REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: GF-3307 (S7K-3-3)

Product name(s): QUEEN

Chemical active substance(s):

Fenpicoxamid (XDE-777), 50 g/L +
Prothioconazole, 100 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(extension of use)

Applicant: Corteva Agriscience

Submission date: March 2025

Finalisation date: August 2025 (initial Core Assessment),
November 2025 (final Core Assessment)

Version history

When	What
March 2025	Submission of GF-3307 (S7K-3-3) Sugar beet/Fodder beet Extension of Use in the Central Zone.
August 2025	Initial ZRMS assessment. The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are ~~struck through~~ and shaded for transparency.
November 2025	Final report (Core Assessment updated following the commenting period) Additional information/assessments included by the zRMS in the report in response to comments received from the cMS and the Applicant are highlighted in yellow. Not agreed or not relevant information are ~~struck through~~ and shaded for transparency.

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7 Metabolism and residue data (KCA section 6)

7.1 Summary and zRMS Conclusion

7.1.1 Critical GAP(s) and overall conclusion

Selection of critical uses and justification
The critical GAPs with respect to consumer intake and risk assessment for the preparation of GF-3307 (S7K-3-3) are presented in Table 7.1 1. They have been selected from the GAPs in CZ for sugar beet/fodder beet. A list of all intended uses is given in Part B, Section 0.

The GAP proposed for GF-3307 (S7K-3-3) results in a total maximum application rate of 2 x 75 g ai/ha (21 days interval) with final application BBCH 49 (21 days PHI) for Fenpicoxamid (XDE-777) in sugar beet/fodder beet. Intended uses of GF-3307 (S7K-3-3) will not lead to residues exceeding the EU MRL.

The GAP proposed for GF-3307 (S7K-3-3) results in a total maximum application rate of 2 x 150 g ai/ha (21 days interval) with final application at BBCH 49 for Prothioconazole in sugar beet/fodder beet. This GAP is less critical than the one in which the EU MRL is based (2 x 150 g ai/ha, 21 days interval, final app at BBCH 49 and minimum 7 days PHI).

Overall conclusion
The data available are considered sufficient for risk assessment. An exceedance of the current MRL of 0.01 and 0.03 mg/kg for Fenpicoxamid (Reg (EU) 2023/1069) and Prothioconazole (Reg. (EU) 2024/1318) respectively is not expected.

The chronic and the short-term intakes of fenpicoxamid and prothioconazole residues are unlikely to present a public health concern.

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

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

Data gaps: none.

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

1	2	3	4	5	6	7		8				9			10	11
GAP number (see part B.0)*	**Crop and/ or situation ****	**Zone**	**Product code**	**F, Fn, Fpn G, Gn, Gpn or I*****	**Pests or Group of pests controlled**	**Formulation**		**Application**				**Application rate**			**PHI (days)**	**Conclusion**
						Type	**Conc. of as**	**Method kind**	**Growth stage & season**	**Max. number a) per use b) per crop/ season**	**Interval between applications (min)**	**L product/ha a) max. rate per appl. b) max. total rate per crop/season**	**water L/ha min max**	**g as/ha a) max. rate per appl. b) max. total rate per crop/season**		
1-2	Sugar Beet Fodder Beet	CZ	GF-3307	F	*Cercospora beticola* (CERCBE) *Uromyces betae* (UROMBE) *Erysiphe betae* (ERYSBE) *Ramularia beticola* (RAMUBE)	EC	Fenpicoxamid, 50 g/L + Prothioconazole, 100 g/L	Tractor mounted spray	BBCH 39-49	a) 1 b) 2	21 days	a) 1.5 L/ha b) 3 L/ha	150-300	a) 75 Fenpicoxamid + 150 Prothioconazole b) 150 Fenpicoxamid + 300 Prothioconazole	21	A

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

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

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

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

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 GF-3307 is composed of fenpicoxamid (XDE-777) and prothioconazole.

Table 7.1-2: Toxicological reference values for the dietary risk assessment of fenpicoxamid (XDE-777) and prothioconazole

Reference value	Source	Year	Value	Study relied upon	Safety factor
Fenpicoxamid (XDE-777) (parent compound)					
ADI	EFSA	2018 (1)	0.05 mg/kg bw/day	18-month mouse carcinogenicity	100
ARfD	EFSA	2018 (1)	1.8 mg/kg bw	Rabbit developmental study	100
Prothioconazole (parent compound)					
ADI	EFSA	2007 (2)	0.05 mg/kg bw/day	Rat oncogenicity study	100
ARfD	EFSA	2007 (2)	0.2 mg/kg bw	Rat developmental study	100
Prothioconazole-desthio (metabolite)					
ADI	EFSA	2007 (2)	0.01 mg/kg bw/day	Rat oncogenicity study	100
ARfD	EFSA	2007 (2)	0.01 mg/kg bw	Rat developmental study	100
Triazole alanine (TA) (triazole derivative metabolite)					
ADI	EFSA	2018 (3)	0.3 mg/kg bw/day	Rabbit developmental study	100
ARfD	EFSA	2018 (3)	0.3 mg/kg bw	Rabbit developmental study	100
Triazole lactic acid (TLA) (triazole derivative metabolite)					
ADI	EFSA	2018 (3)	0.3 mg/kg bw/day	Bridging from TA	--
ARfD	EFSA	2018 (3)	0.3 mg/kg bw	Bridging from TA	--
Triazole acetic acid (TAA) (triazole derivative metabolite)					
ADI	EFSA	2018 (3)	1 mg/kg bw/day	Rat 2-generation & rabbit developmental studies	100
ARfD	EFSA	2018 (3)	1 mg/kg bw	Rat 2-generation & rabbit developmental studies	100
1,2,4-triazole (1,2,4-T) (triazole derivative metabolite)					
ADI	EFSA	2018 (3)	0.023 mg/kg bw/day	Rat 12-month study	300
ARfD	EFSA	2018 (3)	0.1 mg/kg bw	Rabbit developmental study	300

(1) EFSA Journal 2018;16(1):5146
(2) EFSA Scientific Report（2007）106，1-98
(3) EFSA Journal 2018;16(7):5376

7.1.2.1 Summary for fenpicoxamid (XDE-777)

Table 7.1-3: Summary for fenpicoxamid (XDE-777)

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	Sugar Beet/Fodder Beet	Yes	Yes	Yes (PHI 21 days)	Yes	Yes	No	No

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

Based on the metabolism studies, the proposed residue definition for enforcement and risk assessment in plants was proposed by EFSA to be fenpicoxamid (XDE-777) only; this residue definition covers all

crop groups. In livestock commodities the residue definition for risk assessment and enforcement was derived as X12326349, expressed as parent. The residue definition is restricted to ruminants.

The effect on the nature of residue in processed foods was investigated in a high temperature hydrolysis study. The residue definition for risk assessment in processed commodities is proposed to include parent, X12019520, X12314005, X12335723, and X12264475. This residue definition is considered as provisional pending upon the submission of the requested processing residue trials (EFSA Peer Review data gap).
As residues of fenpicoxamid (XDE-777) do not exceed the trigger values defined in Reg (EU) No 283/2013, there is no need to investigate the effect of industrial and/or household processing. However, residue data in processed fractions is provided in the frame of this submission. According to the magnitude of residues in processed foods performed for sugar beet at an exaggerated rate we consider these metabolites not relevant and propose the residue definition to stand as Fenpicoxamid only for processed foods.

Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP for the intended uses. It is very unlikely that residues will be present in succeeding crops. The residue definition in succeeding crops is the same as for primary crops: Fenpicoxamid (XDE-777) only.

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

The proposed uses of fenpicoxamid on the crops under consideration (sugar beet/fodder beet) will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a concern for public health.

7.1.2.2 Summary for prothioconazole

Table 7.1-4: Summary for prothioconazole

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
1-2	Sugar Beet/Fodder Beet	Yes	Yes	Yes (PHI 21)	Yes	Yes	No	No

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

As residues of prothioconazole do not exceed the trigger values defined in Reg (EU) No 283/2013, there is no need to investigate the effect of industrial and/or household processing. However, metabolism data in processed fractions is provided in the frame of this submission.

Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. Residues of prothioconazole in rotational crops are expected to be covered by the residue levels in primary crops (EFSA, 2014).

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

The triazole derivative metabolites triazole acetic acid (TAA), triazole alanine (TA), 1,2,4-triazole (1,2,4-T) and triazole lactic acid (TLA), are common metabolites of the triazole-containing fungicides. Prothioconazole belongs to triazole fungicide group. EFSA concluded that the proposed use of prothioconazole on sugar beet roots will not result in a consumer exposure exceeding the toxicological reference values for prothioconazole and the TDMs and therefore is unlikely to pose a risk to consumers' health (EFSA, 2023).

The proposed uses of prothioconazole on the crops under consideration (sugar beet/fodder beet) will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a concern for public health.

7.1.2.3 Summary for GF-3307 (S7K-3-3)

Table 7.1-4: Information on GF3307 (S7K-3-3) (KCA 6.8)

Crop	PHI for GF-3307 (S7K-3-3) proposed by applicant	PHI/ Withholding period* sufficiently supported for		PHI for GF-3307 (S7K-3-3) proposed by zRMS	zRMS Comments (if different PHI proposed)
		Fenpicoxamid	Prothioconazole		
Sugar Beet/Fodder Beet	21 days	Yes	Yes	21 days	-

* 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).

Table 7.1-5: Waiting periods before planting succeeding crops

Waiting period before planting succeeding crops			Overall waiting period proposed by zRMS for GF-3307 (S7K-3-3)
Crop group	Led by fenpicoxamid	Led by prothioconazole	
Leafy vegetables	Not required	Not required	Not required
Root vegetables	Not required	Not required	Not required
Cereal	Not required	Not required	Not required

Assessment

The EFSA conclusion report on fenpicoxamid (EFSA, 2018) provides evaluation of MRLs for wheat, rye, and triticale.

The reasoned opinion on prothioconazole (EFSA Journal 2012;10(11):2952, EFSA Journal 2014;12(5):3689) and EFSA Journal 2020;18(2):5999) and the Modification of the existing maximum residue levels for prothioconazole in sugar beet and chicory roots (EFSA Journal 2023;21(8):8198) provide information on the existing MRLs for prothioconazole and evaluation of confirmatory data following Article 12 for Prothioconazole.

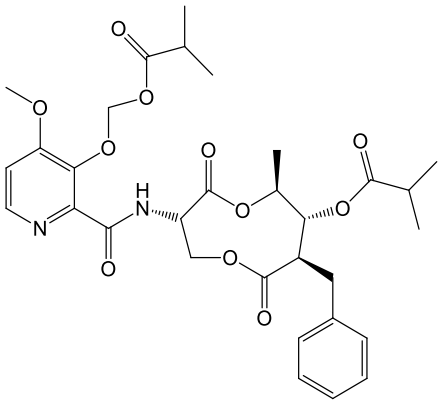
Conclusion on the peer review of the pesticide risk assessment for the triazole derivative metabolites in light of confirmatory data. (EFSA journal 2018b)

Commission Regulation (EU) 2023/1069 of 1 June 2023 amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for bixafen, cyprodinil, fenhexamid, fenpicoxamid, fenpyroximate, flutianil, isoxaflutole, mandipropamid, methoxyfenozide, and spinetoram in or on certain products

7.2 Fenpicoxamid

General data on fenpicoxamid (XDE-777) are summarized in the table below (last updated 2018/01/31)

Table 7.2-1: General information on fenpicoxamid

Active substance (ISO Common Name)	Fenpicoxamid
IUPAC	(3*S*,6*S*,7*R*,8*R*)-8-benzyl-3-{3-[(isobutyryloxy)methoxy]-4-methoxypyridine-2-carboxamido}-6-methyl-4,9-dioxo-1,5-dioxonan-7-yl isobutyrate
Chemical structure	
Molecular formula	$C_{31}H_{38}N_2O_{11}$
Molar mass	614.64
Chemical group	Picolinamide
Mode of action (if available)	FRAC group C4#21 Inhibition of respiration at complex III (QiI fungicides)
Systemic	No
Company (ies)	Corteva Agriscience
Rapporteur Member State (RMS)	UK (coRMS: France)
Approval status	Approved (Commission Implementing Regulation (EU) No 2018/1265)
Restriction (e.g. is restricted to use as "...")	No
Review Report	SANTE/10319/2018 Rev. 2
Current MRL regulation	~~Reg. (EU) 2019/50~~ Reg (EU) 2023/1069
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	New active substance
EFSA Journal : Conclusion on the peer review	EFSA Journal 2018;16(1):5146
EFSA Journal: conclusion on article 12	New active substance
Current MRL applications on intended uses	Approved

7.2.1 Stability of Residues (KCA 6.1)

7.2.1.1 Stability of residues during storage of samples

Available data

New data is being submitted in the framework of this application.

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

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products			
Oilseed rape seed	High oil content	18 months (fenpicoxamid & X642188)	Lindner, M., 2019, Study# 150026 New study
Lettuce	High water content	18 months (fenpicoxamid & X642188)	Lindner, M., 2019, Study# 150026 New study
Wheat forage	High water content	24 months (fenpicoxamid & X642188)	United Kingdom, 2017* (Weir, 2014, 120749, EU agreed)
Potato	High starch content	12 months (fenpicoxamid) 18 months (X642188)	Lindner, M., 2019, Study# 150026 New study
Wheat grain	High starch content	24 months (fenpicoxamid & X642188)	United Kingdom, 2017* (Weir, 2014, 120749, EU agreed)
Wheat straw	No group	24 months (fenpicoxamid & X642188)	United Kingdom, 2017 (Weir, 2014, 120749, EU agreed)
Orange	High acid content	18 months (fenpicoxamid & X642188)	Lindner, M., 2019, Study# 150026 New study
Beans (dried)	High protein content	18 months (fenpicoxamid & X642188)	Lindner, M., 2019, Study# 150026 New study
Wheat bran, flour, bread	Processed commodities (high starch content)	24 months (fenpicoxamid & X642188)	United Kingdom, 2017* (Weir, 2014, 120749, EU agreed)
Wheat germ	Processed commodity (high water content)	9 months (fenpicoxamid) 24 months (X642188)	United Kingdom, 2017* (Weir, 2014, 120749, EU agreed)
Oilseed rape seed	High acid content	12 months (X12314005)	Driss, F., 2021, Study # 200444 New study
Oilseed rape plant	High starch content	12 months (X12314005)	Driss, F., 2021, Study # 200444 New study
Animal Products			
Bovine	Liver	3 months (fenpicoxamid) 6/7 months (X642188 and X12326349)	EFSA Journal 2018;16(1):5146 (Devine, 2013, 130709, EU agreed)
Bovine	Milk	9 months (fenpicoxamid) 6 months (X642188) 3 months (X12326349)	EFSA Journal 2018;16(1):5146 (Devine, 2013, 130709, EU agreed)

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Bovine	Muscle	7 months (fenpicoxamid) 6 months (X642188) 3 months (X12326349)	EFSA Journal 2018;16(1):5146 (Devine, 2013, 130709, EU agreed)
Bovine	Fat	9 months (fenpicoxamid and X642188) 3 months (X12326349)	EFSA Journal 2018;16(1):5146 (Devine, 2013, 130709, EU agreed)

*Inconsistencies were found in EFSA conclusion and agreed with EFSA and RMS. Correct data are located in DAR Vol. 3, B7 AS (2017)

Conclusion on stability of residues during storage

The results from the frozen storage stability studies support the stability of the relevant residues in crop, processed fractions, and animal tissues under frozen conditions for the period of time for which samples from the residue trials presented in this report were stored prior to analysis.

zRMS comments:

Studies on the storage stability of fenpicoxamid under frozen conditions were assessed in the framework at the EU level. In RAR (UK, 2017) it is stated that "*Both parent XDE-777 and metabolite X642188 are stable in wheat raw commodities and processed fractions under freezer conditions up to 2 years. A degradation of the residue in wheat germ was observed from 9 months storage on parent XDE-777."*

This application concerns the extension of the use of GC-3307 on sugar and fodder beet.
Sugar beet and fodder beet roots belong to high starch content commodity categories (OECD 506).
There is not available storage stability study on sugar beet. Hovewer, according to the OECD 506 *If the stability of test substance in two diverse commodities in this category is confirmed, further examination with other commodities that belong to this category is unnecessary* or *If residues are shown to be stable in all commodities studied, a study on one commodity from each of the five commodity categories is acceptable. In such cases, residues in all other commodities (see Annex 1) would be assumed to be stable for the same duration of time under the same storage conditions.*

Applicant provided new study on storage stability of XDE-777 and X642188 in 5 matrices (lettuce - high water content, oilseed rape (seeds) - high oil content, orange (whole fruit) - high acid content, potato - high starch content and beans (dried) - high protein content under deep frozen conditions over a storage period up to 18 months (M. Lindner, A. Büdel, 2019; S17-04000, DAS Study ID: 150026).
Stability upon storage at ≤ -20 °C for up to 18 months was demonstrated for fenpicoxamid in homogenates of lettuce, oilseed rape (seeds), orange (whole fruit) and beans (dried) and for its metabolite X642188 in homogenates of all tested matrices.
Stability of fenpicoxamid in homogenates of potato upon storage at ≤ -20 °C was demonstrated for up to 12 months.
Taking into account the results of the storage stability study, it can be concluded that the stability of fenpicoxamid and its metabolite X642188 in sugar beet is 12 and 18 months, respectively.

The maximum storage interval from sampling to extraction in sugar beet root and tops was 113 days. Sufficient stability data are available to support the residue data presented in the present dossier.
No further data are required.

In addition, the storage stability of metabolite X12314005 has been checked in oilseed rape under deep frozen conditions (≤ -20 C°) in the dark (Driss, F; 2021; 200444; Study No. S20-01461). The stability was demonstrated for X12314005 in homogenates of matrices whole plant, seeds and remaining plant of oilseed rape upon storage at ≤ -18 °C in the dark for 12 months

The results show that the fenpicoxamid, X642188 and X12326349 are stable in animal matrices for a minimum period of 3 months. It has to be noted that all the samples of the ruminant feeding study were analysed within 38 days of collection. Therefore, the storage duration is covered by the current storage stability results on

commodities of animal origin.

No additional data are required.

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

Available data
Stability of analyte residues in sample extracts is verified by the acceptable fortification recovery data summarised in each study. These fortifications were run with the specimens in each analysis set and were stored and treated in every way as the treated and control specimens in that set. Acceptable recoveries were achieved, indicating no significant degradation was observed in the timeframes sample extracts were stored.

Conclusion on stability of residues in sample extracts
The residues of fenpicoxamid and its metabolites are stable in extracts.

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

7.2.2 Nature of residues in plants, livestock and processed commodities

7.2.2.1 Nature of residue in primary crops (KCA 6.2.1)

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

Table 7.2-3: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (g a.s./ha)	No.	Sampling (DAT)	Remarks	
EU data								
Cereals	Wheat	Phenyl-14C and Pyridine-14C	F	133	2	Forage, 28 days after 1st App. (BBCH 49) Hay, 24 days after 2nd App., (BBCH 77) Grain & Straw, 78 days after 2nd App., (BBCH 89)	Low level of residues in grain with each metabolite less than 0.001 mg eq/kg.	EFSA, 2018 (Ma, 2013, 110334)
Leafy vegetables	Cabbage	Phenyl-14C and Pyridine-14C	F	300	2	Immature Crop (14 days after 1st App at BBCH 45) Mature Crop (7 Days after 2nd App at BBCH 49)	Residues were primarily found in the outer leaves	EFSA, 2018 (Wu, 2013, 121002)

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (g a.s./ha)	No.	Sampling (DAT)	Remarks	
EU data								
Fruits and fruiting vegetable	Tomato	Phenyl-14C and Pyridine-14C	F	300	2	Fruit 1 Day After 2nd App (BBCH 88) Fruit 7 Days After 2nd App (BBCH 89) Fruit 14 Days After 2nd App (BBCH 89)	Residues were primarily found on the surface rinse of tomatoes	EFSA, 2018 (Wu, 2013, 121003)

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

Summary of plant metabolism studies reported in the EU

The results from the plant metabolism studies showed that XDE-777 is not extensively metabolized in crops following foliar applications. The metabolite X642188 was found in small amounts, up to 0.08 mg/kg in straw (feed items). The metabolic pathway in the three plant groups appears to be similar yielding the same compounds (except cabbage where X1234005 was found higher than 13% TRR). X12314005 was considered currently not relevant since there is no use on leafy crops, while X642188 is a precursor of the parent and the occurrence ratio, compared to the parent, was very low.

Summary of new plant metabolism studies

Not applicable.

Conclusion on metabolism in primary crops

The parent compound was the major component in all investigated crops, accounting for 38% total radioactive residues (TRRs) (PH labels) in grain, up to 95% in tomato fruit, and up to 96% of the TRR in cabbage. Based on the metabolism studies, the proposed residue definition for enforcement and risk assessment was parent fenpicoxamid; this residue definition covers all crop groups.

zRMS comments:

The metabolism of fenpicoxamid in primary crops was evaluated at the EU level. Information given by the Applicant is sufficient.

According to the EFSA Journal 2018;16(1):5146:

"The metabolism was investigated following foliar application in wheat (representative use), tomatoes and cabbage with both labelled phenyl (PH) and pyridine (PY) fenpicoxamid. The parent compound was the major component in all investigated crops, accounting for 38% total radioactive residues (TRRs) (PH labels) in grain, up to 95% in tomatoes fruits and up to 96% of TRRs in cabbage.

The metabolite X642188 was found in small amounts, up to 0.08 mg/kg in straw (feeds items) and 0.015 mg/kg in cabbage. In addition, X12314005 metabolite occurs up to 13% TRR in cabbage. Results from field trials on wheat analysed for the parent and X642188 confirmed the metabolic pattern. Based on the metabolism studies, the proposed residue definition for enforcement and risk assessment was parent fenpicoxamid, this residue definition cover all crop groups. The experts discussed also the inclusion of metabolites X642188 and X12314005 in the risk assessment residue definition. X12314005 was considered currently not relevant since there is no use on leafy crops while X642188 is precursor of the parent and the occurrence ratio compared to the parent was very low."

The residue definitions for plant agreed for monitoring and risk assessment (EFSA Journal 2018;16(1):5146):

Residue definition for enforcement: Fenpicoxamid (XDE-777)

The residue definition for enforcement set in Regulation (EC) No 396/2005 (Reg (EU) 2023/1069) is identical with the above-mentioned enforcement residue definition.

Residue definition for risk assessment: Fenpicoxamid (XDE-777)

No additional metabolism studies are necessary to support the intended uses for GF-3307.

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

No new data are 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 (g a.s./ha)	Sowing intervals (DAT)	Harvest Timing	Remarks	
EU data								
Leafy vegetables	Lettuce	Phenyl-14C and Pyridine-14C	F	260	30, 180, 270	Immature lettuce (BBCH 44) Mature lettuce (BBCH 49)		EFSA, 2018 (Ma, 2015, 140050)
Root and tuber vegetables	Radish	Phenyl-14C and Pyridine-14C	F	260	30, 180, 270	Radish top and root (BBCH 49)		EFSA, 2018 (Ma, 2015, 140050)
Cereals	Wheat	Phenyl-14C and Pyridine-14C	F	260	30, 180, 270	Forage (BBCH 34) Hay (BBCH 83) Straw and grain (BBCH 89)		EFSA, 2018 (Ma, 2015, 140050)

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

Summary of confined crop metabolism studies reported in the EU

The total radioactive residue levels decreased significantly between the 30 and 180 day plant-back intervals, and further decreased to less than 0.010 mg eq/kg following the 270 day plant-back interval. The extractable residues in all crop tissue samples were multicomponent. The bare soil application in the Confined Rotational Crop study was at an estimated 2X exaggerated rate when soil loading is taken into account.

Summary of new rotational crop metabolism studies

Not applicable

Conclusion on metabolism in rotational crops

Extensive soil degradation prior to plant uptake in the confined rotational crops resulted in multiple low-levels of residues. All individual crop metabolites were well below 0.010 mg/kg when normalized to 1X rate, considering crop interception.
No significant residues are expected in rotational crops. Residue definition in rotational crops is the same as for primary crops: Fenpicoxamid (XDE-777) only.

zRMS comments:
The metabolism of fenpicoxamid in rotational crops was evaluated at the EU level (RAR; UK, 2017). Information given by the Applicant is sufficient.
According to the RAR (UK, 2017):
"Nature and distribution of residues of XDE-777 were investigated in the raw agricultural commodities of three rotational crops, wheat, lettuce, and radish planted in a sandy loam soil at ca 30, 180 and 270 days after treatment (DAT) with a single soil application of ^{14}C-XDE-777, radiolabeled on the phenyl ring and the pyridine ring.

Immature and mature lettuce, radish tops and roots, wheat forage, hay, and mature grain and straw, were harvested from each plant-back interval. Total radioactive residues (TRR) ranged from 0.006 to 0.130 mg XDE-777 eq./kg for 30 day plant-back crop tissues. The residue levels declined to 0.001 to 0.032 mg/kg for 180 day plant-back crops and to less than 0.005 mg XDE-777 eq./kg for 270 day plant-back crops including immature and mature lettuce, radish tops and roots, and wheat forage.
The HPLC results showed that the extractable radioactivity from all characterized tissues was multi-component with no single component exceeding 0.010 mg/kg."
No significant residues expected in rotational crops.

Residue definition in rotational crops is the same as for primary crops: Fenpicoxamid (XDE-777) only.

No additional metabolism studies are necessary to support the intended uses for GF-3307.

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data
No new data are 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) (%)	Reference
EU data		
Pasteurisation (20 minutes, 90°C, pH 4)	Parent (80-87%), X12335723 (15.4%), X12314005 (10%)	EFSA 2018 (Ma, 2013, 121153)
Baking, boiling, brewing (60 minutes, 100°C, pH 5)	Parent (19-28%), X12335723 (77%), X12314005 (48%), X12019520 (12%)	EFSA 2018 (Ma, 2013, 121153)
Sterilisation (20 minutes, 120°C, pH 6)	Parent (Not detectable), X12335723 (65%), X12264475 (18%), X12019520 (87%)	EFSA 2018 (Ma, 2013, 121153)

Conclusion on nature of residues in processed commodities
Under the processing conditions, the XDE-777 degrades to form four compounds in quantities that exceed 10% of the applied radioactivity. The residue definition for risk assessment in processed commodities is proposed to include parent, X12019520, X12314005, X12335723, and X12264475. This residue definition is considered as provisional pending upon the submission of the requested processing residue trials (EFSA Peer Review data gap).

zRMS comments:
The effect of processing on the nature of fenpicoxamid (XDE-777) was investigated under conditions representing pasteurization, baking/brewing/boiling and sterilisation (20 minutes at 90°C, pH 4; 60 minutes at 100°C, pH 5; 20 minutes at 120°C, pH 6) in the framework of the DAR (2017).

According to the List of Endpoints (UK, 2017):
The residue definition for risk assessment in processed commodities has been proposed to include parent, X12019520, X12314005, X12335723, and X12264475. This RD is considered as provisional pending upon the submission of the requested processing residue trials (data gap identified during expert meeting) and toxicological data on all compounds
At this time, no additional data are necessary to support the intended uses for GF-3307.

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

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

Endpoints

Plant groups covered	Cereals (Wheat) Fruit (Tomato) Leafy vegetable (Cabbage)
Rotational crops covered	Cereals (Wheat) Root (Radish) Leafy vegetable (Lettuce)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Fenpicoxamid is not stable under standard hydrolysis conditions; 4 degradates formed at >10%, analyzed in the analytical methods
Residue pattern in processed commodities similar to pattern in raw commodities?	The processing NOR / hydrolysis study indicated potential for fenpicoxamid to degrade to form four compounds in quantities that exceed 10% of the applied radioactivity upon heated processing. In the Magnitude of Residues Processing study, residues of metabolites X642188, X12019520, X12314005, X12264475 and X12335723 were not observed the processed fractions and are not of concern for risk assessment.
Plant residue definition for monitoring	Fenpicoxamid (XDE-777) (EFSA 2018 ; ~~Reg EU 2019/50~~ Reg (EU) 2023/1069)
Plant residue definition for risk assessment	Fenpicoxamid (XDE-777) (EFSA 2018)
Conversion factor from enforcement to RA	1 (EFSA 2018)

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

Available data

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

Table 7.2-7: 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	Phenyl-14C and Pyridine-14C	1 for each label	PH: 0.255 (21.8 mg/kg DM) PY: 0.299 (18.7 mg/kg DM)	5	Milk	twice daily	EFSA 2018 ([redacted], 2013, 110766)
						Muscle (loin, and flank)	at sacrifice	
						Kidney	at sacrifice	
						Liver	at sacrifice	
						Fat (subcutaneous, omental and renal)	at sacrifice	
						GI tract and contents and blood (for mass balance only)	at sacrifice	
						Cage wash	at sacrifice	
Laying poultry	Hens	Phenyl-14C and Pyridine-14C	10 for each label	PH: 0.82 (10.7 mg/kg DM) PY: 0.79	7	Eggs	twice daily	EFSA 2018 ([redacted], 2013, 110421)
						Muscle (leg and breast)	at sacrifice	

				(10.3 mg/kg DM)		Liver	at sacrifice	
						Fat (all available) Skin with subcutaneous fat	at sacrifice	
						Excreta and Cage Washes	at sacrifice	
						GI tracts and contents were collected but not processed due to good recoveries of administered radioactivity in all other samples.	at sacrifice	

Summary of animal metabolism studies reported in the EU
The results from the animal metabolism studies showed that the administered dose of XDE-777 was rapidly eliminated in poultry and ruminant. Most of the radioactivity was excreted *via* faeces and urine. In ruminants, the parent compound was not detected in liver and kidney, whilst the metabolite X12326349 occurred at significant proportions in liver (from 10.4% to 13.2% TRR) and in kidney (from 16.8% to 32.7% TRR) for both labels.

In poultry, the parent compound was only detected in fat at low levels (5% TRR). The predominant compounds were identified as X12264475 in eggs (14% TRR), X129300 in fat (14% TRR), X11963422 in liver (11.6% TRR), in fat (up to 28.4% TRR) and eggs (32.2% TRR) and X696872 in fat (up to 17% TRR).

Summary of new animal metabolism studies
Not applicable

Conclusion on metabolism in livestock
In ruminants, the residue definition for risk assessment was derived as X12326349 expressed as fenpicoxamid. The same residue definition was proposed for monitoring.

The residue levels in the hen metabolism study conducted at approximately 5N the dietary burden were very low; thus, no residue definitions were considered necessary.

zRMS comments:
Information given by the Applicant is sufficient.
One metabolism study on lactating goats and one on laying hens were submitted in the framework of the DAR (2017).
According to the DAR (UK, 2017):
The agreed residue definition for monitoring and risk assessment in ruminant matrices is proposed as X12326349 expressed as parent.
In view of the very low total residues recovered in poultry matrices and the 5N rate dosed study, it is proposed not to set residue definition in poultry matrices for the representative uses.
No additional data are necessary to support the intended uses for GF-3307.

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	3 days in milk
	5 days in eggs (Phenyl label) Plateau may not have been reached at 7 days in eggs (Pyridine Label)
Animal residue definition for monitoring	Ruminants: X12336349 expressed as fenpicoxamid. Not necessary in poultry. (EFSA, 2018; ~~Reg EU 2019/50~~ Reg (EU) 2023/1069)
Animal residue definition for risk assessment	Ruminants: X12336349 expressed as fenpicoxamid. Not necessary in poultry. (EFSA, 2018)
Conversion factor	1 (EFSA, 2018)
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	No

7.2.3 Magnitude of residues in plants (KCA 6.3)

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

The GAP proposed for GF-3307 (S7K-3-3) results in a total maximum application rate of 2 x 75 g ai/ha with final application BBCH 49 for Fenpicoxamid (XDE-777) in Sugar Beet/Fodder Beet. Intended uses of GF-3307 (S7K-3-3) will not lead to residues exceeding the EU MRL.

New magnitude of residue studies conducted with GF-3307 (S7K-3-3) in support of the proposed GAP (see GAP table 7.1-1), are submitted in the frame of this submission (2 x 75g ai/ha, last application BBCH 49, 21 days PHI). The study results are summarized in the Table below and the detailed assessment is presented in Appendix 2.

Table 7.2-9: Summary of EU reported and new data supporting the intended uses of GF-3307 (S7K-3-3) and conformity to existing MRL

Commodity	Source	Residue zone	Evaluation GAP Residue levels (mg fenpicoxamid/kg)	STMR (mg/kg)	HR (mg/kg)	OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) (1)	MRL compliance
Sugar Beet Roots	New Trials	N-EU (4)	*Trials GAP: 2 x 75 g as/ha, Appl at BBCH 49, outdoor* 4 x <0.01	0.01*	0.01*	0.01*	0.01*	Yes
		~~S-EU (4)~~	~~4 x <0.01~~	~~0.01*~~	~~0.01*~~	~~0.01*~~		~~Yes~~
Sugar Beet Tops	New Trials	N-EU (4)	*Trials GAP: 2 x 75 g as/ha, Appl at BBCH 49, outdoor* 0.02 ; 0.10 ; 0.16 ; 0.38	0.13	0.38	-	-	-
		~~S-EU (4)~~	~~0.03 ; 0.10; 0.49 ; 0.51~~	~~0.30~~	~~0.51~~	-		-

(1) Source of EU MRL: Reg. (EU) 2023/1069.

7.2.3.2 Conclusion on the magnitude of residues in plants

According to the available data, the intended use on Sugar Beet/Fodder Beet is considered acceptable, for outdoor uses.
The data set presented is considered acceptable since residues in RAC (roots) are < LOQ in all 8 trials.

The data submitted show that no exceedance of the MRL will occur and the intended uses are considered acceptable on Sugar Beet/Fodder Beet.

zRMS comments:
Residue Definitions (EFSA 2018; Reg (EU) 2023/1069):
Monitoring (Mo): Fenpicoxamid (XDE-777)
Risk Assessment (RA): Fenpicoxamid (XDE-777)

Sugar beet and fodder beet (crop used for animal feed)
Sugar beet and fodder beet are the major crops in northern Europe (SANTE/2019/12752, Rev02). A minimum of eight trials are required.

One new magnitude of residue study has been submitted in the framework of this application (Matthew Munro; 2024, Report no. 685066/ 220541), conducted with the same total rate as the proposed cGAP for GF-3307.

Summary
Report no. 685066/ 220541; Matthew Munro, 2024
Four independent N-EU trials were conducted in accordance with the following GAP: 2 x 75 g a.s. /ha; application interval - 21±1 days, 2nd application at BBCH 49, with PHI of 21 days, outdoor.
Residues of fenpicoxamid (XDE-777), metabolite X642188 and X1231-4005 in sugar beets roots taken at 21 days ranged from < LOD (0.003 mg/kg) to <0.01 mg/kg.
The residues of fenpicoxamid (XDE-777) in sugar beet tops were 0.02; 0.10; 0.16; 0.38 mg/kg.

Available results show that the in force MRL of fenpicoxamid on sugar beet of 0.01* mg/kg (Reg. (EU)2023/1069) will not be exceeded. The current EU MRL for fenpicoxamid is sufficient to support the proposed use.
The trials are supported by valid storage stability data and validated analytical methods.

The proposed uses on sugar beet and fodder beet are considered acceptable.

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

Livestock can be exposed to fenpicoxamid residues through feed intake by consumption of sugar beet, therefore an evaluation of the residues in animal tissues is required. Dietary burden calculations were carried out using the EFSA Excel calculator (ver. 2017). Input values used for this evaluation are summarized in Table 7.2-10.

Table 7.2-10: Input values for the dietary burden calculation (considering the uses authorized in the country of the zRMS/authorized within the zone/evaluated in Art. 12 procedure and the uses under consideration)

Feed commodity	Median dietary burden		Maximum dietary burden	
	(mg/kg)	Comment	(mg/kg)	Comment
Residue definition: Proposed as Fenpicoxamid (XDE-777) (EFSA 2018)				
Wheat, Rye, Triticale grain	0.059	Median residue of NEU trials (EFSA, 2018)	-	-

Feed commodity	Median dietary burden		Maximum dietary burden	
	(mg/kg)	Comment	(mg/kg)	Comment
Wheat, Rye, Triticale straw	-	-	17.79	Highest residue SEU trials (EFSA, 2018)
Wheat gluten meal	0.11	Median residue of NEU trials and default PF 1.8 (EFSA, 2018)	-	-
Wheat milled by products	0.050	Median residue of NEU trials and median PF 0.84 (EFSA, 2018)	-	-
Distiller's grain dried	0.19*	Median residue of N EU trials and default PF 3.3 (EFSA, 2018)	-	-
Barley grain	0.10	Median residue of study 170191: combined date set NEU + SEU (Barley MRL evaluation (ongoing, EMS – ANSES))	-	-
Barley straw	0.48	Median residue of study 170191 SEU + NEU (Barley MRL evaluation (ongoing, EMS – ANSES))	3.67	Highest residue study 170191 SEU + NEU
Brewer's grain (dried)	0.33	0.10 mg/kg in barley grain * 3.3 as Default PF = 0.33 (Barley MRL evaluation (ongoing, EMS – ANSES))	-	-
Rape, canola meal	0.01	Median residue of study 211298 and 201410 (NEU + SEU) of 0.01 mg/kg in rapeseed * PF 1 = 0.01 (evaluation ongoing, EMS – CTGB))	-	-
Sugar Beets Tops	0.30	Median residue of S-EU trials (Study 220541)	0.51	
Sugar Beet, dried pulp	0.02	Median Residue of 0.01 and processing factor of 1.33 (Study 220541)	-	-
Sugar Beet, ensiled pulp	0.01	Median Residue of 0.01 (Study 220541)		
Sugar Beet, molasses	0.01	Median Residue of 0.01 (Study 220541)		

*According to EFSA 2018 document, the input value for Distiller grain dried was 0.06 mg/kg which is the STMR. The input considered of 0.19 mg/kg is based in the STMP by-P.

The intake calculations are based on the percent of each commodity in animal feed, the percent of dry matter of each commodity, the body weight of the animal and the daily maximum feed amount for the animal (dry matter). The intake calculations for total fenpicoxamid in livestock have been performed using the EFSA calculator (2017 model) and are presented in the following table:

Table 7.2-11: Results of the dietary burden calculation

Relevant groups	Dietary burden expressed in				Most critical diet (a)	Most critical commodity (b)		Trigger exceeded (Yes/No)
	mg/kg bw per day		mg/kg DM					0.004
	Median	Maximum	Median	Maximum				mg/kg bw
Cattle (all diets)	0.159	0.159	4.16	4.16	Dairy cattle	Rye	straw	Yes
Cattle (dairy only)	0.159	0.159	4.14	4.14	Dairy cattle	Rye	straw	Yes
Sheep (all diets)	0.349	0.349	8.20	8.23	Lamb	Rye	straw	Yes
Sheep (ewe only)	0.273	0.274	8.20	8.23	Ram/Ewe	Rye	straw	Yes
Swine (all diets)	0.006	0.014	0.25	0.63	Swine (breeding)	Beet, mangel	fodder	Yes
Poultry (all diets)	0.147	0.147	2.15	2.15	Poultry layer	Wheat	straw	Yes
Poultry (layer only)	0.147	0.147	2.15	2.15	Poultry layer	Wheat	straw	Yes

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

The main contributor for cattle, sheep and poultry is straw. The main contributor for swine is beet fooder.
Highest expected intakes are the same as listed in EFSA, 2018; the intended uses for fenpicoxamid (XDE-777) do not alter the dietary burden calculations by EFSA. Based on the highest predicted intakes calculated and the peer-reviewed cow feeding study no residues of X12326349, expressed as parent, are expected above the EFSA proposed MRLs for animal commodities.

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

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

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

Poultry:
Dietary burden for fenpicoxamid in poultry based on available residue data resulted in estimated values of 0.147 mg/kg bw/d (2.15 mg/kg DM) for all diets and layer only. No feeding study was submitted on poultry, however the metabolism study was performed at approximately 10 mg/kg DM for poultry and can be used to estimate the residue level in poultry commodities. This study indicates that residues of the parent compound and individual metabolites are expected to remain below the LOD (<0.003 mg/kg) when adjusted for the 5X-exaggerated dose level.
Therefore, as agreed during the Active Substance EU review (United Kingdom, 2017), it is proposed that a poultry feeding study is not needed.

After a JMPR review, MRLs are proposed at LOQ level of 0.01 mg/kg for all poultry commodities (Reg (EU) 2023/1069).

Ruminants:
Dietary burden for fenpicoxamid in ruminants based on available residue data resulted in estimated values of 0.159 mg/kg bw/d (4.16 mg/kg DM) for all diets and dairy only; 0.349 mg/kg bw/d (8.23 mg/kg DM) for sheep all diets and 0.274 mg/kg bw/d (8.23mg/kg DM) for sheep ewe only.

The trigger value (0.004 mg/kg bw/day) for ruminant is exceeded and a feeding study was performed at three different dose levels. Residues of X12326349, the only relevant residue for risk assessment and monitoring in animal commodities, were estimated based on this study and they were used in the consumer risk assessment and for deriving the MRL proposals. The estimated residue in animal matrices were calculated considering the molecular weight (MW) factor of 1.33 to express X12326349 as parent. Depuration of residues of fenpicoxamid (XDE-777), X642188 and X12326349 from milk, muscle, liver, kidney and fat led to residues <0.003 mg/kg by 3 days after withdrawal of the test item from the cow's diet, indicating rapid elimination of residues from the animals.

After a JMPR review, all ruminants MRLs are proposed according to Reg (EU) 2023/1069 as 0.015 mg/kg for muscle, milk and fat, and as 0.02 for liver, kidney and edible offals.

Pigs:

No feeding study is required in pigs. Since metabolism of fenpicoxamid in ruminants (goats) is similar to the metabolism observed in rodents (rats), the feeding study conducted with dairy cattle may be extrapolated to pigs / swine.

After a JMPR review, Swine MRLs are proposed according to Reg (EU) 2023/1069, as 0.015 mg/kg for muscle and fat, and as 0.02 for liver, kidney and edible offals.

Fish:

The fish dietary burden calculation is provided for common carp and rainbow trout in Appendix 4 (Fraunhofer Institute for Molecular Biology and Applied Ecology IME, calculator version 2.0.3) The fish intake remains below the trigger value of 0.1 mg/kg DM; hence a feeding study is not required.

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

Animal commodity	**Residues at the closet feeding level** (mg/kg)		**Estimated value at 1N level**		**MRL proposal** (mg/kg)	**CF**	**STMR** (mg/kg)	**HR** (mg/kg)
			STMRMo (mg/kg)	HRMo (mg/kg)				
	Mean	Highest						
Cattle (all diets)								
Closest feeding level[a]:	0.142	mg/kg bw	0.9	N Dairy cattle (highest diet)				
Muscle	0.01	0.01	0.01	0.01	0.01	n.c.[c]	0.01	0.01
Fat	0.01	0.01	0.01	0.01	0.01	n.c.	0.01	0.01
Liver	0.01	0.01	0.01	0.01	0.01	n.c.	0.01	0.01
Kidney	0.01	0.01	0.01	0.01	0.01	n.c.	0.01	0.01
Cattle (dairy only)								
Closest feeding level[a]:	0.142	mg/kg bw	0.9	N Dairy cattle				
Milk[b]	0.01	0.01	0.01	0.01	0.01	n.c.	0.01	0.01
Sheep (all diets)								
Closest feeding level[a]:	0.408	mg/kg bw	1.2	N Lamb (highest diet)				
Muscle	0.01	0.01	0.01	0.01	0.01	n.c.	0.01	0.01
Fat	0.01	0.01	0.01	0.01	0.015	n.c.	0.01	0.01
Liver	0.01	0.02	0.01	0.02	0.02	n.c.	0.01	0.02
Kidney	0.01	0.01	0.01	0.02	0.02	n.c.	0.01	0.02
Sheep (dairy only)								
Closest feeding level[a]:	0.408	mg/kg bw	1.5	N Ewe				
Milk[b]	0.01	0.01	0.01	0.01	0.01	n.c.	0.01	0.01

* The MRL for kidney in cattle should all be 0.01ppm since at the 1 x feeding level all residues were <0.01ppm.
(a): Closest feeding level and N dose rate related to the maximum dietary burden.
(b): Highest residue level from day D1 to day D2 (daily mean of X cows).
(c): not calculated
The estimated residue in animal matrices were calculated considering the molecular weight (MW) factor of 1.33 to express X12326349 as parent.

Conclusion on feeding studies
The feeding data available show that no exceedance of the proposed MRL for animal commodities will occur and the intended uses are considered acceptable.

MRLs in poultry commodities: according to the calculated dietary burden in poultry and to the metabolism study in laying hens, no residues in poultry and eggs are expected at the maximum dietary burden corresponding to residues related to the intended GAP. No MRLs are proposed on poultry products including eggs.

MRLs in ruminants commodities and swine are proposed as Reg (EU) 2023/1069, when CXLs for fenpicoxamid animal commodities are included in Regulation (EC) No 396/2005.

zRMS comments:
Information given by the Applicant is sufficient. The livestock feeding studies was sufficiently investigated during the approval of the active substance.
The residues in animal commodities will not exceed MRLs (Reg (EU) 2023/1069).
No further data are required.

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

Data in processed commodities are not required as residues in roots are all < 0.01 mg/kg. However, new data are submitted in the framework of this submission. All individual trials submitted are reported and evaluated in Appendix 2.

Residues, in roots prior to processing taken at 21 days before normal commercial harvest for the plot treated at a target rate of 375 g ai/ha fenpicoxamid and 750 g ai/ha prothioconazole (5x application rate) were found to be between <0.01 mg/kg (LOQ) and 0.02 mg/kg for fenpicoxamid (XDE-777).

7.2.5.1 Available data for Sugar Beet

Table 7.2-13: Overview of the available processing studies

Crop (RAC)/processed commodity	Number of studies	Processing Factor (PF) for fenpicoxamid		Comments	Reference
		Individual values	Median PF		
Enforcement residue definition – Fenpicoxamid (XDE-777)					
New Data					
Enforcement and Risk Assessment residue definition – Fenpicoxamid (XDE-777)					
Press water	3 trials	ND	-		Study/ Report no. 220541
Wet pulp	3 trials	ND	-		
Pressed pulp	3 trials	ND	-		
Dried pulp	3 trials	ND, 2.0, 2.0	1.33		
Ensiled pulp	3 trials	ND	-		
Raw juice	3 trials	ND	-		
Thick juice	3 trials	ND	-		

Crop (RAC)/processed commodity	Number of studies	Processing Factor (PF) for fenpicoxamid		Comments	Reference
		Individual values	Median PF		
Raw sugar	3 trials	ND	-		
Molasses	3 trials	ND	-		
Refined sugar	3 trials	ND	-		

7.2.5.2 Conclusion on processing studies

Processing studies are not triggered based on <LOQ residues in the RAC, The proposed uses for GF-3307 are covered and no further data are required for this application.

zRMS comments:
Information given by the Applicant is sufficient.
As no residues above 0.01 mg/kg are expected in sugar beet roots processing study is not required.
However, Applicant provided new processing study for fenpicoxamid (Matthew Munro. 2024, Report no. 685066/ 220541) conducted at an exaggerated treatment rate GAP (2 applications at 375 g a.i. (fenpicoxamid)/ha and 750 g a.i. (prothioconazole)/ha, with interval of applications of 21 and with PHI of 21 days to the crop) compared to the proposed use in Europe. Processed fractions (roots prior to processing, press water, wet pulp, pressed pulp, dried pulp, ensiled pulp, raw juice, thick juice, raw sugar, molasses and refined sugar) have been evaluated.

Residues of fenpicoxamid amd the hydrolysis degradates X12019520, X12314005, X12264475 and X12335723 were determined.
More details are presented in Appendix 2, Study 685066/ 220541.
Calculated processing factors show concentration of fenpicoxamid only in one processed fraction, in dried pulp.
No additional data is required.

7.2.6 Magnitude of residues in representative succeeding crops

Considering available data dealing with nature of residues (see 7.2.2.2), no study dealing with magnitude of residues in succeeding crops is needed. Residues of fenpicoxamid are anticipated to be <0.01 mg/kg in rotational crop commodities. No mitigation measures are required.

7.2.6.1 Field rotational crop studies (KCA 6.6.2)

Available data
Extensive soil degradation prior to plant uptake in the confined rotational crops resulted in multiple low-levels residues.

Conclusion on rotational crops studies
No study dealing with magnitude of residues in rotational crops is needed.

zRMS comments:
Information given by the Applicant is sufficient.
EFSA concluded that no residues above 0.01 mg/kg are expected in rotational crops and field rotational crop study is not required.

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

Effect on the residue level in pollen and bee product
In order to cover other potential exposures, data on residue levels in aerial parts of Oilseed Rape are available for fenpicoxamid. When calculating the HR in aerial parts of the plant, data pertinent to

flowering parts of the plant (especially nectar data) should be preferentially used. A semi-field residue study in nectar, pollen and plants of Oilseed Rape is submitted to provide data in aerial parts of the plant and derive the MRL proposal in honey. A detailed information of these residue trials is presented are reported and evaluated in Appendix 2.

The honey residue definition for monitoring (RD-Mo) and risk assessment (RD-RA) is proposed as fenpicoxamid.
The study was conducted as five separate field trials in Germany and Spain in 2020. Three trials were located in Germany and two trials in Spain.
The study consisted of one treatment group per trial: the test item group T (3 replicates). Control samples were taken as pre-application samples in the treatment tunnels. There was one application in the test item treatment group at a target rate of 100 g fenpicoxamid + 200 g prothioconazole/ha at BBCH 63 for trial -01, -03 and -05, at BBCH 61-62 for trial -02 and at BBCH 63-64 for trial -04.
Winter oilseed rape plants, forager bees for residue analysis and for determination of sugar content and pollen from winter oilseed rape were collected once before application and six times after application. Sampling of plants for residue analysis after application was conducted first at 0DAA and last sampling 5-8DAA. Sampling of pollen and forager bees for preparation of nectar for residue analysis after application was conducted first at 0DAA and last sampling 7-10DAA. For pollen analysis on each sampling day an A-sample of at least 0.2 g was collected. For plants samples on each sampling day an A- sample of at least 500 g was collected. For forager bees A- sample of at least 300 forager bees each with an additional 50 bees for the determination of sugar content were collected on each sampling day.

Overview of the available residue trials data

Crop (Trial GAP)	**Region/** **Outdoor**	**HR** (mg/kg)	**MRL** proposals (mg/kg)
Oilseed Rape tunnel study GAP: 1 x 100 g fenpicoxamid/ha + 200 g prothioconazole/ ha, application at BBCH 61-64	Germany and Spain (5 trials)	Whole plant: 2.33	0.5 (based on maximum nectar residue levels)
		Nectar: 0.283	
		Pollen: 17.3	

Overall there was a decline of residues of fenpicoxamid for plants, pollen and nectar from the peak concentration to the last sampling observed for all trials.

Although the representative use on Sugar Beet has no melliferous capacity (SANTE/11956/2016, Appendix II), a honey MRL application was submitted to cover the use on Oilseed Rape. For that, a MRL for honey, was conservatively proposed as 0.5 mg/kg (evaluation ongoing) and it is not expected to result in a consumer exposure exceeding the toxicological reference value. Therefore, is unlikely to pose a risk to consumers' health.

zRMS comments:
The proposed uses of GF-3307 in sugar beet and fodder beet are expected to have little potential for contributing residues to bee products. This is in line with the technical guidelines SANTE/11956/2016 rev. 9, 14 September 2018. Technical guidelines SANTE/11956/2016 rev. 9 indicates that sugar beet does not belong to melliferous crops and is not attractive to bees as sources of pollen and nectar.
Non-target plants can contribute to residues in honey, but in small quantities and it is certainly not expected to result in a consumer exposure exceeding toxicological reference values. Therefore, it is unlikely to pose a risk to consumers' health.
The Applicant submitted an additional semi-field residue study in nectar, pollen and plants of oilseed rape to provide data in aerial parts of the plant for honey MRL (evaluation ongoing). The study was not evaluated by the zRMS.

In our opinion, no further data is necessary to support the uses of GF-3307.

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

The consumer risk assessment has been performed with the EFSA Pesticide Residues Intake Model (PRIMo) rev. 3.1 (EFSA Supporting publication 2019:EN-1605). The exposure assessment model contains the relevant European food consumption data for different sub-groups of the EU population (EFSA Journal 2018;16(1):5147).

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

Dietary risk assessments have been performed according to the following EU agreed residue definitions (EFSA Journal 2018;16(1):5146):

- For commodities of plant origin: fenpicoxamid
- For commodities of animal origin: X12326349 expressed as fenpicoxamid

Regarding the provisional residue definition for risk assessment for processed commodities of "*parent, X12019520, X12314005, X12335723, X12264475*", sugar beet processing studies conducted at exaggerated application rates have been conducted (see 7.2.3 and 7.2.5). Measurable residues of the processing metabolites are not expected in the edible processed commodities of sugar beet when taking into account the intended application rate of fenpicoxamid in GF-3307. Therefore, dietary exposure is likely to be very low and is unlikely to impact on the dietary risk assessment. Thus, no further dietary risk assessment consideration is needed for the processing metabolites of fenpicoxamid for the intended use of GF-3307 on sugar beet.

7.2.8.1 Input values for the consumer risk assessment

Input values for the consumer risk assessment are presented in Table 7.2-14. A brief rationale for the selection of the input values is provided below.

Chronic Assessment:
An International Estimated Daily Intake (IEDI) calculation has been performed taking into consideration all uses of fenpicoxamid. Residue input values (STMRs) were derived from the current EU-MRLs (Reg (EU) 2023/1069), except for the commodities where increased EU-MRL modifications are currently under evaluation (selected oilseeds, barley, oat, and honey). For these commodities, residue input values (STMRs) were derived from the proposed EU-MRLs to reflect the future worst-case scenario. As shown in Table 7.2-9, the EU MRL for sugar beet roots covers the intended use of GF-3307, where residues in sugar beet roots were all <0.01 mg/kg.

Acute Assessment:
Acute exposure assessments were conducted only for the commodities under consideration for the intended uses of GF-3307 on sugar beet. An International Estimated Short-Term Intake (IESTI) calculation has been performed for this commodity. Residue input values were derived from the supervised residue trials supporting the intended uses of GF-3307 as reported in Table 7.2-9. For sugar beet roots (RAC), the HR value was selected, but it is noted that for sugar (processed commodity), the STMR value is automatically relied on in the risk assessment calculation because it is a bulked/blended processed commodity.

Table 7.2-14: Input values for the consumer risk assessment

Commodity (code)	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	**Comment**	**Input value (mg/kg)**	**Comment**
Risk assessment residue definition: Fenpicoxamid				
Sugar beet roots (0900010)	**0.01***	**$STMR_{RA}$-RAC (**Table 7.2-9**)**	**0.01***	**HR_{RA}-RAC (**Table 7.2-9**)**
Bananas (0163020)	0.01*	$STMR_{RA}$-peeled fruit (EFSA, 2018)	Acute risk assessment was undertaken only for the crops under consideration	
Rapeseeds/canola seeds (0401060) Linseeds (0401010) Poppy seeds (0401030) Mustard seeds (0401080) Gold of pleasure seeds (0401130)	0.01*	Proposed $STMR_{RA}$-RAC (MRL modification under evaluation)		
Barley (0500010) Oat (0500050)	0.10	Proposed $STMR_{RA}$-RAC (MRL modification under evaluation)		
Wheat (0500090) Rye (0500070)	0.047	$STMR_{RA}$-RAC (EFSA, 2018)		
All other commodities of plant origin	0.01-0.05*	LOQ EU-MRL (Reg (EU) 2023/1069)		
Honey and other apiculture products (1040000)	0.50	Proposed EU-MRL (MRL modification under evaluation)		
Risk assessment residue definition: X12326349 expressed as fenpicoxamid				
Muscle/meat of: Swine (1011010) Bovine (1012010) Sheep (1013010) Goat (1014010) Equine (1015010) Other farmed animals (1017010)	0.013*	$STMR_{RA}$-RAC (FAO, 2021)	Acute risk assessment was undertaken only for the crops under consideration	
Fat tissue of: Swine (1011020) Bovine (1012020) Sheep (1013020) Goat (1014020) Equine (1015020) Other farmed animals (1017020)	0.013	$STMR_{RA}$-RAC (FAO, 2021)		
Liver tissue of: Swine (1011030) Bovine (1012030) Sheep (1013030) Goat (1014030) Equine (1015030) Other farmed animals (1017030)	0.013	$STMR_{RA}$-RAC (FAO, 2021)		

Commodity (code)	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Kidney tissue of: Swine (1011040) Bovine (1012040) Sheep (1013040) Goat (1014040) Equine (1015040) Other farmed animals (1017040)	0.013	$STMR_{RA}$-RAC (FAO, 2021)		
Edible offal (other than liver and kidney) of: Swine (1011050) Bovine (1012050) Sheep (1013050) Goat (1014050) Equine (1015050) Other farmed animals (1017050)	0.013	$STMR_{RA}$-RAC (FAO, 2021)		
Other products of: Swine (1011050) Bovine (1012050) Sheep (1013050) Goat (1014050) Equine (1015050) Other farmed animals (1017050)	0.013	$STMR_{RA}$-RAC (FAO, 2021)		
Milk (1020000)	0.013*	$STMR_{RA}$-RAC (FAO, 2021)		
All other commodities of animal origin	0.01*	LOQ EU-MRL (Reg (EU) 2023/1069)		

* denotes value is at the limit of quantification (LOQ)

7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.
A summary of the consumer risk assessment result is presented below in Table 7.2-15.

Table 7.2-15: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo 3.1	Not performed
IEDI (% ADI) according to EFSA PRIMo 3.1	3% ADI (NL toddler)
IESTI (% ARfD) according to EFSA PRIMo 3.1*	Unprocessed commodities: Not applicable for sugar beet roots Processed commodities: Sugar beets (root) / sugar: 0.06% (children)

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

Conclusion:
A long-term consumer intake concern was not identified for any of the European diets incorporated in the EFSA PRIMo rev. 3.1 model. The highest calculated chronic intake accounted for 3% of the ADI (NL toddler). Considering all diets, the contribution of residues in the crops under consideration to the total consumer exposure accounted individually for a maximum of 0.17% of the ADI (NL child) for sugar beet roots.

An acute consumer risk was not identified for the crops under consideration. The highest acute consumer exposure was calculated to be 0.06% of the ARfD for sugar beet (root) / sugar.

Therefore, the proposed uses of fenpicoxamid in the formulation GF-3307 (S7K-3-3) do not represent unacceptable acute and chronic risks for the consumer.

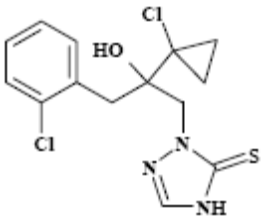
Evaluator comment:
The calculation of the IEDI is acceptable. The intended use and accepted uses will not result in a consumer chronic exposure exceeding the ADI.
An acute consumer risk assessment was performed based on the highest residue values (HR) of sugar beet. The data available are considered sufficient for risk assessment. The chronic and the short-term intakes of fenpicoxamid residues are unlikely to present a public health concern.

7.3 Prothioconazole

zRMS comments:
Corteva Agriscience Poland has the letter of access to the data, files, studies summaries and assessments on the active substance prothioconazole owned and submitted by Bayer for the registration of its product.

