REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: GF-3307

Product name(s): not yet defined

Chemical active substance(s):

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

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Corteva Agriscience

Submission date: July 2021, updated January 2022, May 2022, September 2022

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January 2023 (final Core Assessment)

Version history

When	What
July 2021	New submission of GF-3307 in the Central Zone
January 2022	Genotox study summaries on processing metabolites moved from dRR B7 to dRR B6 in A 2.13
May 2022	Austria removed from cMS, GAP table updated with 1 use = 1 crop + 1 disease. Additional studies on pollen and Nectar, and honey have been added.
September 2022	Clarification on Honey
October 2022	Initial ZRMS assessment. The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are ~~struck through and shaded for transparency~~. Following the evaluation and before sending the document for commenting, all coloured highlighting was removed, from the parts updated by the Applicant, for better legibility.
January 2023	Final report (Core Assessment updated following the commenting period). No additional information or assessments after the commenting period.

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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 are presented in Table 7.1 1. They have been selected from the individual GAPs in CZ for cereals (Wheat, rye, triticale, spelt and barley). A list of all intended uses in Central Zone is given in Part B, Section 0.

The GAP proposed for GF-3307 results in a total maximum application rate of 1x 75 g ai/ha with final application BBCH 69 for Fenpicoxamid (XDE-777) in wheat, barley, rye, spelt and triticale. This is less than the rate upon which the proposed EU MRL is based.
The GAP proposed for GF-3307 results in a total maximum application rate of 1 x 150 g ai/ha with final application at BBCH 69 for Prothioconazole in wheat, barley, rye, spelt and triticale. This is less than the rate upon which the EU MRL is based.

Overall conclusion
The data available for wheat, rye, triticale and spelt are considered sufficient for risk assessment.
The current MRL for fenpicoxamid for barley is 0.01 mg/kg (Reg. (EU) 2019/50). Considering the intended use on barley, an exceedance of the default MRL of 0.01 mg/kg for fenpicoxamid as established in Commission Regulation (EU) 2019/50, is expected. Therefore until the new MRL for fenpicoxamid come into force, authorisation of the GAP for barley will not be possible.

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 agrees with the authorization of the intended use(s): wheat, rye, spelt and triticale.

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 per treatment**			**PHI (days)**	**Conclusion**
						Type	**Conc. of as**	**Method kind**	**Growth stage & season**	**Number min max**	**Interval between applications (min)**	**L product/ha min max**	**water L/ha min max**	**g as/ha min max**		
1-68, 84-117	Winter wheat (TRZAW), Durum wheat (TRZDU), Spelt (TRZSP) Winter triticale (TTLWI) Winter rye (SECCW) Spring wheat (TRZAW) Spring triticale (TTLWI) Spring rye (SECCW)	CZ	GF-3307	F	PYRNTR FUSASP SEPTTR PUCCRT PUCCST ERYSGR	EC	Fenpicoxamid, 50 g/L + Prothioconazole, 100 g/L	Tractor mounted spray	BBCH 30-69	1	-	1.5 L/ha	100-300	75 g/ha Fenpicoxamid + 150 g/ha Prothioconazole	PHI F **** (BBCH 69)	A
69-83, 118-132	Winter Barley (HORVW) Spring Barley (HORVS)	CZ	GF-3307	F	RHYNSE RAMUCC ERYSGR PUCCHD PYRNTE	EC	Fenpicoxamid, 50 g/L + Prothioconazole, 100 g/L	Tractor mounted spray	BBCH 30-69	1	-	1.5 L/ha	100-300	75 g/ha Fenpicoxamid + 150 g/ha Prothioconazole	PHI F **** (BBCH 69)	**N** MRL exceedance for fenpicoxamid

* 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)					
ADI	EFSA	2018	0.05 mg/kg bw/day	18-Month Mouse Carcinogenicity	100
ARfD	EFSA	2018	1.8 mg/kg bw	Developmental study in rabbits	100
Prothioconazole - Parent compound					
ADI	EFSA	2007	0.05 mg/kg bw/day	Rat oncogenicity study	100
ARfD	EFSA	2007	0.2 mg/kg bw	Rat developmental study	100
Desthio-Prothioconazole - Metabolite					
ADI	EFSA	2007	0.01 mg/kg bw/day	18-Month Mouse Carcinogenicity	100
ARfD	EFSA	2007	0.01 mg/kg bw	Developmental study in rabbits	100
1, 2, 4-triazole (1,2,4-T)					
ADI	EFSA Journal 2018; 16(7):5376	2018	0.023 mg/kg bw/day	Rat 12-month study	300
ARfD		2018	0.1 mg/kg bw	Rabbit developmental study	300
Triazole alanine (TA)					
ADI	EFSA Journal 2018; 16(7):5376	2018	0.3 mg/kg bw/day	Rabbit developmental study	100
ARfD		2018	0.3 mg/kg bw	Rabbit developmental study	100
Triazole acetic acid (TAA)					
ADI	EFSA Journal 2018; 16(7):5376	2018	1 mg/kg bw/day	Rat 2 generation and Rabbit developmental studies	100
ARfD		2018	1 mg/kg bw	Rat 2 generation and Rabbit developmental studies	100
Triazole lactic acid (TLA)					
ADI	EFSA Journal 2018; 16(7):5376	2018	0.3 mg/kg bw/day	Bridging from TA	
ARfD		2018	0.3 mg/kg bw	Bridging from TA	

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?
1-68, 84-117	Winter wheat (TRZAW),	Yes	Yes (min 8 trials per zone)	Yes (PHI F)	Yes	Yes	No	No

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
	Durum wheat (TRZDU), Spelt (TRZSP) Winter triticale (TTLWI) Winter rye (SECCW) Spring wheat (TRZAW) Spring triticale (TTLWI) Spring rye (SECCW)							
69-83, 118-132	Winter Barley (HORVW) Spring Barley (HORVS)	Yes	Yes (min 8 trials per zone)	Yes (PHI F)	Yes	~~Yes, the proposed MRL of 0.8 mg/kg for barley is still pending assessment~~ No	~~No~~	~~No~~

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

The current MRL for fenpicoxamid for barley is 0.01 mg/kg (Reg. (EU) 2019/50). Considering the intended use on barley, an exceedance of the default MRL of 0.01 mg/kg for fenpicoxamid as established in Commission Regulation (EU) 2019/50, is expected. Therefore until the new MRL for fenpicoxamid come into force, authorisation of the GAP for barley will not be possible.

As residues of fenpicoxamid (XDE-777) in cereal grain exceeds the trigger values defined in Reg (EU) No 283/2013, the effect on the nature of residue in processed foods was investigated in a high temperature hydrolysis study.

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.

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.

No chronic and acute dietary risk has been identified for wheat, rye, triticale ~~and barley~~. The use of GF-3307 on wheat, rye, triticale ~~and barley~~ is therefore acceptable. The proposed use on barley is not considered acceptable.

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?
1-68, 84-117	Winter wheat (TRZAW), Durum wheat (TRZDU), Spelt (TRZSP) Winter triticale (TTLWI) Winter rye (SECCW) Spring wheat (TRZAW) Spring triticale (TTLWI) Spring rye (SECCW)	Yes	Yes	Yes	Yes	Yes	No	No
69-83, 118-132	Winter Barley (HORVW) Spring Barley (HORVS)	Yes	Yes	Yes	Yes	Yes		No

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

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.

Regarding TDMs, studies show that they remained stable under the standard hydrolysis conditions. Studies on magnitude of residues in processed commodities in wheat and barley after treatment with prothioconazole were presented in the Triazole Derivate Metabolites addendum confirmatory data (B.7.5.2, UK, 2018). These data were not considered for the risk assessment (the most critical processing factors, considering data provided for all active substances belonging to the triazole group, were taken into account in the TDM EU risk assessment).

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

Regarding TDMs, in the framework of the confirmatory data, a number of field rotational crop trials have been conducted to investigate the magnitude of TDM residues in rotational crops after the use of triazole active substances. Residues of TA, TLA and TAA were found above 0.01 mg/kg in succeeding crops. These results were considered in the consumer risk assessment performed in the framework of the review of TDMs confirmatory data.

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

Regarding TDM arising from prothioconazole uses, as concluded by the UK, “further consideration is not required due to the fact that none of the TDMs were identified” in the available livestock metabolism studies conducted with prothioconazole.

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.

Considering these TDMs, zRMS proposed a dietary risk assessment similar to the ones proposed by EFSA in the “Peer review of the Pesticide risk assessment for the triazole derivative metabolites in light of confirmatory data submitted” (EFSA Journal 2018; 16(7):5376). Data gaps have been identified by EFSA.

Nevertheless, zRMS is of opinion that the chronic and short-term intakes of TDMs residues resulting from the use proposed in the framework of this application are unlikely to present a public health concern.

7.1.2.3 Summary for GF-3307

Table 7.1-5: Information on GF3307 (KCA 6.8)

Crop	PHI for GF-3307 proposed by applicant	PHI/ Withholding period* sufficiently supported for		PHI for GF-3307 proposed by zRMS	zRMS Comments (if different PHI proposed)
		Fenpicoxamid	Prothioconazole		
Wheat	F**	Yes	Yes	F**	-
Rye	F**	Yes	Yes	F**	-
Triticale	F**	Yes	Yes	F**	-
Barley	F**	Yes	Yes	F**	-

* 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 7.1-6: Waiting periods before planting succeeding crops

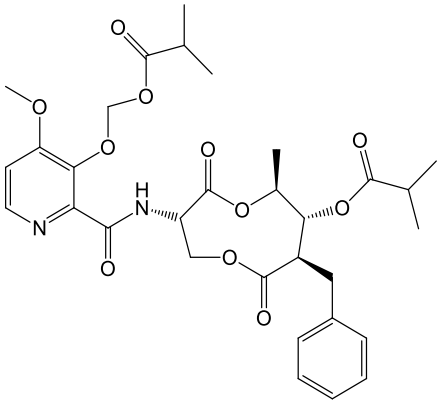
Waiting period before planting succeeding crops			Overall waiting period proposed by zRMS for GF-3307
Crop group	Led by fenpicoxamid	Led by prothioconazole	
Leafy vegetables	Not required	Not required	Not required
Root vegetables	Not required	Not required	Not required
Cereal	Not required	Not required	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 RO, 2014) provides evaluation of MRLs for barley, wheat, rye, and triticale.
Conclusion on the peer review of the pesticide risk assessment for the triazole derivative metabolites in light of confirmatory data. EFSA journal 2018.

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)	Dow AgroSciences
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
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

No new data submitted in the framework of this application.

Available data

No new data are 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			
Wheat grain	High starch content	24 months (fenpicoxamid & X642188)	United Kingdom, 2017* (Watson, 2014, 120749)
Wheat straw	~~High starch content~~ No group	24 months (fenpicoxamid & X642188)	United Kingdom, 2017 (Watson, 2014, 120749)
Wheat forage	High water content	24 months (fenpicoxamid & X642188)	United Kingdom, 2017* (Watson, 2014, 120749)
Wheat bran, flour, bread	Processed commodities (high starch content)	24 months (fenpicoxamid & X642188)	United Kingdom, 2017* (Watson, 2014, 120749)
Wheat germ	Processed commodity (high water content)	9 months (fenpicoxamid) 24 months (~~fenpicoxamid &~~ X642188)	United Kingdom, 2017* (Watson, 2014, 120749)
Animal Products			
Bovine	Liver	3 months (fenpicoxamid) 6/7 months (X642188 and X12326349)	EFSA Journal 2018;16(1):5146 (Betson, 2013, 130709)
Bovine	Milk	9 months (fenpicoxamid) 6 months (X642188) 3 months (X12326349)	EFSA Journal 2018;16(1):5146 (Betson, 2013, 130709)
Bovine	Muscle	7 months (fenpicoxamid) 6 months (X642188) 3 months (X12326349)	EFSA Journal 2018;16(1):5146 (Betson, 2013, 130709)
Bovine	Fat	9 months (fenpicoxamid and X642188) 3 months (X12326349)	EFSA Journal 2018;16(1):5146 (Betson, 2013, 130709)

* 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.*"
Some corrections have been added to the Table 7.2-2. Fenpicoxamid and its metabolite X642188 are demonstrated to be stable in dry commodities (high starch content commodities) for 24 months. Sufficient stability data are available to support the residue data presented in the present dossier.
No further data are required.

The results show that the fenpicoxamid, X642188 and X12326349 are stable 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.

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)

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								
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)
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 2019/50) 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 (97%)	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
Relevant processing simulation for wheat taken into account = baking (60 min, 100°C, pH5).
In DAR, 2017 it is stated that „*Concerning the intended use on cereals, the industrial process simulating baking seems to be the most relevant (pH5, 100°C, 60 min). In that case, relevant metabolites to consider provisionnaly*

are X12019520 and X12314005 considering the PH-label, and X12335723 and X12264475 considering the PY label. It seemed thus necessary to take into account the toxicological relevance of these metabolites. However, in the magnitude of residues studies in processed commodities of wheat (see below), these metabolites were either not detected (<0.003 mg/kg) or were found at <0.01 mg/kg."
According to the EFSA Journal 2018;16(1):5146: „*Under hydrolysis condition investigated with (PH)-^{14}C-fenpicoxamid and (PY)-^{14}C-fenpicoxamid, the parent compound degraded under pasteurisation in X12314005 (10% applied radioactivity (AR)) and X12335723 (15% AR), under baking/brewing/boiling, X12019520 (12% AR), X12314005 (47.5% AR) and X12335723 (76.5% AR) while under sterilisation degraded completely in X12019520 (97% AR), X12335723 (65% AR) and X12264475 (17% AR). Therefore, the residue definition for risk assessment in processed commodities was provisionally proposed as parent, X12019520, X12314005, X12335723, X12264475; pending upon the outcome on the new wheat processing residue trials (see data gap on processing wheat trials). Whether quantifiable residues will be found in the processing trials (> 0.01 mg/kg) the toxicity profile of these compounds have to be investigated. For monitoring, for the commodities processed under baking/brewing/boiling, fenpicoxamid is still a good marker to be monitored, while for the sterilisation X12019520 would be more appropriate."*

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?	Yes, for wheat or barley processed products which are produced by separation of components of the grain or by crushing / milling the grain. 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, X12264475and X12335723 were observed in some processed fractions but based on the consumer risk assessment, these are not of concern for risk assessment at the intended GAP.
Plant residue definition for monitoring	Fenpicoxamid (XDE-777) (EFSA 2018); Reg EU 2019/50)
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: 21.8 mg/kg dry feed/d eq to 0.255 mg/kg bw/d PY: 18.7 dry feed/d eq to 0.299 mg/kg bw/d	5	Milk	twice daily	EFSA 2018 (Rotondaro, 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: 10.7 mg/kg dry feed/d PY: 10.3 mg/kg dry feed /d	7	Eggs	twice daily	EFSA 2018 (Ma, 2013, 110421)
						Muscle (leg and breast)	at sacrifice	
						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 dosing rate 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)
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

Wheat

The EFSA proposed MRL for fenpicoxamid (XDE-777) in wheat, rye and triticale is based on a critical GAP of two applications at a rate of 130 g ai/ha with 14 days interval between applications and the second application at growth stage no later than BBCH 69. The evaluation leading to the currently proposed MRL for fenpicoxamid in wheat, rye and triticale is presented in the EFSA, 2018[1]. The critical GAP upon which the EU MRL for fenpicoxamid was set covers the uses of GF-3307 proposed in this submission.

The GAP proposed for GF-3307 results in a total maximum application rate for fenpicoxamid that is lower than the rate upon which the EU MRL is based (1 x 75 g ai/ha vs 2 x 130 g ai/ha). Both GAPs (GAP for GF-3307 vs GAP for representative use for EU MRL approval) foresee the final application no later than

[1] EFSA Journal 2018;16(1):5146

BBCH 69. Consequently, the existing proposed EU MRL of 0.60 mg/kg for fenpicoxamid in wheat covers the GAP proposed for GF-3307 uses in this submission. Intended uses of GF-3307 will not lead to residues exceeding the proposed EU MRL.

New magnitude of residue studies conducted with GF-3307 and other Emulsifiable Concentrate formulations (comparable to GF-3307) are submitted in the framework of this application at a more critical GAP and at the intended GAP rate for GF-3307. These studies are summarized in the Table below and the detailed assessment is presented in Appendix 2.

Sufficient trials on wheat were previously presented and evaluated (EFSA 2018). A summary of the all residue trials data for wheat is provided in the Table 7.2-9.

Barley

The GAP proposed for GF-3307 results in a total maximum application rate for fenpicoxamid that is lower than the rate upon which the EU MRL is based (1 x 75 g ai/ha vs 2 x 100 g ai/ha). Both GAPs (GAP for GF-3307 vs GAP for representative use for EU MRL approval) foresee the final application no later than BBCH 69. Consequently, the proposed EU MRL of 0.80 mg/kg for Fenpicoxamid in barley (part of an ongoing evaluation) covers the GAP proposed for GF-3307 in this submission with regard to Fenpicoxamid. Intended uses of GF-3307 will not lead to residues exceeding the proposed EU MRL.

New magnitude of residue studies conducted with GF-3307 in support of the proposed GAP (see GAP table 7.1-1), are submitted in the frame of this submission, following the EU representative use (2 x 100 g ai/ha, last application BBCH 69). Additionally, a total of four residue trials on barley during 2018 were conducted in Southern and Northern Europe at the intended GAP rate of GF-3307 (1 x 75 g ai/ha at several crop growth stages, until up to BBCH 65). The study results are summarized in the Table below and the detailed assessment is presented in Appendix 2.

Table 7.2-10: Summary of EU reported and new data supporting the intended uses of GF-3307 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
Wheat grain	EFSA 2018		*Trials GAP: 2 x 130 g as/ha, Appl. interval 14 d, 2nd appl. at BBCH 69, outdoor*					
		N-EU (16)	0.015, 0.021, 0.022, 0.032, 0.034, 0.041, 0.050, 0.051, 0.067, 0.075, 0.110, 0.122, 0.127, 0.137, 0.149, 0.196	0.06	0.20	0.30	0.60	Yes
		S-EU (16)	0.010, 0.021, 0.037, 0.040, 0.041, 0.042, 0.042, 0.047, 0.047, 0.052, 0.062, 0.063, 0.092, 0.098, 0.099, 0.545	0.05	0.55	0.60		Yes
	New Trials(2)	N-EU (10)	*Trials GAP: 2 x 100 g as/ha, Appl. interval 14 d, 2nd appl. at BBCH 69, outdoor*	0.014	0.064	0.09		Yes
			2x<0.01; 0.010; 2 x 0.011; 0.012; 2 x 0.014; 0.022; 0.029; 0.064					
	New Trials	N-EU (2)	*Trials GAP: 1 x 75 g as/ha. at BBCH 55, outdoor*	0.01	0.01	0.01		Yes
			2 < 0.01					
Wheat Straw	EFSA 2018	N-EU (16)	*Trials GAP: 2 x 130 g as/ha, Appl. interval 14 d, 2nd appl. at BBCH 69, outdoor*	6.32	15.94	/	/	/
			2.015, 2.375, 3.499, 4.446, 4.947, 5.949, 6.126, 6.132, 6.516, 7.301, 7.703, 9.340, 9.473, 11.484, 13.761, 15.939					
		S-EU (16)	4.053, 5.320, 6.159, 6.190, 6.669, 7.239, 7.632, 8.059, 8.570, 10.834, 11.104, 11.146, 11.203, 11.732, 12.005, 17.791	8.31	17.79	/		/
	New Trials	N-EU (10)	*Trials GAP: 2 x 100 g as/ha, Appl. interval 14 d, 2nd appl. at BBCH 69, outdoor*	1.92	5.72	/		/
			0.80; 0.96; 1.33; 1.51; 1.52; 1.92; 2.62; 2.64; 4.05; 5.72					
Barley	New trials (3)	N-EU (8) Grain	*Trials GAP: 2 x 100 g fenpicoxamid/ha + 200 g prothioconazole/ ha, last application at BBCH 69, outdoor* < 0.01, 0.01, 0.02, 0.03, 0.04, 0.06, 0.20, 0.29	0.04	0.29	0.50	~~0.80 (Assessment ongoing)~~ 0.01*	~~Yes~~ No
		N-EU (8) Straw	*Trials 2 x 100 g fenpicoxamid/ha + 200 g prothioconazole/ ha, last application at BBCH 69, outdoor* 0.18, 0.23, 0.30, 0.48, 0.99, 1.02, 1.71, 2.28	0.74	2.28	-	-	-
	New trials	NEU (2) Grain	*Trials GAP: 1 x 75 g fenpicoxamid/ha + 150 g prothioconazole/ ha, application up to BBCH 65* 2 x < 0.01	0.01	0.01	0.01*	~~0.80 (Assessment ongoing)~~	Yes

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
							0.01*	

(a): **NEU** for **outdoor** trials in northern Europe,
(b): Residue levels in trials conducted according to GAPs reported in ascending order (*e.g.* 3x <0.01, 0.01, 6x 0.02, 0.04, 0.08, 3x 0.10, 2x 0.15, 0.17). When residue definition for monitoring and risk assessment differ, used **Mo/RA** to differentiate data expressed according to the residue definition for **Mo**nitoring and **R**isk **A**ssessment.
(c): **HR**: Highest residue, according to the residue for risk assessment, (within brackets when expressed according to the residue definition for monitoring)
(d): **STMR:** Supervised Trials Median Residue according to the residue definition risk assessment (within brackets when expressed according to the residue definition for monitoring)
(1) Source of EU MRL: Reg. (EU) 2019/50. Do not include Barley MRL ongoing assessment
(2) Among the trials submitted by the applicant, some were conducted side by side (2 or 3 trials on the same site at the same time). The results were therefore combined and the mean was retained (see Appendix 2 for details).
(3). According to the OECD calculator, samples collected from trial S17-01904-15 in SEU (study 170191) were outliers, yielding substantially higher residues of fenpicoxamid and prothioconazole than the other trials. Further investigation identified a deviation in sample collection at normal commercial harvest; retain samples could not be collected due to insufficient plant material. The plants at this site were among the smallest at application 2, with zero growth reported between application and harvest, indicating poor crop performance across this site. This site was also among the shortest PHI. In summary, reduced biomass, a reduced growth rate, and a short PHI likely contributed to higher residues. The plants in this trial were not considered to be commercially acceptable to have been sprayed and the generated results are not considered representative of normal agronomic practices. Therefore, residues from trial S17-01904-15 are excluded from all discussions..

7.2.3.2 Conclusion on the magnitude of residues in plants

According to the available data, the intended use on wheat, rye, triticale and barley is considered acceptable, for outdoor uses.

The GF-3307, GF-3309 and GF-3312 formulations used in the frame of this submission for supporting residue data are all Emulsifiable Concentrate formulations, as GF-3307, while the EFSA proposed[2] MRL for fenpicoxamid in wheat, rye and triticale was based on a SC formulation. According to the OECD Guidance Document on Crop Field Trials, EC and SC formulations produce comparable residues, especially if the last application is more than seven days prior to harvest, as is the case for the intended GAP.

The data submitted show that no exceedance of the proposed ongoing MRL will occur and the intended uses are considered acceptable on wheat, rye and barley.
Remark – see below zRMS comments.

According to appendix D of EU guidelines, extrapolation to rye is possible with 8 trials on wheat, which is the case here. So the uses are also considered acceptable on rye and triticale.

zRMS comments:
Residue Definitions (EFSA 2018; Reg EU 2019/50):
Monitoring (Mo): Fenpicoxamid (XDE-777)
Risk Assessment (RA): Fenpicoxamid (XDE-777)

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

Sufficient trials on wheat were previously presented and evaluated (EFSA 2018).
Additionally 4 new magnitude of residue studies were submitted in the framework of this application (Studies S15-02628, S14-01569, and S14-01568 & S15-02629, conducted with a higher total rate than the proposed cGAP for GF-3307. The studies S14-01568 & S14-01569 and S15-02628 & S15-02629 on the determination of residues of fenpicoxamid (XDE-777) in winter and spring wheat have been evaluated in Registration Report for GF-3308 on February 2022 by zRMS-PL.
Summary is presented below.

