

REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: ADM.03502.F.1.A

(alternative codes: MCW-2091)

Product name(s): see part A

Chemical active substance(s):

Fenpropidin 250 g/L

Prothioconazole 175 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorisation)

Applicant: Country organisation / representative
as specified in Part A

Submission date: September 2021, updated March 2022, October
2022

Finalisation date: December 2022 (initial Core Assessment)

April 2023 (final Core Assessment)

Version history

When	What
September 2021	Initial dRR – ADAMA Polska Sp. z o.o
March 2022	Updated dRR – ADAMA Polska Sp. z o.o.
October 2022	Updated dRR – ADAMA Polska Sp. z o.o.
December 2022	<p>Initial zRMS assessment</p> <p>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.</p> <p>Following the evaluation and before sending the document for commenting, all coloured highlighting was removed, from the parts updated by the Applicant, for better legibility.</p>
April 2023	<p>Final report (Core Assessment updated following the commenting period)</p> <p>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.</p>

DATA PROTECTION CLAIM

In order to present a dossier fully compliant with today's requirements (Reg. 284/2013), studies have been performed on ADM.03502.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.03502.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

The summaries and evaluations contained in this document may be based on unpublished proprietary data submitted for the purpose of the assessment undertaken by the regulatory authority that prepared it. Other registration authorities should not grant, amend, or renew a registration on the basis of the summaries and evaluation of unpublished proprietary data contained in this document unless they have received the data on which the summaries and evaluation are based, either –

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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.03502.F.1.A are presented in Table 7.1- 1. They have been selected from the individual GAPs in the central zone for wheat, rye, triticale, barley and oat.

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

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

According to Commission regulation (EU) No 752/2014 replacing Annex I to Regulation (EC) No 396/2005 triticale (code number: 0500090-006) can be grouped to wheat (code number: 0500090).

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), 0.2 mg/kg (barley) as laid down in Reg. (EU) 396/2005 (last update Comm. Reg. (EU) No 2019/552) is not expected.

Considering the intended use on oat, an exceedance of the MRL of 0.05 mg/kg for prothioconazole, as established in Commission Regulation (EU) 2019/552, is expected.

An exceedance of the current EU-MRLs for fenpropidin (sum of fenpropidin and its salts, expressed as fenpropidin) of 0.1 mg/kg (wheat, rye, triticale), 0.6 mg/kg (barley), and 0.3 (oat) as laid down in Reg. (EU) 396/2005 (last update Comm. Reg. (EU) No 61/2014) is not expected.

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

As far as consumer health protection is concerned, zRMS agrees with the authorisation of the intended use(s): wheat, rye, triticale, barley and oilseed rape, except oat.

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 update.

Data gaps

Noticed data gaps are:

- None.

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

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	dRR zone (residue zone)	Product code	F, Fn, Fpn G, Gn, Gpn or I**	Pests or Group of pests controlled	Formulation		Application				Application rate per treatment		PHI (days)	Conclusion
							Type	Conc. of as 1) Prothioconazole 2) Fenpro-pidin	method kind	growth stage & season	Max. number a) per use b) per crop/season	Min. interval between applications (days)	water L/ha min max	kg as/ha Prothioconazole / Fenpropidin a) max. rate per appl. b) max. total rate per crop/season		
Critical GAP (1)	1, 3, 4, 6, 8, 9, 11, 13, 14, 16, 18, 19, 21, 23, 25, 26, 28, 106, 108, 109, 112, 114, 115	Spring and winter wheat 0500090 (TRZAS, TRZAW), winter rye 0500070 (SECCW), triticale 0500090-006 (TTLSS)	C-EU (N-EU)	ADM.03502.F.1.A (alternative code: MCW-2091)	F	Foliar diseases	EC	1) 175 g/L 2) 250 g/L	Foliar spraying, overall	BBCH 30-65 Spring	a) 1 b) 1	-	100-400	a) 0.175 / 0.250 b) 0.175 / 0.250	n.a.	A
Critical GAP (2)	2, 5, 7, 10, 12, 15, 17, 20, 22, 24, 27, 29, 107, 110, 113, 116	Spring and winter barley 0500010 (HORVS, HORVW), oat 0500050 (AVESS)	C-EU (N-EU)	ADM.03502.F.1.A (alternative code: MCW-2091)	F	Foliar diseases	EC	1) 175 g/L 2) 250 g/L	Foliar spraying, overall	BBCH 30-65 Spring	a) 1 b) 1	-	100-400	a) 0.175 / 0.250 b) 0.175 / 0.250	n.a.	A for barley N for oat prothioconazole MRL exceedance

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

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

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.03502.F.1.A is composed of prothioconazole 175 g/L and fenpropidin 250 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	
Fenpropidin					
ADI	EFSA Scientific Report (2007) 124, 1-84	2008	0.02 mg/kg bw/d	rat, 2-yr study; dog, 1-yr study	100
ARfD	EFSA Scientific Report (2007) 124, 1-84		0.02 mg/kg bw	dog 28-day to 1-yr studies	100

7.1.2.1 Summary for prothioconazole

Results of the risk assessment on TDMs are not yet completed due to ongoing residue and storage stability studies and therefore not included below. Study reports on TDMs will be submitted after finalisation.

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 GAP (1)	1, 3, 4, 6, 8, 9, 11, 13, 14, 16, 18, 19, 21, 23, 25, 26, 28	Spring and winter wheat (TRZAS, TRZAW), winter rye (SECCW), triticale (TTLSS)	Y	Y	n.a.	Y	Y	N	N
Critical GAP (2)	2, 5, 7, 10, 12, 15, 17, 20, 22, 24, 27, 29	Spring and winter barley (HORVS, HORVW), oat (AVESS)	Y	Y	n.a.	Y	Y (barley) No (oat)		N

* 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 (except TDMs), there is no need to investigate the effect of industrial and/or household processing.

Residues of prothioconazole (except TDMs including 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 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.03502.F.1.A on wheat, rye, triticale and barley is therefore acceptable. The proposed use on oat is not considered acceptable.

7.1.2.2 Summary for fenpropidin

Table 7.1- 4: Summary for fenpropidin

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 GAP (1)	1, 3, 4, 6, 8, 9, 11, 13, 14, 16, 18, 19, 21, 23, 25, 26, 28	Spring and winter wheat (TRZAS, TRZAW), winter rye (SECCW), triticale (TTLSS)	Y	Y	n.a.	Y	Y	N	N
Critical GAP (2)	2, 5, 7, 10, 12, 15, 17, 20, 22, 24, 27, 29	Spring and winter barley (HORVS, HORVW), oat (AVESS)	Y	Y	n.a.	Y	Y		N

* 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 fenpropidin residues have been investigated. Data on effects of processing on the amount of residue have been already evaluated during EU peer review of fenpropidin. These data were not considered for risk assessment.

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

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

7.1.2.3 Summary for ADM.03502.F.1.A

Table 7.1- 5: Information on ADM.03502.F.1.A (KCA 6.8)

Crop	PHI for ADM.03502.F.1.A proposed by applicant	PHI sufficiently supported for		PHI for ADM.03502.F.1.A proposed by zRMS	zRMS Comments (if different PHI proposed)
		Prothioconazole	Fenpropidin		
Wheat, rye, triticale	n/a [#]	Yes	Yes	n/a	-
Barley, oat	n/a [#]	Yes	Yes	n/a	-

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.03502.F.1.A
Crop group	Led by prothioconazole	Led by fenpropidin	
Wheat, rye, triticale	NR	NR	
Barley, oat	NR	NR	
Leafy vegetables	NR	NR	NR
Root and tuber vegetables	NR	NR	NR
Cereals	NR	NR	NR

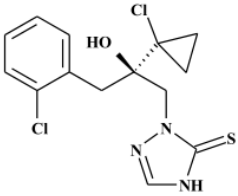
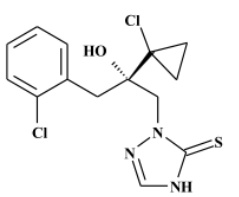
NR: not relevant

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	(<i>RS</i>)-2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-2,4-dihydro-1,2,4-triazole-3-thione
Chemical structure	<div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;">  <p>R - enantiomer</p> </div> <div style="text-align: center;">  <p>S - enantiomer</p> </div> </div>
Molecular formula	C ₁₄ H ₁₅ Cl ₂ N ₃ O S
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, 2018b)**;
EFSA Journal : Conclusion on article 12	Yes (EFSA, 2014 and EFSA 2020)**
Current MRL applications on intended uses	None

* Notifier in the EU process

** 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, 2007, DAR UK, 2004 and 2007) and to the MRL review

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

In addition, 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 summarized in the tables below. The detailed assessments of these studies are presented in Appendix 2.

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 $\leq -18^{\circ}\text{C}$ (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	180 days	Prothioconazole (JAU 6476)	Heinemann, O. (2001), DAR UK, 2004, Vol. 3, B.7, IIA, 6.0/01;
		540 days	Prothioconazole -desthio (JAU 6476-desthio)	EFSA, 2007; EFSA, 2014
Potatoes	High water content	24 months	Prothioconazole- α -hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio	EFSA, 2020
Wheat straw	Dry commodity	360 days	Prothioconazole	Heinemann, O. (2001), DAR UK, 2004, Vol. 3, B.7, IIA, 6.0/01;
		540 days	Prothioconazole -desthio	EFSA, 2007; EFSA, 2014

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	120 days	Prothioconazole	Heinemann, O. (2001), DAR UK, 2004, Vol. 3, B.7, IIA, 6.0/01; EFSA, 2007; EFSA, 2014
		540 days	Prothioconazole -desthio	
Tomatoes	High water content	24 months	Prothioconazole- α -hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio	EFSA, 2020
Rapeseeds	High oil content	24 months	Prothioconazole -desthio	EFSA, 2014
Soya beans, rapeseeds	High oil content	24 months	Prothioconazole- α -hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio	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
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	24 months		
Wheat straw	Dry commodity	24 months		
Oilseed rape	High oil content	24 months		
Strawberry	High acid content	24 months		
Dry bean	Dry commodity	24 months		

n.a.: not applicable

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 $\leq -18^{\circ}\text{C}$ (unless stated otherwise)

Matrix	Characteristic s 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, 2018b (amended 2019); EFSA 2020
Barley, wheat grain	Dry commodity	12	26	26	48	EFSA 2018b (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 2018b (amended 2019); EFSA 2020
Peas, dry; Navy beans	Dry commodity	No data	15	25	48	EFSA 2018b (amended 2019); EFSA 2020
Oranges	High acid content	No data	No data	No data	48	EFSA 2018b (amended 2019); EFSA 2020
Barley, wheat straw	Dry commodity	12	53	40	Covered by 5 matrices and dry com- modity data ¹	EFSA 2018b (amended 2019); EFSA 2020
Animal Products						
Animal products and tissues	Milk	18	No data	No data	No data	EFSA 2018b (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., 2017 (KCA 6.1/01)
Grapes	High acid content	36	36	36	36	
Dried beans	Dry commodity	36	36	36	36	

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

Conclusion on stability of residues during storage

Prothioconazole except TDMs

In addition to the storage stability data evaluated during EU review (EFSA, 2007), the storage stability of prothioconazole-desithio 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 $\leq 18^{\circ}\text{C}$.

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).

TDMs

The freezer storage stability of various TDMs was investigated in the framework of the peer review of TDMs (UK, 2018b, EFSA, 2018, 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.

In addition, storage stability in cucumber, grapes and dried bean was demonstrated in the new storage stability studies submitted with this dossier (Klimmek, 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 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, 2018a). In addition, storage stability in other dry matrices was proven in stability studies summarised in Table 7.2- 3 above.

zRMS comments:

Information given by the Applicant is sufficient and acceptable.

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).

New study on the storage stability of prothioconazole-desthio and its hydroxies metabolites in different matrices was 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 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).

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

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

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.

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

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)

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 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-¹⁴C-phenyl]-labelled prothioconazole. The metabolism of prothioconazole-desthio was also investigated for foliar application on cereals (wheat) using [3,5-¹⁴C-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 [3,5-¹⁴C-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							

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)	
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]-prothioconazole	Foliar treatment, G	0.300	3 (21 days) (BBCH 66-75)	Hay & nuts without shells: 14 days	JMPR: FAO, 2008a, 2008b EFSA, 2014
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
	Wheat	[3,5- ¹⁴ C-triazole] prothioconazole	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] prothioconazole	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] prothioconazole	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 chlorophenyl ring forming various hydroxyl-desthio isomers and dihydroxy-olefins. Similarly, α -hydroxylation of prothioconazole-desthio was also observed. A dimerisation product and other metabolites resulting from combined oxidation of the sulphur atom and hydroxylation of the chlorophenyl ring were also identified. Cleavage of the triazole moiety is also observed resulting in the ‘triazole derivative metabolites’ which consist essentially in triazole alanine and triazole acetic acid. These compounds are common, unspecific metabolites of triazole fungicides. Triazole alanine and triazole acetic acid are massively translocated to wheat grains where they represent 90% of the Total Radioactive Residues (TRR). 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 2018b, amended 2019 and EFSA 2020, the following residue definitions are proposed:

Residue definition for enforcement:

- Prothioconazole-desthio (sum of isomers).

Residue definition for risk assessment:

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

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-prothioconazole-desthio and alpha-hydroxy-prothioconazole-desthio (including all their acid-hydrolysable conjugates).

No further data are required.

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

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 are submitted in the framework of this application.

Prothioconazole except TDMs

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

Crop group	Crop	Commodities sampled	Label position	Application and sampling details					Reference
				Method	Rate (kg a.s./ha)	Planting intervals* (DAT)	Harvest Intervals (DAT)	Remarks	
EU data									
Leafy vegetables	Swiss chard	Swiss chard	[Phenyl-UL- ¹⁴ C]-prothioconazole	Soil treatment	0.58	28, 146, 269	80, 188, 348	--	Haas, M. (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)	--	

* Planting of seedlings.

Summary of rotational crop metabolism studies reported in the EU

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

Conclusion on metabolism in rotational crops

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

According to EFSA, 2014 (Art. 12 MRL review), the following was concluded: “In wheat grain, the total radioactive residues were recovered at a trace level at all DATs (≤ 0.007 mg eq/kg) and no further metabolites’ identification was attempted. In wheat green material, hay and straw, TRR ranged from 0.021

mg eq/kg (green material, DAT 28) to 0.450 mg eq/kg (straw, DAT 28). In turnip roots, tops and Swiss chard, the highest residue levels ranged from 0.043 mg eq/kg (turnip root, DAT 28) to 0.053 mg eq/kg (Swiss chard, DAT 146). No significant decline of the residue levels was observed for any crop part throughout the first, second and third rotation.

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

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

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

TDMs

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, 2018b).

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).

Triazole Derivate Metabolites, addendum – confirmatory data (UK, 2018)

“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, 2018b, amended 2019).

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

Nature of the residues of prothioconazole and prothioconazole-desthio in processed commodities

Stability of the residues of prothioconazole and prothioconazole-desthio 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
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.	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 ($\leq 11\%$ 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, 2018b 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, 2018b, 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 ($\leq 11\%$) to prothioconazole-desthio.*

The Applicant submitted new 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- 6: 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-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers) (EFSA 2014, EFSA, 2020) b) TDMs (EFSA, 2018b), 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, 2018b, 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-¹⁴C-phenyl]-labelled prothioconazole and prothioconazole-desthio and one study in laying hens using [U-¹⁴C-phenyl]-labelled prothioconazole. Besides, two additional studies were assessed by the JMPR (FAO, 2008a, 2008b) on lactating goats and laying hens, using both [3,5-¹⁴C-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- 7: Summary of animal metabolism studies

Table 7.12-1: 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	Weber, H., Spiegel, K. (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	Weber, H., Weber, E., Spiegel, K. (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	Weber, H., Spiegel, K. (2001), DAR UK, 2004 and 2007, Vol. 3, B7, IIA, 6.2.2.3/01;
						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								
								EFSA, 2007
		[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)	
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.”

TDMs

According to EFSA, 2018b: “The compilation of the poultry and ruminant metabolism studies conducted with the triazole pesticide active substances with the ¹⁴C labelling on the triazole moiety showed that besides

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

RD for enforcement: Triazole parent compound only

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

Summary of new animal metabolism studies

No new data 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_{ow} of prothioconazole-desthio equals 3.04 (EFSA, 2007). Since higher prothioconazole-desthio residue levels were found in fat compared to fat free muscle, EFSA concludes that the residue definition for enforcement in commodities of animal origin is fat soluble (EFSA 2014).

TDMs

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

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

RDs for risk assessment: 1) Triazole parent compound and any other relevant metabolite exclusively linked to the parent compound (sum of prothioconazole-desthio and all metabolites

- containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers), see prothioconazole above;
- 2) 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- 8: 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, 2018b)
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, 2018b)
Conversion factor from enforcement to RA	2 (liver);

(Prothioconazole without TDMs)	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, 2018b, 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.

Prothioconazole except TDMs

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.

TDMs

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

Therefore, the respective data are not cited here again but new residue studies 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. However, these trials were considered for risk assessment with the purpose of performing a ‘worst case’ consumer dietary intake calculation. In case residues in untreated samples exceeded residues in treated samples, higher values from untreated samples were used for risk assessment.

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:

Residue definition for enforcement:

- Prothioconazole-desthio (sum of isomers).

Residue definition for risk assessment:

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

Wheat, rye, triticale (KCA 6.3.1)

Table 7.2- 9: Comparison of intended and critical EU GAPs in wheat, rye and triticale (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	0.175 kg as/ha	-	65	n.a.

* Critical GAP number(s) in accordance with column 0 of Table 7.1- 1.

According to the available data, the intended outdoor uses on wheat, rye and triticale in C-EU are considered acceptable. According to EC TG SANTE/2019/12752, extrapolation from wheat to rye (and triticale) is possible without restriction.

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- 10: Summary of EU reported and new data on prothioconazole metabolites supporting the intended uses of ADM.03502.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-triazole)								
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 kg a.s./ha applied in wheat at BBCH 65, PHI n.a., outdoor Wheat grain: E: 4×<0.01, 8× <0.01 RA: (A): 4×<0.06, 8× <0.06 (B): TA: 0.36, 0.28, 0.26, 0.29, 0.27, 0.32, 0.42, 0.40, 0.18, 0.24 TLA: 0.01, 9× <0.01 (C): TAA: 0.14, 0.11, 0.06, 0.22, 0.09, 0.05, 0.07, 3× 0.08 (D): 1,2,4-T: 6× <0.01, 2 x <0.01** For livestock dietary burden assessment only: Wheat straw: E: 0.019, 0.056, 0.20, 0.28, 0.038, 0.040, 0.63, 0.046, 0.082, 0.013, 0.022, 0.018 RA: (A): 0.059, 0.19, 2× 0.67, 0.14, 0.20, 0.96, 0.25, 0.29, <0.06, 0.15, 0.065 (B): TA: 0.03, 0.02, 8× <0.01 TLA: 0.09, 0.18, <0.01, 2× 0.05, 2× 0.02, 3× 0.01 (C): TAA: 0.06, 0.01, 0.05, 0.03, 3× 0.04, 3× 0.02 (D): 1,2,4-T: 6× <0.01, 2 x <0.01**	*Values in italics were derived using RAR method 00979/M001, LC-MS/MS (in contrast to other results derived using methods based on QuEChERS method EN 15662:2009-02). Values E_{all} (prothioconazole-desthio (sum of isomers)) and (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 bold show STMR and HR of prothioconazole residues involving residues from all studies. ** Two additional trials using mixture product prothioconazole and difenoconazole (KCA 6.3.1/04) are included to cover 1,2,4-T.				

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	<p>EU data not included due to more critical GAP than envisaged (3 applications).</p> <p>Wheat grain: E: $4 \times <0.01$, $8 \times <0.01$ RA: (A): $4 \times <0.06$, $8 \times <0.06$ (B): TA: 0.36, 0.28, 0.26, 0.29, 0.27, 0.32, 0.42, 0.40, 0.18, 0.24 TLA: 0.1, $9 \times <0.01$ (C): TAA: 0.14, 0.11, 0.06, 0.22, 0.09, 0.05, 0.07, 3×0.08 (D): 1,2,4-T: $6 \times <0.01$, $2 \times <0.01$</p> <p>For livestock dietary burden assessment only: Wheat straw: E: 0.019, 0.056, 0.20, 0.28, 0.038, 0.040, 0.63, 0.046, 0.082, 0.013, 0.022, 0.018 RA: (A): 0.059, 0.19, 2×0.67, 0.14, 0.20, 0.96, 0.25, 0.29, <0.06, 0.15, 0.065 (B): TA: 0.03, 0.02, $8 \times <0.01$ TLA: 0.09, 0.18, <0.01, 2×0.05, 2×0.02, 3×0.01 (C): TAA: 0.06, 0.01, 0.05, 0.03, 3×0.04, 3×0.02 (D): 1,2,4-T: $6 \times <0.01$, $2 \times <0.01$</p>	<p>Grain:</p> <p>E: 0.010 E: 0.010* E_{all}: 0.010</p> <p>RA: (A): 0.06 0.06 RA_{all}: 0.06 (B): 0.285 (TA) 0.01 (TLA) (C): 0.08 (D): 0.01</p> <p>Straw:</p> <p>RA: (A): 0.43 0.175 RA_{all}: 0.145 (B): 0.01 (TA) 0.02 (TLA) (C): 0.035 (D): 0.01</p>	<p>E: 0.01 E: 0.010* E_{all}: 0.010</p> <p>RA: (A): 0.06 0.06 RA_{all}: 0.06 (B): 0.42 (TA) 0.01 (TLA) (C): 0.22 (D): 0.01</p> <p>RA: (A): 0.67 0.96 RA_{all}: 0.96 (B): 0.03 (TA) 0.18 (TLA) (C): 0.06 (D): 0.01</p>	<p>E: 0.01 E: 0.010* E_{all}: 0.010</p> <p>RA: n.r.</p> <p>RA: n.r.</p>	<p>Wheat grain: 0.1 Rye: 0.05</p>	Yes

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

Barley and oat (KCA 6.3.2)

Table 7.2- 11: Comparison of intended and critical EU GAPs in barley and oat (prothioconazole)

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	0.175 kg as/ha	-	65	n.a.

* Critical GAP number(s) in accordance with column 0 of Table 7.1- 1.

According to the available data, the intended outdoor uses on barley in C-EU are considered acceptable. According to EC TG SANTE/2019/12752 (13/06/2017), extrapolation from barley to oat is possible without restriction.

The intended critical GAPs in barley and oat (spring and winter barley, oat) are covered by the representative EU GAP uses of prothioconazole in cereals (barley and oat) 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 for barley will occur. The uses on barley are considered acceptable.

Considering the intended use on oat, an exceedance of the MRL for prothioconazole is expected.

The proposed use on oat is not considered acceptable.

Table 7.2- 12: Summary of EU reported and new data on prothioconazole metabolites supporting the intended uses of ADM.03502.F.1.A in barley and oat 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-triazole)								
Spring and winter barley, 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 30 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				
Extrapolation from barley → oat	New trials	N-EU	Trials GAP: 1× 0.175 kg a.s./ha applied in barley at BBCH 65, PHI n.a., outdoor					
Extrapolation from spring cereals ↔ winter cereals due to late application timing	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 KCA 6.3.2/07		Barley grain: E: 2× <0.01, 3× <0.01, 0.01, 0.027, 0.030, 4× <0.01, 0.01, 0.013, 0.054, 0.061 RA: (A): 4× <0.06, 10× <0.06, 0.087, 0.095 (B): TA: 0.09, 0.13, 0.18, 0.15, 0.05, 0.12, 0.08, 0.10, 0.14, 0.07, 2× 0.11, 2× 0.04 TLA: 0.02, 13× <0.01 (C): TAA: 0.07, 0.06, 0.05, 0.10, 0.03, 0.09, 0.13, 4× 0.02, 3× 0.04 (D): 1,2,4-T: 10× <0.01 For livestock dietary burden assessment only: Barley straw: E: 0.049, 0.063, 0.083, 0.12, 0.25, 0.28, 0.092, 0.085, 0.055, 1.7, 0.34, 0.041, 0.49, 0.21, 0.052, 0.92 RA: (A): 0.11, 0.16, 0.17, 0.49, 0.61, 1.3, 2× 0.14, 0.33, 0.19, 0.20, 2.2, 1.0, 0.061, 0.93, 0.53 (B): TA: 3× 0.02, 11× <0.01 TLA: 0.06, 0.05, 0.19, 3× 0.03, 2× 0.02, 3× 0.01, 3× <0.01					<i>*Values in italics were derived using RAR method 00979/M001, LC-MS/MS (in contrast to other results derived using methods based on QuEChERS method EN 15662:2009-02).</i> Values E_{all} (prothioconazole-desthio (sum of isomers)) and (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 bold show STMR and HR of prothioconazole residues involving residues from all studies.
Critical GAP (2)								

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
			(C): TAA: 3× 0.03, 3× 0.02, 2× 0.04, 2× 0.01, 4× <0.01 (D): 1,2,4-T: 10× <0.01					
	Overall supporting data for cGAP	N-EU	Barley grain: E: 2× <0.01, 3× <0.01, 0.01, 0.027, 0.030, 4× <0.01, 0.01, 0.013, 0.054, 0.061 RA: (A): 4× <0.06, 10× <0.06, 0.087, 0.095 (B): TA: 0.09, 0.13, 0.18, 0.15, 0.05, 0.12, 0.08, 0.10, 0.14, 0.07, 2× 0.11, 2× 0.04 TLA: 0.02, 13× <0.01 (C): TAA: 0.07, 0.06, 0.05, 0.10, 0.03, 0.09, 0.13, 4× 0.02, 3× 0.04 (D): 1,2,4-T: 10× <0.01 For livestock dietary burden assessment only: Barley straw: E: 0.049, 0.063, 0.083, 0.12, 0.25, 0.28, 0.092, 0.085, 0.055, 1.7, 0.34, 0.041, 0.49, 0.21, 0.052, 0.92 RA: (A): 0.11, 0.16, 0.17, 0.49, 0.61, 1.3, 2× 0.14, 0.33, 0.19, 0.20, 2.2, 1.0, 0.061, 0.93, 0.53 (B): TA: 3× 0.02, 11× <0.01 TLA: 0.06, 0.05, 0.19, 3× 0.03, 2× 0.02, 3× 0.01, 3× <0.01 (C): TAA: 3× 0.03, 3× 0.02, 2× 0.04, 2× 0.01, 4× <0.01 (D): 1,2,4-T: 10× <0.01	Grain: E: 0.010 E: 0.010* E_{all}: 0.010 RA: (A): 0.06 0.06 RA_{all}: 0.06 (B): 0.105 (TA) 0.01 (TLA) (C): 0.04 (D): 0.01 Straw: RA: (A): 0.265 0.265 RA_{all}: 0.245 (B): 0.01 (TA) 0.02 (TLA) (C): 0.02 (D): 0.01	E: 0.033 E: 0.061 E_{all}: 0.061 RA: (A) 0.061 0.095 RA_{all}: 0.095 (B): 0.18 (TA) 0.02 (TLA) (C): 0.13 (D): 0.01 RA: n.r. RA: n.r.	E: 0.053 E: 0.094 E_{all}: 0.085 RA: n.r. RA: n.r.	Barley grain: 0.2 Oat: 0.05	Yes (Barley) No (oat)

* 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. Twelve trials in wheat from 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).

Therefore, the supplementary data submitted show that any exceedance of the current EU-MRLs of 0.1 mg/kg for wheat and 0.05 mg/kg for rye is not to be expected.

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 (TA, TLA, TAA) and 9 trials (1,2,4-T), 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, oat

According to the available data, the intended uses on barley are considered acceptable. 16 trials in barley in Northern Europe showed no or only very low residues at harvest according to the residue definition for enforcement in barley grains at < 0.01 (5×) to 0.061 mg/kg.

Therefore, the supplementary data submitted show that any exceedance of the current EU-MRL of 0.2 mg/kg for barley is not to be expected.

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 except for two trials with residues of 0.087 and 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 (TA, TLA, TAA) and 10 trials (1,2,4-T), 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-desthio) 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 150-200 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 wheat grain at harvest were <0.01 mg/kg.

Total residue for prothioconazole (prothioconazole-desthio and all 5 hydroxy metabolites) in grain at harvest were <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. The current EU MRL for prothioconazole is sufficient to support the proposed uses.

Residues of 1,2,4-T were <LOQ.

Residues of TLA in grain between <0.01 mg/kg and 0.1 mg/kg.

Residues of TA in grain were between 0.18 and 0.42 mg/kg.

Residues of TAA in grain were between 0.05 and 0.22 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 150-200 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 0.18 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.

Remark:

In SANTE/2019/12752, in ANNEX I clarifications on “old/new” data requirements, it is stated that “50% of residue trials should be decline studies, if the consumable part is exposed during application of the plant protection product under the proposed conditions of use.” It means that Applicant should have provided at least 4 decline studies.

For TDMs, not all submitted trials were covered by the storage stability data for the metabolites (for 1,2,4-T). For 1,2,4-T, only 2 decline studies were within the maximum storage period. However, the residue levels in grains were < LOQ in all trials. Taking into above account, zRMS is of the opinion that the available residue data is sufficient to support the proposed use on barley.

The proposed use on barley is considered acceptable.

Oat

Oat is the major crop in northern Europe (SANTE/2019/12752). A minimum of eight trials are required. Based on the SANTE/2019/12752, 8 residue trials on barley can be used for extrapolation to oat before and after forming of the edible part.

Sufficient trials on barley were conducted according to the residue definition for monitoring and risk assessment with the following GAP: 1 x 150-200 g a.s. /ha, application at BBCH 65-69, outdoor. See zRMS comments above. The residue trials on barley can be used for extrapolation to oat.

Residues of prothioconazole-desthio (RD-Mo) in barley grain at harvest were between <0.01 mg/kg and 0.061 mg/kg.

Considering the intended use on oat, an exceedance of the MRL of 0.05 mg/kg for prothioconazole, as established in Commission Regulation (EU) 2019/552, is expected. Therefore until the new MRL for oat come into force, authorization of the GAP (oat) will not be possible.

The proposed use on oat is not 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, 2018b, 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.”

New dietary burden calculations using EFSA animal model 2017, based on the EFSA 2020 calculations and covering the envisaged GAP uses, are presented in the following. 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 the new intake calculations. A more detailed overview of the input values is given in Appendix 4. The corresponding results can be found in Table 7.2- 14.

Table 7.2- 13: 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 <i>H</i> -1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers)				
Rape seed meal (<i>EFSA 2020</i>)	0.16	STMR × PF (2) ^(a)	0.16	STMR × PF (2) ^(a)
Sunflower seed meal (<i>EFSA 2020</i>)	0.04	STMR × CF (2) × PF (2) ^(a) (<i>EFSA, 2015a,b</i>)	0.04	STMR × CF (2) × PF (2) ^(a) (<i>EFSA, 2015a,b</i>)
Head cabbage (<i>EFSA 2020</i>)	0.02	STMR × CF (<i>EFSA, 2014</i>)	0.12	HR × CF (<i>EFSA, 2014</i>)
Maize silage (<i>EFSA 2020</i>)	0.01	STMR (<i>EFSA, 2014</i>)	0.01	HR (<i>EFSA, 2014</i>)
Maize grain (<i>EFSA 2020</i>)	0.02	STMR (<i>FAO, 2014</i>) × CF (2) (<i>EFSA, 2014</i>)	0.02	STMR (<i>FAO, 2014</i>) × CF (2) (<i>EFSA, 2014</i>)
Maize, milled by-products ^(b) ; Maize, hominy meal ^(b) ; Maize gluten feed/gluten meal ^(b) ; Distiller's grain ^(b) (<i>EFSA 2020</i>)	0.02	STMR (<i>FAO, 2014</i>) × CF (2) (<i>EFSA, 2014</i>)	0.02	STMR (<i>FAO, 2014</i>) × CF (2) (<i>EFSA, 2014</i>)
Barley grain (<i>EFSA 2020</i>)	0.07	STMR (<i>FAO, 2009b</i>) × CF (2) (<i>EFSA, 2014</i>)	0.07	STMR (<i>FAO, 2009b</i>) × CF (2) (<i>EFSA, 2014</i>)
Barley grain <i>new</i>	0.06	STMR (new trials submitted, refer to Table 7.2- 12, but covered by higher input value used in <i>EFSA 2020</i> in the line above)	0.06	STMR (new trials submitted, refer to Table 7.2- 12, but covered by higher input value used in <i>EFSA 2020</i> in the line above)
Brewer's grain (<i>EFSA 2020</i>)	0.23	STMR barley grain (<i>FAO, 2009b</i>) × CF (2) (<i>EFSA, 2014</i>) × PF (3.3) ^(a)	0.23	STMR barley grain (<i>FAO, 2009b</i>) × CF (2) (<i>EFSA, 2014</i>) × PF (3.3) ^(a)
Oat grain (<i>EFSA 2020</i>)	0.02	STMR (<i>FAO, 2008a</i>) × CF (2) (<i>EFSA, 2014</i>)	0.02	STMR (<i>FAO, 2008a</i>) × CF (2) (<i>EFSA, 2014</i>)
Oat grain <i>new</i>	0.06	STMR (new trials submitted, refer to Table 7.2- 12, extrapolated from barley)	0.06 (RD for RA)	STMR (new trials submitted, refer to Table 7.2- 12, extrapolated from barley)
Wheat grain (<i>EFSA 2020</i>)	0.04	STMR (<i>FAO, 2009b</i>) × CF (2) (<i>EFSA, 2014</i>)	0.04	STMR (<i>FAO, 2009b</i>) × CF (2) (<i>EFSA, 2014</i>)
Wheat grain <i>new</i>	0.06	STMR (new trials submitted, refer to Table 7.2- 10)	0.06	STMR (new trials submitted, refer to Table 7.2- 10)
Wheat gluten meal ^(b) (<i>EFSA 2020</i>)	0.04	STMR wheat grain (<i>FAO, 2009b</i>) × CF (2) × PF (1.8) ^(a)	0.04	STMR wheat grain (<i>FAO, 2009b</i>) × CF (2) × PF (1.8) ^(a)
Wheat milled by-products ^(b) (<i>EFSA 2020</i>)	0.28	STMR wheat grain (<i>FAO, 2009b</i>) × CF (2) × PF (7) ^(a)	0.28	STMR wheat grain (<i>FAO, 2009b</i>) × CF (2) × PF (7) ^(a)
Rye grain (<i>EFSA 2020</i>)	0.02	STMR (<i>FAO, 2008a</i>) × CF (2)	0.02	STMR (<i>FAO, 2008a</i>) × CF (2)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Rye grain <i>new</i>	0.06	STMR (new trials submitted, refer to Table 7.2- 10, extrapolated from wheat)	0.06	STMR (new trials submitted, refer to Table 7.2- 10, extrapolated from wheat)
Triticale grain <i>new</i>	0.06	STMR (new trials submitted, refer to Table 7.2- 10, extrapolated from wheat)	0.06	STMR (new trials submitted, refer to Table 7.2- 10, 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 (<i>new</i>)	0.245	STMR (new trials submitted, refer to Table 7.2- 12, 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- 12, but covered by higher input value used in EFSA 2020 in the line above)
Oats straw (EFSA 2020)	1.26	STMR ^(d) × CF (3) (EFSA, 2014)	7.50	HR ^(d) × CF (3) (EFSA, 2014)
Oat straw (<i>new</i>)	0.245	STMR (new trials submitted, refer to Table 7.2- 10, extrapolated from barley, 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- 12, extrapolated from barley, but covered by higher input value used in EFSA 2020 in the line above)
Wheat straw (EFSA 2020)	2.69	STMR	5.52	HR ^(d) (EFSA, 2014) × CF (2.3)
Wheat straw (<i>new</i>)	0.154	STMR (new trials submitted, refer to Table 7.2- 10, but covered by higher input value used in EFSA 2020 in the line above)	0.96	HR (new trials submitted, refer to Table 7.2- 10, 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 (<i>new</i>)	0.154	STMR (new trials submitted, refer to Table 7.2- 10, extrapolated from wheat, but covered by higher input value used in EFSA 2020 in the line above)	0.96	HR (new trials submitted, refer to Table 7.2- 10, extrapolated from wheat, but covered by higher input value used in EFSA 2020 in the line above)
Triticale straw <i>new</i>	0.154	STMR (new trials submitted, refer to Table 7.2- 12, extrapolated from wheat, but covered by higher input value used in EFSA 2020 in the line above)	0.96	HR (new trials submitted, refer to Table 7.2- 10, extrapolated from wheat, but covered by higher input value used in EFSA 2020 in the line above)
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)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Potatoes (<i>EFSA 2020</i>)	0.01	STMR (<i>EFSA</i> , 2014)	0.01	HR (<i>EFSA</i> , 2014)
Potato process waste ^(b) ; Potato dried pulp ^(b) (<i>EFSA 2020</i>)	0.01	STMR potato (<i>EFSA</i> , 2014) × PF (1) ^(c)	0.01	HR potato (<i>EFSA</i> , 2014) × PF (1) ^(c)
Turnips, swedes, carrot culls (<i>EFSA 2020</i>)	0.08	STMR	0.10	HR
Peanut meal (<i>EFSA 2020</i>)	0.04	STMR (<i>FAO</i> , 2009b) × CF (2) × PF (2)	0.04	STMR (<i>FAO</i> , 2009b) × CF (2) × PF (2)
Linseed meal (<i>EFSA 2020</i>)	0.12	STMR × CF (2) × PF (2) ^(a) (<i>EFSA</i> , 2015a,b)	0.12	STMR × CF (2) × PF (2) ^(a) (<i>EFSA</i> , 2015a,b)
Soybean seed (<i>EFSA 2020</i>)	0.10	STMR (<i>FAO</i> , 2014) × CF (2)	0.10	STMR (<i>FAO</i> , 2014) × CF (2)
Soybean seed meal (<i>EFSA 2020</i>)	0.13	STMR (<i>FAO</i> , 2014) × CF (2) × PF (1.3) ^(a)	0.13	STMR (<i>FAO</i> , 2014) × CF (2) × PF (1.3) ^(a)
Soybean hulls ^(b) (<i>EFSA 2020</i>)	1.30	STMR soybean (<i>FAO</i> , 2014) × CF (2) × PF (13) ^(a)	1.30	STMR soybean (<i>FAO</i> , 2014) × CF (2) × PF (13) ^(a)

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

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

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

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

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

Table 7.2- 14: 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-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers)) are significant in the diets of livestock (> 0.1 mg/kg dry matter in the diet).

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.

Remark on residue behaviour in fish (B.7.2.2.5 and B.7.2.4)

According to the new Working Documents on the nature and magnitude of pesticide residues in fish (SANTE/10254/2021, SANTE/10252/2021) as well as on the dietary burden calculator for pesticide residues in fish (SANTE/10250/2021), data on residue behaviour in fish are required when the pesticide use may lead to residues >0.1 mg/kg in the total diet (dry weight basis) and when the active substances and/or metabolites are fat soluble, i.e. have a $\log P_{o/w} \geq 3$.

For prothioconazole-desthio the $\log P_{o/w}$ is 3.04 and EFSA concluded that prothioconazole-desthio is fat soluble due to higher residue levels found in fat than in fat free muscle. Cereal grains are used as a fish feeding stuff. However, residues of prothioconazole-desthio ranged from below the LOQ to 0.061 mg/kg in cereals grain. Residues above the trigger value of 0.1 mg/kg are therefore not expected. Further data are not 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, 2018b).” 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- 15: 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 <u>max.</u> dietary burden calculation (bold in brackets: HR/STMRs derived from new supplementary residue studies)						Residues input values for the <u>median</u> dietary burden calculation (bold 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
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

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 (bold in brackets: HR/STMRs derived from new supplementary residue studies)					Residues input values for the <u>median</u> dietary burden calculation (bold in brackets: HR/STMRs derived from new supplementary residue studies)				
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 (0.01)	0.65 (0.05)	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	bold 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											
All cereal grains	Cereal data	STMR	0.05 (0.01)	0.621 (0.225)	0.79 (0.235)	0.02 (0.02)	STMR	0.05 (0.01)	0.62 (0.225)	0.79 (0.235)	0.022 (0.02)
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	0.167	0.25	0.1	STMR-P	0.3	0.17	0.13	0.1

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 (bold in brackets: HR/STMRs derived from new supplementary residue studies)					Residues input values for the <u>median</u> dietary burden calculation (bold in brackets: HR/STMRs derived from new supplementary residue studies)				
			(STMR* default PF (5))	(STMR*PF) (0.32*0.52)	(STMR* default PF (5))	(STMR*PF) (0.04*2.5)		(STMR* default PF (5))	(STMR*PF) (0.32*0.52)	(STMR*PF) (0.05*2.5)	(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)
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

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 (bold in brackets: HR/STMRs derived from new supplementary residue studies)					Residues input values for the <u>median</u> dietary burden calculation (bold in brackets: HR/STMRs derived from new supplementary residue studies)				
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	0.165	2	2.6	0.073	STMR* default PF (3.3)	0.17	2	2.6	0.073
		-3.3									
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
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))	1.45 (STMR*PF)	0.24 (STMR*PF)	0.13 (STMR*PF)	STMR* PF	0.1 (STMR * default PF (2))	1.45 (STMR*PF)	0.24 (STMR*PF)	0.13 (STMR*PF)

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 (bold in brackets: HR/STMRs derived from new supplementary residue studies)					Residues input values for the <u>median</u> dietary burden calculation (bold in brackets: HR/STMRs derived from new supplementary residue studies)				
			(0.05* 2)	(1.039*1.4)	(0.12*2)	(0.065*2)		(0.05* 2)	(1.039*1.4)	(0.12*2)	(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)
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

Table 7.2- 16: The median and maximum dietary burden for 1,2,4-T

(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".