General data on prothioconazole are summarized in the table below

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	C14 H15 Cl2 N3 O S
Molar mass	344.26 g/mol
Chemical group	Triazole
Mode of action (if available)	interference with the synthesis of ergosterol
Systemic	Yes
Company (ies)	Bayer CropScience
Rapporteur Member State (RMS)	First approval: the United Kingdom Renewal (ongoing): Poland
Approval status	Approved SANCO/3923 /07 - final 10 December 2007 http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=activesubstance.detail&language=EN&selectedID=1783
Restriction	No
Review Report	SANCO/3923 /07 - final 10 December 2007 – Updated 26 January 2021
Current MRL regulation	Regulation (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 Scientific Report (2007) 106, 1-98, Conclusion on the peer review of prothioconazole
EFSA Journal: conclusion on article 12	Yes EFSA Journal 2014;12(5):3689 EFSA Journal 2020;18(2):5999 EFSA Journal 2023;21(8):8198
Current MRL applications on intended uses	No

The triazole derivative metabolites triazole acetic acid (TAA), triazole alanine (TA), 1,2,4-triazole (1,2,4-T) and triazole lactic acid (TLA), are common metabolites of the triazole-containing fungicides.

Prothioconazole belongs to triazole fungicide for which data gaps and confirmatory requirements were identified about TDMs. A group of manufactures of the triazole-containing fungicides, whom Bayer CropScience AG, formed an industry taskforce, known as the Triazole Derivative Metabolite Group (TDMG) which made a joint submission of new toxicological, metabolism and residues data to meet these data requirements. These data were assessed by the United Kingdom and EFSA published its conclusion in 2018 about the assessment of Triazole Derivative Metabolites (TDMs) (EFSA Journal, 2018;16(7):5376 "Peer review of the pesticide risk assessment for the triazole derivative metabolites in light of confirmatory data submitted").

7.3.1 Stability of Residues (KCA 6.1)

7.3.1.1 Stability of residues during storage of samples

Available data
New data is being submitted in the framework of this application.

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

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant Products			
Prothioconazole-desthio			
Wheat forage	High water content	18 months	Heinemann, 2001, M-072461-01-1, EU agreed (DAR 2006, EFSA 2007) dRAR 2018
Wheat grain	High starch content		
Wheat straw	High starch content		
Wheat forage	High water content	36 months*	Heinemann, 2003, M-081351-02-1, dRAR 2018*
Wheat grain	High starch content		
Wheat straw	High starch content		
Canola seed	High oil content	24 months	Freitag, 2005, M-258955-02-1, EU agreed (EFSA, 2009, 2010a, 2010b) dRAR 2018
Canola pod	No group, dry commodity		
Canola straw	No group, dry commodity		
Spinach (leaves)	High water content		
Sugar beet (body)	High water content		
Sugar beet (leaf with root collar)	High water content		
Tomato	High water content		
Field pea, dried	High protein content		

*A new FSS study on wheat matrices was submitted by Bayer and is being evaluated within the framework of the active substance renewal.

Table 7.3-3: Summary of stability data (Prothioconazole hydroxies in crop matrices) achieved at ≤ - 18°C (unless stated otherwise)

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant Products			
prothioconazole-a-hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxydesthio			
Tomato	High water content	24 months	EU agreed (EFSA, 2020)
Potato	High starch content		
Soya bean, rapeseed	High oil content		
Orange	High acid content		

Please refer to EFSA Journal 2020;18(2):5999

Table 7.3-4: Summary of stability data (Prothioconazole-desthio in honey) achieved at ≤ - 18°C (unless stated otherwise)

New data			
Prothioconazole, prothioconazole-desthio			
Honey			
Honey	Honey	6 months at -18 °C	Kalathoor, R.2020 M-680823-02-1, Report S19-01124 Appendix 2
JAU 6476-α-hydroxy-desthio, JAU 6476-3-hydroxy-desthio, JAU 6476-4-hydroxy-desthio, JAU 6476-5-hydroxy-desthio, JAU 6476-6-hydroxy-desthio			
Honey			
Honey	Honey	6 months at -18 °C	Kalathoor, R.2020 M-681477-01-1, Report S19-01125 Appendix 2
T, TA, TAA and TLA			
Honey			
Honey	Honey	5 months at -18 °C	Kalathoor, R.2020 M-680825-03-1, Report S19-01126 Appendix 2

Table 7.3-5: Summary of stability data (TDMs) achieved at ≤ - 18°C (unless stated otherwise)

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant Products			
1,2,4-Triazole* **			
Barley, wheat straw	No group, dry commodity	12 months	EU agreed (EFSA, 2018b)
Barley, wheat grain	High starch content	12 months	
Soya bean	High oil content	12 months**	
Various*	High water content	6 months	
Triazole Alanine* **			
Barley, wheat straw	No group, dry commodity	53 months	EU agreed (EFSA, 2018b)
Peas, dry; Navy bean	High protein content	15 months	
Barley, wheat grain	High starch content	26 months	
Soya bean	High oil content	26 months**	
Various*	High water content	53 months	
Triazole Acetic Acid* **			
Barley, wheat straw	No group, dry commodity	40 months	EU agreed (EFSA, 2018b)
Peas, dry; Navy bean	High protein content	25 months	
Barley, wheat grain	High starch content	26 months	
Soya bean, Rapeseed	High oil content	53 months	
Various*	High water content	53 months	
Triazole Lactic Acid			
Peas, dry; Navy bean	High protein content	48 months	EU agreed (EFSA, 2018b)
Barley, wheat grain	High starch content	48 months	
Orange fruit	High acid content	48 months	
Soya bean, Rapeseed	High oil content	48 months	
Lettuce	High water content	48 months	

*Please refer to EFSA Journal (2018a); 16 (7): 5376. ** soya bean only, not stable in rape seed.

***Note to ensure harmonization of assessments for triazole active substances and products, the EU Commission has agreed that additional frozen storage stability studies conducted by the TDMG (Triazole Derivative Metabolite Group) will be submitted and evaluated by Austria in its capacity as RMS for paclobutrazole.

Conclusion on stability of residues during storage

The results from the frozen storage stability studies support the stability of the relevant residues in crops under frozen conditions for the period of time for which samples from the residue trials presented in this report were stored prior to analysis. Residues of prothioconazole-desthio are stable for at least 36 months under deep-freeze storage in cereals material and at least 24 months in other plant material. Residues of prothioconazole hydroxies are stable for at least 24 months under deep-freeze storage in plant material. Residues of prothioconazole, prothioconazole-desthio and its hydroxies are stable for at least 6 months under deep-freeze storage in honey.

The Triazole Derived Metabolites (TDMs) have various storage stability durations, based on the matrix and the metabolite. Residues of 1,2,4-triazole, triazole alanine, triazole acetic acid and triazole lactic acid are stable for at least 5 months under deep-freeze storage in honey.

zRMS comments:

Information given by the Applicant is acceptable and sufficient.
This application concerns the extension of the use of GC-3307 on sugar and fodder beet.
Sugar beet and fodder beet roots belong to high starch content commodity categories (OECD 506).

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

Additionally, the results of the study of Freitag (2005) demonstrate the stability of residues of prothioconazole-α-hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, and prothioconazole-6-hydroxy-desthio upon deep frozen storage at – 18 °C for up to 24 months in all tested matrices of plant origin.

EFSA concluded in EFSA Journal 2020;18(2):5999 that *Freezer storage stability of prothioconazole-a-hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxydesthio was investigated in high water content (tomatoes), high starch content (potatoes), high oil content (soya beans, oilseed rape) and high acid content (oranges) commodities for a period of 24 months. Samples were fortified with a mixture containing all five analytes at a level of 0.1 mg/kg each.*
Since all these compounds are included in the residue definition for risk assessment, spiking with a mixture was considered acceptable. Results demonstrate stability of all compounds in all matrices for a maximum of 24 months (duration of study) when stored at ≤ 18°C.
It is noted that according to EU guidelines (European Commission, 1997f), applicable for the current assessment, cereals are considered as dry matrix, for which the storage stability of hydroxylated metabolites of prothioconazole-desthio has not been investigated. However, it is noted that the applicant has generated data according to the OECD guidelines (OECD, 2007) in the framework of the renewal of the approval of prothioconazole. According to OECD guideline, cereals are considered as high starch matrix. EFSA accepted the storage stability data on potatoes (high starch matrix) to address the storage stability in cereals.

Studies on the storage stability of prothioconazole and its metabolite in crop and animal tissues under frozen conditions were assessed in the framework at the EU level.

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

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

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

New studies on the storage stability of prothioconazole-desthio, its hydroxies and the triazole derivative metabolites in honey (Kalathoor, R, 2020) were submitted by the Applicant. However, these studies were not evaluated by the zRMS in the framework of this application, since the study "*Determination of residues of prothioconazole and its metabolites in honey after two applications of PTZ EC 250 in winter oilseed rape at 5 sites in Northern and Southern Europe in 2019"* (Appeltauer, A., 2020) is not necessary to support the proposed uses of GF-3307 in sugar beet.

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

7.3.1.2 Stability of residues in sample extracts (KCA 6.1)

Available data
Stability of analyte residues in sample extracts is verified by the acceptable fortification recovery data summarised in each study. These fortifications were run with the specimens in each analysis set and were stored and treated in every way as the treated and control specimens in that set. No significant degradation was observed in the timeframes sample extracts were stored.

Conclusion on stability of residues in sample extracts
The residues of prothioconazole and its metabolites are stable in extracts.

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

7.3.2 Nature of residues in plants, livestock and processed commodities

7.3.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

Table 7.3-6: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (g a.s./ha)	No	PHI	Remarks	
EU data								
Cereals	Wheat	[U-^{14}C-phenyl]	G (spring wheat)	220	2	Forage: 6days Hay: 26 days Grain & Straw:48 days		EFSA, 2007 (Haas and Bornatsch, 2000, MR-198/99)
		[3,5-^{14}C-triazole]	G (summer wheat)	250	2	Forage: 0, 14 days Grain& Straw:48 days		EFSA, 2007 (Vogeler, 1993, PF3906)
		[3,5-^{14}C-triazole]	F (spring wheat)	180 & 290	2	Forage, hay, grain, straw		EFSA RO, 2014 (Duah, 2004, 200733)
		[U-^{14}C-phenyl]	G (spring wheat, seed treatment)	20 g a.s./100 kg seed (N) or 100 g a.s./100 kg seed (5N)	2	Forage:57days Hay: 110 days Grain &Straw: 153 days		EFSA, 2007 (Haas, 2001, MR-467/99)
Root and Tuber vegetables	Sugar beet	[U-^{14}C-phenyl]	F	290	4	Roots &Tops/leaves, 7 days		EFSA, 2007 (Beedle, 2004, 200466)
		[3,5-^{14}C-triazole]	F	290	4	Roots &Tops/leaves, 7 days		EFSA RO, 2014 (Beedle, 2004, 200467)
Pulses and Oilseeds	Peanut	[U-^{14}C-phenyl]	G	300	3	Hay & nuts without shells, 14 days		EFSA, 2007 (Haas, 2001, MR-193/01)
		[3,5-^{14}C-triazole]	G	300	3	Hay & nuts without shells, 14 days		EFSA RO, 2014 (Haas, 2003, MR-194/02)

Summary of plant metabolism studies reported in the EU
Metabolism of prothioconazole in primary crops was investigated for foliar application in root and tuber vegetables, pulses and oilseeds and cereals using phenyl and triazole labellings, and for seed treatment in cereals only.

Prothioconazole is extensively metabolised and the metabolic pathway is similar in all crops investigated. The main metabolic pathway consisted in the formation of prothioconazole-desthio: the sulphur group of the triazolinethione ring of parent prothioconazole is firstly oxidized to the corresponding sulfonic acid with subsequent elimination of the sulfonic acid moiety. This metabolite subsequently undergoes different pathways either by hydroxylation on the chlorophenyl ring, forming various hydroxyl-desthio isomers (M14, M15, M17), dihydroxy-olefins (M27) and hydroxyl-dienyl-cysteine (M24) isomers followed by a glucosidation step or by cleavage of the triazole moiety of prothioconazole-desthio resulting in the formation of "triazole derivative metabolites" (TDMs), mainly triazole alanine, triazole lactic acid and triazole acetic acid. These compounds are common metabolites to all triazole fungicides. Finally, a dimerization of the parent molecule was observed resulting from the combined oxidation of the sulphur atom followed by hydroxylation of the chlorophenyl ring.

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. Besides prothioconazole-desthio, other metabolites, which are structurally closely related to this compound, and three TDMs were identified in crops treated with prothioconazole. Triazole alanine (TA) represented the main TDM in the crops investigated, followed by triazole acetic acid (TAA) and triazole lactic acid (TLA). The fourth TDM, 1,2,4-triazole (1,2,4-T), was not detected. (EFSA RO, 2023)

Summary of new plant metabolism studies
Not applicable.

Conclusion on metabolism in primary crops
Metabolism of prothioconazole in primary crops was evaluated previously in EU (United Kingdom 2005, EFSA 2007, EFSA 2014) and a global residue definition for enforcement was proposed as prothioconazole-desthio (sum of isomers) only whilst for risk assessment, the residue was defined as the sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers).

(EFSA, 2023) Based on the metabolic pattern identified in metabolism studies…the residue definitions for prothioconazole in plant products were derived by the EU pesticide peer review on prothioconazole. Additional risk assessment residue definitions related to the presence of TDMs were derived by the peer review of the risk assessment of the TDMs in the light of confirmatory data. For enforcement the residue definition is defined as 'prothioconazole-desthio (sum of isomers)' and, as follows, for the risk assessment:
1) Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3- (2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazoledesthio (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.

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

In the framework of the peer review under Directive 91/414/EEC and the Art.12 MRL review (EFSA, 2007, 2014), the metabolism of prothioconazole was investigated by foliar applications on root (sugar beet), pulses/oilseeds (peanut) and cereal/grass (wheat) crop groups and by seed treatment on cereal (wheat) (EFSA, 2007). In addition, the metabolism of prothioconazole-desthio labelled in the triazole moiety was investigated after foliar applications on cereals (EFSA, 2007).

Prothioconazole is extensively metabolised and the metabolic pathway was similar in all crops investigated. Prothioconazole-desthio was the predominant compound of the total residues with further hydroxylation (with the formation of several closely related metabolites) and glucosidation steps, whilst cleavage of the triazole bound of prothioconazole-desthio molecule resulted in the formation of TDMs.
In EFSA Journal 2018;16(7):5376 it is stated that *Primary crops metabolism data are reported for a total of 16 approved triazole compounds, and 2 triazole active substances that are not approved at EU level (bitertanol, flusilazole), on fruit crops, cereals (straw and grain), pulses and oilseeds and root crops.(…) Based on the metabolism data in primary and rotational crops that were compiled from the assessment of the 18 triazole active substances the triazole active substances were shown to degrade into the common metabolites 1,2,4-T, TA, TLA and TAA, known as TDMs.*

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

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

No further data are required.

7.3.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

Table 7.3-7: 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 Timing	Remarks	
EU data								
Leafy vegetables	Swiss chard	[U-^{14}C-phenyl]	F	580	28, 146, and 269	80, 188 and 348 days after treatment		EFSA, 2007 (Haas, 2001, MR-159/00)
Root and tuber vegetables	Turnip	[U-^{14}C-phenyl]	F	580	28, 146, and 269	Turnip top and root, 94, 201 and 349 days after treatment		EFSA, 2007 (Haas, 2001, MR-159/00)

Cereals	Wheat	[U-^{14}C-phenyl]	F	580	28, 146, and 269	Green material, 73, 178, and 327 days after treatment Hay, 111, 231, and 377 days after treatment Straw and grain, 145, 269, and 412 days after treatment		EFSA, 2007 (Haas, 2001, MR-159/00)

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

Summary of plant metabolism studies reported in the EU
The metabolism of prothioconazole in rotational crops – Swiss chard, turnips, spring wheat – has been evaluated (EFSA, 2007). In wheat grain, the total radioactive residues were recovered at a trace level at all DATs (<0.007 mg eq/kg). The major compounds of the total residues were identified as prothioconazole-desthio, its hydrolxylated derivative metabolites (either free or conjugated forms) and free or conjugated prothioconazole-sulfonic acid.
The metabolism of prothioconazole labelled in triazole ring was assessed by the JMPR (FAO, 2009a, b) and reported in the MRL review (EFSA, 2014). Swiss chards, turnips and spring wheat were grown in soil treated with prothioconazole at a rate of 4 9 204 g/ha. The studies indicate the cleavage of triazole linkage to form major metabolites TA, TLA and TAA, whereas parent prothioconazole and prothioconazole-desthio were identified as minor metabolites (EFSA, 2014). No free 1,2,4-triazole was detected in any matrix (FAO, 2009a,b).

Summary of new plant metabolism studies
Not applicable

Conclusion on metabolism in rotational crops
In summary, 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 (EFSA, 2014).

In the rotational crop metabolism, the major residues identified were prothioconazole-desthio and its hydroxylated derivative metabolites, either free or conjugated. In studies with triazole labelled prothioconazole, the main residues in rotational crops were TDMs, namely TA, TAA and TLA whereby
1,2,4-T was not detected. (EFSA, 2023)

During the peer review of the pesticide risk assessment for the TDMs in light of confirmatory data, it was also concluded that the metabolic behaviour of TDMs is similar both in primary and rotational crops (EFSA, 2018b).

zRMS comments:
No new plant metabolism studies in rotational crops are provided. Information given by the Applicant is acceptable and sufficient.

In EFSA Journal 2020;18(2):5999 it is stated that *The metabolism of prothioconazole in rotational crops was investigated in the framework of the EU pesticides peer review in Swiss chards, turnips and spring wheat following the treatment of bare soil with prothioconazole at an application rate of 580 g/ha using the compound*

labelled in the phenyl ring. The main compounds identified were prothioconazole-desthio and its hydroxylated derivative metabolites, either free or conjugated.
The MRL review concluded that metabolism of prothioconazole in primary and rotational crops was found to be similar and a specific residue definition for rotational crops is not necessary (EFSA, 2014).
The metabolism of prothioconazole labelled in triazole ring was assessed by the JMPR (FAO, 2009a) as reported in the MRL review. The studies indicate the cleavage of triazole linkage to form major metabolites TA, TLA and TAA (EFSA, 2014). During the peer review of TDMs in light of confirmatory data, the metabolism of various triazole compounds in rotational and primary crops was investigated.
It was concluded that for TDMs similar metabolic patterns were depicted both in primary and rotational crops (EFSA, 2018b).

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

No further data are required.

7.3.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data
EFSA RO, 2014

Table 7.3-8: Nature of the residues in processed commodities

Conditions (Duration, Temperature, pH)	Identified compound(s) (%)	Reference
EU data, prothioconazole		
Pasteurisation (20 minutes, 90°C, pH 4)	stable	EFSA RO, 2014 (Gilges, 2001, MR-166/00)
Baking, boiling, brewing (60 minutes, 100°C, pH 5)	stable	EFSA RO, 2014 (Gilges, 2001, MR-166/00)
Sterilisation (20 minutes, 120°C, pH 6)	Slightly degrades (≤11%) to proconazole-desthio	EFSA RO, 2014 (Gilges, 2001, MR-166/00)
EU data, prothioconazole-desthio		
Pasteurisation (20 minutes, 90°C, pH 4)	stable	EFSA RO, 2014 (Gilges, 2001, MR-106/00)
Baking, boiling, brewing (60 minutes, 100°C, pH 5)	stable	EFSA RO, 2014 (Gilges, 2001, MR-106/00)
Sterilisation (20 minutes, 120°C, pH 6)	stable	EFSA RO, 2014 (Gilges, 2001, MR-106/00)

[1] Epoxiconazole, penconazole, tebuconazole, fenbuconazole, flutriafol, paclobutrazole, metconazole, fluquiconazole, difenoconazole, tetraconazole, propiconazole, ipconazole.

Conclusion on nature of residues in processed commodities
Data/information on industrial processing (Annex II data) was peer-reviewed during the EU review of prothioconazole and prothioconazole-desthio was considered to be acceptable (see EFSA RO, 2014). The studies demonstrated that prothioconazole is stable under processing by pasteurization and baking/brewing/boiling, however under sterilization, prothioconazole slightly degrades to prothioconazole-desthio. Prothioconazole-desthio remains stable under all three hydrolytic conditions.

Studies investigating the effect of processing on the nature (hydrolysis studies) of prothioconazoledesthio
and of the TDMs demonstrated that these compounds are stable. (EFSA, 2023)

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

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

No further data are required.

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

Table 7.3-9: Summary of the nature of residues in commodities of plant origin

Endpoints	
Plant groups covered	Cereals (Wheat) Root and tuber vegetables (Sugar beet) Pulse and oilseeds (Penut)
Rotational crops covered	Cereals (Wheat) Root (Turnip) Leafy vegetable (Swiss Chard)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Prothioconazole is mostly stable under processing conditions. Prothioconazole-desthio is stable under processing conditions. TDMs are stable under standard hydrolysis conditions.
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes
Plant residue definition for monitoring	Prothioconazole-desthio (sum of isomers) (EFSA RO, 2014, 2020 ~~and Reg. (EU) 2019/552 and~~ Reg (EU) 2024/1318)
Plant residue definition for 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 prothioconazoledesthio (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). (EFSA, 2023)

Conversion factor from enforcement to RA	2 (cereal grain, pulse and oilseeds, leafy vegetables and root and tuber vegetables); 3 (cereal straw); (EFSA, 2007) 3 (cereal straw only) CF=1 for root & tuber and pulses & oilseed commodities (RAR, 2020)

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

Available data

Table 7.3-10: 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 **Lactating ruminants**	Goat	[U-^{14}C-phenyl] prothioconazole	1	10	3	Milk	twice daily	EFSA RO, 2014 ([redacted], 2011, MEF-11/011)
						Muscle (round, flank and loin)	at sacrifice	
						Kidney	at sacrifice	
						Liver	at sacrifice	
						Fat (subcutaneous, omental and perirenal)	at sacrifice	
						Urine and faeces	Daily and at sacrifice	
		[U-^{14}C-phenyl] prothioconazole-desthio	1	10	3	Milk	twice daily	EFSA RO, 2014 ([redacted] r, 2006, MEF-06/469)
						Muscle (round, flank and loin)	at sacrifice	
						Kidney	at sacrifice	
						Liver	at sacrifice	
						Fat (subcutaneous, omental and perirenal)	at sacrifice	
						Urine and faeces	Daily and at sacrifice	
		[3,5-^{14}C-triazole]prothioconazole	1	10	3	Milk	twice daily	EFSA RO, 2014 ([redacted], 2003, MR-448/02)
						Muscle (round, flank and loin)	at sacrifice	
						Kidney	at sacrifice	

						Liver	at sacrifice	
						Fat (subcutaneous, omental and perirenal)	at sacrifice	
						Urine and faeces	Daily and at sacrifice	
Laying poultry	Hens	[3,5-^{14}C-triazole]prothioconazole	6	10	3	Eggs from ovary/oviduct	Once daily	EFSA RO, 2014 ([redacted], 2003, MEF-005/03)
						Muscle (leg and breast)	at sacrifice	
						Liver	at sacrifice	
						Fat (subcutaneous) Skin w/o subcutaneous fat	at sacrifice	
						Excreta	At regular intervals	
		[U-^{14}C-phenyl] prothioconazole	6	10	3	Eggs from ovary/oviduct	Once daily	EFSA RO, 2014 ([redacted], 2001, MR-309/01)
						Muscle (leg and breast)	at sacrifice	
						Liver	at sacrifice	
						Fat (subcutaneous) Skin w/o subcutaneous fat	at sacrifice	
						Excreta	At regular intervals	

Summary of animal metabolism studies reported in the EU

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

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

Summary of new animal metabolism studies
Not applicable

Conclusion on metabolism in livestock
The metabolism in livestock have been evaluated and concluded in the EFSA RO, 2014 that the metabolism of prothioconazole has been fully investigated in livestock and the residue definition for enforcement in animal products was set as prothioconazole-desthio (sum of isomers) for all the livestock matrices.

The assessment does not yet take into consideration triazole derivative metabolites (TDMs). Since these metabolites may be generated by several pesticides belonging to the group of triazole fungicides, EFSA recommends that a separate risk assessment should be performed for TDMs as soon as the confirmatory data requested for triazole compounds in the framework of Regulation (EC) No 1107/2009 have been evaluated and a general methodology on the risk assessment of triazole compounds and their triazole derivative metabolites is available.

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

According to the EFSA Journal 2018;16(7):5376: *Ruminant and poultry metabolism studies labelled on the triazole ring are available.*
(…) Based on the metabolism studies conducted, respectively, with triazole pesticide active substances and TA and considering the results of the livestock feeding studies carried out with TA and TAA, respectively, the experts agreed on the following residue definitions:
- *Residue definition for enforcement: triazole parent compound only*
- *Residue definition for risk assessment:*
  1. *Triazole parent compound and any other relevant metabolite exclusively linked to the parent compound;*
  2. *TA and TLA, since these compounds share the same toxicity;*
  3. *TAA;*
  4. *1,2,4-triazole.*

No further data are required.

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

Table 7.3-11: 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	Not observed
	Not observed
Animal residue definition for monitoring	Prothioconazole-desthio (sum of isomers) (EFSA RO, 2014 ~~and Reg. (EU) 2019/552~~ and Reg (EU) 2024/1318)
Animal residue definition for risk assessment	RD-RA 1)Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers) (EFSA RO, 2014)

	RD-RA2) TDMs (EFSA, 2018), with separate assessment of: - Triazole alanine (TA) and triazole lactic acid (TLA) - Triazole acetic acid (TAA) - 1,2,4-triazole (1,2,4-T)
Conversion factor	- Ruminant liver: 2 - Ruminant kidney: 9 - not necessary for milk, ruminant muscle and ruminant fat (EFSA RO, 2014) - Liver: 2 - Kidney: 4 Conversion factors not calculated for poultry and milk, muscle and fat where <LOQ residues expected. (RAR, 2020)
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	Yes, Log Pow for desthio-prothioconazole = 3.04

7.3.3 Magnitude of residues in plants (KCA 6.3)

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

The GAP proposed for GF-3307 (S7K-3-3) results in a total maximum application rate of 2 x 150 g ai/ha (21 days interval) with final application at BBCH 49 and minimum 21 days PHI for Prothioconazole in sugar beet. This GAP is less critical than the one in which the EU MRL is based (2 x 150 g ai/ha, 21 days interval, final app at BBCH 49 and minimum 7 days PHI).

New magnitude of residue studies conducted with GF-3307 (S7K-3-3) in support of the proposed GAP (see GAP table 7.1-1), are submitted in the frame of this submission. The study results are summarized in the Table below and the detailed assessment is presented in Appendix 2.

Table 7.3-12: Summary of EU reported and new prothioconazole-desthio residue data supporting the intended uses of GF-3307 (S7K-3-3) and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU)	Evaluation GAP Prothioconazole-desthio Residue levels (mg/kg)	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Sugar Beet Roots	EFSA, 2023	N-EU	*Trials GAP: 2 x 150 g a.s./ha, PHI 7 d (BBCH 49), outdoor* Mo: 8 < 0.010; 0.019 RA: 8 x < 0.060; 0.069	Mo: 0.01 RA: 0.060	Mo: 0.019 RA: 0.069	0.03	0.03	Yes.
	New Trials on GF-3307	N-EU	*Trials GAP: 2 x 150 g a.s./ha, PHI 21 d (BBCH 49), outdoor* Mo: ~~2 x~~ < 0.01; 2 x 0.01; 0.02 RA: 1 x < 0.06; 0.06; 0.06; 0.07	Mo: 0.01 RA:0.06	Mo: 0.02 RA: 0.07	0.03		Yes
		~~S-EU~~	~~*Trials GAP: 2 x 150 g a.s./ha, PHI 21 d (BBCH 49), outdoor* Mo: 4 x < 0.01 RA: 4 x < 0.06~~	~~Mo: 0.01 RA:0.06~~	~~Mo: 0.01 RA: 0.06~~	~~0.01~~		~~Yes~~
Sugar Beet Tops	EFSA, 2023	N-EU	*Trials GAP: 2 x 150 g a.s./ha, PHI 7 d (BBCH 49), outdoor* Mo: 0.19; 0.86; 0.52; 1.1; 0.63; 1.3;0.42; 0.61; 0.51 RA: 0.32; 1.0; 0.82; 1.3; 0.92; 1.5; 0.53;0.78; 0.70	Mo: 0.061 RA : 0.82	Mo: 1.30 RA: 1.50	N/A	N/A	N/A
	New Trials on GF-3307	N-EU	*Trials GAP: 2 x 150 g a.s./ha, PHI 21 d (BBCH 49), outdoor* Mo: 0.13; 0.22; 0.14; 0.14 RA: 0.28; 0.53; 0.21; 0.24	Mo: 0.14 RA:0.26	Mo:0.22 RA: 0.53			
		~~S-EU~~	~~*Trials GAP: 2 x 150 g a.s./ha, PHI 21 d (BBCH 49), outdoor* Mo:0.23; 0.18; 0.26; 0.03 RA: 0.38; 0.96; 0.37; 0.31~~	~~Mo: 0.21 RA:0.38~~	~~Mo:0.23 RA: 0.96~~			
Overall roots supporting data N-EU ~~+ S-EU~~ **		**Mo: ~~14~~ 9 x < LOQ; 2 x 0.01; 0.019; 0;02 RA: ~~13~~ 9 x < 0.06; 2x 0.06; ~~0.06~~; 0.069; 0.07**	**Mo : 0.01 RA :0.06**	**Mo : 0.02 RA :0.07**	**0.03**	**0.03**		**Yes**

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

** Mann-Whitney U-Test shows that populations from different zones are similar so the MRL compliance is based in the combined dataset.

Mo = prothioconazole-desthio (sum of isomers)

RA = sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers). For RA STMR and HR, individual residues reported as ND or < LOQ were considered as 0.01 mg/kg in the sum of sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers).

Triazole Derived Metabolites

The results for Sugar Beet of EU previously evaluated trials are presented in the table below (EFSA, 2023)

Table 7.3-13: Summary of residues data from the supervised residue trials – TDMs
Sugar Beet

Commodity	Source	Residue zone (N-EU, S-EU)	Residue definition for risk assessment: a) Triazole alanine (TA) b) Triazole lactic acid (TLA) c) Triazole acetic acid (TAA) d) 1,2,4-triazole (1,2,4-T)	STMR (mg/kg)	HR (mg/kg)
Sugar Beet Roots	EFSA, 2023	N-EU	TA: 5 x < 0.01; 0.010; 0.013; 0.017; 0.024; TLA: 9 x <0.01 TAA: 9 x <0.01 1,2,4-T: 9 x <0.01	RA_{TA}: 0.01 RA_{TLA}: 0.01* RA_{TAA}: 0.01* $RA_{1,2,4\text{-}T}$: 0.01*	RA_{TA}: 0.024 RA_{TLA} :0.01* RA_{TAA}: 0.01* $RA_{1,2,4\text{-}T}$: 0.01*
Sugar Beet Tops	EFSA, 2023	N-EU	TA: 0.036; 0.038; 0.019; 0.020;0.015; < 0.01; 0.029; 0.017; < 0.01 TLA: 0.093; 0.035; 0.035; 0.016;0.054; < 0.01; < 0.01; 0.016; 0.022 TAA: 8 x < 0.010; 0.076 1,2,4-T: 9 x <0.01	RA_{TA}: 0.019 RA_{TLA}: 0.022 RA_{TAA}: 0.01 $RA_{1,2,4\text{-}T}$: <0.01	RA_{TA}: 0.038 RA_{TLA} :0.093 RA_{TAA}: 0.076 $RA_{1,2,4\text{-}T}$: < 0.01

7.3.3.2 Conclusion on the magnitude of residues in plants

According to the available data, the intended use on Sugar Beet is considered acceptable, for outdoor uses.
The data set presented is considered acceptable since residues in RAC (roots) are < LOQ in all 4 SEU trials. For NEU where data are not < LOQ in roots, 13 trials have been presented.

Regarding TDMs, the results presented in EFSA 2023 were considered for livestock and consumer exposure.
The data submitted show that no exceedance of the MRL will occur.

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

Sugar beet and fodder beet (crop used for animal feed)
Sugar beet and fodder beet are the major crops in northern Europe (SANTE/2019/12752, Rev02). A minimum of eight trials are required.

One new magnitude of residue study has been submitted in the framework of this application (Matthew Munro; 2024, Report no. 685066/ 220541), conducted with the same total rate as the proposed cGAP for GF-3307.

Summary
Report no. 685066/ 220541; Matthew Munro, 2024
Four independent N-EU trials were conducted in accordance with the following GAP: 2 x 150 g a.s./ha; application interval – 21±1 days, 2nd application at BBCH 49, with PHI of 21 days, outdoor.
Prothioconazole-desthio residues in sugar beet roots ranged from <0.003 mg/kg (non-detectable) to 0.02 mg/kg.
Prothioconazole-desthio residues in sugar beet tops ranged from 0.13 mg/kg to 0.22 mg/kg.

The data set presented is considered acceptable. For NEU 13 trials have been presented.

Available results show that the in force MRL of prothioconazole on sugar beet roots of 0.03 mg/kg (Reg EU 2024/1318) will not be exceeded. The current EU MRL for prothioconazole is sufficient to support the proposed use.
The trials are supported by valid storage stability data and validated analytical methods.

The proposed uses on sugar beet and fodder beet are considered acceptable.

7.3.4 Magnitude of residues in livestock

7.3.4.1 Dietary burden calculation

Prothioconazole is authorised for use on crops that might be fed to livestock. Dietary burden calculation according to OECD, 2013 (EFSA Journal 2023;18(2):5999).

Table 7.3-14: Input values for the dietary burden calculation

	Median dietary burden	Maximum dietary burden

Feed commodity	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition in plant commodities: sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2*H*-1,2,4-triazole moiety,expressed as prothioconazole-desthio (sum of isomers)				
Barley straw	1.96	STMR (FAO, 2009b) x CF (3) (EFSA, 2014)	7.50	HR[(d)] x CF (3) (EFSA, 2014)
Beet sugar, tops	0.82	STMR proposed	1.5	HR proposed
Cabbage heads, leaves	0.02	STMR x CF (EFSA, 2014)	0.12	HR x CF (EFSA, 2014)
Corn, field forage/ silage	0.01	STMR (EFSA, 2014)	0.01	HR (EFSA, 2014)
Oats straw	1.26	STMR[(d)] x CF (3) (EFSA, 2014)	7.50	HR[(d)] x CF (3) (EFSA, 2014)
Rye straw	2.25	STMR[(d)] x CF (3) (EFSA, 2014)	5.52	HR[(d)] (EFSA, 2014) x CF (2.3 3)
Wheat straw	2.69	STMR	5.52	HR[(d)] (EFSA, 2014) x CF 2.3 3)
Turnips, swedes,carrot culls	0.08	STMR	0.10	HR
Potatoes	0.01	STMR (EFSA, 2014)	0.01	HR (EFSA, 2014)
Barley grain	0.07	STMR (FAO, 2009b) x CF (2)(EFSA, 2014)	0.07	STMR (FAO, 2009b) x CF (2) (EFSA, 2014)
Beans (dry)	0.02	STMR x CF (2) (EFSA, 2014)	0.02	STMR x CF (2) (EFSA, 2014)
Corn, field (Maize) grain Corn, pop grain	0.02	STMR (FAO, 2014) x CF (2) (EFSA, 2014)	0.02	STMR (FAO, 2014) x CF (2) (EFSA,2014)
Cotton seed	0.10	STMR (FAO, 2018) x CF (2)	0.10	STMR (FAO, 2018) x CF (2)
Peas, lupins (dry)	0.10	STMR (FAO, 2009b) x CF (2)	0.10	STMR (FAO, 2009b) x CF (2)
Oat grain	0.02	STMR (FAO, 2009a) x CF (2) (EFSA, 2014)	0.02	STMR (FAO, 2009a) x CF (2) (EFSA, 2014)
Rye grain	0.02	STMR (FAO, 2009a) x CF (2)	0.02	STMR (FAO, 2009a) x CF (2)
Soybean seed	0.10	STMR (FAO, 2014) x CF (2)	0.10	STMR (FAO, 2014) x CF (2)
Wheat grain	0.04	STMR wheat grain (FAO, 2009b) x CF (2) x PF (1.8)[(a)]	0.04	STMR wheat grain (FAO, 2010) xCF (2) x PF (1.8)[(a)]
Beet sugar, ensiled pulp	1.08	STMR x PF(18) proposed	1.08	STMR x PF(18) proposed
Beet sugar, molasses	0.18	STMR x PF(3) proposed	0.18	STMR x PF(3) proposed
Brewer`s grain	0.23	STMR barley grain (FAO,2009b) x CF (2) (EFSA, 2014) x PF (3.3)[(a)]	0.23	STMR barley grain (FAO, 2009b) x CF (2) (EFSA, 2014) x PF (3.3)[(a)]
Canola (Rape seed) meal	0.16	STMR x PF (2))[(a)] (EFSA, 2020)	0.16	STMR x PF (2))[(a)] (EFSA, 2020)
Corn, milled by-products[(b)]Corn, hominymeal[(b)] Corn gluten feed/ gluten meal[(b)]	0.02	STMR (FAO, 2014) x CF (2) (EFSA, 2014)	0.02	STMR (FAO, 2014) x CF (2) (EFSA,2014)

Distiller`s grain dried [(b)]				
Cotton meal	0.14	STMR (FAO, 2018) x CF (2) x PF (1.3)[(a)]	0.14	STMR (FAO, 2018) x CF (2) x PF(1.3)[(a)]
Flaxseed/ Linseed meal	0.12	STMR x CF (2) x PF (2)[(a)] (EFSA, 2015a,b)	0.12	STMR x CF (2) x PF (2)[(a)] (EFSA,2015a,b)
Lupin seed meal	0.11	STMR (FAO, 2009b) x CF (2) x PF (1.1)[(a)]	0.11	STMR (FAO, 2009b) x CF (2) 9 PF(1.1)[(a)]
Peanut meal	0.04	STMR (FAO, 2009b) x CF (2) x PF (2)	0.04	STMR (FAO, 2009b) x CF (2) x PF(2)
Potato process waste[(b)] Potato dried pulp[(b)]	0.01	STMR potato (EFSA, 2014) x PF (1)[(c)]	0.01	HR potato (EFSA, 2014) x PF (1)[(c)]
Soybean seed meal	0.13	STMR (FAO, 2014) x CF (2) x PF (1.3)[(a)]	0.13	STMR (FAO, 2014) x CF (2) x PF(1.3)[(a)]
Soybean hulls[(b)]	1.30	STMR soybean (FAO, 2014) X CF (2) x PF (13)[(a)]	1.30	STMR soybean (FAO, 2014) x CF (2)X PF (13)[(a)]
Sunflower seed meal	0.04	STMR x CF (2) x PF (2)[(a)] (EFSA, 2015a,b)	0.04	STMR x CF (2) x PF (2)[(a)] (EFSA,2015a,b)[(a)]
Wheat gluten meal[(b)]	0.07	STMR wheat grain (FAO, 2009b) x CF (2) x PF (1.8)[(a)]	0.04	STMR wheat grain (FAO, 2010) xCF (2) x PF (1.8)[(a)]
Wheat milled by-products[(b)]	0.28	STMR wheat grain (FAO, 2009b) x CF (2) x PF (7)[(a)]	0.28	STMR wheat grain (FAO, 2010) xCF (2) x PF (7)[(a)]

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

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

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

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

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

Table 7.3-15: Results of the dietary burden calculation

Relevant groups	Dietary burden expressed in				Most criticaldiet [a]	Most critical commodity [b]		Trigger exceeded (Yes/No)0.10 mg/kg DM	Previous assessment (EFSA, 2020) Max burden mg/kg DM	JMPR 2017 (FAO, 2018) Max burden mg/kg DM
	mg/kg bw per day		mg/kg DM							
	Median	Maximum	Median	Maximum						
Cattle (all diets)	0.066	0.124	1.72	3.23	Dairy cattle	Barley	Straw	Y	3.10	18.42 (AUT dairy cattle)
Cattle (dairyonly)	0.066	0.124	1.72	3.23	Dairy cattle	Barley	Straw	Y	2.85	21.60 (AUTbeef cattle)
Sheep (all diets)	0.075	0.236	1.77	5.55	Lamb	Barley	Straw	Y	5.55	Not calculated
Sheep (ewe only)	0.059	0.185	1.77	5.55	Ram/ewe	Barley	Straw	Y	5.55	Not calculated
Swine (all diets)	0.022	0.030	0.95	1.32	Swine (breeding)	Sugar beet	Tops	Y	0.64	Not calculated
Poultry (alldiets)	0.036	0.059	0.53	0.87	Poultrylayer	Wheat	Straw	Y	0.87	3.05 (EU poultry layer)
Poultry(layer only)	0.036	0.059	0.53	0.87	Poultrylayer	Wheat	Straw	Y	0.87	Not calculated
Fish	N/A									

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

The most recent livestock dietary burden which was calculated in the EFSA opinion on the confirmatory data assessment of prothioconazole (EFSA, 2020) was now updated considering the use of prothioconazole on sugar beet. The results of the dietary burden calculation demonstrated that the intake of additional prothioconazole residues from treated sugar beet roots and tops increases the dietary burden for beef and dairy ruminants and for pigs. However, the existing EU MRLs for prothioconazole in livestock commodities reflect Codex MRLs, which were derived from a significantly higher livestock dietary burdens as calculated by the JMPR (FAO, 2018). Therefore, EFSA concludes that a change of the existing MRLs for products of animal origin is not required.

Triazole Derived Metabolites (dietary burden)

EFSA concluded in EFSA Journal 2023;21(8):8198 that:

A comprehensive livestock exposure to TDMs from the intake of all feed commodities containing TDM residues from the use of various triazole fungicides could not be fully assessed by the peer review of the pesticide risk assessment for the triazole derivative metabolites in light of confirmatory data due to outstanding poultry and ruminant feeding studies with TLA or alternative metabolism studies which could be used as waivers for feeding studies (EFSA, 2018b). Thus, pending these data gaps to be addressed and lacking updated information on TDMs from the uses of all triazole fungicides, the livestock exposure to TDMs from the intake of feed crops treated with triazole fungicides other than prothioconazole could not be undertaken in the framework of the current assessment.

The applicant provided the TDMs data both for sugar beet root and tops. The residue levels of TDMs in sugar beet tops are below the levels assessed by the peer review on the pesticide risk assessment for the TDMs in light of confirmatory data, except for the TAA levels in sugar beet tops, which were higher (0.076 mg/kg vs. 0.02 mg/kg (from use of various triazole fungicides)) (EFSA, 2018b). Since TDM residue data are not available for all feed crops treated with prothioconazole and since the residue data available to the pesticide peer review on the TDM confirmatory data were affected by uncertainties related to storage stability and the number of residue trials, the livestock dietary burden to TDMs cannot be currently estimated. EFSA recommends that the livestock exposure to TDMs originating from the use of prothioconazole is further assessed in the framework of the renewal of the approval of active substance.

zRMS comments:

Information given by the Applicant is acceptable and sufficient.

Sugar beet roots and tops may be used for feed purposes. Hence, it was necessary to perform a dietary burden calculation for livestock to estimate whether the intended use of prothioconazole on sugar beet would have an impact on the residues expected in food of animal origin.

Prothioconazole

The median and maximum dietary burdens for livestock were estimated for prothioconazole and were calculated using the animal model calculator developed by EFSA (Animal model 2017).

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

TDMs

Livestock dietary burden calculation has been performed respectively for each TDM compound in the addendum – confirmatory data on TDMs performed by UK (UK, 2018) using results from residue trials and from rotational crops.

7.3.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

No new data were submitted in the framework of this application. An overview of the ruminant feeding study, already evaluated/peer reviewed at EU level is presented below.

Poultry:

In EFSA's recent Reasoned Opinion (EFSA, Journal 2014;12(5):3689) on the review of the existing maximum residue levels (MRLs), it is stated :

For poultry, although the maximum dietary burden exceeded the threshold of 0.1 mg/kg DM, no residues above the LOQ were expected in poultry matrices at the calculated dietary burden and no feeding study was triggered. Therefore, MRLs can be established at the LOQ in all poultry commodities and no default conversion factors for risk assessment need to be derived.
However, during the 2017 JMPR evaluation of prothioconazole, MRLs for poultry commodities were established and subsequently adopted in the EU (EFSA, 2018a), see table below.

Ruminant:
During the peer review under Council Directive 91/414/EEC, the magnitude of prothioconazole residues in ruminants was investigated in a feeding study with lactating cows (KCA 6.4.2/01 DAR 2006, EFSA, 2007; FAO, 2009a, 2008).
Three groups of lactating cows, each consisting of three animals, were meant to be dosed for 28 consecutive days with prothioconazole-desthio at levels of 4, 25, and 100 mg/kg in the diet (1X, 6.25X and 25X). The actual average dose rates were 1.3X, 7.3X, and 31X the anticipated maximum dietary burden, *i.e.* 5.1 ppm, 29 ppm and 125 mg/kg in the diet. Please note in EFSA Journal 2014; 12(5):3689, the intended values of 4, 25 and 100 mg/kg were erroneously utilised for the ruminant livestock values. The samples were analysed for prothioconazole-desthio, 3-hydroxy-prothioconazole-desthio (M14) and 4-hydroxy-prothioconazole-desthio (M15). Indeed, these 3 analytes were found to represent the major portion of the TRR in the goat metabolism study after acidic treatment (please refer to EU Annex II dossier, 6.2.2.2), in particular in liver, kidney, muscle and fat. They do not however, completely cover the residue definition for risk assessment. Therefore, only the measured average and maximum concentrations for prothioconazole-desthio are compiled in the table below. This covers the residue definition for enforcement.

Table 7.3-16: Highest and mean residue concentrations (mg/kg) in the edible tissues of dairy cattle after 28 days of dosing with JAU 6476-desthio

Dose group	Dose level * (mg/kg bw per d)	Matrix	Mean (mg/kg)	Maximum (mg/kg)
1.3X (5.1 ppm feed)	0.19	Muscle	<0.01	<0.01
7.3X (29 ppm feed)	1.05		<0.01	<0.01
31X (125 ppm feed)	4.54		<0.01	<0.01
1.3X (5.1 ppm feed)	0.19	Fat	<0.01	<0.01
7.3X (29 ppm feed)	1.05		<0.01	0.01
31X (125 ppm feed)	4.54		0.05**	0.09**
1.3X (5.1 ppm feed)	0.19	Liver	0.02	0.03
7.3X (29 ppm feed)	1.05		0.14	0.18
31X (125 ppm feed)	4.54		0.68	1.20
1.3X (5.1 ppm feed)	0.19	Kidney	<0.01	<0.01
7.3X (29 ppm feed)	1.05		0.03	0.03
31X (125 ppm feed)	4.54		0.13	0.24
1.3X (5.1 ppm feed)	0.19	Milk	<0.004	N/A
7.3X (29 ppm feed)	1.05		<0.004	N/A
31X (125 ppm feed)	4.54		<0.004	N/A

* Based on a 550 kg animal consuming 20 kg/feed DM day
** In EFSA Journal 2014; 12(5):3689, the values are lower because one value (at 0.0905) mg/kg was erroneously reported as 0.01 mg/kg instead of 0.09 mg/kg in the study report.

During the JMPR evaluations of prothioconazole (FAO, 2008 and 2017), MRLs for animal commodities were established and subsequently adopted in the EU.

Table 7.3-17: MRL for commodities of animal origin for prothioconazole-desthio

Animal commodities	EU MRL (mg/kg) Reg. (EU) ~~2019/552~~ 2024/1318
Meat	0.01*
Fat of swine and ruminant	0.02
Liver, kidney, offal of swine and ruminant	0.5
Liver and kidney of poultry	0.1
Meat, fat of poultry	0.01*
Milk	0.01*
Eggs	0.01*

* indicates that the MRL is set at the LOQ

Residue levels of prothioconazole-desthio determined in the supplementary residue trials reported in this dossier are in accordance with the residue levels evaluated in the Scientific Report. Therefore, EFSA and JMPR's evaluation are considered to be valid also for the supported use of the product GF-3307 in/on oilseed rape and supplementary livestock feeding studies are not considered necessary for this submission. There is no need to modify MRLs for foodstuff of animal origin.

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Table 7.3-18: Overview of the values derived from livestock feeding studies

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 (DAR, 2006 ; EFSA, 2007; EFSA 2014), M-078342-01-1												
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-chloro-phenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety) expressed as prothioconazole-desthio.												
Ruminant meat	0.075	0.236	**0.19**	3	<0.01	<0.01	N/A	N/A	<0.01	<0.01	0.01*	1.0
			1.05	3	<0.01	<0.01	N/A	N/A				
			4.54	3	<0.01	<0.01	N/A	N/A				
Ruminant fat			**0.19**	3	<0.01	<0.01	N/A	N/A	<0.01	<0.01	0.01*	1.0
			1.05	3	<0.01	<0.01	N/A	N/A				
			4.54	3	0.05***	0.09***	N/A	N/A				
Ruminant liver			**0.19**	3	0.02	0.03	N/A	N/A	<0.01	0.038	0.05	2.0
			1.05	3	0.14	0.18	N/A	N/A				
			4.54	3	0.68	1.20	N/A	N/A				
Ruminant kidney			**0.19**	3	<0.01	<0.01	N/A	N/A	<0.01	<0.01	0.01*	4.0[f]
			1.05	3	0.03	0.03	N/A	N/A				
			4.54	3	0.13	0.24	N/A	N/A				
Milk			**0.19**	42	<0.004 [e]	N/A	N/A	N/A	<0.004	<0.004	0.004*	1.0
			1.05	42	<0.004 [e]	N/A	N/A	N/A				
			4.54	39	0.004 [e]	N/A	N/A	N/A				

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

(*): Indicates that the MRL is set at the limit of analytical quantification.(**)According to EFSA Journal 2014; 12(5):3689, the animal enforcement residue definition is proposed as prothioconazole-desthio (sum of isomers) only. Indeed, as can be seen in the feeding study, prothioconazole-desthio is a valid marker for prothioconazole in animal matrices (even in milk where transfers are extremely low). Prothioconazole-desthio was not detected in milk in the metabolism study because of the very low transfer of prothioconazole in this matrix. This was confirmed by the feeding study. (***):in EFSA Journal 2014; 12(5):3689, the values are lower because one value (at 0.0905) mg/kg was erroneously reported as 0.01 mg/kg instead of 0.09 mg/kg in the study report.

(a): Based on a 550 kg animal consuming 20 kg/feed DM day

(b): Median residue value according to the enforcement residue definition, derived by interpolation/extrapolation from the feeding study for the median dietary burden (FAO, 2009b).
(c): Highest residue value (tissues, eggs) or mean residue value (milk) according to the enforcement residue definition, derived by interpolation/extrapolation of the maximum dietary burden between the relevant feeding groups of the study (FAO, 2009b).
(d): The median conversion factor for enforcement to risk assessment was bwas on metabolism studies
(e): Mean residue level from day 1 or 4 until day 29 (3 cows, 13 or 14 sampling days). (g): based on the metabolism study. In EFSA Journal 2014;12(5):3689, the conversion factor (CF) of 9 for kidney is erroneous. Indeed, in the goat metabolism study with prothioconazole-desthio, the quantitative evaluation of radioactivity was done before and after acid treatment. A hydrolysis was necessary as there were a lot of conjugates. A conversion factor of 9 is derived if the values are taken before acidic treatment, but the CF is 4 if determined after the acidic treatment. Because all of the methods for the determination of prothioconazole-desthio include also a harsh hydrolysis step, the CF to be used for enforcement to risk assessment should be 4, *i.e.* derived from the values of the metabolism study after acidic treatment.
(f): A conversion factor of 9 were established for kidney based on the goat metabolism study (see EFSA, Journal 2014;12(5):3689) but it is erroneous, and should be 4 (please refer to page 151 of amended EU Annex II dossier KIIA, 6.2.2.2). This has been addressed to the UK CRD RMS.

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Conclusion on feeding studies
The feeding data available show that no exceedance of the proposed MRL for animal commodities will occur and the intended uses are considered acceptable.

zRMS comments:
Information given by the Applicant is acceptable and sufficient.
The livestock feeding studies was investigated during the peer review of prothioconazole. The most recent livestock dietary burden updated considering the use of prothioconazole on sugar beet was calculated in the EFSA opinion (EFSA Journal 2023;21(8):8198) and is still valid.
The residues in animal commodities will not exceed MRLs (Reg. (EU) 2024/1318).
No further data are required to support the intended uses of GF-3307.

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

7.3.5.1 Available data for all crops under consideration

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

Data/information on processing studies was reviewed during the approval of prothioconazole and were considered acceptable. According to EFSA 2020, the studies investigating the effect on the magnitude of prothioconazole-desthio, the hydroxy metabolites and the TDMs in processed commodities are currently not required, as the total theoretical maximum daily intake (TMDI) is below the trigger value of 10% of the ADI for the individual crops under assessment.

Nevertheless, one processing study in sugar beets following three treatments with 1000 g a.s./ha (8–10 days interval) and a PHI of 5 days was provided and assessed (EFSA Journal 2023;21(8):8198). Processing of the treated sugar beets to dried pulp, refined sugar and molasses was investigated and indicated that all three processes lead to a reduction of the prothioconazole-desthio residues in the processed product (Germany, 2022).
No information was provided on the levels of metabolites that are included in the risk assessment residue definition. One processing study however is not sufficient to derive robust processing factors to be recommended to be included in Annex VI of Regulation (EC) No 396/2005.

Processed commodity	Number of studies	Individual values	Median PF	Comments	Reference
Refined Sugar	1	0.04	0.04	Tentative – limited dataset Data only for prothioconazole-desthio (and not for the hydroxy-metabolites included in the residue definition for risk assessment) or the TDMs reported (Germany, 2022)	EFSA Journal 2023;21(8):8198
Dried Pulp	1	<0.01	<0.01		
Molasses	1	0.20	0.20		

7.3.5.2 Conclusion on processing studies

According to the EFSA Journal 2023;21(8):8198 studies investigating the magnitude of residues in processed commodities are available.

Studies investigating the effect on the magnitude of the TDMs in processed commodities have not been submitted in the framework of the current assessment. Such studies are currently not required, because residues above the LOQ of 0.1 mg/kg are not expected in the individual crops under assessment.

zRMS comments:
As residues of prothioconazole and TDMs exceeding 0.1 mg/kg are not expected in the treated crops and the consumer exposure to residues in sugar beet roots is individually less than 10% ADI, there is no need to investigate the magnitude of prothioconazole and TDMs residues in processed commodities.

No further data are required.

7.3.6 Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation.

A possible transfer of prothioconazole residues from primary crop uses to crops that are grown in a crop rotation has been assessed in the MRL review (EFSA, 2014). The MRL review concluded that prothioconazole residue levels in food and feed commodities derived from rotational crops are expected to be covered by the residue levels in primary crops (EFSA, 2014).
Since the maximum annual application rate for the crops under consideration (i.e. 2 x 150 g a.s./ha) is lower than the application rate tested in the rotational crop study, it is concluded that the same conclusions are applicable.

This conclusion, nevertheless, is not justified for the occurrence of triazole derivative metabolites in soil from the uses of prothioconazole, other triazole pesticides or fertilisers, and subsequent carry-over to plants. The peer review on the pesticide risk assessment for the TDMs in light of confirmatory data could not conclude on the magnitude of TDMs in rotational crops following the use of triazole fungicides due to data gaps related to storage stability of rotational crop field trial samples (EFSA, 2018b). Thus, without appropriate field data, the magnitude of TDMs in rotational crops currently cannot be estimated.

7.3.6.1 Field rotational crop studies (KCA 6.6.2)

Available data
Residue data for prothioconazole-desthio and the TDMs in rotational crops are available from field rotational crop trials conducted in/on carrot & turnip (root crop), lettuce (leafy crop) and barley (cereal). These studies are summarized in the table below.
As these studies were performed with the aim to address the assessment of consumer exposure to triazole metabolites derivatives (TDMs) in rotational crops, prothioconazole-desthio was also determined but the hydroxy metabolites of prothioconazole-desthio were not.
Indeed, in the confined rotational crop study, it was concluded that prothioconazole residue levels in food and feed rotational commodities are expected to be covered by the residue levels in primary crops. The results of these studies were EU evaluated for the TDMs (EFSA, 2018b, UK, 2018) and for parent prothioconazole (dRAR).

Table 7.3-19: Summary of available studies in field rotational crops

Primary crop	Rate (kg a.s./ha) (GS at application or PHI)	Succeeding crop group	Succeeding crop	Sowing intervals (DAT)	Reference / Remarks
Data relied on in EU (Prothioconazole-desthio and TDMs)					
Bare soil	630 g a.s./ha	Leafy vegetables	Lettuce	21-34 days	09-2500 (M-426697-01-1), 09-2501 (M-426699-02-1), 09-2502 (M-426710-01-1), 09-2503 (M-426705-01-1) dRAR 2018 EU agreed (EFSA, 2018b, UK, 2018) for the TDMs
		Root vegetables	Turnip and carrot		
		Cereal	Barley		
Wheat	15 g a.s./dt (200 kg seed/ha) + 3x200 g/ha (BBCH 32, 39 and 65-69)	Leafy vegetables	Lettuce	56-200 days	
		Root vegetables	Turnip and carrot		
		Cereal	Barley		
Wheat	15 g a.s./dt (200 kg seed/ha) + 3x200 g/ha (BBCH 32, 39	Leafy vegetables	Lettuce	277-345 days	
		Root vegetables	Turnip and carrot		

Primary crop	Rate (kg a.s./ha) (GS at application or PHI)	Succeeding crop group	Succeeding crop	Sowing intervals (DAT)	Reference / Remarks
	and 65-69) equivalent to 630 g a.s./ha	Cereal	Barley		

Supervised field trials to investigate the residues in rotational crops after the use of prothioconazole were conducted at four test sites in Germany, the Netherlands, the southern part of 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 and 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 a.s./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 a.s./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. No residues above the LOQ were found in the control samples. At all samplings dates and for all matrices, no residue of prothioconazole-desthio was detected above 0.01 mg/kg (LOQ).
For the Triazole Derived Metabolites, as expected from the Confined Rotational Crop study, no 1,2,4-T was detected. Residues up to 0.455 mg/kg were observed for TA (barley grain); up to 0.293 mg/kg for TAA (barley grain) and up to 0.208 mg/kg for TLA (barley plant). During the risk assessment for the triazole derivative metabolites in light of confirmatory data submitted (UK, 2018, EFSA, 2018b), some data from these rotational studies were taken into account in the overall assessment: the values of 0.091 mg/kg for TA on lettuce; 0.036 mg/kg for TAA on lettuce and 0.131 mg/kg for TLA on carrot. With these, no unacceptable risk for the consumer was identified.

Conclusion on rotational crops studies
According to the EFSA Journal 2014;12(5):3689 and EFSA Journal 2020;18(2):5999 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 and no risk mitigation measures need to be proposed.

Specific plant-back restrictions related to the use of prothioconazole are therefore not required, provided that prothioconazole is applied in compliance with the GAPs evaluated in the framework of this review.

zRMS comments:
Information given by the Applicant is acceptable and sufficient.
No residues are expected in rotational crops for the intended uses of GF-3307, so additional field rotational crop studies are not considered required.
Regarding TDMs, rotational crop studies were considered by the UK in the assessment of confirmatory data on TDMs (the UK, 2018).

