FINAL REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: **CHR/ZF/PROTI 100 FS**

Product name(s):

Gamelan 100 FS

Doraltes 100 FS

Chemical active substance:

Prothioconazole, 100 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Innvigo Sp. z o.o.

Submission date: 05.2022

MS Finalisation date: 05/09/2022

Version history

When	What
October 2021	Dossier sent for evaluation
May 2022	Updates based on feedback from zRMS Poland
June 2022	zRMS evaluation of dRR
September 2022	Final version prepared by zRMS after Commenting period

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7 Metabolism and residue data (KCA section 6)

7.1 Summary and zRMS Conclusion

New and additional information were highlighted in yellow.

The zRMS text/corrections is on grey background.

The present application is prothioconazole PPP authorisation request submitted on 07.2021. Prothioconazole is the active triazole.
As agreed by the SCoPAFF on December 6, 2019, TDMs reference values and residue definitions (TA; 1,2,4-T; TAA; TLA) agreed in EFSA conclusion of 27 July 2018 (EJ 2018; 16 (7): 5376) should be used from 1 July 2020 as part of the consumer risk assessment for active triazoles and their TDMs in applications for approval or renewal of active substances and authorization of plant protection products.
However, based on the metabolism the residue definitions for plant products are 'prothioconazole-desthio (sum of isomers)' for enforcement, and TDMs are additionally included for risk assessment.
This means that applicants submitting registration applications after 1 July 2020 are required to submit, in addition to the residue data of the triazole in question, also the residue data of TDMs and to apply in the dossier the "EFSA approach to risk assessment for active substances belonging to the triazole class of fungicides", i.e. to include in substance / product evaluation of existing agreed reference values and TDM residue definition.
Therefore, the dossier of the product was completed by the applicant with the acceptable TDMs data (see Appendix 2). According to the requirements the risk assessment from the TDMs could be finalized (see paragraph 7.2.8.2 and the PRiMos Appendix 3). These residues are unlikely to present a public health concern.

Currently valid the representative uses listed in Appendix II of SANCO/3923 /07 26 January 2021 do not include use as a seed treatment. Member States should ensure a full and acceptable risk assessment for such uses, if requested by applicants (SANCO/3923 /07 26 January 2021).

Selection of critical uses and justification

The critical GAPs with respect to consumer intake and risk assessment for the preparation CHR/ZF/PROTI 100 FS are presented in Table 7.1-1. They have been selected from the individual GAPs in the Central Zone for winter cereals. A list of all intended uses within the Central Zone is given in Part B, Section 0.

Overall conclusion

The data available are considered sufficient for risk assessment.
The assessment of this application is based on the toxicological reference values and endpoints determined in the framework of the peer review of the active substance Prothioconazole (EFSA Scientific Report (2007) 106, 1-98).

EFSA Scientific Report (2007) 106, 1-98: For seed treatment in cereals 8 trials in wheat (4 in Northern Europe and 4 in Southern Europe) demonstrate that residues in grains are below the Limit Of Quantification (LOQ) in grains and straw (0.01 and 0.05 mg/kg respectively). This no-residue situation is further supported by 14 additional trials in wheat and barley carried out in both European regions where immature plants were sampled and consistently contained residues below a LOQ of 0.05 mg/kg.

The review of all existing MRLs of Prothioconazole according to Article 12 is ongoing (EFSA Journal 2020;18 (2):5999).
Sufficient residue trials on winter cereals are available to support the central zone assessment. The exceedance of the currently established MRLs of 0.1 mg/kg for Prothioconazole as laid down in Reg. (EU) 552/2019 is not expected.

Please note that two MRL values are currently adopted in the context of the intended GAP:

Code number	Products to which the MRLs apply	Prothioconazole: prothiocona-zole-desthio (sum of isomers)
0500070	Rye	0,05
0500090	Wheat	0,1

The chronic and acute intakes of Prothioconazole residues are unlikely to present a public health concern.

Data gaps

Noticed data gaps are:
~~In general TDMs data i.e. at least justification for the intended seed treatment with prothioconazole in terms of TDMs is expected from the applicant however, recommended is full and acceptable risk assessment. Completions are to be made in the same report (this one, zRMS version).~~
None (addressed).

GAP for PROTHIOCONAZOLE (EFSA Scientific Report (2007) 106, 1-98) in the context of the authorization request

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of a.s. (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hl min max	water l/ha min max	kg as/ha min max		
wheat, rye, triticale, oat, barley	EU North South	Redigo	F	Fusarium spp., Bunt, Smut	FS	100 g/L	seed treat-ment	pre sowing	1	n.a. (0)		200 – 400 ml water /dt	*approx. 9-18 g as/ha (180 kg seed/ha)	n.a.	*5 – 10 g as/dt seed [1]

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

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. (e)	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: develop-mental stages of the pest or pest group)	**Application**				**Application rate per treatment**			**PHI** (days)	**Remarks:** e.g. g safener/syner-gist per ha (f)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap-plications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
3	PL	Winter wheat (TRZAW)	F	*Tilletia caries, Fusarium sp., Microdochium majus, Ustilago tritici*	winter seed treat-ment	n/a	a)1 b)1	n/a	a) Max. 1.0 l /t seed b) Max. 1.0 l /t seed	a) 0.018-0.025 kg a.s/ha b) 0.018-0.025 kg a.s/ha	max. 0.7 L/100 kg seed	n/a	Sowing rate: 180-250 kg/ha
4	PL	Winter triticale (TTLWI)	F	*Fusarium sp., Microdo-chium majus*	winter seed treat-ment	n/a	a)1 b)1	n/a	a) Max. 1.0 l /t seed b) Max. 1.0 l /t seed	a) 0.015-0.025 kg a.s/ha b) 0.015-0.025 kg a.s/ha	max. 0.7 L/100 kg seed	n/a	Sowing rate: 150-250 kg/ha
5	PL	Winter rye (SECCW)	F	*Fusarium sp., Microdo-chium majus, Urocystis occulta*	winter seed treat-ment	n/a	a)1 b)1	n/a	a) Max. 1.0 l /t seed b) Max. 1.0 l /t seed	a) 0.0095-0.025 kg a.s/ha b) 0.0095-0.025 kg a.s/ha	max. 0.7 L/100 kg seed	n/a	Sowing rate: 95-250 kg/ha

* 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

7.1.1 Summary of the evaluation

The preparation CHR/ZF/PROTI is composed of prothioconazole.

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

Reference value	Source	Year	Value	Study relied upon	Safety factor
Prothioconazole - Parent compound					
ADI	EFSA	2007	0.05	rat – oncogenicity	100
ARfD	EFSA	2007	0.02	original & suppl. rat developm. studies combined	100
Prothioconazole – metabolite Prothioconazole-desthio					
ADI	EFSA	2007	0.01	rat – oncogenicity	100
ARfD	EFSA	2007	0.01	Supplementary rat developmental	100

The relevant TDMs Toxicological reference values (Appendix III; SANCO/830/08 – rev. 3 2020)

	Reference value	Study	Uncertainty Factor
1,2,4-Triazole			
ADI	0.023 mg/kg bw per day	Rat 12-month study	300
ARfD	0.1 mg/kg bw	Rabbit developmental study	300
Triazole alanine			
ADI	0.3 mg/kg bw per day	Rabbit developmental study	100
ARfD	0.3 mg/kg bw	Rabbit developmental study	100

Triazole acetic acid			
ADI	1.0 mg/kg bw per day	Rat 2-generation and rabbit developmental studies	100
ARfD	1.0 mg/kg bw	Rat 2-generation and rabbit developmental studies	100
Triazole lactic acid			
ADI	0.3 mg/kg bw per day	Bridging from TA	
ARfD	0.3 mg/kg bw	Bridging from TA	

7.1.1.1 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	Winter wheat	Yes	Yes	N/A	Yes	Yes	No	No
2	Winter triticale	Yes	Yes	N/A	Yes	Yes		No
3	Winter rye	Yes	Yes	N/A	Yes	Yes		No

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

7.1.1.2 Summary for CHR/ZF/PROTI

Table 7.1-4: Information on CHR/ZF/PROTI (KCA 6.8)

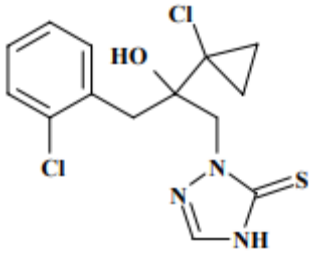
Crop	PHI for CHR/ZF/PROTI proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for CHR/ZF/PROTI proposed by zRMS	zRMS Comments (if different PHI proposed)
		Prothioconazole		
Winter wheat	N/A for seed treatment	N/A for seed treatment	N/A	
Winter triticale	N/A for seed treatment	N/A for seed treatment		
Winter rye	N/A for seed treatment	N/A for seed treatment		

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

7.2 Prothioconazole

General data on Prothioconazole are summarized in the table below (last updated 2021/01/26)

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	C14H15Cl2N3OS
Molar mass	344.26
Chemical group	Triazoles
Mode of action (if available)	Sterol biosynthesis in membranes
Systemic	Yes
Company (ies)	BAYER Cropscience AG
Rapporteur Member State (RMS)	United Kingdom
Approval status	Approved COMMISSION DIRECTIVE 2008/44/EC of 4 April 2008
Restriction	COMMISSION IMPLEMENTING REGULATION (EU) 2019/707 of 7 May 2019
Review Report	SANCO/3923 /07 - final 26 January 2021

Current MRL regulation	COMMISSION REGULATION (EU) 2019/552 of 4 April 2019
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes
EFSA Journal : Conclusion on the peer review	EFSA Scientific Report (2007) 106, 1-98
EFSA Journal: conclusion on article 12	Yes
Current MRL applications on intended uses	EFSA Journal 2020;18 (2):5999 Commodities: all Status: Evaluation report available

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

7.2.1 Stability of Residues (KCA 6.1)

7.2.1.1 Stability of residues during storage of samples

Available data

No new data submitted in the framework of this application.

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

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products			
Wheat	Grain (High starch content)	180 days for prothioconazole 540 days for Prothioconazole-desthio	Heinemann, O., 2001a
	Straw	120 days for prothioconazole 540 days for Prothioconazole-desthio	Heinemann, O., 2001a
	Green material (High water content)	60 days for prothioconazole 540 days for Prothioconazole-desthio	Heinemann, O., 2001a
Wheat, barley	Grain (High starch content)	12 months for 1,2,4-T 26 months for TA 26 months for TAA 48 months for TLA	*EFSA Journal 2018;16(7):5376*
	Straw	12 months for 1,2,4-T 53 months for TA 40 months for TAA 40 months for TLA	*EFSA Journal 2018;16(7):5376*
Wheat	Green material (High water content)	6 months for 1,2,4-T 53 months for TA 53 months for TAA 48 months for TLA	*EFSA Journal 2018;16(7):5376*

TA: triazole alanine; TAA: triazole acetic acid; TLA: triazole lactic acid; 1,2,4-T: 1,2,4-Triazole.

Conclusion on stability of residues during storage

The storage stability evaluated during Annex I inclusion covers plant matrices for use CHR/ZF/PROTI 100 FS according to the label.

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

For all presented studies analysis time were less than 24 hours between extraction and analysis or it was shown that study extracts are stable.

7.2.2 Nature of residues in plants, livestock and processed commodities

7.2.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

No new data submitted in the framework of this application.

Table 7.2-3: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (g a.s./100 kg seed)	No	Sampling (DAT)	Remarks	
EU data								
Cereals	Wheat	phenyl-UL-14C Prothioconazole	Seed treatment	20 g(1 N) or 100 g (5 N)	1	57, 119 and 153 days	-	Haas, M., 2001

Summary of plant metabolism studies reported in the EU

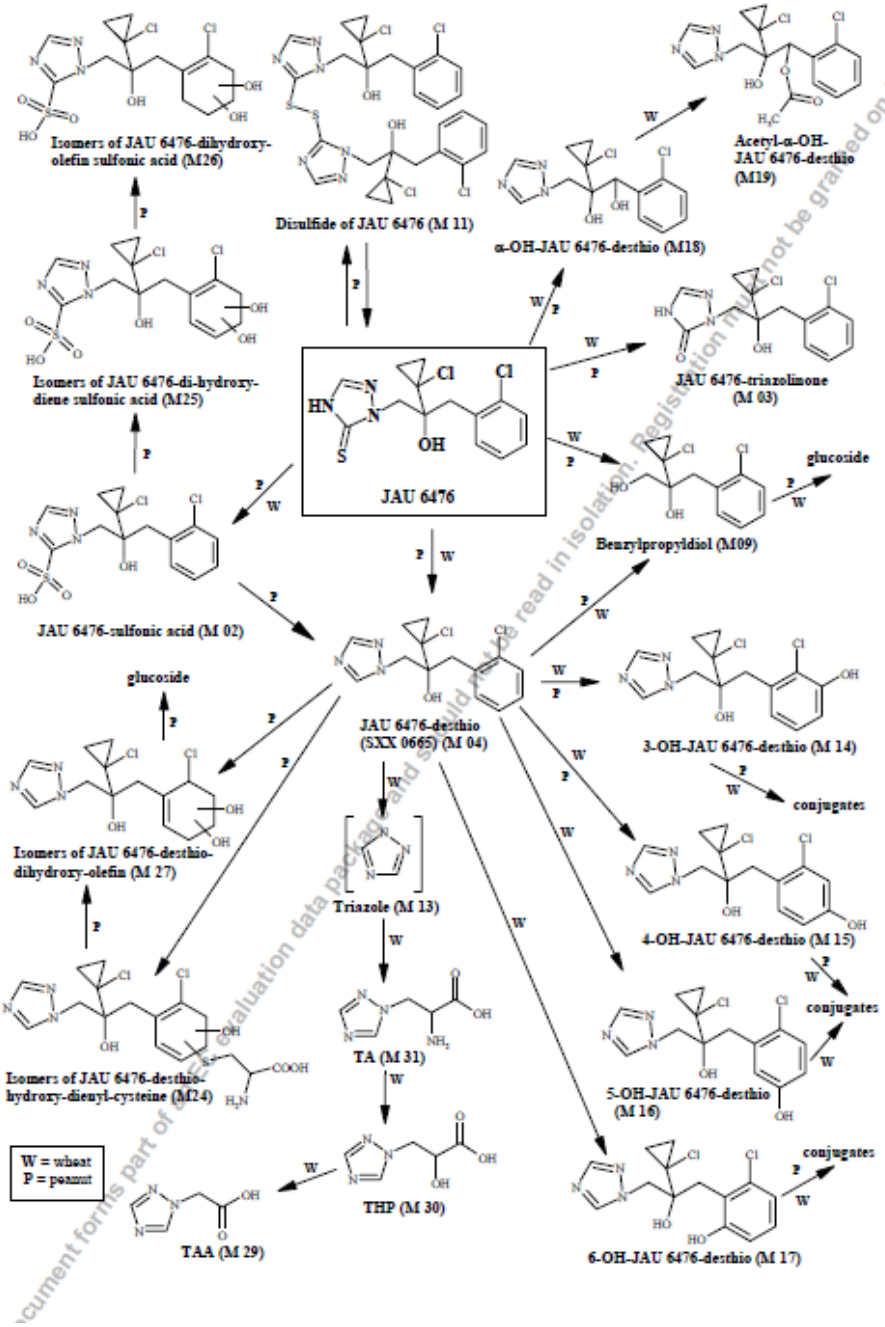
The nature of residues in spring wheat (variety: Kadett) was investigated in a 1997 indoor study (EU and EPA guidelines). [phenyl-UL-14C] JAU 6476 (radiochemical purity >99%) was dissolved in acetone and applied to wheat seeds at either 20 g a.s./100 kg seed (1 N) or 100 g a.s./100 kg seed (5 N). Treated seeds were sown in 0.5 m2 pots at an approximate rate of 220 kg seed/ha. (Proposed EU GAP for original approval for cereals is 9-18 g a.s./ha; 180 kg seed/ha).
All samples were stored at -20 °C until analysed. All matrices except grain were extracted with acetonitrile/water, with added cysteine hydrochloride to prevent oxidation of the parent material. Extracts were then partitioned with dichloromethane and radioactivity quantified by LSC and characterised by TLC and HPLC against authentic samples. Non-extractable residues were determined by combustion LSC.
Total radioactive residues (TRR) were calculated as the sum of extractable and non-extractable radioactivity. Grain samples were not extracted or characterised, as TRR was less than 0.01 mg/kg. Distribution of radioactivity in other matrices is given in Table B.7.2.1-3 for 10 N samples. Similar distribution was found in 2 N rate samples. Characterisation and identification was only carried out for 10 N samples.

Conclusions

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 chlorophenlyl 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).
This study was originally submitted and accepted for the first approval of prothioconazole. The metabolism in primary crops study presented during Annex I inclusion, covers use of CHR/ZF/PROTI on winter cereals. No new studies were necessary.

Figure B.7.1 Proposed metabolic pathway for JAU 6476 in plants



7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

No new data submitted in the framework of this application.

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

Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G *	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks	
EU data								
Leafy vegetables	swisschard	[phenyl-UL-14C]-JAU 6476	F	580 g as/ha	28, 146 and 269 days	80, 188 and 348 days	-	Haas, 2001
Root and tuber vegetables	turnip	[phenyl-UL-14C]-JAU 6476	F	580 g as/ha	28, 146 and 269 days	94, 201 and 349 days	-	Haas, 2001
Cereals	wheat	[phenyl-UL-14C]-JAU 6476	F	580 g as/ha	28, 146 and 269 days	73, 111,145, 178, 231, 269, 327, 377 and 412 days	-	Haas, 2001

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

Summary of plant metabolism studies reported in the EU

There are no significant soil residues of JAU 6476 at times of sowing following crops, residues of JAU 6476-desthio are predicted to be 42% 120 days after treatment. A study of uptake and metabolism in rotational crops showed that residues in all rotational crops 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 crop, also with similar metabolic profiles. Therefore, residues in rotational crops will not lead to any additional exposure to JAU 6476-desthio above that from directly treated crops.

Conclusion on metabolism in rotational crops

The metabolism in rotational crops covers use of CHR/ZF/PROTI according to the label.

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

No significant residues, i.e. >0.1 mg/kg, are expected to be found in winter cereals and therefore processing studies are not required.

7.2.2.4 Conclusion on the nature of residues in commodities of plant origin

(KCA 6.7.1)

Table 7.2-5: Summary of the nature of residues in commodities of plant origin

Endpoints	
Plant groups covered	Cereals (Wheat)
Rotational crops covered	Cereals (wheat) Leafy vegetables (swisschard) Root vegetables (turnip)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Not required
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes
Plant residue definition for monitoring	Prothioconazole-desthio. (JAU 6476-desthio)
Plant 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.
Conversion factor from enforcement to RA	2 (cereal grain)

* If residue pattern in processed commodities is not similar to that in raw commodities
** A more recent proposal by EFSA may be provided as additional information (EFSA RO XXXX).
*** If no EFSA proposal is available, a proposal should be made by the applicant/zRMS.

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 7.2-6: Summary of animal metabolism studies

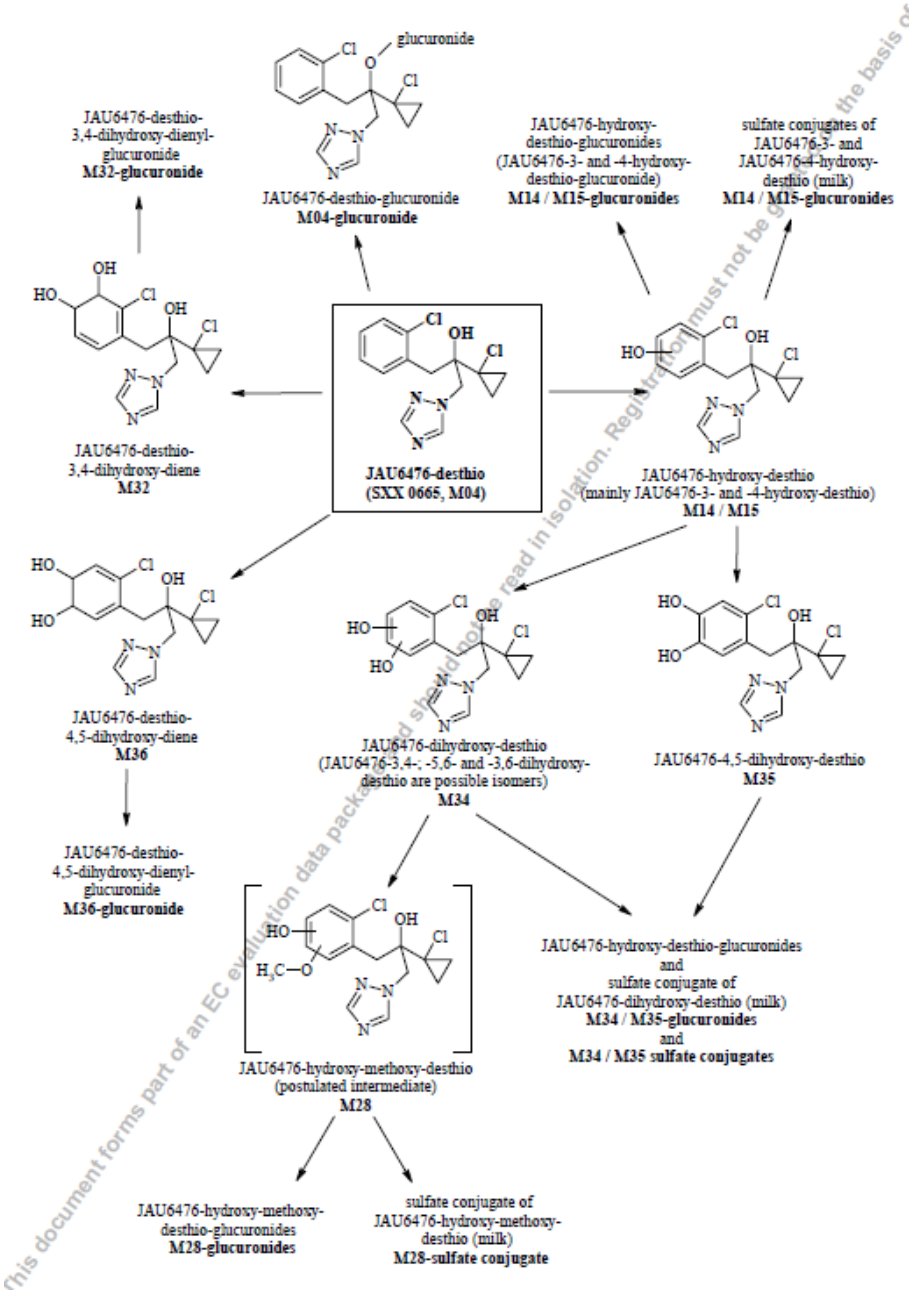
Group	**Species**	**Label position**	**No of animal**	**Application details**		**Sample details**		**Reference**
				Rate (mg/kg bw/d)	**Duration (days)**	**Commodity**	**Time of sampling**	
EU data								
Lactating ruminants	Goat	[Phenyl-UL-14C]JAU 6476	2	10	3	Milk	twice daily	Weber and Spiegel, 2001 Weber, H. Weber, E. Spiegel, K., 2002
						Urine and faeces	daily	
						Tissues	at sacrifice	
Laying poultry	Hens	[Phenyl-UL-14C]JAU 6476	6	10	3	Eggs	twice daily	Weber and Spiegel, 2001
						Excreta	regular intervals	