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- 18: 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 bypds
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 bypds
Poultry (all diets)	0.138	0.140	1.98	2.05	Poultry broiler	Wheat	milled bypds
Poultry (layer only)	0.135	0.140	1.98	2.05	Poultry layer	Wheat	milled bypds

(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- 19: 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.03500.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 were submitted in the framework of this application.

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

Table 7.2- 20: 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 [Table 7.2- 21]. In milk, a plateau level was reached after 1 or 2 days of exposure, according to the dose level group. Since neither the metabolites (free and conjugated) containing the common moiety and included in the residue definition for risk assessment nor the glucuronide conjugates of prothioconazole-desthio were analysed, EFSA reported the residue levels for enforcement only (prothioconazole-desthio) and considered the conversion factors for enforcement to risk assessment of 2 and 9 respectively for liver and kidney based on the goat metabolism study with administration of prothioconazole-desthio. No tentative CF was derived for milk, muscle and fat since the residue levels in these matrices are expected to be negligible (<0.01 mg/kg) at the calculated dietary burden. However, conversion factors reported above should in principle be covered by a new feeding study to estimate prothioconazole metabolites containing the common moiety in accordance with the residue definition for risk assessment.

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

Consequently, the available data allow deriving tentative MRLs in ruminants and pigs. These MRLs were derived in compliance with the latest recommendations on this matter (FAO, 2009b) and are summarised in [Table 7.2- 21]. Tentative MRLs in all commodities are established at the LOQ, except in liver and kidney of ruminants, where MRLs of 0.05 and 0.02 mg/kg respectively are proposed.”

When using the dietary burdens calculated above (considering the uses evaluated in Art. 12 procedure and the uses under consideration, presented in Table 7.2- 14), estimated residues at 1N dietary burden in ruminant and pig matrices and in milk do not exceed the current MRLs in the respective commodities as given in Com. Reg. (EU) 2019/552 (see Table 7.2- 21).

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

According to EFSA, 2020 the following applies with regard to residues in livestock: “The results of the dietary burden calculation are presented in Section B.2 [see Table 7.2- 14 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- 21: Overview of the values derived from livestock feeding studies (EFSA, 2014) and the estimated STMTRs/HRs at 1N intake level when using livestock dietary burden as calculated above (Table 7.2- 14)

Commodity	Dietary burden (Table 7.2- 14)		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.				
			3.64	3	0.02	0.04	n.a.	n.a.				

Commodity	Dietary burden (Table 7.2- 14)		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).												
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.				

N/A: Not applicable – only the mean values are considered for calculating MRLs in milk.

n.a.: Not reported

(*): Indicates that the MRL is set at the limit of analytical quantification.

(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 than 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 than 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 2018b, amended 2019) and reference is made to the respective evaluation.

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

Since livestock feeding studies were not conducted to address the potential transfer of 1,2,4-T and TLA in products of animal origin, the experts agreed that transfer factors for TA derived from the feeding studies conducted with TA should be applied to 1,2,4-T, assuming that the absorption and excretion behaviour of TA and 1,2,4-T are similar. Similarly transfer factors for TAA derived from the feeding studies conducted with TAA should be applied to TLA assuming that the absorption and excretion behaviour of TAA and TLA are comparable and because of the similarity of the functional groups. From the available toxicological studies, the absorption and excretion of TA, 1,2,4-T and TAA were shown to be similar and the experts agreed to estimate the 1,2,4-T residue levels in animal matrices by applying transfer factors for TA derived from the feeding study conducted with TA. A feeding study conducted with 1,2,4-T is therefore not required as no further metabolism of this compound in animal matrices is expected. In contrast and since a similar absorption and excretion behaviour of TLA compared to the other TDMs could not be demonstrated, livestock feeding studies conducted with TLA or metabolism studies performed in accordance with the current recommendations as a surrogate to these feeding studies should be provided (data gap). Meanwhile and provisionally, transfer factors for TAA derived from the feeding study conducted with TAA were applied to estimate the residue levels of TLA in animal commodities. The magnitude of residues of each TDM in animal matrices were therefore estimated by using the approach of a separate dietary burden calculation for each TDM and the application of transfer factors respectively to 1,2,4-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 2018b 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.03502.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)

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 shows residues < 0.1 mg/kg, whereas the trigger of 0.1 is partly exceeded for TA (HR and STMR exceed 0.1) and 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. 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

Triazole lactic acid

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

7.2.5.1 Available data for all crops under consideration

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

7.2.5.2 Conclusion on processing studies

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

Regarding TDMs, processing factors for TA, 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 and barley grain have been evaluated in confirmatory data for Triazole Derivate Metabolites (UK, 2018).

Overview of the available processing studies - TDMs

Processed commodity	Processing factors				Comments	Reference
	T	TA	TAA	TLA		
EU confirmatory data (B.7.5.2, UK, 2018)						
Wheat, aspirated grain fractions	NC	0.20	0.39	NA		UK, 2018
Wheat, Bran	NC	3.7	2.1	NA		
Wheat, Flour	NC	0.30	0.89	NA		
Wheat, Germ	NC	4.9	1.3	NC		
Wheat, Middlings	NC	0.66	0.80	NC		
Wheat, Shorts	NC	1.7	1.2	NC		
Barley, Brewer's malt	NC, NC	0.78, 0.77	1.0, 1.1	>1.1, >1.5		

Barley, Brewer's grain	NC, NC	<0.04, <0.03	<0.05, <0.04	NC, NC		
Barley, Brewer's yeast	NC, NC	0.24, 0.14	0.23, 0.23	NC, NC		
Barley, Beer	NC, NC	0.15, 0.13	0.29, 0.13	NC, NC		

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

Calculated processing factors show concentration of:

- TA and TAA in wheat bran,
- TA in wheat germ and shorts,
- TAA and TLA in barley, brewer's malt.

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 of prothioconazole in plants a 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- 22: Summary of available studies in field rotational crops

Table 7.2- 22: 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- 23.					
New data					
Bare soil	0.30 (Bare soil)	Leafy vegetables	Leaf lettuce	30 120 270	Undertaking: Ongoing study, the study report will be submitted after finalisation: 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	Undertaking: Ongoing study, the study report will be submitted after finalisation: Semrau, J., 2022, KCA 6.6.2/02
		Root and tuber vegetables	Radish root Radish top	28	
		Cereals	Barley whole plant Grain	28	

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
			Straw		

Prothioconazole except TDMs

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- 23: 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

Commodity	No of trials	STMR (mg/kg)				HR (mg/kg)			
		T	TA	TAA	TLA	T	TA	TAA	TLA
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, 2018). 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- 24: 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- 25: 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- 26: 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

	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 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- 27: 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

Underlined 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.

Prothioconazole

No residues are expected in rotational crops for the intended uses of ADM.03502.F.1.A, so additional field rotational crop studies are not considered required.

TDMs

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.

1. Semrau, J., 2021; Study no.: S18-02513

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.

2. Semrau, J., 2022; Study no.: S21-00408

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)

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of ADM.03502.F.1.A. Therefore, other special studies are not required.

Regarding potential residues in honey, the following is to be said:

Prothioconazole is a systemic fungicide applied as a spray at BBCH 30 - 65 in cereals (spring and winter wheat, spring and winter barley, winter rye, oat and triticale).

Any residues in pollen and bee products collected from treated crops are not to be expected in cereals as these crops have no melliferous capacity.

Therefore, any residue levels in honey are not to be expected from the envisaged GAP uses of prothioconazole.

zRMS comments:

Information given by the Applicant is acceptable.

The intended uses of ADM.03502.F.1.A in cereals are expected to have little potential for contributing residues to bee products. This is in line with the technical guidelines SANTE/11956/2016 rev. 9, 14 September 2018. Other special studies including data on prothioconazole residues in pollen and bee products for human consumption are not considered necessary.

In our opinion, no further data is necessary to support the uses of ADM.03502.F.1.A.

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). PRIMo rev. 3.1 also includes the chronic risk assessment according to the Rees Day - model, which is relevant for the United Kingdom.

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 and rye 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. For acute exposure calculations, only the crops under consideration were taken into account.

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.

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- 28: 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)		

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
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, 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- 12, but covered by higher input value	0.06	STMR (new trials submitted, refer to Table 7.2- 12, but covered by higher input value

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
		used in EFSA 2020 in the line above)		used in EFSA 2020 in the line above)
Maize grain	0.02	STMR ^(a) (FAO, 2014) × CF (2) (EFSA 2020)		
Oat, rye grain	0.02	STMR ^(a) (FAO, 2009a) × CF (2) (EFSA 2020)	0.02	STMR ^(a) (FAO, 2009a) × CF (2)
Oat grain (new)	0.06	STMR (new trials submitted, refer to Table 7.2- 12, extrapolated from barley)	0.06	STMR (new trials submitted, refer to Table 7.2- 12, extrapolated from barley)
Rye grain (new)	0.06	STMR (new trials submitted, refer to Table 7.2- 10, extrapolated from wheat)	0.06	STMR (new trials submitted, refer to Table 7.2- 10, 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- 10)	0.06	STMR (new trials submitted, refer to Table 7.2- 10)
Other commodities of plant origin	EU-MRL × CF (2) (CF applied if MRL > LOQ)	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)
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.

TDMs

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

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- 29: 1,2,4-Triazole (T): Input values for the consumer risk assessment (according to UK, 2018b and new trials submitted)

Code	Commodity	existing/ proposed MRL	Source/ type of MRL	Chronic risk assessment ¹⁾		Acute risk assessment ²⁾	
				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		

Code	Commodity	existing/ proposed MRL	Source/ type of MRL	Chronic risk assessment ¹⁾		Acute risk assessment ²⁾	
				Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
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/Mediterranean 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		
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		

Code	Commodity	existing/ proposed MRL	Source/ type of MRL	Chronic risk assessment ¹⁾		Acute risk assessment ²⁾	
				Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
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		
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		

Code	Commodity	existing/ proposed MRL	Source/ type of MRL	Chronic risk assessment ¹⁾		Acute risk assessment ²⁾	
				Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
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		
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		

Code	Commodity	existing/ proposed MRL	Source/ type of MRL	Chronic risk assessment ¹⁾		Acute risk assessment ²⁾	
				Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
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	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		
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

Code	Commodity	existing/ proposed MRL	Source/ type of MRL	Chronic risk assessment ¹⁾		Acute risk assessment ²⁾	
				Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
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- 30: Triazole alanine (TA): Input values for the consumer risk assessment (according to UK, 2018b and new trials submitted)

Code	Commodity	existing/ proposed MRL	Source/ type of MRL	Chronic risk assessment ¹⁾		Acute risk assessment ²⁾	
				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		
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		

Code	Commodity	existing/ proposed MRL	Source/ type of MRL	Chronic risk assessment ¹⁾		Acute risk assessment ²⁾	
				Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
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/Mediterranean 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		
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		

Code	Commodity	existing/ proposed MRL	Source/ type of MRL	Chronic risk assessment ¹⁾		Acute risk assessment ²⁾	
				Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
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		
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		

Code	Commodity	existing/ proposed MRL	Source/ type of MRL	Chronic risk assessment ¹⁾		Acute risk assessment ²⁾	
				Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
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		
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		

Code	Commodity	existing/ proposed MRL	Source/ type of MRL	Chronic risk assessment ¹⁾		Acute risk assessment ²⁾	
				Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
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	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
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

Code	Commodity	existing/ proposed MRL	Source/ type of MRL	Chronic risk assessment ¹⁾		Acute risk assessment ²⁾	
				Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
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- 31: Triazole acetic acid (TAA): Input values for the consumer risk assessment (according to UK, 2018b and new trials submitted)

Code	Commodity	existing/ proposed MRL	Source/ type of MRL	Chronic risk assessment ¹⁾		Acute risk assessment ²⁾	
				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		
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/Meditanean medlar			0.05	STMR-RAC		
154080	Elderberries			0.05	STMR-RAC		

Code	Commodity	existing/ proposed MRL	Source/ type of MRL	Chronic risk assessment ¹⁾		Acute risk assessment ²⁾	
				Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
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		
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		

Code	Commodity	existing/ proposed MRL	Source/ type of MRL	Chronic risk assessment ¹⁾		Acute risk assessment ²⁾	
				Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
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		
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		

Code	Commodity	existing/ proposed MRL	Source/ type of MRL	Chronic risk assessment ¹⁾		Acute risk assessment ²⁾	
				Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
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		
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	0.79	STMR-RAC

Code	Commodity	existing/ proposed MRL	Source/ type of MRL	Chronic risk assessment ⁽¹⁾		Acute risk assessment ⁽²⁾	
				Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
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
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- 32: Triazole lactic acid (TLA): Input values for the consumer risk assessment (according to UK, 2018b and new trials submitted)

Code	Commodity	existing/ proposed MRL	Source/ type of MRL	Chronic risk assessment ¹⁾		Acute risk assessment ²⁾	
				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		
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/Mediterranean 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		

Code	Commodity	existing/ proposed MRL	Source/ type of MRL	Chronic risk assessment ¹⁾		Acute risk assessment ²⁾	
				Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
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		
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		

Code	Commodity	existing/ proposed MRL	Source/ type of MRL	Chronic risk assessment ¹⁾		Acute risk assessment ²⁾	
				Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
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		
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		

Code	Commodity	existing/ proposed MRL	Source/ type of MRL	Chronic risk assessment ¹⁾		Acute risk assessment ²⁾	
				Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
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		
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	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		
1011010	Swine: Muscle/meat			0.03	STMR-RAC	0.03	HR-RAC
1011020	Swine: Fat tissue			0.04	STMR-RAC	0.06	HR-RAC
1011030	Swine: Liver			0.03	STMR-RAC	0.03	HR-RAC
1011040	Swine: Kidney			0.03	STMR-RAC	0.08	HR-RAC

Code	Commodity	existing/ proposed MRL	Source/ type of MRL	Chronic risk assessment ¹⁾		Acute risk assessment ²⁾	
				Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
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 kidney)			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
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- 33: 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: 7% (based on DK child; main contributor: Rye)

IESTI (% ARfD**) according to EFSA PRIMo 3.1	Bovine liver: 19% (based on unprocessed commodities, children) Bovine liver: 9% (based on unprocessed commodities, adults) Wheat (milling flour): 7% (based on processed commodities, children) Barley / beer: 5% (based on processed commodities, adults)
NEDI/NTMDI (% ADI) according to Rees Day-model (Σ 2 highest 97.5 percentile intakes + mean population intake for other foods)	Normal mode: 16% (based on UK infant; main contributor: Beans)

* ADI of prothioconazole-desthio

** ARfD of prothioconazole-desthio

The proposed uses of prothioconazole in the formulation ADM.03502.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 2018b 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.”

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 be given in the following:

Table 7.2- 34: 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)
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*Refined mode includes GAPs under assessment as well as livestock matrices/products.

Table 7.2- 35: 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- 36: 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- 37: 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.03500.F.2.B ADM.03502.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.

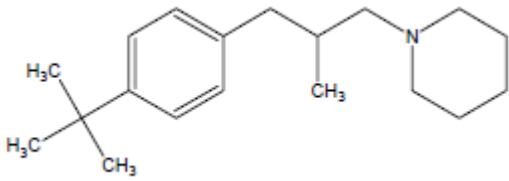
The data available are considered sufficient for risk assessment. The chronic and the short-term intakes of prothioconazole residues and TDMs are unlikely to present a public health concern.

The intended uses of ADM.03502.F.1.A are accepted.

7.3 Fenpropidin

General data on fenpropidin are summarised in the table below (last updated 2021/05/21)

Table 7.3- 1: General information on fenpropidin

Active substance (ISO Common Name)	Fenpropidin
IUPAC	(R,S)-1-[3-(4-tert-butylphenyl)-2-methylpropyl]-piperidine
Chemical structure	
Molecular formula	C ₁₉ H ₃₁ N
Molar mass	273.5 g/mol
Chemical group	Fungicide (piperidines)
Mode of action (if available)	Ergosterol biosynthesis inhibitor
Systemic	Yes
Company (ies)	Syngenta Ltd.*
Rapporteur Member State (RMS)	Sweden (first approval), Czech Republic (AIR)
Approval status	Approved 01/01/2009, <u>COM. IMPLEMENTING REGULATION (EU) No 540/2011</u> and <u>COM. IMPLEMENTING REGULATION (EU) 2020/1511</u>
Restriction (e.g. is restricted to use as "...")	Fenpropidin is restricted to use as fungicide.
Review Report	SANCO/3784/08 – rev. 0, 29 January 2008 (Inclusion) and SANCO/3784/08 – rev. 2, 20 November 2012 (Confirmatory data)
Current MRL regulation	Com. Reg. (EU) No 61/2014, 24 January 2014
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes
EFSA Journal: Conclusion on the peer review	Yes (EFSA, 2007)**
EFSA Journal: conclusion on Article 12	Yes (EFSA, 2011)**
Current MRL applications on intended uses	None

* Notifier in the EU process

** If yes: - see list of reference

7.3.1 Stability of Residues (KCA 6.1)

7.3.1.1 Stability of residues during storage of samples

Available data

Reference is made to the EU peer review (EFSA, 2007, DAR SE, 2006 and 2007) and to the MRL review (EFSA, 2011) for fenpropidin.

No new data submitted in the framework of this application.

Table 7.3- 2: Summary of stability data achieved at ≤ - 18°C (unless stated otherwise)

Matrix	Characteristics of the matrix	Acceptable maximum storage duration	Compounds covered	Reference
Data relied on in EU				
Plant products (unprocessed/ processed)				
Wheat grain	High starch/dry	24 months	Fenpropidin	DAR SE, 2006, Vol. 3, B.7.6.1; EFSA, 2007b; EFSA 2011 (Tribolet, 1995; ...)
Wheat straw	Dry			
Grapes	High acid content			
Banana	High water content			
Wine	Processed commodity			
Animal Products				
Animal tissues	All relevant ruminant matrices (muscle, liver, kidney, fat)	3 months	Fenpropidin, CGA 289267 and CGA 289268	DAR SE, 2006, Vol. 3, B.7.6.1; EFSA, 2007b; EFSA 2011 (...)
Ruminants	Milk	2 months	Fenpropidin, CGA 289267 and CGA 289268	
Blood	-	1 month	Fenpropidin, CGA 289267 and CGA 289268	

Conclusion on stability of residues during storage

According to EFSA, 2011: “storage stability of fenpropidin was demonstrated for a period of 24 months at -18 °C in commodities with high water (bananas) and high acid (grapes) content as well as in dry commodities (wheat grain) (EFSA, 2007b). According to the RMS, all residues trial samples reported were stored in compliance with the above reported storage conditions, except for sugar beet. Despite the fact that no information is available on the storage conditions of sugar beet samples, the storage stability was demonstrated for 24 months and it is very unlikely to store samples for a longer period before analysis.” and

“The storage stability of fenpropidin in animal products was evaluated under the peer review of Directive 91/414/EEC (Sweden, 2005). Studies demonstrated storage stability of fenpropidin and its metabolites CGA 289267 and CGA 289268 for up to 3 months in animal tissues and for up to 2 months in milk when stored deep frozen. All samples were stored in compliance with these conditions.”

7.3.1.2 Stability of residues in sample extracts (KCA 6.1)

Available data

The stability of crop sample extracts was checked as part of the field residue studies. The stability of fenpropidin residues 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 fenpropidin residues in the specimen extracts is sufficiently demonstrated in the frame of the available supervised residue trials.

Evaluator comment:

Information given by the Applicant is acceptable and sufficient. Studies on the storage stability of fenpropidin and its metabolites in crop and animal tissues under frozen conditions were assessed in the framework at the EU level.

In EFSA Journal 2011;9(8):2333 it is stated that “*The potential degradation of residues during storage of the residues trials samples was also assessed. In the framework of the peer review, storage stability of fenpropidin was demonstrated for a period of 24 months at -18 °C in commodities with high water (bananas) and high acid (grapes) content as well as in dry commodities (wheat grain) (EFSA, 2007b). According to the RMS, all residues trial*

samples reported were stored in compliance with the above reported storage conditions, except for sugar beet. Despite the fact that no information is available on the storage conditions of sugar beet samples, the storage stability was demonstrated for 24 months and it is very unlikely to store samples for a longer period before analysis.”

The studies on the magnitude of residues are valid with regard to storage stability.
No further data are required.

7.3.2 Nature of residues in plants, livestock and processed commodities

7.3.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

Reference is made to the EU peer review (EFSA, 2007, DAR SE, 2006 and 2007) and to the MRL review (EFSA, 2011) for fenpropidin.

No new data submitted in the framework of this application.

Table 7.3- 3: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Cereals	Spring wheat	[N-2-methylpropyl-3- ¹⁴ C] fenpropidin	Foliar treatment, G	2x0.5 kg as/ha at BBCH 37 and 67	2	1 DALA (immature), 59 DALA	-	DAR SE, 2006, Vol. 3, B.7.1.1 (Gross, 1994a)
Cereals	Spring wheat	[2,6- ¹⁴ C-piperidine] fenpropidin	Foliar treatment, G	2x 0.5 kg as/ha at BBCH 37 and 67	2	1 DALA (immature), 71 DALA	-	DAR SE, 2006, Vol. 3, B.7.1.2 (Gross, 1994b and Kiffe, 2000))
Root vegetables	Sugar beet	[N-2-methylpropyl-3- ¹⁴ C] fenpropidin	Foliar treatment, F	2x 0.375 kg as/ha at BBCH 31 and 30 DAA1	2	1 hour after each application and 60 DALA	-	DAR SE, 2006, Vol. 3, B.7.1.3 (Gross, 1994b and Kiffe, 2000))
Fruits	Grapevine	[N-2-methylpropyl-3- ¹⁴ C] fenpropidin	Foliar treatment, F	3x 0.3 kg a.s /ha, at BBCH 61, 16 DAA1 and 14 DAA2	3	1 hour after each application (leaves), 28 DALA (immature fruit and leaves) and 81 DALA	-	DAR SE, 2006, Vol. 3, B.7.1.4 (Gross, 1998b)
	Banana	[N-2-methylpropyl-3- ¹⁴ C] fenpropidin	Foliar treatment, G	3x 1.8 kg a.s /ha (1 g/tree), before blooming stage, 35 DAA1 (fruiting stage) and 55 DAA2	3	Just prior 2 nd and 3 rd application, and 1 DALA	-	DAR SE, 2006, Vol. 3, B.7.1.5 (Gentile, 1998)

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

Summary of plant metabolism studies reported in the EU

According to EFSA 2007: “The metabolism of fenpropidin has been investigated in spring wheat, sugar beet, grape vines and bananas. The design of the studies in wheat was in accordance with the representative use supported by the applicant. In all crops the product was applied as foliar treatment.

In wheat grains and straw, sugar beet leaves, grapes as well as bananas the observed metabolic pattern is similar. Fenpropidin represents the major part of the extractable radioactivity and the total amount of metabolites is generally one order of magnitude lower than the amount of parent compound. The nature of the identified metabolites shows that the metabolic pathway of fenpropidin consists in oxidative processes affecting the piperidine ring, the tertiary-butyl side chain and the methyl-propyl bridge. In addition, cleavage of the piperidine bond and glucose conjugation of a number of metabolites was also observed.

In sugar beet roots, Total Radioactive Residues (TRR) are very low and consist mainly of polar material. About 20% of the radioactivity was due to the incorporation of radioactive carbon into natural plant sugars.”

Summary of new plant metabolism studies

Not applicable/ no new studies are submitted.

Conclusion on metabolism in primary crops

Based on EFSA 2007 and EFSA 2011, the following residue definitions are proposed:

Residue definition for enforcement:

Sum of fenpropidin and its salts, expressed as fenpropidin.

Residue definition for risk assessment:

Sum of fenpropidin and its salts, expressed as fenpropidin.

Evaluator comment:

Information given by the Applicant is sufficient.

Metabolism of fenpropidin was investigated after foliar application on cereals (spring wheat), fruits and fruiting vegetables (grapevine and banana) and root and tuber vegetables (sugar beet) using [2,6-¹⁴C-piperidine] labelled and [N-2-methylpropyl-3-¹⁴C] labelled fenpropidin (EFSA, 2007).

According to the List of Endpoints of EFSA Scientific Report (2007):

Summary of data on the metabolism of fenpropidin in plants

Metabolism in plants	
Plant groups covered	Cereals (wheat), root vegetables (sugar beet), fruits (grapes, banana). Foliar application.
Plant residue definition for monitoring	Sum of fenpropidin and its salts, expressed as fenpropidin
Plant residue definition for risk assessment	Sum of fenpropidin and its salts, expressed as fenpropidin
Conversion factor (monitoring to risk assessment)	N/A

In EFSA Journal 2011;9(8):2333 it is stated that “*Metabolism of fenpropidin was investigated in 3 different crop groups following foliar application. Metabolic patterns in the different studies were shown to be similar and the relevant residue for enforcement and risk assessment in all crop groups could be defined as the sum of fenpropidin and its salts, expressed as fenpropidin. A validated analytical method for enforcement of this residue definition with a LOQ of 0.01 mg/kg in all major crop groups is available.*”

Residue definition:

The residue definition for enforcement and risk assessment: *Sum of fenpropidin and its salts, expressed as fenpropidin.*

The current residue definition for plants set in Regulation (EC) No 396/2005 (Reg. (EU) No 61/2014) is identical to the residue definition for enforcement derived in the peer review.

No further data are 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, 2007, DAR SE, 2006 and 2007) and to the MRL review

(EFSA, 2011) for fenpropidin.

No new data submitted in the framework of this application.

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

Table 7.3-4. Summary of metabolism studies in rotational crops								
Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G *	Rate (kg a.s./ha)	Sowing intervals (DALA)	Harvest Intervals (DALA)	Remarks	
EU data								
Leafy vegetables	Lettuce	[N-2-methylpropyl-3- ¹⁴ C] fenpropidin	Application on bare soil, F	2x 0.75 (21 d interval)	28, 96, 365	75, 152, 419	Head	DAR SE, 2006, Vol. 3, B.7.9.1 (Krauss (2000a))
Root and tuber vegetables	Radish				28, 96, 365	75, 159, 419	Roots and tops	
Cereals	Spring wheat				28, 76, 365	75/120, 120/194, 419/475	Whole tops (immature)/ grain & straw (mature)	
	Winter wheat				159	210, 420, 461	Whole tops, whole tops, grain & straw	
Leafy vegetables	Lettuce	[2,6- ¹⁴ C-piperidine] fenpropidin	Application on bare soil, F	2x 0.75 (21 d interval)	28, 96, 365	75, 152, 419	Head	DAR SE, 2006, Vol. 3, B.7.9.1 (Krauss (2000b))
Root and tuber vegetables	Radish				28, 96, 365	75, 159, 419	Roots and tops	
Cereals	Spring wheat				28, 76, 365	75/120, 120/194, 419/475	Whole tops (immature)/ grain & straw (mature)	
	Winter wheat				159	210, 420, 461	Whole tops, whole tops, grain & straw	

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

Summary of metabolism studies in rotational crops reported in the EU

According to EFSA, 2007: “Confined rotational crop studies after application of fenpropidin on bare soil show a moderate uptake of soil residues. The metabolic pattern is similar to that observed in primary crops. Fenpropidin is the major constituent of the residue, but found at low levels (0.01 mg/kg in lettuce and radish roots, 0.003 mg/kg in wheat grains) at 1N rate of application, and only for short plant-back intervals (28 days). Therefore, under normal rotation practices and considering that fenpropidin is applied to established cereals, ensuring a significant degree of interception, no residues of compounds structurally related to fenpropidin is expected to be present in plant products for human consumption from rotational crops. The need for field rotational crops studies should be reconsidered at Member State level in case of uses on other crops at higher application rate and/or lower degree of soil coverage by plants at the time of application.”

According to EFSA, 2011: “A confined rotational crop study with representative crops for the root and tuber vegetables (radish), leafy vegetables (lettuce), and cereals (spring and winter wheat) was assessed during this peer review. Fenpropidin is the major constituent of the residue, but found at low levels at 750 g a.s./ha rate of application (0.01 mg/kg in lettuce and radish roots, 0.003 mg/kg in wheat grains), and only for short plant-back intervals (28 days) (EFSA, 2007b). Therefore, under normal rotation practices and considering that fenpropidin is applied to established cereals and beets, ensuring a significant degree of interception, no residues of compounds structurally related to fenpropidin are expected to be present (<0.01 mg/kg) in plant products for human consumption from rotational crops.”

Summary of new metabolism studies in rotational crops

No new studies are submitted.

Conclusion on metabolism in rotational crops

All crops evaluated in the framework of this submission might be grown in rotation.

The metabolism in rotational crops is similar to that observed in primary crops. No new metabolites were observed. Under normal rotation practices and considering that fenpropidin is applied to established cereals, ensuring a significant degree of interception, no residues of compounds structurally related to fenpropidin are expected to be present (<0.01 mg/kg) in plant products for human consumption from rotational crops.

Based on EFSA, 2007 and EFSA 2011, the following residue definitions are proposed:

Residue definition for enforcement:

Sum of fenpropidin and its salts, expressed as fenpropidin.

Residue definition for risk assessment:

Sum of fenpropidin and its salts, expressed as fenpropidin.

Evaluator comment:

Information given by the Applicant is sufficient.

According to the List of Endpoints of EFSA Scientific Report (2007):

Summary of data on the metabolism of fenpropidin in succeeding crops

Metabolism and residues in succeeding crops	
Rotational crops	Leafy vegetables (lettuce), root vegetables (radish), cereals (spring and winter wheat)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes. No new metabolites were observed.
Residues in succeeding crops	Maximum residues of fenpropidin in human food commodities from succeeding crops (lettuce, radish roots) grown in rotation after cereals are not expected to exceed 0.01 mg/kg.

EFSA (2007) concluded: “Confined rotational crop studies after application of fenpropidin on bare soil show a moderate uptake of soil residues. The metabolic pattern is similar to that observed in primary crops.”
No further data are required.

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, 2007, DAR SE, 2006 and 2007) and to the MRL review (EFSA, 2011) for fenpropidin.

No new data submitted in the framework of this application.

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

Conditions (Duration, Temperature, pH)	Test material	Radioactivity recovery (% of applied) ^a			Reference
		Total	Fenpropidin	Sum of other products	
EU data					
Pasteurisation (20 minutes, 90°C, pH 4.3)	[2,6- ¹⁴ C-piperidine] fenpropidin	98.6	97.1	1.6	DAR SE, 2006, Vol. 3, B.7.7.1 (Reischmann (2000); EFSA 2007
Baking, boiling, brewing (60 minutes, 100°C, pH 5.1)	[2,6- ¹⁴ C-piperidine] fenpropidin	99.5	97.1	2.4	
Sterilisation (20 minutes, 120°C, pH 6.3)	[2,6- ¹⁴ C-piperidine] fenpropidin	98.4	96.1	2.3	

^a after incubation and neutralisation. Mean of two samples.

Conclusion on nature of residues in processed commodities

There is no significant hydrolysis of fenpropidin in buffer solutions in standard conditions simulating pasteurisation, baking, brewing, boiling and sterilisation. Thus, the residue pattern in processed commodities is similar to the residue pattern in raw commodities, and the nature of fenpropidin residues is not affected by processing.

Evaluator comment:

In EFSA Journal 2011;9(8):2333 it is stated that: *“The effect of processing on the nature of fenpropidin residues was investigated in the framework of the peer review. Studies were conducted simulating representative hydrolytic conditions for pasteurisation (20 minutes at 90 C, pH 4), boiling/brewing/baking (60 minutes at 100 C, pH 5) and sterilisation (20 minutes at 120 C, pH 6). These studies showed that fenpropidin is hydrolytically stable under these conditions and that no formation of toxicologically relevant metabolites occurs (EFSA, 2007b). Thus, for processed commodities the same residue definition as for raw agricultural commodities (RAC) is applicable.”*
No further data are required.

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

The following endpoints were proposed by EFSA 2007:

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

Endpoints (EFSA 2007)	
Plant groups covered	Cereals (wheat), root vegetables (sugar beet), fruits (grapes, banana). Foliar application.
Rotational crops covered	Leafy vegetables (lettuce), root vegetables (radish), cereals (spring and winter wheat)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes. No new metabolites were observed.
Processed commodities	Fenpropidin is stable under conditions representative of pasteurisation, baking/brewing/boiling and sterilisation. (96.1 to 97.1% of the applied radioactivity consisted of parent fenpropidin).
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes. The nature of fenpropidin residues is not affected by processing.
Plant residue definition for monitoring	Sum of fenpropidin and its salts, expressed as fenpropidin (EFSA 2007 and 2011; Reg EU 61/2014)
Plant residue definition for risk assessment	Sum of fenpropidin and its salts, expressed as fenpropidin (EFSA 2007 and 2011)
Conversion factor (monitoring to risk assessment)	N/A

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, 2007, DAR SE, 2006 and 2007) and to the MRL review (EFSA, 2011) for fenpropidin.

No new data submitted in the framework of this application.

Table 7.3- 7: Summary of animal metabolism studies

Summary of animal metabolism studies								
Group	Species	Label position	No of animals	Application details		Sample details		Reference
				Rate	Duration (days)	Commodity	Time of sampling	
EU data								
Lactating ruminants	Goat	[N-2-methylpropyl-3- ¹⁴ C] fenpropidin	1	Nominal: 100 mg/kg feed dry matter Actual: 121 mg/kg feed dry matter	4	Milk	twice daily	DAR SE, 2006, Vol. 3, B.7.7.1 (...); EFSA 2007
						Urine and faeces	daily	
						Tissues (muscle, fat, liver, kidneys, bile, contents of gastro-intestinal tract)	after sacrifice	
Laying poultry	Hens	[3- ¹⁴ C-propylpiperidine] fenpropidin	5	10.3 mg/kg diet	4	Eggs	daily?	DAR SE, 2006, Vol. 3, B.7.7.1 (...); EFSA 2007
						Excreta	daily?	
						Tissues (muscle, skin plus attached fat, peritoneal fat, liver, kidneys, blood, contents of gastro-intestinal tract)	after sacrifice	
Laying poultry	Hens	[2,6- ¹⁴ C-piperidine] fenpropidin	5	11.58 mg/kg diet	4	Eggs	daily?	DAR SE, 2006, Vol. 3, B.7.7.1 (...); EFSA 2007
						Excreta	daily?	
						Tissues (muscle, skin plus attached fat, peritoneal fat, liver, kidneys, blood, contents of gastro-intestinal tract)	After sacrifice	
Fish	Not required, as residues fenpropidin > 0.1 mg/kg of the total diet in fish feed (dry weight basis) are not to be expected.							

Summary of animal metabolism studies reported in the EU

According to EFSA, 2007: “The metabolism of fenpropidin has been investigated in lactating goats and laying hens. In both cases the compound is extensively metabolised and represents less than 10% of the TRR in all animal tissues. In particular it was not identified in goat milk and muscle. The identified metabolites suggest that the metabolic pathway in livestock is similar to that observed in rats, involving oxidation of the tertiary-butyl side chain and in a minor extent degradation of the piperidine ring. Major metabolites accounting for a significant part of the radioactivity (from 10 to 40% of the TRR) in goat tissues were metabolites CGA 289267, SYN515213¹ and its sulphate ester (in milk only) and a sulphate ester conjugate of CGA 289268. In hen tissues, only CGA 289267 appeared as major constituent of the residue, forming at least 60% of the TRR in muscles and eggs.”

Summary of new animal metabolism studies

No new data for the product dossier considered to be required.

¹ SYN515213: 3-hydroxy-2-methyl-2-[4-(2-methyl-3-piperidin-1-yl-propyl)-phenyl]-propionic acid.

Conclusion on metabolism in livestock

In EFSA 2007 the following was concluded: “Considering the metabolic pattern in animal commodities it is proposed to use metabolite CGA 289267 as marker compound for monitoring purposes. This metabolite was preferred to metabolite SYN515213, which could also be valid for monitoring of ruminant tissues, on consideration of the results from the hen metabolism. The parent compound is also proposed to be included in the residue definition for monitoring as it was found at low but quantifiable concentration in liver and kidneys in the lactating goat feeding study for realistic exposure level.

For risk assessment the expert meeting recommended to include all major metabolites identified in the goat metabolism study (sum of fenpropidin, CGA 298267, SYN515213, SYN515213 sulphate ester, CGA 298268 sulphate ester expressed as fenpropidin). It was discussed and agreed by the evaluation meeting to amend the expert meeting proposal to ‘sum of fenpropidin and its salts, CGA 289267, SYN515213, CGA289268 and their conjugates expressed as fenpropidin’ to make it practicable from an analytical point of view in case a feeding study with analysis of residues according to the definition for risk assessment would be needed in future. Although this change in theory broadens the scope of the definition, the practical quantitative impact as expected from the metabolism studies is very minor. This definition covers 80% of the TRR in milk and muscle and at least 50% of the TRR in other tissues. Conversion factors ranging from 2 to 5 between residue definitions for monitoring and risk assessment were established by the expert meeting. It was nevertheless recognized that the determination of such conversion factors on the single ground of a metabolism study should be restricted to cases where it clearly appears that consumer exposure is far below the toxicological reference values.”

In DAR SE, 2007 (Final Addendum to DAR) the following was stated regarding the comparability of metabolism in rat and ruminant: “Fenpropidin was rapidly metabolised, with the majority of the administered radioactivity excreted in the urine and faeces (88-92% in hen and 63.6% in goat within 78 hours and 82-102% in rat within 48 hours). CGA 289267 was the major metabolite in rat, goat and laying hens”

and “[...] the metabolic pattern in goat does not significantly differ compared to rats. The proposed major pathway of fenpropidin in the rat, in goat and also in hens, involves oxidation of one of the methyl groups of the tertiary butyl moiety to produce the propyl alcohol intermediate (CGA 289268) that is further oxidised yielding the propionic acid derivate CGA 289267 and SYN 515213.”

Evaluator comment:

Information given by the Applicant is sufficient.

The nature of fenpropidin residues in commodities of animal origin was investigated in the framework of Directive 91/414/EEC (Sweden, 2005). Metabolism was investigated in goat and laying hens. Reported metabolism studies include 3 studies in lactating goats and laying hens using [N-2-methylpropyl-3-¹⁴C] fenpropidin, [3-¹⁴C-propylpiperidine] fenpropidin and [2,6-¹⁴C-piperidine] fenpropidin.

According to the List of Endpoints of EFSA Scientific Report (2007):

Summary of data on the metabolism of fenpropidin in livestock

Metabolism in livestock	
Animals covered	Ruminant (goat), poultry (hen)
Time needed to reach a plateau concentration in milk and eggs	48 hours in milk 72 hours in eggs
Animal residue definition for monitoring	Sum of fenpropidin, its salts and 2-methyl-2-[4-(2-methyl-3-piperidin-1-yl-propyl)-phenyl]-propionic acid expressed as fenpropidin.
Animal residue definition for risk assessment	Definitions for risk assessment: sum of fenpropidin and its salts, 2-methyl-2-[4-(2-methyl-3-piperidin-1-ylpropyl)-phenyl]-propionic acid, 3-hydroxy-2-methyl-2-[4-(2-methyl-3-piperidin-1-yl-propyl)-phenyl]-propionic acid, 2-methyl-2-[4-(2-methyl-3-piperidin-1-yl-propyl)-phenyl]-propan-1-ol and their conjugates expressed as fenpropidin.
Conversion factor (monitoring to risk assessment)	Meat (except poultry meat): 2 Fat (except poultry fat): 3 Liver: 5 Kidney: 4

	Milk: 4 Poultry products: 1
Metabolism in rat and ruminant similar (yes/no)	Yes
Fat soluble residue: (yes/no)	No
<p>Residue definition for animals: The residue definition for enforcement is the sum of fenpropidin, its salts and CGA 289267, expressed as fenpropidin. For risk assessment the residue definition is defined as the sum of fenpropidin and its salts, CGA 289267, SYN515213, CGA 289268 and their conjugates expressed as fenpropidin. The residue as defined is considered not to be fat soluble based on the fact that the log P_{ow} of fenpropidin is lower than 3 (EFSA, 2007). The current residue definition for animals set in Regulation (EC) No 396/2005 (Reg. (EU) No 61/2014) is identical to the residue definition for enforcement derived in the peer review. No further data are required.</p>	

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

The following endpoints were proposed by EFSA 2007:

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

Endpoints (EFSA 2007)	
Animals covered	Ruminant (goat), poultry (hen)
Time needed to reach a plateau concentration	48 hours in milk 72 hours in eggs
Animal residue definition for monitoring	Sum of fenpropidin, its salts and 2-methyl-2-[4-(2-methyl-3-piperidin-1-yl-propyl)-phenyl]-propionic acid expressed as fenpropidin.
Animal residue definition for risk assessment	Sum of fenpropidin and its salts, 2-methyl-2-[4-(2-methyl-3-piperidin-1-ylpropyl)- phenyl]-propionic acid, 3-hydroxy-2-methyl-2-[4-(2-methyl-3-piperidin-1-yl-propyl)-phenyl]-propionic acid, 2-methyl-2-[4-(2-methyl-3-piperidin-1-yl-propyl)-phenyl]-propan-1-ol and their conjugates expressed as fenpropidin.
Conversion factor	Meat (except poultry meat): 2 Fat (except poultry fat): 3 Liver: 5 Kidney: 4 Milk: 4 Poultry products: 1
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	No

7.3.3 Magnitude of residues in plants (KCA 6.3)

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

Available data

Where applicable, reference is made to the EU peer review (EFSA, 2007, DAR SE, 2006 and 2007) and to the MRL review (EFSA, 2011) for fenpropidin.