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

Effect on the residue level in pollen and bee product
In order to support the intended and most critical uses of prothioconazole on melliferous crops and in order to determine the resulting residues of prothioconazole in honey, five GLP honey trials were conducted on oilseed rape in northern and southern European zones under semi-field conditions during the 2019 season. Prothioconazole, prothioconazole-desthio, alpha-hydroxy-prothioconazole-desthio, 3-hydroxy-prothioconazole-desthio, 4-hydroxy-prothioconazole-desthio, 5-hydroxy-prothioconazole-

desthio and 6-hydroxy-prothioconazole-desthio as well as 1,2,4-triazole, triazole acetic acid, triazole alanine and triazole lactic acid were determined. Please refer to Appendix 2. The results are summarised below.

Table 7.3-18 STMRs and HRs for prothioconazole residues in honey

Reference	GAP	No of Trials	Commodity	Analyte	Residues (mg/kg)	
					STMR	HR
S19-00902 M-682401-01-1 Appendix 2	Oilseed rape SPI 2 x 200 g a.s./ha BBCH55-65	5 (2 NEU + 3 SEU)	Honey	Prothioconazole	0.01*	0.01*
				Prothioconazole-desthio (PTZ-DT)	0.01*	0.01*
				alpha-hydroxy-PTZ-DT	0.01*	0.01*
				3-hydroxy- PTZ-DT	0.01*	0.01*
				4-hydroxy- PTZ-DT	0.01*	0.01*
				5-hydroxy- PTZ-DT	0.01*	0.01*
				6-hydroxy- PTZ-DT	0.01*	0.01*
				1,2,4-Triazole	0.01*	0.01*
				Triazole alanine	0.01*	0.043
				Triazole acetic acid	0.01*	0.052
				Triazole lactic acid	0.01*	0.13

These honey trials show that no residue of prothioconazole, prothioconazole-desthio, alpha-hydroxy-prothioconazole-desthio, 3-hydroxy-prothioconazole-desthio, 4-hydroxy-prothioconazole-desthio, 5-hydroxy-prothioconazole-desthio, 6-hydroxy-prothioconazole-desthio and 1,2,4-triazole are expected in honey.
For triazole acetic acid, triazole alanine and triazole lactic acid, residues in honey were observed, up to 0.13 mg/kg for triazole lactic acid.
However, with these input values, there is no impact on the chronic risk assessment (0.0% ADI) and for the acute risk, the ARfD consumption was 0.04% ARfD for 1,2,4-triazole, 0.05% ARfD for triazole alanine, 0.02% ARfD for triazole acetic acid and 0.2% ARfD for triazole lactic acid.
Therefore, as the exposure to the TDMs is much lower with the current prothioconazole uses compared to all the uses presented in "*TDM confirmatory data addendum",* UK, 2018, there is no need to perform new risk assessment calculations from those previously performed with a much higher number of crops (please refer to the "*TDM confirmatory data addendum*), and no unacceptable consumer risk is expected from the representative uses of prothioconazole.

The default MRL of 0.05 mg/kg is applicable for honey.

zRMS comments:
Information given by the Applicant is acceptable.

The intended uses of GF-3307 in sugar beets and fodder beets are expected to have little potential for contributing residues to bee products. This is in line with the technical guidelines SANTE/11956/2016 rev. 9, 14 September 2018. Non-target plants can contribute to residues in honey, but in small quantities and it is certainly not expected to result in a consumer exposure exceeding toxicological reference values. Therefore, it is unlikely to pose a risk to consumers' health. Other special studies including data on prothioconazole residues in pollen and bee products for human consumption are not considered necessary.
The Applicant submitted an additional study to determine residues of prothioconazole and its metabolites in honey after two applications of PTZ EC 250 in winter oilseed rape at 5 sites in Northern and Southern Europe in 2019. The study was not evaluated by the zRMS.

In our opinion, no further data is necessary to support the uses of GF-3307.

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

The consumer risk assessment has been performed with the EFSA Pesticide Residues Intake Model

(PRIMo) rev. 3.1 (EFSA Supporting publication 2019:EN-1605). The exposure assessment model contains the relevant European food consumption data for different sub-groups of the EU population (EFSA Journal 2018;16(1):5147).

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

The relevant risk assessment residue definitions for prothioconazole are summarised below:

For plant and animal commodities:

(1) Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4- triazole moiety, expressed as prothioconazole-desthio (sum of isomers) (EFSA Journal 2014;12(5):3689)

(2) Triazole derivative metabolites (TDMs) (EFSA Journal 2018;16(7):5376), with separate assessment of:
– Triazole alanine (TA) and triazole lactic acid (TLA)
– Triazole acetic acid (TAA)
– 1,2,4-triazole (1,2,4-T)

In the text below, the residue definition (1) is referred to as 'prothioconazole-desthio' for brevity.

7.3.8.1 Input values for the consumer risk assessment

(1) Prothioconazole-desthio

Input values for the consumer risk assessment are presented in Table 7.3-20. A brief rationale for the selection of the input values is provided below.

Chronic Assessment:

An International Estimated Daily Intake (IEDI) calculation has been performed taking into consideration all uses of prothioconazole. Residue input values (STMRs) were derived from the current EU-MRLs (Reg. (EU) 2024/1318, including the MRL increase for sugar beet and chicory roots (EFSA Journal 2023;21(8):8198)), except for the commodities where increased EU-MRL modifications are currently under evaluation:

- garlic, onion and shallots (EFSA Journal 2023;21(1):7717)
- celeriac and rapeseeds (EFSA Journal 2020;18(2):5999)

For these commodities, residue input values (STMR) were derived from the proposed EU-MRLs to reflect the future worst-case scenario. For the intended use of GF-3307 on sugar beet, residue input values were derived from the supervised residue trials supporting the intended uses as reported in Table 7.3-12. It is highlighted that the new EU MRL for sugar beet roots (0.03 mg/kg, Reg. (EU) 2024/1318) covers the intended use of GF-3307.

The expression of residue input values was done in accordance with the approach taken by EFSA, 2023 (EFSA Journal 2023;21(8):8198):

- Where available, residue input values were selected that had been measured according to the residue definition for risk assessment ("*Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4- triazole moiety, expressed as prothioconazole-desthio (sum of isomers)*").
- Where these data were not available, residue input values were selected that have been measured according to the residue definition for monitoring ("*prothioconazole-desthio (sum of isomers)*") and the applicable conversion factor (CF) was applied as previously defined by EFSA to convert the residues to "*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)".

- For a small number of commodities, appropriate conversion factors are not available. In these cases, the residue measured according to the residue definition for monitoring was used instead as proposed by EFSA, 2023 (EFSA Journal 2023;21(8):8198).

In accordance with the methodology in PRIMo 3.1, a CF was not applied for commodities where the residue input value was a MRL value set at the lower limit of analytical quantification.

Acute Assessment:

Acute exposure assessments were conducted only for the commodities under consideration for the intended uses of GF-3307 on sugar beet. An International Estimated Short-Term Intake (IESTI) calculation has been performed for the commodity, sugar beet roots. Residue input values were derived from the supervised residue trials supporting the intended uses of GF-3307 as reported in Table 7.3-12. Residues values were selected according to the residue definition for risk assessment. For sugar beet roots, the HR value was selected, but it is noted that for sugar, the STMR is automatically relied on in the risk assessment calculation because it is a bulked/blended processed commodity.

Table 7.3-20: Input values for the consumer risk assessment (1) Prothioconazole-desthio

Commodity (code)	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	**Comment**	**Input value (mg/kg)**	**Comment**
Risk assessment residue definition: Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4- triazole moiety, expressed as prothioconazole-desthio (sum of isomers)				
Sugar beet roots (0900010)	**0.06**	**$STMR_{RA}$-RAC** (Table 7.3-12)	**0.07**	**HR_{RA}-RAC** (Table 7.3-12)
Cranberries (0154020)	0.025	$STMR_{MO}$-RAC [(a)] (FAO, 2014)	Acute risk assessment was undertaken only for the crops under consideration	
Potatoes (0211000)	0.01	$STMR_{RA}$-RAC (EU MRL)		
Beetroots (0213010) Carrots (0213020) Horse radishes (0213040) Parsnips (0213060) Parsley roots/Hamburg roots parsley (0213070) Salsifies (0213090) Swedes/rutabagas (0213100) Turnips (0213110)	0.08	$STMR_{RA}$-RAC (EFSA, 2014)		
Celeriacs/turnip rooted celeries (0213030)	0.08	Proposed $STMR_{RA}$-RAC (EFSA, 2020)		
Garlic (0220010) Onions (0220020) Shallots (0220030)	0.01	Proposed $STMR_{RA}$-RAC (EFSA, 2023)		
Sweet corn (0234000)	0.018	$STMR_{MO}$-RAC [(a)] (FAO, 2014)		
Broccoli (0241010) Cauliflowers (0241020) Other flowering brassica (0241990)	0.02	$STMR_{RA}$-RAC (EFSA, 2014)		
Brussels sprouts (0242010)	0.06	$STMR_{RA}$-RAC (EFSA, 2014)		

Commodity (code)	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Head cabbages (0242020)	0.02	$STMR_{RA}$-RAC (EFSA, 2014)		
Leeks (0270060)	0.02	$STMR_{MO}$-RAC (EFSA, 2014)		
Beans (0300010)	0.02	$STMR_{MO}$-RAC (0.01) x CF (2) (EFSA, 2014)		
Lentils (0300020) Peas (0300030) Lupins/lupini beans (0300040)	0.1	$STMR_{MO}$-RAC (0.05) x CF (2) (FAO, 2009, EFSA, 2014)		
Linseeds (0401010) Poppy seeds (0401030) Mustard seeds (0401080)	0.06	$STMR_{MO}$-RAC (0.03) x CF (2) (EFSA, 2014)		
Peanuts/groundnuts (0401020)	0.02	$STMR_{MO}$-RAC (0.01) x CF (2) (FAO, 2009)		
Sunflower seeds (0401050)	0.02	$STMR_{MO}$-RAC (0.01) x CF (2) (EFSA, 2015)		
Rapeseeds/canola seeds (0401060)	0.08	Proposed $STMR_{RA}$-RAC (EFSA, 2020)		
Soyabeans (0401070)	0.1	$STMR_{MO}$-RAC (0.05) x CF (2) (FAO, 2014)		
Cotton seeds (0401090)	0.104	$STMR_{MO}$-RAC (0.052) x CF (2) (FAO, 2017)		
Gold of pleasure seeds (0401130)	0.02	$STMR_{MO}$-RAC (0.01) x CF (2) (EFSA, 2014)		
Barley (0500010)	0.07	$STMR_{MO}$-RAC (0.035) x CF (2) (FAO, 2009)		
Maize/corn (0500030)	0.02	$STMR_{MO}$-RAC (0.01) x CF (2) (FAO, 2014)		
Wheat (0500090)	0.04	$STMR_{MO}$-RAC (0.02) x CF (2) (FAO, 2009)		
Chicory roots (0900030)	0.06	Proposed $STMR_{RA}$-RAC (EFSA, 2023)		
Muscle/meat of: Swine (1011010) Bovine (1012010) Sheep (1013010) Goat (1014010) Equine (1015010) Other farmed animals (1017010)	0.01	$STMR_{RA}$-RAC [b, c] (FAO, 2017)		
Fat tissue of: Swine (1011020) Bovine (1012020) Sheep (1013020) Goat (1014020) Equine (1015020) Other farmed animals (1017020)	0.01	$STMR_{RA}$-RAC [b] (FAO, 2017)		

Commodity (code)	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Liver tissue of: Swine (1011030) Bovine (1012030) Sheep (1013030) Goat (1014030) Equine (1015030) Other farmed animals (1017030)	0.05	$STMR_{RA}$-RAC [b] (FAO, 2009)		
Kidney tissue of: Swine (1011040) Bovine (1012040) Sheep (1013040) Goat (1014040) Equine (1015040) Other farmed animals (1017040)	0.025	$STMR_{RA}$-RAC [b] (FAO, 2009)		
Edible offal (other than liver and kidney) of: Swine (1011050) Bovine (1012050) Sheep (1013050) Goat (1014050) Equine (1015050) Other farmed animals (1017050)	0.025	$STMR_{RA}$-RAC [b] (FAO, 2009)		
Poultry: Muscle/meat (1016010)	0.0016	$STMR_{RA}$-RAC [b, c] (FAO, 2017)		
Poultry: Fat tissue (1016020)	0.008	$STMR_{RA}$-RAC [b] (FAO, 2017)		
Poultry: Liver (1016030)	0.071	$STMR_{RA}$-RAC [b] (FAO, 2017)		
Poultry: Kidney (1016040)	0.071	$STMR_{RA}$-RAC [b] (FAO, 2017)		
Poultry: Edible offals (other than liver and kidney) (1016050)	0.071	$STMR_{RA}$-RAC [b] (FAO, 2017)		
Milk (1020000)	0.005	$STMR_{RA}$-RAC (EFSA, 2014)		
Eggs (1030000)	0.01	$STMR_{RA}$-RAC (EFSA, 2014)		
All other commodities	MRL/LOQ	EU MRL [d] Reg. (EU) 2024/1318		

(a): Values refer to the residues of prothioconazole-desthio; data according to EU risk assessment residue definition not available (EFSA, 2020)

(b): Values refer to the sum of prothioconazole-desthio, prothioconazole-desthio-3-hydroxy, prothioconazole-desthio-4-hydroxy and their conjugates expressed as prothioconazole-desthio (EFSA, 2020)

(c): Consumption figures in the EFSA PRIMo are expressed as meat. Since the a.s. is fat soluble, STMR and HR residue values were calculated considering a 80:20 muscle: fat ratio for mammal and 90:10 muscle: fat ratio for poultry

(d): CF = conversion factor, applied unless the MRL is a LOQ value:

- For plant commodities: CF = 2 for cereal grains, oilseeds, pulses, bulb vegetables and leafy vegetables and 2.7 for root and tuber vegetables (EFSA, 2007, 2014, 2020)
- For animal commodities except poultry: CF = 10 for muscle and milk, 4 for fat, and 2 for liver and kidney (EFSA, 2007)

(2) Triazole derivative metabolites (TDMs):

A comprehensive risk assessment considering the TDMs in all crops from all pesticides belonging to the class of triazole fungicides has been performed by EFSA in the context of the confirmatory data assessment for triazole compounds in the framework of Regulation (EC) No 1107/2009 (EFSA Journal 2018;16(7):5376).

This assessment conducted a worst-case consumer dietary intake assessment for the TDMs and concluded that unacceptable risk for the consumers is unlikely (EFSA Journal 2018;16(7):5376).

For the intended uses of GF-3307, residues of the TDMs in the commodities of interest were found to be lower than the residues of these compounds already assessed in this worst-case dietary risk assessment (Table 7.3-13 and Table 7.3-21). Therefore, the assessment previously conducted by EFSA is considered to cover the intended uses of GF-3307.

A reproduction of this worst-case assessment, relevant to the intended uses of GF-3307 is presented below.

Chronic Assessment:

International Estimate of Daily Intake (IEDI) calculations have been performed taking into consideration all uses and the worst-case intakes for the TDMs for the complete group of triazole active substances that were previously assessed by EFSA. The residue input values were derived from Table 7.7-1 of Appendix E in the UK TDM Confirmatory Data Addendum (UK, 2018) and are presented in Table 7.3-21.

Acute Assessment:

Acute exposure assessments were conducted only for the commodities under consideration for the intended uses of GF-3307. An International Estimated Short-Term Intake (IESTI) calculation has been performed for the commodity, sugar beet roots. Residue input values were derived from the worst-case intakes for the TDMs for the complete group of triazole active substances that were previously assessed by EFSA. The residue input values were derived from Table 7.7-1 of Appendix E in the UK TDM Confirmatory Data Addendum (UK, 2018) and are presented in Table 7.3-21. For sugar beet roots, the HR value was selected, but it is noted that for sugar, the STMR is automatically relied on in the risk assessment calculation because it is a bulked/blended processed commodity.

Table 7.3-21: Input values for the consumer risk assessment: (2) Triazole derivative metabolites (TDMs)

Commodity	**Chronic risk assessment**					**Acute risk assessment**				
Risk assessment:	**TA [a]**	**TLA [b]**	**TAA [c]**	**1,2,4-T [d]**	**Comment**	**TA [a]**	**TLA [b]**	**TAA [c]**	**1,2,4-T [d]**	**Comment**
Sugar beet roots	0.01	0.01 *	0.01 *	0.01 *	STMR (Table 7.3-13)	0.024	0.01 *	0.01 *	0.01 *	HR (Table 7.3-13)
	0.050	**0.010**	**0.050**	**0.050**	**STMR (UK, 2018)**	**0.078**	**0.010**	**0.050**	**0.060**	**HR (UK, 2018)**
Citrus fruit	0.320	0.040	0.050	0.050	STMR (UK, 2018)	Acute risk assessment was undertaken only for the crops under consideration				
Pome fruit	0.039	0.030	0.030	0.010						
Stone fruit	0.320	0.038	0.020	0.010						
Berries	0.060	0.040	0.050	0.010						
Banana	0.050	n.a.	0.050	0.050						
Root and tuber vegetables	0.184	0.021	0.010	0.01						
Bulb vegetables	0.060	0.010	0.010	0.010						
Fruiting vegetables	0.21	0.030	0.010	0.010						
Brassica vegetables	0.170	0.010	0.010	0.039						
Leafy vegetables	0.047	0.080	0.023	0.015						
Legume vegetables	0.090	0.010	0.010	0.010						
Stem vegetables	0.090	0.010	0.020	0.010						
Pulses	0.170	0.010	0.050	0.050						
Oilseeds	1.039	0.065	0.120	0.050						
Oil fruits	1.039	0.065	0.120	0.050						
Cereals	0.621	0.022	0.790	0.050						
Sugar plants	0.050	0.010	0.050	0.050						
Swine meat [e]	0.21	0.04	0.04	0.13						
Swine fat	0.09	0.07	0.04	0.10						
Swine liver	0.50	0.04	0.04	0.13						
Swine kidney	0.22	0.05	0.11	0.14						

Commodity	**Chronic risk assessment**					**Acute risk assessment**				
Risk assessment:	**TA [a]**	**TLA [b]**	**TAA [c]**	**1,2,4-T [d]**	**Comment**	**TA [a]**	**TLA [b]**	**TAA [c]**	**1,2,4-T [d]**	**Comment**
Ruminant meat [e]	0.46	0.04	0.04	0.27						
Ruminant fat	0.22	0.07	0.05	0.18						
Ruminant liver	1.01	0.04	0.05	0.31						
Ruminant kidney	0.49	0.09	0.15	0.32						
Ruminant milk	0.04	0.04	0.04	0.30						
Sheep meat [e]	0.51	0.04	0.04	0.29						
Sheep fat	0.23	0.07	0.06	0.19						
Sheep liver	1.13	0.04	0.05	0.34						
Sheep kidney	0.55	0.09	0.18	0.34						
Sheep milk	0.04	0.04	0.04	0.32						
Poultry meat [e]	0.11	0.04	0.04	0.04						
Poultry fat	0.10	0.04	0.04	0.04						
Poultry liver	0.27	0.04	0.05	0.04						
Poultry eggs	0.06	0.04	0.04	0.04						

(a): TA = triazole alanine
(b): TLA = triazole lactic acid
(c): TAA = triazole acetic acid
(d): 1,2,4-T = 1,2,4-triazole (UK, 2018 refers to this as ‘T’)
(e): As none of the TDMs were found to concentrate in fat then the residue levels for meat can be taken as the residue levels found in muscle
n.a. = not analysed

7.3.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.
Summaries of the consumer risk assessment results are presented below in Table 7.3-22 (prothioconazole-desthio) and Table 7.3-23Table 7.3-23 (TDMs).

Table 7.3-22: Consumer risk assessment - (1) Prothioconazole-desthio

TMDI (% ADI) according to EFSA PRIMo 3.1	Not performed
IEDI (% ADI) according to EFSA PRIMo 3.1	17% ADI (NL toddler)
IESTI (% ARfD) according to EFSA PRIMo*	Unprocessed commodities: Not applicable for sugar beet roots Processed commodities: Sugar beets (root) / sugar: 66% (children)

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

Table 7.3-23: Consumer risk assessment - (2) Triazole derivative metabolites (TDMs)

TMDI (% ADI) according to EFSA PRIMo 3.1	Not performed
IEDI (% ADI) according to EFSA PRIMo 3.1	Triazole alanine (TA) and Triazole lactic acid (TLA) combined: 7.4% (based on NL toddler) Triazole acetic acid (TAA): 1.4% (based on NL toddler) 1,2,4-Triazole (1,2,4-T): 88% (based on NL toddler)
IESTI (% ARfD) according to EFSA PRIMo*	Unprocessed commodities: Not applicable for sugar beet roots Triazole alanine (TA) and Triazole lactic acid (TLA) combined: Processed commodities: Sugar beets (root) / sugar: 2.2% (children) Triazole acetic acid (TAA): Processed commodities: Sugar beets (root) / sugar: 0.55% (children) 1,2,4-Triazole (1,2,4-T): Processed commodities: Sugar beets (root) / sugar: 5.5% (children)

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

A long-term consumer intake concern was not identified for any of the European diets incorporated in the EFSA PRIMo rev. 3.1 model:

For (1) prothioconazole-desthio, the highest calculated chronic intake accounted for 17% of the ADI (NL toddler). Considering all diets, the contribution of residues in the crops under consideration to the total consumer exposure accounted individually for a maximum of 5.07% of the ADI (NL child) for sugar beet roots.

For (2) triazole derivative metabolites, the highest calculated chronic intakes accounted for 7.4% of the ADI for TA + TLA, 1.4% for TAA and 88% of the ADI for 1,2,4-T (NL toddler). Considering all diets, the contribution of residues in the crops under consideration to the total consumer exposure accounted individually for a maximum of 0.17%, 0.04% and 1.84% of the ADI (NL child) for TA + TLA, TAA and 1,2,4-T, respectively, for sugar beet.

An acute consumer risk was not identified for the crops under consideration.

For (1) prothioconazole-desthio, the highest acute consumer exposure was calculated to be 66% of the ARfD for sugar beet (root) / sugar.

For (2) triazole derivative metabolites, the highest acute consumer exposure was calculated to be 2.2%, 0.55% and 5.5% of the ARfD for TA + TLA, TAA and 1,2,4-T, respectively for sugar beet (root) / sugar.

Therefore, the proposed uses of prothioconazole in the formulation GF-3307 (S7K-3-3) do not represent unacceptable acute and chronic risks for the consumer.

7.4 Combined exposure and risk assessment

From a scientific point of view it is regarded necessary to take into account potential combination effects. However, the evaluation of cumulative or synergistic effects as requested by Art. 4 (3b) of Regulation (EC) No. 1107/2009 should only be performed when harmonised "scientific methods accepted by the Authority to assess such effects are available."
Currently, no EU-harmonized guidance is available on the risk assessment of combined exposure to multiple active substances; this approach is not mandatory at EU level.

The product is a mixture of two active substances and both of them have an acute reference dose allocated. Therefore, combined acute exposure can be considered.

7.4.1 Acute consumer risk assessment from combined exposure

In a first step, dose-addition of residues of the individual active substances is assumed by making use of the Hazard Index (HI) concept. The Hazard Quotient (HQ) is calculated for all active substances in the PPP that are acutely toxic by performing deterministic IESTI/NESTI calculations with the calculation models EFSA PRIMO (rev. 3.1) and appropriate national models, if required, and dividing the individual exposure levels by the respective ARfD. Addition of the individual HQs irrespective of any considerations on phenomenological effects or mode(s)/mechanisms of action results in the HI. The results of the HQ/HI calculations are summarized in the following table.

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

Crop	Active Ingredient	HQ (based on IESTI according to EFSA PRIMo 3.1) [(a)]
Sugar beets (root) / sugar	Fenpicoxamid	0.0006
	Prothioconazole-desthio	0.66
	TA	0.018
	TLA	0.0037
	TAA	0.0055
	1,2,4-T	0.055
	Cumulative risk Sugar beet (HI)	**0.74**

(a) Calculations performed with unrounded values, but reported to 1-2 significant places

The Hazard Index is <1. Thus combined exposure to all active substances in GF-3307 is not expected to present a consumer risk. No further refinement of the assessment is required.

7.4.2 Chronic consumer risk assessment from combined exposure

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

7.5 References

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EFSA (European Food Safety Authority), 2015b. Reasoned opinion on the modification of the existing maximum residue levels for prothioconazole in sunflower seeds. EFSA Journal 2015;13(12):4371, 24 pp. https://doi.org/ 10.2903/j.efsa.2015.4371

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EFSA (European Food Safety Authority), 2018a. Scientific support for preparing an EU position in the 50th Session of the Codex Committee on Pesticide Residues (CCPR). EFSA Journal 2018;16(7):5306, 229 pp. https://doi.org/10.2903/j.efsa.2018.5306

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MRL review and modification of the existing maximum residue levels for prothioconazole in celeriacs and
rapeseeds. EFSA Journal 2020;18(2):5999, 50 pp. doi: 10.2903/j.efsa.2020.5999

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United Kingdom, 2017. Draft Assessment Report (DAR) on the active substance fenpicoxamid prepared by the rapporteur Member State UK in the framework of Regulation EC/1107/2009, December 2017.

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

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.3.1/1	Matthew Munro	2024	Fenpicoxamid Residues in Sugar Beet Including Processed Fractions Following Two Applications of GF-3307, Europe, 2022. DAS Report No.: 220541/ Study Number: 685066 Charles River Laboratories Edinburgh Limited GLP/GEP (Y/N): Y Published (Y/N): N	N	Corteva Agriscience
~~KCA 6.3.1/2~~	~~Semrau, J., Thomas, B.~~	~~2019~~	~~Residues of Fenpicoxamid and Prothioconazole in Barley at Interval and at Harvest Following Two Applications of GF-3307 – Southern and Northern Europe – 2017 and 2018. Report No. S17-01904/ 170191. Eurofins AgroScience Services GmbH, Carl-Goerdeler-Weg 5 21684 Stade, Germany~~ ~~GLP/GEP (Y/N): Yes~~ ~~Published (Y/N): No~~	~~N~~	~~Corteva Agriscience~~
~~KCA 6.10.1/1~~	~~Appeltauer, A~~	~~2021~~	~~Determination of Residues of Fenpicoxamid and Prothioconazole in Nectar, Pollen and Plants of Winter Oilseed Rape after One Application of GF-3307 in a Semi-Field Residue Study in Central and Southern Europe in 2020.~~ ~~DAS Report No.: 200670~~ ~~Eurofins Agroscience Services Ltd~~ ~~GLP/GEP (Y/N): Y~~ ~~Published (Y/N): N~~	~~N~~	~~Corteva Agriscience~~
~~KCA 6.10.1/2~~	~~Appeltauer, A.~~	~~2020~~	~~Determination of residues of prothioconazole and its metabolites in honey after two applications of PTZ EC 250 in winter oilseed rape at 5 sites in Northern and Southern Europe in 2019.~~ ~~Bayer Report No.: M-682401-01-1 / Study Number: S19-00902~~ ~~Eurofins Agroscience Services Ltd~~ ~~GLP/GEP (Y/N): Y~~ ~~Published (Y/N): Y~~	~~N~~	~~BCS*~~
KCA 6.1/1	M. Lindner, A. Büdel	2019	Storage Stability of XDE-777 and X642188 in 5 Matrices under Deep Frozen Conditions DAS Report No.: 150026 Eurofins Agroscience Services Chem GmbH GLP/GEP (Y/N): Y Published (Y/N): N	N	Corteva Agriscience
KCA 6.1/3	Driss, F.	2021	Storage Stability of XDE-777 metabolite X12314005 in Oilseed Rape under Deep Frozen Conditions DAS Report No.: 200444	N	Corteva Agriscience

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
			Eurofins Agroscience Services Chem SAS GLP/GEP (Y/N): Y Published (Y/N): N		
~~KCA 6.1/4~~	~~Kalathoor, R.~~	~~2020~~	~~Amendment no. 01: Residue analytical method 01600 and short term storage stability of prothioconazole (JAU 6476) and its Metabolite JAU 6476-desthio in/on honey by HPLC-MS/MS~~ ~~Report No. M-68023-02-1, Reference No. S19-01124~~ ~~Eurofins Agroscience Services EcoChem GmbH / Eurofins Agroscience Services Ecotox GmbH, Niefern-Oeschelbronn, Germany~~ ~~GLP/GEP (Y/N): Y~~ ~~Published (Y/N): N~~	~~N~~	~~BCS*~~
~~KCA 6.1/5~~	~~Kalathoor, R.~~	~~2020~~	~~Residue analytical method 01601 and short term storage stability of the metabolites JAU 6476-alpha-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 honey by HPLC-MS/MS~~ ~~Report No. M-681477-01-1, Reference No. S19-01125~~ ~~Eurofins Agroscience Services EcoChem GmbH / Eurofins Agroscience Services Ecotox GmbH, Niefern-Oeschelbronn, Germany~~ ~~GLP/GEP (Y/N): Y~~ ~~Published (Y/N): N~~	~~N~~	~~BCS*~~
~~KCA 6.1/6~~	~~Kalathoor, R.~~	~~2020~~	~~Amendment no. 02: Residue analytical method 01602 and short term storage stability of 1,2,4-triazole, triazole alanine, triazole acetic acid and triazole lactic acid in/on honey by HPLC-DMS-MS/MS - Report amendment no. 1~~ ~~Report No. M-680825-03-1, Reference No. S19-01126~~ ~~Eurofins Agroscience Services EcoChem GmbH / Eurofins Agroscience Services Ecotox GmbH, Niefern-Oeschelbronn, Germany~~ ~~GLP/GEP (Y/N): Y~~ ~~Published (Y/N): N~~	~~N~~	~~BCS*~~
~~KCA 6.1/2~~	~~Heinemann, O.~~	~~2003~~	~~36 months storage stability of residues of JAU6476 and JAU6476-desthio during frozen storage in/on wheat matrices.~~ ~~Report no: MR-354/01~~ ~~Edition No: M-081351-02/1~~ ~~GLP/GEP (Y/N): N~~ ~~Published (Y/N): N~~	~~N~~	~~BCS*~~

*Letter of Access is provided in Part A for Bayer CropScience data

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
KCA 6.1/2	Heinemann, O.	2003	36 months storage stability of residues of JAU6476 and JAU6476-desthio during frozen storage in/on wheat matrices. Report no: MR-354/01 Edition No: M-081351-02/1 GLP/GEP (Y/N): N Published (Y/N): N	N	BCS*
KCA 6.1/2	Weir, A	2014	XDE-777 and Its Metabolite X642188 Storage Stability in Wheat and Wheat Processed Fractions Stored Frozen for up to 24 Months DAS Report No.: 120749 Eurofins Agroscience Services Chem Ltd GLP/GEP (Y/N): Y Published (Y/N): N	N	Corteva Agriscience
KCA 6.1/4	Devine, HC	2014	Frozen Storage Stability of Residues of XDE-777 and Its Metabolites (X642188 and X12326349) in Animal Matrices Final Report DAS Report No.: 130709 CEM Analytical Services Ltd. GLP/GEP (Y/N): Y Published (Y/N): N	N	Corteva Agriscience
KCA 6.2.1/1	Ma, M Jackson, U	2013	A NATURE OF THE RESIDUE STUDY WITH [14C]-XR-777 APPLIED TO WHEAT DAS Report No.: 110334 Dow AgroSciences LLC; Research for Hire GLP/GEP (Y/N): Y Published (Y/N): N	N	Corteva Agriscience
KCA 6.2.1/2	Wu, S	2013a	A Nature of the Residue Study with [14C]-XDE-777 Applied to Tomatoes DAS Report No.: 121003 Symbiotice Research, LLC, Research For Hire (RFH) GLP/GEP (Y/N): Y Published (Y/N): N	N	Corteva Agriscience
KCA 6.2.1/3	Wu, S	2013b	A Nature of the Residue Study with [14C]-XDE-777 Applied to Cabbage DAS Report No.: 121002 Symbiotice Research, LLC, Research For Hire (RFH) GLP/GEP (Y/N): Y	N	Corteva Agriscience

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
			Published (Y/N): N		
KCA 6.2.2	[redacted]	2013	A Nature of the Residue Study in the Laying Hen with [14C]-XDE-777 DAS Report No.: 110421 [redacted] GLP/GEP (Y/N): Y Published (Y/N): N	~~N~~ Y	Corteva Agriscience
KCA 6.2.3	[redacted]	2013	A NATURE OF THE RESIDUE STUDY IN THE RUMINANT WITH [14C]-XR-777 DAS Report No.: 110766 [redacted] GLP/GEP (Y/N): Y Published (Y/N): N	Y	Corteva Agriscience
KCA 6.4.2/1	[redacted]	2013	XDE-777 Livestock Feeding Study: Magnitude of Residue in Milk, Muscle, Liver, Kidney and Fat of Lactating Dairy Cattle DAS Report No.: 130949 [redacted] GLP/GEP (Y/N): Y Published (Y/N): N	~~N~~ Y	Corteva Agriscience
KCA 6.5.1/1	Ma, M Zhou, X Brackman, R	2013	Processing Study to Determine the Nature of Residues of [14C]-XDE-777 Following Industrial or Household Preparation DAS Report No.: 121153 Dow AgroSciences LLC GLP/GEP (Y/N): Y Published (Y/N): N	N	Corteva Agriscience
KCA 6.6.1/1	Ma, M Aldelfinskaya, Y	2014	A Confined Rotational Crop Study with [14C]-XDE-777, 2014 Final Report DAS Report No.: 140050 Dow AgroSciences LLC GLP/GEP (Y/N): Y Published (Y/N): N	N	Corteva Agriscience

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	Heinemann, O.	2001	18 months storage stability of residues of JAU 6476 and JAU 6476-Desthio during frozen storage in/on wheat matrices Bayer CropScience, Report No.: MR-282/00, Edition Number: M-072461-01-1 Date: 2001-09-13 Bayer AG, Leverkusen, Germany GLP/GEP: yes, unpublished	N	BCS*
KCA 6.1/03	Freitag, T.	2005	Storage stability of Prothioconazole-desthio in/on canola, spinach, sugar beet, tomato, and pea during freezer storage for 24 months (incl. Amendment no. 001 dated 04.06.2007) Report no: MR-07/282 (new)/ MR-066/03 (old) Edition No: M-258955-01-1/M258955-02-1 GLP/GEP: Y Published: N	N	BCS*
KCA 6.4.2 /01	[redacted]	2001	JAU 6476-desthio - Dairy cattle feeding study Report No.: MR-535/00, Edition Number: M-078342-01-1, Date: 2001-10-15 [redacted] GLP/GEP: yes, unpublished	Y	BCS*
KCA 6.2.1 /01	Haas, M.; Bornatsch, W.	2000	Metabolism of JAU6476 in spring wheat (after foliar application) Bayer CropScience, Report No.: MR-198/99, Edition Number: M-041657-01-1, EPA MRID No.: 46246141, Date: 2000-07-10 Bayer AG, Leverkusen, Germany GLP/GEP: yes, unpublished	N	BCS*
KCA 6.2.1 /04	Vogeler, K.; Sakamoto, H.; Brauner, A.	1993	Metabolism of SXX 0665 in summer wheat Bayer CropScience, Report No.: PF3906, Edition Number: M-008633-01-1, Date: 1993-08-13 Bayer AG, Leverkusen, Germany GLP/GEP: yes, unpublished	N	BCS*

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.2.1 /02	Duah, F. K.; Lopez, R. T.	2004	The metabolism of [triazole-3,5-14 C] JAU 6476 in wheat Bayer CropScience, Report No.: 200733, Edition Number: M-001524-01-1, EPA MRID No.: 46246143, Date: 2004-03-12 Bayer CropScience LP, Stilwell, KS, USA GLP/GEP: yes, unpublished	N	BCS*
KCA 6.2.1 /03	Haas, M.	2001	Metabolism of JAU 6476 in spring wheat after seed dressing Bayer CropScience, Report No.: MR-467/99, Edition Number: M-030412-01-3, EPA MRID No.: 46246142, Date: 2001-05-10 Bayer AG, Leverkusen, Germany GLP/GEP: yes, unpublished	N	BCS*
KCA 6.2.1 /07	Beedle, E. C.; Ying, S. L.	2004	The metabolism of [phenyl-UL-14C]JAU6476 in sugar beets Bayer CropScience, Report No.: 200466, Edition Number: M-001059-01-1, EPA MRID No.: 46246148, Date: 2004-03-11 Bayer CropScience LP, Stilwell, KS, USA GLP/GEP: yes, unpublished	N	BCS*
KCA 6.2.1 /08	Beedle, E. C.; Ying, S. L.	2004	The metabolism of [triazole-UL-14C]JAU6476 in sugar beets Bayer CropScience, Report No.: 200467, Edition Number: M-001049-01-1, EPA MRID No.: 46246147, Date: 2004-03-11 Bayer CropScience LP, Stilwell, KS, USA GLP/GEP: yes, unpublished	N	BCS*
KCA 6.2.1 /05	Haas, M.	2001	Metabolism of [phenyl-UL-14C]JAU6476 in peanuts Bayer CropScience, Report No.: MR-193/01, Edition Number: M-033059-01-2, EPA MRID No.: 46246145, Date: 2001-11-27 Bayer AG, Leverkusen, Germany GLP/GEP: yes, unpublished	N	BCS*

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.2.1 /06	Haas, M.	2003	Metabolism of [triazole-UL-14C]JAU6476 in peanuts Report No.: MR-194/02, Edition Number: M-103268-01-2, EPA MRID No.: 46246146, Date: 2003-12-01 Bayer CropScience, GLP/GEP: yes, unpublished	N	BCS*
KCA 6.6.1 /01	Haas, M.	2001	Confined rotational crop study with JAU6476 Bayer CropScience, Report No.: MR-159/00, Edition Number: M-049955-01-1, EPA MRID No.: 46246225, Date: 2001-05-14 Bayer AG, Leverkusen, Germany GLP/GEP: yes, unpublished	N	BCS*
KCA 6.5.1 /01	Gilges, M.	2001	Hydrolysis of JAU 6476 under conditions of processing Bayer CropScience, Report No.: MR-166/00, Edition Number: M-035289-01-1, Date: 2001-01-29 Bayer AG, Leverkusen, Germany GLP/GEP: yes, unpublished	N	BCS*
KCA 6.2.3 /06	[redacted]	2011	[Triazole-UL-14C]JAU 6476-desthio: Metabolism in the lactating goat Report No.: MEF-11/011, Edition Number: M-404996-02-1, Date: 2011-03-31, ...Amended: 2011-06-16 GLP/GEP: yes, unpublished	Y	BCS*
KCA 6.2.3 /04	[redacted]	2006	[Phenyl-UL-14C]JAU 6476-desthio: Absorption, distribution, excretion and metabolism in the lactating goat - Subsequent identification of metabolite hydrolysis products Report No.: MEF-06/469, Edition Number: M-279178-01-1 Date: 2006-10-10 GLP/GEP: no, unpublished	Y	BCS*
KCA 5.1.2 /01	[redacted]	2003	[Triazole-UL-14C]JAU 6476: Absorption, distribution, excretion, and metabolism in the lactating goat Report No.: MR-448/02, Edition Number: M-116219-02-1 Date: 2003-10-20, ...Amended: 2005-06-06 GLP/GEP: yes, unpublished	Y	BCS*

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
6.2.2 /02	[redacted]	2003	[Triazole-UL- 14C]JAU6476: Absorption, distribution, excretion, and metabolism in laying hens Report No.: MEF-005/03, Edition Number: M-109936-02-1, Date: 2003-06-23, ...Amended: 2003-07-14 GLP/GEP: yes, unpublished	Y	BCS*
KCA 6.2.2 /01	[redacted]	2001	[Phenyl-UL-14C]JAU6476 - Absorption, distribution, excretion and metabolism in laying hens Report No.: MR-309/01, Edition Number: M-032686-01-2, EPA MRID No.: 46246202, Date: 2001-10-29 [redacted] GLP/GEP: yes, unpublished	Y	BCS*

*Letter of Access is provided in Part A for Bayer CropScience data

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
KCA 6.3.1/2	Semrau, J., Thomas, B.	2019	Residues of Fenpicoxamid and Prothioconazole in Barley at Interval and at Harvest Following Two Applications of GF-3307 – Southern and Northern Europe – 2017 and 2018. Report No. S17-01904/ 170191. Eurofins AgroScience Services GmbH, Carl-Goerdeler-Weg 5 21684 Stade, Germany GLP/GEP (Y/N): Yes Published (Y/N): No	N	Corteva Agriscience
KCA 6.1/4	Kalathoor, R.	2020	Amendment no. 01: Residue analytical method 01600 and short term storage stability of prothioconazole (JAU 6476) and its Metabolite JAU 6476-desthio in/on honey by HPLC-MS/MS Report No. M-68023-02-1, Reference No. S19-01124 Eurofins Agroscience Services EcoChem GmbH / Eurofins Agroscience Services Ecotox GmbH, Niefern-Oeschelbronn, Germany GLP/GEP (Y/N): Y Published (Y/N): N	N	BCS*
KCA 6.1/5	Kalathoor, R.	2020	Residue analytical method 01601 and short term storage stability of the metabolites JAU 6476-alpha-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 honey by HPLC-MS/MS Report No. M-681477-01-1, Reference No. S19-01125	N	BCS*

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Eurofins Agroscience Services EcoChem GmbH / Eurofins Agroscience Services Ecotox GmbH, Niefern-Oeschelbronn, Germany GLP/GEP (Y/N): Y Published (Y/N): N		
KCA 6.1/6	Kalathoor, R.	2020	Amendment no. 02: Residue analytical method 01602 and short term storage stability of 1,2,4-triazole, triazole alanine, triazole acetic acid and triazole lactic acid in/on honey by HPLC-DMS-MS/MS - Report amendment no. 1 Report No. M-680825-03-1, Reference No. S19-01126 Eurofins Agroscience Services EcoChem GmbH / Eurofins Agroscience Services Ecotox GmbH, Niefern-Oeschelbronn, Germany GLP/GEP (Y/N): Y Published (Y/N): N	N	BCS*
KCA 6.10.1/1	Appeltauer, A	2021	Determination of Residues of Fenpicoxamid and Prothioconazole in Nectar, Pollen and Plants of Winter Oilseed Rape after One Application of GF-3307 in a Semi-Field Residue Study in Central and Southern Europe in 2020. DAS Report No.: 200670 Eurofins Agroscience Services Ltd GLP/GEP (Y/N): Y Published (Y/N): N	N	Corteva Agriscience
KCA 6.10.1/2	Appeltauer, A.	2020	Determination of residues of prothioconazole and its metabolites in honey after two applications of PTZ EC 250 in winter oilseed rape at 5 sites in Northern and Southern Europe in 2019. Bayer Report No.: M-682401-01-1 / Study Number: S19-00902 Eurofins Agroscience Services Ltd GLP/GEP (Y/N): Y Published (Y/N): Y	N	BCS*

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

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

Appendix 2 Detailed evaluation of the additional studies relied upon

Fenpicoxamid and Prothioconazole

Stability of residues

Stability of residues during storage of samples

No new studies presented.

Storage stability of residues in plant products

Storage stability study S17-04000/150026

Comments of zRMS:	The storage stability of fenpicoxamid (XDE-777) and X642188 was checked in matrices of plant origin under deep frozen conditions (≤ -20 C°) in the dark over a storage period up to 18 months in accordance to OECD Guideline 506. The stability of the analytes was investigated in the following five (5) matrices: lettuce (high water content), oilseed rape (seeds) (high oil content), orange (whole fruit) (high acid content), potato (high starch content) and beans (dried) (high protein content). The analytical method was successfully validated for determination fenpicoxamid and its metabolite X642188 in/on lettuce, oilseed rape seed, orange (whole fruit), potato and beans (dried) with an LOQ of 0.01 mg/kg. Conclusion: Stability upon storage at ≤ -20 °C for up to 18 months was demonstrated for fenpicoxamid in homogenates of lettuce, oilseed rape (seeds), orange (whole fruit) and beans (dried) and for its metabolite X642188 in homogenates of all tested matrices. Stability of fenpicoxamid in homogenates of potato upon storage at ≤ -20°C was demonstrated for up to 12 months. The study is acceptable.

Reference:	Lindner, M., Büdel, A.; 2019; Storage Stability of XDE-777 and X642188 in 5 Matrices under Deep Frozen Conditions; Lab Study No. S17-04000; DAS Study No. 150026; 27 May 2019; Unpublished
Guideline(s) followed in the study:	Regulation (EC) No 1107/2009, OECD 506, 2007, SANCO/3029/00, rev. 4, OPPTS 860.1380, OPPTS 860.1340
Deviations:	None with impact on the study
GLP:	Yes
Validity of the study:	Yes

STUDY SUMMARY

This study was conducted to demonstrate the stability of fenpicoxamid (XDE-777) in 5 matrices of plant origin when stored under deep frozen conditions (≤ -20 °C) in the dark for up to 18 months.

Samples of lettuce, oilseed rape (seeds), orange (whole fruit), potato and beans (dried) were fortified with fenpicoxamid (XDE-777) at a level of 0.1 mg/kg (ppm) and put into storage at ≤ -20 °C. At intervals of 1, 3, 6, 12 and 18 months, stored samples and freshly fortified samples were analyzed for residues of fenpicoxamid.

At each storage interval, fenpicoxamid was determined using an analytical procedure as validated in Dow AgroSciences Study no. 120615. Residues are extracted from homogenized samples of lettuce, oilseed rape (seeds), orange (whole fruit), potato and beans (dried) using acetonitrile / water (9:1, v/v) and cleaned up by centrifugation and filling up of the centrifuged extracts with acetonitrile / water (9:1, v/v) containing 0.1 % formic acid. Extracted residue levels are determined by LC-MS/MS. The analytical method was previously validated in Dow AgroSciences Study Study no. 120615. Acceptable method validation and concurrent recoveries were reported for crops at fortification levels of 0.01 mg/kg

(ppm) and 0.1 mg/kg (ppm). The limit of quantitation (LOQ) was 0.01 ppm per analyte for all tested matrices.
Furthermore, the method was successfully validated within this study for determination of fenpicoxamid in/on lettuce [high water content], oilseed rape seed [high oil content], orange (whole fruit) [high acid content], potato [high starch content] and beans (dried) [high protein content] with an LOQ of 0.01 mg/kg (ppm) according to the guidance documents OPPTS 860.1340 and SANCO/3029/00, rev.4
Stability upon storage at ≤ -20 °C for up to 18 months was demonstrated for fenpicoxamid in homogenates of lettuce, oilseed rape (seeds), orange (whole fruit) and beans (dried) . Stability of fenpicoxamid in homogenates of potato upon storage at ≤ -20 °C was demonstrated for up to 12 months.
With regard to selectivity, accuracy and precision, the analytical method was applied successfully when analysing the storage samples.

Method Scope

The analytical method used for the determination of fenpicoxamid (XDE-777) was analytical procedure based on Dow AgroSciences Study no. 120615. This method is applicable for the quantitative determination of residues of fenpicoxamid in agricultural commodities (lettuce [high water content], oilseed rape seed [high oil content], orange (whole fruit) [high acid content], potato [high starch content] and beans (dried) [high protein content]). The method was validated over the concentration range of 0.003-0.4 mg/kg with a validated limit of quantitation of 0.01 mg/kg.

Method Principle

Residues of fenpicoxamid are extracted from samples by an analytical procedure based on Dow AgroSciences Study no. 120615. The final sample is analyzed for fenpicoxamid by liquid chromatography coupled with positive-ion electrospray tandem mass spectrometry (LC-MS/MS).

Test Procedure

Sample Weights, Fortification and Storage
Aliquots of the homogenised matrix material were transferred into glass bottles with screw caps and fortified with the test items. For storage samples the analytes were fortified separately, while procedural recovery samples were prepared by fortifying both analytes jointly.
A standard solution of the test items was distributed dropwise to the thawed sample. The sample was then mixed by brief swirling to ensure distribution of the test items in the respective matrices. The solvent was allowed to evaporate for approx. 10 min.

Table 2:Summary of fortification

Sample weight (g)	Analyte	Solvent of Fortification Solution	Analyte concentration of fortification solution (µg/mL)	Volume of fortification solution added (mL)	Fortification level (each) (mg/kg)
5.0 ± 0.05*	Fenpicoxamid	Acetonitrile	5.0	0.100	0.10 (10x LOQ)

* for all test systems: lettuce, oilseed rape (seeds), orange (whole fruit), potato, beans (dried)

After that procedure, the glass bottle with screw cap was closed and placed into the deep freezer in the dark. Storage samples were kept at ≤ 20 °C on average. The temperature was recorded during the entire storage period.
For each storage interval (0, 1, 3, 6, 12 and 18 months), a set of at least three (3) fortified samples were prepared as storage samples for each matrix. In addition a number of two (2) complete interval sets was prepared per matrix at the beginning of the experimental phase as backup samples for each matrix.
On day 0, three (3) of the storage/recovery samples at 10x LOQ per matrix were analysed together with one (1) control sample, while the rest of fortified samples was put into the freezer. Furthermore, two (2) recovery samples at LOQ were analysed at day 0 for each matrix.
For each further testing interval (1, 3, 6, 12 and 18 months) three (3) storage samples per matrix were analysed together with one (1) control sample and three (3) procedural recoveries at the level of 10x LOQ.

Table 3:Summary of numbers of recoveries and analyses

Storage Interval (≤ -20 °C)	No. of untreated (control) samples	No. of procedural recovery samples [a] (level)	No. of storage samples [b] (10x LOQ)	No. of analyses
day 0 (start)	1	2 (LOQ)	N/A	6
		3 (10x LOQ)		
1 months	1	3 (10x LOQ)	6 (3 per analyte)	10
3 months	1	3 (10x LOQ)	6 (3 per analyte)	10
6 months	1	3 (10x LOQ)	6 (3 per analyte)	10
12 months	1	3 (10x LOQ)	6 (3 per analyte)	10
18 months	1	3 (10x LOQ)	6 (3 per analyte)	10

[a] prepared by fortifying all analytes (fenpicoxamid and X642188) jointly
[b] analytes (fenpicoxamid and X642188) fortified separately

Linearity

For each analyte, the linearity of detector response was evaluated using solvent standard solutions. Calibration curves were calculated by linear regression analysis with 1/x weighting.

RESULTS AND DISCUSSION

Method Performance

The validated method performance was further demonstrated by virtue of concurrent recovery samples analyzed in this study. Mean concurrent recovery values were 70-110%; RSD ≤ 20%. The results obtained are summarised in the following tables.

Table 4:Summary of quantitative recovery of fenpicoxamid (m/z 615/239)

Matrix group	Matrix	Fortification level	Recovery (%)*		SD	RSD	n
		(mg/kg)	mean	range	(%)	(%)	
"High water"	Lettuce	0.010	97	96-97	n.a.	n.a.	2
"High water"	Lettuce	0.10	98	87-106	5.4	5.5	18
"High oil"	Oilseed Rape (Seeds)	0.010	73	72-73	n.a.	n.a.	2
"High oil"	Oilseed Rape (Seeds)	0.10	102	82-114	9.4	9.2	18
"High acid"	Orange (Whole Fruit)	0.010	97	76-117	n.a.	n.a.	2
"High acid"	Orange (Whole Fruit)	0.10	101	91-115	5.8	5.8	18
"High starch"	Potato	0.010	96	92-99	n.a.	n.a.	2
"High starch"	Potato	0.10	98	85-119	8.7	8.9	18
"High protein"	Beans (dried)	0.010	86	80-91	n.a.	n.a.	2
"High protein"	Beans (dried)	0.10	100	89-110	7.5	7.5	18

n.a. = not applicable; * including day 0 storage samples

Table 5:Results of frozen storage stability samples for Fenpicoxamid residues – Lettuce

Days of storage	Spike level µg/g	Uncorrected* µg/g found (rounded)	Recovery (%) (rounded)	Mean (%) [a]	SD (%) [a]	RSD (%) [a]	Corrected** µg/g found [a]	Recovery (%) (rounded)	Mean (%) [a]	SD (%) [a]	RSD (%) [a]
0	0.10	0.093	93	97	3.6	3.7	-	-	-	-	-
0	0.10	0.100	100				-	-			
0	0.10	0.098	98				-	-			
14	0.10	0.098	98	97	3.6	3.7	0.096	96	95	3.6	3.8
14	0.10	0.100	100				0.098	98			
14	0.10	0.093	93				0.091	91			

Days of storage	Spike level µg/g	Uncorrected* µg/g found (rounded)	Recovery (%) (rounded)	Mean (%) [a]	SD (%) [a]	RSD (%) [a]	Corrected** µg/g found [a]	Recovery (%) (rounded)	Mean (%) [a]	SD (%) [a]	RSD (%) [a]
88	0.10	0.087	87	82	5.0	6.2	0.097	97	91	5.6	6.1
88	0.10	0.081	81				0.090	90			
88	0.10	0.077	77				0.086	86			
176	0.10	0.085	85	94	9.0	9.6	0.086	86	95	9.0	9.5
176	0.10	0.103	103				0.104	104			
176	0.10	0.093	93				0.094	94			
384	0.10	0.091	91	87	3.6	4.1	0.091	91	87	3.6	4.1
384	0.10	0.084	84				0.084	84			
384	0.10	0.086	86				0.086	86			
552	0.10	0.095	95	88	6.1	6.9	0.094	94	87	6.1	7.0
552	0.10	0.087	87				0.086	86			
552	0.10	0.083	83				0.082	82			

* Uncorrected for procedural recoveries
** Corrected for procedural recoveries
[a] calculated from rounded values

Table 6:Results of frozen storage stability samples for fenpicoxamid residues – Oilseed Rape (Seeds)

Days of storage	Spike level µg/g	Uncorrected* µg/g found (rounded)	Recovery (%) (rounded)	Mean (%) [a]	SD (%) [a]	RSD (%) [a]	Corrected** µg/g found [a]	Recovery (%) (rounded)	Mean (%) [a]	SD (%) [a]	RSD (%) [a]
0	0.100	0.082	82	89	6.1	6.9	-	-	-	-	-
0	0.100	0.094	94				-	-			
0	0.100	0.090	90				-	-			
26	0.100	0.104	104	97	8.9	9.2	0.095	95	88	8.3	9.4
26	0.100	0.100	100				0.091	91			
26	0.100	0.087	87				0.079	79			
101	0.100	0.089	89	88	1.5	1.7	0.085	85	84	1.5	1.8
101	0.100	0.088	88				0.084	84			
101	0.100	0.086	86				0.082	82			
189	0.100	0.078	78	84	5.5	6.6	0.086	86	92	6.0	6.5
189	0.100	0.084	84				0.092	92			
189	0.100	0.089	89				0.098	98			
397	0.100	0.086	86	87	1.7	2.0	0.082	82	83	1.7	2.1
397	0.100	0.086	86				0.082	82			
397	0.100	0.089	89				0.085	85			
565	0.100	0.080	80	81	3.2	4.0	0.073	73	74	2.6	3.6
565	0.100	0.085	85				0.077	77			
565	0.100	0.079	79				0.072	72			

* Uncorrected for procedural recoveries
** Corrected for procedural recoveries
[a] calculated from rounded values

Table 7:Results of frozen storage stability samples for fenpicoxamid residues – Orange (Whole Fruit)

Days of storage	Spike level µg/g	Uncorrected* µg/g found (rounded)	Recovery (%) (rounded)	Mean (%) [a]	SD (%) [a]	RSD (%) [a]	Corrected** µg/g found [a]	Recovery (%) (rounded)	Mean (%) [a]	SD (%) [a]	RSD (%) [a]
0	0.100	0.091	91	95	3.6	3.8	-	-	-	-	-
0	0.100	0.096	96				-	-			
0	0.100	0.098	98				-	-			
20	0.100	0.088	88	86	2.0	2.3	0.086	86	84	2.0	2.4
20	0.100	0.086	86				0.084	84			
20	0.100	0.084	84				0.082	82			
94	0.100	0.081	81	86	5.0	5.9	0.085	85	90	5.6	6.2
94	0.100	0.085	85				0.089	89			
94	0.100	0.091	91				0.096	96			
182	0.100	0.098	98	91	6.6	7.2	0.097	97	90	6.6	7.3
182	0.100	0.085	85				0.084	84			
182	0.100	0.090	90				0.089	89			
390	0.100	0.094	94	94	3.5	3.7	0.088	88	88	3.5	4.0
390	0.100	0.098	98				0.092	92			
390	0.100	0.091	91				0.085	85			
558	0.100	0.095	95	92	3.1	3.3	0.092	92	89	3.1	3.4
558	0.100	0.091	91				0.088	88			
558	0.100	0.089	89				0.086	86			

* Uncorrected for procedural recoveries
** Corrected for procedural recoveries
[a] calculated from rounded values

Table 8:Results of frozen storage stability samples for fenpicoxamid residues – Potato

Days of storage	Spike level µg/g	Uncorrected* µg/g found (rounded)	Recovery (%) (rounded)	Mean (%) [a]	SD (%) [a]	RSD (%) [a]	Corrected** µg/g found [a]	Recovery (%) (rounded)	Mean (%) [a]	SD (%) [a]	RSD (%) [a]
0	0.10	0.100	100	105	11.9	11.3	-	-	-	-	-
0	0.10	0.119	119				-	-			
0	0.10	0.097	97				-	-			
22	0.10	0.092	92	88	5.5	6.2	0.090	90	86	5.5	6.4
22	0.10	0.091	91				0.089	89			
22	0.10	0.082	82				0.080	80			
96	0.10	0.078	78	78	3.0	3.8	0.081	81	81	3.0	3.7
96	0.10	0.075	75				0.078	78			
96	0.10	0.081	81				0.084	84			
203	0.10	0.068	68	70	2.6	3.8	0.078	78	80	3.2	4.0
203	0.10	0.069	69				0.079	79			
203	0.10	0.073	73				0.084	84			
392	0.10	0.070	70	72	7.2	10.0	0.074	74	76	7.6	10.1
392	0.10	0.080	80				0.084	84			
392	0.10	0.066	66				0.069	69			
560	0.10	0.060	60	63	3.0	4.8	0.059	59	62	3.0	4.8

Days of storage	Spike level µg/g	Uncorrected* µg/g found (rounded)	Recovery (%) (rounded)	Mean (%) [a]	SD (%) [a]	RSD (%) [a]	Corrected** µg/g found [a]	Recovery (%) (rounded)	Mean (%) [a]	SD (%) [a]	RSD (%) [a]
560	0.10	0.063	63				0.062	62			
560	0.10	0.066	66				0.065	65			

* Uncorrected for procedural recoveries
** Corrected for procedural recoveries
[a] calculated from rounded values

Table 9:Results of frozen storage stability samples for fenpicoxamid residues – Beans (dried)

Days of storage	Spike level µg/g	Uncorrected* µg/g found (rounded)	Recovery (%) (rounded)	Mean (%) [a]	SD (%) [a]	RSD (%) [a]	Corrected** µg/g found [a]	Recovery (%) (rounded)	Mean (%) [a]	SD (%) [a]	RSD (%) [a]
0	0.10	0.107	107	106	2.1	2.0	-	-	-	-	-
0	0.10	0.108	108				-	-			
0	0.10	0.104	104				-	-			
21	0.10	0.081	81	83	2.1	2.5	0.090	90	92	2.1	2.3
21	0.10	0.084	84				0.093	93			
21	0.10	0.085	85				0.094	94			
96	0.10	0.092	92	92	0.0	0.0	0.091	91	91	0.0	0.0
96	0.10	0.092	92				0.091	91			
96	0.10	0.092	92				0.091	91			
184	0.10	0.090	90	93	2.6	2.8	0.086	86	89	2.3	2.6
184	0.10	0.094	94				0.090	90			
184	0.10	0.095	95				0.090	90			
392	0.10	0.083	83	91	7.4	8.1	0.090	90	99	7.9	8.0
392	0.10	0.094	94				0.102	102			
392	0.10	0.097	97				0.105	105			
560	0.10	0.095	95	99	4.0	4.1	0.090	90	94	3.5	3.7
560	0.10	0.103	103				0.097	97			
560	0.10	0.100	100				0.094	94			

* Uncorrected for procedural recoveries
** Corrected for procedural recoveries
[a] calculated from rounded values

CONCLUSION

The data indicate that residues of fenpicoxamid are stable for at least 552 days (approx. 18 months) in homogenates of lettuce, oilseed rape (seeds), orange (whole fruit) and beans (dried) stored under frozen conditions.

