

FINAL REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: GLOB2021dF

Product name: PIRLANKO

Chemical active substances:

Prothioconazole, 156 g/L

Boscalid, 156 g/L

Central Zone

Zonal Rapporteur Member State:

Poland

CORE ASSESSMENT

(authorization)

Applicant: GLOBACHEM NV

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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

Prothioconazole

Storage stability

The storage stability of prothioconazole-desthio in plant samples stored under frozen conditions was investigated in the framework of the MRL review. In commodities relevant for the intended use on cereals and oilseed rape, prothioconazole and prothioconazole-desthio residues are stable for at least 18, for high water and high starch commodities and for 24 months for high oil commodities when stored at -18°C.

Storage stability data for TDMs are presented in EFSA Journal 2018;16(7):5376. Residues are stable in wheat and barley grain for 12 month - 1,2,4-Triazole, for 26 month – TA, for 26 month – TAA and for 48 month – TLA. Residues are stable in cereal straw for 12 month - 1,2,4-Triazole, for 53 month – TA, for 40 month – TAA and there is no data for TLA. However, storage stability for TLA in cereal straw is covered by acceptable storage stabilities in 5 different group matrices - 48 months. Residues of TAA are stable for 53 month and TLA are stable for 48 month in oilseed rape. Residues of 1,2,4-Triazole and TA are not stable in oilseed rape (seed).

Metabolism in plants and animals

Plant residue definition for monitoring: Prothioconazole: Prothioconazole-desthio (sum of isomers)

Plant residue definition for risk assessment:

a) Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers) (EFSA, 2014)

b)TDMs:

- Triazole alanine (TA) and triazole lactic acid (TLA)
- Triazole acetic acid (TAA)
- 1,2,4-triazole (1,2,4-T), EFSA, 2018.

These residue definitions are applicable to primary and rotational crops.

Processing

Prothioconazole degrades to prothioconazole-desthio which remains stable **stable** under the different hydrolytic conditions. The new hydrolysis study confirmed that prothioconazole-desthio was hydrolytically stable during pasteurisation, baking/brewing/boiling and sterilisation.

According to EFSA (2018) the TDMs are stable under hydrolysis conditions simulating baking/brewing/boiling, pasteurisation and sterilisation.

Magnitude of residues in plants (NEU)

Wheat/Rye

	Application/Interval	BBCH	PHI
NEU GAP (EFSA, 2020)	3 x 0.2 kg a.s./ha/14-21 d	26-69	35 d
Proposed GAP	2 x 0.125 kg a.s./ha/21 d	25-69	35 d
New trials submitted by the Applicant	2 x 0.195 kg a.s./ha/13-14 d	53-61	35 d

Barley/oat			
	Application/Interval	BBCH	PHI
NEU GAP (EFSA, 2020)	2 x 0.175 kg a.s./ha/14-21 d	61	35 d
Proposed GAP	2 x 0.125 kg a.s./ha/21 d	25-69	56 d
New trials submitted by the Applicant	2 x 0.195 kg a.s./ha/13-14 d	53-61	35 d
Oilseed rape			
	Application/Interval	BBCH	PHI
NEU GAP (EFSA, 2020)	2 x 0.120 kg a.s./ha/14 d	Not stated	28 d
Proposed GAP	2 x 0.125 kg a.s./ha/21 d	14-69	35 d
New trials submitted by the Applicant	2 x 0.180 kg a.s./ha/21 d	69	56 d

Prothioconazole

Barley, wheat and rape are the major crops in Northern Europe. Sufficient number of trials is available (EU data and new data). The application requested is considered to be within the scope of EU GAP. The results indicate that MRL exceedance according to the current MRL regulation is not expected.

TDMs

EU data: for wheat the results of 4 NEU trials is available, however residues of TLA were not analysed, for barley and rapeseed 8 and 20 NEU residue trials are available respectively. The number of studies is insufficient to support the intended use in cereals.

New data:

The Applicant submitted sufficient number of NEU residue trials of TDMs in cereals and oilseed rape: 9 for wheat, 8 for barley and 20 for rapeseed.

The trials are sufficient to support the intended use on cereals and rape.

Livestock feeding

No new data submitted in the framework of this application. There is no risk for animal MRL to be exceeded. Considering TDMs, EFSA (2018) concluded: "In the framework of the 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 live-stock exposure assessment (Data gap).

Succeeding crops

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 significant residues of prothioconazole are expected in succeeding crops.

Considering TDMs EFSA (2018) concluded: "Rotational crops residue field trials were submitted in the framework of the confirmatory data assessment but were not supported by acceptable storage stability data. Sufficient residue trials for rotational crops supported by acceptable storage stability data are therefore required (data gap)". However, the available rotational studies were considered in the consumer dietary assessment. The outcome of the consumer intake assessment, based on the data provided, raises no concerns.

Residues in bee products

In a submitted honey study on *Phacelia tanacetifolia* the application of prothioconazole resulted in residue values of prothioconazole and its metabolites prothioconazole-desthio, 1,2,4-triazole (free triazole),

triazole alanine, triazole lactic acid, triazole acetic acid in honey below the default level of 0.05 mg/kg.

Consumer risk assessment

The estimated long-term dietary intake of prothioconazole was below the ADI. The diet with the highest IEDI is NL toddler population with 9% of ADI. For this diet, the highest contributor is cattle milk with 3% of ADI. In addition, the evaluator performed the worst case calculations based on the current MRL values. The estimated long-term dietary intake is much below the ADI. The diet with the highest TMDI is NL toddler population (20% of ADI). The assessment of the acute risk assessment indicated no exceedance of ARfD for children and adults. The worst-case consumer dietary intake assessment with regard to the TDMs for the complete group of triazole active substances were assessed in the confirmatory data. The chronic and acute dietary intakes have been carried out using the highest input residue values derived for each TDM for each crop groups and each product of animal origin. No chronic or acute intake concerns for consumers were identified.

Boscalid

Storage stability

No new data submitted in the framework of this application. Storage stability of boscalid was demonstrated for a period of 16 months at -18 °C in commodities with high acid content and 24 months at -18 °C in commodities with high water content, high oil content, dry commodities and cereal straw. Degradation of residues during storage of the trial samples is not expected.

Metabolism in plants and animals

The metabolism of boscalid is similar in different groups of crops. The residue definition for enforcement and risk assessment in all plant commodities is defined as boscalid only. A specific residue definition for rotational crops is not necessary.

For animals the residue definition for enforcement is:

- muscle, fat, milk and eggs: boscalid
- kidney, liver: sum of boscalid and its hydroxy metabolite M510F01 (free and conjugated), ex-pressed as boscalid, and

the residue definition for risk assessment is:

- muscle, fat: boscalid
- kidney: sum of boscalid and its hydroxy metabolite M510F01 (free and conjugated), expressed as boscalid
- liver: sum of boscalid, its hydroxy metabolite M510F01 (free and conjugated) and its bound residue (measured as M510F53 or M510F52), expressed as boscalid

Processing

No new data has been submitted in the framework of this application. Boscalid was not degraded during the pasteurisation, baking, boiling, brewing and sterilisation.

Magnitude of residues in plants (NEU)

Wheat/Rye

	Application/Interval	BBCH	PHI
NEU GAP (EFSA, 2014)	2 x 0.35 kg a.s./ha	69	35 d
Proposed GAP	2 x 0.125 kg a.s./ha/21 d	25-69	35 d
New trials submitted by the Applicant	2 x 0.35 kg a.s./ha/14 d	69	35 d

Barley/oat

	Application/Interval	BBCH	PHI
NEU GAP (EFSA, 2014)	2 x 0.35 kg a.s./ha	30-65	35 d

Proposed GAP	2 x 0.125 kg a.s./ha/21 d	25-69	56 d
New trials submitted by the Applicant	2 x 0.35 kg a.s./ha/14 d	59	56 d
Oilseed rape			
	Application/Interval	BBCH	PHI
NEU GAP (EFSA, 2014)	2 x 0.25 kg a.s./ha/8-12 d	61-69	-
Proposed GAP	2 x 0.125 kg a.s./ha/21 d	14-69	35 d

Barley, wheat and rape are the major crops in Northern Europe. Sufficient number of residue trials is available. The application requested is considered to be within the scope of EU GAP. The results indicate that MRL exceedance according to the current MRL regulation is not expected.

The trials are sufficient to support the intended use of boscalid on cereals and rape.
zRMS would like to draw attention to evaluation of confirmatory data

Livestock feeding

No new data submitted in the framework of this application. Results of the livestock burden calculation show a significant intake for ruminants, poultry and pigs. The available feeding data indicates that there is no risk for animal MRL to be exceeded.

Succeeding crops

No new field rotational crop studies have been submitted. Due to the high persistence of boscalid in soil, it is not possible to exclude an accumulation and uptake of residues from soil in rotational crops. The 2009 JMPR reported additional field trials investigating the uptake of boscalid in various crops in Europe, Japan and the US following an annual application rate of 2.0 to 2.15 kg a.s./ha on a bare soil. The boscalid residues in the crops tested were below of MRLs. As the proposed GAP is two application at 0.125 kg/ha which is below of the dose used on the bare soil, no residues of boscalid are expected after use of GLOB2021dF.

Residues in bee products

The data from EFSA (2019) show the highest boscalid residues measured in honey samples as 0.082 mg/kg. The current MRL for boscalid residues in honey is 0.15 mg/kg. The Applicant submitted additional study on residues of boscalid in buckwheat honey that indicated no exceedance of MRL of boscalid in honey.

Consumer risk assessment

The estimated long-term dietary intake of boscalid was below the ADI. The diet with the highest IEDI is DK child population with 24% of ADI. For this diet, the highest contributor is rye with 11% of ADI. The assessment of the acute risk assessment is not necessary as no ARfD value is established.
No intake concerns for consumers were identified.

Data gaps

-

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

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-	Member sta te(s)	Crop and/or situation (crop destination / purpose of crop)	F,	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g saf-ener/ syner-gist per ha	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			
Zonal uses (field or outdoor uses, certain types of protected crops)														
1,2	PL, CZ, DE, HU, RO, SK, BE	Oilseed Rape (401060)	F	Leptma Sclerotina Alternaria	Foliar Spray	BBCH 14 - 69	a) 2 b) 2	21	a) 0.8 L/ha b) 1.6 L/ha	a) Prothioconazole : 0.125 kg as/ha Boscalid : 0.125 kg as/ha b) Prothiocon	100 - 300	35	/	A

										azole : 0.250 kg as/ha Boscalid : 0.250 kg as/ha				
3-16	PL, CZ, DE, HU, RO, SK, BE	Cereals Wheat, durum, spelt, triticale (500090) Barley (500010) Rye (500070) Oat (500050)	F	<i>Fusarium</i> Rust Powdery mildew Leaf blotch, leaf spot	Foliar Spray	BBCH 25 - 69	a) 2 b) 2	21	a) 0.8 L/ha b) 1.6 L/ha	a) Prothiocon azole : 0.125 kg as/ha Boscalid : 0.125 kg as/ha b) Prothiocon azole : 0.250 kg as/ha Boscalid : 0.250 kg as/ha	100 - 300	Wheat/ / rye 35 Barley/ oat 56		A
Minor uses according to Article 51 (zonal uses)														
17	HU	Winter oats (AVESW) 500050	F	<i>Fusarium</i> sp. (FUSASP)	Normal downward spraying	BBCH 61 - 69	a) 1 b) 2	21	a) 0.8 L/ha b) 1.6 L/ha	a) Prothioconazole : 0.125 Boscalid : 0.125 b) Prothioconazole : 0.250 Boscalid : 0.250	100 - 300	56	/	
18	CZ, HU	Spring oats (AVESP) 500050	F											
19	RO	Winter rye (SECCW), 500070	F											
20	PL, RO, SK	Spring rye (SECCS) 500070	F	<i>Rhynchosporium secalis</i> (RHYNSE), <i>Blumeria graminis</i> (ERYSGR)	Normal downward spraying	BBCH 61 - 69	a) 1 b) 2	21	a) 0.8 L/ha b) 1.6 L/ha	a) Prothioconazole : 0.125 Boscalid : 0.125 b) Prothioconazole : 0.250 Boscalid : 0.250	100 - 300	35	/	

21	PL, RO, SK	Spring rye (SECCS) 500070	F	<i>Puccinia recondita</i> (PUCCRE), <i>Puccinia striiformis</i> (PUCCST), <i>Zymoseptoria tritici</i> (SEPTTR), <i>Parastagonospora nodorum</i> (LEPTNO)	Normal downward spraying	BBCH 61 - 69	a) 1 b) 2	21	a) 0.8 L/ha b) 1.6 L/ha	a) Prothioconazole : 0.125 Boscalid : 0.125 b) Prothioconazole : 0.250 Boscalid : 0.250	100 - 300	35	/	
22	RO	Winter rye (SECCW), 500070	F	<i>Rhynchosporium secalis</i> (RHYNSE), <i>Blumeria graminis</i> (ERYSGR)	Normal downward spraying	BBCH 61 - 69	a) 1 b) 2	21	a) 0.8 L/ha b) 1.6 L/ha	a) Prothioconazole : 0.125 Boscalid : 0.125 b) Prothioconazole : 0.250	100 - 300	35	/	
23	RO	Winter rye (SECCW), 500070	F	<i>Puccinia recondita</i> (PUCCRE), <i>Puccinia striiformis</i> (PUCCST), <i>Zymoseptoria tritici</i> (SEPTTR), <i>Parastagonospora nodorum</i> (LEPTNO)	Normal downward spraying	BBCH 61 - 69	a) 1 b) 2	21	a) 0.8 L/ha b) 1.6 L/ha	a) Prothioconazole : 0.125 Boscalid : 0.125 b) Prothioconazole : 0.250 Boscalid : 0.250	100 - 300	35	/	
24	RO	Winter tritiale (TTLWI), Spring tritiale (TTLSO) 500090	F	<i>Puccinia recondita</i> (PUCCRE), <i>Puccinia striiformis</i> (PUCCST), <i>Puccinia triticina</i> (PUCCRT), <i>Zymoseptoria tritici</i> (SEPTTR), <i>Parastagonospora nodorum</i> (LEPTNO)	Normal downward spraying	BBCH 61 - 69	a) 1 b) 2	21	a) 0.8 L/ha b) 1.6 L/ha	a) Prothioconazole : 0.125 Boscalid : 0.125 b) Prothioconazole : 0.250 Boscalid : 0.250	100 - 300	35	/	
25	RO	Winter tritiale (TTLWI), Spring tritiale (TTLSO) 500090	F	<i>Rhynchosporium secalis</i> (RHYNSE) <i>Blumeria graminis</i> (ERYSGR)	Normal downward spraying	BBCH 61 - 69	a) 1 b) 2	21	a) 0.8 L/ha b) 1.6 L/ha	a) Prothioconazole : 0.125 Boscalid : 0.125 b) Prothioconazole : 0.250 Boscalid : 0.250	100 - 300	35	/	
26	CZ, HU, RO, SK	Spelt (TRZSP) 500090	F	<i>Zymoseptoria tritici</i> (SEPTTR), <i>Parastagonospora</i>	Normal downward spraying	BBCH 61 - 69	a) 1 b) 2	21	a) 0.8 L/ha b) 1.6 L/ha	a) Prothioconazole : 0.125 Boscalid : 0.125	100 - 300	35	/	

				<i>nodorum</i> (LEPTNO), <i>Puccinia striiformis</i> (PUCST), <i>Puccinia triticina</i> (PUCRT)						b) Prothioconazole : 0.250 Boscalid : 0.250				
27	CZ, HU, RO, SK	Spelt (TRZSP) 500090	F	<i>Rhynchosporium secalis</i> (RHYNSE), <i>Blumeria graminis</i> (ERYSGR)	Normal downward spraying	BBCH 61 - 69	a) 1 b) 2	21	a) 0.8 L/ha b) 1.6 L/ha	a) Prothioconazole : 0.125 Boscalid : 0.125 b) Prothioconazole : 0.250 Boscalid : 0.250	100 - 300	35	/	

Crops added according to B0 section.

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

Explanation for Column 11 "Conclusion"

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

7.1.2 Summary of the evaluation

The preparation GLOB2021dF is composed of boscalid and prothioconazole.

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

Reference value	Source	Year	Value	Study relied upon	Safety factor
Boscalid - Parent					
ADI	EC	2008	0.04 mg/kg bw/d	Rat 2-yr oral feed	100
ARfD	EC	2008	Not allocated	-	-
Prothioconazole - Parent					
ADI	EFSA	2007	0.05 mg/kg bw/d	Rat, 2 year study ; dog, 1 year study	100
ARfD	EFSA	2007	0.2 mg/kg bw	Rat, developmental study	100
Prothioconazole-desthio					
ADI	EFSA	2007	0.01 mg/kg bw/d	Rat, carcinogenicity study	100
ARfD	EFSA	2007	0.01 mg/kg bw	Rat, developmental study	100
Triazole acetic acid (TAA) - Triazole derived metabolite					
ADI	EFSA	2018	1.0 mg/kg bw/d	Rabbit developmental toxicity studies	100
ARfD	EFSA	2018	1.0 mg/kg bw/	Rabbit developmental toxicity studies	100
Triazole alanine (TA) - Triazole derived metabolite					
ADI	EFSA	2018	0.3 mg/kg bw/d	Rabbit developmental toxicity studies	100
ARfD	EFSA	2018	0.3 mg/kg bw/	Rabbit developmental toxicity studies	100
1,2,4-triazole (T) - Triazole derived metabolite					
ADI	EFSA	2018	0.023 mg/kg bw/d	12-month rat study	300 (covering the lack of a DNT study and carcinogenicity and dog studies)
ARfD	EFSA	2018	0.1 mg/kg bw	Rabbit developmental toxicity studies	300 (covering the lack of a DNT study and ensuring a sufficient margin to LOAEL for development)
Triazole lactic acid (TLA) - Triazole derived metabolite					
ADI	EFSA	2018	0.3 mg/kg bw/d	Rabbit developmental toxicity studies	100
ARfD	EFSA	2018	0.3 mg/kg bw/	Rabbit developmental toxicity studies	100

7.1.2.1 Summary for boscalid

Table 7.1-3: Summary for boscalid

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	Oilseed rape	Yes	Yes (12)	Yes	Yes	Yes	No	No
3-16	Cereals	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

7.1.2.2 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	Oilseed rape	Yes	Yes (12)	Yes	Yes	Yes	No	No
3-16	Cereals	Yes	Yes Barley (13) Wheat (16)	Yes	Yes	Yes		No

7.1.2.3 Summary for GLOB2021dF

Table 7.1-5: Information on GLOB2021dF (KCA 6.8)

Crop	PHI for GLOB2021dF proposed by applicant	PHI/ Withholding period* sufficiently supported for		PHI for GLOB2021dF proposed by zRMS	zRMS Comments (if different PHI proposed)
		Boscalid	Prothioconazole		
Oilseed rape	35 days			-	
Cereals (Barley/Oat)	56 days			-	
Cereals (Wheat/Rye)	35 days			-	

NR: not relevant

* Purpose of withholding period to be specified

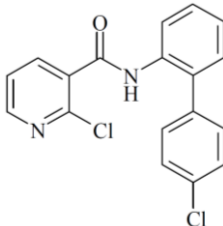
** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

Assessment

7.2 Boscalid

General data on Boscalid are summarized in the table below (last updated 2023/05/02)

Table 7.2-1: General information on Boscalid

Active substance (ISO Common Name)	Boscalid
IUPAC	2-Chloro-N-(4'-chlorobiphenyl-2-yl)nicotinamide
Chemical structure	
Molecular formula	C ₁₈ H ₁₂ Cl ₂ N ₂ O
Molar mass	343.21 g/mol
Chemical group	Pyridine-carboxamides
Mode of action (if available)	Succinate dehydrogenase inhibitor
Systemic	Yes
Company	BASF AG.
Rapporteur Member State (RMS)	Slovakia (original RMS was Germany)
Approval status	Approved Date of (01/08/2008) and reference to decision (COMMISSION DIRECTIVE 2008/44/EC - REGULATION (EU) No 540/2011) http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32008L0044&from=EN http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011R0540&from=EN Extension of the approval period – Reg.(EU) 2021/745 Reg. EU) 2023/918
Restriction	Only uses as fungicide may be authorised
Review Report	SANCO/3919 /2007-rev. 5 21 January 2008
Current MRL regulation	~~Reg. (EU) 2021/590~~ Reg. (EU) 2022/1324
Peer review of MRLs according to Article 12 of Reg. No 396/2005 EC performed	Yes
EFSA Journal : Conclusion on the peer review	Not available
EFSA Journal: conclusion on article 12	Yes
Current MRL applications on intended uses	EFSA-Q-2008-500 (Germany) Status: Reasoned opinion available (EFSA Journal 2014;12(7):3799)

7.2.1 Stability of Residues (KCA 6.1)

Stability of residues during storage of samples

Available data

No new data submitted in the framework of this application.

Table 7.2-2: Summary of stability data achieved at $\leq -18^{\circ}\text{C}$ (unless stated otherwise)

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products			
Cabbage, peach and pea	High water content High protein content	24 months	DAR, 2002 EFSA, 2014
Grape	High acid content	16 months	DAR, 2002 EFSA, 2014
Rape seed	High lipid content	24 months	DAR, 2002 EFSA, 2014
Wheat grain and straw	Dry commodities / high starch content	24 months	DAR, 2002 EFSA, 2014
Animal Products			
Ruminant	Liver	5 months	DAR, 2002 EFSA, 2014
Ruminant	Milk	5 months	DAR, 2002 EFSA, 2014
Ruminant	Muscle	5 months	DAR, 2002 EFSA, 2014
Ruminant	Fat	5 months	DAR, 2002 EFSA, 2014
Ruminant	Kidney	5 months	DAR, 2002 EFSA, 2014
Poultry	Egg	5 months	DAR, 2002 EFSA, 2014

Conclusion on stability of residues during storage

Conclusions drawn from EFSA Journal 2014;12(7):3799 are reported below:

Storage stability of Boscalid was demonstrated for a period of 16 months at -18°C in commodities with high acid content (grape) and 24 months at -18°C in commodities with high water content (cabbage, peach, pea), high oil content (rape seed), dry commodities (wheat grain) and cereal straw. Degradation of residues during storage of the trial samples is therefore not expected. Storage stability of Boscalid and M510F01 in milk, muscle, fat, liver, kidney and egg for up to 5 months was demonstrated, when stored deep frozen.

Stability of residues in sample extracts (KCA 6.1)

No data was submitted and required at EU level during the EU Review of Boscalid.

zRMS comment: No new data regarding stability of residues has been submitted in the framework of this application. No further information is required.

7.2.2 Nature of residues in plants, livestock and processed commodities

Nature of residue in primary crops (KCA 6.2.1)

Available data

No new data submitted in the framework of this application.

Table 7.2-3: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Fruits and fruiting vegetable	Grape	U- ¹⁴ C-diphenyl and 3- ¹⁴ C-pyridine	foliar treatment, F	0.8	3	45	-	DAR, 2002 EFSA, 2014
Leafy vegetables	Lettuce		foliar treatment, G	0.7	3	18	-	DAR, 2002 EFSA, 2014
Pulses and oilseeds	Bean		foliar treatment, G	0.5	3	0 ^(a) , 14 ^(b) , 53 ^(c)	-	DAR, 2002 EFSA, 2014

(a) whole plant

(b) forage, green beans, pods and seeds

(c) bean straw, bean dry pods and dry seeds

Summary of plant metabolism studies reported in the EU

Conclusions drawn from EFSA Journal 2014;12(7):3799 are reported below:

Metabolism of Boscalid was investigated for foliar treatment on fruits and fruiting vegetables (grapes), on pulses and oilseeds (beans) and on leafy vegetables (lettuce), using U-¹⁴C-diphenyl and 3-¹⁴C-pyridine labelled Boscalid (DAR, 2002).

In grapes, the highest TRR was identified in leaves and stalks (63.4 and 19.6 mg eq/kg respectively), whereas only 2 mg eq/kg was found in grapes (fruits). Unchanged parent Boscalid was the main component of the TRR in all plant parts, ranging from 92.7 % in grape fruits to 96.4 % in stalks. In lettuce, Boscalid was almost not metabolised. The residues in beans (edible part) were much lower compared to the rest of the plant. When separating green beans into pods and seeds, the major part of radioactivity was found in pods (0.9 mg eq/kg) rather than in seeds (0.2 mg eq/kg). Residue levels were also higher in dry pods (6.1 mg eq/kg) than in dry seeds (0.2 mg eq/kg). Parent Boscalid was identified as the major compound of the TRR in bean leaves and forage (>98 %), in green beans and green pods (97 %), in bean straw (≥94 %), in dry pods (80-95 %) and in dry seeds (72 %). The cleavage products chlorophenylaminobenzene and 2-chloronicotinic acid were also identified in green beans and seeds but only in low con-

centrations (< 0.01 mg eq/kg). The metabolism studies showed that the metabolic pathway is similar in all crops.

Conclusion on metabolism in primary crops

Conclusions drawn from EFSA Journal 2014;12(7):3799 are reported below:

Consequently, the residue for enforcement and risk assessment in all plant commodities is defined as boscalid only. Validated analytical methods for enforcement of the proposed residue definition are available, except for hops, spices and herbal infusions. The conclusions reached by EFSA reflect the views of the RMS and are also in line with those of the JMPR (FAO, 2006).

zRMS comment: The metabolism of boscalid is similar in different groups of crops. The residue definition for enforcement and risk assessment in all plant commodities is defined as boscalid only.

Nature of residue in rotational crops (KCA 6.6.1)

Available data

No new data submitted in the framework of this application.

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

Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G *	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Re-marks	
EU data								
Leafy vegetables	Lettuce	U- ¹⁴ C-diphenyl and 3- ¹⁴ C-pyridine	Bare soil, G	2.1	30, 120, 270, 365	Mature crops	-	DAR, 2002 EFSA, 2014
Root and tuber vegetables	Radish						-	DAR, 2002 EFSA, 2014
Cereals	Wheat						-	DAR, 2002 EFSA, 2014

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

Summary of plant metabolism studies reported in the EU

Conclusions drawn from EFSA Journal 2014;12(7):3799 are reported below:

The metabolism of Boscalid in rotational crops – lettuce, radish, wheat – has been evaluated (DAR, 2002). One confined rotational crop study investigating the nature of residues following different plant-back intervals is available.

The highest TRR values were observed in radish leaves (0.34 mg eq/kg; 30 DAT, pyridine study) and in wheat straw (9.83 mg eq/kg, 30 DAT, diphenyl study and 4.01 mg eq/kg, 120 DAT, pyridine study). The highest TRR in lettuce amounted to 0.16 mg eq/kg (120 DAT, pyridine study), in radish root to 0.098 mg eq/kg (270 DAT, diphenyl study) and 0.066 mg eq/kg (365 DAT, pyridine study) and in wheat grain to 0.285 mg eq/kg (120 DAT, pyridine study) and 0.243 mg eq/kg (120 DAT, diphenyl study).

Except in wheat grain, parent boscalid was the major component of the TRR in all crops. Levels of the parent compound ranged from 50 % TRR in wheat straw (270 DAT, pyridine label) to 93 % TRR in wheat

forage (270 DAT, pyridine label), and in lettuce leaves from 55.6 % TRR (270 DAT, diphenyl label) to 94.1 % TRR (365 DAT, diphenyl label). In wheat grain, the concentration of parent was low (between 1.9 % TRR at 270 DAT with the pyridine label and 16.8 % TRR at 30 DAT with the diphenyl label). Most of the radioactive residues in grain were not extractable (65 to 96 % TRR) and were detected in the starch fraction (36.2 to 48.4 % TRR, 0.06-0.12 mg eq/kg, pyridine label). The metabolite M510F61 (sugar conjugate of hydroxylated boscalid) was the only metabolite identified at levels exceeding 10 % TRR, in wheat forage (18.1 % TRR, diphenyl label, 270 DAT) and in radish leaves (21.2 % TRR for diphenyl label, 270 DAT and 11.2-15.5 % TRR, 365 DAT).

Conclusion on metabolism in rotational crops

Conclusions drawn from EFSA Journal 2014;12(7):3799 are reported below:

The proposed metabolic pathway in succeeding crops involves hydroxylation and conjugation reactions. A part of the residue was also incorporated into and/or associated with natural products, such as starch, cellulose and lignin. The parent compound is therefore the main substance of concern in rotational crops and no metabolites of concern were identified in soil. Consequently, metabolic patterns in primary and rotational crops are found to be similar and a specific residue definition for rotational crops is not deemed necessary.

zRMS comment: The metabolic pattern in primary and rotational crops is similar and a specific residue definition for rotational crops is not necessary.

Nature of residues in processed commodities (KCA 6.5.1)

Available data

No new data submitted in the framework of this application.

Table 7.2-5: Nature of the residues in processed commodities

Conditions (Duration, Temperature, pH)	Identified compound(s) (%) Diphenyl-label	Reference
EU data		
Pasteurisation (20 minutes, 90°C, pH 4)	Parent (99.3%)	DAR, 2002 EFSA, 2014
Baking, boiling, brewing (60 minutes, 100°C, pH 5)	Parent (100.2%)	DAR, 2002 EFSA, 2014
Sterilisation (20 minutes, 120°C, pH 6)	Parent (91.1%)	DAR, 2002 EFSA, 2014

* Total applied radioactivity after test

Conclusion on nature of residues in processed commodities

Conclusions drawn from EFSA Journal 2014;12(7):3799 are reported below:

The effect of processing on the nature of Boscalid was investigated in the framework of the peer review. Studies were conducted simulating representative hydrolytic conditions for pasteurisation (20 minutes at 90°C, pH 4), boiling/brewing/baking (60 minutes at 100°C, pH 5) and sterilisation (20 minutes at 120°C, pH 6). From these studies, it was concluded that these processing conditions are not expected to have a significant impact on the composition of residues in matrices of plant origin (DAR, 2002). The relevant

residue for enforcement and risk assessment in processed commodities is therefore expected to be the same as for primary crops.

zRMS comment: No new data has been submitted in the framework of this application. Boscalid was not degraded during the pasteurisation, baking, boiling, brewing and sterilisation. No degradation products were observed.

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

Table 7.2-6: Summary of the nature of residues in commodities of plant origin

Endpoints	
Plant groups covered	Fruits and fruiting vegetables (grapes) Leafy vegetables (lettuce) Pulses and oilseeds (bean)
Rotational crops covered	Root and tuber vegetables (Radish) Leafy vegetables (Lettuce) Cereals (Wheat)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	a.s. is stable under standard hydrolysis conditions
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes
Plant residue definition for monitoring	Boscalid (Regulation n° 2021/590 2022/1324)
Plant residue definition for risk assessment	Boscalid (EFSA 2014)
Conversion factor from enforcement to RA	None (DAR, 2002; EFSA, 2014)

Nature of residues in livestock (KCA 6.2.2-6.2.5)

Available data

No new data submitted in the framework of this application.

Table 7.2-7: 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	U- ¹⁴ C-diphenyl	2	1.46 - 1.73	5	Milk	Twice daily	DAR, 2002 EFSA, 2014
						Urine and faeces	Daily	
						Tissues	After sacrifice	
Laying	Hens	U- ¹⁴ C-	10	0.80 - 1.14	10	Eggs	Daily	DAR, 2002

poultry		diphenyl				Excreta	Daily	EFSA, 2014
						Tissues	After sacrifice	

Summary of ~~plant~~ animal metabolism studies reported in the EU

Conclusions drawn from EFSA Journal 2014;12(7):3799 are reported below:

The nature of Boscalid residues in commodities of animal origin was investigated in the framework of Directive 91/414/EEC (DAR, 2002). Reported metabolism studies include one study in lactating goats and one study in laying hens, both using [U-¹⁴C-diphenyl] labelled Boscalid.

Lactating goats were dosed with 1.46 - 1.73 mg/kg bw per day of Boscalid. These dose levels represent at least 0.7 (including uptake of residues from previously treated soil) and 1 (resulting from the primary crop use only) time the maximum dietary burden of meat ruminant.

Boscalid is extensively excreted (89-93 % AR), with a relatively low transfer of residues to tissues (0.4-0.6 % AR in liver, 0.01-0.02 % AR for muscle, fat and kidney) and milk (0.06-0.15 % AR). The highest TRR was found in liver (2.59 mg eq/kg). Other TRR values were 0.27 mg eq/kg in kidney, 0.04 mg eq/kg in milk, 0.036 mg eq/kg in fat and 0.012 mg eq/kg in muscle.

Boscalid was the most abundant compound in fat (0.012 mg eq/kg; 34.6 % TRR) and represented a major part of the residue in muscle (0.002 mg eq/kg; 20.4 % TRR). It was also detected in liver (0.129 mg eq/kg; 5 % TRR), milk (0.001 mg eq/kg; 3.2 % TRR) and kidney (0.007 mg eq/kg; 2.5 % TRR). The metabolite M510F01 was the most abundant compound in muscle (0.003 mg eq/kg; 20.6 % TRR) and represented a major part of the residue in fat (0.009 mg eq/kg; 26.3 % TRR). It was also detected in liver (0.074 mg eq/kg; 2.9 % TRR), milk (0.006 mg eq/kg; 14.9 % TRR) and kidney (0.023 mg eq/kg; 8.6 % TRR). M510F02, the glucuronide conjugate of M510F01, is the most abundant compound in kidney (0.136 mg eq/kg; 50.3 % TRR) and was also detected in muscle (0.001 mg eq/kg; 11.9 % TRR) and milk (0.002 mg eq/kg; 6.4 % TRR).

Non-extractable residues accounted for 85 % TRR (2.2 mg eq/kg) in liver. Further extraction was conducted with either a mixture of acetic acid and acetone or with formic acid. Extraction released either M510F53 (43.6 % TRR; 1.13 mg eq/kg) or M510F52 (35.4 % TRR; 0.92 mg eq/kg), respectively for each solvent. Other compounds were detected but these compounds were demonstrated to be formed from extractable residues only (DAR, 2002). Therefore, only M510F53 and M510F52 are deemed to be representative of the bound residues in liver. It demonstrated that those residues mainly included components containing the unchanged diphenyl moiety, but also that a cleavage on the amine bound of Boscalid cannot be excluded. Consequently, as it is likely that bound residues are released during cooking of liver and that compounds comprising the pyridine moiety will have a different behaviour than the ones containing the diphenyl moiety, further investigation on the fate of the pyridine moiety in ruminant liver is still required.

Laying hens were dosed with 0.80 – 1.14 mg/kg bw per day of Boscalid. These dose levels represent at least 3.5 (including uptake of residues from previously treated soil) and 4.4 (resulting from the primary crop use only) times the maximum dietary burden of poultry.

Boscalid is extensively excreted (97.7 % AR), with a relatively low transfer of residues to tissues (0.04 % AR in liver, 0.003-0.004 % AR for muscle and fat) and eggs (0.12 % AR). The highest TRR was found in liver (0.17 mg eq/kg). Other TRR values were 0.058 mg eq/kg in eggs (with a maximum of 0.08 mg eq/kg), 0.025 mg eq/kg in fat and 0.003 mg eq/kg in muscle. A plateau is reached in eggs at day 6 (0.07 mg eq/kg).

Boscalid is the main compound in fat (0.023 mg eq/kg; 93.3 % TRR) and eggs (0.02 mg eq/kg; 35.5 % TRR). M510F01 was detected in eggs (0.015 mg eq/kg; 26.9 % TRR) and liver (0.009 mg eq/kg; 5.6 %

TRR) and its conjugate M510F02 was detected in muscle (0.001 mg eq/kg; 11.9 % TRR) and eggs (0.01 mg eq/kg, 17.3 % TRR). Liver was only analysed using the microwave extraction used in the metabolism study on goats (only with formic acid). The results are similar to those observed in goats, M510F52 being the main compound (0.071 mg eq/kg; 42 % TRR). Therefore, further investigation on the fate of the pyridine moiety in poultry liver is also required.

The metabolism studies on both ruminant and poultry show that parent compound, its hydroxy metabolite M510F01 and its conjugate are the main components of the residue in animal tissues and products, except in liver where the bound residues (measured as M510F53 and M510F52) were found to be the main components of the residue but the actual identity of those bound residues was not elucidated. The general metabolic pathways in rodents and ruminants were found to be comparable; the findings in ruminants can therefore be extrapolated to pigs.

Conclusion on metabolism in livestock

Conclusions drawn from EFSA Journal 2014;12(7):3799 are reported below:

During the Member States' consultation, it was agreed that conjugates of M510F01 are difficult to analyse routinely and that, based on the findings from metabolism study, Boscalid and M510F01 (free form) are deemed to be sufficient markers in liver and kidney. Nevertheless, as the available livestock feeding studies do not provide separate results for M510F01 and its conjugates, it is not possible to exclude conjugates of M510F01 from the enforcement residue definition in liver and kidney without additional data. Therefore, the relevant residue for enforcement is defined as Boscalid in muscle, fat, milk and eggs and as the sum of Boscalid and its hydroxy metabolite M510F01 including its conjugates expressed as Boscalid in liver and kidney.

For risk assessment in liver, bound residues (measured as M510F53 and M510F52, but expressed as Boscalid) should also be included, but data is sufficient to derive a conversion factor for ruminant and pig livers only and supplementary data on the nature and magnitude of the bound residues in poultry liver are required. Since log Po/w of Boscalid is close to 3 (DAR, 2002) and residues in fat were found to be higher than in muscle, EFSA concludes that the residue in commodities of animal origin is fat soluble.

Validated analytical methods are available in all animal commodities.

The definition for enforcement derived by the JMPR is the same in muscle, fat, milk and eggs, but differs for liver and kidney, for which the residue definition is limited to Boscalid only (FAO, 2006). However, EFSA considers that the residue definition derived by JMPR for liver and kidney is not adequate, based on the results of the available feeding studies.

zRMS comment: The residue definition for enforcement is:

- muscle, fat, milk and eggs: boscalid
- kidney, liver: sum of boscalid and its hydroxy metabolite M510F01 (free and conjugated), expressed as boscalid

The residue definition for risk assessment is:

- muscle, fat: boscalid
- kidney: sum of boscalid and its hydroxy metabolite M510F01 (free and conjugated), expressed as boscalid
- liver: sum of boscalid, its hydroxy metabolite M510F01 (free and conjugated) and its bound residue (measured as M510F53 or M510F52), expressed as boscalid

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

Table 7.2-8: Summary on the nature of residues in commodities of animal origin

	Endpoints
Animals covered	Lactating goats
	Laying hens
Time needed to reach a plateau concentration	2-3 days in milk
	6 days in eggs
Animal residue definition for monitoring	Boscalid in muscle, fat milk and eggs; Sum of Boscalid and its hydroxy metabolite M510F01 including its conjugates expressed as Boscalid in liver and kidney; (Regulation ~~n°2021/590~~ 2022/1324)
Animal residue definition for risk assessment	Boscalid in muscle, fat milk and eggs; Sum of Boscalid and its hydroxy metabolite M510F01 including its conjugates expressed as Boscalid in liver and kidney; Sum of Boscalid and its hydroxy metabolite M510F01 including its conjugates and the bound residues (measured as M510F52 or M510F53) expressed as Boscalid in Liver (ruminant and pig); (EFSA 2014)
Conversion factor	1.5 for ruminant and pig liver (EFSA, 2014)
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	Yes

7.2.3 Magnitude of residues in plants (KCA 6.3)

Summary of European data and new data supporting the intended uses

Oilseed rape

To cover the use of oilseed rape, ten residue trials are available in the DAR (DAR, 2002. Draft Assessment Report of Boscalid. 8 November 2002), carried out with a GAP of 2x 0.25 kg as/ha with an interval of 7-10 days which more critical than proposed by Globachem NV (2x 0.25 kg as/ha with an interval of 15 21 days). Residue levels of Boscalid remained below the LOQ (0.05 mg/kg), which is covered by the EU-agreed MRL of 1 mg/kg in rapeseeds/canola. Therefore, it is possible to assume that for the proposed uses no exceedance of the MRL will occur.

In EFSA Reasoned opinion on the review of the existing maximum residue levels (MRLs) for boscalid (2014) a sufficient number of rape seed residue trials for central zone is presented. The residue level was: 11 x 0.05 mg/kg and 1 x 0.07 mg/kg, which is below the current MRL – 1 mg/kg (Reg.(EU) 2021/590 Reg.(EU) 2022/1324). As the proposed GAP is within the GAP included in EFSA opinion, the requested application is accepted.

Cereals

In the DAR the results of 9 trials in Northern Europe showed that residues at harvest in wheat grains were below of the current MRL of 0.8 mg/kg. In barley grains, 12 trials are available for Northern Europe all resulting in residues of boscalid (of prothioconazole desthio) below 4 mg/kg (MRL).

The Applicant submitted 8 new studies for wheat and 9 new studies for barley indicating no exceedance of the current MRLs for these crops.

Table 7.2-9: Summary of EU reported and new data supporting the intended uses of GLOB2021dF 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
Oilseed rape	DAR 2002	N-EU	GAP on which EU a.s. assessment is based: 2 x 0.125 kg as/ha (0,5 kg pf/ha), interval 7-10 days between application, at BBCH 55-69, no PHI, outdoor	N/A				

			10x <0.05.					
	EFSA 2014	N-EU	2 x 0.25 kg as/ha (0,5 kg pf/ha), interval 8-12 days between application, at BBCH 61-69, no PHI, outdoor 11x <0.05; 0.07	0.05	0.07	R _{ber} = 0.1 R _{max} = 0.07 MRL _{OECD} = 0.07	1	yes
	DAR 2002	S-EU	GAP on which EU a.s. assessment is based: 2 x 0.25 kg as/ha (0,5 kg pf/ha), interval 7-10 days between application, at BBCH 55-69, no PHI, outdoor 2x <0.05.	N/A				
	EFSA 2014	S-EU	2 x 0.25 kg as/ha (0,5 kg pf/ha), interval 8-12 days between application, at BBCH 61-69, no PHI, outdoor 3x <0.05	N/A				
Cereals – Barley/Oat grain Barley straw	EFSA 2014	N-EU	2 x 0.35 kg as/ha (0,5 kg pf/ha), ~~interval 8-12 days between application~~ , at BBCH 30-65, 35d PHI, outdoor E: 0.02; 0.24; 0.72; 0.78; 0.89; 1.05; 1.09; 1.25; 1.29; 1.56; 1.60; 1.79 RA: 0.02; 0.24; 0.72; 0.78; 0.89; 1.05; 1.09; 1.25; 1.29; 1.56; 1.60; 1.79 1.24; 2.21; 6.43; 6.74; 7.36; 8.37; 11.9; 12.0; 12.0; 13.47; 15.07; 15.30; 22.4	N/A				
	New trials	N-EU	Trials GAP: 2 x 0.350 kg as/ha, interval 14 days between application, last at BBCH 53-61, 56d PHI, outdoor Grain:0.04, 0.61, 0.53, 0.12, 0.12, 0.47, 0.13, 0.52, 0.23 Straw: 7.65; 6.76; 9.72; 9.37; 2.13; 4.69; 8.25; 16.23; 31.98					
	Overall supporting data for cGAP	N-EU	0.04, 0.61, 0.53, 0.12, 0.12, 0.47, 0.13, 0.52, 0.23	0.23 0.12	0.61	1.193	4	Yes
	EFSA 2014	S-EU	2 x 0.35 kg as/ha (0,5 kg pf/ha), interval 8-12 days between application, at BBCH 30-65, 35d PHI, outdoor E: 0.02; 0.12; 0.27; 0.31; 0.89; 0.89; 1.05; 1.31; 1.50 RA: 0.02; 0.12; 0.27; 0.31; 0.89; 0.89; 1.05; 1.31; 1.50	N/A				

	New trials	S-EU	Trials GAP: 2 x 0.350 kg as/ha, interval 14 days between application, last at BBCH 59, 56d PHI, outdoor 0.11, 0.01, 0.13, 0.19, 0.17, 0.19, 0.06, 0.21					
	Overall supporting data for cGAP	S-EU	0.11, 0.01, 0.13, 0.19, 0.17, 0.19, 0.06, 0.21	0.134	0.21	0.416	4	Yes
Cereals – Wheat/Rye grain Wheat straw	EFSA 2014	N-EU	2 x 0.35 kg as/ha (0,5 kg pf/ha), interval 8-12 days between application, at BBCH 30-65 69, 35d PHI, outdoor E: 0.05; 0.06; 0.11; 0.12; 0.12; 0.18; 0.24; 0.27; 0.31 RA: 0.05; 0.06; 0.11; 0.12; 0.12; 0.18; 0.24; 0.27; 0.31 13.44; 15.2; 16.08; 17.6; 19.62; 20.77; 30.51; 32.9; 39.5	N/A				
	New trials	N-EU	Trials GAP: 2 x 0.350 kg as/ha, interval 14 days between application, last at BBCH 69, 35d PHI, outdoor Grain: 0.16, 0.06, 0.31, 0.21, 0.07, 0.16, 0.20, 0.14 Straw: 19.75; 29.39; 8.47; 22.16; 7.22; 19.27; 21.15; 17.23					
	Overall supporting data for cGAP	N-EU	0.16, 0.06, 0.31, 0.21, 0.07, 0.16, 0.20, 0.14	0.164 0.14	0.310	0.491	0.8	Yes
	EFSA 2014	S-EU	2 x 0.35 kg as/ha (0,5 kg pf/ha), interval 8-12 days between application, at BBCH 30-65, 35d PHI, outdoor E: 0.05; 0.05; 0.05; 0.19 RA: 0.05; 0.05; 0.05; 0.19	N/A				
	New trials	S-EU	Trials GAP: 2 x 0.350 kg as/ha, interval 14 days between application, last at BBCH 69, 35d PHI, outdoor 0.38, 0.06, 0.06, 0.16, 0.22, 0.03, 0.05, 0.06					
	Overall supporting data for cGAP	S-EU	0.38, 0.06, 0.06, 0.16, 0.22, 0.03, 0.05, 0.06	0.128	0.380	0.612	0.8	Yes

Conclusion on the magnitude of residues in plants

According to the available data, the intended uses on oilseed rape and cereals are considered acceptable, ~~for both indoor and outdoor uses.~~

zRMS comments 7.3.3.2	Oilseed rape cGAP (NEU): 2 x 0.25 kg a.s./ha/7-12 d BBCH: 55-69 PHI: - proposed GAP: 2 x 0.125 kg a.s./ha, interval 21 days, BBCH 14-69, PHI 35 Rape is a major crop in Northern Europe. Sufficient number of EU trials is available. The EU GAP represents the worse case regarding application rate. The results indicate that MRL exceedance according to Reg. (EU) 2022/1324 is not expected. Barley/Oat cGAP (NEU): 2 x 0.35 kg a.s./ha, interval 8-12 days, BBCH 30-65, PHI 35 proposed GAP: 2 x 0.125 kg a.s./ha, interval 21 days, BBCH 25-69, PHI 56 new trials by applicant: 2 x 0.35 kg a.s./ha, interval 14 days, BBCH 53-61, PHI 56 Barley and oat are the major crops in Northern Europe. Sufficient number of EU trials as well as new trials submitted by the Applicant is available. These trials are considered to be more critical compared to the proposed GAP. The results indicate that MRL exceedance according to Reg. (EU) 2022/1324 is not expected. PHI proposed by zRMS: 35 d. Wheat/Rye cGAP (NEU): 2 x 0.35 kg a.s./ha, interval 8-12 days, BBCH 30-65, PHI 35 proposed GAP: 2 x 0.125 kg a.s./ha, interval 21 days, BBCH 25-69, PHI 35 new trials by applicant: 2 x 0.35 kg a.s./ha, interval 14 days, BBCH 69, PHI 35 Wheat and rye are the major crops in Northern Europe. Sufficient number of EU trials as well as new trials submitted by the Applicant is available. These trials are considered to be more critical compared to the proposed GAP. The results indicate that MRL exceedance according to the current MRL regulation is not expected. The intended use of boscalid in GLOB2021dF is supported. This submission does not apply to SEU. The trials from the southern zone were not evaluated.
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7.2.4 Magnitude of residues in livestock

Dietary burden calculation

Boscalid is authorised for use on several crops that might be fed to livestock. The median and maximum dietary burdens were therefore calculated for different groups of livestock. For dietary burden calculation the input values of EFSA Journal (2014) were used and a worst case calculation has been performed.

Table 7.2-10: 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: Boscalid				
Cabbage	1.10	Median residue	2.82	Highest residue
Kale	1.10	Median residue	4.10	Highest residue
Apple pomace	2.52	Median residue × PF	2.52	Median residue × PF
Wheat, rye grain	0.12	Median residue	0.12	Median residue
Barley, oat grain	1.07	Median residue	1.07	Median residue
Wheat, rye bran	0.52	Median residue × PF	0.52	Median residue × PF
Wheat straw	33.7	Median residue	52.7	Highest residue
Barley, oat straw	15.0	Median residue	26.9	Highest residue
Rye straw	19.6	Median residue	39.5	Highest residue
Peas (dry)	0.13	Median residue	0.13	Median residue
Beans(dry)	0.13	Median residue	0.13	Median residue
Potatoes	0.05	Median residue	0.05	Highest residue
Turnips	0.09	Median residue	0.28	Highest residue
Rape seed meal	0.08	Median residue × PF	0.08	Median residue × PF
Linseed meal	0.10	Median residue × 2	0.10	Median residue × 2
Sunflower seed meal	0.32	Median residue × 2	0.32	Median residue × 2
Soya bean	0.05	Median residue	0.05	Median residue
Soya bean meal	0.01	Median residue × PF	0.01	Median residue × PF

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Peanuts meal	0.10	Median residue × 2	0.10	Median residue × 2

Table 7.2-11: Results of the dietary burden calculation

Animals	Median burden (mg/kg bw)	Maximum burden (mg/kg bw)	Above 0.004 mg/kg bw	Maximum burden (mg/kg DM)
Beef cattle	0.352	0.459	yes	19.14
Dairy cattle	0.439	0.615		15.99
Ram/Ewe	0.629	0.922	yes	27.7
Lamb	0.810	1.186		27.91
Pig (breeding)	0.075	0.127	yes	5.51
Pig (finishing)	0.042	0.044		1.48
Poultry broiler	0.095	0.104	yes	1.47
Poultry layer	0.355	0.507		7.41
Turkey	0.075	0.084		1.18

Recalculation of dietary burden using higher values for wheat grain and barley straw.

New data requirements		Regulation (EU) No 283/2013			
Animals	Median burden (mg/kg bw)	Maximum burden (mg/kg bw)	Above 0.004 mg /kg bw	Maximum burden (mg/kg DM)	Highest contributing commodities
Beef cattle	0,232	0,338	Yes	14,10	Wheat straw
Dairy cattle	0,342	0,518	Yes	13,47	Wheat straw
Ram/Ewe	0,550	0,846	Yes	25,39	Wheat straw
Lamb	0,704	1,079	Yes	25,39	Wheat straw
Pig (breeding)	0,041	0,094	Yes	4,09	Kale leaves
Pig (finishing)	0,033	0,044	Yes	1,48	Turnip roots
Poultry broiler	0,067	0,076	Yes	1,07	Turnip roots
Poultry layer	0,337	0,489	Yes	7,15	Wheat straw
Turkey	0,050	0,059	Yes	0,83	Turnip roots

Boscalid is a fat soluble substance and cereals grain and rape seed meal are used as a fish feeding stuff
Therefore, the fish dietary burden was calculated.

Boscalid:

Common carp: Max dietary burden 0.020 mg/kg

Category	Crop (commodity)	IFN Code	CL (%)	CP (%)	Max (%)	Residue input value	Residue (mg/kg)	Feed Composition (%)	Dietary Load (%)
Cereal Grains/Crop Seeds	Wheat (grain, extruded)	---	1.90	13.50	15.00	STMR-P	0.02	15.00	17.48
Plant By-Products	Barley (brewers dried grains)	5-00-516	7.00	25.90	15.00	STMR-P	0.02	15.00	16.60
Plant By-	Cano-	5-	3.80	38.0	10.00	STMR-	0.12	10.00	65.92

Products	la/Rape seed (meal, pre-press solvent extracted)	05-145		0		P			
By-Products	Fish meal (PC)	-	5.00	75.00	100.00	STMR-P	0	33.69	0.00
By-Products	Starch (CC)	-	0.10	0.10	100.00	STMR-P	0	19.73	0.00
By-Products	Oil (F)	-	100.00	0.00	100.00	STMR-P	0	6.58	0.00

Rainbow trout: Max dietary burden 0.015 mg/kg

Category	Crop (commodity)	IFN Code	CL (%)	CP (%)	Max (%)	Residue input value	Residue (mg/kg)	Feed Composition (%)	Dietary Load (%)
Cereal Grains/Crop Seeds	Wheat (grain, extruded)	---	1.90	13.50	10.00	STMR-P	0.02	10.00	15.44
Plant By-Products	Barley (brewers dried grains)	5-00-516	7.00	25.90	10.00	STMR-P	0.02	10.00	14.67
Plant By-Products	Canola/Rape seed (meal, pre-press solvent extracted)	5-05-145	3.80	38.00	8.00	STMR-P	0.12	8.00	69.89
By-Products	Fish meal (PC)	-	5.00	75.00	100.00	STMR-P	0	46.67	0.00
By-Products	Starch (CC)	-	0.10	0.10	100.00	STMR-P	0	13.87	0.00
By-Products	Oil (F)	-	100.00	0.00	100.00	STMR-P	0	11.46	0.00

Atlantic salmon: Max dietary burden 0.011 mg/kg

Category	Crop (commodity)	IFN Code	CL (%)	CP (%)	Max (%)	Residue input value	Residue (mg/kg)	Feed Composition (%)	Dietary Load (%)
Cereal Grains/Crop Seeds	Wheat (grain, extruded)	---	1.90	13.50	9.90	STMR-P	0.02	9.90	20.76
Plant By-Products	Barley (brewers dried grains)	5-00-516	7.00	25.90	10.00	STMR-P	0.02	10.00	19.92
Plant By-Products	Canola/Rape seed (meal, pre-press solvent extracted)	5-05-145	3.80	38.00	5.00	STMR-P	0.12	5.00	59.32
By-	Fish meal	-	5.00	75.00	100.00	STMR-	0	40.22	0.00

Products	(PC)			0	0	P			
By-Products	Starch (CC)	-	0.10	0.10	100.00	STMR-P	0	4.97	0.00
By-Products	Oil (F)	-	100.00	0.00	100.00	STMR-P	0	29.91	0.00

The results indicate no exceedance of the threshold value of 0.1 mg/kg

Livestock feeding studies (KCA 6.4.1-6.4.3)

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

Results of the livestock burden calculation show that feeding studies are required as a significant intake for ruminants, poultry and pigs is expected (> 0.004 mg/Kg bw (Reg. (EU) 283/2013).

Table 7.2-12: Overview of the values derived from livestock feeding studies

Commodity	Dietary burden		Results of the livestock feeding study						Median residue (mg/kg) ^(a)	Highest residue (mg/kg) ^(b)	Calculated MRL (mg/kg)	CF for RA ^(c)
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level (mg/kg bw/d)	No	Result for enforcement		Result for RA					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
EU data (DAR, 2002; EFSA, 2014)												
Enforcement residue definition: - muscle, fat: boscalid - kidney, liver: sum of boscalid and its hydroxy metabolite M510F01 (free and conjugated), expressed as boscalid Risk assessment residue definition: - muscle, fat: boscalid - kidney: sum of boscalid and its hydroxy metabolite M510F01 (free and conjugated), expressed as boscalid - liver: sum of boscalid, its hydroxy metabolite M510F01 (free and conjugated) and its bound residue (measured as M510F53 or M510F52), expressed as boscalid												
Pig meat	0.09	0.26	1.22	3	<0.025	<0.025	<0.025	<0.025	0.025	0.025	0.025*	1.00
			3.36	3	<0.025	<0.025	<0.025	<0.025				
Pig fat			1.22	9	0.15	0.22	0.15	0.22	0.025	0.05	0.05	1.00
			3.36	9	0.17	0.25	0.17	0.25				
Pig liver			1.22	3	0.09	0.11	-	-	0.005	0.05	0.05* (tentative) ^(h)	1.50 ^(h)
			3.36	3	0.20	0.24	-	-				
Pig kidney			1.22	3	0.11	0.11	0.11	0.11	0.05	0.05	0.05*	1.00
			3.36	3	0.18	0.24	0.18	0.24				
Ruminant meat	0.99	1.77	1.22	3	<0.025	<0.025	<0.025	<0.025	0.025	0.025	0.025*	1.00
			3.36	3	<0.025	<0.025	<0.025	<0.025				

Ruminant fat	0.09	0.18	1.22	9	0.15	0.22	0.15	0.22	0.12	0.23	0.3	1.00						
			3.36	9	0.17	0.25	0.17	0.25										
Ruminant liver			1.22	3	0.09	0.11	-	-	0.08	0.14	0.15 (tentative)	1.50 ^(h)						
			3.36	3	0.20	0.24	-	-										
Ruminant kidney			1.22	3	0.11	0.11	0.11	0.11	0.09	0.14	0.15	1.00						
			3.36	3	0.18	0.24	0.18	0.24										
Poultry meat			0.09	0.18	0.06	3	<0.02 ₅	<0.02 ₅	<0.02 ₅	<0.02 ₅	0.025	0.025	0.025*	1.00				
					0.32	3	<0.02 ₅	<0.02 ₅	<0.02 ₅	<0.02 ₅								
					1.26	3	<0.02 ₅	<0.02 ₅	<0.02 ₅	<0.02 ₅								
Poultry fat					0.09	0.18	0.06	3	<0.02 ₅	<0.02 ₅	<0.02 ₅	<0.02 ₅	0.03	0.06	0.06	1.00		
							0.32	3	0.06	0.10	0.06	0.10						
							1.26	3	0.14	0.17	0.14	0.17						
Poultry liver	0.09	0.18					0.06	3	<0.05	0.05	0.08	0.05	0.06	0.11	0.15 (tentative)	1.00		
							0.32	3	0.14	0.18	0.14	0.18						
							1.26	3	0.41	0.47	0.41	0.47						
Milk							0.41	0.86	1.22	30	0.01 ^(d)	N/A	0.01 ^(d)	N/A	0.01	0.01	0.01*	1.00
									3.36	60	0.05 ^(e)	N/A	0.05 ^(e)	N/A				
Eggs							0.09	0.18	0.06	30	<0.01 ^(f) ₎	N/A	<0.01 ^(f) ₎	N/A	0.01	0.01	0.01*	1.00
			0.32	30					<0.01 ^(f) ₎	N/A	<0.01 ^(f) ₎	N/A						
			1.26	30					0.02 ^(g)	N/A	0.02 ^(g)	N/A						

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

n.r.: Not reported

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

(F): MRL is expressed as mg/kg of fat contained in the whole product.

