REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: FGF11

Product name(s): Telaron Alpha / Patton Alpha

Azoxystrobin 160 g/L + Prothioconazole 200 g/L SC

Chemical active substance(s):

Azoxystrobin, 160 g/L

Prothioconazole, 200 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: UPL Holdings Coöperatief U.A.

Submission date: October 2024,
update January 2025, May 2025, December 2025, January 2026

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update August 2025, January 2026
February 2026 (final Core Assessment)

Version history

When	What
November 2024	Initial version prepared by the applicant
January 2025	V2 – Revised version from Applicant following request from evaluator. All changes are highlighted in green.
May 2025	V3 – Revised version from Applicant following request from evaluator. All changes are highlighted in purple.
May 2025	Initial zRMS assessment The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are ~~struck through~~ and shaded for transparency. Following the evaluation and before sending the document for commenting, all coloured highlighting was removed, from the parts updated by the Applicant, for better legibility.
August 2025	Core Assessment updated following the commenting period Additional information/assessments included by the zRMS in the report in response to comments received from the cMS and the Applicant are highlighted in yellow. Not agreed or not relevant information are ~~struck through~~ and shaded for transparency.
December 2025	Core Assessment updated post following the commenting period Additional information added following request by the zRMS (storage stability of metabolite residues in oilseed rape) are highlighted in green. Not agreed or not relevant information are ~~struck through~~ and shaded for transparency
January 2026	Core Assessment updated following the addition of the new storage stability study assessment Additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in purple. Not agreed or not relevant information are ~~struck through~~ and shaded for transparency.
February 2026	Final Core Assessment updated following the commenting period Additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in blue. Not agreed or not relevant information are ~~struck through~~ and shaded for transparency.

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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 FGF11 are presented in Table 7.1-1. They have been selected from the individual GAPs in the CEU for cereals and oilseed rape. A list of all intended uses within the CEU is given in Part B, Section 0.

Overall conclusion
The data available are considered sufficient for risk assessment. An exceedance of the current MRLs for azoxystrobin and prothioconazole as laid down in Reg. (EU) 396/2005 is not expected.
The chronic and the short-term intakes of azoxystrobin and prothioconazole residues are unlikely to present a public health concern.
As far as consumer health protection is concerned, zRMS-PL agrees with the authorization of the intended use(s).

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

Data gaps
Noticed data gaps are:

- ~~Storage stability study for oilseeds for 1,2,4-T and TA. This data gap should be filled at post-registration~~

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

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

1	2	3	4	5	6	7		8				9			10	11
GAP number (see part B.0)*	**Crop and/ or situation ****	**Zone**	**Product code**	**F, Fn, Fpn G, Gn, Gpn or I*****	**Pests or Group of pests controlled**	**Formulation**		**Application**				**Application rate per treatment**			**PHI (days)**	**Conclusion**
						Type	**Conc. of as**	**method kind**	**growth stage & season**	**number min max**	**interval between applications (min)**	**kg as/hL min max**	**water L/ha min max**	**kg as/ha min max**		
1, 2	Winter wheat (TRZAW), Spring wheat (TRZAS), Durum wheat (TRSDU), Spelt wheat (TRZSP), Winter triticale (TTLWI), Spring triticale (TTLSO), Winter rye (SECCW), Spring rye (SECCS)	CEU ~~+ SEU~~	FGF11	F	Wheat: septoria leaf blotch (Zymoseptoria tritici) (SEPTTR), yellow rust (Puccinia striiformis) (PUCCST) brown rust (Puccinia recondita) (PUCCRE) Fusarium (microdochium nivale, Fusarium roseum)	SC	160g/L Azyst. 200g/L Prothio.	Foliar spray	BBCH 30-69	1	-	40-160g/hL Azyst. 50-200g/hL Prothio.	100-400	Prothioconazole 200 g/ha Azoxystrobin 160 g/ha	35	A
3	Winter barley (HORVW), Spring barley (HORVS)	CEU ~~+ SEU~~	FGF11	F	Net blotch (Pyrenophora teres) (PYRNTE) Ramularia (Ramularia collo-cygni) Leaf blotch (Rhyn-chosporium secali) Rust (Puccinia hordeii)	SC	160g/L Azyst. 200g/L Prothio	Foliar spray	BBCH 30-59	1	-	40-160g/hL Azyst. 50-200g/hL Prothio.	100-400	Prothioconazole 200 g/ha Azoxystrobin 160 g/ha	35	A
4	Winter oilseed rape (BRSNW), Spring oilseed rape (BRSNS)	CEU ~~+ SEU~~	FGF11	F	Cottony rot (Sclerotinia sclerotorium) (SCLESC) Black spot	SC	160g/L Azyst. 200g/L Prothio	Foliar spray	BBCH 61-73	1	-	40-160g/hL Azyst. 50-	100-400	Prothioconazole 200 g/ha Azoxystrobin 160 g/ha	35	~~R See remark below~~ A

					(Alternaria brassicae) (ALTESP)							200g/hL Prothio.				

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

Explanation for Column 11 “Conclusion”

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

~~Remark:~~

- ~~The interval from sampling until extraction for 1,2,4-T and TA in the Bousquet's study (647-2023; 2023) was longer than the storage stability period for 1,2,4-T and TA in oilseed rape from S. Baxter, B. Phipps study (QG/21/002). **Therefore additional data on storage stability for 1,2,4-T and TA in oilseed rape are required (data gap).**~~

7.1.2 Summary of the evaluation

The preparation FGF11 is composed of Azoxystrobin and prothioconazole.

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, developmental study	100
ArfD			0.01 mg/kg bw	Rat, developmental study	100
Prothioconazole					
ADI	EFSA Scientific Report (2007) 106, 1-98	2007	0.05 mg/kg bw/d	Rat, developmental study	100
ArfD			0.2 mg/kg bw	Rat, developmental study	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	
Azoxystrobin					
ADI	EFSA Journal 2010; 8(4):1542	2010	0.2 mg/kg bw/d	2-year rat	100
ArfD			Not necessary	-	-

7.1.2.1 Summary for Azoxystrobin

Table 7.1-3: Summary for Azoxystrobin

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
1, 2, ~~3, 4~~, 5, 6 ~~9, 10, 11, 12~~	Spring and winter wheat (TRZAS, TRZAW), rye (SECCW), triticale (TTLSS)	Yes	Yes	Yes	Yes	Yes	No	No
~~5, 6~~ 3,	Spring and winter barley (HORVS, HORVW)	Yes	Yes	Yes	Yes	Yes		No
~~7, 8~~ 4	Winter oilseed rape (BRSNW), spring oilseed rape (BRSNS),	Yes	Yes	Yes	Yes	Yes		No

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

The effects of processing on the nature of azoxystrobin residues were not considered necessary 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.

7.1.2.2 Summary for Prothioconazole

Table 7.1-4: Summary for Prothioconazole

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
1, 2, ~~3, 4~~, 5, 6 ~~9, 10, 11, 12~~	Spring and winter wheat (TRZAS, TRZAW), Rye	Yes	Yes	Yes	Yes	Yes	No	No

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?
	(SECCW), triticale (TTLSS)							
~~5, 6~~ 3,	Spring and Winter barley (HORVS, HORVW)	Yes	Yes	Yes	Yes	Yes		No
~~7, 8~~ 4	Winter oilseed Rape (BRSNW), spring oilseed rape (BRSNS),	Yes	Yes	Yes	Yes	Yes		No

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

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

Residues of prothioconazole residues (except TDMs) in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. It is very unlikely that residues exceeding residues in primary crops will be present in succeeding crops.
Regarding TDMs, in the framework of the confirmatory data, several field rotational crop trials have been conducted to investigate the magnitude of TDM residues in rotational crops after the use of triazole active substances. Residues of TA, TLA and TAA were found above 0.01 mg/kg in succeeding crops. These results were considered in the consumer risk assessment performed in the framework of the review of TDMs confirmatory data.

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

7.1.2.3 Summary for FGF11

Table 7.1-5: Information on FGF11 (KCA 6.8)

Crop	PHI for FGF11 proposed by applicant	PHI/ Withholding period* sufficiently supported for		PHI for FGF11 proposed by zRMS	zRMS Comments (if different PHI proposed)
		Azoxystrobin	Prothioconazole		
Spring and winter	35	Yes	Yes	35	-

Crop	PHI for FGF11 proposed by applicant	PHI/ Withholding period* sufficiently supported for		PHI for FGF11 proposed by zRMS	zRMS Comments (if different PHI proposed)
		Azoxystrobin	Prothioconazole		
wheat (TRZAS, TRZAW), rye (SECCW), triticale (TTLSS)					
Spring and winter barley (HORVS, HORVW)	35	Yes	Yes	35	-
Winter oilseed rape (BRSNW), spring oilseed rape (BRSNS),	35	Yes	Yes	35	-

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

Table 7.1-6: Waiting periods before planting succeeding crops

Waiting period before planting succeeding crops				Overall waiting period proposed by zRMS for FGF11
Crop group	Led by Azoxystrobin	Led by Prothioconazole	Led by TDMs	
Spring and winter wheat (TRZAS, TRZAW), rye (SECCW), triticale (TTLSS)	~~NR~~ Not needed	~~NR~~ Not needed	~~NR~~ Not needed	Not needed
Spring and winter barley (HORVS, HORVW)	~~NR~~ Not needed	~~NR~~ Not needed	~~NR~~ Not needed	Not needed
Winter oilseed rape (BRSNW), spring oilseed rape (BRSNS),	~~NR~~ Not needed	~~NR~~ Not needed	~~NR~~ Not needed	Not needed
All crops	Not needed	Not needed	Not needed	Not needed

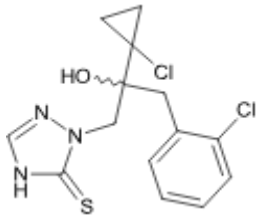
NR: not relevant

Assessment

7.2 Prothioconazole

General data on prothioconazole are summarized in the table below (last updated 2024/08/14)

Table 7.2-1: General information on prothioconazole

Active substance (ISO Common Name)	Prothioconazole
IUPAC	(RS)-2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]- 2,4-dihydro-1,2,4-triazole-3-thione
Chemical structure	
Molecular formula	$C_{14}H_{15}Cl_2N_3OS$
Molar mass	344.26 g/mol
Chemical group	Triazole fungicides
Mode of action (if available)	Steroid demethylation (ergosterol biosynthesis)
Systemic	Yes
Company (ies)	Bayer CropScience AG
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) 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 2024/1318 of 15 May 2024
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): 2018)**
EFSA Journal: conclusion on article 12	Yes (EFSA, 2014 and EFSA 2020)**
Current MRL applications on intended uses	EFSA-Q-2019-00353 (UK) Oilseed rape Status: Reasoned opinion available (EFSA Journal 2020;18(2):5999)

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 United Kingdom, 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 (United Kingdom, 2018, EFSA,
No new data submitted in the framework of this application.

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-hydroxydesthio achieved at ≤ - 18°C (unless stated otherwise)

Matrix	Characteristics of the matrix according to SANTE/2020/12830, Rev.2	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products			
Wheat green material	High water content	540 days Prothioconazole-desthio (JAU 6476-desthio)	DAR, UK (2004) EFSA, 2014
Wheat grain	Dry commodity (high starch content)	540 days Prothioconazole-desthio (JAU 6476-desthio)	DAR, UK (2004) EFSA, 2014
Wheat straw	Dry commodity	540 days Prothioconazole-desthio (JAU 6476-desthio)	DAR, UK (2004) EFSA, 2014
Rapeseeds	High oil content	24 months Prothioconazole-desthio,	EFSA, 2014
Animal Products			
Ruminant	Liver, kidney, muscle, fat & milk	1 month Prothioconazole-desthio, Prothioconazole-3-hydroxy-desthio (M14), Prothioconazole-4-hydroxy-desthio (M15)	DAR, UK, (2004) EFSA, 2014
New data			
Animal Products			
Honey	No group	13 months Prothioconazole-desthio	Giancola, D., 2023, KCP 8.1/01 – Report No. QG21007
Honey	No group	13 months Prothioconazole-α-hydroxy-desthio, Prothioconazole-3-hydroxy-desthio, Prothioconazole-4-hydroxy-desthio, Prothioconazole-5-hydroxy-desthio, Prothioconazole-6-hydroxy-desthio	Giancola, D., 2023, KCP 8.1/01 – Report No. QG21007
Plant products[2]			
[2] Stability data in plant products, to support the use of FGF11 on wheat, barley and oilseed rape, are considered to be covered by 'Data rhelied on in EU', which is unprotected. In addition, the applicant submits a study (Study No. QG/21/001, KCP 8.1-03), to investigate the stability of residues of prothioconazole-desthio (and the 5 hydroxy metabolites) in oilseed rape (seed), field bean (dried), orange, wheat forage, wheat grain and wheat straw stored under deep freeze storage conditions (≤-18°C) for a period of 12 months.			

Matrix	Characteristics of the matrix according to SANTE/2020/12830, Rev.2	Acceptable Maximum Storage duration	Reference
Wheat forage	High water content	24 months Prothioconazole-α-hydroxy-desthio, Prothioconazole-3-hydroxy-desthio, Prothioconazole-4-hydroxy-desthio, Prothioconazole-5-hydroxy-desthio, Prothioconazole-6-hydroxy-desthio 12 months Prothioconazole-6-hydroxy-desthio	KCP 8.1-03 Giancola, D., 2025, study No.: QG/21/001
oilseed rape seed	High oil content	24 months Prothioconazole-desthio Prothioconazole-α-hydroxy-desthio Prothioconazole-3-hydroxy-desthio Prothioconazole-4-hydroxy-desthio Prothioconazole-5-hydroxy-desthio Prothioconazole-6-hydroxy-desthio 18 months Prothioconazole-4-hydroxy-desthio 12 months Prothioconazole-5-hydroxy-desthio 6 months Prothioconazole-6-hydroxy-desthio	
field bean (dried)	High protein content	24 months Prothioconazole-desthio Prothioconazole-α-hydroxy-desthio Prothioconazole-3-hydroxy-desthio Prothioconazole-4-hydroxy-desthio Prothioconazole-5-hydroxy-desthio Prothioconazole-6-hydroxy-desthio 12 months Prothioconazole-α-hydroxy-desthio 18 months Prothioconazole-3-hydroxy-desthio	
orange	High acid content	24 months Prothioconazole-desthio Prothioconazole-α-hydroxy-desthio Prothioconazole-3-hydroxy-desthio Prothioconazole-4-hydroxy-desthio Prothioconazole-5-hydroxy-desthio Prothioconazole-6-hydroxy-desthio	
wheat grain	High starch content	24 months Prothioconazole-α-hydroxy-desthio Prothioconazole-3-hydroxy-desthio Prothioconazole-4-hydroxy-desthio Prothioconazole-5-hydroxy-desthio Prothioconazole-6-hydroxy-desthio 12 months Prothioconazole-6-hydroxy-desthio	
wheat straw	Dry commodity	24 months Prothioconazole-α-hydroxy-desthio Prothioconazole-3-hydroxy-desthio Prothioconazole-4-hydroxy-desthio Prothioconazole-5-hydroxy-desthio Prothioconazole-6-hydroxy-desthio	

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

Matrix	Characteristics of the matrix according to SANTE/2020/12830, Rev.2	Acceptable Maximum Storage duration (months)				Reference
		1,2,4-Triazole	TA	TAA	TLA	
Data relied on in EU						
Plant products						
Barley, wheat grain	Dry commodity (high starch content)	12	26	26	48	EFSA 2018b (amended 2019), EFSA 2020
Barley, wheat straw	Dry commodity	12	53	40	48[1]	EFSA 2018b (amended 2019), EFSA 2020
Rapeseeds, soya beans	High oil content commodity	12 (soya beans only; not stable in rape seed)	26 (soya bean only; not stable in rape seed)	53	48	EFSA 2018b (amended 2019), EFSA 2020
Dry peas, navy beans	Dry commodity (high protein content)	No data	15	25	48	EFSA 2018b (amended 2019), EFSA 2020
Oranges	High acid content commodity	No data	No data	No data	48	EFSA 2018b (amended 2019), EFSA 2020
Apples, tomatoes, mustard leaves, wheat forage, radishes tops/roots, turnip roots, sugar beet roots, cabbages, lettuces	High water content commodity	6	53	53	48	EFSA 2018b (amended 2019), EFSA 2020
[1] Considered to be covered by 5 matrices (high starch, high protein, high oil, high acid and high water) and dry commodity data (wheat grain, dry peas and navy beans) according to SANTE/2020/12830, Rev.2.						
Animal Products						
Ruminant	Milk	18	No data	No data	No data	EFSA 2018b (amended 2019), EFSA 2020
	Eggs	12	No data	No data	No data	
	Liver	12	No data	No data	No data	
	Muscle	12	No data	No data	No data	
	Fat	12	No data	No data	No data	
New data						
Plant products						
Oilseed rape seed	High oil content commodity	15 days	~~12~~ 15 days	12	12	Baxter, B. Phipps, 2025, KCP 8.1-04 – Report No. QG/21/002
Field bean (dried)	Dry commodity (high protein content)	12	~~12~~ 1	12	12	
Wheat grain	Dry commodity (high starch content)	12	~~12~~ 6	12	12	
Wheat straw	-	12	~~12~~ 1	12	12	
Oranges	High acid content commodity	~~12~~ 6	12	12	12	
Wheat forage	High water content commodity	12	12	12	12	
New data						
Oilseed rape seed	High oil content commodity	~~Up to 90 days~~ ~~12~~ 90 days	~~12~~ 90 days	~~12~~ 90 days	~~9~~ 90 days	Sandro Jooß, 2025 Study Code S23-105428 ~~ongoing~~ KCP 8.1/05

Matrix	Characteristics of the matrix according to SANTE/2020/12830, Rev.2	Acceptable Maximum Storage duration (months)				Reference
		1,2,4-Triazole	TA	TAA	TLA	
Cereal grain	Dry commodity (high starch content)	~~Up to 12 months~~ ~~90 days~~ 12 months	~~90 days~~ 12 months	~~90 days~~ 12 months	~~90 days~~ 12 months	Sandro Jooß, 2025 Study Code S23-105428 ~~Ongoing~~ KCP 8.1/05
Animal Products						
Honey		6	6	6	6	Mealing, H., 2024 KCP 8.1-02 – Report No. QG21006

Conclusion on stability of residues during storage

Prothioconazole

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

The storage stability of prothioconazole-desthio in plant samples stored under frozen conditions was further investigated in the framework of the Art. 12 MRL review (EFSA 2014).
The hydroxylated metabolites were demonstrated to be stable for 24 months in high-water (tomato), high starch (potato), high oil (soya beans, oilseed rape) and high acid (orange) commodities when stored at 18°C (EFSA 2020).

New storage stability study is now submitted (Giancola, D., 2024, Study No. QG/21/001 by the applicant to confirm the stability of residues of prothioconazole-desthio and five hydroxylated metabolites stored under deep freeze storage conditions. The stability of the five hydroxylated metabolites in wheat (grain, forage and straw) and in oilseed rape seed, was demonstrated (mean recovery of each analyte at each interval was in the range of 70% to 120%) under deep freeze storage conditions (≤ -18°C) for at least 24months. The exceptions - please see zRMS comments below.

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

TDMs

The freezer storage stability of various TDMs was investigated in the framework of the peer review of TDMs (UK, 2018b, EFSA, 2018b, amended 2019). The data is additionally included in the evaluation of confirmatory data following the Article 12 MRL review of prothioconazole (EFSA 2020): In the commodity groups relevant for the envisaged GAP uses, the stability of all TDMs has been demonstrated as detailed in Table 7.2-3.
New storage stability study is now submitted (Baxter, B. Phipps, 2025, Study No. QG/21/002 and Jooß S, 2025, Study ID KCP 8.1/05) by the applicant to confirm the stability of residues of T, TA, TAA and TLA stored under deep freeze storage conditions. The stability of the TDMs in wheat (grain, forage and straw) and in oilseed rape seed, was demonstrated (mean recovery of each analyte at each interval was in the range of 70% to 120%) under deep freeze storage conditions (≤ -18°C) for at least 12 months. The exception to this was 1,2,4-triazole and TA in oilseed rape seed which, was shown to be stable for at least ~~15 days~~ 90 days.

An Access Agreement for the TDMG study [redacted];2020; Study ID: 869333, KCA 6.1/03 is provided, where the data demonstrates stability of TA, TLA and TAA under deep freeze conditions (<-18°C) for 6 months in milk, cream, eggs, liver, kidney, muscle and fat.

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

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

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

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

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

Remark:
The studies on the magnitude of residues in wheat (Lebrun 2024; 645-2023) and barley (Bougrier 2024; 646-2023) are valid with regard to storage stability.
The Bousquet's study (647-2023; 2023) on the magnitude of residues of the PTZ-OH-desthio metabolites is valid with regard to storage stability. The interval from sampling until extraction for 1,2,4-T and TA in this study was longer than the storage stability period for 1,2,4-T and TA in oilseed rape from S. Baxter, B. Phipps study (QG/21/002). **Therefore additional data on storage stability for 1,2,4-T and TA in oilseed rape are required (data gap). Please see comment below.**

Honey
New studies on the storage stability of prothioconazole-desthio and its hydroxy metabolites (Giancola, D., 2023; Study No.: QG/21/007) and triazole derivative metabolites (TDMs): 1,2,4-triazole, triazole alanine, triazole acetic acid and triazole lactic acid (Mealing H., 2024; Study No.: QG/21/006) in honey were submitted in the framework of this application.
Residues of prothioconazole-desthio and 5 hydroxy metabolites: prothioconazole-α-hydroxy-desthio,

prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio and prothioconazole-6-hydroxy-desthio are considered to be stable in honey when stored frozen (<-18°C) for 13 months. Residues of triazole derivative metabolites (TDMs): 1,2,4-triazole, triazole alanine, triazole acetic acid and triazole lactic acid are considered to be stable in honey when stored frozen (<-18°C) for 6 months.
No significant degradation was demonstrated (<30% of nominal).
The studies were conducted according to the OECD 506 and are acceptable.
More details of these studies are provided in Appendix 2.

Conclusion:
Sufficient stability data for cereals are available to support the residue data presented in the present dossier. **Further storage stability data are required for 1,2,4-Triazole and TA in oilseeds.**

The Applicant provided information on an ongoing new study:
Study title: "Storage Stability of the Triazole Derivative Metabolites (TDMs) in Plant Matrices under Deep Frozen Conditions"; Study Code S23-105428. Lab: Eurofins Agroscience Services EAG Laboratories GmbH. Study Director: Sandro Jooß

- 1,2,4-T, TAA, TLA, TA in oilseed rape seeds (up to 90 days) and cereal grain (up to 12 months).

January 2026:
Applicant provided final report of study: "Storage Stability of the Triazole Derivative Metabolites (TDMs) in Plant Matrices under Deep Frozen Conditions"; Study Code S23-105428. Lab: Eurofins Agroscience Services EAG Laboratories GmbH. Study Director: Sandro Jooß.

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

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

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

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

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

7.2.2 Nature of residues in plants, livestock and processed commodities

7.2.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

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

No new data submitted in the framework of this application.

Table 7.2-4: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (kg a.s./ha)	No (interval in days)	Sampling (DAT)	Remarks	
EU data								
Cereals	Wheat	[U-^{14}C-phenyl] prothioconazole	foliar treatment, G (spring wheat)	0.20	2	Forage: 6 Hay: 26 Grain & straw: 48	The plants were grown under environmental conditions (sunlight and temperatures). A glass roof protected the plants from rainfall. The soil was surface irrigated	DAR, UK 2004. EFSA, 2007
		[3,5-^{14}C-triazole] prothioconazole-desthio	foliar treatment, G (summer wheat)	0.25	2	Forage: 0, 14 Grain & straw: 48	The plants were grown under environmental conditions (sunlight and temperatures). A glass roof protected the plants from rainfall. The soil was surface irrigated	DAR, UK 2004. EFSA, 2007
		[3,5-^{14}C-triazole] prothioconazole-desthio	foliar treatment, F (spring wheat)	0.18 and 0.29	2	Forage, hay, grain, straw	1 day after application, the soil tub was moved to the outside of the greenhouse	JMPR: FAO, 2008a, 2008b EFSA, 2014
		[U-^{14}C-phenyl] prothioconazole	Seed, G (spring wheat)	0.02 or 0.10 kg/100 kg seeds (*ca*. 220 kg seeds/ha	1	Forage: 57 Hay: 110 Grain & straw : 153		DAR, UK 2004. EFSA, 2007
Pulses and oilseeds	Peanut	[U-^{14}C-phenyl] prothioconazole	Foliar, G	0.30	3	Hay & nuts without shells: 14		DAR, UK 2004. EFSA, 2007.
		[3,5-^{14}C-triazole] prothioconazole-desthio	Foliar, G	0.30	3	Hay & nuts without shells: 14		JMPR: FAO, 2008a, 2008b EFSA, 2014.
Root crops	Sugar beet	[U-^{14}C-phenyl] prothioconazole	Foliar, G	0.29	4	Roots, tops, leaves: 7		EFSA, 2014

		[3,5-^{14}C-triazole] prothioconazole-desthio	Foliar, G	0.29	4	Roots, tops, leaves: 7		EFSA, 2014

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

Summary of plant metabolism studies reported in the EU

According to EFSA, 2007: *"Prothioconazole is extensively metabolised. In a first step the sulphur group of the triazolinethione ring is oxydised to the corresponding sulfonic acid. Subsequent elimination of the sulfonic acid moiety results in prothioconazole-desthio (metabolite M04) which is consistently the major prothioconazole-structurally related metabolite in all plant parts and for all growth stages, except in nutmeat, where it was not found. This metabolite is further hydroxylated in the chlorophenlyl ring forming various hydroxyl-desthio isomers and dihydroxy-olefins. Similarly, α-hydroxylation of prothioconazoledesthio 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: *"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 asseseement, 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 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 derivatinve metabolites (TDMs) were identified. […] Based on the metabolic pattern identified in the 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 residues 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, 2018 (amended by EFSA, 2019 and EFSA, 2020), the following residue definitions are proposed based on the plant metabolism data:

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:

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

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

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

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

No further data are required.

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

Reference is made to the EU peer review (EFSA, 2007, DAR United Kingdom, 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 (United Kingdom, 2018, EFSA, 2018, amended 2019). No new data submitted in the framework of this application.

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

Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G *	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks	
EU data								
Leafy vegetables	Swiss chard	U-^{14}C-phenyl] prothioconazole	Bare soil application	1 x 0.58	28,146,269	80, 188, 348	-	DAR, UK, 2004
Root and tuber vegetables	Turnip	U-^{14}C-phenyl] prothioconazole	Bare soil application	1 x 0.58	28,146,269	Roots, tops: 94, 201, 349	-	EFSA, 2007
Cereals	Spring wheat	U-^{14}C-phenyl] prothioconazole	Bare soil application	1 x 0.58	28,146,269	Green material: 73, 178, 327 Hay: 111, 231, 377 Grain, straw: 145, 269, 412	-	
Leafy vegetables	Swiss chard	U-^{14}C-phenyl] prothioconazole	Bare soil application	4 x 0.204	30,125,366	77, 169, 406	-	FAO, 2009a,b;EFSA, 2014, 2023
Root and tuber vegetables	Turnip	U-^{14}C-phenyl] prothioconazole	Bare soil application	4 x 0.204	30,125,366	113, 195, 420	-	FAO, 2009a,b;EFSA, 2014, 2023
Cereals	Wheat	U-^{14}C-phenyl] prothioconazole	Bare soil application	4 x 0.204	30,125,366	Green material: 62, 154, 388 Hay: 80, 171, 420 Grain, straw: 121, 209, 450	-	FAO, 2009a,b;EFSA, 2014, 2023

Summary of plant metabolism studies reported in the EU

United Kingdom, 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."

Summary of new plant metabolism studies
No new studies have been submitted.

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."

According to the EFSA, 2023, *"Swiss chards, turnips and spring wheat were grown in soil treated with prothioconazole at a rate of 4 x 204 g/ha. The studies indicate the cleavage of triazole linkage to form major metabolites TA, TLA and TAA, whereas parent prothioconazole and prothioconazole-desthio were identified as minor metabolites (EFSA, 2014). No free 1,2,4-triazole was detected in any matrix (FAO, 2009a,b)."*

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

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

zRMS comments:
No new plant metabolism studies in rotational crops are provided. Information given by the Applicant is acceptable and sufficient.
In EFSA Journal 2020;18(2):5999 it is stated that *The metabolism of prothioconazole in rotational crops was investigated in the framework of the EU pesticides peer review in Swiss chards, turnips and spring wheat following the treatment of bare soil with prothioconazole at an application rate of 580 g/ha using the compound labelled in the phenyl ring. The main compounds identified were prothioconazole-desthio and its hydroxylated derivative metabolites, either free or conjugated.*
The MRL review concluded that metabolism of prothioconazole in primary and rotational crops was found to be similar and a specific residue definition for rotational crops is not necessary (EFSA, 2014).

The metabolism of prothioconazole labelled in triazole ring was assessed by the JMPR (FAO, 2009a) as reported in the MRL review. The studies indicate the cleavage of triazole linkage to form major metabolites TA, TLA and TAA (EFSA, 2014). During the peer review of TDMs in light of confirmatory data, the metabolism of various triazole compounds in rotational and primary crops was investigated.
It was concluded that for TDMs similar metabolic patterns were depicted both in primary and rotational crops (EFSA, 2018b).

No further data are required.

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data
Reference is made to the EU peer review (EFSA, 2007, DAR United Kingdom, 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 (United Kingdom, 2018, EFSA, 2018, amended 2019).

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

Conditions (Duration, Temperature, pH)	Stable	Identified compound(s) (%)	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**		
EU data (TDMs)			
Pasteurisation (20 minutes, 90°C, pH 4)	**Yes**	Triazole-UL-^{14}C labelled triazole alanine, triazole acetic acid, triazole lactic acid and 1,2,4-Triazole; remain stable under sterilisation processes (96.4–100.5% of AR)	United Kingdom, 2018b
Baking, boiling, brewing (60 minutes, 100°C, pH 5)	**Yes**		
Sterilisation (20 minutes, 120°C, pH 6)	**Yes**		

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

TDMs

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

zRMS comments:
The effect on the nature of prothioconazole and prothioconazole-desthio has not been investigated in the framework of the EU pesticides peer review. EFSA concluded in the MRL review prothioconazole and prothioconazole-desthio remain stable during all processing conditions.
The TDMs are stable under hydrolysis studies simulating baking/brewing/boiling, pasteurisation and sterilisation (EFSA, 2018).
No further data are required.

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

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

Endpoints	
Plant groups covered	Pulses/oilseeds (peanuts) and root crops (sugar beet) foliar application Cereals (Wheat): foliar and seed application
Rotational crops covered	Swiss chard (leafy vegetables), turnip (root and tuber vegetables), spring wheat (cereals)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Prothioconazole-desthio is stable under standard hydrolysis conditions TDMs are stable under standard hydrolysis conditions.
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes
Plant residue definition for monitoring	Prothioconazole: prothioconazole-desthio (sum of isomers) (EFSA, 2020; Commission Regulation (EU) 2024/1318)
Plant residue definition for risk assessment	1) Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chloro-phenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers) 2) TA and TLA, since these compounds share the same toxicity; 3) TAA; 4) 1,2,4-T (EFSA, 2014; EFSA, 2018)
Conversion factor from enforcement to RA	EFSA, 2007: 2 (cereal grain and oilseeds) EFSA, 2014: Based on metabolism study results, the MRL review derived the following tentative conversion factors to account for hydroxy metabolites of prothioconazole-desthio: 2 in cereal grains, pulses and oilseeds, leafy vegetables and tuber vegetables and 3 in cereal straw 1 (maize - derived from metabolism study) EFSA, 2020: 2.7 (Root and tuber vegetables (except sugar beet)) A conversion factor of 2 for crops where no data according to the risk assessment residue definition are available and for which a risk management decision is pending: pulses, flowering brassica, Brussels sprouts, head cabbages, shallots, onions, leeks, rye, barley, oats

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

Available data

Reference is made to the EU peer review (EFSA, 2007, DAR United Kingdom, 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 (United Kingdom, 2018, EFSA, 2018, 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-^{14}C-phenyl]-labelled prothioconazole. Besides, two additional studies were assessed by the JMPR (FAO, 2008) on lactating goats and laying hens, using both [3,5-^{14}C-triazole]-labelled prothioconazole. The characteristics of these studies are summarised in the following table.

Table 7.2-8: Summary of animal metabolism studies

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

Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling	
Pigs	"Following prothioconazole administration to rats, metabolite 1,2,4-triazole was recovered in urine at minor amounts (2.3 % AR), whilst it was not recovered in goats. Therefore, meanwhile a harmonized approach on how to consider TDMs in the risk assessment, the general metabolic pathways in rodents and ruminants can be considered as comparable, mainly involving various types of hydroxylation affecting the chlorophenyl ring and leading to the formation of metabolites both under their free and glucuronide or sulphate conjugated forms. The metabolic pathway of prothioconazole-desthio depicted in ruminants can therefore be extrapolated to pigs."							EFSA, 2014
Fish	Not required, as residues of prothioconazole acc. to the residue definition for risk assessment > 0.1 mg/kg of the total diet in fish feed (dry weight basis) are not to be expected.							
New data								
No new data submitted in the framework of this application.								

Prothioconazole

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

For risk assessment, since all the metabolites are structurally related to prothioconazole-desthio and consist mainly in hydroxylated derivatives, EFSA assumes as a worst case that the toxicological end points allocated to prothioconazole-desthio should also be applied to these metabolites. The residue is therefore defined in all commodities of animal origin as the sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2- chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers). […] The log Po/w of prothioconazole-desthio equals 3.04 (EFSA, 2007b). 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."

Triazole derivative metabolites (TDMs)

According to EFSA, 2018: *"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."

Summary of animal metabolism studies reported in the EU
No new data considered to be required.

Summary of new animal metabolism studies
Prothioconazole

Based on the overall metabolic pattern of prothioconazole and prothioconazole-desthio in animals, the residue definition for enforcement in animal products is proposed as prothioconazole-desthio (sum of isomers) for all livestock matrices.

For risk assessment the residue definition is defined in all commodities of animal origin as the sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers) (EFSA, 2014).

The log $P_{o/w}$ of prothioconazole-desthio equals 3.04 (EFSA, 2007). Since higher prothioconazole-desthio residue levels were found in fat compared to fat free muscle, EFSA concludes that the residue definition for enforcement in commodities of animal origin is fat soluble (EFSA 2014).

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

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

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

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

hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers).

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

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

No further data are required.

~~Conclusion on metabolism in livestock~~

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

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

	Endpoints
Animals covered	Lactating goats
	Laying hens
Time needed to reach a plateau concentration	1-2 days in milk
Animal residue definition for monitoring (Prothioconazole)	Prothioconazole-desthio (sum of isomers) (EFSA, 2014, Reg. (EU) 2024/1318)
Animal residue definition for monitoring (Triazole derived metabolites (TDMs))	Triazole parent compound only (EFSA, ~~2021~~2018)
Animal residue definition for risk assessment (Prothioconazole)	Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers) (EFSA, 2014)
Animal residue definition for risk assessment (triazole derived metabolites (TDMs))	1) Triazole parent compound and any other relevant metabolite exclusively linked to the parent compound 2) TA and TLA, since these compounds share the same toxicity 3) TAA 4) 1,2,4-triazole (EFSA, 2018~~, 2021~~)
Conversion factor	2 (liver); 9 (kidney) (EFSA, 2014) not necessary for milk, ruminant muscle and ruminant fat
Metabolism in rat and ruminant similar	Yes~~/No~~ The metabolic pathway of prothioconazole-desthio depicted in ruminants can be extrapolated to pigs
Fat soluble residue	Yes, log P_{OW} for prothioconazole-desthio (JAU 6476-desthio) = 3.04

7.2.3 Magnitude of residues in plants (KCA 6.3)

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

Where applicable, reference is made to the EU peer review (EFSA, 2007, DAR United Kingdom, 2004 and 2007) as well as to the peer review of the triazole derivative metabolites (TDMs) in the light of confirmatory data submitted (United Kingdom, 2018, EFSA, 2018, amended 2019).

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

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

However, samples in residue studies already evaluated at EU level (EFSA, 2007, DAR United Kingdom, 2004) were only analysed for prothioconazole-desthio (residue definition for enforcement). 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.

Triazole derivative metabolites (TDMs)
Residue studies with prothioconazole analysing for TDMs were evaluated during the peer review of the triazole derivative metabolites (United Kingdom, 2018, EFSA, 2018, 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.

Therefore, 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 2018 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
According to the available data, the intended outdoor uses on wheat, rye and triticale in N-EU are considered acceptable. According to EC technical guideline 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, 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 United Kingdom, 2004) were only analysed for prothioconazole-desthio (residue definition for enforcement). Therefore, studies are considered not relevant.

Thus, to address all potential residues, new supplementary studies are presented in the following table. In these studies residues according to the plant residue definitions for enforcement and for risk assessment as proposed by EFSA 2018 and EFSA 2020 were analysed. The data submitted show that no exceedance of the current EU MRLs will occur. The uses are considered acceptable.

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

However, samples in residue studies already evaluated at EU level EFSA, 2007, DAR United Kingdom, 2004 were only analysed for prothioconazole-desthio (residue definition for enforcement). 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 2018 and EFSA 2020 were analysed.

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

Oilseed rape
The intended critical GAPs in oilseed rape (spring and winter oilseed rape) are covered by the representative EU GAP use of prothioconazole in rape as evaluated during AIR process (EFSA 2007).

However, samples in residue studies already evaluated at EU level EFSA, 2007, DAR United Kingdom, 2004 were only analysed for prothioconazole-desthio (residue definition for enforcement). 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 2018 and EFSA 2020 were analysed. The data submitted show that no exceedance of the current EU MRL will occur. The uses are considered acceptable.

Table 7.2-3: Summary of EU reported and new data supporting the intended uses of FGF11 and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
E: Prothioconazole-desthio (sum of isomers). **RA: (A) Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers);** **(B) Triazole alanine (TA) and triazole lactic acid (TLA);** **(C) Triazole acetic acid (TAA);** **(D) 1,2,4-triazole (1,2,4-triazole)**								
Spring and winter wheat, grain and straw Extrapolation from wheat → rye and Triticale Extrapolation from spring cereals ↔ winter cereals due to late application timing	EFSA, 2007, DAR United Kingdom, 2004	N-EU	GAP on which EU a.s. assessment is based: 3× 0.2 kg as/ha, start BBCH 26-29 up to BBCH 69, 14-21 days interval, PHI 35 days, outdoor. Studies not relevant for envisaged GAP uses due to more critical GAP than envisaged.	N/A				
	New trials	N-EU	Trials GAP; 2 x 0.2 kg as/ha, last application BBCH 69, 14 days interval, PHI 35 days, outdoor. Grain, E: 8 x <0.01 Straw, E: 0.07, 0.18, 2x0.19, 0.49, 0.59, 0.94, 3.3 RA (grain): (A) = 8<0.06 (B) = TA: 0.12, 0.17, 0.25, 0.27, 0.33, 0.41, 0.68, 0.74 TLA: 8 x <0.01 (C) = TAA: 0.04, 0.05, 0.10, 0.11, 2 x 0.14, 0.16, 0.17 (D) = 1,2,4-T: 8 x <0.01 RA (straw): (A) = ~~0.51, 0.58, 0.78,1.12, 1.99, 2.69, 3.44, 9.30~~ 0.39, 0.44, 0.59, 0.94, 1.5, 2.1, 2.5, 5.99 (B) = TA: 2 x <0.01, 2 x 0.01, 0.02, 0.03, 0.04, 0.07 TLA: 1 x <0.01, 2 x 0.02, 4 x 0.03, 0.13 (C) = TAA: <0.01, 0.01, 2 x 0.02, 3 x 0.04, 0.13 (D) = 1,2,4-Triazole: 8 x <0.01					

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	Grain, E: 8 x <0.01 Straw, E: 0.07, 0.18, 2x0.19, 0.49, 0.59, 0.94, 3.3 RA (grain): (A) = 8<0.06 (B) = TA: 0.12, 0.17, 0.25, 0.27, 0.33, 0.41, 0.68, 0.74 TLA: 8 x <0.01 (C) = TAA: 0.04, 0.05, 0.10, 0.11, 2 x 0.14, 0.16, 0.17 (D) = 1,2,4-T: 8 x <0.01 RA (straw): (A) = ~~0.51, 0.58, 0.78,1.12, 1.99, 2.69, 3.44, 9.30~~ 0.39, 0.44, 0.59, 0.94, 1.5, 2.1, 2.5, 5.99 (B) = TA: 2 x <0.01, 2 x 0.01, 0.02, 0.03, 0.04, 0.07 TLA: 1 x <0.01, 2 x 0.02, 4 x 0.03, 0.13 (C) = TAA: <0.01, 0.01, 2 x 0.02, 3 x 0.04, 0.13 (D) = 1,2,4-Triazole: 8 x <0.01	E (grain): 0.01 RA (grain): (A): 0.06 (B): TA: 0.30 TLA: 0.01 (C): 0.125 (D): 0.01 RA (straw): (A): ~~1.555~~ 1.22 (B): TA: 0.015 TLA: 0.03 (C): 0.030 (D): 0.010	E (grain): 0.01 RA (grain): (A): 0.06 (B): TA: 0.74 TLA: 0.01 (C): 0.170 (D): 0.01 RA (straw): (A): ~~9.300~~ 5.99 (B): TA: 0.07 TLA: 0.13 (C): 0.130 (D): 0.010	0.01	0.1	Yes
	~~EFSA, 2007, DAR United Kingdom, 2004~~	~~S-EU~~	~~GAP on which EU a.s. assessment is based: 3× 0.2 kg as/ha, start BBCH 26-29 up to BBCH 69, 14-21 days interval, PHI 35 days, outdoor. Studies not relevant for envisaged GAP uses due to more critical GAP than envisaged.~~	~~N/A~~				

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
	~~New trials~~	~~S-EU~~	~~Trials GAP; 2 x 0.2 kg as/ha, last application BBCH 69, 14 days interval, PHI 35 days, outdoor.~~ ~~Grain, E: 7x <0.01, 0.01~~ ~~Straw, E: 0.32, 0.27, 0.13, 1.2, 0.89, 2.69, 0.22, 1.1~~ ~~RA (grain):~~ ~~(A) = 6x <0.01, 2x <0.02~~ ~~(B) = TA: 0.19, 0.28, 0.24, 0.72, 0.02, 0.04, 0.17, 0.02~~ ~~TLA: 7x <0.01, 0.01~~ ~~(C) = TAA: 0.09, 0.09, 0.06, 0.14, 0.02, 0.04, 0.04, <0.01~~ ~~(D) = 1,2,4 Triazole: 8 x <0.01~~ ~~RA (straw):~~ ~~(A) = 1.3, 0.74, 0.48, 4.36, 1.19, 3.45, 0.99, 1.62~~ ~~(B) = TA: < 0.01, 0.01, 0.01, 0.05, <0.01, 0.01, < 0.01, < 0.01~~ ~~TLA: 0.05, < 0.01, 0.02, 0.21, <0.01, <0.01, 0.01, <0.01~~ ~~(C) = TAA: 0.06, 0.02, 0.03, 0.11, <0.01, 0.02, 0.01, < 0.01~~ ~~(D) = 1,2,4 Triazole: 8 x <0.01~~					

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~~	~~S-EU~~	~~Grain, E: 7x <0.01, 0.01~~ ~~Straw, E: 0.32, 0.27, 0.13, 1.2, 0.89, 2.69, 0.22, 1.1~~ ~~RA (grain):~~ ~~(A) = 6x <0.01, 2x <0.02~~ ~~(B) = TA: 0.19, 0.28, 0.24, 0.72, 0.02, 0.04, 0.17, 0.02~~ ~~TLA: 7x <0.01, 0.01~~ ~~(C) = TAA: 0.09, 0.09, 0.06, 0.14, 0.02, 0.04, 0.04, <0.01~~ ~~(D) = 1,2,4 Triazole: 8 x <0.01~~ ~~RA (straw):~~ ~~(A) = 1.3, 0.74, 0.48, 4.36, 1.19, 3.45, 0.99, 1.62~~ ~~(B) = TA: < 0.01, 0.01, 0.01, 0.05, <0.01, 0.01, < 0.01, < 0.01~~ ~~TLA: 0.05, < 0.01, 0.02, 0.21, <0.01, <0.01, 0.01, <0.01~~ ~~(C) = TAA: 0.06, 0.02, 0.03, 0.11, <0.01, 0.02, 0.01, < 0.01~~ ~~(D) = 1,2,4 Triazole: 8 x <0.01~~	~~E (grain): 0.01~~ ~~RA (grain):~~ ~~(A): 0.01~~ ~~(B): 0.18 / 0.01~~ ~~(C): 0.05~~ ~~(D): 0.01~~ ~~RA (straw):~~ ~~(A): 1.25~~ ~~(B): 0.01 / 0.02~~ ~~(C): 0.02~~ ~~(D): 0.01~~	~~E (grain): 0.01~~ ~~RA (grain):~~ ~~(A): 0.02~~ ~~(B): 0.72 / 0.01~~ ~~(C): 0.14~~ ~~(D): 0.01~~ ~~RA (straw):~~ ~~(A): 4.36~~ ~~(B): 0.05 / 0.21~~ ~~(C): 0.11~~ ~~(D): 0.01~~	~~0.01~~	~~0.1~~	~~Yes~~
Spring and winter barley, grain and straw	EFSA, 2007, DAR United Kingdom, 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. Studies not relevant for envisaged GAP uses due to more critical GAP than envisaged.	N/A				

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
	New trials	N-EU	Trials GAP; 2 x 0.2 kg as/ha, last application BBCH 69, 14 days interval, PHI 35 days, outdoor. Grain, E: 2x<0.01 (n.d), 2x <0.01, 0.01, 0.02, 0.05, 0.12** Straw, E: 0.03, 0.05, ~~0.1~~ 0.06, 0.07, 0.12, 0.43, 0.54, 1.5, ~~<0.01~~ RA (grain): (A) = ~~0.14, 0.07, <0.01, <0.01, 0.04, <0.01, <0.01, 0.01~~ 6x<0.06, 0.09, 0.17** (B) = TA: 0.07, 0.1, 0.12, 0.2, 2x0.22, 0.45, 0.48 TLA: 7x <0.01, 0.01 (C) = TAA: 0.03, 0.04, 0.05, 0.06, 0.07, 0.13, 0.22, 0.25 (D) = 1,2,4-Triazole: 8 x <0.01 RA (straw): (A) = ~~1.05, 2.44, 0.12, 0.02, 0.82, 0.31, 0.20, 0.18~~ 0.09, 0.13, 0.17, 0.19, 0.31, 0.82, 1.1, 2.5 (B) = TA: 2x<0.01, 2x0.01, 0.03, 2x0.04, 0.1 TLA: 0.01, 3x0.02, 0.03, 0.05, 0.09, 0.12 (C) = TAA: 2x<0.01, 0.02, 2x0.04, 0.05, 2x0.07 (D) = 1,2,4-Triazole: 8 x <0.01					

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	Grain, E: 2x<0.01 (n.d), 2x <0.01, 0.01, 0.02, 0.05, 0.12 Straw, E: 0.03, 0.05, ~~0.1~~ 0.06, 0.07, 0.12, 0.43, 0.54, 1.5, ~~<0.01~~ RA (grain): (A) = ~~0.14, 0.07, <0.01, <0.01, 0.04, <0.01, <0.01, 0.01~~ 6x<0.06, 0.09, 0.17 (B) = TA: 0.07, 0.1, 0.12, 0.2, 2x0.22, 0.45, 0.48 TLA: 7x <0.01, 0.01 (C) = TAA: 0.03, 0.04, 0.05, 0.06, 0.07, 0.13, 0.22, 0.25 (D) = 1,2,4-Triazole: 8 x <0.01 RA (straw): (A) = ~~1.05, 2.44, 0.12, 0.02, 0.82, 0.31, 0.20, 0.18~~ 0.09, 0.13, 0.17, 0.19, 0.31, 0.82, 1.1, 2.5 (B) = TA: 2x<0.01, 2x0.01, 0.03, 2x0.04, 0.1 TLA: 0.01, 3x0.02, 0.03, 0.05, 0.09, 0.12 (C) = TAA: 2x<0.01, 0.02, 2x0.04, 0.05, 2x0.07 (D) = 1,2,4-Triazole: 8 x <0.01	E (grain): 0.01 RA (grain): (A): ~~0.01~~0.06 B): TA: 0.21 TLA: 0.01 (C): 0.065 (D): 0.01 RA (straw): (A): 0.25~~5~~ B): TA: 0.02 TLA: 0.025 (C): 0.04 (D): 0.01	E (grain): 0.12 RA (grain): (A): 0.1~~4~~7 (B): TA: 0.48 TLA: 0.01 (C): 0.25 (D): 0.01 RA (straw): (A): 2.~~44~~5 B): TA: 0.1 TLA: 0.12 (C): 0.07 (D): 0.01	0.186	0.2	Yes
	~~EFSA, 2007, DAR United Kingdom, 2004~~	~~S-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 Studies not relevant for envisaged GAP uses due to more critical GAP than envisaged.~~	~~N/A~~				

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
	~~New trials~~	~~S-EU~~	~~Trials GAP; 2 x 0.2 kg as/ha, last application BBCH 69, 14 days interval, PHI 35 days, outdoor.~~ ~~Grain, E: 0.11, <0.01, 0.01, 0.02, <0.01, 0.02, 0.01~~ ~~Straw, E: 0.98, 0.16, 0.04, 1.3, 0.21, 0.39, 0.23~~ ~~RA (grain):~~ ~~(A) = 0.15, <0.01, 0.01, 0.02, <0.01, 0.02, 0.01~~ ~~(B) = TA: 0.08, 0.24, 0.14, 0.21, 0.34, 0.13, 0.19~~ ~~TLA: <0.01, <0.01, <0.01, <0.01, 0.02, <0.01, 0.02~~ ~~(C) = TAA: 0.08, 0.08, 0.04, 0.06, 0.02, 0.15, 0.05, 0.12~~ ~~(D) = 1,2,4 Triazole: 7 x <0.01~~ ~~RA (straw):~~ ~~(A) = 1.78, 0.55, 0.15, 1.89, 0.76, 0.91, 0.71~~ ~~(B) = TA: <0.01, 0.04, 0.07, 0.04, 0.09, < 0.01, < 0.01~~ ~~TLA: 0.04 0.06, 0.02, 0.04, 0.12, 0.02 , 0.02~~ ~~(C) = TAA: 0.03, 0.05, 0.02, 0.08, < 0.01, 0.10, 0.02, 0.03~~ ~~(D) = 1,2,4 Triazole: 7 x <0.01~~					

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~~	~~S-EU~~	~~Grain, E: 0.11, <0.01, 0.01, 0.02, <0.01, 0.02, 0.01~~ ~~Straw, E: 0.98, 0.16, 0.04, 1.3, 0.21, 0.39, 0.23~~ ~~RA (grain):~~ ~~(A) = 0.15, <0.01, 0.01, 0.02, <0.01, 0.02, 0.01~~ ~~(B) = TA: 0.08, 0.24, 0.14, 0.21, 0.34, 0.13, 0.19~~ ~~TLA: <0.01, <0.01, <0.01, <0.01, 0.02, <0.01, 0.02~~ ~~(C) = TAA: 0.08, 0.08, 0.04, 0.06, 0.02, 0.15, 0.05, 0.12~~ ~~(D) = 1,2,4 Triazole: 7 x <0.01~~ ~~RA (straw):~~ ~~(A) = 1.78, 0.55, 0.15, 1.89, 0.76, 0.91, 0.71~~ ~~(B) = TA: <0.01, 0.04, 0.07, 0.04, 0.09, < 0.01, < 0.01~~ ~~TLA: 0.04 0.06, 0.02, 0.04, 0.12, 0.02 , 0.02~~ ~~(C) = TAA: 0.03, 0.05, 0.02, 0.08, < 0.01, 0.10, 0.02, 0.03~~ ~~(D) = 1,2,4 Triazole: 7 x <0.01~~	~~E (grain): 0.01~~ ~~RA (grain):~~ ~~(A): 0.01~~ ~~(B): 0.19 / 0.01~~ ~~(C): 0.08~~ ~~(D): 0.01~~ ~~RA (straw):~~ ~~(A): 0.76~~ ~~(B): 0.04 / 0.04~~ ~~(C): 0.03~~ ~~(D): 0.01~~	~~E (grain): 0.11~~ ~~RA (grain):~~ ~~(A): 0.15~~ ~~(B): 0.34 / 0.02~~ ~~(C): 0.12~~ ~~(D): 0.01~~ ~~RA (straw):~~ ~~(A): 1.89~~ ~~(B): 0.09 / 0.12~~ ~~(C): 0.1~~ ~~(D): 0.01~~	~~0.175~~	~~0.2~~	~~Yes~~
Spring and winter oilseed rape, seeds and	EFSA, 2007, DAR United Kingdom, 2004	N-EU	GAP on which EU a.s. assessment is based: 2× 0.2 kg as/ha, start BBCH 53, 14-28 days interval, PHI 56 days, outdoor Studies not relevant for envisaged GAP uses due to more critical GAP than envisaged.	N/A				

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
straw	New trials	N-EU	Trials GAP; 2 x 0.18 kg as/ha, last application BBCH 80, 14 days interval, outdoor. E: seed: 2x<0.005, 0.00514, 0.00659, 0.0136, 0.0146, 0.0182, 0.0564 RA seed (A) = 2x<0.029, 0.029, 0.030, 0.037, 0.038, 0.042, 0.080 (B): TA = 0.15, 0.2, 0.22, 0.23, 0.29, 0.52, 0.79, 1.3 TLA = 3x<0.01, 0.0105, 0.0290, 0.0365, 0.0491, 0.131 (C) = 4x<0.005, 0.00576, 0.00896, 0.00928, 0.0265 (D) = 6x<0.01 Sum of Prothioconazole-alpha-hydroxy-desthio, prothioconazo-le-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio expressed as prothioconazole-desthio: 8x<0.05					
	Overall supporting data for cGAP	N-EU	E: seed: 2x<0.005, 0.00514, 0.00659, 0.0136, 0.0146, 0.0182, 0.0564 RA seed (A) = 2x<0.029, 0.029, 0.030, 0.037, 0.038, 0.042, 0.080 (B): TA = 0.15, 0.2, 0.22, 0.23, 0.29, 0.52, 0.79, 1.3 TLA = 3x<0.01, 0.0105, 0.0290, 0.0365, 0.0491, 0.131 (C) = 4x<0.005, 0.00576, 0.00896, 0.00928, 0.0265 (D) = 6x<0.01	E: 0.01 RA: (A): 0.0335 (B): TA: 0.26 TLA: 0.01975 (C): 0.00538 (D): 0.01	E: 0.0564 RA: (A): 0.080 (B): TA: 1.3 TLA: 0.131 (C): 0.0265 (D): 0.01	0.085	0.15	Yes
	~~EFSA, 2007, DAR United Kingdom, 2004~~	~~S-EU~~	~~GAP on which EU a.s. assessment is based: 2× 0.2 kg as/ha, start BBCH 53, 14-28 days interval, PHI 56 days, outdoor~~ ~~Studies not relevant for envisaged GAP uses due to more critical GAP than envisaged.~~	~~N/A~~				

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
	New trials	S-EU	Trials GAP; 2 x 0.18 kg as/ha, last application BBCH 80, 14 days interval, outdoor. Seed, E: 0.0516, 0.0447, 0.0645, 0.0645, 0.0609, 0.0393, 0.00755, 0.0738 RA: (A) = 0.0716, 0.0647, 0.0645, 0.0645, 0.0609, 0.1393, 0.02755, 0.0838 (B) = TA: 3.2, 0.13, 0.23, 0.25, 3.4, 0.78, 4.5, 0.14 TLA: 7 x <0.01, 0.012 (C) = TAA: 6 x <0.01, 0.0154, 0.0174 (D) = 1,2,4 Triazole: 8 x <0.01					
	Overall supporting data for cGAP	S-EU	Seed, E: 0.0516, 0.0447, 0.0645, 0.0645, 0.0609, 0.0393, 0.00755, 0.0738 RA: (A) = 0.0716, 0.0647, 0.0645, 0.0645, 0.0609, 0.1393, 0.02755, 0.0838 (B) = TA: 3.2, 0.13, 0.23, 0.25, 3.4, 0.78, 4.5, 0.14 TLA: 7 x <0.01, 0.012 (C) = TAA: 6 x <0.01, 0.0154, 0.0174 (D) = 1,2,4 Triazole: 8 x <0.01	E: 0.056 RA: (A): 0.07 (B): 0.52 / 0.01 (C): 0.01 (D): 0.01	E: 0.074 RA: (A): 0.14 (B): 4.5 / 0.012 (C): 0.0174 (D): 0.01	0.153 (rounded to 0.15)	0.15	Yes

* Source of EU MRL: Reg. (EU) 2024/1318

7.2.3.2 Conclusion on the magnitude of residues in plants

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

** E: 0.12 / RA: 0.17 considering Dixonon's Q test and Grubbs's test this result can be considered as significant outlier, hence should not be taken into account in the further risk assessment.
~~** E: 0.11 / RA: 0.16 considering Dixonon's Q test and Grubbs's test this result can be considered as significant outlier, hence should not be taken into account in the further risk assessment.~~

No exceedances of the MRLs are envisaged based on the requested uses for FGF11.

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

Winter wheat, spring wheat, durum wheat, spelt wheat, winter triticale, spring triticale, winter rye, spring rye
Wheat and rye are the major crops in northern Europe (SANTE/2019/12752). A minimum of eight trials are required. Based on the SANTE/2019/12752, 8 residue trials on wheat can be used for extrapolation to rye, triticale and spelt before and after forming of the edible part.
Sufficient trials on wheat conducted according to the residue definition for monitoring only (trials measuring levels of prothioconazole-desthio only) were previously presented and evaluated (DAR, 2007). There are no data on prothioconazole-hydroxy-desthio in the DAR (2007).

One magnitude of residue study was submitted in the framework of this application: Lebrun, F., 2024; Report No.; 645-2023.

Summary
Eight N-EU trials were conducted in accordance with the following GAP: 2 x 200 g a.s. /ha, application interval - 14 days, 2nd application at BBCH 69, outdoor.
Residues of prothioconazole-desthio in wheat grain at harvest were <0.01 mg/kg.
Total residue for prothioconazole (prothioconazole-desthio and all 5 hydroxy metabolites) in grain at harvest was <0.06 mg/kg.

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

Storage periods of residue samples covered by available storage stability studies.

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

The proposed uses on wheat, rye, triticale, spelt 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 conducted according to the residue definition for monitoring only (trials measuring levels of prothioconazole-desthio only) were previously presented and evaluated (DAR, 2007). There are no data on prothioconazole-hydroxy-desthio in the DAR (2007).

One magnitude of residue study was submitted in the framework of this application (Bougrier 2024; 646-2023). Eight N-EU trials were conducted in accordance with the following GAP: 2 x 200 g a.s. /ha, application interval - 14 days, 2nd application at BBCH 69, outdoor.

In the treated grain specimens at harvest, residue levels of PTZ-desthio ranged between <0.01 mg/kg – 0.12 mg/kg, and the sum of hydroxy- derivatives of prothioconazole-desthio ranged between <0.06 mg/kg – 0.17 mg/kg.

Residues of 1,2,4-triazole in barley grain at harvest were <0.01 mg/kg.
Residues of triazole alanine in barley grain at harvest ranged between 0.05 – 0.48 mg/kg.
Residues of triazole acetic acid in barley grain at harvest ranged between 0.03 – 0.25 mg/kg.
Residues of triazole lactic acid in barley grain at harvest ranged between <0.01 – 0.01 mg/kg.

Available results show that the in force MRL of prothioconazole on barley of 0.2 mg/kg (Reg. (EU) 2024/1318) will not be exceeded. The current EU MRL for prothioconazole is sufficient to support the proposed use.
The trials are supported by valid storage stability data and validated analytical methods.

The proposed uses on barley is considered acceptable.

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

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

Five new magnitude of residue studies were submitted in the framework of this application. Summary is presented below.

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

In the treated seed specimens at harvest, residue levels of PTZ-desthio ranged between <0.005 mg/kg – 0.056 mg/kg.
Residues of hydroxy- derivatives of prothioconazole-desthio in oilseed rape grain at harvest were <0.005 mg/kg.
The study on the magnitude of residues is valid with regard to storage stability, except prothioconazole-6-hydroxy-desthio therefore cannot be used to support the intended use on oilseed rape.

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

In the treated seed specimens at harvest, residue levels of PTZ-desthio ranged between <0.005 mg/kg – 0.00659 mg/kg.
Residues of hydroxy- derivatives of prothioconazole-desthio in oilseed rape grain at harvest were <0.005 mg/kg.
The study on the magnitude of residues is not valid with regard to storage stability, therefore cannot be used to support the intended use on oilseed rape.

3. Study 647-2023; Bousquet 2023
Eight N-EU trial was conducted in accordance with the following GAP: 2 x 175 g a.s. /ha, application interval – 14 days, 2nd application at BBCH 80 (outdoor) to determine of the residues of prothioconazole metabolites: PTZ-

alpha-OH-desthio, PTZ-3-OH-desthio, PTZ-4-OH-desthio, PTZ-5-OH-desthio, PTZ-6-OH-desthio and 1,2,4-triazole (T), triazole alanine (TA) in oilseed rape specimens: seed and forage.

Residues of PTZ-alpha-OH-desthio, PTZ-3-OH-desthio, PTZ-4-OH-desthio, PTZ-5-OH-desthio and PTZ-6-OH-desthio, expressed as prothioconazole-desthio, ranged between:
- 0.21 and 0.55 mg/kg (0.21, 0.30, 0.33, 0.55 mg/kg) in forage specimens
- 0.01 and 0.04 mg/kg (0.01, 3x0.02, 2x0.03, 2x0.04 mg/kg) in seeds specimens
(LOQ: 0.01 mg/kg for each analyte, 0.05 mg/kg for prothioconazole expressed as prothioconazole desthio as a sum of hydroxy-metabolites)

No residue of 1,2,4-T were detected at any time in seed.
Residues of TA ranged between:
- 0.03 and 0.06 mg/kg (0.03, 2x0.04, 0.06 mg/kg) in forage specimens
- 0.02 and 1.3 mg/kg (0.02, , 0.15, 0.22, 0.23, 0.29, 0.52, 0.79, 1.3 mg/kg) in seeds specimens

The study on the magnitude of residues is valid with regard to storage stability for PTZ-OH-desthio metabolites, except 1,2,4-T and TA. These trials can be used to support the intended use on oilseed rape (for PTZ-OH-desthio metabolites, not for 1,2,4-T and TA).

January 2026:
The Applicant provided new storage stability study (Jooß, 2025; Study Code S23-105428). The Bousquet's study (647-2023; 2023) on the magnitude of residues of 1,2,4-T and TA is supported by new valid storage stability data.

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

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

Residues of TLA ranged between:
- <0.01 and 0.0491 mg/kg (2x<0.01, 0.0105, 0.029, 0.0365, 0.0491 mg/kg) in seeds
- <0.01 and 0.0178 mg/kg (3x<0.01, 0.0102, 0.0109, 0.0178 mg/kg) in rest of plants.
The trials are supported by valid storage stability data and validated analytical methods.

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

Residues of TAA were <LOQ and 0.0265 mg/kg in seeds, and <LOQ in rest of plants.
Residues of TLA were <LOQ and 0.131 mg/kg in seeds, and <0.01 in rest of plants.
The trials are supported by valid storage stability data and validated analytical methods.

Conclusions:
Available results show that the in force MRL of prothioconazole on oilseed rape of 0.15 mg/kg (Reg. (EU) 2024/1318) will not be exceeded. The current EU MRL for prothioconazole is sufficient to support the proposed use.
The proposed uses on oilseed rape is considered acceptable.

7.2.4 Magnitude of residues in livestock

Reference is made to the EU peer review (EFSA, 2007, DAR United Kingdom, 2004 and 2007) and to the MRL review (EFSA, 2014 and 2020) for prothioconazole, as well as to the peer review of the triazolederivative metabolites (TDMs) in the light of confirmatory data submitted (United Kingdom, 2018, EFSA, 2018, 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). The envisaged GAP uses are covered by this calculation.

In addition, new dietary burden calculations were conducted in EFSA, 2020. According to EFSA, 2020 "[…] new data on carrots, swedes, turnips and wheat were submitted in the framework of the assessment of the Article 12 confirmatory data application (UK, 2019a). The most recent livestock dietary burden was calculated in the EFSA opinion on the modification of prothioconazole residues in sunflower seeds (EFSA, 2015b), updating the calculation done by the MRL review (EFSA, 2014).

However, due to the fact that existing EU MRLs for livestock and for various feed commodities are set on the basis of CXLs, instead of proposals made by the MRL review, the livestock dietary burden was calculated using Animal Model (OECD methodology), considering the actual existing EU MRLs for feed commodities. The input values for rapeseeds and carrots, swedes, turnips were as derived from the current assessment; for remaining feed commodities the input values were corresponding to the existing EU MRLs and were as reported in the MRL review, or in JMPR reports (in particular for cereals, cotton, maize, peanuts and soya beans, since for these crops the existing EU MRLs are set on the basis of CXLs) (FAO, 2009a, b, 2014, 2018) and in previous EFSA reasoned opinions (for sunflower seeds, EFSA, 2015b). Where residue data according to the risk assessment residue definition were not available, default conversion factors for risk assessment as derived by the MRL review, were applied."

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

As shown in the following table, the input values from the NEU and SEU trials (Appendix 2) supporting the uses of FGF11 are generally far lower than those values used for the same crops in the Article 12 MRL (EFSA, 2013) review's consideration of the livestock dietary burden. The only values which slightly exceed the ones used in the EFSA, 2020 calculation are the HR values for NEU and SEU, wheat straw (and extrapolated commodities) with values of 6.24 and 5.58 (respectively). However, the calculator works by selecting the highest values for the commodity group to determine the livestock dietary burden, which for the EFSA, 2020 calculation would be barley straw (HR), which is higher at 7.50 mg/kg.

Table 7.2-4: Residue trials values from the studies supporting FGF11, compared with those used in the livestock dietary burden calculation presented in the EFSA Article 12 review (EFSA, 2020)

Commodity	Residue values (mg/kg)		
	NEU trials	SEU trials	EFSA, 2020
Barley grain (STMR)	0.01	0.01	0.035
Barley straw (STMR)	0.27	0.80	1.96
Barley straw (HR)	2.44	2.1	7.50
Wheat grain (STMR)	0.01	0.01	0.02
Wheat straw (STMR)	1.22	1.2	2.69
Wheat straw (HR)	6.24	5.58	5.52
Triticale grain (STMR)	0.01	0.01	-
Triticale straw (STMR)	1.22	1.2	-
Triticale straw (HR)	6.24	5.58	-
Rye grain (STMR)	0.01	0.01	0.01
Rye straw (STMR)	1.22	1.2	2.25
Rye straw (HR)	6.24	5.58	5.52
Oilseed rape seed (STMR)	0.01	0.056	0.08

The more critical value (input values EFSA 2020 versus STMRs/HRs derived from the residue studies submitted with this dossier) was used for new intake calculations. The corresponding results can be found in the following tables.

Table 7.2-5: 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-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers)				
Rape seed meal (EFSA 2020)	0.16	STMR x PF (2)[a]	0.16	STMR x PF (2)[a]
Sunflower seed meal (EFSA 2020)	0.04	STMR × CF (2) × PF (2)[a] (EFSA, 2015a,b)	0.04	STMR × CF (2) × PF (2)[a] (EFSA, 2015a,b)
Head cabbage (EFSA 2020)	0.02	STMR × CF (EFSA, 2014)	0.12	STMR × CF (EFSA, 2014)
Maize silage (EFSA 2020)	0.01	STMR (EFSA, 2014)	0.01	STMR (EFSA, 2014)
Maize grain (EFSA 2020)	0.02	STMR (FAO, 2014) × CF (2) (EFSA, 2014)	0.02	STMR (FAO, 2014) × CF (2) (EFSA, 2014)
Maize, milled by-products[b]; Maize, hominy meal[b]; Maize gluten feed/gluten meal[b]; Distiller`s grain[b] (EFSA 2020)	0.02	STMR (FAO, 2014) × CF (2) (EFSA, 2014)	0.02	STMR (FAO, 2014) × CF (2) (EFSA, 2014)
Barley grain (EFSA 2020)	0.07	STMR (FAO, 2009b) × CF (2) (EFSA, 2014)	0.07	STMR (FAO, 2009b) × CF (2) (EFSA, 2014)
Brewer`s grain (EFSA 2020)	0.23	STMR barley grain (FAO, 2009b) × CF (2) (EFSA, 2014) × PF (3.3)[a]	0.23	STMR barley grain (FAO, 2009b) × CF (2) (EFSA, 2014) × PF (3.3)[a]
Oat grain (EFSA 2020)	0.02	STMR (FAO, 2008a) × CF (2) (EFSA, 2014)	0.02	STMR (FAO, 2008a) × CF (2) (EFSA, 2014)
Wheat grain (EFSA 2020)	0.04	STMR (FAO, 2009b) × CF (2) (EFSA, 2014)	0.04	STMR (FAO, 2009b) × CF (2) (EFSA, 2014)
Wheat gluten meal[b] (EFSA 2020)	0.04	STMR wheat grain (FAO, 2009b) × CF (2) × PF (1.8)[a]	0.04	STMR wheat grain (FAO, 2009b) × CF (2) × PF (1.8)[a]
Wheat milled by-products[b] (EFSA 2020)	0.28	STMR wheat grain (FAO, 2009b) × CF (2) × PF (7)[a]	0.28	STMR wheat grain (FAO, 2009b) × CF (2) × PF (7)[a]
Rye grain (EFSA 2020)	0.02	STMR (FAO, 2008a) × CF (2)	0.02	STMR (FAO, 2008a) × CF (2)
Barley straw (EFSA 2020)	1.96	STMR (FAO, 2009b) × CF (3) (EFSA, 2014)	7.50	HR[d] × CF (3) (EFSA, 2014)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Oats straw (EFSA 2020)	1.26	STMR[(d)] × CF (3) (EFSA, 2014)	7.50	HR[(d)] × CF (3) (EFSA, 2014)
Wheat straw (EFSA 2020)	2.69	STMR x CF (3) (EFSA, 2020)	5.52	HR[(d)] (EFSA, 2014) × CF (3)
Rye straw (EFSA 2020)	2.25	STMR[(d)] × CF (3) (EFSA,2014)	5.52	HR[(d)] × CF (3) (EFSA, 2014)
Cotton seed (EFSA 2020)	0.10	STMR (FAO,2018) x CF (2)	0.10	STMR (FAO, 2018) x CF (2) x PF (1.3)[(a)]
Cotton seed meal (EFSA 2020)	0.14	STMR (FAO, 2018) × CF (2) × PF (1.3)[(a)]	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) x CF (2) x PF (1.1)[(a)]	0.11	STMR (FAO, 2009b) x CF (2) x PF (1.1)[(a)]
Potatoes (EFSA 2020)	0.01	STMR (EFSA, 2014)	0.01	HR (EFSA, 2014)
Potato process waste[(b)]; Potato dried pulp[(b)] (EFSA 2020)	0.01	STMR potato (EFSA, 2014) × PF (1)[(c)]	0.01	HR potato (EFSA, 2014) × PF (1)[(c)]
Turnips, swede, carrot culls (EFSA 2020)	0.08	STMR	0.10	HR
Peanut meal (EFSA 2020)	0.04	STMR (FAO, 2009b) × CF (2) × PF (2)	0.04	STMR (FAO, 2009b) × CF (2) × PF (2)
Linseed meal (EFSA 2020)	0.12	STMR × CF (2) × PF (2)(a) (EFSA, 2015a,b)	0.12	STMR × CF (2) × PF (2)(a) (EFSA, 2015a,b)
Soybean seed (EFSA 2020)	0.10	STMR (FAO, 2014) × CF (2)	0.10	STMR (FAO, 2014) × CF (2)
Soybean seed meal (EFSA 2020)	0.13	STMR (FAO, 2014) × CF (2) × PF (1.3)[(a)]	0.13	STMR (FAO, 2014) × CF (2) × PF (1.3)[(a)]
Soybean[(b)] (EFSA 2020)	1.30	STMR soybean (FAO, 2014) × CF (2) × PF (13)[(a)]	1.30	STMR soybean (FAO, 2014) × CF (2) × PF (13)[(a)]

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

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

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

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

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

Table 7.2-6: Results of the dietary burden calculation

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
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~~ 0.036	~~0.111~~ 0.109	Barley Straw	3.10	Y
Cattle (dairy only)	~~0.038~~ 0.036	~~0.111~~ 0.109	Barley Straw	~~2.89~~ 2.85	Y
Sheep (all diets)	0.075	0.236	Barley Straw	5.55	Y
Sheep (ewe only)	0.059	0.185	Barley Straw	5.55	Y
Swine (all diets)	~~0.017~~ 0.015	~~0.020~~ 0.017	Swede roots	0.64	Y
Poultry (all diets)	~~0.036~~ 0.035	~~0.060~~ 0.059	Barley Wheat Straw	0.86	Y
Poultry (layer only)	~~0.036~~ 0.035	~~0.060~~ 0.059	Barley Wheat Straw	0.86	Y
Risk assessment residue definition: 1,2,4-Triazole					
Cattle (all diets)	0.104	0.109	Potato process waste	3.75	Y
Cattle (dairy only)	0.104	0.109	Potato process waste	2.83	Y
Sheep (all diets)	0.118	0.121	Potato process waste	3.63	Y
Sheep (ewe only)	0.118	0.121	Potato process waste	3.63	Y
Swine (all diets)	0.045	0.047	Potato process waste	2.04	Y
Poultry (all diets)	0.037	0.038	Dried pulp	0.54	Y
Poultry (layer only)	0.029	0.032	Dried pulp	0.46	Y
Risk assessment residue definition: TA					
Cattle (all diets)	0.376	0.405	Potato process waste	13.63	y
Cattle (dairy only)	0.376	0.405	Potato process waste	10.52	Y
Sheep (all diets)	0.425	0.454	Potato process waste	13.63	Y
Sheep (ewe only)	0.425	0.454	Potato process waste	13.63	Y
Swine (all diets)	0.163	0.178	Potato process waste	7.71	Y
Poultry (all diets)	0.158	0.165	Dried pulp	2.34	Y
Poultry (layer only)	0.130	0.149	Dried pulp	2.18	Y
Risk assessment residue definition: TAA					
Cattle (all diets)	0.118	0.140	Potato process waste	4.29	Y
Cattle (dairy only)	0.118	0.140	Potato process waste	3.63	Y
Sheep (all diets)	0.153	0.170	Wheat milled byproducts	4.37	Y
Sheep (ewe only)	0.127	0.146	Potato process waste	4.37	Y
Swine (all diets)	0.108	0.109	Wheat milled byproducts	3.76	Y
Poultry (all diets)	0.138	0.140	Wheat milled byproducts	2.05	Y
Poultry (layer only)	0.135	0.140	Wheat milled byproducts	2.05	Y

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Risk assessment residue definition: TLA					
Cattle (all diets)	0.078	0.177	Grass forage (fresh)	4.61	Y
Cattle (dairy only)	0.078	0.177	Grass forage (fresh)	4.61	Y
Sheep (all diets)	0.079	0.187	Grass forage (fresh)	5.61	Y
Sheep (ewe only)	0.079	0.187	Grass forage (fresh)	5.61	Y
Swine (all diets)	0.026	0.055	Grass forage (fresh)	2.37	Y
Poultry (all diets)	0.021	0.055	Clover hay	0.77	Y
Poultry (layer only)	0.021	0.052	Clover hay	0.77	Y

The 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).

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

zRMS comments:
Information given by the Applicant is acceptable and sufficient.
Prothioconazole
The median and maximum dietary burdens for livestock were estimated for prothioconazole and were calculated using the animal model calculator developed by EFSA (Animal model 2017). The summary submitted by the Applicant reflects the conclusions of the EFSA Reasoned Opinion (EFSA, 2020).
The calculated dietary burdens for prothioconazole were found to exceed the trigger value of 0.1 mg/kg DM (or 0.004 mg/kg bw/d, respectively) for all livestock groups. Further investigation of residues is therefore required.

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

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

It should be noted that the results of dietary burdens for TDMs taking into account the intended uses of FGF11 are covered by the dietary burdens calculated by the UK (2018) for the different groups of livestock.

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

According to the new Working Documents on the nature and magnitude of pesticide residues in fish (SANTE/10254/2021, SANTE/10252/2021) as well as on the dietary burden calculator for pesticide residues in fish (SANTE/10250/2021), data on residue behaviour in fish are required when the pesticide use may lead to residues >0.1 mg/kg in the total diet (dry weight basis) and when the active substances and/or metabolites are fat soluble, i.e. have a log Po/w ≥3.
For prothioconazole-desthio the log Po/w is 3.04 and EFSA concluded that prothioconazole-desthio is fat soluble due to higher residue levels found in fat than in fat free muscle. Rape seed meal and cereal grains are used as a fish feeding stuff. However, residues of prothioconazole-desthio ranged from below the LOQ to 0.12 mg/kg in cereals grain and rape seeds. Only one residue result from all field trials for cereals and oilseed rape was above the trigger value of 0.1 mg/kg, all other grain residue results were below 0.1 mg/kg. Residues above 0.1 mg/kg are therefore not expected and in our opinion further data are not required.

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

7.2.4.3 Prothioconazole

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

Available data
Prothioconazole except TDMs

Table 7.2-12: Overview of livestock feeding studies with prothioconazole-desthio

Group	Species	No of animal	Test item	Application details		Sample details		Reference
				Rate	Duration (days)	Commodity	Time of sampling	
EU Data								
Lactating ruminants	Dairy cow	10	Prothioconazole-desthio	4, 25, and 100 mg/kg in the diet (equivalent to 0.145, 0.909 and 3.636 mg/kg bw per d (UK 2007))	28	Milk	24 times during study	UK, 2004 and 2007 (IIA, 6.4/01); EFSA, 2007, evaluated and accepted ([redacted], 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- 13]. In milk, a plateau level was reached after 1 or 2 days of exposure, according to the dose level group. Since neither the metabolites (free and conjugated) containing the common moiety and included in the residue definition for risk assessment nor the glucuronide conjugates of prothioconazole-desthio were analysed, EFSA reported the residue levels for enforcement only (prothioconazole-desthio) and considered the conversion factors for enforcement to risk assessment of 2 and 9 respectively for liver and kidney based on the goat metabolism study with administration of prothioconazole-desthio. No tentative CF was derived for milk, muscle and fat since the residue levels in these matrices are expected to be negligible (<0.01 mg/kg) at the calculated dietary burden. However, conversion factors reported above*

should in principle be covered by a new feeding study to estimate prothioconazole metabolites containing the common moiety in accordance with the residue definition for risk assessment.

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

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

When using the dietary burdens calculated above (considering the uses evaluated in Art. 12 procedure and the uses under consideration, presented in Table 7.2- 16), estimated residues at 1N dietary burden in ruminant and pig matrices and in milk do not exceed the current MRLs in the respective commodities as given in Com. Reg. (EU) 2024/1318 (Table 7.2- 23).

Table 7.2-13: Overview of the values derived from livestock feeding studies

Commodity	Dietary burden		Results of the livestock feeding study (EFSA 2014)						Median residue (mg/kg)[c]	Highest residue (mg/kg)[d]	Calculated MRL (mg/kg)	In-force MRL (mg/kg) Reg. (EU) 2024/1318	CF for RA[e]
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level (mg/kg bw/d)[a]	No	Result for enforcement		Result for RA[b]						
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)					
EU data EFSA 2014													
Enforcement residue definition: prothioconazole-desthio (sum of isomers). **Risk assessment residue definition**: sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers).													
Pig muscle	~~0.017~~ 0.015	~~0.031~~ 0.017	0.15	3	<0.01	<0.01	n.a.	n.a.	<0.01	<0.01	0.01* (tentative)	0.01	1.0
			0.91	3	<0.01	<0.01	n.a.	n.a.					
			3.64	3	<0.01	<0.01	n.a.	n.a.					
Pig fat			0.15	3	<0.01	<0.01	n.a.	n.a.	<0.01	<0.01	0.01* (tentative)	0.02	1.0
			0.91	3	<0.01	0.01	n.a.	n.a.					
			3.64	3	0.02	0.04	n.a.	n.a.					
Pig liver			0.15	3	0.02	0.03	n.a.	n.a.	<0.01	<0.01	0.01* (tentative)	0.5	2.0
			0.91	3	0.14	0.18	n.a.	n.a.					
			3.64	3	0.68	1.20	n.a.	n.a.					
Pig kidney			0.15	3	<0.01	<0.01	n.a.	n.a.	<0.01	<0.01	0.01* (tentative)	0.5	9.0
			0.91	3	0.03	0.03	n.a.	n.a.					
			3.64	3	0.13	0.24	n.a.	n.a.					
Milk	~~0.028~~ 0.075	~~0.086~~ 0.236	0.15	3	<0.005[f]	N/A	n.a.	n.a.	<0.005	<0.005	0.005* (tentative)	0.01*	1.0
			0.91	3	<0.005[f]	N/A	n.a.	n.a.					
			3.64	3	<0.005[f]	N/A	n.a.	n.a.					
Ruminant muscle	~~0.069~~ 0.075	~~0.208~~ 0.236	0.15	3	<0.01	<0.01	n.a.	n.a.	<0.01	<0.01	0.01* (tentative)	0.01	1.0
			0.91	3	<0.01	<0.01	n.a.	n.a.					
			3.64	3	<0.01	<0.01	n.a.	n.a.					
Ruminant fat			0.15	3	<0.01	<0.01	n.a.	n.a.	<0.01	<0.01	0.01*	0.02	1.0

			0.91	3	<0.01	0.01	n.a.	n.a.			(tentative)		
			3.64	3	0.02	0.04	n.a.	n.a.					
Ruminant liver			0.15	3	0.02	0.03	n.a.	n.a.	0.01	~~0.042~~ 0.049	0.05 (tentative)	0.5	2.0
			0.91	3	0.14	0.18	n.a.	n.a.					
			3.64	3	0.68	1.20	n.a.	n.a.					
Ruminant kidney			0.15	3	<0.01	<0.01	n.a.	n.a.	<0.01	0.012	0.02 (tentative)	0.5	9.0
			0.91	3	0.03	0.03	n.a.	n.a.					
			3.64	3	0.13	0.24	n.a.	n.a.					

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

TDMs
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-Tand to TLA for which feeding studies are not available.

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

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.
Table 7.2-6 and Table 7.2-13 have been corrected. The residues in animal commodities will not exceed MRLs (Reg. (EU) 2024/1318).
No further data are required to support the intended uses of FGF11.

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

Prothioconazole
Any studies on the magnitude of residues of prothioconazole (except TDMs) in processed commodities are not required, as residues of the sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers) were ≤ 0.1 mg/kg in wheat grain and oilseed rape 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.

Barley
With the exception 2 trials (1 in NEU - residue = E: 0.12 / RA: 0.17 and 1 in SEU – residue = E: 0.11 / RA: 0.16) residues 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. However, since these 2 trials can be considered as significant outlier by Dixonon's Q test and Grubbs's test, they should not be taken into account in the further risk assessment. Considering the above and the contribution of barley commodity to the theoretical maximum daily intake (TMDI) (below 10% of the ADI) and the estimated daily intake (below 10% of the ARfD) for any European consumer group diet, further processing studies shall not be required.

TDMs
The residues of TDMs partly exceed 0.1 mg/kg in cereal grains (even though significant background residues in untreated samples were also observed in one of the trials). In cereal grain, 1,2,4-T and TLA always show residues < 0.1 mg/kg, whereas the trigger of 0.1 is partly exceeded for TA and TAA(HR and STMR exceed 0.1). The contribution of cereals to the IEDIs and IESTIs of the four relevant TDMs is always < 10 % of the ADI and ARfD, respectively. Due to the low residues in the respective commodities and the low contribution dietary intake, any processing studies are not considered to be required.

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

Overview of the available processing studies

Raw agricultural commodity	Processed commodity	Processing factors				Active	Reference
		T	TA	TAA	TLA		
Wheat (grain)	Aspirated grain fractions	-*	< 0.6			Metconazole	the peer review of the triazole derivative metabolites (TDMs) in the light of confirmatory data submitted (UK, 2018b, EFSA, 2018b, amended 2019)
	Husk	-*	1.1 0.8 0.3 0.7	< 1.0 < 0.8 1.0 1.1	NA NA NA NA		
	Coarse bran	-*	1.9 2.2 1.8 3.0	< 1.0 1.3 1.3 1.1	NA NA NA NA		
	Straight flour	-*	< 0.6 < 0.6 0.4 0.4	< 1.0 < 0.8 0.8 0.9	NA NA NA NA		
	Fine bran	-*	1.9 2.9 1.8 2.9	< 1.0 1.3 1.1 1.2	NA NA NA NA		
	Middlings	-*	0.9 < 0.6 0.6 0.6	< 1.0 < 0.8 0.9 0.9	NA NA NA NA		
	Shorts	-*	1.4 1.4 0.9 1.0	< 1.0 1.0 0.9 1.0	NA NA NA NA		
	Germ	-*	2.5 3.6 1.6 2.2	1.2 1.2 1.0 1.0	NA NA NA NA		
	Low grade meal	-*	1.0 1.3 0.7 0.8	< 1.0 1.0 0.9 0.9	NA NA NA NA		
	Flour type 550	-*	< 0.6 < 0.6 0.5 0.5	< 1.0 < 0.8 0.8 0.9	NA NA NA NA		
	Wholemeal flour	-*	0.8 0.9 0.8 1.0	< 1.0 < 0.8 0.8 0.9	NA NA NA NA		
	Wholemeal bread	-*	< 0.6 < 0.6 0.5 0.6	< 1.0 < 0.8 0.7 0.7	NA NA NA NA		
	Aspirated grain fractions	-*	0.20	0.39	NA	Prothioconazole	
	Bran	-*	3.7	2.1	NA		
	Flour	-*	0.30	0.89	NA		

Raw agricultural commodity	Processed commodity	Processing factors				Active	Reference
		T	TA	TAA	TLA		
	Germ	-*	4.9	1.3	-*		
	Middlings	-*	0.66	0.80	-*		
	Shorts	-*	1.7	1.2	-*		
	Bran	0.86 -*	2.2 1.4	1.4 1.7	-* > 1.3	Tetraconazole	
	Flour	1.0 -*	0.95 0.85	1.3 1.6	-* > 1.1		
	Bran	-*	1.7	< 0.25	-*	Tetraconazole	
	Flour	-*	0.96	1.6	-*		
	Wholemeal flour	-*	0.92	0.8	-*		
Barley (grain)	Brewer's malt	-*	0.78 0.77	1.0 1.1	> 1.1 > 1.5	Prothioconazole	
	Brewer's grain	-*	< 0.04 < 0.03	< 0.05 < 0.04	-* -*		
	Brewer's yeast	-*	0.24 0.14	0.23 0.23	-* -*		
	Beer	-*	0.15 0.13	0.29 0.13	-* -*		
Oilseed rape (seed)	Meal	-*	2.9	> 1.2	NA	Prothioconazole	
	Refined oil	-*	< 0.02	-*	NA		
	Press cake	-* -*	0.61 0.78	-* > 1	> 2 > 2		
	Meal	-* -*	0.52 0.81	> 2 > 2	> 1 > 3		
	Press oil	-* -*	< 0.03 < 0.04	-* -*	-* -*		
	Extraction oil	-* -*	< 0.03 < 0.04	-* -*	-* -*		
	Crude oil	-* -*	< 0.03 < 0.04	-* -*	-* -*		
	Pre-clarified oil	-* -*	< 0.03 < 0.04	-* -*	-* -*		
	Neutralised oil	-* -*	< 0.03 < 0.04	-* -*	-* -*		
	Refined oil	-* -*	< 0.03 < 0.04	-* -*	-* -*		
	Press cake	-*	1.3	-*	-*	Prothioconazole/ tebuconazole	
	Meal	-*	1.9	-*	> 2		
	Press oil	-*	< 0.03	-*	-*		
	Extraction oil	-*	< 0.03	-*	-*		

Raw agricultural commodity	Processed commodity	Processing factors				Active	Reference
		T	TA	TAA	TLA		
	Crude oil	-*	< 0.03	-*	-*		
	Pre-clarified oil	-*	< 0.03	-*	-*		
	Neutralised oil	-*	< 0.03	-*	-*		
	Refined oil	-*	< 0.03	-*	-*		

NA : not analysed
* 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.

7.2.5.1 Conclusion on processing studies

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

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

zRMS comments:
As residues of prothioconazole exceeding 0.1 mg/kg are not expected in the treated wheat and oilseed rape, there is no need to investigate the magnitude of prothioconazole residues in processed commodities. In the case of barley grain, in one of the 8 trials residues of prothioconazole exceeded 0.1 mg/kg and therefore the magnitude of prothioconazole residues in processed commodities should be provided (data gap).
The Applicant provided additional explanation:
With the exception 2 trials (1 in NEU - residue = E: 0.12 / RA: 0.17 and 1 in SEU – residue = E: 0.11 / RA: 0.16) residues 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. However, since these 2 trials can be considered as significant outlier by Dixonon's Q test and Grubbs's test, they should not be taken into account in the further risk assessment. Considering the above and the contribution of barley commodity to the theoretical maximum daily intake (TMDI) (below 10% of the ADI) and the estimated daily intake (below 10% of the ARfD) for any European consumer group diet, further processing studies shall not be required.
zRMS-PL agrees with the applicant's explanation.

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

Table: Overview of the available processing studies - TDMs

Processed commodity	Individual Processing factors (Median)				Comments	Reference
	1,2,4-T	TA	TAA	TLA		
EU confirmatory data (B.7.5.2, UK, 2018)						
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 (0.775)	1.0, 1.1 (1.05)	>1.1, >1.5 (>1.3)		

Barley, Brewer's grain	NC, NC	<0.04, <0.03 (<0.035)	<0.05, <0.04 (<0.045)	NC, NC		
Barley, Brewer's yeast	NC, NC	0.24, 0.14 (0.19)	0.23, 0.23 (0.23)	NC, NC		
Barley, Beer	NC, NC	0.15, 0.13 (0.14)	0.29, 0.13 (0.21)	NC, NC		
Rapeseed, meal	NC, NC, NC, NC	2.9, 0.52, 0.81, 1.9 (1.35)	>1.2, >2, >2, NC (>2)	NA, >1, >3, >2 (>2)		
Rapeseed, press cake	NC, NC, NC	0.61, 0.78, 1.3 (0.78)	NC, NC, >1	>2, >2, NC (>2)		
Rapeseed, refined oil	NC, NC, NC, NC	<0.02, <0.03, <0.04, <0.03 (<0.03)	NC, NC, NC, NC	NA, NC, NC, NC		

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

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

7.2.6 Magnitude of residues in representative succeeding crops

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

7.2.6.1 Field rotational crop studies (KCA 6.6.2)

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

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

TDMs
Rotational crop field trials with prothioconazole in which residues of triazole alanine (TA), triazole lactic acid (TLA), triazole acetic acid (TAA) and 1,2,4-triazole (1,2,4-triazole) were analysed for have been evaluated during EU peer review of the pesticide risk assessment for the triazole derivative metabolites

(UK, 2018b, EFSA, 2018b, amended 2019) to which explicit reference is made.

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

Table 7.2-22: **STMRs and HRs for the triazole derived metabolites in carrot / turnip, lettuce and barley grown as succeeding crops following the use of FS and EC formulations containing 100 g/L and 250 g/L of prothioconazole (UK, 2018b)**

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

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

Conclusion on rotational crops studies

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

TDMs

The peer review of TDMs (EFSA,2018b) investigated the metabolism of triazole compounds in primary and rotational crops and concluded that for TDMs the metabolic patterns were similar.

zRMS comments:

Information given by the Applicant is acceptable and sufficient.

No residues are expected in rotational crops for the intended uses of ~~CA3642 (Joust Pro)~~ FGF11/Patton Alpha, so additional field rotational crop studies are not considered required.

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

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

Studies to investigate the residues of prothioconazole-desthio (and the 5 hydroxy metabolites) and the triazole derivative metabolites have been provided and summarised within Appendix 2 (KCP 8.10.1-01 Study No. QG21003 and KCP 8.10.1-01 Study No. 644-2023). The results show that the residues within honey do not exceed the respective LOQ values (in most cases residues are not detected). Based on these results, it is not considered necessary to amend the MRL for prothioconazole residues within honey. Furthermore there are no implications for the consumer risk assessment.

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

The Applicant submitted two studies to determine residues of the magnitude of residues prothioconazole-desthio, ~~and~~ hydroxy-prothioconazole-desthio metabolites and the triazole derivative metabolites (TDMs) in honey (Study No.: QG21003; Andrews & Coleman 2024 and Study No.: 644-2023; Lebrun, 2024) after two foliar applications of the formulated product FGR06, a DC formulation with a nominal concentration of 250 g/L prothioconazole applied at the target dose rate of 200 g a.s./ha to *Phacelia tanacetifolia* plants.

Residues in honey
Study No.: QG21003:
Residue levels for prothioconazole-desthio in honey samples ranged between <LOQ and 0.0123 mg/kg.
Residue levels for the five prothioconazole-hydroxy-desthio metabolites in honey samples were <LOQ.

Study No.: 644-2023:
No residues of 1,2,4-triazole (T), triazole acetic acid (TAA), triazole alanine (TA) and triazole lactic acid (TLA) were measured above the LOQ in the treated honey.