Table 1: Comparison of intended and critical EU GAPs for wheat

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (EFSA 2018)	2	130 g XDE-777/ha	14 days	BBCH 69	N/A
Intended cGAP	1	75 g XDE-777/ha	NA	BBCH 69	F

Summary
1. Report No. S15-02628; DAS Study ID 150650
Six N-EU trials were conducted in accordance with the following GAP: 2 x 100 g a.s. /ha (instead of 1 x 75 g a.s./ha); application interval - 14 days, 2nd application at BBCH 65-71, outdoor.
Residues of XDE-777 in grain taken at normal commercial harvest for plot / treatment 2 ranged from 0.007 mg/kg, which is <LOQ of 0.01 mg/kg to 0.059 mg/kg (<0.01 mg/kg, 0.011 mg/kg, 0.014 mg/kg, 0.02 mg/kg 0.034 mg/kg, 0.059 mg/kg).

2. Report No. S15-02629, DAS Study ID 150649
Six N-EU trials were conducted in accordance with the following GAP: 2 x 100 g a.s. /ha (instead of 1 x 75 g a.s./ha); application interval - 14 days, 2nd application at BBCH 67-69, outdoor.
Residues of XDE-777 in grain taken at normal commercial harvest for plot / treatment 2 ranged from 0.003 mg/kg,

[2] EFSA Journal 2018;16(1):5146

which is <LOQ of 0.01 mg/kg to 0.069 mg/kg (0.012 mg/kg, 0.014 mg/kg, 0.016 mg/kg, 0.022 mg/kg, 0.023 mg/kg, 0.0687 mg/kg).

3. Report No. S14-01568, DAS Study ID 140649
Four N-EU trials were conducted in accordance with the following GAP: 2 x 100 g a.s. /ha (instead of 1 x 75 g a.s./ha); application interval - 14 days, 2nd application at BBCH 69, outdoor.
Residues of XDE-777 in grain (N-EU) taken at normal commercial harvest for plot / treatment 2 ranged from 0.006 mg/kg, which is <LOQ of 0.01 mg/kg to 0.024 mg/kg (2x<0.01 mg/kg, 0.012 mg/kg, 0.024 mg/kg .
Residues of XDE-777 in grain (N-EU) taken at normal commercial harvest for plot / treatment 3 ranged from 0.006 mg/kg, which is <LOQ of 0.01 mg/kg to 0.012 mg/kg (3<0.01 mg/kg, 0.012 mg/kg, .

4. Report No. S14-01569, DAS Study ID 140648
Four N-EU trials were conducted in accordance with the following GAP: 2 x 100 g a.s. /ha (instead of 1 x 75 g a.s./ha); application interval - 14 days, 2nd application at BBCH 69, outdoor.
Residues of XDE-777 in grain (N-EU) taken at normal commercial harvest for plot / treatment 2 ranged from ND (not detected, <0.003 mg/kg) to <0.01 mg/kg (4x<0.01 mg/kg).
Residues of XDE-777 in grain (N-EU) taken at normal commercial harvest for plot / treatment 3 ranged from 0.011 to 0.03 mg/kg (0.011 mg/kg, 0.012 mg/kg, 0.024 mg/kg, 0.03 mg/kg).

Among the trials submitted by the Applicant, some were conducted side by side (2 or 3 trials on the same site and at the same time; Study S15-02628 & S15-02629 and Study S14-01568 & S14-01569). The results were therefore combined and the mean was retained (see Table 7.2-10).
All available N-EU trials were conducted in accordance with the following GAP: 1 x 75 + 1 x 150 g a.s. /ha or 2 x 100 g a.s. /ha, instead of 1 x 75 g a.s./ha; application interval - 14 days, 2nd application. at BBCH 65-71, outdoor. This can be considered the worst case.

5. Report No. S18-01566, DAS Study ID 180126
Two N-EU trials were conducted in accordance with the following GAP: 1 x 75 g a.s. /ha at BBCH 55, outdoor.
Residues of XDE-777 in grain (N-EU) taken at normal commercial harvest was ND (not detected, <0.003 mg/kg).

Available results show that the in force MRL of fenpicoxamid on wheat, rye, triticale and spelt of 0.6 mg/kg (Reg. (EU) 2019/50) will not be exceeded. The current EU MRL for fenpicoxamid is sufficient to support the proposed uses.
The trials are supported by valid storage stability data and validated analytical methods.

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

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

Two new magnitude of residue studies were submitted in the framework of this application: study S17-01904/ 170191 conducted with a higher total rate than the proposed cGAP for GF-3307 and study S18-01567/ 180128 conducted according to the intended GAP.
Summary is presented below.

Table 2: Comparison of intended and critical EU GAPs for barley

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (EFSA 2018)	2	100 g XDE-777/ha	14 days	BBCH 69	N/A
Intended cGAP	1	75 g XDE-777/ha	NA	BBCH 69	F

Summary
1. Report no. S17-01904/ 170191
Eight N-EU trials were conducted in accordance with the following GAP: 2 x 100 g a.s. /ha, instead of 1 x 75 g a.s./ha; application interval - 14 days, 2nd application at BBCH 69, outdoor.
In seed specimens taken at normal commercial harvest residues of fenpicoxamid were between ND and 0.29 mg/kg.

2. Report no. S18-01567/ 180128
Two N-EU trials were conducted in accordance with the intended GAP: 1 x 75 g a.s. /ha at a different growth stage

(lot 2 was applied at BBCH 32, Plot 3 at BBCH 37-39, Plot 4 at BBCH 45, plot 5 at BBCH 51-61 and plot 6 at BBCH 55-65). In all trials specimens of the crop from the untreated and treated plots were taken at normal commercial harvest (NCH).
In seed specimens taken at normal commercial harvest residues of fenpicoxamid were below LOQ.

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

The current MRL for fenpicoxamid for barley is 0.01 mg/kg (Reg. (EU) 2019/50). The current MRL does not support the proposed GAP.
Considering the intended use on barley, an exceedance of the default MRL of 0.01 mg/kg for fenpicoxamid as established in Commission Regulation (EU) 2019/50, is expected. Therefore until the new MRL for fenpicoxamid come into force, authorization of the GAP (barley) will not be possible.
The proposed use on barley is not 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 barley grain and straw, 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 summarised in Table 7.2-11.

Table 7.2-11: 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)	-	-
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 straw~~	~~0.48~~	~~Median residue of study 170191 SEU + NEU~~	~~2.28~~	~~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~~	~~-~~	~~-~~

*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 7.2-12: 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)	0.004	0.004	0.13	0.13	Swine (finishing)	Distiller's grain	dried	No
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 grain. Highest expected intakes are the same as listed in EFSA, 2018; the intended uses for ~~UNIVOQ~~ GF-3307 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 intended uses on wheat, rye, triticale are covered by the representative uses of fenpicoxamide (EFSA (2018)). 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 summary submitted by the Applicant reflects the conclusions of the peer review.

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 without swine. 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 in wheat, rye and triticale cereal grain, straw, bran, and in barley, grain, straw and brewer's grain resulted in estimated values of 0.147 mg/kg bw/d / 2.15 mg/kg DM for all diets and layer only. Based on these levels of dietary intake the requirement of a poultry feeding study was triggered. 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 or individual metabolites are expected to remain below the LOD (<0.003 mg/kg) at a 5X level.
Therefore, as agreed during the Active Substance EU review (United Kingdom, 2017), it is proposed that a poultry feeding study is not needed.

Ruminants:

Dietary burden for fenpicoxamid in ruminants based on available residue data in wheat, rye and triticale cereal grain, bran and in barley, grain, straw and brewer's grain 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.

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. However, the calculation of the maximum dietary burden for swine indicates that the trigger intake value is not exceeded.

Fish:

A fish feeding study is not considered at this time as there are currently no final, approved guidance documents or test guidelines for determining dietary burden / potential residue intake in the diet or methodology for conducting a fish feeding study. According to the EFSA Conclusion Report the fish intake remains below the trigger value of 0.1 mg/kg DM; hence a feeding study is not required.

Table 7.2-13: 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: according to calculated dietary burden in dairy and beef cattle, the metabolism study and the feeding study no residues in meat nor milk are expected at the maximum dietary burden corresponding to residues related to the intended GAP. All MRLs are proposed at the LOQ level, for ruminant products including milk, except for sheep (all diets) for liver and kidney as described in the overview of the values derived from livestock feeding studies table above.

zRMS comments:
Information given by the Applicant is sufficient. The livestock feeding studies was sufficiently investigated during the approval of the active substance. The intended uses on wheat, rye and triticale are covered by the representative uses of fenpicoxamide (EFSA, 2018).
The residues in animal commodities will not exceed MRLs (Reg. (EU) 2019/50).
No further data are required.

Remark:
Barley can be fed to livestock. However, residues data provided by Applicant did not show compliance with the in-force MRL for barley for fenpicoxamide. See point 7.2.3.2 - zRMS comments.

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

Wheat

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

As reviewed during the active substance approval process (United Kingdom, 2017[3]), 2 processing residue trials are available on wheat from residue trials, with respectively highest residue levels in grain of 0.33 mg/kg (analysed for parent fenpicoxamid and X642188 – Study S12-01369) and 0.06 mg/kg (analysed for all hydrolysis metabolites X12019520, X12314005, X12335723 and X12264475 – Study S14-02186). X12019520, X12314005, X12335723 and X12264475 are hydrolysis degradates observed in the NOR in processed commodities high temperature hydrolysis study. As the later study did not cover the highest residue level observed in the residue trials at the representative uses GAP (0.55 mg/kg), a data gap was identified in EFSA conclusion report.

However, as the proposed GAP for the intended uses of GF-3307 is less intensive than the GAP for the EU representative use (1 x 75 g as/ha vs 2 x 130 g as/ha), the highest residue considered in the EU review is not relevant for this submission.
In the residue data supporting the proposed GAP for GF-3307 and presented in §7.2.3 the STMR for fenpicoxamid is 0.014 mg/kg (NEU) and the highest residue is 0.064 mg/kg (NEU), which is covered by the available processing data.

With regard to the four hydrolysis degradates X12019520, X12314005, X12335723, and X12264475, as agreed during the active substance approval process (United Kingdom, 2017[4]), the only instance in which one of these compounds was observed at a level ≥ 0.01 mg/kg was for X12264475 in gluten where it was observed at ≥ 0.01 mg/kg in 3 out of the total of 4 trials (0.010 mg/kg, 0.012 mg/kg and 0.014 mg/kg, with an average of 0.012 mg/kg across these three trials). In all other instances the hydrolysis degradates were either ND (<0.003 mg/kg) or <0.01 mg/kg. None of the hydrolysis degradates were found in grain (ND,

[3] DAR UK Vol.3 B7 2017-10-12
[4] DAR UK Vol.3 B7 2017-158-159

<0.003 mg/kg) and therefore no processing factors were calculated. X12335723 and X12314005 were not detected (ND, <0.003 mg/kg) in grain or any of the processed products. X12019520 was detected only in gluten and gluten feed meal and only at <0.01 mg/kg. In grain and in all other processed products other than gluten and gluten feed meal X12019520 was not detected (ND, <0.003 mg/kg). X12264475 was not detected (ND, <0.003 mg/kg) in grain, fine bran, refined white flour, white bread, wholemeal flour, or dried starch. X12264475 was detected, but only at levels below the LOQ (<0.01 mg/kg) in bran (coarse bran and total bran), gluten feed meal, wholemeal bread and wheat germ (only 1 trial out of 4 trials for both wholemeal bread and germ).
As only X12264475 was observed at ≥ 0.01 mg/kg and only in gluten at low level, and as gluten is not a food commodity used in risk assessment for consumers nor it is listed in Annex I of Regulation (EU) n°396/2005, **these four hydrolysis degradates do not need to be taken into account in the consumer risk assessment for GF-3307 and no further data are needed on these metabolites.**

Barley
New data are submitted in the framework of this application. All individual new studies submitted in the framework of this submission are reported and evaluated in Appendix 2.

7.2.5.1 Available data for all crops under consideration

Table 7.2-14: 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)					
Total bran	12	0.63; 0.64; 0.69; 0.7; 0.81; 0.89; 0.94;1.07; 1.14; 1.21; 1.25; 2.01	0.84		EFSA, 2018
Refined flour	12	0.16; 0.22; 0.25; 0.26; 0.29; 0.31; 0.32; 0.36; 0.38; 0.4; 0.41; 0.42	0.315		EFSA, 2018
Wholemeal flour	12	0.3; 0.31; 0.36; 0.39; 0.4; 0.44; 0.47; 0.5; 0.55; 0.59; 0.81; 0.96	0.455		EFSA, 2018
New Data					
Enforcement and Risk Assessment residue definition – Fenpicoxamid (XDE-777)					
Barley/ Cleaned grain	3 trials	0.96; 0.35; 0.91	0.74		Study/ Report no. S18-00056/ 170192.
Barley/ Malt sprouts	3 trials	0.45; 0.53; 1.18	0.72		
Barley/ Brewing malt	3 trials	0.30; 0.21; 0.46	0.32		
Barley/ Spent grain	3 trials	0.07; 0.04; 0.07	0.06		
Barley/ Flocs	3 trials	NA; NA; NA	NA		
Barley/ Brewer's yeast	3 trials	NA; NA; NA	NA		
Barley/ Beer	3 trials	NA; NA; NA	NA		
Barley/ Pot barley	3 trials	0.26; 0.09; 0.19	0.18		
Barley/ Barley bran	3 trials	0.63; 0.30; 0.85	0.60		
Barley/ Barley flour	3 trials	0.89; 0.48; 1.0	0.79		
Barley/ Bread	3 trials	0.42; 0.25; 0.57	0.42		

7.2.5.2 Conclusion on processing studies
The proposed uses for GF-3307 are covered by sufficient processing studies and no further data are required

for this application.

For barley:

The processing study provided in this submission was conducted at an exaggerated treatment rate GAP (2 applications at 252-266 g ai/ha or 2 x 500 g ai/ha) compared to the proposed use in Europe (1 application at 75 g ai/ha, up to BBCH 69).

Although residues of metabolites X642188, X12019520, X12314005, X12264475and X12335723 were observed in some processed fractions these are not of concern for risk assessment at the intended GAP. X642188 was not a major metabolite in the nature of processing study (JMPR 2018). Residues of all other metabolites were detected but when considering the registered GAP would be expected to be close, at or be below the LOQ (0.01 mg/kg).

However, estimates of metabolites residues in grain (X12264475, X12019520, 12314005, X1235723) under condition of baking/ brewing/ boiling (beer and barley grain/flour) are provided to allow consumer exposure assessment.

Beer: The processing study S18-00056/170192, provided in Appendix 2, allows metabolite estimates specifically in beer.

Commodities data relevant for risk assessment from processing study information

Sample	Commodity	Fenpicoxamid (mg/kg)	X12019520 (mg/kg)	X12314005 (mg/kg)	X12264475(mg/kg)	X1235723 (mg/kg)
		Molecular weight (MW)				
		614.64	188.2	276.3	256.1	356.3
		MW ratio				
		1	3.265887354	2.224538545	2.4	1.725063149
S18-00056-L2-013A	RAC Grain (prior to processing)	0.76	0.044	<LOQ (0.009)	0.043	0.024
S18-00056-L2-020A	Beer	ND	<LOQ (0.005)	ND	<LOQ (0.007)	ND
S18-00056-L2-037A	RAC Grain (prior to processing)	1.3	0.078	0.062	0.09	0.035
S18-00056-L2-044A	Beer	ND	<LOQ (0.009)	ND	0.014	<LOQ (0.004)
S18-00056-L2-061A	RAC Grain (prior to processing)	1.1	0.055	0.021	0.12	0.028
S18-00056-L2-068A	Beer	ND	0.016	ND	0.032	<LOQ (0.01)

Processing factors for relevant metabolites in beer

Sample	Commodity	X12019520	X12314005	X12264475	X1235723
S18-00056-L2-020A	Beer	0.007	0.004	0.009	0.004
S18-00056-L2-044A	Beer	0.007	0.002	0.011	0.003
S18-00056-L2-068A	Beer	0.015	0.003	0.029	0.009
Average processing factors		0.009	0.003	0.016	0.005

*Transfer factors (metabolite residue, processed commodity (beer) / parent residue, RAC)

Estimates of metabolites residues in beer

Residues (mg/kg) – Beer					
Average processing factors [a]	Parent	X12019520	X12314005	X12264475	X1235723
	NA*	0.009	0.003	0.016	0.005
Start with raw grain					

Initial parent residues in RAC (when treated according to GAP)	0.10 (STMR from Table 3.1.2 Overview of the available residue trials data)	NA	NA	NA	NA
Residues in beer for use in consumer risk assessment [b]	NA	**0.0009**	**0.0003**	**0.0016**	**0.0005**

* Not appropriate
a Processing factor = Residue in processed commodity (mg/kg) / parent residue in RAC (mg/kg); average of 3 processing trials (Second table of this section)
b STMR from Table 3.1.2 in this dossier, parent (mg/kg) x average processing factor

Barley grain/flour (baked/boiled): Estimates for metabolites in cooked barley grain are estimated from metabolites found in the raw grain plus metabolites that might be formed from parent residues during the baking/ boiling process.

Estimates of metabolites residues in cooked grain

Residues (mg/kg) – Baked grain					
MW	Parent	X12019520	X12314005	X12264475	X1235723
	614.64	188.2	276.3	256.1	356.3
Start with raw grain					
Initial residues in RAC (when treated according to GAP)	0.10 (STMR from Table 3.1.2 Overview of the available residue trials data)	0.0056 [a]	0.0026 [a]	0.0078 [a]	0.0028 [a]
Residues from % conversion seen in the NOR per metabolite in baking/brewing/boiling [b]	NA	0.0037	0.0214	0.0000	0.0443
Total metabolite residues for use in consumer risk assessment [c]	**NA**	**0.0093**	**0.0240**	**0.0078**	**0.0471**

* Not appropriate
a STMR, parent (mg/kg) x average ratio of metabolite residue to parent residue

		Ratio of metabolite residues to parent residues (no MW correction)*			
Sample	Commodity	X12019520	X12314005	X12264475	X1235723
S18-00056-L2-013A	RAC Grain (prior to processing)	0.058	0.012	0.057	0.032
S18-00056-L2-037A	RAC Grain (prior to processing)	0.130	0.030	0.340	0.020
S18-00056-L2-061A	RAC Grain (prior to processing)	0.060	0.048	0.069	0.027
	Average	**0.056**	**0.026**	**0.078**	**0.028**

*Metabolite residue/ parent residue
b STMR, parent (mg/kg) x (MW, metabolite / MW, paren)t x % Applied Radioactivity converted to metabolite during baking/brewing/boiling (60 min, 100 °C, pH 5 from EFSA EFSA Journal 2018;16(1):5146)

Processed commodities (standard hydrolysis study) **OECD Guideline 507**	**Conditions**	Fenpicoxamid	X12019520	X12314005	X12264475	X12335723
	20 min, 90°C, pH 4	87 (PH)-80% (PY)		10% (PH)		15% (PY)
	60 min, 100°C, pH 5	28 – PH)-19% (PY)	12.3% (PH)	48% (PH)		77% (PY)
	20 min, 120°C, pH 6		97% (PH)		18% (PY)	65% (PY)
PH: phenyl lable, PY: pyridine label						

c Initial residues (mg/kg) + Residues from % conversion seen in the NOR per metabolite in baking/brewing/boiling (mg/kg)

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

Wheat
The intended uses is less critical than the representative use (application rate of 130 g a.s./ha instead of 75 g a.s./ha). The four hydrolysis degradates (X12019520, X12314005, X12335723, and X12264475) do not need to be taken into account in the consumer risk assessment for GF-3307 and no further data are needed on these metabolites in this dossier.
zRMS-PL agrees with explanation presented by Applicant. The HR value observed for an application rate of 130 g a.s./ha is 0.55 mg/kg, whereas the HR value observed for the intended application rate of 75 g a.s./ha is 0.064 mg/kg, which is covered by the available processing data. Therefore, the derived processing factors can be used and no further data are deemed necessary.

Barley
The processing study was conducted at an exaggerated treatment rate GAP (2 applications at 252-266 g fenpicoxamid/ha or 2 x 500 g fenpicoxamid /ha) compared to the proposed use in N-EU (1 application at 75 g ai/ha, up to BBCH 69).
Residues of fenpicoxamid, its X642188 metabolite as well as the hydrolysis degradates X12019520, X12314005, X12264475 and X12335723 were determined.
Residues of fenpicoxamid in grain (residue) and its processed fractions (RAC grain (prior to processing), cleaned grain, malt sprouts, brewing malt, spent grain, flocs, brewer's yeast, beer, pot barley, barley bran, barley flour and bread) taken at normal commercial harvest for plot / treatment 2 were found to be between ND (not detected, <0.003 mg/kg) and 1.6 mg/kg .
Residues of X642188 in grain (residue) and its processed fractions (RAC grain (prior to processing), cleaned grain, malt sprouts, brewing malt, spent grain, flocs, brewer's yeast, beer, pot barley, barley bran, barley flour and bread) taken at normal commercial harvest for plot / treatment 2 were found to be between ND (not detected, <0.003 mg/kg) and 0.25 mg/kg.
Residues of X12019520 in grain (residue) and its processed fractions (RAC grain (prior to processing), cleaned grain, malt sprouts, brewing malt, spent grain, flocs, brewer's yeast, beer, pot barley, barley bran, barley flour and bread) taken at normal commercial harvest for plot / treatment 2 were found to be between <LOQ (0.005 mg/kg) and 0.078 mg/kg.
Residues of X12314005 in grain (residue) and its processed fractions (RAC grain (prior to processing), cleaned grain, malt sprouts, brewing malt, spent grain, flocs, brewer's yeast, beer, pot barley, barley bran, barley flour and bread) taken at normal commercial harvest for plot / treatment 2 were found to be between ND (not detected, <0.003 mg/kg) and 0.062 mg/kg.
Residues of X12264475 in grain (residue) and its processed fractions (RAC grain (prior to processing), cleaned grain, malt sprouts, brewing malt, spent grain, flocs, brewer's yeast, beer, pot barley, barley bran, barley flour and bread) taken at normal commercial harvest for plot / treatment 2 were found to be between ND (not detected, <0.003 mg/kg) and 0.21 mg/kg.
Residues of X1235723 in grain (residue) and its processed fractions (RAC grain (prior to processing), cleaned grain, malt sprouts, brewing malt, spent grain, flocs, brewer's yeast, beer, pot barley, barley bran, barley flour and bread) taken at normal commercial harvest for plot / treatment 2 were found to be between ND (not detected, <0.003 mg/kg) and 0.16 mg/kg.

Calculated processing factors don't show concentration of fenpicoxamid and its metabolites after all processing steps. No further data are deemed necessary.
More details of the processing study S18-00056/170192 is provided in Appendix 2.

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)

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of GF-3307. Therefore, other special studies are not needed.

Effect on the residue level in pollen and bee product

Barley and wheat, rye, triticale are primarily self-pollinated plants and have no melliferous capacity (SANTE/11956/2016 rev. 9, 14 September 2018). Therefore, the proposed use of XDE-777 in these crops is expected to have little potential for contributing residues to bee products. However, in order to support the intended and most critical uses of XDE-777 on melliferous crops, a honey MRL is proposed for fenpicoxamid. For that, data on residue levels in aerial part 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 was submitted to provide data in aerial parts of the plant for honey MRL (evaluation ongoing). 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.

An MRL for honey, based on the highest nectar residues of fenpicoxamid from the semi-field residue trials submitted, is 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:
RMS-UK concluded in DAR, Vol. 3 - B.7 (2017) that "*EFSA Guidance on the risk assessment of plant protection products on bees (pages 121, 124, 125) indicates that wheat, rye and triticale are not attractive to bees as sources of pollen and nectar. Therefore, it can be reasonably assumed that residues will not be taken up by bees nor found in pollen and bee products for human consumption according to the intended uses. No further studies or data are required."*
However, EFSA concluded in EFSA Journal 2018;16(1):5146 that *"Although wheat, rye and triticale's are considered low attractive to bees for pollen/nectar, their collection cannot be excluded without data. Therefore,*

the determination of fenpicoxamid residues in pollen and bee products for human consumption resulting from residues taken up by honeybees from wheat, rye and triticale's at blossom have to be provided (data gap)."

zRMS agrees with Applicant's statement that the proposed uses of GF-3307 in cereals are expected to have little potential for contributing residues to bee products. This is in line with the technical guidelines SANTE/11956/2016 rev. 9, 14 September 2018.
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)

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

7.2.8.1 Input values for the consumer risk assessment

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

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: Fenpicoxamide (XDE-777)				
Wheat, Rye, Triticale	0.047	STMR (EFSA, 2018)	0.047	STMR (EFSA, 2018)
Barley	0.8	EU MRL evaluation (ongoing)	0.8	EU MRL evaluation (ongoing)
Oats				
Cattle (all diets)		EU MRL (EFSA, 2018)		
Fat	0.01			
Liver	0.01			
Kidney	0.02			
Sheep (all diets)				
Fat	0.01			
Liver	0.02			
Kidney	0.02			
Bananas (imported)	0.15			

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: Fenpicoxamid (XDE-777)				
All commodities	MRL	Regulation (EU) 2019/50	-	-
Wheat, Rye, Triticale			0.064	HR current dossier

A copy of the Excel spreadsheet displaying the PRIMo calculation results is attached in Appendix 3 and the main results summarised in this section.