For potato, the average amount of fenpicoxamid that was recovered after 6, 12 and 18 months relative to the initial recovery at day 0 was < 70 %. However the amount recovered corrected for the mean procedural recovery of the individual date of extraction and the amount recovered corrected for the mean procedural recovery of the individual date of extraction relative the mean recovered at Day 0 were ≥ 70 % after 6 and 12 months.

Therefore, storage stability data for fenpicoxamid in potato indicated a decline in concentration over the tested time interval; nevertheless the data supports storage stability of fenpicoxamid in potato for up to 392 days (approx. 12 months).

Storage stability study #S20-01461/200444

Comments of zRMS:	The storage stability of metabolite X12314005 has been checked in oilseed rape (whole plant, seeds and remaining plant) under deep frozen conditions (≤ -20 C°) in the dark over a storage period up to 12 months in accordance to OECD Guideline 506. The analytical method was successfully validated for determination of metabolite X12314005 in oilseed rape (whole plant, seeds and remaining plant) with an LOQ of 0.01 mg/kg. <u>Conclusion:</u> The stability was demonstrated for X12314005 in homogenates of matrices whole plant, seeds and remaining plant of oilseed rape upon storage at ≤ -18 °C in the dark for 12 months. The study is acceptable.

Reference:	Driss, F; 2021; Storage Stability of XDE-777 metabolite X12314005 in Oilseed Rape under Deep Frozen Conditions ; Eurofins Agroscience Services Chem SAS, 75B, Avenue de Pascalet 30310 Vergèze; Lab Study No. S20-01461; Sponsor Study No. 200444 ; 30 November 2021; Published: No
Guideline(s) followed in the study:	Regulation (EC) No 1107/2009, OECD 506, 2007, SANCO/3029/00, rev. 4, OPPTS 860.1380
Deviations:	None
GLP:	Yes
Validity of the study:	Yes

STUDY SUMMARY

This study is being demonstrated the stability of X12314005 in oilseed rape (whole plant, seeds and remaining plant) at ≤ 20 °C (target) in the dark over a storage period up to 12 months
Residues of X12314005 are extracted with an acetonitrile/ultra-pure water/orthophosphoric acid solution. Extracted residue levels are determined by LC-MS/MS.
Acceptable method validation and concurrent recoveries were reported for oilseed rape samples at fortification levels of 0.01 mg/kg (ppm), thus validating the method.
The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for each matrix.
For all matrices the average amount of analyte recovered relative to the initial recovery at day 0 was ≥ 70 % at any testing interval, which can be seen as criterion for sufficient storage stability. Thus, stability was demonstrated for X12314005 in homogenates of matrices whole plant, seeds and remaining plant of oilseed rape upon storage at ≤ -18 °C in the dark for 12 months.

Method Scope

Method Principle

Test Procedure

An amount of homogenised sample material is weighed into a polypropylene tube with screw cap and fortified at 0.1 mg/kg (10x LOQ) with the reference item.
The reference item in a standard solution is distributed dropwise to the thawed sample with a solvent volume not exceeding a total of 2 % of the sample extraction volume per sample.
The sample is mixed by brief swirling to ensure distribution of the reference item in the respective matrix.
The solvent is allowed to evaporate for approx. 10 min.
After that procedure the polypropylene tube with screw cap is closed and placed into the deep freezer.
For day 0 testing a set of three (3) storage samples will be prepared. For each of the other storage intervals (0, 3, 6, 9 and 12 months) a set of at least nine (9) fortified samples consisting of three (3) storage samples for analysis and six (6) storage samples as backup is prepared.

Linearity

For each analyte, the linearity of detector response was evaluated using solvent standard solutions. Calibration curves were calculated by linear regression analysis with 1/x weighting.

Table 1: Linearity

Days of storage	Analyte	Number of stands	Range min (ng/mL)	Range max (ng/mL)	Regression	Correlation coefficient (R^2)
0	X12314005	8	0.05	10	linear with 1/x weighting	0.98
32	X12314005	8	0.05	10	linear with 1/x weighting	0.98
90	X12314005	8	0.05	10	linear with 1/x weighting	0.98
175	X12314005	8	0.05	10	linear with 1/x weighting	0.98
266	X12314005	8	0.05	10	linear with 1/x weighting	0.98
360	X12314005	8	0.05	10	linear with 1/x weighting	0.98

RESULTS AND DISCUSSION

Method Performance

The method performance was demonstrated by virtue of concurrent recovery samples analyzed in this study. Mean concurrent recovery values were 70-120%; RSD ≤ 20%. The results obtained are summarised in the following tables.

Table 2: Summary of quantitative ~~quantitative~~ recovery of X12314005 (m/z 277.1-189.1)

Matrix	Timepoint (months)	LOQ	Fortification level (mg/kg)	Recovery (%)		RSD	n
			mg/kg	mean	range	(%)	-
	Day 0	0.01	0.01	101	98-105	3.6	3
			0.1	105	98-126	9.8	6

OSR (Whole plant)	1	0.01	0.01	98	94-101	3.6	3
			0.1	96	96-98	1.2	3
	3	0.01	0.01	102	99-105	2.9	3
			0.1	104	101-106	2.8	3
	6	0.01	0.01	96	94-97	1.7	3
			0.1	95	94-97	1.6	3
	9	0.01	0.01	96	94-101	4.1	3
			0.1	99	98-99	0.7	3
	12	0.01	0.01	95	93-100	3.7	3
			0.1	100	97-102	2.6	3
OSR (Seeds)	Day 0	0.01	0.01	101	98-105	3.6	3
			0.1	105	98-126	9.8	6
	1	0.01	0.01	98	94-101	3.6	3
			0.1	96	96-98	1.2	3
	3	0.01	0.01	102	99-105	2.9	3
			0.1	104	101-106	2.8	3
	6	0.01	0.01	96	94-97	1.7	3
			0.1	95	94-97	1.6	3
	9	0.01	0.01	96	94-101	4.1	3
			0.1	99	98-99	0.7	3
	12	0.01	0.01	95	93-100	3.7	3
			0.1	100	97-102	2.6	3
OSR (Remaining plant)	Day 0	0.01	0.01	102	96-105	5.1	3
			0.1	104	98-123	9.1	6
	1	0.01	0.01	101	100-103	1.5	3
			0.1	102	99-104	2.5	3
	3	0.01	0.01	105	104-106	1.0	3
			0.1	105	104-106	1.0	3
	6	0.01	0.01	93	91-95	2.2	3
			0.1	99	95-105	5.6	3
	9	0.01	0.01	98	92-104	6.2	3
			0.1	103	101-105	2.0	3
	12	0.01	0.01	97	96-98	1.2	3
			0.1	97	94-99	2.7	3

Stability

Storage stability of X12314005 was demonstrated for up to 12 months in Oilseed rape.

Table 3: Results of frozen storage stability samples for X12314005 residues – Whole plant

Days of storage	Spike level µg/g	Uncorrected µg/g found	Recovery (%)	Mean (%)	SD (%)	RSD (%)	Corrected µg/g found	Recovery (%)	Mean (%)	SD (%)	RSD (%)
0	0.10	0.0989	99	100	0.016	1.6	0.0898	90	90	0.016	1.6
		0.1014	101				0.0921	92			
		0.0984	98				0.0894	89			
33	0.10	0.0971	97	98	0.014	1.4	0.1007	101	102	0.014	1.4
		0.0997	100				0.1034	103			
		0.0980	98				0.1016	102			
91	0.10	0.0915	91	92	0.013	1.3	0.0883	88	89	0.013	1.3
		0.0936	94				0.0903	90			
		0.0915	91				0.0883	88			
176	0.10	0.0951	95	98	0.063	6.3	0.1000	100	103	0.063	6.3
		0.0935	94				0.0983	98			
		0.1049	105				0.1103	110			
267	0.10	0.0991	99	93	0.033	3.3	0.0960	96	94	0.033	3.3
		0.0974	97				0.0944	94			
		0.0929	93				0.0901	90			
361	0.10	0.0947	95	94	0.018	1.8	0.0952	95	95	0.018	1.8
		0.0957	96				0.0961	96			
		0.0925	92				0.0928	93			

Table 4: Results of frozen storage stability samples for X12314005 residues – Seeds

Days of storage	Spike level µg/g	Uncorrected µg/g found	Recovery (%)	Mean (%)	SD (%)	RSD (%)	Corrected µg/g found	Recovery (%)	Mean (%)	SD (%)	RSD (%)
0	0.10	0.0997	100	99	0.024	2.4	0.0904	90	89	0.024	2.4
		0.1003	100				0.0910	91			
		0.0960	96				0.0870	87			
32	0.10	0.1082	108	108	0.013	1.3	0.1087	109	109	0.013	1.3
		0.1067	107				0.1072	107			
		0.1095	109				0.1100	110			
90	0.10	0.0997	100	99	0.005	0.5	0.0940	94	94	0.005	0.5
		0.0987	99				0.0930	93			
		0.0996	100				0.0938	94			
175	0.10	0.1072	107	107	0.028	2.8	0.1092	109	109	0.028	2.8
		0.1037	104				0.1057	106			
		0.1097	110				0.1118	112			
266	0.10	0.0987	99	101	0.051	5.1	0.0987	99	101	0.051	5.1
		0.0974	97				0.0974	97			
		0.1069	107				0.1069	107			
360	0.10	0.1026	103	106	0.027	2.7	0.1041	104	107	0.027	2.7
		0.1077	108				0.1093	109			
		0.1072	107				0.1088	109			

Table 5: Results of frozen storage stability samples for X12314005 residues – Remaining plant

Days of storage	Spike level µg/g	Uncorrected µg/g found	Recovery (%)	Mean (%)	SD (%)	RSD (%)	Corrected µg/g found	Recovery (%)	Mean (%)	SD (%)	RSD (%)
0	0.10	0.0995	99	99	0.009	0.9	0.0912	91	91	0.0090	0.9
		0.1002	100				0.0919	92			
		0.0984	98				0.0903	90			
32	0.10	0.0989	99	100	0.015	1.5	0.0974	97	99	0.015	1.5
		0.1020	102				0.1005	100			
		0.1003	100				0.0988	99			
90	0.10	0.0932	93	95	0.021	2.1	0.0888	89	90	0.021	2.1
		0.9700	97				0.0924	92			
		0.0941	94				0.0896	90			
175	0.10	0.0975	97	102	0.036	3.6	0.0988	99	103	0.036	3.6
		0.1038	104				0.1052	105			
		0.1037	104				0.1051	105			
266	0.10	0.0962	96	97	0.028	2.8	0.0938	94	95	0.028	2.8
		0.0953	95				0.0929	93			
		0.1004	100				0.0978	98			
360	0.10	0.0924	92	92	0.0070	0.7	0.0953	95	95	0.0070	0.7
		0.0930	93				0.0959	96			
		0.0917	92				0.0945	94			

CONCLUSION

The data indicates that residues of X12314005 are stable for at least 361 days (12 months) in oilseed rape stored under frozen conditions.

Storage stability of residues in animal products

Storage stability study M-680823-02-1/S19-00124

Comments of zRMS:	The study below was not evaluated by the zRMS in the framework of this application, since the study is not necessary to support the proposed uses of GF-3307 in sugar beet.

Title:	Amendment no. 01: Residue analytical method 01600 and short term storage stability of prothioconazole (JAU 6476) and its Metabolite JAU 6476-desthio in/on honey by HPLC-MS/MS
Author:	Kalathoor, R.
Edition Date:	18.05.2020
Report No:	M-680823-02-1
Reference No:	S19-01124
Guideline(s)	Regulation (EC) No 1107/2009 of the European Parliament and the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC Guidance document on residue analytical methods, SANCO/825/00/rev. 8.1, European Commission, Directorate General Health and Consumer Protection 16/11/2010 European Commission Guidance Document for Generating and Reporting Methods of Analysis in Support of Pre-Registration Data Requirements for Annex II (Part A, Section 4) and Annex III (Part A, Section 5) of Directive 91/414, SANCO/3029/99 rev. 4, 11/07/00 OECD 506, 2007; OECD Guideline for the Testing of Chemicals – Stability of Pesticide Residues in Stored Commodities SANTE/11956/2016 rev.9
Guideline Deviation(s)	None
GLP/GEP	yes
Testing Facility:	Eurofins Agroscience Services EcoChem GmbH / Eurofins Agroscience Services Ecotox GmbH, Niefern-Oeschelbronn, Germany
Sponsor:	Bayer
Owner:	BAY

Materials and methods

A study was conducted to determine the stability of residues of prothioconazole and its metabolite prothioconazole-desthio in 10xLOQ fortified samples of honey during deep-freeze storage for a period of *ca.* 6 months (180 days) at -18 °C. Samples were analysed after nominal storage intervals of 0, 1, 3, and 6 months.

The spiking solutions were prepared in acetonitrile/water (1/1, v/v) with addition of cysteine hydrochloride (250 g/L).

On day 0 (zero time analysis) five spiked samples per test item and two control samples were analysed to confirm the fortification level and performance of the method.

Further samples were also spiked with the single analytes at 0.10 mg/kg and stored in a deep-freezer at ≤-18°C. The temperature in the deep-freezer was recorded during the entire storage period. A slight temperature deviation (≤-17 °C for less than an hour) occurred about 90 days after day 0, which had no negative impact on the samples. After 1 month (34 days), 3 months (95 days) and 6 months (190 days), three fortified samples per analyte and one control sample were removed from the deep-freezer. Subsequently, two samples of honey were fortified with a mix of the analytes to determine the concurrent recoveries (fortification levels were at the same magnitude as the spiked storage samples). These samples were extracted and analyzed concurrently with the stored (unfortified) control samples and the spiked storage samples.

For storage samples the analytes were fortified separately, while concurrent recovery samples were prepared by fortifying all analytes jointly as a mix.
Residues of prothioconazole and prothioconazole-desthio in/on honey were determined by HPLC-MS/MS according to method 01600. The Limit of Quantification (LOQ) was defined as 0.01 mg/kg for each analyte expressed as itself.

Results and discussions

The performance of the analytical method was good during the conduct of the whole study. Indeed, average concurrent recoveries were deemed acceptable (between 99 and 105%) for both analytes.
After a deep-freezer storage (≤-18°C) period of about 6 months, the mean recovery rates were 92% for prothioconazole (JAU 6476) and 103% for prothioconazole-desthio in honey.

Table 2.2.1-1: Storage stability data and concurrent recovery data for prothioconazole (JAU 6476) and prothioconazole-desthio in honey

Matrix	Storage period (days)	Residues in stored samples			Average % of fresh concurrent recoveries
		mg/kg	% of nominal spiking level	Average % recovery	
Prothioconazole					
Honey	**0**	0.105, 0.103, 0.105, 0.106, 0.107	105, 103, 105, 106, 107	105	-
	34	0.0979, 0.101, 0.103	98, 101, 103	101	105
	95	0.0973, 0.0963, 0.0961	97, 96, 96	96	99
	190	0.0920, 0.0944, 0.0899	92, 94, 90	92	102
Prothioconazole-desthio					
Honey	**0**	0.107, 0.108, 0.107, 0.105, 0.105	107, 108, 107, 105, 105	106	-
	34	0.107, 0.106, 0.109	107, 106, 109	107	105
	95	0.104, 0.108, 0.106	104, 108, 106	108	105
	190	0.108, 0.100, 0.102	108, 100, 102	103	105

Conclusion

The storage stability demonstrated that the parent prothioconazole and prothioconazole-desthio are stable under deep-freeze conditions (-18 °C) in honey for at least *ca.* 6 months (190 days).

Storage stability study M-681477-01-1/S19-00125

Comments of zRMS:	The study below was not evaluated by the zRMS in the framework of this application, since the study is not necessary to support the proposed uses of GF-3307 in sugar beet.

Title:	Residue analytical method 01601 and short term storage stability of the metabolites JAU 6476-alpha-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 honey by HPLC-MS/MS
Author:	Kalathoor, R.
Edition Date:	26.03.2020
Report No:	M-681477-01-1
Reference No:	S19-01125
Guideline(s)	Regulation (EC) No 1107/2009 of the European Parliament and the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC Guidance document on residue analytical methods, SANCO/825/00/rev. 8.1, European Commission, Directorate General Health and Consumer Protection 16/11/2010 European Commission Guidance Document for Generating and Reporting Methods of Analysis in Support of Pre-Registration Data Requirements for Annex II (Part A, Section 4) and Annex III (Part A, Section 5) of Directive 91/414, SANCO/3029/99 rev. 4, 11/07/00 OECD 506, 2007; OECD Guideline for the Testing of Chemicals - Stability of Pesticide Residues in Stored Commodities SANTE/11956/2016 rev.9
Guideline Deviation(s)	None
GLP/GEP	yes
Testing Facility:	Eurofins Agroscience Services EcoChem GmbH / Eurofins Agroscience Services Ecotox GmbH, Niefern-Oeschelbronn, Germany
Sponsor:	Bayer
Owner:	BAY

Materials and methods

A study was conducted to determine the stability of residues of JAU 6476-α-hydroxy-desthio, JAU 6476-3-hydroxy-desthio, JAU 6476-4-hydroxy-desthio, JAU 6476-5-hydroxy-desthio and JAU 6476-6-hydroxy-desthio in 10xLOQ fortified samples of honey during deep-freeze storage for a period of about 6 months (180 days) at -18 °C. Samples were analysed after nominal storage intervals of 0, 1, 4, and 6 months.

The spiking solutions were prepared in acetonitrile/water (1/1, v/v).

On day 0 (zero time analysis) five spiked samples per test item and two control samples were analysed to confirm the fortification level and performance of the method.

*

Further samples were also spiked with the single analytes at 0.10 mg/kg and stored in a deep-freezer at ≤-18°C. The temperature in the deep-freezer was recorded during the entire storage period. A slight temperature deviation (≤-17 °C for less than 40 minutes) occurred about 90 days after day 0, which had no negative impact on the samples. After 1 month (36-41 days), 4 months (119-120 days) and 6 months (182 days), three fortified samples per analyte and one control sample were removed from the deep-freezer. Subsequently, at least two samples of honey were fortified with a mix of the analytes to determine the concurrent recoveries (fortification levels were at the same magnitude as the spiked storage samples). These samples were extracted and analyzed concurrently with the stored (unfortified) control samples and the spiked storage samples.

For storage samples the analytes were fortified separately, while concurrent recovery samples were prepared by fortifying all analytes jointly as a mix.

Residues of JAU 6476-α-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 honey were determined by

HPLC-MS/MS according to method 01601. The Limit of Quantification (LOQ) was defined as 0.01 mg/kg for each analyte expressed as prothioconazole-desthio.

Results and discussions

The performance of the analytical method was good during the conduct of the whole study. Indeed, average concurrent recoveries were deemed acceptable (between 73 and 102%) for all analytes.
After a deep-freezer storage (≤-18°C) period of about 6 months, the mean recovery rates were 85% for JAU 6476-α-hydroxy-desthio, 84% for JAU 6476-3-hydroxy-desthio, 83% for JAU 6476-4-hydroxy-desthio, 84% for JAU 6476-5-hydroxy-desthio and 77% for JAU 6476-6-hydroxy-desthio in honey.

Table 2.2.2-1: Storage stability data and concurrent recovery data JAU 6476-α-hydroxy-desthio, JAU 6476-3-hydroxy-desthio, JAU 6476-4-hydroxy-desthio, JAU 6476-5-hydroxy-desthio and JAU 6476-6-hydroxy-desthio in honey

Matrix	Storage period (days)	Residues in stored samples			Average % of fresh concurrent recoveries
		mg/kg	% of nominal spiking level	Average % recovery	
JAU 6476-α-hydroxy-desthio					
Honey	**0**	0.0745, 0.0895, 0.0795, 0.0915, 0.0945	75, 90, 80, 92, 95	86	-
	41	0.0975, 0.0870, 0.0655	98, 87, 66	84	84
	119	0.0831, 0.0831, 0.0896	83, 83, 90	85	84
	182	0.0814, 0.0868, 0.0867	81, 87, 87	85	87
JAU 6476-3-hydroxy-desthio					
Honey	**0**	0.0690, 0.0645, 0.0880, 0.0885, 0.0645	69, 65, 88, 89, 65	75	-
	41	0.0875, 0.0730, 0.0905	88, 73, 91	84	107
	119	0.0922, 0.0995, 0.103	92, 99, 103	98	90
	182	0.0774, 0.0853, 0.0897	77, 85, 90	84	88
JAU 6476-4-hydroxy-desthio					
Honey	**0**	0.0770, 0.0560, 0.0640, 0.0860, 0.0870	77, 56, 64, 86, 87	74	-
	36	0.0970, 0.109, 0.0820	97, 109, 82	96	109
	120	0.0836, 0.0985, 0.0788	84, 99, 79	87	103
	182	0.0814, 0.0868, 0.0867	81, 87, 87	83	96
JAU 6476-5-hydroxy-desthio					
Honey	**0**	0.0800, 0.0810, 0.0815, 0.0870, *0.120**	80, 81, 82, 87, *120*	83	-
	36	0.0710, 0.0740, 0.0740	71, 74, 74	73	89
	120	0.0929, 0.103, 0.0927	93, 103, 93	96	94
	182	0.0748, 0.0866, 0.0892	75, 87, 89	84	86
JAU 6476-6-hydroxy-desthio					
Honey	**0**	0.0780, 0.0760, 0.0960, 0.104, 0.109	78, 76, 96, 104, 109	93	-
	36	0.116, 0.0835, 0.106	116, 84, 106	102	104
	120	0.0989, 0.0994, 0.0943	99, 99, 94	97	81
	182	0.0912, 0.0630 0.0778	91, 63, 78	77	84

* Significant outlier according to Grubbs test

Conclusion

The storage stability demonstrated that JAU 6476-α-hydroxy-desthio, JAU 6476-3-hydroxy-desthio, JAU 6476-4-hydroxy-desthio, JAU 6476-5-hydroxy-desthio and JAU 6476-6-hydroxy-desthio are stable under deep-freeze conditions (-18 °C) in honey for at least *ca*. 6 months (182 days).

Storage stability study M-680825-02-1/S19-00126

Comments of zRMS:	The study below was not evaluated by the zRMS in the framework of this application, since the study is not necessary to support the proposed uses of GF-3307 in sugar beet.

Title:	Residue analytical method 01602 and short term storage stability of 1,2,4-triazole, triazole alanine, triazole acetic acid and triazole lactic acid in/on honey by HPLC-DMS-MS/MS - Report amendment no. 1
Author:	Kalathoor, R.
Edition Date:	05.05.2020
Report No:	M-680825-02-1
Reference No:	S19-01126
Guideline(s)	Regulation (EC) No 1107/2009 of the European Parliament and the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC Guidance document on residue analytical methods, SANCO/825/00/rev. 8.1, European Commission, Directorate General Health and Consumer Protection 16/11/2010 European Commission Guidance Document for Generating and Reporting Methods of Analysis in Support of Pre-Registration Data Requirements for Annex II (Part A, Section 4) and Annex III (Part A, Section 5) of Directive 91/414, SANCO/3029/99 rev. 4, 11/07/00 OECD 506, 2007; OECD Guideline for the Testing of Chemicals – Stability of Pesticide Residues in Stored Commodities Technical guidelines for determining the magnitude of pesticide residues in honey and setting Maximum Residue Levels in honey, SANTE/11956/2016 rev.9
Guideline Deviation(s)	None
GLP/GEP	yes
Testing Facility:	Eurofins Agroscience Services EcoChem GmbH / Eurofins Agroscience Services Ecotox GmbH, Niefern-Oeschelbronn, Germany
Sponsor:	Bayer
Owner:	BAY

Materials and methods

A study was conducted to determine the stability of residues of 1,2,4-triazole, triazole alanine, triazole acetic acid and triazole lactic acid in 10xLOQ fortified samples of honey during deep-freeze storage for a period of *ca.* 5 months (150 days) at ≤-18 °C. Samples were analysed after nominal storage intervals of 0, 1, 3, and 5 months.

The spiking solutions were prepared in HPLC water.

On day 0 (zero-time analysis) five spiked samples per test item and two control samples were analysed to confirm the fortification level and performance of the method.

Further samples were also spiked with the single analytes at 0.10 mg/kg and stored in a deep-freezer at ≤-18°C. The temperature in the deep-freezer was recorded during the entire storage period. A slight temperature deviation (≤-17 °C for less than an hour) occurred about 30 days after day 0, which had no negative impact on the samples. After 1 month (30 days), 3 months (92 days) and 5 months (153 days), three fortified samples per analyte and one control sample were removed from the deep-freezer. Subsequently, two samples of honey were fortified with a mix of the analytes to determine the concurrent recoveries (fortification levels were at the same magnitude as the spiked storage samples). These samples were extracted and analysed concurrently with the stored (unfortified) control samples and the spiked storage samples.

For storage samples the analytes were fortified separately, while concurrent recovery samples were prepared by fortifying all analytes jointly as a mix.

Residues of 1,2,4-triazole, triazole alanine, triazole acetic acid and triazole lactic acid in/on honey were determined by HPLC-DMS-MS/MS according to method 01602. The Limit of Quantification (LOQ) was defined as 0.01 mg/kg for each analyte expressed as itself.

Results and discussions

The performance of the analytical method was good during the conduct of the whole study. the mean concurrent recoveries of all investigated days of storage determined from freshly fortified samples were in a range of 93-104% for 1,2,4-triazole, in a range of 89-98% for triazole alanine, in a range of 95-100% for triazole acetic acid and in a range of 94-105% for triazole lactic acid in honey.

After a deep-freezer storage (≤-18°C) period of about 5 months, the mean recovery rates were 109% for 1,2,4-triazole, 96% for triazole alanine, 95% for triazole acetic acid and 89% for triazole lactic acid in honey.

Table 2.2.3-1: Storage stability data and concurrent recovery data for 1,2,4-triazole, triazole alanine, triazole acetic acid and triazole lactic acid in honey

Matrix	Storage period (days)	Residues in stored samples			Average % of fresh concurrent recoveries
		mg/kg	% of nominal spiking level	Average % recovery	
1,2,4-triazole					
Honey	**0**	0.0734, 0.0777, 0.0792, 0.0808, 0.0856	73, 78, 79, 81, 86	79	-
	30	0.104, 0.108, 0.107	104, 108, 107	106	94
	92	0.114, 0.112, 0.102	114, 112, 102	109	93
	153	0.118, 0.110, 0.100	118, 110, 100	109	104
triazole alanine					
Honey	**0**	0.0888, 0.0904, 0.0920, *0.0904*[1)], 0.0912	89, 90, 92, 90, 91	90	-
	30	0.0984, 0.0936, 0.0952	98, 94, 95	96	89
	92	0.0992, 0.0912, *0.104* [1)]	99, 91, 104	98	98
	153	0.0984, 0.0984, 0.0928	98, 98, 93	96	96
triazole acetic acid					
Honey	**0**	0.0984, 0.0976, 0.0960, 0.0976, 0.0944	98, 98, 96, 98, 94	97	-
	30	0.0952, 0.0992, 0.0936	95, 99, 94	96	95
	92	0.0872, 0.0880, 0.0896	87, 88, 90	88	100
	153	0.0952, 0.0952, 0.0952	95, 95, 95	95	96
triazole lactic acid					
Honey	**0**	0.0944, 0.0960, 0.0952, 0.0912, 0.0992	94, 96, 95, 91, 99	95	-
	30	0.106, 0.0984, 0.101	106, 98, 101	102	95
	92	0.0984, 0.0968, 0.0944	98, 97, 94	96	105
	153	0.0880, 0.0896, 0.0880	88, 90, 88	89	94

[1)] *Typographical errors of residue values in mg/kg at day 0 and day 92 were corrected*

Conclusion

The storage stability demonstrated that the 1,2,4-triazole, triazole alanine, triazole acetic acid and triazole lactic are stable under deep-freeze conditions (≤-18 °C) in honey for at least *ca.* 5 months (150 days).

Nature of residues in plants, livestock and processed commodities

Nature of residue in plants

Nature of residue in primary crops

No new studies presented.

Nature of residue in rotational crops

No new studies presented.

Nature of residues in processed commodities

No new studies presented.

Nature of residues in livestock

No new studies presented.

Magnitude of residues in plants

Sugar beet

Table A 1: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU fenpicoxamid (XDE-777)	2	75 g XDE-777/ha	21 days	BBCH 49	21 days
cGAP EU (EFSA 2023) prothioconazole	2	150 g prothioconazole/ha	21 days	BBCH 49	7 days
Intended cGAP (1-2*)	2	75 g XDE-777/ha + 150 g prothioconazole/ha	21 days	BBCH 49	21 days

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

Study 685066/ 220541

Comments of zRMS:	Four trials were conducted in N-EU to determine residues of fenpicoxamid (XDE-777) and its metabolites (X642188 and X12314005) as well as prothioconazole-desthio and its prothioconazole *a*-,3-,4-,5- and 6-hydroxy desthio isomers residues in/on sugar beet following twice treatment with GF-3307 at a target rate of 75 g a.i. (fenpicoxamid)/ha (nominal) and 150 g a.i. (prothioconazole)/ha (nominal), with interval of applications of 21 and with PHI of 21 dyas. Additionally processed fractions (roots prior to processing, press water, wet pulp, pressed pulp, dried pulp, ensiled pulp, raw juice, thick juice, raw sugar, molasses and refined sugar) have been evaluated following two applications of GF-3307 at a target rate of 375 g a.i. (fenpicoxamid)/ha (nominal) and 750 g a.i. (prothioconazole)/ha (nominal), with interval of applications of 21 and with PHI of 21 days to the crop. The methods were validated for the determination of fenpicoxamid and its metabolites and prothioconazole-desthio (PTZ-desthio) and its prothioconazole α-, 3-, 4-, 5- and 6-hydroxy desthio metabolites in accordance to guidance document SANTE/2020/12830, rev. 2 for risk assessment. The limit of detection (LOD) and limit of quantitation (LOQ) for all analytes were 0.003 mg/kg and 0.01 mg/kg respectively. The maximum storage interval from sampling to extraction for XDE-777 and X642188 in sugar beet roots was 88 days, and in sugar beet tops – 113 days. The maximum storage interval from sampling to extraction for PTZ-dethio and PTZ-OH-desthio Metabolites in sugar beet root was 192 and 181 days, respectively, and in sugar beet tops was 265 days and 226 days, respectively. **Residues in sugar beet roots (N-EU):** Generally residues of fenpicoxamid (XDE-777) and its metabolites and prothioconazole-desthio and its metabolites in the control samples were all less than or equal to <0.003 mg/kg (non-detectable). Fenpicoxamid (XDE-777) residues in sugar beet roots ranged from <0.003 mg/kg (non-detectable) to 0.02 mg/kg. Prothioconazole-desthio residues in sugar beet roots ranged from <0.003 mg/kg (non-detectable) to 0.02 mg/kg. **Residues in sugar beet tops (N-EU):** Fenpicoxamid (XDE-777) residues in sugar beet tops ranged from 0.02 mg/kg to 0.38 mg/kg. Prothioconazole-desthio residues in sugar beet tops ranged from 0.13 mg/kg to 0.22 mg/kg.

	Processing part The processing study was conducted at an exaggerated treatment rate GAP (2 applications at 375 g a.i. (fenpicoxamid)/ha and 750 g a.i. (prothioconazole)/ha, with interval of applications of 21 and with PHI of 21 days to the crop) compared to the proposed use in Europe. Residues of fenpicoxamid and the hydrolysis degradates X12019520, X12314005, X12264475 and X12335723 were determined. Residues of fenpicoxamid in roots and its processed fractions taken at normal commercial harvest were found to be between ND (not detected, <0.003 mg/kg) and 0.02 mg/kg. Residues of fenpicoxamid metabolites in the roots prior to processing were not detected except X12264475 metabolite. Residues of X12264475 in roots before processing ranged from ND (not detected, <0.003 mg/kg) to 0.04 mg/kg. The concentration of fenpicoxamid is only in one processed fraction, in dried pulp. The study is acceptable.

Reference:	Fenpicoxamid Residues in Sugar Beet Including Processed Fractions Following Two Applications of GF-3307, Europe, 2022. Matthew Munro. 2024. Report no. 685066/ 220541
Guideline(s):	OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring Number 13. Consensus Document of the Working Group on Good Laboratory Practice. The application of the OECD principles of GLP to the Organisation and Management of Multi-Site Studies (June 2002) OECD Guideline 509, Testing of Chemicals, Crop Field Trials (14 June 2021). EC Guideline 7029/VI/95 Rev 5, General Recommendations for the Design, Preparation and Realisation of Residue Trials (July 1997). EC Guideline 1107/2009 of the European Parliament and the Council of 21 October 2009, Concerning the Placing of Plant Protection Products on the Market and Repealing Council Directives 79/117/EEC and 91/414/EEC. Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-Approval Control and Monitoring Purposes, SANTE/2020/12830 Rev. 1 OECD Guidelines for the Testing of Chemicals, Section 5 Test No. 508: Magnitude of the Pesticide Residues in Processed Commodities
Deviations:	None with impact on the study.
GLP:	Yes
Validity of the study:	Yes

This study determined fenpicoxamid (XDE-777) and its metabolites (X642188 and X12314005) as well as prothioconazole-desthio and its prothioconazole *a*-,3-,4-,5- and 6-hydroxy desthio isomers residues in/on sugar beet in Europe following treatment with GF-3307. The number, location, test type and test system (field sugar beet with the variety being common of the representative growing areas) per growing season used in this study are given as follows.

Growing Season	Test No.	Regulatory Region[A]	Country	Location, Region	Test Type[B]	Crop/Variety[C]
2022	1	NEU	Belgium	Ere, Hainaut	MOR	Sugar beet / BTS3480
2022	2	NEU	North France	Le Meux, Hauts-de-France	MOR + Processing	Sugar beet / Mobidick
2022	3	SEU	Spain	Zurbano, Basque Country	MOR + Processing	Sugar beet / Yucatan
2022	4	SEU	Italy	Castelnuovo Scrivia, Piemonte	MOR + Processing	Sugar beet / Ottavia
2022	5	NEU	Hungary	Bőny, Győr-Moson-Sopron County	Decline	Sugar beet / Deseda
2022	6	NEU	United Kingdom	Slingsby, North Yorkshire	Decline	Sugar beet / BTS1140
2022	7	SEU	Spain	Villamartín, Andalucía	Decline	Sugar beet / Juncal
2022	8	SEU	Italy	San Rocco al Porto, Lombardia	Decline	Sugar beet / Marinella

A NEU = Northern Europe; SEU = Southern Europe
B MOR = Magnitude of Residue
C Variety used were common of the representative growing areas;
Sugar Beet = BEAVA

This was the targeted design of the test conducted

Test Type	Formulation	Number of Appl[A]	Product Rate (FP/ha)	RTI (days)[B]	Rate per Appl (g a.s./ha)	Spray Volume (L/ha)	Sampling Interval[C]
2022							
MOR	GF-3307	2	1.5 L/ha	21±1	75 (fenpicoxamid) 150 (prothioconazole)	150-300	21±1 DALA
Processing	GF-3307	2	7.5 L/ha	21±1	375 (fenpicoxamid) 750 (prothioconazole)	150-300	21±1 DALA
Decline	GF-3307	2	1.5 L/ha	21±1	75 (fenpicoxamid) 150 (prothioconazole)	150-300	-0, +0, 7, 14±1, 21±1 and 35±2 DALA

[A] A1 targeted at 21±1 days before A2 (BBCH 49)
[B] RTI = Retreatment interval
[C] DALA = Days after last application to the Treated plot
ha = hectare; FP = Formulated product

Duplicate specimens were collected from each plot at each sampling timepoint and consisted of at least 2.0 kg sugar beet roots and 1.0 kg of sugar beet tops for residue analysis and 100 kg of sugar beet roots for processing.
For MOR trials 1-4, control and treated plots were sampled at 21 days after last application (DALA).
For trial 1, two control specimens and two treated specimens (one per commodity) were submitted for residue analysis.
For trials 2-4, two control specimens and two treated specimens (one per commodity) were submitted for residue analysis per trial. One control specimen and one treated specimen (of sugar beet roots) were also submitted for processing.
For decline trials 5-8, control and treated plots were sampled at -0 (immediately before the last application), +0 (after the test item has dried), 7, 12-14, 20-21 and 34-35 days after last application (DALA). Twelve control specimens and twelve treated specimens (six per commodity) were submitted for analysis, per trial. In addition, the 21 DALA spare sample from Trial 6 was analysed.
There were no surfactants/additives included in the spray mixture.
Specimens were analyzed for residues of fenpicoxamid (XDE-777) and its metabolite X642188 following the analytical procedure Dow AgroSciences Study ID: 120615 (Reference 2).
Specimens were analyzed for residues of metabolite, X12314005 (also nonpolar analytes (fenpicoxamid (XDE-777) and its metabolite X12314005 and polar analytes X12335723 and X12264475) in processing fractions) following the analytical procedure Dow AgroSciences Study ID: 140696 (Reference 3).
Specimens were analyzed for residues of prothioconazole-desthio following the analytical method MR-06/138, Amendment 4 (Reference 4).
Specimens were analyzed for residues of PTZ-*a*-OH-desthio, PTZ-3-OH-desthio, PTZ-4-OH-desthio, PTZ-5-OH-desthio, and PTZ-6-OH-desthio following the modification M002 of the analytical method 00979/M002 (Reference 5). All methods were supplied by the Sponsor.
Unfortified control samples and untreated control samples fortified at the LOQ (0.010 mg/kg) to as high as 3.0 mg/kg with fenpicoxamid (XDE-777) were analyzed concurrently with the treated samples to verify method performance.
Unfortified control samples and untreated control samples fortified at the LOQ (0.010 mg/kg) to as high as 1.0 mg/kg with X642188 were analyzed concurrently with the treated samples to verify method performance.
Unfortified control samples and untreated control samples fortified at the LOQ (0.010 mg/kg) to as high as 0.1 mg/kg with X12314005 were analyzed concurrently with the treated samples to verify method performance.

Unfortified control samples and untreated control samples fortified at the LOQ (0.010 mg/kg) to as high as 2.0 mg/kg with Prothioconazole-desthio were analyzed concurrently with the treated samples to verify method performance.
Unfortified control samples and untreated control samples fortified at the LOQ (0.010 mg/kg) to as high as 1.0 mg/kg with PTZ-*a*-OH-desthio were analyzed concurrently with the treated samples to verify method performance.
Unfortified control samples and untreated control samples fortified at the LOQ (0.010 mg/kg) to as high as 1.0 mg/kg with PTZ-3-OH-desthio were analyzed concurrently with the treated samples to verify method performance.
Unfortified control samples and untreated control samples fortified at the LOQ (0.010 mg/kg) to as high as 1.0 mg/kg with PTZ-4-OH-desthio were analyzed concurrently with the treated samples to verify method performance.
Unfortified control samples and untreated control samples fortified at the LOQ (0.010 mg/kg) to as high as 1.0 mg/kg with PTZ-5-OH-desthio were analyzed concurrently with the treated samples to verify method performance.
Unfortified control samples and untreated control samples fortified at the LOQ (0.010 mg/kg) to as high as 1.0 mg/kg with PTZ-6-OH-desthio were analyzed concurrently with the treated samples to verify method performance.
Unfortified control samples and untreated control samples fortified at the LOQ (0.010 mg/kg) to as high as 0.1 mg/kg with X12019520 were analyzed concurrently with the treated samples to verify method performance.
Unfortified control samples and untreated control samples fortified at the LOQ (0.010 mg/kg) to as high as 0.1 mg/kg with X12335723 were analyzed concurrently with the treated samples to verify method performance.
Unfortified control samples and untreated control samples fortified at the LOQ (0.010 mg/kg) to as high as 0.1 mg/kg with X12264475 were analyzed concurrently with the treated samples to verify method performance.
Recoveries for all analyte/matrix combinations per fortification level ranged from 69-107%.
The Limit of Quantification (LOQ) was 0.010 mg/kg, and the Limit of Detection (LOD) was 0.003 mg/kg for all analytes and all commodities.
All tests show an overall consistent residue profile when GF-3307 is applied in accordance with the defined good agricultural practice. The residue data demonstrate the following in the residue test conducted in 2022 in which GF-3307 was applied at 99-103% of the targeted rate of application to all treated plots.
All of the residue results for the study are presented collectively below:

Residues of Fenpicoxamid, Prothioconazole and metabolites in Field Sugar Beet from Supervised Trials for Sponsor Reference No.: 220541, Test No. 1: Ere, Hainaut, Belgium

Active ingredient (a.i.)(common name):	Fenpicoxamid + Prothioconazole	Commercial product (name)	:	GF-3307
Crop / Crop Group::	Sugar beet / Beet	Producer of commercial product	:	Corteva Agriscience
Responsible body for reporting	: Corteva Agriscience, LLC	Method of treatment (e)	:	Foliar application using a Knapsack sprayer
(name, address)	: 9330 Zionsville Road, Indianapolis, IN, 46268 USA	Indoor/Outdoor	:	Outdoor
Country	: Belgium	Other active substance in the formulation	:	None
Content of active substance: (g/L)	: 50 g Fenpicoxamid/L + 101 g Prothioconazole/L	Other active substance content (g/kg or g/L)		None
Formulation (e.g., WP)	: EC	Residues calculated as	:	XDE-777, X642188, X12314005, Prothioconazole-desthio, PTZ-α-OH-desthio, PTZ-3-OH-desthio, PTZ-4-OH-desthio, PTZ-5-OH-desthio and PTZ-6-OH-desthio

1	2	3	4			5	6		7	8				9
Report No. Location including Postal Code	**Commodity / Variety**	**Date of: 1. Sowing or Planting 2. Flowering 3. Harvest**	**Plot Application rate per treatment (A1-A2)**			**Dates of treatment(s) or no. of treatment(s) and last date**	**BBCH Growth stage at Application (A)and at Sampling (S)**		**Portion Analyzed**	**Residues (mg/kg) (f)**				**DALA**
	(a)	**(b)**	**g a.i/ha**	**Water (L/ha)**	**g a.i/hL**	**(c)**	**A**	**S**		**Fenpico-xamid (XDE-777)**	**X642188**	**X1231-4005**	**PTZ-desthio**	**(d)**
Sponsor Reference No.: 220541 Ere, B-7506, Hainaut, Belgium	Sugar Beet / BTS 3480	1. 27 Mar 2022 2. Not applicable 3. 16 Nov 2022	--	--	--	Untreated	--	49	Tops	ND	ND	ND	ND	--
									Roots	ND	ND	ND	ND	
			a) 76.25 b) 154.03	305	a) 25.00 b) 50.50	A1 = 05 Oct 2022	45	49	Tops	0.16	0.02	ND	0.13	21 (NCH)
			a) 76.75 b) 155.04	307	a) 25.00 b) 50.50	A2 = 26 Oct 2022	49		Roots	ND	ND	ND	0.01	

[a] According to EEC and Codex Class Classification (both) should be used
[b] Only if relevant
[c] Year must be indicated
[d] DALA = Days after last application; NCH = Normal commercial harvest
a) active ingredient for Fenpicoxamid only; b) active ingredient for Prothioconazole only

[e] High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated
[f] Analytical methods: DAS Reference ID 120615, DAS Reference ID 140696, Analytical Method MR-06/138 Amendment 4 and Modification M002 of the Analytical Method 00979/M002
The designation "ND" is used for treated samples for which the residue was <LOD (0.003 mg/kg)
Residue values below the LOQ (0.01 mg/kg) but greater than or equal to the LOD are reported as <LOQ with the uncorrected concentration in parentheses ( ).

Residues of Fenpicoxamid, Prothioconazole and metabolites in Field Sugar Beet from Supervised Trials for Sponsor Reference No.: 220541, Test No. 1: Ere, Hainaut, Belgium

Active ingredient (a.i.)(common name):		Fenpicoxamid + Prothioconazole	Commercial product (name)	:	GF-3307
Crop / Crop Group::		Sugar beet / Beet	Producer of commercial product	:	Corteva Agriscience
Responsible body for reporting	:	Corteva Agriscience, LLC	Method of treatment (e)	:	Foliar application using a Knapsack sprayer
(name, address)	:	9330 Zionsville Road, Indianapolis, IN, 46268 USA	Indoor/Outdoor	:	Outdoor
Country	:	Belgium	Other active substance in the formulation	:	None
Content of active substance: (g/L)	:	50 g Fenpicoxamid/L + 101 g Prothioconazole/L	Other active substance content (g/kg or g/L)		None
Formulation (e.g., WP)	:	EC	Residues calculated as	:	XDE-777, X642188, X12314005, Prothioconazole-desthio, PTZ-α-OH-desthio, PTZ-3-OH-desthio, PTZ-4-OH-desthio, PTZ-5-OH-desthio and PTZ-6-OH-desthio

1	2	3	4			5	6		7	8					9
Report No. Location including Postal Code	**Commodity / Variety**	**Date of: 1. Sowing or Planting 2. Flowering 3. Harvest**	**Plot Application rate per treatment (A1-A2)**			**Dates of treatment(s) or no. of treatment(s) and last date**	**BBCH Growth stage at Application (A)and at Sampling (S)**		**Portion Analyzed**	**Residues (mg/kg) (f)**					**DALA**
	(a)	**(b)**	**g a.i/ha**	**Water (L/ha)**	**g a.i/hL**	**(c)**	**A**	**S**		**PTZ-α-OH-desthio**	**PTZ-3-OH-desthio**	**PTZ-4-OH-desthio**	**PTZ-5-OH-desthio**	**PTZ-6-OH-desthio**	**(d)**
Sponsor Reference No.: 220541 Ere, B-7506, Hainaut, Belgium	Sugar Beet / BTS 3480	1. 27 Mar 2022 2. Not applicable 3. 16 Nov 2022	--	--	--	Untreated	--	49	Tops	ND	ND	ND	ND	ND	--
									Roots	ND	ND	ND	ND	ND	
			a) 76.25 b) 154.03	305	a) 25.00 b) 50.50	A1 = 05 Oct 2022	45	49	Tops	< 0.01 (0.004)	0.07	0.03	0.03	ND	21 (NCH)
			a) 76.75 b) 155.04	307	a) 25.00 b) 50.50	A2 = 26 Oct 2022	49		Roots	ND	ND	ND	ND	ND	

[a] According to EEC and Codex Class Classification (both) should be used
[b] Only if relevant
[c] Year must be indicated
[d] DALA = Days after last application; NCH = Normal commercial harvest
a) active ingredient for Fenpicoxamid only; b) active ingredient for Prothioconazole only

[e] High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated
[f] Analytical methods: DAS Reference ID 120615, DAS Reference ID 140696, Analytical Method MR-06/138 Amendment 4 and Modification M002 of the Analytical Method 00979/M002
The designation "ND" is used for treated samples for which the residue was <LOD (0.003 mg/kg)
Residue values below the LOQ (0.01 mg/kg) but greater than or equal to the LOD are reported as <LOQ with the uncorrected concentration in parentheses ( ).

Residues of Fenpicoxamid, Prothioconazole and metabolites in Field Sugar Beet from Supervised Trials for Sponsor Reference No.: 220541, Test No. 2: Le Meux, Hauts-de-France, North France

Active ingredient (a.i.)(common name):	Fenpicoxamid + Prothioconazole	Commercial product (name)	:	GF-3307
Crop / Crop Group::	Sugar beet / Beet	Producer of commercial product	:	Corteva Agriscience
Responsible body for reporting	: Corteva Agriscience, LLC	Method of treatment (e)	:	Foliar application using a Knapsack sprayer
(name, address)	: 9330 Zionsville Road, Indianapolis, IN, 46268 USA	Indoor/Outdoor	:	Outdoor
Country	: North France	Other active substance in the formulation	:	None
Content of active substance: (g/L)	: 50 g Fenpicoxamid/L + 101 g Prothioconazole/L	Other active substance content (g/kg or g/L)		None
Formulation (e.g., WP)	: EC	Residues calculated as	:	XDE-777, X642188, X12314005, Prothioconazole-desthio, PTZ-α-OH-desthio, PTZ-3-OH-desthio, PTZ-4-OH-desthio, PTZ-5-OH-desthio and PTZ-6-OH-desthio

1	2	3	4			5	6		7	8				9
Report No. Location including Postal Code	**Commodity / Variety**	**Date of: 1. Sowing or Planting 2. Flowering 3. Harvest**	**Plot Application rate per treatment (A1-A2)**			**Dates of treatment(s) or no. of treatment(s) and last date**	**BBCH Growth stage at Application (A)and at Sampling (S)**		**Portion Analyzed**	**Residues (mg/kg) (f)**				**DALA**
	(a)	**(b)**	**g a.i/ha**	**Water (L/ha)**	**g a.i/hL**	**(c)**	**A**	**S**		**Fenpico-xamid (XDE-777)**	**X642188**	**X1231-4005**	**PTZ-desthio**	**(d)**
Sponsor Reference No.: 220541 Le Meux, 60880, Hauts-de-France, North France	Sugar Beet / Mobidick	1. 26 Mar 2022 2. Not applicable 3. 25 Oct 2022	--	--	--	Untreated	--	49	Tops	ND	ND	ND	ND	--
									Roots	ND	ND	ND	ND	
			a) 74.25 b) 149.99	297	a) 25.00 b) 50.50	A1 = 13 Sep 2022 A2 = 04 Oct 2022	48-49 49	49	Tops	0.38	0.03	ND	0.22	21 (NCH)
			a) 74.75 b) 151.00	299	a) 25.00 b) 50.50				Roots	ND	ND	ND	0.01	

[a] According to EEC and Codex Class Classification (both) should be used
[b] Only if relevant
[c] Year must be indicated
[d] DALA = Days after last application; NCH = Normal commercial harvest
a) active ingredient for Fenpicoxamid only; b) active ingredient for Prothioconazole only

[e] High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated
[f] Analytical methods: DAS Reference ID 120615, DAS Reference ID 140696, Analytical Method MR-06/138 Amendment 4 and Modification M002 of the Analytical Method 00979/M002
The designation "ND" is used for treated samples for which the residue was <LOD (0.003 mg/kg)
Residue values below the LOQ (0.01 mg/kg) but greater than or equal to the LOD are reported as <LOQ with the uncorrected concentration in parentheses ( ).

Residues of Fenpicoxamid, Prothioconazole and metabolites in Field Sugar Beet from Supervised Trials for Sponsor Reference No.: 220541, Test No. 2: Le Meux, Hauts-de-France, North France

Active ingredient (a.i.)(common name):	Fenpicoxamid + Prothioconazole	Commercial product (name)	:	GF-3307
Crop / Crop Group::	Sugar beet / Beet	Producer of commercial product	:	Corteva Agriscience
Responsible body for reporting	: Corteva Agriscience, LLC	Method of treatment (e)	:	Foliar application using a Knapsack sprayer
(name, address)	: 9330 Zionsville Road, Indianapolis, IN, 46268 USA	Indoor/Outdoor	:	Outdoor
Country	: North France	Other active substance in the formulation	:	None
Content of active substance: (g/L)	: 50 g Fenpicoxamid/L + 101 g Prothioconazole/L	Other active substance content (g/kg or g/L)		None
Formulation (e.g., WP)	: EC	Residues calculated as	:	XDE-777, X642188, X12314005, Prothioconazole-desthio, PTZ-α-OH-desthio, PTZ-3-OH-desthio, PTZ-4-OH-desthio, PTZ-5-OH-desthio and PTZ-6-OH-desthio

1	2	3	4			5	6		7	8					9
Report No. Location including Postal Code	**Commodity / Variety**	**Date of: 1. Sowing or Planting 2. Flowering 3. Harvest**	**Plot Application rate per treatment (A1-A2)**			**Dates of treatment(s) or no. of treatment(s) and last date**	**BBCH Growth stage at Application (A)and at Sampling (S)**		**Portion Analyzed**	**Residues (mg/kg) (f)**					**DALA**
	(a)	**(b)**	**g a.i/ha**	**Water (L/ha)**	**g a.i/hL**	**(c)**	**A**	**S**		**PTZ-α-OH-desthio**	**PTZ-3-OH-desthio**	**PTZ-4-OH-desthio**	**PTZ-5-OH-desthio**	**PTZ-6-OH-desthio**	**(d)**
Sponsor Reference No.: 220541 Le Meux, 60880, Hauts-de-France, North France	Sugar Beet / Mobidick	1. 26 Mar 2022 2. Not applicable 3. 25 Oct 2022	--	--	--	Untreated	--	49	Tops	ND	ND	ND	ND	ND	--
									Roots	ND	ND	ND	ND	ND	
			a) 74.25 b) 149.99	297	a) 25.00 b) 50.50	A1 = 13 Sep 2022 A2 = 04 Oct 2022	48-49	49	Tops	0.01	0.18	0.08	0.03	< 0.01 (0.004)	21 (NCH)
			a) 74.75 b) 151.00	299	a) 25.00 b) 50.50		49		Roots	ND	ND	ND	ND	ND	

[a] According to EEC and Codex Class Classification (both) should be used
[b] Only if relevant
[c] Year must be indicated
[d] DALA = Days after last application; NCH = Normal commercial harvest
a) active ingredient for Fenpicoxamid only; b) active ingredient for Prothioconazole only

[e] High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated
[f] Analytical methods: DAS Reference ID 120615, DAS Reference ID 140696, Analytical Method MR-06/138 Amendment 4 and Modification M002 of the Analytical Method 00979/M002
The designation "ND" is used for treated samples for which the residue was <LOD (0.003 mg/kg)
Residue values below the LOQ (0.01 mg/kg) but greater than or equal to the LOD are reported as <LOQ with the uncorrected concentration in parentheses ( ).

Residues of Fenpicoxamid, Prothioconazole and metabolites in Processed Sugar Beet Commodities from Supervised Trials for Sponsor Reference No.: 220541, Test No. 2: Le Meux, Hauts-de-France, North France

Active ingredient (a.i.)(common name):	Fenpicoxamid + Prothioconazole	Commercial product (name)	:	GF-3307
Crop / Crop Group::	Sugar beet / Beet	Producer of commercial product	:	Corteva Agriscience
Responsible body for reporting	: Corteva Agriscience, LLC	Method of treatment (e)	:	None
(name, address)	: 9330 Zionsville Road, Indianapolis, IN, 46268 USA	Indoor/Outdoor	:	Outdoor
Country	: North France	Other active substance in the formulation	:	None
Content of active substance: (g/L)	: 50 g Fenpicoxamid/L + 101 g Prothioconazole/L	Other active substance content (g/kg or g/L)		None
Formulation (e.g., WP)	: EC	Residues calculated as	:	XDE-777, X642188, X12314005, Prothioconazole-desthio, PTZ-α-OH-desthio, PTZ-3-OH-desthio, PTZ-4-OH-desthio, PTZ-5-OH-desthio and PTZ-6-OH-desthio

1	2	3	4			5	6		7	8					9
Report No. Location including Postal Code	**Commodity / Variety**	**Date of: 1. Sowing or Planting 2. Flowering 3. Harvest**	**Plot Application rate per treatment**			**Dates of treatment(s) or no. of treatment(s) and last date**	**BBCH Growth stage at Application (A)and at Sampling (S)**		**Portion Analyzed**	**Residues (mg/kg) (f)**					**DALA**
	(a)	**(b)**	**g a.i/ha**	**Water (L/ha)**	**g a.i/hL**	**(c)**	**A**	**S**		**Fenpico-xamid (XDE-777)**	**X12314005**	**X12019520**	**X12335723**	**X12264475**	**(d)**
Sponsor Reference No.: 220541 Le Meux, 60880, Hauts-de-France, North France	Sugar Beet / Mobidick	1. 26 Mar 2022 2. Not applicable 3. 25 Oct 2022	--	--	--	Untreated	--	--	Roots prior to processing	ND	ND	ND	ND	ND	--
								--	Press water	--	--	--	--	--	--
								--	Wet pulp	--	--	--	--	--	--
								--	Pressed pulp	--	--	--	--	--	--
								--	Dried pulp	--	--	--	--	--	--
								--	Ensiled pulp	--	--	--	--	--	--
								--	Raw juice	--	--	--	--	--	--
								--	Thick juice	--	--	--	--	--	--
								--	Raw sugar	--	--	--	--	--	--
								--	Molasses	--	--	--	--	--	--
								--	Refined sugar	--	--	--	--	--	--

[a] According to EEC and Codex Class Classification (both) should be used
[b] Only if relevant
[c] Year must be indicated
[d] DALA = Days after last application
[e] High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated
[f] Analytical methods: DAS Reference ID 120615, DAS Reference ID 140696, Analytical Method MR-06/138 Amendment 4 and Modification M002 of the Analytical Method 00979/M002
The designation "ND" is used for treated samples for which the residue was <LOD (0.003 mg/kg)
Residue values below the LOQ (0.01 mg/kg) but greater than or equal to the LOD are reported as <LOQ with the uncorrected concentration in parentheses ( ).

Residues of Fenpicoxamid, Prothioconazole and metabolites in Processed Sugar Beet Commodities from Supervised Trials for Sponsor Reference No.: 220541, Test No. 2: Le Meux, Hauts-de-France, North France

Active ingredient (a.i.)(common name):		Fenpicoxamid + Prothioconazole	Commercial product (name)	:	GF-3307
Crop / Crop Group::		Sugar beet / Beet	Producer of commercial product	:	Corteva Agriscience
Responsible body for reporting	:	Corteva Agriscience, LLC	Method of treatment (e)	:	Foliar application using a Knapsack sprayer
(name, address)	:	9330 Zionsville Road, Indianapolis, IN, 46268 USA	Indoor/Outdoor	:	Outdoor
Country	:	North France	Other active substance in the formulation	:	None
Content of active substance: (g/L)	:	50 g Fenpicoxamid/L + 101 g Prothioconazole/L	Other active substance content (g/kg or g/L)		None
Formulation (e.g., WP)	:	EC	Residues calculated as	:	XDE-777, X642188, X12314005, Prothioconazole-desthio, PTZ-α-OH-desthio, PTZ-3-OH-desthio, PTZ-4-OH-desthio, PTZ-5-OH-desthio and PTZ-6-OH-desthio

1	2	3	4			5	6		7	8					9
Report No. Location including Postal Code	**Commodity / Variety**	**Date of: 1. Sowing or Planting 2. Flowering 3. Harvest**	**Plot Application rate per treatment (A1-A2)**			**Dates of treatment(s) or no. of treatment(s) and last date**	**BBCH Growth stage at Application (A)and at Sampling (S)**		**Portion Analyzed**	**Residues (mg/kg) (f)**					**DALA**
	(a)	**(b)**	**g a.i/ha**	**Water (L/ha)**	**g a.i/hL**	**(c)**	**A**	**S**		**Fenpico-xamid (XDE-777)**	**X12314005**	**X12019520**	**X12335723**	**X12264475**	**(d)**
Sponsor Reference No.: 220541 Le Meux, 60880, Hauts-de-France, North France	Sugar Beet / Mobidick	1. 26 Mar 2022 2. Not applicable 3. 25 Oct 2022	a) 370.00 b) 747.40 a) 373.75 b) 754.98	296 299	a) 125.00 b) 252.50 a) 125.00 b) 252.50	A1 = 13 Sep 2022 A2 = 04 Oct 2022	48-49 49	--	Roots prior to processing	< 0.01 (0.007)	ND	ND	ND	ND	--
								--	Press water	--	--	--	--	--	--
								--	Wet pulp	--	--	--	--	--	--
								--	Pressed pulp	--	--	--	--	--	--
								--	Dried pulp	--	--	--	--	--	--
								--	Ensiled pulp	--	--	--	--	--	--
								--	Raw juice	--	--	--	--	--	--
								--	Thick juice	--	--	--	--	--	--
								--	Raw sugar	--	--	--	--	--	--
								--	Molasses	--	--	--	--	--	--
								--	Refined sugar	--	--	--	--	--	--

[a] According to EEC and Codex Class Classification (both) should be used
[b] Only if relevant
[c] Year must be indicated
[d] DALA = Days after last application
[e] High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated
[f] Analytical methods: DAS Reference ID 120615, DAS Reference ID 140696, Analytical Method MR-06/138 Amendment 4 and Modification M002 of the Analytical Method 00979/M002
The designation "ND" is used for treated samples for which the residue was <LOD (0.003 mg/kg)
Residue values below the LOQ (0.01 mg/kg) but greater than or equal to the LOD are reported as <LOQ with the uncorrected concentration in parentheses ( ).