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 in cereals are covered by the representative EU GAP uses of fenpropidin in cereals as evaluated during AIR process (EFSA 2007). However, residue studies with fenpropidin evaluated at EU level (EFSA, 2007, DAR SE, 2006 and 2007) were conducted at a by far more critical GAPs than envisaged in this dossier.

Therefore, the respective data are not used for risk assessment in this dossier but new trials analysing for fenpropidin conducted at the envisaged GAP use are submitted with this dossier for all relevant crops.

Wheat, rye, triticale (KCA 6.3.1)

Table 7.3- 9: Comparison of intended and critical EU GAPs in wheat, rye and triticale (fenpropidin)

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Max. growth stage at last application	PHI (days)
Wheat, rye, triticale (N-EU)					
cGAP EU (EFSA, 2007)	1-2	0.750 kg as/ha	21 days	65	35
cGAP EU (Art. 12, EFSA, 2011)	2	0.750 kg as/ha	14 (rye) 28 (wheat)	65	42 (rye) 35 (wheat)
Intended cGAP (1)*	1	0.250 kg as/ha	-	65	n.a.

* Critical GAP number(s) in accordance with column 0 of Table 7.1- 1.

According to the available data, the intended outdoor uses on wheat, rye and triticale in C-EU are considered acceptable. According to EC TG SANTE/2019/12752 (13/06/2017), extrapolation from wheat to rye (and triticale) is possible without restriction.

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 fenpropidin in cereals as evaluated during AIR process (EFSA 2007). However, EU-studies were conducted at more critical GAPs than envisaged in this dossier. Therefore, these studies are considered not relevant.

Thus, new supplementary studies are presented in the following.

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

Table 7.3- 10: Summary of EU reported and new data supporting the intended uses of ADM.03502.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
Plant residue definition for monitoring (E): Sum of fenpropidin and its salts, expressed as fenpropidin Plant residue definition for risk assessment (RA): Sum of fenpropidin and its salts, expressed as fenpropidin								
Spring and winter wheat, grain and straw	EFSA, 2007, DAR Addendum SE, 2007	N-EU	GAP on which MRL/EU a.s. assessment is based: 1-2 x 0.750 kg as/ha, up to BBCH 65, PHI 35/42d, outdoor. Trials not included as envisaged cGAP is by far exceeded in EU assessment.	N/A				
Extrapolation from wheat → rye and triticale	New trials KCA 6.3.1/01 KCA 6.3.1/03	N-EU	Trials GAP: 1 x 0.250 kg as/ha, BBCH 65, PHI n.a., outdoor Wheat grain E & RA: 4x <0.01, 4x <0.01 For livestock dietary burden assessment only: Wheat straw E & RA: 0.13, 0.21, 0.24, 0.81, 0.85, 0.31, 0.88, 0.49					
Extrapolation from spring cereals ↔ winter cereals due to late application timing Critical GAP (1)	Overall supporting data for cGAP	N-EU	Wheat grain E & RA: 4x <0.01, 4x <0.01 For livestock dietary burden assessment only: Wheat straw E & RA: 0.13, 0.21, 0.24, 0.81, 0.85, 0.31, 0.88, 0.49					
				Grain, E & RA: 0.01 E & RA all: 0.01 Straw, E & RA: 0.225 E & RA all: 0.40	Grain, E & RA: 0.01 E & RA all: 0.01 Straw, E & RA: 0.81 E & RA all: 0.88	0.01 (Grain)	0.1 (wheat & rye)	Yes

* Source of EU MRL: Reg. (EU) 61/2014

Barley and oat (KCA 6.3.2)

Table 7.3- 11: Comparison of intended and critical EU GAPs in barley and oat (fenpropidin)

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Max. growth stage at last application	PHI (days)
Barley, oat (N-EU)					
cGAP EU (EFSA, 2007)	1-2	0.750 kg as/ha	21 days	65	35
cGAP EU (Art. 12, EFSA, 2011)	2 (barley) 3 (oat)	0.750 kg as/ha	28 (barley) n.s. (oat)	65	35
Intended cGAP (2)*	1	0.250 kg as/ha	-	65	n.a.

* Critical GAP number(s) in accordance with column 0 of Table 7.1- 1.

According to the available data, the intended outdoor uses on barley and oat in C-EU are considered acceptable. According to EC TG SANTE/2019/12752 (13/06/2017), extrapolation from barley to oat is possible without restriction.

The intended critical GAPs in barley and oat (spring and winter barley, oat) are covered by the representative EU GAP uses of fenpropidin in cereals as evaluated during AIR process (EFSA 2007). However, EU-studies were conducted at more critical GAPs than envisaged in this dossier. Therefore, these studies are considered not relevant.

Thus, new supplementary studies are presented in the following.

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

Table 7.3- 12: Summary of EU reported and new data supporting the intended uses of ADM.03502.F.1.A in barley and oat 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
Plant residue definition for monitoring (E): Sum of fenpropidin and its salts, expressed as fenpropidin Plant residue definition for risk assessment (RA): Sum of fenpropidin and its salts, expressed as fenpropidin								
Spring and winter barley, grain and straw	EFSA, 2007, DAR Addendum SE, 2007	N-EU	GAP on which MRL/EU a.s. assessment is based: 1-2 x 0.750 kg as/ha, up to BBCH 65, PHI 35d, outdoor. Trials not included as envisaged cGAP is by far exceeded in EU assessment.	N/A				
Extrapolation from barley → oat	New trials	N-EU	Trials GAP: 1 x 0.250 kg as/ha, BBCH 65, PHI n.a., outdoor					
Extrapolation from spring cereals ↔ winter cereals due to late application timing	KCA 6.3.2/01 KCA 6.3.2/03	N-EU	Barley grain, E & RA: < 0.01, 0.012, 0.013, 0.014, 0.024, 0.026, 0.029, 0.042 For livestock dietary burden assessment only: Barley straw, E & RA: 0.037, 0.091, 0.13, 0.15, 0.18, 0.19, 0.20, 0.28					
Critical GAP (2)	Overall supporting data for cGAP	N-EU	Barley grain, E & RA: < 0.01, 0.012, 0.013, 0.014, 0.024, 0.026, 0.029, 0.042 For livestock dietary burden assessment only: Barley straw, E & RA: 0.037, 0.091, 0.13, 0.15, 0.18, 0.19, 0.20, 0.28	Grain, E & RA: 0.019 Straw, E & RA: 0.165	Grain, E & RA: 0.042 Straw, E & RA: 0.28	Grain: 0.065	Grain: Barley: 0.6 oat: 0.3	Yes

* Source of EU MRL: Reg. (EU) 61/2014

7.3.3.2 Conclusion on the magnitude of residues in plants

Wheat, rye, triticale

According to the available data, the intended outdoor uses on wheat, rye and triticale are considered acceptable. Four trials in wheat from Northern Europe showed no residues of fenpropidin at harvest in wheat grains (below the LOQ of 0.01 mg/kg). Due to the non-residue situation four trials are considered sufficient. However, to complete the trial set, one study involving six trials is currently ongoing in wheat in N-EU. The study report will be submitted with a dRR update after finalisation.

Therefore, the supplementary data submitted show that any exceedance of the current EU-MRL of 0.1 mg/kg for wheat and rye is not to be expected.

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, oat

According to the available data, the intended outdoor uses on barley and oat are considered acceptable. Eight trials in barley from Northern Europe showed low residues of fenpropidin at harvest in barley grain (< 0.01 to 0.042 mg/kg).

Therefore, the supplementary data submitted show that any exceedance of the current EU-MRLs of 0.6 mg/kg for barley and 0.3 for oat is not to be expected.

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).

zRMS comments:

Residue Definitions (EFSA 2007, 2011; Reg EU 61/2014):

Monitoring (Mo) and Risk Assessment (RA): Sum of fenpropidin and its salts, expressed as fenpropidin

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 (8 trials) were conducted according to the residue definition for monitoring and risk assessment with the following GAP: 1 x 250 g a.s. /ha, application at BBCH 65, outdoor. The trials are supported by valid storage stability data and validated analytical method.

Residues of fenpropidin in wheat grain at harvest were <0.01 mg/kg.

Available results show that the in force MRL of fenpropidin on wheat and rye of 0.1 mg/kg (Reg. (EU) 61/2014) will not be exceeded. The current EU MRL for fenpropidin is sufficient to support the proposed uses.

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

Remark:

In SANTE/2019/12752, in ANNEX I clarifications on “old/new” data requirements, it is stated that “50% of residue trials should be decline studies, if the consumable part is exposed during application of the plant protection product under the proposed conditions of use.” It means that Applicant should have provided at least 4 decline studies.

For fenpropidin only 2 decline studies were provided by Applicant. However, the residue levels in grains were < LOQ in all trials. Taking into above account, zRMS is of the opinion that the available residue data is sufficient to support the proposed use on wheat, rye and triticale.

Barley

Barley and oat 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 barley can be used for extrapolation to oat before and after forming of the edible part.

Sufficient trials on barley (8 trials) were conducted according to the residue definition for monitoring and risk assessment with the following GAP: 1 x 250 g a.s. /ha, application at BBCH 65, outdoor. The trials are supported

by valid storage stability data and validated analytical method. More details of the residue studies on barley are provided in Appendix 2.

Residues of fenpropidin in barley grain at harvest were between <LOQ and 0.042 mg/kg.

Available results show that the in force MRL of fenpropidin on barley of 0.6 mg/kg and on oat of 0.3 mg/kg (Reg. (EU) 61/2014) will not be exceeded. The current EU MRL for fenpropidin is sufficient to support the proposed uses.

The proposed uses on barley and oat are considered acceptable.

7.3.4 Magnitude of residues in livestock

7.3.4.1 Dietary burden calculation

The dietary burden calculation made by EFSA in the framework of the Article 12 evaluation is available for fenpropidin (see EFSA, 2011). Fenpropidin is authorised for use on several crops that might be fed to livestock. EFSA calculated the livestock dietary burdens for different groups of livestock using the agreed European methodology (European Commission, 1996). The envisaged GAP uses and the resulting residues are covered by this calculation. The input values as used in EFSA, 2011 for the latest exposure calculations for livestock are presented in the table below. However, as EFSA calculations are not in accordance with the latest animal intake calculation model and guide, new calculations based on EFSA 2011 input values (covering envisaged GAPs and results of new residue trials submitted) were conducted using EFSA 2017 model (mrl_guidelines_animal_model_2017)² and are included in the following.

Table 7.3- 13: 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
EU data (EFSA, 2011)				
Sum of fenpropidin and its salts, expressed as fenpropidin				
Sugar beet leaves	1.26	Median residue (EFSA, 2011)	2.90	Highest residue (EFSA, 2011)
Fodder beet leaves	1.06	Median residue (EFSA, 2011)	2.38	Highest residue (EFSA, 2011)
Wheat grain	0.04	Median residue (EFSA, 2011)	0.04	Median residue (EFSA, 2011)
Barley grain	0.22	Median residue (EFSA, 2011)	0.22	Median residue (EFSA, 2011)
Rye grain	0.04	Median residue (EFSA, 2011)	0.04	Median residue (EFSA, 2011)
Oat grain	0.08	Median residue (EFSA, 2011)	0.08	Median residue (EFSA, 2011)
Wheat bran*	0.14	Median residue x PF (EFSA, 2011)	0.14	Median residue (EFSA, 2011)
Rye bran*	0.14	Median residue x PF (EFSA, 2011)	0.14	Median residue x PF (EFSA, 2011)

² As provided on https://food.ec.europa.eu/plants/pesticides/maximum-residue-levels/guidelines-maximum-residue-levels_en (13.09.2022).

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
EU data (EFSA, 2011)				
Wheat straw	1.08	Median residue (EFSA, 2011)	3.70	Median residue x PF (EFSA, 2011)
Barley straw	3.40	Median residue (EFSA, 2011)	6.70	Highest residue (EFSA, 2011)
Rye straw	1.08	Median residue (EFSA, 2011)	3.70	Highest residue (EFSA, 2011)
Oat straw	3.40	Median residue (EFSA, 2011)	6.70	Highest residue (EFSA, 2011)
Sugar beets roots	0.04	Median residue (EFSA, 2011)	0.06	Highest residue (EFSA, 2011)
Fodder beets roots	0.04	Median residue (EFSA, 2011)	0.05	Highest residue (EFSA, 2011)

* Not relevant for EFSA 2017 model (mrl_guidelines_animal_model_2017).

Table 7.3- 14: Results of the dietary burden calculation (EFSA, 2011)

Animal species	Maximum dietary burden (mg/kg bw/d)	Median dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
EU data (EFSA, 2011)					
Sum of fenpropidin and its salts, expressed as fenpropidin					
Dairy ruminants	0.260	0.119	Sugar beet leaves	7.209	Yes
Meat ruminants	0.403	0.188	Sugar beet leaves	9.362	Yes
Poultry	0.015	0.014	Barley grain	0.240	Yes
Pigs	0.190	0.086	Sugar beet leaves	4.750	Yes

Table 7.3- 14b: Results of the dietary burden calculation (new calculations using EFSA 2017 model)

Relevant groups	Dietary burden expressed in				Most critical diet (a)	Most critical commodity (b)		Trigger exceeded (Yes/No)	Previous assessment (EFSA 2011)
	mg/kg bw per day		mg/kg DM					0.004	Max burden
	Median	Maximum	Median	Maximum				mg/kg bw	mg/kg bw
Cattle (all diets)	0.078	0.161	2.04	4.18	Dairy cattle	Beet, sugar	tops	Yes	0.403 (meat ruminants only)
Cattle (dairy only)	0.078	0.161	2.04	4.18	Dairy cattle	Beet, sugar	tops	Yes	0.260
Sheep (all diets)	0.111	0.206	2.62	4.84	Lamb	Barley	straw	Yes	-
Sheep (ewe only)	0.081	0.161	2.42	4.84	Ram/Ewe	Barley	straw	Yes	-
Swine (all diets)	0.020	0.037	0.89	1.60	Swine (breeding)	Beet, sugar	tops	Yes	0.190
Poultry (all diets)	0.039	0.063	0.57	0.92	Poultry layer	Beet, sugar	tops	Yes	0.015
Poultry (layer only)	0.039	0.063	0.57	0.92	Poultry layer	Beet, sugar	tops	Yes	0.015

(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".

Old (EFSA 2011) and new calculations show that the trigger of dietary burden is exceeded in all relevant livestock groups. As newly calculated dietary burdens do not exceed dietary burdens obtained in the previous assessment of EFSA (2011) except for poultry, the evaluations of EFSA (2011) referenced under point 7.3.4.2 below concerning ruminants are still considered valid. Regarding poultry, the evaluations of EFSA (2011) referenced below are also considered still valid and no feeding study is considered to be required, as the available metabolism study, which demonstrates that no residues above the LOQ are to be expected, has been conducted at exaggerated dose rates also by far covering the newly calculated dietary burden.

Evaluator comment:

Data presented by Applicant in point 7.3.4.1 have been accepted and are sufficient to support the proposed uses.

The calculated dietary burdens for fenpropidin were found to exceed the trigger value of 0.1 mg/kg DM (or 0.004 mg/kg bw/d, respectively) for all groups of livestock. Further investigation of residues is therefore required (see point 7.3.4.2).

7.3.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Available data

Reference is made to the EU peer review (EFSA, 2007, DAR SE, 2006 and 2007) and to the MRL review (EFSA, 2011) for fenpropidin, where the magnitude of fenpropidin residues in livestock was evaluated.

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

According to EFSA, 2011: “During the peer review of Directive 91/414/EEC the magnitude of fenpropidin residues in livestock was investigated in the feeding study with lactating cows (Sweden, 2005). 4 groups of lactating cows, each consisting of three animals, were dosed for 30 days with fenpropidin at levels of 0 (control group), 3.15, 15.75 and 31.5 mg/kg DM/day [...]. Results of the livestock feeding study are summarized in [Table 7.3- 15].

This feeding study, conducted at critical exposure level, shows measurable residues of fenpropidin and CGA 289267 in liver and kidneys. These 2 compounds were present at levels below the LOQ in other tissues (0.01 and 0.005 in solid matrices and milk respectively). In milk, only CGA 289267 is detectable. This compound reached a plateau after three to five days of dosing and concentrations were maintained until the end of the study. Analysis of free CGA 289268 was also included in this study. However this information was not considered as this metabolite in its free form is very minor in the metabolic pattern and no indication was available whether its sulphate conjugate, which is a major metabolite, was hydrolyzed or not during the analytical procedure. Conversion factors from enforcement to risk assessment given in the table were therefore derived from the metabolism studies. It was nevertheless recognized that the determination of such conversion factors on the single ground of a metabolism study should be restricted to cases where it clearly appears that consumer exposure is far below the toxicological reference values.”

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

Table A2-15: Overview of the values derived from livestock feeding studies												
Commodity	Dietary burden		Results of the livestock feeding study						Median residue (mg/kg)	Highest residue (mg/kg)	MRL proposal (mg/kg)	CF for RA
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level (mg/kg bw/d)	No	Result for enforcement		Result for RA					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
EU data (Art. 12 MRL review EFSA, 2011) (and new calculated dietary burdens (covered by EFSA 2011 data) in <i>italics</i>)												
Residue definition for enforcement : sum of fenpropidin, its salts and CGA 289267, expressed as fenpropidin												
Milk	0.12 <i>(0.078)</i>	0.26 <i>(0.161)</i>	0.12	33	0.010 ^(a)	n.a.	Not reported. Conversion factors for risk assessment were derived from the metabolism study.	0.010	0.011	0.02	4	
			0.57	33	0.014 ^(a)	n.a.						
			1.14	33	0.025 ^(a)	n.a.						
Ruminant meat	0.19 <i>(0.078)</i>	0.40 <i>(0.161)</i>	0.12	3	0.020	0.020		0.020	0.020	0.02*	2	
			0.57	3	0.020	0.020						
			1.14	3	0.030	0.030						
Ruminant fat			0.12	3	0.020	0.020		0.020	0.020	0.02*	3	
			0.57	3	0.020	0.020						
			1.14	3	0.020	0.020						
Ruminant liver			0.12	3	0.108	0.128		0.149	0.357	0.5	5	
			0.57	3	0.379	0.493						
			1.14	3	0.647	0.719						
Ruminant kidney			0.12	3	0.032	0.033		0.042	0.080	0.1	4	
			0.57	3	0.094	0.108						
			1.14	3	0.177	0.220						

Commodity	Dietary burden		Results of the livestock feeding study						Median residue (mg/kg)	Highest residue (mg/kg)	MRL proposal (mg/kg)	CF for RA
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level (mg/kg bw/d)	No	Result for enforcement		Result for RA					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
EU data (Art. 12 MRL review EFSA, 2011)												
Residue definition for enforcement: sum of fenpropidin, its salts and CGA 289267, expressed as fenpropidin												
Pig meat	0.09 (0.020)	0.19 (0.037)	0.12	3	0.020	0.020	Not reported. Conversion factors for risk assessment were derived from the metabolism study.	0.014	0.020	0.02*	2	
			0.57	3	0.020	0.020						
			1.14	3	0.030	0.030						
Pig fat				0.12	3	0.020		0.020	0.014	0.020	0.02*	3
			0.57	3	0.020	0.020						
			1.14	3	0.020	0.020						
Pig liver				0.12	3	0.108		0.128	0.078	0.185	0.2	5
			0.57	3	0.379	0.493						
			1.14	3	0.647	0.719						
Pig kidney				0.12	3	0.032		0.033	0.023	0.045	0.05	4
			0.57	3	0.094	0.108						
			1.14	3	0.177	0.220						
New data												
None												

n.a.: not applicable – only the mean values are considered for calculating MRLs in milk

(*): Indicates that the MRL is set at the limit of analytical quantification.

(a): mean residue level from day 0 to day 26 (3 cows, 11 sampling days)

Conclusion on feeding studies

According to EFSA, 2011: “The storage stability of fenpropidin in animal products was evaluated under the peer review of Directive 91/414/EEC (Sweden, 2005). Studies demonstrated storage stability of fenpropidin and its metabolites CGA 289267 and CGA 289268 for up to 3 months in animal tissues and for up to 2 months in milk when stored deep frozen. All samples were stored in compliance with these conditions.

Consequently, based on the livestock feeding study, MRL and risk assessment values in ruminants and swine products were calculated according to the latest recommendations of JMPR on this matter (FAO, 2009). For poultry, no feeding study was conducted but the results of the available metabolism study at exaggerated dose rate demonstrates that no residues above the LOQ are to be expected under practical exposure conditions in eggs, fat and meat.”

The requested uses do not modify the theoretical maximum daily intake for animals as calculated in EFSA 2011, and therefore, regarding available feeding data and evaluations in EFSA 2007 and EFSA 2011, there is no risk for animal MRL to be exceeded.

The new dietary burden calculation mode using EFSA 2017 model does not lead to an exceedance of the theoretical maximum daily intake for ruminants as calculated in EFSA 2011, and therefore, there is no risk for ruminant MRLs to be exceeded.

Regarding poultry, new dietary burden calculations exceed results of the calculations conducted by EFSA (2011). However, this is not induced by any higher residues in any feed matrices but due to the new calculation mode of EFSA 2017 model. Any feeding study is still not considered to be required for poultry, as the available metabolism study, which demonstrates that no residues above the LOQ are to be expected, has been conducted at exaggerated dose rates also by far covering the newly calculated dietary burden. Therefore, there is no risk for poultry MRLs to be exceeded.

In addition, residues found in new residue trials in cereals (refer to point 7.3.3) are by far lower than the used input values determined during EFSA Art. 12 MRL review (EFSA 2011).

Evaluator comment:

The livestock feeding studies have been previously evaluated at EU level and are described in detail in EFSA Journal 2011;9(8):2333.

Data presented by Applicant in point 7.3.4.2 have been accepted and are sufficient to support the proposed uses.

The intended uses of fenpropidin in the product ADM.03502.F.1.A do not lead to an exceedance of the existing EU MRLs for animal commodities.

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

Any studies on the magnitude of residues in processed commodities are not considered to be required, as residues of fenpropidin were < 0.1 mg/kg in cereal grains at commercial harvest after application of fenpropidin according to the envisaged GAP uses.

However, as data exists, reference is made to the EU peer review (EFSA, 2007, DAR SE, 2006 and 2007) and to the MRL review (EFSA, 2011) for fenpropidin, where data on the magnitude of fenpropidin residues in processed products was evaluated and was considered acceptable.

7.3.5.1 Available data for all crops under consideration

Available data

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

Table 7.3- 16: Overview of the available processing studies

Table 7/5-16: Overview of the available processing studies					
Processed commodity	Number of studies	Median PF (a)	Median CF (b)	Comments	Reference
EU data (EFSA 2007 and EFSA, 2011)					
Processing factors recommended for enforcement and risk assessment (sufficiently supported by data)					
Bananas, peeled (bagged)	4	0.40	1.00	The PF for peeling of bananas is different depending whether bananas were bagged at treatment or not. Appropriate PF to be selected depending on the trials that were selected for the MRL setting.	EFSA, 2011
Bananas, peeled (unbagged)	4	0.29	1.00		
Rye, bran	4	4.10	1.00	-	EFSA, 2011
Wheat, whole-meal flour	4	1.10	1.00	-	EFSA, 2007 and EFSA, 2011
Wheat, whole-meal/wholegrain bread	4	1.00	1.00	-	
Wheat, white flour	4	0.20	1.00	-	
Wheat, bran	4	4.20/ 4.10	1.00	-	EFSA, 2007/ EFSA, 2011
Indicative processing factors (limited data sets)					
Barley, brewing malt	2	1.1/ 1.15	1.00	Residues of fenpropidin were slightly higher in the processed malt (1.5, 0.8) and the calculated mean transfer factor was 1.15. However, this factor cannot be considered as an increase of fenpropidin residues in processed malt, since the residues in unprocessed grain and processed malt were close to the LOQ in the commodities (grain: 0.05, 0.02; malt: 0.04, 0.03)	EFSA, 2007/ EFSA, 2011
Barley, beer	2	< 0.4/ 0.35	1.00		
Barley - wort	2	0.7	-	-	EFSA, 2007
Sugar beet, thick juice	2	1	1.00	-	EFSA, 2011
Sugar beet, raw sugar	2	1	1.00		
Sugar beet, pulp	2	1	1.00		
Sugar beet, molasses	2	1	1.00		
New data					
None					

(a): The median processing factor is obtained by calculating the median of the individual processing factors of each processing study.

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

7.3.5.2 Conclusion on processing studies

Robust processing factors for enforcement and risk assessment were derived for barley and wheat at EU level.

However, any studies on the magnitude of residues in processed commodities are not required for this application, as residues of fenpropidin were < 0.1 mg/kg in cereal grains at commercial harvest after application of fenpropidin according to the envisaged GAP uses. Based on the results of residue trials, significant residue levels according to the residue definition for risk assessment will not occur in cereals at harvest. Accordingly, processing studies are not required.

Evaluator comment:

Information given by the Applicant is acceptable and sufficient.

In EFSA Journal 2011;9(8):2333 it is stated that “*Studies investigating the magnitude of residues in processed commodities of barley grain and wheat grain were reported in the framework of the peer review (EFSA, 2007b). After fenpropidin was included in Annex I to Directive 91/414/EEC, residues trials on bananas were submitted, determining the distribution of residues between pulp and peel (Sweden, 2009). An overview of all available processing studies is available in Table 3-3. Robust processing factors could be derived for bananas, rye and wheat. The processing factors reported for the remaining commodities should be considered indicative only as they are not sufficiently supported by studies; a minimum of 3 processing studies is normally required. ...For sugar beet no information on processing study conditions is available. Residues in all processed fractions are <0.05 mg/kg. Residues in sugar beet roots <0.05 mg/kg.*”

As residues of fenpropidin exceeding 0.1 mg/kg are not expected in the treated crops, there is no need to investigate the magnitude of fenpropidin residues in processed commodities.

7.3.6 Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation.

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

This is in agreement with the outcome of the EU peer review (EFSA, 2007, DAR SE, 2006 and 2007) and the Art. 12 MRL review (EFSA, 2011) for fenpropidin.

7.3.6.1 Field rotational crop studies (KCA 6.6.2)

Available data

No data available nor required for the reasons given above.

Conclusion on rotational crops studies

Under normal rotation practices and considering that fenpropidin is applied to established cereals, ensuring a significant degree of interception, no residues of compounds structurally related to fenpropidin are expected to be present (<0.01 mg/kg) in plant products for human consumption from rotational crops.

Evaluator comment:

The crops under consideration can be grown in rotation.

In “Conclusion on the peer review of fenpropidin” (EFSA, 2007) EFSA concluded that: “*Fenpropidin is the major constituent of the residue, but found at low levels at 1N rate of application (0.01 mg/kg in lettuce and radish roots, 0.003 mg/kg in wheat grains), and only for short plant-back intervals (28 days). Therefore, under normal rotation practices and considering that fenpropidin is applied to established cereals and beets, ensuring a significant degree of interception, no residues of compounds structurally related to fenpropidin are expected to be present (<0.01 mg/kg) in plant products for human consumption from rotational crops.*”

In EFSA Journal 2011;9(8):2333 it is stated that “*It was concluded that metabolic patterns in primary and succeeding crops are similar and that significant residues in rotational crops are not expected.*”

No residues >0.01 mg/kg in rotational crops are expected and a field study is not deemed necessary.

No waiting periods beyond normal agricultural practice are proposed for succeeding crops to be planted.

7.3.7 Other / special studies (KCA 6.10, 6.10.1)

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of ADM.03502.F.1.A. Therefore, other special studies are not needed.

Regarding potential residues in honey, the following is to be said:

Fenpropidin is a systemic fungicide applied as a spray at BBCH 30 - 65 in cereals (spring and winter wheat,

spring and winter barley, winter rye, oat and triticale).

Any residues in pollen and bee products collected from treated crops are not to be expected in cereals as these crops have no melliferous capacity.

Therefore, any residue levels in honey are not to be expected from the envisaged GAP uses of fenpropidin.

zRMS comments:

Information given by the Applicant is acceptable.

The intended uses of ADM.03502.F.1.A in cereals are expected to have little potential for contributing residues to bee products. This is in line with the technical guidelines SANTE/11956/2016 rev. 9, 14 September 2018. Other special studies including data on fenpropidin residues in pollen and bee products for human consumption are not considered necessary.

In our opinion, no further data is necessary to support the uses of ADM.03502.F.1.A.

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

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

7.3.8.1 Input values for the consumer risk assessment

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). PRIMo rev. 3.1 also includes the chronic risk assessment according to the Rees Day - model, which is relevant for the United Kingdom.

The existing EU MRLs are set according to the residue definition for monitoring as ‘sum of fenpropidin and its salts, expressed as fenpropidin’.

The input values used for the chronic consumer risk assessments are based on existing EU MRLs as set in Commission Regulation (EU) No. 61/2014, see in the table below. For the acute consumer risk assessment, only the crops under consideration were taken into account.

Table 7.3- 17: Input values for the consumer risk assessment (established MRLs for fenpropidin according to Com. Reg. (EU) No 61/2014)

Commodity	Existing/ proposed MRL	Source/ type of MRL	Chronic risk assessment (all crops, normal mode)		Acute risk assessment (only crops with GAP under assessment)	
			Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition in plant commocdities: Sum of fenpropidin and its salts, expressed as fenpropidin						
Grapefruits	0.01	EU-MRL	0.01	LOQ		
Oranges	0.01	EU-MRL	0.01	LOQ		
Lemons	0.01	EU-MRL	0.01	LOQ		
Limes	0.01	EU-MRL	0.01	LOQ		
Mandarins	0.01	EU-MRL	0.01	LOQ		
Other citrus fruit	0.01	EU-MRL	0.01	LOQ		
Tree nuts	0.01	EU-MRL				
Almonds	0.01	EU-MRL	0.01	LOQ		
Brazil nuts	0.01	EU-MRL	0.01	LOQ		

Commodity	Existing/ proposed MRL	Source/ type of MRL	Chronic risk assessment (all crops, normal mode)		Acute risk assessment (only crops with GAP under assessment)	
			Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Cashew nuts	0.01	EU-MRL	0.01	LOQ		
Chestnuts	0.01	EU-MRL	0.01	LOQ		
Coconuts	0.01	EU-MRL	0.01	LOQ		
Hazelnuts/cobnuts	0.01	EU-MRL	0.01	LOQ		
Macadamia	0.01	EU-MRL	0.01	LOQ		
Pecans	0.01	EU-MRL	0.01	LOQ		
Pine nut kernels	0.01	EU-MRL	0.01	LOQ		
Pistachios	0.01	EU-MRL	0.01	LOQ		
Walnuts	0.01	EU-MRL	0.01	LOQ		
Other tree nuts	0.01	EU-MRL	0.01	LOQ		
Pome fruit	0.01	EU-MRL				
Apples	0.01	EU-MRL	0.01	LOQ		
Pears	0.01	EU-MRL	0.01	LOQ		
Quinces	0.01	EU-MRL	0.01	LOQ		
Medlar	0.01	EU-MRL	0.01	LOQ		
Loquats/Japanese medlars	0.01	EU-MRL	0.01	LOQ		
Other pome fruit	0.01	EU-MRL	0.01	LOQ		
Stone fruit	0.01	EU-MRL				
Apricots	0.01	EU-MRL	0.01	LOQ		
Cherries (sweet)	0.01	EU-MRL	0.01	LOQ		
Peaches	0.01	EU-MRL	0.01	LOQ		
Plums	0.01	EU-MRL	0.01	LOQ		
Other stone fruit	0.01	EU-MRL	0.01	LOQ		
Berries & small fruit	0.01	EU-MRL				
Table and wine grapes	0.01	EU-MRL				
Table grapes	0.01	EU-MRL	0.01	LOQ		
Wine grapes	0.01	EU-MRL	0.01	LOQ		
Strawberries	0.01	EU-MRL	0.01	LOQ		
Cane fruit	0.01	EU-MRL				
Blackberries	0.01	EU-MRL	0.01	LOQ		
Dewberries	0.01	EU-MRL	0.01	LOQ		

Commodity	Existing/ proposed MRL	Source/ type of MRL	Chronic risk assessment (all crops, normal mode)		Acute risk assessment (only crops with GAP under assessment)	
			Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Raspberries (red and yellow)	0.01	EU-MRL	0.01	LOQ		
Other cane fruit	0.01	EU-MRL	0.01	LOQ		
Other small fruit & berries	0.01	EU-MRL				
Blueberries	0.01	EU-MRL	0.01	LOQ		
Cranberries	0.01	EU-MRL	0.01	LOQ		
Currants (red, black and white)	0.01	EU-MRL	0.01	LOQ		
Gooseberries (green, red and yellow)	0.01	EU-MRL	0.01	LOQ		
Rose hips	0.01	EU-MRL	0.01	LOQ		
Mulberries (black and white)	0.01	EU-MRL	0.01	LOQ		
Azarole/Mediterranean medlar	0.01	EU-MRL	0.01	LOQ		
Elderberries	0.01	EU-MRL	0.01	LOQ		
Other other small fruit & berries	0.01	EU-MRL	0.01	LOQ		
Miscellaneous fruit						
Miscellaneous fruit (edible peel)	0.01	EU-MRL				
Dates	0.01	EU-MRL	0.01	LOQ		
Figs	0.01	EU-MRL	0.01	LOQ		
Table olives	0.01	EU-MRL	0.01	LOQ		
Kumquats	0.01	EU-MRL	0.01	LOQ		
Carambolas	0.01	EU-MRL	0.01	LOQ		
Kaki/Japanese persimmons	0.01	EU-MRL	0.01	LOQ		
Jambuls/jambolans	0.01	EU-MRL	0.01	LOQ		
Other miscellaneous fruit (edible peel)	0.01	EU-MRL	0.01	LOQ		
Miscellaneous fruit (inedible peel, small)	0.01	EU-MRL				
Kiwi fruits (green, red, yellow)	0.01	EU-MRL	0.01	LOQ		
Litchis/lychees	0.01	EU-MRL	0.01	LOQ		
Passionfruits/maracujas	0.01	EU-MRL	0.01	LOQ		
Prickly pears/cactus fruits	0.01	EU-MRL	0.01	LOQ		

Commodity	Existing/ proposed MRL	Source/ type of MRL	Chronic risk assessment (all crops, normal mode)		Acute risk assessment (only crops with GAP under assessment)	
			Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Star apples/cainitos	0.01	EU-MRL	0.01	LOQ		
American persimmon/Virginia kaki	0.01	EU-MRL	0.01	LOQ		
Other miscellaneous fruit (inedible peel, small)	0.01	EU-MRL	0.01	LOQ		
Miscellaneous fruit (inedible peel, large)						
Avocados	0.01	EU-MRL	0.01	LOQ		
Bananas	0.2	EU-MRL	0.2	MRL		
Mangoes	0.01	EU-MRL	0.01	LOQ		
Papayas	0.01	EU-MRL	0.01	LOQ		
Granate apples/pomegranates	0.01	EU-MRL	0.01	LOQ		
Cherimoyas	0.01	EU-MRL	0.01	LOQ		
Guavas	0.01	EU-MRL	0.01	LOQ		
Pineapples	0.01	EU-MRL	0.01	LOQ		
Breadfruits	0.01	EU-MRL	0.01	LOQ		
Durians	0.01	EU-MRL	0.01	LOQ		
Soursops/guanabanas	0.01	EU-MRL	0.01	LOQ		
Other miscallaneous fruit (inedible peel, large)	0.01	EU-MRL	0.01	LOQ		
VEGETABLES FRESH OR FROZEN						
Root and tuber vegetables incl. potaotes)	0.01	EU-MRL				
Potatoes	0.01	EU-MRL	0.01	LOQ		
Tropical root and tuber vegetables	0.01	EU-MRL				
Cassava roots/manioc	0.01	EU-MRL	0.01	LOQ		
Sweet potatoes	0.01	EU-MRL	0.01	LOQ		
Yams	0.01	EU-MRL	0.01	LOQ		
Arrowroots	0.01	EU-MRL	0.01	LOQ		
Other tropical root and tuber vegetables	0.01	EU-MRL	0.01	LOQ		
Other root and tuber vegetables except sugar beet	0.01	EU-MRL				
Beetroots	0.01	EU-MRL	0.01	LOQ		

Commodity	Existing/ proposed MRL	Source/ type of MRL	Chronic risk assessment (all crops, normal mode)		Acute risk assessment (only crops with GAP under assessment)	
			Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Carrots	0.01	EU-MRL	0.01	LOQ		
Celeriacs/turnip rooted celerics	0.01	EU-MRL	0.01	LOQ		
Horseradishes	0.01	EU-MRL	0.01	LOQ		
Jerusalem artichokes	0.01	EU-MRL	0.01	LOQ		
Parsnips	0.01	EU-MRL	0.01	LOQ		
Parsley roots/Hamburg roots parsley	0.01	EU-MRL	0.01	LOQ		
Radishes	0.01	EU-MRL	0.01	LOQ		
Salsifies	0.01	EU-MRL	0.01	LOQ		
Swedes/rutabagas	0.01	EU-MRL	0.01	LOQ		
Turnips	0.01	EU-MRL	0.01	LOQ		
Other other root and tuber vegetables	0.01	EU-MRL	0.01	LOQ		
Bulb vegetables	0.01	EU-MRL				
Garlic	0.01	EU-MRL	0.01	LOQ		
Onions	0.01	EU-MRL	0.01	LOQ		
Shallots	0.01	EU-MRL	0.01	LOQ		
Spring onions/green onions and Welsh onions	0.01	EU-MRL	0.01	LOQ		
Other bulb vegetables	0.01	EU-MRL	0.01	LOQ		
Fruiting vegetables	0.01	EU-MRL				
Solanacea	0.01	EU-MRL				
Tomatoes	0.01	EU-MRL	0.01	LOQ		
Sweet peppers/bell peppers	0.01	EU-MRL	0.01	LOQ		
Aubergines/egg plants	0.01	EU-MRL	0.01	LOQ		
Okra/lady's fingers	0.01	EU-MRL	0.01	LOQ		
Other solanacea	0.01	EU-MRL	0.01	LOQ		
Cucurbits - edible peel	0.01	EU-MRL				
Cucumbers	0.01	EU-MRL	0.01	LOQ		
Gherkins	0.01	EU-MRL	0.01	LOQ		
Courgettes	0.01	EU-MRL	0.01	LOQ		
Other cucurbits - edible peel	0.01	EU-MRL	0.01	LOQ		

