REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: FHO04

Product name(s): Prothioconazole/Sulphur (50+625) SC, / Patton Supra

Chemical active substance(s): Prothioconazole 50 g/L, Sulphur 625 g/L

Central Zone

Member State: Poland

CORE ASSESSMENT

Applicant: UPL Holdings Cooperatief U.A.

Submission date: 30/05/2024, updated: October, November 2024

MS Finalisation date: November 2024 (initial Core Assessment)

January 2025 (final Core Assessment)

Version history

When	What
May 2024	Initial dRR – UPL Holdings Coöperatief U.A.
October 2024	Revision 1 updated for a) the new Commission Regulation (EU) 2024/1318 for prothioconazole MRLs and b) removal of data not required/not accessible to support the application
November 2024	Revision 2 updated for clarification of the studies referred to by the applicant and relied on, but already evaluated at EU peer review. Additionally, some subsection numbering also corrected.
November 2024	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.
January 2025	Final report (Core Assessment updated following the commenting period) No additional information or assessments after the commenting period.

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7 Metabolism and residue data (KCA section 6)

7.1 Summary and zRMS Conclusion

7.1.1 Critical GAP(s) and overall conclusion

Selection of critical uses and justification
The critical GAPs with respect to consumer intake and risk assessment for the preparation FHO04 are presented in Table 7.1-1. They have been selected from the individual GAPs in the ~~Northern~~ Central zone for wheat.

A list of all intended uses within Poland is given in Part B, Section 0.

Two critical GAP uses for wheat and rye were selected based on the highest application rate and the latest application timing (BBCH) per season of the active substances. For the cGAP for wheat and rye general extrapolation rules apply from wheat to rye. According to SANTE/2019/12752 Rev01, wheat (0500090) can be extrapolated to rye (0500070).

Overall conclusion
The data available for prothioconazole are considered sufficient for risk assessment. An exceedance of the current MRLs of 0.1 mg/kg (wheat) for prothioconazole-desthio (sum of isomers) as laid down in Reg. (EU) 396/2005 (most recently Reg. (EU) No 2024/1318) is not expected.

The chronic and the short-term intakes of prothioconazole residues, according to the residue definition for risk assessment including TDMs are unlikely to present a public health concern.

Sulphur has been included in Annex IV of Regulation (EC) No 396/2005, meaning no MRLs are necessary.

As far as consumer health protection is concerned, zRMS agrees with the authorization of the intended use(s).

According to available data, no specific mitigation measures should apply.

Data gaps: none for FHO04/Patton Supra

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**		
1, 2, 3, 4, 6, 7	Winter wheat (TRZAW) 0500090, Spring wheat (TRZAS) 0500090, Durum wheat† (TRZDU) 0500090-001, Spelt† (TRZSP) 0500090-005, Winter triticale (TTLWI) 0500090-006, Spring triticale (TTLSO) 0500090-006	PL	FHO04	F	(various)	SC	Prothioconazole 50g/L + Sulphur 625g/L	Foliar Spray	BBCH 27-69	a)1 b)2	14	a) 4 L/ha b) 8 L/ha	100/400	a) 0.2 + 2.5 kg/ha b) 0.4 + 5.0 kg/ha	35	A
2 5, 8	Winter rye (SECCW) 0500070, Spring rye† (SECCS) 0500070,	PL	FHO04	F	(various)	SC	Prothioconazole 50g/L + Sulphur 625g/L	Foliar Spray	BBCH 27-69	a)1 b)2	14	a) 4 L/ha b) 8 L/ha	100/400	a) 0.2 + 2.5kg/ha b) 0.4 + 5.0 kg/ha	35	A

† Minor crop according to Article 51
* 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

7.1.2 Summary of the evaluation

The preparation FHO04 is composed of prothioconazole and sulphur.

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

Reference value	Source	Year	Value	Study relied upon	Safety factor
Prothioconazole					
ADI	EFSA Scientific Report (2007) 106, 1-98, Conclusion on the peer review of prothioconazole	2007	0.05 mg/kg bw/day	Rat oncogenicity study	100
ARfD		2007	0.2 mg/kg bw	Rat developmental study	100
Prothioconazole-desthio					
ADI	EFSA Scientific Report (2007) 106, 1-98, Conclusion on the peer review of prothioconazole	2007	0.01 mg/kg bw/day	Rat oncogenicity study	100
ARfD		2007	0.01 mg/kg bw	Rat developmental study	100
1,2,4-triazole (1,2,4-T)					
ADI	EFSA Journal 2018b; 16(7):5376	2018	0.023 mg/kg bw/day	Rat 12-month study	300
ARfD		2018	0.1 mg/kg bw	Rat developmental study	300
Triazole alanine (TA)					
ADI	EFSA Journal 2018b; 16(7):5376	2018	0.3 mg/kg bw/day	Rabbit developmental study	100
ARfD		2018	0.3 mg/kg bw	Rabbit developmental study	100
Triazole acetic acid (TAA)					
ADI	EFSA Journal 2018b; 16(7):5376	2018	1.0 mg/kg bw/day	Rat 2-generation and rabbit developmental studies	100
ARfD		2018	1.0 mg/kg bw	Rat 2-generation and rabbit developmental studies	100
Triazole lactic acid (TLA)					
ADI	EFSA Journal 2018b; 16(7):5376	2018	0.3 mg/kg bw/day	Bridging from triazole alanine (TA)	
ARfD		2018	0.3 mg/kg bw	Bridging from triazole alanine (TA)	
Sulphur					
ADI	EFSA Scientific Report (2008) 221, 1-70	2008	~~NR~~ Not applicable	NR	NR
ARfD		2008	~~NR~~ Not applicable	NR	NR

NR: not relevant

7.1.2.1 Summary for prothioconazole

Table 7.1-3: 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?
1	Cereal (wheat)	Yes	Yes (number of trials)	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 prothioconazole residues have been investigated. As residues of prothioconazole do not exceed the trigger values defined in Reg (EU) No 283/2013 (except 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 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 prothioconazole residues 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.

7.1.2.2 Summary for sulphur

Sulphur has been included in Annex IV of Regulation (EC) No 396/2005, meaning no MRLs are necessary.

Investigation of residues of sulphur and the effect of industrial and/or household processing and in succeeding crops are therefore also not deemed necessary. No further consideration is required.

Table 7.1-4: Summary for sulphur

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
1	Cereal (wheat)	~~Yes~~ NN	~~Yes (number of trials)~~ NN	~~Yes~~ NN	~~Yes~~ NN	~~Yes~~ NR	No	No

NN- not necessary/not needed
NR – not required

7.1.2.3 Summary for FHO04

Table 7.1-5: Information on FHO04 (KCA 6.8)

Crop	PHI for FHO04 proposed by applicant	PHI/ Withholding period* sufficiently supported for		PHI for FHO04 proposed by zRMS	zRMS Comments (if different PHI proposed)
		Prothioconazole	Sulphur		
Cereal (wheat, durum, spelt, triticale)	35 Days	Yes	NR	35 days	-

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

Table 7.1-6: Waiting periods before planting succeeding crops

Waiting period before planting succeeding crops			Overall waiting period proposed by zRMS for FHO04
Crop group	Led by prothioconazole	Led by sulphur	
Wheat (winter, spring, durum, spelt, triticale): TRZAW, TRZAS, TRSDU, TRZSP, TTLSS	~~NR~~ Not needed	~~NR~~ Not needed	Not needed
All crops	Not needed	Not needed	Not needed

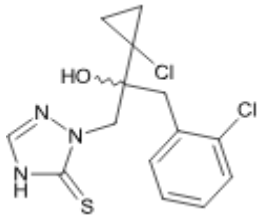
NR: not relevant

Assessment

7.2 Prothioconazole

According to SANTE/11509/2013– rev. 5.2 and since the active substance prothioconazole is not yet renewed, the "old data requirements" (Reg. (EU) No 544/2011) and the endpoints from the inclusion of prothioconazole (DAR) apply to the current assessment. Studies from the DAR are not protected anymore. The active substance prothioconazole belongs to the triazole chemical group. Triazole derivative metabolites (TDMs) are common metabolites of all triazole fungicides and have to be considered in the consumer risk assessment. The data on TDMs provided in the present application are from the "Triazole Derivate Metabolites addendum – confirmatory data prepared by the rapporteur Member State, the United Kingdom" (UK, 2018). As confirmatory data, they are out of data protection. Following this, EFSA issued the "Peer review of the pesticide risk assessment for the triazole derivative metabolites in light of confirmatory data submitted" (EFSA, 2018). These conclusions were taken into account in the present assessment.
General data on prothioconazole are summarized in the table below (last updated 2023/08/01)

Table 7.2-1: 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)	Sterol biosynthesis inhibitor.
Systemic	Yes
Company (ies)	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) 2018b
EFSA Journal: conclusion on article 12	Yes, EFSA Journal 2014 EFSA Journal 2020;18(2):5999
Current MRL applications on intended uses	None

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

7.2.1 Stability of Residues (KCA 6.1)

7.2.1.1 Stability of residues during storage of samples

Table 7.2-2: Summary of stability data 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			
Spinach	High water content	24 months Prothioconazole-desthio	EFSA, 2014 EFSA, 2020
Sugar beet	High water content	24 months Prothioconazole-desthio	EFSA, 2014 EFSA, 2020
Tomatoes	High water content	24 months Prothioconazole-desthio	EFSA, 2014 EFSA, 2020
Wheat green material	High water content	540 days Prothioconazole-desthio (JAU 6476-desthio)	Heinemann, O., 2001, Study No. MR-282/00, DAR, UK (2004), IIA 6.0/01 (Not protected) EFSA, 2007 EFSA, 2014 EFSA, 2020
Potatoes	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	EFSA, 2020
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	EFSA, 2020
Wheat grain	Dry commodity (high starch content)	540 days Prothioconazole-desthio (JAU 6476-desthio)	Heinemann, O., 2001, Study No. MR-282/00, DAR, UK (2004), IIA 6.0/01 (Not protected) EFSA, 2007 EFSA, 2014 EFSA, 2020

Matrix	Characteristics of the matrix according to SANTE/2020/12830, Rev.2	Acceptable Maximum Storage duration	Reference
Wheat straw	Dry commodity	540 days Prothioconazole-desthio (JAU 6476-desthio)	Heinemann, O., 2001, Study No. MR-282/00, DAR, UK (2004), IIA 6.0/01 (Not protected) EFSA, 2007 EFSA, 2014 EFSA, 2020
Oilseed rape straw	Dry commodity	24 months Prothioconazole-desthio	EFSA, 2014 EFSA, 2020
Animal Products			
Ruminant	Liver, kidney, muscle, fat & milk	1 month Prothioconazole-desthio, Prothioconazole-3-hydroxy-desthio (M14), Prothioconazole-4-hydroxy-desthio (M15)	Heinemann, O. and Auer, S., 2001, Study No. MR-535/00, DAR, UK (2004), IIA 6.1/01 (Not protected) EFSA, 2014

Matrix	Characteristics of the matrix according to SANTE/2020/12830, Rev.2	Acceptable Maximum Storage duration	Reference
New data			
Plant products			
Wheat forage	High water content	12 months Prothioconazole-α-hydroxy-desthio, Prothioconazole-3-hydroxy-desthio, Prothioconazole-4-hydroxy-desthio, Prothioconazole-5-hydroxy-desthio, Prothioconazole-6-hydroxy-desthio	KCA 6.1/01: Giancola, D., 2024, Study No.: QG/21/001
Wheat grain	Dry commodity (high starch content)	12 months Prothioconazole-α-hydroxy-desthio, Prothioconazole-3-hydroxy-desthio, Prothioconazole-4-hydroxy-desthio, Prothioconazole-5-hydroxy-desthio,	
		8 months Prothioconazole-6-hydroxy-desthio	
Wheat straw	Dry commodity	12 months Prothioconazole-α-hydroxy-desthio, Prothioconazole-3-hydroxy-desthio, Prothioconazole-4-hydroxy-desthio, Prothioconazole-5-hydroxy-desthio, Prothioconazole-6-hydroxy-desthio	
Animal Products			
No new data were submitted in the framework of this application.			

Table 7.2-3: Summary of stability data for TDMs (1,2,4-triazole, triazole alanine (TA), tri-azole 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 2018b (amended 2019), EFSA 2020
Barley, wheat straw	Dry commodity	12	53	40	48[1]	EFSA 2018b (amended 2019), EFSA 2020
Rapeseeds, soya beans	High oil content commodity	12 (soya beans only)-(not relevant)	26 (soya beans only) (not relevant)	53 (not relevant)	48	EFSA 2018b (amended 2019), EFSA 2020
Dry peas, navy beans	Dry commodity (high protein content)	No data (not relevant)	15 (not relevant)	25 (not relevant)	48	EFSA 2018b (amended 2019), EFSA 2020
Oranges	High acid content commodity	No data (not relevant)	No data (not relevant)	No data (not relevant)	48	EFSA 2018b (amended 2019), EFSA 2020
Apples, tomatoes, mustard leaves, wheat forage, radishes tops/roots, turnip roots, sugar beet roots, cabbages, lettuces	High water content commodity	6	53	53	48	EFSA 2018b (amended 2019), EFSA 2020
[1] Considered to be covered by 5 matrices (high starch, high protein, high oil, high acid and high water) and dry commodity data (wheat grain, dry peas and navy beans) according to SANTE/2020/12830, Rev.2.						
Animal Products						
Ruminant	Milk	18	No data	No data	No data	EFSA 2018b (amended 2019), EFSA 2020
	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[2]						
[2] Stability data in plant products, to support the use of FHO04 on wheat, is considered to be covered by 'Data relied on in EU', which is unprotected. However, if considered needed, the applicant also has a study ongoing (Study No. QG/21/002, KCA 6.1/02), to investigate the stability of residues of triazole derived metabolites (1,2,4-triazole, triazole alanine, triazole acetic acid and triazole lactic acid) in oilseed rape (seed), field bean (dried), orange, wheat forage, wheat grain and wheat straw stored under deep freeze storage conditions (≤-18°C) for a period of 12 months. A copy of the study plan is provided, and the final report is due in January 2025.						
Animal Products						
Matrix not disclosed	Milk	18	6	6	6	KCA 6.1/03: Jooß S. and Tussetsch-läger S., 2020, TDMG Study, Study ID: 869333).
	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	

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	

Conclusion on stability of residues during storage

Prothioconazole

According to the Draft Assessment Report on prothioconazole of 2004, a freezer stability study showed that residues of prothioconazole-desthio were shown to be stable in all wheat matrices (green material/forage, grain and straw) for greater than 540 days.

New storage stability study is now submitted (Giancola, D., 2024, Study No. QG/21/001 – interim report) by the applicant to confirm the stability of residues of prothioconazole-desthio and five hydroxylated metabolites stored under deep freeze storage conditions. The stability of the five hydroxylated metabolites in wheat (grain, forage and straw), was demonstrated (mean recovery of each analyte at each interval was in the range of 70% to 120%) under deep freeze storage conditions (≤ -18°C) for at least 12 months. The exception to this was the metabolite prothioconazole-6-hydroxy-desthio in wheat grain which, was shown to be stable for at least 8 months. The study QG/21/001 is ongoing and is set to continue for 24 months with the final report is due in March 2025.

As samples from the submitted residue trials were stored frozen a maximum of 198 days for wheat forage, 178 days for wheat straw and 184 days for wheat grain, it is concluded that the residue data is valid with regards to storage stability.

TDMs

The freezer storage stability of various TDMs was investigated in the framework of the peer review of TDMs (UK, 2018b, EFSA, 2018b, amended 2019). The data is additionally included in the evaluation of confirmatory data following the Article 12 MRL review of prothioconazole (EFSA 2020): In the commodity groups relevant for the envisaged GAP uses, the stability of all TDMs has been demonstrated as detailed in Table 7.2-3.

For the data gaps addressing the triazole derived metabolites TA, TLA and TAA milk, eggs, liver, muscle and fat, an Access Agreement for the TDMG study Jooß S. and Tussetschläger S.;2020; Study ID: 869333, KCA 6.1/03 is provided, where the data demonstrates stability of TA, TLA and TAA under deep freeze conditions (<-18°C) for 6 months in milk, cream, eggs, liver, kidney, muscle and fat.

As samples from the submitted residue trials were stored frozen a maximum of 178 days for wheat forage, 175 days for wheat straw and 174 days for wheat grain, it is concluded that the residue data is valid with regard to storage stability.

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.

Additionally, new study (an interim report) 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 12 months. It should be noted that prothioconazole-6-hydroxy-desthio in wheat grain and in oilseed rape seed are stable for 8 months and 6 months, respectively.

The study was conducted according to the OECD 506 and is acceptable.

More details of this study are provided in Appendix 2.

The interim report for study KCA 6.1/01 (Giancola, D., 2024, Study No.: QG/21/001) includes 8 –12 months of storage data, which supports the wheat residue trials data provided (the storage period in the interim is sufficient). The final report with 24 months data is now expected in March 2025.

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.

Sufficient stability data are available to support the residue data presented in the present dossier. No further data are required.

7.2.1.2 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.

7.2.2 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
Reference is made to the EU peer review (EFSA, 2007, DAR UK, 2004 and 2007) and to the MRL review (EFSA, 2014 and 2020) for prothioconazole, as well as to the peer review of the triazole derived metabolites (TDMs) in the light of confirmatory data submitted (UK, 2018b, EFSA, 2018b, amended 2019).

No new data submitted in the framework of this application.

Table 7.2-4: 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)	0.22	2	Forage: 6 Hay: 26 Grain & straw: 48	The plants were grown under environmental	Haas, M. and Bornatsch, W. (2000), Study No. MR-

							conditions (sunlight and temperatures). A glass roof protected the plants from rainfall. The soil was surface irrigated	198/99. DAR, UK 2004, IIA 6.1.1/01 EFSA, 2007 EFSA, 2014 EFSA, 2020
		[3,5-^{14}C-triazole] prothioconazole-desthio	foliar treatment, G (summer wheat)	0.25	2	Forage: 0, 14 Grain & 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	Vogeler, K., Sakamoto, H. and Brauner, A. (1993), Study No. MR-PF3906. DAR, UK 2004, IIA 6.1.1/03 EFSA, 2007 EFSA, 2014 EFSA, 2020
		[3,5-^{14}C-triazole] prothioconazole-desthio	foliar treatment, F (spring wheat)	0.18 and 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 EFSA, 2020
		[U-^{14}C-phenyl] prothioconazole	Seed, G (spring wheat)	0.02 or 0.10 kg/100 kg seeds (*ca*. 220 kg seeds/ha	1	Forage: 57 Hay: 110 Grain & straw : 153		Haas, M. (2001a), Study No. MR-467/99. DAR, UK 2004, IIA 6.1.1/02 EFSA, 2007 EFSA, 2014 EFSA, 2020
Pulses and oilseeds (not relevant)	Peanut	[U-^{14}C-phenyl] prothioconazole	Foliar, G	0.30	3	Hay & nuts without shells: 14		DAR, UK 2004 EFSA, 2007 EFSA, 2014 EFSA, 2020
		[3,5-^{14}C-triazole] prothioconazole-desthio	Foliar, G	0.30	3	Hay & nuts without shells: 14		JMPR: FAO, 2008a, 2008b EFSA, 2014 EFSA, 2020
Root crops (not relevant)	Sugar beet	[U-^{14}C-phenyl] prothioconazole	Foliar, G	0.29	4	Roots, tops, leaves: 7		EFSA, 2014 EFSA, 2020
		[3,5-^{14}C-triazole] prothioconazole-desthio	Foliar, G	0.29	4	Roots, tops, leaves: 7		EFSA, 2014 EFSA, 2020

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

Summary of plant metabolism studies reported in the EU

According to EFSA, 2007: "Prothioconazole is extensively metabolised. In a first step the sulphur group of

the triazolinethione ring is oxydised to the corresponding sulfonic acid. Subsequent elimination of the sulfonic acid moiety results in prothioconazole-desthio (metabolite M04) which is consistently the major prothioconazole-structurally related metabolite in all plant parts and for all growth stages, except in nutmeat, where it was not found. This metabolite is further hydroxylated in the chlorophenyl ring forming various hydroxyl-desthio isomers and dihydroxy-olefins. Similarly, α-hydroxylation of prothioconazole-desthio was also observed. A dimerisation product and other metabolites resulting from combined oxidation of the sulphur atom and hydroxylation of the chlorophenyl ring were also identified. Cleavage of the triazole moiety is also observed resulting in the 'triazole derivative metabolites' which consist essentially in triazole alanine and triazole acetic acid. These compounds are common, unspecific metabolites of triazole fungicides. Triazole alanine and triazole acetic acid are massively translocated to wheat grains where they represent 90% of the Total Radioactive Residues (TRR)."

According to EFSA, 2014: "The metabolic pattern of prothioconazole and prothioconazole-desthio was shown to be similar with prothioconazole-desthio being the predominant compound of the total residues with further hydroxylation and glucosidation steps, whilst cleavage of the triazole bound of prothioconazole-desthio molecule resulted in the formation of triazole derivative metabolites (TDMs). A global residue definition for enforcement was proposed as prothioconazole-desthio (sum of isomers) only whilst for risk assessment, the residue was defined 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). As the residue definitions for enforcement and risk assessment are different, conversion factors for enforcement to risk assessment of 2 for cereal grain, pulses and oilseeds, leafy vegetables and root and tuber vegetables and of 3 for cereal straw were derived on the basis of the available plant metabolism data."

According to EFSA, 2020: "The metabolism of prothioconazole was investigated by foliar applications on root, pulses/oilseeds and cereal/grass crop groups and by seed treatment on cereals (spring wheat). The metabolic pattern of prothioconazole was shown to be similar with prothioconazole-desthio being the predominant compound of the total residues. Besides prothioconazole-desthio, other metabolites, which are structurally closely related to this compound, and the main triazole derivative metabolites (TDMs) were identified. […] 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."

Residue definition for risk assessment:

- 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)
- Triazole alanine (TA) and triazole lactic acid (TLA)
- Triazole acetic acid (TAA)
- 1,2,4-triazole (1,2,4-triazole)

Summary of new plant metabolism studies
No new plant metabolism studies.

Conclusion on metabolism in primary crops
Based on the evaluations of EFSA 2018b, amended 2019 and EFSA 2020, the following residue definitions are proposed:

Residue definition for enforcement:
Prothioconazole-desthio (sum of isomers).

Residue definition for risk assessment:

a) 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),
b) TDMs with separate assessment of:
   - Triazole alanine (TA) and triazole lactic acid (TLA)
   - Triazole acetic acid (TAA)
   - 1,2,4-triazole (1,2,4-T)

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.

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

Table 7.2-5: 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	Bare soil application	1 x 0.58	28,146,269	80, 188, 348	-	Haas, M. (2001b), Study No. MR-159/00, DAR, UK, 2004, IIA 6.6/01 (Not protected) EFSA, 2007 EFSA, 2014 EFSA, 2020
Root and tuber vegetables	Turnip	U-^{14}C-phenyl] prothioconazole	Bare soil application	1 x 0.58	28,146,269	Roots, tops: 94, 201, 349	-	
Cereals	Spring wheat	U-^{14}C-phenyl] prothioconazole	Bare soil application	1 x 0.58	28,146,269	Green material: 73, 178, 327 Hay: 111, 231, 377 Grain, straw: 145, 269, 412	-	

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

Summary of plant metabolism studies reported in the EU

UK, 2007 (Final Addendum to the DAR (Addendum 10, pp. 216): "A study of uptake and metabolism in spring wheat, Swiss chard and turnip grown as rotational crops under worst case conditions in a confined study showed that residues declined between first and third rotations. Significant residues (>0.1 mg/kg) were only found in wheat straw and hay and these were at similar or lower levels than those recorded for the directly treated spring wheat. The profile of metabolites was found to be very similar in directly treated wheat and wheat grown as a rotational crop. The level of prothioconazole-desthio (M04, residue of concern), in Swiss chard was 0.014 mg/kg at the shortest plant back interval (30 days). No other single metabolite was present. In turnip leaves and turnip roots, no single metabolite was present at a level greater than 0.01mg/kg."

Conclusion on metabolism in rotational crops

According to UK, 2007 (Final Addendum to the DAR (Addendum 10, pp. 216), the following was concluded: "The Rapporteur concludes that residues in rotational crops will not lead to any additional exposure to JAU 6476-desthio above that from directly treated crops. Therefore, a field rotational crop study is not considered necessary, since any significant additional exposure of the consumer by the uptake of prothioconazole residues from rotated crops can be excluded."

According to EFSA, 2014 (Art. 12 MRL review), the following was concluded: "In wheat grain, the total radioactive residues were recovered at a trace level at all DATs (≤ 0.007 mg eq/kg) and no further metabolites' identification was attempted. In wheat green material, hay and straw, TRR ranged from 0.021 mg eq/kg (green material, DAT 28) to 0.450 mg eq/kg (straw, DAT 28). In turnip roots, tops and Swiss chard,
the highest residue levels ranged from 0.043 mg eq/kg (turnip root, DAT 28) to 0.053 mg eq/kg (Swiss chard, DAT 146). No significant decline of the residue levels was observed for any crop part throughout the first, second and third rotation.

In the edible parts of the crops at harvest 61 to 87 % of the total residues were extracted and the level of identification ranged between 34.4 % TRR (swiss chard, DAT 269) to 77.2 % TRR (turnip leaves, DAT 28). The major compounds of the total residues were identified as prothioconazole-desthio, its hydroxylated derivative metabolites, either free or conjugated (M14, M15, M16, M17), M27, free and conjugated and M02 (prothioconazole-sulfonic acid). Residue levels of the main metabolites recovered in wheat were in general higher in straw than in hay. In straw, they reached the following levels: prothioconazole-desthio (0.066 mg eq/kg) (DAT 28), M02 (0.063 mg eq/kg) (DAT 269), glucoside of M27 (0.056 mg eq/kg) (DAT 269) and glucosides of the hydroxylated metabolites of prothioconazole-desthio (0.097 mg eq/kg) (DAT 28). In Swiss chard, levels of prothioconazole-desthio reached 0.014 mg eq/kg at 28 DAT, while levels of M27 glucosides were below 0.01 mg eq/kg at all sowing intervals. In turnip roots and leaves, the residue levels of the identified major metabolites were always below 0.01 mg eq/kg.

Consequently, the metabolism of prothioconazole in primary and rotational crops was found to be similar and a specific residue definition for rotational crops is not deemed necessary.

No rotational crop studies with prothioconazole radiolabelled on the triazole ring were assessed in the framework of the peer review but such studies were reported and assessed by the JMPR (FAO, 2008a, 2008b). These indicated a cleavage of the triazole linkage with the formation of the major metabolites found in all rotational crop matrices as triazole alanine [TA], triazole lactic acid [TLA] and triazole acetic acid TAA]. Both the parent prothioconazole and prothioconazole-desthio were identified as minor metabolites."

Overall, it can be concluded that the metabolism in primary and rotational crops is similar and the same residue definition for primary crops is appropriate to apply for rotational crops.

TDMs
During the peer review of TDMs, the metabolism of various triazole compounds in rotational and primary crops were investigated. It was concluded that for TDMs similar metabolic patterns were depicted both in primary and rotational crops. For details, please refer to the peer review of the pesticide risk assessment for the triazole derivative metabolites in light of confirmatory data submitted (EFSA, 2018b).

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.

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

Table 7.2-6: Nature of the residues in processed commodities

Conditions (Duration, Temperature, pH)	Stable	Identified compound(s) (%)	Reference
EU data (Prothioconazole)			

Conditions (Duration, Temperature, pH)	Stable	Identified compound(s) (%)	Reference
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)	JMPR: FAO, 2008a, 2008b 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)	KCA 6.6.1/01: Bloβ, K., 2019, Study No. S21-04814
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)	EFSA 2018b (amended 2019), EFSA 2020
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

Prothioconazole

The effect on the nature of prothioconazole and prothioconazole-desthio was investigated in the framework of the MRL review (EFSA, 2014). The MRL review referred to studies with prothioconazole investigated by the JMPR and studies with prothioconazole-desthio reported by Germany (EFSA, 2014). Prothioconazole-desthio was reported to be stable under all standard hydrolysis steps (99.4–99.9% applied radioactivity (AR)), whereas parent prothioconazole slightly degraded to prothioconazole-desthio under sterilisation process (≤ 11% AR). Other compounds which are included in the risk assessment residue definition and contain the 2-(1-chlorocyclopropl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, are expected to be stable under standard hydrolysis conditions, considering their structural similarity to parent compound (EFSA,2014).

A new hydrolysis study (KCA 6.6.1/01) with prothioconazole-desthio is submitted in the framework of this application, showing that [14C] 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.

TDMs

The TDMs are stable under hydrolysis studies simulating baking/brewing/boiling, pasteurisation and sterilisation (EFSA, 2018b). For details, please refer to the peer review of the pesticide risk assessment for the triazole derivative metabolites in light of confirmatory data submitted (UK, 2018b, EFSA, 2018b, amended 2019).

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.

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.

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

Table 7.2-7: 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) 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, since these compounds share the same toxicity; 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: Based on metabolism study results, the MRL review derived the following tentative conversion factors to account for hydroxy metabolites of prothioconazole-desthio: 2 in cereal grains, pulses and 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

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

Available data

No new data submitted in the framework of this application.

Table 7.2-8: 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-phenyl] prothioconazole	1	10 (250 mg a.s./kg feed)	3	Milk	Twice daily	[redacted] 2001a. Study No. MR-092/01, DAR, UK, 2004, IIA 6.2.2.1/01 (Not protected) EFSA,2007 EFSA, 2014
						Urine and faeces	Daily and at sacrifce	
						Tissues	At sacrifice	
		[U-^{14}C-phenyl] prothioconazole-desthio	1	10 (195 mg a.s./kg feed)	3	Milk	Twice daily	[redacted], 2002. Study No. MR-091/01, DAR, UK, 2004, IIA 6.2.2.2/01 (Not protected) EFSA,2007 EFSA, 2014
						Urine and faeces	Daily and at sacrifce	
						Tissues	At sacrifice	
		[3,5-^{14}C-triazole] prothioconazole	1	10	3	Milk	Twice daily	JMPR: FAO, 2008a, 2008b EFSA, 2014
						Urine and faeces	Daily and at sacrifce	
						Tissues	At sacrifice	
Laying poultry	Hens	[U-^{14}C-phenyl] prothioconazole	6	10	3	Eggs	Once daily	[redacted], 2001b. Study No. MR-309/01, DAR, UK, 2004, IIA 6.2.2.3/01 (Not protected) EFSA,2007
						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)	
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 acc. to the residue definition for risk assessment > 0.1 mg/kg of the total diet in fish feed (dry weight basis) are not to be expected.							

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

Summary of animal metabolism studies reported in the EU

EFSA, 2014: "It is noted that in poultry no study was performed with prothioconazole-desthio and that the fate of the triazole moiety in livestock was only investigated for prothioconazole. 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.

Based on the overall metabolic picture 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. It is noted that although only the glucuronide conjugates of prothioconazole-desthio were detected in milk, the actual residue levels are expected at a trace level at the calculated dietary burden (< 0.01 mg/kg) and EFSA considers that analysing the conjugates of prothioconazole-desthio would have a negligible impact on the residue levels enforced in milk. In case the livestock dietary burden is further increased in the future due to additional uses on feed items, the residue definition for enforcement might have to be revised by including the glucuronide conjugates of prothioconazole-desthio for all livestock matrices.

For risk assessment, since all the metabolites are structurally related to prothioconazole-desthio and consist mainly in hydroxylated derivatives, EFSA assumes as a worst case that the toxicological end points allocated to prothioconazole-desthio should also be applied to these metabolites. The residue is therefore 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). […] 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, EFSA concludes that the residue definition for enforcement in commodities of animal origin is fat soluble."

TDMs

According to EFSA, 2018b: "The compilation of the poultry and ruminant metabolism studies conducted with the triazole pesticide active substances with the 14C 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 14C-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 the 14C-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. 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":

RD for enforcement: Triazole parent compound only

RDs 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

Summary of new animal metabolism studies
No new data to be considered

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, EFSA concludes that the residue definition for enforcement in commodities of animal origin is fat soluble (EFSA 2014).

TDMs
"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" (EFSA, 2018b):

RD for enforcement:
Triazole parent compound only (prothioconazole-desthio (sum of isomers), see prothioconazole above)

RDs 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), see prothioconazole above;
2) 2) TA and TLA, since these compounds share the same toxicity;
3) 3) TAA;
4) 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.

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

Table 7.2-9: 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 (Triazole derived metabolites (TDMs))	Triazole parent compound only (EFSA, ~~2021~~ 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 (triazole derived metabolites (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 ~~2021~~)
Conversion factor	2 (liver); 9 (kidney) (EFSA, 2014) not necessary for milk, ruminant muscle and ruminant fat
Metabolism in rat and ruminant similar	Yes~~/No~~ The metabolic pathway of prothioconazole-desthio depicted in ruminants can be extrapolated to pigs
Fat soluble residue	Yes, log P_{OW} for prothioconazole-desthio (JAU 6476-desthio) = 3.04

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

Where applicable, reference is made to the EU peer review (EFSA, 2007, DAR UK, 2004 and 2007) and to the MRL review (EFSA, 2014 and 2020) for prothioconazole, as well as to the peer review of the triazole derivative metabolites (TDMs) in the light of confirmatory data submitted (UK, 2018b, EFSA, 2018b, amended 2019). In addition, new studies on the magnitude of residue are submitted by the applicant in the framework of this application. All studies are summarised in the summary tables below. The detailed assessment of the new studies is presented in Appendix 2.

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application. These studies are summarized in the table below. The detailed assessment of these studies is presented in Appendix 2. Please note that the studies refer to formulation code FGR06, a 250 g/L prothioconazole dispersible concentrate (DC) formulation. A justification for use of this formulation is provided below:

- As per SANTE/2019/12752, experience shows that emulsifiable concentrate (EC) and suspension concentrate (SC) formulations produce comparable residues, especially if the last application is more than seven days prior to harvest. As FHO04 is a SC formulation and FGR06 is a DC formulation (from a formulation perspective, a DC formulation would be considered fall somewhere between an EC and a SC formulation), comparable residues are expected considering that the last application of FHO04 is 35 days prior to harvest.
- FHO04 only contains one active substance (prothioconazole) for which residues in plants need to be determined (the active substance sulphur is included in Annex IV of Regulation (EC) No. 396/2005 and no residues in plants need to be determined). Prothioconazole is the only active substance in FGR06 and so FGR06 can be considered as a good representative formulation to assess prothioconazole residues in plants, from the use of FHO04.
- Residue trials with FGR06 showed no residues (< LOQ of 0.01 mg/kg) at harvest according to the residue definition for enforcement in wheat grains with no exceedance of current EU-MRL of 0.1 mg/kg for wheat. Considering such low residues, no exceedance of current EU-MRL of 0.1 mg/kg for wheat would likewise be expected for residue trials with the FHO04 formulation.

Prothioconazole
The intended critical GAP in wheat is covered by the representative EU GAP use of prothioconazole in wheat, as evaluated (EFSA 2007).

The respective data are not used for risk assessment in this dossier but new studies analysing for prothioconazole-desthio (sum of isomers) as well as for 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) are submitted with this dossier for wheat.
It is noted that in one of the decline residues trials in Northern France (FR04), there were residues of prothioconazole-desthio and the 5 hydroxy metabolites found in the untreated samples at various levels between <0.01 and 0.33 mg/kg in forage and straw. The residue levels were confirmed with the spare samples so contamination did not come from the lab and contamination may have come from a drift application from a neighbouring farmer application.
Residue values measured in the untreated specimens are around 10 times lower than the residue values measured in the treated forage and straw specimens of trial and the values measured in the treated specimens are in line with the values measured in the other field trials, therefore the residue levels in forage and straw can be considered acceptable. When reporting the MRLs from FR04, the highest value out of the three replicates was used in the risk assessment with the purpose of performing a ‘worst case’ consumer risk assessment.

TDMs

Residue studies with prothioconazole analysing for TDMs were evaluated during the peer review of the triazole derivative metabolites (UK, 2018b, EFSA, 2018b, amended 2019) but were considered not to be sufficiently supported by acceptable stability data. Therefore, the respective data are not cited here again but new residue studies investigating all TDMs and supported by storage stability data are submitted with this dossier.

It is noted that residues of TA, TAA and TLA were found in untreated control samples in forage (TA -0.30 mg/kg), straw (TAA - 0.22 mg/kg) and grain (TA - 0.33 mg/kg), This suggests the use of triazole pesticide active substances in previous seasons. When reporting the MRLs from FR04, the highest value out of the three replicates was used in the risk assessment with the purpose of performing a 'worst case' consumer risk assessment.

To address all relevant residue definitions, new studies are included, which investigate the following residue definitions as set in EFSA 2018b, EFSA 2020 and confirmed in EC Review Report 2021.