~~Estimates of potential exposure to fenpicoxamid using EFSA PRiMo V.3.1 show potential long term dietary exposure to be ≤ 3% of the ADI for all dietary sub-populations. The NL toddler predicted the highest intake values of 3% of the ADI.~~

~~Estimates of potential exposure to fenpicoxamid using EFSA PRiMo V.3.1 show potential short term dietary exposure to be ≤ 0.2% of the ARfD for all dietary sub-populations. The highest barley intake value was 0.2% of the ARfD.~~

Dietary Assessment of Four Hydrolysis Degradates (X12019520, X12314005, X12264475 X12335723)

The predicted genotoxic potential of Fenpicoxamid and its plant metabolites X12335723, X12264475, X12314005, and X12019520 was evaluated by *in silico* means using Derek Nexus, OASIS Times, Leadscope, and OECD QSAR Toolbox software packages (Ship, 2019).

Overall, the *in silico* predictions for fenpicoxamid and its plant metabolites X12335723, X12264475, X12314005, and X12019520 indicate that there is no likelihood of a genotoxic outcome.

In addition, genotoxicity studies, Ames and in vitro Micronucleus, have been conducted with X12264475, X12314005, and X12019520 and results were negative in both genotoxicity studies for each of the listed hydrolysis degradates. Genotoxicity studies, Ames and in vitro Micronucleus, are being generated with X12335723. Final reports will be available by end 2021.

All available study reports are presented in dRR B6 A 2.13.

A further dietary assessment using EFSA PRIMo V.3.1 has been conducted on the four identified hydrolysis degradates X12019520, X12314005, X12264475 and X12335723 of fenpicoxamid. An estimation of total metabolite residues in cooked grain and beer has been calculated and is summarised in Table 7.2-15 and further detailed in 7.2.5.2. An estimation of dietary exposure to each metabolite has been conducted and detailed in Appendix 3.

Table 7.2-15 Metabolite residues in cooked grain and beer for each hydrolysis degradate

MW	Parent	X12019520	X12314005	X12264475	X1235723
	614.64	188.2	276.3	256.1	356.3
Total metabolite residues for use in consumer risk assessment	**--**	**0.0093**	**0.0240**	**0.0078**	**0.0471**
Residues in beer for use in consumer risk assessment	**NA**	**0.0009**	**0.0003**	**0.0016**	**0.0005**

Threshold of Toxicological Concern (TTC)

A number of guidance documents and scientific opinions published by EFSA on the use and application of the Threshold of Toxicological Concern (TTC) are available (EFSA, 2012; 2016; 2019) and have been followed in order to assess the potential dietary risk to the four identified hydrolysis degradates.

A number of considerations have been summarised below in order to confirm whether the use of the TTC is appropriate for each metabolite and which threshold value should be assigned to each metabolite.

- Are the substances part of the exclusionary categories? NO
- Are there structural alerts for each metabolite that raises concern for potential genotoxicity? NO (see Genotox assessment section 2.8 and C.2.1)
- Are the compounds organophosphates? NO
- Are the compounds in Cramer structural class III? YES

(A surrogate toxicological reference value for each metabolite is based on a Cramer class assessment conducted using the ToxTree software).

- Does estimated intake for each metabolite exceed the TTC of 1.5 µg/person/day? NO

(See Table 7.2-16)

Table 7.2-16 Summary of calculated exposure expressed as % TTC for each hydrolysis degradate

	X12019520	X12314005	X12264475	X1235723
Calculated chronic exposure (% TTC) EFSA PRIMo v3.1	**0.6%**	**1%**	**0.5%**	**3%**
Calculated Acute Exposure (% TTC) EFSA PRIMo v3.1	**3%**	**9%**	**3%**	**18%**

The long-term and short-term estimated intake of residues of X12019520, X12314005, X12264475, X1235723 do not exceed the TTC threshold of 1.5 µg/person/day and would therefore not be expected to be a dietary safety concern. A copy of the Excel spreadsheet displaying the PRIMo calculation results is located in Appendix 4.

7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.2-16: Consumer risk assessment

~~TMDI (% ADI) according to EFSA PRIMo~~	~~3% (based on NL toddler)~~
~~IEDI (% ADI) according to EFSA PRIMo~~	~~N/A~~
~~IESTI (% ARfD) according to EFSA PRIMo*~~	~~Barley: 0.2% (based on children)~~ ~~Wheat: 0.04% (based on children)~~
~~NTMDI (% ADI) **~~	~~N/A~~
~~NEDI (% ADI)**~~	~~N/A~~
~~NESTI (% ARfD) **~~	~~N/A~~

TMDI (% ADI) according to EFSA PRIMo	13% (based on DK child)
IEDI (% ADI) according to EFSA PRIMo	N/A
IESTI (% ARfD) according to EFSA PRIMo*	Wheat: 0.05% (based on children)
NTMDI (% ADI) **	N/A
NEDI (% ADI)**	N/A
NESTI (% ARfD) **	N/A

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

The proposed uses of fenpicoxamid in the formulation GF-3307 do not represent unacceptable acute and chronic risks for the consumer.

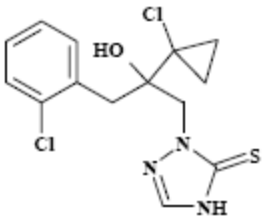
Evaluator comment:
The calculation of the TMDI using EFSA model (version 3.1) and MRLs values according to the Regulation (EU) 2019/50 led to a utilisation of the ADI of 13% with the DK child being the population group with the highest value. For this diet, the highest contributor is rye with 7% of the ADI. The intended 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 wheat, rye, triticale. The highest International Estimated Short-Term Intake (IESTI) is at 0.05% and 0.03% of the ARfD for the consumption of wheat by children and by adults respectively.

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

General data on prothioconazole are summarized in the table below (last updated 2007/12/10)

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)	~~UK~~ 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 (EC) No 834/2013~~ Regulation (EU) 2019/552
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
Current MRL applications on intended uses	No

7.3.1 Stability of Residues (KCA 6.1)

7.3.1.1 Stability of residues during storage of samples

No new data submitted in the framework of this application.

Available data

Table 7.3-2: Summary of stability data (Prothioconazole-desthio) 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 (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* **			

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
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 (2018b); 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.

~~**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. 2020b* M-681477-01-1, Report S19-01125 Appendix 2~~
~~**T, TA, TAA and TLA**~~			
~~**Honey**~~			
~~Honey~~	~~Honey~~	~~5 months at -18 °C~~	~~Kalathoor, R. 2020c* M-680825-03-1, Report S19-01126 Appendix 2~~

~~*Owned by Bayer~~

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. This is longer than the longest period of time for which samples from the field residue trials on cereals presented in this report were stored prior to analysis. 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. The least stable is 1,2,4-T in high water content matrices (6 months). For cereal straw and grain the storage time covered for 1,2,4-T is 12 months. It is noteworthy to add that in the particular case of prothioconazole, 1,2,4-T is not a plant metabolite (primary or rotated crops). This has been observed in the metabolism studies and confirmed by residue data where the samples have been analysed within the period covered by the storage stability data (primary crops). ~~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.
Studies on the storage stability of prothioconazole and its metabolite in crop and animal tissues under frozen conditions were assessed in the framework at the EU level.
Residues of prothioconazole-desthio are stable for 18 months under deep-freeze storage in high water content matrices (wheat green matter), dry commodities (cereal grain) and straw and for 24 months at – 18 °C in commodities with high water content (spinach, sugar beet, tomatoes), high oil content (canola seeds), dry commodities (dried peas) and canola straw.

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

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.

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 cereals.

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 7.3-5: 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.

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).

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 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 7.3-6: 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.

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).

zRMS comments:

Information given by the Applicant is acceptable and sufficient.

In EFSA Journal 2020;18(2):5999 it is stated that *The metabolism of prothioconazole in rotational crops was investigated in the framework of the EU pesticides peer review in Swiss chards, turnips and spring wheat following the treatment of bare soil with prothioconazole at an application rate of 580 g/ha using the compound labelled in the phenyl ring. The main compounds identified were prothioconazole-desthio and its hydroxylated derivative metabolites, either free or conjugated.*

The MRL review concluded that metabolism of prothioconazole in primary and rotational crops was found to be similar and a specific residue definition for rotational crops is not necessary (EFSA, 2014).

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

It was concluded that for TDMs similar metabolic patterns were depicted both in primary and rotational crops (EFSA, 2018b).

Triazole Derivate Metabolites, addendum – confirmatory data (UK, 2018)
"For the rotational crops, metabolism data are available on leafy crops, root crops and cereal grain and straw for a total of 12[5] 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 7.3-7: 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)

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.

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,*

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

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 7.3-8: 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.
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 and Reg. (EU) 2019/552)
Plant residue definition for risk assessment	RD-RA1) 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 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 7.3-9: 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 (Weber, 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 (Weber, 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 (Weber, 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

						Muscle (leg and breast)	at sacrifice	(Weber, 2003, MEF-005/03)
						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 (Weber, 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 been 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 7.3-10: 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)
Animal residue definition for risk assessment	RD-RA1) 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	~~Milk: 10~~ ~~Liver: 2~~ ~~Muscle: 10~~ ~~Kidney: 2~~ ~~Fat: 4~~ - 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

Wheat

The MRL for prothioconazole in wheat is based on a critical GAP of three applications at a rate of 200 g ai/ha with 14 days interval between applications and the third application at growth stage BBCH 69. The evaluation leading to the current MRL for prothioconazole in wheat is presented in the EFSA Reasoned Opinion (EFSA Journal 2014;12(5):3689). The critical GAP upon which the EU MRL for prothioconazole was set covers the use of GF-3307 proposed in this submission.

Sufficient trials on wheat were previously presented and evaluated in the EFSA reasoned opinion of 2014. A summary of the residue trial data for wheat is provided in the Table below.

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application for GF-3307. These studies are summarized in the Table below and the detailed assessment is presented in Appendix 2. The GAP proposed for GF-3307 results in a total maximum application rate for prothioconazole that is lower than the rate upon which the EU MRL is based (1 x 150 g ai/ha vs 3 x 200 g ai/ha). Consequently, the existing EU MRL of 0.10 mg/kg for prothioconazole and the associated critical GAP upon which it is based fully covers the proposed GAP for GF-3307 in this submission with regard to prothioconazole and will not lead to residues exceeding the established EU MRL.

Barley

The GAP proposed for GF-3307 results in a total maximum application rate for Prothioconazole that is lower than the rate upon which the EU MRL is based (1 x 150 g ai/ha vs 2 x 200 g ai/ha). Both GAPs (GAP for GF-3307 vs GAP for representative use for EU MRL approval) foresee the final application no later than BBCH 69. Consequently, the existing EU MRL of 0.2 mg/kg for Prothioconazole in barley covers the GAP proposed for GF-3307 in this submission with regard to Prothioconazole. Intended uses of GF-3307 will not lead to residues exceeding the proposed EU MRL.

Sufficient trials on barley were previously presented and evaluated in the EFSA reasoned opinion of 2014.
New magnitude of residue studies conducted with GF-3307 and are submitted in the framework of this application at a more critical GAP and at the intended GAP rate for GF-3307. These studies are summarized in the Table below and the detailed assessment is presented in Appendix 2.

Table 7.3-11: Summary of EU reported and new prothioconazole-desthio residue data supporting the intended uses of GF-3307 and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Prothioconazole-desthio Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Wheat grain Rye grain	UK, 2005 EFSA, 2007	N-EU (10)	*Trials GAP: 3 x 200 g a.s./ha, BBCH 69, PHI 35-64 d, outdoor* E = RA: 10x <0.01 RA: no data on prothioconazole-hydroxy-desthio	0.01 CF c: 2.0	0.01 CF c: 2.0	0.01	Wheat 0.10 Rye 0.05	Yes
	New Trials on GF-3307, Study S14-01568 and S15-02629	N-EU (10)	*Trials GAP: 2 x 200 g as/ha, Appl. interval 14d, 2nd appl. at BBCH 69, outdoor* E = RA: 6x <0.01x4, 0.012, 0.013, 0.02, 0.023 RA: no data on prothioconazole-hydroxy-desthio	0.01	0.023	0.032	Wheat 0.10; Rye 0.05	Yes
	New Trials Study S18-01566	N-EU (2)	*Trials GAP: 1 x 150 g as/ha. at BBCH 55, outdoor* E = RA: 2 < 0.01 RA: no data on prothioconazole-hydroxy-desthio	0.01	0.01	0.01	Wheat 0.10; Rye 0.05	Yes
	~~UK, 2005 EFSA, 2007~~	~~S-EU (8)~~	~~*Trials GAP: 3 x 200 g a.s./ha, BBCH 67-7169, PHI 28-356 d, outdoor* E = RA: 8x <0.01~~	~~0.01~~	~~0.01~~	~~0.01~~	~~Wheat 0.10 Rye 0.05~~	~~Yes~~
Wheat straw Rye straw	UK, 2005 EFSA, 2007	N-EU (10)	*Trials GAP: 3 x 200 g a.s./ha, BBCH 69, PHI 35-64 d, outdoor* E = RA: 0.08, 0.09, 0.11, 0.14, 0.15, 0.19, 0.20, 0.27, 0.31, 0.72	0.17 CF c: 3.0	0.72 CF c: 3.0	-	-	-
	New Trials on GF-3307, Study S14-01568 and S15-02629	N-EU	*Trials GAP: 2 x 200 g as/ha, Appl. interval 14d, 2nd appl. at BBCH 69, outdoor* E = RA: 0.110, 0.302, 0.353, 0.420, 0.740, 0.851, 0.860, 0.870, 0.942, 1.223	0.796	1.223	-	-	-
	~~UK, 2005 EFSA, 2007~~	~~S-EU (8)~~	~~*Trials GAP: 3 x 200 g a.s./ha, BBCH 67-7169, PHI 28-356 d, outdoor* E = RA: 0.25, 0.42, 0.47, 0.52, 0.53, 0.72, 0.77, 1.00~~	~~0.525~~	~~1.00~~	~~-~~	~~-~~	~~-~~

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Prothioconazole-desthio Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Barley grain	DAR, 2004 EFSA, 2007, EFSA, 2014 [b]	N-EU	*GAP on which MRL/EU a.s. assessment is based: SPI 2 x 200 g a.s./ha alone, BBCH61 outdoor* E: 11x<0.01; 0.01; 0.02 RA: no data	E: 0.01 CF [c]: 2.0	E: 0.02 CF [c]: 2.0	0.02	0.2	Yes
	New Trials on GF-3307, Report no. S17-01904/ 170191**		*Trials GAP: 2 x 200 g as/ha, Appl. interval 14d, 2nd appl. at BBCH 69, outdoor* E: 4 x < 0.01; 0.01; 0.02; 0.07; 0.13 RA: -	E: 0.01	E: 0.13	E: 0.20	E: 0.20	Yes
	New Trials on GF-3307, Report no. 180128	N-EU	*Trials GAP: 1 x 150 g ai/ ha, application up to BBCH 65* E : 2 x < 0.01 RA: -	0.01	0.01	0.01	0.2	Yes
Barley straw	DAR, 2004 EFSA, 2007, EFSA, 2014 [b]	N-EU	*GAP on which MRL/EU a.s. assessment is based: SPI 2 x 200 g a.s./ha alone, BBCH61 outdoor* E: 0.05; 0.08; 2x0.1; 0.11; 2x0.13; 2x0.14; 0.30; 0.36; 0.56 RA: no data	E: 0.13 CF [c]: 3.0	E: 0.56 CF [c]: 3.0	0.78	-	Yes
	New Trials on GF-3307, Report no. S17-01904/ 170191**	N-EU	*Trials GAP: 2 x 200 g as/ha, Appl. interval 14d, 2nd appl. at BBCH 69, outdoor* E: 0.08; 0.21; 0.42; 1.00; 1.04; 1.41; 1.57; 1.58 RA: -	E: 1.02	E: 1.58	-	-	-

* Source of EU MRL: Reg. (EU) 834/2013

[a] SPI: spray

[b] Trials on barley: Bayer references RA-2150/98 (M-073128-02-1), RA-2140/98 (M-072786-02-1), RA-2101/00 (M-086237-01-1), RA-2079/98 (M-075011-01-1), RA-2144/98 (M-072984-02-1), RA-2103/00 (M-086807-01-1), RA-2107/03 (M-060760-01-1), RA-2328/06 (M-294779-02-1), RA-2039/07 (M-298114-03-1)

[c] The median conversion factor for enforcement to risk assessment has been obtained on the basis of the available metabolism studies on cereals after foliar treatment (grain, straw).

**According to the OECD calculator, samples collected from trial S17-01904-15 (study 170191) were outliers, yielding substantially higher residues of fenpicoxamid and prothioconazole than the other trials. Further investigation identified a deviation in sample collection at normal commercial harvest; retain samples could not be collected due to insufficient plant material. The plants at this site were among the smallest at application 2, with zero growth reported between application and harvest, indicating poor crop performance across this site. This site was also among the shortest PHI. In summary, reduced biomass, a reduced growth rate, and a short PHI likely contributed to higher residues. The plants in this trial were not considered to be commercially acceptable to have been sprayed and the generated results are not considered representative of normal agronomic practices. Therefore, residues from trial S17-01904-15 are excluded from all discussions.

Triazole Derived Metabolites

The results for cereal grain and straw of EU previously evaluated trials are presented in the tables below.

Table 7.3-12: Summary of EU reported data regarding TDMs supporting the intended uses

Wheat

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Trial GAP Residue levels (mg/kg)	STMR (mg/kg)	HR (mg/kg)
Wheat grain	Confirmatory data (UK 2018)	N-EU	**3 x 0.1875 kg a.s./ha, up to BBCH 71** 1,2,4 T: 4 x <0.010 TA: 0.332, 0.586, 0.684, 1.069 TAA: 0.138, 0.230, 0.243, 0.517, TLA: not analysed	1,2,4 T: 0.010 TA: 0.434 TAA: 0.189 TLA: not analysed	1,2,4 T: 0.010 TA: 1.069 TAA: 0.517 TLA: not analysed
	Confirmatory data (UK 2018)	S-EU	**3 x 0.1875 kg a.s./ha, up to BBCH 71** 1,2,4 T: 4 x <0.010 TA: 0.042, 0.236, 0.400, 0.469 TAA: 0.011, 0.111, 0.148, 0.257 TLA: not analysed		
Wheat straw	Confirmatory data (UK 2018)	N-EU	**3 x 0.1875 kg a.s./ha, up to BBCH 71** 1,2,4 T: 4 x <0.050 TA: 3 x <0.050, 0.079 TAA: <0.05, 0.067, 0.078, 0.307 TLA: not analysed	1,2,4 T: 0.050 TA: 0.050 TAA: 0.058 TLA: not analysed	1,2,4 T: 0.050 TA: 0.079 TAA: 0.307 TLA: not analysed
	Confirmatory data (UK 2018)	S-EU	**3 x 0.1875 kg a.s./ha, up to BBCH 71** 1,2,4 T: 4 x <0.050 TA: 3 x <0.05, 0.066 TAA: 3 x <0.05, 0.172 TLA: not analysed		

Barley

STMRs and HRs for the triazole derived metabolites in barley of TDMs

Commodity	Source	GAP	No of Trials	STMR (mg/kg)				HR (mg/kg)			
				1,2,4-T	TA	TAA	TLA	1,2,4-T	TA	TAA	TLA
Barley grain	UK, 2018[a]; EFSA, 2018[b] (1)	SPI 2 x 150 g a.s./ha (8 trials) SPI 2 x 200 g a.s./ha (4 trials, grain only). BBCH61 outdoor	12* (8NEU + 4SEU)	0.01	0.208	0.107	0.010	0.011	0.440	0.320	0.010
Barley straw			8 (4NEU + 4SEU)	0.05	0.050	0.057	NA	0.050	0.050	0.136	NA

Note: For the calculation of the STMRs and HRs the residue values measured in the control samples were taken into account whenever they exceeded the values measured in the corresponding treated samples. The STMRs were calculated based on the highest residue levels from each trial. * 4 trials for TLA.

(1) Trials on barley from 2006 and 2007: RA-2328/06 (M-294779-02-1); RA-2329/06 (M-294526-01-1); MR-09/110 (M-354958-03-1); RA-3669/07 (M-303475-01-1); P 1747 G (M-356425-01-1).

[a] 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. Available online (EFSA website)

[b] EFSA (European Food Safety Authority), 2018. Conclusion on the peer review of the pesticide risk assessment for the triazole derivative metabolites in light of confirmatory data submitted. EFSA Journal 2018;16(7):5376, 20 pp. https://doi.org/10.2903/j.efsa.2018.5376

In order to have sufficient data on cereal grain and straw that complies with the storage stability times coverage (in particular for 1,2,4-triazole athough it is not a metabolite of prothioconazole), new trials from 2016 and 2017 that support the representative uses and that were not previously EU evaluated are summarised below. Although prothioconazole-desthio residues were determined in these trials, only the results for the TDMs will be presented below, as the results for prothioconazole-desthio and metabolites do not have an impact on the current risk assessment (they do not lead to higher residues than those evaluated during the Article 12 MRL review of prothioconazole (EFSA, 2014); Nevertheless, they were submitted to EFSA during the request for additional information phase of the procedure for renewal of the approval of prothioconazole).

Highest STMRs and HRs for the triazole derived metabolites in cereal commodities from triazole uses (UK, 2018)

Commodity	STMR (mg/kg)				HR (mg/kg)			
	1,2,4-T	TA	TAA	TLA	1,2,4-T	TA	TAA	TLA
Grain	0.05	0.621	0.790	0.022	0.080	2.200	1.730	0.160
Straw	NR	NR	NR	NR	0.05	0.65	0.78	1.1

NR: not reported

Therefore, as the exposure to the TDMs is much lower with the prothioconazole uses, there is no need to perform dietary burden calculations (from residues of TDMs in feed) nor 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 on barley.

7.3.3.2 Conclusion on the magnitude of residues in plants

According to the available data, the intended uses on wheat, rye, triticale and barley are considered acceptable, for outdoor uses.

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

TDMs
Triazole derivative metabolites (TDMs) are common metabolites of all triazole fungicides and have to be considered in the consumer risk assessment. The data on TDMs provided in the present application are from the "Triazole Derivate Metabolites addendum – confirmatory data prepared by the rapporteur Member State, the United Kingdom" (UK, 2018). As confirmatory data, they are out of data protection. Results for TDMs presented by UK (2018) were considered for livestock and consumer exposure.
No additional studies are required.

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

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

Additionally 2 new magnitude of residue studies were submitted in the framework of this application (S14-01568 & S15-02629), conducted with a higher total rate than the proposed cGAP for GF-3307.
Summary is presented below.

Table 1: Comparison of intended and critical EU GAPs for wheat

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (EFSA 2018)	3	200 g prothioconazole/ha	14 days	BBCH 69	35
Intended cGAP	1	150 g prothioconazole/ha	NA	BBCH 69	F

1. Report No. S15-02629, DAS Study ID 150649
Six N-EU trials were conducted in accordance with the following GAP: 2 x 200 g a.s. /ha, instead of 1 x 150 g a.s./ha; application interval - 14 days, 2nd application at BBCH 67-69, outdoor.

