REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: ADM.03503.F.1.A

Product name(s): see Part A

Chemical active substance(s):

Prothioconazole, 150 g/L
Fluxapyroxad, 75 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Country organisation / representative as specified in Part A

Submission date: April 2022

MS Finalisation date: May 2023 (initial Core Assessment)

December 2023 (final Core Assessment)

Version history

When	What
April 2022	Version 1 Applicant
May 2023	Initial zRMS assessment The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are ~~struck through and shaded for transparency~~.
December 2023	Final report (Core Assessment updated following the commenting period) Additional information/assessments included by the zRMS in the report in response to comments received from the cMS and the Applicant are highlighted in yellow. Information no longer relevant is ~~struck through~~ and shaded.

DATA PROTECTION CLAIM

In order to present a dossier fully compliant with today's requirements (Reg. 284/2013), studies have been performed on ADM.03503.F.1.A. Under Article 59, Regulation 1107/2009/EC, on behalf of the Sponsor Company the applicant claims data protection for the studies conducted with ADM.03503.F.1.A. The data protection status and corresponding justification as valid for the respective country will be confirmed in the respective PART A.

STATEMENT FOR OWNERSHIP

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7 Metabolism and residue data (KCA section 6)

7.1 Summary and zRMS Conclusion

7.1.1 Critical GAP(s) and overall conclusion

Selection of critical uses and justification
The critical GAPs with respect to consumer intake and risk assessment for the preparation ADM.03503.F.1.A are presented in ~~Błąd! Nie można odnaleźć źródła odwołania..~~ Table 7.1- 1. They ave been selected from the individual GAPs in the central zone for cereals (wheat, rye, triticale and barley).

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

Four critical GAP uses, one for wheat, rye, triticale and one for barley were selected based on the highest application rate and the latest application timing (BBCH) per season of the active substances. For the cGAPs intended for wheat, rye and triticale, general extrapolation rules apply from wheat to rye for both active substances.

According to Commission Regulation (EU) No 752/2014 replacing Annex I to Regulation (EC) No 396/2005, MRLs for wheat (code number: 0500090) are also applicable to triticale (code number: 0500090-006).

Overall conclusion
The data available are considered sufficient for risk assessment.

An exceedance of the current EU-MRLs for prothioconazole (prothioconazole-desthio (sum of isomers)) of 0.1 mg/kg (wheat, triticale), 0.05 mg/kg (rye) and 0.2 mg/kg (barley) as laid down in Reg. (EU) 396/2005 (last update Comm. Reg. (EU) No 2019/552) is not expected.

An exceedance of the current EU-MRLs for fluxapyroxad (fluxapyroxad) of 0.4 mg/kg (wheat, rye, triticale) and 3.0 mg/kg (barley) as laid down in Reg. (EU) 396/2005 (last update Comm. Reg. (EU) No ~~2021/644~~ 2022/1324) is not expected.

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

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

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

Regarding the data for triazole derivative metabolites (TDMs) which were newly included in the prothioconazole residue definition for risk assessment (EFSA, 2018b and EFSA 2020), relevant studies (residue studies and storage stability studies) have been conducted. Study reports and final risk assessments on TDMs are submitted with this dRR.

Data gaps
Noticed data gaps are:

- None.

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

~~1~~0	1	2	3	4	5	6	7		8				9		10	11
Critical GAP number	**Use number (see part B.0)***	**Crop and/ or situation ****	**Zone**	**Product code**	**F, Fn, Fpn G, Gn, Gpn or I*****	**Pests or Group of pests controlled**	**Formulation**		**Application**				**Application rate per treatment**		**PHI (days)**	**Conclusion**
							Type	**Conc. of 1) Prothio-conazole 2) Fluxapyroxad**	**method kind**	**growth stage & season**	**Max. number a) per use b) per crop/ season**	**interval between applications (min)**	**water L/ha min max**	**kg as/ha Prothioconazole / Fluxapyroxad a) max. rate per appl. b) max. total rate per crop/season**		
Critical GAP (1)	1, 5, 9, 13, 17, 21, 25, 29, 33,	Winter wheat (TRZAW) Spring wheat (TRZAS) (0500090)	C-EU (N-EU)	ADM.03503.F.1.A	F	*Zymoseptoria tritici Drechslera tritici-repentis (DTR) Puccinia striiformis Puccinia recondita, Blumeria graminis f. sp. tritici, Fusarium + microdochium*	EC	1) 150 g/L 2) 75 g/L	Foliar spraying, overall	BBCH 30-69	a) 1 b) 1	-	125-400	1) 187.5 g/~~L~~ha 2) 93.75 g/~~L~~ha	n/a (PHI defined by application timing)	A
Critical GAP (2)	2, 6, 10, 14, 18, 22, 26, 30, 34	Winter barley (HORVW) Spring barley (HORVS) (0500010)	C-EU (N-EU)	ADM.03503.F.1.A	F	*Rhyncosporium secalis Pyrenophora teres Ramularia collo-cygni Puccinia hordei Blumeria graminis f. sp. hordei*	EC	1) 150 g/L 2) 75 g/L	Foliar spraying, overall	BBCH 30-65	a) 1 b) 1	-	125-400	1) 187.5 g/~~L~~ha 2) 93.75 g/~~L~~ha	n/a (PHI defined by application timing)	A
Critical GAP (3)	3, 7, 11, 15, 19, 23, 27, 31, 35	Rye (SECCW) (0500070)	C-EU (N-EU)	ADM.03503.F.1.A	F	*Rhyncosporium secalis Puccinia recondita Puccinia striiformis*	EC	1) 150 g/L 2) 75 g/L	Foliar spraying, overall	BBCH 30-69	a) 1 b) 1	-	125-400	1) 187.5 g/~~L~~ha 2) 93.75 g/~~L~~ha	n/a (PHI defined by application timing)	A
Critical GAP (4)	4, 8, 12, 16, 20, 24, 28, 32, 36	Triticale (TTLSS) (0500090-006)	C-EU (N-EU)	ADM.03503.F.1.A	F	*Zymoseptoria tritici Puccinia recondita Puccinia striiformis Drechslera tritici-repentis (DTR) Blumeria graminis*	EC	1) 150 g/L 2) 75 g/L	Foliar spraying, overall	BBCH 30-69	a) 1 b) 1	-	125-400	1) 187.5 g/~~L~~ha 2) 93.75 g/~~L~~ha	n/a (PHI defined by application timing)	A

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

** Use also code numbers according to Annex I of Regulation (EU) No 396/2005

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

Explanation for Column 11 “Conclusion”

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

7.1.2 Summary of the evaluation

The preparation ADM.03503.F.1.A is composed of prothioconazole 150 g/L and fluxapyroxad 75 g/L.

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

Reference value	Source	Year	Value	Study relied upon	Safety factor
Prothioconazole-desthio					
ADI	EFSA Scientific Report (2007) 106, 1-98	2007	0.01 mg/kg bw/d	Rat – oncogenicity	100
ARfD			0.01 mg/kg bw	Rat – oncogenicity	100
Prothioconazole (JAU 6476)					
ADI	EFSA Scientific Report (2007) 106, 1-98	2007	0.05 mg/kg bw/d	Rat – oncogenicity	100
ARfD			0.2 mg/kg bw	Rat – oncogenicity	100
1,2,4-triazole (1,2,4-T)					
ADI	EFSA Journal 2018;16(7):5376; EC Review Report 2021	2018	0.023 mg/kg bw/d	Rat 12-month study	300
ARfD			0.1 mg/kg bw	Rabbit developmental study	300
Triazole alanine (TA)					
ADI	EFSA Journal 2018;16(7):5376; EC Review Report 2021	2018	0.3 mg/kg bw/d	Rabbit developmental study	100
ARfD			0.3 mg/kg bw	Rabbit developmental study	100
Triazole acetic acid (TAA)					
ADI	EFSA Journal 2018;16(7):5376; EC Review Report 2021	2018	1.0 mg/kg bw/d	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 (TLA)					
ADI	EFSA Journal 2018;16(7):5376; EC Review Report 2021	2018	0.3 mg/kg bw/d	Bridging from TA	
ARfD			0.3 mg/kg bw	Bridging from TA	
Fluxapyroxad					
ADI	EFSA Conclusion (2012) 10 (1): 2522, 1-90	2012	0.02 mg/kg bw/day	Rat – 2-year study	100
ARfD			0.25 mg/kg bw	Rabbit (developmental effects), and rat, (maternal effects) developmental toxicity studies	100

7.1.2.1 Summary for Prothioconazole

Table 7.1-3: Summary for prothioconazole

Critical GAP number	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?
Critical	1, 3, 4	Spring and	Yes	Yes	n.a.	Yes	Yes	No	No

Critical GAP number	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?
GAP (1)		winter wheat (TRZAS, TRZAW), winter rye (SECCW), triticale (TTLSS)							
Critical GAP (2)	2	Spring and winter barley (HORVS, HORVW)	Yes	Yes	n.a.	Yes	Yes	No	No

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
n.a.: not applicable

The effects of processing on the nature of prothioconazole residues have been investigated. As residues of prothioconazole do not exceed the trigger values defined in Reg (EU) No 283/2013 (excpet TDMs), there is no need to investigate the effect of industrial and/or household processing on prothioconazole residues except for TDMs.

Residues of prothioconazole residues (except TDMs) in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. It is very unlikely that residues exceeding residues in primary crops will be present in succeeding crops.

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

No chronic and acute dietary risk has been identified for wheat, rye, triticale and barley.

The uses of ADM.03503.F.1.A on wheat, rye, triticale and barley is therefore acceptable.

7.1.2.2 Summary for Fluxapyroxad

Table 7.1-4: Summary for fluxapyroxad

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, 3,4	Spring and winter wheat (TRZAS, TRZAW), winter rye (SECCW), triticale (TTLSS)	Yes	Yes	n.a.	Yes	Yes	No	No
2	Spring and winter barley (HORVS, HORVW)	Yes	Yes	n.a.	Yes	Yes	No	No

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
n.a. Not applicable

The effects of processing on the nature of fluxapyroxad residues have been investigated. The default processing factors were used to derive residues of fluxapyroxad in processed commodities of wheat and barley.
It is very unlikely that residues will be present in processed commodities.

Residues of fluxapyroxad in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. It is very unlikely that residues will be present in succeeding crops.

Considering dietary burden and based on the intended uses, no modification of the intake was calculated for livestock. The results are in agreement with the Article 12 MRL evaluation by EFSA (EFSA, 2020a). Therefore, further investigation of residues as well as the modification of MRLs in commodities of animal origin is not necessary.

No chronic and acute dietary risk has been identified for wheat, rye, triticale and barley.

The uses of ADM.03503.F.1.A on wheat, rye, triticale and barley is therefore acceptable.

7.1.2.3 Summary for ADM.03503.F.1.A

Table 7.1-5: Information on ADM.03503.F.1.A (KCA 6.8)

Crop	PHI for ADM.03503.F.1.A proposed by applicant	PHI sufficiently supported for		PHI for ADM.03503.F.1.A proposed by zRMS	zRMS Comments (if different PHI proposed)
		Prothioconazole	Fluxapyroxad		
Wheat, rye, triticale	n/a#	Yes	Yes	Yes	-
Barley	n/a#	Yes	Yes	Yes	-

n/a# The pre-harvest interval for the envisaged area of application is covered by the growing period remaining between the envisaged application and harvest; it is not necessary to lay down /indicate a pre-harvest interval in days

Table 7.1-6: Waiting periods before planting succeeding crops

Waiting period before planting succeeding crops			Overall waiting period proposed by zRMS for ADM.03503.F.1.A
Crop group	**Led by prothioconazole**	**Led by fluxapyroxad**	
Cereals/ Wheat, rye, triticale	NR	NR	NR
Cereals/ Barley	NR	NR	NR
All	NR	NR	NR

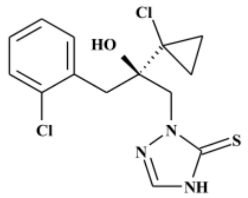
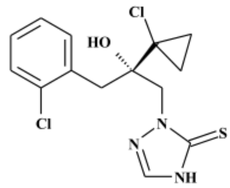
NR: not relevant

Assessment

7.2 Prothioconazole

General data on prothioconazole are summarised in the table below (last updated 2021/06/22)

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	 R - enantiomer  S - enantiomer
Molecular formula	$C_{14}H_{15}Cl_2N_3OS$
Molar mass	344.26 g/mol
Chemical group	Triazole fungicides
Mode of action (if available)	Steroid demethylation (ergosterol biosynthesis)
Systemic	Yes
Company (ies)	Bayer Crop Science*
Rapporteur Member State (RMS)	Poland (previously United Kingdom)
Approval status	Approved. Date of approval: 01/08/2008 COMMISSION DIRECTIVE 2008/44/EC COMMISSION IMPLEMENTING REGULATION (EU) 2020/869 COMMISSION IMPLEMENTING REGULATION (EU) 2021/745 COMMISSION IMPLEMENTING REGULATION (EU) No 540/2011
Restriction (e.g. is restricted to use as "...")	Only uses as fungicide may be authorised.
Review Report	SANCO/3923/07 – final (10/12/2007) and revised version (26/01/2021) involving confirmatory data
Current MRL regulation	COMMISSION REGULATION (EU) No 2019/552 of 04 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	Yes (Prothioconazole: EFSA, 2007, TDMs (confirmatory data): EFSA, 2018c)**;
EFSA Journal: conclusion on article 12	Yes (EFSA, 2014 and EFSA 2020)**
Current MRL applications on intended uses	None

* Notifier in the EU process to whom the a.s. belong(s)
** If yes: 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
Reference is made to the EU peer review (EFSA, 2011, DAR UK, 2004 and 2007) and to the MRL review

(EFSA, 2014 and 2020) for prothioconazole, as well as to the peer review of the triazole derivative metabolites (TDMs) in the light of confirmatory data submitted (UK, 2018b, EFSA, 2018c, amended 2019).

In addition, two new stability studies (KCA 6.1/01 and KCA 6.1/02) are submitted by the applicant in the framework of this application demonstrating stability of prothioconazole metabolites including triazole derivative metabolites (TDMs). Results are summarised in the tables below. The detailed assessments of these studies are presented in Appendix 2.

Further, one new stability study (KCA 6.1/03) analysing the residues of prothioconazole and prothioconazole-desthio in pollen, nectar, flowers and honey are submitted in the framework of this application. Results are summarized in the tables below.

Table 7.2-2: Summary of stability data for prothioconazole-desthio, prothioconazole-α-hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio and prothioconazole-6-hydroxy-desthio achieved at ≤ - 18°C (unless stated otherwise)

Matrix	Characteristics of the matrix acc. to SANTE/2020/12830, Rev.1 (2021)	Acceptable Maximum Storage duration	Compounds covered	Reference
Data relied on in EU				
Plant products				
Wheat grain	Dry commodity High starch content according to the OECD 506	180 days	Prothioconazole (JAU 6476)	Heinemann, O. (2001), DAR UK, 2004, Vol. 3, B.7, IIA, 6.0/01; EFSA, 2007; EFSA, 2014
		540 days	Prothioconazole -desthio (JAU 6476-desthio)	
Potatoes	High water content High starch content according to the OECD 506	24 months	Prothioconazole-α-hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio	EFSA, 2020
Wheat straw	Dry commodity Difficult commodity according to the OECD 506	360 days	Prothioconazole	Heinemann, O. (2001), DAR UK, 2004, Vol. 3, B.7, IIA, 6.0/01; EFSA, 2007; EFSA, 2014
		540 days	Prothioconazole -desthio	

Matrix	Characteristics of the matrix acc. to SANTE/2020/12830, Rev.1 (2021)	Acceptable Maximum Storage duration	Compounds covered	Reference
Wheat green material	High water content High water content according to the OECD 506	120 days	Prothioconazole	Heinemann, O. (2001), DAR UK, 2004, Vol. 3, B.7, IIA, 6.0/01;
		540 days	Prothioconazole -desthio	EFSA, 2007; EFSA, 2014
Tomatoes	High water content High water content according to the OECD 506	24 months	Prothioconazole-α-hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio	EFSA, 2020
Rapeseeds	High oil content High oil content according to the OECD 506	24 months	Prothioconazole -desthio	EFSA, 2014
Soya beans, rapeseeds	High oil content High oil content according to the OECD 506	24 months	Prothioconazole-α-hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio	EFSA, 2020
Animal Products				
All relevant ruminant matrices	Animal tissues	1 month	Prothioconazole -desthio, prothioconazole-3 hydroxy-desthio (M14), and prothioconazole-4 hydroxy-desthio (M15)	Heinemann, O.; Auer, S. (2001), DAR UK, 2004, Vol. 3, B.7, IIA, 6.4/01; EFSA, 2014

Table 7.2 -2 continued

Matrix	Characteristics of the matrix acc. to SANTE/2020/12830, Rev.1 (2021)	Acceptable Maximum Storage duration	Compounds covered	Reference
New data				
Plant Products				
Wheat whole plant	High water content	24 months	Prothioconazole-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio and prothioconazole-α-hydroxy-desthio	Lefresne, S., 2020 (KCA 6.1/02)
Wheat grain	Dry commodity High starch content according to the OECD 506	24 months		
Wheat straw	Dry commodity High starch content according to the OECD 506	24 months		
Oilseed rape	High oil content	24 months		
Strawberry	High acid content	24 months		
Dry bean	Dry commodity High protein content according to the OECD 506	24 months		
Pollen, nectar, flowers, honey	-	13 months	Prothioconazole-desthio	Lindner, M., 2022, (KCA 6.1/03)

Table 7.2-3: Summary of stability data for TDMs (1,2,4-triazole, triazole alanine (TA), triazole lactic acid (TLA) and triazole acetic acid (TAA) achieved at ≤ - 18°C (unless stated otherwise)

Matrix	Characteristics of the matrix acc. to SANTE/ 2020/12830, Rev.1 (2021)	Acceptable Maximum Storage duration (months)				Reference
		1,2,4-Triazole	TA	TAA	TLA	
Data relied on in EU						
Plant products						
Apples, tomatoes, mustard leaves, wheat forage, radishes tops/roots, turnips roots, sugar beet roots, cabbages, lettuces	High water content	6	53	53	48 (lettuce only)	EFSA, 2018c (amended 2019); EFSA 2020
Barley, wheat grain	Dry commodity[1] - High starch content	12	26	26	48	EFSA 2018c (amended 2019); EFSA 2020
Rapeseeds, soya beans	High oil content	12 (soya bean only; not stable in rape seed)	26 (soya bean only; not stable in rape seed)	53	48	EFSA 2018c (amended 2019); EFSA 2020
Peas, dry; Navy beans	Dry commodity[1] - High protein content	No data	15	25	48	EFSA 2018c (amended 2019); EFSA 2020

Matrix	Characteristics of the matrix acc. to SANTE/ 2020/12830, Rev.1 (2021)	Acceptable Maximum Storage duration (months)				Reference
		1,2,4-Triazole	TA	TAA	TLA	
Oranges	High acid content	No data	No data	No data	48	EFSA 2018c (amended 2019); EFSA 2020
Barley, wheat straw	Dry[1] commodity	12	53	40	Covered by 5 matrices and dry commodity data[1]	EFSA 2018c (amended 2019); EFSA 2020
Animal Products						
Animal products and tissues	Milk	18	No data	No data	No data	EFSA 2018c (amended 2019)
	Eggs	12	No data	No data	No data	
	Liver	12	No data	No data	No data	
	Muscle	12	No data	No data	No data	
	Fat	12	No data	No data	No data	
New data						
Plant Products						
Cucumber	High water content	12	36	36	36	Klimmek, S. and Gizler, A. 2017 (KCA 6.1/01)
Grapes	High acid content	36	36	36	36	
Dried beans	Dry commodity	36	36	36	36	

*TDMG = Triazole Derivative Metabolite Group
[1]: New matrix characteristic acc. to SANTE/2020/12830, Rev.1 February 2021 additionally given here.

Conclusion on stability of residues during storage

<u>Prothioconazole except TDMs</u>

In addition to the storage stability data evaluated during EU review (EFSA, 2007), the storage stability of prothioconazole-desthio in plant samples stored under frozen conditions was investigated in the framework of the Art. 12 MRL review. A data gap was noted by EFSA during the MRL review for the need of further storage stability data for at least one hydroxylated metabolite included in the risk assessment residue definition in the relevant commodity groups (i.e. high water, high oil content commodities and dry (high starch/high protein) commodities) (EFSA, 2014).

This data gap is addressed with the new storage stability study submitted with this dossier (Lefresne, 2020, KCA 6.1/02) where storage stability of prothioconazole-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio and prothioconazole-α-hydroxy-desthio is demonstrated in all matrix groups for 24 months.

In addition, in order to address this data gap, during evaluation of confirmatory data following the Article 12 MRL review (EFSA, 2020), the EMS UK referred to storage stability studies submitted in the framework of the renewal of the approval (United Kingdom, 2018). EFSA assessed the submitted studies, noting that the renewal of the approval has not been finalised yet:
"Freezer storage stability of prothioconazole-α-hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxydesthio was investigated in high water content (tomatoes), high starch content (potatoes), high oil content (soya beans, oilseed rape) and high acid content (oranges) commodities for a period of 24 months. Samples were fortified with a mixture containing all five analytes at a level of 0.1 mg/kg each. Since all

these compounds are included in the residue definition for risk assessment, spiking with a mixture was considered acceptable. Results demonstrate stability of all compounds in all matrices for a maximum of 24 months (duration of study) when stored at ≤ 18°C.
It is noted that according to EU guidelines (European Commission, 1997 [Appendix H. Storage stability of residue samples. 7032/VI/95-rev. 5, 22 July 1997]), applicable for the current assessment, cereals are considered as dry matrix, for which the storage stability of hydroxylated metabolites of prothioconazole-desthio has not been investigated. However, it is noted that the applicant has generated data according to the OECD guidelines (OECD, 2007 [Test No 506: Stability of pesticide residues in stored commodities]) in the framework of the renewal of the approval of prothioconazole. According to OECD guideline, cereals are considered as high starch matrix. EFSA accepted the storage stability data on potatoes (high starch matrix) to address the storage stability in cereals." (EFSA 2020).
<u>TDMs</u>
The freezer storage stability of various TDMs was investigated in the framework of the peer review of TDMs (UK, 2018b, EFSA, 2018c, amended 2019). The data is additionally included in the evaluation of confirmatory data following the Article 12 MRL review of prothioconazole (EFSA 2020): In the commodity groups relevant for the envisaged GAP uses, the stability of all TDMs has been demonstrated (refer to Table 7.2-3:).

In addition, storage stability in cucumber, grapes and dried bean was demonstrated in the new storage stability studies submitted with this dossier (Klimmek & Gizler, 2017, KCA 6.1/01): Storage stability was demonstrated for 1,2,4-triazole (1,2,4 T) in cucumber (fruit) stored at -18°C or below for 12 months. Storage stability was demonstrated for triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) in cucumber (fruit) stored at -18°C or below for at least 36 months. Storage stability was also demonstrated for 1,2,4-triazole (1,2,4 T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) in grapes (bunches) and in dried beans (seed) stored at -18°C or below for at least 36 months.

Storage stability of TLA in straw is covered according to OECD guidance 506 as stability for 48 months was demonstrated in each of the relevant five matrix categories. This was also agreed in the Peer Review Report on triazole derivate metabolites (confirmatory data) of Pesticides Peer Review Meeting 171 (13-15 December 2017) (EFSA, 2018c). Since this time SANTE/2020/12830, Rev.1 February 2021 has defined cereal straws as a dry commodity which further supports the acceptability of the existing storage stability data for TLA and that no further data is required.

zRMS comments: Information given by the Applicant is acceptable and sufficient. Studies on the storage stability of prothioconazole and its metabolites in crop and animal tissues under frozen conditions were assessed in the framework at the EU level. Residues of prothioconazole-desthio are stable for 18 months under deep-freeze storage in high water content matrices (wheat green matter), dry commodities (cereal grain) and straw and for 24 months at – 18 °C in commodities with high water content (spinach, sugar beet, tomatoes), high oil content (canola seeds), dry commodities (dried peas) and canola straw. EFSA in EFSA Journal 2014;12(5):3689 concluded that *(…) Furthermore, storage stability of prothioconazole*-desthio *residues was subsequently demonstrated for a period of 24 months at – 18 °C in commodities with high water content (spinach, sugar beet, tomatoes), high oil content (canola seeds), dry commodities (dried peas) and canola straw (EFSA, 2009, 2010a, 2010b, 2012; Netherlands, 2007). According to the RMS and the Member States which submitted additional data during the MS consultation, all residue trial samples reported in the PROFile were stored in compliance with the storage conditions reported above. Degradation of prothioconazole-desthio residues during storage of the trial samples is therefore not expected. However, storage stability was demonstrated for prothioconazole and prothioconazole-desthio only, while further metabolites are included in the residue definition for risk assessment. Therefore, further storage stability data for at least one hydroxylated metabolite included in the risk assessment residue definition are still required in the relevant commodity groups.* *As the proposed residue definitions for enforcement and risk assessment are different (see also Section 3.1.1.1), conversion factors (CF) for enforcement to risk assessment of 2 in cereal grain, pulses and oilseeds, leafy vegetables and root and tuber vegetables and of 3 in cereal straw were derived on the basis of the available metabolism data on wheat, peanut and sugar beet (roots, tops) (EFSA, 2007b, 2009, 2010a, 2010b, 2012; United Kingdom, 2007).*

The studies on the storage stability of prothioconazole-desthio and its hydroxies metabolites in different matrices were submitted by the Applicant:

- the results of new study of Lefresne, S. (2020; Report No.: B18S-A4-P-02) demonstrate the stability of residues of prothioconazole-desthio, prothioconazole-α-hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, and prothioconazole-6-hydroxy-desthio upon deep frozen storage at – 18 °C for up to 24 months in in wheat whole plant (high water content), wheat grain (high starch content), wheat straw (difficult commodity), oilseed rape grain (high oil content), strawberry (high acid content) and dry bean (high protein content).
- the storage stability of prothioconazole-desthio was demonstrated in pollen, nectar surrogate, flowers and honey at ≤ -18 °C in the dark over a storage period of up to 13 months (Lindner, M., 2022; Study no.: S19-02145).

In EFSA Journal 2014;12(5):3689 it is stated that *in the framework of the reported feeding study, the **storage stability of prothioconazole-desthio, M14 and M15** was demonstrated in all matrices for **up to 1 month** when stored deep frozen and was shown to cover the storage time interval of the residue samples of the feeding study. Degradation of prothioconazole-desthio residues during storage of the feeding study residue samples is therefore not expected.*

TDMs

Maximum storage time periods for TDMs in several commodities (EFSA, 2018):

Plant products (category)	Commodity	Storage stability (months)			
		1,2,4 Triazole	TA	TAA	TLA
High water content	Apples, tomatoes, mustard leaves, wheat forage, radishes tops/roots, turnips roots, sugar beet roots, cabbages, lettuces	6	53	53	48 (lettuce only)
High starch content	Barley, wheat	12	26	26	48
High oil content	Rapeseeds, soyabeans	12 (soya bean only; not stable in rape seed)	26 (soya bean only; not stable in rape seed)	53	48
High protein content	Peas, dry; Navy beans	No data	15	25	48
High acid content	Oranges	No data	No data	No data	48
Cereal straw	Barley, wheat	12	53	40	No data
Animal products					
	Milk	18	No data	No data	No data
	Eggs	12	No data	No data	No data
	Liver	12	No data	No data	No data
	Muscle	12	No data	No data	No data
	Fat	12	No data	No data	No data

The studies on the storage stability of prothioconazole-desthio and the triazole derivative metabolites in different matrices were submitted by the Applicant:

- Klimmek, S and Gizler, A. (2017, Report No.: S12-00072) - the storage stability was demonstrated for 1,2,4-triazole (1,2,4 T) in cucumber (fruit) stored at -18°C or below for 12 months, for triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) in cucumber (fruit) stored for at least 36 months, 1,2,4-triazole (1,2,4 T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) in grapes (bunches) and in dried beans (seed) stored for at least 36 months.

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

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

Available data

The stability of crop sample extracts was checked as part of the field residue studies. The stability of prothioconazole metabolites in the specimen extracts during the analytical procedure was proven by the corresponding procedural recovery specimen which were stored under the same conditions together with the field specimens. The results do not indicate any residue decrease within this period of storage and subsequent analytical measurements.

Conclusion on stability of residues in sample extracts

The stability of prothioconazole metabolites in the specimen extracts is sufficiently demonstrated in the frame of the available supervised residue trials.

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

7.2.2 Nature of residues in plants, livestock and processed commodities

7.2.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

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

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

Metabolism of prothioconazole was investigated for foliar application on root and tuber vegetables (sugar beet), pulses and oilseeds (peanuts) and cereals (wheat) as well as for seed treatment in cereals (wheat) using [U-^{14}C-phenyl]-labelled prothioconazole. The metabolism of prothioconazole-desthio was also investigated for foliar application on cereals (wheat) using [3,5-^{14}C-triazole]-labelled prothioconazole-desthio (United Kingdom, 2004, 2007; EFSA, 2007). Furthermore, three additional metabolism studies were conducted on root and tuber vegetables (sugar beet), pulses and oilseeds (peanut) and cereals (wheat) by foliar application using [3,5-^{14}C-triazole]-labelled prothioconazole (EFSA, 2014; FAO, 2008a, 2008b). The characteristics of all these studies are summarised in the following table.

Table 7.2-4: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details				Reference
			Method, F or G [(a)]	**Rate (kg a.s./ha)**	**No (Interval in days)**	**Sampling (DAT)**	
EU data							
Pulses and oilseeds	Peanuts	[Phenyl-UL-^{14}C]-prothioconazole	Foliar treatment, G	0.300[(d)]	3 (21 days) (BBCH 66-75)	Hay & nuts without shells: 14 days	Haas, M. (2001), DAR UK, 2004 and 2007, Vol. 3, B.7, IIA, 6.1.2/01; EFSA, 2007
		[3,5-^{14}C-triazole]-prothio conazole	Foliar treatment, G	0.300	3 (21 days) (BBCH 66-75)	Hay & nuts without shells: 14 days	JMPR: FAO, 2008a, 2008b EFSA, 2014

Crop Group	Crop	Label position	Application and sampling details				Reference
			Method, F or G (a)	Rate (kg a.s./ha)	No (Interval in days)	Sampling (DAT)	
Cereals	Wheat	[Phenyl-UL-^{14}C]-prothioconazole	Foliar treatment, G(e)	0.200	2	Forage: 6, Hay: 26, Grain & straw: 48 DAT	Haas, M., Bornatsch, W. (2000), DAR UK, 2004 and 2007, Vol. 3, B7, IIA, 6.1.1/01; EFSA, 2007
	Wheat	[3,5-^{14}C-triazole] JAU6476-desthio	Foliar treatment, G(e)	0.250	2	Forage: 0, 14 Grain & straw: 48 DAT	Vogeler, K., Sakamoto, H., Brauner, A. (1993), DAR UK, 2004 and 2007, Vol. 3, B7, IIA, 6.1.1/03; EFSA, 2007
	Wheat	[Phenyl-UL-^{14}C]-prothioconazole	Seed treatment, G	0.020 kg a.s./100 kg seed (1N) or 0.100 kg a.s./100 kg seed (5N)	1	Fodder: 57, Hay: 110, Straw: 153 DAT	Haas, M. (2001), DAR UK, 2004 and 2007, Vol. 3, B7, IIA, 6.1.1/02; EFSA, 2007
		[3,5-^{14}C-triazole] prothio conazole	Foliar, F (spring wheat) (f)	0.18 and 0.29	2 (BBCH 32-65)	Forage, hay, grain, straw	JMPR: FAO, 2008a, 2008b EFSA, 2014
Root and tuber	Sugar beet	[U-^{14}C-phenyl] prothio conazole	Foliar, F(b)	0.29	4 (14 days)	Roots & Tops/leaves: 7	Sources: EFSA, 2009; JMPR: FAO, 2008a, 2008b; Netherlands, 2007
		[3,5-^{14}C-triazole] prothio conazole	Foliar, F(c)	0.29	4 (14 days)	Roots & Tops/leaves: 7	JMPR: FAO, 2008a, 2008b

(a): Outdoor/field application (F) or glasshouse/protected/indoor application (G)
(b): Sugar beets were grown in boxes in a greenhouse until seedlings were approximately 2 inches tall. The sugar plants were then planted outdoor and treated (Netherlands, 2007).
(c): The sugar beet plants were moved to a fenced area outside of the greenhouse and remained there until harvest.
(d): In the JMPR report, it is stated, that a 5x application was also tested in order to collect sufficient amounts of radioactivity to identify metabolites.
(e): The plants were grown under environmental conditions (sunlight and temperatures). A glass roof protected the plants from rainfall. The soil was surface irrigated.
(f): 1 day after application, the soil tub was moved to the outside of the greenhouse.

Summary of plant metabolism studies reported in the EU

According to EFSA, 2007: "Prothioconazole is extensively metabolised. In a first step the sulphur group of the triazolinethione ring is oxydised to the corresponding sulfonic acid. Subsequent elimination of the sulfonic acid moiety results in prothioconazole-desthio (metabolite M04) which is consistently the major prothioconazole-structurally related metabolite in all plant parts and for all growth stages, except in nutmeat, where it was not found. This metabolite is further hydroxylated in the 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). Although the metabolism study in peanut did not use radiolabelling in the triazole ring, it is expected from studies carried out with other triazole fungicides that these triazole derivative metabolites are also present as major constituent of the residue in oilseeds."
According to EFSA, 2014: "Metabolism of prothioconazole in primary crops was investigated for foliar application in root and tuber vegetables, pulses and oilseeds and cereals using phenyl and triazole labellings, and for seed treatment in cereals only. The metabolism of prothioconazole-desthio was also investigated for foliar application on cereals. The metabolic pattern of prothioconazole and prothioconazole-desthio was shown to be similar with prothioconazole-desthio being the predominant compound of the total residues with further hydroxylation and glucosidation steps, whilst cleavage of the triazole bound of prothioconazole-desthio molecule resulted in the formation of triazole derivative metabolites (TDMs). A global residue definition for enforcement was proposed as prothioconazole-desthio (sum of isomers) only whilst for risk assessment, the residue was defined as the sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers). As the residue definitions for enforcement and risk assessment are different, conversion factors for enforcement to risk assessment of 2 for cereal grain, pulses and oilseeds, leafy vegetables and root and tuber vegetables and of 3 for cereal straw were derived on the basis of the available plant metabolism data."
According to EFSA, 2020: "The metabolism of prothioconazole was investigated by foliar applications on root, pulses/oilseeds and cereal/grass crop groups and by seed treatment on cereals (spring wheat). The metabolic pattern of prothioconazole was shown to be similar with prothioconazole-desthio being the predominant compound of the total residues. Besides prothioconazole-desthio, other metabolites, which are structurally closely related to this compound, and the main triazole derivative metabolites (TDMs) were identified. […] Based on the metabolic pattern identified in metabolism studies, hydrolysis studies, the toxicological significance of metabolites and degradation products, the residue definitions for plant products were proposed as 'prothioconazole-desthio (sum of isomers)' for enforcement and, as follows, for the risk assessment:

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

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

Summary of new plant metabolism studies
Not applicable / no new studies are submitted.

Conclusion on metabolism in primary crops
Based on the evaluations of EFSA 2018c, amended 2019 and EFSA 2020, the following residue definitions are proposed:
<u>Residue definition for enforcement:</u>
• Prothioconazole-desthio (sum of isomers).

<u>Residue definition for risk assessment:</u>
• Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers)
• Triazole alanine (TA) and triazole lactic acid (TLA)
• Triazole acetic acid (TAA)
• 1,2,4-triazole (1,2,4-triazole)

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

In the framework of the peer review under Directive 91/414/EEC and the Art.12 MRL review (EFSA, 2007, 2014), the metabolism of prothioconazole was investigated by foliar applications on root (sugar beet), pulses/oilseeds (peanut) and cereal/grass (wheat) crop groups and by seed treatment on cereal (wheat) (EFSA, 2007). In addition, the metabolism of prothioconazole-desthio labelled in the triazole moiety was investigated after foliar applications on cereals (EFSA, 2007).
Prothioconazole is extensively metabolised and the metabolic pathway was similar in all crops investigated. Prothioconazole-desthio was the predominant compound of the total residues with further hydroxylation (with the formation of several closely related metabolites) and glucosidation steps, whilst cleavage of the triazole bound of prothioconazole-desthio molecule resulted in the formation of TDMs.
In EFSA Journal 2018;16(7):5376 it is stated that *Primary crops metabolism data are reported for a total of 16 approved triazole compounds, and 2 triazole active substances that are not approved at EU level (bitertanol, flusilazole), on fruit crops, cereals (straw and grain), pulses and oilseeds and root crops.(...) Based on the metabolism data in primary and rotational crops that were compiled from the assessment of the 18 triazole active substances the triazole active substances were shown to degrade into the common metabolites 1,2,4-T, TA, TLA and TAA, known as TDMs.*

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

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

No further data are required.

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

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

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

Table 7.2-5: Summary of metabolism studies in rotational crops

Crop group	Crop	Commodities sampled	Label position	Application and sampling details: Method	Rate (kg a.s./ha)	Planting intervals* (DAT)	Harvest Intervals (DAT)	Remarks	Reference
EU data									
Leafy	Swiss	Swiss chard	[Phenyl-UL-	Soil	0.58	28, 146,	80, 188,	--	Haas, M.

vegetables	chard		[14]C]-prothioconazole	treatment		269	348		(2001), DAR UK, 2004 and 2007, Vol. 3, B7, IIA, 6.6/01; EFSA, 2007
Root and tuber vegetables	Turnip	Roots and tops	[Phenyl-UL-[14]C]-prothioconazole	Soil treatment	0.58	28, 146, 269	94, 201, 349	--	
Cereals	Wheat	Green material, hay, straw and grain	[Phenyl-UL-[14]C]-prothioconazole	Soil treatment	0.58	28, 146, 269	73, 178, 327 (green mat.); 111, 231, 377 (hay); 145, 269, 412 (grain & straw)	--	
Leafy vegetables	Swiss chard	Swiss chard	[3,5-[14]C-triazole] prothioconazole	Soil treatment	4x 0.204	30, 125, 366	-	-	JMPR: FAO, 2008a, 2008b EFSA, 2014
Root and tuber vegetables	Turnip	Roots and tops	[3,5-[14]C-triazole] prothioconazole	Soil treatment	4x 0.204	30, 125, 366	-	-	
Cereals	Wheat	Green material, hay, straw and grain	[3,5-[14]C-triazole] prothioconazole	Soil treatment	4x 0.204	30, 125, 366	-	-	

* Planting of seedlings.

Summary of plant metabolism studies reported in the EU

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

Conclusion on metabolism in rotational crops

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

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

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

Consequently, the metabolism of prothioconazole in primary and rotational crops was found to be similar and a specific residue definition for rotational crops is not deemed necessary.
No rotational crop studies with prothioconazole radiolabelled on the triazole ring were assessed in the framework of the peer review but such studies were reported and assessed by the JMPR (FAO, 2008a, 2008b). These indicated a cleavage of the triazole linkage with the formation of the major metabolites found in all rotational crop matrices as triazole alanine [TA], triazole lactic acid [TLA] and triazole acetic acid TAA]. Both the parent prothioconazole and prothioconazole-desthio were identified as minor metabolites."

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

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

In EFSA Journal 2020;18(2):5999 it is stated that *The metabolism of prothioconazole in rotational crops was investigated in the framework of the EU pesticides peer review in Swiss chards, turnips and spring wheat following the treatment of bare soil with prothioconazole at an application rate of 580 g/ha using the compound labelled in the phenyl ring. The main compounds identified were prothioconazole-desthio and its hydroxylated derivative metabolites, either free or conjugated.*
The MRL review concluded that metabolism of prothioconazole in primary and rotational crops was found to be similar and a specific residue definition for rotational crops is not necessary (EFSA, 2014).
The metabolism of prothioconazole labelled in triazole ring was assessed by the JMPR (FAO, 2009a) as reported in the MRL review. The studies indicate the cleavage of triazole linkage to form major metabolites TA, TLA and TAA (EFSA, 2014). During the peer review of TDMs in light of confirmatory data, the metabolism of various triazole compounds in rotational and primary crops was investigated.
It was concluded that for TDMs similar metabolic patterns were depicted both in primary and rotational crops (EFSA, 2018b).

<u>Triazole Derivate Metabolites, addendum – confirmatory data (UK, 2018)</u>
"For the rotational crops, metabolism data are available on leafy crops, root crops and cereal grain and straw for a total of 12 approved triazole active substances and one non approved triazole active substance (flusilazole).
The rotational crop metabolism studies for the triazole active substances demonstrate that triazole alanine (TA), triazole acetic acid (TAA) and/or triazole lactic acid (TLA) were often found to represent a significant portion of the total radioactive residue in the rotational crops; in addition 1,2,4-triazole (T) was detected but usually at much lower levels. Therefore, a number of field rotational crop trials have been conducted to investigate the magnitude of triazole derivative metabolite (TDM) residues in rotational crops after the use of triazole active substances".

No further data are required.

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

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

A new processing hydrolysis study with prothioconazole-desthio is submitted in the framework of this application.

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

Conditions (Duration, Temperature, pH)	Stable	Comment	Reference
EU data			
Pasteurisation (20 minutes, 90°C, pH 4)	Yes	Prothioconazole degrades to prothioconazole-desthio under sterilisation process (≤ 11% AR). Prothioconazole-desthio remains stable (99.4 - 99.9% of AR)	EFSA, 2014; EFSA, 2020; Gilges, 2001
Baking, boiling, brewing (60 minutes, 100°C, pH 5)	Yes		
Sterilisation (20 minutes, 120°C, pH 6)	Yes		
New data			
Pasteurisation (20 minutes, 90°C, pH 4)	Yes	Prothioconazole-desthio remains stable (98.9 - 102.8% of AR) under the different hydrolytic conditions.	Bloß, K., 2019 (KCA 6.5.1/01)
Baking, boiling, brewing (60 minutes, 100°C, pH 5)	Yes		
Sterilisation (20 minutes, 120°C, pH 6)	Yes		

Conclusion on nature of residues in processed commodities

Prothioconazole except TDMs

The effect on the nature of prothioconazole and prothioconazole-desthio has not been investigated in the framework of the EU pesticides peer review (EFSA, 2007). According to UK, 2004, residues in all treated commodities at harvest were at or near the limit of quantification and thus determination of the nature of residues in processed commodities was not considered relevant.

During MRL review it was referred to studies with prothioconazole investigated by the JMPR (FAO, 2008a, 2008b) and to studies with prothioconazole-desthio reported by Germany (EFSA, 2014; Germany, 2014). Prothioconazole-desthio was reported to be stable under all standard hydrolysis steps (99.4 - 99.9% applied radioactivity (AR)), whereas parent prothioconazole slightly degraded to prothioconazole-desthio under sterilisation process (≤ 11% AR).

The remaining compounds included in the risk assessment residue definition were concluded to be stable under standard hydrolysis conditions, considering their structural similarity to parent compound (EFSA, 2014).

A new processing hydrolysis study with prothioconazole-desthio is submitted in the framework of this application showing that [^{14}C]prothioconazole-desthio was stable during all processing conditions and no hydrolysis or degradation products were formed under conditions representative for simulating pasteurisation, baking/brewing/boiling and sterilisation.

The relevant residues for enforcement and risk assessment in processed commodities are expected to be the same as for primary crops.

TDMs

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

zRMS comments:
Information given by the Applicant is acceptable and sufficient.
The effect on the nature of prothioconazole and prothioconazole-desthio has not been investigated in the framework of the EU pesticides peer review.
In EFSA Journal 2014;12(5):3689 it is stated that *The effect of processing on the nature of prothioconazole residues was not investigated in the framework of the peer review. Nevertheless, studies were assessed by the JMPR (FAO, 2008a, 2008b), simulating representative hydrolytic conditions for pasteurisation (20 minutes at 90 °C, pH 4), boiling/brewing/baking (60 minutes at 100 °C, pH 5) and sterilisation (20 minutes at 120 °C, pH 6). From these studies, it was concluded that parent compound prothioconazole is stable under processing by pasteurisation and baking/brewing/boiling. However, under sterilisation, prothioconazole slightly degrades (≤ 11%) to prothioconazole-desthio.*

The Applicant submitted the hydrolysis study for prothioconazole-desthio (Bloß, K., 2019; Report No.: S18-07655). The results of study showed that prothioconazole-desthio was stable during all processing conditions. No significant hydrolysis or degradation products were formed under conditions representative of pasteurisation, baking/brewing/boiling and sterilisation.
The data confirm previously evaluated data by JMPR (2008) and EFSA (2014, 2020).

The TDMs are stable under hydrolysis studies simulating baking/brewing/boiling, pasteurisation and sterilisation (EFSA, 2018).

No further data are required.

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

Table 7.2-7: Summary of the nature of prothioconazole residues in commodities of plant origin

Endpoints	
Plant groups covered	Pulses and oilseeds (peanuts): foliar application Cereals (Wheat): foliar and seed application
Rotational crops covered	Swiss chard (leafy vegetables), turnip (root and tuber vegetables), spring wheat (cereals)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Prothioconazole-desthio is stable under standard hydrolysis conditions
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes
Plant residue definition for monitoring	Prothioconazole: prothioconazole-desthio (sum of isomers) (Commission Regulation (EU) 2019/552)
Plant residue definition for risk assessment	a) Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2*H*-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers) (EFSA 2014, EFSA, 2020) b) TDMs (EFSA, 2018c), with separate assessment of: • Triazole alanine (TA) and triazole lactic acid (TLA) • Triazole acetic acid (TAA) • 1,2,4-triazole (1,2,4-triazole) (EFSA, 2020)
Conversion factor from enforcement to RA a) (Except TDMs)	EFSA, 2007: 2 (cereal grain and oilseeds) EFSA, 2014: Based on metabolism study results, the MRL review derived the following tentative conversion factors to account for hydroxy metabolites of prothioconazole-desthio: 2 in cereal grains, pulses and oilseeds, leafy vegetables and tuber vegetables and 3 in cereal straw.

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

Available data

Reference is made to the EU peer review (EFSA, 2007, DAR UK, 2004 and 2007) and to the MRL review (EFSA, 2014 and 2020) for prothioconazole, as well as to the peer review of the triazole derivative metabolites (TDMs) in the light of confirmatory data submitted (UK, 2018b, EFSA, 2018c, amended 2019). No new data are submitted in the framework of this application.
Reported metabolism studies include two studies in lactating goats using respectively [U-^{14}C-phenyl]-labelled prothioconazole and prothioconazole-desthio and one study in laying hens using [U-^{14}C-phenyl]-

labelled prothioconazole. Besides, two additional studies were assessed by the JMPR (FAO, 2008a, 2008b) on lactating goats and laying hens, using both [3,5-^{14}C-triazole]-labelled prothioconazole. The characteristics of these studies are summarised in the following table.

Summary of animal metabolism studies reported in the EU

Prothioconazole except TDMs

Table 7.2-8: Summary of animal metabolism studies

Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate (mg/kg bw/d)	**Duration (days)**	**Commodity**	**Time of sampling**	
EU data								
Lactating ruminants	Goat	[U-^{14}C-phenyl] prothioconazole	1	10 (250 mg a.s./kg feed)	3	Milk	Twice daily	[redacted] (2001), DAR UK, 2004 and 2007, Vol. 3, B7, IIA, 6.2.2.1/01; EFSA, 2007
						Urine and faeces	Daily and at sacrifice	
						Tissues	At sacrifice	
		[U-^{14}C-phenyl] prothioconazole-desthio	1	10 (195 mg a.s./kg feed)	3	Milk	Twice daily	[redacted] (2002), DAR UK, 2004 and 2007, Vol. 3, B7, IIA, 6.2.2.2/01; EFSA, 2007
						Urine and faeces	Daily and at sacrifice	
						Tissues	At sacrifice	
		[3,5-^{14}C-triazole] prothioconazole	1	10	3	Milk	Twice daily	JMPR: FAO, 2008a, 2008b; EFSA, 2014
						Urine and faeces	Daily and at sacrifice	
						Tissues	At sacrifice	
Laying poultry	Hens	[U-^{14}C-phenyl] prothioconazole	6	10	3	Eggs	Once daily	[redacted] (2001), DAR UK, 2004 and 2007, Vol. 3, B7, IIA, 6.2.2.3/01; EFSA, 2007
						Excreta	At regular intervals	
						Tissues	At sacrifice (5 h after last administration)	
		[3,5-^{14}C-triazole] prothioconazole	6	10	3	Eggs	Once daily	JMPR: FAO, 2008a, 2008b; EFSA, 2014
						Excreta	At regular intervals	
						Tissues	At sacrifice (5 h after last administration)	

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								
Pigs	"Following prothioconazole administration to rats, metabolite 1,2,4-triazole was recovered in urine at minor amounts (2.3 % AR), whilst it was not recovered in goats. Therefore, meanwhile a harmonized approach on how to consider TDMs in the risk assessment, the general metabolic pathways in rodents and ruminants can be considered as comparable, mainly involving various types of hydroxylation affecting the chlorophenyl ring and leading to the formation of metabolites both under their free and glucuronide or sulphate conjugated forms. The metabolic pathway of prothioconazole-desthio depicted in ruminants can therefore be extrapolated to pigs."							EFSA, 2014
Fish	Not required, as residues of prothioconazole acc. to the residue definition for risk assessment > 0.1 mg/kg of the total diet in fish feed (dry weight basis) are not to be expected.							

EFSA, 2014: "It is noted that in poultry no study was performed with prothioconazole-desthio and that the fate of the triazole moiety in livestock was only investigated for prothioconazole. However, the available studies indicate similar metabolic patterns for the different compounds and moieties investigated. Additional studies addressing these requirements are therefore not expected to provide different results. It is also noted that no livestock metabolism study was performed with administration of all the metabolites included in the residue definition set for risk assessment in plants. Nevertheless, EFSA assumes that the administration of prothioconazole-desthio only in the livestock metabolism studies is acceptable since no different metabolic route of degradation would be expected if all the metabolites containing the moiety of the residue definition for risk assessment in plants were considered. Therefore, no additional metabolism data are deemed necessary.

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

For risk assessment, since all the metabolites are structurally related to prothioconazole-desthio and consist mainly in hydroxylated derivatives, EFSA assumes as a worst case that the toxicological end points allocated to prothioconazole-desthio should also be applied to these metabolites. The residue is therefore defined in all commodities of animal origin as the sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2- chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers). […] The log $P_{o/w}$ of prothioconazole-desthio equals 3.04 (EFSA, 2007). Since higher prothioconazole-desthio residue levels were found in fat compared to fat free muscle, EFSA concludes that the residue definition for enforcement in commodities of animal origin is fat soluble."

<u>TDMs</u>

According to EFSA, 2018c: "The compilation of the poultry and ruminant metabolism studies conducted with the triazole pesticide active substances with the ^{14}C labelling on the triazole moiety showed that besides the parent compound that was detected in significant proportions in all animal matrices ranging between 27% and 81% TRR in milk, eggs and tissues, 1,2,4-T was also found to be a predominant compound of the total residues with levels ranging from 31% to 86% TRR in those matrices. TA was identified at very low levels in poultry muscle only (< 10% TRR) and at levels between 22% and 39% TRR in ruminant matrices. Since TA is a major component in feed items, the potential transfer of this compound in poultry and ruminant matrices was further investigated in a metabolism study conducted with ^{14}C-TA. TA remains the major compound of the total residues in all poultry matrices (84–97.2% TRR) and in ruminant tissues (56–76% TRR) while TA and 1,2,4-T accounted for 8% and 86% TRR, respectively, in milk. TLA and TAA were detected in very low levels in all matrices (< 1% TRR). The potential transfer of TAA, TLA and 1,2,4-T present in feed items to the animal matrices was not further investigated. Although there are indications from the ruminant metabolism study conducted with the ^{14}C-TA, that there is no accumulation of TAA and TLA (4.2% and < 1% of the total administered dose in urine, respectively), these metabolites were however detected in the ruminant matrices from the feeding study conducted with TA. Based on the metabolism studies conducted, respectively, with triazole pesticide active substances and TA and considering the results of the livestock feeding studies carried out with TA and TAA, respectively, the experts agreed on the following residue definitions":

RD for enforcement: Triazole parent compound only

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

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

Conclusion on metabolism in livestock
Prothioconazole except TDMs
Metabolism studies with prothioconazole (ruminants and poultry) labelled in the triazole-moiety as well as in the phenyl ring are available. In addition, a study with phenyl-labelled prothioconazole-desthio in ruminants has been conducted. The available studies indicate similar metabolic patterns for the different compounds and moieties used in the metabolism studies.
Based on the overall metabolic pattern of prothioconazole and prothioconazole-desthio in animals, the residue definition for enforcement in animal products is proposed as prothioconazole-desthio (sum of isomers) for all livestock matrices.
For risk assessment the residue definition is defined in all commodities of animal origin as the sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers) (EFSA, 2014).
The log $P_{o/w}$ of prothioconazole-desthio equals 3.04 (EFSA, 2007). Since higher prothioconazole-desthio residue levels were found in fat compared to fat free muscle, EFSA concludes that the residue definition for enforcement in commodities of animal origin is fat soluble (EFSA 2014).

TDMs
"Based on the metabolism studies conducted, respectively, with triazole pesticide active substances and TA and considering the results of the livestock feeding studies carried out with TA and TAA, respectively, the experts agreed on the following residue definitions" (EFSA, 2018c):

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

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

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

In EFSA Journal 2014;12(5):3689 it is stated that *Based on the overall metabolic picture of prothioconazole and prothioconazole-desthio in animals, the residue definition for enforcement in animal products was set as* ***prothioconazole-desthio (sum of isomers)*** *for all the livestock matrices. This compound is fat soluble.*
(…) For risk assessment, the residue was defined in all commodities of animal origin as the ***sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2- chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers).***

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

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

No further data are required.

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

Table 7.2-9: Summary on the nature of residues in commodities of animal origin

	Endpoints
Animals covered	Lactating ruminants (goat)
	Laying hens (chicken)
Time needed to reach a plateau concentration	1-2 days in milk
Animal residue definition for monitoring (Prothioconazole)	Old: -Sum of prothioconazole-desthio and its glucuronide conjugate, expressed as prothioconazole-desthio (JAU 4676-desthio) (EFSA, 2007) New: -Prothioconazole-desthio (sum of isomers) (EFSA, 2014 and Reg. (EU) 2019/552)
Animal residue definition for monitoring (Triazole derivative metabolites (TDMs))	Triazole parent compound only (EFSA, 2018c)
Animal residue definition for risk assessment (Prothioconazole)	Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers) (EFSA, 2014)
Animal residue definition for risk assessment (Triazole derivative metabolites)	1) Triazole parent compound and any other relevant metabolite exclusively linked to the parent compound; 2) TA and TLA, since these compounds share the same toxicity; 3) TAA; 4) 1,2,4-triazole (EFSA, 2018c)
Conversion factor from enforcement to RA (Prothioconazole without TDMs)	2 (liver); 9 (kidney) not necessary for milk, ruminant muscle and ruminant fat (EFSA, 2014)
Metabolism in rat and ruminant similar	Yes The metabolic pathway of prothioconazole-desthio depicted in ruminants can be extrapolated to pigs
Fat soluble residue	Yes, log P_{ow} for prothioconazole-desthio (JAU 6476-desthio) = 3.04

7.2.3 Magnitude of residues in plants (KCA 6.3)

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

Available data

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

In addition, new residue studies are submitted by the applicant in the framework of this application. All studies are summarised in the summary tables below. The detailed assessment of the new studies is presented in Appendix 2.

<u>Prothioconazole except TDMs</u>

The intended critical GAPs in cereals are covered by the representative EU GAP uses of prothioconazole in cereals as evaluated during AIR process (EFSA 2007).

However, samples in residue studies already evaluated at EU level (EFSA, 2007, DAR UK, 2004) were only analysed for prothioconazole-desthio (residue definition for enforcement) and studies were conducted at more critical GAPs than envisaged in this dossier.

Therefore, the respective data are not used for risk assessment in this dossier but new studies analysing for prothioconazole-desthio (sum of isomers) as well as for the sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers) are submitted with this dossier for all relevant crops.

<u>TDMs</u>

Residue studies with prothioconazole analysing for TDMs were evaluated during the peer review of the triazole derivative metabolites (UK, 2018b, EFSA, 2018b, amended 2019) but were considered not to be sufficiently supported by acceptable stability data.

Therefore, the respective data are not cited here again but new residue studies analysing for all TDMs and supported by storage stability data are submitted with this dossier. It is noted that significant residue levels of TDMs were often found in untreated control samples of the residue trials suggesting the use of triazole pesticide active substances in previous seasons.

Thus, to address all relevant potential residues, new supplementary studies are presented in the following. In these studies residues according to the plant residue definitions for enforcement and for risk assessment as proposed by EFSA 2018b and EFSA 2020 were analysed:

<u>Residue definition for enforcement:</u>

- Prothioconazole-desthio (sum of isomers).

<u>Residue definition for risk assessment:</u>

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

<u>Wheat</u>

Table 7.2-10: Comparison of intended and critical EU GAPs in wheat (prothioconazole)

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Wheat, rye, triticale					
cGAP EU (EFSA, 2007)	3	0.2 kg as/ha	14-21 days	69	35
cGAP EU (Art. 12, EFSA, 2014)	3	0.2 kg as/ha	14-21 days	69	35
Intended cGAP (1)	1	187.5 g as/ha	-	69	n.a.

* Critical GAP number(s) in accordance with column 0 of ~~Błąd! Nie można odnaleźć źródła odwołania.~~ Table 7.1-1.
n.a. Not applicable. The pre-harvest interval for the envisaged area of application is covered by the growing period remaining between the envisaged application and harvest; it is not necessary to indicate a pre-harvest interval in days.

According to the available data, the intended outdoor uses on wheat in C-EU are considered acceptable. According to EC TG SANTE/2019/12752, extrapolation from wheat to rye (and triticale) is acceptable.

The intended critical GAPs in wheat, rye and triticale (spring and winter wheat, winter rye, triticale) are covered by the representative EU GAP uses of prothioconazole in cereals (wheat, rye and triticale) as evaluated during AIR process (EFSA 2007).

However, samples in residue studies already evaluated at EU level (EFSA, 2007, DAR UK, 2004) were only analysed for prothioconazole-desthio (residue definition for enforcement), and studies were conducted at more critical GAPs than envisaged in this dossier. Therefore, studies are considered not relevant.

Thus, to address all potential residues, new supplementary studies are presented in the following. In these studies residues according to the plant residue definitions for enforcement and for risk assessment as proposed by EFSA 2018b and EFSA 2020 were analysed.

The data submitted show that no exceedance of the current EU MRLs will occur. The uses are considered acceptable.

Table 7.2-11: Summary of EU reported and new data on prothioconazole metabolites supporting the intended uses of ADM.03503.F.1.A in wheat, rye and triticale and conformity to existing MRLs

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
E: Prothioconazole-desthio (sum of isomers). **RA: (A) Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers);** **(B) Triazole alanine (TA) and triazole lactic acid (TLA);** **(C) Triazole acetic acid (TAA);** **(D) 1,2,4-triazole (1,2,4-T)**								
Spring and winter wheat, grain and straw	EFSA, 2007, DAR UK, 2004	N-EU	GAP on which EU a.s. assessment is based: 3× 0.2 kg as/ha, start BBCH 26-29 up to BBCH 69, 14-21 days interval, PHI 35 days, outdoor. Trials not included as envisaged cGAP is by far exceeded in EU assessment.	N/A				
Extrapolation from wheat → rye and triticale Extrapolation from spring cereals ↔ winter cereals due to late application timing Critical GAP (1)	New trials KCA 6.3.1/01 KCA 6.3.1/02 KCA 6.3.1/03 KCA 6.3.1/04	N-EU	Trials GAP: 1× 0.175 - 0.20 kg a.s./ha applied in wheat at BBCH 69 **Wheat grain:** E: 12 × <0.01, 0.013 RA: (A): 9 × <0.06, *4 × <0.06*[a] (B): TA: 0.26, 0.29, 0.31, 0.34, 0.34, 0.37, 0.38, 0.54, 0.58, 0.61 TLA: 10 × <0.01 (C): TAA: 2 × 0.06, 2 × 0.07, 2× 0.09, 0.12, 0.13, 0.21, 0.39 (D): 1,2,4-T: 6× <0.01, 3 × <0.01[b], 4 × (<0.01)[c] For livestock dietary burden assessment only: **Wheat straw:** E: 0.018, 0.022, 0.028, 0.047, 0.052, 0.076, 0.095, 0.13, 0.18, 0.49 0.51, 0.53, 0.73 RA: (A): 0.065, 0.14, 0.15, 0.16, 0.17, *0.20*[a], *0.30*[a], 0.31, 0.53, 0.87, *0.88*[a], 1.2, *1.4*[a] (B): TA: 6 × <0.01, 2 × 0.02, 0.04, 0.08 TLA: <0.01, 4 × 0.01, 2 × 0.05, 0.06, 0.16, 0.25 (C): TAA: 0.01, 4 × 0.02, 0.03, 0.04, 0.06, 0.12, 0.13 (D): 1,2,4-T: 6 × <0.01, 3 × <0.01[b], 4 × (<0.01)[c]	(a) Residues of Prothioconazole-sum (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)) in *italics* were analysed by using methods based on QuEChERS method EN 15662:2009-02 instead of the RAR method 00979/M001, LC-MS/MS which included deconjugation of the metabolites. These results are reported but have not been used for risk assessments. For details refer to Appendix 2 (KCA 6.3.1/01). (b) Residues obtained from mixture product prothioconazole and difenoconazole (KCA 6.3.1/04) are included. (c) Residues of 1,2,4-T in the bracket () were outside the acceptable storage stability period and have therefore been removed from the overall supporting data. For details refer to KCA 6.3.1/02. As supplementary information, values (A) RA_{all} (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)) below in *italics* show STMR and HR of prothioconazole residues involving residues from all studies including both analytical methods RAR method 00979/M001 and QuEChERS .				

	Overall supporting data for cGAP	N-EU	Trials GAP: 1× 0.175 - 0.20 kg a.s./ha applied in wheat at BBCH 69 **Wheat grain:** E: 12 × <0.01, 0.013 RA: (A): 9 × <0.06 (B): TA: 0.26, 0.29, 0.31, 0.34, 0.34, 0.37, 0.38, 0.54, 0.58, 0.61 TLA: 10 × <0.01 (C): TAA: 2 × 0.06, 2 × 0.07, 2× 0.09, 0.12, 0.13, 0.21, 0.39 (D): 1,2,4-T: 9× <0.01 For livestock dietary burden assessment only: **Wheat straw:** E: 0.018, 0.022, 0.028, 0.047, 0.052, 0.076, 0.095, 0.13, 0.18, 0.49 0.51, 0.53, 0.73 RA: (A): 0.065, 0.14, 0.15, 0.16, 0.17, 0.31, 0.53, 0.87, 1.2 (B): TA: 6 × <0.01, 2 × 0.02, 0.04, 0.08 TLA: <0.01, 4 × 0.01, 2 × 0.05, 0.06, 0.16, 0.25 (C): TAA: 0.01, 4 × 0.02, 0.03, 0.04, 0.06, 0.12, 0.13 (D): 1,2,4-T: 9 × <0.01	**Grain:** E: 0.010 RA: (A): **0.06** *RA_{all}: 0.06* (B): 0.35 (TA); 0.01 (TLA) (C): 0.09 (D): 0.01 **Straw:** RA: (A): **0.17** *RA_{all}: 0.3* (B): 0.01 (TA); 0.03 (TLA) (C): 0.03 (D): 0.01	E: 0.013 RA: (A): **0.06** *RA_{all}: 0.06* (B): 0.61 (TA); 0.01 (TLA) (C): 0.39 (D): 0.01 RA: (A): **1.2** *RA_{all}: 1.4* (B): 0.08 (TA); 0.25 (TLA) (C): 0.13 (D): 0.01	E: 0.015 RA: n.r. RA: n.r.	Wheat grain: 0.1 Rye: 0.05	Yes

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

Barley

~~Table~~

Table 7.2-12: Comparison of intended and critical EU GAPs in barley (prothioconazole)

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Barley					
cGAP EU (EFSA, 2007)	2	0.2 kg as/ha	14-21 days	61	35
cGAP EU (Art. 12, EFSA, 2014)	2	0.2 kg as/ha	-	61	35
Intended cGAP (2)	1	187.5 g as/ha	-	65	n.a.

* Critical GAP number(s) in accordance with column 0 of ~~Błąd! Nie można odnaleźć źródła odwołania.~~. of **Błąd! Nie można naleźć źródła odwołania.**.

According to the available data, the intended outdoor uses on barley in C-EU are considered acceptable.

The intended critical GAPs in barley (spring and winter barley) are covered by the representative EU GAP uses of prothioconazole in cereals (barley) as evaluated during AIR process (EFSA 2007).

However, samples in residue studies already evaluated at EU level (EFSA, 2007, DAR UK, 2004) were only analysed for prothioconazole-desthio (residue definition for enforcement), and studies were conducted at more critical GAPs than envisaged in this dossier. Therefore, studies are considered not relevant.

Thus, to address all potential residues, new supplementary studies are presented in the following. In these studies residues according to the plant residue definitions for enforcement and for risk assessment as proposed by EFSA 2018b and EFSA 2020 were analysed.

The data submitted show that no exceedance of the current EU MRL will occur. The uses are considered acceptable.

Table 7.2-13: Summary of EU reported and new data on prothioconazole metabolites supporting the intended uses of ADM.03503.F.1.A in barley and conformity to existing MRL

Commodity	**Source**	**Residue zone (N-EU, S-EU, EU, outside EU)**	**Evaluation** **GAP** **Residue levels (mg/kg)** **E = according to enforcement residue definition** **RA = according to risk assessment residue definition**	**STMR (mg/kg)**	**HR (mg/kg)**	**Unrounded OECD calculator MRL (mg/kg)**	**Current EU MRL (mg/kg) ***	**MRL compliance**
E: Prothioconazole-desthio (sum of isomers). **RA: (A) Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers);** **(B) Triazole alanine (TA) and triazole lactic acid (TLA);** **(C) Triazole acetic acid (TAA);** **(D) 1,2,4-triazole (1,2,4-T)**								
Spring and winter barley, grain and straw Extrapolation from spring cereals ↔ winter cereals due to late application timing Critical GAP (2)	EFSA, 2007, DAR UK, 2004	N-EU	GAP on which EU a.s. assessment is based: 2× 0.2 kg as/ha, up to BBCH 61, 14-21 days interval, PHI 35 days, outdoor Trials not included as envisaged cGAP is by far exceeded in EU assessment.	N/A				
	New trials KCA 6.3.2/01 KCA 6.3.2/02 KCA 6.3.2/03 KCA 6.3.2/04 KCA 6.3.2/05 KCA 6.3.2/06	N-EU	Trials GAP: 1× 0.175 - 0.20 kg a.s./ha applied in barley at BBCH 65 **Barley grain:** E: 8 × <0.01, 2 × 0.01, 0.013, 0.03, 0.054, 0.061 RA: (A): 8 × <0.06, *4 × <0.06*[(a)], 0.087, 0.095 (B): TA: 2 × 0.04, 0.05, 0.07, 0.08, 0.10, 2 × 0.12, 2 × 0.13, 0.14, 0.15, 0.19, 0.29 TLA: 13 × <0.01, 0.02 (C): TAA: 3 × 0.02, 2 × 0.03, 5 × 0.04, 0.07, 0.09, 0.12, 0.13 (D): 1,2,4-T: 10 × <0.01, 4 × (<0.01)[(b)] For livestock dietary burden assessment only: **Barley straw:** E: 0.041, 0.049, 0.055, 0.085, 0.092, 0.092, 0.11, 0.12, 0.15, 0.21, 0.34, 0.49, 0.49, 1.7 RA: (A): 0.061, *0.067*[(a)], 0.14, 0.14, 0.19, 0.20, *0.24*[(a)], 0.33, *0.37*[(a)], *0.84*[(a)], 0.93, 1.0, 1.3, 2.2 (B): TA: 9 × <0.01, 2 × 0.01, 3 × 0.02 TLA: 3 × <0.01, 3 × 0.01, 2 × 0.02, 3 × 0.03, 0.05, 0.19, 0.26 (C): TAA: 4 × <0.01, 2 × 0.01, 6 × 0.02, 0.04, 0.12 (D): 1,2,4-T: 10 × <0.01, 4 × (<0.01) [(b)]	(a) Residues of Prothioconazole-sum (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)) in *italics* were analysed by using methods based on QuEChERS method EN 15662:2009-02 instead of the RAR method 00979/M001, LC-MS/MS which included deconjugation of the metabolites. These results are reported but have not been used for risk assessments.. For details refer to Appendix 2 (KCA 6.3.2/01). (b) Residues of 1,2,4-T in the bracket () were outside the acceptable storage stability period and have therefore been removed from the overall supporting data. For details refer to KCA 6.3.2/02. As supplementary information, values (A) RA_{all} (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)) below in *italics* show STMR and HR of prothioconazole residues involving residues from all studies including both analytical methods RAR method 00979/M001 and QuEChERS.				

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
	Overall supporting data for cGAP	N-EU	Trials GAP: 1× 0.175 - 0.20 kg a.s./ha applied in barley at BBCH 65 **Barley grain:** E: 8 × <0.01, 2 × 0.01, 0.013, 0.03, 0.054, 0.061 RA: (A): 8 × <0.06, 0.087, 0.095 (B): TA: 2 × 0.04, 0.05, 0.07, 0.08, 0.10, 2 × 0.12, 2 × 0.13, 0.14, 0.15, 0.19, 0.29 TLA: 13 × <0.01, 0.02 (C): TAA: 3 × 0.02, 2 × 0.03, 5 × 0.04, 0.07, 0.09, 0.12, 0.13 (D): 1,2,4-T: 10 × <0.01 For livestock dietary burden assessment only: **Barley straw:** E: 0.041, 0.049, 0.055, 0.085, 0.092, 0.092, 0.11, 0.12, 0.15, 0.21, 0.34, 0.49, 0.49, 1.7 RA: (A): 0.061, 0.14, 0.14, 0.19, 0.20, 0.33, 0.93, 1.0, 1.3, 2.2 (B): TA: 9 × <0.01, 2 × 0.01, 3 × 0.02 TLA: 3 × <0.01, 3 × 0.01, 2 × 0.02, 3 × 0.03, 0.05, 0.19, 0.26 (C): TAA: 4 × <0.01, 2 × 0.01, 6 × 0.02, 0.04, 0.12 (D): 1,2,4-T: 10 × <0.01	**Grain:** E: 0.01 RA: (A): **0.06** *RA_{all}: 0.06* (B): 0.12 (TA); 0.01 (TLA) (C): 0.04 (D): 0.01 **Straw:** RA: (A): **0.30** *RA_{all}: 0.30* (B): 0.01 (TA); 0.02 (TLA) (C): 0.02 (D): 0.01	E: 0.061 RA: (A): **0.095** *RA_{all}: 0.095* (B): 0.29 (TA); 0.02 (TLA) (C): 0.13 (D): 0.01 RA: (A): **2.2** *RA_{all}: 2.2* (B): 0.02 (TA); 0.26 (TLA) (C): 0.12 (D): 0.01	E: 0.09 RA: n.r. RA: n.r.	Barley grain: 0.2	Yes

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

7.2.3.2 Conclusion on the magnitude of residues in plants

Wheat, rye, triticale

According to the available data, the intended uses on wheat, rye and triticale are considered acceptable. 13 trials in wheat in Northern Europe showed no residues at harvest according to the residue definition for enforcement in wheat grains (below the LOQ of 0.01 mg/kg) except for one trial showing low residues of 0.013 mg/kg.
Therefore, the supplementary data submitted show that no exceedance of the current EU-MRLs of 0.1 mg/kg for wheat and 0.05 mg/kg for rye will occur.

For risk assessment, residues have also been determined as sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers). Residues were always below the cumulative LOQ of 0.06 mg/kg for the sum of metabolites at harvest.

Residues of TDMs according to the residue definition for risk assessment and covered by storage stability data were determined for TA, TLA, TAA and 1,2,4-T in samples from 10, 10, 10 and 9 trials, respectively.

Extrapolation from trials conducted in wheat (grain and straw) to rye and triticale is not restricted according to SANTE/2019/12752 (replacing the existing Guidance Document SANCO 7525/VI/95 Rev. 10.3).

Barley

According to the available data, the intended uses on barley are considered acceptable. 14 trials in barley in Northern Europe showed no or only low residues at harvest according to the residue definition for enforcement in barley grains up to 0.061 mg/kg.
Therefore, the supplementary data submitted show that no exceedance of the current EU-MRL of 0.2 mg/kg for barley will occur.

For risk assessment, residues have also been determined as sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers). Residues were below the cumulative LOQ of 0.06 mg/kg for the sum of metabolites in 8 trials at harvest and exceeded the LOQ in only two trials with a HR of 0.095 mg/kg.

Residues of TDMs according to the residue definition for risk assessment and covered by storage stability data were determined for TA, TLA, TAA and 1,2,4-T in samples from 14, 14, 14 and 10 trials, respectively.

zRMS comments:
Residue Definitions (EFSA 2020; Reg EU 2019/552):
Monitoring (Mo): Prothioconazole-desthio (sum of isomers)
Risk Assessment (RA):
1) Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers) (EFSA, 2014)
2) TDMs (EFSA, 2018), with separate assessment of:
- Triazole alanine (TA) and triazole lactic acid (TLA)
- Triazole acetic acid (TAA)
- 1,2,4-triazole (1,2,4-T)

Trials on wheat and barley previously presented and evaluated in DAR (2004) were conducted according to the residue definition for monitoring only (trials measuring levels of prothioconazole-desthio only; there are no data on prothioconazole-hydroxy-destio) and were conducted at more critical GAPs than envisaged in this dossier.
To address all potential residues, new additionally residue studies conducted according to the plant residue definitions for enforcement and for risk assessment as proposed by EFSA (2018 and 2020) were submitted by Applicant in the framework of this application.

Wheat, triticale and rye

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

Sufficient trials on wheat were conducted according to the residue definition for monitoring and risk assessment with the following GAP: 1 x 175-200 g a.s. /ha, application at BBCH 69, outdoor. The trials are supported by valid storage stability data (for TDMs, not all submitted trials were covered by the storage stability data for the metabolites – see boxes with zRMS comments in Appendix 2) and validated analytical methods.

Residues of prothioconazole-desthio (RD-Mo) in wheat grain at harvest were <0.01 mg/kg except for one trial for which residues equal 0.013 mg/kg.
Total residue for prothioconazole (prothioconazole-desthio and all 5 hydroxy metabolites) in grain at harvest were <0.06 mg/kg.

Available results show that the in force MRL of prothioconazole on wheat of 0.1 mg/kg and on rye of 0.05 (Reg. (EU) 2019/552) will not be exceeded. According to Commission Regulation (EU) No 752/2014 replacing Annex I to Regulation (EC) No 396/2005, MRLs for wheat (code number: 0500090) are also applicable to triticale (code number: 0500090-006).
The current EU MRLs for prothioconazole are sufficient to support the proposed uses.

Residues of 1,2,4-T were <LOQ.
Residues of TLA in grain were <0.01 mg/kg.
Residues of TA in grain were between 0.26 and 0.61 mg/kg.
Residues of TAA in grain were between 0.06 and 0.39 mg/kg.
More details of the residue studies on wheat are provided in Appendix 2.

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

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

Sufficient trials on barley were conducted according to the residue definition for monitoring and risk assessment with the following GAP: 1 x 175-200 g a.s. /ha, application at BBCH 65-69, outdoor. The trials are supported by valid storage stability data (for TDMs, not all submitted trials were covered by the storage stability data for the metabolites – see boxes with zRMS comments in Appendix 2) and validated analytical methods.

Residues of prothioconazole-desthio (RD-Mo) in barley grain at harvest were between <0.01 mg/kg and 0.061 mg/kg.
Total residue for prothioconazole (prothioconazole-desthio and all 5 hydroxy metabolites) in grain at harvest were between <0.06 mg/kg and 0.095 mg/kg.
Available results show that the in force MRL of prothioconazole on barley of 0.2 mg/kg (Reg. (EU) 2019/552) will not be exceeded. The current EU MRL for prothioconazole is sufficient to support the proposed use.

Residues of 1,2,4-T in grain were <LOQ.
Residues of TLA in grain were between <LOQ and 0.02 mg/kg.
Residues of TA in grain were between 0.04 and 0.29 mg/kg.
Residues of TAA in grain were between 0.02 and 0.13 mg/kg.
More details of the residue studies on barley are provided in Appendix 2.

The proposed use on barley is considered acceptable.

7.2.4 Magnitude of residues in livestock

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

7.2.4.1 Dietary burden calculation

Prothioconazole except TDMs

The dietary burden calculation made by EFSA in the framework of the Article 12 evaluation is available for prothioconazole (see EFSA, 2014). Prothioconazole is authorised for use on several crops that might be fed to livestock. EFSA calculated the livestock dietary burdens for different groups of livestock using the agreed European methodology (European Commission, 1996).

In addition, new dietary burden calculations were conducted in EFSA, 2020. According to EFSA, 2020 "[…] *new data on carrots, swedes, turnips and wheat were submitted in the framework of the assessment of the Article 12 confirmatory data application (UK, 2019a). The most recent livestock dietary burden was calculated in the EFSA opinion on the modification of prothioconazole residues in sunflower seeds (EFSA, 2015b), updating the calculation done by the MRL review (EFSA, 2014).*
However, due to the fact that existing EU MRLs for livestock and for various feed commodities are set on the basis of CXLs, instead of proposals made by the MRL review, the livestock dietary burden was calculated using Animal Model (OECD methodology), considering the actual existing EU MRLs for feed commodities. The input values for rapeseeds and carrots, swedes, turnips were as derived from the current assessment; for remaining feed commodities the input values were corresponding to the existing EU MRLs and were as reported in the MRL review, or in JMPR reports (in particular for cereals, cotton, maize, peanuts and soya beans, since for these crops the existing EU MRLs are set on the basis of CXLs) (FAO, 2009a, b, 2014, 2018) and in previous EFSA reasoned opinions (for sunflower seeds, EFSA, 2015b). Where residue data according to the risk assessment residue definition were not available, default conversion factors for risk assessment as derived by the MRL review, were applied."

The input values as used in EFSA 2020 for the latest exposure calculations for livestock are presented in the table below together with STMRs/HRs derived from the submitted residue studies covering the envisaged GAP uses of this dossier. The more critical value (input values EFSA 2020 versus STMRs/HRs derived from the residue studies submitted with this dossier) was used for new intake calculations.. The corresponding results can be found in Table 7.2-15.

Table 7.2-14: Input values for the dietary burden calculation (considering the uses evaluated in Art. 12 procedure and the uses under consideration)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	**Comment**	**Input value (mg/kg)**	**Comment**
Risk assessment residue definition: Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2*H*-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers)				
Rape seed meal *(EFSA 2020)*	0.16	STMR × PF (2)[(a)]	0.16	STMR × PF (2)[(a)]
Sunflower seed meal *(EFSA 2020)*	0.04	STMR × CF (2) × PF (2)[(a)] (EFSA, 2015a,b)	0.04	STMR × CF (2) × PF (2)[(a)] (EFSA, 2015a,b)
Head cabbage *(EFSA 2020)*	0.02	STMR × CF (EFSA, 2014)	0.12	HR × CF (EFSA, 2014)
Maize silage *(EFSA 2020)*	0.01	STMR (EFSA, 2014)	0.01	HR (EFSA, 2014)
Maize grain *(EFSA 2020)*	0.02	STMR (FAO, 2014) × CF (2) (EFSA, 2014)	0.02	STMR (FAO, 2014) × CF (2) (EFSA, 2014)
Maize, milled by-products[(b)]; Maize, hominy meal[(b)]; Maize gluten feed/gluten meal[(b)]; Distiller`s grain[(b)] *(EFSA 2020)*	0.02	STMR (FAO, 2014) × CF (2) (EFSA, 2014)	0.02	STMR (FAO, 2014) × CF (2) (EFSA, 2014)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	**Comment**	**Input value (mg/kg)**	**Comment**
Barley grain *(EFSA 2020)*	0.07	STMR (FAO, 2009b) × CF (2) (EFSA, 2014)	0.07	STMR (FAO, 2009b) × CF (2) (EFSA, 2014)
Barley grain *new*	0.06	STMR (new trials submitted, refer to Table 7.2-13:, but covered by higher input value used in EFSA 2020 in the line above)	0.06	STMR (new trials submitted, refer to Table 7.2-13:, but covered by higher input value used in EFSA 2020 in the line above)
Brewer's grain *(EFSA 2020)*	0.23	STMR barley grain (FAO, 2009b) × CF (2) (EFSA, 2014) × PF (3.3)[a]	0.23	STMR barley grain (FAO, 2009b) × CF (2) (EFSA, 2014) × PF (3.3)[a]
Oat grain *(EFSA 2020)*	0.02	STMR (FAO, 2008a) × CF (2) (EFSA, 2014)	0.02	STMR (FAO, 2008a) × CF (2) (EFSA, 2014)
Wheat grain *(EFSA 2020)*	0.04	STMR (FAO, 2009b) × CF (2) (EFSA, 2014)	0.04	STMR (FAO, 2009b) × CF (2) (EFSA, 2014)
Wheat grain *new*	0.06	STMR (new trials submitted, refer to ~~Błąd! Nie można odnaleźć źródła odwołania.~~ Table 7.2-13:)	0.06	STMR (new trials submitted, refer to ~~Błąd! Nie można odnaleźć źródła odwołania.~~ Table 7.2-13:)
Wheat gluten meal[b] *(EFSA 2020)*	0.04	STMR wheat grain (FAO, 2009b) × CF (2) × PF (1.8)[a]	0.04	STMR wheat grain (FAO, 2009b) × CF (2) × PF (1.8)[a]
Wheat milled by-products[b] *(EFSA 2020)*	0.28	STMR wheat grain (FAO, 2009b) × CF (2) × PF (7)[a]	0.28	STMR wheat grain (FAO, 2009b) × CF (2) × PF (7)[a]
Rye grain *(EFSA 2020)*	0.02	STMR (FAO, 2008a) × CF (2)	0.02	STMR (FAO, 2008a) × CF (2)
Rye grain *new*	0.06	STMR (new trials submitted, refer to Table 7.2-11, extrapolated from wheat)	0.06	STMR (new trials submitted, refer to Table 7.2-11, extrapolated from wheat)
Triticale grain *new*	0.06	STMR (new trials submitted, refer to ~~Błąd! Nie można odnaleźć źródła odwołania.~~ Table 7.2-13:, extrapolated from wheat)	0.06	STMR (new trials submitted, refer to ~~Błąd! Nie można odnaleźć źródła odwołania.~~ Table 7.2-13:, extrapolated from wheat)
Barley straw *(EFSA 2020)*	1.96	STMR (FAO, 2009b) × CF (3) (EFSA, 2014)	7.50	HR[d] × CF (3) (EFSA, 2014)
Barley straw *(new)*	0.30	STMR (new trials submitted, refer to Table 7.2-13:, but covered by higher input value used in EFSA 2020 in the line above)	2.2	HR (new trials submitted, refer to Table 7.2-13:, but covered by higher input value used in EFSA 2020 in the line above)
Oat straw *(EFSA 2020)*	1.26	STMR[d] × CF (3) (EFSA, 2014)	7.50	HR[d] × CF (3) (EFSA, 2014)
Wheat straw *(EFSA 2020)*	2.69	STMR	5.52	HR[d] (EFSA, 2014) × CF (2.3)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Wheat straw *(new)*	0.17	STMR (new trials submitted, refer to Table 7.2-11, but covered by higher input value used in EFSA 2020 in the line above)	1.2	HR (new trials submitted, refer to Table 7.2-11, but covered by higher input value used in EFSA 2020 in the line above)
Rye straw *(EFSA 2020)*	2.25	STMR[d] × CF (3) (EFSA, 2014)	5.52	HR[d] (EFSA, 2014) × CF (2.3)
Rye straw *(new)*	0.17	STMR (new trials submitted, refer to Table 7.2-11, extrapolated from wheat, but covered by higher input value used in EFSA 2020 in the line above)	1.2	HR (new trials submitted, refer to Table 7.2-11, extrapolated from wheat, but covered by higher input value used in EFSA 2020 in the line above)
Triticale straw *new*	0.17	STMR (new trials submitted, refer to Table 7.2-11, extrapolated from wheat	1.2	HR (new trials submitted, refer to Table 7.2-11, extrapolated from wheat)
Cotton seed *(EFSA 2020)*	0.10	STMR (FAO, 2018) × CF (2)	0.10	STMR (FAO, 2018) × CF (2)
Cotton seed meal *(EFSA 2020)*	0.14	STMR (FAO, 2018) × CF (2) × PF (1.3)[a]	0.14	STMR (FAO, 2018) × CF (2) × PF (1.3)[a]
Beans (dry) *(EFSA 2020)*	0.02	STMR × CF (2) (EFSA, 2014)	0.02	STMR × CF (2) (EFSA, 2014)
Peas, lupins (dry) *(EFSA 2020)*	0.10	STMR (FAO, 2009b) × CF (2)	0.10	STMR (FAO, 2009b) × CF (2)
Lupin seed meal *(EFSA 2020)*	0.11	STMR (FAO, 2009b) × CF (2) × PF (1.1)[a]	0.11	STMR (FAO, 2009b) × CF (2) × PF (1.1)[a]
Potatoes *(EFSA 2020)*	0.01	STMR (EFSA, 2014)	0.01	HR (EFSA, 2014)
Potato process waste[b]; Potato dried pulp[b] *(EFSA 2020)*	0.01	STMR potato (EFSA, 2014) × PF (1)[c]	0.01	HR potato (EFSA, 2014) × PF (1)[c]
Turnips, swedes, carrot culls *(EFSA 2020)*	0.08	STMR	0.10	HR
Peanut meal *(EFSA 2020)*	0.04	STMR (FAO, 2009b) × CF (2) × PF (2)	0.04	STMR (FAO, 2009b) × CF (2) × PF (2)
Linseed meal *(EFSA 2020)*	0.12	STMR × CF (2) × PF (2)[a] (EFSA, 2015a,b)	0.12	STMR × CF (2) × PF (2)[a] (EFSA, 2015a,b)
Soybean seed *(EFSA 2020)*	0.10	STMR (FAO, 2014) × CF (2)	0.10	STMR (FAO, 2014) × CF (2)
Soybean seed meal *(EFSA 2020)*	0.13	STMR (FAO, 2014) × CF (2) × PF (1.3)[a]	0.13	STMR (FAO, 2014) × CF (2) × PF (1.3)[a]
Soybean hulls[b] *(EFSA 2020)*	1.30	STMR soybean (FAO, 2014) × CF (2) × PF (13)[a]	1.30	STMR soybean (FAO, 2014) × CF (2) × PF (13)[a]

STMR: supervised trials median residue; HR: highest residue; PF: processing factor; CF: conversion factor for enforcement to risk assessment residue definition.

(a): For rape seed meal/sunflower seed meal, brewer's grain, wheat gluten meal, wheat milled by-products, cotton seed meal, lupin seed meal, soybean meal, lupin seed meal, and soybean hulls in the absence of processing factors supported by data, default processing factors of 2, 3.3, 1.8, 7, 1.3, 1.1, 1.3 and 13 were, respectively, included in the calculation to consider the potential concentration of residues in these commodities.

(b): New commodities (OECD methodology), not considered in MRL review.

(c): Default processing factors were not applied because prothioconazole and its metabolites were below LOQ both in maize, sugar beet root and potatoes, indicating no-residue situation. Thus, concentration of residues in these commodities is therefore not expected.

(d): The STMR and HR values derived by the JMPR (FAO, 2009a,b) are lower than the values derived for cereals straws for the authorised EU uses reported in the MRL review.

Table 7.2-15: Results of the dietary burden calculation (considering the uses evaluated in Art. 12 procedure and the uses under consideration)

Relevant groups	Dietary burden expressed in				Most critical diet [a]	Most critical commodity [b]		Trigger exceeded (Yes/No) 0.004 mg/kg bw Max burden	Previous assessment (EFSA 2020) Max burden mg/kg DM
	mg/kg bw/d		mg/kg DM						
	Median	Max.	Median	Max.					
Risk assessment residue definition: Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers)									
Cattle (all diets)	0.038	0.111	1.14	3.10	Dairy cattle	Barley	straw	Yes	3.10
Cattle (dairy only)	0.038	0.111	0.98	2.89	Dairy cattle	Barley	straw	Yes	2.85
Sheep (all diets)	0.075	0.236	1.76	5.55	Lamb	Barley	straw	Yes	5.55
Sheep (ewe only)	0.059	0.185	1.76	5.55	Ram/Ewe	Barley	straw	Yes	5.55
Swine (all diets)	0.017	0.020	0.57	0.72	Swine (finishing)	Swede	roots	Yes	0.64
Poultry (all diets)	0.036	0.060	0.53	0.87	Poultry layer	Wheat	straw	Yes	0.86
Poultry (layer only)	0.036	0.060	0.53	0.87	Poultry layer	Wheat	straw	Yes	0.86

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

The above intake calculations for the maximum dietary burden of livestock demonstrate that residues of prothioconazole (sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2*H*-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers)) are significant in the diets of livestock (> 0.1 mg/kg dry matter in the diet).

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

Prothioconazole
The median and maximum dietary burdens for livestock were estimated for prothioconazole and were calculated using the animal model calculator developed by EFSA (Animal model 2017).
The calculated dietary burdens for prothioconazole were found to exceed the trigger value of 0.1 mg/kg DM (or 0.004 mg/kg bw/d, respectively) for all livestock groups. Further investigation of residues is therefore required.

TDMs

No new calculations were submitted in the framework of this application. Livestock dietary intake calculations for TDMs have been performed during EU peer review of the pesticide risk assessment for the triazole derivative metabolites (UK, 2018b and EFSA 2018b, amended 2019) and reference is made to the respective evaluation of EFSA 2018b: “The livestock dietary burden calculation has been performed respectively for each TDM compound and triggered livestock feeding studies for 1,2,4-T, TA, TAA and TLA, see chapter B.7.4 of the addendum (United Kingdom, 2015, 2018).” The envisaged GAP uses are considered to be covered by these calculations as input values are considered/expected to cover the highest residues found in the relevant primary and rotational crop residue trials. The respective input values can be found in the confirmatory data assessment on pp 354 to 363 (UK, 2018b).
Input values used in UK, 2018b directly relevant to the envisaged GAP uses are given below and compared with the respective values derived from the new studies (TDM primary and rotational crop studies) submitted with this application.