Commodity	Existing/ proposed MRL	Source/ type of MRL	Chronic risk assessment (all crops, normal mode)		Acute risk assessment (only crops with GAP under assessment)	
			Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Cucurbits - inedible peel	0.01	EU-MRL				
Melons	0.01	EU-MRL	0.01	LOQ		
Pumpkins	0.01	EU-MRL	0.01	LOQ		
Watermelons	0.01	EU-MRL	0.01	LOQ		
Other cucurbits - inedible peel	0.01	EU-MRL	0.01	LOQ		
Sweet corn	0.01	EU-MRL	0.01	LOQ		
Other fruiting vegetables	0.01	EU-MRL				
Brassica vegetables	0.01	EU-MRL				
Flowering brassica	0.01	EU-MRL				
Broccoli	0.01	EU-MRL	0.01	LOQ		
Cauliflowers	0.01	EU-MRL	0.01	LOQ		
Other flowering brassica	0.01	EU-MRL	0.01	LOQ		
Head brassica	0.01	EU-MRL				
Brussels sprouts	0.01	EU-MRL	0.01	LOQ		
Head cabbages	0.01	EU-MRL	0.01	LOQ		
Other head brassica	0.01	EU-MRL	0.01	LOQ		
Leafy brassica	0.01	EU-MRL				
Chinese cabbages/pe-tsai	0.01	EU-MRL	0.01	LOQ		
Kales	0.01	EU-MRL	0.01	LOQ		
Other leafy brassica	0.01	EU-MRL	0.01	LOQ		
Kohlrabies	0.01	EU-MRL	0.01	LOQ		
Leaf vegetables, herbs and edible flowers						
Lettuce and other salad plants including Brassicacea	0.01	EU-MRL				
Lamb's lettuce/corn salads	0.01	EU-MRL	0.01	LOQ		
Lettuces	0.01	EU-MRL	0.01	LOQ		
Escaroles/broad-leaved endives	0.01	EU-MRL	0.01	LOQ		
Cress and other sprouts and shoots	0.01	EU-MRL	0.01	LOQ		
Land cress	0.01	EU-MRL	0.01	LOQ		
Roman rocket/rucola	0.01	EU-MRL	0.01	LOQ		

Commodity	Existing/ proposed MRL	Source/ type of MRL	Chronic risk assessment (all crops, normal mode)		Acute risk assessment (only crops with GAP under assessment)	
			Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Red mustards	0.01	EU-MRL	0.01	LOQ		
Baby leaf crops (including brassica species)	0.01	EU-MRL	0.01	LOQ		
Other lettuce and other salad plants	0.01	EU-MRL	0.01	LOQ		
Spinach & similar (leaves)	0.01	EU-MRL				
Spinaches	0.01	EU-MRL	0.01	LOQ		
Purslanes	0.01	EU-MRL	0.01	LOQ		
Chards/beet leaves	0.01	EU-MRL	0.01	LOQ		
Other spinach and similar	0.01	EU-MRL	0.01	LOQ		
Grape leaves and similar species	0.01	EU-MRL	0.01	LOQ		
Watercress	0.01	EU-MRL	0.01	LOQ		
Witloofs/Belgian endives	0.01	EU-MRL	0.01	LOQ		
Herbs and edible flowers	0.02	EU-MRL				
Chervil	0.02	EU-MRL	0.02	LOQ		
Chives	0.02	EU-MRL	0.02	LOQ		
Celery leaves	0.02	EU-MRL	0.02	LOQ		
Parsley	0.02	EU-MRL	0.02	LOQ		
Sage	0.02	EU-MRL	0.02	LOQ		
Rosemary	0.02	EU-MRL	0.02	LOQ		
Thyme	0.02	EU-MRL	0.02	LOQ		
Basil and edible flowers	0.02	EU-MRL	0.02	LOQ		
Laurel/bay leaves	0.02	EU-MRL	0.02	LOQ		
Tarragon	0.02	EU-MRL	0.02	LOQ		
Other herbs	0.02	EU-MRL	0.02	LOQ		
Legume vegetables	0.01	EU-MRL				
Beans (with pods)	0.01	EU-MRL	0.01	LOQ		
Beans (without pods)	0.01	EU-MRL	0.01	LOQ		
Peas (with pods)	0.01	EU-MRL	0.01	LOQ		
Peas (without pods)	0.01	EU-MRL	0.01	LOQ		
Lentils (fresh)	0.01	EU-MRL	0.01	LOQ		

Commodity	Existing/ proposed MRL	Source/ type of MRL	Chronic risk assessment (all crops, normal mode)		Acute risk assessment (only crops with GAP under assessment)	
			Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Other legume vegetables (fresh)	0.01	EU-MRL	0.01	LOQ		
Stem vegetables	0.01	EU-MRL				
Asparagus	0.01	EU-MRL	0.01	LOQ		
Cardoons	0.01	EU-MRL	0.01	LOQ		
Celeries	0.01	EU-MRL	0.01	LOQ		
Florence fennels	0.01	EU-MRL	0.01	LOQ		
Globe artichokes	0.01	EU-MRL	0.01	LOQ		
Leeks	0.01	EU-MRL	0.01	LOQ		
Rhubarbs	0.01	EU-MRL	0.01	LOQ		
Bamboo shoots	0.01	EU-MRL	0.01	LOQ		
Palm hearts	0.01	EU-MRL	0.01	LOQ		
Other stem vegetables	0.01	EU-MRL	0.01	LOQ		
Fungi	0.01	EU-MRL				
Cultivated fungi	0.01	EU-MRL	0.01	LOQ		
Wild fungi	0.01	EU-MRL	0.01	LOQ		
Mosses and lichens	0.01	EU-MRL	0.01	LOQ		
Algae and prokaryotes organisms	0.01	EU-MRL	0.01	LOQ		
PULSES	0.01	EU-MRL				
Beans	0.01	EU-MRL	0.01	LOQ		
Lentils	0.01	EU-MRL	0.01	LOQ		
Peas	0.01	EU-MRL	0.01	LOQ		
Lupins/lupini beans	0.01	EU-MRL	0.01	LOQ		
Other pulses	0.01	EU-MRL	0.01	LOQ		
OILSEEDS AND OILFRUITS	0.01	EU-MRL				
Oilseeds	0.01	EU-MRL				
Linseeds	0.01	EU-MRL	0.01	LOQ		
Peanuts/groundnuts	0.01	EU-MRL	0.01	LOQ		
Poppy seeds	0.01	EU-MRL	0.01	LOQ		
Sesame seeds	0.01	EU-MRL	0.01	LOQ		
Sunflower seeds	0.01	EU-MRL	0.01	LOQ		

Commodity	Existing/ proposed MRL	Source/ type of MRL	Chronic risk assessment (all crops, normal mode)		Acute risk assessment (only crops with GAP under assessment)	
			Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Rapeseeds/canola seeds	0.01	EU-MRL	0.01	LOQ		
Soyabeans	0.01	EU-MRL	0.01	LOQ		
Mustard seeds	0.01	EU-MRL	0.01	LOQ		
Cotton seeds	0.01	EU-MRL	0.01	LOQ		
Pumpkin seeds	0.01	EU-MRL	0.01	LOQ		
Safflower seeds	0.01	EU-MRL	0.01	LOQ		
Borage seeds	0.01	EU-MRL	0.01	LOQ		
Gold of pleasure seeds	0.01	EU-MRL	0.01	LOQ		
Hemp seeds	0.01	EU-MRL	0.01	LOQ		
Castor beans	0.01	EU-MRL	0.01	LOQ		
Other oilseeds	0.01	EU-MRL	0.01	LOQ		
Oil fruits	0.01	EU-MRL				
Olives for oil production	0.01	EU-MRL	0.01	LOQ		
Oil palm kernels	0.01	EU-MRL	0.01	LOQ		
Oil palm fruits	0.01	EU-MRL	0.01	LOQ		
Kapok	0.01	EU-MRL	0.01	LOQ		
Other oilfruit	0.01	EU-MRL	0.01	LOQ		
CEREALS						
Barley	0.6	EU-MRL	0.6	MRL	0.6	MRL
Buckwheat and other pseudo-cereals	0.01	EU-MRL	0.01	LOQ		
Maize/corn	0.01	EU-MRL	0.01	LOQ		
Common millet/proso millet	0.01	EU-MRL	0.01	LOQ		
Oat	0.3	EU-MRL	0.3	MRL	0.3	MRL
Rice	0.01	EU-MRL	0.01	LOQ		
Rye	0.1	EU-MRL	0.1	MRL	0.1	MRL
Sorghum	0.01	EU-MRL	0.01	LOQ		
Wheat	0.1	EU-MRL	0.1	MRL	0.1	MRL
Other cereals	0.01	EU-MRL	0.01	LOQ		
TEA, COFFEE, HERBAL INFUSIONS AND COCOA	0.05	EU-MRL				
Tea (dried leaves of	0.05	EU-MRL	0.05	LOQ		

Commodity	Existing/ proposed MRL	Source/ type of MRL	Chronic risk assessment (all crops, normal mode)		Acute risk assessment (only crops with GAP under assessment)	
			Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Camellia sinensis)						
Coffee beans	0.05	EU-MRL	0.05	LOQ		
Herbal infusions (dried)	0.05	EU-MRL				
Herbal infusions (dried flowers)	0.05	EU-MRL				
Chamomille	0.05	EU-MRL	0.05	LOQ		
Hybiscus/roselle	0.05	EU-MRL	0.05	LOQ		
Rose	0.05	EU-MRL	0.05	LOQ		
Jasmine	0.05	EU-MRL	0.05	LOQ		
Lime/linden	0.05	EU-MRL	0.05	LOQ		
Other herbal infusions (dried flowers)	0.05	EU-MRL	0.05	LOQ		
Herbal infusions (dried leaves)	0.05	EU-MRL				
Strawberry leaves	0.05	EU-MRL	0.05	LOQ		
Rooibos	0.05	EU-MRL	0.05	LOQ		
Mate/maté	0.05	EU-MRL	0.05	LOQ		
Other herbal infusions (dried leaves)	0.05	EU-MRL	0.05	LOQ		
Herbal infusions (dried roots)	0.05	EU-MRL				
Valerian root	0.05	EU-MRL	0.05	LOQ		
Ginseng root	0.05	EU-MRL	0.05	LOQ		
Other herbal infusions (dried roots)	0.05	EU-MRL	0.05	LOQ		
Herbal infusions -(any other parts of the plant) (other herbal infusions)	0.05	EU-MRL				
Cocoa beans	0.05	EU-MRL	0.05	LOQ		
Carobs/Staint John's bread	0.05	EU-MRL	0.05	LOQ		
HOPS (dried)	0.05	EU-MRL	0.05	LOQ		
SPICES						
Spices (seeds)	0.05	EU-MRL				
Anise/aniseed	0.05	EU-MRL	0.05	LOQ		
Black caraway/black cumin	0.05	EU-MRL	0.05	LOQ		
Celery seed	0.05	EU-MRL	0.05	LOQ		

Commodity	Existing/ proposed MRL	Source/ type of MRL	Chronic risk assessment (all crops, normal mode)		Acute risk assessment (only crops with GAP under assessment)	
			Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Coriander seed	0.05	EU-MRL	0.05	LOQ		
Cumin seed	0.05	EU-MRL	0.05	LOQ		
Dill seed	0.05	EU-MRL	0.05	LOQ		
Fennel seed	0.05	EU-MRL	0.05	LOQ		
Fenugreek	0.05	EU-MRL	0.05	LOQ		
Nutmeg	0.05	EU-MRL	0.05	LOQ		
Other spices (seeds)	0.05	EU-MRL	0.05	LOQ		
Spices (fruits)	0.05	EU-MRL				
Allspice/pimento	0.05	EU-MRL	0.05	LOQ		
Sichuan pepper	0.05	EU-MRL	0.05	LOQ		
Caraway	0.05	EU-MRL	0.05	LOQ		
Cardamom	0.05	EU-MRL	0.05	LOQ		
Juniper berry	0.05	EU-MRL	0.05	LOQ		
Peppercorn (black, green and white)	0.05	EU-MRL	0.05	LOQ		
Vanilla pods	0.05	EU-MRL	0.05	LOQ		
Tamarind	0.05	EU-MRL	0.05	LOQ		
Other spices (fruits)	0.05	EU-MRL	0.05	LOQ		
Spices (bark)	0.05	EU-MRL				
Cinnamon	0.05	EU-MRL	0.05	LOQ		
Other spices (bark)	0.05	EU-MRL	0.05	LOQ		
Spices (roots or rhizome)						
Liquorice	0.05	EU-MRL	0.05	LOQ		
Ginger	0.05	EU-MRL	0.05	LOQ		
Turmeric/curcuma	0.05	EU-MRL	0.05	LOQ		
Horseradish, root spices	0.07	EU-MRL	0.07	MRL		
Other spices (roots)	0.05	EU-MRL	0.05	LOQ		
Spices (buds)	0.05	EU-MRL				
Cloves	0.05	EU-MRL	0.05	LOQ		
Capers	0.05	EU-MRL	0.05	LOQ		
Other spices (buds)	0.05	EU-MRL	0.05	LOQ		
Spices (flower stigma)	0.05	EU-MRL				

Commodity	Existing/ proposed MRL	Source/ type of MRL	Chronic risk assessment (all crops, normal mode)		Acute risk assessment (only crops with GAP under assessment)	
			Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Saffron	0.05	EU-MRL	0.05	LOQ		
Other spices (flower stigma)	0.05	EU-MRL	0.05	LOQ		
Spices (aril)	0.05	EU-MRL				
Mace	0.05	EU-MRL	0.05	LOQ		
Other spices (aril)	0.05	EU-MRL	0.05	LOQ		
SUGAR PLANTS						
Sugar beet roots	0.07	EU-MRL	0.07	MRL		
Sugar canes	0.01	EU-MRL	0.01	LOQ		
Chicory roots	0.01	EU-MRL	0.01	LOQ		
Other sugar plants	0.01	EU-MRL	0.01	LOQ		
PRODUCTS OF ANIMAL ORIGIN -TERRESTRIAL ANIMALS						
Tissue						
Swine						
Swine: Muscle/meat	0.02	EU-MRL	0.02	LOQ	0.02	LOQ
Swine: Fat tissue	0.02	EU-MRL	0.02	LOQ	0.02	LOQ
Swine: Liver	0.2	EU-MRL	0.2	MRL	0.2	MRL
Swine: Kidney	0.05	EU-MRL	0.05	MRL	0.05	MRL
Swine: Edible offals (other than liver and kidney)	0.02	EU-MRL	0.02	LOQ	0.02	LOQ
Swine: Other products	0.02	EU-MRL	0.02	LOQ	0.02	LOQ
Bovine						
Bovine: Muscle/meat	0.02	EU-MRL	0.02	LOQ	0.02	LOQ
Bovine: Fat tissue	0.02	EU-MRL	0.02	LOQ	0.02	LOQ
Bovine: Liver	0.5	EU-MRL	0.5	MRL	0.5	MRL
Bovine: Kidney	0.1	EU-MRL	0.1	MRL	0.1	MRL
Bovine: Edible offals (other than liver and kidney)	0.02	EU-MRL	0.02	LOQ	0.02	LOQ
Bovine: Other products	0.02	EU-MRL	0.02	LOQ	0.02	LOQ
Sheep						
Sheep: Muscle/meat	0.02	EU-MRL	0.02	LOQ	0.02	LOQ

Commodity	Existing/ proposed MRL	Source/ type of MRL	Chronic risk assessment (all crops, normal mode)		Acute risk assessment (only crops with GAP under assessment)	
			Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Sheep: Fat tissue	0.02	EU-MRL	0.02	LOQ	0.02	LOQ
Sheep: Liver	0.5	EU-MRL	0.5	MRL	0.5	MRL
Sheep: Kidney	0.1	EU-MRL	0.1	MRL	0.1	MRL
Sheep: Edible offals (other than liver and kidney)	0.02	EU-MRL	0.02	LOQ	0.02	LOQ
Sheep: other products	0.02	EU-MRL	0.02	LOQ		
Goat						
Goat: Muscle/meat	0.02	EU-MRL	0.02	LOQ	0.02	LOQ
Goat: Fat tissue	0.02	EU-MRL	0.02	LOQ	0.02	LOQ
Goat: Liver	0.5	EU-MRL	0.5	MRL	0.5	MRL
Goat: Kidney	0.1	EU-MRL	0.1	MRL	0.1	MRL
Goat: Edible offals (other tha liver and kindey)	0.02	EU-MRL	0.02	LOQ	0.02	LOQ
Goat: other products	0.02	EU-MRL	0.02	LOQ		
Equine						
Equine: Muscle/meat	0.02	EU-MRL	0.02	LOQ	0.02	LOQ
Equine: Fat tissue	0.02	EU-MRL	0.02	LOQ	0.02	LOQ
Equine: Liver	0.5	EU-MRL	0.5	MRL	0.5	MRL
Equine: Kidney	0.1	EU-MRL	0.1	MRL	0.1	MRL
Equine: Edible offals (other than liver and kidney)	0.02	EU-MRL	0.02	LOQ	0.02	LOQ
Equine: Other products	0.02	EU-MRL	0.02	LOQ		
Poultry	0.02	EU-MRL				
Poultry: Muscle/meat	0.02	EU-MRL	0.02	LOQ	0.02	LOQ
Poultry: Fat tissue	0.02	EU-MRL	0.02	LOQ	0.02	LOQ
Poultry: Liver	0.02	EU-MRL	0.02	LOQ	0.02	LOQ
Poultry: Kidney	0.02	EU-MRL	0.02	LOQ	0.02	LOQ
Poultry: Edible offals (other than liver and kideny)	0.02	EU-MRL	0.02	LOQ	0.02	LOQ
Poultry: Other products	0.02	EU-MRL	0.02	LOQ		
Other farmed terrestrial animals						
Other farmed animals: Muscle/meat	0.02	EU-MRL	0.02	LOQ	0.02	LOQ

Commodity	Existing/ proposed MRL	Source/ type of MRL	Chronic risk assessment (all crops, normal mode)		Acute risk assessment (only crops with GAP under assessment)	
			Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Other farmed animals: Fat tissue	0.02	EU-MRL	0.02	LOQ	0.02	LOQ
Other farmed animals: Liver	0.5	EU-MRL	0.5	MRL	0.5	MRL
Other farmed animals: Kidney	0.1	EU-MRL	0.1	MRL	0.1	MRL
Other farmed animals: Edible offals (other than liver and kidney)	0.02	EU-MRL	0.02	LOQ	0.02	LOQ
Other farmed animals: Other products	0.02	EU-MRL	0.02	LOQ		
Milk	0.02	EU-MRL				
Milk: Cattle	0.02	EU-MRL	0.02	MRL	0.02	MRL
Milk: Sheep	0.02	EU-MRL	0.02	MRL	0.02	MRL
Milk: Goat	0.02	EU-MRL	0.02	MRL	0.02	MRL
Milk: Horse	0.02	EU-MRL	0.02	MRL	0.02	MRL
Milk: Others	0.02	EU-MRL	0.02	MRL	0.02	MRL
Birds eggs	0.02	EU-MRL				
Eggs: Chicken	0.02	EU-MRL	0.02	LOQ	0.02	LOQ
Eggs: Duck	0.02	EU-MRL	0.02	LOQ	0.02	LOQ
Eggs: Goose	0.02	EU-MRL	0.02	LOQ	0.02	LOQ
Eggs: Quail	0.02	EU-MRL	0.02	LOQ	0.02	LOQ
Eggs: Others	0.02	EU-MRL	0.02	LOQ		
Honey and other apiculture products	0.05	EU-MRL	0.05	LOQ	0.05	LOQ
Amphibians and reptiles	0.02	EU-MRL	0.02	LOQ	0.02	LOQ
Terrestrial invertebrate animals	0.02	EU-MRL	0.02	LOQ	0.02	LOQ
Wild terrestrial vertebrate animals	0.02	EU-MRL	0.02	LOQ	0.02	LOQ
FISH, FISHPRODUCTS AND ANY OTHER MARINE AND FRESHWATER FOOD PRODUCTS						
Other crops/commodities		MRL/LOQ				

7.3.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.3- 18: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo 3.1	19% (based on NL toddler; main contributor: Milk: cattle)
IEDI (% ADI) according to EFSA PRIMo 3.1	Normal mode based on MRLs: 19% (based on NL toddler; main contributor: Milk: cattle); Refined calculation mode: 10% (based on NL toddler; main contributor: Milk: cattle)
IESTI (% ARfD) according to EFSA PRIMo 3.1	Barley: 17% (based on unprocessed commodities, children) Barley: 15% (based on unprocessed commodities, adults) Barley/cooked: 11% (based on processed commodities, children) Barley / beer: 22% (based on processed commodities, adults)
NEDI/NTMDI (% ADI) according to Rees Day-model (Σ 2 highest 97.5 percentile intakes + mean population intake for other foods)	Normal mode: 20% (based on UK infant; main contributor: Milk: cattle)

The proposed uses of fenpropidin in the formulation ADM.03502.F.1.A do not represent unacceptable chronic risks for the consumer.

Evaluator comment:

Information given by the Applicant is sufficient.

The calculation of the TMDI using EFSA model (version 3.1) and MRLs according to Reg. (EU) 61/2014 led to a utilisation of the ADI of 19% with the NL toddler being the population group with the highest value. For this diet, the highest contributor is Milk: Cattle with 6% of the ADI. The intended uses will not result in a consumer chronic exposure exceeding the ADI.

An acute consumer risk assessment was performed with MRLs for intended uses and for animal commodities. The highest International Estimated Short-Term Intake (IESTI) is at 17% and 15% of the ARfD for the consumption of barley by children and by adults respectively.

The proposed uses of fenpropidin in the product ADM.03502.F.1.A do not represent unacceptable acute and chronic risks for the consumer.

No further data are required to support the proposed uses.

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-harmonised 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 model EFSA PRIMO (rev.3.1), 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	$0.87/10 = 0.087$
	Fenpropidin	$1.4/20 = 0.07$
	Cumulative risk wheat (HI)	0.157
Barley	Prothioconazole	$0.5/10 = 0.05$
	Fenpropidin	$4.3/20 = 0.215$
	Cumulative risk barley (HI)	0.265

The Hazard Index is <1 for all relevant crops. Thus combined exposure to both active substances in ADM.03502.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 given by the Applicant is sufficient and acceptable.

7.5 References

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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.: R-30330 Eurofins Agrosience Services Chem GmbH, Hamburg, Germany GLP Unpublished	N	ADM	Y evaluated in the dRR for ADM.03500.F.2.B (Soratel) on 11.2022
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.: R-39653 POLLENIZ/GIRPA, Beaucauzé Cedex, France GLP Unpublished	N	ADM	Y evaluated in the dRR for ADM.03500.F.2.B (Soratel) on 11.2022
KCP 8/ KCA 6.3.1/01	Huaultmé, J.-M.	2020	Residue study of prothioconazole and its metabolites, and fenpropidin in wheat whole plant and RAC (grain and straw) after one foliar application of ADM.3502.F.1.A - 2 HS and 2 DCS - Northern Europe (France, Poland and Hungary) - 2019 Report no.: BPL19/770/GC, sponsor no.: 000102759 BIOTEK Agriculture, Saint-Pouange, France GLP Unpublished	N	ADM	N
KCP 8/ KCA 6.3.1/02	Mahlow, S.	2021	Determination of 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 (RAC whole plant, 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), in 4 trials (2 HS + 2 DCS) in Northern Europe (France, Poland and Hungary), 2019 Report no.: S19-00750, sponsor no.: 000102792 Eurofins Agrosience Services Chem GmbH, Hamburg, Germany GLP Unpublished	N	ADM	N

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 6.3.1/03	Le Mineur, A.	2021	Residue study of Prothioconazole and its metabolites, and Fenpropidin in wheat Raw Agricultural Commodities after foliar application of ADM.03502.F.1.A under field conditions - Northern Europe – 2021. Report no.: BPL21/956/GC, sponsor no.: 000107610 SynTech Research France, La Chapelle de Guinchay, France GLP Unpublished	N	ADM	N
KCP 8/ KCA 6.3.1/04	Le Mineur, A.	2022	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. Report no.: BPL21/958/GC, sponsor no.: 000107612 SynTech Research France, La Chapelle de Guinchay, France GLP Unpublished	N	ADM	Y for prothioconazole evaluated in the dRR for ADM.03500.F.2.B (Soratel) on 11.2022; N for TDMs
KCP 8/ KCA 6.3.2/01	Huaultmé, J.-M.	2020	Residue study of prothioconazole and its metabolites, and fenpropidin in barley whole plant and RAC (grain and straw) after one foliar application of ADM.3502.F.1.A - 2 harvest and 2 decline trials - Northern Europe (France, Poland and Hungary) - 2019. Report no.: BPL19/772/GC, sponsor no.: 000102761 BIOTEK Agriculture, Saint-Pouange, France GLP Unpublished	N	ADM	Y for prothioconazole evaluated in the dRR for ADM.03500.F.2.B (Soratel) on 11.2022; N for fenpropidin
KCP 8/ KCA 6.3.2/02	Mahlow, S.	2021	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 (175 g a.s./L of prothioconazole and 250 g a.s./L of fenpropidin) in 4 trials (2 HS + 2 DCS) in Northern Europe (France, Poland and Hungary), 2019. Study no.: S19-00752, sponsor no.: 000102794 Eurofins Agrosience Services Chem GmbH, Hamburg, Germany GLP Unpublished	N	ADM	Y evaluated in the dRR for ADM.03500.F.2.B (Soratel) on 11.2022
KCP 8/ KCA 6.3.2/03	Huaultmé, J.-M.	2021	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 - 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 for prothioconazole evaluated in the dRR for ADM.03500.F.2.B (Soratel) on 11.2022; N for fenpropidin

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 6.3.2/04	Yozgatli, H.P.	2021	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 Agrosience Services EcoChem GmbH, Niefern-Öschelbronn, Germany GLP Unpublished	N	ADM	Y evaluated in the dRR for ADM.03500.F.2.B (Soratel) on 11.2022
KCP 8/ KCA 6.3.2/05	Huaultmé, J.-M.	2022	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. Report no.: BPL21/962/GC, sponsor no.: 000107616 SynTech Research France, La Chapelle de Guinchay, France GLP Unpublished	N	ADM	Y evaluated in the dRR for ADM.03500.F.2.B (Soratel) on 11.2022
KCP 8/ KCA 6.3.2/06	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, Beaucauzé Cedex, France GLP Unpublished	N	ADM	Y evaluated in the dRR for ADM.03500.F.2.B (Soratel) on 11.2022
KCP 8/ KCA 6.3.2/07	Huaultmé, J.-M.	2022	Residue study of prothioconazole, difenoconazole and their metabolites in barley Raw Agricultural Commodities after foliar application of ADM.03501.F.1.A under field conditions – Northern Europe – 2021. Report no.: BPL21/960/GC, sponsor no.: 000107614 SynTech Research France, La Chapelle de Guinchay, France GLP Unpublished	N	ADM	Y evaluated in the dRR for ADM.03500.F.2.B (Soratel) on 11.2022
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 Agrosience Services EcoChem GmbH, Niefern-Öschelbronn, Germany GLP Unpublished	N	ADM	Y evaluated in the dRR for ADM.03500.F.2.B (Soratel) on 11.2022

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 6.6.2/01	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.: R-39638 Eurofins Agrosience Services GmbH, Stade, Germany GLP Unpublished	N	ADM	Y evaluated in the dRR for ADM.03500.F.2.B (Soral) on 11.2022
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 Agrosience Services GmbH, Stade, Germany GLP Unpublished	N	ADM	Y evaluated in the dRR for ADM.03500.F.2.B (Soral) on 11.2022
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 dRR for ADM.03500.F.2.B (Soral) on 11.2022

ADM = Property of ADAMA Agricultural Solution and all affiliates.

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

Data point (DAR ref. no)	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

Data point (DAR ref. no)	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 6/02 (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 (IIA 6.2.2.1/01)	Weber, H.; Spiegel, K.	2001	[Phenyl-UL- ¹⁴ C]JAU 6476 Absorption, distribution, excretion and metabolism in the lactating goat Report No.: MR-092/01 GLP Unpublished	N	BCS

Data point (DAR ref. no)	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 6/08 (IIA, 6.2.2.2/01)	Weber, H.; Weber, E.; Spiegel, K.	2002	[Phenyl-UL- ¹⁴ C] JAU 6476-desthio Absorption, distribution, excretion, and metabolism in the lactating goat Report no. MR-091/01 GLP Unpublished	N	BCS
KCP 8/ KCA 6/09 (IIA, 6.2.2.3/01)	Weber, H.; Spiegel, K.	2001	[Phenyl-UL- ¹⁴ C]JAU 6476 Absorption, distribution, excretion and metabolism in laying hens Report No.: MR-309/01 Bayer AG GLP Unpublished	N	BCS
KCP 8/ KCA 6/10 (IIA, 6.4/01)	Heinemann, O.; Auer, S.	2001	JAU 6476-desthio – Dairy cattle feeding study Report No.: MR-535/00 Report includes trial no.: P 673003007 Bayer AG GLP Unpublished	N	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 fenpropidin

Data point (DAR ref. no)	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 6/12 (IIA, 6.0/01)	Tribolet, R.	1995	Residue stability study for fenpropidin (CGA 114900) in weathered grapes under freezer storage conditions. Report No.: 122/92 Ciba-Geigy AG, CH-4002 Basel GLP Unpublished	N	SYN
KCP 8/ KCA 6/13 (IIA, 6.0/02)	Walser, M.	1995	Residue stability study for CGA 114900 (Fenpropidin) in wine under freezer storage conditions. Report No.: 147/93 Ciba-Geigy AG, CH-4002 Basel GLP Unpublished	N	SYN
KCP 8/ KCA 6/14 (IIA, 6.0/03)	Walser, M.	1996a	Stability of residues of fenpropidin (CGA 114900) in stored analytical specimens of bananas (pulp and peel). Report No.: 128/94 Ciba-Geigy AG, CH-4002 Basel GLP Unpublished	N	SYN
KCP 8/ KCA 6/15 (IIA, 6.0/04)	Walser, M.	1996b	Residue stability study for CGA 114900 (Fenpropidin) in wheat under freezer storage conditions. Report No.: 137/93 Ciba-Geigy AG, CH-4002 Basel GLP Unpublished	N	SYN
KCP 8/ KCA 6/16 (IIA, 6.0/05)	...	1996c	Residues in milk, blood and tissues (muscle, fat, liver, kidney) of dairy cattle resulting from a feeding of three levels of CGA 114900. Report No.: ... GLP Unpublished	N	SYN
KCP 8/ KCA 6/17 (IIA, 6.1/01)	Gross, D.	1994a	Distribution and degradation of [N-2methylpropyl-3- ¹⁴ C] CGA 114900 in spring wheat. Report No.: 17/94 Ciba-Geigy AG, CH-4002 Basel GLP Unpublished	N	SYN

Data point (DAR ref. no)	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 6/18 (IIA, 6.1/02)	Gross, D.	1994b	Distribution and degradation of [2,6- ¹⁴ C-piperidine] CGA 114900 in spring wheat. Report No.: 18/94 Ciba-Geigy AG, CH-4002 Basel GLP Unpublished	N	SYN
KCP 8/ KCA 6/19 (IIA, 6.1/03)	Kiffe, M.	2000	Metabolism of CGA 114900 in greenhouse grown spring wheat after treatment with [2,6- ¹⁴ C-piperidine] labelled material. Report No.: Addendum to Report No. 18/94 Novartis Crop Protection AG, CH-4002 Basel GLP Unpublished	N	SYN
KCP 8/ KCA 6/20 (IIA 6.6/01)	Krauss, J.	2000a	Outdoor confined accumulation study on rotational crops after bareground application of [N-2-methylpropyl-3- ¹⁴ C] CGA 114900. Report No.: 98JK21 Novartis Crop Protection AG., CH-4002 Basel. GLP Unpublished.	N	SYN
KCP 8/ KCA 6/21 (IIA 6.6/02)	Krauss, J.	2000a	Outdoor confined accumulation study on rotational crops after bareground application of [Piperidine-2-6- ¹⁴ C] CGA 114900. Report No.: 98JK22 Novartis Crop Protection AG., CH-4002 Basel. GLP Unpublished.	N	SYN
KCP 8/ KCA 6/22 (IIA 6.5/01)	Reischmann, F.-J.	2000	Hydrolysis of [Piperidine-2,6- ¹⁴ C]-labelled CGA 114900 under processing conditions. Report No.: 00RF03 Novartis Crop Protection AG., CH-4002 Basel. GLP Unpublished.	N	SYN
KCP 8/ KCA 6/23 (IIA 6.2/01)	...	2002	Fenpropidin metabolism in the goat. Report No... GLP Unpublished	Y	SYN

Data point (DAR ref. no)	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 6/24 (IIA 6.2/02)	1997a	Metabolism of [3- ¹⁴ C-propyl]piperidine]CGA 114900 after multiple oral administration to laying hens. Report No.: 13/96 GLP Unpublished	N	SYN
KCP 8/ KCA 6/25 (IIA 6.2/03)	1997b	Metabolism of [2,6- ¹⁴ C-piperidine]CGA 114900 after multiple oral administration to laying hens. Report No.: 14/96 GLP Unpublished	N	SYN
KCP 8/ KCA 6/26 (IIA 6.4/01)	...	1996c	Residues in milk, blood and tissues (muscle, fat, liver, kidney) of dairy cattle resulting from a feeding of three levels of CGA 114900. Report No.: ... GLP Unpublished	Y	SYN
KCP 8/ KCA 6/27 (IIA 6.4/01)	...	1999	Amendment 1 to Report Report No.: ... GLP Unpublished	Y	SYN
KCP 8/ KCA 6/28 (IIA 6.4/01)	2001	Amendment 2 to Report Report No.: ... GLP Unpublished	Y	SYN
KCP 8/ KCA 6/29 (IIA 6.5.2/01)	Maffezzoni, M.	1998a	Magnitude of residues after application of CGA 219417 and CGA 114900 as formulation 70552 A, EC 375 in malting winter barley. Report No.: 9715701 ADME Bioanalyses, F-30310 Vergéze GLP Unpublished	N	SYN
KCP 8/ KCA 6/30 (IIA 6.5.2/02)	Maffezzoni, M.	1998b	Magnitude of residues after application of CGA 219417 and CGA 114900 as formulation 70552 A, EC 375 in malting winter barley. Report No.: 9715702 ADME Bioanalyses, F-30310 Vergéze GLP Unpublished	N	SYN

Data point (DAR ref. no)	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 6/31 (IIA 6.5.2/03)	Gasser, A.	2002f	Residue study with fenpropidin (CGA 114900) in or on wheat in Switzerland, including processing. Report No.: 2022/00 Syngenta, CH-4002 Basel GLP Unpublished.	N	SYN

SYN = Syngenta

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
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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, 2018, amended 2019).

List of data submitted by the applicant and not relied on

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

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

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

Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1 Prothioconazole

A 2.1.1 Stability of residues

A 2.1.1.1 Stability of residues during storage of samples

A 2.1.1.1.1 Storage stability of residues in plant products

A 2.1.1.1.1.1 Study 1

Comments of zRMS:	<p>The study of Klimmek, S. and Gizler, A., 2017 (Report No.: S12-00072) on 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 during 36 months has been evaluated in Registration Report for ADM.03500.F.2.B (Soratel) on November 2022 by zRMS-PL and the summary is presented below.</p> <p>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.</p> <p><u>Results:</u></p> <p>Cucumber</p> <ul style="list-style-type: none"> - 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. <p>Grapes</p> <ul style="list-style-type: none"> - 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). <p>Dried beans (seed)</p> <ul style="list-style-type: none"> - 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. <p>The study is acceptable.</p>
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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 Gizler, A., 2017;
Report No.: S12-00072, Sponsor no.: R-30330

Guideline(s):	Yes, Regulation (EC) No. 1107/2009; Guidance document SANCO/825/00 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 $\leq -18^{\circ}\text{C}$

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:	<p>The study of Lefresne, S., 2020 (Report No.: B18S-A4-P-02) on freezing storage stability of prothioconazole-desthio and hydroxy metabolites in plant matrices at/below -18°C during 24 months has been evaluated in Registration Report for ADM.03500.F.2.B (Soratel) on November 2022 by zRMS-PL and the summary is presented below.</p> <p>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 $\leq -18^\circ\text{C}$ for 24 months.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>The study is acceptable.</p>
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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.: R-39653

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 $\leq -18^{\circ}\text{C}$ 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 $\leq -18^{\circ}\text{C}$) 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 ($\leq -18^{\circ}\text{C}$), 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 $\leq -18^{\circ}\text{C}$

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					% 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)
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, expressed as	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
		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

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)
	prothioconazole-desthio	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	NA	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		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	NA	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		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
	0.1		1	0.076	0.081	NA	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		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
		0.1	3	0.078	0.082	NA	0.080	80	92	96	0.083	83
		0.1	6	0.080	0.082		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
		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,	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

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	0.083	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	NA	0.093	93	100	88	0.105	105
		0.1	3	0.104	0.079		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
	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

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-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
		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	NA	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		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
		0.1	0	0.090	0.090	0.080	0.087	87	100	93	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	1	0.106	0.107	NA	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		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	NA	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		0.083	83	94	86	0.097	97
		0.1	18	0.079	0.079		0.079	79	89	91	0.087	87
	Prothioconazole-5-hydroxy-desthio, expressed as prothioconazole-desthio	0.1	24	0.096	0.093	0.082	0.095	95	107	100	0.095	95
		0.1	0	0.092	0.089		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		0.075	75	86	89	0.084	84
	Prothioconazole-6-hydroxy-desthio, expressed as prothioconazole-desthio	0.1	18	0.076	0.073	NA	0.074	74	84	92	0.080	80
		0.1	24	0.093	0.089		0.091	91	104	96	0.095	95
		0.1	0	0.090	0.088		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		0.079	79	92	75	0.105	105
	Prothioconazole- α -hydroxy-desthio, expressed as prothioconazole-desthio	0.1	12	0.081	0.074	NA	0.078	78	90	86	0.090	90
		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
		0.1	0	0.095	0.090		0.089	89	100	96	0.093	93
		0.1	3	0.127	0.128		0.127	127	143	106	0.120	120
Straw- berry	Prothioconazole-desthio	0.1	6	0.098	0.107	NA	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
		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

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	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 prothioconazole-desthio	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
		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	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

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)
Dry bean	prothioconazole-desthio	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
	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
		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
	Prothioconazole-4-hydroxy-desthio, expressed as prothioconazole-desthio	0.1	24	0.103	0.103		0.103	103	118	108	0.095	95
		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
		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
	Prothioconazole-5-hydroxy-desthio, expressed as prothioconazole-desthio	0.1	24	0.102	0.101		0.102	102	114	105	0.097	97
		0.1	0	0.083	0.089	0.086	0.086	86	100	89	0.097	97
		0.1	3	0.100	0.111	NA	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		0.079	79	91	90	0.087	87
	Prothioconazole-6-hydroxy-desthio, expressed as	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
		0.1	0	0.088	0.094	0.093	0.092	92	100	91	0.101	101
		0.1	3	0.106	0.115	NA	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		0.086	86	94	89	0.097	97

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	0.085	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	NA	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		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 21 months 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 $\leq -18^{\circ}\text{C}$ for a storage period up to 24 months.

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

A 2.1.2.1.3.1 Study 1

Comments of zRMS:	<p>The study of Bloß, K., 2019 (Report No.: S18-07655) on aqueous hydrolysis of [^{14}C]Prothioconazole-desthio at 90, 100 and 120 °C has been evaluated in Registration Report for ADM.03500.F.2.B (Soratel) on November 2022 by zRMS-PL and the summary is presented below.</p> <p>In this study no significant hydrolysis or degradation products were formed under conditions representative of pasteurisation, baking/brewing/boiling and sterilisation.</p> <p>There was no change in sample weight and in radioactivity content after any processing.</p> <p>The test item ([^{14}C]prothioconazole-desthio) was stable:</p> <ul style="list-style-type: none"> - 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. <p>The study is acceptable.</p>
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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-¹⁴C]-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

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

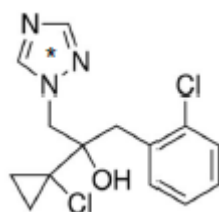


Figure A- 1: [1,2,4-triazole-U-¹⁴C]prothioconazole-desthio: Position of ¹⁴C- label is indicated by *

- | | |
|-----------------------|-------------|
| Batch no.: | XXIV/5/B/1 |
| Radiochemical purity: | 100 % |
| Specific activity: | 2.36 MBq/mg |
-
- 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
 - 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 μ L acetonitrile. The application solution was prepared by diluting 50 μ L of the stock solution in 950 μ L acetonitrile. The radioactivity was determined by LSC and a final volume of 23 μ L 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 μ L 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 μ L). 500 μ L of the aliquot were analysed by HPLC and 50 μ L 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 $\leq -18^{\circ}\text{C}$.

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 3 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 3 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 3 below.

Table A 3: 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-14C]prothioconazole-desthio was in a range of 98.9 % to 102.8 %.

[¹⁴C]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 4: Comparison of intended and critical EU GAPs (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	0.175 kg as/ha	-	65	n.a.

* Critical GAP number(s) in accordance with column 0 of Table 7.1- 1.

Note: In 2021, 6 residue trials were conducted using the mixture product containing prothioconazole plus fenpropidin (only 4 trials analysed for fenpropidin) and 8 crop residue trials were conducted using the mixture product containing prothioconazole plus difenoconazole. In this case 6 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 in bold, underlined and between brackets to indicate a second set of data for the same site is reported. Only worst-case data inside acceptable storage stability periods (underlined) has been used in the summary tables and for risk assessment for all metabolites.