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

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

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

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

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

7.2.8.1 Input values for the consumer risk assessment

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

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
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)				
Sugar beet roots	0,06	STMR-RAC EFSA Journal 2023;21(8):8198		
Chicory roots	0,06	STMR-RAC EFSA Journal 2023;21(8):8198		
Cranberries	0,025	STMR-RAC EFSA Journal 2023;21(8):8198		
Potatoes	0,01	STMR-RAC EFSA Journal 2023;21(8):8198		
Beetroots	0,08	STMR-RAC EFSA Journal 2023;21(8):8198		
Carrots	0,08	STMR-RAC EFSA Journal 2023;21(8):8198		
Celeriacs/turnip rooted celeries	0,08	STMR-RAC EFSA Journal 2023;21(8):8198		
Horseradishes	0,08	STMR-RAC EFSA Journal 2023;21(8):8198		
Parsnips	0,08	STMR-RAC EFSA Journal 2023;21(8):8198		
Parsley roots/Hamburg roots parsley	0,08	STMR-RAC EFSA Journal 2023;21(8):8198		
Salsifies	0,08	STMR-RAC EFSA Journal 2023;21(8):8198		
Swedes/rutabagas	0,08	STMR-RAC EFSA Journal 2023;21(8):8198		
Turnips	0,08	STMR-RAC EFSA Journal 2023;21(8):8198		
Garlic	0,01	STMR-RAC EFSA Journal 2023;21(8):8198		
Onions	0,01	STMR-RAC EFSA Journal 2023;21(8):8198		
Shallots	0,01	STMR-RAC EFSA Journal 2023;21(8):8198		

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Sweet corn	0,018	STMR-RAC EFSA Journal 2023;21(8):8198		
Broccoli	0,02	STMR-RAC EFSA Journal 2023;21(8):8198		
Cauliflowers	0,02	STMR-RAC EFSA Journal 2023;21(8):8198		
Other flowering brassica	0,02	STMR-RAC EFSA Journal 2023;21(8):8198		
Brussels sprouts	0,06	STMR-RAC EFSA Journal 2023;21(8):8198		
Head cabbages	0,02	STMR-RAC EFSA Journal 2023;21(8):8198		
Leeks	0,02	STMR-RAC EFSA Journal 2023;21(8):8198		
Beans	0,02	STMR-RAC*CF(2) EFSA Journal 2023;21(8):8198		
Lentils	0,1	STMR-RAC*CF(2) EFSA Journal 2023;21(8):8198		
Peas	0,1	STMR-RAC*CF(2) EFSA Journal 2023;21(8):8198		
Lupins/lupini beans	0,1	STMR-RAC*CF(2) EFSA Journal 2023;21(8):8198		
Linseeds	0,06	STMR-RAC*CF(2) EFSA Journal 2023;21(8):8198		
Peanuts/groundnuts	0,02	STMR-RAC*CF(2) EFSA Journal 2023;21(8):8198		
Poppy seeds	0,06	STMR-RAC*CF(2) EFSA Journal 2023;21(8):8198		
Sunflower seeds	0,02	STMR-RAC*CF(2) EFSA Journal 2023;21(8):8198		

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Rapeseeds/canola seeds	0,08	STMR-RAC EFSA Journal 2023;21(8):8198	0,08	STMR-RAC EFSA Journal 2023;21(8):8198
Soyabeans	0,1	STMR-RAC*CF(2) EFSA Journal 2023;21(8):8198		
Mustard seeds	0,06	STMR-RAC*CF(2) EFSA Journal 2023;21(8):8198		
Cotton seeds	0,104	STMR-RAC*CF(2) EFSA Journal 2023;21(8):8198		
Gold of pleasure seeds	0,02	STMR-RAC*CF(2) EFSA Journal 2023;21(8):8198		
Barley	0,07	STMR-RAC*CF(2) EFSA Journal 2023;21(8):8198	0,07	STMR-RAC*CF(2) EFSA Journal 2023;21(8):8198
Maize/corn	0,02	STMR-RAC*CF(2) EFSA Journal 2023;21(8):8198		
Wheat	0,04	STMR-RAC*CF(2) EFSA Journal 2023;21(8):8198	0,04	STMR-RAC*CF(2) EFSA Journal 2023;21(8):8198
Swine: Muscle/meat	0,01	STMR-RAC EFSA Journal 2023;21(8):8198		
Swine: Fat tissue	0,01	STMR-RAC EFSA Journal 2023;21(8):8198		
Swine: Liver	0,05	STMR-RAC EFSA Journal 2023;21(8):8198		
Swine: Kidney	0,025	STMR-RAC EFSA Journal 2023;21(8):8198		
Swine: Edible offals (otherthan liver andkidney)	0,025	STMR-RAC EFSA Journal 2023;21(8):8198		
Bovine: Muscle/meat	0,01	STMR-RAC EFSA Journal 2023;21(8):8198		
Bovine: Fat tissue	0,01	STMR-RAC EFSA Journal 2023;21(8):8198		

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Bovine: Liver	0,05	STMR-RAC EFSA Journal 2023;21(8):8198		
Bovine: Kidney	0,025	STMR-RAC EFSA Journal 2023;21(8):8198		
Bovine: Edible offals (otherthan liver andkidney)	0,025	STMR-RAC EFSA Journal 2023;21(8):8198		
Sheep: Muscle/meat	0,01	STMR-RAC EFSA Journal 2023;21(8):8198		
Sheep: Fat tissue	0,01	STMR-RAC EFSA Journal 2023;21(8):8198		
Sheep: Liver	0,05	STMR-RAC EFSA Journal 2023;21(8):8198		
Sheep: Kidney	0,025	STMR-RAC EFSA Journal 2023;21(8):8198		
Sheep: Edible offals (otherthan liver andkidney)	0,025	STMR-RAC EFSA Journal 2023;21(8):8198		
Goat: Muscle/meat	0,01	STMR-RAC EFSA Journal 2023;21(8):8198		
Goat: Fat tissue	0,01	STMR-RAC EFSA Journal 2023;21(8):8198		
Goat: Liver	0,05	STMR-RAC EFSA Journal 2023;21(8):8198		
Goat: Kidney	0,025	STMR-RAC EFSA Journal 2023;21(8):8198		
Goat: Edible offals (otherthan liver andkidney)	0,025	STMR-RAC EFSA Journal 2023;21(8):8198		
Equine: Muscle/meat	0,01	STMR-RAC EFSA Journal 2023;21(8):8198		
Equine: Fattissue	0,01	STMR-RAC EFSA Journal 2023;21(8):8198		
Equine: Liver	0,05	STMR-RAC EFSA Journal 2023;21(8):8198		
Equine: Kidney	0,025	STMR-RAC EFSA Journal 2023;21(8):8198		

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Equine: Edible offals (otherthan liver andkidney)	0,025	STMR-RAC EFSA Journal 2023;21(8):8198		
Poultry: Muscle/meat	0,0016	STMR-RAC EFSA Journal 2023;21(8):8198		
Poultry: Fat tissue	0,008	STMR-RAC EFSA Journal 2023;21(8):8198		
Poultry: Liver	0,071	STMR-RAC EFSA Journal 2023;21(8):8198		
Poultry: Kidney	0,071	STMR-RAC EFSA Journal 2023;21(8):8198		
Poultry: Edible offals (otherthan liver andkidney)	0,071	STMR-RAC EFSA Journal 2023;21(8):8198		
Other farmed animals: Muscle/meat	0,01	STMR-RAC EFSA Journal 2023;21(8):8198		
Other farmed animals: Fat tissue	0,01	STMR-RAC EFSA Journal 2023;21(8):8198		
Other farmed animals: Liver	0,05	STMR-RAC EFSA Journal 2023;21(8):8198		
Other farmed animals: Kidney	0,025	STMR-RAC EFSA Journal 2023;21(8):8198		
Other farmed animals: Edible offals (otherthan liver andkidney)	0,025	STMR-RAC EFSA Journal 2023;21(8):8198		
Milk: Cattle	0,005	STMR-RAC EFSA Journal 2023;21(8):8198		
Milk: Sheep	0,005	STMR-RAC EFSA Journal 2023;21(8):8198		
Milk: Goat	0,005	STMR-RAC EFSA Journal 2023;21(8):8198		
Milk: Horse	0,005	STMR-RAC EFSA Journal 2023;21(8):8198		
Milk: Others	0,005	STMR-RAC EFSA Journal 2023;21(8):8198		
Eggs: Chicken	0,01	STMR-RAC EFSA Journal 2023;21(8):8198		

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Eggs: Duck	0,01	STMR-RAC EFSA Journal 2023;21(8):8198		
Eggs: Goose	0,01	STMR-RAC EFSA Journal 2023;21(8):8198		
Eggs: Quail	0,01	STMR-RAC EFSA Journal 2023;21(8):8198		
Eggs: Others	0,01	STMR-RAC EFSA Journal 2023;21(8):8198		
All other commodities	EU-MRL	Reg. (EU) 2024/1318	EU-MRL (where applicable for supported crop uses)	Reg. (EU) 2024/1318

Commodity	**Chronic risk assessment**		**Acute risk assessment**	
	Input value (mg/kg)	**Comment**	**Input value (mg/kg)**	**Comment**
Risk assessment residue definition: Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers)				
All plant commodities	EU-MRL	Reg. (EU) 2024/1318	EU-MRL (where applicable for supported crop uses)	Reg. (EU) 2024/1318
Risk assessment residue definition: Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers)				
All animal commodities	EU-MRL	Reg. (EU) 2024/1318	EU-MRL	Reg. (EU) 2024/1318

zRMS comments:
Calculations of the TDMI and IESTI were conducted by evaluator.
TMDI calculation was performed using the in-force MRLs (Regulation (EU) 2024/1318) for all crops and animal commodities. An acute consumer risk assessment was performed only for the crops under consideration and animals commodities, based on the in-force MRLs. The following conversion factors for enforcement to risk assessment were used:
- Oilseeds: 2 (derived from residue trials) (EFSA, 2014)
- Wheat: 2 (derived from residue trials) (EFSA, 2014)
- Root and tuber vegetables (except sugar beet): 2.7 (EFSA, 2020)
- Potatoes: 1 (derived from metabolism study) (EFSA, 2014)
- Maize: 1 (derived from metabolism study) (EFSA, 2014)
- Cranberries and Sweet corn: no conversion factor was available as the MRLs for these crops originate from CXLs which are derived according to a different residue definition
- A conversion factor of 2 for crops where no data according to the risk assessment residue definition are available and for which a risk management decision is pending: pulses, flowering brassica, Brussels sprouts, head cabbages, shallots, onions, leeks, rye, barley, oats (EFSA, 2020)
- Ruminant and pig liver: 2 (EFSA, 2014)
- Ruminant and pig kidney: 9 (EFSA, 2014)

7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.2-24: Consumer risk assessment for prothioconazole-desthio (sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers))

TMDI (% ADI) according to EFSA PRIMo	43% (based on NL toddler – main contributor: maize/corn)
IEDI (% ADI) according to EFSA PRIMo	16% (based on NL toddler – main contributor: sugar beet roots)
IESTI (% ARfD) according to EFSA PRIMo*	carrots: 63% (based on unprocessed commodities, children) head cabbages: 50% (based on unprocessed commodities, adults) Sugar beets (root) / sugar: 66% (based on processed commodities, children) Beetroots/boiled: 39% (based on processed commodities, adults)

TMDI (% ADI) according to EFSA PRIMo	42% (based on NL toddler – main contributor: wheat)
IEDI (% ADI) according to EFSA PRIMo	Further refinement not required as TMDI shows no exceedance
IESTI (% ARfD) according to EFSA PRIMo*	Bovine: Kidney: 51% (based on unprocessed commodities, children) Bovine: Kidney: 28% (based on unprocessed commodities, adults) Barley / cooked: 15% (based on processed commodities, children) Barley / beer: 29% (based on processed commodities, adults)
NTMDI (% ADI) **	N/A
NEDI (% ADI)**	N/A
NESTI (% ARfD) **	N/A

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

The proposed uses of prothioconazole in the formulation FGF11 do not represent unacceptable acute and chronic risks for the consumer.

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

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

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

EFSA 2018b: "…a 'worst-case' consumer exposure assessment to the TDMs has been carried out in this conclusion taking into consideration the highest residue input values for risk assessment from all the individual residue data sets for plant commodities and the highest residue levels of each TDM arising in products of animal origin from the triazole active substances and from each of the TDMs. […] The magnitude of the TDMs have been determined in numerous residue trials conducted on crops covering most of the crop categories and for different triazole active substances both in primary and rotational crops. These trials were submitted in the framework of the confirmatory data (United Kingdom, 2015). The submitted residue trials were performed according to specific good agricultural practices (GAPs) authorised for the triazole active substances and residue trials conducted outside Europe were also available. In some cases, these residue trials were compliant with the representative uses of triazole active substances that were approved at EU level. All the residue trials that were used to perform the consumer dietary intake

assessment involve only the use of a single triazole active substance, these residue trials do not reflect the situation where several different triazole active substances may be applied on a crop during the same growing season or from treatments with triazole active substances during the previous seasons. However, it is noted that significant residue levels were often found in untreated control samples of residue trials on primary and rotational crops suggesting the use of triazole pesticide active substances in previous seasons. Despite these uncertainties, the experts were of the opinion that these trials should be considered with the purpose of performing a 'worst case' consumer dietary intake calculation. It was, however, emphasised that residue trials analysing all TDMs and compliant with the European authorised uses should be provided in order to conduct a realistic consumer dietary risk assessment and also the need for monitoring data on the occurrence and background levels of all TDMs in plants. For each commodity the input residue values for risk assessment (supervised trials median residues (STMR) and the supervised trials highest residues (HR) were calculated based on all the residue trials conducted with the same active substance on this commodity and for a commodity group, the highest STMR and HR values derived from all the individual data sets have been applied to each crop within the commodity group in order to conduct the 'worst-case' consumer dietary intake calculation."

Table 7.2-7: Input values for the consumer risk assessment – TDMs (source Triazole Derivative Metabolites February 2018 – Appendices D-F)

Crop group	Residue (mg/kg)							
	T		TA		TAA		TLA	
	STMR	HR	STMR	HR	STMR	HR	STMR	HR
Plants								
Citrus fruit	0.050	0.050	0.320	0.628	0.050	0.100	0.040	0.140
Pome fruit	0.010	0.021	0.039	0.530	0.030	0.060	0.030	0.110
Stone fruit	0.010	0.010	0.320	0.628	0.020	0.034	0.038	0.138
Berries	0.010	0.026	0.060	0.100	0.050	0.100	0.040	0.140
Banana	0.050	0.050	0.050	0.070	0.050	0.050	n.a	n.a
Root & tuber vegetables	0.010	0.016	0.184	0.239	0.010	0.010	0.021	0.131
Bulb vegetables	0.010	0.010	0.060	0.260	0.010	0.010	0.010	0.270
Fruiting vegetables	0.010	0.030	0.210	0.460	0.010	0.020	0.030	0.110
Brassica vegetables	0.039	0.113	0.170	0.500	0.010	0.010	0.010	0.010
Leafy vegetables	0.015	0.020	0.047	0.091	0.023	0.036	0.080	0.140
Legume vegetables	0.010	0.010	0.090	0.340	0.010	0.030	0.010	0.040
Stem vegetables	0.010	0.010	0.090	0.114	0.020	0.030	0.010	0.030
Pulses	0.050	0.050	0.170	3.700	0.050	0.052	0.010	0.060
Oilseeds	0.050	0.100	1.039	2.826	0.120	0.680	0.065	0.192
Oilfruits	0.050	0.100	1.039	2.826	0.120	0.680	0.065	0.192
Cereals	0.050	0.080	0.621	2.200	0.790	1.730	0.022	0.160
Sugar plants	0.050	0.060	0.050	0.078	0.050	0.050	0.010	0.010
Ruminant meat	0.270	0.310	0.460	0.620	0.040	0.040	0.040	0.040
Ruminant fat	0.180	0.240	0.220	0.340	0.050	0.080	0.070	0.100
Ruminant liver	0.310	0.360	1.010	1.360	0.050	0.050	0.040	0.040
Ruminant kidney	0.320	0.340	0.490	0.580	0.150	0.220	0.090	0.130
Ruminant milk	0.300	0.350	0.040	0.040	0.040	0.040	0.040	0.040
Sheep meat	0.290	0.330	0.510	0.680	0.040	0.040	0.040	0.040
Sheep fat	0.190	0.260	0.230	0.380	0.060	0.080	0.070	0.110
Sheet liver	0.340	0.390	1.130	1.800	0.050	0.050	0.040	0.040
Sheep kidney	0.340	0.370	0.550	0.650	0.180	0.250	0.090	0.130
Sheep milk	0.320	0.370	0.040	0.040	0.040	0.040	0.040	0.040
Swine meat	0.130	0.170	0.210	0.270	0.040	0.040	0.040	0.040
Swine fat	0.100	0.130	0.090	0.140	0.040	0.050	0.070	0.080
Swine liver	0.130	0.170	0.500	0.610	0.040	0.050	0.040	0.040

Swine kidney	0.140	0.200	0.220	0.270	0.110	0.140	0.050	0.080
Poultry meat	0.040	0.040	0.110	0.120	0.040	0.040	0.040	0.040
Poultry fat	0.040	0.040	0.010	0.110	0.040	0.040	0.040	0.040
Poultry liver	0.040	0.040	0.270	0.310	0.050	0.050	0.040	0.040
Poultry Eggs	0.040	0.040	0.060	0.060	0.040	0.040	0.040	0.040

TDMs

Consumer risk assessment for 1,2,4-Triazole:

TMDI (% ADI) according to EFSA PRIMo	Not applicable, no MRLs set.
IEDI (% ADI) according to EFSA PRIMo	88% (based on NL toddler)
IESTI (% ARfD) according to EFSA PRIMo***	Unprocessed commodities Results for children 0.72% Wheat 0.32% Rye 0.28% Barley 0.07% Rapeseeds/canola seeds Results for adults 0.42% Wheat 0.24% Rye 0.24% Barley 0.03% Rapeseeds/canola seeds Processed commodities Results for children 0.6% Wheat / milling (flour) 0.3% Wheat / milling (wholemeal)-baking 0.2% Rye / boiled 0.2% Barley / cooked 0.2% Rye / milling (wholemeal)-baking 0.1% Barley / milling (flour) 0.0% Rapeseeds / oils Results for adults 0.4% Barley / beer 0.22% Wheat / bread/pizza 0.19% Wheat / pasta 0.17% Wheat / bread (wholemeal)
NTMDI (% ADI) **	N/A
NEDI (% ADI)**	N/A
NESTI (% ARfD) **	N/A

* if national model is available
** include raw and processed commodities if both values are required for PRIMo 3.1

The proposed uses of prothioconazole in the formulation FGF11 do not represent unacceptable acute and chronic risks for the consumer with regard to residues of 1,2,4-Triazole.

Consumer risk assessment for Triazole Lactic Acid (TLA):

TMDI (% ADI) according to EFSA PRIMo	Not applicable, no MRLs set.
IEDI (% ADI) according to EFSA PRIMo	Normal mode: 1% (based on NL toddler; main contributor: milk: cattle)
IESTI (% ARfD) according to EFSA PRIMo*	Unprocessed commodities Results for children 0.11% Wheat 0.05% Rye 0.04% Barley 0.03% Rapeseeds/canola seeds Results for adults 0.06% Wheat 0.04% Rye 0.04% Barley

	0.01% Rapeseeds/canola seeds Processed commodities Results for children 0.1% Wheat / milling (flour) 0.0% Wheat / milling (wholemeal)-baking 0.0% Rye / boiled 0.0% Barley / cooked 0.0% Rye / milling (wholemeal)-baking 0.0% Barley / milling (flour) 0.0% Rapeseeds / oils Results for adults 0.1% Barley / beer 0.03% Wheat / bread/pizza 0.03% Wheat / pasta 0.03% Wheat / bread (wholemeal)
NTMDI (% ADI) **	N/A
NEDI (% ADI)**	N/A
NESTI (% ARfD) **	N/A

* if national model is available
** include raw and processed commodities if both values are required for PRIMo 3.1

The proposed uses of prothioconazole in the formulation FGF11 do not represent unacceptable acute and chronic risks for the consumer with regard to residues of triazole lactic acid (TLA).

Consumer risk assessment for Triazole Acetic Acid (TAA):

TMDI (% ADI) according to EFSA PRIMo	Not applicable, no MRLs set.
IEDI (% ADI) according to EFSA PRIMo	Normal mode: 1% (based on NL toddler; main contributor: maize/corn)
IESTI (% ARfD) according to EFSA PRIMo*	Unprocessed commodities Results for children 1.14% Wheat 0.50% Rye 0.44% Barley 0.02% Rapeseeds/canola seeds Results for adults 0.66% Wheat 0.38% Rye 0.38% Barley 0.01% Rapeseeds/canola seeds Processed commodities Results for children 1.0% Wheat / milling (flour) 0.4% Wheat / milling (wholemeal)-baking 0.3% Rye / boiled 0.3% Barley / cooked 0.3% Rye / milling (wholemeal)-baking 0.1% Barley / milling (flour) 0.0% Rapeseeds / oils Results for adults 0.6% Barley / beer 0.35% Wheat / bread/pizza 0.30% Wheat / pasta 0.28% Wheat / bread (wholemeal)
NTMDI (% ADI) **	N/A
NEDI (% ADI)**	N/A
NESTI (% ARfD) **	N/A

** if national model is available

*** include raw and processed commodities if both values are required for PRIMo 3.1

The proposed uses of prothioconazole in the formulation FGF11 do not represent unacceptable acute and chronic risks for the consumer with regard to residues of triazole acetic acid (TAA).

Consumer risk assessment for Triazole Alanine (TA):

TMDI (% ADI) according to EFSA PRIMo	Not applicable, no MRLs set.
IEDI (% ADI) according to EFSA PRIMo	6% (based on NL toddler)
IESTI (% ARfD) according to EFSA PRIMo*	Unprocessed commodities Results for children 2.99% Wheat 1.31% Rye 1.16% Barley 0.48% Rapeseeds/canola seeds Results for adults 1.74% Wheat 1.00% Rye 1.00% Barley 0.18% Rapeseeds/canola seeds Processed commodities Results for children 2.5% Wheat / milling (flour) 1.1% Wheat / milling (wholemeal)-baking 0.8% Rye / boiled 0.8% Barley / cooked 0.7% Rye / milling (wholemeal)-baking 0.4% Barley / milling (flour) 0.2% Rapeseeds / oils Results for adults 1.5% Barley / beer 0.91% Wheat / bread/pizza 0.79% Wheat / pasta 0.72% Wheat / bread (wholemeal)
NTMDI (% ADI) **	N/A
NEDI (% ADI)**	N/A
NESTI (% ARfD) **	N/A

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

The proposed uses of prothioconazole in the formulation FGF11 do not represent unacceptable acute and chronic risks for the consumer with regard to residues of triazole alanine (TA).

zRMS comments:
Calculations of the TDMI and IESTI were conducted by evaluator.
TMDI calculation for prothioconazole was performed using the in-force MRLs (Regulation (EU) 2024/1318) and appropriate conversion factors for enforcement to risk assessment.

Prothioconazole
The calculation of the TMDI using EFSA model (version 3.1) and MRLs values according to the Regulation (EU) 2024/1318 and appropriate conversion factors for enforcement to risk assessment led to a utilisation of the ADI of 42% with the NL toddler being the population group with the highest value. For this diet, the highest contributor is wheat with 8% of the ADI. The intended uses will not result in a consumer chronic exposure exceeding the ADI for prothioconazole-desthio.

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Prothioconazole-desthio

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	0,01	ARfD (mg/kg bw):	0,01
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2007	Year of evaluation:	2007

Input values

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI: ---

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

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
42%	NL toddler	4,22	8%	Wheat	7%	Maize/corn	6%	Milk: Cattle		
36%	GEMS/Food G11	3,63	15%	Soybeans	7%	Wheat	3%	Barley		
35%	GEMS/Food G10	3,52	13%	Soybeans	8%	Wheat	2%	Barley		
34%	GEMS/Food G15	3,43	9%	Wheat	7%	Soybeans	3%	Barley		
34%	GEMS/Food G07	3,39	8%	Wheat	7%	Soybeans	2%	Barley		
34%	GEMS/Food G06	3,38	14%	Wheat	5%	Soybeans	2%	Peas		
34%	GEMS/Food G08	3,36	8%	Wheat	8%	Soybeans	4%	Barley		
25%	IE adult	2,53	6%	Peas	5%	Wheat	3%	Lentils		
25%	NL child	2,46	8%	Wheat	3%	Sugar beet roots	2%	Milk: Cattle		
25%	FR child 3 15 yr	2,46	9%	Wheat	4%	Lentils	2%	Milk: Cattle		
23%	DK child	2,34	9%	Wheat	6%	Rye	4%	Carrots		
22%	ES child	2,22	9%	Wheat	5%	Lentils	2%	Peas		
22%	RO general	2,20	10%	Wheat	3%	Sunflower seeds	3%	Head cabbages		
21%	UK infant	2,09	5%	Wheat	4%	Milk: Cattle	4%	Carrots		
20%	DE child	2,04	8%	Wheat	3%	Carrots	2%	Milk: Cattle		
20%	FR toddler 2 3 yr	1,97	6%	Wheat	3%	Milk: Cattle	2%	Lentils		
18%	UK toddler	1,75	8%	Wheat	2%	Milk: Cattle	1%	Carrots		
16%	IT toddler	1,64	13%	Wheat	0,7%	Lentils	0,5%	Carrots		
16%	PT general	1,56	8%	Wheat	2%	Carrots	1%	Soybeans		
16%	SE general	1,55	6%	Wheat	2%	Carrots	1%	Milk: Cattle		
14%	NL general	1,37	4%	Wheat	1%	Barley	0,9%	Sugar beet roots		
14%	ES adult	1,37	5%	Wheat	2%	Lentils	2%	Barley		
13%	DE general	1,34	4%	Wheat	2%	Barley	1%	Sugar beet roots		
13%	DE women 14-50 yr	1,26	4%	Wheat	1%	Sugar beet roots	1%	Milk: Cattle		
11%	FR adult	1,12	4%	Wheat	1%	Lentils	0,5%	Carrots		
11%	IT adult	1,07	8%	Wheat	0,4%	Carrots	0,4%	Lentils		
10%	FI 3 yr	1,05	2%	Wheat	2%	Carrots	0,9%	Potatoes		
10%	FR infant	1,02	3%	Carrots	2%	Milk: Cattle	2%	Wheat		
9%	FI 6 yr	0,90	2%	Wheat	2%	Carrots	1%	Peas		
9%	UK vegetarian	0,89	4%	Wheat	0,8%	Lentils	0,6%	Carrots		
7%	FI adult	0,75	3%	Coffee beans	0,9%	Carrots	0,7%	Peas		
7%	LT adult	0,73	2%	Wheat	1%	Rye	0,7%	Head cabbages		
7%	UK adult	0,70	3%	Wheat	0,5%	Carrots	0,3%	Milk: Cattle		
7%	DK adult	0,67	2%	Wheat	1%	Carrots	0,5%	Milk: Cattle		
4%	PL general	0,44	0,8%	Carrots	0,7%	Potatoes	0,7%	Head cabbages		
4%	IE child	0,39	2%	Wheat	0,5%	Carrots	0,4%	Milk: Cattle		

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

An acute consumer risk assessment was performed only for the crops under consideration , based on the MRLs of wheat, rye, barley, oilseed rape and animals commodities and appropriate conversion factors for enforcement to risk assessment. The IESTI is at 51% and 28% of the ARfD for the consumption of Bovine:Kidney by children and by adults, respectively.

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

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

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

Show results for all crops

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
51%	Bovine: Kidney	0,15 / 1,35	5,1
37%	Bovine: Liver	0,23 / 0,46	3,7
22%	Barley	0,2 / 0,4	2,2
11%	Bovine: Edible offals (other	0,15 / 0,15	1,1
6%	Milk: Cattle	0,01 / 0,01	0,62
5%	Swine: Edible offals (other	0,15 / 0,15	0,45
4%	Rapeseeds/canola seeds	0,15 / 0,3	0,41
3%	Wheat	0,01 / 0,02	0,29
3%	Swine: Liver	0,23 / 0,23	0,28
2%	Swine: Kidney	0,15 / 0,15	0,19
2%	Honey and other apiculture	0,05 / 0,05	0,18
2%	Poultry: Liver	0,07 / 0,14	0,16
1%	Rye	0,01 / 0,02	0,13
1%	Eggs: Chicken	0,01 / 0,01	0,12
1%	Swine: Muscle/meat	0,01 / 0,01	0,12

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
28%	Bovine: Kidney	0,15 / 1,35	2,8
19%	Barley	0,2 / 0,4	1,9
18%	Bovine: Liver	0,23 / 0,46	1,8
16%	Swine: Other products	0,5 / 0,5	1,6
13%	Sheep: Liver	0,23 / 0,46	1,3
10%	Bovine: Other products	0,5 / 0,5	1,00
8%	Poultry: Kidney	0,07 / 0,64	0,82
7%	Poultry: Liver	0,07 / 0,14	0,67
5%	Bovine: Edible offals (other	0,15 / 0,15	0,50
4%	Swine: Edible offals (other	0,15 / 0,15	0,39
3%	Swine: Kidney	0,15 / 0,15	0,33
3%	Swine: Liver	0,23 / 0,23	0,32
2%	Milk: Cattle	0,01 / 0,01	0,19
2%	Wheat	0,01 / 0,02	0,17
2%	Rapeseeds/canola seeds	0,15 / 0,3	0,16

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

Processed commodities

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
15%	Barley / cooked	0,2 / 0,4	1,5
7%	Barley / milling (flour)	0,2 / 0,4	0,72
2%	Wheat / milling (flour)	0,01 / 0,02	0,24
2%	Rapeseeds / oils	0,15 / 0,6	0,18
1%	Wheat / milling (wholemeal)-t	0,01 / 0,02	0,11
0,7%	Rye / boiled	0,01 / 0,02	0,07
0,7%	Rye / milling (wholemeal)-bak	0,01 / 0,02	0,07
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
29%	Barley / beer	0,2 / 0,08	2,9
0,9%	Wheat / bread/pizza	0,01 / 0,02	0,09
0,8%	Wheat / pasta	0,01 / 0,02	0,08
0,7%	Wheat / bread (wholemeal)	0,01 / 0,02	0,07
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!

TDMs

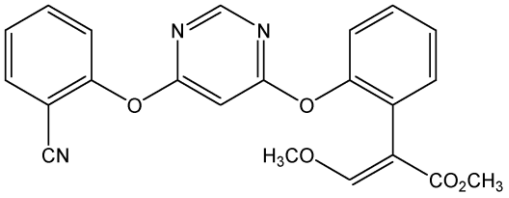
The dietary risk assessment was calculated using PRIMo rev 3.1 for each TDM. Toxicological reference values and input values from EFSA conclusion on confirmatory data on TDMs (EFSA, 2018) were taken into account.

The data available are considered sufficient for risk assessment. The chronic and the short-term intakes of prothioconazole residues and TDMs are unlikely to present a public health concern.
The intended uses of FGF11/Patton Alpha are accepted.

7.3 Azoxystrobin

General data on prothioconazole are summarized in the table below (last updated 2024/08/14)

Table 7.3-1: General information on azoxystrobin

Active substance (ISO Common Name)	Azoxystrobin
IUPAC	methyl (2E)-2-(2-{[6-(2-cyanophenoxy)pyrimidin-4-yl]oxy}phenyl)-3-methoxyacrylate
Chemical structure	
Molecular formula	$C_{22}H_{17}N_3O_5$
Molar mass	403.4 g/mol
Chemical group	Methoxyacrylate strobilurin fungicides
Mode of action (if available)	To prevent the respiration of fungi due to the disruption of electron transport chain, preventing ATP synthesis.
Systemic	Yes
Company (ies)	Syngenta*
Rapporteur Member State (RMS)	Austria (previously United Kingdom)
Approval status	Approved. Date of (01/01/2012) and reference to decision (Commission Directive (EU) 2019/291 - REGULATION (EU) No 703/2011).
Restriction (e.g. is restricted to use as "...")	Only uses as fungicide may be authorised.
Review Report	7581/VI/97-Final, 22 April 1998 SANCO/11027/2011 Rev. 2, 17 June 2011 and SANCO/11027/2011 Rev. 3, 20 March 2015
Current MRL regulation	Regulation (EU) No ~~2022/476~~ 2024/2633
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, 2010)**
EFSA Journal: conclusion on article 12	Yes (EFSA, 2013; EFSA, 2020)**
Current MRL applications on intended uses	Yes (Azoxystrobin - MRLs in oilseed rape and linseed; EFSA-Q-2020-00388) EFSA RO already available (EFSA Journal 2022;20(1):7051)

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

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, 2010, DAR United Kingdom, 2009) and to the MRL review (EFSA, 2013) for azoxystrobin.

No new data submitted in the framework of this application.

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

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products			
Grapes	High acid content	24 months	Burke, S.R. (1997), Azoxystrobin DAR, Vol. 3, B.7, IIA 6.1.2; EFSA, 2010
Wine	Processed commodity	24 months	Burke, S.R. (1997), Azoxystrobin DAR, Vol. 3, B.7, IIA 6.1.2; EFSA, 2010
Apples	High water content	24 months	Burke, S.R. (1997), Azoxystrobin DAR, Vol. 3, B.7, IIA 6.1.2; EFSA, 2010
Orange, oil	Processed commodity	24 months	Burke, S.R. (1997), Azoxystrobin DAR, Vol. 3, B.7, IIA 6.1.2; EFSA, 2010
Orange, pulp	Processed commodity	24 months	Burke, S.R. (1997), Azoxystrobin DAR, Vol. 3, B.7, IIA 6.1.2; EFSA, 2010
Orange, juice	Processed commodity	24 months	Burke, S.R. (1997), Azoxystrobin DAR, Vol. 3, B.7, IIA 6.1.2; EFSA, 2010
Bananas	High water content	24 months	Burke, S.R. (1997), Azoxystrobin DAR, Vol. 3, B.7, IIA 6.1.2; EFSA, 2010
Peaches	High water content	24 months	Burke, S.R. (1997), Azoxystrobin DAR, Vol. 3, B.7, IIA 6.1.2; EFSA, 2010
Tomato, juice	Processed commodity	24 months	Burke, S.R. (1997), Azoxystrobin DAR, Vol. 3, B.7, IIA 6.1.2; EFSA, 2010
Tomato, paste	Processed commodity	24 months	Burke, S.R. (1997), Azoxystrobin DAR, Vol. 3, B.7, IIA 6.1.2; EFSA, 2010
Cucumber	High water content	24 months	Burke, S.R. (1997), Azoxystrobin DAR, Vol. 3, B.7, IIA

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
			6.1.2; EFSA, 2010
Lettuce, leaf	High water content	24 months	Burke, S.R. (1997), Azoxystrobin DAR, Vol. 3, B.7, IIA 6.1.2; EFSA, 2010
Carrot, root	High starch content	24 months	Burke, S.R. (1997), Azoxystrobin DAR, Vol. 3, B.7, IIA 6.1.2; EFSA, 2010
Wheat, straw	Dry commodity	24 months	Burke, S.R. (1997), Azoxystrobin DAR, Vol. 3, B.7, IIA 6.1.2; EFSA, 2010
Wheat, grain	High starch content	24 months	Burke, S.R. (1997), Azoxystrobin DAR, Vol. 3, B.7, IIA 6.1.2; EFSA, 2010
Soybean, meal	Processed commodity	24 months	Burke, S.R. (1997), Azoxystrobin DAR, Vol. 3, B.7, IIA 6.1.2; EFSA, 2010
Oilseed rape	High oil content	24 months	Burke, S.R. (1997), Azoxystrobin DAR, Vol. 3, B.7, IIA 6.1.2; EFSA, 2010
Pecan, oil	Processed commodity	24 months	Burke, S.R. (1997), Azoxystrobin DAR, Vol. 3, B.7, IIA 6.1.2; EFSA, 2010
Pecan, nut meat	Processed commodity	24 months	Burke, S.R. (1997), Azoxystrobin DAR, Vol. 3, B.7, IIA 6.1.2; EFSA, 2010
Peanut, oil	Processed commodity	24 months	Burke, S.R. (1997), Azoxystrobin DAR, Vol. 3, B.7, IIA 6.1.2; EFSA, 2010
Peanut, nut meat	Processed commodity	24 months	Burke, S.R. (1997), Azoxystrobin DAR, Vol. 3, B.7, IIA 6.1.2; EFSA, 2010
Animal Products			
Animal tissues	Ruminant matrices (muscle, liver, kidney, fat)	10 months	[redacted], 1997; Azoxystrobin DAR, Vol. 3, B.7, IIA 6.1.2; 2009 EFSA, 2010; 2013; 2020

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Animal products	Ruminant milk	10 months	DAR, 2009 EFSA, 2010; 2013; 2020
Animal products	Poultry eggs	10 months	DAR, 2009 EFSA, 2010; 2013; 2020
New data			
Animal Products			
Honey	No group	81 days	KCP 8.1-0456 Appeltauer A., 2022 (S21-01128, VV-931501)

Conclusion on stability of residues during storage
According to EFSA, 2010: *"Azoxystrobin and R23310 were stable for up to two years when stored as approximately -18°C in : grapes, wine, apples, orange oil, orange juice, orange pulp, bananas, peaches, tomatoes (juice and paste), cucumbers, lettuce, carrot root, cereal straw, cereal grain, soybean meal, oilseed rape, pecans, and peanuts (oil and nut meat).*

Azoxystrobin was stable for up to ten months when stored at approximately -18°C in animal tissues, eggs and milk."

7.3.1.2 Stability of residues in sample extracts (KCA 6.1)

The stability of crop sample extracts was checked as part of the residue field studies. The stability of the ~~prothioconazole metabolites~~ azoxystrobin in the sample extracts during the analytical phase was demonstrated by the corresponding procedural recovery sample which was stored under the same conditions together with the field samples. The results do not indicate any residue decrease for the storage period (from residue extraction to analysis).

Conclusion on stability of residues in sample extracts
The stability of the ~~prothioconazole metabolites~~ azoxystrobin was demonstrated as part of the supervised residue field trials.

zRMS comments:
In EFSA Journal 2013;11(12):3497 it is stated that *The potential degradation of residues during storage of the residue trials samples was also assessed. In the framework of the peer review, storage stability of azoxystrobin was demonstrated for a period of 24 months at -18°C in commodities with high water content (banana, peach, tomato, cucumber, lettuce, carrot), high acid content (grape, apple, orange), high oil content (soybean meal, oilseed rape, pecans, peanut), dry commodities (cereal grain) as well as cereal straw (United Kingdom, 2009a).*
(…) The storage stability of azoxystrobin residues in animal products was evaluated under the peer review of Directive 91/414/EEC (United Kingdom, 2009a). Studies demonstrated storage stability of azoxystrobin in milk, muscle, fat, liver and kidney, eggs for up to 10 months when stored deep frozen.

Additionally the Applicant submitted the study on storage stability of azoxystrobin in honey (Appeltauer, 2022; Report S21-01128, access from Task Force). It should be noted that this study was reviewed and accepted by zRMS-PL in RR, Part B7 for PPP of Orondis Evo in June 2023.
Azoxystrobin and R230310 have been shown to be stable in honey for at least 81 days when stored frozen at -18°C.

The residue data are valid with regard to storage stability.
No additional data are required.

7.3.2 Nature of residues in plants, livestock and processed commodities

7.3.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

Reference is made to the EU peer review (EFSA, 2010, DAR United Kingdom, 2009) and to the MRL review (EFSA, 2013) for azoxystrobin.

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

Primary crop metabolism of azoxystrobin was investigated in three different crop groups following foliar applications. Metabolic patterns in the different studies were shown to be similar and the relevant residue for enforcement and risk assessment.

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								
Fruits and fruiting vegetable	Grape	^{14}C-cyanophenyl-, pyrimidinyl- or phenylacylate azoxystrobin	Foliar treatment, F	0.25 kg as/ha + 1 kg as/ha + 1 kg as/ha + 0.25 kg as/ha	4	21 days	-	Earl, V.L. et al., (1994), Azoxystrobin DAR, B.7, IIA 6.1 and AR B.7.1.1.1; EFSA, 2010; EFSA, 2013; EFSA, 2020
Pulses and oilseeds	Peanut	^{14}C-cyanophenyl-, pyrimidinyl- or phenylacylate azoxystrobin	Foliar treatment, F	0.85 kg as/ha + 0.85 kg as/ha + 0.3 kg as/ha	3	10 days	-	Webb, J. et al., (1995), Azoxystrobin DAR B.7, IIA 6.1and AR B.7.1.1.1; EFSA, 2010 EFSA, 2013; EFSA, 2020
Cereals	Wheat	^{14}C-cyanophenyl-, pyrimidinyl- or phenylacylate azoxystrobin	Foliar treatment, F	0.5 kg a.s /ha + 0.5 kg a.s /ha	2	Forage: 13 days grain & straw: 61-62 days	Applications at BBCH 30-31 and BBCH 59-61	Allin, R. et al., (1995), Azoxystrobin DAR B.7, IIA 6.1 and AR B.7.1.1.1; EFSA, 2010; EFSA, 2013; EFSA, 2020
Cereals	Wheat	^{14}C-pyrimidinyl azoxystrobin	Foliar treatment, F	0.5 kg a.s./ha	1	28 days	Applications at BBCH 71	Wilkinson, M.J et al, (1994), Azoxystrobin DAR B.7, IIA 6.1 and AR B.7.1.1.1; EFSA, 2010; EFSA, 2013; EFSA, 2020

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

Summary of plant metabolism studies reported in the EU

According to EFSA, 2010: *"No residues are expected in rotational crops, when azoxystrobin is applied according to representative GAPs."*

According to EFSA, 2013: *"The metabolism of azoxystrobin in rotational crops was complex with a large*

number of conjugated metabolites formed. The residues declined significantly at longer plant back intervals. Radioactive residues in the 365 day crops were generally in concentrations below 0.01 mg/kg. As in the primary crops, parent azoxystrobin represented the major residue detected in all rotational crops (up to 17–44% TRR); with very low residue levels in the tested crops (< 0.01–0.08 mg/kg at 30 days and < 0.01–0.01 mg/kg at 200 days). In wheat forage and wheat straw at 30 days, TRRs were 0.15–0.34 and 1.4–1.9 mg/kg, respectively, which declined significantly at the longer plant back intervals of 200 days (0.02–0.05 and 0.06–0.12 mg/kg, respectively) and 365 days (< 0.01 mg/kg). Azoxystrobin residues in wheat grain were < 0.01 mg/kg even in wheat planted 30 days after the treatment. Compounds G219, M4220, N121, N222, O223 and O324, which are the principal metabolites in rotated crops, are glucose conjugates and were also found in the primary crops in both free and conjugated forms. These metabolites are not more toxicologically significant than parent (DAR, 2009).

The potential incorporation of soil residues into succeeding and rotational crops was investigated in lettuce, wheat and radish. These studies showed a metabolism comparable to the primary crops. Based on several rotational crop field trials, significant residues in rotational crops are also not expected to impact MRLs for plant and animal products, provided that azoxystrobin is applied according to the GAPs supported in the framework of this review."

EFSA Journal 2013;11(12):3497
"The metabolism pattern was similar in all plant groups, parent azoxystrobin being the major compound, accounting for 17-43 % TRR in cereal grain and straw, 35-65 % TRR in grapes, and 14-48 % TRR in peanut hulls and hay. Azoxystrobin was not detected in peanut nuts, where radioactivity was found to be mainly incorporated in fatty acids (up to 49 % TRR), but no individual metabolite was present in peanut kernels at a level greater than 1 %. In the other crops, the major metabolites identified were M28, resulting from the cleavage of the ester link between the phenylacrylate and pyrimidyl ring, and metabolite M09 (Z-isomer of azoxystrobin), both mostly below 10 % TRR. Other metabolites were identified but they were all present in very small amounts (EFSA, 2010).
Consequently, the residue for enforcement and risk assessment in all plant commodities following foliar application is defined as azoxystrobin only."

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 (2010, 2013, and 2020), the following residue definitions are proposed based on the plant metabolism data:

Residue definition for enforcement
- Azoxystrobin

Residue definition for risk assessment
- Azoxystrobin

zRMS comments:
In EFSA Journal 2022;20(1):7051 it is stated that *The metabolism of azoxystrobin following foliar applications was investigated in crops belonging to the groups of fruit crops (grapes), cereals/grass (wheat) and pulses/oilseeds (peanuts). The metabolism pattern was similar in all plant groups with the parent azoxystrobin being the major compound, accounting for 17–43% total radioactive residue (TRR) in cereal grain and straw, 35–65% TRR in grapes and 14–48% TRR in peanut hulls and hay.*

Based on the metabolic pattern identified in metabolism studies, the results of hydrolysis studies and the capabilities of enforcement analytical methods, ***the residue definition for enforcement and risk assessment in all plant commodities following foliar application was proposed as 'azoxystrobin'*** *(EFSA, 2010, 2013). The same residue definition is applicable to rotational crops and processed products. The residue definition for enforcement set in Regulation (EC) No 396/2005 is identical with the above mentioned residue definition.*

For the intended uses, the metabolic behaviour in primary crops is sufficiently addressed.

No additional data are required.

7.3.2.2 Nature of residue in rotational crops (KCA 6.6.1)

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

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

Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G *	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks	
EU data								
Leafy vegetables	Lettuce	^{14}C-pyrimidinyl; ^{14}C-cyanophenyl, ^{14}C-phenylacrylate	Application on bare soil, G	2.2	30, 200, 365	At maturity	-	Goldsby, G. et al (1995); Miller, M.M. & Wilson, W. (1995); Tambling, D.R. et al. (1995); Azoxystrobin, DAR, B7, IIA 6.6 and AIRDAR EFSA, 2010; EFSA, 2013; EFSA, 2020
Root and tuber vegetables	Radish							
Cereals	Wheat							

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

Summary of plant metabolism studies reported in the EU
According to EFSA, 2010: *"No residues are expected in rotational crops, when azoxystrobin is applied according to representative GAPs."*

According to EFSA, 2013: *"The metabolism of azoxystrobin in rotational crops was complex with a large number of conjugated metabolites formed. The residues declined significantly at longer plant back intervals. Radioactive residues in the 365 day crops were generally in concentrations below 0.01 mg/kg. As in the primary crops, parent azoxystrobin represented the major residue detected in all rotational crops (up to 17–44% TRR); with very low residue levels in the tested crops (< 0.01–0.08 mg/kg at 30 days and < .01–0.01 mg/kg at 200 days). In wheat forage and wheat straw at 30 days, TRRs were 0.15–0.34 and 1.4–1.9 mg/kg, respectively, which declined significantly at the longer plant back intervals of 200 days (0.02–0.05 and 0.06– 0.12 mg/kg, respectively) and 365 days (< 0.01 mg/kg). Azoxystrobin residues in wheat grain were < 0.01 mg/kg even in wheat planted 30 days after the treatment. Compounds G219, M4220, N121, N222, O223 and O324, which are the principal metabolites in rotated crops, are glucose conjugates and were also found in the primary crops in both free and conjugated forms. These metabolites are not more toxicologically significant than parent (DAR, 2009).*
The potential incorporation of soil residues into succeeding and rotational crops was investigated in lettuce, wheat and radish. These studies showed a metabolism comparable to the primary crops. Based on several rotational crop field trials, significant residues in rotational crops are also not expected to impact MRLs for plant and animal products, provided that azoxystrobin is applied according to the GAPs supported in the framework of this review."

Summary of new plant metabolism studies
No new studies have been submitted.

Conclusion on metabolism in rotational crops
Based on the evaluations of EFSA (2010, 2013, and 2020), the following residue definitions are proposed based on the rotational crop metabolism data:

Residue definition for enforcement
- Azoxystrobin

Residue definition for risk assessment
- Azoxystrobin

EFSA, 2013: *"Azoxystrobin follows a comparable pattern in rotational crops but with a more extensive metabolism, with more metabolites being formed, most of them as glucose or amino acid conjugates. Based on these studies the residue definition for monitoring and risk assessment was defined as azoxystrobin only."*

zRMS comments:
In accordance with the soil degradation studies evaluated in the framework of the peer review, the DT_{50} value of azoxystrobin is 262 days (EFSA, 2010). DT_{90} value is expected to be higher than the trigger value of 100 days (EFSA, 2010), and therefore, studies investigating the nature of residues in rotational crops are required.
In EFSA Journal 2016;14(5):4459 it is stated that *The nature and magnitude of azoxystrobin residues in rotational crops were investigated during the peer review. On the basis of studies conducted in lettuce, radish and wheat at a maximum dose rate of 2,200 g/ha, it was concluded that the metabolism of azoxystrobin is similar to that of the primary crops and that residues above 0.05 mg/kg are not expected in the rotational crops (EFSA, 2013).*

The peer-review concluded that the metabolism of azoxystrobin in succeeding crops is almost similar for all the analysed crops and also similar to that observed in the primary crops. The relevant residue in rotational crops should therefore be defined as parent azoxystrobin.

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, 2010, DAR United Kingdom, 2009) and to the MRL review (EFSA, 2013) for azoxystrobin.

No new data have been submitted to support this product.

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

Conditions (Duration, Temperature, pH)	Identified compound(s) (%)	Reference
EU data		
Pasteurisation (20 minutes, 90°C, pH 4)	Azoxystrobin (103.4%)	Grout, S.J. (2002)
Baking, boiling, brewing (60 minutes, 100°C, pH 5)	Azoxystrobin (96.15%)	Azoxystrobin DAR, Vol. 3, B7, IIA 6.5.1/01 and AIR-DAR
Sterilisation (20 minutes, 120°C, pH 6)	Azoxystrobin (97.25%)	

Conclusion on nature of residues in processed commodities
In processed commodities, parent azoxystrobin was shown to be stable during pasteurisation, cooking, boiling/brewing/baking, and sterilisation, and no formation of toxicologically relevant metabolites occurs (EFSA, 2013).

zRMS comments:
Standard hydrolysis studies simulating the effect on the nature of azoxystrobin residues under processing conditions representative of pasteurisation, boiling and sterilisation were assessed in the peer review and it was concluded that the compound is hydrolytically stable (EFSA, 2010). Thus, for processed commodities, the same residue definition as for raw agricultural commodities is applicable.

Studies to assess the magnitude of azoxystrobin residues during processing have been assessed in the framework of the peer review and the Article 12 MRL review and processing factors were derived for several crops (EFSA, 2010, 2013).
No further data are required to support the proposed uses.

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

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

Endpoints	
Plant groups covered	Pulses and oilseeds (peanuts) Cereal (wheat) Fruit (grapes)
Rotational crops covered	Leafy vegetables (lettuce) Root and tuber vegetables (radish) Cereals (wheat)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Azoxystrobin is stable under standard hydrolysis conditions
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes
Plant residue definition for monitoring	Azoxystrobin (EFSA, 2010; EFSA, 2013; EFSA, 2020; Commission Regulation (EU) 2024/2633)
Plant residue definition for risk assessment	Azoxystrobin (EFSA, 2010; EFSA, 2013; EFSA, 2020)
Conversion factor from enforcement to RA	Not required

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

Available data

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

Table 7.3-7: Summary of animal metabolism studies

Group	**Species**	**Label position**	**No of animal**	**Application details**		**Sample details**		**Reference**
				Rate (mg/kg bw/d)	**Duration (days)**	**Commodity**	**Time of sampling**	
EU data								
Lactating ruminants	Goat	^{14}C-pyrimidinylor ^{14}C-cyanophenylor ^{14}C-phenylacrylate	not reported	23.2 to 32.7	7	Milk	twice daily	[redacted] (1995); [redacted] (1995), Azoxystrobin DAR, Vol. 3, B.7, IIA 6.2; [redacted] (1996); [redacted] (1996), Azoxystrobin, DAR, Vol. 3, B7, IIA 6.2.2/02 EFSA, 2013
						Urine and faeces	daily	
						Tissues	at sacrifice	
		^{14}C-cyanophenyl	1	25	7	Milk	twice daily	
						Urine and faeces	daily	
						Tissues	at sacrifice	
Laying poultry	Hens	^{14}C-pyrimidinylor ^{14}C-	not reported	11	10	Eggs	daily	[redacted] (1994, 1995), Azoxystrobin,
						Excreta	daily	

		cyanophenylor ^{14}C-phenylacrylate				Tissues	at sacrifice	DAR, Vol. 3, B.7, IIA 6.2 EFSA, 2013
			10	12.5	10	Eggs	not reported	
						Excreta	daily	
						Tissues	at sacrifice	
Pigs	Not required, as metabolism in rat and ruminant is considered similar and the findings in ruminants can therefore be extrapolated to pigs.							EFSA, 2010
Fish	Not required, as the log Pow of azoxystrobin is 2.5 at 20 °C. Fish metabolism studies are therefore not required.							-

Summary of plant metabolism studies reported in the EU
Azoxystrobin was rapidly excreted in the metabolism studies performed on goats (2N dose) and poultry (8N dose). The transfer in tissues was limited, the TRRs in muscle, fat, milk, and egg white being ≤ 0.02 mg/kg. Thus, characterisation of residues was only performed in goat liver and kidney, and in poultry liver and egg yolk, where the TRR were in the range of 0.05 to 1.19 mg/kg. In these matrices, the metabolism was shown to be very extensive, more than 20 compounds being identified/characterised, each accounting mostly for less than 5% of the TRR. Some metabolites (M 28, M 20, L4…) were however observed in higher proportions in some matrices, depending on the ^{14}C-label.

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

Conclusion on metabolism in livestock
EFSA, 2013: *"Lactating goats were dosed with approximately 25 mg/kg in the diet of azoxystrobin, corresponding to approximately 1.2 times the exposure of meat ruminant. Laying hens were dosed with 11 - 12.5 mg/kg in the diet of azoxystrobin, corresponding to approximately 7 - 8 times the exposure of poultry. All studies showed that azoxystrobin was rapidly excreted in both lactating goats and laying hens. The transfer in tissues was limited, the TRRs in muscle, fat, milk and egg white being <0.02 mg/kg. Thus, characterisation of residues was only performed in goat liver and kidney, and in poultry liver and egg yolk, where the TRRs were in the range of 0.05 to 1.19 mg/kg. In these matrices, the metabolism was shown to be very extensive, more than 20 compounds being identified/characterised, each accounting mostly for less than 5 % of the TRR. Some metabolites (M28, M2025, L426…) were however observed in higher proportions in some matrices, depending on the 14C-label. The parent compound was less than 2 % of the TRR, except in egg yolk (12 % TRR for the cyanophenyl label). The general metabolic pathways in rodents and ruminants were found to be comparable; the findings in ruminants can therefore be extrapolated to pigs.*

As none of these compounds were considered as a sufficient marker for the residue in animal matrices, the residue for enforcement was then defined by default as azoxystrobin only. Validated analytical methods for enforcement of the proposed residue definition are available (see also section 1.2). However, no conclusion could be drawn on the toxicological profile of metabolites L127, L4 and L928 (EFSA, 2010). Additional data on the toxicological relevance of metabolites L1, L4 and L9 are therefore required. Meanwhile, it is proposed, on a tentative basis, to also define the residue for risk assessment as azoxystrobin only."

EFSA, 2020: "*The data gap identified by EFSA is partially addressed as the genotoxic potential of metabolites L1, L4 and L9 (found exclusively in ruminant liver and kidney) can be ruled out, but a full characterisation of the toxicological profile of these metabolites has not been provided The indicative human exposure resulting to the occurrence of metabolites L1, L4 and L9 in liver and kidney (estimated for the EU livestock dietary burden) was estimated and the RMS concluded that the low exposure does not trigger further investigation for these compounds. The RMS proposed to confirm the risk assessment residue definition in animal commodities as azoxystrobin alone Further risk management considerations should be given to decide whether the argument of the low exposure is acceptable to waive the need to*

submit data on the general toxicity of L1, L4 an L9. Nevertheless, EFSA noted that this argument does not support the existing EU MRLs (based on CXLs and more critical (5N) livestock dietary burden). Therefore, in the case where risk managers would accept the rationale of the RMS to address the data gap, MRLs for liver, kidney and other edible offals should be set at the LOQ (0.01 mg/kg), in line with the EU dietary burden calculated under the present assessment."*

This pending risk management decision relates only to the ruminant liver and kidney, as these metabolites were not observed in other animal products / tissues. Risk assessments undertaken by the RMS were calculated using EU dietary burdens which would cover the dietary risk expected based on the proposed use for FGF11. Therefore, it is considered that these exposure calculations would provide for a reasonable worst case and the residue definition for risk assessment (azoxystrobin only) can support this application.

zRMS comments:
Information given by the Applicant is sufficient.
In EFSA Journal 2010; 8(4):1542 it is stated that *Azoxystrobin was rapidly excreted in the metabolism studies performed on goats (2N dose) and poultry (8N dose). The transfer in tissues was limited, the TRRs in muscle, fat, milk and egg white being <0.02 mg/kg. Thus, characterisation of residues was only performed in goat liver and kidney, and in poultry liver and egg yolk, where the TRRs were in the range of 0.05 to 1.19 mg/kg. In these matrices, the metabolism was shown to be very extensive, more than 20 compounds being identified/characterised, each accounting mostly for less than 5% of the TRR. Some metabolites (M28, M20, L4…) were however observed in higher proportions in some matrices, depending on the ^{14}C-label. The parent compound was less than 2% of the TRR, except in egg yolk (12% TRR for the cyanophenyl label). None of these compounds were considered as a sufficient marker for the residue in animal matrices, and* ***the residue for monitoring and risk assessment was then defined by default as azoxystrobin only****. However, the definition for risk assessment has to be considered provisional, pending additional information on the toxicological relevance of metabolites L1, L4 and L9.*

The data on *the toxicological relevance of metabolites L1, L4 and L9* provided in the present application are from the EFSA Journal 2020;18(8):6231 – "Evaluation of confirmatory data following the Article 12 and modification of the existing MRLs for azoxystrobin". As confirmatory data, they are out of data protection.

According to the EFSA Journal 2020;18(8):6231 – "Evaluation of confirmatory data following the Article 12 and modification of the existing MRLs for azoxystrobin" *In the framework of the MRL review, EFSA identified data gaps related to the toxicological relevance of metabolites L1, L4 and L9, which were identified in ruminant liver and kidney (data gap number 35). In order to address this data gap, the applicant provided, in the framework of the current assessment, information that allowed to conclude that the genotoxic potential of these three compounds can be ruled out (see Section 1). However, the applicant did not provide data on the general toxicity of these metabolites. Instead, calculations were provided to demonstrate that the expected dietary exposure of consumers to these metabolites (from the intake of liver and kidney) is low and would therefore not be of toxicological concern. (…) Regarding the toxicological assessment of livestock metabolites L1, L4 and L9, the submitted data allowed to conclude that the genotoxic potential of these three compounds can be ruled out.*
(…) general toxicity of these metabolites was not addressed.
As confirmatory data, they are out of data protection.

Metabolism studies, methods of analysis and residue definitions in livestock (EFSA, 2020):

Livestock (available studies)	Animal	Dose (mg/kg diet)	Duration (days)	Comment/Source
	Laying hen	11	10	Studies performed on goat using ^{14}C-pyrimidinyl ^{14}C-cyanophenyl and ^{14}C-phenylacrylate radiolabels
		12.5	10	
	Lactating ruminants	23.2–32.7	7	Study performed on goat using ^{14}C-pyrimidinyl ^{14}C-cyanophenyl and ^{14}C-phenylacrylate radiolabels
		25	7	Study performed on goat using ^{14}C-cyanophenyl radiolabel

Time needed to in milk and eggs (days)	Milk: not relevant	TRR in milk is ranging between 0.004–0.01 mg eq/L
	Eggs: 6–8	Observed in egg yolk (United Kingdom, 2009)
Metabolism in rat and ruminant similar	Yes	The general metabolic pathways in rodents and ruminants were found to be comparable
Can a general residue definition be proposed for animals?	Yes	–
Animal residue definition for monitoring (RD-Mo)	Azoxystrobin	
Animal residue definition for risk assessment (RD-RA)	Azoxystrobin (tentative, EFSA, 2010, 2013) [genotoxicity of metabolites L1, L4 and L9 can be ruled out but general toxicity of these metabolites was not addressed]	
Fat soluble residues	No	Log $P_{o/w}$ < 3
Methods of analysis for monitoring of residues (analytical technique, matrix, LOQs)	GC-NPD (United Kingdom, 2009): Milk: LOQ 0.001 mg/kg. Eggs, Muscle, Fat, Liver/kidney: 0.01 mg/kg ILV available but confirmatory method missing. HPLC–MS/MS (validated method in FAO, 2008): LOQ: 0.01 mg/kg in all tissues, milk and eggs	

TRR: total radioactive residue; $P_{o/w}$: partition coefficient between n-octanol and water; GC-NPD: gas chromatography with nitrogen phosphorous detector; HPLC–MS/MS: high-performance liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; ILV: independent laboratory validation.

The log $P_{o/w}$ value for azoxystrobin is 2.5 (at 20°C) which is consistent with no accumulation potential in fish tissues. As the log $P_{o/w}$ of all components of the plant Residue Definition for Risk Assessment does not exceed 3, metabolism studies in fish are not required.

No further data are required to support the proposed uses.

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

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

	Endpoints
Animals covered	Lactating ruminants (goat)
	Laying hens (chicken)
Time needed to reach a plateau concentration	Not relevant. TRR in milk ranging between 0.004 – 0.01 mg eq/L
	6-8 days in egg yolk
Animal residue definition for monitoring	Azoxystrobin (EFSA, 2010; EFSA, 2013; EFSA, 2020; Commission Regulation (EU) 2024/2633)
Animal residue definition for risk assessment	Azoxystrobin (provisional/tentative) (EFSA 2010; EFSA, 2013; EFSA, 2020)
Conversion factor	None (EFSA 2010)
Metabolism in rat and ruminant similar	Yes. The general metabolic pathways in rodents and ruminats were found to be comparable.
Fat soluble residue	No, log P_{ow} is <3

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

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application. These studies are summarised in table 7.2- 9. The detailed assessment of these studies is presented in Appendix 2.

In addition, the envisaged GAP uses are covered by the EU active substance evaluation (cereals: United Kingdom, 2009, EFSA 2010) and by the EU MRL review EFSA 2013 and 2020 (cereals, oilseed rape). The representative GAP uses evaluated are shown in the following.

Table 7.3-9: Summary of EU reported and new data supporting the intended uses of FGF11 and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Plant residue definition for monitoring (E): Azoxystrobin **Plant residue definition for risk assessment (RA): Azoxystrobin**								
Spring and winter wheat, grain and straw Extrapolation from wheat → rye and Triticale Extrapolation from spring cereals ↔ winter cereals due to late application timing	EFSA, 2010, United Kingdom, 2009	N-EU	GAP on which MRL/EU a.s. assessment is based: 1-2 x 0.250 kgas/ha, BBCH 31-69, PHI 35d, outdoor Grain, E & RA: <0.01, 0.01, 0.02, 2x 0.04, 0.08, 0.20, 0.43 Straw, E & RA: 0.11, 0.39, 0.48, 0.91, 1.3, 1.5, 2.7, 5.1	N/A				
	New trials	N-EU	Trials GAP: 1 x 0.25 kg as/ha, BBCH 69 Grain, E & RA: <0.01, 0.04, <0.01, 0.03, 0.08, <0.01, <0.01, 0.04 Straw, E & RA: 0.49, 0.75, 0.36, 3.46, 2.51, 0.25, 0.37, 8.66					
	Overall supporting data for cGAP	N-EU	Grain, E & RA: <0.01, 0.04, <0.01, 0.03, 0.08, <0.01, <0.01, 0.04 Straw, E & RA: 0.49, 0.75, 0.36, 3.46, 2.51, 0.25, 0.37, 8.66	Grain, E & RA: 0.02 Straw, E & RA: 0.76	Grain, E & RA: 0.08 Straw, E & RA: 8.66	0.128 (Grain) Straw: n.r.	Wheat, grain: 0.5 Rye, grain: 0.5	Yes
	~~EFSA, 2010, United Kingdom, 2009~~	~~S-EU~~	~~GAP on which MRL/EU a.s. assessment is based: 1-2 x 0.250 kgas/ha, BBCH 31-69, PHI 35d, outdoor~~ ~~Grain, E & RA: 3 x <0.01, 0.01, 0.02, 0.03, 2 x 0.04, 0.14~~ ~~Straw, E & RA: 1.2, 1.6, 1.9, 2.0, 3.2, 2x 3.5, 3.8, 6.2~~	~~N/A~~				
	~~New trials~~	~~S-EU~~	~~Trials GAP: 1 x 0.25 kg as/ha, BBCH 69~~ ~~Grain, E & RA: 0.02, <0.01, 0.10, 0.16, 0.07, 0.02, 0.03, 0.04~~					

			Straw, E & RA: 0.39, 0.20, 2.8, 1.56, 3.87, 1.31, 3.21, 3.43					
	Overall supporting data for cGAP	S-EU	Grain, E & RA: 0.02, <0.01, 0.10, 0.16, 0.07, 0.02, 0.03, 0.04 Straw, E & RA: 0.39, 0.20, 2.8, 1.56, 3.87, 1.31, 3.21, 3.43	Grain, E & RA: 0.035 Straw, E & RA: 2.18	Grain, E & RA: 0.16 Straw, E & RA: 3.87	0.262 (Grain) Straw: n.r.	Wheat, grain: 0.5 Rye, grain: 0.5	Yes
Spring and winter barley, grain and straw	EFSA, 2010, United Kingdom, 2009	N-EU	GAP on which MRL/EU a.s. assessment is based: 1-2 x 0.250 kg as/ha, BBCH 31-59, PHI 35d, outdoor Grain, E & RA: <0.01, 0.01, 0.02, 2x 0.04, 0.08, 0.20, 0.43 Straw, E & RA: 0.11, 0.39, 0.48, 0.91, 1.3, 1.5, 2.7, 5.1	N/A				
	New trials	N-EU	Trials GAP: 1 x 0.25 kg as/ha, BBCH 59 Grain, E & RA: 0.03, 0.03, 0.02, <0.01, 0.44, 0.07, 0.04, 0.09 Straw, E & RA: 0.18, 0.54, 0.68, 0.56, 5.3, 0.87, 0.96, 1.31					
	Overall supporting data for cGAP	N-EU	Grain, E & RA: 0.03, 0.03, 0.02, <0.01, 0.44, 0.07, 0.04, 0.09 Straw, E & RA: 0.18, 0.54, 0.68, 0.56, 5.3, 0.87, 0.96, 1.31	Grain, E & RA: 0.035 Straw, E & RA: 0.775	Grain, E & RA: 0.440 Straw, E & RA: 5.3	0.665 (Grain) Straw: n.r.	Barley, grain: 1.5	Yes
	EFSA, 2010, United Kingdom, 2009	S-EU	GAP on which MRL/EU a.s. assessment is based: 1-2 x 0.250 kg as/ha, BBCH 31-59, PHI 35d, outdoor Grain, E & RA: 0.01, 0.03, 0.04, 0.08, 2 x 0.10, 0.11, 0.13, 0.28 Straw, E & RA: 0.65, 1.2, 1.3, 2x 2.3, 2.5, 2.9, 4.8, 5.5	N/A				
	New trials	S-EU	Trials GAP: 1 x 0.25 kg as/ha, BBCH 59 Grain, E & RA: 0.02, 0.01, 0.13, 0.06, 0.05, <0.01, 0.01, 0.01 Straw, E & RA: 0.45 0.56, 2.58, 1.21, 6.7, 0.20, 0.28, 0.27					
	Overall supporting data for cGAP	S-EU	Grain, E & RA: 0.02, 0.01, 0.13, 0.06, 0.05, <0.01, 0.01, 0.01 Straw, E & RA: 0.45 0.56, 2.58, 1.21, 6.7, 0.20, 0.28, 0.27	Grain, E & RA: 0.015 Straw, E & RA: 0.505	Grain, E & RA: 0.13 Straw, E & RA: 6.7	0.207 (Grain) Straw: n.r.	Barley, grain: 1.5	Yes
Spring and winter oilseed rape,	EFSA Journal 2013;11(12):3497 EFSA Journal	N-EU	GAP on which MRL/EU a.s. assessment is based: 1-2 x 0.250 kg as/ha, PHI 21d, outdoor Seed, E & RA: 2 x 0.01; 0.03; 0.04;0.07; 0.10; 0.22; 0.24	N/A				

seeds and straw	2011;9(6):2283							
	New trials	N-EU	Trials GAP: 2 x 0.16 kg as/ha, PHI 28d Seed, E & RA: <LOD (0.003), 4x<0.01; 0.015; 0.02; 0.03					
	Overall supporting data for cGAP	N-EU	Seed, E & RA: <LOD (0.003), 4x<0.01; 0.015; 0.02; 0.03	E & RA: 0.01	E & RA: 0.03	0.044	OSR seed: 0.7	Yes
	~~EFSA Journal 2013;11(12):3497 EFSA Journal 2011;9(6):2283~~	~~S-EU~~	~~GAP on which MRL/EU a.s. assessment is based: 2 x 0.250 kg as/ha, PHI 21d, outdoor Seed, E & RA: <0.01; 0.01; 0.02; 0.05~~	~~N/A~~				
	~~New trials~~	~~S-EU~~	~~Trials GAP: 2 x 0.16 kg as/ha, PHI 28d Seed, E & RA: 0.017, 0.018, 0.033, <0.01, 0.010, 0.035~~					
	~~Overall supporting data for cGAP~~	~~S-EU~~	~~Seed, E & RA: 0.017, 0.018, 0.033, <0.01, 0.010, 0.035, <0.01; 0.01; 0.02; 0.05~~	~~E & RA: 0.018~~	~~E & RA: 0.05~~	~~0.076~~	~~OSR seed: 0.7~~	~~Yes~~

* Source of EU MRL: Reg. (EU) ~~2024/1078~~ 2024/2633

7.3.3.2 Conclusion on the magnitude of residues in plants

Wheat
According to the available data, the intended uses on wheat (with extrapolations to rye and triticale), are considered to be acceptable. Extrapolation from trials conducted on wheat (grin and straw) to rye and triticale is not restricted according to SANTE/2019/12752. Please note that the trials referenced in this document (for wheat) have also been provided to support the EU renewal for azoxystrobin, and have been evaluated – please refer to the EU evaluation. UPL have data access to rely on these studies to support the registration of the product FGF11. No exceedance of the current EU MRL is expected based on the results of these trials.

Barley
According to the available data, the intended uses on barley, are considered to be acceptable. Please note that the trials referenced in this document (for barley) have also been provided to support the EU renewal for azoxystrobin, and have been evaluated – please refer to the EU evaluation. UPL have data access to rely on these studies to support the registration of the product FGF11. No exceedance of the current EU MRL is expected based on the results of these trials.

Oilseed rape
According to the available data, the intended uses on oilseed rape, are considered to be acceptable. No exceedance of the current EU MRL is expected based on the results of these trials.

zRMS comments:
Residue Definitions (EFSA 2010, 2013; Reg. (EU) 2024/2633):
Monitoring (Mo): Azoxystrobin
Risk Assessment (RA): Azoxystrobin

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

Sufficient residue studies on wheat (8 trials) conducted according to the residue definition for monitoring and for risk assessment have already been evaluated. Please refer to the Azoxystrobin EU renewal (dRAR) for a summary and conclusions for these studies.
All trials are overdosed (1 x 250 g a.s./ha instead of 1 x 160 g a.s./ha). Consequently, these trials can be considered as a worst-case situation.
Residues of azoxystrobin in grain were: 4x <0.01, 0.03, 2x 0.04, 0.08 mg/kg.

Available results show that the in force MRL of azoxystrobin on wheat and rye of 0.5 mg/kg (Reg. (EU) 2024/2633) will not be exceeded. The current EU MRL for azoxystrobin is sufficient to support the proposed uses.
The trials are supported by valid storage stability data and validated analytical methods.

The proposed uses on winter wheat, spring wheat, durum wheat, spelt wheat, winter triticale, spring triticale, winter rye, spring rye are considered acceptable.

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

Sufficient residue studies on barley (8 trials) conducted according to the residue definition for monitoring and for risk assessment have already been evaluated. Please refer to the Azoxystrobin EU renewal (dRAR) for a summary and conclusions for these studies.
All trials are overdosed (1 x 250 g a.s./ha instead of 1 x 160 g a.s./ha). Consequently, these trials can be considered as a worst-case situation.
Residues of azoxystrobin in grain were: <0.01, 0.02, 2x0.03, 0.04, 0.07, 0.09, 0.44 mg/kg.

Available results show that the in force MRL of azoxystrobin on barley of 1.5 mg/kg (Reg. (EU) 2024/2633) will not be exceeded. The current EU MRL for azoxystrobin is sufficient to support the proposed use.

The trials are supported by valid storage stability data and validated analytical methods.
The proposed use on barley is considered acceptable.

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

New residues study on oilseed rape (8 trials) conducted according to the residue definition for monitoring and for risk assessment was provided by Applicant (Study 2 North 2024, S23-102956).
All trials are overdosed (2 x 160 g a.s./ha instead of 1 x 160 g a.s./ha). Consequently, these trials can be considered as a worst-case situation.
Residues of azoxystrobin in seed were: <LOD (0.003), 4x<0.01; 0.015; 0.02; 0.03 mg/kg.

Available results show that the in force MRL of azoxystrobin on oilseed rape of 0.7 mg/kg (Reg. (EU) 2024/2633) will not be exceeded. The current EU MRL for azoxystrobin is sufficient to support the proposed use.
The trials are supported by valid storage stability data and validated analytical methods.

The proposed use on winter oilseed rape is 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 azoxystrobin (see EFSA, 2013 and EFSA, 2020). Azoxystrobin is authorised for use on several crops that might be fed to livestock. EFSA calculated the livestock dietary burdens for different groups of livestock using the agreed European methodology (European Commission, 1996). The envisaged GAP uses are covered by this calculation.

As shown in the following table, the input values from the NEU and SEU residue trials (Appendix 2) supporting the uses of FGF11 are generally far lower than those values used for the same crops in the Article 12 MRL (EFSA, 2013) review's consideration of the livestock dietary burden.

Table 7.3-10: Residue trials values from the studies supporting FGF11, compared with those used in the livestock dietary burden calculation presented in the EFSA Article 12 review (EFSA, 2013)

Commodity	Residue values (mg/kg)		
	NEU trials	SEU trials	EFSA, 2013
Barley grain (STMR)	0.035	0.015	0.1
Barley straw (STMR)	0.775	0.505	2.30
Barley straw (HR)	5.3	6.7	5.50
Wheat grain (STMR)	0.02	0.035	0.08
Wheat straw (STMR)	0.76	2.18	3.85
Wheat straw (HR)	8.66	3.87	10.1
Triticale grain (STMR)	0.02	0.035	0.08
Triticale straw (STMR)	0.76	2.18	3.85
Triticale straw (HR)	8.66	3.87	10.1
Rye grain (STMR)	0.02	0.035	0.08
Rye straw (STMR)	0.76	2.18	3.85
Rye straw (HR)	8.66	3.87	10.1
Oilseed rape seed (STMR)	0.01	0.018	0.055

The only value which exceeds the one used in the EFSA, 2013 calculation is for SEU, barley straw (HR) with a value of 6.7 mg/kg. However, the calculator works by selecting the highest values for the commodity group to determine the livestock dietary burden, which for the EFSA, 2013 calculation would be wheat straw (HR), which is higher at 10.1 mg/kg.

Based on the side-by-side comparison of the values, it is considered that the livestock dietary burden completed and presented within EFSA, 2013 also suitably covers the intended uses for FGF11. On this basis, no MRL requirements are needed for livestock products.

zRMS comments:
Azoxystrobin is authorised for use on several crops that might be fed to livestock. The median and maximum dietary burdens has been calculated for different groups of livestock using the EFSA Animal model 2017.

Table 7.3-11: Results of the dietary burden calculation (EFSA, 2020)

Relevant groups	Dietary burden expressed in				Most critical commodity[(b)]		Trigger exceeded (Y/N) 0.1 mg/kg DM
	mg/kg bw per day		mg/kg DM				
	Median	Maximum	Median	Maximum			
Risk assessment residue definition: Azoxystrobin							
Cattle (all diets)	0.46	0.59	12.0	15.4	Dairy cattle	Citrus, dried pulp	Y
Cattle (dairy only)	0.46	0.59	12.0	15.4	Dairy cattle	Citrus, dried pulp	Y
Sheep (all diets)	0.10	0.23	2.5	5.79	Lamb	Rye, straw	Y
Sheep (ewe only)	0.10	0.19	2.85	5.49	Ram/Ewe	Rye, straw	Y
Swine (all diets)	0.20	0.25	8.76	10.6	Swine (breeding)	Citrus, dried pulp	Y
Poultry (all diets)	0.05	0.10	0.66	1.42	Poultry layer	Wheat, straw	Y
Poultry (layer only)	0.05	0.10	0.66	1.42	Poultry layer	Wheat, straw	Y

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

The calculated dietary burden for azoxystrobin was 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. Therefore, further investigation of residues is required.

Remark on residue behaviour in fish (B.7.3.2.5 and B.7.3.4)
In accordance with SANCO/10254/2021, an assessment of metabolism in fish is required when pesticide use may lead to significant residues of an active substance or a major metabolite in total diet (i.e. ≥ 0.1 mg/kg feed on a dry matter basis) which also have the potential to accumulate (i.e. log $P_{o/w}$ > 3). Azoxystrobin is the only analyte considered relevant to the consumer from exposure to plants and the log $P_{o/w}$ value for azoxystrobin is 2.5 (at 20°C) which is consistent with no accumulation potential in fish tissues. As the log $P_{o/w}$ of all components of the plant Residue Definition for Risk Assessment does not exceed 3, metabolism studies in fish are not required.

7.3.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

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

As explained in the previous section, reference is made to the livestock dietary burden calculation made within EFSA's reasoned opinion on the Article 12 review of azoxystrobin MRLs (EFSA, 2013). The same input values were used in the confirmatory data assessment to the Article 12 review (EFSA, 2020). The updated livestock dietary intake calculation included within EFSA, 2020 uses the current version of the EU animal model calculation sheet, and used the EFSA, 2013 values as input values for the calculation.

Conclusion on feeding studies
According to EFSA 2013:

"Significant residues in tissues of ruminants, pigs and poultry, eggs and milk, are not expected and MRLs for these commodities can be established at the LOQ."

Based on the requested uses, these is no risk for the MRLs for livestock products to be exceeded.

zRMS comments:
The MRLs for animal commodities calculated during the Evaluation of confirmatory data following the Article 12 MRL review are presented in the table hereafter.

Table 7.3-12: Overview of the values derived from livestock feeding studies (EFSA, 2020)

Animal commodity	Residues at the closet feeding level (mg/kg)		Estimated value at 1N level		MRL proposal (mg/kg)
	Mean	Highest	$STMR_{Mo}$ (mg/kg)	HR_{Mo} (mg/kg)	
Cattle (all diets) Closest feeding level:	0.91	mg/kg bw		1.5 N rate (c)	
Muscle	<0.01	<0.01	<0.01	<0.01	**0.01***
Fat	<0.01	<0.01	<0.01	<0.01	**0.01***
Liver	0.01	0.01	<0.01	<0.01	**0.01* (f)**
Kidney	<0.01	<0.01	<0.01	<0.01	**0.01* (f)**
Cattle (dairy only) Closest feeding level:	0.91	mg/kg bw		1.5 N rate (c)	
Milk (d)	<0.01	n.a.	<0.01	<0.01	**0.01***
Sheep (all diets) (e) Closest feeding level:	0.18	mg/kg bw		0.8 N rate (c)	
Muscle	<0.01	<0.01	<0.01	<0.01	**0.01***
Fat	<0.01	<0.01	<0.01	<0.01	**0.01***
Liver	<0.01	<0.01	<0.01	<0.01	**0.01* (f)**
Kidney	<0.01	<0.01	<0.01	<0.01	**0.01* (f)**
Sheep (dairy only) Closest feeding level(a):	0.18	mg/kg bw		0.9 N rate (c)	
Milk(d)	<0.01	n.a.	<0.01	<0.01	**0.01***
Swine Closest feeding level:	0.18	mg/kg bw		0.7 N rate (c)	
Muscle	<0.01	<0.01	<0.01	<0.01	**0.01***
Fat	<0.01	<0.01	<0.01	<0.01	**0.01***
Liver	<0.01	<0.01	<0.01	<0.01	**0.01* (f)**
Kidney	<0.01	<0.01	<0.01	<0.01	**0.01* (f)**
Poultry (all diets) Closest feeding level(a):	0.39	mg/kg bw		4 N rate (c)	
Muscle	<0.01	<0.01	<0.01	<0.01	**0.01***
Fat	<0.01	<0.01	<0.01	<0.01	**0.01***
Liver	<0.01	<0.01	<0.01	<0.01	**0.01***
Poultry (layer only) Closest feeding level:	0.39	mg/kg bw		4 N rate (c)	
Eggs	<0.01	<0.01	<0.01	<0.01	**0.01***

n.a.: not applicable.
*: Indicates that the MRL is proposed at the limit of quantification.
(a): Median residues recalculated at the 1N rate for the median dietary burden.
(b): Highest residues recalculated at the 1N rate for the maximum dietary burden.
(c): Closest feeding level and N dose rate related to the maximum dietary burden.
(d): For milk, mean was derived from samplings performed from day 1 to day 30 (daily mean of four cows).

(e): Since extrapolation from cattle to other ruminants and swine is acceptable, results of the livestock feeding study on ruminants were relied upon to derive the MRL and risk assessment values in sheep and swine.
(f): Noting that the general toxicity of metabolites L1, L4 and L9 (found in liver and kidney) was not addressed.

The requested uses and the new mode of calculation do not modify the theoretical maximum daily intake for animals and regarding available feeding data, there is no risk for animal MRL to be exceeded (Reg. (EU) 2024/2633). No additional data are required.

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

7.3.5.1 Available data for all crops under consideration

No new data are submitted as part of this application.

Table 7.3-13: Overview of the available processing studies

Processed commodity	Number of studies	Median PF *	Median CF **	Comments	Reference
EU data					
Enforcement residue definition: Azoxystrobin					
Barley, brewing malt	4	0.19	1	-	Azoxystrobin, AIR-DAR, B.7.8.1 and EFSA 2013 and EFSA 2020
Barley, beer	4	0.23	1	-	
Barley, pot / pearl	4	0.25	1	-	
Wheat / rye, wholemeal flour	4	0.68	1	-	Azoxystrobin, AIR-DAR, B.7.8.1 and EFSA 2013 and EFSA 2020
Wheat / rye, wholemeal bred	4	0.51	1	-	
Wheat / rye, white flour	4	0.45	1	-	
Wheat / rye, white bread	4	0.57	1	-	
Wheat / rye, bran	4	1.67	1	-	

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

7.3.5.2 Conclusion on processing studies

Processing factors were previously derived for cereal fractions. According to EFSA Journal (2013) processing factors for barley, brewing malt, beer, and pot barley are actually lower than the value reported as residues were below the LOQ (worst case assumption).

While processing data was provided within some of the residue trials for oilseed rape, the processing of oilseed rape fractions is not considered to be necessary due to low residues found at harvest (STMR for oilseed rape = 0.018 mg/kg for SEU and 0.01 mg/kg for CEU). Furthermore, the Log P_{OW} value for azoxystrobin is <3 (2.5 at 20°C, with no pH dependence) and so the accumulation during processing of high oil matrices is not considered to be significant.

In addition, EFSA 2013 indicated that further processing studies are not required as they are not expected to influence the outcome of the risk assessment.

zRMS comments:
Data presented by Applicant in point 7.3.5 have been accepted and are sufficient to support the proposed uses.
Processing studies are normally required if the supervised residue trials reveal that the total residues in commodities exceed the trigger value of 0.1 mg/kg, or if the total Theoretical Maximum Daily Intake (TMDI) is more than 10% of the ADI.
Based on these data requirements, processing studies are required for barley.

Summary of processing studies reported in the EU:
United Kingdom, 2009
"Adequate mass balance and follow-up processing studies are available for determining transfer factors for azoxystrobin residues in processed wheat commodities. These transfer factors can be used in consumer assessments to estimate dietary exposures to azoxystrobin in the following processed wheat commodities: wheat grain into flour, wheat germ, and bread. As a result of the low incurred residues seen in the processing studies the calculated processing factors are unreliable and careful judgement should be exercised if they are used quantitatively."

EFSA, 2013
"Robust processing factors for enforcement and risk assessment were derived for peeled bananas, white wine, must, grape juice, grape pomace (wet and dry), brewing malt, beer, barley pot, barley bran, whole-meal and white flour, bread, wheat bran, fresh beans with pods cooked and canned. The processing factors reported for the other processed commodities should be considered as indicative as a minimum of 3 processing studies is normally required."

The studies demonstrate that azoxystrobin residues concentrate in cereals bran whereas a reduction is observed in other processed commodities of wheat, barley and oilseed rape.
No additional data are required.

7.3.6 Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation.

7.3.6.1 Field rotational crop studies (KCA 6.6.2)

Available data
No new data submitted in the framework of this application.
Explicit reference is made to the EU peer review (United Kingdom, 2009) and to the Art. 12 MRL review (EFSA 2013 and 2020).

Table 7.3-14: 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					
Wheat, cucumber or lettuce	2× 0.896 or 7-8× 0.224 or 6× 0.373	Leafy vegetables	Lettuce or mustard green	29 60 120	Azoxystrobin AIR-DAR, 2009, Vol.3, Annex B.7, IIA 6.6
		Root and tuber vegetables	Radish top or Turnip tops or beet tops	29 60 120	
		Cereals	Wheat (forage, hay, straw, grain)	29 60 120	

Conclusion on rotational crops studies
In the studies evaluated by United Kingdom, 2009 and covering the envisaged GAP uses, no or only low residues have been determined in rotational crop field studies, showing that any residues of azoxystrobin exceeding the current EU-MRLs are not to be expected in rotational crop matrices used as feed and food.

According to EFSA, 2013:
"In addition to the confined crop study, several rotational crop field trials were evaluated in the framework of the peer review (United Kingdom, 2009). Azoxystrobin was applied on wheat, cucumber or lettuce at 2 x 0.896 kg a.s./ha, 7-8 x 0.224 kg a.s./ha and 6 x 0.373 kg a.s./ha respectively.

After harvest of these crops, rotational crops (mustard, lettuce, radish, turnip, beetroot and wheat) were sown at one, two or three different plant-back intervals (29 to 60 days following application of the active substance) and magnitude of residues was investigated in the different commodities thereof. Considering that all trials were overdosed, a correction factor was applied to the highest residue found in each commodity. At harvest, azoxystrobin residues were expected to be below the LOQ (0.01 mg/kg) in all mature plant parts except in wheat forage and wheat straw. The highest residues were expected to be 0.05 mg/kg and 0.04 mg/kg, respectively. However, although these residues might increase the dietary burden intake of livestock, no impact on the residue level in products of animal origin is awaited.

These studies are considered sufficient by EFSA to demonstrate that residues in rotational crops have no impact on the MRLs in plants and livestock products."

zRMS comments:
Data presented by Applicant in point 7.3.6 have been accepted and are sufficient to support the proposed uses.
EFSA concluded in EFSA Journal 2022;20(1):7051 that *The possible transfer of azoxystrobin residues to crops that are grown in crop rotation has been assessed in the EU pesticides peer review and the MRL review (EFSA, 2010, 2013). In the context of the MRL review, it was concluded that no residues above the LOQ (0.01 mg/kg) are expected in crop parts intended for human consumption and that residues are very low in commodities intended for feed purposes (0.05 mg/kg in wheat forage and 0.04 mg/kg in wheat straw) (EFSA, 2013).*
Since the maximum annual application rate for the crops under consideration (i.e. 0.5 kg a.s./ha) is lower than the maximum seasonal application rate assessed during the MRL review (i.e. 1 kg a.s./ha), the previous conclusion remains valid, provided that the active substance is applied according to the proposed GAP.

No azoxystrobin residues above 0.01 mg/kg is expected in succeeding crops when FGF11 is applied according to the proposed GAP.
No additional data are required.

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

Reference is made to the studies which were generated to support the renewal of azoxystrobin (UPL has data access to rely on the studies generated by Syngenta). The following summary was provided within the MCA 6 for the azoxystrobin renewal:

"Three semi-field trials were conducted in 2007 to determine the magnitude of azoxystrobin residues in honey following application of azoxystrobin to oilseed rape (1 x 250 g ai/ha, BBCH 63; honey sampled at maturity). Residues of azoxystrobin in samples of treated honey ranged from < 0.01 mg/kg to 0.01 mg/kg. Although only one application was made during flowering, whilst the critical use pattern for azoxystrobin includes up to two applications, the trial design (confining bees within tunnels and use of oilseed rape) is considered to afford the worst possible case for exposure of bees and, therefore, the worst case for residues in honey.

A fourth semi-field trial is also available, in which residues of azoxystrobin were determined in nectar following the application of azoxystrobin to oilseed rape at BBCH 60 and BBCH 65 (2 x 250 g ai/ha). Residues of azoxystrobin in samples of treated nectar ranged from < 0.005 mg/kg to 0.046 mg/kg (samples taken at multiple time-points: prior to last application, and 4, 7 and 12 days after the last application (DALA)). In accordance with SANTE/11956/2016 rev. 9, residues in nectar can be used as a surrogate for residues in honey.

Based on the available data, residues of azoxystrobin in honey are not expected to exceed the established MRL.

The available semi-field trials are considered a 'worst-case' situation because oilseed rape is a crop with a high melliferous capacity (SANTE/11956/2016 rev. 9). However, it is acknowledged that the data from the trial in nectar indicates that higher residues could be afforded if two applications are made during flowering according to the critical GAP. In order to assess this, a new study with four semi-field trials was conducted in 2021 with 2 applications during flowering made to oilseed rape. This guideline compliant

study permits a robust assessment of residues of azoxystrobin in honey. The four semi-field trials replicate the worst-case scenario in accordance with SANTE/11956/2016 rev. 9, with bees restricted to foraging on a highly melliferous crop treated according to the most critical GAP for azoxystrobin (2 x 250 g ai/ha, BBCH 62 and BBCH 63-65; honey sampled at maturity). Residues of azoxystrobin in samples of treated honey ranged from < 0.01 mg/kg to 0.02 mg/kg, thus confirming that residues of azoxystrobin in honey are not expected to exceed the established MRL of 0.05 mg/kg.

A number of semi-field trials are available to permit an assessment of residues of azoxystrobin in pollen and bee products. The study Appeltauer A., 2022 (VV-931501) is representative of the most critical GAP for azoxystrobin on melliferous crops and this, coupled with the trial design (i.e. confining bees within tunnels and use of oilseed rape), is considered to afford the worst possible case for exposure of bees and, therefore, the worst case for residues in honey. Hence the trials from this study are considered to supersede the existing honey and nectar data summarised in Bocksch S., 2008 (VV-382035) and Lebrun F., 2019 (VV-906202), which were conducted at a less critical GAP/rely on extrapolation from nectar, respectively. All available data confirms that residues of azoxystrobin in honey are not expected to exceed the established MRL of 0.05 mg/kg."

zRMS comments:
Data presented by Applicant in point 7.3.7 have been accepted and are sufficient to support the proposed uses.

Additionally residue studies on oilseed rape have been submitted by the Applicant in the framework of this application (Bocksch 2008, T011298-06-REG, VV-382035; Lebrun 2019, 349-2018, VV-906202; Appeltauer 2022, S21-01128, VV-931501, access from Task Force). It should be noted that these studies were reviewed and accepted.
More details are presented in Appendix 2.

The residues arising from the proposed uses will not exceed the MRLs established for azoxystrobin for honey of 0.05 mg/kg in Reg. (EU) 2024/ 2633.
No additional data are required.

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).

The existing EU MRLs are set according to the residue definition as azoxystrobin.