(a): Median residue value according to the enforcement residue definition, derived by interpolation/extrapolation from the feeding study for the median dietary burden (FAO, 2009).

(b): Highest residue value (tissues, eggs) or mean residue value (milk) according to the enforcement residue definition, derived by interpolation/extrapolation of the maximum dietary burden between the relevant feeding groups of the study (FAO, 2009).

(c): The median conversion factor for enforcement to risk assessment.

(d): Mean residue level from day 1 until day 28 (3 cows, 10 sampling days).

(e): Mean residue level from day 1 until day 28 (6 cows, 10 sampling days).

(f): Mean residue level from day 1 until day 28 (3 hens, 10 sampling days).

(g): Mean residue level from day 1 until day 28 (5 hens, 10 sampling days).

(h): Tentative conversion factor derived from a separate ruminant feeding study.

Conclusion on feeding studies

The requested uses (or the new mode of calculation) modify the theoretical maximum daily intake for animals, but regarding available feeding data, there is no risk for animal MRL to be exceeded.

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

Available data for all crops under consideration

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

Table 7.2-13: Overview of the available processing studies

Processed commodity	Number of studies	Median PF *	Median CF **	Comments	Reference
EU data					
Processing factors recommended (sufficiently supported by data)					
Apples, juice	6	0.08	1.00		PROFile
Apples, wet pomace	6	6.00	1.00		PROFile
Apples, dry pomace	4	18.35	1.00		PROFile
Apples, sauce	4	0.90	1.00		PROFile
Cherries, canned	4	0.52	1.00		EFSA, 2010
Cherries, jam	4	0.11	1.00		EFSA, 2010
Cherries, juice	4	0.39	1.00		EFSA, 2010
Plums, dried (prunes)	4	2.60	1.00		EFSA, 2010
Plums, jam	4	1.40	1.00		EFSA, 2010
Table grapes, dried (raisins)	4	2.40	1.00		DAR, 2002
Wine grapes, juice	4	0.40	1.00		DAR, 2002
Wine grapes, wet pomace	4	2.50	1.00		DAR, 2002
Strawberries, jam	4	0.44	1.00		PROFile
Strawberries, sauce	4	0.25	1.00		PROFile
Strawberries, canned	4	0.80	1.00		PROFile
Kiwi, peeled	4	0.06	1.00		PROFile
Carrots, canned	4	0.12	1.00		EFSA, 2010
Carrots, cooked	4	0.12	1.00		EFSA, 2010
Carrots, juice	4	0.12	1.00		EFSA, 2010
Tomatoes, unpeeled and canned	4	0.05	1.00		EFSA, 2010
Tomatoes, peeled and canned	4	0.05	1.00		EFSA, 2010
Tomatoes, paste	4	0.30	1.00		EFSA, 2010
Tomatoes, juice	4	0.17	1.00		EFSA, 2010
Gherkins, canned	4	0.56	1.00		EFSA, 2010

Processed commodity	Number of studies	Median PF *	Median CF **	Comments	Reference
Head cabbage, cooked	4	0.07	1.00		EFSA, 2010
Head cabbage, canned	4	0.07	1.00		EFSA, 2010
Head cabbage, sauerkraut	4	0.17	1.00		EFSA, 2010
Head cabbage, sauerkraut juice	4	0.07	1.00		EFSA, 2010
Rape seed, refined oil	4	1.26	1.00		EFSA, 2010
Rape seed, meal/press cake	4	0.56	1.00		EFSA, 2010
Barley, brewing malt	4	0.48	1.00		PROFile
Barley, beer	4	0.02	1.00		PROFile
Barley, pot/pearl	4	0.34	1.00		PROFile
Wheat, whole-meal flour	4	1.21	1.00		PROFile
Wheat, whole-meal bread	4	0.81	1.00		PROFile
Wheat, white flour	4	0.34	1.00		PROFile
Wheat, bran	4	4.32	1.00		PROFile
Indicative processing factors (limited dataset)					
Peas cooked/canned	1	<0.36	1.00		DAR, 2002
Rape seed, crude oil	2	1.11	1.00		EFSA, 2010
Soya bean, refined oil	2	0.40	1.00		EFSA, 2010
Soya bean, meal	2	0.16	1.00		EFSA, 2010

* 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.

Conclusion on processing studies

Conclusions drawn from EFSA Journal 2014;12(7):3799 are reported below:

Studies investigating the magnitude of residues in processed commodities of grapes and peas were also reported in the framework of the peer review (DAR, 2002). After boscalid was included in Annex I to Directive 91/414/EEC, studies investigating the magnitude of residues in processed commodities of apples, cherries, plums, strawberries, kiwi, carrots, tomatoes, gherkins, head cabbage, rape seed, soya bean, barley and wheat were evaluated by EFSA or by the RMS.

It is acknowledged that for most of the studies the exact details on the processing conditions are not available (meaning that the available studies might not be representative for any type of processing). Nevertheless, data are considered acceptable to derive robust processing factors for all processed commodities, except for some processed commodities of soya bean, rape seed and peas, where the number of available studies is not adequate; a minimum of 3 processing studies is normally required.

Meanwhile, further processing studies are not required for the time being as they are not expected to affect the outcome of the risk assessment.

The effect of processing on the nature of boscalid was investigated in the framework of the peer review. Studies were conducted simulating representative hydrolytic conditions for pasteurisation (20 minutes at

90°C, pH 4), boiling/brewing/baking (60 minutes at 100°C, pH 5) and sterilisation (20 minutes at 120°C, pH 6). From these studies, it was concluded that these processing conditions are not expected to have a significant impact on the composition of residues in matrices of plant origin (Germany, 2002). The relevant residue for enforcement and risk assessment in processed commodities is therefore expected to be the same as for primary crops.

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.

Field rotational crop studies (KCA 6.6.2)

Available data

No new data submitted in the framework of this application.

Table 7.2-14: 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					
Lettuce followed by green beans	2.1 kg a.s./ha (2 x 0.3 kg a.s./ha followed by 3 x 0.5 kg a.s./ha)	Cereals	Spring wheat	365, 365, 365 (3-year crop rotation)	DAR, 2002 EFSA, 2014
Carrots followed by cauliflower	1.7 kg a.s./ha (3 x 0.3 kg a.s./ha followed by 2 x 0.4 kg a.s./ha)	Cereals	Spring wheat	365, 365, 365 (3-year crop rotation)	DAR, 2002 EFSA, 2014
Winter oilseed rape	0.25 kg a.s./ha	Cereals	Winter wheat*	365	DAR, 2002 EFSA, 2014

* Sampling not performed under GLP

The rotational crop field trials were evaluated in the framework of the peer review and afterwards by EFSA (2014). Boscalid was applied the first year to lettuce (2 × 0.3 kg a.s./ha) and green beans (3 × 0.5 kg a.s./ha) and the second year to carrots (3 × 0.3 kg a.s./ha) and cauliflower (2 × 0.4 kg a.s./ha). The third year, wheat was sown in the same field. In the second field trial, boscalid was applied on winter rape (0.5 kg a.s./ha) and, 365 days after harvest, wheat was sown on the same plot.

Only wheat was analysed for residues, indicating that boscalid residues were not found above the LOQ in wheat grain when wheat was planted as a succeeding crop after vegetables or rape.

Conclusion on rotational crops studies

Conclusions drawn from EFSA Journal 2014;12(7):3799 are reported below:

Occurrence of Boscalid residues in rotational crops was already investigated during the peer review. It is concluded that metabolic patterns in primary and succeeding crops are similar and that a potential for accumulation of Boscalid residues in crops grown in rotation is expected. EFSA is aware that instead of defining risk mitigating measures, risk managers may have the interest to establish MRLs accommodating

for the uptake of residues from previously treated soils, EFSA therefore re-calculated the MRL proposals to take into account such residues. However, these MRLs are subject to a higher degree of uncertainty; Member States may therefore also consider the establishment of appropriate risk mitigation measures in order to prevent the presence of residues in rotational crops. Furthermore, residue trials after repeated application in permanent crops would be desirable as well.

zRMS comment: No new field rotational crop studies have been submitted. Due to the high persistence of boscalid in soil, it is not possible to exclude an accumulation and uptake of residues from soil in rotational crops.

The 2009 JMPR reported additional field trials investigating the uptake of boscalid in various crops in Europe, Japan and the US following an annual application rate of 2.0 to 2.15 kg a.s./ha on a bare soil (or with strawberry as primary crop, in one study) (FAO, 2010). The median and the highest boscalid residues were respectively identified in root and tuber vegetables at 0.05 and 0.37 mg/kg, in brassica vegetables at 0.035 and 0.05 mg/kg, in sweet corn cobs at 0.05 and 0.05 mg/kg, in pulses and oilseeds at 0.05 and 0.06 mg/kg, in cereal grains at 0.05 and 0.12 mg/kg, in root crop leaves and tops at 0.05 and 0.84 mg/kg, in various legume animal feeds at 0.08 and 1.46 mg/kg and in straw and fodder of cereal grains at 0.21 and 6.8 mg/kg (EFSA, 2014). The proposed GAP is two application at 0.125 kg/ha which is much below of the dose used on the bare soil. Thus, no residues of boscalid are expected after use of GLOB2021dF.

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

According to Regulation (EU) No. 283/2013 studies to determine the residue level in pollen and bee products are required to determine the residue in pollen and bee products for human consumption resulting from residues taken up by honeybees from crops at blossom.

A Guidance Document SANTE/11956/2016 rev. 9 (14 September 2018) 'Technical guidelines for determining the magnitude of pesticide residues in honey and setting Maximum Residue Levels in honey' is available and implemented by 1 January 2020.

According to this Guidance further data on crop or field/tunnel trials are required when residue in honey are expected considering the proposed uses and the properties of the active substance.

Following the different steps in this Guidance, residue in honey can be expected after pesticide application under one of the following conditions:

Residues in honey can occur:

- When a substance is applied during the flowering stage (BBCH 60-69) of a crop which is foraged by bees (the so-called melliferous crops which are attractive to bees and from which it is possible to produce honey)
- When a substance with systemic properties is applied prior to the flowering stage (before BBCH 60), including treatment of seeds, of a crop which is foraged by bees .
- from uses on non-target plants (in-field weeds and adjacent plants) when a substance is applied during the flowering period from April to September.
- from succeeding crops after application of a persistent and systemic active substance
- via honeydew collected from plant-sucking insects in forestry (such as *Picea* spp., *Abies* spp, *Pinus* spp. and *Quercus* spp.)

GLOB2021dF, containing 156 g/L Boscalid, is a fungicide with intended use on oilseed rape and cereals at BBCH 69 at the latest. According to SANTE/11956/2016 rev. 9 Appendix II, the intended crop oilseed rape is considered as a melliferous crop and GLOB2021dF is applied during the flowering stage of

oilseed rape. Cereals are considered non-melliferous.

Next to the exposure of bees to the crop itself, the exposure of bees to non-target plants (in-field flowering weeds and flowering adjacent plants (off-field flowering weeds)) need to be considered. However, if realistic farming practices (e.g. tillage and herbicide applications) are considered, weeds are not usually prevalent in arable fields. This is also confirmed by a recent publication (Maynard et al, 2014), where it was shown that less than 2% of all weeds recorded in arable crops (wheat, oilseed rape, sugar beet, sunflower, potatoes, maize, peas and beans) are at flowering growth stage. For arable crops, it can therefore be considered that the exposure of bees to in-field flowering weeds is not a realistic and relevant scenario as flowering weeds are not present in the field in significant quantities in realistic conditions.

Relating to exposure of bees to the intended melliferous crop oilseed rape itself and the potential to expect residue in honey, the applicant refers to monitoring data. In the minutes of the SCOPAFF meeting (san-te.ddg2.g.5(2019)6930972) the Commission refers to the EFSA residue monitoring programs for the years 2013-2017 and which are outlined in EFSA Scientific Reports. Those reports provide an insight into the official control activities carried out by EU Member States and provide data analysis regarding pesticide residue occurrence in the most important food products consumed including honey. During the SCOPAFF meeting, the Commission gave an overview of these findings and concluded that only a limited number of substances were found regularly in honey and that for most of them the MRLs in honey were not exceeded in any of the samples analysed.

In these monitoring results, a total of 1,590 samples of honey were analysed for boscalid residues in the reference period from 2013 to 2017. Samples originated from 25 different EU Member States and from 15 non-EU countries; most of the samples (61%, 972 samples) were from Germany. For 11% of the samples, the origin was unknown. The validated LOQs for the analytical methods used in the analysis ranged from 0.002 to 0.5 mg/kg. Overall, 27 samples (2%) contained quantifiable boscalid residues (residues above the LOQ). The highest boscalid residue measured in honey in the reference period accounted for 0.082 mg/kg, which is lower than the recently set MRL of 0.15 mg/kg in honey (Reg. (EU) 2021/590 Reg.(EU) 2022/1324). Therefore, it can be concluded that no residues of Boscalid are expected to occur in honey after the use of GLOB2021dF according to the intended GAP. No further data on crop or field/tunnel trials would be necessary.

Furthermore, reference can be made to several unprotected (non-GLP) studies on honey residues in oilseed rape after exposure to Boscalid (submitted in the dRAR (2018) and for the MRL review (EFSA, 2019)) as supportive information. Additionally a study examining the magnitude of residues of boscalid in buckwheat honey is submitted (Porączki, 2023)

Crop	Application and sampling details					Residues (mg/kg)	Reference
	Method	Rate (kg a.s./ha)	No	BBCH	Sampling (DAT)		
Winter oilseed rape	foliar treatment, indoor (tunnel test)	0.25	1	59 (before flowering)	21 26	< 0.05 < 0.05	dRAR, 2018 EFSA, 2019 <i>Rabe U. & Mackenroth C. (2004a)</i>
				65 (full flowering, evening)	8 13	< 0.05 < 0.05	
				65 (full flowering, during foraging)	7 12	0.064 < 0.05	
Winter oilseed	Foliar treat-	0.25	1	n.r.	28	< 0.05	dRAR, 2018

rape	ment, out-door				42	< 0.05	EFSA, 2019 <i>Rabe U. & Mackenroth C. (2004b)</i>
					17	< 0.05	
					15	< 0.05	
					22	< 0.05	
					29	< 0.05	
Buckwheat	Foliar treatment, semi-field (tunnel)	0.25	2	56-59 (1 st before flowering-65 (2 nd during flowering)	14	0.065	Poráčski, 2023
					14	0.13	
					16	0.019	
					17	< 0.0025	

In *Rabe U. & Mackenroth C. (2004a)*, one residue trial was conducted under semi-field conditions, i.e. using tunnel tents. Three different scenarios were tested: in the first one, boscalid (500 g/ha) was applied before flowering (BBCH 59). In the second scenario, the crop was treated at full flowering (BBCH 65) and the bee colonies were placed in the tunnels the day after the treatment. In the third scenario, the crop was also treated at full flowering, with the bee colonies being present in the tunnels already during the application of boscalid. From all scenarios, honey samples were taken twice after the start of the bee exposure. The first sampling was carried out 21, 8 or 7 days after the respective treatment, the second one after the end of flowering period which was 26, 13 and 12 days after application.

In the first and second scenario, boscalid residues in honey were all below the LOQ (0.05 mg/kg). Only in scenario three (treatment of oilseed rape during foraging activity of the bees) quantifiable residues were determined (i.e. 0.064 mg/kg) seven days after the treatment.

In *Rabe U. & Mackenroth C. (2004b)*, six additional residue trials were performed in Germany in which beehives were located near fields of oilseed rape which was treated with boscalid during flowering (application rate 200–250 g/ha). These studies were conducted in open field. Honey samples were taken 15–42 days after the application of boscalid.

In none of the trials, quantifiable residues of boscalid were found in honey.

zRMS comment: Rapeseed is melliferous crop with a flowering period between BBCH 60-69. The intended GAP includes application during flowering therefore the transfer of boscalid to honey is possible. According to EFSA (2019): *For investigating the magnitude of the residues of boscalid in honey, a sufficient number of supervised residue trials were provided (field and semi-field trials); in these trials, beehives were placed near oilseed rape fields treated with boscalid during flowering. Residues of boscalid were determined in honey at different timepoints after the treatment of the crop. The study design of the trials was considered appropriate to use the results of the trials for deriving an MRL proposal of 0.15 mg/kg. In addition, EFSA assessed the monitoring data from official EU National control programmes conducted by several Member States during 2013–2017, to check the plausibility of the residues found in the supervised residue trials. The highest boscalid residue measured in more than 1,500 honey samples was 0.082 mg/kg. The current MRL for boscalid residues in honey is 0.15 mg/kg.*

The terms of the study presented in the EFSA report are consistent with the requested GAP: field and semi-field studies were conducted and validated. For field studies, oilseed rape was treated at BBCH between 60 and 69 with 250 g/ha. For semi-field studies, oilseed rape was treated once with 500 g/ha either at BBCH 59 or at BBCH 65.

Additionally, the Applicant submitted the study on residues of boscalid in buckwheat that indicated no exceedance of the current MRL of boscalid in honey.

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

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

Chronic exposure calculations for all crops were performed using revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo v3.1) (EFSA, 2019).

The chronic risk assessment based on current MRLs (Reg.(EU) 2021/590 2022/1324) significantly exceeds ADI and represents the worst case. Therefore the refinement based the MRLs of only the crops present in the GAP of GLOB2021dF is presented. The acute risk assessment is not necessary as no ARfD value is established also based on the ADI value.

Input values for the consumer risk assessment

Table 7.2-15: Input values for the consumer risk assessment

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Risk assessment residue definition: Boscalid		
Oilseed rape	1	MRL
Barley	4	MRL
Oat	4	MRL
Rye	0.8	MRL
Wheat	0.8	MRL

Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3 2.

Table 7.2-16: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo	Not performed
IEDI (% ADI) according to EFSA PRIMo	24% (Based on DK Child)
IESTI (% ARfD) according to EFSA PRIMo*	Barley: 56% (based on children) Not necessary Wheat: 29% (based on children) Rye: 13% (based on children) Oat: 11% (based on children) Rapeseed: 3% (based on children)

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

** if national model is available

The proposed uses of Boscalid in the formulation GLOB2021dF do not represent unacceptable chronic risks for the consumer.

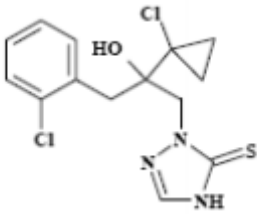
zRMS comment: The evaluator performed the worst case calculations based on the current MRL values for boscalid. The estimated long-term dietary intake is in the range of 18% to 400% of the ADI. The diet with the highest TMDI is NL toddler population (400% of ADI). The refined estimated IEDI was below the ADI. The diet with the highest IEDI is DK child population with 24% of ADI. For this diet, the highest contributor is rye with 11% of ADI. The assessment of the acute risk assessment is not necessary as no ARfD value is established.

 European Food Safety Authority EFSA PRIMo revision 3.1; 2021/01/06		Boscalid (F) LOQs (mg/kg) range from: to: Toxicological reference values ADI (mg/kg bw/day): 0.04 ARfD (mg/kg bw): not necessary 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)											
TMDI/IEDI calculation (based on average food consumption)	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
	400%	NL toddler	159.85	90%	Spinaches	54%	Apples	31%	Escaroles/broad-leaved endives		
	262%	DE child	104.94	62%	Apples	25%	Spinaches	20%	Oranges		
	229%	GEMS/Food G11	91.51	34%	Sugar canes	29%	Soybeans	20%	Potatoes		
	227%	GEMS/Food G10	90.65	41%	Lettuces	24%	Soybeans	23%	Sugar canes		
	222%	GEMS/Food G06	88.83	29%	Sugar canes	27%	Tomatoes	14%	Wheat		
	219%	NL child	87.62	31%	Spinaches	29%	Apples	17%	Potatoes		
	217%	GEMS/Food G08	86.92	28%	Sugar canes	25%	Lettuces	20%	Potatoes		
	216%	GEMS/Food G07	86.26	30%	Lettuces	27%	Sugar canes	19%	Potatoes		
	198%	IE adult	79.30	18%	Sweet potatoes	16%	Wine grapes	16%	Wine grapes		
	189%	GEMS/Food G15	75.57	23%	Sugar canes	18%	Potatoes	14%	Lettuces		
	169%	SE general	67.42	50%	Lettuces	21%	Potatoes	8%	Spinaches		
	146%	FR child 3-15 yr	58.35	17%	Oranges	14%	Other lettuce and other salad plants	13%	Spinaches		
	145%	IT adult	58.02	47%	Lettuces	20%	Other lettuce and other salad plants	12%	Spinaches		
	144%	ES adult	57.64	67%	Lettuces	9%	Spinaches	6%	Oranges		
	140%	ES child	56.09	52%	Lettuces	11%	Oranges	10%	Spinaches		
	134%	NL general	53.43	19%	Spinaches	12%	Escaroles/broad-leaved endives	12%	Potatoes		
	132%	RO general	52.72	21%	Wine grapes	19%	Potatoes	18%	Head cabbages		
	131%	IT toddler	52.42	36%	Lettuces	14%	Other lettuce and other salad plants	13%	Wheat		
	131%	PT general	51.45	31%	Wine grapes	27%	Potatoes	13%	Lettuces		
	128%	FR toddler 2-3 yr	51.20	20%	Spinaches	16%	Apples	10%	Beans (with pods)		
	124%	DE women 14-50 yr	49.43		Lettuces	13%	Apples	10%	Wine grapes		
	122%	FR adult	48.88	29%	Wine grapes	19%	Other lettuce and other salad plants	14%	Tea (dried leaves of Camellia sine		
	119%	DK child	47.56	18%	Lettuces	16%	Cucumbers	12%	Potatoes		
	119%	DE general	47.42	12%	Apples	12%	Lettuces	10%	Wine grapes		
	112%	FI 3 yr	44.79	24%	Potatoes	10%	Cucumbers	8%	Spinaches		
	104%	UK toddler	41.79	17%	Potatoes	10%	Oranges	9%	Apples		
	102%	FR infant	40.74	33%	Spinaches	10%	Potatoes	8%	Apples		
	93%	UK infant	37.10	16%	Potatoes	8%	Apples	7%	Carrots		
	92%	FI 6 yr	36.76	19%	Potatoes	10%	Lettuces	7%	Cucumbers		
	87%	UK vegetarian	34.89	18%	Lettuces	10%	Wine grapes	7%	Potatoes		
	74%	UK adult	29.44	15%	Lettuces	14%	Wine grapes	7%	Potatoes		
	67%	PL general	26.98	17%	Potatoes	10%	Apples	7%	Tomatoes		
	67%	DK adult	26.62	12%	Wine grapes	11%	Lettuces	6%	Potatoes		
	62%	FI adult	24.79	18%	Lettuces	6%	Potatoes	4%	Tomatoes		
	60%	LT adult	23.89	16%	Potatoes	9%	Apples	8%	Lettuces		
	18%	IE child	7.33	3%	Potatoes	2%	Wheat	2%	Apples		
Conclusion: The estimated TMDI/IEDI was in the range of 0 % to 399.6 % of the ADI. For 26 diet(s) the ADI is exceeded. DISCLAIMER: Dietary data from the UK were included in PRIMo when the UK was a member of the European Union.											

7.3 Prothioconazole

General data on Prothioconazole are summarized in the table below (last updated 2021/05/31 2024/11)

Table 7.3-1: 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 ₂ N ₃ OS
Molar mass	344.26 g/mol
Chemical group	Triazole
Mode of action (if available)	Prothioconazole is a fungicide belonging to DMI subgroup, a sterol demethylation (ergosterol biosynthesis)

	inhibitor, of the SBI (Sterol Biosynthesis Inhibitors) Class triazoles. It is applied post-emergence and exhibits penetrant, local and acropetal systemicity. It has both a protective and curative action. It controls a wide range of foliar diseases in cereals and oilseed rape. It can also exhibit some plant growth regulative activity such as thickening of leaves, stunting and darkening of leaf colour.
Systemic	Yes
Company	Bayer CropScience
Rapporteur Member State (RMS)	PL (previously UK)
Approval status	Approved Date of approval 01/08/2008 and reference to decision: 08/44/EC, Reg. (EU) No 540/2011
Restriction	Only uses as fungicide may be authorised.
Review Report	SANCO/3923 /07 – final, 10 December 2007 Update 2021: SANCO/3923/07 – final, 10 December 2007, 26 January 2021
Current MRL regulation	~~Reg. (EU) 2019/552~~ Reg. (EU) 2024/1318
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes
EFSA Journal : Conclusion on the peer review	Yes, EFSA (2007) 106, 1-98,
EFSA Journal: conclusion on article 12	Yes, EFSA 2014; 12(5):3689 and EFSA 2020.18(2):5999 (confirmatory data)
Current MRL applications on intended uses	EFSA 2014; 12(5):3689 EFSA 2020.18(2):5999 (confirmatory data) Cereals, oilseed rape, sugar beet Status: Reasoned opinion available

7.3.1 Stability of Residues (KCA 6.1)

Stability of residues during storage of samples

Available data

Since GLOB2021dF is sought to be used in winter and spring oilseed rape, winter and spring cereals (wheat, rye, barley, triticale, spelt and oat). Since oilseed rape and cereals were the representative uses during the EU inclusion of prothioconazole (2007) no new data is required to cover the uses of GLOB2021dF in both oilseed rape and cereals.

Storage stability data on the triazole derivative metabolites (TDMs) are part of the peer review of the TMDs confirmatory data (EFSA Journal 2018;16(7):5736) and are out of data protection.

Results of all data are summarized in the Table below.

Table 7.3-2: Summary of stability data achieved at $\leq -18^{\circ}\text{C}$ (unless stated otherwise)

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products			
Wheat (green material)	High water content	Prothioconazole: 60-180 days Prothioconazole-desthio: 540 days	EFSA, 2007
Wheat (grain)	High starch content	Prothioconazole: 60-180 days Prothioconazole-desthio: 540 days	EFSA, 2007
Wheat (straw)	Cereal straw	Prothioconazole: 60-180 days Prothioconazole-desthio: 540 days	EFSA, 2007
Apples, tomatoes, mustard leaves, wheat forage, radishes tops: roots, turnips roots, sugar beet roots, cabbages, lettuces	High water	1,2,4-triazole: 6 months TA: 53 months TAA: 53 months TLA: 48 months (lettuce only)	EFSA Journal 2018;16(7):5736 (unprotected data)
Barley, wheat	High starch	1,2,4-triazole: 12 months TA: 26 months TAA: 26 months TLA: 48 months	EFSA Journal 2018;16(7):5736 (unprotected data)
Rapeseeds, soya beans	High oil	1,2,4-triazole: 12 months (soya bean only; not stable in rape seed) TA: 26 months (soya bean only; not stable in rape seed) TAA: 53 months TLA: 48 months	EFSA Journal 2018;16(7):5736 (unprotected data)
Peas, dry; navy beans	High protein	1,2,4-triazole: No data TA: 15 months TAA: 25 months TLA: 48 months	EFSA Journal 2018;16(7):5736 (unprotected data)
Oranges	High acid	1,2,4-triazole: No data TA: No data TAA: No data TLA: 48 months	EFSA Journal 2018;16(7):5736 (unprotected data)
Barley, wheat	Cereal straw	1,2,4-triazole: 12 months TA: 53 months TAA: 40 months TLA: No data	EFSA Journal 2018;16(7):5736 (unprotected data)
Rape, Wheat	High oil (whole plant and seeds), High starch (grain and straw)	PTZ-desthio, PTZ-alpha-, -3-, -4-, -5- and -6-hydroxy-desthio: 18 months	Winter, Amann, 2020
Animal Products			
Poultry	Eggs, poultry tissue	/	
Ruminant	Milk, ruminant tissue	/	
	Milk	1,2,4-triazole: 18 months	EFSA Journal

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
		TA: No data TAA: No data TLA: No data	2018;16(7):5736) (unprotected data)
	Eggs	1,2,4-triazole: No data 12 months TA: No data TAA: No data TLA: No data	EFSA Journal 2018;16(7):5736) (unprotected data)
	Liver	1,2,4-triazole: 12 months TA: No data TAA: No data TLA: No data	EFSA Journal 2018;16(7):5736) (unprotected data)
	Muscle	1,2,4-triazole: 12 months TA: No data TAA: No data TLA: No data	EFSA Journal 2018;16(7):5736) (unprotected data)
	Fat	1,2,4-triazole: 12 months TA: No data TAA: No data TLA: No data	EFSA Journal 2018;16(7):5736) (unprotected data)
New data			
Plant products			
/	/	/	/
Animal Products			
/	/	/	/

TA: triazole alanine; TAA: triazole acetic acid; TLA: triazole lactic acid

Conclusion on stability of residues during storage

Storage stability studies of prothioconazole-desthio and the hydroxy metabolites were assessed in this section and cover the requested use on winter and spring oilseed rape and winter and spring cereals (wheat, barley, triticale, rye and spelt) for GLOB2021dF.

Storage stability data on the triazole derivative metabolites (TDMs) are part of the peer review of the TMDs confirmatory data (EFSA Journal 2018;16(7):5736) and are out of data protection.

zRMS comment: The storage stability of prothioconazole-desthio in plant samples stored under frozen conditions was investigated in the framework of the MRL review. In commodities relevant for the intended use on cereals and oilseed rape, prothioconazole and prothioconazole-desthio residues are stable for at least 18, for high water and high starch commodities and for 24 months for high oil commodities when stored at -18°C.

Storage stability data for TDMs are presented in EFSA Journal 2018;16(7):5376. Residues are stable in wheat and barley grain for 12 month - 1,2,4-Triazole, for 26 month – TA, for 26 month – TAA and for 48 month – TLA. Residues are stable in cereal straw for 12 month - 1,2,4-Triazole, for 53 month – TA, for 40 month – TAA and there is no data for TLA. However, storage stability for TLA in cereal straw is covered by acceptable storage stabilities in 5 different group matrices - 48 months.

Residues of TAA are stable for 53 month and TLA are stable for 48 month in oilseed rape.

Residues of 1,2,4-Triazole and TA are not stable in oilseed rape – data gap.

In the studies submitted by the applicant, stability was demonstrated for prothioconazole-desthio (PTZ-

desthio) and its metabolites PTZ-alpha-, -3-, -4-, -5- and -6-hydroxy-desthio in oilseed rape (whole plant and seeds) and wheat (grain and straw) upon storage at $\leq -18^{\circ}\text{C}$ for 18 months.

Stability of residues in sample extracts (KCA 6.1)

Not relevant

7.3.2 Nature of residues in plants, livestock and processed commodities

Nature of residue in primary crops (KCA 6.2.1)

Available data

No new data submitted in the framework of this application.

Table 7.3-3: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Root and tuber vegetables	Sugar beet	Phenyl	Spray treatment	0.288	4	7 days after last treatment		EFSA peer review, 2007
	Sugar beet	Triazole	Spray treatment	0.289	4	7 days after last treatment		EFSA peer review, 2007
Pulses and oilseeds	Peanut	Phenyl	Spray treatment	0.297	3	157 days after last treatment	EC 250	EFSA peer review, 2007
	Peanut	Triazole	Spray treatment	0.297	3	148 days after treatment	EC 250	EFSA peer review, 2007
Cereals	Wheat	Phenyl	Spray treatment	0.2	2	48 days after last treatment	EC 250	EFSA peer review, 2007
	Wheat	Triazole	Spray treatment	0.178 + 0.292	1	64 days after last treatment	SC 480	EFSA peer review, 2007
	Wheat	Phenyl	Seed treatment	0.2 kg a.s./100 kg seed	1	153 days		EFSA peer review, 2007
	Wheat (prothioconazole-desthio)	Triazole	Spray treatment	0.25	2	48 days after last treatment	WP 25	EFSA peer review, 2007

Summary of plant metabolism studies reported in the EU

The metabolism of prothioconazole has been investigated in wheat, sugar beet and peanut after foliar application and in wheat after seed treatment. The design of the studies was in accordance with the representative uses of the EU review and cover also the proposed GAP of the applicant. The residue extractability is high.

Prothioconazole is extensively metabolised. In a first step the sulphur group of the triazolinethione ring is oxydised to the corresponding sulfonic acid. Subsequent elimination of the sulfonic acid moiety results in prothioconazole-desthio (metabolite M04) which is consistently the major prothioconazole-structurally related metabolite in all plant parts and for all growth stages, except in nutmeat, where it was not found. This metabolite is further hydroxylated in the chlorophenyl ring forming various hydroxyl-desthio isomers and dihydroxy-olefins. Similarly, α -hydroxylation of prothioconazole-desthio was also observed. A dimerization product and other metabolites resulting from combined oxidation of the sulphur atom and hydroxylation of the chlorophenyl ring were also identified.

The residue definition proposed for monitoring is prothioconazole-desthio. The need for monitoring the parent compound was not considered necessary by the expert meeting as its toxicity and its occurrence in plants are lower.

The residue definition for risk assessment was discussed by the expert meeting. Many metabolites are structurally closely related to prothioconazole-desthio and consist mainly in hydroxylated forms of this compound. Their individual level is generally low, but their total amount suggests that they may have a significant contribution to the toxicological burden the consumer is exposed to. It was therefore assumed by the expert meeting on residues as worst case that the toxicological end points allocated to prothioconazole-desthio should also be applied to these metabolites and it was agreed to include in the residue definition for risk assessment all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, their sum being expressed as prothioconazole-desthio. The information on the metabolic pattern in primary crops after seed treatment or foliar spray, as well as in rotational crop is rather consistent and allows establishing conversion factors of 2 for cereal grain and of 3 for cereal straw. For rapeseed, it was considered appropriate to use the same factor as for cereal grains as no conversion factor could be set for oilseeds from the metabolism study in peanut.

In the peer review of the TMDs confirmatory data (EFSA Journal 2018;16(7):5736) 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 (1,2,4-triazole), TA (triazole alanine), TAA (triazole acetic acid) and TLA (triazole lactic acid). Besides the parent compound that was identified at significant residue levels in all crop groups, TA was predominantly found in the organs of storage (79% total radioactive residue (TRR) in potato tuber, 31–88% TRR in oil seeds, 8–69% TRR in cereal grains) but also in cereal straw (1–16% TRR) and in fruit crops (up to 80% TRR). TAA was only detected at significant proportions in cereal grain and straw (5–35% and 7–41% TRR, respectively) and TLA in fruit crops (up to 67% TRR) and in cereal straw (up to 43% TRR). 1,2,4-T was detected at lower levels in all crop parts (up to 12% TRR). Similar metabolic patterns were depicted both in primary and in rotational crops.

The experts of the meeting agreed that general residue definitions for risk assessment for primary, rotational crops and processed commodities can be derived based on the available data and is as follows for triazole pesticide active substances in plants;

- 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-T

zRMS comment: The metabolism of prothioconazole following foliar treatment was investigated in crops belonging to the groups of root crops, cereals and pulses/oilseeds. The metabolic pattern of prothioconazole was shown to be similar in all plant groups with prothioconazole-desthio being the predominant compound of the total residues. For enforcement monitoring for plant commodities, the residue definition is defined as ‘prothioconazole-desthio (sum of isomers)’ 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 (EFSA, 2022).

Nature of residue in rotational crops (KCA 6.6.1)

Available data

No new data submitted in the framework of this application.

Reference is made to the EU review and MRL review of prothioconazole in which the occurrence of prothioconazole residues in rotational crops was investigated. In summary, it is shown that the metabolic pathway in primary and rotational crops is comparable and significant residues in rotational crops are not expected, provided that prothioconazole is applied according to the GAPs supported by the primary metabolism studies.

In the peer review of the TMDs confirmatory data (EFSA Journal 2018;16(7):5736) 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 (1,2,4-triazole), TA (triazole alanine), TAA (triazole acetic acid) and TLA (triazole lactic acid). Besides the parent compound that was identified at significant residue levels in all crop groups, TA was predominantly found in the organs of storage (79% total radioactive residue (TRR) in potato tuber, 31–88% TRR in oil seeds, 8–69% TRR in cereal grains) but also in cereal straw (1–16% TRR) and in fruit crops (up to 80% TRR). TAA was only detected at significant proportions in cereal grain and straw (5–35% and 7–41% TRR, respectively) and TLA in fruit crops (up to 67% TRR) and in cereal straw (up to 43% TRR). 1,2,4-T was detected at lower levels in all crop parts (up to 12% TRR).

As described above, in the peer review of the TMDs confirmatory data (EFSA Journal 2018;16(7):5736) the metabolism data in primary and rotational crops the triazole active substances were shown to degrade into the common metabolites, 1,2,4-T (1,2,4-triazole), TA (triazole alanine), TAA (triazole acetic acid) and TLA (triazole lactic acid). Similar metabolic patterns were depicted both in primary and in rotational crops with TA, TAA and/or TLA often found to represent a significant portion of the total radioactive residue in the rotational crops and in addition, 1,2,4-T detected but usually at much lower level. The residue definition for enforcement for triazole pesticide active substances in plants was finally agreed to set as the triazole parent compound only since it was noted that the levels of the triazole derivative metabolites in untreated control samples were often higher than those found in the treated samples. These residues are attributed to the use of triazole-containing plant products on the test plots during previous seasons. It is also assumed that besides plant protection products other sources (such as fertilizers) potentially contribute to the presence of 1,2,4-triazole residues in agricultural soils.

zRMS comment: 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.

Nature of residues in processed commodities (KCA 6.5.1)

Available data

One new hydrolysis study has been submitted by the applicant in the framework of this application. This study is summarized in the table below. The detailed results of this study are presented in Appendix 2.

Table 7.3-4: Nature of the residues in processed commodities

Conditions (Duration, Temperature, pH)	Identified compound(s) (%)	Reference
EU data		
None available		
New data		
Hydrolysis of prothioconazole-desthio (20 minutes 90°C pH 4, 60 minutes 100°C pH 5 or 20 minutes 120°C pH 6)	Stable during processing: 20 minutes 90°C pH 4: Parent (90.7%) 60 minutes 100°C pH 5: Parent (93.3%) 20 minutes 120°C pH 6: Parent (92.9%)	Völkel W., 2020, 20180355

EFSA, 2020:

Conditions	Stable	Comment
Pasteurisation (20 min, 90°C, pH 4)	Yes	Prothioconazole degrades to prothioconazoledesthio under sterilisation process ($\leq 11\%$ AR).
Baking, brewing and boiling (60 min, 100°C, pH 5)	Yes	Prothioconazole-desthio remains stable (99.4–99.9% of AR)
Sterilisation (20 min, 120°C, pH 6)	Yes	

According to the studies as present in the confirmatory data on TDMs (EFSA Journal 2018;16(7):5736), the TDMs remained stable under the standard hydrolysis conditions simulating processing of pasteurisation, baking, brewing and boiling and sterilisation.

Conclusion on nature of residues in processed commodities

The results of the hydrolysis study indicate that for prothioconazole-desthio, the nature of the residue in the processed commodity is expected to be identical to that in the raw agricultural commodity following pasteurisation, baking, brewing and boiling, and sterilisation.

zRMS comment: Nature of residue in processed commodities was investigated at EU level. Prothioconazole degrades to prothioconazole-desthio which remains stable under the different hydrolytic conditions. The new hydrolysis study confirmed that prothioconazole-desthio was hydrolytically stable during pasteurisation, baking/brewing/boiling and sterilisation. According to EFSA (2018) the TDMs are stable under hydrolysis conditions simulating baking/brewing/boiling, pasteurisation and sterilisation.

Table 7.3-5: Summary of the nature of residues in commodities of plant origin

Endpoints

Plant groups covered	Cereals (wheat), Oilseeds (peanut), Sugar beets (sugar beet)
Rotational crops covered	Cereals (wheat) / Leafy vegetables (swiss chard) and Root crops (turnips)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Hydrolysis
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes
Plant residue definition for monitoring	Prothioconazole-desthio (sum of isomers) (EFSA, 2007)
Plant residue definition for risk assessment	Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety) expressed as prothioconazole-desthio (EFSA, 2007) Triazole alanine (TA) and triazole lactic acid (TLA) triazole acetic acid (TAA) 1,2,4-triazole (1,2,4-T)
Conversion factor from enforcement to RA	EFSA, 2007: 2 (cereal grain and oilseeds)

Nature of residues in livestock (KCA 6.2.2-6.2.5)

Available data

No new data submitted in the framework of this application.

Summary of livestock metabolism studies reported in the EU

A goat metabolism study indicated that prothioconazole is rapidly adsorbed and largely excreted. It was found unchanged in all tissues in amounts varying from 1 % (milk) and 18 % (kidney) of the TRR. About 10 metabolites were identified, suggesting a similar metabolic pathway to that observed in rats. However as animals are more likely to be exposed to the prothioconazole-desthio metabolite, the metabolism of this compound was also investigated. Its metabolic pathway consists in various types of hydroxylation affecting the chlorophenyl ring leading to metabolites existing in free form or as glucuronide or sulphate conjugates. Prothioconazole-desthio is found as major constituent of the TRR in liver (31 % of the TRR), fat (14 % of the TRR), in lesser amount in muscle (2 % of the TRR and kidney (7 % of the TRR), and was not found in milk. Its glucuronide conjugate was found in milk (6 % of the TRR) and in higher amounts in kidney (24 % of the TRR). About 10 different compounds were in total identified of which metabolite JAU 6476-desthio-3,4-dihydroxy-diene (M32) as free or glucuronide conjugate forms was the most abundant (10%, 6%, 32%, 23% and 27 % of the TRR in milk, liver, muscle, kidney and fat respectively).

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

For risk assessment, since all the metabolites are structurally related to prothioconazole-desthio and con-

sist 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).

As for plant commodities, conversion factors between residue definition for monitoring and for risk assessment were established. Based on the ruminants feeding study MRLs were set at the LOQ for all matrices, except for liver and kidney, where MRLs of respectively 0.05 and 0.02 mg/kg were proposed. Since only the residues of prothioconazole-desthio were determined, conversion factors for enforcement to risk assessment of 2 and 9 were established respectively for liver and kidney based on the goat metabolism study with administration of prothioconazole-desthio. It is noted that no conversion factor was set for milk, muscle and fat as the residue levels in these matrices are expected to be negligible (<0.01 mg/kg) at the calculated dietary burden.

Based on the finding of the livestock metabolism studies with the parent triazole fungicides and triazole alanine as described in the TDMs confirmatory data (EFSA Journal 2018;16(7):5736) the following triazole metabolites are considered for inclusion in the residue definition for products of animal origin for risk assessment purposes: T, TA, TAA and TLA together with the parent and any other relevant metabolite exclusively linked to the parent compound.

A residue definition for enforcement is not proposed. As outlined above for the nature of the residue in plants, the magnitude of the residue is not linked to a specific GAP and higher residue levels were often found in untreated control samples. This is likely to be due to the use of triazole pesticides in previous growing seasons. It is also assumed that besides plant protection products other sources (such as fertilizers, where it is used as a fertiliser) potentially contribute to the presence of 1,2,4-triazole residues in agricultural soils. Consequently, a residue definition for enforcement would not be appropriate.

Conclusion on metabolism in livestock

European data are sufficient to support the intended use of Prothioconazole on sugar and fodder beets, cereals (wheat, barley, triticale, rye, oat and spelt) and winter and spring oilseed rape.

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

Table 7.3-6: 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 (ruminants)
Animal residue definition for monitoring	Sum of prothioconazole-desthio (sum of isomers) and its glucuronide conjugate, expressed as prothioconazole-desthio (EFSA, 2007)
Animal residue definition for risk assessment	Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety expressed as prothioconazole-desthio (EFSA, 2007) Triazole alanine (TA) and triazole lactic acid (TLA) triazole acetic acid (TAA) 1,2,4-triazole (1,2,4-T)
Conversion factor	2 Liver 9 Kidney

Metabolism in rat and ruminant similar	Yes
Fat soluble residue	Yes (log P _{ow} for prothioconazole-desthio = 3.04)

EFSA (2014):

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. 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).

EFSA (2018):

Table 4: Agreed residue definitions for triazole pesticide active substances in animal matrices

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

RD: residue definition; TA: triazole alanine; TAA: triazole acetic acid; TLA: triazole lactic acid.

7.3.3 Magnitude of residues in plants (KCA 6.3)

The residue data on cereals and oilseed rape were evaluated during the EU review of prothioconazole. Reference to these studies can be made to support the intended use of GLOB2021dF.

Cereals

In the DAR the results of 10 11 trials in Northern Europe and 8 trials in Southern Europe showed no residues at harvest in wheat grains (below the LOQ of <0.01 mg/kg). In barley grains, 9 trials are available for Northern Europe all resulting in residues (of prothioconazole-desthio) below the LOQ of <0.01 mg/kg. Eight trials were submitted supporting the use in barley in Southern region and showed measurable residues (of prothioconazole-desthio) in some instances, but not exceeding 0.02 mg/kg. A lot of information is available for residues in straw of both wheat and barley in both Northern and Southern regions, ranging from 0.08 to 1.1 mg/kg at normal harvest time.

These trials support the GAP applied for in this submission as 3 treatments (wheat) at up to 0.200 kg a.i./ha and 2 treatments (barley) at 0.175 kg a.i./ha were described with the last treatment performed at BBCH 69 (wheat) and at BBCH 61 (barley). This application scheme is therefore more worst case than the GAP proposed by the applicant which is therefore covered by the trials in the EU review. Moreover, these trials show that residues in grain and straw following treatment at up to 0.200 kg a.i./ha were always below the current MRLs.

It is apparent from these residue trials supplied that prothioconazole-desthio is an appropriate residue definition (risk assessment and monitoring) for cereal grains. It is also noted that for residues in green material and straw whilst prothioconazole-desthio is the most significant residue the hydroxyl metabolites are also present at significant levels. To address this within the risk assessment conversion factors between prothioconazole-desthio and total residues for cereal straw (from foliar applications) have been derived. It is considered that the data presented below supports the conversion factor of 3 for cereal straw previously proposed (based on DAR metabolism data) in EFSA Journal 2014; 12 (5):3689.

In addition to the trials above, additional trials were performed from 2017 up to 2022 in NEU and SEU in barley and wheat and analysing prothioconazole-desthio, its hydroxy metabolites and TDMs in grain, straw and whole plants. These trials were performed with an EC formulation. In line with SANTE 2019/12752, EC and SC formulations are considered equivalent. Therefore the use of trials conducted with the EC formulation containing prothioconazole, support the use of GLOB2021dF.

In Northern Europe, prothioconazole-desthio and its hydroxy metabolites are each measured in 7 residue trials for barley and 8 for wheat.
In Southern Europe, prothioconazole-desthio and its hydroxy metabolites are each measured in 10 residue trials for barley and 8 for wheat.

Additionally in Northern and Southern Europe all TDMs are measured in 8 residue trials for barley. For wheat TDMs are measured in 8 residue trials in Southern Europe and in 6 residue trials in Northern Europe while 2 Northern Europe residue trials are currently ongoing in which TDMs will be analysed. Even though that the results of the last 2 residue trials aren't available yet, the 6 northern EU trials clearly show that lower levels of TDMs are found compared to the worst case HR and STMR for each TDM derived by selecting the highest STMR and HR from all individual datasets for each commodity as presented in the TDM confirmatory data (EFSA Journal, 2018; 16(7):5376). This proves that the intended use on wheat results in lower residue levels compared to the worst case residue trials available in the TDM confirmatory data. The 6 available northern residue trials in wheat on TDMs together with the large data set on wheat in the TDM confirmatory data thus clearly show the safe use of GLOB2021dF in wheat.

In summary in **northern Europe** the following trials were performed at the indicated GAP covering the intended GAP and analysis the different analytes as indicated in the table below:

Study report number	Crop	Number of trials	Analytes measured at harvest *	GAP
EGL-17-28967 Grall E., 2017	Barley	1 DC trials and 2 RH trials	M04, M14, M15, M16, M17, M18, prothioconazole-desthio (sum of isomers)	2x 195 g as/ha 14d interval PHI 35d
EGL-20-42539 Grall E., 2022	Barley	4 DC trials	M04, M14, M15, M16, M17, M18, Prothioconazole-desthio (sum of isomers) 1,2,4-T, TA, TAA, TLA	2x 195 g as/ha 14d interval PHI 35d
IF21-05704459 Thirkell, 2022	Barley	1DC and 1RH	1,2,4-T, TA, TAA, TLA	2x 195 g as/ha 2 nd application at BBCH61 12d interval
EGL-20-45487 Grall E. 2022-2020	Barley	2 RH	M04, M14, M15, M16, M17, M18, Prothioconazole-desthio (sum of isomers) 1,2,4-T, TA, TAA, TLA	2x 195 g as/ha 14d interval PHI 35d
EGL-17-28966 Grall E. 2019	Wheat	2 DC and 2 RH	M04, M14, M15, M16, M17, M18, Prothioconazole-desthio (sum of isomers)	2x 195 g as/ha 14d interval PHI 35d
EGL-18-32944 Grall E. 2019	Wheat	2 DC and 2 RH	M04, M14, M15, M16, M17, M18, Prothioconazole-desthio (sum of isomers)	2x 195 g as/ha 14d interval PHI 35d
EGL-20-42538 Grall E. 2019	Wheat	1 DC	M04, M14, M15, M16, M17, M18, Prothioconazole-desthio (sum of isomers)	2x 195 g as/ha 14d interval

			1,2,4-T, TA, TAA, TLA	2 nd application at BBCH69
IF21-05705310 Thirkell C. 2021	Wheat	2 DC and 4 RH	1,2,4-T, TA, TAA, TLA	2x 195 g as/ha 11-17d interval 2 nd application at BBCH69
IF22-06125006 22-00143 Thirkell C. 2022	Wheat	1 DC and 1 RH	1,2,4-T, TA, TAA, TLA	2x 195 g as/ha 13d interval 2 nd application at BBCH69

* M04 = prothioconazole-desthio, M14 = Prothioconazole-3-hydroxy-desthio, M15 = Prothioconazole-4-hydroxy-desthio, M16 = Prothioconazole-5-hydroxy-desthio, M17 = Prothioconazole-6-hydroxy-desthio, M18 = Prothioconazole-alpha-hydroxy-desthio.

1,2,4-T = 1,2,4-triazole, TA = triazolylalanine, TAA = triazole acetic acid, TLA = triazole lactic acid

In summary in **southern Europe** the following trials were performed at the indicated GAP covering the intended GAP and analysis the different analytes as indicated in the table below:

Study report number	Crop	Number of trials	Analytes measured at harvest *	GAP
EGL-17-28967 Grall, 2017	Barley	2DC trials + 2 RH trials	M04, M14, M15, M16, M17, M18, Prothioconazole-desthio (sum of isomers)	2x 195 g as/ha 14d interval PHI 35d
EGL-20-42539 Grall, 2020	Barley	2 DC trials and 4 RH trials	M04, M14, M15, M16, M17, M18, Prothioconazole-desthio (sum of isomers) 1,2,4-T, TA, TAA, TLA	2x 195 g as/ha 14d interval PHI 35d
IF21-05707589 21-00229 Mayer, 2022	Barley	2 DC	1,2,4-T, TA, TAA, TLA	2x 195 g as/ha 2 nd application at BBCH61 12d interval
EGL-17-28966 Grall E. 2019	Wheat	2 DC and 2 RH	M04, M14, M15, M16, M17, M18, Prothioconazole-desthio (sum of isomers)	2x 195 g as/ha 14d interval PHI 35d
EGL-18-32944 Grall E. 2019	Wheat	2 DC and 2 RH	M04, M14, M15, M16, M17, M18, Prothioconazole-desthio (sum of isomers)	2x 195 g as/ha 14d interval PHI 35d
IF21-05707610 21-00227 Gabriel E., 2022	Wheat	4 DC and 4 RH	1,2,4-T, TA, TAA, TLA	2x 195 g as/ha 11-16d interval

				2 nd application at BBCH69
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* M04 = prothioconazole-desthio, M14 = Prothioconazole-3-hydroxy-desthio, M15 = Prothioconazole-4-hydroxy-desthio, M16 = Prothioconazole-5-hydroxy-desthio, M17 = Prothioconazole-6-hydroxy-desthio, M18 = Prothioconazole-alpha-hydroxy-desthio

These studies are summarized in the Table below. These trials show that residues following 2 treatments at up to 0.125 kg a.i./ha were always below the current MRLs for prothioconazole-desthio (sum of isomers).

No MRLs are currently set at EU level for the TDMs and comparison is therefore made to the worst case HR and STMR for each TDM derived by selecting the highest STMR and HR from all individual datasets for each commodity as presented in the TDM confirmatory data (EFSA Journal, 2018; 16(7):5376). In all residue trials, no exceedance of the HR or STMR occurred for each individual TDM. Studies only measuring TDMs, are not included in the summary table (7.2-6) as they are not used for MRL setting. For completeness, the results can be found in Appendix 2.

The trials referred to were conducted in wheat and barley for both Northern and Southern Europe. According to SANTE/2019/12752, result from wheat and barley can be extrapolated to cover both rye and triticale.

The detailed assessment of these studies is presented in Appendix 2.

Oilseed rape

In the DAR 12 valid trials were performed (8 for NEU and 4 for SEU). Residues in seeds were low, ranging from below the LOQ of <0.01 mg/kg to 0.02 mg/kg. The Highest Residue level (HR) found in rape straw was 0.20 mg/kg.

These trials support the GAP applied for in this submission as 2 treatments at up to 0.190 kg a.i./ha with the last treatment occurring between BBCH 69 and 78 were described. Moreover, these trials show that residues in seed and straw following 2 treatments at up to 0.190 kg a.i./ha were always below the current MRLs.

In addition to the trials above, residue trials were performed from 2017 up to 2022 in NEU and SEU in oilseed rape analysing prothioconazole-desthio, its hydroxy metabolites and TDMs in whole plant, pods, rest of plants, seed and straw. In Northern Europe, prothioconazole-desthio, its hydroxy metabolites and TDMs are each measured in 8 residue trials. In Southern Europe, prothioconazole-desthio and its hydroxy metabolites are each measured in 8 residue trials whereas the TDMs are currently measured in 6 residue trials but will additionally be analysed in 2 ongoing trials. Even though that the results of the last 2 residue trials aren't available yet, the 6 southern EU trials clearly show that lower levels of TDMs are found compared to the worst case HR and STMR for each TDM derived by selecting the highest STMR and HR from all individual datasets for each commodity as presented in the TDM confirmatory data (EFSA Journal, 2018; 16(7):5376). This proves that the intended use on oilseed rape results into lower residue levels compared to the worst case residue trials available in the TDM confirmatory data. The 6 available southern residue trials in oilseed rape on TDMs together with the large data set on oilseed rape in the TDM confirmatory data thus clearly show the safe use of GLOB2021dF on oilseed rape.