						Tissues	at sacrifice	

Summary of plant metabolism studies reported in the EU

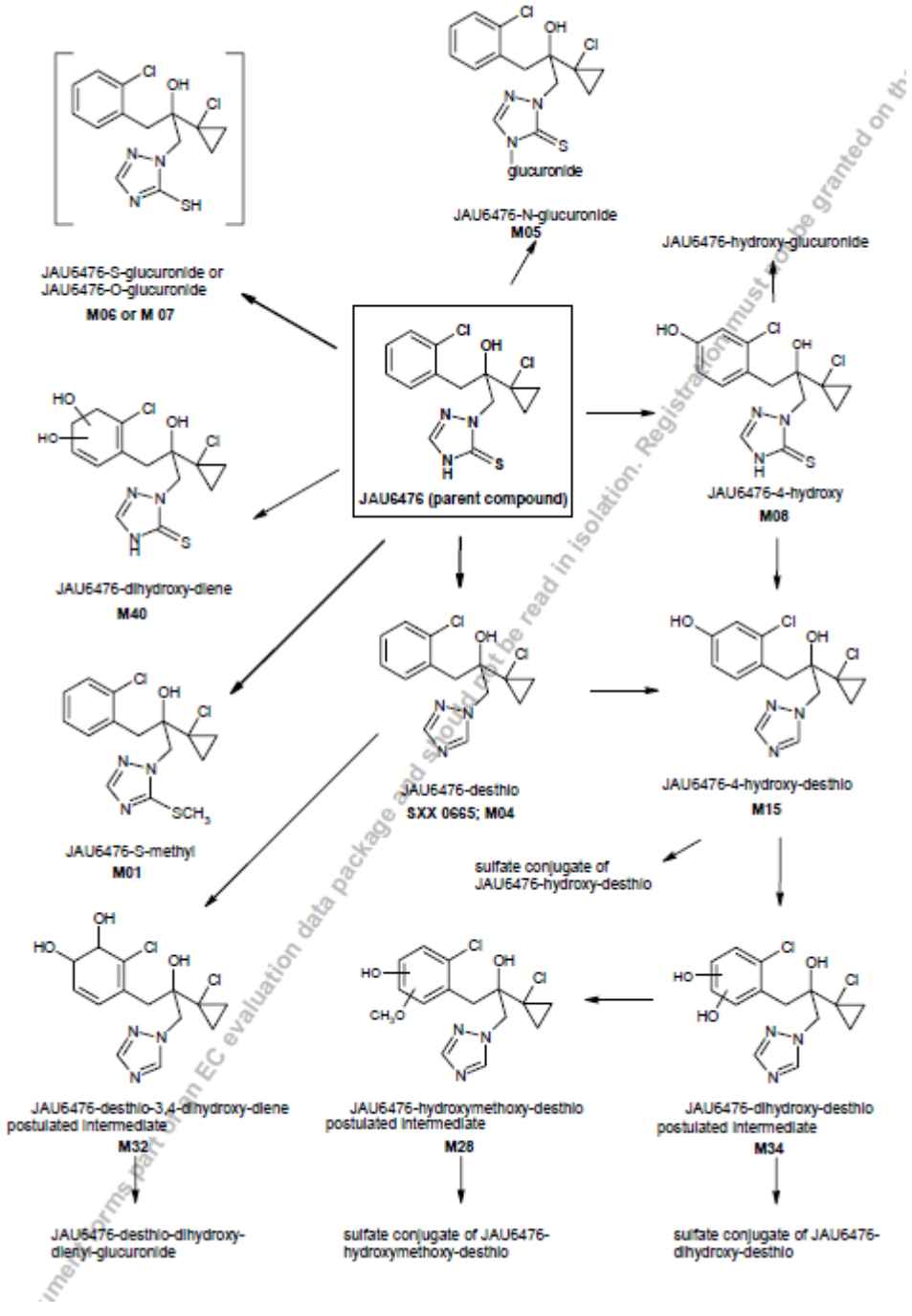
Rat and goat metabolism studies showed that JAU 6476 is rapidly adsorbed but not extensively metabolised. In the rat, JAU 6476 was almost completely excreted and in the goat it was largely excreted. In the goat, only 0.96% of the total dose was found in tissues after sacrifice and JAU 6476 was the major residue. However, as animals are more likely to be exposed to the JAU 6476-desthio metabolite, this compound was also been studied. Again in the rat and goat, JAU 6476-desthio is rapidly adsorbed, although there is more extensive metabolism. Although still largely excreted in the goat, 1.9 % of the total dose was found in tissues after sacrifice. The main metabolic reactions in the goat were hydroxylation of JAU 6476-desthio resulting in the isomers M14 and M15, followed by oxidation of the chlorophenyl moiety leading to M32 and M36. To greater or lesser extent, there was also conjugation of JAU 6476-desthio and metabolites with glucuronic acid. Although these compounds were found in tissues following dosing at very exaggerated levels, they were mainly associated with the excretory organs and are therefore unlikely to be distributed to other parts of the body.

Figure B.7.2 Proposed metabolic pathway for JAU 6476-desthio in the goat



A similar metabolic pathway was observed in poultry, although residue levels in poultry feed are unlikely to lead to significant residues in products of poultry origin.

Figure B.7.3 Proposed metabolic pathway for JAU 6476 in the hen



Conclusion on metabolism in livestock

Available metabolism studies demonstrated the residues of prothioconazole are not expected in significant amount since they are very polar and extensively excreted. The metabolic patterns identified in lactating goats and laying hens is consistent with the rat metabolism and a specific metabolism study in pigs is not considered necessary.

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

Table 7.2-7: 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	4 days in milk
	6 days in eggs
Animal residue definition for monitoring	Sum of prothioconazole-desthio and its glucuronide conjugate, expressed as prothioconazole-desthio (JAU 4676-desthio)
Animal 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.
Conversion factor	10 Milk 2 Liver 10 Muscle 2 Kidney 4 Fat
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	Yes, Log Pow for JAU 6476-desthio = 3.04

* A more recent proposal by EFSA may be provided as additional information (EFSA RO XXXX)
** If no EFSA proposal is available, a proposal should be made by the applicant/zRMS.
*** If metabolism in rat and ruminant are not similar

7.2.3 Magnitude of residues in plants (KCA 6.3)

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

New studies on the magnitude of residue have not been submitted by the applicant in the framework of this application, as studies presented on EU level covers cGAP for CHR/ZF/PROTI 100 FS. These studies are summarized in the Table below.

Table 7.2-8: Summary of EU reported and new data supporting the intended uses of CHR/ZF/PROTI and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Wheat (Grain)	Heinemann, O, 2001, RA-2010/99 Heinemann, O, 2001, RA-2091/00 Heinemann, O, 2001, RA-2003/99	N-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 0.024-0.030 kg as/ha, BBCH 0, outdoor 8 x <0.01	N/A				
	Overall supporting data for cGAP	N-EU	8 x <0.01	<0.01	<0.01	-	0.1	Yes
Wheat (straw)	Heinemann, O, 2001, RA-2010/99 Heinemann, O, 2001, RA-2091/00 Heinemann, O, 2001, RA-	EU	GAP on which MRL/EU a.s. assessment is based: 1 x 0.024-0.030 kg as/ha, BBCH 0, outdoor 4 x <0.05	N/A				

	2003/99							
	Overall supporting data for cGAP	EU	4 x <0.05	<0.05	<0.05	-	-	-
Barley (grain)	Heinemann, O, 2001, RA-2150/98 Heinemann, O, Elke, K., 2001, RA-2140/98	EU	GAP on which MRL/EU a.s. assessment is based: 1 x 0.02 kg as/ha, BBCH 0, outdoor 5 x <0.01	N/A				
	Overall supporting data for cGAP	EU	5 x <0.01	<0.01	<0.01	-	0.2	Yes
New data								
Spring wheat and spring barley (Grain)	Peda, T., Jędrusik, M., 21SGS97, 21SGS98, 21SGS99, 21SGS103 Peda, T., Niewelt-Stasiak, S., 21SGS101, 21SGS102, 21SGS104	N-EU	GAP: 1 l prod./t seeds equivalent to 0,100 kg a. s./t seeds and 0,025 kg a. s./ha considering drilling rate of 250 kg seeds/ha, BBCH 0, outdoor 1,2,4-triazole (1,2,4-T): <0.003, <0.003, <0.003, <0.003, <0.003, <0.01, <0.01 Triazolyl lactic acid (TLA): <0.003, <0.003, <0.003, <0.01, <0.01, <0.01, 0.015 Triazolylalanine (TA): 0.03, 0.058, 0.12, 0.14, 0.22, 0.22, 0.59 Triazolylacetic acid (TAA): 0.012, 0.041, 0.053, 0.076, 0.098, 0.31, 0.51	N/A				

	Overall supporting data for cGAP	N-EU	1,2,4-triazole (1,2,4-T): <0.003, <0.003, <0.003, <0.003, <0.003, <0.01, <0.01	0.003	0.01	0.015	-	-
	Overall supporting data for cGAP	N-EU	Triazolyl lactic acid (TLA): <0.003, <0.003, <0.003, <0.01, <0.01, <0.01, 0.015	0.01	0.015	0.03	-	-
	Overall supporting data for cGAP	N-EU	Triazolylalanine (TA): 0.03, 0.058, 0.12, 0.14, 0.22, 0.22, 0.59	0.14	0.59	1.0	-	-
	Overall supporting data for cGAP	N-EU	Triazolylacetic acid (TAA): 0.012, 0.041, 0.053, 0.076, 0.098, 0.31, 0.51	0.076	0.51	0.9	-	-
Spring wheat and spring barley (Straw)	Peda, T., Jędrusik, M., 21SGS97, 21SGS98, 21SGS99, 21SGS103 Peda, T., Niewelt-Stasiak, S., 21SGS101, 21SGS102, 21SGS104	N-EU	GAP: 1 l prod./t seeds equivalent to 0,100 kg a. s./t seeds and 0,025 kg a. s./ha considering drilling rate of 250 kg seeds/ha, BBCH 0, outdoor 1,2,4-triazole (1,2,4-T): <0.003, 0.010, 0.011, 0.021, 0.022, 0.027, 0.030 Triazolyl lactic acid (TLA): <0.003, 0.011, 0.013, 0.016, 0.022, 0.024, 0.025 Triazolylalanine (TA): <0.003, <0.003, 0.012, 0.018, 0.020, 0.028, 0.092 Triazolylacetic acid (TAA): <0.003, <0.01, 0.018, 0.036, 0.047, 0.17, 0.29	N/A				
	Overall supporting data for cGAP	N-EU	1,2,4-triazole (1,2,4-T): <0.003, 0.010, 0.011, 0.021, 0.022, 0.027, 0.030	0.021	0.03	-	-	-
	Overall supporting data for cGAP	N-EU	Triazolyl lactic acid (TLA): <0.003, 0.011, 0.013, 0.016, 0.022, 0.024, 0.025	0.016	0.25	-	-	-

	Overall supporting data for cGAP	N-EU	Triazolylalanine (TA): <0.003, <0.003, 0.012, 0.018, 0.020, 0.028, 0.092	0.018	0.092	-	-	-
	Overall supporting data for cGAP	N-EU	Triazolylacetic acid (TAA): <0.003, <0.01, 0.018, 0.036, 0.047, 0.17, 0.29	0.036	0.29	-	-	-
Rye	Residue data extrapolated from supervised trials presented above according to SANTE/2019/12752.						0.05	Yes
Triticale							0.1	Yes

* Source of EU MRL: Reg. (EU) 2019/552

According to SANTE/2019/12752, 1 January 2021 guidance document, residue data set for winter rye and triticale can be obtained from wheat and barley. According to GAP winter rye and triticale are designed to be used in the same BBCH 0 phases as seed treatment. The applied for GAP is considered to be covered by the critical EU GAP that was used for the MRL setting assessment. Data/information which are source of extrapolation were reviewed during the Annex I inclusion process and were considered to be acceptable.

7.2.3.2 Conclusion on the magnitude of residues in plants

According to the available data, the intended uses on cereals are considered acceptable, for outdoor uses. The data submitted show that no exceedance of the MRL will occur.
The uses are considered acceptable.

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

Table 7.2-9: Input values for the dietary burden calculation

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)				
Wheat (forage)	0.10	*STMR × CF (2)*	0.10	*STMR × CF (2)*
Wheat (hay)	0.10	*STMR × CF (2)*	0.10	*STMR × CF (2)*
Wheat (straw)	0.10	*STMR × CF (2)*	0.10	*STMR × CF (2)*
Wheat (grain)	0.02	*STMR × CF (2)*	N/A	NA
Rye (forage)	0.10	*STMR × CF (2)*	*STMR × CF (2)*	*STMR × CF (2)*
Rye (straw)	0.10	*STMR × CF (2)*	*STMR × CF (2)*	*STMR × CF (2)*
Rye (grain)	0.02	*STMR × CF (2)*	N/A	NA
Triticale (forage)	0.10	*STMR × CF (2)*	*STMR × CF (2)*	*STMR × CF (2)*
Triticale (hay)	0.10	*STMR × CF (2)*	*STMR × CF (2)*	*STMR × CF (2)*
Triticale (straw)	0.10	*STMR × CF (2)*	*STMR × CF (2)*	*STMR × CF (2)*
Triticale (grain)	0.02	*STMR × CF (2)*	N/A	NA
Brewer's grain (dried)	0.07	*STMR × CF (2) × Default PF*	N/A	NA
Distiller's grain (dried)	0.07	*STMR × CF (2) × Default PF*	N/A	NA
Wheat gluten (meal)	0.04	*STMR × CF (2) × Default PF*	N/A	NA

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Wheat (milled by products)	0.14	*STMR × CF (2) × Default PF*	N/A	NA

Following the recently published EFSA conclusion on TDMs (EFSA, 2018), the animal dietary burden should be calculated in accordance with the agreed residue definitions for risk assessment as derived for triazole pesticide active substances. The livestock exposure to TDMs from the intake of cereals treated with the product was not undertaken here by the applicant. However, in the context of this assessment, the additional data are not required since the maximum dietary burden was considered already in the TDM review (Triazole Derivative Metabolites Addendum – Confirmatory Data, February 2018), and the applicant's input data are covered (see the table below) by the input data that were applied there. Thus, the use of the product in cereals is covered by sufficient EU data which are considered applicable for the present assessment.

The input data applied for cereals in dietary burden considered in the TDM review (2018):

Crop		Residue (mg/kg)			
		T	TA	TAA	TLA
Barley grain	HR	0.08 0,01*	2.20 0,59*	1.73 0,51*	0.16 0,015*
Wheat grain	HR	0.08 0,01*	2.20 0,59*	1.73 0,51*	0.16 0,015*
Barley straw	HR	0.05 0,03*	0.65 0,092*	0.78 0,29*	1.1 0,25*
Wheat straw	HR	0.05 0,03*	0.65 0,092*	0.78 0,29*	1.1 0,25*

***The applicant's data**

New Dietary Burden calculations were performed, taking into account STMR values from residues trials presented in DAR/RAR. New calculations were presented below in Animal model 2017.

Table 7.2-10: Results of the dietary burden calculation

Animal burden calculation — **Prothioconazole**

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

Maximum Intake	Cattle						Sheep					
	Beef	500 kg / 12 kg		Dairy	650 kg / 25 kg		Ram/Ewe	75 kg / 2.5 kg		Lamb	40 kg / 1.7 kg	
(mg/kg bw/d)	0.0406	mg/kg bw/d	%	0.0406	mg/kg bw/d	%	0.0364	mg/kg bw/d	%	0.0636	mg/kg bw/d	%
Contributor 1	Barley	grain	70	Barley	grain	40	Barley	grain	40	Barley	grain	60
Contributor 2	Barley	forage	30	Barley	forage	30	Barley	forage	50	Barley	forage	40
Contributor 3			0	Wheat	milled bypdt	30	Wheat	milled bypdt	10			0
Contributor 4												
Median intake	0.0038	mg/kg bw/d		0.0060	mg/kg bw/d		0.0078	mg/kg bw/d		0.0105	mg/kg bw/d	

Maximum Intake	Swine					
	Breeding	260 kg / 6 kg		Finishing	100 kg / 3 kg	
(mg/kg bw/d)	0.044	mg/kg bw/d	%	0.056	mg/kg bw/d	%
Contributor 1	Barley	grain	80	Barley	grain	80
Contributor 2	Wheat	forage	20	Wheat	milled bypdt	20
Contributor 3			0			
Contributor 4						
Median intake	0.004	mg/kg bw/d		0.003	mg/kg bw/d	

Intakes >0.004 mg/kg bw/d are highlighted

Maximum Intake	Poultry								
	Broiler	1.7 kg / 0.12 kg		Layer	1.9 kg / 0.13 kg		Turkey	7 kg / 0.5 kg	
(mg/kg bw/d)	0.115	mg/kg bw/d	%	0.156	mg/kg bw/d	%	0.083	mg/kg bw/d	%
Contributor 1	Barley	grain	70	Barley	grain	100	Barley	grain	50
Contributor 2	Wheat	milled bypdt	20			0	Wheat	milled bypdt	20
Contributor 3						0			
Contributor 4									
Median intake	0.003	mg/kg bw		0.006	mg/kg bw		0.003	mg/kg bw	

Intakes expressed on the dry mater basis (mg/kg DM)

mg/kg DM	Cattle		Sheep		Swine	
	Beef	Dairy	Ram/Ewe	Lamb	Breeding	Finishing
Maximum	1.6909	1.06	1.09	1.50	1.90	1.85
Median	0.1568	0.16	0.23	0.25	0.17	0.09

	Poultry		
	Broiler	Layer	Turkey
Maximum	1.62	2.27	1.17
Median	0.05	0.09	0.05

Intake >0.1 mg/kg DM in red characters

Table 7.22-10: Results of the dietary burden calculation

Animal species	Median dietary burden (mg/kg bw/d)	Median dietary burden (mg/kg DM)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Risk assessment residue definition: sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers)					
Beef cattle*	0.0038	**0.0406**	Barley (grain)	**0.0406**	Y
Dairy cattle*	0.0060	**0.0406**	Barley (grain)	**0.0406**	Y
Ram/ewe	0.0078	**0.0364**	Barley (grain)	**0.0364**	Y

Animal species	Median dietary burden (mg/kg bw/d)	Median dietary burden (mg/kg DM)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Lamb	0.0105	**0.0636**	Barley (grain)	**0.0636**	Y
Breeding swine	0.004	**0.044**	Barley (grain)	**0.044**	Y
Finishing swine*	0.003	**0.056**	Barley (grain)	**0.056**	Y
Broiler poultry	0.003	**0.115**	Barley (grain)	**0.115**	Y
Layer poultry*	0.006	**0.156**	Barley (grain)	**0.156**	Y
Turkey	0.003	**0.083**	Barley (grain)	**0.083**	Y

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

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Available data

According DAR Prothioconazole - Volume 3, Annex B.7: Residues (2004):

In a 1998 livestock feeding study (EU and EPA guidelines), unlabelled JAU 6476-desthio (chemical purity 96.5%) was administered to lactating dairy cows (2.5-4 years old; 469-652 kg at administration). Nominal doses of 4, 25 and 100 mg/kg feed (approximately 1.3, 7 and 30N respectively, based on calculated animal intakes) were administered orally for 28 consecutive days to three replicate animals in each dose group. An additional control animal was not dosed.
During the dosing period, milk samples were collected twice daily for three days each week. Urine and faeces were not sampled and the health of animals during the study period was not reported. After sacrifice (within 24 hours of the final dose), liver, kidney, fat and muscle samples were taken for analysis. Samples were stored below -18°C until analysis. Tissue and milk samples were processed and analysed by HPLC/MS/MS for M14, M15 and JAU 6476-desthio, using the procedures described in residue analytical method and its modification for milk M001. Reported LOQs were 0.01 mg/kg for muscle, liver, kidney and fat, and 0.004 mg/kg for milk, as total residue. Total residues in milk at the 4 and 25 mg/kg dose levels were below the LOQ. At the 100 mg/kg dose level, total residues increased from <0.004 mg/kg (day 1) to a plateau level of 0.008 to 0.012 mg/kg (day 4 to day 29). Residues in tissues after sacrifice are given in table below and residues in all control samples were below the LOQ.

Commodity	Dietary burden			Results of the livestock feeding study						Median residue (mg/kg)[b]	Highest residue (mg/kg)[c]	Calculated MRL (mg/kg)	CF for RA[d]
	Med. (mg/kg bw/d)	Med. (mg/kg DM)	Diet contribution	Dose Level (mg/kg bw/d)[a]	No	Result for enforcement		Result for RA					
						Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
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-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers).													
Pig muscle	0.04	0.056	80%	0.15	3	<0.01	<0.01	Refer to results for enforcement residue definition		<0.01	<0.01	0.01* (tentative)	1.0
				0.91	3	<0.01	<0.01						
				3.64	3	<0.01	<0.01						
Pig fat			80%	0.15	3	<0.01	<0.01			<0.01	<0.01	0.01* (tentative)	1.0
				0.91	3	<0.01	<0.01						
				3.64	3	0.02	0.04						
Pig liver			80%	0.15	3	0.02	0.03			<0.01	<0.01	0.01* (tentative)	2.0
				0.91	3	0.14	0.18						
				3.64	3	0.68	1.20						
Pig kidney			80%	0.15	3	<0.01	<0.01			<0.01	<0.01	0.01* (tentative)	9.0
				0.91	3	0.03	0.03						
				3.64	3	0.13	0.24						
Milk	0.0060	0.0406	40%	0.15	3	<0.005	N/A			<0.005	<0.005	<0.005*	1.0
				0.91	3	<0.005	N/A						
				3.64	3	<0.005	N/A						

Ruminant muscle	0.0038	0.0406	0%	0.15	3	<0.01	<0.01	Refer to results for enforcement residue definition	<0.01	<0.01	0.01* (tentative)	1.0
				0.91	3	<0.01	<0.01					
				3.64	3	<0.01	<0.01					
Ruminant fat			0%	0.15	3	<0.01	<0.01		<0.01	<0.01	0.01* (tentative)	1.0
				0.91	3	<0.01	0.01					
				3.64	3	0.02	0.04					
Ruminant liver			0%	0.15	3	0.02	0.03		0.01	0.042	0.05 (tentative)	2.0
				0.91	3	0.14	0.18					
				3.64	3	0.68	1.20					
Ruminant kidney			10%	0.15	18	<0.01	<0.01		<0.01	0.012	0.02 (tentative)	9.0
				0.91	18	0.03	0.03					
				3.64	18	0.13	0.24					

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

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

No significant residues, i.e. >0.1 mg/kg, were found in grain and therefore processing studies are not required. No further studies have been performed

7.2.6 Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation.