Enforcement: Prothioconazole-desthio (sum of isomers)

Risk Assessment: 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)
Triazole alanine (TA) and triazole lactic acid (TLA)
Triazole acetic acid (TAA)
1,2,4-triazole (1,2,4-T)

Table 7.2-10: Summary of EU reported and new data supporting the intended uses of FHO04 and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
E: Prothioconazole-desthio (sum of isomers). **RA: (A) 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);** **(B) Triazole alanine (TA) and triazole lactic acid (TLA);** **(C) Triazole acetic acid (TAA);** **(D) 1,2,4-triazole (1,2,4-triazole)**								
Wheat, durum, spelt, triticale Extrapolation from spring cereals to ↔ winter cereals Extrapolation from wheat → rye	EFSA 2007, DAR UK, 2004	N-EU	GAP on which EU a.s. assessment is based: 3× 0.2 kg as/ha, start BBCH 26-29 up to BBCH 69, 14-21 days interval, PHI 35 days, outdoor. Studies not relevant for envisaged GAP as newer residue definitions have subsequently come into force.	N/A				
	New trials KCA 6.3/01	N-EU	Trials GAP; 2 x 0.2 ka as/ha, last application BBCH 69, 14 days interval, PHI 35 days, outdoor. Wheat Grain:					
			E: 8 x <0.01	0.010	0.010	0.010	0.1	Yes
			RA: (A) 4 x <0.01, 0.01, 3 x 0.02	0.010	0.020	0.034	n.a.	n.a.
			(B): TA: 0.12, 0.17, 0.25, 0.27, 0.33, 0.41, 0.68, 0.74	0.300	0.740	1.282	n.a.	n.a.
			TLA: 8 x <0.01	0.010	0.010	0.010	n.a.	n.a.
			(C): TAA: 0.04, 0.05, 0.10, 0.11, 2 x 0.14, 0.16, 0.17	0.125	0.170	0.341	n.a.	n.a.
			(D): 1,2,4-Triazole: 8 x <0.01	0.010	0.010	0.010	n.a.	n.a.
			For livestock dietary burden assessment only: Wheat straw:					
			E: 0.07, 0.18, 2 x 0.19, 0.49, 0.59, 0.94, 3.30	0.340	3.300	5.032	n.a.	n.a.
			RA: (A) 0.51, 0.58, 0.78,1.12, 1.99, 2.69, 3.44, 9.30	1.555	9.300	14.253	n.a.	n.a.
			(B): TA: 2 x <0.01, 2 x 0.01, 0.02, 0.03, 0.04, 0.07	0.015	0.070	0.111	n.a.	n.a.
			TLA: 1 x <0.01, 2 x 0.02, 4 x 0.03, 0.13	0.030	0.190	0.252	n.a.	n.a.
			(C): TAA: <0.01, 0.01, 2 x 0.02, 3 x 0.04, 0.13	0.030	0.130	0.195	n.a.	n.a.
			(D): 1,2,4-Triazole: 8 x <0.01	0.010	0.010	0.01	n.a.	n.a.

* Source of EU MRL: Reg. (EU) 2024/1318. n/a: not applicable

Table 7.2-11: Comparison of intended and critical EU GAPS in wheat

Type of GAP	Number of applications	Application rate per treatment	Interval between application	Growth stage at last application	PHI (days)
Wheat					
cGAP EU (EFSA, 2007)	3	0.2 kg as /ha	14-21 days	69	35
cGAP EU (Art. 12, EFSA, 2014)	3	0.2 kg as /ha	14-21 days	69	35
Intended cGAP (1)*	2	0.2 kg as /ha	14 days	69	35

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

7.2.3.2 Conclusion on the magnitude of residues in plants

According to the available data, the intended outdoor uses on wheat and rye in N-EU are considered acceptable. According to EC technical guideline SANTE/2019/12752 extrapolation from wheat to rye is possible without restriction.

Eight trials (4 decline and 4 harvest) were located in Northern Europe (Northern France, Germany, Poland, Belgium, The Netherlands). The field sites were representative of wheat, grown in a way typical of the producing region in the test countries.

A widely range of pedo-climatic conditions were tested by selecting representative field sites located in distant regions (> 20 km between field sites). Furthermore, different cultivars were used following local good agricultural practices.

According to the available data, the intended uses on wheat are considered acceptable. Of the 8 trials conducted in wheat in Northern Europe no residues were found in wheat grain (below the LOQ of 0.01 mg/kg) apart from in low levels (0.02 mg/kg) in 3 trials, according to the residue definition for enforcement. The data submitted show that no exceedance of the EU MRL of 0.1 mg/kg for wheat, will occur.

For risk assessment, residues have also been determined as 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). Residues were always below the cumulative LOQ of 0.06 mg/kg for the sum of metabolites in wheat grain, at harvest.

Residues of TDMs according to the residue definition for risk assessment are provided in all 8 trials and are covered by the EU storage stability data available on TDMs (at least 6 months).

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)

Wheat, rye
Wheat and rye are the major crops in northern Europe (SANTE/2019/12752). A minimum of eight trials are required. Based on the SANTE/2019/12752, 8 residue trials on wheat can be used for extrapolation to rye, triticale and spelt before and after forming of the edible part. So the uses are also considered acceptable on rye, triticale and spelt.

Sufficient trials on wheat 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).

One magnitude of residue study was submitted in the framework of this application: F. Lebrun (2024), study Report No. 645-2023.
Summary is presented below.

Table 1: Comparison of intended and critical EU GAPs for wheat, rye

Type of GAP	Number of applica-tions	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU EFSA, 2007	3	0.2 kg as/ha	14-21 days	69	35
cGAP EU (Art. 12, EFSA, 2014)	3	0.2 kg as/ha	14-21 days	69	35
Intended cGAP (1)*	2	0.2 kg as /ha	14 days	69	35

Study 645-2023
Eight residue trials (4 decline and 4 harvest) on wheat were conducted in northern Europe in accordance with the following GAP: 2 x 200 g a.s. /ha, application interval - 14±1 days, 2nd application at BBCH 69, outdoor. Samples were taken at harvest.

Residues of prothioconazole-desthio in wheat grain at harvest were <0.01 mg/kg.
Total residue for prothioconazole (prothioconazole-desthio and all 5 hydroxy metabolites) in grain at harvest were between <0.01 mg/kg and 0.02 mg/kg.

Residues of 1,2,4-triazole and triazole lactic acid, in wheat grain at harvest were < 0.01 mg/kg.
Residues of triazole alanine, in wheat grain at harvest ranged between 0.12 and 0.74 mg/kg.
Residues of triazole acetic acid, in wheat grain at harvest ranged between 0.04 and 0.17 mg/kg.

Available results show that the in force MRL of prothioconazole on wheat of 0.1 mg/kg and on rye of 0.05 (Reg. (EU) 2024/1318) will not be exceeded. The current EU MRL for prothioconazole is sufficient to support the proposed uses.
The trials are supported by valid storage stability data and validated analytical methods.

The proposed uses on wheat, triticale, spelt and rye are considered acceptable.

7.2.4 Magnitude of residues in livestock

Reference is made to the EU peer review (EFSA, 2007, DAR UK, 2004 and 2007) and to the MRL review and modification (EFSA, 2014, 2020, 2022 and 2023) for prothioconazole,) as well as to the peer review of the triazole derivative metabolites (TDMs) in the light of confirmatory data submitted (UK, 2018b, EFSA, 2018b, amended 2019).

The following data gaps were identified during the UK 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, 2018b). These data gaps for prothioconazole are addressed by the TDMG study '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 and the TDMG study '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 Access Agreement is provided for this study.

7.2.4.1 Dietary burden calculation

Prothioconazole except TDMs
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. According to EFSA, 2020 "[…] new data on carrots, swedes, turnips and wheat were submitted in the framework of the assessment of the Article 12 confirmatory data application (UK, 2019a). 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, b, 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."

New dietary burden calculations using EFSA animal model 2017, based on the EFSA 2020 calculations and covering the envisaged GAP uses, are presented here. The input values as used in EFSA, 2020 for the latest exposure calculations for livestock are presented in the table below together with STMRs/HRs derived from the submitted residue studies covering the envisaged GAP uses of this dossier.

The more critical value (input values EFSA 2020 versus STMRs/HRs derived from the residue studies submitted with this dossier) is included in Table 7.2-12, however the more critical input values are from EFSA 2020. The detailed input values used in the Animal Model 2017 can be found in Appendix 4.

Table 7.2-12: 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	HR	1.5
Beet sugar, ensiled pulp (EFSA 2023)	1.08	STMER x PF(18)	1.08	STMR x PF(18)
Beet sugar, molasses	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 2020)	0.04	STMR × CF (2) × PF (2)[(a)] (EFSA, 2015a,b)	0.04	STMR × CF (2) × PF (2)[(a)] (EFSA, 2015a,b)
Head cabbage (EFSA 2020)	0.02	STMR × CF (EFSA, 2014)	0.12	STMR × CF (EFSA, 2014)
Corn silage (EFSA 2020)	0.01	STMR (EFSA, 2014)	0.01	STMR (EFSA, 2014)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Corn grain (EFSA 2020)	0.02	STMR (FAO, 2014) × CF (2) (EFSA, 2014)	0.02	STMR (FAO, 2014) × CF (2) (EFSA, 2014)
Corn, milled by-products[(b)]	0.02	STMR (FAO, 2014) × CF (2) (EFSA, 2014)	0.02	STMR (FAO, 2014) × CF (2) (EFSA, 2014)
Corn, hominy meal[(b)]	0.02	STMR (FAO, 2014) × CF (2) (EFSA, 2014)	0.02	STMR (FAO, 2014) × CF (2) (EFSA, 2014)
Corn gluten feed[(b)]	0.02	STMR (FAO, 2014) × CF (2) (EFSA, 2014)	0.02	STMR (FAO, 2014) × CF (2) (EFSA, 2014)
Corn gluten meal[(b)]	0.02	STMR (FAO, 2014) × CF (2) (EFSA, 2014)	0.02	STMR (FAO, 2014) × CF (2) (EFSA, 2014)
Distiller`s grain[(b)] (EFSA 2020)	0.02	STMR (FAO, 2014) × CF (2) (EFSA, 2014)	0.02	STMR (FAO, 2014) × CF (2) (EFSA, 2014)
Barley grain (EFSA 2020)	0.07	STMR (FAO, 2009b) × CF (2) (EFSA, 2014)	0.07	STMR (FAO, 2009b) × CF (2) (EFSA, 2014)
Brewer`s grain (EFSA 2020)	0.23	STMR barley grain (FAO, 2009b) × CF (2) (EFSA, 2014) × PF (3.3)[(a)]	0.23	STMR barley grain (FAO, 2009b) × CF (2) (EFSA, 2014) × PF (3.3)[(a)]
Oat grain (EFSA 2020)	0.02	STMR (FAO, 2009a) × CF (2) (EFSA, 2014)	0.02	STMR (FAO, 2009a) × CF (2) (EFSA, 2014)
Wheat grain (EFSA 2020)	0.04	STMR (FAO, 2009c) × CF (2) (EFSA, 2014)	0.04	STMR (FAO, 2009c) × CF (2) (EFSA, 2014)
Wheat grain (new trials)	0.01	STMR (new trials submitted but value covered by higher input used above.)	0.02	HR (new trials submitted but value covered by higher input used above.)
Wheat gluten meal[(b)] (EFSA 2020)	0.04	STMR wheat grain (FAO, 2009c) × CF (2) × PF (1.8)[(a)]	0.04	STMR wheat grain (FAO, 2009c) × CF (2) × PF (1.8)[(a)]
Wheat milled by-products[(b)] (EFSA 2020)	0.28	STMR wheat grain (FAO, 2009c) × CF (2) × PF (7)[(a)]	0.28	STMR wheat grain (FAO, 2009c) × CF (2) × PF (7)[(a)]
Rye grain (EFSA 2020)	0.02	STMR (FAO, 2009a) × CF (2)	0.02	STMR (FAO, 2009a) × CF (2)
Rye grain (new trials)	0.01	STMR (new trials submitted, extrapolated from wheat, but value covered by higher input used above.)	0.02	HR (new trials sub-mitted, extrapolated from wheat, but value covered by higher in-put used above.)
Barley straw (EFSA 2020)	1.96	STMR (FAO, 2009c) × CF (3) (EFSA, 2014)	7.50	HR[(d)] × CF (3) (EFSA, 2014)
Oats straw (EFSA 2020)	1.26	STMR[(d)] × CF (3) (EFSA, 2014)	7.50	HR[(d)] × CF (3) (EFSA, 2014)
Wheat straw (EFSA 2020)	2.69	STMR x CF (3)	5.52	HR[(d)] (EFSA, 2014) x CF (3 2.3)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Wheat straw (new trials)	0.59	STMR x CF (3) (new trials submitted but value covered by higher input used above.)	9.33	HR x CF (3)
Rye straw (EFSA 2020)	2.25	STMR[(d)] × CF (3) (EFSA, 2014)	5.52	HR[(d)] × CF (3) (EFSA, 2014)
Rye straw (new trials)	0.59	STMR x CF (3) (new trials submitted, extrapolated from wheat but value covered by higher input used above.)	5.99	HR x CF (3)
Cotton seed (EFSA 2020)	0.10	STMR (FAO,2018) x CF (2)	0.10	STMR (FAO, 2018) x CF (2) x PF (1.3)[(a)]
Cotton seed meal (EFSA 2020)	0.14	STMR (FAO, 2018) × CF (2) × PF (1.3)[(a)] STMR x PF (EFSA, 2020)	0.14	STMR (FAO, 2018) × CF (2) × PF (1.3)[(a)] STMR x PF (EFSA, 2020)
Beans (dry) (EFSA 2020)	0.02	STMR × CF (2) (EFSA, 2014)	0.02	STMR × CF (2) (EFSA, 2014)
Peas, lupins (dry) (EFSA 2020)	0.10	STMR (FAO, 2009c) × CF (2)	0.10	STMR (FAO, 2009c) × CF (2)
Lupin seed meal (EFSA 2020)	0.11	STMR (FAO, 2009b) x CF (2) x PF (1.1)[(a)]	0.11	STMR (FAO, 2009b) x CF (2) x PF (1.1)[(a)]
Potatoes (EFSA 2020)	0.01	STMR (EFSA, 2014)	0.01	HR (EFSA, 2014)
Potato process waste[(b)] Potato dried pulp[(b)] (EFSA 2020)	0.01	STMR potato (EFSA, 2014) × PF (1)[(c)]	0.01	HR potato (EFSA, 2014) × PF (1)[(c)]
Turnips, swede, carrot culls (EFSA 2020)	0.08	STMR	0.10	HR
Peanut meal (EFSA 2020)	0.04	STMR (FAO, 2009b) × CF (2) × PF (2)	0.04	STMR (FAO, 2009b) × CF (2) × PF (2)
Linseed meal (EFSA 2020)	0.12	STMR × CF (2) × PF (2)(a) (EFSA, 2015a,b)	0.12	STMR × CF (2) × PF (2)(a) (EFSA, 2015a,b)
Soybean seed (EFSA 2020)	0.10	STMR (FAO, 2014) × CF (2)	0.10	STMR (FAO, 2014) × CF (2)
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, 2009a,b) are lower than the values derived for cereals straws for the authorised EU uses reported in the MRL review.

Table 7.2-13: Results of the dietary burden calculation

Relevant groups	**Dietary burden expressed in**				**Most critical diet (a)**	**Most critical commodity (b)**		Trigger exceeded (Yes/No) 0.004 max. mg/kg bw	Previous assessment (EFSA 2023) Max burden mg/kg DM
	mg/kg bw per day		mg/kg DM						
	Median	Maximum	Median	Maximum					
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)	0.066	0.124	1.72	3.23	Dairy cattle	Barley	straw	Yes	3.23
Cattle (dairy only)	0.066	0.124	1.72	3.22	Dairy cattle	Barley	straw	Yes	3.22
Sheep (all diets)	0.077	0.236	1.81	5.55	Lamb	Barley	straw	Yes	5.55
Sheep (ewe only)	0.059	0.185	1.77	5.55	Ram/Ewe	Barley	straw	Yes	5.55
Swine (all diets)	0.022	0.030	0.95	1.32	Swine (breeding)	Beet, sugar	tops	Yes	1.32
Poultry (all diets)	0.035	0.088	0.52	1.29	Poultry layer	Wheat	straw	Yes	0.87
Poultry (layer only)	0.035	0.088	0.52	1.29	Poultry layer	Wheat	straw	Yes	0.87

bw: body weight; DM: dry matter

(a): When several diets are relevant (e.g. cattle, sheep and poultry "all diets"), the most critical diet is identified from the maximum dietary burdens expressed as "mg/kg bw per day"
(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as "mg/kg bw per day".

The above intake calculation shows an increase in the max. dietary burden for poultry (all diets and layer) from 0.87 mg/kg (EFSA, 2023) to 1.29 mg/kg DM, due to the higher maximum dietary burden input value for wheat straw. 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).

TDMs

Livestock dietary intake calculations for TDMs have been performed during EU peer review of the pesticide risk assessment for the triazole derivative metabolites (UK, 2018b and EFSA 2018b, amended 2019) and reference is made to the respective evaluation of EFSA 2018b: "The livestock dietary burden calculation has been performed respectively for each TDM compound and triggered livestock feeding studies for 1,2,4-T, TA, TAA and TLA, see chapter B.7.4 of the addendum (United Kingdom, 2015, 2018)."

The GAP uses on wheat is to be covered by these calculations as input values are covered by the highest residues found in the relevant primary residue trials. The respective input values can be found in the confirmatory data assessment on pp 354 to 363 (UK, 2018b).

Table 7.2-14: Comparison of input values for dietary burden calculation from confirmatory data assessment (UK 2018b, pp 354 to 363) 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 * default PF (2.5)	0.4	1	0.25	0.3	HR * default PF (2.5)	1.31	3.58	1.085	0.15
Alfalfa meal	HR * default PF (2.5)	0.4	1	0.25	0.3	HR * default PF (2.5)	1.31	3.58	1.085	0.15
Alfalfa silage	HR * default PF (1.1)	0.18	0.44	0.11	0.06	HR * 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 * default PF (3)	0.48	1.2	0.3	0.15	HR * default PF (3)	1.57	4.29	1.3	0.18
Clover silage	STMR * default PF (1)	0.16	0.4	0.1	0.05	HR * 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

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)				
Grass hay	STMR * default PF (3.5)	0.56	1.4	0.35	0.18	HR * default PF (3.5)	1.83	5	1.5	0.21
Grass silage	STMR * default PF (1.6)	0.26	0.64	0.16	0.08	HR * 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 **(0.015)**	0.37 **(0.030)**	0.24 **(0.030)**	0.12 **(0.010)**	HR	0.65 **(0.015)**	1.1 **(0.190)**	0.78 **(0.130)**	0.05 **(0.010)**
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 **(0.300)**	0.05 **(0.010)**	0.02 **(0.125)**	0.621 **(0.010)**	STMR	0.79 **(0.300)**	0.05 **(0.010)**	0.02 **(0.125)**	0.621 **(0.010)**
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 STMR* PF 0.32*0.52	0.1 STMR* PF 0.04*2.5	0.3 STMR* PF 0.05*0.52	0.3 STMR* default PF (5)	STMR-P	0.17 STMR* PF 0.32*0.52	0.1 STMR* PF 0.04*2.5	0.3 STMR* PF 0.05*0.52	0.3 STMR* 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
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 STMR* PF (1.039*1.4)	0.13 STMR* PF 0.065*2	0.24 STMR* PF 0.12*2	0.1	STMR* PF	1.45 STMR* PF (1.039*1.4)	0.13 STMR* PF 0.065*2	0.24 STMR* PF 0.12*2	0.1

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)				
					STMR* default PF (2)					STMR* default PF (2)
Citrus	STMR* P	0.17 STMR* PF (0.32*0.52)	0.1 STMR* PF 0.04*2.5	0.13 STMR* PF 0.05*2.5	0.5 STMR* default PF (10)	STMR-P				
Corn, field milled by-products	STMR* default PF (1)	0.62	0.02	0.79	0.05	STMR* default PF (1)	0.62	0.02	0.79	0.05
Corn, field, hominy meal.	STMR* default PF (6)	3.7	0.13	4.74	0.3	STMR* default PF (6)	3.7	0.13	4.74	0.3
Corn, field gluten feed	STMR* default PF (2.5)	1.6	0.06	1.98	0.13	STMR* default PF (2.5)	1.6	0.06	1.98	0.13
Corn, field, gluten meal	STMR* default PF (1)	0.62	0.02	0.79	0.05	STMR* default PF (1)	0.62	0.02	0.79	0.05
Cotton meal	STMR* PF	1.45 STMR* PF (1.039*1.4)	0.13 STMR* PF (0.065*2)	0.24 STMR* PF (0.12*2)	0.07 STMR* default PF (1.3)	STMR* default PF	1.45 STMR* PF (1.039*1.4)	0.13 STMR* PF (0.065*2)	0.24 STMR* PF (0.12*2)	0.07 STMR* default PF (1.3)
Distiller'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
Flaxseed/linseed meal	STMR* PF	1.45 STMR* PF (1.039*1.4)	0.13 STMR* PF (0.065*2)	0.24 STMR* PF (0.12*2)	0.1 STMR* default PF (2)	STMR*default PF (2)	1.45 STMR* PF (1.039*1.4)	0.13 STMR* PF (0.065*2)	0.24 STMR* PF (0.12*2)	0.1 STMR* default PF (2)
Lupin seed meal	STMR* default PF (1.1)	0.19	0.01	0.06	0.06	STMR* default PF (1.1)	0.19	0.01	0.06	0.06
Potato process waste	STMR* default PF (20)	3.7	0.42	1	1	STMR* default PF (20)	3.7	0.42	1	1
Potato dried pulp	STMR* default PF	6.99	0.8	1.9	1.9	STMR* default PF	6.99	0.8	1.9	1.9

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)				
	(38)					(38)				
Rape meal	STMR * default PF	1.45 STMR* PF (1.039*1.4)	0.13 STMR* PF (0.065*2)	0.24 STMR* PF (0.12*2)	0.1 STMR* default PF (2)	STMR * default PF	1.45 STMR* PF (1.039*1.4)	0.13 STMR* PF (0.065*2)	0.24 STMR* PF (0.12*2)	0.1 STMR* default PF (2)
Safflower meal	STMR * default PF	1.45 STMR*PF 1.039*1.4	0.13 STMR* PF (0.065*2)	0.24 STMR* PF (0.12*2)	0.1 STMR* default PF (2)	STMR * default PF	1.45 STMR*PF 1.039*1.4	0.13 STMR* PF (0.065*2)	0.24 STMR* PF (0.12*2)	0.1 STMR* default PF (2)
Soybean meal	STMR * default PF	1.45 STMR*PF 1.039*1.4	0.13 STMR* PF (0.065*2)	0.24 STMR* PF (0.12*2)	0.07 STMR* default PF (1.3)	STMR * default PF	1.45 STMR*PF 1.039*1.4	0.13 STMR* PF (0.065*2)	0.24 STMR* PF (0.12*2)	0.07 STMR* default PF (1.3)
Soybean hulls	STMR * default PF (13)	13.5	0.85	1.56	0.7	STMR * default PF (13)	13.5	0.85	1.56	0.7
Sugarcane molasses	STMR * default PF (32)	5.89	0.67	1.6	1.6	STMR * default PF (32)	5.89	0.67	1.6	1.6
Sunflower meal	STMR *PF	1.45 STMR*PF 1.039*1.4	0.13 STMR* PF (0.065*2)	0.24 STMR* PF (0.12*2)	0.1 STMR* default PF (2)	STMR *PF	1.45 STMR*PF 1.039*1.4	0.13 STMR* PF (0.065*2)	0.24 STMR* PF (0.12*2)	0.1 STMR* default PF (2)
Wheat gluten	STMR * default PF (1.8)	1.11	0.04	1.42	0.09	STMR * default PF (1.8)	1.11	0.04	1.42	0.09
Wheat milled by-products	STMR * default PF (7)	4.35	0.15	5.53	0.35	STMR * default PF (7)	4.35	0.15	5.53	0.35

The dietary burdens for 1,2,4-T, TA, TAA and TLA according to UK, 2018b are shown in Table 7.2- 18 to Table 7.2- 21, respectively.

Table 7.2-15: The median and maximum dietary burden for 1,2,4-Triazole

Relevant groups	Dietary burden expressed in				Most critical diet (a)	Most critical commodity (b)		Trigger exceeded (Yes/No)	Previous assessment
	mg/kg bw per day		mg/kg DM					0.004	Max burden
	Median	Maximum	Median	Maximum				mg/kg bw	mg/kg bw
Cattle (all diets)	0.104	0.109	3.60	3.75	Dairy cattle	Potato	process waste	Yes	
Cattle (dairy only)	0.104	0.109	2.70	2.83	Dairy cattle	Potato	process waste	Yes	
Sheep (all diets)	0.118	0.121	3.54	3.63	Ram/Ewe	Potato	process waste	Yes	
Sheep (ewe only)	0.118	0.121	3.54	3.63	Ram/Ewe	Potato	process waste	Yes	
Swine (all diets)	0.045	0.047	1.93	2.04	Swine (breeding)	Potato	process waste	Yes	
Poultry (all diets)	0.037	0.038	0.53	0.54	Poultry layer	Potato	dried pulp	Yes	
Poultry (layer only)	0.029	0.032	0.43	0.46	Poultry layer	Potato	dried pulp	Yes	
(a): When several diets are relevant (e.g. cattle, sheep and poultry "all diets"), the most critical diet is identified from the maximum dietary burdens expressed as "mg/kg bw per day"									
(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as "mg/kg bw per day".									

Table 7.2-16: The median and maximum dietary burden for TA

Relevant groups	Dietary burden expressed in				Most critical diet (a)	Most critical commodity (b)		Trigger exceeded (Yes/No)	Previous assessment
	mg/kg bw per day		mg/kg DM					0.004	Max burden
	Median	Maximum	Median	Maximum				mg/kg bw	mg/kg bw
Cattle (all diets)	0.376	0.405	12.97	13.63	Dairy Cattle	Potato	process waste	Yes	
Cattle (dairy only)	0.376	0.405	9.77	10.52	Dairy Cattle	Potato	process waste	Yes	
Sheep (all diets)	0.425	0.454	12.76	13.63	Ram/Ewe	Potato	process waste	Yes	
Sheep (ewe only)	0.425	0.454	12.76	13.63	Ram/Ewe	Potato	process waste	Yes	
Swine (all diets)	0.163	0.178	7.08	7.71	Swine (breeding)	Potato	process waste	Yes	
Poultry (all diets)	0.158	0.165	2.24	2.34	Poultry Broiler	Potato	dried pulp	Yes	
Poultry (layer only)	0.130	0.149	1.91	2.18	Poultry layer	Potato	dried pulp	Yes	
(a): When several diets are relevant (e.g. cattle, sheep and poultry "all diets"), the most critical diet is identified from the maximum dietary burdens expressed as "mg/kg bw per day"									
(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as "mg/kg bw per day".									

Table 7.2-17: The median and maximum dietary burden for TAA

Relevant groups	Dietary burden expressed in				Most critical diet (a)	Most critical commodity (b)		Trigger exceeded (Yes/No)	Previous assessment
	mg/kg bw per day		mg/kg DM					0.004	Max burden
	Median	Maximum	Median	Maximum				mg/kg bw	mg/kg bw
Cattle (all diets)	0.118	0.140	3.87	4.29	Dairy cattle	Potato	process waste	Yes	
Cattle (dairy only)	0.118	0.140	3.06	3.63	Dairy cattle	Potato	process waste	Yes	
Sheep (all diets)	0.153	0.170	3.80	4.37	Lamb	Wheat	milled bypdts	Yes	
Sheep (ewe only)	0.127	0.146	3.80	4.37	Ram/Ewe	Potato	process waste	Yes	
Swine (all diets)	0.108	0.109	3.60	3.76	Swine (finishing)	Wheat	milled bypdts	Yes	
Poultry (all diets)	0.138	0.140	1.98	2.05	Poultry broiler	Wheat	milled bypdts	Yes	
Poultry (layer only)	0.135	0.140	1.98	2.05	Poultry layer	Wheat	milled bypdts	Yes	
(a): When several diets are relevant (e.g. cattle, sheep and poultry "all diets"), the most critical diet is identified from the maximum dietary burdens expressed as "mg/kg bw per day"									
(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as "mg/kg bw per day".									

Table 7.2-18: The median and maximum dietary burden for TLA

Relevant groups	Dietary burden expressed in				Most critical diet (a)	Most critical commodity (b)		Trigger exceeded (Yes/No)	Previous assessment
	mg/kg bw per day		mg/kg DM					0.004	Max burden
	Median	Maximum	Median	Maximum				mg/kg bw	mg/kg bw
Cattle (all diets)	0.078	0.177	2.22	4.61	Dairy cattle	Grass	forage (fresh)	Yes	
Cattle (dairy only)	0.078	0.177	2.03	4.61	Dairy cattle	Grass	forage (fresh)	Yes	
Sheep (all diets)	0.079	0.187	2.36	5.61	Ram/Ewe	Grass	forage (fresh)	Yes	
Sheep (ewe only)	0.079	0.187	2.36	5.61	Ram/Ewe	Grass	forage (fresh)	Yes	
Swine (all diets)	0.026	0.055	1.11	2.37	Swine (breeding)	Grass	forage (fresh)	Yes	
Poultry (all diets)	0.021	0.055	0.31	0.77	Poultry layer	Clover	hay	Yes	
Poultry (layer only)	0.021	0.052	0.31	0.77	Poultry layer	Clover	hay	Yes	
(a): When several diets are relevant (e.g. cattle, sheep and poultry "all diets"), the most critical diet is identified from the maximum dietary burdens expressed as "mg/kg bw per day"									
(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as "mg/kg bw per day".									

The above intake calculations for the maximum dietary burden of livestock demonstrate that residues of T, TA, TAA and TLA are significant in the diets of livestock (>0.1 mg/kg in the diets on an 'as received' basis in accordance with Regulation (EC) 544/2011). The intakes are also above the trigger of 0.1 mg/kg applied on a DM basis (UK, 2018b).

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 summary submitted by the Applicant reflects the conclusions of the EFSA Reasoned Opinion (EFSA, 2020).
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), triazole alanine (TA) and triazole acetic acid (TAA) and triazole lactic acid (TLA) were found to exceed the trigger value of 0.1 mg/kg DM for all livestock groups.

It should be noted that the results of dietary burdens for TDMs taking into account the intended uses of FHO04/Patton Supra 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. Cereal grains are used as a fish feeding stuff. However, residues of prothioconazole-desthio were below the LOQ of 0.01 mg/kg in cereals grain. Residues above the trigger value of 0.1 mg/kg are therefore not expected. Further data are not required.

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

7.2.4.3 Prothioconazole

No new data were submitted in the framework of this application. The magnitude of prothioconazole residues in livestock was evaluated during EU review (UK, 2004 and 2007; EFSA, 2007) and during Article 12 MRL review (EFSA, 2014 and EFSA, 2020) and reference is made to the respective evaluations.

Available data
Prothioconazole

Table 7.2-19: 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, and 100 mg/kg in the diet (equivalent to 0.145, 0.909 and 3.636 mg/kg bw per d (UK 2007))	28	Milk Tissues (liver, kidney, muscle, fat)	24 times during study After sacrifice	UK, 2004 and 2007 EFSA, 2007

Ruminants and pigs (EFSA 2014):
"During the peer review under Directive 91/414/EEC, 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 7.2- 13]. 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 7.2- 23]. 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 7.2- 16), 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) 2024/1318 (Table 7.2- 23).

Poultry (EFSA 2014): "Finally, 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."

According to EFSA, 2020 the following applies with regard to residues in livestock: "The results of the dietary burden calculation are presented in Section B.2 [see Table 7.2- 16 above] and 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 7.2-20: 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)	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	0.15	3	<0.01	<0.01	n.a.	n.a.	<0.01	<0.01	0.01* (tentative)	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)	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* (tentative)	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)	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	0.15	3	<0.005[f]	N/A	n.a.	n.a.	<0.005	<0.005	0.005* (tentative)	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	0.15	3	<0.01	<0.01	n.a.	n.a.	<0.01	<0.01	0.01* (tentative)	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* (tentative)	1.0
			0.91	3	<0.01	0.01	n.a.	n.a.				

			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 (tentative)	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)	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 with regard to TDMs was evaluated during EU peer review of the pesticide risk assessment for the triazole derivative metabolites (UK, 2018b and EFSA 2018b, amended 2019) and reference is made to the respective evaluation.

EFSA 2018b: "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."

These data gaps for prothioconazole are addressed by the TDMG study 'Determination of the Triazole Derived Metabolites in Eggs and Tissues of Laying Hens following Multiple Oral Administration of Triazole Lactic Acid', [redacted], M., 2021, Report No. IF19-05004879, KCA 6.4.2/01 and the TDMG study '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. An Access Agreement is provided for this study.

Conclusion on feeding studies
The requested uses 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 FHO04/Patton Supra.

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

7.2.5.1 Available data for all crops under consideration

Reference is made to the EU peer review (EFSA, 2007, DAR UK, 2004 and 2007) and to the MRL reviews and modifications (EFSA, 2014, 2020, 2022 and 2023) for prothioconazole, the reasoned opinions (EFSA 2022 and 2023) as well as to the peer review of the triazole derivative metabolites (TDMs) in the light of confirmatory data submitted (UK, 2018b, EFSA, 2018b, amended 2019).

Data/information 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 beets has since been assessed, however one study is not sufficient to derive robust processing factors, (EFSA, 2023).

Prothioconazole

Any 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 wheat grain at commercial harvest. Based on the results of residue trials, significant residue levels will not occur in cereals at harvest. Accordingly, processing studies are not required.

TDMs

The residues of TDMs partly exceed 0.1 mg/kg in cereal grains (even though significant background residues in untreated samples were also observed in one of the trials). In cereal grain, 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 residues in the respective commodities and the low contribution dietary intake, any processing studies are not considered to be required.

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

Overview of the available processing studies

Regarding TDMs, processing factors for TA, TLA 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. The processing factors have been given for the sake of completeness.

1,2,4-Triazole

No processing factors are available. Residues in the animal feed items were <0.1 mg/kg and consequently the data requirements for processing are not triggered.

Triazole alanine

Crop	Processing factors available	Processing factor in livestock dietary	Comment

		burden calculation (UK 2018b)	
Bran	1.9, 2.2, 1.8, 3.0, 3.7, 2.2, 1.4	2.2	Median PF

Triazole acetic acid

Crop	Processing factors available	Processing factor in livestock dietary burden calculation (UK 2018b)	Comment
Bran	<1, 1.3, 1.3, 1.1, 2.1, 1.4, 1.7	1.3	Median PF

Triazole lactic acid
No processing factors are available. Residues in the animal feed items were <0.1 mg/kg and consequently the data requirements for processing are not triggered.

7.2.5.2 Conclusion on processing studies

Based on the results of residue trials, significant residue levels of prothioconazole will not occur in cereal grain and oilseed rape at harvest. Accordingly, any processing studies are not considered to be 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:
Information given by the Applicant is acceptable and sufficient.
As residues of prothioconazole exceeding 0.1 mg/kg are not expected in the treated crops, there is no need to investigate the magnitude of prothioconazole residues in processed commodities.

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

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)						
Wheat, aspirated grain fractions	NC	0.20	0.39	NA		UK, 2018
Wheat, Bran	NC	3.7	2.1	NA		
Wheat, Flour	NC	0.30	0.89	NA		
Wheat, Germ	NC	4.9	1.3	NC		
Wheat, Middlings	NC	0.66	0.80	NC		
Wheat, Shorts	NC	1.7	1.2	NC		

Calculated processing factors show concentration of TA and TAA in wheat bran, wheat germ and shorts.
No further data are required.

7.2.6 Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation.
Data dealing with magnitude of residues in succeeding crops are available and are summarized hereafter.

7.2.6.1 Field rotational crop studies (KCA 6.6.2)

Available data

Available data Reference is made to the EU peer review (EFSA, 2007, DAR UK, 2004 and 2007) and to the MRL review (EFSA, 2014 and 2020) for prothioconazole, as well as to the peer review of the triazole derivative metabolites (TDMs) in the light of confirmatory data submitted (UK, 2018b, EFSA, 2018b, amended 2019).

Table 7.2-21: 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					
Prothioconazole residues in rotational crops (Spring wheat, Swiss chard and turnip) were assessed in the metabolism study in rotational crops, with prothioconazole applied at 0.58 kg/ha (summarised in Table 7.2-5). Total residues declined between first and third rotations. Significant total residues (>0.1 mg/kg) were only found in wheat straw and hay and these were at similar or lower levels than those recorded for the directly treated spring wheat.					
For a summary of EU data on TDMs in rotational crops please refer to Table 7.2- 22					
New data					
(bare soil)	0.630	Root vegetables	Turnip	28 120 355	KCA 6.6.2-01: Semrau, J, 2022, Study No.: S22-02433
		Leafy vegetables	Leaf lettuce	28 120 355	
		Cereals	Wheat	28 120 355	

Prothioconazole

Since the intended application rates on cereals are within the range of application rates assessed in the MRL review, the same conclusions are applicable that residues of prothioconazole in rotational crops are expected to be covered by the residue levels in primary crops (EFSA 2014): “Based on the confined rotational crop study, considering that the application rate of prothioconazole within the EU ranges between 0.009 – 0.600 kg a.s./ha and due to the fact that prothioconazole was applied to a bare soil in the metabolism study (interception of prothioconazole by the plants is expected in practice), it can be concluded that prothioconazole residue levels in food and feed rotational commodities are expected to be covered by the residue levels in primary crops. Therefore, no risk mitigation measures (plant back restrictions) need to be proposed.”