~~The input values used for the chronic consumer risk assessments (TMDI) are based on existing EU MRLs as set in Regulation (EU) No. 2021/1807, see table below. Besides commodity data for citrus fruits (except oranges) and oranges were the input values of the MRL review (EFSA, 2013) were considered. For orange fruits (except oranges) the derived median residue (with consideration of CLXs) of 4.90 mg azoxystrobin/kg and for oranges the median residue of 4.75 mg azoxystrobin/kg (EFSA, 2013) were taken into account. IEDI calculations were refined with STMR values derived from new studies as summarised under point 7.3.3 above.~~

~~**Table 7.3-15: Input values for the consumer risk assessment**~~

	~~Chronic risk assessment~~	~~Acute risk assessment~~

	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition in plant commodities: Azoxystrobin				
Citrus fruits (except oranges)	0.29	STMR (EFSA, 2013)	–	–
Oranges	4.75	STMR (EFSA, 2013)	–	–
Table grapes	0.27	STMR (EFSA, 2013)	–	–
Wine grapes	0.30	STMR (EFSA, 2013)	–	–
Strawberries	0.56	STMR (EFSA, 2013)	–	–
Blackberries	0.90	STMR (EFSA, 2013)	–	–
Raspberries	0.90	STMR (EFSA, 2013)	–	–
Bananas	0.03	STMR (EFSA, 2013)	–	–
Potatoes	0.02	STMR (EFSA, 2013)	–	–
Beetroot	0.05	STMR (EFSA, 2013)	–	–
Carrots	0.06	STMR (EFSA, 2013)	–	–
Celeriac	0.08	STMR (EFSA, 2013)	–	–
Horseradish	0.05	STMR (EFSA, 2013)	–	–
Jerusalem artichokes	0.01*	STMR (EFSA, 2013)	–	–
Parsnips	0.06	STMR (EFSA, 2013)	–	–
Radishes	0.30	STMR (EFSA, 2013)	–	–
Salsify	0.05	STMR (EFSA, 2013)	–	–

Swedes	0.05	STMR (EFSA, 2013)	–	–
Turnips	0.06	STMR (EFSA, 2013)	–	–
Garlic	0.01*	STMR (EFSA, 2013)	–	–
Onions	0.01*	STMR (EFSA, 2013)	–	–
Spring onions	0.16	STMR (EFSA, 2013)	–	–
Tomatoes	0.48	STMR (EFSA, 2013)	–	–
Peppers	0.71	STMR (EFSA, 2013)	–	–
Aubergines	0.48	STMR (EFSA, 2013)	–	–
Cucurbits with edible peel	0.19	STMR (EFSA, 2013)	–	–
Melons	0.16	STMR (EFSA, 2013)	–	–
Flowering brassica	0.04	STMR (EFSA, 2013)	–	–
Brussels sprouts	0.10	STMR (EFSA, 2013)	–	–
Head cabbage	0.30	STMR (EFSA, 2013)	–	–
Leafy brassica	1.04	STMR (EFSA, 2013)	–	–
Kohl Rabi	0.06	STMR (EFSA, 2013)	–	–
Lettuce	3.9	STMR (EFSA, 2013)	–	–
Other salad plants	3.9	STMR (EFSA, 2013)	–	–
Spinach and similar	3.9	STMR (EFSA, 2013)	–	–
Beans (fresh, with pods)	0.13	STMR (EFSA, 2013)	–	–
Beans (fresh, without pods)	0.06	STMR (EFSA, 2013)	–	–
Peas (fresh, with pods)	0.14	STMR (EFSA, 2013)	–	–

Peas (fresh, without pods)	0.06	STMR (EFSA, 2013)	–	–
Asparagus	0.06	STMR (EFSA, 2013)	–	–
Celery	1.98	STMR (EFSA, 2013)	–	–
Fennel	1.55	STMR (EFSA, 2013)	–	–
Globe artichoke	0.27	STMR (EFSA, 2013)	–	–
Leek	0.16	STMR (EFSA, 2013)	–	–
Rhubarb	0.10	STMR (EFSA, 2013)	–	–
Pulses (dry)	0.01*	STMR (EFSA, 2013)	–	–
Rape seed	0.06	STMR (EFSA, 2013)	0.06	STMR (EFSA, 2013)
Rape seed (new)	0.018	STMR (new trials submitted, refer to 7.3.3, but covered by higher input value used in EFSA 2013 in the line above)	0.035	STMR (new trials submitted, refer to 7.3.3, but covered by higher input value used in EFSA 2013 in the line above)
Barley grain	0.10	STMR (EFSA, 2013)	0.10	STMR (EFSA, 2013) – superseded by new trials
Barley grain (new)	0.035	STMR (new trials submitted, refer to Table7.2-12, but covered by higher input value used in EFSA 2013 in the line above)	0.44	STMR (new trials)
Maize grain	0.01*	STMR (EFSA, 2013)	–	–
Oat grain	0.10	STMR (EFSA, 2013)	0.10	STMR (EFSA, 2013)
Rice grain	0.52	STMR (EFSA, 2013)	–	–
Rye grain	0.08	STMR (EFSA, 2013)	0.08	STMR (EFSA, 2013) – superseded by new trials
Rye grain (new)	0.035	STMR (new trials submitted, refer to 7.3.3, extrapolated from wheat)	0.16	STMR (new trials)
Wheat grain	0.08	STMR (EFSA, 2013)	0.08	STMR (EFSA, 2013) – superseded by new trials
Wheat grain (new)	0.035	STMR (new trials submitted, refer to 7.3.3)	0.16	STMR (new trials)

Sugar beet (root)	0.01*	STMR (EFSA, 2013)	0.01*	STMR (EFSA, 2013)
Swine meat	0.01*	STMR (EFSA, 2013)	0.01*	STMR (EFSA, 2013)
Swine fat (free and lean meat)	0.01*	STMR (EFSA, 2013)	0.01*	STMR (EFSA, 2013)
Swine liver	0.01*	STMR (EFSA, 2013)	0.01*	STMR (EFSA, 2013)
Swine kidney	0.01*	STMR (EFSA, 2013)	0.01*	STMR (EFSA, 2013)
Ruminant meat	0.01*	STMR (EFSA, 2013)	0.01*	STMR (EFSA, 2013)
Ruminant fat	0.01*	STMR (EFSA, 2013)	0.01*	STMR (EFSA, 2013)
Ruminant liver	0.01*	STMR (EFSA, 2013)	0.01*	STMR (EFSA, 2013)
Ruminant kidney	0.01*	STMR (EFSA, 2013)	0.01*	STMR (EFSA, 2013)
Poultry meat	0.01*	STMR (EFSA, 2013)	0.01*	STMR (EFSA, 2013)
Poultry fat	0.01*	STMR (EFSA, 2013)	0.01*	STMR (EFSA, 2013)
Poultry liver	0.01*	STMR (EFSA, 2013)	0.01*	STMR (EFSA, 2013)
Ruminant milk	0.01*	STMR (EFSA, 2013)	0.01*	STMR (EFSA, 2013)
Bird´s eggs	0.01*	STMR (EFSA, 2013)	0.01*	STMR (EFSA, 2013)

TMDI calculation was performed using the in-force MRLs (Reg. (EU) 2024/2633) and EFSA PRIMo rev.3.1.

Table 7.3-16: Input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: Azoxystrobin				
Barley	1.5	EU MRL	Not relevant as setting of an ARfD was not necessary.	
Wheat, Rye	0.5	EU MRL		
Rapeseed	0.7	EU MRL		
Poppy, Mustard, Gold of pleasure	0.5	EU MRL		
Linseed	0.4	EU MRL		
Swine: Muscle/meat	0.01*	EU MRL		
Swine: Fat tissue	0.05	EU MRL		
Swine: Liver	0.07	EU MRL		

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Swine: Kidney	0.07	EU MRL		
Bovine, Sheep, Goat, Equine muscle/meat	0.01*	EU MRL		
Bovine, Sheep, Goat, Equine fat	0.05	EU MRL		
Bovine, Sheep, Goat, Equine liver	0.07	EU MRL		
Bovine, Sheep, Goat, Equine kidney	0.07	EU MRL		
Poultry, muscle, fat, liver, kidney	0.01*	EU MRL		
Milk	0.01*	EU MRL		
Eggs	0.01*	EU MRL		
Honey	0.05*	EU MRL		
All other commodities	EU MRLs	EU MRLs (Reg. (EU) 2024/ 2633)		

7.3.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

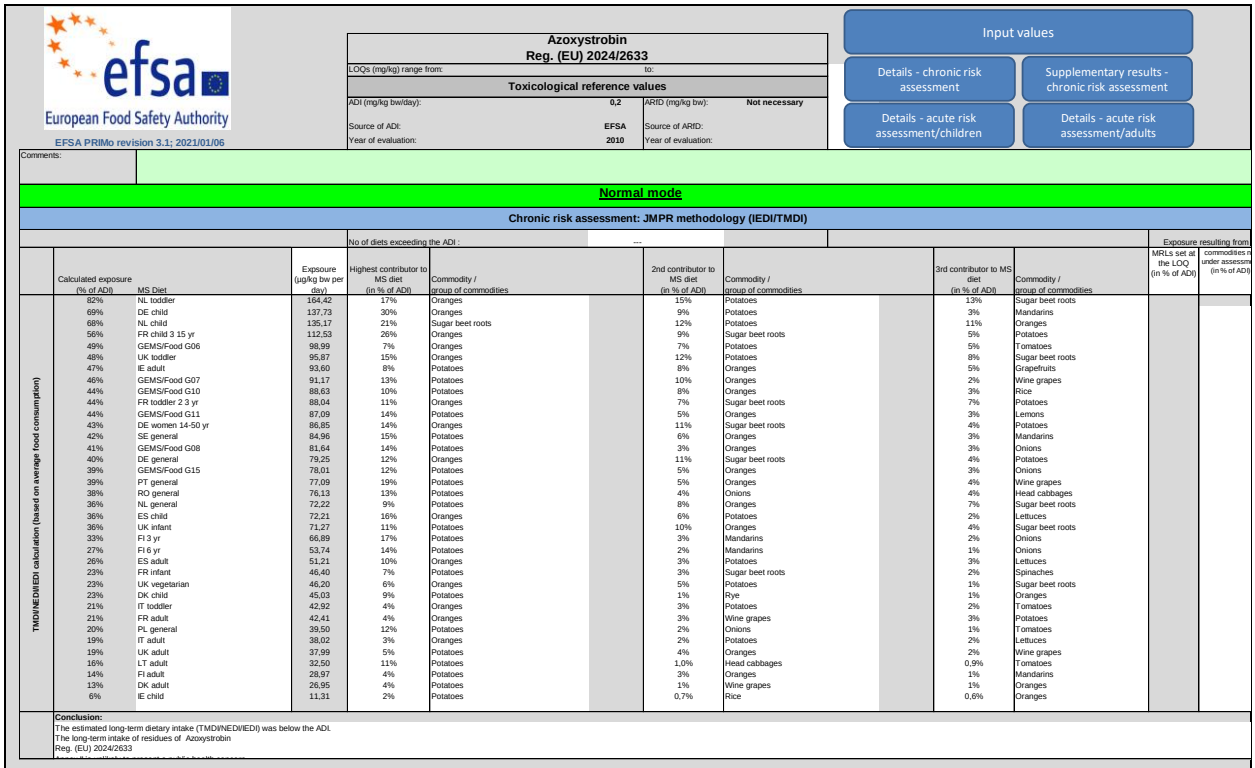
Table 7.3-17: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo	~~Not calculated~~ 82% (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo	~~11% (based on DE child – main contributor: oranges)~~
IESTI (% ARfD) according to EFSA PRIMo*	Not required – no ARfD allocated
NTMDI (% ADI) **	N/A
NEDI (% ADI)**	N/A
NESTI (% ARfD) **	N/A

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

The proposed uses of azoxystrobin in the formulation FGF11 do not represent unacceptable acute and chronic risks for the consumer.

zRMS comment:
The calculation of the TMDI using EFSA model (PRIMo ver. 3.1) and MRLs according to Reg. (EU) 2024/2633 has been conducted by evaluator and led to a utilisation of the ADI of 82% for the NL toddler diet being the population group with the highest value. For this diet, the highest contributor is oranges with 17% of the ADI. The intended uses will not result in a consumer chronic exposure exceeding the ADI.



European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Azoxystrobin
Reg. (EU) 2024/2633

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	0,2	ARfD (mg/kg bw):	Not necessary
Source of ADI:	EFSA	Source of ARfD:	
Year of evaluation:	2010	Year of evaluation:	

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
82%	NL toddler	164,42	17%	Oranges	15%	Potatoes	13%	Sugar beet roots		
69%	DE child	137,73	30%	Oranges	9%	Potatoes	3%	Mandarins		
68%	NL child	135,17	21%	Sugar beet roots	12%	Potatoes	11%	Oranges		
56%	FR child 3 15 yr	112,53	26%	Oranges	9%	Sugar beet roots	5%	Potatoes		
49%	GEMS/Food G06	98,99	7%	Oranges	7%	Potatoes	5%	Tomatoes		
48%	UK toddler	95,87	15%	Oranges	12%	Potatoes	8%	Sugar beet roots		
47%	IE adult	93,60	8%	Potatoes	8%	Oranges	5%	Grapefruits		
46%	GEMS/Food G07	91,17	13%	Potatoes	10%	Oranges	2%	Wine grapes		
44%	GEMS/Food G10	88,63	10%	Potatoes	8%	Oranges	3%	Rice		
44%	FR toddler 2 3 yr	88,04	11%	Oranges	7%	Sugar beet roots	7%	Potatoes		
44%	GEMS/Food G11	87,09	14%	Potatoes	5%	Oranges	3%	Lemons		
43%	DE women 14-50 yr	86,85	14%	Oranges	11%	Sugar beet roots	4%	Potatoes		
42%	SE general	84,96	15%	Potatoes	6%	Oranges	3%	Mandarins		
41%	GEMS/Food G08	81,64	14%	Potatoes	3%	Oranges	3%	Onions		
40%	DE general	79,25	12%	Oranges	11%	Sugar beet roots	4%	Potatoes		
39%	GEMS/Food G15	78,01	12%	Potatoes	5%	Oranges	3%	Onions		
39%	PT general	77,09	19%	Potatoes	5%	Oranges	4%	Wine grapes		
38%	RO general	76,13	13%	Potatoes	4%	Onions	4%	Head cabbages		
36%	NL general	72,22	9%	Potatoes	8%	Oranges	7%	Sugar beet roots		
36%	ES child	72,21	16%	Oranges	6%	Potatoes	2%	Lettuces		
36%	UK infant	71,27	11%	Potatoes	10%	Oranges	4%	Sugar beet roots		
33%	FI 3 yr	66,89	17%	Potatoes	3%	Mandarins	2%	Onions		
27%	FI 6 yr	53,74	14%	Potatoes	2%	Mandarins	1%	Onions		
26%	ES adult	51,21	10%	Oranges	3%	Potatoes	3%	Lettuces		
23%	FR infant	46,40	7%	Potatoes	3%	Sugar beet roots	2%	Spinaches		
23%	UK vegetarian	46,20	6%	Oranges	5%	Potatoes	1%	Sugar beet roots		
23%	DK child	45,03	9%	Potatoes	1%	Rye	1%	Oranges		
21%	IT toddler	42,92	4%	Oranges	3%	Potatoes	2%	Tomatoes		
21%	FR adult	42,41	4%	Oranges	3%	Wine grapes	3%	Potatoes		
20%	PL general	39,50	12%	Potatoes	2%	Onions	1%	Tomatoes		
19%	IT adult	38,02	3%	Oranges	2%	Potatoes	2%	Lettuces		
19%	UK adult	37,99	5%	Potatoes	4%	Oranges	2%	Wine grapes		
16%	LT adult	32,50	11%	Potatoes	1,0%	Head cabbages	0,9%	Tomatoes		
14%	FI adult	28,97	4%	Potatoes	3%	Oranges	1%	Mandarins		
13%	DK adult	26,95	4%	Potatoes	1%	Wine grapes	1%	Oranges		
6%	IE child	11,31	2%	Potatoes	0,7%	Rice	0,6%	Oranges		

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Azoxystrobin
Reg. (EU) 2024/2633

The refinement using STMRs is not required as the unrefined risk assessment does not represent unacceptable chronic risk to the consumer.

An acute consumer risk assessment was not deemed necessary.
The proposed uses of azoxystrobin in the product FGF11 do not represent unacceptable chronic risk 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, but for only one of them (prothioconazole) has an acute reference dose been allocated.

7.4.1 Acute consumer risk assessment from combined exposure

Not applicable since only one of them (prothioconazole) has an acute reference dose been allocated.

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.

zRMS comment:
The product FGF11 is a mixture of prothioconazole and azoxystrobin. Although no acute reference dose has been

allocated to azoxystrobin, acute reference doses were set for the TDMs. Therefore, the risk assessment of combined exposure is relevant.

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

$$HI = \Sigma HQ$$

with HQ (Hazard Quotient) = IESTI/ARfD

The Hazard Index for the commodities under consideration is <1. Thus, combined exposure to all residues in FGF11 is not expected to present a consumer risk. No further refinement of the assessment is required.

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
KCP 8.1-01	Giancola, D.	2023	Prothioconazole-desthio and 5 hydroxy metabolites: Frozen Storage Stability in Honey Study No.: QG/21/007 GLP Unpublished	N	UPL Europe Ltd.
KCP 8.1-02	Mealing, H.	2024	Triazole Derivative Metabolites: Frozen Storage Stability in Honey for 6 months Study No.: QG/21/006 GLP Unpublished	N	UPL Europe Ltd.
KCP 8.1-03	Giancola, D.	2025	Prothioconazole-desthio and 5 hydroxy metabolites: Frozen Storage Stability in crops Study No.: QG/21/001 GLP Unpublished	N	UPL Europe Ltd.
KCP 8.1/04	Baxter, B. Phipps	2025	Triazole Derived Metabolites: Frozen Storage Stability in Crops for 12 Months; Study No.: QG/21/002 GLP Unpublished	N	UPL Europe Ltd.
KCP 8.1/05	Jooß, S.	2025	Storage Stability of the Triazole Derivative Metabolites (TDMs) in Plant Matrices under Deep Frozen Conditions. Study No.: S23-105428 Eurofins Agroscience Services EAG Laboratories GmbH GLP Unpublished	N	UPL Europe Limited
KCP 8.1-0456	Appeltauer A.	2022	Azoxystrobin - Determination of Residues of Azoxystrobin and R230310 (z-isomer) in Honey after Two Applications of A12705B to Winter Oilseed rape at 5 Sites in Northern and Southern Europe in 2021 Report No S21-01128 Document No VV-931501 GLP Unpublished A data access agreement is inplacefor UPL to rely on this study for the registration of FGF11. Please refer to the Azoxystrobin EU renewal (dRAR) for a summary and conclusions for this study.	N	Syngenta
KCP 8.3.1-	Andrews, G., Pearson,	2017	Azoxystrobin – Residue Study on Wheat in Northern Europe in 2016	N	Syngenta

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
01	J.		Report No NC16012 Document No VV-467714 GLP Unpublished A data access agreement is inplacefor UPL to rely on this study for the registration of FGF11. Please refer to the Azoxystrobin EU renewal (dRAR) for a summary and conclusions for this study.		
KCP 8.3.1-02	Ertus, C.	2020	Azoxystrobin - Residue Study on Spring Wheat in Czech Republic, Hungary, Poland and the Netherlands in 2019 Report No B9119 Document No VV-748850 GLP Unpublished A data access agreement is inplacefor UPL to rely on this study for the registration of FGF11. Please refer to the Azoxystrobin EU renewal (dRAR) for a summary and conclusions for this study.	N	Syngenta
~~KCP 8.3.1-03~~	~~Andrews, G., Pearson, J.~~	~~2017~~	~~Azoxystrobin – residue study on wheat in Southern Europe in 2016~~ ~~Report No NC16013~~ ~~Document No VV-467712~~ ~~GLP~~ ~~Unpublished~~ ~~A data access agreement is inplacefor UPL to rely on this study for the registration of FGF11.~~ ~~Please refer to the Azoxystrobin EU renewal (dRAR) for a summary and conclusions for this study.~~	~~N~~	~~Syngenta~~
~~KCP 8.3.1-04~~	~~Brown, D.~~	~~2020~~	~~Azoxystrobin – Magnitude of Residue Study on Spring Wheat in Spain and Portugal in 2019~~ ~~Report No RES-00188~~ ~~Document No VV-864619~~ ~~A data access agreement is inplacefor UPL to rely on this study for the registration of FGF11.~~ ~~Please refer to the Azoxystrobin EU renewal (dRAR) for a summary and conclusions for this study.~~	~~N~~	~~Syngenta~~
KCP 8.3.1-05	Lebrun, F.	2024	Magnitude of the residue of prothioconazole metabolites in wheat in Northern and Southern Europe – 2023 Report No.; 645-2023 GLP Unpublished	N	UPL Europe Ltd.
KCP 8.3.2-01	Souchier, M.	2017	Azoxystrobin – Residue Study on Barley in the United Kingdom, Northern France and Germany in 2016 Report No S16-03841	N	Syngenta

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
			Document No VV-467864 GLP Unpublished A data access agreement is inplacefor UPL to rely on this study for the registration of FGF11. Please refer to the Azoxystrobin EU renewal (dRAR) for a summary and conclusions for this study.		
KCP 8.3.2-02	Ziske, J., Link, T.	2020	Azoxystrobin - Residue Study on Spring Barley in Poland, Germany and Hungary in 2019 Report No IF19-04928654 Document No VV-865884 GLP Unpublished A data access agreement is inplacefor UPL to rely on this study for the registration of FGF11. Please refer to the Azoxystrobin EU renewal (dRAR) for a summary and conclusions for this study.	N	Syngenta
KCP 8.3.2-03	Hoskins, M.	2022	Azoxystrobin – Residue Study on Barley in UK and Northern France, Initiated in 2022 Report No 685286; Document No VV-931335 GLP Unpublished A data access agreement is inplacefor UPL to rely on this study for the registration of FGF11. Please refer to the Azoxystrobin EU renewal (dRAR) for a summary and conclusions for this study.	N	Syngenta
~~KCP 8.3.2-04~~	~~Souchier, M.~~	~~2017~~	~~Azoxystrobin – Residue Study on Barley in the Southern France, Italy and Spain in 2016~~ ~~Report No S16-03842~~ ~~Document No VV-467632~~ ~~GLP~~ ~~Unpublished~~ ~~A data access agreement is inplacefor UPL to rely on this study for the registration of FGF11.~~ ~~Please refer to the Azoxystrobin EU renewal (dRAR) for a summary and conclusions for this study.~~	~~N~~	~~Syngenta~~
~~KCP 8.3.2-05~~	~~Ziske, J., Link, T.~~	~~2020~~	~~Azoxystrobin – Residue Study on Spring Barley in Spain, Greece and Italy in 2019~~ ~~Report No IF19-04928660;~~ ~~Document No VV-870172~~ ~~GLP~~ ~~Unpublished~~	~~N~~	~~Syngenta~~

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
			~~A data access agreement is inplacefor UPL to rely on this study for the registration of FGF11.~~ ~~Please refer to the Azoxystrobin EU renewal (dRAR) for a summary and conclusions for this study.~~		
KCP 8.3.2-06	Bougrier, M.	2024	Magnitude of the residue of prothioconazole metabolites in barley in Northern and Southern Europe – 2023 Study Number: 646-2023 GLP Unpublished	N	UPL Europe Ltd.
~~KCP 8.3.3-01~~	~~North, L.~~	~~2024~~	~~Determination of residues of Azoxystrobin after two applications of FFC03 in Oilseed rape at 7 sites in Southern Europe 2023~~ ~~Report No S23-102957~~ ~~GLP~~ ~~Unpublished~~	~~N~~	~~ARYSTA LifeScience S.A.S.~~
KCP 8.3.3-02	North, L.	2024	Determination of residues of Azoxystrobin after two applications of FFC03 in Oilseed rape and its processed fractions at 8 sites in Northern Europe 2023 Report No S23-102956 GLP Unpublished	N	ARYSTA LifeScience S.A.S.
~~KCP 8.3.3-03~~	~~Toscano Saes, R., Coleman, H.~~	~~2023~~	~~Magnitude of Residues of Prothioconazole-desthio and Hydroxyprothioconazole-desthio metabolites Following Two Applications of Prothioconazole 250 g/L DC (FGR06) to Oilseed rape in southern Europe, 2022;~~ ~~Study No.: QG22006~~ ~~GLP~~ ~~Unpublished~~	~~N~~	~~UPL Europe Ltd.~~
KCP 8.3.3-04	Toscano Saes, R., Coleman, H.	2023	Magnitude of Residues of Prothioconazole-desthio and Hydroxyprothiocon-azole-desthio metabolites Following Two Applications of Prothioconazole 250 g/L DC (FGR06) to Oilseed rape in northern Europe, 2022 Study No.: QG22007 GLP Unpublished	N	UPL Europe Ltd.
KCP 8.3.3-05	Toscano Saes, R., Coleman, H.	2023	Magnitude of Residues of Prothioconazole-desthio and Hydroxyprothiocon-azole-desthio Metabolites Following Two Applications of a Prothioconazole 250 g/L DC Formulation to Oilseed Rape in Northern and Southern Europe, 2021 Study No.: NZ/21/002 GLP Unpublished	N	UPL Europe Ltd.
~~KCP 8.3.3-~~	~~Hardy, J., Coleman, H.~~	~~2024~~	~~Magnitude of Residues of Prothioconazole-desthio, Hydroxy-prothioconazole-desthio metabolites, Triazole Lactic~~	~~N~~	~~UPL Europe~~

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
~~06~~			~~Acid and Triazole Acetic Acid Following Two Applications of a 250 g/L EC Formulation to Oilseed Rape in Southern Europe, 2020~~ ~~Study No.: QG20008~~ ~~GLP~~ ~~Unpublished~~		~~Ltd.~~
KCP 8.3.3-07	Bousquet, C.	2024	Magnitude of the residue of prothioconazole metabolites in oilseed rape in Northern and Southern Europe – 2023 Study Number: 647-2023 GLP Unpublished	N	UPL Europe Ltd.
~~KCP 8.3.3-08~~	~~Toscano Saes, R.~~	~~2023~~	~~Magnitude of Residues of Triazole Derived Metabolites (TDM's) (triazole acetic acid and triazole lactic acid) Following Two Applications of Prothio-conazole 250 g/L DC (FGR06) to Oilseed Rape in Southern Europe, 2022~~ ~~Study number: EE/23/006~~ ~~GLP~~ ~~Unpublished~~	~~N~~	~~UPL Europe Ltd.~~
KCP 8.3.3-09	Phipps, B.	2023	Magnitude of Residues of Triazole Derived Metabolites (TDM's) (triazole acetic acid and triazole lactic acid) in Oilseed Rape Following Two Appli-cations of Prothioconazole 250 g/L DC (FGR06) in Northern Europe, 2022 Study number EE/23/007 GLP Unpublished	N	UPL Europe Ltd.
KCP 8.3.3-10	Gibson, G., Toscano Saes, R.	2022	Magnitude of Residues of Triazole Derived Metabolites (TDM's) (triazole acetic acid and triazole lactic acid) Following Two Applications of Prothio-conazole 250 g/L DC (FGR06) to Oilseed Rape in Northern and Southern Europe, 2021 Study number NZ/21/003 GLP Unpublished	N	UPL Europe Ltd.
KCP 8.10.1-01	Andrews, G., Coleman, H.	2024	Magnitude of Residues of Prothioconazole-desthio and Hydroxyprothioconazole-desthio Metabolites in Honey Following Two Tunnel Applications of a Prothioconazole 250 g/L EC Formulation (FF-065) to Phacelia in Northern and Southern Europe, 2021 Study No.: QG21003 GLP Unpublished	N	UPL Europe Ltd.
KCP 8.10.1-02	Lebrun, F.	2024	Magnitude of the residue of triazole derivative metabolites in phacelia honey in Northern and Southern Europe – 2023 Study No.: 644-2023	N	UPL Europe Ltd.

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	**Vertebrate study Y/N**	**Owner**
			GLP Unpublished		
KCP 8.10.1-03	Bocksch, S.	2008	Azoxystrobin (ICI5504) and cyproconazole (SAN19) – Residues in honey following exposure of bees to treated winter oil-seed rape in Germany during 2007 Report No T011298-06-REG Document No VV-382035 GLP Unpublished A data access agreement is inplacefor UPL to rely on this study for the registration of FGF11. Please refer to the Azoxystrobin EU renewal (dRAR) for a summary and conclusions for this study.	N	Syngenta
KCP 8.10.1-04	Lebrun, F.	2019	Magnitude of the residue of azoxystrobin in oilseed rape pollen and nectar Raw Agricultural Commodity after two foliar applications of ALB 121 in Southern Europe – 2018 Report No 349-2018 Document No VV-906202 GLP Unpublished A data access agreement is inplacefor UPL to rely on this study for the registration of FGF11. Please refer to the Azoxystrobin EU renewal (dRAR) for a summary and conclusions for this study.	N	Syngenta
KCP 8.10.1-05	Appeltauer, A.	2022	Azoxystrobin - Determination of Residues of Azoxystrobin and R230310 (z-isomer) in Honey after Two Applications of A12705B to Winter Oilseed rape at 5 Sites in Northern and Southern Europe in 2021 Report No S21-01128 Document No VV-931501 GLP Unpublished A data access agreement is inplacefor UPL to rely on this study for the registration of FGF11. Please refer to the Azoxystrobin EU renewal (dRAR) for a summary and conclusions for this study	N	Syngenta

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

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

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
KCP 8.3.1-03	Andrews, G., Pearson, J.	2017	Azoxystrobin - residue study on wheat in Southern Europe in 2016 Report No NC16013 Document No VV-467712 GLP Unpublished A data access agreement is inplacefor UPL to rely on this study for the registration of FGF11. Please refer to the Azoxystrobin EU renewal (dRAR) for a summary and conclusions for this study.	N	Syngenta
KCP 8.3.1-04	Brown, D.	2020	Azoxystrobin – Magnitude of Residue Study on Spring Wheat in Spain and Portugal in 2019 Report No RES-00188 Document No VV-864619 A data access agreement is inplacefor UPL to rely on this study for the registration of FGF11. Please refer to the Azoxystrobin EU renewal (dRAR) for a summary and conclusions for this study.	N	Syngenta
KCP 8.3.2-04	Souchier, M.	2017	Azoxystrobin – Residue Study on Barley in the Southern France, Italy and Spain in 2016 Report No S16-03842 Document No VV-467632 GLP Unpublished A data access agreement is inplacefor UPL to rely on this study for the registration of FGF11. Please refer to the Azoxystrobin EU renewal (dRAR) for a summary and conclusions for this study.	N	Syngenta
KCP 8.3.2-05	Ziske, J., Link, T.	2020	Azoxystrobin – Residue Study on Spring Barley in Spain, Greece and Italy in 2019 Report No IF19-04928660; Document No VV-870172 GLP	N	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Unpublished A data access agreement is inplacefor UPL to rely on this study for the registration of FGF11. Please refer to the Azoxystrobin EU renewal (dRAR) for a summary and conclusions for this study.		
KCP 8.3.3-01	North, L.	2024	Determination of residues of Azoxystrobin after two applications of FFC03 in Oilseed rape at 7 sites in Southern Europe 2023 Report No S23-102957 GLP Unpublished	N	ARYSTA LifeScience S.A.S.
KCP 8.3.3-03	Toscano Saes, R., Coleman, H.	2023	Magnitude of Residues of Prothioconazole-desthio and Hydroxyprothioconazole-desthio metabolites Following Two Applications of Prothioconazole 250 g/L DC (FGR06) to Oilseed rape in southern Europe, 2022; Study No.: QG22006 GLP Unpublished	N	UPL Europe Ltd.
KCP 8.3.3-06	Hardy, J., Coleman, H.	2024	Magnitude of Residues of Prothioconazole-desthio, Hydroxy-prothioconazole-desthio metabolites, Triazole Lactic Acid and Triazole Acetic Acid Following Two Applications of a 250 g/L EC Formulation to Oilseed Rape in Southern Europe, 2020 Study No.: QG20008 GLP Unpublished	N	UPL Europe Ltd.
KCP 8.3.3-08	Toscano Saes, R.	2023	Magnitude of Residues of Triazole Derived Metabolites (TDM's) (triazole acetic acid and triazole lactic acid) Following Two Applications of Prothio-conazole 250 g/L DC (FGR06) to Oilseed Rape in Southern Europe, 2022 Study number: EE/23/006 GLP Unpublished	N	UPL Europe Ltd.

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
KCA 6.1/03	[redacted]	2020	Storage Stability of Triazole Alanine (TA), Triazole Acetic	Y	Triazole

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**
			Acid (TAA) and Triazole Lactic Acid (TLA) in Animal Matrices under Deep Frozen Conditions. [redacted] [redacted]ID: 869333. [redacted] ID: P 5069 G. GLP Unpublished		Derivative Metabolite Group

Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1 Azoxystrobin

A 2.1.1 Stability of residues

A 2.1.1.1 Stability of residues during storage of samples

A 2.1.1.1.1 Storage stability of residues in plant products

No new data provided for this endpoint.

A 2.1.1.1.2 Storage stability of residues in animal products

Study 1 - Appeltauer 2022; S21-01128; VV-931501

Comments of zRMS:	This study was reviewed and accepted by zRMS-PL in RR, Part B7 for PPP of Orondis Evo in June 2023). This study has not been reassessed in the framework of this application. The conclusions of the assessment are presented below: *The study has been conducted according to the OECD 506.* *The limit of quantitation (LOQ) was 0.01 mg/kg per analyte for honey.* *All method validation data are within the acceptable criteria: mean recovery range of 70-120% and relative standard deviation ≤ 20%.* *Residues of azoxystrobin and its metabolite R230310 in honey have been shown to be stable under these conditions for 81 days.* *The study is acceptable.*

Reference:	KCP 8.1/0456
Report	Azoxystrobin - Determination of Residues of Azoxystrobin and R230310 (z-isomer) in Honey after Two Applications of A12705B to Winter Oilseed rape at 5 Sites in Northern and Southern Europe in 2021; Appeltauer A., 2022; S21-01128; VV-931501
; Guideline(s):	• Guidelines and Criteria for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for the Inclusion of Active Substances in Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 • OECD Guidelines for the Testing of Chemicals – Crop Field Trial, No. 509, OECD, Paris 2009 • Technical Guidelines for Determining the Magnitude of Pesticide Residues in Honey and Setting Maximum Residue Levels in Honey; SANTE/11956/2016, Rev. 9, 14 September 2018 • Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes; SANTE/2020/12830, Rev. 1, 24 February 2021
Deviations:	None
GLP:	Yes
Acceptability:	Yes

Study Objective
The objective of this study was to provide information on the stability of residues of azoxystrobin and the z-isomer of azoxystrobin (R230310) in honey when stored under deep freeze storage conditions (≤ -18°C).

Materials and methods

Samples of honey were fortified with azoxystrobin and R230310 at a level of 0.1 mg/kg and put into storage at -18°C. One sample was prepared per matrix and per analyte. At intervals of 0 and 81 days, stored samples and freshly fortified samples were analysed for residues of azoxystrobin and R230310.
At each storage interval, azoxystrobin and R230310 were determined using analytical method RAM 305/03. The method involves extraction with acetonitrile/ultra-pure water (90/10, v/v) using an Ultra Turrax homogeniser, followed by C18 SPE clean-up and quantification by high performance liquid chromatography coupled with mass spectrometry (LC-MS/MS). The method has been previously validated for the determination of azoxystrobin and R230310 in honey. Acceptable concurrent recoveries were reported for azoxystrobin in samples of honey at fortification levels of 0.1 mg/kg (ppm), thus validating the method. The limit of quantitation (LOQ) was 0.01 mg/kg per analyte in honey.
Under these conditions, residues of azoxystrobin and R230310 were stable for 81 days.

Study Design and Methods
Homogenised sub-samples of honey (2.0 g) were fortified with standard solutions of azoxystrobin and R230310 to give a fortification rate of 0.1 mg/kg. Samples were transferred to a deep freezer at –18°C immediately after fortification. Untreated samples of honey were stored in the same freezer for use as control and procedural recovery samples.
Three replicate samples were extracted for analysis immediately after fortification. Duplicate stored samples were extracted for analysis at 81 days
After the scheduled storage periods, the required number of fortified samples were removed from frozen storage, along with one untreated control sample. Two untreated samples were fortified as concurrent recovery samples and then the set of samples (untreated, recovery and stored samples) were analysed for azoxystrobin and R230310 using analytical method RAM 305/03, previously validated honey to a limit of quantification (LOQ) of 0.01 mg/kg.

Results
A summary of the procedural/concurrent recoveries of azoxystrobin and R230310 in freshly fortified honey samples tested at each interval are shown in Tables 6.1-38 and 6.1-39.
Residues of azoxystrobin and R230310 found in stored frozen honey tested at each interval are shown in Tables 6.1-40 and 6.1-41.
There was no significant change in the levels of azoxystrobin and R230310 in honey over an 81 day storage period (any apparent losses were less than 30% of the initial value). These losses are not considered significant according to EU, EPA and OECD guidelines (SANCO 7032/VI/95 rev. 5, OPPTS 860.1380 and OECD Guideline 506).

Summary of procedural/concurrent recoveries of azoxystrobin in honey

Matrix	Storage duration (days (months))[1]	Fortification level (mg/kg)	Number of recoveries (n)	Individual recoveries (%)	Mean ± Rel. Std. Dev. (%)
Honey	0	0.1	2	105, 105	98 ± 7.9
	81 (3)		2	90, 93	

[1] Storage duration in months calculated as: (no. of days in storage/365) x 12 and reported to the nearest whole month

Summary of procedural/concurrent recoveries of R230310 in honey

Matrix	Storage duration (days (months))[1]	Fortification level (mg/kg)	Number of recoveries (n)	Individual recoveries (%)	Mean ± Rel. Std. Dev. (%)
Honey	0	0.1	2	105, 103	97 ± 8.9
	81 (3)		2	87, 91	

[1] Storage duration in months calculated as: (no. of days in storage/365) x 12 and reported to the nearest whole month

Stability of azoxystrobin residues in honey during storage at -18°C

Commodity, matrix	Fortification rate / spike level of stored samples (mg/kg)	Storage period (days (months))[1]	Individual concentrations in stored samples (mg/kg)	Residue level in freezer storage stability sample (% of nominal spiking level) [min; max] (mean)	Procedural recovery for freshly spiked control sample (%)
Honey	0.1	0	0.108, 0.108, 0.108	[108; 108] (108)	105, 105

Honey	0.1	81 (3)	0.096, 0.094	[94; 96] (95)	90, 93

[1] Storage duration in months calculated as: (no. of days in storage/365) x 12 and reported to the nearest whole month

Stability of R230310 residues in honey during storage at -18°C

Commodity, matrix	Fortification rate / spike level of stored samples (mg/kg)	Storage period (days (months))[1]	Individual concentrations in stored samples (mg/kg)	Residue level in freezer storage stability sample (% of nominal spiking level) [min; max] (mean)	Procedural recovery for freshly spiked control sample (%)
Honey	0.1	0	0.108, 0.105, 0.106	[105; 108] (106)	105, 103
Honey	0.1	81 (3)	0.096, 0.090	[90; 96] (93)	87, 91

[1] Storage duration in months calculated as: (no. of days in storage/365) x 12 and reported to the nearest whole month

Conclusion
Azoxystrobin and R230310 have been shown to be stable in honey for at least 81 days when stored frozen at -18ºC.

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 data provided for this endpoint.

A 2.1.2.1.2 Nature of residue in rotational crops

No new data provided for this endpoint.

A 2.1.2.1.3 Nature of residues in processed commodities

No new data provided for this endpoint.

A 2.1.2.2 Nature of residues in livestock

No new data provided for this endpoint.

A 2.1.3 Magnitude of residues in plants

A 2.1.3.1 Wheat

Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (DAR, RMS, year)	1-2	250 g as/ha	14 days	BBCH 69	35**
cGAP EU (Art. 12, EFSA, year)	3	250 g as/ha	Not stated	BBCH 71	35
Intended cGAP (numbers 1, 2, 3, 4, 9, 10, 11, 12)	1	1 L product per ha (160 g azoxystrobin per ha)	Not applicable	BBCH 69	35 (GSR)

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0
** Timing of applications determined primarily by growth stage; 1st application not later than BBCH 39, 2nd application no later than BBCH 59.
GSR: Growth Stage Restricted

The following table provides a summary of the available data from residue trial studies:

Analyte	Residue trials zone	Residues (mg/kg)	STMR (mg/kg)	HR (mg/kg)
Azoxystrobin	North EU	NC16012 (grain): <0.01, 0.04, <0.01, 0.03 NC16012 (straw): 0.49, 0.75, 0.36, 3.46 B9119 (grain): 0.08, <0.01, <0.01, 0.04 B9119 (straw): 2.51, 0.25, 0.37, 8.66	Grain = 0.02 Straw = 0.76	Grain = 0.08 Straw = 8.66
	~~South EU~~	~~NC16013 (grain): 0.02, <0.01, 0.10, 0.16~~ ~~NC16013 (straw): 0.39, 0.20, 2.8, 1.56~~ ~~RES-00188 (grain): 0.07, 0.02, 0.03, 0.04~~ ~~RES-00188 (straw): 3.87, 1.31, 3.21, 3.43~~	~~Grain = 0.035~~ ~~Straw = 2.18~~	~~Grain = 0.16~~ ~~Straw = 3.87~~
z-Azoxystrobin	North EU	NC16012 (grain): <0.01, <0.01, <0.01, <0.01 NC16012 (straw): 0.06, 0.11, 0.04, 0.45 B9119 (grain): <0.01, <0.01, <0.01, <0.01 B9119 (straw): 0.37, 0.03, 0.05, 1.02	Grain = <0.01 Straw = 0.085	Grain = <0.01 Straw = 1.02
	~~South EU~~	~~NC16013 (grain): <0.01, <0.01, 0.01, 0.02~~ ~~NC16013 (straw): 0.04, 0.01, 0.24, 0.14~~ ~~RES-00188 (grain): <0.01, <0.01, <0.01, <0.01~~ ~~RES-00188 (straw): 0.30, 0.14, 0.35, 0.34~~	~~Grain = <0.01~~ ~~Straw = 0.19~~	~~Grain = 0.02~~ ~~Straw = 0.35~~

While z-azoxystrobin has been analysed within the samples collected from the residue field trials, only "Azoxystrobin" is included within both the residues definitions for risk assessment and enforcement (monitoring) purposes. The residue concentrations for z-azoxystrobin have been included within the above table (for completeness) and have been included within the following study summaries for the residue field trials, however, the residues data for this compound will not be considered within the risk assessments.

The four residue trials summarised within this section have been submitted for evaluation as part of the azoxystrobin renewal. These studies are owned by Syngenta, and while UPL does not have access to the study reports, UPL has acquired data access from Syngenta to rely on these studies. The data provided within the following summaries have been extracted from the study summaries provided within the draft RAR. For alignment, the evaluating authority for the renewal can be contacted regarding the outcome (and acceptability) of the evaluation of these studies.

While it is noted the trials use a higher single application dose (targeted at 250 g azoxystrobin /ha) than the GAP intended for FGF11 (targeted at 160 g azoxystrobin /ha), it is considered that these data represent a worst-case data-set, which acceptably covers the risk scenario intended for the wheat use included within the FGF11 GAP. Consequently an acceptable risk assessment conducted with these data will also cover the use intended for FGF11.

The residue values were used in the consumer risk assessment without modification, as this represented a worst-case risk assessment, covering the intended use. However, if required for refinement purposes, the residue values have been scaled using the proportionality principle. The resulting values are provided within the following table:

EU trial zone	Commodity fraction	Residue trial	Residue value (mg/kg)	Application rate used in the trial (g a.s./ha)	Target GAP application rate for FGF11 (g a.s./ha)	Scaling factor	Scaled residue (mg/kg)
North EU	Grain	NC16012-01	<0.01	258	160	1.613	<0.01
North EU	Straw	NC16012-01	0.49	258	160	1.613	0.30
North EU	Grain	NC16012-02	0.04	263	160	1.644	0.02
North EU	Straw	NC16012-02	0.75	263	160	1.644	0.46
North EU	Grain	NC16012-03	<0.01	242	160	1.513	<0.01
North EU	Straw	NC16012-03	0.36	242	160	1.513	0.24
North EU	Grain	NC16012-04	0.03	264	160	1.650	0.02

North EU	Straw	NC16012-04	3.46	264	160	1.650	2.10
North EU	Grain	B9119 B9119 CZ1	0.08	240	160	1.500	0.05
North EU	Straw	B9119 B9119 CZ1	2.51	240	160	1.500	1.67
North EU	Grain	B9119 B9119 HU1	<0.01	258	160	1.613	<0.01
North EU	Straw	B9119 B9119 HU1	0.25	258	160	1.613	0.16
North EU	Grain	B9119 B9119 NL1	<0.01	272	160	1.700	<0.01
North EU	Straw	B9119 B9119 NL1	0.37	272	160	1.700	0.22
North EU	Grain	B9119 B9119 PL1	0.04	240	160	1.500	0.03
North EU	Straw	B9119 B9119 PL1	8.66	240	160	1.500	5.77
~~South EU~~	~~Grain~~	~~NC16013-01~~	~~0.02~~	~~268~~	~~160~~	~~1.675~~	~~0.01~~
~~South EU~~	~~Straw~~	~~NC16013-01~~	~~0.39~~	~~268~~	~~160~~	~~1.675~~	~~0.23~~
~~South EU~~	~~Grain~~	~~NC16013-02~~	~~<0.01~~	~~250~~	~~160~~	~~1.563~~	~~<0.01~~
~~South EU~~	~~Straw~~	~~NC16013-02~~	~~0.20~~	~~250~~	~~160~~	~~1.563~~	~~0.13~~
~~South EU~~	~~Grain~~	~~NC16013-03~~	~~0.10~~	~~250~~	~~160~~	~~1.563~~	~~0.06~~
~~South EU~~	~~Straw~~	~~NC16013-03~~	~~2.80~~	~~250~~	~~160~~	~~1.563~~	~~1.79~~
~~South EU~~	~~Grain~~	~~NC16013-04~~	~~0.16~~	~~268~~	~~160~~	~~1.675~~	~~0.10~~
~~South EU~~	~~Straw~~	~~NC16013-04~~	~~1.56~~	~~268~~	~~160~~	~~1.675~~	~~0.93~~
~~South EU~~	~~Grain~~	~~RES-00188 BPL19-810-GC-01-SP~~	~~0.07~~	~~242~~	~~160~~	~~1.513~~	~~0.05~~
~~South EU~~	~~Straw~~	~~RES-00188 BPL19-810-GC-01-SP~~	~~3.87~~	~~242~~	~~160~~	~~1.513~~	~~2.56~~
~~South EU~~	~~Grain~~	~~RES-00188 BPL19-810-GC-02-SP~~	~~0.02~~	~~250~~	~~160~~	~~1.563~~	~~0.01~~
~~South EU~~	~~Straw~~	~~RES-00188 BPL19-810-GC-02-SP~~	~~1.31~~	~~250~~	~~160~~	~~1.563~~	~~0.84~~
~~South EU~~	~~Grain~~	~~RES-00188 BPL19-810-GC-04-PT~~	~~0.03~~	~~252~~	~~160~~	~~1.575~~	~~0.02~~
~~South EU~~	~~Straw~~	~~RES-00188 BPL19-810-GC-04-PT~~	~~3.21~~	~~252~~	~~160~~	~~1.575~~	~~2.04~~
~~South EU~~	~~Grain~~	~~RES-00188 BPL19-810-GC-05-SP~~	~~0.04~~	~~259~~	~~160~~	~~1.619~~	~~0.02~~
~~South EU~~	~~Straw~~	~~RES-00188 BPL19-810-GC-05-SP~~	~~3.43~~	~~259~~	~~160~~	~~1.619~~	~~2.12~~

Study 1 - Andrews 2017, NC16012, VV-467714 - Northern Europe (new data)

Comments of zRMS:	This study has already been evaluated. Please refer to the Azoxystrobin EU renewal (dRAR) for a summary and conclusions for this study. This study has not been reassessed in the framework of this application.

Reference: KCP 8.3.1/01

Report: Azoxystrobin – Residue Study on Wheat in Northern Europe in 2016; Andrews G. and Pearson J., 2017; Report No NC16012; Document No VV-467714

Guideline(s):

- Commission of the European Communities, General Recommendations for the Design, Preparation and Realization of Residue Trials; 7029/VI/95 (rev. 5, working document)
- OECD Guidance Document on Crop Field Trials, Series on Pesticides No. 66 and Series on Testing and Assessment No. 164, ENV/JM/MONO(2011)50
- OECD Guidance Document on Overview of Residue Chemistry Studies (as revised 2009), Series on Testing and Assessment (No. 64) and Series on Pesticides (No. 32), ENV/JM/MONO(2009)31
- Guidelines and Criteria for the Preparation and resentation of Complete Dossiers and of Summary Dossiers for the Inclusion of Active Substances in Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009
- OECD Guidelines for the Testing of Chemicals – Crop Field Trial, No. 509, OECD, Paris 2009
- OECD Series on Testing and Assessment No. 9 “Guidance document on the conduct of studies of occupational exposure to pesticides during agricultural application”, Paris 1997.
- OCDE/GD(97)148
- European Commission Guidance for Generating and Reporting Methods of Analysis in Support of Pre-registration Requirements for Annex II (Part A, Section 4) of Directive 91/414, SANCO/3029/99 revision 4 (11 Jul 2000)
- The Application of the OECD Principles of GLP to the Organisation and Management of Multi-Site Studies, ENV/JM/MONO (2002) 9
- OECD Series on Principles of GLP and Compliance Monitoring No. 1 (as revised in 1997) “OECD Principles on Good Laboratory Practice”, Paris 1998.ENV/MC/CHEM(98)17 and respective national regulations
- The national GLP requirements are based on the OECD Principles of Good Laboratory Practice, which are accepted by regulatory authorities throughout the European Community, the United States of America (FDA and EPA) and Japan (MHW, MAFF and METI) on the basis of intergovernmental agreements

Deviations: None.

GLP: Yes, conducted under GLP/Officially recognised testing facilities

Acceptability: Yes

Summary of the study 1 trials (Report: NC16012)

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Azoxystrobin	R230310		
	(a)	(b)				(c)					(d)	(e)
Trial 1 NC16012 NC16012-01 France (Europe North) (08190, Champagne-Ardenne) 2016	Winter Wheat / Expert	1.30 Oct 2015 2 – 3 -	258	233		10 Jun 2016	(Control) (Control) (Control) BBCH 69 BBCH 69 BBCH 69 BBCH 69 BBCH 69 BBCH 69 BBCH 69 BBCH 69	Whole Plant Straw Grain Whole Plant Whole Plant Whole Plant Whole Plant Grain Straw Straw Grain	< 0.01 < 0.01 < 0.01 3.12 1.02 0.91 0.47 0.04 0.32 0.49 < 0.01	< 0.01 < 0.01 < 0.01 < 0.01 0.03 0.05 0.03 < 0.01 0.03 0.06 < 0.01	0 63 63 0 7 13 28 41 41 63 63	Acceptable. Report: NC16012 Methods: Azoxystrobin (Grain, Straw, Whole plant) RAM 305/03; LOQ = 0.01 mg/kg R230310 (Grain, Straw, Whole plant) RAM 305/03; LOQ = 0.01 mg/kg Acceptable procedural recovery data provided in the report. Max. storage = 248 days (8 months) Test product = Amistar 250 SC (250 g/L Azoxystrobin)

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Azoxystrobin	R230310		
	(a)	(b)				(c)					(d)	(e)
Trial 2 NC16012 NC16012-02 Germany (Europe North) (63868, Bayern) 2016	Winter Wheat / Monopol	1.22 Oct 2015 2 – 3 -	263	212		20 Jun 2016	(Control) (Control) (Control) BBCH 69 BBCH 69 BBCH 69 BBCH 69 BBCH 69 BBCH 69	Whole Plant Grain Straw Whole Plant Whole Plant Whole Plant Whole Plant Straw Grain	< 0.01 < 0.01 < 0.01 5.04 1.56 1.26 2.13 0.75 0.04	< 0.01 < 0.01 < 0.01 0.01 0.07 0.09 0.18 0.11 < 0.01	0 45 45 0 7 15 29 45 45	Acceptable. Report: NC16012 Methods: Azoxystrobin (Grain, Straw, Whole plant) RAM 305/03; LOQ = 0.01 mg/kg R230310 (Grain, Straw, Whole plant) RAM 305/03; LOQ = 0.01 mg/kg Acceptable procedural recovery data provided in the report. Max. storage = 248 days (8 months) Test product = Amistar 250 SC (250 g/L Azoxystrobin)

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Azoxystrobin	R230310		
	(a)	(b)				(c)					(d)	(e)
Trial 3 NC16012 NC16012-03 Poland (Europe North) (62-105, Wielkopolskie) 2016	Winter Wheat / Anthus	1.20 Oct 2015 2 – 3 -	242	194		10 Jun 2016	(Control) (Control) (Control) BBCH 69 BBCH 69 BBCH 69 BBCH 69 BBCH 69 BBCH 69	Whole Plant Straw Grain Whole Plant Whole Plant Whole Plant Whole Plant Grain Straw	< 0.01 < 0.01 < 0.01 6.16 0.79 0.75 0.66 < 0.01 0.36	< 0.01 < 0.01 < 0.01 < 0.01 0.02 0.04 0.06 < 0.01 0.04	0 42 42 0 7 14 28 42 42	Acceptable. Report: NC16012 Methods: Azoxystrobin (Grain, Straw, Whole plant) RAM 305/03; LOQ = 0.01 mg/kg R230310 (Grain, Straw, Whole plant) RAM 305/03; LOQ = 0.01 mg/kg Acceptable procedural recovery data provided in the report. Max. storage = 248 days (8 months) Test product = Amistar 250 SC (250 g/L Azoxystrobin)

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Azoxystrobin	R230310		
	(a)	(b)				(c)					(d)	(e)
Trial 4 NC16012 NC16012-04 United Kingdom (Europe North) (OX27 7LT, Oxfordshire) 2016	Winter Wheat / JB Diego	1.28 Dec 2015 2 – 3 -	264	211		06 Jul 2016	(Control) (Control) (Control) BBCH 69 BBCH 69 BBCH 69 BBCH 69 BBCH 69 BBCH 69 BBCH 69 BBCH 69	Whole Plant Grain Straw Whole Plant Whole Plant Whole Plant Whole Plant Grain Straw Grain Straw	< 0.01 < 0.01 < 0.01 6.08 4.32 4.08 3 0.04 4.09 0.03 3.46	< 0.01 < 0.01 < 0.01 0.02 0.2 0.32 0.32 < 0.01 0.56 < 0.01 0.45	0 48 48 0 7 14 29 42 42 48 48	Acceptable. Report: NC16012 Methods: Azoxystrobin (Grain, Straw, Whole plant) RAM 305/03; LOQ = 0.01 mg/kg R230310 (Grain, Straw, Whole plant) RAM 305/03; LOQ = 0.01 mg/kg Acceptable procedural recovery data provided in the report. Max. storage = 248 days (8 months) Test product = Amistar 250 SC (250 g/L Azoxystrobin)

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

The analyte 'Azoxystrobin' refers to the *E*-isomer of azoxystrobin, which is the active component. R230310 refers to the *Z*-isomer of azoxystrobin (while this component is included in the residue trials, this compound is not currently included within the residue definitions for risk assessment nor enforcement).

Study 2 - Ertus 2020, B9119, VV-748850- Northern Europe (new data)

Comments of zRMS:	This study has already been evaluated. Please refer to the Azoxystrobin EU renewal (dRAR) for a summary and conclusions for this study. This study has not been reassessed in the framework of this application.

Reference: KCP 8.3.1/02

Report: Azoxystrobin - Residue Study on Spring Wheat in Czech Republic, Hungary, Poland and the Netherlands in 2019; Ertus C., 2020; Report No B9119; Document No VV-748850

Guideline(s):

- Commission of the European Communities, General Recommendations for the Design, Preparation and Realization of Residue Trials; 7029/VI/95 (rev. 5, working document)
- OECD Guidance Document on Overview of Residue Chemistry Studies (as revised 2009), Series on Testing and Assessment (No. 64) and Series on Pesticides (No. 32), ENV/JM/MONO(2009)31
- Guidelines and Criteria for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for the Inclusion of Active Substances in Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009
- Guidelines for the Generation of Data concerning Residues as provided in Annex II part A, section 6 and Annex III, part A, section 8 of Directive 91/414/EEC concerning the placing of plant protection products on the market (EU) 1607/VI/97 (1999)
- OECD Guidelines for the Testing of Chemicals – Crop Field Trial, No. 509, OECD, Paris 2009
- OECD Guidance Document on Crop Field Trials, Series on Pesticides No. 66 and Series on Testing and Assessment No. 164, ENV/JM/MONO(2011)50
- European Commission Guidance for Generating and Reporting Methods of Analysis in Support of Pre-registration Requirements for Annex II (Part A, Section 4) of Directive 91/414, SANCO/3029/99 revision 4 (11 Jul 2000).
- OECD GLP ENV/JM/MONO (99) 22
- The Application of the OECD Principles of GLP to the Organisation and Management of Multi-Site Studies, ENV/JM/MONO (2002) 9
- OECD Series on Principles of GLP and Compliance Monitoring No. 1 (as revised in 1997) “OECD Principles on Good Laboratory Practice”, Paris 1998 ENV/MC/CHEM(98)17 and respective national regulations.
- The national GLP requirements are based on the OECD Principles of Good Laboratory Practice, which are accepted by regulatory authorities throughout the European Community, the United States of America (FDA and EPA) and Japan (MHW, MAFF and METI) on the basis of intergovernmental agreements

Deviations: None.

GLP: Yes, conducted under GLP/Officially recognised testing facilities

Acceptability: Yes

Summary of the study 2 trials (Report: B9119)

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Azoxystrobin	R230310		
	(a)	(b)				(c)					(d)	(e)
Trial 1 B9119 B9119 CZ1 CZECHIA (Europe North) (51743, Severovýchod 2019	Spring wheat / Tercie	1.28 Mar 2019 2 – 3 -	240	240		1. 01 Jul 2019	(Control) (Control) BBCH 69 BBCH 69	Grain Straw Grain Straw	< 0.01 < 0.01 0.08 2.51	< 0.01 < 0.01 < 0.01 0.37	54 54 54 54	Acceptable. Report: B9119 Methods: Azoxystrobin (Grain, Straw, Whole plant) RAM 305/03; LOQ = 0.01 mg/kg R230310 (Grain, Straw, Whole plant) RAM 305/03; LOQ = 0.01 mg/kg Acceptable procedural recovery data provided in the report. Max. storage = 209 days (7 months) Test product = Amistar 250 SC (250 g/L Azoxystrobin)

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Azoxystrobin	R230310		
	(a)	(b)				(c)					(d)	(e)
Trial 2 B9119 B9119 HU1 HUNGARY (Europe North) (H-2921, Közép-Dunántúl) 2019	Spring wheat / Leguan	1.07 Mar 2019 2 – 3 -	258	310		11 Jun 2019	(Control) (Control) (Control) BBCH 69 BBCH 69	Whole plant Grain Straw Grain Straw	< 0.01 < 0.01 < 0.01 < 0.01 0.25	< 0.01 < 0.01 < 0.01 < 0.01 0.03	0 41 41 41 41	Acceptable. Report: B9119 Methods: Azoxystrobin (Grain, Straw, Whole plant) RAM 305/03; LOQ = 0.01 mg/kg R230310 (Grain, Straw, Whole plant) RAM 305/03; LOQ = 0.01 mg/kg Acceptable procedural recovery data provided in the report. Max. storage = 209 days (7 months) Test product = Amistar 250 SC (250 g/L Azoxystrobin)

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Azoxystrobin	R230310		
	(a)	(b)				(c)					(d)	(e)
Trial 3 B9119 B9119 NL1 Netherlands (Europe North) (6599, Limburg) 2019	Spring wheat / Tybalt	1.29 Mar 2019 2 – 3 -	272	327		26 Jun 2019	(Control) (Control) (Control) BBCH 69 BBCH 69	Whole plant Grain Straw Grain Straw	< 0.01 < 0.01 < 0.01 < 0.01 0.37	< 0.01 < 0.01 < 0.01 < 0.01 0.05	0 41 41 41 41	Acceptable. Report: B9119 Methods: Azoxystrobin (Grain, Straw, Whole plant) RAM 305/03; LOQ = 0.01 mg/kg R230310 (Grain, Straw, Whole plant) RAM 305/03; LOQ = 0.01 mg/kg Acceptable procedural recovery data provided in the report. Max. storage = 209 days (7 months) Test product = Amistar 250 SC (250 g/L Azoxystrobin)

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Azoxystrobin	R230310		
	(a)	(b)				(c)					(d)	(e)
Trial 4 B9119 B9119 PL1 Poland (Europe North) (99-122, Łódzkie) 2019	Spring wheat / Nimfa	1.03 Apr 2019 2 – 3 -	240	288		18 Jun 2019	(Control) (Control) (Control) BBCH 69 BBCH 69	Whole plant Grain Straw Grain Straw	< 0.01 < 0.01 < 0.01 <u>0.04</u> <u>8.66</u>	< 0.01 < 0.01 < 0.01 <u>< 0.01</u> <u>1.02</u>	0 45 45 45 45	Acceptable. Report: B9119 Methods: Azoxystrobin (Grain, Straw, Whole plant) RAM 305/03; LOQ = 0.01 mg/kg R230310 (Grain, Straw, Whole plant) RAM 305/03; LOQ = 0.01 mg/kg Acceptable procedural recovery data provided in the report. Max. storage = 209 days (7 months) Test product = Amistar 250 SC (250 g/L Azoxystrobin)

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

The analyte 'Azoxystrobin' refers to the *E*-isomer of azoxystrobin, which is the active component. R230310 refers to the *Z*-isomer of azoxystrobin (while this component is included in the residue trials, this compound is not currently included within the residue definitions for risk assessment nor enforcement).

Study 3 - Andrews 2017, NC16013, VV-467712 - Southern Europe (new data)

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

Reference:	KCP 8.3.1/03
Report	Azoxystrobin - residue study on wheat in Southern Europe in 2016; Andrews G. and Pearson J., 2017; Report No NC16013; Document No VV-467712
Guideline(s):	- Commission of the European Communities, General Recommendations for the Design, Preparation and Realization of Residue Trials; 7029/VI/95 (rev. 5, working document) - OECD Guidance Document on Overview of Residue Chemistry Studies (as revised 2009), Series on Testing and Assessment (No. 64) and Series on Pesticides (No. 32), ENV/JM/MONO(2009)31 - Guidelines and Criteria for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for the Inclusion of Active Substances in Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 - Guidelines for the Generation of Data concerning Residues as provided in Annex II part A, section 6 and Annex III, part A, section 8 of Directive 91/414/EEC concerning the placing of plant protection products on the market (EU) 1607/VI/97 (1999) - OECD Guidelines for the Testing of Chemicals – Crop Field Trial, No. 509, OECD, Paris 2009. - OECD Guidance Document on Crop Field Trials, Series on Pesticides No. 66 and Series on Testing and Assessment No. 164, ENV/JM/MONO(2011)50 - European Commission Guidance for Generating and Reporting Methods of Analysis in Support of Pre-registration Requirements for Annex II (Part A, Section 4) of Directive 91/414, SANCO/3029/99 revision 4 (11 Jul 2000) - OECD GLP ENV/JM/MONO (99) 22 - The Application of the OECD Principles of GLP to the Organisation and Management of Multi-Site Studies, ENV/JM/MONO (2002) 9 - OECD Series on Principles of GLP and Compliance Monitoring No. 1 (as revised in 1997) “OECD Principles on Good Laboratory Practice”, Paris 1998 ENV/MC/CHEM(98)17 and respective national regulations - The national GLP requirements are based on the OECD Principles of Good Laboratory Practice, which are accepted by regulatory authorities throughout the European Community, the United States of America (FDA and EPA) and Japan (MHW, MAFF and METI) on the basis of intergovernmental agreements
Deviations:	None.
GLP:	Yes, conducted under GLP/Officially recognised testing facilities
Acceptability:	Yes

Summary of the study 3 trials (Report: NC16013)

Trial No./ Location/ EU zone/ Year (a)	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 (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Azoxystrobin	R230310		
Trial 1 NC16013 NC16013-01 France (Europe South) (33210) 2016	Winter Wheat / Hystar	1.21 Oct 2015 2 – 3 –	268	269		12 May 2016	(Control) (Control) (Control) BBCH 69 BBCH 69 BBCH 69 BBCH 69 BBCH 69 BBCH 69 BBCH 69	Whole Plant Straw Grain Whole Plant Whole Plant Whole Plant Whole Plant Whole Plant Straw Grain	< 0.01 < 0.01 < 0.01 3.92 2.7 0.75 0.41 0.28 0.39 0.02	< 0.01 < 0.01 < 0.01 0.02 0.1 0.04 0.03 0.03 0.04 < 0.01	0 54 54 0 7 14 28 42 54 54	Acceptable. Report: NC16013 Methods: Azoxystrobin (Grain, Straw, Whole plant) RAM 305/03; LOQ = 0.01 mg/kg R230310 (Grain, Straw, Whole plant) RAM 305/03; LOQ = 0.01 mg/kg Acceptable procedural recovery data provided in the report. Max. storage = 260 days (9 months) Test product = Amistar 250 SC (250 g/L Azoxystrobin)

Trial No./ Location/ EU zone/ Year (a)	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 (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Azoxystrobin	R230310		
Trial 2 NC16013 NC16013-02 France (Europe South) (64160) 2016	Winter Wheat / Solehio	1.10 Nov 2015 2 – 3 –	250	251		12 May 2016	(Control) (Control) (Control) BBCH 67-69 BBCH 67-69 BBCH 67-69 BBCH 67-69 BBCH 67-69 BBCH 67-69 BBCH 67-69	Whole Plant Grain Straw Whole Plant Whole Plant Whole Plant Whole Plant Whole Plant Straw Grain	< 0.01 < 0.01 < 0.01 3.24 0.52 0.28 0.18 0.12 0.20 < 0.01	< 0.01 < 0.01 < 0.01 < 0.01 < 0.01 < 0.01 < 0.01 < 0.01 0.01 < 0.01	0 57 57 0 7 14 28 42 42 57	Acceptable. Report: NC16013 Methods: Azoxystrobin (Grain, Straw, Whole plant) RAM 305/03; LOQ = 0.01 mg/kg R230310 (Grain, Straw, Whole plant) RAM 305/03; LOQ = 0.01 mg/kg Acceptable procedural recovery data provided in the report. Max. storage = 260 days (9 months) Test product = Amistar 250 SC (250 g/L Azoxystrobin)

Trial No./ Location/ EU zone/ Year (a)	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 (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Azoxystrobin	R230310		
Trial 3 NC16013 NC16013-03 Spain (Europe South) (49830) 2016	Winter Wheat / Garcia	1.14 Oct 2015 2 – 3 –	250	301		26 May 2016	(Control) (Control) (Control) BBCH 69 BBCH 69 BBCH 69 BBCH 69 BBCH 69 BBCH 69	Whole Plant Straw Grain Whole Plant Whole Plant Whole Plant Whole Plant Grain Straw	< 0.01 < 0.01 < 0.01 3.18 1.49 1.19 1.3 0.10 2.8	< 0.01 < 0.01 < 0.01 < 0.01 0.08 0.09 0.15 0.01 0.24	0 41 41 0 7 13 27 41 41	Acceptable. Report: NC16013 Methods: Azoxystrobin (Grain, Straw, Whole plant) RAM 305/03; LOQ = 0.01 mg/kg R230310 (Grain, Straw, Whole plant) RAM 305/03; LOQ = 0.01 mg/kg Acceptable procedural recovery data provided in the report. Max. storage = 260 days (9 months) Test product = Amistar 250 SC (250 g/L Azoxystrobin)

Trial No./ Location/ EU zone/ Year (a)	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 (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Azoxystrobin	R230310		
Trial 4 NC16013 NC16013-04 Italy (Europe South) (04018) 2016	Winter Wheat / Illico	1.20 Jan 2016 2 – 3 –	268	323		27 May 2016	(Control) (Control) (Control) BBCH 69 BBCH 69 BBCH 69 BBCH 69 BBCH 69 BBCH 69	Whole Plant Grain Straw Whole Plant Whole Plant Whole Plant Whole Plant Grain Straw	< 0.01 < 0.01 < 0.01 4.96 0.84 1.14 0.97 0.16 1.56	< 0.01 < 0.01 < 0.01 0.01 0.04 0.09 0.1 0.02 0.14	0 42 42 0 7 14 28 42 42	Acceptable. Report: NC16013 Methods: Azoxystrobin (Grain, Straw, Whole plant) RAM 305/03; LOQ = 0.01 mg/kg R230310 (Grain, Straw, Whole plant) RAM 305/03; LOQ = 0.01 mg/kg Acceptable procedural recovery data provided in the report. Max. storage = 260 days (9 months) Test product = Amistar 250 SC (250 g/L Azoxystrobin)

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
The analyte 'Azoxystrobin' refers to the *E* isomer of azoxystrobin, which is the active component. R230310 refers to the *Z* isomer of azoxystrobin (while this component is included in the residue trials, this compound is not currently included within the residue definitions for risk assessment nor enforcement).

Study 4 - Brown 2020, RES-00188, VV-864619 - Southern Europe (new data)

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

Reference: KCP 8.3.1/04

Report: Azoxystrobin – Magnitude of Residue Study on Spring Wheat in Spain and Portugal in 2019; Brown D., 2020; Report No RES-00188; Document No VV-864619

Guideline(s):

- Commission of the European Communities, General Recommendations for the Design, Preparation and Realization of Residue Trials; 7029/VI/95 (rev. 5, working document)
- OECD Guidance Document on Overview of Residue Chemistry Studies (as revised 2009), Series on Testing and Assessment (No. 64) and Series on Pesticides (No. 32), ENV/JM/MONO(2009)31
- Guidelines and Criteria for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for the Inclusion of Active Substances in Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009
- Guidelines for the Generation of Data concerning Residues as provided in Annex II part A, section 6 and Annex III, part A, section 8 of Directive 91/414/EEC concerning the placing of plant protection products on the market (EU) 1607/VI/97 (1999)
- OECD Guidelines for the Testing of Chemicals – Crop Field Trial, No. 509, OECD, Paris 2009
- OECD Guidance Document on Crop Field Trials, Series on Pesticides No. 66 and Series on Testing and Assessment No. 164, ENV/JM/MONO(2011)50
- European Commission Guidance for Generating and Reporting Methods of Analysis in Support of Pre-registration Requirements for Annex II (Part A, Section 4) of Directive 91/414, SANCO/3029/99 revision 4 (11 Jul 2000)
- OECD GLP ENV/JM/MONO (99) 22.
- The Application of the OECD Principles of GLP to the Organisation and Management of Multi-Site Studies, ENV/JM/MONO (2002) 9
- OECD Series on Principles of GLP and Compliance Monitoring No. 1 (as revised in 1997) “OECD Principles on Good Laboratory Practice”, Paris 1998. ENV/MC/CHEM(98)17 and respective national regulations
- The national GLP requirements are based on the OECD Principles of Good Laboratory Practice, which are accepted by regulatory authorities throughout the European Community, the United States of America (FDA and EPA) and Japan (MHW, MAFF and METI) on the basis of intergovernmental agreements

Deviations: None

GLP: Yes, conducted under GLP/Officially recognised testing facilities

Acceptability: Yes

Summary of the study 4 trials (RES-00188)

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Azoxystrobin	R230310		
Trial 1 RES-00188 BPL19-810-GC-01-SP Spain (Europe South) (02630)	Spring wheat / Artur Nick	1.11 Mar 2019 2 – 3 –	242	290		17 May 2019	(Control) (Control) BBCH 69 BBCH 69	Straw Grain Straw Grain	< 0.01 < 0.01 3.87 0.07	< 0.01 < 0.01 0.30 < 0.01	38 38 38 38	Acceptable. Report: RES-00188 Methods: Azoxystrobin (Grain, Straw, Whole plant) RAM 305/03; LOQ = 0.01 mg/kg R230310 (Grain, Straw, Whole plant) RAM 305/03; LOQ = 0.01 mg/kg Acceptable procedural recovery data provided in the report. Max. storage = 155 days (5 months) Test product = Amistar 250 SC (250 g/L Azoxystrobin)

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Azoxystrobin	R230310		
(a)		(b)				(c)					(d)	(e)
Trial 2 RES-00188 BPL19-810-GC-02-SP Spain (Europe South) (02490)	Spring wheat / Artur Nick	1.02 Mar 2019 2 – 3 –	250	300		17 May 2019	(Control) (Control) BBCH 69 BBCH 69	Straw Grain Grain Straw	< 0.01 < 0.01 0.02 1.31	< 0.01 < 0.01 < 0.01 0.14	41 41 41 41	Acceptable. Report: RES-00188 Methods: Azoxystrobin (Grain, Straw, Whole plant) RAM 305/03; LOQ = 0.01 mg/kg R230310 (Grain, Straw, Whole plant) RAM 305/03; LOQ = 0.01 mg/kg Acceptable procedural recovery data provided in the report. Max. storage = 155 days (5 months) Test product = Amistar 250 SC (250 g/L Azoxystrobin)

Trial No./ Location/ EU zone/ Year (a)	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 (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Azoxystrobin	R230310		
Trial 3 RES-00188 BPL19-810-GC-04-PT Portugal (Europe South) (5400-649)	Spring wheat / R2	1.30 Mar 2019 2 – 3 –	252	253		11 Jul 2019		Whole plant Straw Grain Straw Grain	< 0.01 < 0.01 < 0.01 3.21 0.03	< 0.01 < 0.01 < 0.01 0.35 < 0.01	0 41 41 41 41	Acceptable. Report: RES-00188 Methods: Azoxystrobin (Grain, Straw, Whole plant) RAM 305/03; LOQ = 0.01 mg/kg R230310 (Grain, Straw, Whole plant) RAM 305/03; LOQ = 0.01 mg/kg Acceptable procedural recovery data provided in the report. Max. storage = 155 days (5 months) Test product = Amistar 250 SC (250 g/L Azoxystrobin)

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Azoxystrobin	R230310		
(a)		(b)				(c)					(d)	(e)
Trial 4 RES-00188 BPL19-810-GC-05-SP Spain (Europe South) (32641)	Spring wheat / Callobre	1.13 May 2019 2 – 3 –	259	312		30 Jul 2019	(Control) (Control) BBCH 69 BBCH 69	Grain Straw Grain Straw	< 0.01 < 0.01 0.04 3.43	< 0.01 < 0.01 < 0.01 0.34	35 35 35 35	Acceptable. Report: RES-00188 Methods: Azoxystrobin (Grain, Straw, Whole plant) RAM 305/03; LOQ = 0.01 mg/kg R230310 (Grain, Straw, Whole plant) RAM 305/03; LOQ = 0.01 mg/kg Acceptable procedural recovery data provided in the report. Max. storage = 155 days (5 months) Test product = Amistar 250 SC (250 g/L Azoxystrobin)

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
The analyte 'Azoxystrobin' refers to the *E* isomer of azoxystrobin, which is the active component. R230310 refers to the *Z* isomer of azoxystrobin (while this component is included in the residue trials, this compound is not currently included within the residue definitions for risk assessment nor enforcement).

A 2.1.3.2 Barley

Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (DAR, RMS, year)	1-2	250 g as/ha	14 days	BBCH 59	35**
cGAP EU (Art. 12, EFSA, year)	3	250 g as/ha	Not stated	BBCH 71	35
Intended cGAP (numbers 5, 6)	1	1 L product per ha (160 g azoxystrobin per ha)	Not applicable	BBCH 59	35 (GSR)

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0
** Timing of applications determined primarily by growth stage; 1st application not later than BBCH 39, 2nd application no later than BBCH 59.
GSR: Growth Stage Restricted

The following table provides a summary of the available data from the residue trials:

Analyte	Residue trials zone	Residues (mg/kg)	STMR (mg/kg)	HR (mg/kg)
Azoxystrobin	North EU	S16-03841 (grain): 0.03, 0.03, 0.02, <0.01 S16-03841 (straw): 0.18, 0.54, 0.68, 0.56, IF19-04928654 (grain): 0.44, 0.07, 0.04 IF19-04928654 (straw): 5.3, 0.87, 0.96 685286 (grain): 0.09 685286 (straw): 1.31	Grain = 0.035 Straw = 0.775	Grain = 0.44 Straw = 5.3
	~~South EU~~	~~S16-03842 (grain): 0.02, 0.01, 0.13, 0.06~~ ~~S16-03842 (straw): 0.45 0.56, 2.58, 1.21~~ ~~IF19-04928660 (grain): 0.05, <0.01, 0.01, 0.01~~ ~~IF19-04928660 (straw): 6.7, 0.20, 0.28, 0.27~~	~~Grain = 0.015~~ ~~Straw = 0.505~~	~~Grain = 0.13~~ ~~Straw = 6.7~~
z-Azoxystrobin	North EU	S16-03841 (grain): <0.01, <0.01, <0.01, <0.01 S16-03841 (straw): 0.01, 0.03, 0.04, 0.04 IF19-04928654 (grain): 0.03, <0.01, <0.01 IF19-04928654 (straw): 0.55, 0.09, 0.08 685286 (grain): <0.01 685286 (straw): 0.10	Grain = <0.01 Straw = 0.06	Grain = 0.03 Straw = 0.55
	~~South EU~~	~~S16-03842 (grain): <0.01, <0.01, 0.02, <0.01~~ ~~S16-03842 (straw): 0.05, 0.05, 0.24, 0.10~~ ~~IF19-04928660 (grain): <0.01, <0.01, <0.01, <0.01~~ ~~IF19-04928660 (straw): 0.87, 0.02, 0.02, 0.02~~	~~Grain = <0.01~~ ~~Straw = 0.05~~	~~Grain = 0.02~~ ~~Straw = 0.87~~

While z-azoxystrobin has been analysed within the samples collected from the residue field trials, only "Azoxystrobin" is included within both the residues definitions for risk assessment and enforcement (monitoring) purposes. The residue concentrations for z-azoxystrobin have been included within the above table (for completeness) and have been included within the following study summaries for the residue field trials, however, the residues data for this compound will not be considered within the risk assessments.

While it is noted the trials use a higher single application dose (targeted at 250 g azoxystrobin /ha) than the GAP intended for FGF11 (targeted at 160 g azoxystrobin /ha), it is considered that these data represent a worst-case data-set, which acceptably covers the risk scenario intended for the wheat use included within the FGF11 GAP. Consequently an acceptable risk assessment conducted with these data will also cover the use intended for FGF11.

The residue values were used in the consumer risk assessment without modification, as this represented a worst-case risk assessment, covering the intended use. However, if required for refinement purposes, the residue values have been scaled using the proportionality principle. The resulting values are provided within

the following table:

EU trial zone	Commodity fraction	Residue trial	Residue value (mg/kg)	Application rate used in the trial (g a.s./ha)	Target GAP application rate for FGF11 (g a.s./ha)	Scaling factor	Scaled residue (mg/kg)
North EU	Grain	S16-03841-01	0.03	254	160	1.588	0.02
North EU	Straw	S16-03841-01	0.18	254	160	1.588	0.11
North EU	Grain	S16-03841-02	0.03	226	160	1.413	0.02
North EU	Straw	S16-03841-02	0.54	226	160	1.413	0.38
North EU	Grain	S16-03841-03	0.02	256	160	1.600	0.01
North EU	Straw	S16-03841-03	0.68	256	160	1.600	0.43
North EU	Grain	S16-03841-04	<0.01	226	160	1.413	<0.01
North EU	Straw	S16-03841-04	0.56	226	160	1.413	0.40
North EU	Grain	IF19-04928654 19-00294-01	0.44	259	160	1.619	0.27
North EU	Straw	IF19-04928654 19-00294-01	5.3	259	160	1.619	3.27
North EU	Grain	IF19-04928654 19-00294-02	0.07	252	160	1.575	0.04
North EU	Straw	IF19-04928654 19-00294-02	0.87	252	160	1.575	0.55
North EU	Grain	IF19-04928654 19-00294-04	0.04	244	160	1.525	0.03
North EU	Straw	IF19-04928654 19-00294-04	0.96	244	160	1.525	0.63
North EU	Grain	685286 Trial 1	0.09	253	160	1.581	0.06
North EU	Straw	685286 Trial 1	1.31	253	160	1.581	0.83
~~South EU~~	~~Grain~~	~~S16-03842-01~~	~~0.02~~	~~263~~	~~160~~	~~1.644~~	~~0.01~~
~~South EU~~	~~Straw~~	~~S16-03842-01~~	~~0.45~~	~~263~~	~~160~~	~~1.644~~	~~0.27~~
~~South EU~~	~~Grain~~	~~S16-03842-02~~	~~0.01~~	~~263~~	~~160~~	~~1.644~~	~~<0.01 (0.006)~~
~~South EU~~	~~Straw~~	~~S16-03842-02~~	~~0.56~~	~~263~~	~~160~~	~~1.644~~	~~0.34~~
~~South EU~~	~~Grain~~	~~S16-03842-03~~	~~0.13~~	~~240~~	~~160~~	~~1.500~~	~~0.09~~
~~South EU~~	~~Straw~~	~~S16-03842-03~~	~~2.58~~	~~240~~	~~160~~	~~1.500~~	~~1.72~~
~~South EU~~	~~Grain~~	~~S16-03842-04~~	~~0.06~~	~~266~~	~~160~~	~~1.663~~	~~0.04~~
~~South EU~~	~~Straw~~	~~S16-03842-04~~	~~1.21~~	~~266~~	~~160~~	~~1.663~~	~~0.73~~
~~South EU~~	~~Grain~~	~~IF19-04928660 19-00299-01~~	~~0.05~~	~~255~~	~~160~~	~~1.594~~	~~0.03~~
~~South EU~~	~~Straw~~	~~IF19-04928660 19-00299-01~~	~~0.67~~	~~255~~	~~160~~	~~1.594~~	~~0.42~~
~~South EU~~	~~Grain~~	~~IF19-04928660 19-00299-02~~	~~<0.01~~	~~257~~	~~160~~	~~1.606~~	~~<0.01~~
~~South EU~~	~~Straw~~	~~IF19-04928660 19-00299-02~~	~~0.2~~	~~257~~	~~160~~	~~1.606~~	~~0.12~~
~~South EU~~	~~Grain~~	~~IF19-04928660 19-00299-03~~	~~0.01~~	~~253~~	~~160~~	~~1.581~~	~~0.006~~

South EU	Straw	IF19-04928660 19-00299-03	0.28	253	160	1.581	0.18
South EU	Grain	IF19-04928660 19-00299-04	0.02	247	160	1.544	0.01
South EU	Straw	IF19-04928660 19-00299-04	0.27	247	160	1.54375	0.17

Study 1 - Souchier 2017, S16-03841, VV-467864 - Northern Europe (new data)

Comments of zRMS:	This study has already been evaluated. Please refer to the Azoxystrobin EU renewal (dRAR) for a summary and conclusions for this study. This study has not been reassessed in the framework of this application.

Reference: KCP 8.3.2/01

Report: Azoxystrobin – Residue Study on Barley in the United Kingdom, Northern France and Germany in 2016; Souchier M., 2017; Report No S16-03841; Document No VV-467864

Guideline(s):

- Commission of the European Communities, General Recommendations for the Design, Preparation and Realization of Residue Trials; 7029/VI/95 (rev. 5, working document)
- OECD Guidance Document on Crop Field Trials, Series on Pesticides No. 66 and Series on Testing and Assessment No. 164, ENV/JM/MONO(2011)50
- OECD Guidance Document on Overview of Residue Chemistry Studies (as revised 2009), Series on Testing and Assessment (No. 64) and Series on Pesticides (No. 32), ENV/JM/MONO(2009)31
- Guidelines and Criteria for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for the Inclusion of Active Substances in Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009
- OECD Guidelines for the Testing of Chemicals – Crop Field Trial, No. 509, OECD, Paris 2009
- European Commission Guidance for Generating and Reporting Methods of Analysis in Support of Pre-registration Requirements for Annex II (Part A, Section 4) of Directive 91/414, SANCO/3029/99 revision 4 (11 Jul 2000
- The Application of the OECD Principles of GLP to the Organisation and Management of Multi-Site Studies, ENV/JM/MONO (2002) 9. OECD Series on Principles of GLP and Compliance Monitoring No. 1 (as revised in 1997) “OECD Principles on Good Laboratory Practice”, Paris 1998. ENV/MC/CHEM(98)17 and respective national regulations
- The national GLP requirements are based on the OECD Principles of Good Laboratory Practice, which are accepted by regulatory authorities throughout the European Community, the United States of America (FDA and EPA) and Japan (MHW, MAFF and METI) on the basis of intergovernmental agreements
- Article Annex II to Article D523-8 of the Environment Code

Deviations: None.

GLP: Yes, conducted under GLP/Officially recognised testing facilities

Acceptability: Yes

Summary of the study 1 trials - S16-03841

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Azoxystrobin	R230310		
	(a)	(b)				(c)					(d)	(e)
Trial 1 S16-03841 S16-03841-01 United Kingdom (Europe North) (NG32 3NZ, Lincolnshire)	Barley / Volume	1.20 Oct 2015 2 – 3 -	254	203		23 May 2016	(Control) (Control) (Control) BBCH 59 BBCH 59 BBCH 59 BBCH 59 BBCH 59 BBCH 59 BBCH 59	Whole Plant Straw Grain Whole Plant Whole Plant Whole Plant Whole Plant Whole Plant Grain Straw	< 0.01 < 0.01 < 0.01 1.85 1.5 0.52 0.09 0.06 0.03 0.18	< 0.01 < 0.01 < 0.01 < 0.01 0.03 < 0.01 < 0.01 < 0.01 < 0.01 0.01	0 59 59 0 7 15 28 43 59 59	Acceptable. Report S16-03841 Methods: Azoxystrobin (Grain, Straw, Whole plant) RAM 305/03; LOQ = 0.01 mg/kg R230310 (Grain, Straw, Whole plant) RAM 305/03; LOQ = 0.01 mg/kg Acceptable procedural recovery data provided in the report. Max. storage = 225 days (7 months) Test product = Amistar 250 SC (250 g/L Azoxystrobin)

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Azoxystrobin	R230310		
	(a)	(b)				(c)					(d)	(e)
Trial 2 S16-03841 S16-03841-02 United Kingdom (Europe North) (PR9 8HD, Lancashire)	Barley / KWS Tower	1.13 Oct 2015 2 – 3 -	226	271		25 May 2016	(Control) (Control) (Control) BBCH 55-59 BBCH 55-59 BBCH 55-59 BBCH 55-59 BBCH 55-59 BBCH 55-59 BBCH 55-59	Whole Plant Grain Straw Whole Plant Whole Plant Whole Plant Whole Plant Whole Plant Grain Straw	< 0.01 < 0.01 < 0.01 1.27 1.25 1.23 0.31 0.36 0.03 0.54	< 0.01 < 0.01 < 0.01 < 0.01 0.04 0.04 0.02 0.02 < 0.01 0.03	0 50 50 0 7 14 28 42 50 50	Acceptable. Report S16-03841 Methods: Azoxystrobin (Grain, Straw, Whole plant) RAM 305/03; LOQ = 0.01 mg/kg R230310 (Grain, Straw, Whole plant) RAM 305/03; LOQ = 0.01 mg/kg Acceptable procedural recovery data provided in the report. Max. storage = 225 days (7 months) Test product = Amistar 250 SC (250 g/L Azoxystrobin)

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Azoxystrobin	R230310		
	(a)	(b)				(c)					(d)	(e)
Trial 3 S16-03841 S16-03841-03 France (Europe North) (45300, Centre)	Barley / Sebastian	1.14 Mar 2016 2 – 3 -	256	206		08 Jun 2016	(Control) (Control) (Control) BBCH 51-54 BBCH 51-54 BBCH 51-54 BBCH 51-54 BBCH 51-54 BBCH 51-54 BBCH 51-54	Whole Plant Grain Straw Whole Plant Whole Plant Whole Plant Whole Plant Straw Grain Straw Grain	< 0.01 < 0.01 < 0.01 2.21 0.56 0.28 0.11 0.60 0.02 0.68 0.02	< 0.01 < 0.01 < 0.01 < 0.01 < 0.01 < 0.01 < 0.01 0.03 < 0.01 0.04 < 0.01	0 47 47 0 7 14 28 42 42 47 47	Acceptable. Report S16-03841 Methods: Azoxystrobin (Grain, Straw, Whole plant) RAM 305/03; LOQ = 0.01 mg/kg R230310 (Grain, Straw, Whole plant) RAM 305/03; LOQ = 0.01 mg/kg Acceptable procedural recovery data provided in the report. Max. storage = 225 days (7 months) Test product = Amistar 250 SC (250 g/L Azoxystrobin)

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Azoxystrobin	R230310		
	(a)	(b)				(c)					(d)	(e)
Trial 4 S16-03841 S16-03841-04 Germany (Europe North) (69124, Baden-Württemberg)	Barley / Avalon	1.14 Mar 2016 2 – 3 -	226	181		02 Jun 2016	(Control) (Control) (Control) BBCH 57-59 BBCH 57-59 BBCH 57-59 BBCH 57-59 BBCH 57-59 BBCH 57-59	Whole Plant Grain Straw Whole Plant Whole Plant Whole Plant Whole Plant Grain Straw	< 0.01 < 0.01 < 0.01 2.47 0.52 0.39 0.13 < 0.01 0.56	< 0.01 < 0.01 < 0.01 < 0.01 < 0.01 < 0.01 < 0.01 < 0.01 0.04	0 46 46 0 7 14 28 46 46	Acceptable. Report S16-03841 Methods: Azoxystrobin (Grain, Straw, Whole plant) RAM 305/03; LOQ = 0.01 mg/kg R230310 (Grain, Straw, Whole plant) RAM 305/03; LOQ = 0.01 mg/kg Acceptable procedural recovery data provided in the report. Max. storage = 225 days (7 months) Test product = Amistar 250 SC (250 g/L Azoxystrobin)

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

Study 2 - Ziske 2020, IF19-04928654, VV-865884 - Northern Europe (new data)

Comments of zRMS:	This study has already been evaluated. Please refer to the Azoxystrobin EU renewal (dRAR) for a summary and conclusions for this study. This study has not been reassessed in the framework of this application.

Reference: KCP 8.3.2/02

Report: Azoxystrobin - Residue Study on Spring Barley in Poland, Germany and Hungary in 2019; Ziske J. and Link T., 2020; Report No IF19-04928654; Document No VV-865884

Guideline(s):

- Guidelines for the Generation of Data concerning Residues as provided in Annex II part A, section 6 and Annex III, part A, section 8 of Directive 91/414/EEC concerning the placing of plant protection products on the market (EU) 1607/VI/97 (1999)
- Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and91/414/EEC
- EC (1997) Guidance Document 7029/VI/95 rev. 5 general recommendations for the design, preparation and realization of residue trials
- OECD (2009). Guidance Document on Overview of Residue Chemistry Studies (as revised2009), Series on Testing and Assessment No. 64 and Series on Pesticides No. 32, ENV/JM/MONO(2009)31
- OECD Guidance Document on Crop Field Trials, Series on Pesticides No. 66 and Series on Testing and Assessment No. 164, ENV/JM/MONO(2011)50
- OECD – Guideline for the Testing of Chemicals, Test Guideline 509; Crop field trial,07/09/2009
- European Commission Guidance for Generating and Reporting Methods of Analysis in Support of Pre-registration Requirements for Annex II (Part A, Section 4) of Directive 91/414, SANCO/3029/99 revision 4 (11 Jul 2000)
- OECD Series on Principles of GLP and Compliance Monitoring No. 1 (as revised in 1997)
- "OECD Principles on Good Laboratory Practice", Paris 1998. ENV/MC/CHEM (98)17 and respective national regulations
- The Application of the OECD Principles of GLP to the Organisation and Management of Multi-Site Studies, ENV/JM/MONO (2002) 9
- OECD GLP ENV/JM/MONO (99) 22
- - The national requirements are based on the OECD Principles of Good Laboratory Practice, which are accepted by regulatory authorities throughout the European Community, the United States of America (FDA and EPA) and Japan (MHW, MAFF and METI) on the basis of intergovernmental agreements

Deviations: None.

GLP: Yes, conducted under GLP/Officially recognised testing facilities

Acceptability: Yes

Summary of the study 2 trials - IF19-04928654

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Azoxystrobin	R230310		
	(a)	(b)				(c)					(d)	(e)
Trial 1 IF19-04928654 19-00294-01 Poland (Europe North) (88-400, Wielkopolskie)	Spring barley / Pengiun	1.22 Mar 2019 2 – 3 -	259	312		18 Jun 2019	(Control) (Control) BBCH 59 BBCH 59	Straw Grain Straw Grain	< 0.01 < 0.01 5.3 0.44	< 0.01 < 0.01 0.55 0.03	35 35 35 35	Acceptable. Report: IF19-04928654 Methods: Azoxystrobin (Grain, Straw, Whole plant) RAM 305/03; LOQ = 0.01 mg/kg R230310 (Grain, Straw, Whole plant) RAM 305/03; LOQ = 0.01 mg/kg Acceptable procedural recovery data provided in the report. Max. storage = 238 days (8 months) Test product = Amistar 250 SC (250 g/L Azoxystrobin)

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Azoxystrobin	R230310		
	(a)	(b)				(c)					(d)	(e)
Trial 2 IF19-04928654 19-00294-02 Germany (Europe North) (49685, Niedersachsen)	Spring barley / Sydney	1.01 Mar 2019 2 – 3 -	252	203		14 Jun 2019	(Control) (Control) BBCH 59 BBCH 59	Grain Straw Grain Straw	< 0.01 < 0.01 0.07 0.87	< 0.01 < 0.01 < 0.01 0.09	47 47 47 47	Acceptable. Report: IF19-04928654 Methods: Azoxystrobin (Grain, Straw, Whole plant) RAM 305/03; LOQ = 0.01 mg/kg R230310 (Grain, Straw, Whole plant) RAM 305/03; LOQ = 0.01 mg/kg Acceptable procedural recovery data provided in the report. Max. storage = 238 days (8 months) Test product = Amistar 250 SC (250 g/L Azoxystrobin) Test product = Amistar 250 SC (250 g/L Azoxystrobin)

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Azoxystrobin	R230310		
	(a)	(b)				(c)					(d)	(e)
Trial 4 IF19-04928654 19-00294-04 HUNGARY (Europe North) (H-4440, Észak-Alföld)	Spring barley / Scarlet	1.01 Mar 2019 2 – 3 -	244	245		06 Jun 2019	Control) (Control) (Control) BBCH 59 BBCH 59	Whole plant Straw Grain Grain Straw	< 0.01 < 0.01 < 0.01 0.04 0.96	< 0.01 < 0.01 < 0.01 < 0.01 0.08	0 42 42 42 42	Acceptable. Report: IF19-04928654 Methods: Azoxystrobin (Grain, Straw, Whole plant) RAM 305/03; LOQ = 0.01 mg/kg R230310 (Grain, Straw, Whole plant) RAM 305/03; LOQ = 0.01 mg/kg Acceptable procedural recovery data provided in the report. Max. storage = 238 days (8 months) Test product = Amistar 250 SC (250 g/L Azoxystrobin)

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

Study 3 - Hoskins 2022, 685286, VV-931335 - Northern Europe (new data)

Comments of zRMS:	This study has already been evaluated. Please refer to the Azoxystrobin EU renewal (dRAR) for a summary and conclusions for this study. This study has not been reassessed in the framework of this application.