Considering available data dealing with nature of residues (see 7.2.2.2), no study regarding magnitude of residues in succeeding crops is needed.

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

The available data on EU level for the active substance sufficiently address aspects of the residue situation that might arise from the use of CHR/ZF/PROTI, therefore, other special studies are not needed.

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

Toxicological reference values relevant for dietary risk assessment are reported in the summary of the evaluation (see 7.1.1).

7.2.8.1 Input values for the consumer risk assessment

Table 7.2-11: Input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment for Prothioconazole-desthio				
TMDI/IESTI				
Wheat	0.2	*MRL × CF (2)* Reg. (EU) 2019/552	0.2	*MRL × CF (2)* Reg. (EU) 2019/552
Barley	0.04	*MRL × CF (2)* Reg. (EU) 2019/552	0.04	*MRL × CF (2)* Reg. (EU) 2019/552
Rye	0.1	*MRL × CF (2)* Reg. (EU) 2019/552	0.1	*MRL × CF (2)* Reg. (EU) 2019/552
Other cereals	0.1	*MRL × CF (2)* Reg. (EU) 2019/552	N/A	N/A
Barley/beer	N/A	N/A	0.008	*MRL × CF (2) × Default PF* Reg. (EU) 2019/552
Barley/milling (flour)	N/A	N/A	0.04	*MRL × CF (2)* Reg. (EU) 2019/552
Barley/cooked	N/A	N/A	0.04	*MRL × CF (2)* Reg. (EU) 2019/552
Rye /milling (wholemeal)-baking	N/A	N/A	0.1	*MRL × CF (2)* Reg. (EU) 2019/552
Rye /boiled	N/A	N/A	0.1	*MRL × CF (2)* Reg. (EU) 2019/552
Wheat /bread (wholemeal)	N/A	N/A	0.2	*MRL × CF (2)* Reg. (EU) 2019/552
Wheat /bread/pizza	N/A	N/A	0.2	*MRL × CF (2)* Reg. (EU) 2019/552
Wheat pasta	N/A	N/A	0.2	*MRL × CF (2)* Reg. (EU) 2019/552
Wheat /milling (wholemeal)-baking	N/A	N/A	0.2	*MRL × CF (2)* Reg. (EU) 2019/552
Wheat /milling (flour)	N/A	N/A	0.2	*MRL × CF (2)* Reg. (EU) 2019/552
IEDI/IESTI				

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Wheat	0.02	*STMR × CF (2)* RAR 2018, vol.3-B7	0.02	*STMR × CF (2)* RAR 2018, vol.3-B7
Barley	0.02	*STMR × CF (2)* RAR 2018, vol.3-B7	0.02	*STMR × CF (2)* RAR 2018, vol.3-B7
Rye	0.02	*STMR × CF (2)* RAR 2018, vol.3-B7	0.02	*STMR × CF (2)* RAR 2018, vol.3-B7
Other cereals	0.02	*STMR × CF (2)* RAR 2018, vol.3-B7	N/A	N/A
Barley/beer	N/A	N/A	0.004	*STMR × CF (2) × Default PF* RAR 2018, vol.3-B7
Barley/milling (flour)	N/A	N/A	0.02	*STMR × CF (2)* RAR 2018, vol.3-B7
Barley/cooked	N/A	N/A	0.02	*STMR × CF (2)* RAR 2018, vol.3-B7
Rye /milling (wholemeal)-baking	N/A	N/A	0.02	*STMR × CF (2)* RAR 2018, vol.3-B7
Rye /boiled	N/A	N/A	0.02	*STMR × CF (2)* RAR 2018, vol.3-B7
Wheat /bread (wholemeal)	N/A	N/A	0.02	*STMR × CF (2)* RAR 2018, vol.3-B7
Wheat /bread/pizza	N/A	N/A	0.02	*STMR × CF (2)* RAR 2018, vol.3-B7
Wheat pasta	N/A	N/A	0.02	*STMR × CF (2)* RAR 2018, vol.3-B7
Wheat /milling (wholemeal)-baking	N/A	N/A	0.02	*STMR × CF (2)* RAR 2018, vol.3-B7
Wheat /milling (flour)	N/A	N/A	0.02	*STMR × CF (2)* RAR 2018, vol.3-B7
Risk assessment for 1,2,4-Triazole				
TMDI/IESTI				
Wheat	0.03	*MRL × CF (2)*	0.03	*MRL × CF (2)*
Barley	0.03	*MRL × CF (2)*	0.03	*MRL × CF (2)*
Rye	0.03	*MRL × CF (2)*	0.03	*MRL × CF (2)*
Other cereals	0.03	*MRL × CF (2)*	0.03	*MRL × CF (2)*

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Barley/beer	N/A	N/A	0.006	*MRL × CF (2) × Default PF*
Barley/milling (flour)	N/A	N/A	0.03	*MRL × CF (2)*
Barley/cooked	N/A	N/A	0.03	*MRL × CF (2)*
Rye /milling (wholemeal)-baking	N/A	N/A	0.03	*MRL × CF (2)*
Rye /boiled	N/A	N/A	0.03	*MRL × CF (2)*
Wheat /bread (wholemeal)	N/A	N/A	0.03	*MRL × CF (2)*
Wheat /bread/pizza	N/A	N/A	0.03	*MRL × CF (2)*
Wheat pasta	N/A	N/A	0.03	*MRL × CF (2)*
Wheat /milling (wholemeal)-baking	N/A	N/A	0.03	*MRL × CF (2)*
Wheat /milling (flour)	N/A	N/A	0.03	*MRL × CF (2)*
IEDI/IESTI				
Wheat	0.006	*STMR × CF (2)* RAR 2018, vol.3-B7	0.006	*STMR × CF (2)* RAR 2018, vol.3-B7
Barley	0.006	*STMR × CF (2)* RAR 2018, vol.3-B7	0.006	*STMR × CF (2)* RAR 2018, vol.3-B7
Rye	0.006	*STMR × CF (2)* RAR 2018, vol.3-B7	0.006	*STMR × CF (2)* RAR 2018, vol.3-B7
Other cereals	0.006	*STMR × CF (2)* RAR 2018, vol.3-B7	0.006	N/A
Barley/beer	N/A	N/A	0.0012	*STMR × CF (2) × Default PF* RAR 2018, vol.3-B7
Barley/milling (flour)	N/A	N/A	0.006	*STMR × CF (2)* RAR 2018, vol.3-B7
Barley/cooked	N/A	N/A	0.006	*STMR × CF (2)* RAR 2018, vol.3-B7
Rye /milling (wholemeal)-baking	N/A	N/A	0.006	*STMR × CF (2)* RAR 2018, vol.3-B7
Rye /boiled	N/A	N/A	0.006	*STMR × CF (2)* RAR 2018, vol.3-B7
Wheat /bread (wholemeal)	N/A	N/A	0.006	*STMR × CF (2)* RAR 2018, vol.3-B7

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Wheat /bread/pizza	N/A	N/A	0.006	*STMR × CF (2)* RAR 2018, vol.3-B7
Wheat pasta	N/A	N/A	0.006	*STMR × CF (2)* RAR 2018, vol.3-B7
Wheat /milling (wholemeal)-baking	N/A	N/A	0.006	*STMR × CF (2)* RAR 2018, vol.3-B7
Wheat /milling (flour)	N/A	N/A	0.006	*STMR × CF (2)* RAR 2018, vol.3-B7
Risk assessment for Triazolyl lactic acid				
TMDI/IESTI				
Wheat	0.06	*MRL × CF (2)*	0.06	*MRL × CF (2)*
Barley	0.06	*MRL × CF (2)*	0.06	*MRL × CF (2)*
Rye	0.06	*MRL × CF (2)*	0.06	*MRL × CF (2)*
Other cereals	0.06	*MRL × CF (2)*	0.06	*MRL × CF (2)*
Barley/beer	N/A	N/A	0.012	*MRL × CF (2) × Default PF*
Barley/milling (flour)	N/A	N/A	0.06	*MRL × CF (2)*
Barley/cooked	N/A	N/A	0.06	*MRL × CF (2)*
Rye /milling (wholemeal)-baking	N/A	N/A	0.06	*MRL × CF (2)*
Rye /boiled	N/A	N/A	0.06	*MRL × CF (2)*
Wheat /bread (wholemeal)	N/A	N/A	0.06	*MRL × CF (2)*
Wheat /bread/pizza	N/A	N/A	0.06	*MRL × CF (2)*
Wheat pasta	N/A	N/A	0.06	*MRL × CF (2)*
Wheat /milling (wholemeal)-baking	N/A	N/A	0.06	*MRL × CF (2)*
Wheat /milling (flour)	N/A	N/A	0.06	*MRL × CF (2)*
IEDI/IESTI				
Wheat	0.02	*STMR × CF (2)*	0.02	*STMR × CF (2)*

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
		RAR 2018, vol.3-B7		RAR 2018, vol.3-B7
Barley	0.02	*STMR × CF (2)* RAR 2018, vol.3-B7	0.02	*STMR × CF (2)* RAR 2018, vol.3-B7
Rye	0.02	*STMR × CF (2)* RAR 2018, vol.3-B7	0.02	*STMR × CF (2)* RAR 2018, vol.3-B7
Other cereals	0.02	*STMR × CF (2)* RAR 2018, vol.3-B7	0.02	N/A
Barley/beer	N/A	N/A	0.004	*STMR × CF (2) × Default PF* RAR 2018, vol.3-B7
Barley/milling (flour)	N/A	N/A	0.02	*STMR × CF (2)* RAR 2018, vol.3-B7
Barley/cooked	N/A	N/A	0.02	*STMR × CF (2)* RAR 2018, vol.3-B7
Rye /milling (wholemeal)-baking	N/A	N/A	0.02	*STMR × CF (2)* RAR 2018, vol.3-B7
Rye /boiled	N/A	N/A	0.02	*STMR × CF (2)* RAR 2018, vol.3-B7
Wheat /bread (wholemeal)	N/A	N/A	0.02	*STMR × CF (2)* RAR 2018, vol.3-B7
Wheat /bread/pizza	N/A	N/A	0.02	*STMR × CF (2)* RAR 2018, vol.3-B7
Wheat pasta	N/A	N/A	0.02	*STMR × CF (2)* RAR 2018, vol.3-B7
Wheat /milling (wholemeal)-baking	N/A	N/A	0.02	*STMR × CF (2)* RAR 2018, vol.3-B7
Wheat /milling (flour)	N/A	N/A	0.02	*STMR × CF (2)* RAR 2018, vol.3-B7
Risk assessment for Triazole alanine				
TMDI/IESTI				
Wheat	2.0	*MRL × CF (2)*	2.0	*MRL × CF (2)*
Barley	2.0	*MRL × CF (2)*	2.0	*MRL × CF (2)*
Rye	2.0	*MRL × CF (2)*	2.0	*MRL × CF (2)*
Other cereals	2.0	*MRL × CF (2)*	2.0	*MRL × CF (2)*

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Barley/beer	N/A	N/A	0.4	*MRL × CF (2) × Default PF*
Barley/milling (flour)	N/A	N/A	2.0	*MRL × CF (2)*
Barley/cooked	N/A	N/A	2.0	*MRL × CF (2)*
Rye /milling (wholemeal)-baking	N/A	N/A	2.0	*MRL × CF (2)*
Rye /boiled	N/A	N/A	2.0	*MRL × CF (2)*
Wheat /bread (wholemeal)	N/A	N/A	2.0	*MRL × CF (2)*
Wheat /bread/pizza	N/A	N/A	2.0	*MRL × CF (2)*
Wheat pasta	N/A	N/A	2.0	*MRL × CF (2)*
Wheat /milling (wholemeal)-baking	N/A	N/A	2.0	*MRL × CF (2)*
Wheat /milling (flour)	N/A	N/A	2.0	*MRL × CF (2)*
IEDI/IESTI				
Wheat	0.28	*STMR × CF (2)* RAR 2018, vol.3-B7	0.28	*STMR × CF (2)* RAR 2018, vol.3-B7
Barley	0.28	*STMR × CF (2)* RAR 2018, vol.3-B7	0.28	*STMR × CF (2)* RAR 2018, vol.3-B7
Rye	0.28	*STMR × CF (2)* RAR 2018, vol.3-B7	0.28	*STMR × CF (2)* RAR 2018, vol.3-B7
Other cereals	0.28	*STMR × CF (2)* RAR 2018, vol.3-B7	0.28	N/A
Barley/beer	N/A	N/A	0.056	*STMR × CF (2) × Default PF* RAR 2018, vol.3-B7
Barley/milling (flour)	N/A	N/A	0.28	*STMR × CF (2)* RAR 2018, vol.3-B7
Barley/cooked	N/A	N/A	0.28	*STMR × CF (2)* RAR 2018, vol.3-B7
Rye /milling (wholemeal)-baking	N/A	N/A	0.28	*STMR × CF (2)* RAR 2018, vol.3-B7
Rye /boiled	N/A	N/A	0.28	*STMR × CF (2)* RAR 2018, vol.3-B7

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Wheat /bread (wholemeal)	N/A	N/A	0.28	*STMR × CF (2)* RAR 2018, vol.3-B7
Wheat /bread/pizza	N/A	N/A	0.28	*STMR × CF (2)* RAR 2018, vol.3-B7
Wheat pasta	N/A	N/A	0.28	*STMR × CF (2)* RAR 2018, vol.3-B7
Wheat /milling (wholemeal)-baking	N/A	N/A	0.28	*STMR × CF (2)* RAR 2018, vol.3-B7
Wheat /milling (flour)	N/A	N/A	0.28	*STMR × CF (2)* RAR 2018, vol.3-B7
Risk assessment for Triazole acetic acid				
TMDI/IESTI				
Wheat	1.8	*MRL × CF (2)*	1.8	*MRL × CF (2)*
Barley	1.8	*MRL × CF (2)*	1.8	*MRL × CF (2)*
Rye	1.8	*MRL × CF (2)*	1.8	*MRL × CF (2)*
Other cereals	1.8	*MRL × CF (2)*	1.8	*MRL × CF (2)*
Barley/beer	N/A	N/A	0.36	*MRL × CF (2) × Default PF*
Barley/milling (flour)	N/A	N/A	1.8	*MRL × CF (2)*
Barley/cooked	N/A	N/A	1.8	*MRL × CF (2)*
Rye /milling (wholemeal)-baking	N/A	N/A	1.8	*MRL × CF (2)*
Rye /boiled	N/A	N/A	1.8	*MRL × CF (2)*
Wheat /bread (wholemeal)	N/A	N/A	1.8	*MRL × CF (2)*
Wheat /bread/pizza	N/A	N/A	1.8	*MRL × CF (2)*
Wheat pasta	N/A	N/A	1.8	*MRL × CF (2)*
Wheat /milling (wholemeal)-baking	N/A	N/A	1.8	*MRL × CF (2)*
Wheat /milling (flour)	N/A	N/A	1.8	*MRL × CF (2)*

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
IEDI/IESTI				
Wheat	0.152	*STMR × CF (2)* RAR 2018, vol.3-B7	0.152	*STMR × CF (2)* RAR 2018, vol.3-B7
Barley	0.152	*STMR × CF (2)* RAR 2018, vol.3-B7	0.152	*STMR × CF (2)* RAR 2018, vol.3-B7
Rye	0.152	*STMR × CF (2)* RAR 2018, vol.3-B7	0.152	*STMR × CF (2)* RAR 2018, vol.3-B7
Other cereals	0.152	*STMR × CF (2)* RAR 2018, vol.3-B7	0.152	N/A
Barley/beer	N/A	N/A	0.0304	*STMR × CF (2) × Default PF* RAR 2018, vol.3-B7
Barley/milling (flour)	N/A	N/A	0.152	*STMR × CF (2)* RAR 2018, vol.3-B7
Barley/cooked	N/A	N/A	0.152	*STMR × CF (2)* RAR 2018, vol.3-B7
Rye /milling (wholemeal)-baking	N/A	N/A	0.152	*STMR × CF (2)* RAR 2018, vol.3-B7
Rye /boiled	N/A	N/A	0.152	*STMR × CF (2)* RAR 2018, vol.3-B7
Wheat /bread (wholemeal)	N/A	N/A	0.152	*STMR × CF (2)* RAR 2018, vol.3-B7
Wheat /bread/pizza	N/A	N/A	0.152	*STMR × CF (2)* RAR 2018, vol.3-B7
Wheat pasta	N/A	N/A	0.152	*STMR × CF (2)* RAR 2018, vol.3-B7
Wheat /milling (wholemeal)-baking	N/A	N/A	0.152	*STMR × CF (2)* RAR 2018, vol.3-B7
Wheat /milling (flour)	N/A	N/A	0.152	*STMR × CF (2)* RAR 2018, vol.3-B7

7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.2-12: Consumer risk assessment

Prothioconazole-desthio	
TMDI (% ADI) according to EFSA PRIMo rev. 3.1	3 % (based on IT toddler for wheat)
IEDI (% ADI) according to EFSA PRIMo rev. 3.1	0.4 % (based on DK child for rye)

IESTI (% ARfD) according to EFSA PRIMo rev. 3.1 for unprocessed commodities	0.1 % for unprocessed wheat for children
IESTI (% ARfD) according to EFSA PRIMo rev. 3.1 for processed commodities	0.1 % for milled wheat (flour)
1,2,4-Triazole	
TMDI (% ADI) according to EFSA PRIMo rev. 3.1	1 % (based on DK child for rye)
IEDI (% ADI) according to EFSA PRIMo rev. 3.1	0.3 % (based on DK child for rye)
IESTI (% ARfD) according to EFSA PRIMo rev. 3.1 for unprocessed commodities	0.09 % (based on child for wheat)
IESTI (% ARfD) according to EFSA PRIMo rev. 3.1 for processed commodities	0.1 % (based on child for wheat milling flour)
Triazolyl lactic acid	
TMDI (% ADI) according to EFSA PRIMo rev. 3.1	0.2 % (based on DK child for rye)
IEDI (% ADI) according to EFSA PRIMo rev. 3.1	0.1 % (based on DK child for rye)
IESTI (% ARfD) according to EFSA PRIMo rev. 3.1 for unprocessed commodities	0.1 % (based on child for wheat)
IESTI (% ARfD) according to EFSA PRIMo rev. 3.1 for processed commodities	0.1 % (based on child for wheat milling flour)
Triazole alanine	
TMDI (% ADI) according to EFSA PRIMo rev. 3.1	7 % (based on DK child for rye)
IEDI (% ADI) according to EFSA PRIMo rev. 3.1	0.9 % (based on DK child for rye)
IESTI (% ARfD) according to EFSA PRIMo rev. 3.1 for unprocessed commodities	1 % (based on child for wheat)
IESTI (% ARfD) according to EFSA PRIMo rev. 3.1 for processed commodities	1 % (based on child for wheat milling flour)
Triazole acetic acid	
TMDI (% ADI) according to EFSA PRIMo rev. 3.1	2 % (based on DK child for rye)
IEDI (% ADI) according to EFSA PRIMo rev. 3.1	0.2 % (based on DK child for rye)
IESTI (% ARfD) according to EFSA PRIMo rev. 3.1 for unprocessed commodities	0.2 % (based on child for wheat)
IESTI (% ARfD) according to EFSA PRIMo rev. 3.1 for processed commodities	0.2 % (based on child for wheat milling flour)

The proposed uses of prothioconazole in the formulation CHR/ZF/PROTI do not represent unacceptable acute and chronic risks for the consumer.

This has been accepted.

7.3 Combined exposure and risk assessment

Not relevant. The product contains only one active substance.