Table 7.2-16: Comparison of input values for dietary burden calculation from confirmatory data assessment (UK 2018b, pp 354 to 363) with values derived from new supplementary primary and rotational crop field residue studies

Crop	Source of data	HR or STMR-P	Residue (mg/kg)				HR or STMR-P	Residue (mg/kg)			
			T	TA	TAA	TLA		T	TA	TAA	TLA
		Residues input values for the max. dietary burden calculation (in brackets: HR/STMRs derived from new supplementary residue studies)					Residues input values for the median dietary burden calculation (in brackets: HR/STMRs derived from new supplementary residue studies)				
Forages											
Alfalfa forage	Wheat or barley plant	HR	0.06	0.524	0.434	1.43	STMR	0.05	0.16	0.1	0.4
Alfalfa hay	Wheat or barley plant	HR * default PF (2.5)	0.15	1.31	1.085	3.58	HR * default PF (2.5)	0.3	0.4	0.25	1
Alfalfa meal	Wheat or barley plant	HR * default PF (2.5)	0.15	1.31	1.085	3.58	HR * default PF (2.5)	0.3	0.4	0.25	1
Alfalfa silage	Wheat or barley plant	HR * default PF (1.1)	0.066	0.576	0.477	1.57	HR * default PF (1.1)	0.06	0.18	0.11	0.44
Beet, mangel fodder	HR of beet leaves or root	HR	0.12	0.239	0.05	0.14	STMR	0.05	0.18	0.05	0.05
Beet tops	Sugar beet leaves	HR	0.12	0.218	0.02	0.14	STMR	0.03	0.04	0.01	0.05
Cabbage heads	brassica	HR	0.113	0.5	0.01	0.01	STMR	0.04	0.17	0.01	0.01
Clover forage	Wheat or barley plant	HR	0.06	0.524	0.434	1.43	STMR	0.05	0.16	0.1	0.4

Crop	Source of data	HR or STMR-P	Residue (mg/kg)				HR or STMR-P	Residue (mg/kg)			
			T	TA	TAA	TLA		T	TA	TAA	TLA
		Residues input values for the max. dietary burden calculation (in brackets: HR/STMRs derived from new supplementary residue studies)					Residues input values for the median dietary burden calculation (in brackets: HR/STMRs derived from new supplementary residue studies)				
Clover hay	Wheat or barley plant	HR * default PF (3)	0.18	1.57	1.3	4.29	STMR * default PF (3)	0.15	0.48	0.3	1.2
Clover silage	Wheat or barley plant	HR * default PF (1)	0.06	0.524	0.434	1.43	STMR * default PF (1)	0.05	0.16	0.1	0.4
Grass forage	Wheat or barley plant	HR	0.06	0.524	0.434	1.43	STMR	0.05	0.16	0.1	0.4
Grass hay	Wheat or barley plant	HR * default PF (3.5)	0.21	1.83	1.5	5	STMR * default PF (3.5)	0.18	0.56	0.35	1.4
Grass silage	Wheat or barley plant	HR * default PF (1.6)	0.096	0.838	0.694	2.3	STMR * default PF (1.6)	0.08	0.26	0.16	0.64
Kale	brassica	HR	0.113	0.5	0.01	0.01	STMR	0.04	0.17	0.01	0.01
Rape forage	Oilseed rape plant	HR	0.023	0.913	0.034	0.04	STMR	0.01	0.1	0.01	0.04
Cereal straws/stover	Cereal data	HR	0.05 **(0.02)**	0.65 **(0.08)**	0.78 **(0.40)**	1.1 **(0.45)**	STMR	0.05 **(0.01)**	0.12 **(0.03)**	0.24 **(0.105)**	0.37 **(0.13)**
Turnip leaves	Sugar beet leaves data	HR	0.12	0.218	0.02	0.14	STMR	0.03	0.04	0.01	0.05
Root and tubers											
Carrot	Root vegetable	HR	0.06 **(0.01)**	0.239 **(0.12)**	0.05 **(0.01)**	0.13 **(0.02)**	STMR	0.05 **(0.01)**	0.18 **(0.06)**	0.05 **(0.01)**	0.02 **(0.01)**
Potato	Root vegetable	HR	0.06 **(0.01)**	0.239 **(0.12)**	0.05 **(0.01)**	0.13 **(0.02)**	STMR	0.05 **(0.01)**	0.18 **(0.06)**	0.05 **(0.01)**	0.02 **(0.01)**
Swede	Root vegetable	HR	0.06 **(0.01)**	0.239 **(0.12)**	0.05 **(0.01)**	0.13 **(0.02)**	STMR	0.05 **(0.01)**	0.18 **(0.06)**	0.05 **(0.01)**	0.02 **(0.01)**
Turnip	Root vegetable	HR	0.06 **(0.01)**	0.239 **(0.12)**	0.05 **(0.01)**	0.13 **(0.02)**	STMR	0.05 **(0.01)**	0.18 **(0.06)**	0.05 **(0.01)**	0.02 **(0.01)**
Cereal grains/ crop seeds											

Crop	Source of data	HR or STMR-P	Residue (mg/kg)				HR or STMR-P	Residue (mg/kg)			
			T	TA	TAA	TLA		T	TA	TAA	TLA
		Residues input values for the max. dietary burden calculation (in brackets: HR/STMRs derived from new supplementary residue studies)					**Residues input values for the median dietary burden calculation (in brackets: HR/STMRs derived from new supplementary residue studies)**				
All cereal grains	Cereal data	STMR	0.05 **(0.01)**	0.621 **(0.31)**	0.79 **(0.235)**	0.02 **(0.01)**	STMR	0.05 **(0.01)**	0.62 **(0.31)**	0.79 **(0.235)**	0.022 **(0.01)**
Pulses	Pulse data	STMR	0.05	0.17	0.05	0.01	STMR	0.05	0.17	0.05	0.01
By products											
Apple pomace	Citrus or apple	STMR-P	0.25 (STMR* default PF (5))	0.167 (STMR*PF) (0.32*0.52)	0.25 (STMR* default PF (5))	0.1 (STMR*PF) (0.04*2.5)	STMR-P	0.3 (STMR* default PF (5))	0.17 (STMR*PF) (0.32*0.52)	0.13 (STMR*PF) (0.05*2.5	0.1 (STMR*PF) (0.04*2.5)
Beet sugar dried pulp	Sugar beet root data	STMR* default PF (18)	0.9	3.3	0.9	0.38	STMR* default PF (18)	0.9	3.3	0.9	0.38
Beet, sugar, ensiled pulp	Sugar beet root data	STMR* default PF (3)	0.15	0.55	0.15	0.06	STMR* default PF (3)	0.15	0.55	0.15	0.06
Beet, sugar molasses	Sugar beet root data	STMR* default PF (28)	1.4	5.1	1.4	0.59	STMR* default PF (28)	1.4	5.1	1.4	0.59
Brewer's grain	Cereal grain data	STMR* default PF (3.3)	0.165	2	2.6	0.073	STMR* default PF (3.3)	0.17	2	2.6	0.073
Canola	Oilseed rape data	STMR* PF	0.1 (STMR * default PF (2)) (0.05* 2)	1.45 (STMR*PF) (1.039*1.4)	0.24 (STMR*PF) (0.12*2)	0.13 (STMR*PF) (0.065*2)	STMR* PF	0.1 (STMR * default PF (2)) (0.05* 2)	1.45 (STMR*PF) (1.039*1.4)	0.24 (STMR*PF) (0.12*2)	0.13 (STMR*PF) (0.065*2)
Citrus pomace	Citrus or apple	STMR-P	0.5 (STMR* default PF (10))	0.167 (STMR*PF) (0.32*0.52)	0.5 (STMR* default PF (10))	0.1 (STMR*PF) (0.04*2.5)	STMR-P	0.5 (STMR* default PF (10))	0.17 (STMR*PF) (0.32*0.52)	0.13 (STMR*PF) (0.05*2.5	0.1 (STMR*PF) (0.04*2.5)

Crop	Source of data	HR or STMR-P	Residue (mg/kg)				HR or STMR-P	Residue (mg/kg)			
			T	TA	TAA	TLA		T	TA	TAA	TLA
		Residues input values for the <u>max.</u> dietary burden calculation (in brackets: HR/STMRs derived from new supplementary residue studies)					Residues input values for the <u>median</u> dietary burden calculation (in brackets: HR/STMRs derived from new supplementary residue studies)				
Corn, field milled by-products	Cereal grain data	STMR* default PF (1)	0.05	0.621	0.79	0.02	STMR* default PF (1)	0.05	0.62	0.79	0.02
Corn, field, hominy meal	Cereal grain data	STMR* default PF (6)	0.3	3.73	4.74	0.13	STMR* default PF (6)	0.3	3.7	4.74	0.13
Corn, field gluten feed	Cereal grain data	STMR* default PF (2.5)	0.125	1.55	1.98	0.06	STMR* default PF (2.5)	0.13	1.6	1.98	0.06
Corn field, gluten meal	Cereal grain data	STMR* default PF (1)	0.05	0.621	0.79	0.02	STMR* default PF (1)	0.05	0.62	0.79	0.02
Cotton meal	Oilseed data	STMR* PF	0.065 (STMR* default PF (1.3)) (0.05* 1.3)	1.45 (STMR*PF) (1.039*1.4)	0.24 (STMR*PF) (0.12*2)	0.13 (STMR*PF) (0.065*2)	STMR* PF	0.07 (STMR* default PF (1.3)) (0.05* 1.3)	1.45 (STMR*PF) (1.039*1.4)	0.24 (STMR*PF) (0.12*2)	0.13 (STMR*PF) (0.065*2)
Distiller's grain	Cereal grain data	STMR* default PF -3.3	0.165	2	2.6	0.073	STMR* default PF (3.3)	0.17	2	2.6	0.073
Flaxseed/linseed meal	Oilseed rape data	STMR* PF	0.1 (STMR * default PF (2)) (0.05* 2)	1.45 (STMR*PF) (1.039*1.4)	0.24 (STMR*PF) (0.12*2)	0.13 (STMR*PF) (0.065*2)	STMR* PF	0.1 (STMR * default PF (2)) (0.05* 2)	1.45 (STMR*PF) (1.039*1.4)	0.24 (STMR*PF) (0.12*2)	0.13 (STMR*PF) (0.065*2)
Lupin seed meal	Pulse data	STMR* default PF (1.1)	0.055	0.187	0.055	0.01	STMR* default PF (1.1)	0.06	0.19	0.06	0.01
Potato process waste	Root vegetable	STMR* default PF (20)	1	3.68	1	0.42	STMR* default PF (20)	1	3.7	1	0.42

Crop	Source of data	HR or STMR-P	Residue (mg/kg)				HR or STMR-P	Residue (mg/kg)			
			T	TA	TAA	TLA		T	TA	TAA	TLA
		Residues input values for the max. dietary burden calculation (in brackets: HR/STMRs derived from new supplementary residue studies)					Residues input values for the median dietary burden calculation (in brackets: HR/STMRs derived from new supplementary residue studies)				
Potato dried pulp	Root vegetable	STMR* default PF (38)	1.9	6.99	1.9	0.8	STMR* default PF (38)	1.9	6.99	1.9	0.8
Rape meal	Oilseed rape data	STMR* PF	0.1 (STMR * default PF (2)) (0.05* 2)	1.45 (STMR*PF) (1.039*1.4)	0.24 (STMR*PF) (0.12*2)	0.13 (STMR*PF) (0.065*2)	STMR* PF	0.1 (STMR * default PF (2)) (0.05* 2)	1.45 (STMR*PF) (1.039*1.4)	0.24 (STMR*PF) (0.12*2)	0.13 (STMR*PF) (0.065*2)
Safflower meal	Oilseed rape data	STMR* PF	0.1 (STMR * default PF (2)) (0.05* 2)	1.45 (STMR*PF) (1.039*1.4)	0.24 (STMR*PF) (0.12*2)	0.13 (STMR*PF) (0.065*2)	STMR* PF	0.1 (STMR * default PF (2)) (0.05* 2)	1.45 (STMR*PF) (1.039*1.4)	0.24 (STMR*PF) (0.12*2)	0.13 (STMR*PF) (0.065*2)
Soybean meal	Oilseed rape data	STMR* PF	0.065 (STMR * default PF (1.3)) (0.05* 1.3)	1.45 (STMR*PF) (1.039*1.4)	0.24 (STMR*PF) (0.12*2)	0.13 (STMR*PF) (0.065*2)	STMR* PF	0.07 (STMR * default PF (1.3)) (0.05* 1.3)	1.45 (STMR*PF) (1.039*1.4)	0.24 (STMR*PF) (0.12*2)	0.13 (STMR*PF) (0.065*2)
Soybean hulls	Oilseed rape data	STMR* default PF (13)	0.65	13.5	1.56	0.85	STMR* default PF (13)	0.7	13.5	1.56	0.85
Sugarcane molasses	Sugar plant data	STMR* default PF (32)	1.6	5.89	1.6	0.67	STMR* default PF (32)	1.6	5.89	1.6	0.67
Sunflower meal	Oilseed rape data	STMR* PF	0.1 (STMR * default PF (2)) (0.05* 2)	1.45 (STMR*PF) (1.039*1.4)	0.24 (STMR*PF) (0.12*2)	0.13 (STMR*PF) (0.065*2)	STMR* PF	0.1 (STMR * default PF (2)) (0.05* 2)	1.45 (STMR*PF) (1.039*1.4)	0.24 (STMR*PF) (0.12*2)	0.13 (STMR*PF) (0.065*2)

Crop	**Source of data**	**HR or STMR-P**	**Residue (mg/kg)**				**HR or STMR-P**	**Residue (mg/kg)**			
			T	**TA**	**TAA**	**TLA**		**T**	**TA**	**TAA**	**TLA**
		Residues input values for the max. dietary burden calculation (in brackets: HR/STMRs derived from new supplementary residue studies)					**Residues input values for the median dietary burden calculation (in brackets: HR/STMRs derived from new supplementary residue studies)**				
Wheat gluten meal	Cereal data	STMR* default PF (1.8)	0.09	1.11	1.42	0.04	STMR* default PF (1.8)	0.09	1.11	1.42	0.04
Wheat milled by products	Cereal data	STMR* default PF (7)	0.035	4.35	5.53	0.15	STMR* default PF (7)	0.35	4.35	5.53	0.15

The dietary burdens for 1,2,4-T, TA, TAA and TLA according to UK, 2018b are shown in Table 7.2-17 to Table 7.2-20, respectively.

Table 7.2-17: The median and maximum dietary burden for 1,2,4-T

Relevant groups	**Dietary burden expressed in**				**Most critical diet (a)**	**Most critical commodity (b)**		Trigger exceeded (Yes/No)	Previous assessment
	mg/kg bw per day		mg/kg DM					0.004	Max burden
	Median	Maximum	Median	Maximum				mg/kg bw	mg/kg bw
Cattle (all diets)	0.104	0.109	3.60	3.75	Dairy cattle	Potato	process waste	Yes	
Cattle (dairy only)	0.104	0.109	2.70	2.83	Dairy cattle	Potato	process waste	Yes	
Sheep (all diets)	0.118	0.121	3.54	3.63	Ram/Ewe	Potato	process waste	Yes	
Sheep (ewe only)	0.118	0.121	3.54	3.63	Ram/Ewe	Potato	process waste	Yes	
Swine (all diets)	0.045	0.047	1.93	2.04	Swine (breeding)	Potato	process waste	Yes	
Poultry (all diets)	0.037	0.038	0.53	0.54	Poultry broiler	Potato	dried pulp	Yes	
Poultry (layer only)	0.029	0.032	0.43	0.46	Poultry layer	Potato	dried pulp	Yes	

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

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

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

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

Table 7.2-19: The median and maximum dietary burden for TAA

Relevant groups	Dietary burden expressed in				Most critical diet (a)	Most critical commodity (b)	
	mg/kg bw per day		mg/kg DM				
	Median	Maximum	Median	Maximum			
Cattle (all diets)	0.118	0.140	3.87	4.29	Dairy cattle	Potato	process waste
Cattle (dairy only)	0.118	0.140	3.06	3.63	Dairy cattle	Potato	process waste
Sheep (all diets)	0.153	0.170	3.80	4.37	Lamb	Wheat	milled bypdts
Sheep (ewe only)	0.127	0.146	3.80	4.37	Ram/Ewe	Potato	process waste
Swine (all diets)	0.108	0.109	3.60	3.76	Swine (finishing)	Wheat	milled bypdts
Poultry (all diets)	0.138	0.140	1.98	2.05	Poultry broiler	Wheat	milled bypdts
Poultry (layer only)	0.135	0.140	1.98	2.05	Poultry layer	Wheat	milled bypdts

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

Table 7.2-20: The median and maximum dietary burden for TLA

Relevant groups	**Dietary burden expressed in**				**Most critical diet (a)**	**Most critical commodity (b)**	
	mg/kg bw per day		mg/kg DM				
	Median	Maximum	Median	Maximum			
Cattle (all diets)	0.078	0.177	2.22	4.61	Dairy cattle	Grass	forage (fresh)
Cattle (dairy only)	0.078	0.177	2.03	4.61	Dairy cattle	Grass	forage (fresh)
Sheep (all diets)	0.079	0.187	2.36	5.61	Ram/Ewe	Grass	forage (fresh)
Sheep (ewe only)	0.079	0.187	2.36	5.61	Ram/Ewe	Grass	forage (fresh)
Swine (all diets)	0.026	0.055	1.11	2.37	Swine (breeding)	Grass	forage (fresh)
Poultry (all diets)	0.021	0.055	0.31	0.77	Poultry layer	Clover	hay
Poultry (layer only)	0.021	0.052	0.31	0.77	Poultry layer	Clover	hay
(a): When several diets are relevant (e.g. cattl0.052e, sheep and poultry "all diets"), the most critical diet is identified from the maximum dietary burdens expressed as "mg/kg bw per day".							
(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as "mg/kg bw per day".							

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

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

TDMs
Livestock dietary burden calculation has been performed respectively for each TDM compound in the addendum – confirmatory data on TDMs performed by UK (UK, 2018) using results from residue trials and from rotational crops.
It should be noted that the results of dietary burdens for TDMs taking into account the intended uses of ADM.03503.F.1.A are covered by the dietary burdens calculated by the UK (UK, 2018) for the different groups of livestock.

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Available data

Prothioconazole except TDMs

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

The magnitude of prothioconazole residues in livestock was evaluated during EU review (UK, 2004 and 2007; EFSA, 2007) and during Article 12 MRL review (EFSA, 2014 and EFSA, 2020) and reference is made to the respective evaluations.

Table 7.2-21: Overview of livestock feeding studies with prothioconazole-desthio

Group	Species	No of animal	Test item	Application details		Sample details		Reference
				Rate	Duration (days)	Commodity	Time of sampling	
EU data								
Lactating ruminants	Dairy cow	10 (3 groups à 3 animals, 1 control animal)	Prothioconazole-desthio	4, 25, and 100 mg/kg in the diet (equivalent to 0.145, 0.909 and 3.636 mg/kg bw per d (UK 2007))	28	Milk	24 times during study	UK, 2004 and 2007 (IIA, 6.4/01); EFSA, 2007, evaluated and accepted (Heinemann, O. and Auer, S., 2001); Report no. MR-535/00
						Tissues (liver, kidney, muscle, fat)	After sacrifice	

Ruminants and pigs (EFSA 2014):

"During the peer review under Directive 91/414/EEC, the magnitude of prothioconazole residues in ruminants was investigated in a feeding study with lactating cows (EFSA, 2007; FAO, 2008a, 2008b; United Kingdom, 2004, 2007). Three groups of lactating cows, each consisting of three animals, were dosed for 28 consecutive days with prothioconazole-desthio at levels of 4, 25, and 100 mg/kg in the diet (equivalent to 0.145, 0.909 and 3.636 mg/kg bw per d, respectively). The samples were analysed for prothioconazole-desthio, M14 (prothioconazole-3-hydroxy-desthio) and M15 (prothioconazole-4-hydroxy-desthio). Results of the ruminant livestock feeding study are summarised in [~~Błąd! Nie można odnaleźć ródła odwołania.~~ Table 7.2-22]. In milk, a plateau level was reached after 1 or 2 days of exposure, according to the dose level group. Since neither the metabolites (free and conjugated) containing the common moiety and included in the residue definition for risk assessment nor the glucuronide conjugates of prothioconazole-desthio were analysed, EFSA reported the residue levels for enforcement only (prothioconazole-desthio) and considered the conversion factors for enforcement to risk assessment of 2 and 9 respectively for liver and kidney based on the goat metabolism study with administration of prothioconazole-desthio. No tentative CF was derived for milk, muscle and fat since the residue levels in these matrices are expected to be negligible (<0.01 mg/kg) at the calculated dietary burden. However, conversion factors reported above should in principle be covered by a new feeding study to estimate prothioconazole metabolites containing the common moiety in accordance with the residue definition for risk assessment.

Furthermore, in the framework of the reported feeding study, the storage stability of prothioconazole-desthio, M14 and M15 was demonstrated in all matrices for up to 1 month when stored deep frozen and was shown to cover the storage time interval of the residue samples of the feeding study. Degradation of prothioconazole-desthio residues during storage of the feeding study residue samples is therefore not expected.

Consequently, the available data allow deriving tentative MRLs in ruminants and pigs. These MRLs were derived in compliance with the latest recommendations on this matter (FAO, 2009b) and are summarised in [~~Błąd! Nie można odnaleźć źródła odwołania.~~ Table 7.2-23]. Tentative MRLs in all commodities are stablished at the LOQ, except in liver and kidney of ruminants, where MRLs of 0.05 and 0.02 mg/kg respectively are proposed.”

When using the dietary burdens calculated above (considering the uses evaluated in Art. 12 procedure and the uses under consideration, presented in ~~Błąd! Nie można odnaleźć źródła odwołania.~~), estimated esidues at 1N dietary burden in ruminant and pig matrices and in milk do not exceed the current MRLs in the respective commodities as given in Com. Reg. (EU) 2019/552 (see ~~Błąd! Nie można odnaleźć źródła dwołania.~~ Table 7.2-24).

Poultry (EFSA 2014): “Finally, although the maximum dietary burden for poultry exceeds the threshold of 0.1 mg/kg DM, no appropriate feeding study is available and is required, since based on the metabolism study, no residues above the LOQ are expected in poultry matrices at the calculated dietary burden.”

According to EFSA, 2020 the following applies with regard to residues in livestock: “The results of the dietary burden calculation are presented in Section B.2 [see ~~Błąd! Nie można odnaleźć źródła odwołania.~~ able 7.2-25 above] and demonstrate that the exposure of all livestock species exceeds the trigger value of 0.1 mg/kg DM […]. EFSA notes that since the residue trials on grass (major component of livestock dietary burden) have not been submitted, the EU livestock dietary burden from the existing EU uses including grass could not be properly calculated. However, since the existing EU MRLs for livestock commodities reflect CXLs, which are derived on the basis of significantly higher livestock dietary burdens as calculated by the JMPR in 2017 for cattle and poultry (FAO, 2018), the nature and magnitude of prothioconazole residues in livestock was not investigated further.”

Table 7.2-26: Overview of the values derived from livestock feeding studies (EFSA, 2014) and the estimated STMRs/HRs at 1N intake level when using livestock dietary burden as calculated above (Błąd! Nie można odnaleźć źródła odwołania. **Table 7.2-27)**

Commodity	**Dietary burden** ~~Błąd! Nie można odnaleźć źródła odwołania.~~ Table 7.2-15		**Results of the livestock feeding study (EFSA 2014)**						**Median residue at 1N dietary burden (mg/kg)(c)**	**Highest residue at 1N dietary burden (mg/kg)(d)**	**Current EU-MRL (mg/kg) Com. Reg. (EU) 2019/552**	**CF for RA(e)**
	Med. (mg/kg bw/d)	**Max. (mg/kg bw/d) (a)**	**Dose Level (mg/kg bw/d)**	**No**	**Result for enforcement**		**Result for RA(b)**					
					Mean (mg/kg)	**Max. (mg/kg)**	**Mean (mg/kg)**	**Max. (mg/kg)**				
EU data (UK, 2004; EFSA, 2014; dietary burden: EFSA 2020)												
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	0.017	0.020	0.15	3	<0.01	<0.01	n.a.	n.a.	<0.01	<0.01	**0.01**	1.0
			0.91	3	<0.01	<0.01	n.a.	n.a.				
			3.64	3	<0.01	<0.01	n.a.	n.a.				
Pig fat			0.15	3	<0.01	<0.01	n.a.	n.a.	<0.01	<0.01	**0.02**	1.0
			0.91	3	<0.01	0.01	n.a.	n.a.				
			3.64	3	0.02	0.04	n.a.	n.a.				
Pig liver			0.15	3	0.02	0.03	n.a.	n.a.	<0.01	<0.01	**0.5**	2.0
			0.91	3	0.14	0.18	n.a.	n.a.				
			3.64	3	0.68	1.20	n.a.	n.a.				
Pig kidney			0.15	3	<0.01	<0.01	n.a.	n.a.	<0.01	<0.01	**0.5**	9.0
			0.91	3	0.03	0.03	n.a.	n.a.				
			3.64	3	0.13	0.24	n.a.	n.a.				
Ruminant muscle	0.038	0.111	0.15	3	<0.01	<0.01	n.a.	n.a.	<0.01	<0.01	**0.01**	1.0
			0.91	3	<0.01	<0.01	n.a.	n.a.				
			3.64	3	<0.01	<0.01	n.a.	n.a.				
Ruminant fat			0.15	3	<0.01	<0.01	n.a.	n.a.	<0.01	<0.01	**0.02**	1.0
			0.91	3	<0.01	0.01	n.a.	n.a.				

Commodity	**Dietary burden** ~~Błąd! Nie można odnaleźć ródła odwołania.~~ Table 7.2-15		**Results of the livestock feeding study (EFSA 2014)**						**Median residue at 1N dietary burden (mg/kg)[c]**	**Highest residue at 1N dietary burden (mg/kg)[d]**	**Current EU-MRL (mg/kg) Com. Reg. (EU) 2019/552**	**CF for RA[e]**
	Med. (mg/kg bw/d)	**Max. (mg/kg bw/d)** [a]	**Dose Level (mg/kg bw/d)**	**No**	**Result for enforcement**		**Result for RA[b]**					
					Mean (mg/kg)	**Max. (mg/kg)**	**Mean (mg/kg)**	**Max. (mg/kg)**				
EU data (UK, 2004; EFSA, 2014; dietary burden: EFSA 2020)												
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).												
			3.64	3	0.02	0.04	n.a.	n.a.				
Ruminant liver			0.15	3	0.02	0.03	n.a.	n.a.	<0.01 (0.01 in EFSA 2014)	0.02 (0.042 in EFSA 2014)	**0.5**	2.0
			0.91	3	0.14	0.18	n.a.	n.a.				
			3.64	3	0.68	1.20	n.a.	n.a.				
Ruminant kidney			0.15	3	<0.01	<0.01	n.a.	n.a.	<0.01	<0.01 (0.012 in EFSA 2014)	**0.5**	9.0
			0.91	3	0.03	0.03	n.a.	n.a.				
			3.64	3	0.13	0.24	n.a.	n.a.				
Milk	0.038	0.111	0.15	42	<0.005 [f]	N/A	n.a.	n.a.	<0.005	<0.005	**0.01***	1.0
			0.91	42	<0.005 [f]	N/A	n.a.	n.a.				
			3.64	42	0.005 [f]	N/A	n.a.	n.a.				

(a): Based on a 560 kg animal consuming 20 kg feed DM/day.
(b): In the feeding study, residues were not determined according to the residue definition for risk assessment. Indeed, only prothioconazole-desthio, M14 and M15 were analysed.
(c): Median residue value according to the enforcement residue definition, derived by interpolation/extrapolation from the feeding study for the median dietary burden (FAO, 2009). As raw data from the feeding study are not available to the applicant, the given STMRs at 1N dietary burden are only rough estimates rather then derived from detailed calculations.
(d): 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). As raw data from the feeding study are not available to the applicant, the given HRs at 1N dietary burden are only rough estimates rather then derived from detailed calculations.
(e): The tentative conversion factors for enforcement to risk assessment in liver and kidney were derived on the basis of the available metabolism study on ruminants. For muscle, fat and milk, no CF was derived as residue levels are expected at the maximum meat ruminant dietary burden in these matrices are negligible (<0.01 mg/kg) (EFSA, 2014).
(f): Mean residue level from day 1 or 4 until day 29 (3 cows, 13 or 14 sampling days).

TDMs

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

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

EFSA 2018c: "Poultry and ruminants feeding studies were conducted respectively with TA and TAA and analysed for the magnitude of TA, TAA, 1,2,4-T and TLA residues. The poultry feeding study conducted with TA showed that TA remained predominant in all matrices and a slight metabolisation to 1,2,4-T in whole eggs, liver and muscle at the highest dosing level was noted. When the animals were fed with TAA, this compound was detected in eggs, fat and liver with residues of TA in liver only at all dosing levels. From the ruminant feeding study conducted with TA, TA remained predominant in all tissues but with a significant metabolisation of TA into 1,2,4-T in milk and to a minor extent into 1,2,4-T and TAA in tissues. TLA was identified in fat only but its detection was rather attributed to a contamination as the respective levels were independent from the dosing levels. When ruminants were fed with TAA, this metabolite was only detected at the highest dose level in whole milk and in all tissues whilst TA was identified in liver, muscle and kidney at all the dosing levels. 1,2,4-T and TLA compounds were never detected (< 0.01 mg/kg). Animal tissues, milk and eggs samples were analysed within 30 days of sampling.
Since livestock feeding studies were not conducted to address the potential transfer of 1,2,4-T and TLA in products of animal origin, the experts agreed that transfer factors for TA derived from the feeding studies conducted with TA should be applied to 1,2,4-T, assuming that the absorption and excretion behaviour of TA and 1,2,4-T are similar. Similarly transfer factors for TAA derived from the feeding studies conducted with TAA should be applied to TLA assuming that the absorption and excretion behaviour of TAA and TLA are comparable and because of the similarity of the functional groups. From the available toxicological studies, the absorption and excretion of TA, 1,2,4-T and TAA were shown to be similar and the experts agreed to estimate the 1,2,4-T residue levels in animal matrices by applying transfer factors for TA derived from the feeding study conducted with TA. A feeding study conducted with 1,2,4-T is therefore not required as no further metabolism of this compound in animal matrices is expected. In contrast and since a similar absorption and excretion behaviour of TLA compared to the other TDMs could not be demonstrated, livestock feeding studies conducted with TLA or metabolism studies performed in accordance with the current recommendations as a surrogate to these feeding studies should be provided (data gap). Meanwhile and provisionally, transfer factors for TAA derived from the feeding study conducted with TAA were applied to estimate the residue levels of TLA in animal commodities. The magnitude of residues of each TDM in animal matrices were therefore estimated by using the approach of a separate dietary burden calculation for each TDM and the application of transfer factors respectively to 1,2,4-T and to TLA for which feeding studies are not available.
Furthermore, the residues of the TDMs (mainly 1,2,4-T and to a minor extent, TA) arising from the metabolism of triazole pesticide active substances in livestock should also be considered to derive the total residue levels of the individual TDMs in animal matrices. In the framework of these confirmatory data assessments and since feeding studies conducted with the triazole compounds were not available, the residue levels of 1,2,4-T and TA were estimated from the metabolism studies conducted with the triazole compounds when these were available. For any future assessment of triazole pesticide active substances, livestock feeding studies or, alternatively metabolism studies should be conducted with the triazole compounds to carry out a complete livestock exposure assessment."

New studies to cover the data gap identified by EFSA 2018c cited above have been conducted by the Triazole Derivative Metabolite Group (TDMG). The data gap will be addressed at EU level and considered to be evaluated in the course of the TDM assessment. Therefore, the relevant studies are not submitted with this dossier.

Conclusion on feeding studies

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

zRMS comments:
Information given by the Applicant is acceptable and sufficient.
The livestock feeding studies was investigated during the peer review of prothioconazole. The intended uses do not modify the theoretical maximum daily intake for animals for prothioconazole and TDMs. The residues in animal commodities will not exceed MRLs (Reg. (EU) 2019/552).
No further data are required to support the intended uses of ADM.03503.F.1.A.

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

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

Available data
Reference is made to the EU peer review (EFSA, 2007, DAR UK, 2004 and 2007) and to the MRL review (EFSA, 2014 and 2020) for prothioconazole, as well as to the peer review of the triazole derivative metabolites (TDMs) in the light of confirmatory data submitted (UK, 2018b, EFSA, 2018b, amended 2019). No new data were submitted in the framework of this application.
Prothioconazole except TDMs
Any studies on the magnitude of residues of prothioconazole (except TDMs) in processed commodities are not required, as residues of

> Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers)

were ≤ 0.1 mg/kg in cereal grains at commercial harvest. Based on the results of residue trials, significant residue levels will not occur in cereals at harvest. Accordingly, processing studies are not required.

TDMs
Residues of TDMs:

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

partly exceed 0.1 mg/kg in cereal grains (even though significant background residues in untreated samples were also observed).

In cereal grain, 1,2,4-T and TLA always show residues < 0.1 mg/kg, whereas the trigger of 0.1 is partly exceeded for TA (HR and STMR exceed 0.1) and for TAA (only HR exceeds 0.1).

The contribution of cereals to the IEDIs and IESTIs of the four relevant TDMs is always < 10% of the ADI and ARfD, respectively and below 10% of the ADI for all uses combined with respect to TA and TAA. Due to the low residues in the respective commodities and the low contribution dietary intake, any processing studies are not considered to be required.

However, for the sake of completeness, available processing data is given in the following.

During the peer review of TDMs, processing studies including cereal grain processing have been evaluated and processing factors for bran for TDMs have been derived (UK, 2018b, pp.464-465):

1,2,4-Triazole
No processing factors are available. Residues in the animal feed items were <0.1 mg/kg and consequently the data requirements for processing are not triggered.

Triazole alanine

Crop	Processing factors available	Processing factor used in livestock dietary burden calculation (UK 2018b)	Comment
Bran	1.9, 2.2, 1.8, 3.0, 3.7, 2.2, 1.4	2.2	Median PF

Triazole acetic acid

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

7.2.5.1 Available data for all crops under consideration

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

TDMs
No new data were submitted in the framework of this application.
Processing studies with prothioconazole in which residues of triazole alanine (TA), triazole lactic acid (TLA), triazole acetic acid (TAA) and 1,2,4-triazole (1,2,4-triazole) were analysed for have been evaluated during EU peer review of the pesticide risk assessment for the triazole derivative metabolites (UK, 2018b, EFSA, 2018c, amended 2019) to which explicit reference is made.

7.2.5.2 Conclusion on processing studies

Based on the results of residue trials, significant residue levels of prothioconazole (except TDMs) will not occur in cereal grain at harvest. Accordingly, any processing studies are not considered to be required.

Regarding TDMs, processing factors for TA, TLA and TAA derived from processing studies with cereals are available, which can be used during risk assessments to account for possible residue concentration during processing.

zRMS comments: Information given by the Applicant is acceptable and sufficient. As residues of prothioconazole exceeding 0.1 mg/kg are not expected in the treated crops, there is no need to investigate the magnitude of prothioconazole residues in processed commodities. Regarding TDMs, processing studies on wheat grain have been evaluated in confirmatory data for Triazole Derivate Metabolites (UK, 2018). Calculated processing factors show concentration of: - TA and TAA in wheat bran, - TA in wheat germ and shorts. No further data are required.

7.2.6 Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation.

7.2.6.1 Field rotational crop studies (KCA 6.6.2)

Available data

Reference is made to the EU peer review (EFSA, 2007, DAR UK, 2004 and 2007) and to the MRL review (EFSA, 2014 and 2020) for prothioconazole, as well as to the peer review of the triazole derivative metabolites (TDMs) in the light of confirmatory data submitted (UK, 2018b, EFSA, 2018b, amended 2019). Two new rotational crop residue studies covering all metabolites of the residue definition for risk assessment residue definition of prothioconazole in plants have been conducted (KCA 6.6.2/01 and KCA 6.6.2/02). The detailed assessments of these studies are presented in Appendix 2.

Table 7.2-28: Summary of available studies in field rotational crops

Primary crop	Rate (kg a.s./ha) (GS at application or PHI)	Residue levels in succeeding crops			
		Succeeding crop group	Succeeding crop	Sowing intervals (DAT)	Reference / Remarks
EU data					
For a summary of EU data on TDMs in rotational crops please refer to Table 7.2-29:.					
New data					
Bare soil	0.30 (Bare soil)	Leafy vegetables	Leaf lettuce	30 120 270	Semrau, J., 2021, KCA 6.6.2/01
		Root and tuber vegetables	Radish root Radish top	30 120 270	
		Cereals	Barley whole plant Grain Straw	30 120 270	
Bare soil	0.30 (Bare soil)	Leafy vegetables	Leaf lettuce	28	Semrau, J., 2022, KCA 6.6.2/02
		Root and tuber vegetables	Radish root Radish top	28	
		Cereals	Barley whole plant Grain Straw	28	

<u>Prothioconazole except TDMs</u>

There are currently no studies investigating the magnitude of prothioconazole residues in rotational crops. Considering available data dealing with the nature of residues in rotational crops (see 7.2.2.2; UK, 2007), no study dealing with the magnitude of these residues in succeeding crops is required.

Since the intended application rates on cereals are within the range of application rates assessed in the MRL review, the same conclusions are applicable that residues of prothioconazole in rotational crops are expected to be covered by the residue levels in primary crops (EFSA 2014): “Based on the confined rotational crop study, considering that the application rate of prothioconazole within the EU ranges between 0.009 – 0.600 kg a.s./ha and due to the fact that prothioconazole was applied to a bare soil in the metabolism study (interception of prothioconazole by the plants is expected in practice), it can be concluded that prothioconazole residue levels in food and feed rotational commodities are expected to be covered by the residue levels in primary crops (see also section 3.1.2.2). Therefore, no risk mitigation measures (plant back restrictions) need to be proposed.”

TDMs

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

UK 2018b:" Supervised field trials to investigate the residues in rotational crops after the use of FS and EC formulations containing 100 g/L and 250 g/L of prothioconazole were conducted at four test sites in Germany, the Netherlands, southern France and Spain. At each test site three ranges of plant-back intervals (20-35 days, 60-200 days and 270-365 days) and three crop groups (root crops represented by turnip and carrot, leafy crops represented by lettuce, cereals represented by barley) were investigated. In the trials simulating a crop failure (emergency rotation) the EC formulation was applied once to bare soil at the rate of 630 g as/ha of prothioconazole. The rotational crops were sown or planted 21-34 days after the application. In the trials simulating a normal rotation the FS formulation was used to treat wheat seed at the rate of 15 g as/dt. The seed was sown at a nominal rate of 200 kg seed/ha and the wheat plants received 3 spray treatments at the rate of 200 g as/ha with the EC formulation. The treatments were conducted at the growth stages BBCH 32, BBCH 39 and BBCH 65-69, respectively, with intervals of 7-30 days between subsequent treatments. At harvest the wheat straw was ploughed in and the plot was left bare until rotational crops were sown or planted. The plant-back intervals were variable depending on the crop and ranged between 56 and 200 days for the short crop rotation and between 277 and 345 days for the annual crop rotation. A summary of the median (STMR) and highest residues (HR) of T, TA, TAA and TLA measured in the rotational crops for emergency rotation and normal rotation is given below:

Table 7.2-29: STMRs and HRs for the triazole derived metabolites in carrot / turnip, lettuce and barley grown as succeeding crops following the use of FS and EC formulations containing 100 g/L and 250 g/L of prothioconazole (UK, 2018b)

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

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

In addition, two new studies have been conducted and are summarised in Appendix 2. Results for TDMs are shortly summarised in the following:

In study KCA 6.6.2/01, residues of prothioconazole (sum of PTZ-desthio, 3- hydroxy-PTZ-desthio, 4-hydroxy-PTZ-desthio, 5-hydroxy-PTZ-desthio, 6-hydroxy-PTZ-desthio and alpha-hydroxy-PTZ-desthio, each expressed as PTZ-desthio (sum of isomers)), as well as of triazole derivative metabolites (TDMs) (1,2,4-triazole (1,2,4-T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA)) were analysed in the raw agricultural commodities radish, leaf lettuce and barley grown as rotational crops after one application of MCW-2073 on bare soil at an exaggerated rate of 300 g prothioconazole/ha. Samples were taken from crops planted at three different plant back intervals of nominal 30-3, 120±5 and 270±10 days. In addition, samples of soil were analysed for residues of prothioconazole-desthio. Four trials were carried out in Poland (2x, N-EU residue zone), Southern France and Italy (S-EU residue zone) in 2018-2019. Samples of radish (leaves and roots) and leaf lettuce (leaves) were taken by hand at normal commercial harvest (NCH). Samples of barley (whole plant) were taken at growth stage BBCH 75 and at normal commercial harvest (grain and straw).

At all three plant back intervals of 30-3, 120±5 and 270±10 days, prothioconazole metabolites (sum of PTZ-desthio, 3- hydroxy-PTZ desthio, 4-hydroxy-PTZ desthio, 5-hydroxy-PTZ -desthio, 6-hydroxy-PTZ-desthio and alpha-hydroxy-PTZ-desthio, expressed as prothioconazole-desthio) were below the LOQ (0.06 mg/kg) in all treated and untreated crop commodities.

Residues of 1,2,4-triazole were always below the LOQ of 0.01 mg/kg. Residues of triazole acetic acid (TAA) were found above the LOQ of 0.01 mg/kg solely in cereals (grain and straw). Residues of triazole alanine (TA) and triazole lactic acid (TLA) were found above the LOQ (0.01 mg/kg) in part of the samples across all crops and all plant back intervals. However, it has to be stated that also in some of the untreated samples background levels of TA, TLA and TAA exceeding the LOQ (0.01 mg/kg) were found. This is due to the widespread occurrence of the analytes. Background levels of the analytes in are considered to be unavoidable. The following residues were observed in treated samples:

- Highest residues found at 30-3 days PBI in radish (roots) were found at 0.02 mg/kg (TLA) and 0.12 mg/kg (TA), those at 120±5 days PBI were found at 0.02 mg/kg (TLA) and 0.05 mg/kg (TA), whereas at 270±10 days, highest residues varied between 0.02 mg/kg (TLA) and 0.07 mg/kg (TA).

- Highest residues found at 30-3 days PBI in leaf lettuce were found at 0.03 mg/kg TA and 0.19 mg/kg TLA, those at 120±5 days PBI were found at 0.01 mg/kg TA and 0.12 mg/kg TLA, whereas at 270±10 days, highest residues were found to be 0.02 mg/kg TA and 0.10 mg/kg TLA.

- Highest residues at 30-3 days PBI in barley (grain) were found to be 0.01 mg/kg TLA, 0.41 mg/kg TA and 0.55 mg/kg TAA, those at 120±5 days PBI were 0.01 mg/kg TLA, 0.28 mg/kg TA and 0.29 mg/kg TAA, whereas at 270±10 days, highest residues were found at 0.02 mg/kg TLA, 0.28 mg/kg TA and 0.32 mg/kg TAA.

- Highest residues found at 30-3 days PBI in barley (straw) were in 0.04 mg/kg TA, 0.40 TAA and 0.45 mg/kg TLA, those at 120±5 days PBI were 0.05 mg/kg TA, 0.24 mg/kg TAA and 0.21 mg/kg TLA, whereas at 270±10 days, highest residues were found at 0.27 mg/kg TLA, 0.04 mg/kg TA and 0.20 mg/kg TAA.

For TA, TAA and TLA all samples were analysed within the demonstrated stability period and showed residues of <0.01-0.41 mg/kg, <0.01-0.55 mg/kg and <0.01-0.45 mg/kg respectively. Control samples also contain residues of these metabolites although generally at lower levels compared to treated samples. Stability of 1,2,4-T was only confirmed for 6 months in high water crops and 12 months in cereal grain and straw, but analysis was performed outside of this period (444-539 days). Nevertheless, residues were <0.01 mg/kg in both treated and control cereal samples, in line with the findings of the confined rotational crop study. To address the insufficient stability period for 1,2,4-T, a second reduced GLP field rotational crop study was conducted to verify the no residue situation observed for 1,2,4-T. The rationale for design of this second study is provided in a position paper submitted with this application.

In study KCA 6.6.2/02, residue levels and behaviour of prothioconazole (PTZ) metabolites (sum of PTZ-desthio, 3- hydroxy-PTZ desthio, 4-hydroxy-PTZ desthio, 5-hydroxy-PTZ -desthio, 6-hydroxy-PTZ-desthio and alpha-hydroxy-PTZ-desthio), as well as of 1,2,4-triazole (1,2,4-T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA)) in the raw agricultural commodities radish, lettuce and barley grown as rotational crops after one application of Prothioconazole 250 EC (ADM.03500.F.2.B) on bare soil were analysed. In addition, samples of soil were analysed for residues of prothioconazole-desthio. Crops were planted after a plant back interval of 28±2 days. Two rotational crop field trials were conducted in radish, leaf lettuce and barley during 2021, one in Germany (S21-00408-01), and one in Southern France (S21-00408-02).

Residues of prothioconazole (mg/kg) (sum of PTZ-desthio, 3- hydroxy-PTZ desthio, 4-hydroxy-PTZ desthio, 5-hydroxy-PTZ -desthio, 6-hydroxy-PTZ-desthio and alpha-hydroxy-PTZ-desthio, expressed as prothioconazole-desthio) were below the LOQ (0.06 mg/kg) in all crops and at all plant back intervals in treated and in untreated samples.

Regarding TDMs, residues of triazole alanine (TA), triazole lactic acid (TLA) and triazole acetic acid (TAA) in untreated samples were registered above the LOQ (0.01 mg/kg) in cereals but not in other crops. Residues of 1,2,4-triazole were below the LOD (0.003 mg/kg) in all samples of all crops.

Residues of triazole alanine (TA) and triazole lactic acid (TLA) in treated samples were found above the LOQ (0.01 mg/kg) in all crops, residues of triazole acetic acid (TAA) were found above the LOQ in cereals only, whereas residues of 1,2,4-triazole were below the LOD in all samples and all crops:

- Highest residues found at 28±2 days PBI in treated radish (roots) were found at 0.01 mg/kg (TLA) and 0.10 mg/kg (TA).

- Highest residues found at 28±2 days PBI in treated leaf lettuce were found at 0.02 mg/kg TA and 0.10 mg/kg TLA.

- Highest residues at 28±2 days PBI in treated barley (grain) were found to be 0.04 mg/kg TLA, 0.82 mg/kg TA and 0.57 mg/kg TAA.

- Highest residues found at 28±2 days PBI in treated barley (straw) were in 0.04 mg/kg TA, 0.13 TAA and 0.12 mg/kg TLA.

The freezer storage period of all crop samples was 96 – 105 days for barley grain, 98 - 107 days for barley straw, 141 - 145 days for barley forage, 158 - 165 days for lettuce, 164 - 178 days for radish roots and 169 – 182 days for radish leaves. Therefore, analysis occurred within the acceptable freezer storage stability for 1,2,4-T of 6 months for high water content crops and 12 months for cereal grain and straw. The maximum frozen storage period of crop samples from sampling until extraction for analysis of prothioconazole triazole derivative metabolites was 92 days.

Conclusion on rotational crops studies

Regarding prothioconazole-desthio (sum of isomers), no study dealing with the magnitude of these residues in succeeding crops is required.
Regarding the TDMs, the application rates used in the rotational crops trials evaluated in UK, 2018b cover the envisaged critical GAPs.
Therefore, any further data investigating the magnitude of prothioconazole residues in rotational crops are not considered to be required.

However, the peer review of TDMs identified a data gap for prothioconazole related to the submission of rotational crop field residue trials supported by acceptable storage stability data on TDMs (EFSA, 2018b). Therefore, two new rotational crop studies comprising six trials in total and covering all metabolites of the residue definition for risk assessment of prothioconazole in plants have been conducted. Derived STMRs and HRs for all four TDMs from the six trials are presented in the following. The detailed assessments of these studies are presented in Appendix 2.

Table 7.2-30: Overview of the STMRs/HRs of 1,2,4-T in treated rotational crop samples at normal commercial harvest

	PBI 30 (KCA 6.6.2/01 & /02) (n=6)		PBI 120 (KCA 6.6.2/01) (n=4)		PBI 270 (KCA 6.6.2/01) (n=4)	
Commodity	**STMR**	**HR**	**STMR**	**HR**	**STMR**	**HR**
Radish leaves	0.01	0.01	0.01	0.01	0.01	0.01
Radish roots	0.01	0.01	0.01	0.01	0.01	0.01
Lettuce leaves	0.01	0.01	0.01	0.01	0.01	0.01
Barley grain	0.01	0.01	0.01	0.01	0.01	0.01
Barley straw	0.01	0.01	0.01	0.01	0.01	0.01

Table 7.2-31: Overview of the STMRs/HRs of TA in treated rotational crop samples at normal commercial harvest

	PBI 30 (KCA 6.6.2/01 & /02) (n=6)		PBI 120 (KCA 6.6.2/01) (n=4)		PBI 270 (KCA 6.6.2/01) (n=4)	
Commodity	**STMR**	**HR**	**STMR**	**HR**	**STMR**	**HR**
Radish leaves	**0.11**	**0.27**	0.08	0.14	0.095	0.22
Radish roots	0.04	**0.12**	0.04	0.05	**0.06**	0.07
Lettuce leaves	**0.015**	**0.03**	0.01	0.02	0.01	0.02
Barley grain	**0.225**	**0.82**	0.195	0.28	0.155	0.28
Barley straw	**0.03**	0.04	0.02	**0.05**	0.025	0.04

Table 7.2-32: Overview of the STMRs/HRs of TAA in treated rotational crop samples at normal commercial harvest

	PBI 30 (KCA 6.6.2/01 & /02) (n=6)		PBI 120 (KCA 6.6.2/01) (n=4)		PBI 270 (KCA 6.6.2/01) (n=4)	
Commodity	**STMR**	**HR**	**STMR**	**HR**	**STMR**	**HR**
Radish leaves	0.01	0.01	0.01	0.01	0.01	0.01
Radish roots	0.01	0.01	0.01	0.01	0.01	0.01
Lettuce leaves	0.01	0.01	0.01	0.01	0.01	0.01
Barley grain	**0.235**	**0.57**	0.19	0.29	0.145	0.32
Barley straw	0.09	**0.40**	0.09	0.24	**0.105**	0.20

Table 7.2-33: Overview of the STMRs/HRs of TLA in treated rotational crop samples at normal commercial harvest

	PBI 30 (KCA 6.6.2/01 & /02) (n=6)		PBI 120 (KCA 6.6.2/01) (n=4)		PBI 270 (KCA 6.6.2/01) (n=4)	
Commodity	**STMR**	**HR**	**STMR**	**HR**	**STMR**	**HR**
Radish leaves	0.01	0.13	0.015	0.05	0.02	0.05
Radish roots	**0.01**	**0.02**	0.01	0.02	0.01	0.02
Lettuce leaves	**0.07**	<u>**0.19**</u>	0.07	0.12	0.065	0.1
Barley grain	**0.01**	**0.04**	0.01	0.01	0.01	0.02
Barley straw	0.09	**0.45**	**0.13**	0.21	0.10	0.27

<u>Underlined</u> value used in consumer RA as higher than the value of 0.14 mg/kg used for leafy vegetables in TDM peer review in the light of confirmatory data submitted (UK, 2018b).

zRMS comments: Information given by the Applicant is acceptable and sufficient. <u>Prothioconazole</u>

No residues are expected in rotational crops for the intended uses of ADM.03503.F.1.A, so additional field rotational crop studies are not considered required.

<u>TDMs</u>
Regarding TDMs, rotational crop studies were considered by the UK in the assessment of confirmatory data on TDMs (the UK, 2018).
According to the EU peer review (EFSA, 2018): "*Residue trials analysing for all TDMs and compliant with the representative uses on cereals (wheat, rye, barley, oats, triticale) and on rapeseeds together with rotational crops residue field trials were submitted in the framework of this confirmatory data assessment but were not supported by acceptable storage stability data for 1,2,4-T in cereal grain, straw and rapeseeds and for TLA in straw. Sufficient residue trials in primary and rotational crops and supported by acceptable storage stability data are therefore required (data gap).*"
The following data gaps were identified for prothioconazole as outlined in section 3 of the peer review conclusion:
14) Residue trials analysing for all TDMs and compliant with the representative use on cereals (wheat, rye, barley, oats, triticale) and on oilseed rapeseeds and supported by acceptable storage stability data on TDMs (prothioconazole).
15) Rotational crops field residue trials supported by acceptable storage stability data on TDMs (prothioconazole).

The applicant provided two rotational crop studies to address the data gap identified in the EFSA peer review.
<u>1. Semrau, J., 2021; Study no.: S18-02513</u>
Four rotational crop field trials were performed in the Northern (two) and Southern (two) residue zone to determine residue levels of prothioconazole-desthio and prothioconazole (PTZ) hydroxy metabolites (sum of PTZ-desthio, 3-hydroxy-PTZ-desthio, 4-hydroxy-PTZ-desthio, 5-hydroxy-PTZ-desthio, 6-hydroxy-PTZ-desthio and alpha-hydroxy-PTZ-desthio), and TDMs (1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA)) in the raw agricultural commodities radish, leaf lettuce and barley grown as rotational crops after one application of MCW-2073 (SC formulation containing 150 g prothioconazole/L and 200 g azoxystrobin/L) with a target rate of 2000 mL product/ha (300 g prothioconazole /ha) on bare soil.

At all three plant back intervals of 30-3, 120±5 and 270±10 days, prothioconazole metabolites (sum of PTZ-desthio, 3- hydroxy-PTZ-desthio, 4-hydroxy-PTZ-desthio, 5-hydroxy-PTZ-desthio, 6-hydroxy-PTZ-desthio and alpha-hydroxy-PTZ-desthio, expressed as prothioconazole-desthio) were below the LOQ (0.06 mg/kg) in all treated and untreated crop commodities.

The trials included analysis of the triazole derivative metabolites.
Residues of 1,2,4-triazole were below the LOQ of 0.01 mg/kg in all crops.
For TA, TAA and TLA all samples were analysed within the demonstrated stability period and showed residues of <0.01-0.41 mg/kg, <0.01-0.55 mg/kg and <0.01-0.45 mg/kg respectively.
However, it has to be stated that also in some of the untreated samples background levels of TA, TLA and TAA exceeding the LOQ (0.01 mg/kg) were found.

As the analysis of 1,2,4-T was not conducted within the demonstrated stability period in the trials performed in 2018-2019, these were repeated in 2020-2021.

<u>2. Semrau, J., 2022; Study no.: S21-00408</u>
The study (contained two rotational crop field trials) was conducted to determine residue levels of prothioconazole-desthio and prothioconazole (PTZ) hydroxy metabolites (sum of PTZ-desthio, 3- hydroxy-PTZ-desthio, 4-hydroxy-PTZ-desthio, 5-hydroxy-PTZ-desthio, 6-hydroxy-PTZ-desthio and alpha-hydroxy-PTZ-desthio), and TDMs (1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA)) in the raw agricultural commodities radish, leaf lettuce and barley grown as rotational crops after one application of Prothioconazole 250 EC (ADM.03500.F.2.B; EC formulation containing 250 g prothioconazole/L) with a target rate of 1.2 L product/ha (300 g prothioconazole /ha) on bare soil. Each trial comprised one plant back interval of 28±2 days.

The maximum frozen storage period of crop samples from sampling until extraction for analysis of prothioconazole metabolites and prothioconazole triazole derivative metabolites was 182 days and 92 days, respectively. Sufficient stability data are available to support the residue data presented in this study.

Results from the second study confirmed the findings of the first study (KCA 6.6.2/01); all residues of 1,2,4-T were <0.01 mg/kg in treated and control samples. Other TDMs were also in a similar range, being <0.01 - 0.82 mg/kg for TA, <0.01 - 0.14 mg/kg for TAA and <0.01 - 0.46 mg/kg for TLA. Again, some control samples also contained residues of TA, TAA and TLA but generally at lower levels than in treated samples.

No additional data are required.

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

Regarding potential residues in honey and other apiculture products, prothioconazole is a systemic fungicide applied as a spray at BBCH 39 - 69 in spring and winter wheat, winter rye and triticale, and at BBCH 39 - 59 in spring and winter barley.
Any residues in pollen and bee products collected from treated crops are not to be expected for cereals as these crops have no melliferous capacity.

zRMS comments:
Information given by the Applicant is acceptable and sufficient.
According to SANTE/11956/2016 rev. 9, cereals are not considered melliferous crops. Effects on the residue level in pollen and bee products have not been investigated.
No additional data are required.

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

Prothioconazole except TDMs
The consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo). This exposure assessment model contains the relevant European food consumption data for different sub-groups of the EU population (EFSA, 2007).

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

The existing EU MRLs are set according to the residue definition for monitoring of prothioconazole: prothioconazole-desthio (sum of isomers).

For the calculation of chronic exposure, input values as given in Appendix D.2. of EFSA 2020 were used for plant and animal commodities except for dry beans and peanuts (values from EFSA 2014 were used). For wheat, barley, oat, rye and oilseed rape for which new GAPs are envisaged in this dossier, median residues according to the residue definition for risk assessment as derived from the submitted residue trials were used if values used in EFSA 2020 were exceeded. For all other commodities of plant origin the current EU-MRLs (last update Reg. (EU) No 2019/552) and the corresponding conversion factor of 2 for risk assessment were used as input values.

The input values used for the dietary exposure calculation are summarised under 7.2.8.1 below.

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

In addition, new worst case calculations based on input values given in UK, 2018b in Table 7.3.17-16 (for crop commodities) and in Table 7.7-1 of Appendix E thereof (for animal commodities) and involving the residue data of the new residue studies submitted with this dossier if higher were conducted.
The consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo). This exposure assessment model contains the relevant European food consumption data for different sub-groups of the EU population (EFSA, 2007).

Toxicological reference values for 1,2,4-triazole (1,2,4-T), triazole alanine (TA) and triazole acetic acid (TAA) relevant for dietary risk assessment are reported in the summary of the evaluation (see 7.1.2).

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

The input values used for the dietary exposure calculation are summarised under 7.2.8.1 below.

7.2.8.1 Input values for the consumer risk assessment

Prothioconazole except TDMs

Table 7.2-34: Input values for the consumer risk assessment (according to EFSA, 2020 and new trials submitted)

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	**Comment**	**Input value (mg/kg)**	**Comment**
Risk assessment residue definition in plant commodities: 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)				
Celeriac	0.08	STMR *(EFSA 2020)*	Acute risk assessment was undertaken only with regard to the crops under consideration	
Beetroots, carrots, horseradish, parsnips, parsley roots, salsifies, swedes, turnips	0.08	STMR *(EFSA 2020)*		
Rape seed	0.08	STMR *(EFSA 2020)*		
Cranberries	0.025	STMR[(a)] (FAO, 2014) *(EFSA 2020)*		
Potatoes	0.01	STMR (EFSA, 2014) *(EFSA 2020)*		
Sweet corn	0.018	STMR[(a)] (FAO, 2014) *(EFSA 2020)*		
Onions, shallots	0.02	STMR (EFSA, 2014, 2015a) × CF (2) *(EFSA 2020)*		
Flowering brassica	0.02	STMR × CF (2) (EFSA, 2014) *(EFSA 2020)*		
Brussels sprouts	0.06	STMR × CF (2) (EFSA, 2014) *(EFSA 2020)*		
Head cabbage	0.02	STMR × CF (2) (EFSA, 2014) *(EFSA 2020)*		
Leeks	0.02	STMR × CF (2) (EFSA, 2014) *(EFSA 2020)*		
Beans (dry)	0.10	STMR × CF (2) (EFSA, 2014) *(EFSA 2014)*		
Lentils, peas, lupins (dry)	0.10	STMR[(a)] (FAO, 2009b) × CF (2) *(EFSA 2020)*		
Linseeds, poppy seeds, mustard seeds	0.06	STMR × CF (2) (EFSA, 2014) *(EFSA 2020)*		
Gold of pleasure seeds	0.02	STMR × CF (2) (EFSA,		

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
		2014) *(EFSA 2020)*		
Peanuts	0.04	STMR (FAO, 2009b) × CF (2) *(EFSA 2014)*		
Sunflower seeds	0.02	STMR (EFSA, 2015b) × CF (2) *(EFSA 2020)*		
Cotton seed	0.1	STMR (FAO, 2018) × CF × 2 *(EFSA 2020)*		
Soybean	0.1	STMR (FAO, 2014) × CF (2) *(EFSA 2020)*		
Barley grain	0.07	STMR[(a)] (FAO, 2009b) × CF (2) *(EFSA 2020)*	0.07	STMR[(a)] (FAO, 2009b) × CF (2)
Barley grain *(new)*	0.06	STMR (new trials submitted, refer to Table 7.2-13:, but covered by higher input value used in EFSA 2020 in the line above)	0.06	STMR (new trials submitted, refer to Table 7.2-13:, but covered by higher input value used in EFSA 2020 in the line above)
Maize grain	0.02	STMR[(a)] (FAO, 2014) × CF (2) *(EFSA 2020)*	Acute risk assessment was undertaken only with regard to the crops under consideration	
Oat grain	0.02	STMR[(a)] (FAO, 2009a) × CF (2) *(EFSA 2020)*	Acute risk assessment was undertaken only with regard to the crops under consideration	
Rye grain *(new)*	0.06	STMR (new trials submitted, refer to Table 7.2-11, extrapolated from wheat)	0.06	STMR (new trials submitted, refer to Table 7.2-11, extrapolated from wheat)
Wheat grain	0.04	STMR[(a)] (FAO, 2009b) × CF (2) *(EFSA 2020)*	0.04	STMR[(a)] (FAO, 2009b) × CF (2)
Wheat grain (*new*)	0.06	STMR (new trials submitted, refer to Table 7.2-11)	0.06	STMR (new trials submitted, refer to Table 7.2-11)
Other commodities of plant origin	EU-MRL × CF (2)	Annexes II and IIIB of Regulation (EC) No 396/2005 (last update Comm. Reg. (EU) No 2019/552)	Acute risk assessment was undertaken only with regard to the crops under consideration	
Muscle of swine, bovine, sheep, goat, equine, other farmed animals	0.01	STMR[(b)] (FAO, 2018) *(EFSA 2020)*	0.01	HR[(b)] (FAO, 2018) *(EFSA 2020)*
Fat of swine, bovine, sheep, goat, equine, other farmed animals	0.01	STMR[(b)] (FAO, 2018) *(EFSA 2020)*	0.018	HR[(b)] (FAO, 2018) *(EFSA 2020)*
Liver of swine, bovine, sheep, goat, equine, other farmed animals	0.05	STMR[(b)] (FAO, 2009b) *(EFSA 2020)*	0.23	HR[(b)] (FAO, 2009b) *(EFSA 2020)*
Kidney, edible offal of swine, bovine, sheep, goat, equine, other farmed animals	0.025	STMR[(b)] (FAO, 2009b) *(EFSA 2020)*	0.15	HR[(b)] (FAO, 2009b) *(EFSA 2020)*
Muscle of poultry	0.0016	STMR[(b)] (FAO, 2018) *(EFSA 2020)*	0.0016	HR[(b)] (FAO, 2018) *(EFSA 2020)*
Fat of poultry	0.008	STMR[(b)] (FAO, 2018) *(EFSA 2020)*	0.008	HR[(b)] (FAO, 2018) *(EFSA 2020)*

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	**Comment**	**Input value (mg/kg)**	**Comment**
Liver, kidney, edible offal of poultry	0.071	STMR[(b)] (FAO, 2018) *(EFSA 2020)*	0.071	HR[(b)] (FAO, 2018) *(EFSA 2020)*
Milks	0.005	STMR (EFSA, 2014) *(EFSA 2020)*	0.005	HR (EFSA, 2014) *(EFSA 2020)*
Eggs	0.01	STMR (EFSA, 2014) *(EFSA 2020)*	0.01	HR (EFSA, 2014) *(EFSA 2020)*

STMR: supervised trials median residue; HR: highest residue; CF: conversion factor for enforcement to risk assessment residue definition.

(a): Values refer to the residues of prothioconazole-desthio; data according to EU risk assessment residue definition not available.

(b): Values refer to the sum of prothioconazole-desthio, prothioconazole-desthio-3-hydroxy, prothioconazole-desthio-4-hydroxy and their conjugates expressed as prothioconazole-desthio.

<u>TDMs</u>

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

EFSA 2018b: "…a 'worst-case' consumer exposure assessment to the TDMs has been carried out in this conclusion taking into consideration the highest residue input values for risk assessment from all the individual residue data sets for plant commodities and the highest residue levels of each TDM arising in products of animal origin from the triazole active substances and from each of the TDMs. [...] The magnitude of the TDMs have been determined in numerous residue trials conducted on crops covering most of the crop categories and for different triazole active substances both in primary and rotational crops. These trials were submitted in the framework of the confirmatory data (United Kingdom, 2015). The submitted residue trials were performed according to specific good agricultural practices (GAPs) authorised for the triazole active substances and residue trials conducted outside Europe were also available. In some cases, these residue trials were compliant with the representative uses of triazole active substances that were approved at EU level. All the residue trials that were used to perform the consumer dietary intake assessment involve only the use of a single triazole active substance, these residue trials do not reflect the situation where several different triazole active substances may be applied on a crop during the same growing season or from treatments with triazole active substances during the previous seasons. However, it is noted that significant residue levels were often found in untreated control samples of residue trials on primary and rotational crops suggesting the use of triazole pesticide active substances in previous seasons. Despite these uncertainties, the experts were of the opinion that these trials should be considered with the purpose of performing a 'worst case' consumer dietary intake calculation. It was, however, emphasised that residue trials analysing all TDMs and compliant with the European authorised uses should be provided in order to conduct a realistic consumer dietary risk assessment and also the need for monitoring data on the occurrence and background levels of all TDMs in plants. For each commodity the input residue values for risk assessment (supervised trials median residues (STMR) and the supervised trials highest residues (HR)) were calculated based on all the residue trials conducted with the same active substance on this commodity and for a commodity group, the highest STMR and HR values derived from all the individual data sets have been applied to each crop within the commodity group in order to conduct the 'worst-case' consumer dietary intake calculation."

In addition, new calculations for 1,2,4-triazole (1,2,4-T), triazole alanine (TA) and triazole acetic acid (TAA) involving the residue data of the new residue studies submitted with this dossier were conducted. However, residues from new trials submitted were covered by input values used during TDM EU peer review (UK, 2018b) for all four TDMs except for residues in lettuce leaves from rotational crops, which showed a HR of 0.19 mg/kg TLA in new trials exceeding 0.14 mg/kg used in TDM EU peer review.

Table 7.2-35: 1,2,4-Triazole (T): Input values for the consumer risk assessment (according to UK, 2018b and new trials submitted)

				Chronic risk assessment[1)]		Acute risk assessment[2)]	
Code	**Commodity**	**existing/ proposed MRL**	**Source/ type of MRL**	**Input value (mg/kg)**	**Comment**	**Input value (mg/kg)**	**Comment**
110010	Grapefruits			0.05	STMR-RAC		
110020	Oranges			0.05	STMR-RAC		
110030	Lemons			0.05	STMR-RAC		
110040	Limes			0.05	STMR-RAC		
110050	Mandarins			0.05	STMR-RAC		
110990	Other citrus fruit			0.05	STMR-RAC		
130010	Apples			0.01	STMR-RAC		
130020	Pears			0.01	STMR-RAC		
130030	Quinces			0.01	STMR-RAC		
130040	Medlar			0.01	STMR-RAC		
130050	Loquats/Japanese medlars			0.01	STMR-RAC		
130990	Other pome fruit			0.01	STMR-RAC		
140010	Apricots			0.01	STMR-RAC		
140020	Cherries (sweet)			0.01	STMR-RAC		
140030	Peaches			0.01	STMR-RAC		
140040	Plums			0.01	STMR-RAC		
140990	Other stone fruit			0.01	STMR-RAC		
151010	Table grapes			0.01	STMR-RAC		
151020	Wine grapes			0.01	STMR-RAC		
152000	Strawberries			0.01	STMR-RAC		
153010	Blackberries			0.01	STMR-RAC		
153020	Dewberries			0.01	STMR-RAC		
153030	Raspberries (red and yellow)			0.01	STMR-RAC		
153990	Other cane fruit			0.01	STMR-RAC		
154010	Blueberries			0.01	STMR-RAC		
154020	Cranberries			0.01	STMR-RAC		
154030	Currants (red, black and white)			0.01	STMR-RAC		
154040	Gooseberries (green, red and yellow)			0.01	STMR-RAC		
154050	Rose hips			0.01	STMR-RAC		
154060	Mulberries (black and white)			0.01	STMR-RAC		
154070	Azarole/Mediteranean medlar			0.01	STMR-RAC		
154080	Elderberries			0.01	STMR-RAC		
154990	Other other small fruit & berries			0.01	STMR-RAC		
163020	Bananas			0.05	STMR-RAC		
211000	Potatoes			0.01	STMR-RAC		
212010	Cassava roots/manioc			0.01	STMR-RAC		
212020	Sweet potatoes			0.01	STMR-RAC		
212030	Yams			0.01	STMR-RAC		
212040	Arrowroots			0.01	STMR-RAC		

				Chronic risk assessment[1)]		Acute risk assessment[2)]	
Code	**Commodity**	**existing/ proposed MRL**	**Source/ type of MRL**	**Input value (mg/kg)**	**Comment**	**Input value (mg/kg)**	**Comment**
212990	Other tropical root and tuber vegetables			0.01	STMR-RAC		
213010	Beetroots			0.01	STMR-RAC		
213020	Carrots			0.01	STMR-RAC		
213030	Celeriacs/turnip rooted celeries			0.01	STMR-RAC		
213040	Horseradishes			0.01	STMR-RAC		
213050	Jerusalem artichokes			0.01	STMR-RAC		
213060	Parsnips			0.01	STMR-RAC		
213070	Parsley roots/Hamburg roots parsley			0.01	STMR-RAC		
213080	Radishes			0.01	STMR-RAC		
213090	Salsifies			0.01	STMR-RAC		
213100	Swedes/rutabagas			0.01	STMR-RAC		
213110	Turnips			0.01	STMR-RAC		
213990	Other other root and tuber vegetables			0.01	STMR-RAC		
220010	Garlic			0.01	STMR-RAC		
220020	Onions			0.01	STMR-RAC		
220030	Shallots			0.01	STMR-RAC		
220040	Spring onions/green onions and Welsh onions			0.01	STMR-RAC		
220990	Other bulb vegetables			0.01	STMR-RAC		
231010	Tomatoes			0.01	STMR-RAC		
231020	Sweet peppers/bell peppers			0.01	STMR-RAC		
231030	Aubergines/egg plants			0.01	STMR-RAC		
231040	Okra/lady’s fingers			0.01	STMR-RAC		
231990	Other solanacea			0.01	STMR-RAC		
232010	Cucumbers			0.01	STMR-RAC		
232020	Gherkins			0.01	STMR-RAC		
232030	Courgettes			0.01	STMR-RAC		
232990	Other cucurbits - edible peel			0.01	STMR-RAC		
233010	Melons			0.01	STMR-RAC		
233020	Pumpkins			0.01	STMR-RAC		
233030	Watermelons			0.01	STMR-RAC		
233990	Other cucurbits - inedible peel			0.01	STMR-RAC		
234000	Sweet corn			0.01	STMR-RAC		
241010	Broccoli			0.039	STMR-RAC		
241020	Cauliflowers			0.039	STMR-RAC		
241990	Other flowering brassica			0.039	STMR-RAC		
242010	Brussels sprouts			0.039	STMR-RAC		
242020	Head cabbages			0.039	STMR-RAC		
242990	Other head brassica			0.039	STMR-RAC		

				Chronic risk assessment[1)]		Acute risk assessment[2)]	
Code	**Commodity**	**existing/ proposed MRL**	**Source/ type of MRL**	**Input value (mg/kg)**	**Comment**	**Input value (mg/kg)**	**Comment**
243010	Chinese cabbages/pe-tsai			0.039	STMR-RAC		
243020	Kales			0.039	STMR-RAC		
243990	Other leafy brassica			0.039	STMR-RAC		
244000	Kohlrabies			0.039	STMR-RAC		
251010	Lamb's lettuce/corn salads			0.015	STMR-RAC		
251020	Lettuces			0.015	STMR-RAC		
251030	Escaroles/broad-leaved endives			0.015	STMR-RAC		
251040	Cress and other sprouts and shoots			0.015	STMR-RAC		
251050	Land cress			0.015	STMR-RAC		
251060	Roman rocket/rucola			0.015	STMR-RAC		
251070	Red mustards			0.015	STMR-RAC		
251080	Baby leaf crops (including brassica species)			0.015	STMR-RAC		
251990	Other lettuce and other salad plants			0.015	STMR-RAC		
252010	Spinaches			0.015	STMR-RAC		
252020	Purslanes			0.015	STMR-RAC		
252030	Chards/beet leaves			0.015	STMR-RAC		
252990	Other spinach and similar			0.015	STMR-RAC		
253000	Grape leaves and similar species			0.015	STMR-RAC		
254000	Watercress			0.015	STMR-RAC		
255000	Witloofs/Belgian endives			0.015	STMR-RAC		
256010	Chervil			0.015	STMR-RAC		
256020	Chives			0.015	STMR-RAC		
256030	Celery leaves			0.015	STMR-RAC		
256040	Parsley			0.015	STMR-RAC		
256050	Sage			0.015	STMR-RAC		
256060	Rosemary			0.015	STMR-RAC		
256070	Thyme			0.015	STMR-RAC		
256080	Basil and edible flowers			0.015	STMR-RAC		
256090	Laurel/bay leaves			0.015	STMR-RAC		
256100	Tarragon			0.015	STMR-RAC		
256990	Other herbs			0.015	STMR-RAC		
260010	Beans (with pods)			0.01	STMR-RAC		
260020	Beans (without pods)			0.01	STMR-RAC		
260030	Peas (with pods)			0.01	STMR-RAC		
260040	Peas (without pods)			0.01	STMR-RAC		
260050	Lentils (fresh)			0.01	STMR-RAC		
260990	Other legume vegetables (fresh)			0.01	STMR-RAC		
270010	Asparagus			0.01	STMR-RAC		
270020	Cardoons			0.01	STMR-RAC		
270030	Celeries			0.01	STMR-RAC		

				Chronic risk assessment[1)]		Acute risk assessment[2)]	
Code	**Commodity**	**existing/ proposed MRL**	**Source/ type of MRL**	**Input value (mg/kg)**	**Comment**	**Input value (mg/kg)**	**Comment**
270040	Florence fennels			0.01	STMR-RAC		
270050	Globe artichokes			0.01	STMR-RAC		
270060	Leeks			0.01	STMR-RAC		
270070	Rhubarbs			0.01	STMR-RAC		
270080	Bamboo shoots			0.01	STMR-RAC		
270090	Palm hearts			0.01	STMR-RAC		
270990	Other stem vegetables			0.01	STMR-RAC		
300010	Beans			0.05	STMR-RAC		
300020	Lentils			0.05	STMR-RAC		
300030	Peas			0.05	STMR-RAC		
300040	Lupins/lupini beans			0.05	STMR-RAC		
300990	Other pulses			0.05	STMR-RAC		
401010	Linseeds			0.05	STMR-RAC		
401020	Peanuts/groundnuts			0.05	STMR-RAC		
401030	Poppy seeds			0.05	STMR-RAC		
401040	Sesame seeds			0.05	STMR-RAC		
401050	Sunflower seeds			0.05	STMR-RAC		
401060	Rapeseeds/canola seeds			0.05	STMR-RAC		
401070	Soyabeans			0.05	STMR-RAC		
401080	Mustard seeds			0.05	STMR-RAC		
401090	Cotton seeds			0.05	STMR-RAC		
401100	Pumpkin seeds			0.05	STMR-RAC		
401110	Safflower seeds			0.05	STMR-RAC		
401120	Borage seeds			0.05	STMR-RAC		
401130	Gold of pleasure seeds			0.05	STMR-RAC		
401140	Hemp seeds			0.05	STMR-RAC		
401150	Castor beans			0.05	STMR-RAC		
401990	Other oilseeds			0.05	STMR-RAC		
402010	Olives for oil production			0.05	STMR-RAC		
402020	Oil palm kernels			0.05	STMR-RAC		
402030	Oil palm fruits			0.05	STMR-RAC		
402040	Kapok			0.05	STMR-RAC		
402990	Other oilfruit			0.05	STMR-RAC		
500010	Barley			0.05	STMR-RAC	0.05	STMR-RAC
500020	Buckwheat and other pseudo-cereals			0.05	STMR-RAC		
500030	Maize/corn			0.05	STMR-RAC		
500040	Common millet/proso millet			0.05	STMR-RAC		
500050	Oat			0.05	STMR-RAC		
500060	Rice			0.05	STMR-RAC		
500070	Rye			0.05	STMR-RAC	0.05	STMR-RAC
500080	Sorghum			0.05	STMR-RAC		
500090	Wheat			0.05	STMR-RAC	0.05	STMR-RAC
500990	Other cereals			0.05	STMR-RAC		
900010	Sugar beet roots			0.05	STMR-RAC		

				Chronic risk assessment[1)]		Acute risk assessment[2)]	
Code	**Commodity**	**existing/ proposed MRL**	**Source/ type of MRL**	**Input value (mg/kg)**	**Comment**	**Input value (mg/kg)**	**Comment**
900020	Sugar canes			0.05	STMR-RAC		
900030	Chicory roots			0.05	STMR-RAC		
900990	Other sugar plants			0.05	STMR-RAC		
1011010	Swine: Muscle/meat			0.12	STMR-RAC	0.21	HR-RAC
1011020	Swine: Fat tissue			0.1	STMR-RAC	0.16	HR-RAC
1011030	Swine: Liver			0.12	STMR-RAC	0.19	HR-RAC
1011040	Swine: Kidney			0.13	STMR-RAC	0.25	HR-RAC
1012010	Bovine: Muscle/meat			0.16	STMR-RAC	0.24	HR-RAC
1012020	Bovine: Fat tissue			0.12	STMR-RAC	0.19	HR-RAC
1012030	Bovine: Liver			0.19	STMR-RAC	0.25	HR-RAC
1012040	Bovine: Kidney			0.2	STMR-RAC	0.28	HR-RAC
1013010	Sheep: Muscle/meat			0.16	STMR-RAC	0.24	HR-RAC
1013020	Sheep: Fat tissue			0.12	STMR-RAC	0.19	HR-RAC
1013030	Sheep: Liver			0.19	STMR-RAC	0.25	HR-RAC
1013040	Sheep: Kidney			0.2	STMR-RAC	0.28	HR-RAC
1014010	Goat: Muscle/meat			0.16	STMR-RAC	0.24	HR-RAC
1014020	Goat: Fat tissue			0.12	STMR-RAC	0.19	HR-RAC
1014030	Goat: Liver			0.19	STMR-RAC	0.25	HR-RAC
1014040	Goat: Kidney			0.2	STMR-RAC	0.28	HR-RAC
1016010	Poultry: Muscle/meat			0.04	STMR-RAC	0.04	HR-RAC
1016020	Poultry: Fat tissue			0.04	STMR-RAC	0.04	HR-RAC
1016030	Poultry: Liver			0.04	STMR-RAC	0.04	HR-RAC
1020010	Milk: Cattle			0.16	STMR-RAC	0.16	STMR-RAC
1020020	Milk: Sheep			0.16	STMR-RAC	0.16	STMR-RAC
1020030	Milk: Goat			0.16	STMR-RAC	0.16	STMR-RAC
1020040	Milk: Horse			0.16	STMR-RAC	0.16	STMR-RAC
1020990	Milk: Others			0.16	STMR-RAC	0.16	STMR-RAC
1030010	Eggs: Chicken			0.04	STMR-RAC	0.04	HR-RAC
1030020	Eggs: Duck			0.04	STMR-RAC	0.04	HR-RAC
1030030	Eggs: Goose			0.04	STMR-RAC	0.04	HR-RAC
1030040	Eggs: Quail			0.04	STMR-RAC	0.04	HR-RAC
1030990	Eggs: Others			0.04	STMR-RAC		
1040000	Honey and other apiculture products			0.01	STMR-RAC		

(1) Normal mode

(2) Assessment of all crops

Table 7.2-36: Triazole alanine (TA): Input values for the consumer risk assessment (according to UK, 2018b and new trials submitted)

				Chronic risk assessment[1)]		Acute risk assessment[2)]	
Code	**Commodity**	**existing/ proposed MRL**	**Source/ type of MRL**	**Input value (mg/kg)**	**Comment**	**Input value (mg/kg)**	**Comment**
110010	Grapefruits			0.32	STMR-RAC		
110020	Oranges			0.32	STMR-RAC		
110030	Lemons			0.32	STMR-RAC		
110040	Limes			0.32	STMR-RAC		
110050	Mandarins			0.32	STMR-RAC		

				Chronic risk assessment[1)]		Acute risk assessment[2)]	
Code	**Commodity**	**existing/ proposed MRL**	**Source/ type of MRL**	**Input value (mg/kg)**	**Comment**	**Input value (mg/kg)**	**Comment**
110990	Other citrus fruit			0.32	STMR-RAC		
130010	Apples			0.039	STMR-RAC		
130020	Pears			0.039	STMR-RAC		
130030	Quinces			0.039	STMR-RAC		
130040	Medlar			0.039	STMR-RAC		
130050	Loquats/Japanese medlars			0.039	STMR-RAC		
130990	Other pome fruit			0.039	STMR-RAC		
140010	Apricots			0.32	STMR-RAC		
140020	Cherries (sweet)			0.32	STMR-RAC		
140030	Peaches			0.32	STMR-RAC		
140040	Plums			0.32	STMR-RAC		
140990	Other stone fruit			0.32	STMR-RAC		
151010	Table grapes			0.06	STMR-RAC		
151020	Wine grapes			0.06	STMR-RAC		
152000	Strawberries			0.06	STMR-RAC		
153010	Blackberries			0.06	STMR-RAC		
153020	Dewberries			0.06	STMR-RAC		
153030	Raspberries (red and yellow)			0.06	STMR-RAC		
153990	Other cane fruit			0.06	STMR-RAC		
154010	Blueberries			0.06	STMR-RAC		
154020	Cranberries			0.06	STMR-RAC		
154030	Currants (red, black and white)			0.06	STMR-RAC		
154040	Gooseberries (green, red and yellow)			0.06	STMR-RAC		
154050	Rose hips			0.06	STMR-RAC		
154060	Mulberries (black and white)			0.06	STMR-RAC		
154070	Azarole/Mediteranean medlar			0.06	STMR-RAC		
154080	Elderberries			0.06	STMR-RAC		
154990	Other other small fruit & berries			0.06	STMR-RAC		
163020	Bananas			0.05	STMR-RAC		
212010	Cassava roots/manioc			0.184	STMR-RAC		
212020	Sweet potatoes			0.184	STMR-RAC		
212030	Yams			0.184	STMR-RAC		
212040	Arrowroots			0.184	STMR-RAC		
212990	Other tropical root and tuber vegetables			0.184	STMR-RAC		
213010	Beetroots			0.184	STMR-RAC		
213020	Carrots			0.184	STMR-RAC		
213030	Celeriacs/turnip rooted celeries			0.184	STMR-RAC		
213040	Horseradishes			0.184	STMR-RAC		
213050	Jerusalem artichokes			0.184	STMR-RAC		
213060	Parsnips			0.184	STMR-RAC		

				Chronic risk assessment[1)]		Acute risk assessment[2)]	
Code	**Commodity**	**existing/ proposed MRL**	**Source/ type of MRL**	**Input value (mg/kg)**	**Comment**	**Input value (mg/kg)**	**Comment**
213070	Parsley roots/Hamburg roots parsley			0.184	STMR-RAC		
213080	Radishes			0.184	STMR-RAC		
213090	Salsifies			0.184	STMR-RAC		
213100	Swedes/rutabagas			0.184	STMR-RAC		
213110	Turnips			0.184	STMR-RAC		
213990	Other other root and tuber vegetables			0.184	STMR-RAC		
220010	Garlic			0.06	STMR-RAC		
220020	Onions			0.06	STMR-RAC		
220030	Shallots			0.06	STMR-RAC		
220040	Spring onions/green onions and Welsh onions			0.06	STMR-RAC		
220990	Other bulb vegetables			0.06	STMR-RAC		
231010	Tomatoes			0.21	STMR-RAC		
231020	Sweet peppers/bell peppers			0.21	STMR-RAC		
231030	Aubergines/egg plants			0.21	STMR-RAC		
231040	Okra/lady's fingers			0.21	STMR-RAC		
231990	Other solanacea			0.21	STMR-RAC		
232010	Cucumbers			0.21	STMR-RAC		
232020	Gherkins			0.21	STMR-RAC		
232030	Courgettes			0.21	STMR-RAC		
232990	Other cucurbits - edible peel			0.21	STMR-RAC		
233010	Melons			0.21	STMR-RAC		
233020	Pumpkins			0.21	STMR-RAC		
233030	Watermelons			0.21	STMR-RAC		
233990	Other cucurbits - inedible peel			0.21	STMR-RAC		
234000	Sweet corn			0.21	STMR-RAC		
241010	Broccoli			0.17	STMR-RAC		
241020	Cauliflowers			0.17	STMR-RAC		
241990	Other flowering brassica			0.17	STMR-RAC		
242010	Brussels sprouts			0.17	STMR-RAC		
242020	Head cabbages			0.17	STMR-RAC		
242990	Other head brassica			0.17	STMR-RAC		
243010	Chinese cabbages/pe-tsai			0.17	STMR-RAC		
243020	Kales			0.17	STMR-RAC		
243990	Other leafy brassica			0.17	STMR-RAC		
244000	Kohlrabies			0.17	STMR-RAC		
251010	Lamb's lettuce/corn salads			0.047	STMR-RAC		
251020	Lettuces			0.047	STMR-RAC		
251030	Escaroles/broad-leaved endives			0.047	STMR-RAC		

				Chronic risk assessment[1)]		Acute risk assessment[2)]	
Code	**Commodity**	**existing/ proposed MRL**	**Source/ type of MRL**	**Input value (mg/kg)**	**Comment**	**Input value (mg/kg)**	**Comment**
251040	Cress and other sprouts and shoots			0.047	STMR-RAC		
251050	Land cress			0.047	STMR-RAC		
251060	Roman rocket/rucola			0.047	STMR-RAC		
251070	Red mustards			0.047	STMR-RAC		
251080	Baby leaf crops (including brassica species)			0.047	STMR-RAC		
251990	Other lettuce and other salad plants			0.047	STMR-RAC		
252010	Spinaches			0.047	STMR-RAC		
252020	Purslanes			0.047	STMR-RAC		
252030	Chards/beet leaves			0.047	STMR-RAC		
252990	Other spinach and similar			0.047	STMR-RAC		
253000	Grape leaves and similar species			0.047	STMR-RAC		
254000	Watercress			0.047	STMR-RAC		
255000	Witloofs/Belgian endives			0.047	STMR-RAC		
256010	Chervil			0.047	STMR-RAC		
256020	Chives			0.047	STMR-RAC		
256030	Celery leaves			0.047	STMR-RAC		
256040	Parsley			0.047	STMR-RAC		
256050	Sage			0.047	STMR-RAC		
256060	Rosemary			0.047	STMR-RAC		
256070	Thyme			0.047	STMR-RAC		
256080	Basil and edible flowers			0.047	STMR-RAC		
256090	Laurel/bay leaves			0.047	STMR-RAC		
256100	Tarragon			0.047	STMR-RAC		
256990	Other herbs			0.047	STMR-RAC		
260010	Beans (with pods)			0.09	STMR-RAC		
260020	Beans (without pods)			0.09	STMR-RAC		
260030	Peas (with pods)			0.09	STMR-RAC		
260040	Peas (without pods)			0.09	STMR-RAC		
260050	Lentils (fresh)			0.09	STMR-RAC		
260990	Other legume vegetables (fresh)			0.09	STMR-RAC		
270010	Asparagus			0.09	STMR-RAC		
270020	Cardoons			0.09	STMR-RAC		
270030	Celeries			0.09	STMR-RAC		
270040	Florence fennels			0.09	STMR-RAC		
270050	Globe artichokes			0.09	STMR-RAC		
270060	Leeks			0.09	STMR-RAC		
270070	Rhubarbs			0.09	STMR-RAC		
270080	Bamboo shoots			0.09	STMR-RAC		
270090	Palm hearts			0.09	STMR-RAC		
270990	Other stem vegetables			0.09	STMR-RAC		
300010	Beans			0.17	STMR-RAC		

				Chronic risk assessment[1)]		Acute risk assessment[2)]	
Code	**Commodity**	**existing/ proposed MRL**	**Source/ type of MRL**	**Input value (mg/kg)**	**Comment**	**Input value (mg/kg)**	**Comment**
300020	Lentils			0.17	STMR-RAC		
300030	Peas			0.17	STMR-RAC		
300040	Lupins/lupini beans			0.17	STMR-RAC		
300990	Other pulses			0.17	STMR-RAC		
401010	Linseeds			1.039	STMR-RAC		
401020	Peanuts/groundnuts			1.039	STMR-RAC		
401030	Poppy seeds			1.039	STMR-RAC		
401040	Sesame seeds			1.039	STMR-RAC		
401050	Sunflower seeds			1.039	STMR-RAC		
401060	Rapeseeds/canola seeds			1.039	STMR-RAC		
401070	Soyabeans			1.039	STMR-RAC		
401080	Mustard seeds			1.039	STMR-RAC		
401090	Cotton seeds			1.039	STMR-RAC		
401100	Pumpkin seeds			1.039	STMR-RAC		
401110	Safflower seeds			1.039	STMR-RAC		
401120	Borage seeds			1.039	STMR-RAC		
401130	Gold of pleasure seeds			1.039	STMR-RAC		
401140	Hemp seeds			1.039	STMR-RAC		
401150	Castor beans			1.039	STMR-RAC		
401990	Other oilseeds			1.039	STMR-RAC		
402010	Olives for oil production			1.039	STMR-RAC		
402020	Oil palm kernels			1.039	STMR-RAC		
402030	Oil palm fruits			1.039	STMR-RAC		
402040	Kapok			1.039	STMR-RAC		
402990	Other oilfruit			1.039	STMR-RAC		
500010	Barley			0.621	STMR-RAC	0.621	STMR-RAC
500020	Buckwheat and other pseudo-cereals			0.621	STMR-RAC		
500030	Maize/corn			0.621	STMR-RAC		
500040	Common millet/proso millet			0.621	STMR-RAC		
500050	Oat			0.621	STMR-RAC		
500060	Rice			0.621	STMR-RAC		
500070	Rye			0.621	STMR-RAC	0.621	STMR-RAC
500080	Sorghum			0.621	STMR-RAC		
500090	Wheat			0.621	STMR-RAC	0.621	STMR-RAC
500990	Other cereals			0.621	STMR-RAC		
900010	Sugar beet roots			0.05	STMR-RAC		
900020	Sugar canes			0.05	STMR-RAC		
900030	Chicory roots			0.05	STMR-RAC		
900990	Other sugar plants			0.05	STMR-RAC		
1011010	Swine: Muscle/meat			0.06	STMR-RAC	0.13	HR-RAC
1011020	Swine: Fat tissue			0.03	STMR-RAC	0.1	HR-RAC
1011030	Swine: Liver			0.13	STMR-RAC	0.34	HR-RAC
1011040	Swine: Kidney			0.06	STMR-RAC	0.22	HR-RAC
1012010	Bovine: Muscle/meat			0.06	STMR-RAC	0.23	HR-RAC

				Chronic risk assessment[1)]		Acute risk assessment[2)]	
Code	**Commodity**	**existing/ proposed MRL**	**Source/ type of MRL**	**Input value (mg/kg)**	**Comment**	**Input value (mg/kg)**	**Comment**
1012020	Bovine: Fat tissue			0.03	STMR-RAC	0.11	HR-RAC
1012030	Bovine: Liver			0.13	STMR-RAC	0.35	HR-RAC
1012040	Bovine: Kidney			0.06	STMR-RAC	0.22	HR-RAC
1013010	Sheep: Muscle/meat			0.06	STMR-RAC	0.23	HR-RAC
1013020	Sheep: Fat tissue			0.03	STMR-RAC	0.11	HR-RAC
1013030	Sheep: Liver			0.13	STMR-RAC	0.35	HR-RAC
1013040	Sheep: Kidney			0.06	STMR-RAC	0.22	HR-RAC
1014010	Goat: Muscle/meat			0.06	STMR-RAC	0.23	HR-RAC
1014020	Goat: Fat tissue			0.03	STMR-RAC	0.11	HR-RAC
1014030	Goat: Liver			0.13	STMR-RAC	0.35	HR-RAC
1014040	Goat: Kidney			0.06	STMR-RAC	0.22	HR-RAC
1016010	Poultry: Muscle/meat			0.04	STMR-RAC	0.11	HR-RAC
1016020	Poultry: Fat tissue			0.03	STMR-RAC	0.09	HR-RAC
1016030	Poultry: Liver			0.09	STMR-RAC	0.22	HR-RAC
1020010	Milk: Cattle			0.02	STMR-RAC	0.02	STMR-RAC
1020020	Milk: Sheep			0.02	STMR-RAC	0.02	STMR-RAC
1020030	Milk: Goat			0.02	STMR-RAC	0.02	STMR-RAC
1020040	Milk: Horse			0.02	STMR-RAC	0.02	STMR-RAC
1020990	Milk: Others			0.02	STMR-RAC	0.02	STMR-RAC
1030010	Eggs: Chicken			0.02	STMR-RAC	0.06	HR-RAC
1030020	Eggs: Duck			0.02	STMR-RAC	0.06	HR-RAC
1030030	Eggs: Goose			0.02	STMR-RAC	0.06	HR-RAC
1030040	Eggs: Quail			0.02	STMR-RAC	0.06	HR-RAC
1030990	Eggs: Others			0.02	STMR-RAC		
1040000	Honey and other apiculture products			0.01	STMR-RAC		

(1) Normal mode

(2) Assessment of all crops

Table 7.2-37: Triazole acetic acid (TAA): Input values for the consumer risk assessment (according to UK, 2018b and new trials submitted)

				Chronic risk assessment[1)]		Acute risk assessment[2)]	
Code	**Commodity**	**existing/ proposed MRL**	**Source/ type of MRL**	**Input value (mg/kg)**	**Comment**	**Input value (mg/kg)**	**Comment**
110010	Grapefruits			0.05	STMR-RAC		
110020	Oranges			0.05	STMR-RAC		
110030	Lemons			0.05	STMR-RAC		
110040	Limes			0.05	STMR-RAC		
110050	Mandarins			0.05	STMR-RAC		
110990	Other citrus fruit			0.05	STMR-RAC		
130010	Apples			0.03	STMR-RAC		
130020	Pears			0.03	STMR-RAC		
130030	Quinces			0.03	STMR-RAC		
130040	Medlar			0.03	STMR-RAC		
130050	Loquats/Japanese medlars			0.03	STMR-RAC		
130990	Other pome fruit			0.03	STMR-RAC		
140010	Apricots			0.02	STMR-RAC		

				Chronic risk assessment[1)]		Acute risk assessment[2)]	
Code	**Commodity**	**existing/ proposed MRL**	**Source/ type of MRL**	**Input value (mg/kg)**	**Comment**	**Input value (mg/kg)**	**Comment**
140020	Cherries (sweet)			0.02	STMR-RAC		
140030	Peaches			0.02	STMR-RAC		
140040	Plums			0.02	STMR-RAC		
140990	Other stone fruit			0.02	STMR-RAC		
151010	Table grapes			0.05	STMR-RAC		
151020	Wine grapes			0.05	STMR-RAC		
152000	Strawberries			0.05	STMR-RAC		
153010	Blackberries			0.05	STMR-RAC		
153020	Dewberries			0.05	STMR-RAC		
153030	Raspberries (red and yellow)			0.05	STMR-RAC		
153990	Other cane fruit			0.05	STMR-RAC		
154010	Blueberries			0.05	STMR-RAC		
154020	Cranberries			0.05	STMR-RAC		
154030	Currants (red, black and white)			0.05	STMR-RAC		
154040	Gooseberries (green, red and yellow)			0.05	STMR-RAC		
154050	Rose hips			0.05	STMR-RAC		
154060	Mulberries (black and white)			0.05	STMR-RAC		
154070	Azarole/Mediteranean medlar			0.05	STMR-RAC		
154080	Elderberries			0.05	STMR-RAC		
154990	Other other small fruit & berries			0.05	STMR-RAC		
163020	Bananas			0.05	STMR-RAC		
211000	Potatoes			0.01	STMR-RAC		
212010	Cassava roots/manioc			0.01	STMR-RAC		
212020	Sweet potatoes			0.01	STMR-RAC		
212030	Yams			0.01	STMR-RAC		
212040	Arrowroots			0.01	STMR-RAC		
212990	Other tropical root and tuber vegetables			0.01	STMR-RAC		
213010	Beetroots			0.01	STMR-RAC		
213020	Carrots			0.01	STMR-RAC		
213030	Celeriacs/turnip rooted celeries			0.01	STMR-RAC		
213040	Horseradishes			0.01	STMR-RAC		
213050	Jerusalem artichokes			0.01	STMR-RAC		
213060	Parsnips			0.01	STMR-RAC		
213070	Parsley roots/Hamburg roots parsley			0.01	STMR-RAC		
213080	Radishes			0.01	STMR-RAC		
213090	Salsifies			0.01	STMR-RAC		
213100	Swedes/rutabagas			0.01	STMR-RAC		
213110	Turnips			0.01	STMR-RAC		

				Chronic risk assessment1)		Acute risk assessment2)	
Code	**Commodity**	**existing/ proposed MRL**	**Source/ type of MRL**	**Input value (mg/kg)**	**Comment**	**Input value (mg/kg)**	**Comment**
213990	Other other root and tuber vegetables			0.01	STMR-RAC		
220010	Garlic			0.01	STMR-RAC		
220020	Onions			0.01	STMR-RAC		
220030	Shallots			0.01	STMR-RAC		
220040	Spring onions/green onions and Welsh onions			0.01	STMR-RAC		
220990	Other bulb vegetables			0.01	STMR-RAC		
231010	Tomatoes			0.01	STMR-RAC		
231020	Sweet peppers/bell peppers			0.01	STMR-RAC		
231030	Aubergines/egg plants			0.01	STMR-RAC		
231040	Okra/lady’s fingers			0.01	STMR-RAC		
231990	Other solanacea			0.01	STMR-RAC		
232010	Cucumbers			0.01	STMR-RAC		
232020	Gherkins			0.01	STMR-RAC		
232030	Courgettes			0.01	STMR-RAC		
232990	Other cucurbits - edible peel			0.01	STMR-RAC		
233010	Melons			0.01	STMR-RAC		
233020	Pumpkins			0.01	STMR-RAC		
233030	Watermelons			0.01	STMR-RAC		
233990	Other cucurbits - inedible peel			0.01	STMR-RAC		
234000	Sweet corn			0.01	STMR-RAC		
241010	Broccoli			0.01	STMR-RAC		
241020	Cauliflowers			0.01	STMR-RAC		
241990	Other flowering brassica			0.01	STMR-RAC		
242010	Brussels sprouts			0.01	STMR-RAC		
242020	Head cabbages			0.01	STMR-RAC		
242990	Other head brassica			0.01	STMR-RAC		
243010	Chinese cabbages/pe-tsai			0.01	STMR-RAC		
243020	Kales			0.01	STMR-RAC		
243990	Other leafy brassica			0.01	STMR-RAC		
244000	Kohlrabies			0.01	STMR-RAC		
251010	Lamb's lettuce/corn salads			0.023	STMR-RAC		
251020	Lettuces			0.023	STMR-RAC		
251030	Escaroles/broad-leaved endives			0.023	STMR-RAC		
251040	Cress and other sprouts and shoots			0.023	STMR-RAC		
251050	Land cress			0.023	STMR-RAC		
251060	Roman rocket/rucola			0.023	STMR-RAC		
251070	Red mustards			0.023	STMR-RAC		
251080	Baby leaf crops (including brassica species)			0.023	STMR-RAC		

				Chronic risk assessment[1)]		Acute risk assessment[2)]	
Code	**Commodity**	**existing/ proposed MRL**	**Source/ type of MRL**	**Input value (mg/kg)**	**Comment**	**Input value (mg/kg)**	**Comment**
251990	Other lettuce and other salad plants			0.023	STMR-RAC		
252010	Spinaches			0.023	STMR-RAC		
252020	Purslanes			0.023	STMR-RAC		
252030	Chards/beet leaves			0.023	STMR-RAC		
252990	Other spinach and similar			0.023	STMR-RAC		
253000	Grape leaves and similar species			0.023	STMR-RAC		
254000	Watercress			0.023	STMR-RAC		
255000	Witloofs/Belgian endives			0.023	STMR-RAC		
256010	Chervil			0.023	STMR-RAC		
256020	Chives			0.023	STMR-RAC		
256030	Celery leaves			0.023	STMR-RAC		
256040	Parsley			0.023	STMR-RAC		
256050	Sage			0.023	STMR-RAC		
256060	Rosemary			0.023	STMR-RAC		
256070	Thyme			0.023	STMR-RAC		
256080	Basil and edible flowers			0.023	STMR-RAC		
256090	Laurel/bay leaves			0.023	STMR-RAC		
256100	Tarragon			0.023	STMR-RAC		
256990	Other herbs			0.023	STMR-RAC		
260010	Beans (with pods)			0.01	STMR-RAC		
260020	Beans (without pods)			0.01	STMR-RAC		
260030	Peas (with pods)			0.01	STMR-RAC		
260040	Peas (without pods)			0.01	STMR-RAC		
260050	Lentils (fresh)			0.01	STMR-RAC		
260990	Other legume vegetables (fresh)			0.01	STMR-RAC		
270010	Asparagus			0.02	STMR-RAC		
270020	Cardoons			0.02	STMR-RAC		
270030	Celeries			0.02	STMR-RAC		
270040	Florence fennels			0.02	STMR-RAC		
270050	Globe artichokes			0.02	STMR-RAC		
270060	Leeks			0.02	STMR-RAC		
270070	Rhubarbs			0.02	STMR-RAC		
270080	Bamboo shoots			0.02	STMR-RAC		
270090	Palm hearts			0.02	STMR-RAC		
270990	Other stem vegetables			0.02	STMR-RAC		
300010	Beans			0.05	STMR-RAC		
300020	Lentils			0.05	STMR-RAC		
300030	Peas			0.05	STMR-RAC		
300040	Lupins/lupini beans			0.05	STMR-RAC		
300990	Other pulses			0.05	STMR-RAC		
401010	Linseeds			0.12	STMR-RAC		
401020	Peanuts/groundnuts			0.12	STMR-RAC		
401030	Poppy seeds			0.12	STMR-RAC		