Residues of Fenpicoxamid, Prothioconazole and metabolites in Field Sugar Beet from Supervised Trials for Sponsor Reference No.: 220541, Test No. 3: Zurbano, Basque Country, Spain

Active ingredient (a.i.)(common name):	Fenpicoxamid + Prothioconazole	Commercial product (name) :	GF-3307
Crop / Crop Group::	Sugar beet / Beet	Producer of commercial product :	Corteva Agriscience
Responsible body for reporting :	Corteva Agriscience, LLC	Method of treatment (e) :	Foliar application using a Knapsack sprayer
(name, address) :	9330 Zionsville Road, Indianapolis, IN, 46268 USA	Indoor/Outdoor :	Outdoor
Country :	Spain	Other active substance in the formulation :	None
Content of active substance: (g/L) :	50 g Fenpicoxamid/L + 101 g Prothioconazole/L	Other active substance content (g/kg or g/L)	None
Formulation (e.g., WP) :	EC	Residues calculated as :	XDE-777, X642188, X12314005, Prothioconazole-desthio, PTZ-a-OH-desthio, PTZ-3-OH-desthio, PTZ-4-OH-desthio, PTZ-5-OH-desthio and PTZ-6-OH-desthio

1	2	3	4			5	6		7	8				9
Report No. Location including Postal Code	**Commodity / Variety**	**Date of: 1. Sowing or Planting 2. Flowering 3. Harvest**	**Plot Application rate per treatment (A1-A2)**			**Dates of treatment(s) or no. of treatment(s) and last date**	**BBCH Growth stage at Application (A)and at Sampling (S)**		**Portion Analyzed**	**Residues (mg/kg) (f)**				**DALA**
	(a)	**(b)**	**g a.i/ha**	**Water (L/ha)**	**g a.i/hL**	**(c)**	**A**	**S**		**Fenpico-xamid (XDE-777)**	**X642188**	**X1231-4005**	**PTZ-desthio**	**(d)**
Sponsor Reference No.: 220541 Zurbano, 01520, Basque Country, Spain	Sugar Beet / Yucatan	1. 26 Mar 2022 2. Not applicable 3. 26 Oct 2022	--	--	--	Untreated	--	49	Tops	ND	ND	ND	0.01[A]	--
									Roots	ND	ND	ND	ND	
			a) 77.00 b) 155.54 a) 75.00 b) 151.50	308 300	a) 25.00 b) 50.50 a) 25.00 b) 50.50	A1 = 14 Sep 2022 A2 = 05 Oct 2022	47 49	49	Tops	0.10	0.03	ND	0.23	21 (NCH)
									Roots	ND	ND	ND	< 0.01 (0.005)	

[a] According to EEC and Codex Class Classification (both) should be used
[b] Only if relevant
[c] Year must be indicated
[d] DALA = Days after last application; NCH = Normal commercial harvest
a) active ingredient for Fenpicoxamid only; b) active ingredient for Prothioconazole only.
[A] Reported residue value is average of three replicate analyses (0.01, 0.01 and 0.01 mg/kg). Equivalent spare sample also analysed in duplicate, residues found were 0.01 and 0.01 m/kg.
[e] High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated
[f] Analytical methods: DAS Reference ID 120615, DAS Reference ID 140696, Analytical Method MR-06/138 Amendment 4 and Modification M002 of the Analytical Method 00979/M002
The designation "ND" is used for treated samples for which the residue was <LOD (0.003 mg/kg)
Residue values below the LOQ (0.01 mg/kg) but greater than or equal to the LOD are reported as <LOQ with the uncorrected concentration in parentheses ( ).

Residues of Fenpicoxamid, Prothioconazole and metabolites in Field Sugar Beet from Supervised Trials for Sponsor Reference No.: 220541, Test No. 3: Zurbano, Basque Country, Spain

Active ingredient (a.i.)(common name):	Fenpicoxamid + Prothioconazole	Commercial product (name) :	GF-3307
Crop / Crop Group::	Sugar beet / Beet	Producer of commercial product :	Corteva Agriscience
Responsible body for reporting :	Corteva Agriscience, LLC	Method of treatment (e) :	Foliar application using a Knapsack sprayer
(name, address) :	9330 Zionsville Road, Indianapolis, IN, 46268 USA	Indoor/Outdoor :	Outdoor
Country :	Spain	Other active substance in the formulation :	None
Content of active substance: (g/L) :	50 g Fenpicoxamid/L + 101 g Prothioconazole/L	Other active substance content (g/kg or g/L)	None
Formulation (e.g., WP) :	EC	Residues calculated as :	XDE-777, X642188, X12314005, Prothioconazole-desthio, PTZ-a-OH-desthio, PTZ-3-OH-desthio, PTZ-4-OH-desthio, PTZ-5-OH-desthio and PTZ-6-OH-desthio

1	2	3	4			5	6		7	8					9
Report No. Location including Postal Code	Commodity / Variety	Date of: 1. Sowing or Planting 2. Flowering 3. Harvest	Plot Application rate per treatment (A1-A2)			Dates of treatment(s) or no. of treatment(s) and last date	BBCH Growth stage at Application (A)and at Sampling (S)		Portion Analyzed	Residues (mg/kg) (f)					DALA
	(a)	(b)	g a.i/ha	Water (L/ha)	g a.i/hL	(c)	A	S		PTZ-a-OH-desthio	PTZ-3-OH-desthio	PTZ-4-OH-desthio	PTZ-5-OH-desthio	PTZ-6-OH-desthio	(d)
Sponsor Reference No.: 220541 Zurbano, 01520, Basque Country, Spain	Sugar Beet / Yucatan	1. 26 Mar 2022 2. Not applicable 3. 26 Oct 2022	--	--	--	Untreated	--	49	Tops	ND	0.01[B]	< 0.01[C] (0.008)	ND	ND	--
									Roots	ND	ND	ND	ND	ND	
			a) 77.00 b) 155.54 a) 75.00 b) 151.50	308 300	a) 25.00 b) 50.50 a) 25.00 b) 50.50	A1 = 14 Sep 2022 A2 = 05 Oct 2022	47 49	49	Tops	< 0.01 (0.007)	0.07	0.04	0.02	ND	21 (NCH)
									Roots	ND	ND	ND	ND	ND	

[a] According to EEC and Codex Class Classification (both) should be used
[b] Only if relevant
[c] Year must be indicated
[d] DALA = Days after last application; NCH = Normal commercial harvest
a) active ingredient for Fenpicoxamid only; b) active ingredient for Prothioconazole only
[B] Reported residue value is average of three replicate analyses (0.02, 0.01 and 0.01 mg/kg). Equivalent spare sample also analysed in duplicate, residues found were 0.01 and 0.02 m/kg.
[C] High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated
[f] Analytical methods: DAS Reference ID 120615, DAS Reference ID 140696, Analytical Method MR-06/138 Amendment 4 and Modification M002 of the Analytical Method 00979/M002
The designation "ND" is used for treated samples for which the residue was <LOD (0.003 mg/kg)
Residue values below the LOQ (0.01 mg/kg) but greater than or equal to the LOD are reported as <LOQ with the uncorrected concentration in parentheses ( ).
[C] Reported residue value is average of three replicate analyses (0.009, 0.007 and 0.007 mg/kg). Equivalent spare sample also analysed in duplicate, residues found were 0.005 and 0.008 m/kg.

Residues of Fenpicoxamid, Prothioconazole and metabolites in Processed Sugar Beet Commodities from Supervised Trials for Sponsor Reference No.: 220541, Test No. 3: Zurbano, Basque Country, Spain

Active ingredient (a.i.)(common name):		Fenpicoxamid + Prothioconazole	Commercial product (name)	:	GF-3307
Crop / Crop Group::		Sugar beet / Beet	Producer of commercial product	:	Corteva Agriscience
Responsible body for reporting	:	Corteva Agriscience, LLC	Method of treatment (e)	:	None
(name, address)	:	9330 Zionsville Road, Indianapolis, IN, 46268 USA	Indoor/Outdoor	:	Outdoor
Country	:	Spain	Other active substance in the formulation	:	None
Content of active substance: (g/L)	:	50 g Fenpicoxamid/L + 101 g Prothioconazole/L	Other active substance content (g/kg or g/L)		None
Formulation (e.g., WP)	:	EC	Residues calculated as	:	XDE-777, X642188, X12314005, Prothioconazole-desthio, PTZ-α-OH-desthio, PTZ-3-OH-desthio, PTZ-4-OH-desthio, PTZ-5-OH-desthio and PTZ-6-OH-desthio

1	2	3	4			5	6		7	8					9
Report No. Location including Postal Code	**Commodity / Variety**	**Date of: 1. Sowing or Planting 2. Flowering 3. Harvest**	**Plot Application rate per treatment**			**Dates of treatment(s) or no. of treatment(s) and last date**	**BBCH Growth stage at Application (A)and at Sampling (S)**		**Portion Analyzed**	**Residues (mg/kg) (f)**					**DALA**
	(a)	**(b)**	**g a.i/ha**	**Water (L/ha)**	**g a.i/hL**	**(c)**	**A**	**S**		**Fenpico-xamid (XDE-777)**	**X12 314005**	**X12 019520**	**X1233 5723**	**X12264475**	**(d)**
Sponsor Reference No.: 220541 Zurbano, 01520, Basque Country, Spain	Sugar Beet / Yucatan	1. 26 Mar 2022 2. Not applicable 3. 26 Oct 2022	--	--	--	Untreated	--	--	Roots prior to processing	ND	ND	ND	ND	ND	--
								--	Press water	ND	--	--	--	ND	--
								--	Wet pulp	ND	--	--	--	ND	--
								--	Pressed pulp	ND	--	--	--	ND	--
								--	Dried pulp	ND	--	--	--	ND	--
								--	Ensiled pulp	ND	--	--	--	ND	--
								--	Raw juice	ND	--	--	--	ND	--
								--	Thick juice	ND	--	--	--	<0.01 (0.005)	--
								--	Raw sugar	ND	--	--	--	ND	--
								--	Molasses	ND	--	--	--	<0.01 (0.006)	--
								--	Refined sugar	ND	--	--	--	ND	--

[a] According to EEC and Codex Class Classification (both) should be used
[b] Only if relevant
[c] Year must be indicated
[d] DALA = Days after last application
[e] High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated
[f] Analytical methods: DAS Reference ID 120615, DAS Reference ID 140696, Analytical Method MR-06/138 Amendment 4 and Modification M002 of the Analytical Method 00979/M002
The designation "ND" is used for treated samples for which the residue was <LOD (0.003 mg/kg)
Residue values below the LOQ (0.01 mg/kg) but greater than or equal to the LOD are reported as <LOQ with the uncorrected concentration in parentheses ( ).

Residues of Fenpicoxamid, Prothioconazole and metabolites in Processed Sugar Beet Commodities from Supervised Trials for Sponsor Reference No.: 220541, Test No. 3: Zurbano, Basque Country, Spain

Active ingredient (a.i.)(common name):		Fenpicoxamid + Prothioconazole		Commercial product (name)	:	GF-3307	
Crop / Crop Group::		Sugar beet / Beet		Producer of commercial product	:	Corteva Agriscience	
Responsible body for reporting	:	Corteva Agriscience, LLC		Method of treatment (e)	:	Foliar application using a Knapsack sprayer	
(name, address)	:	9330 Zionsville Road, Indianapolis, IN, 46268 USA		Indoor/Outdoor	:	Outdoor	
Country	:	Spain		Other active substance in the formulation	:	None	
Content of active substance: (g/L)	:	50 g Fenpicoxamid/L + 101 g Prothioconazole/L		Other active substance content (g/kg or g/L)		None	
Formulation (e.g., WP)	:	EC		Residues calculated as	:	XDE-777, X642188, X12314005, Prothioconazole-desthio, PTZ-α-OH-desthio, PTZ-3-OH-desthio, PTZ-4-OH-desthio, PTZ-5-OH-desthio and PTZ-6-OH-desthio	

1	2	3	4			5	6		7	8		9
Report No. Location including Postal Code	**Commodity / Variety**	**Date of: 1. Sowing or Planting 2. Flowering 3. Harvest**	**Plot Application rate per treatment (A1-A2)**			**Dates of treatment(s) or no. of treatment(s) and last date**	**BBCH Growth stage at Application (A)and at Sampling (S)**		**Portion Analyzed**	**Residues (mg/kg) (f)**		**DALA**
	(a)	**(b)**	**g a.i/ha**	**Water (L/ha)**	**g a.i/hL**	**(c)**	**A**	**S**		**Fenpicoxamid (XDE-777)**	**X12314005**	**(d)**
Sponsor Reference No.: 220541 Zurbano, 01520, Basque Country, Spain	Sugar Beet / Yucatan	1. 26 Mar 2022 2. Not applicable 3. 26 Oct 2022	a) 372.50 b) 752.45 a) 380.00 b) 767.60	298 304	a) 125.00 b) 252.50 a) 125.00 b) 252.50	A1 = 14 Sep 2022 A2 = 05 Oct 2022	47 49	--	Roots prior to processing	0.01	ND	--
								--	Press water	ND	--	--
								--	Wet pulp	< 0.01 (0.005)	--	--
								--	Pressed pulp	< 0.01 (0.007)	--	--
								--	Dried pulp	0.02	--	--
								--	Ensiled pulp	ND	--	--
								--	Raw juice	< 0.01 (0.007)	--	--
								--	Thick juice	ND	--	--
								--	Raw sugar	ND	--	--
								--	Molasses	ND	--	--
								--	Refined sugar	ND	--	--

[a] According to EEC and Codex Class Classification (both) should be used
[b] Only if relevant
[c] Year must be indicated
[d] DALA = Days after last application
a) active ingredient for Fenpicoxamid only; b) active ingredient for Prothioconazole only

[e] High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated
[f] Analytical methods: DAS Reference ID 120615, DAS Reference ID 140696, Analytical Method MR-06/138 Amendment 4 and Modification M002 of the Analytical Method 00979/M002
The designation "ND" is used for treated samples for which the residue was <LOD (0.003 mg/kg)
Residue values below the LOQ (0.01 mg/kg) but greater than or equal to the LOD are reported as <LOQ with the uncorrected concentration in parentheses ( ).

Residues of Fenpicoxamid, Prothioconazole and metabolites in Processed Sugar Beet Commodities from Supervised Trials for Sponsor Reference No.: 220541, Test No. 3: Zurbano, Basque Country, Spain

Active ingredient (a.i.)(common name):		Fenpicoxamid + Prothioconazole	Commercial product (name)	:	GF-3307
Crop / Crop Group::		Sugar beet / Beet	Producer of commercial product	:	Corteva Agriscience
Responsible body for reporting	:	Corteva Agriscience, LLC	Method of treatment (e)	:	Foliar application using a Knapsack sprayer
(name, address)	:	9330 Zionsville Road, Indianapolis, IN, 46268 USA	Indoor/Outdoor	:	Outdoor
Country	:	Spain	Other active substance in the formulation	:	None
Content of active substance: (g/L)	:	50 g Fenpicoxamid/L + 101 g Prothioconazole/L	Other active substance content (g/kg or g/L)		None
Formulation (e.g., WP)	:	EC	Residues calculated as	:	XDE-777, X642188, X12314005, Prothioconazole-desthio, PTZ-α-OH-desthio, PTZ-3-OH-desthio, PTZ-4-OH-desthio, PTZ-5-OH-desthio and PTZ-6-OH-desthio

1	2	3	4			5	6		7	8			9
Report No. Location including Postal Code	**Commodity / Variety**	**Date of: 1. Sowing or Planting 2. Flowering 3. Harvest**	**Plot Application rate per treatment (A1-A2)**			**Dates of treatment(s) or no. of treatment(s) and last date**	**BBCH Growth stage at Application (A)and at Sampling (S)**		**Portion Analyzed**	**Residues (mg/kg) (f)**			**DALA**
	(a)	**(b)**	**g a.i/ha**	**Water (L/ha)**	**g a.i/hL**	**(c)**	**A**	**S**		**X12019520**	**X12335723**	**X12264475**	**(d)**
Sponsor Reference No.: 220541 Zurbano, 01520, Basque Country, Spain	Sugar Beet / Yucatan	1. 26 Mar 2022 2. Not applicable 3. 26 Oct 2022	a) 372.50 b) 752.45 a) 380.00 b) 767.60	298 304	a) 125.00 b) 252.50 a) 125.00 b) 252.50	A1 = 14 Sep 2022 A2 = 05 Oct 2022	47 49	--	Roots prior to processing	ND	ND	0.04	--
								--	Press water	--	--	0.03	--
								--	Wet pulp	--	--	0.02	--
								--	Pressed pulp	--	--	0.02	--
								--	Dried pulp	--	--	0.06	--
								--	Ensiled pulp	--	--	0.03	--
								--	Raw juice	--	--	0.02	--
								--	Thick juice	--	--	0.08	--
								--	Raw sugar	--	--	0.05	--
								--	Molasses	--	--	0.18	--
								--	Refined sugar	--	--	0.02	--

[a] According to EEC and Codex Class Classification (both) should be used
[b] Only if relevant
[c] Year must be indicated
[d] DALA = Days after last application
a) active ingredient for Fenpicoxamid only; b) active ingredient for Prothioconazole only

[e] High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated
[f] Analytical methods: DAS Reference ID 120615, DAS Reference ID 140696, Analytical Method MR-06/138 Amendment 4 and Modification M002 of the Analytical Method 00979/M002
The designation "ND" is used for treated samples for which the residue was <LOD (0.003 mg/kg)
Residue values below the LOQ (0.01 mg/kg) but greater than or equal to the LOD are reported as <LOQ with the uncorrected concentration in parentheses ( ).

Residues of Fenpicoxamid, Prothioconazole and metabolites in Field Sugar Beet from Supervised Trials for Sponsor Reference No.: 220541, Test No. 4: Castelnuovo Scrivia, Piemonte, Italy

Active ingredient (a.i.)(common name):	Fenpicoxamid + Prothioconazole	Commercial product (name) :	GF-3307
Crop / Crop Group::	Sugar beet / Beet	Producer of commercial product :	Corteva Agriscience
Responsible body for reporting :	Corteva Agriscience, LLC	Method of treatment (e) :	Foliar application using a Knapsack sprayer
(name, address) :	9330 Zionsville Road, Indianapolis, IN, 46268 USA	Indoor/Outdoor :	Outdoor
Country :	Italy	Other active substance in the formulation :	None
Content of active substance: (g/L) :	50 g Fenpicoxamid/L + 101 g Prothioconazole/L	Other active substance content (g/kg or g/L)	None
Formulation (e.g., WP) :	EC	Residues calculated as :	XDE-777, X642188, X12314005, Prothioconazole-desthio, PTZ-a-OH-desthio, PTZ-3-OH-desthio, PTZ-4-OH-desthio, PTZ-5-OH-desthio and PTZ-6-OH-desthio

1	2	3	4			5	6		7	8				9
Report No. Location including Postal Code	**Commodity / Variety**	**Date of: 1. Sowing or Planting 2. Flowering 3. Harvest**	**Plot Application rate per treatment (A1-A2)**			**Dates of treatment(s) or no. of treatment(s) and last date**	**BBCH Growth stage at Application (A)and at Sampling (S)**		**Portion Analyzed**	**Residues (mg/kg) (f)**				**DALA**
	(a)	**(b)**	**g a.i/ha**	**Water (L/ha)**	**g a.i/hL**	**(c)**	**A**	**S**		**Fenpico-xamid (XDE-777)**	**X642188**	**X1231-4005**	**PTZ-desthio**	**(d)**
Sponsor Reference No.: 220541 Castelnuovo Scrivia, 15053, Piemonte, Italy	Sugar Beet / Ottavia	1. 01 Mar 2022 2. Not applicable 3. 25 Aug 2022	--	--	--	Untreated	--	49	Tops	ND	ND	ND	ND	--
									Roots	ND	ND	ND	ND	
			a) 75.50 b) 152.51	302	a) 25.00 b) 50.50	A1 = 14 Jul 2022 A2 = 04 Aug 2022	35	49	Tops	0.51	0.02	< 0.01 (0.004)	0.18	21 (NCH)
			a) 74.75 b) 151.00	299	a) 25.00 b) 50.50		49		Roots	ND	ND	ND	ND	

[a] According to EEC and Codex Class Classification (both) should be used
[b] Only if relevant
[c] Year must be indicated
[d] DALA = Days after last application; NCH = Normal commercial harvest
a) active ingredient for Fenpicoxamid only; b) active ingredient for Prothioconazole only
[e] High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated
[f] Analytical methods: DAS Reference ID 120615, DAS Reference ID 140696, Analytical Method MR-06/138 Amendment 4 and Modification M002 of the Analytical Method 00979/M002
The designation "ND" is used for treated samples for which the residue was <LOD (0.003 mg/kg)
Residue values below the LOQ (0.01 mg/kg) but greater than or equal to the LOD are reported as <LOQ with the uncorrected concentration in parentheses ( ).

Residues of Fenpicoxamid, Prothioconazole and metabolites in Field Sugar Beet from Supervised Trials for Sponsor Reference No.: 220541, Test No. 4: Castelnuovo Scrivia, Piemonte, Italy

Active ingredient (a.i.)(common name):	Fenpicoxamid + Prothioconazole	Commercial product (name) :	GF-3307
Crop / Crop Group::	Sugar beet / Beet	Producer of commercial product :	Corteva Agriscience
Responsible body for reporting :	Corteva Agriscience, LLC	Method of treatment (e) :	Foliar application using a Knapsack sprayer
(name, address) :	9330 Zionsville Road, Indianapolis, IN, 46268 USA	Indoor/Outdoor :	Outdoor
Country :	Italy	Other active substance in the formulation :	None
Content of active substance: (g/L) :	50 g Fenpicoxamid/L + 101 g Prothioconazole/L	Other active substance content (g/kg or g/L)	None
Formulation (e.g., WP) :	EC	Residues calculated as :	XDE-777, X642188, X12314005, Prothioconazole-desthio, PTZ-a-OH-desthio, PTZ-3-OH-desthio, PTZ-4-OH-desthio, PTZ-5-OH-desthio and PTZ-6-OH-desthio

1	2	3	4			5	6		7	8					9
Report No. Location including Postal Code	Commodity / Variety	Date of: 1. Sowing or Planting 2. Flowering 3. Harvest	Plot Application rate per treatment (A1-A2)			Dates of treatment(s) or no. of treatment(s) and last date	BBCH Growth stage at Application (A)and at Sampling (S)		Portion Analyzed	Residues (mg/kg) (f)					DALA
	(a)	(b)	g a.i/ha	Water (L/ha)	g a.i/hL	(c)	A	S		PTZ-a-OH-desthio	PTZ-3-OH-desthio	PTZ-4-OH-desthio	PTZ-5-OH-desthio	PTZ-6-OH-desthio	(d)
Sponsor Reference No.: 220541 Castelnuovo Scrivia, 15053, Piemonte, Italy	Sugar Beet / Ottavia	1. 01 Mar 2022 2. Not applicable 3. 25 Aug 2022	--	--	--	Untreated	--	49	Tops	ND	ND	ND	ND	ND	--
									Roots	ND	ND	ND	ND	ND	
			a) 75.50 b) 152.51	302	a) 25.00 b) 50.50	A1 = 14 Jul 2022 A2 = 04 Aug 2022	35 49	49	Tops	0.01	0.47	0.17	0.09	0.04	21 (NCH)
			a) 74.75 b) 151.00	299	a) 25.00 b) 50.50				Roots	ND	ND	ND	ND	ND	

[a] According to EEC and Codex Class Classification (both) should be used
[b] Only if relevant
[c] Year must be indicated
[d] DALA = Days after last application; NCH = Normal commercial harvest
a) active ingredient for Fenpicoxamid only; b) active ingredient for Prothioconazole only

[e] High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated
[f] Analytical methods: DAS Reference ID 120615, DAS Reference ID 140696, Analytical Method MR-06/138 Amendment 4 and Modification M002 of the Analytical Method 00979/M002
The designation "ND" is used for treated samples for which the residue was <LOD (0.003 mg/kg)
Residue values below the LOQ (0.01 mg/kg) but greater than or equal to the LOD are reported as <LOQ with the uncorrected concentration in parentheses ( ).

Residues of Fenpicoxamid, Prothioconazole and metabolites in Processed Sugar Beet Commodities from Supervised Trials for Sponsor Reference No.: 220541, Test No. 4: Castelnuovo Scrivia, Piemonte, Italy

Active ingredient (a.i.)(common name):	Fenpicoxamid + Prothioconazole	Commercial product (name)	:	GF-3307
Crop / Crop Group::	Sugar beet / Beet	Producer of commercial product	:	Corteva Agriscience
Responsible body for reporting	: Corteva Agriscience, LLC	Method of treatment (e)	:	None
(name, address)	: 9330 Zionsville Road, Indianapolis, IN, 46268 USA	Indoor/Outdoor	:	Outdoor
Country	: Italy	Other active substance in the formulation	:	None
Content of active substance: (g/L)	: 50 g Fenpicoxamid/L + 101 g Prothioconazole/L	Other active substance content (g/kg or g/L)		None
Formulation (e.g., WP)	: EC	Residues calculated as	:	XDE-777, X642188, X12314005, Prothioconazole-desthio, PTZ-α-OH-desthio, PTZ-3-OH-desthio, PTZ-4-OH-desthio, PTZ-5-OH-desthio and PTZ-6-OH-desthio

1	2	3	4			5	6		7	8					9
Report No. Location including Postal Code	**Commodity / Variety**	**Date of: 1. Sowing or Planting 2. Flowering 3. Harvest**	**Plot Application rate per treatment**			**Dates of treatment(s) or no. of treatment(s) and last date**	**BBCH Growth stage at Application (A)and at Sampling (S)**		**Portion Analyzed**	**Residues (mg/kg) (f)**					**DALA**
	(a)	**(b)**	**g a.i/ha**	**Water (L/ha)**	**g a.i/hL**	**(c)**	**A**	**S**		**Fenpico-xamid (XDE-777)**	**X1231 4005**	**X1201 9520**	**X1233 5723**	**X1226 4475**	**(d)**
Sponsor Reference No.: 220541 Castelnuovo Scrivia, 15053, Piemonte, Italy	Sugar Beet / Ottavia	1. 01 Mar 2022 2. Not applicable 3. 25 Aug 2022	--	--	--	Untreated	--	--	Roots prior to processing	ND	ND	ND	ND	ND	--
								--	Press water	--	--	--	--	--	--
								--	Wet pulp	--	--	--	--	--	--
								--	Pressed pulp	--	--	--	--	--	--
								--	Dried pulp	--	--	--	--	--	--
								--	Ensiled pulp	--	--	--	--	--	--
								--	Raw juice	--	--	--	--	--	--
								--	Thick juice	--	--	--	--	--	--
								--	Raw sugar	--	--	--	--	--	--
								--	Molasses	--	--	--	--	--	--
								--	Refined sugar	--	--	--	--	--	--

[a] According to EEC and Codex Class Classification (both) should be used
[b] Only if relevant
[c] Year must be indicated
[d] DALA = Days after last application
[e] High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated
[f] Analytical methods: DAS Reference ID 120615, DAS Reference ID 140696, Analytical Method MR-06/138 Amendment 4 and Modification M002 of the Analytical Method 00979/M002
The designation "ND" is used for treated samples for which the residue was <LOD (0.003 mg/kg)
Residue values below the LOQ (0.01 mg/kg) but greater than or equal to the LOD are reported as <LOQ with the uncorrected concentration in parentheses ( ).

Residues of Fenpicoxamid, Prothioconazole and metabolites in Processed Sugar Beet Commodities from Supervised Trials for Sponsor Reference No.: 220541, Test No. 4: Castelnuovo Scrivia, Piemonte, Italy

Active ingredient (a.i.)(common name):		Fenpicoxamid + Prothioconazole	Commercial product (name)	:	GF-3307
Crop / Crop Group::		Sugar beet / Beet	Producer of commercial product	:	Corteva Agriscience
Responsible body for reporting	:	Corteva Agriscience, LLC	Method of treatment (e)	:	Foliar application using a Knapsack sprayer
(name, address)	:	9330 Zionsville Road, Indianapolis, IN, 46268 USA	Indoor/Outdoor	:	Outdoor
Country	:	Italy	Other active substance in the formulation	:	None
Content of active substance: (g/L)	:	50 g Fenpicoxamid/L + 101 g Prothioconazole/L	Other active substance content (g/kg or g/L)		None
Formulation (e.g., WP)	:	EC	Residues calculated as	:	XDE-777, X642188, X12314005, Prothioconazole-desthio, PTZ-α-OH-desthio, PTZ-3-OH-desthio, PTZ-4-OH-desthio, PTZ-5-OH-desthio and PTZ-6-OH-desthio

1	2	3	4			5	6		7	8		9
Report No. Location including Postal Code	**Commodity / Variety**	**Date of: 1. Sowing or Planting 2. Flowering 3. Harvest**	**Plot Application rate per treatment (A1-A2)**			**Dates of treatment(s) or no. of treatment(s) and last date**	**BBCH Growth stage at Application (A)and at Sampling (S)**		**Portion Analyzed**	**Residues (mg/kg) (f)**		**DALA**
	(a)	**(b)**	**g a.i/ha**	**Water (L/ha)**	**g a.i/hL**	**(c)**	**A**	**S**		**Fenpicoxamid (XDE-777)**	**X12314005**	**(d)**
Sponsor Reference No.: 220541 Castelnuovo Scrivia, 15053, Piemonte, Italy	Sugar Beet / Ottavia	1. 01 Mar 2022 2. Not applicable 3. 25 Aug 2022	a) 373.75 b) 754.98 a) 376.25 b) 760.03	299 301	a) 125.00 b) 252.50 a) 125.00 b) 252.50	A1 = 14 Jul 2022 A2 = 04 Aug 2022	35 49	--	Roots prior to processing	0.02	ND	--
								--	Press water	ND	--	--
								--	Wet pulp	< 0.01 (0.009)	--	--
								--	Pressed pulp	0.02	--	--
								--	Dried pulp	0.04	--	--
								--	Ensiled pulp	< 0.01 (0.006)	--	--
								--	Raw juice	0.01	--	--
								--	Thick juice	ND	--	--
								--	Raw sugar	ND	--	--
								--	Molasses	ND	--	--
								--	Refined sugar	ND	--	--

[a] According to EEC and Codex Class Classification (both) should be used
[b] Only if relevant
[c] Year must be indicated
[d] DALA = Days after last application
a) active ingredient for Fenpicoxamid only; b) active ingredient for Prothioconazole only

[e] High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated
[f] Analytical methods: DAS Reference ID 120615, DAS Reference ID 140696, Analytical Method MR-06/138 Amendment 4 and Modification M002 of the Analytical Method 00979/M002
The designation "ND" is used for treated samples for which the residue was <LOD (0.003 mg/kg)
Residue values below the LOQ (0.01 mg/kg) but greater than or equal to the LOD are reported as <LOQ with the uncorrected concentration in parentheses ( ).

Residues of Fenpicoxamid, Prothioconazole and metabolites in Processed Sugar Beet Commodities from Supervised Trials for Sponsor Reference No.: 220541, Test No. 4: Castelnuovo Scrivia, Piemonte, Italy

Active ingredient (a.i.)(common name):		Fenpicoxamid + Prothioconazole	Commercial product (name)	:	GF-3307
Crop / Crop Group::		Sugar beet / Beet	Producer of commercial product	:	Corteva Agriscience
Responsible body for reporting	:	Corteva Agriscience, LLC	Method of treatment (e)	:	Foliar application using a Knapsack sprayer
(name, address)	:	9330 Zionsville Road, Indianapolis, IN, 46268 USA	Indoor/Outdoor	:	Outdoor
Country	:	Italy	Other active substance in the formulation	:	None
Content of active substance: (g/L)	:	50 g Fenpicoxamid/L + 101 g Prothioconazole/L	Other active substance content (g/kg or g/L)		None
Formulation (e.g., WP)	:	EC	Residues calculated as	:	XDE-777, X642188, X12314005, Prothioconazole-desthio, PTZ-α-OH-desthio, PTZ-3-OH-desthio, PTZ-4-OH-desthio, PTZ-5-OH-desthio and PTZ-6-OH-desthio

1	2	3	4			5	6		7	8			9
Report No. Location including Postal Code	**Commodity / Variety**	**Date of: 1. Sowing or Planting 2. Flowering 3. Harvest**	**Plot Application rate per treatment (A1-A2)**			**Dates of treatment(s) or no. of treatment(s) and last date**	**BBCH Growth stage at Application (A)and at Sampling (S)**		**Portion Analyzed**	**Residues (mg/kg) (f)**			**DALA**
	(a)	**(b)**	**g a.i/ha**	**Water (L/ha)**	**g a.i/hL**	**(c)**	**A**	**S**		**X12019520**	**X12335723**	**X12264475**	**(d)**
Sponsor Reference No.: 220541 Castelnuovo Scrivia, 15053, Piemonte, Italy	Sugar Beet / Ottavia	1. 01 Mar 2022 2. Not applicable 3. 25 Aug 2022	a) 373.75 b) 754.98 a) 376.25 b) 760.03	299 301	a) 125.00 b) 252.50 a) 125.00 b) 252.50	A1 = 14 Jul 2022 A2 = 04 Aug 2022	35 49	--	Roots prior to processing	ND	ND	ND	--
								--	Press water	--	--	--	--
								--	Wet pulp	--	--	--	--
								--	Pressed pulp	--	--	--	--
								--	Dried pulp	--	--	--	--
								--	Ensiled pulp	--	--	--	--
								--	Raw juice	--	--	--	--
								--	Thick juice	--	--	--	--
								--	Raw sugar	--	--	--	--
								--	Molasses	--	--	--	--
								--	Refined sugar	--	--	--	--

[a] According to EEC and Codex Class Classification (both) should be used
[b] Only if relevant
[c] Year must be indicated
[d] DALA = Days after last application
a) active ingredient for Fenpicoxamid only; b) active ingredient for Prothioconazole only

[e] High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated
[f] Analytical methods: DAS Reference ID 120615, DAS Reference ID 140696, Analytical Method MR-06/138 Amendment 4 and Modification M002 of the Analytical Method 00979/M002
The designation "ND" is used for treated samples for which the residue was <LOD (0.003 mg/kg)
Residue values below the LOQ (0.01 mg/kg) but greater than or equal to the LOD are reported as <LOQ with the uncorrected concentration in parentheses ( ).

Residues of Fenpicoxamid and its metabolites in Field Sugar Beet from Supervised Trials for Sponsor Reference No.: 220541, Test No. 5: Bőny, Győr-Moson-Sopron County, Hungary

Active ingredient (a.i.)(common name):	Fenpicoxamid + Prothioconazole	Commercial product (name)	:	GF-3307
Crop / Crop Group::	Sugar beet / Beet	Producer of commercial product	:	Corteva Agriscience
Responsible body for reporting	: Corteva Agriscience, LLC	Method of treatment (e)	:	None
(name, address)	: 9330 Zionsville Road, Indianapolis, IN, 46268 USA	Indoor/Outdoor	:	Outdoor
Country	: Hungary	Other active substance in the formulation	:	None
Content of active substance: (g/L)	: 50 g Fenpicoxamid/L + 101 g Prothioconazole/L	Other active substance content (g/kg or g/L)		None
Formulation (e.g., WP)	: EC	Residues calculated as	:	XDE-777, X642188, X12314005, Prothioconazole-desthio, PTZ-α-OH-desthio, PTZ-3-OH-desthio, PTZ-4-OH-desthio, PTZ-5-OH-desthio and PTZ-6-OH-desthio

1	2	3	4			5	6		7	8				9
Report No. Location including Postal Code	**Commodity / Variety**	**Date of: 1. Sowing or Planting 2. Flowering 3. Harvest**	**Plot Application rate per treatment**			**Dates of treatment(s) or no. of treatment(s) and last date**	**BBCH Growth stage at Application (A)and at Sampling (S)**		**Portion Analyzed**	**Residues (mg/kg) (f)**				**DALA**
	(a)	**(b)**	**g a.i/ha**	**Water (L/ha)**	**g a.i/hL**	**(c)**	**A**	**S**		**Fenpico-xamid (XDE-777)**	**X642188**	**X1231-4005**	**PTZ-desthio**	**(d)**
Sponsor Reference No.: 220541 Bőny, 9073, Győr-Moson-Sopron County, Hungary	Sugar Beet / Deseda	1. 08 Apr 2022 2. Not applicable 3. 15 Sep 2022	--	--	--	Untreated	--	49	Tops	ND	ND	ND	ND	--
									Roots	ND	ND	ND	ND	
								49	Tops	ND	ND	ND	ND	--
									Roots	ND	ND	ND	ND	
								49	Tops	ND	ND	ND	ND[A]	--
									Roots	ND	ND	ND	ND	
								49	Tops	ND	ND	ND	ND	--
									Roots	ND	ND	ND	ND	
								49	Tops	ND	ND	ND	ND	--
									Roots	ND	ND	ND	ND	
								49	Tops	ND	ND	ND	ND	--
									Roots	ND	ND	ND	ND	

[a] According to EEC and Codex Class Classification (both) should be used
[b] Only if relevant
[c] Year must be indicated
[d] DALA = Days after last application
[A] Reported residue value is for spare sample. Primary sample was analysed in quintuplicate, residues found were 0.008, 0.01, 0.01, 0.01 and 0.01 mg/kg.
[e] High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated
[f] Analytical methods: DAS Reference ID 120615, DAS Reference ID 140696, Analytical Method MR-06/138 Amendment 4 and Modification M002 of the Analytical Method 00979/M002
The designation "ND" is used for treated samples for which the residue was <LOD (0.003 mg/kg)
Residue values below the LOQ (0.01 mg/kg) but greater than or equal to the LOD are reported as <LOQ with the uncorrected concentration in parentheses ( ).

Residues of Fenpicoxamid and its metabolites in Field Sugar Beet from Supervised Trials for Sponsor Reference No.: 220541, Test No. 5: Bőny, Győr-Moson-Sopron County, Hungary

Active ingredient (a.i.)(common name):		Fenpicoxamid + Prothioconazole	Commercial product (name)	:	GF-3307
Crop / Crop Group::		Sugar beet / Beet	Producer of commercial product	:	Corteva Agriscience
Responsible body for reporting	:	Corteva Agriscience, LLC	Method of treatment (e)	:	None
(name, address)	:	9330 Zionsville Road, Indianapolis, IN, 46268 USA	Indoor/Outdoor	:	Outdoor
Country	:	Hungary	Other active substance in the formulation	:	None
Content of active substance: (g/L)	:	50 g Fenpicoxamid/L + 101 g Prothioconazole/L	Other active substance content (g/kg or g/L)		None
Formulation (e.g., WP)	:	EC	Residues calculated as	:	XDE-777, X642188, X12314005, Prothioconazole-desthio, PTZ-α-OH-desthio, PTZ-3-OH-desthio, PTZ-4-OH-desthio, PTZ-5-OH-desthio and PTZ-6-OH-desthio

1	2	3	4			5	6		7	8					9
Report No. Location including Postal Code	**Commodity / Variety**	**Date of: 1. Sowing or Planting 2. Flowering 3. Harvest**	**Plot Application rate per treatment**			**Dates of treatment(s) or no. of treatment(s) and last date**	**BBCH Growth stage at Application (A)and at Sampling (S)**		**Portion Analyzed**	**Residues (mg/kg) (f)**					**DALA**
	(a)	**(b)**	**g a.i/ha**	**Water (L/ha)**	**g a.i/hL**	**(c)**	**A**	**S**		**PTZ-α-OH-desthio**	**PTZ-3-OH-desthio**	**PTZ-4-OH-desthio**	**PTZ-5-OH-desthio**	**PTZ-6-OH-desthio**	**(d)**
Sponsor Reference No.: 220541 Bőny, 9073, Győr-Moson-Sopron County, Hungary	Sugar Beet / Deseda	1. 08 Apr 2022 2. Not applicable 3. 15 Sep 2022	--	--	--	Untreated	--	49	Tops	ND	ND	ND	ND	ND	--
									Roots	ND	ND	ND	ND	ND	
								49	Tops	ND	ND	ND	ND	ND	--
									Roots	ND	ND	ND	ND	ND	
								49	Tops	ND	ND	ND	ND	ND	--
									Roots	ND	ND	ND	ND	ND	
								49	Tops	ND	ND	ND	ND	ND	--
									Roots	ND	ND	ND	ND	ND	
								49	Tops	ND	ND	ND	ND	ND	--
									Roots	ND	ND	ND	ND	ND	
								49	Tops	ND	ND	ND	ND	ND	--
									Roots	ND	ND	ND	ND	ND	

[a] According to EEC and Codex Class Classification (both) should be used
[b] Only if relevant
[c] Year must be indicated
[d] DALA = Days after last application
[e] High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated
[f] Analytical methods: DAS Reference ID 120615, DAS Reference ID 140696, Analytical Method MR-06/138 Amendment 4 and Modification M002 of the Analytical Method 00979/M002
The designation "ND" is used for treated samples for which the residue was <LOD (0.003 mg/kg)
Residue values below the LOQ (0.01 mg/kg) but greater than or equal to the LOD are reported as <LOQ with the uncorrected concentration in parentheses ( ).

Residues of Fenpicoxamid and its metabolites in Field Sugar Beet from Supervised Trials for Sponsor Reference No.: 220541, Test No. 5: Bőny, Győr-Moson-Sopron County, Hungary

Active ingredient (a.i.)(common name):		Fenpicoxamid + Prothioconazole	Commercial product (name)	:	GF-3307
Crop / Crop Group::		Sugar beet / Beet	Producer of commercial product	:	Corteva Agriscience
Responsible body for reporting	:	Corteva Agriscience, LLC	Method of treatment (e)	:	Foliar application using a Knapsack sprayer
(name, address)	:	9330 Zionsville Road, Indianapolis, IN, 46268 USA	Indoor/Outdoor	:	Outdoor
Country	:	Hungary	Other active substance in the formulation	:	None
Content of active substance: (g/L)	:	50 g Fenpicoxamid/L + 101 g Prothioconazole/L	Other active substance content (g/kg or g/L)		None
Formulation (e.g., WP)	:	EC	Residues calculated as	:	XDE-777, X642188, X12314005, Prothioconazole-desthio, PTZ-α-OH-desthio, PTZ-3-OH-desthio, PTZ-4-OH-desthio, PTZ-5-OH-desthio and PTZ-6-OH-desthio

1	2	3	4			5	6		7	8				9
Report No. Location including Postal Code	**Commodity / Variety**	**Date of: 1. Sowing or Planting 2. Flowering 3. Harvest**	**Plot Application rate per treatment (A1-A2)**			**Dates of treatment(s) or no. of treatment(s) and last date**	**BBCH Growth stage at Application (A)and at Sampling (S)**		**Portion Analyzed**	**Residues (mg/kg) (f)**				**DALA**
	(a)	**(b)**	**g a.i/ha**	**Water (L/ha)**	**g a.i/hL**	**(c)**	**A**	**S**		**Fenpico-xamid (XDE-777)**	**X642188**	**X1231-4005**	**PTZ-desthio**	**(d)**
Sponsor Reference No.: 220541 Bőny, 9073, Győr-Moson-Sopron County, Hungary	Sugar Beet / Deseda	1. 08 Apr 2022 2. Not applicable 3. 15 Sep 2022	a) 74.25 b) 149.99 a) 75.00 b) 151.50	297 300	a) 25.00 b) 50.50 a) 25.00 b) 50.50	A1 = 26 Aug 2022 A2 = 15 Sep 2022	39-49 49	49	Tops	0.03	0.01	ND	0.15	-0
									Roots	ND	ND	ND	ND	
								49	Tops	0.15	0.12	< 0.01 (0.008)	0.45	+0
									Roots	< 0.01 (0.004)	ND	ND	0.03	
								49	Tops	0.09	0.02	ND	0.08	7
									Roots	ND	ND	ND	< 0.01 (0.004)	

[a] According to EEC and Codex Class Classification (both) should be used
[b] Only if relevant
[c] Year must be indicated
[d] DALA = Days after last application
a) active ingredient for Fenpicoxamid only; b) active ingredient for Prothioconazole only

[e] High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated
[f] Analytical methods: DAS Reference ID 120615, DAS Reference ID 140696, Analytical Method MR-06/138 Amendment 4 and Modification M002 of the Analytical Method 00979/M002
The designation "ND" is used for treated samples for which the residue was <LOD (0.003 mg/kg)
Residue values below the LOQ (0.01 mg/kg) but greater than or equal to the LOD are reported as <LOQ with the uncorrected concentration in parentheses ( ).

Residues of Fenpicoxamid and its metabolites in Field Sugar Beet from Supervised Trials for Sponsor Reference No.: 220541, Test No. 5: Bőny, Győr-Moson-Sopron County, Hungary

Active ingredient (a.i.)(common name):		Fenpicoxamid + Prothioconazole	Commercial product (name)	:	GF-3307
Crop / Crop Group::		Sugar beet / Beet	Producer of commercial product	:	Corteva Agriscience
Responsible body for reporting	:	Corteva Agriscience, LLC	Method of treatment (e)	:	Foliar application using a Knapsack sprayer
(name, address)	:	9330 Zionsville Road, Indianapolis, IN, 46268 USA	Indoor/Outdoor	:	Outdoor
Country	:	Hungary	Other active substance in the formulation	:	None
Content of active substance: (g/L)	:	50 g Fenpicoxamid/L + 101 g Prothioconazole/L	Other active substance content (g/kg or g/L)		None
Formulation (e.g., WP)	:	EC	Residues calculated as	:	XDE-777, X642188, X12314005, Prothioconazole-desthio, PTZ-α-OH-desthio, PTZ-3-OH-desthio, PTZ-4-OH-desthio, PTZ-5-OH-desthio and PTZ-6-OH-desthio

1	2	3	4			5	6		7	8				9
Report No. Location including Postal Code	**Commodity / Variety**	**Date of: 1. Sowing or Planting 2. Flowering 3. Harvest**	**Plot Application rate per treatment (A1-A2)**			**Dates of treatment(s) or no. of treatment(s) and last date**	**BBCH Growth stage at Application (A)and at Sampling (S)**		**Portion Analyzed**	**Residues (mg/kg) (f)**				**DALA**
	(a)	**(b)**	**g a.i/ha**	**Water (L/ha)**	**g a.i/hL**	**(c)**	**A**	**S**		**Fenpico-xamid (XDE-777)**	**X642188**	**X1231-4005**	**PTZ-desthio**	**(d)**
Sponsor Reference No.: 220541 Bőny, 9073, Győr-Moson-Sopron County, Hungary	Sugar Beet / Deseda	1. 08 Apr 2022 2. Not applicable 3. 15 Sep 2022	a) 74.25 b) 149.99 a) 75.00 b) 151.50	297 300	a) 25.00 b) 50.50 a) 25.00 b) 50.50	A1 = 26 Aug 2022 A2 = 15 Sep 2022	39-49 49	49	Tops	0.03	< 0.01 (0.009)	ND	0.08	14
									Roots	ND	ND	ND	0.01	
								49	Tops	0.02	< 0.01 (0.006)	ND	0.05	21
									Roots	ND	ND	ND	< 0.01 (0.008)	
								49	Tops	0.02	< 0.01 (0.005)	ND	0.14	35
									Roots	ND	ND	ND	ND	

[a] According to EEC and Codex Class Classification (both) should be used
[b] Only if relevant
[c] Year must be indicated
[d] DALA = Days after last application
a) active ingredient for Fenpicoxamid only; b) active ingredient for Prothioconazole only

[e] High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated
[f] Analytical methods: DAS Reference ID 120615, DAS Reference ID 140696, Analytical Method MR-06/138 Amendment 4 and Modification M002 of the Analytical Method 00979/M002
The designation "ND" is used for treated samples for which the residue was <LOD (0.003 mg/kg)
Residue values below the LOQ (0.01 mg/kg) but greater than or equal to the LOD are reported as <LOQ with the uncorrected concentration in parentheses ( ).

Residues of Fenpicoxamid and its metabolites in Field Sugar Beet from Supervised Trials for Sponsor Reference No.: 220541, Test No. 5: Bőny, Győr-Moson-Sopron County, Hungary

Active ingredient (a.i.)(common name):		Fenpicoxamid + Prothioconazole	Commercial product (name)	:	GF-3307
Crop / Crop Group::		Sugar beet / Beet	Producer of commercial product	:	Corteva Agriscience
Responsible body for reporting	:	Corteva Agriscience, LLC	Method of treatment (e)	:	Foliar application using a Knapsack sprayer
(name, address)	:	9330 Zionsville Road, Indianapolis, IN, 46268 USA	Indoor/Outdoor	:	Outdoor
Country	:	Hungary	Other active substance in the formulation	:	None
Content of active substance: (g/L)	:	50 g Fenpicoxamid/L + 101 g Prothioconazole/L	Other active substance content (g/kg or g/L)		None
Formulation (e.g., WP)	:	EC	Residues calculated as	:	XDE-777, X642188, X12314005, Prothioconazole-desthio, PTZ-α-OH-desthio, PTZ-3-OH-desthio, PTZ-4-OH-desthio, PTZ-5-OH-desthio and PTZ-6-OH-desthio

1	2	3	4			5	6		7	8					9
Report No. Location including Postal Code	**Commodity / Variety**	**Date of: 1. Sowing or Planting 2. Flowering 3. Harvest**	**Plot Application rate per treatment (A1-A2)**			**Dates of treatment(s) or no. of treatment(s) and last date**	**BBCH Growth stage at Application (A)and at Sampling (S)**		**Portion Analyzed**	**Residues (mg/kg) (f)**					**DALA**
	(a)	**(b)**	**g a.i/ha**	**Water (L/ha)**	**g a.i/hL**	**(c)**	**A**	**S**		**PTZ-α-OH-desthio**	**PTZ-3-OH-desthio**	**PTZ-4-OH-desthio**	**PTZ-5-OH-desthio**	**PTZ-6-OH-desthio**	**(d)**
Sponsor Reference No.: 220541 Bőny, 9073, Győr-Moson-Sopron County, Hungary	Sugar Beet / Deseda	1. 08 Apr 2022 2. Not applicable 3. 15 Sep 2022	a) 74.25 b) 149.99 a) 75.00 b) 151.50	297 300	a) 25.00 b) 50.50 a) 25.00 b) 50.50	A1 = 26 Aug 2022 A2 = 15 Sep 2022	39-49 49	49	Tops	0.01	0.06	0.03	< 0.01 (0.009)	ND	-0
									Roots	ND	ND	ND	ND	ND	
								49	Tops	0.02	0.04	0.02	< 0.01 (0.009)	ND	+0
									Roots	ND	ND	ND	ND	ND	
								49	Tops	0.01	0.07	0.03	< 0.01 (0.008)	ND	7
									Roots	ND	ND	ND	ND	ND	

[a] According to EEC and Codex Class Classification (both) should be used
[b] Only if relevant
[c] Year must be indicated
[d] DALA = Days after last application
a) active ingredient for Fenpicoxamid only; b) active ingredient for Prothioconazole only

[e] High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated
[f] Analytical methods: DAS Reference ID 120615, DAS Reference ID 140696, Analytical Method MR-06/138 Amendment 4 and Modification M002 of the Analytical Method 00979/M002
The designation "ND" is used for treated samples for which the residue was <LOD (0.003 mg/kg)
Residue values below the LOQ (0.01 mg/kg) but greater than or equal to the LOD are reported as <LOQ with the uncorrected concentration in parentheses ( ).

Residues of Fenpicoxamid and its metabolites in Field Sugar Beet from Supervised Trials for Sponsor Reference No.: 220541, Test No. 5: Bőny, Győr-Moson-Sopron County, Hungary

Active ingredient (a.i.)(common name):		Fenpicoxamid + Prothioconazole	Commercial product (name)	:	GF-3307
Crop / Crop Group::		Sugar beet / Beet	Producer of commercial product	:	Corteva Agriscience
Responsible body for reporting	:	Corteva Agriscience, LLC	Method of treatment (e)	:	Foliar application using a Knapsack sprayer
(name, address)	:	9330 Zionsville Road, Indianapolis, IN, 46268 USA	Indoor/Outdoor	:	Outdoor
Country	:	Hungary	Other active substance in the formulation	:	None
Content of active substance: (g/L)	:	50 g Fenpicoxamid/L + 101 g Prothioconazole/L	Other active substance content (g/kg or g/L)		None
Formulation (e.g., WP)	:	EC	Residues calculated as	:	XDE-777, X642188, X12314005, Prothioconazole-desthio, PTZ-α-OH-desthio, PTZ-3-OH-desthio, PTZ-4-OH-desthio, PTZ-5-OH-desthio and PTZ-6-OH-desthio

1	2	3	4			5	6		7	8					9
Report No. Location including Postal Code	**Commodity / Variety**	**Date of: 1. Sowing or Planting 2. Flowering 3. Harvest**	**Plot Application rate per treatment (A1-A2)**			**Dates of treatment(s) or no. of treatment(s) and last date**	**BBCH Growth stage at Application (A)and at Sampling (S)**		**Portion Analyzed**	**Residues (mg/kg) (f)**					**DALA**
	(a)	**(b)**	**g a.i/ha**	**Water (L/ha)**	**g a.i/hL**	**(c)**	**A**	**S**		**PTZ-α-OH-desthio**	**PTZ-3-OH-desthio**	**PTZ-4-OH-desthio**	**PTZ-5-OH-desthio**	**PTZ-6-OH-desthio**	**(d)**
Sponsor Reference No.: 220541 Bőny, 9073, Győr-Moson-Sopron County, Hungary	Sugar Beet / Deseda	1. 08 Apr 2022 2. Not applicable 3. 15 Sep 2022	a) 74.25 b) 149.99 a) 75.00 b) 151.50	297 300	a) 25.00 b) 50.50 a) 25.00 b) 50.50	A1 = 26 Aug 2022 A2 = 15 Sep 2022	39-49 49	49	Tops	0.01	0.03	0.01	< 0.01 (0.006)	ND	14
									Roots	ND	ND	ND	ND	ND	
								49	Tops	< 0.01 (0.007)	0.03	0.01	< 0.01 (0.005)	ND	21
									Roots	ND	ND	ND	ND	ND	
								49	Tops	< 0.01 (0.006)	0.03	0.01	< 0.01 (0.004)	ND	35
									Roots	ND	ND	ND	ND	ND	

[a] According to EEC and Codex Class Classification (both) should be used
[b] Only if relevant
[c] Year must be indicated
[d] DALA = Days after last application
a) active ingredient for Fenpicoxamid only; b) active ingredient for Prothioconazole only

[e] High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated
[f] Analytical methods: DAS Reference ID 120615, DAS Reference ID 140696, Analytical Method MR-06/138 Amendment 4 and Modification M002 of the Analytical Method 00979/M002
The designation "ND" is used for treated samples for which the residue was <LOD (0.003 mg/kg)
Residue values below the LOQ (0.01 mg/kg) but greater than or equal to the LOD are reported as <LOQ with the uncorrected concentration in parentheses ( ).

Residues of Fenpicoxamid and its metabolites in Field Sugar Beet from Supervised Trials for Sponsor Reference No.: 220541, Test No. 6: Slingsby, North Yorkshire, United Kingdom

Active ingredient (a.i.)(common name):		Fenpicoxamid + Prothioconazole	Commercial product (name)	:	GF-3307
Crop / Crop Group::		Sugar beet / Beet	Producer of commercial product	:	Corteva Agriscience
Responsible body for reporting	:	Corteva Agriscience, LLC	Method of treatment (e)	:	None
(name, address)	:	9330 Zionsville Road, Indianapolis, IN, 46268 USA	Indoor/Outdoor	:	Outdoor
Country	:	United Kingdom	Other active substance in the formulation	:	None
Content of active substance: (g/L)	:	50 g Fenpicoxamid/L + 101 g Prothioconazole/L	Other active substance content (g/kg or g/L)		None
Formulation (e.g., WP)	:	EC	Residues calculated as	:	XDE-777, X642188, X12314005, Prothioconazole-desthio, PTZ-α-OH-desthio, PTZ-3-OH-desthio, PTZ-4-OH-desthio, PTZ-5-OH-desthio and PTZ-6-OH-desthio

1	2	3	4			5	6		7	8				9
Report No. Location including Postal Code	**Commodity / Variety**	**Date of: 1. Sowing or Planting 2. Flowering 3. Harvest**	**Plot Application rate per treatment**			**Dates of treatment(s) or no. of treatment(s) and last date**	**BBCH Growth stage at Application (A)and at Sampling (S)**		**Portion Analyzed**	**Residues (mg/kg) (f)**				**DALA**
	(a)	**(b)**	**g a.i/ha**	**Water (L/ha)**	**g a.i/hL**	**(c)**	**A**	**S**		**Fenpico-xamid (XDE-777)**	**X642188**	**X1231-4005**	**PTZ-desthio**	**(d)**
Sponsor Reference No.: 220541 Slingsby, YO62 4AY, North Yorkshire, United Kingdom	Sugar Beet / BTS1140	1. 28 Apr 2022 2. Not applicable 3. 26 Oct 2022	--	--	--	Untreated	--	49	Tops	ND	ND	ND	ND	--
									Roots	ND	ND	ND	ND	
								49	Tops	ND	ND	ND	ND	--
									Roots	ND	ND	ND	ND	
								49	Tops	ND	ND	ND	ND	--
									Roots	ND	ND	ND	ND	
								49	Tops	ND	ND	ND	ND	--
									Roots	ND	ND	ND	ND	
								49	Tops	ND	ND	ND	ND	--
									Roots	ND	ND	ND	ND	
								49	Tops	ND	ND	ND	ND[A]	--
									Roots	ND	ND	ND	ND	

[a] According to EEC and Codex Class Classification (both) should be used
[b] Only if relevant
[c] Year must be indicated
[d] DALA = Days after last application
[A] Orignal residue detected for this sample was 0.01 mg/kg. Sample was reanalysed in duplicate and both results were found to be ND.
[e] High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated
[f] Analytical methods: DAS Reference ID 120615, DAS Reference ID 140696, Analytical Method MR-06/138 Amendment 4 and Modification M002 of the Analytical Method 00979/M002
The designation "ND" is used for treated samples for which the residue was <LOD (0.003 mg/kg)
Residue values below the LOQ (0.01 mg/kg) but greater than or equal to the LOD are reported as <LOQ with the uncorrected concentration in parentheses ( ).