7.4 References

- EFSA Scientific Report (2007) 106, 1-98, Conclusion on the peer review of prothioconazole
- Draft Assessment Report, Volume 3, Annex B, B.7, July 2005
- Draft Assessment Report Addendum, 2006

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	Verte-brate study Y/N	Owner
KCA 6.3/01	Peda, T., Jędrusik, M.	2022	*Magnitude of the residue of metabolites triazole alanine (TA), 1,2,4-triazole (1,2,4-T), triazole acetic acid (TAA) and triazole lactic acid (TLA) in spring barley (Raw Agricultural Commodity) after one application of CHR/ZF/PROTI 100 FS - one decline curve study trial in Germany – 2021* 21SGS97, DPL/87/2021 SGS Polska Sp. z o. o. GLP, Pszczyna, Poland GLP Unpublished	N	Chemirol
KCA 6.3/02	Peda, T., Jędrusik, M.	2022	*Magnitude of the residue of metabolites triazole alanine (TA), 1,2,4-triazole (1,2,4-T), triazole acetic acid (TAA) and triazole lactic acid (TLA) in spring barley (Raw Agricultural Commodity) after one application of CHR/ZF/PROTI 100 FS - one decline curve study trial in Denmark – 2021* 21SGS98, DPL/88/2021 SGS Polska Sp. z o. o. GLP, Pszczyna, Poland GLP Unpublished	N	Chemirol
KCA 6.3/03	Peda, T., Jędrusik, M.	2022	*Magnitude of the residue of metabolites triazole alanine (TA), 1,2,4-triazole(1,2,4-T), triazole acetic acid (TAA) and triazole lactic acid (TLA) in spring wheat(Raw Agricultural Commodity) after one application of CHR/ZF/PROTI 100 FS - one harvest study trial in Germany – 2021* 21SGS99, DPL/91/2021 SGS Polska Sp. z o. o. GLP, Pszczyna, Poland GLP Unpublished	N	Chemirol
KCA 6.3/04	Peda, T.,	2022	*Magnitude of the residue of metabolites triazole alanine (TA), 1,2,4-triazole (1,2,4-T), triazole acetic acid (TAA) and triazole lactic acid (TLA) in spring barley (Raw Agricultural Commodity) after one*	N	Chemirol

	Niewelt-Stasiak, S.		*application of CHR/ZF/PROTI 100 FS – one harvest study trial in Poland – 2021* 21SGS101, DPL/89/2021 SGS Polska Sp. z o. o. GLP, Pszczyna, Poland GLP Unpublished		
KCA 6.3/05	Peda, T., Niewelt-Stasiak, S.	2022	*Magnitude of the residue of metabolites triazole alanine (TA), 1,2,4-triazole (1,2,4-T), triazole acetic acid (TAA) and triazole lactic acid (TLA) in spring barley (Raw Agricultural Commodity) after one application of CHR/ZF/PROTI 100 FS – one decline curve study trial in Poland – 2021* 21SGS102, DPL/90/2021 SGS Polska Sp. z o. o. GLP, Pszczyna, Poland GLP Unpublished	N	Chemirol
KCA 6.3/06	Peda, T., Jędrusik, M.	2022	*Magnitude of the residue of metabolites triazole alanine (TA), 1,2,4-triazole (1,2,4-T), triazole acetic acid (TAA) and triazole lactic acid (TLA) in spring wheat (Raw Agricultural Commodity) after one application of CHR/ZF/PROTI 100 FS - one decline curve study trial in Poland – 2021* 21SGS103, DPL/93/2021 SGS Polska Sp. z o. o. GLP, Pszczyna, Poland GLP Unpublished	N	Chemirol
KCA 6.3/07	Peda, T., Niewelt-Stasiak, S.	2022	*Magnitude of the residue of metabolites triazole alanine (TA), 1,2,4-triazole (1,2,4-T), triazole acetic acid (TAA) and triazole lactic acid (TLA) in spring wheat (Raw Agricultural Commodity) after one application of CHR/ZF/PROTI 100 FS - one decline curve study trial in Poland – 2021* 21SGS104, DPL/94/2021 SGS Polska Sp. z o. o. GLP, Pszczyna, Poland GLP Unpublished	N	Chemirol

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Owner
KCP 6.1/01	Heinemann, O.	2001a	*18 months storage stability of residues of JAU 6476 and JAU 6476-Desthio during frozen storage in/on wheat matrices* Bayer AG, Report No.: MR-282/00, GLP Unpublished	N	BAY
KCP 6.2.1	Haas, M.	2001	*Metabolism of JAU6476 in spring wheat after seed dressing* Bayer AG, Report No.: MR-467/99 GLP Unpublished	N	BAY
KCP 6.2.2/01	Weber, H. Spiegel, K.	2001	*[Phenyl-UL-14C]JAU6476 Absorption, distribution, excretion and metabolism in the lactating goat* Bayer AG, Report No.: MR-092/01 GLP Unpublished	N	BAY
KCP 6.2.2/02	Weber, H. Weber, E. Spiegel, K.	2002	*[Phenyl-UL-14C]JAU6476-desthio Absorption, distribution, excretion, and metabolism in the lactating goat* Bayer AG, Report No.: MR-091/01 GLP Unpublished	N	BAY
KCP 6.2.2/03	Weber, H. Spiegel, K.	2001	*[Phenyl-UL-14C]JAU6476 Absorption, distribution, excretion and metabolism in laying hens* Bayer AG, Report No.: MR-309/01 GLP Unpublished	N	BAY
KCP 6.3.1/01	Heinemann, O.	2001	*Determination of residues of JAU 6476-Desthio on spring wheat following seed treatment of JAU 6476 200 FS in Great Britain, Germany and France* Bayer AG, Report No.: RA-2010/99 GLP Unpublished	N	BAY

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Owner
KCP 6.3.1/02	Heinemann, O.	2001	*Determination of residues of JAU 6476-desthio on spring wheat following seed treatment of JAU 6476 200 FS in Germany and France* Bayer AG, Report No.: RA-2091/00 GLP Unpublished	N	BAY
KCP 6.3.1/03	Heinemann, O.	2001	*Determination of residues of JAU 6476-desthio on spring wheat and winter wheat following seed treatment of JAU 6476 200 FS and spray application of JAU 6476 250 EC in Germany, Northern France, and Great Britain* Bayer AG, Report No.: RA-2003/99 GLP Unpublished	N	BAY
KCP 6.3.1/04	Heinemann, O.	2001	*Determination of residues of JAU 6476-desthio on spring barley following seed treatment of JAU 6476 200 FS and spray application of JAU 6476 250 EC in Germany* Bayer AG, Report No.: RA-2150/98 GLP Unpublished	N	BAY
KCP 6.3.1/05	Heinemann, O., Elke, K.	2001	*Determination of residues of JAU 6476-desthio on spring barley following seed treatment of JAU 6476 200 FS and spray application of JAU 6476 250 EC in Germany, France and Great Britain* Bayer AG, Report No.: RA-2140/98 GLP Unpublished	N	BAY
KCP 6.4.1/01	Heinemann, O. Auer, S.	2001	*JAU 6476-desthio - Dairy cattle feeding study* Bayer AG, Report No.: MR-535/00, Report includes Trial Nos.: P 673003007 GLP Unpublished	N	BAY
KCP 6.6.1/01	Haas, M.	2001	*Confined rotational crop study with JAU6476* Bayer AG, Report No.: MR-159/00 GLP	N	BAY

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

Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1.1 Stability of residues

A 2.1.1.1 Stability of residues during storage of samples

A 2.1.1.1.1 Storage stability of residues in plant products

No new studies submitted

A 2.1.1.1.2 Storage stability of residues in animal products

No new studies submitted

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

A 2.1.2.1 Nature of residue in plants

No new studies submitted

A 2.1.2.1.1 Nature of residue in primary crops

No new studies submitted

A 2.1.2.1.2 Nature of residue in rotational crops

No new studies submitted

A 2.1.3 Magnitude of residues in plants

A 2.1.3.1.1.1 Study 1

Comments of zRMS:	Study is acceptable. It was conducted according to acceptable guidelines. It has been used in evaluation. One trial in barley was done consistently with the intended GAP. The analytical method employed was acceptable.

Reference:	KCA 6.3/01
Report	Magnitude of the residue of metabolites triazole alanine (TA), 1,2,4-triazole (1,2,4-T), triazole acetic acid (TAA) and triazole lactic acid (TLA) in spring

	barley (Raw Agricultural Commodity) after one application of CHR/ZF/PROTI 100 FS - one decline curve study trial in Germany – 2021, Peda, T., Jędrusik, M., 21SGS97, DPL/87/2021 SGS, Poland
Guideline(s):	Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997 OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published in September 2009) SANTE/2020/12830 Rev.1, 24 February 2021
Deviations:	Yes
GLP:	Yes
Acceptability:	Yes

Objective of the study
The objective of the study is to determine the magnitude of the residue of metabolites triazole alanine (TA), 1,2,4-triazole (1,2,4-T), triazole acetic acid (TAA) and triazole lactic acid (TLA) in spring barley (Raw Agricultural Commodity) after one application of CHR/ZF/PROTI 100 FS.

Field phase description
One decline curve study trial (DCS) was established in Germany. Trial consisted of one untreated plot U and one treated plot T. Environmental conditions did not alter the normal growth, development and maturity of the crop at the trial site to such a degree as to have negative impact on the integrity and validity of this study.

Untreated seeds were sown before treated seeds on 25/05/2021. CHR/ZF/PROTI 100 FS was mixed with water. The target dose rate of the test item according to study plan was 1 l/t equivalent to 0,100 kg a. s./t and 0,025 kg a. s./ha considering drilling rate of 250 kg seeds/ha. Target drilling rate according to Study Plan was 250 kg/ha, actually it was 264,851 kg/ha (deviation +5,9%) for untreated seeds and 272,885 kg/ha (deviation +9,1%) for treated seeds

RAC specimens for analyses were collected:

- S1 (seeds) – BBCH 0- before application
- S2 (seeds) – BBCH 0- just after application
- S3 (whole plant without root) – BBCH 21
- S4 (whole plant without root) – BBCH 41
- S5 (whole plant without root) – BBCH 59
- S6 (grain, straw) – BBCH 89/CH

Quality control measures were taken to maintain specimen integrity and to avoid contamination at the trial site. RAC specimens were put in deep freezing conditions at a target temperature of ≤ -18°C on the day of sampling, within 12 hours after sampling.
All specimens remained deep frozen during storage at the test site, during shipment to the laboratory.

Deviations

Freezer failure. Specimens number: 21SGS97-01 4; 21SGS97-01 5; 21SGS97-01 6 were lost. Retain specimens were sent to analysis: 21SGS97-01 4R; 21SGS97-01 5R; 21SGS97-01 6R.

Initial sample preparation and homogenisation

The field specimens arrived at the Test Site in good conditions, frozen and were stored in a freezer at ≤ -18ºC before analysis. After removal from the freezer the samples were homogenized at Test Site, using a knife grinder. The homogenized samples were divided into few portions: one portion was used as test sample in this study (DPL/87/2021), other portions were prepared as archival samples and the rest of the homogenized material was kept for use as a reference matrix, e.g. for method validation studies or freezer storage stability studies. The homogenized specimens were further stored at ≤ -18oC until beginning of analysis.

Extraction

5 g (grain, plant)/ 2 g (straw) of the homogenized sample was weighed into a 50 mL centrifuge tube. 10 mL of water and 10 mL of acidified methanol (with 1 % of HCOOH) was added together with 50 µL of internal standard solution (IS WS I), and the mixture was shaken vigorously by hand for one minute, then centrifuged at 4700 rpm for 10 min for phase separation and finally subjected to a freezing process at ≤ 18°C for 2 h. After that, extract was filtered through a membrane filter and the final extract was directly employed for LC-MS/MS analysis.

Fortification and control samples

For analytical sequence one sample blank matrix and two procedural recoveries at the level of LOQ and two at the level 10 x LOQ were prepared together with the study samples.

Table 3. Preparation of fortification and control samples – grain and plant

Fortification level	Amount of standard solution 1.1 added [µL]	Amount of standard solution 1.3 added [µL]
Matrix blank	-	-
PK 0.010 mg/kg (LOQ)	-	50.0
PK 0.10 mg/kg (10 x LOQ)	50.0	-

Table 4. Preparation of fortification and control samples – straw

Fortification level	Amount of standard solution 1.1 added [µL]	Amount of standard solution 1.3 added [µL]
Matrix blank	-	-
PK 0.010 mg/kg (LOQ)	-	20.0
PK 0.10 mg/kg (10 x LOQ)	20.0	-

Extraction of all field samples (treated and untreated), as well as control and fortified samples was performed on 18.03.2022 (whole plant) and 20.03.2022 (grain, straw) and after that the samples were directly employed for LC-MS/MS analysis, that was started on the same day.

Analysis

The extracts were analyzed using liquid chromatography coupled with mass spectrometry, by single extraction and single injection to the detection system. Final extracts were employed for LC-MS/MS analysis directly after completion of the extraction procedure (on the same day). Data acquisition was carried out in the MRM mode. The analysis was performed using internal standard addition.

For each analyte, one mass transitions were evaluated and used for quantification. Representative chromatograms are shown in this report. A second (and third) mass transition was monitored for confirmation of peak identity but was not used for quantification.

Results

Table 12 Residue concentrations of triazole derivative metabolites detected in analyzed field samples (Study No.: 21SG97, Trial No.: 21SGS97-01 Decline Curve Study)

No	Timing	Study sample identification	Type of commodity	Sample number given by the laboratory	Result [mg/kg]			
					triazole-acetic acid TAA	triazole-alanine TA	triazole-lactic acid TLA	1.2.4-triazole 1.2.4-T
1	Before application	21SGS97-01 1	barley (seed)	DPL/87/2021/01U	0.38	0.46	0.016	< LOD
2	Just after application	21SGS97-01 2	barley (seed)	DPL/87/2021/02T	0.33	0.47	0.015	< LOD
3	BBCH 21	21SGS97-01 4R	barley (whole plant without root)	DPL/87/2021/04T	< LOD	0.029	0.018	< LOD
4	BBCH 41	21SGS97-01 5R	barley (whole plant without root)	DPL/87/2021/05T	< LOD	0.023	0.015	< LOD
5	BBCH 59	21SGS97-01 6R	barley (whole plant without root)	DPL/87/2021/06T	0.015	0.015	0.031	< LOD
6	BBCH89/CH	21SGS97-01 7	barley (grain)	DPL/87/2021/07U	0.074	0.089	< LOD	0.011
7		21SGS97-01 8	barley (grain)	DPL/87/2021/08T	0.076	0.12	< LOD	< LOD
8		21SGS97-01 9	barley (straw)	DPL/87/2021/09U	0.054	0.030	0.018	0.025
9		21SGS97-01 10	barley (straw)	DPL/87/2021/10T	0.036	0.028	0.013	0.021

BBCH- According to BBCH Scale, CH- Commercial Harvest
Residues are not corrected for procedural recoveries;
Calculation based on unrounded values

Conclusions

The method was validated according to SANTE/2020/12830, Rev.1 guidelines.
The results acquired during validation of the analytical method (accuracy and repeatability) were in the range of 70 – 120%.
The limit of detection (LOD) that was expressed as the lowest calibration standard and limit of quantification (LOQ) of the analytical method was established at 0.010 mg/kg for each of compounds (TAA, TA, 1,2,4-T, TLA) in barley.
There were no interfering signals at retention time of analyzed compound in examined control matrix.
The analytical method for determining the residues of triazole derivative metabolites (TAA, TA, 1,2,4-T, TLA) meets the criteria of SANTE/2020/12830, Rev.1 guidelines in terms of precision, accuracy and uncertainty.

A 2.1.3.1.1.2 Study 2

Comments of zRMS:	Study is acceptable. It was conducted according to acceptable guidelines. It has been used in evaluation. One trial was done consistently with the intended GAP. The analytical method employed was acceptable.

Reference:	KCA 6.3/02
Report	Magnitude of the residue of metabolites triazole alanine (TA), 1,2,4-triazole (1,2,4-T), triazole acetic acid (TAA) and triazole lactic acid (TLA) in spring barley (Raw Agricultural Commodity) after one application of CHR/ZF/PROTI 100 FS - one decline curve study trial in Denmark – 2021, Peda, T., Jędrusik, M., 21SGS98, DPL/88/2021 SGS, Poland
Guideline(s):	Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009

	concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997 OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published in September 2009) SANTE/2020/12830 Rev.1, 24 February 2021
Deviations:	Yes
GLP:	Yes
Acceptability:	Yes

Objective of the study
The objective of the study is to determine the magnitude of the residue of metabolites triazole alanine (TA), 1,2,4-triazole (1,2,4-T), triazole acetic acid (TAA) and triazole lactic acid (TLA) in spring barley (Raw Agricultural Commodity) after one application of CHR/ZF/PROTI 100 FS.

Field phase description
One decline curve study trial (DCS) was established in Denmark. Trial consisted of one untreated plot U and one treated plot T. Environmental conditions did not alter the normal growth, development and maturity of the crop at the trial site to such a degree as to have negative impact on the integrity and validity of this study.

Untreated seeds were sown before treated seeds on 28/04/2021. CHR/ZF/PROTI 100 FS was mixed with water. The target dose rate of the test item according to study plan was 1 l/t equivalent to 0,100 kg a. s./t and 0,025 kg a. s./ha considering drilling rate of 250 kg seeds/ha. Target drilling rate according to Study Plan was 250 kg/ha, actually it was 241,016 kg/ha (deviation -3,7%) for treated seeds and 242,036 kg/ha (deviation -3,3%) for untreated seeds.

RAC specimens for analyses were collected:

- S1 (seeds) – BBCH 0- before application
- S2 (seeds) – BBCH 0- just after application
- S3 (whole plant without root) – BBCH 21
- S4 (whole plant without root) – BBCH 41
- S5 (whole plant without root) – BBCH 59
- S6 (grain, straw) – BBCH 89/CH

Quality control measures were taken to maintain specimen integrity and to avoid contamination at the trial site. RAC specimens were put in deep freezing conditions at a target temperature of ≤ -18°C on the day of sampling, within 12 hours after sampling.
All specimens remained deep frozen during storage at the test site, during shipment to the laboratory.

Deviations
Freezer failure. Specimens number: 21SGS98-01 4; 21SGS98-01 5; 21SGS98-01 6 were lost. Retain specimens were sent to analysis: 21SGS98-01 4R; 21SGS98-01 5R; 21SGS98-01 6R.

Initial sample preparation and homogenisation
The field specimens arrived at the Test Site in good conditions, frozen and were stored in a freezer at ≤ -18°C before analysis. After removal from the freezer the samples were homogenized at Test Site, using a

knife grinder. The homogenized samples were divided into few portions: one portion was used as test sample in this study (DPL/88/2021), other portions were prepared as archival samples and the rest of the homogenized material was kept for use as a reference matrix, e.g. for method validation studies or freezer storage stability studies. The homogenized specimens were further stored at ≤ -18°C until beginning of analysis.

Extraction

5 g (grain, plant)/ 2 g (straw) of the homogenized sample was weighed into a 50 mL centrifuge tube. 10 mL of water and 10 mL of acidified methanol (with 1 % of HCOOH) was added together with 50 µL of internal standard solution (IS WS I), and the mixture was shaken vigorously by hand for one minute, then centrifuged at 4700 rpm for 10 min for phase separation and finally subjected to a freezing process at ≤ 18°C for 2 h. After that, extract was filtered through a membrane filter and the final extract was directly employed for LC-MS/MS analysis.

Fortification and control samples

For analytical sequence one sample blank matrix and two procedural recoveries at the level of LOQ and two at the level 10 x LOQ were prepared together with the study samples.

Table 3. Preparation of fortification and control samples – grain and plant

Fortification level	Amount of standard solution 1.1 added [µL]	Amount of standard solution 1.3 added [µL]
Matrix blank	-	-
PK 0.010 mg/kg (LOQ)	-	50.0
PK 0.10 mg/kg (10 x LOQ)	50.0	-

Table 4. Preparation of fortification and control samples – straw

Fortification level	Amount of standard solution 1.1 added [µL]	Amount of standard solution 1.3 added [µL]
Matrix blank	-	-
PK 0.010 mg/kg (LOQ)	-	20.0
PK 0.10 mg/kg (10 x LOQ)	20.0	-

Extraction of all field samples (treated and untreated), as well as control and fortified samples was performed on 18.03.2022 (whole plant) and 20.03.2022 (grain, straw) and after that the samples were directly employed for LC-MS/MS analysis, that was started on the same day.

Analysis

The extracts were analyzed using liquid chromatography coupled with mass spectrometry, by single extraction and single injection to the detection system. Final extracts were employed for LC-MS/MS analysis directly after completion of the extraction procedure (on the same day). Data acquisition was carried out in the MRM mode. The analysis was performed using internal standard addition.
For each analyte, one mass transitions were evaluated and used for quantification. Representative chromatograms are shown in this report. A second (and third) mass transition was monitored for confirmation of peak identity but was not used for quantification.

Results

Table 12 Residue concentrations of triazole derivative metabolites detected in analyzed field samples (Study No.: 21SG98, Trial No.: 21SGS98-01 Decline Curve Study)

No	Timing	Study sample identification	Type of commodity	Sample number given by the laboratory	Result [mg/kg]			
					triazole-acetic acid TAA	triazole-alanine TA	triazole-lactic acid TLA	1.2.4-triazole 1.2.4-T
1	Before application	21SGS98-01 1	barley (seeds)	DPL/88/2021/01U	0.26	0.36	< LOQ	< LOD
2	Just after application	21SGS98-01 2	barley (seeds)	DPL/88/2021/02T	0.24	0.30	< LOD	< LOD
3	BBCH 21	21SGS98-01 4R	barley (whole plant without root)	DPL/88/2021/04T	0.017	0.14	0.32	< LOD
4	BBCH 41	21SGS98-01 5R	barley (whole plant without root)	DPL/88/2021/05T	0.069	0.084	0.20	< LOD
5	BBCH 59	21SGS98-01 6R	barley (whole plant without root)	DPL/88/2021/06T	0.074	0.047	0.11	< LOD
6	BBCH89/CH	21SGS98-01 7	barley (grain)	DPL/88/2021/07U	0.36	0.33	< LOD	< LOD
7		21SGS98-01 8	barley (grain)	DPL/88/2021/08T	0.31	0.22	< LOD	< LOD
8		21SGS98-01 9	barley (straw)	DPL/88/2021/09U	0.096	0.041	0.032	0.019
9		21SGS98-01 10	barley (straw)	DPL/88/2021/10T	0.17	0.092	0.024	0.027

BBCH- According to BBCH Scale, CH- Commercial Harvest
Residues are not corrected for procedural recoveries;
Calculation based on unrounded values

Conclusions

The method was validated according to SANTE/2020/12830, Rev.1 guidelines.
The results acquired during validation of the analytical method (accuracy and repeatability) were in the range of 70 – 120%.
The limit of detection (LOD) that was expressed as the lowest calibration standard and limit of quantification (LOQ) of the analytical method was established at 0.010 mg/kg for each of compounds (TAA, TA, 1,2,4-T, TLA) in barley.
There were no interfering signals at retention time of analyzed compound in examined control matrix.
The analytical method for determining the residues of triazole derivative metabolites (TAA, TA, 1,2,4-T, TLA) meets the criteria of SANTE/2020/12830, Rev.1 guidelines in terms of precision, accuracy and uncertainty.

A 2.1.3.1.1.3 Study 3

Comments of zRMS:	Study is acceptable. It was conducted according to acceptable guidelines. It has been used in evaluation. One trial in wheat was done consistently with the intended GAP. The analytical method employed was acceptable.

Reference:	KCA 6.3/03
Report	Magnitude of the residue of metabolites triazole alanine (TA), 1,2,4-triazole(1,2,4-T), triazole acetic acid (TAA) and triazole lactic acid (TLA) in spring wheat(Raw Agricultural Commodity) after one application of CHR/ZF/PROTI 100 FS - one harvest study trial in Germany – 2021, Peda, T., Jędrusik, M., 21SGS99, DPL/91/2021 SGS, Poland
Guideline(s):	Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

	Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997 OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published in September 2009) SANTE/2020/12830 Rev.1, 24 February 2021
Deviations:	Yes (study is not affected)
GLP:	Yes
Acceptability:	Yes

Objective of the study
The objective of the study is to determine the magnitude of the residue of metabolites triazole alanine (TA), 1,2,4-triazole (1,2,4-T), triazole acetic acid (TAA) and triazole lactic acid (TLA) in spring wheat(Raw Agricultural Commodity) after one application of CHR/ZF/PROTI 100 FS.