				Chronic risk assessment[1)]		Acute risk assessment[2)]	
Code	**Commodity**	**existing/ proposed MRL**	**Source/ type of MRL**	**Input value (mg/kg)**	**Comment**	**Input value (mg/kg)**	**Comment**
401040	Sesame seeds			0.12	STMR-RAC		
401050	Sunflower seeds			0.12	STMR-RAC		
401060	Rapeseeds/canola seeds			0.12	STMR-RAC		
401070	Soyabeans			0.12	STMR-RAC		
401080	Mustard seeds			0.12	STMR-RAC		
401090	Cotton seeds			0.12	STMR-RAC		
401100	Pumpkin seeds			0.12	STMR-RAC		
401110	Safflower seeds			0.12	STMR-RAC		
401120	Borage seeds			0.12	STMR-RAC		
401130	Gold of pleasure seeds			0.12	STMR-RAC		
401140	Hemp seeds			0.12	STMR-RAC		
401150	Castor beans			0.12	STMR-RAC		
401990	Other oilseeds			0.12	STMR-RAC		
402010	Olives for oil production			0.12	STMR-RAC		
402020	Oil palm kernels			0.12	STMR-RAC		
402030	Oil palm fruits			0.12	STMR-RAC		
402040	Kapok			0.12	STMR-RAC		
402990	Other oilfruit			0.12	STMR-RAC		
500010	Barley			0.79	STMR-RAC	0.79	STMR-RAC
500020	Buckwheat and other pseudo-cereals			0.79	STMR-RAC		
500030	Maize/corn			0.79	STMR-RAC		
500040	Common millet/proso millet			0.79	STMR-RAC		
500050	Oat			0.79	STMR-RAC		
500060	Rice			0.79	STMR-RAC		
500070	Rye			0.79	STMR-RAC	0.79	STMR-RAC
500080	Sorghum			0.79	STMR-RAC		
500090	Wheat			0.79	STMR-RAC	0.79	STMR-RAC
500990	Other cereals			0.79	STMR-RAC		
900010	Sugar beet roots			0.05	STMR-RAC		
900020	Sugar canes			0.05	STMR-RAC		
900030	Chicory roots			0.05	STMR-RAC		
900990	Other sugar plants			0.05	STMR-RAC		
1011010	Swine: Muscle/meat			0.03	STMR-RAC	0.03	HR-RAC
1011020	Swine: Fat tissue			0.03	STMR-RAC	0.03	HR-RAC
1011030	Swine: Liver			0.03	STMR-RAC	0.03	HR-RAC
1011040	Swine: Kidney			0.05	STMR-RAC	0.1	HR-RAC
1012010	Bovine: Muscle/meat			0.03	STMR-RAC	0.03	HR-RAC
1012020	Bovine: Fat tissue			0.03	STMR-RAC	0.03	HR-RAC
1012030	Bovine: Liver			0.03	STMR-RAC	0.03	HR-RAC
1012040	Bovine: Kidney			0.05	STMR-RAC	0.13	HR-RAC
1013010	Sheep: Muscle/meat			0.03	STMR-RAC	0.03	HR-RAC
1013020	Sheep: Fat tissue			0.03	STMR-RAC	0.03	HR-RAC
1013030	Sheep: Liver			0.03	STMR-RAC	0.03	HR-RAC
1013040	Sheep: Kidney			0.05	STMR-RAC	0.13	HR-RAC

				Chronic risk assessment[1)]		Acute risk assessment[2)]	
Code	**Commodity**	**existing/ proposed MRL**	**Source/ type of MRL**	**Input value (mg/kg)**	**Comment**	**Input value (mg/kg)**	**Comment**
1014010	Goat: Muscle/meat			0.03	STMR-RAC	0.03	HR-RAC
1014020	Goat: Fat tissue			0.03	STMR-RAC	0.03	HR-RAC
1014030	Goat: Liver			0.03	STMR-RAC	0.03	HR-RAC
1014040	Goat: Kidney			0.05	STMR-RAC	0.13	HR-RAC
1016010	Poultry: Muscle/meat			0.03	STMR-RAC	0.03	HR-RAC
1016020	Poultry: Fat tissue			0.03	STMR-RAC	0.03	HR-RAC
1016030	Poultry: Liver			0.03	STMR-RAC	0.03	HR-RAC
1020010	Milk: Cattle			0.03	STMR-RAC	0.03	STMR-RAC
1020020	Milk: Sheep			0.03	STMR-RAC	0.03	STMR-RAC
1020030	Milk: Goat			0.03	STMR-RAC	0.03	STMR-RAC
1020040	Milk: Horse			0.03	STMR-RAC	0.03	STMR-RAC
1020990	Milk: Others			0.03	STMR-RAC	0.03	STMR-RAC
1030010	Eggs: Chicken			0.03	STMR-RAC	0.03	HR-RAC
1030020	Eggs: Duck			0.03	STMR-RAC	0.03	HR-RAC
1030030	Eggs: Goose			0.03	STMR-RAC	0.03	HR-RAC
1030040	Eggs: Quail			0.03	STMR-RAC	0.03	HR-RAC
1030990	Eggs: Others			0.03	STMR-RAC		
1040000	Honey and other apiculture products			0.01	STMR-RAC		

(1) Normal mode

(2) Assessment of all crops

Table 7.2-38: Triazole lactic acid (TLA): Input values for the consumer risk assessment (according to UK, 2018b and new trials submitted)

				Chronic risk assessment[1)]		Acute risk assessment[2)]	
Code	**Commodity**	**existing/ proposed MRL**	**Source/ type of MRL**	**Input value (mg/kg)**	**Comment**	**Input value (mg/kg)**	**Comment**
110010	Grapefruits			0.04	STMR-RAC		
110020	Oranges			0.04	STMR-RAC		
110030	Lemons			0.04	STMR-RAC		
110040	Limes			0.04	STMR-RAC		
110050	Mandarins			0.04	STMR-RAC		
110990	Other citrus fruit			0.04	STMR-RAC		
130010	Apples			0.03	STMR-RAC		
130020	Pears			0.03	STMR-RAC		
130030	Quinces			0.03	STMR-RAC		
130040	Medlar			0.03	STMR-RAC		
130050	Loquats/Japanese medlars			0.03	STMR-RAC		
130990	Other pome fruit			0.03	STMR-RAC		
140010	Apricots			0.038	STMR-RAC		
140020	Cherries (sweet)			0.038	STMR-RAC		
140030	Peaches			0.038	STMR-RAC		
140040	Plums			0.038	STMR-RAC		
140990	Other stone fruit			0.038	STMR-RAC		
151010	Table grapes			0.04	STMR-RAC		
151020	Wine grapes			0.04	STMR-RAC		
152000	Strawberries			0.04	STMR-RAC		

				Chronic risk assessment[1)]		Acute risk assessment[2)]	
Code	Commodity	existing/ proposed MRL	Source/ type of MRL	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
153010	Blackberries			0.04	STMR-RAC		
153020	Dewberries			0.04	STMR-RAC		
153030	Raspberries (red and yellow)			0.04	STMR-RAC		
153990	Other cane fruit			0.04	STMR-RAC		
154010	Blueberries			0.04	STMR-RAC		
154020	Cranberries			0.04	STMR-RAC		
154030	Currants (red, black and white)			0.04	STMR-RAC		
154040	Gooseberries (green, red and yellow)			0.04	STMR-RAC		
154050	Rose hips			0.04	STMR-RAC		
154060	Mulberries (black and white)			0.04	STMR-RAC		
154070	Azarole/Mediteranean medlar			0.04	STMR-RAC		
154080	Elderberries			0.04	STMR-RAC		
154990	Other other small fruit & berries			0.04	STMR-RAC		
211000	Potatoes			0.021	STMR-RAC		
212010	Cassava roots/manioc			0.021	STMR-RAC		
212020	Sweet potatoes			0.021	STMR-RAC		
212030	Yams			0.021	STMR-RAC		
212040	Arrowroots			0.021	STMR-RAC		
212990	Other tropical root and tuber vegetables			0.021	STMR-RAC		
213010	Beetroots			0.021	STMR-RAC		
213020	Carrots			0.021	STMR-RAC		
213030	Celeriacs/turnip rooted celeries			0.021	STMR-RAC		
213040	Horseradishes			0.021	STMR-RAC		
213050	Jerusalem artichokes			0.021	STMR-RAC		
213060	Parsnips			0.021	STMR-RAC		
213070	Parsley roots/Hamburg roots parsley			0.021	STMR-RAC		
213080	Radishes			0.021	STMR-RAC		
213090	Salsifies			0.021	STMR-RAC		
213100	Swedes/rutabagas			0.021	STMR-RAC		
213110	Turnips			0.021	STMR-RAC		
213990	Other other root and tuber vegetables			0.021	STMR-RAC		
220010	Garlic			0.01	STMR-RAC		
220020	Onions			0.01	STMR-RAC		
220030	Shallots			0.01	STMR-RAC		
220040	Spring onions/green onions and Welsh onions			0.01	STMR-RAC		
220990	Other bulb vegetables			0.01	STMR-RAC		

				Chronic risk assessment[1)]		Acute risk assessment[2)]	
Code	**Commodity**	**existing/ proposed MRL**	**Source/ type of MRL**	**Input value (mg/kg)**	**Comment**	**Input value (mg/kg)**	**Comment**
231010	Tomatoes			0.03	STMR-RAC		
231020	Sweet peppers/bell peppers			0.03	STMR-RAC		
231030	Aubergines/egg plants			0.03	STMR-RAC		
231040	Okra/lady’s fingers			0.03	STMR-RAC		
231990	Other solanacea			0.03	STMR-RAC		
232010	Cucumbers			0.03	STMR-RAC		
232020	Gherkins			0.03	STMR-RAC		
232030	Courgettes			0.03	STMR-RAC		
232990	Other cucurbits - edible peel			0.03	STMR-RAC		
233010	Melons			0.03	STMR-RAC		
233020	Pumpkins			0.03	STMR-RAC		
233030	Watermelons			0.03	STMR-RAC		
233990	Other cucurbits - inedible peel			0.03	STMR-RAC		
234000	Sweet corn			0.03	STMR-RAC		
241010	Broccoli			0.01	STMR-RAC		
241020	Cauliflowers			0.01	STMR-RAC		
241990	Other flowering brassica			0.01	STMR-RAC		
242010	Brussels sprouts			0.01	STMR-RAC		
242020	Head cabbages			0.01	STMR-RAC		
242990	Other head brassica			0.01	STMR-RAC		
243010	Chinese cabbages/pe-tsai			0.01	STMR-RAC		
243020	Kales			0.01	STMR-RAC		
243990	Other leafy brassica			0.01	STMR-RAC		
244000	Kohlrabies			0.01	STMR-RAC		
251010	Lamb's lettuce/corn salads			0.08	STMR-RAC		
251020	Lettuces			0.08	STMR-RAC		
251030	Escaroles/broad-leaved endives			0.08	STMR-RAC		
251040	Cress and other sprouts and shoots			0.08	STMR-RAC		
251050	Land cress			0.08	STMR-RAC		
251060	Roman rocket/rucola			0.08	STMR-RAC		
251070	Red mustards			0.08	STMR-RAC		
251080	Baby leaf crops (including brassica species)			0.08	STMR-RAC		
251990	Other lettuce and other salad plants			0.08	STMR-RAC		
252010	Spinaches			0.08	STMR-RAC		
252020	Purslanes			0.08	STMR-RAC		
252030	Chards/beet leaves			0.08	STMR-RAC		
252990	Other spinach and similar			0.08	STMR-RAC		
253000	Grape leaves and similar species			0.08	STMR-RAC		
254000	Watercress			0.08	STMR-RAC		

				Chronic risk assessment[1)]		Acute risk assessment[2)]	
Code	**Commodity**	**existing/ proposed MRL**	**Source/ type of MRL**	**Input value (mg/kg)**	**Comment**	**Input value (mg/kg)**	**Comment**
255000	Witloofs/Belgian endives			0.08	STMR-RAC		
256010	Chervil			0.08	STMR-RAC		
256020	Chives			0.08	STMR-RAC		
256030	Celery leaves			0.08	STMR-RAC		
256040	Parsley			0.08	STMR-RAC		
256050	Sage			0.08	STMR-RAC		
256060	Rosemary			0.08	STMR-RAC		
256070	Thyme			0.08	STMR-RAC		
256080	Basil and edible flowers			0.08	STMR-RAC		
256090	Laurel/bay leaves			0.08	STMR-RAC		
256100	Tarragon			0.08	STMR-RAC		
256990	Other herbs			0.08	STMR-RAC		
260010	Beans (with pods)			0.01	STMR-RAC		
260020	Beans (without pods)			0.01	STMR-RAC		
260030	Peas (with pods)			0.01	STMR-RAC		
260040	Peas (without pods)			0.01	STMR-RAC		
260050	Lentils (fresh)			0.01	STMR-RAC		
260990	Other legume vegetables (fresh)			0.01	STMR-RAC		
270010	Asparagus			0.01	STMR-RAC		
270020	Cardoons			0.01	STMR-RAC		
270030	Celeries			0.01	STMR-RAC		
270040	Florence fennels			0.01	STMR-RAC		
270050	Globe artichokes			0.01	STMR-RAC		
270060	Leeks			0.01	STMR-RAC		
270070	Rhubarbs			0.01	STMR-RAC		
270080	Bamboo shoots			0.01	STMR-RAC		
270090	Palm hearts			0.01	STMR-RAC		
270990	Other stem vegetables			0.01	STMR-RAC		
300010	Beans			0.01	STMR-RAC		
300020	Lentils			0.01	STMR-RAC		
300030	Peas			0.01	STMR-RAC		
300040	Lupins/lupini beans			0.01	STMR-RAC		
300990	Other pulses			0.01	STMR-RAC		
401010	Linseeds			0.065	STMR-RAC		
401020	Peanuts/groundnuts			0.065	STMR-RAC		
401030	Poppy seeds			0.065	STMR-RAC		
401040	Sesame seeds			0.065	STMR-RAC		
401050	Sunflower seeds			0.065	STMR-RAC		
401060	Rapeseeds/canola seeds			0.065	STMR-RAC		
401070	Soyabeans			0.065	STMR-RAC		
401080	Mustard seeds			0.065	STMR-RAC		
401090	Cotton seeds			0.065	STMR-RAC		
401100	Pumpkin seeds			0.065	STMR-RAC		
401110	Safflower seeds			0.065	STMR-RAC		
401120	Borage seeds			0.065	STMR-RAC		

				Chronic risk assessment[1)]		Acute risk assessment[2)]	
Code	**Commodity**	**existing/ proposed MRL**	**Source/ type of MRL**	**Input value (mg/kg)**	**Comment**	**Input value (mg/kg)**	**Comment**
401130	Gold of pleasure seeds			0.065	STMR-RAC		
401140	Hemp seeds			0.065	STMR-RAC		
401150	Castor beans			0.065	STMR-RAC		
401990	Other oilseeds			0.065	STMR-RAC		
402010	Olives for oil production			0.065	STMR-RAC		
402020	Oil palm kernels			0.065	STMR-RAC		
402030	Oil palm fruits			0.065	STMR-RAC		
402040	Kapok			0.065	STMR-RAC		
402990	Other oilfruit			0.065	STMR-RAC		
500010	Barley			0.022	STMR-RAC	0.022	STMR-RAC
500020	Buckwheat and other pseudo-cereals			0.022	STMR-RAC		
500030	Maize/corn			0.022	STMR-RAC		
500040	Common millet/proso millet			0.022	STMR-RAC		
500050	Oat			0.022	STMR-RAC		
500060	Rice			0.022	STMR-RAC		
500070	Rye			0.022	STMR-RAC	0.022	STMR-RAC
500080	Sorghum			0.022	STMR-RAC		
500090	Wheat			0.022	STMR-RAC	0.022	STMR-RAC
500990	Other cereals			0.022	STMR-RAC		
900010	Sugar beet roots			0.01	STMR-RAC		
900020	Sugar canes			0.01	STMR-RAC		
900030	Chicory roots			0.01	STMR-RAC		
900990	Other sugar plants			0.01	STMR-RAC		
1012010	Bovine: Muscle/meat			0.03	STMR-RAC	0.03	HR-RAC
1012020	Bovine: Fat tissue			0.04	STMR-RAC	0.09	HR-RAC
1012030	Bovine: Liver			0.03	STMR-RAC	0.04	HR-RAC
1012040	Bovine: Kidney			0.03	STMR-RAC	0.03	HR-RAC
1013010	Sheep: Muscle/meat			0.03	STMR-RAC	0.03	HR-RAC
1013020	Sheep: Fat tissue			0.04	STMR-RAC	0.09	HR-RAC
1013030	Sheep: Liver			0.03	STMR-RAC	0.04	HR-RAC
1013040	Sheep: Kidney			0.03	STMR-RAC	0.03	HR-RAC
1014010	Goat: Muscle/meat			0.03	STMR-RAC	0.03	HR-RAC
1014020	Goat: Fat tissue			0.04	STMR-RAC	0.09	HR-RAC
1014030	Goat: Liver			0.03	STMR-RAC	0.04	HR-RAC
1014040	Goat: Kidney			0.03	STMR-RAC	0.03	HR-RAC
1016010	Poultry: Muscle/meat			0.03	STMR-RAC	0.03	HR-RAC
1016020	Poultry: Fat tissue			0.03	STMR-RAC	0.03	HR-RAC
1016030	Poultry: Liver			0.03	STMR-RAC	0.03	HR-RAC
1016040	Poultry: Kidney			0.03	STMR-RAC	0.03	HR-RAC
1016050	Poultry: Edible offals (other than liver and kideny)			0.03	STMR-RAC	0.03	HR-RAC
1016990	Poultry: Other products			0.03	STMR-RAC		
1020010	Milk: Cattle			0.03	STMR-RAC	0.03	STMR-RAC

				Chronic risk assessment[1)]		Acute risk assessment[2)]	
Code	**Commodity**	**existing/ proposed MRL**	**Source/ type of MRL**	**Input value (mg/kg)**	**Comment**	**Input value (mg/kg)**	**Comment**
1020020	Milk: Sheep			0.03	STMR-RAC	0.03	STMR-RAC
1020030	Milk: Goat			0.03	STMR-RAC	0.03	STMR-RAC
1020040	Milk: Horse			0.03	STMR-RAC	0.03	STMR-RAC
1020990	Milk: Others			0.03	STMR-RAC	0.03	STMR-RAC
1030010	Eggs: Chicken			0.03	STMR-RAC	0.03	HR-RAC
1030020	Eggs: Duck			0.03	STMR-RAC	0.03	HR-RAC
1030030	Eggs: Goose			0.03	STMR-RAC	0.03	HR-RAC
1030040	Eggs: Quail			0.03	STMR-RAC	0.03	HR-RAC
1030990	Eggs: Others			0.03	STMR-RAC		
1040000	Honey and other apiculture products			0.01	STMR-RAC		

(1) Normal mode
(2) Assessment of all crops

7.2.8.2 Conclusion on consumer risk assessment

Prothioconazole except TDMs
Extensive calculation sheets are presented in Appendix 3.

Table 7.2-39: Consumer risk assessment for prothioconazole-desthio (sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers))

TMDI (% ADI*) according to EFSA PRIMo 3.1	43% (based on NL toddler; main contributor: Milk:cattle)
IEDI (% ADI*) according to EFSA PRIMo 3.1	Normal mode: 15% (based on NL toddler; main contributor: milk: cattle); Refined calculation mode: 6% (based on DK child; main contributor: rye)
IESTI (% ARfD**) according to EFSA PRIMo 3.1	Wheat: 9% (based on unprocessed commodities, children) Wheat: 5% (based on unprocessed commodities, adults) Wheat (milling flour): 7% (based on processed commodities, children) Barley / beer: 5% (based on processed commodities, adults)

* ADI of prothioconazole-desthio
** ARfD of prothioconazole-desthio

The proposed uses of prothioconazole in the formulation ADM.03503.F.1.A do not represent unacceptable acute and chronic risks for the consumer with regard to residues of prothioconazole-desthio (sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers)).

TDMs:
Consumer exposure assessments for all four TDMs have been conducted by UK 2018b and EFSA 2018c during evaluation of the pesticide risk assessment for the triazole derivative metabolites in light of confirmatory data to which explicit reference is made. The EU MS NEDIs and NESTIs for each relevant TDM are below the respective ADIs and ARfDs:
EFSA 2018b: "The 'worst-case' consumer dietary intake assessment with regard to the TDMs for the complete group of triazole active substances that were assessed in the framework of these confirmatory data has been conducted by the RMS using the EFSA PRIMo rev.3 and by EFSA using the EFSA PRIMo rev.2A since PRIMo rev.3 is not applicable in the framework of confirmatory data assessed here.
The chronic and acute dietary intakes have been carried out using the highest input residue values for risk assessment (STMR values and the HR values), derived for each TDM for each crop groups and each product

of animal origin. Since in most of the residue trials in primary and rotational crops, higher residue levels of the TDMs in the control samples were observed, these levels were also considered in the dietary intake calculation. Using the EFSA PRIMo rev.3, the IEDI accounted for 93% of the ADI (NL toddler) for 1,2,4-T, 6% of the ADI (NL toddler) for TA, 1% of the ADI (NL toddler) for TAA and 1% of the ADI (NL toddler) for TLA. No acute intake concern was identified as the calculated international estimated short-term intake (IESTI) accounted for up to 40% of the ARfD (cattle milk) for 1,2,4-T, 28% of the ARfD (oranges) for TA, 1% of the ARfD (oranges) for TAA and 7% of the ARfD (potatoes) for TLA. Using the EFSA PRIMo rev.2A, the IEDI accounted for 60% of the ADI (FR toddler) for 1,2,4-T, 5% of the ADI (WHO Cluster diet B) for TA, 1% of the ADI (WHO Cluster diet B) for TAA and < 1% of the ADI (FR toddler) for TLA. The acute intake was estimated to be 40% of the ARfD (milk) for 1,2,4-T, 28% of the ARfD (oranges) for TA, 1% of the ARfD (oranges) for TAA and 6.7% of the ARfD (potatoes) for TLA. Since the toxicological reference values for TLA were derived by bridging with the reference values of TA, a combined dietary risk assessment for TA and TLA was performed. No chronic or acute intake concerns were identified with up to 6% ADI (WHO Cluster diet B), and 34% and 8% ARfD (watermelons) respectively for children and adults."
calculations based on input values given in UK, 2018b in Table 7.3.17-16 (for crop commodities) and in Table 7.7-1 of Appendix E thereof (for animal commodities) and involving the residue data of the new residue studies submitted with this dossier if higher were conducted.

In addition, new worst case calculations based on input values given in UK, 2018b in Table 7.3.17-16 (for crop commodities) and in Table 7.7-1 of Appendix E thereof (for animal commodities) and involving the residue data of the new residue studies if higher were conducted for the TDMs and results are given in the following:

Extensive calculation sheets are presented in Appendix 3:

Table 7.2-40: Consumer risk assessment for 1,2,4-triazole

TMDI (% ADI) according to EFSA PRIMo 3.1	Not applicable, no MRLs set.
IEDI (% ADI) according to EFSA PRIMo 3.1	Normal mode: 51% (based on NL toddler; main contributor: milk: cattle); Refined mode*: 44% (NL toddler; main contributor: milk: cattle)
IESTI (% ARfD) according to EFSA PRIMo 3.1	Milk: cattle: 20% (based on unprocessed commodities, children) Milk: cattle: 6% (based on unprocessed commodities, adults) Wheat (milling flour): 0.6% (based on processed commodities, children) Barley / beer: 0.4% (based on processed commodities, adults)

*Refined mode includes GAPs under assessment as well as livestock matrices/products.

Table 7.2-41: Consumer risk assessment for TA

TMDI (% ADI) according to EFSA PRIMo 3.1	Not applicable, no MRLs set.
IEDI (% ADI) according to EFSA PRIMo 3.1	Normal mode: 5% (based on NL toddler; main contributor: maize/corn); Refined mode*: 2% (DK child; main contributor: rye)
IESTI (% ARfD) according to EFSA PRIMo 3.1	Wheat: 3% (based on unprocessed commodities, children) Wheat: 2% (based on unprocessed commodities, adults) Wheat (milling flour): 3% (based on processed commodities, children) Barley / beer: 1% (based on processed commodities, adults)

*Refined mode includes GAPs under assessment as well as livestock matrices/products.

Table 7.2-42: Consumer risk assessment for TLA

TMDI (% ADI) according to EFSA PRIMo 3.1	Not applicable, no MRLs set.
IEDI (% ADI) according to EFSA PRIMo 3.1	Normal mode: 1% (based on NL toddler; main contributor: milk: cattle); Refined mode*: 0.7% (based on NL toddler; main contributor: milk: cattle)

IESTI (% ARfD) according to EFSA PRIMo 3.1	Milk: cattle: 1% (based on unprocessed commodities, children) Milk: cattle: 0.4% (based on unprocessed commodities, adults) Wheat (milling flour): 0.1% (based on processed commodities, children) Barley / beer: 0.1% (based on processed commodities, adults)

*Refined mode includes GAPs under assessment as well as livestock matrices/products.

Table 7.2-43: Consumer risk assessment for TAA

TMDI (% ADI) according to EFSA PRIMo 3.1	Not applicable, no MRLs set.
IEDI (% ADI) according to EFSA PRIMo 3.1	Normal mode: 1% (based on NL toddler; main contributor: maize/corn); Refined mode*: 0.9% (DK child; main contributor: rye)
IESTI (% ARfD) according to EFSA PRIMo 3.1	Wheat: 1% (based on unprocessed commodities, children) Wheat: 0.7% (based on unprocessed commodities, adults) Wheat (milling flour): 1% (based on processed commodities, children) Barley / beer: 0.6% (based on processed commodities, adults)

*Refined mode includes GAPs under assessment as well as livestock matrices/products.

TA and TLA can be assigned to a common assessment group. Therefore a combined risk assessment for these TDM can be performed by simple addition of NEDIs and NESTIs of both metabolites.

The combined EU IEDIs are less than the ADI of 0.3 mg/kg bw/day.
The combined EU IESTIs are less than the ARfD of 0.3 mg/kg bw/day.

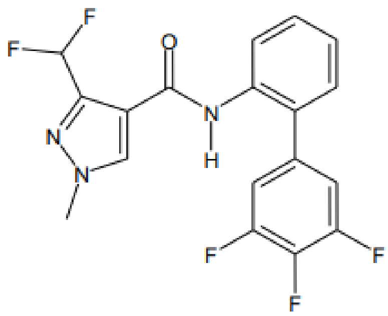
The proposed uses of prothioconazole in the formulation ADM.03503.F.1.A do not represent unacceptable acute and chronic risks for the consumer with regard to the residues of triazole alanine (TA), triazole lactic acid (TLA), triazole acetic acid (TAA) and 1,2,4-triazole (1,2,4-T).

Evaluator comment:
Calculations presented by the Applicant are acceptable.
The data available are considered sufficient for risk assessment. The chronic and the short-term intakes of prothioconazole residues and TDMs are unlikely to present a public health concern.
The intended uses of ADM.03503.F.1.A are accepted.

7.3 Fluxapyroxad

General data on fluxapyroxad are summarised in the table below (last updated 2022/03/11).

Table 7.3-1: General information on Fluxapyroxad

Active substance (ISO Common Name)	Fluxapyroxad
IUPAC	3-(difluoromethyl)-1-methyl-*N*-(3′,4′,5′-trifluorobiphenyl-2-yl)pyrazole-4-carboxamide
Chemical structure	
Molecular formula	$C_{18}H_{12}F_5N_3O$
Molar mass	381.31 g/mol
Chemical group	Pyrazole-carboxamide fungicide
Mode of action (if available)	SDHI (succinate dehydrogenase inhibitors)
Systemic	Yes
Company (ies)	BASF*
Rapporteur Member State (RMS)	RMS: France (previously United Kingdom) Co-RMS: Greece
Approval status	Approved. Date of approval: 01/01/2013 COMMISSION IMPLEMENTING REGULATION Reg. (EU) 2020/2007 COMMISSION IMPLEMENTING REGULATION Reg. (EU) No 589/2012
Restriction (e.g. is restricted to use as "...")	Only uses as fungicide may be authorised.
Review Report	SANCO/10692/2012 – final (01/06/2012) and revised version (25/03/2021)
Current MRL regulation	~~COMMISSION REGULATION (EU) 2021/644 of 15 April 2021~~ COMMISSION REGULATION (EU) 2022/1324 of 28 July 2022
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes
EFSA Journal : Conclusion on the peer review	Yes (Fluxapyroxad: EFSA, 2012)**
EFSA Journal: conclusion on article 12	Yes (EFSA, 2020)**
Current MRL applications on intended uses	None

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

7.3.1 Stability of Residues (KCA 6.2)

7.3.1.1 Stability of residues during storage of samples

Available data

Reference is made to the EU peer review (EFSA, 2012, DAR UK, 2011a and Addendum to DAR UK, 2011b) and to the MRL review (EFSA, 2020a) for fluxapyroxad.

A new storage stability study (KCA 6.1/04) analysing fluxapyroxad in flowers, nectar and pollen is submitted in the framework of this application. Results are summarised in the table below. The detailed assessments of these studies are presented in Appendix 2.

Table 7.3-2: Summary of stability data for fluxapyroxad and metabolites M700F008, M700F048 achieved at ≤ - 20°C

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration (months)	Reference
Data relied on in EU			
Plant products (Fluxapyroxad)			
Apples, tomato, potato, triticale (whole plant)	High water content	24	United Kingdom (2011a); EFSA (2012)
Avocado, soyabean seed	High oil content	24	United Kingdom (2011a); EFSA (2012)
Dried peas	High protein content	24	United Kingdom (2011a); EFSA (2012)
Wheat grain	High starch content	24	United Kingdom (2011a); EFSA (2012)
Lemon, grapes	High acid content	24	United Kingdom (2011a); EFSA (2012)
Wheat straw	Dry* commodity	24	United Kingdom (2011a); EFSA (2012)
New data			
Flowers, nectar, pollen	-	6	Linder, M. 2021, (KCA 6.1/04)
Plant products (M700F008, M700F048, M700F002)			
Apples, tomato, potato, triticale (whole plant)	High water content	24[1]	United Kingdom (2011a); EFSA (2012)
Apples, tomato, potato, triticale (whole plant)	High water content	4[2]	United Kingdom (2011a); EFSA (2012)
Avocado, soyabean seed	High oil content	24[1]	United Kingdom (2011a); EFSA (2012)
Avocado, soyabean seed	High oil content	4[2]	United Kingdom (2011a); EFSA (2012)
Wheat grain	High starch content	24[3]	United Kingdom (2011a); EFSA (2012)
Lemon, grapes	High acid content	24[1]	United Kingdom (2011a); EFSA (2012)
Wheat straw	Dry* commodity	24[3]	United Kingdom (2011a); EFSA (2012)
Apple (juice), soybean (refined oil), potato (crisps), grape (raisins), barley (beer)	Processed commodities	24[4]	United Kingdom (2011b); EFSA (2012)
Animal products			
Not investigated since all samples were stored frozen (-20°C) and analysed within 30 days.	-	-	EFSA (2020)

[1] For metabolites M700F002 and M700F048
[2] For only metabolite M700F008
[3] For metabolites M700F002, M700F048 and M700F008
[4] For only metabolite M700F048

* New matrix characteristic acc. to SANTE/2020/12830, Rev.1 February 2021 additionally given here

According to EFSA, 2012: "*Frozen storage stability studies showed acceptable stability of the residues of the parent compound (737 days) as well as its metabolites M700F002 (824 days) and M700F048 (733 days) in all commodities, and covered the storage period of the residue samples in the field residue trials. The desmethyl metabolite M700F008 was shown to be stable for up to 725 days in wheat grain (high starch content) and straw, but only for 133 days in high water and high oil content matrices*".
According to EFSA, 2020: "*All samples were stored at -20°C and analysed within 30 days, and therefore, specific storage stability studies are not deemed necessary (United Kingdom, 2011a)*".
No new studies are required or submitted.

Conclusion on stability of residues during storage
The storage conditions for all available residue trials were in compliance with the storage stability data. Decline of residues during storage of residue trials samples is therefore not expected.

7.3.1.2 Stability of residues in sample extracts (KCA 6.1)

The procedural recoveries in the residue studies demonstrate the stability of fluxapyroxad during storage in extracts prior to analysis.

Evaluator comments:
The stability of residues for the active substance fluxapyroxad was reviewed at the EU level. According to the EFSA Journal 2012;10(1):2522 (Peer Review of the pesticide risk assessment of the active substance fluxapyroxad (BAS 700 F)): *Frozen storage stability studies showed acceptable stability of the residues of the parent compound (737 days) as well as its metabolites M700F002 (824 days) and M700F048 (733 days) in all commodities, and covered the storage period of the residue samples in the field residue trials. The desmethyl metabolite M700F008 was shown to be stable for up to 725 days in wheat grain (high starch content) and straw, but only for 133 days in high water and high oil content matrices.*

In the matrices: cereal forage, grain and straw, fluxapyroxad and its metabolites M700F002, M700F008 and M700F048 proved to be stable for two years. As far as residues in animal matrices (egg, milk, tissues) are concerned, freezer storage stability data is not required to support the submitted data packages as samples generally were stored frozen, not exceeding 30 days.
The studies on the magnitude of residues are valid with regard to storage stability.

The study of Lindner, M., 2021 - "*Storage Stability of Fluxapyroxad in Flowers, Nectar and Pollen under Deep Frozen Conditions"* was evaluated by the zRMS in the framework of this application. The storage stability of fluxapyroxad was demonstrated in flowers, nectar, pollen at ≤ -18 °C in the dark over a storage period of up to 6 months.

No additional data are required.

7.3.2 Nature of residues in plants, livestock and processed commodities

7.3.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data
Reference is made to the EU peer review (EFSA, 2012, DAR UK, 2011a and Addendum to DAR UK, 2011b) and to the MRL review (EFSA, 2020) for fluxapyroxad.

The metabolism of fluxapyroxad was investigated following foliar applications on fruits, pulses and oilseeds and cereals and also on wheat following seed treatment using fluxapyroxad radiolabelled in both the aniline and pyrazole rings of the molecule. The characteristics of all these studies are summarised in the following table.

Table 7.3-3: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate	No	Sampling (DAT)	Remarks	
EU data								
Fruits and fruiting vegetable	Tomato	Radiolabelled fluxapyroxad: aniline and pyrazole rings	Foliar treatment, G	100 g a.s./ha, interval 7 days	3	3	Fluxapyroxad was the major component	United Kingdom, 2011b; EFSA, 2012; EFSA 2020
Pulses and oilseeds	Soyabean	Radiolabelled fluxapyroxad: aniline and pyrazole rings	Foliar treatment, G	60 g a.s./ha, BBCH 16-17, 51-59, 71-75	3	0 DAT, 34 DALA	Fluxapyroxad was the major component	United Kingdom, 2011b; EFSA, 2012; EFSA 2020
Cereals	Wheat	Radiolabelled fluxapyroxad: aniline and pyrazole rings	Foliar treatment, G	125 g a.s./ha, BBCH 30-35, 69	2	36 DAT, 4, 34-35 DALA	Fluxapyroxad was the major component	United Kingdom, 2011b; EFSA, 2012; EFSA 2020
Cereals	Wheat	Radiolabelled fluxapyroxad: aniline and pyrazole rings	Seed treatment	75 g a.s./100 kg (equivalent to 135 g a.s./ha)	N/A	93, 112, 161 DAT	Fluxapyroxad was the major component	EFSA, 2015

a): Outdoor/field application (F) or glasshouse/protected/indoor application (G)
DALA: Days after last application
DAT: Days after treatment

Summary of plant metabolism studies reported in the EU

According to EFSA, 2012: "The metabolism of fluxapyroxad (BAS 700 F) was investigated in tomatoes (fruit crops), soyabean (pulses and oilseed crops) and in wheat (cereals) under greenhouse conditions after foliar spray applications using the ^{14}C labelling on the aniline and the pyrazole moieties, respectively. Fluxapyroxad (BAS 700 F) was identified as the major component of the radioactive residues in the tomato and cereal plant parts investigated, accounting for 54 % TRR up to more than 90 % TRR and residue concentrations of 0.03 mg/kg in wheat grains and up to 0.16 mg/kg in tomato fruits. The metabolism was more extensive in soyabean seeds where fluxapyroxad (BAS 700 F) accounted for only 7 % TRR up to 21 % TRR, and the major metabolites were identified as M700F002 (33.5 % TRR, pyrazole labelling) and M700F048 (20 % TRR, aniline labelling). Minor metabolites were identified at very low levels, accounting for less than 2 % of the TRR. Based on these studies, the main routes of biotransformation of fluxapyroxad (BAS 700 F) in plants were proposed to consist of N-demethylation of the pyrazole moiety, and hydroxylation of the biphenyl moiety with further glycosidation of the molecule. A minor pathway consisted of the loss of a fluorine atom at the biphenyl ring. No cleavage of the molecule was foreseen and the presence in soyabean seeds of the metabolite M700F002 resulting from the cleavage of the carboxamide bond was assumed to result from its uptake from the soil, where M700F002 was identified as a major soil metabolite. This statement is supported by the fact that the corresponding biphenyl counterpart metabolites were not detected in the primary crops when the labelling on the aniline moiety was used, and also by the higher total radioactive residues measured in soyabean seeds in the ^{14}C-pyrazole study compared to the ^{14}C-aniline study (0.26 mg/kg vs. 0.12 mg/kg).

Fluxapyroxad (BAS 700 F) was considered as a valid marker of the total residues in plants, and the residue definition for monitoring was limited to the parent compound only. For risk assessment, the inclusion of the metabolites M700F002 and M700F048 was considered during the peer review. Since metabolite M700F002 was concluded by the Pesticides Peer Review Experts' Meeting 88 to be less toxic than the parent compound (see section 2), EFSA proposes not to include this metabolite in the residue definition for risk assessment. Metabolite M700F048 was shown to be of similar toxicity as the parent compound, and as it was recovered at comparable levels in soyabean seeds, it was initially suggested to include this metabolite in the residue definition. However, in the framework of a MRL application (EFSA, 2011a), metabolite M700F048 was shown not to be present in supervised residue trials conducted in the USA and Canada in support of an import tolerance request on soyabean crop. Therefore, having regard to the results of the North American residue trials, EFSA is of the opinion not to include metabolite M700F048 and to limit the residue definition for risk assessment to fluxapyroxad (BAS 700 F) only for all categories of crops."

According to EFSA, 2020: "The metabolism of fluxapyroxad was similar in all crops following foliar application and seed treatment. Fluxapyroxad is the only toxicologically relevant compound to be considered in the consumer exposure. In the framework of the peer review, the residue definition for risk assessment was proposed as fluxapyroxad (EFSA, 2012). The same residue definition is proposed in the current review. The metabolism in rotational crops is similar to the metabolism observed in primary crops and the processing of fluxapyroxad is not expected to modify the nature of residues. For soil treatments, the metabolism in primary and rotational crops is depicted by the metabolism studies performed in the confined rotational crops on spinach, white radish and spring wheat.
As the parent compound was found to be a sufficient marker in fruits, pulses and oilseeds and cereals, the residue definition for enforcement is proposed as fluxapyroxad only."

Summary of new plant metabolism studies
No new data submitted in the framework of this application.

Conclusion on metabolism in primary crops
Based on the evaluations of EFSA 2012 and EFSA 2020, the following residue definitions are proposed:
<u>Residue definition for enforcement</u>:

- Fluxapyroxad

<u>Residue definition for risk assessment</u>:

- Fluxapyroxad

Evaluator comments:
Information given by the Applicant is sufficient.
The plant metabolism in tomatoes (fruit crops), soyabean (pulses and oilseed crops) and wheat (cereal crops) was evaluated as part of the EU approval of the active substance.
The agreed plant residue definition for monitoring and risk assessment is: 'fluxapyroxad'.

The metabolism of ~~fludioxonil~~ fluxapyroxad in plants following foliar treatment applications is sufficiently addressed to support the proposed uses of the product ADM.03503.F.1.A. No additional study is required.

7.3.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data
Reference is made to the EU peer review (EFSA, 2012 and DAR UK, 2011a) for fluxapyroxad.
No new data are submitted in the framework of this application.

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

Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G *	Rate (g a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks	
EU data								
Leafy vegetables	Spinach	Radiolabelled fluxapyroxad: aniline and pyrazole rings	Bare soil, F	1 x 250	30, 120/149 and 365	At maturity; Additional immature samples at PBI 365 days only	Fluxapyroxad and metabolite M700F002 were major components	United Kingdom, 2011a; EFSA, 2012
Root and tuber	White	Radiolabelled	Bare soil,	1 x 250	30,	Root	Fluxapyroxad	United

vegetables	radish	fluxapyroxad: aniline and pyrazole rings	F		120/149 and 365	samples at maturity; Additional plant samples at PBI 149 and 365 days	and metabolite M700F002 were major components	Kingdom, 2011a; EFSA, 2012
Cereals	Spring wheat	Radiolabelled fluxapyroxad: aniline and pyrazole rings	Bare soil, F	1 x 250	30, 120/149 and 365	Grain and straw at maturity; Forage samples harvested after 34, 15 to 29 days and 47 to 63 days after sowing at PBIs 30, 149 and 365 days	Fluxapyroxad and metabolite M700F002 were major components	United Kingdom, 2011a; EFSA, 2012

(a): Outdoor/field application (F) or glasshouse/protected/indoor application (G)
n.r. Not reported

Summary of plant metabolism studies reported in the EU
According to EFSA, 2020: "One confined rotational crop study with fluxapyroxad radiolabelled on the aniline and pyrazole rings of the molecule was available for this review (United Kingdom, 2011a; EFSA, 2012). Fluxapyroxad was applied once at a rate of 250 g a.s./ha onto bare soil. Spinach, white radish and spring wheat were planted at nominal plant back intervals (PBI) of 30, 120/149 and 365 days after treatment (DAT). Residues in wheat straw were up to 2.2 mg/kg (pyrazole label) and 2.65 mg/kg (aniline label), in spinach up to 0.18 mg/kg and 0.1 mg/kg for the pyrazole and aniline labels, respectively, and in roots up to 0.015 mg/kg for both labels (United Kingdom, 2011a). Residues in wheat grain accounted for 0.043 mg/kg and 0.02 mg/kg for the pyrazole and aniline labels, respectively (United Kingdom, 2011a).
Fluxapyroxad was the major component in all matrices, while metabolite M700F002 was also present at relevant levels in all matrices. No specific compound for rotational crops was identified. The metabolism and distribution of fluxapyroxad in rotational crops are similar to the metabolic pathway observed in primary crops (EFSA, 2012)".

Summary of new plant metabolism studies
No new data submitted in the framework of this application.

Conclusion on metabolism in rotational crops
Specific plant-back restrictions related to the intended use of fluxapyroxad are not required.

Evaluator comments:
Information given by the Applicant is sufficient.
A similar residue pattern as in the primary crops was observed in the edible parts of the rotated crops.
No further data are required to support the proposed uses.

7.3.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data
Reference is made to the EU peer review (EFSA, 2012 and Addendum to DAR UK, 2011b) for fluxapyroxad.
No new data are submitted in the framework of this application.

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

Conditions (Duration, Temperature, pH)	Identified compound(s) (%)	Reference
EU data		
Pasteurisation (20 minutes, 90°C, pH 4)	Parent (97.3%)	United Kingdom, 2011b; EFSA, 2012
Baking, boiling, brewing (60 minutes, 100°C, pH 5)	Parent (101.6%)	United Kingdom, 2011b; EFSA, 2012
Sterilisation (20 minutes, 120°C, pH 6)	Parent (96.7%)	United Kingdom, 2011b; EFSA, 2012

According to EFSA, 2012: "*Fluxapyroxad (BAS 700 F) was shown to remain stable under standard hydrolytic conditions representative of pasteurisation, baking, boiling, brewing and sterilisation*".

Conclusion on nature of residues in processed commodities

Fluxapyroxad is stable under hydrolytic conditions representative of pasteurisation, baking, brewing and boiling and sterilisation. Therefore, the relevant residues for enforcement and risk assessment in processed commodities are expected to be the same as for primary crops.

Evaluator comments:
In the EFSA Journal 2012;10(1):2522 it is stated that fluxapyroxad (BAS 700 F) was shown to remain stable under standard hydrolytic conditions representative of pasteurisation, baking, boiling, brewing and sterilisation.
The residue definition for processed commodities: 'fluxapyroxad'.
No further data are required to support the proposed uses.

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

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

Endpoints	
Plant groups covered	Cereals (wheat) Fruit (tomato) Pulses and oilseeds (soyabean)
Rotational crops covered	Confined metabolism studies on leafy crops (spinach), root crops (radish) and cereals (wheat).
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Parent compound stable under hydrolytic conditions representative of pasteurisation, baking, brewing and boiling and sterilisation
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes
Plant residue definition for monitoring	Fluxapyroxad* (Reg. (EU) 2022/1324)
Plant residue definition for risk assessment	Fluxapyroxad*
Conversion factor from enforcement to RA	N/A

* Peer review of the pesticide risk assessment of the active substance fluxapyroxad (EFSA, 2012); Reasoned Opinion on the review of the existing maximum residue levels for fluxapyroxad accord-ing to Article 12 (EFSA 2020)
N/A: Not applicable, residue definition for monitoring and risk assessment are same.

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

Available data

Reference is made to the EU peer review (EFSA, 2012, DAR UK, 2011a and Addendum to DAR UK, 2011b) for fluxapyroxad.

No new data submitted in the framework of this application.

Table 7.3-7: Summary of animal metabolism studies

Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling	
EU data								
Lactating ruminants	Goat	Radiolabelled fluxapyroxad: aniline and/or pyrazole rings	4	0.4	8	Milk	Twice daily	United Kingdom, 2011a; EFSA, 2012
						Urine and faeces	Daily	
						Tissues	At sacrifice	
Laying poultry	Hens	Radiolabelled fluxapyroxad: aniline and/or pyrazole rings	12	0.4	12	Eggs	Twice daily	United Kingdom, 2011a; EFSA, 2012
						Excreta	Daily	
						Tissues	at sacrifice	
Lactating ruminants	Goat	Radiolabelled M700F002: pyrazole ring	2	0.4	8	Milk	Twice daily	United Kingdom, 2011a
						Urine and faeces	Daily	
						Tissues	At sacrifice	
Laying poultry	Hens	Radiolabelled M700F002: pyrazole ring	10	0.84	10	Eggs	Twice daily	United Kingdom, 2011b
						Excreta	Daily	
						Tissues	At sacrifice	

Summary of animal metabolism studies reported in the EU

According to EFSA, 2012: “Metabolism studies on lactating goats and laying hens were provided showing that besides the parent compound, the desmethyl metabolite M700F008 was found to be a significant compound of the total residues in all the ruminant and poultry matrices (17 % to 83 % TRR). Further minor metabolites were detected at a trace level (< 0.01 mg/kg) and resulted from the hydroxylation of the biphenyl moiety with a further step of conjugation reactions with glucuronic acid, amino acids or sulfate. An additional metabolism study on poultry using the ^{14}C-labelled M700F002 was provided and evaluated in Addendum 2 to the DAR (The United Kingdom, 2011b). Unchanged M700F002 was the major component of the total residues identified in all matrices (30 % to 90 % TRR). The agreed residue definition for monitoring in animal matrices is the parent compound only, whereas for risk assessment it is proposed to include both the parent compound and the desmethyl metabolite M700F008 expressed as parent equivalent.”

According to EFSA, 2020: “The metabolism of fluxapyroxad residues in livestock was investigated in lactating goats and laying hens (United Kingdom, 2011a) at dose rates covering the maximum dietary burdens calculated in this review (2.5–10N). These studies were assessed in the framework of the peer review (EFSA, 2012). In all studies, fluxapyroxad was radiolabelled in the aniline and/or pyrazole ring of the molecule.

The study on lactating goats fed for 8 consecutive days with 0.4 mg/kg body weight (bw) per day showed that fluxapyroxad was rapidly excreted, with more than 80% of the TRR recovered in urine and faeces. Parent was the main constituent, while another predominant component was metabolite M700F008 present at relevant levels in ruminant matrices (EFSA, 2012).

The study performed on laying hens fed for 12 consecutive days with 11.5 mg/kg feed (equivalent to 0.4 mg/kg bw per day) showed that fluxapyroxad was extensively degraded in livestock matrix (<0.5% and 0.18% of the TRR in tissues and eggs, respectively). The parent and metabolite M700F008 were the main constituents of the residues in hens.

In livestock, parent compound and metabolite M700F008 were the main constituents of the residues in all matrices. All other identified metabolites were present at more than 10% TRR but at levels lower than 0.003 mg/kg. Therefore, the metabolism of fluxapyroxad in livestock is adequately elucidated, and fluxapyroxad and metabolite M700F008 are the most relevant components of the residues in livestock commodities.

As the parent compound was found to be a sufficient marker in livestock commodities, the residue definition for enforcement is proposed as fluxapyroxad only.

In the framework of the peer review upon consideration of metabolism data and mammalian toxicology information, the residue for risk assessment was defined as sum of fluxapyroxad and metabolite M700F008, expressed as parent equivalent (EFSA, 2012). The same residue definition is proposed for the current review."

Summary of new animal metabolism studies
No new data submitted in the framework of this application.

Conclusion on metabolism in livestock
The metabolic patterns identified in lactating goat and laying hens is consistent with the rat metabolism and a specific metabolism study in pigs is not considered necessary. During EU assessment, the relevant residue for enforcement was defined as the parent compound fluxapyroxad in commodities of animal origin. The residue for risk assessment was defined as sum of fluxapyroxad and metabolite M700F008, expressed as parent equivalents. The same residue definitions are used for the current dossier.

Evaluator comments:
Animal metabolism in lactating goats and laying hens were considered during the EU approval of the active substance. The agreed animal residue definition for monitoring is: 'fluxapyroxad'.
The agreed animal residue definition for risk assessment is 'fluxapyroxad + metabolite M700F008 expressed as parent equivalent'.
No further data are required to support the proposed uses.

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

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

	Endpoints
Animals covered	Lactating goats
	Laying hens
Time needed to reach a plateau concentration	5-7 days in milk
	10-12 days in eggs
Animal residue definition for monitoring	Fluxapyroxad[(a)] (Reg. (EU) 2022/1324)
Animal residue definition for risk assessment	Sum of fluxapyroxad and metabolite M700F008 expressed as parent equivalents[(a)]
Conversion factor[(b)]	Ruminants Muscle, Fat, Kidney, Milk: 2 Liver: 3 Poultry Muscle, Fat, Liver: 2 Eggs: 4 (EFSA, 2020)
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	Yes

(a) Peer review of the pesticide risk assessment of the active substance fluxapyroxad (EFSA, 2012)
(b) Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment

7.3.3 Magnitude of residues in plants (KCA 6.3)

Available data
Where applicable, reference is made to the EU peer review (EFSA, 2012) and to the MRL review (EFSA, 2015 and 2020) for fluxapyroxad.

In addition, new residue studies are submitted by the applicant in the framework of this application. All studies are summarised in the summary tables below. The detailed assessment of the new studies is presented in Appendix 2.
The intended critical GAPs for cereals are covered by the representative EU GAP and the US (import) GAP uses of fluxapyroxad as evaluated during the Article 12 MRL review process with regard to residue studies. Therefore, the existing EU/US data are used for risk assessment in this dossier, following the EFSA approach (EFSA, 2020a) and the new trials are provided for information purpose only.

Residue definition for enforcement:
• Fluxapyroxad
Residue definition for risk assessment:
• Fluxapyroxad

Wheat

Table 7.2- 1: Comparison of intended and critical EU GAPs in wheat (fluxapyroxad)

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Wheat					
cGAP, N-EU (EFSA, 2012; France, 2018; EFSA 2020)	2	0.0417-0.125 kg as/ha	21 days	25-69	35
cGAP, US (import) (EFSA, 2020)	2	0.100 kg as/ha	-	-	21
Intended cGAP (1)	1	93.75 g as/ha	-	30-69	n.a.

* Critical GAP number(s) in accordance with column 0 of ~~Błąd! Nie można odnaleźć źródła odwołania.~~. Table 7.1- 1.
n.a. Not applicable

According to the available data, the intended outdoor uses on wheat in C-EU are considered acceptable. According to EC TG SANTE/2019/12752, extrapolation from wheat to rye (and triticale) is acceptable. The data submitted show that no exceedance of the current EU MRL will occur. The uses are considered acceptable.

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

Table 7.3-9: Summary of EU reported and new data on fluxapyroxad supporting the intended uses of ADM.03503.F.1.A in wheat and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg)*	MRL compliance
E: Fluxapyroxad **RA: Fluxapyroxad**								
EU critical GAP Spring and winter wheat, grain and straw Extrapolation from wheat → rye and triticale Extrapolation from spring cereals ↔ winter cereals due to late application timing	EFSA, 2012; France, 2018; EFSA 2020a	N-EU	GAP on which EU a.s. assessment is based: 2 x 0.125 kg as/ha upto BBCH 35, 21 days interval, PHI 35 days, outdoor **Wheat grain**: E/RA: 0.016; 0.019; 0.02; 0.02; 3 x 0.03; 0.04; 0.04; 0.05; 0.06; 0.07 For livestock dietary burden assessment only: **Wheat straw**: RA: 0.41; 0.44; 0.52; 0.95; 1.0; 1.02; 1.04; 1.1; 1.17; 1.53; 1.56; 1.80; 2.78; 3.92; 4.58; 6.05	**Grain**: E: 0.03 **Straw**: RA: 1.14	E: 0.07 RA: 6.05	E: 0.15 RA: n.r.	Wheat grain: 0.4	Yes
US (import) critical GAP Spring and winter wheat, grain and straw	EFSA 2020a	US	GAP on which EU a.s. assessment is based: 2 × 0.100 kg as/ha, PHI 21 days, outdoor **Wheat grain**: E/RA: 0.05; 0.05; 0.07; 0.08; 0.11; 0.12; 0.12; 0.17; 0.19; 0.21 **Wheat Straw[(a)]:** -	**Grain**: E: 0.12 **Straw**: RA: -	E: 0.21 RA: -	E: 0.4 RA: n.a.	Wheat grain: 0.4	Yes

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg)*	MRL compliance
E: Fluxapyroxad RA: Fluxapyroxad								
Critical GAP (1)	New trials KCA 6.3.1/03	N-EU	Trials GAP: 1× 0.09375 kg a.s./ha applied in wheat at BBCH 30-69, PHI n.a., outdoor **Wheat grain:** E/RA: 0.026; 0.035; 0.043; 0.049 For livestock dietary burden assessment only: **Wheat straw:** RA: 0.63; 1.3; 2.9; 5.0	**Grain**: E: 0.039 **Straw**: RA: 2.1	E: 0.049 RA: 5.0	E: 0.15 RA: n.r.	Wheat grain: 0.4	Yes
	Overall supporting data for EU cGAP	N-EU	**Wheat grain (US):** E/RA: 0.05, 0.05, 0.07, 0.08, 0.11, 0.12, 0.12, 0.17, 0.19, 0.21 For livestock dietary burden assessment only: **Wheat straw (N-EU):** RA: 0.41, 0.44, 0.52, 0.95, 1.0, 1.02, 1.04, 1.1, 1.17, 1.53, 1.56, 1.80, 2.78, 3.92, 4.58, 6.05	**Grain**: E: 0.12 **Straw**: RA: 1.14	E: 0.21 RA: 6.05	E: 0.4 RA: n.r.	Wheat grain: 0.4	Yes

*Source of EU MRL: Reg (EU) ~~2021/644~~ Reg. (EU) 2022/1324
(a) STMR and HR for wheat straw are derived from the N-EU data
n.a. Not applicable

Barley

Table 7.3-10: Comparison of intended and critical EU GAPs in barley (fluxapyroxad)

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Barley					
cGAP, N-EU (EFSA, 2012; France, 2018; EFSA 2020)	2	0.0417-0.125 kg as/ha	21 days	25-69	35
cGAP, US (import) (EFSA, 2020)	2	0.100 kg as/ha	-	-	21
Intended cGAP (2)	1	93.75 g as/ha	-	30-65	n.a.

* Critical GAP number(s) in accordance with column 0 of ~~Błąd! Nie można odnaleźć źródła odwołania..~~ Table 7.1- 1.

According to the available data, the intended outdoor uses on barley in C-EU are considered acceptable.
The intended critical GAPs in barley (spring and winter barley) are covered by the representative EU and US (import) GAP uses of fluxapyroxad in cereals (barley) as evaluated during the Article 12 MRL review process with regard to residue studies. Therefore, the existing EU/US data are used for risk assessment in this dossier and the new trials are provided for information purpose only.
The new data submitted show that no exceedance of the current EU MRL will occur. The uses are considered acceptable.

Table 7.3-11: Summary of EU reported and new data on fluxapyroxad metabolites supporting the intended uses of ADM.03503.F.1.A in barley and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
E: Fluxapyroxad RA: Fluxapyroxad								
EU critical GAP Spring and winter barley, grain and straw Extrapolation from spring cereals ↔ winter cereals due to late application timing	EFSA, 2012; France, 2018; EFSA 2020a	N-EU	GAP on which EU a.s. assessment is based: 2× 0.125 kg as/ha, up to BBCH 69, 21 days interval, PHI 35 days, outdoor **Barley grain**: E/RA: 0.08; 0.08; 0.099; 0.11; 0.11; 0.13; 0.17; 0.19; 0.20; 0.21; 0.23; 0.24; 0.36; 0.38; 0.38 For livestock dietary burden assessment only: **Barley straw**: 0.47; 0.62; 0.64; 0.70; 0.74; 0.99; 1.30; 1.50; 1.54; 1.71; 1.79; 2.10; 2.37; 2.39; 2.45; 3.55	**Grain**: E: 0.19 **Straw**: RA: 1.52	E: 0.38 RA: 3.55	E: 0.7 RA: n.r.	Barley grain: 3	Yes
US (import) critical GAP	EFSA 2020a	US	GAP on which EU a.s. assessment is based: 2× 0.125 kg as/ha, up to BBCH 69, 21 days interval, PHI 35 days, outdoor **Barley grain**: E/RA: < 0.01; 0.41; 0.42; 0.42; 0.52; 0.54; 0.54; 0.55; 0.82; 0.88; 1.09; 1.65 **Barley straw[(a)]**: -	**Grain:** E: 0.54 **Straw**: RA: -	E: 1.65 RA: -	E: 3 RA: -	Barley grain: 3	Yes
Critical GAP (2)	New trials KCA 6.3.2/06	N-EU	Trials GAP: 1× 0.09375 kg a.s./ha applied in barley at BBCH 30-65, PHI n.a., outdoor **Barley grain:**	**Grain:** E: 0.17 **Straw**: RA:	E: 0.38	E: 0.7	Barley grain: 3	Yes

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
			E/RA: 0.11; 0.16; 0.18; 0.38 For livestock dietary burden assessment only: **Barley straw:** RA: 0.52; 0.67; 1.3; 1.6	0.99	RA: 1.6	RA: n.r.		
	Overall supporting data for EU cGAP	N-EU	**Barley grain (US):** E/RA: < 0.01; 0.41; 0.42; 0.42; 0.52; 0.54; 0.54; 0.55; 0.82; 0.88; 1.09; 1.65 For livestock dietary burden assessment only: **Barley straw (N-EU):** RA: 0.47; 0.62; 0.64; 0.70; 0.74; 0.99; 1.30; 1.50; 1.54; 1.71; 1.79; 2.10; 2.37; 2.39; 2.45; 3.55	**Grain:** E: 0.54 **Straw**: RA: 1.52	E: 1.65 RA: 3.55	E: 3 RA: n.r.	Barley grain: 3	Yes

* Source of EU MRL: ~~2021/644~~ Reg. (EU) 2022/1324
(a) STMR and HR for barley straw are derived from the N-EU data
n.a. Not applicable

7.3.3.2 Conclusion on the magnitude of residues in plants

Wheat, rye, triticale

According to the available data, the intended uses on wheat, rye and triticale are considered acceptable. Four new trials for the product ADM.03503.F.1.A on wheat from northern Europe are submitted, however the GAP used in the current dRR is less critical than the GAPs evaluated used in Article 12 MRL review. Therefore the EU and US (import) data (EFSA, 2020) are used to perform animal dietary burden calculations and consumer risk assessments. The MRL derived from the new residue trial data on wheat show that no exceedance of the current EU MRL for fluxapyroxad of 0.4 mg/kg for wheat and rye is expected.
Extrapolation from trials conducted in wheat (grain and straw) to rye and triticale is permitted according to SANTE/2019/12752.

Barley

According to the available data, the intended uses on barley are considered acceptable. Four new trials for the product ADM.03503.F.1.A on barley from northern Europe are submitted, however the GAP used in the current dRR is less critical than the GAPs evaluated in Article 12 MRL review. Therefore the EU and US (import) data (EFSA, 2020) are used to perform the animal dietary burden calculations and consumer risk assessments. MRL derived from the new residue trial data on barley show that no exceedance of the current EU-MRL for fluxapyroxad of 3.0 mg/kg for barley is expected.

zRMS comments:
Information given by the Applicant is sufficient.

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

Sufficient residue trial data is presented in EFSA Journal 2011;9(6):2196 68 and in EFSA Journal 2012;10(1):2522. In addition to this new four GAP compliant residue trials on wheat in Northern Europe have been submitted by the Applicant. These trials were conducted within an application rate of 93.75 g/ha of Fluxapyroxad at BBCH 69.
The trials are supported by valid storage stability data and validated analytical method.

In seed specimens taken at normal commercial harvest residues of fluxapyroxad were between 0.026 and 0.049 mg/kg.

Available results show that the in force MRL of fluxapyroxad on wheat and rye of 0.4 mg/kg (Reg. (EU) 2022/1324) will not be exceeded. According to Commission Regulation (EU) No 752/2014 replacing Annex I to Regulation (EC) No 396/2005, MRLs for wheat (code number: 0500090) are also applicable to triticale (code number: 0500090-006).
The current EU MRLs for fluxapyroxad are sufficient to support the proposed uses.

More details of the residue study on wheat are provided in Appendix 2.
The proposed uses on wheat, triticale and rye are considered acceptable.

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

Sufficient residue trial data is presented in EFSA Journal 2011;9(6):2196 68 and in EFSA Journal 2012;10(1):2522. In addition to this new four GAP compliant residue trials on barley in Northern Europe have been submitted by the Applicant. These trials were conducted within an application rate of 93.75 g/ha of Fluxapyroxad at BBCH 69.
The trials are supported by valid storage stability data and validated analytical method.

In seed specimens taken at normal commercial harvest residues of fluxapyroxad were between 0.11 and 0.38 mg/kg. Available results show that the in force MRL of fluxapyroxad on barley of 3 mg/kg (Reg. (EU) 2022/1324) will not be exceeded. The current EU MRLs for fluxapyroxad are sufficient to support the proposed uses.

More details of the residue study on barley are provided in Appendix 2.

The proposed use on barley is considered acceptable.

7.3.4 Magnitude of residues in livestock

7.3.4.1 Dietary burden calculation

The livestock dietary burden calculation made by EFSA in the framework of the Article 12 evaluation is available for fluxapyroxad (see EFSA, 2020). Fluxapyroxad is authorised for use on several crops that might be fed to livestock. EFSA calculated the livestock dietary burdens for different groups of livestock using the agreed European methodology (European Commission, 1996).
According to EFSA, 2020: “Fluxapyroxad is authorised for use on crops that might be fed to livestock (e.g. cereals, sugar beets). Livestock dietary burden calculations were therefore performed for different groups of livestock according to OECD guidance (OECD, 2013), which has now also been agreed upon at European level.” “Since residues from rotational crop field studies could contribute to the dietary burden, combined residue from primary uses and from rotational crop field studies were combined and used as input values (see Appendix B.1.2.2.(c)). According to this calculation, the main contributors to the dietary burden are the residue in wheat straw and rye straw from primary uses and potato (processed) from the combined residues of primary uses and rotational crop field studies. The dietary burdens calculated for all groups of livestock were found to exceed the trigger value of 0.1 mg/kg dry matter (DM). Behaviour of residues was therefore assessed in all commodities of animal origin”.

The input values as used in EFSA, 2020a (Article 12 MRL review by EFSA) for the latest exposure calculations for livestock are presented in the table below. The current GAP for cereals is less critical than the GAP used in Article 12 MRL review process, therefore the dietary burden is calculated using the more critical values from EFSA, 2020 (refer to Table 7.3-12). The corresponding results can be found in Table 7.3-13.

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

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Residue definition for risk assessment: Fluxapyroxad				
Grapefruits, dried pulp (*EFSA 2020*)	0.01	STMR x PF (0.1)	0.01	STMR x PF (0.1)
Apple, pomace, Wet (*EFSA 2020*)	1.20	STMR x PF (4.6)	1.17	STMR x PF (4.6)
Potato, culls (*EFSA 2020*)	0.09	STMR (c)	0.12	HR (c)
Potato, process waste (*EFSA 2020*)	0.45	STMR x PF (5) (c)	0.45	STMR x PF (5) (c)
Potato, dried pulp (*EFSA 2020*)	0.72	STMR x PF (8) (c)	0.72	STMR x PF (8) (c)
Carrot, culls (*EFSA 2020*)	0.12	STMR (c)	0.26	HR (c)
Swede, roots (*EFSA 2020*)	0.12	STMR (c)	0.26	HR (c)
Turnip, roots (*EFSA 2020*)	0.12	STMR (c)	0.26	HR (c)
Cassava, roots	0.03	STMR (d)	0.08	HR (d)
Cabbage, heads, leaves	0.01	STMR (c)	0.27	HR (c)
Bean, seed (dry) (*EFSA 2020*)	0.01	STMR	0.01	STMR
Cowpea, seed (*EFSA 2020*)	0.01	STMR	0.01	STMR

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Residue definition for risk assessment: Fluxapyroxad				
Pea (Field pea), seed (dry) (*EFSA 2020*)	0.04	STMR	0.04	STMR
Lupin, seed (*EFSA 2020*)	0.01	STMR	0.01	STMR
Lupin seed, Meal (*EFSA 2020*)	0.01	STMR x default PF (1.1) (b)	0.01	STMR x default PF (1.1) (b)
Flaxseed/ Linseed, meal (*EFSA 2020*)	0.18	STMR x default PF (2) (b)	0.18	STMR x default PF (2) (b)
Peanut, meal (*EFSA 2020*)	0.00	STMR x PF (0.12)	0.00	STMR x PF (0.12)
Sunflower, meal (*EFSA 2020*)	0.01	STMR x PF (0.14)	0.01	STMR x PF (0.14)
Canola (Rape seed), meal (*EFSA 2020*)	0.04	STMR x PF (0.44)	0.04	STMR x PF (0.44)
Rape, meal (*EFSA 2020*)	0.04	STMR x PF (0.44)	0.04	STMR x PF (0.44)
Soybean, seed (*EFSA 2020*)	0.01	STMR	0.01	STMR
Soybean, meal (*EFSA 2020*)	0.01	STMR x default PF (1.3) (b)	0.01	STMR x default PF (1.3) (b)
Soybean, hulls (*EFSA 2020*)	0.13	STMR x default PF (13) (b)	0.13	STMR x default PF (13) (b)
Safflower, meal (*EFSA 2020*)	0.18	STMR x default PF (2) (b)	0.18	STMR x default PF (2) (b)
Barley, grain *(EFSA 2020)*	0.54	STMR	0.54	STMR
Brewer's grain, dried (*EFSA 2020*)	1.78	STMR x default PF (3.3) (b)	1.78	STMR x default PF (3.3) (b)
Corn, field (Maize), grain (*EFSA 2020*)	0.01	STMR	0.01	STMR
Corn, pop, grain (*EFSA 2020*)	0.01	STMR	0.01	STMR
Corn, field, milled byproducts (*EFSA 2020*)	0.01	STMR (a) x default PF (1.0) (b)	0.01	STMR (a)
Corn, field, hominy meal (*EFSA 2020*)	0.06	STMR (a) x default PF (6.0) (b)	0.01	STMR (a)
Corn, field, distiller's grain (dry) (*EFSA 2020*)	0.01	STMR (a)	0.01	STMR (a)
Corn, field, gluten feed (*EFSA 2020*)	0.03	STMR (a) x default PF (2.5) (b)	0.01	STMR (a)
Corn, field, gluten, meal (*EFSA 2020*)	0.01	STMR (a) x default PF (1.0) (b)	0.01	STMR (a)
Oat, grain (*EFSA 2020*)	0.54	STMR	0.54	STMR
Rice, bran/ pollard	0.78	STMR x PF (0.9)	0.78	STMR x PF (0.9)
Rye, grain (*EFSA 2020*)	0.12	STMR	0.12	STMR
Sorghum, grain	0.19	STMR	0.19	STMR
Triticale, grain (*EFSA 2020*)	0.12	STMR	0.12	STMR

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Residue definition for risk assessment: Fluxapyroxad				
Wheat grain (*EFSA 2020*)	0.12	STMR	0.12	STMR
Wheat, distiller's grain (dry) (*EFSA 2020*)	0.40	STMR x default PF (3.3) [(b)]	0.38	STMR x default PF (3.3) [(b)]
Wheat gluten meal[(b)] (*EFSA 2020)*	0.22	STMR x default PF (1.8) [(b)]	0.21	STMR x default PF (1.8) [(b)]
Wheat milled by-products[(b)] *(EFSA 2020)*	0.81	STMR x default PF (7) [(b)]	0.81	STMR x default PF (7) [(b)]
Beet, sugar, dried pulp (*EFSA 2020*)	0.21	STMR[(c)] x PF (1.74)	0.21	STMR[(c)] x PF (1.74)
Beet, sugar, ensiled pulp (*EFSA 2020*)	0.04	STMR[(c)] x PF (0.37)	0.04	STMR[(c)] x PF (0.37)
Beet, sugar, molasses (*EFSA 2020*)	0.10	STMR[(c)] x PF (0.8)	0.10	STMR[(c)] x PF (0.8)
Sugarcane, molasses (*EFSA 2020*)	0.01	STMR[(c)] x PF (0.04)	0.01	STMR[(c)] x PF (0.04)
Barley, straw (*EFSA 2020*)	1.52	STMR	3.55	HR
Oat, straw (*EFSA 2020*)	1.52	STMR	3.55	HR
Rye, straw (*EFSA 2020*)	1.14	STMR	6.05	HR
Triticale, straw (*EFSA 2020*)	1.14	STMR	6.05	HR
Wheat, straw (*EFSA 2020*)	1.14	STMR	6.05	HR
Turnip, tops (leaves) (*EFSA 2020*)	0.03	STMR [(c)]	0.07	HR [(c)]

STMR: supervised trials median residue; HR: highest residue; PF: processing factor.
(a): For corn, no default processing factor was applied because residues are expected to be below the LOQ. Concentration of residues in this commodity is therefore not expected.
(b): In the absence of processing factors supported by data, a default processing factor was included in the calculation to consider the potential concentration of residues in these commodities.
(c): Combined residues from primary uses and rotational crop field studies.
(d): Residues from rotational crop field studies on potatoes.

The results of the dietary burden calculation are presented in Table 7.3-15. The intake calculations for the maximum dietary burden of livestock demonstrate that residues of fluxapyroxad are significant in the diets of livestock.

Table 7.3-13: Results of the dietary burden calculation

Relevant groups	Dietary burden expressed in				Most critical diet (a)	Most critical commodity (b)		Trigger exceeded (Yes/No) 0.004 mg/kg bw	Previous assessment Max burden mg/kg bw (EFSA, 2020a)
	mg/kg bw per day		mg/kg DM						
	Median	Maximum	Median	Maximum					
Cattle (all diets)	0.077	0.123	2.37	3.92	Dairy cattle	Rye	straw	Yes	0.12
Cattle (dairy only)	0.077	0.123	2.00	3.20	Dairy cattle	Rye	straw	Yes	0.12
Sheep (all diets)	0.085	0.185	2.52	4.77	Lamb	Rye	straw	Yes	0.19
Sheep (ewe only)	0.086	0.159	2.52	4.77	Ram/Ewe	Rye	straw	Yes	0.16
Swine (all diets)	0.034	0.050	1.48	2.15	Swine (breeding)	Potato	Process waste	Yes	0.05
Poultry (all diets)	0.060	0.107	0.87	1.57	Poultry layer	Wheat	straw	Yes	0.11
Poultry (layer only)	0.060	0.107	0.87	1.57	Poultry layer	Wheat	straw	Yes	0.11

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

zRMS comments:
Information given by the Applicant is acceptable and sufficient.
The median and maximum dietary burdens for livestock were estimated for fluxapyroxad and were calculated using the animal model calculator developed by EFSA (Animal model 2017).
The calculated dietary burdens for fluxapyroxad were found to exceed the trigger value of 0.1 mg/kg DM (or 0.004 mg/kg bw/d, respectively) for all livestock groups. Further investigation of residues is therefore required.

7.3.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Available data

The magnitude of fluxapyroxad residues in livestock was evaluated during EU review (UK, 2011a and EFSA, 2012) and during Article 12 MRL review (EFSA, 2020) and reference is made to the respective evaluations.

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

Table 7.3-14: Overview of livestock feeding studies with fluxapyroxad

Group	Species	No of animal	Test item	Application details		Sample details		Reference
				Rate	Duration (days)	Commodity	Time of sampling	
EU data								
Lactating ruminants	Dairy cow	12 (4 groups of 3 animals,)	Fluxapyroxad and M700F002 (co-dosed)	0.11, 0.21, 0.65 and 2.18 mg/kg bw per day (EFSA 2012, EFSA 2020)	28	Whole Milk	Twice daily for 28 days	UK, 2011a (IIA, 6.4.2/01); EFSA, 2012, evaluated and accepted.
						Tissues (liver, kidney, muscle, fat)	After sacrifice	
Poultry	Laying hens	40 (4 groups of 10 animals)	Fluxapyroxad and M700F002 (co-dosed)	0.004, 0.01, 0.03 mg/kg bw per day (EFSA 2012, EFSA 2020)	28	Eggs	Twice daily for 28 days	UK, 2011a (IIA, 6.4.1/1); EFSA, 2012, evaluated and accepted
						Tissues (liver, fat, muscle, skin with fat)	At sacrifice	

According to EFSA, 2020: "Livestock feeding studies were carried out on dairy cows (parent and metabolite M700F002 co-dosed for 28 consecutive days at dose levels of 0.11, 0.21, 0.65 and 2.18 mg/kg bw per day and 0.004, 0.01, 0.03 mg/kg bw per day, respectively) and laying hens (parent and metabolite M700F002 co-dosed for 28 consecutive days at dose levels of 0.019, 0.038, 0.11 and 0.38 mg/kg bw per day and 0.0015, 0.003, 0.009 and 0.03 mg/kg bw per day, respectively) and assessed in the framework of the peer review (United Kingdom, 2011a; EFSA, 2012). Samples of meat, fat, liver, kidney, milk and eggs were taken from dosed animals and analysed for fluxapyroxad and metabolites M700F008 and M700F002.

In the feeding study on cattle, fluxapyroxad residues were found at up to 0.0374 mg/kg in whole milk, up to 0.012 mg/kg in meat, up to 0.171 mg/kg in fat, at up to 0.094 mg/kg in liver and up to 0.019 mg/kg in kidney (highest dose level). Metabolite M700F008 was found at up to 0.0017 mg/kg in whole milk, up to 0.0052 mg/kg in cream and up to 0.032 mg/kg in liver.

In tissues and milk from all the dosing groups, metabolite M700F002 was always below the LOQs of 0.01 and 0.001 mg/kg, respectively. In the feeding study on hens, fluxapyroxad residues were found at up to 0.031 mg/kg in eggs and at low amounts in fat from the highest dose group. In all other tissues analysed, parent was always below the LOQ of 0.01 mg/kg. Metabolite M700F008 was found at up to 0.0055 mg/kg in eggs, at the LOQ of 0.01 mg/kg in liver and at low amounts in fat and liver from the highest dose group."

No new studies are required or submitted.

Table 7.3-15: Overview of the values derived from livestock feeding studies

Commodity	Dietary burden		Results of the livestock feeding study (DAR UK, 2011a)						Median residue (mg/kg)(c)	Highest residue (mg/kg)(d)	Current EU-MRL (mg/kg) Com. Reg. (EU) ~~2021/644~~ 2022/1324	CF for RA(e)
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level (mg/kg bw/d)(a)	No	Result for enforcement		Result for RA(b)					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
EU data (United Kingdom, 2011a; EFSA, 2012, EFSA 2020)												
Enforcement residue definition: Fluxapyroxad **Risk assessment residue definition**: Fluxapyroxad and metabolite M700F008 expressed as parent equivalents												
Dairy Cattle/Swine muscle	0.077	0.123	0.11	3	<0.01	<0.01	<0.02	<0.02	0.01	0.01	**0.015**	2
			0.21	3	<0.01	<0.01	<0.02	<0.02				
			0.65	3	<0.01	<0.01	<0.02	<0.02				
			2.18	3	0.011	0.012	0.036	0.044				
Dairy Cattle/Swine fat	0.077	0.123	0.11	3	0.011	0.011	0.021	0.021	0.01	0.01	**0.2**	2
			0.21	3	0.019	0.024	0.029	0.034				
			0.65	3	0.045	0.059	0.071	0.092				
			2.18	3	0.147	0.171	0.259	0.301				
Dairy Cattle/Swine liver	0.077	0.123	0.11	3	<0.01	<0.01	0.034	0.043	0.01	0.01	**0.1**	3
			0.21	3	0.013	0.015	0.053	0.068				
			0.65	3	0.031	0.032	0.123	0.147				
			2.18	3	0.085	0.094	0.350	0.455				

Commodity	Dietary burden		Results of the livestock feeding study (DAR UK, 2011a)						Median residue (mg/kg)[(c)]	Highest residue (mg/kg)[(d)]	Current EU-MRL (mg/kg) Com. Reg. (EU) ~~2021/644~~ 2022/1324	CF for RA[(e)]
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level (mg/kg bw/d)[(a)]	No	Result for enforcement		Result for RA[(b)]					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
EU data (United Kingdom, 2011a; EFSA, 2012, EFSA 2020)												
Enforcement residue definition: Fluxapyroxad **Risk assessment residue definition**: Fluxapyroxad and metabolite M700F008 expressed as parent equivalents												
Dairy Cattle/Swine kidney	0.077	0.123	0.11	3	<0.01	<0.01	<0.02	<0.02	0.01	0.01	**0.1**	2
			0.21	3	<0.01	<0.01	0.021	0.021				
			0.65	3	<0.01	<0.01	0.028	0.032				
			2.18	3	0.014	0.019	0.066	0.098				
Sheep muscle	0.085	0.185	0.11	3	<0.01	<0.01	<0.02	<0.02	0.01	0.01	**0.015**	
			0.21	3	<0.01	<0.01	<0.02	<0.02				
			0.65	3	<0.01	<0.01	<0.02	<0.02				
			2.18	3	0.011	0.012	0.036	0.044				
Sheep fat	0.085	0.185	0.11	3	0.011	0.011	0.021	0.021	0.011	0.017	**0.2**	
			0.21	3	0.019	0.024	0.029	0.034				
			0.65	3	0.045	0.059	0.071	0.092				
			2.18	3	0.147	0.171	0.259	0.301				
Sheep liver	0.085	0.185	0.11	3	<0.01	<0.01	0.034	0.043	0.01	0.013	**0.1**	
			0.21	3	0.013	0.015	0.053	0.068				
			0.65	3	0.031	0.032	0.123	0.147				
			2.18	3	0.085	0.094	0.350	0.455				
Sheep kidney	0.085	0.185	0.11	3	<0.01	<0.01	<0.02	<0.02	0.01	0.01	**0.1**	
			0.21	3	<0.01	<0.01	0.021	0.021				
			0.65	3	<0.01	<0.01	0.028	0.032				
			2.18	3	0.014	0.019	0.066	0.098				
Poultry meat	0.06	0.107	0.019	10	<0.01	<0.01	<0.02	<0.02	0.01	0.01	**0.02**	2

Commodity	Dietary burden		Results of the livestock feeding study (DAR UK, 2011a)						Median residue (mg/kg)[(c)]	Highest residue (mg/kg)[(d)]	Current EU-MRL (mg/kg) Com. Reg. (EU) ~~2021/644~~ 2022/1324	CF for RA[(e)]
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level (mg/kg bw/d)[(a)]	No	Result for enforcement		Result for RA[(b)]					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
EU data (United Kingdom, 2011a; EFSA, 2012, EFSA 2020)												
Enforcement residue definition: Fluxapyroxad **Risk assessment residue definition**: Fluxapyroxad and metabolite M700F008 expressed as parent equivalents												
			0.038	10	<0.01	<0.01	<0.02	<0.02				
			0.11	10	<0.01	<0.01	<0.02	<0.02				
			0.38	10	<0.01	<0.01	<0.02	<0.02				
Poultry fat	0.06	0.107	0.019	10	<0.01	<0.01	<0.02	<0.02	0.01	0.011	**0.05**	2
			0.038	10	<0.01	<0.01	<0.02	<0.02				
			0.11	10	<0.01	<0.01	<0.02	<0.02				
			0.38	10	0.025	0.028	0.040	0.045				
Poultry liver	0.06	0.107	0.019	10	<0.01	<0.01	<0.02	<0.02	0.01	0.01	**0.02**	2
			0.038	10	<0.01	<0.01	<0.02	<0.02				
			0.11	10	<0.01	<0.01	0.020	0.021				
			0.38	10	<0.01	<0.01	0.025	0.029				
Milk[(f)]	0.085	0.185	0.11	3	0.0011	N/A	0.0023	N/A	0.001	0.001	**0.02**	2
			0.21	3	0.0017	N/A	0.0032	N/A				
			0.65	3	0.0043	N/A	0.0081	N/A				
			2.18	3	0.0139	N/A	0.0275	N/A				
Eggs[(g)]	0.06	0.107	0.019	10	0.0011	N/A	0.0021	N/A	0.001	0.003	**0.02**	4
			0.038	10	0.0011	N/A	0.0025	N/A				
			0.11	10	0.0018	N/A	0.0061	N/A				
			0.38	10	0.0040	N/A	0.0142	N/A				

N/A: Not applicable – only the mean values are considered for calculating MRL in milk and eggs.
(*): 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): The studies were conducted with co-dosing of parent and metabolite M700F002. Dose level given in the table are for parent and not for the metabolite.
(b): A molecular weight conversion factor of 1.04 is applied to express residues of M700F008 as parent fluxapyroxad.
(c): Median residue value according to the enforcement residue definition, derived by interpolation/extrapolation from the feeding study for the median dietary burden (FAO, 2009).
(d): 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).
(e): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment taken from EFSA, 2020.
(f): For milk, mean residue level was derived from day 5 (after plateau is reached) until day 28 (3 cows, 8 sampling days).
(g): For eggs, mean residue level was derived from day 13 to day 27 (10 hens, 5 sampling days)

Conclusion on feeding studies

The requested uses are covered by the referenced intake calculations for livestock. Regarding available feeding data and evaluations in EFSA, 2012 and EFSA, 2020, there is no risk for livestock MRLs of fluxapyroxad to be exceeded.

Evaluator comments:
Information presented by Applicant is sufficient. The zRMS agrees with the assessment prepared by Applicant in relation to magnitude of residues in livestock. The residues in animal commodities will not exceed MRLs (Reg. (EU) 2022/1324). No further data are required to support the intended uses of ADM.03503.F.1.A.

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

Reference is made to the EU peer review (EFSA, 2012, DAR UK, 2011a and Addendum to DAR 2011b) and to the MRL review (EFSA, 2020) for fluxapyroxad.
No new data were submitted in the framework of this application.

7.3.5.1 Available data for all crops under consideration

Table 7.3-16: Overview of the available processing studies

Processed commodity	Number of studies	Median PF *	Median CF	Comments	Reference
EU data					
Enforcement residue definition: Fluxapyroxad					
Barley, brewing malt	4	0.01	N/A	-	EFSA, 2011
Barley, beer	4	0.02	N/A	-	EFSA, 2011
Barley, wholemeal flour	4	0.23	N/A	-	EFSA, 2011
Wheat, wholemeal flour	12	0.94	N/A	-	France, 2018
Wheat, wholemeal bread	12	0.66	N/A	-	France, 2018
Wheat, white flour	12	0.17	N/A	-	France, 2018
Wheat, white bread	12	0.13	N/A	-	France, 2018

* The median processing factor is obtained by calculating the median of the individual processing factors of each processing study (EFSA, 2020)
N/A: Not applicable, the residue definitions for monitoring and risk assessment for processing commodities are same.

According to EFSA, 2012*:* "*Residue trials on wheat and barley were provided to address the magnitude of the residues in processed commodities (bran, flour, germ, bread and beer). A concentration of fluxapyroxad (BAS 700 F) residues was observed in cereal bran and germ only, with average processing factors of 3 and 1.4, respectively*."

7.3.5.2 Conclusion on processing studies

Processing factors for fluxapyroxad have been evaluated for wheat and barley at EU level under the framework of Article 12 MRL review (EFSA, 2020).

No new studies on the magnitude of residues of fluxapyroxad in processed commodities of wheat are required for this application, as residues of fluxapyroxad were ≤ 0.1 mg/kg in wheat grains at normal commercial harvest, wheareas residues in barley exceeded the trigger of 0.1 mg/kg. The contribution of cereal grains to the IEDIs and IESTIs is always <10% of the ADI and ARfD, respectively. Due to the low residues in the respective commodities and low contribution in dietary intake, no processing studies are required for barley grains. Default processing factors for wheat and barley are used in the dietary burden calculation.

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

7.3.6 Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation.

Available data

Reference is made to the EU peer review (EFSA, 2012, DAR UK, 2011a) and to the MRL review (EFSA, 2020) for fluxapyroxad.

No new data submitted in the framework of this application.

Table 7.3-17: Summary of available studies in field rotational crops for fluxapyroxad

Primary crop	Rate (g a.s./ha) (GS at application or PHI)	Succeeding crop group	Succeeding crop	Sowing intervals (DAT)	Reference / Remarks
EU data					
Bare soil	250	Leafy vegetables	Lettuce (whole plant)	30 120 365	UK, 2011a and EFSA, 2012. Evaluated and accepted
		Root and tuber vegetables	Carrot/Radish tops	30 120 365	
			Carrot/Radish root	30 120 365	
		Brassica vegetables	Cauliflower/ Broccoli (whole plant)	30 120 365	
		Brassica vegetables	Cauliflower/ Broccoli (inflorescence)	30 120 365	
		Cereals	Wheat grain	30 120 365	
		Cereals	Wheat straw	30 120 365	

Studies for determination of magnitude of residues of fluxapyroxad in rotational crops were submitted and evaluated in DAR (United Kingdom, 2011) and EFSA 2012. According to EFSA, 2012: “The available rotational field trials carried out on wheat, carrot root, cauliflower, broccoli and lettuce at a dose rate of 250 g a.s./ha were considered acceptable and showed that no significant residue levels of metabolites M700F002, M700F008 and M700F048 were recovered in the edible parts of the rotated crops at all plant back intervals (< 0.01 - 0.02 mg/kg). In contrast, significant levels of fluxapyroxad (BAS 700 F) residues were quantified in carrot roots (0.08 mg/kg) and in immature lettuce and cauliflower leaves (0.03 and 0.06 mg/kg, respectively). Therefore EFSA proposes a default MRL of 0.1 mg/kg respectively for the root and tuber vegetables crop group (including sugar beet and potatoes), and for the crop group "leaves and sprouts of brassica spp"”.
According to EFSA, 2020: “Field rotational crop trials on cereals (wheat), root crops (carrots) and leafy crops (cauliflowers, broccoli and lettuces) were assessed in the framework of the peer review (United Kingdom, 2011a; EFSA, 2012).
The rotational crop field studies were conducted with bare soil previously treated at a rate of 250 g a.s./ha

and at PBI 30, 120 and 365 DAT (United Kingdom, 2011a). Highest residue levels of fluxapyroxad were detected in carrots (0.08 mg/kg), lettuces (0.03 mg/kg) and cauliflowers/broccoli (0.06 mg/kg), 30 DAT (EFSA, 2012). In wheat grain residue level was below 0.01 mg/kg at all PBI, and in wheat straw the highest residue was below 0.01 mg/kg 30 DAT and found at 0.07 mg/kg and 0.08 mg/kg, 120 and 365 DAT, respectively. No significant levels of metabolites M700F002, M700F008 and M700F048 were detected in edible parts of crops at all PBIs, since metabolite residue levels were always below the LOQ (< 0.01–0.02 mg/kg) (EFSA, 2012, 2017). Regarding the concentration of fluxapyroxad in soil, immediately after application, the residues of fluxapyroxad ranged from 0.024 to 0.114 mg/kg (United Kingdom, 2011a). After a 30-day replant interval, ploughing and planting/sowing of the crops, the residue levels in soil were lower (0.016–0.077 mg/kg) (United Kingdom, 2011a). Detailed information on the concentration of fluxapyroxad in the different soils tested were missing (only a range was given). Moreover, EFSA could not retrieve information on the residue level in soil for the 120 DAT and 365 DAT in the study."
BASF intends to address the data gaps from Art. 12 as part of the upcoming active substance renewal and a confirmatory data MRL dossier within the period specified in the current MRL regulation (EU) ~~2021/644~~ 2022/1324.

Conclusion on rotational crops studies
No significant residues (< 0.01 mg/kg) are to be expected in cereal grain (planted as succeeding crops). Higher residues may be expected in rotated cereal straw, however, the current GAP is less critical than the GAP used in the rotational crop studies and therefore no significant residues are expected in cereal straw.

Evaluator comments: Information presented by Applicant is sufficient. Based on the available information, it was concluded that significant residue levels are unlikely to occur in rotational crops, provided that the compound is used according to the proposed good agricultural practice (GAP). The proposed rate of fluxapyroxad (93.75 g/kg) is lower than the dose from the rotational crop field studies (250 g a.s./ha). The crops under consideration can be grown in rotation and there is no potential for residues occurring in succeeding crops.

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

Regarding potential residues in honey and other apiculture products, the following is to be said:
Fluxapyroxad is a fungicide applied as a spray at BBCH 65-69 in spring and winter wheat and in spring and winter barley. Any residues in pollen and bee products collected from treated crops are not to be expected for such cereals as these crops have no melliferous capacity according to EU technical guidelines (SANTE/11956/2016 rev. 9).

zRMS comments: Information given by the Applicant is acceptable and sufficient. According to SANTE/11956/2016 rev. 9, cereals are not considered melliferous crops. Effects on the residue level in pollen and bee products have not been investigated. No additional data are required.

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

<u>Fluxapyroxad</u>
The consumer risk assessment is performed following the same procedure as mentioned in the Article 12 MRL review of fluxapyroxad by EFSA using revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo). This exposure assessment model contains the relevant European food consumption data for different sub-groups of the EU population (EFSA, 2007).
Toxicological reference values relevant for dietary risk assessment are reported in the summary of the evaluation (see 7.1.2).
The existing EU MRLs are set according to the residue definition for monitoring as 'fluxapyroxad'.
The input values used for the chronic consumer risk assessments are based on existing STMR values as derived in the Article 12 MRL review by EFSA (EFSA, 2020a) and setting import tolerance for root crops and coffee beans (EFSA, 2020b). The Theoretical maximum daily intake (TMDI) was not assessed in the EFSA, 2020a evaluation and therefore, is also not performed in the current submission.

The acute exposure assessment was performed only with regard to the commodities under consideration using the HR values as derived in the Article 12 MRL review by EFSA (EFSA, 2020).