In summary in northern Europe the following trials were performed at the indicated GAP covering the intended GAP and analysis the different analytes as indicated in the table below:

Study report number	Crop	Number of trials	Analytes measured at harvest *	GAP
IF21-0570733 21-00230 Meyer, 2021	Oilseed rape	4 RH and 4 DC	1,2,4-T, TA, TAA, TLA	2x 180 g as/ha 10-21d before BBCH 69 and at BBCH69
RDE-17-28968 Delmotte, 2017	Oilseed rape	2 RH and 2 DC	M04, M14, M15, M16, M17, M18, Prothioconazole-desthio (sum of isomers)	2x 180 g as/ha 1 st appl.: 14+-2d before application 2 2 nd appl.: 54 +- 3d PHI
RDE-18-32946 Delmotte, 2019	Oilseed rape	1 RH and 1 DC	M04, M14, M15, M16, M17, M18, Prothioconazole-desthio (sum of isomers)	2x 180 g as/ha 1 st appl.: 14+-2d before application 2 2 nd appl.: 56 +- 3d PHI
RDE-19-38550 Delmotte, 2019	Oilseed rape	1 RH and 1 DC	M04, M14, M15, M16, M17, M18, Prothioconazole-desthio (sum of isomers)	2x 180 g as/ha 1 st appl.: 14+-2d before application 2 2 nd appl.: BBCH 69

* M04 = prothioconazole-desthio, M14 = Prothioconazole-3-hydroxy-desthio, M15 = Prothioconazole-4-hydroxy-desthio, M16 = Prothioconazole-5-hydroxy-desthio, M17 = Prothioconazole-6-hydroxy-desthio, M18 = Prothioconazole-alpha-hydroxy-desthio.

1,2,4-T = 1,2,4-triazole, TA = triazolylalanine, TAA = triazole acetic acid, TLA = triazole lactic acid

In summary in southern Europe the following trials were performed at the indicated GAP covering the intended GAP and analysis the different analytes as indicated in the table below:

Study report number	Crop	Number of trials	Analytes measured at harvest *	GAP
IF21-05707367 21-00231 Stolze, 2022	Oilseed rape	3 RH and 3 DC	1,2,4-T, TA, TAA, TLA	2x 180 g as/ha 1 st appl.: 13-14 before application 2 2 nd appl.: at BBCH 69
RDE-17-28968 Delmotte, 2017	Oilseed rape	2 RH and 2 DC	M04, M14, M15, M16, M17, M18, Prothioconazole-desthio (sum of isomers)	2x 180 g as/ha 1 st appl.: 14+-2d before application 2 2 nd appl.: 54 +- 3d PHI
RDE-18-32946	Oilseed	2 RH and 2 DC	M04, M14, M15, M16, M17, M18,	2x 180 g as/ha

Delmotte, 2019	rape		Prothioconazole-desthio (sum of isomers)	1 st appl.: 14+-2d before application 2 2 nd appl.: 56 +- 3d PHI
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Studies only measuring TDMs, are not included in the summary table (7.2-6) as they are not used for MRL setting. For completeness, the results can be found in Appendix 2.

In table 7.2-9 below the following abbreviations are used:

M04 = prothioconazole-desthio,

M14 = Prothioconazole-3-hydroxy-desthio,

M15 = Prothioconazole-4-hydroxy-desthio,

M16 = Prothioconazole-5-hydroxy-desthio,

M17 = Prothioconazole-6-hydroxy-desthio,

M18 = Prothioconazole-alpha-hydroxy-desthio,

1,2,4-T = 1,2,4-triazole,

TA = triazolylalanine,

TAA = triazole acetic acid,

TLA = triazole lactic acid,

prothioconazole-desthio (sum of isomers) = refers to the residue definition of risk assessment of prothioconazole and is the sum of M04, M14, M15, M16, M17, M18

Table 7.3-7 Summary of EU reported and new data supporting the intended uses of GLOB2021dF and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg)	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Wheat, rye, triticale	Grall E., 2019-01 EGL-17-28966	N-EU	Prothioconazole 300EC Prothioconazole-desthio (sum of isomers): Grain: <LOD, <LOQ, <LOQ, <LOQ Straw: 0.666, 1.13, 2.322, 3.529	N/A				
	Grall E., 2019-02 EGL-18-32944	N-EU	Prothioconazole 300EC Prothioconazole-desthio (sum of isomers): Grain: <LOD, 0.010, <LOQ, 0.024 Straw: 0.899, 0.774, 1.340, 1.572					
	Grall E., 2019-03 EGL-20-42538	N-EU	Prothioconazole 300EC Prothioconazole-desthio (sum of isomers): Grain: <LOQ Straw: 0.151					
	Overall supporting data for cGAP	N-EU	Grain: 1x < LOD, 6x < LOQ, 1x 0.010, 1x 0.024 Straw: 0.666, 1.130, 2.322, 3.529, 0.899, 0.774, 1.340, 1.572, 0.151	0.01 (1.130 0.899)	0.024 (3.529)	0.033	0.1 -	Yes
Barley, oats	Grall E., 2017 EGL-17-28967	N-EU	Prothioconazole 300EC Prothioconazole-desthio (sum of isomers): Grain: 0.074 <LOQ, LOQ Straw: 0.305, 0.330, 0.574	N/A				
	Grall E., 2022 EGL-20-	N-EU	Prothioconazole 300EC Prothioconazole-desthio (sum of isomers): Grain: <LOQ, <LOQ, <LOD, <LOQ,	N/A				

	42539		Straw: 0.320, 0.077, 0.101, 0.028,					
	Overall supporting data for cGAP	N-EU	Grain: 0.074, 5x < LOQ, <LOD Straw: 0.330, 0.305, 0.574, 0.320, 0.077, 0.101, 0.028	0.010 (0.305 0.32)	0.074 (0.574)	0.117	0.2 -	Yes
Rape	Delmotte R., 2017 RDE-17-28968	N-EU	HA 610 01 F Prothioconazole-desthio (sum of isomers): Seeds: 0.024, <LOQ, <LOQ, <LOQ Straw: 0.026, 0.303, 0.141, 0.328					
	Delmotte R., 2019-01 RDE-18-32946	N-EU	HA 610 01 F Prothioconazole-desthio (sum of isomers): Seeds: < LOQ, < LOQ Straw: 0.372, 0.018					
	Delmotte R., 2019-02 RDE-19-38550	N-EU	HA 610 01 F Prothioconazole-desthio (sum of isomers): Seeds: < LOQ, < LOQ Straw: 0.050, 0.035					
	Overall supporting data for cGAP	N-EU	Seeds: 0.024, 7x < LOQ Straw: 0.026, 0.303, 0.141, 0.328, 0.372, 0.018, 0.050, 0.035	0.010 (0.096 0.35)	0.024 (0.372)	0.032	0.15 -	Yes
Wheat, rye, triticale	Grall E., 2019-01 EGL-17-28966	S-EU	Prothioconazole 300EC Prothioconazole-desthio (sum of isomers): Grain: <LOD, <LOQ, <LOD, <LOD Straw: 1.245, 0.696, 2.94, 4.919					

	Grall E., 2019-02 EGL-18- 32944	S-EU	Prothioconazole 300EC Prothioconazole-desthio (sum of isomers): Grain: <LOQ, <LOQ, <LOQ, <LOQ Straw: 0.567, 1.487, 2.616, 1.155					
	Overall supporting data for cGAP	S-EU	Grain: 2x < LOD, 6x < LOQ Straw: 1.245, 0.696, 2.940, 4.919, 0.567, 1.487, 2.616, 1.156	0.010 ~~(1.366)~~ 2.743)	0.010 (4.919)	0.010	0.15 -	Yes
Barley, oats	Grall E., 2017 EGL-17- 28967	S-EU	Prothioconazole 300EC Prothioconazole-desthio (sum of isomers): Grain: <LOQ, 0.049, <LOQ, <LOQ Straw : 1.891, 6.823, 2.160, 0.848					
	Grall E., 2020 EGL-20- 42539	S-EU	Prothioconazole 300EC Prothioconazole-desthio (sum of isomers): Grain: 0.019, <LOQ, 0.040, 0.020, <LOD, <LOQ Straw : 2.624, 1.211, 0.133, 1.295, 0.734, 0.404					
	Overall supporting data for cGAP	S-EU	Grain: 5x <LOQ, 0.049, 0.019, 0.040, 0.020, < LOD Straw: 1.891, 6.823, 2.160, 0.848, 2.624, 1.211, 0.133, 1.295, 0.734, 0.404,	0.010 ~~(1.253)~~ 1.917)	0.049 (6.823)	0.078	0.2 -	Yes
Rape	Delmotte R., 2017 RDE-17- 28968	S-EU	HA 610 01 F Prothioconazole-desthio (sum of isomers): Seeds: < LOQ, 0.035, < LOQ, < LOQ Straw: 0.149, 0.946, 0.182, 0.502					
	Delmotte R., 2019 RDE-18- 32946	S-EU	HA 610 01 F Prothioconazole-desthio (sum of isomers): Seeds: < LOQ, < LOQ, < LOQ, 0.039 Straw: 0.103, 0.088, 0.249, 0.730					
	Overall supporting data for	S-EU	Seeds: 6x < LOQ, 0.035, 0.039 Straw: 0.149, 0.946, 0.182, 0.502, 0.103, 0.088, 0.249, 0.730	0.010 ~~(0.216)~~ 0.3)	0.039 (0.946)	0.067	0.15 -	Yes

	cGAP							

* < LOQ

** Not considered feed items, no MRL available

*** TDMs are present in the untreated due to fertilizer use and/or previous use of triazole active substances. These background levels of TDMs as found in the untreated are not caused by the application of the product in the residue trial and must therefore be subtracted of the residue levels found in the treated plot. This subtraction is already taken into account in the values of the TDMs of sugar beet roots in this table and in the overall supporting data for cGAP of all other uses.

**** No MRL available, worst case STMR and HR for each TDM is given and which has been derived by selecting the highest STMR and HR from all individual datasets for the commodity as presented in the TDM confirmatory data (EFSA Journal, 2018; 16(7):5376)

The applicant submitted new studies on residues in barley. In one field trial, the residues for barley were 0.07 mg/kg, which exceeds the MRL for oats (0.05 mg/kg). The exceedance occurred at a dose above 200 g a.s./ha and PHI 35. The application in evaluated GAP is 125 g a.s./ha and PHI 56 days. The risk of exceeding the MRL of 0.05 mg/kg is negligible.

Studies only measuring TDMs, are not included in the summary tables above as they are not used for MRL setting. For completeness, a summary of the results of the new supervised field residues submitted by the applicant can be found in the table 7.2-11 7.3-8 below. The results obtained in the new residue trials for TDMs are similar with those of the confirmatory data. Additional information of these trials is presented in Appendix 2.

Table 7.3-8: Summary of EU reported and new data supporting the intended uses of GLOB2021F and conformity to existing MRL - TDMs

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)
Cereal grain Wheat 8 trials (4 NEU/4 SEU) Barley 8 trials (4 NEU/4 SEU) 17 trials NEU 16 trials SEU	Confirmatory data (UK, 2018)	N-EU S-EU	Highest STMR and HR from all available GAPs on cereals as presented in the TDM confirmatory data.	Cereals 1,2,4 T: 0.050 TA: 0.621 TAA: 0.790 TLA: 0.022 Wheat grain T: 0.01 Barley grain 0.01	Cereals 1,2,4 T: 0.080 TA: 2.200 TAA: 1.730 TLA: 0.160 Wheat grain T: 0.01 Barley grain 0.011

New trials				TA: 0.434 0.208 TAA: 0.189 0.107 TLA: na 0.01	TA: 1.069 0.440 TAA: 0.517 0.32 TLA: na 0.01
	EGL-20-42539 Grall, E. 2022 (Barley)	NEU (4 trials)	1,2,4 T: 4 x < 0.01 TA: 0.826, 0.0848, 0.164, 0.155 TAA: 0.243, 0.0347, 0.0777, 0.0923 TLA: 0.0189, 2x<0.01, 0.0107		
	EGL-20-45487 Grall, E. 2022 2020 (Barley)	NEU (2 trials)	1,2,4 T: 2 x <0.01 TA: 0.316, 0.122 TAA: 0.260, 0.05 TLA: 2 x <0.01		
	IF21-05704459 Thirkell C. 2022 (Barley)	NEU (2 trials)	1,2,4 T: 2 x <0.01 TA: 0.23, 0.13 TAA: 0.089, 0.066 TLA: 2 x <0.01	Wheat grain Barley grain T: 0.01 0.01 TA: 0.52 0.5 TAA: 0.189 0.1 TLA: 0.01 0.01	Wheat grain Barley grain T: 0.01 0.011 TA: 1.1 0.316 TAA: 0.38 0.260 TLA: 0.01 0.018
	EGL-20-42538 Grall, E. 2019 (wheat)	NEU (1 trial)	1,2,4 T: <0.01 TA: 0.467 TAA: 0.0568 TLA: <0.01		
	IF21-05705310 21-00226 Thirkell C. 2021 (wheat)	N-EU (6 trials)	1,2,4 T: 6 x < 0.01 TA: 0.54, 1.1, 0.45, 0.52, 0.50, 0.27 TAA: 0.29, 0.38, 0.087, 0.38, 0.12, 0.068 TLA: 6 x < 0.01	1,2,4 T: 0.01 TA: 0.2 TAA: 0.09 TLA: 0.01	1,2,4 T : 0.01 TA: 1.10 TAA: 0.38 TLA: 0.10
	IF22-06125006 22-00143 Thirkell C. 2022 (wheat)	N-EU (2 trials)	1,2,4 T: 2 x < 0.01 TA: 0.28, 0.61 TAA: 0.057, 0.15 TLA: 2 x < 0.01		
	EGL-20-42539 Grall, E. 2022 (Barley)	SEU (6 trials)	1,2,4 T: 6 x < 0.01 TA: 0.162, 0.156, 0.348, 0.083, 0.0707, 0.0448 TAA: 0.104, 0.0161, 0.132, 0.0283, 0.0622, 0.0311 TLA: 5x<0.01, 0.0132		
	IF21-05707589	SEU	1,2,4 T: 2 x < 0.01		

	Meyer, M. 2022 (Barley)	(2 trials)	TA: 0.14, 0.21 TAA: 0.089, 0.062 TLA: 0.026, <0.01		
	IF21-05707610 21-00227 Gabriel E., 2022 (wheat)	S-EU (8 trials)	1,2,4 T: 8 x < 0.01 TA: 0.48, 0.30, 0.31, 0.32, 0.17, 0.41, 0.23, 0.16 TAA: 0.16, 0.11, 0.089, 0.15, 0.037, 0.33, 0.09, 0.074 TLA: 8 x < 0.01		
Cereal Straw Wheat 8 trials (4 NEU/4 SEU) Barley 8 trials (4 NEU/4 SEU) 17 trials NEU 16 trials SEU	Confirmatory data (UK, 2018)	N-EU S-EU	Highest STMR and HR from all available GAPs on cereals as presented in the TDM confirmatory data.	~~Straw :~~ ~~1,2,4 T: 0.05~~ ~~TA: 0.65~~ ~~TAA: 0.78~~ ~~TLA: 1.1~~ Wheat straw Barley straw T: 0.015 0.018 TA: 0.079 2.17 TAA: 0.307 0.062 TLA: na 0.05	
New trials	EGL-20-42539 Grall, E. 2022 (Barley)	NEU (4 trials)	1,2,4 T: 4 x < 0.01 TA: 0.13, <0.01, 0.0172, 0.0326 TAA: 0.194, 0.0116, 0.0303, 0.0463 TLA: 0.0125, 0.0144, 0.0244, 0.0962		
	EGL-20-45487 Grall, E. 2022 2020 (Barley)	NEU (2 trials)	1,2,4 T: 2 x < 0.01 TA: 0.032, 0.122 TAA: 0.152, <0.01 TLA: 0.145, <0.01	1,2,4 T: 0.01 TA: 0.03 TAA: 0.04 TLA: 0.03	1,2,4 T: 0.01 TA: 0.22 TAA: 0.33 TLA: 0.22
	IF21-05704459 Thirkell C. 2022	NEU (2 trials)	1,2,4 T: 2 x <LOD TA: 0.029, 0.013 TAA: 0.026, 0.025		

	(Barley)		TLA: 0.018, 0.017		
	EGL-20-42538 Grall, E. 2019 (wheat)	NEU (1 trial)	1,2,4 T: <0.01 TA: 0.0352 TAA: 0.0767 TLA: 0.0741		
	IF21-05705310 21-00226 Thirkell C. 2021 (wheat)	N-EU (6 trials)	1,2,4 T: 6 x < 0.01 TA: 0.10, 0.050, 0.079, 0.22, 0.021, < 0.01 TAA: 0.13, 0.095, 0.048, 0.33, 0.027, 0.024 TLA: 0.031, 0.10, 0.017, 0.13, 0.024, 0.049		
	IF22-06125006 22-00143 Thirkell C. 2022 (wheat)	N-EU (2 trials)	1,2,4 T: 2 x < 0.01 TA: 0.02, 0.094 TAA: 0.13, 0.088 TLA: 0.02, 0.1		
	EGL-20-42539 Grall, E. 2022 (Barley)	SEU	1,2,4 T: 6x<0.01 TA: 0.0139, 0.0296, 0.0505, 0.0208, 2x<0.01 TAA: 0.0323, 0.0464, 0.0507, 0.016, 0.0385, <0.01 TLA: 0.0619, 0.112, 0.0327, 0.0114, 0.0594, 0.0273		
	IF21-05707589 Meyer, M. 2022 (Barley)	SEU (2 trials)	1,2,4 T: 2 x < 0.01 TA: <0.01, 0.02 TAA: 0.014, 0.025 TLA: 0.013, 0.026		
	IF21-05707610 21-00227 Gabriel E., 2022 (wheat)	S-EU (8 trials)	1,2,4 T: 8 x < 0.01 TA: 0.034, 2 x 0.015, 0.088, < 0.01, 0.047, 0.027, 0.016 TAA: 0.061, 0.036, 0.034, 0.067, 0.018, 0.15, 0.046, 0.044 TLA: 0.012, 0.033, 0.085, 0.077, 0.024, 0.22, 0.063, 0.079		
Sugar beet (root) 8 trials NEU 8 trials SEU	Confirmatory data (UK, 2018)	N-EU S-EU	Highest STMR and HR from all available GAPs on cereals as presented in the TDM confirmatory data.	Root & Tuber vegetables: 1,2,4 T: 0.01 TA: 0.184 TAA: 0.01 TLA: 0.021	Root & Tuber vegetables: 1,2,4 T: 0.016 TA: 0.239 TAA: 0.01 TLA: 0.131
	EGL 20 46158 Grall, E. 2021	N-EU (5 trials)	1,2,4 T: 5 x <0.01 TA: 2x <0.01, 0.03, 0.01, 0.1	1,2,4 T: 0.01 TA: 0.01	1,2,4 T: 0.01 TA: 0.10

			TAA: 5x<0.01 TLA: 5x<0.01	TAA: 0.01 TLA: 0.01	TAA: 0.01 TLA: 0.01
	R-C0200 Schneider E 2021	N-EU (3 trials)	1,2,4 T: 3 x<0.01 TA: <0.01, 0.01, 0.03 TAA: 3x<0.01 TLA: 3x<0.01		
	EGL-20-46158 Grall, E. 2021	S-EU (6 trials)	1,2,4 T: 6 x<0.01 TA: 2 x<0.01, 2 x 0.02, 0.01, 0.03 TAA: 6x<0.01 TLA: 6x<0.01		
	R-C0200 Schneider E 2021	S-EU (2 trials)	1,2,4 T: 2 x<0.01 TA: <0.01, 0.01 TAA: 2x<0.01 TLA: 2x<0.01		
Sugar beet (tops) 8 trials NEU 8 trials SEU	Confirmatory data (UK, 2018)	N-EU S-EU	Highest STMR and HR from all available GAPs on cereals as presented in the TDM confirmatory data.	Beet, mangel fodder 1,2,4 T: 0.05 TA: 0.18 TAA: 0.05 TLA: 0.15 Beet, tops 1,2,4 T: 0.03 TA: 0.04 TAA: 0.01 TLA: 0.05	Sugar beet leaves : 1,2,4 T : 0.12 (no storage stability data) TA: 0.218 TAA: 0.02 TLA: 0.14
	EGL-20-46158 Grall, E. 2021	N-EU (5 trials)	1,2,4 T: 5 x<0.01 TA: 2x 0.01, 0.04, 0.1, 0.02 TAA: 3x<0.01, 2 x 0.01 TLA: 2x0.01, 0.15, 2x0.14		
	R-C0200 Schneider E 2021	N-EU (3 trials)	1,2,4 T: 3 x<0.01 TA: 0.02, 0.01, 0.06 TAA: 3x<0.01 TLA: <0.01, 0.02, 0.14	1,2,4 T: 0.01 TA: 0.02 TAA: 0.01 TLA: 0.02	1,2,4 T: 0.01 TA: 0.10 TAA: 0.01 TLA: 0.15
	EGL-20-46158 Grall, E. 2021	S-EU (6 trials)	1,2,4 T: 5 x<0.01 TA: 2x 0.01, 2 x 0.02, 0.05, 0.03		

			TAA: 6x < 0.01 TLA: 0.06, 0.05, 3 x 0.01, 0.02		
	R C0200 Schneider E 2021	S EU (2 trials)	1,2,4 T: 2 x < 0.01 TA: 0.02, 0.01 TAA: 2x < 0.01 TLA: 0.07, 0.02		
Oilseed rape (seeds) NEU 20 trials 8 trials NEU 6 trials SEU	Confirmatory data (UK, 2018)	N-EU S-EU	Highest STMR and HR from all available GAPs on cereals as presented in the TDM confirmatory data.	Oilseeds 1,2,4 T: 0.05 TA: 1.039 TAA: 0.120 TLA: 0.065 T: 0.01 TA: 0.24 TAA: 0.01 TLA: 0.015	Oilseeds 1,2,4 T: 0.100 TA: 2.826 TAA: 0.68 TLA: 0.192 T: 0.018 TA: 2.17 TAA: 0.062 TLA: 0.05
New trials	IF21-05707333 21-00230 Meyer, M. 2021	NEU (8 trials)	1,2,4 T: 8 x < 0.01 TA: 0.96, 0.58, 0.61, 0.30, 0.67, 1.3, 0.44, 0.11 TAA: 7 x < 0.01, 0.018 TLA: 0.037, 0.015, 0.026, 0.013, 0.029, 0.058, 0.012, <0.01	1,2,4 T: 0.01 TA: 0.67 TAA: 0.01 TLA: 0.03	1,2,4 T: 0.01 TA: 2.30 TAA: 0.02 TLA: 0.06
	21-00231 Stolze, J. 2019	SEU (6 trials)	1,2,4 T: 6 x < 0.01 TA: 0.84, 2.3, 0.11, 0.84, 1.9, 0.66 TAA: 0.012, 0.021, 2 x < 0.01, 0.012, 0.02 TLA: 2 x 0.048, 0.045, < 0.01, 0.042, 0.032		
Oilseed rape straw NEU 20 trials	Confirmatory data (UK, 2018)	NEU (20 trials)	Highest STMR and HR from all available GAPs on cereals as presented in the TDM confirmatory data.	T: 0.01 TA: 0.077 TAA: 0.01 TLA: 0.01	T: 0.015 TA: 0.913 TAA: 0.034 TLA: 0.02
Oilseed new trials	IF21-05707333 21-00230 Meyer, M. 2021	NEU (8 trials)	1,2,4 T: 8 x < 0.01 TA: 0.14, 0.50, 0.024, 0.032, 0.093, 0.2, 0.032, <0.01 TAA: 6 x < 0.01, 0.011, 0.052 TLA: 6 x < 0.01, 0.018, 0.039	1,2,4 T: 0.01 TA: 0.05 TAA: 0.01 TLA: 0.01	1,2,4 T: 0.01 TA: 0.50 TAA: 0.14 TLA: 0.15

	21-00231 Stolze, J. 2019	SEU (6 trials)	1,2,4 T: 6 x <0.01 TA: 0.057, 0.26, < 0.01, 0.032, 0.29, 0.044 TAA: 3 x < 0.01, 0.11, 0.14, 0.013 TLA: 0.013, 0.11, < 0.01, 0.012, 0.15, 0.038		
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zRMS comments	Prothioconazole Barley, wheat and rape are the major crops in Northern Europe. Sufficient number of trials is available (EU data and new data). The application requested is considered to be within the scope of EU GAP. The results indicate that MRL exceedance according to the current MRL regulation is not expected. <u>TDMs</u> EU data: for wheat the results of 4 NEU trials is available, however residues of TLA were not analysed, for barley and rapeseed 8 and 20 NEU residue trials are available respectively. The number of studies is insufficient to support the intended use in cereals. New data: The Applicant submitted sufficient number of NEU residue trials of TDMs in cereals and oilseed rape: 9 for wheat, 8 for barley and 20 for rapeseed. The trials are sufficient to support the intended use on cereals and rape. This submission does not apply to SEU. The trials from SEU were not evaluated but can be considered as supplementary. Sugar beet data is not in the scope of this submission and was not evaluated.
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Conclusion on the magnitude of residues in plants

According to the available data, the intended uses on winter and spring oilseed rape, spring and winter cereals (barley, wheat, triticale and spelt) are considered acceptable, for outdoor uses. Wheat trial data can be extrapolated to support the proposed uses on rye. Barley trial data can be extrapolated to support the proposed use on oat.

The EU data referred to and the new data submitted show that no exceedance of the MRL will occur, under the Reg. (EU) ~~2019/552~~ 2024/1318 or under Retained Regulation (EC) No 396/2005, for GB and NL.

The uses are considered acceptable.

Conclusion on the magnitude of residues in plants

According to the available data, the intended uses on spring and winter cereals (barley, wheat, triticale and spelt), spring and winter oilseed rape are considered acceptable, for outdoor uses. Wheat trial data can be extrapolated to support the proposed uses on rye. Barley trial data can be extrapolated to support the proposed use on oat.

The EU data referred to and the data submitted show that no exceedance of the MRL will occur.

The uses are considered acceptable.

7.3.4 Magnitude of residues in livestock

Dietary burden calculation

Prothioconazole is authorised for use on several crops that might be fed to livestock. The median and maximum dietary burdens were therefore calculated for different groups of livestock using the input values according to the MRL review of prothioconazole (Art. 12 – EFSA Journal 2014;12(5):3689).

The input values are summarised in Table 7.3-9

Table 7.3-9: Input values for the dietary burden calculation (considering 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)				
Head cabbage	0.02	Median residue x CF	0.12	Highest residue x CF
Maize silage	0.01	Median residue	0.01	Highest residue

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Maize grain	0.01	Median residue	0.01	Median residue
Barley, oats, rye and wheat grain	0.02	Median residue x CF	0.074	Highest residue
Wheat and rye bran	0.16	Median residue x CF x 8	0.16	Median residue x CF x 8
Barley and oats straw	1.25	Median residue x CF	7.50	Highest residue x CF
Wheat straw	2.24	Median residue x CF	7.20	Highest residue x CF
Rye straw	0.60	Median residue x CF	4.80	Highest residue x CF
Peas and beans (dry)	0.02	Median residue x CF	0.02	Median residue x CF
Potatoes	0.01	Median residue	0.01	Highest residue
Turnips and swedes	0.06	Median residue x CF	0.10	Highest residue x CF
Rape seed meal	0.12	Median residue x CF x 2	0.12	Median residue x CF x 2
Linseed meal	0.12	Median residue x CF x 2	0.12	Median residue x CF x 2

The results of the calculations are reported in the table below. The calculated dietary burden for all groups of livestock were found to be above the maximum dietary burden trigger of 0.004 mg/kg bw per d and thus livestock feeding studies are triggered.

	Median dietary burden (mg/kg bw per d)	Maximum dietary burden (mg/kg bw per 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) (tentative)					
Cattle (all diets)	0.040	0.117	Barley straw	3.21	Y
Cattle (dairy only)	0.040	0.117	Barley straw	3.05	Y
Sheep (all diets)	0.058	0.229	Barley straw	5.72	Y
Sheep (dairy only)	0.056	0.191	Barley straw	5.72	Y
Swine (all diets)	0.009	0.010	Potato process waste	0.44	Y
Poultry (all diets)	0.023	0.062	Wheat straw	0.90	Y
Poultry (layer only)	0.023	0.062	Wheat straw	0.90	Y

For the TDMs, the median and maximum dietary burdens should be calculated for different groups of livestock by using the input values according to the TDMs confirmatory data (EFSA Journal 2018; 16(7):5736).

In the TDMs confirmatory data, 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. For each commodity the input residue values for risk assessment (STMR and 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’ dietary burden calculation.

The input values for the TDMs are summarised in Table 7.2-10 7.3-10.

Table 7.3-10: Input values for the dietary burden calculation

Crop group	Residue (mg/kg)								Source
	T		TA		TAA		TLA		
	STMR	HR	STMR	HR	STMR	HR	STMR	HR	
Citrus fruits	0.050	0.050	0.320	0.628	0.050	0.100	0.040	0.140	EFSA Journal 2018;16(7):5736
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	0.01	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	0.21	0.46	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	
Oil fruits	0.050	0.100	1.039	2.826	0.120	0.0680	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	

The results of the calculations including are reported in the tables below. The calculated dietary burden for all groups of livestock were found to be above the maximum dietary burden trigger of 0.004 mg/kg bw per d and thus livestock feeding studies are triggered.

T	Median dietary burden (mg/kg bw per d)	Maximum dietary burden (mg/kg bw per d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Cattle (all diets)	0.104	0.109	Potato	3.75	Y
Cattle (dairy only)	0.104	0.109	Potato	2.83	Y
Sheep (all diets)	0.118	0.121	Potato	3.63	Y
Sheep (ewe only)	0.118	0.121	Potato	3.63	Y
Swine (all diets)	0.045	0.047	Potato	2.04	Y
Poultry (all diets)	0.037	0.038	Potato	0.54	Y
Poultry (layer only)	0.029	0.032	Potato	0.46	Y

TA	Median dietary burden (mg/kg bw per d)	Maximum dietary burden (mg/kg bw per d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Cattle (all diets)	0.376	0.405	Potato	13.63	Y
Cattle (dairy only)	0.376	0.405	Potato	10.52	Y

Sheep (all diets)	0.425	0.454	Potato	13.63	Y
Sheep (ewe only)	0.425	0.454	Potato	13.63	Y
Swine (all diets)	0.163	0.178	Potato	7.71	Y
Poultry (all diets)	0.158	0.165	Potato	2.34	Y
Poultry (layer only)	0.130	0.149	Potato	2.18	Y

TAA	Median dietary burden (mg/kg bw per d)	Maximum dietary burden (mg/kg bw per d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Cattle (all diets)	0.118	0.140	Potato	4.29	Y
Cattle (dairy only)	0.118	0.140	Potato	3.63	Y
Sheep (all diets)	0.153	0.170	Wheat	4.37	Y
Sheep (ewe only)	0.127	0.146	Potato	4.37	Y
Swine (all diets)	0.108	0.109	Wheat	3.76	Y
Poultry (all diets)	0.138	0.140	Wheat	2.05	Y
Poultry (layer only)	0.135	0.140	Wheat	2.05	Y

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

Prothioconazole is a fat soluble substance and cereals grain and rape seed meal are used as a fish feeding stuff. Therefore, the fish dietary burden was calculated.

Prothioconazole:

Common carp: Max dietary burden 0.018 mg/kg

Category	Crop (commodity)	IFN Code	CL (%)	CP (%)	Max (%)	Residue input value	Residue (mg/kg)	Feed Composition (%)	Dietary Load (%)
Cereal Grains/Crop Seeds	Wheat (grain, extruded)	---	1.90	13.50	15.00	STMR-P	0.01	15.00	9.57
Plant By-Products	Barley (brewers dried grains)	5-00-516	7.00	25.90	15.00	STMR-P	0.02	15.00	18.19
Plant By-Products	Canola/Rape seed (meal, pre-press solvent extracted)	5-05-145	3.80	38.00	10.00	STMR-P	0.12	10.00	72.23
By-Products	Fish meal (PC)	-	5.00	75.00	100.00	STMR-P	0	33.69	0.00
By-Products	Starch (CC)	-	0.10	0.10	100.00	STMR-P	0	19.73	0.00

By-Products	Oil (F)	-	100.0 0	0.00	100.0 0	STMR-P	0	6.58	0.00
Rainbow trout: Max dietary burden 0.014 mg/kg									
Category	Crop (commodity)	IFN Code	CL (%)	CP (%)	Max (%)	Residue input value	Residue (mg/kg)	Feed Composition (%)	Dietary Load (%)
Cereal Grains/Crop Seeds	Wheat (grain, extruded)	---	1.90	13.5 0	10.00	STMR-P	0.01	10.00	8.37
Plant By-Products	Barley (brewers dried grains)	5-00-516	7.00	25.9 0	10.00	STMR-P	0.02	10.00	15.90
Plant By-Products	Canola/Rape seed (meal, pre-press solvent extracted)	5-05-145	3.80	38.0 0	8.00	STMR-P	0.12	8.00	75.74
By-Products	Fish meal (PC)	-	5.00	75.0 0	100.0 0	STMR-P	0	46.67	0.00
By-Products	Starch (CC)	-	0.10	0.10	100.0 0	STMR-P	0	13.87	0.00
By-Products	Oil (F)	-	100.0 0	0.00	100.0 0	STMR-P	0	11.46	0.00
Atlantic salmon: Max dietary burden 0.010 mg/kg									
Category	Crop (commodity)	IFN Code	CL (%)	CP (%)	Max (%)	Residue input value	Residue (mg/kg)	Feed Composition (%)	Dietary Load (%)
Cereal Grains/Crop Seeds	Wheat (grain, extruded)	---	1.90	13.5 0	9.90	STMR-P	0.01	9.90	11.58
Plant By-Products	Barley (brewers dried grains)	5-00-516	7.00	25.9 0	10.00	STMR-P	0.02	10.00	22.23
Plant By-Products	Canola/Rape seed (meal, pre-press solvent extracted)	5-05-145	3.80	38.0 0	5.00	STMR-P	0.12	5.00	66.19
By-Products	Fish meal (PC)	-	5.00	75.0 0	100.0 0	STMR-P	0	40.22	0.00
By-Products	Starch (CC)	-	0.10	0.10	100.0 0	STMR-P	0	4.97	0.00
By-Products	Oil (F)	-	100.0 0	0.00	100.0 0	STMR-P	0	29.91	0.00

The results indicate no exceedance of the threshold value of 0.1 mg/kg

Livestock feeding studies (KCA 6.4.1-6.4.3)

Available data

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

For ruminants and pigs a feeding study is triggered and reference is made to the ruminant feeding study submitted during the EU review of prothioconazole. Based on the results of the ruminant livestock feeding study, 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 conversion factor 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.

Consequently, the available data allowed deriving MRLs in ruminants and pigs. These MRLs were derived in compliance with the latest recommendations on this matter (FAO, 2009b). MRLs in all commodities were established at the LOQ, except in liver and kidney of ruminants, where MRLs of 0.05 and 0.02 mg/kg respectively were established.

Although the maximum dietary burden for poultry exceeds the threshold of 0.004 mg/kg bw/d, no appropriate feeding study is required, since based on the metabolism study, no residues above the LOQ are expected in poultry matrices at the calculated dietary burden. Therefore, MRLs can be established at the LOQ in all poultry commodities and no default conversion factors for risk assessment need to be derived.

Table 7.3-11: Overview of the values derived from livestock feeding studies

Commodity	Dietary burden		Results of the livestock feeding study			CF for RA
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level (mg/kg bw/d)	No	Result for RA Max. (mg/kg)	
Bovine liver	0.040	0.117	4	3	0.04	2
			25	3	0.22	
			100	2	0.95	
Bovine kidney	0.040	0.117	4	3	0.02	9
			25	3	0.14	
			100	2	0.65	
Bovine muscle	0.040	0.117	4	3	<0.01	
			25	3	<0.01	
			100	2	0.02	
Bovine fat	0.040	0.117	4	3	<0.01	
			25	3	0.01	
			100	2	0.07	

zRMS comment: The ruminant livestock feeding studies were evaluated and the results taken from EFSA review (2014) are included in the table below:

Commodity	Dietary burden		Results of the livestock feeding study						Median residue (mg/kg) ^(b)	Highest residue (mg/kg) ^(c)	Calculated MRL (mg/kg)	CF for RA ^(d)
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level (mg/kg bw/d) ^(a)	No	Result for enforcement		Result for RA					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
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-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers).												
Pig muscle	0.017	0.031	0.15	3	<0.01	<0.01	n.a.	n.a.	<0.01	<0.01	0.01* (tentative)	1.0
			0.91	3	<0.01	<0.01	n.a.	n.a.				
			3.64	3	<0.01	<0.01	n.a.	n.a.				
Pig fat			0.15	3	<0.01	<0.01	n.a.	n.a.	<0.01	<0.01	0.01* (tentative)	1.0
			0.91	3	<0.01	0.01	n.a.	n.a.				
			3.64	3	0.02	0.04	n.a.	n.a.				
Pig liver			0.15	3	0.02	0.03	n.a.	n.a.	<0.01	<0.01	0.01* (tentative)	2.0
			0.91	3	0.14	0.18	n.a.	n.a.				
			3.64	3	0.68	1.20	n.a.	n.a.				
Pig kidney			0.15	3	<0.01	<0.01	n.a.	n.a.	<0.01	<0.01	0.01* (tentative)	9.0
			0.91	3	0.03	0.03	n.a.	n.a.				
			3.64	3	0.13	0.24	n.a.	n.a.				
Milk	0.028	0.086	0.15	42	<0.005(f)	N/A	n.a.	n.a.	<0.005	<0.005	0.005* (tentative)	1.0
			0.91	42	<0.005(f)	N/A	n.a.	n.a.				
			3.64	39	0.005(f)	N/A	n.a.	n.a.				
Ruminant muscle	0.069	0.208	0.15	3	<0.01	<0.01	n.a.	n.a.	<0.01	<0.01	0.01* (tentative)	1.0
			0.91	3	<0.01	<0.01	n.a.	n.a.				
			3.64	3	<0.01	<0.01	n.a.	n.a.				
Ruminant fat			0.15	3	<0.01	<0.01	n.a.	n.a.	<0.01	<0.01	0.01* (tentative)	1.0
			0.91	3	<0.01	0.01	n.a.	n.a.				
			3.64	3	0.02	0.04	n.a.	n.a.				
Ruminant liver			0.15	3	0.02	0.03	n.a.	n.a.	0.01	0.042	0.05 (tentative)	2.0
			0.91	3	0.14	0.18	n.a.	n.a.				
			3.64	3	0.68	1.20	n.a.	n.a.				
Ruminant kidney			0.15	3	<0.01	<0.01	n.a.	n.a.	<0.01	0.012	0.02 (tentative)	9.0
			0.91	3	0.03	0.03	n.a.	n.a.				
			3.64	3	0.13	0.24	n.a.	n.a.				

N/A: Not applicable.

n.a.: Not analysed.

(a): Based on a 560 kg animal consuming approximately 20 kg feed DM/day.

(b): In the feeding study, residues were not determined according to the residue definition for risk assessment. Indeed, only prothioconazole-desthio, M14 and M15 were analysed.

(c): Median residue value according to the enforcement residue definition, derived by interpolation/extrapolation from the feeding study for the median dietary burden (FAO, 2009b).

(d): Highest residue value (tissues) or mean residue value (milk) according to the enforcement residue definition, derived by interpolation/extrapolation of the maximum dietary burden between the relevant feeding groups of the study (FAO, 2009b).

(e): The tentative conversion factors for enforcement to risk assessment in liver and kidney were derived on the basis of the available metabolism study on ruminants. For muscle, fat and milk, no CF was derived as residue levels are expected at the maximum meat ruminant dietary burden in these matrices are negligible (<0.01 mg/kg).

(f): Mean residue level from day 1 or 4 until day 29 (3 cows, 13 or 14 sampling days).

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

Livestock feeding studies for the TDMs were conducted on poultry (TA: MR-09/091, 2010 and TAA: MR-09/158, 2010) and ruminants (TA: MR-09/029, 2009; TAA: IF-10/01525218, 2010) respectively with TA and TAA and analysed for the magnitude of TA, TAA, 1,2,4-T and TLA residues. These data are part of the peer review of the TDMs confirmatory data (EFSA Journal 2018;16(7):5736).

The poultry feeding study conducted with TA showed that TA remained predominant in all matrices and a slight metabolization to 1,2,4-T in eggs, liver and muscle at the highest dosing level was noted. When the animals were fed with TAA, this compound was detected in whole eggs, fat and liver with residues of TA in liver only at all dosing levels.

The ruminant feeding study conducted with TA, showed that TA remained predominant in all tissues but with a significant metabolization 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 the 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. The other TDMs, 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. Similarly, transfer factors for TAA derived from the feeding studies conducted with TAA should be applied to TLA. The magnitude of residues of each TDM in animal matrices were therefore estimated by using the approach of a separate dietary burden calculation for each TDM and the application of transfer factors respectively to 1,2,4-T and to TLA for which feeding studies are not available.

zRMS comment: No new livestock feeding study was submitted in the framework of this submission. Regarding available feeding data, there is no risk for animal MRL to be exceeded. Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation) (KCA 6.5.2-6.5.3)

7.3.4.3 Available data for all crops under consideration

During the Annex I inclusion of prothioconazole, based on the residue data on seed dressing and spray application, processing studies were not considered necessary.

During the EU MRL review of prothioconazole (EFSA Journal, 2014;12(5):3689), it was concluded that considering that all the metabolites included in the residue definition for risk assessment in primary crops, i.e. compounds containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, have a similar structure to parent compound and/or prothioconazole-desthio, it can be assumed that they are also expected to remain stable under hydrolysis. Studies investigating the fate of these metabolites under the representative hydrolytic conditions are therefore desirable only, and it can be concluded that the relevant residue for enforcement and risk assessment in processed commodities is expected to be the same as for primary crops. This is confirmed by the new hydrolysis study submitted by the applicant in the framework of this application (see 7.2.2.3). The detailed results of this study are presented in Appendix 2.

Moreover, during the MRL review it was also concluded that studies investigating the magnitude of residues in processed commodities are not expected to affect the outcome of the risk assessment and are not required.

Considering the TDMs, magnitude of residues in processed commodities are part of the peer review of the TDMs confirmatory data (EFSA Journal 2018; 16(7):5736) and are out of data protection. In this peer review, a number of studies have been undertaken to assess the magnitude of residues in processed commodities and processing factors have been calculated when appropriate.

Conclusion on processing studies

Reference is made to 7.2.5.1-7.3.5.1

7.3.5 Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation and occurrence of prothioconazole residues in rotational crops was investigated during the peer review.

In succeeding crops, the residue pattern is similar to that observed in primary crops. The residue definitions proposed for primary crops are evenly valid. Rotational crop studies were submitted during the peer review. Under the experimental conditions of the submitted confined rotational crop study in the EU review residues of prothioconazole-desthio were present in edible part of Swiss chard and turnip at the level of 0.01 mg/kg, when these plants were sowed 28 and 146 days after application of the highest possible annual dose of prothioconazole on bare soil. The total amount of all metabolites containing the prothioconazole-desthio common structural moiety was around 0.03 mg/kg for the same time intervals. Therefore, under practical conditions of use of prothioconazole according to the representative uses and considering that a fraction of the applied rate is intercepted by the cereal crop, no residue of any metabolite above 0.01 mg/kg is expected in rotational crops and no plant back restriction needs to be proposed.

Table 7.3-12: 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	0.580	Cereals	Wheat	28	EFSA 2007
		Leafy vegetables	Swiss Chard	146	
		Root and tuber vegetables	Turnip	269	
New Data					
None					

During the MRL review of prothioconazole, the same conclusion was drawn: 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 (thus covering the proposed GAP by the applicant) 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.

As already indicated above, in the TMDs confirmatory data (EFSA Journal 2018;16(7):5736) a number of field rotational crop trials have been conducted to investigate the magnitude of triazole derivative metabolite residues in rotational crops after the use of triazole active substances. 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.

zRMS comment: 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. Based on the MRL review of the active substance (EFSA, 2014), confined rotational crop studies assessed are sufficient to conclude that no significant residues of prothioconazole are expected in succeeding crops and that no study dealing with magnitude of residues in succeeding crops is needed.

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

Residue level in pollen and bee products (KCA 6.10.1)

In Regulation (EU) No. 283/2013 for active substances, the residue level in pollen and bee products for human consumption resulting from residues taken up by honeybees from crops at blossom need to be determined. Although that this determination of residues level in pollen and bee products is an active substance requirement rather than a plant protection product requirement and therefore such active substance studies should be addressed during the annex I renewal of the active substance, based on the argumentation below, the residue level of prothioconazole in pollen and bee products can be considered as negligible. Indeed, as detailed in the EU report on pesticide residues in food (EFSA journal 2021;19(4):6491), the European monitoring program showed that active substance residues are found rarely in quantifiable amounts in honey and in those few cases in which they are found above the LOQ, the amounts are most often below the MRL.

The uses of GLOB2021dF are on cereals and oilseed rape. Cereals are not considered to be melliferous crops and thus only oilseed rape has to be taken into account. In residue trials with oilseed rape and Prothioconazole, a low amount of the active substance is detected in all residue trials. This together with the results from the EU monitoring program let us conclude that only a small amount of Prothioconazole shall be transferred from the crop to honey.

For the sake of completeness, 4 residue trails in the bee-attractive crop *Phacelia tanacetifolia* were performed to determine residue levels of prothioconazole and its metabolites in honey (see point A 2.1.6.1 in Appendix 2). In these trials, an EC-formulation containing 300 g/L prothioconazole was applied twice to the bee-attractive crop *Phacelia tanacetifolia* at a dose rate of 195g prothioconazole/ha with an interval of 14 days. This is more worst-case than the intended GAP of GLOB2021dF in oilseed rape, which is 2 x 125g prothioconazole/ha with an interval of minimum 15 days. The first application of the test item was conducted at BBCH growth stage 55 to 60. The second application of the test item was performed during bee flight activity and during full flowering of the crop, at BBCH growth stage 62 to 65. Residues of the parent compound (Prothioconazole) and its metabolites (prothioconazole-desthio, 1,2,4-triazole (free triazole), triazole alanine, triazole lactic acid, triazole acetic acid) were below the LOD of 0.003 mg/kg in all control and test item treated honey samples. This is clearly below the default level of 0.05 mg/kg, which is set as maximum residue level (MRL) in honey by the current guidance document (SANTE/11956/2016 rev. 9).

zRMS comment: rape belongs to melliferous crops, therefore the residue study in honey is required according to SANTE/11956/2016 rev. 9. In a submitted honey study the two applications of Prothioconazole 300 EC on *Phacelia tanacetifolia* resulted in residue values of Prothioconazole and its metabolites prothioconazole-desthio, 1,2,4-triazole (free triazole), triazole alanine, triazole lactic acid, triazole acetic acid in honey below the default level of 0.05 mg/kg, which is set as maximum residue level (MRL) in honey in the current guidance document (SANTE/11956/2016 rev. 9).

7.3.7 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).

Input values for the consumer risk assessment

The consumer risk assessment was based on the information provided in the “Evaluation of confirmatory data following Article 12 MRL review and modification of the existing maximum residue levels for prothioconazole in celeriacs and rapeseeds (EFSA Journal 2020;18(2):5999).

The calculation is based on the highest residue levels expected in raw agricultural commodities, for which the existing EU MRLs are set above the LOQ. Default conversion factor (CF) of 2 for risk assessment was applied to the input values of those crops where no data according to the risk assessment residue definition are available (pulses, flowering brassica, Brussels sprouts, head cabbage, shallots, onions, leeks, rye, barley oats). For the remaining commodities, the conversion factor was derived from residue trials (oilseeds concerned (CF 2), wheat (CF 2), root and tuber vegetables (except sugar beet) (CF 2.7)). For cranberries and sweetcorn, no conversion factor was available. The crops on which no uses were reported in the MRL review, were excluded from the calculation.

For the uses assessed in the framework of this submission, the median and highest residue values obtained in the residue trials submitted in this dossier are considered in the calculation if they are more critical than Art.12 values.

For animal commodities, the input values are as derived by the JMPR and are considered to account for a major part of residues included in the EU risk assessment residue definition (i.e., prothioconazole-desthio and its 3-hydroxy and 4-hydroxy metabolites with its conjugates). Therefore, no conversion factors are applied to products of animal origin.

EFSA Primo rev. 3.1 was used to perform the calculations.

Table 7.3-4: 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)				
Celeriac	0.08	STMR	0.10	HR
Beetroots, carrots, horseradish, parsnips, parsley roots, salsifies, swedes, turnips	0.08	STMR	0.10	HR
Rape seed	0.08	STMR	0.08	STMR

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Canberries	0.025	STMR	0.90	HR
Potatoes	0.01	STMR (EFSA, 2014)	0.01	HR (EFSA, 2014)
Sweet corn	0.018	STMR	0.018	HR
Onions, shallots	0.02	STMR x CF (2) (EFSA, 2014, 2015a)	0.04	HR x CF (2) (EFSA, 2014, 2015a)
Flowering brassica	0.02	STMR x CF (2) (EFSA, 2014)	0.04	HR x CF (2) (EFSA, 2014)
Brussels sprouts	0.06	STMR x CF (2) (EFSA, 2014)	0.14	HR x CF (2) (EFSA, 2014)
Head cabbage	0.02	STMR x CF (2) (EFSA, 2014)	0.12	HR x CF (2) (EFSA, 2014)
Leeks	0.02	STMR x CF (2) (EFSA, 2014)	0.08	HR x CF (2) (EFSA, 2014)
Beans	0.02	STMR x CF (2) (EFSA, 2014)	0.02	STMR x CF (2) (EFSA, 2014)
Lentils, peas, lupins	0.10	STMR x CF (2)	0.10	STMR x CF (2)
Linseeds, poppy seeds, mustard seeds	0.06	STMR x CF (2) (EFSA, 2014)	0.06	STMR x CF (2) (EFSA, 2014)
Gold of pleasure seeds	0.02	STMR x CF (2) (EFSA, 2014)	0.02	STMR x CF (2) (EFSA, 2014)
Peanuts	0.02	STMR x CF (2)	0.02	STMR x CF (2)
Sunflower seeds	0.02	STMR x CF (2) (EFSA, 2015b)	0.02	STMR x CF (2) (EFSA, 2015b)
Cotton seeds	0.1	STMR x CF (2)	0.1	STMR x CF (2)
Soyabean	0.1	STMR x CF (2)	0.1	STMR x CF (2)
Barley grain	0.07	STMR x CF (2)	0.07	STMR x CF (2)
Maize grain	0.02	STMR x CF (2)	0.02	STMR x CF (2)
Oat, rye grain	0.02	STMR x CF (2)	0.02	STMR x CF (2)
Wheat grain	0.02	STMR x CF (2)	0.02	STMR x CF (2)

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Muscle of swine, bovine, sheep, goat, equine, other farmed animals	0.01	STMR	0.01	HR
Fat of swine, bovine, sheep, goat, equine, other farmed animals	0.01	STMR	0.018	HR
Liver of swine, bovine, sheep, goat, equine, other farmed animals	0.05	STMR	0.23	HR
Kidney, edible offal of swine, bovine, sheep, goat, equine, other farmed animals	0.025	STMR	0.15	HR
Muscle of poultry	0.0016	STMR	0.0016	HR
Fat of poultry	0.008	STMR	0.008	HR
Liver, kidney, edible offal of poultry	0.071	STMR	0.071	HR
Milk	0.005	STMR (EFSA, 2014)	0.005	HR (EFSA, 2014)
Eggs	0.01	STMR (EFSA, 2014)	0.01	HR (EFSA, 2014)

Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.3-5: Consumer risk assessment-Prothioconazole

TMDI (% ADI) according to EFSA PRIMo	Not performed
IEDI (% ADI) according to EFSA PRIMo	9% (based on NL toddler)
IENTI (% ARfD) according to EFSA PRIMo*	Carrots: 63% (based on children) Beetroots: 57% (based on children) Celeriac/turnips rooted celeries: 55% (based on children) Head cabbages: 53% (based on children) Swedes/rutabagas: 52% (based on children) Leeks: 47% (based on children) Cranberries: 40% (based on children) Other commodities individually below 40% of ARfD

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

The proposed uses of Prothioconazole in the formulation GLOB2021dF do not represent unacceptable acute and chronic risks for the consumer.

Consumer risk assessment – TDMs

TMDI (% ADI) according to EFSA PRIMo 3.1	Not performed
IEDI (% ADI) according to EFSA PRIMo 3 (EFSA 2018)	1,2,4-T: 93 % (based on NL toddler) TA: 6% (based on NL toddler) TLA: 1% (based on NL toddler) TAA: 1% (based on NL toddler) TA + TLA: 7% (based on NL toddler)
IESTI (% ARfD) according to EFSA PRIMo 3	1,2,4-T: Cattle milk: 40% (children) Other commodities individually below 10% of ARfD TA: Oranges: 28% (children) Other commodities individually below 25% of ARfD TAA: Oranges: 1% (children) Wheat: 1% (children) Rice: 1% (children) Other commodities individually below 1% of ARfD TLA: Potatoes: 7% (children) Oranges: 6% (children) Melons: 6% (children) Pears: 5% (children) Other commodities individually below 5% of ARfD TA + TLA: Oranges: 34% (children)

In the TDM confirmatory data (EFSA Journal 2018;16(7):5376) the worst-case consumer exposure to the TDMs has been assessed using the EFSA PRIMo rev. 3 and the input values as described above in 7.2.8.1 7.3.4. The resulting IEDI accounted for 93% of the ADI (NL toddler) for 1,2,4-T, 6% of the ADI (NL toddler) for TA, 1% of the ADI (NL toddler) for TAA and 1% of the ADI (NL toddler) for TLA. No acute intake concern was identified as the calculated international estimated short-term intake (IESTI) accounted for up to 40% of the ARfD (cattle milk) for 1,2,4-T, 28% of the ARfD (oranges) for TA, 1% of the ARfD (oranges) for TAA and 7% of the ARfD (potatoes) for TLA.

As the applications of GLOB2021dF contain no new uses compared to the uses reviewed in the confirmatory data of the TDMs and in addition as the conducted supervised residue trials have proven that the intended GAP results into lower residue levels as compared to those taken into account in the TDMs confirmatory data (EFSA Journal 2018;16(7):5376) the worst case consumer risk assessment performed for the complete group of triazole active substances cover the consumer risk assessment in this dossier.

zRMS comment: The estimated long-term dietary intake of prothioconazole was below the ADI. The diet with the highest IEDI is NL toddler population with 9% of ADI. For this diet, the highest contributor is cattle milk with 3% of ADI. In addition, the evaluator performed the worst case calculations based on the current MRL values. The estimated log-term dietary intake is much below the ADI. The diet with the highest TMDI is NL toddler population (20% of ADI). The assessment of the acute risk assessment indicated no exceedance of ARfD for children and adults. The worst-case consumer dietary intake assessment with regard to the TDMs for the complete group of triazole active substances were assessed in the the confirmatory data. The chronic and acute dietary intakes have been carried out using the highest input residue values derived for each TDM for each crop groups and each product of animal origin. No chronic

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

PROTHIOCONAZOLE		
LOQs (mg/kg) range from:		to:
Toxicological reference values		
ADI (mg/kg bw/day):	0.01	ARID (mg/kg bw): 0.01
Source of ADI:		Source of ARID:
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

Normal mode

Chronic risk assessment: JMPR methodology (IED/TMDI)										
		No of diets exceeding the ADI :				---				
	Calculated exposure (% of ADI)	MS Diet	Exposure to MS diet (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)		2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from
				Commodity / group of commodities	Commodity / group of commodities					MRLs set at the LOQ (in % of ADI)
TMDI/IED (based on average food consumption)	20%	NL toddler	1.97	7%	Maize/corn	4%	Wheat	2%	Sugar beet roots	
	16%	GEMS/Food G10	1.64	7%	Soyabeans	4%	Wheat	1%	Barley	
	16%	GEMS/Food G11	1.63	7%	Soyabeans	4%	Wheat	2%	Barley	
	16%	GEMS/Food G06	1.62	7%	Wheat	2%	Soyabeans	1%	Maize/corn	
	16%	GEMS/Food G15	1.59	5%	Wheat	3%	Soyabeans	2%	Barley	
	15%	GEMS/Food G07	1.54	4%	Wheat	4%	Soyabeans	1%	Barley	
	15%	GEMS/Food G08	1.54	4%	Wheat	4%	Soyabeans	2%	Barley	
	11%	FR child 3 15 y	1.11	5%	Wheat	2%	Lentils	1%	Sugar beet roots	
	11%	IE adult	1.10	3%	Peas	2%	Wheat	1%	Lentils	
	11%	NL child	1.10	4%	Wheat	3%	Sugar beet roots	0.7%	Sunflower seeds	
	10%	RO general	1.02	5%	Wheat	1%	Sunflower seeds	1%	Head cabbages	
	10%	DK child	1.01	4%	Wheat	3%	Rye	1%	Carrots	
	10%	ES child	0.98	4%	Wheat	2%	Lentils	1%	Peas	
	8%	UK infant	0.80	3%	Wheat	1%	Carrots	1%	Maize/corn	
	8%	FR toddler 2 3 y	0.79	3%	Wheat	1.0%	Lentils	0.9%	Sugar beet roots	
	8%	IT toddler	0.75	3%	Wheat	0.4%	Lentils	0.2%	Carrots	
	7%	UK toddler	0.72	4%	Wheat	1.0%	Sugar beet roots	0.5%	Carrots	
	7%	DE child	0.70	4%	Wheat	1%	Carrots	0.4%	Rye	
	7%	PT general	2%	4%	Wheat	0.7%	Carrots	0.6%	Soyabeans	
	6%	ES adult	0.61	2%	Wheat	1%	Lentils	1.0%	Barley	
	6%	NL general	0.61	3%	Wheat	0.9%	Sugar beet roots	0.6%	Barley	
	6%	SE general	0.61	3%	Wheat	0.8%	Carrots	0.6%	Head cabbages	
	6%	DE general	0.60	2%	Wheat	1%	Sugar beet roots	1%	Barley	
	6%	DE women 14-50 y	0.56	2%	Wheat	1%	Sugar beet roots	0.4%	Barley	
	5%	FR adult	0.51	2%	Wheat	0.7%	Lentils	0.3%	Pineapple, Other products	
	5%	IT adult	0.48	4%	Wheat	0.2%	Lentils	0.1%	Carrots	
	4%	FI 3 y	0.39	1%	Wheat	0.8%	Carrots	0.4%	Peas	
	4%	UK vegetarian	0.38	2%	Wheat	0.4%	Lentils	0.3%	Peas	
	4%	FR infant	0.36	1%	Carrots	0.8%	Wheat	0.4%	Sugar beet roots	
	3%	FI 6 y	0.35	1.0%	Wheat	0.7%	Peas	0.6%	Carrots	
3%	UK adult	0.30	2%	Wheat	0.2%	Carrots	0.2%	Sugar beet roots		
3%	LT adult	0.29	1%	Wheat	0.5%	Rye	0.4%	Head cabbages		
3%	DK adult	0.26	1%	Wheat	0.5%	Carrots	0.3%	Rye		
2%	FI adult	0.19	0.4%	Peas	0.4%	Rye	0.3%	Carrots		
2%	IE child	0.16	1%	Wheat	0.2%	Carrots	0.0%	Broccoli		
1%	PL general	0.14	0.3%	Head cabbages	0.3%	Carrots	0.2%	Beetroot		
Conclusion: The estimated long-term dietary intake (TMDI/IED) was below the ADI. The long-term intake of residues of PROTHIOCONAZOLE is unlikely to present a public health concern. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.										