Field phase description
One single harvest study trial (HS) was established in Germany. Trial consisted of one untreated plot U and one treated plot T. Environmental conditions did not alter the normal growth, development and maturity of the crop at the trial site to such a degree as to have negative impact on the integrity and validity of this study.

Untreated seeds were sown before treated seeds on 20/04/2021. CHR/ZF/PROTI 100 FS was mixed with water. The target dose rate of the test item according to study plan was 1 l/t equivalent to 0,100 kg a. s./t and 0,025 kg a. s./ha considering drilling rate of 250 kg seeds/ha. Target drilling rate according to Study Plan was 250 kg/ha, actually it was 250 kg/ha (deviation 0,0%) for treated seeds and 250 kg/ha (deviation 0,0%) for untreated seeds.

RAC specimens for analyses were collected:

- S1 (seeds) – BBCH 0- before application
- S2 (seeds) – BBCH 0- just after application
- S3 (grain, straw) – BBCH 89/CH

Quality control measures were taken to maintain specimen integrity and to avoid contamination at the trial site. RAC specimens were put in deep freezing conditions at a target temperature of ≤ -18°C on the day of sampling, within 12 hours after sampling.
All specimens remained deep frozen during storage at the test site, during shipment to the laboratory.

Deviations
Freezer failure. Specimens number: 21SGS99-01 4; 21SGS99-01 5; 21SGS99-01 6 were lost. Retain specimens were sent to analysis: 21SGS99-01 4R; 21SGS99-01 5R; 21SGS99-01 6R.
Initial sample preparation and homogenisation
The field specimens arrived at the Test Site in good conditions, frozen and were stored in a freezer at ≤ -18ºC before analysis. After removal from the freezer the samples were homogenized at Test Site, using a knife grinder. The homogenized samples were divided into few portions: one portion was used as test sample in this study (DPL/91/2021), other portions were prepared as archival samples and the rest of the homogenized material was kept for use as a reference matrix, e.g. for method validation studies or freezer storage stability studies. The homogenized specimens were further stored at ≤ -18ºC until beginning of analysis.

Extraction

5 g (grain)/ 2 g (straw) of the homogenized sample was weighed into a 50 mL centrifuge tube. 10 mL of water and 10 mL of acidified methanol (with 1 % of HCOOH) was added together with 50 µL of internal standard solution (IS WS I), and the mixture was shaken vigorously by hand for one minute, then centrifuged at 4700 rpm for 10 min for phase separation and finally subjected to a freezing process at ≤ 18°C for 2 h. After that, extract was filtered through a membrane filter and the final extract was directly employed for LC-MS/MS analysis.

Fortification and control samples

For analytical sequence one sample blank matrix and two procedural recoveries at the level of LOQ and two at the level 10 x LOQ were prepared together with the study samples.

Table 3. Preparation of fortification and control samples - grain

Fortification level	Amount of standard solution 1.1 added [µL]	Amount of standard solution 1.3 added [µL]
Matrix blank	-	-
PK 0.010 mg/kg (LOQ)	-	50.0
PK 0.10 mg/kg (10 x LOQ)	50.0	-

Table 4. Preparation of fortification and control samples - straw

Fortification level	Amount of standard solution 1.1 added [µL]	Amount of standard solution 1.3 added [µL]
Matrix blank	-	-
PK 0.010 mg/kg (LOQ)	-	20.0
PK 0.10 mg/kg (10 x LOQ)	20.0	-

Extraction of all field samples (treated and untreated), as well as control and fortified samples was performed on 19.03.2022 (grain) and 20.03.2022 (straw) and after that the samples were directly employed for LC-MS/MS analysis, that was started on the same day.

Analysis

The extracts were analyzed using liquid chromatography coupled with mass spectrometry, by single extraction and single injection to the detection system. Final extracts were employed for LC-MS/MS analysis directly after completion of the extraction procedure (on the same day). Data acquisition was carried out in the MRM mode. The analysis was performed using internal standard addition.

For each analyte, one mass transitions were evaluated and used for quantification. Representative chromatograms are shown in this report. A second (and third) mass transition was monitored for confirmation of peak identity but was not used for quantification.

Results

Table 12. Residue concentrations of triazole derivative metabolites detected in analyzed field samples (Study No.: 21SGS99, Trial No.: 21SGS99-01 Harvest Trial)

No	Timing	Study sample identification	Type of commodity	Sample number given by the laboratory	Result [mg/kg]			
					triazole-acetic acid TAA	triazole-alanine TA	triazole-lactic acid TLA	1.2.4-triazole 1.2.4-T
1	Before application	21SGS99-01 1	wheat (seeds)	DPL/91/2021/01U	0.18	0.46	< LOD	< LOD
2	Just after application	21SGS99-01 2	wheat (seeds)	DPL/91/2021/02T	0.17	0.47	< LOD	< LOD
3	BBCH89/CH	21SGS99-01 5	wheat (grain)	DPL/91/2021/05U	0.015	0.039	< LOD	< LOD
4		21SGS99-01 6	wheat (grain)	DPL/91/2021/06T	0.012	0.030	< LOD	< LOD
5		21SGS99-01 7	wheat (straw)	DPL/91/2021/07U	< LOQ	0.019	0.017	0.033
6		21SGS99-01 8	wheat (straw)	DPL/91/2021/08T	< LOQ	0.020	0.016	0.030

Residues are not corrected for procedural recoveries;
Calculation based on unrounded values

Conclusions

The method was validated according to SANTE/2020/12830, Rev.1 guidelines.
The results acquired during validation of the analytical method (accuracy and repeatability) were in the range of 70 – 120%.
The limit of detection (LOD) that was expressed as the lowest calibration standard and limit of quantification (LOQ) of the analytical method was established at 0.010 mg/kg for each of compounds (TAA, TA, 1,2,4-T, TLA) in barley.
There were no interfering signals at retention time of analyzed compound in examined control matrix.
The analytical method for determining the residues of triazole derivative metabolites (TAA, TA, 1,2,4-T, TLA) meets the criteria of SANTE/2020/12830, Rev.1 guidelines in terms of precision, accuracy and uncertainty.

A 2.1.3.1.1.4 Study 4

Comments of zRMS:	Study is acceptable. It was conducted according to acceptable guidelines. It has been used in evaluation. One trial was conducted consistently with the intended GAP. The analytical method employed was acceptable.

Reference:	KCA 6.3/04
Report	Magnitude of the residue of metabolites triazole alanine (TA), 1,2,4-triazole (1,2,4-T), triazole acetic acid (TAA) and triazole lactic acid (TLA) in spring barley (Raw Agricultural Commodity) after one application of CHR/ZF/PROTI 100 FS – one harvest study trial in Poland - 2021, Peda, T., Niewelt-Stasiak, S., 21SGS101, DPL/89/2021 SGS, Poland
Guideline(s):	Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997 OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published in September 2009)

	SANTE/2020/12830 Rev.1, 24 February 2021
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Objective of the study
The objective of the study was to determine of the residue of metabolites triazole alanine (TA), 1,2,4-triazole (1,2,4-T), triazole acetic acid (TAA) and triazole lactic acid (TLA) in spring barley after one application of CHR/ZF/PROTI 100 FS.

Field phase description
One decline curve study trial (DCS) was established in Poland. Trial consisted of one untreated plot U and one treated plot T. Environmental conditions did not alter the normal growth, development and maturity of the crop at the trial site to such a degree as to have negative impact on the integrity and validity of this study.

Untreated seeds were sown before treated seeds on 22/04/2021. CHR/ZF/PROTI 100 FS was mixed with water. The target dose rate of the test item according to study plan was 1 l/t equivalent to 0,100 kg a. s./t and 0,025 kg a. s./ha considering drilling rate of 250 kg seeds/ha. Target drilling rate according to Study Plan was 250 kg/ha, actually it was 250 kg/ha (deviation 0,0%) for treated seeds and 250 kg/ha (deviation 0,0%) for untreated seeds.

RAC specimens for analyses were collected:

- S1 (seeds) – BBCH 0- before application
- S2 (seeds) – BBCH 0- just after application
- S3 (whole plant without root) – BBCH 21
- S4 (whole plant without root) – BBCH 41
- S5 (whole plant without root) – BBCH 59
- S6 (grain, straw) – BBCH 89/CH

Quality control measures were taken to maintain specimen integrity and to avoid contamination at the trial site. RAC specimens were put in deep freezing conditions at a target temperature of ≤ -18°C on the day of sampling, within 12 hours after sampling.
All specimens remained deep frozen during storage at the test site, during shipment to the laboratory.

Deviations
None.

Initial sample preparation and homogenisation
The field specimens arrived at the Test Site in good conditions, frozen and were stored in a freezer at ≤ -18°C before analysis. After removal from the freezer the samples were homogenized at Test Site, using a knife grinder. The homogenized samples were divided into few portions: one portion was used as test sample in this study (DPL/89/2021), other portions were prepared as archival samples and the rest of the homogenized material was kept for use as a reference matrix, e.g. for method validation studies or freezer storage stability studies. The homogenized specimens were further stored at ≤ -18°C until beginning of analysis.

Extraction

5 g (grain)/ 2 g (straw) of the homogenized sample was weighed into a 50 mL centrifuge tube. 10 mL of water and 10 mL of acidified methanol (with 1 % of HCOOH) was added together with 50 µL of internal standard solution (IS WS I), and the mixture was shaken vigorously by hand for one minute, then centrifuged at 4700 rpm for 10 min for phase separation and finally subjected to a freezing process at ≤ -18°C for 2 h. After that, extract was filtered through a membrane filter and the final extract was directly employed for LC-MS/MS analysis.

Fortification and control samples

For analytical sequence one sample blank matrix and two procedural recoveries at the level of LOQ and two at the level 10 x LOQ were prepared together with the study samples.

Table 3. Preparation of fortification and control samples – grain

Fortification level	Amount of standard solution 1.1 added [µL]	Amount of standard solution 1.3 added [µL]
Matrix blank	-	-
PK 0.010 mg/kg (LOQ)	-	50.0
PK 0.10 mg/kg (10 x LOQ)	50.0	-

Table 4. Preparation of fortification and control samples – straw

Fortification level	Amount of standard solution 1.1 added [µL]	Amount of standard solution 1.3 added [µL]
Matrix blank	-	-
PK 0.010 mg/kg (LOQ)	-	20.0
PK 0.10 mg/kg (10 x LOQ)	20.0	-

Extraction of all field samples (treated and untreated), as well as control and fortified samples was performed on 20.03.2022 (grain and straw) and after that the samples were directly employed for LC-MS/MS analysis, that was started on the same day.

Analysis

The extracts were analyzed using liquid chromatography coupled with mass spectrometry, by single extraction and single injection to the detection system. Final extracts were employed for LC-MS/MS analysis directly after completion of the extraction procedure (on the same day). Data acquisition was carried out in the MRM mode. The analysis was performed using internal standard addition.
For each analyte, one mass transitions were evaluated and used for quantification. Representative chromatograms are shown in this report. A second (and third) mass transition was monitored for confirmation of peak identity but was not used for quantification.

Results

Table 12. Residue concentrations of triazole derivative metabolites detected in analyzed field samples (Study No.: 21SGS101, Trial No.: 21SGS101-01 Harvest Study)

No	Timing	Study sample identification	Type of commodity	Sample number given by the laboratory	Result [mg/kg]			
					triazole-acetic acid TAA	triazole-alanine TA	triazole-lactic acid TLA	1.2.4-triazole 1.2.4-T
1	S1 = Before application	21SGS101-01 1	barley (seeds)	DPL/89/2021/01U	0.51	0.57	0.016	< LOD
2	S2 = Just after application	21SGS101-01 2	barley (seeds)	DPL/89/2021/02T	0.49	0.57	0.016	< LOD
3	S3 = BBCH89/CH	21SGS101-01 5	barley (grain)	DPL/89/2021/05U	0.035	0.040	<LOD	< LOD
4		21SGS101-01 6	barley (grain)	DPL/89/2021/06T	0.041	0.058	<LOD	< LOD
5		21SGS101-01 7	barley (straw)	DPL/89/2021/07U	0.014	<LOD	<LOD	0.013
6		21SGS101-01 8	barley (straw)	DPL/89/2021/08T	<LOD	<LOD	<LOD	0.010

CH- Commercial Harvest
Residues are not corrected for procedural recoveries;
Calculation based on unrounded values

Conclusions

The method was validated according to SANTE/2020/12830, Rev.1 guidelines.
The results acquired during validation of the analytical method (accuracy and repeatability) were in the range of 70 – 120%.
The limit of detection (LOD) that was expressed as the lowest calibration standard and limit of quantification (LOQ) of the analytical method was established at 0.010 mg/kg for each of compounds (TAA, TA, 1,2,4-T, TLA) in barley.
There were no interfering signals at retention time of analyzed compound in examined control matrix.
The analytical method for determining the residues of triazole derivative metabolites (TAA, TA, 1,2,4-T, TLA) meets the criteria of SANTE/2020/12830, Rev.1 guidelines in terms of precision, accuracy and uncertainty.

A 2.1.3.1.1.5 Study 5

Comments of zRMS:	Study is acceptable. It was conducted according to acceptable guidelines. It has been used in evaluation. One trial was done consistently with the intended GAP. The analytical method employed was acceptable.

Reference:	KCA 6.3/05
Report	Magnitude of the residue of metabolites triazole alanine (TA), 1,2,4-triazole (1,2,4-T), triazole acetic acid (TAA) and triazole lactic acid (TLA) in spring barley (Raw Agricultural Commodity) after one application of CHR/ZF/PROTI 100 FS – one decline curve study trial in Poland - 2021, Peda, T., Niewelt-Stasiak, S., 21SGS102, DPL/90/2021 SGS, Poland
Guideline(s):	Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997 OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published in September 2009)

	SANTE/2020/12830 Rev.1, 24 February 2021
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Objective of the study
The objective of the study was to determine of the residue of metabolites triazole alanine (TA), 1,2,4-triazole (1,2,4-T), triazole acetic acid (TAA) and triazole lactic acid (TLA) in spring barley after one application of CHR/ZF/PROTI 100 FS.

Field phase description
One single harvest study trial (HS) was established in Poland. Trial consisted of one untreated plot U and one treated plot T. Environmental conditions did not alter the normal growth, development and maturity of the crop at the trial site to such a degree as to have negative impact on the integrity and validity of this study.

Untreated seeds were sown before treated seeds on 21/04/2021. CHR/ZF/PROTI 100 FS was mixed with water. The target dose rate of the test item according to study plan was 1 l/t equivalent to 0,100 kg a. s./t and 0,025 kg a. s./ha considering drilling rate of 250 kg seeds/ha. Target drilling rate according to Study Plan was 250 kg/ha, actually it was 262,22 kg/ha (deviation +4,9%) for treated seeds and 261,11 kg/ha (deviation +4,4%) for untreated seeds.

RAC specimens for analyses were collected:

- S1 (seeds) – BBCH 0- before application
- S2 (seeds) – BBCH 0- just after application
- S3 (grain, straw) – BBCH 89/CH

Quality control measures were taken to maintain specimen integrity and to avoid contamination at the trial site. RAC specimens were put in deep freezing conditions at a target temperature of ≤ -18°C on the day of sampling, within 12 hours after sampling.
All specimens remained deep frozen during storage at the test site, during shipment to the laboratory.

Deviations
None.

Initial sample preparation and homogenisation
The field specimens arrived at the Test Site in good conditions, frozen and were stored in a freezer at ≤ -18ºC before analysis. After removal from the freezer the samples were homogenized at Test Site, using a knife grinder. The homogenized samples were divided into few portions: one portion was used as test sample in this study (DPL/90/2021), other portions were prepared as archival samples and the rest of the homogenized material was kept for use as a reference matrix, e.g. for method validation studies or freezer storage stability studies. The homogenized specimens were further stored at ≤ -18ºC until beginning of analysis.

Extraction

5 g (grain)/ 2 g (straw) of the homogenized sample was weighed into a 50 mL centrifuge tube. 10 mL of water and 10 mL of acidified methanol (with 1 % of HCOOH) was added together with 50 µL of internal standard solution (IS WS I), and the mixture was shaken vigorously by hand for one minute, then centrifuged at 4700 rpm for 10 min for phase separation and finally subjected to a freezing process at ≤ -18°C for 2 h. After that, extract was filtered through a membrane filter and the final extract was directly employed for LC-MS/MS analysis.

Fortification and control samples

For analytical sequence one sample blank matrix and two procedural recoveries at the level of LOQ and two at the level 10 x LOQ were prepared together with the study samples.

Table 3. Preparation of fortification and control samples – grain

Fortification level	Amount of standard solution 1.1 added [µL]	Amount of standard solution 1.3 added [µL]
Matrix blank	-	-
PK 0.010 mg/kg (LOQ)	-	50.0
PK 0.10 mg/kg (10 x LOQ)	50.0	-

Table 4. Preparation of fortification and control samples – straw

Fortification level	Amount of standard solution 1.1 added [µL]	Amount of standard solution 1.3 added [µL]
Matrix blank	-	-
PK 0.010 mg/kg (LOQ)	-	20.0
PK 0.10 mg/kg (10 x LOQ)	20.0	-

Extraction of all field samples (treated and untreated), as well as control and fortified samples was performed on 20.03.2022 (grain and straw) and after that the samples were directly employed for LC-MS/MS analysis, that was started on the same day.

Analysis

The extracts were analyzed using liquid chromatography coupled with mass spectrometry, by single extraction and single injection to the detection system. Final extracts were employed for LC-MS/MS analysis directly after completion of the extraction procedure (on the same day). Data acquisition was carried out in the MRM mode. The analysis was performed using internal standard addition.
For each analyte, one mass transitions were evaluated and used for quantification. Representative chromatograms are shown in this report. A second (and third) mass transition was monitored for confirmation of peak identity but was not used for quantification.

Results

Table 12. Residue concentrations of triazole derivative metabolites detected in analyzed field samples (Study No.: 21SGS102, Trial No.: 21SGS102-01 Harvest Study)

No	Timing	Study sample identification	Type of commodity	Sample number given by the laboratory	Result [mg/kg]			
					triazole-acetic acid TAA	triazole-alanine TA	triazole-lactic acid TLA	1.2.4-triazole 1.2.4-T
1	S1 = Before application	21SGS102-01 1	barley (seeds)	DPL/90/2021/01U	0.47	0.56	0.016	< LOD
2	S2 = Just after application	21SGS102-01 2	barley (seeds)	DPL/90/2021/02T	0.84	0.46	0.035	< LOQ
3	S3 = BBCH89/CH	21SGS102-01 5	barley (grain)	DPL/90/2021/05U	0.54	0.26	0.028	< LOQ
4		21SGS102-01 6	barley (grain)	DPL/90/2021/06T	0.51	0.59	0.015	< LOQ
5		21SGS102-01 7	barley (straw)	DPL/90/2021/07U	0.22	0.010	0.24	<LOD
6		21SGS102-01 8	barley (straw)	DPL/90/2021/08T	0.29	0.012	0.25	<LOD

CH- Commercial Harvest
Residues are not corrected for procedural recoveries;
Calculation based on unrounded values

Conclusions

The method was validated according to SANTE/2020/12830, Rev.1 guidelines.
The results acquired during validation of the analytical method (accuracy and repeatability) were in the range of 70 – 120%.
The limit of detection (LOD) that was expressed as the lowest calibration standard and limit of quantification (LOQ) of the analytical method was established at 0.010 mg/kg for each of compounds (TAA, TA, 1,2,4-T, TLA) in barley.
There were no interfering signals at retention time of analyzed compound in examined control matrix.
The analytical method for determining the residues of triazole derivative metabolites (TAA, TA, 1,2,4-T, TLA) meets the criteria of SANTE/2020/12830, Rev.1 guidelines in terms of precision, accuracy and uncertainty.

A 2.1.3.1.1.6 Study 6

Comments of zRMS:	Study is acceptable. It was conducted according to acceptable guidelines. It has been used in evaluation. One trial in wheat was done consistently with the intended GAP. The analytical method employed was acceptable.

Reference:	KCA 6.3/06
Report	Magnitude of the residue of metabolites triazole alanine (TA), 1,2,4-triazole (1,2,4-T), triazole acetic acid (TAA) and triazole lactic acid (TLA) in spring wheat (Raw Agricultural Commodity) after one application of CHR/ZF/PROTI 100 FS - one decline curve study trial in Poland – 2021, Peda, T., Jędrusik, M., 21SGS103, DPL/93/2021 SGS, Poland
Guideline(s):	Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997 OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published in September 2009) SANTE/2020/12830 Rev.1, 24 February 2021

Deviations:	No
GLP:	Yes
Acceptability:	Yes

Objective of the study
The objective of the study is to determine magnitude of the residue of metabolites triazole alanine (TA), 1,2,4-triazole (1,2,4-T), triazole acetic acid (TAA) and triazole lactic acid (TLA) in spring wheat (Raw Agricultural Commodity) after one application of CHR/ZF/PROTI 100 FS.

Field phase description
One decline curve study trial (DCS) was established in Poland. Trial consisted of one untreated plot U and one treated plot T. Environmental conditions did not alter the normal growth, development and maturity of the crop at the trial site to such a degree as to have negative impact on the integrity and validity of this study.

Untreated seeds were sown before treated seeds on 28/04/2021. CHR/ZF/PROTI 100 FS was mixed with water. The target dose rate of the test item according to study plan was 1 l/t equivalent to 0,100 kg a. s./t and 0,025 kg a. s./ha considering drilling rate of 250 kg seeds/ha. Target drilling rate according to Study Plan was 250 kg/ha, actually it was 250 kg/ha (deviation 0,0%) for treated seeds and 250 kg/ha (deviation 0,0%) for untreated seeds.

RAC specimens for analyses were collected:

- S1 (seeds) – BBCH 0- before application
- S2 (seeds) – BBCH 0- just after application
- S3 (whole plant without root) – BBCH 21
- S4 (whole plant without root) – BBCH 41
- S5 (whole plant without root) – BBCH 59
- S6 (grain, straw) – BBCH 89/CH

Quality control measures were taken to maintain specimen integrity and to avoid contamination at the trial site. RAC specimens were put in deep freezing conditions at a target temperature of ≤ -18°C on the day of sampling, within 12 hours after sampling.
All specimens remained deep frozen during storage at the test site, during shipment to the laboratory.

Deviations
None.