7.3.8.1 Input values for the consumer risk assessment

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

Table 7.3-18: Input values for the consumer risk assessment [according to EFSA, 2020a and EFSA, 2020b (for root crops and coffee beans)]

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition 1 (in plant commodities): fluxapyroxad				
Wheat grain	0.12	STMR *(EFSA 2020a)*	0.21	HR (*EFSA 2020a*)
Wheat grain (*new*)	0.039	STMR (new trials submitted, refer to Table 7.3-9, but covered by higher input value used in *EFSA 2020a* in the line above)	0.049	HR (new trials submitted, refer to Table 7.3-9, but covered by higher input value used in *EFSA 2020a* in the line above)
Barley grain	0.54	STMR *(EFSA 2020a)*	1.65	HR (*EFSA 2020a*)
Barley grain (*new)*	0.17	STMR (new trials submitted, refer to Table 7.3-11, but covered by higher input value used in *EFSA 2020a* in the line above)	0.38	HR (new trials submitted, refer to Table 7.3-11, but covered by higher input value used in *EFSA 2020a* in the line above)
Rye grain	0.12	STMR *(EFSA 2020a)*	0.21	HR (*EFSA 2020a*)
Rye grain (*new*)	0.039	STMR (new trials submitted, refer to Table 7.3-9, extrapolated from wheat)	0.049	HR (new trials submitted, refer to Table 7.3-9, extrapolated from wheat)
Grapefruits	0.07	STMR *(EFSA 2020a)*	Acute risk assessment made only for the crops under consideration.	
Oranges[(a)]	0.01	STMR (CXL)[(b)] x PeF (0.16) (*EFSA 2020a*)		
Treenuts	0.01	STMR (CXL) [(b)] *(EFSA, 2020a)*		
Apples	0.26	STMR *(EFSA 2020a)*		
Pears	0.26	STMR *(EFSA 2020a)*		
Quinces	0.26	STMR *(EFSA 2020a)*		
Medlars	0.26	STMR *(EFSA 2020a)*		
Loquats/Japanese medlars	0.26	STMR *(EFSA 2020a)*		
Apricots	0.03	STMR *(EFSA 2020a)*		
Cherries (sweet)	0.56	STMR *(EFSA 2020a)*		
Peaches	0.44	STMR *(EFSA 2020a)*		
Plums	0.44	STMR *(EFSA 2020a)*		
Table grapes	0.09	STMR *(EFSA 2020a)*		
Wine grapes	0.15	STMR *(EFSA 2020a)*		

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	**Comment**	**Input value (mg/kg)**	**Comment**
Strawberries	0.82	STMR *(EFSA 2020a)*		
Blueberries	2.39	STMR *(EFSA 2020a)*		
Banana[(a)]	0.04	STMR (CXL) [(b)] x PeF (0.26) (*EFSA 2020a*)		
Mangoes	0.18	STMR *(EFSA 2020a)*		
Potatoes	0.09	STMR *(EFSA 2020a)*		
Cassava roots/manioc	0.03	STMR *(EFSA 2020a)*		
Sweet potatoes	0.03	STMR *(EFSA 2020a)*		
Yams	0.03	STMR *(EFSA 2020a)*		
Arrowroots	0.03	STMR *(EFSA 2020a)*		
Beetroots [(c)]	0.09	STMR *(EFSA 2020a)*		
Carrots[(c)]	0.09	STMR *(EFSA 2020b)*		
Celeriacs/turnip rooted Celeries[(c)]	0.09	STMR *(EFSA 2020b)*		
Horse radishes[(c)]	0.09	STMR *(EFSA 2020b)*		
Jerusalem artichokes[(c)]	0.09	STMR *(EFSA 2020b)*		
Parsnips[(c)]	0.09	STMR *(EFSA 2020b)*		
Parsley roots/Hamburg[(c)] roots parsley	0.09	STMR *(EFSA 2020b)*		
Radishes[(c)]	0.09	STMR *(EFSA 2020b)*		
Salsifies[(c)]	0.09	STMR *(EFSA 2020b)*		
Swedes/rutabagas[(c)]	0.09	STMR *(EFSA 2020b)*		
Turnips[(c)]	0.09	STMR *(EFSA 2020b)*		
Garlic	0.03	STMR *(EFSA 2020a)*		
Onions	0.03	STMR *(EFSA 2020a)*		
Shallots	0.03	STMR *(EFSA 2020a)*		
Spring onions/green onions and Welsh onions	0.19	STMR *(EFSA 2020a)*		
Tomatoes	0.06	STMR *(EFSA 2020a)*		
Sweet peppers/bell peppers	0.07	STMR *(EFSA 2020a)*		
Aubergines/eggplants	0.06	STMR *(EFSA 2020a)*		
Cucumbers	0.05	STMR *(EFSA 2020a)*		
Gherkins	0.05	STMR *(EFSA 2020a)*		
Courgettes	0.05	STMR *(EFSA 2020a)*		
Melons[(a)]	0.02	STMR x PeF (0.38) STMR *(EFSA 2020a)*		

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Pumpkins[(a)]	0.02	STMR x PeF (0.38) *(EFSA 2020a)*		
Watermelons[(a)]	0.02	STMR x PeF (0.38) *(EFSA 2020a)*		
Sweet corn	0.01	STMR *(EFSA 2020a)*		
Broccoli	0.28	STMR *(EFSA 2020a)*		
Cauliflowers	0.07	STMR *(EFSA 2020a)*		
Brussels sprouts	0.11	STMR *(EFSA 2020a)*		
Head cabbages	0.01	STMR *(EFSA 2020a)*		
Chinese cabbages/petsai	0.90	STMR *(EFSA 2020a)*		
Kale	0.01	STMR *(EFSA 2020a)*		
Kohlrabies	0.01	STMR *(EFSA 2020a)*		
Lamb's lettuces/corn salads	0.25	STMR *(EFSA 2020a)*		
Lettuces	0.25	STMR *(EFSA 2020a)*		
Escaroles/broadleaved endives	0.25	STMR *(EFSA 2020a)*		
Cresses and other sprouts and shoots	0.06	STMR *(EFSA 2020a)*		
Land cresses	0.06	STMR *(EFSA 2020a)*		
Roman rocket/rucola	0.25	STMR *(EFSA 2020a)*		
Red mustards	0.06	STMR *(EFSA 2020a)*		
Baby leaf crops (including brassica species)	0.06	STMR *(EFSA 2020a)*		
Spinaches	0.06	STMR *(EFSA 2020a)*		
Purslanes	0.06	STMR *(EFSA 2020a)*		
Chards/beet leaves	0.06	STMR *(EFSA 2020a)*		
Witloofs/Belgian endives	1.95	STMR *(EFSA 2020a)*		
Chervil	0.06	STMR *(EFSA 2020a)*		
Chives	0.06	STMR *(EFSA 2020a)*		
Celery leaves	0.06	STMR *(EFSA 2020a)*		
Parsley	0.06	STMR *(EFSA 2020a)*		
Sage	0.06	STMR *(EFSA 2020a)*		
Rosemary	0.06	STMR *(EFSA 2020a)*		
Thyme	0.06	STMR *(EFSA 2020a)*		
Basil and edible flowers	0.06	STMR *(EFSA 2020a)*		
Laurel/bay leave	0.06	STMR *(EFSA 2020a)*		

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Tarragon	0.06	STMR *(EFSA 2020a)*		
Beans (with pods)	0.58	STMR *(EFSA 2020a)*		
Beans (without pods)	0.03	STMR *(EFSA 2020a)*		
Peas (with pods)	0.58	STMR *(EFSA 2020a)*		
Peas (without pods)	0.03	STMR *(EFSA 2020a)*		
Cardoons	1.68	STMR *(EFSA 2020a)*		
Celeries	1.68	STMR *(EFSA 2020a)*		
Florence fennels	1.68	STMR *(EFSA 2020a)*		
Globe artichokes	0.08	STMR *(EFSA 2020a)*		
Leeks	0.19	STMR *(EFSA 2020a)*		
Rhubarbs	1.68	STMR *(EFSA 2020a)*		
Beans (dry)	0.01	STMR *(EFSA 2020a)*		
Lentil (dry)	0.04	STMR *(EFSA 2020a)*		
Peas (dry)	0.04	STMR *(EFSA 2020a)*		
Lupins/lupini beans (dry)	0.01	STMR *(EFSA 2020a)*		
Linseeds	0.09	STMR *(EFSA 2020a)*		
Peanuts/groundnuts	0.01*	STMR *(EFSA 2020a)*		
Poppy seeds	0.09	STMR *(EFSA 2020a)*		
Sesame seeds	0.09	STMR *(EFSA 2020a)*		
Sunflower seeds	0.09	STMR *(EFSA 2020a)*		
Rapeseeds/canola seeds	0.09	STMR *(EFSA 2020a)*		
Soyabeans	0.01	STMR *(EFSA 2020a)*		
Mustard seeds	0.09	STMR *(EFSA 2020a)*		
Cotton seed	0.30	STMR (CXL) [(b)] *(EFSA 2020a)*		
Pumpkin seeds	0.09	STMR *(EFSA 2020a)*		
Safflower seeds	0.09	STMR *(EFSA 2020a)*		
Borage seeds	0.09	STMR *(EFSA 2020a)*		
Gold of pleasure seeds	0.09	STMR *(EFSA 2020a)*		
Hemp seeds	0.09	STMR *(EFSA 2020a)*		
Castor beans	0.09	STMR *(EFSA 2020a)*		
Maize/corn grains	0.01*	STMR *(EFSA 2020a)*		
Oat grains	0.54	STMR *(EFSA 2020a)*		
Rice grains	0.87	STMR *(EFSA 2020a)*		
Sorghum grain	0.19	STMR *(EFSA 2020a)*		

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	**Comment**	**Input value (mg/kg)**	**Comment**
Herbal infusions from leaves and herbs	0.55	STMR *(EFSA 2020a)*		
Herbal infusions from Roots	0.32	STMR *(EFSA 2020a)*		
Coffee beans[(c)]	0.03	STMR *(EFSA 2020a)*		
Sugar beet roots	0.12	STMR *(EFSA 2020a)*		
Sugar canes	0.26	STMR *(EFSA 2020a)*		
Chicory roots	0.07	STMR *(EFSA 2020a)*		
Risk assessment residue definition 2 (in animal commodities): sum of fluxapyroxad and metabolite M700F008, expressed as parent equivalent				
Muscle of swine, bovine, sheep, goat, equine, other farmed animals	0.02	STMR x CF (2) *(EFSA 2020a)*	0.02	HR x CF (2) *(EFSA 2020a)*
Fat of swine, bovine, sheep, goat, equine, other farmed animals	0.02	STMR x CF (2) *(EFSA 2020a)*	0.03	HR x CF (2) *(EFSA 2020a)*
Liver of swine, bovine, equine, other farmed animals	0.03	STMR x CF (3) *(EFSA 2020a)*	0.03	HR x CF (3) *(EFSA 2020a)*
Liver of sheep, goat	0.03	STMR x CF (3) *(EFSA 2020a)*	0.04	HR x CF (3) *(EFSA 2020a)*
Kidney, edible offal of swine, bovine, sheep, goat, equine, other farmed animals	0.02	STMR x CF (2) *(EFSA 2020a)*	0.02	HR x CF (2) *(EFSA 2020a)*
Muscle of poultry	0.02	STMR x CF (2) *(EFSA 2020a)*	0.02	HR x CF (2) *(EFSA 2020a)*
Fat of poultry	0.02	STMR x CF (2) *(EFSA 2020a)*	0.02	HR x CF (2) *(EFSA 2020a)*
Liver, kidney, edible offal of poultry	0.02	STMR x CF (2) *(EFSA 2020a)*	0.02	HR x CF (2) *(EFSA 2020a)*
Milk	0.002	STMR x CF (2) *(EFSA 2020a)*	0.002	HR x CF (2) *(EFSA 2020a)*
Eggs	0.004	STMR x CF (4) *(EFSA 2020a)*	0.012	HR x CF (4) *(EFSA 2020a)*

(a) Peeling factors are used for oranges, banana, melons, pumpkins and watermelons according to EFSA, 2020a.
(b) Where EU STMRs are not available, Codex STMRs are used For refinements in IEDI calculations
(c) The input values for Other root & tuber vegetables, except sugar beet and coffee beans are used from EFSA, 2020b (setting import tolerances for fluxapyroxad in certain root crops and coffee beans)

7.3.8.2 Conclusion on consumer risk assessment

Fluxapyroxad
Extensive calculation sheets are presented in Appendix 3.

Table 7.3-19: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo	Not assessed
IEDI (% ADI) according to EFSA PRIMo 3.1	Normal mode: 48% (based on NL toddler; main contributor: Apples) Refined calculation mode: 7% (based on DK child; main contributor: Rye)
IESTI (% ARfD) according to EFSA PRIMo 3.1	Barley: 1% (based on unprocessed commodities for children and adults) Barley cooked: 0.8% (based on processed commodities children) Barley/beer: 2% (based on processed commodities for adults)

The proposed uses of fluxapyroxad in the formulation ADM.03503.F.1.A do not represent unacceptable chronic risks for the consumer.
When considering only the uses applied for, the maximum calculated exposure (DK child) utilises only 7% of the ADI, showing the low contribution of cereal grain to the overall consumer exposure (IEDI).

Evaluator comment:
Calculations presented by the Applicant are acceptable.
The data available are considered sufficient for risk assessment. The chronic and the short-term intakes of fluxapyroxad residues are unlikely to present a public health concern.
The intended uses of ADM.03503.F.1.A are accepted.

7.4 Combined exposure and risk assessment

From a scientific point of view it is regarded necessary to take into account potential combination effects. However, the evaluation of cumulative or synergistic effects as requested by Art. 4 (3b) of Regulation (EC) No. 1107/2009 should only be performed when harmonised “scientific methods accepted by the Authority to assess such effects are available.”
Currently, no EU-harmonized guidance is available on the risk assessment of combined exposure to multiple active substances; this approach is not mandatory at EU level.
The product is a mixture of two active substances, and for both of them an acute reference dose has been allocated. Therefore, combined acute exposure can be considered.

7.4.1 Acute consumer risk assessment from combined exposure

In a first step, dose-addition of residues of the individual active substances is assumed by making use of the Hazard Index (HI) concept. The Hazard Quotient (HQ) is calculated for all active substances in the PPP that are acutely toxic by performing deterministic IESTI/NESTI calculations with the calculation models EFSA PRIMO (rev.2) and appropriate national models, if required, and dividing the individual exposure levels by the respective ARfD. Addition of the individual HQs irrespective of any considerations on phenomenological effects or mode(s)/mechanisms of action results in the HI. The results of the HQ/HI calculations are summarized in the following table.

Table 7.4-1: Acute consumer risk assessment from combined exposure

~~Crop~~	~~Active Ingredient~~	~~HQ (based on IESTI according to EFSA PRIMo)~~
~~Wheat~~	~~Prothioconazole~~	~~0.87/10 = 0.087~~

~~Crop~~	~~Active Ingredient~~	~~HQ (based on IESTI according to EFSA PRIMo)~~
	~~Fluxapyroxad~~	~~1.7/250 = 0.0068~~
	~~Cumulative risk Wheat (HI)~~	~~0.09~~
~~Rye~~	~~Prothioconazole~~	~~0.38/10 =0.038~~
	~~Fluxapyroxad~~	~~0.76/250 = 0.003~~
	~~Cumulative risk Rye (HI)~~	~~0.04~~
~~Barley~~	~~Prothioconazole~~	~~0.39/10 = 0.039~~
	~~Fluxapyroxad~~	~~3.0/250 = 0.012~~
	~~Cumulative risk Barley (HI)~~	~~0.05~~

Crop	**Active Ingredient**	**HQ (based on IESTI according to EFSA PRIMo)**
Wheat	Prothioconazole	0.87/10 = 0.087
	Fluxapyroxad	1.7/250 = 0.0068
	1,2,4-Triazole	0.72/100 = 0.0072
	Triazole Alanine	9/300 = 0.03
	Triazole Acetic Acid	11/1000 = 0.011
	Triazole Lactic Acid	0.32/300 = 0.0011
	Cumulative risk Wheat (HI)	**0.14**
Rye	Prothioconazole	0.38/10 =0.038
	Fluxapyroxad	0.76/250 = 0.003
	1,2,4-Triazole	0.32/100 = 0.0032
	Triazole Alanine	3.9/300 = 0.013
	Triazole Acetic Acid	5/1000 = 0.005
	Triazole Lactic Acid	0.14/300 = 0.0005
	Cumulative risk Rye (HI)	**0.06**
Barley	Prothioconazole	0.39/10 = 0.039
	Fluxapyroxad	3.0/250 = 0.012
	1,2,4-Triazole	0.28/100 = 0.0028
	Triazole Alanine	3.5/300 = 0.012
	Triazole Acetic Acid	4.4/1000 = 0.0044

Crop	Active Ingredient	HQ (based on IESTI according to EFSA PRIMo)
	Triazole Lactic Acid	0.12/300 = 0.0004
	Cumulative risk Barley (HI)	**0.07**

The Hazard Index is <1. Thus combined exposure to both active substances in ADM.03503.F.1.A is not expected to present a consumer risk. No further refinement of the assessment is required.

7.4.2 Chronic consumer risk assessment from combined exposure

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

Evaluator comment: Information and calculations presented by the Applicant are acceptable.

7.5 References

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EFSA (European Food Safety Authority), 2020. Reasoned Opinion on the evaluation of confirmatory data following the Article 12 MRL review and modification of the existing maximum residue levels for prothioconazole in celeriacs and rapeseeds. EFSA Journal 2020;18(2):5999, 50 pp

EFSA (European Food Safety Authority), 2020a. Reasoned Opinion on the review of the existing maximum residue levels for fluxapyroxad according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2020; 18(1):5984.

EFSA (European Food Safety Authority), 2020b. Reasoned Opinion on the setting of import tolerances for fluxapyroxad in certain root crops and coffee beans. EFSA Journal 2020;18(1):5950.

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FAO (Food and Agriculture Organization of the United Nations), 2009a. Prothioconazole. In: Pesticide residues in food – 2008. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 193

FAO (Food and Agriculture Organization of the United Nations), 2009b. Prothioconazole. In: Pesticide residues in food – 2009. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 196

FAO (Food and Agriculture Organization of the United Nations), 2014. Prothioconazole In: Pesticide residues in food – 2014. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 221

FAO (Food and Agriculture Organization of the United Nations), 2018. Prothioconazole In: Pesticide residues in food – 2018. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 234. FAO 2018

Germany, 2014. Evaluation Report prepared under Article 12 of Regulation (EC) No 396/2005. Report on two studies on the nature of residue of prothioconazole and prothioconazole-desthio under simulated processing conditions, March 2014

United Kingdom, 2004. Draft Assessment report (DAR) on the active substance prothioconazole prepared by the rapporteur Member state United Kingdom in the framework of Council Directive 91/414/EEC, October 2004

United Kingdom, 2007. Final addendum to the draft assessment report on the active substance prothioconazole prepared by the rapporteur Member State United Kingdom in the framework of Council Directive 91/414/EEC, May 2007.

United Kingdom, 2009. Final addendum to the assessment report on the active substance fluxapyroxad prepared by the rapporteur Member State United Kingdom in the framework of Council Directive 91/414/EEC, December 2009

United Kingdom, 2011. Draft assessment report (DAR) on the initial risk assessment of the active substance fluxapyroxad prepared by the rapporteur Member State the United Kingdom in the framework of Article 8(1) of Council Directive 91/414/EEC, February 2011

United Kingdom, 2018a. Draft renewal assessment report on the active substance prothioconazole prepared by the rapporteur Member State the United Kingdom in the framework of Commission Regulation (EU) No 1107/2009, February 2018

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

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

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner	Previously used Y/N If yes, for which data point?
KCP 8/ KCA 6.1/01	Klimmek, S. and Gizler, A.	2017	Freezing storage stability & validation of residues of 1,2,4-Triazole, Triazole Alanine, Triazole Acetic Acid and Triazole Lactic Acid in water, acid and dry matrix: cucumber, grapes and dry bean at 0, 3, 6, 12, 18, 24 and 36 months. Report No.: S12-00072, sponsor no.: 000074067 Eurofins Agroscience Services Chem GmbH, Hamburg, Germany GLP Unpublished	N	ADM	Y evaluated in the RR for ADM.03500.F.2.B on March 2023
KCP 8/ KCA 6.1/02	Lefresne, S.	2020	Freezing storage stability of prothioconazole-desthio, 3-hydroxy-prothioconazole-desthio, 4-hydroxy-prothioconazole-desthio, 5-hydroxy-prothioconazole-desthio, 6-hydroxy-prothioconazole-desthio and alpha-hydroxy-prothioconazole-desthio in plant matrices at/below -18°C during 24 months (0, 1, 3, 12, 18 and 24 months): Wheat whole plant (high water content), wheat grain (high starch content), wheat straw (difficult commodity), oilseed rape grain (high oil content), strawberry (high acid content) and dry bean (high protein content). Report No.: B18S-A4-P-02, sponsor no.: 000107139 POLLENIZ/GIRPA, Beaucouzé Cedex, France GLP Unpublished	N	ADM	Y evaluated in the RR for ADM.03500.F.2.B on March 2023
KCP 8/ KCA 6.1/03	Lindner, M.	2022	Storage stability of prothioconazole and azoxystrobin in pollen, nectar, flowers and honey under deep frozen conditions Study no.: S19-02145, MAC-1931L, sponsor no.: 000104133 Eurofins Agroscience Services Chem GmbH, Hamburg, Germany GLP Unpublished	N	ADM	Y evaluated in the RR for ADM.03500.F.2.B on March 2023
KCP 8/ KCA 6.1/04	Lindner, M.	2021	Storage Stability of Fluxapyroxad in Flowers, Nectar and Pollen under Deep Frozen Conditions. Report no.: S21-00224, sponsor no.: 000107309 Eurofins Agroscience Services Chem GmbH, Hamburg, Germany GLP Unpublished	N	ADM	N
KCP 8/ KCA 6.3.1/01	Amic, S.	2020b	Residue study of prothioconazole and its metabolites in wheat whole plant and RAC after one foliar application of ADM.3500.F.2.B (250 g a.s./L of prothioconazole) - 2 harvest and 2 decline trials – Northern Europe (FR, HU, PL) – 2019. Report no.: BPL19/762/GC, sponsor no.: 000102751 BIOTEK Agriculture, Saint-Pouange, France	N	ADM	Y evaluated in the RR for ADM.03500.F.2.B on March 2023

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner	Previously used Y/N If yes, for which data point?
			GLP Unpublished			
KCP 8/ KCA 6.3.1/02	Yozgatli, H.P.	2021d	Determination of the residue of 1, 2, 4-Triazole (1, 2, 4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) in wheat (RAC whole plant, grain and straw) following one application of ADM.3500.F.2.B (250g a.s./L of prothioconazole) in 4 trials (2 HS + 2 DCS) in Northern Europe (France, Hungary and Poland) 2019 Study no: S19-00733, sponsor no.: 000102783 Eurofins Agroscience Services Chem GmbH, Hamburg, Germany GLP Unpublished	N	ADM	Y evaluated in the RR for ADM.03500.F.2.B on March 2023
KCP 8/ KCA 6.3.1/03	Le Mineur, A.	2022a	Residue study of Prothioconazole and Fluxapyroxad and their respective metabolites in wheat Raw Agricultural Commodities after foliar application of ADM.03503.F.1.A under field conditions –Northern Europe – 2021 Study no.: BPL21/954/GC, sponsor no.: 000107608 SynTech Research France, La Chapelle de Guinchay, France GLP Unpublished	N	ADM	**Y for prothioconazole**, evaluated in the RR for ADM.03500.F.2.B on March 2023 **N for fluxapyroxad**
KCP 8/ KCA 6.3.1/04	Le Mineur, A.	2022b	Residue study of prothioconazole, difenoconazole and their metabolites in wheat whole plant and raw agricultural commodities after foliar application of ADM.03501.F.1.A under field conditions – Northern Europe - 2021 Study no.: S21-02258, BPL21/958/GC, sponsor no.: 000107612 SynTech Research France, La Chapelle de Guinchay, France GLP Unpublished	N	ADM	Y evaluated in the RR for ADM.03500.F.2.B on March 2023
KCP 8/ KCA 6.3.2/01	Amic, S.	2020d	Residue study of prothioconazole and its metabolites in barley whole plant and RAC after one foliar application of ADM.3500.F.2.B (250 g a.s./L of prothioconazole) - 2 harvest and 2 decline trials – Northern Europe (France, Hungary and Poland) – 2019. Report no.: BPL19/764/GC, sponsor no.: 000102753 BIOTEK Agriculture, Saint-Pouange, France GLP Unpublished	N	ADM	Y evaluated in the RR for ADM.03500.F.2.B on March 2023

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner	Previously used Y/N If yes, for which data point?
KCP 8/ KCA 6.3.2/02	Yozgatli, H.P.	2021g	Determination of the residue of 1, 2, 4-Triazole (1, 2, 4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) in barley (RAC whole plant, grain and straw) following one foliar application of ADM.3500.F.2.B (250 g a.s./L of prothioconazole) in 4 trials (2 HS + 2 DCS) in Northern Europe (France, Hungary and Poland) 2019 Study no.: S19-00735, sponsor no.: 000102785 Eurofins Agroscience Services Chem GmbH, Hamburg, Germany GLP Unpublished	N	ADM	Y evaluated in the RR for ADM.03500.F.2.B on March 2023
KCP 8/ KCA 6.3.2/03	Huaulmé, J.-M.	2021a	Residue study of Prothioconazole and its metabolites, and Fenpropidin in barley whole plant and Raw Agricultural Commodity after one foliar application of ADM.3502.F.1.A (175 g a.s./L of prothioconazole and 250 g a.s./L of fenpropidin) - 2 harvest and 2 decline trials – Northern Europe (FR, PL, HU) - 2020. Report no.: BPL20/844/GC, sponsor no.: 000105350 BIOTEK Agriculture, Saint-Pouange, France GLP Unpublished	N	ADM	Y evaluated in the RR for ADM.03500.F.2.B on March 2023
KCP 8/ KCA 6.3.2/04	Yozgatli, H.P.	2021h	Determination of the residue of 1, 2, 4-Triazole (1, 2, 4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) in barley (RAC whole plant, grain and straw) following one foliar application of ADM.3502.F.1.A (175g a.s./L of prothioconazole and 250 g/L fenpropidin) in 4 trials (2 HS + 2 DCS) in Northern Europe (France, Poland and Hungary), 2020 Study no.: S20-01302, sponsor no.: 000105545 Eurofins Agroscience Services Chem GmbH, Hamburg, Germany GLP Unpublished	N	ADM	Y evaluated in the RR for ADM.03500.F.2.B on March 2023
KCP 8/ KCA 6.3.2/05	Barbier, G.	2022	Analysis of prothioconazole and its metabolites in barley after application of ADM.3502.F.1.A (prothioconazole and fenpropidin) in trial in Northern - 2020 Study no.: B21G-A4-P-05, sponsor no.: 000108763 GIRPA, Beaucouzé Cedex, France GLP Unpublished	N	ADM	Y evaluated in the RR for ADM.03500.F.2.B on March 2023
KCP 8/ KCA 6.3.2/06	Huaulmé, J.-M.	2022a	Residue study of fluxapyroxad and prothioconazole and their metabolites in barley raw agricultural commodities after application of ADM.03503.F.1.A under field conditions - Northern Europe - 2021 Study no.: BPL21/962/GC, sponsor no.: 000107616 SynTech Research France, La Chapelle de Guinchay, France GLP Unpublished	N	ADM	**Y for prothioconazole**, evaluated in the RR for ADM.03500.F.2.B on March 2023

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner	Previously used Y/N If yes, for which data point?
						N for fluxapyroxad
KCP 8/ KCA 6.5.1/01	Bloß, K.	2019	Prothioconazole-desthio: Aqueous Hydrolysis of [^{14}C]Prothioconazole-desthio at 90, 100 and 120 °C. Report no.: S18-07655, sponsor no.: 000101817 Eurofins Agroscience Services EcoChem GmbH, Niefern-Öschelbronn, Germany GLP Unpublished	N	ADM	Y evaluated in the RR for ADM.03500.F.2.B on March 2023
KCP 8/ KCA 6.6.2/01	Semrau, J.	2021	Determination of Residues of Prothioconazole and its Metabolites after One Application of MCW-2073 on Bare Soil in Rotational Crops (Radish, Leaf lettuce and Barley) at 2 Sites in Northern Europe and 2 Sites in Southern Europe 2018/2019 Study no.: S18-02513, sponsor no.: 000109154 Eurofins Agroscience Services GmbH, Stade, Germany GLP Unpublished	N	ADM	Y evaluated in the RR for ADM.03500.F.2.B on March 2023
KCP 8/ KCA 6.6.2/02	Semrau,J.	2022	Determination of residues of prothioconazole metabolites in rotational crops (radish, lettuce, barley) after one application of Prothioconazole 250 EC (ADM.03500.F.2.B) on bare soil at 1 site in Northern Europe and 1 site in Southern Europe 2021 Study no.: S21-00408, sponsor no.: 000107470 Eurofins Agroscience Services GmbH, Stade, Germany GLP Unpublished	N	ADM	Y evaluated in the RR for ADM.03500.F.2.B on March 2023
KCP 8/ KCA 6.6.2/03	Anonymous	2022	Position Paper: 1,2,4-Triazole residues in crop residue trials and rotational crops following the use of Prothioconazole Sponsor no.: 000110079 ADAMA Agricultural Solutions Ltd., Airport City, Israel Not GLP Unpublished	N	ADM	Y evaluated in the RR for ADM.03500.F.2.B on March 2023

ADM = Property of ADAMA Agricultural Solutions and all affiliates.
Under Article 59 of Regulation 1107/2009/EC, the Sponsor Company claims data protection for all ADM studies.

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 8/ KCA 6/01 (IIA, 6.0/01)	Heinemann, O.	2001	18 months storage stability of residues of JAU 6476 and JAU 6476-desthio during frozen storage in/on wheat matrices Report No. : MR-282/00 Bayer AG GLP Unpublished	N	BCS
KCP 8/ KCA 6/02 (IIA, 6.1.2/01)	Haas, M.	2001	Metabolism of [phenyl-UL-^{14}C]JAU 6476 in peanuts Report No.: MR-193/01 Bayer AG GLP Unpublished	N	BCS
KCP 8/ KCA 6/03 (IIA, 6.1.1/01)	Haas, M.; Bornatsch, W.	2000	Metabolism of JAU 6476 in spring wheat (after foliar application) Report no.: MR-198/99 Bayer AG GLP Unpublished	N	BCS
KCP 8/ KCA 6/04 (IIA, 6.1.1/03)	Vogeler, K.; Sakamoto, H.; Brauner, A.	1993	Metabolism of SXX 0665 in summer wheat Report No.: PF3906 Bayer AG GLP Unpublished	N	BCS
KCP 8/ KCA 6/05 (IIA, 6.1.1/02)	Haas, M.	2001	Metabolism of JAU 6476 in spring wheat after seed dressing Report No.: MR-467/99 Bayer AG GLP Unpublished	N	BCS
KCP 8/ KCA 6/06 (IIA, 6.6./01)	Haas, M.	2001	Confined rotational crop study with JAU 6476 Report No.: MR-159/00 Bayer AG GLP Unpublished	N	BCS
KCP 8/ KCA 6/07	[redacted]	2001	[Phenyl-UL-^{14}C]JAU 6476 Absorption, distribution, excretion and metabolism in the lactating goat	~~N~~ Y	BCS

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
(IIA 6.2.2.1/01)			[redacted] GLP Unpublished		
KCP 8/ KCA 6/08 (IIA, 6.2.2.2/01)	[redacted]	2002	[Phenyl-UL-^{14}C] JAU 6476-desthio Absorption, distribution, excretion, and metabolism in the lactating goat [redacted] GLP Unpublished	~~N~~ Y	BCS
KCP 8/ KCA 6/09 (IIA, 6.2.2.3/01)	[redacted]	2001	[Phenyl-UL-^{14}C]JAU 6476 Absorption, distribution, excretion and metabolism in laying hens [redacted] GLP Unpublished	~~N~~ Y	BCS
KCP 8/ KCA 6/10 (IIA, 6.4/01)	[redacted]	2001	JAU 6476-desthio – Dairy cattle feeding study Report No.: MR-535/00 [redacted] GLP Unpublished	~~N~~ Y	BCS
KCP 8/ KCA 6/11 (IIA, 6.5/01)	Gilges, M.	2001	Hydrolysis of JAU 6476 under conditions of processing Report No.: MR-166/00 Bayer AG GLP Unpublished	N	BCS

BCS = Bayer CropScience

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
For the relevant studies please refer to the EU peer review of the triazole derivative metabolites (TDMs) in the light of confirmatory data submitted (UK, 2018b, EFSA, 2018b,					

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
amended 2019).					

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
For the relevant studies please refer to the EU peer review of the fluxapyroxad DAR (UK, 2011), EFSA, 2012 and EFSA 2020b.					

List of data submitted by the applicant and not relied on

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

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

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

Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1 Prothioconazole

A 2.1.1 Stability of residues

A 2.1.1.1 Stability of residues during storage of samples

A 2.1.1.1.1 Storage stability of residues in plant products

A 2.1.1.1.1.1 Study 1

Comments of zRMS:	The study of Klimmek, S. and and Gizler, A., 2017 (Report No.: S12-00072) has been evaluated in Registration Report for ADM.03500.F.2.B on March 2023 by zRMS-PL and the summary is presented below. A deep-freezer storage stability study was conducted to determine the stability of residues of 1,2,4- Triazole (1,2,4 T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) in cucumber (fruit), grapes (bunches) and dried beans (seed) for up to 36 months during storage at <-18 °C. Results: **Cucumber** - According to the OECD 506, point 22, in case a significant difference (greater than 20%) exists between the results for the duplicate samples from the same time point, it should be analysing additional samples of the commodity from that time point. This is the case for samples of 1,2,3-triazole (1,2,4 T) after 12 months storage of cucumber. Unfortunately, the additional sample has not been analyzed. - The level of residue 1,2,4-triazole (1,2,4 T) in cucumber declined by more than 30% after 12 months. The procedural recoveries at this time-point were significantly lower than for the earlier time-points. Despite the above, taking into account the recommendation indicated in point 33 of OECD 506 it is considered that the samples are sufficiently stable over 12 months frozen storage in cucumber. - Storage stability was demonstrated for triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) in cucumber (fruit) stored at -18°C or below for at least 36 months. **Grapes** - Storage stability was demonstrated for 1,2,4-triazole (1,2,4 T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) in grapes (bunches) stored at -18°C or below for at least 36 months (although it is considered that some decline in the 1,2,4 T stability has been observed after 12 months storage of grapes). **Dried beans (seed)** - Storage stability was also demonstrated for 1,2,4-triazole (1,2,4 T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) in dried beans (seed) stored at -18°C or below for at least 36 months. The study is acceptable.

Reference: KCA 6.1/01

Report: Freezing storage stability & validation of residues of 1,2,4-Triazole, Triazole Alanine, Triazole Acetic Acid and Triazole Lactic Acid in water, acid and dry matrix : cucumber, grapes and dry bean at 0, 3, 6,12,18, 24 and 36 months;
Klimmek, S. and and Gizler, A., 2017;
Report No.: S12-00072, Sponsor no.: 000074067

Guideline(s): Regulation (EC) No. 1107/2009;

	Guidance document SANCO/825/OO rev. 8.1 of 16/11/2010, European Commission; Guidance document SANCO/3029/99 rev. 4 of 11/07/00, European Commission; EU Commission Working Document 1607/VI/97, Appendix H: Storage Stability 7032/VI/95, rev. 5 (22/07/97); U.S. EPA Residue Chemistry Test Guidelines, OPPTS 860.1380, Storage Stability Data
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Study objective
The study objective was to validate the method for the determination of residues of 1,2,4-triazole (1,2,4 T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) in cucumber (fruit), grapes (bunches) and dried beans (seed) and to investigate their freezer storage stability at < -18°C for up to 36 months.

Materials and methods
For storage stability determination the matrix material was thoroughly homogenised with dry ice using a cutter or knife mill and stored at < -18 °C until start of analysis.
For cucumber (fruit), grapes (bunches) and dried beans (seed) specimens, untreated homogenised material was weighed into glass jars with screw caps. Specimen weight was 5 g for each matrix. Fortification solutions of 1,2,4-triazole (1,2,4 T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) used for cucumber (fruit), grapes (bunches) and dried beans (seed) specimens were prepared in water (HPLC grade) or methanol using an Eppendorf pipette and volumetric flasks.
Fortification of the specimens to be stored was carried out on day 0 by adding the appropriate fortification solution at a level of 0.20 mg/kg to separate samples of the specimens. Afterwards, the glass jars were capped, transferred to a freezer, and then stored at < -18 °C. These specimens were only removed for analysis at the fixed intervals.
Fortified and control samples of cucumber (fruit), grapes (bunches) and dried beans (seed) were analysed at day 0 and after 3, 6, 12, 18, 24 and 36 months of storage at < -18 °C, respectively. At day 0, three specimens of cucumber (fruit), grapes (bunches) and dried beans (seed) fortified with 1,2,4-triazole (1,2,4 T), Triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) were analysed together with one control sample each. At each time point after day 0, one control sample and two stored fortified samples were analysed together with two freshly fortified specimens for each matrix type.
Analysis of 1,2,4-triazole (1,2,4 T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) in cucumber (fruit), grapes (bunches) and dried beans (seed) was performed according to Syngenta method GRM053.01A. For analysis of all analytes, cucumber (fruit), grapes (bunches) and dried beans (seed) specimens were extracted with methanol/water (4/1, v/v). After filtration and evaporation to the aqueous remainder, the volume was adjusted with ultra-pure water. After sonication, final determination took place with liquid chromatography with tandem mass spectrometry (LC-MS/MS) (for validation samples and for storage samples up until the 18 months storage time point) or with high performance liquid chromatography with triple quadrupole mass spectrometric detection equipped with DMS SelexION technology (LC-DMS-MS/MS) (from July 2014 for storage time points 24 and 36 months, and for an additional validation set). All specimen extracts were stored at 3 - 8 °C in the dark until analysis.

For determination of stability in extracts and following analysis, the final extracts of the validation samples fortified at the LOQ along with the control samples were stored in a refrigerator at 5 ± 4°C for at least 10 days. After this period, these samples were re-analysed by single injection against freshly prepared standards.

Successful method validations for all specimens and analytes have been conducted within the study:

A reduced validation for triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) in cucumber (fruit), grapes (bunches) and dried beans (seed) was successfully performed within this study using LC-MS/MS and LC-DMS-MS/MS.
For 1,2,4-triazole (1,2,4 T), a reduced validation in cucumber (fruit) and grapes (bunches) was successfully performed within this study using LC-MS/MS and LC-DMS-MS/MS.
For 1,2,4-triazole (1,2,4 T), a full validation in dried beans (seed) was successfully performed within this study using LC-MS/MS and a reduced validation in dried beans (seed) was successfully performed within this study using LC-DMS-MS/MS.
The limit of quantification (LOQ) for 1,2,4-triazole (1,2,4 T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) was 0.01 mg/kg.
For details on method validations, please refer to dRR Part B.5, point KCP 5.1.2.

Results and discussions

Analysis of control specimens by LC-MS/MS and LC-DMS-MS/MS during the validation yielded no residues of 1,2,4-triazole (1,2,4 T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) above the limit of quantification of 1,2,4-triazole (1,2,4 T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) in the test systems except for some control specimens for triazole alanine and triazole lactic acid. The residue levels of triazole alanine and triazole lactic acid found in the untreated samples are in line with values found in the latest EU survey of the residue situation of triazole metabolites.
The recoveries of stored samples demonstrate that 1,2,4-triazole (1,2,4 T) is stable in cucumber (fruit) stored at -18°C or below for 12 months. Although the level of residue 1,2,4-triazole seems to have declined by more than 30% in cucumber (fruit) after 12 months, it is considered that the samples are sufficiently stable over 12 months frozen storage, as the procedural recoveries at the 12 months time-point were lower than for the earlier time-points (although it is considered that some decline in stability has been observed).
The recoveries of stored samples demonstrate that triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) are stable in cucumber (fruit) stored at -18°C or below for at least 36 months.
The recoveries of stored samples demonstrate that 1,2,4-triazole (1,2,4 T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) are stable in grapes (bunches) stored at -18°C or below for at least 36 months.
The recoveries of stored samples demonstrate that 1,2,4-triazole (1,2,4 T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) are stable in dried beans (seed) stored at -18°C or below for at least 36 months.

Extract stability was verified during the study for 1,2,4 T, TA, TAA and TLA in cucumber for 31 days, in grapes for 39 days and in dried beans for 10 (1,2,4 T), 17 (TA) and 50 days (TA, TLA).

Table A 1: Stability of 1,2,4-triazole (1,2,4 T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) in cucumber, grapes and dried beans following storage at ≤ -18°C.

Matrix	**Analyte**	**Level (nominal fortification)** (mg/kg)	**Nominal storage interval** (months)	**Actual storage interval** (months)	**Residues after storage** (mg/kg) (mean)	**Residues after storage (**% of nominal spiking level) (mean)	**Procedural recovery of freshly spiked control sample** (%) (mean)	**Residues after storage** (corrected for procedural recovery) (mg/kg)	**Residues after storage** (corrected for procedural recovery) (%)
Cucumber	1,2,4 T	0.2	0	0	0.200, 0.208, 0.188 (0.199)	100, 104, 94 (99)	NA	0.200	100
		0.2	3	3	0.169, 0.152 (0.161)	85, 76 (81)	114, 106 (110)	0.146	73
		0.2	6	6	0.167, 0.176 (0.172)	84, 88 (86)	104, 99 (102)	0.169	85
		0.2	12	12	0.104, 0.133 (0.119)	52, 67 (60)*	72, 76 (74)	0.160	80
		0.2	18	19	0.085, 0.099 (0.092)	43, 50 (47)	105, 101 (103)	0.089	45**
		0.2	24	29	0.099, 0.089 (0.094)	50, 45 (48)	115, 120 (118)	0.080	40**
		0.2	36	45	0.061, 0.067 (0.064)	31, 34 (33)	98, 104 (101)	0.064	32**
	TA	0.2	0	0	0.199, 0.212, 0.189 (0.200)	100, 106, 95 (100)	NA	0.199	100
		0.2	3	3	0.162, 0.148, (0.155)	81, 74 (78)	77, - (77)	0.201	101
		0.2	6	6	0.216, 0.219 (0.218)	108, 110 (109)	108, 111 (110)	0.199	100
		0.2	12	12	0.179, 0.166 (0.173)	90, 83 (87)	90, 95 (93)	0.186	94
		0.2	18	19	0.218, 0.222 (0.220)	109, 111 (110)	104, 102 (103)	0.212	107
		0.2	24	28	0.221, 0.216 (0.219)	111, 108 (110)	107, 112 (110)	0.200	100
		0.2	36	43	0.193, 0.206 (0.200)	97, 103 (100)	102, 105 (104)	0.193	97
	TAA	0.2	0	0	0.189, 0.205, 0.194 (0.196)	95, 103, 97 (98)	NA	0.199	100
		0.2	3	3	0.203, 0.214 (0.209)	102, 107 (105)	108, 110, (109)	0.191	96
		0.2	6	6	0.203, 0.228 (0.216)	102, 114 (108)	98, - (98)	0.220	110
		0.2	12	12	0.167, 0.109 (0.138)	84, 55 (70)	75, 65 (70)	0.197	99
		0.2	18	19	0.199, 0.197 (0.198)	100, 99 (100)	95, 100 (98)	0.203	102
		0.2	24	29	0.212, 0.228 (0.220)	106, 114 (110)	108, 107 (108)	0.205	102
		0.2	36	45	0.213, 0.216 (0.215)	107, 108 (108)	100, 105 (103)	0.209	105
	TLA	0.2	0	0	0.212, 0.205, 0.210 (0.209)	106, 103, 105 (105)	NA	0.200	100
		0.2	3	3	0.191, 0.212 (0.202)	96, 106 (101)	114, 106 (110)	0.183	92
		0.2	6	6	0.214, 0.223 (0.219)	107, 112 (110)	111, 108 (110)	0.200	100
		0.2	12	12	0.226, 0.251 (0.239)	113, 126 (120)	114, 122 (118)	0.202	101
		0.2	18	19	0.221, 0.218 (0.220)	111, 109 (110)	102, 112 (107)	0.205	103
		0.2	24	29	0.220, 0.204 (0.212)	110, 102 (106)	109, 108 (109)	0.195	98
		0.2	36	45	0.224, 0.215 (0.220)	112, 108 (110)	103, 107 (105)	0.209	105
Grapes	1,2,4 T	0.2	0	0	0.211, 0.211, 0.207 (0.210)	106, 106, 104 (105)	NA	0.199	100
		0.2	3	3	0.174, 0.181 (0.178)	87, 91 (89)	106, 106 (106)	0.167	84

Matrix	**Analyte**	**Level (nominal fortification)** (mg/kg)	**Nominal storage interval** (months)	**Actual storage interval** (months)	**Residues after storage** (mg/kg) (mean)	**Residues after storage (**% of nominal spiking level) (mean)	**Procedural recovery of freshly spiked control sample** (%) (mean)	**Residues after storage** (corrected for procedural recovery) (mg/kg)	**Residues after storage** (corrected for procedural recovery) (%)
		0.2	6	6	0.208, 0.198 (0.203)	104, 99 (102)	111, 109 (110)	0.185	92
		0.2	12	12	0.135, 0.136 (0.136)	68, 68 (68)	93, 91 (92)	0.147	74
		0.2	18	19	0.147, 0.149 (0.148)	74, 75 (75)	109, 105 (107)	0.138	70
		0.2	24	29	0.155, 0.149 (0.152)	78, 75 (77)	102, 113 (108)	0.141	71
		0.2	36	45	0.141, 0.136 (0.139)	71, 68 (70)	100, 100 (100)	0.139	70
	TA	0.2	0	0	0.205, 0.207, 0.199 (0.204)	103, 104, 100 (102)	NA	0.199	100
		0.2	3	3	0.190, 0.200, (0.195)	95, 100 (98)	85, 92 (89)	0.220	110
		0.2	6	6	0.215, 0.218 (0.217)	108, 109 (109)	104, 109 (107)	0.203	102
		0.2	12	12	0.177, 0.186 (0.182)	89, 93 (91)	99, 101 (100)	0.182	91
		0.2	18	19	0.224, 0.215 (0.220)	112, 108 (110)	112, 108 (110)	0.200	100
		0.2	24	29	0.214, 0.209 (0.212)	107, 105 (106)	105, 107 (106)	0.200	100
		0.2	36	44	0.220, 0.209 (0.215)	110, 105 (108)	107, 105 (106)	0.202	101
	TAA	0.2	0	0	0.212, 0.190, 0.188 (0.197)	106, 95, 94 (98)	NA	0.200	100
		0.2	3	3	0.235, 0.204 (0.220)	118, 102 (110)	111, 105 (108)	0.203	102
		0.2	6	6	0.207, 0.231 (0.219)	104, 116 (110)	119, 100 (110)	0.200	100
		0.2	12	12	0.207, 0.215 (0.211)	104, 108 (106)	108, 108 (108)	0.195	98
		0.2	18	19	0.200, 0.212 (0.206)	100, 106 (103)	107, 113 (110)	0.187	94
		0.2	24	29	0.216, 0.216 (0.216)	108, 108 (108)	107, 111 (109)	0.198	99
		0.2	36	45	0.199, 0.211 (0.205)	100, 106 (103)	110, 107 (109)	0.189	95
	TLA	0.2	0	0	0.212, 0.199, 0.206 (0.206)	106, 100, 103 (103)	NA	0.200	100
		0.2	3	3	0.197, 0.194 (0.196)	99, 97 (98)	97, 96 (97)	0.203	102
		0.2	6	6	0.201, 0.183 (0.192)	101, 92 (97)	114, 106 (110)	0.175	88
		0.2	12	12	0.189, 0.188 (0.189)	95, 94 (95)	99, 105 (102)	0.185	93
		0.2	18	19	0.220, 0.215 (0.218)	110, 108 (109)	107, 111 (109)	0.200	100
		0.2	24	29	0.214, 0.222 (0.218)	107, 111 (109)	109, 108 (109)	0.201	100
		0.2	36	45	0.209, 0.203 (0.206)	105, 102 (104)	109, 111 (110)	0.187	94
Dried beans	1,2,4 T	0.2	0	0	0.197, 0.174, 0.191 (0.187)	96, 85, 93 (91)	NA	0.205	100
		0.2	3	3	0.153, 0.163 (0.158)	77, 82 (80)	106, 112 (109)	0.145	73
		0.2	6	6	0.145, 0.141 (0.143)	73, 71 (72)	74, 91 (83)	0.173	87
		0.2	12	12	0.153, 0.145 (0.149)	77, 73 (75)	104, 108 (106)	0.141	71
		0.2	18	18	0.181, 0.184 (0.183)	91, 92 (92)	109, 110 (110)	0.167	84
		0.2	24	24	0.140, 0.155 (0.148)	70, 78 (74)	86, 84 (85)	0.174	87
		0.2	36	40	0.172, 0.153 (0.163)	86, 77 (82)	109, 108 (109)	0.150	75

Matrix	**Analyte**	**Level (nominal fortification)** (mg/kg)	**Nominal storage interval** (months)	**Actual storage interval** (months)	**Residues after storage** (mg/kg) (mean)	**Residues after storage (**% of nominal spiking level) (mean)	**Procedural recovery of freshly spiked control sample** (%) (mean)	**Residues after storage** (corrected for procedural recovery) (mg/kg)	**Residues after storage** (corrected for procedural recovery) (%)
	TA	0.2	0	0	0.238, 0.180, 0.194 (0.204)	119, 90, 97 (102)	NA	0.200	100
		0.2	3	3	0.142, 0.145, (0.144)	71, 73 (72)	67, 73 (70)	0.205	103
		0.2	6	6	0.205, 0.234 (0.220)	103, 117 (110)	102, 117 (110)	0.200	100
		0.2	12	12	0.147, 0.158 (0.153)	74, 79 (77)	84, 79 (82)	0.187	94
		0.2	18	19	0.193, 0.212 (0.203)	97, 106 (102)	101, 99 (100)	0.203	102
		0.2	24	29	0.151, 0.128 (0.140)	76, 64 (70)	69, 70 (70)	0.201	101
		0.2	36	44	0.195, 0.146 (0.171)	98, 73 (86)	77, 93 (85)	0.201	101
	TAA	0.2	0	0	0.225, 0.209, 0.218 (0.218)	113, 105, 109 (109)	NA	0.200	100
		0.2	3	3	0.203, 0.182 (0.193)	102, 91 (97)	115, 100 (108)	0.179	90
		0.2	6	6	0.205, 0.212 (0.209)	103, 106 (105)	106, 100 (103)	0.202	101
		0.2	12	12	0.164, 0.206 (0.185)	82, 103 (93)	105, 89 (97)	0.191	95
		0.2	18	19	0.160, 0.133 (0.147)	80, 67 (74)	58, 69 (64)	0.231	116
		0.2	24	29	0.127, 0.152 (0.140)	64, 76 (70)	75, 64 (70)	0.201	101
		0.2	36	44	0.206, 0.184 (0.195)	103, 92 (98)	102, 98 (100)	0.195	98
	TLA	0.2	0	0	0.203, 0.235, 0.207 (0.215)	101, 118, 104 (108)	NA	0.200	100
		0.2	3	3	0.194, 0.219 (0.207)	97, 110 (104)	110, 110 (110)	0.188	94
		0.2	6	6	0.160, 0.199 (0.180)	80, 100 (90)	83, 96 (90)	0.201	101
		0.2	12	12	0.209, 0.142 (0.176)	105, 71 (88)	110, 114 (112)	0.157	79
		0.2	18	19	0.226, 0.213 (0.220)	113, 107 (110)	115, 99 (107)	0.205	103
		0.2	24	29	0.154, 0.130 (0.142)	77, 65 (71)	78, 71 (75)	0.191	95
		0.2	36	44	0.220, 0.212 (0.216)	110, 106 (108)	103, 105 (104)	0.208	104

[a] Corrected percent recovery = (Mean residues after storage (%) / Mean of fresh procedural recoveries (%)) X 100 %
NA = Not Applicable
0-18 months analyses: final determination with LC-MS/MS
24 and 36 months analyses: final determination with LC-DMS-MS/MS

* Although the level of residue 1,2,4-triazole seems to have declined by more than 30%, it is considered that the samples are sufficiently stable over 12 months frozen storage in cucumber (fruit), as the procedural recoveries at the 12 months time-point were lower than for the earlier time-points (although it is considered that some decline in stability has been observed).
** Conversely residues of 1,2,4-triazole are only regarded as sufficiently stable in cucumber (fruit) up to a period of 12 months frozen storage

Conclusion

Storage stability was demonstrated for 1,2,4-triazole (1,2,4 T) in cucumber (fruit) stored at -18°C or below for 12 months.
Storage stability was demonstrated for triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) in cucumber (fruit) stored at -18°C or below for at least 36 months.
Storage stability was also demonstrated for 1,2,4-triazole (1,2,4 T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) in grapes (bunches) and in dried beans (seed) stored at -18°C or below for at least 36 months.

A 2.1.1.1.1.2 Study 2

Comments of zRMS:	The study of Lefresne, S., 2020 (Report No.: B18S-A4-P-02) has been evaluated in Registration Report for ADM.03500.F.2.B on March 2023 by zRMS-PL and the summary is presented below. The storage stability was demonstrated for prothioconazole-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio and prothioconazole-α-hydroxy-desthio in wheat whole plant (high water content), wheat grain (high starch content), wheat straw (difficult commodity), oilseed rape grain (high oil content), strawberry (high acid content) and dry bean (high protein content) upon storage at ≤-18 °C for 24 months. The LOQ of prothioconazole-desthio, 3-hydroxy-prothioconazoledesthio expressed as prothioconazole-desthio, 4-hydroxy-prothioconazole-desthio expressed as prothioconazole-desthio, 5-hydroxy-prothioconazole-desthio expressed as prothioconazoledesthio, 6-hydroxy-prothioconazole-desthio expressed as prothioconazole-desthio and alphahydroxy-prothioconazole-desthio expressed as prothioconazole-desthio was 0.010 mg/kg, for each reference item. The LOQ of prothioconazole (sum of prothioconazole-desthio, 3-hydroxy-prothioconazole-desthio, 4-hydroxy-prothioconazole-desthio, 5-hydroxyprothioconazole-desthio, 6-hydroxy-prothioconazole-desthio and alpha-hydroxyprothioconazole-desthio, expressed as prothioconazole-desthio) was 0.060 mg/kg. Remark: For wheat (grain), after 18 and 21 months of storage stability, loss higher than 30% were not confirmed by another analysis at 24 months. Consequently, these analyses were excluded in the conclusion of storage stability with no adverse impact on the study. The study is acceptable.

Reference:	KCA 6.1/02
Report	Freezing storage stability of prothioconazole-desthio, 3-hydroxy-prothioconazole-desthio, 4-hydroxy-prothioconazole-desthio, 5-hydroxy-prothioconazole-desthio, 6-hydroxy-prothioconazole-desthio and alpha-hydroxy-prothioconazole-desthio in plant matrices at/below -18°C during 24 months (0, 1, 3, 12, 18 and 24 months): Wheat whole plant (high water content), wheat grain (high starch content), wheat straw (difficult commodity), oilseed rape grain (high oil content), strawberry (high acid content) and dry bean (high protein content). Lefresne, S., 2020 Report No.: B18S-A4-P-02, Sponsor no.: 000107139
Guideline(s):	Yes, Guidance document on pesticide residue analytical methods, ENV/JM/MONO(2007)17, Residues: guidance for generating and reporting methods of analysis in support of pre-registration data requirements for Annex II (part A, section 4)

	and Annex III (part A, section 5) of Directive 91/414, SANCO/3029/99 rev.4 of 11/07/2000, Guidance Document on pesticide residue analytical methods, SANCO/825/00 rev.8.1 of 16/11/2010. Guideline 7032/VI/95 rev.5, appendix H, OECD Guideline for the testing of chemical (506/2007) "Stability of Pesticide Residues in Stored Commodities".
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Study objective
The study objective was to determine the freezing storage stability of prothioconazole-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio and prothioconazole-α-hydroxy-desthio in the following plant matrices (stored at ≤ -18°C for 24 months (0, 1, 3, 12, 18, 21 (wheat grain only) and 24 months):

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

Materials and methods
For storage stability determination the matrix material was thoroughly homogenised with dry ice using a mixer and stored at -18 °C until start of analysis.
For strawberry, 10 g of sub-specimens were weighed into 50 mL centrifuge tubes. 50 samples were prepared in this way. 12 of them were kept as control sample with addition of 100 µL acetonitrile, the 38 remaining samples were fortified with each metabolite (prothioconazole-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio and prothioconazole-α-hydroxy-desthio) at 0.100 mg/kg by addition of 100 µL of a 10 mg/L standard solution of each metabolite using a volumetric pipette.
For the other matrices, 2 g of sub-specimens were weighed into 50 mL centrifuge tubes. 50 samples were prepared in this way. 12 of them were kept as control sample with addition of 20 µL acetonitrile, the 38 remaining samples were fortified with each reference item at 0.100 mg/kg with addition of 20 µL of a 10 mg/L standard solution of each reference item.
All sample containers were labelled with the sample identification number and the study code, and were stored in a freezer at about -18°C.

After a storage period of 0, 1, 3, 12, 18, 21 (only for wheat grain) and 24 months for each matrix, two (or three in the case of 0 month) samples fortified at 0.100 mg/kg and two control samples were removed from the freezer for analysis. One control sample was freshly fortified at 0.100 mg/kg and used as recovery experiment (procedural recovery). This freshly fortified control was analysed together with the second control and with the two or three aged fortified samples.

Control samples used for procedural recoveries were handled and stored in the same way and for the same time period as the analytical sample extracts that were prepared within the same analytical set.

The analytical method principle is based on European Committee for Standardization (CEN): EN 15662:2009-02. "Foods of plant origin - Determination of pesticide residues using GC-MS and/or LC-

MS/MS following acetonitrile extraction/partitioning and clean-up by dispersive SPE - QuEChERS-method" and summarised as follows:
Residues of prothioconazole-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio and prothioconazole-α-hydroxy-desthio, all expressed as prothioconazole-desthio were extracted from homogenised matrices by maceration with acetonitrile; water was added if necessary. Then, extracts were purified by dispersive solid phase extraction. The quantification was performed by liquid chromatography with tandem mass spectrometry detection (LC-MS/MS). To ensure unambiguous identification, two mass transitions were monitored for each reference item.

Except for wheat whole plant sample extracts which were analysed within 24 hours following extraction, final sample extracts were stored at about -18°C before injection in LC-MS/MS until analysis. Thus, stability of prothioconazole-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio and prothioconazole-α-hydroxy-desthio in final sample extracts was determined during this study.
Therefore, recovery experiments using aged sample sets were conducted. For each metabolite in wheat straw, an aged sample set was injected again with a freshly prepared standard calibration solution. For each metabolite in other matrices, a freshly prepared standard calibration solution was injected with the calibration standard solutions prepared on the day of extraction.

Successful method validations for all specimens and analytes have been conducted within the study:
For each matrix and each reference item, a full validation has been performed using 10 spiked samples. 5 recovery experiments fortified at the LOQ level and 5 recovery experiments fortified at ten times the LOQ level, 2 control samples and a reagent blank were prepared.

The LOQ (Limit of quantification) of prothioconazole-desthio, prothioconazole-3-hydroxy-desthio expressed as prothioconazole-desthio, prothioconazole-4-hydroxy-desthio expressed as prothioconazole-desthio, prothioconazole-5-hydroxy-desthio expressed as prothioconazole-desthio, prothioconazole-6-hydroxy-desthio expressed as prothioconazole-desthio and prothioconazole-α-hydroxy-desthio expressed as prothioconazole-desthio was 0.010 mg/kg, for each reference item, corresponding to a LOD (Limit of detection, defined as 30 % of the LOQ) of 0.003 mg/kg.

The LOQ (Limit of quantification) of prothioconazole (sum of prothioconazole-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio and prothioconazole-α-hydroxy-desthio, expressed as prothioconazole-desthio) was 0.060 mg/kg corresponding to a LOD (Limit of detection, defined as 30 % of the LOQ) of 0.018 mg/kg.

For further details on method validations, please refer to dRR Part B.5, point KCP 5.1.2.

Results and discussions
The aim of this storage stability study was to demonstrate storage stability of prothioconazole-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio and prothioconazole-α-hydroxy-desthio in wheat (whole plant, grain and straw), oilseed rape (grain), strawberry and dry bean stored under deep frozen conditions ≤ -18°C) over a storage period up to 24 months.

For each matrix and each analyte, the daily sample sets were validated with the determination of one freshly fortified sample per sample set (procedural recovery). At initial time (0 month), the daily sample sets were validated with the mean of the four fortified samples (fortified and procedural recovery are similar). The results were all well accepted as the procedural recoveries (or mean at 0 month) of each reference item in each matrix from freshly fortified samples were in the range 70-110 % for each sampling point.
Each control sample used to perform each recovery experiment was analysed in order to check for any background interferences at the expected retention time of each analyte. In some cases, background

interference below 30% of the level of fortification were detected. In these cases, recoveries were corrected by subtraction of the interferent peak area.

At up to and including 24 months of freezer storage (≤ -18 °C), there is no significant loss of prothioconazole-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio and prothioconazole-α-hydroxy-desthio (<30 %) in samples of wheat whole plant (high water content), wheat grain (high starch content), wheat straw (difficult commodity), oilseed rape grain (high oil content), strawberry (high acid content) and dry bean (high protein content) (refer to the table below).

Regarding stability in final sample extracts, extracts of wheat (whole plant) were analysed within 24 hours after initial extraction and thus no experiment on stability was required for this commodity.
For wheat straw, all analytes in final sample extracts were considered stable for at least 10 days when stored at about - 18°C. For the other matrices, all analytes in final sample extracts were considered stable for at least 3 days (wheat grain and strawberry) or at least 2 days (oilseed rape seeds and dry bean seeds) when stored at about - 18°C, thus covering the storage durations observed within the study.

Table A 2: **Stability of prothioconazole-desthio, 3-hydroxy-prothioconazole-desthio, 4-hydroxy-prothioconazole-desthio, 5-hydroxy-prothioconazole-desthio, 6-hydroxy-prothioconazole-desthio and alpha-hydroxy-prothioconazole-desthio in wheat (whole plant, grain and straw), in oilseed rape (grain), in strawberry and in dry bean seeds following storage at ≤ -18°C**

Storage				Residues and recoveries in specimens stored frozen (not corrected for procedural recoveries)						Residues and recoveries in specimens stored frozen (recovery corrected)		
				Uncorrected residue results (mg/kg)[1]						Procedural recovery of freshly spiked control sample (%) (mean)	Corrected results (corrected for procedural recovery)	
Matrix	**Analyte**	**Level (nominal fortification)** (mg/kg)	**Nominal storage interval** (months)	**sample 1**	**sample 2**	**sample 3**	**mean**	**Residues after storage** (mean, % of nominal spiking level)	**% corrected results with day 0 as 100 %**[2]		**Residues after storage** mean[3] (mg/kg)	**Residues after storage** mean[4] (% of nominal spiking level)
Wheat whole plant	Prothioconazole-desthio	0.1	0	0.082	0.084	0.084	0.083	83	100	82	0.102	102
		0.1	1	0.078	0.082	NA	0.080	80	96	89	0.090	90
		0.1	3	0.091	0.091		0.091	91	109	90	0.101	101
		0.1	12	0.092	0.089		0.091	91	109	86	0.105	105
		0.1	18	0.083	0.088		0.085	85	102	98	0.087	87
		0.1	24	0.085	0.086		0.086	86	103	89	0.096	96
	Prothioconazole-3-hydroxy-desthio, expressed as prothioconazole-desthio	0.1	0	0.081	0.084	0.083	0.083	83	100	82	0.101	101
		0.1	1	0.075	0.078	NA	0.077	77	93	87	0.088	88
		0.1	3	0.089	0.089		0.089	89	108	90	0.099	99
		0.1	12	0.088	0.083		0.085	85	103	89	0.096	96
		0.1	18	0.076	0.083		0.080	80	96	96	0.083	83
		0.1	24	0.096	0.095		0.095	95	115	91	0.104	104
	Prothioconazole-4-hydroxy-desthio, expressed as prothioconazole-desthio	0.1	0	0.080	0.087	0.082	0.083	83	100	82	0.101	101
		0.1	3	0.080	0.084	NA	0.082	82	99	89	0.092	92
		0.1	6	0.093	0.093		0.093	93	112	93	0.100	100
		0.1	12	0.091	0.087		0.089	89	107	90	0.099	99
		0.1	18	0.084	0.092		0.088	88	106	100	0.088	88
		0.1	24	0.097	0.094		0.095	95	114	90	0.106	106
	Prothioconazole-5-hydroxy-desthio, expressed as prothioconazole-desthio	0.1	0	0.081	0.085	0.084	0.083	83	100	82	0.102	102
		0.1	3	0.084	0.087	NA	0.086	86	103	88	0.097	97
		0.1	6	0.092	0.091		0.091	91	109	92	0.099	99
		0.1	12	0.088	0.084		0.086	86	103	90	0.096	96
		0.1	18	0.078	0.084		0.081	81	97	96	0.084	84
		0.1	24	0.100	0.091		0.096	96	115	91	0.105	105
	Prothioconazole-6-hydroxy-desthio,	0.1	0	0.084	0.089	0.087	0.087	87	100	84	0.103	103
		0.1	3	0.088	0.094	NA	0.091	91	105	97	0.094	94

Storage				Residues and recoveries in specimens stored frozen (not corrected for procedural recoveries)						Residues and recoveries in specimens stored frozen (recovery corrected)		
				Uncorrected residue results (mg/kg)[1]						Procedural recovery of freshly spiked control sample (%) (mean)	Corrected results (corrected for procedural recovery)	
Matrix	Analyte	Level (nominal fortification) (mg/kg)	Nominal storage interval (months)	sample 1	sample 2	sample 3	mean	Residues after storage (mean, % of nominal spiking level)	% corrected results with day 0 as 100 %[2]		Residues after storage mean[3] (mg/kg)	Residues after storage mean[4] (% of nominal spiking level)
	expressed as prothioconazole-desthio	0.1	6	0.092	0.091		0.091	91	105	91	0.100	100
		0.1	12	0.090	0.087		0.089	89	102	90	0.098	98
		0.1	18	0.089	0.095		0.092	92	106	102	0.090	90
		0.1	24	0.115	0.109		0.112	112	129	106	0.106	106
	Prothioconazole-α-hydroxy-desthio, expressed as prothioconazole-desthio	0.1	0	0.081	0.085	0.083	0.083	83	100	80	0.104	104
		0.1	3	0.085	0.087		0.086	86	104	89	0.097	97
		0.1	6	0.092	0.091		0.092	92	110	90	0.102	102
		0.1	12	0.092	0.087	NA	0.089	89	107	89	0.100	100
		0.1	18	0.084	0.093		0.089	89	107	98	0.090	90
		0.1	24	0.104	0.096		0.100	100	120	88	0.114	114
Wheat grain	Prothioconazole-desthio	0.1	0	0.099	0.082	0.081	0.087	87	100	82	0.107	107
		0.1	1	0.073	0.077		0.075	75	86	95	0.079	79
		0.1	3	0.080	0.081		0.080	80	92	98	0.082	82
		0.1	12	0.085	0.066	NA	0.076	76	86	89	0.085	85
		0.1	18	0.069	0.055		0.062	62[5]	71	105	0.059	59
		0.1	21	0.067	0.059		0.063	63[5]	72	90	0.070	70
		0.1	24	0.091	0.080		0.086	86	98	100	0.086	86
	Prothioconazole-3-hydroxy-desthio, expressed as prothioconazole-desthio	0.1	0	0.099	0.082	0.083	0.088	88	100	82	0.107	107
		0.1	1	0.076	0.081		0.079	79	89	98	0.080	80
		0.1	3	0.080	0.080		0.080	80	91	98	0.082	82
		0.1	12	0.085	0.068	NA	0.077	77	87	90	0.085	85
		0.1	18	0.068	0.055		0.062	62[5]	70	106	0.058	58
		0.1	21	0.070	0.064		0.067	67[5]	76	88	0.076	76
		0.1	24	0.097	0.085		0.091	91	103	99	0.092	92
	Prothioconazole-4-hydroxy-desthio, expressed as prothioconazole-desthio	0.1	0	0.097	0.082	0.082	0.087	87	100	81	0.107	107
		0.1	3	0.078	0.082		0.080	80	92	96	0.083	83
		0.1	6	0.080	0.082	NA	0.081	81	93	97	0.084	84
		0.1	12	0.083	0.063		0.073	73	84	88	0.083	83
		0.1	18	0.069	0.056		0.062	62[5]	71	101	0.061	61

Storage				Residues and recoveries in specimens stored frozen (not corrected for procedural recoveries)						Residues and recoveries in specimens stored frozen (recovery corrected)		
				Uncorrected residue results (mg/kg)[1]					% corrected results with day 0 as 100 %[2]	Procedural recovery of freshly spiked control sample (%) (mean)	Corrected results (corrected for procedural recovery)	
Matrix	**Analyte**	**Level (nominal fortification)** (mg/kg)	**Nominal storage interval** (months)	**sample 1**	**sample 2**	**sample 3**	**mean**	**Residues after storage** (mean, % of nominal spiking level)			**Residues after storage** mean[3] (mg/kg)	**Residues after storage** mean[4] (% of nominal spiking level)
		0.1	21	0.069	0.063		0.066	66[5]	76	89	0.074	74
		0.1	24	0.095	0.085		0.090	90	103	95	0.095	95
	Prothioconazole-5-hydroxy-desthio, expressed as prothioconazole-desthio	0.1	0	0.097	0.082	0.084	0.088	88	100	82	0.107	107
		0.1	3	0.078	0.081	NA	0.080	80	91	97	0.082	82
		0.1	6	0.083	0.081		0.082	82	94	96	0.085	85
		0.1	12	0.083	0.065		0.074	74	84	89	0.083	83
		0.1	18	0.066	0.057		0.062	62[5]	70	105	0.059	59
		0.1	21	0.070	0.063		0.066	66[5]	75	86	0.077	77
		0.1	24	0.103	0.091		0.097	97	111	98	0.099	99
	Prothioconazole-6-hydroxy-desthio, expressed as prothioconazole-desthio	0.1	0	0.105	0.085		0.093	93	100	88	0.105	105
		0.1	3	0.104	0.079	NA	0.092	92	99	102	0.090	90
		0.1	6	0.081	0.082		0.082	82	88	95	0.086	86
		0.1	12	0.088	0.067		0.077	77	83	89	0.087	87
		0.1	18	0.076	0.065		0.070	70	76	108	0.065	65
		0.1	21	0.083	0.075		0.079	79	85	107	0.074	74
		0.1	24	0.110	0.099		0.105	105	113	110	0.095	95
	Prothioconazole-α-hydroxy-desthio, expressed as prothioconazole-desthio	0.1	0	0.101	0.083	0.086	0.090	90	100	84	0.107	107
		0.1	3	0.086	0.092	NA	0.089	89	99	98	0.091	91
		0.1	6	0.090	0.091		0.091	91	101	108	0.084	84
		0.1	12	0.087	0.073		0.080	80	89	94	0.085	85
		0.1	18	0.073	0.061		0.067	67[5]	74	107	0.063	63
		0.1	21	0.070	0.065		0.067	67[5]	74	87	0.077	77
		0.1	24	0.110	0.097		0.104	104	115	103	0.100	100
Wheat straw	Prothioconazole-desthio	0.1	0	0.086	0.079	0.083	0.083	83	100	86	0.096	96
		0.1	1	0.076	0.080	NA	0.078	78	94	84	0.093	93
		0.1	3	0.089	0.091		0.090	90	109	84	0.107	107
		0.1	12	0.088	0.096		0.092	92	111	89	0.103	103
		0.1	18	0.096	0.087		0.091	91	110	101	0.090	90
		0.1	24	0.081	0.086		0.084	84	101	90	0.093	93

Storage				Residues and recoveries in specimens stored frozen (not corrected for procedural recoveries)						Residues and recoveries in specimens stored frozen (recovery corrected)		
				Uncorrected residue results (mg/kg)[1]					**% corrected results with day 0 as 100 %**[2]	**Procedural recovery of freshly spiked control sample** (%) (mean)	**Corrected results** (corrected for procedural recovery)	
Matrix	**Analyte**	**Level (nominal fortification)** (mg/kg)	**Nominal storage interval** (months)	**sample 1**	**sample 2**	**sample 3**	**mean**	**Residues after storage** (mean, % of nominal spiking level)			**Residues after storage** mean[3] (mg/kg)	**Residues after storage** mean[4] (% of nominal spiking level)
	Prothioconazole-3-hydroxy-desthio, expressed as prothioconazole-desthio	0.1	0	0.086	0.079	0.083	0.083	83	100	87	0.095	95
		0.1	1	0.075	0.075	NA	0.075	75	91	81	0.093	93
		0.1	3	0.090	0.092		0.091	91	110	86	0.106	106
		0.1	12	0.085	0.094		0.090	90	108	89	0.101	101
		0.1	18	0.088	0.087		0.088	88	106	98	0.089	89
		0.1	24	0.083	0.090		0.086	86	104	88	0.098	98
	Prothioconazole-4-hydroxy-desthio, expressed as prothioconazole-desthio	0.1	0	0.086	0.079	0.082	0.082	82	100	82	0.100	100
		0.1	3	0.081	0.079	NA	0.080	80	97	82	0.098	98
		0.1	6	0.092	0.093		0.092	92	112	87	0.106	106
		0.1	12	0.086	0.094		0.090	90	109	91	0.099	99
		0.1	18	0.093	0.087		0.090	90	109	101	0.089	89
		0.1	24	0.090	0.096		0.093	93	113	89	0.104	104
	Prothioconazole-5-hydroxy-desthio, expressed as prothioconazole-desthio	0.1	0	0.086	0.080	0.083	0.083	83	100	85	0.098	98
		0.1	3	0.084	0.083	NA	0.084	84	101	83	0.101	101
		0.1	6	0.091	0.097		0.094	94	113	85	0.111	111
		0.1	12	0.083	0.088		0.086	86	103	89	0.096	96
		0.1	18	0.088	0.082		0.085	85	102	100	0.085	85
		0.1	24	0.090	0.096		0.093	93	112	89	0.104	104
	Prothioconazole-6-hydroxy-desthio, expressed as prothioconazole-desthio	0.1	0	0.090	0.084	0.085	0.086	86	100	88	0.098	98
		0.1	3	0.089	0.089	NA	0.089	89	103	89	0.100	100
		0.1	6	0.091	0.094		0.093	93	107	85	0.109	109
		0.1	12	0.088	0.094		0.091	91	105	94	0.097	97
		0.1	18	0.102	0.099		0.101	101	116	106	0.095	95
		0.1	24	0.102	0.109		0.106	106	122	105	0.100	100
	Prothioconazole-α-hydroxy-desthio, expressed as prothioconazole-desthio	0.1	0	0.088	0.082	0.083	0.085	85	100	86	0.099	99
		0.1	3	0.083	0.083	NA	0.083	83	98	83	0.100	100
		0.1	6	0.091	0.094		0.093	93	109	85	0.109	109
		0.1	12	0.087	0.093		0.090	90	106	90	0.100	100
		0.1	18	0.097	0.087		0.092	92	108	97	0.095	95

Storage				Residues and recoveries in specimens stored frozen (not corrected for procedural recoveries)						Residues and recoveries in specimens stored frozen (recovery corrected)		
				Uncorrected residue results (mg/kg)[1]						**Procedural recovery of freshly spiked control sample** (%) (mean)	**Corrected results** (corrected for procedural recovery)	
Matrix	**Analyte**	**Level (nominal fortification)** (mg/kg)	**Nominal storage interval** (months)	**sample 1**	**sample 2**	**sample 3**	**mean**	**Residues after storage** (mean, % of nominal spiking level)	**% corrected results with day 0 as 100 %**[2]		**Residues after storage** mean[3] (mg/kg)	**Residues after storage** mean[4] (% of nominal spiking level)
		0.1	24	0.091	0.099		0.095	95	112	89	0.107	107
Oilseed rape	Prothioconazole-desthio	0.1	0	0.085	0.082	0.078	0.082	82	100	89	0.092	92
		0.1	1	0.092	0.093		0.092	92	113	83	0.111	111
		0.1	3	0.074	0.079		0.077	77	94	83	0.092	92
		0.1	12	0.082	0.078	NA	0.080	80	98	82	0.098	98
		0.1	18	0.074	0.073		0.073	73	89	85	0.086	86
		0.1	24	0.081	0.079		0.080	80	98	90	0.089	89
	Prothioconazole-3-hydroxy-desthio, expressed as prothioconazole-desthio	0.1	0	0.090	0.090	0.080	0.087	87	100	93	0.093	93
		0.1	1	0.106	0.107		0.106	106	122	94	0.113	113
		0.1	3	0.084	0.090		0.087	87	100	92	0.095	95
		0.1	12	0.090	0.079	NA	0.084	84	97	85	0.099	99
		0.1	18	0.081	0.078		0.079	79	91	90	0.088	88
		0.1	24	0.098	0.096		0.097	97	112	98	0.099	99
	Prothioconazole-4-hydroxy-desthio, expressed as prothioconazole-desthio	0.1	0	0.092	0.092	0.082	0.089	89	100	97	0.091	91
		0.1	3	0.106	0.109		0.107	107	121	93	0.115	115
		0.1	6	0.080	0.086		0.083	83	94	92	0.090	90
		0.1	12	0.086	0.080	NA	0.083	83	94	86	0.097	97
		0.1	18	0.079	0.079		0.079	79	89	91	0.087	87
		0.1	24	0.096	0.093		0.095	95	107	100	0.095	95
	Prothioconazole-5-hydroxy-desthio, expressed as prothioconazole-desthio	0.1	0	0.092	0.089	0.082	0.088	88	100	95	0.092	92
		0.1	3	0.102	0.103		0.102	102	116	94	0.109	109
		0.1	6	0.075	0.081		0.078	78	89	91	0.086	86
		0.1	12	0.077	0.074	NA	0.075	75	86	89	0.084	84
		0.1	18	0.076	0.073		0.074	74	84	92	0.080	80
		0.1	24	0.093	0.089		0.091	91	104	96	0.095	95
	Prothioconazole-6-hydroxy-desthio, expressed as	0.1	0	0.090	0.088	0.080	0.086	86	100	93	0.092	92
		0.1	3	0.102	0.102		0.102	102	119	90	0.113	113
		0.1	6	0.077	0.082	NA	0.079	79	92	75	0.105	105
		0.1	12	0.081	0.074		0.078	78	90	86	0.090	90

Storage				Residues and recoveries in specimens stored frozen (not corrected for procedural recoveries)						Residues and recoveries in specimens stored frozen (recovery corrected)		
				Uncorrected residue results (mg/kg)[1]					**% corrected results with day 0 as 100 %**[2]	**Procedural recovery of freshly spiked control sample** (%) (mean)	Corrected results (corrected for procedural recovery)	
Matrix	**Analyte**	**Level (nominal fortification)** (mg/kg)	**Nominal storage interval** (months)	**sample 1**	**sample 2**	**sample 3**	**mean**	**Residues after storage** (mean, % of nominal spiking level)			**Residues after storage** mean[3] (mg/kg)	**Residues after storage** mean[4] (% of nominal spiking level)
	prothioconazole-desthio	0.1	18	0.079	0.077		0.078	78	91	90	0.087	87
		0.1	24	0.090	0.086		0.088	88	102	95	0.093	93
	Prothioconazole-α-hydroxy-desthio, expressed as prothioconazole-desthio	0.1	0	0.095	0.090	0.082	0.089	89	100	96	0.093	93
		0.1	3	0.127	0.128	NA	0.127	127	143	106	0.120	120
		0.1	6	0.098	0.107		0.102	102	115	109	0.094	94
		0.1	12	0.081	0.076		0.079	79	88	87	0.090	90
		0.1	18	0.081	0.083		0.082	82	92	91	0.090	90
		0.1	24	0.101	0.096		0.098	98	110	95	0.103	103
Straw-berry	Prothioconazole-desthio	0.1	0	0.104	0.104	0.100	0.103	103	100	104	0.099	99
		0.1	1	0.095	0.097	NA	0.096	96	94	93	0.103	103
		0.1	3	0.093	0.093		0.093	93	91	93	0.100	100
		0.1	12	0.089	0.090		0.090	90	87	91	0.098	98
		0.1	18	0.091	0.087		0.089	89	87	96	0.093	93
		0.1	24	0.125	0.116		0.121	121	117	104	0.116	116
	Prothioconazole-3-hydroxy-desthio, expressed as prothioconazole-desthio	0.1	0	0.104	0.103	0.101	0.103	103	100	103	0.100	100
		0.1	1	0.097	0.100	NA	0.099	99	96	96	0.103	103
		0.1	3	0.100	0.099		0.100	100	97	99	0.101	101
		0.1	12	0.081	0.086		0.083	83	81	87	0.095	95
		0.1	18	0.084	0.082		0.083	83	81	94	0.088	88
		0.1	24	0.123	0.112		0.117	117	114	104	0.113	113
	Prothioconazole-4-hydroxy-desthio, expressed as prothioconazole-desthio	0.1	0	0.104	0.104	0.101	0.103	103	100	103	0.100	100
		0.1	3	0.100	0.103	NA	0.102	102	99	95	0.107	107
		0.1	6	0.100	0.101		0.101	101	98	98	0.103	103
		0.1	12	0.084	0.086		0.085	85	83	89	0.096	96
		0.1	18	0.089	0.086		0.087	87	84	94	0.093	93
		0.1	24	0.121	0.110		0.116	116	112	102	0.113	113
	Prothioconazole-5-hydroxy-desthio, expressed as	0.1	0	0.103	0.104	0.100	0.102	102	100	103	0.099	99
		0.1	3	0.098	0.100	NA	0.099	99	97	93	0.106	106
		0.1	6	0.097	0.097		0.097	97	95	95	0.102	102

Storage				Residues and recoveries in specimens stored frozen (not corrected for procedural recoveries)						Residues and recoveries in specimens stored frozen (recovery corrected)		
				Uncorrected residue results (mg/kg)[1]						**Procedural recovery of freshly spiked control sample** (%) (mean)	**Corrected results** (corrected for procedural recovery)	
Matrix	**Analyte**	**Level (nominal fortification)** (mg/kg)	**Nominal storage interval** (months)	**sample 1**	**sample 2**	**sample 3**	**mean**	**Residues after storage** (mean, % of nominal spiking level)	**% corrected results with day 0 as 100 %**[2]		**Residues after storage** mean[3] (mg/kg)	**Residues after storage** mean[4] (% of nominal spiking level)
	prothioconazole-desthio	0.1	12	0.082	0.083		0.083	83	81	88	0.094	94
		0.1	18	0.086	0.084		0.085	85	83	95	0.089	89
		0.1	24	0.126	0.117		0.122	122	119	104	0.117	117
	Prothioconazole-6-hydroxy-desthio, expressed as prothioconazole-desthio	0.1	0	0.105	0.106	0.101	0.104	104	100	102	0.102	102
		0.1	3	0.102	0.104	NA	0.103	103	99	99	0.104	104
		0.1	6	0.101	0.101		0.101	101	97	99	0.102	102
		0.1	12	0.086	0.086		0.086	86	83	89	0.097	97
		0.1	18	0.090	0.090		0.090	90	87	97	0.093	93
		0.1	24	0.135	0.126		0.130	130	125	109	0.119	119
	Prothioconazole-α-hydroxy-desthio, expressed as prothioconazole-desthio	0.1	0	0.105	0.106	0.102	0.105	105	100	105	0.100	100
		0.1	3	0.113	0.109	NA	0.111	111	106	95	0.117	117
		0.1	6	0.102	0.102		0.102	102	97	99	0.103	103
		0.1	12	0.084	0.088		0.086	86	82	89	0.097	97
		0.1	18	0.090	0.088		0.089	89	85	95	0.094	94
		0.1	24	0.133	0.122		0.128	128	121	104	0.123	123
Dry bean	Prothioconazole-desthio	0.1	0	0.086	0.088	0.091	0.088	88	100	89	0.099	99
		0.1	1	0.101	0.111	NA	0.106	106	120	94	0.113	113
		0.1	3	0.087	0.085		0.086	86	97	91	0.095	95
		0.1	12	0.083	0.092		0.088	88	99	88	0.099	99
		0.1	18	0.084	0.078		0.081	81	92	96	0.084	84
		0.1	24	0.092	0.091		0.092	92	104	106	0.086	86
	Prothioconazole-3-hydroxy-desthio, expressed as prothioconazole-desthio	0.1	0	0.084	0.087	0.089	0.087	87	100	90	0.097	97
		0.1	1	0.109	0.119	NA	0.114	114	131	91	0.125	125
		0.1	3	0.089	0.090		0.090	90	103	93	0.096	96
		0.1	12	0.088	0.094		0.091	91	105	93	0.098	98
		0.1	18	0.082	0.078		0.080	80	92	97	0.082	82
		0.1	24	0.103	0.103		0.103	103	118	108	0.095	95
	Prothioconazole-4-hydroxy-desthio,	0.1	0	0.087	0.092	0.089	0.089	89	100	94	0.095	95
		0.1	3	0.108	0.120	NA	0.114	114	128	92	0.124	124

Storage				**Residues and recoveries in specimens stored frozen (not corrected for procedural recoveries)**						**Residues and recoveries in specimens stored frozen (recovery corrected)**		
				Uncorrected residue results (mg/kg)[1]					**% corrected results with day 0 as 100 %**[2]	**Procedural recovery of freshly spiked control sample** (%) (mean)	**Corrected results** (corrected for procedural recovery)	
Matrix	**Analyte**	**Level (nominal fortification)** (mg/kg)	**Nominal storage interval** (months)	**sample 1**	**sample 2**	**sample 3**	**mean**	**Residues after storage** (mean, % of nominal spiking level)			**Residues after storage** mean[3] (mg/kg)	**Residues after storage** mean[4] (% of nominal spiking level)
	expressed as prothioconazole-desthio	0.1	6	0.087	0.087		0.087	87	97	91	0.096	96
		0.1	12	0.086	0.093		0.090	90	100	91	0.098	98
		0.1	18	0.084	0.079		0.081	81	91	96	0.084	84
		0.1	24	0.102	0.101		0.102	102	114	105	0.097	97
	Prothioconazole-5-hydroxy-desthio, expressed as prothioconazole-desthio	0.1	0	0.083	0.089	0.086	0.086	86	100	89	0.097	97
		0.1	3	0.100	0.111		0.105	105	122	91	0.115	115
		0.1	6	0.084	0.084		0.084	84	98	95	0.088	88
		0.1	12	0.074	0.083	NA	0.079	79	91	90	0.087	87
		0.1	18	0.076	0.073		0.075	75	87	95	0.078	78
		0.1	24	0.099	0.099		0.099	99	115	106	0.093	93
	Prothioconazole-6-hydroxy-desthio, expressed as prothioconazole-desthio	0.1	0	0.088	0.094	0.093	0.092	92	100	91	0.101	101
		0.1	3	0.106	0.115		0.110	110	120	92	0.120	120
		0.1	6	0.088	0.088		0.088	88	96	93	0.095	95
		0.1	12	0.082	0.090	NA	0.086	86	94	89	0.097	97
		0.1	18	0.085	0.082		0.083	83	91	97	0.086	86
		0.1	24	0.096	0.101		0.098	98	107	108	0.091	91
	Prothioconazole-α-hydroxy-desthio, expressed as prothioconazole-desthio	0.1	0	0.084	0.090	0.089	0.087	87	100	88	0.099	99
		0.1	3	0.126	0.136		0.131	131	151	100	0.131	131
		0.1	6	0.107	0.109		0.108	108	124	109	0.099	99
		0.1	12	0.080	0.092	NA	0.086	86	99	92	0.093	93
		0.1	18	0.088	0.081		0.085	85	97	97	0.087	87
		0.1	24	0.103	0.103		0.103	103	118	109	0.094	94

[1] calculated as detailed in paragraph 8.8.1 of the study report.
[2] (mean at x months) / (mean at 0 month) * 100 (not included in the final report but calculated during dRR compilation)
[3] (mean at x months) / (procedural recoveries at x months) * 100 (not included in the final report but calculated during dRR compilation)
[4] (mean, corrected for procedural recovery) / (nominal fortification) * 100 (not included in the final report but calculated during dRR compilation)
[5] After 18 and 21months of storage stability, loss higher than 30 % was not confirmed by another analysis at 24 months.

Conclusion

Storage stability is demonstrated for prothioconazole-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio and prothioconazole-α-hydroxy-desthio in wheat (whole plant, grain and straw), in oilseed rape (grain), in strawberry and in dry bean when stored at ≤ -18°C for a storage period up to 24 months.

A 2.1.1.1.1.3 Study 3

Comments of zRMS:	The study of Lindner, M., 2022 - "*Storage Stability of Prothioconazole, Prothioconazole-desthio and Azoxystrobin in Pollen, Nectar, Flowers and Honey under Deep Frozen Conditions"* has been evaluated in Registration Report for ADM.03500.F.2.B on March 2023 by zRMS-PL and the summary is presented below. The storage stability of prothioconazole-desthio was demonstrated in pollen, nectar surrogate, flowers and honey at ≤ -18 °C in the dark over a storage period of up to 13 months. The storage stability of prothioconazole was demonstrated in honey at ≤ -18 °C in the dark over a storage period of up to 13 months and in nectar surrogate up to 6 months. For prothioconazole in/on pollen and flowers the relative recoveries were already below 70% after 2 months of storage. Sample extraction and determination of residues was performed according to an analytical procedure that was previously validated for fluxapyroxad, prothioconazole, prothioconazole-desthio and azoxystrobin in pollen, nectar surrogate, flowers and honey (KCP 5.1.2/23, Lindner, M., Grewe, D. 2020, report no.: S19-20860 (MAC-1940V)). The LOQ was set at 0.01 mg/kg for prothioconazole and prothioconazole-desthio. The study is acceptable.

Reference:	KCA 6.1/03
Report:	Storage Stability of Prothioconazole, Prothioconazole-desthio and Azoxystrobin in Pollen, Nectar, Flowers and Honey under Deep Frozen Conditions Lindner, M., 2022 Study no.: S19-02145, sponsor no.: 000104133
Guideline(s):	EC Guideline 7032/VI/95, Appendix H; OECD 506, 2007
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Study objective

The study objective was to obtain data about the storage stability of prothioconazole, prothioconazole-desthio and azoxystrobin in pollen, nectar surrogate, flowers and honey at ≤ -18°C (target) in the dark over a storage period of up to 13 months. Results for azoxystrobin are not reported here, as not relevant for product ADM.03500.F.2.B.

Materials and methods

Matrix types, sample origin and preparation before extraction are summarised in the following:

Matrix Types	Preparation	Origin
Phacelia Pollen	The sample material was homogenised by use of an appropriate glass rod or spatula before taking subsamples. Further homogenisation was done upon sample extraction.	supplied by the Test Facility
Nectar Surrogate	Instead of nectar a 36 % sucrose solution in water was used as surrogate. The sample material was shaken/inverted before taking subsamples.	supplied by the Test Facility

Phacelia Flowers	The sample material was milled with dry ice using a laboratory mill (batch mill with disposable grinding chamber) before taking subsamples.	supplied by the Test Facility
Honey (Multi–flower, pH ~ 4.0)	None, the material was already in homogenised state.	supplied by the Test Facility

The fortification level for storage samples was at ten times the limit of quantification (LOQ) of the method (i.e. 0.10 mg/kg) on aliquots of homogenised control sample material. For all samples used for assessment of storage stability (storage samples) prothioconazole, prothioconazole-desthio and azoxystrobin were fortified separately. Freshly prepared fortification samples for demonstrating the analytical performance of the method (recovery samples) were prepared by fortifying prothioconazole and azoxystrobin jointly, while prothioconazole-desthio was fortified separately. Storage samples were kept at ≤ -18°C and analysed after 0 days, 2, 6 and 13 months. Day 0 testing was accompanied by analysis of a control sample while the testing after each storage interval was accompanied by analysis of a control sample and procedural recovery samples.

Sample extraction and determination of residues was performed according to an analytical procedure that was previously validated for prothioconazole, prothioconazole-desthio and azoxystrobin in pollen, nectar surrogate, flowers and honey[1]. For further details on method validation, please refer to dRR Part B.5, point KCP 5.1.2.

Samples of flowers, nectar surrogate and pollen were extracted with methanol/L-cystein-solution (50 mg/L)/formic acid (50+50+0.5, v+v+v). The extraction procedure is based on the QuPPe-PO-Method but with L-cystein added. After shaking on a platform shaker for 15 minutes the samples were centrifuged and an aliquot was transferred into a HPLC-Vial. For pollen an additional homogenisation step with a miniaturised cell disruption system (FastPrep) was included to the extraction procedure. Quantification was performed by use of LC-MS/MS detection.

The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for each matrix with a limit of detection (LOD) set at 0.003 mg/kg (30% of the LOQ).

Results and discussions

The residues levels detected in the storage samples allow the monitoring of the stability of the analyte upon storage. The values were as given in the following table.

For prothioconazole the mean recovery for samples extracted without any storage (i.e. day 0 storage samples and procedural recoveries) was 95% for pollen, 91% for nectar surrogate, 93% for flowers and 96% for honey.

For prothioconazole-desthio the mean recovery for samples extracted without any storage (i.e. day 0 storage samples and procedural recoveries) was 100 % for pollen, 97 % for nectar surrogate, 102% for flowers and 98% for honey.

These values demonstrate satisfying analytical performance for all analytes and matrices while analysing the storage samples.

For prothioconazole in nectar surrogate, the recoveries relative to the initial mean recovery at day 0 were ≥ 70 % up to 6 months, while for prothioconazole in/on pollen and flowers the relative recoveries were already below 70 % after 2 months of storage. For honey, the average amount of prothioconazole recovered relative to the initial mean recovery at day 0 was ≥ 70% after 13 months of storage.
For prothioconazole-desthio in pollen, nectar surrogate, flowers and honey, the average amount of analyte recovered relative to the initial mean recovery at day 0 was ≥ 70 % after 13 months of storage.

[1] Study No. S19-20860 “Validation of the Multi-Residue Method QuEChERS for the Determination of Prothioconazole, Prothioconazole-desthio and Azoxystrobin in Nectar, Pollen, Flower and Honey”, Eurofins Agroscience Services Chem GmbH, Hamburg, Germany (22 Oct 2020).

The maximum storage interval of final sample extracts at typically 1°C to 10°C from extraction to injection to LC-MS/MS was 3 days. The stability of the analyte in the final extracts of pollen, nectar surrogate, flowers and honey upon storage at typically 1°C to 10°C for at least 7 days was demonstrated in study S19-20860.

Table A 3: Stability of prothioconazole and prothioconazole-desthio in pollen, nectar surrogate, flowers and honey following storage at ≤ -18°C

Storage				Residues and recoveries in specimens stored frozen (not corrected for procedural recoveries)						Residues and recoveries in specimens stored frozen (recovery corrected)		
				Uncorrected residue results (mg/kg)						Procedural recovery of freshly spiked control sample (%) (mean)	Corrected results (corrected for procedural recovery)	
Matrix	**Analyte**	**Level (nominal fortification)** (mg/kg)	**Nominal storage interval** (months)	**sample 1**	**sample 2**	**sample 3**	**mean**	**Residues after storage** (mean, % of nominal spiking level)	**% corrected results with day 0 as 100 %**[1]		**Residues after storage** mean[2] (mg/kg)	**Residues after storage** mean[3] (% of nominal spiking level)
Pollen	Prothioconazole	0.1	0	0.103	0.098	0.093	0.098	103, 98, 93 (98)	-	-	-	-
		0.1	2	0.030	0.032		0.031	30, 32 (31)	32	100, 98 (99)	0.031	31
		0.1	6	0.030	0.032	NA	0.031	30, 32 (31)	32	97, 92 (95)	0.033	33
		0.1	13	0.030	0.032		0.031	30, 32 (31)	32	94, 84 (89)	0.035	35
	Prothioconazole-desthio	0.1	0	0.100	0.099	0.102	0.100	100, 99, 102 (100)	-	-	-	-
		0.1	2	0.106	0.108		0.107	106, 108 (107)	107	111, 106 (109)	0.098	98
		0.1	6	0.097	0.097	NA	0.097	97, 97 (97)	97	105, 104 (105)	0.092	92
		0.1	13	0.076	0.073		0.075	76, 73 (75)	74	87, 87 (87)	0.086	86
Nectar surrogate	Prothioconazole	0.1	0	0.096	0.095	0.094	0.095	96, 95, 94 (95)	-	-	-	-
		0.1	2	0.088	0.092		0.090	88, 92 (90)	95	83, 87 (85)	0.105	105
		0.1	6	0.075	0.074	NA	0.075	75, 74 (75)	78	93, 91 (92)	0.082	82
		0.1	13	0.024	0.027		0.026	24, 27 (26)	27	94, 90 (92)	0.028	28
	Prothioconazole-desthio	0.1	0	0.102	0.101	0.100	0.101	102, 101, 100 (101)	-	-	-	-
		0.1	2	0.082	0.080		0.081	82, 80 (81)	80	110, 106 (108)	0.075	75
		0.1	6	0.074	0.075	NA	0.075	74, 75 (75)	74	78, 80 (79)	0.095	95
		0.1	13	0.092	0.094		0.093	92, 94 (93)	92	97, 99 (98)	0.095	95
Flowers	Prothioconazole	0.1	0	0.089	0.091	0.084	0.088	89, 91, 84 (88)	-	-	-	-
		0.1	2	0.030	0.031		0.031	30, 31 (31)	35	94, 92 (93)	0.033	33
		0.1	6	0.010	0.011	NA	0.011	10, 11 (11)	12	100, 100 (100)	0.011	11
		0.1	13	0.014	0.011		0.013	14, 11 (14)	14	99, 90 (95)	0.015	15
	Prothioconazole-desthio	0.1	0	0.102	0.105	0.102	0.103	102, 105, 102 (103)	-	-	-	-
		0.1	2	0.089	0.087		0.088	89, 87 (88)	85	99, 97 (98)	0.090	90
		0.1	6	0.088	0.089	NA	0.089	88, 89 (89)	86	108, 104 (106)	0.084	84
		0.1	13	0.084	0.086		0.085	84, 86 (85)	83	99, 98 (99)	0.086	86
Honey	Prothioconazole	0.1	0	0.104	0.106	0.087	0.099	104, 106, 87 (99)	-	-	-	-
		0.1	2	0.110	0.108	NA	0.109	110, 108 (109)	110	114, 99 (107)	0.102	102

Storage				Residues and recoveries in specimens stored frozen (not corrected for procedural recoveries)						Residues and recoveries in specimens stored frozen (recovery corrected)		
				Uncorrected residue results (mg/kg)					% corrected results with day 0 as 100 %[1]	Procedural recovery of freshly spiked control sample (%) (mean)	Corrected results (corrected for procedural recovery)	
Matrix	**Analyte**	**Level (nominal fortification)** (mg/kg)	**Nominal storage interval** (months)	**sample 1**	**sample 2**	**sample 3**	**mean**	**Residues after storage** (mean, % of nominal spiking level)			**Residues after storage** mean[2] (mg/kg)	**Residues after storage** mean[3] (% of nominal spiking level)
		0.1	6	0.069	0.075		0.072	69, 75 (72)	73	79, 78 (79)	0.091	91
		0.1	13	0.081	0.068		0.075	81, 68 (75)	75	103, 96 (100)	0.075	75
	Prothioconazole-desthio	0.1	0	0.101	0.104	0.094	0.100	101, 104, 94 (100)	-	-	-	-
		0.1	2	0.087	0.087	NA	0.087	87, 87 (87)	87	107, 104 (106)	0.082	82
		0.1	6	0.095	0.093		0.094	95, 93 (94)	94	90, 92 (91)	0.103	103
		0.1	13	0.098	0.103		0.101	98, 103 (101)	101	97, 96 (97)	0.104	104

[1] (mean at x months) / (mean at 0 month) * 100
[2] (mean at x months) / (procedural recoveries at x months) * 100
[3] (mean, corrected for procedural recovery) / (nominal fortification) * 100

Conclusion
With regard to selectivity, accuracy and precision, the analytical method was applied successfully for each analytical set when analysing the storage samples.

