability results in field bean (dried)

Nominal Sampling Interval (months)	Nominal Fortification Level (mg/kg)	Stability Sample Recovery (%)*	Mean Stability Sample Recovery (%)*	Mean Procedural Recovery (%)*	Mean Stability Sample Corrected Recovery (%)**
0	2.00	73.8	80.8	94.6	100
0	2.00	87.8			
1	2.00	64.2	64.7	99.4	76.2
1	2.00	65.2			
3	2.00	63.7	62.4	112	65.0
3	2.00	61.1			
4	2.00	59.6	57.6	82.4	81.8
4	2.00	55.7			
6	2.00	66.7	64.5	88.2	85.6
6	2.00	62.2			
12	2.00	79.5	79.1	106	87.5
12	2.00	78.8			

* Corrected for control residues >30%LOQ
** Corrected for procedural recovery and day 0 stability recovery as 100%

Triazole alanine stability results in wheat grain

Nominal Sampling Interval (months)	Nominal Fortification Level (mg/kg)	Stability Sample Recovery (%)*	Mean Stability Sample Recovery (%)*	Mean Procedural Recovery (%)*	Mean Stability Sample Corrected Recovery (%)**
0	0.100	79.8	78.2	81.8	100
0	0.100	76.6			
1	0.100	73.8	75.4	88.6	89.0
1	0.100	77.0			
3	0.100	81.6	76.4	85.6	93.4
3	0.100	71.2			
6	0.100	72.0	70.4	81.2	90.7
6	0.100	68.8			
12	0.100	66.7	67.9	79.5	89.3
12	0.100	69.1			

* Corrected for control residues >30%LOQ
** Corrected for procedural recovery and day 0 stability recovery as 100%

- 1,2,4-T in oranges is stable for 6 months (for clarity, stability results are presented below):

1,2,4-Triazole stability results in orange

Nominal Sampling Interval (months)	Nominal Fortification Level (mg/kg)	Stability Sample Recovery (%)	Mean Stability Sample Recovery (%)	Mean Procedural Recovery (%)	Mean Stability Sample Corrected Recovery (%)*
0	0.0500	88.0	86.0	88.8	100
0	0.0500	84.0			
1	0.0500	80.8	82.8	84.4	101
1	0.0500	84.8			
3	0.0500	85.6	84.4	84.0	104
3	0.0500	83.2			
6	0.0500	80.8	77.4	81.3	98.3
6	0.0500	73.9			
12	0.0500	69.5	66.8	98.4	70.1
12	0.0500	64.2			

* Corrected for procedural recovery and day 0 stability recovery as 100%

The successfully validated method QG/20/012 (B. Phipps, 2024) was used for analysis of TDMs. For more details please refer to Part B5.
The study was conducted according to the OECD 506 and is acceptable.

Reference: KCP 8.1/04, KCA 6.1/03

Report: Triazole Derived Metabolites: Frozen Storage Stability in Crops for 12 Months; Baxter, B. Phipps, 2025; Study No.: QG/21/002

Guideline(s):
- OECD 506 Stability of Pesticide Residues in Stored Commodities
- OECD, ENV/JM/MONO(2009)31 Series on Testing and Assessment Number 64 and Series on Pesticides Number 32. Guidance Document on Overview of Residue Chemistry Studies, 28 July 2009
- SANTE/2020/12830, rev.1 Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes, 24 February 2021

Deviations: Several minor deviations from the internal and field protocols were noted, but none of these deviations impact the validity of the study results.

GLP: Yes

Acceptability: Yes

Study Objective
The objective of this study was to provide information on the stability of TDMs in oilseed rape (seed), field bean (dried), orange and wheat (forage, grain and straw) when stored under deep freeze storage conditions (≤ -18°C).

Materials and methods
Samples of oilseed rape (seed), field bean, wheat (forage, grain and straw) and orange were individually fortified with 1,2,4-triazole, triazole alanine, triazole acetic acid and triazole lactic acid at a concentration of 10 x LOQ and stored at a nominal temperature of -18 °C. Duplicate stability samples were analysed at each interval.

Samples were removed from deep freeze storage for analysis of all triazole derived metabolites at nominal intervals of 0, 1, 3, 6 and 12 months for field bean, wheat (grain, straw and forage) and orange. In addition, field bean samples were removed from deep freeze storage for the analysis of triazole alanine at 4 months and wheat forage samples were removed from deep freeze storage for the analysis of 1,2,4-triazole at 13 months.

For oilseed rape (seed), samples were removed from deep freeze storage for analysis of 1,2,4-triazole at nominal intervals of 0, 15-days, 1, 2, 3 and 6 months. Oilseed rape (seed) samples were removed from deep freeze storage for analysis of triazole alanine, triazole acetic acid and triazole lactic acid at 0, 1, 3, 6 and 12 months. In addition, oilseed rape seed samples were removed from deep freeze storage for the analysis of triazole alanine at 15 days and 2 months.

For each matrix and each interval, 2 stability samples per analyte were weighed along with 2 procedural recovery samples fortified on the day of extraction (at 10 x LOQ) and 1 control sample. For each interval, 1 reagent blank was also analysed. For each matrix, two additional sets of stability samples per analyte were fortified at the start of the study.

Residues of 1,2,4-triazole, triazole alanine, triazole acetic acid and triazole lactic acid were extracted from oilseed rape (seed), field bean, wheat forage, wheat grain, wheat straw and orange with methanol:water (4:1, v/v) by Ultra-Turrax homogenisation for 3 minutes. Samples were filtered under vacuum through celite before further extraction by shaking with methanol:water (4:1, v/v). After filtration, the sample was extracted for a third time by shaking with methanol:water (4:1, v/v) before further filtration. The samples were then passed through a C18 SPE cartridge before evaporation by rotary evaporator. Samples of oilseed rape (seed), wheat forage, wheat grain, wheat straw and orange were then further evaporated by Syncore. For all matrices the sample volume was adjusted with water before filtration through a regenerated cellulose syringe filter. Extracts were then diluted with water and internal standard added before final determination by liquid chromatography with tandem mass spectrometry (LC-MS/MS).
Validation of the analytical method please refer to KCP 5.1.2/03 B. Phipps, 2024, Report No. QG/20/012

Results

Table A 7: Stability of 1,2,4-Triazole in oilseed rape seed following storage at ≤-18°C.

Matrix	Analyte	Nominal storage interval (months)	Sample	Fortification level (mg/kg)	Recovery (%)	Amount found (mg/kg)	Mean Stability Samples Recovery (%)	Mean procedural recoveries	Stability Recovery Corrected for Procedural Recovery (%)*	Stability Samples Corrected day 0 as 100%**
Oilseed Rape Seed	1,2,4-Triazole	0	1	0.05	73.9	0.0370	79.4	91.2	87.0	100
			2	0.05	84.8	0.0424				
		15 days	1	0.05	58.0	0.0290	55.5	89.2	62.2	71.5
			2	0.05	53.0	0.0265				
		1	1	0.05	50.9	0.0254	52.5	92.0	57.1	65.6
			2	0.05	54.2	0.0271				
		2	1	0.05	54.5	0.0272	50.9	90.4	56.3	64.7
			2	0.05	47.3	0.0236				
		3	1	0.05	39.8	0.0199	42.3	78.6	53.8	61.8
			2	0.05	44.8	0.0224				
		6	1	0.05	45.9	0.0230	41.2	86.8	47.5	54.4
			2	0.05	36.5	0.0182				

Amount found in corresponding controls was <30% LOQ therefore the amount found in stability and procedural recovery samples was not corrected for any amount found in the control sample.
*Stability recovery corrected for procedural recovery (%) = Mean stability recovery (%) / Mean procedural recovery (%) x 100
**Stability recovery corrected for procedural recovery and Day 0 as 100 % (%) = Stability recovery corrected for procedural recovery (%) / Day 0 Stability recovery corrected for procedural recovery (%) x 100

Table A 8: Stability of 1,2,4-Triazole in field bean (dried) following storage at ≤-18°C.

Matrix	Analyte	Nominal storage interval (months)	Sample	Fortification level (mg/kg)	Recovery (%)	Amount found (mg/kg)	Amount Found in Corresponding Control (mg/kg)	Corrected Amount Found in Stability Samples (mg/kg)*	Corrected Stability Recovery (%)	Mean Corrected Stability Recovery (%)*	Mean Corrected Procedural Recovery (%)*	Stability Recovery Corrected for Procedural Recovery (%)**	Stability Recovery Corrected for Procedural Recovery and Day 0 as 100 % (%)***
Field bean	1,2,4-Triazole	0	1	0.05	85.6	0.0428	<30% LOQ	N/A	N/A	86.4	94.8	91.1	100
			2	0.05	87.2	0.0436		N/A	N/A				

(dried)		1	1	0.05	95.2	0.0476	<30% LOQ	N/A	N/A	94.8	118	80.6	88.4
			2	0.05	94.4	0.0472		N/A	N/A				
		3	1	0.05	78.3	0.0392	0.00270	0.0365	72.9	77.8	85.0	91.5	100
			2	0.05	88.0	0.0440		0.0413	82.6				
		6	1	0.05	117	0.0584	0.00278	0.0556	111	106	94.4	113	124
			2	0.05	107	0.0536		0.0508	102				
		12	1	0.05	105	0.0524	0.00272	0.0497	99.4	85.0	85.4	100	109
			2	0.05	76.2	0.0381		0.0354	70.7				

*Corrected amount found (mg/kg) = Uncorrected amount found (mg/kg) – Amount found in corresponding control sample (mg/kg).
Correction applies to stability recovery and procedural recovery.
**Stability recovery corrected for procedural recovery (%) = Mean corrected stability recovery (%) / Mean corrected procedural recovery (%) x 100
***Stability recovery corrected for procedural recovery and Day 0 as 100 % (%) = Stability recovery corrected for procedural recovery (%) / Day 0 Stability recovery corrected for procedural recovery (%) x 100

Table A 9: Stability 1,2,4-Triazole in wheat forage following storage at ≤-18°C.

Matrix	Analyte	Nominal storage interval (months)	Sample	Fortification level (mg/kg)	Recovery (%)	Amount found (mg/kg)	Mean Stability Samples Recovery (%)	Mean procedural recoveries	Stability Recovery Corrected for Procedural Recovery (%)*	Stability Samples Corrected day 0 as 100%**
Wheat forage	1,2,4-Triazole	0	1	0.05	89.6	0.0448	90.0	90.4	99.6	100
			2	0.05	90.4	0.0452				
		1	1	0.05	88.8	0.0444	86.0	88.8	96.8	97.3
			2	0.05	83.2	0.0416				
		3	1	0.05	80.8	0.0404	82.4	86.0	95.8	96.2
			2	0.05	84.0	0.0420				
		6	1	0.05	69.0	0.345	71.0	77.8	91.4	91.8
			2	0.05	73.0	0.0365				
		12	1	0.05	65.0	0.0325	76.1	84.2	90.4	90.8
			2	0.05	87.2	0.0436				
		13	1	0.05	63.2	0.0316	63.2	94.0	67.3	67.6

			2	0.05	63.3	0.0316				

Amount found in corresponding controls was <30% LOQ therefore the amount found in stability and procedural recovery samples was not corrected for any amount found in the control sample.
*Stability recovery corrected for procedural recovery (%) = Mean stability recovery (%) / Mean procedural recovery (%) x 100
**Stability recovery corrected for procedural recovery and Day 0 as 100 % (%) = Stability recovery corrected for procedural recovery (%) / Day 0 Stability recovery corrected for procedural recovery (%) x 100

Table A 10: Stability of 1,2,4-Triazole in wheat grain following storage at ≤-18°C.

Matrix	Analyte	Nominal storage interval (months)	Sample	Fortification level (mg/kg)	Recovery (%)	Amount found (mg/kg)	Mean Stability Samples Recovery (%)	Mean procedural recoveries	Stability Recovery Corrected for Procedural Recovery (%)*	Stability Samples Corrected day 0 as 100%**
Wheat grain	1,2,4-Triazole	0	1	0.05	88.0	0.0440	89.6	91.2	98.2	100
			2	0.05	91.2	0.0456				
		1	1	0.05	83.2	0.0416	81.6	88.4	92.3	94.0
			2	0.05	80.0	0.0400				
		3	1	0.05	80.0	0.0400	78.0	82.8	94.3	95.9
			2	0.05	76.1	0.0380				
		6	1	0.05	73.3	0.0366	74.7	76.9	97.1	98.9
			2	0.05	76.1	0.0380				
		12	1	0.05	75.2	0.0376	76.7	85.6	89.6	91.2
			2	0.05	78.2	0.0391				

Amount found in corresponding controls was <30% LOQ therefore the amount found in stability and procedural recovery samples was not corrected for any amount found in the control sample.
*Stability recovery corrected for procedural recovery (%) = Mean stability recovery (%) / Mean procedural recovery (%) x 100
**Stability recovery corrected for procedural recovery and Day 0 as 100 % (%) = Stability recovery corrected for procedural recovery (%) / Day 0 Stability recovery corrected for procedural recovery (%) x 100

Table A 11: Stability of 1,2,4-Triazole in wheat straw following storage at ≤-18°C.

Matrix	Analyte	Nominal storage interval (months)	Sample	Fortification level (mg/kg)	Recovery (%)	Amount found (mg/kg)	Mean Stability Samples Recovery (%)	Mean procedural recoveries	Stability Recovery Corrected for Procedural Recovery (%)*	Stability Samples Corrected day 0 as 100%**
Wheat straw	1,2,4-Triazole	0	1	0.05	110	0.0548	107	104	103	100

			2	0.05	104	0.0520				
		1	1	0.05	82.4	0.0412	85.2	84.0	101	98.8
			2	0.05	88.0	0.0440				
		3	1	0.05	66.7	0.0334	76.2	73.9	103	100
			2	0.05	85.6	0.0428				
		6	1	0.05	71.3	0.0356	70.9	72.7	97.5	94.9
			2	0.05	70.5	0.0352				
		12	1	0.05	81.6	0.0408	77.2	80.8	95.5	93.0
			2	0.05	72.7	0.0364				

Amount found in corresponding controls was <30% LOQ therefore the amount found in stability and procedural recovery samples was not corrected for any amount found in the control sample.
*Stability recovery corrected for procedural recovery (%) = Mean stability recovery (%) / Mean procedural recovery (%) x 100
**Stability recovery corrected for procedural recovery and Day 0 as 100 % (%) = Stability recovery corrected for procedural recovery (%) / Day 0 Stability recovery corrected for procedural recovery (%) x 100

Table A 12: Stability of 1,2,4-Triazole in orange following storage at ≤-18°C.

Matrix	Analyte	Nominal storage interval (months)	Sample	Fortification level (mg/kg)	Recovery (%)	Amount found (mg/kg)	Mean Stability Samples Recovery (%)	Mean procedural recoveries	Stability Recovery Corrected for Procedural Recovery (%)*	Stability Samples Corrected day 0 as 100%**
Orange	1,2,4-Triazole	0	1	0.05	88.0	0.0440	86.0	88.8	96.8	100
			2	0.05	84.0	0.0420				
		1	1	0.05	80.8	0.0404	82.8	84.4	98.1	101
			2	0.05	84.8	0.0424				
		3	1	0.05	85.6	0.0428	84.4	84.0	100	104
			2	0.05	83.2	0.0416				
		6	1	0.05	80.8	0.0404	77.4	81.3	95.2	98.3
			2	0.05	73.9	0.0370				
		12	1	0.05	69.5	0.0348	66.8	98.4	67.9	70.1
			2	0.05	64.2	0.0321				

Amount found in corresponding controls was <30% LOQ therefore the amount found in stability and procedural recovery samples was not corrected for any amount found in the control sample.

*Stability recovery corrected for procedural recovery (%) = Mean stability recovery (%) / Mean procedural recovery (%) x 100
**Stability recovery corrected for procedural recovery and Day 0 as 100 % (%) = Stability recovery corrected for procedural recovery (%) / Day 0 Stability recovery corrected for procedural recovery (%) x 100

Table A 13: Stability Triazole Alanine in oilseed rape seed following storage at ≤-18°C.

Matrix	Analyte	Nominal storage interval (months)	Sample	Fortification level (mg/kg)	Recovery (%)	Amount found (mg/kg)	Amount Found in Corresponding Control (mg/kg)	Corrected Amount Found in Stability Samples (mg/kg)*	Corrected Stability Recovery (%)	Mean Corrected Stability Recovery (%)*	Mean Corrected Procedural Recovery (%)*	Stability Recovery Corrected for Procedural Recovery (%)**	Stability Recovery Corrected for Procedural Recovery and Day 0 as 100 % (%)***
Oilseed rape seed	Triazole Alanine	0	1	1.00	89.6	0.896	0.157	0.736	73.9	71.1	80.3	88.5	100
			2	1.00	84.0	0.840		0.683	68.3				
		15 days	1	1.00	93.6	0.936	0.219	0.717	71.7	73.7	88.9	82.9	93.6
			2	1.00	97.6	0.976		0.757	75.7				
		1	1	1.00	77.5	0.775	0.205	0.570	57.0	58.7	84.7	69.3	78.2
			2	1.00	80.8	0.808		0.603	60.3				
		2	1	1.00	73.4	0.734	0.150	0.584	58.4	57.2	81.8	69.8	78.9
			2	1.00	70.9	0.709		0.559	55.9				
		3	1	1.00	79.6	0.796	0.191	0.605	60.5	61.1	76.5	79.9	90.2
			2	1.00	80.8	0.808		0.617	61.7				
		6	1	1.00	81.6	0.816	0.187	0.629	62.9	57.3	80.9	70.9	80.0
			2	1.00	70.5	0.705		0518	51.8				
		12	1	1.00	74.0	0.740	0.189	0.551	55.1	54.1	79.1	68.4	77.3
			2	1.00	72.0	0.720		0.531	53.1				

*Corrected amount found (mg/kg) = Uncorrected amount found (mg/kg) – Amount found in corresponding control sample (mg/kg).
Correction applies to stability recovery and procedural recovery.
**Stability recovery corrected for procedural recovery (%) = Mean corrected stability recovery (%) / Mean corrected procedural recovery (%) x 100
***Stability recovery corrected for procedural recovery and Day 0 as 100 % (%) = Stability recovery corrected for procedural recovery (%) / Day 0 Stability recovery corrected for procedural recovery (%) x 100

Table A 14: Stability of Triazole Alanine in field bean (dried) following storage at ≤-18°C.

Matrix	Analyte	Nominal storage interval (months)	Sample	Fortification level (mg/kg)	Recovery (%)	Amount found (mg/kg)	Amount Found in Corresponding Control (mg/kg)	Corrected Amount Found in Stability Samples (mg/kg)*	Corrected Stability Recovery (%)	Mean Corrected Stability Recovery (%)*	Mean Corrected Procedural Recovery (%)*	Stability Recovery Corrected for Procedural Recovery (%)**	Stability Recovery Corrected for Procedural Recovery and Day 0 as 100 % (%)***
Field Bean (dried)	Triazole Alanine	0	1	2.00	83.2	1.66	0.189	1.48	73.8	80.8	94.6	85.4	100
			2	2.00	97.3	1.95		1.76	87.8				
		1	1	2.00	72.3	1.45	0.162	1.28	64.2	64.7	99.4	65.1	76.2
			2	2.00	73.3	1.47		1.30	65.2				
		3	1	2.00	72.6	1.45	0.179	1.27	63.7	62.4	112	55.6	65.0
			2	2.00	70.1	1.40		1.22	61.1				
		4	1	2.00	71.7	1.43	0.243	1.19	59.6	57.6	82.4	69.9	81.8
			2	2.00	67.8	1.36		1.11	55.7				
		6	1	2.00	80.0	1.60	0.266	1.33	66.7	64.5	88.2	73.1	85.6
			2	2.00	75.5	1.51		1.24	62.2				
		12	1	2.00	91.2	1.82	0.235	1.59	79.5	79.1	106	74.8	87.5
			2	2.00	90.6	1.81		1.58	78.8				

*Corrected amount found (mg/kg) = Uncorrected amount found (mg/kg) – Amount found in corresponding control sample (mg/kg).
Correction applies to stability recovery and procedural recovery.
**Stability recovery corrected for procedural recovery (%) = Mean corrected stability recovery (%) / Mean corrected procedural recovery (%) x 100
***Stability recovery corrected for procedural recovery and Day 0 as 100 % (%) = Stability recovery corrected for procedural recovery (%) / Day 0 Stability recovery corrected for procedural recovery (%) x 100

Table A 15: Stability of Triazole Alanine in wheat forage following storage at ≤-18°C.

Matrix	Analyte	Nominal storage interval (months)	Sample	Fortification level (mg/kg)	Recovery (%)	Amount found (mg/kg)	Amount Found in Corresponding Control (mg/kg)	Corrected Amount Found in Stability Samples (mg/kg)*	Corrected Stability Recovery (%)	Mean Corrected Stability Recovery (%)*	Mean Corrected Procedural Recovery (%)*	Stability Recovery Corrected for Procedural Recovery (%)**	Stability Recovery Corrected for Procedural Recovery and Day 0 as 100 % (%)***
Wheat forage	Triazole Alanine	0	1	0.200	131	0.262	0.0650	0.197	98.7	96.7	87.9	110	100
			2	0.200	127	0.254		0.189	94.7				
		1	1	0.200	113	0.226	0.0560	0.170	84.8	84.0	86.0	97.7	88.8
			2	0.200	111	0.222		0.166	83.2				
		3	1	0.200	105	0.210	0.0526	0.157	78.5	79.3	83.7	94.7	86.1
			2	0.200	106	0.213		0.160	80.1				
		6	1	0.200	128	0.256	0.0670	0.189	94.5	96.1	99.3	96.8	88.0
			2	0.200	131	0.262		0.195	97.7				
		12	1	0.200	114	0.227	0.0584	0.169	84.4	82.4	87.6	94.1	85.5
			2	0.200	110	0.219		0.161	80.4				

*Corrected amount found (mg/kg) = Uncorrected amount found (mg/kg) – Amount found in corresponding control sample (mg/kg).
Correction applies to stability recovery and procedural recovery.
**Stability recovery corrected for procedural recovery (%) = Mean corrected stability recovery (%) / Mean corrected procedural recovery (%) x 100
***Stability recovery corrected for procedural recovery and Day 0 as 100 % (%) = Stability recovery corrected for procedural recovery (%) / Day 0 Stability recovery corrected for procedural recovery (%) x 100

Table A 16: Stability of Triazole Alanine in wheat grain following storage at ≤-18°C.

Matrix	Analyte	Nominal storage interval (months)	Sample	Fortification level (mg/kg)	Recovery (%)	Amount found (mg/kg)	Amount Found in Corresponding Control (mg/kg)	Corrected Amount Found in Stability Samples (mg/kg)*	Corrected Stability Recovery (%)	Mean Corrected Stability Recovery (%)*	Mean Corrected Procedural Recovery (%)*	Stability Recovery Corrected for Procedural Recovery (%)**	Stability Recovery Corrected for Procedural Recovery and Day 0 as 100 % (%)***
		0	1	0.100	92.0	0.0920	0.0122	0.0798	79.,8	78.2	81.8	95.6	100

Wheat grain	Triazole Alanine		2	0.100	88.8	0.0888		0.0766	76.6				
		1	1	0.100	86.4	0.0864	0.0126	0.0738	73.8	75.4	88.6	85.1	89.0
			2	0.100	89.6	0.0896		0.0770	77.0				
		3	1	0.100	92.0	0.0920	0.0104	0.0816	81.6	76.4	85.6	89.3	93.4
			2	0.100	81.6	0.0816		0.0712	71.2				
		6	1	0.100	84.0	0.0840	0.0120	0.0720	72.0	70.4	81.2	86.7	90.7
			2	0.100	80.8	0.0808		0.0688	68.8				
		12	1	0.100	78.4	0.0784	0.0117	0.0667	66.7	67.9	79.5	85.4	89.3
			2	0.100	80.8	0.0808		0.0691	69.1				

*Corrected amount found (mg/kg) = Uncorrected amount found (mg/kg) – Amount found in corresponding control sample (mg/kg).
Correction applies to stability recovery and procedural recovery.
**Stability recovery corrected for procedural recovery (%) = Mean corrected stability recovery (%) / Mean corrected procedural recovery (%) x 100
***Stability recovery corrected for procedural recovery and Day 0 as 100 % (%) = Stability recovery corrected for procedural recovery (%) / Day 0 Stability recovery corrected for procedural recovery (%) x 100

Table A 17: Stability of Triazole Alanine in wheat straw following storage at ≤-18°C.

Matrix	Analyte	Nominal storage interval (months)	Sample	Fortification level (mg/kg)	Recovery (%)	Amount found (mg/kg)	Mean Stability Samples Recovery (%)	Mean procedural recoveries	Stability Recovery Corrected for Procedural Recovery (%)*	Stability Samples Corrected day 0 as 100%**
Wheat straw	Triazole Alanine	0	1	0.500	68.6	0.343	70.8	76.4	92.6	100
			2	0.500	73.0	0.365				
		1	1	0.500	62.7	0.314	66.6	76.0	87.6	94.6
			2	0.500	70.4	0.352				
		3	1	0.500	57.0	0.285	61.9	73.1	84.7	91.4
			2	0.500	66.8	0.334				
		6	1	0.500	49.0	0.245	52.7	76.1	69.3	74.8
			2	0.500	56.4	0.282				
		12	1	0.500	58.6	0.293	58.8	74.1	79.3	85.6
			2	0.500	58.9	0.294				

Amount found in corresponding controls was <30% LOQ therefore the amount found in stability and procedural recovery samples was not corrected for any amount found in the control sample.
*Stability recovery corrected for procedural recovery (%) = Mean stability recovery (%) / Mean procedural recovery (%) x 100
**Stability recovery corrected for procedural recovery and Day 0 as 100 % (%) = Stability recovery corrected for procedural recovery (%) / Day 0 Stability recovery corrected for procedural recovery (%) x 100

Table A 18: Stability of Triazole Alanine in orange following storage at ≤-18°C.

Matrix	Analyte	Nominal storage interval (months)	Sample	Fortification level (mg/kg)	Recovery (%)	Amount found (mg/kg)	Mean Stability Samples Recovery (%)	Mean procedural recoveries	Stability Recovery Corrected for Procedural Recovery (%)*	Stability Samples Corrected day 0 as 100%**
Orange	Triazole Alanine	0	1	0.500	80.0	0.400	84.4	79.1	107	100
			2	0.500	88.8	0.444				
		1	1	0.500	84.8	0.424	86.0	93.2	92.3	86.5
			2	0.500	87.2	0.436				
		3	1	0.500	91.2	0.456	88.0	104	84.9	79.6
			2	0.500	84.8	0.424				
		6	1	0.500	73.0	0.365	78.5	89.7	87.5	82.0
			2	0.500	84.0	0.420				
		12	1	0.500	89.6	0.448	88.0	115	76.4	71.6
			2	0.500	86.4	0.432				

Amount found in corresponding controls was <30% LOQ therefore the amount found in stability and procedural recovery samples was not corrected for any amount found in the control sample.
*Stability recovery corrected for procedural recovery (%) = Mean stability recovery (%) / Mean procedural recovery (%) x 100
**Stability recovery corrected for procedural recovery and Day 0 as 100 % (%) = Stability recovery corrected for procedural recovery (%) / Day 0 Stability recovery corrected for procedural recovery (%) x 100

Table A 19: Stability of Triazole Acetic Acid in oilseed rape seed following storage at ≤-18°C.

Matrix	Analyte	Nominal storage interval (months)	Sample	Fortification level (mg/kg)	Recovery (%)	Amount found (mg/kg)	Amount Found in Corresponding Control (mg/kg)	Corrected Amount Found in Stability Samples (mg/kg)*	Corrected Stability Recovery (%)	Mean Corrected Stability Recovery (%)*	Mean Corrected Procedural Recovery (%)*	Stability Recovery Corrected for Procedural Recovery (%)**	Stability Recovery Corrected for Procedural Recovery and Day 0 as 100 % (%)***
Oilseed rape seed	Triazole Acetic Acid	0	1	0.05	80.8	0.0404	0.00154	0.0389	77.7	85.7	85.3	100	100
			2	0.05	96.8	0.0484		0.0469	93.7				
		1	1	0.05	97.6	0.0488	0.00172	0.0471	94.2	89.0	99.4	89.5	89.1
			2	0.05	87.2	0.0436		0.0419	83.8				
		3	1	0.05	79.1	0.0396	0.00162	0.0379	75.9	77.5	81.6	95.0	94.6
			2	0.05	82.4	0.0412		0.0396	79.2				
		6	1	0.05	78.3	0.0392	0.00187	0.0373	74.6	78.6	98.3	80.0	79.6
			2	0.05	86.4	0.0432		0.0413	82.7				
		12	1	0.05	77.4	0.0387	0.00184	0.0368	73.7	79.0	87.9	89.9	89.4
			2	0.05	88.0	0.0440		0.0422	84.3				

*Corrected amount found (mg/kg) = Uncorrected amount found (mg/kg) – Amount found in corresponding control sample (mg/kg).
Correction applies to stability recovery and procedural recovery.
**Stability recovery corrected for procedural recovery (%) = Mean corrected stability recovery (%) / Mean corrected procedural recovery (%) x 100
***Stability recovery corrected for procedural recovery and Day 0 as 100 % (%) = Stability recovery corrected for procedural recovery (%) / Day 0 Stability recovery corrected for procedural recovery (%) x 100

Table A 20: Stability of Triazole Acetic Acid in field bean (dried) following storage at ≤-18°C.

Matrix	Analyte	Nominal storage interval (months)	Sample	Fortification level (mg/kg)	Recovery (%)	Amount found (mg/kg)	Amount Found in Corresponding Control (mg/kg)	Corrected Amount Found in Stability Samples (mg/kg)*	Corrected Stability Recovery (%)	Mean Corrected Stability Recovery (%)*	Mean Corrected Procedural Recovery (%)*	Stability Recovery Corrected for Procedural Recovery (%)**	Stability Recovery Corrected for Procedural Recovery and Day 0 as 100 % (%)***
		0	1	0.05	92.0	0.0460		N/A	N/A	87.6	88.0	99.5	100

Field Bean (dried)	Triazole Acetic Acid		2	0.05	83.2	0.0416	<30% LOQ	N/A	N/A				
		1	1	0.05	96.8	0.0484	<30% LOQ	N/A	N/A	96.8	119	81.5	81.9
			2	0.05	96.8	0.0484		N/A	N/A				
		3	1	0.05	82.4	0.0412	0.00173	0.0395	78.9	82.1	86.5	94.9	95.3
			2	0.05	88.8	0.0444		0.0427	85.3				
		6	1	0.05	81.6	0.0408	0.00183	0.0390	77.9	83.5	86.7	96.3	96.8
			2	0.05	92.8	0.0464		0.0466	89.1				
		12	1	0.05	92.0	0.0460	<30% LOQ	N/A	N/A	93.6	94.4	99.2	99.6
			2	0.05	95.2	0.0476		N/A	N/A				

*Corrected amount found (mg/kg) = Uncorrected amount found (mg/kg) – Amount found in corresponding control sample (mg/kg).
Correction applies to stability recovery and procedural recovery.
**Stability recovery corrected for procedural recovery (%) = Mean corrected stability recovery (%) / Mean corrected procedural recovery (%) x 100
***Stability recovery corrected for procedural recovery and Day 0 as 100 % (%) = Stability recovery corrected for procedural recovery (%) / Day 0 Stability recovery corrected for procedural recovery (%) x 100

Table A 21: Stability of Triazole Acetic Acid in wheat forage following storage at ≤-18°C.