Initial sample preparation and homogenisation
The field specimens arrived at the Test Site in good conditions, frozen and were stored in a freezer at ≤ -18°C before analysis. After removal from the freezer the samples were homogenized at Test Site, using a knife grinder. The homogenized samples were divided into few portions: one portion was used as test sample in this study (DPL/93/2021), other portions were prepared as archival samples and the rest of the homogenized material was kept for use as a reference matrix, e.g. for method validation studies or freezer storage stability studies. The homogenized specimens were further stored at ≤ -18°C until beginning of analysis.

Extraction

5 g (grain, plant)/ 2 g (straw) of the homogenized sample was weighed into a 50 mL centrifuge tube. 10 mL of water and 10 mL of acidified methanol (with 1 % of HCOOH) was added together with 50 µL of internal standard solution (IS WS I), and the mixture was shaken vigorously by hand for one minute, then centrifuged at 4700 rpm for 10 min for phase separation and finally subjected to a freezing process at ≤ 18°C for 2 h. After that, extract was filtered through a membrane filter and the final extract was directly employed for LC-MS/MS analysis.

Fortification and control samples

For analytical sequence one sample blank matrix and two procedural recoveries at the level of LOQ and two at the level 10 x LOQ were prepared together with the study samples.

Table 3. Preparation of fortification and control samples – grain and plant

Fortification level	Amount of standard solution 1.1 added [µL]	Amount of standard solution 1.3 added [µL]
Matrix blank	-	-
PK 0.010 mg/kg (LOQ)	-	50.0
PK 0.10 mg/kg (10 x LOQ)	50.0	-

Table 4. Preparation of fortification and control samples – straw

Fortification level	Amount of standard solution 1.1 added [µL]	Amount of standard solution 1.3 added [µL]
Matrix blank	-	-
PK 0.010 mg/kg (LOQ)	-	20.0
PK 0.10 mg/kg (10 x LOQ)	20.0	-

Extraction of all field samples (treated and untreated), as well as control and fortified samples was performed on 18.03.2022 (whole plant), 19.03.2022 (grain), and 20.03.2022 (straw) and after that the samples were directly employed for LC-MS/MS analysis, that was started on the same day.

Analysis

The extracts were analyzed using liquid chromatography coupled with mass spectrometry, by single extraction and single injection to the detection system. Final extracts were employed for LC-MS/MS analysis directly after completion of the extraction procedure (on the same day). Data acquisition was carried out in the MRM mode. The analysis was performed using internal standard addition.
For each analyte, one mass transitions were evaluated and used for quantification. Representative chromatograms are shown in this report. A second (and third) mass transition was monitored for confirmation of peak identity but was not used for quantification.

Results

Table 12 Residue concentrations of triazole derivative metabolites detected in analyzed field samples (Study No.: 21SGS103, Trial No.: 21SGS103-01 Decline Curve Study)

No	Timing	Study sample identification	Type of commodity	Sample number given by the laboratory	Result [mg/kg]			
					triazole-acetic acid TAA	triazole-alanine TA	triazole-lactic acid TLA	1.2.4-triazole 1.2.4-T
1	Before application	21SGS103-01 1	wheat (seeds)	DPL/93/2021/01U	0.14	0.38	< LOD	< LOD
2	Just after application	21SGS103-01 2	wheat (seeds)	DPL/93/2021/02T	0.24	0.64	< LOD	< LOD
3	BBCH 21	21SGS103-01 4	wheat (whole plant without root)	DPL/93/2021/04T	0.027	0.015	< LOD	< LOD
4	BBCH 41	21SGS103-01 5	wheat (whole plant without root)	DPL/93/2021/05T	0.027	0.016	< LOD	< LOD
5	BBCH 59	21SGS103-01 6	wheat (whole plant without root)	DPL/93/2021/06T	0.017	0.016	< LOD	< LOD
6	BBCH89/CH	21SGS103-01 7	wheat (grain)	DPL/93/2021/07U	0.027	0.082	< LOD	< LOD
7		21SGS103-01 8	wheat (grain)	DPL/93/2021/08T	0.053	0.14	< LOD	< LOD
8		21SGS103-01 9	wheat (straw)	DPL/93/2021/09U	0.013	< LOD	< LOQ	< LOD
9		21SGS103-01 10	wheat (straw)	DPL/93/2021/10T	0.018	0.018	0.011	0.011

BBCH- According to BBCH Scale, CH- Commercial Harvest
Residues are not corrected for procedural recoveries;
Calculation based on unrounded values

Conclusions

The method was validated according to SANTE/2020/12830, Rev.1 guidelines.
The results acquired during validation of the analytical method (accuracy and repeatability) were in the range of 70 – 120%.
The limit of detection (LOD) that was expressed as the lowest calibration standard and limit of quantification (LOQ) of the analytical method was established at 0.010 mg/kg for each of compounds (TAA, TA, 1,2,4-T, TLA) in barley.
There were no interfering signals at retention time of analyzed compound in examined control matrix.
The analytical method for determining the residues of triazole derivative metabolites (TAA, TA, 1,2,4-T, TLA) meets the criteria of SANTE/2020/12830, Rev.1 guidelines in terms of precision, accuracy and uncertainty.

A 2.1.3.1.1.7 Study 7

Comments of zRMS:	Study is acceptable. It was conducted according to acceptable guidelines. It has been used in evaluation. One trial was done consistently with the intended GAP. The analytical method employed was acceptable.

Reference:	KCA 6.3/07
Report	Magnitude of the residue of metabolites triazole alanine (TA), 1,2,4-triazole (1,2,4-T), triazole acetic acid (TAA) and triazole lactic acid (TLA) in spring wheat (Raw Agricultural Commodity) after one application of CHR/ZF/PROTI 100 FS - one decline curve study trial in Poland – 2021, Peda, T., Niewelt-Stasiak, S., 21SGS104, DPL/94/2021 SGS, Poland
Guideline(s):	Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

	Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997 OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published in September 2009) SANTE/2020/12830 Rev.1, 24 February 2021
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Objective of the study

The objective of the study is to determine the magnitude of the residue of metabolites triazole alanine (TA), 1,2,4-triazole (1,2,4-T), triazole acetic acid (TAA) and triazole lactic acid (TLA) in spring wheat (Raw Agricultural Commodity) after one application of CHR/ZF/PROTI 100 FS - one decline curve study trial in Poland – 2021.

Field phase description

One decline curve study trial (DCS) was established in Poland. Trial consisted of one untreated plot U and one treated plot T. Environmental conditions did not alter the normal growth, development and maturity of the crop at the trial site to such a degree as to have negative impact on the integrity and validity of this study.

Untreated seeds were sown before treated seeds on 14/04/2021. CHR/ZF/PROTI 100 FS was mixed with water. The target dose rate of the test item according to study plan was 1 l/t equivalent to 0,100 kg a. s./t and 0,025 kg a. s./ha considering drilling rate of 250 kg seeds/ha. Target drilling rate according to Study Plan was 250 kg/ha, actually it was 229,111 kg/ha (deviation -8,4%) for treated seeds and 226,889 kg/ha (deviation -9,2%) for untreated seeds.

RAC specimens for analyses were collected:
- S1 (seeds) – BBCH 0- before application
- S2 (seeds) – BBCH 0- just after application
- S3 (whole plant without root) – BBCH 21
- S4 (whole plant without root) – BBCH 41
- S5 (whole plant without root) – BBCH 59
- S6 (grain, straw) – BBCH 89/CH

Quality control measures were taken to maintain specimen integrity and to avoid contamination at the trial site. RAC specimens were put in deep freezing conditions at a target temperature of ≤ -18°C on the day of sampling, within 12 hours after sampling.

All specimens remained deep frozen during storage at the test site, during shipment to the laboratory.

Deviations

None.

Initial sample preparation and homogenisation

The field specimens arrived at the Test Site in good conditions, frozen and were stored in a freezer at ≤ -18°C before analysis. After removal from the freezer the samples were homogenized at Test Site, using a knife grinder. The homogenized samples were divided into few portions: one portion was used as test sample in this study (DPL/94/2021), other portions were prepared as archival samples and the rest of the homogenized material was kept for use as a reference matrix, e.g. for method validation studies or freezer storage stability studies. The homogenized specimens were further stored at ≤ -18°C until beginning of analysis.

Extraction

5 g (grain, plant)/ 2 g (straw) of the homogenized sample was weighed into a 50 mL centrifuge tube. 10 mL of water and 10 mL of acidified methanol (with 1 % of HCOOH) was added together with 50 µL of internal standard solution (IS WS I), and the mixture was shaken vigorously by hand for one minute, then centrifuged at 4700 rpm for 10 min for phase separation and finally subjected to a freezing process at ≤ -18°C for 2 h. After that, extract was filtered through a membrane filter and the final extract was directly employed for LC-MS/MS analysis.

Fortification and control samples

For analytical sequence one sample blank matrix and two procedural recoveries at the level of LOQ and two at the level 10 x LOQ were prepared together with the study samples.

Table 3. Preparation of fortification and control samples – grain and plant

Fortification level	Amount of standard solution 1.1 added [µL]	Amount of standard solution 1.3 added [µL]
Matrix blank	-	-
PK 0.010 mg/kg (LOQ)	-	50.0
PK 0.10 mg/kg (10 x LOQ)	50.0	-

Table 4. Preparation of fortification and control samples – straw

Fortification level	Amount of standard solution 1.1 added [µL]	Amount of standard solution 1.3 added [µL]
Matrix blank	-	-
PK 0.010 mg/kg (LOQ)	-	20.0
PK 0.10 mg/kg (10 x LOQ)	20.0	-

Extraction of all field samples (treated and untreated), as well as control and fortified samples was performed on 11.03.2022 (whole plant), 19.03.2022 (grain), and 20.03.2022 (straw) and after that the samples were directly employed for LC-MS/MS analysis, that was started on the same day.

Analysis

The extracts were analyzed using liquid chromatography coupled with mass spectrometry, by single extraction and single injection to the detection system. Final extracts were employed for LC-MS/MS analysis directly after completion of the extraction procedure (on the same day). Data acquisition was carried out in the MRM mode. The analysis was performed using internal standard addition.
For each analyte, one mass transitions were evaluated and used for quantification. Representative chromatograms are shown in this report. A second (and third) mass transition was monitored for confirmation of peak identity but was not used for quantification.

Results

Table 12 Residue concentrations of tebuconazole and triazole derivative metabolites detected in analyzed field samples (Study No.: 21SGS104, Trial No.: 21SGS104-01 Decline Curve Study)

No	Timing	Study sample identification	Type of commodity	Sample number given by the laboratory	Result [mg/kg]			
					triazole-acetic acid TAA	triazole-alanine TA	triazole-lactic acid TLA	1.2.4-triazole 1.2.4-T
1	S1 = Before application	21SGS104-01 1	wheat (seeds)	DPL/94/2021/01U	0.15	0.37	< LOD	< LOD
2	S2 = Just after application	21SGS104-01 2	wheat (seeds)	DPL/94/2021/02T	0.24	0.68	< LOQ	< LOD
3	S3 = BBCH 21	21SGS104-01 4	wheat (whole plant without root)	DPL/94/2021/04T	0.040	0.022	0.023	< LOD
4	S4 = BBCH 41	21SGS104-01 5	wheat (whole plant without root)	DPL/94/2021/05T	0.012	0.023	0.012	< LOD
5	S5 = BBCH 59	21SGS104-01 6	wheat (whole plant without root)	DPL/94/2021/06T	<LOD	0.015	< LOD	< LOD
6	S6 = BBCH89/CH	21SGS104-01 7	wheat (grain)	DPL/94/2021/07U	0.11	0.24	< LOQ	< LOD
7		21SGS104-01 8	wheat (grain)	DPL/94/2021/08T	0.098	0.22	< LOQ	< LOD
8		21SGS104-01 9	wheat (straw)	DPL/94/2021/09U	0.048	< LOD	0.023	0.027
9		21SGS104-01 10	wheat (straw)	DPL/94/2021/10T	0.047	< LOD	0.022	0.022

BBCH- According to BBCH Scale, CH- Commercial Harvest
Residues are not corrected for procedural recoveries;
Calculation based on unrounded values,

Conclusions

The method was validated according to SANTE/2020/12830, Rev.1 guidelines.
The results acquired during validation of the analytical method (accuracy and repeatability) were in the range of 70 – 120%.
The limit of detection (LOD) that was expressed as the lowest calibration standard and limit of quantification (LOQ) of the analytical method was established at 0.010 mg/kg for each of compounds (TAA, TA, 1,2,4-T, TLA) in barley.
There were no interfering signals at retention time of analyzed compound in examined control matrix.
The analytical method for determining the residues of triazole derivative metabolites (TAA, TA, 1,2,4-T, TLA) meets the criteria of SANTE/2020/12830, Rev.1 guidelines in terms of precision, accuracy and uncertainty.

Summary results for all performed trials

Active Substance:	Prothioconazole	**Commercial Product:**	CHR/ZF/PROTI 100 FS
Crop / crop group:	Spring barley / Spring wheat	**Producer:**	PUH Chemirol Sp. z o. o
Zone:	N-EU	**Indoor/outdoor:**	outdoor
Nominal Content of a.s.:	100 g/L	**Other active substance:**	-
Formulation:	FS	**Residue calculated for:**	Triazole derivative metabolites

1	2	3	4	5			6	7	8	9				10	11
				Actual application rate						Residues (1)					
Report No. 21SGS97	Commodity Variety	Date of 1-Sowing 2-Flowering 3-Harvest	Method of Treatment	Test item (l/t)	Water (L/100 kg)	kg (a. s./t)	Date of Treatment	BBCH at Treatment	Commodity analysed	triazole-acetic acid TAA	triazole-alanine TA	triazole-lactic acid TLA	1.2.4-triazole 1.2.4-T	DALA or CH (2)	Remarks
Germany Wallsbüll (Schleswig Holstein) Decline Curve Study Trial 21SGS97-01	Spring barley Ella	1- 25/05/21 2- 17/07 to 18/07/21 3- 23/08/21	Seed dresser Concrete mixer	1,0	0,7	0.025	13/04/21	00	Seed Whole plant without root Grain Straw	0.33 < LOD < LOD 0.015 0.076 0.036	0.47 0.029 0.023 0.015 0.12 0.028	0.015 0.018 0.015 0.031 < LOD 0.013	< LOD < LOD < LOD < LOD < LOD 0.021	0 21 34 49 90 90	Analytical Method: LC-MS/MS Max. Storage Interval between sampling and analysis: 341 days
Denmark Syddanmark	Spring barley	1- 28/04/21	Seed dresser	1	0,7	0.025	13/04/21	00	Seed	0.24 0.017	0.36 0.14	< LOQ 0.32	< LOD < LOD	0 40	Analytical Method:

(Røllum) Decline Curve Study Trial 21SGS98-01	Paustian	2- 01/07 to 03/07/21 3- 23/08/21	Concrete mixer						Whole plant without root Grain Straw	0.069 0.074 0.31 0.17	0.084 0.047 0.22 0.092	0.20 0.11 < LOD 0.024	< LOD < LOD < LOD 0.027	51 61 117 117	LC-MS/MS
Germany Emstek (Lower Sax-ony) Harvest Study Trial 21SGS99-01	Spring wheat Mandaryna	1- 20/04/21 2- 25/06 to 05/07/21 3- 12/08 to 14/08/21	Seed dresser Concrete mixer	1,0	0,7	0.025	13/04/21	00	Seed Grain Straw	0.17 0.012 < LOQ	0.47 0.030 0.020	< LOD < LOD 0.016	< LOD < LOD 0.030	0 115 115	Analytical Method: LC-MS/MS
Poland Chwastnica (Dolnośląskie) Harvest Study Trial 21SGS101-01	Spring bar-ley Propino	1- 22/04/21 2- 15/06 to 21/06/21 3- 09/08/21	Seed dresser Concrete mixer	1,0	0,7	0.025	14/04/21	00	Seed Grain Straw	0.49 0.041 < LOD	0.57 0.058 < LOD	0.016 < LOD < LOD	< LOD < LOD 0.010	0 109 109	Analytical Method: LC-MS/MS
Poland Kaczkowo (Kujawsko-po-morskie) Harvest Study Trial 21SGS102-01	Spring bar-ley Dante	1- 21/04/21 2- 04/06 to 13/06/21 3- 03/08/21	Seed dresser Concrete mixer	1,0	0,7	0.025	14/04/21	00	Seed Grain Straw	0.84 0.51 0.29	0.46 0.59 0.012	0.035 0.015 0.25	< LOQ < LOQ < LOD	0 104 104	Analytical Method: LC-MS/MS
Poland	Spring wheat	1- 28/04/21	Seed dresser	1,0	0,7	0.025	14/04/21	00	Seed	0.24	0.64	< LOD	< LOD	0	Analytical Method:

Cebulki (Warmińsko-mazurskie) Decline Curve Study Trial 21SGS103-01	Torridon	2- 25/06 to 03/07/21 3- 10/08/21	Concrete mixer						Whole plant without root Grain Straw	0.027 0.027 0.017 0.053 0.018	0.015 0.016 0.016 0.14 0.018	< LOD < LOD < LOD < LOD 0.011	< LOD < LOD < LOD < LOD 0.011	41 62 69 104 104	LC-MS/MS
Poland Zamarte (Kujawsko-po-morskie) Decline Curve Study Trial 21SGS104-01	Spring wheat Rospuda	1- 14/04/21 2- 28/06 to 03/07/21 3- 10/08/21	Seed dresser Concrete mixer	1,0	0,7	0.025	14/04/21	00	Seed Whole plant without root Grain Straw	0.24 0.040 0.012 < LOD 0.098 0.047	0.68 0.022 0.023 0.015 0.22 < LOD	< LOQ 0.023 0.012 < LOD < LOQ 0.022	< LOD < LOD < LOD < LOD < LOD 0.022	0 43 63 71 118 118	Analytical Method: LC-MS/MS

(1) LOQ = 0.010 mg/kg (2) PHI = DALA - days after last application; CH - commercial harvest

A 2.1.4 Magnitude of residues in livestock

No additional studies were performed.

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

No additional studies were performed.

A 2.1.6 Magnitude of residues in representative succeeding crops

No additional studies were performed.

A 2.1.7 Other/Special Studies

No additional studies were performed.

Appendix 3 Pesticide Residue Intake Model (PRIMo)

A 3.1 TMDI calculations

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

Prothioconazole 100 FS (F)

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	0.05	ARfD (mg/kg bw):	0.2
Source of ADI:		Source of ARfD:	
Year of evaluation:		Year of evaluation:	

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	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)
3%	IT toddler	1.63	3%	Wheat	0.6%	Other cereals	0.0%	Barley		
3%	GEMS/Food G06	1.45	3%	Wheat	0.0%	Rye	0.0%	Barley		
3%	DK child	1.43	2%	Wheat	1%	Rye				
2%	RO general	1.01	2%	Wheat		Grapefruits				
2%	IT adult	0.97	2%	Wheat	0.3%	Other cereals	0.0%	Barley		
2%	GEMS/Food G15	0.96	2%	Wheat	0.1%	Barley	0.0%	Rye		
2%	DE child	0.92	2%	Wheat	0.2%	Rye	0.0%	Other cereals		
2%	FR child 3 15 yr	0.92	2%	Wheat	0.0%	Rye	0.0%	Barley		
2%	GEMS/Food G08	0.91	2%	Wheat	0.1%	Rye	0.1%	Barley		
2%	ES child	0.89	2%	Wheat	0.0%	Barley				
2%	GEMS/Food G07	0.87	2%	Wheat	0.0%	Barley	0.0%	Rye		
2%	NL child	0.84	2%	Wheat	0.0%	Rye	0.0%	Barley		
2%	NL toddler	0.84	2%	Wheat	0.1%	Rye	0.0%	Barley		
2%	GEMS/Food G10	0.82	2%	Wheat	0.0%	Barley	0.0%	Rye		
2%	PT general	0.80	2%	Wheat	0.0%	Rye	0.0%	Barley		
2%	UK toddler	0.78	2%	Wheat	0.0%	Rye	0.0%	Barley		
2%	GEMS/Food G11	0.75	1%	Wheat	0.1%	Barley	0.0%	Rye		
1%	SE general	0.67	1%	Wheat	0.1%	Rye				
1%	FR toddler 2 3 yr	0.62	1%	Wheat	0.0%	Rye	0.0%	Other cereals		
1%	UK infant	0.52	1%	Wheat		Grapefruits				
1.0%	ES adult	0.49	0.3%	Wheat	0.0%	Barley				
1.0%	DE women 14-50 yr	0.48	0.3%	Wheat	0.1%	Rye	0.0%	Barley		
0.9%	IE adult	0.47	0.3%	Wheat	0.0%	Rye	0.0%	Barley		
0.9%	DE general	0.46	0.8%	Wheat	0.1%	Rye	0.0%	Barley		
0.9%	FR adult	0.45	0.3%	Wheat	0.0%	Rye	0.0%	Other cereals		
0.8%	UK vegetarian	0.41	0.8%	Wheat	0.0%	Rye	0.0%	Barley		
0.8%	NL general	0.41	0.8%	Wheat	0.0%	Barley	0.0%	Rye		
0.7%	UK adult	0.34	0.7%	Wheat	0.0%	Barley	0.0%	Rye		
0.6%	LT adult	0.32	0.4%	Wheat	0.2%	Rye	0.0%	Barley		
0.6%	FI 3 yr	0.31	0.5%	Wheat	0.1%	Rye	0.0%	Barley		
0.6%	DK adult	0.28	0.4%	Wheat	0.1%	Rye				
0.5%	FI 6 yr	0.26	0.4%	Wheat	0.1%	Rye	0.0%	Barley		
0.5%	IE child	0.23	0.5%	Wheat	0.0%	Barley				
0.3%	FR infant	0.16	0.3%	Wheat	0.0%	Rye	0.0%	Barley		
0.3%	FI adult	0.14	0.1%	Rye	0.1%	Wheat	0.0%	Barley		
	Column7			Grapefruits		Grapefruits				

A 3.2 IEDI calculations

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

Prothioconazole 100 FS (F)

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	**0.05**	ARfD (mg/kg bw):	**0.2**
Source of ADI:		Source of ARfD:	
Year of evaluation:		Year of evaluation:	