A 2.1.3.1.1 Wheat study 1

Comments of zRMS:	<p>Four field trials were conducted in Northern Europe on winter or spring wheat treated with ADM.3502.F.1.A (prothioconazole, 175 g/L + fenpropidin, 250 g/L). One application was performed at BBCH 65, at dose rate between 0.96 and 1.02 L/ha of test item corresponding to a total dose of active ingredient between 167.3 and 176.8 g/ha of prothioconazole and between 241.0 and 254.8 g/ha of fenpropidin.</p> <p>For fenpropidin and prothioconazole and its metabolites, the analytical methods were validated on wheat (whole plant, grain and straw), following the guideline SANCO/3029/99.</p> <p>All the analytes were determined by LC-MS/MS using a quantitation and confirmation ion. LOQ: 0.01 mg/kg for each analyte,</p> <p>The mean recoveries was between 70% and 110% with a RSD less than or equal to 20% at each level of fortification, for each reference item and for each matrix.</p> <p>The storage duration (interval between sampling and extraction date) was 108 days for the determination of prothioconazole and its metabolites and fenpropidin.</p> <p>Sufficient stability data are available to support the residue data presented in this study.</p> <p><u>Results:</u></p> <p>In grain specimens taken at normal commercial harvest (43-52 days) residues of prothioconazole (sum), prothioconazole-desthio and fenpropidin were <LOQ.</p> <p>The study is acceptable.</p>
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Reference:	KCA 6.3.1/01
Report:	Residue study of prothioconazole and its metabolites, and fenpropidin in wheat whole plant and RAC (grain and straw) after one foliar application of ADM.3502.F.1.A - 2 HS and 2 DCS - Northern Europe (France, Poland and Hungary) - 2019 Huauilmé, J.-M., 2020
Guideline(s):	Report no.: BPL19/770/GC, sponsor no.: 000102759 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:	<p>The study of Mahlow, S., 2021 (Study no.: S19-00750) on determination of 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.3502.F.1.A (175 g a.s./L of prothioconazole and 250 g a.s./L of fenpropidin) has been conducted in Northern Europe.</p> <p>The application had to be performed at crop growth stage BBCH 65.</p> <p>Grain and straw specimens were taken at BBCH growth stage 89, normal commercial harvest (NCH).</p> <p>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.</p> <p><u>Results:</u></p> <p>Residues of 1,2,4-T in grain were <LOQ.</p> <p>Residues of TA in grain were between 0.26 and 0.36 mg/kg.</p> <p>Residues of TAA in grain were between 0.06 and 0.14 mg/kg.</p> <p>Residues of TLA in grain were between <LOQ and 0.01 mg/kg.</p>
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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 intervals from sampling until extraction was as follows:

Sample Type	Days of Storage from Sampling to last Extraction			
	1,2,4-T	TA	TAA	TLA
Whole plants without roots	648 days			
Grain	659 days			
Straw	562 days			

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.

The study is acceptable.

Reference: Report:	KCA 6.3.1/02 Determination of 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 (RAC whole plant, 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), in 4 trials (2 HS + 2 DCS) in Northern Europe (France, Poland and Hungary), 2019 Mahlow, S., 2021
Guideline(s):	Report no.: S19-00750, sponsor no.: 000102792 EC guidance working document SANCO/7029/VI/95 rev. 5 Guidance document SANCO/3029/99 rev. 4 OECD guidance document on pesticide residue analytical methods. Document ENV/JM/MONO(2007)17
Deviations:	n.a.
GLP:	Yes
Acceptability:	n.a.

Table A 5: Summary of the wheat study 1

Crop residue data from supervised field trials

Active ingredient (common name and content): Fenpropidin, nominal 250 g/L (actual 250 g/L)
Prothioconazole, nominal 175 g/L (actual 173.5 g/L)
Crop/crop group: Wheat / Cereals
Country: France, Poland, Hungary
Indoor/outdoor: Outdoor
Responsible body for reporting (name, address): BIOTEK Agriculture, Saint-Pouange, France

Reference no.:

Commercial product (name/code): KCA 6.3.1/01
ADM.3502.F.1.A

Formulation (e.g. SC): EC

Other active substance in the formulation: none

Residues calculated as:

Fenpropidin (mg/kg)

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) (8.2, risk assessment residue definition); Prothioconazole-desthio (mg/kg) (8.3, enforcement residue definition)

1	2	3	4			5	6	7	8.1	8.2	8.3	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				Fenpropidin	Prothioconazole (sum)	Prothioconazole-desthio	Timing (BBCH)	DALA (days)	
(a)	(b)	(b)	(c)			(d)				(f)	(g)			(e)
BPL19/770/GC-01-FR 71 640 Givry France N-EU 2018/19	Winter wheat (TRZAW)/ Complice	1. 25/10/18 2. 27/05/-11/06/19 3. 10/07/-16/07/19	fpn: 0.250 prt: 0.174	200	fpn: 0.125 prt: 0.087	29/05/19	BBCH 65	Grain	<LOQ (nd)	<LOQ (nd)	<LOQ (nd)	89	44	Analytical methods: Study code: S13-05182, QuEChERS method, LC-MS/MS For method validation please refer to dRR Part B.5, point KCP 5.1.2.
								Straw	0.21	0.19	0.056	89	44	
BPL19/770/GC-02-PL 55-110 Prusice Poland N-EU 2018/19	Winter wheat (TRZAW)/ Linus	1. 01/10/18 2. 01/06/-20/06/19 3. 26/07/-27/07/19	fpn: 0.241 prt: 0.167	291	fpn: 0.083 prt: 0.058	07/06/19	BBCH 65	Grain	<LOQ (nd)	<LOQ (nd)	<LOQ (nd)	89	50	LOQ: 0.01 mg/kg for each analyte, 0.06 mg/kg for prothioconazole
								Straw	0.13	0.67	0.28	89	50	

1	2	3	4			5	6	7	8.1	8.2	8.3	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 treatment s 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				Fenpro- pidin	Prothio- conazole (sum)	Prothio- conazole- desthio	Timing (BBCH)	DALA (days)	
(a)	(b)	(b)	(c)			(d)				(f)	(g)			(e)
BPL19/770/GC-03-HU 2141 Csömör Hungary N-EU 2018/19	Winter wheat (TRZAW)/ Astaro	1. 01/10/18 2. 22/05/- 03/06/19 3. 09/07/- 11/07/19	fpn: 0.255 prt: 0.177	256	fpn: 0.100 prt: 0.069	27/05/19	BBCH 65	Whole plant w/o roots	3.5	0.26	0.26	65	0	expressed as prothioconazole-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: 102 108 days (sampling to extraction), max. extract storage time (extraction to analysis) 5 days. Extract stability tested during the study. Results in all untreated specimens were below LOD. *Mean of two analyses concerning the main specimen and its spare
								Whole plant w/o roots	0.79	0.044	0.044	69	10	
								Whole plant w/o roots	0.39	0.045	0.025	77	21	
								Whole plant w/o roots	0.25	0.060	0.020	87	35	
								Grain	<LOQ (nd)	<LOQ (nd)	<LOQ (nd)	89	43	
								Straw	0.24	0.059	0.019	89	43	
BPL19/770/GC-04-FR 60490 Mareuil-Lamotte France N-EU 2019	Spring wheat (TRZAS)/ Lennox	1. 19/02/19 2. 12/06/- 21/06/19 3. 01/08/19	fpn: 0.254 prt: 0.176	203	fpn: 0.125 prt: 0.087	14/06/19	BBCH 65	Whole plant w/o roots	2.9	0.60	0.60	65	0	
								Whole plant w/o roots	0.74	0.14	0.13	71	10	
								Whole plant w/o roots	0.32	0.030	0.030	77	20	
								Whole plant w/o roots	0.35	0.083	0.037	87	35	
								Grain	<LOQ (nd)	<LOQ (nd)	<LOQ (nd)	89	52	
								Straw	0.81*	0.67*	0.20*	89	52	

(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) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
 - (f) 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).
 - (g) Prothioconazole-desthio (sum of isomers) (8.3, enforcement residue definition)
- nd not detectable
LOQ Limit of quantification
LOD Limit of detection

Table A 6: Summary of the wheat study 1 (TDMs)

Crop residue data from supervised field trials

Active ingredient (common name and content): Prothioconazole, 173.5 g/L (actual)

Crop/crop group: Wheat / Cereals

Country: France (N-EU), Poland, Hungary

Indoor/outdoor: Outdoor

Responsible body for reporting (name, address): Eurofins Agrosience Services Chem GmbH, Hamburg, Germany

Reference no.:

Commercial product (name/code):

KCA 6.3.1/02

ADM.3502.F.1.A

Formulation (e.g. SC):

EC

Other active substance in the formulation:

Fenpropidin, 250 g/L (actual)

Residues calculated as:

1,2,4-Triazole, Triazolalanin, Triazole acetic acid, Triazole lactic acid (mg/kg)

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-T	TA	TAA	TLA	Timing (BBCH)	DALA (days)		
(a)	(b)		(c)			(d)	(e)	(a)					(f)	(g)		
BPL19/770/GC -01-FR 71 640 Givry France N-EU 2018/19	Winter wheat (TRZAW)/ Complice	1. 25/10/18 2. 27/05/ - 11/06/19 3. 10-16/07/19	prt: 0.174 fnp: 0.250	200	prt: 0.087 fnp: 0.125	29/05/19	BBCH 65	Grain	<LOQ	<u>0.36</u>	<u>0.14</u>	<u>0.01</u>	89	44	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)	
									Straw	<LOQ (n.d.)	<LOQ	<u>0.04</u>	<u>0.05</u>	89		44
			Untreated					Grain	<LOQ (n.d.)	0.05	0.06	<LOQ (n.d.)	89	44		
								Straw	<LOQ (n.d.)	<LOQ (n.d.)	0.02	0.01	89	44		
BPL19/770/GC -02-PL 55 110 Prusice Poland N-EU 2018/19	Winter wheat (TRZAW)/ Linus	1. 01/10/18 2. 01/06/ - 20/06/19 3. 26-27/07/19	prt: 0.167 fnp: 0.241	291	prt: 0.058 fnp: 0.083	07/06/19	BBCH 65	Grain	<LOQ (n.d.)	<u>0.28</u>	<u>0.11</u>	<LOQ (n.d.)	89	50	Max. sample storage time: 648 days for whole plant w/o roots, 659 days for grain and 562 days for straw (sampling to extraction), max. extract storage time	
									Straw	<LOQ (n.d.)	<LOQ	<u>0.06</u>	<u>0.02</u>	89		50
			Untreated					Grain	<LOQ (n.d.)	0.11	0.08	<LOQ (n.d.)	89	50		
								Straw	<LOQ (n.d.)	<LOQ (n.d.)	0.03	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	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-T	TA	TAA	TLA	Timing (BBCH)	DALA (days)	
(a)	(b)	(b)	(c)			(d)	(e)	(a)						(f)	(g)
BPL19/770/GC -03-HU 2141 Csömör Hungary N-EU 2018/19	Winter wheat (TRZAW)/ Astaro	1. 01/10/18 2. 22/05/ - 03/06/19 3. 09- 11/07/19	prt: 0.177 fnp: 0.255	256	prt: 0.069 fnp: 0.100	27/05/19	BBCH 65	Whole plants	<LOQ (n.d.)	<LOQ	<LOQ	<LOQ	65	0	(extraction to analysis) 1 day for whole plant w/o roots and straw and 2 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.
								w/o roots	<LOQ (n.d.)	0.08	0.01	0.04	69	10	
								Whole plants	<LOQ (n.d.)						
								w/o roots	<LOQ (n.d.)						
								Whole plants	<LOQ (n.d.)	0.08	0.02	0.07	77	21	
								w/o roots	<LOQ (n.d.)						
								Whole plants	<LOQ (n.d.)	0.10	0.06	0.08	87	35	
								w/o roots	<LOQ (n.d.)						
								Grain	<LOQ (n.d.)	0.26	0.06	<LOQ (n.d.)	89	43	
								Straw	<LOQ (n.d.)	0.03	0.04	0.09	89	43	
								Untreated							
								Whole plants	<LOQ (n.d.)	<LOQ (n.d.)	<LOQ	<LOQ	65	0	
								w/o roots	<LOQ (n.d.)	<LOQ (n.d.)	<LOQ	<LOQ	77	21	
								Whole plants	<LOQ (n.d.)						
								w/o roots	<LOQ (n.d.)						
								Grain	<LOQ (n.d.)	0.02	0.01	<LOQ (n.d.)	89	43	
								Straw	<LOQ (n.d.)	<LOQ (n.d.)	0.01	0.01	89	43	
BPL19/770/GC -04-FR 60490 Mareuil- Lamotte France N-EU 2019	Spring wheat (TRZAS)/ Lennox	1. 19/02/19 2. 12/06/ - 21/06/19 3. 01/08/19	prt: 0.176 fnp: 0.254	203	prt: 0.087 fnp: 0.125	14/06/19	BBCH 65	Whole plants	<LOQ	0.01	<LOQ	0.01	65	0	
								w/o roots	<LOQ						
								Whole plants	<LOQ (n.d.)	0.07	0.02	0.04	71	10	
								w/o roots	<LOQ (n.d.)						
								Whole plants	<LOQ (n.d.)	0.08	0.02	0.03	77	20	
								w/o roots	<LOQ (n.d.)						
								Whole plants	<LOQ (n.d.)	0.10	0.03	0.04	87	35	
								w/o roots	<LOQ (n.d.)						
								Grain	<LOQ (n.d.)	0.29	0.08	<LOQ (n.d.)	89	52	
								Straw	<LOQ (n.d.)	<LOQ	0.02	0.05	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	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-T	TA	TAA	TLA	Timing (BBCH)	DALA (days)	
(a)	(b)	(b)	(c)			(d)	(e)	(a)						(f)	(g)
			Untreated					Whole plants w/o roots	<LOQ (n.d.)	0.01	<LOQ	0.01	65	0	
								Whole plants w/o roots	<LOQ	0.03	0.01	0.01	77	20	
								Grain	<LOQ (n.d.)	0.08	0.03	<LOQ (n.d.)	89	52	
								Straw	<LOQ (n.d.)	<LOQ (n.d.)	0.01	0.03	89	52	

(a) According to Codex Classification /Guide

(b) Only if relevant

(c) High or low volume spaying, 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.

(g) Remarks may include: climatic conditions ; reference to analytical method ; information concerning the metabolites included, the method of storage, storage, stability, analysis date.

prt Prothioconazole

fnp Fenpropidin

w/o Without

n.d. Not detectable

LOQ Limit of quantification

LOD Limit of detection

Data in *italics* reported but outside acceptable storage stability and therefore have not been used.

A 2.1.3.1.2 Wheat study 2

Comments of zRMS:	<p>Six field trials were conducted in Northern Europe to determine the residue levels of prothioconazole and its metabolites (including TDMs), and of fenpropidin in specimens of wheat Raw Agricultural Commodity (grain + straw) following one application of ADM.03502.F.1.A (175 g a.s./L of Prothioconazole and 250 g a.s./L of Fenpropidin) at crop growth stage BBCH 65 under typical cultural practices.</p> <p>The target dose rate of test item ADM.03502.F.1.A had to be 1.0 L/ha (175 g a.s./ha of Prothioconazole and 250 g a.s./ha of Fenpropidin).</p> <p>Specimens of grain and straw had to be generated at harvest stage BBCH 89 from all the field trials performed.</p> <p>The trials BPL21/956/GC-05-FR and BPL21/956/GC-06-FR were not analysed for fenpropidin as planned in the study plan and amendments.</p> <p><u>Validation of the method(s):</u></p> <p>For fenpropidin, the analytical method was previously fully validated on wheat (grain and straw), following the guideline SANCO/3029/99 rev.4 of 11/07/2000, during another analytical phase performed at GIRPA in 2019 (GIRPA analytical phase code: B19S-B5-FP-01 of BIOTEK Study reference BPL19/770/GC).</p> <p>The analytical method was validated (reduced validation) on wheat (grain and straw), following the new guideline SANTE/2020/12830, Rev.1 of 24/02/2021, during this analytical phase. For each matrix, 6 spiked samples were performed (3 recovery experiments fortified at the LOQ level and 3 recovery experiments fortified at ten times the LOQ level), 1 sample of blank matrix (non-fortified sample or control sample) was prepared.</p> <p>For prothioconazole and its metabolites, the analytical method was validated (full validations) on barley (grain, straw) and validated (reduced validations) on wheat (grain, straw), in compliance with Guideline SANTE/2020/12830, Rev.1 of 24/02/2021 during another study performed at GIRPA SAS in 2021 (GIRPA SAS study code: B21S-A4-P-01 – Sponsor reference : 000108024). For each matrix and each reference item, 6 or 10 spiked samples were performed (3 or 5 recovery experiments fortified at the LOQ level and 3 or 5 recovery experiments fortified at ten times the LOQ level), 1 or 2 samples of blank matrix (non-fortified sample or control sample) were prepared.</p> <p>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. The analytical method was validated for the determination of TDMs in wheat (grain and straw) according to SANTE/2020/12830, Rev.1 in study S21-02262 and S12-00072 performed by Eurofins Agroscience Services Chem GmbH.</p> <p>The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for each analyte and each matrix with a limit of detection (LOD) set at 0.003 mg/kg (30% of the LOQ).</p> <p>The mean recoveries was between 70% and 110% with a RSD less than or equal to 20% at each level of fortification, for each reference item and for each matrix.</p> <p><u>Results:</u></p> <p><u>Fenpropidin</u></p> <p>In the treated wheat specimens, the residue levels of fenpropidin were <LOQ in all grain specimens and ranged from 0.31 and 0.88 mg/kg in straw.</p> <p>Analysis (extraction) of the specimens took place maximum 132 days after samples collection. Sufficient stability data are available to support the residue data presented in this study.</p> <p><u>Prothioconazole</u></p> <p>In the treated wheat specimens, the residue levels of prothioconazole-desthio and its metabolites ranged from:</p> <p>For prothioconazole-desthio:</p> <p>- All results were <LOQ (nd) in grain,</p>
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	<p>- 0.013 and 0.63 mg/kg in straw. For 3-hydroxy-prothioconazole-desthio, - all results were <LOQ (nd) in grain, - <LOQ and 0.14 mg/kg in straw. For 4-hydroxy-prothioconazole-desthio: - all results were <LOQ (nd) in grain, - <LOQ and 0.086 mg/kg in straw. For 5-hydroxy-prothioconazole-desthio: - all results were <LOQ (nd) in grain, - <LOQ and 0.077 mg/kg in straw. For 6-hydroxy-prothioconazole-desthio: - all results were <LOQ (nd) in grain - <LOQ (nd) and 0.022 straw, For Alpha-hydroxy-prothioconazole-desthio: - all results were <LOQ (nd) in grain, - <LOQ (nd) and 0.030 mg/kg in straw. Analysis (extraction) of the specimens took place maximum 125 days after samples collection. Sufficient stability data are available to support the residue data presented in this study.</p> <p><u>TDMs</u> In the treated wheat specimens, the residue levels of the triazole metabolites ranged from: For 1,2,4-Triazole, <LOQ in grain and <LOQ (nd) in straw specimens, For Triazole alanine: - 0.18 and 0.42 mg/kg in grain, - <LOQ (nd) and 0.02 mg/kg in straw, For Triazole acetic acid: - <0.05 and 0.22 mg/kg in grain, - 0.01 and 0.05 mg/kg in straw, For Triazole lactic acid: - <LOQ in grain, - <LOQ and 0.18 mg/kg in straw. Analysis (extraction) of the specimens took place maximum 91 days after samples collection. Sufficient stability data are available to support the residue data presented in this study.</p> <p>The study is acceptable.</p>
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Reference:	KCA 6.3.1/03
Report:	Residue study of Prothioconazole and its metabolites, and Fenpropidin in wheat Raw Agricultural Commodities after foliar application of ADM.03502.F.1.A under field conditions - Northern Europe – 2021 Le Mineur, A.; 2021
Guideline(s):	Study no.: BPL21/956/GC, sponsor no.: 000107610 - 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 (part to follow concerns only risk assessment)
Deviations:	n.a.
GLP:	Yes
Acceptability:	n.a.

Crop residue data from supervised field trials

Reference no.:

KCA 6.3.1/03

Commercial product (name/code):

ADM.03502.F.1.A

Formulation (e.g. SC):

EC

Other active substance in the formulation:

Prothioconazole, nominal 175 g/L (actual 175.9 g/L)

Residues calculated as:

Fenpropidin (mg/kg)

1	2	3	4			5	6	7	8	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				Fenpropidin	Timing (BBCH)	DALA (days)	
	(a)	(b)	(c)			(d)					(e)	(f)
BPL21/956/GC-01-FR 10 600 La Chapelle Saint-Luc France N-EU 2020/21	Winter wheat (TRZAW) / Pastoral	1/ 20/10/20 2/ 28/05 - 12/06/21 3/ 24/07/21	0.251	297	0.085	02/06/21	BBCH 65	Grain Straw	<u><LOQ</u> <u>0.85*</u>	89 89	58 58	Analytical methods: multi-residue method, – QuEChERS, LC-MS/MS 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 matrix. Max. sample storage time: 132 days (sampling to extraction), max. extract storage time (extraction to analysis) 1 day. Extract stability demonstrated within the study. Results in all untreated specimens were below LOD
BPL21/956/GC-02-GE 74861 Kreßbach Germany N-EU 2020/21	Winter wheat (TRZAW) / Kometus	1/ 20/10/20 2/ 07 - 14/06/21 3/ 29 - 30/07/21	0.251	347	0.072	10/06/21	BBCH 65	Grain Straw	<u><LOQ</u> <u>0.31</u>	89 89	49 49	
BPL21/956/GC-03-HU 2340 Kiskunlacháza Hungary N-EU 2021	Spring wheat (TRZAS) / Mv Pirkadat	1/ 16/03/21 2/ 09 - 15/06/21 3/ 12 - 15/07/21	0.248	293	0.085	11/06/21	BBCH 65	Grain Straw	<u><LOQ</u> <u>0.88</u>	89 89	32 32	

Crop residue data from supervised field trials

Active ingredient (common name and content): Fenpropidin, Nominal 250 g/L (actual 253.7 g/L)

Crop/crop group: Wheat / Cereals

Country: France (N-EU), Germany, Hungary, Poland

Indoor/outdoor: Outdoor

Responsible body for reporting (name, address): SynTech Research France, La Chapelle de Guinchay, France

Reference no.:

Commercial product (name/code): ADM.03502.F.1.A

Formulation (e.g. SC): EC

Other active substance in the formulation: Prothioconazole, nominal 175 g/L (actual 175.9 g/L)

Residues calculated as:

KCA 6.3.1/03

Fenpropidin (mg/kg)

1	2	3	4			5	6	7	8	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				Fenpropidin	Timing (BBCH)	DALA (days)	
	(a)	(b)	(c)			(d)					(e)	(f)
BPL21/956/GC-04-PL 55 110 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	0.248	294	0.085	17/06/21	BBCH 65	Grain	<LOQ	89	44	
								Straw	0.49*	89	44	

(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 250 g a.s./ha of Fenpropidin (equivalent to ADM.03502.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

* Mean of two injections

n.d. Not detectable

LOQ Limit of quantification

LOD Limit of detection

Table A 8: Summary of the wheat study 2

Crop residue data from supervised field trials

Active ingredient (common name and content): Prothioconazole, nominal 175 g/L (actual 175.9 g/L)
Crop/crop group: Wheat / Cereals
Country: France (N-EU), Germany, Hungary, Poland
Indoor/outdoor: Outdoor
Responsible body for reporting (name, address): SynTech Research France, La Chapelle de Guinchay, France

Reference no.:

Commercial product (name/code):
Formulation (e.g. SC):
Other active substance in the formulation:
Residues calculated as:

KCA 6.3.1/03

ADM.03502. F.1.A
EC
Fenpropidin, nominal 250 g/L (actual 253.7 g/L)
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)

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)
BPL21/956/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/ 24/08/21	0.174	297	0.059	02/06/21	BBCH 65	Grain Straw	<u><LOQ</u> (n.d.) <u>0.14</u>	<u><LOQ</u> (n.d.) <u>0.038*</u>	89 89	58 58	Analytical methods: RAR method 00979/M001, LC-MS/MS For method validation please refer to dRR Part B.5, point KCP 5.1.2.
BPL21/956/GC-02-GE 74861 Kreßbach 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	0.174	347	0.050	10/06/21	BBCH 65	Grain Straw	<u><LOQ</u> (n.d.) <u>0.20</u>	<u><LOQ</u> (n.d.) <u>0.040*</u>	89 89	49 49	

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)	(b)	(c)			(d)			(g)	(h)		(e)	(f)
BPL21/956/GC-03-HU 2340 Kiskunlacháza Hungary N-EU 2021 <u>(C)</u> ¹	Spring wheat (TRZAS) / Mv Pirkadat	1/ 16/03/21 2/ 09 - 15/06/21 3/ 12 - 15/07/21	0.172	293	0.059	11/06/21	BBCH 65	Grain Straw	<LOQ (n.d.) 0.96**	<LOQ (n.d.) 0.63**	89 89	32 32	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
BPL21/956/GC-04-PL 55 110 Krościna Mała Poland N-EU 2020/21 <u>(F)</u> ¹	Winter wheat (TRZAW) / RGT Kilimanjaro	1/ 30/10/20 2/ 13/06 - 01/07/21 3/ 16/08/21	0.172	294	0.059	17/06/21	BBCH 65	Grain Straw	<LOQ (n.d.) 0.25	<LOQ (n.d.) 0.046*	89 89	60 60	Max. sample storage time: 125 days (sampling to extraction), max. extract storage time (extraction to analysis) 6 days.
BPL21/956/GC-05-FR 37 210 Parçay Meslay France N-EU 2020/21 <u>(D)</u> ¹	Winter wheat (TRZAW) / Unik	1/ 18/10/20 2/ 25/05 - 08/06/21 3/ 20/07/21	0.164	187	0.088	01/06/21	BBCH 65	Grain Straw	<LOQ (n.d.) 0.29	<LOQ (n.d.) 0.082*	89 89	49 49	Extract stability proven within the study.
BPL21/956/GC-06-FR 51 240 Marson France N-EU 2020/21 <u>(E)</u> ¹	Winter wheat (TRZAW) / Syllon	1/ 18/10/20 2/ 30/05 - 12/06/21 3/ 22/07/21	0.170	291	0.059	04/06/21	BBCH 65	Grain Straw	<LOQ (n.d.) <LOQ*	<LOQ (n.d.) 0.013*	89 89	59 59	Results in all untreated specimens were below LOD.

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 250 g a.s./ha of Fenpropidin (equivalent to ADM.03502.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)
 - * Mean of two injections, mean of two extractions for trial (BPL21/954/GC-06-FR)
 - ** Mean of two extractions (sometimes injected twice)
- n.d. Not detectable
- LOQ Limit of quantification
- LOD Limit of detection

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

Crop residue data from supervised field trials

Active ingredient (common name and content): Prothioconazole, nominal 175 g/L (actual 175.9 g/L)

Crop/crop group: Wheat / Cereals

Country: France (N-EU), Germany, Hungary, Poland

Indoor/outdoor: Outdoor

Responsible body for reporting (name, address): SynTech Research France, La Chapelle de Guinchay, France

Reference no.:

Commercial product (name/code):

Formulation (e.g. SC):

Other active substance in the formulation:

Residues calculated as:

KCA 6.3.1/03

ADM.03502.F.1.A

EC

Fenpropidin, nominal 250 g/L (actual 253.7 g/L)

1,2,4-Triazole, Triazole alanine, Triazole acetic acid, Triazole lactic acid (mg/kg)

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-T	TA	TAA	TLA	Timing (BBCH)	DALA (days)	
	(a)	(b)	(c)			(d)	(e)	(a)						(f)	(g)
BPL21/956/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	0.174	297	0.059	02/06/21	BBCH 65	Grain	<LOQ (n.d.)	0.27	0.08	<LOQ (n.d.)	89	58	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	58	
			Untreated					Grain	<LOQ (n.d.)	0.03	0.01	<LOQ (n.d.)	89	58	
								Straw	<LOQ (n.d.)	<LOQ (n.d.)	<LOQ	<LOQ (n.d.)	89	58	
BPL21/956/GC-02-GE 74861 Kreßbach 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	0.174	347	0.050	10/06/21	BBCH 65	Grain	<LOQ (n.d.)	0.32	0.08	<LOQ (n.d.)	89	49	Max. sample storage time: 84 days (sampling to extraction), max. extract storage time (extraction to
								Straw	<LOQ (n.d.)	<LOQ	0.04	0.02	89	49	

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-T	TA	TAA	TLA	Timing (BBCH)	DALA (days)	
(a)	(b)	(c)	(c)	(L/ha)	(hL)	(d)	(e)	(a)						(f)	(g)
			Untreated					Grain	<LOQ (n.d.)	0.06	0.03	<LOQ (n.d.)	89	49	analysis) 3 days for grain and 1 day for straw.
								Straw	<LOQ (n.d.)	<LOQ (n.d.)	0.02	<LOQ	89	49	
BPL21/956/GC-03-HU 2340 Kiskunlacháza Hungary N-EU 2021 (C) ¹	Spring wheat (TRZAS) / Mv Pirkadat	1/ 16/03/21 2/ 09 - 15/06/21 3/ 12 - 15/07/21	0.172	293	0.059	11/06/21	BBCH 65	Grain	<LOQ	0.42	0.22	<LOQ	89	32	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.)	0.02	0.05	0.18	89	32	
			Untreated					Grain	<LOQ (n.d.)	0.15	0.14	<LOQ	89	32	
								Straw	<LOQ (n.d.)	0.02	0.08	0.15	89	32	
BPL21/956/GC-04-PL 55 110 Krościna Mała Poland N-EU 2020/21 (F) ¹	Winter wheat (TRZAW) / RGT Kilimanjaro	1/ 30/10/20 2/ 13/06 - 01/07/21 3/ 16/08/21	0.172	294	0.059	17/06/21	BBCH 65	Grain	<LOQ	0.40	0.09	<LOQ (n.d.)	89	60	Residues in untreated samples (background levels) were found in a part of samples, and results are given.
								Straw	<LOQ (n.d.)	<LOQ	0.03	0.01	89	60	
			Untreated					Grain	<LOQ (n.d.)	0.14	0.05	<LOQ (n.d.)	89	60	
								Straw	<LOQ (n.d.)	<LOQ	0.02	<LOQ	89	60	

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-T	TA	TAA	TLA	Timing (BBCH)	DALA (days)	
(a)	(b)	(b)	(c)			(d)	(e)	(a)						(f)	(g)
BPL21/956/GC-05-FR 37 210 Parçay Meslay France N-EU 2020/21 <u>(D)</u> ¹	Winter wheat (TRZAW) / Unik	1/ 18/10/20 2/ 25/05 - 08/06/21 3/ 20/07/21	0.164	187	0.088	01/06/21	BBCH 65	Grain	<LOQ (n.d.)	0.18	0.05	<LOQ (n.d.)	89	49	
								Straw	<LOQ (n.d.)	<LOQ	0.02	<LOQ 0.01	89	49	
			Untreated					Grain	<LOQ (n.d.)	0.09	0.05	<LOQ (n.d.)	89	49	
								Straw	<LOQ (n.d.)	<LOQ (n.d.)	0.01	<LOQ	89	49	
BPL21/956/GC-06-FR 51 240 Marson France N-EU 2020/21 <u>(E)</u> ¹	Winter wheat (TRZAW) / Syllon	1/ 18/10/20 2/ 30/05 - 12/06/21 3/ 22/07/21	0.170	291	0.059	04/06/21	BBCH 65	Grain	<LOQ (n.d.)	0.24	0.07	<LOQ (n.d.)	89	59	
								Straw	<LOQ (n.d.)	<LOQ	0.02	<LOQ 0.01	89	59	
			Untreated					Grain	<LOQ (n.d.)	0.04	0.02	<LOQ (n.d.)	89	59	
								Straw	<LOQ (n.d.)	<LOQ (n.d.)	<LOQ	<LOQ	89	59	

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 250 g a.s./ha of Fenpropidin (equivalent to ADM.03502.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.

n.d. Not detectable, LOQ: Limit of quantification, LOD: Limit of detection

A 2.1.3.1.3 Wheat study 3

Comments of zRMS:	<p>The study of Le Mineur, A., 2022 (Report No.: BPL21/958/GC) on determination of residue of prothioconazole in wheat whole plant and Raw Agricultural Commodities after foliar application of ADM.03501.F.1.A under field conditions has been evaluated in Registration Report for ADM.03500.F.2.B (Soratel) on November 2022 by zRMS-PL and the summary is presented below.</p> <p>The residue data for TDMs is evaluated in this document and a summary is also provided below.</p> <p>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 BBCH 69.</p> <p>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.</p> <p>Specimens of grain and straw were generated at harvest stage BBCH 89 from all the field trials performed.</p> <p><u>Prothioconazole</u></p> <p>In seed specimens taken at normal commercial harvest (28 – 72 days) residues of prothioconazole (sum) and prothioconazole-desthio were <LOQ.</p> <p>For prothioconazole-desthio:</p> <ul style="list-style-type: none"> - 0.013 and 0.54 mg/kg in whole plant without roots, - all results were <LOQ (nd) in grain, - 0.018 and 0.29 mg/kg in straw. <p>For 3-hydroxy-prothioconazole-desthio,</p> <ul style="list-style-type: none"> - <LOQ (nd) and 0.048 mg/kg in whole plant without roots, - all results were <LOQ (nd) in grain, - <LOQ and 0.083 mg/kg in straw. <p>For 4-hydroxy-prothioconazole-desthio:</p> <ul style="list-style-type: none"> - <LOQ (nd) and 0.027 mg/kg in whole plant without roots, - all results were <LOQ (nd) in grain, - <LOQ and 0.079 mg/kg in straw. <p>For 5-hydroxy-prothioconazole-desthio:</p> <ul style="list-style-type: none"> - <LOQ (nd) and 0.036 mg/kg in whole plant without roots, - all results were <LOQ (nd) in grain, - 0.017 and 0.093 mg/kg in straw. <p>For 6-hydroxy-prothioconazole-desthio:</p> <ul style="list-style-type: none"> - all results were <LOQ (nd) and <LOQ in whole plant without roots, - all results were <LOQ (nd) in grain, - <LOQ (nd) and 0.011 mg/kg in straw. <p>For Alpha-hydroxy-prothioconazole-desthio:</p> <ul style="list-style-type: none"> - all results were <LOQ (nd) and <LOQ in whole plant without roots, - all results were <LOQ (nd) in grain, - <LOQ and 0.073 mg/kg in straw. <p>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.</p> <p>All the analytes were determined by LC-MS/MS using a quantitation and confirmation ion.</p> <p>LOQ: 0.01 mg/kg for each analyte,</p> <p>LOQ: 0.06 mg/kg for prothioconazole expressed as prothioconazole-desthio as a sum of metabolites.</p> <p>The mean recoveries at each fortification level comply with the standard acceptance criteria of the guidance document SANTE/2020/12830, rev. 1.</p>
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	<p>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.</p> <p>TDMs: For 1,2,4-Triazole, all results were <LOQ in whole plant (without root), grain and straw specimens. For Triazole alanine: - 0.02 and 0.16 mg/kg in whole plant (without root), - 0.06 and 0.37 mg/kg in grain, - 0.01 and 0.03 mg/kg in straw, For Triazole acetic acid: - <LOQ and 0.05 mg/kg in whole plant (without root), - 0.03 and 0.15 mg/kg in grain, - 0.02 and 0.06 mg/kg in straw, For Triazole lactic acid: - 0.01 and 0.03 mg/kg in whole plant (without root), - All results <LOQ in grain, - <LOQ and 0.12 mg/kg in straw.</p> <p>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. The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for each analyte and each matrix. The mean recoveries at each fortification level comply with the standard acceptance criteria of the guidance document SANTE/2020/12830, rev. 1.</p> <p>Analysis (extraction) of the specimens took place maximum 122 days after samples collection. Sufficient stability data are available to support the residue data presented in this study.</p> <p>The study is acceptable.</p>
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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., 2022 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~~ ADM.03502.F.1.A (containing prothioconazole ~~only~~ and fenpropidin) 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 two independent trials were additionally used for risk assessment.

Table A 10: Summary of the wheat study 3

Crop residue data from supervised field trials

Active ingredient (common name and content): Prothioconazole, nominal 175 g/L (actual 172.8 g/L)
Crop/crop group: Wheat / Cereals
Country: France (N-EU), Germany, Hungary, Poland
Indoor/outdoor: Outdoor
Responsible body for reporting (name, address): SynTech Research France, La Chapelle de Guinchay, France

Reference no.:

Commercial product (name/code):

Formulation (e.g. SC):
Other active substance in the formulation:
Residues calculated as:

KCA 6.3.1/04

ADM.03501.F.1.A

EC
Difenoconazole, nominal 125 g/L (actual 125.0 g/L)
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)

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				Prothioconazole (sum)	Prothioconazole-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) ¹	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 Kreßbach 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	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	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)	(b)	(c)			(d)			(g)	(h)		(e)	(f)
BPL21/958/GC-03-HU 2340 Kiskunlacháza Hungary N-EU 2021 <u>(C)</u> ¹	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 Straw	<LOQ (n.d.) 0.45	<LOQ 0.29	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: 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.
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 Straw	<LOQ (n.d.) 0.15	<LOQ (n.d.) 0.022	89 89	44 44	
BPL21/958/GC-05-PL 55 010 Krościna Mała Poland N-EU 2020/21 <u>(F)</u> ¹	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 whole plant w/o roots whole plant w/o roots whole plant w/o roots Grain Straw	0.55 0.16 0.15 0.085 <LOQ (n.d.) 0.17	0.54 0.047 0.027 0.013 <LOQ (n.d.) 0.028*	69 71 73 – 75 87 89 89	0 11 20 33 46 46	

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)	(b)	(c)			(d)			(g)	(h)		(e)	(f)
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 <u>(D)</u> ¹	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 <u>(E)</u> ¹	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	

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) 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 the wheat study 3 (TDMs)

Crop residue data from supervised field trials

Active ingredient (common name and content): Prothioconazole, 172.8 g/L (actual)
Difenoconazole, 125.0 g/L (actual)
Crop/crop group: Wheat / Cereals
Country: France (N-EU), Germany, Hungary, Poland

Indoor/outdoor: Outdoor
Responsible body for reporting (name, address): BIOTEK Agriculture, Saint-Pouange, France

Reference no.:

Commercial product (name/code): KCA 6.3.1/08
ADM.03501.F.1.A

Formulation (e.g. SC): EC

Other active substance in the formulation: None

Residues calculated as:

1,2,4-Triazole, Triazole alanine, Triazole acetic acid, Triazole lactic acid (mg/kg)

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-T	TA	TAA	TLA	Timing (BBCH)	DALA (days)		
(a)	(b)	(b)	(c)			(d)	(e)	(a)						(f)	(g)	
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)	
									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 Kreßbach 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	Max. sample storage time: 122 days (sampling to extraction), max. extract storage time (extraction to	
									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	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-T	TA	TAA	TLA	Timing (BBCH)	DALA (days)	
(a)	(b)	(c)	(c)	(L/ha)	(hL)	(d)	(e)	(a)						(f)	(g)
			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 <u>(C)</u> 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	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-T	TA	TAA	TLA	Timing (BBCH)	DALA (days)	
(a)	(b)	(b)	(c)			(d)	(e)	(a)						(f)	(g)
BPL21/958/GC-05-PL 55 010 Krościna Mała Poland N-EU 2020/21 (F) ¹	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	<LOQ (n.d.)	0.02	0.01	0.02	69	0	
								w/o roots	<LOQ (n.d.)	0.09	0.01	0.02	71	11	
								whole plant	<LOQ (n.d.)	0.14	0.03	0.03	73 – 75	20	
								w/o roots	<LOQ (n.d.)	0.16	0.05	0.02	87	33	
								whole plant	<LOQ (n.d.)	0.16	0.03	<LOQ (n.d.)	89	46	
								w/o roots	<LOQ (n.d.)	0.03	0.04	0.02	89	46	
								Grain	<LOQ (n.d.)	0.03	0.04	0.02	89	46	
								Straw	<LOQ (n.d.)	0.03	0.04	0.02	89	46	
								whole plant	<LOQ (n.d.)	0.03	0.02	0.02	69	0	
								w/o roots	<LOQ (n.d.)	0.05	0.02	0.02	73 – 75	20	
								whole plant	<LOQ (n.d.)	0.13	0.05	<LOQ (n.d.)	89	46	
								w/o roots	<LOQ (n.d.)	0.01	0.02	0.01	89	46	
								Grain	<LOQ (n.d.)	0.01	0.02	0.01	89	46	
								Straw	<LOQ (n.d.)	0.01	0.02	0.01	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	<LOQ (n.d.)	0.02	<LOQ	0.01	69	0	
								w/o roots	<LOQ (n.d.)	0.07	0.01	0.03	83	10	
								whole plant	<LOQ (n.d.)	0.07	0.01	0.03	85	18	
								w/o roots	<LOQ (n.d.)	0.10	0.03	0.03	85	35	
								whole plant	<LOQ (n.d.)	0.23	0.07	<LOQ (n.d.)	89	72	
								w/o roots	<LOQ (n.d.)	0.02	0.04	<LOQ	89	72	
								Grain	<LOQ (n.d.)	0.02	0.04	<LOQ	89	72	
								Straw	<LOQ (n.d.)	0.02	0.04	<LOQ	89	72	
								Straw	<LOQ (n.d.)	0.02	0.04	<LOQ	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	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-T	TA	TAA	TLA	Timing (BBCH)	DALA (days)	
(a)	(b)	(b)	(c)			(d)	(e)	(a)						(f)	(g)
			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 <u>(D)</u> 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 <u>(E)</u> 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: Difenconazole
n.d. Not detectable
LOQ Limit of quantification
LOD Limit of detection

A 2.1.3.2 Barley, oat (KCA 6.3.2)

Table A 12: Comparison of intended and critical EU GAPs (prothioconazole)

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	0.175 kg as/ha	-	65	n.a.