Residues of prothioconazole-desthio in grain taken at normal commercial harvest ranged from ND (not detected, <0.003 mg/kg) to 0.023 mg/kg.
Residues of prothioconazole-desthio in straw taken at normal commercial harvest ranged from 0.302 to 0.942 mg/kg.

2. Report No. S14-01568, DAS Study ID 140649

Four N-EU trials were conducted in accordance with the following GAP: 2 x 200 g a.s. /ha, instead of 1 x 150 g a.s./ha; application interval - 14 days, 2nd application at BBCH 69, outdoor.

Residues of prothioconazole-desthio in grain taken at normal commercial harvest for plot /treatment 2 ranged from ND (not detected, <0.003 mg/kg) to 0.011 mg/kg.
Residues of prothioconazole-desthio in grain taken at normal commercial harvest for plot /treatment 3 ranged from ND (not detected, <0.003 mg/kg) to 0.007 mg/kg.
Residues of prothioconazole-desthio in straw taken at normal commercial harvest for plot /treatment 2 ranged from 0.157 to 1.293 mg/kg.
Residues of prothioconazole-desthio in straw taken at normal commercial harvest for plot /treatment 3 ranged from 0.132 to 1.153 mg/kg.

Plot 2 and 3 of Study S14-01568 were conducted side by side. The results were therefore combined and the mean was retained (see Table 7.3-11).
All available N-EU trials were conducted in accordance with the following GAP: 2 x 200 g a.s. /ha application with interval of 14 days, instead of 1 x 150 g a.s./ha. This can be considered the worst case.

3. Report No. S18-01566, DAS Study ID 180126
Two N-EU trials were conducted in accordance with the following GAP: 1 x 150 g a.s. /ha, application at BBCH 55, outdoor.
Residues of prothioconazole-desthio in grain taken at normal commercial harvest were ND (not detected, <0.003 mg/kg).

Available results show that the in force MRL of prothioconazole on wheat of 0.1 mg/kg and on rye of 0.05 (Reg. (EU) 2019/552) will not be exceeded. The current EU MRL for prothioconazole is sufficient to support the proposed uses.
The trials are supported by valid storage stability data and validated analytical methods.

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

Barley
Barley is the major crop in northern Europe (SANTE/2019/12752). A minimum of eight trials are required.
Sufficient trials on barley conducted according to the residue definition for monitoring only (trials measuring levels of prothioconazole-desthio only) were previously presented and evaluated (DAR, 2007). There are no data on prothioconazole-hydroxy-destio in the DAR (2007).

Table 2: Comparison of intended and critical EU GAPs for barley

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (EFSA 2007) prothioconazole	1-2	200 g prothioconazole/ha	14 days	start 30 up to BBCH 61 (interval 14 -21 d)	35
Intended cGAP	1	150 g prothioconazole/ha	NA	BBCH 69	F

According to the EFSA Scientific Report (2007) 106, 1-98, the results for barley are:
Grains: 9 x < 0.01 mg/kg,
Straw: 0.05, 0.08, 2 x 0.10, 2x 0.13, 2 x 0.14, 0.30 mg/kg.

Two new magnitude of residue studies were submitted in the framework of this application: study S17-01904/ 170191 conducted with a higher total rate than the proposed cGAP for GF-3307 and study S18-01567/ 180128 conducted according to the intended GAP.

Summary
1. Report no. S17-01904/ 170191
Eight N-EU trials were conducted in accordance with the following GAP: 2 x 200 g a.s. /ha, instead of 1 x 150 g a.s./ha; application interval - 14 days, 2nd application at BBCH 69, outdoor.
In seed specimens taken at normal commercial harvest residues of prothioconazole-desthio were between ND and

0.13 mg/kg.
Residues of prothioconazole-desthio in straw taken at normal commercial harvest ranged from 0.21 to 1.58 mg/kg.

Applicant provided following explanation for this study:
According to the OECD calculator, samples collected from trial S17-01904-15 (study 170191) were outliers, yielding substantially higher residues of fenpicoxamid and prothioconazole than the other trials. Further investigation identified a deviation in sample collection at normal commercial harvest; retain samples could not be collected due to insufficient plant material. The plants at this site were among the smallest at application 2, with zero growth reported between application and harvest, indicating poor crop performance across this site. This site was also among the shortest PHI. In summary, reduced biomass, a reduced growth rate, and a short PHI likely contributed to higher residues. The plants in this trial were not considered to be commercially acceptable to have been sprayed and the generated results are not considered representative of normal agronomic practices. Therefore, residues from trial S17-01904-15 are excluded from all discussions.
We agree with the Applicant's proposal to exclude the results of the residue from trial S17-01904-15 from all discussions.

2. Report no. S18-01567/ 180128
Two N-EU trials were conducted in accordance with the intended GAP: 1 x 150 g a.s. /ha at a different growth stage (lot 2 was applied at BBCH 32, Plot 3 at BBCH 37-39, Plot 4 at BBCH 45, plot 5 at BBCH 51-61 and plot 6 at BBCH 55-65). In all trials specimens of the crop from the untreated and treated plots were taken at normal commercial harvest (NCH).
In seed specimens taken at normal commercial harvest residues of prothioconazole-desthio were below LOQ.

Storage periods of residue samples covered by available storage stability studies.
Available results show that the in force MRL of prothioconazole on barley of 0.2 mg/kg (Reg. (EU) 2019/552) will not be exceeded. The current EU MRL for prothioconazole is sufficient to support the proposed use.

The proposed use on barley is 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.

Table 7.3-13: Input values for the dietary burden calculation

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: Sum of JAU 6476-desthio and all metabolites containing the 2-(1-chloro-cyclopropyl)-3-(2- chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety) expressed as JAU 6476-desthio				
Head cabbage	0.02	Median residue x CF (EFSA, 2014)	0.12	Highest Residue x CF (EFSA, 2014)
Maize silage	0.01	Median residue (EFSA, 2014)	0.01	Highest Residue (EFSA, 2014)
Maize grain	0.01	Median residue (EFSA, 2014)	0.01	Median Residue (EFSA, 2014)
Barley, oats, rye and wheat grain	0.02	Median residue x CF (EFSA, 2014)	0.02	Median Residue x CF (EFSA, 2014)
Barley and oats straw	1.25	Median residue x CF (EFSA, 2014)	7.50	Highest Residue x CF (EFSA, 2014)
Wheat straw	2.24	Median residue x CF (EFSA, 2014)	7.20	Highest Residue x CF (EFSA, 2014)
Rye straw	0.60	Median residue x CF (EFSA, 2014)	4.80	Highest Residue x CF (EFSA, 2014)
Peas and beans (dry)	0.02	Median residue x CF	0.02	Median Residue x CF

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
		(EFSA, 2014)		(EFSA, 2014)
Potato	0.01	Median residue (EFSA, 2014)	0.01	Highest Residue (EFSA, 2014)
Carrot, Turnip and swedes	0.06	Median residue x CF (EFSA, 2014)	0.10	Highest Residue x CF (EFSA, 2014)
Turnips tops	0.59	Median residue x CF (from carrot tops, EFSA 2010)	0.93	Highest Residue x CF (from carrot tops, EFSA 2010)
Cotton seed	0.104	STMR x CF(2) (EFSA, 2018a)	0.104	STMR x CF(2) (EFSA, 2018a)
Rape seed meal	0.12	Median residue x CF x 2 (EFSA, 2014)	0.12	Median residue x CF x 2 (EFSA, 2014)
Linseed meal	0.12	Median residue x CF x 2 (EFSA, 2014)	0.12	Median residue x CF x 2 (EFSA, 2014)
Sunflower meal	0.04	Median residue x CF x 2 (EFSA, 2015c)	0.04	Median residue x CF x 2 (EFSA, 2015)
Soybean seed	0.10	Median residue x CF (EFSA, 2015a)	0.10	Median residue x CF (EFSA, 2015a)
Potato	0.01	Median residue (EFSA, 2014)	0.01	Highest Residue (EFSA, 2014)
Sugar beet dried pulp	0.01*	Median residue	N/A	
Sugar beet ensiled pulp	0.01*	Median residue		
molasses	0.01*	Median residue		

The animal dietary burdens have to be estimated considering the OECD feedstuff tables and OECD approaches presented in the Guidance Document on Residues in Livestock, No. 73. The estimated dietary burden of prothioconazole-related residues based on EU crop residue data and the European diet in the OECD feeding tables is presented in the table below.
In the following table, the results of the dietary burden calculation, which expresses the burden which may arise from all authorised uses of prothioconazole, are summarised following the guidance described in the OECD Guidance Document on Residues in Livestock (ENV/JM/MONO(2013)8 dated Sept 2013) and using the Excel spreadsheet dated of 2017 available in the EU Commission website (pesticides_mrl_guidelines_animal_model_2017.xls).
As evident from the calculations above, the trigger value of 0.004 mg/kg bw/day and the threshold of 0.1 mg/kg DM are exceeded for all animals.

Table 7.3-14: Results of the dietary burden calculation

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Risk assessment residue definition: Sum of JAU 6476-desthio and all metabolites containing the 2-(1-chloro-cyclopropyl)-3-(2- chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety) expressed as JAU 6476-desthio					
Beef cattle*	0.038	0.084	Barley straw	3.49	Y
Dairy cattle*	0.066	0.125	Barley straw	3.24	Y
Ram/ewe	0.060	0.191	Barley straw	5.70	Y
Lamb	0.066	0.238	Barley straw	5.59	Y
Breeding swine	0.014	0.019	Potato process waste	0.82	Y
Finishing swine*	0.012	0.017	Soybean hulls	0.57	Y
Broiler poultry	0.012	0.015	Swede roots	0.21	Y
Layer poultry*	0.028	0.069	Wheat straw	1.01	Y
Turkey	0.010	0.013	Swede roots	0.18	Y

Triazole Derived Metabolites (dietary burden)

TDMs from TDMs in feed items

As the exposure to the TDMs is much lower (see section 7.3.3) with the prothioconazole uses than the exposure evaluated during the Peer Review on the pesticide risk assessment for the triazole derivative metabolites in light of confirmatory data submitted (EFSA, 2018b, UK 2018) there is no need to perform dietary burden calculations for these metabolites in feed in this dossier. The exposure levels of livestock to the TDMs in feed (from prothioconazole) are covered by the assessment by EFSA and the transfer into food of animal origin is covered by the risk envelope as prothioconazole uses do not represent the worst case.

TDMs from prothioconazole-desthio in feed items

Because the TDMs in animal matrices could also come from prothioconazole-desthio (and metabolites) in feed, there is a need to calculate the transfer of TDMs in food of animal origin coming from the metabolism of prothioconazole-desthio in feed in ruminant. At the current maximum dietary burdens described in the table above, there is no transfer of triazole derived metabolites expected in food of animal origin above 0.01 mg/kg derived from prothioconazole-desthio residues in feed. Indeed, the dose of the triazole-labeled metabolism study performed with prothioconazole-desthio (10 mg/kg bw/d) is a 42N dose compared to the maximum dietary burden (0.238 mg/kg bw/d for lamb. Based on the occurrence of the TDMs in ruminant matrices, the maximum transfer would be for 1,2,4-triazole in kidney: 0.003 mg /kg when expressed as itself.

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

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

TDMs
Livestock dietary burden calculation has been performed respectively for each TDM compound in the addendum – confirmatory data on TDMs performed by UK (UK, 2018) using results from residue trials and from rotational crops.
It should be noted that the results of dietary burdens for TDMs taking into account the intended uses of GF-3307 are covered by the dietary burdens calculated by the UK (UK, 2018) for the different groups of livestock.

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, 2008_a, 2008_b).

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 7.3-15: 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, 2008b and 2017), MRLs for animal commodities were established and subsequently adopted in the EU.

Table 7.3-16: MRL for commodities of animal origin for prothioconazole-desthio

Animal commodities	EU MRL (mg/kg) Reg. (EU) 2019/552
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 ~~TmpdRRVar(2)~~ GF-3307 in/on cereals and supplementary livestock feeding studies are not considered necessary for this submission. There is no need to modify MRLs for foodstuff of animal origin.

Table 7.3-17: 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	0.066	0.238	**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
Based on the ruminants feeding study tentative MRLs were set at the LOQ for all matrices, except for liver and kidney. Nevertheless, a new feeding study to estimate the potential exposure to all prothioconazole metabolites containing the common moiety in accordance with the residue definition for risk assessment is in principle still required (EFSA RO, 2014). 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. The MRLs for livestock matrices are all tentative due to the tentative dietary burden calculations, the missing livestock feeding study in ruminants and the required validated analytical method for enforcement in eggs.

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 intended uses do not modify the theoretical maximum daily intake for animals for prothioconazole and for TDMs (for TDMs are covered by UK calculation made in the framework of the confirmatory data on TDM (UK, 2018 and EFSA, 2018)). The residues in animal commodities will not exceed MRLs (Reg. (EU) 2019/552).
No further data are required to support the intended uses of GF-3307.

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

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

Data/information on processing studies was reviewed during the approval of prothioconazole and were considered acceptable. No further studies have been performed.

7.3.5.1 Available data for all crops under consideration

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

7.3.5.2 Conclusion on processing studies

According to the EFSA Journal 2014;12(5):3689 no studies investigating the magnitude of residues in processed commodities are available. As such studies are not expected to affect the outcome of the risk assessment, these are not required

For the triazole derived metabolites (TDMs), as stated in the confirmatory data prepared by the RMS (UK, 2018, page 464):
The hydrolysis studies show that all four TDM are stable on processing. As a consequence the relevant residues in processed commodities are the TDM and no breakdown products need be considered. No processing factors have been applied to the consumer risk assessments. However, the processing factors determined do need to be considered for the dietary burden of livestock.

Processed commodity	Number of studies	Median PF *	Median CF **	Comments	Reference
EU data					
1,2,4-Triazole					
No processing factors are available. Residues in the animal feed items were <0.1 mg/kg and consequently the data requirements for processing are not triggered.					EFSA 2018b, UK, 2018 (page 464 onwards)

Processed commodity	Number of studies	Median PF *	Median CF **	Comments	Reference
Triazole alanine					
Bran	7	2.2	NA	-	
Triazole acetic acid					
Bran	7	1.3	NA	-	
Triazole lactic acid					
Bran	1	>1.3	NA	-	

zRMS comments:
Information given by the Applicant is acceptable and sufficient.
As residues of prothioconazole exceeding 0.1 mg/kg are not expected in the treated crops, there is no need to investigate the magnitude of prothioconazole residues in processed commodities.

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

Overview of the available processing studies - <u>TDMs</u>

Processed commodity	Processing factors				Comments	Reference
	T	TA	TAA	TLA		
EU confirmatory data (B.7.5.2, UK, 2018)						
Wheat, aspirated grain fractions	NC	0.20	0.39	NA		UK, 2018
Wheat, Bran	NC	**3.7**	**2.1**	NA		
Wheat, Flour	NC	0.30	0.89	NA		
Wheat, Germ	NC	**4.9**	1.3	NC		
Wheat, Middlings	NC	0.66	0.80	NC		
Wheat, Shorts	NC	**1.7**	1.2	NC		
Barley, Brewer's malt	NC, NC	0.78, 0.77	1.0, 1.1	>1.1, >1.5		
Barley, Brewer's grain	NC, NC	<0.04, <0.03	<0.05, <0.04	NC, NC		
Barley, Brewer's yeast	NC, NC	0.24, 0.14	0.23, 0.23	NC, NC		
Barley, Beer	NC, NC	0.15, 0.13	0.29, 0.13	NC, NC		

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

Calculated processing factors show concentration of:
- TA and TAA in wheat bran,
- TA in wheat germ and shorts,
- TAA and TLA in barley, brewer's malt.

No further data are required.

7.3.6 Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation.

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.

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 7.3-18: Summary of available studies in field rotational crops

Primary crop	Rate (kg a.s./ha) (GS at application or PHI)	Residue levels in succeeding crops			
		Succeeding crop group	Succeeding crop	Sowing intervals (DAT)	Reference / Remarks
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 and 65-69) equivalent to 630 g a.s./ha	Leafy vegetables	Lettuce	277-345 days	
		Root vegetables	Turnip and carrot		
		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)

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of GF-3307. Therefore, other special studies are not needed.

Effect on the residue level in pollen and bee product

~~Wheat, Rye, Triticale and Barley are primarily self pollinated plants and have no melliferous capacity (SANTE/11956/2016 rev. 9, 14 September 2018). Therefore, the proposed use of prothioconazole in these crops is expected to have little potential for contributing residues to bee products. Other special studies including data on prothioconazole residues in pollen and bee products for human consumption resulting from residues taken up by honeybees from barley at blossom are not considered necessary. The default MRL of 0.05* mg/kg should be applied to honey.~~

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.

To conclude, three new additional studies have been performed to cover the storage stability of prothioconazole residues in honey: One for PTZ and PTZ-desthio (S19-01124), one for the hydroxies (S19-01125) and one for TDMs (S19-01126), presented in Table 7.3 4 and in appendix 2. A new study on residues of prothioconazole in honey is available (S19-00902, presented above and in Appendix 2).

zRMS comments:
Information given by the Applicant is acceptable.

The intended uses of GF-3307 in cereals are expected to have little potential for contributing residues to bee products. This is in line with the technical guidelines SANTE/11956/2016 rev. 9, 14 September 2018. Other special studies including data on prothioconazole residues in pollen and bee products for human consumption are not considered necessary.
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)

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

7.3.8.1 Input values for the consumer risk assessment

Table 7.3-19: Input values for the consumer risk assessment

~~Commodity~~	~~Chronic risk assessment~~		~~Acute risk assessment~~	
	~~Input value (mg/kg)~~	~~Comment~~	~~Input value (mg/kg)~~	~~Comment~~
~~Risk assessment definition (plant and animal): 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.~~				
~~Barley~~	~~MRL x CF~~	~~EU MRLs (Reg EU 2019/552) x CF~~	~~0.02 x 2~~	~~$STMR_{Mo}$ x CF~~

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Wheat	0.1		0.01	STMR x CF
Rye	0.05		0.01	STMR x CF
Other crops and commodities of animal origin	MRL x CF		Acute risk assessment was performed only for crops under consideration.	

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition 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)				
Barley	0.4	EU MRL 0.2 x CF (2)	0.02	$STMR_{Mo}$ x CF (2)
Wheat	0.2	EU MRL 0.1 x CF (2)	0.02	$STMR_{Mo}$ x CF (2)
Rye	0.1	EU MRL 0.05 x CF (2)	0.02	Extrapolation from wheat
Other crops and commodities of animal origin	EU MRLs	EU MRLs (Reg. (EU) 2019/552) x CF (EFSA, 2014)	Acute risk assessment performed only for intended uses	

CF = 2 in cereal grain, pulses and oilseeds, root and tuber vegetables (EFSA, 2014; 2015)
CF = 2 and 9 respectively for liver and kidney (EFSA, 2014).

All MRLs from Reg EU 2019/552 on prothioconazole were used in PRIMo rev 3.1. Where conversion factors between monitoring and risk assessment were set, they were used as presented in the table above.

7.3.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.3-20: Consumer risk assessment (prothioconazole)

TMDI (% ADI) according to EFSA PRIMo	40% (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo	N/A
IESTI (% ARfD) according to EFSA PRIMo*	Wheat: 3% (based on children) Rye: 1% (based on children) Wheat flour: 2% Barley: 2% Barley beer: 3% Barley cooked: 1% Barley milling flour: 0.7%
NTMDI (% ADI) **	N/A
NEDI (% ADI)**	N/A
NESTI (% ARfD) **	N/A

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

The proposed uses of prothioconazole in the formulation GF-3307 do not represent unacceptable acute and chronic risks for the consumer linked to prothioconazole and TDMs.

Table 7.3-20 Consumer risk assessment (TDMs)

TMDI (% ADI) according to EFSA PRIMo 3.1	Not performed
IEDI (% ADI) according to EFSA PRIMo 3 (EFSA 2018)	1,2,4-T: 93% of ADI (NL toddler) TA and TLA: 7% of ADI (NL toddler) TAA: 1% of ADI (NL toddler)
IESTI (% ARfD) according to EFSA PRIMo 3 (EFSA 2018)	1,2,4-T: Barley: 0.3% children – 0.2% adults Wheat: 0.7% children – 0.4% adults Rye: 0.3% children – 0.2% adults TA and TLA: Barley: 1% children – 1% adults Wheat: 3,1% children – 1.8% adults Rye: 1,4 % children – 1% adults TAA: Barley: 0.4% children – 0.4% adults Wheat: 1,1% children – 0.7% adults Rye: 0.5% children – 0.4% adults

Evaluator comment:
Calculations presented by the Applicant are acceptable.
Prothioconazole
The calculation of the TMDI using EFSA model (version 3.1) and MRLs values according to the Regulation (EU) 2019/552 and appropriate conversion factors for enforcement to risk assessment led to a utilisation of the ADI of 40% with the NL toddler being the population group with the highest value. For this diet, the highest contributor is wheat with 8% of the ADI. The intended uses will not result in a consumer chronic exposure exceeding the ADI for prothioconazole-desthio.

An acute consumer risk assessment was performed based on the highest residue values (HR) of barley, wheat, rye, triticale. The highest International Estimated Short-Term Intake (IESTI) is at 3% and 2% of the ARfD for the consumption of wheat by children and by adults respectively.

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

The data available are considered sufficient for risk assessment. The chronic and the short-term intakes of prothioconazole residues and TDMs are unlikely to present a public health concern.
The intended uses of GF-3307 are accepted.

7.4 Combined exposure and risk assessment

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

The product is a mixture of two active substances and 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)	HQ (based on NESTI according to national model)*
Barley	Fenpicoxamid	0.02	N/A
	Prothioconazole-desthio	0.02	N/A
	1,2,4-T	0.003	N/A
	TA and TLA	0.001	N/A
	TAA	0.004	N/A
	Cumulative risk Barley (HI)	**0.048**	**N/A**
Wheat/Triticale	fenpicoxamid	0.0005	N/A
	prothioconazole	0.03	N/A
	1,2,4 Triazole	0.007	N/A
	TA and TLA	0.031	N/A
	TAA	0.011	N/A
	Cumulative risk (HI)	**0.08**	**N/A**
Rye	fenpicoxamid	0.0002	N/A
	prothioconazole	0.01	N/A
	1,2,4 Triazole	0.003	N/A
	TA and TLA	0.014	N/A
	TAA	0.005	N/A
	Cumulative risk (HI)	**0.03**	**N/A**

* if national model wanted, otherwise to be deleted

** based on IESTI according to EFSA PRIMo

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.

Evaluator comment:
Calculations and explanations presented by the Applicant are acceptable.