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/WEDI/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)
0.4%	DK child	0.20	0.2%	Rye	0.2%	Wheat				
0.3%	IT toddler	0.16	0.3%	Wheat	0.1%	Other cereals	0.0%	Barley		
0.3%	GEMS/Food G06	0.15	0.3%	Wheat	0.0%	Barley	0.0%	Rye		
0.2%	GEMS/Food G08	0.11	0.2%	Wheat	0.0%	Barley	0.0%	Rye		
0.2%	GEMS/Food G15	0.11	0.2%	Wheat	0.0%	Barley	0.0%	Rye		
0.2%	RO general	0.10	0.2%	Wheat		Grapefruits				
0.2%	DE child	0.10	0.2%	Wheat	0.0%	Rye	0.0%	Barley		
0.2%	GEMS/Food G07	0.10	0.2%	Wheat	0.0%	Barley	0.0%	Rye		
0.2%	IT adult	0.10	0.2%	Wheat	0.0%	Other cereals	0.0%	Barley		
0.2%	GEMS/Food G10	0.09	0.2%	Wheat	0.0%	Barley	0.0%	Rye		
0.2%	FR child 3 15 yr	0.09	0.2%	Wheat	0.0%	Rye	0.0%	Barley		
0.2%	NL toddler	0.09	0.2%	Wheat	0.0%	Rye	0.0%	Barley		
0.2%	ES child	0.09	0.2%	Wheat	0.0%	Barley				
0.2%	GEMS/Food G11	0.09	0.1%	Wheat	0.0%	Barley	0.0%	Rye		
0.2%	NL child	0.09	0.2%	Wheat	0.0%	Rye	0.0%	Barley		
0.2%	PT general	0.08	0.2%	Wheat	0.0%	Rye	0.0%	Barley		
0.2%	UK toddler	0.08	0.2%	Wheat	0.0%	Barley	0.0%	Rye		
0.1%	SE general	0.07	0.1%	Wheat	0.0%	Rye				
0.1%	FR toddler 2 3 yr	0.06	0.1%	Wheat	0.0%	Rye	0.0%	Barley		
0.1%	DE general	0.06	0.1%	Wheat	0.0%	Rye	0.0%	Barley		
0.1%	ES adult	0.06	0.1%	Wheat	0.0%	Barley				
0.1%	DE women 14-50 yr	0.06	0.1%	Wheat	0.0%	Rye	0.0%	Barley		
0.1%	UK infant	0.05	0.1%	Wheat		Grapefruits				
0.1%	IE adult	0.05	0.1%	Wheat	0.0%	Rye	0.0%	Barley		
0.1%	NL general	0.05	0.1%	Wheat	0.0%	Barley	0.0%	Rye		
0.1%	FR adult	0.04	0.1%	Wheat	0.0%	Rye	0.0%	Barley		
0.1%	LT adult	0.04	0.0%	Rye	0.0%	Wheat	0.0%	Barley		
0.1%	UK vegetarian	0.04	0.1%	Wheat	0.0%	Barley	0.0%	Barley		
0.1%	FI 3 yr	0.04	0.0%	Wheat	0.0%	Rye	0.0%	Barley		
0.1%	UK adult	0.03	0.1%	Wheat	0.0%	Barley	0.0%	Rye		
0.1%	DK adult	0.03	0.0%	Wheat	0.0%	Rye				
0.1%	FI 6 yr	0.03	0.0%	Wheat	0.0%	Rye	0.0%	Barley		
0.0%	IE child	0.02	0.0%	Wheat	0.0%	Barley				
0.0%	FI adult	0.02	0.0%	Rye	0.0%	Wheat	0.0%	Barley		
0.0%	FR infant	0.02	0.0%	Wheat	0.0%	Rye	0.0%	Barley		
	Column7			Grapefruits		Grapefruits				

A 3.3 IESTI calculations - Raw commodities

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

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

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

Show results for all crops

Unprocessed commodities

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

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

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

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.1%	Wheat	0.1 / 0.02	0.29
0.06%	Rye	0.05 / 0.02	0.13
0.06%	Barley	0.02 / 0.02	0.11

Expand/collapse list

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.08%	Wheat	0.1 / 0.02	0.17
0.05%	Rye	0.05 / 0.02	0.10
0.05%	Barley	0.02 / 0.02	0.10

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
1%	Wheat	0.1 / 0.2	2.9
0.3%	Rye	0.05 / 0.1	0.63
0.1%	Barley	0.02 / 0.04	0.22

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.6%	Wheat	0.1 / 0.2	1.7
0.2%	Rye	0.05 / 0.1	0.43
0.10%	Barley	0.02 / 0.04	0.19

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

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

A 3.4 IESTI calculations - Processed commodities

Processed commodities

Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---				**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---			
IESTI				**IESTI**			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.1%	Wheat / milling (flour)	0.1 / 0.02	0.24	0.1%	Barley / beer	0.02 / 0	0.14
0.1%	Wheat / milling (wholemeal)-l	0.1 / 0.02	0.11	0.04%	Wheat / bread/pizza	0.1 / 0.02	0.09
0.0%	Rye / boiled	0.05 / 0.02	0.07	0.04%	Wheat / pasta	0.1 / 0.02	0.08
0.0%	Barley / cooked	0.02 / 0.02	0.07	0.03%	Wheat / bread (wholemeal)	0.1 / 0.02	0.07
0.0%	Rye / milling (wholemeal)-bal	0.05 / 0.02	0.07	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
0.0%	Barley / milling (flour)	0.02 / 0.02	0.04	#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!
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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): ---				**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---			
IESTI new				**IESTI new**			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
1%	Wheat / milling (flour)	0.1 / 0.2	2.4	0.4%	Wheat / bread/pizza	0.1 / 0.2	0.88
0.6%	Wheat / milling (wholemeal)-	0.1 / 0.2	1.1	0.4%	Wheat / pasta	0.1 / 0.2	0.76
0.2%	Rye / boiled	0.05 / 0.1	0.36	0.3%	Wheat / bread (wholemeal)	0.1 / 0.2	0.70
0.2%	Rye / milling (wholemeal)-	0.05 / 0.1	0.35	0.1%	Barley / beer	0.02 / 0.01	0.29
0.07%	Barley / cooked	0.02 / 0.04	0.15	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
0.04%	Barley / milling (flour)	0.02 / 0.04	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!
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#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!

A 3.5 TMDI calculations - 1,2,4-T

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

1,2,4-Triazole (F)

LOQs (mg/kg) range from: to:

Toxicological reference values

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

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	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%	DK child	0.30	0.7%	Rye	0.6%	Wheat				
1%	IT toddler	0.24	0.3%	Wheat	0.2%	Other cereals	0.0%	Barley		
1.0%	GEMS/Food G06	0.22	0.3%	Wheat	0.0%	Barley	0.0%	Rye		
0.7%	GEMS/Food G08	0.17	0.5%	Wheat	0.1%	Barley	0.1%	Rye		
0.7%	GEMS/Food G15	0.17	0.6%	Wheat	0.1%	Barley	0.0%	Rye		
0.7%	RO general	0.15	0.7%	Wheat		Grapefruits				
0.7%	DE child	0.15	0.5%	Wheat	0.1%	Rye	0.0%	Barley		
0.6%	GEMS/Food G07	0.15	0.6%	Wheat	0.1%	Barley	0.0%	Rye		
0.6%	IT adult	0.15	0.5%	Wheat	0.1%	Other cereals	0.0%	Barley		
0.6%	GEMS/Food G10	0.14	0.5%	Wheat	0.1%	Barley	0.0%	Rye		
0.6%	FR child 3 15 yr	0.14	0.6%	Wheat	0.0%	Rye	0.0%	Barley		
0.6%	NL toddler	0.14	0.5%	Wheat	0.1%	Rye	0.0%	Barley		
0.6%	ES child	0.13	0.6%	Wheat	0.0%	Barley				
0.6%	GEMS/Food G11	0.13	0.5%	Wheat	0.1%	Barley	0.0%	Rye		
0.6%	NL child	0.13	0.5%	Wheat	0.0%	Rye	0.0%	Barley		
0.5%	PT general	0.12	0.5%	Wheat	0.0%	Rye	0.0%	Barley		
0.5%	UK toddler	0.12	0.5%	Wheat	0.0%	Barley	0.0%	Rye		
0.5%	SE general	0.10	0.4%	Wheat	0.0%	Rye				
0.4%	FR toddler 2 3 yr	0.09	0.4%	Wheat	0.0%	Rye	0.0%	Barley		
0.4%	DE general	0.09	0.2%	Wheat	0.1%	Rye	0.1%	Barley		
0.4%	ES adult	0.09	0.3%	Wheat	0.1%	Barley				
0.4%	DE women 14-50 yr	0.08	0.3%	Wheat	0.1%	Rye	0.0%	Barley		
0.3%	UK infant	0.08	0.3%	Wheat		Grapefruits				
0.3%	IE adult	0.07	0.3%	Wheat	0.0%	Rye	0.0%	Barley		
0.3%	NL general	0.07	0.3%	Wheat	0.0%	Barley	0.0%	Rye		
0.3%	FR adult	0.07	0.3%	Wheat	0.0%	Rye	0.0%	Barley		
0.3%	LT adult	0.07	0.1%	Rye	0.1%	Wheat	0.0%	Barley		
0.3%	UK vegetarian	0.06	0.3%	Wheat	0.0%	Barley	0.0%	Barley		
0.2%	FI 3 yr	0.06	0.2%	Wheat	0.1%	Rye	0.0%	Barley		
0.2%	UK adult	0.05	0.2%	Wheat	0.0%	Barley	0.0%	Rye		
0.2%	DK adult	0.05	0.1%	Wheat	0.1%	Rye				
0.2%	FI 6 yr	0.05	0.1%	Wheat	0.1%	Rye	0.0%	Barley		
0.2%	IE child	0.04	0.2%	Wheat	0.0%	Barley				
0.1%	FI adult	0.03	0.1%	Rye	0.0%	Wheat	0.0%	Barley		
0.1%	FR infant	0.02	0.1%	Wheat	0.0%	Rye	0.0%	Barley		
	Column7			Grapefruits		Grapefruits				

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 (F) is unlikely to present a public health concern.

A 3.6 IEDI calculations- 1,2,4-T

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

1,2,4-Triazole (F)

LOQs (mg/kg) range from: to:

Toxicological reference values

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

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	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)
0.3%	DK child	0.06	0.1%	Rye	0.1%	Wheat				
0.2%	IT toddler	0.05	0.2%	Wheat	0.0%	Other cereals	0.0%	Barley		
0.2%	GEMS/Food G06	0.04	0.2%	Wheat	0.0%	Barley	0.0%	Rye		
0.1%	GEMS/Food G08	0.03	0.1%	Wheat	0.0%	Barley	0.0%	Rye		
0.1%	GEMS/Food G15	0.03	0.1%	Wheat	0.0%	Barley	0.0%	Rye		
0.1%	RO general	0.03	0.1%	Wheat		Grapefruits				
0.1%	DE child	0.03	0.1%	Wheat	0.0%	Rye	0.0%	Barley		
0.1%	GEMS/Food G07	0.03	0.1%	Wheat	0.0%	Barley	0.0%	Rye		
0.1%	IT adult	0.03	0.1%	Wheat	0.0%	Other cereals	0.0%	Barley		
0.1%	GEMS/Food G10	0.03	0.1%	Wheat	0.0%	Barley	0.0%	Rye		
0.1%	FR child 3 15 yr	0.03	0.1%	Wheat	0.0%	Rye	0.0%	Barley		
0.1%	NL toddler	0.03	0.1%	Wheat	0.0%	Rye	0.0%	Barley		
0.1%	ES child	0.03	0.1%	Wheat	0.0%	Barley				
0.1%	GEMS/Food G11	0.03	0.1%	Wheat	0.0%	Barley	0.0%	Rye		
0.1%	NL child	0.03	0.1%	Wheat	0.0%	Rye	0.0%	Barley		
0.1%	PT general	0.02	0.1%	Wheat	0.0%	Rye	0.0%	Barley		
0.1%	UK toddler	0.02	0.1%	Wheat	0.0%	Barley	0.0%	Rye		
0.1%	SE general	0.02	0.1%	Wheat	0.0%	Rye				
0.1%	FR toddler 2 3 yr	0.02	0.1%	Wheat	0.0%	Rye	0.0%	Barley		
0.1%	DE general	0.02	0.0%	Wheat	0.0%	Rye	0.0%	Barley		
0.1%	ES adult	0.02	0.1%	Wheat	0.0%	Barley				
0.1%	DE women 14-50 yr	0.02	0.1%	Wheat	0.0%	Rye	0.0%	Barley		
0.1%	UK infant	0.02	0.1%	Wheat		Grapefruits				
0.1%	IE adult	0.01	0.1%	Wheat	0.0%	Rye	0.0%	Barley		
0.1%	NL general	0.01	0.1%	Wheat	0.0%	Barley	0.0%	Rye		
0.1%	FR adult	0.01	0.1%	Wheat	0.0%	Rye	0.0%	Barley		
0.1%	LT adult	0.01	0.0%	Rye	0.0%	Wheat	0.0%	Barley		
0.1%	UK vegetarian	0.01	0.1%	Wheat	0.0%	Barley	0.0%	Barley		
0.0%	FI 3 yr	0.01	0.0%	Wheat	0.0%	Rye	0.0%	Barley		
0.0%	UK adult	0.01	0.0%	Wheat	0.0%	Barley	0.0%	Rye		
0.0%	DK adult	0.01	0.0%	Wheat	0.0%	Rye				
0.0%	FI 6 yr	0.01	0.0%	Wheat	0.0%	Rye	0.0%	Barley		
0.0%	IE child	0.01	0.0%	Wheat	0.0%	Barley				
0.0%	FI adult	0.01	0.0%	Rye	0.0%	Wheat	0.0%	Barley		
0.0%	FR infant	0.00	0.0%	Wheat	0.0%	Rye	0.0%	Barley		
	Column7			Grapefruits		Grapefruits				

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 (F) is unlikely to present a public health concern.

A 3.7 IESTI calculations - 1,2,4-T

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.09%	Wheat	0.02 / 0.01	0.09
0.04%	Rye	0.02 / 0.01	0.04
0.03%	Barley	0.02 / 0.01	0.03

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)
0.05%	Wheat	0.02 / 0.01	0.05
0.03%	Rye	0.02 / 0.01	0.03
0.03%	Barley	0.02 / 0.01	0.03

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)
0.4%	Wheat	0.02 / 0.03	0.43
0.2%	Rye	0.02 / 0.03	0.19
0.2%	Barley	0.02 / 0.03	0.17

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)
0.3%	Wheat	0.02 / 0.03	0.25
0.1%	Rye	0.02 / 0.03	0.15
0.1%	Barley	0.02 / 0.03	0.15

Expand/collapse list

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

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

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)	0.02 / 0.01	0.07
0.0%	Wheat / milling (wholemeal)-l	0.02 / 0.01	0.03
0.0%	Rye / boiled	0.02 / 0.01	0.02
0.0%	Barley / cooked	0.02 / 0.01	0.02
0.0%	Rye / milling (wholemeal)-bal	0.02 / 0.01	0.02
0.0%	Barley / milling (flour)	0.02 / 0.01	0.01
#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 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%	Barley / beer	0.02 / 0	0.04
0.03%	Wheat / bread/pizza	0.02 / 0.01	0.03
0.02%	Wheat / pasta	0.02 / 0.01	0.02
0.02%	Wheat / bread (wholemeal)	0.02 / 0.01	0.02
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
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#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)
0.4%	Wheat / milling (flour)	0.02 / 0.03	0.36
0.2%	Wheat / milling (wholemeal)-	0.02 / 0.03	0.17
0.1%	Rye / boiled	0.02 / 0.03	0.11
0.1%	Barley / cooked	0.02 / 0.03	0.11
0.1%	Rye / milling (wholemeal)-	0.02 / 0.03	0.11
0.05%	Barley / milling (flour)	0.02 / 0.03	0.05
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
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#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!

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)
0.2%	Barley / beer	0.02 / 0.01	0.22
0.1%	Wheat / bread/pizza	0.02 / 0.03	0.13
0.1%	Wheat / pasta	0.02 / 0.03	0.11
0.1%	Wheat / bread (wholemeal)	0.02 / 0.03	0.10
#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

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short term intake of residues of 1,2,4-Triazole (F) is unlikely to present a public health risk
For processed commodities, no exceedance of the ARfD/ADI was identified.

A 3.8 TMDI calculations - TLA

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

TLA (F)

LOQs (mg/kg) range from: to:

Toxicological reference values

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

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	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)
0.2%	DK child	0.60	0.1%	Rye	0.1%	Wheat				
0.2%	IT toddler	0.49	0.1%	Wheat	0.0%	Other cereals	0.0%	Barley		
0.1%	GEMS/Food G06	0.44	0.1%	Wheat	0.0%	Barley	0.0%	Rye		
0.1%	GEMS/Food G08	0.33	0.1%	Wheat	0.0%	Barley	0.0%	Rye		
0.1%	GEMS/Food G15	0.33	0.1%	Wheat	0.0%	Barley	0.0%	Rye		
0.1%	RO general	0.30	0.1%	Wheat		Grapefruits				
0.1%	DE child	0.30	0.1%	Wheat	0.0%	Rye	0.0%	Barley		
0.1%	GEMS/Food G07	0.29	0.1%	Wheat	0.0%	Barley	0.0%	Rye		
0.1%	IT adult	0.29	0.1%	Wheat	0.0%	Other cereals	0.0%	Barley		
0.1%	GEMS/Food G10	0.28	0.1%	Wheat	0.0%	Barley	0.0%	Rye		
0.1%	FR child 3 15 yr	0.28	0.1%	Wheat	0.0%	Rye	0.0%	Barley		
0.1%	NL toddler	0.27	0.1%	Wheat	0.0%	Rye	0.0%	Barley		
0.1%	ES child	0.27	0.1%	Wheat	0.0%	Barley				
0.1%	GEMS/Food G11	0.26	0.1%	Wheat	0.0%	Barley	0.0%	Rye		
0.1%	NL child	0.26	0.1%	Wheat	0.0%	Rye	0.0%	Barley		
0.1%	PT general	0.25	0.1%	Wheat	0.0%	Rye	0.0%	Barley		
0.1%	UK toddler	0.24	0.1%	Wheat	0.0%	Barley	0.0%	Rye		
0.1%	SE general	0.21	0.1%	Wheat	0.0%	Rye				
0.1%	FR toddler 2 3 yr	0.19	0.1%	Wheat	0.0%	Rye	0.0%	Barley		
0.1%	DE general	0.18	0.0%	Wheat	0.0%	Rye	0.0%	Barley		
0.1%	ES adult	0.17	0.0%	Wheat	0.0%	Barley				
0.1%	DE women 14-50 yr	0.17	0.0%	Wheat	0.0%	Rye	0.0%	Barley		
0.1%	UK infant	0.16	0.1%	Wheat		Grapefruits				
0.0%	IE adult	0.15	0.0%	Wheat	0.0%	Rye	0.0%	Barley		
0.0%	NL general	0.14	0.0%	Wheat	0.0%	Barley	0.0%	Rye		
0.0%	FR adult	0.13	0.0%	Wheat	0.0%	Rye	0.0%	Barley		
0.0%	LT adult	0.13	0.0%	Rye	0.0%	Wheat	0.0%	Barley		
0.0%	UK vegetarian	0.13	0.0%	Wheat	0.0%	Barley	0.0%	Barley		
0.0%	FI 3 yr	0.11	0.0%	Wheat	0.0%	Rye	0.0%	Barley		
0.0%	UK adult	0.10	0.0%	Wheat	0.0%	Barley	0.0%	Rye		
0.0%	DK adult	0.10	0.0%	Wheat	0.0%	Rye				
0.0%	FI 6 yr	0.10	0.0%	Wheat	0.0%	Rye	0.0%	Barley		
0.0%	IE child	0.07	0.0%	Wheat	0.0%	Barley				
0.0%	FI adult	0.06	0.0%	Rye	0.0%	Wheat	0.0%	Barley		
0.0%	FR infant	0.05	0.0%	Wheat	0.0%	Rye	0.0%	Barley		
	Column7			Grapefruits		Grapefruits				

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

A 3.9 IEDI calculations- TLA

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

TLA (F)

LOQs (mg/kg) range from: to:

Toxicological reference values

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

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	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)
0.1%	DK child	0.20	0.0%	Rye	0.0%	Wheat				
0.1%	IT toddler	0.16	0.0%	Wheat	0.0%	Other cereals	0.0%	Barley		
0.0%	GEMS/Food G06	0.15	0.0%	Wheat	0.0%	Barley	0.0%	Rye		
0.0%	GEMS/Food G08	0.11	0.0%	Wheat	0.0%	Barley	0.0%	Rye		
0.0%	GEMS/Food G15	0.11	0.0%	Wheat	0.0%	Barley	0.0%	Rye		
0.0%	RO general	0.10	0.0%	Wheat		Grapefruits				
0.0%	DE child	0.10	0.0%	Wheat	0.0%	Rye	0.0%	Barley		
0.0%	GEMS/Food G07	0.10	0.0%	Wheat	0.0%	Barley	0.0%	Rye		
0.0%	IT adult	0.10	0.0%	Wheat	0.0%	Other cereals	0.0%	Barley		
0.0%	GEMS/Food G10	0.09	0.0%	Wheat	0.0%	Barley	0.0%	Rye		
0.0%	FR child 3 15 yr	0.09	0.0%	Wheat	0.0%	Rye	0.0%	Barley		
0.0%	NL toddler	0.09	0.0%	Wheat	0.0%	Rye	0.0%	Barley		
0.0%	ES child	0.09	0.0%	Wheat	0.0%	Barley				
0.0%	GEMS/Food G11	0.09	0.0%	Wheat	0.0%	Barley	0.0%	Rye		
0.0%	NL child	0.09	0.0%	Wheat	0.0%	Rye	0.0%	Barley		
0.0%	PT general	0.08	0.0%	Wheat	0.0%	Rye	0.0%	Barley		
0.0%	UK toddler	0.08	0.0%	Wheat	0.0%	Barley	0.0%	Rye		
0.0%	SE general	0.07	0.0%	Wheat	0.0%	Rye				
0.0%	FR toddler 2 3 yr	0.06	0.0%	Wheat	0.0%	Rye	0.0%	Barley		
0.0%	DE general	0.06	0.0%	Wheat	0.0%	Rye	0.0%	Barley		
0.0%	ES adult	0.06	0.0%	Wheat	0.0%	Barley				
0.0%	DE women 14-50 yr	0.06	0.0%	Wheat	0.0%	Rye	0.0%	Barley		
0.0%	UK infant	0.05	0.0%	Wheat		Grapefruits				
0.0%	IE adult	0.05	0.0%	Wheat	0.0%	Rye	0.0%	Barley		
0.0%	NL general	0.05	0.0%	Wheat	0.0%	Barley	0.0%	Rye		
0.0%	FR adult	0.04	0.0%	Wheat	0.0%	Rye	0.0%	Barley		
0.0%	LT adult	0.04	0.0%	Rye	0.0%	Wheat	0.0%	Barley		
0.0%	UK vegetarian	0.04	0.0%	Wheat	0.0%	Barley	0.0%	Barley		
0.0%	FI 3 yr	0.04	0.0%	Wheat	0.0%	Rye	0.0%	Barley		
0.0%	UK adult	0.03	0.0%	Wheat	0.0%	Barley	0.0%	Rye		
0.0%	DK adult	0.03	0.0%	Wheat	0.0%	Rye				
0.0%	FI 6 yr	0.03	0.0%	Wheat	0.0%	Rye	0.0%	Barley		
0.0%	IE child	0.02	0.0%	Wheat	0.0%	Barley				
0.0%	FI adult	0.02	0.0%	Rye	0.0%	Wheat	0.0%	Barley		
0.0%	FR infant	0.02	0.0%	Wheat	0.0%	Rye	0.0%	Barley		
	Column7			Grapefruits		Grapefruits				

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

A 3.10 IESTI calculations - TLA

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.10%	Wheat	0.03 / 0.02	0.29
0.04%	Rye	0.03 / 0.02	0.13
0.04%	Barley	0.03 / 0.02	0.11

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)
0.06%	Wheat	0.03 / 0.02	0.17
0.03%	Rye	0.03 / 0.02	0.10
0.03%	Barley	0.03 / 0.02	0.10

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

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.3%	Wheat	0.03 / 0.06	0.87
0.1%	Rye	0.03 / 0.06	0.38
0.1%	Barley	0.03 / 0.06	0.34

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)
0.2%	Wheat	0.03 / 0.06	0.50
0.10%	Rye	0.03 / 0.06	0.29
0.10%	Barley	0.03 / 0.06	0.29

Expand/collapse list

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

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

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)	0.03 / 0.02	0.24
0.0%	Wheat / milling (wholemeal)-l	0.03 / 0.02	0.11
0.0%	Rye / boiled	0.03 / 0.02	0.07
0.0%	Barley / cooked	0.03 / 0.02	0.07
0.0%	Rye / milling (wholemeal)-bal	0.03 / 0.02	0.07
0.0%	Barley / milling (flour)	0.03 / 0.02	0.04
#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!