Reference:	KCP 8.3.2/03
Report	Azoxystrobin – Residue Study on Barley in UK and Northern France, Initiated in 2022; Hoskins M., 2022; Report No 685286; Document No VV-931335
Guideline(s):	- Commission of the European Communities, General Recommendations for the Design, Preparation and Realization of Residue Trials; 7029/VI/95 (rev. 5, working document). - OECD Guidance Document on Crop Field Trials, Series on Pesticides No. 66 and Series on Testing and Assessment No. 164, ENV/JM/MONO(2011)50. - OECD Guidance Document on Overview of Residue Chemistry Studies (as revised 2009), Series on Testing and Assessment (No. 64) and Series on Pesticides (No. 32), ENV/JM/MONO(2009)31. - Guidelines and Criteria for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for the Inclusion of Active Substances in Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009. - OECD Guidelines for the Testing of Chemicals – Crop Field Trial, No. 509, OECD, Paris 2009. - The Application of the OECD Principles of GLP to the Organisation and Management of Multi-Site Studies, ENV/JM/MONO (2002) 9. - OECD Series on Principles of GLP and Compliance Monitoring No. 1 (as revised in 1997) "OECD Principles on Good Laboratory Practice", Paris 1998. ENV/MC/CHEM(98)17 and respective national regulations.
Deviations:	None
GLP:	Yes, conducted under GLP/Officially recognised testing facilities
Acceptability:	Yes

Summary of the study 3 trials - 685286

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Azoxystrobin	R230310		
	(a)	(b)				(c)					(d)	(e)
Trial 1 685286 685286 Trial 1 United Kingdom (Europe North) (YO17 6QA)	Barley / Laurette	1.18 Apr 2022 2. 07 Jul 2022 3. 15 Aug 2022	253	304		30 Jun 2022	(Control) (Control) BBCH 59 BBCH 59	Straw Grain Grain Straw	< 0.01 < 0.01 <u>0.09</u> <u>1.31</u>	< 0.01 < 0.01 <u>< 0.01</u> <u>0.10</u>	46 46 46 46	Acceptable. Report: 685286 Methods: Azoxystrobin (Grain, Straw, Whole plant) RAM 305/03; LOQ = 0.01 mg/kg R230310 (Grain, Straw, Whole plant) RAM 305/03; LOQ = 0.01 mg/kg Acceptable procedural recovery data provided in the report. Max. storage = 18 days (less than 1 month) Test product = Amistar 250 SC (250 g/L Azoxystrobin)

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

Study 4 - Souchier 2017, S16-03842, VV-467632 - Southern Europe (new data)

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

Reference: KCP 8.3.2/04

Report: Azoxystrobin – Residue Study on Barley in the Southern France, Italy and Spain in 2016; Souchier M., 2017; Report No S16-03842; Document No VV-467632

Guideline(s):

- Commission of the European Communities, General Recommendations for the Design, Preparation and Realization of Residue Trials; 7029/VI/95 (rev. 5, working document).
- OECD Guidance Document on Crop Field Trials, Series on Pesticides No. 66 and Series on Testing and Assessment No. 164, ENV/JM/MONO(2011)50.
- OECD Guidance Document on Overview of Residue Chemistry Studies (as revised 2009), Series on Testing and Assessment (No. 64) and Series on Pesticides (No. 32), ENV/JM/MONO(2009)31.
- Guidelines and Criteria for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for the Inclusion of Active Substances in Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009.
- OECD Guidelines for the Testing of Chemicals – Crop Field Trial, No. 509, OECD, Paris 2009.
- European Commission Guidance for Generating and Reporting Methods of Analysis in Support of Pre-registration Requirements for Annex II (Part A, Section 4) of Directive 91/414, SANCO/3029/99 revision 4 (11 Jul 2000).
- The Application of the OECD Principles of GLP to the Organisation and Management of Multi-Site Studies, ENV/JM/MONO (2002) 9. OECD Series on Principles of GLP and Compliance Monitoring No. 1 (as revised in 1997) “OECD Principles on Good Laboratory Practice”, Paris 1998. ENV/MC/CHEM(98)17 and respective national regulations.
- The national GLP requirements are based on the OECD Principles of Good Laboratory Practice, which are accepted by regulatory authorities throughout the European Community, the United States of America (FDA and EPA) and Japan (MHW, MAFF and METI) on the basis of intergovernmental agreements.
- Article Annex II to Article D523-8 of the Environment Code

Deviations: None

GLP: Yes, conducted under GLP/Officially recognised testing facilities

Acceptability: Yes

Summary of the study 4 trials – S16-03842

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Azoxystrobin	R230310		
Trial 1 S16-03842 S16-03842-01 France (Europe South) (82290, Midi Pyrenees)	Barley / Prestige	1.01 Mar 2016 2 – 3 –	263	211		27 May 2016	(Control) (Control) (Control) BBCH 59 BBCH 59 BBCH 59 BBCH 59 BBCH 59 BBCH 59	Whole Plant Straw Grain Whole Plant Whole Plant Whole Plant Whole Plant Straw Grain	< 0.01 < 0.01 < 0.01 4.41 0.49 0.56 0.58 0.45 0.02	< 0.01 < 0.01 < 0.01 < 0.01 0.01 0.02 0.02 0.05 < 0.01	0 41 41 0 6 13 26 41 41	Acceptable. Report: S16-03842 Methods: Azoxystrobin (Grain, Straw, Whole plant) RAM 305/03; LOQ = 0.01 mg/kg R230310 (Grain, Straw, Whole plant) RAM 305/03; LOQ = 0.01 mg/kg Acceptable procedural recovery data provided in the report. Max. storage = 183 days (6 months) Test product = Amistar 250 SC (250 g/L Azoxystrobin)

Trial No./ Location/ EU zone/ Year (a)	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 (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Azoxystrobin	R230310		
Trial 2 S16-03842 S16-03842-02 France (Europe South) (82700, Midi Pyrenees)	Barley / Prestige	1.16 Mar 2016 2 – 3 –	263	211		03 Jun 2016	(Control) (Control) (Control) BBCH 58-59 BBCH 58-59 BBCH 58-59 BBCH 58-59 BBCH 58-59 BBCH 58-59 BBCH 58-59	Whole Plant Straw Grain Whole Plant Whole Plant Whole Plant Whole Plant Whole Plant Grain Straw	< 0.01 < 0.01 < 0.01 4.75 5.17 0.69 0.52 0.46 0.01 0.56	< 0.01 < 0.01 < 0.01 < 0.01 0.05 0.01 0.01 < 0.01 < 0.01 0.05	0 55 55 0 6 13 27 39 55 55	Acceptable. Report: S16-03842 Methods: Azoxystrobin (Grain, Straw, Whole plant) RAM 305/03; LOQ = 0.01 mg/kg R230310 (Grain, Straw, Whole plant) RAM 305/03; LOQ = 0.01 mg/kg Acceptable procedural recovery data provided in the report. Max. storage = 183 days (6 months) Test product = Amistar 250 SC (250 g/L Azoxystrobin)

Trial No./ Location/ EU zone/ Year (a)	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 (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Azoxystrobin	R230310		
Trial 3 S16-03842 S16-03842-03 Spain (Europe South) (50374, Aragon)	Barley / Unia	1.18 Jan 2016 2 – 3 –	240	289		14 Jun 2016	(Control) (Control) (Control) BBCH 59 BBCH 59 BBCH 59 BBCH 59 BBCH 59 BBCH 59	Whole Plant Grain Straw Whole Plant Whole Plant Whole Plant Whole Plant Grain Straw	< 0.01 < 0.01 < 0.01 4.36 1.37 2.81 6.26 0.13 2.58	< 0.01 < 0.01 < 0.01 < 0.01 0.02 0.08 0.74 0.02 0.24	0 38 38 0 6 14 31 38 38	Acceptable. Report: S16-03842 Methods: Azoxystrobin (Grain, Straw, Whole plant) RAM 305/03; LOQ = 0.01 mg/kg R230310 (Grain, Straw, Whole plant) RAM 305/03; LOQ = 0.01 mg/kg Acceptable procedural recovery data provided in the report. Max. storage = 183 days (6 months) Test product = Amistar 250 SC (250 g/L Azoxystrobin)

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Azoxystrobin	R230310		
	(a)	(b)				(c)					(d)	(e)
Trial 4 S16-03842 S16-03842-04 Italy (Europe South) (40068, Emilia Romagna)	Barley / Sidney	1.20 Feb 2016 2 – 3 –	266	321		27 May 2016	(Control) (Control) (Control) BBCH 59 BBCH 59 BBCH 59 BBCH 59 BBCH 59 BBCH 59	Whole Plant Straw Grain Whole Plant Whole Plant Whole Plant Whole Plant Straw Grain	< 0.01 < 0.01 < 0.01 6.18 2.79 2.62 1.34 1.21 0.06	< 0.01 < 0.01 < 0.01 < 0.01 0.03 < 0.01 0.04 0.10 < 0.01	0 45 45 0 7 13 28 45 45	Acceptable. Report: S16-03842 Methods: Azoxystrobin (Grain, Straw, Whole plant) RAM 305/03; LOQ = 0.01 mg/kg R230310 (Grain, Straw, Whole plant) RAM 305/03; LOQ = 0.01 mg/kg Acceptable procedural recovery data provided in the report. Max. storage = 183 days (6 months) Test product = Amistar 250 SC (250 g/L Azoxystrobin)

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

Study 5 - Ziske 2020, IF19-04928660, VV-870172 - Southern Europe (new data)

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

Reference: KCP 8.3.2/05

Report: Azoxystrobin – Residue Study on Spring Barley in Spain, Greece and Italy in 2019; Ziske J. and Link T., 2020; Report No IF19-04928660; Document No VV-870172

Guideline(s):

- Guidelines for the Generation of Data concerning Residues as provided in Annex II part A, section 6 and Annex III, part A, section 8 of Directive 91/414/EEC concerning the placing of plant protection products on the market (EU) 1607/VI/97 (1999).
- Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and91/414/EEC.
- EC (1997) Guidance Document 7029/VI/95 rev. 5 general recommendations for the design, preparation and realization of residue trials
- OECD (2009). Guidance Document on Overview of Residue Chemistry Studies (as revised2009), Series on Testing and Assessment No. 64 and Series on Pesticides No. 32, ENV/JM/MONO(2009)31.
- OECD Guidance Document on Crop Field Trials, Series on Pesticides No. 66 and Series on Testing and Assessment No. 164, ENV/JM/MONO(2011)50.
- OECD – Guideline for the Testing of Chemicals, Test Guideline 509; Crop field trial,07/09/2009
- European Commission Guidance for Generating and Reporting Methods of Analysis in Support of Pre-registration Requirements for Annex II (Part A, Section 4) of Directive 91/414, SANCO/3029/99 revision 4 (11 Jul 2000).
- OECD Series on Principles of GLP and Compliance Monitoring No. 1 (as revised in 1997)
- "OECD Principles on Good Laboratory Practice", Paris 1998. ENV/MC/CHEM (98)17 and respective national regulations.
- The Application of the OECD Principles of GLP to the Organisation and Management of Multi-Site Studies, ENV/JM/MONO (2002) 9.
- OECD GLP ENV/JM/MONO (99) 22.
- - The national requirements are based on the OECD Principles of Good Laboratory Practice, which are accepted by regulatory authorities throughout the European Community, the United States of America (FDA and EPA) and Japan (MHW, MAFF and METI) on the basis of intergovernmental agreements.

Deviations: None

GLP: Yes, conducted under GLP/Officially recognised testing facilities

Acceptability: Yes

Summary of the study 5 trials – IF19-04928660

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Azoxystrobin	R230310		
Trial 1 IF19-04928660 19-00299-01 Spain (Europe South)	Spring barley / Hispanic	1.30 Nov 2018 2 – 3 –	255	255		03 May 2019	(Control) (Control) BBCH 59 BBCH 59	Straw Grain Grain Straw	< 0.01 < 0.01 0.05 6.7	< 0.01 < 0.01 < 0.01 0.87	67 67 67 67	Acceptable. Report: IF19-04928660 Methods: Azoxystrobin (Grain, Straw, Whole plant) RAM 305/03; LOQ = 0.01 mg/kg R230310 (Grain, Straw, Whole plant) RAM 305/03; LOQ = 0.01 mg/kg Acceptable procedural recovery data provided in the report. Max. storage = 244 days (8 months) Test product = Amistar 250 SC (250 g/L Azoxystrobin)

Trial No./ Location/ EU zone/ Year (a)	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 (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Azoxystrobin	R230310		
Trial 2 IF19-04928660 19-00299-02 Greece (Europe South) (53072, Dytiki Makedonia)	Spring barley / Prestige	1.20 Feb 2019 2 – 3 –	257	205		23 May 2019	(Control) (Control) BBCH 59 BBCH 59	Grain Straw Grain Straw	< 0.01 < 0.01 < 0.01 0.20	< 0.01 < 0.01 < 0.01 0.02	60 60 60 60	Acceptable. Report: IF19-04928660 Methods: Azoxystrobin (Grain, Straw, Whole plant) RAM 305/03; LOQ = 0.01 mg/kg R230310 (Grain, Straw, Whole plant) RAM 305/03; LOQ = 0.01 mg/kg Acceptable procedural recovery data provided in the report. Max. storage = 244 days (8 months) Test product = Amistar 250 SC (250 g/L Azoxystrobin)

Trial No./ Location/ EU zone/ Year (a)	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 (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Azoxystrobin	R230310		
Trial 3 IF19-04928660 19-00299-03 Italy (Europe South) (13040, Piemonte)	Spring barley / Tunika	1.11 Feb 2019 2 – 3 –	253	304		22 May 2019	(Control) (Control) (Control) BBCH 59 BBCH 59	Whole plant Straw Grain Grain Straw	< 0.01 < 0.01 < 0.01 0.01 0.28	< 0.01 < 0.01 < 0.01 < 0.01 0.02	0 44 44 44 44	Acceptable. Report: IF19-04928660 Methods: Azoxystrobin (Grain, Straw, Whole plant) RAM 305/03; LOQ = 0.01 mg/kg R230310 (Grain, Straw, Whole plant) RAM 305/03; LOQ = 0.01 mg/kg Acceptable procedural recovery data provided in the report. Max. storage = 244 days (8 months) Test product = Amistar 250 SC (250 g/L Azoxystrobin)

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Azoxystrobin	R230310		
	(a)	(b)				(c)					(d)	(e)
Trial 4 IF19-04928660 19-00299-04 Italy (Europe South) (20062, Lombardia)	Spring barley / Sydney	1.03 Feb 2019 2 – 3 –	247	298		21 May 2019	(Control) (Control) (Control) BBCH 59 BBCH 59	Whole plant Straw Grain Grain Straw	< 0.01 < 0.01 < 0.01 0.02 0.27	< 0.01 < 0.01 < 0.01 < 0.01 0.02	0 44 44 44 44	Acceptable. Report: IF19-04928660 Methods: Azoxystrobin (Grain, Straw, Whole plant) RAM 305/03; LOQ = 0.01 mg/kg R230310 (Grain, Straw, Whole plant) RAM 305/03; LOQ = 0.01 mg/kg Acceptable procedural recovery data provided in the report. Max. storage = 244 days (8 months) Test product = Amistar 250 SC (250 g/L Azoxystrobin)

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

A 2.1.3.3 Oilseed rape (OSR)

Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (DAR, RMS, year)	Not considered within the representative GAP in the DAR or RAR for azoxystrobin.				
cGAP EU (Art. 12, EFSA, 2013)	2	200 g a.i. / ha	Not stated	Not stated	21
Intended cGAP (numbers 7, 8)	1	1 L product per ha (160 g azoxystrobin per ha)	Not applicable	BBCH 73	35 (GSR)

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0
** Timing of applications determined primarily by growth stage; 1st application not later than BBCH 39, 2nd application no later than BBCH 59.
GSR: Growth Stage Restricted

The following table provides a summary of the available data from studies S23-102956 and S23-102957:

Analyte	Residue trials zone	Residues (mg/kg)	STMR (mg/kg)	HR (mg/kg)
Azoxystrobin	North EU	S23-102956 (whole plant): 0.13, 1.3, 0.078, 0.041, 0.18, 0.82, 0.50, <0.01 S23-102956 (seed): <0.01, 0.015, <0.01, <0.01, 0.02, <0.01, 0.03, <0.01	Whole plant = 0.155 Seed = 0.01	Whole plant = 1.3 Seed = 0.03
	~~South EU~~	~~S23-102957 (whole plant): 0.062, 0.079, 0.15, 0.02, 0.046, 0.050, 1.6*~~ ~~S23-102957 (seed): 0.017, 0.018, 0.033, <0.01, 0.010, 0.035, 0.38*~~	~~Whole plant = 0.056~~ ~~Seed = 0.018~~	~~Whole plant = 0.15~~ ~~Seed = 0.035~~
z-Azoxystrobin	North EU	S23-102956 (whole plant): 0.014, 0.075, <0.01, <0.01, 0.014, 0.13, 0.027, 0.01 S23-102956 (seed): <0.01, <0.01, <0.01, <0.01, <0.01, <0.01, <0.01, 0.01	Whole plant = 0.014 Seed = <0.01	Whole plant = 0.13 Seed = 0.01
	~~South EU~~	~~S23-102957 (whole plant): <0.01, <0.01, 0.018, <0.01, <0.01, <0.01, 0.14*~~ ~~S23-102957 (seed): <0.01, <0.01, <0.01, <0.01, <0.01, <0.01, <0.01, 0.039*~~	~~Whole plant = <0.01~~ ~~Seed = <0.01~~	~~Whole plant = 0.018~~ ~~Seed = 0.01~~

* Values deemed to be an outlier by statistical analysis and was not included in the calculation of the endpoints.

A total of eight trials are available for the Northern trials zone, while seven trials are available for the Southern trials zone (six trials, once the outlier has been discounted). While for the Southern zone this is fewer than the usual number of trials required for a major commodity, it is considered that these results are sufficient in the interim to provide an assessment of the consumer risk, based on the intended uses for FGF11. For the long term (to confirm the outcome of the assessment), supplementary residue trials data are being generated – the completed study report is expected during Q1 of 2025.

Study 1 North 2024, S23-102957 - Southern Europe (new data)

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

Reference:	KCP 8.3.3/01
Report	Determination of residues of Azoxystrobin after two applications of FFC03 in Oilseed rape at 7 sites in Southern Europe 2023; North, L., Report No. 2024; S23-102957
Guideline(s):	• OECD (2009) Guidance Document on Overview of Residue Chemistry Studies (Series on Testing and Assessment No. 64 and

Series on Pesticides No. 32)
- OECD Test Guideline 509: Crop field trials
- OECD (2016) Guidance Document ENV/JM/MONO(2011)50/REV1 , Second Edition, on Crop Field Trials (Series on Testing and Assessment No. 164 and Series on Pesticides No. 66)
- EC (1997) Guidance Document 7029/VI/95 rev. 5 general recommendations for the design, preparation and realization of residue trials
- SANTE/2019/12752 Technical Guidelines on Data Requirements for Setting Maximum Residue Levels, Comparability of Residue Trial and Extrapolation of Residue Data on Products from Plant and Animal Origin (Repealing and replacing the existing Guidance Document SANCO 7525/VI/95 Rev. 10.3)
- OECD Test Guideline 508: Magnitude of the pesticide residues in processed commodities
- OECD (2008) Guidance Document on magnitude of pesticide residues in processed commodities (Series on Testing and Assessment No. 96)
- 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)
- OECD (2007) Guidance Document on Pesticide Residue Analytical Methods (Series on Testing and Assessment No. 72 and Series on Pesticides No. 39)

Deviations:
- S23-102957-03: S2 sampling was performed 30DAA2 instead of 28DAA2 requested in the study plan. This was due to unfavourable weather conditions. No impact expected on the study.
- The distance between trial sites S23-102957-02 and S23-102957-08 was 15.5 km. This was due to the severe drought in Northern Spain during this season, the area of crops in good condition was reduced. Different soil type and drilling dates were used. No impact is expected.

GLP: Yes

Acceptability: Yes

Summary of the study 1 trials (S23-102957)

Trial No./ Location/ EU zone/ Year (a)	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 (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Azoxystrobin	z-Azoxystrobin		
Trial 1 S23-102957-01 40057, Granarolo dell Emilia, Bologna, Italy (Southern Europe) 2023	Oilseed rape / Diffusion	1) 10 Oct 2022 2) 15 Apr 2023 to 02 May 2023 3) 15 Jun 2023	161 162	302 303	53 53	04 May 2023 18 May 2023	(Control) (Control) BBCH 75 BBCH 75	Whole plant Seed Whole plant Seed	<LOD <LOD 0.062 0.017	<LOD <LOD <LOD <LOD	0 28 0 28	Acceptable. Report: S23-102957 Methods: Azoxystrobin + z-Azoxystrobin (OSR – whole plant and seed) S23-105890; LOQ = 0.01 mg/kg LOD = 0.003 mg/kg Acceptable procedural recovery data provided in the report. Max. storage = 165 days Test product = FFC03 (SC, 250 g/L Azoxystrobin)

Trial No./ Location/ EU zone/ Year (a)	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 (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Azoxystrobin	z-Azoxystrobin		
Trial 2 S23-102957-02 44492, Lagueruela, Araegon, Spain (Southern Europe) 2023	Oilseed rape / Click CL	1) 10 Feb 2023 2) Not applicable 3) 14 Jul 2023	158 166	296 311	53 53	02 Jun 2023 16 Jun 2023	(Control) (Control) BBCH 73-75 BBCH 73-75	Whole plant Seed Whole plant Seed	<LOD <LOD 0.079 0.018	<LOD <LOD <LOQ <LOD	0 28 0 28	Acceptable. Report: S23-102957 Methods: Azoxystrobin + z-Azoxystrobin (OSR – whole plant and seed) S23-105890; LOQ = 0.01 mg/kg LOD = 0.003 mg/kg Acceptable procedural recovery data provided in the report. Max. storage = 165 days Test product = FFC03 (SC, 250 g/L Azoxystrobin)
Trial 3 S23-102957-03 (82290, la Ville Dieu Du Temple, Tarn et Garonne, France (Southern Europe) 2023	Oilseed rape / DK Expacito	1) 15 Sep 2022 2) Not available 3) 23 Jun 2023	165 162	206 202	80 80	10 May 2023 24 May 2023	(Control) (Control) BBCH 79 BBCH 79	Whole plant Seed Whole plant Seed	<LOD <LOD 0.15 0.033	<LOD <LOD 0.018 <LOQ	0 30 0 30	Acceptable. Report: S23-102957 Methods: Azoxystrobin + z-Azoxystrobin (OSR – whole plant and seed) S23-105890; LOQ = 0.01 mg/kg LOD = 0.003 mg/kg Acceptable procedural recovery data provided in the report. Max. storage = 165 days Test product = FFC03 (SC, 250 g/L Azoxystrobin)

Trial No./ Location/ EU zone/ Year (a)	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 (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Azoxystrobin	z-Azoxystrobin		
Trial 4 S23-102957-04 2068 Polyantsi, Sofia, Bulgaria (Southern Europe) 2023	Oilseed rape / DK Immortal CL	1) 30 Oct 2022 2) 01 May 2023 to 02 Jun 2023 3) 21 Jul 2023	156 162	341 354	46 46	09 Jun 2023 23 Jun 2023	(Control) (Control) BBCH 79 BBCH 79	Whole plant Seed Whole plant Seed	<LOD <LOD 0.020 <LOQ	<LOD <LOD <LOD <LOD	0 28 0 28	Acceptable. Report: S23-102957 Methods: Azoxystrobin + z-Azoxystrobin (OSR – whole plant and seed) S23-105890; LOQ = 0.01 mg/kg LOD = 0.003 mg/kg Acceptable procedural recovery data provided in the report. Max. storage = 165 days Test product = FFC03 (SC, 250 g/L Azoxystrobin)

Trial No./ Location/ EU zone/ Year (a)	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 (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Azoxystrobin	z-Azoxystrobin		
Trial 5 S23-102957-05 GR-57200, Drgmos, Thessaloniki, Greece (Southern Europe) 2023	Oilseed rape / Puncher	1) 03 Nov 2022 2) 05 Apr 2023 to 19 May 2023 3) 29 Jun 2023	161 174	403 435	40 40	18 May 2023 01 Jun 2023	(Control) (Control) BBCH 75-77 BBCH 75-77	Whole plant Seed Whole plant Seed	<LOD <LOD 0.046 0.010	<LOD <LOD <LOQ <LOD	0 28 0 28	Acceptable. Report: S23-102957 Methods: Azoxystrobin + z-Azoxystrobin (OSR – whole plant and seed) S23-105890; LOQ = 0.01 mg/kg LOD = 0.003 mg/kg Acceptable procedural recovery data provided in the report. Max. storage = 165 days Test product = FFC03 (SC, 250 g/L Azoxystrobin)
Trial 6 S23-102957-07 48017, Conselice, Ravenna, Italy (Southern Europe) 2023	Oilseed rape / Dariot	1) 08 Oct 2022 2) 18 Apr 2023 to 15 May 2023 3) 22 Jun 2023	164 160	307 300	53 53	11 May 2023 25 May 2023	(Control) (Control) BBCH 76 BBCH 76	Whole plant Seed Whole plant Seed	<LOD <LOD 0.050 0.035	<LOD <LOD <LOD <LOD	0 28 0 28	Acceptable. Report: S23-102957 Methods: Azoxystrobin + z-Azoxystrobin (OSR – whole plant and seed) S23-105890; LOQ = 0.01 mg/kg LOD = 0.003 mg/kg Acceptable procedural recovery data provided in the report. Max. storage = 165 days Test product = FFC03 (SC, 250 g/L Azoxystrobin)

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Azoxystrobin	z-Azoxystrobin		
Trial 7 44492, Allueva, Aragon, Spain (Southern Europe) 2023	Oilseed rape / Click CL	1) 20 Feb 2023 2) Not applicable 3) 15 Aug 2023	164 156	307 293	53 53	04 Jul 2023 18 Jul 2023	(Control) (Control) BBCH 79 BBCH 79	Whole plant Seed Whole plant Seed	<LOD <LOD 1.6 0.38	<LOD <LOD 0.14 0.039	0 28 0 28	Acceptable. Report: S23-102957 Methods: Azoxystrobin + z-Azoxystrobin (OSR – whole plant and seed) S23-105890; LOQ = 0.01 mg/kg LOD = 0.003 mg/kg Acceptable procedural recovery data provided in the report. Max. storage = 165 days Test product = FFC03 (SC, 250 g/L Azoxystrobin)

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

Study 2 North 2024, S23-102956 - Northern Europe (new data)

Comments of zRMS:	Eight residue trials were conducted on oilseed rape during 2023, two in Germany (S23-102956-01 and S23-102956-07), one in Northern France (S23-102956-02), one in the UK (S23-102956-03), one in Hungary (S23-102956-04), one in Poland (S23-102956-05), one in Austria (S23-102956-06) and one in Romania (S23-102956-08). At all trials, plot 2, two applications of FFC03 (250 g/L, azoxystrobin) were applied at 160 g ai/ha, 42 and 28 days before harvest. Samples of oilseed rape from the untreated and treated plots were taken by hand just before and 25-36 days after the final application (NCH). The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for each matrix and analyte. Max. study storage interval between sampling and extraction for azoxystrobin was 157 days. The study on the magnitude of residues is valid with regard to storage stability. <u>Results:</u> Residues of azoxystrobin in whole plant: <0.01; 0.041; 0.078; 0.13; 0.18; 0.50; 0.82; 1.3 mg/kg Residues of azoxystrobin in seed: <LOD (0.003), 4x<0.01; 0.015; 0.02; 0.03 mg/kg. The study is acceptable.

Reference:	KCP 8.3.3/01
Report	Determination of residues of Azoxystrobin after two applications of FFC03 in Oilseed rape and its processed fractions at 8 sites in Northern Europe 2023; North, L., Report No. 2024; S23-102956
Guideline(s):	• OECD (2009) Guidance Document on Overview of Residue Chemistry Studies (Series on Testing and Assessment No. 64 and Series on Pesticides No. 32) • OECD Test Guideline 509: Crop field trials • OECD (2016) Guidance Document ENV/JM/MONO(2011)50/REV1 , Second Edition, on Crop Field Trials (Series on Testing and Assessment No. 164 and Series on Pesticides No. 66) • EC (1997) Guidance Document 7029/VI/95 rev. 5 general recommendations for the design, preparation and realization of residue trials • SANTE/2019/12752 Technical Guidelines on Data Requirements for Setting Maximum Residue Levels, Comparability of Residue Trial and Extrapolation of Residue Data on Products from Plant and Animal Origin (Repealing and replacing the existing Guidance Document SANCO 7525/VI/95 Rev. 10.3) • OECD Test Guideline 508: Magnitude of the pesticide residues in processed commodities • OECD (2008) Guidance Document on magnitude of pesticide residues in processed commodities (Series on Testing and Assessment No. 96) • 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) • OECD (2007) Guidance Document on Pesticide Residue Analytical Methods (Series on Testing and Assessment No. 72 and Series on Pesticides No. 39)

Deviations:	• Application A2 was performed 16DAA1 instead of 14DAA1 as requested in the Study Plan. This was due to unfavorable weather conditions. No impact is expected as A2 was applied 27 days before harvest. • S23-102956-01: During the shipment temperatures were above -18°C for 46h30min, with a maximum temperature of -14°C and an average of -16°C. Specimens affected were -001A and -002A. Specimens arrived at the laboratory in a good and deep-frozen condition according to the chain of custody. No impact is expected as samples arrived in a good and frozen condition.
GLP:	Yes
Acceptability:	Yes

Summary of the study 2 trials (S23-102956)

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Azoxystrobin	z-Azoxystrobin		
	(a)	(b)				(c)					(d)	(e)
Trial 1 S23-102956-01 21732 Krummendeich, Niedersachsen, Germany (Northern Europe) 2023	Oilseed rape / DK Exception	1) 25 Aug 2022 2) 15 Apr 2023 to 20 May 2023 3) 10 Aug 2023	162 160	353 349	46 46	28 Jun 2023 14 Jul 2023	(Control) (Control) BBCH 88 BBCH 88	Whole plant Seed Whole plant Seed	<LOD <LOD 0.13 <LOD	<LOD <LOD 0.014 <LOD	0 28 0 28	Report: S23-102956 Methods: Azoxystrobin + z-Azoxystrobin (OSR – whole plant and seed) S23-105890; LOQ = 0.01 mg/kg LOD = 0.003 mg/kg Acceptable procedural recovery data provided in the report. Max. storage = 157 days Test product = FFC03 (SC, 250 g/L Azoxystrobin)
Trial 2 S23-102956-02 67860, Boofzheim, Bas-Rhuin, Alsace, France (Northern Europe) 2023	Oilseed rape / DK Exception	1) 24 Aug 2022 2) 10 Apr 2023 to 10 May 2023 3) 03 Jul 2023	163 175	229 246	71 71	22 May 2023 05 Jun 2023	(Control) (Control) BBCH 79 BBCH 79	Whole plant Seed Whole plant Seed	<LOD <LOD 1.3 0.015	<LOD <LOD 0.075 <LOD	28 28 28 28	Report: S23-102956 Methods: Azoxystrobin + z-Azoxystrobin (OSR – whole plant and seed) S23-105890; LOQ = 0.01 mg/kg LOD = 0.003 mg/kg Acceptable procedural recovery data provided in the report. Max. storage = 157 days Test product = FFC03 (SC, 250 g/L Azoxystrobin)

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Azoxystrobin	z-Azoxystrobin		
	(a)	(b)				(c)					(d)	(e)
Trial 3 S23-102956-03 L39 9EN, Bickerstaffe, Lancashire, United Kingdom (Northern Europe) 2023	Oilseed rape / Ramses	1) 23 Aug 2022 2) Not applicable 3) 20 Jul 2023	164 167	307 314	53 53	05 Jun 2023 19 Jun 2023	(Control) (Control) BBCH 75 BBCH 75	Whole plant Seed Whole plant Seed	<LOD <LOD 0.078 <LOQ	<LOD <LOD <LOQ <LOD	31 31 31 31	Report: S23-102956 Methods: Azoxystrobin + z-Azoxystrobin (OSR – whole plant and seed) S23-105890; LOQ = 0.01 mg/kg LOD = 0.003 mg/kg Acceptable procedural recovery data provided in the report. Max. storage = 157 days Test product = FFC03 (SC, 250 g/L Azoxystrobin)
Trial 4 S23-102956-04 H-8248 Nemesvámos, Veszprèm, Hungary (Northern Europe) 2023	Oilseed rape / PX 131	1) 05 Oct 2022 2) Apr 2023 to May 2023 3) 14 Jul 2023	156 174	341 381	46 46	05 Jun 2023 19 Jun 2023	(Control) (Control) BBCH 80 BBCH 80	Whole plant Seed Whole plant Seed	<LOD <LOD 0.041 <LOQ	<LOD <LOD <LOD <LOD	25 25 25 25	Report: S23-102956 Methods: Azoxystrobin + z-Azoxystrobin (OSR – whole plant and seed) S23-105890; LOQ = 0.01 mg/kg LOD = 0.003 mg/kg Acceptable procedural recovery data provided in the report. Max. storage = 157 days Test product = FFC03 (SC, 250 g/L Azoxystrobin)

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Azoxystrobin	z-Azoxystrobin		
	(a)	(b)				(c)					(d)	(e)
Trial 5 S23-102956-05 64-520, Obrzycko, Wielkopolskie, Poland (Northern Europe) 2023	Oilseed rape / Kuga F1	1) 28 Aug 2022 2) Not applicable 3) 24 Jul 2023	159 179	199 223	80 80	12 Jun 2023 26 Jun 2023	(Control) (Control) BBCH 80 BBCH 80	Whole plant Seed Whole plant Seed	<LOD <LOD 0.18 0.020	<LOD <LOD 0.014 <LOD	28 28 28 28	Report: S23-102956 Methods: Azoxystrobin + z-Azoxystrobin (OSR – whole plant and seed) S23-105890; LOQ = 0.01 mg/kg LOD = 0.003 mg/kg Acceptable procedural recovery data provided in the report. Max. storage = 157 days Test product = FFC03 (SC, 250 g/L Azoxystrobin)
Trial 6 S23-102956-06 8181, Wollsdorf, Styria, Austria (Northern Europe) 2023	Oilseed rape / DK Exmore	1) 07 Sep 2022 2) Mid Apr to mid-May 2023 3) 10 Aug 2023	169 160	423 401	40 40	30 Jun 2023 14 Jul 2023	(Control) (Control) BBCH 85-87 BBCH 85-87	Whole plant Seed Whole plant Seed	<LOD <LOD 0.82 <LOQ	<LOD <LOD 0.13 <LOD	26 26 26 26	Report: S23-102956 Methods: Azoxystrobin + z-Azoxystrobin (OSR – whole plant and seed) S23-105890; LOQ = 0.01 mg/kg LOD = 0.003 mg/kg Acceptable procedural recovery data provided in the report. Max. storage = 157 days Test product = FFC03 (SC, 250 g/L Azoxystrobin)

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Azoxystrobin	z-Azoxystrobin		
	(a)	(b)				(c)					(d)	(e)
Trial 7 S23-102956-07 16321, Bernau, Brandenburg, Germany (Northern Europe) 2023	Oilseed rape / PT303	1) 28 Aug 2022 2) 24 Apr 2023 to 22 May 2023 3) 20 Jul 2023	170 175	319 328	53 53	31 May 2023 14 Jun 2023	(Control) (Control) BBCH 79 BBCH 79	Whole plant Seed Whole plant Seed	<LOD <LOD 0.50 0.030	<LOD <LOD 0.027 <LOQ	36 36 36 36	Report: S23-102956 Methods: Azoxystrobin + z-Azoxystrobin (OSR – whole plant and seed) S23-105890; LOQ = 0.01 mg/kg LOD = 0.003 mg/kg Acceptable procedural recovery data provided in the report. Max. storage = 157 days Test product = FFC03 (SC, 250 g/L Azoxystrobin)
Trial 8 S23-102956-08 307347, Stanciova, Timiș, Romania (Northern Europe) 2023	Oilseed rape / SY Floretta	1) 08 Oct 2022 2) Not available 3) 12 Jul 2023	165 161	309 403	53 40	31 May 2023 14 Jun 2023	(Control) (Control) BBCH 82 BBCH 82	Whole plant Seed Whole plant Seed	<LOD <LOD <LOD <LOQ	<LOD <LOD <LOD <LOQ	28 28 28 28	Report: S23-102956 Methods: Azoxystrobin + z-Azoxystrobin (OSR – whole plant and seed) S23-105890; LOQ = 0.01 mg/kg LOD = 0.003 mg/kg Acceptable procedural recovery data provided in the report. Max. storage = 157 days Test product = FFC03 (SC, 250 g/L Azoxystrobin)

(a) According to CODEX Classification / Guide
(b) Only if relevant

(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

A 2.1.4 Magnitude of residues in livestock

A 2.1.4.1 Livestock feeding studies

A 2.1.4.1.1 Livestock feeding study 1

No new data provided for this endpoint.

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 data provided for this endpoint.

A 2.1.5.2 Processing studies on a core set of representative processes

No new data provided for this endpoint.

A 2.1.6 Magnitude of residues in representative succeeding crops

No new data provided for this endpoint.

A 2.1.7 Other/Special Studies

No new data provided for this endpoint.

A 2.2 Prothioconazole

A 2.2.1 Stability of residues

A 2.2.1.1 Stability of residues during storage of samples

A 2.2.1.1.1 Storage stability of residues in plant products

A 2.2.1.1.1.1 Study 1

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

Reference:	KCP 8.1-0.3
Report	Prothioconazole-desthio and 5 hydroxy metabolites: Frozen Storage Stability in crops. Giancola, D., Martin, J., 2024. Report No.: QG/21/001
Guideline(s):	Yes (OECD 506, ENV/JM/MONO(2009)31, SANTE/2020/12830)
Deviations:	No (minor deviations without impact on the study) Deviations from study plan: 1. Test item Prothioconazole-α-hydroxy-desthio batch number 4276-094A18 was used from 26th September onwards. No impact as test item deemed fit for use within study. 2. Samples for field beans matrix due for analysis at 6 months ± 14 days were analysed on the 24th of May (for Prothioconazole-3-hydroxy-desthio, Prothioconazole-4-hydroxy-desthio, Prothioconazole-5-hydroxy-desthio, Prothioconazole-6-hydroxy-desthio) and on the 6th of June (for

	Prothioconazole-α-hydroxy-desthio).Therefore, samples for field beans matrix were analysed at 7 months ± 14 instead of 6 months. No impact on the study as all the other timepoints will be carried out as per study plan. 3. The following test items were used that had the same batch number as stated in the study plan, but differing purities and expiry dates: Prothioconazole-3-hydroxy-desthiowith a purity of 99.6% and expiration date of 23 June 2025; Prothioconazole-4-hydroxy-desthio with a purity of 99.6% and expiration date of 23 June 2025, and Prothioconazole-6-hydroxy-desthio with a purity of 98.0% and expiration date of 23 June 2025. No impact on the study as concentrations of solutions and standards used in the study amened accordingly to the test item purity used. 4. In each batch from 1 to 63 a reagent blank, consisting of ACN: H2O 80:20 v/v was analysed alongside control blank, recovery sample and stability samples. No impact as the RB was analysed to check any contamination from the extraction solvent used. 5. GMS 2995 and std 705 onward, were prepared using Prothioconazole-5-hydroxy-desthio batch number 3922-021A4 expiring on 23 June 2025. No impact as the correct test item with the updated expiry date was used. 6. Calculations to generate final result spreadsheets differed from the calculations reported in the Study Plan. No impact as correct calculation used. No impact as correct calculation used. These deviations have been collectively assessed to have no impact on the study. 7. Procedural recoveries below 70% were accepted for Prothioconazole-α-hydroxy-desthio in batch 48RB, 69RB and 86RD; for Prothioconazole-3-hydroxy-desthio in batch 86RC; for Prothioconazole-5-hydroxy-desthio in batch 32RB and 71RD; for Prothioconazole-6-hydroxy-desthio in batch 56RC. No impact as these data were accepted to allow the comparison with the stability sample data and correctly evaluate a possible residue decline for the analyte.
GLP:	Yes
Acceptability:	Yes

Materials and methods

Samples of orange, field bean (dried) and oilseed rape seed were individually fortified with prothioconazole-desthio and its 5 hydroxy metabolites at a concentration of 0.05 mg/kg (10x LOQ) and stored at nominal temperature of -18°C. Duplicate stability samples were analysed. Samples of wheat (grain, forage and straw) were individually fortified with prothioconazole 5 hydroxy metabolites at a concentration of 0.05 mg/kg (10x LOQ) and stored at nominal temperature of -18°C. Duplicate stability samples were analysed. Wheat (grain, forage and straw), orange, field bean (dried) and oilseed rape seed samples were analysed at 0, 1, 3, 6, 12, 18 and 24 months. The 6-month timepoint was analysed for prothioconazole-desthio (5) hydroxy metabolites in field bean (dried) at 7 months. Additional samples of prothioconazole-6-hydroxy-desthio in wheat grain were analysed at 8 months. For each matrix and each interval, 2 fortified stability samples per analyte and per matrix were weighed along with 2 procedural recovery samples fortified on the day of extraction (at 10x LOQ). For each interval, 1 control sample and 1 reagent blank were also analysed. For each matrix, two additional sets of fortified stability samples were fortified at the start of the study.

Two methods of analysis were used for prothioconazole-desthio and its 5 hydroxy metabolites. Residues of prothioconazole-desthio were extracted from oilseed rape seed, field bean (dried) and orange by dissolving the samples in water and then extracting the analyte with acetonitrile using QuEChERS kits. A portion of the final extract was then taken through the SPE clean-up and then diluted with water 2:3 v/v for final determination by liquid chromatography with tandem mass spectrometry (LC-MS/MS). One ion mass transition (quantitation transition) was monitored for stability samples.

Residues of prothioconazole-desthio and its 5 hydroxy metabolites were extracted from oilseed rape seed, field beans (dried) and orange by shaking in acetonitrile: water (80:20 v/v) followed by filtration through Whatman filter paper. Residues of prothioconazole-desthio and its 5 hydroxy metabolites were extracted from wheat

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

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

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

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

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

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

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

Table A 1: Stability of prothioconazole-α-hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio and prothioconazole-6-hydroxy-desthio in wheat forage following storage at ≤-18°C.

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

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

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

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

n/a: analyte not investigated

Table A 2: Stability of prothioconazole-desthio, prothioconazole-α-hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio and prothioconazole-6-hydroxy-desthio in oilseed rape (seed) following storage at ≤-18°C.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

n/a: analyte not investigated

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

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

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

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

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

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

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

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

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

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Comments of zRMS:

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

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

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

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

Triazole alanine stability results in oilseed rape (seed)

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

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

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

Triazole alanine stability results in field bean (dried)

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

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

Triazole alanine stability results in wheat grain

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

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

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

1,2,4-Triazole stability results in orange

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

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

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

Reference:	KCP 8.1/04
Report	Triazole Derived Metabolites: Frozen Storage Stability in Crops for 12 Months; Baxter, B. Phipps, 2025; Study No.: QG/21/002
Guideline(s):	• OECD 506 Stability of Pesticide Residues in Stored Commodities • OECD, ENV/JM/MONO(2009)31 Series on Testing and Assessment Number 64 and Series on Pesticides Number 32. Guidance Document on Overview of Residue Chemistry Studies, 28 July 2009 • SANTE/2020/12830, rev.1 Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes, 24 February 2021
Deviations:	Several minor deviations from the internal and field protocols were noted, but none of these deviations impact the validity of the study results.
GLP:	Yes
Acceptability:	Yes

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

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

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

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

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

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

Results

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

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

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

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

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

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

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

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

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

			2	0.05	63.3	0.0316				

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

			2	0.200	90.4	0.181				

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

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

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

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

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

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

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

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

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

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

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

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

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

			2	0.100	86.4	0.0864		0.0770	77.0				

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

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

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

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

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

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

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

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

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

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

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

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

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

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

recovery (%) x 100

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

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

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

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

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

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

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

A 2.2.1.1.1.3 Study 3 - Jooß, S., 2025, Report No.: S23-105428

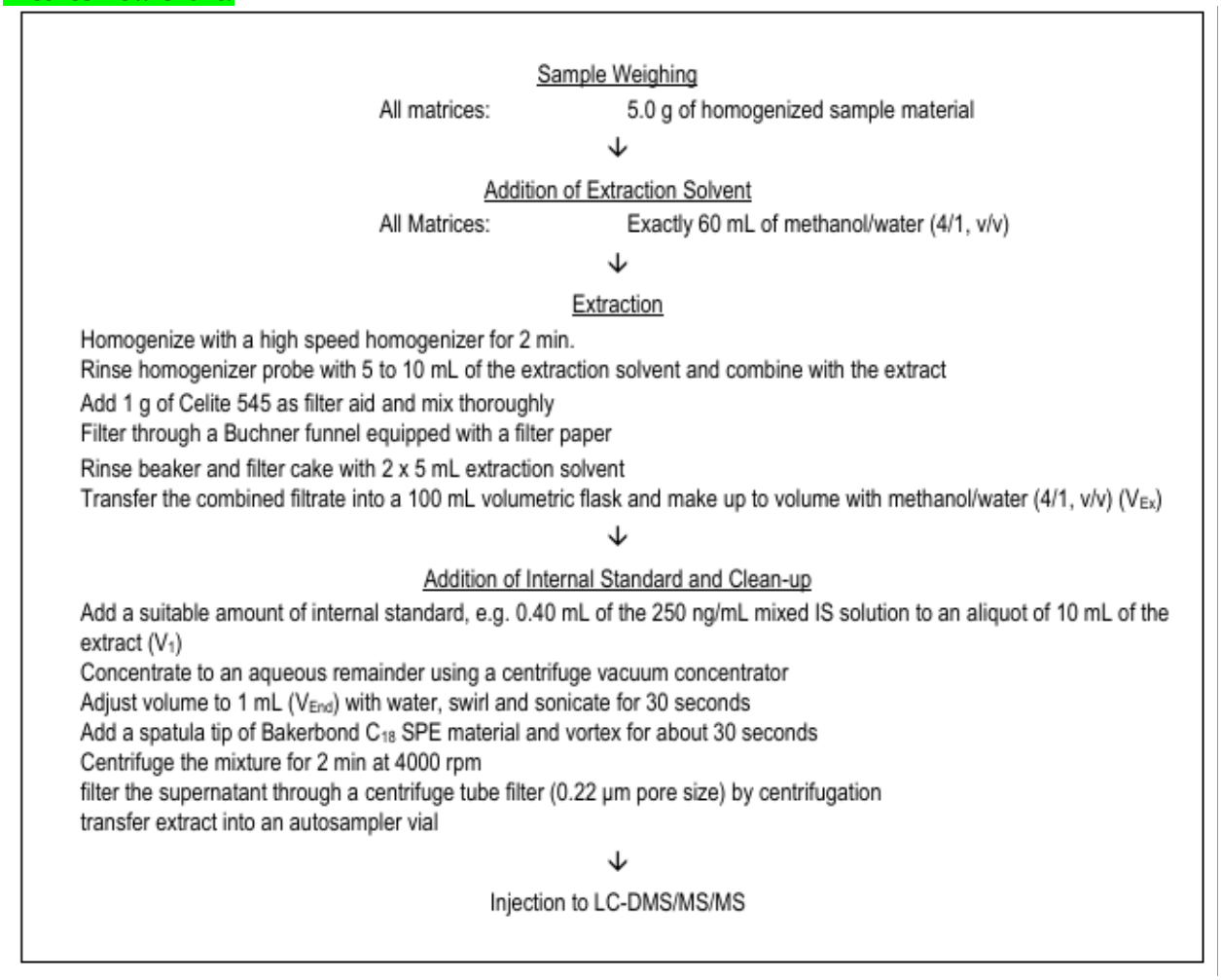
Comments of zRMS:	Residues of triazole derivative metabolites (TDMs): 1,2,4-triazole, triazole alanine, triazole acetic acid and triazole lactic acid are considered to be stable in cereal (grain) and in oilseed rape (seeds) when stored frozen (<-18°C) for 12 months and 90 days, respectively, since no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

Reference:	KCP 8.1/05
Report	Storage Stability of the Triazole Derivative Metabolites (TDMs) in Plant Matrices under Deep Frozen Conditions Jooß, S., 2025 Report No.: S23-105428
Guideline(s):	OECD Guideline 506, ENV/JM/MONO(2007)17 (OECD guidance document on pesticide residue analytical methods)
Deviations:	Not applicable
GLP:	Yes
Acceptability:	Not applicable

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

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

Methos flow chart:



Method Performance:
Selectivity:
One control sample per analyte/matrix combination was extracted and analysed according to the method to investigate the presence of residue and/or background interference at the retention time of the analyte(s) for each analytical set.
For 1,2,4-triazole and triazole lactic acid in cereal grain as well as for 1,2,4-triazole and triazole acetic acid in oilseed rape (seed), the control samples showed no significant interference (above 20 % of LOQ) at the retention time of the analyte(s), therefore showing that the method is highly specific. Blank correction was not performed for these analyte/matrix combinations.
For triazole acetic acid and triazole alanine in cereal grain as well as for triazole alanine and triazole lactic acid in oilseed rape (seed), the control samples showed significant interferences/analyte residues (above 20 % of LOQ). Therefore, blank correction was performed with the residue (only if >20 % of LOQ) detected in the control sample material used for fortification. The uncorrected recoveries can be taken from summary.

Accuracy and Precision:
The recoveries of the day 0 storage samples and freshly fortified concurrent recovery samples document the analytical performance in terms of accuracy and repeatability throughout the study. Fortification levels

were at LOQ (only for concurrent recoveries at Day 0) and 10x LOQ with analytes fortified jointly. Concurrent recoveries were handled and stored in the same way and for the same time period as the extracts of the storage samples that were prepared within the same analytical set. The following recoveries were obtained:

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

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

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

Triazole Acetic Acid (Mass Transition m/z 128→70)											
Oilseed rape (seed)	0.01	92.3, 91.3, 93.3	-	-	-	-	-	92.3	1.1	95.8	7.8
	0.1	89.6, 89.3, 88.1	86.0, 88.8	106, 105	103, 102	100, 105	105, 88.8	96.7	8.4		
Triazole Alanine (Mass Transition m/z 157→88)											
Oilseed rape (seed)	0.01	101 (200)**, 81.7 (181)**, 89.7 (189)**	-	-	-	-	-	90.7	11	85.1	10
	0.1	77.0 (86.9)**, 73.0 (82.9)**, 77.7 (87.6)**	98.3 (130)**, 93.3 (125)**	90.5 (119), 92.5 (121)	87.4 (111), 83.4 (107)	75.4 (99.0)**, 90.4 (114)**	78.1 (101), 73.3 (96.2)	83.9	10		
Triazole Lactic Acid (Mass Transition m/z 158→70)											
Oilseed rape (seed)	0.01	96.6 (121), 91.6 (116), 85.6 (110)	-	-	-	-	-	91.3	6.0	83.3	7.9
	0.1	88.3 (90.7), 86.5 (88.9), 86.3 (88.7)	82.0 (96.2)***, 75.0 (89.2)***	85.8 (90.3), 85.4 (89.9)	77.6 (97.1), 80.4 (99.9)	77.4 (84.3), 81.9 (88.8)	83.0 (89.2), 69.5 (75.7)	81.5	6.6		

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

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

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

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

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

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

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

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

			0.0853	79.1 (85.3)			

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

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

A 2.2.1.1.2 Storage stability of residues in animal products

Study 1 – Giancola 2023, Study No.: QG/21/007

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

Reference:	KCP 8.1/01
Report	Prothioconazole-desthio and 5 hydroxy metabolites: Frozen Storage Stability in Honey; D. Giancola, 2023; Study No.: QG/21/007
Guideline(s):	• OECD 506 Stability of Pesticide Residues in Stored Commodities • OECD, ENV/JM/MONO(2007)17 Background Review Document Supporting the Development of the Test Guideline 433 on Acute Inhalation Toxicity – Fixed Concentration Procedure Harmonised Submission. Series on Testing & Assessment No. 265, 20 July 2017 • OECD, ENV/JM/MONO(2009)31 Series on Testing and Assessment Number 64 and Series on Pesticides Number 32. Guidance Document on Overview of Residue Chemistry Studies, 28 July 2009 • SANTE/2020/12830, rev.1 Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes, 24 February 2021
Deviations:	Several minor deviations from the internal and field protocols were noted, but none of these deviations impact the validity of the study results.
GLP:	Yes
Acceptability:	Yes

Study Objective
The objective of this study was to provide information on the stability of residues of prothioconazole-desthio and 5 hydroxy metabolites in honey when stored under deep freeze storage conditions (≤ -18°C) for up to 13 months.

Materials and methods

Honey samples were analysed at 0, 6 and 13 months. Sample were individually fortified with prothioconazole-desthio, prothioconazole-α-hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio and prothioconazole-6-hydroxy-desthio at 0.05 mg/kg and stored at a nominal temperature of -18°C. Duplicate stability samples were analysed. Reagent blank, control and procedural recovery samples were analysed at each interval alongside stability samples.

Samples were analysed according to the validated analytical method QG21009.

Residues of prothioconazole-desthio were extracted from honey by dissolving the samples in water and then extracting the analyte with acetonitrile using QuEChERS kits. A portion of the final extract was then taken through the SPE clean-up and then diluted with water 2:3 v/v for final determination by liquid chromatography with tandem mass spectrometry (LC-MS/MS).

Residues of the prothioconazole-desthio (5) hydroxy metabolites were extracted from honey by dissolving the samples in water and then extracting the analyte with acetonitrile using QuEChERS kits. The samples were then diluted with water, evaporated to the aqueous remainder through rotary evaporation followed by a hydrolysis step consisting of an overnight incubation at 40°C under acidic conditions. A portion of the final extract was then taken through liquid-liquid extraction, evaporated to dryness using nitrogen flow, reconstituted in acetonitrile, sonicated, and then diluted with water for final determination by liquid chromatography with tandem mass spectrometry (LC-MS/MS).
Calibration curves were obtained from matrix matched calibration solutions containing prothioconazole-desthio in the nominal range of 0.050 – 2.50 ng/mL.

Calibration curves were obtained from matrix matched calibration solutions containing prothioconazole-desthio (5) hydroxy metabolites in the nominal range of 0.375 – 15.0 ng/mL.
During analysis, calibration curves were established with correlation coefficients (r) all greater than 0.995, demonstrating satisfactory linearity.

The mean procedural recovery for each analyte per analytical batch and overall mean recovery were all within the range of 70-120%. The relative standard deviation (RSD) at each fortification level and the overall RSD did not exceed 20%, demonstrating satisfactory precision.

Chromatographic interferences at the retention time of each analyte were either not detected (ND) or less than 30% of the limit of quantification (<30% LOQ) in reagent blank and control samples, demonstrating satisfactory selectivity.

The limit of quantification (LOQ) was 0.005 mg/kg for all analytes.

Results
Stability of prothioconazole-desthio (5) hydroxy metabolites in honey following storage at ≤ -18°C:

Analyte	Storage period (months)	Fortification level (mg/kg)	Recovery (%)	Mean recovery (%)	Mean procedural recovery (%)
Prothioconazole-desthio	0	0.05	83	97	74
			112		
	3	0.05	67	84	101
			101		
	13	0.05	98	98	95
			98		
Prothioconazole-α-hydroxy-desthio	0	0.05	83	82	85
			82		
	3	0.05	91	92	99
			93		
	13	0.05	76	80	77
			85		
Prothioconazole-3-hydroxy-desthio	0	0.05	86	87	88
			89		
	3	0.05	98	95	103

			91		
	13	0.05	84	84	83
			84		
Prothioconazole-4-hydroxy-desthio	0	0.05	90	88	87
			87		
	3	0.05	92	91	100
			90		
	13	0.05	88	84	83
			79		
Prothioconazole-5-hydroxy-desthio	0	0.05	92	94	88
			95		
	3	0.05	95	95	101
			95		
	13	0.05	61	70	79
			79		
Prothioconazole-6-hydroxy-desthio	0	0.05	90	87	88
			84		
	3	0.05	108	104	118
			100		
	13	0.05	78	74	85
			70		

Conclusion
Prothioconazole-desthio stability samples in honey were found to be stable under deep freeze storage conditions (≤ -18°C) for up to 13 months. Prothioconazole-desthio (5) hydroxy metabolites stability samples in honey were found to be stable under deep freeze storage conditions (≤ -18°C) for up to 13 months.

Study 2 – Mealing 2024, Study No.: QG/21/006

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

Reference: KCP 8.1/02

Report: Triazole Derivative Metabolites: Frozen Storage Stability in Honey for 6 months; H. Mealing, 2024; Study No.: QG/21/006

Guideline(s):

- Organisation for Economic Co-operation and Development (OECD). OECD Guideline for the Testing of Chemicals, No. 506, Stability of Pesticide Residues in Stored Commodities. 16 October 2007
- Organisation for Economic Co-operation and Development (OECD), ENV/JM/MONO(2007)17 Guidance Document on Pesticide Residue Analytical Methods [Series on Testing and Assessment No. 72, Series on Pesticides No. 39]. 13 August 2007
- Organisation for Economic Co-operation and Development (OECD), ENV/JM/MONO(2009)31 Guidance Document on Overview of Residue Chemistry Studies [Series on Testing and Assessment No. 64, Series on Pesticides No. 32]. 28 Jul 2009
- European Commission (EC), Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes [SANTE/2020/12830 Rev. 2]. 14 February 2023
- Commission Regulation (EC) 1107/2009 of the European Parliament

	and of the Council of 21 October 2009; Concerning the Placing of Plant Protection Products on the Market
Deviations:	Several minor deviations from the internal and field protocols were noted, but none of these deviations impact the validity of the study results.
GLP:	Yes
Acceptability:	Yes

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

Materials and methods
Honey samples were fortified at a concentration of 0.0500 mg/kg and stored at a nominal temperature of -18°C. Duplicate stability samples individually fortified with each analyte were analysed at 0, 3 and 6 months alongside reagent blank, control and procedural recovery samples.

For day 0 analysis, stability samples were extracted immediately after fortification without storage.

The validated analytical method (QG/21/008) was used in the study. This method involved extraction from honey with water by dilution. The extract was filtered and fortified with internal standards ([$^{13}C_2$,$^{15}N_3$]1,2,4-triazole, [1,2,4-Triazole-$^{13}C_2$,$^{15}N_3$]triazole alanine, [1,2,4-triazole-$^{13}C_2$,$^{15}N_3$]-1,2,4-triazole acetic acid and [1,2,4-triazole-$^{13}C_2$,$^{15}N_3$]triazole lactic acid) prior to final determination by liquid chromatography with tandem mass spectrometry (LC-MS/MS), monitoring two ion mass transitions, or a single ion mass transition using two significantly different HPLC methods. For sample analysis, the primary transition or method was used for quantification, with the exception of timepoint 0 where the transition of the primary HPLC method for triazole acetic acid showed an inconsistent peak shape and therefore the secondary method was used.

Quantification was by comparison to a calibration curve consisting of at least five individual points. Calibration curves were obtained from matrix-matched standards containing 1,2,4-triazole, triazole alanine, triazole acetic acid and triazole lactic acid, covering a range of 0.297 to 49.5 ng/mL, covering a range from 30% of the LOQ to at least 20% above the highest recovery level. Each calibration solution contained the internal standards at a constant nominal concentration of 9.90 ng/mL for [$^{13}C_2$,$^{15}N_3$]1,2,4-triazole, 4.95 ng/mL for [1,2,4-Triazole-$^{13}C_2$,$^{15}N_3$]triazole alanine, and 1.98 ng/mL for [1,2,4-triazole-$^{13}C_2$,$^{15}N_3$]-1,2,4-triazole acetic acid and [1,2,4-triazole-$^{13}C_2$,$^{15}N_3$]triazole lactic acid.

The correlation coefficients, r, were greater than or equal to 0.995, demonstrating satisfactory linearity.

Chromatographic interferences at the retention time of each analyte were either not detected (ND) or less than 30% of the limit of quantification (<30% LOQ) in reagent blank and control samples, demonstrating satisfactory selectivity.

The mean procedural recovery for each analyte per analytical batch and overall mean recovery were all within the range of 70-120%. The overall relative standard deviation (RSD) did not exceed 20%, demonstrating satisfactory precision.

The limit of quantification (LOQ) was 0.00500 mg/kg for all analytes.

Results
Stability of triazole derivative metabolites in honey following storage at ≤ -18°C:

Analyte	Nominal Sampling Interval	Fortification Level (mg/kg)	Residue in Stability	Stability Recovery (%)	Mean Stability Recovery (%)	Mean Procedural Recovery (%)

	(months)		**Sample (mg/kg)**			
1,2,4-Triazole	0	0.05	0.0452	90.4	88.4	100.0
			0.0432	86.4		
	3	0.05	0.0411	82.1	83.6	85.5
			0.0426	85.1		
	6	0.05	0.0431	86.2	86.7	83.1
			0.0436	87.3		
Triazole Alanine	0	0.05	0.0398	79.6	81.1	81.0
			0.0413	82.6		
	3	0.05	0.0461	92.2	95.1	101.9
			0.0490	98.0		
	6	0.05	0.0408	81.5	81.7	90.7
			0.0410	81.9		
Triazole Acetic Acid	0	0.05	0.0491	98.2	98.3	100.1
			0.0492	98.5		
	3	0.05	0.0437	87.4	87.1	101.5
			0.0434	86.9		
	6	0.05	0.0451	90.3	89.3	99.7
			0.0442	88.4		
Triazole Lactic Acid	0	0.05	0.0556	111.1	92.5	91.3
			0.0369	73.8		
	3	0.05	0.0441	88.3	87.2	90.0
			0.0431	86.2		
	6	0.05	0.0505	101.0	101.5	87.1
			0.0510	102.0		

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

A 2.2.2 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 data provided for this endpoint.

A 2.2.2.1.2 Nature of residue in rotational crops

No new data provided for this endpoint.

A 2.2.2.1.3 Nature of residues in processed commodities

No new data provided for this endpoint.

A 2.2.2.2 Nature of residues in livestock

No new data provided for this endpoint.

A 2.2.3 Magnitude of residues in plants

A 2.2.3.1 Wheat

Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (DAR, RMS, year)	3	200 g as / ha	14 to 21 days	BBCH 69	35
cGAP EU (Art. 12, EFSA, year)	3	200 g as / ha	14 to 21 days	BBCH 69	35
Intended cGAP (numbers 1, 2, ~~3, 4, 9, 10, 11, 12~~)*	1	1 L product per ha (200 g prothioconazole per ha)	Not applicable	BBCH 69	35 (GSR)

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

** Timing of applications determined primarily by growth stage; 1st application not later than BBCH 39, 2nd application no later than BBCH 59.

GSR: Growth Stage Restricted

The following tables provide a summary of the available data from the residue trials:

Commodity	Trial	Residue trials zone	PTZ-Desthio	PTZ-α	PTZ-3	PTZ-4	PTZ-5	PTZ-6	T	TA	TAA	TLA
Wheat grain	645-2023	North EU	<0.01	<0.01	nd	nd	nd	nd	nd	0.12	0.04	nd
Wheat grain	645-2023	North EU	<0.01	<0.01	nd	nd	nd	nd	nd	0.25	0.14	nd
Wheat grain	645-2023	North EU	nd	nd	nd	nd	nd	nd	nd	0.41	0.16	nd
Wheat grain	645-2023	North EU	<0.01	<0.01	nd	nd	nd	nd	nd	0.74	0.17	<0.01
Wheat grain	645-2023	North EU	nd	nd	nd	nd	nd	nd	nd	0.17	0.05	nd
Wheat grain	645-2023	North EU	<0.01	nd	nd	nd	nd	nd	nd	0.27	0.1	nd
Wheat grain	645-2023	North EU	nd	nd	nd	nd	nd	nd	nd	0.33	0.14	nd
Wheat grain	645-2023	North EU	nd	nd	nd	nd	nd	nd	nd	0.68	0.11	nd
STMR (mg/kg):			<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0.3	0.125	<0.01
HR (mg/kg):			<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0.74	0.17	<0.01

Commodity	Trial	Residue trials zone	PTZ-Desthio	PTZ-α	PTZ-3	PTZ-4	PTZ-5	PTZ-6	T	TA	TAA	TLA
Wheat straw	645-2023	North EU	0.49	0.18	0.32	0.21	0.24	0.03	n.d.	0.02	0.04	0.03
Wheat straw	645-2023	North EU	0.94	0.40	0.48	0.23	0.35	0.05	n.d.	< 0.01	0.04	0.03
Wheat straw	645-2023	North EU	0.19	0.13	0.11	0.06	0.09	0.01	n.d.	0.07	0.04	0.03
Wheat straw	645-2023	North EU	3.3	0.98	0.79	0.54	0.51	0.12	n.d.	0.03	0.13	0.13
Wheat straw	645-2023	North EU	0.59	0.39	0.52	0.24	0.32	0.06	n.d.	n.d.	0.02	0.03
Wheat straw	645-2023	North EU	0.18	0.19	0.21	0.16	0.19	0.01	n.d.	0.01	0.02	0.02
Wheat straw	645-2023	North EU	0.07	0.04	0.13	0.10	0.09	0.01	n.d.	0.01	<0.01	0.02
Wheat straw	645-2023	North EU	0.19	0.07	0.04	0.03	0.05	<0.01	n.d.	0.03	0.01	<0.01
STMR (mg/kg):			0.34	0.185	0.265	0.185	0.23	0.038	<0.01	0.02	0.03	0.03
HR (mg/kg):			3.3	0.98	0.79	0.54	0.51	0.12	<0.01	0.07	0.13	0.13

~~Commodity~~	~~Trial~~	~~Residue trials zone~~	~~PTZ-Desthio~~	~~PTZ-α~~	~~PTZ-3~~	~~PTZ-4~~	~~PTZ-5~~	~~PTZ-6~~	~~T~~	~~TA~~	~~TAA~~	~~TLA~~
~~Wheat grain~~	~~645-2023~~	~~South EU~~	~~<0.01~~	~~nd~~	~~nd~~	~~nd~~	~~nd~~	~~nd~~	~~nd~~	~~0.19~~	~~0.09~~	~~nd~~
~~Wheat grain~~	~~645-2023~~	~~South EU~~	~~nd~~	~~nd~~	~~nd~~	~~nd~~	~~nd~~	~~nd~~	~~nd~~	~~0,28~~	~~0.09~~	~~nd~~
~~Wheat grain~~	~~645-2023~~	~~South EU~~	~~nd~~	~~nd~~	~~nd~~	~~nd~~	~~nd~~	~~nd~~	~~nd~~	~~0,24~~	~~0.06~~	~~nd~~
~~Wheat grain~~	~~645-2023~~	~~South EU~~	~~<0.01~~	~~nd~~	~~nd~~	~~nd~~	~~nd~~	~~nd~~	~~<0.01~~	~~0,72~~	~~0.14~~	~~0.01~~
~~Wheat grain~~	~~645-2023~~	~~South EU~~	~~<0.01~~	~~<0.01~~	~~nd~~	~~nd~~	~~nd~~	~~nd~~	~~nd~~	~~0.02~~	~~0.02~~	~~nd~~

Wheat grain	645-2023	South EU	0.01	nd	nd	nd	nd	nd	nd	0.04	0.04	nd
Wheat grain	645-2023	South EU	nd	nd	nd	nd	nd	nd	nd	0.17	0.04	nd
Wheat grain	645-2023	South EU	<0.01	nd	nd	nd	nd	nd	nd	0.02	<0.01	nd
STMR (mg/kg):			<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0.18	0.05	<0.01
HR (mg/kg):			0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0.72	0.14	0.01

Commodity	Trial	Residue trials zone	PTZ-Desthio	PTZ-α	PTZ-3	PTZ-4	PTZ-5	PTZ-6	T	TA	TAA	TLA
Wheat straw	645-2023	South EU	0.32	0.10	0.30	0.21	0.33	0.04	n.d.	< 0.01	0.06	0.05
Wheat straw	645-2023	South EU	0.27	0.02	0.14	0.11	0.18	0.02	n.d.	0.01	0.02	< 0.01
Wheat straw	645-2023	South EU	0.13	0.05	0.11	0.09	0.09	0.01	n.d.	0.01	0.03	0.02
Wheat straw	645-2023	South EU	1.2	1.1	0.89	0.57	0.45	0.15	n.d	0.05	0.11	0.21
Wheat straw	645-2023	South EU	0.89	0.02	0.10	0.05	0.10	0.03	n.d.	n.d.	n.d.	n.d.
Wheat straw	645-2023	South EU	2.69	0.08	0.40	0.12	0.13	0.03	< 0.01	0.01	0.02	n.d.
Wheat straw	645-2023	South EU	0.22	0.02	0.28	0.14	0.30	0.03	n.d.	< 0.01	0.01	0.01
Wheat straw	645-2023	South EU	1.1	0.03	0.19	0.10	0.17	0.03	n.d.	< 0.01	< 0.01	n.d.
STMR (mg/kg):			0.605	0.04	0.235	0.115	0.175	0.03	<0.01	0.01	0.02	0.02
HR (mg/kg):			2.69	1.1	0.89	0.57	0.45	0.15	<0.01	0.05	0.11	0.21

Wheat Study 1 Lebrun 2024; 645-2023 - Northern and Southern Europe (new data)

Comments of zRMS:	Eight independent trials (4 decline and 4 harvest) located in Northern Europe (Northern France, Germany, Poland, Belgium, The Netherlands) were conducted on wheat (RAC) following two applications of Prothioconazole 250 g/L DC (200 g as/ha) to determine of the residues of prothioconazole metabolites: PTZ-dethio, PTZ-alpha-OH-desthio, PTZ-3-OH-desthio, PTZ-4-OH-desthio, PTZ-5-OH-desthio, PTZ-6-OH-desthio, 1,2,4-Triazole (T), Triazole alanine (TA) Triazole acetic acid (TAA), Triazole lactic acid (TLA) in wheat specimens: forage, grain and straw. The first application was performed 14 +/-1 days before the second application (actual: 13 to 14 days). The second application was performed on the treated plot at BBCH 69. The methods were successfully validated for determination of all analytes in all matrices with an LOQ of 0.01 mg/kg according to guidance document SANTE/2020/12830, rev. 2. Max. study storage interval between sampling and extraction for PTZ and hydroxy-metabolites of PTZ was 198 days, for TDMs was 178 days. The study on the magnitude of residues is valid with regard to storage stability. <u>Residue results:</u> No residue of PTZ-desthio, PTZ-alpha-OH-desthio, PTZ-3-OH-desthio, PTZ-4-OH-desthio, PTZ-5-OH-desthio and PTZ-6-OH-desthio, all expressed in PTZ-desthio, was measured in the untreated specimens above the LOQ except in forage and straw specimens of trial 645-2023 FR04. In the specimens originating from the untreated plots, no residues of T were detected in any of the untreated specimens, while residue of TAA, TA and TLA were measured above the LOQ in several field specimens. In the treated grain specimens at harvest, residue levels of PTZ-desthio were never above the LOQ (8 x <0.01 mg/kg), and the sum of hydroxy- derivatives of prothioconazole-desthio was <0.06 mg/kg. TDMs: In the treated grain specimens, residue levels of 1,2,4-triazole and TLA were never above the LOQ and residues of TA, TAA in grain specimens at harvest ranged between: - TA: 0.12 – 0.74 mg/kg, - TAA: 0.04 – 0.17 mg/kg.

	The study is acceptable. These trials can be used to support the intended use on wheat.

Reference: KCP 8.3.1/05

Report: Magnitude of the residue of prothioconazole metabolites in wheat in Northern and Southern Europe – 2023; Lebrun, F., 2024; Report No.; 645-2023

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

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

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

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

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

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

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

Deviations: Yes

645-2023 PL03

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

645-2023 GE02 and 645-2023 NL08

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

The following specimens are concerned:
Trial 645-2023 GE02:
645-2023 GE02 1R, 645-2023 GE02 2R, 645-2023 GE02 3R, 645-2023 GE02 4R, 645-2023 GE02 5R, 645-2023 GE02 6R, 645-2023 GE02 7R, 645-2023 GE02 8R, 645-2023 GE02 9R, 645-2023 GE02 10R, 645-2023 GE02 11R, 645-2023 GE02 12R, 645-2023 GE02 13R, 645-2023 GE02 14R, 645-2023 GE02 15R, 645-2023 GE02 16R, 645-2023 GE02 17R, 645-2023 GE02 18R, 645-2023 GE02 19R, 645-2023 GE02 20R
Trial 645-2023 NL08:
645-2023 NL08 1R, 645-2023 NL08 2R, 645-2023 NL08 3R, 645-2023 NL08 4R

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

The deviations have no impact on the compliance to GLP.

GLP: Yes

Acceptability: Yes

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

RESIDUE DATA SUMMARY FROM SUPERVISED TRIALS

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

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

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

1	2	3	4	5			6	7	8	9				10	11
Report No. 645-2023 Location (region)	Commodity Variety	Date of 1-Planting 2-Flowering 3-Harvest	Method of treatment	Actual (nominal) application rate per treatment			Date of treatment	BBCH Crop Growth Stage at treatment	Portions analysed	Residues **expressed in prothioconazole-desthio** (1) PTZ = prothioconazole				DALA (2)	Remarks
				kg a.s./ha	Water (L/ha)	kg (a.s./hL)				PTZ-desthio	PTZ-α-hydroxy-desthio	PTZ-3-hydroxy-desthio	**Sum[1,2]**		
Northern Europe Northern France 49650 Allonnes (Pays de la Loire) Decline curve trial 645-2023 FR01	Winter wheat APACHE	1-26/10/22 2-15/05/23 to 30/05/23 3-07/07/23	Broadcast foliar application Boom sprayer	0.1941 (0.1967) 0.1995 (0.2022)	197 202	0.0987 (0.1000) 0.0987 (0.1000)	15/05/23 30/05/23	61 69	Forage [3] Forage [3] Forage [3] Forage [3] Straw Grain	0.24 1.0 0.51 0.46 0.49 <0.01	0.04 0.04 0.10 0.11 0.18 <0.01	0.08 0.08 0.21 0.22 0.32 n.d.	- - - - - -	-0 +0 14 20 38[4] 38[4]	Untreated specimen: <LOQ LC-MS/MS method validated within this study Max. study storage interval between:

										PTZ-4-hydroxy-desthio	PTZ-5-hydroxy-desthio	PTZ-6-hydroxy-desthio			-sampling and extraction: 198 days -extraction and analyses: 7 days LOQ: 0.01 mg/kg for each analyte, 0.06 mg/kg for prothioconazole expressed as prothioconazole desthio as a sum of metabolites
									Forage [3]	0.07	0.06	<0.01	**0.50**	-0	
									Forage [3]	0.07	0.05	<0.01	**1.3**	+0	
									Forage [3]	0.14	0.11	0.02	**1.1**	14	
									Forage [3]	0.16	0.12	0.03	**1.1**	20	
									Straw	0.21	0.24	0.03	**<u>1.5</u>**	38[4]	
									Grain	n.d.	n.d.	n.d.	**<LOQ**	38[4]	
Northern Europe Germany 46342 Velen-Ramsdorf (North Rhine-Westphalia) Decline curve trial 645-2023 GE02	Winter Wheat BENCHMARK	1- 29/10/22 2- 29/05/23 to 09/06/23 3- 04/08/23	Broadcast foliar application Boom sprayer	0.2010 (0.2037) 0.1974 (0.2000)	306 300	0.0658 (0.0667) 0.0658 (0.0667)	25/05/23 06/06/23	52 69		PTZ-desthio	PTZ-α-hydroxy-desthio	PTZ-3-hydroxy-desthio	**Sum[1,2]**		Untreated specimen: <LOQ LC-MS/MS method validated within this study Max. study storage interval between: -sampling and extraction: 198 days -extraction and analyses: 7 days LOQ: 0.01 mg/kg for each analyte, 0.06 mg/kg for prothioconazole expressed as prothioconazole desthio as a sum of metabolites
									Forage [3]	0.28	0.04	0.09	-	-0	
									Forage [3]	1.0	0.05	0.09	-	+0	
									Forage [3]	0.52	0.19	0.21	-	14	
									Forage [3]	0.33	0.22	0.22	-	21	
									Straw	<u>0.94</u>	0.40	0.48	-	56[4]	
									Grain	<u>< 0.01</u>	< 0.01	n.d.	-	56[4]	
										PTZ-4-hydroxy-desthio	PTZ-5-hydroxy-desthio	PTZ-6-hydroxy-desthio			
									Forage [3]	0.06	0.08	0.01	**0.56**	-0	
									Forage [3]	0.07	0.10	0.01	**1.3**	+0	
									Forage [3]	0.14	0.16	0.04	**1.3**	14	
									Forage [3]	0.15	0.17	0.05	**1.1**	21	
									Straw	0.23	0.35	0.05	**<u>2.5</u>**	56[4]	
									Grain	n.d.	n.d.	n.d.	**<LOQ**	56[4]	

Northern Europe Poland 55200 Gać (Lower Silesia) Decline curve trial 645-2023 PL03	Spring Wheat MERKAWA C1	1- 22/04/23 2- 22/06/23 to 26/06/23 3- 12/08/23	Broadcast foliar application Boom sprayer	0.2022 (0.2049) 0.1979 (0.2005)	307 301	0.0658 (0.0667) 0.0658 (0.0667)	12/06/23 26/06/23	45-47 69		PTZ-desthio	PTZ-α-hydroxy-desthio	PTZ-3-hydroxy-desthio	**Sum[1,2]**		Untreated specimen: <LOQ LC-MS/MS method validated within this study Max. study storage interval between: -sampling and extraction: 198 days -extraction and analyses: 7 days LOQ: 0.01 mg/kg for each analyte, 0.06 mg/kg for prothioconazole expressed as prothioconazole desthio as a sum of metabolites
									Forage [3] Forage [3] Forage [3] Forage [3] Straw Grain	0.37 1.2 0.50 0.32 0.19 n.d.	0.25 0.18 0.25 0.26 0.13 n.d.	0.23 0.18 0.43 0.42 0.11 n.d.	- - - - - -	-0 +0 14 21 47[4] 47[4]	
										PTZ-4-hydroxy-desthio	PTZ-5-hydroxy-desthio	PTZ-6-hydroxy-desthio			
									Forage [3] Forage [3] Forage [3] Forage [3] Straw Grain	0.14 0.12 0.20 0.20 0.06 n.d.	0.13 0.10 0.16 0.17 0.09 n.d.	0.04 0.04 0.05 0.05 0.01 n.d.	**1.2** **1.8** **1.6** **1.4** **0.59** **<LOQ (n.d.)**	-0 +0 14 21 47[4] 47[4]	
Northern Europe Northern France 37370 Saint Christophe sur le Nais (Centre Val de Loire) Decline curve trial 645-2023 FR04	Spring Wheat TOGANO	1- 05/03/23 2- 20/06/23 to 27/06/23 3- 20/07/23 to 30/07/23	Broadcast foliar application Boom sprayer	0.1897 (0.1922) 0.1907 (0.1933)	192 193	0.0987 (0.1000) 0.0987 (0.1000)	12/06/23 26/06/23	59 69		PTZ-desthio	PTZ-α-hydroxy-desthio	PTZ-3-hydroxy-desthio	**Sum[1,2]**		Untreated specimen: <0.01 – 0.33 LC-MS/MS method validated within this study Max. study storage interval between: -sampling and extraction: 198 days -extraction and analyses: 7 days LOQ: 0.01 mg/kg for each analyte,
									Forage [3] Forage [3] Forage [3] Forage [3] Straw Grain	0.39, 0.34, 0.35* 1.4, 1.2, 1.4* 1.1, 0.99, 1.0* 1.2, 1.1, 0.92* 3.3, 3.1, 2.1* <0.01	0.20, 0.20, 0.18* 0.19, 0.18, 0.17* 0.35, 0.31, 0.36* 0.50, 0.42, 0.37* 0.96, 0.98, 0.98* <0.01	0.16, 0.16, 0.17* 0.17, 0.17, 0.15* 0.23, 0.21, 0.26* 0.30, 0.25, 0.23* 0.70, 0.78, 0.79* n.d.	- - - - - -	-0 +0 14 21 28[4] 28[4]	

										PTZ-4-hydroxy-desthio	PTZ-5-hydroxy-desthio	PTZ-6-hydroxy-desthio	**Sum[1,2]**		0.06 mg/kg for prothioconazole expressed as prothioconazole desthio as a sum of metabolites
									Forage [(3)]	0.12,0.11, 0.12*	0.10, 0.09, 0.10*	0.03, 0.03, 0.03*	**1.00, 0.93, 095***	-0	
														+0	
									Forage [(3)]	0.12, 0.11, 0.11*	0.10, 0.09, 0.09*	0.03, 0.02, 0.02*	**2.01, 1.78, 1.94***	14	
									Forage [(3)]	0.15, 0.13, 0.18*	0.14, 0.13, 0.16*	0.04, 0.03, 0.04*	**2.01, 1.80, 2.00***	21	
									Forage [(3)]	0.20, 0.16, 0.16*	0.18, 0.16, 0.12*	0.06, 0.04, 0.04*	**2.44, 2.13, 1.84***	28[(4)]	
														28[(4)]	
									Straw	0.44, 0.50, 0.54*	0.46, 0.51, 0.44*	0.12, 0.12, 0.11*	**5.98, <u>5.99</u>, 4.96***		
									Grain	n.d.	n.d.	n.d.	**<LOQ**		
Northern Europe Belgium 6221 Saint-Armand (Province of Hainaut) Harvest trial 645-2023 BE05	Winter Wheat CHRISTOPH	1- 28/10/22 2- 31/05/23 to 08/06/23 3- 19/07/23 to 11/08/23	Broadcast foliar application Boom sprayer	0.1959 (0.1985) 0.1959 (0.1985)	298 298	0.0658 (0.0667) 0.0658 (0.0667)	24/05/23 08/06/23	51 69		PTZ-desthio	PTZ-α-hydroxy-desthio	PTZ-3-hydroxy-desthio	**Sum[1,2]**		Untreated specimen: <LOQ LC-MS/MS method validated within this study Max. study storage interval between: -sampling and extraction: 198 days -extraction and analyses: 7 days LOQ: 0.01 mg/kg for each analyte, 0.06 mg/kg for prothioconazole expressed as prothioconazole desthio as a sum of metabolites
									Straw	<u>0.59</u>	0.39	0.52	-	41[(3)]	
									Grain	<u>n.d.</u>	n.d.	n.d.	-	41[(3)]	
										PTZ-4-hydroxy-desthio	PTZ-5-hydroxy-desthio	PTZ-6-hydroxy-desthio			
									Straw	0.24	0.32	0.06	**<u>2.1</u>**	41[(3)]	
									Grain	n.d.	n.d.	n.d.	**<LOQ <u>(n.d.)</u>**	41[(3)]	

Northern Europe Germany 04827 Gerichshain (Saxony) Harvest trial 645-2023 GE06	Spring Wheat KWS SHARKI	1- 30/03/23 2- 13/06/23 to 27/06/23 3- 19/08/23	Broadcast foliar application Boom sprayer	0.2053 (0.2080) 0.2040 (0.2067)	312 310	0.0658 (0.0667) 0.0658 (0.0667)	13/06/23 27/06/23	59-61 69		PTZ-desthio	PTZ-α-hydroxy-desthio	PTZ-3-hydroxy-desthio	**Sum[1,2]**		Untreated specimen: <LOQ LC-MS/MS method validated within this study Max. study storage interval between: -sampling and extraction: 198 days -extraction and analyses: 7 days LOQ: 0.01 mg/kg for each analyte, 0.06 mg/kg for prothioconazole expressed as prothioconazole desthio as a sum of metabolites
									Straw	0.18	0.19	0.21	-	53[3]	
									Grain	< 0.01	n.d.	n.d.	-	53[3]	
										PTZ-4-hydroxy-desthio	PTZ-5-hydroxy-desthio	PTZ-6-hydroxy-desthio			
									Straw	0.16	0.19	0.01	**0.94**	53[3]	
									Grain	n.d.	n.d.	n.d.	**<LOQ**	53[3]	
Northern Europe Poland 48320 Czarnolas (Opolskie Province) Harvest trial 645-2023 PL07	Spring Wheat MERKAWA C1	1- 22/03/23 2- 18/06/23 to 23/06/23 3- 11/08/23	Broadcast foliar application Boom sprayer	0.2042 (0.2069) 0.1973 (0.2000)	310 300	0.0658 (0.0667) 0.0658 (0.0667)	09/06/23 23/06/23	45-47 69		PTZ-desthio	PTZ-α-hydroxy-desthio	PTZ-3-hydroxy-desthio	**Sum[1,2]**		Untreated specimen: <LOQ LC-MS/MS method validated within this study Max. study storage interval between: -sampling and extraction: 198 days -extraction and analyses: 7 days LOQ: 0.01 mg/kg for each analyte, 0.06 mg/kg for prothioconazole
									Straw	0.07	0.04	0.13	-	49[3]	
									Grain	n.d.	n.d.	n.d.	-	49[3]	
										PTZ-4-hydroxy-desthio	PTZ-5-hydroxy-desthio	PTZ-6-hydroxy-desthio			
									Straw	0.10	0.09	0.01	**0.44**	49[3]	
									Grain	n.d.	n.d.	n.d.	**<LOQ (n.d.)**	49[3]	

															expressed as prothioconazole desthio as a sum of metabolites
Northern Europe The Netherlands 5853EJ Siebengewald (Limburg) Harvest trial 645-2023 NL08	Spring Wheat ALICIA	1- 19/04/23 2- 18/06/23 to 30/06/23 3- 08/08/23	Broadcast foliar application Boom sprayer	0.2047 (0.2074) 0.2047 (0.2074)	311 311	0.0658 (0.0667) 0.0658 (0.0667)	16/06/23 30/06/23	57-59 69	Straw Grain	PTZ-desthio <u>0.19</u> <u>n.d.</u>	PTZ-α-hydroxy-desthio 0.07 n.d.	PTZ-3-hydroxy-desthio 0.04 n.d.	**Sum[1,2]** - -	39[(3)] 39[(3)]	Untreated specimen: <LOQ LC-MS/MS method validated within this study Max. study storage interval between: -sampling and extraction: 198 days -extraction and analyses: 7 days LOQ: 0.01 mg/kg for each analyte, 0.06 mg/kg for prothioconazole expressed as prothioconazole desthio as a sum of metabolites
									Straw Grain	PTZ-4-hydroxy-desthio 0.03 n.d.	PTZ-5-hydroxy-desthio 0.05 n.d.	PTZ-6-hydroxy-desthio < 0.01 n.d.	 **<u>0.39</u>** **<LOQ <u>(n.d.)</u>**	 39[(3)] 39[(3)]	

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

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

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

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

RESIDUE DATA SUMMARY FROM SUPERVISED TRIALS

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

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

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

1	2	3	4	5			6	7	8	9				10	11
Report No. 645-2023 Location (region)	Commodity Variety	Date of 1-Planting 2-Flowering 3-Harvest	Method of treatment	Actual (nominal) application rate per treatment			Date of treatment	BBCH Crop Growth Stage at treatment	Portions analysed	Residues (1)				DALA (2)	Remarks
				kg a.s./ha	Water (L/ha)	kg (a.s./hL)				T	TA	TAA	TLA		
Northern Europe Northern France 49650 Allonnes (Pays de la Loire) Decline curve trial 645-2023 FR01	Winter wheat APACHE	1-26/10/22 2-15/05/23 to 30/05/23 3-07/07/23	Broadcast foliar application Boom sprayer	0.1941 (0.1967) 0.1995 (0.2022)	197 202	0.0987 (0.1000) 0.0987 (0.1000)	15/05/23 30/05/23	61 69	**Untreated** Forage(3) Forage(3) Forage(3) Forage(3) Straw Grain **Treated** Forage(3) Forage(3) Forage(3) Forage(3) Straw Grain	 n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d.	 0.01 0.01 0.01 0.01 <0.01 0.03 0.05 0.05 0.08 0.07 0.02 0.12	 0.01 0.01 0.01 0.02 0.02 0.02 0.02 0.02 0.03 0.03 0.04 0.04	 0.01 <0.01 <0.01 <0.01 0.01 n.d. 0.02 0.02 0.02 0.02 0.03 n.d.	 -0 +0 14 20 38(4) 38(4) -0 +0 14 20 38(4) 38(4)	LC-MS/MS Method Validated in within this study Max. study storage interval between: -sampling and extraction: 178 days -extraction and analyses: 4 days
Northern Europe Germany 46342 Velen-Ramsdorf (North	Winter Wheat BENCHMARK	1- 29/10/22 2- 29/05/23 to 09/06/23 3- 04/08/23	Broadcast foliar application Boom sprayer	0.2010 (0.2037) 0.1974 (0.2000)	306 300	0.0658 (0.0667) 0.0658 (0.0667)	25/05/23 06/06/23	52 69	**Untreated** Forage(3) Forage(3) Forage(3) Forage(3) Straw Grain	 n.d. n.d. n.d. n.d. n.d. n.d.	 0.01 0.02 0.03 0.03 n.d. 0.05	 < 0.01 0.01 0.02 0.02 0.01 0.04	 < 0.01 < 0.01 < 0.01 < 0.01 < 0.01 n.d.	 -0 +0 14 21 56(4) 56(4)	LC-MS/MS Method Validated in within this study

Rhine-Westphalia) Decline curve trial 645-2023 GE02									**Treated** Forage[3] Forage[3] Forage[3] Forage[3] Straw Grain	 n.d. n.d. n.d. n.d. n.d. n.d.	 0.06 0.07 0.16 0.21 < 0.01 0.25	 0.02 0.02 0.04 0.05 0.04 0.14	 0.02 0.02 0.03 0.03 0.03 n.d.	 -0 +0 14 21 56[4] 56[4]	Max. study storage interval between: -sampling and extraction: 178 days -extraction and analyses: 4 days
Northern Europe Poland 55200 Gać (Lower Silesia) Decline curve trial 645-2023 PL03	Spring Wheat MERKAWA C1	1- 22/04/23 2- 22/06/23 to 26/06/23 3- 12/08/23	Broadcast foliar application Boom sprayer	0.2022 (0.2049) 0.1979 (0.2005)	307 301	0.0658 (0.0667) 0.0658 (0.0667)	12/06/23 26/06/23	45-47 69	**Untreated** Forage[3] Forage[3] Forage[3] Forage[3] Straw Grain **Treated** Forage[3] Forage[3] Forage[3] Forage[3] Straw Grain	 n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d.	 0.02 0.01 0.03 0.02 n.d. 0.06 0.12 0.11 0.38 0.28 0.07 0.41	 0.01 0.01 0.01 0.02 n.d. 0.03 0.04 0.05 0.07 0.08 0.04 0.16	 < 0.01 0.02 0.01 0.01 n.d. n.d. 0.07 0.07 0.11 0.10 0.03 n.d.	 -0 +0 14 21 47[4] 47[4] -0 +0 14 21 47[4] 47[4]	LC-MS/MS Method Validated in within this study Max. study storage interval between: -sampling and extraction: 178 days -extraction and analyses: 4 days
Northern Europe Northern France 37370 Saint Christophe sur le Nais (Centre Val de Loire) Decline curve trial 645-2023 FR04	Spring Wheat TOGANO	1- 05/03/23 2- 20/06/23 to 27/06/23 3- 20/07/23 to 30/07/23	Broadcast foliar application Boom sprayer	0.1897 (0.1922) 0.1907 (0.1933)	192 193	0.0987 (0.1000) 0.0987 (0.1000)	12/06/23 26/06/23	59 69	**Untreated** Forage[3] Forage[3] Forage[3] Forage[3] Straw Grain **Treated** Forage[3] Forage[3] Forage[3] Forage[3] 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., n.d.* n.d., n.d., n.d.* n.d., n.d., n.d.* n.d., n.d., n.d.*	 0.23, 0.22, 0.22* 0.22, 0.20, 0.24* 0.25, 0.23, 0.28* 0.26, 0.22, 0.30* 0.03, 0.02, 0.04* 0.33 0.27, 0.24, 0.24* 0.27, 0.29, 0.29* 0.29, 0.34, 0.36* 0.31, 0.36, 0.54*	 0.13, 0.14, 0.14* 0.13, 0.13, 0.14* 0.20, 0.24, 0.21* 0.28, 0.22, 0.29* 0.19, 0.20, 0.22* 0.19 0.08, 0.08, 0.08* 0.09, 0.10, 0.08* 0.15, 0.19, 0.18* 0.17, 0.22, 0.22*	 0.12, 0.13, 0.14* 0.12, 0.14, 0.11* 0.10, 0.11, 0.09* 0.10, 0.11, 0.09* 0.16, 0.17, 0.17* <0.01 0.09, 0.10, 0.09* 0.11, 0.12, 0.09* 0.08, 0.08, 0.09* 0.07, 0.08, 0.08*	 -0 +0 14 21 28[4] 28[4] -0 +0 14 21 28[4]	LC-MS/MS Method Validated in within this study Max. study storage interval between: -sampling and extraction: 178 days -extraction and analyses: 4 days

									Grain	n.d., n.d., n.d.* n.d.	0.02, 0.02, 0.03* 0.74	0.13, 0.13, 0.13* 0.17	0.12, 0.12, 0.13* <0.01	28(4)	
Northern Europe Belgium 6221 Saint-Armand (Province of Hainaut) Harvest trial 645-2023 BE05	Winter Wheat CHRISTOPH	1- 28/10/22 2- 31/05/23 to 08/06/23 3- 19/07/23 to 11/08/23	Broadcast foliar application Boom sprayer	0.1959 (0.1985) 0.1959 (0.1985	298 298	0.0658 (0.0667) 0.0658 (0.0667)	24/05/23 08/06/23	51 69	**Untreated** Straw Grain **Treated** Straw Grain	 n.d. n.d. n.d. n.d.	 < 0.01 0.03 n.d. 0.17	 < 0.01 0.03 0.02 0.05	 0.01 n.d. 0.03 n.d.	 41(3) 41(3) 41(3) 41(3)	LC-MS/MS Method Validated in within this study Max. study storage interval between: -sampling and extraction: 178 days -extraction and analyses: 4 days
Northern Europe Germany 04827 Gerichshain (Saxony) Harvest trial 645-2023 GE06	Spring Wheat KWS SHARKI	1- 30/03/23 2- 13/06/23 to 27/06/23 3- 19/08/23	Broadcast foliar application Boom sprayer	0.2053 (0.2080) 0.2040 (0.2067)	312 310	0.0658 (0.0667) 0.0658 (0.0667)	13/06/23 27/06/23	59-61 69	**Untreated** Straw Grain **Treated** Straw Grain	 n.d. n.d. n.d. n.d.	 n.d. 0.03 0.01 0.27	 < 0.01 0.02 0.02 0.10	 n.d. n.d. 0.02 n.d.	 53(3) 53(3) 53(3) 53(3)	LC-MS/MS Method Validated in within this study Max. study storage interval between: -sampling and extraction: 178 days -extraction and analyses: 4 days
Northern Europe Poland 48320 Czarnolas (Opolskie Province)	Spring Wheat MERKAWA C1	1- 22/03/23 2- 18/06/23 to 23/06/23 3- 11/08/23	Broadcast foliar application Boom sprayer	0.2042 (0.2069) 0.1973 (0.2000)	310 300	0.0658 (0.0667) 0.0658 (0.0667)	09/06/23 23/06/23	45-47 69	**Untreated** Straw Grain	 n.d. n.d.	 n.d. 0.04	 < 0.01 0.03	 < 0.01 n.d.	 49(3) 49(3)	LC-MS/MS Method Validated in within this study