7.5 References

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Triazole Derivative Metabolites

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Conclusion on the peer review of the pesticide risk assessment for the triazole derivative metabolites in light of confirmatory data submitted. EFSA Journal 2018;16(7):5376, 20 pp. https://doi.org/10.2903/j.efsa.2018.5376

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	**Previously used Y/N** If yes, for which data point?
KCA 6.3.1/01	White, T.	2016	Determination of Residues of XDE-777 And Pyraclostrobin, After Two Applications of GF-3309 To Spring And Winter Wheat, At 5 Sites In Northern Europe And 5 Sites In Southern Europe, 2015 Report No. S15-02628, DAS Study ID 150650 Eurofins AgroScience Services, Wilson, Derbyshire DE73 1AG, UK GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS	Y evaluated in the dRR for GF-3308 on 24.08.2022
KCA 6.3.1/02	Eversfield, S.	2016	Determination of Residues of XDE-777 And Pyraclostrobin After Two Applications of GF-3312 And After Two Applications of GF-2925 In Winter Wheat And Spring Wheat At 4 Sites In Northern Europe And 4 Sites In Southern Europe In 2014 Report No. S14-01569, DAS Study ID 140648 Eurofins Agroscience Services, Wilson, Derbyshire, DE73 8AG, UK GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS	Y evaluated in the dRR for GF-3308 on 24.08.2022
KCA 6.3.1/03	Eversfield, S.	2016	Determination of Residues of XDE-777 and Prothioconazole after Two Applications of GF-3307 and after Two Applications of GF-3310 in Winter Wheat and Spring Wheat at 4 sites in Northern Europe and 4 sites in Southern Europe in 2014, Report No. S14-01568, DAS Study ID 140649, Eurofins Agroscience Services Ltd GLP, Unpublished	N	DAS	**Y for XDE-777** evaluated in the dRR for GF-3308 on 24.08.2022; **N for PTZ**
KCA 6.3.1/04	White, T.	2016	Determination of Residues of XDE-777 and Prothioconazole after Two Applications of GF-3307 to Spring and Winter Wheat, at 5 sites in Northern Europe and 5 sites in Southern Europe, 2015, Report No. S15-02629, DAS Study ID 150649, Eurofins Agroscience Services Ltd GLP, Unpublished	N	DAS	**Y for XDE-777** evaluated in the dRR for GF-3308 on 24.08.2022; **N for PTZ**
KCA 6.3.1/05	Semrau J, Thomas B	2019	Residues of Fenpicoxamid and Prothioconazole in Wheat at Harvest Following One Application of GF-3307 – Southern and Northern Europe – 2018. Report No.S18-01566, DAS Study ID 180126 Eurofins Agroscience Services Ltd	N	DAS	N

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner	Previously used Y/N If yes, for which data point?
			GLP, Unpublished			
KCA 6.3.1/06	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	DAS	N
KCA 6.3.1/08	Eversfield, S.	2019	Residues of Fenpicoxamid in Barley and its Processed Commodities at Harvest Following Two Applications of GF-3307 – Europe – 2018. Report No. S18-00056/ 170192 Eurofins Agroscience Services, Wilson, Derbyshire, DE73 8AG, UK GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS	N
KCA 6.3.1/07	~~Eversfield, S.~~ Semrau, J., Kühnel S	2019	Residues of Fenpicoxamid and Prothioconazole in Barley at Harvest Following One Application of UNIVOQ – Southern and Northern Europe – 2018. Semrau, J., Kühnel S. 2019. Report no. S18-01567/ 180128. Eurofins AgroScience Services GmbH, Carl-Goerdeler-Weg 5 21684 Stade, Germany GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS	N
~~KCA 6.10.1~~	~~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.~~ ~~Eurofins Agroscience Services Ltd~~ ~~DAS Report No.: 200670~~ ~~GLP/GEP (Y/N): Y~~ ~~Published (Y/N): N~~	~~N~~	~~Corteva Agriscience~~	not evaluated; not necessary to support the uses of GF-3307
~~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.~~ ~~Eurofins Agroscience Services Ltd~~ ~~Bayer Report No.: M-682401-01-1/ Study Number: S19-00902~~ ~~GLP/GEP (Y/N): Y~~ ~~Published (Y/N): N~~	~~N~~	~~BCS*~~	not evaluated; not necessary to support the uses of GF-3307

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner	Previously used Y/N If yes, for which data point?
KCA 6.1/02	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*	DAR reference: Section B.7.7.1

*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 6.1/1	Weir, A	2014	XDE-777 and Its Metabolite X642188 Storage Stability in Wheat and Wheat Processed Fractions Stored Frozen for up to 24 Months Eurofins Agroscience Services Chem Ltd DAS Report No.: 120749 GLP/GEP (Y/N): Y Published (Y/N): N	N	DAS
KCA 6.1/3	Devine, HC	2014	Frozen Storage Stability of Residues of XDE-777 and Its Metabolites (X642188 and X12326349) in Animal Matrices Final Report CEM Analytical Services Ltd. DAS Report No.: 130709 GLP/GEP (Y/N): Y Published (Y/N): N	N	DAS
KCA 6.2.1/1	Ma, M Jackson, U	2013	A NATURE OF THE RESIDUE STUDY WITH [^{14}C]-XR-777 APPLIED TO WHEAT Dow AgroSciences LLC; Research for Hire DAS Report No.: 110334 GLP/GEP (Y/N): Y Published (Y/N): N	N	DAS
KCA	Wu, S	2013a	A Nature of the Residue Study with [^{14}C]-XDE-777 Applied to Tomatoes	N	DAS

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
6.2.1/2			Symbiotice Research, LLC Research For Hire (RFH) DAS Report No.: 121003 GLP/GEP (Y/N): Y Published (Y/N): N		
KCA 6.2.1/3	Wu, S	2013b	A Nature of the Residue Study with [^{14}C]-XDE-777 Applied to Cabbage Symbiotice Research, LLC Research For Hire (RFH) DAS Report No.: 121002 GLP/GEP (Y/N): Y Published (Y/N): N	N	DAS
KCA 6.2.2	Ma, M Adelfinskaya, Y Kish, B	2013	A Nature of the Residue Study in the Laying Hen with [14C]-XDE-777 Dow AgroSciences LLC Southwest Bio-Labs, Inc. DAS Report No.: 110421 GLP/GEP (Y/N): Y Published (Y/N): N	N	DAS
KCA 6.2.3	Rotondaro, S Adelfinskaya, Y	2013	A NATURE OF THE RESIDUE STUDY IN THE RUMINANT WITH [14C]-XR-777 xxxxxxxxxxx GLP/GEP (Y/N): Y Published (Y/N): N	Y	DAS
KCA 6.4.2/1	Rawle, NW	2013	XDE-777 Livestock Feeding Study: Magnitude of Residue in Milk, Muscle, Liver, Kidney and Fat of Lactating Dairy Cattle CEM Analytical Services Ltd. DAS Report No.: 130949 GLP/GEP (Y/N): Y Published (Y/N): N	N	DAS
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 Dow AgroSciences LLC DAS Report No.: 121153 GLP/GEP (Y/N): Y Published (Y/N): N	N	DAS
KCA 6.6.1/1	Ma, M Aldelfinskaya, Y	2014	A Confined Rotational Crop Study with [14C]-XDE-777, 2014 Final Report Dow AgroSciences LLC DAS Report No.: 140050	N	DAS

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GLP/GEP (Y/N): Y Published (Y/N): N		
KCA 6.6.1/1	Ma, M Aldelfinskaya, Y	2015	A Confined Rotational Crop Study with [14C]-XDE-777, 2014 Final Report Dow AgroSciences LLC DAS Report No.: 140050 GLP/GEP (Y/N): Y Published (Y/N): N	N	DAS
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 AG, Leverkusen, Germany Bayer CropScience, Report No.: MR-282/00, Edition Number: M-072461-01-1 Date: 2001-09-13 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	Heinemann and Auer	2001	JAU 6476-desthio - Dairy cattle feeding study xxxxxxxxxx -1 Date: 2001-10-15 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 AG, Leverkusen, Germany Bayer CropScience, Report No.: MR-198/99, Edition Number: M-041657-01-1 EPA MRID No.: 46246141 Date: 2000-07-10 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 /04	Vogeler, K.; Sakamoto, H.; Brauner, A.	1993	Metabolism of SXX 0665 in summer wheat Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: PF3906, Edition Number: M-008633-01-1 Date: 1993-08-13 GLP/GEP: yes, unpublished	N	BCS*
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 LP, Stilwell, KS, USA Bayer CropScience, Report No.: 200733, Edition Number: M-001524-01-1 EPA MRID No.: 46246143 Date: 2004-03-12 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 AG, Leverkusen, Germany Bayer CropScience, Report No.: MR-467/99, Edition Number: M-030412-01-3 EPA MRID No.: 46246142 Date: 2001-05-10 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 LP, Stilwell, KS, USA Bayer CropScience, Report No.: 200466, Edition Number: M-001059-01-1 EPA MRID No.: 46246148 Date: 2004-03-11 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 /08	Beedle, E. C.; Ying, S. L.	2004	The metabolism of [triazole-UL-14C]JAU6476 in sugar beets Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: 200467, Edition Number: M-001049-01-1 EPA MRID No.: 46246147 Date: 2004-03-11 GLP/GEP: yes, unpublished	N	BCS*
KCA 6.2.1 /05	Haas, M.	2001	Metabolism of [phenyl-UL-14C]JAU6476 in peanuts Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: MR-193/01, Edition Number: M-033059-01-2 EPA MRID No.: 46246145 Date: 2001-11-27 GLP/GEP: yes, unpublished	N	BCS*
KCA 6.2.1 /06	Haas, M.	2003	Metabolism of [triazole-UL-14C]JAU6476 in peanuts Bayer CropScience, Report No.: MR-194/02, Edition Number: M-103268-01-2 EPA MRID No.: 46246146 Date: 2003-12-01 GLP/GEP: yes, unpublished	N	BCS*
KCA 6.6.1 /01	Haas, M.	2001	Confined rotational crop study with JAU6476 Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: MR-159/00, Edition Number: M-049955-01-1 EPA MRID No.: 46246225 Date: 2001-05-14 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 6.5.1 /01	Gilges, M.	2001	Hydrolysis of JAU 6476 under conditions of processing Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: MR-166/00, Edition Number: M-035289-01-1 Date: 2001-01-29 GLP/GEP: yes, unpublished	N	BCS*
KCA 6.2.3 /06	Weber	2011	[Triazole-UL-14C]JAU 6476-desthio: Metabolism in the lactating goat xxxxxxxxxxx...Amended: 2011-06-16 GLP/GEP: yes, unpublished	Y	BCS*
KCA 6.2.3 /04	Weber	2006	[Phenyl-UL-14C]JAU 6476-desthio: Absorption, distribution, excretion and metabolism in the lactating goat - Subsequent identification of metabolite hydrolysis products xxxxxxxxxxx Date: 2006-10-10 GLP/GEP: no, unpublished	Y	BCS*
KCA 5.1.2 /01	Weber	2003	[Triazole-UL-14C]JAU 6476: Absorption, distribution, excretion, and metabolism in the lactating goat xxxxxxxxxxx...Amended: 2005-06-06 GLP/GEP: yes, unpublished	Y	BCS*
6.2.2 /02	Weber	2003	[Triazole-UL- 14C]JAU6476: Absorption, distribution, excretion, and metabolism in laying hens xxxxxxxxxxx...Amended: 2003-07-14 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
KCA 6.2.2 /01	Weber, H. Spiegel, K.	2001	[Phenyl-UL-14C]JAU6476 - Absorption, distribution, excretion and metabolism in laying hens xxxxxxxxxx -2 EPA MRID No.: 46246202 Date: 2001-10-29 GLP/GEP: yes, unpublished	Y	BCS*
~~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-680623-02-1~~ ~~GLP/GEP (Y/N): Y~~ ~~Published (Y/N): N~~	~~N~~	~~BCS*~~
~~KCA 6.1/5~~	~~Kalathoor, R.~~	~~2020b~~	~~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~~ ~~GLP/GEP (Y/N): Y~~ ~~Published (Y/N): N~~	~~N~~	~~BCS*~~
~~KCA 6.1/6~~	~~Kalathoor, R.~~	~~2020c~~	~~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-680825-02-1~~ ~~GLP/GEP (Y/N): Y~~ ~~Published (Y/N): N~~	~~N~~	~~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 6.10.1	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. Eurofins Agroscience Services Ltd	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
			DAS Report No.: 200670 GLP/GEP (Y/N): Y Published (Y/N): N		
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. Eurofins Agroscience Services Ltd Bayer Report No.: M-682401-01-1/ Study Number: S19-00902 GLP/GEP (Y/N): Y Published (Y/N): N	N	BCS*
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-680623-02-1 GLP/GEP (Y/N): Y Published (Y/N): N	N	BCS*
KCA 6.1/5	Kalathoor, R.	2020b	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 GLP/GEP (Y/N): Y Published (Y/N): N	N	BCS*
KCA 6.1/6	Kalathoor, R.	2020c	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-680825-02-1 GLP/GEP (Y/N): Y Published (Y/N): N	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

A 2.1 Fenpicoxamid and Prothioconazole

A 2.1.1 Stability of residues

A 2.1.1.1 Stability of residues during storage of samples

A 2.1.1.1.1 Storage stability of residues in plant products

No new studies presented.

A 2.1.1.1.2 Storage stability of residues in animal products

No new studies presented.

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

A 2.1.2.1 Nature of residue in plants

A 2.1.2.1.1 Nature of residue in primary crops

No new studies presented.

A 2.1.2.1.2 Nature of residue in rotational crops

No new studies presented.

A 2.1.2.1.3 Nature of residues in processed commodities

No new studies presented.

A 2.1.2.2 Nature of residues in livestock

No new studies presented.

A 2.1.3 Magnitude of residues in plants

A 2.1.3.1 Wheat

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 (EFSA 2018) fenpicoxamid (XDE-777)	2	130 g XDE-777/ha	14 days	BBCH 69	N/A
cGAP EU (EFSA 2007) prothioconazole	3	200 g prothioconazole/ha	14 days	start 26-29 up to BBCH69	35 days
Intended cGAP (1-6*)	1	75 g XDE-777/ha + 150 g prothioconazole/ha	NA	BBCH 69	F

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0
Uses 7-14 are covered by Uses 1-6

A 2.1.3.1.1 Studies S14-01568 & S14-01569

Comments of zRMS:	The studies S14-01568 & S14-01569 on the determination of residues of fenpicoxamid (XDE-777) in winter and spring wheat have been evaluated in Registration Report for GF-3308 on February 2022 by zRMS-PL and the summary is presented below. The residue data for prothioconazole is evaluated in this document and a summary is also provided below. <u>Study Number: S14-01568, DAS Study ID 140649</u> The magnitude of residues of XDE-777 in winter and spring wheat was determined following two post emergent broadcast applications of GF-3307 (Plot 2) and GF-3310 (Plot 3) fungicides to wheat. To determine maximum XDE-777 and prothioconazole-desthio residue levels in wheat, field trials were established in which (1) two post-emergent foliar applications of GF-3307 (Plot 2), an emulsifiable concentrate (EC) formulation containing XDE-777 and prothioconazole at nominal concentrations of 50 g/L and 100 g/L respectively, were applied in a nominal 14-day interval (actual interval ranged from 11 to 19 days) between applications and the last application at BBCH growth stage 69, and (2) two postemergent foliar applications of GF-3310 (Plot 3), an emulsifiable concentrate (EC) formulation containing XDE-777 and prothioconazole at nominal concentrations of 66.7 g/L and 133 g/L respectively, were applied in a nominal 14-day interval (actual interval ranged from 11 to 19 days) between applications and the last application at BBCH growth stage 69. Trials were conducted at 8 sites: 4 in Northern Europe and 4 in Southern Europe. Each site had a control plot and 2 treated plots. Two applications of GF-3307 were applied at a target rate of 2.0 L product/ha (100 g ai/ha XDE-777 + 200 g ai/ha prothioconazole) to Plot 2 in each trial, for a seasonal total of 4.0 L product/ha. Two applications of GF-3310 were applied at a target rate of 1.5 L product/ha (100 g ai/ha XDE- 777 + 200 g ai/ha prothioconazole) to Plot 3 in each trial, for a seasonal total of 3.0 L product/ha. At the four harvest trials, grain and straw specimens were taken at BBCH growth stage 89, normal commercial harvest (NCH). At the four decline trials whole plant specimens were collected immediately before the second application (0 DBA2) and at 0 (immediately following the second application; 0 DAA2), 6-8, 14 and 26-28 days after the final applications to plot 2. Grain and straw specimens were taken 6/7 days before normal commercial harvest (NCH), at NCH, and 7, and 12-14 days after NCH. Residues of XDE-777 and its X642188 metabolite were determined using a validated

	analytical method (reported in Eurofins study no. S12-01537 / Dow AgroSciences study code 120615) using Liquid Chromatography Mass Spectrometry (LC-MS/MS). The limit of detection (LOD) and limit of quantitation (LOQ) for XDE-777 and its X642188 metabolite in wheat whole plant, grain and straw were 0.003 mg/kg and 0.01 mg/kg, respectively. Residues of prothioconazole-desthio were determined using a validated analytical method (reported in Bayer study no. P60293002) using Liquid Chromatography Mass Spectrometry (LCMS/MS). The limit of detection (LOD) and limit of quantitation (LOQ) for prothionconazoledesthio in wheat grain were 0.003 mg/kg and 0.01 mg/kg, respectively. The limit of detection (LOD) and limit of quantitation (LOQ) for prothionconazole-desthio in wheat straw were 0.015 mg/kg and 0.05 mg/kg, respectively. Recoveries in wheat whole plant averaged 96.2% for XDE-777 and 94.0% for X642188. Recoveries in wheat grain averaged 108.5% for XDE-777 and 100.9% for X642188 and 106.3% for Prothioconazole-desthio. Recoveries in wheat straw averaged 109.4% for XDE-777 and 98.3% for X642188 and 102.6% for Prothioconazole-desthio. The maximum period of frozen storage for XDE-777, X642188 and prothioconazole-desthio were 247 days, 246 days and 575 days respectively. With one exception, analyte residues were not detected above the analytical method LOQ in untreated samples. The exception is specimen L14-01568-06-024A where a mean XDE-777 residue level of 0.019 mg/kg was found. The maximum residue of XDE-777 in whole plant for plot / treatment 2 was 2.822 mg/kg immediately after the second application and 0.989 mg/kg for specimens taken 26-28 days after the applications. The maximum residue of XDE-777 in whole plant for plot / treatment 3 was 2.444 mg/kg immediately after the second application and 0.772 mg/kg for specimens taken 26-28 days after the applications. The maximum residue of X642188 in whole plant for plot / treatment 2 was 0.163 mg/kg immediately after the second application and 0.059 mg/kg for specimens taken 26-28 days after the applications. The maximum residue of X642188 in whole plant for plot / treatment 3 was 0.147 mg/kg immediately after the second application and 0.067 mg/kg for specimens taken 26-28 days after the applications. **Residues in grain** Residues of XDE-777 in grain taken at normal commercial harvest for plot / treatment 2 ranged from 0.006 mg/kg, which is <LOQ of 0.01 mg/kg to 0.066 mg/kg. Residues of XDE-777 in grain taken at normal commercial harvest for plot / treatment 3 ranged from 0.006 mg/kg, which is <LOQ of 0.01 mg/kg to 0.051 mg/kg. Residues of X642188 in grain taken at normal commercial harvest for plot / treatment 2 and 3 were ND (not detected, <0.003 mg/kg). Residues of prothioconazole-desthio in grain taken at normal commercial harvest for plot /treatment 2 ranged from ND (not detected, <0.003 mg/kg) to 0.011 mg/kg. Residues of prothioconazole-desthio in grain taken at normal commercial harvest for plot /treatment 3 ranged from ND (not detected, <0.003 mg/kg) to 0.007 mg/kg. **Residues in straw** Residues of XDE-777 in straw taken at normal commercial harvest for plot / treatment 2 ranged from 1.251 to 11.967 mg/kg. Residues of XDE-777 in straw taken at normal commercial harvest for plot / treatment 3 ranged from 1.250 to 8.308 mg/kg. Residues of X642188 in straw taken at normal commercial harvest for plot / treatment 2 ranged from 0.027 to 0.311 mg/kg. Residues of X642188 in straw taken at normal commercial harvest for plot / treatment 3 ranged from 0.004 mg/kg, which is <LOQ of 0.01 mg/kg to 0.305 mg/kg.

	Residues of prothioconazole-desthio in straw taken at normal commercial harvest for plot /treatment 2 ranged from 0.157 to 1.293 mg/kg. Residues of prothioconazole-desthio in straw taken at normal commercial harvest for plot /treatment 3 ranged from 0.132 to 1.153 mg/kg. Some deviations have been identified, but do not affect the study. The study is acceptable. <u>Report No. S14-01569, DAS Study ID 140648</u> The magnitude of residues of XDE-777 and pyraclostrobin in winter and spring wheat was determined following two post emergent broadcast applications of GF-3312 (plot 2) and GF-2925 (plot 3) fungicide to wheat. To determine maximum XDE-777 and pyraclostrobin residue levels in wheat, field trials were established in which two post-emergent foliar applications of GF-3312 (plot 2), an emulsifiable concentrate (EC) formulation containing XDE-777 at a nominal concentration of 66.7 g/L and pyraclostrobin at a nominal concentration of 83.3 g/L, were applied in a nominal 14-day interval (actual interval ranged from 11 to 19 days) between applications and the last application at BBCH growth stage 69. To determine maximum XDE-777 residue levels in wheat, field trials were established in which two post-emergent foliar applications of GF-2925, a suspension concentrate (SC) formulation containing XDE-777 at a nominal concentration of 130 g/L, were applied in a nominal 14-day interval (actual interval ranged from 11 to 19 days) between applications and the last application at BBCH growth stage 69. Trials were conducted at 8 sites: 4 in Northern Europe and 4 in Southern Europe. Each site had a control plot and 2 treated plots. Two applications of GF-3312 were applied at a target rate of 1.5 L product/ha (100 g ai/ha XDE-777 + 125 g ai/ha pyraclostrobin) to Plot 2, for a seasonal total of 3.0 L product/ha. Two applications of GF-2925 were applied at a target rate of 0.77 L product/ha (100 g ai/ha XDE-777) to Plot 3, for a seasonal total of 1.54 L product/ha. At the four harvest trials, grain and straw specimens were taken at BBCH growth stage 89, normal commercial harvest (NCH). At the four decline trials, whole plant specimens were collected immediately before the second application (0 DBA2) and at 0 (immediately following the second application; 0 DAA2), 6-8, 14 and 26-28 days after the final applications to plot 2. Grain and straw specimens were taken 6/7 days before normal commercial harvest (NCH), at NCH, and 7, and 12-14 days after NCH. Residues of XDE-777 and its X642188 metabolite were determined using a validated analytical method (reported in Eurofins study no. S12-01537 / Dow AgroSciences study code 120615) using Liquid Chromatography Mass Spectrometry (LC-MS/MS). The limit of detection (LOD) and limit of quantitation (LOQ) for XDE-777 and its X642188 metabolite in wheat whole plant, grain and straw were 0.003 mg/kg and 0.01 mg/kg, respectively. Recoveries in wheat whole plant averaged 98% for XDE-777 and 101% for X642188. Recoveries in wheat grain averaged 96% for XDE-777 and 103% for X642188. Recoveries in wheat straw averaged 106% for XDE-777 and 107% for X642188. The maximum period of frozen storage for XDE-777 and X642188 was 232 days. With two exceptions, analyte residues were not detected above the analytical method LOQ in untreated samples. The exceptions are specimens L14-01569-06-024A and L14-01569-07-004A where mean XDE-777 residue levels of 0.029 mg/kg and 0.026 mg/kg respectively were found. The maximum residue of XDE-777 in whole plant for plot / treatment 2 was 3.103 mg/kg immediately after the second application and 0.582 mg/kg for specimens taken 26-28 days after the applications. The maximum residue of X642188 in whole plant for plot / treatment 2 was 0.137 mg/kg immediately after the second application and 0.053 mg/kg for specimens taken 26-28 days after the applications.