Acute risk assessment /children

Details - acute risk assessment /children

Acute risk assessment / adults / general population

Details - acute risk assessment/adults

Acute risk assessment /children

Hide IESTI new calculations

Acute risk assessment / adults / general population

Show IESTI new calculations

The acute risk assessment is based on the ARD. **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.

ESTI new calculations:

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

Show results for all crops

Unprocessed commodities

Results for children
No. of commodities for which ARD/ADI is exceeded (ESTI)

ESTI

Highest % of ARD/ADI	Commodities	MRL /input for RA (mg/kg)	Exposure (µg/kg bw)
14%	Wheat	0.1/0.1	1.4
11%	Barley	0.2/0.2	1.1
3%	Rye	0.05/0.05	0.32
2%	Rapeseeds/canola	0.15/0.15	0.21
0.6%	Oat	0.05/0.05	0.06

Expand/collapse list

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

Results for adults
No. of commodities for which ARD/ADI is exceeded (ESTI)

ESTI

Highest % of ARD/ADI	Commodities	MRL /input for RA (mg/kg)	Exposure (µg/kg bw)
10%	Barley	0.2/0.2	0.97
8%	Wheat	0.1/0.1	0.84
2%	Rye	0.05/0.05	0.24
0.8%	Rapeseeds/canola seeds	0.15/0.15	0.08
	Oat	0.05/0.05	0.03

Expand/collapse list

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

ESTI new
Results for children
No. of commodities for which ARD/ADI is exceeded (ESTI new)

ESTI new

Highest % of ARD/ADI	Commodities	MRL /input for RA (mg/kg)	Exposure (µg/kg bw)
14%	Wheat	0.1/0.1	1.4
11%	Barley	0.2/0.2	1.1
3%	Rye	0.05/0.05	0.32
2%	Rapeseeds/canola	0.15/0.15	0.21
0.6%	Oat	0.05/0.05	0.06

Expand/collapse list

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

ESTI new
Results for adults
No. of commodities for which ARD/ADI is exceeded (ESTI new)

ESTI new

Highest % of ARD/ADI	Commodities	MRL /input for RA (mg/kg)	Exposure (µg/kg bw)
10%	Barley	0.2/0.2	0.97
8%	Wheat	0.1/0.1	0.84
2%	Rye	0.05/0.05	0.24
0.8%	Rapeseeds/canola seeds	0.15/0.15	0.08
0.3%	Oat	0.05/0.05	0.03

Expand/collapse list

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

Processed commodities

Results for children
No. of processed commodities for which ARD/ADI is exceeded (ESTI)

ESTI

Highest % of ARD/ADI	Processed commodities	MRL /input for RA (mg/kg)	Exposure (µg/kg bw)
12%	Wheat /milling (flour)	0.1/0.1	1.2
7%	Barley /cooked	0.2/0.2	0.73
6%	Wheat /milling (wholemeal)	0.1/0.1	0.55
4%	Barley /milling (flour)	0.2/0.2	0.36
2%	Rye /boiled	0.05/0.05	0.18
2%	Oat /boiled	0.05/0.05	0.18
2%	Rye /milling (wholemeal)	0.05/0.05	0.18
2%	Oat /milling (flakes)	0.05/0.05	0.15
0.9%	Rapeseeds /oils	0.15/0.3	0.09
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Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

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
KCA 6.1-01	Winter, O.	2020	Storage Stability of Prothioconazole-desthio and its Metabolites in/on Crop Matrices under Deep Frozen Conditions S17-02583 (HEL-1702L) Eurofins Agrosience Services Chem GmbH GLP Unpublished	N	Globachem NV
KCA 6.1-02	Winter, O.	2020	Storage Stability of Prothioconazole-desthio and its Metabolites in/on Crop Matrices under Deep Frozen Conditions S19-04836 (HEL-1901L) Eurofins Agrosience Services Chem GmbH GLP Unpublished	N	Globachem NV
KCA 6.5.1	Wolfgang V..	2020	Prothioconazole-desthio – Simulated Processing: Hydrolysis of Prothioconazole-desthio at 90 °C, 100 °C and 120 °C S19-04836 Innovative Environmental Services 20180355 (HEL-1901L) GLP Unpublished	N	Globachem NV
KCA 6.3-04	Grall E.	2019	Magnitude of the residues of prothioconazole and its metabolites in barley (whole plant, grain and straw), following two applications of prothioconazole 300 EC in eight trials (4 DCS and 4 HS), Northern and	N	Globachem NV

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
			Southern Europe (Poland, Hungary, Portugal and Greece) – 2017 Report: EGL-17-28967 Staphyt Spain S.L. GLP Unpublished		
KCA 6.3-05	Grall E.	2022	Prothioconazole – Residue study on barley in Northern and Southern Europe – 2020 Report: EGL-20-42539 Staphyt Spain S.L. GLP Unpublished	N	Globachem NV
KCA 6.3-06	Grall E.	~~2022~~ 2020	Prothioconazole – Residue study on barley in Northern Europe – 2020 Report: EGL-20-45487 Staphyt Spain S.L. GLP Unpublished	N	Globachem NV
KCA 6.3-07	Thirkell C.	2022	Study on the behaviour of prothioconazole in barley after treatment with Prothioconazole 300 EC at two sites under field conditions Northern Europe, 2021 Report: IF21-05704459 21-00228 SGS INSTITUT FRESENIUS GmbH GLP Unpublished	N	Globachem NV
KCA 6.3-08	Meyer M.	2022	Study on the behaviour of prothioconazole in barley after treatment with Prothioconazole 300 EC at two sites under field conditions Southern Europe, 2021 Report: IF21-05707589 21-00229 SGS INSTITUT FRESENIUS GmbH GLP Unpublished	N	Globachem NV
KCA 6.3-09	Grall E.	2019	Magnitude of the residues of prothioconazole and its metabolites in wheat (whole plants, grain and straw), following two applications of prothioconazole 300 EC in eight trials (4 DCS and 4 HS), Northern and Southern Europe (Poland, Hungary, Portugal and Greece) - 2017	N	Globachem NV

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
			Report: EGL-17-28966 Staphyt Spain S.L GLP Unpublished		
KCA 6.3-10	Grall E.	2019	Magnitude of the residues of prothioconazole and its metabolites in wheat (whole plants, grain and straw), following two applications of prothioconazole 300 EC in eight trials (4 DCS and 4 HS), Northern and Southern Europe (Poland, Hungary, Portugal and Greece) - 2018 Report: EGL-18-32944 Staphyt Spain S.L GLP Unpublished	N	Globachem NV
KCA 6.3-11	Grall E.	2019	Prothioconazole – Residue study on wheat in Northern Europe - 2020 Report: EGL-20-42538 Staphyt Spain S.L GLP Unpublished	N	Globachem NV
KCA 6.3-12	Thirkell C.	2021	Study on the residue behaviour of prothioconazole in wheat after treatment with Prothioconazole 300 EC at six sites under field conditions in Northern Europe, 2021 Report: IF21-05705310-21-00226 SGS INSTITUT FRESENIUS GmbH GLP Unpublished	N	Globachem NV
KCA 6.3-13	Thirkell C.	2022	Study on the residue behaviour of prothioconazole in wheat after treatment with Prothioconazole 300 EC at two sites under field conditions in Northern Europe, 2022 Report: IF22-06125006 SGS INSTITUT FRESENIUS GmbH GLP Unpublished	N	Globachem NV
KCA 6.3-14	Gabriel E.	2022	Study on the residue behaviour of prothioconazole in wheat after treatment with Prothioconazole 300 EC at eight sites under field conditions in Southern Europe, 2021	N	Globachem NV

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
			Report: IF21-05707610 21-00227 SGS INSTITUT FRESENIUS GmbH GLP Unpublished		
KCA 6.3-15	MeyerM.	2021	Study on the behaviour of prothioconazole in oilseed rape after treatment with Prothioconazole 300 EC at eight sites under field conditions in northern europe, 2021 Report IF21-05707333 SGS INSTITUT FRESENIUS GmbH GLP	N	Globachem NV
KCA 6.3-17	Delmotte R.	2019	Magnitude of the residues of prothioconazole and its metabolites in oilseed rape (whole plants, seeds and straw), following two applications of HAG 610 01F in eight trials (4 DCS and 4 HS), Northern and Southern Europe (Poland, Hungary, Portugal and Greece) -2017 Report RDE-17-28968 Staphyt France GLP	N	Globachem NV
KCA 6.3-18	Delmotte R.	2019	Magnitude of the residues of prothioconazole and its metabolites in oilseed rape (whole plants, seeds and straw), following two applications of HAG 610 01F in six trials (3 DCS and 3 HS), Northern and Southern Europe (Poland, Hungary, Portugal and Greece) -2018 Report RDE-18-32946 Staphyt France GLP	N	Globachem NV
KCA 6.3-19	Delmotte R.	2019	Magnitude of the residues of prothioconazole and its metabolites in oilseed rape (whole plants, seeds and straw), following two applications of HAG 610 01F, Northern Europe - 2019 Report RDE-19-38550 Staphyt France GLP	N	Globachem NV
KCA 6.3-20	Stolze J.	2019	Study on the residue behaviour of prothioconazole in oilseed rape after treatment with Prothioconazole 300 EC at six sites under field conditions in southern Europe, 2021 Report IF21-05707367 21-00231 SGS INSTITUT FRESENIUS GmbH	N	Globachem NV

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		
KCA 6.3-20	Ertus C.	2023	Determination of Boscalid Residues in Wheat Following Foliar Applications with GLOB1811F (Boscalid 500 g/kg WG) under Field Conditions in Northern Europe in 2023 C3086 Anadiag GLP Unpublished	N	Globachem N.V.
KCA 6.3-22	Ertus C.	2023	Determination of Boscalid Residues in Wheat Following Foliar Applications with GLOB1811F (Boscalid 500 g/kg WG) under Field Conditions in Southern Europe in 2023 C3087 Anadiag GLP Unpublished	N	Globachem N.V.
KCA 6.3-23	Ertus C.	2023	Determination of Boscalid Residues in Barley Following Foliar Applications with GLOB1811F (Boscalid 500 g/kg WG) under Field Conditions in Northern Europe in 2023 C3088 Anadiag GLP Unpublished	N	Globachem N.V.
KCA 6.3-24	Ertus C.	2023	Determination of Boscalid Residues in Barley Following Foliar Applications with GLOB1811F (Boscalid 500 g/kg WG) under Field Conditions in Southern Europe in 2023 C3089 Anadiag GLP Unpublished	N	Globachem N.V.
KCA 6.10.1-01	Schnetzer, N.	2022	Tunnel study for determining the magnitude of residues of Prothioconazole 300 EC in honey according to SANTE/11956/2016 rev. 9 Report: R2140030 EFSA: 2021-0005000	N	Globachem NV Helm AG

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
					Ascenza Agro, S.A.

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner
	Heinemann, O.	2001a	18 months storage stability of residues of JAU 6476 and JAU 6476-Desthio during frozen storage in/on wheat matrices, Bayer AG, Report No.: MR-282/00	N	Bayer AG
	Haas, M.; Bomatsch, W.	2000	Metabolism of JAU 6476 in spring wheat (after foliar application, Bayer AG, Report No.: MR-198/99	N	Bayer AG
	Haas, M.	2001a	Metabolism of JAU 6476 in spring wheat after seed dressing, Bayer AG, Report No.: MR-467/99	N	Bayer AG

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
	Vogeler, K.; Sakamoto, H.; Brauner, A.	1993	Metabolism of SXX 0665 in summer wheat, Bayer AG, Report No.: PF3906	N	Bayer AG
	Haas, M.	2001b	Extraction efficiency testing of the residue method (00647) for the determinaton of JAU 6476 residues in spring wheat using aged radioactive residues, Bayer AG, Report No.: MR-084/01	N	Bayer AG
	Haas, M.	2001d	Metabolism of [phenyl-UL-14C]JAU 6476 in peanuts, Bayer AG, Report No.: MR-193/01	N	Bayer AG
	Weber, H.; Spiegel, K.	2001a	[Phenyl-UL-14C]JAU 6476 absorption, distribution, excretion and metabolism in the lactating goats, Bayer AG, Report No.: MR-092/01	N	Bayer AG
	[REDACTED]	2002a	[Phenyl-UL-14C]JAU 6476-desthio absorption, distribution, excretion and metabolism in the lactating goat, [REDACTED]	Y	Bayer AG
	Weber, H.; Weber, E.; Spiegel, K.	2002b	Validation of the residue analytical method for the determination of JAU 6476-desthio, and hydroxides residues in animal matrices using aged radioactive residues [REDACTED]	N	Bayer AG
	[REDACTED]	2001b	[Phenyl-UL-14C]JAU 6476 absorption, distribution, excretion and metabolism in the laying hens, Bayer AG, Report No.: MR-309/01	Y	Bayer AG
	Heinemann, O.	2001h	Determination of residues of JAU 6476-desthio on spring wheat and winter wheat following seed treatment of JUA 6476 200 FS and spray application of JAU 6476 250 EC in Germany, Northern France and Great Britain, Bayer AG, Report No.: RA-2003/99	N	Bayer AG

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
	Heinemann, O.	2001i	Determination of residues of JAU 6476-desthio on spring wheat after spray application of JAU 6476 250 EC in Sweden, Germany, Northern France and Great Britain, Bayer AG, Report No.: RA-2104/00	N	Bayer AG
	Heinemann, O.; Elke, K.	2001c	Determination of residues of JAU 6476-desthio on winter wheat following seed treatment of JUA 6476 200 FS and spray application of JAU 6476 250 EC in France, Spain and Italy, Bayer AG, Report No.: RA-2149/98	N	Bayer AG
	Heinemann, O.	2001l	Determination of residues of JAU 6476-desthio in/on wheat and triticale after spray application of JAU 6476 250 EC in Spain and France, Bayer AG, Report No.: RA-2105/00	N	Bayer AG
	Heinemann, O.	2001e	Determination of residues of JAU 6476-desthio on spring barley following seed treatment of JUA 6476 200 FS and spray application of JAU 6476 250 EC in Germany, Bayer AG, Report No.: RA-2150/98	N	Bayer AG
	Heinemann, O.; Elke, K.	2001a	Determination of residues of JAU 6476-desthio on spring barley following seed treatment of JUA 6476 200 FS and spray application of JAU 6476 250 EC in Germany, France and Great Britain, Bayer AG, Report No.: RA-2140/98	N	Bayer AG
	Heinemann, O.	2001j	Determination of residues of JAU 6476-desthio on spring barley after spray application of JAU 6476 250 EC in Sweden, Germany, Northern France and Great Britain, Bayer AG, Report No.: RA-2101/00	N	Bayer AG
	Heinemann, O.	2001f	Determination of residues of JAU 6476-desthio on spring barley following seed treatment of JUA 6476 200 FS and spray application of JAU 6476 250 EC in Southern France, Bayer AG, Report No.: RA-2079/98	N	Bayer AG
	Heinemann, O.; Elke, K.	2001b	Determination of residues of JAU 6476-desthio on spring barley following seed treatment of JUA 6476	N	Bayer AG

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
	K.		200 FS and spray application of JAU 6476 250 EC in Southern France, Bayer AG, Report No.: RA-2079/98		
	Heinemann, O.	2002a	Determination of residues of JAU 6476-desthio on winter barley after spray application of JAU 6476 250 EC in France, Italy and Portugal Bayer AG, Report No.: RA-2144/98	N	Bayer AG
	Heinemann, O.	2001g	Determination of residues of JAU 6476-desthio on spring barley after spray application of JAU 6476 250 EC in Germany, Sweden, Northern France and Great Britain Bayer AG, Report No.: RA-2088/00	N	Bayer AG
	Heinemann, O.	2002c	Determination of residues of JAU 6476-desthio on rape after spray application of JAU 6476 250 EC in Southern France, Bayer AG, Report No.: RA-2178/01	N	Bayer AG
	Heinemann, O.	2002b	Determination of residues of JAU 6476-desthio on rape after spray application of JAU 6476 250 EC in Southern France, Bayer AG, Report No.: RA-2179/01	N	Bayer AG
		2001	Jau 6476-Desthio – Dairy cattle feeding study 	Y	Bayer AG
	Gilges, M.	2001	Hydrolysis of Jau 6476 under condition of processing Bayer AG, Report No.: RA-MR-166/00	N	Bayer AG
	Haas, M.	2001	Confined rotational crop study with Jau 6476 Bayer AG, Report No.: RA-MR-159/00	N	Bayer AG

The following tables are to be completed by MS.

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 XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

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

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

Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1 Prothioconazole

A 2.1.1 Stability of residues

A 2.1.1.1 Stability of residues during storage of samples

A 2.1.1.1.1 Storage stability of residues in plant products

A 2.1.1.1.1.1 Study 1 (S17-02583) - Storage Stability of Prothioconazole-desthio and its Metabolites in/on Crop Matrices under Deep Frozen Conditions

Comments of zRMS:	Study is acceptable. Study conducted according to relevant guideline and GLP requirements. The analytical methods are considered appropriate regarding selectivity, accuracy and precision during analysing the storage samples. The recoveries indicate sufficient storage stability. The stability of prothioconazole and its metabolites (PTZ- α -, -3-, -4-, -5- and -6-hydroxy-desthio) in wheat (grain and straw) and rape (whole plant and seeds) was 18 months at $\leq -18^\circ\text{C}$ in the dark.
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Reference: KCA 6.1-01

Report Storage Stability of Prothioconazole-desthio and its Metabolites in/on Crop Matrices under Deep Frozen Conditions, Winter O.; Amann S., 2020, S17-02583

Guideline(s): OECD 506

Deviations: NO

GLP: YES

Acceptability: Yes

Materials and methods

All samples for storage were fortified at the beginning of the experimental phase. Analysis of storage samples was done directly at day0 and after each storage interval. Testing after each interval was accompanied by analysis of one control sample and one procedural recovery sample.

Storage samples allow assessment of storage stability, while procedural recoveries demonstrate the performance of the analytical method.

The fortification level was at ten times the limit of quantification (LOQ) of each method with all analytes fortified separately on aliquots of homogenised control sample material.

Storage samples were kept at $\leq -18^\circ\text{C}$ with no exceedance(see Appendix B).

Method 1 (PTZ-desthio): Sample extraction and determination of residues were performed according to the multi-residue method QuEChERS that was previously validated according to SANCO/3029/99, rev. 4 for oilseed rape (whole plant and seeds) and wheat (grain and straw).

Method 2 (prothioconazole metabolites): Sample extraction and determination of residues were performed according to the hydrolysis method that was previously validated according to SANCO/3029/99, rev. 4 for oilseed rape (whole plant and seeds) and wheat (grain and straw). Quantification was performed by use of LC-MS/MS detection.

The limit of quantification (LOQ) of the analytical methods was 0.01 mg/kg for each analyte and each matrix with a limit of detection (LOD) set at 0.003 mg/kg (30 % of the LOQ). The LOQ of the prothioconazole metabolites is defined as PTZ-desthio equivalent.

Results and discussions

Table A 1: Summary of concurrent recoveries of Prothioconazole-desthio from Oilseed rape and wheat.

Matrix	Spike level (mg/kg)	Storage Interval (months)	Sample size (n)	Individual procedural recoveries (%)	Mean ± std dev
PTZ-desthio					
OSR seed	0.1	18	2	82	-
OSR whole plant	0.1	18	2	97	-
Wheat grain	0.1	18	2	94	-
Wheat straw	0.1	18	2	102	-
PTZ- α -OH-desthio					
OSR seed	0.1	18	2	104	-
OSR whole plant	0.1	18	2	106	-
Wheat grain	0.1	18	2	102	-
Wheat straw	0.1	18	2	88	-
PTZ-3-OH-desthio					
OSR seed	0.1	18	2	97	-
OSR whole plant	0.1	18	2	98	-
Wheat grain	0.1	18	2	96	-
Wheat straw	0.1	18	2	90	-
PTZ-4-OH-desthio					
OSR seed	0.1	18	2	94	-
OSR whole plant	0.1	18	2	100	-
Wheat grain	0.1	18	2	96	-
Wheat straw	0.1	18	2	87	-
PTZ-5-OH-desthio					
OSR seed	0.1	18	2	99	-
OSR whole plant	0.1	18	2	99	-
Wheat grain	0.1	18	2	97	-
Wheat straw	0.1	18	2	86	-
PTZ-6-OH-desthio					

Matrix	Spike level (mg/kg)	Storage Interval (months)	Sample size (n)	Individual procedural recoveries (%)	Mean $\pm$ std dev
OSR seed	0.1	18	2	83	-
OSR whole plant	0.1	18	2	90	-
Wheat grain	0.1	18	2	93	-
Wheat straw	0.1	18	2	80	-

Table A 2: Stability of Prothioconazole-desthio residues in oilseed rape and wheat following storage at -18°C

Matrix	Spike level (mg/kg)	Storage Interval (months)	Individual recoveries (%)
PTZ-desthio			
OSR seed	0.1	18	91
OSR whole plant	0.1	18	83
Wheat grain	0.1	18	84
Wheat straw	0.1	18	96
PTZ- α -OH-desthio			
OSR seed	0.1	18	99
OSR whole plant	0.1	18	93
Wheat grain	0.1	18	97
Wheat straw	0.1	18	97
PTZ-3-OH-desthio			
OSR seed	0.1	18	96
OSR whole plant	0.1	18	93
Wheat grain	0.1	18	102
Wheat straw	0.1	18	93
PTZ-4-OH-desthio			
OSR seed	0.1	18	95
OSR whole plant	0.1	18	93
Wheat grain	0.1	18	96
Wheat straw	0.1	18	90
PTZ-5-OH-desthio			
OSR seed	0.1	18	95
OSR whole plant	0.1	18	99
Wheat grain	0.1	18	93
Wheat straw	0.1	18	91
PTZ-6-OH-desthio			
OSR seed	0.1	18	92
OSR whole plant	0.1	18	96

Matrix	Spike level (mg/kg)	Storage Interval (months)	Individual recoveries (%)
Wheat grain	0.1	18	96
Wheat straw	0.1	18	91

Conclusion

Stability was demonstrated for prothioconazole-desthio (PTZ-desthio) and its metabolites PTZ-alpha-, -3-, -4-, -5- and -6-hydroxy-desthio in oilseed rape (whole plant and seeds) and wheat (grain and straw) upon storage at ≤ -18 °C for 18 months.

A 2.1.1.1.2 Study 2 (S19-04836) - Storage Stability of Prothioconazole-desthio and its Metabolites in/on Crop Matrices under Deep Frozen Conditions

Comments of zRMS:	The study does not apply to the requested GAP, therefore is considered as supplementary.
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Reference:	KCA 6.1-02
Report	Storage Stability of Prothioconazole-desthio and its Metabolites in/on Crop Matrices under Deep Frozen Conditions, Winter O.; Nachtigall S.; Graf, H., 2020, S19-04836
Guideline(s):	OECD 506, SANCO/3029/99, rev. 4
Deviations:	NO
GLP:	YES
Acceptability:	Supplementary

Materials and methods

All samples for storage were fortified at the beginning of the experimental phase. Analysis of storage samples was done directly at day 0 and after each storage interval. Testing after each interval was accompanied by analysis of one control sample and one procedural recovery sample.

Storage samples allow assessment of storage stability, while procedural recoveries demonstrate the performance of the analytical method.

The fortification level was at ten times the limit of quantification (LOQ) of each method with all analytes fortified separately on aliquots of homogenised control sample material.

Storage samples were kept at $\leq -18^{\circ}\text{C}$ with no exceedance (see Appendix B).

Method 1 (PTZ-desthio): Sample extraction and determination of residues were performed according to the multi-residue method QuEChERS that was previously validated according to SANCO/3029/99, rev. 4 for oilseed rape (whole plant and seeds) and wheat (grain and straw).

Method 2 (prothioconazole metabolites): Sample extraction and determination of residues were performed according to the hydrolysis method that was previously validated according to SANCO/3029/99, rev. 4 for oilseed rape (whole plant and seeds) and wheat (grain and straw). Quantification was performed by use of LC-MS/MS detection.

The limit of quantification (LOQ) of the analytical methods was 0.01 mg/kg for each analyte and each matrix with a limit of detection (LOD) set at 0.003 mg/kg (30 % of the LOQ). The LOQ of the prothioconazole metabolites is defined as PTZ-desthio equivalent.

Results and discussions

Table A 3: Summary of concurrent recoveries of Prothioconazole-desthio from Beans and grapes.

Matrix	Spike level (mg/kg)	Storage Interval (months)	Sample size (n)	Individual procedural recoveries (%)	Mean ± std dev
PTZ-desthio					
Grape (bunch of grapes)	0.1	12	2	97	-
Beans (Dry beans)	0.1	12	2	100	-
PTZ- α -OH-desthio					
Grape (bunch of grapes)	0.1	12	2	109	-
Beans (Dry beans)	0.1	12	2	109	-
PTZ-3-OH-desthio					
Grape (bunch of grapes)	0.1	12	2	110	-
Beans (Dry beans)	0.1	12	2	101	-
PTZ-4-OH-desthio					
Grape (bunch of grapes)	0.1	12	2	103	-
Beans (Dry beans)	0.1	12	2	106	-
PTZ-5-OH-desthio					
Grape (bunch of grapes)	0.1	12	2	105	-
Beans (Dry beans)	0.1	12	2	101	-
PTZ-6-OH-desthio					
Grape (bunch of grapes)	0.1	12	2	88	-
Beans (Dry beans)	0.1	12	2	96	-

Table A 4: Stability of Prothioconazole-desthio residues in oilseed rape and wheat following storage at -18°C

Matrix	Spike level (mg/kg)	Storage Interval (months)	Individual recoveries (%)
PTZ-desthio			
Grape (bunch of grapes)	0.1	12	113
Beans (Dry beans)	0.1	12	106
PTZ- α -OH-desthio			

Matrix	Spike level (mg/kg)	Storage Interval (months)	Individual recoveries (%)
Grape (bunch of grapes)	0.1	12	94
Beans (Dry beans)	0.1	12	88
PTZ-3-OH-desthio			
Grape (bunch of grapes)	0.1	12	95
Beans (Dry beans)	0.1	12	105
PTZ-4-OH-desthio			
Grape (bunch of grapes)	0.1	12	96
Beans (Dry beans)	0.1	12	101
PTZ-5-OH-desthio			
Grape (bunch of grapes)	0.1	12	95
Beans (Dry beans)	0.1	12	90
PTZ-6-OH-desthio			
Grape (bunch of grapes)	0.1	12	102
Beans (Dry beans)	0.1	12	94

Conclusion

Stability was demonstrated for prothioconazole-desthio (PTZ-desthio) and its metabolites PTZ-alpha-, -3-, -4-, -5- and -6-hydroxy-desthio in grape (bunch of grapes) and bean (dry beans) upon storage at $\leq -18^{\circ}\text{C}$ for 12 months.

A 2.1.1.2 Nature of residue in plants

A 2.1.1.2.1 Storage stability of residues in animal products

A 2.1.2.1.1 Nature of residue in primary crops

A 2.1.2.1.2 Nature of residue in rotational crops

A 2.1.2.1.3 Nature of residues in processed commodities

Comments of zRMS:	Study performed according to GLP requirements and relevant guideline. The study is acceptable. The objective of the study was to investigate the hydrolytic stability of prothioconazole-desthio. The results show that prothioconazole-desthio is stable during processing simulating pasteurisation, baking/brewing/boiling and sterilisation.
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Reference: KCA 6.5.1

Report Prothioconazole-desthio – Simulated Processing: Hydrolysis of Prothiocona-

	zole-desthio at 90 °C, 100 °C and 120 °C, Völkel W., 2020, 20180355
Guideline(s):	OECD 507, OPPTS 860.1520, 7035/VI/95 rev 5
Deviations:	NO
GLP:	YES
Acceptability:	Yes

Materials and methods

The hydrolytic stability of Prothioconazole-desthio was investigated in sterile aqueous acetate buffer solutions at three pH values and temperatures in order to simulate processing practice.

The study was performed at pH 4, 5 and 6 at temperatures of 90 °C, 100 °C and 120 °C for 20 or 60 minutes, respectively. The range of hydrolytic conditions used, represent the processes of pasteurisation, baking/brewing/boiling and sterilisation.

Buffer solutions containing the test item at an initial average concentration of 4.9 mg/L were incubated in closed high pressure stainless steel vessels placed in a water bath (pH 4 and 5) or autoclave (pH 6) at the desired temperature. At time 0, single samples and after 20 or 60 minutes of incubation, duplicate samples per pH value were taken. After sampling, the pH was determined and the aqueous phases were analysed by High Performance Liquid Chromatography-Mass Spectrometry (LC-MS) to determine the amount of test item.

Results and discussion

Table A 5: Identification of compounds from high temperature hydrolysis study

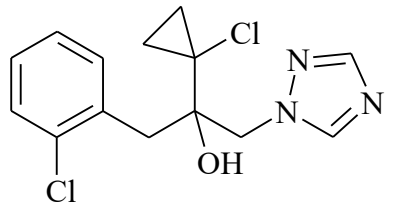
Common name/code ID No.	Chemical name	Chemical structure
Prothioconazole-desthio	α -(1-chlorocyclopropyl)- α -(2-chlorophenyl)methyl-1H-1,2,4-triazole-1-ethanol	

Table A 6: Standard hydrolysis study of Prothioconazole-desthio

Process represented	T° (°C)	Time (min)	pH	Parent Initial conc. (mg/L)	% of TRR
					Parent
pasteurization	90	20	4	4.902	90.7
Baking, Brewing, Boiling	100	60	5	4.971	93.3
Sterilisation	120*	20	6	4.916	92.2

Independent of temperature and pH at the end of incubation 91% to 93% of the amount applied was recovered, demonstrating the stability of the test item.

Conclusions

The results show that Prothioconazole-desthio is stable during processing at pH 4, 90 °C, at pH 5, 100 °C simulating pasteurisation and baking/brewing/boiling, respectively and at pH 6, 120 °C simulating sterilisation.

A 2.1.2.2 Nature of residues in livestock

A 2.1.3 Magnitude of residues in plants

A 2.1.3.1 Barley / Prothioconazole – Magnitude of the residues of prothioconazole and its metabolites in barley (whole plant, grain and straw), following two applications of prothioconazole 300 EC in eight trials (4 DCS and 4 HS), Northern and Southern Europe (Poland, Hungary, Portugal and Greece) – 2017

Table A 7: Intended GAP

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP (number 200, 201, 51, 55, 59, 63, 67, 71, 75, 79, 83, 87*)	1 2	0.5 0.8 L/ha (125 g as/ha)	21 days	BBCH 25-69	56 d

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

Comments of zRMS:	Study performed according to GLP requirements, relevant guidelines and in line with the proposed GAP. The study is accepted. Deviations were issued during the field phase of the study regarding trial HU03 - the specimens of grain and straw is missing. The objective of the study was to determine the magnitude of prothioconazole and its metabolite prothioconazole-desthio in barley, following two applications of prothioconazole 300 EC. Eight residue trials (4 decline and 4 harvest) were conducted in Northern and Southern Europe (Poland, Hungary, Portugal and Greece). The SEU trials are considered as supporting. Target application rate was 2 x ~0.2 kg/ha of prothioconazole. The interval between application was 14 days. The second application took place 35 (±3) days before the commercial harvest. The last stage of application was at BBCH 75. No residues above the current MRL of 0.2 mg/kg for barley was found. Trials were performed according to a more critical GAP than the intended GAP, and are considered as acceptable for the intended uses.
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Reference: KCA 6.3-04

Report: Magnitude of the residues of prothioconazole and its metabolites in barley (whole plant, grain and straw), following two applications of prothioconazole 300 EC in eight trials (4 DCS and 4 HS), Northern and Southern Europe (Poland, Hungary, Portugal and Greece) – 2017, Grall E., 2019, EGL-17-28967

Guideline(s): Yes (SANCO 7029/VI/95 rev.5, TG 509, SANTE/2020/12830 Rev.1, SANCO/825/00 rev.8.1, OECD (2007) ENV/JM/MONO(2007)17.

Deviations: None with impact

GLP: Yes

Acceptability: Yes

Table A 23-1: Summary of the study trials –

Active ingredient:	Prothioconazole	Commercial product (name):	HAG 610 01 F
Crop/crop group	Winter Barley	Producer of commercial product:	HELM AG, Germany
Responsible body for reporting	STAPHYT SPAIN S.L. 41960 Gines	Indoor/Glasshouse/Outdoor:	Outdoor
Country	Spain	Other a.s. in formulation:	None
Content of active substance (g/kg or g/L):	300 g/L	Residues calculated as:	Prothioconazole and Prothioconazole-desthio (as sum of isomers) EN 15662:2008 for prothioconazole and prothioconazole-desthio 00979/M001 for the other metabolites 0.01
Formulation:	EC	Analytical Method	LOQ

1	2	3		4	5			6	7	8	9		10	11
Report No.	Commodity /Variety	Date of 1) Sowing 2) Flowering 3) Harvest		Method of treatment	Application rate per treatment			Date of treatment	BBCH Crop Growth Stage at Treatment	Portions analysed	Residues (mg/kg)		PHI (days)	Remarks
					g a.s./ha	Water (L/ha)	g a.s./hL				Prothioconazole	Prothioconazole-desthio		
EGL-17-28967 PL01 Poland Wielkopolskie 64-610 Pruśce	Winter Barley Meridian	1 2 3	20/09/16 27/05–06/06/17 17/07/17	Foliar broadcast application	0.206 0.203	303 298	0.068 0.068	01/06/17 13/06/17	65 75	Wh. Plants Wh. Plants Wh. Plants Wh. Plants Wh. Plants Wh. Plants Grain Straw	1.082* 0.368 0.360 0.011 0.011* <LOQ <LOQ NA NA	1.286* 1.527 1.427 0.462 0.754* 0.463 0.249 0.074 0.330	0 1 3 5 7 14 21 35 35	All un-treated specimens: <LOQ Max. storage interval: 442 days
EGL-17-28967 PL02 Poland Warmińsko-Mazurskie 14-229 Kazanice	Winter Barley Sandra	1 2 3	19/09/16 27/05–02/06/17 14/07/17	Foliar broadcast application	0.204 0.211	300 310	0.068 0.068	17/05/17 31/05/17	39 67-71	Grain Straw	NA NA	<LOQ 0.305	37 37	All un-treated specimens: <LOQ Max. storage interval: 410 days

EGL-17-28967 HU03 Hungary Győr-Moson-Sopron 9200 Mosonmagyaróvár	Winter Barley	1	06/10/16	Foliar	0.203	298	0.068	16/05/17	45	Wh. Plants	1.807*	3.126*	0	All untreated specimens: <LOQ Max. storage interval: 457 days Grain and straw specimens are missing for this trial (trial harvested by the farmer before the specimens could be collected).
	Hanzi	2	22/05–28/05/17	broadcast application	0.206	303	0.068	30/05/17	71	Wh. Plants	0.065	3.174	1	
		3	29/06-02/07/17							Wh. Plants	0.020	2.686	3	
		Wh. Plants	0.015							2.464	5			
		Wh. Plants	<LOQ							2.114*	7			
		Wh. Plants	<LOQ							2.032	15			
		Wh. Plants	<LOQ							2.109	21			
EGL-17-28967 HU04 Hungary Komárom-Esztergom megye 2855 Bokod	Winter Barley	1	25/09/16	Foliar	0.207	304	0.068	01/05/17	32	Grain	NA	<LOQ	38	All untreated specimens: <LOQ Max. storage interval: 426 days
GK Judy	2	13/05–20/05/17	broadcast application	0.218	320	0.068	15/05/17	61	Straw	NA	0.57	38		
	3	26/06/17												
EGL-17-28967 GR05 Greece Central Macedonia GR 54500 Drymos	Winter Barley	1	07/11/16	Foliar	0.204	300	0.068	13/04/17	33	Wh. Plants	2.523*	4.306*	0	All untreated specimens: <LOQ Max. storage interval: 487 days
	Hyvito	2	20/04–30/04/17	broadcast application	0.204	300	0.068	27/04/17	61	Wh. Plants	0.471	5.436	1	
		3	11/06/17							Wh. Plants	0.020	3.417	3	
		Wh. Plants	0.013							2.972	5			
		Wh. Plants	0.010*							3.455*	7			
		Wh. Plants	<LOQ							1.940	14			
		Wh. Plants	<LOQ							1.834	21			
Grain	NA	<LOQ	43											
Straw	NA	1.891	43											

EGL-17-28967 PT06 Portugal Alentejo 7350 Elvas	Winter Barley Sanett	1 2 3	18/12/16 04/04–18/04/17 10/06/17	Foliar broadcast application	0.218 0.214	372 365	0.059 0.059	26/04/17 08/05/17	71 73	Grain Straw	NA NA	0.049 6.823	32 32	All un- treated specimens: <LOQ Max. storage interval: 487 days
EGL-17-28967 GR07 Greece Central Macedonia GR 58300 Akrolimni	Winter Barley Mucho	1 2 3	15/11/16 15/04–25/04/17 02/06/17	Foliar broadcast application	0.204 0.208	300 306	0.068 0.068	10/04/17 24/04/17	51 69	Wh. Plants Wh. Plants Wh. Plants Wh. Plants Wh. Plants Wh. Plants Grain Straw	1.572* 0.264 0.033 0.014 <LOQ <LOQ <LOQ NA NA	2.671* 3.765 3.115 2.051 1.968* 2.005 1.213 <LOQ 2.160	0 1 3 5 7 14 21 38 38	All un- treated specimens: <LOQ Max. storage interval: 491 days
EGL-17-28967 GR08 Greece West Mace- donia GR 50100 Polymylos	Winter Barley Colorado	1 2 3	11/11/16 05/05–12/05/17 07/07/17	Foliar broadcast application	0.205 0.206	301 303	0.068 0.068	15/05/17 29/05/17	71 73	Grain Straw	NA NA	<LOQ 0.848	37 37	All un- treated specimens: <LOQ Max. storage interval: 412 days

* average of two samples
NA: not analysed

Summary:

Study Objective

The objective of the study was to determine the magnitude of residues of prothioconazole and its metabolite prothioconazole-desthio in raw agricultural commodity (RAC whole plant, grain and straw) of barley after two applications of HAG 610 01 F (Prothioconazole 300 EC). The crop was subjected to a residue program which simulated the use of HAG 610 01 F as a fungicide in barley in Northern and Southern Europe (Poland, Hungary, Portugal and Greece).

Target application rate was 0.65 L/ha and target application time: Application (A1) 14 ± 2 days before application A2, and application (A2) was 35 ± 3 days before commercial harvest.

Field phase of the study

Two plots were established in each trial: U plot was left untreated. T plot was intended for residue at harvest, treated twice with HAG 610 01 F at the rate of 0.65 L/ha. Application 1 took place $14 (\pm 2)$ days before application 2. Application 2 took place 35 ± 3 days before the commercial harvest.

4 trials were Decline Curve Study trials with eight samplings. The first six samplings were specimens of whole plants and were taken at 0, 1, 3, 5, $7(\pm 1)$, $14 (\pm 1)$, and $21 (\pm 2)$ days after the last application. At $35 (\pm 3)$ DALA (harvest) grain and straw were collected.

4 trials were Harvest Study trials and one sampling was taken at harvest, $35 (\pm 3)$ DALA. Grain and straw were collected in each plot.

Specimens were placed into labelled plastic bags, weighed and double bagged. Specimens were frozen and shipped on freezer truck or with dry ice. They were delivered to analytical site between 20 June 2017 and 29 September 2017.

Analytical Phase of the study

Analyses of specimens were performed at Food Safety Laboratory, Skierniewice, Poland.

Two different analytical methods were used: The method for the analysis of prothioconazole and prothioconazole-desthio in barley whole plants, was based on the method described in EN 15662:2008 “foods of plant origin – Determination of pesticide residues using GC-MS and/or LC-MS/MS following acetonitrile extraction/partitioning and clean-up by dispersive SPE – QuEChERS-method”.

The method for the analysis of JAU-6476-desthio (M04), JAU-6476-3-hydroxy-desthio (M14), JAU-6476-4-hydroxy-desthio (M15), JAU-6476-5-hydroxy-desthio (M16), JAU-6476-6-hydroxy-desthio (M17) and JAU-6476- α -hydroxy-desthio (M18) in barley whole plant, seed and straw was based on the BAYER CropScience method “Analytical Method 00979/M001 for the determination of residues of JAU-6476-a-hydroxy-desthio, JAU-6476-3-hydroxy-desthio, JAU-6476-4-hydroxy-desthio, JAU 6476-5-hydroxy-desthio, and JAU-6476-6-hydroxy-desthio in/on matrices of plant origin by HPLCMS/ MS”, Report: KCA 4.1.2/34; Freitag, Th.; Daniels, M.; 2009; M-328686-01-1.

Limit of quantification (LOQ) achieved was 0.01 mg/kg for all analytes.

Limit of determination (LOD) was found to be 0.003 mg/kg for prothioconazole and prothioconazole-desthio, and 0.002 mg/kg for the other analytes.

Both methods were validated in barley whole plant, grain and straw during this study. Acceptance criteria for method validations were met, with average recoveries ranging from 70% to 110% and relative standard deviations $\leq 20\%$.

Residues

No residue of prothioconazole or prothioconazole-desthio was found above LOQ in untreated specimen.

After two applications with HAG 610 01 F at the rate of 0.65 L/ha, the residues of prothioconazole in barley whole plant specimens:

- from 1.082 mg/kg to 2.523 mg/kg at 0 DALA,
- from 0.065 mg/kg to 0.471 mg/kg at 1 DALA,
- from 0.020 mg/kg to 0.360 mg/kg at 3 DALA,
- from 0.011 mg/kg to 0.015 mg/kg at 5 DALA,
- from below LOQ to 0.011 mg/kg at 7 DALA,
- below LOQ at 14 DALA,
- below LOQ at 21 DALA,

After two applications with HAG 610 01 F (plot T) at the rate of 0.65 L/ha, the residues of prothioconazole-desthio (as sum of isomers) in barley specimens

In whole plants specimens:

- from 1.286 mg/kg to 4.306 mg/kg at 0 DALA,
- from 1.527 mg/kg to 5.436 mg/kg at 1 DALA,
- from 1.427 mg/kg to 3.417 mg/kg at 3 DALA,
- from 0.462 mg/kg to 2.972 mg/kg at 5 DALA,
- from 0.754 mg/kg to 3.455 mg/kg at 7 DALA,
- from 0.463 mg/kg to 2.032 mg/kg at 14 DALA,
- from 0.249 mg/kg to 2.109 mg/kg at 21 DALA,

in grain at commercial harvest: < LOD to 0.074 mg/kg.

in straw at commercial harvest: from 0.305 mg/kg to 6.823 mg/kg

A 2.1.3.2 Barley / Prothioconazole – Residue study on barley in Northern and Southern Europe - 2020

Table A 8: Intended GAP

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP (number 200, 201, 51, 55, 59, 63, 67, 71, 75, 79, 83, 87*)	2	0.5 0.8 L/ha (125 g as/ha)	21 days	BBCH 25-69	56 d

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

Comments of zRMS:	Study performed according to GLP requirements, relevant guidelines and in line with the proposed GAP. The study is accepted. The objective of the study was to determine the magnitude of prothioconazole, its metabolite prothioconazole-desthio and Triazole Derivative Metabolites (1,2,4-T, TA, TAA, TLA) in barley, following two applications of prothioconazole 300 EC. Ten trials were conducted in Northern and Southern Europe (Poland, Hungary, Spain, Italy, Greece and Austria). The SEU trials are considered as supporting. Target application rate was 2 x ~0.2 kg/ha of prothioconazole. The interval between application was 14 days. The second application took place at BBCH 61, between 31 and 64 days before harvest. No residues of prothioconazole above the current MRL of 0.2 mg/kg for barley was found. No residue of 1,2,4-T was detected in treated specimens, except in 1 control specimen at 0 DALA. In treated specimens: Some residue of TA, TAA and TLA were detected in the control specimens, despite no application of triazole in the field for at least 3 years. Residue of Triazole Alanine (TA) were 0.0102 to 0.258 mg/kg in whole plant the day of application and remained present in grain and straw. Residue of Triazole Acetic Acid (TAA) were <LOQ to 0.0952 mg/kg in whole plant the day of application, and remained present in grain and straw. Residue of Triazole Lactic Acid (TLA) were <LOQ to 0.233 mg/kg in whole plant the day of application, and remained present in grain (<LOQ to 0.0189 mg/kg) and straw (0.0114 to 0.125 mg/kg). Trials were performed according to a more critical GAP than the intended GAP, and are considered as acceptable for the intended uses.
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Reference:	KCA 6.3-05
Report	Prothioconazole – Residue study on barley in Northern and Southern Europe – 2020, Grall E., 2022, EGL-20-42539
Guideline(s):	Yes (SANCO 7029/VI/95 rev.5, TG 509, SANTE/2020/12830 Rev.1, SANCO/825/00 rev.8.1, OECD (2007) ENV/JM/MONO(2007)17.
Deviations:	None with impact
GLP:	Yes

Acceptability: Yes

Active ingredient:	Prothioconazole	Commercial product (name):	Prothioconazole 300 EC HAG 610 01 F
Crop/crop group	Winter Barley	Producer of commercial product:	HELM AG, Germany
Responsible body for reporting	STAPHYT SPAIN S.L. 41927 Mairena del Aljate	Indoor/Glasshouse/Outdoor:	Outdoor
Country	Spain	Other a.s. in formulation:	None
Content of active substance (g/kg or g/L):	300 g/L	Residues calculated as:	Prothioconazole and Prothioconazole-desthio (as sum of isomers) EN 15662:2008 for prothioconazole and prothioconazole-desthio 00979/M001 for the other metabolites
Formulation:	EC	Analytical Method	LOQ 0.01 (0.06 mg/kg for sum of isomers)

1	2	3		4	5			6	7	8	9		10	11
Report No.	Commodity /Variety	Date of 1) Sowing 2) Flowering 3) Harvest		Method of treatment	Application rate per treatment			Date of treatment	BBCH Crop Growth Stage at Treatment	Portions analysed	Residues (mg/kg)		PHI (days)	Remarks
					g a.s./ha	Water (L/ha)	g a.s./hL				Prothioconazole	Prothioconazole-desthio		
EGL-20-42539 PL01 Poland Wielkopolskie 64-610 Pruśce	Winter Barley Sandra	1	17/09/19	Foliar broadcast application	0.195	307	0.064	29/04/20	49	Wh. Plants	1.434	1.236	0	All untreated specimens: <LOQ* Max. storage interval: 175 days
		2	12/05-23/05/20		0.186	293	0.063	12/05/20	61	Wh. Plants	0.088	1.746	8	
		3	14/07/20						Wh. Plants	0.045	0.976	14		
									Ear	NA	0.054	36		
									Straw	NA	0.057	36		
									Grain	NA	<LOQ	64		
										Straw	NA	0.320	64	
EGL-20-42539 PL10 Poland Warmińsko-Mazurskie 14-100 Brzydowo	Winter Barley Argento	1	06/04/20	Foliar broadcast application	0.191	301	0.063	04/06/20	33	Grain	NA	<LOQ	54	All untreated specimens: <LOQ Max. storage interval: 141 days
		2	15/06–26/06/20		0.181	286	0.063	17/06/20	61				54	
		3	10/08/20							Straw	NA	0.028		

EGL-20-42539 AT9 Austria Wiener Um- land 2471 Rohrau	Spring Barley Elena	1 2 3	12/03/20 09/06–19/06/20 23/07/20	Foliar broadcast application	0.198 0.200	312 316	0.063 0.063	28/05/20 09/06/20	37 61	Wh. Plants Wh. Plants Wh. Plants Ear Straw Grain Straw	1.632 <LOQ <LOQ NA NA NA NA	1.663 0.468 0.202 <LOQ 0.182 <LOD 0.101	0 8 14 36 36 44 44	All un- treated specimens: <LOQ Max. storage interval: 148 days
EGL-20-42539 HU08 Hungary Jász-Nagykun- Szolnok 5054 Jászsószer- yörgy	Spring Barley Bente	1 2 3	10/03/20 06/06–14/06/20 11/07/20	Foliar broadcast application	0.189 0.196	248 257	0.076 0.076	29/05/20 09/06/20	43 61	Wh. Plants Wh. Plants Wh. Plants Ear Straw Grain Straw	2.301 0.017 0.010 NA NA NA NA	2.472 2.408 1.492 0.209 2.006 0.019 2.624	0 6 13 36 36 46 46	All un- treated specimens: <LOQ Max. storage interval: 207 days
EGL-20-42539 ES02 Spain Andalucia 41400 Ecija	Winter Barley Asteroid	1 2 3	18/11/19 10/04–17/04/20 08/06/20	Foliar broadcast application	0.198 0.197	312 310	0.063 0.064	27/03/20 11/04/20	39 61	Wh. Plants Wh. Plants Wh. Plants Ear Straw Grain Straw	2.301 0.017 0.010 NA NA NA NA	2.472 2.408 1.492 0.209 2.006 0.019 2.624	0 13 36 36 46 46	All un- treated specimens: <LOQ Max. storage interval: 207 days

EGL-20-42539 ES03 Spain Extremadura 06250 Bienverida	Winter Barley Planet	1	29/11/19	Foliar broadcast application	0.193	303	0.064	26/03/20	37	Ear	NA	0.055	33	All un- treated specimens: <LOQ Max. storage interval: 204 days
		2	08/04-15/04/20		0.201	317	0.063	11/04/20	61	Straw	NA	0.573	33	
		3	20/06/20							Grain	NA	<LOQ	51	
										Straw	NA	1.211	51	
EGL-20-42539 IT04 Italy Veneto 37066 Sommacampagna	Winter Barley Calanque	1	28/10/19	Foliar broadcast application	0.180	283	0.064	23/04/20	56	Wh. Plants	2.304	2.601	0	All un- treated specimens: <LOQ Max. storage interval: 179 days
		2	30/04-10/05/20		0.190	298	0.064	07/05/20	61	Wh. Plants	0.017	2.228	7	
		3	20/06/20							Wh. Plants	<LOQ	0.859	14	
										Ear	NA	0.176	35	
										Straw	NA	0.342	35	
										Grain	NA	0.040	43	
EGL-20-42539 IT05 Italy Piemonte 14100 Asti	Winter Barley Etoile	1	12/03/20	Foliar broadcast application	0.173	273	0.063	21/05/20	49	Grain	NA	0.020	31	All un- treated specimens: <LOQ Max. storage interval: 151 days
		3	03/05-18/05/20 09/07/20		0.191	302	0.063	05/06/20	61	Straw	NA	1.295	31	

EGL-20-42539 GR06 Greece Central Macedonia GR 57100 Koufalia	Winter Barley	1	15/12/19	Foliar broadcast application	0.191	300	0.064	08/04/20	49	Ear	NA	<LOD	35	All un- treated specimens: <LOQ Max. storage interval: 195 days (572 for retain speci- mens)
		2	22/04-30/04/20		0.191	300	0.064	23/04/20	61	Straw	NA	0.635**	35	
		3	12/06/20							Grain	NA	<LOD	48	
	Planet									Straw	NA	0.734	48	
EGL-20-42539 GR07 Greece Central Macedonia GR 57400 Sindos	Winter Barley	1	10/11/19	Foliar broadcast application	0.187	295	0.063	06/04/20	41	Ear	NA	<LOQ	35	All un- treated specimens: <LOQ Max. storage interval: 196 days
		2	20/04-30/04/20		0.190	300	0.063	22/04/20	61	Straw	NA	1.419	35	
		3	29/5+05/06/20							Grain	NA	<LOQ	43	
	Colorado									Straw	NA	0.404	43	

* contamination at 0 DALA (0.069/0.151 mg/kg), and at 35 DALA in straw (NA/0.015 mg/kg), that disappeared at harvest

** Actual analysis data is <LOQ, but there was an inversion of labels in the field. 0.635 is average of 3 measures (0.612/0.579/0.714 mg/kg)

NA: not analysed

Summary:

Study Objective

The objective of the study was to determine the magnitude of residues of prothioconazole, prothioconazole-desthio (M04) and the prothioconazole OH metabolites (M14, M15, M16, M17 and M18), as well as Triazole Derivative Metabolites (1,2,4-T, TA, TAA, TLA) in raw agricultural commodity (RAC whole plants, grain and straw) of barley after two applications of PROTHIOCONAZOLE 300 EC. The crop was subjected to a residue program which simulated the use of PROTHIOCONAZOLE 300 EC as a fungicide in barley in Northern and Southern Europe (Poland, Spain, Italy, Greece, Hungary and Austria) in 2020.

Target application rate was 0.65 L/ha and target application time: Application 1 14 ± 2 days before BBCH 61, and application 2 at BBH 61.

Field phase of the study

Two plots were established in the trial: U plot was left untreated. T plot was intended for residue at harvest, treated twice with PROTHIOCONAZOLE 300 EC at the rate of 0.65 L/ha. Application 1 took place 14 ± 2 days before application 2. Application 2 took place at BBCH 61. Specimens of whole plant were taken at 0, 7 ± 1 and 14 ± 1 DALA. At 35 ± 3 DALA, ears and rest of plant were collected and grain and straw were collected at commercial harvest. Specimens were placed into labelled plastic bags, weighed and double bagged. Specimens were frozen and shipped by freezer truck to the analytical test site for prothioconazole, prothioconazole-desthio and prothioconazole OH metabolites. The last delivery was done on 01 September 2020.

Analytical Phase of the study

Prothioconazole, prothioconazole desthio and prothioconazole OH metabolites: Analyses of specimens were performed at Food Safety Laboratory, Skierniewice, Poland. Two different analytical methods were used:

The method for the analysis of prothioconazole and prothioconazole-desthio in barley whole plants, was based on the method described in EN 15662:2018 “foods of plant origin – Multimethod for the determination of pesticide residues using GC and LC-based analysis following acetonitrile extraction/partitioning and clean-up by dispersive SPE – Modular QuEChERS-method.”

The method for the analysis of JAU-6476-desthio (M04), JAU-6476-3-hydroxy-desthio (M14), JAU-6476-4-hydroxy-desthio (M15), JAU-6476-5-hydroxy-desthio (M16), JAU-6476-6-hydroxy-desthio (M17) and JAU-6476- α -hydroxy-desthio (M18) in barley whole plant, grain and straw was based on the BAYER CropScience method “Analytical Method 00979/M001 for the determination of residues of JAU-6476-a-hydroxy-desthio, JAU-6476-3-hydroxy-desthio, JAU-6476-4-hydroxydesthio, JAU-6476-5-hydroxy-desthio, and JAU-6476-6-hydroxy-desthio in/on matrices of plant origin by HPLC-MS/MS”, Report: KCA 4.1.2/34; Freitag, Th.; Daniels, M.; 2009; M-328686-01-1.

Limit of quantification (LOQ) achieved was 0.01 mg/kg for all analytes.

Limit of detection (LOD) was found to be 0.003 mg/kg for prothioconazole and prothioconazole-desthio (in whole plant), and 0.002 mg/kg for the other analytes.