* Critical GAP number(s) in accordance with column 0 of Table 7.1- 1.

Note: In 2021, 6 crop 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. Due to the challenges in locating sites which had not previously used triazole compounds, all 6 of the trial sites reported in Barley Study 3 were also used to generate data in Barley Study 4.

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 in bold, underlined and between brackets to indicate a second set of data for the same site is reported. Only worst-case data inside acceptable storage stability periods (underlined) has been used in the summary tables and for risk assessment for all metabolites.

A 2.1.3.2.1 Barley study 1

Comments of zRMS:	<p>The study of Huauhmé, J.-M., 2020 (Report No.: BPL19/772/GC) on determination of residue of prothioconazole and their metabolites in barley whole plant and RAC (grain and straw) after one foliar application of ADM.3502.F.1.A has been evaluated in Registration Report for ADM.03500.F.2.B (Soratel) on November 2022 by zRMS-PL and the summary is presented below.</p> <p>The residue data for fenpropidin is evaluated in this document and a summary is also provided below.</p> <p>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 except for trial 04-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.</p> <p><u>Prothioconazole</u> In seed specimens taken at normal commercial harvest residues of prothioconazole (sum) were <LOQ.</p> <p>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. LOQ = 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.</p> <p><u>Fenpropidin</u> In seed specimens taken at normal commercial harvest residues of fenpropidin were between</p>
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	<p><LOQ and 0.042 mg/kg.</p> <p>The analytical method was fully validated for each matrix in compliance with the guideline SANCO/3029/99 rev.4 of 11/07/2000.</p> <p>LOQ: 0.01 mg/kg.</p> <p>The mean recovery was between 70% and 110% at each level of fortification, for each reference item and for each matrix.</p> <p>The storage duration (interval between sampling and extraction date) was 114 days for the determination of prothioconazole and its metabolites and fenpropidin.</p> <p>Sufficient stability data are available to support the residue data presented in this study.</p> <p>The study is acceptable.</p>
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Reference:	KCA 6.3.2/01
Report:	Residue study of prothioconazole and its metabolites, and fenpropidin in barley whole plant and RAC (grain and straw) after one foliar application of ADM.3502.F.1.A - 2 harvest and 2 decline trials - Northern Europe (France, Poland and Hungary) - 2019 Hualmé, J.-M., 2020
Guideline(s):	Report no.: BPL19/772/GC, sponsor no.: 000102761 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:	<p>The study of Mahlow, S., 2021 (Study no.: S19-00752) on determination of 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 in Northern Europe has been evaluated in Registration Report for ADM.03500.F.2.B (Soratel) on November 2022 by zRMS-PL and the summary is presented below.</p> <p>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).</p> <p>The application had to be performed at crop growth stage BBCH 65 or 69.</p> <p>Grain and straw specimens were taken at BBCH growth stage 89, normal commercial harvest (NCH).</p> <p>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.</p> <p><u>Results:</u></p> <p>Residues of 1,2,4-T and TLA in grain were <LOQ.</p> <p>Residues of TA in grain were between 0.07 and 0.13 mg/kg.</p> <p>Residues of TAA in grain were between 0.02 and 0.07 mg/kg.</p> <p>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.</p> <p>The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for each analyte</p>
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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 intervals from sampling until extraction was as follows:

Sample Type	Days of Storage from Sampling to last Extraction			
	1,2,4-T	TA	TAA	TLA
Whole plants without roots	712	751	712	712
Grain	664	699	664	664
Straw	660	660	660	660

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:

Report:

KCA 6.3.2/02

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 (175 g a.s./L of prothioconazole and 250 g a.s./L of fenpropidin) in 4 trials (2 HS + 2 DCS) in Northern Europe (France, Poland and Hungary), 2019

Mahlow, S., 2021

Guideline(s):

Study no.: S19-00752, sponsor no.: 000102794

EC Guideline SANCO/7029/VI/95 rev. 5

Guidance document SANCO/3029/99 rev. 4

OECD ENV/JM/MONO(2007)17

Deviations:

n.a.

GLP:

Yes

Acceptability:

n.a.

Table A 13: Summary of the barley study 1

Crop residue data from supervised field trials

Active ingredient (common name and content): Fenpropidin, nominal 250 g/L (actual 250 g/L)
Prothioconazole, nominal 175 g/L (actual 173.5 g/L)
Crop/crop group: Barley / Cereals
Country: France, Poland, Hungary

Indoor/outdoor: Outdoor
Responsible body for reporting (name, address): BIOTEK Agriculture, Saint-Pouange, France

Reference no.:

Commercial product (name/code): ADM.3502.F.1.A

Formulation (e.g. SC): EC

Other active substance in the formulation: none

Residues calculated as:

KCA 6.3.2/01

Fenpropidin (mg/kg);
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) (8.2, risk assessment residue definition);
Prothioconazole-desthio (mg/kg) (8.3, enforcement residue definition)

1	2	3	4			5	6	7	8.1	8.2	8.3	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				Fenpropidin	Prothioconazole (sum)	Prothioconazole-desthio	Timing (BBCH)	DALA (days)	
(a)	(b)	(b)	(c)			(d)				(f)	(g)			(e)
BPL19/772/GC-01-FR 60490 Mareuil-Lamotte France N-EU 2019	Spring barley (HORVS)/ RGT Planet	1. 19/02/19 2. 06/06/- 21/06/19 3. 01/08/19	fpn: 0.261 prt: 0.181	209	fpn: 0.125 prt: 0.087	06/06/19	BBCH 65	Grain Straw	<LOQ (nd) 0.28	<LOQ (nd) 0.17	<LOQ (nd) 0.083	89 89	53 53	Analytical methods: Study code: S13-05182, QuEChERS method, 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 metabolites;
BPL19/772/GC-02-PL 98-300 Masłowice, Wieluń Poland N-EU 2019	Spring barley (HORVS)/ Paustian	1. 22/03/19 2. 09/06/- 15/06/19 3. 02/08/19	fpn: 0.244 prt: 0.169	294	fpn: 0.083 prt: 0.058	11/06/19	BBCH 65	Grain Straw	0.042 0.19	<LOQ (nd) 0.61	0.027 0.28	89 89	52 52	

1	2	3	4			5	6	7	8.1	8.2	8.3	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 treatment s 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				Fenpro- pidin	Prothio- conazole (sum)	Prothio- conazole- desthio	Timing (BBCH)	DALA (days)	
(a)	(b)	(b)	(c)			(d)				(f)	(g)			(e)
BPL19/772/GC-03-HU 2141 Csömör Hungary N-EU 2018/19	Winter barley (HORVW) / Monique	1. 29/09/18 2. 07/05/- 02/05/19 3. 27/06/- 03/07/19	fpn: 0.246 prt: 0.170	247	fpn: 0.100 prt: 0.069	11/05/19	BBCH 65	Whole plant w/o roots	4.6	0.87	0.87	65	0	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: 114 days (sampling to extraction), max. extract storage time (extraction to analysis) 13 days. Extract stability tested during the study.
								Whole plant w/o roots	0.68	0.28	0.24	71	11	
								Whole plant w/o roots	0.31	0.11	0.089	75	20	
								Whole plant w/o roots	0.17	0.13	0.042	85	37	
								Grain	0.013	<LOQ (nd)	<LOQ (nd)	89	52	
								Straw	0.13	0.16	0.063	89	52	
BPL19/772/GC-04-FR 49320 Vauchrétien France N-EU 2018/19	Winter barley (HORVW) / Etincel	1. 15/11/18 2. 06/05/- 15/05/19 3. 03/07/19	fpn: 0.250 prt: 0.174	250	fpn: 0.100 prt: 0.069	13/05/19	BBCH 69	Whole plant w/o roots	2.7	1.1	1.1	69	0	Results in all untreated specimens were below LOD.
								Whole plant w/o roots	0.75	0.54	0.51	71	10	
								Whole plant w/o roots	0.38	0.15	0.12	77	22	
								Whole plant w/o roots	0.22	0.088	0.046	85	35	
								Grain	0.026	<LOQ (nd)	0.010	89	50	
								Straw	0.20	0.49	0.25	89	50	

(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) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
 - (f) 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).
 - (g) Prothioconazole-desthio (sum of isomers) (8.3, enforcement residue definition)
- nd not detectable
LOQ Limit of quantification
LOD Limit of detection

Table A 14: Summary of Barley study 1 (TDMs)

Crop residue data from supervised field trials

Active ingredient (common name and content): Prothioconazole, nominal 175 g/L (actual 173.5 g/L)
Crop/crop group: Barley / Cereals
Country: France (N-EU), Poland, Hungary

Indoor/outdoor: Outdoor
Responsible body for reporting (name, address): Eurofins Agroscience Services Chem GmbH, Hamburg, Germany

Reference no.:

Commercial product (name/code):

KCA 6.3.2/01

ADM.3502.F.1.A

Formulation (e.g. SC):

EC

Other active substance in the formulation:

Fenpropidin, nominal 250 g/L (actual 250 g/L)

Residues calculated as:

1,2,4-Triazole, Triazole alanine, Triazole acetic acid, Triazole lactic acid (mg/kg)

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-T	TA	TAA	TLA	Timing (BBCH)	DALA (days)			
(a)	(a)	(b)	(c)			(d)	(e)	(a)						(f)	(g)		
BPL19/772/GC-01-FR 60490 Mareuil-Lamotte France N-EU 2019	Spring barley (HORVS)/ RGT Planet	1. 19/02/19 2. 06 - 21/06/19 3. 01/08/19	prt: 0.181 fnp: 0.244	209	prt: 0.087 fnp: 0.083	06/06/19	BBCH 65	Grain	<LOQ (n.d.)	<u>0.11</u>	<u>0.07</u>	<LOQ	89	53	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)		
								Straw	<LOQ (n.d.)	<LOQ	<u>0.03</u>	<u>0.06</u>	89	53			
			Untreated						Grain	<LOQ (n.d.)	0.06	0.06	<LOQ (n.d.)	89		53	
									Straw	<LOQ (n.d.)	<LOQ (n.d.)	0.02	0.04	89		53	
BPL19/772/GC-02-PL 98-300 Masłowice, Wieluń Poland N-EU 2019	Spring barley (HORVS)/ Paustian	1. 22/03/19 2. 09 - 15/06/19 3. 02/08/19	prt: 0.169 fnp: 0.244	294	prt: 0.058 fnp: 0.083	11/06/19	BBCH 65	Grain	<LOQ	<u>0.09</u>	<u>0.06</u>	<LOQ	89	52	Max. sample storage time: for whole plant w/o roots (712 days for 1,2,4-T, 751 days for TA, 712 days for		
								Straw	<LOQ (n.d.)	<LOQ	<u>0.02</u>	<u>0.02</u>	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	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-T	TA	TAA	TLA	Timing (BBCH)	DALA (days)	
(a)	(b)	(b)	(c)			(d)	(e)	(a)						(f)	(g)
			Untreated					Grain	<LOQ (n.d.)	0.02	0.02	<LOQ (n.d.)	89	52	TAA and TLA; for grain (699 days for TA and 664 days for 1,2,4-T, TAA and TLA); for straw (660 days for all metabolites) (sampling to extraction), max. extract storage time (extraction to analysis) 6 days for 1,2,4-T, 3 days for TAA and TLA and 1 day for TA. 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	<LOQ	0.01	<LOQ	89	52	
BPL19/772/GC-03-HU 2141 Csömör Hungary N-EU 2018/19	Winter barley (HORVW)/ Monique	1. 28/09/18 2. 07/05/ - 20/05/19 3. 27/06/ - 03/07/19	prt: 0.170 fnp: 0.246	247	prt: 0.069 fnp: 0.100	11/05/19	BBCH 65	Whole plant w/o roots	<LOQ	0.01	<LOQ	0.02	65	0	
								Whole plant w/o roots	<LOQ	0.08	0.01	0.02	71	11	
								Whole plant w/o roots	<LOQ	0.08	0.01	0.02	75	20	
								Whole plant w/o roots	<LOQ (n.d.)						
								Whole plant w/o roots	<LOQ (n.d.)	0.11	0.04	0.03	85	37	
								Grain	<LOQ (n.d.)	<u>0.11</u>	<u>0.02</u>	<u><LOQ</u>	89	52	
								Straw	<LOQ (n.d.)	<u>0.02</u>	<u>0.04</u>	<u>0.05</u>	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	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-T	TA	TAA	TLA	Timing (BBCH)	DALA (days)					
(a)	(a)	(b)	(c)			(d)	(e)	(a)						(f)	(g)				
			Untreated					Whole plant w/o roots	<LOQ	0.01	<LOQ	0.02	65	0					
								Whole plant w/o roots	<LOQ (n.d.)	0.02	<LOQ	<LOQ	75	20					
								Grain	<LOQ (n.d.)	0.03	<LOQ	<LOQ (n.d.)	89	52					
								Straw	<LOQ (n.d.)	<LOQ	<LOQ	<LOQ	89	52					
BPL19/772/GC- 04-FR 49320 Vauchrétien France N-EU 2018/19	Winter barley (HORVW)/Etincel	1. 15/11/18 2. 06/05/ - 15/05/19 3. 03/07/19	prt: 0.174 fnp: 0.250	250	prt: 0.069 fnp: 0.100	13/05/19	BBCH 69	Whole plant w/o roots	<LOQ	0.02	<LOQ	0.02	69	0					
								Whole plant w/o roots	<LOQ	0.03	<LOQ	0.02	71	10					
								Whole plant w/o roots	<LOQ (n.d.)	0.05	0.01	0.02	77	22					
								Whole plant w/o roots	<LOQ (n.d.)	0.08	0.02	<LOQ	85	35					
								Grain	<LOQ (n.d.)	0.13	0.05	<LOQ	89	50					
								Straw	<LOQ (n.d.)	<LOQ	0.03	0.03	89	50					
			Untreated					Whole plant w/o roots	<LOQ	0.02	<LOQ	0.02	69	0					
								Whole plant w/o roots	<LOQ	0.02	<LOQ	0.01	77	22					
								Grain	<LOQ (n.d.)	0.07	0.03	<LOQ	89	50					
								Straw	<LOQ (n.d.)	<LOQ (n.d.)	0.01	0.02	89	50					

(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

prt Prothioconazole

fnp Fenpropidin

n.d. Not detectable

LOQ Limit of quantification

LOD Limit of detection

Data in *italics* reported but outside acceptable storage stability and therefore have not been used.

A 2.1.3.2.2 Barley study 2

Comments of zRMS:	<p>The study of Huauhmé, J.-M., 2021 (Report no.: BPL20/844/GC) on determination of residue of prothioconazole and their metabolites in barley whole plant and RAC (grain and straw) after one foliar application of ADM.3502.F.1.A has been evaluated in Registration Report for ADM.03500.F.2.B (Soratel) on November 2022 by zRMS-PL and the summary is presented below.</p> <p>The residue data for fenpropidin is evaluated in this document and a summary is also provided below.</p> <p>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.</p> <p>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.</p> <p>Specimens of grain and straw were generated at harvest stage BBCH 89 from all the field trials performed.</p> <p><u>Prothioconazole</u></p> <p>In the barley specimens, the residue level of prothioconazole (expressed as sum of prothioconazole-desthio) ranged from:</p> <ul style="list-style-type: none"> - 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. <p>Analytical method: Study code: S13-05182, QuEChERS method, LC-MS/MS</p> <p>The analytical method was validated for barley whole plant without roots, grain and straw according to guideline SANCO/3029/99 rev. 4 (reduced validation).</p> <p>LOQ: 0.01 mg/kg for each analyte, 0.06 mg/kg for prothioconazole expressed as prothioconazole-desthio as a sum of metabolites.</p> <p>The mean recovery was between 70% and 110% at each level of fortification, for each reference item and for each matrix.</p> <p>The storage duration (interval between sampling and extraction date) was 70 days for the determination of prothioconazole and its metabolites.</p> <p>Sufficient stability data are available to support the residue data presented in this study.</p> <p><u>Fenpropidin</u></p> <p>In the barley whole plant specimens, the residue level of fenpropidin ranged from 0.081 and 3.5 mg/kg.</p> <p>In the barley grain specimens, the residue level of fenpropidin ranged from 0.012 and 0.029 mg/kg.</p> <p>In the barley straw specimens, the residue level of Fenpropidin ranged from 0.091 and 0.37 mg/kg.</p> <p>The analytical method was previously fully validated in barley (whole plants without roots, grain, straw), in compliance with Guideline SANCO/3029/99 rev.4 of 11/07/2000 during another study or analytical phase performed at GIRPA in 2019-2020 (study code: B19S-A4-P-01 and analytical phase code: B19G-B5-FP-03).</p> <p>The analytical method was validated for barley whole plant without roots, grain and straw according to guideline SANCO/3029/99 rev. 4 (reduced validation).</p> <p>LOQ: 0.01 mg/kg.</p> <p>The mean recovery was between 70% and 110% at each level of fortification, for each matrix.</p> <p>The storage duration (interval between sampling and extraction date) was 147 days for the determination of prothioconazole and its metabolites.</p> <p>Sufficient stability data are available to support the residue data presented in this study.</p> <p>The study is acceptable.</p>
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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 - 2 harvest and 2 decline trials – Northern Europe (FR, PL, HU) - 2020
Huaulmé, J.-M., 2021
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:	<p>The study of Yozgatli, H.P., 2021 (Study no.: S20-01302) on determination of 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 in Northern Europe has been evaluated in Registration Report for ADM.03500.F.2.B (Soratel) on November 2022 by zRMS-PL and the summary is presented below.</p> <p>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).</p> <p>The application had to be performed at crop growth stage BBCH 65.</p> <p>Grain and straw specimens were taken at BBCH growth stage 89, normal commercial harvest (NCH).</p> <p>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.</p> <p><u>Results:</u></p> <p>Residues of 1,2,4-T and TLA in grain were <LOQ.</p> <p>Residues of TA in grain were between 0.05 and 0.15 mg/kg.</p> <p>Residues of TAA in grain were between 0.02 and 0.04 mg/kg.</p> <p>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.</p> <p>With regard to selectivity, accuracy and precision, the analytical method was applied successfully for each analytical set when analysing the samples of the study.</p> <p>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.</p> <p>The study is acceptable.</p>
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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., 2021
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

and

Comments of zRMS:	<p>The study of Barbier, G., 2022 (Study no.: B21G-A4-P-05) on determination of residue of prothioconazole and its metabolites in barley after application of ADM.3502.F.1.A has been evaluated in Registration Report for ADM.03500.F.2.B (Soratel) on November 2022 by zRMS-PL and the summary is presented below.</p> <p>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 6.3.2/03).</p> <p>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.</p> <p>In the barley specimens, the residue level of prothioconazole (expressed as sum of prothioconazoledesthio) ranged from:</p> <ul style="list-style-type: none"> - <LOQ in grain, - 0.14 and 1.3 mg/kg in straw. <p>In the barley specimens, the residue level of prothioconazole-desthio ranged from:</p> <ul style="list-style-type: none"> - <LOQ and 0.026 mg/kg in grain, - 0.056 and 0.91 mg/kg in straw. <p>The storage duration (interval between sampling and extraction date) was 504 days for the determination of prothioconazole and its metabolites.</p> <p>Sufficient stability data are available to support the residue data presented in this study.</p> <p>The study is acceptable.</p>
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Reference: KCA 6.3.2/06
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

This analytical report (study KCA 6.3.2/06) comprises a second analysis of prothioconazole and its metabolites (except TDMs) including a deconjugation step to account for potential conjugated metabolites.

Table A 15: Summary of the barley study 2 (Fenpropidin)

Crop residue data from supervised field trials

Active ingredient (common name and content): Fenpropidin, nominal 250 g/L (actual 253.7 g/L)
Prothioconazole, nominal 175 g/L (actual 175.9 g/L)
Crop/crop group: Barley / Cereals
Country: France, Poland, Hungary

Indoor/outdoor: Outdoor
Responsible body for reporting (name, address): BIOTEK Agriculture, Saint-Pouange, France

Reference no.:

Commercial product (name/code): KCA 6.3.2/03
ADM.3502.F.1.A

Formulation (e.g. SC):

EC

Other active substance in the formulation:

none

Residues calculated as:

**Fenpropidin (mg/kg);
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) (8.3, enforcement residue definition)**

1	2	3	4			5	6	7	8.1	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				Fenpropidin	Timing (BBCH)	DALA (days)	
(a)	(b)	(c)	(c)			(d)						(e)
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	fpn: 0.251 prt: 0.174	199	fpn: 0.126 prt: 0.087	25/06/20	BBCH 65	Grain Straw	<u>0.024</u> <u>0.037</u>	89 89	29 29	Analytical methods: Study code: S13-05182, QuEChERS method, 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 metabolites; LOD: 0.003 mg/kg for each analyte, 0.018 mg/kg for prothioconazole expressed
BPL20/844/GC-02-PL 98-300 Masłowice, Wieluń Poland N-EU 2020	Spring barley (HORVS)/ KWS Dante	1. 30/03/20 2. 08/-18/06/20 3. 10/08/20	fpn: 0.245 prt: 0.170	290	fpn: 0.085 prt: 0.059	13/06/20	BBCH 65	Grain Straw	<u>0.014</u> <u>0.091</u>	89 89	58 58	

1	2	3	4			5	6	7	8.1	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				Fenpro- pidin	Timing (BBCH)	DALA (days)	
(a)	(a)	(b)	(c)			(d)						(e)
BPL20/844/GC-02-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	fpn: 0.252 prt: 0.175	248	fpn: 0.101 prt: 0.070	13/05/20	BBCH 65	Whole plant w/o roots	3.5	65	0	as prothioconazole-desthio as a sum of metabolites Max. sample storage time: 70 days (sampling to extraction), max. extract storage time (extraction to analysis) 2 days. Extract stability tested during the study.
								Whole plant w/o roots	0.53	71	9	
								Whole plant w/o roots	0.28	75	20	
								Whole plant w/o roots	0.081	83	35	
								Grain	<u>0.029</u>	89	50	
								Straw	<u>0.15</u>	89	50	
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	fpn: 0.258 prt: 0.179	305	fpn: 0.085 prt: 0.059	10/06/20	BBCH 65	Whole plant w/o roots	3.0	65	0	Results in all untreated specimens were below LOD. *Mean of two extractions with value at 0.060 mg/kg for results < LOQ. **Mean of two extractions.
								Whole plant w/o roots	0.81	69	9	
								Whole plant w/o roots	0.46	71	20	
								Whole plant w/o roots	0.45	83	33	
								Grain	<u>0.012</u>	89	62	
								Straw	<u>0.18</u>	89	62	

(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) 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

Table A 16: Summary of the barley study 2 (including second analysis using another method to account for potential conjugated metabolites)

Crop residue data from supervised field trials

Active ingredient (common name and content): Prothioconazole, nominal 175 g/L (actual 175.9 g/L)
Crop/crop group: Barley / Cereals
Country: France, Poland, Hungary

Reference no.:

Commercial product (name/code): ADM.3502.F.1.A

Formulation (e.g. SC): EC

Other active substance in the formulation:

Residues calculated as:

KCA 6.3.2/03 & /06

ADM.3502.F.1.A

EC

Fenpropidin, nominal 250 g/L (actual 253.7 g/L)

Indoor/outdoor: Outdoor
Responsible body for reporting (name, address): BIOTEK Agriculture, Saint-Pouange, France

**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)**

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				Prothioconazole (sum) ²	3-OH	4-OH	5-OH	6-OH	α-OH	Prothioconazole-desthio	Timing (BBCH)	DALA (days)	
(a)	(a)	(b)	(c)			(d)			(g)						(h)		(e)	(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 and for study 6.3.2/06 method 00979/M001, LC-MS/MS.
								Straw	1.3	0.15	0.061	0.036	<LOQ	0.14	0.93** 0.91 Mean: 0.92	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 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 2020	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	<u><LOD</u>	<LOD	<LOD	<LOD	<LOD	<LOD	<LOQ (nd) <LOD Mean: <u><LOQ</u>	89	58	For method validation please refer to dRR Part B.5, point KCP 5.1.2.
								Straw	<u>0.14</u>	0.034	0.021	0.014	<LOD	<LOQ	0.041 0.056 Mean: <u>0.049</u>	89	58	LOQ: 0.01 mg/kg for each analyte, 0.06 mg/kg for prothioconazole

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 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)	(a)	(b)	(c)			(d)			(g)						(h)		(e)	(f)
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	expressed as prothioconazole- 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.
								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	Max. sample storage time: 70 days and 504 days for study KCA 6.3.2/06 (sampling to extraction), max. extract storage time (extraction to analysis) 2 days. Extract stability

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)	(a)	(b)	(c)			(d)			(g)						(h)		(e)	(f)
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	tested during the studies.
								Whole plant w/o roots	0.42						0.39	69	9	Results in all untreated specimens were below LOD.
								Whole plant w/o roots	0.11						0.076	71	20	**Mean of two extractions.
								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 6.3.2/06) including a deconjugation step to account for potential conjugated metabolites.

² Sum calculated during dossier compilation to include new results from study KCA 6.3.2/06 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 17: Summary of the barley study 2 (TDMs)

Crop residue data from supervised field trials

Active ingredient (common name and content): Prothioconazole, 175.9 g/L (actual)

Crop/crop group: Barley / Cereals

Country: France (N-EU), Poland, Hungary

Indoor/outdoor: Outdoor

Responsible body for reporting (name, address): Eurofins Agroscience Services Chem GmbH, Hamburg, Germany

Reference no.:

Commercial product (name/code):

KCA 6.3.2/04

ADM.03502.F.1.B

Formulation (e.g. SC):

EC

Other active substance in the formulation:

Fenpropidin, 253.7 g/L (actual)

Residues calculated as:

1,2,4-Triazole, Triazole alanine, Triazole acetic acid, Triazole lactic acid (mg/kg)

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 treatme nt 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-T	TA	TAA	TLA	Timing (BBCH)	DALA (days)				
	(a)	(b)	(c)			(d)	(e)	(a)						(f)	(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	prt: 0.174 fnp: 0.251	199	prt: 0.087 fnp: 0.126	25/06/20	BBCH 65	Grain	<u><LOQ</u> <u>(n.d.)</u>	0.13	0.04	<u><LOQ</u> <u>(n.d.)</u>	89	29	Analytical methods: Syngenta GRM053.01 A, 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			
								Straw	<u><LOQ</u>	<u>0.01</u>	0.02	<u>0.03</u>	89	29				
			Untreated					Grain	<u><LOQ</u> <u>(n.d.)</u>	<u>0.18</u>	<u>0.10</u>	<u><LOQ</u> <u>(n.d.)</u>	89	29				
								Straw	<u><LOQ</u> <u>(n.d.)</u>	<u><LOQ</u>	<u>0.03</u>	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	prt: 0.170 fnp: 0.245	290	prt: 0.059 fnp: 0.085	13/06/20	BBCH 65	Grain	<u><LOQ</u> <u>(n.d.)</u>	<u>0.15</u>	<u>0.04</u>	<u><LOQ</u> <u>(n.d.)</u>	89	58				
								Straw	<u><LOQ</u> <u>(n.d.)</u>	<u><LOQ</u>	<u><LOQ</u>	<u><LOQ</u>	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	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 treatme nt 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-T	TA	TAA	TLA	Timing (BBCH)	DALA (days)	
(a)	(b)	(b)	(c)			(d)	(e)	(a)						(f)	(g)
			Untreated					Grain	<LOQ (n.d.)	0.06	0.02	<LOQ (n.d.)	89	58	roots, 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.
								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	prt: 0.175 fnp: 0.252	248	prt: 0.070 fnp: 0.101	13/05/20	BBCH 65	Whole plant	<LOQ (n.d.)	0.02	0.01	<LOQ	65	0	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.
								w/o roots	<LOQ (n.d.)	0.02	0.01	<LOQ	71	9	
								Whole plant	<LOQ (n.d.)	0.02	<LOQ	<LOQ	73	20	
								w/o roots	<LOQ (n.d.)	0.02	0.01	<LOQ (n.d.)	83	35	
								Whole plant	<LOQ (n.d.)	0.02	0.01	<LOQ (n.d.)	89	50	
								Grain	<LOQ (n.d.)	0.05	0.02	<LOQ (n.d.)	89	50	
								Straw	<LOQ (n.d.)	0.02	0.02	0.03	89	50	
								Untreated					65	0	
								Whole plant	<LOQ (n.d.)	<LOQ	<LOQ (n.d.)	<LOQ (n.d.)	73	20	
								Whole plant	<LOQ (n.d.)	<LOQ	<LOQ	<LOQ (n.d.)	89	50	
								w/o roots	<LOQ (n.d.)	<LOQ	<LOQ	<LOQ (n.d.)	89	50	
								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 treatme nt 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-T	TA	TAA	TLA	Timing (BBCH)	DALA (days)	
(a)	(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	prt: 0.179 fnp: 0.258	305	prt: 0.059 fnp: 0.085	10/06/20	BBCH 65	Whole plant	<LOQ (n.d.)	0.01	<LOQ	0.02	65	0	
								Whole plant	<LOQ (n.d.)	0.02	<LOQ	0.01	69	9	
								Whole plant	<LOQ (n.d.)	0.04	0.02	0.02	71	20	
								Whole plant	<LOQ (n.d.)	0.04	0.03	0.04	83	33	
								Whole plant	<LOQ (n.d.)	0.12	0.04	<LOQ (n.d.)	89	62	
								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	<LOQ (n.d.)	<LOQ	<LOQ	0.01	65	0	
								Whole plant	<LOQ (n.d.)	0.01	0.02	0.01	71	20	
								Whole plant	<LOQ (n.d.)	0.05	0.04	<LOQ (n.d.)	89	62	
								Grain	<LOQ (n.d.)	<LOQ	<LOQ	<LOQ	89	62	
								Straw	<LOQ (n.d.)	<LOQ	<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

prt: 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:	<p>The study of Huauilmé, J.-M., 2022 (Report No.: BPL21/962/GC) on determination of residue of prothioconazole and their metabolites in barley Raw Agricultural Commodities after application of ADM.03503.F.1.A has been evaluated in Registration Report for ADM.03500.F.2.B (Soratel) on November 2022 by zRMS-PL and the summary is presented below.</p> <p>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).</p> <p>Application was performed at BBCH 65.</p> <p>Specimens of grain and straw were generated at harvest stage BBCH 89 from all the field trials performed.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>The mean recovery was between 70% and 110% at each level of fortification, for each reference item and for each matrix.</p> <p>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.</p> <p>Sufficient stability data are available to support the residue data presented in this study.</p> <p>In the treated barley specimens, the residue levels of prothioconazole-desthio and its metabolites ranged from:</p> <p>For prothioconazole-desthio:</p> <ul style="list-style-type: none"> - <LOQ (nd) and 0.061 mg/kg in grain, - 0.041 and 1.7 mg/kg in straw. <p>For 3-hydroxy-prothioconazole-desthio,</p> <ul style="list-style-type: none"> - LOQ (nd) and 0.014 in grain, - <LOQ and 0.25 mg/kg in straw. <p>For 4-hydroxy-prothioconazole-desthio:</p> <ul style="list-style-type: none"> - All results are <LOQ in grain, - <LOQ (nd) and 0.21 mg/kg in straw. <p>For 5-hydroxy-prothioconazole-desthio:</p> <ul style="list-style-type: none"> - All results are <LOQ in grain, - <LOQ (nd) and 0.089 mg/kg in straw. <p>For 6-hydroxy-prothioconazole-desthio:</p> <ul style="list-style-type: none"> - All results are <LOQ in grain, - <LOQ (nd) and 0.012 mg/kg in straw. <p>For Alpha-hydroxy-prothioconazole-desthio:</p> <ul style="list-style-type: none"> - All results are <LOQ in grain, - <LOQ and 0.17 mg/kg in straw. <p>For 1,2,4-Triazole, all results were <LOQ in grain and straw specimens,</p> <p>For Triazole alanine:</p> <ul style="list-style-type: none"> - 0.04 and 0.14 mg/kg in grain, - <LOQ (nd) and 0.02 mg/kg in straw, <p>For Triazole acetic acid:</p> <ul style="list-style-type: none"> - 0.02 and 0.13 mg/kg in grain,
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	<ul style="list-style-type: none"> - <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. <p>The study is acceptable.</p>
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Reference: KCA 6.3.2/05

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 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
- 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 (part to follow concerns only risk assessment)
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

Table A 18: Summary of the barley study 3

Crop residue data from supervised field trials

Active ingredient (common name and content): Prothioconazole, nominal 150 g/L (actual 148 g/L)
Crop/crop group: Barley / Cereals
Country: France (N-EU), Germany, Hungary, Poland
Indoor/outdoor: Outdoor
Responsible body for reporting (name, address): SynTech Research France, La Chapelle de Guinchay, France

Reference no.:

Commercial product (name/code):
Formulation (e.g. SC):
Other active substance in the formulation:
Residues calculated as:

KCA 6.3.2/05

ADM.03503. F.1.A
EC
Fluxapyroxad, nominal 75 g/L (actual 77.4 g/L)
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)

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				Prothioconazole (sum)	Prothioconazole-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) ¹	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	<LOQ 0.14	0.013 0.085*	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.
BPL21/962/GC-02-GE 74861 Kreßbach Germany N-EU 2020/21 (B) ¹	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	<LOQ 0.20	<LOQ 0.055	89 89	62 62	LOQ: 0.01 mg/kg for each analyte, 0.06 mg/kg for prothioconazole expressed as prothioconazole-

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)	(b)	(c)			(d)			(g)	(h)		(e)	(f)
BPL21/962/GC-03-HU 2340 Kiskunlacháza Hungary N-EU 2021 <u>(C)</u> ¹	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	<u>0.087</u> <u>2.2</u>	<u>0.054</u> <u>1.7</u>	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
BPL21/962/GC-04-PL 55 110 Krościna Mała, Poland N-EU 2021 <u>(D)</u> ¹	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	<u><LOQ</u> <u>1.0</u>	<u>0.010</u> <u>0.34</u>	89 89	43 43	Max. sample storage time: 115 days (sampling to extraction), max. extract storage time (extraction to analysis) 4 days.
BPL21/962/GC-05-GE 85368 Moosburg an der Isar Germany N-EU 2021 <u>(E)</u> ¹	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	<u><LOQ</u> <u>(n.d.)</u> <u>0.061</u>	<u><LOQ</u> <u>(n.d.)</u> <u>0.041*</u>	89 89	44 44	Extract stability proven within the study.
BPL21/962/GC-06-HU 5126 Jászfényszaru Hungary N-EU 2021 <u>(F)</u> ¹	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	<u>0.095</u> <u>0.93</u>	<u>0.061</u> <u>0.49</u>	89 89	29 29	Results in all untreated specimens were below LOD.

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 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 19: Summary of the barley study 3 (TDMs)

Crop residue data from supervised field trials

Active ingredient (common name and content): Prothioconazole, 148 g/L (actual)
Crop/crop group: Barley / Cereals
Country: France (N-EU), Germany, Hungary, Poland
Indoor/outdoor: Outdoor
Responsible body for reporting (name, address): SynTech Research France, La Chapelle de Guinchay, France

Reference no.:

Commercial product (name/code):

Formulation (e.g. SC):

Other active substance in the formulation:

Residues calculated as:

KCA 6.3.2/05

ADM.03503. F.1.A

EC

Fluxapyroxad, nominal 75 g/L (actual 77.4 g/L)

1,2,4-Triazole, Triazole alanine, Triazole acetic acid, Triazole lactic acid (mg/kg)

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-T	TA	TAA	TLA	Timing (BBCH)	DALA (days)	
	(a)	(b)	(c)			(d)	(e)	(a)						(f)	(g)
BPL21/962/GC-01-FR 10600 La Chapelle Saint-Luc France N-EU 2021 (A) ¹	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	
								Straw	<LOQ	<LOQ (n.d.)	<LOQ (n.d.)	<LOQ (n.d.)	89	39	
BPL21/962/GC-02-GE 74861 Kreßbach Germany N-EU 2020/21 (B) ¹	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	LOQ: 0.01 mg/kg with LOD: 0.003 mg/kg (for each analyte and each matrix) Max. sample storage time: 114 days (sampling to extraction), max. extract storage time (extraction to
								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-T	TA	TAA	TLA	Timing (BBCH)	DALA (days)	
(a)	(b)	(b)	(c)			(d)	(e)	(a)						(f)	(g)
			Untreated					Grain	<LOQ (n.d.)	0.04	0.05	<LOQ (n.d.)	89	62	analysis) 1 day for grain and 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	0.01	<LOQ	89	62	
BPL21/962/GC-03-HU 2340 Kiskunlacháza Hungary N-EU 2021 (C) ¹	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) ¹	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) ¹	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	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-T	TA	TAA	TLA	Timing (BBCH)	DALA (days)	
(a)	(b)	(b)	(c)			(d)	(e)	(a)						(f)	(g)
BPL21/962/GC-06-HU 5126 Jászfényszaru Hungary N-EU 2021 <u>(F)</u> ¹	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	

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 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 2.1.3.2.4 Barley study 4

Comments of zRMS:	<p>The study of Huauilmé, J.-M., 2022 (Report No.: BPL21/962/GC) on determination of residue of prothioconazole and their metabolites in barley Raw Agricultural Commodities after application of ADM.03501.F.1.A has been evaluated in Registration Report for ADM.03500.F.2.B (Soral) on November 2022 by zRMS-PL and the summary is presented below.</p> <p>Eight field trials were conducted in Northern Europe to determine the residue level of prothioconazole and its metabolites, and of difenoconazole in specimens of barley 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).</p> <p>Application was performed at BBCH 59 or 61.</p> <p>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.</p> <p>Specimens of grain and straw were generated at harvest stage BBCH 89 from all the field trials performed.</p> <p>Results:</p> <p>For prothioconazole-desthio:</p> <ul style="list-style-type: none"> - 0.049 and 0.69 mg/kg in whole plant, - <LOQ (nd) and 0.027 mg/kg in grain, - 0.015 and 1.1 mg/kg in straw. <p>For prothioconazole (sum): <LOQ.</p> <p>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 on barley (whole plant, grain and straw), following the guideline SANTE/2020/12830, Rev.1 of 24/02/2021.</p> <p>All the analytes were determined by LC-MS/MS using a quantitation and confirmation ion.</p> <p>LOQ: 0.01 mg/kg for each analyte,</p> <p>LOQ: 0.06 mg/kg for prothioconazole expressed as prothioconazole-desthio as a sum of metabolites.</p> <p>The mean recoveries at each fortification level comply with the standard acceptance criteria of the guidance document SANTE/2020/12830, rev. 1.</p> <p>The storage duration (interval between sampling and extraction date) was 166 days for the determination of prothioconazole and its metabolites.</p> <p>Sufficient stability data are available to support the residue data presented in this study.</p> <p>Remark:</p> <p>Only residues of prothioconazole expressed as prothioconazole-desthio are reported in the following summary without data of TDMs.</p> <p>The study is acceptable.</p>
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Reference:

KCA 6.3.2/07

Report:

Residue study of prothioconazole, difenoconazole and their metabolites in barley Raw Agricultural Commodities after foliar application of ADM.03501.F.1.A under field conditions – Northern Europe – 2021.

Huauilmé, J.-M., 2022,

Report no.: BPL21/960/GC, sponsor no.: 000107614

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/REV1 07-Sep-2016 Crop Field Trials, - Series on Testing & Assessment - No. 164

SANTE/2020/12830, Rev.1 of 24/02/21

ENV/JM/MONO(2007)17 OECD Series on Testing and Assessment, Number 72

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). Therefore, only residues of prothioconazole expressed as prothioconazole-desthio are reported in the following summary. As six of the trials are not independent due to same year and location as trials in study KCA 6.3.2/05, only two of the trials were included in the risk assessments.