Residues of Fenpicoxamid and its metabolites in Field Sugar Beet from Supervised Trials for Sponsor Reference No.: 220541, Test No. 6: Slingsby, North Yorkshire, United Kingdom

Active ingredient (a.i.)(common name):		Fenpicoxamid + Prothioconazole	Commercial product (name)	:	GF-3307
Crop / Crop Group::		Sugar beet / Beet	Producer of commercial product	:	Corteva Agriscience
Responsible body for reporting	:	Corteva Agriscience, LLC	Method of treatment (e)	:	None
(name, address)	:	9330 Zionsville Road, Indianapolis, IN, 46268 USA	Indoor/Outdoor	:	Outdoor
Country	:	United Kingdom	Other active substance in the formulation	:	None
Content of active substance: (g/L)	:	50 g Fenpicoxamid/L + 101 g Prothioconazole/L	Other active substance content (g/kg or g/L)		None
Formulation (e.g., WP)	:	EC	Residues calculated as	:	XDE-777, X642188, X12314005, Prothioconazole-desthio, PTZ-α-OH-desthio, PTZ-3-OH-desthio, PTZ-4-OH-desthio, PTZ-5-OH-desthio and PTZ-6-OH-desthio

1	2	3	4			5	6		7	8					9
Report No. Location including Postal Code	**Commodity / Variety**	**Date of: 1. Sowing or Planting 2. Flowering 3. Harvest**	**Plot Application rate per treatment**			**Dates of treatment(s) or no. of treatment(s) and last date**	**BBCH Growth stage at Application (A)and at Sampling (S)**		**Portion Analyzed**	**Residues (mg/kg) (f)**					**DALA**
	(a)	**(b)**	**g a.i/ha**	**Water (L/ha)**	**g a.i/hL**	**(c)**	**A**	**S**		**PTZ-α-OH-desthio**	**PTZ-3-OH-desthio**	**PTZ-4-OH-desthio**	**PTZ-5-OH-desthio**	**PTZ-6-OH-desthio**	**(d)**
Sponsor Reference No.: 220541 Slingsby, YO62 4AY, North Yorkshire, United Kingdom	Sugar Beet / BTS1140	1. 28 Apr 2022 2. Not applicable 3. 26 Oct 2022	--	--	--	Untreated	--	49	Tops	ND	ND	ND	ND	ND	--
									Roots	ND	ND	ND	ND	ND	
								49	Tops	ND	ND	ND	ND	ND	--
									Roots	ND	ND	ND	ND	ND	
								49	Tops	ND	ND	ND	ND	ND	--
									Roots	ND	ND	ND	ND	ND	
								49	Tops	ND	ND	ND	ND	ND	--
									Roots	ND	ND	ND	ND	ND	
								49	Tops	ND	ND	ND	ND	ND	--
									Roots	ND	ND	ND	ND	ND	
								49	Tops	ND	ND	ND	ND	ND	--
									Roots	ND	ND	ND	ND	ND	

[a] According to EEC and Codex Class Classification (both) should be used
[b] Only if relevant
[c] Year must be indicated
[d] DALA = Days after last application
[e] High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated
[f] Analytical methods: DAS Reference ID 120615, DAS Reference ID 140696, Analytical Method MR-06/138 Amendment 4 and Modification M002 of the Analytical Method 00979/M002
The designation "ND" is used for treated samples for which the residue was <LOD (0.003 mg/kg)
Residue values below the LOQ (0.01 mg/kg) but greater than or equal to the LOD are reported as <LOQ with the uncorrected concentration in parentheses ( ).

Residues of Fenpicoxamid and its metabolites in Field Sugar Beet from Supervised Trials for Sponsor Reference No.: 220541, Test No. 6: Slingsby, North Yorkshire, United Kingdom

Active ingredient (a.i.)(common name):		Fenpicoxamid + Prothioconazole		Commercial product (name)	:	GF-3307
Crop / Crop Group::		Sugar beet / Beet		Producer of commercial product	:	Corteva Agriscience
Responsible body for reporting	:	Corteva Agriscience, LLC		Method of treatment (e)	:	Foliar application using a Knapsack sprayer
(name, address)	:	9330 Zionsville Road, Indianapolis, IN, 46268 USA		Indoor/Outdoor	:	Outdoor
Country	:	United Kingdom		Other active substance in the formulation	:	None
Content of active substance: (g/L)	:	50 g Fenpicoxamid/L + 101 g Prothioconazole/L		Other active substance content (g/kg or g/L)		None
Formulation (e.g., WP)	:	EC		Residues calculated as	:	XDE-777, X642188, X12314005, Prothioconazole-desthio, PTZ-α-OH-desthio, PTZ-3-OH-desthio, PTZ-4-OH-desthio, PTZ-5-OH-desthio and PTZ-6-OH-desthio

1	2	3	4			5	6		7	8				9
Report No. Location including Postal Code	**Commodity / Variety**	**Date of: 1. Sowing or Planting 2. Flowering 3. Harvest**	**Plot Application rate per treatment (A1-A2)**			**Dates of treatment(s) or no. of treatment(s) and last date**	**BBCH Growth stage at Application (A)and at Sampling (S)**		**Portion Analyzed**	**Residues (mg/kg) (f)**				**DALA**
	(a)	**(b)**	**g a.i/ha**	**Water (L/ha)**	**g a.i/hL**	**(c)**	**A**	**S**		**Fenpico-xamid (XDE-777)**	**X642188**	**X1231-4005**	**PTZ-desthio**	**(d)**
Sponsor Reference No.: 220541 Slingsby, YO62 4AY, North Yorkshire, United Kingdom	Sugar Beet / BTS1140	1. 28 Apr 2022 2. Not applicable 3. 26 Oct 2022	a) 75.50 b) 152.51 a) 75.00 b) 151.50	302 300	a) 25.00 b) 50.50 a) 25.00 b) 50.50	A1 = 05 Oct 2022 A2 = 26 Oct 2022	49 49	49	Tops	0.02	< 0.01 (0.003)	ND	0.01	-0
									Roots	ND	ND	ND	0.01	
								49	Tops	0.92	0.20	0.01	1.1	+0
									Roots	0.02	0.01	ND	0.04	
								49	Tops	0.15	0.03	ND	0.36	7
									Roots	0.02	< 0.01 (0.009)	ND	0.04	

[a] According to EEC and Codex Class Classification (both) should be used
[b] Only if relevant
[c] Year must be indicated
[d] DALA = Days after last application
a) active ingredient for Fenpicoxamid only; b) active ingredient for Prothioconazole only

[e] High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated
[f] Analytical methods: DAS Reference ID 120615, DAS Reference ID 140696, Analytical Method MR-06/138 Amendment 4 and Modification M002 of the Analytical Method 00979/M002
The designation "ND" is used for treated samples for which the residue was <LOD (0.003 mg/kg)
Residue values below the LOQ (0.01 mg/kg) but greater than or equal to the LOD are reported as <LOQ with the uncorrected concentration in parentheses ( ).

Residues of Fenpicoxamid and its metabolites in Field Sugar Beet from Supervised Trials for Sponsor Reference No.: 220541, Test No. 6: Slingsby, North Yorkshire, United Kingdom

Active ingredient (a.i.)(common name):		Fenpicoxamid + Prothioconazole	Commercial product (name)	:	GF-3307
Crop / Crop Group::		Sugar beet / Beet	Producer of commercial product	:	Corteva Agriscience
Responsible body for reporting	:	Corteva Agriscience, LLC	Method of treatment (e)	:	Foliar application using a Knapsack sprayer
(name, address)	:	9330 Zionsville Road, Indianapolis, IN, 46268 USA	Indoor/Outdoor	:	Outdoor
Country	:	United Kingdom	Other active substance in the formulation	:	None
Content of active substance: (g/L)	:	50 g Fenpicoxamid/L + 101 g Prothioconazole/L	Other active substance content (g/kg or g/L)		None
Formulation (e.g., WP)	:	EC	Residues calculated as	:	XDE-777, X642188, X12314005, Prothioconazole-desthio, PTZ-α-OH-desthio, PTZ-3-OH-desthio, PTZ-4-OH-desthio, PTZ-5-OH-desthio and PTZ-6-OH-desthio

1	2	3	4			5	6		7	8				9
Report No. Location including Postal Code	**Commodity / Variety**	**Date of: 1. Sowing or Planting 2. Flowering 3. Harvest**	**Plot Application rate per treatment (A1-A2)**			**Dates of treatment(s) or no. of treatment(s) and last date**	**BBCH Growth stage at Application (A)and at Sampling (S)**		**Portion Analyzed**	**Residues (mg/kg) (f)**				**DALA**
	(a)	**(b)**	**g a.i/ha**	**Water (L/ha)**	**g a.i/hL**	**(c)**	**A**	**S**		**Fenpico-xamid (XDE-777)**	**X642188**	**X1231-4005**	**PTZ-desthio**	**(d)**
Sponsor Reference No.: 220541 Slingsby, YO62 4AY, North Yorkshire, United Kingdom	Sugar Beet / BTS1140	1. 28 Apr 2022 2. Not applicable 3. 26 Oct 2022	a) 75.50 b) 152.51 a) 75.00 b) 151.50	302 300	a) 25.00 b) 50.50 a) 25.00 b) 50.50	A1 = 05 Oct 2022 A2 = 26 Oct 2022	49 49	49	Tops	0.10	0.02	ND	0.25	14
									Roots	0.01	< 0.01 (0.007)	ND	0.03[B]	
								49	Tops	0.10	< 0.01 (0.007)	ND	0.14	21
									Roots	< 0.01 (0.005)	< 0.01 (0.004)	ND	0.02[#]	
								49	Tops	0.07	< 0.01 (0.006)	ND	0.12	35
									Roots	< 0.01 (0.005)	< 0.01 (0.004)	ND	0.01	

[a] According to EEC and Codex Class Classification (both) should be used
[b] Only if relevant
[c] Year must be indicated
[d] DALA = Days after last application
a) active ingredient for Fenpicoxamid only; b) active ingredient for Prothioconazole only
[B] Orignal residue detected for this sample was 0.004 mg/kg. Sample was reanalysed in duplicate and both results were found to be 0.03 mg/kg.

[e] High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated
[f] Analytical methods: DAS Reference ID 120615, DAS Reference ID 140696, Analytical Method MR-06/138 Amendment 4 and Modification M002 of the Analytical Method 00979/M002
The designation "ND" is used for treated samples for which the residue was <LOD (0.003 mg/kg)
Residue values below the LOQ (0.01 mg/kg) but greater than or equal to the LOD are reported as <LOQ with the uncorrected concentration in parentheses ( ).
[#] This value is a mean of the original analysis of the sample along with reanalysis of 3 replicates. The equivalent spare sample was also analysed in triplicate and an average residue of 0.04 mg/kg was detected.

Residues of Fenpicoxamid and its metabolites in Field Sugar Beet from Supervised Trials for Sponsor Reference No.: 220541, Test No. 6: Slingsby, North Yorkshire, United Kingdom

Active ingredient (a.i.)(common name):		Fenpicoxamid + Prothioconazole	Commercial product (name)	:	GF-3307
Crop / Crop Group::		Sugar beet / Beet	Producer of commercial product	:	Corteva Agriscience
Responsible body for reporting	:	Corteva Agriscience, LLC	Method of treatment (e)	:	Foliar application using a Knapsack sprayer
(name, address)	:	9330 Zionsville Road, Indianapolis, IN, 46268 USA	Indoor/Outdoor	:	Outdoor
Country	:	United Kingdom	Other active substance in the formulation	:	None
Content of active substance: (g/L)	:	50 g Fenpicoxamid/L + 101 g Prothioconazole/L	Other active substance content (g/kg or g/L)		None
Formulation (e.g., WP)	:	EC	Residues calculated as	:	XDE-777, X642188, X12314005, Prothioconazole-desthio, PTZ-α-OH-desthio, PTZ-3-OH-desthio, PTZ-4-OH-desthio, PTZ-5-OH-desthio and PTZ-6-OH-desthio

1	2	3	4			5	6		7	8					9
Report No. Location including Postal Code	**Commodity / Variety**	**Date of: 1. Sowing or Planting 2. Flowering 3. Harvest**	**Plot Application rate per treatment (A1-A2)**			**Dates of treatment(s) or no. of treatment(s) and last date**	**BBCH Growth stage at Application (A)and at Sampling (S)**		**Portion Analyzed**	**Residues (mg/kg) (f)**					**DALA**
	(a)	**(b)**	**g a.i/ha**	**Water (L/ha)**	**g a.i/hL**	**(c)**	**A**	**S**		**PTZ-α-OH-desthio**	**PTZ-3-OH-desthio**	**PTZ-4-OH-desthio**	**PTZ-5-OH-desthio**	**PTZ-6-OH-desthio**	**(d)**
Sponsor Reference No.: 220541 Slingsby, YO62 4AY, North Yorkshire, United Kingdom	Sugar Beet / BTS1140	1. 28 Apr 2022 2. Not applicable 3. 26 Oct 2022	a) 75.50 b) 152.51 a) 75.00 b) 151.50	302 300	a) 25.00 b) 50.50 a) 25.00 b) 50.50	A1 = 05 Oct 2022 A2 = 26 Oct 2022	49 49	49	Tops	ND	< 0.01 (0.010)	< 0.01 (0.005)	ND	ND	-0
									Roots	ND	ND	ND	ND	ND	
								49	Tops	ND	0.01	< 0.01 (0.005)	ND	ND	+0
									Roots	ND	ND	ND	ND	ND	
								49	Tops	< 0.01 (0.003)	0.03	0.01	< 0.01 (0.004)	ND	7
									Roots	ND	ND	ND	ND	ND	

[a] According to EEC and Codex Class Classification (both) should be used
[b] Only if relevant
[c] Year must be indicated
[d] DALA = Days after last application
a) active ingredient for Fenpicoxamid only; b) active ingredient for Prothioconazole only

[e] High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated
[f] Analytical methods: DAS Reference ID 120615, DAS Reference ID 140696, Analytical Method MR-06/138 Amendment 4 and Modification M002 of the Analytical Method 00979/M002
The designation "ND" is used for treated samples for which the residue was <LOD (0.003 mg/kg)
Residue values below the LOQ (0.01 mg/kg) but greater than or equal to the LOD are reported as <LOQ with the uncorrected concentration in parentheses ( ).

Residues of Fenpicoxamid and its metabolites in Field Sugar Beet from Supervised Trials for Sponsor Reference No.: 220541, Test No. 6: Slingsby, North Yorkshire, United Kingdom

Active ingredient (a.i.)(common name):		Fenpicoxamid + Prothioconazole	Commercial product (name)	:	GF-3307
Crop / Crop Group::		Sugar beet / Beet	Producer of commercial product	:	Corteva Agriscience
Responsible body for reporting	:	Corteva Agriscience, LLC	Method of treatment (e)	:	Foliar application using a Knapsack sprayer
(name, address)	:	9330 Zionsville Road, Indianapolis, IN, 46268 USA	Indoor/Outdoor	:	Outdoor
Country	:	United Kingdom	Other active substance in the formulation	:	None
Content of active substance: (g/L)	:	50 g Fenpicoxamid/L + 101 g Prothioconazole/L	Other active substance content (g/kg or g/L)		None
Formulation (e.g., WP)	:	EC	Residues calculated as	:	XDE-777, X642188, X12314005, Prothioconazole-desthio, PTZ-α-OH-desthio, PTZ-3-OH-desthio, PTZ-4-OH-desthio, PTZ-5-OH-desthio and PTZ-6-OH-desthio

1	2	3	4			5	6		7	8					9
Report No. Location including Postal Code	**Commodity / Variety**	**Date of: 1. Sowing or Planting 2. Flowering 3. Harvest**	**Plot Application rate per treatment (A1-A2)**			**Dates of treatment(s) or no. of treatment(s) and last date**	**BBCH Growth stage at Application (A)and at Sampling (S)**		**Portion Analyzed**	**Residues (mg/kg) (f)**					**DALA**
	(a)	**(b)**	**g a.i/ha**	**Water (L/ha)**	**g a.i/hL**	**(c)**	**A**	**S**		**PTZ-α-OH-desthio**	**PTZ-3-OH-desthio**	**PTZ-4-OH-desthio**	**PTZ-5-OH-desthio**	**PTZ-6-OH-desthio**	**(d)**
Sponsor Reference No.: 220541 Slingsby, YO62 4AY, North Yorkshire, United Kingdom	Sugar Beet / BTS1140	1. 28 Apr 2022 2. Not applicable 3. 26 Oct 2022	a) 75.50 b) 152.51 a) 75.00 b) 151.50	302 300	a) 25.00 b) 50.50 a) 25.00 b) 50.50	A1 = 05 Oct 2022 A2 = 26 Oct 2022	49 49	49	Tops	< 0.01 (0.003)	0.03	0.02	< 0.01 (0.004)	ND	14
									Roots	ND	ND	ND	ND	ND	
								49	Tops	< 0.01 (0.006)	0.04	0.02	< 0.01 (0.005)	ND	21
									Roots	ND	ND	ND	ND	ND	
								49	Tops	< 0.01 (0.007)	0.06	0.03	< 0.01 (0.006)	ND	35
									Roots	ND	ND	ND	ND	ND	

[a] According to EEC and Codex Class Classification (both) should be used
[b] Only if relevant
[c] Year must be indicated
[d] DALA = Days after last application
a) active ingredient for Fenpicoxamid only; b) active ingredient for Prothioconazole only

[e] High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated
[f] Analytical methods: DAS Reference ID 120615, DAS Reference ID 140696, Analytical Method MR-06/138 Amendment 4 and Modification M002 of the Analytical Method 00979/M002
The designation "ND" is used for treated samples for which the residue was <LOD (0.003 mg/kg)
Residue values below the LOQ (0.01 mg/kg) but greater than or equal to the LOD are reported as <LOQ with the uncorrected concentration in parentheses ( ).

Residues of Fenpicoxamid and its metabolites in Field Sugar Beet from Supervised Trials for Sponsor Reference No.: 220541, Test No. 7: Villamartín, Andalucía, Spain

Active ingredient (a.i.)(common name):	Fenpicoxamid + Prothioconazole	Commercial product (name) :	GF-3307
Crop / Crop Group::	Sugar beet / Beet	Producer of commercial product :	Corteva Agriscience
Responsible body for reporting :	Corteva Agriscience, LLC	Method of treatment (e) :	None
(name, address) :	9330 Zionsville Road, Indianapolis, IN, 46268 USA	Indoor/Outdoor :	Outdoor
Country :	Spain	Other active substance in the formulation :	None
Content of active substance: (g/L) :	50 g Fenpicoxamid/L + 101 g Prothioconazole/L	Other active substance content (g/kg or g/L)	None
Formulation (e.g., WP) :	EC	Residues calculated as :	XDE-777, X642188, X12314005, Prothioconazole-desthio, PTZ-α-OH-desthio, PTZ-3-OH-desthio, PTZ-4-OH-desthio, PTZ-5-OH-desthio and PTZ-6-OH-desthio

1	2	3	4			5	6		7	8				9
Report No. Location including Postal Code	Commodity / Variety	Date of: 1. Sowing or Planting 2. Flowering 3. Harvest	Plot Application rate per treatment			Dates of treatment(s) or no. of treatment(s) and last date	BBCH Growth stage at Application (A)and at Sampling (S)		Portion Analyzed	Residues (mg/kg) (f)				DALA
	(a)	(b)	g a.i/ha	Water (L/ha)	g a.i/hL	(c)	A	S		Fenpico-xamid (XDE-777)	X642188	X1231-4005	PTZ-desthio	(d)
Sponsor Reference No.: 220541 Villamartín, 11650, Andalucía, Spain	Sugar Beet / Juncal	1. 20 Oct 2021 2. Not applicable 3. 28 Jul 2022	–	–	–	Untreated	–	49	Tops	ND	ND	ND	ND	–
									Roots	ND	ND	ND	ND	
								49	Tops	ND	ND	ND	ND	–
									Roots	ND	ND	ND	ND	
								49	Tops	ND	ND	ND	ND	–
									Roots	ND	ND	ND	ND	
								49	Tops	ND	ND	ND	ND	–
									Roots	ND	ND	ND	ND	
								49	Tops	ND	ND	ND	ND	–
									Roots	ND	ND	ND	ND	
								49	Tops	ND	ND	ND	ND	–
									Roots	ND	ND	ND	ND	

[a] According to EEC and Codex Class Classification (both) should be used
[b] Only if relevant
[c] Year must be indicated
[d] DALA = Days after last application
[e] High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated
[f] Analytical methods: DAS Reference ID 120615, DAS Reference ID 140696, Analytical Method MR-06/138 Amendment 4 and Modification M002 of the Analytical Method 00979/M002
The designation "ND" is used for treated samples for which the residue was <LOD (0.003 mg/kg)
Residue values below the LOQ (0.01 mg/kg) but greater than or equal to the LOD are reported as <LOQ with the uncorrected concentration in parentheses ( ).

Residues of Fenpicoxamid and its metabolites in Field Sugar Beet from Supervised Trials for Sponsor Reference No.: 220541, Test No. 7: Villamartín, Andalucía, Spain

Active ingredient (a.i.)(common name):	Fenpicoxamid + Prothioconazole	Commercial product (name) :	GF-3307
Crop / Crop Group::	Sugar beet / Beet	Producer of commercial product :	Corteva Agriscience
Responsible body for reporting :	Corteva Agriscience, LLC	Method of treatment (e) :	None
(name, address) :	9330 Zionsville Road, Indianapolis, IN, 46268 USA	Indoor/Outdoor :	Outdoor
Country :	Spain	Other active substance in the formulation :	None
Content of active substance: (g/L) :	50 g Fenpicoxamid/L + 101 g Prothioconazole/L	Other active substance content (g/kg or g/L)	None
Formulation (e.g., WP) :	EC	Residues calculated as :	XDE-777, X642188, X12314005, Prothioconazole-desthio, PTZ-α-OH-desthio, PTZ-3-OH-desthio, PTZ-4-OH-desthio, PTZ-5-OH-desthio and PTZ-6-OH-desthio

1	2	3	4			5	6		7	8					9
Report No. Location including Postal Code	Commodity / Variety	Date of: 1. Sowing or Planting 2. Flowering 3. Harvest	Plot Application rate per treatment			Dates of treatment(s) or no. of treatment(s) and last date	BBCH Growth stage at Application (A)and at Sampling (S)		Portion Analyzed	Residues (mg/kg) (f)					DALA
	(a)	(b)	g a.i/ha	Water (L/ha)	g a.i/hL	(c)	A	S		PTZ-α-OH-desthio	PTZ-3-OH-desthio	PTZ-4-OH-desthio	PTZ-5-OH-desthio	PTZ-6-OH-desthio	(d)
Sponsor Reference No.: 220541 Villamartín, 11650, Andalucía, Spain	Sugar Beet / Juncal	1. 20 Oct 2021 2. Not applicable 3. 28 Jul 2022	--	--	--	Untreated	--	49	Tops	ND	ND	ND	ND	ND	--
									Roots	ND	ND	ND	ND	ND	
								49	Tops	ND	ND	ND	ND	ND	--
									Roots	ND	ND	ND	ND	ND	
								49	Tops	ND	ND	ND	ND	ND	--
									Roots	ND	ND	ND	ND	ND	
								49	Tops	ND	ND	ND	ND	ND	--
									Roots	ND	ND	ND	ND	ND	
								49	Tops	ND	ND	ND	ND	ND	--
									Roots	ND	ND	ND	ND	ND	
								49	Tops	ND	ND	ND	ND	ND	--
									Roots	ND	ND	ND	ND	ND	

[a] According to EEC and Codex Class Classification (both) should be used
[b] Only if relevant
[c] Year must be indicated
[d] DALA = Days after last application
[e] High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated
[f] Analytical methods: DAS Reference ID 120615, DAS Reference ID 140696, Analytical Method MR-06/138 Amendment 4 and Modification M002 of the Analytical Method 00979/M002
The designation "ND" is used for treated samples for which the residue was <LOD (0.003 mg/kg)
Residue values below the LOQ (0.01 mg/kg) but greater than or equal to the LOD are reported as <LOQ with the uncorrected concentration in parentheses ( ).

Residues of Fenpicoxamid and its metabolites in Field Sugar Beet from Supervised Trials for Sponsor Reference No.: 220541, Test No. 7: Villamartín, Andalucía, Spain

Active ingredient (a.i.)(common name):	Fenpicoxamid + Prothioconazole	Commercial product (name) :	GF-3307
Crop / Crop Group::	Sugar beet / Beet	Producer of commercial product :	Corteva Agriscience
Responsible body for reporting :	Corteva Agriscience, LLC	Method of treatment (e) :	Foliar application using a Knapsack sprayer
(name, address) :	9330 Zionsville Road, Indianapolis, IN, 46268 USA	Indoor/Outdoor :	Outdoor
Country :	Spain	Other active substance in the formulation :	None
Content of active substance: (g/L) :	50 g Fenpicoxamid/L + 101 g Prothioconazole/L	Other active substance content (g/kg or g/L)	None
Formulation (e.g., WP) :	EC	Residues calculated as :	XDE-777, X642188, X12314005, Prothioconazole-desthio, PTZ-α-OH-desthio, PTZ-3-OH-desthio, PTZ-4-OH-desthio, PTZ-5-OH-desthio and PTZ-6-OH-desthio

1	2	3	4			5	6		7	8				9
Report No. Location including Postal Code	Commodity / Variety	Date of: 1. Sowing or Planting 2. Flowering 3. Harvest	Plot Application rate per treatment (A1-A2)			Dates of treatment(s) or no. of treatment(s) and last date	BBCH Growth stage at Application (A)and at Sampling (S)		Portion Analyzed	Residues (mg/kg) (f)				DALA
	(a)	(b)	g a.i/ha	Water (L/ha)	g a.i/hL	(c)	A	S		Fenpico-xamid (XDE-777)	X642188	X1231-4005	PTZ-desthio	(d)
Sponsor Reference No.: 220541 Villamartín, 11650, Andalucía, Spain	Sugar Beet / Juncal	1. 20 Oct 2021 2. Not applicable 3. 28 Jul 2022	a) 75.75 b) 153.02 a) 77.00 b) 155.54	303 308	a) 25.00 b) 50.50 a) 25.00 b) 50.50	A1 = 06 Jul 2022 A2 = 28 Jul 2022	49 49	49	Tops	0.77	0.04	< 0.01 (0.009)	0.27	-0
									Roots	ND	ND	ND	ND	
								49	Tops	2.5	0.11	0.02	1.0	+0
									Roots	ND	ND	ND	ND	
								49	Tops	1.5	0.04	0.02	0.36	7
									Roots	< 0.01 (0.006)	ND	ND	0.02	

[a] According to EEC and Codex Class Classification (both) should be used
[b] Only if relevant
[c] Year must be indicated
[d] DALA = Days after last application
a) active ingredient for Fenpicoxamid only; b) active ingredient for Prothioconazole only

[e] High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated
[f] Analytical methods: DAS Reference ID 120615, DAS Reference ID 140696, Analytical Method MR-06/138 Amendment 4 and Modification M002 of the Analytical Method 00979/M002
The designation "ND" is used for treated samples for which the residue was <LOD (0.003 mg/kg)
Residue values below the LOQ (0.01 mg/kg) but greater than or equal to the LOD are reported as <LOQ with the uncorrected concentration in parentheses ( ).

Residues of Fenpicoxamid and its metabolites in Field Sugar Beet from Supervised Trials for Sponsor Reference No.: 220541, Test No. 7: Villamartín, Andalucía, Spain

Active ingredient (a.i.)(common name):	Fenpicoxamid + Prothioconazole	Commercial product (name) :	GF-3307
Crop / Crop Group::	Sugar beet / Beet	Producer of commercial product :	Corteva Agriscience
Responsible body for reporting :	Corteva Agriscience, LLC	Method of treatment (e) :	Foliar application using a Knapsack sprayer
(name, address) :	9330 Zionsville Road, Indianapolis, IN, 46268 USA	Indoor/Outdoor :	Outdoor
Country :	Spain	Other active substance in the formulation :	None
Content of active substance: (g/L) :	50 g Fenpicoxamid/L + 101 g Prothioconazole/L	Other active substance content (g/kg or g/L)	None
Formulation (e.g., WP) :	EC	Residues calculated as :	XDE-777, X642188, X12314005, Prothioconazole-desthio, PTZ-α-OH-desthio, PTZ-3-OH-desthio, PTZ-4-OH-desthio, PTZ-5-OH-desthio and PTZ-6-OH-desthio

1	2	3	4			5	6		7	8				9
Report No. Location including Postal Code	**Commodity / Variety**	**Date of: 1. Sowing or Planting 2. Flowering 3. Harvest**	**Plot Application rate per treatment (A1-A2)**			**Dates of treatment(s) or no. of treatment(s) and last date**	**BBCH Growth stage at Application (A)and at Sampling (S)**		**Portion Analyzed**	**Residues (mg/kg) (f)**				**DALA**
	(a)	**(b)**	**g a.i/ha**	**Water (L/ha)**	**g a.i/hL**	**(c)**	**A**	**S**		**Fenpico-xamid (XDE-777)**	**X642188**	**X1231-4005**	**PTZ-desthio**	**(d)**
Sponsor Reference No.: 220541 Villamartín, 11650, Andalucía, Spain	Sugar Beet / Juncal	1. 20 Oct 2021 2. Not applicable 3. 28 Jul 2022	a) 75.75 b) 153.02 a) 77.00 b) 155.54	303 308	a) 25.00 b) 50.50 a) 25.00 b) 50.50	A1 = 06 Jul 2022 A2 = 28 Jul 2022	49 49	49	Tops	1.1	0.03	0.02	0.26	12
									Roots	ND	ND	ND	< 0.01 (0.003)	
								49	Tops	0.49	0.02	0.01	0.11	20
									Roots	ND	ND	ND	ND	
								49	Tops	0.45	0.02	0.02	0.26	34
									Roots	ND	ND	ND	ND	

[a] According to EEC and Codex Class Classification (both) should be used
[b] Only if relevant
[c] Year must be indicated
[d] DALA = Days after last application
a) active ingredient for Fenpicoxamid only; b) active ingredient for Prothioconazole only

[e] High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated
[f] Analytical methods: DAS Reference ID 120615, DAS Reference ID 140696, Analytical Method MR-06/138 Amendment 4 and Modification M002 of the Analytical Method 00979/M002
The designation "ND" is used for treated samples for which the residue was <LOD (0.003 mg/kg)
Residue values below the LOQ (0.01 mg/kg) but greater than or equal to the LOD are reported as <LOQ with the uncorrected concentration in parentheses ( ).

Residues of Fenpicoxamid and its metabolites in Field Sugar Beet from Supervised Trials for Sponsor Reference No.: 220541, Test No. 7: Villamartín, Andalucía, Spain

Active ingredient (a.i.)(common name):	Fenpicoxamid + Prothioconazole	Commercial product (name) :	GF-3307
Crop / Crop Group::	Sugar beet / Beet	Producer of commercial product :	Corteva Agriscience
Responsible body for reporting :	Corteva Agriscience, LLC	Method of treatment (e) :	Foliar application using a Knapsack sprayer
(name, address) :	9330 Zionsville Road, Indianapolis, IN, 46268 USA	Indoor/Outdoor :	Outdoor
Country :	Spain	Other active substance in the formulation :	None
Content of active substance: (g/L) :	50 g Fenpicoxamid/L + 101 g Prothioconazole/L	Other active substance content (g/kg or g/L)	None
Formulation (e.g., WP) :	EC	Residues calculated as :	XDE-777, X642188, X12314005, Prothioconazole-desthio, PTZ-α-OH-desthio, PTZ-3-OH-desthio, PTZ-4-OH-desthio, PTZ-5-OH-desthio and PTZ-6-OH-desthio

1	2	3	4			5	6		7	8					9
Report No. Location including Postal Code	**Commodity / Variety**	**Date of: 1. Sowing or Planting 2. Flowering 3. Harvest**	**Plot Application rate per treatment (A1-A2)**			**Dates of treatment(s) or no. of treatment(s) and last date**	**BBCH Growth stage at Application (A)and at Sampling (S)**		**Portion Analyzed**	**Residues (mg/kg) (f)**					**DALA**
	(a)	**(b)**	**g a.i/ha**	**Water (L/ha)**	**g a.i/hL**	**(c)**	**A**	**S**		**PTZ-α-OH-desthio**	**PTZ-3-OH-desthio**	**PTZ-4-OH-desthio**	**PTZ-5-OH-desthio**	**PTZ-6-OH-desthio**	**(d)**
Sponsor Reference No.: 220541 Villamartín, 11650, Andalucía, Spain	Sugar Beet / Juncal	1. 20 Oct 2021 2. Not applicable 3. 28 Jul 2022	a) 75.75 b) 153.02 a) 77.00 b) 155.54	303 308	a) 25.00 b) 50.50 a) 25.00 b) 50.50	A1 = 06 Jul 2022 A2 = 28 Jul 2022	49 49	49	Tops	ND	0.09	0.04	0.01	ND	0
									Roots	ND	ND	ND	ND	ND	
								49	Tops	ND	0.09	0.04	0.01	ND	0
									Roots	ND	ND	ND	ND	ND	
								49	Tops	< 0.01 (0.004)	0.18	0.06	0.02	< 0.01 (0.006)	7
									Roots	ND	ND	ND	ND	ND	

[a] According to EEC and Codex Class Classification (both) should be used
[b] Only if relevant
[c] Year must be indicated
[d] DALA = Days after last application
a) active ingredient for Fenpicoxamid only; b) active ingredient for Prothioconazole only

[e] High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated
[f] Analytical methods: DAS Reference ID 120615, DAS Reference ID 140696, Analytical Method MR-06/138 Amendment 4 and Modification M002 of the Analytical Method 00979/M002
The designation "ND" is used for treated samples for which the residue was <LOD (0.003 mg/kg)
Residue values below the LOQ (0.01 mg/kg) but greater than or equal to the LOD are reported as <LOQ with the uncorrected concentration in parentheses ( ).

Residues of Fenpicoxamid and its metabolites in Field Sugar Beet from Supervised Trials for Sponsor Reference No.: 220541, Test No. 7: Villamartín, Andalucía, Spain

Active ingredient (a.i.)(common name):	Fenpicoxamid + Prothioconazole	Commercial product (name) :	GF-3307
Crop / Crop Group::	Sugar beet / Beet	Producer of commercial product :	Corteva Agriscience
Responsible body for reporting :	Corteva Agriscience, LLC	Method of treatment (e) :	Foliar application using a Knapsack sprayer
(name, address) :	9330 Zionsville Road, Indianapolis, IN, 46268 USA	Indoor/Outdoor :	Outdoor
Country :	Spain	Other active substance in the formulation :	None
Content of active substance: (g/L) :	50 g Fenpicoxamid/L + 101 g Prothioconazole/L	Other active substance content (g/kg or g/L)	None
Formulation (e.g., WP) :	EC	Residues calculated as :	XDE-777, X642188, X12314005, Prothioconazole-desthio, PTZ-α-OH-desthio, PTZ-3-OH-desthio, PTZ-4-OH-desthio, PTZ-5-OH-desthio and PTZ-6-OH-desthio

1	2	3	4			5	6		7	8					9
Report No. Location including Postal Code	**Commodity / Variety**	**Date of: 1. Sowing or Planting 2. Flowering 3. Harvest**	**Plot Application rate per treatment (A1-A2)**			**Dates of treatment(s) or no. of treatment(s) and last date**	**BBCH Growth stage at Application (A)and at Sampling (S)**		**Portion Analyzed**	**Residues (mg/kg) (f)**					**DALA**
	(a)	**(b)**	**g a.i/ha**	**Water (L/ha)**	**g a.i/hL**	**(c)**	**A**	**S**		**PTZ-α-OH-desthio**	**PTZ-3-OH-desthio**	**PTZ-4-OH-desthio**	**PTZ-5-OH-desthio**	**PTZ-6-OH-desthio**	**(d)**
Sponsor Reference No.: 220541 Villamartín, 11650, Andalucía, Spain	Sugar Beet / Juncal	1. 20 Oct 2021 2. Not applicable 3. 28 Jul 2022	a) 75.75 b) 153.02 a) 77.00 b) 155.54	303 308	a) 25.00 b) 50.50 a) 25.00 b) 50.50	A1 = 06 Jul 2022 A2 = 28 Jul 2022	49 49	49	Tops	ND	0.09	0.03	< 0.01 (0.010)	< 0.01 (0.003)	12
									Roots	ND	ND	ND	ND	ND	
								49	Tops	ND	0.07	0.03	< 0.01 (0.007)	ND	20
									Roots	ND	ND	ND	ND	ND	
								49	Tops	ND	0.06	0.02	< 0.01 (0.007)	ND	34
									Roots	ND	ND	ND	ND	ND	

[a] According to EEC and Codex Class Classification (both) should be used
[b] Only if relevant
[c] Year must be indicated
[d] DALA = Days after last application
a) active ingredient for Fenpicoxamid only; b) active ingredient for Prothioconazole only

[e] High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated
[f] Analytical methods: DAS Reference ID 120615, DAS Reference ID 140696, Analytical Method MR-06/138 Amendment 4 and Modification M002 of the Analytical Method 00979/M002
The designation "ND" is used for treated samples for which the residue was <LOD (0.003 mg/kg)
Residue values below the LOQ (0.01 mg/kg) but greater than or equal to the LOD are reported as <LOQ with the uncorrected concentration in parentheses ( ).

Residues of Fenpicoxamid and its metabolites in Field Sugar Beet from Supervised Trials for Sponsor Reference No.: 220541, Test No. 8: San Rocco Al Porto, Lombardia, Italy

Active ingredient (a.i.)(common name):	Fenpicoxamid + Prothioconazole	Commercial product (name) :	GF-3307
Crop / Crop Group::	Sugar beet / Beet	Producer of commercial product :	Corteva Agriscience
Responsible body for reporting :	Corteva Agriscience, LLC	Method of treatment (e) :	None
(name, address) :	9330 Zionsville Road, Indianapolis, IN, 46268 USA	Indoor/Outdoor :	Outdoor
Country :	Italy	Other active substance in the formulation :	None
Content of active substance: (g/L) :	50 g Fenpicoxamid/L + 101 g Prothioconazole/L	Other active substance content (g/kg or g/L)	None
Formulation (e.g., WP) :	EC	Residues calculated as :	XDE-777, X642188, X12314005, Prothioconazole-desthio, PTZ-α-OH-desthio, PTZ-3-OH-desthio, PTZ-4-OH-desthio, PTZ-5-OH-desthio and PTZ-6-OH-desthio

1	2	3	4			5	6		7	8				9
Report No. Location including Postal Code	Commodity / Variety	Date of: 1. Sowing or Planting 2. Flowering 3. Harvest	Plot Application rate per treatment			Dates of treatment(s) or no. of treatment(s) and last date	BBCH Growth stage at Application (A)and at Sampling (S)		Portion Analyzed	Residues (mg/kg) (f)				DALA
	(a)	(b)	g a.i/ha	Water (L/ha)	g a.i/hL	(c)	A	S		Fenpico-xamid (XDE-777)	X642188	X1231-4005	PTZ-desthio	(d)
Sponsor Reference No.: 220541 San Rocco Al Porto, 26865, Lombardia, Italy	Sugar Beet / Marinella	1. 02 Mar 2022 2. Not applicable 3. 26 Jul 2022	–	–	–	Untreated	–	49	Tops	ND	ND	ND	ND	–
									Roots	ND	ND	ND	ND	
								49	Tops	ND	ND	ND	ND	–
									Roots	ND	ND	ND	ND	
								49	Tops	ND	ND	ND	ND	–
									Roots	ND	ND	ND	ND	
								49	Tops	ND	ND	ND	ND	–
									Roots	ND	ND	ND	ND	
								49	Tops	ND	ND	ND	ND	–
									Roots	ND	ND	ND	ND	
								49	Tops	ND	ND	ND	ND	–
									Roots	ND	ND	ND	ND	

[a] According to EEC and Codex Class Classification (both) should be used
[b] Only if relevant
[c] Year must be indicated
[d] DALA = Days after last application
[e] High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated
[f] Analytical methods: DAS Reference ID 120615, DAS Reference ID 140696, Analytical Method MR-06/138 Amendment 4 and Modification M002 of the Analytical Method 00979/M002
The designation "ND" is used for treated samples for which the residue was <LOD (0.003 mg/kg)
Residue values below the LOQ (0.01 mg/kg) but greater than or equal to the LOD are reported as <LOQ with the uncorrected concentration in parentheses ( ).

Residues of Fenpicoxamid and its metabolites in Field Sugar Beet from Supervised Trials for Sponsor Reference No.: 220541, Test No. 8: San Rocco Al Porto, Lombardia, Italy

Active ingredient (a.i.)(common name):	Fenpicoxamid + Prothioconazole	Commercial product (name) :	GF-3307
Crop / Crop Group::	Sugar beet / Beet	Producer of commercial product :	Corteva Agriscience
Responsible body for reporting :	Corteva Agriscience, LLC	Method of treatment (e) :	None
(name, address) :	9330 Zionsville Road, Indianapolis, IN, 46268 USA	Indoor/Outdoor :	Outdoor
Country :	Italy	Other active substance in the formulation :	None
Content of active substance: (g/L) :	50 g Fenpicoxamid/L + 101 g Prothioconazole/L	Other active substance content (g/kg or g/L)	None
Formulation (e.g., WP) :	EC	Residues calculated as :	XDE-777, X642188, X12314005, Prothioconazole-desthio, PTZ-α-OH-desthio, PTZ-3-OH-desthio, PTZ-4-OH-desthio, PTZ-5-OH-desthio and PTZ-6-OH-desthio

1	2	3	4			5	6		7	8					9
Report No. Location including Postal Code	Commodity / Variety	Date of: 1. Sowing or Planting 2. Flowering 3. Harvest	Plot Application rate per treatment			Dates of treatment(s) or no. of treatment(s) and last date	BBCH Growth stage at Application (A)and at Sampling (S)		Portion Analyzed	Residues (mg/kg) (f)					DALA
	(a)	(b)	g a.i/ha	Water (L/ha)	g a.i/hL	(c)	A	S		PTZ-α-OH-desthio	PTZ-3-OH-desthio	PTZ-4-OH-desthio	PTZ-5-OH-desthio	PTZ-6-OH-desthio	(d)
Sponsor Reference No.: 220541 San Rocco Al Porto, 26865, Lombardia, Italy	Sugar Beet / Marinella	1. 02 Mar 2022 2. Not applicable 3. 26 Jul 2022	–	–	–	Untreated	–	49	Tops	ND	ND	ND	ND	ND	–
									Roots	ND	ND	ND	ND	ND	
								49	Tops	ND	ND	ND	ND	ND	–
									Roots	ND	ND	ND	ND	ND	
								49	Tops	ND	ND	ND	ND	ND	–
									Roots	ND	ND	ND	ND	ND	
								49	Tops	ND	ND	ND	ND	ND	–
									Roots	ND	ND	ND	ND	ND	
								49	Tops	ND	ND	ND	ND	ND	–
									Roots	ND	ND	ND	ND	ND	
								49	Tops	ND	ND	ND	ND	ND	–
									Roots	ND	ND	ND	ND	ND	

[a] According to EEC and Codex Class Classification (both) should be used
[b] Only if relevant
[c] Year must be indicated
[d] DALA = Days after last application
[e] High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated
[f] Analytical methods: DAS Reference ID 120615, DAS Reference ID 140696, Analytical Method MR-06/138 Amendment 4 and Modification M002 of the Analytical Method 00979/M002
The designation "ND" is used for treated samples for which the residue was <LOD (0.003 mg/kg)
Residue values below the LOQ (0.01 mg/kg) but greater than or equal to the LOD are reported as <LOQ with the uncorrected concentration in parentheses ( ).

Residues of Fenpicoxamid and its metabolites in Field Sugar Beet from Supervised Trials for Sponsor Reference No.: 220541, Test No. 8: San Rocco Al Porto, Lombardia, Italy

Active ingredient (a.i.)(common name):	Fenpicoxamid + Prothioconazole	Commercial product (name) :	GF-3307
Crop / Crop Group::	Sugar beet / Beet	Producer of commercial product :	Corteva Agriscience
Responsible body for reporting :	Corteva Agriscience, LLC	Method of treatment (e) :	Foliar application using a Knapsack sprayer
(name, address) :	9330 Zionsville Road, Indianapolis, IN, 46268 USA	Indoor/Outdoor :	Outdoor
Country :	Italy	Other active substance in the formulation :	None
Content of active substance: (g/L) :	50 g Fenpicoxamid/L + 101 g Prothioconazole/L	Other active substance content (g/kg or g/L)	None
Formulation (e.g., WP) :	EC	Residues calculated as :	XDE-777, X642188, X12314005, Prothioconazole-desthio, PTZ-α-OH-desthio, PTZ-3-OH-desthio, PTZ-4-OH-desthio, PTZ-5-OH-desthio and PTZ-6-OH-desthio

1	2	3	4			5	6		7	8				9
Report No. Location including Postal Code	Commodity / Variety	Date of: 1. Sowing or Planting 2. Flowering 3. Harvest	Plot Application rate per treatment (A1-A2)			Dates of treatment(s) or no. of treatment(s) and last date	BBCH Growth stage at Application (A)and at Sampling (S)		Portion Analyzed	Residues (mg/kg) (f)				DALA
	(a)	(b)	g a.i/ha	Water (L/ha)	g a.i/hL	(c)	A	S		Fenpico-xamid (XDE-777)	X642188	X1231-4005	PTZ-desthio	(d)
Sponsor Reference No.: 220541 San Rocco Al Porto, 26865, Lombardia, Italy	Sugar Beet / Marinella	1. 02 Mar 2022 2. Not applicable 3. 26 Jul 2022	a) 74.50 b) 150.49 a) 75.25 b) 152.01	298 301	a) 25.00 b) 50.50 a) 25.00 b) 50.50	A1 = 05 Jul 2022 A2 = 26 Jul 2022	44 49	49	Tops	0.03	ND	ND	0.02	-0
									Roots	ND	ND	ND	< 0.01 (0.009)	
								49	Tops	1.6	0.10	0.02	1.0	+0
									Roots	0.01	ND	ND	0.01	
								49	Tops	0.09	< 0.01 (0.005)	< 0.01 (0.005)	0.14	7
									Roots	ND	ND	ND	0.01	

[a] According to EEC and Codex Class Classification (both) should be used
[b] Only if relevant
[c] Year must be indicated
[d] DALA = Days after last application
a) active ingredient for Fenpicoxamid only; b) active ingredient for Prothioconazole only

[e] High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated
[f] Analytical methods: DAS Reference ID 120615, DAS Reference ID 140696, Analytical Method MR-06/138 Amendment 4 and Modification M002 of the Analytical Method 00979/M002
The designation "ND" is used for treated samples for which the residue was <LOD (0.003 mg/kg)
Residue values below the LOQ (0.01 mg/kg) but greater than or equal to the LOD are reported as <LOQ with the uncorrected concentration in parentheses ( ).

Residues of Fenpicoxamid and its metabolites in Field Sugar Beet from Supervised Trials for Sponsor Reference No.: 220541, Test No. 8: San Rocco Al Porto, Lombardia, Italy

Active ingredient (a.i.)(common name):	Fenpicoxamid + Prothioconazole	Commercial product (name) :	GF-3307
Crop / Crop Group::	Sugar beet / Beet	Producer of commercial product :	Corteva Agriscience
Responsible body for reporting :	Corteva Agriscience, LLC	Method of treatment (e) :	Foliar application using a Knapsack sprayer
(name, address) :	9330 Zionsville Road, Indianapolis, IN, 46268 USA	Indoor/Outdoor :	Outdoor
Country :	Italy	Other active substance in the formulation :	None
Content of active substance: (g/L) :	50 g Fenpicoxamid/L + 101 g Prothioconazole/L	Other active substance content (g/kg or g/L)	None
Formulation (e.g., WP) :	EC	Residues calculated as :	XDE-777, X642188, X12314005, Prothioconazole-desthio, PTZ-α-OH-desthio, PTZ-3-OH-desthio, PTZ-4-OH-desthio, PTZ-5-OH-desthio and PTZ-6-OH-desthio

1	2	3	4			5	6		7	8				9
Report No. Location including Postal Code	Commodity / Variety	Date of: 1. Sowing or Planting 2. Flowering 3. Harvest	Plot Application rate per treatment (A1-A2)			Dates of treatment(s) or no. of treatment(s) and last date	BBCH Growth stage at Application (A)and at Sampling (S)		Portion Analyzed	Residues (mg/kg) (f)				DALA
	(a)	(b)	g a.i/ha	Water (L/ha)	g a.i/hL	(c)	A	S		Fenpico-xamid (XDE-777)	X642188	X1231-4005	PTZ-desthio	(d)
Sponsor Reference No.: 220541 San Rocco Al Porto, 26865, Lombardia, Italy	Sugar Beet / Marinella	1. 02 Mar 2022 2. Not applicable 3. 26 Jul 2022	a) 74.50 b) 150.49 a) 75.25 b) 152.01	298 301	a) 25.00 b) 50.50 a) 25.00 b) 50.50	A1 = 05 Jul 2022 A2 = 26 Jul 2022	44 49	49	Tops	0.06	ND	< 0.01 (0.004)	0.08	14
									Roots	ND	ND	ND	< 0.01 (0.006)	
								49	Tops	0.03	ND	ND	0.03	21
									Roots	ND	ND	ND	< 0.01 (0.004)	
								49	Tops	0.01	ND	ND	0.03	35
									Roots	ND	ND	ND	< 0.01 (0.004)	

[a] According to EEC and Codex Class Classification (both) should be used
[b] Only if relevant
[c] Year must be indicated
[d] DALA = Days after last application
a) active ingredient for Fenpicoxamid only; b) active ingredient for Prothioconazole only

[e] High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated
[f] Analytical methods: DAS Reference ID 120615, DAS Reference ID 140696, Analytical Method MR-06/138 Amendment 4 and Modification M002 of the Analytical Method 00979/M002
The designation "ND" is used for treated samples for which the residue was <LOD (0.003 mg/kg)
Residue values below the LOQ (0.01 mg/kg) but greater than or equal to the LOD are reported as <LOQ with the uncorrected concentration in parentheses ( ).

Residues of Fenpicoxamid and its metabolites in Field Sugar Beet from Supervised Trials for Sponsor Reference No.: 220541, Test No. 8: San Rocco Al Porto, Lombardia, Italy

Active ingredient (a.i.)(common name):	Fenpicoxamid + Prothioconazole	Commercial product (name) :	GF-3307
Crop / Crop Group::	Sugar beet / Beet	Producer of commercial product :	Corteva Agriscience
Responsible body for reporting :	Corteva Agriscience, LLC	Method of treatment (e) :	Foliar application using a Knapsack sprayer
(name, address) :	9330 Zionsville Road, Indianapolis, IN, 46268 USA	Indoor/Outdoor :	Outdoor
Country :	Italy	Other active substance in the formulation :	None
Content of active substance: (g/L) :	50 g Fenpicoxamid/L + 101 g Prothioconazole/L	Other active substance content (g/kg or g/L)	None
Formulation (e.g., WP) :	EC	Residues calculated as :	XDE-777, X642188, X12314005, Prothioconazole-desthio, PTZ-α-OH-desthio, PTZ-3-OH-desthio, PTZ-4-OH-desthio, PTZ-5-OH-desthio and PTZ-6-OH-desthio

1	2	3	4			5	6		7	8					9
Report No. Location including Postal Code	Commodity / Variety	Date of: 1. Sowing or Planting 2. Flowering 3. Harvest	Plot Application rate per treatment (A1-A2)			Dates of treatment(s) or no. of treatment(s) and last date	BBCH Growth stage at Application (A)and at Sampling (S)		Portion Analyzed	Residues (mg/kg) (f)					DALA
	(a)	(b)	g a.i/ha	Water (L/ha)	g a.i/hL	(c)	A	S		PTZ-α-OH-desthio	PTZ-3-OH-desthio	PTZ-4-OH-desthio	PTZ-5-OH-desthio	PTZ-6-OH-desthio	(d)
Sponsor Reference No.: 220541 San Rocco Al Porto, 26865, Lombardia, Italy	Sugar Beet / Marinella	1. 02 Mar 2022 2. Not applicable 3. 26 Jul 2022	a) 74.50 b) 150.49 a) 75.25 b) 152.01	298 301	a) 25.00 b) 50.50 a) 25.00 b) 50.50	A1 = 05 Jul 2022 A2 = 26 Jul 2022	44 49	49	Tops	< 0.01 (0.004)	0.16	0.05	0.02	0.01	-0
									Roots	ND	ND	ND	ND	ND	
								49	Tops	< 0.01 (0.004)	0.17	0.06	0.02	0.01	+0
									Roots	ND	ND	ND	ND	ND	
								49	Tops	< 0.01 (0.009)	0.23	0.08	0.03	0.01	7
									Roots	ND	ND	ND	ND	ND	

[a] According to EEC and Codex Class Classification (both) should be used
[b] Only if relevant
[c] Year must be indicated
[d] DALA = Days after last application
a) active ingredient for Fenpicoxamid only; b) active ingredient for Prothioconazole only

[e] High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated
[f] Analytical methods: DAS Reference ID 120615, DAS Reference ID 140696, Analytical Method MR-06/138 Amendment 4 and Modification M002 of the Analytical Method 00979/M002
The designation "ND" is used for treated samples for which the residue was <LOD (0.003 mg/kg)
Residue values below the LOQ (0.01 mg/kg) but greater than or equal to the LOD are reported as <LOQ with the uncorrected concentration in parentheses ( ).

Residues of Fenpicoxamid and its metabolites in Field Sugar Beet from Supervised Trials for Sponsor Reference No.: 220541, Test No. 8: San Rocco Al Porto, Lombardia, Italy

Active ingredient (a.i.)(common name):	Fenpicoxamid + Prothioconazole	Commercial product (name) :	GF-3307
Crop / Crop Group::	Sugar beet / Beet	Producer of commercial product :	Corteva Agriscience
Responsible body for reporting :	Corteva Agriscience, LLC	Method of treatment (e) :	Foliar application using a Knapsack sprayer
(name, address) :	9330 Zionsville Road, Indianapolis, IN, 46268 USA	Indoor/Outdoor :	Outdoor
Country :	Italy	Other active substance in the formulation :	None
Content of active substance: (g/L) :	50 g Fenpicoxamid/L + 101 g Prothioconazole/L	Other active substance content (g/kg or g/L)	None
Formulation (e.g., WP) :	EC	Residues calculated as :	XDE-777, X642188, X12314005, Prothioconazole-desthio, PTZ-α-OH-desthio, PTZ-3-OH-desthio, PTZ-4-OH-desthio, PTZ-5-OH-desthio and PTZ-6-OH-desthio

1	2	3	4			5	6		7	8					9
Report No. Location including Postal Code	Commodity / Variety	Date of: 1. Sowing or Planting 2. Flowering 3. Harvest	Plot Application rate per treatment (A1-A2)			Dates of treatment(s) or no. of treatment(s) and last date	BBCH Growth stage at Application (A)and at Sampling (S)		Portion Analyzed	Residues (mg/kg) (f)					DALA
	(a)	(b)	g a.i/ha	Water (L/ha)	g a.i/hL	(c)	A	S		PTZ-α-OH-desthio	PTZ-3-OH-desthio	PTZ-4-OH-desthio	PTZ-5-OH-desthio	PTZ-6-OH-desthio	(d)
Sponsor Reference No.: 220541 San Rocco Al Porto, 26865, Lombardia, Italy	Sugar Beet / Marinella	1. 02 Mar 2022 2. Not applicable 3. 26 Jul 2022	a) 74.50 b) 150.49 a) 75.25 b) 152.01	298 301	a) 25.00 b) 50.50 a) 25.00 b) 50.50	A1 = 05 Jul 2022 A2 = 26 Jul 2022	44 49	49	Tops	< 0.01 (0.005)	0.20	0.07	0.02	< 0.01 (0.006)	14
									Roots	ND	ND	ND	ND	ND	
								49	Tops	< 0.01 (0.003)	0.18	0.06	0.02	< 0.01 (0.008)	21
									Roots	ND	ND	ND	ND	ND	
								49	Tops	ND	0.19	0.07	0.02	< 0.01 (0.009)	35
									Roots	ND	ND	ND	ND	ND	

[a] According to EEC and Codex Class Classification (both) should be used
[b] Only if relevant
[c] Year must be indicated
[d] DALA = Days after last application
a) active ingredient for Fenpicoxamid only; b) active ingredient for Prothioconazole only

[e] High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated
[f] Analytical methods: DAS Reference ID 120615, DAS Reference ID 140696, Analytical Method MR-06/138 Amendment 4 and Modification M002 of the Analytical Method 00979/M002
The designation "ND" is used for treated samples for which the residue was <LOD (0.003 mg/kg)
Residue values below the LOQ (0.01 mg/kg) but greater than or equal to the LOD are reported as <LOQ with the uncorrected concentration in parentheses ( ).

Processing studies on a core set of representative processes

The processing study was conducted within the study 220541.

Magnitude of residues in representative succeeding crops

No new studies presented.

Other/Special Studies

Magnitude of residues in Pollen and Nectar

Comments of zRMS:	The study below was not evaluated by the zRMS in the framework of this application, since this study (Appeltauer, A., 2021) is not necessary to support the proposed uses of GF-3307 in sugar beet and fodder beet.

Reference:	Determination of Residues of Fenpicoxamid and Prothioconazole in Nectar, Pollen and Plants of Winter Oilseed Rape after One Application of GF-3307 in a Semi-Field Residue Study in Central and Southern Europe in 2020. Appeltauer, A., 2021. Report no. S20-01926/ DAS 200670.
Guideline(s):	Guideline 7029/VI/95 (rev. 5) to Directive 91/414/EEC and Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 and repealing Council Directives 79/17/EEC and 91/414/EEC
Deviations:	None with impact on the study.
GLP:	Yes
Validity of the study:	Yes

The study was conducted as five separate field trials in Germany and Spain in 2020. Three trials were located in Germany and two trials in Spain. Trial -01 was located in 75177 Pforzheim (Southern Germany), trial -02 in 76703 Kraichtal (Southern Germany), trial -03 in 21726 Heinbockel-Willahermoor (Northern Germany), trial -04 in 02150 Valdeganga (Spain) and trial -05 in 16700 Sisante (Spain). The distance between trials was at least 25 km. The fields for the different trials showed different varieties of winter oilseed rape with exception of trials -04 and -05, which had the same variety.
The study consisted of one treatment group per trial: the test item group T (3 replicates). Control samples were taken as pre-application samples in the treatment tunnels. There was one application in the test item treatment group at a target rate of 100 g fenpicoxamide + 200 g prothioconazole/ha (Ta, Tb, Tc; 2 000 mL product/ha) at BBCH 63 for trial -01, -03 and -05, at BBCH 61-62 for trial -02 and at BBCH 63-64 for trial -04.
Winter oilseed rape plants, forager bees for residue analysis and for determination of sugar content and pollen from winter oilseed rape were collected once before application and six times after application. Sampling of plants for residue analysis after application was conducted first at 0DAA and last sampling 5-8DAA. Sampling of pollen and forager bees for preparation of nectar for residue analysis after application was conducted first at 0DAA and last sampling 7-10DAA. For pollen analysis on each sampling day an A-sample of at least 0.2 g was collected. An R-sample was taken if possible. For plants samples on each sampling day an A- and if possible an R-sample of at least 500 g was collected. For forager bees A and R-samples of at least 300 forager bees each with an additional 50 bees for the determination of sugar content were collected on each sampling day.
Samples of nectar, pollen and plants from oilseed rape were analysed for residues of fenpicoxamid, prothioconazole and prothioconazole-desthio with a limit of quantification (LOQ) of 0.001 mg/kg for

each analyte and each matrix with a limit of detection (LOD) set at 0.0003 mg/kg (30% of the LOQ). Quantification was performed by use of LC-MS/MS detection. The analytical method was validated according to SANCO/3029/99, rev. 4 within this analytical phase by fortification of control samples with test items and subsequent determination of the recoveries. Five (5) fortifications of untreated control samples at the level of LOQ and five (5) fortifications at the level of 10x LOQ were performed.