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

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

Summary of the wheat study 1 trials for prothioconazole-desthio- and prothioconazole-hydroxy-desthio metabolites
RESIDUE DATA SUMMARY FROM SUPERVISED TRIALS

Active Substance: prothioconazole
Commercial Product: Prothioconazole 250 g/L DC
Crop / crop group: Wheat / cereals
Producer: UPL Europe Limited
Responsible for reporting: Frédéric LEBRUN / TESTAPI
115 route du Pô, 49650 Allonnes – France
Countries: Southern France, Greece, Italy, & Spain
Indoor/glasshouse/outdoor: outdoor
Nominal Content of a.s.: 250 g/L
Other a.s. in formulation:
Formulation: DC
Residue calculated as: Prothioconazole-desthio (enforcement residue definition)
Prothioconazole-alpha-hydroxy-desthio,
prothioconazole-3-hydroxy-desthio,prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio (mg/kg) (risk assessment residue definition)

1	2	3	4	5			6	7	8	9				10	11
Report No. 645-2023 Location (region)	Commodity Variety	Date of 1-Planting 2-Flowering 3-Harvest	Method of treatment	Actual (nominal) application rate per treatment			Date of treatment	BBCH Crop Growth Stage at treatment	Portions analysed	Residues **expressed in prothioconazole-desthio** (1) PTZ = prothioconazole				DALA (2)	Remarks
				kg a.s./ha	Water (L/ha)	kg (a.s./hL)				PTZ-desthio	PTZ-α-hydroxy-desthio	PTZ-3-hydroxy-desthio	**Sum[1,2]**		
Southern Europe Southern France 79100 Plaine et Vallées (Nouvelle Aquitaine) Decline curve trial 645-2023 FR09	Winter Wheat KWS SPHERE	1- 21/10/22 2- 14/05/23 to 26/05/23 3- 05/07/23 to 10/07/23	Broadcast foliar application Boom sprayer	0.1918 (0.1944) 0.1985 (0.2011)	194 201	0.0986 (0.1000) 0.0987 (0.1000)	12/05/23 25/05/23	59 69	Forage[3] Forage[3] Forage[3] Forage[3] Straw Grain	0.29 1.1 0.76 0.77 0.32 < 0.01	0.03 0.02 0.06 0.08 0.10 n.d.	0.08 0.06 0.17 0.25 0.30 n.d.	- - - - - -	-0 +0 13 20 42[4] 42[4]	Untreated specimen: <LOQ LC-MS/MS method validated within this study Max. study storage interval between: -sampling and extraction: 198 days -extraction and analyses: 7 days
										PTZ-4-hydroxy-desthio	PTZ-5-hydroxy-desthio	PTZ-6-hydroxy-desthio			
									Forage[3] Forage[3] Forage[3] Forage[3] Straw Grain	0.06 0.04 0.10 0.18 0.21 n.d.	0.08 0.06 0.15 0.25 0.33 n.d.	0.02 0.01 0.02 0.06 0.04 n.d.	**0.56** **1.3** **1.3** **1.6** **1.3** **0.01**	-0 +0 13 20 42[4] 42[4]	

Southern Europe Greece 57400 Sindos (Central Macedonia) Decline curve trial 645-2023 GR10	Winter Wheat ACHILLE	1- 16/11/22 2- 17/04/23 to 27/04/23 3- 22/06/23	Broadcast foliar application Boom sprayer	0.1978 (0.2004) 0.1979 (0.2005)	301 301	0.0658 (0.0667) 0.0658 (0.0667)	12/04/23 27/04/23	39 69		PTZ-desthio	PTZ-α-hydroxy-desthio	PTZ-3-hydroxy-desthio	**Sum[1,2]**		Untreated specimen: <LOQ LC-MS/MS method validated within this study Max. study storage interval between: -sampling and extraction: 198 days -extraction and analyses: 7 days
									Forage[3] Forage[3] Forage[3] Forage[3] Straw Grain	0.93 1.85 1.05 0.98 0.27 n.d.	< 0.01 n.d. < 0.01 0.01 0.02 n.d.	0.06 0.05 0.09 0.11 0.14 n.d.	- - - - - -	0 +0 14 21 54[4] 54[4]	
										PTZ-4-hydroxy-desthio	PTZ-5-hydroxy-desthio	PTZ-6-hydroxy-desthio			
									Forage[3] Forage[3] Forage[3] Forage[3] Straw Grain	0.06 0.05 0.07 0.07 0.11 n.d.	0.11 0.09 0.13 0.13 0.18 n.d.	0.02 0.02 0.02 0.03 0.02 n.d.	**1.2** **2.1** **1.4** **1.3** **0.74** **n.d.**	0 +0 14 21 54[4] 54[4]	
Southern Europe Italy 12040 Govone (Piedmont) Decline curve trial 645-2023 IT11	Winter Wheat RECIPROC	1- 25/10/22 2- 13/05/23 to 18/05/23 3- 03/07/23	Broadcast foliar application Boom sprayer	0.1908 (0.1934) 0.1941 (0.1967)	290 295	0.0658 (0.0667) 0.0658 (0.0667)	05/05/23 18/05/23	58 69		PTZ-desthio	PTZ-α-hydroxy-desthio	PTZ-3-hydroxy-desthio	**Sum[1,2]**		Untreated specimen: <LOQ LC-MS/MS method validated within this study Max. study storage interval between: -sampling and extraction: 198 days -extraction and analyses: 7 days
									Forage[3] Forage[3] Forage[3] Forage[3] Straw Grain	0.50 1.16 0.05 0.08 0.13 n.d.	0.13 0.11 0.05 0.05 0.05 n.d.	0.15 0.14 0.10 0.12 0.11 n.d.	- - - - - -	0 +0 13 22 46[4] 46[4]	
										PTZ-4-hydroxy-desthio	PTZ-5-hydroxy-desthio	PTZ-6-hydroxy-desthio			
									Forage[3] Forage[3] Forage[3] Forage[3] Straw Grain	0.14 0.11 0.09 0.10 0.09 n.d.	0.11 0.09 0.07 0.08 0.09 n.d.	0.02 0.02 0.02 0.02 0.01 n.d.	**1.1** **1.7** **0.38** **0.45** **0.48** **n.d.**	0 +0 13 22 46[4] 46[4]	

Southern Europe Spain 41710 Utrera (Andalucia) Decline curve trial 645-2023 SP12	Spring Wheat CALIFA SUR	1- 23/02/23 2- 27/05/23 to 07/06/23 3- 20/07/23	Broadcast foliar application Boom sprayer	0.2001 (0.2028) 0.1957 (0.1983)	304 298	0.0658 (0.0667) 0.0658 (0.0667)	25/05/23 07/06/23	59 69		PTZ-desthio	PTZ-α-hydroxy-desthio	PTZ-3-hydroxy-desthio	**Sum**[1,2]		Untreated specimen: <LOQ LC-MS/MS method validated within this study Max. study storage interval between: -sampling and extraction: 198 days -extraction and analyses: 7 days
									Forage[3] Forage[3] Forage[3] Forage[3] Straw Grain	0.44 2.6 0.58 0.49 1.2 < 0.01	0.23 0.24 0.38 0.41 1.1 n.d.	0.19 0.22 0.33 0.41 0.89 n.d.	- - - - - -	0 +0 13 21 43[4] 43[4]	
										PTZ-4-hydroxy-desthio	PTZ-5-hydroxy-desthio	PTZ-6-hydroxy-desthio			
									Forage[3] Forage[3] Forage[3] Forage[3] Straw Grain	0.15 0.17 0.21 0.25 0.57 n.d.	0.14 0.14 0.22 0.22 0.45 n.d.	0.04 0.04 0.06 0.07 0.15 n.d.	**1.2** **3.4** **1.8** **1.9** **4.4** **0.01**	0 +0 13 21 43[4] 43[4]	
Southern Europe Italy 94015 Piazza Armerina (Sicily) Harvest trial 645-2023 IT13	Winter Wheat CORE	1- 07/11/22 2- 10/04/23 to 26/04/23 3- 19/06/23	Broadcast foliar application Boom sprayer	0.2053 (0.2080) 0.1895 (0.1920)	416 384	0.0493 (0.0500) 0.0493 (0.0500)	12/04/23 26/04/23	61 69		PTZ-desthio	PTZ-α-hydroxy-desthio	PTZ-3-hydroxy-desthio	**Sum**[1,2]		Untreated specimen: <LOQ LC-MS/MS method validated within this study Max. study storage interval between: -sampling and extraction: 198 days -extraction and analyses: 7 days
									Straw Grain	0.89 < 0.01	0.02 n.d.	0.10 n.d.	- -	54[3] 54[3]	
										PTZ-4-hydroxy-desthio	PTZ-5-hydroxy-desthio	PTZ-6-hydroxy-desthio			
									Straw Grain	0.05 n.d.	0.10 n.d.	0.03 n.d.	**1.2** **0.01**	54[3] 54[3]	

Southern Europe Spain 21700 La Palma de Londado (Andalucia) Harvest trial 645-2023 SP14	Winter Wheat ANTALIS	1- 22/12/22 2- 17/04/23 to 26/04/23 3- 16/06/23	Broadcast foliar application Boom sprayer	0.1974 (0.2000) 0.1948 (0.1974)	300 296	0.0658 (0.0667) 0.0658 (0.0667)	13/04/23 26/04/23	59 69	Straw Grain	PTZ-desthio 2.69 0.01	PTZ-α-hydroxy-desthio 0.08 n.d.	PTZ-3-hydroxy-desthio 0.40 n.d.	**Sum**[1,2] - -	49[3] 49[3]	Untreated specimen: <LOQ LC-MS/MS method validated within this study Max. study storage interval between: -sampling and extraction: 198 days -extraction and analyses: 7 days
									Straw Grain	PTZ-4-hydroxy-desthio 0.12 n.d.	PTZ-5-hydroxy-desthio 0.13 n.d.	PTZ-6-hydroxy-desthio 0.03 n.d.	**3.5** **0.01**	49[3] 49[3]	
Southern Europe Greece 57100 Koufalia (Central Macedonia) Harvest trial 645-2023 GR15	Winter Wheat CANNAVARO	1- 15/12/22 2- 27/04/23 to 04/05/23 3- 23/06/23	Broadcast foliar application Boom sprayer	0.1984 (0.2010) 0.1995 (0.2022)	302 303	0.0658 (0.0666) 0.0658 (0.0666)	20/04/23 04/05/23	49 69	Straw Grain	PTZ-desthio 0.22 n.d.	PTZ-α-hydroxy-desthio 0.02 n.d.	PTZ-3-hydroxy-desthio 0.28 n.d.	**Sum**[1,2] - -	49[3] 49[3]	Untreated specimen: <LOQ LC-MS/MS method validated within this study Max. study storage interval between: -sampling and extraction: 198 days -extraction and analyses: 7 days
									Straw Grain	PTZ-4-hydroxy-desthio 0.14 n.d.	PTZ-5-hydroxy-desthio 0.30 n.d.	PTZ-6-hydroxy-desthio 0.03 n.d.	**0.99** **n.d.**	49[3] 49[3]	

Southern Europe Italy 94010 Assoro (Sicily) Harvest trial 645-2023 IT16	Winter Wheat CORE	1- 14/11/22 2- 11/04/23 to 27/04/23 3- 12/06/23	Broadcast foliar application Boom sprayer	0.2003 (0.2030) 0.1974 (0.2000)	406 400	0.0493 (0.0500) 0.0493 (0.0500)	14/04/23 27/04/23	61 69	Straw Grain	PTZ-desthio 1.1 < 0.01	PTZ-α-hydroxy-desthio 0.03 n.d.	PTZ-3-hydroxy-desthio 0.19 n.d.	**Sum**[1,2] - -	46[3] 46[3]	Untreated specimen: <LOQ LC-MS/MS method validated within this study Max. study storage interval between: -sampling and extraction: 198 days -extraction and analyses: 7 days
									Straw Grain	PTZ-4-hydroxy-desthio 0.10 n.d.	PTZ-5-hydroxy-desthio 0.17 n.d.	PTZ-6-hydroxy-desthio 0.03 n.d.	**1.6** **0.01**	46[3] 46[3]	

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

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

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

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

RESIDUE DATA SUMMARY FROM SUPERVISED TRIALS

Active Substance: prothioconazole
Commercial Product: Prothioconazole 250 g/L DC
Crop / crop group: Wheat / cereals
Producer: UPL Europe Limited
Responsible for reporting: Frédéric LEBRUN / TESTAPI
115 route du Pô, 49650 Allonnes – France
Countries: Southern France, Greece, Italy, & Spain
Indoor/glasshouse/outdoor: outdoor
Nominal Content of a.s.: 250 g/L
Other a.s. in formulation:
Formulation: DC
Residue calculated as: triazole derivative metabolites (T, TA, TAA, TLA) (mg/kg)

1	2	3	4	5			6	7	8	9				10	11
Report No. 645-2023 Location (region)	Commodity Variety	Date of 1-Planting 2-Flowering 3-Harvest	Method of treatment	Actual (nominal) application rate per treatment			Date of treatment	BBCH Crop Growth Stage at treatment	Portions analysed	Residues (1)				DALA (2)	Remarks
				kg a.s./ha	Water (L/ha)	kg (a.s./hL)				T	TA	TAA	TLA		
Southern Europe Southern France 79100 Plaine et Vallées (Nouvelle Aquitaine) Decline – curve trial 645-2023 FR09	Winter Wheat KWS SPHERE	1- 21/10/22 2- 14/05/23 to 26/05/23 3- 05/07/23 to 10/07/23	Broadcast foliar application Boom sprayer	0.1918 (0.1944) 0.1985 (0.2011)	194 201	0.0986 (0.1000) 0.0987 (0.1000)	12/05/23 25/05/23	59 69	**Untreated** Forage(3) Forage(3) Forage(3) Forage(3) Straw Grain **Treated** Forage(3) Forage(3) Forage(3) Forage(3) Straw Grain	n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d.	0.03 0.04 0.04 0.04 n.d. 0.08 0.07 0.06 0.12 0.14 < 0.01 0.19	0.03 0.04 0.05 0.05 0.05 0.08 0.03 0.03 0.05 0.07 0.06 0.09	0.04 0.04 0.03 0.03 0.03 n.d. 0.05 0.05 0.06 0.06 0.05 n.d.	0 +0 13 20 42(4) 42(4) 0 +0 13 20 42(4) 42(4)	LC-MS/MS Method Validated in within this study Max. study storage interval between: sampling and extraction: 178 days extraction and analyses: 4 days
Southern Europe Greece 57400 – Sindos (Central Macedonia)	Winter Wheat ACHILLE	1- 16/11/22 2- 17/04/23 to 27/04/23 3- 22/06/23	Broadcast foliar application Boom sprayer	0.1978 (0.2004) 0.1979 (0.2005)	301 301	0.0658 (0.0667) 0.0658 (0.0667)	12/04/23 27/04/23	39 69	**Untreated** Forage(3) Forage(3) Forage(3) Forage(3) Straw Grain **Treated**	n.d. n.d. n.d. n.d. n.d. n.d.	0.01 0.01 0.02 < 0.01 n.d. 0.04	< 0.01 < 0.01 0.01 < 0.01 < 0.01 0.02	< 0.01 < 0.01 < 0.01 < 0.01 n.d. n.d.	0 +0 14 21 54(4) 54(4)	LC-MS/MS Method Validated in within this study Max. study storage interval between:

Decline – curve trial 645-2023-GR10									Forage[3] Forage[3] Forage[3] Forage[3] Straw Grain	n.d. n.d. n.d. n.d. n.d. n.d.	0.02 0.02 0.03 0.08 0.01 0.28	< 0.01 0.01 0.02 0.02 0.02 0.09	< 0.01 0.01 0.01 0.02 < 0.01 n.d.	-0 +0 14 21 54[4] 54[4]	-sampling and extraction: 178 days -extraction and analyses: 4 days
Southern Europe Italy 12040 – Govone (Piedmont) Decline – curve trial 645-2023-IT11	Winter Wheat RECIPROC	1- 25/10/22 2- 13/05/23 to 18/05/23 3- 03/07/23	Broadcast foliar application Boom sprayer	0.1908 (0.1934) 0.1941 (0.1967)	290 295	0.0658 (0.0667) 0.0658 (0.0667)	05/05/23 18/05/23	58 69	**Untreated** Forage[3] Forage[3] Forage[3] Forage[3] Straw Grain **Treated** Forage[3] Forage[3] Forage[3] Forage[3] Straw Grain	n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d.	n.d. < 0.01 < 0.01 < 0.01 n.d. 0.03 0.08 0.07 0.10 0.15 0.01 0.24	< 0.01 < 0.01 < 0.01 < 0.01 < 0.01 0.02 < 0.01 0.01 0.01 0.02 0.03 0.06	< 0.01 < 0.01 < 0.01 n.d. n.d. n.d. 0.03 0.03 0.03 0.03 0.02 n.d.	-0 +0 13 22 46[4] 46[4] -0 +0 13 22 46[4] 46[4]	LC-MS/MS Method Validated in within this study Max. study storage interval between: -sampling and extraction: 178 days -extraction and analyses: 4 days
Southern Europe Spain 41710 – Utrera (Andalucia) Decline – curve trial 645-2023-SP12	Spring Wheat CALIFA SUR	1- 23/02/23 2- 27/05/23 to 07/06/23 3- 20/07/23	Broadcast foliar application Boom sprayer	0.2001 (0.2028) 0.1957 (0.1983)	304 298	0.0658 (0.0667) 0.0658 (0.0667	25/05/23 07/06/23	59 69	**Untreated** Forage[3] Forage[3] Forage[3] Forage[3] Straw Grain **Treated** Forage[3] Forage[3] Forage[3] Forage[3] Straw Grain	n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d. < 0.01	0.01 0.01 0.01 < 0.01 n.d. 0.03 0.16 0.18 0.25 0.21 0.05 0.72	0.01 < 0.01 0.01 0.01 0.01 0.02 0.03 0.03 0.05 0.08 0.11 0.14	< 0.01 < 0.01 0.02 0.01 0.01 n.d. 0.06 0.06 0.13 0.16 0.21 0.01	-0 +0 13 21 43[4] 43[4] -0 +0 13 21 43[4] 43[4]	LC-MS/MS Method Validated in within this study Max. study storage interval between: -sampling and extraction: 178 days -extraction and analyses: 4 days
Southern Europe Italy 94015 – Piazza Armerina (Sicily)	Winter Wheat CORE	1- 07/11/22 2- 10/04/23 to 26/04/23 3- 19/06/23	Broadcast foliar application Boom sprayer	0.2053 (0.2080) 0.1895 (0.1920)	416 384	0.0493 (0.0500) 0.0493 (0.0500)	12/04/23 26/04/23	61 69	**Untreated** Straw Grain	n.d. n.d.	n.d. 0.01	< 0.01 0.02	n.d. n.d.	54[3] 54[3]	LC-MS/MS Method Validated in within this study Max. study storage interval between:

Harvest trial 645-2023-IT13									**Treated** Straw Grain	 n.d. n.d.	 n.d. 0.02	 n.d. 0.02	 n.d. n.d.	 54(3) 54(3)	-sampling and extraction: 178 days -extraction and analyses: 4 days
Southern Europe Spain 21700 La Palma de Londado (Andalucia) Harvest trial 645-2023-SP14	Winter Wheat ANTALIS	1- 22/12/22 2- 17/04/23 to 26/04/23 3- 16/06/23	Broadcast foliar application Boom sprayer	0.1974 (0.2000) 0.1948 (0.1974)	300 296	0.0658 (0.0667) 0.0658 (0.0667)	13/04/23 26/04/23	59 69	**Untreated** Straw Grain **Treated** Straw Grain	 n.d. n.d. <0.01 n.d.	 <0.01 0.03 0.01 0.04	 0.01 0.04 0.02 0.04	 n.d. n.d. n.d. n.d.	 49(3) 49(3) 49(3) 49(3)	LC-MS/MS Method Validated in within this study Max. study storage interval between: -sampling and extraction: 178 days -extraction and analyses: 4 days
Southern Europe Greece 57100 Koufalia (Central Macedonia) Harvest trial 645-2023-GR15	Winter Wheat CANNAVARO	1- 15/12/22 2- 27/04/23 to 04/05/23 3- 23/06/23	Broadcast foliar application Boom sprayer	0.1984 (0.2010) 0.1995 (0.2022)	302 303	0.0658 (0.0666) 0.0658 (0.0666)	20/04/23 04/05/23	49 69	**Untreated** Straw Grain **Treated** Straw Grain	 n.d. n.d. n.d. n.d.	 n.d. 0.06 <0.01 0.17	 <0.01 0.03 0.01 0.04	 <0.01 n.d. 0.01 n.d.	 49(3) 49(3) 49(3) 49(3)	LC-MS/MS Method Validated in within this study Max. study storage interval between: -sampling and extraction: 178 days -extraction and analyses: 4 days
Southern Europe Italy 94010 Assoro (Sicily)	Winter Wheat CORE	1- 14/11/22 2- 11/04/23 to 27/04/23 3- 12/06/23	Broadcast foliar application Boom sprayer	0.2003 (0.2030) 0.1974	406 400	0.0493 (0.0500) 0.0493	14/04/23 27/04/23	61 69	**Untreated** Straw Grain	 n.d. n.d.	 n.d. <0.01	 n.d. <0.01	 n.d. n.d.	 46(3) 46(3)	LC-MS/MS Method Validated in within this study

Harvest trial 645-2023-IT16				(0.2000)		(0.0500)			**Treated** Straw Grain	 n.d. n.d.	 < 0.01 0.02	 < 0.01 < 0.01	 n.d. n.d.	 46[3] 46[3]	Max. study storage interval between: -sampling and extraction: 178 days -extraction and analyses: 4 days

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

A 2.2.3.2 Barley

Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (DAR, RMS, year)	2	200 g as / ha	14 to 21 days	BBCH 61	35
cGAP EU (Art. 12, EFSA, year)	2	200 g as / ha	14 to 21 days	BBCH 69	35
Intended cGAP (numbers 5, 6)*	1	1 L product per ha (200 g prothioconazole per ha)	Not applicable	BBCH 59	35 (GSR)

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0
** Timing of applications determined primarily by growth stage; 1st application not later than BBCH 39, 2nd application no later than BBCH 59.
GSR: Growth Stage Restricted

The following tables provide a summary of the available data from the residue trials:

Commodity	Trial	Residue trials zone	PTZ-Desthio	PTZ-α	PTZ-3	PTZ-4	PTZ-5	PTZ-6	T	TA	TAA	TLA
Barley grain	646-2023	North EU	0.12	<0.01	0.02	<0.01	<0.01	nd	nd	0.1	0.06	<0.01
Barley grain	646-2023	North EU	0.05	<0.01	0.01	<0.01	0.01	nd	nd	0.22	0.13	<0.01
Barley grain	646-2023	North EU	nd	nd	nd	nd	nd	nd	nd	0.45	0.22	<0.01
Barley grain	646-2023	North EU	<0.01	nd	<0.01	nd	<0.01	nd	nd	0.48	0.25	0.01
Barley grain	646-2023	North EU	0.02	nd	0.01	<0.01	0.01	nd	nd	0.07	0.03	nd
Barley grain	646-2023	North EU	<0.01	nd	<0.01	nd	nd	nd	nd	0.12	0.04	nd
Barley grain	646-2023	North EU	nd	nd	nd	nd	nd	nd	nd	0.22	0.07	nd
Barley grain	646-2023	North EU	0.01	nd	<0.01	nd	nd	nd	nd	0.2	0.05	nd
STMR (mg/kg):			0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0.21	0.07	<0.01
HR (mg/kg):			0.12	<0.01	0.02	<0.01	0.01	<0.01	<0.01	0.48	0.25	0.01

Commodity	Trial	Residue trials zone	PTZ-Desthio	PTZ-α	PTZ-3	PTZ-4	PTZ-5	PTZ-6	T	TA	TAA	TLA
Barley straw	646-2023	North EU	0.54	0.08	0.19	0.16	0.08	< 0.01	n.d.	< 0.01	0.02	0.02
Barley straw	646-2023	North EU	1.5	0.16	0.25	0.37	0.16	< 0.01	n.d.	< 0.01	0.02	0.02
Barley straw	646-2023	North EU	0.03	< 0.01	0.03	0.04	0.02	n.d.	n.d.	0.01	0.04	0.05
Barley straw	646-2023	North EU	<0.01	< 0.01	0.01	0.01	< 0.01	n.d.	n.d.	0.10	0.07	0.12
Barley straw	646-2023	North EU	0.43	0.03	0.12	0.15	0.08	0.01	n.d.	0.03	0.05	0.03
Barley straw	646-2023	North EU	0.12	0.01	0.08	0.05	0.05	n.d.	n.d.	< 0.01	< 0.01	0.02
Barley straw	646-2023	North EU	0.1	< 0.01	0.05	0.03	0.02	n.d.	n.d.	0.01	< 0.01	0.01
Barley straw	646-2023	North EU	0.07	< 0.01	0.05	0.03	0.03	n.d.	n.d.	0.04	0.04	0.09
STMR (mg/kg):			0.11	0.01	0.065	0.045	0.04	<0.01	<0.01	0.01	0.03	0.025
HR (mg/kg):			1.5	0.16	0.25	0.37	0.16	0.01	<0.01	0.1	0.07	0.12

~~Commodity~~	~~Trial~~	~~Residue trials zone~~	~~PTZ-Desthio~~	~~PTZ-α~~	~~PTZ-3~~	~~PTZ-4~~	~~PTZ-5~~	~~PTZ-6~~	~~T~~	~~TA~~	~~TAA~~	~~TLA~~
~~Barley grain~~	~~646-2023~~	~~South EU~~	~~0.11~~	~~<0.01~~	~~0.02~~	~~0.01~~	~~0.01~~	~~nd~~	~~nd~~	~~0.08~~	~~0.08~~	~~<0.01~~
~~Barley grain~~	~~646-2023~~	~~South EU~~	~~<0.01~~	~~nd~~	~~<0.01~~	~~nd~~	~~<0.01~~	~~nd~~	~~nd~~	~~0.24~~	~~0.08~~	~~<0.01~~

Barley grain	646-2023	South EU	0.01	nd	<0.01	nd	<0.01	nd	nd	0.14	0.04	nd
Barley grain	646-2023	South EU	0.02	nd	<0.01	nd	nd	nd	nd	0.21	0.06	<0.01
Barley grain	646-2023	South EU	<0.01	nd	nd	nd	nd	nd	nd	0.34	0.15	0.02
Barley grain	646-2023	South EU	0.02	nd	<0.01	nd	<0.01	nd	nd	0.13	0.05	<0.01
Barley grain	646-2023	South EU	0.01	nd	<0.01	nd	<0.01	nd	nd	0.19	0.12	0.02
		STMR (mg/kg):	0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0.19	0.08	<0.01
		HR (mg/kg):	0.11	<0.01	0.02	0.01	0.01	<0.01	<0.01	0.34	0.12	0.02

* The row highlighted in grey indicate an outlier (as determined by statistical analysis). The impacted results are not included within the calculations of the HR / STMR endpoints

Commodity	Trial	Residue trials zone	PTZ-Desthio	PTZ-α	PTZ-3	PTZ-4	PTZ-5	PTZ-6	T	TA	TAA	TLA
Barley straw	646-2023	South EU	0.98	0.13	0.25	0.28	0.14	< 0.01	n.d.	n.d.	0.03	0.04
Barley straw	646-2023	South EU	0.16	0.02	0.14	0.11	0.12	< 0.01	n.d.	0.04	0.05	0.06
Barley straw	646-2023	South EU	0.04	< 0.01	0.03	0.04	0.04	n.d.	n.d.	0.07	0.02	0.02
Barley straw	646-2023	South EU	1.3	0.10	0.20	0.16	0.12	0.01	n.d.	0.04	0.08	0.04
Barley straw	646-2023	South EU	0.21	0.04	0.24	0.19	0.08	< 0.01	n.d.	0.09	0.10	0.12
Barley straw	646-2023	South EU	0.39	0.03	0.17	0.19	0.13	< 0.01	n.d.	< 0.01	0.02	0.02
Barley straw	646-2023	South EU	0.23	0.04	0.14	0.19	0.11	< 0.01	n.d.	< 0.01	0.03	0.02
		STMR (mg/kg):	0.31	0.04	0.155	0.175	0.115	<0.01	<0.01	0.04	0.03	0.04
		HR (mg/kg):	1.3	0.13	0.25	0.28	0.14	<0.01	0.01	0.09	0.1	0.12

* The row highlighted in grey indicate an outlier (as determined by statistical analysis of the results for barley grain). The impacted results are not included within the calculations of the HR / STMR endpoints

Barley Study 1 Bougrier 2024; 646-2023 - Northern and Southern Europe (new data)

Comments of zRMS:	Eight independent trials (4 decline and 4 harvest) located in Northern Europe (Northern France, Germany, Poland, Belgium, The Netherlands and Denmark) were conducted on barley (RAC) following two applications of Prothioconazole 250 g/L DC (200 g as/ha) to determine of the residues of prothioconazole metabolites: PTZ-dethio, PTZ-alpha-OH-desthio, PTZ-3-OH-desthio, PTZ-4-OH-desthio, PTZ-5-OH-desthio, PTZ-6-OH-desthio, 1,2,4-Triazole (T), Triazole alanine (TA), Triazole acetic acid (TAA), Triazole lactic acid (TLA) in barley specimens: forage, grain and straw. The first application was performed 14 +/-1 days before the second application (actual: 13 to 15 days). The second application was performed on the treated plot at BBCH 69. The methods were successfully validated for determination of all analytes in all matrices with an LOQ of 0.01 mg/kg according to guidance document SANTE/2020/12830, rev. 2. Max. study storage interval between sampling and extraction for PTZ and hydroxy-metabolites of PTZ was 354 days, for TDMs was 185 days. The study on the magnitude of residues is valid with regard to storage stability. <u>Residue results:</u> No residue of PTZ-desthio, PTZ-alpha-OH-desthio, PTZ-3-OH-desthio, PTZ-4-OH-desthio, PTZ-5-OH-desthio and PTZ-6-OH-desthio, all expressed in PTZ-desthio, was measured in the untreated specimens above the LOQ. In the specimens originating from the untreated plots, no residues of T were detected in any

	of the untreated specimens, while residues of TAA, TA and TLA were measured above the LOQ in several field specimens. PTZ: In the treated grain specimens at harvest, residue levels of PTZ-desthio ranged between <0.01 mg/kg – 0.12 mg/kg, and the sum of hydroxy- derivatives of prothioconazole-desthio ranged between <0.06 mg/kg – 0.17 mg/kg. TDMs: In the treated specimens, residue levels of 1,2,4-triazole in grain specimens at harvest were never above the LOD. In the treated specimens residues of TA, TAA and TLA in grain at harvest ranged between: - TA: 0.05 – 0.48 mg/kg, - TAA: 0.03 – 0.25 mg/kg, - TLA: <0.01 – 0.01 mg/kg. The study is acceptable. These trials can be used to support the intended use on barley.

Reference:	KCP 8.3.2/06
Report	Magnitude of the residue of prothioconazole metabolites in barley in Northern and Southern Europe – 2023; M. Bougrier, 2024 ;Study Number: 646-2023
Guideline(s):	• Regulation (EC) N°1107/2009 of 21 October 2009 (Repealing the Council Directives 79/117/EEC and 91/414/EEC) concerning the placing of plant protection products on the market • Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market • OECD (2021), Test No. 509: Crop Field Trial, OECD Guidelines for the Testing of Chemicals, Section 5, OECD Publishing • SANTE/2020/12830, Rev.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) • OECD (2007), Guidance Document on Pesticide Residue Analytical Methods. Series on testing and assessment Number 72. Series on pesticides Number 39. ENV/JM/MONO(2007)17 • The Application of GLP Principles to Field Studies, OECD Series on Principles of GLP and Compliance Monitoring Number 6 (Revised 1999), ENV/JM/MONO(99)22 • The Application of the OECD Principles of GLP to the Organisation and Management of Multi-Site Studies, OECD Series on Principles of GLP and Compliance Monitoring Number 13, ENV/JM/MONO(2002)9
Deviations:	None.
GLP:	Yes
Acceptability:	Acceptable

At the time of the submission of this dossier, the field and analytical phases of the study 646-2023 have been completed, however the final study report has not yet been issued at this time. The following tables include a summary of the residues data which were provided within the non-QA preliminary data report. These data can be used in the interim to conduct the risk assessment and progress the evaluation of the intended use. When the final report is available, the report will be provided and this study summary will be

updated.

Sampling Occasion	Treatment	Sample Id	EAS Chem Internal code	Sample Type	Residue of 1,2,4-Triazole (mg/kg)	Residue of Triazole alanine (mg/kg)	Residue of Triazole acetic acid (mg/kg)	Residue of Triazole lactic acid (mg/kg)
Trial 646-2023 FR09								
S1 = 0 DBA2	U	646-2023 FR09 1	901	Forage *	n.d.	0.01	0.02	0.03
S2 = + 0 DAA2	U	646-2023 FR09 3	903	Forage *	n.d.	0.01	0.02	0.03
S3 = 14 +/-1 DAA2	U	646-2023 FR09 5	905	Forage *	n.d.	< 0.01	0.02	0.01
S4 = 21 +/-2 DAA2	U	646-2023 FR09 7	907	Forage *	n.d.	0.01	0.03	0.02
S5 = CH – BBCH 89	U	646-2023 FR09 9	909	Straw	n.d.	n.d.	0.02	0.03
S5 = CH – BBCH 89	U	646-2023 FR09 10	910	Grain	n.d.	0.02	0.05	n.d.
S1 = 0 DBA2	T	646-2023 FR09 2	902	Forage *	n.d.	0.02	0.03	0.04
S2 = + 0 DAA2	T	646-2023 FR09 4	904	Forage *	n.d.	0.03	0.03	0.03
S3 = 14 +/-1 DAA2	T	646-2023 FR09 6	906	Forage *	n.d.	0.04	0.04	0.02
S4 = 21 +/-2 DAA2	T	646-2023 FR09 8	908	Forage *	n.d.	0.03	0.04	0.04
S5 = CH – BBCH 89	T	646-2023 FR09 11	911	Straw	n.d.	n.d.	0.03	0.04
S5 = CH – BBCH 89	T	646-2023 FR09 12	912	Grain	n.d.	0.08	0.08	< 0.01
Trial 646-2023 GR10								
S1 = 0 DBA2	U	646-2023 GR10 1	1001	Forage *	n.d.	< 0.01	< 0.01	0.02
S2 = + 0 DAA2	U	646-2023 GR10 3	1003	Forage *	n.d.	< 0.01	< 0.01	0.01
S3 = 14 +/-1 DAA2	U	646-2023 GR10 5	1005	Forage *	n.d.	n.d.	n.d.	n.d.
S4 = 21 +/-2 DAA2	U	646-2023 GR10 7	1007	Forage *	n.d.	< 0.01	n.d.	< 0.01
S5 = CH – BBCH 89	U	646-2023 GR10 9	1009	Straw	n.d.	n.d.	0.01	< 0.01
S5 = CH – BBCH 89	U	646-2023 GR10 10	1010	Grain	n.d.	0.01	< 0.01	n.d.
S1 = 0 DBA2	T	646-2023 GR10 2	1002	Forage *	n.d.	0.04	< 0.01	0.04
S2 = + 0 DAA2	T	646-2023 GR10 4	1004	Forage *	n.d.	0.04	< 0.01	0.03
S3 = 14 +/-1 DAA2	T	646-2023 GR10 6	1006	Forage *	n.d.	0.07	0.02	0.03
S4 = 21 +/-2 DAA2	T	646-2023 GR10 8	1008	Forage *	n.d.	0.09	0.02	0.03
S5 = CH – BBCH 89	T	646-2023 GR10 11	1011	Straw	n.d.	0.04	0.05	0.06
S5 = CH – BBCH 89	T	646-2023 GR10 12	1012	Grain	n.d.	0.24	0.08	< 0.01
Trial 646-2023 IT11								
S1 = 0 DBA2	U	646-2023 IT11 1	1101	Forage *	n.d.	n.d.	n.d.	n.d.
S2 = + 0 DAA2	U	646-2023 IT11 3	1103	Forage *	n.d.	n.d.	n.d.	n.d.
S3 = 14 +/-1 DAA2	U	646-2023 IT11 5	1105	Forage *	n.d.	n.d.	n.d.	n.d.
S4 = 21 +/-2 DAA2	U	646-2023 IT11 7	1107	Forage *	n.d.	n.d.	n.d.	n.d.
S5 = CH – BBCH 89	U	646-2023 IT11 9	1109	Straw	n.d.	n.d.	n.d.	n.d.

S5 = CH – BBCH 89	U	646-2023 IT11 10	1110	Grain	n.d.	< 0.01	n.d.	n.d.
S1 = 0 DBA2	T	646-2023 IT11 2	1102	Forage *	n.d.	n.d.	n.d.	n.d.
S2 = + 0 DAA2	T	646-2023 IT11 4	1104	Forage *	n.d.	< 0.01	n.d.	n.d.
S3 = 14 +/-1 DAA2	T	646-2023 IT11 6	1106	Forage *	n.d.	0.04	< 0.01	< 0.01
S4 = 21 +/-2 DAA2	T	646-2023 IT11 8	1108	Forage *	n.d.	0.04	< 0.01	< 0.01
S5 = CH – BBCH 89	T	646-2023 IT11 11	1111	Straw	n.d.	0.07	0.02	0.02
S5 = CH – BBCH 89	T	646-2023 IT11 12	1112	Grain	n.d.	0.14	0.04	n.d.

Summary of the barley study 1 trials for prothioconazole-desthio and prothioconazole-hydroxy-desthio metabolites
RESIDUE DATA SUMMARY FROM SUPERVISED TRIALS

Active Substance: prothioconazole
Commercial Product: Prothioconazole 250 g/L DC
Crop / crop group: Barley / cereals
Producer: UPL Europe Limited
Responsible for reporting: Frédéric LEBRUN / TESTAPI
115 route du Pô, 49650 Allonnes - France
Countries: Germany, Poland, Denmark, the Netherlands,France, Greece, Italy, & Spain
Indoor/glasshouse/outdoor: outdoor
Nominal Content of a.s.: 250 g/L
Other a.s. in formulation: -
Formulation: DC
Residue calculated as: Prothioconazole-desthio (enforcement residue definition)
Prothioconazole-alpha-hydroxy-desthio, prothioconazole-3-hydroxy-desthio,prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio expressed as prothioconazole-desthio (mg/kg) (risk assessment residue definition)

1	2	3	4	5			6	7	8	9				10	11
Report No. 646-2023 Location (region)	Commodity Variety	Date of 1-Planting 2-Flowering 3-Harvest	Method of treatment	Actual application rate per treatment			Date of treatment	BBCH Crop Growth Stage at treatment	Portions analysed	Residues **expressed in prothioconazole-desthio** (1) PTZ = prothioconazole				DALA (2)	Remarks
				kg a.s./ha	Water (L/ha)	kg (a.s./hL)									
Northern Europe Northern France 49650 Allonnes (pays de la Loire) 646-2023 FR01	Spring barley PLANET	1- 15/02/23 2- 26/05/23 to 06/06/23 3- 12/07/23	Broadcast foliar application Boom sprayer	0.1995 0.1990	202 202	0.0986 0.0987	22/05/23 05/06/23	58 69		PTZ-desthio	PTZ-α-hydroxy-desthio	PTZ-3-hydroxy-desthio	**Sum[1,2]**		Untreated specimen: <LOQ LC-MS/MS method validated within this study Max. study storage interval between: -sampling and extraction: 354 days -extraction and analyses: 5 days *retain sample LOQ: 0.01 mg/kg for each analyte, 0.06 mg/kg for prothioconazole
									Forage [3]	0.75	0.03	0.12	-	-0	
									Forage [3]	2.0	0.02	0.13	-	+0	
									Forage [3]	1.3	0.05	0.21	-	14	
									Forage [3]	1.2	0.09	0.25	-	22	
									Straw	0.54	0.08	0.19	-	37	
									Grain	0.12	<0.01	0.02	-	37	
									Grain*	0.12	-	-		37	
										PTZ-4-hydroxy-desthio	PTZ-5-hydroxy-desthio	PTZ-6-hydroxy-desthio			
									Forage [3]	0.27	0.07	<0.01	**1.3**	-0	
									Forage [3]	0.27	0.08	<0.01	**2.5**	+0	
									Forage [3]	0.30	0.09	0.01	**2.0**	14	
									Forage [3]	0.25	0.11	0.01	**1.9**	22	
									Straw	0.16	0.08	<0.01	**1.1**	37	
									Grain	<0.01	<0.01	n.d.	**0.17**	37	

															expressed as prothioconazole desthio as a sum of metabolites
Northern Europe Germany 46342 Velen-Ramsdorf (North Rhine Westphalia) 646-2023 GE02	Spring barley QUENCH	1- 15/04/23 2- 12/06/23 to 23/06/23 3- 21/07/23	Broadcast foliar application Boom sprayer	0.1991 0.2009	303 305	0.0658 0.0658	09/06/23 23/06/23	56 69		PTZ-desthio	PTZ-α-hydroxy-desthio	PTZ-3-hydroxy-desthio	**Sum[1,2]**		Untreated specimen: <LOQ LC-MS/MS method validated within this study Max. study storage interval between: -sampling and extraction: 354 days -extraction and analyses: 5 days LOQ: 0.01 mg/kg for each analyte, 0.06 mg/kg for prothioconazole expressed as prothioconazole desthio as a sum of metabolites;
									Forage [3]	0.31	n.d.	0.06	-	-0	
									Forage [3]	0.67	n.d.	0.06	-	+0	
									Forage [3]	1.1	0.01	0.13	-	13	
									Forage [3]	0.68	0.02	0.11	-	20	
									Straw	1.5	0.16	0.25	-	28	
									Grain	0.05	<0.01	0.01	-	28	
										PTZ-4-hydroxy-desthio	PTZ-5-hydroxy-desthio	PTZ-6-hydroxy-desthio			
									Forage [3]	0.11	0.04	.<0.01	**0.53**	-0	
									Forage [3]	0.11	0.04	.<0.01	**0.89**	+0	
									Forage [3]	0.20	0.07	.<0.01	**1.5**	13	
									Forage [3]	0.19	0.07	.<0.01	**1.1**	20	
									Straw	0.37	0.16	.<0.01	**2.5**	28	
									Grain	<0.01	0.01	n.d.	**0.09**	28	
Northern Europe Poland 55-200 Gać (Lower Silesia) 646-2023 PL03	Spring barley FEEDWAY	1- 22/04/23 2- 11/06/23 to 16/06/23 3- 12/08/23	Broadcast foliar application Boom sprayer	0.1987 0.1979	302 301	0.0658 0.0658	02/06/23 16/06/23	37-39 69		PTZ-desthio	PTZ-α-hydroxy-desthio	PTZ-3-hydroxy-desthio	**Sum[1,2]**		Untreated specimen: <LOQ LC-MS/MS method validated within this study
									Forage [3]	0.84	0.01	0.13	-	-0	
									Forage [3]	1.8	0.01	0.14	-	+0	
									Forage [3]	0.85	0.03	0.27	-	14	
									Forage [3]	0.42	0.02	0.19	-	21	
									Straw	0.03	<0.01	0.03	-	57	
									Grain	n.d.	n.d.	n.d.	-	57	

										PTZ-4-hydroxy-desthio	PTZ-5-hydroxy-desthio	PTZ-6-hydroxy-desthio			Max. study storage interval between: -sampling and extraction: 354 days -extraction and analyses: 5 days LOQ: 0.01 mg/kg for each analyte, 0.06 mg/kg for prothioconazole expressed as prothioconazole desthio as a sum of metabolites
									Forage [3]	0.15	0.07	.<0.01	**1.2**	-0	
									Forage [3]	0.17	0.07	<0.01	**2.2**	+0	
									Forage [3]	0.25	0.12	0.01	**1.5**	14	
									Forage [3]	0.16	0.08	<0.01	**0.88**	21	
									Straw	0.04	0.02	n.d.	**0.13**	57	
									Grain	n.d.	n.d.	n.d.	**<0.06**	57	
Northern Europe The Netherlands 5853EJ Siebengewald (Limburg) 646-2023 NL04	Spring barley RGT PLANET	1- 19/04/23 2- 19/06/23 to 30/06/23 3- 08/08/23	Broadcast foliar application Boom sprayer	0.1965 0.1991	299 303	0.0658 0.0658	16/06/23 30/06/23	57-59 69		PTZ-desthio	PTZ-α-hydroxy-desthio	PTZ-3-hydroxy-desthio	**Sum[1,2]**		Untreated specimen: <LOQ LC-MS/MS method validated within this study Max. study storage interval between: -sampling and extraction: 354 days -extraction and analyses: 5 days LOQ: 0.01 mg/kg for each analyte, 0.06 mg/kg for prothioconazole expressed as prothioconazole desthio as a sum of metabolites
									Forage [3]	0.48	<0.01	0.06	-	-0	
									Forage [3]	1.2	0.01	0.06	-	+0	
									Forage [3]	0.9	0.03	0.08	-	14	
									Forage [3]	1.1	0.04	0.09	-	20	
									Straw	0.05	<0.01	0.01	-	39	
									Grain	<0.01	n.d.	<0.01	-	39	
										PTZ-4-hydroxy-desthio	PTZ-5-hydroxy-desthio	PTZ-6-hydroxy-desthio			
									Forage [3]	0.07	0.02	.<0.01	**0.65**	-0	
									Forage [3]	0.08	0.03	<0.01	**1.4**	+0	
									Forage [3]	0.06	0.03	<0.01	**1.1**	14	
									Forage [3]	0.08	0.04	<0.01	**1.4**	20	
									Straw	0.01	<0.01	n.d.	**0.09**	39	
									Grain	n.d.	<0.01	n.d.	**<0.06**	39	

Northern Europe Belgium 6221 Saint-Amand (Province of Hainault) 646-2023 BE05	Winter barley ESPRIT	1- 31/10/22 2- 19/05/23 to 31/05/23 3- 04/07/23 to 11/07/23	Broadcast foliar application Boom sprayer	0.1988 0.1930	302 293	0.0658 0.0658	17/05/23 31/0523	55 69		PTZ-desthio Straw 0.43 Grain 0.02	PTZ-α-hydroxy-desthio 0.03 n.d.	PTZ-3-hydroxy-desthio 0.12 0.01	**Sum[1,2]** - -	34 34	Untreated specimen: <LOQ LC-MS/MS method validated within this study Max. study storage interval between: -sampling and extraction: 354 days -extraction and analyses: 5 days LOQ: 0.01 mg/kg for each analyte, 0.06 mg/kg for prothioconazole expressed as prothioconazole desthio as a sum of metabolites
										PTZ-4-hydroxy-desthio Straw 0.15 Grain <0.01	PTZ-5-hydroxy-desthio 0.08 0.01	PTZ-6-hydroxy-desthio 0.01 n.d..	**0.82** **<0.06**	34 34	
Northern Europe Germany 04827 Gerichshain (Saxony) 646-2023 GE06	Spring barley RGT PLANET	1- 19/04/23 2- 09/06/23 to 22/06/23 3- 19/08/23	Broadcast foliar application Boom sprayer	0.2000 0.1895	304 288	0.0658 0.0658	09/06/23 22/06/23	59-61 69		PTZ-desthio Straw 0.12 Grain <0.01	PTZ-α-hydroxy-desthio 0.01 n.d.	PTZ-3-hydroxy-desthio 0.08 <0.01	**Sum[1,2]** - -	58 58	Untreated specimen: <LOQ LC-MS/MS method validated within this study Max. study storage interval between: -sampling and extraction: 354 days -extraction and analyses: 5 days LOQ: 0.01 mg/kg for each analyte, 0.06 mg/kg for prothioconazole expressed as prothioconazole
										PTZ-4-hydroxy-desthio Straw 0.05 Grain n.d.	PTZ-5-hydroxy-desthio 0.05 n.d.	PTZ-6-hydroxy-desthio n.d. n.d..	**0.31** **<0.06**	58 58	

															desthio as a sum of metabolites
Northern Europe Poland 48320 Czamolas (Opolskie Province) 646-2023 PL07	Spring barley FREEDWAY	1- 22/03/23 2- 09/06/23 to 16/06/23 3- 11/08/23	Broadcast foliar application Boom sprayer	0.1946 0.1960	296 298	0.0658 0.0658	01/06/23 16/06/23	39-41 69	Straw Grain	PTZ-desthio 0.06 n.d.	PTZ-α-hydroxy-desthio <0.01 n.d.	PTZ-3-hydroxy-desthio 0.05 n.d.	**Sum[1,2]** - -	 56 56	Untreated specimen: <LOQ LC-MS/MS method validated within this study Max. study storage interval between: -sampling and extraction: 354 days -extraction and analyses: 5 days LOQ: 0.01 mg/kg for each analyte, 0.06 mg/kg for prothioconazole expressed as prothioconazole desthio as a sum of metabolites
									Straw Grain	PTZ-4-hydroxy-desthio 0.03 n.d.	PTZ-5-hydroxy-desthio 0.02 n.d.	PTZ-6-hydroxy-desthio n.d. n.d..	 **0.17** **<0.06**	 56 56	
Northern Europe Denmark 5580 Norre Aby (South Denmark)	Spring barley PROSPECT	1- 22/03/23 2- 09/06/23 to 16/06/23 3- 11/08/23	Broadcast foliar application Boom sprayer	0.2039 0.1941	207 197	0.0987 0.0987	25/06/23 09/07/23	52-55 69	Straw Grain	PTZ-desthio 0.07 0.01	PTZ-α-hydroxy-desthio <0.01 n.d.	PTZ-3-hydroxy-desthio 0.05 <0.01	**Sum[1,2]** - -	 44 44	Untreated specimen: <LOQ LC-MS/MS method validated within this study

646-2023 DK-08									Straw Grain	PTZ-4-hydroxy-desthio 0.03 n.d.	PTZ-5-hydroxy-desthio 0.03 n.d.	PTZ-6-hydroxy-desthio n.d. n.d..	**0.19** **<0.06**	44 44	Max. study storage interval between: -sampling and extraction: 354 days -extraction and analyses: 5 days LOQ: 0.01 mg/kg for each analyte, 0.06 mg/kg for prothioconazole expressed as prothioconazole desthio as a sum of metabolites
~~Southern Europe~~ ~~Southern France~~ ~~796600 Availles-Thouarsais (Nouvelle Aquitaine)~~ ~~646-2023 FR09~~	~~Spring barley~~ ~~RGT PLANET~~	~~1- 15/02/23~~ ~~2- 27/05/23 to 08/06/23~~ ~~3- 01/07/23 to 10/07/23~~	~~Broadcast foliar application~~ ~~Boom sprayer~~	~~0.1952~~ ~~0.1940~~	~~198~~ ~~197~~	~~0.0987~~ ~~0.0986~~	~~24/05/23~~ ~~07/06/23~~	~~58~~ ~~69~~	~~Forage (3)~~ ~~Forage (3)~~ ~~Forage (3)~~ ~~Forage (3)~~ ~~Straw~~ ~~Grain~~ ~~Grain*~~	~~PTZ-desthio~~ ~~0.57~~ ~~1.1~~ ~~0.52~~ ~~0.72~~ ~~0.98~~ ~~0.11~~ ~~0.09~~	~~PTZ-α-hydroxy-desthio~~ ~~<0.01~~ ~~<0.01~~ ~~0.08~~ ~~0.03~~ ~~0.13~~ ~~<0.01~~ ~~-~~	~~PTZ-3-hydroxy-desthio~~ ~~0.07~~ ~~0.06~~ ~~0.15~~ ~~0.09~~ ~~0.25~~ ~~0.02~~ ~~-~~	~~**Sum**[1,2]~~ ~~-~~ ~~-~~ ~~-~~ ~~-~~ ~~-~~ ~~-~~	~~0~~ ~~+0~~ ~~14~~ ~~20~~ ~~27~~ ~~27~~ ~~27~~	~~Untreated specimen: <LOQ~~ ~~LC-MS/MS method validated within this study~~ ~~Max. study storage interval between:~~ ~~-sampling and extraction: 354 days~~ ~~-extraction and analyses: 5 days~~ ~~*retain sample~~
									~~Forage (3)~~ ~~Forage (3)~~ ~~Forage (3)~~ ~~Forage (3)~~ ~~Straw~~ ~~Grain~~	~~PTZ-4-hydroxy-desthio~~ ~~0.09~~ ~~0.08~~ ~~0.13~~ ~~0.07~~ ~~0.28~~ ~~0.01~~	~~PTZ-5-hydroxy-desthio~~ ~~0.03~~ ~~0.03~~ ~~0.07~~ ~~0.04~~ ~~0.14~~ ~~0.01~~	~~PTZ-6-hydroxy-desthio~~ ~~n.d.~~ ~~n.d.~~ ~~<0.01~~ ~~<0.01~~ ~~<0.01~~ ~~n.d.~~	~~**0.77**~~ ~~**1.3**~~ ~~**0.96**~~ ~~**0.96**~~ ~~**1.8**~~ ~~**0.16**~~	~~0~~ ~~+0~~ ~~14~~ ~~20~~ ~~27~~ ~~27~~	

Southern Europe Greece 57400 – Sindos (Central Macedonia) 646-2023 GR10	Winter barley ZHANA	1- 16/11/22 2- 17/04/23 to 27/04/23 3- 09/06/23	Broadcast foliar application Boom sprayer	0.1980 0.1967	301 299	0.0658 0.0658	12/04//23 27/04/23	51 69		PTZ-desthio	PTZ-α-hydroxy-desthio	PTZ-3-hydroxy-desthio	**Sum**[1,2]		Untreated specimen: <LOQ LC-MS/MS method validated within this study Max. study storage interval between: -sampling and extraction: 354 days -extraction and analyses: 5 days
									Forage[3] Forage[3] Forage[3] Forage[3] Straw Grain	1.0 1.9 0.29 0.27 0.16 <0.01	0.02 0.02 0.01 0.01 0.02 n.d.	0.10 0.10 0.13 0.14 0.14 <0.01	- - - - - -	0 +0 14 21 43 43	
										PTZ-4-hydroxy-desthio	PTZ-5-hydroxy-desthio	PTZ-6-hydroxy-desthio			
									Forage[3] Forage[3] Forage[3] Forage[3] Straw Grain	0.11 0.09 0.14 0.11 0.11 n.d.	0.05 0.05 0.06 0.05 0.12 <0.01	<0.01 <0.01 0.01 <0.01 <0.01 n.d.	**1.3** **2.2** **0.64** **0.59** **0.56** **<0.06**	0 +0 14 21 43 43	
Southern Europe Italy 12062 Cherasco (Piedmont) 646-2023 IT11	Winter barley COMETA	1- 26/10/22 2- 01/05/23 to 05/05/23 3- 29/06/23	Broadcast foliar application Boom sprayer	0.1923 0.1908	292 290	0.0658 0.0658	22/04//23 05/05/23	58 69		PTZ-desthio	PTZ-α-hydroxy-desthio	PTZ-3-hydroxy-desthio	**Sum**[1,2]		Untreated specimen: <LOQ LC-MS/MS method validated within this study Max. study storage interval between: -sampling and extraction: 354 days -extraction and analyses: 5 days
									Forage[3] Forage[3] Forage[3] Forage[3] Straw Grain	0.43 1.3 0.77 0.27 0.04 0.01	<0.01 <0.01 0.02 0.02 <0.01 n.d.	0.07 0.07 0.16 0.16 0.03 <0.01	- - - - - -	0 +0 13 20 55 55	
										PTZ-4-hydroxy-desthio	PTZ-5-hydroxy-desthio	PTZ-6-hydroxy-desthio			
									Forage[3] Forage[3] Forage[3] Forage[3] Straw Grain	0.10 0.11 0.21 0.20 0.04 n.d.	0.05 0.05 0.12 0.11 0.04 <0.01	<0.01 <0.01 0.01 0.01 n.d. n.d.	**0.67** **1.6** **1.3** **0.77** **0.16** **<0.06**	0 +0 13 20 55 55	

Southern Europe Spain 41710 Andalusia (Utrera) 646-2023 SP12	Spring barley PRESTIGE	1- 23/02/23 2- 07/05/23 to 17/05/23 3- 12/07/23	Broadcast foliar application Boom sprayer	0.1935 0.1930	294 293	0.0658 0.0658	04/05//23 17/05/23	59 69		PTZ-desthio	PTZ-α-hydroxy-desthio	PTZ-3-hydroxy-desthio	**Sum**[1,2]		Untreated specimen: <LOQ LC-MS/MS method validated within this study Max. study storage interval between: -sampling and extraction: 354 days -extraction and analyses: 5 days
									Forage[3] Forage[3] Forage[3] Forage[3] Straw Grain	0.66 1.0 0.81 0.35 1.3 0.02	0.02 0.02 0.04 0.02 0.10 n.d.	0.11 0.10 0.16 0.11 0.20 <0.01	- - - - - -	0 +0 13 20 56 56	
										PTZ-4-hydroxy-desthio	PTZ-5-hydroxy-desthio	PTZ-6-hydroxy-desthio			
									Forage[3] Forage[3] Forage[3] Forage[3] Straw Grain	0.12 0.11 0.18 0.12 0.16 n.d.	0.06 0.06 0.09 0.04 0.12 n.d.	<0.01 <0.01 0.01 <0.01 0.01 n.d.	**0.98** **1.3** **1.3** **0.65** **1.9** **<0.06**	0 +0 13 20 56 56	
Southern Europe Italy 94010 – Assoro (Sicily) 646-2023 IT3	Winter barley NURE	1- 10/11/22 2- 03/04/23 to 19/04/23 3- 09/06/23	Broadcast foliar application Boom sprayer	0.1993 0.2003	404 406	0.0493 0.0493	06/04/23 19/04/23	64 69		PTZ-desthio	PTZ-α-hydroxy-desthio	PTZ-3-hydroxy-desthio	**Sum**[1,2]		Untreated specimen: <LOQ LC-MS/MS method validated within this study Max. study storage interval between: -sampling and extraction: 354 days -extraction and analyses: 5 days
									Straw Grain	0.56 -	0.08 -	0.10 -	- -	51 51	
										PTZ-4-hydroxy-desthio	PTZ-5-hydroxy-desthio	PTZ-6-hydroxy-desthio			
									Straw Grain	0.11 -	0.08 -	<0.01 -	**0.94** -	51 51	

Southern Europe Spain 41320 Cantillana (Andalucia) 646-2023-SP14	Spring barley PRESTIGE	1- 02/03/22 2- 21/05/23 to 01/06/23 3- 11/07/23	Broadcast foliar application Boom sprayer	0.2062 0.1986	313 302	0.0658 0.0658	18/05/23 01/06/23	59 69	Straw Grain	PTZ-desthio 0.21 <0.01	PTZ-α-hydroxy-desthio 0.04 n.d.	PTZ-3-hydroxy-desthio 0.24 n.d.	**Sum[1,2]** - -	40 40	Untreated specimen: <LOQ LC-MS/MS method validated within this study Max. study storage interval between: -sampling and extraction: 354 days -extraction and analyses: 5 days
									Straw Grain	PTZ-4-hydroxy-desthio 0.19 n.d.	PTZ-5-hydroxy-desthio 0.08 n.d.	PTZ-6-hydroxy-desthio <0.01 n.d.	**0.77** **<0.06**	40 40	
Southern Europe Greece 57100 Koufalia (Central Macedonia) 646-2023-GR15	Winter barley NURE	1- 05/12/22 2- 15/04/23 to 25/04/23 3- 06/06/23	Broadcast foliar application Boom sprayer	0.1960 0.1971	298 300	0.0658 0.0658	11/04/23 25/04/12	51-59 69	Straw Grain	PTZ-desthio 0.39 0.02	PTZ-α-hydroxy-desthio 0.03 n.d.	PTZ-3-hydroxy-desthio 0.17 <0.01	**Sum[1,2]** - -	42 42	Untreated specimen: <LOQ LC-MS/MS method validated within this study Max. study storage interval between: -sampling and extraction: 354 days -extraction and analyses: 5 days
									Straw Grain	PTZ-4-hydroxy-desthio 0.19 n.d.	PTZ-5-hydroxy-desthio 0.13 <0.01	PTZ-6-hydroxy-desthio <0.01 n.d.	**0.92** **<0.06**	42 42	

Southern Europe Italy 14100 San Marzanotoo (Piedmont) 646-2023-IT16	Winter barley COMETA	1- 04/11/22 2- 09/05/23 to 16/05/23 3- 29/06/23	Broadcast foliar application Boom sprayer	0.1923 0.1988	292 302	0.0658 0.0658	03/05/23 16/05/23	58 69	 Straw Grain	PTZ-desthio 0.23 0.01	PTZ-α-hydroxy-desthio 0.04 n.d.	PTZ-3-hydroxy-desthio 0.14 <0.01	**Sum**[1,2] - -	44 44	Untreated specimen: <LOQ LC-MS/MS method validated within this study Max. study storage interval between: -sampling and extraction: 354 days -extraction and analyses: 5 days

[1,2] 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 n.d.

LOQ = 0.01 mg/kg / n.d. = not detected (<LOD = <0.003 mg/kg)
n.d. residues are considered as 0.00 mg/kg, <LOQ residues are considered as 0.01 mg/kg
The Sum of PTZ-desthio metabolites is based on values from a single trial

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

RESIDUE DATA SUMMARY FROM SUPERVISED TRIALS

Active Substance: prothioconazole
Crop / crop group: Barley / cereals
Responsible for reporting: Frédéric LEBRUN / TESTAPI
115 route du Pô, 49650 Allonnes - France
Countries: Germany, Poland, Denmark, the Netherlands,France, Greece, Italy, & Spain
Nominal Content of a.s.: 250 g/L
Formulation: DC

Commercial Product: Prothioconazole 250 g/L DC
Producer: UPL Europe Limited
Indoor/glasshouse/outdoor: outdoor
Other a.s. in formulation: -
Residue calculated as: triazole derivative metabolites (T, TA, TAA, TLA) (mg/kg)

1	2	3	4	5			6	7	8	9				10	11
Report No. 646-2023 Location (region)	Commodity Variety	Date of 1-Planting 2-Flowering 3-Harvest	Method of treatment	Actual (nominal) application rate per treatment			Date of treatment	BBCH Crop Growth Stage at treatment	Portions analysed	Residues (1)				DALA (2)	Remarks
				kg a.s./ha	Water (L/ha)	kg (a.s./hL)				T	TA	TAA	TLA		
Northern Europe Northern France 49650 Allonnes (pays de la Loire) 646-2023 FR01	Spring barley PLANET	1- 15/02/23 2- 26/05/23 to 06/06/23 3- 12/07/23	Broadcast foliar application Boom sprayer	0.1995 0.1990	202 202	0.0986 0.0987	22/05/23 05/06/23	58 69	**Untreated** Forage(3) Forage(3) Forage(3) Forage(3) Straw Grain **Treated** Forage(3) Forage(3) Forage(3) Forage(3) Straw Grain	 n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d.	 0.02 0.01 0.01 0.01 <0.01 0.03 0.03 0.04 0.06 0.03 <0.01 0.10	 0.02 0.02 0.03 0.02 0.02 0.04 0.02 0.02 0.04 0.02 0.02 0.06	 0.02 0.02 0.02 0.01 0.01 n.d. 0.03 0.03 0.03 0.02 0.02 <0.01	 -0 +0 14 22 37 37 -0 +0 14 22 37 37	 LC-MS/MS Method Validated in within this study Max. study storage interval between: -sampling and extraction: 185 days -extraction and analyses: 4 days
Northern Europe Germany 46342 Velen-Ramsdorf (North Rhine Westphalia)	Spring barley QUENCH	1- 15/04/23 2- 12/06/23 to 23/06/23 3- 21/07/23	Broadcast foliar application Boom sprayer	0.1991 0.2009	303 305	0.0658 0.0658	09/06/23 23/06/23	56 69	**Untreated** Forage(3) Forage(3) Forage(3) Forage(3) Straw Grain	 n.d. n.d. n.d. n.d. n.d. n.d.	 0.02 0.01 0.02 0.02 n.d. 0.05	 0.02 0.02 0.03 0.02 0.02 0.07	 0.02 0.02 0.02 0.01 0.02 n.d.	 -0 +0 14 22 37 37	 LC-MS/MS Method Validated in within this study Max. study storage interval between:

646-2023 GE02									**Treated** Forage[3] Forage[3] Forage[3] Forage[3] Straw Grain	 n.d. n.d. n.d. n.d. n.d. n.d.	 0.05 0.05 0.08 0.10 0.01 0.22	 0.05 0.05 0.05 0.09 0.04 0.13	 0.06 0.06 0.04 0.06 0.05 <0.01	 -0 +0 14 22 37 37	-sampling and extraction: 185 days -extraction and analyses: 4 days
Northern Europe Poland 55-200 Gać (Lower Silesia) 646-2023 PL03	Spring barley FEEDWAY	1- 22/04/23 2- 11/06/23 to 16/06/23 3- 12/08/23	Broadcast foliar application Boom sprayer	0.1987 0.1979	302 301	0.0658 0.0658	02/06/23 16/06/23	37-39 69	**Untreated** Forage[3] Forage[3] Forage[3] Forage[3] Straw Grain **Treated** Forage[3] Forage[3] Forage[3] Forage[3] Straw Grain	 n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d.	 0.03 0.06 0.13 0.11 0.02 0.32 0.10 0.09 0.21 0.27 0.10 0.45	 0.03 0.04 0.07 0.09 0.01 0.16 0.07 0.06 0.13 0.16 0.07 0.22	 0.07 0.10 0.08 0.06 0.02 n.d. 0.12 0.14 0.14 0.13 0.12 <0.01	 -0 +0 14 21 57 57 -0 +0 14 21 57 57	LC-MS/MS Method Validated in within this study Max. study storage interval between: -sampling and extraction: 185 days -extraction and analyses: 4 days
Northern Europe The Netherlands 5853EJ Siebengewald (Limburg) 646-2023 NL04	Spring barley RGT PLANET	1- 19/04/23 2- 19/06/23 to 30/06/23 3- 08/08/23	Broadcast foliar application Boom sprayer	0.1965 0.1991	299 303	0.0658 0.0658	16/06/23 30/06/23	57-59 69	**Untreated** Forage[3] Forage[3] Forage[3] Forage[3] Straw Grain **Treated** Forage[3] Forage[3] Forage[3] Forage[3] Straw Grain	 n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d.	 0.18 0.17 0.15 0.09 0.07 0.48 0.18 0.18 0.17 0.14 0.03 0.48	 0.16 0.11 0.20 0.23 0.10 0.35 0.09 0.10 0.15 0.20 0.05 0.25	 0.18 0.13 0.08 0.08 0.05 0.01 0.14 0.12 0.10 0.09 0.03 0.01	 -0 +0 14 20 39 39 -0 +0 14 20 39 39	LC-MS/MS Method Validated in within this study Max. study storage interval between: -sampling and extraction: 185 days -extraction and analyses: 4 days
Northern Europe Belgium 6221 Saint-Amand	Winter barley ESPRIT	1- 31/10/22 2- 19/05/23 to 31/05/23	Broadcast foliar application Boom sprayer	0.1988 0.1930	302 293	0.0658 0.0658	17/05/23 31/0523	55 69	**Untreated** Straw Grain **Treated** Straw	 n.d. n.d. n.d.	 n.d 0.05 <0.01	 <0.01 0.03 <0.01	 0.02 n.d. 0.02	 34 34 34	LC-MS/MS Method Validated in within this study

(Province of Hainault) 646-2023 BE05		3- 04/07/23 to 11/07/23							Grain	n.d.	0.07	0.03	n.d.	34	Max. study storage interval between: -sampling and extraction: 185 days -extraction and analyses: 4 days
Northern Europe Germany 04827 Gerichshain (Saxony) 646-2023 GE06	Spring barley RGT PLANET	1- 19/04/23 2- 09/06/23 to 22/06/23 3- 19/08/23	Broadcast foliar application Boom sprayer	0.2000 0.1895	304 288	0.0658 0.0658	09/06/23 22/06/23	59-61 69	**Untreated** Straw Grain **Treated** Straw Grain	 n.d. n.d. n.d. n.d.	 n.d. 0.03 0.01 0.12	 <0.01 0.02 <0.01 0.04	 0.01 n.d. 0.01 n.d.	 58 58 58 58	LC-MS/MS Method Validated in within this study Max. study storage interval between: -sampling and extraction: 185 days -extraction and analyses: 4 days
Northern Europe Poland 48320 Czamolas (Opolskie Province) 646-2023 PL07	Spring barley FREEDWAY	1- 22/03/23 2- 09/06/23 to 16/06/23 3- 11/08/23	Broadcast foliar application Boom sprayer	0.1946 0.1960	296 298	0.0658 0.0658	01/06/23 16/06/23	39-41 69	**Untreated** Straw Grain **Treated** Straw Grain	 n.d. n.d. n.d. n.d.	 <0.01 0.04 0.04 0.22	 <0.01 0.06 0.04 0.07	 0.01 n.d. 0.09 n.d.	 56 56 56 56	LC-MS/MS Method Validated in within this study Max. study storage interval between: -sampling and extraction: 185 days -extraction and analyses: 4 days
Northern Europe Denmark 5580 Norre Aby (South Denmark) 646-2023 DK-08	Spring barley PROSPECT	1- 22/03/23 2- 09/06/23 to 16/06/23 3- 11/08/23	Broadcast foliar application Boom sprayer	0.2039 0.1941	207 197	0.0987 0.0987	25/06/23 09/07/23	52-55 69	**Untreated** Straw Grain **Treated** Straw Grain	 n.d. n.d. n.d. n.d.	 n.d. 0.02 0.04 0.20	 <0.01 0.01 0.07 0.05	 n.d. n.d. 0.02 n.d.	 44 44 44 44	LC-MS/MS Method Validated in within this study Max. study storage interval between: -sampling and extraction: 185 days -extraction and analyses: 4 days

Southern Europe Southern France 796600 Availles-Thouarsais (Nouvelle Aquitaine) 646-2023 FR09	Spring barley RGT PLANET	1- 15/02/23 2- 27/05/23 to 08/06/23 3- 01/07/23 to 10/07/23	Broadcast foliar application Boom sprayer	0.1952 0.1940	198 197	0.0987 0.0986	24/05/23 07/06/23	58 69	**Untreated** Forage[3] Forage[3] Forage[3] Forage[3] Straw Grain **Treated** Forage[3] Forage[3] Forage[3] Forage[3] Straw Grain	n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d.	0.01 0.01 <0.01 0.01 n.d. 0.02 0.02 0.03 0.04 0.03 n.d 0.08	0.02 0.02 0.02 0.03 0.02 0.05 0.03 0.03 0.04 0.04 0.03 0.08	0.03 0.03 0.01 0.02 0.03 n.d 0.04 0.03 0.02 0.04 0.04 <0.01	-0 +0 14 20 27 27 -0 +0 14 20 27 27	LC-MS/MS Method Validated in within this study Max. study storage interval between: -sampling and extraction: 185 days -extraction and analyses: 4 days
Southern Europe Greece 57400 Sindos (Central Macedonia) 646-2023 GR10	Winter barley ZHANA	1- 16/11/22 2- 17/04/23 to 27/04/23 3- 09/06/23	Broadcast foliar application Boom sprayer	0.1980 0.1967	301 299	0.0658 0.0658	12/04//23 27/04/23	51 69	**Untreated** Forage[3] Forage[3] Forage[3] Forage[3] Straw Grain **Treated** Forage[3] Forage[3] Forage[3] Forage[3] Straw Grain	n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d.	<0.01 <0.01 n.d. <0.01 n.d. 0.01 0.04 0.04 0.07 0.09 0.04 0.24	<0.01 <0.01 n.d. n.d. 0.01 <0.01 <0.01 <0.01 0.02 0.02 0.05 0.08	0.02 0.01 n.d. <0.01 <0.01 n.d. 0.04 0.03 0.03 0.03 0.06 <0.01	-0 +0 14 21 43 43 -0 +0 14 21 43 43	LC-MS/MS Method Validated in within this study Max. study storage interval between: -sampling and extraction: 185 days -extraction and analyses: 4 days
Southern Europe Italy 12062 Cherasco (Piedmont) 646-2023 IT11	Winter barley COMETA	1- 26/10/22 2- 01/05/23 to 05/05/23 3- 29/06/23	Broadcast foliar application Boom sprayer	0.1923 0.1908	292 290	0.0658 0.0658	22/04//23 05/05/23	58 69	**Untreated** Forage[3] Forage[3] Forage[3] Forage[3] Straw Grain **Treated** Forage[3] Forage[3] Forage[3] Forage[3] Straw Grain	n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d.	n.d. n.d. n.d. n.d. n.d. <0.01 n.d. <0.01 0.04 0.04 0.07 0.14	n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d. <0.01 <0.01 0.02 0.04	n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d. <0.01 <0.01 0.02 n.d.	-0 +0 13 20 55 55 -0 +0 13 20 55 55	LC-MS/MS Method Validated in within this study Max. study storage interval between: -sampling and extraction: 185 days -extraction and analyses: 4 days

Southern Europe Spain 41710 Andalusia (Utrera) 646-2023 SP12	Spring barley PRESTIGE	1- 23/02/23 2- 07/05/23 to 17/05/23 3- 12/07/23	Broadcast foliar application Boom sprayer	0.1935 0.1930	294 293	0.0658 0.0658	04/05//23 17/05/23	59 69	**Untreated** Forage(3) Forage(3) Forage(3) Forage(3) Straw Grain **Treated** Forage(3) Forage(3) Forage(3) Forage(3) Straw Grain	n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d.	<0.01 <0.01 <0.01 0.01 <0.01 0.05 0.04 0.04 0.06 0.08 0.04 0.21	<0.01 <0.01 0.01 0.02 0.04 0.04 <0.01 <0.01 0.02 0.04 0.08 0.06	0.01 0.01 0.01 <0.01 0.02 n.d. 0.02 0.02 0.02 0.02 0.04 <0.01	-0 +0 13 20 56 56 -0 +0 13 20 56 56	LC-MS/MS Method Validated in within this study Max. study storage interval between: -sampling and extraction: 185 days -extraction and analyses: 4 days
Southern Europe Italy 94010 — Assoro (Sicily) 646-2023 IT3	Winter barley NURE	1- 10/11/22 2- 03/04/23 to 19/04/23 3- 09/06/23	Broadcast foliar application Boom sprayer	0.1993 0.2003	404 406	0.0493 0.0493	06/04/23 19/04/23	64 69	**Untreated** Straw Grain **Treated** Straw Grain	n.d. n.d. n.d. -	n.d. 0.02 <0.01 -	n.d. <0.01 <0.01 -	n.d. n.d. <0.01 -	51 51 51 51	LC-MS/MS Method Validated in within this study Max. study storage interval between: -sampling and extraction: 185 days -extraction and analyses: 4 days
Southern Europe Spain 41320 Cantillana (Andalucia) 646-2023 SP14	Spring barley PRESTIGE	1- 02/03/22 2- 21/05/23 to 01/06/23 3- 11/07/23	Broadcast foliar application Boom sprayer	0.2062 0.1986	313 302	0.0658 0.0658	18/05/23 01/06/23	59 69	**Untreated** Straw Grain **Treated** Straw Grain	n.d. n.d. n.d. n.d.	n.d. 0.01 0.09 0.34	<0.01 <0.01 0.10 0.15	<0.01 n.d. 0.12 0.02	40 40 40 40	LC-MS/MS Method Validated in within this study Max. study storage interval between: -sampling and extraction: 185 days -extraction and analyses: 4 days
Southern Europe	Winter barley	1- 05/12/22		0.1960	298	0.0658	11/04/23	51-59	**Untreated** Straw	n.d.	n.d.	n.d.	n.d.	42	LC-MS/MS

Greece 57100 Koufalia (Central Macedonia) 646-2023-GR15	NURE	2- 15/04/23 to 25/04/23 3- 06/06/23	Broadcast foliar application Boom sprayer	0.1971	300	0.0658	25/04/12	69	Grain **Treated** Straw Grain	n.d. n.d. n.d.	n.d. <0.01 0.13	<0.01 0.02 0.05	n.d. 0.02 <0.01	42 42 42	Method Validated in within this study Max. study storage interval between: -sampling and extraction: 185 days -extraction and analyses: 4 days
Southern Europe Italy 14100 San Marzanotoo (Piedmont) 646-2023-IT16	Winter barley COMETA	1- 04/11/22 2- 09/05/23 to 16/05/23 3- 29/06/23	Broadcast foliar application Boom sprayer	0.1923 0.1988	292 302	0.0658 0.0658	03/05/23 16/05/23	58 69	**Untreated** Straw Grain **Treated** Straw Grain	n.d. n.d. n.d. n.d.	<0.01 0.07 <0.01 0.19	0.03 0.07 0.03 0.12	0.02 <0.01 0.02 0.02	44 44 44 44	LC-MS/MS Method Validated in within this study Max. study storage interval between: -sampling and extraction: 185 days -extraction and analyses: 4 days

A 2.2.3.3 Oilseed rape (OSR)

Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (DAR, RMS, year)	2	175 g as / ha	14 to 28 days	Not stated	56
cGAP EU (Art. 12, EFSA, year)	2	120 g as / ha	14 days	Not stated	28
Intended cGAP (numbers 7, 8)*	1	1 L product per ha (200 g prothioconazole per ha)	Not applicable	BBCH 73	35 (GSR)

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0
** Timing of applications determined primarily by growth stage; 1st application not later than BBCH 39, 2nd application no later than BBCH 59.
GSR: Growth Stage Restricted

The following tables provide a summary of the available data from the residue trials:

Commodity	Trial	Residue trials zone	PTZ-Desthio	PTZ-α	PTZ-3	PTZ-4	PTZ-5	PTZ-6	T	TA	TAA	TLA
OSR seed	645-2023	North EU	-	0.01	0.01	<0.01	<0.01	nd	nd	0.29	-	-
OSR seed	645-2023	North EU	-	<0.01	<0.01	nd	nd	nd	nd	0.15	-	-
OSR seed	645-2023	North EU	-	<0.01	<0.01	nd	nd	nd	nd	0.23	-	-
OSR seed	645-2023	North EU	-	nd	<0.01	nd	nd	nd	nd	0.22	-	-
OSR seed	645-2023	North EU	-	<0.01	<0.01	nd	nd	nd	nd	0.2	-	-
OSR seed	645-2023	North EU	-	<0.01	0.01	nd	<0.01	nd	nd	0.52	-	-
OSR seed	645-2023	North EU	-	0.01	0.01	<0.01	<0.01	nd	nd	0.79	-	-
OSR seed	645-2023	North EU	-	<0.01	0.01	<0.01	nd	nd	nd	1.3	-	-
OSR seed	NZ/21/003	North EU	-	-	-	-	-	-	-	-	<0.005	<0.01
OSR seed	NZ/21/003	North EU	-	-	-	-	-	-	-	-	<0.005	<0.01
OSR seed	NZ/21/002	North EU	<0.005	<0.005	<0.005	<0.005	<0.005	<0.005	-	-	-	-
OSR seed	NZ/21/002	North EU	0.00659	<0.005	<0.005	<0.005	<0.005	<0.005	-	-	-	-
OSR seed	EE/23/007	North EU	-	-	-	-	-	-	-	-	0.00576	0.029
OSR seed	EE/23/007	North EU	-	-	-	-	-	-	-	-	0.00928	0.0365
OSR seed	EE/23/007	North EU	-	-	-	-	-	-	-	-	0.00896	0.0491
OSR seed	EE/23/007	North EU	-	-	-	-	-	-	-	-	<0.005	0.0105
OSR seed	EE/23/007	North EU	-	-	-	-	-	-	-	-	<0.005	<0.01
OSR seed	EE/23/007	North EU	-	-	-	-	-	-	-	-	<0.005	<0.01
OSR seed	QG22007	North EU	0.0564	<0.005	<0.005	<0.005	<0.005	<0.005	-	-	-	-
OSR seed	QG22007	North EU	<0.005	<0.005	<0.005	<0.005	<0.005	<0.005	-	-	-	-
OSR seed	QG22007	North EU	0.0182	<0.005	<0.005	<0.005	<0.005	<0.005	-	-	-	-
OSR seed	QG22007	North EU	0.00514	<0.005	<0.005	<0.005	<0.005	<0.005	-	-	-	-
OSR seed	QG22007	North EU	0.0146	<0.005	<0.005	<0.005	<0.005	<0.005	-	-	-	-
OSR seed	QG22007	North EU	0.0136	<0.005	<0.005	<0.005	<0.005	<0.005	-	-	-	-
STMR (mg/kg):			0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0.26	<0.01	0.01
HR (mg/kg):			0.056	0.01	0.01	<0.01	<0.01	<0.01	<0.01	1.3	<0.01	0.05

Commodity	Trial	Residue trials zone	PTZ-Desthio	PTZ-α	PTZ-3	PTZ-4	PTZ-5	PTZ-6	T	TA	TAA	TLA

OSR forage	647-2023	North EU	-	0.04	0.30	0.16	0.04	<0.01	<0.01	0.04	-	-
OSR forage	647-2023	North EU	-	0.01	0.23	0.07	0.02	n.d.	n.d.	0.03	-	-
OSR forage	647-2023	North EU	-	0.01	0.15	0.03	0.01	<0.01	n.d.	0.06	-	-
OSR forage	647-2023	North EU	-	0.03	0.18	0.06	0.02	<0.01	n.d.	0.04	-	-
OSR forage	647-2023	North EU	-	-	-	-	-	-	-	-	-	-
OSR forage	647-2023	North EU	-	-	-	-	-	-	-	-	-	-
OSR forage	647-2023	North EU	-	-	-	-	-	-	-	-	-	-
OSR forage	647-2023	North EU	-	-	-	-	-	-	-	-	-	-
OSR RoP	NZ/21/003	North EU	-	-	-	-	-	-	-	-	<0.005	<0.01
OSR RoP	NZ/21/003	North EU	-	-	-	-	-	-	-	-	<0.005	<0.01
OSR RoP	NZ/21/002	North EU	<0.005	<0.005	<0.005	<0.005	<0.005	<0.005	-	-	-	-
OSR RoP	NZ/21/002	North EU	0.0785	0.0313	0.0833	0.0394	0.0111	<0.005	-	-	-	-
OSR RoP	EE/23/007	North EU	-	-	-	-	-	-	-	-	0.006	0.011
OSR RoP	EE/23/007	North EU	-	-	-	-	-	-	-	-	<0.005	<0.01
OSR RoP	EE/23/007	North EU	-	-	-	-	-	-	-	-	0.0324	0.0178
OSR RoP	EE/23/007	North EU	-	-	-	-	-	-	-	-	<0.005	<0.01
OSR RoP	EE/23/007	North EU	-	-	-	-	-	-	-	-	0.007	0.01
OSR RoP	EE/23/007	North EU	-	-	-	-	-	-	-	-	<0.005	<0.01
OSR RoP	QG22007	North EU	0.0217	0.0608	0.136	0.0558	0.0127	<0.005	-	-	-	-
OSR RoP	QG22007	North EU	0.0366	0.00978	0.0236	0.0127	<0.005	<0.005	-	-	-	-
OSR RoP	QG22007	North EU	0.673	0.0977	0.240	0.0880	0.0242	<0.005	-	-	-	-
OSR RoP	QG22007	North EU	0.196	0.0138	0.132	0.0564	0.0103	<0.005	-	-	-	-
OSR RoP	QG22007	North EU	<0.005	<0.005	<0.005	<0.005	<0.005	<0.005	-	-	-	-
OSR RoP	QG22007	North EU	0.230	0.230	0.230	0.230	0.230	0.230	-	-	-	-
STMR (mg/kg):			0.058	0.022	0.143	0.056	0.012	0.01	<0.01	0.04	<0.01	<0.01
HR (mg/kg):			0673	0.230	0.30	0.230	0.230	0.230	<0.01	0.06	0.032	0.017

~~Commodity~~	~~Trial~~	~~Residue trials zone~~	~~PTZ-Desthio~~	~~PTZ-α~~	~~PTZ-3~~	~~PTZ-4~~	~~PTZ-5~~	~~PTZ-6~~	~~T~~	~~TA~~	~~TAA~~	~~TLA~~
~~OSR seed~~	~~645-2023~~	~~South EU~~	~~-~~	~~<0.01~~	~~0.02~~	~~<0.01~~	~~<0.01~~	~~<0.01~~	~~nd~~	~~3.2~~	~~-~~	~~-~~
~~OSR seed~~	~~645-2023~~	~~South EU~~	~~-~~	~~<0.01~~	~~0.02~~	~~<0.01~~	~~nd~~	~~nd~~	~~nd~~	~~0.13~~	~~-~~	~~-~~
~~OSR seed~~	~~645-2023~~	~~South EU~~	~~-~~	~~nd~~	~~<0.01~~	~~nd~~	~~nd~~	~~nd~~	~~nd~~	~~0.23~~	~~-~~	~~-~~
~~OSR seed~~	~~645-2023~~	~~South EU~~	~~-~~	~~nd~~	~~<0.01~~	~~<0.01~~	~~nd~~	~~nd~~	~~nd~~	~~0.25~~	~~-~~	~~-~~
~~OSR seed~~	~~645-2023~~	~~South EU~~	~~-~~	~~nd~~	~~<0.01~~	~~nd~~	~~nd~~	~~nd~~	~~nd~~	~~3.4~~	~~-~~	~~-~~
~~OSR seed~~	~~645-2023~~	~~South EU~~	~~-~~	~~0.02~~	~~0.05~~	~~0.02~~	~~0.01~~	~~<0.01~~	~~nd~~	~~0.78~~	~~-~~	~~-~~
~~OSR seed~~	~~645-2023~~	~~South EU~~	~~-~~	~~<0.01~~	~~0.02~~	~~nd~~	~~<0.01~~	~~nd~~	~~nd~~	~~4.5~~	~~-~~	~~-~~
~~OSR seed~~	~~645-2023~~	~~South EU~~	~~-~~	~~<0.01~~	~~0.01~~	~~<0.01~~	~~<0.01~~	~~nd~~	~~nd~~	~~0.14~~	~~-~~	~~-~~
~~OSR seed~~	~~EE/23/006~~	~~South EU~~	~~-~~	~~-~~	~~-~~	~~-~~	~~-~~	~~-~~	~~-~~	~~-~~	~~<0.005~~	~~<0.01~~
~~OSR seed~~	~~EE/23/006~~	~~South EU~~	~~-~~	~~-~~	~~-~~	~~-~~	~~-~~	~~-~~	~~-~~	~~-~~	~~<0.005~~	~~0.0121~~
~~OSR seed~~	~~QG20008~~	~~South EU~~	~~0.0516~~	~~<0.005~~	~~<0.005~~	~~<0.005~~	~~<0.005~~	~~<0.005~~	~~-~~	~~-~~	~~<0.005~~	~~<0.01~~
~~OSR seed~~	~~QG20008~~	~~South EU~~	~~0.0447~~	~~<0.005~~	~~<0.005~~	~~<0.005~~	~~<0.005~~	~~<0.005~~	~~-~~	~~-~~	~~0.0154~~	~~<0.01~~
~~OSR seed~~	~~QG20008~~	~~South EU~~	~~0.0645~~	~~0.0118~~	~~<0.005~~	~~<0.005~~	~~<0.005~~	~~<0.005~~	~~-~~	~~-~~	~~<0.005~~	~~<0.01~~
~~OSR seed~~	~~QG20008~~	~~South EU~~	~~0.0645~~	~~0.0129~~	~~<0.005~~	~~<0.005~~	~~<0.005~~	~~<0.005~~	~~-~~	~~-~~	~~<0.005~~	~~<0.01~~
~~OSR seed~~	~~QG22006~~	~~South EU~~	~~0.0609~~	~~0.00867~~	~~<0.005~~	~~<0.005~~	~~<0.005~~	~~<0.005~~	~~-~~	~~-~~	~~-~~	~~-~~
~~OSR seed~~	~~QG22006~~	~~South EU~~	~~0.0393~~	~~<<0.005~~	~~<0.005~~	~~<0.005~~	~~<0.005~~	~~<0.005~~	~~-~~	~~-~~	~~-~~	~~-~~
~~OSR seed~~	~~NZ/21/003~~	~~South EU~~	~~-~~	~~-~~	~~-~~	~~-~~	~~-~~	~~-~~	~~-~~	~~-~~	~~<0.005~~	~~<0.01~~
~~OSR seed~~	~~NZ/21/003~~	~~South EU~~	~~-~~	~~-~~	~~-~~	~~-~~	~~-~~	~~-~~	~~-~~	~~-~~	~~0.0174~~	~~<0.01~~
~~OSR seed~~	~~NZ/21/002~~	~~South EU~~	~~0.00755~~	~~<0.005~~	~~<0.005~~	~~<0.005~~	~~<0.005~~	~~<0.005~~	~~-~~	~~-~~	~~-~~	~~-~~

OSR seed	NZ/21/002	South EU	0.0738	<0.005	<0.005	<0.005	<0.005	<0.005	-	-	-	-
STMR (mg/kg):			0.056	<0.01	<0,01	<0.01	<0.01	<0.01	<0.01	0.52	<0.01	<0.01
HR (mg/kg):			0.074	0.02	0.05	0.02	0.01	<0.01	<0.01	4.50	0.017	0.012

Commodity	Trial	Residue trials zone	PTZ-Desthio	PTZ-α	PTZ-3	PTZ-4	PTZ-5	PTZ-6	T	TA	TAA	TLA
OSR forage	647-2023	South EU	-	0.08	0.42	0.15	0.05	0.01	n.d.	0.65	-	-
OSR forage	647-2023	South EU	-	0.02	0.24	0.09	0.03	<0.01	n.d.	0.05	-	-
OSR forage	647-2023	South EU	-	<0.01	0.09	0.02	<0.01	n.d.	n.d.	0.06	-	-
OSR forage	647-2023	South EU	-	<0.01	0.27	0.14	0.04	<0.01	n.d	0.14	-	-
OSR forage	647-2023	South EU	-	-	-	-	-	-	-	-	-	-
OSR forage	647-2023	South EU	-	-	-	-	-	-	-	-	-	-
OSR forage	647-2023	South EU	-	-	-	-	-	-	-	-	-	-
OSR forage	647-2023	South EU	-	-	-	-	-	-	-	-	-	-
OSR RoP	EE/23/006	South EU	-	-	-	-	-	-	-	-	<0.005	<0.01
OSR RoP	EE/23/006	South EU	-	-	-	-	-	-	-	-	<0.005	<0.01
OSR RoP	QG20008	South EU	0.0628	<0.005	0.0254	0.0117	<0.005	<0.005	-	-	<0.0100	<0.005
OSR RoP	QG20008	South EU	0.0793	0.0128	0.0336	0.0126	<0.005	<0.005	-	-	<0.0100	<0.005
OSR RoP	QG20008	South EU	0.265	0.110	0.109	0.0480	0.0142	<0.005	-	-	<0.0100	<0.005
OSR RoP	QG20008	South EU	0.0953	0.0268	0.0482	0.0256	0.00790	<0.005	-	-	<0.0100	<0.005
OSR RoP	QG22006	South EU	0.442	0.104	0.186	0.103	0.0304	<0.005	-	-	-	-
OSR RoP	QG22006	South EU	1.58	0.0166	0.144	0.0774	0.0153	<0.005	-	-	-	-
OSR RoP	NZ/21/003	South EU	-	-	-	-	-	-	-	-	<0.005	<0.01
OSR RoP	NZ/21/003	South EU	-	-	-	-	-	-	-	-	0.0196	<0.01
OSR RoP	NZ/21/002	South EU	0.0344	<0.005	0.0105	<0.005	<0.005	<0.005	-	-	-	-
OSR RoP	NZ/21/002	South EU	2.30	0.0981	0.118	0.0710	0.0222	0.00698	-	-	-	-
STMR (mg/kg):			0.18	0.018	0.114	0.06	0.015	<0.01	<0.01	0.1	<0.01	<0.01
HR (mg/kg):			2.3	0.11	0.42	0.15	0.05	0.01	<0.01	0.65	0.02	<0.01

RoP = rest of plant

Study 1 - Toscano Saes & Coleman 2023, QG22006- Southern Europe (new data)

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

Reference: KCP 8.3.3/03

Report: Magnitude of Residues of Prothioconazole-desthio and Hydroxyprothioconazole-desthio metabolites Following Two Applications of Prothioconazole 250 g/L DC (FGR06) to Oilseed rape in southern Europe, 2022; R. Toscano Saes & H. Coleman, 2023; Study No.: QG22006

Guideline(s):

- General recommendations for the design, preparation and realization of residue trials (SANCO 7029/VI/95 rev.5, 22 July 1997).
- OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published on 7 September 2016).
- SANTE/2020/12830, rev.1 Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes, 24 February 2021

Deviations: There were two study plan deviations:

- Retain samples were shipped to the test facility which the study plan did not allow for. There was no impact on the study as samples were shipped and stored in a GLP manner.
- The reference item Prothioconazole-α-hydroxy-desthio has reported a synonym which is different to the study plan due to a typographical error in the study plan. No impact on the study

GLP: Yes

Acceptability: Yes

Summary of the study 1 trials – QG22006

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)						PHI (days)	Details on trial
			kg a.s./ ha	Water (l/ha)	kg a.s./hl				Prothioconazole-desthio	α	3-OH	4-OH	5-OH	6-OH		
	(a)	(b)				(c)									(d)	(e)
Trial 1 Italy, Castagnito d'Alba 12050 (Europe South)	Oilseed Rape/ Cherokee	1. 23/09/2021 2. 01/05/2022 to 23/05/2022 3. 13/06/2022 13/06/2022 20/06/2022 03/07/2022 10/07/2022 10/07/2022	0.174 0.171	303 297	0.0574 0.0576	30/05/2022 2 13/06/2022 2	(Control) (Control) (Control) (Control) (Control) (Control) BBCH 80 BBCH 80 BBCH 80 BBCH 80 BBCH 80 BBCH 80	Immature plant Immature plant Immature plant Immature plant Seed Rest of plant Immature plant Immature plant Immature plant Immature plant Seed Rest of plant	<0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.0015 0.335 1.02 0.633 0.193 0.0609 0.442	<0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.0015 0.0297 0.0207 0.0508 0.0561 0.00867 0.104	<0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.0015 0.0468 0.0350 0.0712 0.174 <0.005 0.186	<0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.0015 0.0228 0.0184 0.0440 0.104 <0.005 0.103	<0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.0015 0.00708 0.00522 0.0120 0.0190 <0.005 0.0304	<0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.005 <0.005 <0.005 <0.005 <0.005 <0.005	-0 0 8 20 27 27 -0 0 8 20 27 27	Acceptable Report: QG22006 Prothioconazole-desthio: Method: Battelle No. QG/20/011 LOQ = 0.005 mg/kg Metabolites: Method: Battelle No. QG/22/001 LOQ = 0.005 mg/kg LOD = 0.0015 Max/ Frozen storage = 357 days

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)						PHI (days) (d)	Details on trial (e)
			kg a.s./ ha	Water (l/ha)	kg a.s./hl				Prothioconazole-desthio	α	3-OH	4-OH	5-OH	6-OH		
Trial 2 Spain, Utrera, Sevilla ES-41710 (Europe South)	Oilseed Rape/ 44YS4	1. 01/02/2022 2. 23/03/2022 to 23/04/2022 3. 23/05/2022 23/05/2022 30/05/2022 13/06/2022 21/06/2022 21/06/2022	0.176 0.166	305.6 288.3	0.0576 0.0576	09/05/2022 23/05/2022	(Control) (Control) (Control) (Control) (Control) (Control) BBCH 80 BBCH 80 BBCH 80 BBCH 80 BBCH 80 BBCH 80	Immature plant Immature plant Immature plant Immature plant Seed Rest of plant Immature plant Immature plant Immature plant Immature plant Seed Rest of plant	<0.0015 <0.0015 <0.005 <0.005 <0.0015 <0.005 0.162 0.571 0.943 1.25 0.0393 1.58	<0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.005 0.00580 0.0103 0.0225 <0.005 0.0166	<0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.0015 0.0248 0.0358 0.0708 0.197 <0.005 0.144	<0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.0015 0.00838 0.0151 0.0330 0.0966 <0.005 0.0774	<0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.005 <0.005 0.00762 0.0186 <0.005 0.0153	<0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.005 <0.005 <0.005 0.00650 <0.005 <0.005	-0 0 7 21 29 29 -0 0 7 21 29 29	Acceptable Report: QG22006 Prothioconazole-desthio: Method: Battelle No. QG/20/011 LOQ = 0.005 mg/kg Metabolites: Method: Battelle No. QG/22/001 LOQ = 0.005 mg/kg LOD = 0.0015 Max/ Frozen storage = 357 days

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

α Prothioconazole-α-hydroxy-desthio
3-OH Prothioconazole-3-hydroxy-desthio
4-OH Prothioconazole-4-hydroxy-desthio
5-OH Prothioconazole-5-hydroxy-desthio
6-OH Prothioconazole-6-hydroxy-desthio

Study 2 - Toscano Saes & Coleman 2023, QG22007- Northern Europe (new data)

Comments of zRMS:	Six independent trials (4 decline and 2 harvest) located in Northern Europe (Germany, Poland, Belgium, The Netherlands) were conducted on oilseed rape following two applications of Prothioconazole 250 g/L DC (175 g as/ha) to determine of the residues of prothioconazole metabolites: PTZ-dethio, PTZ-alpha-OH-desthio, PTZ-3-OH-desthio, PTZ-4-OH-desthio, PTZ-5-OH-desthio, PTZ-6-OH-desthio, in oilseed rape specimens: seed and plant (rest of plant or immature plant). The first application was performed 14 +/-1 days before the second application. The second application was performed on the treated plot at BBCH 80. The methods were successfully validated for determination of all analytes in all matrices with an LOQ of 0.005 mg/kg according to guidance document SANTE/2020/12830, rev. 2. Max. study storage interval between sampling and extraction for PTZ and hydroxy-metabolites of PTZ was 314 days for seed, and 411 days for plant. The study on the magnitude of residues is valid with regard to storage stability, except prothioconazole-6-hydroxy-desthio. <u>Residue results:</u> Residues in control (untreated) samples were either not detected or <30% LOQ (0.0015 mg/kg) for prothioconazole-desthio and hydroxy-prothioconazole-desthio metabolites with the exception of samples QG22007-005 (rest of plant) which were <LOQ (0.005 mg/kg) for prothioconazole-3-hydroxy-desthio; QG22007-033 (seed) and QG22007-081 (seed) which were <LOQ and 0.0445 mg/kg for prothioconazole-desthio, respectively. PTZ: In the treated seed specimens at harvest, residue levels of PTZ-desthio ranged between <0.005 mg/kg – 0.056 mg/kg. **These trials cannot be used to support the intended use on oilseed rape due to the lack of storage stability for prothioconazole-6-hydroxy-desthio.**

Reference:	KCP 8.3.3/04
Report	Magnitude of Residues of Prothioconazole-desthio and Hydroxyprothioconazole-desthio metabolites Following Two Applications of Prothioconazole 250 g/L DC (FGR06) to Oilseed rape in northern Europe, 2022; R. Toscano Saes & H. Coleman; Study No.: QG22007
Guideline(s):	• General recommendations for the design, preparation and realization of residue trials (SANCO 7029/VI/95 rev.5, 22 July 1997). • OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published on 7 September 2016). • SANTE/2020/12830, rev.1 Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes, 24 February 2021
Deviations:	There was four study plan deviations - Collectively there was no impact of these deviations to the study. • Deviation to the study plan: Appendix 1 – Sampling schedule for trial 2 • A typographical error has been noticed in the study plan for sample 015 and 016. They are wrongly labelled as 015 Retain and 016 Ship, they should be 015 Ship, 016 Retain, as per the pattern of the rest of the samples, all odd numbers are ship, all even numbers are retain. Although this was a typographical error, technically, the study plan was not followed in terms of shipment, storage and analysis of SHIP samples as such this deviation has been recorded. No impact to the

study.