	Residues in grain Residues of XDE-777 in grain taken at normal commercial harvest for plot / treatment 2 ranged from ND (not detected, <0.003 mg/kg) to 0.050 mg/kg. Residues of X642188 in grain taken at normal commercial harvest for plot / treatment 2 were ND (not detected, <0.003 mg/kg). **Residues in straw** Residues of XDE-777 in straw taken at normal commercial harvest for plot / treatment 2 ranged from 0.594 to 4.669 mg/kg. Residues of X642188 in straw taken at normal commercial harvest for plot / treatment 2 ranged from 0.026 to 0.292 mg/kg. The maximum residue of XDE-777 in whole plant for plot / treatment 3 was 2.343 mg/kg immediately after the second application and 2.181 mg/kg for specimens taken 26-28 days after the applications. The maximum residue of X642188 in whole plant for plot / treatment 3 was 0.046 mg/kg immediately after the second application and 0.140 mg/kg for specimens taken 26-28 days after the applications. Residues of XDE-777 in grain taken at normal commercial harvest for plot / treatment 3 ranged from 0.010 to 0.095 mg/kg. Residues of X642188 in grain taken at normal commercial harvest for plot / treatment 3 were ND (not detected, <0.003 mg/kg). Residues of XDE-777 in straw taken at normal commercial harvest for plot / treatment 3 ranged from 1.409 to 10.560 mg/kg. Residues of X642188 in straw taken at normal commercial harvest for plot / treatment 3 ranged from 0.020 to 0.367 mg/kg. Some deviations have been identified, but do not affect the study. The study is acceptable. **Remark:** **The trials of the study S14-01568 and the study S14-01569 were conducted at the same sites and at the same times, and therefore cannot be considered independent. The results were therefore combined and the mean was retained (see table 7.2-10).**

Reference:	KCA 6.3.1/03	KCA 6.3.1/02
Report	Determination of Residues of XDE-777 and Prothioconazole after Two Applications of GF-3307 and after Two Applications of GF-3310 in Winter Wheat and Spring Wheat at 4 sites in Northern Europe and 4 sites in Southern Europe in 2014, S. Eversfield, 2016, Report No. S14-01568, DAS Study ID 140649	Determination of Residues Of XDE-777 and Pyraclostrobin after Two Applications of GF-3312 and after Two Applications Of GF-2925 in Winter Wheat and Spring Wheat at 4 Sites in Northern Europe and 4 Sites in Southern Europe in 2014, S. Eversfield, 2016, Report No. S14-01569, DAS Study ID 140648
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	Guideline 7029/VI/95 (rev. 5) to Directive 91/414/EEC and Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009
Deviations:	None with impact on the study. S14-01568-01: At application A1/A3 the amount of test item was > 1% of the water volume however it was not considered in the total spray solution for plot 2. This has no impact on the study. S14-01568-01: At application A1/A3 the spray solution for plot 3 was applied to the first 12m of plot 2. Subsequently plot 3 was reduced in size to ensure that the remaining	None with impact on the study. S14-01569-03: The test item was weighed out by volume (not weight). This has no impact on the study. S14-01569-03: Crop height and cloud cover were not recorded at sampling. This has no impact on the study. S14-01569-03: At application A2 / A4 both plots were oversprayed, plot 2 by +20.83% and plot 3

solution was applied at the correct rate, and the area of plot 2 was marked and excluded from sampling. This has no impact on the study.
S14-01568-01: Application A2/A4 was applied 19 DAA1/A3 instead of 14. This was done to ensure the crop was at the correct growth stage. This has no impact on the study.
S14-01568-01: At sampling S3, the weather conditions or crop height were not recorded at sampling. This has no impact on the study.
S14-01568-01: At sampling S8 the plant was cut at 10 cm above the soil instead of 15 cm as required by the study plan. This has no impact on the study.
S14-01568-02: The weather station was 27.4km from the trial site instead of < 20 km as required by the study plan. This has no impact on the study.
S14-01568-02: The calibration for the balance used for application A1 /
A3 was out of date. It was calibrated the following day with no errors.
This has no impact on the study.
S14-01568-02: Crop height was not recorded at sampling. This has no impact on the study.
S14-01568-02: S6 - Whole plant material was taken from the field on 05 Aug 2014 – due to wet weather the material was dried until the 06 Aug 2014 in ambient, contamination free conditions. The whole plant was then threshed and grain/straw specimens taken. This has no impact on the study.
S14-01568-02: S9 - Whole plant material was taken from the field on 26 Aug 2014 – due to wet weather the material was dried until the 27 Aug 2014 in ambient, contamination free conditions. The whole plant was then threshed and grain/straw specimens taken. This has no impact on the study.
S14-01568-03: Crop height and cloud cover were not recorded at sampling. This has no impact on the study.
S14-01568-04: The test item GF-3310 (plot 3) was not allocated the test item code described in the study plan. This has no impact on the study as it was the same batch.
Deviations S14-01568-04: The interval between applications A1 and A2 was 11 instead of 14 as required by the study plan, this is because unfavourable weather was forecast. This has no impact on the study.
S14-01568-04: The interval between applications A3 and A4 was 11 instead of 14 as required by the study plan, this is because unfavourable weather was forecast. This has no impact on the study.
S14-01568-06 and -08: The distance between by +15.0%. This has an impact on the study – the residue data generated can be considered to be "worst case".
S14-01569-04: The interval between applications A1 and A2 (and therefore A3 and A4) was 11 instead of 14 as required by the study plan, this is because unfavorable weather was forecast. This has no impact on the study.
S14-01569-06 and -08: The distance between the trials is 11.5 km instead of > 15 km as required by the study plan. This has no impact on the study as the applications were made on different dates.
S14-01569-06: The closest weather station is 32 km instead of < 20 km as required by the study plan. This has no impact on the study.
S14-01569-06: During the shipment of the S6 - S8 specimens the temperature reached -14 °C for approximately 32 hours. The specimens remained frozen throughout, so this has no impact.
S14-01569-06: During the shipment of the S9 specimens the temperature reached -13 °C for approximately 64 hours. The specimens remained frozen throughout, so this has no impact.
S14-01569-06: The closest longterm weather station is 75 km instead of < 30 km as required by the study plan. This has no impact on the study.
S14-01569-07: At sampling, the crop height was not recorded. This has no impact.

S14-01569-07: During storage of the retain specimens the temperature reached a maximum of -17.3 °C for approximately 150 hours. This has no impact as the specimens remained frozen.Eurofins Agroscience Services

Deviations S14-01569-08: No conditions at sampling were recorded at S1. Temperatures have been taken from the closest weather station (32 km from the trial site) however soil temperatures, relative humidity, wind speed and cloud cover are not available. This has no impact on the study.

S14-01569-08: During the shipment of the specimens the temperature reached -14 °C for approximately 32 hours. The specimens remained frozen throughout, so this has no impact.
S14-01569-08: The closest longterm weather station is 72 km instead of < 30 km as required by the study plan. This has no impact on the study

	the trials is 11.5 km instead of > 15 km as required by the study plan. This has no impact on the study as the applications were made on different dates. S14-01568-06: The closest weather station is 32 km instead of < 20 km as required by the study plan. This has no impact on the study. S14-01568-06: During the shipment of the S6 - S8 specimens the temperature reached -14°C for approximately 32 hours. The specimens remained frozen throughout, so this has no impact. S14-01568-06: During the shipment of the S9 specimens the temperature reached -13°C for approximately 64 hours. The specimens remained frozen throughout, so this has no impact. S14-01568-06: The closest longterm weather station is 75 km instead of < 30 km as required by the study plan. This has no impact on the study. S14-01568-07: Crop height was not recorded at sampling. This has no impact on the study. S14-01568-07: During storage of the retain specimens the temperature reached a maximum of -17.3°C for approximately 150 hours. This has no impact as the specimens remained frozen. S14-01568-08: No conditions at sampling were recorded at S1. Temperatures have been taken from the closest weather station (32 km from the trial site) however soil temperatures, relative humidity, wind speed and cloud cover are not available. This has no impact on the study. S14-01568-08: During the shipment of the specimens the temperature reached -14°C for approximately 32 hours. The specimens remained frozen throughout, so this has no impact. S14-01568-08: The closest longterm weather station is 72 km instead of < 30 km as required by the study plan. This has no impact on the study. S14-01568: The freezer main fuse tripped causing freezer UKW/0372/M to reach -15°C for up to 13 hours, UKW/0572/M to reach -5°Cfor up to 44 hours, UKW/5481/M reached 0°C for up to 53 hours. This has no impact as the specimens remained frozen.	
GLP:	Yes	Yes
Acceptability:	Yes	Yes

The trials of the study S14-01568 were conducted at the same sites and times than the respective trials in study & S14-01569. Therefore, they cannot be considered as independent from these trials and the summary have been merged by zRMS. GF-3307 is an EC formulation, 2 EC formulations were tested in these 2 studies. Therefore, the considered results are the mean of the plots tested with EC formulations.

Summary of global information on study S14-01568

Comparative trials (between formulations, with and adjuvant/safener/synergist)	Y: - GF-3307 (Plot 2), an emulsifiable concentrate (EC) formulation containing XDE-777 and prothioconazole at nominal concentrations of 50 g/L and 100 g/L - GF-3310 (Plot 3), an emulsifiable concentrate (EC) formulation containing XDE-777 and prothioconazole at nominal concentrations of 66.7 g/L and 133 g/L
Number of applications	2
Dose (g as/ha)	Fenpicoxamide: 100 g a.s./ha Prothioconazole: 200 g/ha
Mode of application	Folair spray
PHI (days) and/or growth stage (BBCH)	BBCH 69-71, PHI: F
Analytical method (Code +Type)	XDE-777 and X642188 (reported in Eurofins study no. S12-01537 / Dow AgroSciences study code 120615) (LC-MS/MS). Prothioconazole-desthio (reported in Bayer study no. P60293002) (LC-MS/MS).
LoQ (mg/kg)	XDE-777 and X642188: 0.01 mg/kg (all matrices) Prothioconazole-desthio : - wheat grain: 0.01 mg/kg - wheat straw: 0.05 mg/kg

Summary of the study S14-01568 trials – Fenpicoxamid (XDE-777)

N° Trial		1	2	3	4	5	6	7	8
North/South/Indoor		N	N	N	S N	S	S	S	N S
Decline (D)/Harvest (H) trial?		D	H D	H	D H	H D	H D	H	D H
Formulation		EC	EC	EC	EC	EC	EC	EC	EC
Equivalence between formulations		Y	Y	Y	Y	Y	Y	Y	Y
Accordance with intended GAP		Y	Y	Y	Y	Y	Y	Y	Y
Correct sampling		Y	Y	Y	Y	Y	Y	Y	Y
Samples frozen within 24h		Y	Y	Y	Y	Y	Y	Y	Y
Storage period (in days)	Sample	250 days							
	Extract	8 (a)							
Storage T° <-18°C		Y	Y	Y	Y	Y	Y	Y	Y
Validated analytical method		Y	Y	Y	Y	Y	Y	Y	Y
Negative controls		Y	Y	Y	Y	Y	Y (b)	Y	Y
Considered trial		Y	Y	Y	Y	Y	Y	Y	Y
Remarks									

(a): Recoveries were conducted concurrently to analysis of untreated and treated samples (recoveries in wheat whole plant averaged 96.2 % for XDE-777 and 94.0 % for X642188. Recoveries in wheat grain averaged 108.5 % for XDE-777, 100.9 % for X642188. Recoveries in wheat straw averaged 109.4 % for XDE-777 and 98.3% for X642188.), therefore the storage of extracts for more than 24 hours is deemed acceptable.
(b): 0.019 mg/kg in 60 DAT straw control samples (0.020 mg/kg in the corresponding retained control sample). No explication is given; however, considering that the treated sample contains residue in the range [1.4; 5.7] mg/kg, this deviation is deemed acceptable.

Summary of the study S14-01568 trials – Prothioconazole

N° Trial		1	2	3	4	5	6	7	8
North/South/Indoor		N	N	N	S N	S	S	S	N S
Decline (D)/Harvest (H) trial?		D	H D	H	D H	H D	H D	H	D H
Formulation		EC	EC	EC	EC	EC	EC	EC	EC
Equivalence between formulations		Y	Y	Y	Y	Y	Y	Y	Y
Accordance with intended GAP		Y	Y	Y	Y	Y	Y	Y	Y
Correct sampling		Y	Y	Y	Y	Y	Y	Y	Y
Samples frozen within 24h		Y	Y	Y	Y	Y	Y	Y	Y
Max Storage period (in days)	Sample	184	163	168	163	232	528	575(1)	541
	Extract	1	1	1	1	1	4(2)	4(2)	4(2)

Storage T° <-18°C	Y	Y	Y	Y	Y	Y	Y	Y
Validated analytical method	Y	Y	Y	Y	Y	Y	Y	Y
Negative controls	Y	Y	Y	Y	Y	Y	Y	Y
Considered trial	Y	Y	Y	Y	Y	Y	Y	Y
Remarks								

(1) Samples of straw L14-01568-07-005R1 and -006R1 were stored 575 days (sampling to extraction interval). The residue of prothioconazole-desthio found in these samples lead to higher residue level and were therefore considered in the assessment. Samples of grain were stored up to 216 days.

(2) Recoveries in wheat grain averaged 106.3% for Prothioconazole-desthio. Recoveries in wheat straw averaged 102.6% for Prothioconazole-desthio.

Summary of global information on study S14-01569

Comparative trials (between formulations, with and adjuvant/safener/synergist)	Y (comparison of formulations): - GF-3312 (plot 2), an emulsifiable concentrate (EC) formulation containing XDE-777 at a nominal concentration of 66.7 g/L and pyraclostrobin at a nominal concentration of 83.3 g/L. - GF-2925 (plot 3), a suspension concentrate (SC) formulation containing XDE-777 at a nominal concentration of 130 g/L
Number of applications	2
Dose (g as/ha)	Fenpicoxamide: 100 (plots 2 and 3) Pyraclostrobine: 125 (plot2 only)
Mode of application	Foliar application
PHI (days) and/or growth stage (BBCH)	BBCH 51-69
Analytical method (Code +Type)	LC-MS/MS
LoQ (mg/kg)	0.01 (all analytes)

Summary of the study S14-01569 trials – Fenpicoxamide

N° Trial		1	2	3	4	5	6	7	8
North/South/Indoor		N	N	N	S N	S	S	S	N S
Decline (D)/Harvest (H) trial?		D	H D	H	D H	H D	H D	H	D H
Formulation		EC	EC	EC	EC	EC	EC	EC	EC
Equivalence between formulations		Y	Y	Y	Y	Y	Y	Y	Y
Accordance with intended GAP		Y	Y	Y	Y	Y	Y	Y	Y
Correct sampling		Y	Y	Y	Y	Y	Y	Y	Y
Samples frozen within 24h		Y	Y	Y	Y	Y	Y	Y	Y
Storage period (in days)	Sample	527 232 days							
	Extract	8 (a)							
Storage T° <-18°C		Y	Y	Y	Y	Y	Y	Y	Y
Validated analytical method		Y	Y	Y	Y	Y	Y	Y	Y
Negative controls		Y	Y	Y	Y	Y	Y (1)	Y (2)	Y
Considered trial		Y	Y	Y	Y	Y	Y	Y	Y
Remarks									

(a): Recoveries were conducted concurrently to analysis of untreated and treated samples (Recoveries in wheat whole plant averaged 96.2 98% for XDE-777 and 94.0 101% for X642188. Recoveries in wheat grain averaged 108.5 96% for XDE-777, 100.9 103% for X642188. Recoveries in wheat straw averaged 109.4 106% for XDE-777 and 98.3 107% for X642188), therefore the storage of extracts for more than 24 hours is deemed acceptable.

(1): 0.029 mg/kg XDE-777 in 60 DAT control straw samples. No explication is given; however, considering that the treated sample contains residue in the range [3.2; 8.7] mg/kg, this deviation is deemed acceptable.

(2): 0.026 mg/kg XDE-777 in 36 DAT control straw samples No explication is given; however, considering that the treated sample contains residue in the range [4.7; 9.6] mg/kg, this deviation is deemed acceptable.

Table A 2: Summary of the studies S14-01568 and S14-01569 trials – Residues of XDE-777 and X642188

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days) (d)	Details on trial (e)	Value retained for risk assessment and MRL compliance in this dossier
			g a.s./ ha	Water (l/ha)	g a.s./hl				XDE-777	X642188			
S14-01568-01/ 45300, Loiret, Rouvres-Saint-Jean, France NEU/ 2014	Winter wheat / Arezzo	1. 12 Nov 2013 2. N/A 3. 22 Jul 2014	99.9 98.4	200 197	50.0 49.9	14 May 14 02 Jun 14	BBCH 55 BBCH 69	Whole plant Whole plant Whole plant Whole plant Whole plant Grain Straw Grain Straw Grain Straw Grain Straw	0.366 1.597 0.373 0.369 0.355 <0.01 1.221 <0.01 1.251 <0.01 1.105 <0.01 1.586	0.022 0.075 0.020 <0.01 0.011 ND 0.059 ND 0.049 ND 0.039 ND 0.024	-0 0 8 14 28 43 43 50* 50* 57 57 64 64	Plot 2: GF-3307 (EC)	Grain: <0.01 Straw: 1.33
			101.1 101.6	202 203	50.0 50.0			Whole plant Whole plant Whole plant Whole plant Whole plant Grain Straw Grain Straw Grain Straw Grain Straw	0.243 1.577 0.363 0.414 0.300 <0.01 1.040 <0.01 1.250 <0.01 1.142 <0.01 1.102	(0.009) 0.065 0.019 0.010 0.012 ND 0.044 ND 0.051 ND 0.036 ND 0.018	-0 0 8 14 28 43 43 50* 50* 57 57 64 64	Plot 3: GF-3310 (EC)	
S14-01569-01/ 45300, Loiret, Rouvres-Saint-Jean,France/ NEU/2014	Winter wheat / Arezzo	12 Nov 2013 N/A 22 Jul 2014	102.2 98.8	204 198	50.1 49.9	14 May 14 02 Jun 14	51 69	Whole plant Whole plant Whole plant Whole plant Whole plant Grain Straw Grain Straw Grain Straw Grain	0.347 1.482 0.400 0.281 0.220 <0.01 0.729 <0.01 0.879 <0.01 1.160 ND	0.016 0.084 0.016 <0.01 <0.01 ND 0.065 ND 0.049 ND 0.035 ND	-0 0 8 14 28 43 43 50* 50* 57 57 64	Plot2 : formulation GF-3312 (EC)	Cf previous line

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days) (d)	Details on trial (e)	Value retained for risk assessment and MRL compliance in this dossier
			g a.s./ ha	Water (l/ha)	g a.s./hl				XDE-777	X642188			
								Straw	0.972	0.013	64		
			97.1 99.4	194 199	50.1 49.9			Whole plant Whole plant Whole plant Whole plant Whole plant Grain Straw Grain Straw Grain Straw Grain Straw	0.648 1.723 0.882 0.568 0.658 0.011 2.675 0.010 3.110 <0.01 3.455 0.011 3.125	0.016 0.039 0.025 0.015 0.018 ND 0.163 ND 0.154 ND 0.090 ND 0.054	-0 0 8 14 28 43 43 50* 50* 57 57 64 64	Plot3 : formulation GF-2925 (SC)	(not retained, SC formulation)
S14-01568-02/ CV9 3DT, Atherstone, Warwickshire, UK/ NEU/2014	Spring wheat / Mulika	19 Mar 2014 N/A	98.3 104.4	197 209	49.9 50.0	25 Jun 14 08 Jul 14	BBCH 61 BBCH 69	Whole plant Whole plant Whole plant Whole plant Whole plant Grain Straw Grain Straw Grain Straw Grain Straw	0.248 1.331 0.476 0.611 0.397 0.024 1.585 0.010 1.531 <0.01 1.414 <0.01 1.652	0.017 0.163 0.055 0.067 0.059 ND 0.080 ND 0.083 ND 0.062 ND 0.109	-0 0 7 14 28 28 28 35* 35* 42 42 49 49	Plot 2: GF-3307 (EC)	Grain: 0.015 Straw: 1.52
			102.8 104.4	206 209	49.9 50.0			Whole plant Whole plant Whole plant Whole plant Whole plant Grain Straw Grain Straw Grain Straw Grain	0.152 1.171 0.731 0.448 0.416 0.021 2.094 <0.01 1.729 0.012 1.457 <0.01	0.012 0.147 0.057 0.060 0.067 ND 0.109 ND 0.094 ND 0.072 ND	-0 0 7 14 28 28 28 35* 35* 42 42 49	Plot 3: GF-3310 (EC)	Cf previous line

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days) (d)	Details on trial (e)	Value retained for risk assessment and MRL compliance in this dossier
			g a.s./ ha	Water (l/ha)	g a.s./hl				XDE-777	X642188			
								Straw	1.312	0.085	49		
S14-01569-02/ CV9 3DT, Atherstone, Warwickshire UK/NEU/2014	Spring wheat / Mulika	19 Mar 2014 N/A 12 Aug 2014	99.4 105.6	199 211	49.9 50.0	25 Jun 14 08 Jul 14	61 69	Whole plant Whole plant Whole plant Whole plant Whole plant Grain Straw Grain Straw Grain Straw Grain Straw	0.159 1.051 0.517 0.262 0.319 0.028 0.999 <0.01 1.029 <0.01 1.145 <0.01 1.182	0.016 0.124 0.059 0.031 0.053 ND 0.105 ND 0.087 ND 0.065 ND 0.093	-0 0 7 14 28 28 28 35* 35* 42 42 49 49	Plot2 : formulation GF-3312 (EC)	Cf previous line
			98.3 99.4	197 199	49.9 49.9			Whole plant Whole plant Whole plant Whole plant Whole plant Grain Straw Grain Straw Grain Straw Grain Straw	1.142 1.537 1.544 1.439 2.181 0.032 6.312 0.024 5.600 0.030 6.800 0.018 6.200	0.046 0.055 0.048 0.069 0.140 ND 0.226 ND 0.219 ND 0.214 ND 0.250	-0 0 7 14 28 28 28 35* 35* 42 42 49 49	Plot3 : formulation GF-2925 (SC)	(not retained, SC formulation)
S14-01568-03/ DE73 7FW, Twyford, Derbyshire, UK/ NEU/ 2014	Winter wheat / KWS Santiago	29 Sep 2013 N/A	101.6 99.2	203 198	50.0 50.1	02 Jun 14 16 Jun 14	BBCH 55	Grain Straw	<0.01 1.912	ND 0.053	45* 45*	Plot 2: GF-3307 (EC)	Grain: <0.01 Straw: 1.51
			100.8 100.0	202 200	49.9 50.0		BBCH 69		<0.01 2.038	ND 0.065	45* 45*	Plot 3: GF-3310 (EC)	
S14-01569-03/	Winter wheat /	29 Sep 2013 N/A 31 Jul 2014	101.7 120.8	203 242	50.1 49.9	02 Jun 14 16 Jun 14	55 69	Grain Straw	ND 0.594	ND 0.060	45* 45	Plot2 : formulation GF-3312 (EC)	

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days) (d)	Details on trial (e)	Value retained for risk assessment and MRL compliance in this dossier
			g a.s./ ha	Water (l/ha)	g a.s./hl				XDE-777	X642188			
DE73 7FW, Twyford, Derbyshire UK/NEU/2014	KWS Santiago		103.3 115.0	207 230	49.9 50.0			Grain Straw	0.012 5.337	ND 0.162	45* 45	Plot3 : formulation GF-2925 (SC)	(not retained, SC formulation)
S14-01568-04/ 71691, Freiberg, Baden-Württemberg, Germany 2014	Spring wheat / Triso	10 Mar 2014 N/A	100.0 95.8	200 192	50.0 49.9	13 Jun 14 24 Jun 14	BBCH 61	Grain Straw	0.012 5.465	ND 0.311	42* 42*	Plot 2: GF-3307 (EC)	Grain: 0.01 Straw: 4.05
			103.3 105.8	207 212	49.9 49.9		BBCH 69	Grain Straw	<0.01 5.200	ND 0.305	42* 42*	Plot 3: GF-3310 (EC)	
S14-01569-04/ 71691, Freiberg, Baden-Württemberg, Germany/ NEU/ 2014	Spring wheat / Triso	10 Mar 2014 N/A 05 Aug 2014	97.5 103.3	195 207	50.0 49.9	13 Jun 14 24 Jun 14	61 69	Grain Straw	ND 1.486	ND 0.225	42* 42*	Plot2 : formulation GF-3312 (EC)	
			96.7 105.8	193 212	50.1 49.9			Grain Straw	0.024 9.912	ND 0.367	42* 42*	Plot3 : formulation GF-2925 (SC)	(not retained, SC formulation)
S14-01568-05/ 40054, Prunaro Di Budrio, Province of Bologna, Italy/ SEU/2014	Winter wheat / Masarrio	21 Oct 2013 N/A	100.7 99.3	302 298	33.3 33.3	10 Apr 14 24 Apr 14	BBCH 53 BBCH 69	Whole plant Whole plant Whole plant Whole plant Whole plant Grain Straw Grain Straw Grain Straw (031A) Straw(031R1) Grain Straw (037A) Straw(037R1)	0.607 1.619 0.968 0.647 0.706 0.020 1.342 0.017 1.391 0.011 0.405 ND ND 1.319 <0.01	0.018 0.086 0.031 0.019 0.013 ND 0.025 ND 0.027 ND 0.029 ND ND 0.079 ND	-0 0 6 14 28 49 49 55* 55* 62 62 62 67 67 67	Plot 2: GF-3307 (EC)	Grain: 0.03 Straw: 1.61
			33.4 33.3	292 310	33.4 33.3			Whole plant Whole plant Whole plant Whole plant Whole plant	0.506 1.868 0.874 0.524 0.502	0.015 0.079 0.019 0.010 (0.006)	-0 0 6 14 28	Plot 3: GF-3310 (EC)	See previous line