Table A 20: Summary of the barley study 4

Crop residue data from supervised field trials

Active ingredient (common name and content): Prothioconazole, nominal 175 g/L (actual 172.8 g/L)
Crop/crop group: Barley / Cereals
Country: France (N-EU), Germany, Hungary, Poland
Indoor/outdoor: Outdoor
Responsible body for reporting (name, address): SynTech Research France, La Chapelle de Guinchay, France

Reference no.:

Commercial product (name/code):

Formulation (e.g. SC):

Other active substance in the formulation:

Residues calculated as:

KCA 6.3.2/07

ADM.03501. F.1.A

EC

Difenoconazole, nominal 125 g/L (actual 125 g/L)

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)

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				Prothioconazole (sum)	Prothioconazole-desthio	Timing (BBCH)	DALA (days)	
(a)	(b)	(c)	(c)		(d)	(d)			(g)	(h)		(e)	(f)
BPL21/960/GC-01-FR 10600 La Chapelle Saint-Luc France N-EU 2021 <u>(A)</u> ¹	Spring barley (HORVS) / Planet	1/ 27/03/21 2/ 16 - 25/06/21 3/ 30/07/21	0.173	300	0.058	14/06/21	BBCH 69	Grain Straw	<LOQ (n.d.) 0.17	<LOQ (n.d.) 0.083	89 89	46 46	Analytical methods: RAR method 00979/M001, LC-MS/MS For method validation please refer to dRR Part B.5, point KCP 5.1.2.
BPL21/960/GC-02-GE 74861 Krefßbach Germany N-EU 2020/21 <u>(B)</u> ¹	Winter barley (HORVW) / Su Vireni	1/ 22/10/20 2/ 23 - 31/05/21 3/ 29 - 30/07/21	0.165	334	0.049	22/05/21	BBCH 59	Grain Straw	<LOQ (n.d.) <LOQ	<LOQ 0.015	89 89	68 68	

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)	(b)	(c)			(d)			(g)	(h)		(e)	(f)
BPL21/960/GC-03-HU 2340 Kiskunlacháza Hungary N-EU 2021 <u>(C)</u> ¹	Spring barley (HORVS) / Conchita	1/ 16/03/21 2/ 11 - 17/06/21 3/ 12 - 15/07/21	0.172	298	0.058	08/06/21	BBCH 59	Grain Straw	<LOQ 1.6	0.027 1.1	89 89	35 35	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
BPL21/960/GC-04-PL 98 300 Masłowice Poland N-EU 2021	Spring barley (HORVS) / KWS Dante	1/ 04/03/20 2/ 14 - 22/06/21 3/ 20 - 25/07/21	0.177	308	0.058	14/06/21	BBCH 59/61	Grain Straw	<LOQ <u>0.53</u>	<LOQ <u>0.21</u>	89 89	36 36	Max. sample storage time: 185 days (sampling to extraction), max. extract storage time (extraction to analysis) 2 days.
BPL21/960/GC-05-FR 71570 La Chapelle de Guinchay France N-EU 2020/21	Winter barley (HORVW) / Amistar	1/ 20/10/20 2/ 07 - 21/05/21 3/ 15 - 30/07/21	0.174	203	0.086	07/05/21	BBCH 59/61	whole plant w/o roots whole plant w/o roots whole plant w/o roots whole plant w/o roots Grain Straw	0.69 0.39 0.23 0.18 <LOQ (n.d.) <u>0.11</u>	0.69 0.31 0.11* 0.049 <LOQ <u>0.052</u>	59/61 65 – 69 71 85 89 89	+0 11 20 38 83 83	Results in all untreated specimens were below LOD.

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)	(b)	(c)			(d)			(g)	(h)		(e)	(f)
BPL21/960/GC-06-PL Krościna Mała, 55-110 Poland N-EU 2021 <u>(D)</u> ¹	Spring barley (HORVS) / KWS Harris	1/ 08/03/21 2/ 15 - 23/06/21 3/ 31/07/21	0.169	294	0.058	15/06/21	BBCH 59/61	whole plant w/o roots	0.62	0.62	59/61	+0	
								whole plant w/o roots	0.50	0.36	69 – 71	10	
								whole plant w/o roots	0.96	0.54	75 – 77	20	
								whole plant w/o roots	0.52	0.18	83 – 85	36	
								Grain	<LOQ	0.014	89	46	
								Straw	0.77	0.27	89	46	
BPL21/960/GC-07-GE 85368 Moosburg an der Isar Germany N-EU 2021 <u>(E)</u> ¹	Spring barley (HORVS) / Marthe	1/ 23/04/21 2/ 08 - 15/07/21 3/ 25/08/21	0.166	337	0.049	15/06/21	BBCH 59	Grain	<LOQ (n.d.)	<LOQ	89	51	
								Straw	0.11	0.070	89	51	
BPL21/960/GC-08-HU 5126 Jászfényszaru Hungary N-EU 2021 <u>(F)</u> ¹	Spring barley (HORVS) / Conchita	1/ 29/03/21 2/ 19 - 23/06/21 3/ 16 - 22/07/21	0.175	304	0.058	16/06/21	BBCH 59	Grain	<LOQ	<LOQ	89	34	
								Straw	0.48	0.13*	89	34	

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) 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

A 2.1.4 Magnitude of residues in livestock

A 2.1.4.1 Livestock feeding studies

No new study submitted.

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

A 2.1.5.1 Distribution of the residue in peel/pulp

No new study submitted.

A 2.1.5.2 Processing studies on a core set of representative processes

No new study submitted.

A 2.1.6 Magnitude of residues in representative succeeding crops

A 2.1.6.1 Magnitude of residues in representative succeeding crops 1

Comments of zRMS:	<p>The study of Semrau, J., 2021 (Study no.: S18-02513) on determination of residue of prothioconazole and its metabolites after one application of MCW-2073 on bare soil in rotational crops in Northern and Southern Europe has been evaluated in Registration Report for ADM.03500.F.2.B (Soratel) on November 2022 by zRMS-PL and the summary is presented below.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p><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</p>
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	<p>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.</p> <p><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)</p> <p>The study is acceptable.</p>
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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.: R-39638
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 (2011) 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.

Residues of prothioconazole except TDMs

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 21: 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	0(-1) DBP	2	28	-008A	8	soil	0.016
		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 22: Residues of prothioconazole (except TDMs) in plant matrices

[illegible]

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.

[illegible]

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 23: 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)										
S5		U1	--	-011A	11	radish leaves	< 0.003 n.d.	0.05	< 0.003 n.d.	0.01

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)
	BBCH 49 (NCH)	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
		3	125	-015A	15	radish leaves	< 0.01	0.14	< 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	-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.
		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.

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)
		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 split 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 trial 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 (1.7N) and proposed application to cereals would be BBCH 59-65 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.

TDMs:

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 24: 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, R-39638		
GLP:	Yes	Sample storage conditions:	below -18 °C
Preceding 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

Active ingredient (common name and content): Prothioconazole, nominal 150 g/L (actual 145.0 g/L)
Crop/crop group: Radish / root vegetables, Leaf lettuce / leaf vegetables, Barley / cereals
Country: Poland, France (S-EU), Italy
Indoor/outdoor: Outdoor
Responsible body for reporting (name, address): ADAMA Makhteshim Ltd, Beer Sheva, Israel

Reference no.:

Commercial product (name/code):

Formulation (e.g. SC):

Other active substance in the formulation:

Residues calculated as:

KCA 6.6.2/01

MCW-2073

SC

Azoxystrobin, nominal 200 g/L (actual 201.6 g/L)

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)

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	6 Growth stage at last treatment or date BBCH	7 Portion analysed	8.1 Residues (mg/kg)		8.2 Residues (mg/kg)		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	6 Growth stage at last treatment or date BBCH	7 Portion analysed	8.1 Residues (mg/kg)		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	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	6 Growth stage at last treatment or date BBCH	7 Portion analysed	8.1 Residues (mg/kg)		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)
S18-02513-02 88-400 Podgórzyn, Kujawskopomor skie 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	

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	6 Growth stage at last treatment or date 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)
	Leaf lettuce (LACSP) / Fynly	1-25/04/19 2- n.a 3-06/06/19	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	
			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 (n.d.)	<LOQ (n.d.)	89	222	
			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 (n.d.)	<LOQ (n.d.)	89	376	

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	6 Growth stage at last treatment or date BBCH	7 Portion analysed	8.1 Residues (mg/kg)		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)	(a)	(b)	(c)			(d)	(e)		(g)	(h)		(i)	(f)
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	6 Growth stage at last treatment or date BBCH	7 Portion analysed	8.1 Residues (mg/kg)		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	6 Growth stage at last treatment or date BBCH	7 Portion analysed	8.1 Residues (mg/kg)		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)
S18-02513-04 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	<LOQ (n.d.)	<LOQ (n.d.)	49	114	
								Roots	<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.)	49	204	
								Roots	<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 (n.d.)	49	356	
								Roots	<LOQ (n.d.)	<LOQ (n.d.)	49	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	

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	6 Growth stage at last treatment or date BBCH	7 Portion analysed	8.1 Residues (mg/kg)		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)	(b)	(c)			(d)	(e)		(g)	(h)		(i)	(f)
			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	<LOQ (n.d.)	<LOQ (n.d.)	75	161	
								Grain	<LOQ (n.d.)	<LOQ (n.d.)	89	170	
								Straw	<LOQ (n.d.)	<LOQ (n.d.)	89	170	
			0.1	287	0.287	16/10/18 (PBI 120±5)	Bare soil	Whole plant	<LOQ (n.d.)	<LOQ (n.d.)	75	251	
								Grain	<LOQ (n.d.)	<LOQ (n.d.)	89	260	
								Straw	<LOQ (n.d.)	<LOQ (n.d.)	89	260	
			0.1	290	0.145	15/05/18 (PBI 270±10)	Bare soil	Whole plant	<LOQ (n.d.)	<LOQ (n.d.)	75	405	
								Grain	<LOQ (n.d.)	<LOQ (n.d.)	89	414	
								Straw	<LOQ (n.d.)	<LOQ (n.d.)	89	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 25: 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	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 BBCH	Portion analyzed	Residues (mg/kg)				Timing (BBCH)	PHI (days)	Remarks		
			g a.s./ hL	Water (l/ha)	kg a.s./ha				1,2,4-T	TA	TAA	TLA					
	(a)	(b)	(c)			(d)	(e)							(f)	(g)		
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)		
								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		-	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.
									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	Residues in untreated samples (background levels) were found in a part of samples, and		
								0.1	309	0.309	28/12/18 (PBI 120±5)	Bare soil	Leaves	<LOQ (n.d.)		<LOQ	<LOQ (n.d.)
			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.)

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 Grain Straw	<LOQ (n.d.)	0.04	0.04	0.06	75	100	results are given.	
									<LOQ (n.d.)	0.17	0.10	<LOQ (n.d.)	89	139		
									<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 Grain Straw	<LOQ (n.d.)	0.04	0.03	0.07	75	189		
									<LOQ (n.d.)	0.18	0.10	<LOQ	89	228		
									<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 Grain Straw	<LOQ	0.04	0.04	0.08	75	344		
									<LOQ (n.d.)	0.15	0.09	<LOQ	89	383		
									<LOQ (n.d.)	0.03	0.04	0.05	89	383		
			Untreated						Whole plant Grain Straw	<LOQ (n.d.)	0.01	<LOQ	<LOQ	75		-
			<LOQ (n.d.)	0.13	0.02	<LOQ (n.d.)	89	-								
			<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			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			
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 (n.d.)	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 (n.d.)	<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	
	Leaf lettuce (LACSP) / Fynly	1-24/04/19 2- n.a 3-07/06/19	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	-	
			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 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	Water (l/ha)	kg a.s./ha				1,2,4-T	TA	TAA	TLA			
			(c)												
			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	<LOQ (n.d.)	0.10	0.15	0.17	75	110	
								Grain	<LOQ (n.d.)	0.28	0.33	0.01	89	130	
								Straw	<LOQ (n.d.)	0.03	0.22	0.28	89	130	
			0.1	292	0.292	20/12/18 (PBI 120±5)	Bare soil	Whole plant	<LOQ (n.d.)	0.05	0.08	0.10	75	201	
								Grain	<LOQ (n.d.)	0.21	0.28	0.01	89	221	
								Straw	<LOQ (n.d.)	0.01	0.14	0.21	89	221	
			0.1	312	0.312	01/08/18 (PBI 270±10)	Bare soil	Whole plant	<LOQ (n.d.)	0.11	0.15	0.16	75	342	
								Grain	<LOQ (n.d.)	0.28	0.32	0.02	89	362	
								Straw	<LOQ (n.d.)	0.02	0.17	0.27	89	362	

Table continued

1	2	3	4			5	6	7	8				9	10	11	
Trial No./ Location/ 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 BBCH	Portion analyzed	Residues (mg/kg)				Timing (BBCH)	PHI (days)	Remarks	
			g a.s./ hL	Water (l/ha)	kg a.s./ha				1,2,4-T	TA	TAA	TLA				
																(c)
(a)	(b)					(d)	(e)						(f)	(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		

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	Water (l/ha)	kg a.s./ha				1,2,4-T	TA	TAA	TLA			
			(c)												
			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 (n.d.)	<LOQ	<LOQ (n.d.)	<LOQ (n.d.)	49	-	
								Roots	<LOQ (n.d.)	<LOQ (n.d.)	<LOQ (n.d.)	<LOQ (n.d.)	49	-	
			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	
			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	

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	Water (l/ha)	kg a.s./ha				1,2,4-T	TA	TAA	TLA			
			(c)												
			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 (n.d.)	<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 2.1.6.2 Magnitude of residues in representative succeeding crops 2

Comments of zRMS:	<p>The study of Semrau, J., 2022 (Study no.: S21-00408) on determination of residue of prothioconazole metabolites after one application of Prothioconazole 250 EC (ADM.03500.F.2.B) on bare soil in Northern and Southern Europe has been evaluated in Registration Report for ADM.03500.F.2.B (Soratel) on November 2022 by zRMS-PL and the summary is presented below.</p> <p>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.</p> <p>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.</p> <p>Methods were validated according to SANCO/3029/99, rev. 4 and SANTE/2020/12830, Rev.1 of 24/02/2021.</p> <p>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.</p> <p>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.</p> <p>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-</p>
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	<p>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.</p> <p><u>TDMs</u></p> <p>Residues of 1,2,4-triazole were below the LOQ of 0.01 mg/kg in all crops.</p> <p>Residues of triazole acetic acid (TAA) were found above the LOQ of 0.01 mg/kg solely in cereals.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>The study is acceptable.</p>
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Reference:	KCA 6.6.2/02
Report:	<p>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</p> <p>Semrau, J., 2022</p>
Guideline(s):	<p>Study no.: S21-00408, sponsor no.: 000107470</p> <p>OECD (2009) Guidance Document on Overview of Residue Chemistry Studies (Series on Testing and Assessment No. 64 and Series on Pesticides No. 32);</p> <p>OECD Test Guideline 509: Crop field trials;</p> <p>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);</p> <p>EC (1997) Guidance Document 7029/VI/95 rev. 5 general recommendations for the design, preparation and realization of residue trials;</p> <p>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)</p> <p>OECD Test Guideline 504: Residues in rotational crops (limited field studies);</p> <p>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);</p>
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 locations:	Trial S21-00408-02 (PBI 30d): 23.03.2021
	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 Agrosience 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 (1.7N) and proposed application to cereals would be BBCH 59-65 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 26: 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 27: TDM residues in rotational crops

Samplin g Code	Target Timing	Treatme nt	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

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 28: 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)	Eurofins Agroscience Services GmbH, Stade, Germany		
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 Burgweg, 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**
Crop/crop group: **Radish / root vegetables**
Responsible body for reporting (name, address): Eurofins Agroscience Services GmbH, Stade, Germany
Country (of trial sites): Germany
Content of active substance nominal (g/kg or g/L): 250 g/L

Commercial Product (name): Prothioconazole 250 EC
Producer of commercial product: ADAMA Makhteshim Ltd.

Indoor/Glasshouse/Outdoor: outdoor
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- hydrox y desthio	PTZ-4- hydrox y desthio	PTZ-5- hydrox y desthio	PTZ-6- hydrox y desthio	PTZ- alpha- hydrox y desthio		
S21-00408-01: 21709 Burgweg, 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**
Crop/crop group: **Leaf lettuce / leaf vegetables**
Responsible body for reporting (name, address): Eurofins Agroscience Services GmbH, Stade, Germany
Country (of trial sites): Germany
Content of active substance nominal (g/kg or g/L): 250 g/L

Commercial Product (name): Prothioconazole 250 EC
Producer of commercial product: ADAMA Makhteshim Ltd.

Indoor/Glasshouse/Outdoor: outdoor
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- hydrox y desthio	PTZ-4- hydrox y desthio	PTZ-5- hydrox y desthio	PTZ-6- hydrox y desthio	PTZ- alpha- hydrox y desthio		
S21-00408-01: 21709 Burgweg, 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**
Crop/crop group: **Barley / cereals**
Responsible body for reporting (name, address): Eurofins Agroscience Services GmbH, Stade, Germany
Country (of trial sites): Germany
Content of active substance nominal (g/kg or g/L): 250 g/L

Commercial Product (name): Prothioconazole 250 EC
Producer of commercial product: ADAMA Makhteshim Ltd.

Indoor/Glasshouse/Outdoor: outdoor
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- hydrox y desthio	PTZ-4- hydrox y desthio	PTZ-5- hydrox y desthio	PTZ-6- hydrox y desthio	PTZ- alpha- hydrox y desthio		
S21-00408-01: 21709 Burgweg, 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**
Crop/crop group: **Radish / root vegetables**
Responsible body for reporting (name, address): Eurofins Agrosience Services GmbH, Stade, Germany
Country (of trial sites): Germany
Content of active substance nominal (g/kg or g/L): 250 g/L

Commercial Product (name): Prothioconazole 250 EC
Producer of commercial product: ADAMA Makhteshim Ltd.

Indoor/Glasshouse/Outdoor: outdoor
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 Commodit y/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 Burgweg, 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**
Crop/crop group: **Leaf lettuce / leaf vegetables**
Responsible body for reporting (name, address): Eurofins Agrosience Services GmbH, Stade, Germany
Country (of trial sites): Germany
Content of active substance nominal (g/kg or g/L): 250 g/L

Commercial Product (name): Prothioconazole 250 EC
Producer of commercial product: ADAMA Makhteshim Ltd.

Indoor/Glasshouse/Outdoor: outdoor
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 Commodit y/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 Interva (g)
				kg as/hL	Water (L/ha)	kg as/ha				1,2,4-T	TA	TAA	TLA		
S21-00408-01: 21709 Burgweg, 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**
Crop/crop group: **Barley / cereals**
Responsible body for reporting (name, address): Eurofins Agrosience Services GmbH, Stade, Germany
Country (of trial sites): Germany
Content of active substance nominal (g/kg or g/L): 250 g/L

Commercial Product (name): Prothioconazole 250 EC
Producer of commercial product: ADAMA Makhteshim Ltd.

Indoor/Glasshouse/Outdoor: outdoor
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 Burgweg, 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**
 Crop/crop group: **Soil**
 Responsible body for reporting (name, address): **Eurofins Agrosience Services GmbH, Stade, Germany**
 Country (of trial sites): **France (South)**
 Content of active substance nominal (g/kg or g/L): **250 g/L**
 Commercial Product (name): **Prothioconazole 250 EC**
 Producer of commercial product: **ADAMA Makhteshim Ltd.**
 Indoor/Glasshouse/Outdoor: **outdoor**
 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**
Crop/crop group: **Radish / root vegetables**
Responsible body for reporting (name, address): Eurofins Agroscience Services GmbH, Stade, Germany
Country (of trial sites): France (South)
Content of active substance nominal (g/kg or g/L): 250 g/L

Commercial Product (name): Prothioconazole 250 EC
Producer of commercial product: ADAMA Makhteshim Ltd.

Indoor/Glasshouse/Outdoor: outdoor
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- hydrox y desthio	PTZ-4- hydrox y desthio	PTZ-5- hydrox y desthio	PTZ-6- hydrox y desthio	PTZ- alpha- hydrox y 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**
Crop/crop group: **Leaf lettuce / leaf vegetables**
Responsible body for reporting (name, address): Eurofins Agrosience Services GmbH, Stade, Germany
Country (of trial sites): France (South)
Content of active substance nominal (g/kg or g/L): 250 g/L

Commercial Product (name): Prothioconazole 250 EC
Producer of commercial product: ADAMA Makhteshim Ltd.

Indoor/Glasshouse/Outdoor: outdoor
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- hydrox y desthio	PTZ-4- hydrox y desthio	PTZ-5- hydrox y desthio	PTZ-6- hydrox y desthio	PTZ- alpha- hydrox y 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**
Crop/crop group: **Barley / cereals**
Responsible body for reporting (name, address): Eurofins Agroscience Services GmbH, Stade, Germany
Country (of trial sites): France (South)
Content of active substance nominal (g/kg or g/L): 250 g/L

Commercial Product (name): Prothioconazole 250 EC
Producer of commercial product: ADAMA Makhteshim Ltd.

Indoor/Glasshouse/Outdoor: outdoor
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- hydrox y desthio	PTZ-4- hydrox y desthio	PTZ-5- hydrox y desthio	PTZ-6- hydrox y desthio	PTZ- alpha- hydrox y 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 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.	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**
Crop/crop group: **Radish / root vegetables**
Responsible body for reporting (name, address): Eurofins Agrosience Services GmbH, Stade, Germany
Country (of trial sites): France (South)
Content of active substance nominal (g/kg or g/L): 250 g/L

Commercial Product (name): Prothioconazole 250 EC
Producer of commercial product: ADAMA Makhteshim Ltd.

Indoor/Glasshouse/Outdoor: outdoor
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**
Crop/crop group: **Leaf lettuce / leaf vegetables**
Responsible body for reporting
(name, address): Eurofins Agrosience Services GmbH, Stade,
Germany
Country (of trial sites): France (South)
Content of active substance nominal (g/kg or g/L): 250 g/L

Commercial Product (name): Prothioconazole 250 EC
Producer of commercial product: ADAMA Makhteshim Ltd.

Indoor/Glasshouse/Outdoor: outdoor
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 Commodit y/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 Interva (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**
Crop/crop group: **Barley / cereals**
Responsible body for reporting
(name, address): Eurofins Agrosience Services GmbH, Stade,
Germany
Country (of trial sites): France (South)
Content of active substance nominal (g/kg or
g/L): 250 g/L

Commercial Product (name): Prothioconazole 250 EC
Producer of commercial product: ADAMA Makhteshim Ltd.

Indoor/Glasshouse/Outdoor: outdoor
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 29: 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	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	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	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	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	0.01	0.01

Table A 30: 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 31: 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	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	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	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 32: Overview of the STMRs/HRs of TLA in treated rotational crop samples at normal commercial harvest

Commodity	PBI 30 (KCA 6.6.2/01 & /02)			PBI 120 (KCA 6.6.2/01)			PBI 270 (KCA 6.6.2/01)		
	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
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 2.1.7 Other/Special Studies

No new study submitted.

A 2.2 Fenpropidin

A 2.2.1 Stability of residues

No new study submitted.

A 2.2.1.1 Stability of residues during storage of samples

No new study submitted.

A 2.2.1.1.1 Storage stability of residues in plant products

No new study submitted.

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

A 2.2.2.1 Nature of residue in plants

A 2.2.2.1.1 Nature of residue in primary crops

No new study submitted.

A 2.2.2.1.2 Nature of residue in rotational crops

No new study submitted.

A 2.2.2.1.3 Nature of residues in processed commodities

No new study submitted.

A 2.2.2.2 Nature of residues in livestock

No new study submitted.

A 2.2.3 Magnitude of residues in plants

A 2.2.3.1 Wheat, triticale, rye (KCA 6.3.1)

Table A 33: Comparison of intended and critical EU GAPs (fenpropidin)

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Max. growth stage at last application	PHI (days)
Wheat, rye, triticale (N-EU)					
cGAP EU (EFSA, 2007)	1-2	0.750 kg as/ha	21 days	65	35
cGAP EU (Art. 12, EFSA, 2011)	2	0.750 kg as/ha	14 (rye) 28 (wheat)	65	42 (rye) 35 (wheat)
Intended cGAP (1)*	1	0.250 kg as/ha	-	65	n.a.

* Critical GAP number(s) in accordance with column 0 of Table 7.1- 1.

For residue trials data please refer to A 1.1.1.1.1 and A 2.1.3.1.2.

A 2.2.3.2 Barley (KCA 6.3.2)

Table A 34: Comparison of intended and critical EU GAPs (fenpropidin)

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Max. growth stage at last application	PHI (days)
Barley, oat (N-EU)					
cGAP EU (EFSA, 2007)	1-2	0.750 kg as/ha	21 days	65	35
cGAP EU (Art. 12, EFSA, 2011)	2 (barley) 3 (oat)	0.750 kg as/ha	28 (barley) n.s. (oat)	65	35
Intended cGAP (2)*	1	0.250 kg as/ha	-	65	n.a.

* Critical GAP number(s) in accordance with column 0 of Table 7.1- 1.

For residue trials data please refer to A 2.1.3.2.1 and A 2.1.3.2.2.

A 2.2.4 Magnitude of residues in livestock

A 2.2.4.1 Livestock feeding studies

No new study submitted.

A 2.2.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)

A 2.2.5.1 Distribution of the residue in peel/pulp

No new study submitted.

A 2.2.5.2 Processing studies on a core set of representative processes

No new study submitted.

A 2.2.6 Magnitude of residues in representative succeeding crops

No new study submitted.

A 2.2.7 Other/Special Studies

No new study submitted.

A 3.1 TMDI calculations

Prothioconazole except TDMs

Chronic risk assessment:TMDI calculation									
Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	commodities not under assessment (in % of ADI)
43%	NL toddler	0.63	3%	Milk: Cattle	2%	Wheat	0.2%	Rye	13%
32%	GEMS/Food G11	0.34	2%	Wheat	0.5%	Barley	0.4%	Milk: Cattle	8%
31%	GEMS/Food G10	0.34	2%	Wheat	0.4%	Barley	0.3%	Milk: Cattle	8%
29%	GEMS/Food G15	0.41	3%	Wheat	0.5%	Barley	0.4%	Milk: Cattle	10%
28%	GEMS/Food G08	0.41	2%	Wheat	0.6%	Barley	0.4%	Rye	9%
28%	GEMS/Food G06	0.47	4%	Wheat	0.1%	Milk: Cattle	0.1%	Barley	8%
28%	GEMS/Food G07	0.38	3%	Wheat	0.4%	Barley	0.3%	Milk: Cattle	9%
22%	IE adult	0.21	1%	Wheat	0.2%	Milk: Cattle	0.1%	Sheep: Liver	5%
20%	FR child 3 15 yr	0.45	3%	Wheat	1%	Milk: Cattle	0.1%	Bovine: Muscle/meat	8%
20%	NL child	0.42	2%	Wheat	1%	Milk: Cattle	0.1%	Swine: Muscle/meat	8%
18%	ES child	0.37	3%	Wheat	0.6%	Milk: Cattle	0.1%	Bovine: Muscle/meat	7%
18%	RO general	0.39	3%	Wheat	0.6%	Milk: Cattle	0.1%	Swine: Muscle/meat	7%
17%	DE child	0.44	3%	Wheat	1.0%	Milk: Cattle	0.5%	Rye	7%
16%	UK infant	0.40	2%	Milk: Cattle	2%	Wheat	0.2%	Oat	8%
16%	FR toddler 2 3 yr	0.38	2%	Wheat	1%	Milk: Cattle	0.1%	Bovine: Muscle/meat	7%
14%	DK child	0.73	3%	Rye	3%	Wheat	0.6%	Milk: Cattle	10%
13%	UK toddler	0.37	2%	Wheat	1%	Milk: Cattle	0.1%	Bovine: Muscle/meat	7%
12%	PT general	0.25	2%	Wheat	0.1%	Rye	0.0%	Barley	4%
12%	ES adult	0.23	1%	Wheat	0.3%	Barley	0.2%	Milk: Cattle	5%
11%	NL general	0.21	1%	Wheat	0.4%	Milk: Cattle	0.2%	Barley	5%
11%	DE general	0.28	1%	Wheat	0.6%	Milk: Cattle	0.4%	Barley	6%
11%	SE general	0.33	2%	Wheat	0.6%	Milk: Cattle	0.4%	Bovine: Muscle/meat	5%
10%	DE women 14-50 yr	0.26	1%	Wheat	0.6%	Milk: Cattle	0.3%	Rye	5%
10%	IT toddler	0.40	4%	Wheat	0.0%	Barley	0.0%	Oat	7%
9%	FI adult	0.07	0.4%	Rye	0.2%	Wheat	0.1%	Oat	0.8%
9%	FR adult	0.18	1%	Wheat	0.2%	Milk: Cattle	0.1%	Swine: Muscle/meat	3%
8%	FI 3 yr	0.15	0.7%	Wheat	0.4%	Rye	0.3%	Oat	2%
7%	FR infant	0.14	0.8%	Milk: Cattle	0.5%	Wheat	0.0%	Swine: Muscle/meat	3%
7%	IT adult	0.25	2%	Wheat	0.0%	Barley	0.0%	Oat	4%
7%	FI 6 yr	0.12	0.6%	Wheat	0.4%	Rye	0.2%	Oat	2%
7%	UK vegetarian	0.15	1%	Wheat	0.2%	Milk: Cattle	0.0%	Eggs: Chicken	3%
5%	LT adult	0.18	0.6%	Rye	0.6%	Wheat	0.2%	Milk: Cattle	3%
5%	UK adult	0.13	1%	Wheat	0.1%	Milk: Cattle	0.1%	Bovine: Muscle/meat	2%
5%	DK adult	0.15	0.7%	Wheat	0.3%	Rye	0.3%	Milk: Cattle	2%
4%	PL general	0.00	0.0%	FRUIT AND TREE NUTS	0.0%	FRUIT AND TREE NUTS	0.0%	FRUIT AND TREE NUTS	0.0%
2%	IE child	0.09	0.7%	Wheat	0.2%	Milk: Cattle	0.0%	Swine: Muscle/meat	2%
0.0%									0.0%

The TMDI calculations are for information purpose only.

The results of the more refined intake calculations are presented in the spreadsheet "Results".

Fenpropidin (sum of fenpropidin and its salts, expressed as fenpropidin)			
LOQs (mg/kg) range from:		0.01	to: 0.05
Toxicological reference values			
ADI (mg/kg bw/day):		0.02	ARfD (mg/kg bw): 0.02
Source of ADI:		EFSA	Source of ARfD: EFSA
Year of evaluation:		2007	Year of evaluation: 2007

Chronic risk assessment:TMDI calculation											
	Calculated exposure (% of ADI)		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)	
	MS Diet										
TMDI/NEDI calculation (based on average food consumption)	19%	NL toddler	3.85	6%	Milk: Cattle	5%	Bananas	2%	Wheat	12%	
	11%	NL child	2.27	3%	Sugar beet roots	2%	Milk: Cattle	2%	Wheat	8%	
	9%	DK child	1.84	3%	Rye	2%	Wheat	1%	Milk: Cattle	7%	
	9%	UK infant	1.75	4%	Milk: Cattle	1%	Bananas	1%	Wheat	7%	
	8%	DE child	1.69	2%	Wheat	2%	Milk: Cattle	2%	Bananas	5%	
	8%	FR child 3 15 yr	1.64	2%	Wheat	2%	Milk: Cattle	1%	Sugar beet roots	7%	
	8%	GEMS/Food G08	1.55	3%	Barley	2%	Wheat	0.6%	Milk: Cattle	6%	
	8%	GEMS/Food G15	1.52	2%	Barley	2%	Wheat	0.7%	Milk: Cattle	6%	
	7%	FR toddler 2 3 yr	1.49	3%	Milk: Cattle	2%	Wheat	1.0%	Sugar beet roots	6%	
	7%	UK toddler	1.46	2%	Milk: Cattle	2%	Wheat	1%	Sugar beet roots	6%	
	7%	GEMS/Food G07	1.44	2%	Wheat	2%	Barley	0.6%	Milk: Cattle	6%	
	7%	GEMS/Food G11	1.40	2%	Barley	2%	Wheat	0.8%	Milk: Cattle	5%	
	7%	DE general	1.38	2%	Barley	1%	Sugar beet roots	1%	Milk: Cattle	6%	
	7%	GEMS/Food G10	1.31	2%	Wheat	2%	Barley	0.5%	Milk: Cattle	5%	
	7%	GEMS/Food G06	1.30	4%	Wheat	0.5%	Sugar beet roots	0.3%	Bananas	5%	
	6%	DE women 14-50 yr	1.23	2%	Sugar beet roots	1%	Milk: Cattle	1%	Wheat	5%	
	6%	SE general	1.21	2%	Bananas	2%	Wheat	1%	Milk: Cattle	4%	
	6%	ES child	1.17	2%	Wheat	1%	Milk: Cattle	1%	Bananas	4%	
	5%	RO general	1.10	3%	Wheat	1%	Milk: Cattle	0.5%	Sugar beet roots	4%	
	5%	NL general	1.02	1%	Sugar beet roots	1.0%	Wheat	0.9%	Barley	4%	
	5%	IE adult	0.94	1%	Wheat	0.8%	Bananas	0.6%	Sheep: Liver	3%	
	4%	ES adult	0.87	1%	Barley	1%	Wheat	0.5%	Milk: Cattle	4%	
	4%	IT toddler	0.87	3%	Wheat	0.5%	Bananas	0.1%	Other cereals	3%	
	4%	FI 3 yr	0.81	1%	Bananas	0.9%	Oat	0.6%	Wheat	2%	
	3%	FR infant	0.67	2%	Milk: Cattle	0.5%	Sugar beet roots	0.4%	Wheat	3%	
	3%	PT general	0.66	2%	Wheat	0.3%	Bananas	0.3%	Potatoes	2%	
	3%	FR adult	0.58	1%	Wheat	0.4%	Milk: Cattle	0.3%	Sugar beet roots	2%	
	3%	FI 6 yr	0.56	0.8%	Bananas	0.5%	Wheat	0.5%	Oat	1%	
	3%	FI adult	0.55	1%	Coffee beans	0.4%	Rye	0.3%	Bananas	0.8%	
	3%	IT adult	0.54	2%	Wheat	0.2%	Bananas	0.1%	Tomatoes	2%	
2%	UK vegetarian	0.50	1%	Wheat	0.4%	Bananas	0.3%	Milk: Cattle	2%		
2%	LT adult	0.50	0.5%	Rye	0.5%	Wheat	0.4%	Milk: Cattle	2%		
2%	DK adult	0.49	0.6%	Wheat	0.5%	Milk: Cattle	0.5%	Bananas	2%		
2%	UK adult	0.46	0.8%	Wheat	0.4%	Bananas	0.3%	Milk: Cattle	2%		
1%	IE child	0.27	0.6%	Wheat	0.4%	Milk: Cattle	0.2%	Bananas	1%		
	0.7%	PL general	0.13	0.2%	Bananas	0.2%	Potatoes	0.1%	Apples		
	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.

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	ARd (mg/kg bw): 0.01
Source of ADI:		EFSA	Source of ARd: 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							
	Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	MRLs set at the LOQ (in % of ADI)	commodities under assessment (in % of ADI)
TMDI(NED/IEDI) calculation (based on average food consumption)	15%	NL toddler	1.48	3%	Milk: Cattle	2%	Wheat	1%	Maize/corn	4%	6%
	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%	7%
	10%	GEMS/Food G06	0.96	4%	Wheat	1%	Soyabeans	0.4%	Tomatoes	2%	5%
	10%	GEMS/Food G08	0.95	2%	Wheat	2%	Soyabeans	0.6%	Barley	1%	4%
	9%	GEMS/Food G07	0.93	3%	Wheat	2%	Soyabeans	0.4%	Rapeseeds/canola seeds	1%	4%
	9%	GEMS/Food G15	0.93	3%	Wheat	2%	Soyabeans	0.5%	Barley	1%	4%
	9%	DE child	0.90	3%	Wheat	1%	Apples	1.0%	Milk: Cattle	3%	4%
	9%	NL child	0.88	2%	Wheat	1%	Milk: Cattle	0.8%	Sugar beet roots	3%	4%
	8%	FR child 3 15 yr	0.83	3%	Wheat	1%	Milk: Cattle	0.6%	Swine: Other products	2%	4%
	7%	UK infant	0.74	2%	Milk: Cattle	2%	Wheat	1%	Carrots	0.9%	4%
	7%	FR toddler 2 3 yr	0.70	2%	Wheat	1%	Milk: Cattle	0.6%	Carrots	2%	4%
	7%	UK toddler	0.67	2%	Wheat	1%	Milk: Cattle	0.8%	Beans	1%	4%
	7%	RO general	0.65	3%	Wheat	0.6%	Milk: Cattle	0.4%	Potatoes	1.0%	4%
	6%	IE adult	0.62	1%	Wheat	0.4%	Sweet potatoes	0.3%	Peas	2%	2%
	6%	ES child	0.60	3%	Wheat	0.6%	Milk: Cattle	0.3%	Cocoa beans	1%	4%
	6%	SE general	0.59	2%	Wheat	0.7%	Carrots	0.6%	Milk: Cattle	1.0%	3%
	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%	3%
	5%	DE women 14-50 yr	0.50	1%	Wheat	0.6%	Milk: Cattle	0.5%	Sugar beet roots	2%	3%
	5%	NL general	0.46	1%	Wheat	0.4%	Milk: Cattle	0.3%	Sugar beet roots	1%	2%
	5%	FI adult	0.45	3%	Coffee beans	0.4%	Rye	0.3%	Carrots	3%	0.7%
	4%	FI 3 yr	0.40	0.7%	Wheat	0.7%	Carrots	0.5%	Potatoes	0.9%	2%
	4%	FR adult	0.39	1%	Wheat	0.3%	Swine: Other products	0.2%	Wine grapes	1%	2%
	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%	1%
	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%
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%	2%	
3%	DK adult	0.26	0.7%	Wheat	0.4%	Carrots	0.3%	Rye	0.5%	1%	
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%	0.9%	
Conclusion: The estimated long-term dietary intake (TMDI/NED/IEDI) was below the ADI. The long-term intake of residues of Prothioconazole: prothioconazole-desithio (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						Exposure resulting from	
	Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	7%	DK child	0.73	3%	Rye	3%	Wheat	0.6%	Milk: Cattle	0.0%	7%
	6%	NL toddler	0.63	3%	Milk: Cattle	2%	Wheat	0.2%	Rye	0.0%	6%
	5%	GEMS/Food G06	0.47	4%	Wheat	0.1%	Milk: Cattle	0.1%	Barley	0.0%	5%
	4%	FR child 3 15 yr	0.45	3%	Wheat	1%	Milk: Cattle	0.1%	Bovine: Muscle/meat	0.0%	4%
	4%	DE child	0.44	3%	Wheat	1.0%	Milk: Cattle	0.5%	Rye	0.1%	4%
	4%	NL child	0.42	2%	Wheat	1%	Milk: Cattle	0.1%	Swine: Muscle/meat	0.0%	4%
	4%	GEMS/Food G15	0.41	3%	Wheat	0.5%	Barley	0.4%	Milk: Cattle	0.0%	4%
	4%	GEMS/Food G08	0.41	2%	Wheat	0.6%	Barley	0.4%	Rye	0.0%	4%
	4%	UK infant	0.40	2%	Milk: Cattle	2%	Wheat	0.2%	Oat	0.0%	4%
	4%	IT toddler	0.40	4%	Wheat	0.0%	Barley	0.0%	Oat	0.0%	4%
	4%	RO general	0.39	3%	Wheat	0.6%	Milk: Cattle	0.1%	Swine: Muscle/meat	0.0%	4%
	4%	GEMS/Food G07	0.38	3%	Wheat	0.4%	Barley	0.3%	Milk: Cattle	0.0%	4%
	4%	FR toddler 2 3 yr	0.38	2%	Wheat	1%	Milk: Cattle	0.1%	Bovine: Muscle/meat	0.0%	4%
	4%	ES child	0.37	3%	Wheat	0.6%	Milk: Cattle	0.1%	Bovine: Muscle/meat	0.0%	4%
	4%	UK toddler	0.37	2%	Wheat	1%	Milk: Cattle	0.1%	Bovine: Muscle/meat	0.0%	4%
	3%	GEMS/Food G10	0.34	2%	Wheat	0.4%	Barley	0.3%	Milk: Cattle	0.0%	3%
	3%	GEMS/Food G11	0.34	2%	Wheat	0.5%	Barley	0.4%	Milk: Cattle	0.0%	3%
	3%	SE general	0.33	2%	Wheat	0.6%	Milk: Cattle	0.4%	Bovine: Muscle/meat	0.0%	3%
	3%	DE general	0.28	1%	Wheat	0.6%	Milk: Cattle	0.4%	Barley	0.0%	3%
	3%	DE women 14-50 yr	0.26	1%	Wheat	0.6%	Milk: Cattle	0.3%	Rye	0.0%	3%
	2%	IT adult	0.25	2%	Wheat	0.0%	Barley	0.0%	Oat	0.0%	2%
	2%	PT general	0.25	2%	Wheat	0.1%	Rye	0.0%	Barley	0.0%	2%
	2%	ES adult	0.23	1%	Wheat	0.3%	Barley	0.2%	Milk: Cattle	0.0%	2%
	2%	IE adult	0.21	1%	Wheat	0.2%	Milk: Cattle	0.1%	Sheep: Liver	0.0%	2%
	2%	NL general	0.21	1%	Wheat	0.4%	Milk: Cattle	0.2%	Barley	0.0%	2%
	2%	FR adult	0.18	1%	Wheat	0.2%	Milk: Cattle	0.1%	Swine: Muscle/meat	0.0%	2%
	2%	LT adult	0.18	0.6%	Rye	0.6%	Wheat	0.2%	Milk: Cattle	0.0%	2%
	2%	FI 3 yr	0.15	0.7%	Wheat	0.4%	Rye	0.3%	Oat	0.0%	2%
	1%	DK adult	0.15	0.7%	Wheat	0.3%	Rye	0.3%	Milk: Cattle	0.0%	1%
	1%	UK vegetarian	0.15	1%	Wheat	0.2%	Milk: Cattle	0.0%	Eggs: Chicken	0.0%	1%
	1%	FR infant	0.14	0.8%	Milk: Cattle	0.5%	Wheat	0.0%	Swine: Muscle/meat	0.0%	1%
	1%	UK adult	0.13	1%	Wheat	0.1%	Milk: Cattle	0.1%	Bovine: Muscle/meat	0.0%	1%
1%	FI 6 yr	0.12	0.6%	Wheat	0.4%	Rye	0.2%	Oat	0.0%	1%	
0.9%	IE child	0.09	0.7%	Wheat	0.2%	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	0.9%	
0.7%	FI adult	0.07	0.4%	Rye	0.2%	Wheat	0.1%	Oat	0.0%	0.7%	
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.											