Matrix	Analyte	Nominal storage interval (months)	Sample	Fortification level (mg/kg)	Recovery (%)	Amount found (mg/kg)	Mean Stability Samples Recovery (%)	Mean procedural recoveries	Stability Recovery Corrected for Procedural Recovery (%)*	Stability Samples Corrected day 0 as 100%**
Wheat forage	Triazole Acetic Acid	0	1	0.200	94.4	0.189	93.2	91.6	102	100
			2	0.200	92.0	0.184				
		1	1	0.200	88.8	0.178	88.4	87.6	101	99.2
			2	0.200	88.0	0.176				
		3	1	0.200	93.6	0.187	94.4	91.2	104	102
			2	0.200	95.2	0.190				
		6	1	0.200	69.9	0.140	70.2	71.9	97.6	95.9
			2	0.200	70.5	0.141				
		12	1	0.200	88.0	0.176	89.2	81.0	110	108

			2	0.200	90.4	0.181				

Amount found in corresponding controls was <30% LOQ therefore the amount found in stability and procedural recovery samples was not corrected for any amount found in the control sample.
*Stability recovery corrected for procedural recovery (%) = Mean stability recovery (%) / Mean procedural recovery (%) x 100
**Stability recovery corrected for procedural recovery and Day 0 as 100 % (%) = Stability recovery corrected for procedural recovery (%) / Day 0 Stability recovery corrected for procedural recovery (%) x 100

Table A 22: Stability of Triazole Acetic Acid in wheat grain following storage at ≤-18°C.

Matrix	Analyte	Nominal storage interval (months)	Sample	Fortification level (mg/kg)	Recovery (%)	Amount found (mg/kg)	Amount Found in Corresponding Control (mg/kg)	Corrected Amount Found in Stability Samples (mg/kg)*	Corrected Stability Recovery (%)	Mean Corrected Stability Recovery (%)*	Mean Corrected Procedural Recovery (%)*	Stability Recovery Corrected for Procedural Recovery (%)**	Stability Recovery Corrected for Procedural Recovery and Day 0 as 100 % (%)***
Wheat grain	Triazole Acetic Acid	0	1	0.100	102	0.102	0.00968	0.0919	91.9	89.5	89.9	99.6	100
			2	0.100	96.8	0.0968		0.0871	87.1				
		1	1	0.100	91.2	0.0912	0.00992	0.0813	81.3	79.7	84.1	94.8	95.2
			2	0.100	88.0	0.0880		0.0781	78.1				
		3	1	0.100	77.7	0.0777	0.00793	0.0698	69.8	72.1	79.3	91.0	91.4
			2	0.100	82.4	0.0824		0.0745	74.5				
		6	1	0.100	94.4	0.0944	0.0105	0.0839	83.9	78.7	80.3	98.0	98.4
			2	0.100	84.0	0.0840		0.0735	73.5				
		12	1	0.100	85.6	0.0856	0.00705	0.0786	78.6	81.0	95.0	85.3	85.6
			2	0.100	90.4	0.0904		0.0834	83.4				

*Corrected amount found (mg/kg) = Uncorrected amount found (mg/kg) – Amount found in corresponding control sample (mg/kg).
Correction applies to stability recovery and procedural recovery.
**Stability recovery corrected for procedural recovery (%) = Mean corrected stability recovery (%) / Mean corrected procedural recovery (%) x 100
***Stability recovery corrected for procedural recovery and Day 0 as 100 % (%) = Stability recovery corrected for procedural recovery (%) / Day 0 Stability recovery corrected for procedural recovery (%) x 100

Table A 23: Stability of Triazole Acetic Acid in wheat straw following storage at ≤-18°C.

Matrix	Analyte	Nominal storage interval (months)	Sample	Fortification level (mg/kg)	Recovery (%)	Amount found (mg/kg)	Amount Found in Corresponding Control (mg/kg)	Corrected Amount Found in Stability Samples (mg/kg)*	Corrected Stability Recovery (%)	Mean Corrected Stability Recovery (%)*	Mean Corrected Procedural Recovery (%)*	Stability Recovery Corrected for Procedural Recovery (%)**	Stability Recovery Corrected for Procedural Recovery and Day 0 as 100 % (%)***
Wheat straw	Triazole Acetic Acid	0	1	0.500	88.0	0.440	0.0165	0.423	84.7	83.5	87.1	95.9	100
			2	0.500	85.6	0.428		0.411	82.3				
		1	1	0.500	95.2	0.476	0.0157	0.460	92.1	87.7	88.9	98.6	103
			2	0.500	86.4	0.432		0.416	83.3				
		3	1	0.500	87.2	0.436	0.0165	0.419	83.9	88.7	86.3	103	107
			2	0.500	96.8	0.484		0.467	93.5				
		6	1	0.500	88.8	0.444	<30% LOQ	N/A	N/A	79.1	93.2	84.8	88.5
			2	0.500	69.4	0.347		N/A	N/A				
		12	1	0.500	86.4	0.432	<30% LOQ	N/A	N/A	86.8	84.4	103	107
			2	0.500	87.2	0.436		N/A	N/A				

*Corrected amount found (mg/kg) = Uncorrected amount found (mg/kg) – Amount found in corresponding control sample (mg/kg).
Correction applies to stability recovery and procedural recovery.
**Stability recovery corrected for procedural recovery (%) = Mean corrected stability recovery (%) / Mean corrected procedural recovery (%) x 100
***Stability recovery corrected for procedural recovery and Day 0 as 100 % (%) = Stability recovery corrected for procedural recovery (%) / Day 0 Stability recovery corrected for procedural recovery (%) x 100

Table A 24: Stability of Triazole Acetic Acid in orange following storage at ≤-18°C.

Matrix	Analyte	Nominal storage interval (months)	Sample	Fortification level (mg/kg)	Recovery (%)	Amount found (mg/kg)	Mean Stability Samples Recovery (%)	Mean procedural recoveries	Stability Recovery Corrected for Procedural Recovery (%)*	Stability Samples Corrected day 0 as 100%**
Orange	Triazole Acetic Acid	0	1	0.0500	83.2	0.0416	83.6	83.4	100	100
			2	0.0500	84.0	0.0420				

		1	1	0.0500	80.0	0.0400	79.8	83.6	95.4	95.2
			2	0.0500	79.5	0.0398				
		3	1	0.0500	84.0	0.0420	87.2	91.6	95.2	95.0
			2	0.0500	90.4	0.0452				
		6	1	0.0500	84.0	0.0420	89.6	100	89.6	89.4
			2	0.0500	95.2	0.0476				
		12	1	0.0500	95.2	0.0476	94.0	82.8	114	113
			2	0.0500	92.8	0.0464				

Amount found in corresponding controls was <30% LOQ therefore the amount found in stability and procedural recovery samples was not corrected for any amount found in the control sample.
*Stability recovery corrected for procedural recovery (%) = Mean stability recovery (%) / Mean procedural recovery (%) x 100
**Stability recovery corrected for procedural recovery and Day 0 as 100 % (%) = Stability recovery corrected for procedural recovery (%) / Day 0 Stability recovery corrected for procedural recovery (%) x 100

Table A 25: Stability of Triazole Lactic Acid in oilseed rape seed following storage at ≤-18°C.

Matrix	Analyte	Nominal storage interval (months)	Sample	Fortification level (mg/kg)	Recovery (%)	Amount found (mg/kg)	Amount Found in Corresponding Control (mg/kg)	Corrected Amount Found in Stability Samples (mg/kg)*	Corrected Stability Recovery (%)	Mean Corrected Stability Recovery (%)*	Mean Corrected Procedural Recovery (%)*	Stability Recovery Corrected for Procedural Recovery (%)**	Stability Recovery Corrected for Procedural Recovery and Day 0 as 100 % (%)***
Oilseed rape seed	Triazole Lactic Acid	0	1	0.100	97.6	0.0976	0.00787	0.0897	89.7	88.9	93.3	95.3	100
			2	0.100	96.0	0.0960		0.0881	88.1				
		1	1	0.100	91.2	0.0912	0.0101	0.0811	81.1	79.9	93.9	85.1	89.3
			2	0.100	88.8	0.0888		0.0787	78.7				
		3	1	0.100	94.4	0.0944	0.0110	0.0834	83.4	82.2	91.4	89.9	94.4
			2	0.100	92.0	0.0920		0.0810	81.0				
		6	1	0.100	92.8	0.0928	0.0104	0.0824	82.4	83.2	87.6	95.0	99.7
			2	0.100	94.4	0.0944		0.0840	84.0				
		12	1	0.100	88.0	0.0880	0.00936	0.0786	78.6	77.8	87.4	89.0	93.4

			2	0.100	86.4	0.0864		0.0770	77.0				

*Corrected amount found (mg/kg) = Uncorrected amount found (mg/kg) – Amount found in corresponding control sample (mg/kg).
Correction applies to stability recovery and procedural recovery.
**Stability recovery corrected for procedural recovery (%) = Mean corrected stability recovery (%) / Mean corrected procedural recovery (%) x 100
***Stability recovery corrected for procedural recovery and Day 0 as 100 % (%) = Stability recovery corrected for procedural recovery (%) / Day 0 Stability recovery corrected for procedural recovery (%) x 100

Table A 26: Stability of Triazole Lactic Acid in field bean (dried) following storage at ≤-18°C.

Matrix	Analyte	Nominal storage interval (months)	Sample	Fortification level (mg/kg)	Recovery (%)	Amount found (mg/kg)	Amount Found in Corresponding Control (mg/kg)	Corrected Amount Found in Stability Samples (mg/kg)*	Corrected Stability Recovery (%)	Mean Corrected Stability Recovery (%)*	Mean Corrected Procedural Recovery (%)*	Stability Recovery Corrected for Procedural Recovery (%)**	Stability Recovery Corrected for Procedural Recovery and Day 0 as 100 % (%)***
Field bean (dried)	Triazole Lactic Acid	0	1	0.200	86.4	0.173	0.0121	0.161	80.3	82.7	88.7	93.2	100
			2	0.200	91.2	0.182		0.170	85.1				
		1	1	0.200	88.0	0.176	0.0105	0.166	82.8	79.6	112	71.1	76.2
			2	0.200	81.6	0.163		0.153	76.4				
		3	1	0.200	90.4	0.181	0.0184	0.162	81.2	78.0	87.6	89.0	95.5
			2	0.200	84.0	0.168		0.150	74.8				
		6	1	0.200	98.4	0.197	0.0197	0.177	88.6	91.0	100	90.8	97.4
			2	0.200	103	0.206		0.187	93.4				
		12	1	0.200	89.6	0.179	0.0107	0.168	84.2	83.0	90.2	92.0	98.7
			2	0.200	87.2	0.174		0.164	81.8				

*Corrected amount found (mg/kg) = Uncorrected amount found (mg/kg) – Amount found in corresponding control sample (mg/kg).
Correction applies to stability recovery and procedural recovery.
**Stability recovery corrected for procedural recovery (%) = Mean corrected stability recovery (%) / Mean corrected procedural recovery (%) x 100
***Stability recovery corrected for procedural recovery and Day 0 as 100 % (%) = Stability recovery corrected for procedural recovery (%) / Day 0 Stability recovery corrected for procedural recovery (%) x 100

Table A 27: Stability of Triazole Lactic Acid in wheat forage following storage at ≤-18°C.

Matrix	Analyte	Nominal storage interval (months)	Sample	Fortification level (mg/kg)	Recovery (%)	Amount found (mg/kg)	Amount Found in Corresponding Control (mg/kg)	Corrected Amount Found in Stability Samples (mg/kg)*	Corrected Stability Recovery (%)	Mean Corrected Stability Recovery (%)*	Mean Corrected Procedural Recovery (%)*	Stability Recovery Corrected for Procedural Recovery (%)**	Stability Recovery Corrected for Procedural Recovery and Day 0 as 100 % (%)***
Wheat forage	Triazole Lactic Acid	0	1	0.500	105	0.524	0.0424	0.482	96.3	97.5	95.1	103	100
			2	0.500	107	0.536		0.494	98.7				
		1	1	0.500	99.2	0.496	0.0452	0.451	90.2	89.0	91.0	97.8	95.4
			2	0.500	96.8	0.484		0.439	87.8				
		3	1	0.500	87.2	0.436	0.0396	0.396	79.3	78.9	78.1	101	98.5
			2	0.500	86.4	0.432		0.392	78.5				
		6	1	0.500	85.6	0.428	0.0456	0.382	76.5	75.7	70.6	107	105
			2	0.500	84.0	0.420		0.374	74.9				
		12	1	0.500	109	0.544	0.0528	0.491	98.2	97.4	77.4	126	123
			2	0.500	107	0.536		0.483	96.6				

*Corrected amount found (mg/kg) = Uncorrected amount found (mg/kg) – Amount found in corresponding control sample (mg/kg).
Correction applies to stability recovery and procedural recovery.
**Stability recovery corrected for procedural recovery (%) = Mean corrected stability recovery (%) / Mean corrected procedural recovery (%) x 100
***Stability recovery corrected for procedural recovery and Day 0 as 100 % (%) = Stability recovery corrected for procedural recovery (%) / Day 0 Stability recovery corrected for procedural recovery (%) x 100

Table A 28: Stability of Triazole Lactic Acid in wheat grain following storage at ≤-18°C.

Matrix	Analyte	Nominal storage interval (months)	Sample	Fortification level (mg/kg)	Recovery (%)	Amount found (mg/kg)	Mean Stability Samples Recovery (%)	Mean procedural recoveries	Stability Recovery Corrected for Procedural Recovery (%)*	Stability Samples Corrected day 0 as 100%**
Wheat grain	Triazole Lactic Acid	0	1	0.0500	81.6	0.0408	81.6	85.2	95.8	100
			2	0.0500	81.6	0.0408				
		1	1	0.0500	76.9	0.0384	79.2	81.6	97.1	101

			2	0.0500	81.6	0.0408				
		3	1	0.0500	84.8	0.0424	82.8	84.8	97.6	102
			2	0.0500	80.8	0.0404				
		6	1	0.0500	79.7	0.0398	81.8	73.1	112	117
			2	0.0500	84.0	0.0420				
		12	1	0.0500	79.9	0.0400	82.0	84.0	97.6	102
			2	0.0500	84.0	0.0420				

Amount found in corresponding controls was <30% LOQ therefore the amount found in stability and procedural recovery samples was not corrected for any amount found in the control sample.
*Stability recovery corrected for procedural recovery (%) = Mean stability recovery (%) / Mean procedural recovery (%) x 100
**Stability recovery corrected for procedural recovery and Day 0 as 100 % (%) = Stability recovery corrected for procedural recovery (%) / Day 0 Stability recovery corrected for procedural recovery (%) x 100

Table A 29: Stability of Triazole Lactic Acid in wheat straw following storage at ≤-18°C.

Matrix	Analyte	Nominal storage interval (months)	Sample	Fortification level (mg/kg)	Recovery (%)	Amount found (mg/kg)	Mean Stability Samples Recovery (%)	Mean procedural recoveries	Stability Recovery Corrected for Procedural Recovery (%)*	Stability Samples Corrected day 0 as 100%**
Wheat straw	Triazole Lactic Acid	0	1	0.500	92.8	0.464	88.0	87.6	100	100
			2	0.500	83.2	0.416				
		1	1	0.500	79.6	0.398	83.0	90.4	91.8	91.4
			2	0.500	86.4	0.432				
		3	1	0.500	101	0.504	102	79.3	128	128
			2	0.500	102	0.512				
		6	1	0.500	93.6	0.468	98.0	88.8	110	110
			2	0.500	102	0.512				
		12	1	0.500	92.0	0.460	92.4	87.6	105	105
			2	0.500	92.8	0.464				

Amount found in corresponding controls was <30% LOQ therefore the amount found in stability and procedural recovery samples was not corrected for any amount found in the control sample.
*Stability recovery corrected for procedural recovery (%) = Mean stability recovery (%) / Mean procedural recovery (%) x 100
**Stability recovery corrected for procedural recovery and Day 0 as 100 % (%) = Stability recovery corrected for procedural recovery (%) / Day 0 Stability recovery corrected for procedural

recovery (%) x 100

Table A 30: Stability of Triazole Lactic Acid in orange following storage at ≤-18°C.

Matrix	Analyte	Nominal storage interval (months)	Sample	Fortification level (mg/kg)	Recovery (%)	Amount found (mg/kg)	Amount Found in Corresponding Control (mg/kg)	Corrected Amount Found in Stability Samples (mg/kg)*	Corrected Stability Recovery (%)	Mean Corrected Stability Recovery (%)*	Mean Corrected Procedural Recovery (%)*	Stability Recovery Corrected for Procedural Recovery (%)**	Stability Recovery Corrected for Procedural Recovery and Day 0 as 100 % (%)***
Orange	Triazole Lactic Acid	0	1	0.05	99.2	0.0496	0.00948	0.0401	80.2	80.6	85.0	94.8	100
			2	0.05	100	0.0500		0.0405	81.0				
		1	1	0.05	93.6	0.0468	0.00301	0.0438	84.6	88.0	96.0	91.7	96.7
			2	0.05	94.4	0.0472		0.0442	88.4				
		3	1	0.05	137	0.0652	0.0122	0.0562	112	113	99.5	113	119
			2	0.05	138	0.0664		0.0566	113				
		6	1	0.05	96.8	0.0484	0.00239	0.0460	92.0	93.6	92.8	101	106
			2	0.05	100	0.0500		0.0476	95.2				
		12	1	0.05	100	0.0500	0.00386	0.0461	92.3	90.7	92.7	97.8	103
			2	0.05	96.8	0.0484		0.0445	89.1				

*Corrected amount found (mg/kg) = Uncorrected amount found (mg/kg) – Amount found in corresponding control sample (mg/kg).
Correction applies to stability recovery and procedural recovery.
**Stability recovery corrected for procedural recovery (%) = Mean corrected stability recovery (%) / Mean corrected procedural recovery (%) x 100
***Stability recovery corrected for procedural recovery and Day 0 as 100 % (%) = Stability recovery corrected for procedural recovery (%) / Day 0 Stability recovery corrected for procedural recovery (%) x 100

Conclusion
For all analytes in all matrices, the mean stability recoveries at the 12-month timepoint, when corrected for on the day procedural and day 0 recoveries, were all within 70-120% with a less than 20% difference between duplicate stability samples. As such all analytes can be considered stable after 12 months of frozen storage in all matrices. There are three exceptions to this.

For 1,2,4-triazole in oilseed rape (seed), stability samples were not analysed at the 12-month timepoint. The mean stability sample recovery at the 15-day timepoint when corrected for on the day procedural and day 0 recoveries was 71.5% and as such can be considered stable for a minimum of 15 days of frozen storage. The mean stability sample recoveries at 1, 2, 3 and 6 month intervals when corrected for on the day procedural and day 0 recoveries was less than 70% therefore 1,2,4-triazole in oilseed rape (seed) can only be considered stable for 15 days.

For 1,2,4-triazole in wheat forage, the mean stability recovery at the 12-month timepoint, when corrected for on the day procedural and day 0 recoveries, was 90.8% however the difference between duplicate stability samples was greater than 20%. An additional set of stability samples was analysed at a 13-month timepoint. The mean stability recovery at the 13-month timepoint when corrected for on the day procedural and day 0 recoveries was 67.6% and as such 1,2,4-triazole in wheat forage cannot be considered stable after 13 months of frozen storage. Nevertheless, the 12-month recoveries are considered to demonstrate stability of 1,2,4-triazole in wheat forage.

For triazole lactic acid in wheat forage, the mean stability sample recovery at the 12-month timepoint when corrected for on the day procedural and day 0 recoveries was 123%. As there is no decline in the residues of triazole lactic acid in wheat forage, the analyte can be considered stable after 12 months of frozen storage.

A 2.2.1.1.1.3 Study 3

Comments of zRMS:	Residues of triazole derivative metabolites (TDMs): 1,2,4-triazole, triazole alanine, triazole acetic acid and triazole lactic acid are considered to be stable in oilseed rape (seeds) and cereal (grain) when stored frozen (<-18°C) for 12 months and 90 days, respectively, since no significant degradation was demonstrated (<30% of nominal). Samples were analysed according to the validated analytical method detailed in study S23-105427. The limit of quantification (LOQ) was 0.01 mg/kg for all analytes. The study complies with OECD 506 and is acceptable.

Reference:	KCA 6.1/04 (CP 7.3.1)
Report	Storage Stability of the Triazole Derivative Metabolites (TDMs) in Plant Matrices under Deep Frozen Conditions Jooß, S., 2025 Report No.: S23-105428
Guideline(s):	OECD Guideline 506, ENV/JM/MONO(2007)17 (OECD guidance document on pesticide residue analytical methods)
Deviations:	Not applicable
GLP:	Yes
Acceptability:	Not applicable

The objective of the study was to obtain data about the storage stability of triazole derivative metabolites (TDMs) 1,2,4-triazole (1,2,4-T), triazole acetic acid (TAA), triazole lactic acid (TLA) and triazole alanine (TA) in oilseed rape (seeds) and cereal (grain) at ≤ 18 °C (target) in the dark over a storage period up to 12 months for cereal (grain) and up to 90 days for oilseed rape (seeds) in accordance to OECD Guideline 506.

Principal of the Method:

In brief, for 1,2,4-triazole (T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) homogenized samples of cereal grain and oilseed rape (seed) were extracted with methanol/water (4/1, v/v). Clean-up of the extract was performed by dispersive SPE with C18 material. Quantification was performed by use of LC-DMS/MS/MS detection with isotopically labelled internal standard(s).

Methos flow chart:

Sample Weighing

All matrices: 5.0 g of homogenized sample material

↓

Addition of Extraction Solvent

All Matrices: Exactly 60 mL of methanol/water (4/1, v/v)

↓

Extraction

Homogenize with a high speed homogenizer for 2 min.
Rinse homogenizer probe with 5 to 10 mL of the extraction solvent and combine with the extract
Add 1 g of Celite 545 as filter aid and mix thoroughly
Filter through a Buchner funnel equipped with a filter paper
Rinse beaker and filter cake with 2 x 5 mL extraction solvent
Transfer the combined filtrate into a 100 mL volumetric flask and make up to volume with methanol/water (4/1, v/v) (V_{Ex})

↓

Addition of Internal Standard and Clean-up

Add a suitable amount of internal standard, e.g. 0.40 mL of the 250 ng/mL mixed IS solution to an aliquot of 10 mL of the extract (V_1)
Concentrate to an aqueous remainder using a centrifuge vacuum concentrator
Adjust volume to 1 mL (V_{End}) with water, swirl and sonicate for 30 seconds
Add a spatula tip of Bakerbond C_{18} SPE material and vortex for about 30 seconds
Centrifuge the mixture for 2 min at 4000 rpm
filter the supernatant through a centrifuge tube filter (0.22 µm pore size) by centrifugation
transfer extract into an autosampler vial

↓

Injection to LC-DMS/MS/MS

Method Performance:

Selectivity:

One control sample per analyte/matrix combination was extracted and analysed according to the method to investigate the presence of residue and/or background interference at the retention time of the analyte(s) for each analytical set.

For 1,2,4-triazole and triazole lactic acid in cereal grain as well as for 1,2,4-triazole and triazole acetic acid in oilseed rape (seed), the control samples showed no significant interference (above 20 % of LOQ) at the retention time of the analyte(s), therefore showing that the method is highly specific. Blank correction was not performed for these analyte/matrix combinations.

For triazole acetic acid and triazole alanine in cereal grain as well as for triazole alanine and triazole lactic acid in oilseed rape (seed), the control samples showed significant interferences/analyte residues (above 20 % of LOQ). Therefore, blank correction was performed with the residue (only if >20 % of LOQ) detected in the control sample material used for fortification. The uncorrected recoveries can be taken from summary.

Accuracy and Precision:

The recoveries of the day 0 storage samples and freshly fortified concurrent recovery samples document the analytical performance in terms of accuracy and repeatability throughout the study. Fortification levels were at LOQ (only for concurrent recoveries at Day 0) and 10x LOQ with analytes fortified jointly.

Concurrent recoveries were handled and stored in the same way and for the same time period as the extracts of the storage samples that were prepared within the same analytical set. The following recoveries were obtained:

Matrix	Fortification Level (mg/kg)	Recovery (%)					Mean (%)	Rel. Std. Dev. (%)	Overall Mean (%)	Overall Rel. Std. Dev. (%)
		Day 0 Testing*	3 Months Testing	6 Months Testing	9 Months Testing	12 Months Testing				
1,2,4-Triazole (Mass Transition m/z 70→43)										
Cereal (grain)	0.01	105, 99.3, 106	-	-	-	- -	96.7	7.7	97.5	7.6
	0.1	92.7, 93.1, 94.6	86.1, 91.7	108, 94.7	110, 108	99.3, 96.1	97.7	8.0		
Triazole Acetic Acid (Mass Transition m/z 128→70)										
Cereal (grain)	0.01	74.3 (141), 77.3 (144), 81.3 (148)	-	-	-	-	77.6	4.5	85.5	10
	0.1	81.4 (88.1), 79.5 (86.2), 81.4 (88.1)	101 (111), 105 (115)	86.3 (93.7), 80.6 (88.0)	83.4 (92.1), 89.7 (98.4)	89.3 (97.6), 86.0 (94.3)	87.6	9.6		
Triazole Alanine (Mass Transition m/z 157→88)										
Cereal (grain)	0.01	70.0 (250), 95.0 (275), 93.0 (273)	-	-	-	-	86.0	16	93.2	10
	0.1	96.0 (114), 103 (121), 92.0 (110)	95.1 (114), 92.1 (111)	88.7 (108), 76.2 (95.5)	101 (129) 105 (133)	103 (123), 95.5 (116)	95.1	8.5		
Triazole Lactic Acid (Mass Transition m/z 158→70)										
Cereal (grain)	0.01	79.2, 82.5, 76.2	-	-	-	-	79.3	4.0	77.7	7.4
	0.1	76.7, 73.5, 77.8					77.2	8.2		

*Day 0 storage samples included; analytes spiked jointly.
Recoveries were corrected for corresponding control residues if those were >20 % of LOQ. Uncorrected recoveries are given in brackets.

Matrix	Fortification Level (mg/kg)	Recovery (%)						Mean (%)	Rel. Std. Dev. (%)	Overall Mean (%)	Overall Rel. Std. Dev. (%)
		Day 0 Testing*	30 Days Testing	45 Days Testing	60 Days Testing	75 Days Testing	90 Days Testing				
1,2,4-Triazole (Mass Transition m/z 70→43)											
Oilseed rape (seed)	0.01	93.8, 83.9, 91.2	-	-	-	-	-	96.7	7.7	97.5	7.6
	0.1	84.1, 82.0, 82.3	82.1, 84.3	108, 94.7	110, 108	99.3, 96.1		97.7	8.0		
Triazole Acetic Acid (Mass Transition m/z 128→70)											

Oilseed rape (seed)	0.01	92.3, 91.3, 93.3	-	-	-	-	-	92.3	1.1	95.8	7.8
	0.1	89.6, 89.3, 88.1	86.0, 88.8	106, 105	103, 102	100, 105	105, 88.8	96.7	8.4		
Triazole Alanine (Mass Transition m/z 157→88)											
Oilseed rape (seed)	0.01	101 (200)**, 81.7 (181)**, 89.7 (189)**	-	-	-	-	-	90.7	11	85.1	10
	0.1	77.0 (86.9)**, 73.0 (82.9)**, 77.7 (87.6)**	98.3 (130)**, 93.3 (125)**	90.5 (119), 92.5 (121)	87.4 (111), 83.4 (107)	75.4 (99.0)**, 90.4 (114)**	78.1 (101), 73.3 (96.2)	83.9	10		
Triazole Lactic Acid (Mass Transition m/z 158→70)											
Oilseed rape (seed)	0.01	96.6 (121), 91.6 (116), 85.6 (110)	-	-	-	-	-	91.3	6.0	83.3	7.9
	0.1	88.3 (90.7), 86.5 (88.9), 86.3 (88.7)	82.0 (96.2)***, 75.0 (89.2)***	85.8 (90.3), 85.4 (89.9)	77.6 (97.1), 80.4 (99.9)	77.4 (84.3), 81.9 (88.8)	83.0 (89.2), 69.5 (75.7)	81.5	6.6		

* Day 0 storage samples included; analytes spiked jointly. **m/z 157/70 was used for quantification. ***m/z 158/43 was used for quantification.
Recoveries were corrected for corresponding control residues if those were >20 % of LOQ. Uncorrected recoveries are given in brackets.
Analyte:
1,2,4-Triazole
Triazole acetic acid
Triazole alanine
Triazole lactic acid
Final determination as:
1,2,4-Triazole
Triazole acetic acid
Triazole alanine
Triazole lactic acid
Residues calculated as:
1,2,4-Triazole
Triazole acetic acid
Triazole alanine
Triazole lactic acid

For 1,2,4-triazole in cereal grain, the mean recovery at a level of LOQ at Day 0 was 96.7 % and the mean recovery at a level of 10xLOQ over all testing intervals was 97.7 %.
For triazole acetic acid in cereal grain, the mean recovery at a level of LOQ at Day 0 was 77.6 % and the mean recovery at a level of 10xLOQ over all testing intervals was 87.6 %.
For triazole alanine in cereal grain, the mean recovery at a level of LOQ at Day 0 was 86.0 % and the mean recovery at a level of 10xLOQ over all testing intervals was 95.1 %.
For triazole lactic acid in cereal grain, the mean recovery at a level of LOQ at Day 0 was 79.3 % and the mean recovery at a level of 10xLOQ over all testing intervals was 77.2 %.
For 1,2,4-triazole in oilseed rape (seed), the mean recovery at a level of LOQ at Day 0 was 89.6 % and the mean recovery at a level of 10xLOQ over all testing intervals was 84.2 %.
For triazole acetic acid in oilseed rape (seed), the mean recovery at a level of LOQ at Day 0 was 92.3 % and the mean recovery at a level of 10xLOQ over all testing intervals was 96.7 %.
For triazole alanine in oilseed rape (seed), the mean recovery at a level of LOQ at Day 0 was 90.7 % and the mean recovery at a level of 10xLOQ over all testing intervals was 83.9 %.
For triazole lactic acid in oilseed rape (seed), the mean recovery at a level of LOQ at Day 0 was 91.3 % and the mean recovery at a level of 10xLOQ over all testing intervals was 81.5 %.
The relative standard deviations were ≤ 20 % for all analyte/matrix combinations.
As can be taken from the summary, for triplicate analysis of storage samples from the same time point the difference between the highest and lowest recovery usually did not exceed 20 % (only exception was observed for triazole alanine in cereal grain after a storage interval of 12 months) and relative standard deviations of the recoveries obtained for storage samples from the same time point did not exceed 20 %.