- Deviation to the study plan: Trials 1, 5 and 6. Storage temperature (air temperature) of the retain samples increased above -18 ºC. No impact as the core temperature did not increase above frozen.

GLP:	Yes
Acceptability:	Yes

Summary of the study 2 trials - QG22007

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)							PHI (days)	Details on trial
			kg a.s./ ha	Water (l/ha)	kg a.s./hl				Prothioconazole-desthio	α	3-OH	4-OH	5-OH	6-OH	Sum*		
	(a)	(b)				(c)										(d)	(e)
Trial 1 Belgium Kortenaken 3470 (Europe North)	Spring Oilseed Rape/ Mirakel	1. 29/03/2022 2. 01/05/2022 to 25/05/2022 3. 26/07/ 2022	0.177 0.177	204 204	0.0868 0.0868	20/06/2022 04/07/2022	BBCH 80	Seed Rest of Plant Seed Rest of Plant	<0.0015 <0.0015 <u>0.0564</u> <u>0.0217</u>	<0.0015 <0.0015 <u><0.005</u> <u>0.0608</u>	<0.0015 <0.005 <u><0.005</u> <u>0.136</u>	<0.0015 <0.0015 <u><0.005</u> <u>0.0558</u>	<0.0015 <0.0015 <u><0.005</u> <u>0.0127</u>	<0.0015 <0.0015 <u><0.005</u> <u><0.005</u>	<u>0.080</u> 0.279	22 22 22 22	Acceptable Report: QG22006 Prothioconazole-desthio: Method: Battelle No. QG/20/011 LOQ = 0.005 mg/kg Metabolites: Method: Battelle No. QG/22/001 LOQ = 0.005 mg/kg LOD = 0.0015 Max/ Frozen storage = 411 days
Trial 2 Poland Urbanowice / Opole 47-270 (Europe North)	Winter Oilseed Rape/ Umberto	1. 28/08/2021 2. 10/05/2022 to 03/06/2022 3. 09/08/ 2022	0.178 0.181	310 314	0.0574 0.0576	22/06/2022 07/07/2022	(Control) (Control) BBCH 80 BBCH 80	Seed Rest of plant Seed Rest of plant	<0.0015 <0.0015 <u><0.005</u> <u>0.0366</u>	<0.0015 <0.0015 <u><0.005</u> <u>0.00978</u>	<0.0015 <0.0015 <u><0.005</u> <u>0.0236</u>	<0.0015 <0.0015 <u><0.005</u> <u>0.0127</u>	<0.0015 <0.0015 <u><0.005</u> <u><0.005</u>	<0.0015 <0.0015 <u><0.005</u> <u><0.005</u>	<u><0.029</u> 0.09	33 33 33 33	Acceptable Report: QG22006 Prothioconazole-desthio: Method: Battelle No. QG/20/011 LOQ = 0.005 mg/kg Metabolites: Method: Battelle No. QG/22/001 LOQ = 0.005 mg/kg LOD = 0.0015 Max/ Frozen storage = 411 days

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)							PHI (days)	Details on trial
			kg a.s./ ha	Water (l/ha)	kg a.s./hl				Prothioconazole-desthio	α	3-OH	4-OH	5-OH	6-OH	Sum*		
	(a)	(b)				(c)										(d)	(e)
Trial 3 Poland Peckowo / Greater 64-520 (Europe North)	Winter Oilseed Rape/ Dominator	1. 02/09/2021 2. 18/04/2022 to 15/05/2022 3. 15/06/2022 15/06/2022 22/06/2022 06/07/2022 09/07/2022 09/07/2022	0.180 0.175	312 304	0.0577 0.0576	01/06/2022 15/06/2022	(Control) (Control) (Control) (Control) (Control) (Control) BBCH 80 BBCH 80 BBCH 80 BBCH 80 BBCH 80 BBCH 80	Immature plant Immature plant Immature plant Immature plant Seed Rest of plant Immature plant Immature plant Immature plant Immature plant Seed Rest of plant	<0.0015 <0.0015 <0.0015 <0.0015 <0.005 <0.0015 0.0448 0.925 0.415 0.385 <u>0.0182</u> <u>0.673</u>	<0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.005 <0.005 0.0185 0.0472 <u><0.005</u> <u>0.0977</u>	<0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.0015 0.00564 0.00862 0.0310 0.103 <u><0.005</u> <u>0.240</u>	<0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.005 <0.005 0.00872 0.0418 <u><0.005</u> <u>0.0880</u>	<0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.005 <0.005 <0.005 0.0109 <u><0.005</u> <u>0.0242</u>	<0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.005 <0.005 <0.005 <0.005 <u><0.005</u> <u><0.005</u>	0.069 0.952 0.480 0.583 <u>0.042</u> 1.106	-0 0 7 21 24 24 -0 0 7 21 24 24	Acceptable Report: QG22006 Prothioconazole-desthio: Method: Battelle No. QG/20/011 LOQ = 0.005 mg/kg Metabolites: Method: Battelle No. QG/22/001 LOQ = 0.005 mg/kg LOD = 0.0015 Max/ Frozen storage = 411 days
Trial 4 Germany Machern OT Gerichshain / Saxony 04827 (Europe North)	Spring Oilseed Rape/ INV 160 CL	1. 11/03/2022 2. 20/05/2022 to 05/06/2022 3. 17/06/2022 17/06/2022 23/06/2022 08/07/2022 03/08/2022 03/08/2022	0.165 0.171	287 298	0.0575 0.0574	02/06/2022 17/06/2022	(Control) (Control) (Control) (Control) (Control) (Control) BBCH 80 BBCH 80 BBCH 80 BBCH 80 BBCH 80 BBCH 80	Immature plant Immature plant Immature plant Immature plant Seed Rest of plant Immature plant Immature plant Immature plant Immature plant Seed Rest of plant	<0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.0015 0.0362 0.683 0.287 0.0513 0.00514 0.196	<0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.005 <0.005 0.00759 0.00737 <0.005 0.0138	<0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.0015 0.00638 0.0100 0.0246 0.0181 <0.005 0.132	<0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.005 <0.005 0.00630 0.00978 <0.005 0.0564	<0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.005 <0.005 <0.005 <0.005 <0.005 0.0103	<0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.005 <0.005 <0.005 <0.005 <0.005 <0.005	0.061 0.712 0.333 0.094 <u>0.029</u> 0.403	-0 0 6 21 47 47 -0 0 6 21 47 47	Acceptable Report: QG22006 Prothioconazole-desthio: Method: Battelle No. QG/20/011 LOQ = 0.005 mg/kg Metabolites: Method: Battelle No. QG/22/001 LOQ = 0.005 mg/kg LOD = 0.0015 Max/ Frozen storage = 411 days

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)							PHI (days) (d)	Details on trial (e)
			kg a.s./ ha	Water (l/ha)	kg a.s./hl				Prothioconazole-desthio	α	3-OH	4-OH	5-OH	6-OH	Sum*		
Trial 5 Germany Velen 46342 (Europe North)	Spring Oilseed Rape/ Ability	1. 05/04/2022 2. 05/06/2022 to 25/06/2022 3. 12/07/2022 12/07/2022 20/07/2022 03/08/2022 18/08/2022 18/08/2022	0.174 0.172	201 199	0.0866 0.0864	27/06/2022 12/07/2022	(Control) (Control) (Control) (Control) (Control) (Control) BBCH 80 BBCH 80 BBCH 80 BBCH 80 BBCH 80 BBCH 80	Immature plant Immature plant Immature plant Immature plant Seed Rest of plant Immature plant Immature plant Immature plant Immature plant Seed Rest of plant	<0.0015 <0.0015 <0.0015 <0.0015 0.0445 <0.0015 0.297 1.19 <0.005 <0.005 0.0146 <0.005	<0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.0015 0.0338 0.0292 <0.005 <0.005 <0.005 <0.005	<0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.0015 0.0384 0.0342 <0.005 <0.005 <0.005 <0.005	<0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.0015 0.0140 0.0119 <0.005 <0.005 <0.005 <0.005	<0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.0015 0.00568 0.00526 <0.005 <0.005 <0.005 <0.005	<0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.005 <0.005 <0.005 <0.005 <0.005 <0.005	0.389 1.271 <0.029 <0.029 0.038 <0.029	-0 0 6 21 28 28 -0 0 6 21 28 28	Acceptable Report: QG22006 Prothioconazole-desthio: Method: Battelle No. QG/20/011 LOQ = 0.005 mg/kg Metabolites: Method: Battelle No. QG/22/001 LOQ = 0.005 mg/kg LOD = 0.0015 Max/ Frozen storage = 411 days
Trial 6 The Netherlands AV Ven-Zelderheide 6599 (Europe North)	Spring Oilseed Rape/ Ability	1. 11/04/2022 2. 02/06/2022 to 20/06/2022 3. 05/07/2022 05/07/2022 11/07/2022 26/07/2022 01/08/2022 01/08/2022	0.174 0.175	201 203	0.0866 0.0862	21/06/2022 05/07/2022	(Control) (Control) (Control) (Control) (Control) (Control) BBCH 80 BBCH 80 BBCH 80 BBCH 80 BBCH 80 BBCH 80	Immature plant Immature plant Immature plant Immature plant Seed Rest of plant Immature plant Immature plant Immature plant Immature plant Seed Rest of plant	<0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.0015 0.0156 0.446 0.250 0.0980 0.0136 0.230	<0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.005 <0.005 <0.005 0.0151 <0.005 0.0246	<0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.005 <0.005 0.00904 0.0438 <0.005 0.139	<0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.005 <0.005 <0.005 0.0152 <0.005 0.0410	<0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.005 <0.005 <0.005 <0.005 <0.005 0.0100	<0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.005 <0.005 <0.005 <0.005 <0.005 <0.005	0.039 0.470 0.278 0.178 0.037 0.439	-0 0 6 21 28 28 -0 0 6 21 28 28	Acceptable Report: QG22006 Prothioconazole-desthio: Method: Battelle No. QG/20/011 LOQ = 0.005 mg/kg Metabolites: Method: Battelle No. QG/22/001 LOQ = 0.005 mg/kg LOD = 0.0015 Max/ Frozen storage = 411 days

(a) According to CODEX Classification / Guide
(b) Only if relevant

(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

α	Prothioconazole-α-hydroxy-desthio
3-OH	Prothioconazole-3-hydroxy-desthio
4-OH	Prothioconazole-4-hydroxy-desthio
5-OH	Prothioconazole-5-hydroxy-desthio
6-OH	Prothioconazole-6-hydroxy-desthio

*sum of prothioconazole-desthio, 3-hydroxyprothioconazole-desthio, 4-hydroxyprothioconazole-desthio, 5-hydroxyprothioconazole-desthio, 6-hydroxyprothioconazole-desthio and alpha-hydroxyprothioconazole-desthio, expressed as prothioconazole-desthio. Where the residue of analyte expressed as prothioconazole-desthio (mg/kg) was calculated as follow = MW prothioconazole-desthio (g/mol) x analyte residue measured (mg/kg) / Analyte MW (g/mol)

The molecular weight (MW) of each analyte is: prothioconazole-desthio: 312.19 g/mol, Prothioconazole-α-hydroxy-desthio: 328.19 g/mol, Prothioconazole-3-hydroxy-desthio: 328.19 g/mol, Prothioconazole-4-hydroxy-desthio: 328.19 g/mol, Prothioconazole-5-hydroxy-desthio: 328.19 g/mol, Prothioconazole-6-hydroxy-desthio: 328.19 g/mol

The LOQ for the sum expressed as prothioconazole-desthio (0.029 mg/kg) was calculated using the formula: LOQ of prothioconazole-desthio + Prothioconazole-α-hydroxy-desthio expressed as 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.

Study 3 - Toscano Saes & Coleman 2023, NZ/21/002- Northern & Southern Europe (new data)

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

Reference:	KCP 8.3.3/05
Report	Magnitude of Residues of Prothioconazole-desthio and Hydroxyprothioconazole-desthio Metabolites Following Two Applications of a Prothioconazole 250 g/L DC Formulation to Oilseed Rape in Northern and Southern Europe, 2021; R. Toscano Saes & H. Coleman, 2023; Study No.: NZ/21/002
Guideline(s):	• OECD No. 1 Principles on Good Laboratory Practice. • OECD No. 13 The Application of the OECD Principles of GLP to the Organisation and Management of Multi-Site Studies. • General recommendations for the design, preparation and realization of residue trials (SANCO 7029/VI/95 rev.5, 22 July 1997). • European Community Guidelines SANTE/2019/12752 on data requirements for setting maximum residue levels, comparability of residue trials and extrapolation of residue data on products from plant and animal origin. • OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published on 7 September 2009). • SANTE/2020/12830, Rev.1, Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes, 24. February 2021.
Deviations:	Several minor deviations from the internal and field protocols were noted, but none of these deviations impact the validity of the study results.
GLP:	Yes
Acceptability:	Yes

Summary of the study 3 trials - NZ21002

Trial No./ Location/ EU zone/ Year	Commodity / Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)							PHI (days)	Details on trial
			kg a.s./ ha	Water (l/ha)	kg a.s./hl				Prothioconazole-desthio	α	3-OH	4-OH	5-OH	6-OH	Sum*		
	(a)	(b)				(c)										(d)	(e)
Trial 1 NZ21002-01 Velen-Ramsdorf 46342 Germany (Europe North)	Spring Oilseed Rape/ Ability	1. 05/04/2021 2. 15/05/2021 to 12/06/2021 3. 18/08/2021	0.174 0.168	209 202	0.0833 0.0832	28/06/2021 12/07/2021	(Control) (Control) BBCH 80 BBCH 80	Seed Rest of plant Seed Rest of plant	<0.0015 0.0015 <0.005 <0.005	<0.0015 0.0015 <0.005 <0.005	<0.0015 0.0015 <0.005 <0.005	<0.0015 0.0015 <0.005 <0.005	<0.0015 0.0015 <0.005 <0.005	<0.0015 0.0015 <0.005 <0.005	<0.029 <0.029	37 37 37 37	Acceptable Report: NZ21002 Prothioconazole-desthio: Method: Battelle No. QG/20/011 LOQ = 0.005 mg/kg Metabolites: Method: Battelle No. QG/22/001 LOQ = 0.005 mg/kg LOD = 0.0015 Max/ Frozen storage = 630 days

Trial No./ Location/ EU zone/ Year	Commodity / Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)							PHI (days)	Details on trial
			kg a.s./ ha	Water (l/ha)	kg a.s./hl				Prothioconazole-desthio	α	3-OH	4-OH	5-OH	6-OH	Sum*		
	(a)	(b)				(c)										(d)	(e)
Trial 2 NZ21002-02 Ottersum 6595 ME The Netherlands (Europe North)	Spring Oilseed Rape/ Ability	1. 05/04/2021 2. 12/05/2021 to 10/06/2021 3. 20/08/2021	0.168 0.172	202 207	0.0832 0.0831	28/06/2021 12/07/2021	(Control) (Control) BBCH 80 BBCH 80	Seed Rest of plant Seed Rest of plant	<0.0015 <0.0015 0.00659 0.0785	<0.0015 <0.0015 <0.005 0.0313	<0.0015 <0.0015 <0.005 0.0833	<0.0015 <0.0015 <0.005 0.0394	<0.0015 <0.0015 <0.005 0.0111	<0.0015 <0.0015 <0.005 <0.005	0.030 0.240	39 39 39 39	Acceptable Report: NZ21002 Prothioconazole-desthio: Method: Battelle No. QG/20/011 LOQ = 0.005 mg/kg Metabolites: Method: Battelle No. QG/22/001 LOQ = 0.005 mg/kg LOD = 0.0015 Max/ Frozen storage = 630 days

Trial No./ Location/ EU zone/ Year	Commodity / Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)							PHI (days)	Details on trial
			kg a.s./ ha	Water (l/ha)	kg a.s./hl				Prothioconazole-desthio	α	3-OH	4-OH	5-OH	6-OH	Sum*		
	(a)	(b)				(c)										(d)	(e)
Trial 3 NZ21002-03 12050 Italy (Europe South)	Oilseed Rape/ Cherokee	1. 15/09/2020 2. 26/04/2021 to 18/05/2021 3. 05/07/2021	0.174 0.161	313 290	0.0556 0.0555	13/05/2021 27/05/2021	(Control) (Control) BBCH 80 BBCH 80	Seed Rest of plant Seed Rest of plant	<0.0015 <0.0015 0.00755 0.0344	<0.0015 <0.0015 <0.005 <0.005	<0.0015 <0.0015 <0.005 0.0105	<0.0015 <0.0015 <0.005 <0.005	<0.0015 <0.0015 <0.005 <0.005	<0.0015 <0.0015 <0.005 <0.005	 0.031 0.063	39 39 39 39	Acceptable Report: NZ21002 Prothioconazole-desthio: Method: Battelle No. QG/20/011 LOQ = 0.005 mg/kg Metabolites: Method: Battelle No. QG/22/001 LOQ = 0.005 mg/kg LOD = 0.0015 Max/ Frozen storage = 630 days

Trial No./ Location/ EU zone/ Year	Commodity / Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)							PHI (days)	Details on trial
			kg a.s./ ha	Water (l/ha)	kg a.s./hl				Prothioconazole-desthio	α	3-OH	4-OH	5-OH	6-OH	Sum*		
	(a)	(b)				(c)										(d)	(e)
Trial 4 NZ21002-04 ES-41710 Spain (Europe South)	Oilseed Rape/ Salsa CL	1. 20/01/2021 2. 20/04/2021 to 12/05/2021 3. 16/07/2021	0.163 0.160	294 288	0.0554 0.0555	07/06/2021 21/06/2021	(Control) (Control) BBCH 80 BBCH 80	Seed Rest of plant Seed Rest of plant	<0.0015 <0.0015 0.0738 2.30	<0.0015 <0.0015 <0.005 0.0981	<0.0015 <0.0015 <0.005 0.118	<0.0015 <0.0015 <0.005 0.0710	<0.0015 <0.0015 <0.005 0.0222	<0.0015 <0.0015 <0.005 0.00698	0.098 2.601	25 25 25 25	Acceptable Report: NZ21002 Prothioconazole-desthio: Method: Battelle No. QG/20/011 LOQ = 0.005 mg/kg Metabolites: Method: Battelle No. QG/22/001 LOQ = 0.005 mg/kg LOD = 0.0015 Max/ Frozen storage = 630 days

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

α Prothioconazole-α-hydroxy-desthio
3-OH Prothioconazole-3-hydroxy-desthio
4-OH Prothioconazole-4-hydroxy-desthio
5-OH Prothioconazole-5-hydroxy-desthio
6-OH Prothioconazole-6-hydroxy-desthio

*sum of prothioconazole-desthio, 3-hydroxyprothioconazole-desthio, 4-hydroxyprothioconazole-desthio, 5-hydroxyprothioconazole-desthio, 6-hydroxyprothioconazole-desthio and alpha-

hydroxyprothioconazole-desthio, expressed as prothioconazole-desthio. Where the residue of analyte expressed as prothioconazole-desthio (mg/kg) was calculated as follow = MW prothioconazole-desthio (g/mol) x analyte residue measured (mg/kg) / Analyte MW (g/mol)
The molecular weight (MW) of each analyte is: prothioconazole-desthio: 312.19 g/mol, Prothioconazole-α-hydroxy-desthio: 328.19 g/mol, Prothioconazole-3-hydroxy-desthio: 328.19 g/mol, Prothioconazole-4-hydroxy-desthio: 328.19 g/mol, Prothioconazole-5-hydroxy-desthio: 328.19 g/mol, Prothioconazole-6-hydroxy-desthio: 328.19 g/mol
The LOQ for the sum expressed as prothioconazole-desthio (0.029 mg/kg) was calculated using the formula: LOQ of prothioconazole-desthio + Prothioconazole-α-hydroxy-desthio expressed as 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.

Study 4 – Hardy & Coleman, 2020, QG20008- Southern Europe (new data)

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

Reference:	KCP 8.3.3/06
Report	Magnitude of Residues of Prothioconazole-desthio, Hydroxy-prothioconazole-desthio metabolites, Triazole Lactic Acid and Triazole Acetic Acid Following Two Applications of a 250 g/L EC Formulation to Oilseed Rape in Southern Europe, 2020; J. Hardy & H. Coleman, 2024; Study No.: QG20008
Guideline(s):	• General recommendations for the design, preparation and realization of residue trials (SANCO 7029/VI/95 rev.5, 22 July 1997). • OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published on 7 September 2009). • SANTE/2020/12830, Rev.1, Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes, 24. February 2021
Deviations:	Several minor deviations from the internal and field protocols were noted, but none of these deviations impact the validity of the study results.
GLP:	Yes
Acceptability:	Yes

Summary of the study 4 trials – QG20008

Trial No./ Location/ EU zone/ Year (a)	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 (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)						PHI (days) (d)	Details on trial (e)
			kg a.s./ ha	Water (l/ha)	kg a.s./hl				Prothioconazole-desthio	α	3-OH	4-OH	5-OH	6-OH		
Trial 1 QG20008-01 Spain ES-50670 (Europe South)	Oilseed Rape/ DK Expression	1. 28/10/2019 2. 13/04/2020 to 20/05/2020 3. 21/05/2020	0.177 0.181	200 204	0.0885 0.0887	06/05/2020 21/05/2020	(Control) (Control) (Control) (Control) (Control) BBCH 80 BBCH 80 BBCH 80 BBCH 80 BBCH 80	Immature plant Immature plant Immature plant Immature plant Seed Rest of plant Immature plant Immature plant Immature plant Immature plant Seed Rest of plant	<0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.0015 0.119 1.01 0.718 0.318 0.0516 0.0628	<0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.005 <0.005 0.0150 0.0195 <0.005 <0.005	<0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.0015 0.0102 0.0113 0.0230 0.0376 <0.005 0.0254	<0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.005 <0.005 0.00700 0.0202 <0.005 0.0117	<0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.005 <0.005 <0.005 <0.005 <0.005 <0.005	<0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.005 <0.005 <0.005 <0.005 <0.005 <0.005	-0 0 7 21 35 35 -0 0 7 21 35 35	Acceptable Report: QG20008 Prothioconazole-desthio: Method: Battelle No. QG/20/011 LOQ = 0.005 mg/kg Metabolites: Method: Battelle No. QG/22/001 LOQ = 0.005 mg/kg LOD = 0.0015
Trial 2 QG20008-02 Spain ES-31195 (Europe South)	Oilseed Rape/ DK Expression	1. 24/09/2019 2. 05/04/2020 to 20/05/2020 3. 09/07/2020	0.177 0.180	200 203	0.0885 0.0887	11/05/2020 25/05/2020	(Control) (Control) BBCH 80 BBCH 80	Seed Rest of plant Seed Rest of plant	<0.0015 <0.0015 0.0447 0.0793	<0.0015 <0.0015 <0.005 0.0128	<0.0015 <0.0015 <0.005 0.0336	<0.0015 <0.0015 <0.005 0.0126	<0.0015 <0.0015 <0.005 <0.005	<0.0015 <0.0015 <0.005 <0.005	45 45 45 45	Acceptable Report: QG20008 Prothioconazole-desthio: Method: Battelle No. QG/20/011 LOQ = 0.005 mg/kg Metabolites: Method: Battelle No. QG/22/001 LOQ = 0.005 mg/kg LOD = 0.0015

Trial No./ Location/ EU zone/ Year (a)	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 (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)						PHI (days) (d)	Details on trial (e)
			kg a.s./ ha	Water (l/ha)	kg a.s./hl				Prothioconazole-desthio	α	3-OH	4-OH	5-OH	6-OH		
Trial 3 QG20008-03 Italy 12050 (Europe South)	Oilseed Rape/ Cherokee	1. 16/09/2019 2. 13/04/2020 to 02/05/2020 3. 03/06/2020 03/06/2020 10/06/2020 24/06/2020 08/07/2020 08/07/2020	0.177 0.169	300 286	0.0590 0.0591	20/05/2020 03/06/2020	(Control) (Control) (Control) (Control) (Control) (Control) BBCH 80 BBCH 80 BBCH 80 BBCH 80 BBCH 80 BBCH 80	Immature plant Immature plant Immature plant Immature plant Seed Rest of plant Immature plant Immature plant Immature plant Immature plant Seed Rest of plant	<0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.0015 0.192 1.49 0.836 0.288 0.0645 0.265	<0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.0015 0.0139 0.0147 0.0563 0.0584 0.0118 0.110	<0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.0015 0.0208 0.0238 0.0362 0.0496 <0.005 0.109	<0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.0015 0.00668 0.00822 0.0161 0.0292 <0.005 0.0480	<0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.005 <0.005 0.00628 0.00664 <0.005 0.0142	<0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.005 <0.005 <0.005 <0.005 <0.005 <0.005	-1 0 7 21 35 35 -1 0 7 21 35 35	Acceptable Report: QG20008 Prothioconazole-desthio: Method: Battelle No. QG/20/011 LOQ = 0.005 mg/kg Metabolites: Method: Battelle No. QG/22/001 LOQ = 0.005 mg/kg LOD = 0.0015
Trial 4 QG20008-04 Italy 13012 (Europe South)	Oilseed Rape/ Cherokee	1. 27/09/2019 2. 20/04/2020 to 06/05/2020 3. 08/07/2020	0.169 0.177	287 300	0.0589 0.0590	20/05/2020 03/06/2020	(Control) (Control) BBCH 80 BBCH 80	Seed Rest of plant Seed Rest of plant	<0.0015 <0.0015 0.0645 0.0953	<0.0015 <0.0015 0.0129 0.0268	<0.0015 <0.0015 <0.005 0.0482	<0.0015 <0.0015 <0.005 0.0256	<0.0015 <0.0015 <0.005 0.00790	<0.0015 <0.0015 <0.005 <0.005	35 35 35 35	Acceptable Report: QG20008 Prothioconazole-desthio: Method: Battelle No. QG/20/011 LOQ = 0.005 mg/kg Metabolites: Method: Battelle No. QG/22/001 LOQ = 0.005 mg/kg LOD = 0.0015

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days)	Details on trial
			kg a.s./ ha	Water (l/ha)	kg a.s./hl				TLA	TAA		
	(a)	(b)				(c)					(d)	(e)
Trial 1 QG20008-01 Spain ES-50670 (Europe South)	Oilseed Rape/ DK Expression	1. 28/10/2019 2. 13/04/2020 to 20/05/2020 3. 21/05/2020 21/05/2020 28/05/2020 11/06/2020 25/06/2020 25/06/2020	0.177 0.181	200 204	0.0885 0.0887	06/05/2020 21/05/2020	(Control) (Control) (Control) (Control) (Control) (Control) BBCH 80 BBCH 80 BBCH 80 BBCH 80 BBCH 80 BBCH 80	Immature plant Immature plant Immature plant Immature plant Seed Rest of plant Immature plant Immature plant Immature plant Immature plant Seed Rest of plant	<0.00300 <0.00300 <0.00300 <0.00300 <0.00300 <0.00300 <0.0100 <0.0100 <0.0100 <0.0100 <0.0100 <0.0100	<0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.005 <0.005 <0.005 <0.005 <0.005 <0.005	-0 0 7 21 35 35 -0 0 7 21 35 35	Acceptable Report: QG20008 TAA: Method: Battelle No. QG/20/012 LOQ = 0.00500 mg/kg LOD = 0.00150 mg/kg TLA: Method: Battelle No. QG/20/012 LOQ = 0.0100 mg/kg LOD = 0.00300 mg/kg
Trial 2 QG20008-02 Spain ES-31195 (Europe South)	Oilseed Rape/ DK Expression	1. 24/09/2019 2. 05/04/2020 to 20/05/2020 3. 09/07/2020	0.177 0.180	200 203	0.0885 0.0887	11/05/2020 25/05/2020	(Control) (Control) BBCH 80 BBCH 80	Seed Rest of plant Seed Rest of plant	0.0190 <0.0100 0.0154 <0.0100	0.00536 <0.005 <0.005 <0.005	45 45 45 45	Acceptable Report: QG20008 TAA: Method: Battelle No. QG/20/012 LOQ = 0.00500 mg/kg LOD = 0.00150 mg/kg TLA: Method: Battelle No. QG/20/012 LOQ = 0.0100 mg/kg LOD = 0.00300 mg/kg

Trial No./ Location/ EU zone/ Year (a)	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 (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days) (d)	Details on trial (e)
			kg a.s./ ha	Water (l/ha)	kg a.s./hl				TLA	TAA		
Trial 3 QG20008-03 Italy 12050 (Europe South)	Oilseed Rape/ Cherokee	1. 16/09/2019 2. 13/04/2020 to 02/05/2020 3. 03/06/2020 03/06/2020 10/06/2020 24/06/2020 08/07/2020 08/07/2020	0.177 0.169	300 286	0.0590 0.0591	20/05/2020 03/06/2020	(Control) (Control) (Control) (Control) (Control) (Control) BBCH 80 BBCH 80 BBCH 80 BBCH 80 BBCH 80 BBCH 80	Immature plant Immature plant Immature plant Immature plant Seed Rest of plant Immature plant Immature plant Immature plant Immature plant Seed Rest of plant	<0.00300 <0.00300 <0.00300 <0.00300 <0.00300 <0.00300 <0.0100 <0.0100 <0.0100 <0.0100 <0.0100 <0.0100	<0.0015 <0.0015 <0.0015 <0.0015 <0.0015 <0.005 <0.005 <0.005 <0.005 <0.005 <0.005 <0.005	-1 0 7 21 35 35 -1 0 7 21 35 35	Acceptable Report: QG20008 TAA: Method: Battelle No. QG/20/012 LOQ = 0.00500 mg/kg LOD = 0.00150 mg/kg TLA: Method: Battelle No. QG/20/012 LOQ = 0.0100 mg/kg LOD = 0.00300 mg/kg
Trial 4 QG20008-04 Italy 13012 (Europe South)	Oilseed Rape/ Cherokee	1. 27/09/2019 2. 20/04/2020 to 06/05/2020 3. 08/07/2020	0.169 0.177	287 300	0.0589 0.0590	20/05/2020 03/06/2020	(Control) (Control) BBCH 80 BBCH 80	Seed Rest of plant Seed Rest of plant	<0.0100 <0.00300 <0.0100 <0.0100	<0.0015 <0.005 <0.005 <0.005	35 35 35 35	Acceptable Report: QG20008 TAA: Method: Battelle No. QG/20/012 LOQ = 0.00500 mg/kg LOD = 0.00150 mg/kg TLA: Method: Battelle No. QG/20/012 LOQ = 0.0100 mg/kg LOD = 0.00300 mg/kg

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

α	Prothioconazole-α-hydroxy-desthio
3-OH	Prothioconazole-3-hydroxy-desthio
4-OH	Prothioconazole-4-hydroxy-desthio
5-OH	Prothioconazole-5-hydroxy-desthio
6-OH	Prothioconazole-6-hydroxy-desthio
TLA	Triazole lactic acid
TAA	Triazole acetic acid

Study 5- Bousquet 2023, 647-2023- Northern & Southern Europe (new data)

Comments of zRMS:	Eight independent trials (4 decline and 4 harvest) located in Northern Europe (Northern France, Germany, Poland, The Netherlands, Denmark) were conducted on oilseed rape following two applications of Prothioconazole 250 g/L DC (175 g as/ha) to determine of the residues of prothioconazole metabolites: PTZ-alpha-OH-desthio, PTZ-3-OH-desthio, PTZ-4-OH-desthio, PTZ-5-OH-desthio, PTZ-6-OH-desthio and 1,2,4-triazole (T), triazole alanine (TA) in oilseed rape specimens: seed and forage. The first application was performed 14 +/-1 days before the second application. The second application was performed on the treated plot at BBCH 80. The methods were successfully validated for determination of all analytes in all matrices with an LOQ of 0.01 mg/kg according to guidance document SANTE/2020/12830, rev. 2. The maximum storage interval from sampling until extraction was 147 days for the PTZ-OH-desthio metabolites for oilseed rape forage and 138 days for oilseed rape seeds. The maximum storage interval from sampling until extraction for 1,2,4-T and TA was 77 days in forage and was 23 days in seeds. The study on the magnitude of residues of the PTZ-OH-desthio metabolites is valid with regard to storage stability. **According to the S. Baxter, B. Phipps study (QG/21/002) 1,2,4-T and TA in oilseed rape seed are stable for 15 days under frozen storage at -18 °C. This storage stability period is not sufficient, because the interval time from sampling until extraction for 1,2,4-T and TA was longer.** <u>Residue results:</u> PTZ: No residue of PTZ-alpha-OH-desthio, PTZ-3-OH-desthio, PTZ-4-OH-desthio, PTZ-5-OH-desthio and PTZ-6-OH-desthio, all expressed as equivalent PTZ-desthio, was measured in the untreated specimens above the LOQ. In the treated specimens, residues of PTZ-alpha-OH-desthio, PTZ-3-OH-desthio, PTZ-4-OH-desthio, PTZ-5-OH-desthio and PTZ-6-OH-desthio, expressed as prothioconazole-desthio, ranged between: - 0.21 and 0.55 mg/kg (0.21, 0.30, 0.33, 0.55 mg/kg) in forage specimens - 0.01 and 0.04 mg/kg (0.01, 3x0.02, 2x0.03, 2x0.04 mg/kg) in seeds specimens (LOQ: 0.01 mg/kg for each analyte, 0.05 mg/kg for prothioconazole expressed as prothioconazole desthio as a sum of hydroxy-metabolites) TDMs: In the untreated and treated specimens for both matrices, no residue of T were detected at any time. In the untreated specimens, residues of TA ranged between: - 0.02 and 0.05 mg/kg (0.02, 0.03, 2x0.05, mg/kg) in forage specimens - 0.11 and 1.7 mg/kg (0.11, 0.16, 0.19, 0.26, 0.27, 0.41, 0.91, 1.7 mg/kg) in seeds specimens In the treated specimens, residues of TA ranged between: - 0.03 and 0.06 mg/kg (0.03, 2x0.04, 0.06 mg/kg) in forage specimens - 0.02 and 1.3 mg/kg (0.02, 0.15, 0.22, 0.23, 0.29, 0.52, 0.79, 1.3 mg/kg) in seeds specimens **These trials can be used to support the intended use on oilseed rape (for PTZ-OH-desthio metabolites, not for 1,2,4-T and TA).**

Reference:	KCP 8.3.3/07
Report	Magnitude of the residue of prothioconazole metabolites in oilseed rape in Northern and Southern Europe – 2023; C. Bousquet, 2024; Study Number: 647-2023
Guideline(s):	• Regulation (EC) N°1107/2009 of 21/10/2009 (Repealing the Council Directive 91/414/EEC) concerning the placing of plant protection

products on the market

- Regulation (EU) No 283/2013 of 01/03/2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market
- OECD (2021),Test No. 509: Crop Field Trial, OECD Guidelines for the Testing of Chemicals, Section 5, OECD Publishing
- SANTE/2020/12830, Rev.2, 14 February 2023; Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes (Supersedes Guidance Documents SANCO/3029/99 and SANCO/825/00)
- OECD (2007), Guidance Document on Pesticide Residue Analytical Methods. Series on testing and assessment Number 72. Series on pesticides Number 39. ENV/JM/MONO(2007)17
- The Application of GLP Principles to Field Studies, OECD Series on Principles of GLP and Compliance Monitoring Number 6 (Revised 1999), ENV/JM/MONO(99)22
- The Application of the OECD Principles of GLP to the Organisation and Management of Multi-Site Studies, OECD Series on Principles of GLP and Compliance Monitoring Number 13, ENV/JM/MONO(2002)9

Deviations: Minimal deviations for the field phase were noted in the report, but these are not considered to impact the validity of the study results.

GLP: Yes

Acceptability: Acceptable

The following table provides a summary of the storage interval between sampling and extraction from the residue trials:

Zone	trial no	date of sampling	date of extraction - T124	Max storage interval between sampling and extraction - T124 (days)	date of extraction - TA	Max storage interval between sampling and extraction - TA (days)
SEU	sp12	24.05.2023	12.06.2023	19	12.06.2023	19
SEU	gr09	28.06.2023	10.07.2023	12	10.07.2023	12
SEU	it11	28.06.2023	10.07.2023	12	10.07.2023	12
SEU	it13	22.06.2023	10.07.2023	18	10.07.2023	18
SEU	gr15	29.06.2023	10.07.2023	11	10.07.2023	11
NEU	fr01	26.06.2023	17.07.2023	21	19.07.2023	23
NEU	fr07	10.07.2023	17.07.2023	7	19.07.2023	9
SEU	fr14	03.07.2023	17.07.2023	14	19.07.2023	16
SEU	it10	11.07.2023	24.07.2023	13	24.07.2023	13
NEU	be02	18.07.2023	02.08.2023	15	02.08.2023	15
NEU	pl06	20.07.2023	02.08.2023	13	02.08.2023	13
NEU	ge03	14.08.2023	29.08.2023	15	29.08.2023	15
NEU	ge05	19.08.2023	29.08.2023	10	29.08.2023	10
NEU	nl08	08.08.2023	29.08.2023	21	29.08.2023	21

SEU	it16	18.08.2023	29.08.2023	11	29.08.2023	11
NEU	dk04	05.09.2023	15.09.2023	10	15.09.2023	10

Based on the report “Triazole Derived Metabolites: Frozen Storage Stability in Crops for 12 Months; Baxter, B. Phipps, 2025; Study No.: QG/21/002” 1,2,4-triazole in oilseed rape (seed) can be considered stable for a minimum of 15 days of frozen storage, hence trials: sp12, it13, fr01, nl08 are not considered for further assessment of the 1,2,4-triazole metabolite.
However, since the residue trials indicate ‘<LOQ residue’ situation, the number of independent trials may be reduced. According to Regulation (EU) No 283/2013, in case of ‘<LOQ residue’ situation the number of trials shall not be below the minimum of three per zone for minor crops and four per zone for major crops, which is the case here.

Residue data summary from supervised trials (647-2023 FR01)

Active Substance: prothioconazole
Crop / crop group: Oilseed rape / oilseeds
Responsible for reporting: Céline BOUSQUET / TESTAPI
115 route du Pô, 49650 Allonnes - France
Country: Northern France
Nominal Content of a.s.: 250 g/L
Formulation: DC

Commercial Product: Prothioconazole 250 g/L DC (FGR06)
Producer: UPL Europe Limited
Indoor/glasshouse/outdoor: outdoor
Other a.s. in formulation: -
Residue calculated as: triazole derivative metabolites (T, TA) (mg/kg) / separately

1	2	3	4	5			6	7	8	9		10	11
Report No. 647-2023 Location (region)	Commodity Variety	Date of 1-Planting 2-Flowering 3-Harvest	Method of treatment	Actual (nominal) application rate per treatment			Date of treatment	BBCH Crop Growth Stage at treatment	Portions analysed (4)	Residues (1)		DALA (2)	Remarks
				kg a.s./ha	Water (L/ha)	kg (a.s./hL)				T	TA		
Northern Europe Northern France 49700 Cizay la Madeleine (Pays de la Loire) Decline curve trial 647-2023 FR01	Oilseed rape (winter) KWS ARIANOS	1- 14/08/22 2- 03/04/23 to 01/05/23 3- 25/06/23 to 27/06/23	Broadcast foliar application Boom sprayer	0.1670 (0.1692) 0.1776 (0.1799)	193 206	0.0864 (0.0875) 0.0864 (0.0875)	17/05/23 31/05/23	76 80	**Untreated** Forage Forage Forage Forage Seeds **Treated** Forage Forage Forage Forage Seeds	 n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d.	 0.05 0.06 0.05 0.05 0.26 0.08 0.04 0.05 0.04 0.29	 -0 +0 6 23 26(3) -0 +0 6 23 26(3)	LC-DMS-MS/MS Method Validated in within this study Max. study storage interval between: -sampling and extraction: Triazole Alanine 68 days for forage 23 days for seeds 1,2,4-Triazole: 68 days for forage 21 days for seeds -extraction and analyses: 1 day

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

Residue data summary from supervised trials (647-2023 FR01)

Active Substance: prothioconazole
Crop / crop group: Oilseed rape / oilseeds
Responsible for reporting: Céline BOUSQUET / TESTAPI
115 route du Pô, 49650 Allonnes - France
Country: Northern France
Nominal Content of a.s.: 250 g/L
Formulation: DC

Commercial Product: Prothioconazole 250 g/L DC
Producer: UPL Europe Limited
Indoor/glasshouse/outdoor: outdoor
Other a.s. in formulation: -
Residue calculated as: Prothioconazole-alpha-hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio (mg/kg)

1	2	3	4	5			6	7	8	9			10	11
Report No. 647-2023 Location (region)	Commodity Variety	Date of 1-Planting 2-Flowering 3-Harvest	Method of treatment	Actual (nominal) application rate per treatment			Date of treatment	BBCH Crop Growth Stage at treatment	Portions analysed	Residues **expressed as prothioconazole-desthio** (1) PTZ = prothioconazole			DALA (2)	Remarks
				kg a.s./ha	Water (L/ha)	kg (a.s./hL)				PTZ-α-hydroxy-desthio	PTZ-3-hydroxy-desthio	PTZ-4-hydroxy-desthio		Untreated specimen:<0.01
Northern Europe	Oilseed rape (winter)	1-14/08/22	Broadcast foliar application	0.1670 (0.1692)	193	0.0864 (0.0875)	17/05/23	76						
Northern France 49700 Cizay la Madeleine (Pays de la Loire) Decline curve trial 647-2023 FR01	KWS ARIANOS	2-03/04/23 to 01/05/23 3-25/06/23 to 27/06/23	Boom sprayer	0.1776 (0.1799)	206	0.0864 (0.0875)	31/05/23	80	Forage [3] Forage [3] Forage [3] Forage [3] Seeds	<0.01 <0.01 0.02 0.04 0.01	0.10 0.07 0.16 0.30 0.01	0.04 0.03 0.08 0.16 <0.01	-0 +0 6 23 26[4]	LC-MS/MS method validated within this study Max. study storage interval between: -sampling and extraction: 147 days -extraction and analyses: 2 days LOQ: 0.01 mg/kg for each analyte, 0.05 mg/kg for prothioconazole expressed as prothioconazole desthio as a sum of
										PTZ-5-hydroxy-desthio	PTZ-6-hydroxy-desthio	**Sum of PTZ-OH-desthio metabolites (5)**		
									Forage [3] Forage [3] Forage [3] Forage [3] Seeds	<0.01 <0.01 0.02 0.04 <0.01	n.d. n.d. <0.01 <0.01 n.d.	**0.16** **0.12** **0.29** **0.55** **<LOQ**	-0 +0 6 23 26[4]	

														hydroxy-metabolites

(1) LOQ = 0.01 mg/kg / n.d. = non detected (<LOD = <0.003 mg/kg) (2) DALA = days after last application (3) Forage = whole plant without roots (4) Sampled at commercial harvest date (5) for calculation of the sum of PTZ-OH-desthio metabolites “n.d.” is taken as 0 mg/kg, whilst for “< 0.01” a residue of 0.01 mg/kg is accounted; calculation of the sum is based on rounded values.

Residue data summary from supervised trials (647-2023 BE02)

Active Substance: prothioconazole
Crop / crop group: Oilseed rape / oilseeds
Responsible for reporting: Céline BOUSQUET / TESTAPI
115 route du Pô, 49650 Allonnes - France
Country: Belgium
Nominal Content of a.s.: 250 g/L
Formulation: DC

Commercial Product: Prothioconazole 250 g/L DC
Producer: UPL Europe Limited
Indoor/glasshouse/outdoor: outdoor
Other a.s. in formulation: -
Residue calculated as: triazole derivative metabolites (T, TA) (mg/kg) / separately

1	2	3	4	5			6	7	8	9		10	11
Report No. 647-2023 Location (region)	Commodity Variety	Date of 1-Planting 2-Flowering 3-Harvest	Method of treatment	Actual (nominal) application rate per treatment			Date of treatment	BBCH Crop Growth Stage at treatment	Portions analysed (4)	Residues (1)		DALA (2)	Remarks
				kg a.s./ha	Water (L/ha)	kg (a.s./hL)				T	TA		
Northern Europe Belgium 6221 Saint-Armand (Province of Hainaut) Decline curve trial 647-2023 BE02	Oilseed rape (winter) FELICIANO KWS	1- 08/09/22 2- 17/04/23 to 10/05/23 3- 12/07/23 to 26/07/23	Broadcast foliar application Boom sprayer	0.1752 (0.1776) 0.1746 (0.1769)	304 303	0.0576 (0.0583) 0.0576 (0.0583)	30/05/23 12/06/23	76 80	**Untreated** Forage Forage Forage Forage Seeds	n.d. n.d. n.d. n.d. n.d.	0.03 0.03 0.04 0.03 0.16	-0 +0 7 21 36(3)	LC-DMS-MS/MS Method Validated in within this study Max. study storage interval between: -sampling and extraction: Triazole Alanine 56 days for forage 15 days for seeds 1,2,4-Triazole: 56 days for forage 15 days for seeds -extraction and analyses: 1 day
									Treated Forage Forage Forage Forage Seeds	n.d. n.d. n.d. n.d. n.d.	0.02 0.03 0.02 0.03 0.15	-0 +0 7 21 36(3)	

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

Residue data summary from supervised trials (647-2023 BE02)

Active Substance: prothioconazole
Crop / crop group: Oilseed rape / oilseeds
Responsible for reporting: Céline BOUSQUET / TESTAPI
115 route du Pô, 49650 Allonnes - France
Country: Belgium
Nominal Content of a.s.: 250 g/L
Formulation: DC

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

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

1	2	3	4	5			6	7	8	9			10	11
Report No. 647-2023 Location (region)	Commodity Variety	Date of 1-Planting 2-Flowering 3-Harvest	Method of treatment	Actual (nominal) application rate per treatment			Date of treatment	BBCH Crop Growth Stage at treatment	Portions analysed	Residues **expressed as prothioconazole-desthio** (1) PTZ = prothioconazole			DALA (2)	Remarks
				kg a.s./ha	Water (L/ha)	kg (a.s./hL)				PTZ-α-hydroxy-desthio	PTZ-3-hydroxy-desthio	PTZ-4-hydroxy-desthio		
Northern Europe	Oilseed rape (winter)	1-08/09/22	Broadcast foliar application	0.1752 (0.1776)	304	0.0576 (0.0583)	30/05/23	76						Untreated specimen:<0.01
Belgium 6221 Saint-Armand (Province of Hainaut) Decline curve trial 647-2023 BE02	FELICIANO KWS	2-17/04/23 to 10/05/23 3-12/07/23 to 26/07/23	Boom sprayer	0.1746 (0.1769)	303	0.0576 (0.0583)	12/06/23	80	Forage [3] Forage [3] Forage [3] Forage [3] Seeds	n.d. < 0.01 0.02 0.01 < 0.01	0.07 0.09 0.19 0.23 < 0.01	0.02 0.03 0.06 0.07 n.d.	-0 +0 7 21 36[4]	LC-MS/MS method validated within this study Max. study storage interval between: -sampling and extraction: 147 days -extraction and analyses: 2 days LOQ: 0.01 mg/kg for each analyte, 0.05 mg/kg for prothioconazole expressed as prothioconazole desthio as a sum
										PTZ-5-hydroxy-desthio	PTZ-6-hydroxy-desthio	**Sum of PTZ-OH-desthio metabolites (5)**		
									Forage [3] Forage [3] Forage [3] Forage [3] Seeds	< 0.01 < 0.01 0.02 0.02 n.d.	n.d. n.d. n.d. n.d. n.d.	**0.10** **0.14** **0.29** **0.33** **<LOQ**	-0 +0 7 21 36[4]	

														of hydroxy-metabolites

(1) LOQ = 0.01 mg/kg / n.d. = non detected (<LOD = <0.003 mg/kg) (2) DALA = days after last application (3) Forage = whole plant without roots (4) Sampled at commercial harvest date (5) for calculation of the sum of PTZ-OH-desthio metabolites "n.d." is taken as 0 mg/kg, whilst for "< 0.01" a residue of 0.01 mg/kg is accounted; calculation of the sum is based on rounded values.

Residue data summary from supervised trials (647-2023 GE03)

Active Substance: prothioconazole
Crop / crop group: Oilseed rape / oilseeds
Responsible for reporting: Céline BOUSQUET / TESTAPI
115 route du Pô, 49650 Allonnes - France
Country: Germany
Nominal Content of a.s.: 250 g/L
Formulation: DC

Commercial Product: Prothioconazole 250 g/L DC (FGR06)
Producer: UPL Europe Limited
Indoor/glasshouse/outdoor: outdoor
Other a.s. in formulation: -
Residue calculated as: triazole derivative metabolites (T, TA) (mg/kg) / separately

1	2	3	4	5			6	7	8	9		10	11
Report No. 647-2023 Location (region)	Commodity Variety	Date of 1-Planting 2-Flowering 3-Harvest	Method of treatment	Actual (nominal) application rate per treatment			Date of treatment	BBCH Crop Growth Stage at treatment	Portions analysed (4)	Residues (1)		DALA (2)	Remarks
				kg a.s./ha	Water (L/ha)	kg (a.s./hL)				T	TA		
Northern Europe Germany 46342 Velen-Ramsdorf	Oilseed rape (spring) MIRAKEL	1- 10/04/23 2- 02/06/23 to 21/06/23 3- 14/08/23	Broadcast foliar application Boom sprayer	0.1741 (0.1765) 0.1760 (0.1784)	303 306	0.0576 (0.0583) 0.0576 (0.0583)	21/06/23 04/07/23	69 80	**Untreated** Forage Forage Forage Forage Seeds	 n.d. n.d. n.d. n.d. n.d.	 0.06 0.05 0.09 0.05 0.41	 -0 +0 12 21 41(3)	LC-DMS-MS/MS Method Validated in within this study Max. study storage interval between:

(North Rhine-Westphalia) Decline curve trial 647-2023 GE03									**Treated** Forage Forage Forage Forage Seeds	 n.d. n.d. n.d. n.d. n.d.	 0.06 0.05 0.06 0.06 0.23	 -0 +0 12 21 41 (3)	-sampling and extraction: Triazole Alanine 77 days for forage 15 days for seeds 1,2,4-Triazole: 77 days for forage 15 days for seeds -extraction and analyses: 1 day

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

Residue data summary from supervised trials (647-2023 GE03)

Active Substance: prothioconazole
Crop / crop group: Oilseed rape / oilseeds
Responsible for reporting: Céline BOUSQUET / TESTAPI
115 route du Pô, 49650 Allonnes - France
Country: Germany
Nominal Content of a.s.: 250 g/L
Formulation: DC

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

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

1	2	3	4	5			6	7	8	9			10	11
Report No. 647-2023 Location (region)	Commodity Variety	Date of 1-Planting 2-Flowering 3-Harvest	Method of treatment	Actual (nominal) application rate per treatment			Date of treatment	BBCH Crop Growth Stage at treatment	Portions analysed	Residues **expressed as prothioconazole-desthio** (1) PTZ = prothioconazole			DALA (2)	Remarks
				kg a.s./ha	Water (L/ha)	kg (a.s./hL)								
Northern Europe Germany 46342 Velen-Ramsdorf (North Rhine-Westphalia) Decline curve trial 647-2023 GE03	Oilseed rape (spring) MIRAKEL	1-10/04/23 2-02/06/23 to 21/06/23 3-14/08/23	Broadcast foliar application Boom sprayer	0.1741 (0.1765) 0.1760 (0.1784)	303 306	0.0576 (0.0583) 0.0576 (0.0583)	21/06/23 04/07/23	69 80		PTZ-α-hydroxy-desthio	PTZ-3-hydroxy-desthio	PTZ-4-hydroxy-desthio		Untreated specimen: n.d. LC-MS/MS method validated within this study Max. study storage interval between: -sampling and extraction: 147 days -extraction and analyses: 2 days LOQ: 0.01 mg/kg for each analyte, 0.05 mg/kg for prothioconazole expressed as prothioconazole
									Forage (3)	< 0.01	0.09	0.02	-0	
									Forage (3)	< 0.01	0.08	0.02	+0	
									Forage (3)	0.02	0.16	0.04	12	
									Forage (3)	0.01	0.15	0.03	21	
									Seeds	< 0.01	< 0.01	n.d.	41(4)	
										PTZ-5-hydroxy-desthio	PTZ-6-hydroxy-desthio	**Sum of PTZ-OH-desthio metabolites (5)**		
									Forage (3)	< 0.01	n.d.	**0.13**	-0	
									Forage (3)	< 0.01	n.d.	**0.12**	+0	
									Forage (3)	0.01	< 0.01	**0.24**	12	
									Forage (3)	0.01	< 0.01	**0.21**	21	
									Seeds	n.d.	n.d.	**<LOQ**	41(4)	

														desthio as a sum of hydroxy-metabolites

(1) LOQ = 0.01 mg/kg / n.d. = non detected (<LOD = <0.003 mg/kg) (2) DALA = days after last application (3) Forage = whole plant without roots (4) Sampled at commercial harvest date (5) for calculation of the sum of PTZ-OH-desthio metabolites "n.d." is taken as 0 mg/kg, whilst for "< 0.01" a residue of 0.01 mg/kg is accounted; calculation of the sum is based on rounded values.

Residue data summary from supervised trials (647-2023 DK04)

Active Substance: prothioconazole
Crop / crop group: Oilseed rape / oilseeds
Responsible for reporting: Céline BOUSQUET / TESTAPI
115 route du Pô, 49650 Allonnes - France
Country: Denmark
Nominal Content of a.s.: 250 g/L
Formulation: DC

Commercial Product: Prothioconazole 250 g/L DC (FGR06)
Producer: UPL Europe Limited
Indoor/glasshouse/outdoor: outdoor
Other a.s. in formulation: -
Residue calculated as: triazole derivative metabolites (T, TA) (mg/kg)

1	2	3	4	5			6	7	8	9		10	11
Report No. 647-2023 Location (region)	Commodity Variety	Date of 1-Planting 2-Flowering 3-Harvest	Method of treatment	Actual (nominal) application rate per treatment			Date of treatment	BBCH Crop Growth Stage at treatment	Portions analysed (4)	Residues (1)		DALA (2)	Remarks
				kg a.s./ha	Water (L/ha)	kg (a.s./hL)				T	TA		
Northern Europe Denmark 5580 Nørre Aby (South Denmark)	Oilseed rape (spring) MIRAKEL	1- 26/04/23 2- 19/06/23 to 11/07/23 3- 01/09/23 to 15/09/23	Broadcast foliar application Boom sprayer	0.1681 (0.1703) 0.1701 (0.1724)	195 197	0.0863 (0.0875) 0.0864 (0.0875)	19/07/23 02/08/23	73 79	**Untreated** Forage Forage Forage Forage Seeds	 n.d. n.d. n.d. n.d. n.d.	 0.02 0.02 0.02 0.02 0.11	 -0 +0 7 22 34(3)	LC-DMS-MS/MS Method Validated in within this study Max. study storage interval between: -sampling and extraction:

Decline curve trial 647-2023 DK04									**Treated** Forage Forage Forage Forage Seeds	 n.d. n.d. n.d. n.d. n.d.	 0.03 0.03 0.04 0.04 0.22	 -0 +0 7 22 34(3)	Triazole Alanine 69 days for forage 10 days for seeds 1,2,4-Triazole: 69 days for forage 10 days for seeds -extraction and analyses: 1 day

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

Residue data summary from supervised trials (647-2023 DK04)

Active Substance: prothioconazole
Crop / crop group: Oilseed rape / oilseeds
Responsible for reporting: Céline BOUSQUET / TESTAPI
115 route du Pô, 49650 Allonnes - France
Country: Denmark
Nominal Content of a.s.: 250 g/L
Formulation: DC

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

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

1	2	3	4	5			6	7	8	9			10	11
Report No. 647-2023 Location (region)	Commodity Variety	Date of 1-Planting 2-Flowering 3-Harvest	Method of treatment	Actual (nominal) application rate per treatment			Date of treatment	BBCH Crop Growth Stage at treatment	Portions analysed	Residues **expressed as prothioconazole-desthio** (1) PTZ = prothioconazole			DALA (2)	Remarks
				kg a.s./ha	Water (L/ha)	kg (a.s./hL)								
Northern Europe Denmark 5580 Nørre Aby (South Denmark) Decline curve trial 647-2023 DK04	Oilseed rape (spring) MIRAKEL	1- 26/04/23 2- 19/06/23 to 11/07/23 3- 01/09/23 to 15/09/23	Broadcast foliar application Boom sprayer	0.1681 (0.1703) 0.1701 (0.1724)	195 197	0.0863 (0.0875) 0.0864 (0.0875)	19/07/23 02/08/23	73 79		PTZ-α-hydroxy-desthio	PTZ-3-hydroxy-desthio	PTZ-4-hydroxy-desthio		Untreated specimen: n.d. LC-MS/MS method validated within this study Max. study storage interval between: -sampling and extraction: 147 days -extraction and analyses: 2 days LOQ: 0.01 mg/kg for each analyte, 0.05 mg/kg for prothioconazole expressed as prothioconazole desthio as a sum
									Forage (3)	0.01	0.10	0.04	-0	
									Forage (3)	< 0.01	0.07	0.03	+0	
									Forage (3)	0.02	0.10	0.03	7	
									Forage (3)	0.03	0.18	0.06	22	
									Seeds	n.d.	< 0.01	n.d.	34(4)	
										PTZ-5-hydroxy-desthio	PTZ-6-hydroxy-desthio	**Sum of PTZ-OH-desthio metabolites (5)**		
									Forage (3)	0.01	n.d.	**0.16**	-0	
									Forage (3)	< 0.01	n.d.	**0.12**	+0	
									Forage (3)	< 0.01	n.d.	**0.16**	7	
									Forage (3)	0.02	< 0.01	**0.30**	22	
									Seeds	n.d.	n.d.	**<LOQ**	34(4)	

														of hydroxy-metabolites

(1) LOQ = 0.01 mg/kg / n.d. = non detected (<LOD = <0.003 mg/kg) (2) DALA = days after last application (3) Forage = whole plant without roots (4) Sampled at commercial harvest date (5) for calculation of the sum of PTZ-OH-desthio metabolites "n.d." is taken as 0 mg/kg, whilst for "< 0.01" a residue of 0.01 mg/kg is accounted; calculation of the sum is based on rounded values.

Residue data summary from supervised trials (647-2023 GE05)

Active Substance: prothioconazole
Crop / crop group: Oilseed rape / oilseeds
Responsible for reporting: Céline BOUSQUET / TESTAPI
115 route du Pô, 49650 Allonnes - France
Country: Germany
Nominal Content of a.s.: 250 g/L
Formulation: DC

Commercial Product: Prothioconazole 250 g/L DC (FGR06)
Producer: UPL Europe Limited
Indoor/glasshouse/outdoor: outdoor
Other a.s. in formulation: -
Residue calculated as: triazole derivative metabolites (T, TA) (mg/kg)

1	2	3	4	5			6	7	8	9		10	11
Report No. 647-2023 Location (region)	Commodity Variety	Date of 1-Planting 2-Flowering 3-Harvest	Method of treatment	Actual (nominal) application rate per treatment			Date of treatment	BBCH Crop Growth Stage at treatment	Portions analysed	Residues (1)		DALA (2)	Remarks
				kg a.s./ha	Water (L/ha)	kg (a.s./hL)				T	TA		
Northern Europe Germany	Oilseed rape (spring) MIRAKEL	1- 30/03/23 2- 05/06/23 to 19/06/23 3- 19/08/23	Broadcast foliar application Boom sprayer	0.1733 (0.1756) 0.1774 (0.1797)	301 308	0.0576 (0.0583) 0.0576 (0.0583)	19/06/23 04/07/23	69 80	**Untreated** Seeds	n.d.	0.19	43(3)	LC-DMS-MS/MS Method Validated in within this study

04827 Gerichshain (Saxony) Harvest trial 647-2023 GE05									**Treated** Seeds	n.d.	0.20	43(3)	Max. study storage interval between: -sampling and extraction: 77 days for forage Triazole Alanine 10 days for seeds 1,2,4-Triazole: 10 days for seeds -extraction and analyses: 1 day

(1) LOQ = 0.01 mg/kg / n.d. = non detected (<LOD = <0.003 mg/kg) / T= 1,2,4-Triazole / TA = Triazole Alanine (2) DALA = days after last application (3) Sampled at commercial harvest date

Residue data summary from supervised trials (647-2023 GE05)

Active Substance: prothioconazole
Crop / crop group: Oilseed rape / oilseeds
Responsible for reporting: Céline BOUSQUET / TESTAPI
115 route du Pô, 49650 Allonnes - France
Country: Germany
Nominal Content of a.s.: 250 g/L
Formulation: DC

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

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

1	2	3	4	5			6	7	8	9			10	11
Report No. 647-2023 Location (region)	Commodity Variety	Date of 1-Planting 2-Flowering 3-Harvest	Method of treatment	Actual (nominal) application rate per treatment			Date of treatment	BBCH Crop Growth Stage at treatment	Portions analysed	Residues **expressed as prothioconazole-desthio** (1) PTZ = prothioconazole			DALA (2)	Remarks
				kg a.s./ha	Water (L/ha)	kg (a.s./hL)								
Northern Europe Germany 04827 Gerichshain (Saxony) Harvest trial 647-2023 GE05	Oilseed rape (spring) MIRAKEL	1-30/03/23 2-05/06/23 to 19/06/23 3-19/08/23	Broadcast foliar application Boom sprayer	0.1733 (0.1756) 0.1774 (0.1797)	301 308	0.0576 (0.0583) 0.0576 (0.0583)	19/06/23 04/07/23	69 80	Seeds	PTZ-α-hydroxy-desthio < 0.01	PTZ-3-hydroxy-desthio < 0.01	PTZ-4-hydroxy-desthio n.d.	43(3)	Untreated specimen: n.d. LC-MS/MS method validated within this study
									Seeds	PTZ-5-hydroxy-desthio n.d.	PTZ-6-hydroxy-desthio n.d.	**Sum of PTZ-OH-desthio metabolites (4)** **<LOQ**	43(3)	Max. study storage interval between: -sampling and extraction: 147 days -extraction and analyses: 2 days LOQ: 0.01 mg/kg for each analyte, 0.05 mg/kg for prothioconazole expressed as prothioconazole

														desthio as a sum of hydroxy-metabolites

(1) LOQ = 0.01 mg/kg / n.d. = non detected (<LOD = <0.003 mg/kg) (2) DALA = days after last application (3) Sampled at commercial harvest date (4) for calculation of the sum of PTZ-OH-desthio metabolites "n.d." is taken as 0 mg/kg, whilst for "< 0.01" a residue of 0.01 mg/kg is accounted; calculation of the sum is based on rounded values.

Residue data summary from supervised trials (647-2023 PL06)

Active Substance: prothioconazole
Crop / crop group: Oilseed rape / oilseeds
Responsible for reporting: Céline BOUSQUET / TESTAPI
115 route du Pô, 49650 Allonnes - France
Country: Poland
Nominal Content of a.s.: 250 g/L
Formulation: DC

Commercial Product: Prothioconazole 250 g/L DC (FGR06)
Producer: UPL Europe Limited
Indoor/glasshouse/outdoor: outdoor
Other a.s. in formulation: -
Residue calculated as: triazole derivative metabolites (T, TA) (mg/kg)

1	2	3	4	5			6	7	8	9		10	11
Report No. 647-2023 Location (region)	Commodity Variety	Date of 1-Planting 2-Flowering 3-Harvest	Method of treatment	Actual (nominal) application rate per treatment			Date of treatment	BBCH Crop Growth Stage at treatment	Portions analysed	Residues (1)		DALA (2)	Remarks
				kg a.s./ha	Water (L/ha)	kg (a.s./hL)				T	TA		
Northern Europe Poland 49200 Kolnica (Opolskie Province) Harvest trial 647-2023 PL06	Oilseed rape (winter) DJANGO C1	1- 28/08/22 2- 27/04/23 to 02/06/23 3- 20/07/23	Broadcast foliar application Boom sprayer	0.1736 (0.1759) 0.1790 (0.1814)	302 311	0.0576 (0.0583) 0.0576 (0.0583)	02/06/23 15/06/23	69-74 80	**Untreated** Seeds	n.d.	0.27	35(3)	LC-DMS-MS/MS Method Validated in within this study Max. study storage interval between: -sampling and extraction: 77 days for forage Triazole Alanine 13 days for seeds 1,2,4-Triazole: 13 days for seeds -extraction and analyses: 1 day
									Treated Seeds	n.d.	0.52	35(3)	

(1) LOQ = 0.01 mg/kg / n.d. = non detected (<LOD = <0.003 mg/kg) / T= 1,2,4-Triazole / TA = Triazole Alanine (2) DALA = days after last application (3) Sampled at commercial harvest date

Residue data summary from supervised trials (647-2023 PL06)

Active Substance: prothioconazole
Crop / crop group: Oilseed rape / oilseeds
Responsible for reporting: Céline BOUSQUET / TESTAPI
115 route du Pô, 49650 Allonnes - France
Country: Poland
Nominal Content of a.s.: 250 g/L
Formulation: DC

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

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

1	2	3	4	5			6	7	8	9			10	11
Report No. 647-2023 Location (region)	Commodity Variety	Date of 1-Planting 2-Flowering 3-Harvest	Method of treatment	Actual (nominal) application rate per treatment			Date of treatment	BBCH Crop Growth Stage at treatment	Portions analysed	Residues **expressed as prothioconazole-desthio** (1) PTZ = prothioconazole			DALA (2)	Remarks
				kg a.s./ha	Water (L/ha)	kg (a.s./hL)								
Northern Europe Poland 49200 Kolnica (Opolskie Province) Harvest trial 647-2023 PL06	Oilseed rape (winter) DJANGO C1	1-28/08/22 2-27/04/23 to 02/06/23 3-20/07/23	Broadcast foliar application Boom sprayer	0.1736 (0.1759) 0.1790 (0.1814)	302 311	0.0576 (0.0583) 0.0576 (0.0583)	02/06/23 15/06/23	69-74 80	Seeds	PTZ-α-hydroxy-desthio < 0.01	PTZ-3-hydroxy-desthio 0.01	PTZ-4-hydroxy-desthio n.d.	35(3)	Untreated specimen: n.d. LC-MS/MS method validated within this study
									Seeds	PTZ-5-hydroxy-desthio < 0.01	PTZ-6-hydroxy-desthio n.d.	**Sum of PTZ-OH-desthio metabolites (4)** **<LOQ**	35(3)	Max. study storage interval between: -sampling and extraction: 147 days -extraction and analyses: 2 days LOQ: 0.01 mg/kg for each analyte, 0.05 mg/kg for prothioconazole expressed as prothioconazole desthio as a sum

														of hydroxy-metabolites

(1) LOQ = 0.01 mg/kg / n.d. = non detected (<LOD = <0.003 mg/kg) (2) DALA = days after last application (3) Sampled at commercial harvest date (4) for calculation of the sum of PTZ-OH-desthio metabolites “n.d.” is taken as 0 mg/kg, whilst for “< 0.01” a residue of 0.01 mg/kg is accounted; calculation of the sum is based on rounded values.

Residue data summary from supervised trials (647-2023 FR07)

Active Substance: prothioconazole
Crop / crop group: Oilseed rape / oilseeds
Responsible for reporting: Céline BOUSQUET / TESTAPI
115 route du Pô, 49650 Allonnes - France
Country: Northern France
Nominal Content of a.s.: 250 g/L
Formulation: DC

Commercial Product: Prothioconazole 250 g/L DC (FGR06)
Producer: UPL Europe Limited
Indoor/glasshouse/outdoor: outdoor
Other a.s. in formulation: -
Residue calculated as: triazole derivative metabolites (T, TA) (mg/kg)

1	2	3	4	5			6	7	8	9		10	11
Report No. 647-2023 Location (region)	Commodity Variety	Date of 1-Planting 2-Flowering 3-Harvest	Method of treatment	Actual (nominal) application rate per treatment			Date of treatment	BBCH Crop Growth Stage at treatment	Portions analysed	Residues (1)		DALA (2)	Remarks
				kg a.s./ha	Water (L/ha)	kg (a.s./hL)				T	TA		
Northern Europe Northern France 72500 Saint Pierre de Chevillé (Pays de la Loire) Harvest trial 647-2023 FR07	Oilseed rape (winter) ELIPSE	1- 25/08/22 2- 03/04/23 to 01/05/23 3- 05/07/23 to 15/07/23	Broadcast foliar application Boom sprayer	0.1767 (0.1791) 0.1644 (0.1666)	256 238	0.0692 (0.0701) 0.0691 (0.0700)	17/05/23 31/05/23	75 80	**Untreated** Seeds	n.d.	0.91	40(3)	LC-DMS-MS/MS Method Validated in within this study Max. study storage interval between: -sampling and extraction: 77 days for forage Triazole Alanine 9 days for seeds 1,2,4-Triazole: 7 days for seeds -extraction and analyses: 1 day
									Treated Seeds	n.d.	0.79	40(3)	

(1) LOQ = 0.01 mg/kg / n.d. = non detected (<LOD = <0.003 mg/kg) / T= 1,2,4-Triazole / TA = Triazole Alanine (2) DALA = days after last application (3) Sampled at commercial harvest date

Residue data summary from supervised trials (647-2023 FR07)

Active Substance: prothioconazole
Crop / crop group: Oilseed rape / oilseeds
Responsible for reporting: Céline BOUSQUET / TESTAPI
115 route du Pô, 49650 Allonnes - France
Country: Northern France
Nominal Content of a.s.: 250 g/L
Formulation: DC

Commercial Product: Prothioconazole 250 g/L DC (FGR06)
Producer: UPL Europe Limited
Indoor/glasshouse/outdoor: outdoor
Other a.s. in formulation: -
Residue calculated as: Prothioconazole-alpha-hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio (mg/kg)

1	2	3	4	5			6	7	8	9			10	11
Report No. 647-2023 Location (region)	Commodity Variety	Date of 1-Planting 2-Flowering 3-Harvest	Method of treatment	Actual (nominal) application rate per treatment			Date of treatment	BBCH Crop Growth Stage at treatment	Portions analysed	Residues **expressed as prothioconazole-desthio** (1) PTZ = prothioconazole			DALA (2)	Remarks
				kg a.s./ha	Water (L/ha)	kg (a.s./hL)								
Northern Europe Northern France 72500 Saint Pierre de Chevillé (Pays de la Loire) Harvest trial 647-2023 FR07	Oilseed rape (winter) ELIPSE	1- 25/08/22 2- 03/04/23 to 01/05/23 3- 05/07/23 to 15/07/23	Broadcast foliar application Boom sprayer	0.1767 (0.1791) 0.1644 (0.1666)	256 238	0.0692 (0.0701) 0.0691 (0.0700)	17/05/23 31/05/23	75 80	Seeds	PTZ-α-hydroxy-desthio 0.01	PTZ-3-hydroxy-desthio 0.01	PTZ-4-hydroxy-desthio < 0.01	40(3)	Untreated specimen: n.d. LC-MS/MS method validated within this study Max. study storage interval between: -sampling and extraction: 147 days -extraction and analyses: 2 days LOQ: 0.01 mg/kg for each analyte, 0.05 mg/kg for prothioconazole expressed as
									Seeds	PTZ-5-hydroxy-desthio < 0.01	PTZ-6-hydroxy-desthio n.d.	**Sum of PTZ-OH-desthio metabolites (4)** **<LOQ**	40(3)	

														prothioconazole desthio as a sum of hydroxy-metabolites

(1) LOQ = 0.01 mg/kg / n.d. = non detected (<LOD = <0.003 mg/kg) (2) DALA = days after last application (3) Sampled at commercial harvest date (4) for calculation of the sum of PTZ-OH-desthio metabolites "n.d." is taken as 0 mg/kg, whilst for "< 0.01" a residue of 0.01 mg/kg is accounted; calculation of the sum is based on rounded values.

Residue data summary from supervised TRIALS (647-2023 NL08)

Active Substance: prothioconazole
Crop / crop group: Oilseed rape / oilseeds
Responsible for reporting: Céline BOUSQUET / TESTAPI
115 route du Pô, 49650 Allonnes - France
Country: The Netherlands
Nominal Content of a.s.: 250 g/L
Formulation: DC

Commercial Product: Prothioconazole 250 g/L DC (FGR06)
Producer: UPL Europe Limited
Indoor/glasshouse/outdoor: outdoor
Other a.s. in formulation: -
Residue calculated as: triazole derivative metabolites (T, TA) (mg/kg)

1	2	3	4	5			6	7	8	9		10	11
Report No. 647-2023 Location (region)	Commodity Variety	Date of 1-Planting 2-Flowering 3-Harvest	Method of treatment	Actual (nominal) application rate per treatment			Date of treatment	BBCH Crop Growth Stage at treatment	Portions analysed	Residues (1)		DALA (2)	Remarks
				kg a.s./ha	Water (L/ha)	kg (a.s./hL)				T	TA		
Northern Europe The Netherlands	Oilseed rape (winter) LAKRITZ	1- 19/04/23 2- 05/06/23 to 23/06/23 3- 08/08/23	Broadcast foliar application Boom sprayer	0.1698 (0.1721) 0.1741 (0.1765)	295 303	0.0576 (0.0583) 0.0576 (0.0583)	23/06/23 06/07/23	69-71 80	**Untreated** Seeds	n.d.	1.7	33(3)	LC-DMS-MS/MS Method Validated in within this study

5853EJ Siebengewald (Limburg) Harvest trial 647-2023 NL08									**Treated** Seeds	n.d.	1.3	33(3)	Max. study storage interval between: -sampling and extraction: 77 days for forage Triazole Alanine 21 days for seeds 1,2,4-Triazole: 21 days for seeds -extraction and analyses: 1 day

(1) LOQ = 0.01 mg/kg / n.d. = non detected (<LOD = <0.003 mg/kg) / T= 1,2,4-Triazole / TA = Triazole Alanine (2) DALA = days after last application (3) Sampled at commercial harvest date

Residue data summary from supervised trials (647-2023 NL08)

Active Substance: prothioconazole
Crop / crop group: Oilseed rape / oilseeds
Responsible for reporting: Céline BOUSQUET / TESTAPI
115 route du Pô, 49650 Allonnes - France
Country: The Netherlands
Nominal Content of a.s.: 250 g/L
Formulation: DC

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

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

1	2	3	4	5			6	7	8	9			10	11
Report No. 647-2023 Location (region)	Commodity Variety	Date of 1-Planting 2-Flowering 3-Harvest	Method of treatment	Actual (nominal) application rate per treatment			Date of treatment	BBCH Crop Growth Stage at treatment	Portions analysed	Residues **expressed as prothioconazole-desthio** (1) PTZ = prothioconazole			DALA (2)	Remarks
				kg a.s./ha	Water (L/ha)	kg (a.s./hL)								
Northern Europe The Netherlands 5853EJ Siebengewald (Limburg) Harvest trial 647-2023 NL08	Oilseed rape (winter) LAKRITZ	1-19/04/23 2-05/06/23 to 23/06/23 3-08/08/23	Broadcast foliar application Boom sprayer	0.1698 (0.1721) 0.1741 (0.1765)	295 303	0.0576 (0.0583) 0.0576 (0.0583)	23/06/23 06/07/23	69-71 80	Seeds Seeds	PTZ-α-hydroxy-desthio < 0.01 PTZ-5-hydroxy-desthio n.d.	PTZ-3-hydroxy-desthio 0.01 PTZ-6-hydroxy-desthio n.d.	PTZ-4-hydroxy-desthio < 0.01 **Sum of PTZ-OH-desthio metabolites (4)** **<LOQ**	33(3) 33(3)	Untreated specimen: n.d. LC-MS/MS method validated within this study Max. study storage interval between: -sampling and extraction: 147 days -extraction and analyses: 2 days LOQ: 0.01 mg/kg for each analyte, 0.05 mg/kg for prothioconazole expressed as prothioconazole

														desthio as a sum of hydroxy-metabolites

(1) LOQ = 0.01 mg/kg / n.d. = non detected (<LOD = <0.003 mg/kg) (2) DALA = days after last application (3) Sampled at commercial harvest date (4) for calculation of the sum of PTZ-OH-desthio metabolites “n.d.” is taken as 0 mg/kg, whilst for “< 0.01” a residue of 0.01 mg/kg is accounted; calculation of the sum is based on rounded values.

Residue data summary from supervised trials (647-2023 GR09)

Active Substance: prothioconazole
Crop / crop group: Oilseed rape / oilseeds
Responsible for reporting: Céline BOUSQUET / TESTAPI
115 route du Pô, 49650 Allonnes - France
Country: Greece
Nominal Content of a.s.: 250 g/L
Formulation: DC

Commercial Product: Prothioconazole 250 g/L DC (FGR06)
Producer: UPL Europe Limited
Indoor/glasshouse/outdoor: outdoor
Other a.s. in formulation:
Residue calculated as: triazole derivative metabolites (T, TA) (mg/kg)

1	2	3	4	5			6	7	8	9		10	11
Report No. 647-2023 Location (region)	Commodity Variety	Date of 1-Planting 2-Flowering 3-Harvest	Method of treatment	Actual (nominal) application rate per treatment			Date of treatment	BBCH Crop Growth Stage at treatment	Portions analysed (4)	Residues (1)		DALA (2)	Remarks
				kg a.s./ha	Water (L/ha)	kg (a.s./hL)				T	TA		
Southern Europe Greece 54500 - Drymos (Thessaloniki) (Central Macedonia) Decline curve trial 647-2023 GR09	Oilseed rape (winter) EXPOWER	1- 05/11/22 2- 20/04/23 to 15/05/23 3- 30/06/23	Broadcast foliar application Boom sprayer	0.1735 (0.1759) 0.1740 (0.1763)	302 302	0.0576 (0.0583) 0.0576 (0.0583)	16/05/23 31/05/23	77 80	**Untreated** Forage Forage Forage Forage Seeds **Treated** Forage Forage Forage Forage Seeds	n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d.	0.95 0.74 0.70 0.65 1.4 0.60 0.69 0.70 0.78 3.2	0 ±0 7 21 28(3) 0 ±0 7 21 28(3)	LC-DMS-MS/MS Method Validated in-within this study Max. study storage interval between: -sampling and extraction: 77 days for forage 23 days for seeds -extraction and analyses: 1 day

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

Residue data summary from supervised trials (647-2023 GR09)

Active Substance: prothioconazole
Crop / crop group: Oilseed rape / oilseeds
Responsible for reporting: Céline BOUSQUET / TESTAPI
115 route du Pô, 49650 Allonnes - France
Country: Greece
Nominal Content of a.s.: 250 g/L
Formulation: DC

Commercial Product: Prothioconazole 250 g/L DC (FGR06)
Producer: UPL Europe Limited
Indoor/glasshouse/outdoor: outdoor
Other a.s. in formulation:
Residue calculated as: Prothioconazole-alpha-hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio (mg/kg)

1	2	3	4	5			6	7	8	9			10	11
Report No. 647-2023 Location (region)	Commodity Variety	Date of 1-Planting 2-Flowering 3-Harvest	Method of treatment	Actual (nominal) application rate per treatment			Date of treatment	BBCH Crop Growth Stage at treatment	Portions analysed	Residues **expressed as prothioconazole-desthio** (1) PTZ = prothioconazole			DALA (2)	Remarks
				kg a.s./ha	Water (L/ha)	kg (a.s./hL)								
Southern Europe Greece 54500 - Drymos (Thessaloniki) (Central Macedonia) Decline curve trial 647-2023 GR09	Oilseed rape (winter) EXPOWER	1- 05/11/22 2- 20/04/23 to 15/05/23 3- 30/06/23	Broadcast foliar application Boom sprayer	0.1735 (0.1759) 0.1740 (0.1763)	302 302	0.0576 (0.0583) 0.0576 (0.0583)	16/05/23 31/05/23	77 80	Forage (3) Forage (3) Forage (3) Forage (3) Seeds	PTZ-α-hydroxy-desthio < 0.01 < 0.01 0.03 0.08 < 0.01	PTZ-3-hydroxy-desthio 0.09 0.10 0.23 0.42 0.02	PTZ-4-hydroxy-desthio 0.03 0.03 0.08 0.15 < 0.01	0 +0 7 21 28 (4)	Untreated specimen: n.d. LC-MS/MS method validated within this study Max. study storage interval between: -sampling and extraction: 147 days -extraction and analyses: 2 days
									Forage (3) Forage (3) Forage (3) Forage (3) Seeds	PTZ-5-hydroxy-desthio 0.01 0.01 0.02 0.05 < 0.01	PTZ-6-hydroxy-desthio n.d. n.d. < 0.01 0.01 < 0.01	**Sum of PTZ-OH-desthio metabolites (5)** **0.14** **0.15** **0.37** **0.71** **0.06**	0 +0 7 21 28 (4)	

(1) LOQ = 0.01 mg/kg / n.d. = non detected (<LOD = <0.003 mg/kg) (2) DALA = days after last application (3) Forage = whole plant without roots (4) Sampled at commercial harvest date (5) for calculation of the sum of PTZ-OH-desthio metabolites "n.d." is taken as 0 mg/kg, whilst for "< 0.01" a residue of 0.01 mg/kg is accounted; calculation of the sum is based on rounded values.

Residue data summary from supervised trials (647-2023 IT10)

Active Substance: prothioconazole
Crop / crop group: Oilseed rape / oilseeds
Responsible for reporting: Céline BOUSQUET / TESTAPI
115 route du Pô, 49650 Allonnes - France
Country: Italy
Nominal Content of a.s.: 250 g/L
Formulation: DC

Commercial Product: Prothioconazole 250 g/L DC (FGR06)
Producer: UPL Europe Limited
Indoor/glasshouse/outdoor: outdoor
Other a.s. in formulation:
Residue calculated as: triazole derivative metabolites (T, TA) (mg/kg)

1	2	3	4	5			6	7	8	9		10	11
Report No. 647-2023 Location (region)	Commodity Variety	Date of 1-Planting 2-Flowering 3-Harvest	Method of treatment	Actual (nominal) application rate per treatment			Date of treatment	BBCH Crop Growth Stage at treatment	Portions analysed (4)	Residues (1)		DALA (2)	Remarks
				kg a.s./ha	Water (L/ha)	kg (a.s./hL)				T	TA		
Southern Europe Italy 95024 Acireale (Sicily) Decline curve trial 647-2023 IT10	Oilseed rape (spring) LAGONDA	1- 13/03/23 2- 05/05/23 to 13/06/23 3- 11/07/23	Broadcast foliar application Boom sprayer	0.1810 (0.1834) 0.1658 (0.1680)	419 384	0.0432 (0.0438) 0.0432 (0.0438)	30/05/23 13/06/23	69-73 80	**Untreated** Forage Forage Forage Forage Seeds **Treated** Forage Forage Forage Forage Seeds	n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d.	< 0.01 < 0.01 < 0.01 < 0.01 0.05 0.02 0.02 0.01 0.05 0.13	0 ±0 7 21 28(3) 0 ±0 7 21 28(3)	LC-DMS-MS/MS Method Validated in within this study Max. study storage interval between: -sampling and extraction: 77 days for forage 23 days for seeds -extraction and analyses: 1 day

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

Residue data summary from supervised trials (647-2023 IT10)

Active Substance: prothioconazole
Crop / crop group: Oilseed rape / oilseeds
Responsible for reporting: Céline BOUSQUET / TESTAPI
115 route du Pô, 49650 Allonnes - France
Country: Italy
Nominal Content of a.s.: 250 g/L
Formulation: DC

Commercial Product: Prothioconazole 250 g/L DC (FGR06)
Producer: UPL Europe Limited
Indoor/glasshouse/outdoor: outdoor
Other a.s. in formulation:
Residue calculated as: Prothioconazole-alpha-hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio (mg/kg)

1	2	3	4	5			6	7	8	9			10	11
Report No. 647-2023 Location (region)	Commodity Variety	Date of 1 Planting 2 Flowering 3 Harvest	Method of treatment	Actual (nominal) application rate per treatment			Date of treatment	BBCH Crop Growth Stage at treatment	Portions analysed	Residues **expressed as prothioconazole-desthio** (1) PTZ = prothioconazole			DALA (2)	Remarks
				kg a.s./ha	Water (L/ha)	kg (a.s./hL)								
Southern Europe Italy 95024 Acireale (Sicily) Decline curve trial 647-2023 IT10	Oilseed rape (spring) LAGONDA	1- 13/03/23 2- 05/05/23 to 13/06/23 3- 11/07/23	Broadcast foliar application Boom sprayer	0.1810 (0.1834) 0.1658 (0.1680)	419 384	0.0432 (0.0438) 0.0432 (0.0438)	30/05/23 13/06/23	69-73 80	Forage (3) Forage (3) Forage (3) Forage (3) Seeds	PTZ-a-hydroxy-desthio < 0.01 0.04 0.01 0.02 < 0.01	PTZ-3-hydroxy-desthio 0.10 0.08 0.14 0.24 0.02	PTZ-4-hydroxy-desthio 0.02 0.02 0.05 0.09 < 0.01	0 +0 7 21 28 (4)	Untreated specimen: n.d. LC-MS/MS method validated within this study Max. study storage interval between: - sampling and extraction: 147 days - extraction and analyses: 2 days
									Forage (3) Forage (3) Forage (3) Forage (3) Seeds	PTZ-5-hydroxy-desthio < 0.01 < 0.01 0.02 0.03 n.d.	PTZ-6-hydroxy-desthio n.d. n.d. < 0.01 < 0.01 n.d.	**Sum of PTZ-OH-desthio metabolites (5)** **0.14** **0.15** **0.23** **0.39** **0.04**	0 +0 7 21 28 (4)	

(1) LOQ = 0.01 mg/kg / n.d. = non detected (<LOD = <0.003 mg/kg) (2) DALA = days after last application (3) Forage = whole plant without roots (4) Sampled at commercial harvest date (5) for calculation of the sum of PTZ-OH-desthio metabolites "n.d." is taken as 0 mg/kg, whilst for "< 0.01" a residue of 0.01 mg/kg is accounted; calculation of the sum is based on rounded values.