The study is deemed sufficient for assessing the stability of flowers, nectar surrogate and pollen upon storage at ≤ -18°C for 13 months.

For prothioconazole in nectar surrogate, the recoveries relative to the initial mean recovery at day 0 were ≥ 70% up to 6 months, while for prothioconazole in/on pollen and flowers the relative recoveries were already below 70% after 2 months of storage. For honey, the average amount of prothioconazole recovered relative to the initial mean recovery at day 0 was ≥ 70% even after 13 months of storage.

For prothioconazole-desthio in pollen, nectar surrogate, flowers and honey, the average amount of analyte recovered relative to the initial mean recovery at day 0 was ≥ 70% after 13 months of storage.

A 2.1.1.1.2 Storage stability of residues in animal products

No new study submitted.

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

A 2.1.2.1 Nature of residue in plants

A 2.1.2.1.1 Nature of residue in primary crops

No new study submitted.

A 2.1.2.1.2 Nature of residue in rotational crops

No new study submitted.

A 2.1.2.1.3 Nature of residues in processed commodities

Comments of zRMS:	The study of Bloß, K., 2019 (Report No.: S18-07655) has been evaluated in Registration Report for ADM.03500.F.2.B on March 2023 by zRMS-PL and the summary is presented below. In this study no significant hydrolysis or degradation products were formed under conditions representative of pasteurisation, baking/brewing/boiling and sterilisation. There was no change in sample weight and in radioactivity content after any processing. The test item ([^{14}C]prothioconazole-desthio) was stable: - at pH 4 at 90°C for 20 minutes which simulates the pasteurisation process; - at pH 5 at 100°C for 60 minutes which simulates the baking/brewing/boiling proces; - at pH 6 at 120°C for 20 minutes which simulates the sterilisation process. The study is acceptable.

A 2.1.2.1.3.1 Study 1

Reference:	KCA 6.5.1/01
Report	Prothioconazole-desthio: Aqueous Hydrolysis of [^{14}C]Prothioconazole-desthio at 90, 100 and 120 °C; Bloß, K., 2019; Report No.: S18-07655, Sponsor no.: 000101817
Guideline(s):	Yes, OECD Guideline No 507 “Nature of the pesticide residues in processed

	commodities - high temperature hydrolysis", Adopted 16th October, 2007; EC working document, 1607/VI/97, rev. 2, Appendix E, 7035/VI/95, rev.5; Processing studies 22 July 1997
Deviations:	None
GLP:	Yes
Acceptability:	Yes

Executive summary

The objective of this study was to establish whether or not breakdown or reaction products arise from prothioconazole-desthio residues in raw agricultural commodities when subjected to processing.
The following hydrolytic conditions, representative of processing procedures, were used:
Condition 1: 90°C x 20 min (pH 4), representative of pasteurisation
Condition 2: 100°C x 60 min (pH 5), representative of baking, brewing, and boiling
Condition 3: 120°C x 20 min (pH 6), representative of sterilisation (closed system under pressure)

This study was performed with [1,2,4-triazole-U-^{14}C]-prothioconazole-desthio. The radiochemical purity was checked before application and confirmed to be > 95 %. An initial amount of 4.15 MBq/L, corresponding to 1.76 mg/L (specific activity: 2.36 MBq/mg) was applied.
Analysis of the samples was performed using Liquid Scintillation Counting (LSC) for quantification and High-Performance Liquid Chromatography (radio-HPLC) for characterisation. HPLC results were confirmed by analysis with Thin Layer Chromatography (TLC).
The content of radioactivity labelled prothioconazole-desthio before processing was set to 100%. After simulated processing prothioconazole-desthio represented 98.9 - 102.8 % of the applied radioactivity.
No cleavage of prothioconazole-desthio was observed.
The test item was stable during all processing conditions and no hydrolysis or degradation products were formed under conditions representative of simulating pasteurisation, baking/brewing/boiling and sterilisation.

Materials and methods

A. Materials

1. Test item (labelled): Prothioconazole-desthio, [1,2,4-triazole-U-^{14}C]

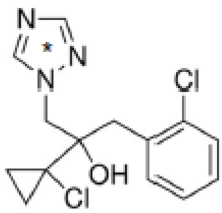

Figure A- 1: [1,2,4-triazole-U-^{14}C]prothioconazole-desthio: Position of ^{14}C- label is indicated by *

Batch no.:	XXIV/5/B/1
Radiochemical purity:	100 %
Specific activity:	2.36 MBq/mg

2. Reference item (unlabelled): Prothioconazole-desthio

CAS no.:	120983-64-4
Batch no.:	534-191-00
Purity:	98.7 % (w/w)
Stability:	Expiry date: 03.03.2021

3. Test conditions: Pasteurisation: 90 °C, at pH 4, for 20 min

Baking, brewing and boiling: 100 °C, at pH 5, for 60 min
Sterilisation: 120 °C, at pH 6, for 20 min, (closed system under pressure)

B. Study design and methods

1. Buffer Solutions

The study was performed with buffer solutions at three different pH-values chosen to simulate normal processing practice.

pH 4 citrate buffer: 0.05 M citrate monohydrate was dissolved in demineralized water, adjusted to pH 4 with 2 M sodium hydroxide and filled up to 1000 ml with demineralized water.

pH 5 citrate buffer: 0.05 M acetic acid was dissolved in demineralized water, adjusted to pH 5 with 2 M sodium hydroxide and filled up to 1000 ml with demineralized water.

pH 6 citrate buffer: 0.05 M citrate monohydrate was dissolved in demineralized water, adjusted to pH 6 with 2 M sodium hydroxide and filled up to 1000 ml with demineralized water.

The buffer solutions were sterilised by autoclaving. After sterilisation the pH of the buffer solution was checked and confirmed to deviate less than 0.1 in regards of the nominal pH value.

2. Application Solution

A stock solution with the test item was prepared by diluting the test substance in 200 µL acetonitrile. The application solution was prepared by diluting 50 µL of the stock solution in 950 µL acetonitrile. The radioactivity was determined by LSC and a final volume of 23 µL application solution was used for application in 15 mL buffer. The concentration of the application solution was 3090 MBq/L.

The actual amount of applied radioactivity, based on the application control, was 4.15 MBq/L, corresponding to 1.76 mg test item assuming a specific activity of 2.36 MBq/mg.

3. Preparation of Test Solution

The samples were prepared as follows: 15 mL of buffer solution were added to the test vessel, followed by 23 µL of the application solution. All test vessels were covered with aluminium foil in order to shield it from light.

4. Test condition 1: Pasteurisation:

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

5. Test condition 2: Baking, Brewing and Boiling:

The stability of the test item was determined under conditions typical for baking and boiling (e.g. for making bread and cooking vegetables). The processing temperature was 100° C in an oil bath. The incubation time at this temperature and pH for processing was 60 minutes. The test was performed in the dark with two independent (duplicate) samples.

6. Test condition 3: Sterilisation:

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

7. Sampling:

The test vessels were weighed before undergoing processing conditions, and the weight of the sample in each vessel was calculated.

An aliquot of 2 mL was taken from the test vessel before and after processing and analysed by LSC (two times 100 µL). 500µL of the aliquot were analysed by HPLC and 50 µL by TLC.

The pH was measured in the test solution before and after processing.

8. Determination of radioactivity and of metabolite profiles:
For quantification, the radioactivity in solutions was determined by liquid scintillation counting (LSC). From every sample an aliquot was mixed with scintillation cocktail.
For characterisation, the radioactivity of the samples was determined with HPLC by a Mira Star (Raytest) radioactivity-HPLC flow detector. Quantification was done by integration.
TLC measurement was used as confirmation method.

9. Storage stability:
Regarding stability of the samples before analysis, all samples were analysed within 1 day after preparation and were kept refrigerated within this period. Therefore, according to OECD guideline 507 no storage stability data was required.
After analysis, samples were stored in a freezer at ≤-18°C.

Results and discussion

Test condition 1: Pasteurisation
The conditions were citrate buffer pH 4 at a temperature of 90°C for 20 minutes. The test was performed in the dark with two independent (duplicate) samples.
The treatment had no impact on the pH value of the test solution (pH 4.02 before and pH 4.01 after processing).
There was no change in sample weight and in radioactivity content after processing (mass recovery: 100.1 %, recovery of radioactivity: 98.9 % AR).
The radio-HPLC results showed that no degradation products were formed during processing under pasteurisation conditions. TLC analysis confirmed HPLC results.
The test item was stable at pH 4 at 90°C for 20 minutes which simulates the pasteurisation process.
The results after processing are summarised in Table A 4 below.

Test condition 2: Baking, Brewing and Boiling
The conditions were acetic acid buffer pH 5 at a temperature of 100°C for 60 minutes. The test was performed in the dark with two independent (duplicate) samples.
The treatment had no impact on the pH value of the test solution (pH 5.01 before and pH 5.01 after processing).
There was no change in sample weight and in radioactivity content after processing (mass recovery: 100.2 %, recovery of radioactivity: 100.4 % AR).
The radio-HPLC results showed that no degradation products were formed during processing under baking/brewing/boiling conditions. TLC analysis confirmed HPLC results.
The test item was stable at pH 5 at 100°C for 60 minutes which simulates the baking/brewing/boiling process.
The results after processing are summarised in Table A 4 below.

Test condition 3: Sterilisation
The conditions were citrate buffer pH 6 at a temperature of 120°C for 20 minutes. The test was performed in the dark with two independent (duplicate) samples.
The treatment had no impact on the pH value of the test solution (pH 6.02 before and pH 6.02 after processing).
There was no change in sample weight and in radioactivity content after processing (mass recovery: 99.9 %, recovery of radioactivity: 102.8 % AR).
The radio-HPLC results showed that no degradation products were formed during processing under sterilisation conditions (selected chromatograms are shown in Figure 8 and Figure 9). TLC analysis confirmed HPLC results.
The test item was stable at pH 6 at 120°C for 20 minutes which simulates the sterilisation process.
The results after processing are summarised in Table A 4 below.

Table A 4: Standard hydrolysis study of [1,2,4-triazole-U-14C]prothioconazole-desthio (values are given in % of applied radioactivity) after processing

Processes represented	T° (°C)	Time (min)	pH	Parent Initial conc. (mg/L)	Recoveries (% applied radioactivity)*
					Prothioconazole-desthio
Pasteurisation	90	20	4.0	1.76	98.9
Baking, brewing, boiling	100	60	5.0	1.76	100.4
Sterilisation	120	20	6.0	1.76	102.8

* mean value of two determinations

Conclusions

The results of this study demonstrated that no significant hydrolysis or reaction products were formed under conditions representative of pasteurisation, baking/brewing/boiling and sterilisation.

There was no significant change in the radioactivity content following processing under the three different conditions. The recovery of the applied [1,2,4-triazole-U-^{14}C]prothioconazole-desthio was in a range of 98.9 % to 102.8 %.

[^{14}C]Prothioconazole-desthio was stable during all processing conditions and no hydrolysis or degradation products were formed under conditions representative for simulating pasteurisation, baking/brewing/boiling and sterilisation.

A 2.1.2.2 Nature of residues in livestock

No new study submitted.

A 2.1.3 Magnitude of residues in plants

A 2.1.3.1 Wheat, rye, triticale (KCA 6.3.1)

Table A 5: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (EFSA, 2007)	3	0.2 kg as/ha	14-21 days	69	35
cGAP EU (Art. 12, EFSA, 2014)	3	0.2 kg as/ha	14-21 days	69	35
Intended cGAP (1)	1	187.5 g as/ha	-	69	n.a.

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

Note: In 2021, 6 residue trials were conducted using the mixture product containing prothioconazole plus fluxapyroxad and 8 crop residue trials were conducted using the mixture product containing prothioconazole plus difenoconazole. In this case 5 of the trial sites reported in Wheat Study 2 were also used to generate data in Wheat Study 3. All data has been reported for each study and to assist the review trials performed at the same site within different studies have been annotated in Column 1 with capital letters A, B, C etc. to indicate a second set of data for the same site is reported. The worst case residues from co-located trials are used for the assessment and relied upon residue values are underlined.

A 2.1.3.1.1 Wheat study 1

Comments of zRMS:	The study of Amic, S., 2020b (Report No.: BPL19/762/GC) has been evaluated in Registration Report for ADM.03500.F.2.B on March 2023 by zRMS-PL and the summary is presented below. Four field trials were conducted in Northern Europe to determine the residue level of prothioconazole and its metabolites in specimens of wheat whole plant without roots, grain and straw following one foliar application of ADM.3500.F.2.B (250 g a.s./L of prothioconazole) at the dose rate 0.8 L/ha (200 g a.s./ha of prothioconazole). Application was performed at BBCH 69. Specimens of whole plant without roots were generated at ±0 DAA, 10 DAA, 20 DAA and 35 (±3) DAA for the two decline trials. Specimens of grain and straw were generated at harvest stage BBCH 89 from all the field trials performed. In seed specimens taken at normal commercial harvest (34-45 days) residues of prothioconazole (sum) and prothioconazole-desthio were <LOQ. The analytical method was validated for wheat whole plant without roots, grain and straw according to guideline SANCO/3029/99 rev. 4. All the analytes were determined by LC-MS/MS using a quantitation and confirmation ion. The LOQ of each analyte was at 0.01 mg/kg for each matrix. The mean recovery was between 70% and 110% at each level of fortification, for each reference item and for each matrix. The storage duration (interval between sampling and extraction date) was 149 days for the determination of prothioconazole and its metabolites. Sufficient stability data are available to support the residue data presented in this study. The study is acceptable.

Reference: KCA 6.3.1/01
Report: Residue study of prothioconazole and its metabolites in wheat whole plant and RAC after one foliar application of ADM.3500.F.2.B (250 g a.s./L of prothioconazole) - 2 harvest and 2 decline trials – Northern Europe (FR, HU, PL) – 2019
Amic, S., 2020b

	Report no.: BPL19/762/GC, Sponsor no.: 000102751
Guideline(s):	EC guidance working document SANCO/7029/VI/95 rev. 5 (22/07/1997) OECD 509, adopted 7 September 2009 Guidance document SANCO/3029/99 rev. 4 of 11/07/00 OECD guidance document on pesticide residue analytical methods. Document ENV/JM/MONO(2007)17
Deviations:	None with impact on study results
GLP:	Yes
Acceptability:	Yes

And

Comments of zRMS:	The study of Yozgatli, H.P., 2021d (Report No.: S19-00733) has been evaluated in Registration Report for ADM.03500.F.2.B on March 2023 by zRMS-PL and the summary is presented below. Four field trials were conducted in Northern Europe to determine the residues of 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) in wheat (whole plants without roots, grain and straw) following one foliar application of ADM.3500.F.2.B (250 g a.s./L of prothioconazole). The application had to be performed at crop growth stage BBCH 69. Grain and straw specimens were taken at BBCH growth stage 89, normal commercial harvest (NCH). Specimens of whole plant without roots were generated at ±0 DAA, 10 DAA, 20 DAA and 35 (±3) DAA for the two decline trials. <u>Results:</u> Residues of 1,2,4-T and TLA in grain were <LOQ. Residues of TA in grain were between 0.29 and 0.58 mg/kg. Residues of TAA in grain were between 0.09 and 0.21 mg/kg. The analytical method GRM053.01A was validated for the determination of 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) in wheat (whole plants without roots, grain and straw) according to SANCO/3029/99, rev.4. Three fortifications of untreated control samples at the level of LOQ (0.01 mg/kg) and three fortifications at the level of tenfold LOQ (0.1 mg/kg) were performed, representing a reduced validation data set. The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for each analyte and each matrix. The coefficients of determination (R^2) of linear regression of the calibration plots were ≥ 0.98. The accuracy and precision of the method during sample analysis were considered to be acceptable since single recoveries were in the range of 60 - 120% and the mean recoveries at each fortification level were in the range of 70 – 110% with relative standard deviation(s) below 20% for all combinations of matrices and analytes. The maximum storage interval from sampling to extraction was 538 days (above 17 months) for wheat - whole plants without roots, 525 days (above 17 months) for wheat grain and 499 (above 16 months) for wheat straw. **It should be noted that the storage period exceeded the maximum storage stability for 1,2,4-T (whole plant, grain and straw).** For this reason, the obtained results cannot be used for evaluation and risk assessment.

Reference:	KCA 6.3.1/02
Report:	Determination of the residue of 1, 2, 4-Triazole (1, 2, 4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) in wheat (RAC whole plant, grain and straw) following one foliar application of ADM.3500.F.2.B (250g a.s./L of prothioconazole), in 4

	trials (2 HS + 2 DCS) in Northern Europe (France, Hungary and Poland), 2019 Yozgatli, H.P., 2021d Study no: S19-00733, sponsor no.: 000102783
Guideline(s):	EC Guideline SANCO/7029/VI/95 rev. 5 Guidance document SANCO/3029/99 rev. 4 OECD ENV/JM/MONO(2007)17
Deviations:	None with impact on study results
GLP:	Yes
Acceptability:	Yes

Table A 6: Summary of the wheat study 1 - 4 trials

Crop residue data from supervised field trials		**Reference no.:**	**KCA 6.3.1/01**
Active ingredient (common name and content):	Prothioconazole, nominal 250 g/L (actual 248.2 g/L)	Commercial product (name/code):	ADM.3500.F.2.B (MCW-2075)
Crop/crop group:	Wheat / Cereals	Formulation (e.g. SC):	EC
Country:	FR, HU, PL	Other active substance in the formulation:	None
Indoor/outdoor:	Outdoor	Residues calculated as:	**Prothioconazole as sum of prothioconazole-desthio, 3-hydroxyprothioconazole-desthio, 4-hydroxyprothioconazole-desthio, 5-hydroxyprothioconazole-desthio, 6-hydroxyprothioconazole-desthio and alpha-hydroxyprothioconazole-desthio, expressed as prothioconazole-desthio (mg/kg) (8.1, risk assessment residue definition);** **Prothioconazole-desthio (mg/kg) (8.2, enforcement residue definition)**
Responsible body for reporting (name, address):	BIOTEK Agriculture, Saint-Pouange, France		

1	2	3	4			5	6	7	8.1	8.2	9		10
Trial No./ Location/ EU zone/ Year	**Commodity/ Variety**	**Date of 1.Sowing or planting 2.Flowering 3. Harvest**	**Application rate per treatment**			**Dates of treatment or no. of treatments and last date**	**Growth stage at last treatment or date**	**Portion analysed**	**Residues (mg/kg)**		**Assessment**		**Details on trial(s)**
			kg a.s./ ha	**Water (L/ha)**	**kg a.s./ hL**				**Prothio-conazole (sum)****	**Prothio-conazole-desthio**	**Timing (BBCH)**	**DALA (days)**	
	(a)	(b)	(c)			(d)			(g)	(h)		(e)	(f)
BPL19/762/GC-01-FR 71640 Givry, France N-EU 2018/19 (A)	Winter wheat (TRZAW)/ Complice	1. 25/10/18 2. 27/05/-11/06/19 3. 10-16/07/19	0.201	198	0.099	08/06/19	BBCH 69	Grain Straw	<LOQ 0.20	<u><LOQ</u> <u>0.076</u>	89 89	34 34	Analytical methods: based on European Committee for Standardization (CEN): EN 15662:2009-02, quantification via LC-MS/MS For method validation please refer to dRR Part B.5, point KCP 5.1.2. LOQ: Prothioconazole-desthio (g) 0.01 mg/kg,
BPL19/762/GC-02-HU 2141 Csömör, Hungary N-EU 2018/19 (B)	Winter wheat (TRZAW)/ Astardo	1. 01/10/18 2. 22/05/-03/06/19 3. 09-11/07/19	0.202	256	0.079	03/06/19	BBCH 69	Grain Straw	<LOQ 0.30	<u><LOQ</u> <u>0.13</u>	89 89	36 36	

1	2	3	4			5	6	7	8.1	8.2	9		10
Trial No./ Location/ EU zone/ Year	**Commodity/ Variety** (a)	**Date of 1.Sowing or planting 2.Flowering 3. Harvest** (b)	**Application rate per treatment**			**Dates of treatment or no. of treatments and last date** (d)	**Growth stage at last treatment or date**	**Portion analysed**	**Residues (mg/kg)**		**Assessment**		**Details on trial(s)** (f)
			kg a.s./ ha (c)	**Water (L/ha)**	**kg a.s./ hL**				**Prothio-conazole (sum)**** (g)	**Prothio-conazole-desthio** (h)	**Timing (BBCH)**	**DALA (days)** (e)	
BPL19/762/GC-03-PL 55-110 Krościna Mała, Poland N-EU 2018/19	Winter wheat (TRZAW)/ Linus	1. 01/10/18 2. 01-20/06/19 3. 26-27/07/19	0.195	297	0.066	18/06/19	BBCH 69	Whole plant w/o roots Whole plant w/o roots Whole plant w/o roots Whole plant w/o roots Grain Straw	0.51* 1.1* 1.1 1.2 <LOQ* 0.88	0.51* 0.905* 0.86 0.67 0.013* 0.49	69 83-84 85-87 87-89 89 89	0 10 20 32 39 39	prothioconazole expressed as prothioconazole-desthio as a sum of the metabolites (h) = 0.06 mg/kg Max. sample storage time (sampling to extraction): 149 days, max. extract storage time, 15 days (extraction to analysis). Results in all untreated specimens were below LOD. *Mean of two extractions
BPL19/762/GC-04-FR 60490 Mareuil-Lamotte, France N-EU 2018/19 (C)	Spring wheat (TRZAW)/ Lennox	1. 19/02/19 2. 18-21/06/19 3. 01/08/19	0.192	195	0.099	21/06/19	BBCH 69	Whole plant w/o roots Whole plant w/o roots Whole plant w/o roots Whole plant w/o roots Grain Straw	1.2 0.30 0.21 0.35 <LOQ 1.4	1.2 0.26 0.16 0.22 <LOQ 0.53	69 75 83 87-89 89 89	0 10 20 35 45 45	

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) These values are actual rate of active substance as they were calculated with the actual concentration of the active substance: (Dose rate target 200 g a.s./ha prothioconazole equivalent to ADM.3500.F.2B at 0.8 L/ha)
(d) Year must be indicated
(e) Days after last application not given in the study report. Calculated during dossier compilation.
(f) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
(g) Prothioconazole (mg/kg) as sum of prothioconazole-desthio, 3-hydroxyprothioconazole-desthio, 4-hydroxyprothioconazole-desthio, 5-hydroxyprothioconazole-desthio, 6-hydroxyprothioconazole-desthio and alpha-hydroxyprothioconazole-desthio, expressed as prothioconazole-desthio (8.1, acc. to risk assessment residue definition). For the sum of prothioconazole-desthio, the calculations were performed with value of 0.01 mg/kg for results <LOQ and as zero for results <LOQ (nd).
(h) Prothioconazole-desthio (sum of isomers) (8.2, enforcement residue definition)
n.d. not detectable
LOQ Limit of quantification

LOD Limit of detection
** Residues were derived using QuEChERS method EN 15662:2009-02(in contrast to other results derived using methods based on RAR method 00979/M001, LC-MS/MS), and therefore not underlined

Table A 7: Summary of the wheat study 1 - 4 trials (TDMs)

Crop residue data from supervised field trials		**Reference no.:**	**KCA 6.3.1/02**
Active ingredient (common name and content):	Prothioconazole, 248.2 g/L (actual)	Commercial product (name/code):	ADM.3500.F.2.B
Crop/crop group:	Winter Wheat / Cereals	Formulation (e.g. SC):	EC
Country:	France (N-EU), Hungary, Poland	Other active substance in the formulation:	None
Indoor/outdoor:	Outdoor	Residues calculated as:	**1,2,4-Triazole, Triazole alanine, Triazole acetic acid, Triazole lactic acid (mg/kg)**
Responsible body for reporting (name, address):	Eurofins Agroscience Services Chem GmbH, Hamburg, Germany		

1	2	3	4			5	6	7	8.1	8.2	8.3	8.4	9		10
Trial No./ Location/ EU zone/ Year	**Commodity / Variety** (a)	**Date of 1.Sowing or planting 2.Flowering 3. Harvest** (b)	**Application rate per treatment**			**Dates of treatment or no. of treatments and last date** (d)	**Growth stage at last treatment or date** (e)	**Portion analysed** (a)	**Residues (mg/kg)**				**Assessment**		**Details on trial(s)** (g)
			kg a.s./ ha (c)	**Water (L/ha)**	**kg a.s./ hL**				**1,2,4-triazole**	**Triazole alanine**	**Triazole acetic acid**	**Triazole lactic acid**	**Timing (BBCH)**	**DALA (days)** (f)	
BPL19/762/GC-01-FR 71640 Givry France N-EU 2018/19 (A)	Winter wheat (TRZAW)/ Complice	1. 25/10/18 2. 27/05/ - 11/06/19 3. 10/07/ - 16/07/19	0.201	202	0.099	08/06/19	BBCH 69	Grain	*<LOQ (n.d.)*	0.29	0.13	<LOQ	89	34	Analytical method: Syngenta GRM053.01A, LC-DMS-MS/MS detection. For method validation please refer to dRR Part B.5, point KCP 5.1.2. LOQ: 0.01 mg/kg with LOD: 0.003 mg/kg (for each analyte and each matrix) Max. sample storage time: 538 days for whole plant w/o roots, 525 days for grain and 499 days for straw (sampling to
								Straw	*<LOQ (n.d.)*	<LOQ	0.04	0.05	89	34	
			Untreated					Grain	*<LOQ (n.d.)*	0.05	0.06	<LOQ (n.d.)	89	34	
								Straw	*<LOQ (n.d.)*	<LOQ (n.d.)	0.02	0.02	89	34	
BPL19/762/GC-02-HU 2141 Csömör Hungary N-EU 2018/19 (B)	Winter wheat (TRZAW)/ Astardo	1. 01/10/18 2. 22/05/- 03/06/19 3. 09/07/- 11/07/19	0.202	256	0.079	03/06/19	BBCH 69	Grain	*<LOQ*	0.58	0.12	0.01	89	36	
								Straw	*<LOQ (n.d.)*	0.08	0.06	0.16	89	36	
			Untreated					Grain	*<LOQ (n.d.)*	0.02	0.01	<LOQ (n.d.)	89	36	
								Straw	*<LOQ (n.d.)*	<LOQ (n.d.)	<LOQ	0.01	89	36	

1	2	3	4			5	6	7	8.1	8.2	8.3	8.4	9		10
Trial No./ Location/ EU zone/ Year	Commodity / Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (d)	Growth stage at last treatment or date (e)	Portion analysed (a)	Residues (mg/kg)				Assessment		Details on trial(s) (g)
			kg a.s./ ha (c)	Water (L/ha)	kg a.s./ hL				1,2,4-triazole	Triazole alanine	Triazole acetic acid	Triazole lactic acid	Timing (BBCH)	DALA (days) (f)	
BPL19/762/GC-03-PL 55-110 Krościna Mala Poland N-EU 2018/19	Winter wheat (TRZAW)/ Linus	1. 01/10/18 2. 01/06/-20/06/19 3. 26/07/-26/07/19	0.195	296	0.066	18/06/19	BBCH 69	whole plant w/o roots	*<LOQ (n.d.)*	0.05	0.10	0.08	69	0	extraction), max. extract storage time (extraction to analysis) 0 day for straw and 1 day for whole plant w/o roots and grain. Possible instability of the analytes in final sample extracts was automatically levelled out when using the response ratio of analyte to internal standard for quantification. Residues in untreated samples (background levels) were found in a part of samples, and results are given.
								whole plant w/o roots	*<LOQ (n.d.)*	0.05	0.12	0.06	83-84	10	
								whole plant w/o roots	*<LOQ (n.d.)*	0.06	0.13	0.05	85-87	20	
								whole plant w/o roots	*<LOQ*	0.08	0.12	0.03	87-89	32	
								Grain	*<LOQ*	0.34	0.21	<LOQ (n.d.)	89	39	
								Straw	*<LOQ*	0.02	0.13	0.05	89	39	
			Untreated					whole plant w/o roots	*<LOQ (n.d.)*	0.01	0.02	0.01	69	0	
								whole plant w/o roots	*<LOQ (n.d.)*	0.02	0.04	0.02	85-87	20	
								Grain	*<LOQ*	0.08	0.07	<LOQ (n.d.)	89	39	
								Straw	*<LOQ (n.d.)*	<LOQ (n.d.)	0.05	0.02	89	39	
BPL19/762/GC-04-FR 60490 Mareuil-Lamotte France N-EU 2019 (C)	Spring wheat (TRZAS)/ Lennox	1. 19/02/19 2. 18/06/ - 21/06/19 3. 01/08/19	0.192	194	0.099	21/06/19	BBCH 69	whole plant w/o roots	*<LOQ (n.d.)*	0.01	<LOQ	<LOQ	69	0	
								whole plant w/o roots	*<LOQ (n.d.)*	0.13	0.02	0.04	75	10	
								whole plant w/o roots	*<LOQ (n.d.)*	0.16	0.02	0.04	83	20	
								whole plant w/o roots	*<LOQ (n.d.)*	0.14	0.04	0.06	87-89	35	
								Grain	*<LOQ*	0.54	0.09	<LOQ	89	45	
								Straw	*<LOQ (n.d.)*	<LOQ (n.d.)	0.02	0.06	89	45	

1	**2**	**3**	**4**			**5**	**6**	**7**	**8.1**	**8.2**	**8.3**	**8.4**	**9**		**10**
Trial No./ Location/ EU zone/ Year	**Commodity / Variety** (a)	**Date of 1.Sowing or planting 2.Flowering 3. Harvest** (b)	**Application rate per treatment**			**Dates of treatment or no. of treatments and last date** (d)	**Growth stage at last treatment or date** (e)	**Portion analysed** (a)	**Residues (mg/kg)**				**Assessment**		**Details on trial(s)** (g)
			kg a.s./ ha (c)	**Water (L/ha)**	**kg a.s./ hL**				**1,2,4-triazole**	**Triazole alanine**	**Triazole acetic acid**	**Triazole lactic acid**	**Timing (BBCH)**	**DALA (days)** (f)	
			Untreated					whole plant w/o roots	*<LOQ (n.d.)*	0.01	0.01	0.01	69	0	
								whole plant w/o roots	*<LOQ (n.d.)*	0.01	0.01	0.01	83	20	
								Grain	*<LOQ*	0.03	0.03	<LOQ (n.d.)	89	45	
								Straw	*<LOQ (n.d.)*	0.02	0.02	0.04	89	45	

(a) According to Codex Classification / Guide
(b) Only if relevant
(c) These values are actual rate of active substance as they were calculated with the actual concentration of the active substance:
(Dose rate target 200 g a.s./ha prothioconazole equivalent to ADM.3500.F.2B at 0.8 L/ha)
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4.
(f) Minimum number of days after last application.
(g) Remarks may include: climatic conditions ; reference to analytical method ; information concerning the metabolites included, the method of storage, storage, stability, analysis date.
w/o Without
n.d. Not detectable
LOQ Limit of quantification
LOD Limit of detection
Data in *italics* reported but outside acceptable storage stability

A 2.1.3.1.2 Wheat study 2

Comments of zRMS:	The study of Le Mineur, A., 2022a (Report No.: BPL21/954/GC) has been evaluated in Registration Report for ADM.03500.F.2.B on March 2023 by zRMS-PL and the summary is presented below. Six field trials were conducted in Northern Europe to determine the residue level of prothioconazole and fluxapyroxad and their respective metabolites in specimens of wheat grain and straw following one foliar application of ADM.03503.F.1.A (150 g/L of Prothioconazole and 75 g/L of Fluxapyroxad). The target dose rate of test item ADM.03503.F.1.A was 1.25 L/ha (187.5 g/ha of Prothioconazole and 93.75 g/ha of Fluxapyroxad). Application was performed at BBCH 69. Specimens of grain and straw were generated at harvest stage BBCH 89 from all the field trials performed. <u>Prothioconazole</u> In seed specimens taken at normal commercial harvest (24-52 days) residues of prothioconazole (sum) and prothioconazole-desthio were <LOQ. The analytical method based on the method 00979/M001 was validated for wheat grain and straw according to guideline SANTE/2020/12830, Rev.1. All the analytes were determined by LC-MS/MS using a quantitation and confirmation ion. The LOQ of each analyte was at 0.01 mg/kg for each matrix, 0.06 mg/kg for prothioconazole expressed as prothioconazole-desthio as a sum of metabolites. The mean recovery was between 70% and 110% at each level of fortification, for each reference item and for each matrix. The storage duration (interval between sampling and extraction date) was 125 days for the determination of prothioconazole and its metabolites. Sufficient stability data are available to support the residue data presented in this study. <u>Triazole metabolites</u> The analytical method GRM053.01A was validated for the determination of 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) in wheat (whole plants without roots, grain and straw) according to SANTE/2020/12830, Rev.1. The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for each analyte and each matrix. The mean recovery was between 70% and 110% at each level of fortification, for each reference item and for each matrix. In the treated wheat specimens, the residue levels of the triazole metabolites ranged from: For 1,2,4-Triazole, all results were<LOQ (nd) to <LOQ in grain and <LOQ (nd) in straw specimens, For Triazole alanine: - 0.26 and 0.61 mg/kg in grain, - <LOQ and 0.04 mg/kg in straw, For Triazole acetic acid: - 0.06 and 0.39 mg/kg in grain, - 0.01 and 0.12 mg/kg in straw, For Triazole lactic acid: - All results were <LOQ in grain, - <LOQ and 0.25 mg/kg in straw. Analysis (extraction) of the specimens took place maximum 106 days after samples collection. Sufficient stability data are available to support the residue data presented in this study. The study is acceptable.

Reference:	KCA 6.3.1/03
Report:	Residue study of Prothioconazole and Fluxapyroxad and their respective metabolites in wheat Raw Agricultural Commodities after foliar application of ADM.03503.F.1.A under field conditions –Northern Europe – 2021 Le Mineur, A., 2022a Study no.: BPL21/954/GC, sponsor no.: 000107608
Guideline(s):	OECD/OCDE 509 Adopted: 7 September 2009, OECD Guidelines for the testing of chemicals, Crop Field Trial. ENV/JM/MONO(2011)50/REV1 07-Sep-2016 OECD Guidance Document on crop field trials, second edition, Series on Pesticides - No. 66 Series on Testing & Assessment - No. 164 SANTE/2020/12830, Rev.1 24, February 2021, Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes - Supersedes Guidance Documents SANCO/3029/99 and SANCO/825/00.
Deviations:	None with impact on study results
GLP:	Yes
Acceptability:	Yes

Table A 8: Summary of wheat study 2 – 6 trials

Crop residue data from supervised field trials		**Reference no.:**	**KCA 6.3.1/03**
Active ingredient (common name and content):	Prothioconazole, nominal 150 g/L (actual 148 g/L)	Commercial product (name/code):	ADM.03503. F.1.A
Crop/crop group:	Wheat / Cereals	Formulation (e.g. SC):	EC
Country:	France (N-EU), Germany, Hungary, Poland	Other active substance in the formulation:	Fluxapyroxad, nominal 75 g/L (actual 77.4 g/L)
Indoor/outdoor:	Outdoor	Residues calculated as:	**Prothioconazole as sum of prothioconazole-desthio, 3-hydroxyprothioconazole-desthio, 4-hydroxyprothioconazole-desthio, 5-hydroxyprothioconazole-desthio, 6-hydroxyprothioconazole-desthio and alpha-hydroxyprothioconazole-desthio, expressed as prothioconazole-desthio (mg/kg) (8.1, risk assessment residue definition);** **Prothioconazole-desthio (mg/kg) (8.2, enforcement residue definition)**
Responsible body for reporting (name, address):	BIOTEK Agriculture, Saint-Pouange, France		

1	**2**	**3**	**4**			**5**	**6**	**7**	**8.1**	**8.2**	**9**		**10**
Trial No./ Location/ EU zone/ Year	**Commodity/ Variety**	**Date of 1.Sowing or planting 2.Flowering 3. Harvest**	**Application rate per treatment**			**Dates of treatment or no. of treatments and last date**	**Growth stage at last treatment or date**	**Portion analysed**	**Residues (mg/kg)**		**Assessment**		**Details on trial(s)**
			kg a.s./ ha	**Water (L/ha)**	**kg a.s./ hL**				**Prothio-conazole (sum)**	**Prothio-conazole-desthio**	**Timing (BBCH)**	**DALA (days)**	
	(a)	(b)	(c)			(d)			(g)	(h)		(e)	(f)
BPL21/954/GC-01-FR 10 600 La Chapelle Saint-Luc France N-EU 2020/21 (A)	Winter wheat (TRZAW) / Pastoral	1/ 20/10/20 2/ 28/05 - 12/06/21 3/ 24/07/21	0.177	288	0.062	10/06/21	BBCH 69	Grain Straw	<LOQ (n.d.) 0.16*	<LOQ (n.d.) 0.052*	89 89	50 50	Analytical methods: RAR method 00979/M001, LC-MS/MS For method validation please refer to dRR Part B.5, point KCP 5.1.2. LOQ: 0.01 mg/kg for each analyte, 0.06 mg/kg for prothioconazole expressed as prothioconazole-desthio as a sum of
BPL21/954/GC-02-GE 74861 Kreβbach Germany N-EU 2020/21 (B)	Winter wheat (TRZAW) / Kometus	1/ 20/10/20 2/ 07 - 14/06/21 3/ 29 - 30/07/21	0.188	356	0.053	15/06/21	BBCH 69	Grain Straw	<LOQ (n.d.) 0.31	<LOQ (n.d.) 0.095	89 89	44 44	

1	2	3	4			5	6	7	8.1	8.2	9		10
Trial No./ Location/ EU zone/ Year	**Commodity/ Variety**	**Date of 1.Sowing or planting 2.Flowering 3. Harvest**	**Application rate per treatment**			**Dates of treatment or no. of treatments and last date**	**Growth stage at last treatment or date**	**Portion analysed**	**Residues (mg/kg)**		**Assessment**		**Details on trial(s)**
			kg a.s./ ha	**Water (L/ha)**	**kg a.s./ hL**				**Prothio-conazole (sum)**	**Prothio-conazole-desthio**	**Timing (BBCH)**	**DALA (days)**	
	(a)	(b)	(c)			(d)			(g)	(h)		(e)	(f)
BPL21/954/GC-03-HU 2340 Kiskunlacháza Hungary N-EU 2021 (C)	Spring wheat (TRZAS) / Pirkadat	1/ 16/03/21 2/ 09 - 15/06/21 3/ 12 - 15/07/21	0.181	293	0.062	15/06/21	BBCH 69	Grain Straw	<LOQ (n.d.) 0.87	<LOQ 0.73	89 89	28 28	metabolites; LOD: 0.003 mg/kg for each analyte, 0.018 mg/kg for prothioconazole expressed as prothioconazole-desthio as a sum of metabolites Max. sample storage time: 125 days (sampling to extraction), max. extract storage time (extraction to analysis) 17 days. Extract stability proven within the study. Results in all untreated specimens were below LOD.
BPL21/954/GC-04-PL 98 300 Masłowice Poland N-EU 2021	Spring wheat (TRZAS) / Nimfa C1	1/ 05/03/21 2/ 25/06 - 04/07/21 3/ 26/07/21	0.186	301	0.062	02/07/21	BBCH 69	Grain Straw	<LOQ (n.d.) 1.2	<LOQ 0.51	89 89	24 24	
BPL21/954/GC-05-FR 37 210 Parçay Meslay France N-EU 2020/21 (D)	Winter wheat (TRZAW) / Unik	1/ 18/10/20 2/ 25/05 - 08/06/21 3/ 20/07/21	0.182	197	0.093	05/06/21	BBCH 69	Grain Straw	<LOQ (n.d.) 0.53*	<LOQ (n.d.) 0.18*	89 89	45 45	
BPL21/954/GC-06-FR 51 240 Marson France N-EU 2021 (E)	Winter wheat (TRZAW) / Syllon	1/ 18/10/20 2/ 30/05 - 12/06/21 3/ 22/07/21	0.183	297	0.062	11/06/21	BBCH 69	Grain Straw	<LOQ (n.d.) 0.068	<LOQ (n.d.) 0.021	89 89	52 52	

(a) According to Codex Classification /Guide
(b) Only if relevant
(c) These values are actual rate of active substance as they were calculated with the actual concentration of the active substance:
(Dose rate targeted was 187.5 g a.s./ha of Prothioconazole and 93.75 g a.s./ha of Fluxapyroxad (equivalent to ADM.03503. F.1.A at 1.25 L/ha)

(d) Year must be indicated
(e) Days after last application.
(f) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
(g) Prothioconazole (mg/kg) as sum of prothioconazole-desthio, 3-hydroxyprothioconazole-desthio, 4-hydroxyprothioconazole-desthio, 5-hydroxyprothioconazole-desthio, 6-hydroxyprothioconazole-desthio and alpha-hydroxyprothioconazole-desthio, expressed as prothioconazole-desthio (8.1, acc. to risk assessment residue definition). For the sum of prothioconazole-desthio, the calculations were performed with value of 0.01 mg/kg for results <LOQ and as zero for results <LOQ (nd).
(h) Prothioconazole-desthio (sum of isomers) (8.2, enforcement residue definition)
* Mean of two extractions
n.d. Not detectable
LOQ Limit of quantification
LOD Limit of detection

Table A 9: Summary of wheat study 2 – 6 trials (TDMs)

Crop residue data from supervised field trials		**Reference no.:**	**KCA 6.3.1/03**
Active ingredient (common name and content):	Prothioconazole, 148 g/L (actual)	Commercial product (name/code):	ADM.03503.F.1.A
Crop/crop group:	Wheat / Cereals	Formulation (e.g. SC):	EC
Country:	France (N-EU), Germany, Hungary, Poland	Other active substance in the formulation:	Fluxapyroxad Nominal 77.4 g/L (actual)
Indoor/outdoor:	Outdoor	Residues calculated as:	**1,2,4-Triazole, Triazole alanine, Triazole acetic acid, Triazole lactic acid (mg/kg)**
Responsible body for reporting (name, address):	BIOTEK Agriculture, Saint-Pouange, France		

1	2	3	4			5	6	7	8.1	8.2	8.3	8.4	9		10
Trial No./ Location/ EU zone/ Year	**Commodity/ Variety** (a)	**Date of 1.Sowing or planting 2.Flowering 3. Harvest** (b)	**Application rate per treatment**			**Dates of treatment or no. of treatments and last date** (d)	**Growth stage at last treatment or date** (e)	**Portion analysed** (a)	**Residues (mg/kg)**				**Assessment**		**Details on trial(s)** (g)
			kg a.s./ ha (c)	**Water (L/ha)**	**kg a.s./ hL**				**1,2,4-triazole**	**Triazole alanine**	**Triazole acetic acid**	**Triazole lactic acid**	**Timing (BBCH)**	**DALA (days)** (f)	
BPL21/954/GC-01-FR 10 600 La Chapelle Saint-Luc France N-EU 2020/21 (A)	Winter wheat (TRZAW) / Pastoral	1/ 20/10/20 2/ 28/05 - 12/06/21 3/ 24/07/21	0.177	288	0.062	10/06/21	BBCH 69	Grain	<LOQ (n.d.)	0.31	0.07	<LOQ (n.d.)	89	50	Analytical methods: GRM053.01A, LC-DMS-MS/MS detection. For method validation please refer to dRR Part B.5, point KCP 5.1.2.
								Straw	<LOQ (n.d.)	<LOQ	0.01	<LOQ	89	50	
			Untreated					Grain	<LOQ (n.d.)	0.02	0.01	<LOQ (n.d.)	89	50	LOQ: 0.01 mg/kg with LOD: 0.003 mg/kg (for each analyte and each matrix)
								Straw	<LOQ (n.d.)	<LOQ	<LOQ	<LOQ (n.d.)	89	50	
BPL21/954/GC-02-GE 74861 Kreβbach Germany N-EU 2020/21 (B)	Winter wheat (TRZAW) / Kometus	1/ 20/10/20 2/ 07 - 14/06/21 3/ 29 - 30/07/21	0.188	356	0.053	15/06/21	BBCH 69	Grain	<LOQ	0.34	0.07	<LOQ (n.d.)	89	44	Max. sample storage time: 106 days (sampling to extraction), max. extract storage time (extraction to analysis) 7 days for grain and 3
								Straw	<LOQ (n.d.)	<LOQ	0.03	0.01	89	44	

1	2	3	4			5	6	7	8.1	8.2	8.3	8.4	9		10
Trial No./ Location/ EU zone/ Year	**Commodity/ Variety** (a)	**Date of 1.Sowing or planting 2.Flowering 3. Harvest** (b)	**Application rate per treatment**			**Dates of treatment or no. of treatments and last date** (d)	**Growth stage at last treatment or date** (e)	**Portion analysed** (a)	**Residues (mg/kg)**				**Assessment**		**Details on trial(s)** (g)
			kg a.s./ ha (c)	**Water (L/ha)**	**kg a.s./ hL**				**1,2,4-triazole**	**Triazole alanine**	**Triazole acetic acid**	**Triazole lactic acid**	**Timing (BBCH)**	**DALA (days)** (f)	
			Untreated					Grain Straw	<LOQ (n.d.) <LOQ (n.d.)	0.06 <LOQ	0.03 0.01	<LOQ (n.d.) <LOQ	89 89	44 44	days for straw. Extract stability proven within the study.
BPL21/954/GC-03-HU 2340 Kiskunlacháza Hungary N-EU 2021(C)	Spring wheat (TRZAS) / Pirkadat	1/ 16/03/21 2/ 09 - 15/06/21 3/ 12 - 15/07/21	0.181	293	0.062	15/06/21	BBCH 69	Grain Straw	<LOQ <LOQ (n.d.)	0.61 0.04	0.39 0.12	<LOQ 0.25	89 89	28 28	Residues in untreated samples (background levels) were found in a part of samples, and results are given.
			Untreated					Grain Straw	<LOQ (n.d.) <LOQ (n.d.)	0.17 0.01	0.20 0.06	<LOQ 0.14	89 89	28 28	
BPL21/954/GC-04-PL 98 300 Masłowice Poland N-EU 2021	Spring wheat (TRZAS) / Nimfa C1	1/ 05/03/21 2/ 25/06 - 04/07/21 3/ 26/07/21	0.186	301	0.062	02/07/21	BBCH 69	Grain Straw	<LOQ (n.d.) <LOQ (n.d.)	0.38 0.02	0.06 0.02	<LOQ 0.01	89 89	24 24	
			Untreated					Grain Straw	<LOQ (n.d.) <LOQ (n.d.)	0.06 <LOQ	0.04 0.02	<LOQ (n.d.) <LOQ	89 89	24 24	

1	2	3	4			5	6	7	8.1	8.2	8.3	8.4	9		10
Trial No./ Location/ EU zone/ Year	**Commodity/ Variety**	**Date of 1.Sowing or planting 2.Flowering 3. Harvest**	**Application rate per treatment**			**Dates of treatment or no. of treatments and last date**	**Growth stage at last treatment or date**	**Portion analysed**	**Residues (mg/kg)**				**Assessment**		**Details on trial(s)**
			kg a.s./ ha	**Water (L/ha)**	**kg a.s./ hL**				**1,2,4-triazole**	**Triazole alanine**	**Triazole acetic acid**	**Triazole lactic acid**	**Timing (BBCH)**	**DALA (days)**	
	(a)	(b)	(c)			(d)	(e)	(a)						(f)	(g)
BPL21/954/GC-05-FR 37 210 Parçay Meslay France N-EU 2020/21 (D)	Winter wheat (TRZAW) / Unik	1/ 18/10/20 2/ 25/05 - 08/06/21 3/ 20/07/21	0.182	197	0.093	05/06/21	BBCH 69	Grain	<LOQ (n.d.)	0.26	0.06	<LOQ (n.d.)	89	45	
								Straw	<LOQ (n.d.)	<LOQ	0.02	0.01	89	45	
			Untreated					Grain	<LOQ (n.d.)	0.12	0.05	<LOQ (n.d.)	89	45	
								Straw	<LOQ (n.d.)	<LOQ (n.d.)	0.02	0.01	89	45	
BPL21/954/GC-06-FR 51 240 Marson France N-EU 2021 (E)	Winter wheat (TRZAW) / Syllon	1/ 18/10/20 2/ 30/05 - 12/06/21 3/ 22/07/21	0.183	297	0.062	11/06/21	BBCH 69	Grain	<LOQ (n.d.)	0.37	0.09	<LOQ (n.d.)	89	52	
								Straw	<LOQ (n.d.)	<LOQ	0.02	0.01	89	52	
			Untreated					Grain	<LOQ (n.d.)	0.04	0.02	<LOQ (n.d.)	89	52	
								Straw	<LOQ (n.d.)	<LOQ (n.d.)	<LOQ	<LOQ (n.d.)	89	52	

(a) According to Codex Classification /Guide
(b) Only if relevant
(c) These values are actual rate of active substance as they were calculated with the actual concentration of the active substance:
(Dose rate targeted was 187.5 g a.s./ha of Prothioconazole and 93.75 g a.s./ha of Fluxapyroxad (equivalent to ADM.03503.F.1.A at 1.25 L/ha)
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4.
(f) Minimum number of days after last application.
(g) Remarks may include: climatic conditions; reference to analytical method ; information concerning the metabolites included, the method of storage, storage, stability, analysis date.
n.d. Not detectable
LOQ Limit of quantification, LOD Limit of detection

A 2.1.3.1.3 Wheat study 3

Comments of zRMS:	The study of Le Mineur, A., 2022b (Report No.: BPL21/958/GC) has been evaluated in Registration Report for ADM.03500.F.2.B on March 2023 by zRMS-PL and the summary is presented below. Eight field trials were conducted in Northern Europe to determine the residue level of prothioconazole and its metabolites, and of difenoconazole in specimens of wheat whole plant without roots, grain and straw following one foliar application of ADM.03501.F.1.A (175 g a.s./L of prothioconazole and 125 g a.s./L of difenoconazole) at the dose rate 1 L/ha (175 g a.s./ha of prothioconazole and 125 g a.s./ha of difenoconazole). Application was performed at BBCH1 69. Specimens of whole plant without roots were generated at ±0 DAA, 10 (±1) DAA, 20 (±2) DAA and 35 (±3) DAA for the decline trials. Specimens of grain and straw were generated at harvest stage BBCH 89 from all the field trials performed. In seed specimens taken at normal commercial harvest (28 – 72 days) residues of prothioconazole (sum) and prothioconazole-desthio were <LOQ. For prothioconazole and its metabolites, the principle of analytical method was based on the method 00979/M001. For prothioconazole and its metabolites, the analytical method was validated (reduced validations) on wheat (whole plant, grain and straw), following the guideline SANTE/2020/12830, Rev.1 of 24/02/2021. All the analytes were determined by LC-MS/MS using a quantitation and confirmation ion. LOQ: 0.01 mg/kg for each analyte, LOQ: 0.06 mg/kg for prothioconazole expressed as prothioconazole-desthio as a sum of metabolites. The mean recoveries at each fortification level comply with the standard acceptance criteria of the guidance document SANTE/2020/12830, rev. 1. The storage duration (interval between sampling and extraction date) was 109 days for the determination of prothioconazole and its metabolites. Sufficient stability data are available to support the residue data presented in this study. Remark: Only residues of prothioconazole expressed as prothioconazole-desthio are reported in the following summary without data of TDMs. The study is acceptable.

Reference:	KCA 6.3.1/04
Report:	Residue study of prothioconazole, difenoconazole and their metabolites in wheat whole plant and Raw Agricultural Commodities after foliar application of ADM.03501.F.1.A under field conditions – Northern Europe - 2021. Le Mineur, A., 2022b Report no.: BPL21/958/GC, sponsor no.: 000107612
Guideline(s):	EC guidance working document 7029/VI/95 rev. 5 (22/07/1997) Appendix B OECD/OCDE 509 (2009) Crop field trial ENV/JM/MONO(2011)50 SANTE/2020/12830, Rev.1 of 24/02/21 ENV/JM/MONO(2007)17
Deviations:	None with impact on study results
GLP:	Yes
Acceptability:	Yes

Additional residue data of difenoconazole and triazole derivative metabolites (TDMs) have been determined in this study. However, difenoconazole residues are not relevant for ADM.03500.F.2.B (containing prothioconazole only) and TDMs are overestimated with regard to the product as they results from both active substances in the used formulation (prothioconazole and difenoconazole). However, it is demonstrated in all trials that 1,2,4-T is below LOQ (<0.01 mg/kg) in all matrices. Therefore, residues of 1,2,4-T from the three independent trials were additionally used for risk assessment.

Table A 10: Summary of the wheat study 3 - 8 trials

Crop residue data from supervised field trials		**Reference no.:**	**KCA 6.3.1/04**
Active ingredient (common name and content):	Prothioconazole, nominal 175 g/L (actual 172.8 g/L)	Commercial product (name/code):	ADM.03501.F.1.A
Crop/crop group:	Wheat / Cereals	Formulation (e.g. SC):	EC
Country:	France (N-EU), Germany, Hungary, Poland	Other active substance in the formulation:	Difenoconazole, nominal 125 g/L (actual 125.0 g/L)
Indoor/outdoor:	Outdoor	Residues calculated as:	**Prothioconazole as sum of prothioconazole-desthio, 3-hydroxyprothioconazole-desthio, 4-hydroxyprothioconazole-desthio, 5-hydroxyprothioconazole-desthio, 6-hydroxyprothioconazole-desthio and alpha-hydroxyprothioconazole-desthio, expressed as prothioconazole-desthio (mg/kg) (8.1, risk assessment residue definition);** **Prothioconazole-desthio (mg/kg) (8.2, enforcement residue definition)**
Responsible body for reporting (name, address):	SynTech Research France, La Chapelle de Guinchay, France		

1	2	3	4			5	6	7	8.1	8.2	9		10
Trial No./ Location/ EU zone/ Year	**Commodity/ Variety**	**Date of 1.Sowing or planting 2.Flowering 3. Harvest**	**Application rate per treatment**			**Dates of treatment or no. of treatments and last date**	**Growth stage at last treatment or date**	**Portion analysed**	**Residues (mg/kg)**		**Assessment**		**Details on trial(s)**
			kg a.s./ ha	**Water (L/ha)**	**kg a.s./ hL**				**Prothio-conazole (sum)**	**Prothio-conazole-desthio**	**Timing (BBCH)**	**DALA (days)**	
	(a)	(b)	(c)			(d)			(g)	(h)		(e)	(f)
BPL21/958/GC-01-FR 10 600 La Chapelle Saint-Luc France N-EU 2020/21 (A)	Winter wheat (TRZAW) / Pastoral	1/ 20/10/20 2/ 28/05 - 12/06/21 3/ 24/07/21	0.173	300	0.058	10/06/21	BBCH 69	Grain Straw	<LOQ (n.d.) 0.16	<LOQ (n.d.) 0.050*	89 89	50 50	Analytical methods: RAR method 00979/M001, LC-MS/MS For method validation please refer to dRR Part B.5, point KCP 5.1.2. LOQ: 0.01 mg/kg for each analyte, 0.06 mg/kg for prothioconazole expressed as prothioconazole-desthio as a sum of
BPL21/958/GC-02-GE 74861 Kreβbach Germany N-EU 2020/21 (B)	Winter wheat (TRZAW) / Kometus	1/ 20/10/20 2/ 07 - 14/06/21 3/ 29 - 30/07/21	0.175	354	0.049	15/06/21	BBCH 69	Grain Straw	<LOQ (n.d.) 0.26	<LOQ (n.d.) 0.072*	89 89	44 44	

1	2	3	4			5	6	7	8.1	8.2	9		10
Trial No./ Location/ EU zone/ Year	**Commodity/ Variety** (a)	**Date of 1.Sowing or planting 2.Flowering 3. Harvest** (b)	**Application rate per treatment**			**Dates of treatment or no. of treatments and last date** (d)	**Growth stage at last treatment or date**	**Portion analysed**	**Residues (mg/kg)**		**Assessment**		**Details on trial(s)** (f)
			kg a.s./ ha (c)	**Water (L/ha)**	**kg a.s./ hL**				**Prothio-conazole (sum)** (g)	**Prothio-conazole-desthio** (h)	**Timing (BBCH)**	**DALA (days)** (e)	
BPL21/958/GC-03-HU 2340 Kiskunlacháza Hungary N-EU 2021 (C)	Spring wheat (TRZAS) / Pirkadat	1/ 16/03/21 2/ 09 - 15/06/21 3/ 12 - 15/07/21	0.170	295	0.058	15/06/21	BBCH 69	Grain	<LOQ (n.d.)	<LOQ	89	28	metabolites; LOD: 0.003 mg/kg for each analyte, 0.018 mg/kg for prothioconazole expressed as prothioconazole-desthio as a sum of metabolites Max. sample storage time: 109 days (sampling to extraction), max. extract storage time (extraction to analysis) 8 days. Extract stability proven within the study. Results in all untreated specimens were below LOD.
								Straw	0.45	0.29	89	28	
BPL21/958/GC-04-PL 57 200 Tarnów Poland N-EU 2020/21	Winter wheat (TRZAW) / Euforia C1	1/ 15/11/20 2/ 23/06 - 02/07/21 3/ 14/08/21	0.170	296	0.058	01/07/21	BBCH 69	Grain	<LOQ (n.d.)	<LOQ (n.d.)	89	44	
								Straw	0.15	0.022	89	44	
BPL21/958/GC-05-PL 55 010 Krościna Mała Poland N-EU 2020/21	Winter wheat (TRZAW) / RGT Kilimanjaro	1/ 30/10/20 2/ 13/06 - 01/07/21 3/ 16/08/21	0.169	294	0.058	01/07/21	BBCH 69	whole plant w/o roots	0.55	0.54	69	0	
								whole plant w/o roots	0.16	0.047	71	11	
								whole plant w/o roots	0.15	0.027	73 – 75	20	
								whole plant w/o roots	0.085	0.013	87	33	
								Grain	<LOQ (n.d.)	<LOQ (n.d.)	89	46	
								Straw	0.17	0.028*	89	46	

1	2	3	4			5	6	7	8.1	8.2	9		10
Trial No./ Location/ EU zone/ Year	**Commodity/ Variety** (a)	**Date of 1.Sowing or planting 2.Flowering 3. Harvest** (b)	**Application rate per treatment**			**Dates of treatment or no. of treatments and last date** (d)	**Growth stage at last treatment or date**	**Portion analysed**	**Residues (mg/kg)**		**Assessment**		**Details on trial(s)** (f)
			kg a.s./ ha (c)	**Water (L/ha)**	**kg a.s./ hL**				**Prothio-conazole (sum)** (g)	**Prothio-conazole-desthio** (h)	**Timing (BBCH)**	**DALA (days)** (e)	
BPL21/958/GC-06-FR 80560 Arqueves France N-EU 2020/21	Winter wheat (TRZAW) / Fructidor	1/ 18/10/20 2/ 07 - 14/06/21 3/ 26/08/21	0.176	204	0.086	14/06/21	BBCH 69	whole plant w/o roots	0.44	0.44	69	0	
								whole plant w/o roots	0.17	0.081	83	10	
								whole plant w/o roots	0.071	0.023	85	18	
								whole plant w/o roots	0.088	0.016	85	35	
								Grain	<LOQ (n.d.)	<LOQ (n.d.)	89	72	
								Straw	0.065	0.018	89	72	
BPL21/958/GC-07-FR 37 210 Parçay Meslay France N-EU 2020/21 (D)	Winter wheat (TRZAW) / Unik	1/ 18/10/20 2/ 25/05 - 08/06/21 3/ 20/07/21	0.171	199	0.086	05/06/21	BBCH 69	Grain	<LOQ (n.d.)	<LOQ (n.d.)	89	45	
								Straw	0.49	0.015*	89	45	
BPL21/958/GC-08-FR 51240 Marson France N-EU 2020/21 (E)	Winter wheat (TRZAW) / Syllon	1/ 18/10/20 2/ 30/05 - 12/06/21 3/ 22/07/21	0.178	309	0.058	11/06/21	BBCH 69	Grain	<LOQ (n.d.)	<LOQ (n.d.)	89	52	
								Straw	0.14	0.047*	89	52	

(a) According to Codex Classification /Guide
(b) Only if relevant
(c) These values are actual rate of active substance as they were calculated with the actual concentration of the active substance:
(Dose rate targeted was 175 g a.s./ha of Prothioconazole and 125 g a.s./ha of Difenoconazole (equivalent to ADM.03501.F.1.A at 1.0 L/ha)
(d) Year must be indicated
(e) Days after last application.
(f) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

(g) Prothioconazole (mg/kg) as sum of prothioconazole-desthio, 3-hydroxyprothioconazole-desthio, 4-hydroxyprothioconazole-desthio, 5-hydroxyprothioconazole-desthio, 6-hydroxyprothioconazole-desthio and alpha-hydroxyprothioconazole-desthio, expressed as prothioconazole-desthio (8.1, acc. to risk assessment residue definition). For the sum of prothioconazole-desthio, the calculations were performed with value of 0.01 mg/kg for results <LOQ and as zero for results <LOQ (nd).
(h) Prothioconazole-desthio (sum of isomers) (8.2, enforcement residue definition)
w/o Without
* Mean of two extractions
n.d. Not detectable
LOQ Limit of quantification
LOD Limit of detection

Table A 11: Summary of wheat study 3 – 8 trials (TDMs)

Crop residue data from supervised field trials		**Reference no.:**	**KCA 6.3.1/04**
Active ingredient (common name and content):	Prothioconazole, 172.8 g/L (actual) Difenoconazole, 125.0 g/L (actual)	Commercial product (name/code):	ADM.03501.F.1.A
Crop/crop group:	Wheat / Cereals	Formulation (e.g. SC):	EC
Country:	France (N-EU), Germany, Hungary, Poland	Other active substance in the formulation:	None
Indoor/outdoor:	Outdoor	Residues calculated as:	**1,2,4-Triazole, Triazole alanine, Triazole acetic acid, Triazole lactic acid (mg/kg)**
Responsible body for reporting (name, address):	BIOTEK Agriculture, Saint-Pouange, France		

1	2	3	4			5	6	7	8.1	8.2	8.3	8.4	9		10
Trial No./ Location/ EU zone/ Year	**Commodity/ Variety** (a)	**Date of 1.Sowing or planting 2.Flowering 3. Harvest** (b)	**Application rate per treatment**			**Dates of treatment or no. of treatments and last date** (d)	**Growth stage at last treatment or date** (e)	**Portion analysed** (a)	**Residues (mg/kg)**				**Assessment**		**Details on trial(s)** (g)
			kg a.s./ ha (c)	**Water (L/ha)**	**kg a.s./ hL**				**1,2,4-T**	**TA**	**TAA**	**TLA**	**Timing (BBCH)**	**DALA (days)** (f)	
BPL21/958/GC-01-FR 10 600 La Chapelle Saint-Luc France N-EU 2020/21 **(A)** [1]	Winter wheat (TRZAW) / Pastoral	1/ 20/10/20 2/ 28/05 - 12/06/21 3/ 24/07/21	ptz: 0.173 dfz: 0.125	300	ptz: 0.058 dfz: 0.042	10/06/21	BBCH 69	Grain	<LOQ (n.d.)	0.06	0.03	<LOQ (n.d.)	89	50	Analytical methods: GRM053.01A, LC-DMS-MS/MS detection. For method validation please refer to dRR Part B.5, point KCP 5.1.2. LOQ: 0.01 mg/kg with LOD: 0.003 mg/kg (for each analyte and each matrix) Max. sample storage time: 122 days (sampling to extraction), max. extract storage time (extraction to
								Straw	<LOQ	0.01	0.02	<LOQ	89	50	
			Untreated					Grain	<LOQ (n.d.)	<LOQ	<LOQ	<LOQ (n.d.)	89	50	
								Straw	<LOQ (n.d.)	<LOQ	<LOQ	<LOQ (n.d.)	89	50	
BPL21/958/GC-02-GE 74861 Kreβbach Germany N-EU 2020/21 **(B)** [1]	Winter wheat (TRZAW) / Kometus	1/ 20/10/20 2/ 07 - 14/06/21 3/ 29 - 30/07/21	ptz: 0.175 dfz: 0.127	354	ptz: 0.049 dfz: 0.036	15/06/21	BBCH 69	Grain	<LOQ (n.d.)	0.23	0.04	<LOQ (n.d.)	89	44	
								Straw	<LOQ	0.02	0.05	0.01	89	44	

1	2	3	4			5	6	7	8.1	8.2	8.3	8.4	9		10
Trial No./ Location/ EU zone/ Year	**Commodity/ Variety** (a)	**Date of 1.Sowing or planting 2.Flowering 3. Harvest** (b)	**Application rate per treatment**			**Dates of treatment or no. of treatments and last date** (d)	**Growth stage at last treatment or date** (e)	**Portion analysed** (a)	**Residues (mg/kg)**				**Assessment**		**Details on trial(s)** (g)
			kg a.s./ ha (c)	**Water (L/ha)**	**kg a.s./ hL**				**1,2,4-T**	**TA**	**TAA**	**TLA**	**Timing (BBCH)**	**DALA (days)** (f)	
			Untreated					Grain	<LOQ (n.d.)	0.05	0.03	<LOQ (n.d.)	89	44	analysis) 1 day for whole plant w/o roots 5 days for grain and 1 day for straw.
								Straw	<LOQ (n.d.)	<LOQ	0.02	0.01	89	44	
BPL21/958/GC-03-HU 2340 Kiskunlacháza Hungary N-EU 2021 **(C)** [1]	Spring wheat (TRZAS) / Pirkadat	1/ 16/03/21 2/ 09 - 15/06/21 3/ 12 - 15/07/21	ptz: 0.170 dfz: 0.123	295	ptz: 0.058 dfz: 0.042	15/06/21	BBCH 69	Grain	<LOQ	0.26	0.13	<LOQ	89	28	Possible instability of the analytes in final sample extracts was automatically levelled out when using the response ratio of analyte to internal standard for quantification.
								Straw	<LOQ (n.d.)	0.01	0.03	0.12	89	28	
			Untreated					Grain	<LOQ	0.11	0.12	<LOQ (n.d.)	89	28	
								Straw	<LOQ (n.d.)	<LOQ (n.d.)	0.05	0.15	89	28	
BPL21/958/GC-04-PL 57 200 Tarnów Poland N-EU 2020/21	Winter wheat (TRZAW) / Euforia C1	1/ 15/11/20 2/ 23/06 - 02/07/21 3/ 14/08/21	ptz: 0.170 dfz: 0.123	296	ptz: 0.058 dfz: 0.042	01/07/21	BBCH 69	Grain	<LOQ	0.31	0.08	<LOQ (n.d.)	89	44	Residues in untreated samples (background levels) were found in a part of samples, and results are given.
								Straw	<LOQ	0.03	0.05	0.03	89	44	
			Untreated					Grain	<LOQ (n.d.)	0.12	0.05	<LOQ (n.d.)	89	44	
								Straw	<LOQ (n.d.)	0.01	0.02	<LOQ	89	44	

1	2	3	4			5	6	7	8.1	8.2	8.3	8.4	9		10
Trial No./ Location/ EU zone/ Year	**Commodity/ Variety** (a)	**Date of 1.Sowing or planting 2.Flowering 3. Harvest** (b)	**Application rate per treatment**			**Dates of treatment or no. of treatments and last date** (d)	**Growth stage at last treatment or date** (e)	**Portion analysed** (a)	**Residues (mg/kg)**				**Assessment**		**Details on trial(s)** (g)
			kg a.s./ ha (c)	**Water (L/ha)**	**kg a.s./ hL**				**1,2,4-T**	**TA**	**TAA**	**TLA**	**Timing (BBCH)**	**DALA (days)** (f)	
BPL21/958/GC-05-PL 55 010 Krościna Mała Poland N-EU 2020/21	Winter wheat (TRZAW) / RGT Kilimanjaro	1/ 30/10/20 2/ 13/06 - 01/07/21 3/ 16/08/21	ptz: 0.169 dfz: 0.122	294	ptz: 0.058 dfz: 0.042	01/07/21	BBCH 69	whole plant w/o roots	<LOQ (n.d.)	0.02	0.01	0.02	69	0	
								whole plant w/o roots	<LOQ (n.d.)	0.09	0.01	0.02	71	11	
								whole plant w/o roots	<LOQ (n.d.)	0.14	0.03	0.03	73 – 75	20	
								whole plant w/o roots	<LOQ (n.d.)	0.16	0.05	0.02	87	33	
								Grain	<LOQ (n.d.)	0.16	0.03	<LOQ (n.d.)	89	46	
								Straw	<LOQ	0.03	0.04	0.02	89	46	
			Untreated					whole plant w/o roots	<LOQ (n.d.)	0.03	0.02	0.02	69	0	
								whole plant w/o roots	<LOQ (n.d.)	0.05	0.02	0.02	73 – 75	20	
								Grain	<LOQ	0.13	0.05	<LOQ (n.d.)	89	46	
								Straw	<LOQ (n.d.)	0.01	0.02	0.01	89	46	
BPL21/958/GC-06-FR 80560 Arqueves France N-EU 2020/21	Winter wheat (TRZAW) / Fructidor	1/ 18/10/20 2/ 07 - 14/06/21 3/ 26/08/21	ptz: 0.176 dfz: 0.128	204	ptz: 0.086 dfz: 0.063	14/06/21	BBCH 69	whole plant w/o roots	<LOQ (n.d.)	0.02	<LOQ	0.01	69	0	
								whole plant w/o roots	<LOQ (n.d.)	0.07	0.01	0.03	83	10	
								whole plant w/o roots	<LOQ (n.d.)	0.07	0.01	0.03	85	18	
								whole plant w/o roots	<LOQ (n.d.)	0.10	0.03	0.03	85	35	
								Grain	<LOQ (n.d.)	0.23	0.07	<LOQ (n.d.)	89	72	
								Straw	<LOQ (n.d.)	0.02	0.04	<LOQ	89	72	

1	2	3	4			5	6	7	8.1	8.2	8.3	8.4	9		10
Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (d)	Growth stage at last treatment or date (e)	Portion analysed (a)	Residues (mg/kg)				Assessment		Details on trial(s) (g)
			kg a.s./ ha (c)	Water (L/ha)	kg a.s./ hL				1,2,4-T	TA	TAA	TLA	Timing (BBCH)	DALA (days) (f)	
			Untreated					whole plant w/o roots	<LOQ (n.d.)	0.01	0.01	0.01	69	0	
								whole plant w/o roots	<LOQ (n.d.)	0.02	0.01	0.01	85	18	
								Grain	<LOQ (n.d.)	0.07	0.03	<LOQ (n.d.)	89	72	
								Straw	<LOQ (n.d.)	<LOQ	<LOQ	<LOQ (n.d.)	89	72	
BPL21/958/GC-07-FR 37 210 Parçay Meslay France N-EU 2020/21 **(D)** [1]	Winter wheat (TRZAW) / Unik	1/ 18/10/20 2/ 25/05 - 08/06/21 3/ 20/07/21	ptz: 0.170 dfz: 0.123	197	ptz: 0.086 dfz: 0.062	05/06/21	BBCH 69	Grain	<LOQ	0.27	0.07	<LOQ (n.d.)	89	45	
								Straw	<LOQ	0.02	0.06	0.02	89	45	
			Untreated					Grain	<LOQ (n.d.)	0.06	0.04	<LOQ (n.d.)	89	45	
								Straw	<LOQ (n.d.)	<LOQ	0.01	<LOQ	89	45	
BPL21/958/GC-08-FR 51240 Marson France N-EU 2020/21 **(E)** [1]	Winter wheat (TRZAW) / Syllon	1/ 18/10/20 2/ 30/05 - 12/06/21 3/ 22/07/21	ptz: 0.178 dfz: 0.129	309	ptz: 0.058 dfz: 0.042	11/06/21	BBCH 69	Grain	<LOQ (n.d.)	0.37	0.15	<LOQ	89	52	
								Straw	<LOQ	0.02	0.04	0.01	89	52	
			Untreated					Grain	<LOQ	0.03	0.02	<LOQ (n.d.)	89	52	
								Straw	<LOQ (n.d.)	<LOQ (n.d.)	<LOQ	<LOQ (n.d.)	89	52	

[1] Underlined capital letter in brackets (column 1) indicate a second set of data for the same trial site.
(a) According to Codex Classification /Guide
(b) Only if relevant

(c) These values are actual rate of active substance as they were calculated with the actual concentration of the active substance:
(Dose rate targeted was 175 g a.s./ha of Prothioconazole and 125 g a.s./ha of difenoconazole (equivalent to ADM.03501.F.1.A at 1.0 L/ha)
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4.
(f) Minimum number of days after last application.
(g) Remarks may include: climatic conditions ; reference to analytical method ; information concerning the metabolites included, the method of storage, storage, stability, analysis date.
w/o Without
ptz: Prothioconazole
dfz: Difenoconazole
n.d. Not detectable
LOQ Limit of quantification
LOD Limit of detection

A 2.1.3.2 Barley (KCA 6.3.2)

Table A 12: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Barley, oat					
cGAP EU (EFSA, 2007)	2	0.2 kg as/ha	14-21 days	61	35
cGAP EU (Art. 12, EFSA, 2014)	2	0.2 kg as/ha	14-21 days	69	35
Intended cGAP (2)*	1	187.5 g as/ha	-	65	n/a

*Critical GAP number(s) in accordance with column 0 of Table 7.1-1.
n/a Not applicable. The pre-harvest interval for the envisaged area of application is covered by the growing period remaining between the envisaged application and harvest; it is not necessary to indicate a pre-harvest interval in days.

Note: The relied upon residue values are underlined in the following tables.

A 2.1.3.2.1 Barley study 1

Comments of zRMS:	The study of Amic, S., 2020d (Report No.: BPL19/764/GC) has been evaluated in Registration Report for ADM.03500.F.2.B on March 2023 by zRMS-PL and the summary is presented below. Four field trials were conducted in Northern Europe to determine the residue level of prothioconazole and its metabolites in specimens of barley whole plant without roots, grain and straw following one foliar application of ADM.3500.F.2.B (250 g a.s./L of prothioconazole) at the dose rate 0.8 L/ha (200 g a.s./ha of prothioconazole). Application was performed at BBCH 65 except for trial 03-FR (BBCH 69). Specimens of whole plant without roots were generated at ±0 DAA, 10 (±1) DAA, 20 (±2) DAA and 35 DAA for the two decline trials. Specimens of grain and straw were generated at harvest stage BBCH 89 from all the field trials performed. In seed specimens taken at normal commercial harvest (46-52 days) residues of prothioconazole (sum) and prothioconazole-desthio were <LOQ. The analytical method was validated for barley whole plant without roots, grain and straw according to guideline SANCO/3029/99 rev. 4. All the analytes were determined by LC-MS/MS using a quantitation and confirmation ion. The LOQ of each analyte was at 0.01 mg/kg for each matrix. The mean recovery was between 70% and 110% at each level of fortification, for each reference item and for each matrix. The storage duration (interval between sampling and extraction date) was 158 days for the determination of prothioconazole and its metabolites. Sufficient stability data are available to support the residue data presented in this study. The study is acceptable.

Reference:	KCA 6.3.2/01
Report:	Residue study of prothioconazole and its metabolites in barley whole plant and RAC after one foliar application of ADM.3500.F.2.B (250 g a.s./L of prothioconazole) - 2 harvest and 2 decline trials – Northern Europe (France, Hungary and Poland) – 2019 Amic, S., 2020d Report no.: BPL19/764/GC, sponsor no.: 000102753
Guideline(s):	EC guidance working document SANCO/7029/VI/95 rev. 5 (22/07/1997) OECD 509, adopted: 7 September 2009 Guidance document SANCO/3029/99 rev. 4 of 11/07/00

	OECD guidance document on pesticide residue analytical methods. Document ENV/JM/MONO(2007)17
Deviations:	None with impact on study results
GLP:	Yes
Acceptability:	Yes

and

Comments of zRMS:	The study of Yozgatli, H.P., 2021g (Report No.: S19-00735) has been evaluated in Registration Report for ADM.03500.F.2.B on March 2023 by zRMS-PL and the summary is presented below. Four field trials were conducted in Northern Europe to determine the residues of 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) in barley (whole plants without roots, grain and straw) following one foliar application of ADM.3500.F.2.B (250 g a.s./L of prothioconazole). The application had to be performed at crop growth stage BBCH 65 or 69. Grain and straw specimens were taken at BBCH growth stage 89, normal commercial harvest (NCH). Specimens of whole plant without roots were generated at ±0 DAA, 10 (±1) DAA, 20 (±2) DAA and 35 (±3) DAA for the two decline trials. <u>Results:</u> Residues of 1,2,4-T in grain were <LOQ. Residues of TLA in grain were <LOQ between and 0.01 mg/kg. Residues of TA in grain were between 0.12 and 0.29 mg/kg. Residues of TAA in grain were between 0.03 and 0.12 mg/kg. The analytical method GRM053.01A was validated for the determination of 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) in barley (whole plants without roots, grain and straw) according to SANCO/3029/99, rev.4. Three fortifications of untreated control samples at the level of LOQ (0.01 mg/kg) and three fortifications at the level of tenfold LOQ (0.1 mg/kg) were performed, representing a reduced validation data set. The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for each analyte and each matrix. The coefficients of determination (R^2) of linear regression of the calibration plots were ≥ 0.98. The accuracy and precision of the method during sample analysis were considered to be acceptable since single recoveries were in the range of 60 - 120% and the mean recoveries at each fortification level were in the range of 70 – 110% with relative standard deviation(s) below 20% for all combinations of matrices and analytes. The maximum storage interval from sampling to extraction was 667 days (above 22 months) for barley - whole plants without roots, 700 days (above 23 months) for grain and 513 (above 17 months) for straw. **It should be noted that the storage period exceeded the maximum storage stability for 1,2,4-T (whole plant, grain and straw).** For this reason, the obtained results cannot be used for evaluation and risk assessment.

Reference:	KCA 6.3.2/02
Report:	Determination of the residue of 1, 2, 4-Triazole (1, 2, 4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) in barley (RAC whole plant, grain and straw) following one foliar application of ADM.3500.F.2.B (250 g a.s./L of prothioconazole) in 4 trials (2 HS + 2 DCS) in Northern Europe (France, Hungary and Poland) 2019 Yozgatli, H.P., 2021g Study no.: S19-00735, sponsor no.: 000102785
Guideline(s):	EC Guideline SANCO/7029/VI/95 rev. 5

	Guidance document SANCO/3029/99 rev. 4 OECD ENV/JM/MONO(2007)17
Deviations:	None with impact on study results
GLP:	Yes
Acceptability:	Yes

Table A 13: Summary of barley study 1 - 4 trials

Crop residue data from supervised field trials		**Reference no.:**	**KCA 6.3.2/01**
Active ingredient (common name and content):	Prothioconazole, nominal 250 g/L (actual 248.2 g/L)	Commercial product (name/code):	ADM.3500.F.2.B
Crop/crop group:	Barley / Cereal	Formulation (e.g. SC):	EC
Country:	France, Poland, Hungary	Other active substance in the formulation:	None
Indoor/outdoor:	Outdoor	Residues calculated as:	**Prothioconazole as sum of prothioconazole-desthio, 3-hydroxyprothioconazole-desthio, 4-hydroxyprothioconazole-desthio, 5-hydroxyprothioconazole-desthio, 6-hydroxyprothioconazole-desthio and alpha-hydroxyprothioconazole-desthio, expressed as prothioconazole-desthio (mg/kg) (8.1, risk assessment residue definition);** **Prothioconazole-desthio (mg/kg) (8.2, enforcement residue definition)**
Responsible body for reporting (name, address):	BIOTEK Agriculture, Saint-Pouange, France		

1	2	3	4			5	6	7	8.1	8.2	9		10
Trial No./ Location/ EU zone/ Year	**Commodity/ Variety** (a)	**Date of 1.Sowing or planting 2.Flowering 3. Harvest** (b)	**Application rate per treatment**			**Dates of treatment or no. of treatments and last date** (d)	**Growth stage at last treatment or date**	**Portion analysed**	**Residues (mg/kg)**		**Assessment**		**Details on trial(s)** (f)
			kg a.s./ ha (c)	**Water (L/ha)**	**kg a.s./ hL**				**Prothio-conazole (sum)*** (g)	**Prothio-conazole-desthio** (h)	**Timing (BBCH)**	**DALA (days)** (e)	
BPL19/764/GC-01-FR 60490 Mareuil-Lamotte France N-EU 2019 (A)	Spring barley (HORVS)/ Planet	1. 19/02/19 2. 06/06/ - 21/06/19 3. 01/08/19	0.193	195	0.099	06/06/19	BBCH 65	Grain Straw	<LOQ (n.d.) 0.24	<LOQ 0.11	89 89	53 53	Analytical methods: Analogous to QuEChERS method, HPLC-MS/MS For method validation please refer to dRR Part B.5, point KCP 5.1.2.
BPL19/764/GC-02-HU 2141 Csömör Hungary N-EU 2019 (B)	Spring barley (HORVS) / Monique	1. 28/09/18 2. 07/05/- 20/05/19 3. 27/06/19-03/07/19	0.197	249	0.079	11/05/19	BBCH 65	Grain Straw	<LOQ (n.d.) 0.069	<LOQ (n.d.) 0.21	89 89	52 52	LOQ: 0.01 mg/kg for each analyte (except prothioconazole expressed as prothioconazole-desthio as a sum of the metabolites = 0.06 mg/kg)

1	2	3	4			5	6	7	8.1	8.2	9		10
Trial No./ Location/ EU zone/ Year	**Commodity/ Variety** (a)	**Date of 1.Sowing or planting 2.Flowering 3. Harvest** (b)	**Application rate per treatment**			**Dates of treatment or no. of treatments and last date** (d)	**Growth stage at last treatment or date**	**Portion analysed**	**Residues (mg/kg)**		**Assessment**		**Details on trial(s)** (f)
			kg a.s./ ha (c)	**Water (L/ha)**	**kg a.s./ hL**				**Prothio-conazole (sum)*** (g)	**Prothio-conazole-desthio** (h)	**Timing (BBCH)**	**DALA (days)** (e)	
BPL19/764/GC-03-FR 49320 Vauchrétien, France N-EU 2018/19 (C)	Winter barley (HORVW) / Etincel	1. 15/11/18 2. 06/05/-15/05/19 3. 03/07/19	0.196	247	0.079	13/05/19	BBCH 69	Whole plant w/o roots Whole plant w/o roots Whole plant w/o roots Whole plant w/o roots Grain Straw	0.63 0.31 0.087 0.062 <LOQ (n.d.) 0.37	0.63 0.31 0.077 0.031 <LOQ 0.15	69 71 77 85 89 89	0 10 22 35 50 50	LOD: 0.003 mg/kg for each analyte, 0.018 mg/kg for prothioconazole expressed as prothioconazole-desthio as a sum of the metabolites Max. sample storage time: 158 days (sampling to analytical completion); max. extract storage time (extraction to analysis) 1 day. Results in all untreated specimens were below LOD (n.d.).
BPL19/764/GC-04-PL 48-320 Skoroszyce, Poland N-EU 2018/19 (D)	Spring barley (HORVS) / KWS Dante	1. 23/03/19 2. 11/06/-15/06/19 3. 29/07/19	0.203	296	0.066	13/06/19	BBCH 65	Whole plant w/o roots Whole plant w/o roots Whole plant w/o roots Whole plant w/o roots Grain Straw	0.49 0.34 0.48 0.46 <LOQ (n.d.) 0.84	0.49 0.29 0.37 0.32 <LOQ 0.49	65 73-75 83-85 87-89 89 89	0 11 20 35 46 46	

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) These values are actual rate of active substance as they were calculated with the actual concentration of the active substance: (Dose rate target 200 g a.s./ha prothioconazole equivalent to ADM.3500.F.2B at 0.8 L/ha)
(d) Year must be indicated
(e) Days after last application not given in the study report. Calculated during dossier compilation.
(f) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
(g) Prothioconazole (mg/kg) as sum of prothioconazole-desthio, 3-hydroxyprothioconazole-desthio, 4-hydroxyprothioconazole-desthio, 5-hydroxyprothioconazole-desthio, 6-hydroxyprothioconazole-desthio and alpha-hydroxyprothioconazole-desthio, expressed as prothioconazole-desthio (8.1, acc. to risk assessment residue definition). For the sum of prothioconazole-desthio, the calculations were performed with value of 0.01 mg/kg for results <LOQ and as zero for results <LOQ (nd).
(h) Prothioconazole-desthio (sum of isomers) (8.2, enforcement residue definition)
n.d. = not detectable

LOQ Limit of quantification,
LOD Limit of detection
* Residues were derived using methods based on QuEChERS method EN 15662:2009- (in contrast to other results derived using methods based on 02RAR method 00979/M001, LC-MS/MS), and therefore not underlined

Table A 14: Summary of barley study 1 - 4 trials (TDMs)

Crop residue data from supervised field trials		**Reference no.:**	**KCA 6.3.2/02**
Active ingredient (common name and content):	Prothioconazole, 248.2 g/L (actual)	Commercial product (name/code):	ADM.3500.F.2.B
Crop/crop group:	Barley / Cereals	Formulation (e.g. SC):	EC
Country:	France (N-EU), Hungary, Poland	Other active substance in the formulation:	None
Indoor/outdoor:	Outdoor	Residues calculated as:	**1,2,4-Triazole, Triazole alanine, Triazole acetic acid, Triazole lactic acid (mg/kg)**
Responsible body for reporting (name, address):	Eurofins Agroscience Services Chem GmbH, Hamburg, Germany		

1	2	3	4			5	6	7	8.1	8.2	8.3	8.4	9		10
Trial No./ Location/ EU zone/ Year	**Commodity/ Variety**	**Date of 1.Sowing or planting 2.Flowering 3. Harvest**	**Application rate per treatment**			**Dates of treatment or no. of treatments and last date**	**Growth stage at last treatment or date**	**Portion analysed**	**Residues (mg/kg)**				**Assessment**		**Details on trial(s)**
			kg a.s./ ha	**Water (L/ha)**	**kg a.s./ hL**				**1,2,4-triazole**	**Triazole alanine**	**Triazole acetic acid**	**Triazole lactic acid**	**Timing (BBCH)**	**DALA (days)**	
	(a)	(b)	(c)			(d)	(e)	(a)						(f)	(g)
BPL19/764/GC-01-FR 60490 Mareuil-la-Motte France N-EU 2019 (A)	Spring barley (HORVS)/ Planet	1. 19/02/19 2. 06/06/ - 21/06/19 3. 01/08/19	0.193	195	0.099	06/06/19	BBCH 65	Grain	*<LOQ*	0.12	0.07	<LOQ	89	53	Analytical methods: Syngenta GRM053.01A, LC-DMS-MS/MS detection. For method validation please refer to dRR Part B.5, point KCP 5.1.2. LOQ: 0.01 mg/kg with LOD: 0.003 mg/kg (for each analyte and each matrix) Max. sample storage time: 667 days for whole plant w/o roots, 700 days for
								Straw	*<LOQ*	<LOQ (n.d.)	0.02	0.05	89	53	
			Untreated					Grain	*<LOQ (n.d.)*	0.05	0.05	<LOQ (n.d.)	89	53	
								Straw	*<LOQ (n.d.)*	<LOQ (n.d.)	0.02	0.03	89	53	
BPL19/764/GC-02-HU 2141 Csömör Hungary N-EU 2018/19 (B)	Spring barley (HORVS)/ Monique	1. 28/09/18 2. 07/05/ - 20/05/19 3. 27/06/ - 03/07/19	0.197	249	0.079	11/05/19	BBCH 65	Grain	*<LOQ*	0.19	0.04	<LOQ	89	52	
								Straw	*<LOQ*	0.01	0.02	0.03	89	52	

1	2	3	4			5	6	7	8.1	8.2	8.3	8.4	9		10
Trial No./ Location/ EU zone/ Year	**Commodity/ Variety** (a)	**Date of 1.Sowing or planting 2.Flowering 3. Harvest** (b)	**Application rate per treatment**			**Dates of treatment or no. of treatments and last date** (d)	**Growth stage at last treatment or date** (e)	**Portion analysed** (a)	**Residues (mg/kg)**				**Assessment**		**Details on trial(s)** (g)
			kg a.s./ ha (c)	**Water (L/ha)**	**kg a.s./ hL**				**1,2,4-triazole**	**Triazole alanine**	**Triazole acetic acid**	**Triazole lactic acid**	**Timing (BBCH)**	**DALA (days)** (f)	
			Untreated					Grain	*<LOQ (n.d.)*	0.04	0.01	<LOQ (n.d.)	89	52	grain and 513 days for straw (sampling to extraction), max. extract storage time (extraction to analysis) 1 day for whole plant w/o roots, 14 days for straw and 16 days for grain. Possible instability of the analytes in final sample extracts was automatically levelled out when using the response ratio of analyte to internal standard for quantification. Residues in untreated samples (background levels) were found in a part of samples, and results are given.
								Straw	*<LOQ (n.d.)*	<LOQ (n.d.)	<LOQ	<LOQ	89	52	
BPL19/764/GC-03-FR 49320 Vauchrétien France N-EU 2018/19 (C)	Winter barley (HORVW)/ Etincel	1. 15/11/18 2. 06/05/ - 15/05/19 3. from 03/07/19	0.196	247	0.079	13/05/19	BBCH 69	Whole plant w/o roots	*<LOQ*	0.01	<LOQ	0.02	69	0	
								Whole plant w/o roots	*<LOQ*	0.01	<LOQ	<LOQ	71	10	
								Whole plant w/o roots	*<LOQ (n.d.)*	0.02	<LOQ	0.01	77	22	
								Whole plant w/o roots	*<LOQ (n.d.)*	0.03	<LOQ	<LOQ	85	35	
								Grain	*<LOQ (n.d.)*	0.13	0.03	<LOQ	89	50	
								Straw	*<LOQ (n.d.)*	<LOQ	0.02	0.02	89	50	
			Untreated					Whole plant w/o roots	*<LOQ (n.d.)*	0.01	<LOQ	0.02	69	0	
								Whole plant w/o roots	*<LOQ*	0.02	<LOQ	0.01	77	22	
								Grain	*<LOQ (n.d.)*	0.04	0.01	<LOQ (n.d.)	89	50	
								Straw	*<LOQ*	<LOQ (n.d.)	0.01	0.01	89	50	

1	2	3	4			5	6	7	8.1	8.2	8.3	8.4	9		10
Trial No./ Location/ EU zone/ Year	**Commodity/ Variety** (a)	**Date of 1.Sowing or planting 2.Flowering 3. Harvest** (b)	**Application rate per treatment**			**Dates of treatment or no. of treatments and last date** (d)	**Growth stage at last treatment or date** (e)	**Portion analysed** (a)	**Residues (mg/kg)**				**Assessment**		**Details on trial(s)** (g)
			kg a.s./ ha (c)	**Water (L/ha)**	**kg a.s./ hL**				**1,2,4-triazole**	**Triazole alanine**	**Triazole acetic acid**	**Triazole lactic acid**	**Timing (BBCH)**	**DALA (days)** (f)	
BPL19/764/GC-04-PL 48-320 Skoroszyce Poland N-EU 2019 (D)	Spring barley (HORVS)/KWS Dante	1. 23/03/19 2. 11/06/ - 15/06/19 3. 29/07/19	0.203	308	0.066	13/06/19	BBCH 65	Whole plant w/o roots	*<LOQ (n.d.)*	0.03	0.02	0.07	65	0	
								Whole plant w/o roots	*<LOQ (n.d.)*	0.09	0.06	0.12	73-75	11	
								Whole plant w/o roots	*<LOQ*	0.11	0.10	0.14	83-85	20	
								Whole plant w/o roots	*<LOQ (n.d.)*	0.09	0.11	0.12	87-89	35	
								Grain	*<LOQ*	0.29	0.12	<LOQ	89	46	
								Straw	*0.02*	0.02	0..12	0.26	89	46	
			Untreated					Whole plant w/o roots	*<LOQ*	0.04	0.04	0.14	65	0	
								Whole plant w/o roots	*<LOQ (n.d.)*	0.02	0.06	0.10	83-85	20	
								Grain	*<LOQ*	0.22	0.21	0.01	89	46	
								Straw	*<LOQ*	<LOQ	0.11	0.31	89	46	

(a) According to Codex Classification / Guide
(b) Only if relevant
(c) These values are actual rate of active substance as they were calculated with the actual concentration of the active substance:
(Dose rate target 200 g a.s./ha prothioconazole equivalent to ADM.3500.F.2B at 0.8 L/ha)
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4.
(f) Minimum number of days after last application.
(g) Remarks may include: climatic conditions ; reference to analytical method ; information concerning the metabolites included, the method of storage, storage, stability, analysis date.
w/o Without
n.d. Not detectable
LOQ Limit of quantification
LOD Limit of detection
Data in *italics* reported but outside acceptable storage stability

A 2.1.3.2.2 Barley study 2

Comments of zRMS:	The study of Huaulmé, J.-M., 2021a (Report No.: BPL20/844/GC) has been evaluated in Registration Report for ADM.03500.F.2.B on March 2023 by zRMS-PL and the summary is presented below. Four field trials were conducted in Northern Europe to determine the residue level of prothioconazole and its metabolites, and of fenpropidin in specimens of barley whole plant without roots, grain and straw following one foliar application of ADM.3502.F.1.A (175 g a.s./L of prothioconazole and 250 g a.s./L of fenpropidin) at the dose rate 1 L/ha. Application was performed at BBCH 65. Specimens of whole plant without roots were generated at ±0 DAA, 9 DAA, 20 DAA and 33 to 35 DAA for the two decline trials. Specimens of grain and straw were generated at harvest stage BBCH 89 from all the field trials performed. In the barley specimens, the residue level of prothioconazole (expressed as sum of prothioconazole-desthio) ranged from: - 0.069 and 0.43 mg/kg in whole plant, **- <LOQ (nd) and 0.062 mg/kg in grain,** - 0.11 and 1.3 mg/kg in straw. Analytical method: Study code: S13-05182, QuEChERS method, LC-MS/MS The analytical method was validated for barley whole plant without roots, grain and straw according to guideline SANCO/3029/99 rev. 4 (reduced validation). LOQ: 0.01 mg/kg for each analyte, 0.06 mg/kg for prothioconazole expressed as prothioconazole-desthio as a sum of metabolites. The mean recovery was between 70% and 110% at each level of fortification, for each reference item and for each matrix. The storage duration (interval between sampling and extraction date) was 70 days for the determination of prothioconazole and its metabolites. Sufficient stability data are available to support the residue data presented in this study. The study is acceptable.

Reference:	KCA 6.3.2/03
Report:	Residue study of Prothioconazole and its metabolites, and Fenpropidin in barley whole plant and Raw Agricultural Commodity after one foliar application of ADM.3502.F.1.A (175 g a.s./L of prothioconazole and 250 g a.s./L of fenpropidin) - 2 harvest and 2 decline trials – Northern Europe (FR, PL, HU) - 2020 Huaulmé, J.-M., 2021a Report no.: BPL20/844/GC, sponsor no.: 000105350
Guideline(s):	EC guidance working document SANCO/7029/VI/95 rev. 5 (22/07/1997) OECD 509, adopted 7 September 2009 ENV-JM-MONO(2011)50-REV1., 07-Sep-2016 Guidance document SANCO/3029/99 rev. 4 of 11/07/00 OECD guidance document on pesticide residue analytical methods. Document ENV/JM/MONO(2007)17
Deviations:	None with impact on study results
GLP:	Yes
Acceptability:	Yes

and

Comments of zRMS:	The study of Yozgatli, H.P., 2021h (Report No.: S20-01302) has been evaluated in Registration Report for ADM.03500.F.2.B on March 2023 by zRMS-PL and the summary is presented below. Four field trials were conducted in Northern Europe to determine the residues of 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) in barley (whole plants without roots, grain and straw) following one foliar application of ADM.3502.F.1.A (175 g a.s./L of prothioconazole and 250 g a.s./L of fenpropidin). The application had to be performed at crop growth stage BBCH 65. Grain and straw specimens were taken at BBCH growth stage 89, normal commercial harvest (NCH). Specimens of whole plant without roots were generated at ±0 DAA, 10 (±1) DAA, 20 (±2) DAA and 35 (±3) DAA for the two decline trials. <u>Results:</u> Residues of 1,2,4-T and TLA in grain were <LOQ. Residues of TA in grain were between 0.05 and 0.15 mg/kg. Residues of TAA in grain were between 0.02 and 0.04 mg/kg. The analytical method GRM053.01A was successfully validated for the determination of 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) in barley (whole plants without roots, grain and straw) with an LOQ of 0.01 mg/kg and up to 0.1 mg/kg according to SANCO/3029/99, rev.4. With regard to selectivity, accuracy and precision, the analytical method was applied successfully for each analytical set when analysing the samples of the study. The maximum storage interval from sampling to extraction was 153 days (above 5 months) for barley - whole plants without roots, 103 days (above 3 months) for grain and for straw. Sufficient stability data are available to support the residue data presented in this study. The study is acceptable.