Analysis of Storage Samples:
The analyte levels detected in the storage samples allow the monitoring of the stability of the analytes upon storage. The values were as follows:

Storage Samples							
Storage Period		Nominal Fortification Level (mg/kg)	Residue Level in Storage Samples (mg/kg)	Percentage of analyte found relative to the Nominal Fortification Level (%)		Percentage recovered corrected for the (mean) concurrent recovery of the individual date of extraction [a]	Percentage recovered relative to the mean percentage recovered at Day 0 [a]
Nominal (Months)	Actual (Days)			Single Values (%) [b, c]	Mean [a] in brackets: rel. std. deviation (%)		
1,2,4-Triazole / Cereal (grain)							
0	0	0.10	0.0927, 0.0931, 0.0946	92.7, 93.1, 94.6	93.5 (1.1)	-	-
3	89	0.10	0.0726, 0.0799, 0.0739	72.6, 79.9, 73.9	75.5 (5.2)	84.9	80.7
6	195	0.10	0.0725, 0.0701, 0.0750	72.5, 70.1, 75.0	72.5 (3.4)	71.6	77.6
9	329	0.10	0.0857, 0.0901, 0.0822	85.7, 90.1, 82.2	86.0 (4.6)	78.9	92.0
12	399	0.10	0.0753, 0.0747, 0.0783	75.3, 74.7, 78.3	76.1 (2.5)	77.9	81.4
Triazole Acetic Acid / Cereal (grain)							
0	0	0.10	0.0881, 0.0862, 0.0881	81.4 (88.1), 79.5 (86.2), 81.4 (88.1)	80.8 (1.4)	-	-
3	89	0.10	0.0800, 0.0800,	70.0 (80.0), 70.0 (80.0),	72.1 (5.0)	70.0	89.2

			0.0862	76.2 (86.2)			
6	195	0.10	0.0810, 0.0726, 0.0823	73.6 (81.0), 65.2 (72.6), 74.9 (82.3)	71.2 (7.4)	85.4	88.1
9	329	0.10	0.105, 0.111, 0.109	96.3 (105), 102 (111), 100 (109)	99.7 (3.1)	115	123
12	399	0.10	0.113, 0.100, 0.104	105 (113), 91.7 (100), 95.7 (104)	97.4 (6.8)	111	120
Triazole Alanine / Cereal (grain)							
0	0	0.10	0.114, 0.121, 0.110	96.0 (114), 103 (121), 92.0 (110)	97.0 (5.7)	-	-
3	89	0.10	0.0892, 0.0892, 0.0898	70.3 (89.2), 70.3 (89.2), 70.9 (89.8)	70.5 (0.49)	75.3	72.7
6	195	0.10	0.0863, 0.0925, 0.0911	67.0 (86.3), 73.2 (92.5), 71.8 (91.1)	70.7 (4.6)	85.7	72.9
9	329	0.10	0.136, 0.132, 0.132	108 (136), 104 (132), 104 (132)	105 (2.2)	102	108
12	399	0.10	0.122, 0.127, 0.0971	102 (122), 107 (127), 76.6 (97.1)	94.9 (17)	95.8	97.8
Triazole Lactic Acid / Cereal (grain)							
0	0	0.10	0.0767, 0.0735, 0.0778	76.7, 73.5, 77.8	76.0 (2.9)	-	-
3	89	0.10	0.0715, 0.0711, 0.0727	71.5, 71.1, 72.7	71.8 (1.2)	96.7	94.4
6	195	0.10	0.0700, 0.0708, 0.0704	70.0, 70.8, 70.4	70.4 (0.57)	89.2	92.6
9	329	0.10	0.0798, 0.0825, 0.0863	79.8, 82.5, 86.3	82.9 (3.9)	118	109
12	399	0.10	0.0998, 0.0996, 0.0990	99.8, 99.6, 99.0	99.5 (0.42)	114	131

[a] calculated from unrounded values; [b] not corrected for concurrent recoveries; [c] if applicable, corrected for blank residues >20% of LOQ, uncorrected recoveries are given in brackets.

Storage Samples							
Storage Period		Nominal Fortification Level (mg/kg)	Residue Level in Storage Samples (mg/kg)	Percentage of analyte found relative to the Nominal Fortification Level (%)		Percentage recovered corrected for the (mean) concurrent recovery of the individual date of extraction [a]	Percentage recovered relative to the mean percentage recovered at Day 0 [a]
Nominal (days)	Actual (Days)			Single Values (%) [b, c]	Mean [a] in brackets: rel. std. deviation (%)		
1,2,4-Triazole / Oilseed rape (seed)							
0	0	0.10	0.0841, 0.0820, 0.0823	84.1, 82.0, 82.3	82.8 (1.4)	-	-
30	30	0.10	0.0708, 0.0715, 0.0701	70.8, 71.5, 70.1	70.8 (1.0)	85.1	85.5

45	45	0.10	0.0766, 0.0736, 0.0731	76.6, 73.6, 73.1	74.4 (2.5)	82.7	89.9
60	60	0.10	0.0705, 0.0716, 0.0720	70.5, 71.6, 72.0	71.4 (1.1)	90.6	86.2
75	80	0.10	0.0712, 0.0714, 0.0716	71.2, 71.4, 71.6	71.4 (0.28)	80.2	86.2
90	106	0.10	0.0714, 0.0722, 0.0700	71.4, 72.2, 70.0	71.2 (1.6)	87.0	86.0
Triazole Acetic Acid / Oilseed rape (seed)							
0	0	0.10	0.0896, 0.0893, 0.0881	89.6, 89.3, 88.1	89.0 (0.89)	-	-
30	30	0.10	0.0893, 0.0883, 0.0904	89.3, 88.3, 90.4	89.3 (1.2)	102	100
45	45	0.10	0.104, 0.106, 0.107	104, 106, 107	106 (1.4)	100	119
60	60	0.10	0.0962, 0.101, 0.0974	96.2, 101, 97.4	98.2 (2.5)	95.8	110
75	80	0.10	0.103, 0.105, 0.102	103, 105, 102	103 (1.5)	101	116
90	106	0.10	0.103, 0.101, 0.102	103, 101, 102	102 (1.0)	105	115
Triazole Alanine / Oilseed rape (seed)							
0	0	0.10	0.0869, 0.0829, 0.0876	77.0 (86.9), 73.0 (82.9), 77.7 (87.6)	75.9 (3.3)	-	-
30	30	0.10	0.106, 0.104, 0.103	74.3 (106), 72.3 (104), 71.3 (103)	72.6 (2.1)	75.8	95.7
45	45	0.10	0.102, 0.112, 0.0992	73.5 (102), 83.5 (112), 70.7 (99.2)	75.9 (8.9)	83.0	100
60	60	0.10	0.0948, 0.101, 0.0942	71.2 (94.8), 77.4 (101), 70.6 (94.2)	73.1 (5.2)	85.6	96.3
75	80	0.10	0.0966, 0.0965, 0.0941	73.0 (96.6), 72.9 (96.5), 70.5 (94.1)	72.1 (2.0)	87.0	95.1
90	106	0.10	0.0930, 0.0936, 0.0942	70.1 (93.0), 70.7 (93.6), 71.3 (94.2)	70.7 (0.85)	93.4	93.2
Triazole Lactic Acid / Oilseed rape (seed)							
0	0	0.10	0.0907, 0.0889, 0.0887	88.3 (90.7), 86.5 (88.9), 86.3 (88.7)	87.0 (1.3)	-	-
30	30	0.10	0.849, 0.0941, 0.0911	70.7 (84.9), 79.9 (94.1), 76.9 (91.1)	75.8 (6.2)	96.6	87.2
45	45	0.10	0.0813, 0.0820, 0.0790	76.8 (81.3), 77.5 (82.0), 74.5 (79.0)	76.2 (2.1)	89.1	87.6
60	60	0.10	0.128, 0.139	109 (128), 120 (139)	114	144	131
75	80	0.10	0.0782, 0.0769, 0.0807	71.3 (78.2), 70.0 (76.9), 73.8 (80.7)	71.7 (2.7)	90.0	82.4
90	106	0.10	0.0822, 0.0783,	76.0 (82.2), 72.1 (78.3),	75.7 (4.6)	99.3	87.1

			0.0853	79.1 (85.3)			

[a] calculated from unrounded values; [b] not corrected for concurrent recoveries; [c] if applicable, corrected for blank residues >20% of LOQ, uncorrected recoveries are given in brackets.

Conclusion:
With regard to selectivity, accuracy and precision, the analytical method was applied successfully for each analytical set when analysing the storage samples.
For all combinations of analytes and matrices the average amount of analyte recovered relative to the initial mean recovery at day 0 and relative to the nominal fortification level was ≥ 70 % at any testing interval.
The study is deemed sufficient for assessing the stability of 1,2,4-triazole, triazole acetic acid, triazole lactic acid and triazole alanine in homogenates of cereal grain upon storage at typically ≤ -18 °C for 12 months as well as assessing the stability of 1,2,4-triazole, triazole acetic acid, triazole lactic acid and triazole alanine in homogenates of oilseed rape (seed) upon storage at typically ≤ -18 °C for 106 days.

A 2.2.1.1.2 Storage stability of residues in animal products

A 2.2.1.1.2.1 Study 1

Comments of zRMS:	Residues of prothioconazole-desthio and 5 hydroxy metabolites: prothioconazole-α-hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio and prothioconazole-6-hydroxy-desthio are considered to be stable in honey when stored frozen (<-18°C) for 13 months since no significant degradation was demonstrated (<30% of nominal). Samples were analysed according to the validated analytical method detailed in Battelle UK Limited report QG21009. The limit of quantification (LOQ) was 0.005 mg/kg for all analytes. The study complies with OECD 506 and is acceptable.

	KCA 6.1/035 (CP 7.3.1)
Report	Prothioconazole-desthio and 5 hydroxy metabolites: Frozen Storage Stability in Honey. Giancola, D., 2023, report No. QG/21/007
Guideline(s):	Yes (OECD 506, SANTE/2020/12830 rev.1, ENV/JM/MONO(2007)17 and ENV/JM/MONO(2009)31)
Deviations:	Yes (minor deviations without impact on the study)
GLP:	Yes
Acceptability:	Yes

Materials and methods
Samples of honey were individually fortified with prothioconazole-desthio and its (5) hydroxy metabolites at a concentration of 0.05 mg/kg (10x LOQ) and stored at nominal temperature of -18°C. Duplicate stability samples were analysed at 0, 6 and 13 months. One control sample and one reagent blank were also analysed.
Two methods of analysis were used for prothioconazole-desthio and its 5 hydroxy metabolites. Residues of prothioconazole-desthio were extracted from honey by dissolving the samples in water and then extracting the analyte with acetonitrile using QuEChERS kits. A portion of the final extract was then taken through the SPE clean-up and then diluted with water 2:3 v/v for final determination by liquid chromatography with tandem mass spectrometry (LC-MS/MS). One ion mass transition (quantitation transition) was monitored for stability samples.
Residues of prothioconazole-desthio and 5 hydroxy prothioconazole-desthio metabolites were extracted from honey by shaking in water and extracting the analyte with acetonitrile using QuEChERS kits. The samples were then diluted with water, evaporated to the aqueous remainder through rotary evaporation followed by a hydrolysis step consisting of an overnight incubation at 40°C under acidic conditions. A portion of the final extract is taken for final determination by liquid chromatography with tandem mass spectrometry (LC-MS/MS).

The objective of this study was to provide information on the stability of residues of prothioconazole-desthio and its 5 hydroxy metabolites in honey when stored under deep freeze storage conditions (≤ -18°C) for up to 13 months.
The limit of quantification (LOQ) was 0.005 mg/kg for all analytes.

Results and discussions
Residues in control samples were less than the LOQ. Recovery efficiency results for prothioconazole-desthio and its 5 hydroxy metabolites in honey are presented in Table A 2.2-2, below.

Table A 2.2- 2: Summary of concurrent recoveries of prothioconazole-desthio and 5 hydroxy metabolites from honey

Matrix	Spike level (mg/kg)	Storage Interval (days)	Sample size (n)	Individual procedural recoveries (%)	Mean
Prothioconazole-desthio					
Honey	0.05	0	2	83, 112	97
		6	2	67, 101	84
		13	2	98, 98	98
Prothioconazol-3-hydroxy-desthio					
Honey	0.05	0	2	86, 89	88
		6	2	91, 98	103
		13	2	84, 84	84
Prothioconazol-4-hydroxy-desthio					
Honey	0.05	0	2	87, 90	88
		6	2	90, 92	91
		13	2	79, 88	84
Prothioconazol-5-hydroxy-desthio					
Honey	0.05	0	2	92, 95	88
		6	2	95, 95	101
		13	2	67, 79	79
Prothioconazol-6-hydroxy-desthio					
Honey	0.05	0	2	84, 90	88
		6	2	100, 108	118
		13	2	70, 78	85
Prothioconazol-α-hydroxy-desthio					
Honey	0.05	0	2	82, 82	85
		6	2	91, 93	99
		13	2	76, 85	80

Conclusion
Residues of prothioconazole-desthio and its (5) hydroxy metabolites were found to be stable in honey under deep freeze storage conditions (≤ -18°C) for up to 13 months.

A 2.2.1.1.2.2 Study 2

Comments of zRMS:	Residues of triazole derivative metabolites (TDMs): 1,2,4-triazole, triazole alanine, triazole acetic acid and triazole lactic acid are considered to be stable in honey when stored frozen

	(<-18°C) for 6 months since no significant degradation was demonstrated (<30% of nominal). Samples were analysed according to the validated analytical method detailed in Battelle UK Limited report QG/21/008. The limit of quantification (LOQ) was 0.005 mg/kg for all analytes. The study complies with OECD 506 and is acceptable.

Reference:	KCA 6.1/0 6 (CP 7.3.1)
Report	Triazole derivate metabolites: Frozen Storage Stability in Honey. Mealing, H., 2024, report No. QG/21/006
Guideline(s):	Yes (OECD 506, SANTE/2020/12830 rev.2, ENV/JM/MONO(2007)17 and ENV/JM/MONO(2009)31)
Deviations:	No (minor deviations without impact on the study)
GLP:	Yes
Acceptability:	Yes

Study Objective

The objective of this study was to determine the stability of residues of triazole derivative metabolites (TDMs) (1,2,4-triazole, triazole alanine, triazole acetic acid and triazole lactic acid) in honey under deep freezer storage (nominally -18°C) for a period of 6 months.

Materials and methods

Samples of honey were individually fortified with triazole derivative metabolites (TDMs) (1,2,4-triazole, triazole alanine, triazole acetic acid and triazole lactic acid) at a concentration of 0.05 mg/kg (10x LOQ) and stored at nominal temperature of -18°C. Duplicate stability samples were analysed at 0, 3 and 6 months. One control sample and one reagent blank were also analysed.

Residues of triazole derivative metabolites (TDMs) (1,2,4-triazole, triazole alanine, triazole acetic acid and triazole lactic acid) were extracted from honey by shaking in water. Final extracted was filtered and fortified with internal standards ([$^{13}C_2$;$^{15}N_3$]1,2,4-triazole, [1,2,4-Triazole-$^{13}C_2$;$^{15}N_3$]triazole alanine, [1,2,4-triazole-$^{13}C_2$;$^{15}N_3$]-1,2,4-triazole acetic acid and [1,2,4-triazole-$^{13}C_2$;$^{15}N_3$]triazole lactic acid) prior to final determination by liquid chromatography with tandem mass spectrometry (LC-MS/MS), monitoring two mass ion transition, or a single ion mass transition using two significantly different HPLC methods. For sample analysis, the primary transition or method was used for quantification, with the exception of timepoint 0 where the transition of the primary HPLC method for triazole acetic acid showed an inconsistent peak shape and therefore the secondary method was used.

The objective of this study was to provide information on the stability of residues of triazole derivative metabolites (TDMs) in honey when stored under deep freeze storage conditions (≤ -18°C) for up to 6 months. The limit of quantification (LOQ) was 0.005 mg/kg for all analytes.

Results and discussions

Residues in control samples were less than the LOQ. Recovery efficiency results for all the triazole derivate metabolites (TDMs) in honey are presented in Table A 2.2-3, below.

Table A 2.2-3: Summary of concurrent recoveries of triazole derivative metabolites (TDMs) from honey

Matrix	Spike level (mg/kg)	Storage Interval (days)	Sample size (n)	Individual procedural Stability recoveries (%)	Mean	Mean Procedural Recovery (%)
1,2,4-triazole						
Honey	0.05	0	2	86.4, 90.4	88.4	100.0
		3	2	82.1, 85.1	83.6	85.5

Matrix	Spike level (mg/kg)	Storage Interval (days)	Sample size (n)	~~Individual procedural~~ Stability recoveries (%)	Mean	Mean Procedural Recovery (%)
		6	2	86.2, 87.3	86.7	83.1
Triazole alanine (TA)						
Honey	0.05	0	2	79.6, 82.6	81.1	81.0
		3	2	92.2, 98.0	95.1	101.9
		6	2	81.5, 81.9	81.7	90.7
Triazole acetic acid (TAA)						
Honey	0.05	0	2	98.2, 98.5	98.3	100.1
		3	2	86.9, 87.4	87.1	101.5
		6	2	88.4, 90.3	89.3	99.7
Triazole lactic acid (TLA)						
Honey	0.05	0	2	73.8, 111.1	92.5	91.3
		3	2	86.2, 88.3	87.2	90.0
		6	2	101.0, 102.0	101.5	87.1

Conclusion
Residues of 1,2,4-triazole, triazole alanine, triazole acetic acid and triazole lactic acid are considered to remain stable in honey for at least 6 months when stored at frozen at a nominal temperature of -18°C.

A 2.2.1.1.2.3 Study 3

A 2.2.1.1.2.4 Study 4

Comments of zRMS:	Residues of triazole derivative metabolites (TDMs): 1,2,4-triazole, triazole alanine, triazole acetic acid and triazole lactic acid are considered to be stable in honey when stored frozen (<-18°C) for 6 months since no significant degradation was demonstrated (<30% of nominal). Samples were analysed according to the validated analytical method detailed in Battelle UK Limited report QG/21/008. The limit of quantification (LOQ) was 0.005 mg/kg for all analytes. The study complies with OECD 506 and is acceptable.

Reference:	KCA 6.1/~~04~~ 07 (CP 7.3.1)
Report	Triazole derivate metabolites: Frozen Storage Stability in Honey. Mealing, H., 2024, report No. QG/21/006
Guideline(s):	Yes (OECD 506, SANTE/2020/12830 rev.2, ENV/JM/MONO(2007)17 and ENV/JM/MONO(2009)31)
Deviations:	No (minor deviations without impact on the study)
GLP:	Yes
Acceptability:	Yes

Study Objective

The objective of this study was to determine the stability of residues of triazole derivative metabolites (TDMs) (1,2,4-triazole, triazole alanine, triazole acetic acid and triazole lactic acid) in honey under deep freezer storage (nominally -18°C) for a period of 6 months.

Materials and methods

Samples of honey were individually fortified with triazole derivative metabolites (TDMs) (1,2,4-triazole, triazole alanine, triazole acetic acid and triazole lactic acid) at a concentration of 0.05 mg/kg (10x LOQ) and stored at nominal temperature of -18°C. Duplicate stability samples were analysed at 0, 3 and 6 months. One control sample and one reagent blank were also analysed.

Residues of triazole derivative metabolites (TDMs) (1,2,4-triazole, triazole alanine, triazole acetic acid and triazole lactic acid) were extracted from honey by shaking in water. Final extracted was filtered and fortified with internal standards ([$^{13}C_2$;$^{15}N_3$]1,2,4-triazole, [1,2,4-Triazole-$^{13}C_2$;$^{15}N_3$]triazole alanine, [1,2,4-triazole-$^{13}C_2$;$^{15}N_3$]-1,2,4-triazole acetic acid and [1,2,4-triazole-$^{13}C_2$;$^{15}N_3$]triazole lactic acid) prior to final determination by liquid chromatography with tandem mass spectrometry (LC-MS/MS), monitoring two mass ion transition, or a single ion mass transition using two significantly different HPLC methods. For sample analysis, the primary transition or method was used for quantification, with the exception of timepoint 0 where the transition of the primary HPLC method for triazole acetic acid showed an inconsistent peak shape and therefore the secondary method was used.

The objective of this study was to provide information on the stability of residues of triazole derivative metabolites (TDMs) in honey when stored under deep freeze storage conditions (≤ -18°C) for up to 6 months. The limit of quantification (LOQ) was 0.005 mg/kg for all analytes.

Results and discussions

Residues in control samples were less than the LOQ. Recovery efficiency results for all the triazole derivate metabolites (TDMs) in honey are presented in Table A 2.2-3, below.

Table A 2.2-3: Summary of concurrent recoveries of triazole derivative metabolites (TDMs) from honey

Matrix	Spike level (mg/kg)	Storage Interval (days)	Sample size (n)	Individual procedural Stability recoveries (%)	Mean	Mean Procedural Recovery (%)
1,2,4-triazole						
Honey	0.05	0	2	86.4, 90.4	88.4	100.0
		3	2	82.1, 85.1	83.6	85.5
		6	2	86.2, 87.3	86.7	83.1
Triazole alanine (TA)						
Honey	0.05	0	2	79.6, 82.6	81.1	81.0
		3	2	92.2, 98.0	95.1	101.9
		6	2	81.5, 81.9	81.7	90.7
Triazole acetic acid (TAA)						
Honey	0.05	0	2	98.2, 98.5	98.3	100.1
		3	2	86.9, 87.4	87.1	101.5
		6	2	88.4, 90.3	89.3	99.7
Triazole lactic acid (TLA)						
Honey	0.05	0	2	73.8, 111.1	92.5	91.3
		3	2	86.2, 88.3	87.2	90.0
		6	2	101.0, 102.0	101.5	87.1

Conclusion

Residues of 1,2,4-triazole, triazole alanine, triazole acetic acid and triazole lactic acid are considered to remain stable in honey for at least 6 months when stored at frozen at a nominal temperature of -18°C.

A 2.2.1.1.2.5 Study 5

Comments of zRMS:	Not evaluated by zRMS-PL.

Reference:	KCA 6.1/~~05~~ 06(CP 7.3.1)
Report	Storage Stability of Triazole Alanine (TA), Triazole Acetic Acid (TAA) and Triazole Lactic Acid (TLA) in Animal Matrices under Deep Frozen Conditions. [redacted], 2024, report No. 869333
Guideline(s):	Yes
Deviations:	Not applicable
GLP:	Yes
Acceptability:	Not applicable

Study owner: Triazole Derivative Metabolite Group. Access via Letter of Access.

Note: The summary of the validation data is not described in this dossier since the applicant is not the owner of the study. The details of the study have not been disclosed. Access to the study report is via a Letter of Access (provided with the initial submission of the dossier). The information provided is that the analytical methods have been assessed by the RMS and is considered acceptable.

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 additional study.

A 2.2.2.1.2 Nature of residue in rotational crops

No additional study.

A 2.2.2.1.3 Nature of residues in processed commodities

Comments of zRMS:	In our opinion, the study on the nature of residues and the conclusion regarding the residue definition should be evaluated at the EU level, not at the MS level. A study concerning the effects of processing on the nature of the residue [^{14}C] Prothioconazole-desthio was performed according to guidelines 7035/VI/95 rev. 5 and OECD 507. Three different hydrolysis conditions were chosen to simulate normal processing practices: pasteurisation, baking/brewing/boiling and sterilisation. The results of this study demonstrated that no significant hydrolysis or reaction products were formed under conditions representative of pasteurisation, baking/brewing/boiling and sterilisation. There was no significant change in the radioactivity content following processing under the three different conditions. Test Item was stable during all processing conditions and no hydrolysis or degradation products were formed under conditions representative of simulating pasteurisation, baking/brewing/boiling and sterilisation. The study is acceptable.

Reference:	KCA 6.5.1/01 (CP 7.3.2.3)
Report	[^{14}C]Prothioconazole-desthio Hydrolysis under Typical Conditions (pH, temperature and time) of Processing. Bloß, K., 2019; report No.: S21-04814
Guideline(s):	Yes (OECD 507; Appendix E - processing studies – 7035/VI/95 rev. 5)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

The objective of this study was to investigate whether breakdown or reaction products arise from residues of the test item in raw agricultural commodities when subjected to processing. The parameter which is most likely to affect the nature of the residue during most processing operations is hydrolysis, because processes like heating would generally inactivate enzymes present in the substrate, leaving abiotic hydrolysis as the most important degradation mechanism. The following hydrolytic conditions, representative of processing procedures, were used:

Condition 1: 90°C for 20 min (pH 4), representative of pasteurisation
Condition 2: 100°C for 60 min (pH 5), representative of baking, brewing, and boiling
Condition 3: 120°C (closed system under pressure) for 20 min (pH 6), representative of sterilisation

This study was performed with radiolabelled [^{14}C]prothioconazole-desthio applied at a nominal concentration of 6.53 MBq/L per vessel, corresponding to 1.04 mg/L (at a specific activity of 6.28 MBq/mg). Analysis of the samples was performed using Liquid Scintillation Counting (LSC) and High-Performance Liquid Chromatography (HPLC). For confirmation the samples were analysed by Thin Layer Chromatography (TLC). No-cleavage of prothioconazole was observed.
The test item was stable during all processing conditions and no hydrolysis or degradation products were formed under conditions representative of simulating pasteurisation, baking/brewing/boiling, and sterilisation.

Results and discussion

Condition 1: Pasteurisation
The treatment had no impact on the pH value of the test solution (pH 3.98 before and pH 4.01 after processing). There was no change in sample weight and in radioactivity content after processing (mass recovery: 99.9%, recovery of radioactivity: 99.4% AR). The radio-HPLC results showed that no degradation products were formed during processing under pasteurisation conditions. TLC analysis confirmed HPLC results. The test item was stable at pH 4 at 90°C for 20 minutes which simulates the pasteurisation process.

Condition 2: Baking, brewing and boiling
The treatment had no impact on the pH value of the test solution (pH 5.01 before and pH 5.00 after processing). There was no change in sample weight and in radioactivity content after processing (mass recovery: 100.0%, recovery of radioactivity: 98.4% AR). The radio-HPLC results showed that no degradation products were formed during processing under baking/brewing/boiling conditions. TLC analysis confirmed HPLC results. The test item was stable at pH 5 at 100°C for 60 minutes which simulates the baking/brewing/boiling process.

Condition 3: Sterilisation
The treatment had no impact on the pH value of the test solution (pH 5.91 before and pH 5.90 after processing). There was no change in sample weight and in radioactivity content after processing (mass recovery: 99.8%, recovery of radioactivity: 100.4% AR). The radio-HPLC results showed that no degradation products were formed during processing under sterilisation conditions (selected chromatograms are shown in Figure 8 and Figure 9). TLC analysis confirmed HPLC results.

The test item was stable at pH 6 at 120°C for 20 minutes which simulates the sterilisation process.

The results after processing in the three hydrolysis tested conditions are summarised in Table A 2.2-4.

Table A 2.2-4: Standard hydrolysis study of [1,2,4-triazole-U-^{14}C]prothioconazole-desthio

Process represented	T° (°C)	Time (min)	pH	Parent Initial conc. (mg/kg)	% of TRR
					Prothioconazole-desthio
Pasteurisation	90	20	4	1.09	99.4
Baking, brewing, boiling	100	60	5	1.09	98.4
Sterilisation	120	20	6	1.09	100.4

Conclusions

No significant hydrolysis or reaction products were formed under conditions representative of pasteurisation, baking/brewing/boiling and sterilisation. There was no significant change in the radioactivity content following processing under the three different conditions. The recovery of the applied [1,2,4-triazole-U-^{14}C]prothioconazole-desthio] was in a range of 98.4% to 100.4%.

Therefore, [^{14}C]prothioconazole-desthio can be considered stable during all processing conditions and no hydrolysis or degradation products were formed under conditions representative of simulating pasteurisation, baking/brewing/boiling and sterilisation.

A 2.2.2.2 Nature of residues in livestock

No additional study.

A 2.2.3 Magnitude of residues in plants

A 2.2.3.1 Oilseed rape

Table A 2.2-5: Comparison of intended and critical EU GAPs

Type of GAP	Number of applica-tions	Application rate per treatment (g a.s./ha)	Interval between application (days)	Growth stage at last application	PHI (days)
cGAP EU (DAR, United Kingdom, 2004)	2	200	14 - 28	BBCH 53	56
cGAP EU (Art. 12, EFSA, 2012)	1-2	120	14	Not stated	30
Intended cGAP (numbers 1 and 2*)	2	175	14	BBCH 61-73	35

* 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

Comments of zRMS:	The study is not evaluated by zRMS-PL, because it was conducted in southern Europe.

Reference:	KCA 6.3.1/03 (CP 7.3.3)
Report	Magnitude of Residues of Prothioconazole-desthio, Hydroxy-prothioconazole-desthio metabolites, Triazole Lactic Acid and Triazole Acetic Acid Following Two Applications of a 250 g/L EC Formulation to Oilseed Rape in Southern Europe, 2020. Hardy, J. and Coleman, H. 2024; report No. QG20008.
Guideline(s):	Yes (OECD 509, SANCO 7029/VI/95 rev.5, SANTE/2020/12830 rev.1)
Deviations:	No (minor deviations without impact on the study)
GLP:	Yes
Acceptability:	Yes

Materials and methods

The objective of the study was to determine the residue level of prothioconazole-desthio, hydroxy-prothioconazole-desthio metabolites, triazole lactic acid and triazole acetic acid in oilseed rape (plant and seed). Four trials were conducted on field oilseed rape during 2020 in Southern Europe. Test sites were in Italy (2) and Spain (2). Half of the trials were performed as decline trials and half as harvest.

Oilseed rape fields were treated with two foliar applications with Prothioconazole 250 g/L EC formulation at a dose rate of 180 g prothioconazole/ha and 200-300 L/ha water spray volume. The applications targeted a 15±1 day retreatment interval with the second application performed during BBCH 80.

Specimens consisted of oilseed rape whole plant and seed. In the decline trials, specimens were taken at 0 days after last application (DALA), at 7 DALA, 21 DALA and 35 DALA, which represents the normal commercial harvest. Specimen from the harvest trials was taken at normal commercial harvest (35-45 DALA).

Results and discussions

Specimens were analysed for residues of prothioconazole-desthio, hydroxy-prothioconazole-desthio metabolites, triazole lactic acid and triazole acetic acid. However, only the data for the analyte prothioconazole-desthio are covered by the maximum storage stability period and therefore it is the only analyte summarized in the framework of this application.

The analyte prothioconazole-desthio was validated by the analytical procedure developed at Battelle described in study no. QG/20/011 (for details see study summarised in dRR Part B5). Extraction was performed with a QuEchERS salt kit with cleaning via d-SPE, followed by filtration and dilution. Quantification was performed by LC-MS/MS detection. Samples were stored for up to 665 days (plant) and 631 days (seed) at < -18°C between sampling and extraction.