Residue data summary from supervised trials (647-2023 IT11)

Active Substance: prothioconazole
Crop / crop group: Oilseed rape / oilseeds
Responsible for reporting: Céline BOUSQUET / TESTAPI
115 route du Pô, 49650 Allonnes - France
Country: Italy
Nominal Content of a.s.: 250 g/L
Formulation: DC

Commercial Product: Prothioconazole 250 g/L DC (FGR06)
Producer: UPL Europe Limited
Indoor/glasshouse/outdoor: outdoor
Other a.s. in formulation:
Residue calculated as: triazole derivative metabolites (T, TA) (mg/kg)

1	2	3	4	5			6	7	8	9		10	11
Report No. 647-2023 Location (region)	Commodity Variety	Date of 1-Planting 2-Flowering 3-Harvest	Method of treatment	Actual (nominal) application rate per treatment			Date of treatment	BBCH Crop Growth Stage at treatment	Portions analysed (4)	Residues (1)		DALA (2)	Remarks
				kg a.s./ha	Water (L/ha)	kg (a.s./hL)				T	TA		
Southern Europe Italy 12062 Cherasco (Piedmont) Decline curve trial 647-2023 IT11	Oilseed rape (winter) GORDON KWS	1- 02/10/22 2- 05/04/23 to 27/04/23 3- 28/06/23 to 30/06/23	Broadcast foliar application Boom sprayer	0.1760 (0.1783) 0.1808 (0.1832)	306 314	0.0576 (0.0584) 0.0576 (0.0584)	06/05/23 18/05/23	74 80	**Untreated** Forage Forage Forage Forage Seeds **Treated** Forage Forage Forage Forage Seeds	 n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d. n.d.	 < 0.01 < 0.01 0.06 0.02 0.06 0.02 0.02 0.03 0.06 0.23	 0 ±0 6 21 41(3) 0 ±0 7 21 41(3)	LC-DMS-MS/MS Method Validated in within this study Max. study storage interval between: -sampling and extraction: 77 days for forage 23 days for seeds -extraction and analyses: 1 day

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

Residue data summary from supervised trials (647-2023 IT11)

Active Substance: prothioconazole
Crop / crop group: Oilseed rape / oilseeds
Responsible for reporting: Céline BOUSQUET / TESTAPI
115 route du Pô, 49650 Allonnes - France
Country: Italy
Nominal Content of a.s.: 250 g/L
Formulation: DC

Commercial Product: Prothioconazole 250 g/L DC (FGR06)
Producer: UPL Europe Limited
Indoor/glasshouse/outdoor: outdoor
Other a.s. in formulation:
Residue calculated as: Prothioconazole-alpha-hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio (mg/kg)

1	2	3	4	5			6	7	8	9			10	11
Report No. 647-2023 Location (region)	Commodity Variety	Date of 1-Planting 2-Flowering 3-Harvest	Method of treatment	Actual (nominal) application rate per treatment			Date of treatment	BBCH Crop Growth Stage at treatment	Portions analysed	Residues **expressed as prothioconazole-desthio** (1) PTZ = prothioconazole			DALA (2)	Remarks
				kg a.s./ha	Water (L/ha)	kg (a.s./hL)								
Southern Europe Italy 12062 Cherasco (Piedmont) Decline curve trial 647-2023 IT11	Oilseed rape (winter) GORDON KWS	1- 02/10/22 2- 05/04/23 to 27/04/23 3- 28/06/23 to 30/06/23	Broadcast foliar application Boom sprayer	0.1760 (0.1783) 0.1808 (0.1832)	306 314	0.0576 (0.0584) 0.0576 (0.0584)	06/05/23 18/05/23	74 80	Forage [3] Forage [3] Forage [3] Forage [3] Seeds	PTZ-α-hydroxy-desthio n.d. n.d. < 0.01 < 0.01 n.d.	PTZ-3-hydroxy-desthio 0.06 0.05 0.09 0.09 < 0.01	PTZ-4-hydroxy-desthio 0.01 0.01 0.02 0.02 n.d.	0 +0 6 21 41 [4]	Untreated specimen: n.d. LC-MS/MS method validated within this study Max. study storage interval between: -sampling and extraction: 147 days -extraction and analyses: 2 days
									Forage [3] Forage [3] Forage [3] Forage [3] Seeds	PTZ-5-hydroxy-desthio < 0.01 n.d. < 0.01 < 0.01 n.d.	PTZ-6-hydroxy-desthio n.d. n.d. n.d. n.d. n.d.	**Sum of PTZ-OH-desthio metabolites (5)** **0.08** **0.06** **0.13** **0.13** **0.01**	0 +0 6 21 41 [4]	

(1) LOQ = 0.01 mg/kg / n.d. = non detected (<LOD = <0.003 mg/kg) (2) DALA = days after last application (3) Forage = whole plant without roots (4) Sampled at commercial harvest date (5) for calculation of the sum of PTZ-OH-desthio metabolites "n.d." is taken as 0 mg/kg, whilst for "< 0.01" a residue of 0.01 mg/kg is accounted; calculation of the sum is based on rounded values.

Residue data summary from supervised trials (647-2023 SP12)

Active Substance: prothioconazole
Crop / crop group: Oilseed rape / oilseeds
Responsible for reporting: Céline BOUSQUET / TESTAPI
115 route du Pô, 49650 Allonnes - France
Country: Spain
Nominal Content of a.s.: 250 g/L
Formulation: DC

Commercial Product: Prothioconazole 250 g/L DC (FGR06)
Producer: UPL Europe Limited
Indoor/glasshouse/outdoor: outdoor
Other a.s. in formulation:
Residue calculated as: triazole derivative metabolites (T, TA) (mg/kg)

1	2	3	4	5			6	7	8	9		10	11
Report No. 647-2023 Location (region)	Commodity Variety	Date of 1-Planting 2-Flowering 3-Harvest	Method of treatment	Actual (nominal) application rate per treatment			Date of treatment	BBCH Crop Growth Stage at treatment	Portions analysed (4)	Residues (1)		DALA (2)	Remarks
				kg a.s./ha	Water (L/ha)	kg (a.s./hL)				T	TA		
Southern Europe Spain 14620 El Carpio (Andalucia) Decline curve trial 647-2023 SP12	Oilseed rape (winter) NXH213CLS	1- 30/09/23 2- 15/03/23 to 10/04/23 3- 19/05/23 to 26/05/23	Broadcast foliar application Boom sprayer	0.1796 (0.1820) 0.1692 (0.1715)	208 196	0.0863 (0.0875) 0.0863 (0.0875)	12/04/23 25/04/23	69-71 80	**Untreated** Forage Forage Forage Forage Seeds	n.d. n.d. n.d. n.d. n.d.	0.02 0.02 < 0.01 0.06 0.15	0 ±0 7 21 29(3)	LC-DMS-MS/MS Method Validated in within this study Max. study storage interval between: -sampling and extraction: 77 days for forage 23 days for seeds -extraction and analyses: 1 day
									Treated Forage Forage Forage Forage Seeds	n.d. n.d. n.d. n.d. n.d.	0.07 0.05 0.05 0.14 0.25	0 ±0 7 21 29(3)	

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

Residue data summary from supervised trials (647-2023 SP12)

Active Substance: prothioconazole
Crop / crop group: Oilseed rape / oilseeds
Responsible for reporting: Céline BOUSQUET / TESTAPI
115 route du Pô, 49650 Allonnes - France
Country: Spain
Nominal Content of a.s.: 250 g/L
Formulation: DC

Commercial Product: Prothioconazole 250 g/L DC (FGR06)
Producer: UPL Europe Limited
Indoor/glasshouse/outdoor: outdoor
Other a.s. in formulation:
Residue calculated as: Prothioconazole-alpha-hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio (mg/kg)

1	2	3	4	5			6	7	8	9			10	11
Report No. 647-2023 Location (region)	Commodity Variety	Date of 1-Planting 2-Flowering 3-Harvest	Method of treatment	Actual (nominal) application rate per treatment			Date of treatment	BBCH Crop Growth Stage at treatment	Portions analysed	Residues **expressed as prothioconazole-desthio** (1) PTZ = prothioconazole			DALA (2)	Remarks
				kg a.s./ha	Water (L/ha)	kg (a.s./hL)								
Southern Europe Spain 14620 El Carpio (Andalucia) Decline curve trial 647-2023 SP12	Oilseed rape (winter) NXH213CLS	1- 30/09/23 2- 15/03/23 to 10/04/23 3- 19/05/23 to 26/05/23	Broadcast foliar application Boom sprayer	0.1796 (0.1820) 0.1692 (0.1715)	208 196	0.0863 (0.0875) 0.0863 (0.0875)	12/04/23 25/04/23	69-71 80		PTZ-4-hydroxy-desthio				Untreated specimen: n.d. LC-MS/MS method validated within this study Max. study storage interval between: -sampling and extraction: 147 days -extraction and analyses: 2 days
									Forage (3)	< 0.01	0.16	0.08	0	
									Forage (3)	< 0.01	0.20	0.10	+0	
									Forage (3)	0.02	0.35	0.19	7	
									Forage (3)	< 0.01	0.27	0.14	21	
									Seeds	n.d.	< 0.01	< 0.01	29(4)	
										PTZ-5-hydroxy-desthio	PTZ-6-hydroxy-desthio	**Sum of PTZ-OH-desthio metabolites (5)**		
									Forage (3)	0.02	< 0.01	**0.28**	0	
									Forage (3)	0.02	< 0.01	**0.34**	+0	
									Forage (3)	0.05	< 0.01	**0.62**	7	
									Forage (3)	0.04	< 0.01	**0.47**	21	
									Seeds	n.d.	n.d.	**0.02**	29(4)	

(1) LOQ = 0.01 mg/kg / n.d. = non detected (<LOD = <0.003 mg/kg) (2) DALA = days after last application (3) Forage = whole plant without roots (4) Sampled at commercial harvest date (5) for calculation of the sum of PTZ-OH-desthio metabolites "n.d." is taken as 0 mg/kg, whilst for "< 0.01" a residue of 0.01 mg/kg is accounted; calculation of the sum is based on rounded values.

Residue data summary from supervised trials (647-2023-IT13)

Active Substance: prothioconazole
Crop / crop group: Oilseed rape / oilseeds
Responsible for reporting: Céline BOUSQUET / TESTAPI
115 route du Pô, 49650 Allonnes - France
Country: Italy
Nominal Content of a.s.: 250 g/L
Formulation: DC
Commercial Product: Prothioconazole 250 g/L DC (FGR06)
Producer: UPL Europe Limited
Indoor/glasshouse/outdoor: outdoor
Other a.s. in formulation:
Residue calculated as: triazole derivative metabolites (T, TA) (mg/kg)

1	2	3	4	5			6	7	8	9		10	11
Report No. 647-2023 Location (region)	Commodity Variety	Date of 1-Planting 2-Flowering 3-Harvest	Method of treatment	Actual (nominal) application rate per treatment			Date of treatment	BBCH Crop Growth Stage at treatment	Portions analysed	Residues (1)		DALA (2)	Remarks
				kg a.s./ha	Water (L/ha)	kg (a.s./hL)				T	TA		
Southern Europe Italy 15045 - Sale (Piedmont) Harvest trial 647-2023 IT13	Oilseed rape (winter) DK EXCEPTION	1- 20/09/22 2- 02/04/23 to 25/04/23 3- 22/06/23	Broadcast foliar application Boom sprayer	0.1657 (0.1679) 0.1689 (0.1712)	288 293	0.0576 (0.0584) 0.0576 (0.0584)	06/05/23 18/05/23	75-76 80	**Untreated** Seeds	n.d.	1.2	35(3)	LC-DMS-MS/MS Method Validated in-within this study Max. study storage interval between: -sampling and extraction: 77 days for forage 23 days for seeds -extraction and analyses: 1 day
									Treated Seeds	n.d.	3.4	35(3)	

(1) LOQ = 0.01 mg/kg / n.d. = non detected (<LOD = <0.003 mg/kg) / T= 1,2,4-Triazole / TA = Triazole Alanine (2) DALA = days after last application (3) Sampled at commercial harvest date

Residue data summary from supervised trials (647-2023 IT13)

Active Substance: prothioconazole
Crop / crop group: Oilseed rape / oilseeds
Responsible for reporting: Céline BOUSQUET / TESTAPI
115 route du Pô, 49650 Allonnes - France
Country: Italy
Nominal Content of a.s.: 250 g/L
Formulation: DC

Commercial Product: Prothioconazole 250 g/L DC (FGR06)
Producer: UPL Europe Limited
Indoor/glasshouse/outdoor: outdoor
Other a.s. in formulation:
Residue calculated as: Prothioconazole-alpha-hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio (mg/kg)

1	2	3	4	5			6	7	8	9			10	11
Report No. 647-2023 Location (region)	Commodity Variety	Date of 1-Planting 2-Flowering 3-Harvest	Method of treatment	Actual (nominal) application rate per treatment			Date of treatment	BBCH Crop Growth Stage at treatment	Portions analysed	Residues **expressed as prothioconazole-desthio** (1) PTZ = prothioconazole			DALA (2)	Remarks
				kg a.s./ha	Water (L/ha)	kg (a.s./hL)								
Southern Europe Italy 15045 - Sale (Piedmont) Harvest trial 647-2023 IT13	Oilseed rape (winter) DK EXCEPTION	1- 20/09/22 2- 02/04/23 to 25/04/23 3- 22/06/23	Broadcast foliar application Boom sprayer	0.1657 (0.1679) 0.1689 (0.1712)	288 293	0.0576 (0.0584) 0.0576 (0.0584)	06/05/23 18/05/23	75-76 80	Seeds	PTZ-α-hydroxy-desthio n.d.	PTZ-3-hydroxy-desthio < 0.01	PTZ-4-hydroxy-desthio n.d.	35(3)	Untreated specimen: n.d. LC-MS/MS method validated within this study Max. study storage interval between: -sampling and extraction: 147 days -extraction and analyses: 2 days
									Seeds	PTZ-5-hydroxy-desthio n.d.	PTZ-6-hydroxy-desthio n.d.	**Sum of PTZ-OH-desthio metabolites (4)** **0.01**	35(3)	

(1) LOQ = 0.01 mg/kg / n.d. = non detected (<LOD = <0.003 mg/kg) (2) DALA = days after last application (3) Sampled at commercial harvest date (4) for calculation of the sum of PTZ-OH-desthio metabolites "n.d." is taken as 0 mg/kg, whilst for "< 0.01" a residue of 0.01 mg/kg is accounted; calculation of the sum is based on rounded values.

Residue data summary from supervised trials (647-2023 FR14)

Active Substance: prothioconazole
Crop / crop group: Oilseed rape / oilseeds
Responsible for reporting: Céline BOUSQUET / TESTAPI
115 route du Pô, 49650 Allonnes - France
Country: Southern France
Nominal Content of a.s.: 250 g/L
Formulation: DC

Commercial Product: Prothioconazole 250 g/L DC (FGR06)
Producer: UPL Europe Limited
Indoor/glasshouse/outdoor: outdoor
Other a.s. in formulation:
Residue calculated as: triazole derivative metabolites (T, TA) (mg/kg)

1	2	3	4	5			6	7	8	9		10	11
Report No. 647-2023 Location (region)	Commodity Variety	Date of 1-Planting 2-Flowering 3-Harvest	Method of treatment	Actual (nominal) application rate per treatment			Date of treatment	BBCH Crop Growth Stage at treatment	Portions analysed	Residues (1)		DALA (2)	Remarks
				kg a.s./ha	Water (L/ha)	g (a.s./hL)				T	TA		
Southern Europe Southern France 79100 Plaine et Vallées (Nouvelle Aquitaine) Harvest trial 647-2023 FR14	Oilseed rape (winter) ES CAPELLO	1- 05/08/22 2- 03/04/23 to 01/05/23 3- 01/07/23 to 05/07/23	Broadcast foliar application Boom sprayer	0.1785 (0.1808) 0.1710 (0.1733)	207 198	0.0863 (0.0875) 0.0864 (0.0876)	17/05/23 31/05/23	76 80	**Untreated** Seeds	n.d.	0.92	33(3)	LC-DMS-MS/MS Method Validated in-within this study Max. study storage interval between: -sampling and extraction: 77 days for forage 23 days for seeds -extraction and analyses: 1 day
									Treated Seeds	n.d.	0.78	33(3)	

(1) LOQ = 0.01 mg/kg / n.d. = non detected (<LOD = <0.003 mg/kg) / T= 1,2,4-Triazole / TA = Triazole Alanine (2) DALA = days after last application (3) Sampled at commercial harvest date

Residue data summary from supervised trials (647-2023 FR14)

Active Substance: prothioconazole
Crop / crop group: Oilseed rape / oilseeds
Responsible for reporting: Céline BOUSQUET / TESTAPI
115 route du Pô, 49650 Allonnes - France
Country: Southern France
Nominal Content of a.s.: 250 g/L
Formulation: DC

Commercial Product: Prothioconazole 250 g/L DC (FGR06)
Producer: UPL Europe Limited
Indoor/glasshouse/outdoor: outdoor
Other a.s. in formulation:
Residue calculated as: Prothioconazole-alpha-hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio (mg/kg)

1	2	3	4	5			6	7	8	9			10	11
Report No. 647-2023 Location (region)	Commodity Variety	Date of 1-Planting 2-Flowering 3-Harvest	Method of treatment	Actual (nominal) application rate per treatment			Date of treatment	BBCH Crop Growth Stage at treatment	Portions analysed	Residues **expressed as prothioconazole-desthio** (1) PTZ = prothioconazole			DALA (2)	Remarks
				kg a.s./ha	Water (L/ha)	kg (a.s./hL)								
Southern Europe Southern France 79100 Plaine et Vallées (Nouvelle Aquitaine) Harvest trial 647-2023 FR14	Oilseed rape (winter) ES CAPELLO	1- 05/08/22 2- 03/04/23 to 01/05/23 3- 01/07/23 to 05/07/23	Broadcast foliar application Boom sprayer	0.1785 (0.1808) 0.1710 (0.1733)	207 198	0.0863 (0.0875) 0.0864 (0.0876)	17/05/23 31/05/23	76 80	Seeds	PTZ-α-hydroxy-desthio 0.02	PTZ-3-hydroxy-desthio 0.05	PTZ-4-hydroxy-desthio 0.02	33(3)	Untreated specimen: n.d. LC-MS/MS method validated within this study
									Seeds	PTZ-5-hydroxy-desthio 0.01	PTZ-6-hydroxy-desthio < 0.01	**Sum of PTZ-OH-desthio metabolites (4)** **0.11**	33(3)	Max. study storage interval between: -sampling and extraction: 147 days -extraction and analyses: 2 days

(1) LOQ = 0.01 mg/kg / n.d. = non detected (<LOD = <0.003 mg/kg) (2) DALA = days after last application (3) Sampled at commercial harvest date (4) for calculation of the sum of PTZ-OH-desthio metabolites "n.d." is taken as 0 mg/kg, whilst for "< 0.01" a residue of 0.01 mg/kg is accounted; calculation of the sum is based on rounded values.

Residue data summary from supervised trials (647-2023 GR15)

Active Substance: prothioconazole
Crop / crop group: Oilseed rape / oilseeds
Responsible for reporting: Céline BOUSQUET / TESTAPI
115 route du Pô, 49650 Allonnes - France
Country: Greece
Nominal Content of a.s.: 250 g/L
Formulation: DC

Commercial Product: Prothioconazole 250 g/L DC (FGR06)
Producer: UPL Europe Limited
Indoor/glasshouse/outdoor: outdoor
Other a.s. in formulation:
Residue calculated as: triazole derivative metabolites (T, TA) (mg/kg)

1	2	3	4	5			6	7	8	9		10	11
Report No. 647-2023 Location (region)	Commodity Variety	Date of 1-Planting 2-Flowering 3-Harvest	Method of treatment	Actual (nominal) application rate per treatment			Date of treatment	BBCH Crop Growth Stage at treatment	Portions analysed	Residues (1)		DALA (2)	Remarks
				kg a.s./ha	Water (L/ha)	kg (a.s./hL)				T	TA		
Southern Europe Greece 50200 Anatoliko Ptolemaida (West Macedonia) Harvest trial 647-2023 GR15	Oilseed rape (winter) DK IMPLEMENTCL	1- 25/09/22 2- 10/04/23 to 05/05/23 3- 01/07/23	Broadcast foliar application Boom sprayer	0.1748 (0.1771) 0.1754 (0.1777)	304 305	0.0576 (0.0583) 0.0576 (0.0583)	15/05/23 29/05/23	75 80	**Untreated** Seeds	n.d.	2.3	31(3)	LC-DMS-MS/MS Method Validated in-within this study Max. study storage interval between: -sampling and extraction: 77 days for forage 23 days for seeds -extraction and analyses: 1 day
									Treated Seeds	n.d.	4.5	31(3)	

(1) LOQ = 0.01 mg/kg / n.d. = non detected (<LOD = <0.003 mg/kg) / T= 1,2,4-Triazole / TA = Triazole Alanine (2) DALA = days after last application (3) Sampled at commercial harvest date

Residue data summary from supervised trials (647-2023-GR15)

Active Substance: prothioconazole
Crop / crop group: Oilseed rape / oilseeds
Responsible for reporting: Céline BOUSQUET / TESTAPI
115 route du Pô, 49650 Allonnes - France
Country: Greece
Nominal Content of a.s.: 250 g/L
Formulation: DC

Commercial Product: Prothioconazole 250 g/L DC (FGR06)
Producer: UPL Europe Limited
Indoor/glasshouse/outdoor: outdoor
Other a.s. in formulation:
Residue calculated as: Prothioconazole-alpha-hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio (mg/kg)

1	2	3	4	5			6	7	8	9			10	11
Report No. 647-2023 Location (region)	Commodity Variety	Date of 1-Planting 2-Flowering 3-Harvest	Method of treatment	Actual (nominal) application rate per treatment kg a.s./ha	Water (L/ha)	kg (a.s./hL)	Date of treatment	BBCH Crop Growth Stage at treatment	Portions analysed	Residues **expressed as prothioconazole-desthio** (1) PTZ = prothioconazole			DALA (2)	Remarks
Southern Europe Greece 50200 Anatoliko Ptolemaida (West Macedonia) Harvest trial 647-2023 GR15	Oilseed rape (winter) DK IMPLEMENT CL	1- 25/09/22 2- 10/04/23 to 05/05/23 3- 01/07/23	Broadcast foliar application Boom sprayer	0.1748 (0.1771) 0.1754 (0.1777)	304 305	0.0576 (0.0583) 0.0576 (0.0583)	15/05/23 29/05/23	75 80	Seeds	PTZ-α-hydroxy-desthio < 0.01	PTZ-3-hydroxy-desthio 0.02	PTZ-4-hydroxy-desthio n.d.	31(3)	Untreated specimen: n.d. LC-MS/MS method validated within this study Max. study storage interval between: - sampling and extraction: 147 days - extraction and analyses: 2 days
									Seeds	PTZ-5-hydroxy-desthio < 0.01	PTZ-6-hydroxy-desthio n.d.	**Sum of PTZ-OH-desthio metabolites (4)** **0.04**	31(3)	

(1) LOQ = 0.01 mg/kg / n.d. = non detected (<LOD = <0.003 mg/kg) (2) DALA = days after last application (3) Sampled at commercial harvest date (4) for calculation of the sum of PTZ-OH-desthio metabolites "n.d." is taken as 0 mg/kg, whilst for "< 0.01" a residue of 0.01 mg/kg is accounted; calculation of the sum is based on rounded values.

Residue data summary from supervised trials (647-2023 IT16)

Active Substance: prothioconazole
Crop / crop group: Oilseed rape / oilseeds
Responsible for reporting: Céline BOUSQUET / TESTAPI
115 route du Pô, 49650 Allonnes - France
Country: Italy
Nominal Content of a.s.: 250 g/L
Formulation: DC

Commercial Product: Prothioconazole 250 g/L DC (FGR06)
Producer: UPL Europe Limited
Indoor/glasshouse/outdoor: outdoor
Other a.s. in formulation:
Residue calculated as: triazole derivative metabolites (T, TA) (mg/kg)

1	2	3	4	5			6	7	8	9		10	11
Report No. 647-2023 Location (region)	Commodity Variety	Date of 1-Planting 2-Flowering 3-Harvest	Method of treatment	Actual (nominal) application rate per treatment			Date of treatment	BBCH Crop Growth Stage at treatment	Portions analysed	Residues (1)		DALA (2)	Remarks
				kg a.s./ha	Water (L/ha)	kg (a.s./hL)				T	TA		
Southern Europe Italy 94010 - Assoro (Sicily) Harvest trial 647-2023 IT16	Oilseed rape (spring) LAGONDA	1- 15/04/23 2- 16/06/23 to 30/07/23 3- 18/08/23	Broadcast foliar application Boom sprayer	0.1763 (0.1787) 0.1756 (0.1779)	408 407	0.0432 (0.0438) 0.0432 (0.0438)	14/07/23 28/07/23	69-75 80	**Untreated** Seeds	n.d.	0.04	21(3)	LC-DMS-MS/MS Method Validated in-within this study Max. study storage interval between: -sampling and extraction: 77 days for forage 23 days for seeds -extraction and analyses: 1 day
									Treated Seeds	n.d.	0.14	21(3)	

(1) LOQ = 0.01 mg/kg / n.d. = non detected (<LOD = <0.003 mg/kg) / T= 1,2,4-Triazole / TA = Triazole Alanine (2) DALA = days after last application (3) Sampled at commercial harvest date

Residue data summary from supervised trials (647-2023 IT16)

Active Substance: prothioconazole
Crop / crop group: Oilseed rape / oilseeds
Responsible for reporting: Céline BOUSQUET / TESTAPI
115 route du Pô, 49650 Allonnes - France
Country: Italy
Nominal Content of a.s.: 250 g/L
Formulation: DC

Commercial Product: Prothioconazole 250 g/L DC (FGR06)
Producer: UPL Europe Limited
Indoor/glasshouse/outdoor: outdoor
Other a.s. in formulation:
Residue calculated as: Prothioconazole-alpha-hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio (mg/kg)

1	2	3	4	5			6	7	8	9			10	11
Report No. 647-2023 Location (region)	Commodity Variety	Date of 1-Planting 2-Flowering 3-Harvest	Method of treatment	Actual (nominal) application rate per treatment			Date of treatment	BBCH Crop Growth Stage at treatment	Portions analysed	Residues **expressed as prothioconazole-desthio** (1) PTZ = prothioconazole			DALA (2)	Remarks
				kg a.s./ha	Water (L/ha)	kg (a.s./hL)								
Southern Europe Italy 94010 Assoro (Sicily) Harvest trial 647-2023 IT16	Oilseed rape (spring) LAGONDA	1- 15/04/23 2- 16/06/23 to 30/07/23 3- 18/08/23	Broadcast foliar application Boom sprayer	0.1763 (0.1787) 0.1756 (0.1779)	408 407	0.0432 (0.0438) 0.0432 (0.0438)	14/07/23 28/07/23	69-75 80	Seeds Seeds	PTZ-a-hydroxy-desthio < 0.01 PTZ-5-hydroxy-desthio < 0.01	PTZ-3-hydroxy-desthio 0.01 PTZ-6-hydroxy-desthio n.d.	PTZ-4-hydroxy-desthio < 0.01 **Sum of PTZ-OH-desthio metabolites (4)** **0.04**	21(3) 21(3)	Untreated specimen: n.d. LC-MS/MS method validated within this study Max. study storage interval between: - sampling and extraction: 147 days - extraction and analyses: 2 days

(1) LOQ = 0.01 mg/kg / n.d. = non detected (<LOD = <0.003 mg/kg) (2) DALA = days after last application (3) Sampled at commercial harvest date (4) for calculation of the sum of PTZ-OH-desthio metabolites "n.d." is taken as 0 mg/kg, whilst for "< 0.01" a residue of 0.01 mg/kg is accounted; calculation of the sum is based on rounded values.

Study 6 - Toscano Saes 2023, EE/23/006- Southern Europe (new data)

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

Reference:	KCP 8.3.3/08
Report	Magnitude of Residues of Triazole Derived Metabolites (TDM's) (triazole acetic acid and triazole lactic acid) Following Two Applications of Prothioconazole 250 g/L DC (FGR06) to Oilseed Rape in Southern Europe, 2022; R Toscano Saes, 2023; study number: EE/23/006
Guideline(s):	• Organisation for Economic Co-operation and Development (OECD), Section 5, Other Test Guidelines, Crop Field Trial (OECD TG No. 509, 14 June 2021). • Organisation for Economic Co-operation and Development (OECD), Series on Testing and Assessment No. 72, Series on Pesticides No. 39, Guidance Document on Pesticide Residue Analytical Methods (ENV/JM/MONO(2007)17, 13 August 2007). • Organisation for Economic Co-operation and Development (OECD), Series on Testing and Assessment No. 64, Series on Pesticides No. 32, Guidance Document on Overview Of Residue Chemistry Studies (As Revised in 2009) (ENV/JM/MONO(2009)31, 28 July 2009). • European Commission (EC), Technical Guidance, Appendix B, General recommendations for the design, preparation and realization of residue trials (SANCO 7029/VI/95, rev.5, 22 July 1997). • European Commission (EC), Analytical methods, Residues Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes (SANTE/2020/12830, rev.2, 14 February 2023). • European Commission (EC), Regulation (EC) No 1107/2009 of The European Parliament and of the Council of 21 October 2009, Concerning the Placing of Plant Protection Products on the Market and Repealing Council Directives 79/117/EEC and 91/414/EEC, (REGULATION (EC) No 1107/2009, 21 October 2009).
Deviations:	The section 7 of the Study Plan states that an example of the calculations is present in the Appendix 2. This appendix states the calculations to measure the concentration of TDM's and the procedural recovery data. The extraction batches used the analytical method to measure the concentration of TDM's and apply corrected values to procedural recoveries where the calculated level in control samples was above 30% LOQ. Therefore, the analytical method deviated from the Study Plan.
GLP:	Yes
Acceptability:	Acceptable

Tier 1 Summary Tables – Trial 1

Active substance (common name): Prothioconazole
Crop/crop Group: Oil Seed Rape
Albaugh Europe Sàrl
Responsible body for reporting (name, address): Barclay Chemicals (R&D) Limited
UPL EUROPE LIMITED
Country: Italy (Europe South)
Content of active substance (g/kg or g/L): 250 g/L
Formulation (e.g. WP): DC

Commercial Product (name): Prothioconazole 250 g/L DC (FGR06)
Producer of commercial product: UPL Europe Limited
Indoor/Glasshouse/Outdoor: Outdoor
Other active substance in the formulation (common name and content): None
Residues calculated as: Individual components

1	2	3	4	5			6	7	8	9		10	11
Report No. Trial No. Location (region) including postal code	Commodity/ Variety	Date of 1. Sowing or Planting 2. Flowering 3. Harvest	Method of Treatment	Application rate per treatment (Prothioconazole)			Date of treatment(s) or no. of treatment(s) and last date	Growth stage at treatment	Portion Analysed	Residues (mg/kg)		PHI (days)	Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./hL				TAA	TLA		
	(a)	(b)	(c)				(d)	(e)	(a)			(f)	(g)
QG22006-01 U: QG22006-001 U: QG22006-005 U: QG22006-009 U: QG22006-013 U: QG22006-017 U: QG22006-021	Oilseed Rape/ Cherokee	1. 23/09/2021 2. 01/05/2022 to 23/05/2022 3. 13/06/2022	Boom sprayer	0	0	0	Control (U)	N/A	Immature plant Immature plant Immature plant Immature plant Seed Rest of plant	<0.00500 <0.00150 <0.00500 <0.00500 <0.00150 <0.00500	<0.00300 <0.00300 <0.00300 <0.00300 <0.00300 <0.00300	0 0 8 20 27 27	TAA: Method: Battelle No. QG/20/012 LOQ = 0.005 mg/kg LOD = 0.0015 mg/kg TLA: Method: Battelle No. QG/20/012 LOQ = 0.010 mg/kg LOD = 0.0030 mg/kg
T: QG22006-003 T: QG22006-007 T: QG22006-011 T: QG22006-015 T: QG22006-019 T: QG22006-023 Italy 12050 (Europe South)		13/06/2022 20/06/2022 03/07/2022 10/07/2022 10/07/2022		0.174 0.171	303 297	0.0574 0.0576	30/05/2022 13/06/2022	BBCH 74 BBCH 80	Immature plant Immature plant Immature plant Immature plant Seed Rest of plant	<0.00500 <0.00500 <0.00500 <0.00500 <0.00500 <0.00500	<0.0100 <0.0100 <0.0100 <0.0100 <0.0100 <0.0100	0 0 8 20 27 27	

All original sample history information used for the Tier 1 tables is from study QG22006 with the exception of the column 9 that is from this study EE/23/006 and column 11 that is from study QG/20/012

(a) According to Codex (or other e.g. EU) classification
(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
(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)
(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites included, method of storage, storage stability, analysis date and analytical method.

Tier 1 Summary Tables – Trial 2

Active substance (common name):	Prothioconazole	**Commercial Product (name):**	Prothioconazole 250 g/L DC (FGR06)
Crop/crop Group:	Oil Seed Rape	**Producer of commercial product:**	UPL Europe Limited
	Albaugh Europe Sàrl		
Responsible body for reporting (name, address):	Barclay Chemicals (R&D) Limited UPL EUROPE LIMITED	**Indoor/Glasshouse/Outdoor:**	Outdoor
Country:	Spain (Europe South)	**Other active substance in the formulation (common name and content):**	None
Content of active substance (g/kg or g/L):	250 g/L	**Residues calculated as:**	Individual components
Formulation (e.g. WP):	DC		

1	2	3	4	5			6	7	8	9		10	11
Report No. Trial No. Location (region) including postal code	Commodity/ Variety	Date of 1. Sowing or Planting 2. Flowering 3. Harvest	Method of Treatment	Application rate per treatment (Prothioconazole)			Date of treatment(s) or no. of treatment(s) and last date	Growth stage at treatment	Portion Analysed	Residues (mg/kg)		PHI (days)	Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./hL				TAA	TLA		
	(a)	(b)	(c)				(d)	(e)	(a)			(f)	(g)
QG22006-02 U: QG22006-025 U: QG22006-029 U: QG22006-033 U: QG22006-037 U: QG22006-041 U: QG22006-045	Oilseed Rape/ 44YS4	1. 01/02/2022 2. 23/03/2022 to 23/04/2022	Boom sprayer	0	0	0	Control (U)	N/A	Immature plant Immature plant Immature plant Immature plant Seed Rest of plant	<0.00150 <0.00150 <0.00500 <0.00500 <0.00150 <0.00150	<0.00300 <0.00300 <0.00300 <0.00300 <0.0100 <0.00300	0 DBLA 0 7 21 29 29	TAA: Method: Battelle No. QG/20/012 LOQ = 0.005 mg/kg LOD = 0.0015 mg/kg TLA: Method: Battelle No. QG/20/012 LOQ = 0.010 mg/kg LOD = 0.0030 mg/kg
T: QG22006-027 T: QG22006-031 T: QG22006-035 T: QG22006-039 T: QG22006-043 T: QG22006-047 Spain ES-41710 (Europe South)		3. 23/05/2022 23/05/2022 30/05/2022 13/06/2022 21/06/2022 21/06/2022		0.176 0.166	305.6 288.3	0.0576 0.0576	09/05/2022 23/05/2022	BBCH 75 BBCH 80	Immature plant Immature plant Immature plant Immature plant Seed Rest of plant	<0.00500 <0.00500 <0.00500 0.00500 <0.00500 <0.00500	<0.0100 <0.0100 <0.0100 <0.0100 0.0121 <0.0100	0 DBLA 0 7 21 29 29	

All original sample history information used for the Tier 1 tables is from study QG22006 with the exception of the column 9 that is from this study EE/23/006 and column 11 that is from study QG/20/012

(a) According to Codex (or other e.g. EU) classification
(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
(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)
(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites included, method of storage, storage stability, analysis date and analytical method.

Analyte	Matrix	Maximum storage interval (days)
Triazole Acetic Acid	Plant*	548
	Seed	535

~~Triazole Lactic Acid~~	~~Plant*~~	~~548~~
	~~Seed~~	~~535~~

Study 7 - Phipps 2023, EE/23/007- Northern Europe (new data)

Comments of zRMS:	Six independent trials (2 harvest and 4 decline) located in Northern Europe (Germany, Poland, The Netherlands, Belgium) were conducted on oilseed rape following two applications of Prothioconazole 250 g/L DC (175 g as/ha) to determine of the residues of triazole derived metabolites (TDM's) (triazole acetic acid and triazole lactic acid) in oilseed rape specimens: seed, immature plant and rest of plant. The first application was performed 14 +/-1 days before the second application. The second application was performed on the treated plot at BBCH 80. The limit of quantification (LOQ) was 0.005 mg/kg for triazole acetic acid (for both seed and plant) and 0.01 mg/kg for triazole lactic acid (for both seed and plant). The maximum storage interval from sampling until extraction for TAA and TLA was 593 days in forage and was 576 days in seeds. The study on the magnitude of residues is valid with regard to storage stability. Residue results: TDMs: In the untreated seed samples residues were beetween <LOQ of 0.005 mg/kg and 0.00692 mg/kg for TAA and <0.01 and 0.0413 for TLA. In the treated specimens, residues of TAA ranged between: - <0.005 and 0.00928 mg/kg (3x<0.005, 0.00576, 0.00896, 0.00928mg/kg) in seeds, - <0.005 and 0.0324 mg/kg (3x<0.005, 0.00548, 0.00660, 0.0324 mg/kg) in rest of plants. In the treated specimens, residues of TLA ranged between: - <0.01 and 0.0491 mg/kg (2x<0.01, 0.0105, 0.029, 0.0365, 0.0491 mg/kg) in seeds - <0.01 and 0.0178 mg/kg (3x<0.01, 0.0102, 0.0109, 0.0178 mg/kg) in rest of plants. The study is acceptable. These trials can be used to support the intended use on oilseed rape.

Reference:	KCP 8.3.3/09
Report	Magnitude of Residues of Triazole Derived Metabolites (TDM's) (triazole acetic acid and triazole lactic acid) in Oilseed Rape Following Two Applications of Prothioconazole 250 g/L DC (FGR06) in Northern Europe, 2022; B Phipps, 2023; study number EE/23/007
Guideline(s):	• Organisation for Economic Co-operation and Development (OECD), Section 5, Other Test Guidelines, Crop Field Trial (OECD TG No. 509, 14 June 2021). • Organisation for Economic Co-operation and Development (OECD), Series on Testing and Assessment No. 72, Series on Pesticides No. 39, Guidance Document on Pesticide Residue Analytical Methods (ENV/JM/MONO(2007)17, 13 August 2007). • Organisation for Economic Co-operation and Development (OECD), Series on Testing and Assessment No. 64, Series on Pesticides No. 32, Guidance Document on Overview Of Residue Chemistry Studies (As Revised in 2009) (ENV/JM/MONO(2009)31, 28 July 2009). • European Commission (EC), Technical Guidance, Appendix B, General recommendations for the design, preparation and realization of residue trials (SANCO 7029/VI/95, rev.5, 22 July 1997). • European Commission (EC), Analytical methods, Residues Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes (SANTE/2020/12830, rev.2, 14 February 2023). • European Commission (EC), Regulation (EC) No 1107/2009 of The European Parliament and of the Council of 21 October 2009,

Concerning the Placing of Plant Protection Products on the Market and Repealing Council Directives 79/117/EEC and 91/414/EEC, (REGULATION (EC) No 1107/2009, 21 October 2009).

Deviations:	The study plan states that control values will be determined and should not be higher than 30% of the LOQ. Across multiple batches for both analytes, control values are greater than 30% of the LOQ. In instances where the control sample used for recovery sample preparation is greater than 30% of the LOQ, the recovery result has been corrected by subtraction of the control residue level from the recovery residue level to give a corrected residue level. Control results that are higher than 30% of the LOQ are therefore accepted as genuine results. There is no impact on the study.
GLP:	Yes
Acceptability:	Acceptable

Tier 1 Summary Tables – Trial 1

Active substance (common name): Prothioconazole
Crop/crop Group: Oil Seed Rape
Albaugh Europe Sàrl
Responsible body for reporting (name, address): Barclay Chemicals (R&D) Limited
UPL EUROPE LIMITED
Country: Belgium (Europe North)
Content of active substance (g/kg or g/L): 250 g/L
Formulation (e.g. WP): DC

Commercial Product (name): Prothioconazole 250 g/L DC (FGR06)
Producer of commercial product: UPL Europe Limited
Indoor/Glasshouse/Outdoor: Outdoor
Other active substance in the formulation (common name and content): None
Residues calculated as: Individual components

1	2	3	4	5			6	7	8	9		10	11
Report No. Trial No. Location (region) including postal code	Commodity/ Variety	Date of 1. Sowing or Planting 2. Flowering 3. Harvest	Method of Treatment	Application rate per treatment (Prothioconazole)			Date of treatment(s) or no. of treatment(s) and last date	Growth stage at treatment	Portion Analysed	Residues (mg/kg)		PHI (days)	Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./hL				TAA	TLA		
	(a)	(b)	(c)				(d)	(e)	(a)			(f)	(g)
QG22007-01 U: QG22007-001 U: QG22007-005	Spring Oilseed Rape/ Mirakel	1. 29/03/2022 2. 01/05/2022 to 25/05/2022 3. 26/07/2022	Boom sprayer	0	0	0	Control (U)	N/A	Seed Rest of plant	<0.005 <0.005	0.0154 <0.01	22 22	TAA: Method: Battelle No. QG/20/012 LOQ = 0.005 mg/kg LOD = 0.0012 mg/kg TLA: Method: Battelle No. QG/20/012 LOQ = 0.01 mg/kg LOD = 0.0024 mg/kg
T: QG22007-003 T: QG22007-007 Belgium Kortenaken 3470 (Europe North)				0.177 0.177	204 204	0.0868 0.0868	20/06/2022 04/06/2022	BBCH 75 BBCH 80	Seed Rest of plant	0.00576 0.00548	0.0290 0.0109	22 22	

All details in the above table are taken from study QG22007 with the exception of column 9 which is taken from study EE/23/007 and column 11 which is taken from study QG/20/012.

(a) According to Codex (or other e.g. EU) classification
(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
(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)
(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites included, method of storage, storage stability, analysis date and analytical method.

Table 18: Tier 1 Summary Tables – Trial 2

Active substance (common name): Prothioconazole
Crop/crop Group: Oil Seed Rape
Albaugh Europe Sàrl
Responsible body for reporting (name, address): Barclay Chemicals (R&D) Limited
UPL EUROPE LIMITED
Country: Poland (Europe North)
Content of active substance (g/kg or g/L): 250 g/L
Formulation (e.g. WP): DC

Commercial Product (name): Prothioconazole 250 g/L DC (FGR06)
Producer of commercial product: UPL Europe Limited
Indoor/Glasshouse/Outdoor: Outdoor
Other active substance in the formulation (common name and content): None
Residues calculated as: Individual components

1	2	3	4	5			6	7	8	9		10	11
Report No. Trial No. Location (region) including postal code	Commodity/ Variety	Date of 1. Sowing or Planting 2. Flowering 3. Harvest	Method of Treatment	Application rate per treatment (Prothioconazole)			Date of treatment(s) or no. of treatment(s) and last date	Growth stage at treatment	Portion Analysed	Residues (mg/kg)		PHI (days)	Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./hL				TAA	TLA		
	(a)	(b)	(c)				(d)	(e)	(a)			(f)	(g)
QG22007-02 U: QG22007-009 U: QG22007-013	Winter Oilseed Rape/ Umberto	1. 28/08/2021 2. 10/05/2022 to 03/06/2022 3. 09/08/2022	Boom sprayer	0	0	0	Control (U)	N/A	Seed Rest of plant	<0.005 <0.005	0.0199 <0.01	33 33	TAA: Method: Battelle No. QG/20/012 LOQ = 0.005 mg/kg LOD = 0.0012 mg/kg TLA: Method: Battelle No. QG/20/012 LOQ = 0.01 mg/kg LOD = 0.0024 mg/kg
T: QG22007-011 T: QG22007-015 Poland Urbanowice/ Opole 47-270 (Europe North)				0.178 0.181	310 314	0.0574 0.0576	22/06/2022 07/07/2022	BBCH 74 BBCH 80	Seed Rest of plant	0.00928 <0.005	0.0365 <0.01	33 33	

All details in the above table are taken from study QG22007 with the exception of column 9 which is taken from study EE/23/007 and column 11 which is taken from study QG/20/012

(a) According to Codex (or other e.g. EU) classification
(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
(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)
(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites included, method of storage, storage stability, analysis date and analytical method.

Table 19: Tier 1 Summary Tables – Trial 3

Active substance (common name): Prothioconazole
Crop/crop Group: Oil Seed Rape
Responsible body for reporting (name, address): Barclay Chemicals (R&D) Limited
UPL EUROPE LIMITED
Country: Poland (Europe North)
Content of active substance (g/kg or g/L): 250 g/L
Formulation (e.g. WP): DC

Commercial Product (name): Prothioconazole 250 g/L DC (FGR06)
Producer of commercial product: UPL Europe Limited
Albaugh Europe Sàrl
Indoor/Glasshouse/Outdoor: Outdoor
Other active substance in the formulation (common name and content): None
Residues calculated as: Individual components

1	2	3	4	5			6	7	8	9		10	11
Report No. Trial No. Location (region) including postal code	Commodity/ Variety	Date of 1. Sowing or Planting 2. Flowering 3. Harvest	Method of Treatment	Application rate per treatment (Prothioconazole)			Date of treatment(s) or no. of treatment(s) and last date	Growth stage at treatment	Portion Analysed	Residues (mg/kg)		PHI (days)	Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./hL				TAA	TLA		
	(a)	(b)	(c)				(d)	(e)	(a)			(f)	(g)
QG22007-03	Winter Oilseed Rape/ Dominator	1. 02/09/2021	Boom sprayer	0	0	0	Control (U)	N/A	Immature plant	0.00744	<0.01	0**	TAA: Method: Battelle No. QG/20/012 LOQ = 0.005 mg/kg LOD = 0.0012 mg/kg TLA: Method: Battelle No. QG/20/012 LOQ = 0.01 mg/kg LOD = 0.0024 mg/kg
U: QG22007-017		2. 18/04/2022 to 15/05/2022							Immature plant	<0.005	<0.01	0	
U: QG22007-021									Immature plant	0.00544	<0.01	7	
U: QG22007-025									Immature plant	0.0140	0.0146	21	
U: QG22007-029									Seed	0.00692	0.0413	24	
U: QG22007-033									Rest of plant	0.0291	0.0146	24	
U: QG22007-037													
T: QG22007-019		3. 15/06/2022		0.180	312	0.0577	01/06/2022	BBCH 74	Immature plant	<0.005	<0.01	0**	
T: QG22007-023		15/06/2022							Immature plant	<0.005	<0.01	0	
T: QG22007-027		22/06/2022							Immature plant	0.00548	<0.01	7	
T: QG22007-031		06/07/2022							Immature plant	0.0124	0.0135	21	
T: QG22007-035		09/07/2022							Seed	0.00896	0.0491	24	
T: QG22007-039 Poland Peckown/Greater 64-520 (Europe North)		09/07/2022		0.175	304	0.0576	15/06/2022	BBCH 80	Rest of plant	0.0324	0.0178	24	

****Sampling was conducted on the day of the second application before the application was made.**
All details in the above table are taken from study QG22007 with the exception of column 9 which is taken from study EE/23/007 and column 11 which is taken from study QG/20/012.

(a) According to Codex (or other e.g. EU) classification
(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
(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)
(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites included, method of storage, storage stability, analysis date and analytical method.

Table 20: Tier 1 Summary Table Trial 4

Active substance (common name): Prothioconazole
Crop/crop Group: Oil Seed Rape
Albaugh Europe Sàrl
Responsible body for reporting (name, address): Barclay Chemicals (R&D) Limited
UPL EUROPE LIMITED
Country: Germany (Europe North)
Content of active substance (g/kg or g/L): 250 g/L
Formulation (e.g. WP): DC

Commercial Product (name): Prothioconazole 250 g/L DC (FGR06)
Producer of commercial product: UPL Europe Limited
Indoor/Glasshouse/Outdoor: Outdoor
Other active substance in the formulation (common name and content): None
Residues calculated as: Individual components

1	2	3	4	5			6	7	8	9		10	11
Report No. Trial No. Location (region) including postal code	Commodity/ Variety	Date of 1. Sowing or Planting 2. Flowering 3. Harvest	Method of Treatment	Application rate per treatment (Prothioconazole)			Date of treatment(s) or no. of treatment(s) and last date	Growth stage at treatment	Portion Analysed	Residues (mg/kg)		PHI (days)	Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./hL				TAA	TLA		
	(a)	(b)	(c)				(d)	(e)	(a)			(f)	(g)
QG22007-04 U: QG22007-041 U: QG22007-045 U: QG22007-049 U: QG22007-053 U: QG22007-057 U: QG22007-061	Spring Oilseed Rape/ INV 160 CL	1. 11/03/2022 2. 20/05/2022 to 05/06/2022	Boom sprayer	0	0	0	Control (U)	N/A	Immature plant Immature plant Immature plant Immature plant Seed Rest of plant	<0.0012 <0.0012 <0.0012 <0.0012 <0.005 <0.0012	<0.0024 <0.0024 <0.0024 <0.0024 <0.01 <0.01	0** 0 6 21 47 24	TAA: Method: Battelle No. QG/20/012 LOQ = 0.005 mg/kg LOD = 0.0012 mg/kg TLA: Method: Battelle No. QG/20/012 LOQ = 0.01 mg/kg LOD = 0.0024 mg/kg
T: QG22007-043 T: QG22007-047 T: QG22007-051 T: QG22007-055 T: QG22007-059 T: QG22007-063 Germany Machern OT Gerichshain/ Saxony 04827 (Europe North)		3. 17/06/2022 17/06/2022 23/06/2022 08/07/2022 03/08/2022 03/08/2022		0.165 0.171	287 298	0.0575 0.0574	02/06/2022 17/06/2022	BBCH 67 BBCH 80	Immature plant Immature plant Immature plant Immature plant Seed Rest of plant	<0.005 <0.005 <0.005 <0.005 <0.005 <0.005	<0.01 <0.01 <0.01 <0.01 0.0105 <0.01	0** 0 6 21 47 47	

****Sampling was conducted on the day of the second application before the application was made.**
All details in the above table are taken from study QG22007 with the exception of column 9 which is taken from study EE/23/007 and column 11 which is taken from study QG/20/012.

(a) According to Codex (or other e.g. EU) classification
(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
(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)
(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites included, method of storage, storage stability, analysis date and analytical method.

Table 21: Tier 1 Summary Table Trial 5

Active substance (common name): Prothioconazole
Crop/crop Group: Oil Seed Rape
Albaugh Europe Sàrl
Responsible body for reporting (name, address): Barclay Chemicals (R&D) Limited
UPL EUROPE LIMITED
Country: Germany (Europe North)
Content of active substance (g/kg or g/L): 250 g/L
Formulation (e.g. WP): DC

Commercial Product (name): Prothioconazole 250 g/L DC (FGR06)
Producer of commercial product: UPL Europe Limited
Indoor/Glasshouse/Outdoor: Outdoor
Other active substance in the formulation (common name and content): None
Residues calculated as: Individual components

1	2	3	4	5			6	7	8	9		10	11
Report No. Trial No. Location (region) including postal code	Commodity/ Variety	Date of 1. Sowing or Planting 2. Flowering 3. Harvest	Method of Treatment	Application rate per treatment (Prothioconazole)			Date of treatment(s) or no. of treatment(s) and last date	Growth stage at treatment	Portion Analysed	Residues (mg/kg)		PHI (days)	Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./hL				TAA	TLA		
	(a)	(b)	(c)				(d)	(e)	(a)			(f)	(g)
QG22007-05	Spring Oilseed Rape/ Ability	1. 05/04/2022	Boom sprayer	0	0	0	Control (U)	N/A	Immature plant	<0.005	<0.01	0**	TAA: Method: Battelle No. QG/20/012 LOQ = 0.005 mg/kg LOD = 0.0012 mg/kg
U: QG22007-065									Immature plant	<0.005	<0.01	0	
U: QG22007-069									Immature plant	<0.005	<0.01	6	
U: QG22007-073									Immature plant	0.00616	0.0117	21	
U: QG22007-077									Seed	<0.005	0.0192	28	
U: QG22007-081									Rest of plant	<0.005	<0.01	28	
U: QG22007-085		2. 05/06/2022 to 25/06/2022											
T: QG22007-067		3. 12/07/2022		0.174	201	0.0866	27/06/2022	BBCH 75	Immature plant	<0.005	<0.01	0**	TLA: Method: Battelle No. QG/20/012 LOQ = 0.01 mg/kg LOD = 0.0024 mg/kg
T: QG22007-071		12/07/2022							Immature plant	<0.005	<0.01	0	
T: QG22007-075		20/07/2022							Immature plant	<0.005	<0.01	6	
T: QG22007-079		03/08/2022							Immature plant	<0.005	<0.01	21	
T: QG22007-083		18/08/2022		0.172	199	0.0864	12/07/2022	BBCH 80	Seed	<0.005	<0.01	28	
T: QG22007-087		18/08/2022							Rest of plant	0.00660	0.0102	28	
Germany Velen 46342 (Europe North)													

****Sampling was conducted on the day of the second application before the application was made.**
All details in the above table are taken from study QG22007 with the exception of column 9 which is taken from study EE/23/007 and column 11 which is taken from study QG/20/012.

(a) According to Codex (or other e.g. EU) classification
(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
(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)
(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites included, method of storage, storage stability, analysis date and analytical method.

Table 22: Tier 1 Summary Table Trial 6

Active substance (common name): Prothioconazole
Crop/crop Group: Oil Seed Rape
Albaugh Europe Sàrl
Responsible body for reporting (name, address): Barclay Chemicals (R&D) Limited
UPL EUROPE LIMITED
Country: The Netherlands (Europe North)
Content of active substance (g/kg or g/L): 250 g/L
Formulation (e.g. WP): DC

Commercial Product (name): Prothioconazole 250 g/L DC (FGR06)
Producer of commercial product: UPL Europe Limited
Indoor/Glasshouse/Outdoor: Outdoor
Other active substance in the formulation (common name and content): None
Residues calculated as: Individual components

1	2	3	4	5			6	7	8	9		10	11
Report No. Trial No. Location (region) including postal code	Commodity/ Variety	Date of 1. Sowing or Planting 2. Flowering 3. Harvest	Method of Treatment	Application rate per treatment (Prothioconazole)			Date of treatment(s) or no. of treatment(s) and last date	Growth stage at treatment	Portion Analysed	Residues (mg/kg)		PHI (days)	Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./hL				TAA	TLA		
	(a)	(b)	(c)				(d)	(e)	(a)			(f)	(g)
QG22007-06	Spring Oilseed Rape/ Ability	1. 11/04/2022	Boom sprayer	0	0	0	Control (U)	N/A	Immature plant	<0.0012	<0.0024	0**	TAA: Method: Battelle No. QG/20/012 LOQ = 0.005 mg/kg LOD = 0.0012 mg/kg TLA: Method: Battelle No. QG/20/012 LOQ = 0.01 mg/kg LOD = 0.0024 mg/kg
U: QG22007-089									Immature plant	<0.0012	<0.0024	0	
U: QG22007-093									Immature plant	<0.0012	<0.0024	6	
U: QG22007-097									Immature plant	<0.0012	<0.01	21	
U: QG22007-101									Seed	<0.005	0.0111	28	
U: QG22007-105									Rest of plant	<0.005	<0.01	28	
U: QG22007-109													
T: QG22007-091		2. 02/06/2022 to 20/06/2022 3. 05/07/2022		0.174	201	0.0866	21/06/2022	BBCH 69-71	Immature plant	<0.005	<0.01	0**	
T: QG22007-095									Immature plant	<0.005	<0.01	0	
T: QG22007-099									Immature plant	<0.005	<0.01	6	
T: QG22007-103									Immature plant	<0.005	<0.01	21	
T: QG22007-107									Seed	<0.005	<0.01	28	
T: QG22007-111 The Netherlands AV Ven-Zelderheide 6599 (Europe North)		05/07/2022 11/07/2022 26/07/2022 01/08/2022 01/08/2022		0.175	203	0.0862	05/07/2022	BBCH 80	Rest of plant	<0.005	<0.01	28	

****Sampling was conducted on the day of the second application before the application was made.**

All details in the above table are taken from study QG22007 with the exception of column 9 which is taken from study EE/23/007 and column 11 which is taken from study QG/20/012.

(a) According to Codex (or other e.g. EU) classification
(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
(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)
(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites included, method of storage, storage stability, analysis date and analytical method.

Analyte	Matrix	Maximum storage interval (days)
Triazole Acetic Acid	Plant	593
	Seed	565
Triazole Lactic Acid	Plant	593
	Seed	576

Study 8 – Gibson & Toscano Saes 2022, NZ/21/003- Northern & Southern Europe (new data)

Comments of zRMS:	Two independent trials (2 harvest) located in Northern Europe (Germany, The Netherlands) were conducted on oilseed rape following two applications of Prothioconazole 250 g/L DC (175 g as/ha) to determine of the residues of triazole derived metabolites (TDM's) (triazole acetic acid and triazole lactic acid) in oilseed rape specimens: seed and rest of plant. The first application was performed 14 +/-1 days before the second application. The second application was performed on the treated plot at BBCH 80. The limit of quantification (LOQ) was 0.005 mg/kg for triazole acetic acid (for both seed and plant) and 0.01 mg/kg for triazole lactic acid (for both seed and plant). The maximum storage interval from sampling until extraction for TAA and TLA was 890 days in rest of plants and was 884 days in seeds. The study on the magnitude of residues is valid with regard to storage stability. Residue results: TDMs: In the untreated seed samples residues were <LOQ and 0.0222 mg/kg for TAA, and <0.01 and 0.126 for TLA. In the untreated rest of plants samples residues were < LOQ for TAA and for TLA. In the treated specimens, residues of TAA were <LOQ and 0.0265 mg/kg in seeds, and <LOQ in rest of plants. In the treated specimens, residues of TLA were <LOQ and 0.131 mg/kg in seeds, and <0.01 in rest of plants. The study is acceptable. These trials can be used to support the intended use on oilseed rape.

Reference:	KCP 8.3.3/10
Report	Magnitude of Residues of Triazole Derived Metabolites (TDM's) (triazole acetic acid and triazole lactic acid) Following Two Applications of Prothioconazole 250 g/L DC (FGR06) to Oilseed Rape in Northern and Southern Europe, 2021; G Gibson, R Toscano Saes, 2022; study number NZ/21/003
Guideline(s):	• Organisation for Economic Co-operation and Development (OECD), Section 5, Other Test Guidelines, Crop Field Trial (OECD TG No. 509, 14 June 2021). • European Commission (EC), Technical Guidance, Appendix B, General recommendations for the design, preparation and realization of residue trials (SANCO 7029/VI/95, rev.5, 22 July 1997). • European Commission (EC), Analytical methods, Residues Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes (SANTE/2020/12830, rev.2, 14 February 2023). • European Commission (EC), Regulation (EC) No 1107/2009 of The European Parliament and of the Council of 21 October 2009, Concerning the Placing of Plant Protection Products on the Market and Repealing Council Directives 79/117/EEC and 91/414/EEC, (REGULATION (EC) No 1107/2009, 21 October 2009).
Deviations:	The section 7 of the Study Plan states that an example of the calculations is present in the Appendix 2. This appendix states the calculations to measure the concentration of TDM's and the procedural recovery data. The batches B1RA and B2RA use the AM1v1 to measure the concentration of TDM's and apply corrected values to procedural recoveries where the

	calculated level in control samples is above 30% LOQ. That deviates from the calculations presented in the Appendix 2. The calculations to measure the concentration of TDM's in the samples are following a validated method. Therefore, no impact in the quality of the data generated in this study for TAA and TLA. The Study Plan allows corrections in the procedural recovery samples that presents control samples above 30% LOQ the recovery levels. Therefore, no impact in the study.
GLP:	Yes
Acceptability:	Acceptable

Tier 1 Summary Tables – Trial 1

Active substance (common name): Prothioconazole
Crop/crop Group: Oilseed Rape
Responsible body for reporting (name, address): UPL Europe Limited
Albaugh Europe Sàrl
BARCLAY CHEMICALS (R&D) LIMITED
Country: Germany (Europe North)
Content of active substance (g/kg or g/L): 250 g/L
Formulation (e.g. WP): DC

Commercial Product (name): Prothioconazole 250 g/L (FGR06)
Producer of commercial product: UPL AgroSolutions Canada Inc.
Indoor/Glasshouse/Outdoor: Outdoor
Other active substance in the formulation (common name and content): None
Residues calculated as: Individual components

1	2	3	4	5			6	7	8	9		10	11
Report No. Trial No. Location (region) including postal code	Commodity/ Variety	Date of 1. Sowing or Planting 2. Flowering 3. Harvest	Method of Treatment	Application rate per treatment (Prothioconazole)			Date of treatment(s) or no. of treatment(s) and last date	Growth stage at treatment	Portion Analysed	Residues (mg/kg)		PHI (days)	Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./hL				TAA	TLA		
	(a)	(b)	(c)				(d)	(e)	(a)			(f)	(g)
NZ21002-01 U: NZ21002-001 U: NZ21002-005	Spring Oilseed Rape/ Ability	1. 05/04/2021 2. 15/05/2021 to 12/06/2021 3. 18/08/2021	Boom sprayer	0	0	0	Control (U)	N/A	Seed Rest of Plant	>0.00500 <0.00500	>0.0100 <0.00300	37 37	TAA: Method: Battelle No. QG/20/012 LOQ = 0.00500 mg/kg LOD = 0.00150 mg/kg TLA: Method: Battelle No. QG/20/012 LOQ = 0.0100 mg/kg LOD = 0.00300 mg/kg
T: NZ21002-003 T: NZ21002-007 Velen-Ramsdorf 46342 Germany (Europe North)				0.174 0.168	209 202	0.0833 0.0832	28/06/2021 12/07/2021	BBCH 73 BBCH 80	Seed Rest of plant	0.0265 <0.00500	0.131 <0.0100	37 37	

(a) According to Codex (or other e.g. EU) classification
(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
(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)
(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites included, method of storage, storage stability, analysis date and analytical method.

All original sample history information used for the Tier 1 tables is from the study NZ21002 with the exception of the column 9 that is from the actual study NZ/21/003 and the column 11 that is from the study QG/20/012

Table 23: Tier 1 Summary Tables – Trial 2

Active substance (common name):	Prothioconazole	**Commercial Product (name):**	Prothioconazole 250 g/L (FGR06)
Crop/crop Group:	Oilseed Rape	**Producer of commercial product:**	UPL AgroSolutions Canada Inc.
Responsible body for reporting (name, address):	UPL Europe Limited Albaugh Europe Sàrl BARCLAY CHEMICALS (R&D) LIMITED	**Indoor/Glasshouse/Outdoor:**	Outdoor
Country:	The Netherlands (Europe North)	**Other active substance in the formulation (common name and content):**	None
Content of active substance (g/kg or g/L):	250 g/L	**Residues calculated as:**	Individual components
Formulation (e.g. WP):	DC		

1	2	3	4	5			6	7	8	9		10	11
Report No. Trial No. Location (region) including postal code	Commodity/ Variety	Date of 1. Sowing or Planting 2. Flowering 3. Harvest	Method of Treatment	Application rate per treatment (Prothioconazole)			Date of treatment(s) or no. of treatment(s) and last date	Growth stage at treatment	Portion Analysed	Residues (mg/kg)		PHI (days)	Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./hL				TAA	TLA		
	(a)	(b)	(c)				(d)	(e)	(a)			(f)	(g)
NZ21002-02 U: NZ21002-009 U: NZ21002-013	Spring Oilseed Rape/ Ability	1. 05/04/2021 2. 12/05/2021 to 10/06/2021 3. 20/08/2021	Boom sprayer	0	0	0	Control (U)	N/A	Seed Rest of Plant	<0.00150 <0.00500	<0.0100 <0.00300	39 39	TAA: Method: Battelle No. QG/20/012 LOQ = 0.00500 mg/kg LOD = 0.00150 mg/kg TLA: Method: Battelle No. QG/20/012 LOQ = 0.0100 mg/kg LOD = 0.00300 mg/kg
T: NZ21002-011 T: NZ21002-015 Ottersum 6595 ME The Netherlands (Europe North)				0.168 0.172	202 207	0.0832 0.0831	28/06/2021 12/07/2021	BBCH 72 BBCH 80	Seed Rest of plant	<0.00500 <0.00500	<0.0100 <0.0100	39 39	

(a) According to Codex (or other e.g. EU) classification
(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
(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)
(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites included, method of storage, storage stability, analysis date and analytical method.

All original sample history information used for the Tier 1 tables is from the study NZ21002 with the exception of the column 9 that is from the actual study NZ/21/003 and the column 11 that is from the study QG/20/012

Table 24: Tier 1 Summary Tables – Trial 3

Active substance (common name):	Prothioconazole	**Commercial Product (name):**	Prothioconazole 250 g/L (FGR06)
Crop/crop Group:	Oilseed Rape	**Producer of commercial product:**	UPL AgroSolutions Canada Inc.
Responsible body for reporting (name, address):	UPL Europe Limited Albaugh Europe Sàrl BARCLAY CHEMICALS (R&D) LIMITED	**Indoor/Glasshouse/Outdoor:**	Outdoor
Country:	Italy (Europe South)	**Other active substance in the formulation (common name and content):**	None
Content of active substance (g/kg or g/L):	250 g/L	**Residues calculated as:**	Individual components
Formulation (e.g. WP):	DC		

1	2	3	4	5			6	7	8	9		10	11
Report No. Trial No. Location (region) including postal code	Commodity/ Variety	Date of 1. Sowing or Planting 2. Flowering 3. Harvest	Method of Treatment	Application rate per treatment (Prothioconazole)			Date of treatment(s) or no. of treatment(s) and last date	Growth stage at treatment	Portion Analysed	Residues (mg/kg)		PHI (days)	Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./hL				TAA	TLA		
	(a)	(b)	(c)				(d)	(e)	(a)			(f)	(g)
NZ21002-03 U: NZ21002-017 U: NZ21002-021	Oilseed Rape/ Cherokee	1. 15/09/2020 2. 26/04/2021 to 18/05/2021 3. 05/07/2021	Boom sprayer	0	0	0	Control (U)	N/A	Seed Rest of Plant	<0.00150 <0.00150	<0.00300 <0.00300	39 39	TAA: Method: Battelle No. QG/20/012 LOQ = 0.00500 mg/kg LOD = 0.00150 mg/kg TLA: Method: Battelle No. QG/20/012 LOQ = 0.0100 mg/kg LOD = 0.00300 mg/kg
T: NZ21002-019 T: NZ21002-023 12050 Italy (Europe South)				0.174 0.161	313 290	0.0556 0.0555	13/05/2021 27/05/2021	BBCH 67 BBCH 80	Seed Rest of plant	<0.00500 <0.00500	<0.0100 <0.0100	39 39	

(a) According to Codex (or other e.g. EU) classification
(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
(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)
(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites included, method of storage, storage stability, analysis date and analytical method.

All original sample history information used for the Tier 1 tables is from the study NZ21002 with the exception of the column 9 that is from the actual study NZ/21/003 and the column 11 that is from the study QG/20/012.

Table 25: Tier 1 Summary Tables – Trial 4

Active substance (common name):	Prothioconazole	**Commercial Product (name):**	Prothioconazole 250 g/L (FGR06)
Crop/crop Group:	Oilseed Rape	**Producer of commercial product:**	UPL AgroSolutions Canada Inc.
	UPL Europe Limited		
Responsible body for reporting (name, address):	Albaugh Europe Sàrl BARCLAY CHEMICALS (R&D) LIMITED	**Indoor/Glasshouse/Outdoor:**	Outdoor
Country:	Spain (Europe South)	**Other active substance in the formulation (common name and content):**	None
Content of active substance (g/kg or g/L):	250 g/L	**Residues calculated as:**	Individual components
Formulation (e.g. WP):	DC		

1	2	3	4	5			6	7	8	9		10	11
Report No. Trial No. Location (region) including postal code	Commodity/ Variety	Date of 1. Sowing or Planting 2. Flowering 3. Harvest	Method of Treatment	Application rate per treatment (Prothioconazole)			Date of treatment(s) or no. of treatment(s) and last date	Growth stage at treatment	Portion Analysed	Residues (mg/kg)		PHI (days)	Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./hL				TAA	TLA		
	(a)	(b)	(c)				(d)	(e)	(a)			(f)	(g)
NZ21002-04 U: NZ21002-025 U: NZ21002-029	Oilseed Rape/ Salsa CL	1. 20/01/2021 2. 20/04/2021 to 12/05/2021 3. 16/07/2021	Boom sprayer	0	0	0	Control (U)	N/A	Seed Rest of Plant	<0.00500 >0.00500	<0.0100 <0.0100	25 25	TAA: Method: Battelle No. QG/20/012 LOQ = 0.00500 mg/kg LOD = 0.00150 mg/kg
T: NZ21002-027 T: NZ21002-031 ES-41710 Spain (Europe South)				0.163 0.160	294 288	0.0554 0.0555	07/06/2021 21/06/2021	BBCH 75 BBCH 80	Seed Rest of plant	0.0174 0.0196	0.134 <0.0100	25 25	TLA: Method: Battelle No. QG/20/012 LOQ = 0.0100 mg/kg LOD = 0.00300 mg/kg

(a) According to Codex (or other e.g. EU) classification
(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
(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)
(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites included, method of storage, storage stability, analysis date and analytical method.

All original sample history information used for the Tier 1 tables is from the study NZ21002 with the exception of the column 9 that is from the actual study NZ/21/003 and the column 11 that is from the study QG/20/012.

Analyte	Matrix	Maximum storage interval (days)
Triazole Acetic Acid	Plant*	890
	Seed	884
Triazole Lactic Acid	Plant*	890
	Seed	884

A 2.2.4 Magnitude of residues in livestock

A 2.2.4.1 Livestock feeding studies

A 2.2.4.1.1 Livestock feeding study 1

No new data provided for this endpoint.

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 data provided for this endpoint.

A 2.2.5.2 Processing studies on a core set of representative processes

No new data provided for this endpoint.

A 2.2.6 Magnitude of residues in representative succeeding crops

No new data provided for this endpoint.

A 2.2.7 Other/Special Studies

Study 1 - Andrews & Coleman 2024, Study No.: QG21003

Comments of zRMS:	Four residues trials was conducted to determine the magnitude of residues prothioconazole-desthio and hydroxyprothioconazole-desthio metabolites in honey following exposure of honeybees to treated *Phacelia tanacetifolia* plants. Two applications of 250 g/L prothioconazole EC formulation were made representing 200 g/ha prothioconazole per applicationu under light plastic gauze tunnels. The method was succesfully validated for the determination of rothioconazole-desthio and the five prothioconazole-hydroxy-desthio metabolite in honey with a limit of quantification of 0.005 mg/kg in compliance with SANTE/2020/12830 guideline. For prothioconazole-desthio, the maximum storage interval from sampling to last analysis was 282 days. For the five prothioconazole-hydroxy-desthio metabolites, the maximum storage interval from sampling to last analysis was 391 days. This is covered by the storage stability test. In the untreated samples residues rothioconazole-desthio and the five prothioconazole-hydroxy-desthio metabolites were <LOQ. Residue levels for prothioconazole-desthio in treated samples ranged between <LOQ and 0.0123 mg/kg. Residue levels for the five prothioconazole-hydroxy-desthio metabolites in treated samples were <LOQ. The study is acceptable.

Reference:	KCP 8.10.1/01
Report	Magnitude of Residues of Prothioconazole-desthio and Hydroxyprothioconazole-desthio Metabolites in Honey Following Two

	Tunnel Applications of a Prothioconazole 250 g/L EC Formulation (FF-065) to Phacelia in Northern and Southern Europe, 2021; G. Andrews & H. Coleman, 2024; Study No.: QG21003
Guideline(s):	• General recommendations for the design, preparation and realization of residue trials (SANCO 7029/VI/95 rev.5, 22 July 1997). • OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published on 7 September 2009). • Technical guidelines for determining the magnitude of pesticide residues in honey and setting Maximum Residue Levels in honey, SANTE/11956/2016 rev. 9, 14 September 2018. • SANTE/2020/12830, Rev.1, Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes, 24. February 2021
Deviations:	Several minor deviations from the internal and field protocols were noted, but none of these deviations impact the validity of the study results.
GLP:	Yes
Acceptability:	Yes

Study Objective
The objective of the study is to determine the magnitude of residues of prothioconazole-desthio and five prothioconazole-hydroxy-desthio metabolites in honey following two tunnel applications of an EC formulation containing prothioconazole to phacelia in Northern and Southern Europe, 2021, to meet residue regulatory requirements.

Materials and methods
Field Phase
The field phase consisted of four trials conducted on honeybee colonies confined under light plastic gauze tunnels in Northern and Southern Europe (France, Spain, Germany, United Kingdom). Two applications of 250 g/L prothioconazole EC formulation were made to phacelia during flowering at the target rate of 0.8 L/ha, representing 200 g/ha prothioconazole per application.

Method of Analysis
Honey samples are analysed for prothioconazole-desthio and five prothioconazole-hydroxy-desthio according to two validated methods (QG/21/009 and QG/20/011) .

Residues of prothioconazole-desthio are extracted from honey dissolving the samples in water and then extracting the analyte with acetonitrile using QuEChERS kits. A portion of the final extract is then taken through the SPE clean-up and then diluted with water 1:2.5 v/v for final determination by liquid chromatography with tandem mass spectrometry (LC-MS/MS) monitoring two ion mass transitions.

Residues of the five prothioconazole-hydroxy-desthio metabolites are extracted from honey dissolving the samples in water and then extracting the analyte with acetonitrile using QuEChERS kits. The samples are then diluted with water, evaporated to the aqueous remainder through rotary evaporation followed by the hydrolysis step consisting in an overnight incubation at 40°C under acidic conditions. A portion of the final extract is then taken through liquid-liquid extraction, evaporated to dryness using nitrogen flow and then reconstituted in acetonitrile for final determination by liquid chromatography with tandem mass spectrometry (LC-MS/MS) monitoring two ion mass transitions.

Limits of Quantification and Detection

The limit of quantification (LOQ) was 0.005 mg/kg for all analytes and the limit of detection (LOD) was defined as the lowest calibration standard (0.00125 mg/kg) for prothioconazole-desthio and as the lowest calibration standard (0.0015 mg/kg) for the five prothioconazole-hydroxy-desthio metabolites.

Linearity
Calibration curves containing prothioconazole-desthio from matrix-matched solutions were obtained in the range of 0.05 to 2.5 ng/mL for honey analyses.

Calibration curves containing the five prothioconazole-hydroxy-desthio metabolites from matrix-matched solutions were obtained in the range of 0.375 to 15.0 ng/mL for honey analyses.

Specificity
Chromatographic interferences at the retention time of prothioconazole-desthio and the five prothioconazole-hydroxy-desthio metabolites were less than 30% of the limit of quantification in blank and control samples, demonstrating satisfactory selectivity.

Accuracy and Precision
Mean recovery per analytical batch and overall mean recovery were all within the range of 60-120% (LOQ) and 70-120% (10xLOQ). The relative standard deviation (RSD) was not calculated due to reduced number of recovery samples.

Stability of analytes in standard solutions and sample extracts:

- Stability of analytes in standard solutions has been determined within study QG20011.
- Stability of analytes in sample extracts has been determined within study QG21009.
- Stability of frozen samples of prothioconazole-desthio the five prothioconazole-hydroxy-desthio metabolites in honey has been determined within study QG21007.

All extracts were analysed within proven extract stability.

Results

Trial 1

Active substance (common name): Prothioconazole
Crop/crop Group: Phacelia (honey)
Responsible body for reporting (name, address): Prothioconazole data-matching taskforce
Country: France (Southern EU)
Content of active substance (g/kg or g/L): 250 g/L
Formulation (e.g. WP): EC

Commercial Product (name): Prothioconazole 250 g/L EC
Producer of commercial product: Rotam Agrochemical Co. Ltd, Hong Kong
Indoor/Glasshouse/Outdoor: Tunnel
Other active substance in the formulation (common name and content): None
Residues calculated as: Individual Components

1	2	3	4	5			6	7	8	9						10	11
Report No. Trial No. Location (region) including postal code	Commodity/ Variety	Date of 1. Sowing or Planting 2. Flowering 3. Harvest	Method of Treatment	Application rate per treatment (Prothioconazole)			Date of treatment(s) or no. of treatment(s) and last date	Growth stage at treatment	Portion Analysed	Residues (mg/kg)						PHI (days)	Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./hL				Prothioconazole-desthio	α-OH	3-OH	4-OH	5-OH	6-OH		
	(a)	(b)	(c)				(d)	(e)	(a)							(f)	(g)
QG21003-01 U:QG21003-01 T: QG21003-03 Villemur sur tam, France, 31340 (Europe South)	Phacelia (PHCTA) *Boratus*	1. 22/07/2021 2. 24/09/2021 to 29/10/2021 3. 20/10/2021	Broadcast Foliar	0	0	0	Control (U)	n/a	Honey	<0.0015	<0.0015	<0.0015	<0.0015	<0.0015	<0.0015	8	Prothioconazole-desthio: Method: Battelle No. QG/20/011 LOQ = 0.005 mg/kg LOD = 0.0015 mg/kg Metabolites: Method Battelle No. QG/21/009 LOQ = 0.005 mg/kg LOD = 0.0015 mg/kg
				0.199 0.201	296 299	0.0674 0.0674	29/09/2021 12/10/2021	BBCH 61 BBCH 65	Honey	<0.005	<0.005	<0.005	<0.005	<0.005	<0.005	8	

(a) According to Codex (or other e.g. EU) classification
(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
(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)
(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites included, method of storage, storage stability, analysis date and analytical method.

Trial 2

Active substance (common name): Prothioconazole
Crop/crop Group: Phacelia (honey)
Responsible body for reporting (name, address): Prothioconazole data-matching taskforce
Country: Spain (Southern EU)
Content of active substance (g/kg or g/L): 250 g/L
Formulation (e.g. WP): EC

Commercial Product (name): Prothioconazole 250 g/L EC
Producer of commercial product: Rotam Agrochemical Co. Ltd, Hong Kong
Indoor/Glasshouse/Outdoor: Tunnel
Other active substance in the formulation (common name and content): None
Residues calculated as: Individual Components

1	2	3	4	5			6	7	8	9						10	11
Report No. Trial No. Location (region) including postal code	Commodity/ Variety	Date of 1. Sowing or Planting 2. Flowering 3. Harvest	Method of Treatment	Application rate per treatment (Prothioconazole)			Date of treatment(s) or no. of treatment(s) and last date	Growth stage at treatment	Portion Analysed	Residues (mg/kg)						PHI (days)	Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./hL				Prothioconazole-desthio	α-OH	3-OH	4-OH	5-OH	6-OH		
	(a)	(b)	(c)				(d)	(e)	(a)							(f)	(g)
QG21003-02 U:QG21003-05 T: QG21003-07 Los Palacios y Villafranca Spain 41720 (Europe South)	Phacelia (PHCTA)	1. 24/12/2020 2. 10/05/2021 to 27/05/2021 3. 27/05/2021	Broadcast Foliar	0	0	0	Control (U)	n/a	Honey	<0.0015	<0.0015	<0.0015	<0.0015	<0.0015	<0.0015	6	Prothioconazole-desthio: Method: Battelle No. QG/20/011 LOQ = 0.005 mg/kg LOD = 0.0015 mg/kg Metabolites: Method Battelle No. QG/21/009 LOQ = 0.005 mg/kg LOD = 0.0015 mg/kg
				0.202 0.197	300 293	0.0673 0.0672	11/05/2021 21/05/2021	BBCH 61 BBCH 67	Honey	0.0123	<0.005	<0.005	<0.005	<0.005	<0.005	6	

(a) According to Codex (or other e.g. EU) classification
(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
(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)
(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites included, method of storage, storage stability, analysis date and analytical method.

Trial 3

Active substance (common name): Prothioconazole
Crop/crop Group: Phacelia (honey)
Responsible body for reporting (name, address): Prothioconazole data-matching taskforce
Country: Germany (Northern EU)
Content of active substance (g/kg or g/L): 250 g/L
Formulation (e.g. WP): EC

Commercial Product (name): Prothioconazole 250 g/L EC
Producer of commercial product: Rotam Agrochemical Co. Ltd, Hong Kong
Indoor/Glasshouse/Outdoor: Tunnel
Other active substance in the formulation (common name and content): None
Residues calculated as: Individual Components

1	2	3	4	5			6	7	8	9						10	11
Report No. Trial No. Location (region) including postal code	Commodity/ Variety	Date of 1. Sowing or Planting 2. Flowering 3. Harvest	Method of Treatment	Application rate per treatment (Prothioconazole)			Date of treatment(s) or no. of treatment(s) and last date	Growth stage at treatment	Portion Analysed	Residues (mg/kg)						PHI (days)	Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./hL				Prothioconazole-desthio	α-OH	3-OH	4-OH	5-OH	6-OH		
	(a)	(b)	(c)				(d)	(e)	(a)							(f)	(g)
QG21003-03 U:QG21003-09 T: QG21003-11 Blaufelden Germany, 74572 (Europe North)	Phacelia (PHCTA) *Stala*	1. 19/06/2021 2. 20/09/2021 to 15/10/2021 3. 13/10/2021	Broadcast Foliar	0	0	0	Control (U)	n/a	Honey	<0.0015	<0.0015	<0.0015	<0.0015	<0.0015	<0.0015	12	Prothioconazole-desthio: Method: Battelle No. QG/20/011 LOQ = 0.005 mg/kg LOD = 0.0015 mg/kg Metabolites: Method Battelle No. QG/21/009 LOQ = 0.005 mg/kg LOD = 0.0015 mg/kg
				0.197 0.203	292 302	0.0675 0.0672	21/09/2021 01/10/2021	BBCH 61 BBCH 65	Honey	<0.005	<0.005	<0.005	<0.005	<0.005	<0.005	12	

(a) According to Codex (or other e.g. EU) classification
(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
(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)
(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites included, method of storage, storage stability, analysis date and analytical method.

Trial 4

Active substance (common name): Prothioconazole
Crop/crop Group: Phacelia (honey)
Responsible body for reporting (name, address): Prothioconazole data-matching taskforce
Country: United Kingdom (Northern EU)
Content of active substance (g/kg or g/L): 250 g/L
Formulation (e.g. WP): EC

Commercial Product (name): Prothioconazole 250 g/L EC
Producer of commercial product: Rotam Agrochemical Co. Ltd, Hong Kong
Indoor/Glasshouse/Outdoor: Tunnel
Other active substance in the formulation (common name and content): None
Residues calculated as: Individual Components

1	2	3	4	5			6	7	8	9						10	11
Report No. Trial No. Location (region) including postal code	Commodity/ Variety	Date of 1. Sowing or Planting 2. Flowering 3. Harvest	Method of Treatment	Application rate per treatment (Prothioconazole)			Date of treatment(s) or no. of treatment(s) and last date	Growth stage at treatment	Portion Analysed	Residues (mg/kg)						PHI (days)	Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./hL				Prothioconazole-desthio	α-OH	3-OH	4-OH	5-OH	6-OH		
	(a)	(b)	(c)				(d)	(e)	(a)							(f)	(g)
QG21003-04 U:QG21003-13 T: QG21003-15 Bucknell, United Kingdom OX27 7LT (Europe North)	Phacelia (PHCTA) *Factotum*	1. 03/06/2021 2. 15/08/2021 to 08/09/2021 3. 08/09/2021	Broadcast Foliar	0	0	0	Control (U)	n/a	Honey	<0.0015	<0.0015	<0.0015	<0.0015	<0.0015	<0.0015	8	Prothioconazole-desthio: Method: Battelle No. QG/20/011 LOQ = 0.005 mg/kg LOD = 0.0015 mg/kg Metabolites: Method Battelle No. QG/21/009 LOQ = 0.005 mg/kg LOD = 0.0015 mg/kg
				0.214 0.216	212 214	0.101 0.101	17/08/2021 31/08/2021	BBCH 61 BBCH 65-67	Honey	<0.005	<0.005	<0.005	<0.005	<0.005	<0.005	8	

(a) According to Codex (or other e.g. EU) classification
(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
(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)
(g) Remarks may include: climatic conditions, references to analytical method, info concerning the metabolites included, method of storage, storage stability, analysis date and analytical method.

*sum of prothioconazole-desthio, 3-hydroxyprothioconazole-desthio, 4-hydroxyprothioconazole-desthio, 5-hydroxyprothioconazole-desthio, 6-hydroxyprothioconazole-desthio and alpha-hydroxyprothioconazole-desthio, expressed as prothioconazole-desthio. Where the residue of analyte expressed as prothioconazole-desthio (mg/kg) was calculated as follow = MW prothioconazole-desthio (g/mol) x analyte residue measured (mg/kg) / Analyte MW (g/mol)
The molecular weight (MW) of each analyte is: prothioconazole-desthio: 312.19 g/mol, Prothioconazole-α-hydroxy-desthio: 328.19 g/mol, Prothioconazole-3-hydroxy-desthio: 328.19 g/mol, Prothioconazole-4-hydroxy-desthio: 328.19 g/mol, Prothioconazole-5-hydroxy-desthio: 328.19 g/mol, Prothioconazole-6-hydroxy-desthio: 328.19 g/mol
The LOQ for the sum expressed as prothioconazole-desthio (0.029 mg/kg) was calculated using the formula: LOQ of prothioconazole-desthio + Prothioconazole-α-hydroxy-desthio expressed as 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.
Sum of residues expressed as prothioconazole-desthio for Trial QG21003-01 = <0.029 mg/kg

Study 2 - Lebrun, 2024; Study No.: 644-2023

Comments of zRMS:	Four semi-field residues trials was conducted to determine the magnitude of residues triazole derivative metabolites in honey following exposure of honeybees to treated *Phacelia tanacetifolia* plants following two foliar applications of the formulated product FGR06, a DC formulation with a nominal concentration of 250 g/L prothioconazole applied at the target dose rate of 200 g a.s./ha. The analytical method was validated on honey in compliance with SANTE/2020/12830, Rev.2 within this study at LOQ. The maximum storage interval from sampling until extraction was 153 days. This is covered by the storage stability test. No residues of 1,2,4-triazole (T), triazole acetic acid (TAA), triazole alanine (TA) and triazole lactic acid (TLA) were measured above the LOQ in the untreated or treated honey specimens. The study is acceptable.

Reference: KCP 8.10.1/02

Report: Magnitude of the residue of triazole derivative metabolites in phacelia honey in Northern and Southern Europe – 2023, F. Lebrun, 2024; Study No.: 644-2023

Guideline(s):

- Regulation (EC) N°1107/2009 of 21/10/2009 (Repealing the Council Directives 79/117/EEC and 91/414/EEC) concerning the placing of plant protection products on the market
- Regulation (EU) No 283/2013 of 01/03/2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market
- OECD No. 509, OCDE Guidelines for the Testing of Chemicals - Crop Field Trial, 07/09/2009
- SANTE/11956/2016 rev. 9, Technical guidelines for determining the magnitude of pesticide residues in honey and setting Maximum Residue Levels in honey, 14 September 2018.
- SANTE/2020/12830, Rev.2, 14 February 2023: Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes (Supersedes Guidance Documents SANCO/3029/99 and SANCO/825/00)
- OECD (2007), Guidance Document on Pesticide Residue Analytical Methods. Series on testing and assessment Number 72. Series on pesticides Number 39. ENV/JM/MONO(2007)17
- The Application of GLP Principles to Field Studies, OECD Series on Principles of GLP and
- Compliance Monitoring Number 6 (Revised 1999), ENV/JM/MONO(99)22
- The Application of the OECD Principles of GLP to the Organisation and Management of Multi-Site Studies, OECD Series on Principles of GLP and Compliance Monitoring Number 13, ENV/JM/MONO(2002)9

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

GLP:	Yes
Acceptability:	Yes

Study Objective
The study was conducted under semi-field conditions (use of insect-proof tunnels) to determine the residue levels of triazole derivative metabolites (T, TAA, TA, TLA) in phacelia honey specimens following two foliar applications of the formulated product FGR06, a DC formulation with a nominal concentration of 250g/L prothioconazole applied at the target dose rate of 200 g a.s./ha.

Materials and methods
Field Phase
Four semi-field trials were set up on phacelia using bee tunnels, in Northern Europe (Northern France and Denmark) and Southern Europe (Italy, Spain).The trials were conducted under semi-field conditions using insect-proof bee tunnels that were big enough to guarantee the collection of representative amounts of mature honey under optimal conditions (plots (U)/tunnel and (T)/tunnel reported minimum size 152 m^2, and up to 280 m^2).

Two broadcast foliar applications were performed in the treated tunnel with a 7 (+/-1) days interval during the flowering period of phacelia, as a direct spray application on the crop aerial parts:

- The first application was made at BBCH ranging between 61-63.
- The second application occurred 6 to 7 days after the first application, at BBCH 64-65.

At each application: the target dose rate was 0.800 L FP/ha (and actual range 0.786 to 0.849 L product/ha), equivalent to 200 g a.s./ha (calculated with the nominal concentration of the active substance in the test item of 250 g as/L). The actual dose rate ranged between 0.786 and 0.849 L product/ha.

Method of Analysis
The analytical method principle is based on 01062/M004 (the method used in the dRAR for the prothioconazole renewal).

Residues of the triazole derivative metabolites are extracted from honey by dissolving the samples in methanol/water (4/1, v/v), and an aliquot is filtered, concentrated, and cleaned-up by a simple dispersive C18-SPE step. The analytes are determined by LC-DMS/MS/MS. Residues are quantified using isotopically labelled internal standards in solvent.

Limits of Quantification and Detection
The limit of quantification (LOQ) was 0.01 mg/kg for all analytes and the limit of detection (LOD) was defined as the lowest calibration standard (0.003 mg/kg).

Linearity
The linearity of the detector response was demonstrated by single determination of solvent calibration standards at eight (8) concentration levels ranging from 0.30 ng/mL to 30 ng/mL. This range corresponds to a mass fraction level of 0.003 mg/kg to 0.3 mg/kg and thus covers the range from no more than 30 % of the LOQ and at least + 20 % of the highest analyte concentration detected in any sample extract. The calibration curve did not exceed two (2) orders of magnitude.

Calibration standards contained isotopically labelled standards at a constant concentration level of 20 ng/mL. The peak area ratio of analyte and internal standard was calculated and used for the generation of calibration curves.

The calibration curves obtained for all analytes were linear since the regression residuals were randomly distributed. Furthermore, coefficients of determination (R^2) were ≥ 0.99. Linear regression was performed with 1/x-weighting.

Specificity

Chromatographic interferences at the retention time of triazole derivative metabolites were less than 30% of the limit of quantification in blank and control samples, demonstrating satisfactory selectivity.

Accuracy and Precision

Mean recovery per analytical batch and overall mean recovery were all within the range of 60-120% (LOQ) and 70-120% (10xLOQ). The relative standard deviation (RSD) was not calculated due to reduced number of recovery samples.

Results

Trial 1

Active Substance: Prothioconazole
Crop / crop group: Phacelia / Melliferous crop
Responsible for reporting: Frédéric Lebrun / TESTAPI
115 route de Pô, 49650 Allonnes - France
Country: Denmark
Nominal Content of a.s.: 250 g/L
Formulation: DC

Commercial Product: FGR06
Producer: UPL Europe Ltd.

Indoor/glasshouse/outdoor: outdoor (semi-field using bee tunnels)
Other a.s. in formulation: -
Residue calculated as: 1,2,4-triazole (T), triazole acetic acid (TAA), triazole alanine (TA) and triazole lactic acid (TLA in mg/kg

1	2	3	4	5			6	7	8	9		10	11
Location Trial No.	Commodity Variety	Date of 1-Sowing 2-Flowering 3-Harvest	Method of treatment	Actual (nominal) application rate per treatment			Date of treatment	BBCH Crop Growth Stage at treatment	Portions analysed	Residues (1)		DALA (2)	Remarks
				kg a.s./ha	Water (L/ha)	kg (a.s./hL)							
Northern Europe Denmark 5580 Nørre Aby (South Denmark) Semi-field trial 644-2023 DK01	Phacelia HAPPY BEE	1- 17/04/23 2- 12/06/23 to 12/07/23 3- N/A	Broadcast foliar applications Boom sprayer	0.1940 (0.1966) 0.1950 (0.1976)	197 198	0.0987 (0.1000) 0.0987 (0.1000)	19/06/23 25/06/23	61-63 65	Honey	T n.d. TA n.d.	TAA n.d. TLA n.d.	8	Untreated specimen: n.d. LC-DMS-MS/MS Method validated within this study in honey Max. Study Storage Interval between: -sampling and extraction: 153 days -extraction and analyses: 1 day

(1) LOQ = 0.010 mg/kg / *n.d. = not detected (below LOD set at 30 % of the LOQ)*
(2) DALA = days after last application

Trial 2

Active Substance: Prothioconazole
Crop / crop group: Phacelia / Melliferous crop
Responsible for reporting: Frédéric Lebrun / TESTAPI
115 route de Pô, 49650 Allonnes - France
Country: Northern France
Nominal Content of a.s.: 250 g/L
Formulation: DC

Commercial Product: FGR06
Producer: UPL Europe Ltd.

Indoor/glasshouse/outdoor: outdoor (semi-field using bee tunnels)
Other a.s. in formulation: -
Residue calculated as: 1,2,4-triazole (T), triazole acetic acid (TAA), triazole alanine (TA) and triazole lactic acid (TLA) in mg/kg

1	2	3	4	5			6	7	8	9		10	11
Location Trial No.	Commodity Variety	Date of 1-Sowing 2-Flowering 3-Harvest	Method of treatment	Actual (nominal) application rate per treatment			Date of treatment	BBCH Crop Growth Stage at treatment	Portions analysed	Residues (1)		DALA (2)	Remarks
				kg a.s./ha	Water (L/ha)	kg (a.s./hL)							
Northern Europe Northern France 49650 Allonnes (Pays de Loire) Semi-field trial 644-2023 FR02	Phacelia PHCSS	1- 26/10/22 2- 27/04/23 to 25/05/23 3- N/A	Broadcast foliar applications Boom sprayer	0.1997 (0.2023) 0.1989 (0.2016)	304 302	0.0658 (0.0667) 0.0658 (0.0667)	03/05/23 10/05/23	62 64	Honey	T n.d. TA n.d.	TAA n.d. TLA n.d.	6	Untreated specimen: n.d. LC-DMS-MS/MS Method validated within this study in honey Max. Study Storage Interval between: -sampling and extraction: 153 days -extraction and analyses: 1 day

(1) LOQ = 0.010 mg/kg / *n.d. = not detected (below LOD set at 30 % of the LOQ)*
(2) DALA = days after last application

Trial 3

Active Substance: Prothioconazole
Crop / crop group: Phacelia / Melliferous crop
Responsible for reporting: Frédéric Lebrun / TESTAPI
115 route de Pô, 49650 Allonnes - France
Country: Italy
Nominal Content of a.s.: 250 g/L
Formulation: DC

Commercial Product: FGR06
Producer: UPL Europe Ltd.