Triazole Derivative Metabolites:

Analyses of specimens were performed at SGS INSTITUT FRESENIUS GmbH, Germany. Homogenized field specimens aliquots were received deep frozen by SGS from Food Safety Laboratory. They were delivered on 29 October 2020, and kept deep frozen until analysis. The method for the analysis of 1,2,4-T, TA, TAA and TLA, was based on the analytical method 01062/M004 (T. Class; “Modification M004 of BCS residue analytical method 01062 for the determination of 1,2,4-triazole, triazolyalanine, triazole acetic acid and triazole lactic acid by LC/DMS/MS/MS in plant materials”, BASF DocID 2012/1294644,

07 December 2011) Analytes were extracted with a mixture of methanol and water, filtered, concentrated and cleaned up by dispersive SPE cartridge. The analytes were determined by LC-DMS/MS/MS.

Limit of quantification (LOQ) achieved was 0.01 mg/kg for all analytes.

Limit of detection (LOD) was found to be 0.003 mg/kg for all analytes.

Residues

No residue of prothioconazole or prothioconazole-desthio was found above LOD in untreated specimen, with the exception of a contamination that disappeared at harvest for trial PL01.

After two applications with PROTHIOCONAZOLE 300 EC at the rate of 0.65 L/ha, the residues of prothioconazole in barley whole plants specimens decreased from 1.434-3.519 mg/kg the day of applications from <LOQ to 0.045 mg/kg at 14 DALA in whole plants. The residues of prothioconazole-desthio (as sum of isomers) in barley specimens ranged from 0.880 to 2.601 mg/kg the day of applications and from 0.096 to 1.492 mg/kg at 14 DALA in whole plants.

At commercial harvest, the residues of prothioconazole-desthio (as sum of isomers) in barley grain specimens were <LOD to 0.040 mg/kg, and 0.028 to 2.624 mg/kg in straw. Triazole Derivative Metabolites were also analysed: No residue of 1,2,4-T was detected in untreated or treated specimens, except in the control specimen at 0 DALA in trial PL01 (contamination already visible in prothioconazole analysis) Some residue of TA, TAA and TLA were detected in the control specimens, despite no application of triazole in the field for at least 3 years (2020, 2019 and 2018) in all the fields except trial PL01.

In treated plots:

Residue of Triazole Alanine (TA) were 0.0102 to 0.258 mg/kg in whole plant the day of application, and remained present in grain (0.0448 to 0.826 mg/kg) and straw (<LOQ to 0.13 mg/kg).

Residue of Triazole Acetic Acid (TAA) were <LOQ to 0.0952 mg/kg in whole plant the day of application, and remained present in grain (0.0283 to 0.243 mg/kg) and straw (0.0116 to 0.194 mg/kg).

Residue of Triazole Lactic Acid (TLA) were <LOQ to 0.233 mg/kg in whole plant the day of application, and remained present in grain (<LOQ to 0.0189 mg/kg) and straw (0.0114 to 0.125 mg/kg).

A 2.1.3.3 Barley / Prothioconazole – Residue study on barley in Northern Europe - 2020

Table A 9: Intended GAP

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP (number 200, 201, 51, 55, 59, 63, 67, 71, 75, 79, 83, 87*)	2	0.5 0.8 L/ha (125 g as/ha)	21days	BBCH 25-69	56 d

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

Comments of zRMS:	Study performed according to GLP requirements, relevant guidelines and in line with the proposed GAP. The study is accepted. The objective of the study was to determine the magnitude of prothioconazole and its metabolites prothioconazole-desthio and Triazole Derivative Metabolites (1,2,4-T, TA, TAA, TLA), in barley, following two applications of prothioconazole 300 EC. The residue trials were conducted in Northern Europe (Poland and Hungary). Target application rate was 2 x ~0.2 kg/ha of prothioconazole. The interval between application was 14 days. The second application took place at BBCH 61, between 41 and 55 days before harvest. No residues of prothioconazole above the LOD for barley was found. No residue of 1,2,4-T above LOQ was measured in untreated or treated specimens. Some residue of TA, TAA and TLA were detected in the control specimens, despite no application of triazole in the field for at least 3 years. In treated plots: Residue of Triazole Alanine (TA) were 0.122 to 0.316 mg/kg in grain and <LOQ to 0.032 mg/kg in straw at commercial harvest. Residue of Triazole Acetic Acid (TAA) were 0.050 to 0.260 mg/kg in grain and <LOQ to 0.152 mg/kg in straw at commercial harvest. Residue of Triazole Lactic Acid (TLA) were <LOQ in grain and <LOQ to 0.145 mg/kg in straw at commercial harvest. Trials were performed according to a more critical GAP than the intended GAP, and are considered as acceptable for the intended uses.
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Reference:	KCA 6.3-06
Report	Prothioconazole – Residue study on barley in Northern Europe – 2020, Grall E., 2022, EGL-20-45487
Guideline(s):	Yes (SANCO 7029/VI/95 rev.5, TG 509, SANTE/2020/12830 Rev.1, SANCO/825/00 rev.8.1, OECD (2007) ENV/JM/MONO(2007)17.
Deviations:	None with impact
GLP:	Yes
Acceptability:	Yes

Active ingredient:	Prothioconazole	Commercial product (name):	Prothioconazole 300 EC HAG 610 01 F
Crop/crop group	Winter Barley	Producer of commercial product:	Globachem NV, Belgium
Responsible body for reporting	STAPHYT SPAIN S.L. 41927 Mairena del Aljara	Indoor/Glasshouse/Outdoor:	Outdoor
Country	Spain	Other a.s. in formulation:	None
Content of active substance (g/kg or g/L):	300 g/L	Residues calculated as:	Prothioconazole and Prothioconazole-desthio (as sum of isomers) EN 15662:2008 for prothioconazole and prothioconazole-desthio 00979/M001 for the other metabolites 0.01 (0.06 mg/kg for sum of isomers)
Formulation:	EC	Analytical Method	LOQ

1	2	3		4	5			6	7	8	9		10	11
Report No.	Commodity /Variety	Date of 1) Sowing 2) Flowering 3) Harvest		Method of treatment	Application rate per treatment			Date of treatment	BBCH Crop Growth Stage at Treatment	Portions analysed	Residues (mg/kg)	PHI (days)	Remarks	
					g a.s./ha	Water (L/ha)	g a.s./hL				Prothioconazole-desthio			
EGL-20-45487 PL01 Poland Wielkopolskie 63-040 Chwałęcín	Spring Barley Soldo	1	03/04/20	Foliar broadcast application	0.196	309	0.063	20/05/20 06/06/20	31 61	Ear	<LOQ	37	All untreated specimens: <LOQ Max. storage interval: 102 days	
		2	05/06-12/06/20		0.192	302	0.064			Straw	0.247	37		
		3	31/07/20							Grain	<LOQ	55		
										Straw	0.45	55		
EGL-20-45487 HU02 Hungary Csongrad county 6795 Bordány	Spring Barley Bojos	1	12/03/20	Foliar broadcast application	0.191	301	0.063	04/06/20 17/06/20	39 61	Ear/grain	<LOQ	37	All untreated specimens: <LOQ Max. storage interval: 113 days	
		2	25/05-28/05/20		0.181	286	0.063			Straw	0.356	37		
		3	13/07/20							Grain	<LOQ	41		
										Straw	0.155	41		

Summary:

Study Objective

The objective of the study was to determine the magnitude of residues of prothioconazole-desthio (M04) and the prothioconazole OH metabolites (M14, M15, M16, M17 and M18), as well as Triazole Derivative Metabolites (1,2,4-T, TA, TAA, TLA) in raw agricultural commodity (RAC whole plants, grain and straw) of barley after two applications of PROTHIOCONAZOLE 300 EC. The crop was subjected to a residue program which simulated the use of PROTHIOCONAZOLE 300 EC as a fungicide in barley in Northern Europe (Poland and Hungary) in 2020.

Target application rate was 0.65 L/ha and target application time: Application 1 14 ± 2 days before BBCH 61, and application 2 at BBH 61.

Field phase of the study

Two plots were established in the trial: U plot was left untreated. T plot was intended for residue at harvest, treated twice with PROTHIOCONAZOLE 300 EC at the rate of 0.65 L/ha. Application 1 took place 14 ± 2 days before application 2 (17 in trial PL01). Application 2 took place at BBCH 61.

At 35 ± 3 DALA, specimens of ears/grain and straw were collected and grain and straw were collected at commercial harvest.

Specimens were placed into labelled plastic bags, weighed and double bagged. Specimens were frozen and shipped by freezer truck to the analytical test site for prothioconazole-desthio and prothioconazole OH metabolites. The delivery was done on 25 August 2020.

Analytical Phase of the study

Prothioconazole desthio and prothioconazole OH metabolites:

Analyses of specimens were performed at Food Safety Laboratory, Skierniewice, Poland.

The method for the analysis of JAU-6476-desthio (M04), JAU-6476-3-hydroxy-desthio (M14), JAU-6476-4-hydroxy-desthio (M15), JAU-6476-5-hydroxy-desthio (M16), JAU-6476-6-hydroxy-desthio (M17) and JAU-6476- α -hydroxy-desthio (M18) in barley, grain and straw was based on the BAYER CropScience method "Analytical Method 00979/M001 for the determination of residues of JAU-6476-a-hydroxy-desthio, JAU-6476-3-hydroxy-desthio, JAU-6476-4-hydroxy-desthio, JAU-6476-5-hydroxy-desthio, and JAU-6476-6-hydroxy-desthio in/on matrices of plant origin by HPLC-MS/MS", Report: KCA 4.1.2/34; Freitag, Th.; Daniels, M.; 2009; M-328686-01-1.

Limit of quantification (LOQ) achieved was 0.01 mg/kg for all analytes.

Limit of detection (LOD) was found to be 0.002 mg/kg for all analytes.

Triazole Derivative Metabolites:

Analyses of specimens were performed at SGS INSTITUT FRESENIUS GmbH, Germany.

Homogenized field specimens aliquots were received deep frozen by SGS from Food Safety Laboratory. They were delivered on 21 October 2020, and kept deep frozen until analysis.

The method for the analysis of 1,2,4-T, TA, TAA and TLA, was based on the analytical method 01062/M004 (T. Class; "Modification M004 of BCS residue analytical method 01062 for the determination of 1,2,4-triazole, triazolylalanine, triazole acetic acid and triazole lactic acid by LC/DMS/MS/MS in plant materials", BASF DocID 2012/1294644, 07 December 2011)

Analytes were extracted with a mixture of methanol and water, filtered, concentrated and cleaned up by dispersive SPE cartridge. The analytes were determined by LC-DMS/MS/MS.

Limit of quantification (LOQ) achieved was 0.01 mg/kg for all analytes.

Limit of detection (LOD) was found to be 0.003 mg/kg for all analytes.

Residues

No residue of prothioconazole-desthio was found above LOQ in untreated specimens.

After two applications with PROTHIOCONAZOLE 300 EC at the rate of 0.65 L/ha, the residues of prothioconazole-desthio (as sum of isomers) in barley specimens were <LOD in grain collected at Normal Commercial Harvest, and between 0.155-0.245 mg/kg in straw.

Triazole Derivative Metabolites were also analysed:

No residue of 1,2,4-T above LOQ was measured in untreated or treated specimens.
Some residue of TA, TAA and TLA were detected in the control specimens, despite no application of triazole in the field for at least 3 years (2020, 2019 and 2018).

In treated plots:

Residue of Triazole Alanine (TA) were 0.122 to 0.316 mg/kg in grain and <LOQ to 0.032 mg/kg in straw at commercial harvest.

Residue of Triazole Acetic Acid (TAA) were 0.050 to 0.260 mg/kg in grain and <LOQ to 0.152 mg/kg in straw at commercial harvest.

Residue of Triazole Lactic Acid (TLA) were <LOQ in grain and <LOQ to 0.145 mg/kg in straw at commercial harvest.

A 2.1.3.4 Barley / Prothioconazole – Study on the behaviour of prothioconazole in barley after treatment with Prothioconazole 300 EC at two sites under field conditions in Northern Europe, 2021

Table A 10: Intended GAP

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP (number 200, 201, 51, 55, 59, 63, 67, 71, 75, 79, 83, 87*)	2	0.5-0.8 L/ha (125 g as/ha)	21 days	BBCH 25-69	56 d

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

Comments of zRMS:	Study performed according to GLP requirements, relevant guidelines and in line with the proposed GAP. The study is accepted. The objective of the study was to determine the magnitude of prothioconazole and its metabolite prothioconazole-desthio and Triazole Derivative Metabolites (1,2,4-T, TA, TAA, TLA) in barley, following two applications of prothioconazole 300 EC. Two residue trials were conducted in Northern Europe (Germany and northern France). Target application rate was 2 x ~0.2 kg/ha of prothioconazole. The spraying applications of Prothioconazole 300 EC were performed at 12 days before BBCH 61. In treated specimens of barley no residues equal or above the LOQ of 0.010 mg/kg were found for 1,2,4-Triazole and Triazole lactic acid. Residues ranged between 0.13 - 0.23 mg/kg for Triazole alanine, between 0.066 - 0.089 mg/kg for Triazole acetic acid.
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Reference: KCA 6.3-07

Report	Prothioconazole – Study on the behaviour of prothioconazole in barley after treatment with Prothioconazole 300 EC at two sites under field conditions in Northern Europe, 2021, Thirkell C., 2022, IF21-05704459 21-00228
Guideline(s):	Yes (SANCO 7029/VI/95 rev.5, TG 509, SANTE/2020/12830 Rev.1, SANCO/825/00 rev.8.1, OECD (2007) ENV/JM/MONO(2007)17.
Deviations:	None with impact
GLP:	Yes
Acceptability:	Yes

Active ingredient:	Prothioconazole	Commercial product (name):	N/A
Crop/crop group	Wheat/cereals	Producer of commercial product:	Globachem NV HELM AG ASCENZA AGRO, S.A.
Responsible body for reporting	Globachem NV, 3800 Sint-Truiden HELM AG, 20097 Hamburg ASCENZA AGRO, S.A., 2910-440 Setúbal	Indoor/Glasshouse/Outdoor:	Outdoor
Country	Belgium, Germany, Portugal	Other a.s. in formulation:	None
Content of active substance (g/kg or g/L):	300 g/L	Residues calculated as:	1,2,4-Triazole (T); Triazole Acetic Acid (TAA) ; Triazole Lactic Acid (TLA); Triazolalalanine (TA)
Formulation:	EC	Analytical Method	01062/M004
		LOQ	0.010

1	2	3	4	5			6	7	8	9				10	11	12	
Report No.	Commodity/E PPO-Code/Variety *	Date of 1) Sowing ¹ 2) Flowering ¹ 3) Harvest ¹		Method of treatment	Application rate per treatment ⁴			Date of treatment	BBCH Crop Growth Stage at Treatment	Portions analysed	Residues (mg/kg)				PHI (days)	Gro wth stage at sam-pling (BB CH)	Re-marks
					Water L/ha	Kg ai/hL ³	Prothio (kg ai/ha)				T	TAA	TLA	TA			
24857 Fahrdorf Germany IF21-05704459 21-00228-01	Spring Barley GC0640 ² HORVS KWS Jesse	1	12/04/21	Foliar broad- cast applica- tion	260	0.0781	0.203	11/06/21	49	Grain	<LOQ	0.089	<LOQ	0.23	37	89	/
		2	23/06- 24/06/21		260	0.0781	0.203	23/06/21	61	Straw	<LOQ	0.026	0.018	0.029	37	89	
		3	30/07/21	untreated	-	-	-	-	-	Grain Straw	<LOQ <LOQ	0.041 0.013	<LOQ 0.014	0.069 <LOQ	37 37	89 89	
51110 Aumenancour t-Le-Grand France IF21-05704459 21-00228-02	Spring Barley GC0640 ² HORVS RGT Planet	1	16/03/21	Foliar broad- cast applica- tion	283	0.0654	0.185	28/05/21	43	Ears	<LOQ	0.072	0.014	0.13	40	83	
		2	08/06- 15/06/21		287	0.0648	0.186	09/06/21	61	Rest of Plant	<LOQ	0.014	0.028	0.016	40	83	
		3	26/07/21		untreated	-	-	-	-	-	Grain Straw	<LOQ <LOQ	0.066 0.025	<LOQ 0.017	0.13 0.013	47 47	
					untreated	-	-	-	-	-	Grain Straw	<LOQ <LOQ	0.016 <LOQ	<LOQ <LOQ	0.016 <LOQ	47 47	89 89

¹Non-GLP-Data; ²According to the Codex Classification of food and animal feed commodities; ³calculated, ⁴Nominal rates: 0.195 kg ai/ha, water 200-400 L/ha

Summary:

Study Objective

The objective of the study IF21-05704459 was to determine the magnitude of the residues of prothioconazole metabolites (1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA)) in raw agricultural commodity specimens of barley (RAC grain/ears and rest of plant/straw) after two applications of Prothioconazole 300 EC, an emulsifiable concentrate formulation containing 300 g/L prothioconazole.

Field phase of the study

The study included two supervised residue trials conducted under field conditions in northern Europe (Germany and northern France) during the 2021 season. Two harvest trials were conducted.

The spraying applications of Prothioconazole 300 EC were performed at 12 days before BBCH 61 and BBCH 61 with a nominal application rate of 0.65 L test item/ha and a water rate of 200 – 400 L/ha.

Table 11: Application summary

Rial No. Country	Formulation	Appl. mode	Treated area/reference	Application						
				No. of appl.	Interval (days)	Growth stage (BBCH)	Test item rate (L/ha)	Water rate (L/ha)	a.s.	Appl. Rate (kg a.s./ha)
21-00228-01 Germany	Prothioconazole 300 EC	SPI	F/WF	1	-	49	0.676	260	Prothioconazole	0.203
				2	12	61	0.676	260	Prothioconazole	0.203
21-00228-02 Northern France	Prothioconazole 300 EC	SPI	F/WF	1	-	43	0.614	283	Prothioconazole	0.185
				2	12	61	0.621	287	Prothioconazole	0.186

a.s.: Active substance; Appl.: Application; SPI: Spraying; F: field; WF: whole field

Analytical Phase of the study

Specimens of barley were collected at sampling timing 37-40 DALA (S1) as ears and rest of plant, or grain and straw, and at normal commercial harvest (growth stage BBCH 89) as grain and straw (S2). Where growth stage BBCH 89 was reached at S1 only the normal commercial harvest sampling was conducted.

The analytical method 01062/M004 was used for analysis of 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) by LCDMS/MS/MS. The Limit of Quantification (LOQ) of the analytical method was defined as 0.010 mg/kg for each analyte.

Procedural Recoveries

Concurrent recoveries, performed with fortified untreated specimens, were analysed together with the field specimens. Overall and average recoveries were all in the range of 70 – 110 % and relative standard deviations (RSD) were < 20 %.

A summary of the values obtained for the mean recoveries, standard deviation (SD) and relative standard deviation (RSD) for the field specimen analysis is given below.

Table 62: Summary of procedural recoveries for 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA)

Crop	Matrix	Fortification Level (nominal) [mg/kg]	1,2,4-T		
			Mean [%]	RSD [±]	n
Barley	Grain	0.010, 0.10 and 1.0	93.6	3.4	6
	Straw	0.010, 0.10 and 1.0	91.6	8.6	6
	Ears	0.010, 0.10 and 1.0	97.9	6.3	6
	Rest of Plant	0.010, 0.10 and 1.0	94.3	4.7	6
Overall			94.3	6.2	24
Crop	Matrix	Fortification Level (nominal) [mg/kg]	TA		
			Mean [%]	RSD [±]	n
Barley	Grain	0.010, 0.10 and 1.0	84.8	12	9
	Straw	0.010, 0.10 and 1.0	85.9	12	6
	Ears	0.010, 0.10 and 1.0	86.5	4.2	6
	Rest of Plant	0.010, 0.10 and 1.0	96.1	6.9	6
Overall			87.9	10	27
Crop	Matrix	Fortification Level (nominal) [mg/kg]	TAA		
			Mean [%]	RSD [±]	n
Barley	Grain	0.010, 0.10 and 1.0	85.5	8.1	6
	Straw	0.010, 0.10 and 1.0	82.8	4.5	6
	Ears	0.010, 0.10 and 1.0	85.9	4.7	6
	Rest of Plant	0.010, 0.10 and 1.0	96.8	4.4	6
Overall			87.7	8.1	24
Crop	Matrix	Fortification Level (nominal) [mg/kg]	TLA		
			Mean [%]	RSD [±]	n
Barley	Grain	0.010, 0.10 and 1.0	78.1	5.3	6
	Straw	0.010, 0.10 and 1.0	78.0	5.3	6
	Ears	0.010, 0.10 and 1.0	81.3	2.6	6
	Rest of Plant	0.010, 0.10 and 1.0	95.9	1.5	6
Overall			83.3	9.8	24

RSD: relative standard deviation; n: number of specimens

Table 13: Summary of the residues of 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA)

Sampling No.	Portion analysed	Plot	DALA	BBCH	n	Residues [mg/kg]							
						1,2,4-T		TA		TAA		TLA	
Trial: 21-00228-						01	02	01	02	01	02	01	02
2	Grain	U	37 - 47	89	2	< 0.010	< 0.010	0.069	0.016	0.041	0.016	< 0.010	< 0.010
	Straw				2	< 0.010	< 0.010	< 0.010	< 0.010	0.013	< 0.010	0.014	< 0.010
1	Ears	T	40	83	1	---	< 0.010	---	0.13	---	0.072	---	0.014
	Rest of Plant				1	---	< 0.010	---	0.016	---	0.014	---	0.028
2	Grain	T	37 - 47	89	2	< 0.010	< 0.010	0.23	0.13	0.089	0.066	< 0.010	< 0.010
	Straw				2	< 0.010	< 0.010	0.029	0.013	0.026	0.025	0.018	0.017

Residues

In untreated specimens of barley - straw taken at normal commercial harvest (NCH, BBCH 89) no residues equal or above the LOQ of 0.010 mg/kg were found for 1,2,4-Triazole and Triazole alanine. Residues ranged between < 0.010 - 0.013 mg/kg for Triazole acetic acid and between < 0.010 - 0.014 mg/kg for Triazole lactic acid.

In untreated specimens of barley - grain taken at normal commercial harvest (NCH, BBCH 89) no residues equal or above the LOQ of 0.010 mg/kg were found for 1,2,4-Triazole and Triazole lactic acid. Residues ranged between 0.016 - 0.069 mg/kg for Triazole alanine and between 0.016 - 0.041 mg/kg for Triazole acetic acid.

In treated specimens of barley - straw taken at normal commercial harvest (NCH, BBCH 89) no residues equal or above the LOQ of 0.010 mg/kg were found for 1,2,4-Triazole. Residues ranged between 0.013 - 0.029 mg/kg for Triazole alanine, between 0.025 - 0.026 mg/kg for Triazole acetic acid and between 0.017 - 0.018 mg/kg for Triazole lactic acid.

In treated specimens of barley - grain taken at normal commercial harvest (NCH, BBCH 89) no residues equal or above the LOQ of 0.010 mg/kg were found for 1,2,4-Triazole and Triazole lactic acid. Residues ranged between 0.13 - 0.23 mg/kg for Triazole alanine, between 0.066 - 0.089 mg/kg for Triazole acetic acid.

Table 14: Summary of the residues of 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA)

Sampling No.	Portion analysed	Plot	DALA	BBCH	n	Residues [mg/kg]							
						1,2,4-T		TA		TAA		TLA	
Trial: 21-00228-						01	02	01	02	01	02	01	02
2	Grain	U	37 - 47	89	2	< 0.010	< 0.010	0.069	0.016	0.041	0.016	< 0.010	< 0.010
	Straw				2	< 0.010	< 0.010	< 0.010	< 0.010	0.013	< 0.010	0.014	< 0.010
1	Ears	T	40	83	1	---	< 0.010	---	0.13	---	0.072	---	0.014
	Rest of Plant				1	---	< 0.010	---	0.016	---	0.014	---	0.028
2	Grain	T	37 - 47	89	2	< 0.010	< 0.010	0.23	0.13	0.089	0.066	< 0.010	< 0.010
	Straw				2	< 0.010	< 0.010	0.029	0.013	0.026	0.025	0.018	0.017

DALA: Days after last application; U: Untreated plot; T: treated plot

A 2.1.3.5 Barley / Prothioconazole – Study on the behaviour of prothioconazole in barley after treatment with Prothioconazole 300 EC at two sites under field conditions in Southern Europe, 2021

Table A 15: Intended GAP

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP (number 200, 201, 51, 55, 59, 63, 67, 71, 75, 79, 83, 87*)	1 2	0.5 0.8 L/ha (125 g as/ha)	1 21days	BBCH 25-69	56 d

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

Comments of zRMS:	This submission does not apply to SEU. The study is not evaluated.
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Reference: KCA 6.3-08

Report Prothioconazole – Study on the behaviour of prothioconazole in barley after treatment with Prothioconazole 300 EC at two sites under field conditions in Southern Europe, 2021, Meyer M., 2022, IF21-05707589 21-00229

Guideline(s): Yes (SANCO 7029/VI/95 rev.5, TG 509, SANTE/2020/12830 Rev.1, SANCO/825/00 rev.8.1, OECD (2007) ENV/JM/MONO(2007)17.

Deviations: None with impact

GLP: Yes

Acceptability: Yes/No/Supplementary

Active ingredient:	Prothioconazole	Commercial product (name):	N/A
Crop/crop group	Barley/cereals	Producer of commercial product:	Globachem NV HELM AG ASCENZA AGRO, S.A.
Responsible body for reporting	Globachem NV, 3800 Sint-Truiden HELM AG, 20097 Hamburg ASCENZA AGRO, S.A., 2910-440 Setúbal	Indoor/Glasshouse/Outdoor:	Outdoor
Country	Belgium, Germany, Portugal	Other a.s. in formulation:	None
Content of active substance (g/kg or g/L):	300 g/L	Residues calculated as:	1,2,4-Triazole (T); Triazole Acetic Acid (TAA) ; Triazole Lactic Acid (TLA); Triazolalalanine (TA)
Formulation:	EC	Analytical Method	01062/M004
		LOQ	0.010

1	2	3	4	5			6	7	8	9				10	11	12
Report No.	Commodity/E PPO-Code/Variety *	Date of 1) Sowing ¹ 2) Flowering ¹ 3) Harvest ¹	Method of treatment	Application rate per treatment ⁴			Date of treatment	BBCH Crop Growth Stage at Treatment	Portions analysed	Residues (mg/kg)				PHI (days)	Gro wth stage at sam- pling (BB CH)	Re- marks
				Water L/ha	Kg ai/hL ³	Prothio (kg ai/ha)				T	TAA	TLA	TA			
	Winter Barley GC0640 ² HORVW Amistar	1 07/11/20 2 12/05- 3 19/05/21 05/07/21	Foliar broad- cast applica- tion	297 303	0.0646 0.0650	0.192 0.197	30/04/21 12/05/21	49 61	WholePlant WholePlant WholePlant Grain Straw	<LOQ <LOQ <LOQ <LOQ <LOQ	<LOQ <LOQ 0.061 0.013 0.089 0.014	0.011 <LOQ <LOQ 0.021 <LOQ 0.013	0.013 0.020 0.011 0.13 <LOQ 0.14 <LOQ	0 6 13 34 34 54 54	61 69 73 87 87 89 89	/
			untreated	-	-	-	-	-	Grain Straw	<LOQ <LOQ	0.033 <LOQ	<LOQ <LOQ	0.030 <LOQ	54 54	89 89	
	Spring Barley GC0640 ² HORVS Esopo	1 15/02/21 2 10/05- 3 22/05/21 16/06/21	Foliar broad- cast applica- tion	298 313	0.0648 0.0649	0.193 0.203	28/04/21 10/05/21	47-51 61	WholePlant WholePlant WholePlant Grain Straw	<LOQ <LOQ <LOQ <LOQ <LOQ	<LOQ <LOQ <LOQ 0.062 0.025	<LOQ <LOQ <LOQ <LOQ 0.026	<LOQ 0.057 0.010 0.21 0.020	0 7 15 37 37	61 69 71 89 89	
			untreated	-	-	-	-	-	Grain Straw	<LOQ <LOQ	<LOQ <LOQ	<LOQ <LOQ	0.014 <LOQ	37 37	89 89	

¹Non-GLP-Data; ²According to the Codex Classification of food and animal feed commodities; ³calculated, ⁴Nominal rates: 0.195 kg ai/ha, water 200-400 L/ha

Summary:

Study Objective

The objective of the study IF21-05707589 was to determine the magnitude of the residues of the prothioconazole metabolites (1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA)) in raw agricultural commodity specimens of barley (whole plant, grain and straw) after two applications of Prothioconazole 300 EC, an emulsifiable concentrate formulation containing 300 g prothioconazole/L.

Field phase of the study

The study included two supervised residue trials conducted under field conditions in southern Europe (southern France and Italy) during the 2021 season. Both trials were conducted as decline trials.

The spraying applications of Prothioconazole 300 EC were performed at 12 days before BBCH 61 and BBCH 61 with a nominal application rate of 0.65 L test item/ha and a water rate of 200 – 400 L/ha.

The actual application data are presented in the following table.

Table 16: Application summary

Trial No. Country	Formulation	Appl. mode	Treated area / Reference	Application						
				No. of appl.	Interval (days)	Growth stage (BBCH code)	Test item rate (L/ha)	Water rate (L/ha)	a.s.	Appl. rate (kg a.s./ha)
21-00229-01 southern France	Prothioconazole 300 EC	SPI	F/WF	1	-	49	0.642	297	prothioconazole	0.192
				2	12	61	0.656	303	prothioconazole	0.197
-02 Italy	Prothioconazole 300 EC	SPI	F/WF	1	-	47-51	0.645	298	prothioconazole	0.193
				2	12	61	0.677	313	prothioconazole	0.203

a.s.: Active substance

Appl.: Application

SPI: Spraying

WF: Whole Field

F: Field

Analytical Phase of the study

Specimens of barley were collected at a sampling timing 0 (S1), 6-7 (S2) and 13-15 (S3) DALA as whole plant, 34-37 DALA (S4) as grain and straw and at normal commercial harvest (growth stage BBCH 89) as grain and straw (S5) (only in case BBCH 89 was not reached at S4).

The analytical method 01062/M004 was used for analysis of 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) by LCDMS/MS/MS. The Limit of Quantification (LOQ) of the analytical method was defined as 0.010 mg/kg for each analyte.

Procedural Recoveries

Concurrent recoveries, performed with fortified untreated specimens, were analyzed together with the field specimens. Overall and average recoveries were all in the range of 70 – 110 % and relative standard deviations (RSD) were < 20 %.

A summary of the values obtained for the mean recoveries, standard deviation (SD) and relative standard deviation (RSD) for the field specimen analysis is given below.

Table 177: Summary of procedural recoveries for 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA)

Crop	Matrix	Fortification Level (nominal) [mg/kg]	1,2,4-T		
			Mean [%]	RSD [±]	n
Barley	Grain	0.010, 0.10 and 2.0	92.9	6.3	7
	Straw	0.010, 0.10 and 2.0	93.9	6.6	7
	Whole Plant no Roots	0.010, 0.10 and 2.0	91.1	8.4	7
Overall			92.6	6.9	21
Crop	Matrix	Fortification Level (nominal) [mg/kg]	TA		
			Mean [%]	RSD [±]	n
Barley	Grain	0.010, 0.10 and 2.0	80.2	13	7
	Straw	0.010, 0.10 and 2.0	84.1	5.7	7
	Whole Plant no Roots	0.010, 0.10 and 2.0	96.1	6.4	7
Overall			86.8	11	21
Crop	Matrix	Fortification Level (nominal) [mg/kg]	TAA		
			Mean [%]	RSD [±]	n
Barley	Grain	0.010, 0.10 and 2.0	79.5	4.1	7
	Straw	0.010, 0.10 and 2.0	90.8	6.5	7
	Whole Plant no Roots	0.010, 0.10 and 2.0	96.1	6.0	7
Overall			88.8	9.7	21
Crop	Matrix	Fortification Level (nominal) [mg/kg]	TLA		
			Mean [%]	RSD [±]	n
Barley	Grain	0.010, 0.10 and 2.0	80.8	5.3	7
	Straw	0.010, 0.10 and 2.0	88.7	5.2	7
	Whole Plant no Roots	0.010, 0.10 and 2.0	94.5	4.5	7
Overall			88.0	8.0	21

RSD: Relative standard deviation; n: Number of specimens

Residues

In untreated specimens of barley - straw taken at normal commercial harvest (NCH, BBCH 89) no residues equal or above the LOQ of 0.010 mg/kg were found for 1,2,4-Triazole, Triazole alanine, Triazole acetic acid and Triazole lactic acid. In untreated specimens of barley - grain taken at normal commercial harvest (NCH, BBCH 89) no residues equal or above the LOQ of 0.010 mg/kg were found for 1,2,4-Triazole and Triazole lactic acid. Residues ranged between 0.014 – 0.030 mg/kg for Triazole alanine and between < 0.010 - 0.033 mg/kg for Triazole acetic acid.

In treated specimens of barley - straw taken at normal commercial harvest (NCH, BBCH 89) no residues equal or above the LOQ of 0.010 mg/kg were found for 1,2,4-Triazole. Residues ranged between < 0.010 - 0.020 mg/kg for Triazole alanine, between 0.014 - 0.025 mg/kg for Triazole acetic acid and between 0.013 - 0.026 mg/kg for Triazole lactic acid.

In treated specimens of barley - grain taken at normal commercial harvest (NCH, BBCH 89) no residues equal or above the LOQ of 0.010 mg/kg were found for 1,2,4-Triazole and Triazole lactic acid. Residues ranged between 0.14 – 0.21 mg/kg for Triazole alanine and between 0.062 - 0.089 mg/kg for Triazole acetic acid.

The residues detected in field specimens can be summarized as in the following table.

Table 18: Summary of the residues of 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA)

Sampling No.	Portion analysed	Plot	DALA	BBCH	n	Range of residues			
						1,2,4-T [mg/kg]	TA [mg/kg]	TAA [mg/kg]	TLA [mg/kg]
5	Grain	U	37 - 54	89	2	< 0.010	0.014 - 0.030	< 0.010 - 0.033	< 0.010
	Straw				2	< 0.010	< 0.010	< 0.010	< 0.010
1	Whole Plant no Roots	T	0	61	2	< 0.010	< 0.010 - 0.013	< 0.010	< 0.010 - 0.011
2			6 - 7	69	2	< 0.010	0.020 - 0.057	< 0.010	< 0.010
3			13 - 15	71 - 73	2	< 0.010	0.026 - 0.087	< 0.010	0.010 - 0.011
4	Grain		34	87	1	< 0.010	0.13	0.061	< 0.010
	Straw				1	< 0.010	< 0.010	0.013	0.021
5	Grain		37 - 54	89	2	< 0.010	0.14 - 0.21	0.062 - 0.089	< 0.010
	Straw				2	< 0.010	< 0.010 - 0.020	0.014 - 0.025	0.013 - 0.026

DALA: Days after last application;; U: Untreated plot; T: Treated plot

A 2.1.3.6 Wheat / Prothioconazole – Magnitude of the residues of prothioconazole and its metabolites in wheat (whole plants, grain and straw), following two applications of prothioconazole 300 EC in eight trials (4 DCS and 4 HS), Northern and Southern Europe (Poland, Hungary, Portugal and Greece) - 2017

Table A 19: Intended GAP

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP (number 9-11, 13, 15, 17, 19, 23, 27, 31, 35, 39, 43, 95, 97, 101, 105, 109, 113, 117, 121, 125, 129, 137, 139, 143, 147, 151, 155, 159, 163, 167, 171, 184, 186, 188, 190, 192, 194, 196, 21, 25, 29, 33, 37, 41, 45, 96, 99, 103, 107, 111, 115, 119, 123, 127, 131, 138, 141, 145, 149, 153, 157, 161, 165, 169, 173, 201, 200)	2	0.5 0.8 L/ha (125 g as/ha)	21days	BBCH 25-69	35d

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

Comments of zRMS:	Study performed according to GLP requirements, relevant guidelines and in line with the proposed GAP. The study is accepted. The objective of the study was to determine the magnitude of prothioconazole in wheat following two applications of prothioconazole 300 EC. Eight residue trials (4 decline and 4 harvest) were conducted in Northern and Southern Europe (Poland, Hungary, Portugal and Greece). The SEU trials are considered as supporting. Target application rate was ~ 0.2 kg/ha of prothioconazole at each application. The interval between application was 14 days. The second application took place 35 days before the commercial harvest. The last stage of the application was at BBCH 75. The residues of prothioconazole-desthio (as sum of isomers) were below LOQ.
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Reference: KCA 6.3-09

Report Prothioconazole – Magnitude of the residues of prothioconazole and its metabolites in wheat (whole plants, grain and straw), following two applications of prothioconazole 300 EC in eight trials (4 DCS and 4 HS), Northern and Southern Europe (Poland, Hungary, Portugal and Greece) - 2017, Grall E., 2019, EGL-17-28966

Guideline(s): Yes (SANCO 7029/VI/95 rev.5, TG 509, SANTE/2020/12830 Rev.1, SANCO/825/00 rev.8.1, OECD (2007) ENV/JM/MONO(2007)17.

Deviations: None with impact

GLP: Yes
Acceptability: Yes

Active ingredient:	Prothioconazole	Commercial product (name):	HAG 610 01 F
Crop/crop group	Winter Barley	Producer of commercial product:	HELM AG, Germany
Responsible body for reporting	STAPHYT SPAIN S.L. 41927 Mairena del Aljate	Indoor/Glasshouse/Outdoor:	Outdoor
Country	Spain	Other a.s. in formulation:	None
Content of active substance (g/kg or g/L):	300 g/L	Residues calculated as:	Prothioconazole and Prothioconazole-desthio (as sum of isomers) EN 15662:2008 for prothioconazole and prothioconazole-desthio 00979/M001 for the other metabolites
Formulation:	EC	Analytical Method	LOQ 0.01

1	2	3		4	5			6	7	8	9		10	11
Report No.	Commodity /Variety	1 2 3	Date of 1) Sowing 2) Flowering 3) Harvest	Method of treatment	Application rate per treatment			Date of treatment	BBCH Crop Growth Stage at Treat- ment	Portions analysed	Residues (mg/kg)		PHI (days)	Remarks
					g a.s./ha	Water (L/ha)	g a.s./hL				Prothioconazole-desthio			
EGL-17- 28966 PL01 Poland Lubelskie 21-200 Przewłoka	Winter Wheat Skagen	1 2 3	13/10/16 20/06-26/06/17 26/07/17	Foliar broadcast application	0.202 0.202	297 296	0.068 0.068	30/05/17 13/06/17	39 53	Wh. Plants Wh. Plants Wh. Plants Wh. Plants Wh. Plants Wh. Plants Grain Straw	1.338* 0.272 0.035 0.01 <LOQ* <LOQ <LOD NA NA	1.322* 2.201 2.177 1.376 1.579* 0.925 0.582 <LOD 0.666	0 1 3 5 7 14 21 38 38	All un- treated specimens: <LOQ* Max. storage interval: 414 days
EGL-17- 28966 PL02 Poland Wielkopolski 63-233 Łobez	Winter Wheat Tobak	1 2 3	16/10/16 03/06-17/06/17 04/08/17	Foliar broadcast application	0.200 0.209	293 307	0.068 0.068	19/06/17 03/07/17	71 75	Grain Straw	NA NA	<LOQ 0.1.13	32 32	All un- treated specimens: <LOQ Max. storage interval: 356 days

EGL-17-28966 HU03 Hungary Győr-Moson-Sopron 9200 Mosonmagyaróvár	Winter Wheat MV Kolo	1	16/10/16	Foliar broadcast application	0.210	309	0.068	27/05/17	65	Wh. Plants	0.923*	2.023*	0	All un- treated specimens: <LOQ Max. storage interval: 419 days
		2	23/05-30/05/17		0.205	302	0.068	09/06/17	75	Wh. Plants	0.201	2.089	1	
		3	13/07/17							Wh. Plants	0.033	1.494	3	
										Wh. Plants	0.025	1.503	5	
										Wh. Plants	0.017*	1.964*	7	
										Wh. Plants	0.011	1.778	14	
										Wh. Plants	<LOQ	2.301	21	
EGL-17-28966 HU04 Hungary Komárom-Esztergom megye 2855 Bokod	Winter Wheat GK Csillag	1	03/10/16	Foliar broadcast application	0.214	314	0.068	19/05/17	52	Grain	NA	<LOQ	33	All un- treated specimens: <LOQ Max. storage interval: 386 days
		2	24/05-04/06/17		0.217	319	0.068	02/06/17	67-69	Straw	NA	3.529	33	
		3	06/07/17											
EGL-17-28966 GR05 Greece Central Macedonia GR 58300 Esosvalta	Winter Wheat Claudio	1	15/11/16	Foliar broadcast application	0.207	304	0.068	18/04/17	51	Wh. Plants	1.166*	1.470*	0	All un- treated specimens: <LOQ Max. storage interval: 459 days
		2	22/04-30/04/17		0.205	301	0.068	02/05/17	71	Wh. Plants	0.202	2.372	1	
		3	10/06/17							Wh. Plants	0.021	1.637	3	
										Wh. Plants	0.014	1.481	5	
										Wh. Plants	0.011*	1.541*	6	
										Wh. Plants	<LOQ	0.711	13	
										Wh. Plants	<LOD	0.449	20	
										Grain	NA	<LOD	36	
										Straw	NA	1.245	36	

EGL-17-28966 PT06 Portugal Alentejo 7350-953 Elvas	Winter Wheat Azul	1 2 3	25/11/16 30/03-12/04/17 10/06/17	Foliar broadcast application	0.211 0.209	360 357	0.059 0.059	26/04/17 08/05/17	71 73	Grain Straw	NA NA	<LOQ 0.696	32 32	All un- treated specimens: <LOQ Max. storage interval: 411 days
EGL-17-28966 GR07 Greece Central Macedonia GR 57200 Kavallari	Winter Wheat Genesi	1 2 3	10/11/16 27/04-04/05/17 10/06/17	Foliar broadcast application	0.204 0.205	301 302	0.068 0.068	20/04/17 04/05/17	49 69	Grain Straw	NA NA	<LOD 2.94	34 34	All un- treated specimens: <LOQ Max. storage interval: 463 days
EGL-17-28966 GR08 Greece West Mace- donia GR50100 Polymylos	Winter Wheat Doirani	1 2 3	08/11/16 10/05-17/05/17 08/07/17	Foliar broadcast application	0.205 0.205	301 301	0.068 0.068	15/05/2017 29/05/17	69 73	Grain Straw	NA NA	<LOD 4.919	38 38	All un- treated specimens: <LOQ Max. storage interval: 408 days

* average of two samples

NA: not analysed

Summary:

Study Objective

The objective of the study was to determine the magnitude of residues of prothioconazole and its metabolites prothioconazole-desthio in raw agricultural commodity (RAC whole plants, grain and straw) of wheat after two applications of HAG 610 01 F (Prothioconazole 300 EC). The crop was subjected to a residue program which simulated the use of HAG 610 01 F as a fungicide in wheat in Northern and Southern Europe (Poland, Hungary, Portugal and Greece).

Target application rate was 0.65 L/ha and target application time: Application (A1) 14 ± 2 days before application 2, and application 2 35 ± 3 days before commercial harvest.

Field phase of the study

Two plots were established in each trial: U plot was left untreated. T plot was intended for residue at harvest, treated twice with HAG 610 01 F at the rate of 0.65 L/ha. Application 1 took place $14 (\pm 2)$ days before application 2. Application 2 took place 35 ± 3 days before the commercial harvest.

4 trials were Decline Curve Study trials with eight samplings. The first six samplings were specimens of whole plants and were taken at 0, 1, 3, 5, 7, 14 (± 1), and 21 (± 2) days after the last application. At 35 (± 3) DALA (harvest) grain and straw were collected.

4 trials were Harvest Study trials and one sampling was taken at harvest, 35 ± 3) DALA. Grain and straw were collected in each plot. Specimens were placed into labelled plastic bags, weighed and double bagged.

Specimens were frozen and shipped on freezer truck or with dry ice. They were delivered to analytical site between 20 June 2017 and 29 September 2017.

Analytical Phase of the study

Analyses of specimens were performed at Food Safety Laboratory, Skierniewice, Poland. Two different analytical methods were used:

The method for the analysis of prothioconazole and prothioconazole-desthio in wheat whole plants, was based on the method described in EN 15662:2008 “foods of plant origin – Determination of pesticide residues using GC-MS and/or LC-MS/MS following acetonitrile extraction/portioning and clean-up by dispersive SPE – QuEChERS-method”.

The method for the analysis of JAU-6476-desthio (M04), JAU-6476-3-hydroxy-desthio (M14), JAU-6476-4-hydroxy-desthio (M15), JAU-6476-5-hydroxy-desthio (M16), JAU-6476-6-hydroxy-desthio (M17) and JAU-6476- α -hydroxy-desthio (M18) in wheat whole plant, seed and straw was based on the BAYER CropScience method “Analytical Method 00979/M001 for the determination of residues of JAU-6476-a-hydroxy-desthio, JAU-6476-3-hydroxy-desthio, JAU-6476-4-hydroxy-desthio, JAU-6476-5-hydroxy-desthio, and JAU-6476-6-hydroxy-desthio in/on matrices of plant origin by HPLCMS/MS”, Report: KCA 4.1.2/34; Freitag, Th.; Daniels, M.; 2009; M-328686-01-1.

Limit of quantification (LOQ) achieved was 0.01 mg/kg for all analytes.

Limit of determination (LOD) was found to be 0.003 mg/kg for prothioconazole and prothioconazole-desthio, and 0.002 mg/kg for the other analytes.

Both methods were validated in wheat whole plant, grain and straw during this study. Acceptance criteria for method validations were met, with average recoveries ranging from 70% to 110% and relative standard deviations $\leq 20\%$.

Residues

No residue of prothioconazole or prothioconazole-desthio was found above LOQ in untreated specimen.

After two applications with HAG 610 01 F at the rate of 0.65 L/ha, the residues of prothioconazole in wheat whole plants specimens:

- from 0.854 mg/kg to 1.955 mg/kg at 0 DALA,
- from 0.153 mg/kg to 0.272 mg/kg at 1 DALA,
- from 0.021 mg/kg to 0.038 mg/kg at 3 DALA,
- from 0.01 mg/kg to 0.025 mg/kg at 5 DALA,
- from below LOQ to 0.017 mg/kg at 7 DALA,
- from below LOQ to 0.011 mg/kg at 14 DALA,
- below LOQ at 21 DALA,

After two applications with HAG 610 01 F (plot T) at the rate of 0.65 L/ha, the residues of prothioconazole-desthio (as sum of isomers) in wheat specimens

In whole plants specimens:

- from 1.245 mg/kg to 4.075 mg/kg at 0 DALA,
- from 2.089 mg/kg to 4.939 mg/kg at 1 DALA,
- from 1.494 mg/kg to 4.549 mg/kg at 3 DALA,
- from 1.376 mg/kg to 3.757 mg/kg at 5 DALA,
- from 1.475 mg/kg to 3.067 mg/kg at 7 DALA,
- from 0.711 mg/kg to 3.063 mg/kg at 14 DALA,
- from 0.449 mg/kg to 3.365 mg/kg at 21 DALA,

in grain at commercial harvest: below LOQ.

in straw at commercial harvest: from 0.666 mg/kg to 4.919 mg/kg

A 2.1.3.7 Wheat / Prothioconazole – Magnitude of the residues of prothioconazole and its metabolites in wheat (whole plants, grain and straw), following two applications of prothioconazole 300 EC in eight trials (4 DCS and 4 HS), Northern and Southern Europe (Poland, Hungary, Portugal and Greece) - 2018

Table A 20: Intended GAP

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP (number 9-11, 13, 15, 17, 19, 23, 27, 31, 35, 39, 43, 95, 97, 101, 105, 109, 113, 117, 121, 125, 129, 137, 139, 143, 147, 151, 155, 159, 163, 167, 171, 184, 186, 188, 190, 192, 194, 196, 21, 25, 29, 33, 37, 41, 45, 96, 99, 103, 107, 111, 115, 119, 123, 127, 131, 138, 141, 145, 149, 153, 157, 161, 165, 169, 173, 201, 200)	2	0.5 0.8 L/ha (125 g as/ha)	21days	BBCH 25-69	35d

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

Comments of zRMS:	Study performed according to GLP requirements, relevant guidelines and in line with the proposed GAP. The study is accepted. The objective of the study was to determine the magnitude of prothioconazole and its metabolites in wheat, following two applications of prothioconazole 300 EC. Eight residue trials (4 decline and 4 harvest) were conducted in Northern and Southern Europe (Poland, Hungary, Portugal and Greece). The SEU trials are considered as supporting. Target application rate was ~ 0.2 kg/ha of prothioconazole at each application. The interval between application was 14 days. The second application took place 35 days before the commercial harvest. The last stage of the application was at BBCH 85 Trials were performed according to a more critical GAP than the intended GAP, and are considered as acceptable for the intended uses. No residue of prothioconazole or prothioconazole-desethio was found above LOQ.
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Reference: KCA 6.3-10

Report Prothioconazole – Magnitude of the residues of prothioconazole and its metabolites in wheat (whole plants, grain and straw), following two applications of prothioconazole 300 EC in eight trials (4 DCS and 4 HS), Northern and Southern Europe (Poland, Hungary, Portugal and Greece) - 2018, Grall E., 2019, EGL-18-32944

Guideline(s): Yes (SANCO 7029/VI/95 rev.5, TG 509, SANTE/2020/12830 Rev.1,

SANCO/825/00 rev.8.1, OECD (2007) ENV/JM/MONO(2007)17.

Deviations: None with impact
GLP: Yes
Acceptability: Yes

Active ingredient:	Prothioconazole	Commercial product (name):	HAG 610 01 F
Crop/crop group	Winter Barley	Producer of commercial product:	HELM AG, Germany
Responsible body for reporting	STAPHYT SPAIN S.L. 41960 Gines	Indoor/Glasshouse/Outdoor:	Outdoor
Country	Spain	Other a.s. in formulation:	None
Content of active substance (g/kg or g/L):	300 g/L	Residues calculated as:	Prothioconazole and Prothioconazole-desthio (as sum of isomers)
Formulation:	EC	Analytical Method	EN 15662:2008 for prothioconazole and prothioconazole-desthio
		LOO	00979/M001 for the other metabolites
			0.01

1	2	3		4	5			6	7	8	9		10	11
Report No.	Commodity /Variety	Date of 1) Sowing 2) Flowering 3) Harvest		Method of treatment	Application rate per treatment			Date of treatment	BBCH Crop Growth Stage at Treatment	Portions analysed	Residues (mg/kg)		PHI (days)	Remarks
					g a.s./ha	Water (L/ha)	g a.s./hL				Prothioconazole-desthio			
EGL-18-32944 PL01 Poland Wielkopolski 63-233 Łobez	Winter Wheat	1	28/10/17	Foliar broadcast application	0.206	302	0.068	14/06/18	73	Wh. Plants	0.992	1.386	0	All untreated specimens: <LOQ Max. storage interval: 167 days
	Tobak	2	29/05-08/06/18		0.203	299	0.068	27/06/18	83	Wh. Plants	0.041	1.582	7	
		3	29/07/18							Wh. Plants	0.025	1.684	14	
									Wh. Plants	0.015	0.447	22		
									Grain	NA	<LOD	32		
							Straw	NA	0.899	32				
EGL-18-32944 PL02 Poland Warmińsko-Mazurskie 14-100 Kąkrowo	Winter Wheat	1	10/10/17	Foliar broadcast application	0.213	313	0.068	15/06/18	15/06/18	Grain	NA	0.010	34	All untreated specimens: <LOQ Max. storage interval: 97 days
	Arkadia	2	09/06-16/06/18		0.222	327	0.068	29/06/18	29/06/18			0.774	34	
		3	02/08/18							Straw	NA			

EGL-18-32944 HU03 Hungary Jász-Nagykun-Szolnok 5081 Szajol	Winter Wheat GK Bekes	1	13/10/17	Foliar broadcast application	0.211	258	0.082	17/05/18	69	Wh. Plants Wh. Plants Wh. Plants Grain Straw	1.361	1.300	0	All un-treated specimens: <LOQ Max. storage interval: 194 days
		2	06/05-15/05/18		0.203	248	0.082	30/05/18	75		0.022	1.126	7	
		3	01/07/18								0.013	1.406	15	
											0.012	1.720	21	
EGL-18-32944 HU04 Hungary Jász-Nagykun-Szolnok 5420 Túrkeve	Winter Wheat Genius	1	02/10/17	Foliar broadcast application	0.219	268	0.082	18/05/18	63	Grain Straw	NA	0.024	35	All un-treated specimens: <LOQ Max. storage interval: 126 days
		3	10/06-20/06/18 04/07/2018		0.196	240	0.082	30/05/18	71		NA	1.572	35	
EGL-18-32944 PT05 Portugal Alentejo 7830 Serpa	Winter Wheat Aventadura	1	20/11/17	Foliar broadcast application	0.213	313	0.068	18/04/18	61	Wh. Plants Wh. Plants Wh. Plants Grain Straw	0.657	1.485	0	All un-treated specimens: <LOQ Max. storage interval: 217 days
		2	18/04-28/04/18		0.192	283	0.068	03/05/18	75		0.010	0.630	6	
		3	10/06/18								<LOQ	0.472	13	
											<LOQ	0.480	20	
											NA	<LOQ	34	
											NA	0.567	34	

EGL-18-32944 PT06 Portugal Alentejo 7800 Beja	Winter Wheat Don Ricardo	1 2 3	10/12/17 28/04-06/05/18 11/06/18	Foliar broadcast application	0.208 0.206	308 305	0.068 0.068	17/04/18 03/05/18	57 65	Grain Straw	NA NA	<LOQ 1.487	34 34	All un- treated specimens: <LOQ Max. storage interval: 153 days
EGL-18-32944 GR07 Greece Central Macedonia GR 57200 Drymos	Winter Wheat Cannavaro	1 2 3	05/11/17 25/04-05/05/18	Foliar broadcast application	0.205 0.204	301 300	0.068 0.068	20/04/18 04/05/18	49 69	Wh. Plants Wh. Plants Wh. Plants Wh. Plants Grain Straw	1.388 0.012 <LOQ <LOQ NA NA	2.092 1.319 1.323 1.092 <LOQ 2.616	0 7 13 20 35 35	All un- treated specimens: <LOQ Max. storage interval: 217 days
EGL-18-32944 GR08 Greece Central Macedonia GR58300 Agros Loukas	Winter Wheat Salvia	1 2 3	15/11/17 17/04-25/04/18 08/06/18	Foliar broadcast application	0.204 0.207	299 303	0.068 0.068	18/04/18 02/05/18	61 69	Grain Straw	NA NA	<LOQ 4.1.156	35 35	All un- treated specimens: <LOQ Max. storage interval: 153 days

NA: not analysed

Summary:

Study Objective

The objective of the study was to determine the magnitude of residues of prothioconazole and its metabolites prothioconazole-desthio in raw agricultural commodity (RAC whole plants, grain and straw) of wheat after two applications of HAG 610 01 F (Prothioconazole 300 EC). The crop was subjected to a residue program which simulated the use of HAG 610 01 F as a fungicide in wheat in Northern and Southern Europe (Poland, Hungary, Portugal and Greece).

Target application rate was 0.65 L/ha and target application time: Application 1 14 ± 2 days before application 2, and application 2 35 ± 3 days before commercial harvest.

Field phase of the study

Two plots were established in each trial: U plot was left untreated. T plot was intended for residue at harvest, treated twice with HAG 610 01 F at the rate of 0.65 L/ha. Application 1 took place $14 (\pm 2)$ days before application 2. Application 2 took place 35 ± 3 days before the commercial harvest.

4 trials were Decline Curve Study trials with five samplings. The first four samplings were specimens of whole plants and were taken at 0, 7 (± 1), 14 (± 1), and 21 (± 2) days after the last application. At 35 (± 3) DALA (harvest) grain and straw were collected.

4 trials were Harvest Study trials and one sampling was taken at harvest, 35 (± 3) DALA. Grain and straw were collected in each plot

Specimens were placed into labelled plastic bags, weighed and double bagged. Specimens were frozen and shipped on freezer truck or with dry ice. They were delivered to analytical site between 13 June 2018 and 12 September 2018.

Analytical Phase of the study

Analyses of specimens were performed at Food Safety Laboratory, Skierniewice, Poland. Two different analytical methods were used:

The method for the analysis of prothioconazole and prothioconazole-desthio in wheat whole plants, was based on the method described in EN 15662:2008 “foods of plant origin – Determination of pesticide residues using GC-MS and/or LC-MS/MS following acetonitrile extraction/partitioning and clean-up by dispersive SPE – QuEChERS-method”.