~~The limit of quantification (LOQ) for the analysis of prothio-desthio in oilseed rape was 0.005 mg/kg. No residues of prothioconazole-desthio above the limit of detection were found in any of the untreated specimens.~~

~~Overall mean recovery efficiencies for prothioconazole in oilseed rape within this study were within the required range of 70 – 120%. The relative standard deviation was less than 20% at all fortification levels, thus demonstrating sufficient accuracy and precision of the method in accordance with SANTE/2020/12830, rev.1. Calibration curves were established with satisfactory linearity (r > 0.995).~~

~~The levels of residues of prothioconazole-desthio in treated oilseed rape seed samples ranged from 0.047 mg/kg to 0.0645 mg/kg. Detailed results are described in Table A 2.2-6.~~

Table A 2.2-6: Summary of study no. QG20008 – 4 trials (SEU)

Reference:	KCA 6.3.1/03 (CP 7.3.3)		
Report	Magnitude of Residues of Prothioconazole-desthio, Hydroxy-prothioconazole-desthio metabolites, Triazole Lactic Acid and Triazole Acetic Acid Following Two Applications of a 250 g/L EC Formulation to Oilseed Rape in Southern Europe, 2020. Hardy, J. and Coleman, H. 2024; report No. QG20008		
GLP:	Yes	Sample storage conditions:	Up to 665 days; -18°C
Crop:	Oilseed rape	Analytical method:	QG/20/011, validated
Succeeding crop:	-	Limit of Quantification (mg/kg):	0.005 mg/kg
Indoor/Outdoor:	Field	Limit of Detection (mg/kg):	0.0015 mg/kg
Content of active substance (g/kg or g/L):	250 g/L	Residues calculated as:	Prothioconazole-desthio

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of Sowing or planting Flowering 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 Prothio-desthio (mg/kg)	PHI (days)	Details on trial
			kg a.s./ ha	Water (L/ha)	kg a.s./hL						
QG20008-01 ES-50670 Spain 2020	Oilseed Rape/ DK Expression	28/10/2019 13/04/2020 – 20/05/2020 25/06/2020	-	-	-	-	-	Whole plant Whole plant Whole plant Whole plant Seed	<0.0015 <0.0015 <0.0015 <0.0015 <0.0015	0 7 21 35 35	Analytical procedure QG/20/011 LOQ = 0.005 mg/kg LOD = 0.0015 mg/kg extracts were analysed within 24 hours
			0.177 0.181	200 204	0.0885 0.0887	06/05/2020 21/05/2020	BBCH 80	Whole plant Whole plant Whole plant Whole plant Seed	1.01 0.718 0.318 0.0628 0.0516	0 7 21 35 35	
QG20008-02 ES-31195 Spain 2020	Oilseed Rape/ DK Expression	24/09/2019 05/04/2020 – 20/05/2020 09/07/2020	-	-	-	-	-	Whole plant Seed	<0.0015 <0.0015	45 45	
			0.177 0.180	200 203	0.0885 0.0887	11/05/2020 25/05/2020	BBCH 80	Whole plant Seed	0.0793 0.0447	45 45	
QG20008-03 12050 Italy 2020	Oilseed Rape/ Cherokee	16/09/2019 13/04/2020 – 02/05/2020 08/07/2020	-	-	-	-	-	Whole plant Whole plant Whole plant Whole plant Seed	<0.0015 <0.0015 <0.0015 <0.0015 <0.0015	0 7 21 35 35	
			0.177 0.169	300 286	0.0590 0.0591	20/05/2020 03/06/2020	BBCH 80	Whole plant Whole plant Whole plant Whole plant Seed	1.49 0.836 0.288 0.265 0.064	0 7 21 35 35	

~~QG20008-04~~ ~~13012~~ ~~Italy,~~ ~~2020~~	~~Oilseed Rape/~~ ~~Cherokee~~	~~27/09/2019~~ ~~20/04/2020 –~~ ~~06/05/2020~~ ~~08/07/2020~~	~~–~~	~~–~~	~~–~~	~~–~~	~~–~~	~~Whole plant~~ ~~Seed~~	~~<0.0015~~ ~~<0.0015~~	~~35~~ ~~35~~	
			~~0.169~~ ~~0.177~~	~~287~~ ~~300~~	~~0.0589~~ ~~0.0590~~	~~20.05.2020~~ ~~03.06.2020~~	~~BBCH 80~~	~~Whole plant~~ ~~Seed~~	~~0.0953~~ ~~0.0645~~	~~35~~ ~~35~~	

A 2.2.3.1.2 Study 2

Comments of zRMS:	Two independent trials (2 harvest) located in Northern Europe (Germany, The Netherlands) were conducted on oilseed rape following two applications of Prothioconazole 250 g/L DC (175 g as/ha) to determine of the residues of prothioconazole metabolites: PTZ-dethio, PTZ-alpha-OH-desthio, PTZ-3-OH-desthio, PTZ-4-OH-desthio, PTZ-5-OH-desthio, PTZ-6-OH-desthio, in oilseed rape specimens: seed and rest of plant. The first application was performed 14 +/-1 days before the second application. The second application was performed on the treated plot at BBCH 80. The methods were successfully validated for determination of all analytes in all matrices with an LOQ of 0.005 mg/kg according to guidance document SANTE/2020/12830, rev. 2. Max. study storage interval between sampling and extraction for PTZ and hydroxy-metabolites of PTZ was 630 days for seed, and 627 days for plant. **The study on the magnitude of residues is not valid with regard to storage stability.** <u>Residue results:</u> Residues of prothioconazole-desthio and hydroxy-prothioconazole-desthio metabolites were either found <30% LOQ or N/D (<LOD = <0.0015 mg/kg) in all control samples. PTZ: In the treated seed specimens at harvest, residue levels of PTZ-desthio ranged between <0.005 mg/kg – 0.00659 mg/kg. **These trials cannot be used to support the intended use on oilseed rape due to the lack of storage stability.**

Reference:	KCA 6.3.1/04 (CP 7.3.3)
Report	Magnitude of Residues of Prothioconazole-desthio and Hydroxy prothioconazole-desthio Metabolites Following Two Applications of a Prothioconazole 250 g/L DC Formulation to Oilseed Rape in Northern and Southern Europe, 2021. Toscano Saes, R. and Coleman, H. 2023; report No. NZ/21/002.
Guideline(s):	Yes (OECD 509, SANCO 7029/VI/95 rev.5, SANTE/2019/12752, SANTE/2020/12830 rev.1, OECD no. 01, OECD no. 13)
Deviations:	No (minor deviations without impact on the study)
GLP:	Yes
Acceptability:	Yes

Materials and methods

The objective of the study was to determine the residue level of prothioconazole-desthio and hydroxy-prothioconazole-desthio metabolites in oilseed rape (plant and seed). Four harvest trials were conducted on field oilseed rape during 2021 in Southern (2) and Northern Europe (2). Test sites were in Germany, The Netherlands, Italy and Spain.

Oilseed rape fields were treated with two foliar applications with Prothioconazole 250 g/L DC formulation at a dose rate of 180 g prothioconazole/ha and 200-300 L/ha water spray volume. The applications targeted a 15±1 day retreatment interval with the second application performed during BBCH 80. Specimens consisted of oilseed rape whole plant and seed were taken at normal commercial harvest (25-39 DALA).

Results and discussions

Specimens were analysed for residues of prothioconazole-desthio and hydroxy-prothioconazole-desthio metabolites. However, only the data for the analyte prothioconazole-desthio are covered by the maximum storage stability period and therefore it is the only analyte summarized in the framework of this application. The analyte prothioconazole-desthio was validated by the analytical procedure developed at Battelle described in study no. QG/20/011 (for details see study summarised in dRR Part B5). Extraction was

performed with a QuEchERS salt kit with cleaning via d-SPE, followed by filtration and dilution. Quantification was performed by LC-MS/MS detection. Samples used for the analysis of prothioconazole-desthio were stored for up to 289 days (plant and seed) at < -18°C between sampling and extraction.
The limit of quantification (LOQ) for the analysis of all analytes in oilseed rape was 0.005 mg/kg. No residues of prothioconazole-desthio above the limit of detection were found in any of the untreated specimens. Overall mean recovery efficiencies for prothioconazole in oilseed rape within this study were within the required range of 70 – 120%. The relative standard deviation was less than 20% at all fortification levels, thus demonstrating sufficient accuracy and precision of the method in accordance with SANTE/2020/12830, rev.1. Calibration curves were established with satisfactory linearity (r > 0.995).
The levels of residues of prothioconazole-desthio in treated oilseed rape seed samples ranged from <0.005 mg/kg (<LOQ) to 0.0738 mg/kg. Detailed results are described in Table A 2.2-7.

Table A 2.2-7: Summary of study no. NZ/21/002- 4 trials (2 NEU and 2 SEU)

Reference:	KCA 6.3.1/04 (CP 7.3.3)		
Report	Magnitude of Residues of Prothioconazole-desthio and Hydroxy prothioconazole-desthio Metabolites Following Two Applications of a Prothioconazole 250 g/L DC Formulation to Oilseed Rape in Northern and Southern Europe, 2021.Toscano Saes, R. and Coleman, H. 2023; report No. NZ/21/002		
GLP:	Yes	Sample storage conditions:	Up to 289 days; -18°C
Crop:	Oilseed rape	Analytical method:	QG/20/011, validated
Formulation code:	FGR-06	Limit of Quantification (mg/kg):	0.005 mg/kg
Indoor/Outdoor:	Field	Limit of Detection (mg/kg):	0.0015 mg/kg
Content of active substance (g/kg or g/L):	250 g/L	Residues calculated as:	Prothioconazole-desthio

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of Sowing or planting Flowering 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 Prothio-desthio (mg/kg)	PHI (days)	Details on trial
			kg a.s./ ha	Water (L/ha)	kg a.s./hL						
NZ21002-01 Velen-Ramsdorf 46342 Germany 2021	Oilseed Rape/ Ability	05.04.2021 15.05.2021 - 12.06.2021 18.08.2021	-	-	-	-	-	Whole plant Seed	<0.0015 <0.0015	37 37	Analytical procedure QG.20.011 LOQ = 0.005 mg.kg LOD = 0.0015 mg.kg extracts were analysed within 24 hours
			0.174 0.168	209 202	0.0833 0.0832	28.06.2021 12.07.2021	BBCH 80	Whole plant Seed	<0.005 <0.005	37 37	
NZ21002-02 Ottersum 6595 ME The Netherlands 2021	Oilseed Rape. Ability	05.04.2021 12.05.2021 - 10.06.2021 20.08.2021	-	-	-	-	-	Whole plant Seed	<0.0015 <0.0015	39 39	
			0.168 0.172	202 207	0.0832 0.0831	28.06.2021 17.07.2021	BBCH 80	Whole plant Seed	0.0785 0.00659	39 39	
~~NZ21002-03~~ ~~12050~~ ~~Italy~~ ~~2021~~	~~Oilseed Rape.~~ ~~Cherokee~~	~~15.09.2020~~ ~~26.04.2021 –~~ ~~18.05.2021~~ ~~05.07.2021~~	-	-	-	-	-	~~Whole plant~~ ~~Seed~~	~~<0.0015~~ ~~<0.0015~~	~~39~~ ~~39~~	
			~~0.174~~ ~~0.161~~	~~313~~ ~~290~~	~~0.0556~~ ~~0.0555~~	~~13.05.2021~~ ~~27.05.2021~~	~~BBCH 80~~	~~Whole plant~~ ~~Seed~~	~~0.0344~~ ~~0.00755~~	~~39~~ ~~39~~	
~~NZ21002-04~~ ~~ES-41710~~ ~~Spain,~~ ~~2021~~	~~Oilseed Rape.~~ ~~Salsa CL~~	~~27.09.2019~~ ~~20.04.2020 –~~ ~~06.05.2020~~ ~~08.07.2020~~	-	-	-	-	-	~~Whole plant~~ ~~Seed~~	~~<0.0015~~ ~~<0.0015~~	~~25~~ ~~25~~	
			~~0.163~~ ~~0.160~~	~~294~~ ~~288~~	~~0.0554~~ ~~0.0555~~	~~07.06.2021~~ ~~21.06.2021~~	~~BBCH 80~~	~~Whole plant~~ ~~Seed~~	~~2.3~~ ~~0.0738~~	~~25~~ ~~25~~	

A 2.2.3.1.3 Study 3

Comments of zRMS:	The study is not evaluated by zRMS-PL, because it was conducted in southern Europe.

Reference:	KCA 6.3.1/05 (CP 7.3.3)
Report	Magnitude of Residues of Prothioconazole-desthio and Hydroxy prothioconazole-desthio metabolites Following Two Applications of Prothioconazole 250 g/L DC (FGR06) to Oilseed rape in southern Europe, 2022. Toscano-Saes, R. and Coleman, H. 2023; report No. QG22006.
Guideline(s):	Yes (OECD 509, SANCO 7029.VI.95 rev.5, SANTE.2020.12830 rev.1)
Deviations:	No (minor deviations without impact on the study)
GLP:	Yes
Acceptability:	Yes

Materials and methods

The objective of the study was to determine the residue level of prothioconazole-desthio and hydroxy-prothioconazole-desthio metabolites in oilseed rape (plant and seed). Two decline trials were conducted on field oilseed rape during 2022 in Italy and Spain (Southern Europe).

Oilseed rape fields were treated with two foliar applications with Prothioconazole 250 g/L EC formulation at a dose rate of 180 g prothioconazole/ha and 200-300 L/ha water spray volume. The applications targeted a 15±1 day retreatment interval with the second application performed during BBCH 80. Specimens consisted of oilseed rape whole plant and seed. In the decline trials, specimens were taken at 0 days after last application (DALA), at 7±1 DALA, 21±1 DALA and at normal commercial harvest (27±2 DALA).

Results and discussions

Specimens were analysed for residues of prothioconazole-desthio and hydroxy prothioconazole-desthio metabolites. However, only the data for the analyte prothioconazole-desthio are covered by the maximum storage stability period and therefore it is the only analyte summarized in the framework of this application. The analyte prothioconazole-desthio was validated by the analytical procedure developed at Battelle described in study no. QG/20/011 (for details see study summarised in dRR Part B5). Extraction was performed with a QuEchERS salt kit with cleaning via d-SPE, followed by filtration and dilution. Quantification was performed by LC-MS/MS detection. Samples used for the analysis of prothioconazole-desthio were stored for up to 353 days (plant) and 324 days (seed) at < -18°C between sampling and extraction.

The limit of quantification (LOQ) for the analysis of all analytes in oilseed rape was 0.005 mg/kg. No residues of prothioconazole-desthio above the limit of detection were found in any of the untreated specimens.

Overall mean recovery efficiencies for prothioconazole in oilseed rape within this study were within the required range of 70 – 120%. The relative standard deviation was less than 20% at all fortification levels, thus demonstrating sufficient accuracy and precision of the method in accordance with SANTE/2020/12830, rev.1. Calibration curves were established with satisfactory linearity (r > 0.995).

The levels of residues of prothioconazole-desthio in treated oilseed rape seed samples ranged from 0.0393 mg/kg (<LOQ) to 0.0609 mg/kg. Detailed results are described in Table A 2.2-8.

Table A 2.2-8: Summary of study no. QG22006 – 2 trials (SEU)

Reference:	KCA 6.3.1/05 (CP 7.3.3)		
Report	Magnitude of Residues of Prothioconazole-desthio and Hydroxy-prothioconazole-desthio metabolites Following Two Applications of Prothioconazole 250 g/L DC (FGR-06) to Oilseed rape in southern Europe, 2022. Toscano-Saes, R. and Coleman, H. 2023; report No. QG22006.		
GLP:	Yes	Sample storage conditions:	Up to 353 days; -18°C
Crop:	Oilseed rape	Analytical method:	QG/20/011, validated
Formulation code:	FGR-06	Limit of Quantification (mg/kg):	0.005 mg/kg
Indoor/Outdoor:	Field	Limit of Detection (mg/kg):	0.0015 mg/kg
Content of active substance (g/kg or g/L):	250 g/L	Residues calculated as:	Prothioconazole-desthio

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of Sowing or planting Flowering 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 Prothio-desthio (mg/kg)	PHI (days)	Details on trial
			kg a.s./ ha	Water (L/ha)	kg a.s./hL						
QG22006-01 Castagnito d'Alba 12050 Italy, 2020	Oilseed Rape/ Cherokee	23.09.2021 01.05.2022 – 23.05.2022 10.07.2022	-	-	-	-	-	Whole plant Whole plant Whole plant Whole plant Seed	<0.0015 <0.0015 <0.0015 <0.0015 <0.0015	0 8 20 27 27	Analytical procedure QG/20/011 LOQ = 0.005 mg.kg LOD = 0.0015 mg.kg extracts were analysed within 24 hours
			0.174 0.177	303 297	0.0574 0.0576	30.05.2022 13.06.2022	BBCH 80	Whole plant Whole plant Whole plant Whole plant Seed	1.02 0.633 0.193 0.442 0.0609	0 8 20 27 27	
QG22006-01 Utrera, Sevilla ES-41710 Spain 2020	Oilseed Rape/ 44YS4	01.02.2022 23.03.2022 – 23.04.2022 21.06.2022	-	-	-	-	-	Whole plant Whole plant Whole plant Whole plant Seed	<0.0015 <0.0015 <0.0015 <0.0015 <0.0015	0 7 21 29 29	
			0.176 0.166	305.6 288.3	0.0576 0.0576	09.05.2022 23.05.2022	BBCH 80	Whole plant Whole plant Whole plant Whole plant Seed	0.571 0.943 1.25 1.58 0.0393	0 7 21 29 29	

A 2.2.3.1.4 Study 4

Comments of zRMS:	Six independent trials (4 decline and 2 harvest) located in Northern Europe (Germany, Poland, Belgium, The Netherlands) were conducted on oilseed rape following two applications of Prothioconazole 250 g/L DC (175 g as/ha) to determine of the residues of prothioconazole metabolites: PTZ-dethio, PTZ-alpha-OH-desthio, PTZ-3-OH-desthio, PTZ-4-OH-desthio, PTZ-5-OH-desthio, PTZ-6-OH-desthio, in oilseed rape specimens: seed and plant (rest of plant or immature plant). The first application was performed 14 +/-1 days before the second application. The second application was performed on the treated plot at BBCH 80. The methods were successfully validated for determination of all analytes in all matrices with an LOQ of 0.005 mg/kg according to guidance document SANTE/2020/12830, rev. 2. Max. study storage interval between sampling and extraction for PTZ and hydroxy-metabolites of PTZ was 314 days for seed, and 411 days for plant. The study on the magnitude of residues is valid with regard to storage stability, except prothioconazole-6-hydroxy-desthio. <u>Residue results:</u> Residues in control (untreated) samples were either not detected or <30% LOQ (0.0015 mg/kg) for prothioconazole-desthio and hydroxy-prothioconazole-desthio metabolites with the exception of samples QG22007-005 (rest of plant) which were <LOQ (0.005 mg/kg) for prothioconazole-3-hydroxy-desthio; QG22007-033 (seed) and QG22007-081 (seed) which were <LOQ and 0.0445 mg/kg for prothioconazole-desthio, respectively. PTZ: In the treated seed specimens at harvest, residue levels of PTZ-desthio ranged between <0.005 mg/kg – 0.056 mg/kg. **These trials cannot be used to support the intended use on oilseed rape due to the lack of storage stability for prothioconazole-6-hydroxy-desthio.**

Reference:	KCA 6.3.1/06 (CP 7.3.3)
Report	Magnitude of Residues of Prothioconazole-desthio and Hydroxy prothioconazole-desthio metabolites Following Two Applications of Prothioconazole 250 g/L DC (FGR06) to Oilseed rape in northern Europe, 2022. Toscano-Saes, R. and Coleman, H.; report No. QG22007.
Guideline(s):	Yes (OECD 509, SANTE 2020/1230 rev.1, SANCO/7029/VI/95 rev.5)
Deviations:	~~No (minor deviations without impact on the study)~~ There was four study plan deviations - Collectively there was no impact of these deviations to the study. • Deviation to the study plan: Appendix 1 – Sampling schedule for trial 2 • A typographical error has been noticed in the study plan for sample 015 and 016. They are wrongly labelled as 015 Retain and 016 Ship, they should be 015 Ship, 016 Retain, as per the pattern of the rest of the samples, all odd numbers are ship, all even numbers are retain. Although this was a typographical error, technically, the study plan was not followed in terms of shipment, storage and analysis of SHIP samples as such this deviation has been recorded. No impact to the study. • Deviation to the study plan: Trials 1, 5 and 6. Storage temperature (air temperature) of the retain samples increased above -18 ºC. No impact as the core temperature did not increase above frozen.
GLP:	Yes
Acceptability:	Yes

Materials and methods

The objective of the study was to determine the residue level of prothioconazole-desthio and hydroxy-prothioconazole-desthio metabolites in oilseed rape (plant and seed). Six trials were conducted on field oilseed rape during 2022 in Belgium (1), Germany (2), Poland (2) and The Netherlands (1) (Northern Europe). Four of the trials were performed as decline trials and two trials as harvest.
Oilseed rape fields were treated with two foliar applications with Prothioconazole 250 g/L DC formulation at a dose rate of 180 g prothioconazole/ha and 200-300 L/ha water spray volume. The applications targeted a 15±1 day retreatment interval with the second application performed during BBCH 80. Specimens consisted of oilseed rape whole plant and seed. In the decline trials, specimens were taken at 0 days after last application (DALA), at 7±1 DALA, 21 DALA and at normal commercial harvest (24 – 47 DALA). Specimen from the harvest trials were taken at normal commercial harvest (22 – 33 DALA).

Results and discussions
Specimens were analysed for residues of prothioconazole-desthio and hydroxy-prothioconazole-desthio metabolites. However, only the data for the analyte prothioconazole-desthio are covered by the maximum storage stability period and therefore it is the only analyte summarized in the framework of this application. The analyte prothioconazole-desthio was validated by the analytical procedure developed at Battelle described in study no. QG/20/011 (see study Rastogi, 2022, KCP 5.2/01 summarised in dRR Part B5). Extraction was performed with a QuEchERS salt kit with cleaning via d-SPE, followed by filtration and dilution. Quantification was performed by LC-MS/MS detection. Samples used for the analysis of prothioconazole-desthio were stored for up to 411 days (plant) and 411 days (seed) at < -18°C between sampling and extraction.
The limit of quantification (LOQ) for the analysis of all analytes in oilseed rape was 0.005 mg/kg. No residues of prothioconazole-desthio above the limit of detection were found in any of the untreated specimens. Overall mean recovery efficiencies for prothioconazole in oilseed rape within this study were within the required range of 70 – 120%. The relative standard deviation was less than 20% at all fortification levels, thus demonstrating sufficient accuracy and precision of the method in accordance with SANTE/2020/12830, rev.1. Calibration curves were established with satisfactory linearity (r > 0.995).
The levels of residues of prothioconazole-desthio in treated oilseed rape seed samples ranged from <0.005 mg/kg (<LOQ) to 0.0564 mg/kg. Detailed results are described in Table A 2.2-9.

Table A 2.2-9: Summary of study no. QG20007 - 6 trials (NEU)

Reference:	KCA 6.3.1/06 (CP 7.3.3)		
Report	Magnitude of Residues of Prothioconazole-desthio and Hydroxy prothioconazole-desthio metabolites Following Two Applications of Prothioconazole 250 g/L DC (FGR06) to Oilseed rape in northern Europe, 2022. Toscano-Saes, R. and Coleman, H. report No. QG22007.		
GLP:	Yes	Sample storage conditions:	Up to 411 days; -18°C
Crop:	Oilseed rape	Analytical method:	QG/20/011, validated
Formulation code	FGR-06	Limit of Quantification (mg/kg):	0.005 mg/kg
Indoor/Outdoor:	Field	Limit of Detection (mg/kg):	0.0015 mg/kg
Content of active substance (g/kg or g/L):	250 g/L	Residues calculated as:	Prothioconazole-desthio

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of Sowing or planting Flowering 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 Prothio-desthio (mg/kg)	PHI (days)	Details on trial
			kg a.s./ ha	Water (L/ha)	kg a.s./hL						
QG22007-01 Kortenaken 3470 Belgium 2022	Oilseed Rape/ Mirakel	29.03.2022 01.05.2022 - 25.05.2022 26.07. 2022	-	-	-	-	-	Whole plant Seed	<0.0015 <0.0015	22 22	Analytical procedure QG/20/011 LOQ = 0.005 mg.kg LOD = 0.0015 mg.kg extracts were analysed within 24 hours
			0.177 0.177	204 204	0.0868 0.0868	20.06.2022 04.07.2022	BBCH 80	Whole plant Seed	0.0217 0.0564	22 22	
QG22007-02 Urbanowice - Opole 47-270 Poland 2022	Oilseed Rape/ Umberto	28.08.2021 10.05.202 - 03.06.2022 09.08. 2022	-	-	-	-	-	Whole plant Seed	<0.0015 <0.0015	33 33	
			0.178 0.181	310 314	0.0574 0.0576	22.06.2022 07.07.2022	BBCH 80	Whole plant Seed	0.0366 <0.005	33 33	
QG22007-03 Peckowo -Greater 64-520 Poland 2022	Oilseed Rape/ Dominator	28.08.2021 10.05.2022 - 03.06.2022 09.08. 2022	-	-	-	-	-	Whole plant Whole plant Whole plant Whole plant Seed	<0.0015 <0.0015 <0.0015 <0.0015 <0.0015	0 7 21 24 24	
			0.180 0.175	312 304	0.0577 0.0576	01.06.2022 15.06.2022	BBCH 80	Whole plant Whole plant Whole plant Whole plant Seed	0.925 0.415 0.385 0.673 0.0182	0 7 21 24 24	
QG22007-04 Machern OT Gerichshain - Saxony 04827 Germany 2022	Oilseed Rape/ INV 160 CL	11.03.2022 20.05.2022- 05.06.2022 03.08.2022	-	-	-	-	-	Whole plant Whole plant Whole plant Whole plant Seed	<0.0015 <0.0015 <0.0015 <0.0015 <0.0015	0 6 21 47 47	
			0.165	287	0.0575	02.06.2022	BBCH 80	Whole plant	0.683	0	

			0.171	298	0.0574	17.06.2022		Whole plant Whole plant Whole plant Seed	0.287 0.0513 0.196 0.00514	6 21 47 47	
QG22007-05 Velen 46342 Germany 2022	Oilseed Rape/ Cherokee	05.04.2022 05.06.2022 - 25.06.2022 18.08.2022	-	-	-	-	-	Whole plant Whole plant Whole plant Whole plant Seed	<0.0015 <0.0015 <0.0015 <0.0015 <0.0015	0 6 21 28 28	
			0.174 0.172	201 199	0.0590 0.0591	27.06.2022 12.07.2022	BBCH 80	Whole plant Whole plant Whole plant Whole plant Seed	1.19 <0.005 <0.005 <0.005 0.0146	0 6 21 28 28	
QG22007-06 AV Ven-Zelderheide 6599 The Netherlands 2022	Oilseed Rape/ Cherokee	11.04.2022 02.06.2022 - 20.06.2022 01.08.2022	-	-	-	-	-	Whole plant Whole plant Whole plant Whole plant Seed	<0.0015 <0.0015 <0.0015 <0.0015 <0.0015	0 6 21 28 28	
			0.174 0.175	201 203	0.0866 0.0862	21.06.2022 05.07.2022	BBCH 80	Whole plant Whole plant Whole plant Whole plant Seed	0.446 0.250 0.0980 0.230 0.0136	0 6 21 28 28	

A 2.2.3.1.5 Study 5

Comments of zRMS:	Eight independent trials (4 decline and 4 harvest) located in Northern Europe (Northern France, Germany, Poland, The Netherlands, Denmark) were conducted on oilseed rape following two applications of Prothioconazole 250 g/L DC (175 g as/ha) to determine of the residues of prothioconazole metabolites: PTZ-alpha-OH-desthio, PTZ-3-OH-desthio, PTZ-4-OH-desthio, PTZ-5-OH-desthio, PTZ-6-OH-desthio and 1,2,4-triazole (T), triazole alanine (TA) in oilseed rape specimens: seed and forage. The first application was performed 14 +/-1 days before the second application. The second application was performed on the treated plot at BBCH 80. The methods were successfully validated for determination of all analytes in all matrices with an LOQ of 0.01 mg/kg according to guidance document SANTE/2020/12830, rev. 2. The maximum storage interval from sampling until extraction was 147 days for the PTZ-OH-desthio metabolites for oilseed rape forage and 138 days for oilseed rape seeds. The maximum storage interval from sampling until extraction for 1,2,4-T and TA was 77 days in forage and was 23 days in seeds. The study on the magnitude of residues of the PTZ-OH-desthio metabolites is valid with regard to storage stability. **According to the S. Baxter, B. Phipps study (QG/21/002) 1,2,4-T and TA in oilseed rape seed are stable for 15 days under frozen storage at -18 °C. This storage stability period is not sufficient, because the interval time from sampling until extraction for 1,2,4-T and TA was longer.** **Commenting period, 09.2025:** The Applicant provided new storage stability study (Jooß, 2025; Study Code S23-105428). The Bousquet's study (647-2023; 2023) on the magnitude of residues of 1,2,4-T and TA is supported by new valid storage stability data. <u>Residue results:</u> PTZ: No residue of PTZ-alpha-OH-desthio, PTZ-3-OH-desthio, PTZ-4-OH-desthio, PTZ-5-OH-desthio and PTZ-6-OH-desthio, all expressed as equivalent PTZ-desthio, was measured in the untreated specimens above the LOQ. In the treated specimens, residues of PTZ-alpha-OH-desthio, PTZ-3-OH-desthio, PTZ-4-OH-desthio, PTZ-5-OH-desthio and PTZ-6-OH-desthio, expressed as prothioconazole-desthio, ranged between: - 0.21 and 0.55 mg/kg (0.21, 0.30, 0.33, 0.55 mg/kg) in forage specimens - 8x<LOQ in seeds specimens (LOQ: 0.01 mg/kg for each analyte, 0.05 mg/kg for prothioconazole expressed as prothioconazole desthio as a sum of hydroxy-metabolites) TDMs: In the untreated and treated specimens for both matrices, no residue of T were detected at any time. In the untreated specimens, residues of TA ranged between: - 0.02 and 0.05 mg/kg (0.02, 0.03, 2x0.05, mg/kg) in forage specimens - 0.11 and 1.7 mg/kg (0.11, 0.16, 0.19, 0.26, 0.27, 0.41, 0.91, 1.7 mg/kg) in seeds specimens In the treated specimens, residues of TA ranged between: - 0.03 and 0.06 mg/kg (0.03, 2x0.04, 0.06 mg/kg) in forage specimens - 0.02 and 1.3 mg/kg (0.02, 0.15, 0.22, 0.23, 0.29, 0.52, 0.79, 1.3 mg/kg) in seeds specimens **These trials can be used to support the intended use on oilseed rape** ~~**(for PTZ-OH-desthio metabolites, not for 1,2,4-T and TA).**~~

Reference:	KCA 6.3.1/07 (CP 7.3.3)
Report	Magnitude of Residues prothioconazole metabolites in oilseed rape in Northern and Southern Europe – 2023. Bousquet, C., 2024; report No. 647-2023.

Guideline(s):	Yes (OECD 509, SANTE 2020/1230 rev.2, ENV/JM/MONO(2007)17, ENV.JM.MONO(99)22, ENV/JM/MONO(2002)9)
Deviations:	No (minor deviations without impact on the study)
GLP:	Yes
Acceptability:	Yes

The following table provides a summary of the storage interval between sampling and extraction from the residue trials:

Zone	trial no	date of sampling	date of extraction - T124	Max storage interval between sampling and extraction - T124 (days)	date of extraction - TA	Max storage interval between sampling and extraction - TA (days)
SEU	sp12	24.05.2023	12.06.2023	19	12.06.2023	19
SEU	gr09	28.06.2023	10.07.2023	12	10.07.2023	12
SEU	it11	28.06.2023	10.07.2023	12	10.07.2023	12
SEU	it13	22.06.2023	10.07.2023	18	10.07.2023	18
SEU	gr15	29.06.2023	10.07.2023	11	10.07.2023	11
NEU	fr01	26.06.2023	17.07.2023	21	19.07.2023	23
NEU	fr07	10.07.2023	17.07.2023	7	19.07.2023	9
SEU	fr14	03.07.2023	17.07.2023	14	19.07.2023	16
SEU	it10	11.07.2023	24.07.2023	13	24.07.2023	13
NEU	be02	18.07.2023	02.08.2023	15	02.08.2023	15
NEU	pl06	20.07.2023	02.08.2023	13	02.08.2023	13
NEU	ge03	14.08.2023	29.08.2023	15	29.08.2023	15
NEU	ge05	19.08.2023	29.08.2023	10	29.08.2023	10
NEU	nl08	08.08.2023	29.08.2023	21	29.08.2023	21
SEU	it16	18.08.2023	29.08.2023	11	29.08.2023	11
NEU	dk04	05.09.2023	15.09.2023	10	15.09.2023	10

Based on the report “Triazole Derived Metabolites: Frozen Storage Stability in Crops for 12 Months; Baxter, B. Phipps, 2025; Study No.: QG/21/002” 1,2,4-triazole in oilseed rape (seed) can be considered stable for a minimum of 15 days of frozen storage, hence trials: sp12, it13, fr01, nl08 are not considered for further assessment of the 1,2,4-triazole metabolite.
However, since the residue trials indicate ‘<LOQ residue’ situation, the number of independent trials may be reduced. According to Regulation (EU) No 283/2013, in case of ‘<LOQ residue’ situation the number of trials shall not be below the minimum of three per zone for minor crops and four per zone for major crops, which is the case here.