Reference:	KCA 6.3.2/04
Report:	Determination of the residue of 1, 2, 4-Triazole (1, 2, 4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) in barley (RAC whole plant, grain and straw) following one foliar application of ADM.3502.F.1.A (175g a.s./L of prothioconazole and 250 g/L fenpropidin) in 4 trials (2 HS + 2 DCS) in Northern Europe (France, Poland and Hungary), 2020 Yozgatli, H.P., 2021h Study no.: S20-01302, sponsor no.: 000105545
Guideline(s):	EC Guideline SANCO/7029/VI/95 rev. 5 Guidance document SANCO/3029/99 rev. 4 OECD ENV/JM/MONO(2007)17
Deviations:	None with impact on study results
GLP:	Yes
Acceptability:	Yes

Comments of zRMS:	The study of Barbier, G., 2022 (Report No.: B21G-A4-P-05) has been evaluated in Registration Report for ADM.03500.F.2.B on March 2023 by zRMS-PL and the summary is presented below. The objective of this study was to determine residues of prothioconazole (sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazoledesthio (sum of isomers)) residues in barley (grain, straw) after one foliar application of ADM.3502.F.1.A (175 g a.s./L of prothioconazole and 250 g a.s./L of fenpropidin) in 2 harvest and 2 decline trials in Northern Europe obtained during the study referenced BPL20/844/GC – ADAMA Sponsor code 000105350 (see KCA 6.3.2/09).

	The analytical method has been demonstrated to be a reliable and accurate procedure for the determination of prothioconazole (sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers)) in barley (grain, straw). The method complies with the Guideline SANTE/2020/12830, Rev.1 of 24/02/2021. LOQ (Limit of quantification): 0.060 mg/kg expressed as prothioconazole-desthio. In the barley specimens, the residue level of prothioconazole (expressed as sum of prothioconazoledesthio) ranged from: - <LOQ in grain, - 0.14 and 1.3 mg/kg in straw. In the barley specimens, the residue level of prothioconazole-desthio ranged from: - <LOQ and 0.026 mg/kg in grain, - 0.056 and 0.91 mg/kg in straw. The storage duration (interval between sampling and extraction date) was 504 days for the determination of prothioconazole and its metabolites. Sufficient stability data are available to support the residue data presented in this study. The study is acceptable.

Reference:	KCA 6.3.2/05
Report:	Analysis of prothioconazole and its metabolites in barley after application of ADM.3502.F.1.A (prothioconazole and fenpropidin) in trial in Northern - 2020 Barbier, G., 2022 Study no.: B21G-A4-P-05, sponsor no.: 000108763
Guideline(s):	SANTE/2020/12830, Rev.1 of 24/02/2021 OECD ENV/JM/MONO(2007)17
Deviations:	None with impact on study results
GLP:	Yes
Acceptability:	Yes

Table A 15: Summary of the barley study 2 - 4 trials (*including second analysis using another method to account for potential conjugated metabolites*)

Crop residue data from supervised field trials		**Reference no.:**	**KCA 6.3.2/03 *& /05***
Active ingredient (common name and content):	Prothioconazole, nominal 175 g/L (actual 175.9 g/L)	Commercial product (name/code):	ADM.3502.F.1.A
Crop/crop group:	Barley / Cereals	Formulation (e.g. SC):	EC
Country:	France, Poland, Hungary	Other active substance in the formulation:	Fenpropidin, nominal 250 g/L (actual 253.7 g/L)
Indoor/outdoor:	Outdoor	Residues calculated as:	**Prothioconazole as sum of prothioconazole-desthio, 3-hydroxyprothioconazole-desthio, 4-hydroxyprothioconazole-desthio, 5-hydroxyprothioconazoledesthio, 6-hydroxyprothioconazole-desthio and alpha-hydroxyprothioconazole-desthio, expressed as prothioconazole-desthio (mg/kg) (8.1, risk assessment residue definition);** **Prothioconazole-desthio (mg/kg) (8.2, enforcement residue definition)**
Responsible body for reporting (name, address):	BIOTEK Agriculture, Saint-Pouange, France		

1	**2**	**3**	**4**			**5**	**6**	**7**	**8.1**						**8.2**	**9**		**10**
			Application rate per treatment						**Residues (mg/kg)[1]**							**Assessment**		
Trial No./ Location/ EU zone/ Year	**Commodity/ Variety** (a)	**Date of 1.Sowing or planting 2.Flowering 3. Harvest** (b)	**kg a.s./ ha** (c)	**Water (L/ha)**	**kg a.s./ hL**	**Dates of treatment or no. of treatments and last date** (d)	**Growth stage at last treatment or date**	**Portion analysed**	**Prothio-conazole (sum)[2]** (g)	**3-OH**	**4-OH**	**5-OH**	**6-OH**	**α-OH**	**Prothio-conazole-desthio** (h)	**Timing (BBCH)**	**DALA (days)** (e)	**Details on trial(s)** (f)
BPL20/844/GC-01-FR 71 570 La Chapelle de Guinchay, France N-EU 2020	Spring barley (HORVS)/ RGT Planet	1. 23/03/20 2. 22/-29/06/20 3. 15/-31/07/20	0.174	199	0.087	25/06/20	BBCH 65	Grain	<LOQ	*<LOQ*	*<LOD*	*<LOD*	*<LOD*	*<LOD*	0.033** *0.026* **Mean: 0.030**	89	29	Analytical methods: Study code: S13-05182, QuEChERS method, LC-MS/MS. For method validation please refer to dRR Part B.5, point KCP
								Straw	*1.3*	*0.15*	*0.061*	*0.036*	*<LOQ*	*0.14*	0.93** *0.91* **Mean: 0.092**	89	29	

1	2	3	4			5	6	7	8.1						8.2	9		10
Trial No./ Location/ EU zone/ Year	**Commodity/ Variety**	**Date of 1.Sowing or planting 2.Flowering 3. Harvest**	**Application rate per treatment**			**Dates of treatment or no. of treatments and last date**	**Growth stage at last treatment or date**	**Portion analysed**	**Residues (mg/kg)[1]**							**Assessment**		**Details on trial(s)**
			kg a.s./ ha	**Water (L/ha)**	**kg a.s./ hL**				**Prothio-conazole (sum)[2]**	**3-OH**	**4-OH**	**5-OH**	**6-OH**	**α-OH**	**Prothio-conazole-desthio**	**Timing (BBCH)**	**DALA (days)**	
(a)		(b)	(c)			(d)			(g)						(h)		(e)	(f)
BPL20/844/GC-02-PL 98-300 Masłowice, Wieluń Poland N-EU 2019	Spring barley (HORVS)/ KWS Dante	1. 30/03/20 2. 08/-18/06/20 3. 10/08/20	0.170	290	0.059	13/06/20	BBCH 65	Grain Straw	<u>*<LOD*</u> <u>*0.14*</u>	*<LOD* *0.034*	*<LOD* *0.021*	*<LOD* *0.014*	*<LOD* *<LOD*	*<LOD* *<LOQ*	<LOQ (nd) *<LOD* **<u>Mean: <LOQ</u>** 0.041 *0.056* **Mean: <u>0.049</u>**	89 89	58 58	5.1.2. LOQ: 0.01 mg/kg for each analyte, 0.06 mg/kg for prothioconazole expressed as prothioconazole-desthio as a sum of

1	2	3	4			5	6	7	8.1						8.2	9		10
Trial No./ Location/ EU zone/ Year	**Commodity/ Variety** (a)	**Date of 1.Sowing or planting 2.Flowering 3. Harvest** (b)	**Application rate per treatment**			**Dates of treatment or no. of treatments and last date** (d)	**Growth stage at last treatment or date**	**Portion analysed**	**Residues (mg/kg)**[1]							**Assessment**		**Details on trial(s)** (f)
			kg a.s./ ha (c)	**Water (L/ha)**	**kg a.s./ hL**				**Prothio-conazole (sum)**[2] (g)	**3-OH**	**4-OH**	**5-OH**	**6-OH**	**α-OH**	**Prothio-conazole-desthio** (h)	**Timing (BBCH)**	**DALA (days)** (e)	
BPL20/844/GC-03-HU 2141 Csömör Hungary N-EU 2019/20	Winter barley (HORVW)/ Monique	1. 28/09/19 2. 03/-13/05/20 3. 02/-06/07/20	0.175	248	0.070	13/05/20	BBCH 65	Whole plant w/o roots	0.43						0.43	65	0	metabolites; LOD: 0.003 mg/kg for each analyte, 0.018 mg/kg for prothioconazole expressed as prothioconazole-desthio as a sum of metabolites. Max. sample storage time: 70 days and 504 days (sampling to extraction), max. extract storage time (extraction to
								Whole plant w/o roots	0.43						0.42	71	9	
								Whole plant w/o roots	0.30						0.27	75	20	
								Whole plant w/o roots	0.11						0.048	83	35	
								Grain	*<LOD*	*<LOD*	*<LOD*	*<LOD*	*<LOD*	*<LOD*	<LOQ (nd) *<LOQ* **Mean: <LOQ**	89	50	
								Straw	*0.33*	*0.077*	*0.071*	*0.042*	*<LOQ*	*0.014*	0.12 *0.12* **Mean: 0.12**	89	50	

1	2	3	4			5	6	7	8.1						8.2	9		10
Trial No./ Location/ EU zone/ Year	**Commodity/ Variety** (a)	**Date of 1.Sowing or planting 2.Flowering 3. Harvest** (b)	**Application rate per treatment**			**Dates of treatment or no. of treatments and last date** (d)	**Growth stage at last treatment or date**	**Portion analysed**	**Residues (mg/kg)[1]**							**Assessment**		**Details on trial(s)** (f)
			kg a.s./ ha (c)	**Water (L/ha)**	**kg a.s./ hL**				**Prothio-conazole (sum)[2]** (g)	**3-OH**	**4-OH**	**5-OH**	**6-OH**	**α-OH**	**Prothio-conazole-desthio** (h)	**Timing (BBCH)**	**DALA (days)** (e)	
BPL20/844/GC-04-PL 55-110 Krościna Mała Poland N-EU 2020	Spring barley (HORVS)/ Harris	1. 23/03/20 2. 07/-18/06/20 3. 11/08/20	0.179	305	0.059	10/06/20	BBCH 65	Whole plant w/o roots	0.37						0.37	65	0	analysis) 2 days. Extract stability tested during the studies. Results in all untreated specimens were below LOD. **Mean of two extractions.
								Whole plant w/o roots	0.42						0.39	69	9	
								Whole plant w/o roots	0.11						0.076	71	20	
								Whole plant w/o roots	0.069						0.027	83	33	
								Grain	*<LOD*	*<LOD*	*<LOD*	*<LOD*	*<LOD*	*<LOD*	<LOQ (nd) *<LOQ* **Mean: <LOQ**	89	62	
								Straw	*0.19*	*0.036*	*0.021*	*0.018*	*<LOD*	*0.013*	0.084 *0.10* **Mean: 0.092**	89	62	

[1] *Results in italics originate from second analysis (study KCA 6.3.2/13) including a deconjugation step to account for potential conjugated metabolites.*
[2] Sum calculated during dossier compilation to include new results from study KCA 6.3.2/13 as well as mean of results for PTZ-Desthio from both studies. For PTZ-Desthio analysis in the new study is technically a replicate analysis even though 2 different methods have been used, as in both only free PTZ-desthio is measured. Therefore, the results for PTZ-Desthio from both methods are considered equivalent and the mean is presented.
(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) These values are actual rate of active substance(s) as they were calculated with the actual concentration of the active substance(s).
(d) Year must be indicated
(e) Days after last application not given in the study report. Calculated during dossier compilation.
(f) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

(g) Prothioconazole (mg/kg) as sum of prothioconazole-desthio, 3-hydroxyprothioconazole-desthio, 4-hydroxyprothioconazole-desthio, 5-hydroxyprothioconazole-desthio, 6-hydroxyprothioconazole-desthio and alpha-hydroxyprothioconazole-desthio, expressed as prothioconazole-desthio (8.1, acc. to risk assessment residue definition). For the sum of prothioconazole-desthio, the calculations were performed with value of 0.01 mg/kg for results <LOQ and as zero for results <LOQ (nd).
(h) Prothioconazole-desthio (sum of isomers) (8.2, enforcement residue definition)
nd not detectable
LOQ Limit of quantification
LOD Limit of detection

Table A 16: Summary of the barley study 2 - 4 trials (TDMs)

Crop residue data from supervised field trials		**Reference no.:**	**KCA 6.3.2/04**
Active ingredient (common name and content):	Prothioconazole, 175.9 g/L (actual)	Commercial product (name/code):	ADM.03502.F.1.B
Crop/crop group:	Barley / Cereals	Formulation (e.g. SC):	EC
Country:	France (N-EU), Poland, Hungary	Other active substance in the formulation:	Fenpropidin, 253.7 g/L (actual)
Indoor/outdoor:	Outdoor	Residues calculated as:	**1,2,4-Triazole, Triazole alanine, Triazole acetic acid, Triazole lactic acid (mg/kg)**
Responsible body for reporting (name, address):	Eurofins Agroscience Services Chem GmbH, Hamburg, Germany		

1	2	3	4			5	6	7	8.1	8.2	8.3	8.4	9		10
			Application rate per treatment						**Residues (mg/kg)**				**Assessment**		
Trial No./ Location/ EU zone/ Year	**Commodity/ Variety** (a)	**Date of 1.Sowing or planting 2.Flowering 3. Harvest** (b)	**kg a.s./ ha** (c)	**Water (L/ha)**	**kg a.s./ hL**	**Dates of treatment or no. of treatments and last date** (d)	**Growth stage at last treatment or date** (e)	**Portion analysed** (a)	**1,2,4-triazole**	**Triazole alanine**	**Triazole acetic acid**	**Triazole lactic acid**	**Timing (BBCH)**	**DALA (days)** (f)	**Details on trial(s)** (g)
BPL20/844/GC-01-FR 71570 La Chapelle de Guinchay France N-EU 2020	Spring barley (HORVS)/ RGT Planet	1. 23/03/20 2. 22 - 29/06/20 3. 15-31/07/20	ptz: 0.174 fnp: 0.251	199	ptz: 0.087 fnp: 0.126	25/06/20	BBCH 65	Grain	<LOQ (n.d.)	0.13	0.04	<LOQ (n.d.)	89	29	Analytical methods: Syngenta GRM053.01A, LC-DMS-MS/MS detection. For method validation please refer to dRR Part B.5, point KCP 5.1.2. LOQ: 0.01 mg/kg with LOD: 0.003 mg/kg (for each analyte and each matrix) Max. sample storage time: 153 days for whole plant w/o roots,
								Straw	<LOQ	0.01	0.02	0.03	89	29	
			Untreated					Grain	<LOQ (n.d.)	0.18	0.10	<LOQ (n.d.)	89	29	
								Straw	<LOQ (n.d.)	<LOQ	0.03	0.04	89	29	
BPL20/844/GC-02-PL 98-300 Maslowice Poland N-EU 2020	Spring barley (HORVS)/KWS Dante	1. 20/03/20 2. 08 - 18/06/20 3. 10/08/20	ptz: 0.170 fnp: 0.245	290	ptz: 0.059 fnp: 0.085	13/06/20	BBCH 65	Grain	<LOQ (n.d.)	0.15	0.04	<LOQ (n.d.)	89	58	
								Straw	<LOQ (n.d.)	<LOQ	<LOQ	<LOQ	89	58	

1	2	3	4			5	6	7	8.1	8.2	8.3	8.4	9		10
Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (d)	Growth stage at last treatment or date (e)	Portion analysed (a)	Residues (mg/kg)				Assessment		Details on trial(s) (g)
			kg a.s./ ha (c)	Water (L/ha)	kg a.s./ hL				1,2,4-triazole	Triazole alanine	Triazole acetic acid	Triazole lactic acid	Timing (BBCH)	DALA (days) (f)	
			Untreated					Grain	<LOQ (n.d.)	0.06	0.02	<LOQ (n.d.)	89	58	103 days for grain and straw (sampling to extraction), max. extract storage time (extraction to analysis) 0 days for whole plant w/o roots and grain and 23 days for straw. Possible instability of the analytes in final sample extracts was automatically levelled out when using the response ratio of analyte to internal standard for quantification. Residues in untreated samples (background levels) were found in a part of samples, and results are given.
								Straw	<LOQ (n.d.)	<LOQ	<LOQ	<LOQ	89	58	
BPL20/844/GC-03-HU 202141 Csömör Hungary N-EU 2019/20	Winter barley (HORVW)/Monique	1. 28/09/19 2. 03 - 13/05/20 3. 02 - 06/07/20	ptz: 0.175 fnp: 0.252	248	ptz: 0.070 fnp: 0.101	13/05/20	BBCH 65	Whole plant w/o roots	<LOQ (n.d.)	0.02	0.01	<LOQ	65	0	
								Whole plant w/o roots	<LOQ (n.d.)	0.02	0.01	<LOQ	71	9	
								Whole plant w/o roots	<LOQ (n.d.)	0.02	<LOQ	<LOQ	73	20	
								Whole plant w/o roots	<LOQ (n.d.)	0.02	0.01	<LOQ (n.d.)	83	35	
								Grain	<LOQ (n.d.)	0.05	0.02	<LOQ (n.d.)	89	50	
								Straw	<LOQ	0.02	0.02	0.03	89	50	
			Untreated					Whole plant w/o roots	<LOQ (n.d.)	<LOQ	<LOQ (n.d.)	<LOQ (n.d.)	65	0	
								Whole plant w/o roots	<LOQ (n.d.)	<LOQ	<LOQ	<LOQ (n.d.)	73	20	
								Grain	<LOQ (n.d.)	<LOQ	<LOQ	<LOQ (n.d.)	89	50	
								Straw	<LOQ (n.d.)	<LOQ (n.d.)	<LOQ (n.d.)	<LOQ (n.d.)	89	50	

1	2	3	4			5	6	7	8.1	8.2	8.3	8.4	9		10
Trial No./ Location/ EU zone/ Year	**Commodity/ Variety**	**Date of 1.Sowing or planting 2.Flowering 3. Harvest**	**Application rate per treatment**			**Dates of treatment or no. of treatments and last date**	**Growth stage at last treatment or date**	**Portion analysed**	**Residues (mg/kg)**				**Assessment**		**Details on trial(s)**
			kg a.s./ ha	**Water (L/ha)**	**kg a.s./ hL**				**1,2,4-triazole**	**Triazole alanine**	**Triazole acetic acid**	**Triazole lactic acid**	**Timing (BBCH)**	**DALA (days)**	
	(a)	(b)	(c)			(d)	(e)	(a)						(f)	(g)
BPL20/844/GC-04-PL 55-110 Krościna Mała Poland N-EU 2020	Spring barley (HORVS) Harris	1. 23/03/20 2. 07 - 18/06/20 3. 11/08/20	ptz: 0.179 fnp: 0.258	305	ptz: 0.059 fnp: 0.085	10/06/20	BBCH 65	Whole plant w/o roots	<LOQ (n.d.)	0.01	<LOQ	0.02	65	0	
								Whole plant w/o roots	<LOQ (n.d.)	0.02	<LOQ	0.01	69	9	
								Whole plant w/o roots	<LOQ (n.d.)	0.04	0.02	0.02	71	20	
								Whole plant w/o roots	<LOQ (n.d.)	0.04	0.03	0.04	83	33	
								Grain	<LOQ (n.d.)	0.12	0.04	<LOQ (n.d.)	89	62	
								Straw	<LOQ (n.d.)	<LOQ	0.01	0.01	89	62	
			Untreated					Whole plant w/o roots	<LOQ (n.d.)	<LOQ	<LOQ	0.01	65	0	
								Whole plant w/o roots	<LOQ (n.d.)	0.01	0.02	0.01	71	20	
								Grain	<LOQ (n.d.)	0.05	0.04	<LOQ (n.d.)	89	62	
								Straw	<LOQ (n.d.)	<LOQ (n.d.)	<LOQ	<LOQ	89	62	

(a) According to Codex classification / Guide
(b) Only if relevant
(c) These values are actual rate of active substance as they were calculated with the actual concentration of the active substance:
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4.
(f) Minimum number of days after last application.
(g) Remarks may include: climatic conditions ; reference to analytical method ; information concerning the metabolites included, the method of storage, storage, stability, analysis date.
w/o Without
ptz: Prothioconazole
fnp: Fenpropidin
n.d. Not detectable
LOQ Limit of quantification
LOD Limit of detection

A 2.1.3.2.3 Barley study 3

Comments of zRMS:	The study of Huaulmé, J.-M., 2022a (Report No.: BPL21/962/GC) has been evaluated in Registration Report for ADM.03500.F.2.B on March 2023 by zRMS-PL and the summary is presented below. Six field trials were conducted in Northern Europe to determine the residue level of prothioconazole and fluxapyroxad and their respective metabolites in specimens of barley grain and straw following one foliar application of ADM.03503.F.1.A (150 g/L of Prothioconazole and 75 g/L of Fluxapyroxad). The target dose rate of test item ADM.03503.F.1.A was 1.25 L/ha (187.5 g/ha of Prothioconazole and 93.75 g/ha of Fluxapyroxad). Application was performed at BBCH 65. Specimens of grain and straw were generated at harvest stage BBCH 89 from all the field trials performed. The analytical method for determination of prothioconazole and metabolites based on the method 00979/M001 was validated for barley grain and straw according to guideline SANTE/2020/12830, Rev.1. For the triazole metabolites 1,2,4-triazole, triazole alanine, triazole acetic acid and triazole lactic acid, sample extraction and determination of residues were performed according to the analytical method GRM053.01A. All the analytes were determined by LC-MS/MS using a quantitation and confirmation ion. The LOQ of each analyte was at 0.01 mg/kg for each matrix, 0.06 mg/kg for prothioconazole expressed as prothioconazole-desthio as a sum of metabolites. The mean recovery was between 70% and 110% at each level of fortification, for each reference item and for each matrix. The storage duration (interval between sampling and extraction date) was 115 days for the determination of prothioconazole and its metabolites and 114 days for TDMs. Sufficient stability data are available to support the residue data presented in this study. In the treated barley specimens, the residue levels of prothioconazole-desthio and its metabolites ranged from: For prothioconazole-desthio: - <LOQ (nd) and 0.061 mg/kg in grain, - 0.041 and 1.7 mg/kg in straw. For 3-hydroxy-prothioconazole-desthio, - LOQ (nd) and 0.014 in grain, - <LOQ and 0.25 mg/kg in straw. For 4-hydroxy-prothioconazole-desthio: - All results are <LOQ in grain, - <LOQ (nd) and 0.21 mg/kg in straw. For 5-hydroxy-prothioconazole-desthio: - All results are <LOQ in grain, - <LOQ (nd) and 0.089 mg/kg in straw. For 6-hydroxy-prothioconazole-desthio: - All results are <LOQ in grain, - <LOQ (nd) and 0.012 mg/kg in straw. For Alpha-hydroxy-prothioconazole-desthio: - All results are <LOQ in grain, - <LOQ and 0.17 mg/kg in straw. For 1,2,4-Triazole, all results were <LOQ in grain and straw specimens, For Triazole alanine: - 0.04 and 0.14 mg/kg in grain, - <LOQ (nd) and 0.02 mg/kg in straw, For Triazole acetic acid: - 0.02 and 0.13 mg/kg in grain, - <LOQ and 0.04 mg/kg in straw, For Triazole lactic acid:

	- <LOQ (nd) and 0.02 mg/kg in grain, - <LOQ and 0.19 mg/kg in straw. The study is acceptable.

Reference:	KCA 6.3.2/06
Report:	Residue study of fluxapyroxad and prothioconazole and their metabolites in barley Raw Agricultural Commodities after application of ADM.03503.F.1.A under field conditions –Northern Europe - 2021 Huaulmé, J.-M., 2022a Study no.: BPL21/962/GC, sponsor no.: 000107616
Guideline(s):	OECD/OCDE 509 Adopted: 7 September 2009, OECD Guidelines for the testing of chemicals, Crop Field Trial. ENV/JM/MONO(2011)50/REV1 07-Sep-2016 OECD Guidance Document on crop field trials, second edition, Series on Pesticides - No. 66 Series on Testing & Assessment - No. 164 SANTE/2020/12830, Rev.1 24, February 2021, Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes - Supersedes Guidance Documents SANCO/3029/99 and SANCO/825/00.
Deviations:	None with impact on study results
GLP:	Yes
Acceptability:	Yes

Table A 17: Summary of the barley study 3 - 6 trials

Crop residue data from supervised field trials		**Reference no.:**	**KCA 6.3.2/06**
Active ingredient (common name and content):	Prothioconazole, nominal 150 g/L (actual 148 g/L)	Commercial product (name/code):	ADM.03503. F.1.A
Crop/crop group:	Barley / Cereals	Formulation (e.g. SC):	EC
Country:	France (N-EU), Germany, Hungary, Poland	Other active substance in the formulation:	Fluxapyroxad, nominal 75 g/L (actual 77.4 g/L)
Indoor/outdoor:	Outdoor	Residues calculated as:	**Prothioconazole as sum of prothioconazole-desthio, 3-hydroxyprothioconazole-desthio, 4-hydroxyprothioconazole-desthio, 5-hydroxyprothioconazole-desthio, 6-hydroxyprothioconazole-desthio and alpha-hydroxyprothioconazole-desthio, expressed as prothioconazole-desthio (mg/kg) (8.1, risk assessment residue definition);** **Prothioconazole-desthio (mg/kg) (8.2, enforcement residue definition)**
Responsible body for reporting (name, address):	SynTech Research France, La Chapelle de Guinchay, France		

1	2	3	4			5	6	7	8.1	8.2	9		10
Trial No./ Location/ EU zone/ Year	**Commodity/ Variety**	**Date of 1.Sowing or planting 2.Flowering 3. Harvest**	**Application rate per treatment**			**Dates of treatment or no. of treatments and last date**	**Growth stage at last treatment or date**	**Portion analysed**	**Residues (mg/kg)**		**Assessment**		**Details on trial(s)**
			kg a.s./ ha	**Water (L/ha)**	**kg a.s./ hL**				**Prothio-conazole (sum)**	**Prothio-conazole-desthio**	**Timing (BBCH)**	**DALA (days)**	
	(a)	(b)	(c)			(d)			(g)	(h)		(e)	(f)
BPL21/962/GC-01-FR 10600 La Chapelle Saint-Luc France N-EU 2021 (A)	Spring barley (HORVS) / Planet	1/ 27/03/21 2/ 16 - 25/06/21 3/ 30/07/21	0.187	303	0.062	21/06/21	BBCH 65	Grain Straw	<u><LOQ</u> <u>0.14</u>	<u>0.013</u> <u>0.085</u>*	89 89	39 39	Analytical methods: RAR method 00979/M001, LC-MS/MS For method validation please refer to dRR Part B.5, point KCP 5.1.2. LOQ: 0.01 mg/kg for each analyte, 0.06 mg/kg for prothioconazole expressed as prothioconazole-
BPL21/962/GC-02-GE 74861 Kreβbach Germany N-EU 2020/21 (B)	Winter barley (HORVW) / Su Vireni	1/ 22/10/20 2/ 23 - 31/05/21 3/ 29 - 30/07/21	0.172	326	0.053	28/05/21	BBCH 65	Grain Straw	<u><LOQ</u> <u>0.20</u>	<u><LOQ</u> <u>0.055</u>	89 89	62 62	

1	2	3	4			5	6	7	8.1	8.2	9		10
Trial No./ Location/ EU zone/ Year	**Commodity/ Variety** (a)	**Date of 1.Sowing or planting 2.Flowering 3. Harvest** (b)	**Application rate per treatment**			**Dates of treatment or no. of treatments and last date** (d)	**Growth stage at last treatment or date**	**Portion analysed**	**Residues (mg/kg)**		**Assessment**		**Details on trial(s)** (f)
			kg a.s./ ha (c)	**Water (L/ha)**	**kg a.s./ hL**				**Prothio-conazole (sum)** (g)	**Prothio-conazole-desthio** (h)	**Timing (BBCH)**	**DALA (days)** (e)	
BPL21/962/GC-03-HU 2340 Kiskunlacháza Hungary N-EU 2021 (C)	Spring barley (HORVS) / Conchita	1/ 16/03/21 2/ 11 - 17/06/21 3/ 12 - 15/07/21	0.177	287	0.062	15/06/21	BBCH 65	Grain Straw	0.087 2.2	0.054 1.7	89 89	28 28	desthio as a sum of metabolites; LOD: 0.003 mg/kg for each analyte, 0.018 mg/kg for prothioconazole expressed as prothioconazole-desthio as a sum of metabolites Max. sample storage time: 115 days (sampling to extraction), max. extract storage time (extraction to analysis) 4 days. Extract stability proven within the study. Results in all untreated specimens were below LOD.
BPL21/962/GC-04-PL 55 110 Krościna Mała, Poland N-EU 2021(D)	Spring barley (HORVS) / KWS Harris	1/ 08/03/20 2/ 15 - 23/06/21 3/ 31/07/21	0.186	302	0.062	18/06/21	BBCH 65	Grain Straw	<LOQ 1.0	0.010 0.34	89 89	43 43	
BPL21/960/GC-05-GE 85368 Moosburg an der Isar Germany N-EU 2021 (E)	Spring barley (HORVS) / Marthe	1/ 23/04/21 2/ 08 - 15/07/21 3/ 25/08/21	0.182	345	0.053	12/07/21	BBCH 65	Grain Straw	<LOQ (n.d.) 0.061	<LOQ (n.d.) 0.041*	89 89	44 44	
BPL21/962/GC-06-HU 5126 Jászfényszaru Hungary N-EU 2021 (F)	Spring barley (HORVS) / Conchita	1/ 29/03/21 2/ 19 - 23/06/21 3/ 16 - 22/07/21	0.180	291	0.062	21/06/21	BBCH 65	Grain Straw	0.095 0.93	0.061 0.49	89 89	29 29	

(a) According to Codex Classification /Guide
(b) Only if relevant
(c) These values are actual rate of active substance as they were calculated with the actual concentration of the active substance:
(Dose rate targeted was 187.5 g a.s./ha of Prothioconazole and 93.75 g a.s./ha of Fluxapyroxad (equivalent to ADM.03503. F.1.A at 1.25 L/ha)

(d) Year must be indicated
(e) Days after last application.
(f) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
(g) Prothioconazole (mg/kg) as sum of prothioconazole-desthio, 3-hydroxyprothioconazole-desthio, 4-hydroxyprothioconazole-desthio, 5-hydroxyprothioconazole-desthio, 6-hydroxyprothioconazole-desthio and alpha-hydroxyprothioconazole-desthio, expressed as prothioconazole-desthio (8.1, acc. to risk assessment residue definition). For the sum of prothioconazole-desthio, the calculations were performed with value of 0.01 mg/kg for results <LOQ and as zero for results <LOQ (nd).
(h) Prothioconazole-desthio (sum of isomers) (8.2, enforcement residue definition)
* Mean of two extractions
n.d. Not detectable
LOQ Limit of quantification
LOD Limit of detection

Table A 18: Summary of the barley study 3 - 6 trials (TDMs)

Crop residue data from supervised field trials		**Reference no.:**	**KCA 6.3.2/06**
Active ingredient (common name and content):	Prothioconazole, 148 g/L (actual)	Commercial product (name/code):	ADM.03503. F.1.A
Crop/crop group:	Barley / Cereals	Formulation (e.g. SC):	EC
Country:	France (N-EU), Germany, Hungary, Poland	Other active substance in the formulation:	Fluxapyroxad, nominal 75 g/L (actual 77.4 g/L)
Indoor/outdoor:	Outdoor	Residues calculated as:	**1,2,4-Triazole, Triazole alanine, Triazole acetic acid, Triazole lactic acid (mg/kg)**
Responsible body for reporting (name, address):	SynTech Research France, La Chapelle de Guinchay, France		

1	2	3	4			5	6	7	8.1	8.2	8.3	8.4	9		10
Trial No./ Location/ EU zone/ Year	**Commodity/ Variety** (a)	**Date of 1.Sowing or planting 2.Flowering 3. Harvest** (b)	**Application rate per treatment**			**Dates of treatment or no. of treatments and last date** (d)	**Growth stage at last treatment or date** (e)	**Portion analysed** (a)	**Residues (mg/kg)**				**Assessment**		**Details on trial(s)** (g)
			kg a.s./ ha (c)	**Water (L/ha)**	**kg a.s./ hL**				**1,2,4-triazole**	**Triazole alanine**	**Triazole acetic acid**	**Triazole lactic acid**	**Timing (BBCH)**	**DALA (days)** (f)	
BPL21/962/GC-01-FR 10600 La Chapelle Saint-Luc France N-EU 2021 (A)	Spring barley (HORVS) / Planet	1/ 27/03/21 2/ 16 - 25/06/21 3/ 30/07/21	0.187	303	0.062	21/06/21	BBCH 65	Grain	<LOQ	0.08	0.03	<LOQ (n.d.)	89	39	Analytical methods: GRM053.01A, LC-DMS-MS/MS detection. For method validation please refer to dRR Part B.5, point KCP 5.1.2.
								Straw	<LOQ (n.d.)	<LOQ	<LOQ	<LOQ	89	39	
			Untreated					Grain	<LOQ	0.01	<LOQ	<LOQ (n.d.)	89	39	LOQ: 0.01 mg/kg with LOD: 0.003 mg/kg (for each analyte and each matrix)
								Straw	<LOQ	<LOQ (n.d.)	<LOQ (n.d.)	<LOQ (n.d.)	89	39	
BPL21/962/GC-02-GE 74861 Kreβbach Germany N-EU 2020/21 (B)	Winter barley (HORVW) / Su Vireni	1/ 22/10/20 2/ 23 - 31/05/21 3/ 29 - 30/07/21				28/05/21	BBCH 65	Grain	<LOQ (n.d.)	0.10	0.09	<LOQ (n.d.)	89	62	Max. sample storage time: 114 days (sampling to extraction), max. extract storage time (extraction to analysis) 1 day for
								Straw	<LOQ (n.d.)	0.02	0.02	<LOQ	89	62	

1	2	3	4			5	6	7	8.1	8.2	8.3	8.4	9		10
Trial No./ Location/ EU zone/ Year	**Commodity/ Variety**	**Date of 1.Sowing or planting 2.Flowering 3. Harvest**	**Application rate per treatment**			**Dates of treatment or no. of treatments and last date**	**Growth stage at last treatment or date**	**Portion analysed**	**Residues (mg/kg)**				**Assessment**		**Details on trial(s)**
			kg a.s./ ha	**Water (L/ha)**	**kg a.s./ hL**				**1,2,4-triazole**	**Triazole alanine**	**Triazole acetic acid**	**Triazole lactic acid**	**Timing (BBCH)**	**DALA (days)**	
	(a)	(b)	(c)			(d)	(e)	(a)						(f)	(g)
			Untreated					Grain	<LOQ (n.d.)	0.04	0.05	<LOQ (n.d.)	89	62	grain and straw. Extract stability proven within the study. Residues in untreated samples (background levels) were found in a part of samples, and results are given.
								Straw	<LOQ (n.d.)	<LOQ	0.01	<LOQ	89	62	
BPL21/962/GC-03-HU 2340 Kiskunlacháza Hungary N-EU 2021 (C)	Spring barley (HORVS) / Conchita	1/ 16/03/21 2/ 11 - 17/06/21 3/ 12 - 15/07/21	0.177	287	0.062	15/06/21	BBCH 65	Grain	<LOQ	0.14	0.13	0.02	89	28	
								Straw	<LOQ (n.d.)	<LOQ	0.04	0.19	89	28	
			Untreated					Grain	<LOQ (n.d.)	<LOQ	<LOQ	<LOQ (n.d.)	89	35	
								Straw	<LOQ (n.d.)	<LOQ (n.d.)	<LOQ	0.02	89	35	
BPL21/962/GC-04-PL Krościna Mała, 55-110 Poland N-EU 2021 (D)	Spring barley (HORVS) / KWS Harris	1/ 08/03/21 2/ 15 - 23/06/21 3/ 31/07/21	0.186	302	0.062	18/06/21	BBCH 65	Grain	<LOQ (n.d.)	0.07	0.04	<LOQ	89	43	
								Straw	<LOQ	<LOQ	0.01	0.01	89	43	
			Untreated					Grain	<LOQ (n.d.)	0.02	0.02	<LOQ (n.d.)	89	43	
								Straw	<LOQ (n.d.)	<LOQ (n.d.)	<LOQ	<LOQ	89	43	
BPL21/962/GC-05-GE 85368 Moosburg an der Isar Germany N-EU 2021 (E)	Spring barley (HORVS) / Marthe	1/ 23/04/21 2/ 08 - 15/07/21 3/ 25/08/21	0.182	345	0.053	12/07/21	BBCH 65	Grain	<LOQ	0.04	0.02	<LOQ (n.d.)	89	44	
								Straw	<LOQ (n.d.)	<LOQ	<LOQ	0.02	89	44	
			Untreated					Grain	<LOQ (n.d.)	0.02	0.02	<LOQ (n.d.)	89	44	
								Strain	<LOQ	<LOQ (n.d.)	<LOQ (n.d.)	<LOQ (n.d.)	89	44	

1	2	3	4			5	6	7	8.1	8.2	8.3	8.4	9		10
Trial No./ Location/ EU zone/ Year	**Commodity/ Variety** (a)	**Date of 1.Sowing or planting 2.Flowering 3. Harvest** (b)	**Application rate per treatment**			**Dates of treatment or no. of treatments and last date** (d)	**Growth stage at last treatment or date** (e)	**Portion analysed** (a)	**Residues (mg/kg)**				**Assessment**		**Details on trial(s)** (g)
			kg a.s./ ha (c)	**Water (L/ha)**	**kg a.s./ hL**				**1,2,4-triazole**	**Triazole alanine**	**Triazole acetic acid**	**Triazole lactic acid**	**Timing (BBCH)**	**DALA (days)** (f)	
BPL21/962/GC-06-HU 5126 Jászfényszaru Hungary N-EU 2021 (F)	Spring barley (HORVS) / Conchita	1/ 29/03/21 2/ 19 - 23/06/21 3/ 16 - 22/07/21	0.180	291	0.062	21/06/21	BBCH 65	Grain	<LOQ	0.04	0.02	<LOQ	89	29	
								Straw	<LOQ	<LOQ (n.d.)	<LOQ	0.01	89	29	
			Untreated					Grain	<LOQ (n.d.)	0.01	0.01	<LOQ (n.d.)	89	29	
								Straw	<LOQ (n.d.)	<LOQ (n.d.)	<LOQ	<LOQ	89	29	

(a) According to Codex Classification /Guide
(b) Only if relevant
(c) These values are actual rate of active substance as they were calculated with the actual concentration of the active substance:
(Dose rate targeted was 187.5 g a.s./ha of Prothioconazole and 93.75 g a.s./ha of Fluxapyroxad (equivalent to ADM.03503. F.1.A at 1.25 L/ha)
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4.
(f) Minimum number of days after last application.
(g) Remarks may include: climatic conditions ; reference to analytical method ; information concerning the metabolites included, the method of storage, storage, stability, analysis date.
n.d. Not detectable
LOQ Limit of quantification
LOD Limit of detection

A 2.1.4 Magnitude of residues in livestock

A 2.1.4.1 Livestock feeding studies

No new studies are conducted or submitted.

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

No new studies are conducted or submitted.

A 2.1.6 Magnitude of residues in representative succeeding crops 1

Comments of zRMS:	The study of Semrau, J., 2021 (Report No.: S18-02513) has been evaluated in Registration Report for ADM.03500.F.2.B on March 2023 by zRMS-PL and the summary is presented below. The study (contained four rotational crop field trials) was conducted to determine residue levels of prothioconazole-desthio and prothioconazole (PTZ) hydroxy metabolites (sum of PTZ-desthio, 3- hydroxy-PTZ-desthio, 4-hydroxy-PTZ-desthio, 5-hydroxy-PTZ-desthio, 6-hydroxy-PTZ-desthio and alpha-hydroxy-PTZ-desthio), and TDMs (1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA)) in the raw agricultural commodities radish, leaf lettuce and barley grown as rotational crops after one application of MCW-2073 (SC formulation containing 150 g prothioconazole/L and 200 g azoxystrobin/L) with a target rate of 2000 mL product/ha (300 g prothioconazole /ha) on bare soil. Methods were validated according to SANCO/3029/99, rev. 4. Quantification was performed by use of LC-MS/MS detection for all analytes and matrices. The limit of quantification (LOQ) of both analytical methods was 0.01 mg/kg for each analyte and each matrix The mean recoveries at each fortification level were in the range of 70 – 120% with relative standard deviation(s) below 20% for all combinations of matrices and analytes. Results: <u>Prothioconazole</u> At all three plant back intervals of 30-3, 120±5 and 270±10 days, prothioconazole metabolites (sum of PTZ-desthio, 3- hydroxy-PTZ-desthio, 4-hydroxy-PTZ-desthio, 5-hydroxy-PTZ-desthio, 6-hydroxy-PTZ-desthio and alpha-hydroxy-PTZ-desthio, expressed as prothioconazole-desthio) were below the LOQ (0.06 mg/kg) in all treated and untreated crop commodities. <u>TDMs</u> Residues of 1,2,4-triazole were below the LOQ of 0.01 mg/kg in all crops. Residues of triazole acetic acid (TAA) were found above the LOQ of 0.01 mg/kg solely in cereals. Residues of triazole alanine (TA) and triazole lactic acid (TLA) were found above the LOQ (0.01 mg/kg) in part of the samples across all crops and all plant back intervals. However, it has to be stated that also in some of the untreated samples background levels of TA, TLA and TAA exceeding the LOQ (0.01 mg/kg) were found. <u>Remark:</u> It should be noted that the sample storage period for 1,2,4-T (444-539 days) **exceeded the maximum storage stability** demonstrated **for 1,2,4-T** in high water commodities (6 months) and cereal grains and straws (12 months). To address the insufficient stability period for 1,2,4-T, a second reduced GLP field rotational crop study (Semrau, 2022; Report No. S21-00408, ADAMA No. 000107470) was conducted to verify the no residue situation observed for 1,2,4-T (see below, point A 2.1.6.2)

	The study is acceptable.

Reference:	KCA 6.6.2/01
Report:	Determination of Residues of Prothioconazole and its Metabolites after One Application of MCW-2073 on Bare Soil in Rotational Crops (Radish, Leaf lettuce and Barley) at 2 Sites in Northern Europe and 2 Sites in Southern Europe 2018/2019 Semrau, J., 2021 Study no.: S18-02513, sponsor no.: 000109154
Guideline(s):	OECD (2009) Guidance Document on Overview of Residue Chemistry Studies (Series on Testing and Assessment No. 64 and Series on Pesticides No. 32); OECD Test Guideline 509: Crop field trials; OECD (2016) Guidance Document on Crop Field Trials (Series on Testing and Assessment No. 164 and Series on Pesticides No. 66); EC (1997) Guidance Document 7029/VI/95 rev. 5 general recommendations for the design, preparation and realization of residue trials; OECD Test Guideline 504: Residues in rotational crops (limited field studies); EU Guidance Document SANCO/3029/99 rev. 4 for generating and reporting methods of analysis in support of pre-registration data requirements
Deviations:	None with impact on the study results
GLP:	Yes
Acceptability:	Yes

Executive summary

The aim of the study was to determine residues of prothioconazole (sum of PTZ-desthio, 3- hydroxy-PTZ-desthio, 4-hydroxy-PTZ-desthio, 5-hydroxy-PTZ-desthio, 6-hydroxy-PTZ-desthio and alpha-hydroxy-PTZ-desthio, each expressed as PTZ-desthio (sum of isomers)), as well as of triazole derivative metabolites (TDMs) (1,2,4-triazole (1,2,4-T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA)) in the raw agricultural commodities radish, leaf lettuce and barley grown as rotational crops after one application of MCW-2073 on bare soil at three plant back intervals of nominal 30-3, 120±5 and 270±10 days. In addition, samples of soil were analysed for residues of prothioconazole-desthio. Four trials were carried out in Poland (2x, N-EU residue zone), Southern France and Italy (S-EU residue zone) in 2018-2019.

Samples of radish (leaves and roots) and leaf lettuce (leaves) were taken by hand at normal commercial harvest (NCH). Samples of barley (whole plant) were taken at growth stage BBCH 75 and at normal commercial harvest. Samples of barley taken at BBCH 75 were sampled manually while barley grain and straw samples were obtained by mechanical threshing. Samples of soil cores were taken directly after application (except trial -03 where control samples of sampling 2 were taken before application) and directly before planting for each plant back interval from the untreated and respective treated plots.

<u>Residues of prothioconazole except TDMs</u>

No residues of analytes at or above the LOD were detected in any of the untreated samples of soil. The following residues were detected in the treated soil samples:

Table A 19: Residues of prothioconazole-desthio in soil

Sampling Point	Timing (nominal)	Plot No.	PBI (days)	Sample Code	EAS (Chem) Internal code	Sample Type	Residue of PTZ-desthio (mg/kg)
Trial S18-02513-01 (Poland)							
S1	0 DAA1	4	272	-036A	2	soil	<0.01
S2	0 DAA2	3	117	-004A	4	soil	0.022
S3	0 DAA3	2	28	-006A	6	soil	<0.01
S4		2	28	-008A	8	soil	0.016

Sampling Point	Timing (nominal)	Plot No.	PBI (days)	Sample Code	EAS (Chem) Internal code	Sample Type	Residue of PTZ-desthio (mg/kg)
	0(-1) DBP	3	117	-009A	9	soil	<0.01
		4	272	-010A	10	soil	<0.01
Trial S18-02513-02 (Poland)							
S1	0 DAA1	4	273	-036A	102	soil	<0.01
S2	0 DAA2	3	119	-004A	104	soil	0.015
S3	0 DAA3	2	28	-006A	106	soil	<0.01
S4	0(-1) DBP	2	28	-008A	108	soil	<0.01
		3	119	-009A	109	soil	<0.01
		4	273	-010A	110	soil	<0.01
Trial S18-02513-03 (Southern France)							
S1	0 DAA1	4	266	-036A	202	soil	0.015
S2	0 DAA2	3	125	-004A	204	soil	0.011
S3	0 DAA3	2	34	-006A	206	soil	0.013
S4	0(-1) DBP	2	34	-008A	208	soil	0.019
		3	125	-009A	209	soil	<0.01
		4	266	-010A	210	soil	<0.01
Trial S18-02513-04 (Italy)							
S1	0 DAA1	5	274	-002A	302	soil	<0.01
S2	0 DAA2	4	120	-004A	304	soil	0.010
S3	0 DAA3	3	30	-006A	306	soil	0.016
S4	0(-1) DBP	3	30	-008A	308	soil	0.049
		4	120	-009A	309	soil	<0.01
		5	274	-010A	310	soil	0.013

DAA = days after last application; DBP = days before planting; 2, 3, 4, 5 = treated; U1= untreated
Residues are not corrected for procedural recoveries. Residues are given as “dry matter”, i.e. corrected for their moisture content

No residues of analytes at or above the LOD were detected in any of the untreated samples of plant matrices. The following residues were detected in the treated samples of plant matrices:

Table A 20: Residues of prothioconazole (except TDMs) in plant matrices

Sampling Point	Timing (nominal)	Plot No.	Sample Code	Nominal PBI (days)	EAS (Chem) Internal code	Sample Type	Residue of PTZ-desthio (mg/kg)	Residue of 3-OH-PTZ-desthio* (mg/kg)	Residue of 4-OH-PTZ-desthio* (mg/kg)	Residue of 5-OH-PTZ-desthio* (mg/kg)	Residue of 6-OH-PTZ-desthio* (mg/kg)	Residue of alpha-OH-PTZ-desthio* (mg/kg)	Sum of residues of PTZ-desthio isomers** (mg/kg)
Trial S18-02513-01 (Poland)													
S5	BBCH 49 (NCH)	2	-013A	28	13	radish leaves	<0.01	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.018 n.d.
		2	-014A	28	14	radish roots	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.018 n.d.
		3	-015A	117	15	radish leaves	<0.01	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.018 n.d.
		3	-016A	117	16	radish roots	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.018 n.d.
		4	-017A	272	17	radish leaves	<0.01	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.018 n.d.
		4	-018A	272	18	radish roots	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.018 n.d.
S6	BBCH 49 (NCH)	2	-020A	28	20	lettuce leaves	<0.01	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.018 n.d.
		3	-021A	117	21	lettuce leaves	<0.01	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.018 n.d.
		4	-022A	272	22	lettuce leaves	<0.01	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.018 n.d.
S7	BBCH 75 (NCH)	2	-024A	28	24	barley whole plant	<0.01	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.018 n.d.
		3	-025A	117	25	barley whole plant	<0.01	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.018 n.d.
		4	-026A	272	26	barley whole plant	<0.01	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.018 n.d.
S8	BBCH 89 (NCH)	2	-029A	28	29	barley grain	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.018 n.d.
		2	-030A	28	30	barley straw	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.018 n.d.
		3	-031A	117	31	barley grain	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.018 n.d.
		3	-032A	117	32	barley straw	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.018 n.d.
		4	-033A	272	33	barley grain	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.018 n.d.
		4	-034A	272	34	barley straw	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.018 n.d.

Sampling Point	Timing (nominal)	Plot No.	Sample Code	Nominal PBI (days)	EAS (Chem) Internal code	Sample Type	Residue of PTZ-desthio (mg/kg)	Residue of 3-OH-PTZ-desthio* (mg/kg)	Residue of 4-OH-PTZ-desthio* (mg/kg)	Residue of 5-OH-PTZ-desthio* (mg/kg)	Residue of 6-OH-PTZ-desthio* (mg/kg)	Residue of alpha-OH-PTZ-desthio* (mg/kg)	Sum of residues of PTZ-desthio isomers** (mg/kg)
Trial S18-02513-02 (Poland)													
S5	BBCH 49 (NCH)	2	-013A	28	113	radish leaves	0.015	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.018 n.d.
		2	-014A	28	114	radish roots	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.018 n.d.
		3	-015A	119	115	radish leaves	0.018	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d	< 0.003 n.d.	< 0.06
		3	-016A	119	116	radish roots	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.018 n.d.
		4	-017A	273	117	radish leaves	<0.01	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.018 n.d.
		4	-018A	273	118	radish roots	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.018 n.d.
S6	BBCH 49 (NCH)	2	-020A	28	120	lettuce leaves	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.018 n.d.
		3	-021A	119	121	lettuce leaves	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.018 n.d.
		4	-022A	273	122	lettuce leaves	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.018 n.d.
S7	BBCH 75 (NCH)	2	-024A	28	124	barley whole plant	<0.01	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.018 n.d.
		3	-025A	119	125	barley whole plant	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.018 n.d.
		4	-026A	273	126	barley whole plant	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.018 n.d.
S8	BBCH 89 (NCH)	2	-029A	28	129	barley grain	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.018 n.d.
		2	-030A	28	130	barley straw	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.018 n.d.
		3	-031A	119	131	barley grain	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.018 n.d.
		3	-032A	119	132	barley straw	<0.01	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.018 n.d.
		4	-033A	273	133	barley grain	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.018 n.d.
		4	-034A	273	134	barley straw	<0.01	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.018 n.d.

Sampling Point	Timing (nominal)	Plot No.	Sample Code	Nominal PBI (days)	EAS (Chem) Internal code	Sample Type	Residue of PTZ-desthio (mg/kg)	Residue of 3-OH-PTZ-desthio* (mg/kg)	Residue of 4-OH-PTZ-desthio* (mg/kg)	Residue of 5-OH-PTZ-desthio* (mg/kg)	Residue of 6-OH-PTZ-desthio* (mg/kg)	Residue of alpha-OH-PTZ-desthio* (mg/kg)	Sum of residues of PTZ-desthio isomers** (mg/kg)
Trial S18-02513-03 (Southern France)													
S5	BBCH 49 (NCH)	2	-013A	34	213	radish leaves	<0.01	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.018 n.d.
		2	-014A	34	214	radish roots	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.018 n.d.
		3	-015A	125	215	radish leaves	<0.01	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.018 n.d.
		3	-016A	125	216	radish roots	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.018 n.d.
		4	-017A	266	217	radish leaves	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.018 n.d.
		4	-018A	266	218	radish roots	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.018 n.d.
S6	BBCH 49 (NCH)	2	-020A	34	220	lettuce leaves	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.018 n.d.
		3	-021A	125	221	lettuce leaves	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.018 n.d.
		4	-022A	266	222	lettuce leaves	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.018 n.d.
S7	BBCH 75 (NCH)	2	-024A	34	224	barley whole plant	<0.01	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.018 n.d.
		3	-025A	125	225	barley whole plant	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.018 n.d.
		4	-026A	266	226	barley whole plant	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.018 n.d.
S8	BBCH 89 (NCH)	2	-029A	34	229	barley grain	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.018 n.d.
		2	-030A	34	230	barley straw	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.018 n.d.
		3	-031A	125	231	barley grain	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.018 n.d.
		3	-032A	125	232	barley straw	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.018 n.d.
		4	-033A	266	233	barley grain	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.018 n.d.
		4	-034A	266	234	barley straw	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.018 n.d.

Sampling Point	Timing (nominal)	Plot No.	Sample Code	Nominal PBI (days)	EAS (Chem) Internal code	Sample Type	Residue of PTZ-desthio (mg/kg)	Residue of 3-OH-PTZ-desthio* (mg/kg)	Residue of 4-OH-PTZ-desthio* (mg/kg)	Residue of 5-OH-PTZ-desthio* (mg/kg)	Residue of 6-OH-PTZ-desthio* (mg/kg)	Residue of alpha-OH-PTZ-desthio* (mg/kg)	Sum of residues of PTZ-desthio isomers** (mg/kg)
Trial S18-02513-04 (Italy)													
S5	BBCH 49 (NCH)	6	-013A	30	313	radish leaves	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.018 n.d.
		6	-014A	30	314	radish roots	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.018 n.d.
		7	-015A	120	315	radish leaves	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.018 n.d.
		7	-016A	120	316	radish roots	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.018 n.d.
		8	-017A	272	317	radish leaves	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.018 n.d.
		8	-018A	272	318	radish roots	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.018 n.d.
S6	BBCH 49 (NCH)	6	-020A	30	320	lettuce leaves	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.018 n.d.
		7	-021A	120	321	lettuce leaves	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.018 n.d.
		8	-022A	272	322	lettuce leaves	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.018 n.d.
S7	BBCH 75 (NCH)	3	-024A	30	324	barley whole plant	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.018 n.d.
		4	-025A	120	325	barley whole plant	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.018 n.d.
		5	-026A	274	326	barley whole plant	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.018 n.d.
S8	BBCH 89 (NCH)	3	-029A	30	329	barley grain	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.018 n.d.
		3	-030A	30	330	barley straw	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.018 n.d.
		4	-031A	120	331	barley grain	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.018 n.d.
		4	-032A	120	332	barley straw	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.018 n.d.
		5	-033A	274	333	barley grain	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.018 n.d.
		5	-034A	274	334	barley straw	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.018 n.d.

NCH = normal commercial harvest; 3, 4, 5, 6, 7, 8 = treated; U1= untreated; n.d. not detected (below LOD, set at 30 % of LOQ)
Residues are not corrected for procedural recoveries
* expressed as prothioconazole-desthio
** Sum of isomers: PTZ-desthio, 3-hydroxy-PTZ-desthio; 4-hydroxy-PTZ-desthio; 5-hydroxy-PTZ-desthio; 6-hydroxy-PTZ-desthio and alpha-hydroxy-PTZ-desthio; with an LOQ of 0.06 mg/kg and an LOD of 0.018 mg/kg.

Residues of TDMs

The following residues were detected in the untreated and treated samples:

Table A 21: Residues of TDMs in plant matrices

Sampling Point	Timing (nominal)	Plot No.	PBI (days)	Sample Code	EAS Chem Internal code	Sample Type	1,2,4-Triazole (mg/kg)	Triazole alanine (mg/kg)	Triazole acetic acid (mg/kg)	Triazole lactic acid (mg/kg)
Trial S18-02513-01 (Poland)										
S5	BBCH 49 (NCH)	U1	--	-011A	11	radish leaves	< 0.01	< 0.01	< 0.003 n.d.	< 0.003 n.d.
		U1	--	-012A	12	radish roots	< 0.003 n.d.	< 0.01	< 0.003 n.d.	< 0.003 n.d.
		2	28	-013A	13	radish leaves	< 0.01	0.05	< 0.003 n.d.	< 0.01
		2	28	-014A	14	radish roots	< 0.003 n.d.	0.04	< 0.003 n.d.	< 0.003 n.d.
		3	117	-015A	15	radish leaves	< 0.01	0.06	< 0.003 n.d.	< 0.01
		3	117	-016A	16	radish roots	< 0.003 n.d.	0.04	< 0.003 n.d.	< 0.003 n.d.
		4	272	-017A	17	radish leaves	< 0.003 n.d.	0.07	< 0.003 n.d.	0.02
		4	272	-018A	18	radish roots	< 0.003 n.d.	0.05	< 0.003 n.d.	< 0.003 n.d.
S6	BBCH 49 (NCH)	U1	--	-019A	19	lettuce leaves	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.01
		2	28	-020A	20	lettuce leaves	< 0.003 n.d.	< 0.01	< 0.003 n.d.	0.04
		3	117	-021A	21	lettuce leaves	< 0.003 n.d.	< 0.01	< 0.003 n.d.	0.04
		4	272	-022A	22	lettuce leaves	< 0.003 n.d.	< 0.01	< 0.003 n.d.	0.04
S7	BBCH 75 (NCH)	U1	--	-023A	23	barley whole plant	< 0.003 n.d.	0.01	< 0.01	<0.01
		2	28	-024A	24	barley whole plant	< 0.003 n.d.	0.04	0.04	0.06
		3	117	-025A	25	barley whole plant	< 0.003 n.d.	0.04	0.03	0.07
		4	272	-026A	26	barley whole plant	< 0.01	0.04	0.04	0.08
S8	BBCH 89 (NCH)	U1	--	-027A	27	barley grain	< 0.003 n.d.	0.13	0.02	< 0.003 n.d.
		U1	--	-028A	28	barley straw	< 0.003 n.d.	< 0.01	< 0.01	0.01
		2	28	-029A	29	barley grain	< 0.003 n.d.	0.17	0.10	< 0.003 n.d.
		2	28	-030A	30	barley straw	< 0.003 n.d.	0.03	0.05	0.06
		3	117	-031A	31	barley grain	< 0.003 n.d.	0.18	0.10	< 0.01
		3	117	-032A	32	barley straw	< 0.003 n.d.	0.03	0.04	0.06
		4	272	-033A	33	barley grain	< 0.003 n.d.	0.15	0.09	< 0.01
		4	272	-034A	34	barley straw	< 0.003 n.d.	0.03	0.04	0.05
Trial S18-02513-02 (Poland)										

Sampling Point	Timing (nominal)	Plot No.	PBI (days)	Sample Code	EAS Chem Internal code	Sample Type	1,2,4-Triazole (mg/kg)	Triazole alanine (mg/kg)	Triazole acetic acid (mg/kg)	Triazole lactic acid (mg/kg)
S5	BBCH 49 (NCH)	U1	--	-011A	11	radish leaves	< 0.003 n.d.	0.05	< 0.003 n.d.	0.01
		U1	--	-012A	12	radish roots	< 0.003 n.d.	0.02	< 0.003 n.d.	< 0.003 n.d.
		2	28	-013A	13	radish leaves	< 0.01	0.27	< 0.01	0.13
		2	28	-014A	14	radish roots	< 0.003 n.d.	0.12	< 0.003 n.d.	0.02
		3	119	-015A	15	radish leaves	< 0.003 n.d.	0.10	< 0.003 n.d.	0.05
		3	119	-016A	16	radish roots	< 0.003 n.d.	0.04	< 0.003 n.d.	< 0.01
		4	273	-017A	17	radish leaves	< 0.01	0.12	< 0.003 n.d.	0.05
		4	273	-018A	18	radish roots	< 0.003 n.d.	0.07	< 0.003 n.d.	< 0.01
S6	BBCH 49 (NCH)	U1	--	-019A	19	lettuce leaves	< 0.01 n.d.	< 0.01	< 0.003 n.d.	0.03
		2	28	-020A	20	lettuce leaves	< 0.003 n.d.	0.03	< 0.01	0.19
		3	119	-021A	21	lettuce leaves	< 0.01 n.d.	0.01	< 0.003 n.d.	0.12
		4	273	-022A	22	lettuce leaves	< 0.003 n.d.	0.01	< 0.003 n.d.	0.09
S7	BBCH 75 (NCH)	U1	--	-023A	23	barley whole plant	< 0.003 n.d.	0.04	0.03	0.04
		2	28	-024A	24	barley whole plant	< 0.003 n.d.	0.11	0.19	0.25
		3	119	-025A	25	barley whole plant	< 0.003 n.d.	0.07	0.15	0.27
		4	273	-026A	26	barley whole plant	< 0.01	0.06	0.08	0.11
S8	BBCH 89 (NCH)	U1	--	-027A	27	barley grain	< 0.003 n.d.	0.11	0.07	< 0.003 n.d.
		U1	--	-028A	28	barley straw	< 0.003 n.d.	0.02	0.08	0.08
		2	28	-029A	29	barley grain	< 0.003 n.d.	0.41	0.55	0.01
		2	28	-030A	30	barley straw	< 0.01	0.04	0.40	0.45
		3	119	-031A	31	barley grain	<0.01	0.28	0.29	0.01
		3	119	-032A	32	barley straw	< 0.01	0.05	0.24	0.20
		4	273	-033A	33	barley grain	< 0.003 n.d.	0.16	0.20	< 0.01
		4	273	-034A	34	barley straw	< 0.003 n.d.	0.04	0.20	0.15
Trial S18-02513-03 (Southern France)										
S5	BBCH 49 (NCH)	U1	--	-011A	11	radish leaves	< 0.01	< 0.01 n.d.	< 0.003 n.d.	< 0.003 n.d.
		U1	--	-012A	12	radish roots	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.
		2	34	-013A	13	radish leaves	< 0.01	0.18	< 0.003 n.d.	0.01
		2	34	-014A	14	radish roots	< 0.003 n.d.	0.04	< 0.003 n.d.	0.02

Sampling Point	Timing (nominal)	Plot No.	PBI (days)	Sample Code	EAS Chem Internal code	Sample Type	1,2,4-Triazole (mg/kg)	Triazole alanine (mg/kg)	Triazole acetic acid (mg/kg)	Triazole lactic acid (mg/kg)
		3	125	-015A	15	radish leaves	< 0.01	0.14	< 0.003 n.d.	0.02
		3	125	-016A	16	radish roots	< 0.003 n.d.	0.05	< 0.003 n.d.	0.02
		4	266	-017A	17	radish leaves	< 0.01	0.22	< 0.003 n.d.	0.02
		4	266	-018A	18	radish roots	< 0.003 n.d.	0.07	< 0.01	0.02
S6	BBCH 49 (NCH)	U1	--	-019A	19	lettuce leaves	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.01
		2	34	-020A	20	lettuce leaves	< 0.003 n.d.	0.02	< 0.003 n.d.	0.10
		3	125	-021A	21	lettuce leaves	< 0.003 n.d.	0.02	< 0.003 n.d.	0.10
		4	266	-022A	22	lettuce leaves	< 0.003 n.d.	0.02	< 0.003 n.d.	0.10
S7	BBCH 75 (NCH)	U1	--	-023A	23	barley whole plant	< 0.003 n.d.	< 0.01	< 0.01	0.01
		2	34	-024A	24	barley whole plant	< 0.003 n.d.	0.10	0.15	0.17
		3	125	-025A	25	barley whole plant	< 0.003 n.d.	0.05	0.08	0.10
		4	266	-026A	26	barley whole plant	< 0.003 n.d.	0.11	0.15	0.16
S8	BBCH 89 (NCH)	U1	--	-027A	27	barley grain	< 0.003 n.d.	0.02	0.02	< 0.003 n.d.
		U1	--	-028A	28	barley straw	< 0.003 n.d.	< 0.003 n.d.	0.02	0.02
		2	34	-029A	29	barley grain	< 0.003 n.d.	0.28	0.33	0.01
		2	34	-030A	30	barley straw	< 0.003 n.d.	0.03	0.22	0.28
		3	125	-031A	31	barley grain	< 0.003 n.d.	0.21	0.28	0.01
		3	125	-032A	32	barley straw	< 0.003 n.d.	0.01	0.14	0.21
		4	266	-033A	33	barley grain	< 0.003 n.d.	0.28	0.32	0.02
		4	266	-034A	34	barley straw	< 0.003 n.d.	0.02	0.17	0.27
Trial S18-02513-04 (Italy)										
S5	BBCH 49 (NCH)	U2	--	-011A	11	radish leaves	< 0.01	< 0.01	< 0.003 n.d.	< 0.003 n.d.
		U2	--	-012A	12	radish roots	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.
		6	30	-013A	13	radish leaves	< 0.01	< 0.01	< 0.003 n.d.	< 0.003 n.d.
		6	30	-014A	14	radish roots	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.
		7	120	-015A	15	radish leaves	< 0.003 n.d.	< 0.01	< 0.003 n.d.	< 0.003 n.d.

Sampling Point	Timing (nominal)	Plot No.	PBI (days)	Sample Code	EAS Chem Internal code	Sample Type	1,2,4-Triazole (mg/kg)	Triazole alanine (mg/kg)	Triazole acetic acid (mg/kg)	Triazole lactic acid (mg/kg)
		7	120	-016A	16	radish roots	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.
		8	272	-017A	17	radish leaves	< 0.003 n.d.	< 0.01	< 0.003 n.d.	< 0.003 n.d.
		8	272	-018A	18	radish roots	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.
S6	BBCH 49 (NCH)	U2	--	-019A	19	lettuce leaves	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.
		6	30	-020A	20	lettuce leaves	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.01
		7	120	-021A	21	lettuce leaves	< 0.003 n.d.	< 0.01	< 0.003 n.d.	< 0.01
		8	272	-022A	22	lettuce leaves	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.01
S7	BBCH 75 (NCH)	U1	--	-023A	23	barley whole plant	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.01
		3	30	-024A	24	barley whole plant	< 0.01	0.03	0.02	0.04
		4	120	-025A	25	barley whole plant	< 0.01	0.02	0.01	0.02
		5	274	-026A	26	barley whole plant	< 0.003 n.d.	0.01	< 0.01	0.01
S8	BBCH 89 (NCH)	U1	--	-027A	27	barley grain	< 0.003 n.d.	0.13	0.08	< 0.01
		U1	--	-028A	28	barley straw	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	0.01
		3	30	-029A	29	barley grain	< 0.003 n.d.	0.14	0.11	< 0.01
		3	30	-030A	30	barley straw	< 0.003 n.d.	< 0.01	0.03	0.06
		4	120	-031A	31	barley grain	< 0.003 n.d.	0.11	0.08	< 0.01
		4	120	-032A	32	barley straw	< 0.003 n.d.	< 0.01	0.02	0.04
		5	274	-033A	33	barley grain	< 0.003 n.d.	0.14	0.09	< 0.01
		5	274	-034A	34	barley straw	< 0.01	< 0.01	0.02	0.02

NCH = normal commercial harvest; 2, 3, 4, 5, 6, 7, 8 = treated; U1, U2= untreated
n.d. not detected (below LOD, set at 30 % of LOQ)
Residues are not corrected for procedural recoveries, but corrected for background level of reagent blank sample

Materials and methods

A. Materials

Test item:	MCW-2073 (Azoxystrobin Prothioconazole 200 150 SC)
Active ingredient (a.s.):	Azoxystrobin (a.s 1) Prothioconazole (a.s 2)
CAS no.:	a.s 1: 131860-33-8, a.s 2: 178928-70-6
Lot/Batch no.:	1032-040218-01
Expiry date:	February 2020
Application rate (nominal):	300 g prothioconazole/ha
No. and growth stage at application:	One application, (application on bare soil)
Application time points:	Trial S18-02513-01, Trial S18-02513-02, Trial S18-02513-03 270±10: 07-08.2018 (A1) 120±5: 12.2018 (A2) 30-3: 03.2019 (A3) Trial S18-02513-04: 270±10: 05.2018 (A1), 07.2018 (A2) 120±5: 10.2018 (A3), 01.2019 (A5) 0-3: 12.2018 (A4), 03.2019 (A6)
Trial locations:	Trial S18-02513-01: 64-520 Gaj Mały, Wielkopolska, Poland Trial S18-02513-02: 88- 400 Podgórzyn, Kujawskopomorskie, Poland Trial S18-02513-03: 82290 Barry d'Islemade,Tarn et Garonne, Southern France Trial S18-02513-04: 40016 San Giorgio di Piano, Bologna, Italy
Sampled commodities:	Radish (leaves and roots): BBCH 49 (NCH) Leaf lettuce (leaves): BBCH 49 (NCH) Barley (whole plant, grain and straw): BBCH 75 and BBCH 89 (NCH)

B. Study design and method

1. Field part:

The four residue trials were conducted in open field at four locations in Poland, Southern France and Italy. Regions, varieties and cultivation were typical for the rotational crops radish, leaf lettuce and barley. Each trial comprised three plant back intervals of nominal 30-3, 120±5 and 270±10 days. Trials -01 to -03 were consisted of four plots, one untreated and three treated with MCW-2073 (SC formulation containing 150 g prothioconazole/L and 200 g azoxystrobin/L, nominal content), the plots U1, 2, 3 and 4 plots were splitted into three equal sub-plots on which radish, leaf lettuce and barley were planted in 2019 after the dedicated plant back interval (PBI). Trial -04 comprised eight plots: two untreated and six treated with MCW-2073 (SC formulation containing 150 g prothioconazole/L and 200 g azoxystrobin/L, nominal content), the plots U2, 6, 7 and 8 were divided into two equal sub-plots on which radish and leaf lettuce were planted in 2019 after the dedicated PBI while plots U1, 3, 4 and 5 remained undivided only planted with barley after the dedicated PBI. In each trail one application of MCW-2073 per treated plot and plant back interval was performed to bare soil with a target rate of 2000 mL product/ha (300 g prothioconazole /ha) using boom sprayer equipment. The test item was diluted with water immediately prior to application to a spray volume of 300 L/ha (nominal).

For Radish samples, plants were taken from the entire subplot, with the exception of a 0.5 m wide strip round the edge of the subplot and at the ends of rows. Tops (foliage) and roots were separated, and both were sampled by hand. If necessary, adhering soil from roots was removed. Leaf lettuce samples were taken from the entire subplot, with the exception of a 0.5 m wide strip round the edge of the subplot and at the ends of rows. Any decayed leaves, roots and soil were removed and discarded before deep freezing. Leaf lettuce samples were sampled by hand. Whole plant barley samples comprised at least 12 short lengths from rows over the entire plot. Culms were cut approx. 15 cm above the ground. Grain and straw samples were threshed mechanically. Control samples were taken before treated samples, they were kept later on separated by an adequate space at all times. All samples were immediately deep frozen (-18 °C or below) after arrival at the test facility.

2. Stability of Prothioconazole and Triazole metabolites in final sample extracts

Extract stability is not considered to be an issue since matrix-matched standards that were used for quantification were always prepared on the same day as the work up of the sample for residue analysis took place and stability was confirmed from the acceptable procedural recovery samples analysed with each analytical batch (70-110 % range).

3. Analytical part

This study comprised two analytical phases.

Prothioconazole metabolites (except TDMs):

In the analytical phase S18-02513-L2 of this study samples of radish (leaves and roots), leaf lettuce (leaves) and barley (whole plant, grain and straw) were analysed for residues of prothioconazole-desthio (sum of isomers of PTZ-desthio, PTZ-3-; -4-; -5-; and -6-hydroxy desthio and alpha-hydroxy-PTZ-desthio, each expressed as PTZ-desthio). In addition, samples of soil were analysed for residues of prothioconazole-desthio.

Sample extraction and determination of residues in the matrices radish (leaves and roots), barley (grain, straw and whole plant) and lettuce (leaves) were performed according to the GIRPA Method R-39651 based on the multi-residue method QuEChERS that was validated within this analytical phase for the matrices radish (roots), barley (grain and straw) and lettuce (leaves) according to SANCO/3029/99, rev. 4. For the analysis of soil, sample extraction and determination of residues were performed according to the multi-residue method QuEChERS that was also validated within this analytical phase according to SANCO/3029/99, rev. 4. Quantification was performed by use of LC-MS/MS detection for all analytes and matrices.
The limit of quantification (LOQ) of both analytical methods was 0.01 mg/kg (expressed as prothioconazole-desthio) for each analyte and each matrix with a limit of detection (LOD) set at 0.003 mg/kg (30 % of the LOQ).
For prothioconazole-desthio (sum of isomers of prothioconazole-desthio, 3-hydroxy-prothioconazole-desthio, 4-hydroxy-prothioconazole-desthio, 5-hydroxy-prothioconazole-desthio, 6-hydroxy-prothioconazole-desthio and alpha-hydroxy-prothioconazole-desthio) the LOQ was 0.06 mg/kg for all matrices with a limit of detection (LOD) set at 0.018 mg/kg (30 % of the LOQ). A description and validation of the analytical method is provided in dRR Part B.5, point KCP 5.1.2.

TDMs:

In the analytical phase S18-02513-L3 of this study, samples of radish (leaves and roots), lettuce (leaves) and barley (whole plant, grain and straw) were analysed for residues of 1,2,4-triazole (1,2,4-T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) with a limit of quantification of 0.01 mg/kg for each analyte and matrix type. Analyses were performed according to method GRM053.01A that was provided by Sponsor. For method transfer and applicability this method was reduced validated within this analytical phase according to SANCO/3029/99, rev.4 on all matrices of radish (leaves and roots), leaf lettuce and barley (whole plant, grain and straw) at the LOQ level (0.01 mg/kg) and 10xLOQ level (0.1 mg/kg). Quantification was performed by addition of internal standard(s) and use of LC-DMS-MS/MS detection for all analytes and matrices. A description and validation of the analytical method is provided in dRR Part B.5, point KCP 5.1.2.

Results and discussion

During analysis of the field specimen mean recoveries values obtained by LC-MS/MS for Prothioconazole and Triazole metabolites in radish (leaves, roots), leaf lettuce (leaves) and barley (whole plant, grain, straw) were in the range of 70-110% with relative standard deviation below 20%.

Prothioconazole metabolites (except TDMs):

No residues of analytes at or above the LOD were detected in any of the untreated samples of plant matrices.

Residues of prothioconazole-desthio in treated samples were below the LOQ (0.01 mg/kg) in all crops and at all plant back intervals, except for one trial (PL02) where radish leaves had a residue of 0.015 and 0.018 mg/kg at PBI 28 days and 119 days respectively. Since application rate to bare soil was at an exaggerated rate (1.6N) and proposed application to cereals would be BBCH 65-69 when 90% interception to soil would be expected, it is concluded that these residues found at a single site are more reflective of the worst case conditions used in the study. Under proposed use conditions a no residue situation would be expected following the use of prothioconazole as shown in the confined rotational crop metabolism study.

Residues of prothioconazole (mg/kg) as sum of prothioconazole-desthio, 3-hydroxyprothioconazole-desthio, 4-hydroxyprothioconazole-desthio, 5-hydroxyprothioconazole-desthio, 6-hydroxyprothioconazole-desthio and alpha-hydroxyprothioconazole-desthio, expressed as prothioconazole-desthio were below the LOQ (0.06 mg/kg) in all crops and at all plant back intervals.

<u>TDMs:</u>
In untreated samples residues of triazole alanine (TA) and triazole lactic acid (TLA) were above the LOQ (0.01 mg/kg) in several samples across all crops whereas residues of triazole acetic acid (TAA) were registered over the LOQ (0.01 mg/kg) only in cereals. Residues of 1,2,4-triazole were below the LOQ (0.01 mg/kg) in all samples and all crops.

Regarding the treated samples, residues of triazole alanine (TA) and triazole lactic acid (TLA) were found above the LOQ (0.01 mg/kg) in all crops and at all plant back intervals, residues of triazole acetic acid (TAA) were found above the LOQ in cereals only, whereas residues of 1,2,4-triazole were below the LOQ in all samples and all crops.

- Highest residues found at 30-3 days PBI in radish (roots) were found at 0.02 mg/kg (TLA) and 0.12 mg/kg (TA), those at 120±5 days PBI were found at 0.02 mg/kg (TLA) and 0.05 mg/kg (TA), whereas at 270±10 days, highest residues varied between 0.02 mg/kg (TLA) and 0.07 mg/kg (TA).

- Highest residues found at 30-3 days PBI in leaf lettuce were found at 0.03 mg/kg TA and 0.19 mg/kg TLA, those at 120±5 days PBI were found at 0.01 mg/kg TA and 0.12 mg/kg TLA, whereas at 270±10 days, highest residues were found to be 0.02 mg/kg TA and 0.10 mg/kg TLA.

- Highest residues at 30-3 days PBI in barley (grain) were found to be 0.01 mg/kg TLA, 0.41 mg/kg TA and 0.55 mg/kg TAA, those at 120±5 days PBI were 0.01 mg/kg TLA, 0.28 mg/kg TA and 0.29 mg/kg TAA, whereas at 270±10 days, highest residues were found at 0.02 mg/kg TLA, 0.28 mg/kg TA and 0.32 mg/kg TAA.

- Highest residues found at 30-3 days PBI in barley (straw) were in 0.04 mg/kg TA, 0.40 TAA and 0.45 mg/kg TLA, those at 120±5 days PBI were 0.05 mg/kg TA, 0.24 mg/kg TAA and 0.21 mg/kg TLA, whereas at 270±10 days, highest residues were found at 0.27 mg/kg TLA, 0.04 mg/kg TA and 0.20 mg/kg TAA.

For TA, TAA and TLA all samples were analysed within the demonstrated stability period and showed residues of <0.01-0.41 mg/kg, <0.01-0.55 mg/kg and <0.01-0.45 mg/kg respectively. Control samples also contain residues of these metabolites although generally at lower levels compared to treated samples. Stability of 1,2,4-T was only confirmed for 6 months in high water crops and 12 months in cereal grain and straw, but analysis was performed outside of this period (444-539 days). Nevertheless, residues were <0.01 mg/kg in both treated and control cereal samples, in line with the findings of the confined rotational crop study.

Detailed results can be found in the following tables:

Table A 22: Summary of the rotational crop field study 1 - 4 trials (Prothioconazole residues except TDMs)

Reference no.:	KCA 6.6.2/01		
Report	Determination of residues of prothioconazole and its metabolites after one application of MCW-2073 on bare soil in rotational crops (radish, leaf lettuce and barley) at 2 sites in Northern Europe and 2 sites in Southern Europe 2018/2019 Semrau, J., 2021 Report No.: S18-02513, 000109154		
GLP:	Yes	**Sample storage conditions:**	below -18 °C
Preceeding crop:	Bare soil	**Analytical method:**	For plant matrices: Prothioconazole metabolites: GIRPA Method R-39651, based on DIN EN 15662:2018-07, QuEChERS-method, validated within the analytical phase; TDMs: GRM053.01A validated within the analytical phase For soil: multi-residue method,– QuEChERS, validated within the analytical phase
Succeeding crop:	Radish, Leaf lettuce, spring barley	**Limit of Quantification (mg/kg):**	0.01 mg/kg for each analyte and matrix; 0.06 mg/kg for prothioconazole as sum of prothioconazole-desthio, 3-hydroxy-prothioconazole-desthio, 4-hydroxy-prothioconazole-desthio, 5-hydroxy-prothioconazole-desthio, 6-hydroxy-prothioconazole-desthio and alpha-hydroxy-prothioconazole-desthio expressed as prothioconazole-desthio (mg/kg)
Indoor/Outdoor:	outdoor	**Limit of Detection (mg/kg):**	0.003 mg/kg for each analyte and matrix; 0.018 mg/kg for prothioconazole as sum of prothioconazole-desthio, 3-hydroxy-prothioconazole-desthio, 4-hydroxy-prothioconazole-desthio, 5-hydroxy-prothioconazole-desthio, 6-hydroxy-prothioconazole-desthio and alpha-hydroxy-prothioconazole-desthio expressed as prothioconazole-desthio (mg/kg)
Formulation:	MCW-2073 SC	**Residues calculated as:**	1. Prothioconazole-desthio (sum of isomers) (acc. to enforcement residue definition) 2. Prothioconazole as sum of prothioconazole-desthio, 3-hydroxyprothioconazole-desthio, 4-hydroxy-prothioconazole-desthio, 5-hydroxy-prothioconazole-desthio, 6-hydroxy-prothioconazole-desthio alpha-hydroxy-prothioconazole-desthio, expressed as prothioconazole-desthio (mg/kg) (acc. to risk assessment residue definition) 3. 1,2,4-Triazole, Triazole alanine, Triazole acetic acid, Triazole lactic acid (mg/kg)
Content of active substance (g/kg or g/L):	Prothioconazole, nominal 150 g/L (actual 145 g/L), Azoxystrobin, nominal 200 g/L (actual 201.6 g/L)		

Crop residue data from supervised field trials		**Reference no.:**	KCA 6.6.2/01
Active ingredient (common name and content):	Prothioconazole, nominal 150 g/L (actual 145.0 g/L)	Commercial product (name/code):	MCW-2073
Crop/crop group:	Radish / root vegetables, Leaf lettuce / leaf vegetables, Barley / cereals	Formulation (e.g. SC):	SC
Country:	Poland, France (S-EU), Italy	Other active substance in the formulation:	Azoxystrobin, nominal 200 g/L (actual 201.6 g/L)
Indoor/outdoor:	Outdoor	Residues calculated as:	**Prothioconazole as sum of prothioconazole-desthio, 3-hydroxyprothioconazole-desthio, 4-hydroxyprothioconazole-desthio, 5-hydroxyprothioconazole-desthio, 6-hydroxyprothioconazole-desthio and alpha-hydroxyprothioconazole-desthio, expressed as prothioconazole-desthio (mg/kg) (8.2, risk assessment residue definition); Prothioconazole-desthio (mg/kg) (8.1, enforcement residue definition)**
Responsible body for reporting (name, address):	ADAMA Makhteshim Ltd, Beer Sheva, Israel		

1 **Trial No./ Location/ EU zone/ Year**	2 **Commodity/ Variety**	3 **Date of 1.Sowing or planting 2.Flowering 3. Harvest**	4 **Application rate per treatment**			5 **Dates of treatment(s) or no. of treatment(s) and last date (d)**	6 **Growth stage at last treatment or date (e) BBCH**	7 **Portion analysed**	8.1 **Residues (mg/kg)**	8.2	10 **Assessment**		11 **Details on trial(s)**
			kg a.s./ hL	**Water (L/ha)**	**kg a.s./ ha**				**PTZ-desthio**	**PTZ (sum)**	**Timing (BBCH)**	**DALA (days)**	
	(a)	(b)	(c)			(d)	(e)		(g)	(h)		(i)	(f)
S18-02513-01 64-520 Gaj Mały, Wielkopolska, Poland N-EU 2019	Radish (RAPSR) / Escala	1-24/04/19 2- n.a 3-05/06/19	0.1	304	0.305	27/03/19 (PBI 30-3)	Bare soil	Leaves	<LOQ	<LOQ (n.d.)	49	70	LC-MS/MS detection for all analytes and matrices. For method validation please refer to dRR Part B.5, point KCP 5.1.2. Max. sample storage time in all four trials: 488 days (sampling to extraction), max. extract storage time (extraction to analysis) 7 days. Extract stability verified during the study. Results in all untreated specimens were below LOD.
								Roots	<LOQ (n.d.)	<LOQ (n.d.)	49	70	
			0.1	304	0.305	28/12/18 (PBI 120±5)	Bare soil	Leaves	<LOQ	<LOQ (n.d.)	49	159	
								Roots	<LOQ (n.d.)	<LOQ (n.d.)	49	159	
			0.1	308	0.308	26/07/18 (PBI 270±10)	Bare soil	Leaves	<LOQ	<LOQ (n.d.)	49	314	
								Roots	<LOQ (n.d.)	<LOQ (n.d.)	49	314	
	Leaf lettuce (LACSP) / Fynly	1-24/04/19 2- n.a 3-07/06/19	0.1	306	0.306	27/03/19 (PBI 30-3)	Bare soil	Leaves	<LOQ	<LOQ (n.d.)	49	72	
			0.1	309	0.309	28/12/18 (PBI 120±5)	Bare soil	Leaves	<LOQ	<LOQ (n.d.)	49	161	
			0.1	313	0.313	26/07/18 (PBI 270±10)	Bare soil	Leaves	<LOQ	<LOQ (n.d.)	49	316	

1 **Trial No./ Location/ EU zone/ Year**	2 **Commodity/ Variety**	3 **Date of 1.Sowing or planting 2.Flowering 3. Harvest**	4 **Application rate per treatment**			5 **Dates of treatment(s) or no. of treatment(s) and last date (d)**	6 **Growth stage at last treatment or date (e) BBCH**	7 **Portion analysed**	8.1 **Residues (mg/kg)**	8.2	10 **Assessment**		11 **Details on trial(s)**
			kg a.s./ hL	**Water (L/ha)**	**kg a.s./ ha**				**PTZ-desthio**	**PTZ (sum)**	**Timing (BBCH)**	**DALA (days)**	
	(a)	(b)	(c)			(d)	(e)		(g)	(h)		(i)	(f)
	Spring Barley (HORVS)/ Airway	1-24/04/19 2- n.a 3-13/08/19	0.1	300	0.300	27/03/19 (PBI 30-3)	Bare soil	Whole plant	<LOQ	<LOQ (n.d.)	75	100	
								Grain	<LOQ (n.d.)	<LOQ (n.d.)	89	139	
								Straw	<LOQ (n.d.)	<LOQ (n.d.)	89	139	
			0.1	299	0.299	28/12/18 (PBI 120±5)	Bare soil	Whole plant	<LOQ	<LOQ (n.d.)	75	189	
								Grain	<LOQ (n.d.)	<LOQ (n.d.)	89	228	
								Straw	<LOQ (n.d.)	<LOQ (n.d.)	89	228	
			0.1	306	0.306	26/07/18 (PBI 270±10)	Bare soil	Whole plant	<LOQ	<LOQ (n.d.)	75	344	
								Grain	<LOQ (n.d.)	<LOQ (n.d.)	89	383	
								Straw	<LOQ (n.d.)	<LOQ (n.d.)	89	383	

Table continued

1 Trial No./ Location/ EU zone/ Year	2 Commodity/ Variety (a)	3 Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	4 Application rate per treatment kg a.s./ hL (c)	 Water (L/ha)	 kg a.s./ ha	5 Dates of treatment(s) or no. of treatment(s) and last date (d) (d)	6 Growth stage at last treatment or date (e) BBCH (e)	7 Portion analysed	8.1 Residues (mg/kg) PTZ-desthio (g)	8.2 PTZ (sum) (h)	10 Assessment Timing (BBCH)	 DALA (days) (i)	11 Details on trial(s) (f)
S18-02513-02 88-400 Podgórzyn, Kujawskopomorskie Poland N-EU 2019	Radish (RAPSR) / Escala	1-25/04/19 2- n.a 3-06/06/19	0.1	304	0.303	28/03/19 (PBI 30-3)	Bare soil	Leaves	0.015	<LOQ (n.d.)	49	70	
								Roots	<LOQ (n.d.)	<LOQ (n.d.)	49	70	
			0.1	303	0.303	27/12/18 (PBI 120±5)	Bare soil	Leaves	0.018	<LOQ	49	161	
								Roots	<LOQ (n.d.)	<LOQ (n.d.)	49	161	
			0.1	306	0.306	26/07/18 (PBI 270±10)	Bare soil	Leaves	<LOQ	<LOQ (n.d.)	49	315	
								Roots	<LOQ (n.d.)	<LOQ (n.d.)	49	315	
	Leaf lettuce (LACSP) / Fynly	1-25/04/19 2- n.a 3-06/06/19	0.1	305	0.305	28/03/19 (PBI 30-3)	Bare soil	Leaves	<LOQ (n.d.)	<LOQ (n.d.)	49	70	
			0.1	309	0.310	27/12/18 (PBI 120±5)	Bare soil	Leaves	<LOQ (n.d.)	<LOQ (n.d.)	49	161	
			0.1	286	0.286	26/07/18 (PBI 270±10)	Bare soil	Leaves	<LOQ (n.d.)	<LOQ (n.d.)	49	315	
	Spring Barley (HORVS)/ Airway	1-25/04/19 2- n.a 3-06/08/19	0.1	298	0.298	28/03/19 (PBI 30-3)	Bare soil	Whole plant	<LOQ	<LOQ (n.d.)	75	102	
								Grain	<LOQ (n.d.)	<LOQ (n.d.)	89	131	
								Straw	<LOQ (n.d.)	<LOQ (n.d.)	89	131	
			0.1	299	0.299	27/12/18 (PBI 120±5)	Bare soil	Whole plant	<LOQ (n.d.)	<LOQ (n.d.)	75	193	
								Grain	<LOQ (n.d.)	<LOQ (n.d.)	89	222	
								Straw	<LOQ	<LOQ (n.d.)	89	222	

1 **Trial No./ Location/ EU zone/ Year**	2 **Commodity/ Variety**	3 **Date of 1.Sowing or planting 2.Flowering 3. Harvest**	4 **Application rate per treatment**			5 **Dates of treatment(s) or no. of treatment(s) and last date (d)**	6 **Growth stage at last treatment or date (e) BBCH**	7 **Portion analysed**	8.1 **Residues (mg/kg)**	8.2	10 **Assessment**		11 **Details on trial(s)**
			kg a.s./ hL	**Water (L/ha)**	**kg a.s./ ha**				**PTZ-desthio**	**PTZ (sum)**	**Timing (BBCH)**	**DALA (days)**	
	(a)	(b)	(c)			(d)	(e)		(g)	(h)		(i)	(f)
			0.1	296	0.296	26/07/18 (PBI 270±10)	Bare soil	Whole plant	<LOQ (n.d.)	<LOQ (n.d.)	75	347	
								Grain	<LOQ (n.d.)	<LOQ (n.d.)	89	376	
								Straw	<LOQ	<LOQ (n.d.)	89	376	

Table continued

1 **Trial No./ Location/ EU zone/ Year**	2 **Commodity/ Variety** (a)	3 **Date of 1.Sowing or planting 2.Flowering 3. Harvest** (b)	4 **Application rate per treatment**			5 **Dates of treatment(s) or no. of treatment(s) and last date (d)** (d)	6 **Growth stage at last treatment or date (e) BBCH** (e)	7 **Portion analysed**	8.1 **Residues (mg/kg)**	8.2	10 **Assessment**		11 **Details on trial(s)** (f)
			kg a.s./ hL (c)	**Water (L/ha)**	**kg a.s./ ha**				**PTZ-desthio** (g)	**PTZ (sum)** (h)	**Timing (BBCH)**	**DALA (days)** (i)	
S18-02513-03 82290 Barry d'Islemade, Tarn et Garonne France S-EU 2019	Radish (RAPSR) / Radis de 18 jours	1-24/04/19 2- n.a 3-31/05/19	0.1	293	0.293	21/03/19 (PBI 30-3)	Bare soil	Leaves	<LOQ	<LOQ (n.d.)	49	71	
								Roots	<LOQ (n.d.)	<LOQ (n.d.)	49	71	
			0.1	292	0.292	20/12/18 (PBI 120±5)	Bare soil	Leaves	<LOQ	<LOQ (n.d.)	49	162	
								Roots	<LOQ (n.d.)	<LOQ (n.d.)	49	162	
			0.1	312	0.292	01/08/18 (PBI 270±10)	Bare soil	Leaves	<LOQ (n.d.)	<LOQ (n.d.)	49	303	
								Roots	<LOQ (n.d.)	<LOQ (n.d.)	49	303	
	Leaf lettuce (LACSP) / Grafitti	1-24/04/19 2- n.a 3-11/06/19	0.1	293	0.293	21/03/19 (PBI 30-3)	Bare soil	Leaves	<LOQ (n.d.)	<LOQ (n.d.)	49	82	
			0.1	292	0.292	20/12/18 (PBI 120±5)	Bare soil	Leaves	<LOQ (n.d.)	<LOQ (n.d.)	49	173	
			0.1	312	0.312	01/08/18 (PBI 270±10)	Bare soil	Leaves	<LOQ (n.d.)	<LOQ (n.d.)	49	314	
	Spring Barley (HORVS)/ Planet	1-24/04/19 2- n.a 3-29/07/19	0.1	293	0.293	21/03/19 (PBI 30-3)	Bare soil	Whole plant	<LOQ	<LOQ (n.d.)	75	110	
								Grain	<LOQ (n.d.)	<LOQ (n.d.)	89	130	
								Straw	<LOQ (n.d.)	<LOQ (n.d.)	89	130	
			0.1	292	0.292	20/12/18 (PBI 120±5)	Bare soil	Whole plant	<LOQ (n.d.)	<LOQ (n.d.)	75	201	
								Grain	<LOQ (n.d.)	<LOQ (n.d.)	89	221	
								Straw	<LOQ (n.d.)	<LOQ (n.d.)	89	221	

1 **Trial No./ Location/ EU zone/ Year**	2 **Commodity/ Variety**	3 **Date of 1.Sowing or planting 2.Flowering 3. Harvest**	4 **Application rate per treatment**			5 **Dates of treatment(s) or no. of treatment(s) and last date (d)**	6 **Growth stage at last treatment or date (e) BBCH**	7 **Portion analysed**	8.1 **Residues (mg/kg)**	8.2	10 **Assessment**		11 **Details on trial(s)**
			kg a.s./ hL	**Water (L/ha)**	**kg a.s./ ha**				**PTZ-desthio**	**PTZ (sum)**	**Timing (BBCH)**	**DALA (days)**	
	(a)	(b)	(c)			(d)	(e)		(g)	(h)		(i)	(f)
			0.1	312	0.312	01/08/18 (PBI 270±10)	Bare soil	Whole plant	<LOQ (n.d.)	<LOQ (n.d.)	75	342	
								Grain	<LOQ (n.d.)	<LOQ (n.d.)	89	362	
								Straw	<LOQ (n.d.)	<LOQ (n.d.)	89	362	