The method for the analysis of JAU-6476-desthio (M04), JAU-6476-3-hydroxy-desthio (M14), JAU-6476-4-hydroxy-desthio (M15), JAU-6476-5-hydroxy-desthio (M16), JAU-6476-6-hydroxy-desthio (M17) and JAU-6476- α -hydroxy-desthio (M18) in wheat whole plant, seed and straw was based on the BAYER CropScience method “Analytical Method 00979/M001 for the determination of residues of JAU-6476-a-hydroxy-desthio, JAU-6476-3-hydroxy-desthio, JAU-6476-4-hydroxy-desthio, JAU-6476-5-hydroxy-desthio, and JAU-6476-6-hydroxy-desthio in/on matrices of plant origin by HPLCMS/MS”, Report: KCA 4.1.2/34; Freitag, Th.; Daniels, M.; 2009; M-328686-01-1.

Limit of quantification (LOQ) achieved was 0.01 mg/kg for all analytes.

Limit of detection (LOD) was found to be 0.003 mg/kg for prothioconazole and prothioconazoledesthio, and 0.002 mg/kg for the other analytes.

Both method were validated in wheat whole plant, grain and straw in a previous study (EGL-17-28966 - analytical phase ZBBZ-2017/17/DPL/2). Acceptance criteria for method validations were met, with average recoveries ranging from 70% to 110% and relative standard deviations $\leq 20\%$.

Residues

No residue of prothioconazole or prothioconazole-desthio was found above LOQ in untreated specimen.

After two applications with HAG 610 01 F at the rate of 0.65 L/ha, the residues of prothioconazole in wheat whole plants specimens

- from 0.657 mg/kg to 1.388 mg/kg at 0 DALA,
- from 0.010 to 0.041 mg/kg at 7 DALA,
- from below LOQ to 0.025 mg/kg at 14 DALA,
- from below LOQ to 0.015 mg/kg at 21 DALA,

After two applications with HAG 610 01 F (plot T) at the rate of 0.65 L/ha, the residues of prothioconazole-desthio (as sum of isomers) in wheat specimens

In whole plants specimens:

- from 1.300 mg/kg to 2.092 mg/kg at 0 DALA,
- from 0.630 mg/kg to 1.582 mg/kg at 7 DALA,
- from 0.472 mg/kg to 1.684 mg/kg at 14 DALA,
- from 0.447 mg/kg to 1.720 mg/kg at 21 DALA,

in grain at commercial harvest: from below LOQ to 0.024 mg/kg

in straw at commercial harvest: from 0.567 mg/kg to 2.616 mg/kg

A 2.1.3.8 Wheat / Prothioconazole – Residue study on wheat in Northern Europe

Table A 21: Intended GAP

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP (number 9-11, 13, 15, 17, 19, 23, 27, 31, 35, 39, 43, 95, 97, 101, 105, 109, 113, 117, 121, 125, 129, 137, 139, 143, 147, 151, 155, 159, 163, 167, 171, 184, 186, 188, 190, 192, 194, 196, 21, 25, 29, 33, 37, 41, 45, 96, 99, 103, 107, 111, 115, 119, 123, 127, 131, 138, 141, 145, 149, 153, 157, 161, 165, 169, 173, 201, 200)	2	0.5 0.8 L/ha (125 g as/ha)	21days	BBCH 25-69	35d

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

Comments of zRMS:	The objective of the study was to determine the magnitude of prothioconazole and its TDMs metabolites (1,2,4-T, TA, TAA and TLA) in wheat, following two applications of prothioconazole 300 EC. One residue trial was conducted in Northern Europe (Poland). Target application rate was 2 x ~0.2 kg/ha of prothioconazole. The interval between application was 19 days. The second application took place 35 days before the commercial harvest. The last stage of application was at BBCH 69. The residues of prothioconazole-desthio (as sum of isomers) in wheat grain specimens were <LOQ. No residues of 1,2,4-T was detected in untreated or treated specimens. Some residue of TA, TAA and TLA were detected in the control specimens, despite no application of triazole in the field for at least 3 years. All TDM residues in control specimens were close to LOQ (maximum 0.0122 mg/kg in whole plant at 0 DALA) and increased slightly in grain at harvest (up to 0.0609 mg/kg for TA in grain). Residue of Triazole Alanine (TA) were 0.0339 mg/kg in whole plant the day of application, and remained present in grain and straw at harvest (0.467 and 0.0352 mg/kg respectively). Residue of Triazole Acetic Acid (TAA) were 0.0163 mg/kg in whole plant the day of application, and remained present in grain and straw at harvest (0.0568 and 0.0767 mg/kg respectively). Residue of Triazole Lactic Acid (TLA) were 0.0131 mg/kg in whole plant the day of application, and remained present in straw at harvest (0.0741 mg/kg, < LOQ in grain).
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Reference: KCA 6.3-11

Report Prothioconazole – Residue study on wheat in Northern Europe - 2020, Grall E.,

	2019, EGL-20-42538
Guideline(s):	Yes (SANCO 7029/VI/95 rev.5, TG 509, SANTE/2020/12830 Rev.1, SANCO/825/00 rev.8.1, OECD (2007) ENV/JM/MONO(2007)17.
Deviations:	None with impact
GLP:	Yes
Acceptability:	Yes

Active ingredient:	Prothioconazole	Commercial product (name):	Prothioconazole 300 EC HAG 610 01 F
Crop/crop group	Winter Wheat	Producer of commercial product:	HELM AG, Germany
Responsible body for reporting	STAPHYT SPAIN S.L. 41927 Mairena del Aljefe	Indoor/Glasshouse/Outdoor:	Outdoor
Country	Spain	Other a.s. in formulation:	None
Content of active substance (g/kg or g/L):	300 g/L	Residues calculated as:	Prothioconazole and Prothioconazole-desthio (as sum of isomers) EN 15662:2018 for prothioconazole and prothioconazole-desthio 00979/M001 for the other metabolites 0.01 (0.06 mg/kg for sum of isomers)
Formulation:	EC	Analytical Method	LOQ

0.01 (0.00 mg/kg for sum of isomers)														
1	2	3		4	5			6	7	8	9		10	11
Report No.	Commodity /Variety	Date of 1) Sowing 2) Flowering 3) Harvest		Method of treatment	Application rate per treatment			Date of treatment	BBCH Crop Growth Stage at Treatment	Portions analysed	Residues (mg/kg)		PHI (days)	Remarks
					g a.s./ha	Water (L/ha)	g a.s./hL				Prothioconazole-desthio			
EGL-20-42538 PL01 Poland Warminsko Mazurskie 14-100 Brzydowo	Winter Wheat Julius	1	20/09/19	Foliar broadcast application	0.190	298	0.065	04/06/20 23/06/20	49 69	Wh. Plants	1.115	1.130	0	All untreated specimens: <LOQ Max. storage interval: 115 days
		2	13/06-23/06/20		0.190	298	0.065			Wh. Plants	0.013	0.306	7	
		3	10/08/20							Wh. Plants	0.010	0.183	14	
										Ear	NA	0.121	35	
										Straw	NA	0.154	35	
										Grain	NA	<LOQ	48	
										Straw	NA	0.151	18	

NA: not analysed

Summary:

Study Objective

The objective of the study was to determine the magnitude of residues of prothioconazole and its metabolites prothioconazole-desthio, as well as Triazole Derivative Metabolites in raw agricultural commodity (RAC whole plants, grain and straw) of wheat after two applications of PROTHIOCONAZOLE 300 EC. The crop was subjected to a residue program which simulated the use of PROTHIOCONAZOLE 300 EC as a fungicide in wheat in Northern Europe (Poland) in 2020.

Target application rate was 0.65 L/ha and target application time: Application 1 14 ± 2 days before application 2, and application 2 at BBH69

Field phase of the study

Two plots were established in the trial: U plot was left untreated. T plot was intended for residue at harvest, treated twice with PROTHIOCONAZOLE 300 EC at the rate of 0.65 L/ha. Application 1 took place 19 days before application 2 (deviation from study plan, application 2 was delayed by rain and waiting for crop stage). Application 2 took place at BBCH 69.

Specimens of whole plant were taken at 0, 7 and 14 DALA. At 35 DALA, ears and rest of plant were collected and grain and straw were collected at commercial harvest.

Specimens were placed into labelled plastic bags, weighed and double bagged. Specimens were frozen and shipped by freezer truck to the analytical test site for prothioconazole and prothioconazole-desthio metabolites. They were delivered on 25 August 2020.

Analytical Phase of the study

Prothioconazole and prothioconazole OH metabolites:

Analyses of specimens were performed at Food Safety Laboratory, Skierniewice, Poland.

Two different analytical methods were used:

The method for the analysis of prothioconazole and prothioconazole-desthio in wheat whole plants, was based on the method described in EN 15662:2018 “foods of plant origin – Multimethod for the determination of pesticide residues using GC and LC-based analysis following acetonitrile extraction/partitioning and clean-up by dispersive SPE – Modular QuEChERS-method.”

The method for the analysis of JAU-6476-desthio (M04), JAU-6476-3-hydroxy-desthio (M14), JAU-6476-4-hydroxy-desthio (M15), JAU-6476-5-hydroxy-desthio (M16), JAU-6476-6-hydroxy-desthio (M17) and JAU-6476- α -hydroxy-desthio (M18) in wheat whole plant, grain and straw was based on the BAYER CropScience method “Analytical Method 00979/M001 for the determination of residues of JAU-6476-a-hydroxy-desthio, JAU-6476-3-hydroxy-desthio, JAU-6476-4-hydroxy-desthio, JAU-6476-5-hydroxy-desthio, and JAU-6476-6-hydroxy-desthio in/on matrices of plant origin by HPLCMS/MS”, Report: KCA 4.1.2/34; Freitag, Th.; Daniels, M.; 2009; M-328686-01-1.

Limit of quantification (LOQ) achieved was 0.01 mg/kg for all analytes.

Limit of detection (LOD) was found to be 0.003 mg/kg for prothioconazole and prothioconazole-desthio (in whole plant), and 0.002 mg/kg for the other analytes.

Triazole Derivative Metabolites:

Analyses of specimens were performed at SGS INSTITUT FRESENIUS GmbH, Germany.

Homogenized field specimens aliquots were received deep frozen by SGS from Food Safety Laboratory. They were delivered on 29 October 2020, and kept deep frozen until analysis.

The method for the analysis of 1,2,4-T, TA, TAA and TLA, was based on the analytical method 01062/M004 (T. Class; “Modification M004 of BCS residue analytical method 01062 for the determination of 1,2,4-triazole, triazolylalanine, triazole acetic acid and triazole lactic acid by LC/DMS/MS/MS in plant materials”, BASF DocID 2012/1294644, 07 December 2011) Analytes were extracted with a mixture of methanol and water, filtered, concentrated and cleaned up by dispersive SPE cartridge. The analytes were determined by LC-DMS/MS/MS.

Limit of quantification (LOQ) achieved was 0.01 mg/kg for all analytes.

Limit of detection (LOD) was found to be 0.003 mg/kg for all analytes.

Residues

No residue of prothioconazole or prothioconazole-desthio was found above LOD in untreated specimen.

After two applications with PROTHIOCONAZOLE 300 EC at the rate of 0.65 L/ha, the residues of prothioconazole in wheat whole plants specimens decreased from 1.115 mg/kg the day of applications to 0.010 mg/kg at 14 DALA in whole plants.

The residues of prothioconazole-desthio (as sum of isomers) in wheat specimens decreased from 1.130 mg/kg the day of applications to 0.183 mg/kg at 14 DALA in whole plants.

At commercial harvest, the residues of prothioconazole-desthio (as sum of isomers) in wheat grain specimens were <LOQ, and 0.151 mg/kg in straw.

Triazole Derivative Metabolites were also analysed:

No residue of 1,2,4-T was detected in untreated or treated specimens.

Some residue of TA, TAA and TLA were detected in the control specimens, despite no application of triazole in the field for at least 3 years (2020, 2019 and 2018). All TDM residues in control specimens were close to LOQ (maximum 0.0122 mg/kg in whole plant at 0 DALA) and increased slightly in grain at harvest (up to 0.0609 mg/kg for TA in grain).

Residue of Triazole Alanine (TA) were 0.0339 mg/kg in whole plant the day of application, and remained present in grain and straw at harvest (0.467 and 0.0352 mg/kg respectively).

Residue of Triazole Acetic Acid (TAA) were 0.0163 mg/kg in whole plant the day of application, and remained present in grain and straw at harvest (0.0568 and 0.0767 mg/kg respectively).

Residue of Triazole Lactic Acid (TLA) were 0.0131 mg/kg in whole plant the day of application, and remained present in straw at harvest (0.0741 mg/kg, < LOQ in grain).

A 2.1.3.9 Wheat / Prothioconazole – Study on the behaviour of prothioconazole in wheat after treatment with Prothioconazole 300 EC at six sites under field conditions in Northern Europe Residue study on wheat in Northern Europe, 2021

Table A 22: Intended GAP

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP (number 9-11, 13, 15, 17, 19, 23, 27, 31, 35, 39, 43, 95, 97, 101, 105, 109, 113, 117, 121, 125, 129, 137, 139, 143, 147, 151, 155, 159, 163, 167, 171, 184, 186, 188, 190, 192, 194, 196, 21, 25, 29, 33, 37, 41, 45, 96, 99, 103, 107, 111, 115, 119, 123, 127, 131, 138, 141, 145, 149, 153, 157, 161, 165, 169, 173, 201, 200)	2	0.5 0.8 L/ha (125 g as/ha)	21days	BBCH 25-69	35d

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

Comments of zRMS:	Study performed according to GLP requirements, relevant guidelines and in line with the proposed GAP. The study is acceptable. The objective of the study was to determine the magnitude of the residues of prothioconazole TDMs metabolites in wheat following two applications of prothioconazole 300 EC. Six residue trials (2 decline and 4 harvest) were conducted in Northern Europe (Germany, Poland and Hungary). Target application rate ~0.2 kg/ha of prothioconazole at each application. The spraying applications of Prothioconazole 300 EC were performed at 11-17 days before BBCH 69. In treated specimens of wheat no residues equal or above the LOQ of 0.010 mg/kg were found for 1,2,4-Triazole. Residues ranged between 0.27 – 1.1 mg/kg for Triazole alanine, between 0.068 - 0.38 mg/kg for Triazole acetic acid and were <0.010 mg/kg for Triazole lactic acid.
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Reference: KCA 6.3-12

Report Study on the behaviour of prothioconazole in wheat after treatment with Prothiconzole 300 EC at six sites under field conditions in Northern Europe, 2021 IF21-05705310 21-00226

Guideline(s): Yes (SANCO 7029/VI/95 rev.5, SANTE/2019/12752, OECD 509, OECD (2016), SANTE/2020/12830 Rev.1, OECD (2007) ENV/JM/MONO(2007)17

Deviations: None with impact

GLP: Yes
Acceptability: Yes

Active ingredient:			Prothioconazole					Commercial product (name):		N/A							
Crop/crop group			Wheat/cereals					Producer of commercial product:		Globachem NV HELM AG ASCENZA AGRO, S.A.							
Responsible body for reporting			Globachem NV, 3800 Sint-Truiden HELM AG, 20097 Hamburg ASCENZA AGRO, S.A., 2910-440 Setúbal Belgium, Germany, Portugal					Indoor/Glasshouse/Outdoor:		Outdoor							
Country			Belgium, Germany, Portugal					Other a.s. in formulation:		None							
Content of active substance (g/kg or g/L):			300 g/L					Residues calculated as:		1,2,4-Triazole (T); Triazole Acetic Acid (TAA) ; Triazole Lactic Acid (TLA); Triazolalalanine (TA)							
Formulation:			EC					Analytical Method LOQ		01062/M004 0.010							
1	2	3		4	5			6	7	8	9				10	11	12
Report No.	Commodity/E PPO-Code/Variety *	Date of 1) Sowing ¹ 2) Flowering ¹ 3) Harvest ¹		Method of treatment	Application rate per treatment ⁴			Date of treatment	BBCH Crop Growth Stage at Treatment	Portions analysed	Residues (mg/kg)				PHI (days)	Gro wth stage at sampling (BB CH)	Re- marks
					Water L/ha	Kg ai/hL ³	Prothio (kg ai/ha)				T	TAA	TLA	TA			
24980 Walls-büll Germany IF21-05705310 21-00226-01	Winter Wheat GC0654 ² TRZAW RGT Reform	1	25/10/20	Foliar appli- cation with boom	258 252	0.0779 0.0778	0.201 0.196	31/05/21 17/06/21	43 69	WholePlant	<LOQ	0.11	0.11	0.15	0	69	/
		2	15-							WholePlant	<LOQ	0.11	0.11	0.022	6	71	
		3	17/06/21							WholePlant	<LOQ	0.097	0.095	0.020	13	71	
			05/08/21							Ears	<LOQ	0.30	<LOQ	0.49	33	83	
										Rest	<LOQ	0.083	0.16	0.012	33	83	
										Grain	<LOQ	0.29	<LOQ	0.54	49	89	
				Straw	<LOQ	0.13	0.031	0.10	49	89							
				untreated	-	-	-	-	-	Grain Straw	<LOQ <LOQ	0.19 0.081	<LOQ 0.015	0.3 0.047	49 49	89 89	
		88-320 Os- trowo Poland IF21-05705310 21-00226-03	Winter Wheat GC0654 ² TRZAW Tonnage	1	30/09/20	Foliar appli- cation with boom	298 296	0.0638 0.0639	0.190 0.189	02/06/21 16/06/21	49 69	WholePlant	<LOQ	0.066	0.074	0.13	
2	08-20/06/21			WholePlant	<LOQ							0.098	0.11	0.24	6	71	
3	28/06/21			WholePlant	<LOQ							0.15	0.15	0.46	14	71	
				Ears	<LOQ							0.43	0.013	1.2	35	83	
				Rest	<LOQ							0.058	0.080	0.055	35	83	
				Grain	<LOQ							0.38	<LOQ	1.1	42	89	
				Straw	<LOQ	0.095	0.100	0.050	42	89							
				untreated	-	-	-	-	-	Grain Straw	<LOQ <LOQ	0.18 0.065	<LOQ 0.046	0.48 0.020	42 42	89 89	

¹Non-GLP-Data; ²According to the Codex Classification of food and animal feed commodities; ³calculated, ⁴Nominal rates: 0.195 kg ai/ha, water 200-400 L/ha

Active ingredient:	Prothioconazole	Commercial product (name):	N/A
Crop/crop group	Wheat/cereals	Producer of commercial product:	Globachem NV HELM AG ASCENZA AGRO, S.A.
Responsible body for reporting	Globachem NV, 3800 Sint-Truiden HELM AG, 20097 Hamburg ASCENZA AGRO, S.A., 2910-440 Setúbal	Indoor/Glasshouse/Outdoor:	Outdoor
Country	Belgium, Germany, Portugal	Other a.s. in formulation:	None
Content of active substance (g/kg or g/L):	300 g/L	Residues calculated as:	1,2,4-Triazole (T); Triazole Acetic Acid (TAA) ; Triazole Lactic Acid (TLA); Triazolalalanine (TA)
Formulation:	EC	Analytical Method	01062/M004
		LOQ	0.010

1	2	3	4	5			6	7	8	9				10	11	12
Report No.	Commodity/E PPO- Code/Variety *	Date of 1) Sowing ¹ 2) Flowering ¹ 3) Harvest ¹	Method of treatment	Application rate per treatment ⁴			Date of treatment	BBCH Crop Growth Stage at Treat- ment	Portions analysed	Residues (mg/kg)				PHI (days)	Gro wth stage at sam- pling (BB CH)	Re- marks
				Water L/ha	Kg ai/hL ³	Prothio (kg ai/ha)				T	TAA	TLA	TA			
16775 Teschendorf Germany	Winter Wheat GC0654 ² TRZAW JACK (IB)	1 19/10/20 2 10- 15/06/21 3 19- 25/06/21	Foliar appli- cation with boom	258 252	0.0779 0.0778	0.201 0.196	31/05/21 17/06/21	43 69	Grain Straw	<LOQ <LOQ	0.087 0.048	<LOQ 0.017	0.45 0.079	38 38	89 89	/
IF21- 05705310 21-00226-04			untreated	-	-	-	-	-	Grain Straw	<LOQ <LOQ	0.011 0.011	<LOQ <LOQ	0.020 <LOQ	38 38	89 89	
16835 Wul- kow Germany	Winter Wheat GC0654 ² TRZAW RGT Reform	1 20/10/20 2 10- 15/06/21 3 19-25/06/21	Foliar appli- cation with boom	298 296	0.0638 0.0639	0.190 0.189	02/06/21 16/06/21	49 69	Grain Straw	<LOQ <LOQ	0.38 0.33	<LOQ 0.13	0.52 0.22	37 37	89 89	
IF21- 05705310 21-00226-05			untreated	-	-	-	-	-	Grain Straw	<LOQ <LOQ	0.38 0.031	<LOQ 0.12	0.31 0.12	37 37	89 89	

¹Non-GLP-Data; ²According to the Codex Classification of food and animal feed commodities; ³calculated, ⁴Nominal rates: 0.195 kg ai/ha, water 200-400 L/ha

Active ingredient:	Prothioconazole	Commercial product (name):	N/A
Crop/crop group	Wheat/cereals	Producer of commercial product:	Globachem NV HELM AG ASCENZA AGRO, S.A.
Responsible body for reporting	Globachem NV, 3800 Sint-Truiden HELM AG, 20097 Hamburg ASCENZA AGRO, S.A., 2910-440 Setúbal	Indoor/Glasshouse/Outdoor:	Outdoor
Country	Belgium, Germany, Portugal	Other a.s. in formulation:	None
Content of active substance (g/kg or g/L):	300 g/L	Residues calculated as:	1,2,4-Triazole (T); Triazole Acetic Acid (TAA) ; Triazole Lactic Acid (TLA); Triazolalalanine (TA)
Formulation:	EC	Analytical Method	01062/M004
		LOQ	0.010

1	2	3	4	5			6	7	8	9				10	11	12
Report No.	Commodity/E PPO-Code/Variety *	Date of 1) Sowing ¹ 2) Flowering ¹ 3) Harvest ¹	Method of treatment	Application rate per treatment ⁴			Date of treatment	BBCH Crop Growth Stage at Treatment	Portions analysed	Residues (mg/kg)				PHI (days)	Gro wth stage at sam-pling (BB CH)	Re-marks
				Water L/ha	Kg ai/hL ³	Prothio (kg ai/ha)				T	TAA	TLA	TA			
83-430 Kamien Krajen-ski Poland IF21-05705310 21-00226-06	Spring Wheat GC0654 ² TRZAS Tybalt	1	Foliar appli-cation with boom	298	0.0638	0.190	15/06/21	45	Grain Straw	<LOQ	0.12	<LOQ	0.5	38	89	/
		2		297	0.0640	0.190										
		3	untreated	-	-	-	-	Grain Straw	<LOQ	0.010	<LOQ	0.32	38	89		
									<LOQ	0.046	0.028	<LOQ	38	89		
H-4461 Nyirtelek Ferenc tanya IF21-05705310 21-00226-07	Winter Wheat GC0654 ² TRZAW GK Csillag	1	Foliar appli-cation with boom	293	0.0642	0.188	21/05/21	47	Grain Straw	<LOQ	0.068	<LOQ	0.27	38	89	
		2		293	0.0638	0.187										
					3	untreated	-	-	-	-	Grain Straw	<LOQ	0.015	<LOQ	0.041	
									<LOQ	<LOQ	0.016	<LOQ	38	89		

¹Non-GLP-Data; ²According to the Codex Classification of food and animal feed commodities; ³calculated, ⁴Nominal rates: 0.195 kg ai/ha, water 200-400 L/ha

Summary:

Study Objective

The objective of the study IF21-05705310 was to determine the magnitude of the residues of prothioconazole metabolites (1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA)) in raw agricultural commodity specimens of wheat (whole plant, ears, rest of plant, grain and straw) after two applications of Prothioconazole 300 EC, an emulsifiable concentrate formulation containing 300 g/L prothioconazole.

Field phase of the study

The study included six supervised residue trials conducted under field conditions in northern Europe (Germany, Poland and Hungary) during the 2021 season. Four trials were conducted as harvest trials and two trials were conducted as decline trials.

The spraying applications of Prothioconazole 300 EC were performed at 11 – 17 days before BBCH 69 and BBCH 69 with a nominal application rate of 0.65 L test item/ha and a water rate of 200 – 400 L/ha. The actual application data are presented in the following table.

Table 23: Application summary

Trial No. Country	Formulation	Appl. mode	Treated area / Reference	Application						
				No. of appl.	Interval (days)	Growth stage (BBCH code)	Test item rate (L/ha)	Water rate (L/ha)	a.s.	Appl. rate (kg a.s./ha)
21-00226-01 Germany	Prothioconazole 300 EC	SPI	F/WF	1	-	43	0.671	258	prothioconazole	0.201
				2	17	69	0.655	252	prothioconazole	0.196
-03 Poland	Prothioconazole 300 EC	SPI	F/WF	1	-	49	0.644	298	prothioconazole	0.193
				2	14	69	0.641	296	prothioconazole	0.192
-04 Germany	Prothioconazole 300 EC	SPI	F/WF	1	-	49	0.621	287	prothioconazole	0.186
				2	11	69	0.650	300	prothioconazole	0.195
-05 Germany	Prothioconazole 300 EC	SPI	F/WF	1	-	49	0.664	307	prothioconazole	0.199
				2	12	69	0.679	313	prothioconazole	0.204
-06 Poland	Prothioconazole 300 EC	SPI	F/WF	1	-	45	0.645	298	prothioconazole	0.193
				2	17	69	0.643	297	prothioconazole	0.193
-07 Hungary	Prothioconazole 300 EC	SPI	F/WF	1	-	47	0.636	293	prothioconazole	0.191
				2	14	69	0.636	293	prothioconazole	0.191

a.s.: Active substance

Appl.: Application

SPI: Spraying

WF: Whole Field

F: Field

Analytical Phase of the study

Decline trials were sampled five times at 0 DALA (S1), 6 DALA (S2) and 13-14 DALA (S3) as whole plant, 33-35 DALA (S4) as ears and rest of plant, and BBCH 89 (normal commercial harvest (NCH) (S5) as grain and straw. Harvest trials were sampled once at NCH (BBCH 89) (S1). As an exception grain and straw specimens were sampled from BBCH 85 or greater, in the case of growth stages below BBCH 85 ears and rest of plant were sampled.

Procedural recoveries

Table 24: Summary of procedural recoveries for 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA)

Crop	Matrix	Fortification Level (nominal) [mg/kg]	1,2,4-T		
			Mean [%]	RSD [±]	n
Wheat	Grain	0.010, 0.10 and 2.0	97.4	6.7	7
	Straw	0.010, 0.10 and 2.0	90.8	15	9
	Ears	0.010, 0.10 and 2.0	89.9	5.8	7
	Rest of Plant without Roots	0.010, 0.10 and 2.0	92.3	5.7	7
	Whole Plant no Roots	0.010, 0.10 and 2.0	93.2	8.4	9
Overall			92.7	9.4	39
Crop	Matrix	Fortification Level (nominal) [mg/kg]	TA		
			Mean [%]	RSD [±]	n
Wheat	Grain	0.010, 0.10 and 2.0	86.8	16	7
	Straw	0.010, 0.10 and 2.0	80.1	14	9
	Ears	0.010, 0.10 and 2.0	86.1	8.0	7
	Rest of Plant without Roots	0.010, 0.10 and 2.0	89.9	5.0	7
	Whole Plant no Roots	0.010, 0.10 and 2.0	93.3	6.4	9
Overall			87.2	11	39
Crop	Matrix	Fortification Level (nominal) [mg/kg]	TAA		
			Mean [%]	RSD [±]	n
Wheat	Grain	0.010, 0.10 and 2.0	88.3	14	7
	Straw	0.010, 0.10 and 2.0	77.6	7.8	9
	Ears	0.010, 0.10 and 2.0	87.1	3.5	7
	Rest of Plant without Roots	0.010, 0.10 and 2.0	90.2	4.5	7
	Whole Plant no Roots	0.010, 0.10 and 2.0	93.0	6.4	9
Overall			87.1	10	39
Crop	Matrix	Fortification Level (nominal) [mg/kg]	TLA		
			Mean [%]	RSD [±]	n
Wheat	Grain	0.010, 0.10 and 2.0	72.6	3.4	7
	Straw	0.010, 0.10 and 2.0	83.4	15	9
	Ears	0.010, 0.10 and 2.0	84.5	4.4	7
	Rest of Plant without Roots	0.010, 0.10 and 2.0	89.4	1.6	7
	Whole Plant no Roots	0.010, 0.10 and 2.0	89.1	4.4	9
Overall			84.1	10	39

RSD: relative standard deviation; n: number of specimens

Residues

Summary of the residues of 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA).

Table 25: Summary of the residues of 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA)

Sampling No.	Portion analysed	Plot	DALA	BBCH	n	Residues [mg/kg]					
Trial: 21-00226-					01	03	04	05	06	07	
1,2,4-Triazole (1,2,4-T)											
5	Grain	U	37-49	89	6	< 0.010	< 0.010	< 0.010	< 0.010	< 0.010	< 0.010
	Straw				6	< 0.010	< 0.010	< 0.010	< 0.010	< 0.010	< 0.010
1	Whole Plant	T	0	65-69	2	< 0.010	< 0.010	---	---	---	---
2	Whole Plant		6	69-71	2	< 0.010	< 0.010	---	---	---	---
3	Whole Plant		13 - 14	71-73	2	< 0.010	< 0.010	---	---	---	---
4	Ears		33 - 35	77 - 85	2	< 0.010	< 0.010	---	---	---	---
	Rest of Plant		33 - 35	77 - 85	2	< 0.010	< 0.010	---	---	---	---
	Grain		37 - 49	89	6	< 0.010	< 0.010	< 0.010	< 0.010	< 0.010	< 0.010
	Straw		37 - 49	89	6	< 0.010	< 0.010	< 0.010	< 0.010	< 0.010	< 0.010
Triazole alanine (TA)											
5	Grain	U	38-49	89	6	0.30	0.48	0.020	0.31	0.32	0.041
	Straw				6	0.047	0.020	< 0.010	0.12	< 0.010	< 0.010
1	Whole Plant	T	0	65-69	2	0.15	0.13	---	---	---	---
2	Whole Plant		6	69-71	2	0.022	0.24	---	---	---	---
3	Whole Plant		13 - 14	71-73	2	0.020	0.46	---	---	---	---
4	Ears		33 - 35	77 - 85	2	0.49	1.2	---	---	---	---
	Rest of Plant		33 - 35	77 - 85	2	0.012	0.055	---	---	---	---
5	Grain		37 - 49	89	6	0.54	1.1	0.45	0.52	0.50	0.27
	Straw		37 - 49	89	6	0.10	0.050	0.079	0.22	0.021	< 0.010
Triazole acetic acid (TAA)											
5	Grain	U	38-49	89	6	0.19	0.18	0.011	0.38	0.010	0.015
	Straw				6	0.081	0.065	0.011	0.031	0.046	< 0.010
1	Whole Plant	T	0	65-69	2	0.11	0.066	---	---	---	---
2	Whole Plant		6	69-71	2	0.11	0.098	---	---	---	---
3	Whole Plant		13 - 14	71-73	2	0.097	0.15	---	---	---	---
4	Ears		33 - 35	77 - 85	2	0.30	0.43	---	---	---	---
	Rest of Plant		33 - 35	77 - 85	2	0.083	0.058	---	---	---	---
5	Grain		37 - 49	89	6	0.29	0.38	0.087	0.38	0.12	0.068
	Straw		37 - 49	89	6	0.13	0.095	0.048	0.33	0.027	0.024
Triazole lactic acid (TLA)											
5	Grain	U	38-49	89	6	< 0.010	< 0.010	< 0.010	< 0.010	< 0.010	< 0.010
	Straw				6	0.015	0.046	< 0.010	0.12	0.028	0.016
1	Whole Plant	T	0	65-69	2	0.11	0.074	---	---	---	---
2	Whole Plant		6	69-71	2	0.11	0.11	---	---	---	---
3	Whole Plant		13 - 14	71-73	2	0.095	0.15	---	---	---	---
4	Ears		33 - 35	77 - 85	2	< 0.010	0.013	---	---	---	---
	Rest of Plant		33 - 35	77 - 85	2	0.16	0.080	---	---	---	---
5	Grain		37 - 49	89	6	< 0.010	< 0.010	< 0.010	< 0.010	< 0.010	< 0.010
	Straw		37 - 49	89	6	0.031	0.10	0.017	0.13	0.024	0.049

DALA: Days after last application; U: Untreated plot; T: Treated plot

A 2.1.3.10 Wheat / Prothioconazole – Study on the behaviour of prothioconazole in wheat after treatment with Prothioconazole 300 EC at two sites under field conditions in Northern Europe (ongoing)

Table A 26: Intended GAP

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP (number 9-11, 13, 15, 17, 19, 23, 27, 31, 35, 39, 43, 95, 97, 101, 105, 109, 113, 117, 121, 125, 129, 137, 139, 143, 147, 151, 155, 159, 163, 167, 171, 184, 186, 188, 190, 192, 194, 196, 21, 25, 29, 33, 37, 41, 45, 96, 99, 103, 107, 111, 115, 119, 123, 127, 131, 138, 141, 145, 149, 153, 157, 161, 165, 169, 173, 201, 200)	1 2	0.5 0.8 L/ha (125 g as/ha)	21 days	BBCH 25-69	35d

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

Comments of zRMS:	Study performed according to GLP requirements, relevant guidelines and in line with the proposed GAP. The study is accepted. The objective of the study was to determine the magnitude of the residues of prothioconazole TDMs metabolites in wheat following two applications of prothioconazole 300 EC. Two residue trials (1 decline and 1 harvest) were conducted in Northern Europe (France and Denmark). Target application rate ~0.2 kg/ha of prothioconazole at each application. The spraying applications of Prothioconazole 300 EC were performed at 13 days before BBCH 69. In treated specimens of wheat no residues equal or above the LOQ of 0.010 mg/kg were found for 1,2,4-Triazole. Residues ranged between 0.28 – 0.61 mg/kg for Triazole alanine, between 0.057 - 0.15 mg/kg for Triazole acetic acid and were <0.010 mg/kg for Triazole lactic acid.
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Reference: KCA 6.3-13

Report Study on the behaviour of prothioconazole in wheat after treatment with Prothioconazole 300 EC at two sites under field conditions in Northern Europe, Thirkell C., 2022 IF22-06125006 22-00143

Guideline(s): Yes (SANCO 7029/VI/95 rev.5, SANTE/2019/12752, OECD 509, OECD (2016), SANTE/2020/12830 Rev.1, OECD (2007) ENV/JM/MONO(2007)17

Deviations: None with impact

GLP: Yes

Acceptability: Yes

Summary

The objective of the study IF22-06125006 was to determine the magnitude of the residues of prothioconazole metabolites (1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA)) in raw agricultural commodity specimens of wheat (whole plant, ears, rest of plant, grain and straw) after two applications of Prothioconazole 300 EC, an emulsifiable concentrate formulation containing 300 g/L prothioconazole.

The study included two supervised residue trials conducted under field conditions in northern Europe (France and Denmark) during the 2022 season. One trial was conducted as a harvest trial and one trial was conducted as a decline trial.

The spraying applications of Prothioconazole 300 EC were performed at 13 days before BBCH 69 and BBCH 69 with a nominal application rate of 0.65 L test item/ha and a water rate of 200 – 400 L/ha.

The actual application data are presented in the following table.

Table 27: Application summary

Trial No. Country	Formulation	Appl. mode	Treated area / Reference	Application						
				No. of appl.	Interval (days)	Growth stage (BBCH code)	Test item rate (L/ha)	Water rate (L/ha)	a.s.	Appl. rate (kg a.s./ha)
22-00143-01 France	Prothioconazole 300 EC	SPI	F/WF	1	-	61	0.634	293	prothioconazole	0.190
				2	13	69	0.630	291	prothioconazole	0.189
22-00143-02 Denmark	Prothioconazole 300 EC	SPI	F/WF	1	-	47	0.643	297	prothioconazole	0.193
				2	13	69	0.657	303	prothioconazole	0.197

a.s.: Active substance
Appl.: Application

SPI: Spraying
WF: Whole Field

F: Field

The decline trial was sampled four times at 0 DALA (S1), 8 DALA (S2) and 14 DALA (S3) as whole plant and 35 DALA (normal commercial harvest (NCH) BBCH 89 (S5)¹ as grain and straw. The harvest trial was sampled once at NCH (BBCH 89) (S1) as grain and straw.

¹ The S4 sampling event was not conducted because BBCH 89 coincided with 35 DALA.

Table 28: Summary of procedural recoveries for 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA)

Crop	Matrix	Fortification Level (nominal) [mg/kg]	1,2,4-T		
			Mean [%]	RSD [±]	n
Wheat	Grain	0.010, 0.10 and 2.0	97.4	6.7	7
	Straw	0.010, 0.10 and 2.0	90.8	15	9
	Ears	0.010, 0.10 and 2.0	89.9	5.8	7
	Rest of Plant without Roots	0.010, 0.10 and 2.0	92.3	5.7	7
	Whole Plant no Roots	0.010, 0.10 and 2.0	93.2	8.4	9
Overall			92.7	9.4	39
Crop	Matrix	Fortification Level (nominal) [mg/kg]	TA		
			Mean [%]	RSD [±]	n
Wheat	Grain	0.010, 0.10 and 2.0	86.8	16	7
	Straw	0.010, 0.10 and 2.0	80.1	14	9
	Ears	0.010, 0.10 and 2.0	86.1	8.0	7
	Rest of Plant without Roots	0.010, 0.10 and 2.0	89.9	5.0	7
	Whole Plant no Roots	0.010, 0.10 and 2.0	93.3	6.4	9
Overall			87.2	11	39
Crop	Matrix	Fortification Level (nominal) [mg/kg]	TAA		
			Mean [%]	RSD [±]	n
Wheat	Grain	0.010, 0.10 and 2.0	88.3	14	7
	Straw	0.010, 0.10 and 2.0	77.6	7.8	9
	Ears	0.010, 0.10 and 2.0	87.1	3.5	7
	Rest of Plant without Roots	0.010, 0.10 and 2.0	90.2	4.5	7
	Whole Plant no Roots	0.010, 0.10 and 2.0	93.0	6.4	9
Overall			87.1	10	39
Crop	Matrix	Fortification Level (nominal) [mg/kg]	TLA		
			Mean [%]	RSD [±]	n
Wheat	Grain	0.010, 0.10 and 2.0	72.6	3.4	7
	Straw	0.010, 0.10 and 2.0	83.4	15	9
	Ears	0.010, 0.10 and 2.0	84.5	4.4	7
	Rest of Plant without Roots	0.010, 0.10 and 2.0	89.4	1.6	7
	Whole Plant no Roots	0.010, 0.10 and 2.0	89.1	4.4	9
Overall			84.1	10	39

RSD: relative standard deviation; n: number of specimens

Table 29: Summary of the residues of 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA)

Sampling No.	Portion analysed	Plot	DALA	BBCH	n	Residues [mg/kg]	
Trial: 22-00143-						01	02
						1,2,4-Triazole (1,2,4-T)	
5	Grain	U	35 - 42	89	6	< 0.010	< 0.010
	Straw				6	< 0.010	< 0.010
1	Whole Plant	T	0	69	2	< 0.010	-
2	Whole Plant		8	75	2	< 0.010	-
3	Whole Plant		14	77	2	< 0.010	-
5	Grain		35 - 42	89	2	< 0.010	< 0.010
	Straw			89	2	< 0.010	< 0.010
						Triazole alanine (TA)	
5	Grain	U	35 - 42	89	6	< 0.010	< 0.010
	Straw				6	< 0.010	< 0.010
1	Whole Plant	T	0	69	2	< 0.010	-
2	Whole Plant		8	75	2	< 0.010	-
3	Whole Plant		14	77	2	< 0.010	-
5	Grain		35 - 42	89	2	< 0.010	< 0.010
	Straw			89	2	< 0.010	< 0.010
						Triazole acetic acid (TAA)	
5	Grain	U	35 - 42	89	6	< 0.010	< 0.010
	Straw				6	< 0.010	< 0.010
1	Whole Plant	T	0	69	2	< 0.010	-
2	Whole Plant		8	75	2	< 0.010	-
3	Whole Plant		14	77	2	< 0.010	-
5	Grain		35 - 42	89	2	< 0.010	< 0.010
	Straw			89	2	< 0.010	< 0.010
						Triazole lactic acid (TLA)	
5	Grain	U	35 - 42	89	6	< 0.010	< 0.010
	Straw				6	< 0.010	< 0.010
1	Whole Plant	T	0	69	2	< 0.010	-
2	Whole Plant		8	75	2	< 0.010	-
3	Whole Plant		14	77	2	< 0.010	-
5	Grain		35 - 42	89	2	< 0.010	< 0.010
	Straw			89	2	< 0.010	< 0.010

DALA: Days after last application; U: Untreated plot; T: Treated plot

Wheat / Prothioconazole – Study on the residue behaviour of prothioconazole in wheat after treatment with Prothioconazole 300 EC at eight sites under field conditions in Southern Europe, 2021

Table A 30: Intended GAP

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP (number 9-11, 13, 15, 17, 19, 23, 27, 31, 35, 39, 43, 95, 97, 101, 105, 109, 113, 117, 121, 125, 129, 137, 139, 143, 147, 151, 155, 159, 163, 167, 171, 184, 186, 188, 190, 192, 194, 196, 21, 25, 29, 33, 37, 41, 45, 96, 99, 103, 107, 111, 115, 119, 123, 127, 131, 138, 141, 145, 149, 153, 157, 161, 165, 169, 173, 201, 200)	1 2	0.5 0.8 L/ha (125 g as/ha)	21 d	BBCH 25-69	35d

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

Comments of zRMS: This submission does not apply to SEU. The study was not evaluated.

Reference: KCA 6.3-14

Report Study on the behaviour of prothioconazole in wheat after treatment with Prothiconazole 300 EC at eight sites under field conditions in Southern Europe, 2022 IF21-05707610 21-00227

Guideline(s): Yes (SANCO 7029/VI/95 rev.5, SANTE/2019/12752, OECD 509, OECD (2016), SANTE/2020/12830 Rev.1, OECD (2007) ENV/JM/MONO(2007)17

Deviations: None with impact

GLP: Yes

Acceptability: Supplementary

Active ingredient:			Prothioconazole					Commercial product (name):		N/A										
Crop/crop group			Wheat/cereals					Producer of commercial product:		Globachem NV HELM AG ASCENZA AGRO, S.A.										
Responsible body for reporting			Globachem NV, 3800 Sint-Truiden HELM AG, 20097 Hamburg ASCENZA AGRO, S.A., 2910-440 Setúbal Belgium, Germany, Portugal					Indoor/Glasshouse/Outdoor:		Outdoor										
Country			Belgium, Germany, Portugal					Other a.s. in formulation:		None										
Content of active substance (g/kg or g/L):			300 g/L					Residues calculated as:		1,2,4-Triazole (T); Triazole Acetic Acid (TAA) ; Triazole Lactic Acid (TLA); Triazolalalanine (TA)										
Formulation:			EC					Analytical Method LOQ		01062/M004 0.010										
1	2	3	4	5			6	7	8	9				10	11	12				
Report No.	Commodity/E PPO-Code/Variety *	Date of 1) Sowing ¹ 2) Flowering ¹ 3) Harvest ¹		Method of treatment	Application rate per treatment ⁴			Date of treatment	BBCH Crop Growth Stage at Treatment	Portions analysed	Residues (mg/kg)				PHI (days)	Gro wth stage at sampling (BB CH)	Re- marks			
					Water L/ha	Kg ai/hL ³	Prothio (kg ai/ha)				T	TAA	TLA	TA						
33124 Bran-nens Frnace IF21-05707610 21-00227-01	Winter Wheat GC0654 ² TRZAW Oregrain	1	05/11/20	Foliar appli- cation with boom	298 303	0.0648 0.0650	0.193 0.197	04/05/21 20/05/21	55 69	Wh. Plant	<LOQ	0.020	0.024	0.038	0	69	/			
		2	12-							Wh. Plant	<LOQ	0.022	0.033	0.099	6	71				
		3	20/05/21							Wh. Plant	<LOQ	0.029	0.033	0.13	13	75				
			20/07/21							Grain	<LOQ	0.12	<LOQ	0.43	34	87				
										Straw	<LOQ	0.017	0.030	<LOQ	34	87				
			Grain							<LOQ	0.16	<LOQ	0.48	61	89					
			Straw							<LOQ	0.061	0.012	0.034	61	89					
				untreated	-	-	-	-	-	Grain Straw	<LOQ <LOQ	0.050 0.018	<LOQ <LOQ	0.10 <LOQ	61 61	89 89				
		47130 Port-Sainte-Marie France IF21-05707610 21-00227-02	Winter Wheat GC0654 ² TRZAW Centurion	1	20/11/20	Foliar appli- cation with boom	298 297	0.0648 0.0646	0.193 0.192	03/05/21 19/05/21	55 69	Wh. Plant	<LOQ	0.021	0.027	0.043		0	69	
				2	13-19/05/21							Wh. Plant	<LOQ	0.021	0.028	0.074		6	71	
3	16/07/21			Wh. Plant	<LOQ							0.026	0.036	0.11	13	75				
				Grain	<LOQ							0.11	<LOQ	0.30	34	87				
				Straw	<LOQ							0.021	0.014	0.012	34	87				
	Grain			<LOQ	0.11							<LOQ	0.30	58	89					
	Straw			<LOQ	0.036							0.033	0.015	58	89					
				untreated	-	-	-	-	-	Grain Straw	<LOQ <LOQ	0.047 0.027	0.085 <LOQ	0.085 <LOQ	58 58	89 89				

¹Non-GLP-Data; ²According to the Codex Classification of food and animal feed commodities; ³calculated, ⁴Nominal rates: 0.195 kg ai/ha, water 200-400 L/ha

Active ingredient:			Prothioconazole					Commercial product (name):			N/A						
Crop/crop group			Wheat/cereals					Producer of commercial product:			Globachem NV HELM AG ASCENZA AGRO, S.A.						
Responsible body for reporting			Globachem NV, 3800 Sint-Truiden HELM AG, 20097 Hamburg ASCENZA AGRO, S.A., 2910-440 Setúbal Belgium, Germany, Portugal					Indoor/Glasshouse/Outdoor:			Outdoor						
Country			Belgium, Germany, Portugal					Other a.s. in formulation:			None						
Content of active substance (g/kg or g/L):			300 g/L					Residues calculated as:			1,2,4-Triazole (T); Triazole Acetic Acid (TAA) ; Triazole Lactic Acid (TLA); Triazolalalanine (TA)						
Formulation:			EC					Analytical Method			01062/M004						
								LOQ			0.010						
1	2	3	4	5			6	7	8	9				10	11	12	
Report No.	Commodity/E PPO-Code/Variety *	Date of 1) Sowing ¹ 2) Flowering ¹ 3) Harvest ¹		Method of treatment	Application rate per treatment ⁴			Date of treatment	BBCH Crop Growth Stage at Treatment	Portions analysed	Residues (mg/kg)				PHI (days)	Gro wth stage at sam-pling (BB CH)	Re-marks
					Water L/ha	Kg ai/hL ³	Prothio (kg ai/ha)				T	TAA	TLA	TA			
18128 Zafar- raya Spain IF21- 05707610 21-00227-03	Winter Wheat GC0654 ² TRZAW Marius	1	18/12/20	Foliar appli- cation with boom	303 312	0.0650 0.0651	0.197 0.203	19/04/21 04/05/21	51 69	Wh. Plant	<LOQ	<LOQ	<LOQ	0.036	0	69	/
		2	26/04-							Wh. Plant	<LOQ	<LOQ	0.018	0.065	8	71	
		3	10/05/21							Wh. Plant	<LOQ	0.012	0.024	0.087	14	75	
			08/06/21							Ears	<LOQ	0.054	<LOQ	0.20	35	83	
										Rest	<LOQ	<LOQ	0.042	0.012	35	83	
										Grain	<LOQ	0.089	<LOQ	0.31	65	89	
		Straw	<LOQ	0.034	0.085	0.015	65	89									
		untreated	-	-	-	-	-	Grain Straw	<LOQ <LOQ	<LOQ <LOQ	<LOQ <LOQ	<LOQ <LOQ	65 65	89 89			
57006 Lakkia Greece IF21- 05707610 21-00227-02	Spring Wheat GC0654 ² TRZAS Yecora	1	05/01/21	Foliar appli- cation with boom	297 303	0.0650 0.0650	0.193 0.197	16/04/21 28/04/21	55 69	Wh. Plant	<LOQ	0.029	0.091	0.065	0	69	
		2	20/04-							Wh. Plant	<LOQ	0.017	0.14	0.22	7	71	
		3	28/04/21							Wh. Plant	<LOQ	0.059	0.12	0.23	14	75	
			04/06-							Grain	<LOQ	0.079	<LOQ	0.32	37	89	
			05/06/21							Straw	<LOQ	0.084	0.077	0.088	37	89	
											untreated	-	-	-	-	Grain Straw	<LOQ <LOQ

¹Non-GLP-Data; ²According to the Codex Classification of food and animal feed commodities; ³calculated, ⁴Nominal rates: 0.195 kg ai/ha, water 200-400 L/ha

Active ingredient:	Prothioconazole	Commercial product (name):	N/A
Crop/crop group	Wheat/cereals	Producer of commercial product:	Globachem NV HELM AG ASCENZA AGRO, S.A.
Responsible body for reporting	Globachem NV, 3800 Sint-Truiden HELM AG, 20097 Hamburg ASCENZA AGRO, S.A., 2910-440 Setúbal	Indoor/Glasshouse/Outdoor:	Outdoor
Country	Belgium, Germany, Portugal	Other a.s. in formulation:	None
Content of active substance (g/kg or g/L):	300 g/L	Residues calculated as:	1,2,4-Triazole (T); Triazole Acetic Acid (TAA) ; Triazole Lactic Acid (TLA); Triazolalanine (TA)
Formulation:	EC	Analytical Method	01062/M004
		LOQ	0.010

1	2	3	4	5			6	7	8	9				10	11	12	
Report No.	Commodity/E PPO-Code/Variety *	Date of 1) Sowing ¹ 2) Flowering ¹ 3) Harvest ¹	Method of treatment	Application rate per treatment ⁴			Date of treatment	BBCH Crop Growth Stage at Treatment	Portions analysed	Residues (mg/kg)				PHI (days)	Gro wth stage at sam-pling (BB CH)	Re-marks	
				Water L/ha	Kg ai/hL ³	Prothio (kg ai/ha)				T	TAA	TLA	TA				
29200 Antequera Spain IF21-05707610 21-00227-05	Winter Wheat GC0654 ² TRZAW Athoris	1	Foliar appli-cation with boom	313	0.0652	0.204	19/04/21	57	Grain Straw	<LOQ	0.027	<LOQ	0.16	34	87	/	
		2								<LOQ	<LOQ	0.012	0.010	34	87		
		3								22/06/21	<LOQ	0.037	<LOQ	0.17	53		89
											<LOQ	0.018	0.024	<LOQ	53		89
	untreated	-	-	-	-	-	Grain Straw	<LOQ <LOQ	<LOQ <LOQ	<LOQ <LOQ	<LOQ <LOQ	53 53	89 89				
58300 Galatades Greece IF21-05707610 21-00227-06	Winter Wheat GC0654 ² TRZAW Rebelde	1	Foliar appli-cation with boom	308	0.0649	0.200	16/04/21	33	Grain Rest	<LOQ	0.26	0.016	0.28	36	83		
		2								<LOQ	0.064	0.32	0.011	36	83		
		3								10-16/06/21	<LOQ	0.33	<LOQ	0.41	48		89
											<LOQ	0.15	0.22	0.047	48		89
	untreated	-	-	-	-	-	Grain Straw	<LOQ <LOQ	0.40 0.18	<LOQ 0.20	0.37 0.043	48 48	89 89				

¹Non-GLP-Data; ²According to the Codex Classification of food and animal feed commodities; ³calculated, ⁴Nominal rates: 0.195 kg ai/ha, water 200-400 L/ha

Active ingredient:	Prothioconazole	Commercial product (name):	N/A
Crop/crop group	Wheat/cereals	Producer of commercial product:	Globachem NV HELM AG ASCENZA AGRO, S.A.
Responsible body for reporting	Globachem NV, 3800 Sint-Truiden HELM AG, 20097 Hamburg ASCENZA AGRO, S.A., 2910-440 Setúbal	Indoor/Glasshouse/Outdoor:	Outdoor
Country	Belgium, Germany, Portugal	Other a.s. in formulation:	None
Content of active substance (g/kg or g/L):	300 g/L	Residues calculated as:	1,2,4-Triazole (T); Triazole Acetic Acid (TAA) ; Triazole Lactic Acid (TLA); Triazolalanine (TA)
Formulation:	EC	Analytical Method	01062/M004
		LOQ	0.010

1	2	3	4	5			6	7	8	9				10	11	12										
Report No.	Commodity/E PPO-Code/Variety *	Date of 1) Sowing ¹ 2) Flowering ¹ 3) Harvest ¹	Method of treatment	Application rate per treatment ⁴			Date of treatment	BBCH Crop Growth Stage at Treatment	Portions analysed	Residues (mg/kg)				PHI (days)	Gro wth stage at sam-pling (BB CH)	Re-marks										
				Water L/ha	Kg ai/hL ³	Prothio (kg ai/ha)				T	TAA	TLA	TA													
20090 Settala Italy IF21-05707610 21-00227-07	Spring Wheat GC0654 ² TRZAS Solehio	1	Foliar appli-cation with boom	307 310	0.0648 0.0648	0.199 0.201	05/05/21 19/05/21	55-57 69	Ears Rest Grain Straw	<LOQ	0.070	0.014	0.16	35	84	/										
		2								<LOQ	0.036	0.057	0.038	35	84											
		3								22/06/21	<LOQ	0.090	<LOQ	0.23	43		89									
											<LOQ	0.046	0.063	0.027	43		89									
13040 Borgo d'Ale Italy IF21-05707610 21-00227-08	Spring Wheat GC0654 ² TRZAS Vespucci	1 2 3	Foliar appli-cation with boom	300 300	0.0650 0.0650	0.195 0.195	07/05/21 21/05/21	57 69	Grain Straw	<LOQ	0.074 0.044	<LOQ	0.16 0.016	38	89											
										<LOQ		0.028 0.021		<LOQ	0.06 <LOQ		38	89								
										untreated				-			-	-	-	Grain Straw	<LOQ	0.041	0.048	<LOQ	43	89
																					<LOQ	0.033	0.048	<LOQ	43	89

¹Non-GLP-Data; ²According to the Codex Classification of food and animal feed commodities; ³calculated, ⁴Nominal rates: 0.195 kg ai/ha, water 200-400 L/ha

Summary:

Study Objective

The objective of the study IF21-05707610 was to determine the magnitude of the residues of prothioconazole metabolites (1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA)) in raw agricultural commodity specimens of wheat (ears, rest of plant, whole plant, grain and straw) after two applications of Prothioconazole 300 EC, an emulsifiable concentrate formulation containing 300 g prothioconazole/L.

Field phase of the study

The study included eight supervised residue trials conducted under field conditions in southern Europe (southern France, Spain, Greece and Italy) during the 2021 season. Four trials were conducted as harvest trials and four trials were conducted as decline trials. The spraying applications of Prothioconazole 300 EC were performed at 11 – 16 days before BBCH 69 and BBCH 69 with a nominal application rate of 0.65 L test item/ha and a water rate of 200 – 400 L/ha.

The actual application data are presented in the following table.

Table 31: Application summary

Trial No. Country	Formulation	Appl. mode	Treated area / Reference	Application						
				No. of appl.	Interval (days)	Growth stage (BBCH code)	Test item rate (L/ha)	Water rate (L/ha)	a.s.	Appl. rate (kg a.s./ha)
21-00227-01 southern France	Prothioconazole 300 EC	SPI	F/WF	1	-	55	0.645	298	prothioconazole	0.193
				2	16	69	0.656	303	prothioconazole	0.197
21-00227-02 southern France	Prothioconazole 300 EC	SPI	F/WF	1	-	55	0.645	298	prothioconazole	0.193
				2	16	69	0.642	297	prothioconazole	0.192
21-00227-03 Spain	Prothioconazole 300 EC	SPI	F/WF	1	-	51	0.657	303	prothioconazole	0.197
				2	15	69	0.675	312	prothioconazole	0.203
21-00227-04 Greece	Prothioconazole 300 EC	SPI	F/WF	1	-	55	0.642	297	prothioconazole	0.193
				2	12	69	0.656	303	prothioconazole	0.197
21-00227-05 Spain	Prothioconazole 300 EC	SPI	F/WF	1	-	57	0.679	313	prothioconazole	0.204
				2	11	69	0.650	300	prothioconazole	0.195
21-00227-06 Greece	Prothioconazole 300 EC	SPI	F/WF	1	-	33	0.666	308	prothioconazole	0.200
				2	13	69	0.658	304	prothioconazole	0.197
21-00227-07 Italy	Prothioconazole 300 EC	SPI	F/WF	1	-	55-57	0.664	307	prothioconazole	0.199
				2	14	69	0.672	310	prothioconazole	0.201
21-00227-08 Italy	Prothioconazole 300 EC	SPI	F/WF	1	-	57	0.650	300	prothioconazole	0.195
				2	14	69	0.650	300	prothioconazole	0.195

a.s.: Active substance
Appl.: Application

SPI: Spraying
WF: Whole Field

F: Field

Analytical Phase of the study

For decline trials specimens of wheat were collected at a sampling timing 0 (S1), 6-8 (S2) and 13-14 (S3) DALA as whole plant, 34-37 DALA (S4) as ears and rest of plant or grain and straw (depending on growth stage) and at normal commercial harvest (58-65 DALA, growth stage BBCH 89) as grain and

straw (S5). If 35 ± 3 DALA and NCH (BBCH 89) sampling occurred at the same time, only the NCH was done using specimen numbers of NCH.