Fenpropidin (sum of fenpropidin and its salts, expressed as fenpropidin)			
LOQs (mg/kg) range from:		0.01	to: 0.05
Toxicological reference values			
ADI (mg/kg bw/day):		0.02	ARID (mg/kg bw): 0.02
Source of ADI:		EFSA	Source of ARID: EFSA
Year of evaluation:		2007	Year of evaluation: 2007

Normal mode											
Chronic risk assessment: JMPR methodology (IED/TMDI)											
			No of diets exceeding the ADI :							Exposure resulting from	
	Calculated exposure (% of ADI)		Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	MRLs set at the LOQ (in % of ADI)	commodities n under assessment (in % of ADI)
	MS Diet										
TMDI/NEDI/IEDI calculation (based on average food consumption)	19%	NL toddler	3.85	6%	Milk: Cattle	5%	Bananas	2%	Wheat	3%	10%
	11%	NL child	2.27	3%	Sugar beet roots	2%	Milk: Cattle	2%	Wheat	2%	5%
	9%	DK child	1.84	3%	Rye	2%	Wheat	1%	Milk: Cattle	1%	7%
	9%	UK infant	1.75	4%	Milk: Cattle	1%	Bananas	1%	Wheat	1.0%	6%
	8%	DE child	1.69	2%	Wheat	2%	Milk: Cattle	2%	Bananas	2%	5%
	8%	FR child 3 15 yr	1.64	2%	Wheat	2%	Milk: Cattle	1%	Sugar beet roots	1%	5%
	8%	GEMS/Food G08	1.55	3%	Barley	2%	Wheat	0.6%	Milk: Cattle	1%	6%
	8%	GEMS/Food G15	1.52	2%	Barley	2%	Wheat	0.7%	Milk: Cattle	1%	6%
	7%	FR toddler 2 3 yr	1.49	3%	Milk: Cattle	2%	Wheat	1.0%	Sugar beet roots	1%	5%
	7%	UK toddler	1.46	2%	Milk: Cattle	2%	Wheat	1%	Sugar beet roots	0.9%	4%
	7%	GEMS/Food G07	1.44	2%	Wheat	2%	Barley	0.6%	Milk: Cattle	1%	6%
	7%	GEMS/Food G11	1.40	2%	Barley	2%	Wheat	0.8%	Milk: Cattle	2%	5%
	7%	DE general	1.38	2%	Barley	1%	Sugar beet roots	1%	Milk: Cattle	0.9%	4%
	7%	GEMS/Food G10	1.31	2%	Wheat	2%	Barley	0.5%	Milk: Cattle	1%	5%
	7%	GEMS/Food G06	1.30	4%	Wheat	0.5%	Sugar beet roots	0.3%	Bananas	1%	4%
	6%	DE women 14-50 yr	1.23	2%	Sugar beet roots	1%	Milk: Cattle	1%	Wheat	0.9%	4%
	6%	SE general	1.21	2%	Bananas	2%	Wheat	1%	Milk: Cattle	1%	4%
	6%	ES child	1.17	2%	Wheat	1%	Milk: Cattle	1%	Bananas	1%	4%
	5%	RO general	1.10	3%	Wheat	1%	Milk: Cattle	0.5%	Sugar beet roots	1%	4%
	5%	NL general	1.02	1%	Sugar beet roots	1.0%	Wheat	0.9%	Barley	0.9%	3%
	5%	IE adult	0.94	1%	Wheat	0.8%	Bananas	0.6%	Sheep: Liver	1%	3%
	4%	ES adult	0.87	1%	Barley	1%	Wheat	0.5%	Milk: Cattle	0.8%	3%
	4%	IT toddler	0.87	3%	Wheat	0.5%	Bananas	0.1%	Other cereals	0.5%	3%
	4%	FI 3 yr	0.81	1%	Bananas	0.9%	Oat	0.6%	Wheat	0.7%	2%
	3%	FR infant	0.67	2%	Milk: Cattle	0.5%	Sugar beet roots	0.4%	Wheat	0.6%	2%
	3%	PT general	0.66	2%	Wheat	0.3%	Bananas	0.3%	Potatoes	0.8%	2%
	3%	FR adult	0.58	1%	Wheat	0.4%	Milk: Cattle	0.3%	Sugar beet roots	0.8%	2%
	3%	FI 6 yr	0.56	0.8%	Bananas	0.5%	Wheat	0.5%	Oat	0.6%	1%
	3%	FI adult	0.55	1%	Coffee beans	0.4%	Rye	0.3%	Bananas	2%	0.8%
	3%	IT adult	0.54	2%	Wheat	0.2%	Bananas	0.1%	Tomatoes	0.4%	2%
	2%	UK vegetarian	0.50	1%	Wheat	0.4%	Bananas	0.3%	Milk: Cattle	0.4%	2%
	2%	LT adult	0.50	0.5%	Rye	0.5%	Wheat	0.4%	Milk: Cattle	0.6%	2%
2%	DK adult	0.49	0.6%	Wheat	0.5%	Milk: Cattle	0.5%	Bananas	0.6%	2%	
2%	UK adult	0.46	0.8%	Wheat	0.4%	Bananas	0.3%	Milk: Cattle	0.5%	1%	
1%	IE child	0.27	0.6%	Wheat	0.4%	Milk: Cattle	0.2%	Bananas	0.2%	1%	
0.7%	PL general	0.13	0.2%	Bananas	0.2%	Potatoes	0.1%	Apples	0.5%		
Conclusion: The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI. The long-term intake of residues of Fenpropidin (sum of fenpropidin and its salts, expressed as fenpropidin) is unlikely to present a public health concern.											

Refined calculation mode											
Chronic risk assessment: JMPR methodology (IEDI/TMDI)											
			No of diets exceeding the ADI :							Exposure resulting from	
	Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
TMDI/NED/IEDI calculation (based on average food consumption)	10%	NL toddler	1.96	6%	Milk: Cattle	2%	Wheat	0.5%	Barley	0.3%	10%
	7%	DK child	1.49	3%	Rye	2%	Wheat	1%	Milk: Cattle	0.5%	7%
	6%	GEMS/Food G08	1.25	3%	Barley	2%	Wheat	0.6%	Milk: Cattle	0.4%	6%
	6%	UK infant	1.23	4%	Milk: Cattle	1%	Wheat	0.4%	Oat	0.3%	6%
	6%	GEMS/Food G15	1.22	2%	Barley	2%	Wheat	0.7%	Milk: Cattle	0.3%	6%
	6%	GEMS/Food G07	1.13	2%	Wheat	2%	Barley	0.6%	Milk: Cattle	0.4%	6%
	5%	GEMS/Food G11	1.08	2%	Barley	2%	Wheat	0.8%	Milk: Cattle	0.3%	5%
	5%	FR child 3 15 yr	1.07	2%	Wheat	2%	Milk: Cattle	0.1%	Bovine: Muscle/meat	0.5%	5%
	5%	NL child	1.06	2%	Milk: Cattle	2%	Wheat	0.2%	Bovine: Liver	0.3%	5%
	5%	DE child	1.03	2%	Wheat	2%	Milk: Cattle	0.4%	Rye	0.3%	5%
	5%	FR toddler 2 3 yr	1.02	3%	Milk: Cattle	2%	Wheat	0.1%	Bovine: Muscle/meat	0.4%	5%
	5%	GEMS/Food G10	1.00	2%	Wheat	2%	Barley	0.5%	Milk: Cattle	0.3%	5%
	4%	UK toddler	0.90	2%	Milk: Cattle	2%	Wheat	0.1%	Bovine: Muscle/meat	0.3%	4%
	4%	GEMS/Food G06	0.89	4%	Wheat	0.2%	Milk: Cattle	0.2%	Barley	0.1%	4%
	4%	DE general	0.88	2%	Barley	1%	Milk: Cattle	0.9%	Wheat	0.2%	4%
	4%	ES child	0.82	2%	Wheat	1%	Milk: Cattle	0.1%	Bovine: Muscle/meat	0.5%	4%
	4%	RO general	0.80	3%	Wheat	1%	Milk: Cattle	0.1%	Swine: Muscle/meat	0.3%	4%
	4%	SE general	0.70	2%	Wheat	1%	Milk: Cattle	0.4%	Bovine: Muscle/meat	0.5%	4%
	4%	DE women 14-50 yr	0.70	1%	Milk: Cattle	1%	Wheat	0.6%	Barley	0.2%	4%
	3%	ES adult	0.70	1%	Barley	1%	Wheat	0.5%	Milk: Cattle	0.3%	3%
	3%	IT toddler	0.67	3%	Wheat	0.0%	Barley	0.0%	Oat		3%
	3%	NL general	0.62	1.0%	Wheat	0.9%	Barley	0.8%	Milk: Cattle	0.3%	3%
	3%	IE adult	0.55	1%	Wheat	0.6%	Sheep: Liver	0.4%	Milk: Cattle	0.2%	3%
	2%	FR infant	0.45	2%	Milk: Cattle	0.4%	Wheat	0.0%	Swine: Muscle/meat	0.1%	2%
	2%	PT general	0.43	2%	Wheat	0.1%	Barley	0.1%	Rye		2%
	2%	IT adult	0.42	2%	Wheat	0.0%	Barley	0.0%	Oat		2%
	2%	LT adult	0.41	0.5%	Rye	0.5%	Wheat	0.4%	Milk: Cattle	0.2%	2%
	2%	FI 3 yr	0.40	0.9%	Oat	0.6%	Wheat	0.3%	Rye	0.0%	2%
	2%	FR adult	0.38	1%	Wheat	0.4%	Milk: Cattle	0.1%	Swine: Muscle/meat	0.2%	2%
	2%	DK adult	0.33	0.6%	Wheat	0.5%	Milk: Cattle	0.3%	Rye	0.2%	2%
	2%	UK vegetarian	0.31	1%	Wheat	0.3%	Milk: Cattle	0.1%	Oat	0.0%	2%
	1%	FI 6 yr	0.29	0.5%	Wheat	0.5%	Oat	0.3%	Rye	0.0%	1%
	1%	UK adult	0.29	0.8%	Wheat	0.3%	Milk: Cattle	0.1%	Barley	0.1%	1%
1%	IE child	0.21	0.6%	Wheat	0.4%	Milk: Cattle	0.0%	Swine: Muscle/meat	0.1%	1%	
0.8%	FI adult	0.15	0.4%	Rye	0.2%	Oat	0.2%	Wheat		0.8%	
	Column7				FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
Conclusion: The estimated long-term dietary intake (TMDI/NED/IEDI) was below the ADI. The long-term intake of residues of Fenpropidin (sum of fenpropidin and its salts, expressed as fenpropidin) is unlikely to present a public health concern.											

1,2,4-Triazole

Normal mode

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.

<h1>Triazole alanine (TA)</h1>			
LOQs (mg/kg) range from:		to:	
Toxicological reference values			
ADI (mg/kg bw/day):	0.3	ARfD (mg/kg bw):	0.3
Source of ADI:	EC	Source of ARfD:	EC
Year of evaluation:	2018	Year of evaluation:	2018

Normal mode											
Chronic risk assessment: JMPR methodology (IED/TMDI)											
			No of diets exceeding the ADI :							Exposure resulting from	
	Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	MRLs set at the LOQ (in % of ADI)	commodities n under assessment (in % of ADI)
TMDI(NED)/IEDI calculation (based on average food consumption)	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(NED)/IEDI) was below the ADI. The long-term intake of residues of Triazole alanine (TA) is unlikely to present a public health concern.											

<h2 style="text-align: center;">Triazole acetic acid (TAA)</h2>			
LOQs (mg/kg) range from:		to:	
Toxicological reference values			
ADI (mg/kg bw/day):	1	ARfD (mg/kg bw):	1
Source of ADI:	EC	Source of ARfD:	EC
Year of evaluation:	2018	Year of evaluation:	2018

Normal mode												
Chronic risk assessment: JMPR methodology (IEDI/TMDI)												
				No of diets exceeding the ADI :								
								Exposure resulting from				
	Calculated exposure (% of ADI)		MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	MRLs set at the LOQ (in % of ADI)	commodities under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	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			0.9%
	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			0.4%
	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			0.2%
	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 Triazolo acetic acid (TAA) is unlikely to present a public health concern.												

<h2 style="text-align: center;">Triazole lactic acid (TLA)</h2>			
LOQs (mg/kg) range from:		to:	
Toxicological reference values			
ADI (mg/kg bw/day):	0.3	ARfD (mg/kg bw):	0.3
Source of ADI:	EC	Source of ARfD:	EC
Year of evaluation:	2018	Year of evaluation:	2018

Normal mode											
Chronic risk assessment: JMPR methodology (IED/TMDI)											
				No of diets exceeding the ADI :							
	Calculated exposure (% of ADI)		Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOO (in % of ADI)	
	MS Diet										
TMDI/NEDI calculation (based on average food consumption)	1%	NL toddler	3.39	0.6%	Milk: Cattle	0.1%	Apples	0.1%	Maize/corn		0.7%
	0.6%	NL child	1.73	0.2%	Milk: Cattle	0.1%	Apples	0.0%	Wheat		0.3%
	0.6%	DE child	1.73	0.2%	Milk: Cattle	0.1%	Apples	0.1%	Oranges		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	1.49	0.3%	Milk: Cattle	0.0%	Apples	0.0%	Wheat		0.4%
	0.5%	FR child 3 15 yr	1.45	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	1.15	0.1%	Soyabeans	0.1%	Milk: Cattle	0.0%	Potatoes		0.1%
	0.4%	GEMS/Food G10	1.09	0.1%	Soyabeans	0.1%	Milk: Cattle	0.0%	Wheat		0.1%
	0.4%	GEMS/Food G07	1.09	0.1%	Milk: Cattle	0.0%	Soyabeans	0.0%	Wheat		0.1%
	0.4%	DK child	1.07	0.1%	Milk: Cattle	0.0%	Rye	0.0%	Wheat		0.3%
	0.4%	GEMS/Food G08	1.07	0.1%	Milk: Cattle	0.0%	Soyabeans	0.0%	Wheat		0.1%
	0.3%	GEMS/Food G15	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%	RO general	1.01	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes		0.2%
	0.3%	ES child	1.01	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Oranges		0.2%
	0.3%	SE general	0.97	0.1%	Milk: Cattle	0.0%	Bovine: Muscle/meat	0.0%	Potatoes		0.2%
	0.3%	DE women 14-50 yr	0.91	0.1%	Milk: Cattle	0.0%	Apples	0.0%	Oranges		0.2%
	0.3%	DE general	0.88	0.1%	Milk: Cattle	0.0%	Apples	0.0%	Oranges		0.2%
	0.3%	FR infant	0.79	0.2%	Milk: Cattle	0.0%	Apples	0.0%	Potatoes		0.2%
	0.3%	IE adult	0.79	0.0%	Milk: Cattle	0.0%	Sweet potatoes	0.0%	Wheat		0.1%
	0.3%	NL general	0.78	0.1%	Milk: Cattle	0.0%	Potatoes	0.0%	Apples		0.1%
	0.2%	ES adult	0.59	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	0.54	0.0%	Milk: Cattle	0.0%	Wine grapes	0.0%	Wheat		0.1%
	0.2%	DK adult	0.46	0.1%	Milk: Cattle	0.0%	Wine grapes	0.0%	Apples		0.1%
	0.1%	LT adult	0.43	0.0%	Milk: Cattle	0.0%	Potatoes	0.0%	Apples		0.1%
	0.1%	IT toddler	0.43	0.0%	Wheat	0.0%	Tomatoes	0.0%	Other cereals		0.0%
	0.1%	FI 3 yr	0.38	0.0%	Potatoes	0.0%	Cucumbers	0.0%	Apples		0.0%
	0.1%	UK vegetarian	0.37	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Oranges		0.1%
	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		0.0%	
0.1%	IE child	0.21	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes		0.1%	
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.											

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: Rees Day-model								
	NEDI/TMDI=Σ 2 highest 97.5th percentile intakes + mean population intake for other foods) ^{*)}								
TMDI/NEDI Rees-Day-model	Highest calculated TMDI/NEDI values in % of ADI	MS Diet		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
	16%	UK infant	*)	6%	Beans	5%	Milk: Cattle	2%	Wheat
	13%	UK toddler	*)	5%	Wheat	5%	Beans	1%	Milk: Cattle
	8%	FI 3 yr	*)	3%	Carrots	2%	Wheat	0.5%	Potatoes
	7%	UK adult	*)	3%	Bovine: Other products	2%	Wheat	0.2%	Beans
	6%	FI 6 yr	*)	2%	Carrots	2%	Wheat	0.4%	Potatoes
	6%	FI adult	*)	3%	Coffee beans	1%	Rye	1.0%	Carrots
	6%	UK vegetarian	*)	3%	Wheat	2%	Beans	0.2%	Carrots
	*) Calculation according to the UK approach (Rees-Day model equation; TMDI/NEDI = Σ 2 highest 97.5th percentile intakes + mean population intake for other foods Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.								

Fenpropidin (sum of fenpropidin and its salts, expressed as fenpropidin)			
LOQs (mg/kg) range from:		0.01	to: 0.05
Toxicological reference values			
ADI (mg/kg bw/day):		0.02	ARfD (mg/kg bw): 0.02
Source of ADI:		EFSA	Source of ARfD: EFSA
Year of evaluation:		2007	Year of evaluation: 2007

Chronic risk assessment: Rees Day-model								
NEDI/TMDI=Σ 2 highest 97.5th percentile intakes + mean population intake for other foods) ^{*)}								
TMDI/NEDI Rees-Day-model	Highest calculated TMDI/NEDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	2nd contributor to MS diet (in % of ADI)		Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities
	20%	UK infant *)	10%	Milk: Cattle	7%	Bananas	1%	Wheat
	19%	UK toddler *)	7%	Bananas	6%	Bovine: Liver	2%	Milk: Cattle
	13%	FI 3 yr *)	7%	Bananas	4%	Oat	0.6%	Wheat
	8%	FI 6 yr *)	5%	Bananas	2%	Oat	0.5%	Wheat
	5%	UK vegetarian *)	2%	Bananas	2%	Wheat	0.3%	Milk: Cattle
	5%	UK adult *)	2%	Bananas	2%	Wheat	0.3%	Milk: Cattle
	5%	FI adult *)	2%	Bananas	1%	Coffee beans	0.9%	Rye
	*) Calculation according to the UK approach (Rees-Day model equation; TMDI/NEDI = Σ 2 highest 97.5th percentile intakes + mean population intake for other foods) Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.							

A 3.4 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				Results for adults			
	No. of commodities for which ARfD/ADI is exceeded (IESTI):			---	No. of commodities for which ARfD/ADI is exceeded (IESTI):			---
	IESTI				IESTI			
	Highest % of ARfD/ADI		MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI		MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
		Commodities				Commodities		
	19%	Bovine: Liver	0.5 / 0.23	1.9	9%	Bovine: Liver	0.5 / 0.23	0.92
	11%	Bovine: Edible offals (other than liver and kidney)	0.5 / 0.15	1.1	6%	Sheep: Liver	0.5 / 0.23	0.64
	9%	Wheat	0.1 / 0.06	0.87	5%	Wheat	0.1 / 0.06	0.50
	6%	Milk: Cattle	0.01 / 0.01	0.62	5%	Bovine: Edible offals (other than liver and kidney)	0.5 / 0.15	0.50
	6%	Bovine: Kidney	0.5 / 0.15	0.56	4%	Swine: Edible offals (other than liver and kidney)	0.5 / 0.15	0.39
	5%	Swine: Edible offals (other than liver and kidney)	0.5 / 0.15	0.45	3%	Barley	0.2 / 0.07	0.34
	4%	Barley	0.2 / 0.07	0.39	3%	Poultry: Liver	0.1 / 0.07	0.33
	4%	Rye	0.05 / 0.06	0.38	3%	Swine: Kidney	0.5 / 0.15	0.33
	3%	Swine: Liver	0.5 / 0.23	0.28	3%	Swine: Liver	0.5 / 0.23	0.32
	2%	Swine: Kidney	0.5 / 0.15	0.19	3%	Bovine: Kidney	0.5 / 0.15	0.32
	2%	Honey and other apiculture products	0.05 / 0.05	0.18	3%	Rye	0.05 / 0.06	0.29
	1%	Eggs: Chicken	0.01 / 0.01	0.12	2%	Milk: Cattle	0.01 / 0.01	0.19
	1%	Swine: Muscle/meat	0.01 / 0.01	0.12	1%	Sheep: Edible offals (other than liver and kidney)	0.5 / 0.15	0.10
	1%	Milk: Goat	0.01 / 0.01	0.12	0.9%	Milk: Goat	0.01 / 0.01	0.09
	0.8%	Poultry: Liver	0.1 / 0.07	0.08	0.9%	Poultry: Kidney	0.1 / 0.07	0.09
Expand/collapse list								
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)				0				

Fenpropidin

Fenpropidin (sum of fenpropidin and its salts, expressed as fenpropidin)			
LOQs (mg/kg) range from:		0.01	to: 0.05
Toxicological reference values			
ADI (mg/kg bw/day):		0.02	ARfD (mg/kg bw): 0.02
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				Results for adults			
	No. of commodities for which ARfD/ADI is exceeded (IESTI):				No. of commodities for which ARfD/ADI is exceeded (IESTI):			
	---				---			
	IESTI				IESTI			
			MRL / input				MRL / input	
	Highest % of ARfD/ADI	Commodities	for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	for RA (mg/kg)	Exposure (µg/kg bw)
	20%	Bovine: Liver	0.5 / 0.5	4.0	15%	Barley	0.6 / 0.6	2.9
	17%	Barley	0.6 / 0.6	3.4	10%	Bovine: Liver	0.5 / 0.5	2.0
	12%	Milk: Cattle	0.02 / 0.02	2.5	7%	Sheep: Liver	0.5 / 0.5	1.4
	7%	Wheat	0.1 / 0.1	1.4	4%	Wheat	0.1 / 0.1	0.84
3%	Rye	0.1 / 0.1	0.63	4%	Milk: Cattle	0.02 / 0.02	0.77	
2%	Milk: Goat	0.02 / 0.02	0.48	2%	Rye	0.1 / 0.1	0.49	
2%	Bovine: Kidney	0.1 / 0.1	0.38	2%	Milk: Goat	0.02 / 0.02	0.37	
2%	Poultry: Muscle/meat	0.02 / 0.02	0.34	2%	Milk: Sheep	0.02 / 0.02	0.30	
2%	Oat	0.3 / 0.3	0.33	1%	Swine: Liver	0.2 / 0.2	0.28	
1%	Eggs: Chicken	0.02 / 0.02	0.25	1%	Poultry: Muscle	0.02 / 0.02	0.23	
1%	Swine: Liver	0.2 / 0.2	0.25	1%	Bovine: Kidney	0.1 / 0.1	0.21	
1%	Swine: Muscle/meat	0.02 / 0.02	0.24	1.0%	Oat	0.3 / 0.3	0.19	
0.9%	Honey and other	0.05 / 0.05	0.18	0.6%	Bovine: Muscle	0.02 / 0.02	0.11	
0.7%	Bovine: Edible offals	0.02 / 0.02	0.15	0.6%	Other farmed animals:	0.02 / 0.02	0.11	
0.7%	Bovine: Muscle/meat	0.02 / 0.02	0.14	0.6%	Swine: Kidney	0.05 / 0.05	0.11	
Expand/collapse list								
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)								

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

Show results of IESTI calculation only for crops with GAPs under assessment								
Unprocessed commodities	Results for children				Results for adults			
	No. of commodities for which ARfD/ADI is exceeded (IESTI):				No. of commodities for which ARfD/ADI is exceeded (IESTI):			
	---				---			
	IESTI				IESTI			
	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
	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
Expand/collapse list	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
	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):		0.3	ARfD (mg/kg bw): 0.3
Source of ADI:		EC	Source of ARfD: EC
Year of evaluation:		2018	Year of evaluation: 2018

Show results of IESTI calculation only for crops with GAPs under assessment								
Unprocessed commodities	Results for children				Results for adults			
	No. of commodities for which ARfD/ADI is exceeded (IESTI):				No. of commodities for which ARfD/ADI is exceeded (IESTI):			
	---				---			
	IESTI				IESTI			
	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
	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%	Oat	0 / 0.62	0.69	0.2%	Swine: Kidney	0 / 0.22	0.48
	0.2%	Milk: Goat	0 / 0.02	0.48	0.2%	Swine: Liver	0 / 0.34	0.48
	0.1%	Swine: Liver	0 / 0.34	0.42	0.2%	Bovine: Kidney	0 / 0.22	0.46
	0.09%	Swine: Kidney	0 / 0.22	0.28	0.1%	Oat	0 / 0.62	0.40
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):	1	ARfD (mg/kg bw):	1
Source of ADI:	EC	Source of ARfD:	EC
Year of evaluation:	2018	Year of evaluation:	2018

Show results of IESTI calculation only for crops with GAPs under assessment								
Unprocessed commodities	Results for children				Results for adults			
	No. of commodities for which ARfD/ADI is exceeded (IESTI):				No. of commodities for which ARfD/ADI is exceeded (IESTI):			
	---				---			
	IESTI				IESTI			
	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
	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
Unprocessed commodities	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
	0.09%	Oat	0 / 0.79	0.88	0.06%	Milk: Goat	0 / 0.03	0.55
	0.07%	Milk: Goat	0 / 0.03	0.73	0.05%	Oat	0 / 0.79	0.51
	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
	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):	0.3	ARfD (mg/kg bw):	0.3
Source of ADI:	EC	Source of ARfD:	EC
Year of evaluation:	2018	Year of evaluation:	2018

Show results of IESTI calculation only for crops with GAPs under assessment								
Unprocessed commodities	Results for children				Results for adults			
	No. of commodities for which ARfD/ADI is exceeded (IESTI):				No. of commodities for which ARfD/ADI is exceeded (IESTI):			
	---				---			
	IESTI				IESTI			
	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
	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
Unprocessed commodities	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%	Swine: Muscle/meat	0 / 0.03	0.36	0.06%	Wheat	0 / 0.02	0.18
	0.1%	Bovine: Liver	0 / 0.04	0.32	0.06%	Swine: Kidney	0 / 0.08	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%	Swine: Muscle/meat	0 / 0.03	0.15
	0.05%	Sheep: Muscle/meat	0 / 0.03	0.16	0.05%	Sheep: Muscle/meat	0 / 0.03	0.14
	0.05%	Rye	0 / 0.02	0.14	0.05%	Poultry: Liver	0 / 0.03	0.14
	0.04%	Barley	0 / 0.02	0.12	0.04%	Eggs: Chicken	0 / 0.03	0.13
	0.04%	Bovine: Kidney	0 / 0.03	0.11	0.04%	Swine: Fat tissue	0 / 0.06	0.12
	0.04%	Milk: Sheep	0 / 0.03	0.11	0.04%	Sheep: Liver	0 / 0.04	0.11
	0.03%	Swine: Fat tissue	0 / 0.06	0.10	0.04%	Rye	0 / 0.02	0.11
	Expand/collapse list							
	Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)							

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				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)
	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	0.1 / 0.06	0.21
	2%	Oat / boiled	0.05 / 0.06	0.22	0.9%	Oat / boiled	0.05 / 0.06	0.09
	2%	Rye / milling (wholemeal)-	0.05 / 0.06	0.21				
	2%	Oat / milling (flakes)	0.05 / 0.06	0.18				
	1%	Barley / milling (flour)	0.2 / 0.07	0.13				
Expand/collapse list								
Conclusion:								
No exceedance of the toxicological reference value was identified for any unprocessed commodity.								
A short term intake of residues of Prothioconazole: prothioconazole-desthio (sum of isomers) (F)								
For processed commodities, no exceedance of the ARfD/ADI was identified.								

Fenpropidin (sum of fenpropidin and its salts, expressed as fenpropidin)

LOQs (mg/kg) range from:	0.01	to:	0.05
Toxicological reference values			
ADI (mg/kg bw/day):	0.02	ARfD (mg/kg bw):	0.02
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2007	Year of evaluation:	2007

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)
	11%	Barley / cooked	0.6 / 0.6	2.2	22%	Barley / beer	0.6 / 0.12	4.3
	6%	Wheat / milling (flour)	0.1 / 0.1	1.2	2%	Oat / boiled	0.3 / 0.3	0.46
	5%	Oat / boiled	0.3 / 0.3	1.1	2%	Wheat / bread/pizza	0.1 / 0.1	0.44
	5%	Barley / milling (flour)	0.6 / 0.6	1.1	2%	Wheat / pasta	0.1 / 0.1	0.38
	5%	Oat / milling (flakes)	0.3 / 0.3	0.90	2%	Wheat / bread	0.1 / 0.1	0.35
3%	Wheat / milling (wholemea	0.1 / 0.1	0.55					
2%	Rye / boiled	0.1 / 0.1	0.36					
2%	Rye / milling (wholemeal)-	0.1 / 0.1	0.35					
Conclusion:								
No exceedance of the toxicological reference value was identified for any unprocessed commodity.								
A short term intake of residues of Fenpropidin (sum of fenpropidin and its salts, expressed as fenpropidin) is unlikely to present a public health risk.								
For processed commodities, no exceedance of the ARfD/ADI was identified.								

<h1 style="text-align: center;">1,2,4-Triazole</h1>			
LOQs (mg/kg) range from:		to:	
Toxicological reference values			
ADI (mg/kg bw/day):	0.023	ARfD (mg/kg bw):	0.1
Source of ADI:	EC	Source of ARfD:	EC
Year of evaluation:	2021	Year of evaluation:	2021

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		MRL / input for RA Exposure		Highest % of ARfD/ADI		MRL / input for RA Exposure	
	Processed commodities		(mg/kg) (µg/kg bw)		Processed commodities		(mg/kg) (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%	Oat / boiled	0 / 0.05	0.18	0.2%	Wheat / bread	0 / 0.05	0.17
0.2%	Barley / cooked	0 / 0.05	0.18	0.08%	Oat / boiled	0 / 0.05	0.08	
0.2%	Rye / milling (wholemeal)-l	0 / 0.05	0.18					
0.2%	Oat / milling (flakes)	0 / 0.05	0.15					
0.1%	Barley / milling (flour)	0 / 0.05	0.09					
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.								

<h1>Triazole alanine (TA)</h1>			
LOQs (mg/kg) range from:		to:	
Toxicological reference values			
ADI (mg/kg bw/day):	0.3	ARfD (mg/kg bw):	0.3
Source of ADI:	EC	Source of ARfD:	EC
Year of evaluation:	2018	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		MRL / input for RA Exposure		Highest % of ARfD/ADI		MRL / input for RA Exposure	
	Processed commodities		(mg/kg) (µg/kg bw)		Processed commodities		(mg/kg) (µg/kg bw)	
	3%	Wheat / milling (flour)	0 / 0.62	7.5	1%	Barley / beer	0 / 0.12	4.5
	1%	Wheat / milling (wholemea	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%	Oat / boiled	0 / 0.62	2.3	0.7%	Wheat / bread	0 / 0.62	2.2
0.8%	Barley / cooked	0 / 0.62	2.3	0.3%	Oat / boiled	0 / 0.62	0.94	
0.7%	Rye / milling (wholemeal)-l	0 / 0.62	2.2					
0.6%	Oat / milling (flakes)	0 / 0.62	1.9					
0.4%	Barley / milling (flour)	0 / 0.62	1.1					
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 alanine (TA) is unlikely to present a public health risk.								
For processed commodities, no exceedance of the ARfD/ADI was identified.								

<h1 style="text-align: center;">Triazole acetic acid (TAA)</h1>			
LOQs (mg/kg) range from:		to:	
Toxicological reference values			
ADI (mg/kg bw/day):	1	ARfD (mg/kg bw):	1
Source of ADI:	EC	Source of ARfD:	EC
Year of evaluation:	2018	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		MRL /input for RA Exposure		Highest % of ARfD/ADI		MRL /input for RA Exposure	
	Processed commodities		(mg/kg) (µg/kg bw)		Processed commodities		(mg/kg) (µg/kg bw)	
	1.0%	Wheat / milling (flour)	0 / 0.79	9.6	0.6%	Barley / beer	0 / 0.16	5.7
	0.4%	Wheat / milling (wholemea	0 / 0.79	4.4	0.3%	Wheat / bread/pizza	0 / 0.79	3.5
	0.3%	Rye / boiled	0 / 0.79	2.9	0.3%	Wheat / pasta	0 / 0.79	3.0
	0.3%	Oat / boiled	0 / 0.79	2.9	0.3%	Wheat / bread	0 / 0.79	2.8
0.3%	Barley/ cooked	0 / 0.79	2.9	0.1%	Oat / boiled	0 / 0.79	1.2	
0.3%	Rye / milling (wholemeal)-l	0 / 0.79	2.8					
0.2%	Oat / milling (flakes)	0 / 0.79	2.4					
0.1%	Barley/ milling (flour)	0 / 0.79	1.4					
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.								

<h2 style="text-align: center;">Triazole lactic acid (TLA)</h2>			
LOQs (mg/kg) range from:		to:	
Toxicological reference values			
ADI (mg/kg bw/day):	0.3	ARID (mg/kg bw):	0.3
Source of ADI:	EC	Source of ARID:	EC
Year of evaluation:	2018	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		MRL /input for RA (mg/kg)		Highest % of ARfD/ADI		MRL /input for RA (mg/kg)	
	Processed commodities		Exposure (µg/kg bw)		Processed commodities		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 (wholemea	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%	Oat / boiled	0 / 0.02	0.08	0.03%	Wheat / bread	0 / 0.02	0.08
0.0%	Barley / cooked	0 / 0.02	0.08	0.01%	Oat / boiled	0 / 0.02	0.03	
0.0%	Rye / milling (wholemeal)-l	0 / 0.02	0.08					
0.0%	Oat / milling (flakes)	0 / 0.02	0.07					
0.0%	Barley / milling (flour)	0 / 0.02	0.04					
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.								

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

1 - Forages		STMR	HR	PF	CF	Default PF	STMR by-P	HR by-P
Alfalfa	forage (green)			-		-		
Alfalfa	hay (fodder)					2.5		
Alfalfa	meal					2.5		
Alfalfa	silage					1.1		
Barley	forage			-		-		
Barley	straw	0.65	2.50	-	3.0	-	1.95	7.50
Barley	silage					1.3		
Bean	vines (fodder green)			-		-		
Beet, mangel	fodder			-		-		
Beet, sugar	tops			-		-		
Cabbage, heads	leaves	0.01	0.06	-	2.0	-	0.02	0.12
Clover	forage			-		-		
Clover	hay					3		
Clover	silage					1		
Com, field	forage/silage	0.01	0.01	-		-	0.01	0.01
Com, field	stover (fodder)			-		-		
Com, pop	stover (fodder)			-		-		
Cowpea	forage			-		-		
Cowpea	hay					2.9		
Grass	forage (fresh)			-		-		
Grass	hay					3.5		
Grass	silage					1.6		
Kale	leaves (forage)			-		-		
Lespedeza	forage			-		-		
Lespedeza	hay					4		
Millet	forage			-		-		
Millet	straw (fodder, dry)			-		-		
Oat	forage			-		-		
Oat	hay					3		
Oat	straw	0.42	2.50	-	3.0	-	1.26	7.50
Pea	vines (green)			-		-		
Pea	hay (hay or fodder)					3.5		
Pea	silage					1.6		
Rape	forage			-		-		
Rice	straw			-		-		
Rye	forage (greens)			-		-		
Rye	straw	2.25	5.52	-		-	2.25	5.52
Sorghum	forage			-		-		
Sorghum, grain	stover			-		-		
Sorghum	silage					0.6		
Soybean	forage (green)			-		-		
Soybean	hay (fodder)					1.5		
Soybean	silage					0.5		
Trefoil	forage			-		-		
Trefoil	hay					2.8		
Triticale	forage			-		-		
Triticale	hay					2.9		
Triticale	straw	0.15	0.96	-		-	0.15	0.96
Tumip	tops (leaves)			-		-		
Vetch	forage			-		-		
Vetch	hay					2.8		
Wheat	forage			-		-		
Wheat	hay (fodder dry)					3.5		
Wheat	straw	2.69	5.52	-		-	2.69	5.52

2 - Roots & Tubers		STMR	HR	-	CF	-	STMR	HR
Carrot	culls	0.08	0.10				0.08	0.10
Cassava/tapioca	roots							
Potato	culls	0.01	0.01				0.01	0.01
Swede	roots	0.08	0.10				0.08	0.10
Turnip	roots	0.08	0.10				0.08	0.10
3 - Cereal grains/Crop seeds		STMR	Post-h?	HR	CF	-	STMR	HR
Barley	grain	0.07	N				0.07	
Bean	seed (dry)	0.01	N		2.0		0.02	
Corn, field (Maize)	grain	0.01	N		2.0		0.02	
Corn, pop	grain	0.01	N		2.00		0.02	
Cotton	undelinted seed	0.05	N		2.0		0.10	
Cowpea	seed		N					
Lupin	seed	0.05	N		2.0		0.10	
Millet	grain		N					
Oat	grain	0.06	N				0.06	
Pea (Field pea)	seed (dry)	0.05	N		2.0		0.10	
Rye	grain	0.06	N				0.06	
Sorghum	grain		N					
Soybean	seed	0.05	N		2.0		0.10	
Triticale	grain	0.06	N				0.06	
Wheat	grain	0.06	N				0.06	
4 - By-products		STMR	-	PF	CF	Default PF	STMR by-P	-
Apple	pomace, wet					5		
Beet, sugar	dried pulp					18		
Beet, sugar	ensiled pulp					3		
Beet, sugar	molasses					28		
Brewer's grain	dried	0.07		3.3		3.3	0.23	
Canola (Rape seed)	meal	0.08				2	0.16	
Citrus	dried pulp					10		
Coconut	meal					1.5		
Corn, field	milled by-pdts	0.01			2.0	1	0.02	
Corn, field	hominy meal	0.01			2.0	6	0.12	
Corn, field	gluten feed	0.01			2.0	2.5	0.05	
Corn, field	gluten, meal	0.01			2.0	1	0.02	
Cotton	meal	0.05			2.0	1.3	0.13	
Distiller's grain	dried	0.06			2.0	3.3	0.40	
Flaxseed/Linseed	meal	0.03			2.0	2	0.12	
Lupin seed	meal	0.05			2.0	1.1	0.11	
Palm (hearts)	kernel meal					2		
Peanut	meal	0.01			2.0	2	0.04	
Potato	process waste	0.01		1.0		20	0.01	
Potato	dried pulp	0.01		1.0		38	0.01	
Rape	meal	0.08				2	0.16	
Rice	bran/pollard					10		
Safflower	meal					2		
Soybean	meal	0.05			2.0	1.3	0.13	
Soybean	hulls	0.05			2.0	13	1.30	
Sugarcane	molasses					32		
Sunflower	meal	0.01		2.0	2.0	2	0.04	
Wheat gluten	meal	0.06				1.8	0.11	
Wheat	milled by-pdts	0.06				7	0.42	