Table continued

1 **Trial No./ Location/ EU zone/ Year**	2 **Commodity/ Variety**	3 **Date of 1.Sowing or planting 2.Flowering 3. Harvest**	4 **Application rate per treatment**			5 **Dates of treatment(s) or no. of treatment(s) and last date (d)**	6 **Growth stage at last treatment or date (e) BBCH**	7 **Portion analysed**	8.1 **Residues (mg/kg)**	8.2	10 **Assessment**		11 **Details on trial(s)**
	(a)	(b)	**kg a.s./ hL** (c)	**Water (L/ha)**	**kg a.s./ ha**	(d)	(e)		**PTZ-desthio** (g)	**PTZ (sum)** (h)	**Timing (BBCH)**	**DALA (days)** (i)	(f)
S18-02513-04 40016 San Giorgio di Piano, Bologna Italy S-EU 2019	Radish (RAPSR) / Saxa 2	1-18/04/19 2- n.a 3-11/07/19	0.1	288	0.288	19/03/19 (PBI 30-3)	Bare soil	Leaves Roots	<LOQ (n.d.) <LOQ (n.d.)	<LOQ (n.d.) <LOQ (n.d.)	49 49	114 114	
			0.1	317	0.317	19/12/18 (PBI 120±5)	Bare soil	Leaves Roots	<LOQ (n.d.) <LOQ (n.d.)	<LOQ (n.d.) <LOQ (n.d.)	49 49	204 204	
			0.1	277	0.277	20/07/18 (PBI 270±10)	Bare soil	Leaves Roots	<LOQ (n.d.) <LOQ (n.d.)	<LOQ (n.d.) <LOQ (n.d.)	49 49	356 356	
	Leaf lettuce (LACSP) / Gentilina	1-18/04/19 2- n.a 3-02/07/19	0.1	288	0.288	19/03/19 (PBI 30-3)	Bare soil	Leaves	<LOQ (n.d.)	<LOQ (n.d.)	49	105	
			0.1	317	0.317	19/12/18 (PBI 120±5)	Bare soil	Leaves	<LOQ (n.d.)	<LOQ (n.d.)	49	195	
			0.1	277	0.277	20/07/18 (PBI 270±10)	Bare soil	Leaves	<LOQ (n.d.)	<LOQ (n.d.)	49	347	
	Spring Barley (HORVS)/ Campagne	1-13/02/19 2- n.a 3-03/07/19	0.1	323	0.323	14/01/19 (PBI 30-3)	Bare soil	Whole plant Grain Straw	<LOQ (n.d.) <LOQ (n.d.) <LOQ (n.d.)	<LOQ (n.d.) <LOQ (n.d.) <LOQ (n.d.)	75 89 89	161 170 170	
			0.1	287	0.287	16/10/18 (PBI 120±5)	Bare soil	Whole plant Grain Straw	<LOQ (n.d.) <LOQ (n.d.) <LOQ (n.d.)	<LOQ (n.d.) <LOQ (n.d.) <LOQ (n.d.)	75 89 89	251 260 260	

1 **Trial No./ Location/ EU zone/ Year**	2 **Commodity/ Variety**	3 **Date of 1.Sowing or planting 2.Flowering 3. Harvest**	4 **Application rate per treatment**			5 **Dates of treatment(s) or no. of treatment(s) and last date (d)**	6 **Growth stage at last treatment or date (e) BBCH**	7 **Portion analysed**	8.1 **Residues (mg/kg)**	8.2	10 **Assessment**		11 **Details on trial(s)**
			kg a.s./ hL	**Water (L/ha)**	**kg a.s./ ha**				**PTZ-desthio**	**PTZ (sum)**	**Timing (BBCH)**	**DALA (days)**	
	(a)	(b)	(c)			(d)	(e)		(g)	(h)		(i)	(f)
			0.1	290	0.145	15/05/18 (PBI 270±10)	Bare soil	Whole plant Grain Straw	<LOQ (n.d.) <LOQ (n.d.) <LOQ (n.d.)	<LOQ (n.d.) <LOQ (n.d.) <LOQ (n.d.)	75 89 89	405 414 414	

(a) According to EPPO codes
(b) Only if relevant
(c) These values are actual rate of active substance as they were calculated with the actual concentration of the active substance: (Nominal rate: 150 g a.s./ha prothioconazole equivalent to MCW-2073 at 1.0 L/ha)
(d) Year must be indicated
(e) BBCH Monograph. Growth Stages of Plants. 1997. Blackwell. ISBN 3-8263-3152-4
(f) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
(g) Prothioconazole-desthio (sum of isomers) (8.1, enforcement residue definition)
(h) Prothioconazole (mg/kg) as sum of prothioconazole-desthio, 3-hydroxyprothioconazole-desthio, 4-hydroxyprothioconazole-desthio, 5-hydroxyprothioconazole-desthio, 6-hydroxyprothioconazole-desthio and alpha-hydroxyprothioconazole-desthio, expressed as prothioconazole-desthio (8.2, acc. to risk assessment residue definition). For the sum of prothioconazole-desthio, the calculations were performed with value of 0.01 mg/kg for results <LOQ and as zero for results <LOQ (nd).
(i) Minimum number of days after last application
n.d. Not detectable
LOQ Limit of quantification
LOD Limit of detection

Table A 23: Summary of the rotational crop field study 1 - 4 trials (TDMs)

1	2	3	4			5	6	7	8				9	10	11
Trial No./ Location/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (d)	Growth stage at last treatment or date BBCH (e)	Portion analyzed	Residues (mg/kg)				Timing (BBCH)	PHI (days) (f)	Remarks (g)
			g a.s./ hL (c)	Water (l/ha)	kg a.s./ha				1,2,4-T	TA	TAA	TLA			
S18-02513-01 64-520 Gaj Mały, Wielkopolska Poland N-EU 2018/19	Radish (RAPSR) / Escala	1-24/04/19 2- n.a 3-05/06/19	0.1	304	0.305	27/03/19 (PBI 30-3)	Bare soil	Leaves	*<LOQ*	0.05	<LOQ (n.d.)	<LOQ	49	70	Analytical methods: GRM053.01A, LC-DMS-MS/MS detection. For method validation please refer to dRR Part B.5, point KCP 5.1.2. LOQ: 0.01 mg/kg with LOD: 0.003 mg/kg (for each analyte and each matrix) Max. sample storage time in all four trials: 539 days (sampling to extraction), max. extract storage time (extraction to analysis) 9 days. Extract stability verified during the study. Residues in untreated samples (background levels)
								Roots	*<LOQ (n.d.)*	0.04	<LOQ (n.d.)	<LOQ (n.d.)	49	70	
			0.1	304	0.305	28/12/18 (PBI 120±5)	Bare soil	Leaves	*<LOQ*	0.06	<LOQ (n.d.)	<LOQ	49	159	
								Roots	*<LOQ (n.d.)*	0.04	<LOQ (n.d.)	<LOQ (n.d.)	49	159	
			0.1	308	0.308	26/07/18 (PBI 270±10)	Bare soil	Leaves	*<LOQ (n.d.)*	0.07	<LOQ (n.d.)	0.02	49	314	
								Roots	*<LOQ (n.d.)*	0.05	<LOQ (n.d.)	<LOQ (n.d.)	49	314	
			Untreated					Leaves	*<LOQ*	<LOQ	<LOQ (n.d.)	<LOQ (n.d.)	49	-	
								Roots	*<LOQ (n.d.)*	<LOQ	<LOQ (n.d.)	<LOQ (n.d.)	49	-	
	Leaf lettuce (LACSP) / Fynly	1-24/04/19 2- n.a 3-07/06/19	0.1	306	0.306	27/03/19 (PBI 30-3)	Bare soil	Leaves	*<LOQ (n.d.)*	<LOQ	<LOQ (n.d.)	0.04	49	72	
			0.1	309	0.309	28/12/18 (PBI 120±5)	Bare soil	Leaves	*<LOQ (n.d.)*	<LOQ	<LOQ (n.d.)	0.04	49	161	
			0.1	313	0.313	26/07/18 (PBI 270±10)	Bare soil	Leaves	*<LOQ (n.d.)*	<LOQ	<LOQ (n.d.)	0.04	49	316	
			Untreated					Leaves	*<LOQ (n.d.)*	<LOQ (n.d.)	<LOQ (n.d.)	<LOQ	49	-	

1	2	3	4			5	6	7	8				9	10	11
Trial No./ Location/ Year	**Commodity/ Variety** (a)	**Date of 1.Sowing or planting 2.Flowering 3. Harvest** (b)	**Application rate per treatment**			**Dates of treatment or no. of treatments and last date** (d)	**Growth stage at last treatment or date BBCH** (e)	**Portion analyzed**	**Residues (mg/kg)**				**Timing (BBCH)**	**PHI (days)** (f)	**Remarks** (g)
			g a.s./ hL (c)	**Water (l/ha)**	**kg a.s./ha**				**1,2,4-T**	**TA**	**TAA**	**TLA**			
	Spring Barley (HORVS)/ Airway	1-24/04/19 2- n.a 3-13/08/19	0.1	300	0.300	27/03/19 (PBI 30-3)	Bare soil	Whole plant	*<LOQ (n.d.)*	0.04	0.04	0.06	75	100	were found in a part of samples, and results are given.
								Grain	*<LOQ (n.d.)*	0.17	0.10	<LOQ (n.d.)	89	139	
								Straw	*<LOQ (n.d.)*	0.03	0.05	0.06	89	139	
			0.1	299	0.299	28/12/18 (PBI 120±5)	Bare soil	Whole plant	*<LOQ (n.d.)*	0.04	0.03	0.07	75	189	
								Grain	*<LOQ (n.d.)*	0.18	0.10	<LOQ	89	228	
								Straw	*<LOQ (n.d.)*	0.03	0.04	0.06	89	139	
			0.1	306	0.306	26/07/18 (PBI 270±10)	Bare soil	Whole plant	*<LOQ*	0.04	0.04	0.08	75	344	
								Grain	*<LOQ (n.d.)*	0.15	0.09	<LOQ	89	383	
								Straw	*<LOQ (n.d.)*	0.03	0.04	0.05	89	383	
			Untreated					Whole plant	*<LOQ (n.d.)*	0.01	<LOQ	<LOQ	75	-	
								Grain	*<LOQ (n.d.)*	0.13	0.02	<LOQ (n.d.)	89	-	
								Straw	*<LOQ (n.d.)*	<LOQ	<LOQ	0.01	89	-	

Table continued

1 Trial No./ Location/ Year	2 Commodity/ Variety (a)	3 Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	4 Application rate per treatment g a.s./ hL (c)	 Water (l/ha)	 kg a.s./ha	5 Dates of treatment or no. of treatments and last date (d)	6 Growth stage at last treatment or date BBCH (e)	7 Portion analyzed	8 Residues (mg/kg) 1,2,4-T	 TA	 TAA	 TLA	9 Timing (BBCH)	10 PHI (days) (f)	11 Remarks (g)
S18-02513-02 88-400 Podgórzyn, Kujawskopo morskie Poland N-EU 2018/19	Radish (RAPSR) / Escala	1-25/04/19 2- n.a 3-06/06/19	0.1	304	0.304	28/03/19 (PBI 30-3)	Bare soil	Leaves	*<LOQ (n.d.)*	<LOQ (n.d.)	<LOQ (n.d.)	<LOQ (n.d.)	49	70	
								Roots	*<LOQ (n.d.)*	<LOQ (n.d.)	<LOQ (n.d.)	<LOQ (n.d.)	49	70	
			0.1	303	0.303	27/12/18 (PBI 120±5)	Bare soil	Leaves	*<LOQ (n.d.)*	<LOQ (n.d.)	<LOQ (n.d.)	<LOQ	49	161	
								Roots	*<LOQ (n.d.)*	<LOQ (n.d.)	<LOQ (n.d.)	<LOQ (n.d.)	49	161	
			0.1	306	0.306	26/07/18 (PBI 270±10)	Bare soil	Leaves	*<LOQ*	<LOQ (n.d.)	<LOQ (n.d.)	<LOQ (n.d.)	49	315	
								Roots	*<LOQ (n.d.)*	<LOQ (n.d.)	<LOQ (n.d.)	<LOQ (n.d.)	49	315	
			Untreated					Leaves	*<LOQ (n.d.)*	0.05	<LOQ (n.d.)	0.01	49	-	
								Roots	*<LOQ (n.d.)*	0.02	<LOQ (n.d.)	<LOQ (n.d.)	49	-	
	Leaf lettuce (LACSP) / Fynly	1-24/04/19 2- n.a 3-07/06/19	0.1	305	0.305	28/03/19 (PBI 30-3)	Bare soil	Leaves	*<LOQ (n.d.)*	0.03	<LOQ	0.19	49	70	
			0.1	309	0.310	27/12/18 (PBI 120±5)	Bare soil	Leaves	*<LOQ*	0.01	<LOQ (n.d.)	0.12	49	161	
			0.1	286	0.286	26/07/18 (PBI 270±10)	Bare soil	Leaves	*<LOQ (n.d.)*	0.01	<LOQ (n.d.)	0.09	49	315	
			Untreated					Leaves	*<LOQ (n.d.)*	<LOQ	<LOQ (n.d.)	0.03	49	-	

1	2	3	4			5	6	7	8				9	10	11
Trial No./ Location/ Year	**Commodity/ Variety** (a)	**Date of 1.Sowing or planting 2.Flowering 3. Harvest** (b)	**Application rate per treatment**			**Dates of treatment or no. of treatments and last date** (d)	**Growth stage at last treatment or date BBCH** (e)	**Portion analyzed**	**Residues (mg/kg)**				**Timing (BBCH)**	**PHI (days)** (f)	**Remarks** (g)
			g a.s./ hL (c)	**Water (l/ha)**	**kg a.s./ha**				**1,2,4-T**	**TA**	**TAA**	**TLA**			
	Spring Barley (HORVS)/ Airway	1-25/04/19 2- n.a 3-06/08/19	0.1	298	0.298	28/03/19 (PBI 30-3)	Bare soil	Whole plant	*<LOQ (n.d.)*	0.11	0.19	0.25	75	102	
								Grain	*<LOQ (n.d.)*	0.41	0.55	0.01	89	131	
								Straw	*<LOQ*	0.04	0.40	0.45	89	131	
			0.1	299	0.299	27/12/18 (PBI 120±5)	Bare soil	Whole plant	*<LOQ (n.d.)*	0.07	0.15	0.27	75	193	
								Grain	*<LOQ*	0.28	0.29	<LOQ	89	222	
								Straw	*<LOQ*	0.05	0.24	0.20	89	222	
			0.1	296	0.296	26/07/18 (PBI 270±10)	Bare soil	Whole plant	*<LOQ*	0.06	0.08	0.11	75	347	
								Grain	*<LOQ (n.d.)*	0.16	0.20	<LOQ	89	376	
								Straw	*<LOQ (n.d.)*	0.04	0.20	0.15	89	376	
			Untreated					Whole plant	*<LOQ (n.d.)*	0.04	0.03	0.04	75	-	
								Grain	*<LOQ (n.d.)*	0.11	0.07	<LOQ (n.d.)	89	-	
								Straw	*<LOQ (n.d.)*	0.02	0.08	0.08	89	-	

Table continued

1 Trial No./ Location/ Year	2 Commodity/ Variety (a)	3 Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	4 Application rate per treatment g a.s./ hL (c)	 Water (l/ha)	 kg a.s./ha	5 Dates of treatment or no. of treatments and last date (d)	6 Growth stage at last treatment or date BBCH (e)	7 Portion analyzed	8 Residues (mg/kg) 1,2,4-T	 TA	 TAA	 TLA	9 Timing (BBCH)	10 PHI (days) (f)	11 Remarks (g)
S18-02513-03 82290 Barry d'Islemade, Tarn et Garonne France S-EU 2018/19	Radish (RAPSR) / Radis de 18 jours	1-24/04/19 2- n.a 3-31/05/19	0.1	293	0.293	21/03/19 (PBI 30-3)	Bare soil	Leaves	*<LOQ*	0.18	<LOQ (n.d.)	0.01	49	71	
								Roots	*<LOQ (n.d.)*	0.04	<LOQ (n.d.)	0.02	49	71	
			0.1	292	0.292	20/12/18 (PBI 120±5)	Bare soil	Leaves	*<LOQ*	0.14	<LOQ (n.d.)	0.02	49	162	
								Roots	*n.d.*	0.05	<LOQ (n.d.)	0.02	49	162	
			0.1	312	0.312	01/08/18 (PBI 270±10)	Bare soil	Leaves	*<LOQ*	0.22	<LOQ (n.d.)	0.02	49	315	
								Roots	*<LOQ (n.d.)*	0.07	<LOQ	0.02	49	315	
			Untreated					Leaves	*<LOQ*	<LOQ	<LOQ (n.d.)	<LOQ (n.d.)	49	-	
								Roots	*<LOQ (n.d.)*	<LOQ (n.d.)	<LOQ (n.d.)	<LOQ (n.d.)	49	-	
	Leaf lettuce (LACSP) / Grafitti	1-24/04/19 2- n.a 3-11/06/19	0.1	293	0.293	21/03/19 (PBI 30-3)	Bare soil	Leaves	*<LOQ (n.d.)*	0.02	<LOQ (n.d.)	0.10	49	82	
			0.1	292	0.292	20/12/18 (PBI 120±5)	Bare soil	Leaves	*<LOQ (n.d.)*	0.02	<LOQ (n.d.)	0.10	49	173	

1 Trial No./ Location/ Year	2 Commodity/ Variety (a)	3 Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	4 Application rate per treatment			5 Dates of treatment or no. of treatments and last date (d)	6 Growth stage at last treatment or date BBCH (e)	7 Portion analyzed	8 Residues (mg/kg)				9 Timing (BBCH)	10 PHI (days) (f)	11 Remarks (g)
			g a.s./ hL (c)	Water (l/ha)	kg a.s./ha				1,2,4-T	TA	TAA	TLA			
			0.1	312	0.312	01/08/18 (PBI 270±10)	Bare soil	Leaves	*<LOQ (n.d.)*	0.02	<LOQ (n.d.)	0.10	49	314	
			Untreated					Leaves	*<LOQ (n.d.)*	<LOQ (n.d.)	<LOQ (n.d.)	<LOQ	49	-	
	Spring Barley (HORVS)/ Planet	1-24/04/19 2- n.a 3-29/07/19	0.1	293	0.293	21/03/19 (PBI 30-3)	Bare soil	Whole plant Grain Straw	*<LOQ (n.d.)* *<LOQ (n.d.)* *<LOQ (n.d.)*	0.10 0.28 0.03	0.15 0.33 0.22	0.17 0.01 0.28	75 89 89	110 130 130	
			0.1	292	0.292	20/12/18 (PBI 120±5)	Bare soil	Whole plant Grain Straw	*<LOQ (n.d.)* *<LOQ (n.d.)* *<LOQ (n.d.)*	0.05 0.21 0.01	0.08 0.28 0.14	0.10 0.01 0.21	75 89 89	201 221 221	
			0.1	312	0.312	01/08/18 (PBI 270±10)	Bare soil	Whole plant Grain Straw	*<LOQ (n.d.)* *<LOQ (n.d.)* *<LOQ (n.d.)*	0.11 0.28 0.02	0.15 0.32 0.17	0.16 0.02 0.27	75 89 89	342 362 362	

1 Trial No./ Location/ Year	2 Commodity/ Variety (a)	3 Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	4 Application rate per treatment			5 Dates of treatment or no. of treatments and last date (d)	6 Growth stage at last treatment or date BBCH (e)	7 Portion analyzed	8 Residues (mg/kg)				9 Timing (BBCH)	10 PHI (days) (f)	11 Remarks (g)
			g a.s./ hL (c)	Water (l/ha)	kg a.s./ha				1,2,4-T	TA	TAA	TLA			
			Untreated					Whole plant	*<LOQ (n.d.)*	<LOQ	<LOQ	0.01	75	-	
								Grain	*<LOQ (n.d.)*	0.02	0.02	<LOQ (n.d.)	89	-	
								Straw	*<LOQ (n.d.)*	<LOQ (n.d.)	0.02	0.02	89	-	

Table continued

1 Trial No./ Location/ Year	2 Commodity/ Variety (a)	3 Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	4 Application rate per treatment g a.s./ hL (c)	 Water (l/ha)	 kg a.s./ha	5 Dates of treatment or no. of treatments and last date (d)	6 Growth stage at last treatment or date BBCH (e)	7 Portion analyzed	8 Residues (mg/kg) 1,2,4-T	 TA	 TAA	 TLA	9 Timing (BBCH)	10 PHI (days) (f)	11 Remarks (g)
S18-02513-04 40016 San Giorgio di Piano, Bologna Italy S-EU 2018/19	Radish (RAPSR) / Saxa 2	1-18/04/19 2- n.a 3-11/07/19	0.1	288	0.288	19/03/19 (PBI 30-3)	Bare soil	Leaves	*<LOQ*	<LOQ	<LOQ (n.d.)	<LOQ (n.d.)	49	114	
								Roots	*<LOQ (n.d.)*	<LOQ (n.d.)	<LOQ (n.d.)	<LOQ (n.d.)	49	114	
			0.1	317	0.317	19/12/18 (PBI 120±5)	Bare soil	Leaves	*<LOQ (n.d.)*	<LOQ (n.d.)	<LOQ (n.d.)	<LOQ (n.d.)	49	204	
								Roots	*<LOQ (n.d.)*	<LOQ (n.d.)	<LOQ (n.d.)	<LOQ (n.d.)	49	204	
			0.1	277	0.277	20/07/18 (PBI 270±10)	Bare soil	Leaves	*<LOQ (n.d.)*	<LOQ	<LOQ (n.d.)	<LOQ (n.d.)	49	356	
								Roots	*<LOQ (n.d.)*	<LOQ (n.d.)	<LOQ (n.d.)	<LOQ (n.d.)	49	356	
			Untreated					Leaves	*<LOQ*	<LOQ	<LOQ (n.d.)	<LOQ (n.d.)	49	-	
								Roots	*<LOQ (n.d.)*	<LOQ (n.d.)	<LOQ (n.d.)	<LOQ (n.d.)	49	-	
	Leaf lettuce (LACSP) / Gentilina	1-18/04/19 2- n.a 3-02/07/19	0.1	288	0.288	19/03/19 (PBI 30-3)	Bare soil	Leaves	*<LOQ (n.d.)*	<LOQ (n.d.)	<LOQ (n.d.)	<LOQ	49	105	
			0.1	317	0.317	19/12/18 (PBI 120±5)	Bare soil	Leaves	*<LOQ (n.d.)*	<LOQ	<LOQ (n.d.)	<LOQ	49	195	
			0.1	277	0.277	20/07/18 (PBI 270±10)	Bare soil	Leaves	*<LOQ (n.d.)*	<LOQ (n.d.)	<LOQ (n.d.)	<LOQ	49	347	

1	2	3	4			5	6	7	8				9	10	11
Trial No./ Location/ Year	**Commodity/ Variety** (a)	**Date of 1.Sowing or planting 2.Flowering 3. Harvest** (b)	**Application rate per treatment**			**Dates of treatment or no. of treatments and last date** (d)	**Growth stage at last treatment or date BBCH** (e)	**Portion analyzed**	**Residues (mg/kg)**				**Timing (BBCH)**	**PHI (days)** (f)	**Remarks** (g)
			g a.s./ hL (c)	**Water (l/ha)**	**kg a.s./ha**				**1,2,4-T**	**TA**	**TAA**	**TLA**			
			Untreated					Leaves	*<LOQ (n.d.)*	<LOQ (n.d.)	<LOQ (n.d.)	<LOQ (n.d.)	49	-	
	Spring Barley (HORVS)/ Campagne	1-13/02/19 2- n.a 3-03/07/19	0.1	323	0.323	14/01/19 (PBI 30-3)	Bare soil	Whole plant	*<LOQ*	0.03	0.02	0.04	75	161	
								Grain	*<LOQ (n.d.)*	0.14	0.11	<LOQ	89	170	
								Straw	*<LOQ (n.d.)*	<LOQ	0.03	0.06	89	170	
			0.1	287	0.287	16/10/18 (PBI 120±5)	Bare soil	Whole plant	*<LOQ*	0.02	0.01	0.02	75	251	
								Grain	*<LOQ (n.d.)*	0.11	0.08	<LOQ	89	260	
								Straw	*<LOQ (n.d.)*	<LOQ	0.02	0.04	89	260	
			0.1	290	0.145	15/05/18 (PBI 270±10)	Bare soil	Whole plant	*<LOQ (n.d.)*	0.01	<LOQ	0.01	75	405	
								Grain	*<LOQ (n.d.)*	0.14	0.09	<LOQ	89	414	
								Straw	*<LOQ*	<LOQ	0.02	0.02	89	414	
			Untreated					Whole plant	*<LOQ (n.d.)*	<LOQ (n.d.)	<LOQ (n.d.)	<LOQ	75	-	
								Grain	*<LOQ (n.d.)*	0.13	0.08	<LOQ	89	-	
								Straw	*<LOQ (n.d.)*	<LOQ (n.d.)	<LOQ (n.d.)	0.01	89	-	

(a) According to EPPO codes
(b) Only if relevant
(c) High or low volume spraying, , spreading, dusting etc., overall, broadcast, type of equipment used must be indicated
(d) Year must be indicated
* One application to each subplot

(e) BBCH Monograph. Growth Stages of Plants. 1997. Blackwell. ISBN 3-8263-3152-4.
(f) Minimum number of days after last application (Label pre-harvest interval. PHI. underline); DBLA =days before last application; DAA1= days after application A1
(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date
n.a. Not applicable
n.d. Not detected
LOQ Limit of quantification
LOD Limit of detection
Data in *italics* reported but outside acceptable storage stability.

Conclusion
Four rotational crop field trials were performed in the Northern (two) and Southern (two) residue zone.

At all three plant back intervals of 30-3, 120±5 and 270±10 days, prothioconazole metabolites (sum of PTZ-desthio, 3- hydroxy-PTZ desthio, 4-hydroxy-PTZ desthio, 5-hydroxy-PTZ -desthio, 6-hydroxy-PTZ-desthio and alpha-hydroxy-PTZ-desthio, expressed as prothioconazole-desthio) were below the LOQ (0.06 mg/kg) in all treated and untreated crop commodities.

Concerning TDMs, residues of 1,2,4-triazole were below the LOQ of 0.01 mg/kg in all crops. Residues of triazole acetic acid (TAA) were found above the LOQ of 0.01 mg/kg solely in cereals. Residues of triazole alanine (TA) and triazole lactic acid (TLA) were found above the LOQ (0.01 mg/kg) in part of the samples across all crops and all plant back intervals. However, it has to be stated that also in some of the untreated samples background levels of TA, TLA and TAA exceeding the LOQ (0.01 mg/kg) were found.

For TA, TAA and TLA all samples were analysed within the demonstrated stability period and showed residues of <0.01-0.41 mg/kg, <0.01-0.55 mg/kg and <0.01-0.45 mg/kg respectively. Control samples also contain residues of these metabolites although generally at lower levels compared to treated samples. Stability of 1,2,4-T was only confirmed for 6 months in high water crops and 12 months in cereal grain and straw, but analysis was performed outside of this period (444-539 days). Nevertheless, residues were <0.01 mg/kg in both treated and control cereal samples, in line with the findings of the confined rotational crop study.

A 2.1.7 Magnitude of residues in representative succeeding crops 2

Comments of zRMS:	The study of Semrau, J., 2022 (Report No.: S21-00408) has been evaluated in Registration Report for ADM.03500.F.2.B on March 2023 by zRMS-PL and the summary is presented below. To address the insufficient stability period for 1,2,4-T, a second reduced GLP field rotational crop study (Semrau, 2022; Report No. S21-00408, ADAMA No. 000107470) was conducted to verify the no residue situation observed for 1,2,4-T. The study (contained two rotational crop field trials) was conducted to determine residue levels of prothioconazole-desthio and prothioconazole (PTZ) hydroxy metabolites (sum of PTZ-desthio, 3- hydroxy-PTZ-desthio, 4-hydroxy-PTZ-desthio, 5-hydroxy-PTZ-desthio, 6-hydroxy-PTZ-desthio and alpha-hydroxy-PTZ-desthio), and TDMs (1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA)) in the raw agricultural commodities radish, leaf lettuce and barley grown as rotational crops after one application of Prothioconazole 250 EC (ADM.03500.F.2.B; EC formulation containing 250 g prothioconazole/L) with a target rate of 1.2 L product/ha (300 g prothioconazole /ha) on bare soil. Each trial comprised one plant back interval of 28±2 days. Methods were validated according to SANCO/3029/99, rev. 4 and SANTE/2020/12830, Rev.1 of 24/02/2021. Quantification was performed by use of LC-MS/MS detection for all analytes and matrices. The limit of quantification (LOQ) of both analytical methods was 0.01 mg/kg for each analyte and each matrix. The mean recoveries at each fortification level were in the range of 70 – 120% with relative standard deviation(s) below 20% for all combinations of matrices and analytes. Results: <u>Prothioconazole</u> At plant back interval of 28±2 days, prothioconazole metabolites (sum of PTZ-desthio, 3-hydroxy-PTZ-desthio, 4-hydroxy-PTZ-desthio, 5-hydroxy-PTZ-desthio, 6-hydroxy-PTZ-desthio and alpha-hydroxy-PTZ-desthio, expressed as prothioconazole-desthio) were below the LOQ (0.06 mg/kg) in all treated and untreated crop commodities. <u>TDMs</u>

	Residues of 1,2,4-triazole were below the LOQ of 0.01 mg/kg in all crops. Residues of triazole acetic acid (TAA) were found above the LOQ of 0.01 mg/kg solely in cereals. Residues of triazole alanine (TA) and triazole lactic acid (TLA) were found above the LOQ (0.01 mg/kg) in part of the samples across all crops at 28±2 days PBI. Highest residues in treated radish (roots) were found at 0.01 mg/kg (TLA) and 0.10 mg/kg (TA), in treated leaf lettuce were found at 0.02 mg/kg TA and 0.10 mg/kg TLA, in treated barley (grain) were found to be 0.04 mg/kg TLA, 0.82 mg/kg TA and 0.57 mg/kg TAA and in treated barley (straw) were in 0.04 mg/kg TA, 0.13 TAA and 0.12 mg/kg TLA. However, it has to be stated that also in some of the untreated samples background levels of TA, TLA and TAA exceeding the LOQ (0.01 mg/kg) were found. The maximum frozen storage period of crop samples from sampling until extraction for analysis of prothioconazole metabolites and prothioconazole triazole derivative metabolites was 182 days and 92 days, respectively. Sufficient stability data are available to support the residue data presented in this study. The study is acceptable.

Reference:	KCA 6.6.2/02
Report:	Determination of residues of prothioconazole metabolites in rotational crops (radish, lettuce, barley) after one application of Prothioconazole 250 EC (ADM.03500.F.2.B) on bare soil at 1 site in Northern Europe and 1 site in Southern Europe 2021 Semrau, J., 2022 Study no.: S21-00408, sponsor no.: 000107470
Guideline(s):	OECD (2009) Guidance Document on Overview of Residue Chemistry Studies (Series on Testing and Assessment No. 64 and Series on Pesticides No. 32); OECD Test Guideline 509: Crop field trials; OECD (2016) Guidance Document ENV/JM/MONO(2011)50/REV1 , Second Edition, on Crop Field Trials (Series on Testing and Assessment No. 164 and Series on Pesticides No. 66); EC (1997) Guidance Document 7029/VI/95 rev. 5 general recommendations for the design, preparation and realization of residue trials; SANTE/2019/12752 Technical Guidelines on Data Requirements for Setting Maximum Residue Levels, Comparability of Residue Trial and Extrapolation of Residue Data on Products from Plant and Animal Origin (Repealing and replacing the existing Guidance Document SANCO 7525/VI/95 Rev. 10.3) OECD Test Guideline 504: Residues in rotational crops (limited field studies); SANTE/2020/12830, Rev.1 Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes (Supersedes Guidance Documents SANCO/3029/99 and SANCO/825/00);
Deviations:	None with impact on the study results
GLP:	Yes
Acceptability:	Yes

Executive summary

The objective of the study was to determine the residue levels and behaviour of prothioconazole (PTZ) metabolites (sum of PTZ-desthio, 3- hydroxy-PTZ desthio, 4-hydroxy-PTZ desthio, 5-hydroxy-PTZ -desthio, 6-hydroxy-PTZ-desthio and alpha-hydroxy-PTZ-desthio), as well as of 1,2,4-triazole (1,2,4-T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA)) in the raw agricultural commodities radish, lettuce and barley grown as rotational crops after one application of Prothioconazole 250 EC (ADM.03500.F.2.B) on bare soil. In addition, samples of soil were analysed for residues of prothioconazole-desthio. Two rotational crop field trials were conducted in radish, leaf lettuce and barley during 2021, one in Germany (S21-00408-01), and one in Southern France (S21-00408-02).

Samples of radish (leaves and roots) and leaf lettuce (leaves) were taken by hand at normal commercial harvest (NCH). Samples of barley (whole plant) were taken at growth stage BBCH 51-55 and at normal commercial harvest. Samples of barley taken at BBCH 51-55 were sampled manually while barley grain and straw samples were obtained by mechanical threshing. Samples of soil cores (0-20 cm) were taken directly after application and directly before planting from the untreated and treated plot.

Prothioconazole metabolites (except TDMs):
Residues of prothioconazole (mg/kg) as sum of prothioconazole-desthio, 3-hydroxyprothioconazole-desthio, 4-hydroxyprothioconazole-desthio, 5-hydroxyprothioconazole-desthio, 6-hydroxyprothioconazole-desthio and alpha-hydroxyprothioconazole-desthio, expressed as prothioconazole-desthio were below the LOQ (0.06 mg/kg) in all crops and at all plant back intervals in treated and in untreated samples.

TDMs:
In untreated samples, residues of triazole alanine (TA), triazole lactic acid (TLA) and triazole acetic acid (TAA) were registered above the LOQ (0.01 mg/kg) in cereals but not in other crops. Residues of 1,2,4-triazole were below the LOD (0.003 mg/kg) in all samples of all crops.

Residues of triazole alanine (TA) and triazole lactic acid (TLA) in treated samples were found above the LOQ (0.01 mg/kg) in all crops, residues of triazole acetic acid (TAA) were found above the LOQ in cereals only, whereas residues of 1,2,4-triazole were below the LOD in all samples and all crops:

- Highest residues found at 28±2 days PBI in treated radish (roots) were found at 0.01 mg/kg (TLA) and 0.10 mg/kg (TA).
- Highest residues found at 28±2 days PBI in treated leaf lettuce were found at 0.02 mg/kg TA and 0.10 mg/kg TLA.
- Highest residues at 28±2 days PBI in treated barley (grain) were found to be 0.04 mg/kg TLA, 0.82 mg/kg TA and 0.57 mg/kg TAA.
- Highest residues found at 28±2 days PBI in treated barley (straw) were in 0.04 mg/kg TA, 0.13 TAA and 0.12 mg/kg TLA.

Materials and methods
A. Materials

Test item:	Prothioconazole 250 EC/ ADM.03500.F.2.B (Prothioconazole 250 g/L EC)
Active ingredient (a.s.):	Prothioconazole
CAS no.:	178928-70-6
Lot/Batch no.:	3178-010519-01
Expiry date:	April 2021
Application rate (nominal):	300 g prothioconazole/ha
No. and growth stage at application:	One application, (application on bare soil)
Application time points:	Trial S21-00408-01 (PBI 29d): 24.03.2021 Trial S21-00408-02 (PBI 30d): 23.03.2021
Trial locations:	Trial S21-00408-01: 21709 Burgweg, Lower Saxony, Germany

	Trial S21-00408-02: 82290 Barry d'Islemade, Tarn-et-Garonne, France
Sampled commodities:	Radish (leaves and roots): BBCH 49 (NCH) Leaf lettuce (leaves): BBCH 49 (NCH) Barley (whole plant, grain and straw): BBCH 51-55 and BBCH 89 (NCH)

B. Study design and method

1. Field part:

The residue field rotational crop trials were carried out at two locations in Germany and Southern France. Regions, varieties and cultivation were typical for the rotational crops radish, leaf lettuce and barley. The trials comprised two plots (one untreated and one treated with Prothioconazole 250 EC) which were protected against wild life and livestock damage as appropriate.
In both trials the untreated and treated plots were divided into three equal sub-plots on which radish, leaf lettuce and barley were planted in 2021 after a plant back interval (PBI) of 28±2 days.
Treated plots were applied once to bare soil with a target rate of 1.2 L product/ha (300 g a.s./ha).
Radish samples were taken from the entire subplot, with the exception of a 0.5 m wide strip round the edge of the subplot and at the ends of rows. Tops (foliage) and roots were separated and both were sampled by hand. If necessary, adhering soil from roots was removed. Leaf lettuce samples were taken from the entire subplot, with the exception of a 0.5 m wide strip round the edge of the subplot and at the ends of rows. Any decayed leaves, roots and soil were removed and discarded before deep freezing. Leaf lettuce samples were sampled by hand. Whole plant barley samples comprised at least 12 short lengths from rows over the entire plot. Culms were cut approx. 15 cm above the ground. Grain and straw samples were threshed mechanically (cut height 15 cm above ground level). At least 12 grab samples of grain and straw per sample were taken. Control samples were taken before treated samples. Sampling equipment was cleaned before usage. No diseased or damaged crop was collected. Duplicate samples were taken as cover. After sampling, the control samples and treated samples were kept separated by an adequate space at all times. Samples were deep frozen immediately after arrival at the test sites / test facility.
Soil samples (5 cores of 0-20 cm per sample) were taken at application (0 DAA) and planting (0 DBP) from the untreated and treated plots using manual stainless steel corers containing 20 cm plastic liners and capped with different colours marking top and bottom of each core. The cores were taken randomly across each plot, holes back-filled with soil and compacted. Samples were deep frozen immediately after arrival at the test sites / test facility.

Treated and untreated field samples were maintained in a deep frozen condition (typically -18 °C or less) and adequately separated during storage and shipment.
The maximum frozen storage period of soil samples from sampling until extraction was 153 days. The maximum frozen storage period of crop samples from sampling until extraction for analysis of prothioconazole triazole derivative metabolites was 92 days. The maximum frozen storage period of crop samples from sampling until extraction for analysis of prothioconazole metabolites was 182 days.

2. Stability of Prothioconazole and Triazole metabolites in final sample extracts

The interval from preparation of the final extracts to injection for PTZ-desthio did not exceed 24 hours. Due to the shortness of the interval any effects on the results due to a possible instability of the analyte in final sample extracts are considered to be insignificant.
The interval from preparation of the final extracts to injection for triazole metabolites in radish (leaves and roots), lettuce leaves and barley (whole plant, grain) did not exceed 24 hours. Due to the shortness of the interval any effect on the results due to a possible instability of the analyte(s) in final sample extracts are considered to be insignificant. An exception was made for barley straw, where the interval from preparation of the final extracts to injection was within 6 days. The stability of the analyte(s) in the final extracts of barley straw was proven by the corresponding procedural recovery samples, which were stored under the same conditions together with the extracts of the barley straw samples for residue analysis. The mean recovery value(s) were in the range of 70 % – 120 %. In addition, isotopically labelled internal standard was used for quantification and was added directly at the end of the sample extraction procedure. The

internal standard is considered to show the same degradation behaviour as the analyte itself so that the stability of the analyte(s) in sample extracts was not investigated.

3. Analytical part

This study comprised two analytical phases.

S21-00408-L2: Analysis of prothioconazole metabolites in plants (except TDMs):
The analytical method for analysis of PTZ-desthio followed the principles of the multi-residue method QuEChERS. In the analytical phase S21-00408-L2 of this study, samples of radish (leaves and roots), leaf lettuce (leaves) and barley (whole plant, grain and straw) were analysed for residues of prothioconazole-desthio, 3-hydroxyprothioconazole-desthio, 4-hydroxy-prothioconazole-desthio, 5-hydroxy-prothioconazole-desthio, 6-hydroxyprothioconazole-desthio, alpha-hydroxy-prothioconazole-desthio, all expressed as prothioconazole-desthio (sum of isomers).
For barley (whole plants, grain, straw) and sugar beet (roots), the analytical method was validated (full validation) following the guideline SANTE/2020/12830, Rev.1 of 24/02/2021 (section relevant to validation requirements for quantitative methods for risk assessment), during another study performed at GIRPA in 2021.
For radish (leaves, roots) and lettuce (leaves) (commodities with high water content as sugar beet roots), the analytical method was validated (reduced validation) following the guideline SANTE/2020/12830, Rev.1 of 24/02/2021 (section relevant to validation requirements for quantitative methods for risk assessment), within the analytical phase S21-00408-L2. The quantification of each analyte was performed by liquid chromatography with tandem mass spectrometry detection (LC-MS/MS). A description and validation of the analytical method is provided in dRR Part B.5, point KCP 5.1.2.

S21-00408-L1: Analysis of TDMs in plants and of prothioconazole-desthio in soil:
In the analytical phase S21-00408-L1 of this study, samples of radish (leaves and roots), leaf lettuce (leaves) and barley (whole plant, grain and straw) were analysed for residues of prothioconazole (PTZ) metabolites, namely 1,2,4-triazole (1,2,4-T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA). In addition, samples of soil were analysed for residues of prothioconazole-desthio (PTZ-desthio).
Sample extraction and determination of residues were performed according to the analytical method GRM053.01A for analytes 1,2,4-triazole (1,2,4-T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) and the multi-residue method QuEChERS (for prothioconazole-desthio in soil) that was previously validated at Eurofins Agroscience Services Chem GmbH according to SANCO/3029/99, rev. 4 for matrices soil, radish (leaves and roots), lettuce leaves and barley (whole plant, grain and straw). The applicability and suitability of the methods for matrices soil, radish (leaves and roots), lettuce leaves and barley (whole plant, grain and straw) were demonstrated by concurrent recoveries within the analytical phase S21-00408-L1. For analytes 1,2,4-triazole (1,2,4-T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) in samples of matrix radish (leaves and roots), lettuce leaves and barley (whole plant, grain and straw) quantification was performed by use of liquid chromatography-differential mobility spectrometry-tandem mass spectrometry (LC-DMS-MS/MS) detection with isotopically labelled internal standard(s).A description and validation of the analytical method is provided in dRR Part B.5, point KCP 5.1.2.

Results and discussion

Prothioconazole metabolites (except TDMs):

Residues of prothioconazole-desthio in treated samples were below the LOQ (0.01 mg/kg) in all crops and at all plant back intervals, except for one trial (S21-00408-02) where radish leaves had a residue of 0.021 mg/kg at PBI 30 days. Since application rate to bare soil was at an exaggerated rate (1.6N) and proposed application to cereals would be BBCH 65-69 when 90% interception to soil would be expected, it is concluded that these residues found are more reflective of the worst case conditions used in the study. Under proposed use conditions a no residue situation (<0.01 mg/kg) would be expected following the use of prothioconazole as shown in the confined rotational crop metabolism study.

Residues of prothioconazole (mg/kg) as sum of prothioconazole-desthio, 3-hydroxyprothioconazole-desthio, 4-hydroxyprothioconazole-desthio, 5-hydroxyprothioconazole-desthio, 6-hydroxyprothioconazole-desthio and alpha-hydroxyprothioconazole-desthio, expressed as prothioconazole-desthio were below the LOQ (0.06 mg/kg) in all crops and at all plant back intervals in treated and in untreated samples.

Table A 24: Prothioconazole residues in rotational crops

Sampling Code	Target Timing	Treatment	Sample Code	Sample Type	Sum of prothioconazole-desthio and metabolites (sum of isomers) (mg/kg)
Trial S21-00408-01 (Germany)					
S3	BBCH 49 (NCH)	U1	S21-00408-01-005A	Radish leaves	<LOD
		U1	S21-00408-01-006A	Radish roots	<LOD
		T1	S21-00408-01-007A	Radish leaves	<LOD
		T1	S21-00408-01-008A	Radish roots	<LOD
S4	BBCH 49 (NCH)	U1	S21-00408-01-009A	Lettuce leaves	<LOD
		T1	S21-00408-01-010A	Lettuce leaves	<LOD
S5	BBCH 51-55 (Forage)	U1	S21-00408-01-011A	Barley whole plant	<LOD
		T1	S21-00408-01-012A	Barley whole plant	<LOD
S6	BBCH 89 (NCH)	U1	S21-00408-01-013A	Barley grain	<LOD
		U1	S21-00408-01-014A	Barley straw	<LOD
		T1	S21-00408-01-015A	Barley grain	<LOD
		T1	S21-00408-01-016A	Barley straw	<LOD
Trial S21-00408-02 (South France)					
S3	BBCH 49 (NCH)	U1	S21-00408-02-005A	Radish leaves	<LOD
		U1	S21-00408-02-006A	Radish roots	<LOD
		T1	S21-00408-02-007A	Radish leaves	<LOQ
		T1	S21-00408-02-008A	Radish roots	<LOD
S4	BBCH 49 (NCH)	U1	S21-00408-02-009A	Lettuce leaves	<LOD
		T1	S21-00408-02-010A	Lettuce leaves	<LOD
S5	BBCH 51-55 (Forage)	U1	S21-00408-02-011A	Barley whole plant	<LOD
		T1	S21-00408-02-012A	Barley whole plant	<LOD
S6	BBCH 89 (NCH)	U1	S21-00408-02-013A	Barley grain	<LOD
		U1	S21-00408-02-014A	Barley straw	<LOD
		T1	S21-00408-02-015A	Barley grain	<LOD
		T1	S21-00408-02-016A	Barley straw	<LOD

NCH = normal commercial harvest; T1 = treated; U1= untreated

LOQ (Limit of quantification): 0.060 mg/kg expressed as prothioconazole-desthio

LOD (Limit of detection, defined as 30 % of the LOQ): 0.018 mg/kg expressed as prothioconazole-desthio

All residue results between LOD and LOQ are noted <LOQ

TDMs:

In untreated samples, residues of triazole alanine (TA), triazole lactic acid (TLA) and triazole acetic acid (TAA) were registered above the LOQ (0.01 mg/kg) in cereals but not in other crops. Residues of 1,2,4-triazole were below the LOD (0.003 mg/kg) in all samples of all crops.

Residues of triazole alanine (TA) and triazole lactic acid (TLA) in treated samples were found above the LOQ (0.01 mg/kg) in all crops, residues of triazole acetic acid (TAA) were found above the LOQ in cereals only, whereas residues of 1,2,4-triazole were below the LOD in all samples and all crops.

Table A 25: TDM residues in rotational crops

Sampling Code	Target Timing	Treatment	Sample Code	Sample Type	1,2,4-Triazole (mg/kg)	Triazole alanine (mg/kg)	Triazole acetic acid (mg/kg)	Triazole lactic acid (mg/kg)
Trial S21-00408-01 (Germany)								
S3	BBCH 49 (NCH)	U1	S21-00408-01-005A	Radish leaves	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.
		U1	S21-00408-01-006A	Radish roots	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.
		T1	S21-00408-01-007A	Radish leaves	< 0.003 n.d.	0.01	< 0.003 n.d.	< 0.003 n.d.
		T1	S21-00408-01-008A	Radish roots	< 0.003 n.d.	0.01	< 0.003 n.d.	< 0.003 n.d.
S4	BBCH 49 (NCH)	U1	S21-00408-01-009A	Lettuce leaves	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.
		T1	S21-00408-01-010A	Lettuce leaves	< 0.003 n.d.	< 0.01	< 0.003 n.d.	0.01
S5	BBCH 51-55 (Forage)	U1	S21-00408-01-011A	Barley whole plant	< 0.003 n.d.	< 0.01	< 0.003 n.d.	0.02
		T1	S21-00408-01-012A	Barley whole plant	< 0.003 n.d.	0.02	0.01	0.08
S6	BBCH 89 (NCH)	U1	S21-00408-01-013A	Barley grain	< 0.003 n.d.	0.03	0.03	< 0.003 n.d.
		U1	S21-00408-01-014A	Barley straw	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.
		T1	S21-00408-01-015A	Barley grain	< 0.003 n.d.	0.15	0.14	< 0.01
		T1	S21-00408-01-016A	Barley straw	< 0.003 n.d.	< 0.01	< 0.01	0.01
Trial S21-00408-02 (South France)								
S3	BBCH 49 (NCH)	U1	S21-00408-02-005A	Radish leaves	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.
		U1	S21-00408-02-006A	Radish roots	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.
		T1	S21-00408-02-007A	Radish leaves	< 0.003 n.d.	0.17	< 0.003 n.d.	0.03
		T1	S21-00408-02-008A	Radish roots	< 0.003 n.d.	0.10	< 0.003 n.d.	0.01
S4	BBCH 49 (NCH)	U1	S21-00408-02-009A	Lettuce leaves	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.
		T1	S21-00408-02-010A	Lettuce leaves	< 0.003 n.d.	0.02	< 0.003 n.d.	0.10
S5	BBCH 51-55 (Forage)	U1	S21-00408-02-011A	Barley whole plant	< 0.003 n.d.	< 0.01	< 0.003 n.d.	0.01
		T1	S21-00408-02-012A	Barley whole plant	< 0.003 n.d.	0.16	0.08	0.46
S6	BBCH 89 (NCH)	U1	S21-00408-02-013A	Barley grain	< 0.003 n.d.	0.04	0.04	< 0.003 n.d.
		U1	S21-00408-02-014A	Barley straw	< 0.003 n.d.	< 0.01	< 0.01	< 0.01
		T1	S21-00408-02-015A	Barley grain	< 0.003 n.d.	0.82	0.57	0.04
		T1	S21-00408-02-016A	Barley straw	< 0.003 n.d.	0.04	0.13	0.12

Sampling Code	Target Timing	Treatment	Sample Code	Sample Type	1,2,4-Triazole (mg/kg)	Triazole alanine (mg/kg)	Triazole acetic acid (mg/kg)	Triazole lactic acid (mg/kg)

NCH = normal commercial harvest; T1 = treated; U1= untreated; n.d. = not detected (below LOD set at 30 % of the LOQ)

Residues are not corrected for procedural recoveries; LOQ = limit of quantification of 0.01 mg/kg

Table A 26: Summary of the rotational crop field study 2 - 2 trials

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	**Prothioconazole**	Commercial Product (name):	Prothioconazole 250 EC
Crop/crop group:	**Soil**	Producer of commercial product:	ADAMA Makhteshim Ltd.
Responsible body for reporting (name, address)	ADAMA Makhteshim Ltd. PO Box 60, Industrial Zone 8410001 Beer Sheva Israel		
Country (of trial sites):	Germany	Indoor/Glasshouse/Outdoor:	outdoor
Content of active substance nominal (g/kg or g/L):	250 g/L	Other active substance in the formulation (common name and content):	none
Formulation (*e.g.* WP):	EC	Residues calculated as:	mg/kg prothioconazole-desthio

1 Report No. Location (region)	2 Commodity/Variety (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date (d)	7 Growth stage at last treatment or date (e) BBCH	8 Portion analysed (a)	9 Residues (mg/kg) (*)	10 PHI (days) (f)	11 Remarks: Actual Plant Back Interval (g)
				kg as/hL	Water (L/ha)	kg as/ha				PTZ-desthio		
S21-00408-01: 21709 Burweg, Lower Saxony, Germany	Soil	1) n/a 2) n/a 3) n/a	Bare soil with boom sprayer (Lechler, ID 120-02 reduced drift fan nozzles)	0.10	297	0.2971	24 Mar 2021	n/a	Soil Soil	0.02 0.02	0 DAA 29 DAA	29 (plot T1) Residues in mg/kg dry soil weight

(a) According to EPPO codes

(b) Only if relevant, n/a = not applicable

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated

(e) BBCH Monograph. Growth Stages of Plants. 1997. Blackwell. ISBN 3-8263-3152-4

(f) Minimum number of days after last application (Label pre-harvest interval. PHI. underline); DBLA = days before last application; DAA1= days after application A1

(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date

(*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg, n.d. = not detected (<LOD)

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	**Prothioconazole**	Commercial Product (name):	Prothioconazole 250 EC
Crop/crop group:	**Radish / root vegetables**	Producer of commercial product:	ADAMA Makhteshim Ltd.
Responsible body for reporting (name, address)	ADAMA Makhteshim Ltd. PO Box 60, Industrial Zone 8410001 Beer Sheva Israel		
Country (of trial sites):	Germany	Indoor/Glasshouse/Outdoor:	outdoor
Content of active substance nominal (g/kg or g/L):	250 g/L	Other active substance in the formulation (common name and content):	none
Formulation (*e.g.* WP):	EC	Residues calculated as:	mg/kg prothioconazole-desthio, PTZ-3-hydroxy-desthio, PTZ-4-hydroxy-desthio, PTZ-5-hydroxy-desthio, PTZ-6-hydroxy-desthio, PTZ-alpha-hydroxy-desthio

1 Report No. Location (region)	2 Commodity/Variety (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date (d)	7 Growth stage at last treatment or date (e) BBCH	8 Portion analysed (a)	9 Residues (mg/kg) (*)						10 PHI (days) (f)	11 Remarks: Actual Plant Back Interval (g)
				kg as/hL	Water (L/ha)	kg as/ha				PTZ-desthio	PTZ-3-hydroxy desthio	PTZ-4-hydroxy desthio	PTZ-5-hydroxy desthio	PTZ-6-hydroxy desthio	PTZ-alpha-hydroxy desthio		
S21-00408-01: 21709 Burweg, Lower Saxony, Germany	Radish / RAPSR / Lucia F1	1) 22 Apr 2021 2) n/a 3) 07 Jun 2021	Bare soil with boom sprayer (Lechler, ID 120-02 reduced drift fan nozzles)	0.10	297	0.2971	24 Mar 2021	Bare soil	Leaves Roots	<0.01 n.d.	n.d. n.d.	n.d. n.d.	n.d. n.d.	n.d. n.d.	n.d. n.d.	75 DAA 75 DAA	29 (plot T1)

(a) According to EPPO codes
(b) Only if relevant, n/a = not applicable
(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated
(d) Year must be indicated
(e) BBCH Monograph. Growth Stages of Plants. 1997. Blackwell. ISBN 3-8263-3152-4
(f) Minimum number of days after last application (Label pre-harvest interval. PHI. underline); DBLA = days before last application; DAA1= days after application A1
(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date
(*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg for each analyte, n.d. = not detected (<LOD)

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	**Prothioconazole**	Commercial Product (name):	Prothioconazole 250 EC
Crop/crop group:	**Leaf lettuce / leaf vegetables**	Producer of commercial product:	ADAMA Makhteshim Ltd.
Responsible body for reporting (name, address)	ADAMA Makhteshim Ltd. PO Box 60, Industrial Zone 8410001 Beer Sheva Israel		
Country (of trial sites):	Germany	Indoor/Glasshouse/Outdoor:	outdoor
Content of active substance nominal (g/kg or g/L):	250 g/L	Other active substance in the formulation (common name and content):	none
Formulation (*e.g.* WP):	EC	Residues calculated as:	mg/kg prothioconazole-desthio, PTZ-3-hydroxy-desthio, PTZ-4-hydroxy-desthio, PTZ-5-hydroxy-desthio, PTZ-6-hydroxy-desthio, PTZ-alpha-hydroxy-desthio

1 Report No. Location (region)	2 Commodity/Variety (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date (d)	7 Growth stage at last treatment or date (e) BBCH	8 Portion analysed (a)	9 Residues (mg/kg) (*)						10 PHI (days) (f)	11 Remarks: Actual Plant Back Interval (g)
				kg as/hL	Water (L/ha)	kg as/ha				PTZ-desthio	PTZ-3-hydroxy desthio	PTZ-4-hydroxy desthio	PTZ-5-hydroxy desthio	PTZ-6-hydroxy desthio	PTZ-alpha-hydroxy desthio		
S21-00408-01: 21709 Burweg, Lower Saxony, Germany	Leaf lettuce / LACSP / Finity red	1) 22 Apr 2021 2) n/a 3) 07 Jun 2021	Bare soil with boom sprayer (Lechler, ID 120-02 reduced drift fan nozzles)	0.10	297	0.2971	24 Mar 2021	Bare soil	Leaves	< 0.01	n.d.	n.d.	n.d.	n.d.	n.d.	75 DAA	29 (plot T1)

(a) According to EPPO codes

(b) Only if relevant, n/a = not applicable

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated

(e) BBCH Monograph. Growth Stages of Plants. 1997. Blackwell. ISBN 3-8263-3152-4

(f) Minimum number of days after last application (Label pre-harvest interval. PHI. underline); DBLA = days before last application; DAA1= days after application A1

(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date

(*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg for each analyte, n.d. = not detected (<LOD)

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	**Prothioconazole**	Commercial Product (name):	Prothioconazole 250 EC
Crop/crop group:	**Barley / cereals**	Producer of commercial product:	ADAMA Makhteshim Ltd.
Responsible body for reporting (name, address)	ADAMA Makhteshim Ltd. PO Box 60, Industrial Zone 8410001 Beer Sheva Israel		
Country (of trial sites):	Germany	Indoor/Glasshouse/Outdoor:	outdoor
Content of active substance nominal (g/kg or g/L):	250 g/L	Other active substance in the formulation (common name and content):	none
Formulation (*e.g.* WP):	EC	Residues calculated as:	mg/kg prothioconazole-desthio, PTZ-3-hydroxy-desthio, PTZ-4-hydroxy-desthio, PTZ-5-hydroxy-desthio, PTZ-6-hydroxy-desthio, PTZ-alpha-hydroxy-desthio

1 Report No. Location (region)	2 Commodity/Variety (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment (c)	5 Application rate per treatment kg as/hL	 Water (L/ha)	 kg as/ha	6 Dates of treatment(s) or no. of treatment(s) and last date (d)	7 Growth stage at last treatment or date (e) BBCH	8 Portion analysed (a)	9 Residues (mg/kg) (*) PTZ-desthio	 PTZ-3-hydroxy desthio	 PTZ-4-hydroxy desthio	 PTZ-5-hydroxy desthio	 PTZ-6-hydroxy desthio	 PTZ-alpha-hydroxy desthio	10 PHI (days) (f)	11 Remarks: Actual Plant Back Interval (g)
S21-00408-01: 21709 Burweg, Lower Saxony, Germany	Barley / HORVS / Avalon	1) 22 Apr 2021 2) n/a 3) 12 Aug 2021	Bare soil with boom sprayer (Lechler, ID 120-02 reduced drift fan nozzles)	0.10	297	0.2971	24 Mar 2021	Bare soil	Whole plant Grain Straw	n.d. n.d. n.d.	n.d. n.d. n.d.	n.d. n.d. n.d.	n.d. n.d. n.d.	n.d. n.d. n.d.	n.d. n.d. n.d.	90 DAA 141 DAA 141 DAA	29 days (plot T1)

(a) According to EPPO codes
(b) Only if relevant, n/r = not recorded
(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated
(d) Year must be indicated
(e) BBCH Monograph. Growth Stages of Plants. 1997. Blackwell. ISBN 3-8263-3152-4
(f) Minimum number of days after last application (Label pre-harvest interval. PHI. underline); DBLA = days before last application; DAA1= days after application A1
(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date
(*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg for each analyte, n.d. = not detected (<LOD)

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	**Prothioconazole**	Commercial Product (name):	Prothioconazole 250 EC
Crop/crop group:	**Radish / root vegetables**	Producer of commercial product:	ADAMA Makhteshim Ltd.
Responsible body for reporting (name, address)	ADAMA Makhteshim Ltd. PO Box 60, Industrial Zone 8410001 Beer Sheva Israel		
Country (of trial sites):	Germany	Indoor/Glasshouse/Outdoor:	outdoor
Content of active substance nominal (g/kg or g/L):	250 g/L	Other active substance in the formulation (common name and content):	none
Formulation (*e.g.* WP):	EC	Residues calculated as:	mg/kg 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA), Triazole lactic acid (TLA)

1 Report No. Location (region)	2 Commodity/Variety (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date (d)	7 Growth stage at last treatment or date (e) BBCH	8 Portion analysed (a)	9 Residues (mg/kg) (*)				10 PHI (days) (f)	11 Remarks: Actual Plant Back Interval (g)
				kg as/hL	Water (L/ha)	kg as/ha				1,2,4-T	TA	TAA	TLA		
S21-00408-01: 21709 Burweg, Lower Saxony, Germany	Radish / RAPSR / Lucia F1	1) 22 Apr 2021 2) n/a 3) 07 Jun 2021	Bare soil with boom sprayer (Lechler, ID 120-02 reduced drift fan nozzles)	0.10	297	0.2971	24 Mar 2021	Bare soil	Leaves Roots	n.d. n.d.	0.01 0.01	n.d. n.d.	n.d. n.d.	75 DAA 75 DAA	29 (plot T1)

(a) According to EPPO codes

(b) Only if relevant, n/a = not applicable

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated

(e) BBCH Monograph. Growth Stages of Plants. 1997. Blackwell. ISBN 3-8263-3152-4

(f) Minimum number of days after last application (Label pre-harvest interval. PHI. underline); DBLA = days before last application; DAA1= days after application A1

(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date

(*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg for each analyte, n.d. = not detected (<LOD)

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	**Prothioconazole**	Commercial Product (name):	Prothioconazole 250 EC
Crop/crop group:	**Leaf lettuce / leaf vegetables**	Producer of commercial product:	ADAMA Makhteshim Ltd.
Responsible body for reporting (name, address)	ADAMA Makhteshim Ltd. PO Box 60, Industrial Zone 8410001 Beer Sheva Israel		
Country (of trial sites):	Germany	Indoor/Glasshouse/Outdoor:	outdoor
Content of active substance nominal (g/kg or g/L):	250 g/L	Other active substance in the formulation (common name and content):	none
Formulation (*e.g.* WP):	EC	Residues calculated as:	mg/kg 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA), Triazole lactic acid (TLA)

1 Report No. Location (region)	2 Commodity/Variety (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date (d)	7 Growth stage at last treatment or date (e) BBCH	8 Portion analysed (a)	9 Residues (mg/kg) (*)				10 PHI (days) (f)	11 Remarks: Actual Plant Back Interval (g)
				kg as/hL	Water (L/ha)	kg as/ha				1,2,4-T	TA	TAA	TLA		
S21-00408-01: 21709 Burweg, Lower Saxony, Germany	Leaf lettuce / LACSP / Finity red	1) 22 Apr 2021 2) n/a 3) 07 Jun 2021	Bare soil with boom sprayer (Lechler, ID 120-02 reduced drift fan nozzles)	0.10	297	0.2971	24 Mar 2021	Bare soil	Leaves	n.d.	< 0.01	n.d.	0.01	75 DAA	29 (plot T1)

(a) According to EPPO codes

(b) Only if relevant, n/a = not applicable

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated

(e) BBCH Monograph. Growth Stages of Plants. 1997. Blackwell. ISBN 3-8263-3152-4

(f) Minimum number of days after last application (Label pre-harvest interval. PHI. underline); DBLA = days before last application; DAA1= days after application A1

(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date

(*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg for each analyte, n.d. = not detected (<LOD)

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	**Prothioconazole**	Commercial Product (name):	Prothioconazole 250 EC
Crop/crop group:	**Barley / cereals**	Producer of commercial product:	ADAMA Makhteshim Ltd.
Responsible body for reporting (name, address)	ADAMA Makhteshim Ltd. PO Box 60, Industrial Zone 8410001 Beer Sheva Israel		
Country (of trial sites):	Germany	Indoor/Glasshouse/Outdoor:	outdoor
Content of active substance nominal (g/kg or g/L):	250 g/L	Other active substance in the formulation (common name and content):	none
Formulation (*e.g.* WP):	EC	Residues calculated as:	mg/kg 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA), Triazole lactic acid (TLA)

1 Report No. Location (region)	2 Commodity/Variety (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date (d)	7 Growth stage at last treatment or date (e) BBCH	8 Portion analysed (a)	9 Residues (mg/kg) (*)				10 PHI (days) (f)	11 Remarks: Actual Plant Back Interval (g)
				kg as/hL	Water (L/ha)	kg as/ha				1,2,4-T	TA	TAA	TLA		
S21-00408-01: 21709 Burweg, Lower Saxony, Germany	Barley / HORVS / Avalon	1) 22 Apr 2021 2) n/a 3) 12 Aug 2021	Bare soil with boom sprayer (Lechler, ID 120-02 reduced drift fan nozzles)	0.10	297	0.2971	24 Mar 2021	Bare soil	Whole plant Grain Straw	n.d. n.d. n.d.	0.02 0.15 < 0.01	0.01 0.14 < 0.01	0.08 < 0.01 0.01	90 DAA 141 DAA 141 DAA	29 days (plot T1)

(a) According to EPPO codes

(b) Only if relevant, n/r = not recorded

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated

(e) BBCH Monograph. Growth Stages of Plants. 1997. Blackwell. ISBN 3-8263-3152-4

(f) Minimum number of days after last application (Label pre-harvest interval. PHI. underline); DBLA = days before last application; DAA1= days after application A1

(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date

(*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg for each analyte, n.d. = not detected (<LOD)

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	**Prothioconazole**	Commercial Product (name):	Prothioconazole 250 EC
Crop/crop group:	**Soil**	Producer of commercial product:	ADAMA Makhteshim Ltd.
Responsible body for reporting (name, address)	ADAMA Makhteshim Ltd. PO Box 60, Industrial Zone 8410001 Beer Sheva Israel		
Country (of trial sites):	France (South)	Indoor/Glasshouse/Outdoor:	outdoor
Content of active substance nominal (g/kg or g/L):	250 g/L	Other active substance in the formulation (common name and content):	none
Formulation (*e.g.* WP):	EC	Residues calculated as:	mg/kg prothioconazole-desthio (PTZ-desthio)

1 Report No. Location (region)	2 Commodity/Variety (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date (d)	7 Growth stage at last treatment or date (e) BBCH	8 Portion analysed (a)	9 Residues (mg/kg) (*)	10 PHI (days) (f)	11 Remarks: Actual Plant Back Interval (g)
				kg as/hL	Water (L/ha)	kg as/ha				PTZ-desthio		
S21-00408-02: 82290 Barry d'Islemade, Tarn-et-Garonne, France (South)	Soil	1) n/a 2) n/a 3) n/a	Bare soil with boom sprayer (Teejet TT110015 flat fan nozzles)	0.1202	250	0.3005	23 Mar 2021	n/a	Soil Soil	0.05 0.06	0 DAA 30 DAA	30 (plot T1)

(a) According to EPPO codes
(b) Only if relevant, n/a = not applicable
(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated
(d) Year must be indicated
(e) BBCH Monograph. Growth Stages of Plants. 1997. Blackwell. ISBN 3-8263-3152-4
(f) Minimum number of days after last application (Label pre-harvest interval. PHI. underline); DBLA = days before last application; DAA1= days after application A1
(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date
(*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg, n.d. = not detected (<LOD)

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	**Prothioconazole**	Commercial Product (name):	Prothioconazole 250 EC
Crop/crop group:	**Radish / root vegetables**	Producer of commercial product:	ADAMA Makhteshim Ltd.
Responsible body for reporting (name, address)	ADAMA Makhteshim Ltd. PO Box 60, Industrial Zone 8410001 Beer Sheva Israel		
Country (of trial sites):	France (South)	Indoor/Glasshouse/Outdoor:	outdoor
Content of active substance nominal (g/kg or g/L):	250 g/L	Other active substance in the formulation (common name and content):	none
Formulation (*e.g.* WP):	EC	Residues calculated as:	mg/kg prothioconazole-desthio, PTZ-3-hydroxy-desthio, PTZ-4-hydroxy-desthio, PTZ-5-hydroxy-desthio, PTZ-6-hydroxy-desthio, PTZ-alpha-hydroxy-desthio

1 Report No. Location (region)	2 Commodity/Variety (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date (d)	7 Growth stage at last treatment or date (e) BBCH	8 Portion analysed (a)	9 Residues (mg/kg) (*)						10 PHI (days) (f)	11 Remarks: Actual Plant Back Interval (g)
				kg as/hL	Water (L/ha)	kg as/ha				PTZ-desthio	PTZ-3-hydroxy desthio	PTZ-4-hydroxy desthio	PTZ-5-hydroxy desthio	PTZ-6-hydroxy desthio	PTZ-alpha-hydroxy desthio		
S21-00408-02: 82290 Barry d'Islemade, Tarn-et-Garonne, France (South)	Radish / RAPSR / Kiva	1) 22 Apr 2021 2) n/a 3) 25 May 2021	Bare soil with boom sprayer (Teejet TT110015 flat fan nozzles)	0.1202	250	0.3005	23 Mar 2021	Bare soil	Leaves Roots	0.021 < 0.01	0.012 n.d.	n.d. n.d.	n.d. n.d.	n.d. n.d.	n.d. n.d.	63 DAA 63 DAA	30 (plot T1)

(a) According to EPPO codes
(b) Only if relevant, n/a = not applicable
(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated
(d) Year must be indicated
(e) BBCH Monograph. Growth Stages of Plants. 1997. Blackwell. ISBN 3-8263-3152-4
(f) Minimum number of days after last application (Label pre-harvest interval. PHI. underline); DBLA = days before last application; DAA1= days after application A1
(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date
(*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg for each analyte, n.d. = not detected (<LOD)

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	**Prothioconazole**	Commercial Product (name):	Prothioconazole 250 EC
Crop/crop group:	**Leaf lettuce / leaf vegetables**	Producer of commercial product:	ADAMA Makhteshim Ltd.
Responsible body for reporting (name, address)	ADAMA Makhteshim Ltd. PO Box 60, Industrial Zone 8410001 Beer Sheva Israel		
Country (of trial sites):	France (South)	Indoor/Glasshouse/Outdoor:	outdoor
Content of active substance nominal (g/kg or g/L):	250 g/L	Other active substance in the formulation (common name and content):	none
Formulation (*e.g.* WP):	EC	Residues calculated as:	mg/kg prothioconazole-desthio, PTZ-3-hydroxy-desthio, PTZ-4-hydroxy-desthio, PTZ-5-hydroxy-desthio, PTZ-6-hydroxy-desthio, PTZ-alpha-hydroxy-desthio

1 Report No. Location (region)	2 Commodity/Variety (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date (d)	7 Growth stage at last treatment or date (e) BBCH	8 Portion analysed (a)	9 Residues (mg/kg) (*)						10 PHI (days) (f)	11 Remarks: Actual Plant Back Interval (g)
				kg as/hL	Water (L/ha)	kg as/ha				PTZ-desthio	PTZ-3-hydroxy desthio	PTZ-4-hydroxy desthio	PTZ-5-hydroxy desthio	PTZ-6-hydroxy desthio	PTZ-alpha-hydroxy desthio		
S21-00408-02: 82290 Barry d'Islemade, Tarn-et-Garonne, France (South)	Leaf lettuce / LACSP / Avenir	1) 22 Apr 2021 2) n/a 3) 14 Jun 2021	Bare soil with boom sprayer (Teejet TT110015 flat fan nozzles)	0.1202	250	0.3005	23 Mar 2021	Bare soil	Leaves	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	83 DAA	30 (plot T1)

(a) According to EPPO codes
(b) Only if relevant, n/a = not applicable
(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated
(d) Year must be indicated
(e) BBCH Monograph. Growth Stages of Plants. 1997. Blackwell. ISBN 3-8263-3152-4
(f) Minimum number of days after last application (Label pre-harvest interval. PHI. underline); DBLA = days before last application; DAA1= days after application A1
(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date
(*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg for each analyte, n.d. = not detected (<LOD)

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	**Prothioconazole**	Commercial Product (name):	Prothioconazole 250 EC
Crop/crop group:	**Barley / cereals**	Producer of commercial product:	ADAMA Makhteshim Ltd.
Responsible body for reporting (name, address)	ADAMA Makhteshim Ltd. PO Box 60, Industrial Zone 8410001 Beer Sheva Israel		
Country (of trial sites):	France (South)	Indoor/Glasshouse/Outdoor:	outdoor
Content of active substance nominal (g/kg or g/L):	250 g/L	Other active substance in the formulation (common name and content):	none
Formulation (*e.g.* WP):	EC	Residues calculated as:	mg/kg prothioconazole-desthio, PTZ-3-hydroxy-desthio, PTZ-4-hydroxy-desthio, PTZ-5-hydroxy-desthio, PTZ-6-hydroxy-desthio, PTZ-alpha-hydroxy-desthio

1 Report No. Location (region)	2 Commodity/Variety (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date (d)	7 Growth stage at last treatment or date (e) BBCH	8 Portion analysed (a)	9 Residues (mg/kg) (*)						10 PHI (days) (f)	11 Remarks: Actual Plant Back Interval (g)
				kg as/hL	Water (L/ha)	kg as/ha				PTZ-desthio	PTZ-3-hydroxy desthio	PTZ-4-hydroxy desthio	PTZ-5-hydroxy desthio	PTZ-6-hydroxy desthio	PTZ-alpha-hydroxy desthio		
S21-00408-02: 82290 Barry d'Islemade, Tarn-et-Garonne, France (South)	Barley / HORVS / Etoile	1) 22 Apr 2021 2) 25 Jun - 05 Jul 2021 3) 03 Aug 2021	Bare soil with boom sprayer (Teejet TT110015 flat fan nozzles)	0.1202	250	0.3005	23 Mar 2021	Bare soil	Whole plan Grain Straw	n.d. n.d. n.d.	n.d. n.d. n.d.	n.d. n.d. n.d.	n.d. n.d. n.d.	n.d. n.d. n.d.	n.d. n.d. n.d.	87 DAA 133 DAA 133 DAA	30 days (plot T1)

(a) According to EPPO codes
(b) Only if relevant, n/r = not recorded
(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated
(d) Year must be indicated
(e) BBCH Monograph. Growth Stages of Plants. 1997. Blackwell. ISBN 3-8263-3152-4
(f) Minimum number of days after last application (Label pre-harvest interval. PHI. underline); DBLA = days before last application; DAA1= days after application A1
(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date
(*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg for each analyte, n.d. = not detected (<LOD)

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	**Prothioconazole**	Commercial Product (name):	Prothioconazole 250 EC
Crop/crop group:	**Radish / root vegetables**	Producer of commercial product:	ADAMA Makhteshim Ltd.
Responsible body for reporting (name, address)	ADAMA Makhteshim Ltd. PO Box 60, Industrial Zone 8410001 Beer Sheva Israel		
Country (of trial sites):	France (South)	Indoor/Glasshouse/Outdoor:	outdoor
Content of active substance nominal (g/kg or g/L):	250 g/L	Other active substance in the formulation (common name and content):	none
Formulation (*e.g.* WP):	EC	Residues calculated as:	mg/kg 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA), Triazole lactic acid (TLA)

1 Report No. Location (region)	2 Commodity/Variety (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date (d)	7 Growth stage at last treatment or date (e) BBCH	8 Portion analysed (a)	9 Residues (mg/kg) (*)				10 PHI (days) (f)	11 Remarks: Actual Plant Back Interval (g)
				kg as/hL	Water (L/ha)	kg as/ha				1,2,4-T	TA	TAA	TLA		
S21-00408-02: 82290 Barry d'Islemade, Tarn-et-Garonne, France (South)	Radish / RAPSR / Kiva	1) 22 Apr 2021 2) n/a 3) 25 May 2021	Bare soil with boom sprayer (Teejet TT110015 flat fan nozzles)	0.1202	250	0.3005	23 Mar 2021	Bare soil	Leaves Roots	n.d. n.d.	0.17 0.10	n.d. n.d.	0.03 0.01	63 DAA 63 DAA	30 (plot T1)

(a) According to EPPO codes
(b) Only if relevant, n/a = not applicable
(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated
(d) Year must be indicated
(e) BBCH Monograph. Growth Stages of Plants. 1997. Blackwell. ISBN 3-8263-3152-4
(f) Minimum number of days after last application (Label pre-harvest interval. PHI. underline); DBLA = days before last application; DAA1= days after application A1
(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date
(*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg for each analyte, n.d. = not detected (<LOD)

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	**Prothioconazole**	Commercial Product (name):	Prothioconazole 250 EC
Crop/crop group:	**Leaf lettuce / leaf vegetables**	Producer of commercial product:	ADAMA Makhteshim Ltd.
Responsible body for reporting (name, address)	ADAMA Makhteshim Ltd. PO Box 60, Industrial Zone 8410001 Beer Sheva Israel		
Country (of trial sites):	France (South)	Indoor/Glasshouse/Outdoor:	outdoor
Content of active substance nominal (g/kg or g/L):	250 g/L	Other active substance in the formulation (common name and content):	none
Formulation (*e.g.* WP):	EC	Residues calculated as:	mg/kg 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA), Triazole lactic acid (TLA)

1 Report No. Location (region)	2 Commodity/Variety (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date (d)	7 Growth stage at last treatment or date (e) BBCH	8 Portion analysed (a)	9 Residues (mg/kg) (*)				10 PHI (days) (f)	11 Remarks: Actual Plant Back Interval (g)
				kg as/hL	Water (L/ha)	kg as/ha				1,2,4-T	TA	TAA	TLA		
S21-00408-02: 82290 Barry d'Islemade, Tarn-et-Garonne, France (South)	Leaf lettuce / LACSP / Avenir	1) 22 Apr 2021 2) n/a 3) 14 Jun 2021	Bare soil with boom sprayer (Teejet TT110015 flat fan nozzles)	0.1202	250	0.3005	23 Mar 2021	Bare soil	Leaves	n.d.	0.02	n.d.	0.10	83 DAA	30 (plot T1)

(a) According to EPPO codes
(b) Only if relevant, n/a = not applicable
(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated
(d) Year must be indicated
(e) BBCH Monograph. Growth Stages of Plants. 1997. Blackwell. ISBN 3-8263-3152-4
(f) Minimum number of days after last application (Label pre-harvest interval. PHI. underline); DBLA = days before last application; DAA1= days after application A1
(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date
(*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg for each analyte, n.d. = not detected (<LOD)

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	**Prothioconazole**	Commercial Product (name):	Prothioconazole 250 EC
Crop/crop group:	**Barley / cereals**	Producer of commercial product:	ADAMA Makhteshim Ltd.
Responsible body for reporting (name, address)	ADAMA Makhteshim Ltd. PO Box 60, Industrial Zone 8410001 Beer Sheva Israel		
Country (of trial sites):	France (South)	Indoor/Glasshouse/Outdoor:	outdoor
Content of active substance nominal (g/kg or g/L):	250 g/L	Other active substance in the formulation (common name and content):	none
Formulation (*e.g.* WP):	EC	Residues calculated as:	mg/kg 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA), Triazole lactic acid (TLA)

1 Report No. Location (region)	2 Commodity/Variety (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date (d)	7 Growth stage at last treatment or date (e) BBCH	8 Portion analysed (a)	9 Residues (mg/kg) (*)				10 PHI (days) (f)	11 Remarks: Actual Plant Back Interval (g)
				kg as/hL	Water (L/ha)	kg as/ha				1,2,4-T	TA	TAA	TLA		
S21-00408-02: 82290 Barry d'Islemade, Tarn–et-Garonne, France (South)	Barley / HORVS / Etoile	1) 22 Apr 2021 2) 25 Jun – 05 Jul 2021 3) 03 Aug 2021	Bare soil with boom sprayer (Teejet TT110015 flat fan nozzles)	0.1202	250	0.3005	23 Mar 2021	Bare soil	Whole plant Grain Straw	n.d. n.d. n.d.	0.16 0.82 0.04	0.08 0.57 0.13	0.46 0.04 0.12	87 DAA 133 DAA 133 DAA	30 days (plot T1)

(a) According to EPPO codes

(b) Only if relevant, n/r = not recorded

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated

(e) BBCH Monograph. Growth Stages of Plants. 1997. Blackwell. ISBN 3-8263-3152-4

(f) Minimum number of days after last application (Label pre-harvest interval. PHI. underline); DBLA = days before last application; DAA1= days after application A1

(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date

(*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg for each analyte, n.d. = not detected (<LOD)

Conclusion

Two rotational crop field trials were performed in the Northern (one) and Southern (one) EU residue zone.

At the tested plant back interval of 28±2 days, prothioconazole metabolites (sum of PTZ-desthio, 3-hydroxy-PTZ desthio, 4-hydroxy-PTZ desthio, 5-hydroxy-PTZ -desthio, 6-hydroxy-PTZ-desthio and alpha-hydroxy-PTZ-desthio, expressed as prothioconazole-desthio) were below the LOQ (0.06 mg/kg) in all treated and untreated crop commodities.

The maximum frozen storage period of crop samples from sampling until extraction for analysis of prothioconazole metabolites was 182 days.

Concerning TDMs, residues of 1,2,4-triazole were below the LOQ of 0.01 mg/kg in all crops. Residues of triazole acetic acid (TAA) were found above the LOQ of 0.01 mg/kg solely in cereals. Residues of triazole alanine (TA) and triazole lactic acid (TLA) were found above the LOQ (0.01 mg/kg) in part of the samples across all crops and all plant back intervals:

- Highest residues found at 28±2 days PBI in treated radish (roots) were found at 0.01 mg/kg (TLA) and 0.10 mg/kg (TA).
- Highest residues found at 28±2 days PBI in treated leaf lettuce were found at 0.02 mg/kg TA and 0.10 mg/kg TLA.
- Highest residues at 28±2 days PBI in treated barley (grain) were found to be 0.04 mg/kg TLA, 0.82 mg/kg TA and 0.57 mg/kg TAA.
- Highest residues found at 28±2 days PBI in treated barley (straw) were in 0.04 mg/kg TA, 0.13 TAA and 0.12 mg/kg TLA.

However, it has to be stated that also in some of the untreated samples background levels of TA, TLA and TAA exceeding the LOQ (0.01 mg/kg) were found.

The maximum frozen storage period of crop samples from sampling until extraction for analysis of prothioconazole triazole derivative metabolites was 92 days.

Overall conclusion on the magnitude of residues in representative succeeding crops

In both studies, residues of prothioconazole as sum of PTZ-desthio, 3- hydroxy-PTZ desthio, 4-hydroxy-PTZ desthio, 5-hydroxy-PTZ -desthio, 6-hydroxy-PTZ-desthio and alpha-hydroxy-PTZ-desthio (expressed as prothioconazole-desthio) were below the LOQ (0.06 mg/kg) in all treated and untreated crop commodities and at all plant back intervals.

The second reduced rotational crop field study (KCA 6.6.2/02) was conducted to address the insufficient stability period for 1,2,4-T in the first study (KCA 6.6.2/01). The rationale for design of this second study is provided in a position paper (KCA 6.6.2/03) submitted with this application.

Results from the second study confirmed the findings of the first study (KCA 6.6.2/01); all residues of 1,2,4-T were <0.01 mg/kg in treated and control samples. Other TDMs were also in a similar range, being <0.01 - 0.82 mg/kg for TA, <0.01 - 0.14 mg/kg for TAA and <0.01 - 0.46 mg/kg for TLA. Again, some control samples also contained residues of TA, TAA and TLA but generally at lower levels than in treated samples.

In conclusion, all samples were analysed for 1,2,4-T within 182 days, complying with the demonstrated freezer storage period of 6 months for high water content crops and 12 months for cereal grain and straw. The new data confirm the findings of both the confined rotational crop study and the first rotational crop field trials; residues of 1,2,4-T would not be expected above the LOQ (0.01 mg/kg) in rotational crops, even when applied at exaggerated dose rates.

The following STMRs/HRs can be derived from the two studies:

Table A 27: Overview of the STMRs/HRs of 1,2,4-T in treated rotational crop samples at normal commercial harvest

	PBI 30 (KCA 6.6.2/01 & /02)			PBI 120 (KCA 6.6.2/01)			PBI 270 (KCA 6.6.2/01)		
Commodity	**Residues**	**STMR**	**HR**	**Residues**	**STMR**	**HR**	**Residues**	**STMR**	**HR**
Radish leaves	<0.01, <0.01, <0.01, <0.01, <0.01, <0.01	0.01	0.01	<0.01, <0.01, <0.01, <0.01	0.01	0.01	<0.01, <0.01, <0.01, <0.01	0.01	0.01
Radish roots	<0.01, <0.01, <0.01, <0.01, <0.01, <0.01	0.01	0.01	<0.01, <0.01, <0.01, <0.01	0.01	0.01	<0.01, <0.01, <0.01, <0.01	0.01	0.01
Lettuce leaves	<0.01, <0.01, <0.01, <0.01, <0.01, <0.01	0.01	0.01	<0.01, <0.01, <0.01, <0.01	0.01	0.01	<0.01, <0.01, <0.01, <0.01	0.01	0.01
Barley grain	<0.01, <0.01, <0.01, <0.01, <0.01, <0.01	0.01	0.01	<0.01, <0.01, <0.01, <0.01	0.01	0.01	<0.01, <0.01, <0.01, <0.01	0.01	0.01
Barley straw	<0.01, <0.01, <0.01, <0.01, <0.01, <0.01	0.01	0.01	<0.01, <0.01, <0.01, <0.01	0.01	0.01	<0.01, <0.01, <0.01, <0.01	0.01	0.01

Table A 28: Overview of the STMRs/HRs of TA in treated rotational crop samples at normal commercial harvest

	PBI 30 (KCA 6.6.2/01 & /02)			PBI 120 (KCA 6.6.2/01)			PBI 270 (KCA 6.6.2/01)		
Commodity	**Residues**	**STMR**	**HR**	**Residues**	**STMR**	**HR**	**Residues**	**STMR**	**HR**
Radish leaves	0.05, 0.27, 0.18, <0.01, 0.01, 0.17	0.11	0.27	0.06, 0.10, 0.14, <0.01	0.08	0.14	0.07, 0.12, 0.22, <0.01	0.095	0.22
Radish roots	0.04, 0.12, 0.04, <0.01, 0.01, 0.10	0.04	0.12	0.04, 0.04, 0.05, <0.01	0.04	0.05	0.05, 0.07, 0.07, <0.01	0.06	0.07
Lettuce leaves	<0.01, 0.03, 0.02, <0.01, <0.01, 0.02	0.015	0.03	<0.01, 0.01, 0.02, <0.01	0.01	0.02	<0.01, 0.01, 0.02, <0.01	0.01	0.02
Barley grain	0.17, 0.41, 0.28, 0.14, 0.15, 0.82	0.225	0.82	0.18, 0.28, 0.21, 0.11	0.195	0.28	0.15, 0.16, 0.28, 0.14	0.155	0.28
Barley straw	0.03, 0.04, 0.03, <0.01, <0.01, 0.04	0.03	0.04	0.03, 0.05, 0.01, <0.01	0.02	0.05	0.03, 0.04, 0.02, <0.01	0.025	0.04

Table A 29: Overview of the STMRs/HRs of TAA in treated rotational crop samples at normal commercial harvest

	PBI 30 (KCA 6.6.2/01 & /02)			PBI 120 (KCA 6.6.2/01)			PBI 270 (KCA 6.6.2/01)		
Commodity	**Residues**	**STMR**	**HR**	**Residues**	**STMR**	**HR**	**Residues**	**STMR**	**HR**
Radish leaves	<0.01, <0.01, <0.01, <0.01, <0.01, <0.01	0.01	0.01	<0.01, <0.01, <0.01, <0.01	0.01	0.01	<0.01, <0.01, <0.01, <0.01	0.01	0.01
Radish roots	<0.01, <0.01, <0.01, <0.01, <0.01, <0.01	0.01	0.01	<0.01, <0.01, <0.01, <0.01	0.01	0.01	<0.01, <0.01, <0.01, <0.01	0.01	0.01
Lettuce leaves	<0.01, <0.01, <0.01, <0.01, <0.01, <0.01	0.01	0.01	<0.01, <0.01, <0.01, <0.01	0.01	0.01	<0.01, <0.01, <0.01, <0.01	0.01	0.01
Barley grain	0.10, 0.55, 0.33, 0.11, 0.14, 0.57	0.235	0.57	0.10, 0.29, 0.28, 0.08	0.19	0.29	0.09, 0.20, 0.32, 0.09	0.145	0.32
Barley straw	0.05, 0.40, 0.22, 0.03, <0.01, 0.13	0.09	0.40	0.04, 0.24, 0.14, 0.02	0.09	0.24	0.04, 0.20, 0.17, 0.02	0.105	0.20

Table A 30: Overview of the STMRs/HRs of TLA in treated rotational crop samples at normal commercial harvest

	PBI 30 (KCA 6.6.2/01 & /02)			PBI 120 (KCA 6.6.2/01)			PBI 270 (KCA 6.6.2/01)		
Commodity	**Residues**	**STMR**	**HR**	**Residues**	**STMR**	**HR**	**Residues**	**STMR**	**HR**
Radish leaves	<0.01, 0.13, 0.01, <0.01, <0.01, 0.03	0.01	0.13	<0.01, 0.05, 0.02, <0.01	0.015	0.05	0.02, 0.05, 0.02, <0.01	0.02	0.05
Radish roots	<0.01, 0.02, 0.02, <0.01, <0.01, 0.01	0.01	0.02	<0.01, <0.01, 0.02, <0.01	0.01	0.02	<0.01, <0.01, 0.02, <0.01	0.01	0.02

	PBI 30 (KCA 6.6.2/01 & /02)			**PBI 120 (KCA 6.6.2/01)**			**PBI 270 (KCA 6.6.2/01)**		
Commodity	**Residues**	**STMR**	**HR**	**Residues**	**STMR**	**HR**	**Residues**	**STMR**	**HR**
Lettuce leaves	0.04, 0.19, 0.10, <0.01, 0.01, 0.10	0.07	0.19	0.04, 0.12, 0.10, <0.01	0.07	0.12	0.04, 0.09, 0.10, <0.01	0.065	0.1
Barley grain	<0.01, 0.01, 0.01, <0.01, <0.01, 0.04	0.01	0.04	<0.01, 0.01, 0.01, <0.01	0.01	0.01	<0.01, <0.01, 0.02, <0.01	0.01	0.02
Barley straw	0.06, 0.45, 0.28, 0.06, 0.01, 0.12	0.09	0.45	0.06, 0.20, 0.21, 0.04	0.13	0.21	0.05, 0.15, 0.27, 0.02	0.10	0.27

A 2.1.8 Other/Special Studies

No studies are conducted or submitted.

A 2.2 Fluxapyroxad

A 2.2.1 Stability of residues

A 2.2.1.1.1.1 Study 1

Comments of zRMS:	The storage stability of fluxapyroxad was demonstrated in Phacelia flowers, nectar and pollen at ≤ -18 °C in the dark over a storage period of up to 6 months. Sample extraction and determination of residues was performed according to an analytical procedure that was previously validated for fluxapyroxad (Study No. S21-00223 (MAC-2110V): "Validation of an Analytical Method for Determination of Fluxapyroxad in Flowers, Nectar and Pollen", Eurofins Agroscience Services Chem GmbH, Germany (10 Jun 2021)). The LOQ was set at 0.01 mg/kg for fluxapyroxad. The study is acceptable.

Reference:	KCA 6.1/04
Report:	Storage Stability of Fluxapyroxad in Flowers, Nectar and Pollen under Deep Frozen Conditions Lindner, M., 2021 Study no.: S21-00224, sponsor no.: 000107309
Guideline(s):	EC Guideline 7032/VI/95, Appendix H; OECD 506, 2007
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Study objective
The study objective was to obtain data about the storage stability of fluxapyroxad in flowers, nectar and pollen at ≤ -18°C (target) in the dark over a storage period of up to 6 months.

Materials and methods
Matrix types, sample origin and preparation before extraction are summarised in the following:

Matrix Types	Preparation	Origin
Phacelia Flowers	The sample material was milled with dry ice using a laboratory mill (batch mill with disposable grinding chamber) before taking a representative subsample for analysis.	supplied by the Test Facility
Nectar Surrogate	Instead of nectar a 36 % sucrose solution in water was used as surrogate. The sample material was shaken/inverted before taking subsamples.	supplied by the Test Facility
Pollen	The sample material was carefully homogenised by use of an appropriate glass rod or spatula before taking a representative subsample for analysis. Further homogenisation was done upon sample extraction.	supplied by the Test Facility

The fortification level for storage samples was at ten times the limit of quantification (10x LOQ) of the method (i.e. 0.10 mg/kg) on aliquots of homogenised control sample material. All samples used for assessment of storage stability (storage samples) were fortified with fluxapyroxad. Storage samples were kept at ≤ -18°C and analysed either immediately after fortification (0 days) or after frozen storage of 1, 3 and 6 months. Day 0 testing was accompanied by analysis of a control sample while the testing after each storage interval was accompanied by analysis of a control sample and procedural recovery samples.

Sample extraction and determination of residues was performed according to an analytical procedure that was previously validated for fluxapyroxad in flowers, nectar and pollen[2]. For further details on method validation, please refer to dRR Part B.5, point KCP 5.1.2.

Samples of flowers, nectar surrogate and pollen were extracted with methanol/aqueous L-cystein-solution (50 mg/L)/formic acid (50+50+0.5, v+v+v). The extraction procedure is based on the QuPPe-PO-Method but with L-cystein added. After shaking on a platform shaker for 15 minutes the samples were centrifuged and an aliquot was transferred into an HPLC-Vial. For pollen an additional homogenisation step with a miniaturised cell disruption system (FastPrep) was included to the extraction procedure. Quantification was performed by use of LC-MS/MS detection.

The validated limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for each matrix with a limit of detection (LOD) set at 0.003 mg/kg (30% of the LOQ).

Results and discussions

The residues levels detected in the storage samples allow the monitoring of the stability of the analyte upon storage. The values were as given in the following table.

For fluxapyroxad the mean recovery for samples extracted without any storage (i.e. day 0 storage samples and procedural recoveries) was 91% for flowers, 93% for nectar surrogate and 100% for pollen. These values demonstrate satisfying analytical performance for all analytes and matrices while analysing the storage samples.

For all matrices, the recoveries relative to the initial mean recovery at day 0 were ≥ 70% at any testing interval.

The maximum storage interval of final sample extracts at typically 1°C to 10°C from extraction to injection to LC-MS/MS was 2 days.

[2] Study No. S21-00223 (MAC-2110V): “Validation of an Analytical Method for Determination of Fluxapyroxad in Flowers, Nectar and Pollen”, Eurofins Agroscience Services Chem GmbH, Germany (10 Jun 2021).

Table A 31: Stability of fluxapyroxad in flowers, nectar surrogate and pollen following storage at ≤ -18°C

Storage				Residues and recoveries in specimens stored frozen (not corrected for procedural recoveries)						Residues and recoveries in specimens stored frozen (recovery corrected)		
				Uncorrected residue results (mg/kg)					% corrected results with day 0 as 100 %[1]	Procedural recovery of freshly spiked control sample (%) (mean)	Corrected results (corrected for procedural recovery)	
Matrix	**Analyte**	**Level (nominal fortification)** (mg/kg)	**Nominal storage interval** (months)	**sample 1**	**sample 2**	**sample 3**	**mean**	**Residues after storage** (mean, % of nominal spiking level)			**Residues after storage** mean[2] (mg/kg)	**Residues after storage** mean[3] (% of nominal spiking level)
Flowers	Fluxapyroxad	0.1	0	0.089	0.096	0.092	0.092	89, 96, 92 (92)	-	-	-	-
		0.1	1	0.086	0.090	NA	0.088	86, 90 (88)	95	96, 95 (96)	0.092	92
		0.1	3	0.100	0.097		0.099	100, 97 (99)	107	90, 93 (92)	0.108	108
		0.1	6	0.085	0.082		0.084	85, 82 (84)	90	84, 81 (83)	0.101	101
Nectar surrogate	Fluxapyroxad	0.1	0	0.096	0.100	0.091	0.096	96, 100, 91 (96)	-	-	-	-
		0.1	1	0.104	0.100	NA	0.102	104, 100 (102)	107	96, 109 (103)	0.099	100
		0.1	3	0.099	0.105		0.102	99, 105 (102)	107	91, 85 (88)	0.116	116
		0.1	6	0.102	0.093		0.098	102, 93 (98)	102	84, 86 (85)	0.115	115
Pollen	Fluxapyroxad	0.1	0	0.099	0.103	0.098	0.100	99, 103, 98 (100)	-	-	-	-
		0.1	1	0.107	0.099	NA	0.103	107, 99 (103)	103	103, 102 (103)	0.100	100
		0.1	3	0.105	0.101		0.103	105, 101 (103)	103	99, 102 (101)	0.102	102
		0.1	6	0.103	0.103		0.103	103, 103 (103)	103	97, 100 (99)	0.104	105

[1] (mean at x months) / (mean at 0 month) * 100
[2] (mean at x months) / (procedural recoveries at x months) * 100
[3] (mean, corrected for procedural recovery) / (nominal fortification) * 100

Conclusion
With regard to selectivity, accuracy and precision, the analytical method was applied successfully for each analytical set when analysing the storage samples.

The study is deemed sufficient for assessing the stability of fluxapyroxad in flowers, nectar surrogate and pollen upon storage at ≤ -18 °C for 6 months.

For all matrices the average amount of analyte recovered relative to the initial recovery at day 0 was ≥ 70% after 6 months of storage.

A 2.2.1.1.2 Storage stability of residues in animal products

No new study submitted.

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

No new studies are conducted or submitted.

A 2.2.3 Magnitude of residues in plants

A 2.2.3.1 Wheat, triticale, rye (KCA 6.3.1)

Table A 32: Comparison of intended and critical EU GAPs (fluxapyroxad)

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Wheat					
cGAP, N-EU (EFSA, 2012; France, 2018; EFSA 2020)	2	0.0417-0.125 kg as/ha	21 days	25-69	35
cGAP, US (import) (EFSA, 2020)	2	0.100 kg as/ha	-	-	21
Intended cGAP (1)	1	93.75 g as/ha	-	30-69	n.a.