Results

No residues of fenpicoxamid, prothioconazole and prothioconazole-desthio were detected above LOD in untreated plant, pollen and nectar specimen, with two exceptions: In plant specimen of trial -02 residues of prothioconazole-desthio <LOQ were determined in replicate Cc. In pollen specimen of trial -02 residues of prothioconazole-desthio were between 0.0120 mg/kg and 0.0444 mg/kg.

Overall there was a decline of residues of fenpicoxamid and prothioconazole for plants, pollen and nectar from the peak concentration to the last sampling observed for all trials.

Plants

No residues of fenpicoxamid, prothioconazole and prothioconazole-desthio were detected above LOD in untreated plant specimen, with exception of trial -02 where residues <LOQ were determined in replicate Cc.

Maximum residues over all trials of fenpicoxamid in plant specimens ranged from 1.75 mg/kg to 2.33 mg/kg.

Maximum residues over all trials of prothioconazole in plant specimens ranged from 0.319 mg/kg to 1.17 mg/kg.

Maximum residues over all trials of prothioconazole-desthio in plant specimens ranged from 1.57 mg/kg to 2.65 mg/kg.

Nectar

No residues of fenpicoxamid, prothioconazole and prothioconazole-desthio were detected above LOD in untreated nectar specimen.

Maximum residues over all trials of fenpicoxamid in nectar specimen ranged from 0.0435 mg/kg to 0.283 mg/kg.

Maximum residues over all trials of prothioconazole in nectar specimen ranged from 0.0312 mg/kg to 0.232 mg/kg.

Maximum residues over all trials of prothioconazole-desthio in nectar specimen ranged from 0.0108 mg/kg to 0.136 mg/kg.

Pollen

No residues of fenpicoxamid, prothioconazole and prothioconazole-desthio were detected above LOD in untreated pollen specimen, with one exception: In trial -02 residues of prothioconazole-desthio were between 0.0120 mg/kg and 0.0444 mg/kg.

Maximum residues over all trials of fenpicoxamid in pollen specimen ranged from 5.31 mg/kg to 17.3 mg/kg.

Maximum residues over all trials of prothioconazole in pollen specimen ranged from 9.21 mg/kg to 36.6 mg/kg.

Maximum residues over all trials of prothioconazole-desthio in pollen specimen ranged from 0.900 mg/kg to 4.98 mg/kg.

Table 01: Residues of fenpicoxamid, prothioconazole and prothioconazole-desthio in plants samples (S20-01926-01 to -05)

Sampling Code	Timing	Treatment	Sample Code L20-01926-	Sample Type	Residues [mg/kg]		
					Fenpicoxamid	Prothioconazole	Prothioconazole-desthio
Trial S20-01926-01 (Germany)							
S1	2DBA	C	01-Ca-S1-F-A	Whole Plant	n.d.	n.d.	n.d.
		C	01-Cb-S1-F-A	Whole Plant	n.d.	n.d.	n.d.
		C	01-Cc-S1-F-A	Whole Plant	n.d.	n.d.	n.d.
S2	0DAA	Ta	01-Ta-S2-F-A	Whole Plant	2.09	1.09	1.29
		Tb	01-Tb-S2-F-A	Whole Plant	2.15	1.17	1.43
		Tc	01-Tc-S2-F-A	Whole Plant	1.72	0.970	1.26
S3	1DAA	Ta	01-Ta-S3-F-A	Whole Plant	1.37	0.372	1.56
		Tb	01-Tb-S3-F-A	Whole Plant	1.87	0.532	1.66
		Tc	01-Tc-S3-F-A	Whole Plant	1.69	0.429	1.90
S4	2DAA	Ta	01-Ta-S4-F-A	Whole Plant	1.11	0.172	1.41
		Tb	01-Tb-S4-F-A	Whole Plant	1.22	0.210	1.33
		Tc	01-Tc-S4-F-A	Whole Plant	1.54	0.294	1.91
S5	4DAA	Ta	01-Ta-S5-F-A	Whole Plant	1.37	0.148	1.75
		Tb	01-Tb-S5-F-A	Whole Plant	1.15	0.121	1.18
		Tc	01-Tc-S5-F-A	Whole Plant	1.03	0.112	1.29
S6	6DAA	Ta	01-Ta-S6-F-A	Whole Plant	0.961	0.0841	1.13
		Tb	01-Tb-S6-F-A	Whole Plant	1.07	0.0893	1.37
		Tc	01-Tc-S6-F-A	Whole Plant	1.11	0.110	2.13
S7	8DAA	Ta	01-Ta-S7-F-A	Whole Plant	0.760	0.0741	1.12
		Tb	01-Tb-S7-F-A	Whole Plant	0.777	0.0730	0.876
		Tc	01-Tc-S7-F-A	Whole Plant	1.05	0.102	1.37

DBA = days before application, DAA = days after application; T = treated; C= untreated; n.d. not detected (below LOD set at 30 % of the LOQ))
Residues are not corrected for procedural recoveries

Table 01 (continued): Residues of fenpicoxamid, prothioconazole and prothioconazole-desthio in plants samples (S20-01926-01 to -05)

Sampling Code	Timing	Treatment	Sample Code L20-01926-	Sample Type	Residues [mg/kg]		
					Fenpicoxamid	Prothioconazole	Prothioconazole-desthio
Trial S20-01926-02 (Germany)							
S1	1DBA	C	02-Ca-S1-F-A	Whole Plant	n.d.	n.d.	n.d.
		C	02-Cb-S1-F-A	Whole Plant	n.d.	n.d.	n.d.
		C	02-Cc-S1-F-A	Whole Plant	n.d.	n.d.	< 0.001 (0.000308)
S2	0DAA	Ta	02-Ta-S2-F-A	Whole Plant	1.53	0.839	1.02
		Tb	02-Tb-S2-F-A	Whole Plant	1.41	0.747	0.948
		Tc	02-Tc-S2-F-A	Whole Plant	2.33	1.08	1.40
S3	1DAA	Ta	02-Ta-S3-F-A	Whole Plant	1.97	0.446	1.92
		Tb	02-Tb-S3-F-A	Whole Plant	1.49	0.432	1.28
		Tc	02-Tc-S3-F-A	Whole Plant	1.90	0.402	2.14
S4	2DAA	Ta	02-Ta-S4-F-A	Whole Plant	1.77	0.347	1.71
		Tb	02-Tb-S4-F-A	Whole Plant	1.08	0.251	1.20
		Tc	02-Tc-S4-F-A	Whole Plant	1.68	0.272	1.83
S5	4DAA	Ta	02-Ta-S5-F-A	Whole Plant	0.695	0.0838	1.01
		Tb	02-Tb-S5-F-A	Whole Plant	0.843	0.123	1.18
		Tc	02-Tc-S5-F-A	Whole Plant	1.16	0.137	1.84
S6	6DAA	Ta	02-Ta-S6-F-A	Whole Plant	0.637	0.0556	1.47
		Tb	02-Tb-S6-F-A	Whole Plant	1.49	0.115	1.82
		Tc	02-Tc-S6-F-A	Whole Plant	1.34	0.116	1.64
S7	7DAA	Ta	02-Ta-S7-F-A	Whole Plant	1.32	0.0960	1.89
		Tb	02-Tb-S7-F-A	Whole Plant	0.747	0.0524	1.18
		Tc	02-Tc-S7-F-A	Whole Plant	1.07	0.0818	1.59

DBA = days before application, DAA = days after application; T = treated; C= untreated; n.d. not detected (below LOD set at 30 % of the LOQ))
Residues are not corrected for procedural recoveries

Table 01 (continued): Residues of fenpicoxamid, prothioconazole and prothioconazole-desthio in plants samples (S20-01926-01 to -05)

Sampling Code	Timing	Treatment	Sample Code L20-01926-	Sample Type	Residues [mg/kg]		
					Fenpicoxamid	Prothioconazole	Prothioconazole-desthio
Trial S20-01926-03 (Spain)							
S1	1DBA	C	03-Ca-S1-F-A	Whole Plant	n.d.	n.d.	n.d.
		C	03-Cb-S1-F-A	Whole Plant	n.d.	n.d.	n.d.
		C	03-Cc-S1-F-A	Whole Plant	n.d.	n.d.	n.d.
S2	0DAA	Ta	03-Ta-S2-F-A	Whole Plant	1.05	0.533	0.806
		Tb	03-Tb-S2-F-A	Whole Plant	1.61	0.732	1.16
		Tc	03-Tc-S2-F-A	Whole Plant	1.46	0.667	1.33
S3	1DAA	Ta	03-Ta-S3-F-A	Whole Plant	1.35	0.322	1.09
		Tb	03-Tb-S3-F-A	Whole Plant	1.75	0.452	1.55
		Tc	03-Tc-S3-F-A	Whole Plant	1.70	0.352	1.57
S4	2DAA	Ta	03-Ta-S4-F-A	Whole Plant	1.27	0.157	1.13
		Tb	03-Tb-S4-F-A	Whole Plant	1.17	0.150	1.10
		Tc	03-Tc-S4-F-A	Whole Plant	1.39	0.142	1.24
S5	4DAA	Ta	03-Ta-S5-F-A	Whole Plant	0.973	0.0774	0.902
		Tb	03-Tb-S5-F-A	Whole Plant	1.19	0.0957	1.23
		Tc	03-Tc-S5-F-A	Whole Plant	1.33	0.0957	1.22
S6	5DAA	Ta	03-Ta-S6-F-A	Whole Plant	0.674	0.0447	0.616
		Tb	03-Tb-S6-F-A	Whole Plant	0.688	0.0428	0.579
		Tc	03-Tc-S6-F-A	Whole Plant	0.994	0.0499	0.914
S7	7DAA	Ta	03-Ta-S7-F-A	Whole Plant	0.718	0.0340	0.648
		Tb	03-Tb-S7-F-A	Whole Plant	0.453	0.0211	0.482
		Tc	03-Tc-S7-F-A	Whole Plant	0.524	0.0256	0.679

DBA = days before application, DAA = days after application; T = treated; C= untreated; n.d. not detected (below LOD set at 30 % of the LOQ))
Residues are not corrected for procedural recoveries

Table 01 (continued): Residues of fenpicoxamid, prothioconazole and prothioconazole-desthio in plants samples (S20-01926-01 to -05)

Sampling Code	Timing	Treatment	Sample Code L20-01926-	Sample Type	Residues [mg/kg]		
					Fenpicoxamid	Prothioconazole	Prothioconazole-desthio
Trial S20-01926-04 (Spain)							
S1	0DBA	C	04-Ca-S1-F-A	Whole Plant	n.d.	n.d.	n.d.
		C	04-Cb-S1-F-A	Whole Plant	n.d.	n.d.	n.d.
		C	04-Cc-S1-F-A	Whole Plant	n.d.	n.d.	n.d.
S2	0DAA	Ta	04-Ta-S2-F-A	Whole Plant	1.52	0.817	1.53
		Tb	04-Tb-S2-F-A	Whole Plant	2.26	1.09	2.32
		Tc	04-Tc-S2-F-A	Whole Plant	1.76	0.885	1.71
S3	1DAA	Ta	04-Ta-S3-F-A	Whole Plant	1.12	0.206	1.69
		Tb	04-Tb-S3-F-A	Whole Plant	1.27	0.255	2.08
		Tc	04-Tc-S3-F-A	Whole Plant	0.581	0.141	0.984
S4	2DAA	Ta	04-Ta-S4-F-A	Whole Plant	1.32	0.150	2.10
		Tb	04-Tb-S4-F-A	Whole Plant	1.33	0.131	1.94
		Tc	04-Tc-S4-F-A	Whole Plant	0.846	0.0970	1.50
S5	4DAA	Ta	04-Ta-S5-F-A	Whole Plant	1.02	0.0714	2.03
		Tb	04-Tb-S5-F-A	Whole Plant	1.23	0.0895	2.65
		Tc	04-Tc-S5-F-A	Whole Plant	0.806	0.0544	1.44
S6	7DAA	Ta	04-Ta-S6-F-A	Whole Plant	0.711	0.0404	1.35
		Tb	04-Tb-S6-F-A	Whole Plant	1.01	0.0569	1.71
		Tc	04-Tc-S6-F-A	Whole Plant	0.564	0.0310	1.10
S7	8DAA	Ta	04-Ta-S7-F-A	Whole Plant	0.423	0.0233	0.959
		Tb	04-Tb-S7-F-A	Whole Plant	0.891	0.0406	1.54
		Tc	04-Tc-S7-F-A	Whole Plant	0.518	0.0364	1.02

DBA = days before application, DAA = days after application; T = treated; C= untreated; n.d. not detected (below LOD set at 30 % of the LOQ))
Residues are not corrected for procedural recoveries

Table 01 (continued): Residues of fenpicoxamid, prothioconazole and prothioconazole-desthio in plants samples (S20-01926-01 to -05)

Sampling Code	Timing	Treatment	Sample Code L20-01926-	Sample Type	Residues [mg/kg]		
					Fenpicoxamid	Prothioconazole	Prothioconazole-desthio
Trial S20-01926-05 (Spain)							
S1	1DBA	C	05-Ca-S1-F-A	Whole Plant	n.d.	n.d.	n.d.
		C	05-Cb-S1-F-A	Whole Plant	n.d.	n.d.	n.d.
		C	05-Cc-S1-F-A	Whole Plant	n.d.	n.d.	n.d.
S2	0DAA	Ta	05-Ta-S2-F-A	Whole Plant	0.936	0.158	1.22
		Tb	05-Tb-S2-F-A	Whole Plant	1.64	0.319	2.06
		Tc	05-Tc-S2-F-A	Whole Plant	0.845	0.171	1.01
S3	1DAA	Ta	05-Ta-S3-F-A	Whole Plant	1.31	0.255	1.89
		Tb	05-Tb-S3-F-A	Whole Plant	1.75	0.280	2.19
		Tc	05-Tc-S3-F-A	Whole Plant	0.952	0.131	1.11
S4	2DAA	Ta	05-Ta-S4-F-A	Whole Plant	1.05	0.135	1.34
		Tb	05-Tb-S4-F-A	Whole Plant	1.35	0.192	1.72
		Tc	05-Tc-S4-F-A	Whole Plant	1.01	0.126	1.32
S5	5DAA	Ta	05-Ta-S5-F-A	Whole Plant	0.859	0.0562	1.23
		Tb	05-Tb-S5-F-A	Whole Plant	1.04	0.0811	1.33
		Tc	05-Tc-S5-F-A	Whole Plant	0.720	0.0458	1.13
S6	6DAA	Ta	05-Ta-S6-F-A	Whole Plant	0.541	0.0348	1.02
		Tb	05-Tb-S6-F-A	Whole Plant	0.676	0.0402	1.07
		Tc	05-Tc-S6-F-A	Whole Plant	0.615	0.0306	0.860
S7	7DAA	Ta	05-Ta-S7-F-A	Whole Plant	0.400	0.0233	0.776
		Tb	05-Tb-S7-F-A	Whole Plant	0.757	0.0524	1.14
		Tc	05-Tc-S7-F-A	Whole Plant	0.478	0.0251	0.924

DBA = days before application, DAA = days after application; T = treated; C= untreated; n.d. not detected (below LOD set at 30 % of the LOQ))
Residues are not corrected for procedural recoveries

Table 02: Residues of fenpicoxamid, prothioconazole and prothioconazole-desthio in nectar samples (S20-01926-01 to -05)

Sampling Code	Timing	Treatment	Sample Code L20-01926-	Sample Type	Residues [mg/kg]		
					Fenpicoxamid	Prothioconazole	Prothioconazole-desthio
Trial S20-01926-01 (Germany)							
S1	2DBA	C	01-Ca-S1-NFB-A	Nectar	n.d.	n.d.	n.d.
		C	01-Cb-S1-NFB-A	Nectar	n.d.	n.d.	n.d.
		C	01-Cc-S1-NFB-A	Nectar	n.d.	n.d.	n.d.
S2	0DAA	Ta	01-Ta-S2-NFB-A	Nectar	0.0215	0.0222	0.00609
		Tb	01-Tb-S2-NFB-A	Nectar	0.0435	0.0582	0.0181
		Tc	01-Tc-S2-NFB-A	Nectar	0.0345	0.0405	0.00558
S3	1DAA	Ta	01-Ta-S3-NFB-A	Nectar	0.00333	0.00687	0.00573
		Tb	01-Tb-S3-NFB-A	Nectar	0.00633	0.0182	0.00912
		Tc	01-Tc-S3-NFB-A	Nectar	0.00272	0.00537	0.00495
S4	2DAA	Ta	01-Ta-S4-NFB-A	Nectar	0.00141	< 0.001 (0.000525)	0.0185
		Tb	01-Tb-S4-NFB-A	Nectar	0.00121	< 0.001 (0.000417)	0.0135
		Tc	01-Tc-S4-NFB-A	Nectar	0.00223	< 0.001 (0.000684)	0.0166
S5	4DAA	Ta	01-Ta-S5-NFB-A	Nectar	0.00459	< 0.001 (0.000534)	0.00149
		Tb	01-Tb-S5-NFB-A	Nectar	0.00492	< 0.001 (0.000813)	0.00248
		Tc	01-Tc-S5-NFB-A	Nectar	0.00259	< 0.001 (0.000309)	0.00252
S6	6DAA	Ta	01-Ta-S6-NFB-A	Nectar	0.00152	n.d.	0.00291
		Tb	01-Tb-S6-NFB-A	Nectar	< 0.001 (0.000339)	n.d.	< 0.001 (0.000849)
		Tc	01-Tc-S6-NFB-A	Nectar	0.00226	n.d.	0.00312
S7	8DAA	Ta	01-Ta-S7-NFB-A	Nectar	0.00144	n.d.	0.00136
		Tb	01-Tb-S7-NFB-A	Nectar	< 0.001 (0.000486)	n.d.	0.00122
		Tc	01-Tc-S7-NFB-A	Nectar	0.00176	n.d.	0.00177

DBA = days before application, DAA = days after application; T = treated; C= untreated; n.d. not detected (below LOD set at 30 % of the LOQ))
Residues are not corrected for procedural recoveries

Table 02 (continued): Residues of fenpicoxamid, prothioconazole and prothioconazole-desthio in nectar samples (S20-01926-01 to -05)

Sampling Code	Timing	Treatment	Sample Code L20-01926-	Sample Type	Residues [mg/kg]		
					Fenpicoxamid	Prothioconazole	Prothioconazole-desthio
Trial S20-01926-02 (Germany)							
S1	1DBA	C	02-Ca-S1-NFB-A	Nectar	n.d.	n.d.	n.d.
		C	02-Cb-S1-NFB-A	Nectar	n.d.	n.d.	n.d.
		C	02-Cc-S1-NFB-A	Nectar	n.d.	n.d.	n.d.
S2	0DAA	Ta	02-Ta-S2-NFB-A	Nectar	0.0564	0.0804	0.0184
		Tb	02-Tb-S2-NFB-A	Nectar	0.0702	0.107	0.0220
		Tc	02-Tc-S2-NFB-A	Nectar	0.0540	0.0948	0.0186
S3	1DAA	Ta	02-Ta-S3-NFB-A	Nectar	0.00263	0.00256	0.00768
		Tb	02-Tb-S3-NFB-A	Nectar	0.00579	0.00299	0.00519
		Tc	02-Tc-S3-NFB-A	Nectar	0.00396	0.00283	0.00573
S4	2DAA	Ta	02-Ta-S4-NFB-A	Nectar	0.00141	< 0.001 (0.000777)	0.0225
		Tb	02-Tb-S4-NFB-A	Nectar	0.00151	0.00142	0.00498
		Tc	02-Tc-S4-NFB-A	Nectar	0.00136	< 0.001 (0.000756)	0.00546
S5	4DAA	Ta	02-Ta-S5-NFB-A	Nectar	0.00588	< 0.001 (0.000720)	0.00283
		Tb	02-Tb-S5-NFB-A	Nectar	0.00167	n.d.	0.00846
		Tc	02-Tc-S5-NFB-A	Nectar	0.00546	0.00126	0.00345
S6	6DAA	Ta	02-Ta-S6-NFB-A	Nectar	0.00130	n.d.	0.00354
		Tb	02-Tb-S6-NFB-A	Nectar	0.00186	n.d.	0.00531
		Tc	02-Tc-S6-NFB-A	Nectar	0.0256	0.00942	0.0309
S7	7DAA	Ta	02-Ta-S7-NFB-A	Nectar	< 0.001 (0.000474)	n.d.	0.00230
		Tb	02-Tb-S7-NFB-A	Nectar	< 0.001 (0.000774)	n.d.	0.00375
		Tc	02-Tc-S7-NFB-A	Nectar	0.00153	n.d.	0.00144

DBA = days before application, DAA = days after application; T = treated; C= untreated; n.d. not detected (below LOD set at 30 % of the LOQ))
Residues are not corrected for procedural recoveries

Table 02 (continued): Residues of fenpicoxamid, prothioconazole and prothioconazole-desthio in nectar samples (S20-01926-01 to -05)

Sampling Code	Timing	Treatment	Sample Code L20-01926-	Sample Type	Residues [mg/kg]		
					Fenpicoxamid	Prothioconazole	Prothioconazole-desthio
Trial S20-01926-03 (Spain)							
S1	1DBA	C	03-Ca-S1-NFB-A	Nectar	n.d.	n.d.	n.d.
		C	03-Cb-S1-NFB-A	Nectar	n.d.	n.d.	n.d.
		C	03-Cc-S1-NFB-A	Nectar	n.d.	n.d.	n.d.
S2	0DAA	Ta	03-Ta-S2-NFB-A	Nectar	0.0192	0.0238	0.00552
		Tb	03-Tb-S2-NFB-A	Nectar	0.0444	0.0312	0.0108
		Tc	03-Tc-S2-NFB-A	Nectar	0.00498	0.00756	0.00438
S3	1DAA	Ta	03-Ta-S3-NFB-A	Nectar	0.00633	0.00501	0.00459
		Tb	03-Tb-S3-NFB-A	Nectar	0.00816	0.00339	0.00564
		Tc	03-Tc-S3-NFB-A	Nectar	0.0125	0.00807	0.00384
S4	3DAA	Ta	03-Ta-S4-NFB-A	Nectar	0.00175	n.d.	0.00375
		Tb	03-Tb-S4-NFB-A	Nectar	0.00224	< 0.001 (0.000459)	0.00238
		Tc	03-Tc-S4-NFB-A	Nectar	0.00372	< 0.001 (0.000363)	0.00238
S5	4DAA	Ta	03-Ta-S5-NFB-A	Nectar	0.00257	n.d.	< 0.001 (0.000900)
		Tb	03-Tb-S5-NFB-A	Nectar	0.00104	n.d.	0.00124
		Tc	03-Tc-S5-NFB-A	Nectar	0.00208	n.d.	< 0.001 (0.000996)
S6	9DAA	Ta	03-Ta-S6-NFB-A	Nectar	n.d.	n.d.	< 0.001 (0.000483)
		Tb	03-Tb-S6-NFB-A	Nectar	< 0.001 (0.000441)	< 0.001 (0.000300)	< 0.001 (0.000870)
		Tc	03-Tc-S6-NFB-A	Nectar	< 0.001 (0.000336)	n.d.	0.00120
S7	10DAA	Ta	03-Ta-S7-NFB-A	Nectar	0.00133	0.00522	0.00201
		Tb	03-Tb-S7-NFB-A	Nectar	n.d.	n.d.	< 0.001 (0.000726)
		Tc	03-Tc-S7-NFB-A	Nectar	0.00102	n.d.	0.00157

DBA = days before application, DAA = days after application; T = treated; C= untreated; n.d. not detected (below LOD set at 30 % of the LOQ))
Residues are not corrected for procedural recoveries

Table 02 (continued): Residues of fenpicoxamid, prothioconazole and prothioconazole-desthio in nectar samples (S20-01926-01 to -05)

Sampling Code	Timing	Treatment	Sample Code L20-01926-	Sample Type	Residues [mg/kg]		
					Fenpicoxamid	Prothioconazole	Prothioconazole-desthio
Trial S20-01926-04 (Spain)							
S1	0DBA	C	04-Ca-S1-NFB-A	Nectar	n.d.	n.d.	n.d.
		C	04-Cb-S1-NFB-A	Nectar	n.d.	n.d.	n.d.
		C	04-Cc-S1-NFB-A	Nectar	n.d.	n.d.	n.d.
S2	0DAA	Ta	04-Ta-S2-NFB-A	Nectar	0.104	0.139	0.0393
		Tb	04-Tb-S2-NFB-A	Nectar	0.0318	0.0420	0.0213
		Tc	04-Tc-S2-NFB-A	Nectar	0.0546	0.0837	0.0256
S3	1DAA	Ta	04-Ta-S3-NFB-A	Nectar	0.00278	0.00259	0.00489
		Tb	04-Tb-S3-NFB-A	Nectar	0.00122	0.00170	0.00546
		Tc	04-Tc-S3-NFB-A	Nectar	0.00186	0.00281	0.00582
S4	2DAA	Ta	04-Ta-S4-NFB-A	Nectar	0.0405	0.00408	0.0239
		Tb	04-Tb-S4-NFB-A	Nectar	0.00399	< 0.001 (0.000792)	0.0127
		Tc	04-Tc-S4-NFB-A	Nectar	0.00378	0.00114	0.0174
S5	4DAA	Ta	04-Ta-S5-NFB-A	Nectar	0.00639	0.00156	0.00375
		Tb	04-Tb-S5-NFB-A	Nectar	0.0843	< 0.001 (0.000885)	0.0129
		Tc	04-Tc-S5-NFB-A	Nectar	0.283	0.0141	0.115
S6	7DAA	Ta	04-Ta-S6-NFB-A	Nectar	0.175	0.0164	0.136
		Tb	04-Tb-S6-NFB-A	Nectar	0.0384	0.00221	0.0212
		Tc	04-Tc-S6-NFB-A	Nectar	0.138	0.0122	0.0462
S7	8DAA	Ta	04-Ta-S7-NFB-A	Nectar	0.156	0.0150	0.100
		Tb	04-Tb-S7-NFB-A	Nectar	0.0807	0.00372	0.0447
		Tc	04-Tc-S7-NFB-A	Nectar	0.0516	0.00903	0.0495

DBA = days before application, DAA = days after application; T = treated; C= untreated; n.d. not detected (below LOD set at 30 % of the LOQ))
Residues are not corrected for procedural recoveries

Table 02 (continued): Residues of fenpicoxamid, prothioconazole and prothioconazole-desthio in nectar samples (S20-01926-01 to -05)

Sampling Code	Timing	Treatment	Sample Code L20-01926-	Sample Type	Residues [mg/kg]		
					Fenpicoxamid	Prothioconazole	Prothioconazole-desthio
Trial S20-01926-05 (Spain)							
S1	1DBA	C	05-Ca-S1-NFB-A	Nectar	n.d.	n.d.	n.d.
		C	05-Cb-S1-NFB-A	Nectar	n.d.	n.d.	n.d.
		C	05-Cc-S1-NFB-A	Nectar	n.d.	n.d.	n.d.
S2	0DAA	Ta	05-Ta-S2-NFB-A	Nectar	0.139	0.232	0.132
		Tb	05-Tb-S2-NFB-A	Nectar	0.161	0.128	0.0345
		Tc	05-Tc-S2-NFB-A	Nectar	0.134	0.161	0.115
S3	1DAA	Ta	05-Ta-S3-NFB-A	Nectar	0.00702	0.00591	0.00927
		Tb	05-Tb-S3-NFB-A	Nectar	0.0135	0.00624	0.0195
		Tc	05-Tc-S3-NFB-A	Nectar	0.0183	0.0187	0.0207
S4	2DAA	Ta	05-Ta-S4-NFB-A	Nectar	0.0366	0.00999	0.0152
		Tb	05-Tb-S4-NFB-A	Nectar	0.0113	0.0107	0.0152
		Tc	05-Tc-S4-NFB-A	Nectar	0.0171	0.00268	0.0154
S5	5DAA	Ta	05-Ta-S5-NFB-A	Nectar	< 0.001 (0.000588)	n.d.	0.00753
		Tb	05-Tb-S5-NFB-A	Nectar	< 0.001 (0.000387)	n.d.	0.00648
		Tc	05-Tc-S5-NFB-A	Nectar	< 0.001 (0.000459)	n.d.	0.00468
S6	6DAA	Ta	05-Ta-S6-NFB-A	Nectar	< 0.001 (0.000678)	n.d.	0.00723
		Tb	05-Tb-S6-NFB-A	Nectar	< 0.001 (0.000615)	n.d.	0.00855
		Tc	05-Tc-S6-NFB-A	Nectar	< 0.001 (0.000750)	n.d.	0.0115
S7	7DAA	Ta	05-Ta-S7-NFB-A	Nectar	n.d.	n.d.	0.00262
		Tb	05-Tb-S7-NFB-A	Nectar	n.d.	n.d.	0.00555
		Tc	05-Tc-S7-NFB-A	Nectar	n.d.	n.d.	0.00450

DBA = days before application, DAA = days after application; T = treated; C= untreated; n.d. not detected (below LOD set at 30 % of the LOQ))
Residues are not corrected for procedural recoveries

Table 03: Residues of fenpicoxamid, prothioconazole and prothioconazole-desthio in pollen samples (S20-01926-01 to -05)

Sampling Code	Timing	Treatment	Sample Code L20-01926-	Sample Type	Residues [mg/kg]		
					Fenpicoxamid	Prothioconazole	Prothioconazole-desthio
Trial S20-01926-01 (Germany)							
S1	2DBA	C	01-Ca-S1-P-A	Pollen	n.d.	n.d.	n.d.
		C	01-Cb-S1-P-A	Pollen	n.d.	n.d.	n.d.
		C	01-Cc-S1-P-A	Pollen	n.d.	n.d.	n.d.
S2	0DAA	Ta	01-Ta-S2-P-A	Pollen	4.80	10.0	0.573
		Tb	01-Tb-S2-P-A	Pollen	6.36	15.1	0.690
		Tc	01-Tc-S2-P-A	Pollen	7.92	18.9	0.792
S3	1DAA	Ta	01-Ta-S3-P-A	Pollen	1.02	0.777	0.900
		Tb	01-Tb-S3-P-A	Pollen	0.756	0.720	0.702
		Tc	01-Tc-S3-P-A	Pollen	1.06	1.06	0.837
S4	2DAA	Ta	01-Ta-S4-P-A	Pollen	0.579	0.118	0.498
		Tb	01-Tb-S4-P-A	Pollen	0.507	0.145	0.477
		Tc	01-Tc-S4-P-A	Pollen	0.447	0.164	0.363
S5	4DAA	Ta	01-Ta-S5-P-A	Pollen	0.750	0.0275	0.378
		Tb	01-Tb-S5-P-A	Pollen	0.717	0.0292	0.396
		Tc	01-Tc-S5-P-A	Pollen	0.654	0.0274	0.336
S6	6DAA	Ta	01-Ta-S6-P-A	Pollen	0.525	0.0339	0.348
		Tb	01-Tb-S6-P-A	Pollen	0.480	0.0321	0.405
		Tc	01-Tc-S6-P-A	Pollen	0.624	0.0522	0.438
S7	8DAA	Ta	01-Ta-S7-P-A	Pollen	0.465	0.0214	0.477
		Tb	01-Tb-S7-P-A	Pollen	0.477	0.0192	0.567
		Tc	01-Tc-S7-P-A	Pollen	0.453	0.0116	0.486

DBA = days before application, DAA = days after application; T = treated; C= untreated; n.d. not detected (below LOD set at 30 % of the LOQ))
Residues are not corrected for procedural recoveries

Table 03 (continued): Residues of fenpicoxamid, prothioconazole and prothioconazole-desthio in pollen samples (S20-01926-01 to -05)

Sampling Code	Timing	Treatment	Sample Code L20-01926-	Sample Type	Residues [mg/kg]		
					Fenpicoxamid	Prothioconazole	Prothioconazole-desthio
Trial S20-01926-02 (Germany)							
S1	1DBA	C	02-Ca-S1-P-A	Pollen	n.d.	n.d.	0.0120
		C	02-Cb-S1-P-A	Pollen	n.d.	n.d.	0.0444
		C	02-Cc-S1-P-A	Pollen	n.d.	n.d.	0.0162
S2	0DAA	Ta	02-Ta-S2-P-A	Pollen	13.7	28.1	3.06
		Tb	02-Tb-S2-P-A	Pollen	15.7	29.8	3.06
		Tc	02-Tc-S2-P-A	Pollen	16.6	36.6	4.29
S3	1DAA	Ta	02-Ta-S3-P-A	Pollen	1.06	0.765	1.03
		Tb	02-Tb-S3-P-A	Pollen	1.01	0.639	1.09
		Tc	02-Tc-S3-P-A	Pollen	0.999	0.648	0.999
S4	2DAA	Ta	02-Ta-S4-P-A	Pollen	0.528	0.207	0.525
		Tb	02-Tb-S4-P-A	Pollen	0.525	0.219	0.519
		Tc	02-Tc-S4-P-A	Pollen	0.702	0.252	0.666
S5	4DAA	Ta	02-Ta-S5-P-A	Pollen	1.18	0.0600	0.630
		Tb	02-Tb-S5-P-A	Pollen	0.957	0.0486	0.516
		Tc	02-Tc-S5-P-A	Pollen	1.04	0.111	0.666
S6	6DAA	Ta	02-Ta-S6-P-A	Pollen	0.876	0.0444	0.630
		Tb	02-Tb-S6-P-A	Pollen	0.906	0.0324	0.597
		Tc	02-Tc-S6-P-A	Pollen	1.09	0.0342	0.801
S7	7DAA	Ta	02-Ta-S7-P-A	Pollen	0.696	0.0129	0.594
		Tb	02-Tb-S7-P-A	Pollen	0.495	0.00855	0.504
		Tc	02-Tc-S7-P-A	Pollen	1.05	0.0299	0.894

DBA = days before application, DAA = days after application; T = treated; C= untreated; n.d. not detected (below LOD set at 30 % of the LOQ))
Residues are not corrected for procedural recoveries

Table 03 (continued): Residues of fenpicoxamid, prothioconazole and prothioconazole-desthio in pollen samples (S20-01926-01 to -05)

Sampling Code	Timing	Treatment	Sample Code L20-01926-	Sample Type	Residues [mg/kg]		
					Fenpicoxamid	Prothioconazole	Prothioconazole-desthio
Trial S20-01926-03 (Spain)							
S1	1DBA	C	03-Ca-S1-P-A	Pollen	n.d.	n.d.	n.d.
		C	03-Cb-S1-P-A	Pollen	n.d.	n.d.	n.d.
		C	03-Cc-S1-P-A	Pollen	n.d.	n.d.	n.d.
S2	0DAA	Ta	03-Ta-S2-P-A	Pollen	3.93	7.17	1.75
		Tb	03-Tb-S2-P-A	Pollen	5.31	9.21	2.45
		Tc	03-Tc-S2-P-A	Pollen	0.489	3.30	0.663
S3	1DAA	Ta	03-Ta-S3-P-A	Pollen	0.879	0.660	0.822
		Tb	03-Tb-S3-P-A	Pollen	0.999	0.822	0.858
		Tc	03-Tc-S3-P-A	Pollen	1.08	0.846	0.951
S4	3DAA	Ta	03-Ta-S4-P-A	Pollen	0.489	0.0738	0.378
		Tb	03-Tb-S4-P-A	Pollen	0.813	0.198	0.675
		Tc	03-Tc-S4-P-A	Pollen	1.01	0.324	0.744
S5	4DAA	Ta	03-Ta-S5-P-A	Pollen	0.269	0.0207	0.221
		Tb	03-Tb-S5-P-A	Pollen	0.266	0.0253	0.263
		Tc	03-Tc-S5-P-A	Pollen	0.459	0.0384	0.357
S6	9DAA	Ta	03-Ta-S6-P-A	Pollen	0.0453	< 0.001 (0.000510)	0.172
		Tb	03-Tb-S6-P-A	Pollen	0.0543	0.00243	0.237
		Tc	03-Tc-S6-P-A	Pollen	0.0516	0.00214	0.245
S7	10DAA	Ta	03-Ta-S7-P-A	Pollen	0.0870	0.00795	0.321
		Tb	03-Tb-S7-P-A	Pollen	0.0396	< 0.001 (0.000744)	0.294
		Tc	03-Tc-S7-P-A	Pollen	0.0402	< 0.001 (0.000381)	0.294

DBA = days before application, DAA = days after application; T = treated; C= untreated; n.d. not detected (below LOD set at 30 % of the LOQ))
Residues are not corrected for procedural recoveries

Table 03 (continued): Residues of fenpicoxamid, prothioconazole and prothioconazole-desthio in pollen samples (S20-01926-01 to -05)

Sampling Code	Timing	Treatment	Sample Code L20-01926-	Sample Type	Residues [mg/kg]		
					Fenpicoxamid	Prothioconazole	Prothioconazole-desthio
Trial S20-01926-04 (Spain)							
S1	0DBA	C	04-Ca-S1-NFB-A	Pollen	n.d.	n.d.	n.d.
		C	04-Cb-S1-NFB-A	Pollen	n.d.	n.d.	n.d.
		C	04-Cc-S1-NFB-A	Pollen	n.d.	n.d.	n.d.
S2	0DAA	Ta	04-Ta-S2-NFB-A	Pollen	17.3	18.2	4.98
		Tb	04-Tb-S2-NFB-A	Pollen	7.89	6.90	3.54
		Tc	04-Tc-S2-NFB-A	Pollen	8.91	11.0	2.93
S3	1DAA	Ta	04-Ta-S3-NFB-A	Pollen	1.09	0.453	0.693
		Tb	04-Tb-S3-NFB-A	Pollen	0.696	0.327	0.552
		Tc	04-Tc-S3-NFB-A	Pollen	0.789	0.336	0.519
S4	2DAA1	Ta	04-Ta-S4-NFB-A	Pollen	0.903	0.0522	0.345
		Tb	04-Tb-S4-NFB-A	Pollen	0.654	0.0474	0.293
		Tc	04-Tc-S4-NFB-A	Pollen	0.552	0.0402	0.247
S5	4DAA	Ta	04-Ta-S5-NFB-A	Pollen	0.840	0.0154	0.272
		Tb	04-Tb-S5-NFB-A	Pollen	0.990	0.0136	0.274
		Tc	04-Tc-S5-NFB-A	Pollen	0.840	0.0233	0.246
S6	7DAA	Ta	04-Ta-S6-NFB-A	Pollen	0.303	0.00411	0.315
		Tb	04-Tb-S6-NFB-A	Pollen	0.229	0.00342	0.219
		Tc	04-Tc-S6-NFB-A	Pollen	0.348	0.0282	0.369
S7	8DAA	Ta	04-Ta-S7-NFB-A	Pollen	0.462	0.00471	0.495
		Tb	04-Tb-S7-NFB-A	Pollen	0.214	0.00172	0.303
		Tc	04-Tc-S7-NFB-A	Pollen	0.276	0.00414	0.399

DBA = days before application, DAA = days after application; T = treated; C= untreated; n.d. not detected (below LOD set at 30 % of the LOQ))
Residues are not corrected for procedural recoveries

Table 03 (continued): Residues of fenpicoxamid, prothioconazole and prothioconazole-desthio in pollen samples (S20-01926-01 to -05)

Sampling Code	Timing	Treatment	Sample Code L20-01926-	Sample Type	Residues [mg/kg]		
					Fenpicoxamid	Prothioconazole	Prothioconazole-desthio
Trial S20-01926-05 (Spain)							
S1	1DBA	C	05-Ca-S1-P-A	Pollen	n.d.	n.d.	n.d.
		C	05-Cb-S1-P-A	Pollen	n.d.	n.d.	n.d.
		C	05-Cc-S1-P-A	Pollen	n.d.	n.d.	n.d.
S2	0DAA	Ta	05-Ta-S2-P-A	Pollen	8.64	8.67	2.37
		Tb	05-Tb-S2-P-A	Pollen	14.0	13.7	2.93
		Tc	05-Tc-S2-P-A	Pollen	14.2	17.9	3.06
S3	1DAA	Ta	05-Ta-S3-P-A	Pollen	0.477	0.264	0.750
		Tb	05-Tb-S3-P-A	Pollen	0.861	0.723	1.55
		Tc	05-Tc-S3-P-A	Pollen	1.06	0.690	1.85
S4	2DAA	Ta	05-Ta-S4-P-A	Pollen	0.213	0.0519	0.459
		Tb	05-Tb-S4-P-A	Pollen	0.204	0.0741	0.720
		Tc	05-Tc-S4-P-A	Pollen	0.285	0.0462	0.450
S5	5DAA	Ta	05-Ta-S5-P-A	Pollen	0.194	0.00669	0.164
		Tb	05-Tb-S5-P-A	Pollen	0.360	0.0137	0.227
		Tc	05-Tc-S5-P-A	Pollen	0.235	0.00663	0.217
S6	6DAA	Ta	05-Ta-S6-P-A	Pollen	0.279	0.00780	0.248
		Tb	05-Tb-S6-P-A	Pollen	0.185	0.00435	0.254
		Tc	05-Tc-S6-P-A	Pollen	0.252	0.00873	0.262
S7	7DAA	Ta	05-Ta-S7-P-A	Pollen	0.135	n.d.	0.243
		Tb	05-Tb-S7-P-A	Pollen	0.0777	n.d.	0.238
		Tc	05-Tc-S7-P-A	Pollen	0.150	0.00423	0.248

DBA = days before application, DAA = days after application; T = treated; C= untreated; n.d. not detected (below LOD set at 30 % of the LOQ))
Residues are not corrected for procedural recoveries

Prothioconazole

Stability of residues

Stability of residues during storage of samples

Storage stability of residues in plant products

DAR reference: Section B.7.7.1

Report: **KCA 6.1/01; Heinemann, O., 2001**
Title: 18 Months storage stability of residues of JAU6476 and JAU6476-desthio during frozen storage in/on wheat matrices
Report No.: MR-282/00
Guidelines: Not specified
GLP: Yes

Wheat
Samples of homogenised wheat matrices were fortified separately with unlabelled JAU 6476 and JAU 6476-desthio (chemical purities 99.5%) at concentrations of 0.5-1.5mg/kg (green material), 0.5-0.75mg/kg (straw) and 0.1-0.15 mg/kg (grain). Subsamples from each concentration were stored below -18°C and analysed after 0, 30, 60, 90, 120, 180, 360, and 540 days. All samples were extracted with acetonitrile/water, with added cysteine hydrochloride to prevent oxidation of the parent material. Extracts were then partitioned with n-hexane and dichloromethane and analytes were determined with HPLC- MS/MS, with a validated LOD of 0.05 mg/kg for straw and green material and 0.01 mg/kg for grain (Heinemann 2000a).

The recovery results are summarised in Table B.7.1-2. Results indicate that JAU 6476 is stable in deep frozen wheat matrices for 60-180 days and JAU 6476-desthio is stable in deep frozen wheat matrices for greater than 540 days

Table B.7.1-2 Freezer stability of JAU 6476 in wheat matrices. Mean percentage recoveries

Storage period (days)	Green material		Straw		Grain	
	JAU 6476	JAU 6476-desthio	JAU 6476	JAU 6476-desthio	JAU 6476	JAU 6476-desthio
0	100	100	100	100	100	100
30	87	106	92	101	77	94
60	89	106	93	101	88	101
90	68	102	80	100	86	100
120	75	103	92	114	93	114
180	61	102	73	103	81	98
360	59	93	74	98	59	105
540	52	98	67	93	62	97

Report: **KCA 6.1/02; Heinemann, O., 2003**
Title: 36 Months storage stability of residues of JAU 6476 and JAU 6476-desthio during frozen storage in/on wheat matrices
Report No.: MR-354/01
Guidelines: EU Council Directive 91/414/EEC amended by the Commission Directive 96/68/EC
US EPA Residue Chemistry Test Guideline OPPTS 860.1380: Storage Stability Data
GLP: Yes

The above frozen storage stability study on prothioconazole and prothioconazole-desthio in wheat matrices was extended until 36 months (with analysis at approx. 720 days and 1080 days). Sample preparation and analysis is therefore as described above in MR-282/00.
Additional details have been provided in this study about the preparation of spiked samples. Fortification of samples was achieved using 2 kg fresh bulk material which was placed in a stainless steel container andsprayed with spiking solution in dichloromethane. The material was mixed for approximately 5 min. Following evaporation of the solvent dry ice was added, and after 1 h the frozen bulk material was homogenised. Due to potential losses as a result of drift of the spray liquid and adhesion of test substance to the container surface, excess test substance was needed to obtain target fortifications of 10x the LOQ orlevels expected from residue studies. The actual fortification level of prothioconazole-desthio was therefore confirmed by performing a "day-zero analysis".
Recoveries after storage and procedural recoveries are displayed in Table B.7.1-3 and Table B.7.1-4.

Table B.7.1-3 Storage stability of prothioconazole in wheat matrices for up to 36 months

Sample material	Storage interval (days)	Residue level in stored samples		Mean procedural recovery (%)
		Recoveries (mean) (mg/kg)	% of Time 0 measurement	
Wheat Forage	0	1.21, 1.20, 1.26, 1.22, 1.16 **(1.21)**	**100**	97
	34	1.09, 1.06, 1.01 **(1.05)**	**87**	74
	57	1.05,1.03, 1.14 **(1.07)**	**89**	91
	97	0.861, 0.774, 0.782 **(0.81)**	**67**[1]	84
	100	0.800, 0.818, 0.812 **(0.81)**	**67**[1]	96
	105	0.878, 0.841 **(0.86)**	**71**[1]	99
	121	0.940, 0.928, 0.843 **(0.90)**	**75**	95
	169	0.751, 0.753, 0.724 **(0.74)**	**61**	94
	393	0.672, 0.757 **(0.71)**	**59**	80
	576	0.720, 0.504, 0.659 **(0.63)**	**52**	89
	763	0.538, 0.442, 0.553 **(0.51)**	**42**	84
	1022	0.631, 0.541, 0.603 **(0.59)**	**49**	77
	1126	0.520, 0.626, 0.451 **(0.53)**	**44**	88
Wheat Grain	0	0.121, 0.118, 0.118, 0.124 **(0.12)**	**100**	95
	23	0.097, 0.098, 0.083 **(0.093)**	**77**	88
	53	0.102, 0.111, 0.103 **(0.105)**	**88**	99
	92	0.102, 0.102, 0.105 **(0.103)**	**86**	114
	122	0.114, 0.109, 0.111 **(0.111)**	**93**	100
	197	0.096, 0.098, 0.096 **(0.097)**	**81**	83
	352	0.076, 0.073, 0.064 **(0.071)**	**59**	85
	535	0.074, 0.082, 0.066 **(0.074)**	**62**	96
	731	0.082, 0.056, 0.093 **(0.077)**	**64**	85
	975	0.060, 0.059, 0.061 **(0.060)**	**50**	91
	1088	0.067, 0.063, 0.059 **(0.063)**	**53**	85
Wheat Straw	0	1.49, 1.51, 1.44, 1.50, 1.48 **(1.48)**	**100**	93
	34	1.38, 1.46, 1.25 **(1.36)**	**92**	93
	57	1.45, 1.24, 1.46 **(1.38)**	**93**	88
	96	1.20, 1.19, 1.16 **(1.18)**	**80**	85
	120	1.39, 1.35, 1.35 **(1.36)**	**92**	104
	167	0.918, 1.13, 1.18 **(1.08)**	**73**	94
	392	1.11, 1.10, 1.09 **(1.10)**	**74**	84
	575	0.982, 0.966, 1.03 **(0.99)**	**67**	79
	762	0.840, 0.821, 1.03 **(0.90)**	**61**	100
	1016	1.03, 0.991, 1.02 **(1.01)**	**68**	87
	1128	0.927, 0.764, 0.885 **(0.86)**	**58**	84

[1] Note: The 97, 100 and 105 day samples have been presented as a mean of 68% in Table B.7.1-2.

Table B.7.1-4 Storage stability of prothioconazole-desthio in wheat matrices for up to 36 months

Sample material	Storage interval (days)	Residue level in stored samples		Mean procedural recovery (%)
		Recoveries (mean) (mg/kg)	% of Time 0 measurement	
Wheat Forage	0	1.56, 1.71, 1.42, 1.62, 1.77 **(1.62)**	**100**	93
	34	1.65, 1.90, 1.58 **(1.71)**	**106**	92
	57	1.73, 1.74, 1.67 **(1.71)**	**106**	93
	97	1.56, 1.59, 1.51 **(1.55)**	**96**[1]	91
	100	1.69, 1.74, 1.82 **(1.75)**	**108**[1]	96
	121	1.86, 1.57, 1.55 **(1.66)**	**103**	100
	169	1.71, 1.62, 1.61 **(1.65)**	**102**	100
	393	1.50, 1.54, 1.45 **(1.50)**	**93**	87
	576	1.55, 1.55, 1.67 **(1.59)**	**98**	87
	763	1.55, 1.49, 1.49 **(1.51)**	**93**	88
	1022	1.92, 1.80, 1.78 **(1.83)**	**113**	86
	1126	1.96, 1.72, 1.97 **(1.88)**	**116**	89
Wheat Grain	0	0.220, 0.238, 0.233, 0.237, 0.224 **(0.23)**	**100**	85
	23	0.226, 0.209, 0.211 **(0.22)**	**94**	81
	53	0.240, 0.237, 0.218 **(0.23)**	**101**	90
	92	0.229, 0.231 **(0.23)**	**100**	92
	122	0.259, 0.251, 0.275 **(0.26)**	**114**	98
	197	0.250, 0.237, 0.191 **(0.23)**	**98**	84
	352	0.225, 0.271, 0.230 **(0.24)**	**105**	87
	535	0.225, 0.230, 0.216 **(0.22)**	**97**	86
	731	0.171, 0.178, 0.242 **(0.20)**	**86**	76
	975	0.224, 0.224 **(0.22)**	**97**	83
	987	0.231, 0.228, 0.182 **(0.21)**	**93**	92
	1088	0.223, 0.227, 0.200 **(0.22)**	**94**	90
Wheat Straw	0	1.88, 1.95, 1.98, 1.90, 1.95 **(1.93)**	**100**	90
	34	1.93, 1.99, 1.95 **(1.96)**	**101**	89
	57	1.86, 1.97, 2.03 **(1.95)**	**101**	89
	96	1.90, 1.98, 1.93 **(1.94)**	**100**	91
	120	2.13, 2.15, 2.34 **(2.21)**	**114**	93
	167	2.00, 1.98, 1.97 **(1.98)**	**103**	93
	392	1.92, 1.84, 1.88 **(1.88)**	**98**	91
	575	1.76, 1.78, 1.85 **(1.80)**	**93**	81
	762	1.90, 1.99, 1.96 **(1.95)**	**101**	96
	1016	1.86, 1.96, 2.04 **(1.95)**	**101**	89
	1128	1.90, 1.87, 1.99 **(1.92)**	**99**	90

[1] Note: The 97 and 100 day samples have been presented as a mean of 102% in Table B.7.1-2.

Conclusion

Prothioconazole shows significant decline over the storage period with concomitant increases in Prothioconazole-desthio. Prothioconazole residues can be considered stable for only 57, 197 and 392 days for wheat forage, wheat grain and wheat straw respectively.

The results indicate that prothioconazole-desthio is stable under frozen storage at -18 °C or below for at least 1088 days (approximately 36 months) in wheat grain, 1128 days (approximately 37 months) in wheat straw and 1126 days (approximately 37 months) in wheat forage.

It should be noted that the results have been calculated against a measured time 0 result rather than nominal spiking levels. This is not ideal and the study report indicates this is to compensate for losses of test substance by drift and adhesion to the containers. It is not clear why similar issues were not experienced with the concurrent recoveries, which are generally acceptable. Nevertheless, the study demonstrates the stability of prothioconazole residues over the storage period.

Storage stability of residues in animal products

No new studies presented.

Magnitude of residues in plants

Other / special studies (KCA6.10, 6.10.1)

Study S19-00902

Comments of zRMS:	The study below was not evaluated by the zRMS in the framework of this application, since this study (Appeltauer, A., 2020) is not necessary to support the proposed uses of GF-3307 in sugar beet and fodder beet.

Title:	Determination of residues of prothioconazole and its metabolites in honey after two applications of PTZ EC 250 in winter oilseed rape at 5 sites in Northern and Southern Europe in 2019
Author:	Appeltauer, A.
Edition Date:	16.04.2020
Report No:	M-682401-01-1
Reference No:	S19-00902
Guideline(s)	OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published in September 2009) EC (2018) Technical guidelines for determining the magnitude of pesticide residues in honey and setting Maximum Residue Levels in honey (SANTE/11956/2016 rev. 9) Commission Regulation (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 (Oct. 2009)
Guideline Deviation(s)	None
GLP/GEP	yes
Testing Facility:	Eurofins Agroscience Services EcoChem GmbH / Eurofins Agroscience Services Ecotox GmbH, Niefern-Oeschelbronn, Germany
Sponsor:	Bayer
Owner:	BAY

Test system

In order to support the intended and most critical uses of prothioconazole on melliferous crops and in order to determine the resulting residues of prothioconazole in honey, five GLP honey trials were conducted on oilseed rape in northern and southern European zones under semi-field conditions during the 2019 season.

The trials were performed in Germany (2), southern France, Italy and Spain.

The formulation prothioconazole EC 250, an emulsifiable concentrate containing 250 g Prothioconazole/L was applied twice at 0.8 L/ha during flowering (BBCH63-65) with an interval of 12-14 days, representing the most critical GAP of the crops intended for authorisation in EU MSs and, covering the whole flowering period.

Table 2.2.2-1: Use pattern applied for the honey residue trials after spray application of prothioconazole under semi-field conditions

Description	Application Type	Formulation	No. of appl.	Growth stage at last application	Application rate per treatment (g a.s./ha)	Interval (days)
Oilseed rape (Honey tunnel trials)	Semi-field	EC 250*	2	BBCH63-65 (flowering)	200	12-14

* Emulsifiable Concentrate containing 250 g prothioconazole /L

On each trial site one tunnel confining the bees was established on the control and the treated plot. One bee hive was set up per tunnel for the control and treated plot, each. Colony assessments were performed before set-up of the hives in the tunnels and after sampling of the honey.

Honey was collected from initially empty combs which were introduced in the hives shortly before the last application. Honey was collected once mature at the end of flowering or if the water content was < 20% or after comb closure – whatever occurred first - for subsequent residue analysis. In case the water content was >20% at the end of flowering a subsample was dried in a compartment dryer at the laboratory at conditions simulating the bee hive conditions. In one trial (S19-00902-02) honey was sampled before end of flowering and with a water content of > 20% as rainy weather was forecasted, and new honey was only available at low amounts in the colonies. In order not to risk losing the produced honey, the honey was sampled already before the end of flowering. An additional honey sample was collected in this trial at the end of flowering to obtain honey with water content of < 20% (for further information see Appendix D of the report).
Honey samples were taken 7 to 28 days after the last application.
All honey samples were transported on dry ice from the field to the test facility, with exception of samples destinated for further drying in a compartment dryer which were transported at ambient temperature. Samples were stored deep frozen within 24 hours after sampling, or after end of drying, respectively. The field samples were stored in a freezer at -18 °C or below until preparation of the examination samples.
The samples were analysed for prothioconazole and its metabolites (prothioconazole-desthio, JAU 6476-alpha-hydroxy-desthio, JAU 6476-3-hydroxy-desthio, JAU 6476-4-hydroxy-desthio, JAU 6476-5-hydroxy-desthio, JAU 6476-6-hydroxy-desthio and 1,2,4-triazole, triazole alanine, triazole acetic acid and triazole lactic acid) using analytical method 01600 (prothioconazole and prothioconazole-desthio), method 01601 (JAU 6476-alpha-hydroxy-desthio, JAU 6476-3-hydroxy-desthio, JAU 6476-4-hydroxy-desthio, JAU 6476-5-hydroxy-desthio, JAU 6476-6-hydroxy-desthio) and method 01602 (1,2,4-triazole, triazole alanine, triazole acetic acid and triazole lactic acid) which were fully validated for honey.
The Limit of Quantification (LOQ) was 0.01 mg/kg for all analytes.

Findings
- Method performance: Full validation data is documented within the methods 01600, 01601 and 01602 for honey. A limited set of validation recoveries (one control sample, at least 3 repetitions each at two fortification levels) at the LOQ (0.010 mg/kg, for JAU 6476-alpha-hydroxy-desthio, JAU 6476-3-hydroxy-desthio, JAU 6476-4-hydroxy-desthio, JAU 6476-5-hydroxy-desthio and JAU 6476-6-hydroxy-desthio expressed as JAU 6476-desthio equivalent) and at the 10-fold LOQ level (0.10 mg/kg, for JAU 6476-alpha-hydroxy-desthio, JAU 6476-3-hydroxy-desthio, JAU 6476-4-hydroxy-desthio, JAU 6476-5-hydroxy-desthio and JAU 6476-6-hydroxy-desthio expressed as JAU 6476-desthio equivalent) was performed within this study. In order to check the performance of the method, concurrent recovery determinations were included in each set of analyses (at least one recovery for ten study samples). Higher residues were confirmed by at least five (5) recovery determinations in the range of the level or higher than the level of the highest residues found in a sample.
The mean recovery values of the analytes in honey ranged between 77 and 102% per fortification level with relative standard deviations between 1.1% and 19.6%. The overall mean recoveries of the analytes ranged between 79% and 100% and the corresponding overall relative standard deviation (RSD) ranged between 1.9% and 15.9% (n = 6 to 14 depending on the analyte). The obtained recovery data show the validity of the method used.