Materials and methods

The objective of the study was to determine the residue levels of prothioconazole-5-hydroxy-desthio (prothioconazole-alpha-hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio), and of the triazole derivate metabolites (1,2,4-Triazole (T) and Triazole alanine (TA)) in oilseed rape (plant and seed).

A total of sixteen trials were conducted during 2023 in oilseed rape field located in Northern Europe (8 NEU - Northern France (2), Belgium, Germany (2), Poland, The Netherlands, Denmark) and Southern Europe (8 SEU - Southern France (2), Greece, Spain and Italy (4)). Half of the trials were performed as decline trials and half as harvest.

Oilseed rape fields were treated with two foliar applications with Prothioconazole 250 g/L DC formulation at a dose rate of 175 g prothioconazole/ha (equivalent of 0.7 L product/ha) and 200-400 L/ha water spray volume. The applications targeted a 14±1 day retreatment interval with the second application performed during BBCH 80. Specimens consisted of oilseed rape whole plant and seed. In the decline trials, specimens were taken at 0 days after last application (DALA), at 7±1 DALA, 21±2 DALA and at normal commercial harvest. Specimen from the harvest trials was taken at normal commercial harvest (26-43 DALA).

Results and discussions

Specimens were analysed for residues of 5 hydroxy prothioconazole-desthio and triazole derivate metabolites (1,2,4-Triazole (T) and Triazole alanine (TA) in plant and seed.

The analytes of prothioconazole-5-hydroxy-desthio were validated within this analytical phase (see study Bousquet, 2024, summarised in dRR Part B5). Extraction was performed with acetonitrile: water (4:1) followed by heat hydrolysis with 5M hydrochloric, pH adjustment and dilution. Quantification was performed by LC-MS/MS detection. Samples for the analysis of prothioconazole-5-hydroxy-desthio were stored for up to 147 days (plant) and 138 days (seed) at < -18°C between sampling and extraction.

The limit of quantification (LOQ) for the analysis of prothioconazole-5-hydroxy-desthio in oilseed rape was 0.01 mg/kg and limit of detection was 0.003 mg/kg. No residues of prothioconazole-5-hydroxy-desthio above the limit of detection were found in any of the untreated specimens.

Overall mean recovery efficiencies for all analytes in oilseed rape within this study were within the required range of 70 – 120%. The relative standard deviation was less than 20% at all fortification levels, thus demonstrating sufficient accuracy and precision of the method in accordance with SANTE/2020/12830, rev.1. Calibration curves were established with satisfactory linearity (r > 0.995).

The levels of residues of PTZ-α-OH-desthio and PTZ-4-OHdesthio in treated oilseed rape seed samples ranged from not detectable to 0.02, for PTZ-3-OH-desthio residues ranged from <0.01 to 0.05. The analyte PTZ-5-OH-desthio ranged from not detectable to 0.01 mg/kg and PTZ-6-OH-desthio, ranged from not detectable to <0.01 mg/kg. All the prothio-5-hydroxy-desthio metabolites were expressed as equivalent prothioconazole-desthio. Detailed results are described in Table A 2.2-10.

The method for the two triazoles analytes (1,2,4-T and TA) was also validated within this analytical phase (see study Bousquet, 2024, summarised in dRR Part B5). Extraction was performed with water: methanol (4:1) followed by homogenization with high speed. An isotopically labelled step followed by water bath with nitrogen stream was used. Quantification was performed by LC-DMS-MS/MS detection. Samples for the analysis of prothioconazole-5-hydroxy-desthio were stored for up to 77 days (plant) and 23 days (seed) at < -18°C between sampling and extraction.

The limit of quantification (LOQ) for both TDMs analytes in oilseed rape was 0.01 mg/kg and limit of detection was 0.003 mg/kg. No residues of 1,2,4-T above the limit of detection were found in any of the untreated specimens. Levels of triazole alanine ranged from <LOQ to 0.65 in plants and from 0.04 to 2.30 in oilseed rape seeds. It is noted that significant residue levels of TDMs were often found in untreated control samples of the residue trials suggesting the use of triazole pesticide active substances in previous seasons.

Overall mean recovery efficiencies for all analytes in oilseed rape within this study were within the required range of 70 – 120%. The relative standard deviation was less than 20% at all fortification levels, thus demonstrating sufficient accuracy and precision of the method in accordance with SANTE/2020/12830, rev.1. Calibration curves were established with satisfactory linearity (r > 0.995).

The residue levels of 1,2,4-T metabolite was not detectable (<LOD) in all the treated specimens (plant and seed). Whilst it is clear from these data and studies evaluated in the EU peer review of the pesticide risk assessment for the triazole derivative metabolites (United Kingdom, 2018b and EFSA, 2018) that the

metabolite 1,2,4-T is rapidly degraded in oilseed rape seed, the samples were analyzed with the shortest frozen storage interval possible. The storage intervals of the samples ranged from 7 to 21 days. Levels of TA in treated oilseed rape seed samples ranged from 0.13 to 4.5 mg/kg and from 0.01 to 0.78 mg/kg in plants. Samples were storage within the proved stability period. Detailed results are described in Table A 2.2-11.

Table A 2.2-10: Summary of study no. 647-2023 - 16 trials (8 NEU and 8 SEU))

Reference:	KCA 6.3.1/07 (CP 7.3.3)		
Report	Magnitude of Residues prothioconazole metabolites in oilseed rape in Northern and Southern Europe – 2023. Bousquet, C., 2024; report No. 647-2023		
GLP:	Yes	Sample storage conditions:	Up to 147 days; -18°C
Crop:	Oilseed rape	Analytical method:	Validated at this study
Formulation code:	FGR-06	Limit of Quantification (mg/kg):	0.01 mg/kg
Indoor/Outdoor:	Field	Limit of Detection (mg/kg):	0.003 mg/kg
Content of active substance (g/kg or g/L):	250 g/L	Residues calculated as:	PTZ-α-hydroxy-desthio, PTZ-3-hydroxy-desthio, PTZ-4-hydroxy-desthio, PTZ-5-hydroxy-desthio, PTZ-6-hydroxy-desthio

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of Sowing or planting Flowering 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 expressed as prothioconazole-desthio PTZ-5 hydroxydesthio						PHI (days)	Details on trial
			kg a.s./ ha	Water (L/ha)	kg a.s./hL				α	3	4	5	6	Sum		
647-2023 FR01 49650 Allonnes (Pays de la Loire) Northern France 2023	Oilseed Rape/ APACHE	26.10.22 15.05.23 - 30.05.23 07.07.23	0.167 0.177	193 206	0.0864 0.0864	17.05.23 31.05.23	76 80	Whole plant Whole plant Whole plant Seed	<0.01 0.02 0.04 0.01	0.07 0.16 0.30 0.01	0.03 0.08 0.16 <0.01	<0.01 0.02 0.04 <0.01	n.d. <0.01 <0.01 n.d.	0.12 0.29 0.55 <LOQ	0 6 23 26	Analytical procedure within this study LOQ = 0.01 mg/kg LOD = 0.003 mg/kg extracts were analysed within 24-48 hours LOQ: 0.01 mg/kg for each analyte, 0.05 mg/kg for prothioconazole expressed as prothioconazole desthio as a sum of hydroxy-metabolites;
647-2023 BE02 6221 Saint-Armand (Province of Hainaut) Belgium 2023	Oilseed Rape/ FELICIANO KWS	08.09.22 17.04.23 - 10.05.23 26.07.23	0.175 0.174	304 303	0.0576 0.0576	30.05.23 12.06.23	76 80	Whole plant Whole plant Whole plant Seed	0.01 0.02 0.01 < 0.01	0.09 0.19 0.23 < 0.01	0.03 0.06 0.07 n.d.	< 0.01 0.02 0.02 n.d.	n.d. n.d. n.d. n.d..	0.14 0.29 0.33 <LOQ	0 7 21 36	
647-2023 GE03 46342 Velen-Ramsdorf (North-Rhine-Westphalia) Germany 2023	Oilseed Rape/ MIRAKEL	10.04.23 02.06.23 - 21.06.23 14.08.23	0.174 0.176	303 306	0.0576 0.0576	21.06.23 04.07.23	69 80	Whole plant Whole plant Whole plant Seed	0.01 0.02 0.01 < 0.01	0.08 0.16 0.15 < 0.01	0.02 0.04 0.03 n.d.	< 0.01 0.01 0.01 n.d	n.d. < 0.01 < 0.01 n.d.	0.12 0.24 0.21 <LOQ	0 12 21 41	

647-2023 DK04 5580 Nørre Aby Denmark 2023	Oilseed Rape/ MIRAKEL	26.04.23 19.06.23 - 11.07.23 15.09.23	0.168 0.170	195 197	0.0863 0.0864	19.07.23 02.08.23	73 79	Whole plant Whole plant Whole plant Seed	< 0.01 0.02 0.03 n.d.	0.07 0.10 0.18 < 0.01	0.03 0.03 0.06 n.d.	< 0.01 < 0.01 0.02 n.d.	n.d. n.d. < 0.01 n.d.	0.12 0.16 0.30 <LOQ	0 7 22 34	Analytical procedure within this study LOQ = 0.01 mg/kg LOD = 0.003 mg/kg extracts were analysed within 24-48 hours LOQ: 0.01 mg/kg for each analyte, 0.05 mg/kg for prothioconazole expressed as prothioconazole desthio as a sum of hydroxy-metabolites;
647-2023 GE05 04827 Gerichshain (Saxony) Germany 2023	Oilseed Rape/ MIRAKEL	30.03.23 05.06.23 - 19.06.23 19.08.23	0.173 0.177	301 308	0.0576 0.0576	19.06.23 04.07.23	60 80	Seed	< 0.01	< 0.01	n.d.	n.d	n.d.	<LOQ	43	
647-2023 PL06 49200 Kolnica (Opolskie Province) Poland 2023	Oilseed Rape/ DJANGO	28.08.22 27.04.23 to 02.06.23 20.07.23	0.176 0.179	302 311	0.0576 0.0576	02.06.23 15.06.23	69-74 80	Seed	< 0.01	0.01	n.d.	< 0.01	n.d.	<LOQ	35	
647-2023 FR07 72500 Saint Pierre de Chevillé (Pays de la Loire) Northern France 2023	Oilseed Rape/ ELIPSE	25.08.22 03.04.23 - 01.05.23 15.07.23	0.176 0.1644	256 238	0.069 0.069	17.05.23 31.05.23	78 80	Seed	<0.01	0.01	< 0.01	< 0.01	n.d.	<LOQ	40	
647-2023 NL08 5853EJ Siebengewald (Limburg) The Netherlands 2023	Oilseed rape/ LAKRITZ	19.04.23 05.06.23 - 23.06.23 08.08.23	0.169 0.174	295 303	0.057 0.057	23.06.23 06.07.23	71 80	Seed	<0.01	0.01	< 0.01	n.d.	n.d.	<LOQ	33	
~~647-2023 GR09~~ ~~54500 Drymos (Thessaloniki) (Central Macedonia)~~ ~~Greece~~ ~~2023~~	~~Oilseed Rape/~~ ~~EXPOWER~~	~~05.11.22~~ ~~20.04.23 -~~ ~~15.05.23~~ ~~30.06.23~~	~~0.173~~ ~~0.174~~	~~302~~ ~~302~~	~~0.0576~~ ~~0.0576~~	~~19.07.23~~ ~~02.08.23~~	~~77~~ ~~80~~	~~Whole plant~~ ~~Whole plant~~ ~~Whole plant~~ ~~Seed~~	~~< 0.01~~ ~~0.03~~ ~~0.08~~ ~~< 0.01.~~	~~0.10~~ ~~0.23~~ ~~0.42~~ ~~0.02~~	~~0.03~~ ~~0.08~~ ~~0.15~~ ~~< 0.01~~	~~0.01~~ ~~0.02~~ ~~0.05~~ ~~< 0.01~~	~~n.d.~~ ~~< 0.01~~ ~~0.01~~ ~~< 0.01~~	~~0.15~~ ~~0.37~~ ~~0.71~~ ~~0.06~~	~~0~~ ~~7~~ ~~21~~ ~~28~~	~~Analytical procedure within this study~~ ~~LOQ = 0.01 mg/kg~~ ~~LOD = 0.003 mg/kg~~

647-2023 IT10 95024 Acireale (Sicily) Italy 2023	Oilseed Rape/ LAGONDA	13.03.23 05.05.23 – 13.06.23 11.07.23	0.181 0.166	419 384	0.0432 0.0432	30.05.23 13.06.23	69-73 80	Whole plant Whole plant Whole plant Seed	0.04 0.01 0.02 < 0.01	0.08 0.14 0.24 0.02	0.02 0.05 0.09 < 0.01	< 0.01 0.02 0.03 n.d.	n.d. < 0.01 < 0.01 n.d.	0.15 0.23 0.39 0.04	0 7 21 28	extracts were analysed within 24-48 hours
647-2023 IT11 12062 Cherasco (Piedmont) Italy 2023	Oilseed Rape/ Gordon KWS	02.10.22 05.04.23 – 27.04.23 30.06.23	0.176 0.181	306 314	0.0576 0.0576	06.05.23 18.05.23	74 80	Whole plant Whole plant Whole plant Seed	n.d. < 0.01 < 0.01 n.d.	0.05 0.09 0.09 < 0.01	0.01 0.02 0.02 n.d.	0.01 0.02 0.02 n.d.	n.d. n.d. n.d. n.d.	0.06 0.13 0.13 0.01	0 6 21 41	
647-2023 ES12 14620 El Carpio (Andalucia) Spain 2023	Oilseed Rape/ NXH213CLS	30.09.23 5.03.23 – 10.04.23 26.05.23	0.176 0.169	208 196	0.0863 0.0863	12.04.23 25.04.23	69-71 80	Whole plant Whole plant Whole plant Seed	< 0.01 0.02 < 0.01 n.d.	0.20 0.35 0.27 < 0.01	0.10 0.19 0.14 < 0.01	0.02 0.05 0.04 n.d.	< 0.01 < 0.01 < 0.01 n.d.	0.34 0.62 0.47 0.02	0 7 21 29	
647-2023 IT13 15045 Sale (Piedmont) Italy 2023	Oilseed Rape/ DK-EXCEPTION	20.09.22 02.04.23 – 25.04.23 22.06.23	0.166 0.169	288 293	0.0576 0.0576	06.05.23 18.05.23	75-76 80	Seed	n.d.	< 0.01	n.d.	n.d.	n.d.	0.01	35	
647-2023 FR14 79100 Plaine et Vallées Southern France 2023	Oilseed Rape/ ES CAPELLO	05.08.22 03.04.23 – 01.05.23 05.07.23	0.178 0.171	207 198	0.0864 0.0864	17.05.23 31.05.23	76 80	Seed	0.02	0.05	0.02	0.01	< 0.01	0.11	33	
647-2023 GR15 50200 Anatoliko Ptolemaida (West Macedonia) Greece 2023	Oilseed Rape/ DK-IMPLEMENT CL	25.09.22 10.04.23 – 05.05.23 01.07.23	0.175 0.175	304 305	0.0576 0.0576	15.05.23 29.05.23	75 80	Seed	<0.01	0.02	n.d.	<0.01	n.d.	0.04	31	Analytical procedure within this study LOQ = 0.01 mg/kg LOD = 0.003 mg/kg extracts were analysed within 24-48 hours
647-2023 IT16 94010 Assoro (Sicily) Italy 2023	Oilseed Rape/ LAGONDA	15.04.23 16.06.23 – 30.07.23	0.176 0.176	408 407	0.0576 0.0576	14.07.23 28.07.23	69-75 80	Seed	<0.01	0.01	<0.01	<0.01	n.d.	0.04	21	

		~~18.08.23~~														

n.d. – not detectable
for calculation of the sum of PTZ-OH-desthio metabolites “n.d.” is taken as 0 mg/kg, whilst for “< 0.01” a residue of 0.01 mg/kg is accounted; calculation of the sum is based on rounded values.

Table A 2.2-11: Summary of study no. 647-2023 - 16 trials (8 NEU and 8 SEU)

Reference:	KCA 6.3.1/07 (CP 7.3.3)		
Report	Magnitude of Residues prothioconazole metabolites in wheat in Northern and Southern Europe – 2023. Bousquet, C., 2024; report No. 647-2023		
GLP:	Yes	Sample storage conditions:	Up to 77 days; -18°C
Crop:	Oilseed rape	Analytical method:	Validated at this study
Formulation code:	FGR-06	Limit of Quantification (mg/kg):	0.01 mg/kg
Indoor/Outdoor:	Field	Limit of Detection (mg/kg):	0.003 mg/kg
Content of active substance (g/kg or g/L):	250 g/L	Residues calculated as:	Triazole derivate metabolite (T and TA) mg/kg

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of Sowing or planting Flowering 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 of TDMS (mg/kg)		PHI (days)	Details on trial
			kg a.s./ ha	Water (L/ha)	kg a.s./hL				T	TA		
647-2023 FR01 49650 Allonnes (Pays de la Loire) Northern France 2023	Oilseed Rape/ APACHE	26.10.22 15.05.23 - 30.05.23 07.07.23	-	-	-	-	-	Whole plant Whole plant Whole plant Seed	n.d. n.d. n.d. n.d.	0.06 0.05 0.05 0.26	0 6 23 26	Analytical procedure within this study LOQ = 0.01 mg/kg LOD = 0.003 mg/kg extracts were analysed within 24-48 hours
			0.167 0.177	193 206	0.0864 0.0864	17.05.23 31.05.23	76 80	Whole plant Whole plant Whole plant Seed	n.d. n.d. n.d. n.d.	0.04 0.05 0.04 0.29	0 6 23 26	
647-2023 BE02 6221 Saint-Armand (Province of Hainaut) Belgium 2023	Oilseed Rape/ FELICIANO KWS	08.09.22 17.04.23 - 10.05.23 26.07.23	-	-	-	-	-	Whole plant Whole plant Whole plant Seed	n.d. n.d. n.d. n.d.	0.03 0.04 0.03 0.16	0 7 21 36	
			0.175 0.174	304 303	0.0576 0.0576	30.05.23 12.06.23	76 80	Whole plant Whole plant Whole plant Seed	n.d. n.d. n.d. n.d.	0.03 0.02 0.03 0.15	0 7 21 36	
647-2023 GE03 46342 Velen-Ramsdorf (North-Rhine-Westphalia) Germany 2023	Oilseed Rape/ MIRAKEL	10.04.23 02.06.23 - 21.06.23 14.08.23	-	-	-	-	-	Whole plant Whole plant Whole plant Seed	n.d. n.d. n.d. n.d.	0.05 0.09 0.05 0.41	0 12 21 41	
			0.174 0.176	303 306	0.0576 0.0576	21.06.23 04.07.23	69 80	Whole plant Whole plant Whole plant Seed	n.d. n.d. n.d. n.d.	0.05 0.06 0.06 0.23	0 12 21 41	Analytical procedure within this study LOQ = 0.01 mg/kg

647-2023 DK04 5580 Nørre Aby Denmark 2023	Oilseed Rape/ MIRAKEL	26.04.23 19.06.23 - 11.07.23 15.09.23	-	-	-	-	-	Whole plant Whole plant Whole plant Seed	n.d. n.d. n.d. n.d.	0.02 0.02 0.02 0.11	0 7 22 34	LOD = 0.003 mg/kg extracts were analysed within 24-48 hours
			0.168 0.170	195 197	0.0863 0.0864	19.07.23 02.08.23	73 79	Whole plant Whole plant Whole plant Seed	n.d. n.d. n.d. n.d.	0.03 0.04 0.04 0.22	0 7 22 34	
647-2023 GE05 04827 Gerichshain (Saxony) Germany 2023	Oilseed Rape/ MIRAKEL	30.03.23 05.06.23 - 19.06.23 19.08.23	-	-	-	-	-	Whole plant Whole plant Whole plant Seed	n.d. n.d. n.d. n.d.	0.19	43	
			0.173 0.177	301 308	0.0576 0.0576	19.06.23 04.07.23	60 80	Seed	n.d.	0.20	43	
647-2023 PL06 49200 Kolnica (Opolskie Province) Poland 2023	Oilseed Rape/ DJANGO	28.08.22 27.04.23 - 02.06.23 20.07.23	-	-	-	-	-	Seed	n.d.	0.27	35	
			0.176 0.179	302 311	0.0576 0.0576	02.06.23 15.06.23	69-74 80	Seed	n.d.	0.52	35	
647-2023 FR07 72500 Saint Pierre de Chevillé (Pays de la Loire) Northern France 2023	Oilseed Rape/ ELIPSE	25.08.22 03.04.23 - 01.05.23 15.07.23	-	-	-	-	-	Seed	n.d.	0.91	40	
			0.176 0.1644	256 238	0.069 0.069	17.05.23 31.05.23	78 80	Seed	n.d.	0.79	40	
647-2023 NL08 5853EJ Siebengewald (Limburg) The Netherlands 2023	Oilseed rape/ LAKRITZ	19.04.23 05.06.23 - 23.06.23 08.08.23	-	-	-	-	-	Seed	n.d.	1.7	33	
			0.169 0.174	295 303	0.057 0.057	23.06.23 06.07.23	71 80	Seed	n.d.	1.3	33	Analytical procedure within this study LOQ = 0.01 mg/kg LOD = 0.003 mg/kg
~~647-2023 GR09~~	~~Oilseed Rape/ EXPOWER~~	~~05.11.22 20.04.23 - 15.05.23~~	~~-~~	~~-~~	~~-~~	~~-~~	~~-~~	~~Whole plant Whole plant Whole plant Seed~~	~~n.d. n.d. n.d. n.d.~~	~~0.74 0.70 0.65 1.4~~	~~0 7 21 28~~	

54500 Drymos (Thessaloniki) (Central Macedonia) Greece 2023		30.06.23	0.173 0.174	302 302	0.0576 0.0576	19.07.23 02.08.23	77 80	Whole plant Whole plant Whole plant Seed	n.d. n.d. n.d. n.d.	0.69 0.70 0.78 3.2	0 7 21 28	extracts were analysed within 24-48 hours
647-2023 IT10 95024 Acireale (Sicily) Italy 2023	Oilseed Rape/ LAGONDA	13.03.23 05.05.23 – 13.06.23	-	–	-	-	-	Whole plant Whole plant Whole plant Seed	n.d. n.d. n.d. n.d.	< 0.01 < 0.01 < 0.01 0.05	0 7 21 28	
		11.07.23	0.181 0.166	419 384	0.0432 0.0432	30.05.23 13.06.23	69-73 80	Whole plant Whole plant Whole plant Seed	n.d. n.d. n.d. n.d.	0.02 0.01 0.05 0.13	0 7 21 28	
647-2023 IT11 12062 Cherasco (Piedmont) Italy 2023	Oilseed Rape/ Gordon KWS	02.10.22 05.04.23 – 27.04.23	-	–	-	-	-	Whole plant Whole plant Whole plant Seed	n.d. n.d. n.d. n.d.	< 0.01 0.06 0.02 0.06	0 6 21 41	
		30.06.23	0.176 0.181	306 314	0.0576 0.0576	06.05.23 18.05.23	74 80	Whole plant Whole plant Whole plant Seed	n.d. n.d. n.d. n.d.	0.02 0.03 0.06 0.23	0 6 21 41	
647-2023 ES12 14620 El Carpio (Andalucia) Spain 2023	Oilseed Rape/ NXH213CLS	30.09.23 5.03.23 – 10.04.23 26.05.23	-	–	-	-	-	Whole plant Whole plant Whole plant Seed	n.d. n.d. n.d. n.d.	0.02 < 0.01 0.06 0.15	0 7 21 29	
			0.176 0.169	208 196	0.0863 0.0863	12.04.23 25.04.23	69-71 80	Whole plant Whole plant Whole plant Seed	n.d. n.d. n.d. n.d.	0.05 0.05 0.14 0.25	0 7 21 29	Analytical procedure within this study LOQ = 0.01 mg/kg LOD = 0.003 mg/kg extracts were analysed within 24-48 hours
647-2023 IT13 15045 Sale (Piedmont) Italy 2023	Oilseed Rape/ DK-EXCEPTION	20.09.22 02.04.23 – 25.04.23 22.06.23	-	-	-	-	-	Seed	n.d.	1.2	35	
			0.166 0.169	288 293	0.0576 0.0576	06.05.23 18.05.23	75-76 80	Seed	n.d.	3.4	35	
647-2023 FR14 79100 Plaine et Vallées (Nouvelle Aquitaine) Southern France 2023	Oilseed Rape/ ES CAPELLO	05.08.22 03.04.23 – 01.05.23 05.07.23	-	-	-	-	-	Seed	n.d	0.92	33	
			0.178 0.171	207 198	0.0864 0.0864	17.05.23 31.05.23	76 80	Seed	n.d.	0.78	33	

647-2023 GR15 50200 Anatoliko Ptolemaida (West Macedonia) Greece 2023	Oilseed Rape/ DK-IMPLEMENT CL	25.09.22 10.04.23 - 05.05.23 01.07.23	-	-	-	-	-	Seed	n.d.	2.3	31	
			0.175 0.175	304 305	0.0576 0.0576	15.05.23 29.05.23	75 80	Seed	n.d.	4.5	31	
647-2023 IT16 94010 Assoro (Sicily) Italy 2023	Oilseed Rape/ LAGONDA	15.04.23 16.06.23 - 30.07.23 18.08.23	-	-	-	-	-	Seed	n.d.	0.04	21	
			0.176 0.176	408 407	0.0576 0.0576	14.07.23 28.07.23	69-75 80	Seed	n.d.	0.14	21	

n.d. – not detectable

A 2.2.3.1.6 Study 6

Comments of zRMS:	Two independent trials (2 harvest) located in Northern Europe (Germany, The Netherlands) were conducted on oilseed rape following two applications of Prothioconazole 250 g/L DC (175 g as/ha) to determine of the residues of triazole derived metabolites (TDM's) (triazole acetic acid and triazole lactic acid) in oilseed rape specimens: seed and rest of plant. The first application was performed 14 +/-1 days before the second application. The second application was performed on the treated plot at BBCH 80. The limit of quantification (LOQ) was 0.005 mg/kg for triazole acetic acid (for both seed and plant) and 0.01 mg/kg for triazole lactic acid (for both seed and plant). The maximum storage interval from sampling until extraction for TAA and TLA was 890 days in rest of plants and was 884 days in seeds. The study on the magnitude of residues is valid with regard to storage stability. Residue results: TDMs: In the untreated seed samples residues were <LOQ and 0.0222 mg/kg for TAA, and <0.01 and 0.126 for TLA. In the untreated rest of plants samples residues were < LOQ for TAA and for TLA. In the treated specimens, residues of TAA were <LOQ and 0.0265 mg/kg in seeds, and <LOQ in rest of plants. In the treated specimens, residues of TLA were <LOQ and 0.131 mg/kg in seeds, and <0.01 in rest of plants. The study is acceptable. These trials can be used to support the intended use on oilseed rape

Reference:	KCA 6.3.1/08 (CP 7.3.3)
Report	Magnitude of Residues of Triazole Derived Metabolites (TDM's) (triazole acetic acid and triazole lactic acid) Following Two Applications of Prothioconazole 250 g/L DC (FGR06) to Oilseed Rape in Northern and Southern Europe, 2021. Gibson, G. and Toscano-Saes, R. 2022; study number; report No. NZ21003.
Guideline(s):	Yes (OECD 509, SANCO 7029/VI/95 rev.5, SANTE/2020/12830 rev.2)
Deviations:	No (minor deviations without impact on the study)
GLP:	Yes
Acceptability:	Yes

Materials and methods

The objective of the study was to determine the residue level of the two triazoles derivate metabolites analytes (TAA and TLA) in oilseed rape (plant and seed). Four harvest trials (2 NEU and 2 SEU) were conducted on field oilseed rape during 2021 in Germany, The Netherlands, Italy and Spain.

Oilseed rape fields were treated with two foliar applications with Prothioconazole 250 g/L EC formulation at a dose rate of 180 g prothioconazole/ha and 200-315 L/ha water spray volume. The applications targeted a 15±1 day retreatment interval with the second application performed during BBCH 80. Specimens consisted of oilseed rape whole plant and seed and were taken at normal commercial harvest (25 – 39 DALA).

Results and discussions

Specimens were analysed for residues of triazole derivate metabolites (Triazole acetic acid (TAA) and Triazole lactic acid (TLA)) in plant and seed. Both analytes were validated by the analytical procedure developed at Battelle described in study no. QG/20/012 (described in the dRR B5).

The analytical procedure for both matrices involved extraction via blending the samples with methanol: water (4:1 v/v) followed by filtration in vacuum with a glass Buchner funnel and glass frit with Celite 545. Reconstituting with solvent, shaking and further filtration. Clean up was via a C18 SPE cartridge followed

by evaporation. The final extract was filtered, before final determination. Quantification was performed by LC-MS/MS detection. Samples used for the analysis for both analytes were stored for up to 890 days (plant) and 884 days (seed) at < -18°C between sampling and extraction.
The limit of quantification (LOQ) was 0.005 mg/kg for triazole acetic acid (for both seed and plant) and 0.01 mg/kg for triazole lactic acid (seed and plant). No residues above the limit of detection were found in any of the untreated specimens. Overall mean recovery efficiencies for all analytes in oilseed rape within this study were within the required range of 70 – 120%. The relative standard deviation was less than 20% at all fortification levels, thus demonstrating sufficient accuracy and precision of the method in accordance with SANTE/2020/12830, rev.1. Calibration curves were established with satisfactory linearity (r > 0.995). Residue of triazole acetic acid (TAA) in treated oilseed rape seed samples ranged from <0.005 to 0.0265 mg/kg. Residue of triazole lactic acid (TLA) ranged from <0.01 to 0.134 mg/kg. Samples were storage within the proved stability period. Detailed results are described in Table A 2.2-12.