TDMs

Rotational crop field trials with prothioconazole in which residues of triazole alanine (TA), triazole lactic acid (TLA), triazole acetic acid (TAA) and 1,2,4-triazole (1,2,4-triazole) were analysed for have been evaluated during EU peer review of the pesticide risk assessment for the triazole derivative metabolites (UK, 2018b, EFSA, 2018b, amended 2019) to which explicit reference is made.

UK 2018b:” Supervised field trials to investigate the residues in rotational crops after the use of FS and EC formulations containing 100 g/L and 250 g/L of prothioconazole were conducted at four test sites in Germany, the Netherlands, southern France and Spain. At each test site three ranges of plant-back intervals (20-35 days, 60-200 days and 270-365 days) and three crop groups (root crops represented by turnip and carrot, leafy crops represented by lettuce, cereals represented by barley) were investigated. In the trials simulating a crop failure (emergency rotation) the EC formulation was applied once to bare soil at the rate of 630 g as/ha of prothioconazole. The rotational crops were sown or planted 21-34 days after the

application. In the trials simulating a normal rotation the FS formulation was used to treat wheat seed at the rate of 15 g as/dt. The seed was sown at a nominal rate of 200 kg seed/ha and the wheat plants received 3 spray treatments at the rate of 200 g as/ha with the EC formulation. The treatments were conducted at the growth stages BBCH 32, BBCH 39 and BBCH 65-69, respectively, with intervals of 7-30 days between subsequent treatments. At harvest the wheat straw was ploughed in and the plot was left bare until rotational crops were sown or planted. 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 rotation and normal rotation is given below:

However, the peer review on the pesticide risk assessment for the TDMs in light of confirmatory data 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 of rotational crop field trial samples (EFSA, 2018b). To address this data gap, a new study, Semrau, J., 2022; Study No. S22-02433, KCA 6.6.2-01 has been commissioned to determine 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 the raw agricultural commodities turnip, leaf lettuce and wheat grown as rotational crops after one application of Prothioconazole 250g g/L EC on bare soil. This study 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 due January 2026.

Table 7.2-22: **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 (UK, 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

Regarding prothioconazole-desthio (sum of isomers), no study dealing with the magnitude of these residues in succeeding crops is required.

TDMs

The peer review of TDMs (EFSA,2018b) investigated the metabolism of triazole compounds in primary and rotational crops and concluded that for TDMs the metabolic patterns were similar, however a data gap was identified specific to prothioconazole: "Rotational crops field residue trials supported by acceptable storage stability data on TDMs".

zRMS comments:
Information given by the Applicant is acceptable.

No residues are expected in rotational crops for the intended uses of FHO04/Patton Supra, 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."

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

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of FHO04. Therefore, other special studies are not needed.

7.2.7.1 Residue level in pollen and bee products

Regarding potential residues in honey and other apiculture products, the following is to be said:
Prothioconazole is a systemic fungicide applied as a spray at BBCH 30 - 69 in spring and winter wheat any residues in pollen and bee products collected from treated crops are not to be expected for wheat as wheat has no melliferous capacity (SANTE/11956/2016 rev. 9).

zRMS comments:
Information given by the Applicant is acceptable.

The intended uses of FHO04/Patton Supra in cereals are expected to have little potential for contributing residues to bee products. This is in line with the technical guidelines SANTE/11956/2016 rev. 9, 14 September 2018. Other special studies including data on prothioconazole residues in pollen and bee products for human consumption are not considered necessary.
In our opinion, no further data is necessary to support the uses of FHO04/Patton Supra.

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

Prothioconazole
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 (EFSA, 2007).

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

The existing EU MRLs are set according to the residue definition for monitoring of prothioconazole: prothioconazole-desthio (sum of isomers). For commodities of plant origin, the current EU-MRLs (last update Reg. (EU) No 2024/1318) and the corresponding conversion factor of 2 for risk assessment were used as input values. For acute exposure calculations, only the crops under consideration were taken into account. For wheat and rye, where the values from the submitted residue trials exceed the values in Reg, (EU) 2024/1318, these new values are used in the risk assessment.

7.2.8.1 Input values for the consumer risk assessment

Table 7.2-23: Input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Prothioconazole: prothioconazole-desthio (sum of isomers) (F) **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)				
All plant commodities	EU-MRL	Reg. (EU) 2024/1318	EU-MRL (where applicable for supported crop uses)	Reg. (EU) 2024/1318
Prothioconazole: prothioconazole-desthio (sum of isomers) (F) **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)				
All animal commodities	EU-MRL	Reg. (EU) 2024/1318	EU-MRL	Reg. (EU) 2024/1318

7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.2-24: Consumer risk assessment for prothioconazole-desthio (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))

Prothioconazole – please see zRMS comments below in grey box.

All commodities

TMDI (% ADI) according to EFSA PRIMo	29% (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*	Lentils: 67% (based on unprocessed commodities, children) Lentils: 62% (based on unprocessed commodities, adults) Lentils /boiled: 81% (based on processed commodities, children) Beetroots/boiled: 33% (based on processed commodities, 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

Wheat

TMDI (% ADI) according to EFSA PRIMo	7% (based on GEMS/Food G06)
IEDI (% ADI) according to EFSA PRIMo	Further refinement not required as TMDI shows no exceedance
IESTI (% ARfD) according to EFSA PRIMo*	Wheat: 14% (based on unprocessed commodities, children) Wheat: 8% (based on unprocessed commodities, adults) Wheat/milling flour: 12% (based on processed commodities, children) Wheat/bread/pizza: 4% (based on processed commodities, adults)
NTMDI (% ADI) **	N/A
NEDI (% ADI)**	N/A
NESTI (% ARfD) **	N/A

The proposed uses of prothioconazole in the formulation FHO04 do not represent unacceptable acute and

chronic risks for the consumer.

TDMs
Consumer exposure assessments for all four TDMs have been conducted by UK, 2018b and EFSA 2018b during evaluation of the pesticide risk assessment for the triazole derivative metabolites in light of confirmatory data to which explicit reference is made. Input values were selected according to the following criteria:

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.

Any MRLs have not been set for the triazole derivative metabolites at EU-level yet

EFSA 2018b: "…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."

Table 7.2-25 1,2,4-Triazole: Input values for the consumer risk assessment (according to UK, 2018b)

Code	Commodity	existing/ proposed MRL	Source/ type of MRL	Chronic Input value	Comment	acute input value	comment
0110010	Grapefruits	N/A	N/A	0.05	STMR-RAC		
0110020	Oranges			0.05	STMR-RAC		
0110030	Lemons			0.05	STMR-RAC		
0110040	Limes			0.05	STMR-RAC		
0110050	Mandarins			0.05	STMR-RAC		
0110990	Others (2)			0.05	STMR-RAC		
0130010	Apples			0.01	STMR-RAC		
0130020	Pears			0.01	STMR-RAC		
0130030	Quinces			0.01	STMR-RAC		
0130040	Medlars			0.01	STMR-RAC		

0130050	Loquats/Japanese medlars			0.01	STMR-RAC		
0130990	Others (2)			0.01	STMR-RAC		
0140010	Apricots			0.01	STMR-RAC		
0140020	Cherries (sweet)			0.01	STMR-RAC		
0140030	Peaches			0.01	STMR-RAC		
0140040	Plums			0.01	STMR-RAC		
0140990	Other stone fruit			0.01	STMR-RAC		
0150000	Berries and small fruits			0.01	STMR-RAC		
0151000	grapes			0.01	STMR-RAC		
0151010	Table grapes			0.01	STMR-RAC		
0151020	Wine grapes			0.01	STMR-RAC		
0152000	strawberries			0.01	STMR-RAC		
0153010	Blackberries			0.01	STMR-RAC		
0153020	Dewberries			0.01	STMR-RAC		
0153030	Raspberries (red and yellow)			0.01	STMR-RAC		
0153990	Others (2)			0.01	STMR-RAC		
0154000	other small fruits and berries			0.01	STMR-RAC		
0154010	Blueberries			0.01	STMR-RAC		
0154020	Cranberries			0.01	STMR-RAC		
0154030	Currants (black, red and white)			0.01	STMR-RAC		
0154040	Gooseberries (green, red and yellow)			0.01	STMR-RAC		
0154050	Rose hips			0.01	STMR-RAC		
0154060	Mulberries (black and white)			0.01	STMR-RAC		
0154070	Azaroles/Mediterranean medlars			0.01	STMR-RAC		
0154080	Elderberries			0.01	STMR-RAC		
0154990	Others (2)			0.01	STMR-RAC		
0163020	Bananas			0.05	STMR-RAC		
0211000	potatoes			0.01	STMR-RAC		
0212010	Cassava roots/manioc			0.01	STMR-RAC		
0212020	Sweet potatoes			0.01	STMR-RAC		
0212030	Yams			0.01	STMR-RAC		
0212040	Arrowroots			0.01	STMR-RAC		
0212990	Others (2)			0.01	STMR-RAC		
0213010	Beetroots			0.01	STMR-RAC		
0213020	Carrots			0.01	STMR-RAC		
0213030	Celeriacs/turnip rooted celeries			0.01	STMR-RAC		
0213040	Horseradishes			0.01	STMR-RAC		
0213050	Jerusalem artichokes			0.01	STMR-RAC		
0213060	Parsnips			0.01	STMR-RAC		
0213070	Parsley roots/Hamburg roots parsley			0.01	STMR-RAC		
0213080	Radishes			0.01	STMR-RAC		
0213090	Salsifies			0.01	STMR-RAC		
0213100	Swedes/rutabagas			0.01	STMR-RAC		
0213110	Turnips			0.01	STMR-RAC		
0213990	Others (2)			0.01	STMR-RAC		
0220000	Bulb vegetables			0.01	STMR-RAC		
0220010	Garlic			0.01	STMR-RAC		

0220020	Onions			0.01	STMR-RAC		
0220030	Shallots			0.01	STMR-RAC		
0220040	Spring onions/green onions and Welsh onions			0.01	STMR-RAC		
0220990	Others (2)			0.01	STMR-RAC		
0231010	Tomatoes			0.01	STMR-RAC		
0231020	Sweet peppers/bell peppers			0.01	STMR-RAC		
0231030	Aubergines/eggplants			0.01	STMR-RAC		
0231040	Okra/lady's fingers			0.01	STMR-RAC		
0231990	Others (2)			0.01	STMR-RAC		
0232010	Cucumbers			0.01	STMR-RAC		
0232020	Gherkins			0.01	STMR-RAC		
0232030	Courgettes			0.01	STMR-RAC		
0232990	Others (2)			0.01	STMR-RAC		
0233010	Melons			0.01	STMR-RAC		
0233020	Pumpkins			0.01	STMR-RAC		
0233030	Watermelons			0.01	STMR-RAC		
0233990	Others (2)			0.01	STMR-RAC		
0234000	(d) sweet corn			0.01	STMR-RAC		
0241010	Broccoli			0.039	STMR-RAC		
0241020	Cauliflowers			0.039	STMR-RAC		
0241990	Others (2)			0.039	STMR-RAC		
0242010	Brussels sprouts			0.039	STMR-RAC		
0242020	Head cabbages			0.039	STMR-RAC		
0242990	Others (2)			0.039	STMR-RAC		
0243010	Chinese cabbages/pe-tsai			0.039	STMR-RAC		
0243020	Kales			0.039	STMR-RAC		
0243990	Others (2)			0.039	STMR-RAC		
0244000	Kohlrabies			0.039	STMR-RAC		
0251010	Lamb's lettuces/corn salads			0.015	STMR-RAC		
0251020	Lettuces			0.015	STMR-RAC		
0251030	Escaroles/broad-leaved endives			0.015	STMR-RAC		
0251040	Cresses and other sprouts and shoots			0.015	STMR-RAC		
0251050	Land cresses			0.015	STMR-RAC		
0251060	Roman rocket/rucola			0.015	STMR-RAC		
0251070	Red mustards			0.015	STMR-RAC		
0251080	Baby leaf crops (including brassica species)			0.015	STMR-RAC		
0251990	Others (2)			0.015	STMR-RAC		
0252010	Spinaches			0.015	STMR-RAC		
0252020	Purslanes			0.015	STMR-RAC		
0252030	Chards/beet leaves			0.015	STMR-RAC		
0252990	Others (2)			0.015	STMR-RAC		
0253000	grape leaves and similar species			0.015	STMR-RAC		
0254000	Watercresses			0.015	STMR-RAC		
0255000	Witloofs/Belgian endives			0.015	STMR-RAC		
0256010	Chervil			0.015	STMR-RAC		
0256020	Chives			0.015	STMR-RAC		

0256030	Celery leaves			0.015	STMR-RAC		
0256040	Parsley			0.015	STMR-RAC		
0256050	Sage			0.015	STMR-RAC		
0256060	Rosemary			0.015	STMR-RAC		
0256070	Thyme			0.015	STMR-RAC		
0256080	Basil and edible flowers			0.015	STMR-RAC		
0256090	Laurel/bay leaves			0.015	STMR-RAC		
0256100	Tarragon			0.015	STMR-RAC		
0256990	Others (2)			0.015	STMR-RAC		
0260010	Beans (with pods)			0.01	STMR-RAC		
0260020	Beans (without pods)			0.01	STMR-RAC		
0260030	Peas (with pods)			0.01	STMR-RAC		
0260040	Peas (without pods)			0.01	STMR-RAC		
0260050	Lentils			0.01	STMR-RAC		
0260990	Others (2)			0.01	STMR-RAC		
0270010	Asparagus			0.01	STMR-RAC		
0270020	Cardoons			0.01	STMR-RAC		
0270030	Celeries			0.01	STMR-RAC		
0270040	Florence fennels			0.01	STMR-RAC		
0270050	Globe artichokes			0.01	STMR-RAC		
0270060	Leeks			0.01	STMR-RAC		
0270070	Rhubarbs			0.01	STMR-RAC		
0270080	Bamboo shoots			0.01	STMR-RAC		
0270090	Palm hearts			0.01	STMR-RAC		
0270990	Others (2)			0.01	STMR-RAC		
0300010	Beans			0.05	STMR-RAC		
0300020	Lentils			0.05	STMR-RAC		
0300030	Peas			0.05	STMR-RAC		
0300040	Lupins/lupini beans			0.05	STMR-RAC		
0300990	Others (2)			0.05	STMR-RAC		
0401010	Linseeds			0.05	STMR-RAC		
0401020	Peanuts/groundnuts			0.05	STMR-RAC		
0401030	Poppy seeds			0.05	STMR-RAC		
0401040	Sesame seeds			0.05	STMR-RAC		
0401050	Sunflower seeds			0.05	STMR-RAC		
0401060	Rapeseeds/canola seeds			0.05	STMR-RAC		
0401070	Soyabeans			0.05	STMR-RAC		
0401080	Mustard seeds			0.05	STMR-RAC		
0401090	Cotton seeds			0.05	STMR-RAC		
0401100	Pumpkin seeds			0.05	STMR-RAC		
0401110	Safflower seeds			0.05	STMR-RAC		
0401120	Borage seeds			0.05	STMR-RAC		
0401130	Gold of pleasure seeds			0.05	STMR-RAC		
0401140	Hemp seeds			0.05	STMR-RAC		
0401150	Castor beans			0.05	STMR-RAC		
0401990	Others (2)			0.05	STMR-RAC		
0402000	Oil fruits				STMR-RAC		
0402010	Olives for oil production			0.05	STMR-RAC		
0402020	Oil palms kernels			0.05	STMR-RAC		
0402030	Oil palms fruits			0.05	STMR-RAC		
0402040	Kapok			0.05	STMR-RAC		
0402990	Others (2)			0.05	STMR-RAC		

0500010	Barley			0.05	STMR-RAC		
0500020	Buckwheat and other pseudocereals			0.05	STMR-RAC		
0500030	Maize/corn			0.05	STMR-RAC		
0500040	Common millet/proso millet			0.05	STMR-RAC		
0500050	Oat			0.05	STMR-RAC		
0500060	Rice			0.05	STMR-RAC		
0500070	Rye			0.05	STMR-RAC		
0500080	Sorghum			0.05	STMR-RAC		
0500090	Wheat			0.05	STMR-RAC	0.05	STMR-RAC
0500990	Others (2)			0.05	STMR-RAC		
0900010	Sugar beet roots			0.05	STMR-RAC		
0900020	Sugar canes			0.05	STMR-RAC		
0900030	Chicory roots			0.05	STMR-RAC		
0900990	Others (2)			0.05	STMR-RAC		
1011010	Swine: Muscle			0.1	STMR-RAC	0.21	HR-RAC
1011020	Swine: Fat			0.1	STMR-RAC	0.16	HR-RAC
1011030	Swine: Liver			0.12	STMR-RAC	0.19	HR-RAC
1011040	Swine: Kidney			0.13	STMR-RAC	0.25	HR-RAC
1012010	Bovine: Muscle			0.16	STMR-RAC	0.24	HR-RAC
1012020	Bovine: Fat			0.12	STMR-RAC	0.19	HR-RAC
1012030	Bovine: Liver			0.19	STMR-RAC	0.25	HR-RAC
1012040	Bovine: Kidney			0.2	STMR-RAC	0.28	HR-RAC
1013010	Sheep: Muscle			0.16	STMR-RAC	0.19	HR-RAC
1013020	Sheep: Fat			0.12	STMR-RAC	0.25	HR-RAC
1013030	Sheep: Liver			0.19	STMR-RAC	0.28	HR-RAC
1013040	Sheep: Kidney			0.2	STMR-RAC		
1014010	Goat: Muscle			0.16	STMR-RAC	0.19	HR-RAC
1014020	Goat: Fat			0.12	STMR-RAC	0.25	HR-RAC
1014030	Goat: Liver			0.19	STMR-RAC	0.28	HR-RAC
1014040	Goat: Kidney			0.2	STMR-RAC		
1016010	Poultry: Muscle			0.04	STMR-RAC	0.04	HR-RAC
1016020	Poultry: Fat			0.04	STMR-RAC	0.04	HR-RAC
1016030	Poultry: Liver			0.04	STMR-RAC	0.04	HR-RAC
1020010	Milk: Cattle			0.16	STMR-RAC	0.16	STMR-RAC
1020020	Milk: Sheep			0.16	STMR-RAC	0.16	STMR-RAC
1020030	Milk: Goat			0.16	STMR-RAC	0.16	STMR-RAC
1020040	Milk: Horse			0.16	STMR-RAC	0.16	STMR-RAC
1020990	Milk: Others (2)			0.16	STMR-RAC	0.16	STMR-RAC
1030010	Eggs: Chicken			0.04	STMR-RAC	0.04	HR-RAC
1030020	Eggs: Duck			0.04	STMR-RAC	0.04	HR-RAC
1030030	Eggs: Geese			0.04	STMR-RAC	0.04	HR-RAC
1030040	Eggs: Quail			0.04	STMR-RAC	0.04	HR-RAC
1030990	Eggs: Others (2)			0.04	STMR-RAC		
1040000	Honey and other apiculture products (7)			0.01	STMR-RAC		

Table 7.2-26 Triazole acetic acid (TAA): Input values for the consumer risk assessment (according to UK, 2018b)

Code	Commodity	existing/ proposed MRL	Source/ type of MRL	Chronic input value	Comment	Acute input value	comment
0110010	Grapefruits			0.05	STMR-RAC		
0110020	Oranges			0.05	STMR-RAC		

0110030	Lemons			0.05	STMR-RAC		
0110040	Limes			0.05	STMR-RAC		
0110050	Mandarins			0.05	STMR-RAC		
0110990	Others (2)			0.05	STMR-RAC		
0130010	Apples			0.03	STMR-RAC		
0130020	Pears			0.03	STMR-RAC		
0130030	Quinces			0.03	STMR-RAC		
0130040	Medlars			0.03	STMR-RAC		
0130050	Loquats/Japanese medlars			0.03	STMR-RAC		
0130990	Others (2)			0.03	STMR-RAC		
0140010	Apricots			0.02	STMR-RAC		
0140020	Cherries (sweet)			0.02	STMR-RAC		
0140030	Peaches			0.02	STMR-RAC		
0140040	Plums			0.02	STMR-RAC		
0140990	Other stone fruit			0.02	STMR-RAC		
0151010	Table grapes			0.05	STMR-RAC		
0151020	Wine grapes			0.05	STMR-RAC		
0152000	strawberries			0.05	STMR-RAC		
0153000	cane fruits			0.05	STMR-RAC		
0153010	Blackberries			0.05	STMR-RAC		
0153020	Dewberries			0.05	STMR-RAC		
0153030	Raspberries (red and yellow)			0.05	STMR-RAC		
0153990	Others (2)			0.05	STMR-RAC		
0154000	other small fruits and berries			0.05	STMR-RAC		
0154010	Blueberries			0.05	STMR-RAC		
0154020	Cranberries			0.05	STMR-RAC		
0154030	Currants (black, red and white)			0.05	STMR-RAC		
0154040	Gooseberries (green, red and yellow)			0.05	STMR-RAC		
0154050	Rose hips			0.05	STMR-RAC		
0154060	Mulberries (black and white)			0.05	STMR-RAC		
0154070	Azaroles/Mediterranean medlars			0.05	STMR-RAC		
0154080	Elderberries			0.05	STMR-RAC		
0154990	Others (2)			0.05	STMR-RAC		
0163020	Bananas			0.05	STMR-RAC		
0211000	potatoes			0.01	STMR-RAC		
0212010	Cassava roots/manioc			0.01	STMR-RAC		
0212020	Sweet potatoes			0.01	STMR-RAC		
0212030	Yams			0.01	STMR-RAC		
0212040	Arrowroots			0.01	STMR-RAC		
0212990	Others (2)			0.01	STMR-RAC		
0213010	Beetroots			0.01	STMR-RAC		
0213020	Carrots			0.01	STMR-RAC		
0213030	Celeriacs/turnip rooted celeries			0.01	STMR-RAC		
0213040	Horseradishes			0.01	STMR-RAC		
0213050	Jerusalem artichokes			0.01	STMR-RAC		
0213060	Parsnips			0.01	STMR-RAC		
0213070	Parsley roots/Hamburg roots parsley			0.01	STMR-RAC		

0213080	Radishes			0.01	STMR-RAC		
0213090	Salsifies			0.01	STMR-RAC		
0213100	Swedes/rutabagas			0.01	STMR-RAC		
0213110	Turnips			0.01	STMR-RAC		
0213990	Others (2)			0.01	STMR-RAC		
0220000	Bulb vegetables			0.01	STMR-RAC		
0220010	Garlic			0.01	STMR-RAC		
0220020	Onions			0.01	STMR-RAC		
0220030	Shallots			0.01	STMR-RAC		
0220040	Spring onions/green onions and Welsh onions			0.01	STMR-RAC		
0220990	Others (2)			0.01	STMR-RAC		
0231010	Tomatoes			0.01	STMR-RAC		
0231020	Sweet peppers/bell peppers			0.01	STMR-RAC		
0231030	Aubergines/eggplants			0.01	STMR-RAC		
0231040	Okra/lady's fingers			0.01	STMR-RAC		
0231990	Others (2)			0.01	STMR-RAC		
0232010	Cucumbers			0.01	STMR-RAC		
0232020	Gherkins			0.01	STMR-RAC		
0232030	Courgettes			0.01	STMR-RAC		
0232990	Others (2)			0.01	STMR-RAC		
0233010	Melons			0.01	STMR-RAC		
0233020	Pumpkins			0.01	STMR-RAC		
0233030	Watermelons			0.01	STMR-RAC		
0233990	Others (2)			0.01	STMR-RAC		
0234000	(d) sweet corn			0.01	STMR-RAC		
0241010	Broccoli			0.01	STMR-RAC		
0241020	Cauliflowers			0.01	STMR-RAC		
0242010	Brussels sprouts			0.01	STMR-RAC		
0242020	Head cabbages			0.01	STMR-RAC		
0242990	Others (2)			0.01	STMR-RAC		
0243010	Chinese cabbages/pe-tsai			0.01	STMR-RAC		
0243020	Kales			0.01	STMR-RAC		
0243990	Others (2)			0.01	STMR-RAC		
0244000	Kohlrabies			0.01	STMR-RAC		
0251010	Lamb's lettuces/corn salads			0.023	STMR-RAC		
0251020	Lettuces			0.023	STMR-RAC		
0251030	Escaroles/broad-leaved endives			0.023	STMR-RAC		
0251040	Cresses and other sprouts and shoots			0.023	STMR-RAC		
0251050	Land cresses			0.023	STMR-RAC		
0251060	Roman rocket/rucola			0.023	STMR-RAC		
0251070	Red mustards			0.023	STMR-RAC		
0251080	Baby leaf crops (including brassica species)			0.023	STMR-RAC		
0251990	Others (2)			0.023	STMR-RAC		
0252010	Spinaches			0.023	STMR-RAC		

0252020	Purslanes			0.023	STMR-RAC		
0252030	Chards/beet leaves			0.023	STMR-RAC		
0252990	Others (2)			0.023	STMR-RAC		
0253000	grape leaves and similar species			0.023	STMR-RAC		
0254000	Watercresses			0.023	STMR-RAC		
0255000	Witloofs/Belgian endives			0.023	STMR-RAC		
0256010	Chervil			0.023	STMR-RAC		
0256020	Chives			0.023	STMR-RAC		
0256030	Celery leaves			0.023	STMR-RAC		
0256040	Parsley			0.023	STMR-RAC		
0256050	Sage			0.023	STMR-RAC		
0256060	Rosemary			0.023	STMR-RAC		
0256070	Thyme			0.023	STMR-RAC		
0256080	Basil and edible flowers			0.023	STMR-RAC		
0256090	Laurel/bay leaves			0.023	STMR-RAC		
0256100	Tarragon			0.023	STMR-RAC		
0256990	Others (2)			0.023	STMR-RAC		
0260010	Beans (with pods)			0.01	STMR-RAC		
0260020	Beans (without pods)			0.01	STMR-RAC		
0260030	Peas (with pods)			0.01	STMR-RAC		
0260040	Peas (without pods)			0.01	STMR-RAC		
0260050	Lentils			0.01	STMR-RAC		
0260990	Others (2)			0.01	STMR-RAC		
0270010	Asparagus			0.02	STMR-RAC		
0270020	Cardoons			0.02	STMR-RAC		
0270030	Celeries			0.02	STMR-RAC		
0270040	Florence fennels			0.02	STMR-RAC		
0270050	Globe artichokes			0.02	STMR-RAC		
0270060	Leeks			0.02	STMR-RAC		
0270070	Rhubarbs			0.02	STMR-RAC		
0270080	Bamboo shoots			0.02	STMR-RAC		
0270090	Palm hearts			0.02	STMR-RAC		
0270990	Others (2)			0.02	STMR-RAC		
0300010	Beans			0.05	STMR-RAC		
0300020	Lentils			0.05	STMR-RAC		
0300030	Peas			0.05	STMR-RAC		
0300040	Lupins/lupini beans			0.05	STMR-RAC		
0300990	Others (2)			0.05	STMR-RAC		
0401010	Linseeds			0.12	STMR-RAC		
0401020	Peanuts/groundnuts			0.12	STMR-RAC		
0401030	Poppy seeds			0.12	STMR-RAC		
0401040	Sesame seeds			0.12	STMR-RAC		
0401050	Sunflower seeds			0.12	STMR-RAC		
0401060	Rapeseeds/canola seeds			0.12	STMR-RAC		
0401070	Soyabeans			0.12	STMR-RAC		
0401080	Mustard seeds			0.12	STMR-RAC		
0401090	Cotton seeds			0.12	STMR-RAC		
0401100	Pumpkin seeds			0.12	STMR-RAC		
0401110	Safflower seeds			0.12	STMR-RAC		
0401120	Borage seeds			0.12	STMR-RAC		
0401130	Gold of pleasure seeds			0.12	STMR-RAC		

0401140	Hemp seeds			0.12	STMR-RAC		
0401150	Castor beans			0.12	STMR-RAC		
0401990	Others (2)			0.12	STMR-RAC		
0402010	Olives for oil production			0.12	STMR-RAC		
0402020	Oil palms kernels			0.12	STMR-RAC		
0402030	Oil palms fruits			0.12	STMR-RAC		
0402040	Kapok			0.12	STMR-RAC		
0402990	Others (2)			0.12	STMR-RAC		
0500010	Barley			0.079	STMR-RAC		
0500020	Buckwheat and other pseudocereals			0.079	STMR-RAC		
0500030	Maize/corn			0.079	STMR-RAC		
0500040	Common millet/proso millet			0.079	STMR-RAC		
0500050	Oat			0.079	STMR-RAC		
0500060	Rice			0.079	STMR-RAC		
0500070	Rye			0.079	STMR-RAC		
0500080	Sorghum			0.079	STMR-RAC		
0500090	Wheat			0.079	STMR-RAC	0.079	STMR-RAC
0500990	Others (2)			0.079	STMR-RAC		
0900010	Sugar beet roots			0.05	STMR-RAC		
0900020	Sugar canes			0.05	STMR-RAC		
0900030	Chicory roots			0.05	STMR-RAC		
0900990	Others (2)			0.05	STMR-RAC		
1011010	Swine: Muscle			0.03	STMR-RAC	0.03	HR-RAC
1011020	Swine: Fat			0.03	STMR-RAC	0.03	HR-RAC
1011030	Swine: Liver			0.03	STMR-RAC	0.03	HR-RAC
1011040	Swine: Kidney			0.05	STMR-RAC	0.13	HR-RAC
1012010	Bovine: Muscle			0.03	STMR-RAC	0.03	HR-RAC
1012020	Bovine: Fat			0.03	STMR-RAC	0.03	HR-RAC
1012030	Bovine: Liver			0.03	STMR-RAC	0.03	HR-RAC
1012040	Bovine: Kidney			0.05	STMR-RAC	0.13	HR-RAC
1013010	Sheep: Muscle			0.03	STMR-RAC	0.03	HR-RAC
1013020	Sheep: Fat			0.03	STMR-RAC	0.03	HR-RAC
1013030	Sheep: Liver			0.03	STMR-RAC	0.03	HR-RAC
1013040	Sheep: Kidney			0.03	STMR-RAC	0.13	HR-RAC
1014010	Goat: Muscle			0.03	STMR-RAC	0.03	HR-RAC
1014020	Goat: Fat			0.03	STMR-RAC	0.03	HR-RAC
1014030	Goat: Liver			0.03	STMR-RAC	0.03	HR-RAC
1014040	Goat: Kidney			0.05	STMR-RAC	0.13	HR-RAC
1016010	Poultry: Muscle			0.03	STMR-RAC	0.03	HR-RAC
1016020	Poultry: Fat			0.03	STMR-RAC	0.03	HR-RAC
1016030	Poultry: Liver			0.03	STMR-RAC	0.03	HR-RAC
1020010	Milk: Cattle			0.03	STMR-RAC	0.13	STMR-RAC
1020020	Milk: Sheep			0.03	STMR-RAC	0.03	STMR-RAC
1020030	Milk: Goat			0.03	STMR-RAC	0.03	STMR-RAC
1020040	Milk: Horse			0.03	STMR-RAC	0.03	STMR-RAC
1020990	Milk: Others (2)			0.03	STMR-RAC	0.03	STMR-RAC
1030010	Eggs: Chicken			0.03	STMR-RAC	0.03	HR-RAC
1030020	Eggs: Duck			0.03	STMR-RAC	0.03	HR-RAC
1030030	Eggs: Geese			0.03	STMR-RAC	0.03	HR-RAC
1030040	Eggs: Quail			0.03	STMR-RAC	0.03	HR-RAC
1030990	Eggs: Others (2)			0.03	STMR-RAC	0.03	HR-RAC

1040000	Honey and other apiculture products (7)			0.01	STMR-RAC		

Table 7.2-27 Triazole alanine: Input values for the consumer risk assessment (according to UK, 2018b)

Code	Commodity	existing/ proposed MRL	Source/ type of MRL	Chronic Input value	Comment	acute input value	comment
0110010	Grapefruits	N/A	N/A	0.32	STMR-RAC		
0110020	Oranges			0.32	STMR-RAC		
0110030	Lemons			0.32	STMR-RAC		
0110040	Limes			0.32	STMR-RAC		
0110050	Mandarins			0.32	STMR-RAC		
0110990	Others (2)			0.32	STMR-RAC		
0130010	Apples			0.039	STMR-RAC		
0130020	Pears			0.039	STMR-RAC		
0130030	Quinces			0.039	STMR-RAC		
0130040	Medlars			0.039	STMR-RAC		
0130050	Loquats/Japanese medlars			0.039	STMR-RAC		
0130990	Others (2)			0.039	STMR-RAC		
0140010	Apricots			0.32	STMR-RAC		
0140020	Cherries (sweet)			0.32	STMR-RAC		
0140030	Peaches			0.32	STMR-RAC		
0140040	Plums			0.32	STMR-RAC		
0140990	Other stone fruit			0.32	STMR-RAC		
0151010	Table grapes			0.06	STMR-RAC		
0151020	Wine grapes			0.06	STMR-RAC		
0152000	strawberries			0.06	STMR-RAC		
0153000	cane fruits			0.06	STMR-RAC		
0153010	Blackberries			0.06	STMR-RAC		
0153020	Dewberries			0.06	STMR-RAC		
0153030	Raspberries (red and yellow)			0.06	STMR-RAC		
0153990	Others (2)			0.06	STMR-RAC		
0154000	other small fruits and berries			0.06	STMR-RAC		
0154010	Blueberries			0.06	STMR-RAC		
0154020	Cranberries			0.06	STMR-RAC		
0154030	Currants (black, red and white)			0.06	STMR-RAC		
0154040	Gooseberries (green, red and yellow)			0.06	STMR-RAC		
0154050	Rose hips			0.06	STMR-RAC		
0154060	Mulberries (black and white)			0.06	STMR-RAC		
0154070	Azaroles/Mediterranean medlars			0.06	STMR-RAC		
0154080	Elderberries			0.06	STMR-RAC		
0154990	Others (2)			0.06	STMR-RAC		
0163020	Bananas			0.05	STMR-RAC		
0211000	potatoes			0.184	STMR-RAC		
0212010	Cassava roots/manioc			0.184	STMR-RAC		
0212020	Sweet potatoes			0.184	STMR-RAC		
0212030	Yams			0.184	STMR-RAC		
0212040	Arrowroots			0.184	STMR-RAC		
0212990	Others (2)				STMR-RAC		
0213010	Beetroots			0.184	STMR-RAC		

0213020	Carrots			0.184	STMR-RAC		
0213030	Celeriacs/turnip rooted celeries			0.184	STMR-RAC		
0213040	Horseradishes			0.184	STMR-RAC		
0213050	Jerusalem artichokes			0.184	STMR-RAC		
0213060	Parsnips			0.184	STMR-RAC		
0213070	Parsley roots/Hamburg roots parsley			0.184	STMR-RAC		
0213080	Radishes			0.184	STMR-RAC		
0213090	Salsifies			0.184	STMR-RAC		
0213100	Swedes/rutabagas			0.184	STMR-RAC		
0213110	Turnips			0.184	STMR-RAC		
0213990	Others (2)			0.184	STMR-RAC		
0220000	Bulb vegetables				STMR-RAC		
0220010	Garlic			0.06	STMR-RAC		
0220020	Onions			0.06	STMR-RAC		
0220030	Shallots			0.06	STMR-RAC		
0220040	Spring onions/green onions and Welsh onions			0.06	STMR-RAC		
0220990	Others (2)			0.06	STMR-RAC		
0231010	Tomatoes			0.21	STMR-RAC		
0231020	Sweet peppers/bell peppers			0.21	STMR-RAC		
0231030	Aubergines/eggplants			0.21	STMR-RAC		
0231040	Okra/lady's fingers			0.21	STMR-RAC		
0231990	Others (2)			0.21	STMR-RAC		
0232010	Cucumbers			0.21	STMR-RAC		
0232020	Gherkins			0.21	STMR-RAC		
0232030	Courgettes			0.21	STMR-RAC		
0232990	Others (2)			0.21	STMR-RAC		
0233010	Melons			0.21	STMR-RAC		
0233020	Pumpkins			0.21	STMR-RAC		
0233030	Watermelons			0.21	STMR-RAC		
0233990	Others (2)			0.21	STMR-RAC		
0234000	(d) sweet corn			0.21	STMR-RAC		
0241010	Broccoli			0.17	STMR-RAC		
0241020	Cauliflowers			0.17	STMR-RAC		
0242010	Brussels sprouts			0.17	STMR-RAC		
0242020	Head cabbages			0.17	STMR-RAC		
0242990	Others (2)			0.17	STMR-RAC		
0243010	Chinese cabbages/pe-tsai			0.17	STMR-RAC		
0243020	Kales			0.17	STMR-RAC		
0243990	Others (2)			0.17	STMR-RAC		
0244000	Kohlrabies			0.17	STMR-RAC		
0251010	Lamb's lettuces/corn salads			0.047	STMR-RAC		
0251020	Lettuces			0.047	STMR-RAC		
0251030	Escaroles/broad-leaved endives			0.047	STMR-RAC		
0251040	Cresses and other sprouts and shoots			0.047	STMR-RAC		
0251050	Land cresses			0.047	STMR-RAC		