For harvest trials specimens of wheat were collected at a sampling timing 34-38 DALA (S1) as ears and rest of plant or grain and straw (depending on growth stage) and at normal commercial harvest (43-53 DALA, growth stage BBCH 89) as grain and straw (S2). If 35 ± 3 DALA and NCH (BBCH 89) sampling occurred at the same time, only the NCH was done using specimen numbers of NCH.

The analytical method 01062/M004 was used for analysis of 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) by LCDMS/MS/MS. The Limit of Quantification (LOQ) of the analytical method was defined as 0.010 mg/kg for each analyte.

The method was validated at the analytical test site in study IF21-05707367 [2] for the matrix groups relevant in this study.

Procedural recoveries

Concurrent recoveries, performed with fortified untreated specimens, were analyzed together with the field specimens. Overall and average recoveries were all in the range of 70 – 110 % and relative standard deviations (RSD) were < 20 %. A summary of the values obtained for the mean recoveries, standard deviation (SD) and relative standard deviation (RSD) for the field specimen analysis is given below.

Table 32: Summary of procedural recoveries for 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA)

Crop	Matrix	Fortification Level (nominal) [mg/kg]	1,2,4-T		
			Mean [%]	RSD [±]	n
Wheat	Grain	0.010, 0.10 and 2.0	96.9	11	9
	Straw	0.010, 0.10 and 2.0	89.2	8.8	7
	Ears	0.010, 0.10 and 2.0	102	5.1	7
	Rest of Plant without Roots	0.010, 0.10 and 2.0	102	6.9	7
	Whole Plant no Roots	0.010, 0.10 and 2.0	97.1	5.1	8
Overall			97.4	8.6	38
Crop	Matrix	Fortification Level (nominal) [mg/kg]	TA		
			Mean [%]	RSD [±]	n
Wheat	Grain	0.010, 0.10 and 2.0	81.7	10	9
	Straw	0.010, 0.10 and 2.0	89.7	14	7
	Ears	0.010, 0.10 and 2.0	81.1	3.3	7
	Rest of Plant without Roots	0.010, 0.10 and 2.0	91.9	3.7	7
	Whole Plant no Roots	0.010, 0.10 and 2.0	92.2	5.7	8
Overall			87.2	9.7	38
Crop	Matrix	Fortification Level (nominal) [mg/kg]	TAA		
			Mean [%]	RSD [±]	n
Wheat	Grain	0.010, 0.10 and 2.0	77.4	7.0	9
	Straw	0.010, 0.10 and 2.0	88.0	5.6	7
	Ears	0.010, 0.10 and 2.0	88.4	5.2	7
	Rest of Plant without Roots	0.010, 0.10 and 2.0	97.3	4.2	7
	Whole Plant no Roots	0.010, 0.10 and 2.0	98.7	4.1	8

Overall			89.4	10	38
Crop	Matrix	Fortification Level (nominal) [mg/kg]	TLA		
			Mean [%]	RSD [±]	n
Wheat	Grain	0.010, 0.10 and 2.0	80.2	8.7	9
	Straw	0.010, 0.10 and 2.0	86.3	8.0	7
	Ears	0.010, 0.10 and 2.0	82.5	4.9	7
	Rest of Plant without Roots	0.010, 0.10 and 2.0	94.6	3.8	7
	Whole Plant no Roots	0.010, 0.10 and 2.0	93.7	3.6	8
Overall			87.2	9.0	38

SD: Standard deviation; CV: Coefficient of variation; n: Number of specimens

Residues

The residues detected in field specimens can be summarized as in the following table.

Table 33: Summary of the residues of 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA)

Sampling No.	Portion analysed	Plot	DALA	BBCH	n	Range of Residues [mg/kg]			
						1,2,4-T	TA	TAA	TLA
5	Grain	U	37 - 65	89	8	< 0.010	< 0.010 - 0.37	< 0.010 - 0.40	< 0.010
	Straw				8	< 0.010	< 0.010 - 0.043	< 0.010 - 0.18	< 0.010 - 0.20
1	Whole Plant no Roots	T	0	69	4	< 0.010	0.036 - 0.065	< 0.010 - 0.059	< 0.010 - 0.091
2			6 - 8	71	4	< 0.010	0.065 - 0.22	< 0.010 - 0.079	0.018 - 0.14
3			13 - 14	75	4	< 0.010	0.087 - 0.23	0.012 - 0.084	0.024 - 0.12
4	Ears		35 - 36	83 - 84	3	< 0.010	0.16 - 0.28	0.054 - 0.26	< 0.010 - 0.016
	Rest of Plant without Roots				3	< 0.010	0.011 - 0.038	< 0.010 - 0.064	0.042 - 0.32
	Grain		34	83 - 87	3	< 0.010	0.16 - 0.43	0.027 - 0.12	< 0.010
	Straw				3	< 0.010	< 0.010 - 0.012	< 0.010 - 0.021	0.012 - 0.030
5	Grain		37-65	89	8	< 0.010	0.16 - 0.48	0.037 - 0.33	< 0.010
	Straw					< 0.010	< 0.010 - 0.088	0.018 - 0.15	0.012 - 0.22

DALA: Days after last application;; U: Untreated plot; T: Treated plot

In untreated specimens of wheat - straw taken at normal commercial harvest (NCH, BBCH 89) no residues equal or above the LOQ of 0.010 mg/kg were found for 1,2,4-Triazole. Residues ranged between < 0.010 - 0.043 mg/kg for Triazole alanine, between < 0.010 - 0.18 mg/kg for Triazole acetic acid and between < 0.010 - 0.20 mg/kg for Triazole lactic acid.

In untreated specimens of wheat - grain taken at normal commercial harvest (NCH, BBCH 89) residues were < 0.010 for 1,2,4-Triazole, between < 0.010 – 0.37 mg/kg for Triazole alanine, between < 0.010 - 0.40 mg/kg for Triazole acetic acid and were <0.010 mg/kg for Triazole lactic acid.

For trial 21-00227-08 the residues found in the untreated grain ship specimen (taken at BBCH 89) were unplausible. The following residues were measured: 1,2,4-T: 0.029 mg/kg, TA: 0.51 mg/kg, TAA: 0.22 mg/kg, TLA: < 0.010 mg/kg. No reason could be found to explain the higher residues. Therefore the re-

tain specimens was analysed. The residue results of the retain sample were reported in the summary and result tables.

In treated specimens of wheat - straw taken at normal commercial harvest (NCH, BBCH 89) no residues equal or above the LOQ of 0.010 mg/kg were found for 1,2,4-Triazole. Residues ranged between < 0.010 - 0.088 mg/kg for Triazole alanine, between 0.018 - 0.15 mg/kg for Triazole acetic acid and between 0.012 - 0.22 mg/kg for Triazole lactic acid.

In treated specimens of wheat - grain taken at normal commercial harvest (NCH, BBCH 89) no residues equal or above the LOQ of 0.010 mg/kg were found for 1,2,4-Triazole. Residues ranged between 0.016 – 0.48 mg/kg for Triazole alanine, between 0.037 - 0.33 mg/kg for Triazole acetic acid and were <0.010 mg/kg for Triazole lactic acid.

A 2.1.3.11 Oilseed rape / Prothioconazole – Study on the behaviour of prothioconazole in oilseed rape after treatment with Prothioconazole 300 EC at eight sites under field conditions in northern Europe 2021

Table A 34: Intended GAP

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP (number 204-209)	2	0.5 0.8 L/ha (125 g as/ha)	21d	BBCH 14-69	65 35 d

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

Comments of zRMS:	Study performed according to GLP requirements, relevant guidelines and in line with the proposed GAP. The study is acceptable. The objective of the study was to determine the magnitude of the residues of prothioconazole TDMs metabolites in oilseed rape after two applications of Prothioconazole 300 EC Eight residue trials (four decline and four harvest) were conducted in northern Europe (Germany, northern France, Poland, Denmark and Hungary) Target application rate was 2 x ~0.18 kg/ha of prothioconazole. The interval between application was 10-21 days. The last stage of application was at BBCH 69. In treated specimens of oilseed rape no residues equal or above the LOQ of 0.010 mg/kg were found for 1,2,4-Triazole. Residues ranged between 0.11 - 1.3 mg/kg for Triazole alanine, between < 0.010 - 0.018 mg/kg for Triazole acetic acid and between < 0.010 - 0.058 mg/kg for Triazole lactic acid.
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Reference:	KCA 6.3-15
Report	Study on the behaviour of prothioconazole in oilseed rape after treatment with Prothioconazole 300 EC at eight sites under field conditions in Northern Europe, 2021, Mayer M., Gabriel E., 2021; IF21-05707333 21-00230
Guideline(s):	Yes (SANCO 7029/VI/95 rev.5, SANTE/2019/12752, OECD 509, OECD (2016), SANTE/2020/12830 Rev.1, OECD (2007) ENV/JM/MONO(2007)17
Deviations:	None with impact
GLP:	Yes
Acceptability:	Yes

Table A 23-1: Summary of the study trials –

Active ingredient:

Prothioconazole

Commercial product (name): **N/A**

Crop/crop group

Oilseed rape/oilseed

Producer of commercial product:
Globachem NV
HELM AG
ASCENZA AGRO, S.A.

Responsible body for reporting

Globachem NV, 3800 Sint-Truiden
HELM AG, 20097 Hamburg
ASCENZA AGRO, S.A., 2910-440 Setúbal
Belgium, Germany, Portugal

Indoor/Glasshouse/Outdoor: Outdoor

Country

Other a.s. in formulation: None

Content of active substance (g/kg or g/L):

300 g/L

Residues calculated as:
1,2,4-Triazole (T); Triazole Acetic Acid (TAA) ; Triazole Lactic Acid (TLA); Triazolalanine (TA)

Formulation:

EC

Analytical Method
LOQ
0.010

1	2	3	4	5			6	7	8	9				10	11	12	
Report No.	Commodity/E PPO-Code/Variety *	Date of 1) Sowing ¹ 2) Flowering ¹ 3) Harvest ¹		Method of treatment	Application rate per treatment ⁴			Date of treatment	BBCH Crop Growth Stage at Treatment	Portions analysed	Residues (mg/kg)				PHI (days)	Gro wth stage at sam-pling (BB CH)	Re-marks
					Water L/ha	Kg ai/hL ³	Prothio (kg ai/ha)				T	TAA	TLA	TA			
24988 Murk-wolstrup Germany IF21-05707333 21-00230-01	Oilseed rape SO 0495 ² BRSNN Orocodile	1	28/08/20	Foliar appli-cation with boom	261 247	0.0720 0.0721	0.188 0.178	31/05/21 14/06/21	65 69	Wh. Plant	<LOQ	<LOQ	<LOQ	0.13	0	69	/
		2	15/05-							Wh. Plant	<LOQ	<LOQ	<LOQ	0.18	7	75	
		3	14/06/21							Wh. Plant	<LOQ	<LOQ	<LOQ	0.15	15	77	
			03/08/21							pods	<LOQ	0.020	0.043	0.42	36	83	
										Rest	<LOQ	<LOQ	<LOQ	0.032	36	83	
										Seed	<LOQ	<LOQ	0.037	0.96	50	89	
										Straw	<LOQ	<LOQ	<LOQ	0.14	50	89	
		untreated	-	-	-	-	-	Wh. Plant	<LOQ	<LOQ	<LOQ	0.15	0	69			
								pods	<LOQ	0.022	0.044	0.45	36	83			
								Rest	<LOQ	<LOQ	<LOQ	0.024	36	83			
Seed	<LOQ							<LOQ	0.032	0.76	50	89					
Straw	<LOQ							<LOQ	<LOQ	0.083	50	89					
24988 Fahrddorf Germany IF21-05707333 21-00230-02	Oilseed rape SO 0495 ² BRSNN Ernesto	1	20/08/20	Foliar appli-cation with boom	262 255	0.0718 0.0722	0.188 0.184	31/05/21 14/06/21	65 69	Wh. Plant	<LOQ	<LOQ	<LOQ	0.092	0	69	
		2	15/05-							Wh. Plant	<LOQ	<LOQ	<LOQ	0.15	7	75	
		3	14/06/21							Wh. Plant	<LOQ	<LOQ	<LOQ	0.14	15	78	
			03/08/21							pods	<LOQ	0.012	0.018	0.30	35	83	
										Rest	<LOQ	<LOQ	<LOQ	0.018	35	83	
										Seed	<LOQ	<LOQ	0.015	0.58	50	89	
										Straw	<LOQ	<LOQ	<LOQ	0.50	50	89	
		untreated	-	-	-	-	-	Wh. Plant	<LOQ	<LOQ	<LOQ	0.092	0	69			
								pods	<LOQ	0.015	0.015	0.22	35	83			
								Rest	<LOQ	<LOQ	<LOQ	0.017	35	83			
Seed	<LOQ							0.024	0.024	0.61	50	89					
Straw	<LOQ							<LOQ	<LOQ	0.055	50	89					

				untreated	-	-	-	-	-	Wh. Plant pods	<LOQ	<LOQ	<LOQ	0.059	0	69	
										Rest	<LOQ	<LOQ	<LOQ	0.078	34	83	
										Seed	<LOQ	<LOQ	<LOQ	0.014	34	83	
										Straw	<LOQ	<LOQ	<LOQ	0.011	52	89	
											<LOQ	<LOQ	<LOQ	0.014	52	89	

¹Non-GLP-Data; ²According to the Codex Classification of food and animal feed commodities; ³calculated, ⁴Nominal rates: 0.180 kg ai/ha, water 200-400 L/ha

Active ingredient: **Prothioconazole** Commercial product (name): **N/A**

Crop/crop group: Oilseed rape/oilseed Producer of commercial product: Globachem NV
HELM AG
ASCENZA AGRO, S.A.

Responsible body for reporting: Globachem NV, 3800 Sint-Truiden
HELM AG, 20097 Hamburg
ASCENZA AGRO, S.A., 2910-440 Setúbal
Belgium, Germany, Portugal Indoor/Glasshouse/Outdoor: Outdoor

Country: Other a.s. in formulation: None

Content of active substance (g/kg or g/L): 300 g/L Residues calculated as: 1,2,4-Triazole (T); Triazole Acetic Acid (TAA) ; Triazole Lactic Acid (TLA); Triazolalalanine (TA)

Formulation: EC Analytical Method: 01062/M004
LOQ 0.010

1	2	3	4	5			6	7	8	9				10	11	12
Report No.	Commodity/E PPO- Code/Variety *	Date of 1) Sowing ¹ 2) Flowering ¹ 3) Harvest ¹	Method of treatment	Application rate per treatment ⁴			Date of treatment	BBCH Crop Growth Stage at Treat- ment	Portions analysed	Residues (mg/kg)				PHI (days)	Gro wth stage at sam- pling (BB CH)	Re- marks
				Water L/ha	Kg ai/hL ³	Prothio (kg ai/ha)				T	TAA	TLA	TA			
25813 Südermarsch Germany IF21- 05707333 21-00230-05	Oilseed rape SO 0495 ² BRSNN Architekt	1 20/08/20 2 15/05- 14/06/21 3 03/08/21	Foliar appli- cation with boom	260 253	0.0719 0.0719	0.187 0.182	31/05/21 14/06/21	65 69	Seed Straw	<LOQ <LOQ	<LOQ 0.011	0.029 <LOQ	0.67 0.093	50 50	89 89	/
			untreated	-	-	-	-	-	Seed Straw	<LOQ <LOQ	<LOQ <LOQ	0.017 <LOQ	0.36 0.051	50 50	89 89	
6200 Rollum Denmark IF21- 05707333 21-00230-06	Oilseed rape SO 0495 ² BRSNN DK Exalte	1 03/08/20 2 16/05- 08/06/21 3 22/07/21	Foliar appli- cation with boom	257 253	0.0720 0.0719	0.185 0.182	29/05/21 08/06/21	65 69	Seed Straw	<LOQ <LOQ	0.018 0.052	0.058 0.039	1.3 0.20	44 44	89 89	
			untreated	-	-	-	-	-	Seed Straw	<LOQ <LOQ	<LOQ 0.029	0.034 0.015	0.78 0.12	44 44	89 89	
55-120 Przeclawice Poland	Oilseed rape SO 0495 ² BRSNN	1 21/08/20 2 07/05- 02/06/21	Foliar appli- cation with boom	298 306	0.0601 0.0601	0.179 0.184	19/05/21 04/06/21	66 69	Seed Straw	<LOQ <LOQ	<LOQ <LOQ	0.012 <LOQ	0.44 0.032	52 52	89 89	/

IF21-05707333 21-00230-07	DK Excited	3	26/07/21	untreated	-	-	-	-	-	Seed Straw	<LOQ <LOQ	<LOQ 0.015	0.017 <LOQ	0.59 0.028	52 52	89 89	
H-3905 Monok Hungary IF21-05707333 21-00230-08	Oilseed rape SO 0495 ² BRSNN Umberto	1	28/08/20	Foliar appli- cation with boom	297	0.0599	0.178	0.6/05/21	65	Seed Straw	<LOQ	<LOQ	<LOQ	0.11	60	89	
		2	26/04- 27/05/21		290	0.0600	0.174	27/05/21	69		<LOQ	<LOQ	<LOQ	<LOQ	60	89	
		3	26-27/06/21	untreated	-	-	-	-	-	Seed Straw	<LOQ <LOQ	<LOQ <LOQ	<LOQ <LOQ	0.17 0.011	60 60	89 89	

¹Non-GLP-Data; ²According to the Codex Classification of food and animal feed commodities; ³calculated, ⁴Nominal rates: 0.180 kg ai/ha, water 200-400 L/ha

Summary:

Study Objective

The objective of the study IF21-05707333 was to determine the magnitude of the residue of prothioconazole metabolites (1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA)) in raw agricultural commodity specimens of oilseed rape (whole plant, pods, rest of plants, seed and straw) after two applications of Prothioconazole 300 EC, an emulsifiable concentrate formulation containing 300 g/L prothioconazole.

The study included eight supervised residue trials conducted under field conditions in northern Europe (Germany, northern France, Poland, Denmark and Hungary) during the 2021 season. Four trials were conducted as harvest trials and four trials were conducted as decline trials.

The spraying applications of Prothioconazole 300 EC were performed at 10 – 21 days before BBCH 69 and BBCH 69 with a nominal application rate of 0.60 L test item/ha and a water rate of 200 – 400 L/ha.

The application scenario to be investigated is summarized in the table below:

Table 35: Application summary

Trial No. Country	Formulation	Appl. mode	Treated area / Reference	Application						
				No. of appl.	Interval (days)	Growth stage (BBCH code)	Test item rate (L/ha)	Water rate (L/ha)	a.s.	Appl. rate (kg a.s./ha)
21-00230-01 Germany	Prothioconazole 300 EC	SPI	F/WF	1	-	65	0.626	261	prothioconazole	0.188
				2	14	69	0.592	247	prothioconazole	0.178
21-00230-02 Germany	Prothioconazole 300 EC	SPI	F/WF	1	-	65	0.628	262	prothioconazole	0.188
				2	14	69	0.612	255	prothioconazole	0.184
21-00230-03 northern France	Prothioconazole 300 EC	SPI	F/WF	1	-	67	0.626	313	prothioconazole	0.188
				2	15	69	0.599	300	prothioconazole	0.180
21-00230-04 Poland	Prothioconazole 300 EC	SPI	F/WF	1	-	65	0.584	292	prothioconazole	0.175
				2	15	69	0.588	294	prothioconazole	0.176
21-00230-05 Germany	Prothioconazole 300 EC	SPI	F/WF	1	-	65	0.624	260	prothioconazole	0.187
				2	14	69	0.608	253	prothioconazole	0.182
21-00230-06 Denmark	Prothioconazole 300 EC	SPI	F/WF	1	-	65	0.616	257	prothioconazole	0.185
				2	10	69	0.608	253	prothioconazole	0.182
21-00230-07 Poland	Prothioconazole 300 EC	SPI	F/WF	1	-	66	0.596	298	prothioconazole	0.179
				2	16	69	0.613	306	prothioconazole	0.184
21-00230-08 Hungary	Prothioconazole 300 EC	SPI	F/WF	1	-	65	0.593	297	prothioconazole	0.178
				2	21	69	0.580	290	prothioconazole	0.174

a.s.: Active substance
Appl.: Application

SPI: Spraying
WF: Whole Field

F: Field

For decline trials specimens of oilseed rape were collected at sampling timing 0 (S1), 7-8 (S2) and 13-15 (S3) DALA as whole plant, 34-36 DALA (S4) as pods and rest of plant and at normal commercial harvest (growth stage BBCH 89) (50-58 DALA) as seed and straw (S5). For harvest trials specimens of oilseed rape were collected at normal commercial harvest (growth stage BBCH 89) (44-60 DALA) as seed and straw only.

Field phase of the study

This study comprised eight supervised residue trials in/on oilseed rape in Germany, northern France, Poland, Denmark and Hungary under field conditions. At each trial site there was one untreated plot in addition to the treated plot. The treated and untreated plots were cultivated in the same manner. Information about the untreated and treated plots is given in the tables below.

Table 36: Description of the trial locations and cropping information

Trial number	21-00230-01	21-00230-02	21-00230-03	21-00230-04
Principal investigator	Mathias Ketelsen	Mathias Ketelsen	Anthony Lombard	Adrian Sowiński
Trial location	24988 Munkwolstrup	24857 Fährdorf	08300 Sorbon	57-100 Ludów Polski
Country	Germany	Germany	northern France	Poland
GPS coordinates	54°43'21.04'' N 09°28'33.61'' E	54°29'27.41'' N, 9°35'29.15'' E	49°31'35.918'' N, 4°20'27.891'' E	50°49'21.8'' N 17°03'14.0'' E
Trial type	Decline	Decline	Decline	Decline
Area of application	Field	Field	Field	Field
Plot size [m²]	U/T: 60	U/T: 60	U/T: 30	U/T: 45
Type of soil	Sand	Sand	Silt loam	Silt loam
pH-value of soil	6.4 (CaCl ₂)	5.8 (CaCl ₂)	8.5 (water)	5.7 (KCl)
Soil organic content [%] C _{org} = organic matter / 1.72	1.1	1.0	2.7	1.8
Test system	Oilseed rape	Oilseed rape	Oilseed rape	Oilseed rape
Variety	Crocodile	Ernesto	DK Expansion	SY Ilona
Seeding rate	42 seeds/m²	40 seeds/m²	3 kg/ha	3.5 kg/ha
Date of seeding	28 Aug 2020	20 Aug 2020	10 Aug 2020	10 Sep 2020
Start of flowering	15 May 2021	15 May 2021	01 May 2021	04 May 2021
End of flowering	14 Jun 2021	14 Jun 2021	27 May 2021	06 Jun 2021
Date of commercial harvest	03 Aug 2021	03 Aug 2021	24 Jul 2021	26 Jul 2021
Row Spacing [cm]	12.5	12.5	45	12.5
Plant Spacing [cm]	na	na	4	na
Number of plants per ha (calculated)	420 000	400 000	555 556	na

na = not applicable

The soil characterisation was not conducted according to GLP.

Table 37: Description of the trial locations and cropping information (continued)

Trial number	21-00230-05	21-00230-06	21-00230-07	21-00230-08
Principal investigator	Mathias Ketelsen	Jakob Festersen	Adrian Sowinski	Istvan Tömöri
Trial location	25813 Südermarsch	6200 Røllum	55-120 Przecławice	H-3905 Monok
Country	Germany	Denmark	Poland	Hungary
GPS coordinates	54°24'59.23''N, 9°5'32.59''E	54°59'19.4'' N, 9°22'45.1'' E	51°19'38.9'' N, 16°59'03.2'' E	48°11'56.12'' N, 21°8'47.7'' E
Trial type	Harvest	Harvest	Harvest	Harvest
Area of application	Field	Field	Field	Field
Plot size [m²]	U: 60 T: 30	U/T: 30	U/T: 45	U/T: 30
Type of soil	Loam	Sand	Silt loam	Silty Clay
pH-value of soil	7.0 (CaCl ₂)	6.6 (CaCl ₂)	6.6 (KCl)	7.3 (water)

Soil organic content [%] C_{org} = organic matter / 1.72	1.5	1.0	0.9	1.5
Test system	Oilseed rape	Oilseed rape	Oilseed rape	Oilseed rape
Variety	Architekt	DK Exalte	DK Excited	Umberto
Seeding rate	48 seeds/m ²	35 seeds/m ²	50 seeds/m ²	40 seeds/m ²
Date of seeding	28 Aug 2020	03 Aug 2020	21 Aug 2020	28 Aug 2020
Start of flowering	15 May 2021	16 May 2021	07 May 2021	26 Apr 2021
End of flowering	14 Jun 2021	08 Jun 2021	02 Jun 2021	27 May 2021
Date of commercial harvest	03 Aug 2021	22 Jul 2021	26 Jul 2021	26 Jun 2021 to 27 Jun 2021
Row Spacing [cm]	12.5	12.5	25	30
Plant Spacing [cm]	na	na	na	8.3
Number of plants per ha (calculated)	480 000	350 000	500 000	400 161

na = not applicable

The soil characterisation was not conducted according to GLP.

The distance between trials 21-00230-01 and 21-00230-02 was about 27 km, between trials 21-00230-01 and 21-00230-05 about 42 km, between trials 21-00230-02 and 21-00230-05 about 33 km and between trials 21-00230-04 and 21-00230-07 about 56 km.

The distance between trials 21-00230-01 and 21-00230-02 was about 27 km, between trials 21-00230-01 and 21-00230-05 about 42 km, between trials 21-00230-02 and 21-00230-05 about 33 km and between trials 21-00230-04 and 21-00230-07 about 56 km.

The measured application rates were within +/- 5% of the planned rates.

All maintenance products (plant protection products and fertilizers) were used simultaneously on the untreated (U) and treated (T) plots during the conduct of these trials (first application to final sampling). No product was used during the whole vegetation period and at least the previous two years that was expected to interfere analytically with the test item.

Analytical Phase of the study

For the analysis of 1,2,4-T, TA, TAA and TLA the analytical method 01062/M004 was used, which determined the analytes by LC-DMS/MS/MS. The method was validated at the analytical test site in study IF21-05707367 for the matrix groups relevant in this study.

Principle of the method:

1,2,4-T, TA, TAA and TLA were extracted with a mixture of methanol and water. An aliquot was filtered, concentrated and cleaned-up by dispersive C18-SPE step. The analytes were determined by LC-DMS/MS/MS, using two different HPLC stationary phases and a LCMS/MS instrument equipped with SelexION ion mobility technology which is based on planar differential spectrometry (DMS). Residues were quantified using stable isotopically labelled internal standards to compensate matrix effects. The Limit of Quantification (LOQ), defined as the lowest quantification level, was set to 0.010 mg/kg for each analyte. The Limit of Detection of the method (LOD) was defined to be 0.003 mg/kg for each analyte (lowest calibration standard used).

Procedural Recoveries

Summary of the values obtained for the mean recoveries, standard deviations (SD) and relative standard

deviation (RSD) for field specimen analysis is given below:

Table 38: Summary of procedural recoveries for 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA)

Crop	Matrix	Fortification Level (nominal) [mg/kg]	1,2,4-T		
			Mean [%]	RSD [±]	n
Oilseed Rape	Whole Plant	0.010, 0.10 and 1.0	86.1	8.3	7
	Pods	0.010, 0.10 and 1.0	98.9	7.0	7
	Rest of Plant	0.010, 0.10 and 1.0	93.1	10	7
	Straw	0.010, 0.10 and 1.0	92.9	12	12
	Seed	0.010, 0.10, 1.0 and 10	87.5	14	10
Overall			91.6	11	43
Crop	Matrix	Fortification Level (nominal) [mg/kg]	TA		
			Mean [%]	RSD [±]	n
Oilseed Rape	Whole Plant	0.010, 0.10 and 1.0	90.6	11	7
	Pods	0.010, 0.10 and 1.0	88.7	12	7
	Rest of Plant	0.010, 0.10 and 1.0	91.2	9.8	7
	Straw	0.010, 0.10 and 1.0	79.7	18	12
	Seed	0.010, 0.10, 1.0 and 10	80.6	13	8
Overall			85.2	14	41
Crop	Matrix	Fortification Level (nominal) [mg/kg]	TAA		
			Mean [%]	RSD [±]	n
Oilseed Rape	Whole Plant	0.010, 0.10 and 1.0	96.5	6.5	7
	Pods	0.010, 0.10 and 1.0	97.8	2.2	7
	Rest of Plant	0.010, 0.10 and 1.0	94.4	5.2	7
	Straw	0.010, 0.10 and 1.0	83.1	8.3	12
	Seed	0.010, 0.10, 1.0 and 10	90.6	7.2	10
Overall			91.3	8.8	43
Crop	Matrix	Fortification Level (nominal) [mg/kg]	TLA		
			Mean [%]	RSD [±]	n
Oilseed Rape	Whole Plant	0.010, 0.10 and 1.0	98.5	6.1	7
	Pods	0.010, 0.10 and 1.0	91.6	7.1	7
	Rest of Plant	0.010, 0.10 and 1.0	90.5	5.5	7
	Straw	0.010, 0.10 and 1.0	76.4	13	12
	Seed	0.010, 0.10, 1.0 and 10	86.7	6.1	10
Overall			87.2	12	43

RSD: Relative Standard Deviation; n: Number of specimens

Residues

The residues detected in field specimens can be summarised in the following table:

Table 39: Summary of the residues of 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA)

Sampling No.	Portion analysed	Plot	DALA	BBCH	n	Range of residues			
						1,2,4-T [mg/kg]	TA [mg/kg]	TAA [mg/kg]	TLA [mg/kg]
1	Whole Plant	U	0 DBLA	69	4	< 0.010	0.048 - 0.15	< 0.010	< 0.010
4	Pods		34 - 36	82 - 83	4	< 0.010	0.078 - 0.45	< 0.010 - 0.022	< 0.010 - 0.044
	Rest of Plant				4	< 0.010	0.014 - 0.024	< 0.010	< 0.010
5	Seed		44 - 60	89	8	< 0.010	0.17 - 0.78	< 0.010	< 0.010 - 0.034
	Straw				8	< 0.010	0.011 - 0.12	< 0.010 - 0.029	< 0.010 - 0.015
1	Whole Plant	T	0	69	4	< 0.010	0.053 - 0.13	< 0.010	< 0.010
2			7 - 8	73 - 75	4	< 0.010	0.048 - 0.18	< 0.010	< 0.010
3			13 - 15	77 - 80	4	< 0.010	0.060 - 0.15	< 0.010	< 0.010
4	Pods		34 - 36	82 - 83	4	< 0.010	0.11 - 0.42	< 0.010 - 0.020	0.011 - 0.043
	Rest of Plant				4	< 0.010	< 0.010 - 0.032	< 0.010	< 0.010
5	Seed		44 - 60	89	8	< 0.010	0.11 - 1.3	< 0.010 - 0.018	< 0.010 - 0.058
	Straw				8	< 0.010	< 0.010 - 0.20	< 0.010 - 0.052	< 0.010 - 0.039

DALA: Days after last application;; U: Untreated plot; T: Treated plot

In untreated specimens of oilseed rape - seeds taken at 44-60 DALA (NCH, BBCH 89) no residues equal or above the LOQ of 0.010 mg/kg were found for 1,2,4-Triazole and Triazole acetic acid. Residues ranged between 0.17 - 0.78 mg/kg for Triazole alanine and between < 0.010 - 0.034 mg/kg for Triazole lactic acid.

In untreated specimens of oilseed rape - straw taken at 44-60 DALA (NCH, BBCH 89) no residues equal or above the LOQ of 0.010 mg/kg were found for 1,2,4-Triazole. Residues ranged between 0.011 - 0.12 mg/kg for Triazole alanine, between < 0.010 - 0.029 mg/kg for Triazole acetic acid and between < 0.010 - 0.015 mg/kg for Triazole lactic acid.

In treated specimens of oilseed rape - seeds taken at 44-60 DALA (NCH, BBCH 89) no residues equal or above the LOQ of 0.010 mg/kg were found for 1,2,4-Triazole. Residues ranged between 0.11 - 1.3 mg/kg for Triazole alanine, between < 0.010 - 0.018 mg/kg for Triazole acetic acid and between < 0.010 - 0.058 mg/kg for Triazole lactic acid.

In treated specimens of oilseed rape - straw taken at 44-60 DALA (NCH, BBCH 89) no residues equal or above the LOQ of 0.010 mg/kg were found for 1,2,4-Triazole. Residues ranged between < 0.010 - 0.20 mg/kg for Triazole alanine, between < 0.010 - 0.052 mg/kg for Triazole acetic acid and between < 0.010 - 0.039 mg/kg for Triazole lactic acid.

A 2.1.3.12 Oilseed rape / Prothioconazole – Magnitude of the residues of prothioconazole and its metabolites in oilseed rape (whole plants, seeds and straw), following two applications of HAG 610 01 F in eight trials (4 DC and 4 HS), Northern and Southern Europe (Poland, Hungary, Portugal and Greece)- 2017

Table A 40: Intended GAP

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP (number 204-209)	2	~~0.5~~ 0.8 L/ha (125 g as/ha)	21d	BBCH 14-69	~~65~~ 35 d

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

Comments of zRMS:	Study performed according to GLP requirements, relevant guidelines and in line with the proposed GAP. The study is acceptable. The objective of the study was to determine the magnitude of residues of prothioconazole and its metabolites prothioconazole-desthio in winter oilseed rape after two applications of formulation HAG 610 01 F. Target application rate was 0.6 L/ha and target application time was: first application 14 ± 2 days before application 2, and second application 56 ± 3 days before commercial harvest. Eight residue trials (four decline and four harvest) were conducted in northern and southern Europe (Poland, Hungary, Portugal and Greece). Target application rate was 2 x ~0.18 kg/ha of prothioconazole.. The last stage of application was at BBCH 63-73. No residue of prothioconazole or prothioconazole-desthio was found above LOQ in untreated specimens. After two applications with HAG 610 01 F the residues of prothioconazole-desthio (as sum of isomers) in oilseed rape specimens range (NEU and SEU trials) were: in whole plants without pods at 35 DALA: from 0.062 mg/kg to 0.238 mg/kg, in pods at 35 DALA: from below LOQ to 0.040 mg/kg, in seed at commercial harvest: from below LOQ to 0.035 mg/kg, in straw at commercial harvest: from 0.026 mg/kg to 0.946 mg/kg.
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Reference:	KCA 6.3-16
Report	Magnitude of the residues of prothioconazole and its metabolites in oilseed rape (whole plants, seeds and straw), following two applications of HA 610 01 F in eight trials (4 DCS and 4 HS), Northern and Southern Europe (Poland, Hungary, Portugal and Greece) – 2017, Delmotte R., RDE-17-28968
Guideline(s):	Yes (SANCO 7029/VI/95 rev.5, SANTE/2019/12752, OECD 509, OECD (2016), SANTE/2020/12830 Rev.1, OECD (2007) ENV/JM/MONO(2007)17
Deviations:	None with impact
GLP:	Yes
Acceptability:	Yes

Table A 23-1: Summary of the study trials –

Active ingredient:	Prothioconazole	Commercial product (name):	Prothioconazole 300 EC HAG 610 01 F
Crop/crop group	Winter Wheat	Producer of commercial product:	HELM AG, Germany
Responsible body for reporting	STAPHYT 62860 Inchy en Artois	Indoor/Glasshouse/Outdoor:	Outdoor
Country	France	Other a.s. in formulation:	None
Content of active substance (g/kg or g/L):	300 g/L	Residues calculated as:	Prothioconazole and Prothioconazole-desthio (as sum of isomers) EN 15662:2008 for prothioconazole and prothioconazole-desthio 00979/M001 for the other metabolites
Formulation:	EC	Analytical Method	LOQ 0.01

1	2	3	4	5	6	7	8	9	10	11
Report No.	Commodity /Variety	Date of 1) Sowing 2) Flowering 3) Harvest	Method of treatment	Application rate per treatment g a.s./ha Water (L/ha) g a.s./hL	Date of treatment	BBCH Crop Growth Stage at Treatment	Portions analysed	Residues (mg/kg) Prothioconazole-desthio	PHI (days)	Remarks
RDE-17-28968 PL01 Poland Wielkopolska 63-040 Michałów	Oilseed rape Extrovert	1 28/09/16 2 09-27/05/17 3 25/07/17	Foliar broadcast application	0.187 298 0.063 0.190 302 0.063	23/05/17 05/06/17	67 73	Wh. Plants Wh. Plants Wh. Plants Wh. Plants Wh. Plants Wh. Plants Wh. Plants w/o pods Pods Seeds Straw	1.279 1.123 0.399 1.405 <LOQ 0.310 <LOQ 0.198 <LOQ 0.129 <LOQ 0.062 <LOQ 0.052 <LOQ 0.062 NA 0.040 NA 0.024 NA 0.026	0 1 3 5 7 15 21 35 35 58 58	All untreated specimens: <LOQ Max. storage interval: 395 days
RDE-17-28968 PL02 Poland Łódzkie 96-127 Wólka Krosnowska	Oilseed rape NK Technik F1	1 25/08/16 2 08-30/05/17 3 31/07/17	Foliar broadcast application	0.191 302 0.063 0.193 307 0.063	12/05/17 26/05/17	63 67	Seeds Straw	NA <LOQ NA 0.303	64 64	All untreated specimens: <LOQ Max. storage interval: 339 days

RDE-17-28968 HU03	Oilseed rape	1 2 3	26/08/16 11/04-16/05/17 05/07/17	Foliar broadcast application	0.193 0.185	308 294	0.063 0.063	24/04/17 07/05/17	64 67	Wh. Plants Wh. Plants Wh. Plants Wh. Plants Wh. Plants Wh. Plants Wh. Plants w/o pods Pods Seeds Straw	0.760 0.172 0.056 0.016 0.011 <LOQ <LOQ <LOQ NA NA NA	1.265 1.276 1.320 0.764 0.616 0.259 0.173 0.134 <LOQ <LOQ 0.303	0 1 3 5 7 13 21 38 38 56 56	All un-treated specimens: <LOQ Max. storage interval: 425 days
RDE-17-28968 HU04	Oilseed rape	1 2 3	26/08/16 10/04-15/05/17 03/07/17	Foliar broadcast application	0.203 0.201	324 320	0.063 0.063	24/04/17 07/05/17	65 67	Seeds Straw	NA NA	<LOQ 0.328	56 56	All un-treated specimens: <LOQ Max. storage interval: 366 days
RDE-17-28968 GR05	Oilseed rape	1 2 3	20/10/16 02/04/17 13/06/17	Foliar broadcast application	0.189 0.189	301 302	0.063 0.063	05/04/17 19/04/17	62 67	Wh. Plants Wh. Plants Wh. Plants Wh. Plants Wh. Plants Wh. Plants w/o pods Pods Seeds Straw	2.000 0.505 0.041 0.022 0.012 <LOQ <LOQ <LOQ NA NA NA	1.762 2.637 1.685 1.389 1.323 0.393 0.313 0.238 0.038 <LOQ 0.149	0 1 3 5 7 14 22 34 34 55 55	All un-treated specimens: <LOQ Max. storage interval: 443 days
RDE-17-28968 PT06	Oilseed rape	1 2 3	15/12/16 10/03-06/04/17 24/05/17	Foliar broadcast application	0.184 0.192	343 358	0.054 0.054	29/03/17 05/04/17	68 69	Seeds Straw	NA NA	0.035 0.946	47 47	All un-treated specimens: <LOQ Max. storage interval: 408 days

RDE-17-28968 GR07 Greece Central Macedonia GR 54500 Drymos	Oilseed rape PT200CL	1	25/09/16	Foliar broadcast application	0.189	302	0.063	04/04/17	61	Wh. Plants	2.933	2.667	0	All un-treated specimens: <LOQ Max. storage interval: 445 days
		2	04/04-02/05/17		0.189	301	0.063	18/04/17	65	Wh. Plants	0.675	4.239	1	
		3	15/06/17							Wh. Plants	0.106	2.886	3	
										Wh. Plants	0.035	2.203	5	
										Wh. Plants	0.021	1.917	7	
										Wh. Plants	<LOQ	0.865	14	
										Wh. Plants	<LOQ	0.114	21	
										Wh. Plants	<LOQ	0.236	34	
										w/o pods				
										Pods	NA	0.038	34	
RDE-17-28968 GR08 Greece East Macedonia and Thrace GR 67200 Exochi	Oilseed rape PT240CL	1	22/09/16	Foliar broadcast application	0.189	301	0.063	08/04/17	62	Seeds	NA	<LOQ	53	All un-treated specimens: <LOQ Max. storage interval: 385 days
		2	01/04-04/05/17		0.190	403	0.047	22/04/17	67	Seeds	NA	0.502	53	
		3	15/06/17							Straw	NA			

NA: not analysed

Summary:

Study Objective

The objective of the study was to determine the magnitude of residues of prothioconazole and its metabolites prothioconazole-desthio in raw agricultural commodity (RAC whole plants, seeds and straw) of winter oilseed rape after two applications of HAG 610 01 F. The crop was subjected to a residue program which simulated the use of HAG 610 01 F as a fungicide in winter oilseed rape in Northern and Southern Europe (Poland, Hungary, Portugal and Greece).

Target application rate was 0.6 L/ha and target application time was: first application 14 ± 2 days before application 2, and second application 56 ± 3 days before commercial harvest.

Field phase of the study

Two plots were established in each trial. U plot was left untreated. T plot was intended for residue at harvest, treated twice with HAG 610 01 F at the rate of 0.6 L/ha. Application 1 took place 14 ± 2 days before application 2, with the exception of trial PT06 where the first application took place 7 days before application 2. Application 2 took place 56 ± 3 days before the commercial harvest. Amounts of mixture applied were between 294 (lower limit) and 403 (upper limit) L/ha.

4 trials were Decline Curve Study trials with nine samplings. The first seven samplings were specimens of whole plants and were taken at 0, 1, 3, 5, 7, 14 (± 1) and 21 (± 2) days after the last application. At 35 (± 3) DALA, pods and whole plants without pods were taken. At harvest, 56 (± 3) DALA, seeds and straw were collected.

4 trials were Harvest Study trials and one sampling was taken at harvest, 56 (± 3) DALA, in each plot. Specimens taken were seeds and straw. Specimens were placed into labelled plastic bags, weighed and double bagged.

Specimens were frozen and shipped on freezer truck or with dry ice. They were delivered to analytical site on June 20th 2017, June 27th 2017, July 11th 2017, July 12th 2017, July 26th 2017 and August 25th 2017

Analytical Phase of the study

Analyses of specimens were performed at Food Safety Laboratory.

For the analysis of prothioconazole and prothioconazole-desthio in oilseed rape whole plants and whole plants without pods was described and validated in study EN 15662:2008 "Foods of plant origin – Determination of pesticide residues using GC-MS and/or LC-MS/MS following acetonitrile extraction/partitioning and clean-up by dispersive SPE – QuEChERS-method".

For the analysis of JAU-6476-desthio (M04), JAU-6476-3-hydroxy-desthio (M14), JAU-6476-4-hydroxy-desthio (M15), JAU-6476-5-hydroxy-desthio (M16), JAU-6476-6-hydroxy-desthio (M17) and JAU-6476- α -hydroxy-desthio (M18) in oilseed rape pods, straw and seeds were analysed according the BAYER CropScience method "Analytical Method 00979/M001 for the determination of residues of JAU-6476-a-hydroxy-desthio, JAU-6476-3-hydroxy-desthio, JAU-6476-4-hydroxydesthio, JAU-6476-5-hydroxy-desthio, and JAU-6476-6-hydroxy-desthio in/on matrices of plant origin by HPLC-MS/MS", Report: KCA 4.1.2/34; Freitag, Th.; Daniels, M.; 2009; M-328686-01-1.

Limit of quantification (LOQ) achieved was 0.01 mg/kg for prothioconazole, prothioconazole-desthio and all the metabolites.

Limit of determination (LOD) was found to be 0.003 mg/kg for prothioconazole and prothioconazole-desthio in oilseed rape whole plants and whole plants without pods.

Limit of determination (LOD) was found to be 0.002 mg/kg for prothioconazole-desthio and all metabolites in oilseed rape seeds, straw and pods.

Acceptance criteria for method validations were met, with average recoveries ranging from 70% to 110% and relative standard deviations $\leq 20\%$.

Procedural Recoveries

The analytical methods were validated in former this study. Procedural recoveries were performed during this study.

Residues

No residue of prothioconazole or prothioconazole-desthio was found above LOQ in untreated specimens.

After two applications with HAG 610 01 F (plot T) at the rate of 0.6 L/ha, the residues of prothioconazole in oilseed rape whole plants specimens range:

- from 0.760 mg/kg to 2.933 mg/kg at 0 DALA,
- from 0.172 mg/kg to 0.675 mg/kg at 1 DALA,
- from below LOQ to 0.106 mg/kg at 3 DALA,
- from below LOQ to 0.035 mg/kg at 5 DALA,
- from below LOQ to 0.021 mg/kg at 7 DALA,
- below LOQ at 14 and 21 DALA

After two applications with HAG 610 01 F (plot T) at the rate of 0.6 L/ha, the residues of prothioconazole-desthio (as sum of isomers) in oilseed rape specimens range:

in whole plants specimens:

- from 1.123 mg/kg to 2.667 mg/kg at 0 DALA,
- from 1.276 mg/kg to 4.239 mg/kg at 1 DALA,
- from 0.310 mg/kg to 2.886 mg/kg at 3 DALA,
- from 0.198 mg/kg to 2.203 mg/kg at 5 DALA,
- from 0.129 mg/kg to 1.917 mg/kg at 7 DALA,
- from 0.062 mg/kg to 0.865 mg/kg at 14 DALA,
- from 0.052 mg/kg to 0.312 mg/kg at 21 DALA,

in whole plants without pods at 35 DALA: from 0.062 mg/kg to 0.238 mg/kg,

in pods at 35 DALA: from below LOQ to 0.040 mg/kg,

in seed at commercial harvest: from below LOQ to 0.035 mg/kg,

in straw at commercial harvest: from 0.026 mg/kg to 0.946 mg/kg

A 2.1.3.13 Oilseed rape / Prothioconazole – Magnitude of the residues of prothioconazole and its metabolites in oilseed rape (whole plants, seeds and straw), following two applications of HAG 610 01 F in six trials (3 DC and 3 HS), Northern and Southern Europe (Poland, Hungary, Portugal and Greece)-2017

Table A 41: Intended GAP

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP (number 204-209)	2	~~0.5~~ 0.8 L/ha (125 g as/ha)	21d	BBCH 14-69	~~65~~ 56 d

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0
No PHI is indicated in GAP in Part B0

Comments of zRMS:	Study performed according to GLP requirements, relevant guidelines and in line with the proposed GAP. The study is acceptable. The objective of the study was to determine the magnitude of residues of prothioconazole and its metabolites prothioconazole-desthio in winter oilseed rape after two applications of formulation HAG 610 01 F. Target application rate was 0.6 L/ha and target application time was: first application 14 ± 2 days before application 2, and second application 56 ± 3 days before commercial harvest. Six residue trials (three decline and three harvest) were conducted in northern and southern Europe (Poland, Hungary, Portugal and Greece). Target application rate was 2 x ~0.18 kg/ha of prothioconazole.. The last stage of application was at BBCH 63-73. No residue of prothioconazole or prothioconazole-desthio was found above LOQ in untreated specimens. The residues of prothioconazole in oilseed rape whole plants specimens range: - from 0.925 mg/kg to 2.216 mg/kg at 0 DALA, - from below LOQ to 0.010 mg/kg at 7 DALA, - below LOQ at 21 DALA. After two applications with HAG 610 01 F the residues of prothioconazole-desthio (as sum of isomers) in oilseed rape specimens range (NEU and SEU trials) were: - in whole plants without pods at 35 DALA: from below LOQ to 0.430 mg/kg, - in pods at 35 DALA: from 0.010 mg/kg to 0.882 mg/kg, - in seed at commercial harvest: from below LOQ to 0.039 mg/kg, - in straw at commercial harvest: from 0.018 mg/kg to 0.730 mg/kg.
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Reference: KCA 6.3-17

Report Magnitude of the residues of prothioconazole and its metabolites in oilseed rape (whole plants, seeds and straw), following two applications of HA 610 01 F in six trials (3 DCS and 3 HS), Northern and Southern Europe (Poland, Hungary, Portugal and Greece) – 2017, Delmotte R., ~~RDE-17-28968~~ RDE-18-32946

Guideline(s): Yes (SANCO 7029/VI/95 rev.5, SANTE/2019/12752, OECD 509, OECD (2016), SANTE/2020/12830 Rev.1, OECD (2007) ENV/JM/MONO(2007)17

Deviations: None with impact

GLP: Yes
Acceptability: Yes

Table A 23-1: Summary of the study trials –

Active ingredient:	Prothioconazole	Commercial product (name):	Prothioconazole 300 EC HAG 610 01 F
Crop/crop group	Winter Wheat	Producer of commercial product:	HELM AG, Germany
Responsible body for reporting	STAPHYT 62860 Inchy en Artois	Indoor/Glasshouse/Outdoor:	Outdoor
Country	France	Other a.s. in formulation:	None
Content of active substance (g/kg or g/L):	300 g/L	Residues calculated as:	Prothioconazole and Prothioconazole-desthio (as sum of isomers) EN 15662:2008 for prothioconazole and prothioconazole-desthio 00979/M001 for the other metabolites
Formulation:	EC	Analytical Method	LOQ 0.01

1	2	3	4	5	6	7	8	9	10	11
Report No.	Commodity /Variety	Date of 1) Sowing 2) Flowering 3) Harvest	Method of treatment	Application rate per treatment g a.s./ha Water (L/ha) g a.s./hL	Date of treatment	BBCH Crop Growth Stage at Treatment	Portions analysed	Residues (mg/kg) Prothioconazole-desthio	PHI (days)	Remarks
RDE-18-32946 PL02 Poland Warmińsko-Mazurskie 14-106 Grabinek	Oilseed rape Pamela	1 2 3 24/08/17 26/04-24/05/18 31/07/18	Foliar broadcast application	0.192 0.197 307 313 0.063 0.063	23/05/18 06/06/18	69 73	Seeds Straw	NA NA NA NA <LOQ 0.372	55 55	All untreated specimens: <LOQ Max. storage interval: 70 days
RDE-18-32946 HU03 Hungary Jász-Nagykun-Szolnok 5125 Pusztamonostor	Oilseed rape Architekt	1 2 3 08/09/17 15-28/04/18 27/06/18	Foliar broadcast application	0.184 0.189 294 302 0.063 0.063	25/04/18 08/05/18	65 73	Wh. Plants Wh. Plants Wh. Plants Wh. Plants w/o pods Pods Seeds Straw	0.925 <LOQ <LOQ <LOQ NA NA NA 0.404 0.095 0.056 <LOQ 0.046 <LOQ 0.018	0 7 21 35 35 55 55	All untreated specimens: <LOQ Max. storage interval: 157 days

RDE-18-32946 PT05 Portugal Alentejo 7370 Campo Maior	Oilseed rape PR45M73	1 2 3	11/11/17 28/03-30/04/18 17/06/18	Foliar broadcast application	0.177 0.196	283 310	0.063 0.063	20/03/2018 05/04/18	53 65	Wh. Plants Wh. Plants Wh. Plants w/o pods Pods Seeds Straw	1.200 0.010 <LOQ <LOQ NA NA NA	1.356 0.828 0.155 0.091 0.010 <LOQ 0.103	0 7 20 35 35 70 70	All untreated specimens: <LOQ Max. storage interval: 195 days
RDE-18-32946 PT06 Portugal Alentejo 7830 Serpa	Oilseed rape Trobador	1 2 3	15/10/17 26/03-20/04/18 16/06/18	Foliar broadcast application	0.192 0.188	304 299	0.063 0.063	21/03/18 04/04/18	57 69	Seeds Straw	NA NA	<LOQ 0.088	70 70	All untreated specimens: <LOQ Max. storage interval: 118 days
RDE-18-32946 GR07 Greece Central Macedonia GR 57200 Drymos	Oilseed rape Exception	1 2 3	21/09/17 01-20/04/18 14/06/18	Foliar broadcast application	0.188 0.192	199 204	0.094 0.094	02/04/18 17/04/18	61 67	Wh. Plants Wh. Plants Wh. Plants w/o pods Pods Seeds Straw	2.216 0.010 <LOQ <LOQ NA NA NA	3.670 1.969 0.126 0.430 0.882 <LOQ 0.249	0 7 21 34 34 57 57	All untreated specimens: <LOQ Max. storage interval: 182 days
RDE-18-32946 GR08 Greece Central Macedonia GR 62045 Lefkotnea	Oilseed rape Expower	1 2 3	05/10/17 01-20/04/18 21/06/18	Foliar broadcast application	0.190 0.187	303 299	0.063 0.063	03/04/18 17/04/18	62 67	Seeds Straw	NA NA	0.039 0.730	58 58	All untreated specimens: <LOQ Max. storage interval: 117 days

NA: not analysed

Summary:

Study Objective

The objective of the study was to determine the magnitude of residues of prothioconazole and its metabolites prothioconazole-desthio in raw agricultural commodity (RAC whole plants, seeds and straw) of winter oilseed rape after two applications of HAG 610 01 F.

The crop was subjected to a residue program which simulated the use of HAG 610 01 F as a fungicide in winter oilseed rape in Northern and Southern Europe (Poland, Hungary, Portugal and Greece).

Target application rate was 0.6 L/ha and target application time was: first application 14 ± 2 days before application 2, and second application 56 ± 3 days before commercial harvest.

Field phase of the study

Two plots were established in each trial. U plot was left untreated. T plot was intended for residue at harvest, treated twice with HAG 610 01 F at the rate of 0.6 L/ha. Application 1 took place 13 to 16 days before application 2. Application 2 took place 55 to 70 days before the commercial harvest. Amounts of mixture applied were between 199 (lower limit) and 313 (upper limit) L/ha.

3 trials were Decline Curve Study trials with five samplings. The first three samplings were specimens of whole plants and were taken at 0, 7 and 20-21 days after the last application. At 34-35 DALA, pods and whole plants without pods were taken. At harvest, 55-57 DALA, seeds and straw were collected except for trial PT05, where the specimens were collected at 70 DALA, a deviation was written.

3 trials were Harvest Study trials and one sampling was taken at harvest, 55-58 DALA, in each plot except on trial PT06, where the specimens were collected at 70 DALA, a deviation was written. Specimens taken were seeds and straw.

Specimens were placed into labelled plastic bags, weighed and double bagged. Specimens were frozen and shipped on freezer truck or with dry ice. They were delivered to analytical site on June 26th 2018, July 12th 2018, September 12th 2018 and October 04th 2018.

Analytical Phase of the study

Analyses of specimens were performed at Food Safety Laboratory.

For the analysis of prothioconazole and prothioconazole-desthio in oilseed rape whole plants and whole plants without pods was described and validated in study EN 15662:2008 "Foods of plant origin – Determination of pesticide residues using GC-MS and/or LC-MS/MS following acetonitrile extraction/partitioning and clean-up by dispersive SPE – QuEChERS-method".

For the analysis of JAU-6476-desthio (M04), JAU-6476-3-hydroxy-desthio (M14), JAU-6476-4-hydroxy-desthio (M15), JAU-6476-5-hydroxy-desthio (M16), JAU-6476-6-hydroxy-desthio (M17) and JAU-6476- α -hydroxy-desthio (M18) in oilseed rape whole plants, pods, straw and seeds were analysed according the BAYER CropScience method "Analytical Method 00979/M001 for the determination of residues of JAU-6476-a-hydroxy-desthio, JAU-6476-3-hydroxy-desthio, JAU- 6476-4-hydroxy-desthio, JAU-6476-5-hydroxy-desthio, and JAU-6476-6-hydroxy-desthio in/on matrices of plant origin by HPLC-MS/MS", Report: KCA 4.1.2/34; Freitag, Th.; Daniels, M.; 2009; M-328686-01-1.

Limit of quantification (LOQ) achieved was 0.01 mg/kg for prothioconazole, prothioconazole-desthio and all the metabolites.

Limit of determination (LOD) was found to be 0.003 mg/kg for prothioconazole and prothioconazole-desthio in oilseed rape whole plants and whole plants without pods.