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%	Barley / beer	0.03 / 0	0.14
0.03%	Wheat / bread/pizza	0.03 / 0.02	0.09
0.03%	Wheat / pasta	0.03 / 0.02	0.08
0.02%	Wheat / bread (wholemeal)	0.03 / 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!

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)
0.2%	Wheat / milling (flour)	0.03 / 0.06	0.73
0.1%	Wheat / milling (wholemeal)-	0.03 / 0.06	0.33
0.07%	Rye / boiled	0.03 / 0.06	0.22
0.07%	Barley / cooked	0.03 / 0.06	0.22
0.07%	Rye / milling (wholemeal)-	0.03 / 0.06	0.21
0.04%	Barley / milling (flour)	0.03 / 0.06	0.11
#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!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!

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)
0.1%	Barley / beer	0.03 / 0.01	0.43
0.09%	Wheat / bread/pizza	0.03 / 0.06	0.26
0.08%	Wheat / pasta	0.03 / 0.06	0.23
0.07%	Wheat / bread (wholemeal)	0.03 / 0.06	0.21
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
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#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
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#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!

Expand/collapse list

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

A 3.11 TMDI calculations – TA

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

TA (F)

LOQs (mg/kg) range from: to:

Toxicological reference values

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

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
7%	DK child	19.85	4%	Rye	3%	Wheat				
5%	IT toddler	16.32	4%	Wheat	1%	Other cereals	0.0%	Barley		
5%	GEMS/Food G06	14.68	5%	Wheat	0.0%	Barley	0.0%	Rye		
4%	GEMS/Food G08	11.12	3%	Wheat	0.6%	Barley	0.4%	Rye		
4%	GEMS/Food G15	11.11	3%	Wheat	0.5%	Barley	0.2%	Rye		
3%	RO general	10.13	3%	Wheat		Grapefruits				
3%	DE child	10.04	3%	Wheat	0.5%	Rye	0.0%	Barley		
3%	GEMS/Food G07	9.75	3%	Wheat	0.4%	Barley	0.0%	Rye		
3%	IT adult	9.70	3%	Wheat	0.5%	Other cereals	0.0%	Barley		
3%	GEMS/Food G10	9.23	3%	Wheat	0.4%	Barley	0.1%	Rye		
3%	FR child 3 15 yr	9.23	3%	Wheat	0.0%	Rye	0.0%	Barley		
3%	NL toddler	9.06	3%	Wheat	0.3%	Rye	0.1%	Barley		
3%	ES child	8.88	3%	Wheat	0.0%	Barley				
3%	GEMS/Food G11	8.82	2%	Wheat	0.5%	Barley	0.0%	Rye		
3%	NL child	8.59	3%	Wheat	0.1%	Rye	0.0%	Barley		
3%	PT general	8.17	3%	Wheat	0.1%	Rye	0.0%	Barley		
3%	UK toddler	7.88	3%	Wheat	0.0%	Barley	0.0%	Rye		
2%	SE general	6.39	2%	Wheat	0.2%	Rye				
2%	FR toddler 2 3 yr	6.18	2%	Wheat	0.0%	Rye	0.0%	Barley		
2%	DE general	5.95	1%	Wheat	0.4%	Rye	0.3%	Barley		
2%	ES adult	5.68	2%	Wheat	0.3%	Barley				
2%	DE women 14-50 yr	5.63	1%	Wheat	0.3%	Rye	0.1%	Barley		
2%	UK infant	5.24	2%	Wheat		Grapefruits				
2%	IE adult	4.91	2%	Wheat	0.1%	Rye	0.0%	Barley		
2%	NL general	4.59	1%	Wheat	0.2%	Barley	0.0%	Rye		
1%	FR adult	4.46	1%	Wheat	0.0%	Rye	0.0%	Barley		
1%	LT adult	4.38	0.7%	Rye	0.7%	Wheat	0.0%	Barley		
1%	UK vegetarian	4.17	1%	Wheat	0.0%	Barley	0.0%	Barley		
1%	FI 3 yr	3.82	0.8%	Wheat	0.4%	Rye	0.0%	Barley		
1%	UK adult	3.42	1%	Wheat	0.0%	Barley	0.0%	Rye		
1%	DK adult	3.30	0.7%	Wheat	0.4%	Rye				
1%	FI 6 yr	3.29	0.6%	Wheat	0.4%	Rye	0.0%	Barley		
0.8%	IE child	2.33	0.8%	Wheat	0.0%	Barley				
0.7%	FI adult	2.09	0.5%	Rye	0.2%	Wheat	0.0%	Barley		
0.5%	FR infant	1.57	0.5%	Wheat	0.0%	Rye	0.0%	Barley		
	Column7			Grapefruits		Grapefruits				

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

A 3.12 IEDI calculations- TA

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

TA (F)

LOQs (mg/kg) range from: to:

Toxicological reference values

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

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	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)
0.9%	DK child	2.78	0.5%	Rye	0.4%	Wheat				
0.8%	IT toddler	2.28	0.6%	Wheat	0.1%	Other cereals	0.0%	Barley		
0.7%	GEMS/Food G06	2.06	0.7%	Wheat	0.0%	Barley	0.0%	Rye		
0.5%	GEMS/Food G08	1.56	0.4%	Wheat	0.1%	Barley	0.1%	Rye		
0.5%	GEMS/Food G15	1.56	0.4%	Wheat	0.1%	Barley	0.0%	Rye		
0.5%	RO general	1.42	0.5%	Wheat		Grapefruits				
0.5%	DE child	1.41	0.4%	Wheat	0.1%	Rye	0.0%	Barley		
0.5%	GEMS/Food G07	1.37	0.4%	Wheat	0.1%	Barley	0.0%	Rye		
0.5%	IT adult	1.36	0.4%	Wheat	0.1%	Other cereals	0.0%	Barley		
0.4%	GEMS/Food G10	1.29	0.4%	Wheat	0.1%	Barley	0.0%	Rye		
0.4%	FR child 3 15 yr	1.29	0.4%	Wheat	0.0%	Rye	0.0%	Barley		
0.4%	NL toddler	1.27	0.4%	Wheat	0.0%	Rye	0.0%	Barley		
0.4%	ES child	1.24	0.4%	Wheat	0.0%	Barley				
0.4%	GEMS/Food G11	1.23	0.3%	Wheat	0.1%	Barley	0.0%	Rye		
0.4%	NL child	1.20	0.4%	Wheat	0.0%	Rye	0.0%	Barley		
0.4%	PT general	1.14	0.4%	Wheat	0.0%	Rye	0.0%	Barley		
0.4%	UK toddler	1.10	0.4%	Wheat	0.0%	Barley	0.0%	Rye		
0.3%	SE general	0.98	0.3%	Wheat	0.0%	Rye				
0.3%	FR toddler 2 3 yr	0.86	0.3%	Wheat	0.0%	Rye	0.0%	Barley		
0.3%	DE general	0.83	0.2%	Wheat	0.1%	Rye	0.0%	Barley		
0.3%	ES adult	0.80	0.2%	Wheat	0.0%	Barley				
0.3%	DE women 14-50 yr	0.79	0.2%	Wheat	0.0%	Rye	0.0%	Barley		
0.2%	UK infant	0.73	0.2%	Wheat		Grapefruits				
0.2%	IE adult	0.69	0.2%	Wheat	0.0%	Rye	0.0%	Barley		
0.2%	NL general	0.64	0.2%	Wheat	0.0%	Barley	0.0%	Rye		
0.2%	FR adult	0.62	0.2%	Wheat	0.0%	Rye	0.0%	Barley		
0.2%	LT adult	0.61	0.1%	Rye	0.1%	Wheat	0.0%	Barley		
0.2%	UK vegetarian	0.58	0.2%	Wheat	0.0%	Barley	0.0%	Barley		
0.2%	FI 3 yr	0.53	0.1%	Wheat	0.1%	Rye	0.0%	Barley		
0.2%	UK adult	0.48	0.2%	Wheat	0.0%	Barley	0.0%	Rye		
0.2%	DK adult	0.46	0.1%	Wheat	0.0%	Rye				
0.2%	FI 6 yr	0.46	0.1%	Wheat	0.1%	Rye	0.0%	Barley		
0.1%	IE child	0.33	0.1%	Wheat	0.0%	Barley				
0.1%	FI adult	0.29	0.1%	Rye	0.0%	Wheat	0.0%	Barley		
0.1%	FR infant	0.22	0.1%	Wheat	0.0%	Rye	0.0%	Barley		
	Column7			Grapefruits		Grapefruits				

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

A 3.13 IESTI calculations - TA

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	1 / 0.28	4.0
0.6%	Rye	1 / 0.28	1.8
0.5%	Barley	1 / 0.28	1.6

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)
0.8%	Wheat	1 / 0.28	2.4
0.5%	Rye	1 / 0.28	1.4
0.5%	Barley	1 / 0.28	1.4

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)
10%	Wheat	1 / 2	29
4%	Rye	1 / 2	13
4%	Barley	1 / 2	11

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)
6%	Wheat	1 / 2	17
3%	Rye	1 / 2	9.7
3%	Barley	1 / 2	9.7

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)
1%	Wheat / milling (flour)	1 / 0.28	3.4
0.5%	Wheat / milling (wholemeal)-l	1 / 0.28	1.6
0.3%	Rye / boiled	1 / 0.28	1.0
0.3%	Barley / cooked	1 / 0.28	1.0
0.3%	Rye / milling (wholemeal)-bal	1 / 0.28	0.98
0.2%	Barley / milling (flour)	1 / 0.28	0.51
#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)
0.7%	Barley / beer	1 / 0.06	2.0
0.4%	Wheat / bread/pizza	1 / 0.28	1.2
0.4%	Wheat / pasta	1 / 0.28	1.1
0.3%	Wheat / bread (wholemeal)	1 / 0.28	0.98
#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!
#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)
8%	Wheat / milling (flour)	1 / 2	24
4%	Wheat / milling (wholemeal)-	1 / 2	11
2%	Rye / boiled	1 / 2	7.3
2%	Barley / cooked	1 / 2	7.3
2%	Rye / milling (wholemeal)-	1 / 2	7.0
1%	Barley / milling (flour)	1 / 2	3.6
#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 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)
5%	Barley / beer	1 / 0.4	14
3%	Wheat / bread/pizza	1 / 2	8.8
3%	Wheat / pasta	1 / 2	7.6
2%	Wheat / bread (wholemeal)	1 / 2	7.0
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
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#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 TA (E) is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

A 3.14 TMDI calculations – TAA

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

TAA (F)

LOQs (mg/kg) range from: to:

Toxicological reference values

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

Input values

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	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)
2%	DK child	17.86	1.0%	Rye	0.8%	Wheat				
1%	IT toddler	14.69	1%	Wheat	0.3%	Other cereals	0.0%	Barley		
1%	GEMS/Food G06	13.22	1%	Wheat	0.0%	Barley	0.0%	Rye		
1%	GEMS/Food G08	10.01	0.7%	Wheat	0.2%	Barley	0.1%	Rye		
1.0%	GEMS/Food G15	10.00	0.8%	Wheat	0.1%	Barley	0.0%	Rye		
0.9%	RO general	9.12	0.9%	Wheat		Grapefruits				
0.9%	DE child	9.04	0.8%	Wheat	0.1%	Rye	0.0%	Barley		
0.9%	GEMS/Food G07	8.78	0.8%	Wheat	0.1%	Barley	0.0%	Rye		
0.9%	IT adult	8.73	0.7%	Wheat	0.1%	Other cereals	0.0%	Barley		
0.8%	GEMS/Food G10	8.31	0.7%	Wheat	0.1%	Barley	0.0%	Rye		
0.8%	FR child 3 15 yr	8.30	0.8%	Wheat	0.0%	Rye	0.0%	Barley		
0.8%	NL toddler	8.15	0.7%	Wheat	0.1%	Rye	0.0%	Barley		
0.8%	ES child	7.99	0.8%	Wheat	0.0%	Barley				
0.8%	GEMS/Food G11	7.94	0.6%	Wheat	0.1%	Barley	0.0%	Rye		
0.8%	NL child	7.73	0.7%	Wheat	0.0%	Rye	0.0%	Barley		
0.7%	PT general	7.35	0.7%	Wheat	0.0%	Rye	0.0%	Barley		
0.7%	UK toddler	7.09	0.7%	Wheat	0.0%	Barley	0.0%	Rye		
0.6%	SE general	6.29	0.6%	Wheat	0.1%	Rye				
0.6%	FR toddler 2 3 yr	5.56	0.6%	Wheat	0.0%	Rye	0.0%	Barley		
0.5%	DE general	5.35	0.3%	Wheat	0.1%	Rye	0.1%	Barley		
0.5%	ES adult	5.11	0.4%	Wheat	0.1%	Barley				
0.5%	DE women 14-50 yr	5.07	0.4%	Wheat	0.1%	Rye	0.0%	Barley		
0.5%	UK infant	4.72	0.5%	Wheat		Grapefruits				
0.4%	IE adult	4.42	0.4%	Wheat	0.0%	Rye	0.0%	Barley		
0.4%	NL general	4.13	0.3%	Wheat	0.1%	Barley	0.0%	Rye		
0.4%	FR adult	4.01	0.4%	Wheat	0.0%	Rye	0.0%	Barley		
0.4%	LT adult	3.94	0.2%	Rye	0.2%	Wheat	0.0%	Barley		
0.4%	UK vegetarian	3.76	0.4%	Wheat	0.0%	Barley	0.0%	Barley		
0.3%	FI 3 yr	3.44	0.2%	Wheat	0.1%	Rye	0.0%	Barley		
0.3%	UK adult	3.08	0.3%	Wheat	0.0%	Barley	0.0%	Rye		
0.3%	DK adult	2.97	0.2%	Wheat	0.1%	Rye				
0.3%	FI 6 yr	2.96	0.2%	Wheat	0.1%	Rye	0.0%	Barley		
0.2%	IE child	2.10	0.2%	Wheat	0.0%	Barley				
0.2%	FI adult	1.88	0.1%	Rye	0.1%	Wheat	0.0%	Barley		
0.1%	FR infant	1.41	0.1%	Wheat	0.0%	Rye	0.0%	Barley		
	Column7			Grapefruits		Grapefruits				

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

A 3.15 IEDI calculations- TAA

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

TAA (F)

LOQs (mg/kg) range from: to:

Toxicological reference values

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

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	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)
0.2%	DK child	1.51	0.1%	Rye	0.1%	Wheat				
0.1%	IT toddler	1.24	0.1%	Wheat	0.0%	Other cereals	0.0%	Barley		
0.1%	GEMS/Food G06	1.12	0.1%	Wheat	0.0%	Barley	0.0%	Rye		
0.1%	GEMS/Food G08	0.85	0.1%	Wheat	0.0%	Barley	0.0%	Rye		
0.1%	GEMS/Food G15	0.84	0.1%	Wheat	0.0%	Barley	0.0%	Rye		
0.1%	RO general	0.77	0.1%	Wheat		Grapefruits				
0.1%	DE child	0.76	0.1%	Wheat	0.0%	Rye	0.0%	Barley		
0.1%	GEMS/Food G07	0.74	0.1%	Wheat	0.0%	Barley	0.0%	Rye		
0.1%	IT adult	0.74	0.1%	Wheat	0.0%	Other cereals	0.0%	Barley		
0.1%	GEMS/Food G10	0.70	0.1%	Wheat	0.0%	Barley	0.0%	Rye		
0.1%	FR child 3 15 yr	0.70	0.1%	Wheat	0.0%	Rye	0.0%	Barley		
0.1%	NL toddler	0.69	0.1%	Wheat	0.0%	Rye	0.0%	Barley		
0.1%	ES child	0.67	0.1%	Wheat	0.0%	Barley				
0.1%	GEMS/Food G11	0.67	0.1%	Wheat	0.0%	Barley	0.0%	Rye		
0.1%	NL child	0.65	0.1%	Wheat	0.0%	Rye	0.0%	Barley		
0.1%	PT general	0.62	0.1%	Wheat	0.0%	Rye	0.0%	Barley		
0.1%	UK toddler	0.60	0.1%	Wheat	0.0%	Barley	0.0%	Rye		
0.1%	SE general	0.53	0.0%	Wheat	0.0%	Rye				
0.0%	FR toddler 2 3 yr	0.47	0.0%	Wheat	0.0%	Rye	0.0%	Barley		
0.0%	DE general	0.45	0.0%	Wheat	0.0%	Rye	0.0%	Barley		
0.0%	ES adult	0.43	0.0%	Wheat	0.0%	Barley				
0.0%	DE women 14-50 yr	0.43	0.0%	Wheat	0.0%	Rye	0.0%	Barley		
0.0%	UK infant	0.40	0.0%	Wheat		Grapefruits				
0.0%	IE adult	0.37	0.0%	Wheat	0.0%	Rye	0.0%	Barley		
0.0%	NL general	0.35	0.0%	Wheat	0.0%	Barley	0.0%	Rye		
0.0%	FR adult	0.34	0.0%	Wheat	0.0%	Rye	0.0%	Barley		
0.0%	LT adult	0.33	0.0%	Rye	0.0%	Wheat	0.0%	Barley		
0.0%	UK vegetarian	0.32	0.0%	Wheat	0.0%	Barley	0.0%	Barley		
0.0%	FI 3 yr	0.29	0.0%	Wheat	0.0%	Rye	0.0%	Barley		
0.0%	UK adult	0.26	0.0%	Wheat	0.0%	Barley	0.0%	Rye		
0.0%	DK adult	0.25	0.0%	Wheat	0.0%	Rye				
0.0%	FI 6 yr	0.25	0.0%	Wheat	0.0%	Rye	0.0%	Barley		
0.0%	IE child	0.18	0.0%	Wheat	0.0%	Barley				
0.0%	FI adult	0.16	0.0%	Rye	0.0%	Wheat	0.0%	Barley		
0.0%	FR infant	0.12	0.0%	Wheat	0.0%	Rye	0.0%	Barley		
	Column7			Grapefruits		Grapefruits				

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

A 3.16 IESTI calculations - TAA

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.2%	Wheat	0.9 / 0.15	2.2
0.10%	Rye	0.9 / 0.15	0.96
0.09%	Barley	0.9 / 0.15	0.85

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.1%	Wheat	0.9 / 0.15	1.3
0.07%	Rye	0.9 / 0.15	0.74
0.07%	Barley	0.9 / 0.15	0.74

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)
3%	Wheat	0.9 / 1.8	26
1%	Rye	0.9 / 1.8	11
1%	Barley	0.9 / 1.8	10

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

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
2%	Wheat	0.9 / 1.8	15
0.9%	Rye	0.9 / 1.8	8.7
0.9%	Barley	0.9 / 1.8	8.7

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)
0.2%	Wheat / milling (flour)	0.9 / 0.15	1.8
0.1%	Wheat / milling (wholemeal)-l	0.9 / 0.15	0.84
0.1%	Rye / boiled	0.9 / 0.15	0.55
0.1%	Barley / cooked	0.9 / 0.15	0.55
0.1%	Rye / milling (wholemeal)-bal	0.9 / 0.15	0.53
0.0%	Barley / milling (flour)	0.9 / 0.15	0.28
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#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)
0.1%	Barley / beer	0.9 / 0.03	1.1
0.07%	Wheat / bread/pizza	0.9 / 0.15	0.67
0.06%	Wheat / pasta	0.9 / 0.15	0.58
0.05%	Wheat / bread (wholemeal)	0.9 / 0.15	0.53
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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)	0.9 / 1.8	22
1.0%	Wheat / milling (wholemeal)-	0.9 / 1.8	10.0
0.7%	Rye / boiled	0.9 / 1.8	6.5
0.7%	Barley / cooked	0.9 / 1.8	6.5
0.6%	Rye / milling (wholemeal)-	0.9 / 1.8	6.3
0.3%	Barley / milling (flour)	0.9 / 1.8	3.3
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#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!

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)
1%	Barley / beer	0.9 / 0.36	13
0.8%	Wheat / bread/pizza	0.9 / 1.8	7.9
0.7%	Wheat / pasta	0.9 / 1.8	6.9
0.6%	Wheat / bread (wholemeal)	0.9 / 1.8	6.3
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
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Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short term intake of residues of TAA (F) is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

Appendix 4 Additional information provided by the applicant