0251060	Roman rocket/rucola			0.047	STMR-RAC		
0251070	Red mustards			0.047	STMR-RAC		
0251080	Baby leaf crops (including brassica species)			0.047	STMR-RAC		
0251990	Others (2)			0.047	STMR-RAC		
0252010	Spinaches			0.047	STMR-RAC		
0252020	Purslanes			0.047	STMR-RAC		
0252030	Chards/beet leaves			0.047	STMR-RAC		
0252990	Others (2)			0.047	STMR-RAC		
0253000	grape leaves and similar species			0.047	STMR-RAC		
0254000	Watercresses			0.047	STMR-RAC		
0255000	Witloofs/Belgian endives			0.047	STMR-RAC		
0256010	Chervil			0.047	STMR-RAC		
0256020	Chives			0.047	STMR-RAC		
0256030	Celery leaves			0.047	STMR-RAC		
0256040	Parsley			0.047	STMR-RAC		
0256050	Sage			0.047	STMR-RAC		
0256060	Rosemary			0.047	STMR-RAC		
0256070	Thyme			0.047	STMR-RAC		
0256080	Basil and edible flowers			0.047	STMR-RAC		
0256090	Laurel/bay leaves			0.047	STMR-RAC		
0256100	Tarragon			0.047	STMR-RAC		
0256990	Others (2)			0.047	STMR-RAC		
0260010	Beans (with pods)			0.09	STMR-RAC		
0260020	Beans (without pods)			0.09	STMR-RAC		
0260030	Peas (with pods)			0.09	STMR-RAC		
0260040	Peas (without pods)			0.09	STMR-RAC		
0260050	Lentils			0.09	STMR-RAC		
0260990	Others (2)			0.09	STMR-RAC		
0270010	Asparagus			0.09	STMR-RAC		
0270020	Cardoons			0.09	STMR-RAC		
0270030	Celeries			0.09	STMR-RAC		
0270040	Florence fennels			0.09	STMR-RAC		
0270050	Globe artichokes			0.09	STMR-RAC		
0270060	Leeks			0.09	STMR-RAC		
0270070	Rhubarbs			0.09	STMR-RAC		
0270080	Bamboo shoots			0.09	STMR-RAC		
0270090	Palm hearts			0.09	STMR-RAC		
0270990	Others (2)			0.09	STMR-RAC		
0300010	Beans			0.17	STMR-RAC		
0300020	Lentils			0.17	STMR-RAC		
0300030	Peas			0.17	STMR-RAC		
0300040	Lupins/lupini beans			0.17	STMR-RAC		
0300990	Others (2)			0.17	STMR-RAC		
0401010	Linseeds			1.039	STMR-RAC		
0401020	Peanuts/groundnuts			1.039	STMR-RAC		
0401030	Poppy seeds			1.039	STMR-RAC		
0401040	Sesame seeds			1.039	STMR-RAC		
0401050	Sunflower seeds			1.039	STMR-RAC		

0401060	Rapeseeds/canola seeds			1.039	STMR-RAC		
0401070	Soyabeans			1.039	STMR-RAC		
0401080	Mustard seeds			1.039	STMR-RAC		
0401090	Cotton seeds			1.039	STMR-RAC		
0401100	Pumpkin seeds			1.039	STMR-RAC		
0401110	Safflower seeds			1.039	STMR-RAC		
0401120	Borage seeds			1.039	STMR-RAC		
0401130	Gold of pleasure seeds			1.039	STMR-RAC		
0401140	Hemp seeds			1.039	STMR-RAC		
0401150	Castor beans			1.039	STMR-RAC		
0401990	Others (2)			1.039	STMR-RAC		
0402000	Oil fruits			1.039	STMR-RAC		
0402010	Olives for oil production			1.039	STMR-RAC		
0402020	Oil palms kernels			1.039	STMR-RAC		
0402030	Oil palms fruits			1.039	STMR-RAC		
0402040	Kapok			1.039	STMR-RAC		
0402990	Others (2)			1.039	STMR-RAC		
0500010	Barley			0.621	STMR-RAC		
0500020	Buckwheat and other pseudocereals			0.621	STMR-RAC		
0500030	Maize/corn			0.621	STMR-RAC		
0500040	Common millet/proso millet			0.621	STMR-RAC		
0500050	Oat			0.621	STMR-RAC		
0500060	Rice			0.621	STMR-RAC		
0500070	Rye			0.621	STMR-RAC		
0500080	Sorghum			0.621	STMR-RAC		
0500090	Wheat			0.621	STMR-RAC	(0.74)	HR-RAC
0500990	Others (2)			0.621	STMR-RAC		
0900010	Sugar beet roots			0.05	STMR-RAC		
0900020	Sugar canes			0.05	STMR-RAC		
0900030	Chicory roots			0.05	STMR-RAC		
0900990	Others (2)			0.05	STMR-RAC		
1011010	Swine: Muscle			0.06	STMR-RAC	0.13	HR-RAC
1011020	Swine: Fat			0.03	STMR-RAC	0.1	HR-RAC
1011030	Swine: Liver			0.13	STMR-RAC	0.34	HR-RAC
1011040	Swine: Kidney			0.06	STMR-RAC	0.22	HR-RAC
1012010	Bovine: Muscle			0.06	STMR-RAC	0.23	HR-RAC
1012020	Bovine: Fat			0.03	STMR-RAC	0.11	HR-RAC
1012030	Bovine: Liver			0.13	STMR-RAC	0.35	HR-RAC
1012040	Bovine: Kidney			0.06	STMR-RAC	0.22	HR-RAC
1013010	Sheep: Muscle			0.06	STMR-RAC	0.23	HR-RAC
1013020	Sheep: Fat			0.03	STMR-RAC	0.11	HR-RAC
1013030	Sheep: Liver			0.13	STMR-RAC	0.35	HR-RAC
1013040	Sheep: Kidney			0.06	STMR-RAC	0.22	
1014010	Goat: Muscle			0.06	STMR-RAC	0.23	HR-RAC
1014020	Goat: Fat			0.03	STMR-RAC	0.11	HR-RAC
1014030	Goat: Liver			0.13	STMR-RAC	0.35	HR-RAC
1014040	Goat: Kidney			0.06	STMR-RAC	0.22	
1016010	Poultry: Muscle			0.04	STMR-RAC	0.11	HR-RAC
1016020	Poultry: Fat			0.03	STMR-RAC	0.09	HR-RAC
1016030	Poultry: Liver			0.09	STMR-RAC	0.22	HR-RAC
1020010	Milk: Cattle			0.02	STMR-RAC	0.02	STMR-RAC

1020020	Milk: Sheep			0.02	STMR-RAC	0.02	STMR-RAC
1020030	Milk: Goat			0.02	STMR-RAC	0.02	STMR-RAC
1020040	Milk: Horse			0.02	STMR-RAC	0.02	STMR-RAC
1020990	Milk: Others (2)			0.02	STMR-RAC	0.02	STMR-RAC
1030010	Eggs: Chicken			0.02	STMR-RAC	0.06	HR-RAC
1030020	Eggs: Duck			0.02	STMR-RAC	0.06	HR-RAC
1030030	Eggs: Geese			0.02	STMR-RAC	0.06	HR-RAC
1030040	Eggs: Quail			0.02	STMR-RAC	0.06	HR-RAC
1030990	Eggs: Others (2)			0.02	STMR-RAC	0.06	HR-RAC
1040000	Honey and other apiculture products (7)			0.01	STMR-RAC		

Table 7.2-28 Triazole lactic acid (TLA): Input values for the consumer risk assessment (according to UK, 2018b)

Code	Commodity	existing/ proposed MRL	Source/ type of MRL	Chronic input value	Comment	Acute input value	comment
0110010	Grapefruits	N/A	N/A	0.04	STMR-RAC		
0110020	Oranges			0.04	STMR-RAC		
0110030	Lemons			0.04	STMR-RAC		
0110040	Limes			0.04	STMR-RAC		
0110050	Mandarins			0.04	STMR-RAC		
0110990	Others (2)			0.04	STMR-RAC		
0130010	Apples			0.03	STMR-RAC		
0130020	Pears			0.03	STMR-RAC		
0130030	Quinces			0.03	STMR-RAC		
0130040	Medlars			0.03	STMR-RAC		
0130050	Loquats/Japanese medlars			0.03	STMR-RAC		
0130990	Others (2)			0.03	STMR-RAC		
0140010	Apricots			0.038	STMR-RAC		
0140020	Cherries (sweet)			0.038	STMR-RAC		
0140030	Peaches			0.038	STMR-RAC		
0140040	Plums			0.038	STMR-RAC		
0140990	Other stone fruit			0.038	STMR-RAC		
0151010	Table grapes			0.04	STMR-RAC		
0151020	Wine grapes			0.04	STMR-RAC		
0152000	strawberries			0.04	STMR-RAC		
0153000	cane fruits			0.04	STMR-RAC		
0153010	Blackberries			0.04	STMR-RAC		
0153020	Dewberries			0.04	STMR-RAC		
0153030	Raspberries (red and yellow)			0.04	STMR-RAC		
0153990	Others (2)			0.04	STMR-RAC		
0154000	other small fruits and berries			0.04	STMR-RAC		
0154010	Blueberries			0.04	STMR-RAC		
0154020	Cranberries			0.04	STMR-RAC		
0154030	Currants (black, red and white)			0.04	STMR-RAC		
0154040	Gooseberries (green, red and yellow)			0.04	STMR-RAC		
0154050	Rose hips			0.04	STMR-RAC		
0154060	Mulberries (black and white)			0.04	STMR-RAC		
0154070	Azaroles/Mediterranean medlars			0.04	STMR-RAC		
0154080	Elderberries			0.04	STMR-RAC		

0154990	Others (2)			0.04	STMR-RAC		
0211000	potatoes			0.021	STMR-RAC		
0212010	Cassava roots/manioc			0.021	STMR-RAC		
0212020	Sweet potatoes			0.021	STMR-RAC		
0212030	Yams			0.021	STMR-RAC		
0212040	Arrowroots			0.021	STMR-RAC		
0212990	Others (2)			0.021	STMR-RAC		
0213010	Beetroots			0.021	STMR-RAC		
0213020	Carrots			0.021	STMR-RAC		
0213030	Celeriacs/turnip rooted celeries			0.021	STMR-RAC		
0213040	Horseradishes			0.021	STMR-RAC		
0213050	Jerusalem artichokes			0.021	STMR-RAC		
0213060	Parsnips			0.021	STMR-RAC		
0213070	Parsley roots/Hamburg roots parsley			0.021	STMR-RAC		
0213080	Radishes			0.021	STMR-RAC		
0213090	Salsifies			0.021	STMR-RAC		
0213100	Swedes/rutabagas			0.021	STMR-RAC		
0213110	Turnips			0.021	STMR-RAC		
0213990	Others (2)			0.021	STMR-RAC		
0220010	Garlic			0.01	STMR-RAC		
0220020	Onions			0.01	STMR-RAC		
0220030	Shallots			0.01	STMR-RAC		
0220040	Spring onions/green onions and Welsh onions			0.01	STMR-RAC		
0220990	Others (2)			0.01	STMR-RAC		
0231010	Tomatoes			0.03	STMR-RAC		
0231020	Sweet peppers/bell peppers			0.03	STMR-RAC		
0231030	Aubergines/eggplants			0.03	STMR-RAC		
0231040	Okra/lady's fingers			0.03	STMR-RAC		
0231990	Others (2)			0.03	STMR-RAC		
0232010	Cucumbers			0.03	STMR-RAC		
0232020	Gherkins			0.03	STMR-RAC		
0232030	Courgettes			0.03	STMR-RAC		
0232990	Others (2)			0.03	STMR-RAC		
0233010	Melons			0.03	STMR-RAC		
0233020	Pumpkins			0.03	STMR-RAC		
0233030	Watermelons			0.03	STMR-RAC		
0233990	Others (2)			0.03	STMR-RAC		
0234000	(d) sweet corn			0.03	STMR-RAC		
0241010	Broccoli			0.01	STMR-RAC		
0241020	Cauliflowers			0.01	STMR-RAC		
0242010	Brussels sprouts			0.01	STMR-RAC		
0242020	Head cabbages			0.01	STMR-RAC		
0242990	Others (2)			0.01	STMR-RAC		
0243010	Chinese cabbages/pe-tsai			0.01	STMR-RAC		
0243020	Kales			0.01	STMR-RAC		
0243990	Others (2)			0.01	STMR-RAC		
0244000	Kohlrabies			0.01	STMR-RAC		

0251010	Lamb's lettuces/corn salads			0.08	STMR-RAC		
0251020	Lettuces			0.08	STMR-RAC		
0251030	Escaroles/broad-leaved endives			0.08	STMR-RAC		
0251040	Cresses and other sprouts and shoots			0.08	STMR-RAC		
0251050	Land cresses			0.08	STMR-RAC		
0251060	Roman rocket/rucola			0.08	STMR-RAC		
0251070	Red mustards			0.08	STMR-RAC		
0251080	Baby leaf crops (including brassica species)			0.08	STMR-RAC		
0251990	Others (2)			0.08	STMR-RAC		
0252010	Spinaches			0.08	STMR-RAC		
0252020	Purslanes			0.08	STMR-RAC		
0252030	Chards/beet leaves			0.08	STMR-RAC		
0252990	Others (2)			0.08	STMR-RAC		
0253000	grape leaves and similar species			0.08	STMR-RAC		
0254000	Watercresses			0.08	STMR-RAC		
0255000	Witloofs/Belgian endives			0.08	STMR-RAC		
0256010	Chervil			0.08	STMR-RAC		
0256020	Chives			0.08	STMR-RAC		
0256030	Celery leaves			0.08	STMR-RAC		
0256040	Parsley			0.08	STMR-RAC		
0256050	Sage			0.08	STMR-RAC		
0256060	Rosemary			0.08	STMR-RAC		
0256070	Thyme			0.08	STMR-RAC		
0256080	Basil and edible flowers			0.08	STMR-RAC		
0256090	Laurel/bay leaves			0.08	STMR-RAC		
0256100	Tarragon			0.08	STMR-RAC		
0256990	Others (2)			0.08	STMR-RAC		
0260010	Beans (with pods)			0.01	STMR-RAC		
0260020	Beans (without pods)			0.01	STMR-RAC		
0260030	Peas (with pods)			0.01	STMR-RAC		
0260040	Peas (without pods)			0.01	STMR-RAC		
0260050	Lentils			0.01	STMR-RAC		
0260990	Others (2)			0.01	STMR-RAC		
0270010	Asparagus			0.01	STMR-RAC		
0270020	Cardoons			0.01	STMR-RAC		
0270030	Celeries			0.01	STMR-RAC		
0270040	Florence fennels			0.01	STMR-RAC		
0270050	Globe artichokes			0.01	STMR-RAC		
0270060	Leeks			0.01	STMR-RAC		
0270070	Rhubarbs			0.01	STMR-RAC		
0270080	Bamboo shoots			0.01	STMR-RAC		
0270090	Palm hearts			0.01	STMR-RAC		
0270990	Others (2)			0.01	STMR-RAC		
0300010	Beans			0.01	STMR-RAC		
0300020	Lentils			0.01	STMR-RAC		
0300030	Peas			0.01	STMR-RAC		
0300040	Lupins/lupini beans			0.01	STMR-RAC		

0300990	Others (2)			0.01	STMR-RAC		
0401010	Linseeds			0.065	STMR-RAC		
0401020	Peanuts/groundnuts			0.065	STMR-RAC		
0401030	Poppy seeds			0.065	STMR-RAC		
0401040	Sesame seeds			0.065	STMR-RAC		
0401050	Sunflower seeds			0.065	STMR-RAC		
0401060	Rapeseeds/canola seeds			0.065	STMR-RAC		
0401070	Soyabeans			0.065	STMR-RAC		
0401080	Mustard seeds			0.065	STMR-RAC		
0401090	Cotton seeds			0.065	STMR-RAC		
0401100	Pumpkin seeds			0.065	STMR-RAC		
0401110	Safflower seeds			0.065	STMR-RAC		
0401120	Borage seeds			0.065	STMR-RAC		
0401130	Gold of pleasure seeds			0.065	STMR-RAC		
0401140	Hemp seeds			0.065	STMR-RAC		
0401150	Castor beans			0.065	STMR-RAC		
0401990	Others (2)			0.065	STMR-RAC		
0402010	Olives for oil production			0.065	STMR-RAC		
0402020	Oil palms kernels			0.065	STMR-RAC		
0402030	Oil palms fruits			0.065	STMR-RAC		
0402040	Kapok			0.065	STMR-RAC		
0402990	Others (2)			0.065	STMR-RAC		
0500010	Barley			0.022	STMR-RAC		
0500020	Buckwheat and other pseudocereals			0.022	STMR-RAC		
0500030	Maize/corn			0.022	STMR-RAC		
0500040	Common millet/proso millet			0.022	STMR-RAC		
0500050	Oat			0.022	STMR-RAC		
0500060	Rice			0.022	STMR-RAC		
0500070	Rye			0.022	STMR-RAC		
0500080	Sorghum			0.022	STMR-RAC		
0500090	Wheat			0.022	STMR-RAC	0.022	STMR-RAC
0500990	Others (2)			0.022	STMR-RAC		
0900010	Sugar beet roots			0.01	STMR-RAC		
0900020	Sugar canes			0.01	STMR-RAC		
0900030	Chicory roots			0.01	STMR-RAC		
0900990	Others (2)			0.01	STMR-RAC		
1012010	Bovine: Muscle			0.03	STMR-RAC	0.03	HR-RAC
1012020	Bovine: Fat			0.04	STMR-RAC	0.03	HR-RAC
1012030	Bovine: Liver			0.03	STMR-RAC	0.09	HR-RAC
1012040	Bovine: Kidney			0.03	STMR-RAC	0.04	HR-RAC
1013010	Sheep: Muscle			0.03	STMR-RAC	0.03	HR-RAC
1013020	Sheep: Fat			0.04	STMR-RAC	0.09	HR-RAC
1013030	Sheep: Liver			0.03	STMR-RAC	0.04	HR-RAC
1013040	Sheep: Kidney			0.03	STMR-RAC	0.03	HR-RAC
1014010	Goat: Muscle			0.03	STMR-RAC	0.03	HR-RAC
1014020	Goat: Fat			0.04	STMR-RAC	0.09	HR-RAC
1014030	Goat: Liver			0.03	STMR-RAC	0.04	HR-RAC
1014040	Goat: Kidney			0.03	STMR-RAC	0.03	HR-RAC
1016010	Poultry: Muscle			0.03	STMR-RAC	0.03	HR-RAC
1016020	Poultry: Fat			0.03	STMR-RAC	0.03	HR-RAC
1016030	Poultry: Liver			0.03	STMR-RAC	0.03	HR-RAC

1020010	Milk: Cattle			0.03	STMR-RAC	0.13	STMR-RAC
1020020	Milk: Sheep			0.03	STMR-RAC	0.03	STMR-RAC
1020030	Milk: Goat			0.03	STMR-RAC	0.03	STMR-RAC
1020040	Milk: Horse			0.03	STMR-RAC	0.03	STMR-RAC
1020990	Milk: Others (2)			0.03	STMR-RAC	0.03	STMR-RAC
1030010	Eggs: Chicken			0.03	STMR-RAC	0.03	HR-RAC
1030020	Eggs: Duck			0.03	STMR-RAC	0.03	HR-RAC
1030030	Eggs: Geese			0.03	STMR-RAC	0.03	HR-RAC
1030040	Eggs: Quail			0.03	STMR-RAC	0.03	HR-RAC
1030990	Eggs: Others (2)			0.03	STMR-RAC	0.03	HR-RAC
1040000	Honey and other apiculture products (7)			0.01	STMR-RAC		

TDMs

Table 7.2-29: 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	**Normal Mode** 52% (NL toddler) 1st contributor: 42% Milk: Cattle 2nd contributor: 2% Maize/corn 3rd contributor: 1% Bananas **Refined mode** As above
IESTI (% ARfD) according to EFSA PRIMo*	**Normal Mode** Milk: Cattle: 20% (based on unprocessed commodities, children) Milk: Cattle: 6% (based on unprocessed commodities, adults) Sugar beets (roots)/sugar: 6% (based on processed commodities, children) Sugar beets (roots)/sugar: 2% (based on processed commodities, adults) **Refined mode** Wheat/milling (flour): 0.6% (based on processed commodities, children) Wheat/bread/pizza: 0.2% (based on processed commodities, 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 FHO04 do not represent unacceptable acute and chronic risks for the consumer with regard to residues of 1,2,4-Triazole.

Table 7.2-30: 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

	Refined mode 0.1% (GEMS/Food G06) 1st contributor: 0.1% Wheat
IESTI (% ARfD) according to EFSA PRIMo*	**Normal Mode** Milk: Cattle: 1% (based on unprocessed commodities, children) Milk: Cattle: 0.4% (based on unprocessed commodities, adults) Oranges/juice: 0.7% (based on processed commodities, children) Apples/juice: 0.3% (based on processed commodities, adults) **Refined mode** Wheat: 0.1% (based on unprocessed commodities, children) Wheat: 0.06% (based on unprocessed commodities, adults) Wheat/milling (flour): 0.1% (based on processed commodities, children) Wheat/bread/pizza: 0.0% (based on processed commodities, 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 FHO04 do not represent unacceptable acute and chronic risks for the consumer with regard to residues of triazole lactic acid (TLA).

Table 7.2-31: 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) **Refined mode** Wheat: 1% (based on unprocessed commodities, children) Wheat/milling (flour): 0.1% (based on processed commodities, children) Wheat/bread/pizza: 0.0% (based on processed commodities, 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 FHO04 do not represent unacceptable acute and chronic risks for the consumer with regard to residues of triazole acetic acid (TAA).

Table 7.2-32: Consumer risk assessment for Triazole Alanine (TA)

TMDI (% ADI) according to EFSA PRIMo	Not applicable, no MRLs set.
IEDI (% ADI) according to EFSA PRIMo	**Normal Mode** 5% (NL toddler) 1st contributor: 1% Maize/Corn 2nd contributor: 0.4% Milk: Cattle 3rd contributor: 0.4% Wheat **Refined mode** 0.7% GEMS/Food G06 1st contributor: 0.7% Wheat
IESTI (% ARfD) according to EFSA PRIMo*	**Normal Mode** Wheat: 4% (based on unprocessed commodities, children) Wheat: 2% (based on unprocessed commodities, adults) Oranges/juice 6% (based on processed commodities, children) Maize/oil: 3% (based on processed commodities, adults) **Refined mode** Wheat: 4% (based on unprocessed commodities, children) Wheat: 2% (based on unprocessed commodities, adults) Wheat/milling (flour): 1% (based on processed commodities, children) Wheat/bread/pizza: 0. 4% (based on processed commodities, 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 FHO04 do not represent unacceptable acute and chronic risks for the consumer with regard to residues of triazole alanine (TA).

zRMS comments:
Calculations of the TDMI and IESTI were conducted by evaluator.
TMDI calculation was performed using the in-force MRLs (Regulation (EU) 2024/1318). The following conversion factors for enforcement to risk assessment were used:
- Oilseeds: 2 (derived from residue trials) (EFSA, 2014)
- Wheat: 2 (derived from residue trials) (EFSA, 2014)
- Root and tuber vegetables (except sugar beet): 2.7 (EFSA, 2020)
- Potatoes: 1 (derived from metabolism study) (EFSA, 2014)
- Maize: 1 (derived from metabolism study) (EFSA, 2014)
- Cranberries and Sweet corn: no conversion factor was available as the MRLs for these crops originate from CXLs which are derived according to a different residue definition
- 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 (EFSA, 2020)

- Ruminant and pig liver: 2 (EFSA, 2014)
- Ruminant and pig kidney: 9 (EFSA, 2014)

Input values for the consumer risk assessment for IESTI calculation:

Commodity	Acute risk assessment	
	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)		
Wheat, rye	0.01 x 2	STMR x CF (2)
Muscle of swine, bovine, sheep, goat, equine, other farmed animals	0.01	HR[(a)] (FAO, 2018)
Fat of swine, bovine, sheep, goat, equine, other farmed animals	0.018	HR[(a)] (FAO, 2018)
Liver of swine, bovine, sheep, goat, equine, other farmed animals	0.23	HR[(a)] (FAO, 2009b)
Kidney, edible offal of swine, bovine, sheep, goat, equine, other farmed animals	0.15	HR[(a)] (FAO, 2009b)
Muscle of poultry	0.0016	HR[(a)] (FAO, 2018)
Fat of poultry	0.008	HR[(a)] (FAO, 2018)
Liver, kidney, edible offal of poultry	0.071	HR[(a)] (FAO, 2018)
Milk	0.005	HR (EFSA, 2014)
Eggs	0.01	HR (EFSA, 2014)

STMR: supervised trials median residue; HR: highest residue;
CF: conversion factor for enforcement to risk assessment residue definition.
(a): Values refer to the sum of prothioconazole-desthio, prothioconazole-desthio-3-hydroxy, prothioconazole-desthio-4-hydroxyand their conjugates expressed as prothioconazole-desthio

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.

EFSA PRIMo revision 3.1; 2019/03/19

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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
42%	NL toddler	4,22	8%	Wheat	7%	Maize/corn	6%	Milk: Cattle		
36%	GEMS/Food G11	3,63	15%	Soyabeans	7%	Wheat	3%	Barley		
35%	GEMS/Food G10	3,52	13%	Soyabeans	8%	Wheat	2%	Barley		
34%	GEMS/Food G15	3,43	9%	Wheat	7%	Soyabeans	3%	Barley		
34%	GEMS/Food G07	3,39	8%	Wheat	7%	Soyabeans	2%	Barley		
34%	GEMS/Food G06	3,38	14%	Wheat	5%	Soyabeans	2%	Peas		
34%	GEMS/Food G08	3,36	8%	Wheat	8%	Soyabeans	4%	Barley		
25%	IE adult	2,53	6%	Peas	5%	Wheat	3%	Lentils		
25%	NL child	2,46	8%	Wheat	3%	Sugar beet roots	2%	Milk: Cattle		
25%	FR child 3 15 yr	2,46	9%	Wheat	4%	Lentils	2%	Milk: Cattle		
23%	DK child	2,34	9%	Wheat	6%	Rye	4%	Carrots		
22%	ES child	2,22	9%	Wheat	5%	Lentils	2%	Peas		
22%	RO general	2,20	10%	Wheat	3%	Sunflower seeds	3%	Head cabbages		
21%	UK infant	2,09	5%	Wheat	4%	Milk: Cattle	4%	Carrots		
20%	DE child	2,04	8%	Wheat	3%	Carrots	2%	Milk: Cattle		
20%	FR toddler 2 3 yr	1,97	6%	Wheat	3%	Milk: Cattle	2%	Lentils		
18%	UK toddler	1,75	8%	Wheat	2%	Milk: Cattle	1%	Carrots		
16%	IT toddler	1,64	13%	Wheat	0,7%	Lentils	0,5%	Carrots		
16%	PT general	1,56	8%	Wheat	2%	Carrots	1%	Soyabeans		
16%	SE general	1,55	6%	Wheat	2%	Carrots	1%	Milk: Cattle		
14%	NL general	1,37	4%	Wheat	1%	Barley	0,9%	Sugar beet roots		
14%	ES adult	1,37	5%	Wheat	2%	Lentils	2%	Barley		
13%	DE general	1,34	4%	Wheat	2%	Barley	1%	Sugar beet roots		
13%	DE women 14-50 yr	1,26	4%	Wheat	1%	Sugar beet roots	1%	Milk: Cattle		
11%	FR adult	1,12	4%	Wheat	1%	Lentils	0,5%	Carrots		
11%	IT adult	1,07	8%	Wheat	0,4%	Carrots	0,4%	Lentils		
10%	FI 3 yr	1,05	2%	Wheat	2%	Carrots	0,9%	Potatoes		
10%	FR infant	1,02	3%	Carrots	2%	Milk: Cattle	2%	Wheat		
9%	FI 6 yr	0,90	2%	Wheat	2%	Carrots	1%	Peas		
9%	UK vegetarian	0,89	4%	Wheat	0,8%	Lentils	0,6%	Carrots		
7%	FI adult	0,75	3%	Coffee beans	0,9%	Carrots	0,7%	Peas		
7%	LT adult	0,73	2%	Wheat	1%	Rye	0,7%	Head cabbages		
7%	UK adult	0,70	3%	Wheat	0,5%	Carrots	0,3%	Milk: Cattle		
7%	DK adult	0,67	2%	Wheat	1%	Carrots	0,5%	Milk: Cattle		
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		

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.

An acute consumer risk assessment was performed only for the crops under consideration , based on the STMRs of wheat, rye and animals commodities and appropriate conversion factors for enforcement to risk assessment. The IESTI is at 19% of the ARfD for the consumption of Bovine:Liver by children and at 16% of the ARfD for the consumption of Swine:Other products by adults respectively.

Acute risk assessment /children | **Acute risk assessment / adults / general population** | **Acute risk assessment /children** | **Acute risk assessment / adults / general population**

Details - acute risk assessment /children | Details - acute risk assessment/adults | Hide IESTI new calculations | Show IESTI new calculations

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

IESTI new calculations:
The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.
Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.

Show results for all crops

Unprocessed commodities

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

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
19%	Bovine: Liver	0,23 / 0,23	1,9	16%	Swine: Other products	0,5 / 0,5	1,6
11%	Bovine: Edible offals	0,15 / 0,15	1,1	10%	Bovine: Other products	0,5 / 0,5	1,00
6%	Milk: Cattle	0,01 / 0,01	0,62	9%	Bovine: Liver	0,23 / 0,23	0,92
6%	Bovine: Kidney	0,15 / 0,15	0,56	6%	Sheep: Liver	0,23 / 0,23	0,64
5%	Swine: Edible offals	0,15 / 0,15	0,45	5%	Bovine: Edible offals (other	0,15 / 0,15	0,50
3%	Wheat	0,01 / 0,02	0,29	4%	Swine: Edible offals (other	0,15 / 0,15	0,39
3%	Swine: Liver	0,23 / 0,23	0,28	3%	Poultry: Liver	0,07 / 0,07	0,33
2%	Swine: Kidney	0,15 / 0,15	0,19	3%	Swine: Kidney	0,15 / 0,15	0,33
2%	Honey and other	0,05 / 0,05	0,18	3%	Swine: Liver	0,23 / 0,23	0,32
1%	Rye	0,01 / 0,02	0,13	3%	Bovine: Kidney	0,15 / 0,15	0,32
1%	Eggs: Chicken	0,01 / 0,01	0,12	2%	Milk: Cattle	0,01 / 0,01	0,19
1%	Swine: Muscle/meat	0,01 / 0,01	0,12	2%	Wheat	0,01 / 0,02	0,17
1%	Milk: Goat	0,01 / 0,01	0,12	1%	Sheep: Edible offals (other	0,15 / 0,15	0,10
0,8%	Poultry: Liver	0,07 / 0,07	0,08	1,0%	Rye	0,01 / 0,02	0,10
0,7%	Bovine: Muscle/meat	0,01 / 0,01	0,07	0,9%	Milk: Goat	0,01 / 0,01	0,09

Expand/collapse list

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

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

IESTI new
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)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
19%	Bovine: Liver	0,23 / 0,23	1,9	16%	Swine: Other products	0,5 / 0,5	1,6
11%	Bovine: Edible offals	0,15 / 0,15	1,1	10%	Bovine: Other products	0,5 / 0,5	1,00
6%	Milk: Cattle	0,01 / 0,01	0,62	9%	Bovine: Liver	0,23 / 0,23	0,92
6%	Bovine: Kidney	0,15 / 0,15	0,56	6%	Sheep: Liver	0,23 / 0,23	0,64
5%	Swine: Edible offals	0,15 / 0,15	0,45	5%	Bovine: Edible offals (other than	0,15 / 0,15	0,50
3%	Wheat	0,01 / 0,02	0,29	4%	Swine: Edible offals (other than	0,15 / 0,15	0,39
3%	Swine: Liver	0,23 / 0,23	0,28	3%	Poultry: Liver	0,07 / 0,07	0,33
2%	Swine: Kidney	0,15 / 0,15	0,19	3%	Swine: Kidney	0,15 / 0,15	0,33
2%	Honey and other	0,05 / 0,05	0,18	3%	Swine: Liver	0,23 / 0,23	0,32
1%	Rye	0,01 / 0,02	0,13	3%	Bovine: Kidney	0,15 / 0,15	0,32
1%	Other farmed animals:	0,01 / 0,02	0,12	2%	Milk: Cattle	0,01 / 0,01	0,19
1%	Eggs: Chicken	0,01 / 0,01	0,12	2%	Wheat	0,01 / 0,02	0,17
1%	Swine: Muscle/meat	0,01 / 0,01	0,12	1%	Sheep: Edible offals (other than	0,15 / 0,15	0,10
1%	Milk: Goat	0,01 / 0,01	0,12	1%	Other farmed animals:	0,01 / 0,02	0,10
0,8%	Poultry: Liver	0,07 / 0,07	0,08	1,0%	Rye	0,01 / 0,02	0,10

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

Processed commodities

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

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
2%	Wheat / milling (flour)	0,01 / 0,02	0,24	0,9%	Wheat / bread/pizza	0,01 / 0,02	0,09
1%	Wheat / milling (wholemea	0,01 / 0,02	0,11	0,8%	Wheat / pasta	0,01 / 0,02	0,08
0,7%	Rye / boiled	0,01 / 0,02	0,07	0,7%	Wheat / bread	0,01 / 0,02	0,07
0,7%	Rye / milling (wholemeal)-l	0,01 / 0,02	0,07	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!

Expand/collapse list

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

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

IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
2%	Wheat / milling (flour)	0,01 / 0,02	0,24	0,9%	Wheat / bread/pizza	0,01 / 0,02	0,09
1%	Wheat / milling	0,01 / 0,02	0,11	0,8%	Wheat / pasta	0,01 / 0,02	0,08
0,7%	Rye / boiled	0,01 / 0,02	0,07	0,7%	Wheat / bread (wholemeal)	0,01 / 0,02	0,07
0,7%	Rye / milling (wholemeal)-	0,01 / 0,02	0,07	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!

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.

TDMs

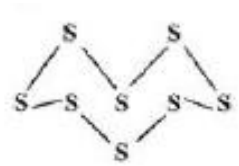
The dietary risk assessment was calculated using PRIMo rev 3.1 for each TDM. Toxicological reference values and input values from EFSA conclusion on confirmatory data on TDMs (EFSA, 2018) were taken into account.

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 FHO04/Patton Supra are accepted.

7.3 Sulphur

General data on sulphur are summarized in the table below (last updated 2023/12/01)

Table 7.3-1: General information on sulphur

Active substance (ISO Common Name)	Sulfur
IUPAC	Sulfur
Chemical structure	 S_x
Molecular formula	S_8
Molar mass	32.06 g/mol
Chemical group	Element; Inorganic compounds
Mode of action (if available)	Signal transduction
Systemic	No
Company (ies)	Sulfur Working Group (SWG) & Sulphur Task Force (STF)
Rapporteur Member State (RMS)	France (co-RMS Slovenia)
Approval status	Approved Date of (01/01/2010) and reference to decision (REGULATION (EU) No 2017/555)
Restriction	To be used as fungicide or acaracide
Review Report	SANCO/2676/08 – final 13/07/2012
Current MRL regulation	Regulation (EC) No 459/2010
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	~~Yes~~ No
EFSA Journal : Conclusion on the peer review	Yes EFSA Scientific Report (2008) 221, 1-70 EFSA Journal 2023; 21(3):7805, 25
EFSA Journal: conclusion on article 12	No
Current MRL applications on intended uses	EFSA-Q-2017-00275 Wheat Rye

7.3.1 Stability of Residues (KCA 6.1)

zRMS comments:
No new data were submitted in the framework of this application.
According to the EFSA Scientific Report (2008) 221, 1-70 elemental Sulfhur is stable.

Sulphur was included in the Annex IV of the Regulation (EC) No 396/2005 (Reg. 459/2010). Therefore, no residue definition was set up and no residue trials were considered as required. Consequently, data on storage stability of residues in samples or sample extracts is not required.

7.3.1.1 Stability of residues during storage of samples

Sulphur is included in Annex IV of Regulation (EC) No. 396/2005. Therefore, no residue definition was proposed, residue trials were not required, and therefore demonstration of the stability of residues is not required.

7.3.1.2 Stability of residues in sample extracts (KCA 6.1)

Please refer to 7.3.1.1.

7.3.2 Nature of residues in plants, livestock and processed commodities

Sulphur is included in Annex IV of Regulation (EC) No. 396/2005. Therefore, no residue definition was proposed, residue trials were not required, and therefore metabolism in plants, livestock and processed commodities is not required.

zRMS comments:
No new data were submitted in the framework of this application.
Excerpt from the EFSA Scientific Report (2008) 221, 1-70:
Metabolism of elemental sulfur in the plant was studied following foliar application of [^{35}S]- labelled micronised sulfur to the surface of wheat leaves (10 mg [^{35}S]-sulfur/ leaf).
Individual leaves were sampled at different time intervals up to seven days after application and processed for analysis. Unincorporated sulfur was removed by surface washing previous to a solvent extraction of the leaf material. The rate of uptake by treated leaves was determined to be around 2% of the applied [^{35}S]-labelled micronised sulfur.
Upon analysis of the leaf extracts, 13 radio-labelled compounds were separated, out of which sulfate, cysteine, cystine, methionine, and oxidised and reduced glutathion were identified.
The unextractable fraction contained mainly proteins.
Of the extractable radioactivity (ERR), the amount incorporated in the pool of cysteine and cystine decreased from 35% to 10%, within 4 hours to 7 days after application. In contrary, the amount of [^{35}S]-sulfate increased from 10% to 60% of the ERR within the same period of time. No hydrogen sulfide was detected; however the authors could not exclude the hypothesis that the detected sulfate could originate from a secondary, fast oxidation of sulfide.
Based on the findings in wheat leaves, the authors proposed the metabolism of elemental sulfur applied to leaves of higher plants as follows: sulfur is not only incorporated into organic compounds, such as amino acids, peptides and proteins, but is also oxidised to sulfate.
This oxidation of elemental sulfur to sulfate ions, directly or maybe through intermediate generation of sulfide, has been considered as a mechanism of detoxification.
Given the fact that the vast majority of the foliar applied elemental sulfur is not absorbed and metabolised by the plants, the rapporteur Member State has concluded that the pertinent residue on treated crops was elemental sulfur.