Limit of determination (LOD) was found to be 0.002 mg/kg for prothioconazole-desthio and all metabolites in oilseed rape seeds, straw and pods.

Acceptance criteria for method validations were met, with average recoveries ranging from 70% to 110% and relative standard deviations $\leq 20\%$.

Procedural Recoveries

The analytical methods were validated in former this study. Procedural recoveries were performed during this study.

Residues

No residue of prothioconazole or prothioconazole-desthio was found above LOQ in untreated specimens.

After two applications with HAG 610 01 F (plot T) at the rate of 0.6 L/ha, the residues of prothioconazole in oilseed rape whole plants specimens range:

- from 0.925 mg/kg to 2.216 mg/kg at 0 DALA,
- from below LOQ to 0.010 mg/kg at 7 DALA,
- below LOQ at 21 DALA.

After two applications with HAG 610 01 F (plot T) at the rate of 0.6 L/ha, the residues of prothioconazole-desthio (as sum of isomers) in oilseed rape specimens range:

in whole plants specimens:

- from 0.404 mg/kg to 3.670 mg/kg at 0 DALA,
- from 0.095 mg/kg to 1.969 mg/kg at 7 DALA,
- from 0.056 mg/kg to 0.155 mg/kg at 21 DALA,

in whole plants without pods at 35 DALA: from below LOQ to 0.430 mg/kg,

in pods at 35 DALA: from 0.010 mg/kg to 0.882 mg/kg,

in seeds at commercial harvest: from below LOQ to 0.039 mg/kg,

in straw at commercial harvest: from 0.018 mg/kg to 0.730 mg/kg.

A 2.1.3.14 Oilseed rape / Prothioconazole – Magnitude of the residues of prothioconazole and its metabolites in oilseed rape (whole plants, seeds and straw), following two applications of HAG 610 01 F, Northern Euope - 2019

Table A 42: Intended GAP

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP (number 204-209)	2	~~0.5~~ 0.8 L/ha (125 g as/ha)	21d	BBCH 14-69	~~65~~ 35 d

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

Comments of zRMS:	Study performed according to GLP requirements, relevant guidelines and in line with the proposed GAP. The study is acceptable. The objective of the study was to determine the magnitude of residues of prothioconazole and its metabolites prothioconazole-desthio in winter oilseed rape after two applications of formulation HAG 610 01 F. Target application rate was 0.6 L/ha and target application time was: first application 14 ± 2 days before application 2 and second application at BBCH crop stage 69. Two residue trials (one decline and one harvest) were conducted in northern Europe (Poland, and Hungary). Target application rate was 2 x ~0.18 kg/ha of prothioconazole.. The last stage of application was at BBCH 63-73. No residue of prothioconazole or prothioconazole-desthio was found above LOQ in untreated specimens. After two applications with HAG 610 01 F (plot T) at the rate of 0.6 L/ha, the residues of prothioconazole-desthio (as sum of isomers) in oilseed rape specimens ranged: - in whole plants specimens: - 0.950 mg/kg at 0 DALA, - 0.422 mg/kg at 7 DALA, - 0.029 mg/kg at 21 DALA, - in whole plants without pods at 35 DALA: 0.061 mg/kg, - in pods at 35 DALA: from 0.010 mg/kg, - in seed at commercial harvest: from below LOQ, - in straw at commercial harvest: from 0.039 mg/kg to 0.050 mg/kg.
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Reference:	KCA 6.3-18
Report	Magnitude of the residues of prothioconazole and its metabolites in oilseed rape (whole plants, seeds and straw), following two applications of HA 610 01 F, Northern Europe – 2019, <u>Delmotte R.</u> RDE-19-38550
Guideline(s):	Yes (SANCO 7029/VI/95 rev.5, SANTE/2019/12752, OECD 509, OECD (2016), SANTE/2020/12830 Rev.1, OECD (2007) ENV/JM/MONO(2007)17
Deviations:	None with impact
GLP:	Yes
Acceptability:	<u>Yes</u>

Table A 23-1: Summary of the study trials –

Active ingredient:	Prothioconazole	Commercial product (name):	Prothioconazole 300 EC HAG 610 01 F
Crop/crop group	Winter Wheat	Producer of commercial product:	HELM AG, Germany
Responsible body for reporting	STAPHYT 62860 Inchy en Artois	Indoor/Glasshouse/Outdoor:	Outdoor
Country	France	Other a.s. in formulation:	None
Content of active substance (g/kg or g/L):	300 g/L	Residues calculated as:	Prothioconazole and Prothioconazole-desthio (as sum of isomers) EN 15662:2018 for prothioconazole and prothioconazole-desthio 00979/M001 for the other metabolites
Formulation:	EC	Analytical Method	LOQ 0.01

1	2	3	4	5	6	7	8	9	10	11
Report No.	Commodity /Variety	Date of 1) Sowing 2) Flowering 3) Harvest	Method of treatment	Application rate per treatment g a.s./ha Water (L/ha) g a.s./hL	Date of treatment	BBCH Crop Growth Stage at Treatment	Portions analysed	Residues (mg/kg) Prothioconazole-desthio	PHI (days)	Remarks
RDE-19-38550 PL01 Poland Wielkopolskie 63-233 Wojociego-wo	Winter Oilseed rape Exodus	1 22/08/18 2 19/04-13/05/19 3 08/07/19	Foliar broadcast application	0.190 305 0.062 0.186 298 0.062	26/04/19 10/05/19	65 69	Wh. Plants Wh. Plants Wh. Plants w/o pods Pods Seeds Straw	1.207 0.950 0.018 0.422 <LOQ 0.029 <LOQ 0.061 NA 0.010 NA <LOQ NA 0.050	0 7 21 34 34 59 59	All untreated specimens: <LOQ Max. storage interval: 113 days
RDE-19-38550 HU02 Hungary Jász-Nagykun-Szolnok 5125 Pusztamonostor	Oilseed rape Umberto KWS	1 25/08/18 2 10/04-16/05/19 3 01/07/19	Foliar broadcast application	0.184 295 0.062 0.194 310 0.063	17/04/19 08/05/19	62 69	Seeds Straw	NA <LOQ NA 0.035	56 56	All untreated specimens: <LOQ Max. storage interval: 56 days

Summary:

Study Objective

The objective of the study was to determine the magnitude of residues of prothioconazole and its metabolites prothioconazole-desthio in raw agricultural commodity (RAC whole plants, seeds and straw) of winter oilseed rape after two applications of HAG 610 01 F.

The crop was subjected to a residue program which simulated the use of HAG 610 01 F as a fungicide in winter oilseed rape in Northern Europe (Poland and Hungary).

Target application rate was 0.6 L/ha and target application time was: first application 14 ± 2 days before application 2 and second application at BBCH crop stage 69.

Field phase of the study

Two plots were established in each trial. U plot was left untreated. T plot was intended for residue at harvest, treated twice with HAG 610 01 F at the rate of 0.6 L/ha. Application 1 took place 14 to 21 days before application 2. A deviation was written for the 21 days interval. Application 2 took place at BBCH 69. Amounts of mixture applied were between 295 (lower limit) and 310 (upper limit) L/ha.

One trial was a Decline Curve Study with five samplings. The first three samplings were specimens of whole plants and were taken at 0, 7 and 21 days after the last application. At 34 DALA, pods and whole plants without pods were taken. At harvest, seeds and straw were collected.

One trial was a Harvest Study and one sampling was taken at harvest. Specimens taken were seeds and straw.

Specimens were placed into labelled plastic bags, weighed and double bagged. Specimens were frozen and shipped with dry ice. They were delivered to analytical site on July 16th 2019 and July 18th 2019.

Analytical Phase of the study

Analyses of specimens were performed at Food Safety Laboratory.

For the analysis of prothioconazole and prothioconazole-desthio in oilseed rape whole plants and whole plants without pods was described and validated in method EN 15662:2018 “Foods of plant origin – Multimethod for the determination of pesticide residues using GC- and LC-based analysis following acetonitrile extraction/partitioning and clean-up by dispersive SPE – Modular QuEChERS-method”, with some modifications.

JAU-6476-desthio (M04), JAU-6476-3-hydroxy-desthio (M14), JAU-6476-4-hydroxy-desthio (M15), JAU-6476-5-hydroxy-desthio (M16), JAU-6476-6-hydroxy-desthio (M17) and JAU-6476- α -hydroxydesthio (M18) in oilseed rape whole plants, whole plants without pods, pods, straw and seeds were analysed according to the BAYER CropScience analytical method 00979/M001 “Analytical Method 00979/M001 for the determination of residues of JAU-6476-a-hydroxy-desthio, JAU-6476-3-hydroxy-desthio, JAU-6476-4-hydroxy-desthio, JAU-6476-5-hydroxy-desthio, and JAU-6476-6-hydroxy-desthio in/on matrices of plant origin by HPLC-MS/MS”, Report: KCA 4.1.2/34; Freitag, Th.; Daniels, M.; 2009; M-328686-01-1.

Limit of quantification (LOQ) achieved was 0.01 mg/kg for prothioconazole, prothioconazole-desthio and all the metabolites.

Limit of determination (LOD) was found to be 0.003 mg/kg for prothioconazole and prothioconazole-desthio in oilseed rape whole plants and whole plants without pods.

Limit of determination (LOD) was found to be 0.002 mg/kg for prothioconazole-desthio and all metabolites in oilseed rape seeds, straw and pods.

Acceptance criteria for method validations were met, with average recoveries ranging from 70% to 110% and relative standard deviations $\leq 20\%$.

Procedural Recoveries

The analytical methods were validated in former this study. Procedural recoveries were performed during this study.

Residues

No residue of prothioconazole or prothioconazole-desthio was found above LOQ in untreated specimens.

After two applications with HAG 610 01 F (plot T) at the rate of 0.6 L/ha, the residues of prothioconazole in oilseed rape whole plants specimens were:

- 1.207 mg/kg at 0 DALA,
- 0.018 mg/kg at 7 DALA,
- below LOQ at 21 DALA.

After two applications with HAG 610 01 F (plot T) at the rate of 0.6 L/ha, the residues of prothioconazole-desthio (as sum of isomers) in oilseed rape specimens ranged:

in whole plants specimens:

- 0.950 mg/kg at 0 DALA,
- 0.422 mg/kg at 7 DALA,
- 0.029 mg/kg at 21 DALA,

in whole plants without pods at 35 DALA: 0.061 mg/kg,

in pods at 35 DALA: from 0.010 mg/kg,

in seed at commercial harvest: from below LOQ,

in straw at commercial harvest: from 0.039 mg/kg to 0.050 mg/kg.

A 2.1.3.15 Oilseed rape / Prothioconazole – Study on the residue behaviour of prothioconazole in oilseed rape after treatment with Prothioconazole 300 EC at six trials under field conditions in Southern Europe, 2021

Table A 43: Intended GAP

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP (number 204-209)	2	0.5 0.8 L/ha (125 g as/ha)	21d	BBCH 14-69	65 35d

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

Comments of zRMS:	The application concerns the central zone - studies from the southern zone were not evaluated.
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Reference:	KCA 6.3-19
Report	Study on the behaviour of prothioconazole in oilseed rape after treatment with Prothioconazole 300 EC at six sites under field conditions in Southern Europe, 2021 IF21-05707367 21-00231
Guideline(s):	Yes (SANCO 7029/VI/95 rev.5, SANTE/2019/12752, OECD 509, OECD (2016), SANTE/2020/12830 Rev.1, OECD (2007) ENV/JM/MONO(2007)17
Deviations:	None with impact
GLP:	Yes
Acceptability:	Supplementary

Table A 23-1: Summary of the study trials –

Active ingredient:

Prothioconazole

Commercial product (name): **N/A**

Crop/crop group

Oilseed rape/oilseed

Producer of commercial product:
Globachem NV
HELM AG
ASCENZA AGRO, S.A.

Responsible body for reporting

Globachem NV, 3800 Sint-Truiden
HELM AG, 20097 Hamburg
ASCENZA AGRO, S.A., 2910-440 Setúbal
Belgium, Germany, Portugal

Indoor/Glasshouse/Outdoor: Outdoor

Country

Other a.s. in formulation: None

Content of active substance (g/kg or g/L):

300 g/L

Residues calculated as:
1,2,4-Triazole (T); Triazole Acetic Acid (TAA) ; Triazole Lactic Acid (TLA); Triazolalanine (TA)

Formulation:

EC

Analytical Method
LOQ
0.010

1	2	3	4	5			6	7	8	9				10	11	12	
Report No.	Commodity/E PPO-Code/Variety *	Date of 1) Sowing ¹ 2) Flowering ¹ 3) Harvest ¹		Method of treatment	Application rate per treatment ⁴			Date of treatment	BBCH Crop Growth Stage at Treatment	Portions analysed	Residues (mg/kg)				PHI (days)	Gro wth stage at sam-pling (BB CH)	Re-marks
					Water L/ha	Kg ai/hL ³	Prothio (kg ai/ha)				T	TAA	TLA	TA			
47120 Cau-bon Saint Sauveur France IF21-05707367 21-00231-01	Oilseed rape SO 0495 ² BRSNN Medley	1	22/09/20	Foliar appli-cation with boom	307 307	0.0599 0.0599	0.184 0.184	19/04/21 03/05/21	65 69	Wh. Plants	<LOQ	<LOQ	<LOQ	0.12	0	69	/
		2	11/04-03/05/21							Wh. Plants	<LOQ	<LOQ	<LOQ	0.079	7	72	
		3	02/07/21							Wh. Plants	<LOQ	<LOQ	<LOQ	0.10	14	75	
										Pods	<LOQ	<LOQ	0.024	0.290	35	81	
										Rest	<LOQ	<LOQ	<LOQ	0.033	35	81	
										Seed	<LOQ	0.012	0.048	0.84	60	89	
										Straw	<LOQ	<LOQ	0.013	0.057	60	89	
		untreated								Wh. Plants	<LOQ	<LOQ	<LOQ	0.18	0	69	
										Pods	<LOQ	0.016	0.039	0.42	35	81	
										Rest	<LOQ	<LOQ	<LOQ	0.014	35	81	
										Seed	<LOQ	0.017	0.075	1.2	60	89	
										Straw	<LOQ	0.025	0.020	0.040	60	89	
20049 Premenugo Italy IF21-05707367 21-00231-02	Oilseed rape SO 0495 ² BRSNN Expower	1	29/09/20	Foliar appli-cation with boom	313 300	0.0559 0.0600	0.175 0.180	09/04/21 23/04/21	65 69	Wh. Plants	<LOQ	0.029	0.039	0.98	0	69	
		2	01/04-23/04/21							Wh. Plants	<LOQ	0.021	0.027	0.65	6	71	
		3	24/06/21							Wh. Plants	<LOQ	<LOQ	0.014	0.34	13	73	
										Pods	<LOQ	0.022	0.037	0.69	32	77	
										Rest	<LOQ	<LOQ	<LOQ	0.025	32	77	
										Seed	<LOQ	0.021	0.045	2.3	62	89	
										Straw	<LOQ	0.11	0.11	0.26	62	89	
		untreated								Wh. Plants	<LOQ	0.011	0.016	0.47	0	69	
										Pods	<LOQ	<LOQ	<LOQ	0.31	32	77	
										Rest	<LOQ	<LOQ	<LOQ	0.19	32	77	
										Seed	<LOQ	<LOQ	0.014	0.70	62	89	
										Straw	<LOQ	0.017	0.010	0.14	62	89	

57200 Dry-mos Greece IF21- 05707367 21-00231-04	Oilseed rape SO 0495 ² BRSNN Puncher	1	16/09/20	Foliar appli- cation with boom	307 312	0.0599 0.0599	0.184 0.187	22/04/21 06/05/21	63 69	Wh. Plants	<LOQ	<LOQ	<LOQ	0.022	0	69										
		2	21/04-							Wh. Plants	<LOQ	<LOQ	<LOQ	0.018	6	75										
		3	04/05/21							Wh. Plants	<LOQ	<LOQ	<LOQ	0.017	13	79										
			26/06/21							Pods	<LOQ	<LOQ	<LOQ	0.035	34	86										
										Rest	<LOQ	<LOQ	<LOQ	<LOQ	34	86										
										Seed	<LOQ	<LOQ	<LOQ	0.11	50	89										
										Straw	<LOQ	<LOQ	<LOQ	<LOQ	50	89										
			untreated								-	-	-	-	-	Wh. Plants	<LOQ	<LOQ	<LOQ	0.016	0	69				
		Pods														<LOQ	<LOQ	0.018	0.12	34	86					
		Rest														<LOQ	<LOQ	<LOQ	<LOQ	34	86					
Seed	<LOQ	<LOQ		<LOQ	0.14	50	89																			
Straw	<LOQ	<LOQ	<LOQ	<LOQ	50	89																				
47300 Pujois France IF21- 05707367 21-00231-05	Oilseed rape SO 0495 ² BRSNN LG Acropole	1	21/09/20	Foliar appli- cation with boom	310 303	0.0600 0.0601	0.186 0.182	19/04/21 03/05/21	65 69	Seed	<LOQ	0.012	0.048	0.84	60	89										
		2	11/04-							Straw	<LOQ	<LOQ	0.012	0.032	60	89										
		3	02/07/21	untreated	-	-	-	-	-	Seed	<LOQ	0.017	0.073	1.4	60	89										
										Straw	<LOQ	0.013	0.014	0.034	60	89										
										13040 Borgo D'Ale Italy IF21- 05707367 21-00231-06	Oilseed rape SO 0495 ² BRSNN Puncher	1	15/10/20	Foliar appli- cation with boom	310 308	0.0558 0.0601	0.173 0.185	09/04/21 23/04/21	65 69	Seed	<LOQ	0.020	0.042	1.9	62	89
												2	07-							Straw	<LOQ	0.14	0.15	0.29	62	89
3	24/06/21	untreated	-	-	-	-	-	Seed	<LOQ	<LOQ	<LOQ	0.14	62	89												
								Straw	<LOQ	<LOQ	<LOQ	0.067	62	89												
50200 Ana- toliko Greece IF21- 05707367 21-00231-08	Oilseed rape SO 0495 ² BRSNN DK Imple- ment	1	25/09/20	Foliar appli- cation with boom	306 303	0.0601 0.0597	0.184 0.181	22/04/21 05/05/21	61 69	Seed	<LOQ	<LOQ	0.020	0.71	55	89										
		2	22/04-							Straw	<LOQ	<LOQ	0.018	0.026	55	89										
		3	30/06/21	untreated	-	-	-	-	-	Seed	<LOQ	<LOQ	0.032	0.66	55	89										
										Straw	<LOQ	0.013	0.038	0.044	55	89										

¹Non-GLP-Data; ²According to the Codex Classification of food and animal feed commodities; ³calculated, ⁴Nominal rates: 0.180 kg ai/ha, water 200-400 L/ha

Summary:

Study Objective

The objective of the study IF21-05707367 was to determine the magnitude of the residues of prothioconazole metabolites (1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA)) in raw agricultural commodity specimens of oilseed rape (whole plant, pods, rest of plants, seed and straw) after two applications of Prothioconazole 300 EC, an emulsifiable concentrate formulation containing 300 g/L prothioconazole.

Field phase of the study

The study included six supervised residue trials conducted under field conditions in southern Europe (southern France, Italy and Greece) during the 2021 season. Three trials were conducted as harvest trials and three trials were conducted as decline trials.

Originally eight trials were planned in this study but one harvest trial and one decline trial in Spain were cancelled as the crop did not develop.

The spraying applications of Prothioconazole 300 EC were performed at 13 – 14 days before BBCH 69 and at BBCH 69 with a nominal application rate of 0.6 L test item/ha and a water rate of 200 – 400 L/ha.

Analytical Phase of the study

For decline trials specimens of oilseed rape were collected at sampling timing 0 (S1), 6-7 (S2) and 13-14 (S3) DALA as whole plant, 32-35 DALA (S4) as pods and rest of plant and at normal commercial harvest (growth stage BBCH 89) (50-62 DALA) as seed and straw (S5). For harvest trials specimens of oilseed rape were collected at normal commercial harvest (growth stage BBCH 89) (55-62 DALA) as seed and straw only.

The analytical method 01062/M004 was used for analysis of 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) by LCDMS/MS/MS. The Limit of Quantification (LOQ) of the analytical method was defined as 0.010 mg/kg for each analyte.

Procedural Recoveries

Concurrent recoveries, performed with fortified untreated specimens, were analyzed together with the field specimens. Overall and average recoveries were all in the range of 70 – 110 % and relative standard deviations (RSD) were < 20 %.

A summary of the values obtained for the mean recoveries, standard deviation (SD) and relative standard deviation (RSD) for the field specimen analysis is given below.

Table 44: Summary of procedural recoveries for 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA)

Crop	Matrix	Fortification Level (nominal) [mg/kg]	1,2,4-T		
			Mean [%]	RSD [±]	n
Oilseed rape	Whole Plant	0.010, 0.10 and 1.0	90.5	5.8	11
	Pods	0.010, 0.10 and 1.0	93.6	5.3	10
	Rest of Plant	0.010 and 0.10	89.3	3.9	6
	Straw	0.010, 0.10, 1.0 and 10	88.9	4.9	11
	Seed	0.010, 0.10, 1.0 and 10	93.9	6.0	13
Overall:			91.5	5.7	51
Crop	Matrix	Fortification Level (nominal) [mg/kg]	TA		
			Mean [%]	RSD [±]	n

Oilseed rape	Whole Plant	0.010, 0.10 and 1.0	93.8	7.5	11
	Pods	0.010, 0.10 and 1.0	83.8	8.7	11
	Rest of Plant	0.010 and 0.10	91.7	15	6
	Straw	0.010, 0.10, and 1.0	83.1	6.1	11
	Seed	0.010, 0.10, 1.0 and 10	88.1	14	12
Overall:			87.7	11	51
Crop	Matrix	Fortification Level (nominal) [mg/kg]	TAA		
			Mean [%]	RSD [±]	n
Oilseed rape	Whole Plant	0.010, 0.10 and 1.0	99.0	4.3	11
	Pods	0.010, 0.10 and 1.0	93.9	7.3	10
	Rest of Plant	0.010 and 0.10	95.3	4.0	6
	Straw	0.010, 0.10 and 1.0	94.6	3.9	11
	Seed	0.010, 0.10, 1.0 and 10	90.6	4.9	13
Overall:			94.2	5.7	51
Crop	Matrix	Fortification Level (nominal) [mg/kg]	TLA		
			Mean [%]	RSD [±]	n
Oilseed rape	Whole Plant	0.010, 0.10 and 1.0	93.6	4.2	11
	Pods	0.010, 0.10 and 1.0	86.9	10.4	10
	Rest of Plant	0.010 and 0.10	90.6	3.4	6
	Straw	0.010, 0.10 and 1.0	92.6	6.6	11
	Seed	0.010, 0.10, 1.0 and 10	95.0	7.8	13
Overall:			92.1	7.5	51

RSD: Relative standard deviation; n: Number of specimens

Residues

The residues detected in field specimens can be summarised as in the following table:

Table 45: Summary of the residues of 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA)

Sampling No.	Portion analysed	Plot	DALA	BBCH	n	Range of residues			
						1,2,4-T [mg/kg]	TA [mg/kg]	TAA [mg/kg]	TLA [mg/kg]
1	Whole Plant	U	0 DBLA	69	3	< 0.010	0.016 – 0.47	< 0.010 – 0.011	< 0.010 – 0.016
4	Pods		32 - 35	77 - 86	3	< 0.010	0.12 – 0.42	< 0.010 – 0.016	< 0.010 – 0.039
	Rest of Plant				3	< 0.010	< 0.010 – 0.019	< 0.010	< 0.010
5	Seed		50 - 62	89	6	< 0.010	0.14 – 1.4	< 0.010 – 0.017	< 0.010 – 0.075
	Straw				6	< 0.010	< 0.010 – 0.14	< 0.010 – 0.025	< 0.010 – 0.038
1	Whole Plant	T	0	69	3	< 0.010	0.022 – 0.98	< 0.010 – 0.029	< 0.010 – 0.039
2			6 - 7	71 - 75	3	< 0.010	0.018 – 0.65	< 0.010 – 0.021	< 0.010 – 0.027
3			13 - 14	73 - 79	3	< 0.010	0.017 – 0.34	< 0.010	< 0.010 – 0.014
4			32 - 35	77 - 86	3	< 0.010	0.035 – 0.69	< 0.010 – 0.022	< 0.010 – 0.037

	Rest of Plant				3	< 0.010	< 0.010 – 0.033	< 0.010	< 0.010
5	Seed		50 - 62	89	6	< 0.010	0.11 – 2.3	< 0.010 – 0.021	< 0.010 – 0.048
	Straw				6	< 0.010	< 0.010 – 0.29	< 0.010 – 0.14	< 0.010 – 0.15

DALA: Days after last application; U: Untreated plot; T: Treated plot

In untreated specimens of oilseed rape straw taken at normal commercial harvest (NCH, BBCH 89) no residues equal or above the LOQ of 0.010 mg/kg were found for 1,2,4-Triazole. Residues ranged between < 0.010 – 0.14 mg/kg for Triazole alanine, between < 0.010 - 0.025 mg/kg for Triazole acetic acid and between < 0.010 – 0.038 mg/kg for Triazole lactic acid.

In untreated specimens of oilseed rape seed taken at normal commercial harvest (NCH, BBCH 89) no residues equal or above the LOQ of 0.010 mg/kg were found for 1,2,4-Triazole. Residues ranged between 0.14 – 1.4 mg/kg for Triazole alanine, between < 0.010 - 0.017 mg/kg for Triazole acetic acid and between < 0.010 – 0.075 mg/kg for Triazole lactic acid.

In treated specimens of oilseed rape straw taken at normal commercial harvest (NCH, BBCH 89) no residues equal or above the LOQ of 0.010 mg/kg were found for 1,2,4-Triazole. Residues ranged between < 0.010 – 0.29 mg/kg for Triazole alanine, between < 0.010 - 0.14 mg/kg for Triazole acetic acid and between < 0.010 – 0.15 mg/kg for Triazole lactic acid.

In treated specimens of oilseed rape seed taken at normal commercial harvest (NCH, BBCH89) no residues equal or above the LOQ of 0.010 mg/kg were found for 1,2,4-Triazole. Residues ranged between 0.11 – 2.3 mg/kg for Triazole alanine, between < 0.010 - 0.021 mg/kg for Triazole acetic acid and between < 0.010 – 0.048 mg/kg for Triazole lactic acid.

A 2.2 Boscalid

Intended GAP

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP (number 204-209)	2	0.8 L/ha (125 g as/ha)	21d	BBCH 25-69	35 d

Comments of zRMS:	Study performed according to GLP requirements and relevant guidelines. The study is acceptable. The aim of the study was to determine the magnitude of the residues of boscalid in wheat after two application of Boscalid 500 g/kg WG at the application rate of 0.7 kg/ha (350 g boscalid/ha). The applications were made at 14-15 days interval. The last stage of application was BBCH 69. Nine residue trials were conducted in northern Europe (Germany, France, Czech Republic and Poland). No residues of boscalid above the current MRL of 0.8 mg/kg were found in wheat grain.
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Reference: KCA 6.3-20

Report Determination of Boscalid Residues in Wheat Following Foliar Applications with GLOB1811F (Boscalid 500 g/kg WG) under Field Conditions in Northern Europe in 2023, Ertus C., C3086

Guideline(s): Yes (SANCO 7029/VI/95 rev.5, SANTE/2019/12752, OECD 509, OECD (2016), SANTE/2020/12830 Rev.1, OECD (2007) ENV/JM/MONO(2007)17

Deviations: None with impact

GLP: Yes

Acceptability: Yes

The objective of the study was to determine the residue levels of boscalid in wheat raw agricultural commodity (RAC) after two foliar applications of the formulated product GLOB1811F () (500 g boscalid/kg), at the rate of 0.7 kg/ha.

The study consisted of two phases: the field phase and the analytical phase.

The study was conducted under field conditions at 9 sites in Northern Europe. One of these trials was a contingency trial. It was not analysed but the field phase was reported.

In each trial one plot was treated twice with GLOB1811F (Boscalid 500 g/kg WG) at the application rate of 0.7 kg/ha (350 g boscalid/ha). The applications were made at 13-15 days interval and the last application was performed at BBCH 69 (not later).

One plot remained untreated.

In 4 trials sampling was performed just before last application in the untreated plot, just after last application in the treated plot, then 6-7, 13-15, 20-21 and 34-36 days after the last application (DALA) corresponding to maturity of the crop (NCH) in both plots.

In 3 trials sampling was performed at 32-37 days after the last application (DALA) corresponding to maturity of the crop (NCH) in both plots.

In 2 trials sampling was performed at 33-34 DALA and at 44-48 DALA corresponding to maturity of the crop (NCH) in both plots because the crop was not at NCH at 35 (± 3) DALA.

Boscalid residues were analysed in samples harvested during the field phase.

Location of the trials:



SUMMARIZED RESULTS

Residues in control samples were non-detectable or below the limit of quantification. The residue results for boscalid in the treated specimens are summarized below:

Trial No.	Matrix	Boscalid residues (mg/kg)					
		0 DALA	6-7 DALA	13-15 DALA	20-21 DALA	33-34 DALA	BBCH 89 (32-48 DALA)
C3086 BW1	Whole plant	-	-	-	-	*	-
	Grain	-	-	-	-	-	0.16
	Straw	-	-	-	-	-	19.75
C3086 MA1	Whole plant	-	-	-	-	15.10	-
	Grain	-	-	-	-	-	0.06
	Straw	-	-	-	-	-	29.39
C3086 CZ1	Whole plant	-	-	-	-	7.14	-
	Grain	-	-	-	-	-	0.31
	Straw	-	-	-	-	-	8.47
C3086 PL1	Whole plant	-	-	-	-	*	-
	Grain	-	-	-	-	-	0.21
	Straw	-	-	-	-	-	22.16
C3086 AN1	Whole plant	5.20	6.01	4.79	3.88	*	-
	Grain	-	-	-	-	-	0.07
	Straw	-	-	-	-	-	7.22
C3086 ND1	Whole plant	6.89	6.04	4.41	7.63	*	-
	Grain	-	-	-	-	-	0.16
	Straw	-	-	-	-	-	19.27
C3086 BW2	Whole plant	8.14	10.0	9.98	9.39	*	-
	Grain	-	-	-	-	-	0.20
	Straw	-	-	-	-	-	21.15
C3086 PL2	Whole plant	7.56	9.24	8.38	7.12	*	-
	Grain	-	-	-	-	-	0.14
	Straw	-	-	-	-	-	17.23
C3086 CZ2	Whole plant	-	-	-	-	*	-
	Grain	-	-	-	-	-	-
	Straw	-	-	-	-	-	-

DALA: Days after last application

NDR: No detectable residues (residues below the limit of detection)

LOD = 0.003 mg/kg

LOQ = 0.01 mg/kg

* Not sampled because maturity reached at or before 35 (±3) DALA

Comments of zRMS:	The application concerns the central zone - studies from the southern zone were not evaluated.
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Report	Determination of Boscalid Residues in Wheat Following Foliar Applications with GLOB1811F (Boscalid 500 g/kg WG) under Field Conditions in Southern Europe in 2023, Ertus C., C3087
Guideline(s):	Yes (SANCO 7029/VI/95 rev.5, SANTE/2019/12752, OECD 509, OECD (2016), SANTE/2020/12830 Rev.1, OECD (2007) ENV/JM/MONO(2007)17
Deviations:	None with impact
GLP:	Yes
Acceptability:	Supplementary

The objective of the study was to determine the residue levels of boscalid in wheat raw agricultural commodity (RAC) after two foliar applications of the formulated product GLOB1811F (Boscalid 500 g/kg WG) (500 g boscalid/kg), at the rate of 0.7 kg/ha.

The study consisted of two phases: the field phase and the analytical phase.

The study was conducted under field conditions at 9 sites in Southern Europe. One of these trials was a contingency trial.

In each trial one plot was treated twice with GLOB1811F (Boscalid 500 g/kg WG) at the application rate of 0.7 kg/ha (350 g boscalid/ha). The applications were made at 13-15 days interval and the last application was performed at BBCH 69 (not later).

One plot remained untreated.

In 4 trials sampling was performed just before last application in the untreated plot, just after last application in the treated plot, then 6-7, 13-15, 20-21 and 35 days after the last application (DALA) (sampling S5 not performed in trial C3087 IT1) and 35-62 DALA corresponding to maturity of the crop (NCH) in both plots.

In 5 trials sampling was performed at 34-36 DALA and 41-61 DALA corresponding to maturity of the crop (NCH) in both plots.

Boscalid residues were analysed in samples harvested during the field phase.

SUMMARIZED RESULTS

Residues in control samples were non-detectable or below the limit of quantification. The residue results for boscalid in the treated specimens are summarized below:

Trial No.	Matrix	Boscalid residues (mg/kg)					
		0 DALA	6-7 DALA	13-15 DALA	20-21 DALA	34-36 DALA	BBCH 89 (35-62 DALA)
C3087 AV1	Whole plant	15.35	8.12	5.60	7.06	5.34	-
	Grain	-	-	-	-	-	0.38
	Straw	-	-	-	-	-	6.13
C3087 TL1	Whole plant	10.34	3.22	2.91	3.04	2.29	-
	Grain	-	-	-	-	-	0.06
	Straw	-	-	-	-	-	6.11
C3087 IT1	Whole plant	8.33	4.07	3.30	3.12	*	-
	Grain	-	-	-	-	-	0.06
	Straw	-	-	-	-	-	5.06
C3087 ES2	Whole plant	13.27	7.91	5.06	5.32	5.36	-
	Grain	-	-	-	-	-	0.16
	Straw	-	-	-	-	-	10.78
C3087 EF1	Whole plant	-	-	-	-	5.41	-
	Grain	-	-	-	-	-	0.22
	Straw	-	-	-	-	-	6.94
C3087 ES1	Contingency						
C3087 GR1	Whole plant	-	-	-	-	1.93	-
	Grain	-	-	-	-	-	0.03
	Straw	-	-	-	-	-	3.26
C3087 GR2	Whole plant	-	-	-	-	1.97	-
	Grain	-	-	-	-	-	0.05
	Straw	-	-	-	-	-	5.18
C3087 IT2	Whole plant	-	-	-	-	0.58	-
	Grain	-	-	-	-	-	0.06
	Straw	-	-	-	-	-	2.76

DALA: Days after last application

LOD = 0.003 mg/kg

LOQ = 0.01 mg/kg

* Not sampled because maturity reached at or before 35 (±3) DALA

Comments of zRMS:	Study performed according to GLP requirements and relevant guidelines. The study is acceptable. The aim of the study was to determine the magnitude of the residues of boscalid in barley after two application of Boscalid 500 g/kg WG at the application rate of 0.7 kg/ha (350 g boscalid/ha). The applications were made at 14-15 days interval. The last stage of application was BBCH 59. Nine residue
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	trials were conducted in northern Europe (Germany, France, Czech Republic and Poland). No residues of boscalid above the current MRL of 4.0 mg/kg were found in barley grain.
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Reference:	KCA 6.3-23
Report	Determination of Boscalid Residues in Barley Following Foliar Applications with GLOB1811F (Boscalid 500 g/kg WG) under Field Conditions in Northern Europe in 2023, Ertus C., C3088
Guideline(s):	Yes (SANCO 7029/VI/95 rev.5, SANTE/2019/12752, OECD 509, OECD (2016), SANTE/2020/12830 Rev.1, OECD (2007) ENV/JM/MONO(2007)17
Deviations:	None with impact
GLP:	Yes
Acceptability:	Yes

The objective of the study was to determine the residue levels of boscalid in barley raw agricultural commodity (RAC) after two foliar applications of the formulated product GLOB1811F (Boscalid 500 g/kg WG), at the rate of 0.7 kg/ha.

The study consisted of two phases: the field phase and the analytical phase.

The study was conducted under field conditions at 9 sites in Northern Europe. One of these trials was a contingency trial. It was analysed and reported upon request of the Sponsor.

In each trial one plot was treated twice with GLOB1811F (Boscalid 500 g/kg WG) at the application rate of 0.7 kg/ha (350 g boscalid/ha). The applications were made at 13-14 days interval, except for trials C3088 AN1 and C3088 BW1 (see deviations No. 09/05/2023 and 19/05/2023) and the last application was performed at BBCH 59 (not later), except for trial C3088 BW1 (see deviation No.19/05/2023).

One plot remained untreated.

In 4 trials sampling was performed just before last application in the untreated plot, just after last application in the treated plot, then 7-8, 13-15, 20-23 and 43-47 days after the last application (DALA) corresponding to maturity of the crop (NCH) in both plots.

In 5 trials sampling was performed at 35-60 days after the last application (DALA) corresponding to maturity of the crop (NCH) in both plots.

Boscalid residues were analysed in samples harvested during the field phase.

SUMMARIZED RESULTS

Residues in control samples were non-detectable or below the limit of quantification. The residue results for boscalid in the treated specimens are summarized below:

Trial No.	Matrix	Boscalid residues (mg/kg)				
		0 DALA	7-8 DALA	13-15 DALA	20-23 DALA	BBCH 89 (35-60 DALA)
C3088 BW1	Whole plant	6.98	7.22	5.78	3.47	-
	Grain	-	-	-	-	0.04
	Straw	-	-	-	-	7.65
C3088 CZ1	Whole plant	11.34	10.92	10.26	7.41	-
	Grain	-	-	-	-	0.61
	Straw	-	-	-	-	6.76
C3088 MA1	Whole plant	7.93	7.58	5.59	5.67	-
	Grain	-	-	-	-	0.53
	Straw	-	-	-	-	9.72
C3088 ND1	Whole plant	8.23	3.94	4.04	3.30	-
	Grain	-	-	-	-	0.12
	Straw	-	-	-	-	9.37
C3088 AN1	Grain	-	-	-	-	0.12
	Straw	-	-	-	-	2.13
C3088 CZ2	Grain	-	-	-	-	0.47
	Straw	-	-	-	-	4.69
C3088 PL1	Grain	-	-	-	-	0.13
	Straw	-	-	-	-	8.25
C3088 PL2	Grain	-	-	-	-	0.52
	Straw	-	-	-	-	16.23
C3088 MA2*	Grain	-	-	-	-	0.23
	Straw	-	-	-	-	31.98

DALA: Days after last application

NDR: No detectable residues (residues below the limit of detection)

LOD = 0.003 mg/kg

LOQ = 0.01 mg/kg

Note: Sampling S5 of whole plants was not performed because maturity was reached at or before 56 (±5) DALA.

* Contingency trial analysed upon Sponsor's request.

Comments of zRMS:	The application concerns the central zone - studies from the southern zone were not evaluated.
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Report	Determination of Boscalid Residues in Barley Following Foliar Applications with GLOB1811F (Boscalid 500 g/kg WG) under Field Conditions in Southern Europe in 2023, Ertus C., C3089
Guideline(s):	Yes (SANCO 7029/VI/95 rev.5, SANTE/2019/12752, OECD 509, OECD (2016), SANTE/2020/12830 Rev.1, OECD (2007) ENV/JM/MONO(2007)17
Deviations:	None with impact
GLP:	Yes
Acceptability:	Supplementary

The objective of the study was to determine the residue levels of boscalid in barley raw agricultural commodity (RAC) after two foliar applications of the formulated product GLOB1811F (500 g boscalid/kg), at the rate of 0.7 kg/ha.

The study consisted of two phases: the field phase and the analytical phase.

The study was conducted under field conditions at 9 sites in Southern Europe. One of these trials (C3089 ES2) was a contingency trial and was not analysed upon request of the Sponsor.

In each trial one plot was treated twice with GLOB1811F (Boscalid 500 g/kg WG) at the application rate of 0.7 kg/ha (350 g boscalid/ha). The applications were made at 13-14 days interval (16 days interval for trial C3089 AV1, see deviation No. 19/05/2023) and the last application was performed at BBCH 59.

One plot remained untreated.

In 4 trials sampling was performed just before last application in the untreated plot, just after last application in the treated plot, then 6-7, 13-14, 20-21 and 50-59 days after the last application (DALA) corresponding to maturity of the crop (NCH) in both plots.

In 4 trials sampling was performed at 42-50 DALA corresponding to maturity of the crop (NCH) in both plots. Boscalid residues were analysed in samples harvested during the field phase.

SUMMARIZED RESULTS

Residues in control samples were non-detectable or below the limit of quantification, except for C3089 AV1 (the analysis of the untreated whole plants (collected at 0 DBLA) showed residue at 0.01 mg boscalid/kg). The residue results for boscalid in the treated specimens are summarized below:

Trial No.	Matrix	Boscalid residues (mg/kg)				
		0 DALA	6-7 DALA	13-14 DALA	20-21 DALA	BBCH 89 (42-59 DALA)
C3089 AV1	Whole plant	12.12	6.64	3.63	2.90	-
	Grain	-	-	-	-	0.11
	Straw	-	-	-	-	4.35
C3089 EF1	Whole plant	5.51	5.74	2.65	1.16	-
	Grain	-	-	-	-	0.01
	Straw	-	-	-	-	4.48
C3089 TL1	Whole plant	5.43	4.03	2.78	2.83	-
	Grain	-	-	-	-	0.13
	Straw	-	-	-	-	4.58
C3089 IT2	Whole plant	7.37	6.86	3.63	2.46	-
	Grain	-	-	-	-	0.19
	Straw	-	-	-	-	1.67
C3089 IT1	Grain	-	-	-	-	0.17
	Straw	-	-	-	-	1.16
C3089 GR1	Grain	-	-	-	-	0.19
	Straw	-	-	-	-	1.28
C3089 GR2	Grain	-	-	-	-	0.06
	Straw	-	-	-	-	0.70
C3089 ES1	Grain	-	-	-	-	0.21
	Straw	-	-	-	-	16.31

DALA: Days after last application

LOD = 0.003 mg/kg

LOQ = 0.01 mg/kg

Note: Sampling S5 of whole plants was not performed because maturity was reached at or before 56 (±5) DALA.

A 2.1.4 Other/Special Studies

Comments of zRMS:

Study is acceptable. Study conducted according to relevant guideline and GLP requirements. The aim of the study was to determine residue levels of prothioconazole and its metabolites in honey following two applications of prothioconazole (2 x 195 g prothioconazole/ha within two weeks). The study represents a worst case situation compared to the intended GAP for rape. The intended GAP for oilseed rape is 2 x 125 g as/ha. Prothioconazole was applied before and during flowering of *Phacelia tanacetifolia*.

Stability of Prothioconazole and Prothioconazole-desthio in honey samples was proven for at least 135 days after storage $\leq -18^{\circ}\text{C}$.
Stability of 1,2,4-T, TA, TAA and TLA in honey samples was proven for at least 95 days after storage $\leq -18^{\circ}\text{C}$.
No residues of Prothioconazole and its metabolites prothioconazole-desthio, 1,2,4-triazole (free triazole), triazole alanine, triazole lactic acid, triazole acetic acid, lactic acid, triazole acetic acid were found in the control and test item honey sample.

Reference: KCA 6.10.1-01
Report Tunnel study for determining the magnitude of residues of Prothioconazole 300 EC in honey according to SANTE/11956/2016 rev. 9, Schnetzer N., 2022
Guideline: SANTE/11956/2016 rev.9
Deviations: No
GLP: Yes
Acceptability: Yes

Summary:

Author(s) (year)	N Schnetzer (2022)	
Title	Tunnel study for determining the magnitude of residues of Prothioconazole 300 EC in honey according to SANTE/11956/2016 rev. 9	
Owner, Date	Globachem nv; HELM AG, ASCENZA AG-RO, S.A., 19 September 2022	Unpubl. RIFCON GmbH report No. R2140030
Test Facility	RIFCON GmbH, Goldbeckstraße 13, 69493 Hirschberg, Germany	
Dates of work	13 August 2021 to 29 April 2022	
Test item	Prothioconazole 300 EC, contains nominal 300 g a.s./L, analysed 298.4 g a.s./L	
Guidance	SANTE/11956/2016 (2018) rev. 9	
GLP	Yes (Test Facility certified by the LUBW Landesanstalt für Umwelt Baden-Württemberg, Griesbachstraße 1, 76185 Karlsruhe, Germany)	
GLP Study No.	558	
EFSA-Study ID	EFSA-2021-00005000 (Regulation (EC) No. 178/2002 and Regulation (EU) 2019/1391)	
Phase Report (Analytical Phase)	Tunnel study for determining the magnitude of residues of Prothioconazole 300 EC in honey according to SANTE/11956/2016 rev. 9	Project No.: IF21-05844957

Study Objective:

The main focus was to determine residue levels of prothioconazole and its metabolites in honey after two applications of Prothioconazole 300 EC according to the GAP (cereals: 2x 195 g prothioconazole/ha within two weeks) in order to allow a dietary risk assessment and to establish scientifically-based MRLs.

Material and methods

Test organism

For the four locations, healthy honeybee (*Apis mellifera* L.) colonies (seven combs) with queens hatched in 2020 and 3,870 (control colony, location L4) to 8,840 (control colony, location L3) worker bees, four food combs and three brood combs were used.

The colonies at all locations were set up in the tunnels on the evenings before the second application of the test item was conducted.

Test design

The study was conducted on four different study fields (locations) grown with the bee-attractive crop *Phacelia tanacetifolia*. On each study field two tunnels were setup. The closest distance between two locations was approximately 17 km (distance between locations L2 and L3). At each location a control tunnel and a test item treated tunnel were setup. Each tunnel covered at least a total area of approximately 144 m² and approximately 117 m² crop area.

The first application of the test item was conducted 16 days (location L1, see Table A 2), 15 days (location L2, see Table A 2), 13 days (location L3, see Table A 3) and 13 days (location L4, see Table A 3) before the second application and at BBCH growth stages 55 (location L1 and L2), 59-60 (location L3) and 60 (location L4).

The second applications of the test item were all performed during bee flight activity and during full flowering of the crop, at BBCH growth stages 63-65 (locations L1 and L4), 64-65 (location L2) and 62-63 (location L3).

Samplings

Two honey samples (A (main)- and B (backup)-sample) were taken from each colony.

Treatment groups

Test item: Prothioconazole 300 EC (a.s. prothioconazole); 650 mL product/ha (nominal), equivalent to nominal 195 g a.s./ha prothioconazole (one application before flowering and one application during flowering of the crop and during honeybee flight activity).

The amount of test item was chosen to cover the maximum intended application rate of the active substance.

All applications were performed with approximately 400 L water/ha.

Test conditions

The study was conducted in tunnels, i.e. under semi-field conditions. The weather conditions at all locations were in general comparable for the respective time period from the first application of the test item until the honey sampling or the last colony assessment, respectively, in terms of minimum, maximum and mean temperature and humidity. The daily mean temperatures ranged from 13.4 °C (location L3) to 17.8 °C (location L1) and the mean humidity ranged from 80.1% (location L1) to 88.5% (location L3).

Precipitation occurred on nine days (out of 23 days, location L1), on seven days (out of 25 days, at location L2), on ten days (out of 18 days, at location L3) and on 13 days (out of 21 days, at location L4), with

total precipitations of 32.2 mm at location L1, 12.6 mm at location L2, 17.4 mm at location L3 and 57.4 mm at location L4.

Results

The overall residues in the analysed honey samples are given in Table S 1.

Table S 1: Analytical results of test item treated samples for Prothioconazole 300 EC and its metabolites in honey

Residues [mg/kg] in honey samples								
	L1		L2		L3		L4	
	C	T	C	T	C	T	C	T
Prothioconazole	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD
prothioconazole-desthio	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD
1,2,4-triazole (free triazole)	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD
triazole alanine	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD
triazole lactic acid	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD
triazole acetic acid	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD

L1 = Location 1 (Limburgerhof); L2 = Location 2 (Stutensee); L3 = Location 3 (Kuhardt); L4 = Location 4 (Georgenhausen); C = Control samples; T = Test item treated samples

LOQ = limit of quantification (0.01 mg/kg for all active substances and matrices)

LOD = limit of detection (0.003 mg/kg for all active substances and matrices)

Conclusion

The two applications of the test item over a period of 16 days (site L1), 15 days (site L2) and 13 days (sites L3 and L4) did not result in residues of the parent compound (Prothioconazole) and its metabolites (prothioconazole-desthio, 1,2,4-triazole (free triazole), triazole alanine, triazole lactic acid, triazole acetic acid) in any of the control and test item treated honey samples (Table 8 and Table 9).

Thus, the two applications of the test item Prothioconazole 300 EC over time periods of 16 days (location L1), 15 days (location L2) and 13 days (locations L3 and L4) resulted in residue values of Prothioconazole and its metabolites prothioconazole-desthio, 1,2,4-triazole (free triazole), triazole alanine, triazole lactic acid, triazole acetic acid in honey below the default level of 0.05 mg/kg, which is set as maximum residue level (MRL) in honey in the current guidance document (SAN-TE/11956/2016 rev. 9).

Comments of zRMS: Study is acceptable. Study conducted according to relevant guideline and GLP requirements. The objective of this study was to determine the residues of Boscalid in Buckwheat honey after two applications of GLOB1811F (2 x 250 g a.i./ha, interval of 14 days) in Central and Southern Europe (Germany and Spain).
The maximum freezer storage period for honey samples of the field part was 103 days. Storage stability was proven for 113 days
The residues of boscalid were 0.065 mg/kg, 0.13 mg/kg, 0.019 mg/kg and < 0.0025 mg/kg in the trials which is below of the current MRL of 0.15 mg/kg.

Reference: KCA 6.10.1-01

Report Magnitude of residues of Boscalid in Buckwheat (*Fagopyrum esculentum* MOENCH) honey after two applications of GLOB1811F under semi-field

conditions in Central and Southern Europe. Poráčski, K. 2023

Guideline: SANTE/11956/2016 rev.9
Deviations: No
GLP: Yes
Acceptability: Yes

The objective of this study was to determine the inadvertent residues of Boscalid in Buckwheat (*Fagopyrum esculentum* MOENCH) honey after two applications of GLOB1811F under semi-field conditions in Central and Southern Europe in order to allow dietary risk assessment and to establish scientifically-based Maximum Residue Levels (MRLs).

During the growing season in 2022 four separate field trials were conducted at various places in Southern Spain and Eastern Germany. Trials 22BTR0003_T1 and 22BTR0003_T2 (subsequently named T1 and T2) were performed in the area of Eastern Germany (Leipzig and Wurzen; Saxony; Germany), respectively. Trials 22BTR0003_T3 and 22BTR0003_T4 (subsequently named T3 and T4) were performed in the area of Southern Spain (Utrera and Adriano; Seville; Spain).

Two plots (tunnel) with one beehive each, were set up per trial. Each tunnel covered an area of 216 m² (192.5 m² effective crop size). GLOB1811F was applied twice at a rate equivalent to 250 g a.i./ha of Boscalid (500 g GLOB1811F/ha). The spray volume amounted to 400 L/ha and the two applications were carried before flowering and at full flowering of Buckwheat with an interval of 14 days.

Two assessments of the colony condition were performed per plot, once before second application and once directly before sampling. The bee hives were set up in the tunnels directly after second application and remained in the tunnels until the honey showed a water content < 20%. Precisely 14 to 17 days after the application, honey combs were removed from the bee hives and gathered in the laboratory using a honey extractor.

The purpose of the analytical phase of the study was the determination of residues of Boscalid in honey of *Fagopyrum esculentum* MOENCH. The determination was conducted by an in-house developed method at SGS INSTITUT FRESENIUS GmbH, c/o SGS Germany GmbH, Hamburg, Germany using liquid chromatography with tandem mass spectrometric detection (LC-MS/MS) for Boscalid. The analytical methods were validated according to guideline SANTE 2020/12830 rev. 2. The validity of the analytical methods was proven within the analytical phase by SGS INSTITUT FRESENIUS GmbH, c/o SGS Germany GmbH, Hamburg, Germany.

The residue levels in honey were determined after two applications of GLOB1811F at a rate of 250 g a.i./ha in four independent trials, performed in Southern Spain and Eastern Germany during the 2022 growing season, respectively. No residues of Boscalid above the LOQ of 0.0025 mg/kg were found in any untreated control honey sample. The highest residues of Boscalid in Buckwheat honey analysed over all trials were found in Trial T2, where residues amounted to 0.13 mg/kg. In general, residues

amounted to 0.065 mg/kg in Trial T1, 0.13 mg/kg in Trial T2, 0.019 mg/kg in Trial T3 and < 0.0025 mg/kg in Trial T4, respectively.

Material and methods:

Test item: GLOB1811F,
Batch No.: 220612,
Active ingredient: Boscalid, 500 g/kg nominal

Test system: Buckwheat (*Fagopyrum esculentum* MOENCH)

Test design: Honey from Buckwheat was analysed for residues of Boscalid. The study comprised four trials covering two different regions under Central Europe (Germany) as well as two different regions under Southern Europe (Spain) growing conditions. Each trial comprised two tunnels, each with a bee colony inside. The trials were performed under semi-field conditions. Trial sites in one climatic region/country were located at least 10 km apart from each other

Trial location:

Field Phase	Trial No.	Field location
I	22BTR0003_T1	04319 Leipzig, Germany, Central Europe
I	22BTR0003_T2	04808 Wurzen, Germany, Central Europe
II	22BTR0003_T3	41710 Utrera, Spain, Southern Europe
II	22BTR0003_T4	41728 Adriano, Spain, Southern Europe

Application rate: Two applications with 500 g product/ha corresponding to 250 g a.i./ha in 400 L/ha of tap water

Endpoints: Magnitude of Residues of Boscalid in honey.

Analytical method: The analytical method for the determination of Boscalid in honey was conducted by using liquid chromatography with tandem mass spectrometric detection (LC-MS/MS)

The limit of quantification (LOQ) for Boscalid was defined as 0.0025 mg/kg. The limit of detection (LOD) was defined to be 30 % of the LOQ. This procedure meets the quality criteria of the guideline SANTE/2020/12830 rev.2, which describes the requirements for analytical method validation in residue studies for pre-registration purposes.

Details of the analytical methods and results are given in analytical phase report.

Method of sampling: For determination of residues of Boscalid in Buckwheat honey, specimens were sampled from sufficient honey combs after it had reached commercial maturity (water content < 20%). For each trial, sampling was performed for honey from untreated crop (control) as well as for honey from treated crop (test item treatment) separately. Therefore, the honey filled combs were transported to the laboratory in separate boxes to avoid contamination. Honey harvesting took place in the laboratory using appropriate equipment (*e.g.* spatula or by centrifugation via honey extractor).

For each untreated (control) and treated (test item treatment) sample per trial an amount of approximately 100 g of matured honey was taken and divided into two samples (“A”- Analysis; “R”-Retain).

Specimen storage: After extraction of the honey samples from the combs, the respective specimen containers were stored at the test facility (field phase I) under deep-frozen conditions ($\leq -18\text{ }^{\circ}\text{C}$) until shipment on dry ice to the PI of the analytical phase on 26 October 2022, and received on 27 October 2022.

Specimens generated at the test site for field phase II were stored under deep-frozen ($\leq -18\text{ }^{\circ}\text{C}$) conditions until shipment on dry ice to the PI of the analytical phase on 23 November 2022, and received on 24 November 2022.

In order to confirm the analytical results, the retain samples of Trial T4 were shipped on 14 February 2023, and received on 15 February 2023.

Results and Discussion:

The residue levels in honey in four independent trials, performed in Southern Spain and Eastern Germany during the 2022 growing season were determined after two applications of GLOB1811F at a rate of 250 g a.i./ha with an interval of 14 days under semi-field conditions. The first application was conducted before flowering in BBCH growth stage 56-59 and the second during full flowering of the crop in BBCH growth stage 65.

No residues of Boscalid above the LOQ of 0.0025 mg/kg were detected in any untreated control honey sample. The highest residues of Boscalid in Buckwheat honey analysed over all trials were found in Trial T2, where residues amounted to 0.13 mg/kg. In general, residues amounted to 0.065 mg/kg in Trial T1, 0.13 mg/kg in Trial T2, 0.019 mg/kg in Trial T3 and < 0.0025 mg/kg in Trial T4, respectively.

The maximum freezer storage period for honey samples of the field part was 103 days. Storage stability was proven for 113 days.

Table 8: Summarized results of the residue analysis

Field phase	Trial	Treatment-group	Residues of Boscalid [mg/kg]
I	T1	Control	< 0.0025
		Test item	0.065
	T2	Control	< 0.0025
		Test item	0.13
II	T3	Control	< 0.0025
		Test item	0.019
	T4 ¹⁾	Control	< 0.0025
		Test item	< 0.0025

T = Trial

¹⁾ Retain samples were analysed additionally to confirm the initial results

A 2.2 TMDI calculations


GLOB2021dF_Prothi
oconazole_EFSA_PRI


GLOB2021dF_Boscal
id_EFSA_PRIMo_rev.

A 2.3 IESTI calculations


GLOB2021dF_Prothi
oconazole_EFSA_PRI


GLOB2021dF_Boscal
id_EFSA_PRIMo_rev.

Appendix 3 Additional information provided by the applicant

No additional information provided.