Table 2.2.2-2: Recoveries for prothioconazole and prothioconazole-desthio in bee honey

Report No.	Analyte	Sample Material	Fortification* level [mg/kg]	Single Values [%]	Mean Value [%]	RSD [%]	LOQ [mg/kg]
S19-00902	Prothioconazole (Method 01600)	Honey	0.01	102, 102, 100	101	1.1	0.01
			0.10	100, 97, 98	98	1.6	
			Overall Recovery (n = 6)		**100**	**2.0**	
	Prothioconazole-desthio (Method 01600)	bee honey	0.01	100, 102, 100	101	1.1	0.01
			0.10	101, 97, 98	99	2.1	
			Overall Recovery (n = 6)		**100**	**1.9**	

RSD = relative standard deviation n = number of tests
* expressed as itself

Table 2.2.2-3: Recoveries for the five hydroxies* of prothioconazole-desthio in bee honey

Report No.	Analyte	Sample Material	Fortification* level [mg/kg]	Single Values [%]	Mean Value [%]	RSD [%]	LOQ [mg/kg]
S19-00902	JAU 6476 -alpha-hydroxy desthio (Method 01601)	Honey	0.01	63, 69, 96, 71, 91	78	18.1	0.01
			0.10	87, 65, 72, 87, 86, 87, 95, 97, 69	83	13.8	
			Overall Recovery (n = 14)		**81**	**15.1**	
	JAU 6476 -3-hydroxy desthio (Method 01601)	Honey	0.01	68, 82, 95, 72, 74	78	13.7	0.01
			0.10	89, 67, 73, 87, 87, 86, 95, 91, 71	83	11.9	
			Overall Recovery (n = 14)		**81**	**12.4**	
	JAU 6476 -4-hydroxy desthio (Method 01601)	Honey	0.01	63, 77, 93, 73, 95	80	17.0	0.01
			0.10	85, 64, 67, 86, 85, 84, 94, 89, 69	80	13.4	
			Overall Recovery (n = 14)		**80**	**14.4**	
	JAU 6476 -5-hydroxy desthio (Method 01601)	Honey	0.01	72, 90, 103, 70, 94	86	16.7	0.01
			0.10	85, 68, 71, 86, 86, 86, 96, 87, 74	82	11.2	
			Overall Recovery (n = 14)		**80**	**13.0**	
	JAU 6476 -6-hydroxy desthio (Method 01601)	Honey	0.01	72, 82, 102, 65, 92	83	18.0	0.01*
			0.10	84, 66, 67, 90, 88, 75, 85, 72, 63	77	13.4	
			Overall Recovery (n = 14)		**79**	**15.1**	

RSD = relative standard deviation n = number of tests
* fortified and determined as themselves and expressed as prothioconazole-desthio

Table 2.2.2-4: Recoveries for the triazole derived metabolites (TDMs) in bee honey

Report No.	Analyte	Sample Material	Fortification* level [mg/kg]	Single Values* [%]	Mean Value [%]	RSD [%]	LOQ [mg/kg]
S19-00902	1,2,4-Triazole (Method 01602)	Honey	0.01	74, 86, 68, 82, 99, 94	84	14.0	0.01
			0.10	87, 88, 93	89	3.6	
			0.20	97, 94, 96, 92, 100	96	3.2	
			Overall Recovery (n = 14)		**89**	**10.5**	
	Triazole Alanine (Method 01602)	Honey	0.01	65, 57, 82, 71, 90, 96	77	19.6	0.01
			0.10	90, 90, 83	88	4.6	
			0.20	99, 98, 102, 91, 100	98	4.3	
			Overall Recovery (n = 14)		**87**	**15.9**	
	Triazole Acetic Acid (Method 01602)	Honey	0.01	106, 111, 92, 91, 102, 100	100	7.8	0.01
			0.10	97, 101, 94	97	3.6	
			0.20	101, 92, 102, 100, 105	100	4.8	
			Overall Recovery (n = 14)		**100**	**5.9**	
	Triazole Lactic Acid (Method 01602)	Honey	0.01	86, 74, 78, 90, 88, 91	85	8.2	0.01
			0.10	92, 90, 91	91	1.1	
			0.20	99, 95, 104, 105, 109	102	5.3	
			Overall Recovery (n = 14)		**92**	**10.6**	

RSD = relative standard deviation n = number of tests * expressed as itself

- Storage stability: The storage periods of deep-frozen samples intended for the analysis of prothioconazole, prothioconazole-desthio and its hydroxy-metabolites and the triazole derived metabolites was 68 to 118 days. They are covered by the storage stability studies performed in honey for about 5 to 6 months under frozen storage conditions (see above).

- Residue results: After two spray applications of prothioconazole EC 250 to oilseed rape, the residues of prothioconazole and its metabolites were determined in honey sampled 3-29 days after the last application to the flowering oilseed rape.
No residues of prothioconazole, prothioconazole-desthio, JAU 6476-alpha-hydroxy-desthio, JAU 6476-3-hydroxy-desthio, JAU 6476-4-hydroxy-desthio, JAU 6476-5-hydroxy-desthio, JAU 6476-6- hydroxy-desthio and 1,2,4-triazole above the LOD were found in any of the control sample of honey. Residues of triazole alanine in the control samples ranged between <LOD and 0.014 mg/kg, residues of triazole acetic acid ranged between <LOD and <LOQ and residues of triazole lactic acid in control ranged between <LOD and 0.11 mg/kg.
Residues of prothioconazole, prothioconazole-desthio, JAU 6476 -alpha-hydroxy desthio, JAU 6476 -3-hydroxy desthio, JAU 6476 -4-hydroxy desthio, JAU 6476 -5-hydroxy desthio JAU 6476 -6-hydroxy desthio and 1,2,4-triazole were all below the LOQ of 0.01 mg/kg.
Residues of 1,2,4-T were always below 0.01 mg/kg. Residues of Triazole Alanine ranged from <0.01 ppm to 0.043 mg/kg, those of Triazole Acetic Acid form <0.01 mg/kg to 0.052 mg/kg and those of Triazole Lactic Acid from <0.01 mg/kg to 0.13 mg/kg .

Table 2.2.2-5 Summary of the study S19-00902 trials – GAP summary

Trial No. / Location / EU zone / Year	Commodity / Variety (a)	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting (b)	Application rate per treatment			Dates of treatment / Application interval (c)	Growth stage at last treatment (d)	Details on trial (f)
			g a.s./ha	Water (L/ha)	g a.s./hL			
S19-00902-01 Germany 76356 Weingarten Europe, North G 2019	Rape, winter Attletick	1) 06.09.2018	200 200	400 399	50.0 50.1	05.04.2019/0 19.04.2019/14	63	(g) S19-00902 (h) EC (prothioconazole 250 g/L) (i) Application method: Spraying
S19-00902-02 Germany 76684 Tiefenbach Europe, North G 2019	Rape, winter LG Architekt	1) 06.09.2018	203 198	405 396	50.0 49.9	12.04.2019/0 25.04.2019/13	63	(g) S19-00902 (h) EC (prothioconazole 250 g/L) (i) Application method: Spraying
S19-00902-03 France, south 47460 Monheurt Europe, South G 2019	Rape, winter Memori	1) 14.09.2018	197 197	395 394	49.9 50.0	21.03.2019/0 04.04.2019/14	63 - 65	(g) S19-00902 (h) EC (prothioconazole 250 g/L) (i) Application method: Spraying
S19-00902-04 Italy 40068 Idice Europe, South G 2019	Rape, winter Dario T	1) 20.10.2018	211 211	423 422	49.9 49.9	05.04.2019/0 17.04.2019/12	65	(g) S19-00902 (h) EC (prothioconazole 250 g/L) (i) Application method: Spraying
S19-00902-05 Spain 16700 Sisante Europe, South	Rape, winter Florida	1) 18.09.2018	201 203	398 403	50.4 50.3	21.03.2019/0 04.04.2019/14	63 - 65	(g) S19-00902 (h) EC (prothioconazole 250 g/L) (i) Application method: Spraying

Trial No. / Location / EU zone / Year	Commodity / Variety (a)	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting (b)	Application rate per treatment			Dates of treatment / Application interval (c)	Growth stage at last treatment (d)	Details on trial (f)
			g a.s./ha	Water (L/ha)	g a.s./hL			
G 2019								

Analytical part

Analyte 1: prothioconazole (determined as prothioconazole, calculated as prothioconazole), Analyte 2: JAU 6476-desthio (determined as JAU 6476-desthio, calculated as JAU 6476-desthio), Analyte 3: JAU 6476-alpha-hydroxy-desthio (determined as JAU 6476-alpha-hydroxy-desthio, calculated as JAU 6476-alpha-hydroxy-desthio), Analyte 4: JAU 6476-3-hydroxy-desthio (determined as JAU 6476-3-hydroxy-desthio, calculated as JAU 6476-3-hydroxy-desthio), Analyte 5: JAU 6476-4-hydroxy-desthio (determined as JAU 6476-4-hydroxy-desthio, calculated as JAU 6476-4-hydroxy-desthio), Analyte 6: JAU 6476-5-hydroxy-desthio (determined as JAU 6476-5-hydroxy-desthio, calculated as JAU 6476-5-hydroxy-desthio), Analyte 7: JAU 6476-6-hydroxy-desthio (determined as JAU 6476-6-hydroxy-desthio, calculated as JAU 6476-6-hydroxy-desthio)

Trial No. / Location / EU zone / Year	Commodity / Variety (a)	Portion analyzed	Growth stage at sampling (d)	Residues (mg/kg)							PHI (days) (e)	Details on trial (f)
				Analyte 1 prothioconazole as prothioconazole	Analyte 2 JAU 6476-desthio as JAU 6476-desthio	Analyte 3 JAU 6476-alpha-hydroxy-desthio as JAU 6476-alpha-hydroxy-desthio	Analyte 4 JAU 6476-3-hydroxy-desthio as JAU 6476-3-hydroxy-desthio	Analyte 5 JAU 6476-4-hydroxy-desthio as JAU 6476-4-hydroxy-desthio	Analyte 6 JAU 6476-5-hydroxy-desthio as JAU 6476-5-hydroxy-desthio	Analyte 7 JAU 6476-6-hydroxy-desthio as JAU 6476-6-hydroxy-desthio		
S19-00902-01 Germany 76356 Weingarten Europe, North G 2019	Rape, winter Attletick	honey, dry >80% sugar content	BBCH: 67-69	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	7	(g) S19-00902 (j) Analytical method: Analyte 1,2: S19-01124 Analyte 3,4,5,6,7: S19-01125 (k) LOQ: S19-01124 Analyte 1,2,: 0.01 mg/kg S19-01125 Analyte 3,4,5,6,7,: 0.01 mg/kg (l) Method Validation Data: 01600, 01601, 01602 (m) Storage: Analyte 1, 2 honey, fresh >80% sugar conten: 95 days Analyte 3, 4, 5, 6, 7 honey, fresh >80% sugar conten: 115 days Analyte 1, 2 honey, dry >80% sugar content: 95 days Analyte 3, 4, 5, 6, 7 honey, dry >80% sugar content: 109 days
		honey, fresh >80% sugar content	BBCH: 67-69	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	7	

Trial No. / Location / EU zone / Year	Commodity / Variety (a)	Portion analyzed	Growth stage at sampling (d)	Residues (mg/kg)							PHI (days) (e)	Details on trial (f)
				Analyte 1 prothioconazole as prothioconazole	Analyte 2 JAU 6476-desthio as JAU 6476-desthio	Analyte 3 JAU 6476-alpha-hydroxy-desthio as JAU 6476-alpha-hydroxy-desthio	Analyte 4 JAU 6476-3-hydroxy-desthio as JAU 6476-3-hydroxy-desthio	Analyte 5 JAU 6476-4-hydroxy-desthio as JAU 6476-4-hydroxy-desthio	Analyte 6 JAU 6476-5-hydroxy-desthio as JAU 6476-5-hydroxy-desthio	Analyte 7 JAU 6476-6-hydroxy-desthio as JAU 6476-6-hydroxy-desthio		
S19-00902-02 Germany 76684 Tiefenbach Europe, North G 2019	Rape, winter LG Architekt	honey, dry >80% sugar content	65	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	8	(g) S19-00902 (j) Analytical method: Analyte 1,2: 01600 Analyte 3,4,5,6,7: 01601 (k) LOQ: 01600 Analyte 1,2,: 0.01 mg/kg 01601 Analyte 3,4,5,6,7,: 0.01 mg/kg (l) Method Validation Data: 01600, 01601, 01602 (m) Storage: Analyte 1, 2 honey, fresh >80% sugar conten: 83 days Analyte 3, 4, 5, 6, 7 honey, fresh >80% sugar conten: 105 days Analyte 1, 2 honey, dry >80% sugar content: 88 days Analyte 3, 4, 5, 6, 7 honey, dry >80% sugar content: 108 days
		honey, fresh >80% sugar content	67	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	13	
S19-00902-03 France, south 47460 Monheurt Europe, South G 2019	Rape, winter Memori	honey, fresh >80% sugar content	69	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	29	(g) S19-00902 (j) Analytical method: Analyte 1,2: 01600 Analyte 3,4,5,6,7: 01601 (k) LOQ: 01600 Analyte 1,2,: 0.01 mg/kg 01601 Analyte 3,4,5,6,7,: 0.01 mg/kg (l) Method Validation Data: 01600; 01601; 01602 (m) Storage: Analyte 1, 2 honey, fresh >80% sugar conten: 88 days Analyte 3, 4, 5, 6, 7 honey, fresh >80% sugar conten: 108 days

Trial No. / Location / EU zone / Year	Commodity / Variety (a)	Portion analyzed	Growth stage at sampling (d)	Residues (mg/kg)							PHI (days) (e)	Details on trial (f)
				Analyte 1 prothioconazole as prothioconazole	Analyte 2 JAU 6476-desthio as JAU 6476-desthio	Analyte 3 JAU 6476-alpha-hydroxy-desthio as JAU 6476-alpha-hydroxy-desthio	Analyte 4 JAU 6476-3-hydroxy-desthio as JAU 6476-3-hydroxy-desthio	Analyte 5 JAU 6476-4-hydroxy-desthio as JAU 6476-4-hydroxy-desthio	Analyte 6 JAU 6476-5-hydroxy-desthio as JAU 6476-5-hydroxy-desthio	Analyte 7 JAU 6476-6-hydroxy-desthio as JAU 6476-6-hydroxy-desthio		
01602-04 Italy 40068 Idice Europe, South G 2019	Rape, winter Dario T	honey, fresh <80% sugar content	BBCH: 69-71	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	36	(g) S19-00902 (j) Analytical method: Analyte 1,2: 01600 Analyte 3,4,5,6,7: 01601 (k) LOQ: 01600 Analyte 1,2,: 0.01 mg/kg 01601 Analyte 3,4,5,6,7,: 0.01 mg/kg (l) Method Validation Data: 01600; 01601; S19-00902 (m) Storage: Analyte 1, 2 honey,fresh <80% sugar content: 68 days Analyte 3, 4, 5, 6, 7 honey,fresh <80% sugar content: 88 days sugar content < 65 %; water content was measured with 19%.
S19-00902-05 Spain 16700 Sisante Europe, South G 2019	Rape, winter Florida	honey, dry >80% sugar content	BBCH: 67-69	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	28	(g) S19-00902 (j) Analytical method: Analyte 1,2: 01600 Analyte 3,4,5,6,7: 01601 (k) LOQ: 01600 Analyte 1,2,: 0.01 mg/kg 01601 Analyte 3,4,5,6,7,: 0.01 mg/kg (l) Method Validation Data: 01600; 01601; S19-00902 (m) Storage: Analyte 1, 2 honey, fresh >80% sugar conten: 89 days Analyte 3, 4, 5, 6, 7 honey, fresh >80% sugar conten: 109 days Analyte 1, 2 honey, dry >80% sugar content: 89 days Analyte 3, 4, 5, 6, 7 honey, dry >80% sugar content: 109 days
		honey, fresh >80% sugar content	BBCH: 67-69	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	28	

Analyte 1: 1,2,4-triazole (determined as 1,2,4-triazole, calculated as 1,2,4-triazole), Analyte 2: triazole alanine (determined as triazole alanine, calculated as triazole alanine), Analyte 3: triazole acetic acid (determined as triazole acetic acid, calculated as triazole acetic acid), Analyte 4: triazole lactic acid (determined as triazole lactic acid, calculated as triazole lactic acid)

Trial No. / Location / EU zone / Year	Commodity / Variety (a)	Portion analyzed	Growth stage at sampling (d)	Residues (mg/kg)				PHI (days) (e)	Details on trial (f)
				Analyte 1 1,2,4-triazole as 1,2,4-triazole	Analyte 2 triazole alanine as triazole alanine	Analyte 3 triazole acetic acid as triazole acetic acid	Analyte 4 triazole lactic acid as triazole lactic acid		
S19-00902-01 Germany 76356 Weingarten Europe, North G 2019	Rape, winter Attletick	honey, dry >80% sugar content	BBCH: 67-69	<0.01	<0.01	<0.01	<0.01	7	(g) S19-00902 (j) Analytical method: 01602 (k) LOQ: 0.01 mg/kg (l) Method Validation Data: 01602; S19-00902 (m) Storage: Analyte 1, 2, 3, 4 honey, fresh >80% sugar conten: 97 days Analyte 1, 2, 3, 4 honey, dry >80% sugar content: 118 days
		honey, fresh >80% sugar content	BBCH: 67-69	<0.01	<0.01	<0.01	<0.01	7	
S19-00902-02 Germany 76684 Tiefenbach Europe, North G 2019	Rape, winter LG Architekt	honey, dry >80% sugar content	65	<0.01	0.011	<0.01	<0.01	8	(g) S19-00902 (j) Analytical method: 01602 (k) LOQ: 0.01 mg/kg (l) Method Validation Data: 01602; S19-00902 (m) Storage: Analyte 1, 2, 3, 4 honey, fresh >80% sugar conten: 85 days Analyte 1, 2, 3, 4 honey, dry >80% sugar content: 90 days
		honey, fresh >80% sugar content	67	<0.01	0.01	<0.01	<0.01	13	
S19-00902-03 France, north 47460 Monheurt Europe, North G 2019	Rape, winter Memori	honey, fresh >80% sugar content	69	<0.01	<0.01	<0.01	<0.01	29	(g) S19-00902 (j) Analytical method: 01602 (k) LOQ: 0.01 mg/kg (l) Method Validation Data: 01602; S19-00902 (m) Storage: Analyte 1, 2, 3, 4 honey, fresh >80% sugar conten: 90 days
S19-00902-04 Italy 40068 Idice Europe, South G 2019	Rape, winter Dario T	honey, fresh <80% sugar content	BBCH: 69-71	<0.01	<0.01	<0.01	<0.01	36	(g) S19-00902 (j) Analytical method: 01602 (k) LOQ: 0.01 mg/kg (l) Method Validation Data: 01602; S19-00902 (m) Storage: Analyte 1, 2, 3, 4 honey,fresh <80% sugar content: 70 days sugar content < 65 %; water content was measured with 19%.

Trial No. / Location / EU zone / Year	Commodity / Variety (a)	Portion analyzed	Growth stage at sampling (d)	Residues (mg/kg)				PHI (days) (e)	Details on trial (f)
				Analyte 1 1,2,4-triazole as 1,2,4-triazole	Analyte 2 triazole alanine as triazole alanine	Analyte 3 triazole acetic acid as triazole acetic acid	Analyte 4 triazole lactic acid as triazole lactic acid		
S19-00902-05 Spain 16700 Sisante Europe, South G 2019	Rape, winter Florida	honey, dry >80% sugar content	BBCH: 67-69	<0.01	0.037	0.049	0.11	28	(g) S19-00902 (j) Analytical method: 01602 (k) LOQ: 0.01 mg/kg (l) Method Validation Data: 01602; S19-00902 (m) Storage: Analyte 1, 2, 3, 4 honey, fresh >80% sugar conten: 112 days Analyte 1, 2, 3, 4 honey, dry >80% sugar content: 91 days
		honey, fresh >80% sugar content	BBCH: 67-69	<0.01	0.043/0.014**	0.052	0.13	28	

Appendix 3 Pesticide Residue Intake Model (PRIMo)

A 3.1 TMDI calculations

Not performed.

A 3.2 IEDI calculations – Fenpicoxamid

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Fenpicoxamid

LOQs (mg/kg) range from: 0.01 to: 0.05

Toxicological reference values

ADI (mg/kg bw/day):	0.05	ARfD (mg/kg bw):	1.8
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2018	Year of evaluation:	2018

Input values

Details - chronic risk assessment | Supplementary results - chronic risk assessment

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (tased on average food consumption)	3%	NL toddler	1.64	2%	Milk: Cattle	0.4%	Wheat	0.2%	Apples	0.9%	0.1%
	2%	DE child	0.95	0.5%	Milk: Cattle	0.4%	Wheat	0.2%	Apples	0.7%	
	2%	NL child	0.92	0.6%	Milk: Cattle	0.4%	Wheat	0.2%	Sugar beet roots	0.5%	0.2%
	2%	UK infant	0.87	1%	Milk: Cattle	0.2%	Wheat	0.1%	Potatoes	0.3%	0.0%
	2%	DK child	0.86	0.5%	Rye	0.4%	Wheat	0.3%	Milk: Cattle	0.3%	
	2%	FR child 3 15 yr	0.82	0.6%	Milk: Cattle	0.4%	Wheat	0.1%	Sugar beet roots	0.4%	0.1%
	2%	FR toddler 2 3 yr	0.79	0.8%	Milk: Cattle	0.3%	Wheat	0.1%	Apples	0.3%	0.1%
	1%	UK toddler	0.68	0.5%	Milk: Cattle	0.4%	Wheat	0.1%	Potatoes	0.3%	0.1%
	1%	GEMS/Food G06	0.67	0.7%	Wheat	0.1%	Tomatoes	0.1%	Milk: Cattle	0.5%	0.0%
	1%	GEMS/Food G08	0.67	0.4%	Wheat	0.2%	Barley	0.1%	Milk: Cattle	0.5%	
	1%	GEMS/Food G15	0.66	0.4%	Wheat	0.2%	Milk: Cattle	0.2%	Barley	0.4%	
	1%	GEMS/Food G11	0.66	0.3%	Wheat	0.2%	Milk: Cattle	0.2%	Barley	0.5%	
	1%	GEMS/Food G07	0.63	0.4%	Wheat	0.2%	Milk: Cattle	0.1%	Barley	0.5%	0.0%
	1%	RO general	0.61	0.5%	Wheat	0.3%	Milk: Cattle	0.1%	Potatoes	0.4%	0.0%
	1%	GEMS/Food G10	0.60	0.4%	Wheat	0.1%	Milk: Cattle	0.1%	Barley	0.5%	0.0%
	1%	ES child	0.60	0.4%	Wheat	0.3%	Milk: Cattle	0.1%	Cocoa beans	0.3%	0.0%
	1%	DE general	0.57	0.3%	Milk: Cattle	0.2%	Wheat	0.1%	Barley	0.3%	0.1%
	1%	SE general	0.57	0.3%	Milk: Cattle	0.3%	Wheat	0.1%	Bovine: Muscle/meat	0.3%	
	1%	DE women 14-50 yr	0.55	0.3%	Milk: Cattle	0.2%	Wheat	0.1%	Sugar beet roots	0.3%	0.1%
	0.9%	IE adult	0.46	0.2%	Wheat	0.1%	Milk: Cattle	0.1%	Sweet potatoes	0.5%	
	0.9%	NL general	0.44	0.2%	Milk: Cattle	0.2%	Wheat	0.1%	Barley	0.3%	0.1%
	0.8%	IT toddler	0.41	0.6%	Wheat	0.0%	Other cereals	0.0%	Tomatoes	0.2%	
	0.8%	FI adult	0.40	0.6%	Coffee beans	0.1%	Rye	0.0%	Wheat	0.7%	
	0.8%	FR infant	0.38	0.4%	Milk: Cattle	0.1%	Wheat	0.0%	Potatoes	0.2%	0.0%
	0.7%	ES adult	0.37	0.2%	Wheat	0.1%	Milk: Cattle	0.1%	Barley	0.2%	0.0%
	0.7%	PT general	0.36	0.4%	Wheat	0.1%	Potatoes	0.0%	Wine grapes	0.3%	
	0.7%	FR adult	0.33	0.2%	Wheat	0.1%	Milk: Cattle	0.0%	Wine grapes	0.2%	0.0%
	0.6%	FI 3 yr	0.31	0.1%	Oat	0.1%	Wheat	0.1%	Potatoes	0.3%	
	0.6%	IT adult	0.28	0.4%	Wheat	0.0%	Tomatoes	0.0%	Apples	0.2%	
	0.5%	LT adult	0.27	0.1%	Milk: Cattle	0.1%	Rye	0.1%	Wheat	0.2%	
	0.5%	DK adult	0.25	0.1%	Milk: Cattle	0.1%	Wheat	0.0%	Rye	0.1%	
	0.5%	FI 6 yr	0.24	0.1%	Wheat	0.1%	Potatoes	0.1%	Oat	0.2%	
	0.5%	UK vegetarian	0.24	0.2%	Wheat	0.1%	Milk: Cattle	0.0%	Potatoes	0.2%	0.0%
	0.4%	UK adult	0.22	0.2%	Wheat	0.1%	Milk: Cattle	0.0%	Potatoes	0.1%	0.0%
	0.3%	IE child	0.14	0.1%	Wheat	0.1%	Milk: Cattle	0.0%	Potatoes	0.1%	
	0.2%	PL general	0.10	0.1%	Potatoes	0.0%	Apples	0.0%	Tomatoes	0.2%	

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Fenpicoxamid is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

A 3.3 IEDI calculations – Prothioconazole-desthio

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Prothioconazole (1) (PTZ-desthio) (F)

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

Input values

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

	Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	17%	NL toddler	1.67	3%	Sugar beet roots	3%	Milk: Cattle	2%	Wheat	4%	3%
	12%	NL child	1.22	5%	Sugar beet roots	2%	Wheat	1%	Milk: Cattle	2%	5%
	11%	DK child	1.11	6%	Rye	2%	Wheat	1%	Carrots	0.8%	
	10%	GEMS/Food G11	1.03	4%	Soyabeans	1%	Wheat	0.6%	Carrots	2%	
	10%	FR child 3 15 yr	0.97	2%	Sugar beet roots	2%	Wheat	1%	Milk: Cattle	1%	2%
	9%	GEMS/Food G10	0.90	3%	Soyabeans	2%	Wheat	0.4%	Barley	1%	0.0%
	9%	GEMS/Food G08	0.89	2%	Soyabeans	2%	Wheat	0.6%	Barley	1%	
	9%	GEMS/Food G06	0.88	3%	Wheat	1%	Soyabeans	0.9%	Sugar beet roots	2%	0.9%
	8%	DE child	0.85	2%	Wheat	1%	Apples	1.0%	Milk: Cattle	3%	
	8%	GEMS/Food G07	0.84	2%	Soyabeans	2%	Wheat	0.4%	Rapeseeds/canola seeds	1%	0.0%
	8%	GEMS/Food G15	0.84	2%	Wheat	2%	Soyabeans	0.5%	Barley	1%	
	8%	FR toddler 2 3 yr	0.81	2%	Sugar beet roots	1%	Milk: Cattle	1%	Wheat	1%	2%
	7%	UK infant	0.72	2%	Milk: Cattle	1%	Carrots	1%	Wheat	0.8%	0.8%
	7%	DE women 14-50 yr	0.71	3%	Sugar beet roots	0.9%	Wheat	0.6%	Milk: Cattle	1%	3%
	7%	DE general	0.71	3%	Sugar beet roots	0.8%	Wheat	0.6%	Milk: Cattle	1%	3%
	7%	UK toddler	0.69	2%	Sugar beet roots	2%	Wheat	1%	Milk: Cattle	0.9%	2%
	6%	RO general	0.60	2%	Wheat	0.8%	Sugar beet roots	0.6%	Milk: Cattle	0.9%	0.8%
	6%	IE adult	0.57	0.9%	Wheat	0.4%	Sweet potatoes	0.3%	Peas	2%	
	6%	NL general	0.56	2%	Sugar beet roots	0.8%	Wheat	0.4%	Milk: Cattle	1%	2%
	5%	SE general	0.53	1%	Wheat	0.7%	Carrots	0.6%	Milk: Cattle	0.9%	
	5%	ES child	0.51	2%	Wheat	0.6%	Milk: Cattle	0.3%	Cocoa beans	1%	0.1%
	5%	FI adult	0.48	3%	Coffee beans	0.7%	Rye	0.3%	Carrots	3%	
	4%	PT general	0.43	2%	Wheat	0.5%	Potatoes	0.5%	Potatoes	0.9%	
	4%	FI 3 yr	0.41	0.7%	Carrots	0.7%	Rye	0.6%	Oat	0.9%	
	4%	FR infant	0.41	0.9%	Carrots	0.8%	Milk: Cattle	0.8%	Sugar beet roots	0.5%	0.8%
	4%	FR adult	0.40	0.9%	Wheat	0.5%	Swine: Other products	0.5%	Sugar beet roots	1%	0.5%
	4%	IT toddler	0.39	3%	Wheat	0.2%	Other cereals	0.1%	Carrots	0.8%	
	3%	FI 6 yr	0.33	0.6%	Rye	0.5%	Carrots	0.4%	Wheat	0.7%	
	3%	ES adult	0.32	0.9%	Wheat	0.3%	Barley	0.2%	Milk: Cattle	0.8%	0.1%
	3%	LT adult	0.31	1%	Rye	0.4%	Wheat	0.3%	Potatoes	0.4%	
	3%	IT adult	0.26	2%	Wheat	0.1%	Tomatoes	0.1%	Carrots	0.7%	
	3%	UK vegetarian	0.26	0.8%	Wheat	0.3%	Sugar beet roots	0.2%	Carrots	0.6%	0.3%
	3%	DK adult	0.26	0.5%	Rye	0.4%	Wheat	0.4%	Carrots	0.5%	
	2%	UK adult	0.24	0.7%	Wheat	0.3%	Sugar beet roots	0.2%	Bovine: Other products	0.5%	0.3%
	1%	PL general	0.15	0.3%	Potatoes	0.2%	Carrots	0.2%	Apples	0.5%	
	1%	IE child	0.11	0.5%	Wheat	0.2%	Milk: Cattle	0.1%	Carrots	0.1%	

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Prothioconazole (1) (PTZ-desthio) (F) is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

A 3.4 IEDI calculations – Triazole alanine (TA)

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Triazole alanine (TA)

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	0.3	ARfD (mg/kg bw):	0.3
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2018	Year of evaluation:	2018

Input values

Details - chronic risk assessment | Supplementary results - chronic risk assessment

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)	Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
	6%	NL toddler	18.22	1%	Maize/corn	0.8%	Wheat	0.8%	Milk: Cattle		0.1%
	4%	GEMS/Food G06	12.64	1%	Wheat	0.4%	Soyabeans	0.3%	Rice		0.0%
	4%	GEMS/Food G10	12.27	1%	Soyabeans	0.8%	Wheat	0.3%	Rice		0.0%
	4%	GEMS/Food G08	11.31	0.8%	Wheat	0.7%	Soyabeans	0.3%	Olives for oil production		
	4%	GEMS/Food G11	11.31	1%	Soyabeans	0.7%	Wheat	0.2%	Potatoes		
	4%	GEMS/Food G07	11.00	0.9%	Wheat	0.6%	Soyabeans	0.2%	Potatoes		0.0%
	4%	GEMS/Food G15	10.59	0.9%	Wheat	0.6%	Soyabeans	0.2%	Potatoes		
	3%	NL child	10.13	0.9%	Wheat	0.3%	Milk: Cattle	0.3%	Oil palm fruits		0.1%
	3%	DK child	10.10	1%	Rye	0.9%	Wheat	0.2%	Bovine: Muscle/meat		
	3%	FR child 3 15 yr	9.10	1.0%	Wheat	0.4%	Oranges	0.3%	Milk: Cattle		0.1%
	3%	DE child	8.96	0.9%	Wheat	0.4%	Oranges	0.3%	Milk: Cattle		
	3%	RO general	8.01	1%	Wheat	0.2%	Sunflower seeds	0.2%	Potatoes		0.0%
	3%	ES child	7.76	0.9%	Wheat	0.3%	Olives for oil production	0.2%	Oranges		0.0%
	2%	SE general	7.38	0.7%	Bovine: Muscle/meat	0.7%	Wheat	0.3%	Potatoes		
	2%	UK infant	7.29	0.5%	Wheat	0.5%	Milk: Cattle	0.2%	Maize/corn		0.0%
	2%	FR toddler 2 3 yr	7.10	0.6%	Wheat	0.4%	Milk: Cattle	0.2%	Bovine: Muscle/meat		0.0%
	2%	IE adult	6.93	0.5%	Wheat	0.2%	Sweet potatoes	0.1%	Potatoes		
	2%	UK toddler	6.79	0.8%	Wheat	0.3%	Milk: Cattle	0.2%	Potatoes		0.1%
	2%	IT toddler	6.53	1%	Wheat	0.3%	Other cereals	0.1%	Tomatoes		
	2%	PT general	6.37	0.8%	Wheat	0.3%	Potatoes	0.2%	Rice		
	2%	NL general	5.49	0.4%	Wheat	0.2%	Oil palm fruits	0.1%	Potatoes		0.0%
	2%	DE women 14-50 yr	5.01	0.4%	Wheat	0.2%	Oranges	0.2%	Milk: Cattle		0.1%
	2%	DE general	5.00	0.4%	Wheat	0.2%	Oranges	0.2%	Milk: Cattle		0.1%
	2%	ES adult	4.73	0.5%	Wheat	0.1%	Olives for oil production	0.1%	Oranges		0.0%
	1%	IT adult	4.30	0.9%	Wheat	0.1%	Other cereals	0.1%	Tomatoes		
	1%	FI 3 yr	4.12	0.3%	Potatoes	0.2%	Wheat	0.1%	Rye		
	1%	FR adult	3.73	0.5%	Wheat	0.1%	Bovine: Muscle/meat	0.1%	Oranges		0.0%
	1%	LT adult	3.38	0.2%	Rye	0.2%	Wheat	0.2%	Potatoes		
	1%	FI 6 yr	3.26	0.2%	Potatoes	0.2%	Wheat	0.1%	Rye		
	1.0%	UK vegetarian	2.98	0.4%	Wheat	0.1%	Oranges	0.1%	Potatoes		0.0%
	1.0%	FR infant	2.87	0.2%	Milk: Cattle	0.2%	Wheat	0.1%	Potatoes		0.0%
	0.9%	UK adult	2.79	0.3%	Wheat	0.1%	Bovine: Muscle/meat	0.1%	Potatoes		0.0%
	0.9%	DK adult	2.74	0.2%	Wheat	0.1%	Rye	0.1%	Bovine: Muscle/meat		
	0.6%	FI adult	1.80	0.1%	Rye	0.1%	Potatoes	0.1%	Wheat		
	0.5%	IE child	1.45	0.2%	Wheat	0.1%	Rice	0.0%	Milk: Cattle		
	0.5%	PL general	1.39	0.2%	Potatoes	0.1%	Tomatoes	0.0%	Apples		

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Triazole alanine (TA) is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

A 3.5 IEDI calculations – Triazole lactic acid (TLA)

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Triazole lactic acid (TLA)

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	0.3	ARfD (mg/kg bw):	0.3
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2018	Year of evaluation:	2018

Input values

Details - chronic risk assessment | Supplementary results - chronic risk assessment

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	1%	NL toddler	4.01	0.8%	Milk: Cattle	0.1%	Apples	0.1%	Maize/corn		0.0%
	0.7%	UK infant	2.07	0.5%	Milk: Cattle	0.0%	Potatoes	0.0%	Wheat		0.0%
	0.7%	NL child	2.02	0.3%	Milk: Cattle	0.1%	Apples	0.0%	Wheat		0.0%
	0.7%	DE child	1.96	0.3%	Milk: Cattle	0.1%	Apples	0.1%	Oranges		
	0.6%	FR toddler 2 3 yr	1.83	0.4%	Milk: Cattle	0.0%	Apples	0.0%	Wheat		0.0%
	0.6%	FR child 3 15 yr	1.74	0.3%	Milk: Cattle	0.0%	Oranges	0.0%	Wheat		0.0%
	0.5%	UK toddler	1.40	0.3%	Milk: Cattle	0.0%	Wheat	0.0%	Oranges		0.0%
	0.4%	GEMS/Food G11	1.27	0.1%	Milk: Cattle	0.1%	Soyabeans	0.0%	Potatoes		
	0.4%	DK child	1.25	0.2%	Milk: Cattle	0.0%	Rye	0.0%	Wheat		
	0.4%	GEMS/Food G07	1.20	0.1%	Milk: Cattle	0.0%	Soyabeans	0.0%	Wheat		0.0%
	0.4%	GEMS/Food G10	1.19	0.1%	Milk: Cattle	0.1%	Soyabeans	0.0%	Wheat		0.0%
	0.4%	ES child	1.19	0.2%	Milk: Cattle	0.0%	Wheat	0.0%	Oranges		0.0%
	0.4%	GEMS/Food G08	1.17	0.1%	Milk: Cattle	0.0%	Soyabeans	0.0%	Wheat		
	0.4%	GEMS/Food G15	1.16	0.1%	Milk: Cattle	0.0%	Soyabeans	0.0%	Wheat		
	0.4%	RO general	1.15	0.2%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes		0.0%
	0.4%	SE general	1.15	0.2%	Milk: Cattle	0.1%	Bovine: Muscle/meat	0.0%	Potatoes		
	0.4%	GEMS/Food G06	1.06	0.1%	Wheat	0.0%	Tomatoes	0.0%	Milk: Cattle		0.0%
	0.4%	DE women 14-50 yr	1.05	0.2%	Milk: Cattle	0.0%	Apples	0.0%	Oranges		0.0%
	0.3%	DE general	1.03	0.2%	Milk: Cattle	0.0%	Apples	0.0%	Oranges		0.0%
	0.3%	FR infant	0.97	0.2%	Milk: Cattle	0.0%	Apples	0.0%	Potatoes		0.0%
	0.3%	NL general	0.89	0.1%	Milk: Cattle	0.0%	Potatoes	0.0%	Apples		0.0%
	0.3%	IE adult	0.86	0.1%	Milk: Cattle	0.0%	Sweet potatoes	0.0%	Wheat		
	0.2%	ES adult	0.67	0.1%	Milk: Cattle	0.0%	Oranges	0.0%	Wheat		0.0%
	0.2%	FR adult	0.61	0.1%	Milk: Cattle	0.0%	Wine grapes	0.0%	Wheat		0.0%
	0.2%	PT general	0.56	0.0%	Potatoes	0.0%	Wine grapes	0.0%	Wheat		
	0.2%	DK adult	0.54	0.1%	Milk: Cattle	0.0%	Wine grapes	0.0%	Swine: Muscle/meat		
	0.2%	LT adult	0.49	0.1%	Milk: Cattle	0.0%	Potatoes	0.0%	Apples		
	0.1%	IT toddler	0.43	0.0%	Wheat	0.0%	Tomatoes	0.0%	Other cereals		
	0.1%	UK vegetarian	0.41	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Oranges		0.0%
	0.1%	UK adult	0.40	0.0%	Milk: Cattle	0.0%	Wine grapes	0.0%	Wheat		0.0%
	0.1%	FI 3 yr	0.38	0.0%	Potatoes	0.0%	Cucumbers	0.0%	Apples		
	0.1%	IT adult	0.35	0.0%	Wheat	0.0%	Tomatoes	0.0%	Lettuces		
	0.1%	FI 6 yr	0.30	0.0%	Potatoes	0.0%	Wheat	0.0%	Cucumbers		
	0.1%	IE child	0.25	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes		
	0.1%	PL general	0.23	0.0%	Potatoes	0.0%	Apples	0.0%	Tomatoes		
	0.1%	FI adult	0.19	0.0%	Potatoes	0.0%	Apples	0.0%	Tomatoes		

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Triazole lactic acid (TLA) is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

A 3.6 IEDI calculations – Triazole acetic acid (TAA)

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Triazole acetic acid (TAA)

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	1	ARfD (mg/kg bw):	1
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2018	Year of evaluation:	2018

Input values

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
	1%	NL toddler	14.21	0.6%	Maize/corn	0.3%	Wheat	0.2%	Milk: Cattle		0.0%
	0.9%	DK child	9.35	0.4%	Rye	0.3%	Wheat	0.1%	Milk: Cattle		
	0.9%	GEMS/Food G06	9.03	0.6%	Wheat	0.1%	Rice	0.1%	Maize/corn		0.0%
	0.7%	IT toddler	6.81	0.5%	Wheat	0.1%	Other cereals	0.0%	Rice		
	0.7%	GEMS/Food G10	6.52	0.3%	Wheat	0.1%	Rice	0.1%	Maize/corn		0.0%
	0.6%	DE child	6.35	0.3%	Wheat	0.1%	Milk: Cattle	0.1%	Rye		
	0.6%	GEMS/Food G15	6.32	0.4%	Wheat	0.1%	Barley	0.1%	Maize/corn		
	0.6%	GEMS/Food G08	6.26	0.3%	Wheat	0.1%	Barley	0.0%	Rye		
	0.6%	FR child 3 15 yr	6.23	0.4%	Wheat	0.1%	Milk: Cattle	0.0%	Rice		0.0%
	0.6%	NL child	6.21	0.3%	Wheat	0.1%	Milk: Cattle	0.0%	Sugar beet roots		0.0%
	0.6%	RO general	5.99	0.4%	Wheat	0.1%	Maize/corn	0.0%	Milk: Cattle		0.0%
	0.6%	GEMS/Food G07	5.75	0.3%	Wheat	0.0%	Barley	0.0%	Rice		0.0%
	0.6%	UK infant	5.66	0.2%	Wheat	0.2%	Milk: Cattle	0.1%	Maize/corn		0.0%
	0.5%	GEMS/Food G11	5.29	0.3%	Wheat	0.1%	Barley	0.0%	Soyabeans		
	0.5%	ES child	5.25	0.4%	Wheat	0.0%	Milk: Cattle	0.0%	Rice		0.0%
	0.5%	UK toddler	5.09	0.3%	Wheat	0.1%	Milk: Cattle	0.0%	Rice		0.0%
	0.5%	FR toddler 2 3 yr	4.92	0.2%	Wheat	0.1%	Milk: Cattle	0.0%	Rice		0.0%
	0.5%	PT general	4.69	0.3%	Wheat	0.1%	Rice	0.0%	Maize/corn		
	0.4%	IT adult	4.15	0.3%	Wheat	0.1%	Other cereals	0.0%	Rice		
	0.4%	SE general	4.12	0.3%	Wheat	0.0%	Milk: Cattle	0.0%	Rice		
	0.4%	DE general	3.61	0.1%	Wheat	0.0%	Milk: Cattle	0.0%	Rye		0.0%
	0.4%	DE women 14-50 yr	3.53	0.2%	Wheat	0.0%	Milk: Cattle	0.0%	Rye		0.0%
	0.3%	IE adult	3.46	0.2%	Wheat	0.0%	Buckwheat and other pseudo-cereals	0.0%	Rice		
	0.3%	ES adult	3.10	0.2%	Wheat	0.0%	Barley	0.0%	Milk: Cattle		0.0%
	0.3%	NL general	3.02	0.2%	Wheat	0.0%	Milk: Cattle	0.0%	Barley		0.0%
	0.3%	FI 3 yr	2.73	0.1%	Wheat	0.1%	Rye	0.0%	Oat		
	0.3%	FR adult	2.57	0.2%	Wheat	0.0%	Milk: Cattle	0.0%	Rice		0.0%
	0.3%	LT adult	2.51	0.1%	Rye	0.1%	Wheat	0.0%	Rice		
	0.2%	UK vegetarian	2.38	0.2%	Wheat	0.0%	Rice	0.0%	Milk: Cattle		0.0%
	0.2%	FI 6 yr	2.13	0.1%	Wheat	0.0%	Rye	0.0%	Rice		
	0.2%	UK adult	2.04	0.1%	Wheat	0.0%	Rice	0.0%	Milk: Cattle		0.0%
	0.2%	DK adult	1.85	0.1%	Wheat	0.0%	Rye	0.0%	Milk: Cattle		
	0.2%	FR infant	1.67	0.1%	Milk: Cattle	0.1%	Wheat	0.0%	Sugar beet roots		0.0%
	0.1%	IE child	1.38	0.1%	Wheat	0.0%	Rice	0.0%	Milk: Cattle		
	0.1%	FI adult	1.19	0.1%	Rye	0.0%	Wheat	0.0%	Oat		
	0.0%	PL general	0.18	0.0%	Apples	0.0%	Potatoes	0.0%	Table grapes		

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Triazole acetic acid (TAA) is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

A 3.7 IEDI calculations – 1,2,4-Triazole (1,2,4-T)

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

1,2,4-Triazole (1,2,4-T)

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	**0.023**	ARfD (mg/kg bw):	**0.1**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2018**	Year of evaluation:	**2018**

Input values

Details - chronic risk assessment | Supplementary results - chronic risk assessment

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
88%	NL toddler	20.23	78%	Milk: Cattle	2%	Maize/corn	1%	Bovine: Muscle/meat		1%
55%	UK infant	12.68	50%	Milk: Cattle	1%	Bovine: Muscle/meat	0.6%	Wheat		0.3%
44%	FR toddler 2 3 yr	10.09	38%	Milk: Cattle	1%	Bovine: Muscle/meat	0.7%	Wheat		0.6%
39%	NL child	9.02	32%	Milk: Cattle	2%	Sugar beet roots	1%	Bovine: Muscle/meat		2%
37%	FR child 3 15 yr	8.50	30%	Milk: Cattle	2%	Bovine: Muscle/meat	1.0%	Wheat		0.8%
32%	UK toddler	7.34	27%	Milk: Cattle	2%	Bovine: Muscle/meat	0.9%	Wheat		0.7%
31%	DE child	7.05	26%	Milk: Cattle	0.9%	Wheat	0.9%	Oranges		
24%	FR infant	5.46	22%	Milk: Cattle	0.4%	Bovine: Muscle/meat	0.3%	Sugar beet roots		0.3%
24%	SE general	5.44	16%	Milk: Cattle	5%	Bovine: Muscle/meat	0.7%	Wheat		
23%	DK child	5.25	16%	Milk: Cattle	2%	Bovine: Muscle/meat	1%	Swine: Muscle/meat		
22%	ES child	5.05	16%	Milk: Cattle	2%	Bovine: Muscle/meat	1.0%	Wheat		0.0%
20%	DE women 14-50 yr	4.65	16%	Milk: Cattle	1.0%	Sugar beet roots	0.5%	Swine: Muscle/meat		1.0%
20%	DE general	4.63	16%	Milk: Cattle	0.9%	Sugar beet roots	0.6%	Swine: Muscle/meat		0.9%
19%	RO general	4.43	15%	Milk: Cattle	1%	Wheat	0.7%	Swine: Muscle/meat		0.3%
16%	GEMS/Food G11	3.62	10%	Milk: Cattle	0.8%	Bovine: Muscle/meat	0.8%	Soyabeans		
15%	NL general	3.44	11%	Milk: Cattle	0.9%	Bovine: Muscle/meat	0.6%	Sugar beet roots		0.6%
15%	GEMS/Food G15	3.40	9%	Milk: Cattle	1.0%	Wheat	0.8%	Swine: Muscle/meat		
14%	GEMS/Food G07	3.33	8%	Milk: Cattle	1%	Bovine: Muscle/meat	0.9%	Wheat		0.0%
13%	GEMS/Food G10	2.99	7%	Milk: Cattle	1%	Bovine: Muscle/meat	0.9%	Wheat		0.0%
13%	GEMS/Food G08	2.97	7%	Milk: Cattle	1%	Swine: Muscle/meat	0.9%	Wheat		
10%	IE adult	2.32	6%	Milk: Cattle	0.5%	Wheat	0.5%	Bovine: Muscle/meat		
10%	ES adult	2.26	6%	Milk: Cattle	0.9%	Bovine: Muscle/meat	0.5%	Wheat		0.0%
9%	DK adult	2.12	7%	Milk: Cattle	0.6%	Bovine: Muscle/meat	0.5%	Swine: Muscle/meat		
9%	GEMS/Food G06	2.10	3%	Milk: Cattle	2%	Wheat	0.4%	Sugar canes		0.3%
9%	FR adult	2.04	6%	Milk: Cattle	0.7%	Bovine: Muscle/meat	0.5%	Wheat		0.2%
7%	LT adult	1.66	5%	Milk: Cattle	0.5%	Swine: Muscle/meat	0.3%	Bovine: Muscle/meat		
6%	UK adult	1.38	4%	Milk: Cattle	0.8%	Bovine: Muscle/meat	0.4%	Wheat		0.1%
6%	UK vegetarian	1.31	4%	Milk: Cattle	0.4%	Wheat	0.2%	Oranges		0.1%
5%	IE child	1.25	5%	Milk: Cattle	0.3%	Wheat	0.1%	Swine: Muscle/meat		
2%	IT toddler	0.56	1%	Wheat	0.3%	Other cereals	0.1%	Bananas		
2%	PT general	0.52	0.9%	Wheat	0.2%	Potatoes	0.2%	Rice		
2%	FI 3 yr	0.38	0.3%	Bananas	0.3%	Wheat	0.2%	Potatoes		
2%	IT adult	0.37	0.9%	Wheat	0.2%	Other cereals	0.1%	Oranges		
1%	FI 6 yr	0.29	0.2%	Wheat	0.2%	Potatoes	0.2%	Bananas		
0.7%	FI adult	0.17	0.2%	Rye	0.1%	Oranges	0.1%	Wheat		
0.5%	PL general	0.13	0.1%	Potatoes	0.1%	Apples	0.1%	Head cabbages		

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of 1,2,4-Triazole (1,2,4-T) is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

A 3.8 IESTI calculations - Raw commodities

Not applicable for sugar beet roots because they are always consumed in the processed form.

A 3.9 IESTI calculations - Processed commodities – Fenpicoxamid

Acute risk assessment /children	Acute risk assessment / adults / general population
Details - acute risk assessment /children	Details - acute risk assessment/adults

The acute risk assessment is based on the ARfD. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the Eu

The calculation is based on the large portion of the most critical consumer group.

Show results of IESTI calculation only for crops with GAPs under assessment

Processed commodities

Results for children				**Results for adults**			
No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---	No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				**IESTI**			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.06%	Sugar beets (root) / sugar	0.01 / 0.12	1.1	0.02%	Sugar beets (root) / sugar	0.01 / 0.12	0.44
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
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Expand/collapse list							

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short term intake of residues of Fenpicoxamid is unlikely to present a public health risk.

For processed commodities, no exceedance of the ARfD/ADI was identified.

A 3.10 IESTI calculations - Processed commodities – Prothioconazole-desthio

Acute risk assessment /children	Acute risk assessment / adults / general population
Details - acute risk assessment /children	Details - acute risk assessment/adults

The acute risk assessment is based on the ARfD. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the Eu

The calculation is based on the large portion of the most critical consumer group.

Show results of IESTI calculation only for crops with GAPs under assessment

Processed commodities

Results for children				**Results for adults**			
No of processed commodities for which ARfD/ADI is exceeded (IESTI):		---		No of processed commodities for which ARfD/ADI is exceeded (IESTI):		---	
IESTI				**IESTI**			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
66%	Sugar beets (root) / sugar	0.03 / 0.72	6.6	26%	Sugar beets (root) / sugar	0.03 / 0.72	2.6
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
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#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
Expand/collapse list							

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

A 3.11 IESTI calculations - Processed commodities – Triazole alanine (TA)

Details - acute risk assessment /children

Details - acute risk assessment/adults

The acute risk assessment is based on the ARfD. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the Eu

The calculation is based on the large portion of the most critical consumer group.

Show results of IESTI calculation only for crops with GAPs under assessment

Processed commodities

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
2%	Sugar beets (root) / sugar	0 / 0.6	5.5
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.7%	Sugar beets (root) / sugar	0 / 0.6	2.2
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!

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

A 3.12 IESTI calculations - Processed commodities – Triazole lactic acid (TLA)

Acute risk assessment /children	Acute risk assessment / adults / general population
Details - acute risk assessment /children	Details - acute risk assessment/adults

The acute risk assessment is based on the ARfD. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the Eu

The calculation is based on the large portion of the most critical consumer group.

Show results of IESTI calculation only for crops with GAPs under assessment

Processed commodities

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.4%	Sugar beets (root) / sugar	0 / 0.12	1.1
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.1%	Sugar beets (root) / sugar	0 / 0.12	0.44
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!

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

A 3.13 IESTI calculations - Processed commodities – Triazole acetic acid (TAA)

Acute risk assessment /children	Acute risk assessment / adults / general population
Details - acute risk assessment /children	Details - acute risk assessment/adults

The acute risk assessment is based on the ARfD. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the Eu

The calculation is based on the large portion of the most critical consumer group.

Show results of IESTI calculation only for crops with GAPs under assessment

Processed commodities

Results for children				**Results for adults**			
No of processed commodities for which ARfD/ADI is exceeded (IESTI):		---		No of processed commodities for which ARfD/ADI is exceeded (IESTI):		---	
IESTI				**IESTI**			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.6%	Sugar beets (root) / sugar	0 / 0.6	5.5	0.2%	Sugar beets (root) / sugar	0 / 0.6	2.2
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
Expand/collapse list							

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short term intake of residues of Triazole acetic acid (TAA) is unlikely to present a public health risk.

For processed commodities, no exceedance of the ARfD/ADI was identified.

A 3.14 IESTI calculations - Processed commodities – 1,2,4-Triazole (1,2,4-T)

Acute risk assessment /children	Acute risk assessment / adults / general population
Details - acute risk assessment /children	Details - acute risk assessment/adults

The acute risk assessment is based on the ARfD. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the Eu

The calculation is based on the large portion of the most critical consumer group.

Show results of IESTI calculation only for crops with GAPs under assessment

Processed commodities

Results for children				**Results for adults**			
No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---	No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				**IESTI**			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
6%	Sugar beets (root) / sugar	0 / 0.6	5.5	2%	Sugar beets (root) / sugar	0 / 0.6	2.2
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
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#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
Expand/collapse list							

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

Appendix 4 Fish Dietary Burden Assessment

Common carp

Dietary Burden Calculation concerning Inatreq

DietaryBurdenCalculator 2.0.3

Fraunhofer Institute for Molecular Biology and Applied Ecology IME

INPUT

=====

Target content for Common carp:

Crude fat 10.00%

Crude protein 35.00%

Maximum principal content of components in the diet:

Brewer's grain (dried) 15.00%

Canola meal (Solvent extracted) 10.00%

Wheat (bran) 5.00%

Wheat (flour) 15.00%

Wheat (germ) 5.00%

Wheat (middlings) 20.00%

Wheat (gluten meal) 5.00%

Wheat (Grain (extruded)) 15.00%

Fish meal(PC) 100.00%

Starch(CC) 100.00%

Oil(F) 100.00%

Percent dry matter of components:

Brewer's grain (dried) 92.0%

Canola meal (Solvent extracted) 91.0%

Wheat (bran) 88.7%

Wheat (flour) 88.0%

Wheat (germ) 88.7%

Wheat (middlings) 89.4%

Wheat (gluten meal) 91.4%

Wheat (Grain (extruded)) 87.7%

Inatreq residues in the components:

Brewer's grain (dried) 0.330 mg/kg (STMR-P)

Canola meal (Solvent extracted) 0.010 mg/kg (STMR-P)

Wheat (bran) 0.060 mg/kg (STMR-P)

Wheat (flour) 0.060 mg/kg (STMR-P)

Wheat (germ) 0.060 mg/kg (STMR-P)

Wheat (middlings) 0.060 mg/kg (STMR-P)

Wheat (gluten meal) 0.060 mg/kg (STMR-P)

Wheat (Grain (extruded)) 0.060 mg/kg (STMR-P)

Inatreq residues in the components (dry matter):

Brewer's grain (dried) 0.359 mg/kg (STMR-P)
Canola meal (Solvent extracted) 0.011 mg/kg (STMR-P)
Wheat (bran) 0.068 mg/kg (STMR-P)
Wheat (flour) 0.068 mg/kg (STMR-P)
Wheat (germ) 0.068 mg/kg (STMR-P)
Wheat (middlings) 0.067 mg/kg (STMR-P)
Wheat (gluten meal) 0.066 mg/kg (STMR-P)
Wheat (Grain (extruded)) 0.068 mg/kg (STMR-P)

RESULTS
=======

Maximum dietary burden based on Inatreq is 0.090 mg/kg (dry matter).

The respective composition of the feed is:
Brewer's grain (dried) 15.00%
Canola meal (Solvent extracted) 0.00%
Wheat (bran) 5.00%
Wheat (flour) 15.00%
Wheat (germ) 5.00%
Wheat (middlings) 20.00%
Wheat (gluten meal) 5.00%
Wheat (Grain (extruded)) 4.18%
Fish meal(PC) 25.09%
Starch(CC) 0.00%
Oil(F) 5.73%

The dietary load of Inatreq caused by the individual components is:
Brewer's grain (dried) 59.54%
Canola meal (Solvent extracted) 0.00%
Wheat (bran) 3.74%
Wheat (flour) 11.32%
Wheat (germ) 3.74%
Wheat (middlings) 14.85%
Wheat (gluten meal) 3.63%
Wheat (Grain (extruded)) 3.17%
Fish meal(PC) 0.00%
Starch(CC) 0.00%
Oil(F) 0.00%

Rainbow trout

Dietary Burden Calculation concerning Inatreq

DietaryBurdenCalculator 2.0.3

Fraunhofer Institute for Molecular Biology and Applied Ecology IME

INPUT
=====

Target content for Rainbow trout:
Crude fat 15.00%
Crude protein 42.00%

Maximum principal content of components in the diet:
Brewer's grain (dried) 10.00%
Canola meal (Solvent extracted) 8.00%
Wheat (bran) 2.00%
Wheat (flour) 10.00%
Wheat (germ) 2.00%
Wheat (middlings) 10.00%
Wheat (gluten meal) 2.00%
Wheat (Grain (extruded)) 10.00%
Fish meal(PC) 100.00%
Starch(CC) 100.00%
Oil(F) 100.00%

Percent dry matter of components:
Brewer's grain (dried) 92.0%
Canola meal (Solvent extracted) 91.0%
Wheat (bran) 88.7%
Wheat (flour) 88.0%
Wheat (germ) 88.7%
Wheat (middlings) 89.4%
Wheat (gluten meal) 91.4%
Wheat (Grain (extruded)) 87.7%

Inatreq residues in the components:
Brewer's grain (dried) 0.330 mg/kg (STMR-P)
Canola meal (Solvent extracted) 0.010 mg/kg (STMR-P)
Wheat (bran) 0.060 mg/kg (STMR-P)
Wheat (flour) 0.060 mg/kg (STMR-P)
Wheat (germ) 0.060 mg/kg (STMR-P)
Wheat (middlings) 0.060 mg/kg (STMR-P)
Wheat (gluten meal) 0.060 mg/kg (STMR-P)
Wheat (Grain (extruded)) 0.060 mg/kg (STMR-P)

Inatreq residues in the components (dry matter):
Brewer's grain (dried) 0.359 mg/kg (STMR-P)
Canola meal (Solvent extracted) 0.011 mg/kg (STMR-P)
Wheat (bran) 0.068 mg/kg (STMR-P)
Wheat (flour) 0.068 mg/kg (STMR-P)
Wheat (germ) 0.068 mg/kg (STMR-P)
Wheat (middlings) 0.067 mg/kg (STMR-P)
Wheat (gluten meal) 0.066 mg/kg (STMR-P)
Wheat (Grain (extruded)) 0.068 mg/kg (STMR-P)

RESULTS
=======

Maximum dietary burden based on Inatreq is 0.060 mg/kg (dry matter).

The respective composition of the feed is:
Brewer's grain (dried) 10.00%
Canola meal (Solvent extracted) 0.00%
Wheat (bran) 2.00%
Wheat (flour) 10.00%
Wheat (germ) 2.00%
Wheat (middlings) 10.00%
Wheat (gluten meal) 2.00%
Wheat (Grain (extruded)) 9.62%
Fish meal(PC) 43.34%
Starch(CC) 0.00%
Oil(F) 11.04%

The dietary load of Inatreq caused by the individual components is:
Brewer's grain (dried) 59.79%
Canola meal (Solvent extracted) 0.00%
Wheat (bran) 2.25%
Wheat (flour) 11.36%
Wheat (germ) 2.25%
Wheat (middlings) 11.19%
Wheat (gluten meal) 2.19%
Wheat (Grain (extruded)) 10.97%
Fish meal(PC) 0.00%
Starch(CC) 0.00%
Oil(F) 0.00%