Sulphur was included in the Annex IV of the Regulation (EC) No 396/2005 (Reg. 459/2010), therefore, metabolism in plants, livestock and processed commodities is not required.

7.3.2.1 Nature of residue in primary crops (KCA 6.2.1)

Please refer to 7.3.1.1.

7.3.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Please refer to 7.3.1.1.

7.3.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Please refer to 7.3.1.1.

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

Please refer to 7.3.1.1.

Table 7.3-2: Summary of the nature of residues in commodities of plant

Endpoints	
Plant groups covered	Cereals (Wheat, foliar application)
Rotational crops covered	Not applicable
Metabolism in rotational crops similar to metabolism in primary crops?	Not applicable
Processed commodities	No study on the nature of the residue was performed in processed commodities
Residue pattern in processed commodities similar to pattern in raw commodities?	Not applicable
Residue pattern in livestock's and animal	Not applicable
Plant residue definition for monitoring	None (EFSA Scientific Report (2008) 221, 32-70; Reg. 459/2010)
Plant residue definition for risk assessment	None required as no ADI and ARfD was set (EFSA Scientific Report (2008) 221, 32-70)
Conversion factor from enforcement to RA	None applicable

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

Please refer to 7.2.3.1.1.

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

Please refer to 7.2.3.1.1.

Table 7.3-3: Summary of the nature of residues in commodities of animal origin

Endpoints	
Animals covered	Food producing animals (animal health and nutrition literature review) Sulfur is a natural product transformed into sulfate by all the animals.
Time needed to reach a plateau concentration	Not applicable
Animal residue definition for monitoring	None (EFSA Scientific Report (2008) 221, 32-70; Reg. 459/2010)
Animal residue definition for risk assessment	Not required
Conversion factor	Not applicable as no ADI and ARfD was set
Metabolism in rat and ruminant similar	Not applicable
Fat soluble residue	Not applicable

7.3.3 Magnitude of residues in plants (KCA 6.3)

Sulphur is included in Annex IV of Regulation (EC) No. 396/2005. Therefore, no residue definition was proposed and residue trials were not required.

zRMS comments:
No new data were submitted in the framework of this application. The meeting of experts did not propose a residue definition for monitoring and an MRL for elemental sulphur (EFSA, 2008). Sulphur was included in the Annex IV of the Regulation (EC) No 396/2005 (Reg. 459/2010).
Therefore, no residue trials were considered as needed. Consequently, intended uses on wheat, durum wheat, triticale, spelt and rye are acceptable and no further data are required.

7.3.4 Magnitude of residues in livestock

Sulphur is included in Annex IV of Regulation (EC) No. 396/2005. Therefore, no residue definition was proposed, residue trials were not required, and livestock feeding study is required.

zRMS comments:
No new data were submitted in the framework of this application.
Sulphur is listed in Annex IV of Regulation (EC) 396/2006, no MRLs have been set. Thus, no residue definition was set up and no residue trials were considered as needed. Consequently, no livestock feeding study is required.

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

Sulphur is included in Annex IV of Regulation (EC) No. 396/2005. Therefore, no residue definition was proposed, residue trials were not required, and no data on residue in processed commodities are required.

zRMS comments:
No new data were submitted in the framework of this application.
Excerpt from the EFSA Scientific Report (2008) 221, 1-70:
„No studies were submitted that investigate the fate of sulfur in livestock.
In the DAR the rapporteur Member State has made reference to an evaluation report by the European Medicines Agency (EMEA) on elemental sulphur, used as therapeutic agent in food-producing animals. The report concluded that residues in animal tissues from sulfur administration could not be regarded as being of any concern, neither in terms of human health nor effects on micro-organisms used during processing of food stuffs.
With respect to the assessment of plant protection uses of sulfur in terms of consumer safety, elaboration on residue levels in food of animal origin is not required, since no ADI and ARfD were set for sulfur."
No additional data are required.

7.3.6 Magnitude of residues in representative succeeding crops

Sulphur is included in Annex IV of Regulation (EC) No. 396/2005. Therefore, no residue definition was proposed, residue trials were not required, and no data on succeeding crops are required.

zRMS comments:
No new data were submitted in the framework of this application.
Excerpt from the EFSA Scientific Report (2008) 221, 1-70:
„The route of degradation of sulfur in soil was considered satisfactorily addressed by an open literature review. There is a natural cycle of oxidation and reduction reactions, which transform elemental sulfur into both organic and inorganic products. Plants absorb sulfur via the roots as sulfate ions (SO4 2-), formed by chemical or microbial oxidation of elemental sulfur or other forms of sulfur in the soil. In the plant, sulfate is reduced to sulphide, and subsequently incorporated in various sulfur-containing organic molecules, including plant proteins. This is a naturally driven process, and therefore the use of elemental sulfur as a plant protection product is not deemed to lead to any relevant residues in rotational crops."
No additional data are required.

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

Sulphur is included in Annex IV of Regulation (EC) No. 396/2005. Therefore, no residue definition was proposed, residue trials were not required, and no other / special studies are required.

zRMS comments:
No new data were submitted in the framework of this application.
According to SANTE/11956/2016 rev. 9, cereals are not considered as melliferous crops, therefore no additional data are required.

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

Sulphur is included in Annex IV of Regulation (EC) No. 396/2005. Therefore, neither ADI nor ARfD were proposed. Sulphur has a low acute and short-term toxicity as well as no genotoxicity potential. In addition, Sulphur is an essential element needed at high dose level and occurring with a wide range of background exposure. Consequently, it can be assumed that it presents no significant acute or long-term risk to

consumers.

zRMS comments:
According to the Peer review of the pesticide risk assessment of the active substance sulphur (EFSA Scientific Report (2008) 221, 1-70) the mammalian toxicology assessment concluded that sulphur was a substance of low toxicity, and it was not necessary to set an ADI or ARfD. A risk for consumers through the consumption of food possibly containing residues of the active substances is not expected. Sulphur has been included in Annex IV to Reg. (EC) No 396/2005.

7.4 Combined exposure and risk assessment

The product is a mixture of two active substances but for only one of them has an acute reference dose been allocated and as such the combined exposure and risk assessment can be considered as prothioconazole and TDMs alone.

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

7.5 References

EC (European Commission), 2021. Review report for prothioconazole, SANCO/3923 /07 – final (10 December 2007, update 26 January 2021)

EFSA (European Food Safety Authority), 2007. Conclusion regarding the peer review of the pesticide risk assessment of the active substance prothioconazole. EFSA Scientific Report (2007)106, 1-98.

EFSA (European Food Safety Authority), 2014. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for prothioconazole according to Article 12 of Regulation (EC) No 396/2005.
EFSA Journal 2014; 12(5):3689, 72 pp. doi:10.2903/j.efsa.2014.3689

EFSA (European Food Safety Authority), 2015a. Reasoned opinion on the modification of the existing maximum residue level (MRL) for prothioconazole in shallots. EFSA Journal 2015; 13(5):4105, 20 pp. https://doi.org/10.2903/j.efsa.2015.4105

EFSA (European Food Safety Authority), 2015b. Reasoned opinion on the modification of the existing maximum residue levels for prothioconazole in sunflower seeds. EFSA Journal 2015;13(12):4371, 24 pp. https://doi.org/10.2903/j.efsa.2015.4371

EFSA (European Food Safety Authority), 2018a. Report of Pesticides Peer Review meeting 171, Triazole derivative metabolites, 13-15 December 2017

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

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
KCP 8/ KCA 6.1/01	Giancola, D.	2024	Prothioconazole-desthio and 5 hydroxy metabolites: Frozen Storage Stability in Crops - Interim Report Report No.: QG/21/001 GLP Battelle UK, Essex, UK Unpublished	N	UPL
KCP 8/ KCA 6.1/02	Phipps, B.	2024	Triazole Derived Metabolites: Frozen Storage Stability in Crops for 12 Months – Study Plan Study No.: QG/21/002 GLP Battelle UK, Essex, UK Unpublished	N	UPL
KCP 8/ KCA 6.1/03	[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 (Access agreement to UPL)
KCP 8/ KCA 6.3/01	Lebrun, F.	2024	Magnitude of the residue of prothioconazole metabolites in wheat in Northern and Southern Europe – 2023 Report No.; 645-2023 Testapi, 49650 Allonnes – France GLP Unpublished	N	UPL
KCP 8/ KCA 6.4.2/01	[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 (Access agreement to UPL)
KCP 8/ KCA 6.4.2/02	[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]	Y	TDMG (Access agreement to 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**
			GLP Unpublished		
KCP 8/ KCA 6.6.1/01	Bloß, K	2019	[^{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
KCP 8/ KCA 6.6.2/01	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 – Study Plan Study No. S22-02433 Eurofins Agroscience Services EcoChem GmbH GLP Unpublished	N	UPL

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

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**
KCP 8/ KCA 6/01 (IIA, 6.0/01)	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 Bayer AG GLP Unpublished	N	Bayer
KCP 8/ KCA 6/02 (IIA, 6.4/01)	[redacted]	2001	JAU 6476-desthio – Dairy cattle feeding study Report No.: MR-535/00 GLP Unpublished	Y	Bayer
KCP 8/ KCA 6/03 (IIA,	Haas, M.; Bornatsch, W.	2000	Metabolism of JAU 6476 in spring wheat (after foliar application) Report no.: MR-198/99 Bayer AG GLP	N	Bayer

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**
6.1.1/01)			Unpublished		
KCP 8/ KCA 6/04 (IIA, 6.1.1/03)	Vogeler, K.; Sakamoto, H.; Brauner, A.	1993	Metabolism of SXX 0665 in summer wheat Report No.: PF3906 Bayer AG GLP Unpublished	N	Bayer
KCP 8/ KCA 6/05 (IIA, 6.1.1/02)	Haas, M.	2001a	Metabolism of JAU 6476 in spring wheat after seed dressing Report No.: MR-467/99 Bayer AG GLP Unpublished	N	Bayer
KCP 8/ KCA 6/06 (IIA, 6.6./01)	Haas, M.	2001b	Confined rotational crop study with JAU 6476 Report No.: MR-159/00 Bayer AG GLP Unpublished	N	Bayer
KCP 8/ KCA 6/07 (IIA 6.2.2.1/01)	[redacted]	2001a	[Phenyl-UL-14C]JAU 6476 Absorption, distribution, excretion and metabolism in the lactating goat Report No.: MR-092/01 GLP Unpublished	Y	Bayer
KCP 8/ KCA 6/08 (IIA, 6.2.2.2/01)	[redacted]	2002	[Phenyl-UL-14C] JAU 6476-desthio Absorption, distribution, excretion, and metabolism in the lactating goat Report no. MR-091/01 GLP Unpublished	Y	Bayer
KCP 8/ KCA 6/09 (IIA, 6.2.2.3/01)	[redacted]	2001b	[Phenyl-UL-14C]JAU 6476 Absortion, distribution, excretion and metabolism in laying hens Report No.: MR-309/01 [redacted] GLP Unpublished	Y	Bayer

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review of triazole derivative metabolites (TDMs)

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
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 Prothioconazole

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

A 2.1.1.1.1.1 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, which supports the wheat residue trials data provided. The final report with 24 months data is now expected in March 2025. 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 12 months. It should be noted that prothioconazole-6-hydroxy-desthio in wheat grain and in oilseed rape seed are stable for 8 months and 6 months, respectively. Mean recovery of each analyte at each interval was in the range of 70% to 120%. 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 6.1/01
Report	Prothioconazole-desthio and 5 hydroxy metabolites: Frozen Storage Stability in crops – Interim Report Giancola, D., Martin, J.,2024 Report No.: QG/21/001
Guideline(s):	Yes: OECD 506 (16/10/07). OECD Guideline for testing of Chemicals: 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:	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.

GLP: Yes.

Acceptability: Interim report with 12 months of data is provided. Full report with 24 months of data expected July 2024

Study Objective

The objective of this study was to determine the freezer storage 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 the following plant matrices (stored at ≤-18°C for 24 months (0, 1 month ± 3 days, 3 months ± 1 week, 6 months ± 2 weeks, 12 months ± 2 weeks, 18 months ± 2 weeks and 24 months ± 2 weeks).
This interim report will provide results for stability samples analysed at 0, 1, 3, 6, 12, months. Also, it will provide data for prothioconazole-desthio (5) hydroxy metabolites in field bean analysed at 7 months and for prothioconazole-6-hydroxy-desthio in wheat grain analysed at 8 months.

Group	Matrices
High water content	Whole plant of wheat
High oil content	Grain of oilseed rape
High starch content	Grain of wheat
High protein content	Dry bean
Dry commodity	Straw of wheat
High acid content	Orange

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 and 12 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 10xLOQ). 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 (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 (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 interim report was to provide information on the stability of residues of prothioconazole-desthio and 5 hydroxy metabolites in wheat (grain, forage and straw), orange, field bean (dried) and oilseed rape seed when stored under deep freeze storage conditions (≤ -18°C) for up to 12 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, months. Additional samples for prothioconazole-desthio (5) hydroxy metabolites in field bean were analysed at 7 months, and for Prothioconazole-6-hydroxy-desthio in Wheat grain at 8 months.
The range of temperature during storage was approximately ≤ -18ºC 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 prothioconazole-desthio 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.
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 1 to Table 33. The mean recovery efficiencies ranged from 70-120%.
The uncorrected and corrected prothioconazole-desthio and its (5) hydroxy metabolites stability data in wheat (grain, forage and straw), orange, field bean (dried) and oilseed rape seed are presented in detail

in Tables A 1 to A 6, below.

Table A 1: 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)	Prothioconazole-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					
	Prothioconazole-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					
		0	1	0.0504	100	0.0506	102	100	85	120	100

	Prothioconazole-4-hydroxy-desthio		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					
	Prothioconazole-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					
	Prothioconazole-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					
	Prothioconazole-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					

n/a: analyte not investigated

Table A 2: 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)	Prothioconazole-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					
	Prothioconazole-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					
	Prothioconazole-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					
	Prothioconazole-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					
	Prothioconazole-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					
	Prothioconazole-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					

* 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 and stability will be assessed at the end of the study with the subsequent timepoints.

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	Mean Stability Samples Recovery (%)	Uncorrected Stability Samples day 0 as 100%	Mean procedural recoveries	Stability samples	Stability Samples Corrected day 0 as 100%

						(mg/kg)					
Wheat (grain)	Prothioconazole-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					
	Prothioconazole-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					
	Prothioconazole-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					
	Prothioconazole-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					
	Prothioconazole-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	1010	0.0498	100	105	105	95	84	
			2	0.0488	99	0.0484						
	Prothioconazole-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						

n/a: analyte not investigated, *: Current data for 12-month timepoint for wheat grain is not within acceptance criteria due to calibration line failure and are therefore not reported. Wheat grain samples were not re-extracted at 12-month timepoint because only one set of additional samples is left as one spare set was used for the additional timepoint at 8 months. Wheat grain samples have been re-weighed and fortified with Prothioconazole-6-hydroxy-desthio only, to repeat the 12-month timepoint at the end of the study.

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		0	1	0.05	99	0.0494	98	100	97	101	100

	Prothioconazole-desthio		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					
	Prothioconazole-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					
	Prothioconazole-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					
	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					
	Prothioconazole-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					
	Prothioconazole-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					

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)	Prothioconazole-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					
	Prothioconazole-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					
	Prothioconazole-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					
	Prothioconazole-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					
	Prothioconazole-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					
	Prothioconazole-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					

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)	Prothioconazole-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					
	Prothioconazole-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					
	Prothioconazole-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					
	Prothioconazole-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					
	Prothioconazole-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					

	Prothioconazole-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					

* 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 under deep freeze storage conditions (≤ -18°C) for up to 12 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 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 12 months. However, the following exceptions have been noted:

- Prothioconazole-6-hydroxy-desthio in wheat grain is considered to be stable up to 8 months. Stability after 12 months of storage could not be assessed because of failure of procedural recovery samples. A new set of stability samples has been fortified to repeat the 12-month timepoint and stability will be assessed further on completion of the 12 months timepoint repeat.

- Prothioconazole-6-hydroxy-desthio in oilseed rape seed is considered to be stable up to 6 months if corrected results are considered. Stability at 12-month timepoint could not be assessed because of failure or procedural recoveries. However, corrected results seem to indicate stability of Prothioconazole-6-hydroxy-desthio in oilseed rape seed after 12 months and stability will be assessed at the end of the study with the subsequent timepoints.

A.2.1.1.1.2 Study 2

Comments of zRMS:	The Applicant only submitted a study plan. The final report will be available in January 2025.

Reference:	KCA 6.1/02
Report	Triazole Derived Metabolites: Frozen Storage Stability in Crops for 12 Months – Study Plan Phipps, B.,2025 Report No.: QG/21/002
Guideline(s):	
Deviations:	n.a
GLP:	Yes
Acceptability:	n.a

Study No. QG/21/002, will provide information on 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) for a period of 12 months. The final report is due in January 2025.

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:	Not evaluated by zRMS-PL.

Reference:	6.1/05
Report	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

Guideline(s):	Yes
Deviations:	n.a
GLP:	Yes
Acceptability:	n.a

Study owner: Triazole Derivative Metabolite Group. Access via Access Agreement.
Note: The summary of the validation data is not presents in the dRR since the applicant is not the owner of the study, and do not have access to the study report. Access to the study report is via an Access Agreemnt (provided with the initial submission of the dossier). However, the analytical methods have been assessed by the RMS and considered acceptable.

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

A 2.1.2.1 Nature of residue in plants

A 2.1.2.1.1 Nature of residue in primary crops

No new study submitted.

A 2.1.2.1.2 Nature of residue in rotational crops

No new study submitted.

A 2.1.2.1.3 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:	6.6.1/01
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 Guideline for the Testing of Chemicals No. 507 “Nature of the pesticide residues in processed commodities - high temperature hydrolysis”; Appendix E - processing studies – 7035/VI/95 rev. 5.
Deviations:	No
GLP:	Yes

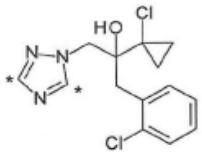
Acceptability: Yes

Materials and methods

The objective of this study was to establish whether or not 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. 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) was applied.
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.

Test Item			
Test Item name	[triazole-U-^{14}C]Prothioconazole-desthio	Other name(s)	-
Chemical name (IUPAC) or CAS name	2-(1-Chlorocyclopropyl)- 1-(2-chlorophenyl)-3-(1,2,4-[U-14C]-triazol-1-yl)propan-2-ol		
Chemical Structure		CAS number (unlabeled)	120983-64-4
		Empirical formula (unlabeled)	$C_{14}H_{15}Cl_2N_3O$
		Molecular weight	313.9g/mol
Batch no.:			
Radiochemical purity	100%		
Specific activity	6.28 MBq/mg		
Batch no.:	12538SXD002-1		
Stability	Expiry Date 19th July 2023		

pH	Buffer	Preparation
pH 4	Citrate	10.51 g of citric acid monohydrate were dissolved in demineralised water, adjusted to pH 4 with sodium hydroxide and filled up to 1 L volume with demineralised water to give a final concentration of 50 mmol/L.
pH 5	Citrate	10.51 g of citric acid monohydrate were dissolved in demineralised water, adjusted to pH 5 with sodium hydroxide and filled up to 1 L volume with demineralised water to give a final concentration of 50 mmol/L.
pH 6	Citrate	10.51 g of citric acid monohydrate were dissolved in demineralised water, adjusted to pH 6 with sodium hydroxide and filled up to 1 L volume with demineralised water to give a final concentration of 50 mmol/L.

Application Solution

The application solution was prepared by dissolving 100 µL of the original test item solution in 200µL acetonitrile. A dilution of the application solution was used to determine the radioactivity on LSC. A final

volume from the application solution of 9.3 µL was used for application to achieve a nominal concentration of 1 mg/L, respective 6.3 MBq/L.

Test Solution
The samples were prepared as follows: 15 mL of buffer solution were added to the test vessel (glass vial), followed by a defined volume of the application solution. The test vessel was closed with a PTFE sealed cap.

Test Condition 1: Pasteurisation
The stability of the test item was determined under conditions typical for pasteurisation (e.g. for making fruit juice). The processing temperature was 90° C in an oil bath. The incubation time at this temperature and pH for processing was 20 minutes. The test was performed in duplicate.

Test Condition 2: Baking, Brewing and Boiling
The stability of the test item was determined under conditions typical for baking and boiling (e.g. for making bread and cooking vegetables). The stability of the test item was determined under conditions typical for baking and boiling (e.g. for making bread and cooking vegetables). The processing temperature was 100° C in an oil bath. The incubation time at this temperature and pH for processing was 60 minutes. The test was performed in duplicate.

Test Condition 3: Sterilisation
The stability of the test item was determined at conditions typical for sterilisation (e.g. for making canned vegetables). The processing temperature was 120° C (controlled by autoclave paper) in an autoclave. The incubation time at this temperature and pH for processing was 20 minutes. The test was performed in duplicate.

Sampling and sample analysis
The weight of the samples before and after incubation was determined by weighing.
Aliquots of 2.0 mL were taken from the test vessel before and after the respective processing. Aliquots were analysed by LSC and radio-HPLC within one day. After analysis, samples were stored in a freezer at ≤ -18 °C.

Sterility
Sterility of the test solutions was checked by their application to sterile agar plates and incubation at 19.9°C. for 5 days. In addition, a negative and a positive control were incubated under the same conditions. The colonies developed on the plates were counted.

pH Measurement
For pH measurement, the blank vessel was used and an additional vessel (vessel TR3) was applied for each condition with the test item (same concentration) and incubated likewise. A separate applied test flask was used in order to prevent any contamination in the test vessels. pH was measured before and after processing.

Determination of radioactivity and of metabolite profiles
The radioactivity in solutions was determined by liquid scintillation counting. From every sample an aliquot was mixed with scintillation cocktail. The radioactivity of the samples was determined with HPLC by a Mira Star/ Ramona Star (Raytest) radioactivity-HPLC detector. Quantification was done by integration.

Results and discussion
Condition 1: Pasteurisation
The conditions were citrate buffer pH 4 at a temperature of 90°C for 20 minutes. The test was performed in duplicate. 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.

The results after processing are summarised in Table A 14.

Condition 2: Baking, Brewing and Boiling
The conditions were citrate buffer pH 5 at a temperature of 100°C for 60 minutes. The test was performed in duplicate. 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.
The results after processing are summarised in Table A 14.

Condition 3: Sterilisation
The conditions were citrate buffer pH 6 at a temperature of 120°C for 20 minutes. The test was performed in duplicate.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 are summarised in Table A 14.

Table A 3: Standard hydrolysis study of [1,2,4-triazole-U-14C]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
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. The recovery of the applied [1,2,4-triazole-U-14C]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 2.1.2.2 Nature of residues in livestock

No new study submitted.

A 2.1.3 Magnitude of residues in plants

A 2.1.3.1 Wheat

Table A 4: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU EFSA, 2007	3	0.2 kg as/ha	14-21 days	69	35
cGAP EU (Art. 12, EFSA, 2014)	3	0.2 kg as/ha	14-21 days	69	35
Intended cGAP (1)*	2	0.2 kg as /ha	14 days	69	35

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

Eight trials (4 decline and 4 harvest) were located in Northern Europe (Northern France, Germany, Poland, Belgium, The Netherlands).
The field sites were representative of wheat, grown in a way typical of the producing region in the test countries.

A 2.1.3.1.1 Wheat Study 1

Comments of zRMS:	Eight residue trials (4 decline and 4 harvest) on wheat were conducted in northern Europe to determine residue of prothioconazole-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio and prothioconazole-alpha-hydroxy-desthio and TDMs. Wheat was treated twice at application rate of 0.200 kg a.s./ha of prothioconazole with 14±1 days interval between applications. The time of application was 1. at BBCH 45-61, 2. at BBCH 69. Samples were taken at harvest. Analytical method for determination of prothioconazole-desthio - method 01013. Analytical method for determination of prothioconazole -alpha-hydroxy-desthio, -3-hydroxy-desthio, -4-hydroxy-desthio, -5-hydroxy-desthio and -6-hydroxy-desthio – method 00979/M01. The residues of 1,2,4-triazole (1,2,4-T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) in/on plant material were analysed according to the method 01062/M004. Limit of quantitation was 0.01 mg/kg for grain, forage and straw for all substances. Mean recoveries in acceptable range (70 - 110%), RSD <20%. Maximum storage period – 198 days. Residues of prothioconazole-desthio in wheat grain at harvest were <0.01 mg/kg. Total residue for prothioconazole (prothioconazole-desthio and all 5 hydroxy metabolites) in grain at harvest were between <0.01 mg/kg and 0.02 mg/kg. Residues of 1,2,4-triazole and triazole lactic acid, in wheat grain at harvest were < 0.01 mg/kg. Residues of triazole alanine, in wheat grain at harvest ranged between 0.12 and 0.74 mg/kg. Residues of triazole acetic acid, in wheat grain at harvest ranged between 0.04 and 0.17 mg/kg. The study is acceptable.

Reference:	KCA 6.3/01
Report	Magnitude of the residue of prothioconazole metabolites in wheat in Northern and Southern Europe – 2023 Author Frédéric Lebrun

Report No.: 645-2023

Guideline(s): Yes
Regulation (EC) N°1107/2009 of 21/10/2009 (Repealing the Council Directive 91/414/EEC) concerning the placing of plant protection products on the market

Regulation (EU) No 283/2013 of 01/03/2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market

OECD (2021),Test No. 509: Crop Field Trial, OECD Guidelines for the Testing of Chemicals, Section 5, OECD Publishing

SANTE/2020/12830, Rev.2, 14 February 2023; Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes (Supersedes Guidance Documents SANCO/3029/99 and SANCO/825/00)

OECD (2007), Guidance Document on Pesticide Residue Analytical Methods. Series on testing and assessment Number 72. Series on pesticides Number 39. ENV/JM/MONO(2007)17

The Application of GLP Principles to Field Studies, OECD Series on Principles of GLP and Compliance Monitoring Number 6 (Revised 1999), ENV/JM/MONO(99)22

The Application of the OECD Principles of GLP to the Organisation and Management of Multi-Site Studies, OECD Series on Principles of GLP and Compliance Monitoring Number 13, ENV/JM/MONO(2002)9

Deviations: Yes
645-2023 PL03
The untreated and treated plots have an area of 76.8 m² which is below the study plan requirements (min 90 m²). The dimensions are corresponding to the maximum area that could be obtained from the selected field and taking into account the other study plan requirements (distance between plots, buffer, boom width). The plots were more than big enough and all trials actions were all well performed and homogeneous.

645-2023 GE02 and 645-2023 NL08
Due to a human error followed by a technical malfunction of the alarm system starting late 24/10/23 until the early morning of 25/10/23, the temperatures in freezer storage AGR-GL-04-0215, used for the storage of **retain** samples, raised.
For the core temperature, which is measured inside a representative sample amount (dummy) the following temperatures were registered:
Above -18.0°C for a duration of 19:30 (hh:mm) and above -12.0°C for a duration of 13:00 (hh:mm) with a maximum of -4.7°C. Consequently, we expect specimens were never defrosted.

The following specimens are concerned:
Trial 645-2023 GE02:
645-2023 GE02 1R, 645-2023 GE02 2R, 645-2023 GE02 3R, 645-2023 GE02 4R, 645-2023 GE02 5R, 645-2023 GE02 6R, 645-2023 GE02 7R, 645-2023

GE02 8R, 645-2023 GE02 9R, 645-2023 GE02 10R, 645-2023 GE02 11R, 645-2023 GE02 12R, 645-2023 GE02 13R, 645-2023 GE02 14R, 645-2023 GE02 15R, 645-2023 GE02 16R, 645-2023 GE02 17R, 645-2023 GE02 18R, 645-2023 GE02 19R, 645-2023 GE02 20R

Trial 645-2023 NL08:
645-2023 NL08 1R, 645-2023 NL08 2R, 645-2023 NL08 3R, 645-2023 NL08 4R

The peak temperature was short (<24 hours) with a maximum of -4.7°C. Therefore, these spare specimens remained frozen and are suitable for analyses if needed.

The deviations have no impact on the compliance to GLP.

GLP: Yes

Acceptability: Yes

Table A 5: Summary of the wheat study 1 trials for Prothioconazole-desthio and the 5 hydroxy metabolites

RESIDUE DATA SUMMARY FROM SUPERVISED TRIALS

Active Substance: prothioconazole
Crop / crop group: Wheat / cereals
Responsible for reporting: Frédéric LEBRUN / TESTAPI
115 route du Pô, 49650 Allonnes - France
Countries: Northern France, Germany , Poland, Belgium and The Netherlands
Nominal Content of a.s.: 250 g/L
Formulation: DC

Commercial Product: Prothioconazole 250 g/L DC (FGR06)
Producer: UPL Europe Limited

Indoor/glasshouse/outdoor: outdoor
Other a.s. in formulation: -
Residue calculated as: Prothioconazole-desthio (enforcement residue definition)
Prothioconazole-alpha-hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio (mg/kg) (risk assessment residue definition)

1	2	3	4	5			6	7	8	9				10	11
Report No. 645-2023 Location (region)	Commodity Variety	Date of 1-Planting 2-Flowering 3-Harvest	Method of treatment	Actual (nominal) application rate per treatment			Date of treatment	BBCH Crop Growth Stage at treatment	Portions analysed	Residues **expressed in prothioconazole-desthio** (1) PTZ = prothioconazole				DALA (2)	Remarks
				kg a.s./ha	Water (L/ha)	kg (a.s./hL)				PTZ-desthio	PTZ-α-hydroxy-desthio	PTZ-3-hydroxy-desthio	**Sum[1,2]**		
Northern Europe	Winter wheat	1-26/10/22	Broadcast foliar application	0.1941 (0.1967)	197	0.0987 (0.1000)	15/05/23	61		0.24					Untreated specimen: <LOQ
Northern France 49650 Allonnes (Pays de la Loire)	APACHE	2-15/05/23 to 30/05/23 3-07/07/23	Boom sprayer	0.1995 (0.2022)	202	0.0987 (0.1000)	30/05/23	69	Forage [3] Forage [3] Forage [3] Forage [3] Straw Grain	1.0 0.51 0.46 0.49 <0.01	0.04 0.04 0.10 0.11 0.18 <0.01	0.08 0.08 0.21 0.22 0.32 n.d.	- - - - - -	-0 +0 14 20 38[4] 38[4]	LC-MS/MS method validated within this study Max. study storage interval between:
Decline curve trial															

645-2023 FR01										PTZ-4-hydroxy-desthio	PTZ-5-hydroxy-desthio	PTZ-6-hydroxy-desthio			-sampling and extraction: 198 days -extraction and analyses: 7 days
									Forage [3]	0.07	0.06	<0.01	**0.50**	-0	
									Forage [3]	0.07	0.05	<0.01	**1.3**	+0	
									Forage [3]	0.14	0.11	0.02	**1.1**	14	
									Forage [3]	0.16	0.12	0.03	**1.1**	20	
									Straw	0.21	0.24	0.03	**1.5**	38[4]	
									Grain	n.d.	n.d.	n.d.	**0.02**	38[4]	
Northern Europe Germany 46342 Velen-Ramsdorf (North Rhine-Westphalia) Decline curve trial 645-2023 GE02	Winter Wheat BENCHMARK	1- 29/10/22 2- 29/05/23 to 09/06/23 3- 04/08/23	Broadcast foliar application Boom sprayer	0.2010 (0.2037) 0.1974 (0.2000)	306 300	0.0658 (0.0667) 0.0658 (0.0667)	25/05/23 06/06/23	52 69		PTZ-desthio	PTZ-α-hydroxy-desthio	PTZ-3-hydroxy-desthio	**Sum[1,2]**		Untreated specimen: <LOQ LC-MS/MS method validated within this study Max. study storage interval between: -sampling and extraction: 198 days -extraction and analyses: 7 days
									Forage [3]	0.28 1.0	0.04	0.09	-	-0	
									Forage [3]	0.52	0.05	0.09	-	+0	
									Forage [3]	0.33	0.19	0.21	-	14	
									Forage [3]	0.94	0.22	0.22	-	21	
									Straw	< 0.01	0.40	0.48	-	56[4]	
									Grain		< 0.01	n.d.	-	56[4]	
										PTZ-4-hydroxy-desthio	PTZ-5-hydroxy-desthio	PTZ-6-hydroxy-desthio			
									Forage [3]	0.06	0.08	0.01	**0.56**	-0	
									Forage [3]	0.07	0.10	0.01	**1.3**	+0	
									Forage [3]	0.14	0.16	0.04	**1.3**	14	
									Forage [3]	0.15	0.17	0.05	**1.1**	21	
									Straw	0.23	0.35	0.05	**2.5**	56[4]	
									Grain	n.d.	n.d.	n.d.	**0.02**	56[4]	
Northern Europe Poland 55200 Gać (Lower Silesia)	Spring Wheat MERKAWA C1	1- 22/04/23 2- 22/06/23 to 26/06/23 3- 12/08/23	Broadcast foliar application Boom sprayer	0.2022 (0.2049) 0.1979 (0.2005)	307 301	0.0658 (0.0667) 0.0658 (0.0667)	12/06/23 26/06/23	45-47 69		PTZ-desthio	PTZ-α-hydroxy-desthio	PTZ-3-hydroxy-desthio	**Sum[1,2]**		Untreated specimen: <LOQ LC-MS/MS method validated within this study
									Forage [3]	0.37 1.2	0.25	0.23	-	-0	
									Forage [3]	0.50	0.18	0.18	-	+0	
									Forage [3]	0.32	0.25	0.43	-	14	
									Forage [3]	0.19	0.26	0.42	-	21	
									Straw	n.d.	0.13	0.11	-	47[4]	
									Grain		n.d.	n.d.	-	47[4]	

Decline curve trial 645-2023 PL03										PTZ-4-hydroxy-desthio	PTZ-5-hydroxy-desthio	PTZ-6-hydroxy-desthio			Max. study storage interval between: -sampling and extraction: 198 days -extraction and analyses: 7 days
									Forage [3] Forage [3] Forage [3] Forage [3] Straw Grain	0.14 0.12 0.20 0.20 0.06 n.d.	0.13 0.10 0.16 0.17 0.09 n.d.	0.04 0.04 0.05 0.05 0.01 n.d.	**1.2** **1.8** **1.6** **1.4** **<u>0.59</u>** **<u>n.d.</u>**	-0 +0 14 21 47[4] 47[4]	
Northern Europe Northern France 37370 Saint Christophe sur le Nais (Centre Val de Loire) Decline curve trial 645-2023 FR04	Spring Wheat TOGANO	1- 05/03/23 2- 20/06/23 to 27/06/23 3- 20/07/23 to 30/07/23	Broadcast foliar application Boom sprayer	0.1897 (0.1922) 0.1907 (0.1933)	192 193	0.0987 (0.1000) 0.0987 (0.1000)	12/06/23 26/06/23	59 69		PTZ-desthio	PTZ-α-hydroxy-desthio	PTZ-3-hydroxy-desthio	**Sum[1,2]**		Untreated specimen: <0.01 – 0.33 LC-MS/MS method validated within this study Max. study storage interval between: -sampling and extraction: 198 days -extraction and analyses: 7 days
									Forage [3] Forage [3] Forage [3] Forage [3] Straw Grain	0.39, 0.34, 0.35* 1.4, 1.2, 1.4* 1.1, 0.99, 1.0* 1.2, 1.1, 0.92* <u>3.3</u>, 3.1, 2.1* <u><0.01</u>	0.20, 0.20, 0.18* 0.19, 0.18, 0.17* 0.35, 0.31, 0.36* 0.50, 0.42, 0.37* 0.96, 0.98, 0.98* <0.01	0.16, 0.16, 0.17* 0.17, 0.17, 0.15* 0.23, 0.21, 0.26* 0.30, 0.25, 0.23* 0.70, 0.78, 0.79* n.d.	- - - - - -	-0 +0 14 21 28[4] 28[4]	
										PTZ-4-hydroxy-desthio	PTZ-5-hydroxy-desthio	PTZ-6-hydroxy-desthio	**Sum[1,2]**		
									Forage [3] Forage [3] Forage [3] Forage [3] Straw Grain	0.12,0.11, 0.12* 0.12, 0.11, 0.11* 0.15, 0.13, 0.18* 0.20, 0.16, 0.16* 0.44, 0.50, 0.54* n.d.	0.10, 0.09, 0.10* 0.10, 0.09, 0.09* 0.14, 0.13, 0.16* 0.18, 0.16, 0.12* 0.46, 0.51, 0.44* n.d.	0.03, 0.03, 0.03* 0.03, 0.02, 0.02* 0.04, 0.03, 0.04* 0.06, 0.04, 0.04* 0.12, 0.12, 0.11* n.d.	**1.00, 0.93, 095*** **2.01, 1.78, 1.94*** **2.01, 1.80, 2.00*** **2.44, 2.13, 1.84*** **5.98, <u>5.99</u>, 4.96*** **<u>0.02</u>**	-0 +0 14 21 28[4] 28[4]	