Table A 2.2-12: Summary of study no.NZ21003 - 4 trials (2 NEU and 2 SEU)

Reference:	KCA 6.3.1/08 (CP 7.3.3)		
Report	Magnitude of Residues of Triazole Derived Metabolites (TDM's) (triazole acetic acid and triazole lactic acid) Following Two Applications of Prothioconazole 250 g/L EC (FGR06) to Oilseed Rape in Northern and Southern Europe, 2021. Gibson, G. and Toscano-Saes, R. 2022; study number; report No. NZ/21/003		
GLP:	Yes	Sample storage conditions:	Up to 890 days; -18°C
Crop:	Oilseed rape	Analytical method:	QG/20/012, validated
Formulation code:	FGR-06	Limit of Quantification (mg/kg):	0.005 mg/kg for TAA and 0.01 mg/kg for TLA
Indoor/Outdoor:	Field	Limit of Detection (mg/kg):	0.0015 mg/kg and 0.003 mg/kg for TLA
Content of active substance (g/kg or g/L):	250 g/L	Residues calculated as:	Triazole derivate metabolite (TAA and TLA) mg/kg

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of Sowing or planting Flowering 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 of TDMS (mg/kg)		PHI 39(days)	Details on trial
			kg a.s./ ha	Water (L/ha)	kg a.s./hL				TAA	TLA		
NZ21002-01 Velen-Ramsdorf 46342 Germany 2021	Oilseed Rape/ Ability	05.04.2021 15.05.2021 - 12.06.2021 18.08.2021	-	-	-	-	-	Whole plant Seed	<0.005 <0.005	<0.01 <0.003	37 37	Analytical procedure QG/20/012 TAA LOQ = 0.005 mg/kg LOD = 0.0015 mg/kg TLA LOQ = 0.01 mg/kg LOD = 0.003 mg/kg extracts were analysed within 24 hours
			0.174 0.168	209 202	0.0833 0.0832	28.06.21 12.07.21	73 80	Whole plant Seed	<0.005 0.0265	<0.01 0.131	37 37	
NZ21002-02 Ottersum 6595 ME The Netherlands 2021	Oilseed Rape/ Ability	05.04.2021 12.05.2021 - 10.06.2021 20.08.2021	-	-	-	-	-	Whole plant Seed	<0.005 <0.005	<0.01 <0.003	39 39	
			0.168 0.172	202 207	0.0832 0.0831	28.06.21 12.07.21	72 80	Whole plant Seed	<0.005 <0.005	<0.01 <0.01	39 39	
~~NZ21002-03 12050 Italy 2021~~	~~Oilseed Rape/ Cherokee~~	~~15.09.2020 26.04.2021 – 18.05.2021 05.07.2021~~	~~-~~	~~-~~	~~-~~	~~-~~	~~-~~	~~Whole plant Seed~~	~~<0.005 <0.005~~	~~<0.01 <0.01~~	~~39 39~~	
			~~0.174 0.161~~	~~313 290~~	~~0.0556 0.0555~~	~~13.05.21 27.05.21~~	~~67 80~~	~~Whole plant Seed~~	~~<0.005 <0.005~~	~~<0.01 <0.01~~	~~39 39~~	~~Analytical procedure QG/20/012~~

~~NZ21002-04~~ ~~ES-41710~~ ~~Spain~~ ~~2021~~	~~Oilseed Rape/~~ ~~Salsa CL~~	~~20.01.2021~~ ~~20.04.2021~~ ~~12.05.2021~~ ~~16.07.2021~~	-	-	-	-	-	~~Whole plant~~ ~~Seed~~	~~<0.005~~ ~~<0.005~~	~~<0.01~~ ~~<0.01~~	~~25~~ ~~25~~	~~TAA~~ ~~LOQ = 0.005 mg/kg~~ ~~LOD = 0.0015 mg/kg~~
			~~0.163~~ ~~0.160~~	~~294~~ ~~288~~	~~0.0554~~ ~~0.0555~~	~~07.06.21~~ ~~21.06.21~~	~~80~~ ~~80~~	~~Whole plant~~ ~~Seed~~	~~0.0196~~ ~~0.0174~~	~~<0.01~~ ~~0.134~~	~~25~~ ~~25~~	~~TLA~~ ~~LOQ = 0.01 mg/kg~~ ~~LOD = 0.003 mg/kg~~ ~~extracts were analysed within 24 hours~~

Analyte	Matrix	Maximum storage interval (days)
Triazole Acetic Acid	Plant*	890
	Seed	884
Triazole Lactic Acid	Plant*	890
	Seed	884

A 2.2.3.1.7 Study 7

Comments of zRMS:	The study is not evaluated by zRMS-PL, because it was conducted in southern Europe.

Reference:	KCA 6.3.1/09 (CP 7.3.3)
Report	Magnitude of Residues of Triazole Derived Metabolites (TDM's) (triazole acetic acid and triazole lactic acid) Following Two Applications of Prothioconazole 250 g/L EC (FGR06) to Oilseed Rape in Southern Europe, 2022. Toscano-Saes, R. 2023; report No. EE/23/006.
Guideline(s):	Yes (OECD 509, SANCO 7029/VI/95 rev.5, SANTE/2020/12830 rev.2, ENV/JM/MONO(2007)17, ENV/JM/MONO(2009)31)
Deviations:	No (minor deviations without impact on the study)
GLP:	Yes
Acceptability:	Yes

Materials and methods

The objective of the study was to determine the residue level of the two triazoles derivate metabolites analytes (TAA and TLA) in oilseed rape (plant and seed). Two decline trials (2 SEU) were conducted on field oilseed rape during 2022 in Italy and Spain.

Oilseed rape fields were treated with two foliar applications with Prothioconazole 250 g/L EC formulation at a dose rate of 180 g prothioconazole/ha and 200-315 L/ha water spray volume. The applications targeted a 15±1 day retreatment interval with the second application performed during BBCH 80. Specimens consisted of oilseed rape whole plant and seed and were taken at 0, 7±1, 21±1 DALA and at normal commercial harvest (27 – 29 DALA).

Results and discussions

Specimens were analysed for residues of triazole derivate metabolites (Triazole acetic acid (TAA) and Triazole lactic acid (TLA)) in plant and seed. Both analytes were validated by the analytical procedure developed at Battelle described in study no. QG/20/012 (described in the dRR B5).

The analytical procedure for both matrices involved extraction via blending the samples with methanol: water (4:1 v/v) followed by filtration in vacuum with a glass Buchner funnel and glass frit with Celite 545. Reconstituting with solvent, shaking and further filtration. Clean up was via a C18 SPE cartridge followed by evaporation. The final extract was filtered, before final determination. Quantification was performed by LC-MS/MS detection. Samples used for the analysis for both analytes were stored for up to 548 days (plant) and 535 days (seed) at < -18°C between sampling and extraction.

The limit of quantification (LOQ) was 0.005 mg/kg for triazole acetic acid (for both seed and plant) and 0.01 mg/kg for triazole lactic acid (seed and plant). No residues above the limit of detection were found in any of the untreated specimens. Overall mean recovery efficiencies for all analytes in oilseed rape within this study were within the required range of 70 – 120%. The relative standard deviation was less than 20% at all fortification levels, thus demonstrating sufficient accuracy and precision of the method in accordance with SANTE/2020/12830, rev.1. Calibration curves were established with satisfactory linearity (r > 0.995). Residue of triazole acetic acid (TAA) in treated oilseed rape seed samples were <0.005 mg/kg and for triazole lactic acid (TLA) ranged from <0.01 to 0.0121 mg/kg. Samples were storage within the proved stability period. Detailed results are described in Table A 2.2-13.

Table A 2.2-13 Summary of study no. EE/23/006 – 2 trials (SEU)

Reference:	KCA 6.3.1/09 (CP 7.3.3)		
Report	Magnitude of Residues of Triazole Derived Metabolites (TDM's) (triazole acetic acid and triazole lactic acid) Following Two Applications of Prothioconazole 250 g/L EC (FGR06) to Oilseed Rape in Southern Europe, 2022. Toscano-Saes, R. 2023; report No. EE/23/006.		
GLP:	Yes	Sample storage conditions:	Up to 548 days; -18°C
Crop:	Oilseed rape	Analytical method:	QG/20/012, validated
Formulation code:	FGR-06	Limit of Quantification (mg/kg):	0.005 mg/kg for TAA and 0.01 mg/kg for TLA
Indoor/Outdoor:	Field	Limit of Detection (mg/kg):	0.0015 mg/kg and 0.003 mg/kg for TLA
Content of active substance (g/kg or g/L):	250 g/L	Residues calculated as:	Triazole derivate metabolite (TAA and TLA) mg/kg

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of Sowing or planting Flowering 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 of TDMS (mg/kg)		PHI 39(days)	Details on trial
			kg a.s./ ha	Water (L/ha)	kg a.s./hL				TAA	TLA		
QG22006-01 Italy 12050 2022	Oilseed Rape/ Cherokee	23.09.2021 01.05.2022 – 23.05.2022 10.07.2022	-	-	-	-	-	Whole plant Whole plant Whole plant Whole plant Seed	<0.005 <0.0015 <0.005 <0.005 <0.0015	<0.003 <0.003 <0.003 <0.003 <0.003	0 8 20 27 27	Analytical procedure QG/20/012 TAA LOQ = 0.005 mg/kg LOD = 0.0015 mg/kg TLA LOQ = 0.01 mg/kg LOD = 0.003 mg/kg extracts were analysed within 24 hours
			0.174 0.171	303 297	0.0574 0.0576	30.05.22 13.06.22	74 80	Whole plant Whole plant Whole plant Whole plant Seed	<0.005 <0.005 <0.005 <0.005 <0.005	<0.01 <0.01 <0.01 <0.01 <0.01	0 8 20 27 27	
QG22006-02 ES-41710 Spain 2022	Oilseed Rape/ 44YS4	01.02.2022 23.03.2022 – 23.04.2022 21.06.2022	-	-	-	-	-	Whole plant Whole plant Whole plant Whole plant Seed	<0.0015 <0.005 <0.005 <0.0015 <0.0015	<0.003 <0.003 <0.003 <0.01 <0.003	0 7 21 29 29	
			0.176 0.166	305.6 288.3	0.0576 0.0576	09.05.22 23.05.22	75 80	Whole plant Whole plant Whole plant Whole plant Seed	<0.005 <0.005 0.005 <0.005 <0.005	<0.01 <0.01 <0.01 <0.01 0.0121	0 7 21 29 29	

A 2.2.3.1.8 Study 8

Comments of zRMS:	Six independent trials (2 harvest and 4 decline) located in Northern Europe (Germany, Poland, The Netherlands, Belgium) were conducted on oilseed rape following two applications of Prothioconazole 250 g/L DC (175 g as/ha) to determine of the residues of triazole derived metabolites (TDM's) (triazole acetic acid and triazole lactic acid) in oilseed rape specimens: seed, immature plant and rest of plant. The first application was performed 14 +/-1 days before the second application. The second application was performed on the treated plot at BBCH 80. The limit of quantification (LOQ) was 0.005 mg/kg for triazole acetic acid (for both seed and plant) and 0.01 mg/kg for triazole lactic acid (for both seed and plant). The maximum storage interval from sampling until extraction for TAA and TLA was 593 days in forage and was 576 days in seeds. The study on the magnitude of residues is valid with regard to storage stability. Residue results: TDMs: In the untreated seed samples residues were beetween <LOQ of 0.005 mg/kg and 0.00692 mg/kg for TAA and <0.01 and 0.0413 for TLA. In the treated specimens, residues of TAA ranged between: - <0.005 and 0.00928 mg/kg (3x<0.005, 0.00576, 0.00896, 0.00928mg/kg) in seeds, - <0.005 and 0.0324 mg/kg (3x<0.005, 0.00548, 0.00660, 0.0324 mg/kg) in rest of plants. In the treated specimens, residues of TLA ranged between: - <0.01 and 0.0491 mg/kg (2x<0.01, 0.0105, 0.029, 0.0365, 0.0491 mg/kg) in seeds - <0.01 and 0.0178 mg/kg (3x<0.01, 0.0102, 0.0109, 0.0178 mg/kg) in rest of plants. The study is acceptable. These trials can be used to support the intended use on oilseed rape

Reference:	KCA 6.3.1/10 (CP 7.3.3)
Report	Magnitude of Residues of Triazole Derived Metabolites (TDM's) (triazole acetic acid and triazole lactic acid) Following Two Applications of Prothioconazole 250 g/L DC (FGR06) to Oilseed Rape in Northern Europe, 2022. Phipps, B. 2022; report No. EE/23/007.
Guideline(s):	Yes (OECD 509, OECD 39, SANCO 7029/VI/95 rev.5, SANTE/2020/12830 rev.2)
Deviations:	No (minor deviations without impact on the study)
GLP:	Yes
Acceptability:	Yes

Materials and methods

The objective of the study was to determine the residue level of the two triazoles derivate metabolites analytes (TAA and TLA) in oilseed rape (plant and seed). Six trials (NEU) were conducted on field oilseed rape during 2022 in Belgium, Germany (2), The Netherlands, Poland (2). Four trials were performed as decline and two as harvest.

Oilseed rape fields were treated with two foliar applications with Prothioconazole 250 g/L EC formulation at a dose rate of 180 g prothioconazole/ha and 200-315 L/ha water spray volume. The applications targeted a 15±1 day retreatment interval with the second application performed during BBCH 80. Specimens consisted of oilseed rape whole plant and seed. In the decline trials, specimens were taken at 0, 7±1, 21±1 DALA and at normal commercial harvest (24 – 47 DALA). Specimen from the harvest trials were taken at normal commercial harvest (22 – 33 DALA).

Results and discussions

Specimens were analysed for residues of triazole derivate metabolites (Triazole acetic acid (TAA) and Triazole lactic acid (TLA)) in plant and seed. Both analytes were validated by the analytical procedure developed at Battelle described in study no. QG/20/012 (described in the dRR B5).
The analytical procedure for both matrices involved extraction with methanol: water (4:1 v/v) followed by filtration under vacuum through Celite. Clean up was via a C18 SPE cartridge followed by evaporation and filtration. An aliquot of internal standard was then added to the final extract. Quantification was performed by LC-MS/MS detection. Samples used for the analysis for both analytes were stored for up to 593 days (plant) and 565 days (seed) at < -18°C between sampling and extraction.
The limit of quantification (LOQ) was 0.005 mg/kg for triazole acetic acid (for both seed and plant) and 0.01 mg/kg for triazole lactic acid (seed and plant). It is noted that significant residue levels of TDMs were often found in untreated control samples of the residue trials suggesting the use of triazole pesticide active substances in previous seasons. Overall mean recovery efficiencies for all analytes in oilseed rape within this study were within the required range of 70 – 120%. The relative standard deviation was less than 20% at all fortification levels, thus demonstrating sufficient accuracy and precision of the method in accordance with SANTE/2020/12830, rev.1. Calibration curves were established with satisfactory linearity (r > 0.995). Residue of triazole acetic acid (TAA) in treated oilseed rape seed ranged from <0.005 to 0.00928 and ranged from <0.01 to 0.0491 mg/kg for triazole lactic acid (TLA). Samples were storage within the proved stability period. Detailed results are described in Table A 2.2-13.

Table A 2.2-14 Summary of study no. EE/23/007 - 6 trials (NEU)

Reference:	KCA 6.3.1/10 (CP 7.3.3)		
Report	Magnitude of Residues of Triazole Derived Metabolites (TDM's) (triazole acetic acid and triazole lactic acid) Following Two Applications of Prothioconazole 250 g/L DC (FGR06) to Oilseed Rape in Northern Europe, 2022. Phipps, B. 2022; report No. EE/23/007.		
GLP:	Yes	Sample storage conditions:	Up to 593 days; -18°C
Crop:	Oilseed rape	Analytical method:	QG/20/012, validated
Formulation code:	FGR-06	Limit of Quantification (mg/kg):	0.005 mg/kg for TAA and 0.01 mg/kg for TLA
Indoor/Outdoor:	Field	Limit of Detection (mg/kg):	0.0012 mg/kg and 0.0024 mg/kg for TLA
Content of active substance (g/kg or g/L):	250 g/L	Residues calculated as:	Triazole derivate metabolite (TAA and TLA) mg/kg

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of Sowing or planting Flowering 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 of TDMS (mg/kg)		PHI (days)	Details on trial
			kg a.s./ ha	Water (L/ha)	kg a.s./hL				TAA	TLA		
QG22007-01 Kortenaken 3470 Belgium 2022	Oilseed Rape/ Mirakel	29.03.2022 01.05.2022 - 25.05.2022 26.07.2022	-	-	-	-	-	Whole plant Seed	<0.005 <0.005	<0.01 0.154	22 22	Analytical procedure QG/20/012 TAA LOQ = 0.005 mg/kg LOD = 0.0012 mg/kg TLA LOQ = 0.01 mg/kg LOD = 0.0024 mg/kg extracts were analysed within 24 hours
			0.17 0.177	204 204	0.0868 0.0868	20.06.22 04.06.22	75 80	Whole plant Seed	0.00548 0.00576	0.0109 0.0290	22 22	
QG22007-02 Urbanowice/ Opole 47-270 Poland 2022	Oilseed Rape/ Umberto	28.08.2021 10.05.2022 - 03.06.2022 09.08.2022	-	-	-	-	-	Whole plant Seed	<0.005 <0.005	<0.01 0.0199	33 33	
			0.178 0.181	310 314	0.0574 0.0576	22.06.22 07.07.22	74 80	Whole plant Seed	<0.005 0.00928	<0.01 0.0365	33 33	
QG22007-03 Peckown/Greater 64-520 Pland 2022	Oilseed Rape/ Dominator	02.09.2021 18.04.2022 to 15.05.2022 09.07.2022	-	-	-	-	-	Whole plant Whole plant Whole plant Whole plant Seed	<0.005 0.00544 0.0140 0.029 0.00692	<0.01 <0.01 0.0146 0.0146 0.0413	0 7 21 29 29	
			0.180 0.175	312 304	0.0577 0.0576	01.06.2022 15.06.2022	74 80	Whole plant Whole plant Whole plant Whole plant Seed	<0.005 0.00548 0.0124 0.0324 0.00896	<0.01 <0.01 0.0135 0.0178 0.0491	0 7 21 24 24	
QG22007-04 Machern OT Gerichshain/ Saxony 04827	Oilseed Rape/ INV 160 CL	11.03.2022 20.05.2022 - 05.06.2022	-	-	-	-	-	Whole plant Whole plant Whole plant Whole plant Seed	<0.0012 <0.0012 <0.0012 <0.0012 <0.005	<0.0024 <0.0024 <0.0024 <0.01 <0.01	0 6 21 47 47	Analytical procedure QG/20/012 TAA

Germany 2022		03.08.2022	0.165 0.171	287 298	0.0575 0.0574	02.06.2022 17.06.2022	67 80	Whole plant Whole plant Whole plant Whole plant Seed	<0.005 <0.005 <0.005 <0.005 <0.005	<0.01 <0.01 <0.01 <0.01 0.0105	0 6 21 47 47	LOQ = 0.005 mg/kg LOD = 0.0012 mg/kg TLA LOQ = 0.01 mg/kg LOD = 0.0024 mg/kg extracts were analysed within 24 hours
QG22007-05 Velen 46342 Germany 2022	Oilseed Rape/ Ability	05.04.2022 05.06.2022 - 25.06.2022 18.08.2022	-	-	-	-	-	Whole plant Whole plant Whole plant Whole plant Seed	<0.005 <0.005 0.00616 <0.005 <0.005	<0.01 <0.01 0.0117 <0.01 0.0192	0 6 21 28 28	
			0.174 0.172	201 199	0.0866 0.0864	27.06.2022 12.07.2022	75 80	Whole plant Whole plant Whole plant Whole plant Seed	<0.005 <0.005 <0.005 0.0066 <0.005	<0.01 <0.01 <0.01 0.0102 <0.01	0 6 21 28 28	
QG22007-06 Ven-Zelderheide 6599 The Netherlands 2022	Oilseed Rape/ Ability	11.04.2022 02.06.2022 - 20.06.2022 01.08.2022	-	-	-	-	-	Whole plant Whole plant Whole plant Whole plant Seed	<0.0012 <0.0012 <0.0012 <0.005 <0.005	<0.0024 <0.0024 <0.01 <0.01 0.0105	0 6 21 28 28	
			0.174 0.175	201 203	0.0866 0.0862	21.06.2022 05.07.2022	69-71 80	Whole plant Whole plant Whole plant Whole plant Seed	<0.005 <0.005 <0.005 <0.005 <0.005	<0.01 <0.01 <0.01 <0.01 <0.01	0 6 21 28 28	

A 2.2.4 Magnitude of residues in livestock

A 2.2.4.1 Livestock feeding studies

A 2.2.4.1.1 Study 1

Comments of zRMS:	Not evaluated.

Reference:	KCA 6.4.2/01 (CP 7.3.4)
Report	Determination of the Triazole Derived Metabolites in Eggs and Tissues of Laying Hens following Multiple Oral Administration of Triazole Lactic Acid [redacted] 2021. Report No. IF19-05004879
Guideline(s):	Yes OECD (2007), Test No. 505: Residues in Livestock, OECD Guidelines for the Testing of Chemicals,
Deviations:	Not applicable
GLP:	Yes
Acceptability:	Not applicable
Duplication (if vertebrate study)	No

Study owner: Triazole Derivative Metabolite Group. Access via Letter of Access.

Note: The summary of the validation data is not described in this dossier since the applicant is not the owner of the study. The details of the study have not been disclosed. Access to the study report is via a Letter of Access (provided with the initial submission of the dossier). The information provided is that the analytical methods have been assessed by the RMS and is considered acceptable.

A 2.2.4.1.2 Study 2

Comments of zRMS:	Not evaluated.

Reference:	KCA 6.4.2/02 (CP 7.3.4)
Report	Determination of the Triazole Derived Metabolites in Milk and Tissues of Dairy Cows Multiple Oral Administration of Triazole Lactic Acid. [redacted] 2021, report No. IF19-05004884.
Guideline(s):	Yes OECD (2007), Test No. 505: Residues in Livestock, OECD Guidelines for the Testing of Chemicals,
Deviations:	Not applicable
GLP:	Yes
Acceptability:	Not applicable
Duplication (if vertebrate study)	No

Study owner: Triazole Derivative Metabolite Group. Access via Letter of Access.

Note: The summary of the validation data is not described in this dossier since the applicant is not the owner of the study. The details of the study have not been disclosed. Access to the study report is via a Letter of Access (provided with the initial submission of the dossier). The information provided is that the analytical

methods have been assessed by the RMS and is considered acceptable.

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

Not relevant.

A 2.2.5.2 Processing studies on a core set of representative processes

No additional study.

A 2.2.5.2 Magnitude of residues in representative succeeding crops

A 2.2.5.2.1 Study 1

Comments of zRMS:	The Applicant only submitted study plan. Applicant statement: "*Unfortunately, the final version of the KCA 6.6.2-01 report is not yet available. However, we can provide the final report as soon as available - it is now expected in January 2026.*"

Reference:	KCA 6.6.2/01 (CP 7.3.6)		
Report	Determination of residues of prothioconazole metabolites and triazole derivative metabolites in rotational crops (turnip, leaf lettuce, wheat) after one application of Prothioconazole 250g.L EC on bare soil at 2 sites in Northern Europe and 2 sites in Southern Europe 2022-2024 – Study Plan.		
GLP:	Yes	Sample storage conditions:	Up to 6 months ≤-18°C
Preceding crop:	Bare soil	Analytical method:	-
Succeeding crop:	Turnip. Leaf Lettuce. Wheat	Limit of Quantification (mg.kg):	-
Indoor.Outdoor:	Outdoor	Limit of Detection (mg.kg):	-
Formulation:	No code	Residues calculated as:	PTZ-desthio, PTZ-alpha-, 3, 4, 5 and 6-hydroxy desthio, and TDMs (1,2,4-Triazol, TA, TAA and TLA)
Content of active substance:	250 g.L		

Note: Access to a Triazole Derivative Metabolite Group method, used in the study for the determination of triazole in soil, is via a Letter of Access (provided with the initial submission of the dossier).

A 2.2.6 Other/Special Studies

A 2.2.6.1 Study 1

Comments of zRMS:	Four residues trials was conducted to determine the magnitude of residues prothioconazole-desthio and hydroxyprothioconazole-desthio metabolites in honey following exposure of honeybees to treated *Phacelia tanacetifolia* plants. Two applications of 250 g/L prothioconazole EC formulation were made representing 200 g/ha prothioconazole per applicationu under light plastic gauze tunnels.

	The method was succesfully validated for the determination of rothioconazole-desthio and the five prothioconazole-hydroxy-desthio metabolite in honey with a limit of quantification of 0.005 mg/kg in compliance with SANTE/2020/12830 guideline. For prothioconazole-desthio, the maximum storage interval from sampling to last analysis was 282 days. For the five prothioconazole-hydroxy-desthio metabolites, the maximum storage interval from sampling to last analysis was 391 days. This is covered by the storage stability test. In the untreated samples residues rothioconazole-desthio and the five prothioconazole-hydroxy-desthio metabolites were <LOQ. Residue levels for prothioconazole-desthio in treated samples ranged between <LOQ and 0.0123 mg/kg. Residue levels for the five prothioconazole-hydroxy-desthio metabolites in treated samples were <LOQ. The study is acceptable.

Reference:	KCA 6.10/02 (CP 7.3.7)
Report	Magnitude of Residues of Prothioconazole-desthio and Hydroxy prothioconazole-desthio Metabolites in Honey Following Two Tunnel Applications of a Prothioconazole 250 g.L EC Formulation (FF-065) to Phacelia in Northern and Southern Europe, 2021. Andrews, G. and Coleman, H., 2023, report No. QG.21.003.
Guideline(s):	Yes (SANTE 11956/2016 rev.9, SANTE 2020/1238 rev.1, SANCO 7029/VI/95, OECD 509)
Deviations:	No (minor deviations without impact on the study)
GLP:	Yes
Acceptability:	Yes

Materials and methods

The objective of the study was to determine the residue level of prothioconazole-desthio and 5 hydroxy prothioconazole-desthio metabolites in honey.
Four trials were conducted on protected phacelia during 2021 in Northern Europe (2 NEU) and Southern Europe (2 SEU). Test sites were in Germany, United Kingdom, South of France and Spain.
Protected (tunnels) phacelia was treated with two foliar applications with prothioconazole 250 g/L (EC formulation) (code FF-065) at a dose rate of 200 g prothioconazole/ha (equivalent to 0.8 L product/ha) and nominal 300 L/ha water spray volume. The applications targeted a 10-14 days retreatment interval, both applications were performed during the flowering period (BBCH 60-69), representing the worst-case scenario.

Results and discussions

Specimens were analysed for residues of prothioconazole-desthio and 5 hydroxy prothioconazole-desthio metabolites by following the validated analytical procedure developed at Battelle UK Ltd. described in studies no. QG/21/009 and QG.20.011 (see studies summarised in dRR Part B5).
Residues of prothioconazole-desthio are extracted from honey dissolving the samples in water, followed by extracting the analyte with acetonitrile using QuEChERS. A portion of the final extract was cleaned-up with SPE and diluted with water 1:2.5 v/v for final quantification.
Residues of the 5 hydroxy prothioconazole-desthio metabolites are extracted from honey dissolving the samples in water, followed with extraction with acetonitrile using QuEChERS. The samples were diluted with water, evaporated to the aqueous remainder through rotary evaporation followed by a hydrolysis step consisting in an overnight incubation at 40°C under acidic conditions. A portion of the final extract was taken through liquid-liquid extraction, evaporated to dryness using nitrogen flow and reconstituted in acetonitrile for final quantification.

Quantification of all analytes was performed by LC-MS/MS detection. All samples were extracted within the known extract stability periods.
The limit of quantification (LOQ) for the analysis of all analytes in honey was 0.005 mg.kg and the limit of detection (LOD) was 0.0015 mg.kg. No residues above the limit of detection were found in any of the untreated specimens.
Overall mean recovery efficiencies for prothioconazole-desthio and five prothioconazole-hydroxy-desthio metabolites in honey within this study were within the required range of 70 – 120%. The relative standard deviation was less than 20% at all fortification levels, thus demonstrating sufficient accuracy and precision of the method in accordance with SANTE/2020/12830, rev.1. Calibration curves were established with satisfactory linearity (r > 0.995).
Residues in treated honey samples were < 0.005 mg.kg (<LOQ). Detailed results are described in Table A 2.2-15.

Conclusion
Residues levels of prothioconazole-desthio and 5 hydroxy prothioconazole-desthio metabolites will not occur in honey, therefore an MRL exceedance above the current value for honey of 0.05 mg.kg (at LOQ) is not expected.

Table A 2.2-15: Summary of study no. QG/21/003 - 4 trials (2 NEU and 2 SEU)

Reference:	KCA 6.10/02 (CP 7.3.7)		
Report	Magnitude of Residues of Prothioconazole-desthio and Hydroxy prothioconazole-desthio Metabolites in Honey Following Two Tunnel Applications of a Prothioconazole 250 g.L EC Formulation (FF-065) to Phacelia in Northern and Southern Europe, 2021. Andrews, G. and Coleman, H., 2023, report No. QG.21.003.		
GLP:	Yes	Sample storage conditions:	Up to 391 days; -18°C
Crop:	Phacelia (Honey*)	Analytical method:	QG/20/011 and QG/21/009, validated
Succeeding crop:	-	Limit of Quantification (mg/kg):	0.005 mg/kg
Indoor/Outdoor:	Protected – DE, UK, FR and ES	Limit of Detection (mg/kg):	0.0015 mg/kg
Formulation:	FF-065	Residues calculated as:	Prothioconazole-desthio and sum of isomers
Content of active substance (g.kg or g.L):	250 g/L		

Location including Postal Code	Commodity /Variety	Date of 1. Sowing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment	Growth stage at Application	Portion analysed	Residues (mg/kg)						PHI Days	Details on trial
			kg a.s./ha	water (L/ha)	kg a.s./hL				Prothioconazole -desthio	α-OH	3-OH	4-OH	5-OH	6-OH		
Villemur sur tam, 31340, France	Phacelia (PHCTA) *Boratus*	1. 22.07.2021 2. 24.09 - 29.10.2021 3.20.10.2021	--	--	--	Untreated	--	Honey	<0.0015	<0.0015	<0.0015	<0.0015	<0.0015	<0.0015	8	Prothioconazole-desthio: study No. QG.20.011 LOQ = 0.005 mg.kg LOD = 0.0015 mg.kg TDMs: study No. QG.21.009 LOQ = 0.005 mg.kg LOD = 0.0015 mg.kg
			0.199 0.201	296 296	0.0674 0.0674	29.09.2021 12.10.2021	61 65	Honey	<0.005	<0.005	<0.005	<0.005	<0.005	<0.005	8	
Los Palacios y Villafranca 41720, Spain	Phacelia (PHCTA)	1. 24.12.2020 2. 10 - 27.05.2021 3.27.05.2021	--	--	--	Untreated	--	Honey	<0.0015	<0.0015	<0.0015	<0.0015	<0.0015	<0.0015	6	
			0.202 0.197	300 293	0.0673 0.0673	11.05.2021 21.05.2021	61 67	Honey	~~<0.005~~ 0.0123	<0.005	<0.005	<0.005	<0.005	<0.005	6	
Blaufelden, 74572 Germany	Phacelia (PHCTA) *Stala*	1. 19.06.2021 2. 20.09 - 15.10.2021 3.13.10.2021	--	--	--	Untreated	--	Honey	<0.0015	<0.0015	<0.0015	<0.0015	<0.0015	<0.0015	12	
			0.197 0.203	292 302	0.0675 0.0672	21.09.2021 01.10.2021	61 65	Honey	<0.005	<0.005	<0.005	<0.005	<0.005	<0.005	12	
Bucknell, OX27 7LT United Kingdom	Phacelia (PHCTA) Factotum	1. 03.06.2021 2. 15.08 - 08.09.2021 3.08.09.2021	--	--	--	Untreated	--	Honey	<0.0015	<0.0015	<0.0015	<0.0015	<0.0015	<0.0015	8	
			0.214 0.216	212 214	0.101 0.101	17.08.2021 31.08.2021	61 65	Honey	<0.005	<0.005	<0.005	<0.005	<0.005	<0.005	8	

The limit of quantification (LOQ) was 0.005 mg.kg for the analyte. Sample residues below the validated LOQ are reported as <0.005 mg.kg and LOD as <0.0015 kg.kg.