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days) (d)	Details on trial (e)	Value retained for risk assessment and MRL compliance in this dossier
			g a.s./ ha	Water (l/ha)	g a.s./hl				XDE-777	X642188			
								Grain Straw Grain Straw Grain Straw (032A) Straw (032R1) Grain Straw (038A) Straw (038R1)	0.018 1.815 0.035 1.683 0.010 0.711 <0.01 ND 0.056 ND	ND 0.015 ND 0.013 ND 0.053 ND ND ND ND	49 49 55* 55* 62 62 62 67 67 67		
S14-01569-05/ 40054, Prunaro Di Budrio, Province of Bologna, Italy/ SEU/ 2014	Winter wheat / Masarrio	21 Oct 2013 N/A 18 Jun 2014	96.7 105.9	290 318	33.3 33.3	10 Apr 14 24 Apr 14	53 69	Whole plant Whole plant Whole plant Whole plant Whole plant Grain Straw Grain Straw Grain Straw Grain Straw	0.506 2.411 1.251 0.512 0.403 <0.01 1.421 0.038 1.768 0.014 0.023 ND 0.030	0.019 0.137 0.039 0.017 0.012 ND 0.026 ND 0.026 ND ND ND ND	-0 0 6 14 28 49 49 55* 55* 62 62 67 67	Plot2 : formulation GF-3312 (EC)	See previous line
			103.0 97.0	309 291	33.3 33.3			Whole plant Whole plant Whole plant Whole plant Whole plant Grain Straw Grain Straw Grain Straw Grain Straw	1.026 1.995 1.225 1.062 0.766 0.027 2.563 0.040 1.409 0.012 0.425 ND 0.143	0.022 0.046 0.030 0.029 0.015 ND 0.035 ND 0.020 ND <0.01 ND <0.01	-0 0 6 14 28 49 49 55* 55* 62 62 67 67	Plot3 : formulation GF-2925 (SC)	(not retained, SC formulation)
S14-01568-06/ 44492 Fonfría, Teruel, Spain/	Spring wheat / Marius	03 Jan 2014 N/A	95.6 98.9	287 297	33.3 33.3	20 May 14 05 Jun 14	BBCH 39-45	Whole plant Whole plant Whole plant	0.815 2.822 2.488	0.031 0.073 0.077	-0 0 6	Plot 2: GF-3307 (EC)	Grain: 0.02 Straw:4.61

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days) (d)	Details on trial (e)	Value retained for risk assessment and MRL compliance in this dossier
			g a.s./ ha	Water (l/ha)	g a.s./hl				XDE-777	X642188			
SEU/2014							BBCH 69	Whole plant Whole plant Grain Straw Grain Straw Grain Straw Grain Straw	1.878 0.989 0.017 5.147 0.021 5.692 0.027 4.077 0.014 5.089	0.029 0.020 ND 0.051 ND 0.063 ND 0.035 ND 0.040	14 26 53 53 60* 60* 67 67 74 74	There were no residues above the LOQ (0.01 mg/kg) in any of the untreated specimens except for L14-01568-06-024A where 0.019 mg/kg XDE-777 was found. Specimen L14-01568-06-024R1 was analysed in duplicate and 0.020 mg/kg XDE-777 was found.	
			96.1 101.9	288 306	33.4 33.3			Whole plant Whole plant Whole plant Whole plant Whole plant Grain Straw Grain Straw Grain Straw Grain Straw	0.874 2.444 2.227 1.598 0.772 0.012 3.874 0.017 4.903 0.016 4.493 0.015 3.267	0.021 0.075 0.059 0.025 0.010 ND 0.035 ND 0.042 ND 0.035 ND 0.033	-0 0 6 14 26 53 53 60* 60* 67 67 74 74	Plot 3: GF-3310 (EC) There were no residues above the LOQ (0.01 mg/kg) in any of the untreated specimens except for L14-01568-06-024A where 0.019 mg/kg XDE-777 was found. Specimen L14-01568-06-024R1 was analysed in duplicate and	See previous line

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days) (d)	Details on trial (e)	Value retained for risk assessment and MRL compliance in this dossier
			g a.s./ ha	Water (l/ha)	g a.s./hl				XDE-777	X642188			
												0.020 mg/kg XDE-777 was found.	
S14-01569-06/ 44492 Fonfría, Teruel, Spain/ SEU/2014	Spring wheat / Marius	03 Jan 2014 N/A 04 Aug 2014	95.0 101.4	285 304	33.3 33.4	20 May 14 05 Jun 14	39 – 45 69	Whole plant Whole plant Whole plant Whole plant Whole plant Grain Straw Grain Straw Grain Straw Grain Straw	0.664 3.103 1.769 1.014 0.582 0.013 2.935 <0.01 3.224 <0.01 2.596 0.011 2.328	0.026 0.137 0.052 0.026 0.013 ND 0.031 ND 0.033 ND 0.024 ND 0.027	-0 0 6 14 26 53 53 60* 60* 67 67 74 74	Plot2 : formulation GF-3312 (EC) There were no residues above the LOQ (0.01 mg/kg) in any of the untreated specimens except for L14-01569-06-024A where 0.029 mg/kg XDE-777 was found.	See previous line
			99.4 105.3	298 316	33.4 33.3			Whole plant Whole plant Whole plant Whole plant Whole plant Grain Straw Grain Straw Grain Straw Grain Straw	0.948 2.343 2.370 1.645 1.291 0.017 8.349 0.023 8.698 0.036 7.495 0.021 7.185	0.020 0.044 0.039 0.026 0.024 ND 0.096 ND 0.092 ND 0.081 ND 0.072	-0 0 6 14 26 53 53 60* 60* 67 67 74 74	Plot3 : formulation GF-2925 (SC) There were no residues above the LOQ (0.01 mg/kg) in any of the untreated specimens except for L14-01569-06-024A where 0.029 mg/kg XDE-777 was found.	(not retained, SC formulation)
S14-01568-07/		30 Nov 2013 N/A	94.2 100.0	188 200	50.1 50.0	23 Apr 14 06 May 14	BBCH 61	Grain Straw	0.066 11.967	ND 0.125	36* 36*	Plot 2: GF-3307 (EC)	Grain: 0.06 Straw: 8.31

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days) (d)	Details on trial (e)	Value retained for risk assessment and MRL compliance in this dossier
			g a.s./ ha	Water (l/ha)	g a.s./hl				XDE-777	X642188			
66750, Saint-Cyprien, Pyrénées-Orientales France/ SEU/ 2014	Winter wheat / Babylone		50.0 50.1	190 208	95.0 104.2		BBCH 69	Grain Straw	0.051 8.308	ND (0.004)	36* 36*	Plot 3: GF-3310 (EC)	
S14-01569-07/ 66750 Saint-Cyprien, Pyrénées-Orientales, France/ SEU/ 2014	Winter wheat / Babylone	30 Nov 2013 N/A 11 Jun 2014	94.2 105.0	188 210	50.1 50.0	23 Apr 14 06 May 14	61 69	Grain Straw	0.050 4.669	ND 0.292	36* 36*	Plot2 : formulation GF-3312 (EC) There were no residues above the LOQ (0.01 mg/kg) in any of the untreated specimens except for L14-01569-07-004A where 0.026 mg/kg XDE-777 was found.	
			98.3 105.0	197 210	49.9 50.0			Grain Straw	0.095 9.590	ND 0.177	36* 36*	Plot3 : formulation GF-2925 (SC) There were no residues above the LOQ (0.01 mg/kg) in any of the untreated specimens except for L14-01569-07-004A where 0.026 mg/kg XDE-777 was found.	(not retained, SC formulation)

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days) (d)	Details on trial (e)	Value retained for risk assessment and MRL compliance in this dossier
			g a.s./ ha	Water (l/ha)	g a.s./hl				XDE-777	X642188			
S14-01568-08/ 44492, Lagueruela, Aragon, Spain/ SEU/2014	Spring wheat / Marius	26 Dec 2013 N/A	105.6 103.9	317 312	33.3 33.3	19 May 14 04 Jun 14	BBCH 39-45	Grain Straw	0.020 7.095	ND 0.156	41* 41*	Plot 2: GF-3307 (EC)	Grain: 0.02 Straw: 5.50
			102.8 101.7	308 305	33.4 33.3		BBCH 69	Grain Straw	0.022 5.811	ND 0.120	41* 41*	Plot 3: GF-3310 (EC)	
S14-01569-08/ 44492 Lagueruela, Aragon, Spain/ SEU/2014	Spring wheat / Marius	26 Dec 2013 N/A 15 Jul 2014	107.2 105.0	322 315	33.3 33.3	19 May 14 04 Jun 14	39 – 45 69	Grain Straw	0.013 3.583	ND 0.099	41* 41*	Plot2 : formulation GF-3312 (EC)	
			106.1 97.2	318 292	33.4 33.3			Grain Straw	0.040 10.560	ND 0.277	41* 41*	Plot3 : formulation GF-2925 (SC)	(not retained, SC formulation)

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

Specimens L14-01568-05-031A and L14-01568-05-037A showed unexpected residues of XDE-777 and prothioconazole-desthio. The associated retain specimens were analysed in duplicate. The results of all the analysis are presented in the table above with specimen numbers included in column 8 for those affected.

Table A 3: Summary of the study S14-01568 trials on GF-3307 – Residues of Prothioconazole-desthio

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Prothioconazole-desthio		
S14-01568-01/ France/ NEU/ 2014	Winter wheat / Arezzo	1. 12 Nov 2013 2. N/A 3. 22 Jul 2014	199.8 196.9	200 197	99.9 99.9	14 May 14 02 Jun 14	BBCH 55 BBCH 69	Whole plant Whole plant Whole plant Whole plant Whole plant Grain Straw Grain Straw	- - - - - ND 0.117 ND 0.157	-0 0 8 14 28 43 43 50* 50*	There were no residues above the LOQ (0.01 mg/kg) in any of the untreated specimens

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Prothioconazole-desthio		
								Grain Straw Grain Straw	ND 0.146 ND 0.169	57 57 64 64	
S14-01568-02/ UK/ NEU/ 2014	Spring wheat / Mulika	19 Mar 2014 N/A	196.7 208.9	197 209	99.8 100.0	25 Jun 14 08 Jul 14	BBCH 61 BBCH 69	Whole plant Whole plant Whole plant Whole plant Whole plant Grain Straw Grain Straw Grain Straw Grain Straw	- - - - - 0.029 0.885 0.010 0.790 0.011 0.625 (0.008) 0.504	-0 0 7 14 28 28 28 35* 35* 42 42 49 49	There were no residues above the LOQ (0.01 mg/kg) in any of the untreated specimens
S14-01568-03/ UK/ NEU/ 2014	Winter wheat / KWS Santiago	29 Sep 2013 N/A	203.3 198.3	203 198	100.1 100.2	02 Jun 14 16 Jun 14	BBCH 55 BBCH 69	Grain Straw	ND 0.299	45* 45*	There were no residues above the LOQ (0.01 mg/kg) in any of the untreated specimens
S14-01568-04/ Germany/ NEU/ 2014	Spring wheat / Triso	10 Mar 2014 N/A	200.0 191.7	200 192	100.0 99.8	13 Jun 14 24 Jun 14	BBCH 61 BBCH 69	Grain Straw	0.011 1.293	42* 42*	There were no residues above the LOQ (0.01 mg/kg) in any of the untreated specimens

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

A 2.1.3.1.2 Studies S15-02628 & S15-02629

Comments of zRMS:	The studies S15-02628 & S15-02629 on the determination of residues of fenpicoxamid (XDE-777) in winter and spring wheat have been evaluated in Registration Report for GF-3308 on February 2022 by zRMS-PL and the summary is presented below. The residue data for prothioconazole is evaluated in this document and a summary is also provided below. <u>Study Number: S15-02628; DAS Study ID 150650</u> The magnitude of residues of XDE-777 and pyraclostrobin in winter and spring wheat was determined following two post emergent broadcast applications of GF-3309 fungicide to wheat. To determine maximum XDE-777 and pyraclostrobin residue levels in wheat, field trials were established in which two post-emergent foliar applications of GF-3309, an emulsifiable concentrate (EC) formulation containing XDE-777 at a nominal concentration of 50 g/L and pyraclostrobin at a nominal concentration of 62.5 g/L, were applied in a nominal 14-day interval (actual interval ranged from 12 to 15 days) between applications and the last application at BBCH growth stage 65-71. Trials were conducted at 10 sites: 6 in N-EU and 4 in S-EU. Each site had a control plot and a treated plot. Two applications of GF-3309 were applied at a target rate of 2.0 L product/ha (100 g ai/ha XDE-777 + 125 g ai/ha pyraclostrobin) to Plot 2, for a seasonal total of 4.0 L product/ha. At the six harvest trials, grain and straw specimens were taken at BBCH growth stage 89-93, normal commercial harvest (NCH). At the four decline trials whole plant specimens were collected immediately before the second application (0 DBA2) and at 0 (immediately following the second application; 0 DAA2), 7, 14 and 28/30 days after the final applications to plot 2. Grain and straw specimens were taken 6/7 days before normal commercial harvest (NCH), at NCH, and 6-8, and 14 days after NCH. Residues of XDE-777 and its X642188 metabolite were determined using a validated analytical method (reported in Eurofins study no. S12-01537 / Dow AgroSciences study code 120615) using Liquid Chromatography Mass Spectrometry (LC-MS/MS). The limit of detection (LOD) and limit of quantitation (LOQ) for XDE-777 and its X642188 metabolite in wheat whole plant, grain and straw were 0.003 mg/kg and 0.01 mg/kg, respectively. Recoveries in wheat whole plant averaged 90% for XDE-777 and 100% for X642188. Recoveries in wheat grain averaged 98% for XDE-777 and 101% for X642188. Recoveries in wheat straw averaged 107% for XDE-777 and 106% for X642188. The maximum period of frozen storage for XDE-777 and X642188 were 162 days and 191 days respectively. Analyte residues were not detected above the analytical method LOQ in untreated samples. Residues of XDE-777 in grain taken at normal commercial harvest for plot / treatment 2 ranged from 0.007 mg/kg, which is <LOQ of 0.01 mg/kg to 0.059 mg/kg. Residues of X642188 in grain taken at normal commercial harvest for plot / treatment 2 were ND (not detected, <0.003 mg/kg). The maximum residue of XDE-777 in whole plant for plot / treatment 2 was 2.349 mg/kg immediately after the second application and 0.808 mg/kg for specimens taken 28/30 days after the applications. The maximum residue of X642188 in whole plant for plot / treatment 2 was 0.146 mg/kg immediately after the second application and 0.042 mg/kg for specimens taken 28/30 days after the applications. Residues of XDE-777 in straw taken at normal commercial harvest for plot / treatment 2 ranged from 0.457 to 6.260 mg/kg. Residues of X642188 in straw taken at normal commercial harvest for plot / treatment 2 ranged from 0.032 to 0.191 mg/kg.

	Some deviations have been identified, but do not affect the study. The study is acceptable. <u>Report No. S15-02629, DAS Study ID 150649</u> The magnitude of residues of XDE-777 and prothioconazole-desthio in winter and spring wheat was determined following two post emergent broadcast applications of GF-3307 fungicide to wheat. To determine maximum XDE-777 and prothioconazole-desthio residue levels in wheat, field trials were established in which two post-emergent foliar applications of GF-3307, an emulsifiable concentrate (EC) formulation containing XDE-777 and prothioconazole at nominal concentrations of 50 g/L and 100 g/L respectively, were applied in a nominal 14-day interval (actual interval ranged from 12 to 15 days) between applications and the last application at BBCH growth stage 67-69. Trials were conducted at 10 sites: 6 in N-EU and 4 in S-EU. Each site had a control plot and a treated plot. Two applications of GF-3307 were applied at a target rate of 2.0 L product/ha (100 g ai/ha XDE-777 + 200 g ai/ha prothioconazole) to Plot 2 in each trial, for a seasonal total of 4.0 L product/ha. At the six harvest trials, grain and straw specimens were taken at BBCH growth stage 89-93, normal commercial harvest (NCH). At the four decline trials whole plant specimens were collected immediately before the second application (0 DBA2) and at 0 (immediately following the second application; 0 DAA2), 7, 14 and 28/30 days after the final applications to plot 2. Grain and straw specimens were taken 6/7 days before normal commercial harvest (NCH), at NCH, and 6-8, and 14 days after NCH. Residues of XDE-777 and its X642188 metabolite were determined using a validated analytical method (reported in Eurofins study no. S12-01537 / Dow AgroSciences study code 120615) using Liquid Chromatography Mass Spectrometry (LC-MS/MS). The limit of detection (LOD) and limit of quantitation (LOQ) for XDE-777 and its X642188 metabolite in wheat whole plant, grain and straw were 0.003 mg/kg and 0.01 mg/kg, respectively. Residues of prothioconazole-desthio were determined using a validated analytical method (Bayer Ag. method number '00598') using Liquid Chromatography Mass Spectrometry (LC-MS/MS). The limit of detection (LOD) and limit of quantitation (LOQ) for prothionconazole-desthio in wheat grain were 0.003 mg/kg and 0.01 mg/kg, respectively. The limit of detection (LOD) and limit of quantitation (LOQ) for prothioconazole-desthio in wheat straw were 0.015 mg/kg and 0.05 mg/kg, respectively. Recoveries in wheat whole plant averaged 97% for XDE-777 and 94% for X642188. Recoveries in wheat grain averaged 104% for XDE-777, 109% for X642188 and 100% for Prothioconazole-desthio. Recoveries in wheat straw averaged 110% for XDE-777, 110% for X642188 and 102% for Prothioconazole-desthio. The maximum period of frozen storage for XDE-777, X642188 and prothioconazole-desthio were 204 day, 204 days and 178 days respectively. With two exceptions, analyte residues were not detected above the analytical method LOQ in untreated samples. The exceptions are specimens L15-02629-01-011A where a residue of XDE-777 at 0.016 mg/kg was found, and L15-02629-09-002A where an average residue of prothioconazole-desthio at 0.082 mg/kg was found. On two occasions residues above the analytical method LOD were detected in untreated field specimens. This data indicates that untreated control plots and samples remained largely uncontaminated through the course of the study. **Residues in grain** Residues of XDE-777 in grain taken at normal commercial harvest for plot / treatment 2 ranged from 0.003 mg/kg, which is <LOQ of 0.01 mg/kg to 0.069 mg/kg. Residues of X642188 in grain taken at normal commercial harvest for plot / treatment 2

	were ND (not detected, <0.003 mg/kg). Residues of prothioconazole-desthio in grain taken at normal commercial harvest for plot / treatment 2 ranged from ND (not detected, <0.003 mg/kg) to 0.023 mg/kg. **Residues in whole plant** The maximum residue of XDE-777 in whole plant for plot / treatment 2 was 2.791 mg/kg immediately after the second application and 1.579 mg/kg for specimens taken 28/30 days after the applications. The maximum residue of X642188 in whole plant for plot / treatment 2 was 0.090 mg/kg immediately after the second application and 0.025 mg/kg for specimens taken 28/30 days after the applications. **Residues in straw** Residues of XDE-777 in straw taken at normal commercial harvest for plot / treatment 2 ranged from 0.487 to 3.589 mg/kg. Residues of X642188 in straw taken at normal commercial harvest for plot / treatment 2 ranged from 0.028 to 0.231 mg/kg. Residues of prothioconazole-desthio in straw taken at normal commercial harvest for plot / treatment 2 ranged from 0.302 to 0.942 mg/kg. Some deviations have been identified, but do not affect the study. The study is acceptable. **Remark:** **1. The trials of the study S15-02628 and the study S15-02629 were conducted at the same sites and at the same times, and therefore cannot be considered independent. The results were therefore combined and the mean was retained (see table 7.2-9).** 2. Trials were conducted at 10 sites: 6 in N-EU: trials 1, 2, 3, 5, 8 and 9 and 4 in S-EU: trials 4, 6 , 7 and 10. The trial 5 - S15-02629-05 has been located in 71290 Simandre, Saône-et-Loire in France. According to the Authors of study S15-02629, the trial is located in Southern EU (EU Climatic Zone). However, according to the SANTE/2019/12752 – "Technical Guidelines On Data Requirements For Setting Maximum Residue Levels, Comparability Of Residue Trials And Extrapolation Of Residue Data On Products From Plant And Animal Origin", 71290 Simandre, Saône-et-Loire is located in Bourgogne-Franche-Comté Region in Northern France. Taking into the above account, in our opinion, 6 trials were conducted in N-EU and 4 trials were conducted in S-EU according to the current guidance.

Reference:	KCA 6.3.1/01	KCA 6.3.1/04
Report	Determination of Residues Of XDE-777 and Pyraclostrobin after Two Applications of GF-3309 to Spring Wheat and Winter Wheat at 5 Sites in Northern Europe and 5 Sites in Southern Europe, 2015, T. White, 2016, Report No. S15-02628, DAS Study ID 150650	Determination of Residues of XDE-777 and Prothioconazole after Two Applications of GF-3307 to Spring and Winter Wheat, at 5 sites in Northern Europe and 5 sites in Southern Europe, 2015, T. White, 2016, Report No. S15-02629, DAS Study ID 150649
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	Guideline 7029/VI/95 (rev. 5) to Directive 91/414/EEC and Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009
Deviations:	None with consequences: S15-02628 ALL FIELD TRIALS: The long term weather averages were not taken from the previous 10 (or 5 years) as required by the study plan. This has no impact on the study.	None with impact S15-02629 ALL FIELD TRIALS: The long term weather averages were not taken from the previous 10 (or 5 years) as required by the study plan. This has no impact on the study. S15-02629-01: The distance between plots 1 and 2 was only 10 m instead of 15 m as required by

S15-02628-01: During the storage of the S1 and S2 specimens the temperature reached a maximum of -5.1 °C for approximately 17.5 hours. This was caused by the specimens being placed in the freezer, and the temperature remained below 0°C this has no impact on the study.
S15-02628-02: No photographs were taken at application A2. This has no impact on the study.
S15-02628-03: During the storage of the S1 specimens the temperature reached a maximum of -14 °C for approximately 16.5 hours. This has no impact on the study.
S15-02628-03: No maintenance history is available for 2012.
This has no impact on the study.
S15-02629-04: As the start/end time of sampling of each specimen was not recorded it is not possible to confirm the exact time between sampling/storage, however it is confirmed that it was less than 12 hours. This has no impact on the study.

S15-02628-04: Specimen L15-02628-04-010R1 was less than 1kg as required by the study plan. This has no impact on the study.
S15-02628-04: No previous year's maintenance history is available. This has no impact on the study.Eurofins Agroscience Services

S15-02628-06: The distance between plots 1 and 2 was only 10 m instead of 15 m as required by the study plan. This has no impact on the study.

S14-02628-07: The weather station was 30 km from the trial site instead of < 20 km as required by the study plan. This has no impact on the study.

S15-02628-08: In error treated specimens L15-02628-08-002A and -002R1 were not taken. These specimens were not available for analysis.
S15-02628-08: Due to the farmers tight crop rotation it was not going to be possible to generate the S8 and S9 specimens.
Additional bulk specimens were taken at S7 which were then stored to be threshed at a later date to generate the S8 and S9 specimens. This has no impact on the study.

S15-02628-09: The distance between plots 1 and 2 was only 10 m instead of 15 m as required by the study plan. This has no impact on the study.