Northern Europe Belgium 6221 Saint-Armand (Province of Hainaut) Harvest trial 645-2023 BE05	Winter Wheat CHRISTOPH	1- 28/10/22 2- 31/05/23 to 08/06/23 3- 19/07/23 to 11/08/23	Broadcast foliar application Boom sprayer	0.1959 (0.1985) 0.1959 (0.1985)	298 298	0.0658 (0.0667) 0.0658 (0.0667)	24/05/23 08/06/23	51 69	Straw Grain	PTZ-desthio <u>0.59</u> <u>n.d.</u>	PTZ-α-hydroxy-desthio 0.39 n.d.	PTZ-3-hydroxy-desthio 0.52 n.d.	**Sum[1,2]** - -	41[(3)] 41[(3)]	Untreated specimen: <LOQ LC-MS/MS method validated within this study Max. study storage interval between: -sampling and extraction: 198 days -extraction and analyses: 7 days
									Straw Grain	PTZ-4-hydroxy-desthio 0.24 n.d.	PTZ-5-hydroxy-desthio 0.32 n.d.	PTZ-6-hydroxy-desthio 0.06 n.d.	**<u>2.1</u>** **<u>n.d.</u>**	41[(3)] 41[(3)]	
Northern Europe Germany 04827 Gerichshain (Saxony) Harvest trial 645-2023 GE06	Spring Wheat KWS SHARKI	1- 30/03/23 2- 13/06/23 to 27/06/23 3- 19/08/23	Broadcast foliar application Boom sprayer	0.2053 (0.2080) 0.2040 (0.2067)	312 310	0.0658 (0.0667) 0.0658 (0.0667)	13/06/23 27/06/23	59-61 69	Straw Grain	PTZ-desthio <u>0.18</u> <u>< 0.01</u>	PTZ-α-hydroxy-desthio 0.19 n.d.	PTZ-3-hydroxy-desthio 0.21 n.d.	**Sum[1,2]** - -	53[(3)] 53[(3)]	Untreated specimen: <LOQ LC-MS/MS method validated within this study Max. study storage interval between: -sampling and extraction: 198 days -extraction and analyses: 7 days
									Straw Grain	PTZ-4-hydroxy-desthio 0.16 n.d.	PTZ-5-hydroxy-desthio 0.19 n.d.	PTZ-6-hydroxy-desthio 0.01 n.d.	**<u>0.94</u>** **<u>0.01</u>**	53[(3)] 53[(3)]	

Northern Europe Poland 48320 Czarnolas (Opolskie Province) Harvest trial 645-2023 PL07	Spring Wheat MERKAWA C1	1- 22/03/23 2- 18/06/23 to 23/06/23 3- 11/08/23	Broadcast foliar application Boom sprayer	0.2042 (0.2069) 0.1973 (0.2000)	310 300	0.0658 (0.0667) 0.0658 (0.0667)	09/06/23 23/06/23	45-47 69	Straw Grain	PTZ-desthio <u>0.07</u> <u>n.d.</u>	PTZ-α-hydroxy-desthio 0.04 n.d.	PTZ-3-hydroxy-desthio 0.13 n.d.	**Sum[1,2]** - -	49[(3)] 49[(3)]	Untreated specimen: <LOQ LC-MS/MS method validated within this study Max. study storage interval between: -sampling and extraction: 198 days -extraction and analyses: 7 days
									Straw Grain	PTZ-4-hydroxy-desthio 0.10 n.d.	PTZ-5-hydroxy-desthio 0.09 n.d.	PTZ-6-hydroxy-desthio 0.01 n.d.	**<u>0.44</u>** **<u>n.d.</u>**	49[(3)] 49[(3)]	
Northern Europe The Netherlands 5853EJ Siebengewald (Limburg) Harvest trial 645-2023 NL08	Spring Wheat ALICIA	1- 19/04/23 2- 18/06/23 to 30/06/23 3- 08/08/23	Broadcast foliar application Boom sprayer	0.2047 (0.2074) 0.2047 (0.2074)	311 311	0.0658 (0.0667) 0.0658 (0.0667)	16/06/23 30/06/23	57-59 69	Straw Grain	PTZ-desthio <u>0.19</u> <u>n.d.</u>	PTZ-α-hydroxy-desthio 0.07 n.d.	PTZ-3-hydroxy-desthio 0.04 n.d.	**Sum[1,2]** - -	39[(3)] 39[(3)]	Untreated specimen: <LOQ LC-MS/MS method validated within this study Max. study storage interval between: -sampling and extraction: 198 days -extraction and analyses: 7 days
									Straw Grain	PTZ-4-hydroxy-desthio 0.03 n.d.	PTZ-5-hydroxy-desthio 0.05 n.d.	PTZ-6-hydroxy-desthio < 0.01 n.d.	**<u>0.39</u>** **<u>n.d.</u>**	39[(3)] 39[(3)]	

(1) LOQ = 0.01 mg/kg / n.d. = non detected (<LOD = <0.003 mg/kg) (2) DALA = days after last application (3) Forage = whole plant without roots (4) Sampled at commercial harvest date

[1] n.d. residues are considered as 0.00 mg/kg, <LOQ residues are considered as 0.01 mg/kg

[2] The sum of PTZ-hydroxy-desthio metabolites is based on the rounded values displayed in this table

Table A 21 Summary of the wheat study 1 trials for triazole derivative metabolites (1,2,4-Triazole, TA, TAA & TLA).

RESIDUE DATA SUMMARY FROM SUPERVISED TRIALS

Active Substance: prothioconazole
Crop / crop group: Wheat / cereals
Responsible for reporting: Frédéric LEBRUN / TESTAPI
115 route du Pô, 49650 Allonnes - France
Countries: Northern France, Germany, Poland, Belgium and The Netherlands
Nominal Content of a.s.: 250 g/L
Formulation: DC

Commercial Product: Prothioconazole 250 g/L DC (FGR06)
Producer: UPL Europe Limited

Indoor/glasshouse/outdoor: outdoor
Other a.s. in formulation: -
Residue calculated as: triazole derivative metabolites (T, TA, TAA, TLA) (mg/kg)

1	2	3	4	5			6	7	8	9				10	11
Report No. 645-2023 Location (region)	Commodity Variety	Date of 1-Planting 2-Flowering 3-Harvest	Method of treatment	Actual (nominal) application rate per treatment			Date of treatment	BBCH Crop Growth Stage at treatment	Portions analysed	Residues (1)				DALA (2)	Remarks
				kg a.s./ha	Water (L/ha)	kg (a.s./hL)				T	TA	TAA	TLA		
Northern Europe Northern France 49650 Allonnes (Pays de la Loire) Decline curve trial 645-2023 FR01	Winter wheat APACHE	1-26/10/22 2-15/05/23 to 30/05/23 3-07/07/23	Broadcast foliar application Boom sprayer	0.1941 (0.1967) 0.1995 (0.2022)	197 202	0.0987 (0.1000) 0.0987 (0.1000)	15/05/23 30/05/23	61 69	**Untreated** Forage(3) Forage(3) Forage(3) Forage(3) Straw Grain **Treated** Forage(3) Forage(3) Forage(3) Forage(3) Straw Grain	 n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d.	 0.01 0.01 0.01 0.01 <0.01 0.03 0.05 0.05 0.08 0.07 0.02 0.12	 0.01 0.01 0.01 0.02 0.02 0.02 0.02 0.02 0.03 0.03 0.04 0.04	 0.01 <0.01 <0.01 <0.01 0.01 n.d. 0.02 0.02 0.02 0.02 0.03 n.d.	 -0 +0 14 20 38(4) 38(4) -0 +0 14 20 38(4) 38(4)	LC-MS/MS Method Validated in within this study Max. study storage interval between: -sampling and extraction: 178 days -extraction and analyses: 4 days
Northern Europe Germany	Winter Wheat BENCHMARK	1- 29/10/22 2- 29/05/23 to 09/06/23 3- 04/08/23	Broadcast foliar application Boom sprayer	0.2010 (0.2037) 0.1974 (0.2000)	306 300	0.0658 (0.0667) 0.0658 (0.0667)	25/05/23 06/06/23	52 69	**Untreated** Forage(3) Forage(3) Forage(3) Forage(3) Straw	 n.d. n.d. n.d. n.d. n.d.	 0.01 0.02 0.03 0.03 n.d.	 < 0.01 0.01 0.02 0.02 0.01	 < 0.01 < 0.01 < 0.01 < 0.01 < 0.01	 -0 +0 14 21 56(4)	LC-MS/MS Method Validated in within this study

46342 Velen-Ramsdorf (North Rhine-Westphalia) Decline curve trial 645-2023 GE02									Grain **Treated** Forage[3] Forage[3] Forage[3] Forage[3] Straw Grain	n.d. n.d. n.d. n.d. n.d. n.d. n.d.	0.05 0.06 0.07 0.16 0.21 < 0.01 0.25	0.04 0.02 0.02 0.04 0.05 0.04 0.14	n.d. 0.02 0.02 0.03 0.03 0.03 n.d.	56[4] -0 +0 14 21 56[4] 56[4]	Max. study storage interval between: -sampling and extraction: 178 days -extraction and analyses: 4 days
Northern Europe Poland 55200 Gać (Lower Silesia) Decline curve trial 645-2023 PL03	Spring Wheat MERKAWA C1	1- 22/04/23 2- 22/06/23 to 26/06/23 3- 12/08/23	Broadcast foliar application Boom sprayer	0.2022 (0.2049) 0.1979 (0.2005)	307 301	0.0658 (0.0667) 0.0658 (0.0667)	12/06/23 26/06/23	45-47 69	**Untreated** Forage[3] Forage[3] Forage[3] Forage[3] Straw Grain **Treated** Forage[3] Forage[3] Forage[3] Forage[3] Straw Grain	n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d.	0.02 0.01 0.03 0.02 n.d. 0.06 0.12 0.11 0.38 0.28 0.07 0.41	0.01 0.01 0.01 0.02 n.d. 0.03 0.04 0.05 0.07 0.08 0.04 0.16	< 0.01 0.02 0.01 0.01 n.d. n.d. 0.07 0.07 0.11 0.10 0.03 n.d.	-0 +0 14 21 47[4] 47[4] -0 +0 14 21 47[4] 47[4]	LC-MS/MS Method Validated in within this study Max. study storage interval between: -sampling and extraction: 178 days -extraction and analyses: 4 days
Northern Europe Northern France 37370 Saint Christophe sur le Nais (Centre Val de Loire) Decline curve trial 645-2023 FR04	Spring Wheat TOGANO	1- 05/03/23 2- 20/06/23 to 27/06/23 3- 20/07/23 to 30/07/23	Broadcast foliar application Boom sprayer	0.1897 (0.1922) 0.1907 (0.1933)	192 193	0.0987 (0.1000) 0.0987 (0.1000)	12/06/23 26/06/23	59 69	**Untreated** Forage[3] Forage[3] Forage[3] Forage[3] Straw Grain **Treated** Forage[3] Forage[3] Forage[3]	n.d., n.d., n.d.* n.d., n.d., n.d.* n.d., n.d., n.d.* n.d., n.d., n.d.* n.d., n.d., n.d.* n.d. n.d., n.d., n.d.* n.d., n.d., n.d.* n.d., n.d., n.d.*	0.23, 0.22, 0.22* 0.22, 0.20, 0.24* 0.25, 0.23, 0.28* 0.26, 0.22, 0.30* 0.03, 0.02, 0.04* 0.33 0.27, 0.24, 0.24* 0.27, 0.29, 0.29* 0.29, 0.34, 0.36*	0.13, 0.14, 0.14* 0.13, 0.13, 0.14* 0.20, 0.24, 0.21* 0.28, 0.22, 0.29* 0.19, 0.20, 0.22* 0.19 0.08, 0.08, 0.08* 0.09, 0.10, 0.08* 0.15, 0.19, 0.18*	0.12, 0.13, 0.14* 0.12, 0.14, 0.11* 0.10, 0.11, 0.09* 0.10, 0.11, 0.09* 0.16, 0.17, 0.17* <0.01 0.09, 0.10, 0.09* 0.11, 0.12, 0.09* 0.08, 0.08, 0.09*	-0 +0 14 21 28[4] 28[4] -0 +0 14	LC-MS/MS Method Validated in within this study Max. study storage interval between: -sampling and extraction: 178 days -extraction and analyses: 4 days

									Forage[3] Straw Grain	n.d., n.d., n.d.* n.d., n.d., n.d.* n.d.	0.31, 0.36, 0.54* 0.02, 0.02, 0.03* 0.74	0.17, 0.22, 0.22* 0.13, 0.13, 0.13* 0.17	0.07, 0.08, 0.08* 0.12, 0.12, 0.13* <0.01	21 28[4] 28[4]	
Northern Europe Belgium 6221 Saint-Armand (Province of Hainaut) Harvest trial 645-2023 BE05	Winter Wheat CHRISTOPH	1- 28/10/22 2- 31/05/23 to 08/06/23 3- 19/07/23 to 11/08/23	Broadcast foliar application Boom sprayer	0.1959 (0.1985) 0.1959 (0.1985	298 298	0.0658 (0.0667) 0.0658 (0.0667)	24/05/23 08/06/23	51 69	**Untreated** Straw Grain **Treated** Straw Grain	n.d. n.d. n.d. n.d.	< 0.01 0.03 n.d. 0.17	< 0.01 0.03 0.02 0.05	0.01 n.d. 0.03 n.d.	41[3] 41[3] 41[3] 41[3]	LC-MS/MS Method Validated in within this study Max. study storage interval between: -sampling and extraction: 178 days -extraction and analyses: 4 days
Northern Europe Germany 04827 Gerichshain (Saxony) Harvest trial 645-2023 GE06	Spring Wheat KWS SHARKI	1- 30/03/23 2- 13/06/23 to 27/06/23 3- 19/08/23	Broadcast foliar application Boom sprayer	0.2053 (0.2080) 0.2040 (0.2067)	312 310	0.0658 (0.0667) 0.0658 (0.0667)	13/06/23 27/06/23	59-61 69	**Untreated** Straw Grain **Treated** Straw Grain	n.d. n.d. n.d. n.d.	n.d. 0.03 0.01 0.27	< 0.01 0.02 0.02 0.10	n.d. n.d. 0.02 n.d.	53[3] 53[3] 53[3] 53[3]	LC-MS/MS Method Validated in within this study Max. study storage interval between: -sampling and extraction: 178 days -extraction and analyses: 4 days
Northern Europe Poland	Spring Wheat MERKAWA C1	1- 22/03/23 2- 18/06/23 to 23/06/23	Broadcast foliar application Boom sprayer	0.2042 (0.2069) 0.1973	310 300	0.0658 (0.0667) 0.0658	09/06/23 23/06/23	45-47 69	**Untreated** Straw	n.d.	n.d.	< 0.01	< 0.01	49[3]	LC-MS/MS Method

48320 Czarnolas (Opolskie Province) Harvest trial 645-2023 PL07		3- 11/08/23		(0.2000)		(0.0667)			Grain **Treated** Straw Grain	n.d. n.d. n.d.	0.04 0.01 0.33	0.03 < 0.01 0.14	n.d. 0.02 n.d.	49(3) 49(3) 49(3)	Validated in within this study Max. study storage interval between: -sampling and extraction: 178 days -extraction and analyses: 4 days
Northern Europe The Netherlands 5853EJ Siebengewald (Limburg) Harvest trial 645-2023 NL08	Spring Wheat ALICIA	1- 19/04/23 2- 18/06/23 to 30/06/23 3- 08/08/23	Broadcast foliar application Boom sprayer	0.2047 (0.2074) 0.2047 (0.2074)	311 311	0.0658 (0.0667) 0.0658 (0.0667)	16/06/23 30/06/23	57-59 69	**Untreated** Straw Grain **Treated** Straw Grain	 n.d. n.d. n.d. n.d.	 0.03 0.41 0.03 0.68	 0.04 0.25 0.01 0.11	 0.02 n.d. < 0.01 n.d.	 39(3) 39(3) 39(3) 39(3)	LC-MS/MS Method Validated in within this study Max. study storage interval between: -sampling and extraction: 178 days -extraction and analyses: 4 days

(1) LOQ = 0.01 mg/kg / n.d. = non detected (<LOD = <0.003 mg/kg) / T= 1,2,4-Triazole / TA = Triazole Alanine / TAA = Triazole Acetic Acid / TLA = Triazole Lactic Acid (2) DALA = days after last application (3) Forage = whole plant without roots (4) Sampled at commercial harvest date

A 2.1.4 Magnitude of residues in livestock

A 2.1.4.1 Livestock feeding studies

A 2.1.4.1.1 Livestock feeding study 1

Comments of zRMS:	Not evaluated.

Reference:	KCA 6.4.2/01
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:	n.a
GLP:	Yes
Acceptability:	n.a
Duplication (if vertebrate study)	No

Study owner: Triazole Derivative Metabolite Group. Access via Access Agreement.

Note: The summary of the validation data is not presents in the dRR since the applicant is not the owner of the study, and do not have access to the study report. Access to the study report and the associated method is via an Access Agreement (provided with the initial submission of the dossier).

A 2.1.4.1.2 Livestock feeding study 2

Comments of zRMS:	Not evaluated.

Reference:	KCA 6.4.2/02
Report	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] 2021.
Guideline(s):	Yes OECD (2007), Test No. 505: Residues in Livestock, OECD Guidelines for the Testing of Chemicals,
Deviations:	n.a
GLP:	Yes
Acceptability:	n.a
Duplication (if vertebrate study)	No

Study owner: Triazole Derivative Metabolite Group. Access via Access Agreement.

Note: The summary of the validation data is not presents in the dRR since the applicant is not the owner of the study, and do not have access to the study report. Access to the study report and the associated method is via an Access Agreement (provided with the initial submission of the dossier).

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 new study submitted.

A 2.1.5.2 Processing studies on a core set of representative processes

No new study submitted.

A 2.1.6 Magnitude of residues in representative succeeding crops

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."*

A 2.1.6.1	**Study 1**		
Reference:	KCA 6.6.2-01		
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:	Max 6 months at ≤ -18°C
Preceeding 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: EC	(no code)	Residues calculated as:	PTZ-desthio, PTZ-alpha-, -3-, -4-, -5- and -6-hydroxy desthio, expressed as prothioconazole-desthio) and Triazole derivative metabolites (1 ,2,4-Triazol, TA, TAA and TLA)
Content of active substance (g/kg or g/L):	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 an Access Agreement (3rd Amendment) provided with the initial submission of the dossier.

A 2.1.7 Other/Special Studies

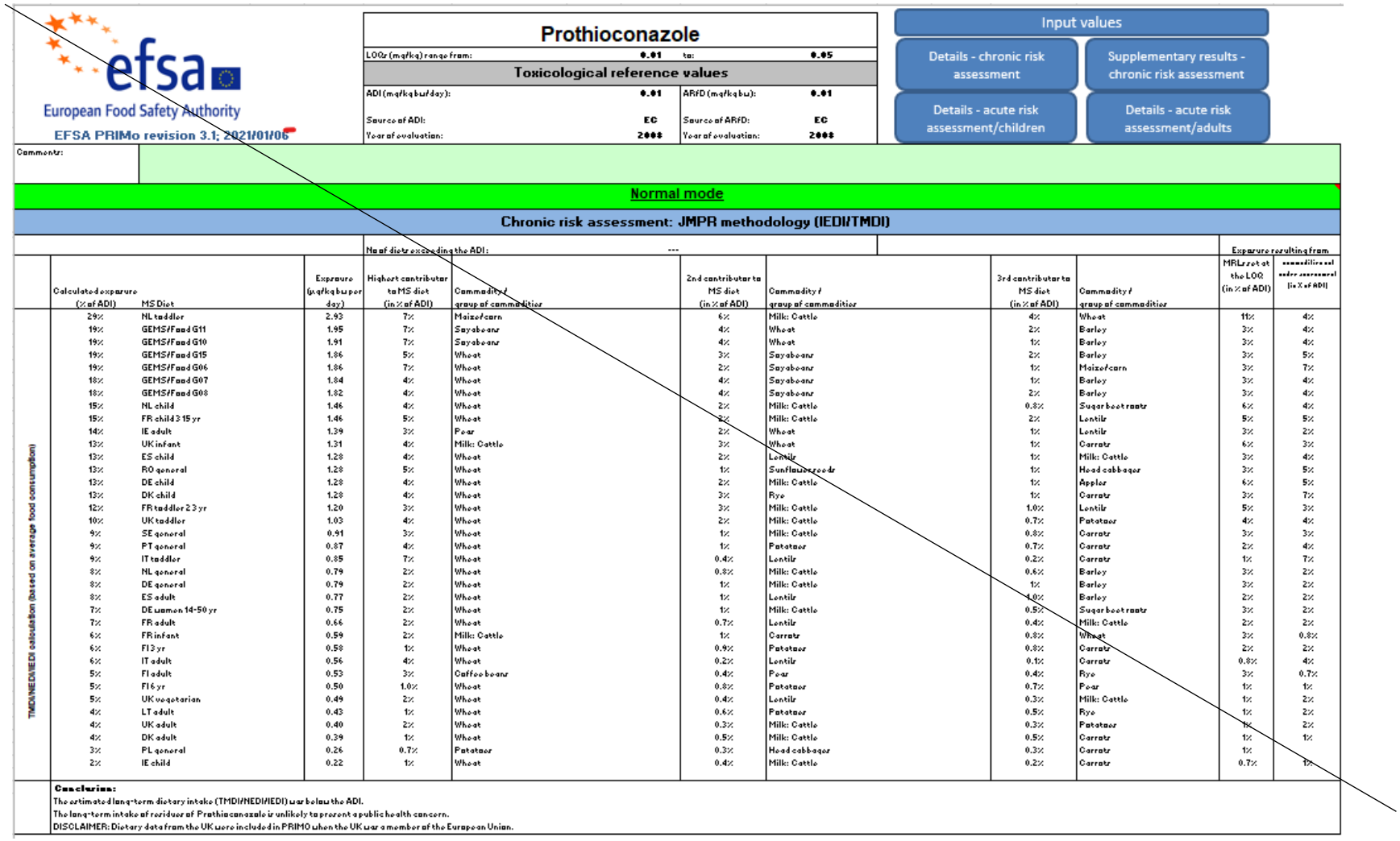
No new study submitted.

A 2.2 Sulphur

No new studies submitted.

Appendix 3 Pesticide Residue Intake Model (PRIMo) Calculation Sheets

Prothioconazole: PRIMo 3.1



European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Prothioconazole

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

Toxicological reference values

ADI (mg/kg bw/day):	0.01	ARfD (mg/kg bw):	0.01
Source of ADI:	EC	Source of ARfD:	EC
Year of evaluation:	2008	Year of evaluation:	2008

Input values

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI: ---

	Calculated exposure (% of ADI)	MS Diet	Exposure (in mg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	29%	NL toddler	2.93	7%	Maize/corn	6%	Milk: Cattle	4%	Wheat	11%	4%
	19%	GEMS/Food G11	1.95	7%	Soyabeans	4%	Wheat	2%	Barley	3%	4%
	19%	GEMS/Food G10	1.91	7%	Soyabeans	4%	Wheat	1%	Barley	3%	4%
	19%	GEMS/Food G15	1.86	5%	Wheat	3%	Soyabeans	2%	Barley	3%	5%
	19%	GEMS/Food G06	1.86	7%	Wheat	2%	Soyabeans	1%	Maize/corn	3%	7%
	18%	GEMS/Food G07	1.84	4%	Wheat	4%	Soyabeans	1%	Barley	3%	4%
	18%	GEMS/Food G08	1.82	4%	Wheat	4%	Soyabeans	2%	Barley	3%	4%
	15%	NL child	1.46	4%	Wheat	2%	Milk: Cattle	0.8%	Sugar beet roots	6%	4%
	15%	FR child 3 15 yr	1.46	5%	Wheat	2%	Milk: Cattle	2%	Lentils	5%	5%
	14%	IE adult	1.39	3%	Pear	2%	Wheat	1%	Lentils	3%	2%
	13%	UK infant	1.31	4%	Milk: Cattle	3%	Wheat	1%	Carrots	6%	3%
	13%	ES child	1.28	4%	Wheat	2%	Lentils	1%	Milk: Cattle	3%	4%
	13%	RO general	1.28	5%	Wheat	1%	Sunflower seeds	1%	Head cabbages	3%	5%
	13%	DE child	1.28	4%	Wheat	2%	Milk: Cattle	1%	Apples	6%	5%
	13%	DK child	1.28	4%	Wheat	3%	Rye	1%	Carrots	3%	7%
	12%	FR toddler 2 3 yr	1.20	3%	Wheat	3%	Milk: Cattle	1.0%	Lentils	5%	3%
	10%	UK toddler	1.03	4%	Wheat	2%	Milk: Cattle	0.7%	Potatoes	4%	4%
	9%	SE general	0.91	3%	Wheat	1%	Milk: Cattle	0.8%	Carrots	3%	3%
	9%	PT general	0.87	4%	Wheat	1%	Potatoes	0.7%	Carrots	2%	4%
	9%	IT toddler	0.85	7%	Wheat	0.4%	Lentils	0.2%	Carrots	1%	7%
	8%	NL general	0.79	2%	Wheat	0.8%	Milk: Cattle	0.6%	Barley	3%	2%
	8%	DE general	0.79	2%	Wheat	1%	Milk: Cattle	1%	Barley	3%	2%
	8%	ES adult	0.77	2%	Wheat	1%	Lentils	1.0%	Barley	2%	2%
	7%	DE women 14-50 yr	0.75	2%	Wheat	1%	Milk: Cattle	0.5%	Sugar beet roots	3%	2%
	7%	FR adult	0.66	2%	Wheat	0.7%	Lentils	0.4%	Milk: Cattle	2%	2%
	6%	FR infant	0.59	2%	Milk: Cattle	1%	Carrots	0.8%	Wheat	3%	0.8%
	6%	FI 3 yr	0.58	1%	Wheat	0.9%	Potatoes	0.8%	Carrots	2%	2%
	6%	IT adult	0.56	4%	Wheat	0.2%	Lentils	0.1%	Carrots	0.8%	4%
	5%	FI adult	0.53	3%	Coffee beans	0.4%	Pear	0.4%	Rye	3%	0.7%
	5%	FI 6 yr	0.50	1.0%	Wheat	0.8%	Potatoes	0.7%	Pear	1%	1%
	5%	UK vegetarian	0.49	2%	Wheat	0.4%	Lentils	0.3%	Milk: Cattle	1%	2%
	4%	LT adult	0.43	1%	Wheat	0.6%	Potatoes	0.5%	Rye	1%	2%
	4%	UK adult	0.40	2%	Wheat	0.3%	Milk: Cattle	0.3%	Potatoes	1%	2%
	4%	DK adult	0.39	1%	Wheat	0.5%	Milk: Cattle	0.5%	Carrots	1%	1%
	3%	PL general	0.26	0.7%	Potatoes	0.3%	Head cabbages	0.3%	Carrots	1%	
	2%	IE child	0.22	1%	Wheat	0.4%	Milk: Cattle	0.2%	Carrots	0.7%	1%

Conclusion:

The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.

The long-term intake of residues of Prothioconazole 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.

EFSA PRIMo revision 3.1; 2019/03/19

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 : ---

	Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	42%	NL toddler	4,22	8%	Wheat	7%	Maize/corn	6%	Milk: Cattle		
	36%	GEMS/Food G11	3,63	15%	Soyabeans	7%	Wheat	3%	Barley		
	35%	GEMS/Food G10	3,52	13%	Soyabeans	8%	Wheat	2%	Barley		
	34%	GEMS/Food G15	3,43	9%	Wheat	7%	Soyabeans	3%	Barley		
	34%	GEMS/Food G07	3,39	8%	Wheat	7%	Soyabeans	2%	Barley		
	34%	GEMS/Food G06	3,38	14%	Wheat	5%	Soyabeans	2%	Peas		
	34%	GEMS/Food G08	3,36	8%	Wheat	8%	Soyabeans	4%	Barley		
	25%	IE adult	2,53	6%	Peas	5%	Wheat	3%	Lentils		
	25%	NL child	2,46	8%	Wheat	3%	Sugar beet roots	2%	Milk: Cattle		
	25%	FR child 3 15 yr	2,46	9%	Wheat	4%	Lentils	2%	Milk: Cattle		
	23%	DK child	2,34	9%	Wheat	6%	Rye	4%	Carrots		
	22%	ES child	2,22	9%	Wheat	5%	Lentils	2%	Peas		
	22%	RO general	2,20	10%	Wheat	3%	Sunflower seeds	3%	Head cabbages		
	21%	UK infant	2,09	5%	Wheat	4%	Milk: Cattle	4%	Carrots		
	20%	DE child	2,04	8%	Wheat	3%	Carrots	2%	Milk: Cattle		
	20%	FR toddler 2 3 yr	1,97	6%	Wheat	3%	Milk: Cattle	2%	Lentils		
	18%	UK toddler	1,75	8%	Wheat	2%	Milk: Cattle	1%	Carrots		
	16%	IT toddler	1,64	13%	Wheat	0,7%	Lentils	0,5%	Carrots		
	16%	PT general	1,56	8%	Wheat	2%	Carrots	1%	Soyabeans		
	16%	SE general	1,55	6%	Wheat	2%	Carrots	1%	Milk: Cattle		
	14%	NL general	1,37	4%	Wheat	1%	Barley	0,9%	Sugar beet roots		
	14%	ES adult	1,37	5%	Wheat	2%	Lentils	2%	Barley		
	13%	DE general	1,34	4%	Wheat	2%	Barley	1%	Sugar beet roots		
	13%	DE women 14-50 yr	1,26	4%	Wheat	1%	Sugar beet roots	1%	Milk: Cattle		
	11%	FR adult	1,12	4%	Wheat	1%	Lentils	0,5%	Carrots		
	11%	IT adult	1,07	8%	Wheat	0,4%	Carrots	0,4%	Lentils		
	10%	FI 3 yr	1,05	2%	Wheat	2%	Carrots	0,9%	Potatoes		
	10%	FR infant	1,02	3%	Carrots	2%	Milk: Cattle	2%	Wheat		
	9%	FI 6 yr	0,90	2%	Wheat	2%	Carrots	1%	Peas		
	9%	UK vegetarian	0,89	4%	Wheat	0,8%	Lentils	0,6%	Carrots		
	7%	FI adult	0,75	3%	Coffee beans	0,9%	Carrots	0,7%	Peas		
	7%	LT adult	0,73	2%	Wheat	1%	Rye	0,7%	Head cabbages		
	7%	UK adult	0,70	3%	Wheat	0,5%	Carrots	0,3%	Milk: Cattle		
	7%	DK adult	0,67	2%	Wheat	1%	Carrots	0,5%	Milk: Cattle		
	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		

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.

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	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	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

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
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
11%	Sugar beets (root) / sugar	0.01 / 0.12	1.1

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%	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 /	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
4%	Wheat / bread/pizza	0.1 / 0.1	0.44

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Prothioconazole

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

Toxicological reference values

ADI (mg/kg bw/day):	0.01	ARfD (mg/kg bw):	0.01
Source of ADI:	EC	Source of ARfD:	EC
Year of evaluation:	2008	Year of evaluation:	2008

Input values

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

Comments:

Refined calculation 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)	commodities not under assessment (in % of ADI)
7%	GEMS/Food G06	0.73	7%	Wheat	0.0%	Rye				7%
7%	DK child	0.72	4%	Wheat	3%	Rye				7%
7%	IT toddler	0.66	7%	Wheat		FRUIT AND TREE NUTS				7%
5%	RO general	0.51	5%	Wheat		FRUIT AND TREE NUTS				5%
5%	GEMS/Food G15	0.47	5%	Wheat	0.1%	Rye				5%
5%	DE child	0.46	4%	Wheat	0.4%	Rye				5%
5%	FR child 3 15 yr	0.46	5%	Wheat	0.0%	Rye				5%
4%	ES child	0.44	4%	Wheat		FRUIT AND TREE NUTS				4%
4%	GEMS/Food G08	0.44	4%	Wheat	0.3%	Rye				4%
4%	GEMS/Food G07	0.42	4%	Wheat	0.0%	Rye				4%
4%	NL child	0.42	4%	Wheat	0.1%	Rye				4%
4%	NL toddler	0.42	4%	Wheat	0.2%	Rye				4%
4%	IT adult	0.41	4%	Wheat		FRUIT AND TREE NUTS				4%
4%	PT general	0.40	4%	Wheat	0.1%	Rye				4%
4%	GEMS/Food G10	0.40	4%	Wheat	0.1%	Rye				4%
4%	UK toddler	0.39	4%	Wheat	0.0%	Rye				4%
4%	GEMS/Food G11	0.36	4%	Wheat	0.0%	Rye				4%
3%	SE general	0.33	3%	Wheat	0.1%	Rye				3%
3%	FR toddler 2 3 yr	0.31	3%	Wheat	0.0%	Rye				3%
3%	UK infant	0.26	3%	Wheat		FRUIT AND TREE NUTS				3%
2%	DE women 14-50 yr	0.24	2%	Wheat	0.2%	Rye				2%
2%	IE adult	0.24	2%	Wheat	0.1%	Rye				2%
2%	ES adult	0.23	2%	Wheat		FRUIT AND TREE NUTS				2%
2%	FR adult	0.22	2%	Wheat	0.0%	Rye				2%
2%	DE general	0.22	2%	Wheat	0.3%	Rye				2%
2%	UK vegetarian	0.21	2%	Wheat	0.0%	Rye				2%
2%	NL general	0.20	2%	Wheat	0.0%	Rye				2%
2%	UK adult	0.17	2%	Wheat	0.0%	Rye				2%
2%	LT adult	0.16	1%	Wheat	0.5%	Rye				2%
2%	FI 3 yr	0.15	1%	Wheat	0.3%	Rye				2%
1%	DK adult	0.14	1%	Wheat	0.3%	Rye				1%
1%	FI 6 yr	0.13	1.0%	Wheat	0.3%	Rye				1%
1%	IE child	0.12	1%	Wheat		FRUIT AND TREE NUTS				1%
0.8%	FR infant	0.08	0.8%	Wheat	0.0%	Rye				0.8%
0.7%	FI adult	0.07	0.4%	Rye	0.3%	Wheat				0.7%
	Column7			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				

Show results for all crops

Unprocessed commodities

Results for children				**Results for adults**			
No. of commodities for which ARfD/ADI is exceeded (IESTI):			---	No. of commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				**IESTI**			
Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
14%	Wheat	0.1 / 0.1	1.4	8%	Wheat	0.1 / 0.1	0.84
3%	Rye	0.05 / 0.05	0.32	2%	Rye	0.05 / 0.05	0.24
Expand/collapse list							
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)							

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)
12%	Wheat / milling (flour)	0.1 / 0.1	1.2	4%	Wheat / bread/pizza	0.1 / 0.1	0.44
6%	Wheat / milling (wholemeal)	0.1 / 0.1	0.55	4%	Wheat / pasta	0.1 / 0.1	0.38
2%	Rye / boiled	0.05 / 0.05	0.18	3%	Wheat / bread (wholemeal)	0.1 / 0.1	0.35
2%	Rye / milling (wholemeal)-bc	0.05 / 0.05	0.18				
Expand/collapse list							

Acute risk assessment /children	Acute risk assessment / adults / general population	Acute risk assessment /children	Acute risk assessment / adults / general population
Details - acute risk assessment /children	Details - acute risk assessment/adults	Hide IESTI new calculations	Show IESTI new calculations

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

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.