A 2.2.6.2 Study 2

Comments of zRMS:	Four semi-field residues trials was conducted to determine the magnitude of residues triazole derivative metabolites in honey following exposure of honeybees to treated *Phacelia tanacetifolia* plants following two foliar applications of the formulated product FGR06, a DC formulation with a nominal concentration of 250 g/L prothioconazole applied at the target dose rate of 200 g a.s./ha. The analytical method was validated on honey in compliance with SANTE/2020/12830, Rev.2 within this study at LOQ. The maximum storage interval from sampling until extraction was 153 days. This is covered by the storage stability test. No residues of 1,2,4-triazole (T), triazole acetic acid (TAA), triazole alanine (TA) and triazole lactic acid (TLA) were measured above the LOQ in the untreated or treated honey specimens. The study is acceptable.

Reference:	KCA 6.10/03 (CP 7.3.7)
Report	Magnitude of the residue of triazole derivative metabolites in phacelia honey in Northern and Southern Europe – 2023. Lebrun, F., 2024, report No. 644-2023.
Guideline(s):	Yes (SANTE 11956/2016 rev.9, SANTE 2020/1238 rev.2, OECD 509, SANCO/3029/99 and SANCO/825/00)
Deviations:	No (minor deviations without impact on the study)
GLP:	Yes
Acceptability:	Yes

Materials and methods

The objective of the study was to determine the residue level of triazole derivate metabolites (TDMs) in honey. Four trials were conducted on protected phacelia during 2023 in Northern Europe (2 NEU) and Southern Europe (2 SEU). Test sites were in Denmark, North of France, Italy and Spain.

Protected (tunnels) phacelia was treated with two foliar applications with prothioconazole 250 g/L (DC formulation) (code FGR-06) at a dose rate of 200 g prothioconazole/ha (equivalent to 0.8 L product/ha) and nominal 200 – 400 L/ha water spray volume. The applications targeted a 7±1 day retreatment interval, both applications were performed during the flowering period (BBCH 60-69), representing the worst-case scenario.

Results and discussions

Specimens were analysed for residues of triazole derivate metabolites (TDMs) - 1,2,4-triazole (T), triazole acetic acid (TAA), triazole alanine (TA) and triazole lactic acid (TLA) were investigated in the honey. The method validated and the analytical procedure was developed within the same study (for details please refer to study summarised in dRR Part B5).

Residues of all TDMs were analysed in honey following the analytical validation procedure in compliance with SANTE/2020/12380 rev.2. Extraction was performed by dissolving the samples in water, followed by extracting the analyte with methanol. Isotopically labelled standards were added and used for quantification. Evaporation to aqueous remainder (methanol free) and final fill up with water. Final samples were stored at 1-10°C for final quantification. Quantification was performed by two independent methods, one specific for triazole alanine (TA) and one for 1,2,4-triazole, triazole acetic acid (TAA) and triazole lactic acid (TLA). Detection was done by LC-DMS/MS-MS. Samples were stored for up to 153 days at < -18°C between sampling and extraction. The limit of quantification (LOQ) was 0.01 mg.kg and the limit of detection (LOD) was 0.003 mg.kg.

Residues of triazole derivate metabolites (TDMs) were extracted from honey dissolving the samples in water, followed with extraction with methanol:water (4:1 v.v). The samples were evaporated to the aqueous remainder through rotary evaporation followed by a hydrolysis step. Final sample extracts were stored at 1°C to 10°C (target) in the dark until analysis. Quantification of all analytes was performed by LC-DMS-MS.MS detection. All samples were extracted within the known extract stability periods.
The limit of quantification (LOQ) for the analysis of all analytes in honey was 0.01 mg.kg. No residues above the limit of detection were found in any of the untreated specimens. Overall mean recovery efficiencies for triazole metabolites derivate (TDMs) in honey within this study were within the required range of 70 – 120%. The relative standard deviation was less than 20% at all fortification levels, thus demonstrating sufficient accuracy and precision of the method in accordance with SANTE/2020/12830, rev.1. Calibration curves were established with satisfactory linearity (r > 0.995).
Residues in treated honey samples were < 0.01 mg.kg (<LOQ). Detailed results are described in Table A 2.2-16. No residues of the triazole derivate metabolites (TDMs) are expected in honey.

Conclusion
Residues levels of triazole derivate metabolites (TDMs), 1,2,4-triazole (T), triazole acetic acid (TAA), triazole alanine (TA) and triazole lactic acid (TLA), will not occur in honey.

Table A 2.2-16: Summary of study no. 644-2023 - 4 trials (2 NEU and 2 SEU)

Reference:	KCA 6.10/03 (CP 7.3.7)		
Report	Magnitude of the residue of triazole derivative metabolites in phacelia honey in Northern and Southern Europe – 2023 Lebrun, F. H., 2024, report No. 644-2023.		
GLP:	Yes	Sample storage conditions:	Up to 153 days; -18°C
Crop:	Phacelia (Honey*)	Analytical method:	Validated in this study
Succeeding crop:	-	Limit of Quantification (mg/kg):	0.01 mg/kg
Indoor/Outdoor:	Protected – DK, FR, IT and ES	Limit of Detection (mg/kg):	0.003 mg/kg
Formulation:	DC (product code: FGR-06)	Residues calculated as:	triazole derivate metabolites (TDMs)
Content of active substance (g.kg or g.L):	250 g.L		

Location including Postal Code	Commodity /Variety	Date of 1. Sowing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment	Growth stage at Application	Portion analysed	Residues (mg/kg)				PHI Days	Details on trial
			kg a.s./ha	water (L/ha)	kg a.s./hL				Prothioconazole-desthio	triazole acetic acid (TAA)	triazole alanine (TA)	triazole lactic acid (TLA)		
Nørre Aby, 5580 Denmark	Phacelia (PHCTA) Happy Bee	1. 17.04.2023 2. 12.06 – 12.07.2021 3. n.a.	--	--	--	Untreated	--	Honey	<0.003	<0.003	<0.003	<0.003	8	-
			0.1940 0.1950	197 198	0.0987 0.0987	19.06.2023 25.06.2023	61-63 65	Honey	<0.003	<0.003	<0.003	<0.003	8	
Allonnes (Pays de Loire) 49650, France	Phacelia (PHCTA)	1. 26.10.2022 2. 27.04 – 25.05.2023 3. n.a.	--	--	--	Untreated	--	Honey	<0.003	<0.003	<0.003	<0.003	6	
			0.1997 0.1989	304 302	0.0658 0.0658	03.05.2023 10.05.2023	62 64	Honey	<0.003	<0.003	<0.003	<0.003	6	
Poggio Renatico (Emilia-Romagna) 44028, Italy	Phacelia (PHCTA) Angelia	1. 08.04.2023 2. 08.06 – 30.06.2023 3. n.a.	--	--	--	Untreated	--	Honey	<0.003	<0.003	<0.003	<0.003	7	
			0.2004 0.2021	305 307	0.0658 0.0658	15.06.2023 22.06.2023	63 65	Honey	<0.003	<0.003	<0.01	<0.003	7	
Picassent (Valencia) 46220, Spain	Phacelia (PHCTA) Stala	1. 10.01.2023 2. Mid Apr – 23.05.2023 3. n.a.	--	--	--	Untreated	--	Honey	<0.003	<0.003	<0.003	<0.003	7	
			0.1995 0.2095	404 425	0.0493 0.0493	11.04.2023 18.04.2023	62 65	Honey	<0.003	<0.003	<0.003	<0.003	7	

The limit of quantification (LOQ) was 0.01 mg.kg for all analytes. Sample residues below the validated LOQ are reported as <0.01 and below LOD as <0.003 mg.kg.

Appendix 3 Pesticide Residue Intake Model (PRIMo)

A 3.1 TMDI calculations

A 3.1.1 Boscalid

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Boscalid

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

Toxicological reference values

ADI (mg/kg bw/day):	0.04	ARfD (mg/kg bw):	not necessary
Source of ADI:	08/44/EC	Source of ARfD:	08/44/EC
Year of evaluation:		Year of evaluation:	

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)
70%	NL toddler	27.87	11%	Apples	10%	Spinaches	5%	Table grapes	0.0%	
50%	DE child	19.84	13%	Apples	5%	Table grapes	3%	Spinaches	0.0%	
37%	NL child	14.76	6%	Apples	4%	Table grapes	4%	Spinaches	0.0%	
36%	GEMS/Food G08	14.42	4%	Wine grapes	3%	Potatoes	3%	Onions		
35%	GEMS/Food G06	13.85	4%	Onions	4%	Table grapes	4%	Tomatoes		
34%	GEMS/Food G10	13.68	5%	Lettuces	3%	Onions	2%	Potatoes		
34%	GEMS/Food G07	13.61	5%	Wine grapes	3%	Lettuces	3%	Potatoes		
34%	IE adult	13.59	4%	Wine grapes	3%	Sweet potatoes	2%	Potatoes	0.0%	
33%	GEMS/Food G11	13.07	4%	Wine grapes	3%	Potatoes	2%	Barley		
33%	GEMS/Food G15	13.05	4%	Wine grapes	3%	Onions	3%	Potatoes		
30%	SE general	11.86	6%	Lettuces	3%	Potatoes	2%	Onions	0.0%	
29%	RO general	11.63	6%	Wine grapes	4%	Onions	4%	Head cabbages	0.0%	
27%	PT general	10.74	9%	Wine grapes	4%	Potatoes	2%	Onions		
24%	FR child 3 15 yr	9.75	2%	Wheat	2%	Apples	2%	Other lettuce and other salad plants	0.0%	
23%	DK child	9.30	3%	Cucumbers	2%	Apples	2%	Rye	0.0%	
23%	NL general	9.24	2%	Spinaches	2%	Wine grapes	2%	Potatoes	0.0%	
22%	FR toddler 2 3 yr	8.97	3%	Apples	2%	Spinaches	2%	Leeks	0.0%	
22%	IT adult	8.86	5%	Lettuces	2%	Other lettuce and other salad plants	2%	Wheat		
22%	FR adult	8.64	8%	Wine grapes	2%	Other lettuce and other salad plants	0.9%	Wheat	0.0%	
22%	ES adult	8.60	7%	Lettuces	1%	Wine grapes	1%	Barley	0.0%	
21%	DE general	8.55	3%	Wine grapes	3%	Apples	1%	Barley	0.0%	
21%	DE women 14-50 yr	8.55	3%	Wine grapes	3%	Apples	2%	Lettuces	0.0%	
21%	IT toddler	8.44	4%	Lettuces	3%	Wheat	2%	Other lettuce and other salad plants		
21%	FI 3 yr	8.22	4%	Potatoes	2%	Onions	2%	Cucumbers		
20%	ES child	8.19	6%	Lettuces	2%	Wheat	1%	Potatoes	0.0%	
18%	FR infant	7.07	4%	Spinaches	2%	Apples	2%	Leeks	0.0%	
18%	UK infant	7.03	3%	Potatoes	2%	Milk: Cattle	2%	Apples	0.0%	
17%	UK toddler	6.95	3%	Potatoes	2%	Apples	2%	Wheat	0.0%	
16%	FI 6 yr	6.41	3%	Potatoes	2%	Onions	1%	Strawberries		
15%	UK vegetarian	5.94	3%	Wine grapes	2%	Lettuces	1%	Onions	0.0%	
14%	PL general	5.58	3%	Potatoes	2%	Apples	2%	Onions		
13%	DK adult	5.30	3%	Wine grapes	1%	Lettuces	1%	Apples	0.0%	
13%	UK adult	5.20	4%	Wine grapes	2%	Lettuces	1%	Potatoes	0.0%	
11%	LT adult	4.28	2%	Potatoes	2%	Apples	1%	Head cabbages	0.0%	
11%	FI adult	4.27	2%	Lettuces	1%	Wine grapes	0.9%	Potatoes		
4%	IE child	1.56	0.5%	Wheat	0.5%	Potatoes	0.3%	Apples	0.0%	

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Boscalid is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Boscalid

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	**0,04**	ARfD (mg/kg bw):	**not necessary**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2008**	Year of evaluation:	**2008**

Input values

Details - chronic risk assessment

Supplementary results - chronic risk assessment

Details - acute risk assessment/children

Details - acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : 26

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)
400%	NL toddler	159,85	90%	Spinaches	54%	Apples	31%	Escaroles/broad-leaved endives		
262%	DE child	104,96	62%	Apples	25%	Spinaches	20%	Oranges		
229%	GEMS/Food G11	91,52	34%	Sugar canes	28%	Soyabeans	20%	Potatoes		
227%	GEMS/Food G10	90,63	41%	Lettuces	24%	Soyabeans	23%	Sugar canes		
222%	GEMS/Food G06	88,83	29%	Sugar canes	27%	Tomatoes	14%	Wheat		
219%	NL child	87,62	31%	Spinaches	29%	Apples	17%	Potatoes		
217%	GEMS/Food G08	86,92	28%	Sugar canes	25%	Lettuces	20%	Potatoes		
216%	GEMS/Food G07	86,23	30%	Lettuces	27%	Sugar canes	19%	Potatoes		
199%	IE adult	79,41	18%	Sweet potatoes	16%	Wine grapes	16%	Wine grapes		
189%	GEMS/Food G15	75,57	23%	Sugar canes	18%	Potatoes	14%	Lettuces		
168%	SE general	67,22	50%	Lettuces	21%	Potatoes	8%	Spinaches		
146%	FR child 3 15 yr	58,30	17%	Oranges	14%	Other lettuce and other salad plants	13%	Spinaches		
145%	IT adult	58,02	47%	Lettuces	20%	Other lettuce and other salad plants	12%	Spinaches		
144%	ES adult	57,60	67%	Lettuces	9%	Spinaches	6%	Oranges		
140%	ES child	56,03	52%	Lettuces	11%	Oranges	10%	Spinaches		
134%	NL general	53,43	19%	Spinaches	12%	Escaroles/broad-leaved endives	12%	Potatoes		
132%	RO general	52,70	21%	Wine grapes	19%	Potatoes	18%	Head cabbages		
131%	IT toddler	52,42	36%	Lettuces	14%	Other lettuce and other salad plants	13%	Wheat		
131%	PT general	52,33	31%	Wine grapes	27%	Potatoes	13%	Lettuces		
128%	FR toddler 2 3 yr	51,15	20%	Spinaches	16%	Apples	10%	Beans (with pods)		
124%	DE women 14-50 yr	49,44	14%	Lettuces	13%	Apples	10%	Wine grapes		
122%	FR adult	48,87	29%	Wine grapes	19%	Other lettuce and other salad plants	14%	Tea (dried leaves of Camellia sinensi		
119%	DK child	47,50	18%	Lettuces	16%	Cucumbers	12%	Potatoes		
119%	DE general	47,43	12%	Apples	12%	Lettuces	10%	Wine grapes		
112%	FI 3 yr	44,80	24%	Potatoes	10%	Cucumbers	8%	Spinaches		
104%	UK toddler	41,73	17%	Potatoes	10%	Oranges	9%	Apples		
102%	FR infant	40,72	33%	Spinaches	10%	Potatoes	8%	Apples		
93%	UK infant	37,06	16%	Potatoes	8%	Apples	7%	Carrots		
92%	FI 6 yr	36,76	19%	Potatoes	10%	Lettuces	7%	Cucumbers		
87%	UK vegetarian	34,90	18%	Lettuces	10%	Wine grapes	7%	Potatoes		
74%	UK adult	29,41	15%	Lettuces	14%	Wine grapes	7%	Potatoes		
67%	PL general	26,98	17%	Potatoes	10%	Apples	7%	Tomatoes		
66%	DK adult	26,60	12%	Wine grapes	11%	Lettuces	6%	Potatoes		
63%	FI adult	25,07	18%	Lettuces	6%	Potatoes	4%	Tomatoes		
60%	LT adult	23,88	16%	Potatoes	9%	Apples	8%	Lettuces		
18%	IE child	7,33	3%	Potatoes	2%	Wheat	2%	Apples		

Conclusion:
The estimated TMDI/NEDI/IEDI was in the range of 0 % to 399,6 % of the ADI.
For 26 diet(s) the ADI is exceeded.

A 3.1.2 Prothioconazole

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Prothioconazole-desthio

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	**0.01**	ARfD (mg/kg bw):	**0.01**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2007**	Year of evaluation:	**2007**

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	MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
42%	NL toddler	4.20	8%	Wheat	7%	Maize/corn	6%	Milk: Cattle		12%
36%	GEMS/Food G11	3.62	15%	Soyabeans	7%	Wheat	3%	Barley		2%
35%	GEMS/Food G10	3.50	13%	Soyabeans	8%	Wheat	2%	Barley		3%
34%	GEMS/Food G15	3.42	9%	Wheat	7%	Soyabeans	3%	Barley		3%
34%	GEMS/Food G07	3.38	8%	Wheat	7%	Soyabeans	2%	Barley		5%
34%	GEMS/Food G06	3.36	14%	Wheat	5%	Soyabeans	2%	Peas		1%
33%	GEMS/Food G08	3.35	8%	Wheat	8%	Soyabeans	4%	Barley		3%
25%	IE adult	2.46	6%	Peas	5%	Wheat	3%	Lentils		3%
25%	NL child	2.45	8%	Wheat	3%	Sugar beet roots	2%	Milk: Cattle		6%
24%	FR child 3 15 yr	2.45	9%	Wheat	4%	Lentils	2%	Milk: Cattle		4%
23%	DK child	2.34	9%	Wheat	6%	Rye	4%	Carrots		3%
22%	ES child	2.21	9%	Wheat	5%	Lentils	2%	Peas		3%
22%	RO general	2.20	10%	Wheat	3%	Sunflower seeds	3%	Head cabbages		1%
21%	UK infant	2.08	5%	Wheat	4%	Milk: Cattle	4%	Carrots		7%
20%	DE child	2.03	8%	Wheat	3%	Carrots	2%	Milk: Cattle		2%
20%	FR toddler 2 3 yr	1.96	6%	Wheat	3%	Milk: Cattle	2%	Lentils		4%
17%	UK toddler	1.75	8%	Wheat	2%	Milk: Cattle	1%	Carrots		3%
16%	IT toddler	1.62	13%	Wheat	0.7%	Lentils	0.5%	Carrots		
15%	PT general	1.55	8%	Wheat	2%	Carrots	1%	Soyabeans		
15%	SE general	1.54	6%	Wheat	2%	Carrots	1%	Milk: Cattle		2%
14%	NL general	1.37	4%	Wheat	1%	Barley	0.9%	Sugar beet roots		2%
14%	ES adult	1.36	5%	Wheat	2%	Lentils	2%	Barley		1%
13%	DE general	1.34	4%	Wheat	2%	Barley	1%	Sugar beet roots		2%
13%	DE women 14-50 yr	1.26	4%	Wheat	1%	Sugar beet roots	1%	Milk: Cattle		2%
11%	FR adult	1.12	4%	Wheat	1%	Lentils	0.5%	Carrots		2%
11%	IT adult	1.05	8%	Wheat	0.4%	Carrots	0.4%	Lentils		
10%	FI 3 yr	1.04	2%	Wheat	2%	Carrots	0.9%	Potatoes		0.2%
10%	FR infant	1.02	3%	Carrots	2%	Milk: Cattle	2%	Wheat		2%
9%	FI 6 yr	0.89	2%	Wheat	2%	Carrots	1%	Peas		0.2%
9%	UK vegetarian	0.88	4%	Wheat	0.8%	Lentils	0.6%	Carrots		0.4%
7%	FI adult	0.74	3%	Coffee beans	0.9%	Carrots	0.7%	Peas		0.0%
7%	LT adult	0.72	2%	Wheat	1%	Rye	0.7%	Head cabbages		1.0%
7%	UK adult	0.70	3%	Wheat	0.5%	Carrots	0.3%	Milk: Cattle		0.8%
7%	DK adult	0.67	2%	Wheat	1%	Carrots	0.5%	Milk: Cattle		1%
4%	PL general	0.44	0.8%	Carrots	0.7%	Potatoes	0.7%	Head cabbages		
4%	IE child	0.39	2%	Wheat	0.5%	Carrots	0.4%	Milk: Cattle		0.4%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Prothioconazole-desthio is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

A 3.2 IEDI calculations

~~IEDI was not calculated for both active substances since the TMDI does not exceed 100% of the ADI.~~

Boscalid

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Boscalid

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	0,04	ARfD (mg/kg bw):	not necessary
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2008	Year of evaluation:	2008

Input values

Details - chronic risk assessment | Supplementary results - chronic risk assessment

Details - acute risk assessment/children | Details - acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	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)
72%	NL toddler	28,98	11%	Apples	10%	Spinaches	5%	Table grapes		
67%	GEMS/Food G11	26,70	34%	Sugar canes	4%	Tea (dried leaves of Camellia sinensis)	4%	Wine grapes		
65%	IE adult	25,97	18%	Sweet potatoes	13%	Tea (dried leaves of Camellia sinensis)	4%	Wine grapes		
64%	GEMS/Food G06	25,63	29%	Sugar canes	5%	Tea (dried leaves of Camellia sinensis)	4%	Table grapes		
62%	GEMS/Food G07	24,72	27%	Sugar canes	5%	Wine grapes	5%	Tea (dried leaves of Camellia sinens		
60%	GEMS/Food G08	23,91	28%	Sugar canes	4%	Wine grapes	3%	Tea (dried leaves of Camellia sinens		
53%	GEMS/Food G10	21,39	23%	Sugar canes	5%	Lettuces	3%	Tea (dried leaves of Camellia sinens		
51%	GEMS/Food G15	20,39	23%	Sugar canes	4%	Wine grapes	2%	Head cabbages		
46%	DE child	18,38	13%	Apples	5%	Table grapes	3%	Spinaches		
39%	NL child	15,45	6%	Apples	4%	Table grapes	4%	Spinaches		
35%	FR adult	13,82	14%	Tea (dried leaves of Camellia sinensis)	8%	Wine grapes	2%	Other lettuce and other salad plants		
25%	FR child 3 15 yr	10,10	2%	Tea (dried leaves of Camellia sinensis)	2%	Wheat	2%	Apples		
25%	DE women 14-50 yr	9,99	3%	Tea (dried leaves of Camellia sinensis)	3%	Wine grapes	3%	Apples		
25%	DE general	9,83	3%	Tea (dried leaves of Camellia sinensis)	3%	Wine grapes	3%	Apples		
24%	NL general	9,68	4%	Tea (dried leaves of Camellia sinensis)	2%	Spinaches	2%	Wine grapes		
23%	RO general	9,26	6%	Wine grapes	4%	Head cabbages	2%	Wheat		
23%	SE general	9,23	6%	Lettuces	2%	Head cabbages	1%	Wheat		
22%	FR toddler 2 3 yr	8,78	3%	Apples	3%	Beans (with pods)	2%	Spinaches		
21%	IT adult	8,57	5%	Lettuces	2%	Other lettuce and other salad plants	2%	Wheat		
21%	PT general	8,52	9%	Wine grapes	2%	Wheat	1%	Lettuces		
21%	UK infant	8,20	6%	Tea (dried leaves of Camellia sinensis)	2%	Milk: Cattle	2%	Apples		
20%	ES adult	8,09	7%	Lettuces	1%	Wine grapes	1%	Barley		
20%	IT toddler	8,08	4%	Lettuces	3%	Wheat	2%	Other lettuce and other salad plants		
20%	DK child	7,98	3%	Cucumbers	2%	Apples	2%	Rye		
19%	ES child	7,49	6%	Lettuces	2%	Wheat	1%	Apples		
18%	UK toddler	7,14	3%	Tea (dried leaves of Camellia sinensis)	2%	Apples	2%	Wheat		
18%	UK vegetarian	7,09	5%	Tea (dried leaves of Camellia sinensis)	3%	Wine grapes	2%	Lettuces		
17%	FI 3 yr	6,85	2%	Cucumbers	2%	Strawberries	2%	Oat		
17%	UK adult	6,72	5%	Tea (dried leaves of Camellia sinensis)	4%	Wine grapes	2%	Lettuces		
17%	FR infant	6,67	4%	Spinaches	2%	Apples	2%	Beans (with pods)		
13%	FI 6 yr	5,27	1%	Strawberries	1%	Cucumbers	1%	Lettuces		
12%	DK adult	4,97	3%	Wine grapes	1%	Lettuces	1%	Apples		
10%	FI adult	4,06	2%	Lettuces	1%	Wine grapes	0,7%	Coffee beans		
10%	PL general	3,87	2%	Apples	1%	Table grapes	1%	Head cabbages		
9%	LT adult	3,60	2%	Apples	1%	Head cabbages	0,9%	Lettuces		
3%	IE child	1,34	0,5%	Wheat	0,3%	Apples	0,3%	Currants (red, black and white)		

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

1,2,4-triazole

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

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:	Source of ARfD:
Year of evaluation:	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)
88%	NL toddler	20.23	78%	Milk: Cattle	2%	Maize/corn	1%	Bovine: Muscle/meat		80%
55%	UK infant	12.62	50%	Milk: Cattle	1%	Bovine: Muscle/meat	0.6%	Wheat		52%
44%	FR toddler 2 3 yr	10.08	38%	Milk: Cattle	1%	Bovine: Muscle/meat	0.7%	Wheat		41%
39%	NL child	9.02	32%	Milk: Cattle	2%	Sugar beet roots	1%	Bovine: Muscle/meat		34%
37%	FR child 3 15 yr	8.47	30%	Milk: Cattle	2%	Bovine: Muscle/meat	1.0%	Wheat		33%
32%	UK toddler	7.32	27%	Milk: Cattle	2%	Bovine: Muscle/meat	0.9%	Wheat		29%
31%	DE child	7.05	26%	Milk: Cattle	0.9%	Wheat	0.9%	Oranges		27%
24%	FR infant	5.46	22%	Milk: Cattle	0.4%	Bovine: Muscle/meat	0.3%	Sugar beet roots		23%
24%	SE general	5.44	16%	Milk: Cattle	5%	Bovine: Muscle/meat	0.7%	Wheat		21%
23%	DK child	5.25	16%	Milk: Cattle	2%	Bovine: Muscle/meat	1%	Swine: Muscle/meat		20%
22%	ES child	5.03	16%	Milk: Cattle	2%	Bovine: Muscle/meat	1.0%	Wheat		19%
20%	DE women 14-50 yr	4.65	16%	Milk: Cattle	1.0%	Sugar beet roots	0.5%	Swine: Muscle/meat		17%
20%	DE general	4.63	16%	Milk: Cattle	0.9%	Sugar beet roots	0.6%	Swine: Muscle/meat		18%
19%	RO general	4.43	15%	Milk: Cattle	1%	Wheat	0.7%	Swine: Muscle/meat		16%
16%	GEMS/Food G11	3.62	10%	Milk: Cattle	0.8%	Bovine: Muscle/meat	0.8%	Soyabeans		12%
15%	NL general	3.44	11%	Milk: Cattle	0.9%	Bovine: Muscle/meat	0.6%	Sugar beet roots		13%
15%	GEMS/Food G15	3.40	9%	Milk: Cattle	1.0%	Wheat	0.8%	Swine: Muscle/meat		11%
14%	GEMS/Food G07	3.33	8%	Milk: Cattle	1%	Bovine: Muscle/meat	0.9%	Wheat		11%
13%	GEMS/Food G10	2.99	7%	Milk: Cattle	1%	Bovine: Muscle/meat	0.9%	Wheat		9%
13%	GEMS/Food G08	2.97	7%	Milk: Cattle	1%	Swine: Muscle/meat	0.9%	Wheat		9%
10%	ES adult	2.24	6%	Milk: Cattle	0.9%	Bovine: Muscle/meat	0.5%	Wheat		8%
10%	IE adult	2.24	6%	Milk: Cattle	0.5%	Wheat	0.5%	Bovine: Muscle/meat		7%
9%	DK adult	2.12	7%	Milk: Cattle	0.6%	Bovine: Muscle/meat	0.5%	Swine: Muscle/meat		8%
9%	GEMS/Food G06	2.10	3%	Milk: Cattle	2%	Wheat	0.4%	Sugar canes		5%
9%	FR adult	2.01	6%	Milk: Cattle	0.7%	Bovine: Muscle/meat	0.5%	Wheat		7%
7%	LT adult	1.66	5%	Milk: Cattle	0.5%	Swine: Muscle/meat	0.3%	Bovine: Muscle/meat		6%
6%	UK adult	1.37	4%	Milk: Cattle	0.8%	Bovine: Muscle/meat	0.4%	Wheat		5%
6%	UK vegetarian	1.31	4%	Milk: Cattle	0.4%	Wheat	0.2%	Oranges		4%
5%	IE child	1.25	5%	Milk: Cattle	0.3%	Wheat	0.1%	Swine: Muscle/meat		5%
2%	IT toddler	0.56	1%	Wheat	0.3%	Other cereals	0.1%	Bananas		
2%	PT general	0.52	0.9%	Wheat	0.2%	Potatoes	0.2%	Rice		
2%	FI 3 yr	0.38	0.3%	Bananas	0.3%	Wheat	0.2%	Potatoes		0.0%
2%	IT adult	0.37	0.9%	Wheat	0.2%	Other cereals	0.1%	Oranges		
1%	FI 6 yr	0.29	0.2%	Wheat	0.2%	Potatoes	0.2%	Bananas		0.0%
0.7%	FI adult	0.17	0.2%	Rye	0.1%	Oranges	0.1%	Wheat		0.0%
0.5%	PL general	0.13	0.1%	Potatoes	0.1%	Apples	0.1%	Head cabbages		

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of T is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

TAA

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

TA

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	**0.3**	ARfD (mg/kg bw):	**0.3**
Source of ADI:		Source of ARfD:	
Year of evaluation:		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)
6%	NL toddler	18.22	1%	Maize/corn	0.8%	Wheat	0.8%	Milk: Cattle		1%
4%	GEMS/Food G06	12.64	1%	Wheat	0.4%	Soyabeans	0.3%	Rice		0.2%
4%	GEMS/Food G10	12.27	1%	Soyabeans	0.8%	Wheat	0.3%	Rice		0.5%
4%	GEMS/Food G08	11.31	0.8%	Wheat	0.7%	Soyabeans	0.3%	Olives for oil production		0.5%
4%	GEMS/Food G11	11.31	1%	Soyabeans	0.7%	Wheat	0.2%	Potatoes		0.4%
4%	GEMS/Food G07	11.00	0.9%	Wheat	0.6%	Soyabeans	0.2%	Potatoes		0.7%
4%	GEMS/Food G15	10.59	0.9%	Wheat	0.6%	Soyabeans	0.2%	Potatoes		0.4%
3%	NL child	10.13	0.9%	Wheat	0.3%	Milk: Cattle	0.3%	Oil palm fruits		0.8%
3%	DK child	10.10	1%	Rye	0.9%	Wheat	0.2%	Bovine: Muscle/meat		0.6%
3%	FR child 3 15 yr	9.03	1.0%	Wheat	0.4%	Oranges	0.3%	Milk: Cattle		0.7%
3%	DE child	8.96	0.9%	Wheat	0.4%	Oranges	0.3%	Milk: Cattle		0.4%
3%	RO general	8.01	1%	Wheat	0.2%	Sunflower seeds	0.2%	Potatoes		0.3%
3%	ES child	7.74	0.9%	Wheat	0.3%	Olives for oil production	0.2%	Oranges		0.6%
2%	SE general	7.38	0.7%	Bovine: Muscle/meat	0.7%	Wheat	0.3%	Potatoes		0.9%
2%	UK infant	7.13	0.5%	Wheat	0.5%	Milk: Cattle	0.2%	Maize/corn		0.8%
2%	FR toddler 2 3 yr	7.06	0.6%	Wheat	0.4%	Milk: Cattle	0.2%	Bovine: Muscle/meat		0.7%
2%	IE adult	6.81	0.5%	Wheat	0.2%	Sweet potatoes	0.1%	Potatoes		0.3%
2%	UK toddler	6.75	0.8%	Wheat	0.3%	Milk: Cattle	0.2%	Potatoes		0.5%
2%	IT toddler	6.53	1%	Wheat	0.3%	Other cereals	0.1%	Tomatoes		
2%	PT general	6.37	0.8%	Wheat	0.3%	Potatoes	0.2%	Rice		
2%	NL general	5.49	0.4%	Wheat	0.2%	Oil palm fruits	0.1%	Potatoes		0.4%
2%	DE women 14-50 yr	5.01	0.4%	Wheat	0.2%	Oranges	0.2%	Milk: Cattle		0.3%
2%	DE general	4.99	0.4%	Wheat	0.2%	Oranges	0.2%	Milk: Cattle		0.3%
2%	ES adult	4.71	0.5%	Wheat	0.1%	Olives for oil production	0.1%	Oranges		0.3%
1%	IT adult	4.30	0.9%	Wheat	0.1%	Other cereals	0.1%	Tomatoes		
1%	FI 3 yr	4.12	0.3%	Potatoes	0.2%	Wheat	0.1%	Rye		0.0%
1%	FR adult	3.67	0.5%	Wheat	0.1%	Bovine: Muscle/meat	0.1%	Oranges		0.2%
1%	LT adult	3.38	0.2%	Rye	0.2%	Wheat	0.2%	Potatoes		0.2%
1%	FI 6 yr	3.26	0.2%	Potatoes	0.2%	Wheat	0.1%	Rye		0.0%
1.0%	UK vegetarian	2.97	0.4%	Wheat	0.1%	Oranges	0.1%	Potatoes		0.1%
1.0%	FR infant	2.86	0.2%	Milk: Cattle	0.2%	Wheat	0.1%	Potatoes		0.3%
0.9%	UK adult	2.77	0.3%	Wheat	0.1%	Bovine: Muscle/meat	0.1%	Potatoes		0.2%
0.9%	DK adult	2.74	0.2%	Wheat	0.1%	Rye	0.1%	Bovine: Muscle/meat		0.3%
0.6%	FI adult	1.80	0.1%	Rye	0.1%	Potatoes	0.1%	Wheat		0.0%
0.5%	IE child	1.45	0.2%	Wheat	0.1%	Rice	0.0%	Milk: Cattle		0.1%
0.5%	PL general	1.39	0.2%	Potatoes	0.1%	Tomatoes	0.0%	Apples		