~~*Critical GAP number(s) in accordance with column 0 of **Błąd! Nie można odnaleźć źródła odwołania.**.~~
n.a. Not applicable

A 2.2.3.1.1 Wheat study 1

Comments of zRMS:	The study of Le Mineur, A., 2022a (Report No.: BPL21/954/GC) on prothioconazole only has been evaluated in Registration Report for ADM.03500.F.2.B on March 2023 by zRMS-PL. Fluxapyroxad data are evaluated in this submission. Four field trials were conducted in Northern Europe to determine the residue level of fluxapyroxad and their respective metabolites in specimens of wheat grain and straw following one foliar application of ADM.03503.F.1.A (150 g/L of Prothioconazole and 75 g/L of Fluxapyroxad). The target dose rate of test item ADM.03503.F.1.A was 1.25 L/ha (187.5 g/ha of Prothioconazole and 93.75 g/ha of Fluxapyroxad). Application was performed at BBCH 69. Specimens of grain and straw were generated at harvest stage BBCH 89 from all the field trials performed. Fluxapyroxad In seed specimens taken at normal commercial harvest residues of fluxapyroxad were between 0.026 and 0.049 mg/kg.

	The analytical method has been demostrated to be reliable and accurate procedure for the determination of fluxapyrozad, M700F002, M700F008 and M700F048 in wheat (grain and straw). The method complies withe the guideline SANTE/2020/12830, Rev.1. All the analytes were determined by LC-MS/MS using a quantitation and confirmation ion. The LOQ of each analyte was at 0.01 mg/kg for each matrix. The storage duration (interval between sampling and extraction date) was 97 days for the determination of fluxapyroxad and its metabolites. Sufficient stability data are available to support the residue data presented in this study. The study is acceptable.

Reference:	KCA 6.3.1/03
Report:	Residue study of Prothioconazole and Fluxapyroxad and their respective metabolites in wheat Raw Agricultural Commodities after foliar application of ADM.03503.F.1.A under field conditions –Northern Europe – 2021, Le Mineur, A., 2022 Report no.: BPL21/954/GC, sponsor no.: 000107608
Guideline(s):	OECD 509 - adopted 7 September 2009; ENV/JM/MONO(2011)50/REV1, OECD Guidance Document on Crop Field Trials - No. 66; SANTE/2020/12830, Rev.1, February 2021; ENV/JM/MONO(2007)17, OECD guidance document on pesticide residue analytical methods
Deviations:	None with impact on study results
GLP:	Yes
Acceptability:	Yes

Table A 33: Summary of the wheat study 1

Crop residue data from supervised field trials		**Reference no.:**	**KCA 6.3.1/03**
Active ingredient (common name and content):	Fluxapyroxad, nominal 75 g/L (actual 77.4 g/L) Prothioconazole, nominal 150 g/L (actual 148 g/L)	Commercial product (name/code):	ADM.3503.F.1.A
Crop/crop group:	Wheat / Cereals	Formulation (e.g. SC):	EC
Country:	France, Germany, Hungary, Poland	Other active substance in the formulation:	none
Indoor/outdoor:	Outdoor	Residues calculated as:	**Fluxapyroxad (mg/kg)** **M700F002 (mg/kg)** **M700F008 (mg/kg)** **M700F048 (mg/kg)**
Responsible body for reporting (name, address):	ADAMA MAKHTESHIM Ltd. Israel		

1	2	3	4			5	6	7	8.1	8.2	8.3		9		10
Trial No./ Location/ EU zone/ Year	**Commodity/ Variety** (a)	**Date of 1.Sowing or planting 2.Flowering 3. Harvest** (b)	**Application rate per treatment**			**Dates of treatment or no. of treatments and last date** (d)	**Growth stage at last treatment or date**	**Portion analysed**	**Residues (mg/kg)**				**Assessment**		**Details on trial(s)** (f)
			kg a.s./ ha (c)	**Water (L/ha)**	**kg a.s./ hL**				**Fluxa-pyroxad**	**M700-F002**	**M700-F008**	**M700-F048**	**Timing (BBCH)**	**DALA (days)** (e)	
BPL21/954/GC-01-FR 10 600 La Chapelle-Saint-Luc France N-EU 2020/2021	Winter wheat (TRZAW)/ Pastoral	1. 20/10/2020 2. 28/05/-12/06/2021 3. 24/07/2021	FXD: 0.093 PTZ: 0.177	288	FXD: 0.032 PTZ: 0.062	10/06/2021	BBCH 69	Grain	0.049	<0.01 (nd)	<0.01	<0.01 (nd)	89	50	Analytical methods: BASF Method N° L0137/01, LC-MS/MS; For method validations please refer to dRR Part B.5, point KCP 5.1.2.
								Straw	0.63	<0.01 (nd)	0.27	<0.01			
BPL21/954/GC-02-GE 74861 Kressbach Germany N-EU 2020/2021	Winter wheat (TRZAW)/ Kometus	1. 20/10/2020 2. 07/06/-14/06/2021 3. 29/07/-30/07/2021	FXD: 0.098 PTZ: 0.188	356	FXD: 0.028 PTZ: 0.053	15/06/2021	BBCH 69	Grain	0.035	<0.01 (nd)	<0.01	<0.01 (nd)	89	44	LOQ: 0.01 mg/kg (for each fluxapyroxad, M700F002, M700F008, M700F048)
								Straw	1.3	<0.01 (nd)	0.24	<0.01			

1	2	3	4			5	6	7	8.1	8.2	8.3		9		10
Trial No./ Location/ EU zone/ Year	**Commodity/ Variety** (a)	**Date of 1.Sowing or planting 2.Flowering 3. Harvest** (b)	**Application rate per treatment**			**Dates of treatment or no. of treatments and last date** (d)	**Growth stage at last treatment or date**	**Portion analysed**	**Residues (mg/kg)**				**Assessment**		**Details on trial(s)** (f)
			kg a.s./ ha (c)	**Water (L/ha)**	**kg a.s./ hL**				**Fluxa-pyroxad**	**M700-F002**	**M700-F008**	**M700-F048**	**Timing (BBCH)**	**DALA (days)** (e)	
BPL21/954/GC-03-HU 2340 Kiskunlacháza Hungary N-EU 2021	Spring wheat (TRZAS)/ Mv Pirkadat	1. 16/03/2021 2. 09/06/-15/06/2021 3. 12/07/-15/07/2021	FXD: 0.094 PTZ: 0.181	293	FXD: 0.032 PTZ: 0.062	15/06/2021	BBCH 69	Grain Straw	0.026 2.9	<0.01 (nd) <0.01 (nd)	<0.01 (nd) 0.026[#]	<0.01 (nd) <0.01 (nd)	89	28	LOD: 0.003 mg/kg (for each fluxapyroxad, M700F002, M700F008, M700F048). Max. sample storage time: 97 days (sampling to extraction). Results in all untreated specimens were below LOD. [#] Mean of two injections
BPL21/954/GC-04-PL 98 300 Masłowice Poland N-EU 2021	Spring wheat (TRZAS)/N imfa C1	1. 05/03/2021 2. 25/06/-04/07/2021 3. 26/07/2021	FXD: 0.097 PTZ: 0.186	301	FXD: 0.032 PTZ: 0.062	02/07/2021	BBCH 69	Grain Straw	0.043 5.0	<0.01 (nd) <0.01 (nd)	<0.01 (nd) 0.063	<0.01 (nd) <0.01 (nd)	89	24	

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) These values are actual rate of active substance(s) as they were calculated with the actual concentration of the active substance(s)
(d) Year must be indicated
(e) Days after last application.
(f) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
nd not detectable
LOQ Limit of quantification
LOD Limit of detection

A 2.2.3.1.2 Barley

Table A 34: Comparison of intended and critical EU GAPs in barley (fluxapyroxad)

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Barley					
cGAP, N-EU (EFSA, 2012; France, 2018; EFSA 2020)	2	0.0417-0.125 kg as/ha	21 days	25-69	35
cGAP, US (import) (EFSA, 2020)	2	0.100 kg as/ha	-	-	21
Intended cGAP (2)	1	93.75 g as/ha	-	30-65	n.a.

~~*Critical GAP number(s) in accordance with column 0 of **Błąd! Nie można odnaleźć źródła odwołania.**.~~
n.a. Not applicable

A 2.2.3.1.3 Barley study 1

Comments of zRMS:	The study of Huaulmé, J.-M., 2022a (Report No.: BPL21/962/GC) on prothioconazole only has been evaluated in Registration Report for ADM.03500.F.2.B on March 2023 by zRMS-PL . Fluxapyroxad data are evaluated in this submission. Four field trials were conducted in Northern Europe to determine the residue level of fluxapyroxad and their respective metabolites in specimens of barley grain and straw following one foliar application of ADM.03503.F.1.A (150 g/L of Prothioconazole and 75 g/L of Fluxapyroxad). The target dose rate of test item ADM.03503.F.1.A was 1.25 L/ha (187.5 g/ha of Prothioconazole and 93.75 g/ha of Fluxapyroxad). Application was performed at BBCH 65. Specimens of grain and straw were generated at harvest stage BBCH 89 from all the field trials performed. <u>Fluxapyroxad</u> In seed specimens taken at normal commercial harvest residues of fluxapyroxad were between 0.11 and 0.38 mg/kg. The analytical method has been demostrated to be reliable and accurate procedure for the determination of fluxapyrozad, M700F002, M700F008 and M700F048 in barley (grain and straw). The method complies withe the guideline SANTE/2020/12830, Rev.1. All the analytes were determined by LC-MS/MS using a quantitation and confirmation ion. The LOQ of each analyte was at 0.01 mg/kg for each matrix. The storage duration (interval between sampling and extraction date) was 111 days for the determination of fluxapyroxad and its metabolites. Sufficient stability data are available to support the residue data presented in this study. The study is acceptable.

Reference:	KCA 6.3.2/06
Report:	Residue study of fluxapyroxad and prothioconazole and their metabolites in barley Raw Agricultural Commodities after application of ADM.03503.F.1.A under field conditions –Northern Europe - 2021, Huaulmé, J.M., 2022, Report no.: BPL21/962/GC, sponsor no.: 000107616
Guideline(s):	EC working document 7029/VI/95 rev. 5 (22/07/1997) Appendix B; EC guideline 1607/VI/97 rev.2 (10/06/1999); OECD 509 - adopted 7 September 2009; SANTE/2020/12830, Rev.1, February 2021;

	ENV/JM/MONO(2007)17, OECD guidance document on pesticide residue analytical methods
Deviations:	None
GLP:	Yes
Acceptability:	Yes

Table A 35: Summary of the barley study 1

Crop residue data from supervised field trials		**Reference no.:**	**KCA 6.3.2/06**
Active ingredient (common name and content):	Fluxapyroxad, nominal 75 g/L (actual 77.4 g/L) Prothioconazole, nominal 150 g/L (actual 148 g/L)	Commercial product (name/code):	ADM.3503.F.1.A
Crop/crop group:	Barley / Cereals	Formulation (e.g. SC):	EC
Country:	France, Germany, Hungary, Poland	Other active substance in the formulation:	none
Indoor/outdoor:	Outdoor	Residues calculated as:	**Fluxapyroxad (mg/kg)** **M700F002 (mg/kg)** **M700F008 (mg/kg)** **M700F048 (mg/kg)**
Responsible body for reporting (name, address):	ADAMA MAKHTESHIM Ltd. Israel		

1	2	3	4			5	6	7	8.1	8.2	8.3		9		10
Trial No./ Location/ EU zone/ Year	**Commodity/ Variety** (a)	**Date of 1.Sowing or planting 2.Flowering 3. Harvest** (b)	**Application rate per treatment**			**Dates of treatment or no. of treatments and last date** (d)	**Growth stage at last treatment or date**	**Portion analysed**	**Residues (mg/kg)**				**Assessment**		**Details on trial(s)** (f)
			kg a.s./ ha (c)	**Water (L/ha)**	**kg a.s./ hL**				**Fluxapyroxad**	**M700F002**	**M700F008**	**M700F048**	**Timing (BBCH)**	**DALA (days)** (e)	
BPL21/962/GC-01-FR 10600 La Chapelle Saint Luc France N-EU 2021	Spring barley (HORVS)/ Planet	1. 27/03/2021 2. 16/06/-25/06/2021 3. 30/07/2021	FXD: 0.098 PTZ: 0.187	303	FXD: 0.032 PTZ: 0.062	21/06/2021	BBCH 65	Grain Straw	<u>0.18</u> <u>0.52</u>[#]	<0.01 (nd) <0.01 (nd)	<0.01 0.011	<0.01 (nd) <0.01 (nd)	89	39	Analytical methods: BASF Method N° L0137/01, LC-MS/MS; For method validations refer to dRR Part B.5, point KCP 5.1.2. LOQ: 0.01 mg/kg (for each fluxapyroxad, M700F002, M700F008,
BPL/21/962/GC-02-GE 74861 Kressbach Germany N-EU 2020/2021	Winter barley (HORVW)/ Su Vireni	1. 22/10/2020 2. 23/05/-31/05/2021 3. 29/07/-30/07/2021	FXD: 0.090 PTZ: 0.172	303	FXD: 0.028 PTZ: 0.053	28/05/2021	BBCH 65	Grain Straw	<u>0.16</u> <u>0.67</u>[#]	<0.01 (nd) <0.01 (nd)	0.012 0.023	<0.01 (nd) <0.01 (nd)	89	62	

Crop residue data from supervised field trials		**Reference no.:**	**KCA 6.3.2/06**
Active ingredient (common name and content):	Fluxapyroxad, nominal 75 g/L (actual 77.4 g/L) Prothioconazole, nominal 150 g/L (actual 148 g/L)	Commercial product (name/code):	ADM.3503.F.1.A
Crop/crop group:	Barley / Cereals	Formulation (e.g. SC):	EC
Country:	France, Germany, Hungary, Poland	Other active substance in the formulation:	none
Indoor/outdoor:	Outdoor	Residues calculated as:	**Fluxapyroxad (mg/kg)** **M700F002 (mg/kg)** **M700F008 (mg/kg)** **M700F048 (mg/kg)**
Responsible body for reporting (name, address):	ADAMA MAKHTESHIM Ltd. Israel		

1	2	3	4			5	6	7	8.1	8.2	8.3		9		10
Trial No./ Location/ EU zone/ Year	**Commodity/ Variety** (a)	**Date of 1.Sowing or planting 2.Flowering 3. Harvest** (b)	**Application rate per treatment**			**Dates of treatment or no. of treatments and last date** (d)	**Growth stage at last treatment or date**	**Portion analysed**	**Residues (mg/kg)**				**Assessment**		**Details on trial(s)** (f)
			kg a.s./ ha (c)	**Water (L/ha)**	**kg a.s./ hL**				**Fluxapyroxad**	**M700F002**	**M700F008**	**M700F048**	**Timing (BBCH)**	**DALA (days)** (e)	
BPL21/962/GC-03-HU 2340 Kiskunlachaza Hungary N-EU 2021	Spring barley (HORVS)/ Conchita	1. 16/03/2021 2. 11/06/-17/06/2021 3. 12/07/-15/07/2021	FXD: 0.092 PTZ: 0.177	287	FXD: 0.032 PTZ: 0.062	15/06/2021	BBCH 65	Grain	<u>0.38</u>	<0.01 (nd)	0.014	<0.01 (nd)	89	28	M700F048) LOD: 0.003 mg/kg (for each fluxapyroxad, M700F002, M700F008, M700F048).
								Straw	<u>1.6</u>	<0.01 (nd)	0.11	<0.01			
BPL/21/962/GC-04-PL Krościna Mała, 55-110 Prusice Poland N-EU 2021	Spring barley (HORVS)/ KWS Harris	1. 08/03/2021 2. 15/06/-23/06/2021 3. 31/07/2021	FXD: 0.097 PTZ: 0.186	302	FXD: 0.032 PTZ: 0.062	18/06/2021	BBCH 65	Grain	<u>0.11</u>	<0.01 (nd)	<0.01	<0.01 (nd)	89	43	Max. sample storage time: 111 days (sampling to extraction). Results in all untreated specimens were below LOD. [#] Mean of two injections
								Straw	<u>1.3</u>	<0.01 (nd)	0.077	<0.01 (nd)			

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) These values are actual rate of active substance(s) as they were calculated with the actual concentration of the active substance(s)

(d) Year must be indicated
(e) Days after last application.
(f) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
nd not detectable
LOQ Limit of quantification
LOD Limit of detection

A 2.2.4 Magnitude of residues in livestock

No new studies are conducted or submitted.

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

No new studies are conducted or submitted.

A 2.2.6 Magnitude of residues in representative succeeding crops

No new studies are conducted or submitted.

A 2.2.7 Other/Special Studies

No new studies are submitted.

Appendix 3 Pesticide Residue Intake Model (PRIMo)

A 3.1 TMDI calculations

Prothioconazole except TDMs

Prothioconazole: prothioconazole-desthio (sum of isomers) (F)			
LOQs (mg/kg) range from:	**0.01**	to:	**0.05**
Toxicological reference values			
ADI (mg/kg bw/day):	**0.01**	ARfD (mg/kg bw):	**0.01**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2007**	Year of evaluation:	**2007**

Chronic risk assessment: TMDI calculation

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

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	commodities not under assessment (in % of ADI)
43%	NL toddler	1.48	3%	Milk: Cattle	2%	Wheat	1%	Maize/corn	6%
32%	GEMS/Food G11	1.09	4%	Soyabeans	2%	Wheat	0.6%	Carrots	7%
31%	GEMS/Food G10	0.98	3%	Soyabeans	2%	Wheat	0.4%	Barley	7%
29%	GEMS/Food G15	0.93	3%	Wheat	2%	Soyabeans	0.5%	Barley	8%
28%	GEMS/Food G08	0.95	2%	Wheat	2%	Soyabeans	0.6%	Barley	8%
28%	GEMS/Food G06	0.96	4%	Wheat	1%	Soyabeans	0.4%	Tomatoes	8%
28%	GEMS/Food G07	0.93	3%	Wheat	2%	Soyabeans	0.4%	Rapeseeds/canola seeds	8%
22%	IE adult	0.62	1%	Wheat	0.4%	Sweet potatoes	0.3%	Peas	3%
20%	FR child 3 15 yr	0.83	3%	Wheat	1%	Milk: Cattle	0.6%	Swine: Other products	5%
20%	NL child	0.88	2%	Wheat	1%	Milk: Cattle	0.8%	Sugar beet roots	5%
18%	ES child	0.60	3%	Wheat	0.6%	Milk: Cattle	0.3%	Cocoa beans	4%
18%	RO general	0.65	3%	Wheat	0.6%	Milk: Cattle	0.4%	Potatoes	5%
17%	DE child	0.90	3%	Wheat	1%	Apples	1.0%	Milk: Cattle	5%
16%	UK infant	0.74	2%	Milk: Cattle	2%	Wheat	1%	Carrots	3%
16%	FR toddler 2 3 yr	0.70	2%	Wheat	1%	Milk: Cattle	0.6%	Carrots	3%
14%	DK child	0.97	3%	Rye	3%	Wheat	1%	Carrots	7%
13%	UK toddler	0.67	2%	Wheat	1%	Milk: Cattle	0.8%	Beans	4%
12%	PT general	0.52	2%	Wheat	0.5%	Potatoes	0.5%	Potatoes	4%
12%	ES adult	0.36	1%	Wheat	0.3%	Barley	0.2%	Milk: Cattle	4%
11%	NL general	0.46	1%	Wheat	0.4%	Milk: Cattle	0.3%	Sugar beet roots	4%
11%	DE general	0.51	1%	Wheat	0.6%	Milk: Cattle	0.4%	Sugar beet roots	4%
11%	SE general	0.59	2%	Wheat	0.7%	Carrots	0.6%	Milk: Cattle	3%
10%	DE women 14-50 yr	0.50	1%	Wheat	0.6%	Milk: Cattle	0.5%	Sugar beet roots	3%
10%	IT toddler	0.53	4%	Wheat	0.2%	Other cereals	0.1%	Carrots	7%
9%	FI adult	0.45	3%	Coffee beans	0.4%	Rye	0.3%	Carrots	0.8%
9%	FR adult	0.39	1%	Wheat	0.3%	Swine: Other products	0.2%	Wine grapes	2%
8%	FI 3 yr	0.40	0.7%	Wheat	0.7%	Carrots	0.5%	Potatoes	2%
7%	FR infant	0.36	0.9%	Carrots	0.8%	Milk: Cattle	0.5%	Wheat	0.8%
7%	IT adult	0.35	2%	Wheat	0.1%	Tomatoes	0.1%	Carrots	4%
7%	FI 6 yr	0.32	0.6%	Wheat	0.5%	Carrots	0.4%	Potatoes	2%
7%	UK vegetarian	0.30	1%	Wheat	0.4%	Beans	0.2%	Carrots	2%
5%	LT adult	0.28	0.6%	Rye	0.6%	Wheat	0.3%	Potatoes	2%
5%	UK adult	0.26	1%	Wheat	0.2%	Beans	0.1%	Milk: Cattle	2%
5%	DK adult	0.26	0.7%	Wheat	0.4%	Carrots	0.3%	Rye	1%
4%	PL general	0.15	0.3%	Potatoes	0.2%	Carrots	0.2%	Apples	
2%	IE child	0.14	0.7%	Wheat	0.2%	Milk: Cattle	0.1%	Carrots	1%

The TMDI calculations are for information purpose only.
The results of the more refined intake calculations are presented in the spreadsheet "Results".

TDMs

TMDI calculation is not applicable, as no MRLs set for triazole derivative metabolites 1,2,4-triazole, triazole alanine, triazole acetic acid, triazole lactic acid.

Fluxapyroxad

The chronic risk assessments are performed using STMR values as derived in the Article 12 MRL review by EFSA (EFSA, 2020). The Theoretical maximum daily intake (TMDI) was not assessed in the EFSA, 2020 evaluation and therefore, is also not performed in the current submission.

A 3.2 IEDI calculations

Prothioconazole except TDMs

Prothioconazole: prothioconazole-desthio (sum of isomers) (F)			
LOQs (mg/kg) range from:	0.01	to:	0.05
Toxicological reference values			
ADI (mg/kg bw/day):	0.01	ARfD (mg/kg bw):	0.01
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2007	Year of evaluation:	2007

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : --- 0

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

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
15%	NL toddler	1.48	3%	Milk: Cattle	2%	Wheat	1%	Maize/corn	4%	3%
11%	GEMS/Food G11	1.09	4%	Soyabeans	2%	Wheat	0.6%	Carrots	2%	3%
10%	GEMS/Food G10	0.98	3%	Soyabeans	2%	Wheat	0.4%	Barley	1%	3%
10%	DK child	0.97	3%	Rye	3%	Wheat	1%	Carrots	0.8%	6%
10%	GEMS/Food G06	0.96	4%	Wheat	1%	Soyabeans	0.4%	Tomatoes	2%	4%
10%	GEMS/Food G08	0.95	2%	Wheat	2%	Soyabeans	0.6%	Barley	1%	3%
9%	GEMS/Food G07	0.93	3%	Wheat	2%	Soyabeans	0.4%	Rapeseeds/canola seeds	1%	3%
9%	GEMS/Food G15	0.93	3%	Wheat	2%	Soyabeans	0.5%	Barley	1%	3%
9%	DE child	0.90	3%	Wheat	1%	Apples	1.0%	Milk: Cattle	3%	3%
9%	NL child	0.88	2%	Wheat	1%	Milk: Cattle	0.8%	Sugar beet roots	3%	3%
8%	FR child 3 15 yr	0.83	3%	Wheat	1%	Milk: Cattle	0.6%	Swine: Other products	2%	3%
7%	UK infant	0.74	2%	Milk: Cattle	2%	Wheat	1%	Carrots	0.9%	2%
7%	FR toddler 2 3 yr	0.70	2%	Wheat	1%	Milk: Cattle	0.6%	Carrots	2%	2%
7%	UK toddler	0.67	2%	Wheat	1%	Milk: Cattle	0.8%	Beans	1%	2%
7%	RO general	0.65	3%	Wheat	0.6%	Milk: Cattle	0.4%	Potatoes	1.0%	3%
6%	IE adult	0.62	1%	Wheat	0.4%	Sweet potatoes	0.3%	Peas	2%	1%
6%	ES child	0.60	3%	Wheat	0.6%	Milk: Cattle	0.3%	Cocoa beans	1%	3%
6%	SE general	0.59	2%	Wheat	0.7%	Carrots	0.6%	Milk: Cattle	1.0%	2%
5%	IT toddler	0.53	4%	Wheat	0.2%	Other cereals	0.1%	Carrots	0.8%	4%
5%	PT general	0.52	2%	Wheat	0.5%	Potatoes	0.5%	Potatoes	0.9%	2%
5%	DE general	0.51	1%	Wheat	0.6%	Milk: Cattle	0.4%	Sugar beet roots	2%	2%
5%	DE women 14-50 yr	0.50	1%	Wheat	0.6%	Milk: Cattle	0.5%	Sugar beet roots	2%	2%
5%	NL general	0.46	1%	Wheat	0.4%	Milk: Cattle	0.3%	Sugar beet roots	1%	1%
5%	FI adult	0.45	3%	Coffee beans	0.4%	Rye	0.3%	Carrots	3%	0.6%
4%	FI 3 yr	0.40	0.7%	Wheat	0.7%	Carrots	0.5%	Potatoes	0.9%	1%
4%	FR adult	0.39	1%	Wheat	0.3%	Swine: Other products	0.2%	Wine grapes	1%	1%
4%	ES adult	0.36	1%	Wheat	0.3%	Barley	0.2%	Milk: Cattle	0.9%	2%
4%	FR infant	0.36	0.9%	Carrots	0.8%	Milk: Cattle	0.5%	Wheat	0.6%	0.5%
4%	IT adult	0.35	2%	Wheat	0.1%	Tomatoes	0.1%	Carrots	0.7%	2%
3%	FI 6 yr	0.32	0.6%	Wheat	0.5%	Carrots	0.4%	Potatoes	0.7%	1.0%
3%	UK vegetarian	0.30	1%	Wheat	0.4%	Beans	0.2%	Carrots	0.6%	1%
3%	LT adult	0.28	0.6%	Rye	0.6%	Wheat	0.3%	Potatoes	0.4%	1%
3%	DK adult	0.26	0.7%	Wheat	0.4%	Carrots	0.3%	Rye	0.5%	1.0%
3%	UK adult	0.26	1%	Wheat	0.2%	Beans	0.1%	Milk: Cattle	0.5%	1%
2%	PL general	0.15	0.3%	Potatoes	0.2%	Carrots	0.2%	Apples	0.5%	0.0%
1%	IE child	0.14	0.7%	Wheat	0.2%	Milk: Cattle	0.1%	Carrots	0.1%	0.7%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Prothioconazole: prothioconazole-desthio (sum of isomers) (F)
Reg. (EU) 2019/552
Annex II (F) is unlikely to present a public health concern.

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : --- 0

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

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
6%	DK child	0.60	3%	Rye	3%	Wheat	0.0%		0.0%	6%
4%	GEMS/Food G06	0.44	4%	Wheat	0.1%	Barley	0.0%	Rye	0.0%	4%
4%	IT toddler	0.40	4%	Wheat	0.0%	Barley	0.0%		0.0%	4%
3%	GEMS/Food G08	0.34	2%	Wheat	0.6%	Barley	0.4%	Rye	0.0%	3%
3%	GEMS/Food G15	0.34	3%	Wheat	0.5%	Barley	0.1%	Rye	0.0%	3%
3%	RO general	0.30	3%	Wheat	0.0%	FRUIT AND TREE NUTS	0.0%		0.0%	3%
3%	DE child	0.30	3%	Wheat	0.5%	Rye	0.0%	Barley	0.0%	3%
3%	GEMS/Food G07	0.30	3%	Wheat	0.4%	Barley	0.0%	Rye	0.0%	3%
3%	GEMS/Food G10	0.28	2%	Wheat	0.4%	Barley	0.1%	Rye	0.0%	3%
3%	FR child 3 15 yr	0.28	3%	Wheat	0.0%	Barley	0.0%	Rye	0.0%	3%
3%	NL toddler	0.27	2%	Wheat	0.2%	Rye	0.1%	Barley	0.0%	3%
3%	GEMS/Food G11	0.27	2%	Wheat	0.5%	Barley	0.0%	Rye	0.0%	3%
3%	ES child	0.27	3%	Wheat	0.0%	Barley	0.0%		0.0%	3%
3%	NL child	0.26	2%	Wheat	0.1%	Rye	0.0%	Barley	0.0%	3%
2%	IT adult	0.25	2%	Wheat	0.0%	Barley	0.0%		0.0%	2%
2%	PT general	0.25	2%	Wheat	0.1%	Rye	0.0%	Barley	0.0%	2%
2%	UK toddler	0.24	2%	Wheat	0.0%	Barley	0.0%	Rye	0.0%	2%
2%	SE general	0.21	2%	Wheat	0.2%	Rye	0.0%		0.0%	2%
2%	FR toddler 2 3 yr	0.19	2%	Wheat	0.0%	Rye	0.0%	Barley	0.0%	2%
2%	DE general	0.18	1%	Wheat	0.4%	Barley	0.3%	Rye	0.0%	2%
2%	ES adult	0.18	1%	Wheat	0.3%	Barley	0.0%		0.0%	2%
2%	DE women 14-50 yr	0.17	1%	Wheat	0.3%	Rye	0.1%	Barley	0.0%	2%
2%	UK infant	0.16	2%	Wheat	0.0%	FRUIT AND TREE NUTS	0.0%		0.0%	2%
1%	IE adult	0.15	1%	Wheat	0.1%	Rye	0.0%	Barley	0.0%	1%
1%	NL general	0.14	1%	Wheat	0.2%	Barley	0.0%	Rye	0.0%	1%
1%	FR adult	0.13	1%	Wheat	0.0%	Rye	0.0%	Barley	0.0%	1%
1%	LT adult	0.13	0.6%	Rye	0.6%	Wheat	0.0%	Barley	0.0%	1%
1%	UK vegetarian	0.13	1%	Wheat	0.0%	Barley	0.0%	Rye	0.0%	1%
1%	FI 3 yr	0.12	0.7%	Wheat	0.4%	Rye	0.0%	Barley	0.0%	1%
1%	UK adult	0.10	1%	Wheat	0.0%	Barley	0.0%	Rye	0.0%	1%
1.0%	FI 6 yr	0.10	0.6%	Wheat	0.4%	Rye	0.0%	Barley	0.0%	1.0%
1.0%	DK adult	0.10	0.7%	Wheat	0.3%	Rye	0.0%		0.0%	1.0%
0.7%	IE child	0.07	0.7%	Wheat	0.0%	Barley	0.0%		0.0%	0.7%
0.6%	FI adult	0.06	0.4%	Rye	0.2%	Wheat	0.0%	Barley	0.0%	0.6%
0.5%	FR infant	0.05	0.5%	Wheat	0.0%	Rye	0.0%	Barley	0.0%	0.5%
0.0%	Column7	0.00	0.0%	FRUIT AND TREE NUTS	0.0%	FRUIT AND TREE NUTS	0.0%		0.0%	0.0%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Prothioconazole: prothioconazole-desthio (sum of isomers) (F)
Reg. (EU) 2019/552
Annex II (F) is unlikely to present a public health concern.

TDMs: 1,2,4-triazole (1,2,4-T)

1,2,4-Triazole	
LOQs (mg/kg) range from:	to:
Toxicological reference values	
ADI (mg/kg bw/day):	ARfD (mg/kg bw): **0.1**
Source of ADI:	Source of ARfD: **EC**
Year of evaluation:	Year of evaluation: **2021**

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI :

	Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	51%	NL toddler	11.71	42%	Milk: Cattle	2%	Maize/corn	1%	Bananas		44%
	31%	UK infant	7.05	27%	Milk: Cattle	0.9%	Bovine: Muscle/meat	0.6%	Wheat		29%
	25%	FR toddler 2 3 yr	5.76	20%	Milk: Cattle	0.8%	Bovine: Muscle/meat	0.7%	Wheat		23%
	24%	NL child	5.44	17%	Milk: Cattle	2%	Sugar beet roots	0.9%	Wheat		20%
	22%	FR child 3 15 yr	5.04	16%	Milk: Cattle	1%	Bovine: Muscle/meat	1.0%	Wheat		19%
	19%	UK toddler	4.28	14%	Milk: Cattle	0.9%	Bovine: Muscle/meat	0.9%	Wheat		16%
	18%	DE child	4.23	14%	Milk: Cattle	0.9%	Wheat	0.9%	Oranges		16%
	14%	DK child	3.30	9%	Milk: Cattle	1%	Rye	1%	Swine: Muscle/meat		13%
	14%	SE general	3.23	9%	Milk: Cattle	3%	Bovine: Muscle/meat	0.7%	Wheat		13%
	13%	ES child	3.08	9%	Milk: Cattle	1.0%	Bovine: Muscle/meat	1.0%	Wheat		12%
	13%	FR infant	3.06	12%	Milk: Cattle	0.3%	Sugar beet roots	0.2%	Bovine: Muscle/meat		12%
	12%	DE women 14-50 yr	2.83	9%	Milk: Cattle	1.0%	Sugar beet roots	0.5%	Wheat		10%
	12%	DE general	2.82	9%	Milk: Cattle	0.9%	Sugar beet roots	0.6%	Swine: Muscle/meat		10%
	12%	RO general	2.75	8%	Milk: Cattle	1%	Wheat	0.6%	Swine: Muscle/meat		10%
	11%	GEMS/Food G11	2.42	5%	Milk: Cattle	0.8%	Soyabeans	0.8%	Wheat		8%
	10%	GEMS/Food G15	2.29	5%	Milk: Cattle	1.0%	Wheat	0.7%	Swine: Muscle/meat		8%
	10%	GEMS/Food G07	2.25	4%	Milk: Cattle	0.9%	Wheat	0.6%	Bovine: Muscle/meat		8%
	9%	NL general	2.15	6%	Milk: Cattle	0.6%	Sugar beet roots	0.5%	Bovine: Muscle/meat		8%
	9%	GEMS/Food G08	2.10	4%	Milk: Cattle	1%	Swine: Muscle/meat	0.9%	Wheat		7%
	9%	GEMS/Food G10	2.09	4%	Milk: Cattle	0.9%	Wheat	0.7%	Soyabeans		6%
	7%	GEMS/Food G06	1.63	2%	Milk: Cattle	2%	Wheat	0.4%	Sugar canes		4%
	7%	IE adult	1.50	3%	Milk: Cattle	0.5%	Wheat	0.3%	Bovine: Muscle/meat		5%
	6%	ES adult	1.44	3%	Milk: Cattle	0.5%	Bovine: Muscle/meat	0.5%	Wheat		5%
	6%	DK adult	1.30	4%	Milk: Cattle	0.5%	Swine: Muscle/meat	0.4%	Bovine: Muscle/meat		5%
	6%	FR adult	1.28	3%	Milk: Cattle	0.5%	Wheat	0.4%	Bovine: Muscle/meat		5%
	5%	LT adult	1.06	3%	Milk: Cattle	0.5%	Swine: Muscle/meat	0.2%	Rye		4%
	4%	UK adult	0.88	2%	Milk: Cattle	0.5%	Bovine: Muscle/meat	0.4%	Wheat		3%
	4%	UK vegetarian	0.85	2%	Milk: Cattle	0.4%	Wheat	0.2%	Oranges		3%
	3%	IE child	0.74	2%	Milk: Cattle	0.3%	Wheat	0.1%	Swine: Muscle/meat		3%
	2%	IT toddler	0.56	1%	Wheat	0.3%	Other cereals	0.1%	Bananas		1%
	2%	PT general	0.52	0.9%	Wheat	0.2%	Potatoes	0.2%	Rice		0.9%
	2%	FI 3 yr	0.38	0.3%	Bananas	0.3%	Wheat	0.2%	Potatoes		0.6%
	2%	IT adult	0.37	0.9%	Wheat	0.2%	Other cereals	0.1%	Oranges		0.9%
	1%	FI 6 yr	0.29	0.2%	Wheat	0.2%	Potatoes	0.2%	Bananas		0.4%
	0.7%	FI adult	0.17	0.2%	Rye	0.1%	Oranges	0.1%	Wheat		0.3%
	0.5%	PL general	0.13	0.1%	Potatoes	0.1%	Apples	0.1%	Head cabbages		

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

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
44%	NL toddler	10.15	42%	Milk: Cattle	0.9%	Wheat	0.7%	Bovine: Muscle/meat		44%
29%	UK infant	6.62	27%	Milk: Cattle	0.9%	Bovine: Muscle/meat	0.6%	Wheat		29%
23%	FR toddler 2 3 yr	5.30	20%	Milk: Cattle	0.8%	Bovine: Muscle/meat	0.7%	Wheat		23%
20%	NL child	4.49	17%	Milk: Cattle	0.9%	Wheat	0.6%	Bovine: Muscle/meat		20%
19%	FR child 3 15 yr	4.44	16%	Milk: Cattle	1%	Bovine: Muscle/meat	1.0%	Wheat		19%
16%	UK toddler	3.78	14%	Milk: Cattle	0.9%	Bovine: Muscle/meat	0.9%	Wheat		16%
16%	DE child	3.61	14%	Milk: Cattle	0.9%	Wheat	0.3%	Swine: Muscle/meat		16%
13%	DK child	3.08	9%	Milk: Cattle	1%	Rye	1%	Swine: Muscle/meat		13%
13%	SE general	2.89	9%	Milk: Cattle	3%	Bovine: Muscle/meat	0.7%	Wheat		13%
12%	FR infant	2.85	12%	Milk: Cattle	0.2%	Bovine: Muscle/meat	0.2%	Swine: Muscle/meat		12%
12%	ES child	2.73	9%	Milk: Cattle	1.0%	Bovine: Muscle/meat	1.0%	Wheat		12%
10%	DE general	2.38	9%	Milk: Cattle	0.6%	Swine: Muscle/meat	0.4%	Wheat		10%
10%	RO general	2.37	8%	Milk: Cattle	1%	Wheat	0.6%	Swine: Muscle/meat		10%
10%	DE women 14-50 yr	2.35	9%	Milk: Cattle	0.5%	Wheat	0.5%	Swine: Muscle/meat		10%
8%	GEMS/Food G11	1.81	5%	Milk: Cattle	0.8%	Wheat	0.6%	Swine: Muscle/meat		8%
8%	GEMS/Food G15	1.80	5%	Milk: Cattle	1.0%	Wheat	0.7%	Swine: Muscle/meat		8%
8%	NL general	1.74	6%	Milk: Cattle	0.5%	Bovine: Muscle/meat	0.5%	Swine: Muscle/meat		8%
7%	GEMS/Food G07	1.71	4%	Milk: Cattle	0.9%	Wheat	0.6%	Bovine: Muscle/meat		7%
7%	GEMS/Food G08	1.56	4%	Milk: Cattle	1%	Swine: Muscle/meat	0.9%	Wheat		7%
6%	GEMS/Food G10	1.46	4%	Milk: Cattle	0.9%	Wheat	0.6%	Bovine: Muscle/meat		6%
5%	ES adult	1.22	3%	Milk: Cattle	0.5%	Bovine: Muscle/meat	0.5%	Wheat		5%
5%	DK adult	1.19	4%	Milk: Cattle	0.5%	Swine: Muscle/meat	0.4%	Bovine: Muscle/meat		5%
5%	FR adult	1.08	3%	Milk: Cattle	0.5%	Wheat	0.4%	Bovine: Muscle/meat		5%
5%	IE adult	1.06	3%	Milk: Cattle	0.5%	Wheat	0.3%	Bovine: Muscle/meat		5%
4%	LT adult	0.94	3%	Milk: Cattle	0.5%	Swine: Muscle/meat	0.2%	Rye		4%
4%	GEMS/Food G06	0.94	2%	Milk: Cattle	2%	Wheat	0.2%	Bovine: Muscle/meat		4%
3%	UK adult	0.71	2%	Milk: Cattle	0.5%	Bovine: Muscle/meat	0.4%	Wheat		3%
3%	IE child	0.69	2%	Milk: Cattle	0.3%	Wheat	0.1%	Swine: Muscle/meat		3%
3%	UK vegetarian	0.64	2%	Milk: Cattle	0.4%	Wheat	0.1%	Eggs: Chicken		3%
1%	IT toddler	0.33	1%	Wheat	0.0%	Barley				1%
0.9%	IT adult	0.21	0.9%	Wheat	0.0%	Barley				0.9%
0.9%	PT general	0.20	0.9%	Wheat	0.0%	Rye	0.0%	Barley		0.9%
0.4%	FI 3 yr	0.10	0.3%	Wheat	0.1%	Rye	0.0%	Barley		0.4%
0.4%	FI 6 yr	0.08	0.2%	Wheat	0.1%	Rye	0.0%	Barley		0.4%
0.2%	FI adult	0.05	0.2%	Rye	0.1%	Wheat	0.0%	Barley		0.2%
	Column7			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				

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

Triazole alanine (TA)

Triazole alanine (TA)			
LOQs (mg/kg) range from:		to:	
Toxicological reference values			
ADI (mg/kg bw/day):		ARfD (mg/kg bw):	**0.3**
Source of ADI:		Source of ARfD:	**EC**
Year of evaluation:		Year of evaluation:	**2018**

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI :

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

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
5%	NL toddler	15.44	1%	Maize/corn	0.8%	Wheat	0.4%	Milk: Cattle		2%
4%	GEMS/Food G06	11.90	1%	Wheat	0.4%	Soyabeans	0.3%	Rice		2%
4%	GEMS/Food G10	10.90	1%	Soyabeans	0.8%	Wheat	0.3%	Rice		1%
3%	GEMS/Food G08	9.84	0.8%	Wheat	0.7%	Soyabeans	0.3%	Olives for oil production		1%
3%	GEMS/Food G11	9.80	1%	Soyabeans	0.7%	Wheat	0.2%	Barley		1%
3%	GEMS/Food G07	9.25	0.9%	Wheat	0.6%	Soyabeans	0.2%	Rapeseeds/canola seeds		1%
3%	GEMS/Food G15	9.15	0.9%	Wheat	0.6%	Soyabeans	0.2%	Sunflower seeds		1%
3%	DK child	8.37	1%	Rye	0.9%	Wheat	0.1%	Cucumbers		2%
3%	NL child	8.27	0.9%	Wheat	0.3%	Oil palm fruits	0.2%	Milk: Cattle		1%
3%	DE child	7.78	0.9%	Wheat	0.4%	Oranges	0.2%	Rye		1%
2%	FR child 3 15 yr	7.27	1.0%	Wheat	0.4%	Oranges	0.2%	Milk: Cattle		1%
2%	RO general	6.68	1%	Wheat	0.2%	Sunflower seeds	0.2%	Maize/corn		1%
2%	IT toddler	6.36	1%	Wheat	0.3%	Other cereals	0.1%	Tomatoes		1%
2%	ES child	6.16	0.9%	Wheat	0.3%	Olives for oil production	0.2%	Oranges		1%
2%	IE adult	5.65	0.5%	Wheat	0.2%	Sweet potatoes	0.1%	Oranges		0.6%
2%	PT general	5.39	0.8%	Wheat	0.2%	Rice	0.1%	Soyabeans		0.9%
2%	FR toddler 2 3 yr	5.33	0.6%	Wheat	0.2%	Milk: Cattle	0.2%	Oranges		0.9%
2%	UK infant	5.09	0.5%	Wheat	0.3%	Milk: Cattle	0.2%	Maize/corn		0.9%
2%	UK toddler	5.07	0.8%	Wheat	0.2%	Oranges	0.1%	Milk: Cattle		1%
2%	SE general	4.57	0.7%	Wheat	0.1%	Bovine: Muscle/meat	0.1%	Rice		0.9%
1%	NL general	4.35	0.4%	Wheat	0.2%	Oil palm fruits	0.1%	Oranges		0.7%
1%	DE women 14-50 yr	4.24	0.4%	Wheat	0.2%	Oranges	0.1%	Rye		0.7%
1%	IT adult	4.19	0.9%	Wheat	0.1%	Other cereals	0.1%	Tomatoes		0.9%
1%	DE general	4.13	0.4%	Wheat	0.2%	Oranges	0.1%	Rye		0.8%
1%	ES adult	3.87	0.5%	Wheat	0.1%	Olives for oil production	0.1%	Oranges		0.7%
1%	FI 3 yr	3.25	0.2%	Wheat	0.1%	Rye	0.1%	Oat		0.5%
1.0%	FR adult	3.00	0.5%	Wheat	0.1%	Oranges	0.0%	Wine grapes		0.5%
0.9%	UK vegetarian	2.63	0.4%	Wheat	0.1%	Oranges	0.1%	Rice		0.5%
0.8%	FI 6 yr	2.55	0.2%	Wheat	0.1%	Rye	0.1%	Rice		0.4%
0.8%	LT adult	2.41	0.2%	Rye	0.2%	Wheat	0.0%	Rice		0.5%
0.7%	UK adult	2.12	0.3%	Wheat	0.1%	Rice	0.1%	Oranges		0.4%
0.7%	DK adult	1.95	0.2%	Wheat	0.1%	Rye	0.0%	Tomatoes		0.4%
0.6%	FR infant	1.94	0.2%	Wheat	0.1%	Milk: Cattle	0.1%	Carrots		0.3%
0.5%	FI adult	1.59	0.1%	Rye	0.1%	Wheat	0.0%	Oranges		0.2%
0.4%	IE child	1.19	0.2%	Wheat	0.1%	Rice	0.0%	Milk: Cattle		0.3%
0.3%	PL general	0.75	0.1%	Tomatoes	0.0%	Apples	0.0%	Head cabbages		

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

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

	Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
				No of diets exceeding the ADI :	---						
TMDI/NEDI/IEDI calculation (based on average food consumption)	2%	DK child	6.69	1%	Rye	0.9%	Wheat	0.1%	Milk: Cattle		2%
	2%	GEMS/Food G06	4.68	1%	Wheat	0.0%	Milk: Cattle	0.0%	Barley		2%
	1%	NL toddler	4.19	0.8%	Wheat	0.4%	Milk: Cattle	0.1%	Rye		1%
	1%	IT toddler	4.13	1%	Wheat	0.0%	Barley				1%
	1%	GEMS/Food G15	3.78	0.9%	Wheat	0.2%	Barley	0.0%	Rye		1%
	1%	GEMS/Food G08	3.77	0.8%	Wheat	0.2%	Barley	0.1%	Rye		1%
	1%	DE child	3.61	0.9%	Wheat	0.2%	Rye	0.1%	Milk: Cattle		1%
	1%	FR child 3 15 yr	3.57	1.0%	Wheat	0.2%	Milk: Cattle	0.0%	Bovine: Muscle/meat		1%
	1%	RO general	3.51	1%	Wheat	0.1%	Milk: Cattle	0.0%	Swine: Muscle/meat		1%
	1%	GEMS/Food G07	3.38	0.9%	Wheat	0.1%	Barley	0.0%	Milk: Cattle		1%
	1%	NL child	3.33	0.9%	Wheat	0.2%	Milk: Cattle	0.0%	Rye		1%
	1%	ES child	3.25	0.9%	Wheat	0.1%	Milk: Cattle	0.0%	Bovine: Muscle/meat		1%
	1%	GEMS/Food G10	3.16	0.8%	Wheat	0.1%	Barley	0.0%	Milk: Cattle		1%
	1%	GEMS/Food G11	3.07	0.7%	Wheat	0.2%	Barley	0.1%	Milk: Cattle		1%
	1.0%	UK toddler	2.98	0.8%	Wheat	0.1%	Milk: Cattle	0.0%	Bovine: Muscle/meat		1.0%
	0.9%	SE general	2.70	0.7%	Wheat	0.1%	Bovine: Muscle/meat	0.1%	Milk: Cattle		0.9%
	0.9%	FR toddler 2 3 yr	2.70	0.6%	Wheat	0.2%	Milk: Cattle	0.0%	Bovine: Muscle/meat		0.9%
	0.9%	IT adult	2.57	0.9%	Wheat	0.0%	Barley				0.9%
	0.8%	PT general	2.54	0.8%	Wheat	0.0%	Rye	0.0%	Barley		0.8%
	0.8%	UK infant	2.53	0.5%	Wheat	0.3%	Milk: Cattle	0.0%	Bovine: Muscle/meat		0.8%
	0.7%	DE general	2.21	0.4%	Wheat	0.1%	Rye	0.1%	Barley		0.7%
	0.7%	DE women 14-50 yr	2.09	0.4%	Wheat	0.1%	Rye	0.1%	Milk: Cattle		0.7%
	0.7%	ES adult	2.00	0.5%	Wheat	0.1%	Barley	0.0%	Milk: Cattle		0.7%
	0.6%	IE adult	1.73	0.5%	Wheat	0.0%	Rye	0.0%	Milk: Cattle		0.6%
	0.6%	NL general	1.73	0.4%	Wheat	0.1%	Barley	0.1%	Milk: Cattle		0.6%
	0.5%	FR adult	1.58	0.5%	Wheat	0.0%	Milk: Cattle	0.0%	Swine: Muscle/meat		0.5%
	0.5%	LT adult	1.54	0.2%	Rye	0.2%	Wheat	0.0%	Milk: Cattle		0.5%
	0.5%	UK vegetarian	1.37	0.4%	Wheat	0.0%	Milk: Cattle	0.0%	Barley		0.5%
	0.4%	DK adult	1.25	0.2%	Wheat	0.1%	Rye	0.0%	Milk: Cattle		0.4%
	0.4%	UK adult	1.19	0.3%	Wheat	0.0%	Milk: Cattle	0.0%	Bovine: Muscle/meat		0.4%
	0.4%	FI 3 yr	1.19	0.2%	Wheat	0.1%	Rye	0.0%	Barley		0.4%
	0.3%	FI 6 yr	1.02	0.2%	Wheat	0.1%	Rye	0.0%	Barley		0.3%
	0.3%	FR infant	0.88	0.2%	Wheat	0.1%	Milk: Cattle	0.0%	Swine: Muscle/meat		0.3%
	0.3%	IE child	0.82	0.2%	Wheat	0.0%	Milk: Cattle	0.0%	Swine: Muscle/meat		0.3%
	0.2%	FI adult	0.65	0.1%	Rye	0.1%	Wheat	0.0%	Barley		0.2%
		Column7			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				

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

Triazole acetic acid (TAA)

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

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
1%	NL toddler	13.58	0.6%	Maize/corn	0.3%	Wheat	0.2%	Milk: Cattle		0.6%
0.9%	DK child	9.17	0.4%	Rye	0.3%	Wheat	0.0%	Milk: Cattle		0.8%
0.9%	GEMS/Food G06	8.99	0.6%	Wheat	0.1%	Rice	0.1%	Maize/corn		0.6%
0.7%	IT toddler	6.81	0.5%	Wheat	0.1%	Other cereals	0.0%	Rice		0.5%
0.6%	GEMS/Food G10	6.42	0.3%	Wheat	0.1%	Rice	0.1%	Maize/corn		0.4%
0.6%	GEMS/Food G15	6.21	0.4%	Wheat	0.1%	Barley	0.1%	Maize/corn		0.5%
0.6%	GEMS/Food G08	6.17	0.3%	Wheat	0.1%	Barley	0.0%	Rye		0.5%
0.6%	DE child	6.13	0.3%	Wheat	0.1%	Rye	0.1%	Milk: Cattle		0.5%
0.6%	NL child	5.93	0.3%	Wheat	0.1%	Milk: Cattle	0.0%	Sugar beet roots		0.5%
0.6%	FR child 3 15 yr	5.93	0.4%	Wheat	0.1%	Milk: Cattle	0.0%	Rice		0.5%
0.6%	RO general	5.84	0.4%	Wheat	0.1%	Maize/corn	0.0%	Milk: Cattle		0.5%
0.6%	GEMS/Food G07	5.64	0.3%	Wheat	0.0%	Barley	0.0%	Rice		0.4%
0.5%	UK infant	5.22	0.2%	Wheat	0.1%	Milk: Cattle	0.1%	Maize/corn		0.3%
0.5%	GEMS/Food G11	5.18	0.3%	Wheat	0.1%	Barley	0.0%	Soyabeans		0.4%
0.5%	ES child	5.06	0.4%	Wheat	0.0%	Rice	0.0%	Milk: Cattle		0.4%
0.5%	UK toddler	4.85	0.3%	Wheat	0.1%	Milk: Cattle	0.0%	Rice		0.4%
0.5%	PT general	4.69	0.3%	Wheat	0.1%	Rice	0.0%	Maize/corn		0.3%
0.5%	FR toddler 2 3 yr	4.57	0.2%	Wheat	0.1%	Milk: Cattle	0.0%	Rice		0.4%
0.4%	IT adult	4.15	0.3%	Wheat	0.1%	Other cereals	0.0%	Rice		0.3%
0.4%	SE general	3.94	0.3%	Wheat	0.0%	Milk: Cattle	0.0%	Rice		0.3%
0.3%	DE general	3.46	0.1%	Wheat	0.0%	Rye	0.0%	Barley		0.3%
0.3%	DE women 14-50 yr	3.39	0.2%	Wheat	0.0%	Rye	0.0%	Milk: Cattle		0.3%
0.3%	IE adult	3.36	0.2%	Wheat	0.0%	Buckwheat and other pseudo-cereals	0.0%	Rice		0.2%
0.3%	ES adult	3.02	0.2%	Wheat	0.0%	Barley	0.0%	Rice		0.2%
0.3%	NL general	2.91	0.2%	Wheat	0.0%	Milk: Cattle	0.0%	Barley		0.2%
0.3%	FI 3 yr	2.73	0.1%	Wheat	0.1%	Rye	0.0%	Oat		0.2%
0.2%	FR adult	2.49	0.2%	Wheat	0.0%	Milk: Cattle	0.0%	Rice		0.2%
0.2%	LT adult	2.45	0.1%	Rye	0.1%	Wheat	0.0%	Rice		0.2%
0.2%	UK vegetarian	2.34	0.2%	Wheat	0.0%	Rice	0.0%	Milk: Cattle		0.2%
0.2%	FI 6 yr	2.13	0.1%	Wheat	0.0%	Rye	0.0%	Rice		0.1%
0.2%	UK adult	1.99	0.1%	Wheat	0.0%	Rice	0.0%	Milk: Cattle		0.2%
0.2%	DK adult	1.78	0.1%	Wheat	0.0%	Rye	0.0%	Milk: Cattle		0.2%
0.1%	FR infant	1.48	0.1%	Wheat	0.1%	Milk: Cattle	0.0%	Sugar beet roots		0.1%
0.1%	IE child	1.34	0.1%	Wheat	0.0%	Rice	0.0%	Milk: Cattle		0.1%
0.1%	FI adult	1.19	0.1%	Rye	0.0%	Wheat	0.0%	Oat		0.1%
0.0%	PL general	0.18	0.0%	Apples	0.0%	Potatoes	0.0%	Table grapes		

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

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
0.8%	DK child	8.37	0.4%	Rye	0.3%	Wheat	0.0%	Milk: Cattle		0.8%
0.6%	GEMS/Food G06	6.08	0.6%	Wheat	0.0%	Sugar canes	0.0%	Milk: Cattle		0.6%
0.6%	NL toddler	5.73	0.3%	Wheat	0.2%	Milk: Cattle	0.0%	Rye		0.6%
0.5%	IT toddler	5.26	0.5%	Wheat	0.0%	Barley				0.5%
0.5%	GEMS/Food G15	4.77	0.4%	Wheat	0.1%	Barley	0.0%	Milk: Cattle		0.5%
0.5%	GEMS/Food G08	4.75	0.3%	Wheat	0.1%	Barley	0.0%	Rye		0.5%
0.5%	FR child 3 15 yr	4.67	0.4%	Wheat	0.1%	Milk: Cattle	0.0%	Sugar beet roots		0.5%
0.5%	NL child	4.65	0.3%	Wheat	0.1%	Milk: Cattle	0.0%	Sugar beet roots		0.5%
0.5%	DE child	4.63	0.3%	Wheat	0.1%	Rye	0.1%	Milk: Cattle		0.5%
0.5%	RO general	4.51	0.4%	Wheat	0.0%	Milk: Cattle	0.0%	Sugar beet roots		0.5%
0.4%	GEMS/Food G07	4.24	0.3%	Wheat	0.0%	Barley	0.0%	Milk: Cattle		0.4%
0.4%	ES child	4.04	0.4%	Wheat	0.0%	Milk: Cattle	0.0%	Bovine: Muscle/meat		0.4%
0.4%	GEMS/Food G10	3.98	0.3%	Wheat	0.0%	Barley	0.0%	Milk: Cattle		0.4%
0.4%	UK toddler	3.97	0.3%	Wheat	0.1%	Milk: Cattle	0.0%	Sugar beet roots		0.4%
0.4%	GEMS/Food G11	3.93	0.3%	Wheat	0.1%	Barley	0.0%	Milk: Cattle		0.4%
0.4%	FR toddler 2 3 yr	3.58	0.2%	Wheat	0.1%	Milk: Cattle	0.0%	Sugar beet roots		0.4%
0.3%	UK infant	3.40	0.2%	Wheat	0.1%	Milk: Cattle	0.0%	Sugar beet roots		0.3%
0.3%	SE general	3.29	0.3%	Wheat	0.0%	Milk: Cattle	0.0%	Rye		0.3%
0.3%	IT adult	3.27	0.3%	Wheat	0.0%	Barley				0.3%
0.3%	PT general	3.23	0.3%	Wheat	0.0%	Rye	0.0%	Barley		0.3%
0.3%	DE general	3.00	0.1%	Wheat	0.0%	Rye	0.0%	Barley		0.3%
0.3%	DE women 14-50 yr	2.89	0.2%	Wheat	0.0%	Rye	0.0%	Milk: Cattle		0.3%
0.2%	ES adult	2.48	0.2%	Wheat	0.0%	Barley	0.0%	Milk: Cattle		0.2%
0.2%	NL general	2.29	0.2%	Wheat	0.0%	Milk: Cattle	0.0%	Barley		0.2%
0.2%	IE adult	2.13	0.2%	Wheat	0.0%	Milk: Cattle	0.0%	Rye		0.2%
0.2%	FR adult	2.00	0.2%	Wheat	0.0%	Milk: Cattle	0.0%	Sugar beet roots		0.2%
0.2%	LT adult	1.91	0.1%	Rye	0.1%	Wheat	0.0%	Milk: Cattle		0.2%
0.2%	UK vegetarian	1.79	0.2%	Wheat	0.0%	Milk: Cattle	0.0%	Sugar beet roots		0.2%
0.2%	DK adult	1.53	0.1%	Wheat	0.0%	Rye	0.0%	Milk: Cattle		0.2%
0.2%	UK adult	1.51	0.1%	Wheat	0.0%	Milk: Cattle	0.0%	Sugar beet roots		0.2%
0.2%	FI 3 yr	1.51	0.1%	Wheat	0.1%	Rye	0.0%	Barley		0.2%
0.1%	FI 6 yr	1.30	0.1%	Wheat	0.0%	Rye	0.0%	Barley		0.1%
0.1%	FR infant	1.23	0.1%	Wheat	0.1%	Milk: Cattle	0.0%	Sugar beet roots		0.1%
0.1%	IE child	1.05	0.1%	Wheat	0.0%	Milk: Cattle	0.0%	Swine: Muscle/meat		0.1%
0.1%	FI adult	0.82	0.1%	Rye	0.0%	Wheat	0.0%	Barley		0.1%
	Column7			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				

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

Triazole lactic acid (TLA)

Triazole lactic acid (TLA)			
LOQs (mg/kg) range from:		to:	
Toxicological reference values			
ADI (mg/kg bw/day):		ARfD (mg/kg bw):	0.3
Source of ADI:		Source of ARfD:	EC
Year of evaluation:		Year of evaluation:	2018

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI :

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

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
1%	NL toddler	3.35	0.6%	Milk: Cattle	0.1%	Apples	0.1%	Maize/corn		0.7%
0.6%	DE child	1.71	0.2%	Milk: Cattle	0.1%	Apples	0.1%	Oranges		0.3%
0.6%	NL child	1.70	0.2%	Milk: Cattle	0.1%	Apples	0.0%	Wheat		0.3%
0.5%	UK infant	1.63	0.4%	Milk: Cattle	0.0%	Potatoes	0.0%	Wheat		0.4%
0.5%	FR toddler 2 3 yr	1.45	0.3%	Milk: Cattle	0.0%	Apples	0.0%	Wheat		0.3%
0.5%	FR child 3 15 yr	1.40	0.2%	Milk: Cattle	0.0%	Oranges	0.0%	Wheat		0.3%
0.4%	UK toddler	1.16	0.2%	Milk: Cattle	0.0%	Wheat	0.0%	Oranges		0.3%
0.4%	GEMS/Food G11	1.11	0.1%	Soyabeans	0.1%	Milk: Cattle	0.0%	Potatoes		0.1%
0.4%	GEMS/Food G10	1.06	0.1%	Soyabeans	0.1%	Milk: Cattle	0.0%	Wheat		0.1%
0.3%	GEMS/Food G07	1.05	0.1%	Milk: Cattle	0.0%	Soyabeans	0.0%	Wheat		0.1%
0.3%	GEMS/Food G06	1.02	0.1%	Wheat	0.0%	Tomatoes	0.0%	Soyabeans		0.1%
0.3%	DK child	1.00	0.1%	Milk: Cattle	0.0%	Rye	0.0%	Wheat		0.2%
0.3%	GEMS/Food G08	1.00	0.1%	Milk: Cattle	0.0%	Soyabeans	0.0%	Wheat		0.1%
0.3%	GEMS/Food G15	0.99	0.1%	Milk: Cattle	0.0%	Soyabeans	0.0%	Wheat		0.1%
0.3%	RO general	0.97	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes		0.2%
0.3%	SE general	0.97	0.1%	Milk: Cattle	0.0%	Bovine: Muscle/meat	0.0%	Potatoes		0.2%
0.3%	ES child	0.97	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Oranges		0.2%
0.3%	DE women 14-50 yr	0.88	0.1%	Milk: Cattle	0.0%	Apples	0.0%	Oranges		0.2%
0.3%	DE general	0.84	0.1%	Milk: Cattle	0.0%	Apples	0.0%	Oranges		0.2%
0.3%	FR infant	0.78	0.2%	Milk: Cattle	0.0%	Apples	0.0%	Potatoes		0.2%
0.3%	IE adult	0.78	0.0%	Milk: Cattle	0.0%	Sweet potatoes	0.0%	Wheat		0.1%
0.2%	NL general	0.75	0.1%	Milk: Cattle	0.0%	Potatoes	0.0%	Apples		0.1%
0.2%	ES adult	0.57	0.0%	Milk: Cattle	0.0%	Oranges	0.0%	Wheat		0.1%
0.2%	PT general	0.56	0.0%	Potatoes	0.0%	Wine grapes	0.0%	Wheat		0.0%
0.2%	FR adult	0.52	0.0%	Milk: Cattle	0.0%	Wine grapes	0.0%	Wheat		0.1%
0.1%	IT toddler	0.43	0.0%	Wheat	0.0%	Tomatoes	0.0%	Other cereals		0.0%
0.1%	DK adult	0.42	0.1%	Milk: Cattle	0.0%	Wine grapes	0.0%	Apples		0.1%
0.1%	LT adult	0.39	0.0%	Milk: Cattle	0.0%	Potatoes	0.0%	Apples		0.1%
0.1%	FI 3 yr	0.38	0.0%	Potatoes	0.0%	Cucumbers	0.0%	Apples		0.0%
0.1%	UK vegetarian	0.37	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Oranges		0.1%
0.1%	UK adult	0.35	0.0%	Milk: Cattle	0.0%	Wine grapes	0.0%	Wheat		0.1%
0.1%	IT adult	0.35	0.0%	Wheat	0.0%	Tomatoes	0.0%	Lettuces		0.0%
0.1%	FI 6 yr	0.30	0.0%	Potatoes	0.0%	Wheat	0.0%	Cucumbers		0.0%
0.1%	PL general	0.23	0.0%	Potatoes	0.0%	Apples	0.0%	Tomatoes		
0.1%	IE child	0.20	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes		0.0%
0.1%	FI adult	0.19	0.0%	Potatoes	0.0%	Apples	0.0%	Tomatoes		0.0%

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

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

	Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
				No of diets exceeding the ADI :	---						
TMDI/NEDI/IEDI calculation (based on average food consumption)	0.7%	NL toddler	1.95	0.6%	Milk: Cattle	0.0%	Wheat	0.0%	Bovine: Muscle/meat		0.7%
	0.4%	UK infant	1.31	0.4%	Milk: Cattle	0.0%	Wheat	0.0%	Eggs: Chicken		0.4%
	0.3%	FR toddler 2 3 yr	1.03	0.3%	Milk: Cattle	0.0%	Wheat	0.0%	Bovine: Muscle/meat		0.3%
	0.3%	FR child 3 15 yr	0.90	0.2%	Milk: Cattle	0.0%	Wheat	0.0%	Bovine: Muscle/meat		0.3%
	0.3%	NL child	0.89	0.2%	Milk: Cattle	0.0%	Wheat	0.0%	Bovine: Muscle/meat		0.3%
	0.3%	UK toddler	0.79	0.2%	Milk: Cattle	0.0%	Wheat	0.0%	Bovine: Muscle/meat		0.3%
	0.3%	DE child	0.77	0.2%	Milk: Cattle	0.0%	Wheat	0.0%	Eggs: Chicken		0.3%
	0.2%	DK child	0.68	0.1%	Milk: Cattle	0.0%	Rye	0.0%	Wheat		0.2%
	0.2%	SE general	0.61	0.1%	Milk: Cattle	0.0%	Bovine: Muscle/meat	0.0%	Wheat		0.2%
	0.2%	ES child	0.58	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Bovine: Muscle/meat		0.2%
	0.2%	FR infant	0.54	0.2%	Milk: Cattle	0.0%	Wheat	0.0%	Bovine: Muscle/meat		0.2%
	0.2%	RO general	0.51	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Poultry: Muscle/meat		0.2%
	0.2%	DE general	0.47	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Rye		0.2%
	0.2%	DE women 14-50 yr	0.47	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Rye		0.2%
	0.1%	GEMS/Food G15	0.39	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Poultry: Muscle/meat		0.1%
	0.1%	GEMS/Food G11	0.39	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Poultry: Muscle/meat		0.1%
	0.1%	GEMS/Food G07	0.38	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Poultry: Muscle/meat		0.1%
	0.1%	NL general	0.35	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Bovine: Muscle/meat		0.1%
	0.1%	GEMS/Food G10	0.34	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Poultry: Muscle/meat		0.1%
	0.1%	GEMS/Food G08	0.33	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Poultry: Muscle/meat		0.1%
	0.1%	GEMS/Food G06	0.28	0.1%	Wheat	0.0%	Milk: Cattle	0.0%	Poultry: Muscle/meat		0.1%
	0.1%	ES adult	0.27	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Bovine: Muscle/meat		0.1%
	0.1%	IE adult	0.23	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Bovine: Muscle/meat		0.1%
	0.1%	DK adult	0.23	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Bovine: Muscle/meat		0.1%
	0.1%	FR adult	0.23	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Bovine: Muscle/meat		0.1%
	0.1%	LT adult	0.19	0.0%	Milk: Cattle	0.0%	Rye	0.0%	Wheat		0.1%
	0.1%	UK adult	0.17	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Bovine: Muscle/meat		0.1%
	0.1%	UK vegetarian	0.16	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Eggs: Chicken		0.1%
	0.0%	IT toddler	0.15	0.0%	Wheat	0.0%	Barley				0.0%
	0.0%	IE child	0.15	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Eggs: Chicken		0.0%
	0.0%	IT adult	0.09	0.0%	Wheat	0.0%	Barley				0.0%
	0.0%	PT general	0.09	0.0%	Wheat	0.0%	Rye	0.0%	Barley		0.0%
	0.0%	FI 3 yr	0.04	0.0%	Wheat	0.0%	Rye	0.0%	Barley		0.0%
	0.0%	FI 6 yr	0.04	0.0%	Wheat	0.0%	Rye	0.0%	Barley		0.0%
	0.0%	FI adult	0.02	0.0%	Rye	0.0%	Wheat	0.0%	Barley		0.0%
		Column7			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				

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

Fluxapyroxad

Fluxapyroxad (F)			
LOQs (mg/kg) range from:	0.01	to:	0.01
Toxicological reference values			
ADI (mg/kg bw/day):	0.02	ARfD (mg/kg bw):	0.25
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2012	Year of evaluation:	2012

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

	Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	48%	NL toddler	9.60	14%	Apples	6%	Pears	3%	Sugar beet roots	0.2%	4%
	32%	DE child	6.42	16%	Apples	3%	Wheat	2%	Strawberries	0.3%	3%
	30%	NL child	5.92	8%	Apples	5%	Sugar beet roots	3%	Oil palm fruits	0.2%	3%
	24%	GEMS/Food G06	4.89	7%	Rice	4%	Wheat	2%	Sugar canes	0.1%	5%
	22%	GEMS/Food G11	4.46	3%	Sugar canes	2%	Celeries	2%	Wheat	0.2%	5%
	21%	GEMS/Food G10	4.30	5%	Rice	2%	Wheat	2%	Sugar canes	0.1%	4%
	20%	GEMS/Food G07	4.01	3%	Wheat	2%	Sugar canes	2%	Potatoes	0.1%	5%
	20%	GEMS/Food G08	3.92	2%	Wheat	2%	Barley	2%	Sugar canes	0.1%	6%
	20%	FR child 3 15 yr	3.91	3%	Wheat	2%	Sugar beet roots	2%	Other lettuce and other salad pla	0.2%	3%
	19%	FR toddler 2 3 yr	3.75	4%	Apples	3%	Rice	2%	Beans (with pods)	0.2%	2%
	18%	GEMS/Food G15	3.66	3%	Wheat	2%	Barley	2%	Sugar canes	0.1%	5%
	17%	DK child	3.41	3%	Rye	3%	Apples	3%	Wheat	0.0%	7%
	17%	IE adult	3.39	2%	Rhubarbs	1%	Wheat	1%	Celeries	0.2%	2%
	15%	NL general	3.01	2%	Apples	2%	Oil palm fruits	2%	Sugar beet roots	0.1%	2%
	15%	PT general	2.92	3%	Rice	2%	Potatoes	2%	Wheat	0.0%	3%
	14%	IT toddler	2.88	4%	Wheat	2%	Other lettuce and other salad plants	1%	Apples	0.1%	4%
	14%	UK toddler	2.86	3%	Rice	2%	Wheat	2%	Apples	0.1%	3%
	14%	DE general	2.79	3%	Apples	3%	Sugar beet roots	1%	Barley	0.1%	3%
	14%	SE general	2.77	2%	Wheat	2%	Potatoes	2%	Rice	0.1%	3%
	14%	DE women 14-50 yr	2.76	3%	Apples	3%	Sugar beet roots	1%	Wheat	0.1%	2%
	14%	RO general	2.75	3%	Wheat	2%	Apples	2%	Potatoes	0.0%	3%
	14%	UK infant	2.74	3%	Rice	2%	Apples	2%	Wheat	0.0%	2%
	14%	IT adult	2.72	3%	Other lettuce and other salad plants	2%	Wheat	1%	Apples	0.1%	3%
	13%	FR adult	2.61	3%	Other lettuce and other salad plants	2%	Wine grapes	1%	Wheat	0.1%	2%
	13%	FI 3 yr	2.57	2%	Rice	2%	Potatoes	2%	Oat	0.1%	1%
	12%	ES child	2.45	3%	Wheat	2%	Rice	1%	Apples	0.2%	3%
	11%	FI adult	2.11	6%	Coffee beans	0.8%	Apples	0.6%	Strawberries	0.0%	0.7%
	10%	ES adult	1.98	1%	Wheat	1%	Barley	1%	Rice	0.1%	3%
	10%	FI 6 yr	1.96	2%	Rice	2%	Potatoes	1%	Strawberries	0.1%	1%
	10%	FR infant	1.95	2%	Apples	1%	Beans (with pods)	0.9%	Potatoes	0.0%	0.7%
	8%	LT adult	1.56	2%	Apples	1%	Potatoes	0.9%	Rice	0.0%	2%
	8%	UK vegetarian	1.52	2%	Rice	1%	Wheat	0.8%	Apples	0.0%	1%
	7%	UK adult	1.33	2%	Rice	1%	Wheat	0.8%	Wine grapes	0.0%	1%
	7%	PL general	1.31	3%	Apples	2%	Potatoes	0.4%	Plums	0.0%	
	6%	DK adult	1.24	1%	Apples	0.7%	Wine grapes	0.7%	Wheat	0.0%	1%
	4%	IE child	0.71	1%	Rice	0.7%	Wheat	0.4%	Apples	0.0%	0.8%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Fluxapyroxad (F) is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
7%	DK child	1.31	3%	Rye	3%	Wheat	0.2%	Swine: Muscle/meat		7%
6%	GEMS/Food G08	1.13	2%	Wheat	2%	Barley	0.4%	Rye		6%
5%	GEMS/Food G15	1.08	3%	Wheat	2%	Barley	0.1%	Swine: Muscle/meat		5%
5%	GEMS/Food G06	0.94	4%	Wheat	0.2%	Barley	0.1%	Poultry: Muscle/meat		5%
5%	GEMS/Food G11	0.94	2%	Wheat	2%	Barley	0.1%	Swine: Muscle/meat		5%
5%	GEMS/Food G07	0.93	3%	Wheat	2%	Barley	0.1%	Poultry: Muscle/meat		5%
4%	GEMS/Food G10	0.88	2%	Wheat	2%	Barley	0.1%	Poultry: Muscle/meat		4%
4%	IT toddler	0.80	4%	Wheat	0.0%	Barley				4%
4%	NL toddler	0.80	2%	Wheat	0.6%	Milk: Cattle	0.5%	Barley		4%
3%	FR child 3 15 yr	0.69	3%	Wheat	0.2%	Milk: Cattle	0.1%	Bovine: Muscle/meat		3%
3%	DE child	0.68	3%	Wheat	0.5%	Rye	0.2%	Milk: Cattle		3%
3%	RO general	0.68	3%	Wheat	0.1%	Milk: Cattle	0.1%	Swine: Muscle/meat		3%
3%	ES child	0.65	3%	Wheat	0.1%	Bovine: Muscle/meat	0.1%	Poultry: Muscle/meat		3%
3%	DE general	0.63	1%	Barley	1%	Wheat	0.3%	Rye		3%
3%	NL child	0.63	2%	Wheat	0.2%	Milk: Cattle	0.1%	Swine: Muscle/meat		3%
3%	ES adult	0.61	1%	Wheat	1%	Barley	0.1%	Bovine: Muscle/meat		3%
3%	UK toddler	0.56	2%	Wheat	0.2%	Milk: Cattle	0.1%	Bovine: Muscle/meat		3%
3%	SE general	0.54	2%	Wheat	0.4%	Bovine: Muscle/meat	0.2%	Rye		3%
3%	PT general	0.50	2%	Wheat	0.1%	Rye	0.1%	Barley		3%
3%	IT adult	0.50	2%	Wheat	0.0%	Barley				3%
2%	FR toddler 2 3 yr	0.49	2%	Wheat	0.3%	Milk: Cattle	0.1%	Bovine: Muscle/meat		2%
2%	DE women 14-50 yr	0.47	1%	Wheat	0.5%	Barley	0.3%	Rye		2%
2%	NL general	0.46	1%	Wheat	0.8%	Barley	0.1%	Swine: Muscle/meat		2%
2%	UK infant	0.43	2%	Wheat	0.4%	Milk: Cattle	0.1%	Bovine: Muscle/meat		2%
2%	IE adult	0.35	1%	Wheat	0.1%	Rye	0.0%	Milk: Cattle		2%
2%	LT adult	0.33	0.6%	Rye	0.6%	Wheat	0.2%	Barley		2%
2%	FR adult	0.31	1%	Wheat	0.1%	Swine: Muscle/meat	0.1%	Bovine: Muscle/meat		2%
1%	UK vegetarian	0.27	1%	Wheat	0.1%	Barley	0.0%	Milk: Cattle		1%
1%	FI 3 yr	0.26	0.7%	Wheat	0.4%	Rye	0.2%	Barley		1%
1%	DK adult	0.25	0.7%	Wheat	0.3%	Rye	0.1%	Swine: Muscle/meat		1%
1%	UK adult	0.25	1%	Wheat	0.1%	Barley	0.1%	Bovine: Muscle/meat		1%
1%	FI 6 yr	0.22	0.6%	Wheat	0.4%	Rye	0.2%	Barley		1%
0.8%	IE child	0.16	0.7%	Wheat	0.0%	Milk: Cattle	0.0%	Swine: Muscle/meat		0.8%
0.7%	FR infant	0.15	0.5%	Wheat	0.2%	Milk: Cattle	0.0%	Swine: Muscle/meat		0.7%
0.7%	FI adult	0.13	0.4%	Rye	0.2%	Wheat	0.1%	Barley		0.7%
	Column7			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Fluxapyroxad is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

A 3.3 IESTI calculations - Raw commodities

Prothioconazole except TDMs

Prothioconazole: prothioconazole-desthio (sum of isomers) (F)			
LOQs (mg/kg) range from:	**0.01**	to:	**0.05**
Toxicological reference values			
ADI (mg/kg bw/day):	**0.01**	ARfD (mg/kg bw):	**0.01**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2007**	Year of evaluation:	**2007**

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

Unprocessed commodities

Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI):			---	**Results for adults** No. of commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				**IESTI**			
Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
9%	Wheat	0.1 / 0.06	0.87	5%	Wheat	0.1 / 0.06	0.50
4%	Barley	0.2 / 0.07	0.39	3%	Barley	0.2 / 0.07	0.34
4%	Rye	0.05 / 0.06	0.38	3%	Rye	0.05 / 0.06	0.29
0.00%		0.00		0.00%		0.00	
0.00%		0.00		0.00%		0.00	
0.00%		0.00		0.00%		0.00	
0.00%		0.00		0.00%		0.00	
0.00%		0.00		0.00%		0.00	
0.00%		0.00		0.00%		0.00	
0.00%		0.00		0.00%		0.00	
0.00%		0.00		0.00%		0.00	
0.00%		0.00		0.00%		0.00	
0.00%		0.00		0.00%		0.00	
0.00%		0.00		0.00%		0.00	
0.00%		0.00		0.00%		0.00	
Expand/collapse list							
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)			0				

TDMs: 1,2,4-triazole (1,2,4-T)

1,2,4-Triazole			
LOQs (mg/kg) range from:		to:	
Toxicological reference values			
ADI (mg/kg bw/day):		ARfD (mg/kg bw):	**0.1**
Source of ADI:		Source of ARfD:	**EC**
Year of evaluation:		Year of evaluation:	**2021**

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

Unprocessed commodities

Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI):			---	Results for adults No. of commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				**IESTI**			
Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
20%	Milk: Cattle	0 / 0.16	20	6%	Milk: Cattle	0 / 0.16	6.2
4%	Milk: Goat	0 / 0.16	3.9	3%	Milk: Goat	0 / 0.16	2.9
3%	Swine: Muscle/meat	0 / 0.21	2.5	2%	Milk: Sheep	0 / 0.16	2.4
2%	Bovine: Liver	0 / 0.25	2.0	1%	Bovine: Muscle	0 / 0.24	1.4
2%	Bovine: Muscle/meat	0 / 0.24	1.7	1%	Sheep: Muscle/meat	0 / 0.24	1.1
1%	Sheep: Muscle/meat	0 / 0.24	1.3	1%	Swine: Muscle/meat	0 / 0.21	1.0
1%	Bovine: Kidney	0 / 0.28	1.1	1%	Bovine: Liver	0 / 0.25	1.00
0.7%	Wheat	0 / 0.05	0.72	0.7%	Sheep: Liver	0 / 0.25	0.70
0.7%	Poultry: Muscle/meat	0 / 0.04	0.68	0.6%	Bovine: Kidney	0 / 0.28	0.59
0.6%	Milk: Sheep	0 / 0.16	0.57	0.6%	Swine: Kidney	0 / 0.25	0.55
0.5%	Eggs: Chicken	0 / 0.04	0.50	0.5%	Poultry: Muscle	0 / 0.04	0.47
0.4%	Bovine: Fat tissue	0 / 0.19	0.40	0.4%	Wheat	0 / 0.05	0.42
0.3%	Swine: Kidney	0 / 0.25	0.32	0.4%	Goat: Muscle	0 / 0.24	0.37
0.3%	Rye	0 / 0.05	0.32	0.3%	Swine: Fat tissue	0 / 0.16	0.32
0.3%	Barley	0 / 0.05	0.28	0.3%	Swine: Liver	0 / 0.19	0.27
Expand/collapse list							
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)							

Triazole alanine (TA)

Triazole alanine (TA)

LOQs (mg/kg) range from:		to:	
Toxicological reference values			
ADI (mg/kg bw/day):		ARfD (mg/kg bw):	**0.3**
Source of ADI:		Source of ARfD:	**EC**
Year of evaluation:		Year of evaluation:	**2018**

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

Unprocessed commodities

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

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
3%	Wheat	0 / 0.62	9.0	2%	Wheat	0 / 0.62	5.2
1%	Rye	0 / 0.62	3.9	1%	Rye	0 / 0.62	3.0
1%	Barley	0 / 0.62	3.5	1%	Barley	0 / 0.62	3.0
0.9%	Bovine: Liver	0 / 0.35	2.8	0.5%	Bovine: Liver	0 / 0.35	1.4
0.8%	Milk: Cattle	0 / 0.02	2.5	0.4%	Bovine: Muscle	0 / 0.23	1.3
0.6%	Poultry: Muscle/meat	0 / 0.11	1.9	0.4%	Poultry: Muscle	0 / 0.11	1.3
0.6%	Bovine: Muscle/meat	0 / 0.23	1.7	0.4%	Sheep: Muscle/meat	0 / 0.23	1.1
0.5%	Swine: Muscle/meat	0 / 0.13	1.6	0.3%	Poultry: Liver	0 / 0.22	1.0
0.4%	Sheep: Muscle/meat	0 / 0.23	1.3	0.3%	Sheep: Liver	0 / 0.35	0.98
0.3%	Bovine: Kidney	0 / 0.22	0.83	0.3%	Milk: Cattle	0 / 0.02	0.77
0.2%	Eggs: Chicken	0 / 0.06	0.74	0.2%	Swine: Muscle/meat	0 / 0.13	0.63
0.2%	Milk: Goat	0 / 0.02	0.48	0.2%	Swine: Kidney	0 / 0.22	0.48
0.1%	Swine: Liver	0 / 0.34	0.42	0.2%	Swine: Liver	0 / 0.34	0.48
0.09%	Swine: Kidney	0 / 0.22	0.28	0.2%	Bovine: Kidney	0 / 0.22	0.46
0.08%	Poultry: Liver	0 / 0.22	0.24	0.1%	Milk: Goat	0 / 0.02	0.37

Expand/collapse list

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

Triazole acetic acid (TAA)

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

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

Unprocessed commodities

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

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
1%	Wheat	0 / 0.79	11	0.7%	Wheat	0 / 0.79	6.6
0.5%	Rye	0 / 0.79	5.0	0.4%	Rye	0 / 0.79	3.8
0.4%	Barley	0 / 0.79	4.4	0.4%	Barley	0 / 0.79	3.8
0.4%	Milk: Cattle	0 / 0.03	3.7	0.1%	Milk: Cattle	0 / 0.03	1.2
0.07%	Milk: Goat	0 / 0.03	0.73	0.06%	Milk: Goat	0 / 0.03	0.55
0.05%	Poultry: Muscle/meat	0 / 0.03	0.51	0.05%	Milk: Sheep	0 / 0.03	0.45
0.05%	Bovine: Kidney	0 / 0.13	0.49	0.04%	Poultry: Muscle	0 / 0.03	0.35
0.04%	Eggs: Chicken	0 / 0.03	0.37	0.03%	Bovine: Kidney	0 / 0.13	0.27
0.04%	Swine: Muscle/meat	0 / 0.03	0.36	0.02%	Swine: Kidney	0 / 0.1	0.22
0.02%	Bovine: Liver	0 / 0.03	0.24	0.02%	Bovine: Muscle	0 / 0.03	0.17
0.02%	Bovine: Muscle/meat	0 / 0.03	0.22	0.01%	Swine: Muscle/meat	0 / 0.03	0.15
0.02%	Sheep: Muscle/meat	0 / 0.03	0.16	0.01%	Sheep: Muscle/meat	0 / 0.03	0.14
0.01%	Swine: Kidney	0 / 0.1	0.13	0.01%	Poultry: Liver	0 / 0.03	0.14
0.01%	Milk: Sheep	0 / 0.03	0.11	0.01%	Eggs: Chicken	0 / 0.03	0.13
0.01%	Bovine: Fat tissue	0 / 0.03	0.06	0.01%	Bovine: Liver	0 / 0.03	0.12

Expand/collapse list

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

Triazole lactic acid (TLA)

Triazole lactic acid (TLA)			
LOQs (mg/kg) range from:		to:	
Toxicological reference values			
ADI (mg/kg bw/day):		ARfD (mg/kg bw):	0.3
Source of ADI:		Source of ARfD:	EC
Year of evaluation:		Year of evaluation:	2018

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

Unprocessed commodities

Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI):			---	**Results for adults** No. of commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				**IESTI**			
Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
1%	Milk: Cattle	0 / 0.03	3.7	0.4%	Milk: Cattle	0 / 0.03	1.2
0.2%	Milk: Goat	0 / 0.03	0.73	0.2%	Milk: Goat	0 / 0.03	0.55
0.2%	Poultry: Muscle/meat	0 / 0.03	0.51	0.2%	Milk: Sheep	0 / 0.03	0.45
0.1%	Eggs: Chicken	0 / 0.03	0.37	0.1%	Poultry: Muscle	0 / 0.03	0.35
0.1%	Bovine: Liver	0 / 0.04	0.32	0.06%	Wheat	0 / 0.02	0.18
0.1%	Wheat	0 / 0.02	0.32	0.06%	Bovine: Muscle	0 / 0.03	0.17
0.07%	Bovine: Muscle/meat	0 / 0.03	0.22	0.05%	Bovine: Liver	0 / 0.04	0.16
0.06%	Bovine: Fat tissue	0 / 0.09	0.19	0.05%	Sheep: Muscle/meat	0 / 0.03	0.14
0.05%	Sheep: Muscle/meat	0 / 0.03	0.16	0.05%	Poultry: Liver	0 / 0.03	0.14
0.05%	Rye	0 / 0.02	0.14	0.04%	Eggs: Chicken	0 / 0.03	0.13
0.04%	Barley	0 / 0.02	0.12	0.04%	Sheep: Liver	0 / 0.04	0.11
0.04%	Bovine: Kidney	0 / 0.03	0.11	0.04%	Rye	0 / 0.02	0.11
0.04%	Milk: Sheep	0 / 0.03	0.11	0.04%	Barley	0 / 0.02	0.11
0.01%	Poultry: Liver	0 / 0.03	0.03	0.03%	Bovine: Fat tissue	0 / 0.09	0.09
0.00%	Poultry: Fat tissue	0 / 0.03	0.00	0.02%	Bovine: Kidney	0 / 0.03	0.06
Expand/collapse list							
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)							

Fluxapyroxad

Fluxapyroxad (F)

LOQs (mg/kg) range from:	0.01	to:	0.01
Toxicological reference values			
ADI (mg/kg bw/day):	0.02	ARfD (mg/kg bw):	0.25
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2012	Year of evaluation:	2012

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

Unprocessed commodities

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

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
1%	Barley	3 / 0.54	3.0	1%	Barley	3 / 0.54	2.6
0.7%	Wheat	0.4 / 0.12	1.7	0.4%	Wheat	0.4 / 0.12	1.0
0.3%	Rye	0.4 / 0.12	0.76	0.2%	Rye	0.4 / 0.12	0.58
0.1%	Poultry: Muscle/meat	0.02 / 0.02	0.34	0.09%	Poultry: Muscle	0.02 / 0.02	0.23
0.10%	Milk: Cattle	0.02 / 0	0.25	0.06%	Sheep: Liver	0.1 / 0.05	0.14
0.10%	Swine: Muscle/meat	0.02 / 0.02	0.24	0.05%	Bovine: Liver	0.1 / 0.03	0.12
0.10%	Bovine: Liver	0.1 / 0.03	0.24	0.05%	Bovine: Muscle	0.02 / 0.02	0.11
0.06%	Eggs: Chicken	0.02 / 0.01	0.15	0.04%	Swine: Muscle/meat	0.02 / 0.02	0.10
0.06%	Bovine: Muscle/meat	0.02 / 0.02	0.14	0.04%	Equine: Muscle/meat	0.02 / 0.02	0.10
0.05%	Equine: Muscle/meat	0.02 / 0.02	0.12	0.04%	Sheep: Muscle/meat	0.02 / 0.02	0.09
0.04%	Sheep: Muscle/meat	0.02 / 0.02	0.11	0.04%	Poultry: Liver	0.02 / 0.02	0.09
0.03%	Bovine: Kidney	0.1 / 0.02	0.08	0.03%	Milk: Cattle	0.02 / 0	0.08
0.02%	Bovine: Fat tissue	0.2 / 0.03	0.06	0.02%	Eggs: Chicken	0.02 / 0.01	0.05
0.02%	Milk: Goat	0.02 / 0	0.05	0.02%	Swine: Kidney	0.1 / 0.02	0.04
0.01%	Swine: Liver	0.1 / 0.03	0.04	0.02%	Swine: Liver	0.1 / 0.03	0.04

Expand/collapse list

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

A 3.4 IESTI calculations - Processed commodities

Prothioconazole except TDMs

Prothioconazole: prothioconazole-desthio (sum of isomers) (F)			
LOQs (mg/kg) range from:	0.01	to:	0.05
Toxicological reference values			
ADI (mg/kg bw/day):	0.01	ARfD (mg/kg bw):	0.01
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2007	Year of evaluation:	2007

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)
7%	Wheat / milling (flour)	0.1 / 0.06	0.73	5%	Barley / beer	0.2 / 0.01	0.50
3%	Wheat / milling (wholemeal)	0.1 / 0.06	0.33	3%	Wheat / bread/pizza	0.1 / 0.06	0.26
3%	Barley / cooked	0.2 / 0.07	0.25	2%	Wheat / pasta	0.1 / 0.06	0.23
2%	Rye / boiled	0.05 / 0.06	0.22	2%	Wheat / bread (wholemeal)	0.1 / 0.06	0.21
2%	Rye / milling (wholemeal)-b	0.05 / 0.06	0.21	#NUM!	#NUM!	#NUM!	#NUM!
1%	Barley / milling (flour)	0.2 / 0.07	0.13	#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!

TDMs: 1,2,4-triazole (1,2,4-T)

1,2,4-Triazole			
LOQs (mg/kg) range from:		to:	
Toxicological reference values			
ADI (mg/kg bw/day):		ARfD (mg/kg bw):	0.1
Source of ADI:		Source of ARfD:	EC
Year of evaluation:		Year of evaluation:	2021

Processed commodities

Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---	**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				**IESTI**			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.6%	Wheat / milling (flour)	0 / 0.05	0.60	0.4%	Barley / beer	0 / 0.01	0.36
0.3%	Wheat / milling (wholemea	0 / 0.05	0.28	0.2%	Wheat / bread/pizza	0 / 0.05	0.22
0.2%	Rye / boiled	0 / 0.05	0.18	0.2%	Wheat / pasta	0 / 0.05	0.19
0.2%	Barley / cooked	0 / 0.05	0.18	0.2%	Wheat / bread	0 / 0.05	0.17
0.2%	Rye / milling (wholemeal)-	0 / 0.05	0.18	#NUM!	#NUM!	#NUM!	#NUM!
0.1%	Barley / milling (flour)	0 / 0.05	0.09	#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
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#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
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 is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

Triazole alanine (TA)

Triazole alanine (TA)			
LOQs (mg/kg) range from:		to:	
Toxicological reference values			
ADI (mg/kg bw/day):		ARfD (mg/kg bw):	**0.3**
Source of ADI:		Source of ARfD:	**EC**
Year of evaluation:		Year of evaluation:	**2018**

Processed commodities

Results for children				Results for adults			
No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---	No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				IESTI			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
3%	Wheat / milling (flour)	0 / 0.62	7.5	1%	Barley / beer	0 / 0.12	4.5
1%	Wheat / milling (wholeme:	0 / 0.62	3.4	0.9%	Wheat / bread/pizza	0 / 0.62	2.7
0.8%	Rye / boiled	0 / 0.62	2.3	0.8%	Wheat / pasta	0 / 0.62	2.4
0.8%	Barley / cooked	0 / 0.62	2.3	0.7%	Wheat / bread	0 / 0.62	2.2
0.7%	Rye / milling (wholemeal)-	0 / 0.62	2.2	#NUM!	#NUM!	#NUM!	#NUM!
0.4%	Barley / milling (flour)	0 / 0.62	1.1	#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
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#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
Expand/collapse list							

Triazole acetic acid (TAA)

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

Processed commodities

Results for children				Results for adults			
No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---	No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				**IESTI**			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
1.0%	Wheat / milling (flour)	0 / 0.79	9.6	0.6%	Barley / beer	0 / 0.16	5.7
0.6%	Sugar beets (root) / sugar	0 / 0.6	5.5	0.3%	Wheat / bread/pizza	0 / 0.79	3.5
0.4%	Wheat / milling (wholemea	0 / 0.79	4.4	0.3%	Wheat / pasta	0 / 0.79	3.0
0.3%	Rye / boiled	0 / 0.79	2.9	0.3%	Wheat / bread	0 / 0.79	2.8
0.3%	Barley / cooked	0 / 0.79	2.9	0.2%	Sugar beets (root) / sugar	0 / 0.6	2.2
0.3%	Rye / milling (wholemeal)-	0 / 0.79	2.8	0.03%	Sugar canes / sugar	0 / 0.05	0.28
0.1%	Barley / milling (flour)	0 / 0.79	1.4	0.00%	Chicory roots / processed	0 / 0.05	0.02
0.0%	Sugar canes / sugar	0 / 0.05	0.46	#NUM!	#NUM!	#NUM!	#NUM!
0.0%	Chicory roots / processec	0 / 0.05	0.04	#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
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#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
Expand/collapse list							

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

Triazole lactic acid (TLA)

Triazole lactic acid (TLA)			
LOQs (mg/kg) range from:		to:	
Toxicological reference values			
ADI (mg/kg bw/day):		ARfD (mg/kg bw):	**0.3**
Source of ADI:		Source of ARfD:	**EC**
Year of evaluation:		Year of evaluation:	**2018**

Processed commodities

Results for children				Results for adults			
No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---	No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				**IESTI**			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.1%	Wheat / milling (flour)	0 / 0.02	0.27	0.1%	Barley / beer	0 / 0	0.16
0.0%	Wheat / milling (wholeme:	0 / 0.02	0.12	0.03%	Wheat / bread/pizza	0 / 0.02	0.10
0.0%	Rye / boiled	0 / 0.02	0.08	0.03%	Wheat / pasta	0 / 0.02	0.08
0.0%	Barley / cooked	0 / 0.02	0.08	0.03%	Wheat / bread	0 / 0.02	0.08
0.0%	Rye / milling (wholemeal)-	0 / 0.02	0.08	#NUM!	#NUM!	#NUM!	#NUM!
0.0%	Barley / milling (flour)	0 / 0.02	0.04	#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
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#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
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Expand/collapse list							

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

Fluxapyroxad

Fluxapyroxad (F)

LOQs (mg/kg) range from:	0.01	to:	0.01
Toxicological reference values			
ADI (mg/kg bw/day):	0.02	ARfD (mg/kg bw):	0.25
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2012	Year of evaluation:	2012

Processed commodities

Results for children				Results for adults			
No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---	No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				IESTI			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.8%	Barley / cooked	0 / 0.54	2.0	2%	Barley / beer	0 / 0.11	3.9
0.6%	Wheat / milling (flour)	0 / 0.12	1.5	0.2%	Wheat / bread/pizza	0 / 0.12	0.53
0.4%	Barley / milling (flour)	0 / 0.54	0.98	0.2%	Wheat / pasta	0 / 0.12	0.46
0.3%	Wheat / milling (wholemeal)	0 / 0.12	0.67	0.2%	Wheat / bread (wholemeal)	0 / 0.12	0.42
0.2%	Rye / boiled	0 / 0.12	0.44	#NUM!	#NUM!	#NUM!	#NUM!
0.2%	Rye / milling (wholemeal)-b	0 / 0.12	0.42	#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
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Expand/collapse list							

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short term intake of residues of Fluxapyroxad (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