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	0,23 / 0,23	1,9
11%	Bovine: Edible offals	0,15 / 0,15	1,1
6%	Milk: Cattle	0,01 / 0,01	0,62
6%	Bovine: Kidney	0,15 / 0,15	0,56
5%	Swine: Edible offals	0,15 / 0,15	0,45
3%	Wheat	0,01 / 0,02	0,29
3%	Swine: Liver	0,23 / 0,23	0,28
2%	Swine: Kidney	0,15 / 0,15	0,19
2%	Honey and other	0,05 / 0,05	0,18
1%	Rye	0,01 / 0,02	0,13
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%	Poultry: Liver	0,07 / 0,07	0,08
0,7%	Bovine: Muscle/meat	0,01 / 0,01	0,07

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
16%	Swine: Other products	0,5 / 0,5	1,6
10%	Bovine: Other products	0,5 / 0,5	1,00
9%	Bovine: Liver	0,23 / 0,23	0,92
6%	Sheep: Liver	0,23 / 0,23	0,64
5%	Bovine: Edible offals (other	0,15 / 0,15	0,50
4%	Swine: Edible offals (other	0,15 / 0,15	0,39
3%	Poultry: Liver	0,07 / 0,07	0,33
3%	Swine: Kidney	0,15 / 0,15	0,33
3%	Swine: Liver	0,23 / 0,23	0,32
3%	Bovine: Kidney	0,15 / 0,15	0,32
2%	Milk: Cattle	0,01 / 0,01	0,19
2%	Wheat	0,01 / 0,02	0,17
1%	Sheep: Edible offals (other	0,15 / 0,15	0,10
1,0%	Rye	0,01 / 0,02	0,10
0,9%	Milk: Goat	0,01 / 0,01	0,09

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

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
19%	Bovine: Liver	0,23 / 0,23	1,9
11%	Bovine: Edible offals	0,15 / 0,15	1,1
6%	Milk: Cattle	0,01 / 0,01	0,62
6%	Bovine: Kidney	0,15 / 0,15	0,56
5%	Swine: Edible offals	0,15 / 0,15	0,45
3%	Wheat	0,01 / 0,02	0,29
3%	Swine: Liver	0,23 / 0,23	0,28
2%	Swine: Kidney	0,15 / 0,15	0,19
2%	Honey and other	0,05 / 0,05	0,18
1%	Rye	0,01 / 0,02	0,13
1%	Other farmed animals:	0,01 / 0,02	0,12
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%	Poultry: Liver	0,07 / 0,07	0,08

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

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
16%	Swine: Other products	0,5 / 0,5	1,6
10%	Bovine: Other products	0,5 / 0,5	1,00
9%	Bovine: Liver	0,23 / 0,23	0,92
6%	Sheep: Liver	0,23 / 0,23	0,64
5%	Bovine: Edible offals (other than	0,15 / 0,15	0,50
4%	Swine: Edible offals (other than	0,15 / 0,15	0,39
3%	Poultry: Liver	0,07 / 0,07	0,33
3%	Swine: Kidney	0,15 / 0,15	0,33
3%	Swine: Liver	0,23 / 0,23	0,32
3%	Bovine: Kidney	0,15 / 0,15	0,32
2%	Milk: Cattle	0,01 / 0,01	0,19
2%	Wheat	0,01 / 0,02	0,17
1%	Sheep: Edible offals (other than	0,15 / 0,15	0,10
1%	Other farmed animals:	0,01 / 0,02	0,10
1,0%	Rye	0,01 / 0,02	0,10

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

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

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)
2%	Wheat / milling (flour)	0,01 / 0,02	0,24
1%	Wheat / milling (wholemea	0,01 / 0,02	0,11
0,7%	Rye / boiled	0,01 / 0,02	0,07
0,7%	Rye / milling (wholemeal)-l	0,01 / 0,02	0,07
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!

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)
0,9%	Wheat / bread/pizza	0,01 / 0,02	0,09
0,8%	Wheat / pasta	0,01 / 0,02	0,08
0,7%	Wheat / bread	0,01 / 0,02	0,07
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
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#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!

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)
2%	Wheat / milling (flour)	0,01 / 0,02	0,24
1%	Wheat / milling	0,01 / 0,02	0,11
0,7%	Rye / boiled	0,01 / 0,02	0,07
0,7%	Rye / milling (wholemeal)-	0,01 / 0,02	0,07
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
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#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
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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)
0,9%	Wheat / bread/pizza	0,01 / 0,02	0,09
0,8%	Wheat / pasta	0,01 / 0,02	0,08
0,7%	Wheat / bread (wholemeal)	0,01 / 0,02	0,07
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!

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.

1,2,4-Triazole – PRIMo

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

1,2,4-Triazole

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:	EC	Source of ARfD:	EC
Year of evaluation:	2021	Year of evaluation:	2021

Input values

Details - chronic risk assessment | Supplementary results - chronic risk assessment

Details - acute risk assessment/children | Details - acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
52%	NL toddler	11.95	42%	Milk: Cattle	2%	Maize/corn	1%	Bananas		0.3%
31%	UK infant	7.09	27%	Milk: Cattle	0.3%	Bovine: Muscle/meat	0.6%	Wheat		0.6%
26%	FR toddler 2 3 yr	5.92	20%	Milk: Cattle	0.8%	Bovine: Muscle/meat	0.7%	Wheat		0.7%
24%	NL child	5.62	17%	Milk: Cattle	2%	Sugar beet roots	0.3%	Wheat		0.3%
23%	FR child 3 15 yr	5.25	16%	Milk: Cattle	1%	Bovine: Muscle/meat	1.0%	Wheat		1%
19%	DE child	4.37	14%	Milk: Cattle	0.3%	Wheat	0.3%	Oranges		1%
19%	UK toddler	4.31	14%	Milk: Cattle	0.3%	Bovine: Muscle/meat	0.3%	Wheat		0.3%
16%	DK child	3.59	3%	Milk: Cattle	1%	Swine	1%	Rye		2%
14%	SE general	3.30	3%	Milk: Cattle	3%	Bovine: Muscle/meat	0.7%	Wheat		0.8%
14%	ES child	3.25	3%	Milk: Cattle	1.0%	Bovine: Muscle/meat	1.0%	Wheat		1.0%
14%	FR infant	3.12	12%	Milk: Cattle	0.3%	Sugar beet roots	0.2%	Bovine: Muscle/meat		0.2%
13%	DE general	2.97	3%	Milk: Cattle	0.3%	Sugar beet roots	0.6%	Swine		0.5%
13%	DE women 14-50 yr	2.96	3%	Milk: Cattle	1.0%	Sugar beet roots	0.5%	Swine		0.6%
13%	RO general	2.91	6%	Milk: Cattle	1%	Wheat	0.6%	Swine		1%
11%	GEMS/Food G11	2.60	5%	Milk: Cattle	0.8%	Soyabeans	0.8%	Wheat		0.8%
11%	GEMS/Food G15	2.50	5%	Milk: Cattle	1.0%	Wheat	0.3%	Swine		1%
11%	GEMS/Food G07	2.43	4%	Milk: Cattle	0.3%	Wheat	0.7%	Swine		0.3%
10%	GEMS/Food G08	2.36	4%	Milk: Cattle	1%	Swine	0.3%	Wheat		1%
10%	NL general	2.27	6%	Milk: Cattle	0.6%	Sugar beet roots	0.5%	Swine		0.4%
10%	GEMS/Food G10	2.24	4%	Milk: Cattle	0.3%	Wheat	0.7%	Soyabeans		0.3%
7%	GEMS/Food G06	1.71	2%	Milk: Cattle	2%	Wheat	0.4%	Sugar canes		2%
7%	IE adult	1.61	3%	Milk: Cattle	0.5%	Wheat	0.3%	Bovine: Muscle/meat		0.5%
7%	ES adult	1.54	3%	Milk: Cattle	0.5%	Bovine: Muscle/meat	0.5%	Wheat		0.5%
6%	DK adult	1.42	4%	Milk: Cattle	0.6%	Swine	0.4%	Swine: Muscle/meat		0.4%
6%	FR adult	1.39	3%	Milk: Cattle	0.5%	Wheat	0.4%	Bovine: Muscle/meat		0.5%
5%	LT adult	1.18	3%	Milk: Cattle	0.6%	Swine	0.4%	Swine: Muscle/meat		0.5%
4%	UK adult	0.90	2%	Milk: Cattle	0.5%	Bovine: Muscle/meat	0.4%	Wheat		0.4%
4%	UK vegetarian	0.88	2%	Milk: Cattle	0.4%	Wheat	0.2%	Oranges		0.4%
3%	IE child	0.77	2%	Milk: Cattle	0.3%	Wheat	0.2%	Swine		0.3%
3%	IT toddler	0.59	1%	Wheat	0.3%	Other cereals	0.1%	Bananas		1%
2%	PT general	0.57	0.3%	Wheat	0.2%	Potatoes	0.2%	Rice		0.3%
2%	FI 3 yr	0.43	0.3%	Bananas	0.3%	Wheat	0.2%	Potatoes		0.4%
2%	IT adult	0.39	0.3%	Wheat	0.2%	Other cereals	0.1%	Oranges		0.3%
1%	FI 6 yr	0.33	0.2%	Wheat	0.2%	Potatoes	0.2%	Bananas		0.3%
0.8%	FI adult	0.19	0.2%	Rye	0.1%	Oranges	0.1%	Wheat		0.2%
0.6%	PL general	0.14	0.1%	Potatoes	0.1%	Apples	0.1%	Head cabbages		

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

1,2,4-Triazole

LOQr (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	0.023	ARfD (mg/kg bw):	0.1
Source of ADI:	EC	Source of ARfD:	EC
Year of evaluation:	2021	Year of evaluation:	2021

Input values

Details - chronic risk assessment | Supplementary results - chronic risk assessment

Details - acute risk assessment/children | Details - acute risk assessment/adults

Comments:

Refined calculation 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 set under assessment (in % of ADI)
	52%	NL toddler	11.95	42%	Milk: Cattle	2%	Maize/corn	1%	Banana/s		0.9%
	31%	UK infant	7.09	27%	Milk: Cattle	0.9%	Bovine: Muscle/meat	0.6%	Wheat		0.6%
	26%	FR toddler 2-3 yr	5.92	20%	Milk: Cattle	0.8%	Bovine: Muscle/meat	0.7%	Wheat		0.7%
	24%	NL child	5.62	17%	Milk: Cattle	2%	Sugar beet root/s	0.9%	Wheat		0.9%
	23%	FR child 3-15 yr	5.25	16%	Milk: Cattle	1%	Bovine: Muscle/meat	1.0%	Wheat		1%
	19%	DE child	4.37	14%	Milk: Cattle	0.9%	Wheat	0.9%	Orange/s		1%
	19%	UK toddler	4.31	14%	Milk: Cattle	0.9%	Bovine: Muscle/meat	0.9%	Wheat		0.9%
	16%	DK child	3.59	9%	Milk: Cattle	1%	Suine	1%	Rye		2%
	14%	SE general	3.30	9%	Milk: Cattle	3%	Bovine: Muscle/meat	0.7%	Wheat		0.8%
	14%	ES child	3.25	9%	Milk: Cattle	1.0%	Bovine: Muscle/meat	1.0%	Wheat		1.0%
	14%	FR infant	3.12	12%	Milk: Cattle	0.3%	Sugar beet root/s	0.2%	Bovine: Muscle/meat		0.2%
	13%	DE general	2.97	9%	Milk: Cattle	0.9%	Sugar beet root/s	0.6%	Suine		0.5%
	13%	DE women 14-50 yr	2.96	9%	Milk: Cattle	1.0%	Sugar beet root/s	0.5%	Suine		0.6%
	13%	RO general	2.91	8%	Milk: Cattle	1%	Wheat	0.6%	Suine		1%
	11%	GEMS/Food G11	2.60	5%	Milk: Cattle	0.8%	Soyabean/s	0.8%	Wheat		0.8%
	11%	GEMS/Food G15	2.50	5%	Milk: Cattle	1.0%	Wheat	0.9%	Suine		1%
	11%	GEMS/Food G07	2.43	4%	Milk: Cattle	0.9%	Wheat	0.7%	Suine		0.9%
	10%	GEMS/Food G08	2.36	4%	Milk: Cattle	1%	Suine	0.9%	Wheat		1%
	10%	NL general	2.27	6%	Milk: Cattle	0.6%	Sugar beet root/s	0.5%	Suine		0.4%
	10%	GEMS/Food G10	2.24	4%	Milk: Cattle	0.9%	Wheat	0.7%	Soyabean/s		0.9%
	7%	GEMS/Food G06	1.71	2%	Milk: Cattle	2%	Wheat	0.4%	Sugar cane/s		2%
	7%	IE adult	1.61	3%	Milk: Cattle	0.5%	Wheat	0.3%	Bovine: Muscle/meat		0.5%
	7%	ES adult	1.54	3%	Milk: Cattle	0.5%	Bovine: Muscle/meat	0.5%	Wheat		0.5%
	6%	DK adult	1.42	4%	Milk: Cattle	0.6%	Suine	0.4%	Suine: Muscle/meat		0.4%
	6%	FR adult	1.39	3%	Milk: Cattle	0.5%	Wheat	0.4%	Bovine: Muscle/meat		0.5%
	5%	LT adult	1.18	3%	Milk: Cattle	0.6%	Suine	0.4%	Suine: Muscle/meat		0.5%
	4%	UK adult	0.90	2%	Milk: Cattle	0.5%	Bovine: Muscle/meat	0.4%	Wheat		0.4%
	4%	UK vegetarian	0.88	2%	Milk: Cattle	0.4%	Wheat	0.2%	Orange/s		0.4%
	3%	IE child	0.77	2%	Milk: Cattle	0.3%	Wheat	0.2%	Suine		0.3%
	3%	IT toddler	0.59	1%	Wheat	0.3%	Other cereal/s	0.1%	Banana/s		1%
	2%	PT general	0.57	0.9%	Wheat	0.2%	Potato/es	0.2%	Rice		0.9%
	2%	FI 3 yr	0.43	0.3%	Banana/s	0.3%	Wheat	0.2%	Potato/es		0.4%
	2%	IT adult	0.39	0.9%	Wheat	0.2%	Other cereal/s	0.1%	Orange/s		0.9%
	1%	FI 6 yr	0.33	0.2%	Wheat	0.2%	Potato/es	0.2%	Banana/s		0.3%
	0.8%	FI adult	0.19	0.2%	Rye	0.1%	Orange/s	0.1%	Wheat		0.2%
	0.6%	PL general	0.14	0.1%	Potato/es	0.1%	Apple/s	0.1%	Head cabbage/s		

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of 1,2,4-Triazole 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.

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)
20%	Milk: Cattle	0 / 0.16	20
4%	Milk: Goat	0 / 0.16	3.9
3%	Swine: Muscle/meat	0 / 0.21	2.5
2%	Bovine: Liver	0 / 0.25	2.0
2%	Bovine: Muscle/meat	0 / 0.24	1.7
1%	Bovine: Kidney	0 / 0.28	1.1
1%	Sheep: Muscle/meat	0 / 0.19	1.0
0.7%	Wheat	0 / 0.05	0.72
0.7%	Poultry: Muscle/meat	0 / 0.04	0.68
0.6%	Milk: Sheep	0 / 0.16	0.57
0.5%	Eggs: Chicken	0 / 0.04	0.50
0.4%	Bovine: Fat tissue	0 / 0.19	0.40
0.3%	Swine: Kidney	0 / 0.25	0.32
0.3%	Rye	0 / 0.05	0.32
0.3%	Swine: Fat tissue	0 / 0.16	0.27

Expand/collapse list

Results for adults

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
6%	Milk: Cattle	0 / 0.16	6.2
3%	Milk: Goat	0 / 0.16	2.9
2%	Milk: Sheep	0 / 0.16	2.4
1%	Bovine: Muscle	0 / 0.24	1.4
1%	Swine: Muscle/meat	0 / 0.21	1.0
1%	Bovine: Liver	0 / 0.25	1.00
0.9%	Sheep: Muscle/meat	0 / 0.19	0.90
0.8%	Sheep: Liver	0 / 0.28	0.78
0.6%	Bovine: Kidney	0 / 0.28	0.59
0.6%	Swine: Kidney	0 / 0.25	0.55
0.5%	Poultry: Muscle	0 / 0.04	0.47
0.4%	Wheat	0 / 0.05	0.42
0.3%	Swine: Fat tissue	0 / 0.16	0.32
0.3%	Goat: Muscle	0 / 0.19	0.30
0.3%	Swine: Liver	0 / 0.19	0.27

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

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)
6%	Sugar beets (root) / sugar	0 / 0.6	5.5
3%	Oranges / juice	0 / 0.05	2.6
1%	Maize / oil	0 / 1.25	1.2
0.6%	Wheat / milling (flour)	0 / 0.05	0.60
0.6%	Potatoes / dried (flakes)	0 / 0.05	0.59
0.5%	Apples / juice	0 / 0.01	0.54
0.5%	Sugar canes / sugar	0 / 0.05	0.46
0.4%	Wine grapes / juice	0 / 0.01	0.44
0.4%	Lentils / boiled	0 / 0.05	0.40
0.4%	Carrots / juice	0 / 0.01	0.36
0.4%	Peas / canned	0 / 0.02	0.36
0.3%	Pears / juice	0 / 0.01	0.33
0.3%	Rice / milling (polishing)	0 / 0.02	0.31
0.3%	Currants (red, black and whit	0 / 0.01	0.29
0.3%	Wheat / milling (wholemeal)-I	0 / 0.05	0.28

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)
2%	Sugar beets (root) / sugar	0 / 0.6	2.2
0.8%	Oranges / juice	0 / 0.05	0.76
0.6%	Maize / oil	0 / 1.25	0.63
0.5%	Grapefruits / juice	0 / 0.05	0.54
0.4%	Head cabbages / canned	0 / 0.04	0.37
0.4%	Barley / beer	0 / 0.01	0.36
0.4%	Beans / canned	0 / 0.05	0.36
0.3%	Apples / juice	0 / 0.01	0.33
0.3%	Sugar canes / sugar	0 / 0.05	0.28
0.2%	Wheat / bread/pizza	0 / 0.05	0.22
0.2%	Wine grapes / juice	0 / 0.01	0.21
0.2%	Rice / milling (polishing)	0 / 0.02	0.19
0.2%	Wheat / pasta	0 / 0.05	0.19
0.2%	Wheat / bread (wholemeal)	0 / 0.05	0.17
0.1%	Peas / canned	0 / 0.02	0.13

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)
20%	Milk: Cattle	0 / 0.16	20
4%	Milk: Goat	0 / 0.16	3.9
3%	Swine: Muscle/meat	0 / 0.21	2.5
2%	Bovine: Liver	0 / 0.25	2.0
2%	Bovine: Muscle/meat	0 / 0.24	1.7
1%	Bovine: Kidney	0 / 0.28	1.1
1%	Sheep: Muscle/meat	0 / 0.19	1.0
0.7%	Wheat	0 / 0.05	0.72
0.7%	Poultry: Muscle/meat	0 / 0.04	0.68
0.6%	Milk: Sheep	0 / 0.16	0.57
0.5%	Eggs: Chicken	0 / 0.04	0.50
0.4%	Bovine: Fat tissue	0 / 0.19	0.40
0.3%	Swine: Kidney	0 / 0.25	0.32
0.3%	Rye	0 / 0.05	0.32
0.3%	Swine: Fat tissue	0 / 0.16	0.27

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
6%	Milk: Cattle	0 / 0.16	6.2
3%	Milk: Goat	0 / 0.16	2.9
2%	Milk: Sheep	0 / 0.16	2.4
1%	Bovine: Muscle	0 / 0.24	1.4
1%	Swine: Muscle/meat	0 / 0.21	1.0
1%	Bovine: Liver	0 / 0.25	1.00
0.9%	Sheep: Muscle/meat	0 / 0.19	0.90
0.8%	Sheep: Liver	0 / 0.28	0.78
0.6%	Bovine: Kidney	0 / 0.28	0.59
0.6%	Swine: Kidney	0 / 0.25	0.55
0.5%	Poultry: Muscle	0 / 0.04	0.47
0.4%	Wheat	0 / 0.05	0.42
0.3%	Swine: Fat tissue	0 / 0.16	0.32
0.3%	Goat: Muscle	0 / 0.19	0.30
0.3%	Swine: Liver	0 / 0.19	0.27

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

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)
0.6%	Wheat / milling (flour)	0 / 0.05	0.60
0.3%	Wheat / milling (wholemeal)	0 / 0.05	0.28
0.2%	Rye / boiled	0 / 0.05	0.18
0.2%	Rye / milling (wholemeal)-bo	0 / 0.05	0.18

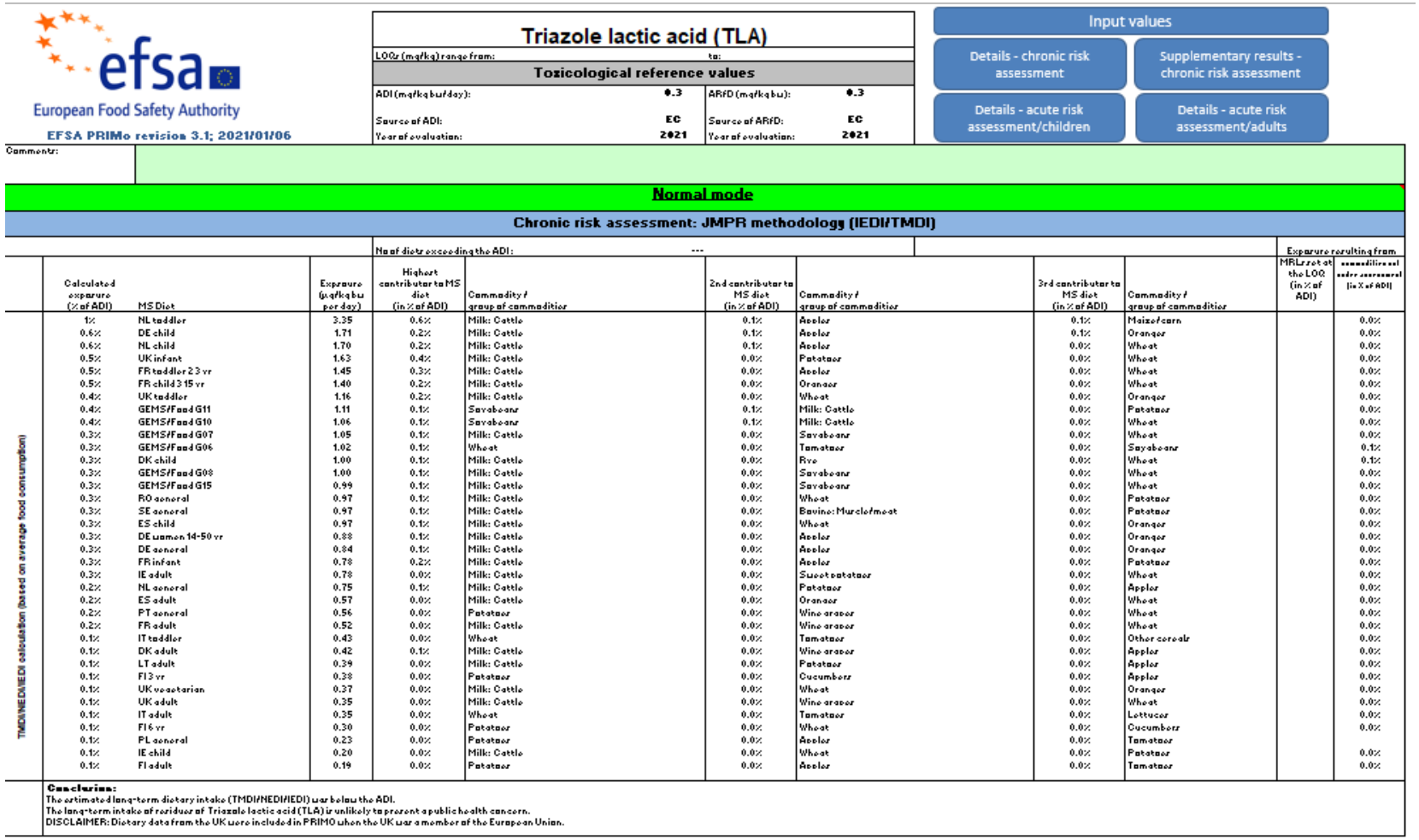
Expand/collapse list

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)
0.2%	Wheat / bread/pizza	0 / 0.05	0.22
0.2%	Wheat / pasta	0 / 0.05	0.19
0.2%	Wheat / bread (wholemeal)	0 / 0.05	0.17

Triazole Lactic Acid – PRIMo



European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Triazole lactic acid (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:	EC	Source of ARfD:	EC
Year of evaluation:	2021	Year of evaluation:	2021

Input values

Details - chronic risk assessment | Supplementary results - chronic risk assessment

Details - acute risk assessment/children | Details - acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI: ---

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

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
1%	NL toddler	3.35	0.6%	Milk: Cattle	0.1%	Apples	0.1%	Maize/corn		0.0%
0.6%	DE child	1.71	0.2%	Milk: Cattle	0.1%	Apples	0.1%	Oranges		0.0%
0.6%	NL child	1.70	0.2%	Milk: Cattle	0.1%	Apples	0.0%	Wheat		0.0%
0.5%	UK infant	1.63	0.4%	Milk: Cattle	0.0%	Potatoes	0.0%	Wheat		0.0%
0.5%	FR toddler 2-3 yr	1.45	0.3%	Milk: Cattle	0.0%	Apples	0.0%	Wheat		0.0%
0.5%	FR child 3-15 yr	1.40	0.2%	Milk: Cattle	0.0%	Oranges	0.0%	Wheat		0.0%
0.4%	UK toddler	1.16	0.2%	Milk: Cattle	0.0%	Wheat	0.0%	Oranges		0.0%
0.4%	GEMS/Food G11	1.11	0.1%	Soybeans	0.1%	Milk: Cattle	0.0%	Potatoes		0.0%
0.4%	GEMS/Food G10	1.06	0.1%	Soybeans	0.1%	Milk: Cattle	0.0%	Wheat		0.0%
0.3%	GEMS/Food G07	1.05	0.1%	Milk: Cattle	0.0%	Soybeans	0.0%	Wheat		0.0%
0.3%	GEMS/Food G06	1.02	0.1%	Wheat	0.0%	Tomatoes	0.0%	Soybeans		0.1%
0.3%	DK child	1.00	0.1%	Milk: Cattle	0.0%	Rye	0.0%	Wheat		0.1%
0.3%	GEMS/Food G08	1.00	0.1%	Milk: Cattle	0.0%	Soybeans	0.0%	Wheat		0.0%
0.3%	GEMS/Food G15	0.99	0.1%	Milk: Cattle	0.0%	Soybeans	0.0%	Wheat		0.0%
0.3%	RO general	0.97	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes		0.0%
0.3%	SE general	0.97	0.1%	Milk: Cattle	0.0%	Bovine: Muscle/meat	0.0%	Potatoes		0.0%
0.3%	ES child	0.97	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Oranges		0.0%
0.3%	DE women 14-50 yr	0.88	0.1%	Milk: Cattle	0.0%	Apples	0.0%	Oranges		0.0%
0.3%	DE general	0.84	0.1%	Milk: Cattle	0.0%	Apples	0.0%	Oranges		0.0%
0.3%	FR infant	0.78	0.2%	Milk: Cattle	0.0%	Apples	0.0%	Potatoes		0.0%
0.3%	IE adult	0.78	0.0%	Milk: Cattle	0.0%	Sweet potatoes	0.0%	Wheat		0.0%
0.2%	NL general	0.75	0.1%	Milk: Cattle	0.0%	Potatoes	0.0%	Apples		0.0%
0.2%	ES adult	0.57	0.0%	Milk: Cattle	0.0%	Oranges	0.0%	Wheat		0.0%
0.2%	PT general	0.56	0.0%	Potatoes	0.0%	Wine grapes	0.0%	Wheat		0.0%
0.2%	FR adult	0.52	0.0%	Milk: Cattle	0.0%	Wine grapes	0.0%	Wheat		0.0%
0.1%	IT toddler	0.43	0.0%	Wheat	0.0%	Tomatoes	0.0%	Other cereals		0.0%
0.1%	DK adult	0.42	0.1%	Milk: Cattle	0.0%	Wine grapes	0.0%	Apples		0.0%
0.1%	LT adult	0.39	0.0%	Milk: Cattle	0.0%	Potatoes	0.0%	Apples		0.0%
0.1%	FI 3 yr	0.38	0.0%	Potatoes	0.0%	Cucumbers	0.0%	Apples		0.0%
0.1%	UK vegetarian	0.37	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Oranges		0.0%
0.1%	UK adult	0.35	0.0%	Milk: Cattle	0.0%	Wine grapes	0.0%	Wheat		0.0%
0.1%	IT adult	0.35	0.0%	Wheat	0.0%	Tomatoes	0.0%	Lettuces		0.0%
0.1%	FI 6 yr	0.30	0.0%	Potatoes	0.0%	Wheat	0.0%	Cucumbers		0.0%
0.1%	PL general	0.23	0.0%	Potatoes	0.0%	Apples	0.0%	Tomatoes		
0.1%	IE child	0.20	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes		0.0%
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 Triazole lactic acid (TLA) is unlikely to represent a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

Unprocessed commodities

Show results for all crops

Results for children

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
1%	Milk: Cattle	0 / 0.03	3.7
0.2%	Milk: Goat	0 / 0.03	0.73
0.2%	Poultry: Muscle/meat	0 / 0.03	0.51
0.1%	Eggs: Chicken	0 / 0.03	0.37
0.1%	Bovine: Liver	0 / 0.04	0.32
0.1%	Wheat	0 / 0.02	0.32
0.09%	Rice	0 / 0.02	0.28
0.07%	Bovine: Muscle/meat	0 / 0.03	0.22
0.07%	Sunflower seeds	0 / 0.07	0.21
0.07%	Safflower seeds	0 / 0.07	0.20
0.06%	Peanuts/groundnuts	0 / 0.07	0.19
0.06%	Bovine: Fat tissue	0 / 0.03	0.19
0.06%	Beans	0 / 0.01	0.18
0.05%	Sheep: Muscle/meat	0 / 0.03	0.16
0.05%	Soyabeans	0 / 0.07	0.15

Expand/collapse list

Results for adults

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.4%	Milk: Cattle	0 / 0.03	1.2
0.2%	Milk: Goat	0 / 0.03	0.55
0.2%	Milk: Sheep	0 / 0.03	0.45
0.1%	Soyabeans	0 / 0.07	0.36
0.1%	Poultry: Muscle	0 / 0.03	0.35
0.10%	Oil palm fruits	0 / 0.07	0.29
0.06%	Rice	0 / 0.02	0.19
0.06%	Wheat	0 / 0.02	0.18
0.06%	Bovine: Muscle	0 / 0.03	0.17
0.05%	Bovine: Liver	0 / 0.04	0.16
0.05%	Peanuts/groundnuts	0 / 0.07	0.15
0.05%	Sheep: Muscle/meat	0 / 0.03	0.14
0.05%	Poultry: Liver	0 / 0.03	0.14
0.04%	Eggs: Chicken	0 / 0.03	0.13
0.04%	Sheep: Liver	0 / 0.04	0.11

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

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)
0.7%	Oranges / juice	0 / 0.04	2.1
0.6%	Wine grapes / juice	0 / 0.04	1.7
0.5%	Apples / juice	0 / 0.03	1.6
0.4%	Potatoes / dried (flakes)	0 / 0.1	1.2
0.4%	Currants (red, black and whit	0 / 0.04	1.1
0.4%	Sugar beets (root) / sugar	0 / 0.12	1.1
0.3%	Pears / juice	0 / 0.03	0.98
0.3%	Carrots / juice	0 / 0.02	0.75
0.2%	Elderberries / juice	0 / 0.04	0.64
0.2%	Peaches / juice	0 / 0.04	0.63
0.2%	Tomatoes / juice	0 / 0.03	0.57
0.2%	Maize / oil	0 / 0.55	0.51
0.2%	Raspberries / juice	0 / 0.04	0.47
0.1%	Plums / juice	0 / 0.04	0.36
0.1%	Celeriacs / juice	0 / 0.02	0.30

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)
0.3%	Apples / juice	0 / 0.03	1.00
0.3%	Wine grapes / juice	0 / 0.04	0.83
0.2%	Oranges / juice	0 / 0.04	0.60
0.2%	Currants (red, black and	0 / 0.04	0.51
0.1%	Sugar beets (root) / sugar	0 / 0.12	0.44
0.1%	Grapefruits / juice	0 / 0.04	0.43
0.1%	Elderberries / juice	0 / 0.04	0.37
0.09%	Maize / oil	0 / 0.55	0.28
0.08%	Tomatoes / sauce/puree	0 / 0.03	0.25
0.06%	Potatoes / chips	0 / 0.02	0.18
0.06%	Carrots / canned	0 / 0.02	0.17
0.05%	Barley / beer	0 / 0	0.16
0.04%	Potatoes / dried (flakes)	0 / 0.1	0.12
0.03%	Wheat / bread/pizza	0 / 0.02	0.10
0.03%	Head cabbages / canned	0 / 0.01	0.09

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Triazole lactic acid (TLA)

LOQr (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	0.3	ARfD (mg/kg bw):	0.3
Source of ADI:	EC	Source of ARfD:	EC
Year of evaluation:	2021	Year of evaluation:	2021

Input values

Details - chronic risk assessment | Supplementary results - chronic risk assessment

Details - acute risk assessment/children | Details - acute risk assessment/adults

Comments:

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI: ---

	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs not at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	0.1%	GEMS/Food G06	0.16	0.1%	Wheat						0.1%
	0.0%	IT toddler	0.15	0.0%	Wheat		FRUIT AND TREE NUTS				0.0%
	0.0%	RO general	0.11	0.0%	Wheat		FRUIT AND TREE NUTS				0.0%
	0.0%	FR child 3 15 yr	0.10	0.0%	Wheat		FRUIT AND TREE NUTS				0.0%
	0.0%	GEMS/Food G15	0.10	0.0%	Wheat		FRUIT AND TREE NUTS				0.0%
	0.0%	ES child	0.10	0.0%	Wheat		FRUIT AND TREE NUTS				0.0%
	0.0%	DK child	0.10	0.0%	Wheat		FRUIT AND TREE NUTS				0.0%
	0.0%	GEMS/Food G07	0.09	0.0%	Wheat		FRUIT AND TREE NUTS				0.0%
	0.0%	DE child	0.09	0.0%	Wheat		FRUIT AND TREE NUTS				0.0%
	0.0%	IT adult	0.09	0.0%	Wheat		FRUIT AND TREE NUTS				0.0%
	0.0%	NL child	0.09	0.0%	Wheat		FRUIT AND TREE NUTS				0.0%
	0.0%	GEMS/Food G08	0.09	0.0%	Wheat		FRUIT AND TREE NUTS				0.0%
	0.0%	NL toddler	0.09	0.0%	Wheat		FRUIT AND TREE NUTS				0.0%
	0.0%	GEMS/Food G10	0.09	0.0%	Wheat		FRUIT AND TREE NUTS				0.0%
	0.0%	PT general	0.09	0.0%	Wheat		FRUIT AND TREE NUTS				0.0%
	0.0%	UK toddler	0.09	0.0%	Wheat		FRUIT AND TREE NUTS				0.0%
	0.0%	GEMS/Food G11	0.08	0.0%	Wheat		FRUIT AND TREE NUTS				0.0%
	0.0%	SE general	0.07	0.0%	Wheat		FRUIT AND TREE NUTS				0.0%
	0.0%	FR toddler 2 3 yr	0.07	0.0%	Wheat		FRUIT AND TREE NUTS				0.0%
	0.0%	UK infant	0.06	0.0%	Wheat		FRUIT AND TREE NUTS				0.0%
	0.0%	ES adult	0.05	0.0%	Wheat		FRUIT AND TREE NUTS				0.0%
	0.0%	IE adult	0.05	0.0%	Wheat		FRUIT AND TREE NUTS				0.0%
	0.0%	FR adult	0.05	0.0%	Wheat		FRUIT AND TREE NUTS				0.0%
	0.0%	DE women 14-50 yr	0.05	0.0%	Wheat		FRUIT AND TREE NUTS				0.0%
	0.0%	UK vegetarian	0.05	0.0%	Wheat		FRUIT AND TREE NUTS				0.0%
	0.0%	NL general	0.04	0.0%	Wheat		FRUIT AND TREE NUTS				0.0%
	0.0%	DE general	0.04	0.0%	Wheat		FRUIT AND TREE NUTS				0.0%
	0.0%	UK adult	0.04	0.0%	Wheat		FRUIT AND TREE NUTS				0.0%
	0.0%	FI 3 yr	0.03	0.0%	Wheat		FRUIT AND TREE NUTS				0.0%
	0.0%	IE child	0.03	0.0%	Wheat		FRUIT AND TREE NUTS				0.0%
	0.0%	DK adult	0.02	0.0%	Wheat		FRUIT AND TREE NUTS				0.0%
	0.0%	LT adult	0.02	0.0%	Wheat		FRUIT AND TREE NUTS				0.0%
	0.0%	FI 6 yr	0.02	0.0%	Wheat		FRUIT AND TREE NUTS				0.0%
	0.0%	FR infant	0.02	0.0%	Wheat		FRUIT AND TREE NUTS				0.0%
	0.0%	FI adult	0.01	0.0%	Wheat		FRUIT AND TREE NUTS				0.0%
		Column7			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Triazole lactic acid (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.