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of TA is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

TAA

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

TAA

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	1	ARfD (mg/kg bw):	1
Source of ADI:		Source of ARfD:	
Year of evaluation:		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)
1%	NL toddler	14.21	0.6%	Maize/corn	0.3%	Wheat	0.2%	Milk: Cattle		0.3%
0.9%	DK child	9.35	0.4%	Rye	0.3%	Wheat	0.1%	Milk: Cattle		0.1%
0.9%	GEMS/Food G06	9.03	0.6%	Wheat	0.1%	Rice	0.1%	Maize/corn		0.0%
0.7%	IT toddler	6.81	0.5%	Wheat	0.1%	Other cereals	0.0%	Rice		
0.7%	GEMS/Food G10	6.52	0.3%	Wheat	0.1%	Rice	0.1%	Maize/corn		0.0%
0.6%	DE child	6.35	0.3%	Wheat	0.1%	Milk: Cattle	0.1%	Rye		0.1%
0.6%	GEMS/Food G15	6.32	0.4%	Wheat	0.1%	Barley	0.1%	Maize/corn		0.0%
0.6%	GEMS/Food G08	6.26	0.3%	Wheat	0.1%	Barley	0.0%	Rye		0.0%
0.6%	NL child	6.21	0.3%	Wheat	0.1%	Milk: Cattle	0.0%	Sugar beet roots		0.1%
0.6%	FR child 3 15 yr	6.21	0.4%	Wheat	0.1%	Milk: Cattle	0.0%	Rice		0.1%
0.6%	RO general	5.99	0.4%	Wheat	0.1%	Maize/corn	0.0%	Milk: Cattle		0.1%
0.6%	GEMS/Food G07	5.75	0.3%	Wheat	0.0%	Barley	0.0%	Rice		0.0%
0.6%	UK infant	5.64	0.2%	Wheat	0.2%	Milk: Cattle	0.1%	Maize/corn		0.2%
0.5%	GEMS/Food G11	5.29	0.3%	Wheat	0.1%	Barley	0.0%	Soyabeans		0.0%
0.5%	ES child	5.24	0.4%	Wheat	0.0%	Milk: Cattle	0.0%	Rice		0.1%
0.5%	UK toddler	5.09	0.3%	Wheat	0.1%	Milk: Cattle	0.0%	Rice		0.1%
0.5%	FR toddler 2 3 yr	4.91	0.2%	Wheat	0.1%	Milk: Cattle	0.0%	Rice		0.1%
0.5%	PT general	4.69	0.3%	Wheat	0.1%	Rice	0.0%	Maize/corn		
0.4%	IT adult	4.15	0.3%	Wheat	0.1%	Other cereals	0.0%	Rice		
0.4%	SE general	4.12	0.3%	Wheat	0.0%	Milk: Cattle	0.0%	Rice		0.1%
0.4%	DE general	3.61	0.1%	Wheat	0.0%	Milk: Cattle	0.0%	Rye		0.1%
0.4%	DE women 14-50 yr	3.53	0.2%	Wheat	0.0%	Milk: Cattle	0.0%	Rye		0.1%
0.3%	IE adult	3.43	0.2%	Wheat	0.0%	Buckwheat and other pseudo-cereals	0.0%	Rice		0.0%
0.3%	ES adult	3.10	0.2%	Wheat	0.0%	Barley	0.0%	Milk: Cattle		0.0%
0.3%	NL general	3.02	0.2%	Wheat	0.0%	Milk: Cattle	0.0%	Barley		0.0%
0.3%	FI 3 yr	2.73	0.1%	Wheat	0.1%	Rye	0.0%	Oat		0.0%
0.3%	FR adult	2.55	0.2%	Wheat	0.0%	Milk: Cattle	0.0%	Rice		0.0%
0.3%	LT adult	2.51	0.1%	Rye	0.1%	Wheat	0.0%	Rice		0.0%
0.2%	UK vegetarian	2.38	0.2%	Wheat	0.0%	Rice	0.0%	Milk: Cattle		0.0%
0.2%	FI 6 yr	2.13	0.1%	Wheat	0.0%	Rye	0.0%	Rice		0.0%
0.2%	UK adult	2.04	0.1%	Wheat	0.0%	Rice	0.0%	Milk: Cattle		0.0%
0.2%	DK adult	1.85	0.1%	Wheat	0.0%	Rye	0.0%	Milk: Cattle		0.0%
0.2%	FR infant	1.66	0.1%	Milk: Cattle	0.1%	Wheat	0.0%	Sugar beet roots		0.1%
0.1%	IE child	1.38	0.1%	Wheat	0.0%	Rice	0.0%	Milk: Cattle		0.0%
0.1%	FI adult	1.19	0.1%	Rye	0.0%	Wheat	0.0%	Oat		0.0%
0.0%	PL general	0.18	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.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

TLA

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

TLA

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	**0.3**	ARfD (mg/kg bw):	**0.3**
Source of ADI:		Source of ARfD:	
Year of evaluation:		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)
1%	NL toddler	4.01	0.8%	Milk: Cattle	0.1%	Apples	0.1%	Maize/corn		0.9%
0.7%	UK infant	2.05	0.5%	Milk: Cattle	0.0%	Potatoes	0.0%	Wheat		0.6%
0.7%	NL child	2.02	0.3%	Milk: Cattle	0.1%	Apples	0.0%	Wheat		0.4%
0.7%	DE child	1.96	0.3%	Milk: Cattle	0.1%	Apples	0.1%	Oranges		0.3%
0.6%	FR toddler 2 3 yr	1.82	0.4%	Milk: Cattle	0.0%	Apples	0.0%	Wheat		0.4%
0.6%	FR child 3 15 yr	1.73	0.3%	Milk: Cattle	0.0%	Oranges	0.0%	Wheat		0.4%
0.5%	UK toddler	1.39	0.3%	Milk: Cattle	0.0%	Wheat	0.0%	Oranges		0.3%
0.4%	GEMS/Food G11	1.27	0.1%	Milk: Cattle	0.1%	Soyabeans	0.0%	Potatoes		0.2%
0.4%	DK child	1.25	0.2%	Milk: Cattle	0.0%	Rye	0.0%	Wheat		0.2%
0.4%	GEMS/Food G07	1.20	0.1%	Milk: Cattle	0.0%	Soyabeans	0.0%	Wheat		0.2%
0.4%	GEMS/Food G10	1.19	0.1%	Milk: Cattle	0.1%	Soyabeans	0.0%	Wheat		0.1%
0.4%	ES child	1.18	0.2%	Milk: Cattle	0.0%	Wheat	0.0%	Oranges		0.2%
0.4%	GEMS/Food G08	1.17	0.1%	Milk: Cattle	0.0%	Soyabeans	0.0%	Wheat		0.1%
0.4%	GEMS/Food G15	1.16	0.1%	Milk: Cattle	0.0%	Soyabeans	0.0%	Wheat		0.2%
0.4%	RO general	1.15	0.2%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes		0.2%
0.4%	SE general	1.15	0.2%	Milk: Cattle	0.1%	Bovine: Muscle/meat	0.0%	Potatoes		0.2%
0.4%	GEMS/Food G06	1.06	0.1%	Wheat	0.0%	Tomatoes	0.0%	Milk: Cattle		0.1%
0.4%	DE women 14-50 yr	1.05	0.2%	Milk: Cattle	0.0%	Apples	0.0%	Oranges		0.2%
0.3%	DE general	1.03	0.2%	Milk: Cattle	0.0%	Apples	0.0%	Oranges		0.2%
0.3%	FR infant	0.97	0.2%	Milk: Cattle	0.0%	Apples	0.0%	Potatoes		0.2%
0.3%	NL general	0.89	0.1%	Milk: Cattle	0.0%	Potatoes	0.0%	Apples		0.2%
0.3%	IE adult	0.85	0.1%	Milk: Cattle	0.0%	Sweet potatoes	0.0%	Wheat		0.1%
0.2%	ES adult	0.67	0.1%	Milk: Cattle	0.0%	Oranges	0.0%	Wheat		0.1%
0.2%	FR adult	0.61	0.1%	Milk: Cattle	0.0%	Wine grapes	0.0%	Wheat		0.1%
0.2%	PT general	0.56	0.0%	Potatoes	0.0%	Wine grapes	0.0%	Wheat		
0.2%	DK adult	0.54	0.1%	Milk: Cattle	0.0%	Wine grapes	0.0%	Swine: Muscle/meat		0.1%
0.2%	LT adult	0.49	0.1%	Milk: Cattle	0.0%	Potatoes	0.0%	Apples		0.1%
0.1%	IT toddler	0.43	0.0%	Wheat	0.0%	Tomatoes	0.0%	Other cereals		
0.1%	UK vegetarian	0.41	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Oranges		0.0%
0.1%	UK adult	0.40	0.0%	Milk: Cattle	0.0%	Wine grapes	0.0%	Wheat		0.1%
0.1%	FI 3 yr	0.38	0.0%	Potatoes	0.0%	Cucumbers	0.0%	Apples		0.0%
0.1%	IT adult	0.35	0.0%	Wheat	0.0%	Tomatoes	0.0%	Lettuces		
0.1%	FI 6 yr	0.30	0.0%	Potatoes	0.0%	Wheat	0.0%	Cucumbers		0.0%
0.1%	IE child	0.25	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes		0.1%
0.1%	PL general	0.23	0.0%	Potatoes	0.0%	Apples	0.0%	Tomatoes		
0.1%	FI adult	0.19	0.0%	Potatoes	0.0%	Apples	0.0%	Tomatoes		0.0%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of TLA is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

A 3.3 IESTI calculations - Raw commodities

A 3.3.1 Boscalid

IESTI was not calculated for boscalid since no ARfD has been set

A 3.3.2 Prothioconazole

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

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)
67%	Lentils	1/1	6.7
66%	Peas	1/1	6.6
63%	Carrots	0.1/0.1	6.3
57%	Beetroots	0.1/0.1	5.7
52%	Swedes/rutabagas	0.1/0.1	5.2
40%	Bovine: Liver	0.5/0.5	4.0
40%	Head cabbages	0.09/0.09	4.0
36%	Bovine: Edible offals	0.5/0.5	3.6
36%	Parsnips	0.1/0.1	3.6
36%	Turnips	0.1/0.1	3.6
35%	Leeks	0.06/0.06	3.5
31%	Salsifies	0.1/0.1	3.1
31%	Potatoes	0.02/0.02	3.1
29%	Cauliflowers	0.05/0.05	2.9
21%	Broccoli	0.05/0.05	2.1

Expand/collapse list

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

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
62%	Lentils	1/1	6.2
38%	Head cabbages	0.09/0.09	3.8
34%	Swedes/rutabagas	0.1/0.1	3.4
33%	Peas	1/1	3.3
23%	Beetroots	0.1/0.1	2.3
20%	Bovine: Liver	0.5/0.5	2.0
20%	Carrots	0.1/0.1	2.0
17%	Bovine: Edible offals (other	0.5/0.5	1.7
16%	Swine: Other products	0.5/0.5	1.6
14%	Parsnips	0.1/0.1	1.4
14%	Sheep: Liver	0.5/0.5	1.4
13%	Swine: Edible offals (other	0.5/0.5	1.3
12%	Broccoli	0.05/0.05	1.2
12%	Cauliflowers	0.05/0.05	1.2
11%	Turnips	0.1/0.1	1.1

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)
67%	Lentils	1/1	6.7
66%	Peas	1/1	6.6
40%	Bovine: Liver	0.5/0.5	4.0
36%	Bovine: Edible offals	0.5/0.5	3.6
31%	Swedes/rutabagas	0.1/0.1	3.1
27%	Carrots	0.1/0.1	2.7
24%	Beetroots	0.1/0.1	2.4
24%	Head cabbages	0.09/0.09	2.4
19%	Bovine: Kidney	0.5/0.5	1.9
17%	Cauliflowers	0.05/0.05	1.7
17%	Salsifies	0.1/0.1	1.7
15%	Parsnips	0.1/0.1	1.5
15%	Turnips	0.1/0.1	1.5
15%	Leeks	0.06/0.06	1.5
15%	Swine: Edible offals (other	0.5/0.5	1.5

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

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)
62%	Lentils	1/1	6.2
33%	Peas	1/1	3.3
23%	Head cabbages	0.09/0.09	2.3
20%	Swedes/rutabagas	0.1/0.1	2.0
20%	Bovine: Liver	0.5/0.5	2.0
17%	Bovine: Edible offals (other than	0.5/0.5	1.7
16%	Swine: Other products	0.5/0.5	1.6
14%	Sheep: Liver	0.5/0.5	1.4
13%	Swine: Edible offals (other than	0.5/0.5	1.3
12%	Carrots	0.1/0.1	1.2
11%	Soyabeans	0.2/0.2	1.1
11%	Swine: Kidney	0.5/0.5	1.1
11%	Bovine: Kidney	0.5/0.5	1.1
10%	Beetroots	0.1/0.1	1.0
10%	Bovine: Other products	0.5/0.5	1.00

Acute risk assessment /children	Acute risk assessment / adults / general population
Details - acute risk assessment /children	Details - acute risk assessment/adults

The acute risk assessment is based on the ARfD. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the Eur

The calculation is based on the large portion of the most critical consumer group.

Show results of IESTI calculation only for crops with GAPs under assessment

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)
19%	Bovine: Liver	0.5 / 0.23	1.9
11%	Bovine: Edible offals (other	0.5 / 0.15	1.1
6%	Milk: Cattle	0.01 / 0.01	0.62
6%	Bovine: Kidney	0.5 / 0.15	0.56
5%	Swine: Edible offals (other	0.5 / 0.15	0.45
3%	Swine: Liver	0.5 / 0.23	0.28
2%	Swine: Kidney	0.5 / 0.15	0.19
1%	Eggs: Chicken	0.01 / 0.01	0.12
1%	Swine: Muscle/meat	0.01 / 0.01	0.12
1%	Milk: Goat	0.01 / 0.01	0.12
0.8%	Rapeseeds/canola seeds	0.15 / 0.06	0.08
0.8%	Poultry: Liver	0.1 / 0.07	0.08
0.7%	Bovine: Muscle/meat	0.01 / 0.01	0.07
0.7%	Other farmed animals:	0.01 / 0.01	0.07
0.6%	Equine: Muscle/meat	0.01 / 0.01	0.06

Expand/collapse list

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

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
16%	Swine: Other products	0.5 / 0.5	1.6
10%	Bovine: Other products	0.5 / 0.5	1.00
9%	Bovine: Liver	0.5 / 0.23	0.92
6%	Sheep: Liver	0.5 / 0.23	0.64
5%	Bovine: Edible offals (other	0.5 / 0.15	0.50
4%	Swine: Edible offals (other	0.5 / 0.15	0.39
3%	Poultry: Liver	0.1 / 0.07	0.33
3%	Swine: Kidney	0.5 / 0.15	0.33
3%	Swine: Liver	0.5 / 0.23	0.32
3%	Bovine: Kidney	0.5 / 0.15	0.32
2%	Milk: Cattle	0.01 / 0.01	0.19
1%	Sheep: Edible offals (other	0.5 / 0.15	0.10
0.9%	Milk: Goat	0.01 / 0.01	0.09
0.9%	Poultry: Kidney	0.1 / 0.07	0.09
0.8%	Milk: Sheep	0.01 / 0.01	0.08

T

Acute risk assessment /children	Acute risk assessment / adults / general population
Details - acute risk assessment /children	Details - acute risk assessment/adults

The acute risk assessment is based on the ARfD. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the Eu

The calculation is based on the large portion of the most critical consumer group.

Show results of IESTI calculation only for crops with GAPs under assessment

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)
37%	Milk: Cattle	0 / 0.3	37
7%	Milk: Goat	0 / 0.3	7.3
3%	Bovine: Liver	0 / 0.36	2.9
2%	Bovine: Muscle/meat	0 / 0.31	2.2
2%	Swine: Muscle/meat	0 / 0.17	2.1
2%	Equine: Muscle/meat	0 / 0.31	1.9
2%	Sheep: Muscle/meat	0 / 0.33	1.8
1%	Bovine: Kidney	0 / 0.34	1.3
1%	Milk: Sheep	0 / 0.32	1.1
0.7%	Poultry: Muscle/meat	0 / 0.04	0.68
0.5%	Bovine: Fat tissue	0 / 0.24	0.50
0.5%	Eggs: Chicken	0 / 0.04	0.50
0.3%	Swine: Kidney	0 / 0.2	0.25
0.2%	Swine: Fat tissue	0 / 0.13	0.22
0.2%	Swine: Liver	0 / 0.17	0.21

Expand/collapse list

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

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
12%	Milk: Cattle	0 / 0.3	12
6%	Milk: Goat	0 / 0.3	5.5
5%	Milk: Sheep	0 / 0.32	4.8
2%	Bovine: Muscle	0 / 0.31	1.8
2%	Sheep: Muscle/meat	0 / 0.33	1.6
1%	Equine: Muscle/meat	0 / 0.31	1.5
1%	Bovine: Liver	0 / 0.36	1.4
1%	Sheep: Liver	0 / 0.39	1.1
0.8%	Swine: Muscle/meat	0 / 0.17	0.82
0.7%	Bovine: Kidney	0 / 0.34	0.72
0.5%	Goat: Muscle	0 / 0.31	0.48
0.5%	Poultry: Muscle	0 / 0.04	0.47
0.4%	Swine: Kidney	0 / 0.2	0.44
0.3%	Swine: Fat tissue	0 / 0.13	0.26
0.2%	Swine: Liver	0 / 0.17	0.24

TA

Acute risk assessment /children	Acute risk assessment / adults / general population
Details - acute risk assessment /children	Details - acute risk assessment/adults

The acute risk assessment is based on the ARfD. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the Eu

The calculation is based on the large portion of the most critical consumer group.

Show results of IESTI calculation only for crops with GAPs under assessment

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)
4%	Bovine: Liver	0 / 1.36	11
2%	Milk: Cattle	0 / 0.04	5.0
1%	Bovine: Muscle/meat	0 / 0.62	4.5
1%	Equine: Muscle/meat	0 / 0.62	3.7
1%	Sheep: Muscle/meat	0 / 0.68	3.7
1%	Swine: Muscle/meat	0 / 0.27	3.3
0.7%	Bovine: Kidney	0 / 0.58	2.2
0.7%	Poultry: Muscle/meat	0 / 0.12	2.0
0.5%	Rapeseeds/canola	0 / 1.04	1.4
0.3%	Milk: Goat	0 / 0.04	0.97
0.2%	Swine: Liver	0 / 0.61	0.75
0.2%	Eggs: Chicken	0 / 0.06	0.74
0.2%	Bovine: Fat tissue	0 / 0.34	0.71
0.1%	Swine: Kidney	0 / 0.27	0.34
0.1%	Poultry: Liver	0 / 0.31	0.34

Expand/collapse list

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

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
2%	Bovine: Liver	0 / 1.36	5.4
2%	Sheep: Liver	0 / 1.8	5.0
1%	Bovine: Muscle	0 / 0.62	3.5
1%	Sheep: Muscle/meat	0 / 0.68	3.2
1.0%	Equine: Muscle/meat	0 / 0.62	3.0
0.5%	Milk: Cattle	0 / 0.04	1.5
0.5%	Poultry: Liver	0 / 0.31	1.5
0.5%	Poultry: Muscle	0 / 0.12	1.4
0.4%	Swine: Muscle/meat	0 / 0.27	1.3
0.4%	Bovine: Kidney	0 / 0.58	1.2
0.3%	Goat: Muscle	0 / 0.62	0.97
0.3%	Swine: Liver	0 / 0.61	0.86
0.2%	Milk: Goat	0 / 0.04	0.74
0.2%	Milk: Sheep	0 / 0.04	0.60
0.2%	Swine: Kidney	0 / 0.27	0.59

TAA

Acute risk assessment /children	Acute risk assessment / adults / general population
Details - acute risk assessment /children	Details - acute risk assessment/adults

The acute risk assessment is based on the ARfD. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the Eu

The calculation is based on the large portion of the most critical consumer group.

Show results of IESTI calculation only for crops with GAPs under assessment

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)
0.5%	Milk: Cattle	0 / 0.04	5.0
0.10%	Milk: Goat	0 / 0.04	0.97
0.08%	Bovine: Kidney	0 / 0.22	0.83
0.07%	Poultry: Muscle/meat	0 / 0.04	0.68
0.05%	Eggs: Chicken	0 / 0.04	0.50
0.05%	Swine: Muscle/meat	0 / 0.04	0.48
0.04%	Bovine: Liver	0 / 0.05	0.40
0.03%	Bovine: Muscle/meat	0 / 0.04	0.29
0.02%	Equine: Muscle/meat	0 / 0.04	0.24
0.02%	Sheep: Muscle/meat	0 / 0.04	0.22
0.02%	Swine: Kidney	0 / 0.14	0.18
0.02%	Bovine: Fat tissue	0 / 0.08	0.17
0.02%	Rapeseeds/canola	0 / 0.12	0.17
0.01%	Milk: Sheep	0 / 0.04	0.14
0.01%	Swine: Fat tissue	0 / 0.05	0.09

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)
0.2%	Milk: Cattle	0 / 0.04	1.5
0.07%	Milk: Goat	0 / 0.04	0.74
0.06%	Milk: Sheep	0 / 0.04	0.60
0.05%	Poultry: Muscle	0 / 0.04	0.47
0.05%	Bovine: Kidney	0 / 0.22	0.46
0.03%	Swine: Kidney	0 / 0.14	0.31
0.02%	Poultry: Liver	0 / 0.05	0.24
0.02%	Bovine: Muscle	0 / 0.04	0.23
0.02%	Bovine: Liver	0 / 0.05	0.20
0.02%	Swine: Muscle/meat	0 / 0.04	0.19
0.02%	Equine: Muscle/meat	0 / 0.04	0.19
0.02%	Sheep: Muscle/meat	0 / 0.04	0.19
0.02%	Eggs: Chicken	0 / 0.04	0.17
0.01%	Sheep: Liver	0 / 0.05	0.14
0.01%	Swine: Fat tissue	0 / 0.05	0.10

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

TLA

Acute risk assessment /children	Acute risk assessment / adults / general population
Details - acute risk assessment /children	Details - acute risk assessment/adults

The acute risk assessment is based on the ARfD. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the Eu

The calculation is based on the large portion of the most critical consumer group.

Show results of IESTI calculation only for crops with GAPs under assessment

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)
2%	Milk: Cattle	0 / 0.04	5.0
0.3%	Milk: Goat	0 / 0.04	0.97
0.2%	Poultry: Muscle/meat	0 / 0.04	0.68
0.2%	Eggs: Chicken	0 / 0.04	0.50
0.2%	Bovine: Kidney	0 / 0.13	0.49
0.2%	Swine: Muscle/meat	0 / 0.04	0.48
0.1%	Bovine: Liver	0 / 0.04	0.32
0.10%	Bovine: Muscle/meat	0 / 0.04	0.29
0.08%	Equine: Muscle/meat	0 / 0.04	0.24
0.07%	Sheep: Muscle/meat	0 / 0.04	0.22
0.07%	Bovine: Fat tissue	0 / 0.1	0.21
0.05%	Milk: Sheep	0 / 0.04	0.14
0.05%	Swine: Fat tissue	0 / 0.08	0.14
0.03%	Swine: Kidney	0 / 0.08	0.10
0.03%	Rapeseeds/canola	0 / 0.07	0.09

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)
0.5%	Milk: Cattle	0 / 0.04	1.5
0.2%	Milk: Goat	0 / 0.04	0.74
0.2%	Milk: Sheep	0 / 0.04	0.60
0.2%	Poultry: Muscle	0 / 0.04	0.47
0.09%	Bovine: Kidney	0 / 0.13	0.27
0.08%	Bovine: Muscle	0 / 0.04	0.23
0.06%	Swine: Muscle/meat	0 / 0.04	0.19
0.06%	Equine: Muscle/meat	0 / 0.04	0.19
0.06%	Sheep: Muscle/meat	0 / 0.04	0.19
0.06%	Poultry: Liver	0 / 0.04	0.19
0.06%	Swine: Kidney	0 / 0.08	0.18
0.06%	Eggs: Chicken	0 / 0.04	0.17
0.05%	Swine: Fat tissue	0 / 0.08	0.16
0.05%	Bovine: Liver	0 / 0.04	0.16
0.04%	Sheep: Liver	0 / 0.04	0.11

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

A 3.4 IESTI calculations - Processed commodities

A 3.4.1 Boscalid

IESTI was not calculated for boscalid since no ARfD has been set

A 3.4.2 Prothioconazole

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

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

Processed commodities

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
81%	Lentils / boiled	1 / 1	8.1
71%	Peas / canned	1 / 0.4	7.1
51%	Turnips / boiled	0.1 / 0.1	5.1
51%	Parsnips / boiled	0.1 / 0.1	5.1
44%	Beetroots / boiled	0.1 / 0.1	4.4
39%	Broccoli / boiled	0.05 / 0.05	3.9
36%	Carrots / juice	0.1 / 0.1	3.6
35%	Cauliflowers / boiled	0.05 / 0.05	3.5
34%	Leeks / boiled	0.06 / 0.06	3.4
33%	Sugar beets (root) / sugar	0.03 / 0.36	3.3
26%	Salsifies / boiled	0.1 / 0.1	2.6
23%	Maize / oil	0.1 / 2.5	2.3
19%	Potatoes / fried	0.02 / 0.02	1.9
12%	Wheat / milling (flour)	0.1 / 0.1	1.2
12%	Potatoes / dried (flakes)	0.02 / 0.09	1.2

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
39%	Beetroots / boiled	0.1 / 0.1	3.9
26%	Peas / canned	1 / 0.4	2.6
21%	Parsnips / boiled	0.1 / 0.1	2.1
21%	Cauliflowers / boiled	0.05 / 0.05	2.1
19%	Turnips / boiled	0.1 / 0.1	1.9
14%	Barley / beer	0.2 / 0.04	1.4
13%	Sugar beets (root) / sugar	0.03 / 0.36	1.3
13%	Maize / oil	0.1 / 2.5	1.3
12%	Broccoli / boiled	0.05 / 0.05	1.2
10%	Leeks / boiled	0.06 / 0.06	1.0
8%	Head cabbages / canned	0.09 / 0.09	0.85
8%	Salsifies / boiled	0.1 / 0.1	0.82
8%	Carrots / canned	0.1 / 0.1	0.82
6%	Pumpkins / boiled	0.01 / 0.01	0.55
5%	Onions / boiled	0.05 / 0.05	0.47

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

IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
81%	Lentils / boiled	1 / 1	8.1
71%	Peas / canned	1 / 0.4	7.1
36%	Carrots / juice	0.1 / 0.1	3.6
33%	Sugar beets (root) / sugar	0.03 / 0.36	3.3
24%	Broccoli / boiled	0.05 / 0.05	2.4
23%	Maize / oil	0.1 / 2.5	2.3
22%	Turnips / boiled	0.1 / 0.1	2.2
22%	Salsifies / boiled	0.1 / 0.1	2.2
22%	Parsnips / boiled	0.1 / 0.1	2.2
21%	Cauliflowers / boiled	0.05 / 0.05	2.1
20%	Leeks / boiled	0.06 / 0.06	2.0
19%	Beetroots / boiled	0.1 / 0.1	1.9
12%	Wheat / milling (flour)	0.1 / 0.1	1.2
12%	Potatoes / dried (flakes)	0.02 / 0.09	1.2
10%	Brussels sprouts / boiled	0.1 / 0.1	1.0

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

IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
26%	Peas / canned	1 / 0.4	2.6
17%	Beetroots / boiled	0.1 / 0.1	1.7
14%	Barley / beer	0.2 / 0.04	1.4
13%	Sugar beets (root) / sugar	0.03 / 0.36	1.3
13%	Maize / oil	0.1 / 2.5	1.3
12%	Cauliflowers / boiled	0.05 / 0.05	1.2
10%	Broccoli / boiled	0.05 / 0.05	1.0
9%	Parsnips / boiled	0.1 / 0.1	0.91
9%	Turnips / boiled	0.1 / 0.1	0.91
9%	Salsifies / boiled	0.1 / 0.1	0.91
8%	Head cabbages / canned	0.09 / 0.09	0.85
8%	Carrots / canned	0.1 / 0.1	0.82
8%	Leeks / boiled	0.06 / 0.06	0.81
4%	Wheat / bread/pizza	0.1 / 0.1	0.44
4%	Pumpkins / boiled	0.01 / 0.01	0.40

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

Processed commodities

Results for children				**Results for adults**			
No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---	No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				**IESTI**			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.4%	Rapeseeds / oils	0.15 / 0.12	0.04	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
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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 Prothioconazole-desthio, is unlikely to present a public health risk.

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

T

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)
	0.0%	Rapeseeds / oils	0 / 0.1	0.03	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
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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 T is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

TA

Processed commodities

Results for children				**Results for adults**			
No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---	No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				**IESTI**			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.2%	Rapeseeds / oils	0 / 2.08	0.61	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
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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 TA is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

TAA

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)
0.0%	Rapeseeds / oils	0 / 0.24	0.07	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
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Expand/collapse list							

Conclusion:

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

TLA

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)
0.0%	Rapeseeds / oils	0 / 0.13	0.04	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
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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 TLA is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

Appendix 4 Additional information provided by the applicant

No additional data.