Indoor/glasshouse/outdoor: outdoor (semi-field using bee tunnels)
Other a.s. in formulation: -
Residue calculated as: 1,2,4-triazole (T), triazole acetic acid (TAA), triazole alanine (TA) and triazole lactic acid (TLA in mg/kg

1	2	3	4	5			6	7	8	9		10	11
Location Trial No.	Commodity Variety	Date of 1-Sowing 2-Flowering 3-Harvest	Method of treatment	Actual (nominal) application rate per treatment			Date of treatment	BBCH Crop Growth Stage at treatment	Portions analysed	Residues (1)		DALA (2)	Remarks
				kg a.s./ha	Water (L/ha)	kg (a.s./hL)							
Southern Europe Italy 44028 Poggio Renatico (Emilia-Romagna) Semi-field trial 644-2023 IT03	Phacelia ANGELIA	1- 08/04/23 2- 08/06/23 to 30/06/23 3- N/A	Broadcast foliar applications Boom sprayer	0.2004 (0.2030) 0.2021 (0.2048)	305 307	0.0658 (0.0667) 0.0658 (0.0667)	15/06/23 22/06/23	63 65	Honey	T n.d. TA <LOQ	TAA n.d. TLA n.d.	7	Untreated specimen: <LOQ LC-DMS-MS/MS Method validated within this study in honey Max. Study Storage Interval between: -sampling and extraction: 153 days -extraction and analyses: 1 day

(1) LOQ = 0.010 mg/kg / *n.d. = not detected (below LOD set at 30 % of the LOQ)*
(2) DALA = days after last application

Trial 4

Active Substance:	Prothioconazole	**Commercial Product:**	FGR06
Crop / crop group:	Phacelia / Melliferous crop	**Producer:**	UPL Europe Ltd.
Responsible for reporting:	Frédéric Lebrun / TESTAPI 115 route de Pô, 49650 Allonnes - France		
Country:	Spain	**Indoor/glasshouse/outdoor:**	outdoor (semi-field using bee tunnels)
Nominal Content of a.s.:	250 g/L	**Other a.s. in formulation:**	-
Formulation:	DC	**Residue calculated as:**	1,2,4-triazole (T), triazole acetic acid (TAA), triazole alanine (TA) and triazole lactic acid (TLA) in mg/kg

1	2	3	4	5			6	7	8	9		10	11
Location Trial No.	Commodity Variety	Date of 1-Sowing 2-Flowering 3-Harvest	Method of treatment	Actual (nominal) application rate per treatment			Date of treatment	BBCH Crop Growth Stage at treatment	Portions analysed	Residues (1)		DALA (2)	Remarks
				kg a.s./ha	Water (L/ha)	kg (a.s./hL)							
Southern Europe Spain 46220 Picassent (Valencia) Semi-field trial 644-2023 SP04	Phacelia STALA	1- 10/01/23 2- Mid-April to mid-May 23 3- N/A	Broadcast foliar applications Boom sprayer	0.1995 (0.2022) 0.2095 (0.2123)	404 425	0.0493 (0.0500) 0.0493 (0.0500)	11/04/23 18/04/23	62 65	Honey	T n.d. TA n.d.	TAA n.d. TLA n.d.	7	Untreated specimen: n.d. LC-DMS-MS/MS Method validated within this study in honey Max. Study Storage Interval between: -sampling and extraction: 153 days -extraction and analyses: 1 day

(1) LOQ = 0.010 mg/kg / *n.d. = not detected (below LOD set at 30 % of the LOQ)*
(2) DALA = days after last application

Study 3 - Bocksch 2008, T011298-06-REG, VV-382035

Comments of zRMS:	This study has already been evaluated. Please refer to the Azoxystrobin EU renewal (dRAR) for a summary and conclusions for this study. *"Three semi-field trials are available that determine the magnitude of azoxystrobin residues in honey following application of azoxystrobin to oilseed rape (1 x 250 g a.s./ha, BBCH 63; honey sampled at maturity). Residues of azoxystrobin in samples of treated honey ranged from < 0.01 mg/kg to 0.01 mg/kg".*

Reference:	KCP 8.10.1/03
Report	Azoxystrobin (ICI5504) and cyproconazole (SAN19) – Residues in honey following exposure of bees to treated winter oil-seed rape in Germany during 2007; Bocksch S , 2008; T011298-06-REG; VV-382035
Guideline(s):	• Federal Office for Consumer Protection and Food Safety Guidance Document Part C4 • Commission of the European Communities Guidelines for the generation of data concerning residues as provided in Annex II part A, section 6 and Annex III, part A, section 8 of Directive 91/414/EEC concerning the placing of plant protection products on the market, 1607/VI/97 rev. 1
Deviations:	• Only three trial sites were evaluated • Number of applications made during flowering is not representative of the critical GAP for the representative uses • Samples were stored for approximately 2 months prior to analysis and no storage stability data are reported
GLP:	Yes
Acceptability:	Yes

Executive Summary

A semi-field study was conducted with three trials in Northern Europe (Germany) on oilseed rape in 2007. Three treated plots and one untreated plot (each 100 m2) were established in separate tunnels at each field site and one bee colony (honey bee, Apis mellifera L.) was introduced into each tunnel one day before treatment.

A tank mix of azoxystrobin and cyproconazole was applied once by foliar application at a rate of 250 g azoxystrobin/ha and 100 g cyproconazole/ha to the treated plots. The control plot was treated with local water at one of the trial sites (Cunnersdorf) and not treated at the other two sites (Bodelshausen and Celle). During application, the crop was at BBCH 63 across all plots.

Samples of mature, capped honey (9.27-296 g) were taken at BBCH 65-69 for residue analysis. In circumstances where low amounts of honey were extracted, 'ship' and 'retain' samples were pooled where possible. All samples were maintained frozen (-20 ± 5°C) at the testing facility, during shipping to the laboratory, and were stored frozen for a maximum of 2 months until analysis. Residues of azoxystrobin and R230310 have been shown to be stable in various crops for up to 24 months under these conditions.

The bee colonies remained in good health throughout the trial, free of visible symptoms of diseases.

Samples were analysed using analytical method RAM 305/03, an LC-MS/MS method to determine residues of azoxystrobin and R230310. The method was modified for use in honey. Acceptable method validation and concurrent recoveries were reported for honey at fortification levels of 0.01 mg/kg and 0.10 mg/kg, thus validating the method. The limit of quantification (LOQ) was 0.01 mg/kg per analyte.

Samples were also analysed using analytical method RAM 397/02, an LC-MS/MS method to determine residues of cyproconazole. These data are not reported in this study summary as they are not relevant to the evaluation of azoxystrobin.

No residues of azoxystrobin or R230310 were found at or above the LOQ in honey from the untreated control plots.
Individual sample residues of azoxystrobin residues in the collected honey from the treated plots ranged from < 0.01 mg/kg to 0.01 mg/kg. Residues of R230310 were < 0.01 mg/kg from all treated plots.

Materials and methods
A semi-field study was conducted with three trials in Germany (Northern Europe) on oilseed rape in 2007. Three treated plots and one untreated plot (each 100 m2) were established in separate tunnels at each field site and one bee colony (honey bee, Apis mellifera L.) was introduced into each tunnel one day before treatment.
A tank mix of azoxystrobin and cyproconazole was applied once by foliar application at a rate of 250 g azoxystrobin/ha and 100 g cyproconazole/ha to the treated plots. The control plot was treated with local water at one of the trial sites (Cunnersdorf) and not treated at the other two sites (Bodelshausen and Celle). During application the crop was at BBCH 63 across all plots.
For the purpose of this summary, only data relating to azoxystrobin are presented below.

Crop information

Trial Location (City, Province or State Country /Year)	**Crop/crop group**	**Variety**	**Growth stage at application (BBCH code)**
G07N011B, Bodelshausen, D-72411, Germany, 2007	Oilseed rape (Brassica napus)	Titan	63
G07N012B, Cunnersdorf, D-04827, Germany, 2007	Oilseed rape (Brassica napus)	Elektra	63
G07N013B, Celle, 29229, Germany, 2007	Oilseed rape (Brassica napus)	Titan	63

Application and use pattern in the end-use product A12705B tested at Bodelshausen, Germany in 2007

Tunnel	Method/ Timing	Rate g ai/ha	Vol L/ha	Spray interval days	Total rate g ai/ha	Tank mix adjuvants
T1	Foliar spray	250	200	N/A1	250	None
T2		230	184	N/A1	230	None
T3		230	184	N/A1	230	None

1 Not applicable, all tunnels were treated once on 17 April 2007

Application and use pattern in the end-use product A12705B tested at Cunnersdorf, Germany in 2007

Tunnel	Method/ Timing	Rate g ai/ha	Vol L/ha	Spray interval days	Total rate g ai/ha	Tank mix adjuvants
T1	Foliar spray	230	184	N/A1	230	None
T2		235	188	N/A1	235	None
T3		240	192	N/A1	240	None

1 Not applicable, all tunnels were treated once on 17 April 2007

Application and use pattern of azoxystrobin in the end-use product A12705B tested at Celle, Germany in 2007

Tunnel	Method/ Timing	Rate g ai/ha	Vol L/ha	Spray interval days	Total rate g ai/ha	Tank mix adjuvants
T1	Foliar spray	259	207	N/A1	259	None
T2		245	196	N/A1	245	None
T3		254	203	N/A1	254	None

1 Not applicable, all tunnels were treated once on 17 April 2007

Climatic conditions

Trial Location (City, Province or State Country /Year)	Study conditions		Long-term average	
	Overall daily rainfall range (mm)	Overall temperature range (°C)	Overall daily/ monthly rainfall range (mm)	Overall temperature range (°C)
G07N011B, Bodelshausen, D-72411, Germany, 2007	0.0 - 0.0	-1.6 - 25.7	Not reported	Not reported
G07N012B, Cunnersdorf, D-04827, Germany, 2007	0.0 - 2.3	-1.3 - 27.1	Not reported	Not reported
G07N013B, Celle, 29229, Germany, 2007	0.0 - 3.0	0.0 - 27.4	Not reported	Not reported

Samples of mature, capped honey (9.27-296 g) were taken at BBCH 65-69 for residue analysis. In circumstances where low amounts of honey were extracted, 'ship' and 'retain' samples were pooled where possible.
All samples were frozen (-20 ± 5°C) within 12 hours, maintained frozen at the testing facility, during shipment to the laboratory, and were stored frozen until analysis. The maximum storage interval between collection and analysis was 2 months. Residues of azoxystrobin and R230310 have been shown to be stable in various crops for up to 24 months under these conditions.

Summary of storage conditions

Matrix (RAC or extract)	Storage temp. (°C)	Actual storage duration (days or months)	Interval of demonstrated storage stability (days or months)
Honey	-20 ± 5	2 months	Not available

Samples were analysed using analytical method RAM 305/03, an LC-MS/MS method to determine residues of azoxystrobin and R230310. The method was modified for use in honey. Acceptable method validation and concurrent recoveries were reported for honey at fortification levels of 0.01 mg/kg and 0.10 mg/kg, thus validating the method. The limit of quantification (LOQ) was 0.01 mg/kg per analyte for honey.
The health of the colonies was assessed before introduction to the tunnels and at the end of the trials, by assessing the strength of the colony (number of frames covered with bees), the presence of a healthy queen (i.e. presence of eggs or presence of queen cells), and visual assessment of the percentage of frames containing pollen, nectar and brood (eggs, larvae and capped cells).

Results
Acceptable concurrent recoveries were reported as in the following table.

Fortification and recovery

Matrix	Fortification level (mg/kg)	Sample size (n)	Recoveries (%)	Mean recovery (%)	RSD (%)
Azoxystrobin					
Primary mass transition m/z = 404.2 → 372.4					
Honey	0.01	5	78, 77, 75, 81, 71	76	4.8
	0.10	5	83, 82, 83, 89, 82	84	3.4
	Overall	10	-	80	6.3
Secondary mass transition m/z = 404.2 → 343.8					
Honey	0.01	5	98, 93, 95, 103, 90	96	5.2
	0.10	5	83, 80, 81, 90, 85	84	4.5
	Overall	10	-	90	8.4
R230310					
Primary mass transition m/z = 404.2 → 372.4					
Honey	0.01	5	75, 83, 80, 84, 73	79	6.2
	0.10	5	92, 92, 92, 94, 88	92	2.3
	Overall	10	-	85	9.0
Secondary mass transition m/z = 404.2 → 343.8					
Honey	0.01	5	79, 82, 74, 94, 85	83	9.3
	0.10	5	90, 91, 91, 93, 89	91	1.7
	Overall	10	-	87	7.8

Details of the trials, the individual applications and the analytical residue results obtained are summarised in Table 6.10.1-8.
No residues were found at or above the LOQ in honey from the untreated control plots.

Residue trial summary for azoxystrobin and R230310 in honey from bees foraging on oilseed rape

Trial No./ Location/ Year	Commodity / Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Tunnel	Application rate per treatment			Dates of treatment or number and last date	Growth stage at each treatment	Date colony placed in tunnel	Portion analysed	Residues (mg/kg)		Sampling occasion	Remarks
				g ai/ha	Water (L/ha)	g ai/hL					Azoxystrobin	R230310		
G07N011B / Bodelshausen, D-72411, Germany / 2007	Oilseed rape / Titan	1. 05 Sep 2006 2. 01-30 Apr 2007 3. 30 Apr 2007	T1	250	200	125	17 Apr 2007	BBCH 63	16 Apr 2007	Honey	0.01	< 0.01	Honey maturity; 13 DAA	-
			T2	230	184	125	17 Apr 2007		16 Apr 2007	Honey	0.01	< 0.01		
			T3	230	184	125	17 Apr 2007		16 Apr 2007	Honey	< 0.01	< 0.01		
G07N012B / Cunnersdorf, D-04827, Germany / 2007	Oilseed rape / Elektra	1. 28 Aug 2006 2. 10-30 Apr 2007 3. 30 Apr 2007	T1	230	184	125	16 Apr 2007	BBCH 63	15 Apr 2007	Honey	< 0.01	< 0.01	Honey maturity; 14 DAA	-
			T2	235	188	125	16 Apr 2007		15 Apr 2007	Honey	< 0.01	< 0.01		
			T3	240	192	125	16 Apr 2007		15 Apr 2007	Honey	< 0.01	< 0.01		
G07N013B / Celle, 29229, Germany / 2007	Oilseed rape / Titan	1. 25 Aug 2006 2. 02 Apr – 01 May 2007 3. 20-26 Apr 2007	T1	259	207	125	12 Apr 2007	BBCH 63	11 Apr 2007	Honey	< 0.01	< 0.01	Honey maturity; 14 DAA1	-
			T2	245	196	125	12 Apr 2007		11 Apr 2007	Honey	< 0.01	< 0.01		
			T3	254	203	125	12 Apr 2007		11 Apr 2007	Honey	< 0.01	< 0.01		

DAA: days after application
1 For tunnel 1 and 3, additional preliminary samples were taken 8 DAA as there was a concern that honey stores would be consumed by the colonies due to poor weather conditions. Residues of azoxystrobin and R230310 were both < 0.01 mg/kg in these samples

Conclusion
A semi-field study was conducted with three trials in Northern Europe on oilseed rape during 2007. Three treated plots and one control plot (each 100 m2) were established in separate tunnels at each field site and one bee colony (honey bee, Apis mellifera L.) was introduced into each tunnel one day before treatment.
A tank mix of azoxystrobin and cyproconazole was applied once by foliar application at a rate of 250 g azoxystrobin/ha and 100 g cyproconazole/ha to the treated plots. The application was made when the crop was at BBCH growth stage 63. Samples of mature, capped honey were taken at honey maturity for residue analysis. The bee colonies remained in good health throughout the trial, free of visible symptoms of disease.
Samples were analysed using analytical method RAM 305/03, an LC-MS/MS method to determine residues of azoxystrobin and R230310. No residues were found at or above the LOQ in honey from the untreated control plots. Individual sample residues of azoxystrobin residues in the collected honey from the treated plots ranged from < 0.01 mg/kg to 0.01 mg/kg. Residues of R230310 were < 0.01 mg/kg from all treated plots.

Study 4 - Lebrun 2019, 349-2018, VV-906202

Comments of zRMS:	This study has already been evaluated. Please refer to the Azoxystrobin EU renewal (dRAR) for a summary and conclusions for this study. "*A fourth semi-field trial is also available, in which residues of azoxystrobin were determined in nectar following the application of azoxystrobin to oilseed rape at BBCH 60 and BBCH 65 (2 x 250 g a.s./ha). Residues of azoxystrobin in samples of treated nectar ranged from <0.005 mg/kg to 0.046 mg/kg. In accordance with SANTE/11956/2016 rev. 9, residues in nectar can be used as a surrogate for residues in honey.* *Based on the available data, residues of azoxystrobin in honey are not expected to exceed the established MRL.* *The available semi-field trials are considered a 'worst-case' situation because oilseed rape is a crop with a high melliferous capacity (SANTE/11956/2016 rev. 9)."*

Reference:	KCP 8.10.1/04
Report	Magnitude of the residue of azoxystrobin in oilseed rape pollen and nectar Raw Agricultural Commodity after two foliar applications of ALB 121 in Southern Europe - 2018; Lebrun F., 2019; 349-2018; VV-906202
; Guideline(s):	• SANCO 7029/VI/95 rev 5 (22/07/1997) General recommendations for the design, preparation and realization of residue trials • OECD Test Guideline No. 509 (07/09/2009) Guidelines for the Testing of Chemicals - Crop Field Trial • SANCO/3029/99 rev 4 (11/07/2000) 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 • OECD ENV/JM/MONO(2007)17 Guidance Document on Pesticide Residue Analytical Methods
Deviations:	• Samples were not taken within one day of drying of the residue • Number of bees used for sampling is not specified • Insufficient detail provided on the hand sampling approach used
GLP:	Yes
Acceptability:	Yes

Executive Summary

A semi-field study was conducted with one trial in Southern Europe (Spain) on oilseed rape during 2018. One treated plot and one untreated plot (each ≥ 200 m2) were established at the field site with a buffer zone of at least 20 m around each plot. One bee colony (honey bee, Apis mellifera L.) was introduced to each plot; the timing of the introduction was not reported.
Azoxystrobin was applied twice by foliar application at a rate of 250 g azoxystrobin/ha to the treated plot. The control plot was not treated. During initial application the crop was at BBCH 60 and the second application was performed 8 days later when the crop was at BBCH 65.
Samples of nectar and pollen were taken one day before the last application (which was 7 days after the first application) and during main flowering at 4, 7 and 12 days after the last application (DALA) for residue analysis. All samples were maintained frozen (< -18°C) at the testing facility, during shipping to the laboratory, and were frozen for a maximum of 22 days until analysis. Storage stability data are not needed to support the storage conditions and intervals for samples in the current trial as samples were analysed within 30 days of collection.
The bee colonies remained in good health prior to the trial, free of visible symptoms of diseases.
Samples were analysed using a QuEChERS method based on the European Committee for Standardization (CEN): EN 15663:2009. This is an LC-MS/MS method to determine residues of azoxystrobin. Acceptable method validation and concurrent recoveries were reported for nectar at fortification levels of 0.005 mg/kg, 0.050 mg/kg and 0.20 mg/kg and for pollen at fortification levels of 0.005 mg/kg, 0.05 mg/kg and 2.0 mg/kg, thus validating the method. The limit of quantification (LOQ) was 0.005 mg/kg in both matrices.
No residues of azoxystrobin were found at or above the LOQ in pollen or nectar from the untreated control plot. Individual sample residues in the collected pollen from the treated plot ranged from 0.05 mg/kg to 1.2 mg/kg. Individual samples residues in the collected nectar from the treated plot ranged from < 0.005 mg/kg to 0.046 mg/kg.

Study Design and Methods
A semi-field study was conducted with one trial in Southern Europe (Spain) on oilseed rape during 2018. One treated plot and one untreated plot (each ≥ 200 m2) were established at the field site with a buffer zone of at least 20 m around each plot. One bee colony (honey bee, Apis mellifera L.) was introduced to each plot; the timing of the introduction was not reported.
Azoxystrobin was applied twice by foliar application at a nominal rate of 250 g azoxystrobin/ha to the treated plot. The control plot was not treated. During initial application the crop was at BBCH 60 and the second application was performed 8 days later when the crop was at BBCH 65.

Crop information

Trial Location (City, Province or State Country /Year)	Crop/crop group	Variety	Growth stage at application (BBCH code)
349-2018 SP01, Albacete, Castilla La Mancha, Spain, 2018	Oilseed rape (Brassica napus)	NK OCTANS	60, 65

Application and use pattern of end-use product ALB 121 tested at Albacete, Spain in 2018

Method/ Timing	Rate (g ai/ha)	Vol (L/ha)	Spray interval (days)	Total rate (g ai/ha)	Tank mix adjuvants
Foliar spray	259	414	8	514	None
	255	408			None

Climatic conditions

Trial Location (City, Province or State Country /Year)	Study conditions		Long-term average	
	Overall monthly rainfall range (mm)	Overall temperature range (°C)	Overall monthly rainfall range (mm)	Overall temperature range (°C)
349-2018 SP01, Albacete, Castilla La Mancha, Spain, 2018	24 - 38	4.9 - 22.6	18.5 - 30.4	4.6 - 15.9

Samples of nectar and pollen were taken one day before the last application (which was 7 days after the first application) and during main flowering at 4, 7 and 12 days after the last application (DALA) for residue analysis. At each sampling, 4 samples of each commodity were collected, with a minimum sample size of 0.2 g. Two different nectar sample collection approaches were used; either the flowers were collected then the nectar was extracted with a microcentrifuge and/or the foraging bees were collected then killed with dry ice (CO2), and the nectar was collected from the honey stomach (by dissection). For pollen sample collection, foraging bees were collected then killed with dry ice (CO2) and the pollen loads were taken directly from the bees.
All samples were frozen (< -18°C) within 12 hours, maintained frozen at the testing facility, during shipment to the laboratory and were stored frozen at ≤ -18°C until analysis. The maximum storage interval between collection and analysis was 22 days. Storage stability data are not needed to support the storage conditions and intervals for samples in the current trials as samples were analysed within 30 days of collection.

Summary of storage conditions

Matrix (RAC or extract)	Storage temp. (°C)	Actual storage duration (days or months)	Interval of demonstrated storage stability (days or months)
Pollen	≤ -18	22 days	Not required1
Nectar	≤ -18	21 days	Not required1
Extracts	0-9	<1 day	Not required1

1 Not required as samples were analysed within 30 days of collection

Samples were analysed using a QuEChERS method based on the European Committee for Standardization (CEN): EN 15663:2009. This is an LC-MS/MS method to determine residues of azoxystrobin and was validated within the study. Acceptable method validation and concurrent recoveries were reported for nectar at fortification levels of 0.005 mg/kg, 0.050 mg/kg and 0.20 mg/kg and for pollen at fortification levels of 0.005 mg/kg, 0.05 mg/kg and 2.0 mg/kg, thus validating the method. The limit of quantification (LOQ) was 0.005 mg/kg in both matrices.

Results
Acceptable method validations and concurrent recoveries were reported as in the following table.

Fortification and recovery – method validation

Matrix	Fortification level (mg/kg)	Sample size (n)	Recoveries (%)	Mean recovery (%)	RSD (%)
Azoxystrobin					
Primary mass transition m/z = 404 → 372					
Nectar	0.005	5	85, 86, 83, 83, 82	84	2
	0.05	5	89, 89, 91, 92, 88	90	2
	Overall	10	-	87	4
Pollen	0.005	5	113, 85, 76, 89, 69	86	19
	0.05	5	86, 84, 92, 87, 88	87	3
	Overall	10	-	87	13
Secondary mass transition m/z = 404 → 344					
Nectar	0.005	5	83, 85, 84, 83, 87	85	2
	0.05	5	87, 87, 89, 89, 88	88	1
	Overall	10	-	86	3
Pollen	0.005	5	103, 81, 68, 85, 63	80	20
	0.05	5	86, 81, 90, 85, 91	87	5
	Overall	10	-	83	14

Fortification and recovery – concurrent recoveries

Matrix	Fortification level	Sample size	Recoveries (%)	Mean recovery1	RSD1 (%)

	(mg/kg)	(n)		(%)	
Azoxystrobin					
Primary mass transition m/z = 404 → 372					
Nectar	0.005	2	93, 88	90	3
	0.20	1	88		
Pollen	0.005	2	94, 94	90	8
	2.0	1	81		

1 Manually calculated for the purpose of this reporting table.

Details of the trials, the individual applications and the analytical residue results obtained are summarised in the following table.
No residues were found at or above the LOQ in nectar and pollen from the untreated control plots.

Residue trial summary for azoxystrobin in pollen and nectar from honey bees foraging on oilseed rape

Trial No./ Location/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or number and last date	Growth stage at each treatment	Date colony placed in tunnel	Portion analysed	Residues1 (mg/kg)	Sampling occasion (DALA)	Remarks
			g ai/ha	Water (L/ha)	g ai/hL					Azoxystrobin		
349-2018 SP01 / Albacete, Castilla La Mancha, Spain / 2018	Oilseed rape / NK OCTANS	1. 20 Oct 2017 2. Apr-May 2018 3. Jun 2018	259 255	414 408	62.5 62.5	12 Apr 2018 20 Apr 2018	BBCH 60 BBCH 65	n/r	Pollen	1.0, 0.76, 0.89 (0.88) 1.2, 0.86, 1.1 (1.1) 0.55, 0.47, 0.47 (0.50) 0.061, 0.050, 0.060 (0.057)	-1 4 7 12	-
									Nectar	0.045, 0.046, 0.041 (0.044) 0.011, 0.011, 0.011 (0.011) <0.005, <0.005, <0.005 (<0.005) <0.005, <0.005, <0.005 (<0.005)	-1 4 7 12	-

DALA: days after last application
n/r: not recorded
1 Residue values are three sampling replicates. Mean values are calculated for the purpose of this reporting table and presented in brackets

Conclusion
A semi-field study was conducted with one trial in Southern Europe (Spain) on oilseed rape during 2018. One treated plot and one untreated plot (each ≥ 200 m2) were established at the field site with a buffer zone of at least 20 m around each plot. One bee colony (honey bee, Apis mellifera L.) was introduced to each plot; the timing of the introduction was not reported.
Azoxystrobin was applied by foliar spray two times at a nominal rate of 250 g azoxystrobin/ha to the treated plots. The applications were made when the crop was at BBCH growth stage 60 and 65, with an 8-day spray interval. Samples of nectar and pollen were taken one day before the last application (which was 7 days after the first application) and during main flowering at 4, 7 and 12 days after the last application (DALA) for residue analysis. The bee colonies were in good health prior to the trial, free of visible symptoms of disease.
Samples were analysed using a QuEChERS method based on the European Committee for Standardization (CEN): EN 15663:2009. This is a LC-MS/MS method to determine residues of azoxystrobin and was validated within the study. No residues were found at or above the LOQ in pollen or nectar from the untreated control plot. Individual sample residues in the collected pollen from the treated plot ranged from 0.05 mg/kg to 1.2 mg/kg. Individual sample residues in the collected nectar from the treated plot ranged from < 0.005 mg/kg to 0.046 mg/kg.

Study 5 - Appeltauer 2022, S21-01128, VV-931501
In order to further support the assessment of azoxystrobin in honey in accordance with current guideline requirements a new study (Appeltauer A., 2022 (VV-931501)) has been conducted is ongoing. Application was will be performed at a nominal rate of 2 x 250 g ai/ha, at BBCH 61-69 to oilseed rape, in four semi-field trials. Samples of mature honey were will be analysed for azoxystrobin and R230310. The study will also includes an assessment of the stability of azoxystrobin and R230310 in honey.

Comments of zRMS:	This study has already been evaluated in RR, Part B7 for A22773A/ Orondis Evo (06.2023). This study has not been reassessed in the framework of this application. The conclusions of the assessment are presented below: *The study contained five field trials (four were performed successfully) on winter oilseed rape was conducted in northern/southern Europe. Azoxystrobin was applied to winter oilseed rape as A12705B, an SC formulation containing nominally 250 g azoxystrobin per litre. Two applications, (applied at growth stage 62-65 BBCH), separated by a 5-7 day interval were made at a nominal rate of 250 g ai/ha for A1 and A2.* *Treated samples were collected once at maturity (trials -01 and -04) of honey or at the end of flowering (trials -02 and -05) at 2-18 days after the last application (DALA).* *Untreated samples were collected once at maturity (trials -01 and -04) of honey or at the end of flowering (trials -02 and -05) at 2-18 days after the last application (DALA). In trial -03 no samples could be collected. The samples of trials -02 and -05 were dried in the laboratory to reach the requested sugar content of at least 80%. The sugar content of the honey samples was assessed by performing BRIX analysis.* *The ranges of residues of azoxystrobin were <0.01 – 0.02 mg/kg and R230310 were <0.01 mg/kg.* *No residues of azoxystrobin and its metabolite R230310 at or above the limit of quantification of 0.01 mg/kg were found in any of the untreated honey samples.* *Samples were stored frozen for a maximum period of 76 days from sampling to extraction.* *Field samples for residue analysis were analysed for azoxystrobin and its metabolite R230310 in honey using method RAM 305/03 as described in Syngenta Report Number: T011298-06-REG. The analytical method has been validated for beer, wheat flour and various crop matrices and honey.* *Limit of Quantification: 0.01 mg/kg* *The study is acceptable.*

Reference:	KCP 8.10.1/05
Report	Azoxystrobin - Determination of Residues of Azoxystrobin and R230310 (z-isomer) in Honey after Two Applications of A12705B to Winter Oilseed

	rape at 5 Sites in Northern and Southern Europe in 2021; Appeltauer A., 2022; S21-01128; VV-931501
; Guideline(s):	• Guidelines and Criteria for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for the Inclusion of Active Substances in Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 • OECD Guidelines for the Testing of Chemicals – Crop Field Trial, No. 509, OECD, Paris 2009 • Technical Guidelines for Determining the Magnitude of Pesticide Residues in Honey and Setting Maximum Residue Levels in Honey; SANTE/11956/2016, Rev. 9, 14 September 2018 • Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes; SANTE/2020/12830, Rev. 1, 24 February 2021
Deviations:	None
GLP:	Yes
Acceptability:	Yes

Executive Summary

A semi-field study was conducted with four trials in Germany, Austria and Spain on winter oilseed rape in 2021. A fifth residue trial on winter oilseed rape in Romania was not successfully conducted because no honey could be sampled; information for this trial is therefore not summarised. One untreated plot and one treated plot (each 200 m²) were established in separate tunnels at each field site and one bee colony (honey bee, Apis mellifera L.) was introduced into each tunnel one day before treatment.
Azoxystrobin was applied twice by foliar application at a rate of 250 g azoxystrobin/ha to the treated plots, with a 5-7 day application interval. During the first application the crop was at BBCH 62 and during the second application the crop was at BBCH 63-65. The bee colonies were protected from direct spray with plastic foil during application.
Samples of mature honey (4.72-62.35g), with a water content of < 20%, were taken 2-18 days after the last application (DALA), at BBCH 65-69, for residue analysis. Where samples had a water content > 20% at the end of flowering, these were dried at ambient temperature until the water content had sufficiently reduced (3-7days). All samples were maintained frozen (-18°C) at the testing facility, during shipping to the laboratory, and were stored frozen for a maximum of 76 days until analysis. Residues of azoxystrobin and R230310 have been shown to be stable in honey for up to 81 days under these conditions.
The bee colonies remained in good health throughout the trial, free of visible symptoms of diseases.
Samples were analysed using analytical method RAM 305/03, an LC-MS/MS method to determine residues of azoxystrobin and R230310. Acceptable concurrent recoveries were reported for honey at fortification levels of 0.01 mg/kg and 0.10 mg/kg, thus validating the method. The limit of quantification (LOQ) was 0.01 mg/kg per analyte.
No residues of azoxystrobin or R230310 were found at or above the LOQ in honey from the untreated control plot.
Individual sample residues of azoxystrobin in the collected honey from the treated plot ranged from < 0.01mg/kg to 0.02 mg/kg. Residues of R230310 were below the LOQ (0.01 mg/kg) in all samples from treated plots.

Study Design and Methods

A semi-field study was conducted with four trials in Germany, Austria and Spain on winter oilseed rape in 2021. A fifth residue trial on winter oilseed rape in Romania was not successfully conducted because no honey could be sampled; information for this trial is therefore not summarised. One untreated plot and one treated plot (each 200 m²) were established in separate tunnels at each field site and one bee colony (honey bee, Apis mellifera L.) was introduced into each tunnel one day before treatment.

Azoxystrobin was applied twice by foliar application at a rate of 250 g azoxystrobin/ha to the treated plots, with a 5-7 day application interval. During the first application the crop was at BBCH 62 and during the second application the crop was at BBCH 63-65. The bee colonies were protected from direct spray with plastic foil during application.

Crop information

Trial Location (City, Province or State Country/Year)	Crop/crop group	Variety	Growth stage at application (BBCH code)
Heidelsheim, Baden-Württemberg Germany / 2021	Winter oilseed rape (Brassica napus)	LG Architect	Application 1: BBCH 62 Application 2: BBCH 63
Großwilfersdorf, Styria Austria / 2021	Winter oilseed rape (Brassica napus)	PT 271	Application 1: BBCH 62 Application 2: BBCH 63
Almansa, Castilla La Mancha Spain / 2021	Winter oilseed rape (Brassica napus)	Florida	Application 1: BBCH 62 Application 2: BBCH 65
Valdeganga, Castilla La Manche Spain / 2021	Winter oilseed rape (Brassica napus)	Florida	Application 1: BBCH 62 Application 2: BBCH 63-65

Application and use pattern of end-use product A12705B tested at Heidelsheim, Baden-Württemberg in 2021

Application Number	Method/ Timing	Vol L/ha	Rate g ai/ha	Spray interval days	Total rate g ai/ha	Tank mix adjuvants
1	Foliar spray/ BBCH 62	195	243.3	N/A1	490.3	None
2	Foliar spray/ BBCH 63	198	247.0	5		

1 Not applicable as this was the first application to the tunnel

Application and use pattern of end-use product A12705B tested at Großwilfersdorf, Styria in 2021

Application Number	Method/ Timing	Vol mL/ha	Rate g ai/ha	Spray interval days	Total rate g ai/ha	Tank mix adjuvants
1	Foliar spray/ BBCH 62	397	247.9	N/A1	497.5	None
2	Foliar spray/ BBCH 63	399	249.6	6		

1 Not applicable as this was the first application to the tunnel

Application and use pattern of end-use product A12705B tested at Almansa, Castilla La Manche in 2021

Application Number	Method/ Timing	Vol mL/ha	Rate g ai/ha	Spray interval days	Total rate g ai/ha	Tank mix adjuvants
1	Foliar spray/ BBCH 62	302	251.8	N/A1	496.8	None
2	Foliar spray/ BBCH 65	294	245.0	7		

1 Not applicable as this was the first application to the tunnel

Application and use pattern of end-use product A12705B tested at Valdeganga, Castilla La Manche in 2021

Application Number	Method/ Timing	Vol mL/ha	Rate g ai/ha	Spray interval days	Total rate g ai/ha	Tank mix adjuvants
1	Foliar spray/ BBCH 62	307	255.9	N/A1	501.7	None
2	Foliar spray/ BBCH 63-65	295	245.8	6		

1 Not applicable as this was the first application to the tunnel

Climatic conditions

Trial Location (City, Province or State Country/Year)	Study conditions		Long-term average	
	Overall daily rainfall range (mm)	Overall temperature range (°C)	Overall daily/ monthly rainfall range (mm)	Overall temperature range (°C)
Heidelsheim, Baden-Württemberg Germany / 2021	0.0 – 9.4	8.2 – 12.5	Not reported	Not reported
Großwilfersdorf, Styria Austria / 2021	0.0 – 23.3	8.2 – 21.3	Not reported	Not reported
Almansa, Castilla La Mancha Spain / 2021	0.0 – 20.1	8.3 – 15.4	Not reported	Not reported
Valdeganga, Castilla La Manche Spain / 2021	0.0 – 22.1	7.4 – 15.4	Not reported	Not reported

Samples of mature, capped honey (4.72-62.35g) were taken 2-18 days after the last application (DALA), at BBCH 65-69, for residue analysis. All samples were maintained frozen (-18°C) at the testing facility, during shipping to the laboratory, and were stored frozen for a maximum of 76 days until analysis. Residues of azoxystrobin and R230310 have been shown to be stable in honey for up to 81 days under these conditions.
All samples were frozen (-18°C) within 2.5 hours (with the exception of those with a water content of > 20% at sampling, which were dried at ambient temperature (up to 28°C) for up to 7 days prior to freezing), maintained frozen at the testing facility, during shipment to the laboratory, and were stored frozen at -18°C until analysis. The maximum storage interval for samples between collection and analysis was 76 days. Residues of azoxystrobin and R230310 have been shown to be stable in honey for up to 81 days under these conditions.

Summary of storage conditions

Matrix (RAC or extract)	Storage temp. (°C)	Actual storage duration (days)	Interval of demonstrated storage stability1 (days)
Honey	<-18oC	76	81

1 The stability of azoxystrobin and R230310 residues in honey during storage at ≤ -18°C was assessed within this study

Samples were analysed using analytical method RAM 305/03, an LC-MS/MS method to determine residues of azoxystrobin and R230310. Acceptable concurrent recoveries were reported for honey at fortification levels of 0.01 mg/kg and 0.10 mg/kg, thus validating the method. The limit of quantification (LOQ) was 0.01 mg/kg per analyte.
The health of the colonies was assessed before introduction to the tunnels and at the end of the trial, by assessing the strength of the colony (number of frames covered with bees), the presence of a healthy queen (i.e., presence of eggs or presence of queen cells), and visual assessment of the percentage of frames containing pollen, nectar, and brood (eggs, larvae and capped cells).

Results

Acceptable concurrent recoveries were reported as in the table below.

Fortification and recovery

Matrix	Fortification level (mg/kg)	Sample size (n)	Recoveries (%)	Mean recovery (%)	RSD (%)
Azoxystrobin					
Primary mass transition m/z = 404 → 372					
Honey	0.01	5	100, 118, 103, 104, 100	103	5.2
	0.10	5	100, 100, 102, 100, 100		
R230310					

Primary mass transition m/z = 404 → 372					
Honey	0.01	5	100, 102, 101. 103, 100	100	1.5
	0.10	5	99, 100, 100, 99, 99, 100		

Details of the trials, the individual applications and the analytical residue results obtained are summarised in the following table.
No residues were found at or above the LOQ in honey from the untreated control plots.

Residue trial summary for azoxystrobin and R230310 in honey from bees foraging on winter oilseed rape

Trial No./ Location/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or number and last date	Growth stage at each treatment	Date colony placed in tunnel	Portion analysed	Residues (mg/kg)		Sampling occasion	Remarks
			g ai/ha	Water (L/ha)	g ai/hL					Azoxystrobin	R230310		
S21-01128-01/ Germany/ 2021	Winter oilseed rape / LG Architect	1. 24 Aug 2020 2. Apr to May 2021 3. nr	243.3 247.0	195 198	124.8 124.7	22 Apr 2021 27 Apr 2021	BBCH 62 BBCH 63	21 Apr 2021	Honey	0.02	< 0.01	Honey maturity; 2 DALA	-
S21-01128-02/ Austria/ 2021	Winter oilseed rape / PT-271	1. 05 Sep 2020 2. 26 Apr to 24 May 2021 3. nr	247.9 249.6	397 399	62.4 62.6	30 Apr 2021 06 May 2021	BBCH 62 BBCH 63	29 Apr 2021	Honey	< 0.01	< 0.01	Honey maturity; 14 DALA	-
S21-01128-04/ Spain/ 2021	Winter oilseed rape / Florida	1. 17 Oct 2020 2. Apr to May 2021 3. nr	251.8 245.0	302 294	83.4 83.3	11 Apr 2021 18 Apr 2021	BBCH 62 BBCH 65	10 Apr 2021	Honey	< 0.01	< 0.01	Honey maturity; 12 DALA	-
S21-01128-05/ Spain/ 2021	Winter oilseed rape / Florida	1. 11 Sep 2020 2. Mar to Apr 2021 3. nr	255.9 245.8	307 295	83.4 83.3	06 Apr 2021 12 Apr 2021	BBCH 62 BBCH 63-65	05 Apr 2021	Honey	< 0.01	< 0.01	Honey maturity; 18 DALA	-

DALA: days after last application
n/r: not recorded

Conclusion

A semi-field study was conducted with four trials in Germany, Austria and Spain on winter oilseed rape in 2021. A fifth residue trial on winter oilseed rape in Romania was not successfully conducted because no honey could be sampled; information for this trial is therefore not summarised. One untreated plot and one treated plot (each 200 m²) were established in separate tunnels at each field site and one bee colony (honey bee, Apis mellifera L.) was introduced into each tunnel one day before treatment.

Azoxystrobin was applied twice by foliar application at a rate of 250 g azoxystrobin/ha to the treated plots. During the first application the crop was at BBCH 62 and during the second application the crop was at BBCH 63-65. The bee colonies were protected from direct spray with plastic foil during application.

Samples of mature honey (4.72-62.35g), with a water content of < 20%, were taken 2-18 days after the last application (DALA), at BBCH 65-69, for residue analysis. Where samples had a water content > 20% at the end of flowering, these were dried at ambient temperature until the water content had sufficiently reduced (3-7days). The bee colonies remained in good health throughout the trial, free of visible symptoms of disease.

Samples were analysed using analytical method RAM 305/03, an LC-MS/MS method to determine residues of azoxystrobin and R230310. No residues of azoxystrobin or R230310 were found at or above the LOQ in honey from the untreated control plots. Individual sample residues of azoxystrobin in the collected honey from the treated plot ranged from < 0.01 mg/kg to 0.02 mg/kg. Residues of R230310 were below the LOQ (0.01 mg/kg) in all samples from treated plots.

Appendix 3 Pesticide Residue Intake Model (PRIMo)

A 3.1 TMDI calculations

Azoxystrobin:

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Azoxystrobin	
Reg. (EU) 2024/2633	
LOQs (mg/kg) range from:	to:
Toxicological reference values	
ADI (mg/kg bw/day):	0,2
Source of ADI:	EFSA
Year of evaluation:	2010
ARfD (mg/kg bw):	Not necessary
Source of ARfD:	
Year of evaluation:	

Input values

Details - chronic risk assessment

Supplementary results - chronic risk assessment

Details - acute risk assessment/children

Details - acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)	Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
	82%	NL toddler	164,42	17%	Oranges	15%	Potatoes	13%	Sugar beet roots		
	69%	DE child	137,73	30%	Oranges	9%	Potatoes	3%	Mandarins		
	68%	NL child	135,17	21%	Sugar beet roots	12%	Potatoes	11%	Oranges		
	56%	FR child 3 15 yr	112,53	26%	Oranges	9%	Sugar beet roots	5%	Potatoes		
	49%	GEMS/Food G06	98,99	7%	Oranges	7%	Potatoes	5%	Tomatoes		
	48%	UK toddler	95,87	15%	Oranges	12%	Potatoes	8%	Sugar beet roots		
	47%	IE adult	93,60	8%	Potatoes	8%	Oranges	5%	Grapefruits		
	46%	GEMS/Food G07	91,17	13%	Potatoes	10%	Oranges	2%	Wine grapes		
	44%	GEMS/Food G10	88,63	10%	Potatoes	8%	Oranges	3%	Rice		
	44%	FR toddler 2 3 yr	88,04	11%	Oranges	7%	Sugar beet roots	7%	Potatoes		
	44%	GEMS/Food G11	87,09	14%	Potatoes	5%	Oranges	3%	Lemons		
	43%	DE women 14-50 yr	86,85	14%	Oranges	11%	Sugar beet roots	4%	Potatoes		
	42%	SE general	84,96	15%	Potatoes	6%	Oranges	3%	Mandarins		
	41%	GEMS/Food G08	81,64	14%	Potatoes	3%	Oranges	3%	Onions		
	40%	DE general	79,25	12%	Oranges	11%	Sugar beet roots	4%	Potatoes		
	39%	GEMS/Food G15	78,01	12%	Potatoes	5%	Oranges	3%	Onions		
	39%	PT general	77,09	19%	Potatoes	5%	Oranges	4%	Wine grapes		
	38%	RO general	76,13	13%	Potatoes	4%	Onions	4%	Head cabbages		
	36%	NL general	72,22	9%	Potatoes	8%	Oranges	7%	Sugar beet roots		
	36%	ES child	72,21	16%	Oranges	6%	Potatoes	2%	Lettuces		
	36%	UK infant	71,27	11%	Potatoes	10%	Oranges	4%	Sugar beet roots		
	33%	FI 3 yr	66,89	17%	Potatoes	3%	Mandarins	2%	Onions		
	27%	FI 6 yr	53,74	14%	Potatoes	2%	Mandarins	1%	Onions		
	26%	ES adult	51,21	10%	Oranges	3%	Potatoes	3%	Lettuces		
	23%	FR infant	46,40	7%	Potatoes	3%	Sugar beet roots	2%	Spinaches		
	23%	UK vegetarian	46,20	6%	Oranges	5%	Potatoes	1%	Sugar beet roots		
	23%	DK child	45,03	9%	Potatoes	1%	Rye	1%	Oranges		
	21%	IT toddler	42,92	4%	Oranges	3%	Potatoes	2%	Tomatoes		
	21%	FR adult	42,41	4%	Oranges	3%	Wine grapes	3%	Potatoes		
	20%	PL general	39,50	12%	Potatoes	2%	Onions	1%	Tomatoes		
	19%	IT adult	38,02	3%	Oranges	2%	Potatoes	2%	Lettuces		
	19%	UK adult	37,99	5%	Potatoes	4%	Oranges	2%	Wine grapes		
	16%	LT adult	32,50	11%	Potatoes	1,0%	Head cabbages	0,9%	Tomatoes		
	14%	FI adult	28,97	4%	Potatoes	3%	Oranges	1%	Mandarins		
	13%	DK adult	26,95	4%	Potatoes	1%	Wine grapes	1%	Oranges		
	6%	IE child	11,31	2%	Potatoes	0,7%	Rice	0,6%	Oranges		

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Azoxystrobin
Reg. (EU) 2024/2633
Agency it is unlikely to present a public health concern.

Prtohioconazole-dethio:

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Prothioconazole-desthio

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	0.01	ARfD (mg/kg bw):	0.01
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2007	Year of evaluation:	2007

Input values

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

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI: ---

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

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
43%	NL toddler	4.27	14%	Maize/corn	8%	Wheat	6%	Milk: Cattle		
33%	GEMS/Food G11	3.34	15%	Soyabeans	7%	Wheat	3%	Barley		
33%	GEMS/Food G06	3.32	14%	Wheat	5%	Soyabeans	3%	Maize/corn		
33%	GEMS/Food G10	3.29	13%	Soyabeans	8%	Wheat	2%	Barley		
31%	GEMS/Food G15	3.08	9%	Wheat	7%	Soyabeans	3%	Barley		
30%	GEMS/Food G08	3.03	8%	Wheat	8%	Soyabeans	4%	Barley		
30%	GEMS/Food G07	2.98	8%	Wheat	7%	Soyabeans	2%	Barley		
23%	FR child 3 15 yr	2.28	9%	Wheat	4%	Lentils	2%	Milk: Cattle		
22%	NL child	2.21	8%	Wheat	3%	Sugar beet roots	2%	Milk: Cattle		
21%	ES child	2.14	9%	Wheat	5%	Lentils	2%	Peas		
21%	IE adult	2.13	6%	Peas	5%	Wheat	3%	Lentils		
20%	RO general	2.05	10%	Wheat	3%	Sunflower seeds	2%	Maize/corn		
18%	DE child	1.76	8%	Wheat	2%	Milk: Cattle	1%	Apples		
17%	FR toddler 2 3 yr	1.73	6%	Wheat	3%	Milk: Cattle	2%	Lentils		
17%	UK infant	1.73	5%	Wheat	4%	Milk: Cattle	2%	Maize/corn		
17%	DK child	1.72	9%	Wheat	3%	Rye	1%	Carrots		
16%	IT toddler	1.58	13%	Wheat	0.7%	Lentils	0.2%	Peas		
16%	UK toddler	1.57	8%	Wheat	2%	Milk: Cattle	1.0%	Sugar beet roots		
15%	PT general	1.45	8%	Wheat	1%	Soyabeans	1%	Sunflower seeds		
13%	ES adult	1.31	5%	Wheat	2%	Lentils	2%	Barley		
12%	SE general	1.23	6%	Wheat	1%	Milk: Cattle	0.8%	Carrots		
12%	DE general	1.20	4%	Wheat	2%	Barley	1%	Sugar beet roots		
12%	NL general	1.20	4%	Wheat	1%	Barley	0.9%	Sugar beet roots		
11%	DE women 14-50 yr	1.13	4%	Wheat	1%	Sugar beet roots	1%	Milk: Cattle		
10%	IT adult	1.02	8%	Wheat	0.4%	Lentils	0.2%	Peas		
10%	FR adult	1.02	4%	Wheat	1%	Lentils	0.4%	Milk: Cattle		
8%	UK vegetarian	0.80	4%	Wheat	0.8%	Lentils	0.6%	Peas		
8%	FI 3 yr	0.76	2%	Wheat	0.9%	Potatoes	0.9%	Peas		
7%	FR infant	0.75	2%	Milk: Cattle	2%	Wheat	1%	Carrots		
7%	FI 6 yr	0.68	2%	Wheat	1%	Peas	0.8%	Potatoes		
6%	UK adult	0.62	3%	Wheat	0.3%	Milk: Cattle	0.3%	Potatoes		
6%	FI adult	0.61	3%	Coffee beans	0.7%	Peas	0.6%	Wheat		
6%	LT adult	0.56	2%	Wheat	0.6%	Potatoes	0.5%	Rye		
5%	DK adult	0.51	2%	Wheat	0.5%	Milk: Cattle	0.5%	Carrots		
3%	IE child	0.34	2%	Wheat	0.4%	Milk: Cattle	0.2%	Carrots		
3%	PL general	0.28	0.7%	Potatoes	0.4%	Peas	0.3%	Head cabbages		

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Prothioconazole-desthio is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

EFSA PRIMo revision 3.1; 2019/03/19

Prothioconazole-desthio

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	0,01	ARfD (mg/kg bw):	0,01
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2007	Year of evaluation:	2007

Input values

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

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

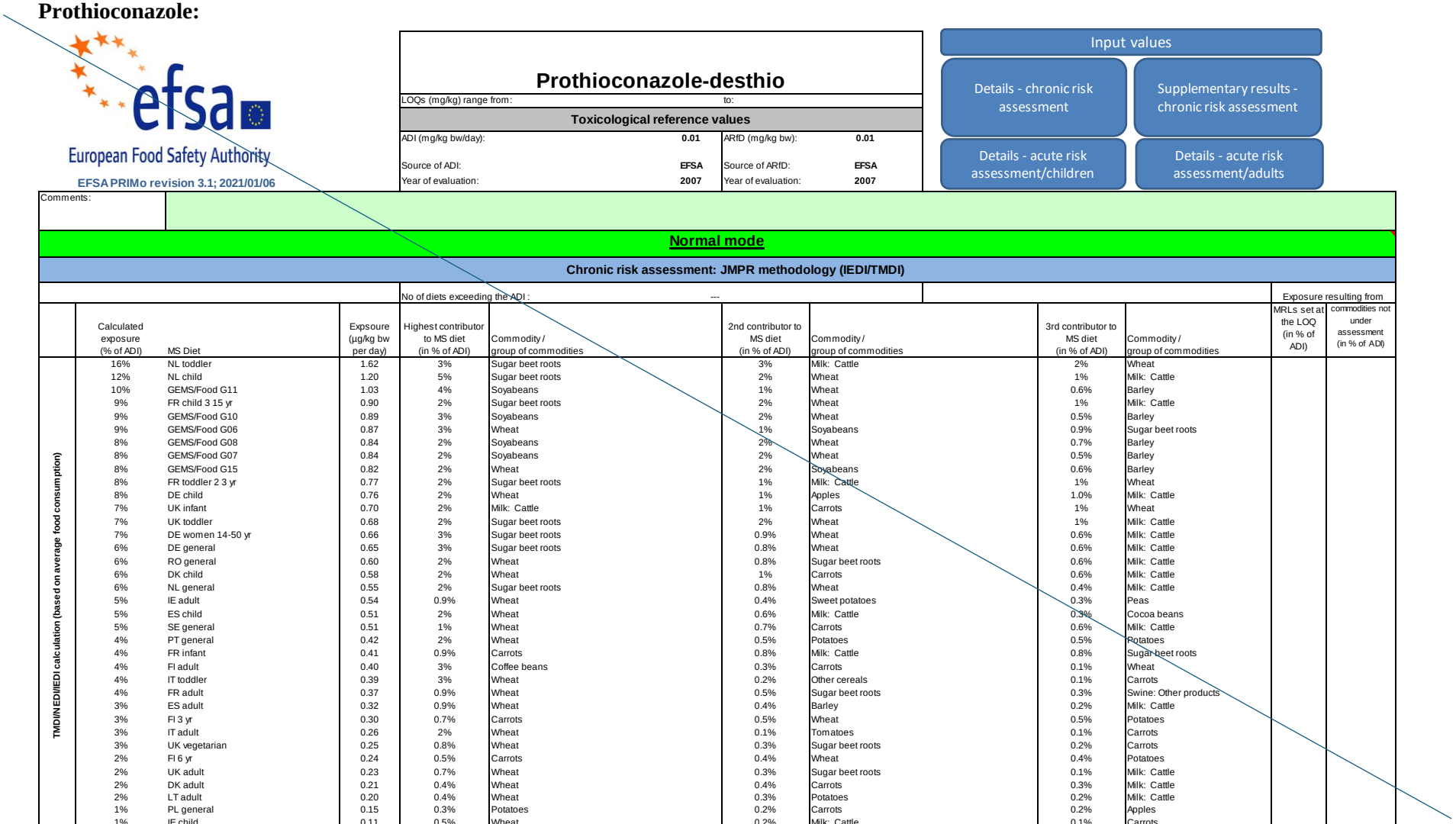
TMDI/NEDI/IEDI calculation (based on average food consumption)	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
	42%	NL toddler	4,22	8%	Wheat	7%	Maize/corn	6%	Milk: Cattle		
	36%	GEMS/Food G11	3,63	15%	Soyabeans	7%	Wheat	3%	Barley		
	35%	GEMS/Food G10	3,52	13%	Soyabeans	8%	Wheat	2%	Barley		
	34%	GEMS/Food G15	3,43	9%	Wheat	7%	Soyabeans	3%	Barley		
	34%	GEMS/Food G07	3,39	8%	Wheat	7%	Soyabeans	2%	Barley		
	34%	GEMS/Food G06	3,38	14%	Wheat	5%	Soyabeans	2%	Peas		
	34%	GEMS/Food G08	3,36	8%	Wheat	8%	Soyabeans	4%	Barley		
	25%	IE adult	2,53	6%	Peas	5%	Wheat	3%	Lentils		
	25%	NL child	2,46	8%	Wheat	3%	Sugar beet roots	2%	Milk: Cattle		
	25%	FR child 3 15 yr	2,46	9%	Wheat	4%	Lentils	2%	Milk: Cattle		
	23%	DK child	2,34	9%	Wheat	6%	Rye	4%	Carrots		
	22%	ES child	2,22	9%	Wheat	5%	Lentils	2%	Peas		
	22%	RO general	2,20	10%	Wheat	3%	Sunflower seeds	3%	Head cabbages		
	21%	UK infant	2,09	5%	Wheat	4%	Milk: Cattle	4%	Carrots		
	20%	DE child	2,04	8%	Wheat	3%	Carrots	2%	Milk: Cattle		
	20%	FR toddler 2 3 yr	1,97	6%	Wheat	3%	Milk: Cattle	2%	Lentils		
	18%	UK toddler	1,75	8%	Wheat	2%	Milk: Cattle	1%	Carrots		
	16%	IT toddler	1,64	13%	Wheat	0,7%	Lentils	0,5%	Carrots		
	16%	PT general	1,56	8%	Wheat	2%	Carrots	1%	Soyabeans		
	16%	SE general	1,55	6%	Wheat	2%	Carrots	1%	Milk: Cattle		
	14%	NL general	1,37	4%	Wheat	1%	Barley	0,9%	Sugar beet roots		
	14%	ES adult	1,37	5%	Wheat	2%	Lentils	2%	Barley		
	13%	DE general	1,34	4%	Wheat	2%	Barley	1%	Sugar beet roots		
	13%	DE women 14-50 yr	1,26	4%	Wheat	1%	Sugar beet roots	1%	Milk: Cattle		
	11%	FR adult	1,12	4%	Wheat	1%	Lentils	0,5%	Carrots		
	11%	IT adult	1,07	8%	Wheat	0,4%	Carrots	0,4%	Lentils		
	10%	FI 3 yr	1,05	2%	Wheat	2%	Carrots	0,9%	Potatoes		
	10%	FR infant	1,02	3%	Carrots	2%	Milk: Cattle	2%	Wheat		
	9%	FI 6 yr	0,90	2%	Wheat	2%	Carrots	1%	Peas		
	9%	UK vegetarian	0,89	4%	Wheat	0,8%	Lentils	0,6%	Carrots		
	7%	FI adult	0,75	3%	Coffee beans	0,9%	Carrots	0,7%	Peas		
	7%	LT adult	0,73	2%	Wheat	1%	Rye	0,7%	Head cabbages		
	7%	UK adult	0,70	3%	Wheat	0,5%	Carrots	0,3%	Milk: Cattle		
	7%	DK adult	0,67	2%	Wheat	1%	Carrots	0,5%	Milk: Cattle		
	4%	PL general	0,44	0,8%	Carrots	0,7%	Potatoes	0,7%	Head cabbages		
	4%	IE child	0,39	2%	Wheat	0,5%	Carrots	0,4%	Milk: Cattle		

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

TMDI calculations were not undertaken for ~~azoxystrobin and~~ the triazole derivative metabolites (TDMs).

A 3.2 IEDI calculations

Prothioconazole:



European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Prothioconazole-desthio

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	0.01	ARfD (mg/kg bw):	0.01
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2007	Year of evaluation:	2007

Input values

Details - chronic risk assessment

Supplementary results - chronic risk assessment

Details - acute risk assessment/children

Details - acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

	Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	16%	NL toddler	1.62	3%	Sugar beet roots	3%	Milk: Cattle	2%	Wheat		
	12%	NL child	1.20	5%	Sugar beet roots	2%	Wheat	1%	Milk: Cattle		
	10%	GEMS/Food G11	1.03	4%	Soyabeans	1%	Wheat	0.6%	Barley		
	9%	FR child 3 15 yr	0.90	2%	Sugar beet roots	2%	Wheat	1%	Milk: Cattle		
	9%	GEMS/Food G10	0.89	3%	Soyabeans	2%	Wheat	0.5%	Barley		
	9%	GEMS/Food G06	0.87	3%	Wheat	1%	Soyabeans	0.9%	Sugar beet roots		
	8%	GEMS/Food G08	0.84	2%	Soyabeans	2%	Wheat	0.7%	Barley		
	8%	GEMS/Food G07	0.84	2%	Soyabeans	2%	Wheat	0.5%	Barley		
	8%	GEMS/Food G15	0.82	2%	Wheat	2%	Soyabeans	0.6%	Barley		
	8%	FR toddler 2 3 yr	0.77	2%	Sugar beet roots	1%	Milk: Cattle	1%	Wheat		
	8%	DE child	0.76	2%	Wheat	1%	Apples	1.0%	Milk: Cattle		
	7%	UK infant	0.70	2%	Milk: Cattle	1%	Carrots	1%	Wheat		
	7%	UK toddler	0.68	2%	Sugar beet roots	2%	Wheat	1%	Milk: Cattle		
	7%	DE women 14-50 yr	0.66	3%	Sugar beet roots	0.9%	Wheat	0.6%	Milk: Cattle		
	6%	DE general	0.65	3%	Sugar beet roots	0.8%	Wheat	0.6%	Milk: Cattle		
	6%	RO general	0.60	2%	Wheat	0.8%	Sugar beet roots	0.6%	Milk: Cattle		
	6%	DK child	0.58	2%	Wheat	1%	Carrots	0.6%	Milk: Cattle		
	6%	NL general	0.55	2%	Sugar beet roots	0.8%	Wheat	0.4%	Milk: Cattle		
	5%	IE adult	0.54	0.9%	Wheat	0.4%	Sweet potatoes	0.3%	Peas		
	5%	ES child	0.51	2%	Wheat	0.6%	Milk: Cattle	0.3%	Cocoa beans		
	5%	SE general	0.51	1%	Wheat	0.7%	Carrots	0.6%	Milk: Cattle		
	4%	PT general	0.42	2%	Wheat	0.5%	Potatoes	0.5%	Potatoes		
	4%	FR infant	0.41	0.9%	Carrots	0.8%	Milk: Cattle	0.8%	Sugar beet roots		
	4%	FI adult	0.40	3%	Coffee beans	0.3%	Carrots	0.1%	Wheat		
	4%	IT toddler	0.39	3%	Wheat	0.2%	Other cereals	0.1%	Carrots		
	4%	FR adult	0.37	0.9%	Wheat	0.5%	Sugar beet roots	0.3%	Swine: Other products		
	3%	ES adult	0.32	0.9%	Wheat	0.4%	Barley	0.2%	Milk: Cattle		
	3%	FI 3 yr	0.30	0.7%	Carrots	0.5%	Wheat	0.5%	Potatoes		
	3%	IT adult	0.26	2%	Wheat	0.1%	Tomatoes	0.1%	Carrots		
	3%	UK vegetarian	0.25	0.8%	Wheat	0.3%	Sugar beet roots	0.2%	Carrots		
	2%	FI 6 yr	0.24	0.5%	Carrots	0.4%	Wheat	0.4%	Potatoes		
	2%	UK adult	0.23	0.7%	Wheat	0.3%	Sugar beet roots	0.1%	Milk: Cattle		
	2%	DK adult	0.21	0.4%	Wheat	0.4%	Carrots	0.3%	Milk: Cattle		
	2%	LT adult	0.20	0.4%	Wheat	0.3%	Potatoes	0.2%	Milk: Cattle		
	1%	PL general	0.15	0.3%	Potatoes	0.2%	Carrots	0.2%	Apples		
	1%	IE child	0.11	0.5%	Wheat	0.2%	Milk: Cattle	0.1%	Carrots		

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Prothioconazole-desthio is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

Azoxystrobin:

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Azoxystrobin

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	**0.2**	ARfD (mg/kg bw):	**not necessary**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2010**	Year of evaluation:	**2010**

Input values

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

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

	Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	11%	DE child	22.59	10%	Oranges	0.4%	Spinaches	0.2%	Table grapes		
	9%	FR child 3 15 yr	18.65	8%	Oranges	0.2%	Other lettuce and other salad plants	0.2%	Spinaches		
	9%	NL toddler	17.08	5%	Oranges	1%	Spinaches	0.5%	Escaroles/broad-leaved endives		
	7%	ES child	13.63	5%	Oranges	0.8%	Lettuces	0.2%	Wheat		
	6%	DE women 14-50 yr	11.01	5%	Oranges	0.2%	Lettuces	0.1%	Wine grapes		
	5%	UK toddler	10.98	5%	Oranges	0.2%	Wheat	0.1%	Rice		
	5%	NL child	10.30	3%	Oranges	0.5%	Spinaches	0.2%	Escaroles/broad-leaved endives		
	5%	GEMS/Food G07	9.90	3%	Oranges	0.5%	Lettuces	0.2%	Wine grapes		
	5%	ES adult	9.76	3%	Oranges	1%	Lettuces	0.2%	Chards/beet leaves		
	5%	GEMS/Food G10	9.59	3%	Oranges	0.6%	Lettuces	0.3%	Rice		
	5%	DE general	9.23	4%	Oranges	0.2%	Lettuces	0.1%	Wine grapes		
	5%	FR toddler 2 3 yr	9.04	3%	Oranges	0.3%	Spinaches	0.2%	Rice		
	4%	GEMS/Food G06	8.62	2%	Oranges	0.4%	Rice	0.3%	Wheat		
	4%	IE adult	8.40	2%	Oranges	0.2%	Spinaches	0.2%	Wine grapes		
	4%	SE general	7.35	2%	Oranges	0.8%	Lettuces	0.1%	Spinaches		
	4%	UK infant	7.31	3%	Oranges	0.2%	Rice	0.1%	Wheat		
	4%	NL general	7.27	2%	Oranges	0.3%	Spinaches	0.2%	Escaroles/broad-leaved endives		
	3%	GEMS/Food G11	6.98	2%	Oranges	0.3%	Celeries	0.2%	Spinaches		
	3%	GEMS/Food G15	5.97	2%	Oranges	0.2%	Lettuces	0.2%	Sweet peppers/bell peppers		
	3%	UK vegetarian	5.86	2%	Oranges	0.3%	Lettuces	0.1%	Wine grapes		
	3%	IT adult	5.83	0.9%	Oranges	0.7%	Lettuces	0.3%	Other lettuce and other salad plants		
	3%	IT toddler	5.79	1%	Oranges	0.6%	Lettuces	0.3%	Wheat		
	3%	GEMS/Food G08	5.51	1%	Oranges	0.4%	Lettuces	0.2%	Wheat		
	3%	PT general	5.48	1%	Oranges	0.4%	Wine grapes	0.2%	Lettuces		
	3%	FR adult	5.12	1%	Oranges	0.3%	Wine grapes	0.3%	Other lettuce and other salad plants		
	2%	UK adult	4.14	1%	Oranges	0.2%	Lettuces	0.2%	Wine grapes		
	2%	RO general	3.57	0.7%	Oranges	0.3%	Wine grapes	0.2%	Head cabbages		
	2%	DK child	3.34	0.4%	Oranges	0.3%	Lettuces	0.2%	Rye		
	2%	FI adult	3.20	1.0%	Oranges	0.3%	Lettuces	0.0%	Wine grapes		
	2%	FR infant	3.10	0.6%	Oranges	0.5%	Spinaches	0.1%	Chards/beet leaves		
	1%	FI 3 yr	2.67	0.3%	Oranges	0.1%	Rice	0.1%	Spinaches		
	1%	FI 6 yr	2.52	0.4%	Oranges	0.2%	Lettuces	0.1%	Rice		
	1.0%	DK adult	1.97	0.3%	Oranges	0.2%	Lettuces	0.1%	Wine grapes		
	0.6%	LT adult	1.25	0.2%	Oranges	0.1%	Lettuces	0.1%	Head cabbages		
	0.4%	IE child	0.81	0.2%	Oranges	0.1%	Rice	0.0%	Wheat		
	0.3%	PL general	0.64	0.1%	Head cabbages	0.0%	Table grapes	0.0%	Oranges		

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Azoxystrobin is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

1,2,4-Triazole

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

T

LOQs (mg/kg) range from: to:

Toxicological reference values

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

Input values

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

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	88%	NL toddler	20.23	78%	Milk: Cattle	2%	Maize/corn	1%	Bovine: Muscle/meat		1%
	55%	UK infant	12.62	50%	Milk: Cattle	1%	Bovine: Muscle/meat	0.6%	Wheat		0.6%
	44%	FR toddler 2 3 yr	10.08	38%	Milk: Cattle	1%	Bovine: Muscle/meat	0.7%	Wheat		0.7%
	39%	NL child	9.02	32%	Milk: Cattle	2%	Sugar beet roots	1%	Bovine: Muscle/meat		1%
	37%	FR child 3 15 yr	8.47	30%	Milk: Cattle	2%	Bovine: Muscle/meat	1.0%	Wheat		1%
	32%	UK toddler	7.32	27%	Milk: Cattle	2%	Bovine: Muscle/meat	0.9%	Wheat		0.9%
	31%	DE child	7.05	26%	Milk: Cattle	0.9%	Wheat	0.9%	Oranges		1%
	24%	FR infant	5.46	22%	Milk: Cattle	0.4%	Bovine: Muscle/meat	0.3%	Sugar beet roots		0.2%
	24%	SE general	5.44	16%	Milk: Cattle	5%	Bovine: Muscle/meat	0.7%	Wheat		0.8%
	23%	DK child	5.25	16%	Milk: Cattle	2%	Bovine: Muscle/meat	1%	Swine: Muscle/meat		2%
	22%	ES child	5.03	16%	Milk: Cattle	2%	Bovine: Muscle/meat	1.0%	Wheat		1.0%
	20%	DE women 14-50 yr	4.65	16%	Milk: Cattle	1.0%	Sugar beet roots	0.5%	Swine: Muscle/meat		0.6%
	20%	DE general	4.63	16%	Milk: Cattle	0.9%	Sugar beet roots	0.6%	Swine: Muscle/meat		0.6%
	19%	RO general	4.43	15%	Milk: Cattle	1%	Wheat	0.7%	Swine: Muscle/meat		1%
	16%	GEMS/Food G11	3.62	10%	Milk: Cattle	0.8%	Bovine: Muscle/meat	0.8%	Soyabeans		1.0%
	15%	NL general	3.44	11%	Milk: Cattle	0.9%	Bovine: Muscle/meat	0.6%	Sugar beet roots		0.6%
	15%	GEMS/Food G15	3.40	9%	Milk: Cattle	1.0%	Wheat	0.8%	Swine: Muscle/meat		1%
	14%	GEMS/Food G07	3.33	8%	Milk: Cattle	1%	Bovine: Muscle/meat	0.9%	Wheat		1%
	13%	GEMS/Food G10	2.99	7%	Milk: Cattle	1%	Bovine: Muscle/meat	0.9%	Wheat		1%
	13%	GEMS/Food G08	2.97	7%	Milk: Cattle	1%	Swine: Muscle/meat	0.9%	Wheat		1%
	10%	ES adult	2.24	6%	Milk: Cattle	0.9%	Bovine: Muscle/meat	0.5%	Wheat		0.6%
	10%	IE adult	2.24	6%	Milk: Cattle	0.5%	Wheat	0.5%	Bovine: Muscle/meat		0.5%
	9%	DK adult	2.12	7%	Milk: Cattle	0.6%	Bovine: Muscle/meat	0.5%	Swine: Muscle/meat		0.4%
	9%	GEMS/Food G06	2.10	3%	Milk: Cattle	2%	Wheat	0.4%	Sugar canes		2%
	9%	FR adult	2.01	6%	Milk: Cattle	0.7%	Bovine: Muscle/meat	0.5%	Wheat		0.5%
	7%	LT adult	1.66	5%	Milk: Cattle	0.5%	Swine: Muscle/meat	0.3%	Bovine: Muscle/meat		0.5%
	6%	UK adult	1.37	4%	Milk: Cattle	0.8%	Bovine: Muscle/meat	0.4%	Wheat		0.4%
	6%	UK vegetarian	1.31	4%	Milk: Cattle	0.4%	Wheat	0.2%	Oranges		0.5%
	5%	IE child	1.25	5%	Milk: Cattle	0.3%	Wheat	0.1%	Swine: Muscle/meat		0.3%
	2%	IT toddler	0.56	1%	Wheat	0.3%	Other cereals	0.1%	Bananas		1%
	2%	PT general	0.52	0.9%	Wheat	0.2%	Potatoes	0.2%	Rice		0.9%
	2%	FI 3 yr	0.38	0.3%	Bananas	0.3%	Wheat	0.2%	Potatoes		0.4%
	2%	IT adult	0.37	0.9%	Wheat	0.2%	Other cereals	0.1%	Oranges		0.9%
	1%	FI 6 yr	0.29	0.2%	Wheat	0.2%	Potatoes	0.2%	Bananas		0.4%
	0.7%	FI adult	0.17	0.2%	Rye	0.1%	Oranges	0.1%	Wheat		0.2%
	0.5%	PL general	0.13	0.1%	Potatoes	0.1%	Apples	0.1%	Head cabbages		

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of T is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

Triazole alanine

EFSA PRIMo revision 3.1; 2021/01/06

TA

LOQs (mg/kg) range from: to:

Toxicological reference values

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

Input values

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

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
6%	NL toddler	18.22	1%	Maize/corn	0.8%	Wheat	0.8%	Milk: Cattle		1%
4%	GEMS/Food G06	12.64	1%	Wheat	0.4%	Soyabeans	0.3%	Rice		2%
4%	GEMS/Food G10	12.27	1%	Soyabeans	0.8%	Wheat	0.3%	Rice		1%
4%	GEMS/Food G08	11.31	0.8%	Wheat	0.7%	Soyabeans	0.3%	Olives for oil production		1%
4%	GEMS/Food G11	11.31	1%	Soyabeans	0.7%	Wheat	0.2%	Potatoes		0.9%
4%	GEMS/Food G07	11.00	0.9%	Wheat	0.6%	Soyabeans	0.2%	Potatoes		1%
4%	GEMS/Food G15	10.59	0.9%	Wheat	0.6%	Soyabeans	0.2%	Potatoes		1%
3%	NL child	10.13	0.9%	Wheat	0.3%	Milk: Cattle	0.3%	Oil palm fruits		1%
3%	DK child	10.10	1%	Rye	0.9%	Wheat	0.2%	Bovine: Muscle/meat		2%
3%	FR child 3 15 yr	9.03	1.0%	Wheat	0.4%	Oranges	0.3%	Milk: Cattle		1.0%
3%	DE child	8.96	0.9%	Wheat	0.4%	Oranges	0.3%	Milk: Cattle		1%
3%	RO general	8.01	1%	Wheat	0.2%	Sunflower seeds	0.2%	Potatoes		1%
3%	ES child	7.74	0.9%	Wheat	0.3%	Olives for oil production	0.2%	Oranges		0.9%
2%	SE general	7.38	0.7%	Bovine: Muscle/meat	0.7%	Wheat	0.3%	Potatoes		0.7%
2%	UK infant	7.13	0.5%	Wheat	0.5%	Milk: Cattle	0.2%	Maize/corn		0.5%
2%	FR toddler 2 3 yr	7.06	0.6%	Wheat	0.4%	Milk: Cattle	0.2%	Bovine: Muscle/meat		0.6%
2%	IE adult	6.81	0.5%	Wheat	0.2%	Sweet potatoes	0.1%	Potatoes		0.5%
2%	UK toddler	6.75	0.8%	Wheat	0.3%	Milk: Cattle	0.2%	Potatoes		0.8%
2%	IT toddler	6.53	1%	Wheat	0.3%	Other cereals	0.1%	Tomatoes		1%
2%	PT general	6.37	0.8%	Wheat	0.3%	Potatoes	0.2%	Rice		0.8%
2%	NL general	5.49	0.4%	Wheat	0.2%	Oil palm fruits	0.1%	Potatoes		0.6%
2%	DE women 14-50 yr	5.01	0.4%	Wheat	0.2%	Oranges	0.2%	Milk: Cattle		0.6%
2%	DE general	4.99	0.4%	Wheat	0.2%	Oranges	0.2%	Milk: Cattle		0.6%
2%	ES adult	4.71	0.5%	Wheat	0.1%	Olives for oil production	0.1%	Oranges		0.6%
1%	IT adult	4.30	0.9%	Wheat	0.1%	Other cereals	0.1%	Tomatoes		0.9%
1%	FI 3 yr	4.12	0.3%	Potatoes	0.2%	Wheat	0.1%	Rye		0.4%
1%	FR adult	3.67	0.5%	Wheat	0.1%	Bovine: Muscle/meat	0.1%	Oranges		0.5%
1%	LT adult	3.38	0.2%	Rye	0.2%	Wheat	0.2%	Potatoes		0.5%
1%	FI 6 yr	3.26	0.2%	Potatoes	0.2%	Wheat	0.1%	Rye		0.4%
1.0%	UK vegetarian	2.97	0.4%	Wheat	0.1%	Oranges	0.1%	Potatoes		0.4%
1.0%	FR infant	2.86	0.2%	Milk: Cattle	0.2%	Wheat	0.1%	Potatoes		0.2%
0.9%	UK adult	2.77	0.3%	Wheat	0.1%	Bovine: Muscle/meat	0.1%	Potatoes		0.4%
0.9%	DK adult	2.74	0.2%	Wheat	0.1%	Rye	0.1%	Bovine: Muscle/meat		0.3%
0.6%	FI adult	1.80	0.1%	Rye	0.1%	Potatoes	0.1%	Wheat		0.2%
0.5%	IE child	1.45	0.2%	Wheat	0.1%	Rice	0.0%	Milk: Cattle		0.2%
0.5%	PL general	1.39	0.2%	Potatoes	0.1%	Tomatoes	0.0%	Apples		

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of TA is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

Triazole acetic acid

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

TAA

LOQs (mg/kg) range from: to:

Toxicological reference values

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

Input values

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

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
1%	NL toddler	14.21	0.6%	Maize/corn	0.3%	Wheat	0.2%	Milk: Cattle		0.4%
0.9%	DK child	9.35	0.4%	Rye	0.3%	Wheat	0.1%	Milk: Cattle		0.8%
0.9%	GEMS/Food G06	9.03	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%
0.7%	GEMS/Food G10	6.52	0.3%	Wheat	0.1%	Rice	0.1%	Maize/corn		0.4%
0.6%	DE child	6.35	0.3%	Wheat	0.1%	Milk: Cattle	0.1%	Rye		0.4%
0.6%	GEMS/Food G15	6.32	0.4%	Wheat	0.1%	Barley	0.1%	Maize/corn		0.4%
0.6%	GEMS/Food G08	6.26	0.3%	Wheat	0.1%	Barley	0.0%	Rye		0.4%
0.6%	NL child	6.21	0.3%	Wheat	0.1%	Milk: Cattle	0.0%	Sugar beet roots		0.3%
0.6%	FR child 3 15 yr	6.21	0.4%	Wheat	0.1%	Milk: Cattle	0.0%	Rice		0.4%
0.6%	RO general	5.99	0.4%	Wheat	0.1%	Maize/corn	0.0%	Milk: Cattle		0.4%
0.6%	GEMS/Food G07	5.75	0.3%	Wheat	0.0%	Barley	0.0%	Rice		0.4%
0.6%	UK infant	5.64	0.2%	Wheat	0.2%	Milk: Cattle	0.1%	Maize/corn		0.2%
0.5%	GEMS/Food G11	5.29	0.3%	Wheat	0.1%	Barley	0.0%	Soyabeans		0.3%
0.5%	ES child	5.24	0.4%	Wheat	0.0%	Milk: Cattle	0.0%	Rice		0.4%
0.5%	UK toddler	5.09	0.3%	Wheat	0.1%	Milk: Cattle	0.0%	Rice		0.3%
0.5%	FR toddler 2 3 yr	4.91	0.2%	Wheat	0.1%	Milk: Cattle	0.0%	Rice		0.2%
0.5%	PT general	4.69	0.3%	Wheat	0.1%	Rice	0.0%	Maize/corn		0.3%
0.4%	IT adult	4.15	0.3%	Wheat	0.1%	Other cereals	0.0%	Rice		0.3%
0.4%	SE general	4.12	0.3%	Wheat	0.0%	Milk: Cattle	0.0%	Rice		0.3%
0.4%	DE general	3.61	0.1%	Wheat	0.0%	Milk: Cattle	0.0%	Rye		0.2%
0.4%	DE women 14-50 yr	3.53	0.2%	Wheat	0.0%	Milk: Cattle	0.0%	Rye		0.2%
0.3%	IE adult	3.43	0.2%	Wheat	0.0%	Buckwheat and other pseudo-cereals	0.0%	Rice		0.2%
0.3%	ES adult	3.10	0.2%	Wheat	0.0%	Barley	0.0%	Milk: Cattle		0.2%
0.3%	NL general	3.02	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%
0.3%	FR adult	2.55	0.2%	Wheat	0.0%	Milk: Cattle	0.0%	Rice		0.2%
0.3%	LT adult	2.51	0.1%	Rye	0.1%	Wheat	0.0%	Rice		0.2%
0.2%	UK vegetarian	2.38	0.2%	Wheat	0.0%	Rice	0.0%	Milk: Cattle		0.2%
0.2%	FI 6 yr	2.13	0.1%	Wheat	0.0%	Rye	0.0%	Rice		0.1%
0.2%	UK adult	2.04	0.1%	Wheat	0.0%	Rice	0.0%	Milk: Cattle		0.1%
0.2%	DK adult	1.85	0.1%	Wheat	0.0%	Rye	0.0%	Milk: Cattle		0.1%
0.2%	FR infant	1.66	0.1%	Milk: Cattle	0.1%	Wheat	0.0%	Sugar beet roots		0.1%
0.1%	IE child	1.38	0.1%	Wheat	0.0%	Rice	0.0%	Milk: Cattle		0.1%
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 TAA is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

Triazole lactic acid

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

TLA

LOQs (mg/kg) range from: to:

Toxicological reference values

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

Input values

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

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	1%	NL toddler	4.01	0.8%	Milk: Cattle	0.1%	Apples	0.1%	Maize/corn		0.1%
	0.7%	UK infant	2.05	0.5%	Milk: Cattle	0.0%	Potatoes	0.0%	Wheat		0.0%
	0.7%	NL child	2.02	0.3%	Milk: Cattle	0.1%	Apples	0.0%	Wheat		0.0%
	0.7%	DE child	1.96	0.3%	Milk: Cattle	0.1%	Apples	0.1%	Oranges		0.0%
	0.6%	FR toddler 2 3 yr	1.82	0.4%	Milk: Cattle	0.0%	Apples	0.0%	Wheat		0.0%
	0.6%	FR child 3 15 yr	1.73	0.3%	Milk: Cattle	0.0%	Oranges	0.0%	Wheat		0.0%
	0.5%	UK toddler	1.39	0.3%	Milk: Cattle	0.0%	Wheat	0.0%	Oranges		0.0%
	0.4%	GEMS/Food G11	1.27	0.1%	Milk: Cattle	0.1%	Soyabeans	0.0%	Potatoes		0.0%
	0.4%	DK child	1.25	0.2%	Milk: Cattle	0.0%	Rye	0.0%	Wheat		0.1%
	0.4%	GEMS/Food G07	1.20	0.1%	Milk: Cattle	0.0%	Soyabeans	0.0%	Wheat		0.0%
	0.4%	GEMS/Food G10	1.19	0.1%	Milk: Cattle	0.1%	Soyabeans	0.0%	Wheat		0.0%
	0.4%	ES child	1.18	0.2%	Milk: Cattle	0.0%	Wheat	0.0%	Oranges		0.0%
	0.4%	GEMS/Food G08	1.17	0.1%	Milk: Cattle	0.0%	Soyabeans	0.0%	Wheat		0.0%
	0.4%	GEMS/Food G15	1.16	0.1%	Milk: Cattle	0.0%	Soyabeans	0.0%	Wheat		0.0%
	0.4%	RO general	1.15	0.2%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes		0.0%
	0.4%	SE general	1.15	0.2%	Milk: Cattle	0.1%	Bovine: Muscle/meat	0.0%	Potatoes		0.0%
	0.4%	GEMS/Food G06	1.06	0.1%	Wheat	0.0%	Tomatoes	0.0%	Milk: Cattle		0.1%
	0.4%	DE women 14-50 yr	1.05	0.2%	Milk: Cattle	0.0%	Apples	0.0%	Oranges		0.0%
	0.3%	DE general	1.03	0.2%	Milk: Cattle	0.0%	Apples	0.0%	Oranges		0.0%
	0.3%	FR infant	0.97	0.2%	Milk: Cattle	0.0%	Apples	0.0%	Potatoes		0.0%
	0.3%	NL general	0.89	0.1%	Milk: Cattle	0.0%	Potatoes	0.0%	Apples		0.0%
	0.3%	IE adult	0.85	0.1%	Milk: Cattle	0.0%	Sweet potatoes	0.0%	Wheat		0.0%
	0.2%	ES adult	0.67	0.1%	Milk: Cattle	0.0%	Oranges	0.0%	Wheat		0.0%
	0.2%	FR adult	0.61	0.1%	Milk: Cattle	0.0%	Wine grapes	0.0%	Wheat		0.0%
	0.2%	PT general	0.56	0.0%	Potatoes	0.0%	Wine grapes	0.0%	Wheat		0.0%
	0.2%	DK adult	0.54	0.1%	Milk: Cattle	0.0%	Wine grapes	0.0%	Swine: Muscle/meat		0.0%
	0.2%	LT adult	0.49	0.1%	Milk: Cattle	0.0%	Potatoes	0.0%	Apples		0.0%
	0.1%	IT toddler	0.43	0.0%	Wheat	0.0%	Tomatoes	0.0%	Other cereals		0.0%
	0.1%	UK vegetarian	0.41	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Oranges		0.0%
	0.1%	UK adult	0.40	0.0%	Milk: Cattle	0.0%	Wine grapes	0.0%	Wheat		0.0%
	0.1%	FI 3 yr	0.38	0.0%	Potatoes	0.0%	Cucumbers	0.0%	Apples		0.0%
	0.1%	IT adult	0.35	0.0%	Wheat	0.0%	Tomatoes	0.0%	Lettuces		0.0%
	0.1%	FI 6 yr	0.30	0.0%	Potatoes	0.0%	Wheat	0.0%	Cucumbers		0.0%
	0.1%	IE child	0.25	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes		0.0%
	0.1%	PL general	0.23	0.0%	Potatoes	0.0%	Apples	0.0%	Tomatoes		
	0.1%	FI adult	0.19	0.0%	Potatoes	0.0%	Apples	0.0%	Tomatoes		0.0%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of TLA is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

The IEDI calculation was not undertaken for prothioconazole, as the results of the TMDI showed that a refinement was unnecessary.

A 3.3 IESTI calculations - Raw commodities and processed commodities

Prothioconazole-desthio

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)
6%	Wheat	0.1 / 0.04	0.58	3%	Barley	0.2 / 0.07	0.34
4%	Barley	0.2 / 0.07	0.39	3%	Wheat	0.1 / 0.04	0.34
3%	Rye	0.05 / 0.05	0.32	2%	Rye	0.05 / 0.05	0.24
1%	Rapeseeds/canola seeds	0.15 / 0.08	0.11	0.4%	Rapeseeds/canola seeds	0.15 / 0.08	0.04
Expand/collapse list							
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)							

Processed commodities

Results for children				**Results for adults**			
No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---	No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				**IESTI**			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
5%	Wheat / milling (flour)	0.1 / 0.04	0.48	5%	Barley / beer	0.2 / 0.01	0.50
3%	Barley / cooked	0.2 / 0.07	0.25	2%	Wheat / bread/pizza	0.1 / 0.04	0.18
2%	Wheat / milling (wholemeal)	0.1 / 0.04	0.22	2%	Wheat / pasta	0.1 / 0.04	0.15
2%	Rye / boiled	0.05 / 0.05	0.18	1%	Wheat / bread	0.1 / 0.04	0.14
2%	Rye / milling (wholemeal)-b	0.05 / 0.05	0.18	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
1%	Barley / milling (flour)	0.2 / 0.07	0.13	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
0.5%	Rapeseeds / oils	0.15 / 0.16	0.05	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!

Acute risk assessment /children	Acute risk assessment / adults / general population
Details - acute risk assessment /children	Details - acute risk assessment/adults

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

Show results for all crops

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
51%	Bovine: Kidney	0,15 / 1,35	5,1
37%	Bovine: Liver	0,23 / 0,46	3,7
22%	Barley	0,2 / 0,4	2,2
11%	Bovine: Edible offals (other	0,15 / 0,15	1,1
6%	Milk: Cattle	0,01 / 0,01	0,62
5%	Swine: Edible offals (other	0,15 / 0,15	0,45
4%	Rapeseeds/canola seeds	0,15 / 0,3	0,41
3%	Wheat	0,01 / 0,02	0,29
3%	Swine: Liver	0,23 / 0,23	0,28
2%	Swine: Kidney	0,15 / 0,15	0,19
2%	Honey and other apiculture	0,05 / 0,05	0,18
2%	Poultry: Liver	0,07 / 0,14	0,16
1%	Rye	0,01 / 0,02	0,13
1%	Eggs: Chicken	0,01 / 0,01	0,12
1%	Swine: Muscle/meat	0,01 / 0,01	0,12

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
28%	Bovine: Kidney	0,15 / 1,35	2,8
19%	Barley	0,2 / 0,4	1,9
18%	Bovine: Liver	0,23 / 0,46	1,8
16%	Swine: Other products	0,5 / 0,5	1,6
13%	Sheep: Liver	0,23 / 0,46	1,3
10%	Bovine: Other products	0,5 / 0,5	1,00
8%	Poultry: Kidney	0,07 / 0,64	0,82
7%	Poultry: Liver	0,07 / 0,14	0,67
5%	Bovine: Edible offals (other	0,15 / 0,15	0,50
4%	Swine: Edible offals (other	0,15 / 0,15	0,39
3%	Swine: Kidney	0,15 / 0,15	0,33
3%	Swine: Liver	0,23 / 0,23	0,32
2%	Milk: Cattle	0,01 / 0,01	0,19
2%	Wheat	0,01 / 0,02	0,17
2%	Rapeseeds/canola seeds	0,15 / 0,3	0,16

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

Processed commodities

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
15%	Barley / cooked	0,2 / 0,4	1,5
7%	Barley / milling (flour)	0,2 / 0,4	0,72
2%	Wheat / milling (flour)	0,01 / 0,02	0,24
2%	Rapeseeds / oils	0,15 / 0,6	0,18
1%	Wheat / milling (wholemeal)-l	0,01 / 0,02	0,11
0,7%	Rye / boiled	0,01 / 0,02	0,07
0,7%	Rye / milling (wholemeal)-bal	0,01 / 0,02	0,07
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
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Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
29%	Barley / beer	0,2 / 0,08	2,9
0,9%	Wheat / bread/pizza	0,01 / 0,02	0,09
0,8%	Wheat / pasta	0,01 / 0,02	0,08
0,7%	Wheat / bread (wholemeal)	0,01 / 0,02	0,07
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
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1,2,4-Triazole

Acute risk assessment /children	Acute risk assessment / adults / general population
Details - acute risk assessment /children	Details - acute risk assessment/adults

The acute risk assessment is based on the ARfD. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the Eu

The calculation is based on the large portion of the most critical consumer group.

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

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.7%	Wheat	0 / 0.05	0.72
0.3%	Rye	0 / 0.05	0.32
0.3%	Barley	0 / 0.05	0.28
0.07%	Rapeseeds/canola	0 / 0.05	0.07

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.4%	Wheat	0 / 0.05	0.42
0.2%	Rye	0 / 0.05	0.24
0.2%	Barley	0 / 0.05	0.24
0.03%	Rapeseeds/canola seeds	0 / 0.05	0.03

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

Processed commodities

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.6%	Wheat / milling (flour)	0 / 0.05	0.60
0.3%	Wheat / milling (wholemea	0 / 0.05	0.28
0.2%	Rye / boiled	0 / 0.05	0.18
0.2%	Barley / cooked	0 / 0.05	0.18
0.2%	Rye / milling (wholemeal)-l	0 / 0.05	0.18
0.1%	Barley / milling (flour)	0 / 0.05	0.09
0.0%	Rapeseeds / oils	0 / 0.1	0.03
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
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Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.4%	Barley / beer	0 / 0.01	0.36
0.2%	Wheat / bread/pizza	0 / 0.05	0.22
0.2%	Wheat / pasta	0 / 0.05	0.19
0.2%	Wheat / bread	0 / 0.05	0.17
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
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Triazole alanine

Acute risk assessment /children	Acute risk assessment / adults / general population
Details - acute risk assessment /children	Details - acute risk assessment/adults

The acute risk assessment is based on the ARfD. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the Eu

The calculation is based on the large portion of the most critical consumer group.

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

Unprocessed commodities

Results for children				**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
0.5%	Rapeseeds/canola	0 / 1.04	1.4	0.2%	Rapeseeds/canola seeds	0 / 1.04	0.55
Expand/collapse list							
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)							

Processed commodities

Results for children				**Results for adults**			
No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---	No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				**IESTI**			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
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%	Barley / cooked	0 / 0.62	2.3	0.7%	Wheat / bread	0 / 0.62	2.2
0.7%	Rye / milling (wholemeal)-I	0 / 0.62	2.2	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
0.4%	Barley / milling (flour)	0 / 0.62	1.1	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
0.2%	Rapeseeds / oils	0 / 2.08	0.61	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
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Expand/collapse list							

Triazole acetic acid

Acute risk assessment /children	Acute risk assessment / adults / general population
Details - acute risk assessment /children	Details - acute risk assessment/adults

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The calculation is based on the large portion of the most critical consumer group.

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

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
1%	Wheat	0 / 0.79	11
0.5%	Rye	0 / 0.79	5.0
0.4%	Barley	0 / 0.79	4.4
0.02%	Rapeseeds/canola	0 / 0.12	0.17

Expand/collapse list

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

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.7%	Wheat	0 / 0.79	6.6
0.4%	Rye	0 / 0.79	3.8
0.4%	Barley	0 / 0.79	3.8
0.01%	Rapeseeds/canola seeds	0 / 0.12	0.06

Processed commodities

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
1.0%	Wheat / milling (flour)	0 / 0.79	9.6
0.4%	Wheat / milling (wholemea	0 / 0.79	4.4
0.3%	Rye / boiled	0 / 0.79	2.9
0.3%	Barley / cooked	0 / 0.79	2.9
0.3%	Rye / milling (wholemeal)-l	0 / 0.79	2.8
0.1%	Barley / milling (flour)	0 / 0.79	1.4
0.0%	Rapeseeds / oils	0 / 0.24	0.07
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
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Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.6%	Barley / beer	0 / 0.16	5.7
0.3%	Wheat / bread/pizza	0 / 0.79	3.5
0.3%	Wheat / pasta	0 / 0.79	3.0
0.3%	Wheat / bread	0 / 0.79	2.8
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
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Triazole lactic acid

Acute risk assessment /children	Acute risk assessment / adults / general population
Details - acute risk assessment /children	Details - acute risk assessment/adults

The acute risk assessment is based on the ARfD. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the Eu

The calculation is based on the large portion of the most critical consumer group.

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

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.1%	Wheat	0 / 0.02	0.32
0.05%	Rye	0 / 0.02	0.14
0.04%	Barley	0 / 0.02	0.12
0.03%	Rapeseeds/canola	0 / 0.07	0.09

Expand/collapse list

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

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.06%	Wheat	0 / 0.02	0.18
0.04%	Rye	0 / 0.02	0.11
0.04%	Barley	0 / 0.02	0.11
0.01%	Rapeseeds/canola seeds	0 / 0.07	0.03

Processed commodities

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.1%	Wheat / milling (flour)	0 / 0.02	0.27
0.0%	Wheat / milling (wholemea	0 / 0.02	0.12
0.0%	Rye / boiled	0 / 0.02	0.08
0.0%	Barley / cooked	0 / 0.02	0.08
0.0%	Rye / milling (wholemeal)-I	0 / 0.02	0.08
0.0%	Barley / milling (flour)	0 / 0.02	0.04
0.0%	Rapeseeds / oils	0 / 0.13	0.04
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
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Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.1%	Barley / beer	0 / 0	0.16
0.03%	Wheat / bread/pizza	0 / 0.02	0.10
0.03%	Wheat / pasta	0 / 0.02	0.08
0.03%	Wheat / bread	0 / 0.02	0.08
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
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The IESTI calculation was not undertaken for azoxystrobin, as no ARfD is allocated.

Additional information provided by the applicant

No additional information is provided.