Show results of IESTI calculation only for crops with GAPs under assessment

Unprocessed commodities

Results for children				**Results for adults**			
No. of commodities for which ARfD/ADI is exceeded (IESTI):			---	No. of commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				**IESTI**			
Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.1%	Wheat	0 / 0.02	0.32	0.06%	Wheat	0 / 0.02	0.18
Expand/collapse list							
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)							

Processed commodities

Results for children				**Results for adults**			
No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---	No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				**IESTI**			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.1%	Wheat / milling (flour)	0 / 0.02	0.27	0.0%	Wheat / bread/pizza	0 / 0.02	0.10
0.0%	Wheat / milling (wholemeal)	0 / 0.02	0.12	0.03%	Wheat / pasta	0 / 0.02	0.08
Expand/collapse list							

Triazole Acetic Acid (TAA) – PRIMo

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

Triazole acetic acid (TAA)

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	1	ARfD (mg/kg bw):	1
Source of ADI:	EC	Source of ARfD:	EC
Year of evaluation:	2021	Year of evaluation:	2021

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/MEDI 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)
0.5%	NL toddler	4.76	0.2%	Milk: Cattle	0.1%	Maize/corn	0.0%	Apples		0.0%
0.3%	NL child	2.58	0.1%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Wheat		0.0%
0.2%	DE child	2.18	0.1%	Milk: Cattle	0.0%	Apples	0.0%	Wheat		0.0%
0.2%	UK infant	2.04	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Maize/corn		0.0%
0.2%	FR child 3 15 yr	2.02	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Sugar beet roots		0.0%
0.2%	GEMS/Food G06	1.89	0.1%	Wheat	0.0%	Soybeans	0.0%	Rice		0.1%
0.2%	FR toddler 2 3 yr	1.89	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Sugar beet roots		0.0%
0.2%	GEMS/Food G11	1.78	0.0%	Soybeans	0.0%	Wheat	0.0%	Milk: Cattle		0.0%
0.2%	GEMS/Food G10	1.78	0.0%	Soybeans	0.0%	Wheat	0.0%	Milk: Cattle		0.0%
0.2%	GEMS/Food G08	1.71	0.0%	Wheat	0.0%	Soybeans	0.0%	Milk: Cattle		0.0%
0.2%	DK child	1.71	0.0%	Rye	0.0%	Milk: Cattle	0.0%	Wheat		0.1%
0.2%	GEMS/Food G07	1.68	0.0%	Wheat	0.0%	Soybeans	0.0%	Milk: Cattle		0.0%
0.2%	GEMS/Food G15	1.65	0.0%	Wheat	0.0%	Milk: Cattle	0.0%	Soybeans		0.0%
0.2%	UK toddler	1.64	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Sugar beet roots		0.0%
0.1%	RO general	1.49	0.0%	Wheat	0.0%	Milk: Cattle	0.0%	Wine grapes		0.0%
0.1%	ES child	1.40	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Oranges		0.0%
0.1%	DE women 14-50 yr	1.32	0.0%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Wheat		0.0%
0.1%	DE general	1.28	0.0%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Wheat		0.0%
0.1%	SE general	1.25	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Bovine: Muscle/meat		0.0%
0.1%	NL general	1.11	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Sugar beet roots		0.0%
0.1%	IE adult	1.06	0.0%	Wheat	0.0%	Milk: Cattle	0.0%	Wine grapes		0.0%
0.1%	PT general	0.91	0.0%	Wheat	0.0%	Wine grapes	0.0%	Rice		0.0%
0.1%	IT toddler	0.90	0.1%	Wheat	0.0%	Other cereals	0.0%	Bananas		0.1%
0.1%	FR infant	0.90	0.1%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Wheat		0.0%
0.1%	ES adult	0.81	0.0%	Wheat	0.0%	Milk: Cattle	0.0%	Oranges		0.0%
0.1%	FR adult	0.76	0.0%	Wheat	0.0%	Milk: Cattle	0.0%	Wine grapes		0.0%
0.1%	FI 3 yr	0.62	0.0%	Wheat	0.0%	Bananas	0.0%	Rye		0.0%
0.1%	IT adult	0.60	0.0%	Wheat	0.0%	Other cereals	0.0%	Apples		0.0%
0.1%	UK vegetarian	0.58	0.0%	Wheat	0.0%	Milk: Cattle	0.0%	Oranges		0.0%
0.1%	DK adult	0.57	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Wine grapes		0.0%
0.1%	LT adult	0.56	0.0%	Milk: Cattle	0.0%	Rye	0.0%	Wheat		0.0%
0.1%	UK adult	0.53	0.0%	Wheat	0.0%	Milk: Cattle	0.0%	Wine grapes		0.0%
0.0%	FI 6 yr	0.47	0.0%	Wheat	0.0%	Rye	0.0%	Potatoes		0.0%
0.0%	IE child	0.30	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Rice		0.0%
0.0%	FI adult	0.28	0.0%	Rye	0.0%	Wheat	0.0%	Oranges		0.0%
0.0%	PL general	0.22	0.0%	Apples	0.0%	Potatoes	0.0%	Table grapes		

Show results for all crops

Unprocessed commodities

Results for children

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
1%	Wheat	0 / 0.79	11
1.0%	Rice	0 / 0.79	10.0
0.5%	Rye	0 / 0.79	5.0
0.3%	Bovine: Liver	0 / 0.35	2.8
0.2%	Milk: Cattle	0 / 0.02	2.5
0.2%	Poultry: Muscle/meat	0 / 0.11	1.9
0.2%	Bovine: Muscle/meat	0 / 0.23	1.7
0.2%	Swine: Muscle/meat	0 / 0.13	1.6
0.1%	Sheep: Muscle/meat	0 / 0.23	1.3
0.08%	Bovine: Kidney	0 / 0.22	0.83
0.07%	Eggs: Chicken	0 / 0.06	0.74
0.05%	Milk: Goat	0 / 0.02	0.48
0.04%	Swine: Liver	0 / 0.34	0.42
0.03%	Swine: Kidney	0 / 0.22	0.28
0.02%	Poultry: Liver	0 / 0.22	0.24

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)
0.7%	Rice	0 / 0.79	6.7
0.7%	Wheat	0 / 0.79	6.6
0.4%	Rye	0 / 0.79	3.8
0.1%	Bovine: Liver	0 / 0.35	1.4
0.1%	Bovine: Muscle	0 / 0.23	1.3
0.1%	Poultry: Muscle	0 / 0.11	1.3
0.1%	Sheep: Muscle/meat	0 / 0.23	1.1
0.1%	Poultry: Liver	0 / 0.22	1.0
0.10%	Sheep: Liver	0 / 0.35	0.98
0.08%	Milk: Cattle	0 / 0.02	0.77
0.06%	Swine: Muscle/meat	0 / 0.13	0.63
0.05%	Swine: Kidney	0 / 0.22	0.48
0.05%	Swine: Liver	0 / 0.34	0.48
0.05%	Bovine: Kidney	0 / 0.22	0.46
0.04%	Milk: Goat	0 / 0.02	0.37

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

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)
0.6%	Sugar beets (root) / sugar	0 / 0.6	5.5
0.3%	Oranges / juice	0 / 0.05	2.6
0.2%	Wine grapes / juice	0 / 0.05	2.2
0.2%	Maize / oil	0 / 1.98	1.8
0.2%	Apples / juice	0 / 0.03	1.6
0.1%	Currants (red, black and whit	0 / 0.05	1.4
0.1%	Pears / juice	0 / 0.03	0.98
0.1%	Wheat / milling (flour)	0 / 0.08	0.96
0.1%	Elderberries / juice	0 / 0.05	0.80
0.1%	Potatoes / dried (flakes)	0 / 0.05	0.59
0.1%	Raspberries / juice	0 / 0.05	0.59
0.1%	Soyabeans / soya drink	0 / 0.12	0.50
0.0%	Rice / milling (polishing)	0 / 0.03	0.48
0.0%	Sugar canes / sugar	0 / 0.05	0.46
0.0%	Wheat / milling (wholemeal)-I	0 / 0.08	0.44

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)
0.2%	Sugar beets (root) / sugar	0 / 0.6	2.2
0.1%	Wine grapes / juice	0 / 0.05	1.0
0.1%	Maize / oil	0 / 1.98	1.0
0.10%	Apples / juice	0 / 0.03	1.00
0.08%	Oranges / juice	0 / 0.05	0.76
0.06%	Currants (red, black and	0 / 0.05	0.64
0.06%	Barley / beer	0 / 0.02	0.57
0.05%	Grapefruits / juice	0 / 0.05	0.54
0.05%	Elderberries / juice	0 / 0.05	0.46
0.04%	Beans / canned	0 / 0.05	0.36
0.03%	Wheat / bread/pizza	0 / 0.08	0.35
0.03%	Rice / milling (polishing)	0 / 0.03	0.31
0.03%	Wheat / pasta	0 / 0.08	0.30
0.03%	Sugar canes / sugar	0 / 0.05	0.28
0.03%	Wheat / bread (wholemeal)	0 / 0.08	0.28

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

Triazole acetic acid (TAA)

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	1	ARfD (mg/kg bw):	1
Source of ADI:	EC	Source of ARfD:	EC
Year of evaluation:	2021	Year of evaluation:	2021

Input values

Details - chronic risk assessment | Supplementary results - chronic risk assessment

Details - acute risk assessment/children | Details - acute risk assessment/adults

Comments:

Refined calculation 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)
0.5%	NL toddler	4.76	0.2%	Milk: Cattle	0.1%	Maize/corn	0.0%	Apples		0.0%
0.3%	NL child	2.58	0.1%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Wheat		0.0%
0.2%	DE child	2.18	0.1%	Milk: Cattle	0.0%	Apples	0.0%	Wheat		0.0%
0.2%	UK infant	2.04	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Maize/corn		0.0%
0.2%	FR child 3 15 yr	2.02	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Sugar beet roots		0.0%
0.2%	GEMS/Food G06	1.89	0.1%	Wheat	0.0%	Soyabeans	0.0%	Rice		0.1%
0.2%	FR toddler 2 3 yr	1.89	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Sugar beet roots		0.0%
0.2%	GEMS/Food G11	1.78	0.0%	Soyabeans	0.0%	Wheat	0.0%	Milk: Cattle		0.0%
0.2%	GEMS/Food G10	1.78	0.0%	Soyabeans	0.0%	Wheat	0.0%	Milk: Cattle		0.0%
0.2%	GEMS/Food G08	1.71	0.0%	Wheat	0.0%	Soyabeans	0.0%	Milk: Cattle		0.0%
0.2%	DK child	1.71	0.0%	Rye	0.0%	Milk: Cattle	0.0%	Wheat		0.1%
0.2%	GEMS/Food G07	1.68	0.0%	Wheat	0.0%	Soyabeans	0.0%	Milk: Cattle		0.0%
0.2%	GEMS/Food G15	1.65	0.0%	Wheat	0.0%	Milk: Cattle	0.0%	Soyabeans		0.0%
0.2%	UK toddler	1.64	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Sugar beet roots		0.0%
0.1%	RO general	1.49	0.0%	Wheat	0.0%	Milk: Cattle	0.0%	Wine grapes		0.0%
0.1%	ES child	1.40	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Oranges		0.0%
0.1%	DE women 14-50 yr	1.32	0.0%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Wheat		0.0%
0.1%	DE general	1.28	0.0%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Wheat		0.0%
0.1%	SE general	1.25	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Bovine: Muscle/meat		0.0%
0.1%	NL general	1.11	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Sugar beet roots		0.0%
0.1%	IE adult	1.06	0.0%	Wheat	0.0%	Milk: Cattle	0.0%	Wine grapes		0.0%
0.1%	PT general	0.91	0.0%	Wheat	0.0%	Wine grapes	0.0%	Rice		0.0%
0.1%	IT toddler	0.90	0.1%	Wheat	0.0%	Other cereals	0.0%	Bananas		0.1%
0.1%	FR infant	0.90	0.1%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Wheat		0.0%
0.1%	ES adult	0.81	0.0%	Wheat	0.0%	Milk: Cattle	0.0%	Oranges		0.0%
0.1%	FR adult	0.76	0.0%	Wheat	0.0%	Milk: Cattle	0.0%	Wine grapes		0.0%
0.1%	FI 3 yr	0.62	0.0%	Wheat	0.0%	Bananas	0.0%	Rye		0.0%
0.1%	IT adult	0.60	0.0%	Wheat	0.0%	Other cereals	0.0%	Apples		0.0%
0.1%	UK vegetarian	0.58	0.0%	Wheat	0.0%	Milk: Cattle	0.0%	Oranges		0.0%
0.1%	DK adult	0.57	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Wine grapes		0.0%
0.1%	LT adult	0.56	0.0%	Milk: Cattle	0.0%	Rye	0.0%	Wheat		0.0%
0.1%	UK adult	0.53	0.0%	Wheat	0.0%	Milk: Cattle	0.0%	Wine grapes		0.0%
0.0%	FI 6 yr	0.47	0.0%	Wheat	0.0%	Rye	0.0%	Potatoes		0.0%
0.0%	IE child	0.30	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Rice		0.0%
0.0%	FI adult	0.28	0.0%	Rye	0.0%	Wheat	0.0%	Oranges		0.0%
0.0%	PL general	0.22	0.0%	Apples	0.0%	Potatoes	0.0%	Table grapes		

Show results for all crops

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
1%	Wheat	0 / 0.79	11
1.0%	Rice	0 / 0.79	10.0
0.5%	Rye	0 / 0.79	5.0
0.3%	Bovine: Liver	0 / 0.35	2.8
0.2%	Milk: Cattle	0 / 0.02	2.5
0.2%	Poultry: Muscle/meat	0 / 0.11	1.9
0.2%	Bovine: Muscle/meat	0 / 0.23	1.7
0.2%	Swine: Muscle/meat	0 / 0.13	1.6
0.1%	Sheep: Muscle/meat	0 / 0.23	1.3
0.08%	Bovine: Kidney	0 / 0.22	0.83
0.07%	Eggs: Chicken	0 / 0.06	0.74
0.05%	Milk: Goat	0 / 0.02	0.48
0.04%	Swine: Liver	0 / 0.34	0.42
0.03%	Swine: Kidney	0 / 0.22	0.28
0.02%	Poultry: Liver	0 / 0.22	0.24

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)
0.7%	Rice	0 / 0.79	6.7
0.7%	Wheat	0 / 0.79	6.6
0.4%	Rye	0 / 0.79	3.8
0.1%	Bovine: Liver	0 / 0.35	1.4
0.1%	Bovine: Muscle	0 / 0.23	1.3
0.1%	Poultry: Muscle	0 / 0.11	1.3
0.1%	Sheep: Muscle/meat	0 / 0.23	1.1
0.1%	Poultry: Liver	0 / 0.22	1.0
0.10%	Sheep: Liver	0 / 0.35	0.98
0.08%	Milk: Cattle	0 / 0.02	0.77
0.06%	Swine: Muscle/meat	0 / 0.13	0.63
0.05%	Swine: Kidney	0 / 0.22	0.48
0.05%	Swine: Liver	0 / 0.34	0.48
0.05%	Bovine: Kidney	0 / 0.22	0.46
0.04%	Milk: Goat	0 / 0.02	0.37

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

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)
0.1%	Wheat / milling (flour)	0 / 0.08	0.96
0.0%	Wheat / milling (wholemeal)	0 / 0.08	0.44
0.0%	Rye / boiled	0 / 0.08	0.29
0.0%	Rye / milling (wholemeal)-bo	0 / 0.08	0.28

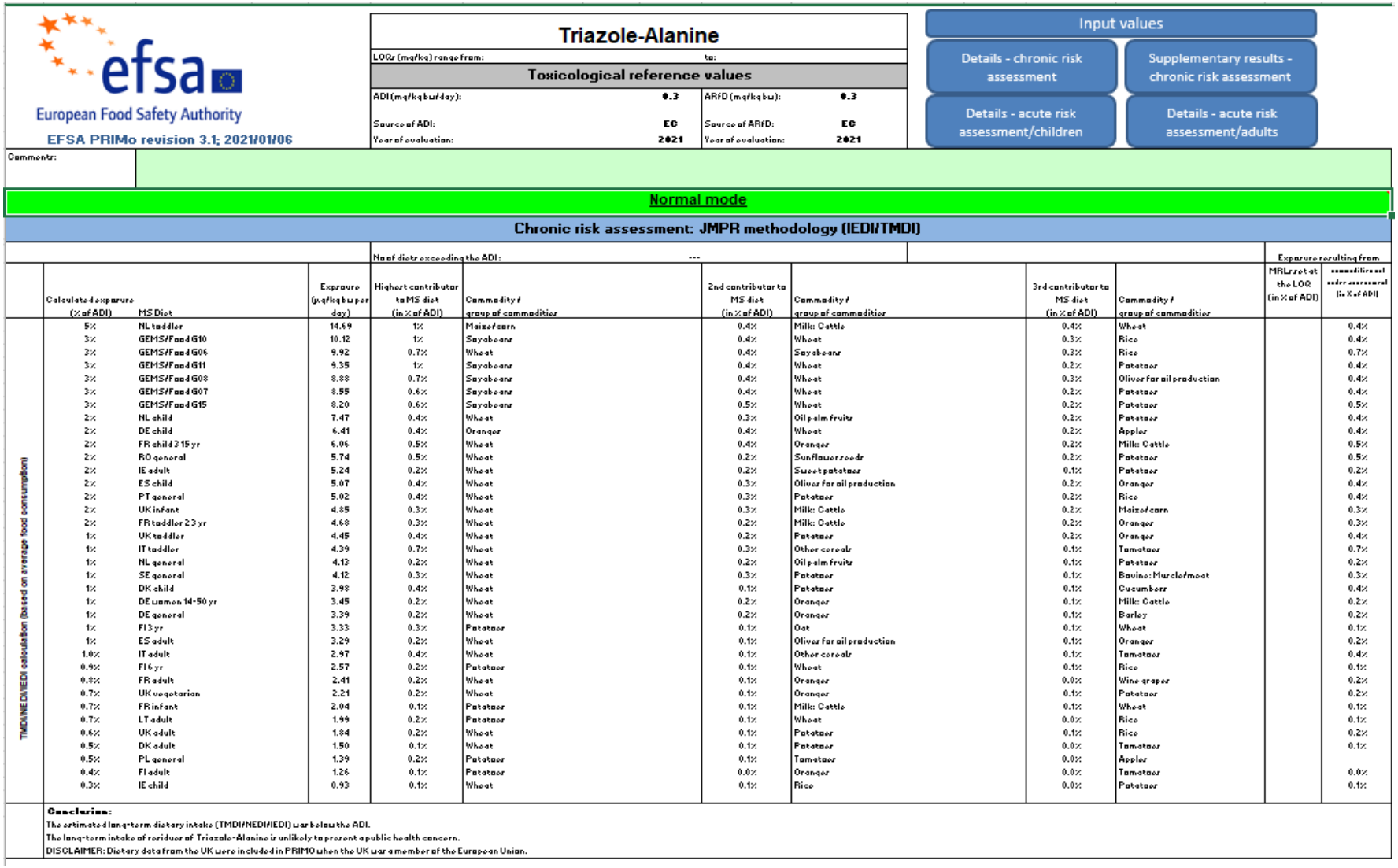
Expand/collapse list

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)
0.0%	Wheat / bread/pizza	0 / 0.08	0.35
0.03%	Wheat / pasta	0 / 0.08	0.30
0.03%	Wheat / bread (wholemeal)	0 / 0.08	0.28

Triazole Alanine (TA) – PRIMo



European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Triazole-Alanine

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:	EC	Source of ARfD:	EC
Year of evaluation:	2021	Year of evaluation:	2021

Input values

Details - chronic risk assessment | Supplementary results - chronic risk assessment

Details - acute risk assessment/children | Details - acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI: ---

TMDI/NEDI/IEDI calculation (based on average food consumption)	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs not at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
	5%	NL toddler	14.69	1%	Maize/corn	0.4%	Milk: Cattle	0.4%	Wheat		0.4%
	3%	GEMS/Food G10	10.12	1%	Soybeans	0.4%	Wheat	0.3%	Rice		0.4%
	3%	GEMS/Food G06	9.92	0.7%	Wheat	0.4%	Soybeans	0.3%	Rice		0.7%
	3%	GEMS/Food G11	9.35	1%	Soybeans	0.4%	Wheat	0.2%	Potatoes		0.4%
	3%	GEMS/Food G08	8.88	0.7%	Soybeans	0.4%	Wheat	0.3%	Olives for oil production		0.4%
	3%	GEMS/Food G07	8.55	0.6%	Soybeans	0.4%	Wheat	0.2%	Potatoes		0.4%
	3%	GEMS/Food G15	8.20	0.6%	Soybeans	0.5%	Wheat	0.2%	Potatoes		0.5%
	2%	NL child	7.47	0.4%	Wheat	0.3%	Oil palm fruits	0.2%	Potatoes		0.4%
	2%	DE child	6.41	0.4%	Oranges	0.4%	Wheat	0.2%	Apples		0.4%
	2%	FR child 3-15 yr	6.06	0.5%	Wheat	0.4%	Oranges	0.2%	Milk: Cattle		0.5%
	2%	RO general	5.74	0.5%	Wheat	0.2%	Sunflower seeds	0.2%	Potatoes		0.5%
	2%	IE adult	5.24	0.2%	Wheat	0.2%	Sweet potatoes	0.1%	Potatoes		0.2%
	2%	ES child	5.07	0.4%	Wheat	0.3%	Olives for oil production	0.2%	Oranges		0.4%
	2%	PT general	5.02	0.4%	Wheat	0.3%	Potatoes	0.2%	Rice		0.4%
	2%	UK infant	4.85	0.3%	Wheat	0.3%	Milk: Cattle	0.2%	Maize/corn		0.3%
	2%	FR toddler 2-3 yr	4.68	0.3%	Wheat	0.2%	Milk: Cattle	0.2%	Oranges		0.3%
	1%	UK toddler	4.45	0.4%	Wheat	0.2%	Potatoes	0.2%	Oranges		0.4%
	1%	IT toddler	4.39	0.7%	Wheat	0.3%	Other cereals	0.1%	Tomatoes		0.7%
	1%	NL general	4.13	0.2%	Wheat	0.2%	Oil palm fruits	0.1%	Potatoes		0.2%
	1%	SE general	4.12	0.3%	Wheat	0.3%	Potatoes	0.1%	Bovine: Muscle/meat		0.3%
	1%	DK child	3.98	0.4%	Wheat	0.1%	Potatoes	0.1%	Cucumbers		0.4%
	1%	DE women 14-50 yr	3.45	0.2%	Wheat	0.2%	Oranges	0.1%	Milk: Cattle		0.2%
	1%	DE general	3.39	0.2%	Wheat	0.2%	Oranges	0.1%	Barley		0.2%
	1%	FI 3 yr	3.33	0.3%	Potatoes	0.1%	Oat	0.1%	Wheat		0.1%
	1%	ES adult	3.29	0.2%	Wheat	0.1%	Olives for oil production	0.1%	Oranges		0.2%
	1.0%	IT adult	2.97	0.4%	Wheat	0.1%	Other cereals	0.1%	Tomatoes		0.4%
	0.9%	FI 6 yr	2.57	0.2%	Potatoes	0.1%	Wheat	0.1%	Rice		0.1%
	0.8%	FR adult	2.41	0.2%	Wheat	0.1%	Oranges	0.0%	Wine grapes		0.2%
	0.7%	UK vegetarian	2.21	0.2%	Wheat	0.1%	Oranges	0.1%	Potatoes		0.2%
	0.7%	FR infant	2.04	0.1%	Potatoes	0.1%	Milk: Cattle	0.1%	Wheat		0.1%
	0.7%	LT adult	1.99	0.2%	Potatoes	0.1%	Wheat	0.0%	Rice		0.1%
	0.6%	UK adult	1.84	0.2%	Wheat	0.1%	Potatoes	0.1%	Rice		0.2%
	0.5%	DK adult	1.50	0.1%	Wheat	0.1%	Potatoes	0.0%	Tomatoes		0.1%
	0.5%	PL general	1.39	0.2%	Potatoes	0.1%	Tomatoes	0.0%	Apples		
	0.4%	FI adult	1.26	0.1%	Potatoes	0.0%	Oranges	0.0%	Tomatoes		0.0%
	0.3%	IE child	0.93	0.1%	Wheat	0.1%	Rice	0.0%	Potatoes		0.1%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) is/are below the ADI.
The long-term intake of residues of Triazole-Alanine 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.

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)
4%	Wheat	0 / 0.74	11
3%	Rice	0 / 0.62	7.8
1%	Maize/corn	0 / 0.62	4.2
1%	Barley	0 / 0.62	3.5
1%	Sunflower seeds	0 / 1.04	3.3
1%	Safflower seeds	0 / 1.04	3.2
1%	Beans	0 / 0.17	3.1
1%	Buckwheat and other	0 / 0.62	3.1
1%	Peanuts/groundnuts	0 / 1.04	3.0
0.9%	Bovine: Liver	0 / 0.35	2.8
0.8%	Milk: Cattle	0 / 0.02	2.5
0.8%	Soybeans	0 / 1.04	2.4
0.7%	Sorghum	0 / 0.62	2.0
0.6%	Poultry: Muscle/meat	0 / 0.11	1.9
0.6%	Oil palm kernels	0 / 1.04	1.7

Expand/collapse list

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

Results for adults

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
2%	Wheat	0 / 0.74	6.2
2%	Soybeans	0 / 1.04	5.7
2%	Rice	0 / 0.62	5.3
2%	Oil palm fruits	0 / 1.04	4.6
1%	Barley	0 / 0.62	3.0
0.8%	Peanuts/groundnuts	0 / 1.04	2.4
0.7%	Buckwheat and other	0 / 0.62	2.2
0.6%	Pumpkin seeds	0 / 1.04	1.7
0.5%	Bovine: Liver	0 / 0.35	1.4
0.4%	Maize/corn	0 / 0.62	1.3
0.4%	Bovine: Muscle	0 / 0.23	1.3
0.4%	Poultry: Muscle	0 / 0.11	1.3
0.4%	Beans	0 / 0.17	1.1
0.3%	Lentils	0 / 0.17	1.0
0.3%	Sunflower seeds	0 / 1.04	1.0

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)
6%	Orange/juice	0 / 0.32	17
5%	Maize/oil	0 / 15.53	14
4%	Potatoes/dried (flakes)	0 / 0.85	11
2%	Carrots/juice	0 / 0.18	6.6
2%	Sugar beets (root)/sugar	0 / 0.6	5.5
2%	Peaches/juice	0 / 0.32	5.3
1%	Soybeans/soya drink	0 / 1.04	4.3
1%	Tomatoes/juice	0 / 0.21	4.0
1%	Rice/milling (polishing)	0 / 0.25	3.8
1%	Peanuts/peanut butter	0 / 1.04	3.8
1%	Wheat/milling (flour)	0 / 0.3	3.6
1%	Millet/boiled	0 / 0.25	3.4
1%	Buckwheat/bulgur and grits	0 / 0.62	3.3
1%	Plums/juice	0 / 0.32	3.0
0.9%	Coriander/juice	0 / 0.18	2.7

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)
3%	Maize/oil	0 / 15.53	7.9
2%	Orange/juice	0 / 0.32	4.8
1%	Barley/beer	0 / 0.12	4.5
1%	Grapefruits/juice	0 / 0.32	3.5
0.8%	Rice/milling (polishing)	0 / 0.25	2.4
0.7%	Sugar beets (root)/sugar	0 / 0.6	2.2
0.6%	Tomatoes/sauce/puree	0 / 0.21	1.7
0.5%	Head cabbages/canned	0 / 0.17	1.6
0.5%	Potatoes/chips	0 / 0.18	1.6
0.5%	Carrots/canned	0 / 0.18	1.5
0.5%	Millet/boiled	0 / 0.25	1.4
0.4%	Wheat/bread/pizza	0 / 0.3	1.3
0.4%	Apples/juice	0 / 0.04	1.3
0.4%	Wine grapes/juice	0 / 0.06	1.2
0.4%	Beans/canned	0 / 0.17	1.2

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Triazole-Alanine

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:	EC	Source of ARfD:	EC
Year of evaluation:	2021	Year of evaluation:	2021

Input values

Details - chronic risk assessment | Supplementary results - chronic risk assessment

Details - acute risk assessment/children | Details - acute risk assessment/adults

Comments:

Refined calculation 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 (mg/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 not at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
	0.7%	GEMS/Food G06	2.17	0.7%	Wheat		FRUIT AND TREE NUTS				0.7%
	0.7%	IT toddler	1.99	0.7%	Wheat		FRUIT AND TREE NUTS				0.7%
	0.5%	RO general	1.52	0.5%	Wheat		FRUIT AND TREE NUTS				0.5%
	0.5%	FR child 3-15 yr	1.38	0.5%	Wheat		FRUIT AND TREE NUTS				0.5%
	0.5%	GEMS/Food G15	1.36	0.5%	Wheat		FRUIT AND TREE NUTS				0.5%
	0.4%	ES child	1.33	0.4%	Wheat		FRUIT AND TREE NUTS				0.4%
	0.4%	DK child	1.33	0.4%	Wheat		FRUIT AND TREE NUTS				0.4%
	0.4%	GEMS/Food G07	1.27	0.4%	Wheat		FRUIT AND TREE NUTS				0.4%
	0.4%	DE child	1.26	0.4%	Wheat		FRUIT AND TREE NUTS				0.4%
	0.4%	IT adult	1.24	0.4%	Wheat		FRUIT AND TREE NUTS				0.4%
	0.4%	NL child	1.23	0.4%	Wheat		FRUIT AND TREE NUTS				0.4%
	0.4%	GEMS/Food G08	1.22	0.4%	Wheat		FRUIT AND TREE NUTS				0.4%
	0.4%	NL toddler	1.18	0.4%	Wheat		FRUIT AND TREE NUTS				0.4%
	0.4%	GEMS/Food G10	1.18	0.4%	Wheat		FRUIT AND TREE NUTS				0.4%
	0.4%	PT general	1.18	0.4%	Wheat		FRUIT AND TREE NUTS				0.4%
	0.4%	UK toddler	1.18	0.4%	Wheat		FRUIT AND TREE NUTS				0.4%
	0.4%	GEMS/Food G11	1.08	0.4%	Wheat		FRUIT AND TREE NUTS				0.4%
	0.3%	SE general	0.96	0.3%	Wheat		FRUIT AND TREE NUTS				0.3%
	0.3%	FR toddler 2-3 yr	0.92	0.3%	Wheat		FRUIT AND TREE NUTS				0.3%
	0.3%	UK infant	0.79	0.3%	Wheat		FRUIT AND TREE NUTS				0.3%
	0.2%	ES adult	0.70	0.2%	Wheat		FRUIT AND TREE NUTS				0.2%
	0.2%	IE adult	0.69	0.2%	Wheat		FRUIT AND TREE NUTS				0.2%
	0.2%	FR adult	0.67	0.2%	Wheat		FRUIT AND TREE NUTS				0.2%
	0.2%	DE women 14-50 yr	0.64	0.2%	Wheat		FRUIT AND TREE NUTS				0.2%
	0.2%	UK vegetarian	0.61	0.2%	Wheat		FRUIT AND TREE NUTS				0.2%
	0.2%	NL general	0.58	0.2%	Wheat		FRUIT AND TREE NUTS				0.2%
	0.2%	DE general	0.57	0.2%	Wheat		FRUIT AND TREE NUTS				0.2%
	0.2%	UK adult	0.50	0.2%	Wheat		FRUIT AND TREE NUTS				0.2%
	0.1%	FI 3 yr	0.36	0.1%	Wheat		FRUIT AND TREE NUTS				0.1%
	0.1%	IE child	0.35	0.1%	Wheat		FRUIT AND TREE NUTS				0.1%
	0.1%	DK adult	0.34	0.1%	Wheat		FRUIT AND TREE NUTS				0.1%
	0.1%	LT adult	0.32	0.1%	Wheat		FRUIT AND TREE NUTS				0.1%
	0.1%	FI 6 yr	0.29	0.1%	Wheat		FRUIT AND TREE NUTS				0.1%
	0.1%	FR infant	0.24	0.1%	Wheat		FRUIT AND TREE NUTS				0.1%
	0.0%	FI adult	0.10	0.0%	Wheat		FRUIT AND TREE NUTS				0.0%
		Column7			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) is/are below the ADI.
The long-term intake of residues of Triazole-Alanine 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.

Show results for all crops

Unprocessed commodities

Results for children				**Results for adults**			
No. of commodities for which ARfD/ADI is exceeded (IESTI):			---	No. of commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				**IESTI**			
Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
4%	Wheat	0 / 0.74	11	2%	Wheat	0 / 0.74	6.2
Expand/collapse list							
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)							

Processed commodities

Results for children				**Results for adults**			
No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---	No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				**IESTI**			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
1%	Wheat / milling (flour)	0 / 0.3	3.6	0.4%	Wheat / bread/pizza	0 / 0.3	1.3
0.6%	Wheat / milling (wholemeal)	0 / 0.3	1.7	0.4%	Wheat / pasta	0 / 0.3	1.1
				0.3%	Wheat / bread (wholemeal)	0 / 0.3	1.0
Expand/collapse list							

Appendix 4 Input values for livestock dietary burden calculation (Prothioconazole)

1 - Forages		STMR	HR	PF	CF	Default PF	STMR by-P	HR by-P
Alfalfa	forage (green)			-		-		
Alfalfa	hay (fodder)					2.5		
Alfalfa	meal					2.5		
Alfalfa	silage					1.1		
Barley	forage			-		-		
Barley	straw	0.65	2.50	-	3.0	-	1.96	7.50
Barley	silage					1.3		
Bean	vines (fodder green)			-		-		
Beet, mangel	fodder			-		-		
Beet, sugar	tops	0.82	1.50	-		-	0.82	1.50
Cabbage, heads	leaves	0.01	0.06	-	2.0	-	0.02	0.12
Clover	forage			-		-		
Clover	hay					3		
Clover	silage					1		
Corn, field	forage/silage	0.01	0.01	-		-	0.01	0.01
Corn, field	stover (fodder)			-		-		
Corn, pop	stover (fodder)			-		-		
Cowpea	forage			-		-		
Cowpea	hay					2.9		
Grass	forage (fresh)			-		-		
Grass	hay					3.5		
Grass	silage					1.6		
Kale	leaves (forage)			-		-		
Lespedeza	forage			-		-		
Lespedeza	hay					4		
Millet	forage			-		-		
Millet	straw (fodder, dry)			-		-		
Oat	forage			-		-		

Oat	hay					3		
Oat	straw	0.42	2.50	-	3.0	-	1.26	7.50
Pea	vines (green)			-		-		
Pea	hay (hay or fodder)					3.5		
Pea	silage					1.6		
Rape	forage			-		-		
Rice	straw			-		-		
Rye	forage (greens)			-		-		
Rye	straw	2.25	5.99	-		-	2.25	5.52
Sorghum	forage			-		-		
Sorghum, grain	stover			-		-		
Sorghum	silage					0.6		
Soybean	forage (green)			-		-		
Soybean	hay (fodder)					1.5		
Soybean	silage					0.5		
Trefoil	forage			-		-		
Trefoil	hay					2.8		
Triticale	forage			-		-		
Triticale	hay					2.9		
Triticale	straw	0.30	1.40	-		-	0.30	1.40
Turnip	tops (leaves)			-		-		
Vetch	forage			-		-		
Vetch	hay					2.8		
Wheat	forage			-		-		
Wheat	hay (fodder dry)					3.5		
Wheat	straw	2.69	9.30	-		-	2.69	5.99
2 - Roots & Tubers		**STMR**	**HR**	**-**	**CF**	**-**	**STMR**	**HR**
Carrot	culls	0.08	0.10				0.08	0.10
Cassava/tapioca	roots							
Potato	culls	0.01	0.01				0.01	0.01
Swede	roots	0.08	0.10				0.08	0.10
Turnip	roots	0.08	0.10				0.08	0.10

3 - Cereal grains/Crop seeds		STMR	Post-h?	HR	CF	-	STMR	HR
Barley	grain	0.07	N				0.07	
Bean	seed (dry)	0.01	N		2.0		0.02	
Corn, field (Maize)	grain	0.01	N		2.0		0.02	
Corn, pop	grain	0.01	N		2.00		0.02	
Cotton	undelinted seed	0.05	N		2.0		0.10	
Cowpea	seed		N					
Lupin	seed	0.05	N		2.0		0.10	
Millet	grain		N					
Oat	grain	0.01	N		2.0		0.02	
Pea (Field pea)	seed (dry)	0.05	N		2.0		0.10	
Rye	grain	0.01	N		2.0		0.02	
Sorghum	grain		N					
Soybean	seed	0.05	N		2.0		0.10	
Triticale	grain	0.06	N				0.06	
Wheat	grain	0.04	N				0.04	
4 - By-products		**STMR**	**-**	**PF**	**CF**	**Default PF**	**STMR by-P**	**-**
Apple	pomace, wet					5		
Beet, sugar	dried pulp	0.06				18	1.08	
Beet, sugar	ensiled pulp	0.06				3	0.18	
Beet, sugar	molasses	0.06				28	1.68	
Brewer's grain	dried	0.07		3.3		3.3	0.23	
Canola (Rape seed)	meal	0.08				2	0.16	
Citrus	dried pulp					10		
Coconut	meal					1.5		
Corn, field	milled by-pdts	0.01		1.0	2.0	1	0.02	
Corn, field	hominy meal	0.01		1.0	2.0	6	0.02	
Corn, field	gluten feed	0.01		1.0	2.0	2.5	0.02	
Corn, field	gluten, meal	0.01		1.0	2.0	1	0.02	
Cotton	meal	0.05			2.0	1.3	0.13	
Distiller's grain	dried	0.04		1.0	0.5	3.3	0.02	
Flaxseed/Linseed	meal				2.0	2		

Lupin seed	meal	0.05			2.0	1.1	0.11	
Palm (hearts)	kernel meal					2		
Peanut	meal	0.01			2.0	2	0.04	
Potato	process waste	0.01		1.0		20	0.01	
Potato	dried pulp	0.01		1.0		38	0.01	
Rape	meal	0.08				2	0.16	
Rice	bran/pollard					10		
Safflower	meal					2		
Soybean	meal	0.05			2.0	1.3	0.13	
Soybean	hulls	0.05			2.0	13	1.30	
Sugarcane	molasses					32		
Sunflower	meal	0.01			2.0	2	0.04	
Wheat gluten	meal	0.04				1.8	0.07	
Wheat	milled by-pdts	0.04				7	0.28	