S15-02628-09: Application A1 was overdosed by 12.5 %, however as application the study plan. This has no impact on the study.
S15-02629-01: During the storage of the S1 and S2 specimens the temperature reached a maximum of -5.1 °C for approximately 17.5 hours. This was caused by the specimens being placed in the freezer, and the temperature remained below 0°C this has no impact on the study.
S15-02629-02: No photographs were taken at application A2. This has no impact on the study.
S15-02629-03: During the storage of the S1 specimens the temperature reached a maximum of -14 °C for approximately 16.5 hours. This has no impact on the study.
S15-02629-03: No maintenance history is available for 2012. This has no impact on the study.
S15-02629-04: As the start/end time of sampling of each specimen was not recorded it is not possible to confirm the exact time between sampling/storage, however it is confirmed that it was less than 12 hours. This has no impact on the study.
S15-02629-04: No previous year's maintenance history is available. This has no impact on the study.
Deviations S15-02629-06: The distance between plots 1 and 2 was only 10 m instead of 15 m as required by the study plan. This has no impact on the study.
S14-02628-07: The weather station was 30 km from the trial site instead of < 20 km as required by the study plan. This has no impact on the study.
S15-02629-08: In error treated specimens L15-02629-08-002A and -002R1 were not taken. These specimens will not be available for analysis.
S15-02629-08: Due to the farmers tight crop rotation it was not going to be possible to generate the S8 and S9 specimens.
Additional bulk specimens were taken at S7 which were then stored to be threshed at a later date to generate the S8 and S9 specimens.
S15-02629-09: The distance between plots 1 and 2 was only 10 m instead of 15 m as required by the study plan. This has no impact on the study.
S15-02629-09: Application A1 was overdosed by 15 %, however as application A2 was applied correctly this has no impact on the study.
S15-02629-09: No photographs were taken at sampling S1. This has no impact on the study.
S15-02629-L1: The correct limit of quantification for the determination of prothioconazole-desthio in straw should be 0.05 mg/kg not 0.01 mg/kg as stated in the study plan.
S15-02629-L1:
Run 1 X642188: The mean procedural recovery at the LOQ level is slightly above 110%. Data will be accepted as it is only slightly above 110%, and there is no residues in any of the samples (all

	A2 was applied at -5% this has no impact on the study. S15-02628-09: Application A2 was carried out at BBCH growth stage 69-71 instead of 69 as required by the study plan. This has no impact on the study. S15-02628-09: No photographs were taken at sampling S1. This has no impact on the study. S15-02628-L1: For X642188, the recoveries at the limit of quantification, across the study, are slightly higher than 110 % (actual 114 %). However as the precision (RSD%) at the LOQ level is good and satisfactory overall mean recoveries were obtained this is deemed to have no impact and the data was accepted. S15-02628-L1: Batch 6, Run 9, X642188: Recoveries at the LOQ were slightly higher than 110% in this run, and 114% overall for the study at the LOQ level, however a good RSD at LOQ level and satisfactory overall mean (at all levels) were obtained, therefore the data can be accepted. This has no impact on the study. S15-02628-L1: Batch 7, Run 13, Pyr	reported as ND = Not detected), satisfactory mean procedural recovery is also achieved at the 10x LOQ level. Runs 8 and 9 X642188: The mean procedural recovery at the higher level is slightly above 110% across the whole study. Data will be accepted as it is only slightly above 110% (111%) and satisfactory mean procedural recovery is also achieved at the LOQ level and overall for both levels. This has no impact on the study. S15-02629-L1: Run 12 and 13 XDE-777: The mean procedural recovery at the LOQ level is slightly above 110% across the whole study. Data will be accepted as it is only slightly above 110% (112%) and satisfactory mean procedural recovery is also achieved at the higher level and overall for both levels. This has no impact on the study.
GLP:	Yes	Yes
Acceptability:	Yes	Yes

The trials of the study S15-02628 were conducted at the same sites and times than the respective trials in study S15-02629. Therefore, they cannot be considered as independent from these trials and the summary have been merged by zRMS. GF-3307 is an EC formulation, 2 EC formulations were tested in these 2 studies. Therefore, the considered results are the mean of the plots tested with EC formulations.

Summary of global information on study S15-02628

Comparative trials (between formulations, with and adjuvant/safener/synergist)	N
Number of applications	2
Dose (g as/ha)	Fenpicoxamide (XDE-777): 100 g a.s./ha Pyraclostrobin: 125 g a.s./ha
Mode of application	Foliar spray
PHI (days) and/or growth stage (BBCH)	BBCH 65-71
Analytical method (Code +Type)	XDE-777 and its X642188 metabolite: Eurofins study no. S12-01537 / Dow AgroSciences study code 120615 (LC-MS/MS). T Pyraclostrobin were determined using a validated analytical method (BASF Method No. 535/1) using Liquid Chromatography Mass Spectrometry (LC-MS/MS). The limit of detection (LOD) and limit of quantitation (LOQ) for pyraclostrobin in wheat grain and straw were 0.003 mg/kg and 0.01 mg/kg, respectively.
LoQ (mg/kg)	XDE-777 and its X642188 metabolite in wheat whole plant, grain and straw: 0.01 mg/kg

	Pyraclostrobin: wheat whole plant, grain and straw: 0.01 mg/kg

Summary of the study S15-02628 trials

N° Trial		1	2	3	4	5	6	7	8	9	10
North/South/Indoor		N	N	N	S	N	S	S	N	N	S
Decline (D)/Harvest (H) trial?		D	H	H	D	H	H	H	D	H	D
Formulation		EC	EC	EC	EC	EC	EC	EC	EC	EC	EC
Equivalence between formulations		Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Accordance with intended GAP		Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Correct sampling		Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Samples frozen within 24h		Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Storage period (in days)	Sample	Whole plant: 191; Grain: 143; Straw: 162									
	Extract	8[(a)]									
Storage T° < -18°C		Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Validated analytical method		Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Negative controls		Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Considered trial		Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Remarks											

(a): Recoveries were conducted concurrently to analysis of untreated and treated samples (recoveries in wheat whole plant averaged 90 % for XDE-777 and 100 % for X642188. Recoveries in wheat straw averaged 107 % for XDE-777 and 106 % for X642188.), therefore the storage of extracts for more than 24 hours is deemed acceptable.

Summary of global information on study S15-02629

Comparative trials (between formulations, with and adjuvant/safener/synergist)	N
Number of applications	2
Dose (g as/ha)	Fenpicoxamide: 100 Prothioconazole: 200
Mode of application	Foliar spray
PHI (days) and/or growth stage (BBCH)	BBCH 61-69
Analytical method (Code +Type)	Fenpicoxamide and metabolite X642188 Eurofins study no. S12-01537 / Dow AgroSciences study code 120615: LC-MS/MS Grain and straw: 0.01 mg/kg Prothioconazole-desthio Bayer Ag. method number '00598': LC-MS/MS Grain: 0.01 mg/kg Straw: 0.05 mg/kg
LoQ (mg/kg)	Fenpicoxamide and metabolite X642188: Grain and straw: 0.01 mg/kg Prothioconazole: Grain: 0.01 mg/kg Straw: 0.05 mg/kg

Summary of the study S15-02629 trials - Fenpicoxamide

N° Trial		1	2	3	4	5	6	7	8	9	10
North/South/Indoor		N	N	N	S	N	S	S	N	N	S
Decline (D)/ Harvest (H) trial?		D	H	H	D	H	H	H	D	H	D
Formulation		EC	EC	EC	EC	EC	EC	EC	EC	EC	EC
Equivalence between formulations		Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Accordance with intended GAP		Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Correct sampling		Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Samples frozen within 24h		Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Storage period (in days)	Sample	~~205~~ 204									
	Extract	5(a)									
Storage T° <-18°C		Y	Y	Y	Y	Y	Y	Y	Y	Y	Y

Validated analytical method	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Negative controls	Y(b)	Y	Y	Y	Y	Y	Y	Y	Y(c)	Y
Considered trial	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Remarks										

a) Recoveries were conducted concurrently to analysis of untreated and treated samples (Recoveries in wheat whole plant averaged 97 % for XDE-777 and 94 % for X642188. Recoveries in wheat grain averaged 104 % for XDE-777, 109 % for X642188 and 100 % for Prothioconazole-desthio. Recoveries in wheat straw averaged 110 % for XDE-777, 110 % for X642188 and 102 % for Prothioconazole-desthio.), therefore the storage of extracts for more than 24 hours is deemed acceptable.

b) Residues of fenpicoxamide were quantified (0.016 mg/kg) in the 45DAT straw sample. No explanation has been given for this result; however, considering that the treated sample contains residue at 0.713 mg/kg, this deviation is deemed acceptable.

c) Residues of prothioconazole-desthio were quantified (0.082 mg/kg) in the 46DAT straw sample. No explanation has been given for this result; however, considering that the treated sample contains residue at 0.851 mg/kg, this deviation is deemed acceptable.

Summary of the study S15-02629 trials – Prothioconazole

N° Trial		1	2	3	4	5	6	7	8	9	10
North/South/Indoor		N	N	N	S	N	S	S	N	N	S
Decline (D)/ Harvest (H) trial?		D	H	H	D	H	H	H	D	H	D
Formulation		EC	EC	EC	EC	EC	EC	EC	EC	EC	EC
Equivalence between formulations		Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Accordance with intended GAP		Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Correct sampling		Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Samples frozen within 24h		Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Max Storage period (in days)	Sample	113	108	144	147	150	149	127	148	136	165
	Extract	1	1	1	1	1	1	1	1	1	1
Storage T° <-18°C		Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Validated analytical method		Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Negative controls		Y	Y	Y	Y	Y	Y	Y	Y	Y(1)	Y
Considered trial		Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Remarks											

(1) Residues of prothioconazole-desthio were quantified (0.082 mg/kg) in the 46DAT straw sample. No explanation has been given for this result.

Table A 4: Summary of the study S15-02628 trials on GF-3309 – Residues of XDE-777 and X642188

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days) (d)	Details on trial (e)	Value retained for risk assessment and MRL compliance in this dossier
			g a.s./ ha	Water (l/ha)	g a.s./hl				XDE-777	X642188			
S15-02628-01/ HU17 8JF, Bishop Burton UK/ NEU/ 2015	Winter wheat / Reflection	27 Sep 2014 N/A 19 Aug 2015	102.1 97.6	204 195	50.0 50.1	15 Jun 15 29 Jun 15	BBCH 61 BBCH 69	Whole plant Whole plant Whole plant Whole plant Whole plant Grain Straw Grain Straw Grain Straw Grain Straw	0.278 ~~2.809~~ 1.124 0.479 0.31 0.318 (0.008) 1.155 0.012 0.457 **0.014** 0.712 (0.009) **0.839**	00.018 0.058 0.033 0.016 0.013 ND 0.054 ND 0.056 ND 0.081 ND 0.045	-0 0 7 14 28 45 45 51* 51* 59 59 65 65		Grain: 0.01 Straw: 0.80
S15-02629-01/ HU17 8JF, Bishop Burton, East Yorkshire, UK/NEU/2015	Winter wheat / Reflection	27 Sep 2014 N/A 19 Aug 2015	99.0 98.3	198 197	50.0 49.9	15 Jun 15 29 Jun 15	BBCH 61 BBCH 69	Whole plant Whole plant Whole plant Whole plant Whole plant Grain Straw Grain Straw Grain Straw Grain Straw	0.288 1.663 0.422 0.275 0.225 0.011 0.713 **0.014** 0.487 0.012 **0.767** <0.01 0.198	0.027 0.090 0.026 0.017 0.010 ND 0.032 ND 0.054 ND 0.059 ND 0.014	-0 0 7 14 28 45 45 51* 51* 59 59 65 65	There were no residues above the LOQ in any of the untreated specimens, except 45DAT samples straw sample (0.016 mg/kg of XDE-777)	

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days) (d)	Details on trial (e)	Value retained for risk assessment and MRL compliance in this dossier
			g a.s./ ha	Water (l/ha)	g a.s./hl				XDE-777	X642188			
S15-02628-02/ L39 6SX, Lydiate, Lancashire UK/ NEU/ 2015	Winter wheat / KWS Kielder	03 Oct 2014 N/A 18 Aug 2015	110.0 106.7	220 213	50.0 50.1	23 Jun 15 07 Jul 15	BBCH 65-67 BBCH 69	Grain Straw	**0.034** **2.38**	ND 0.122	42* 42*		Grain: 0.03 Straw: 1.92
S15-02629-02/ L39 6SX, Lydiate, Lancashire, UK/NEU/2015	Winter wheat / KWS Kielder	03 Oct 2014 N/A 18 Aug 2015	108.3 110.0	217 220	49.9 50.0	23 Jun 15 07 Jul 15	BBCH 65–67 BBCH 69	Grain Straw	**0.023** **1.465**	ND 0.112	42* 42*	There were no residues above the LOQ in any of the untreated specimens	
S15-02628-03/ 67140 Saint-Pierre, Alsace, Bas-Rhin France/ NEU/ 2015	Winter wheat / Pakilo	22 Oct 2014 N/A 13 Jul 2015	95.8 100.4	287 301	33.4 33.4	19 May 15 01 Jun 15	BBCH 59 BBCH 69	Grain Straw	**0.011** **2.69**	ND 0.045	42* 42*		Grain: 0.01 Straw: 2.64
S15-02629-03/ 67140 Saint-Pierre, Alsace, Bas-Rhin, France/NEU/ 2015	Winter wheat / Pakilo	22 Oct 2014 N/A 13 Jul 2015	98.8 102.7	296 308	33.4 33.3	19 May 15 01 Jun 15	BBCH 59 BBCH 69	Grain Straw	**0.016** **2.580**	ND 0.035	42* 42*	There were no residues above the LOQ in any of the untreated specimens	

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days) (d)	Details on trial (e)	Value retained for risk assessment and MRL compliance in this dossier
			g a.s./ ha	Water (l/ha)	g a.s./hl				XDE-777	X642188			
S15-02628-04/ 86120 Morton, Vienne France/ SEU/ 2015	Winter wheat / Cellule	15 Dec 2014 N/A 16 Jul 2015	100.0 103.2	300 310	33.3 33.3	19 May 15 01 Jun 15	BBCH 56 BBCH 69	Whole plant Whole plant Whole plant Whole plant Whole plant Grain Straw Grain Straw Grain Straw Grain Straw	0.675 2.349 1.512 0.527 0.808 **0.025** 2.655 0.01 2.316 0.023 **3.698** 0.009 3.612	0.014 0.051 0.036 0.023 0.014 ND 0.043 ND 0.032 ND 0.056 ND 0.103	-0 0 7 14 30 39 39 45* 45* 51 51 59 59		Grain: 0.03 Straw: 4.22
S15-02629-04/ 86120 Morton, Vienne, FranceFrance/ SEU/ 2015	Winter wheat / Cellule	15 Dec 2014 N/A 16 Jul 2015	94.7 105.0	284 315	33.3 33.3	19 May 15 01 Jun 15	BBCH 59 BBCH 69	Whole plant Whole plant Whole plant Whole plant Whole plant Grain Straw Grain Straw Grain Straw Grain Straw	0.671 2.791 1.571 0.823 1.579 **0.028** 3.571 0.011 2.693 0.020 4.168 <0.01 **4.742**	0.015 0.054 0.033 0.033 0.023 ND 0.049 ND 0.031 ND 0.039 ND 0.118	-0 0 7 14 30 39 39 45* 45* 51 51 59 59	There were no residues above the LOQ in any of the untreated specimens	
S15-02628-05/ 71290 Simandre, Saône-et-Loire, France/ NEU/ 2015	Spring wheat / Sensus	07 Mar 2015 N/A 07 Jul 2015	108.7 93.2	217 186	50.1 50.1	29 May 15 11 Jun 15	BBCH 59 BBCH 69	Grain Straw	**0.059** **2.488**	ND 0.082	26* 26*		Grain: 0.06 Straw: 2.62
S15-02629-05/ 71290 Simandre, Saône-et-Loire, France/	Spring wheat / Sensus	07 Mar 2015 N/A 07 Jul 2015	105.3 93.0	211 186	49.9 50.0	29 May 15 11 Jun 15	BBCH 59 BBCH 69	Grain Straw	**0.0687** **2.742**	ND 0.051	26* 26*	There were no residues above the LOQ in any of the untreated	

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days) (d)	Details on trial (e)	Value retained for risk assessment and MRL compliance in this dossier
			g a.s./ ha	Water (l/ha)	g a.s./hl				XDE-777	X642188			
~~SEU~~ NEU/2015												specimens	
S15-02628-06/ 50367 Retascón Spain/ SEU/2015	Winter wheat / Garcia	10 Nov 2014 N/A 08 Jul 2015	108.3 92.9	217 186	49.9 49.9	13 May 15 28 May 15	BBCH 47 BBCH 67-69	Grain Straw	**0.01** **6.26**	ND 0.112	41* 41*		Grain: 0.01 Straw: 4.19
S15-02629-06/ 50367 Retascón, Spain/ SEU/2015	Winter wheat / Garcia	10 Nov 2014 N/A 08 Jul 2015	95.2 92.9	190 186	50.1 49.9	13 May 15 28 May 15	BBCH 47 BBCH 67-69	Grain Straw	**<0.01** **2.124**	ND 0.045	41* 41*	There were no residues above the LOQ in any of the untreated specimens	
S15-02628-07/ 44492 Fonfría, Teruel Spain/ SEU/2015	Winter wheat / Marius	01 Nov 2014 N/A 30 Jul 2015	91.9 95.6	276 287	33.3 33.3	27 May 15 10 Jun 15	BBCH 57-61 BBCH 69	Grain Straw	**0.01** **2.453**	ND 0.044	50* 50*		Grain: 0.01 Straw: 2.25
S15-02629-07/ 44492 Fonfría, Teruel,Spain/ SEU/2015	Winter wheat / Marius	01 Nov 2014 N/A 30 Jul 2015	108.1 95.6	324 287	33.4 33.3	27 May 15 10 Jun 15	BBCH 57-61 BBCH 69	Grain Straw	**<0.01** **2.048**	ND 0.028	50* 50*	There were no residues above the LOQ in any of the untreated specimens	

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days) (d)	Details on trial (e)	Value retained for risk assessment and MRL compliance in this dossier
			g a.s./ ha	Water (l/ha)	g a.s./hl				XDE-777	X642188			
S15-02628-08/ NG34 8PE, Silk Willoughby, Lincolnshire UK/ NEU/ 2015	Spring wheat / Mulika	12 May 2015 N/A 19 Aug 2015	105.4 108.3	211 217	50.0 49.9	16 Jun 15 29 Jun 15	BBCH 39 BBCH 69	Whole plant Whole plant Whole plant Whole plant Whole plant Grain Straw Grain Straw Grain Straw Grain Straw	* 1.1 0.804 0.406 0.62 **0.02** 2.671 0.011 3.828 0.008 4.557 0.007 **5.174**	* 0.085 0.045 0.036 0.042 ND 0.126 ND 0.191 ND 0.116 ND 0.1	-0 0 7 14 30 44 44 51* 51* 58 58 65 65		Grain: 0.02 Straw: 5.72
S15-02629-08/ NG34 8PE, Silk Willoughby, Lincolnshire, UK/NEU/2015	Spring wheat / Mulika	12 Mar 2015 N/A 19 Aug 2015	108.3 107.5	217 215	49.9 50.0	16 Jun 15 29 Jun 15	BBCH 39 BBCH 69	Whole Plant Whole Plant Whole Plant Whole Plant Grain Straw Grain Straw Grain Straw Grain Straw	1.653 1.605 0.834 0.831 **0.022** 3.134 0.012 3.589 0.011 4.702 <0.01 **6.263**	0.076 0.043 0.033 0.025 ND 0.081 ND 0.231 ND 0.111 ND 0.141	0 7 14 30 44 44 51* 51* 58 58 65 65	There were no residues above the LOQ in any of the untreated specimens	

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days) (d)	Details on trial (e)	Value retained for risk assessment and MRL compliance in this dossier
			g a.s./ ha	Water (l/ha)	g a.s./hl				XDE-777	X642188			
S15-02628-09/ LE12 5RQ, West Leake, Leicestershire UK/NEU/ 2015	Spring wheat / Mulika	05 Mar 2015 N/A 24 Aug 2015	112.5 95.0	225 190	50.0 50.0	25 Jun 15 09 Jul 15	BBCH 61 BBCH 69	Grain Straw	**<u><0.01</u>** **<u>0.762</u>**	ND 0.061	46* 46*		Grain: 0.01 Straw: 0.96
S15-02629-09/ LE12 5RQ, West Leake, Leicestershire, UK/NEU/2015	Spring wheat / Mulika	05 Mar 2015 N/A 24 Aug 2015	115.0 96.7	230 193	50.0 50.1	25 Jun 15 09 Jul 15	BBCH 61 BBCH 69	Grain Straw	**<u>0.012</u>** **<u>1.148</u>**	ND 0.066	46* 46*	There were no residues above the LOQ in any of the untreated specimens, except in the 46DAT straw sample, where residues of prothioconazole-desthio were quantified (0.082 mg/kg).	
S15-02628-10/ 40057, Granarolo, Emilia-Romagna, Italy/ SEU/ 2015	Spring wheat / Aquilante	10 Feb 2015 N/A 29 Jul 2015	105.1 108.4	315 325	33.4 33.4	08 May 15 20 May 15	BBCH 51 BBCH 69	Whole plant Whole plant Whole plant Whole plant Whole plant Grain Straw Grain Straw Grain Straw Grain Straw	0.33 1.362 0.236 0.19 0.175 **<u>0.013</u>** 0.892 <0.01 1.193 0.004 0.722 0.006 **<u>1.265</u>**	0.02 0.146 0.035 0.018 0.013 ND 0.058 ND 0.034 ND 0.018 ND 0.021	-0 0 7 14 28 33 33 40* 40* 47 47 54 54		Grain: 0.02 Straw: 3.00
S15-02629-10/ 40057, Granarolo, Emilia-Romagna, Italy/	Spring wheat / Aquilante	10 Feb 2015 N/A 29 Jul 2015	109.1 108.9	327 327	33.4 33.3	08 May 15 20 May 15	BBCH 51 BBCH 69	Whole Plant Whole Plant Whole Plant Whole Plant Whole Plant	0.872 2.548 0.448 0.682 0.308	0.024 0.089 0.028 0.023 0.017	-0 0 7 14 28	There were no residues above the LOQ in any of the untreated specimens	

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days) (d)	Details on trial (e)	Value retained for risk assessment and MRL compliance in this dossier
			g a.s./ ha	Water (l/ha)	g a.s./hl				XDE-777	X642188			
SEU/2015								Grain	**<u>0.031</u>**	ND	33		
								Straw	0.979	0.05	33		
								Grain	<0.01	ND	40*		
								Straw	1.579	0.047	40*		
								Grain	<0.01	ND	47		
								Straw	1.75	0.026	47		
								Grain	0.02	ND	54		
								Straw	**<u>4.728</u>**	0.084	54		

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

Table A 5: Summary of the study S15-02629 trials – Residues of Prothioconazole-desthio

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Prothioconazole-desthio		
	(a)	(b)				(c)				(d)	(e)
S15-02629-01/ HU17 8JF, Bishop Burton, East Yorkshire, UK/ NEU/ 2015	Winter wheat / Reflection	27 Sep 2014 N/A 19 Aug 2015	197.9 196.5	198 197	99.9 99.7	15 Jun 15 29 Jun 15	BBCH 61 BBCH 69	Grain Straw Grain Straw Grain Straw Grain Straw	ND 0.331 **(0.005)** 0.180 (0.003) **0.302** ND 0.064	45 45 51* 51* 59 59 65 65	There were no residues above the LOQ in any of the untreated specimens
S15-02629-02/ L39 6SX, Lydiate, Lancashire, UK/ NEU/ 2015	Winter wheat / KWS Kielder	03 Oct 2014 N/A 18 Aug 2015	216.7 220.0	217 220	99.9 100	23 Jun 15 07 Jul 15	BBCH 65–67 BBCH 69	Grain Straw	**0.023** **0.860**	42* 42*	There were no residues above the LOQ in any of the untreated specimens
S15-02629-03/ 67140 Saint-Pierre, Alsace, Bas-Rhin France/ NEU/ 2015	Winter wheat / Pakilo	22 Oct 2014 N/A 13 Jul 2015	197.6 205.3	296 308	66.8 66.7	19 May 15 01 Jun 15	BBCH 59 BBCH 69	Grain Straw	**(0.003)** **0.420**	42* 42*	There were no residues above the LOQ in any of the untreated specimens
S15-02629-04/ 86120 Morton, Vienne France/ SEU/ 2015	Winter wheat / Cellule	15 Dec 2014 N/A 16 Jul 2015	189.5 209.9	284 315	66.7 66.6	19 May 15 01 Jun 15	BBCH 59 BBCH 69	Grain Straw Grain Straw Grain Straw Grain Straw	(0.003) 0.273 ND 0.271 **(0.004)** 0.365 ND **0.628**	39 39 45* 45* 51 51 59 59	There were no residues above the LOQ in any of the untreated specimens
S15-02629-05/ 71290 Simandre, Saône-et-Loire, France/ ~~SEU/~~ NEU 2015	Spring wheat / Sensus	07 Mar 2015 N/A 07 Jul 2015	210.7 186.0	211 186	99.9 100.0	29 May 15 11 Jun 15	BBCH 59 BBCH 69	Grain Straw	**ND** **0.942**	26* 26*	There were no residues above the LOQ in any of the untreated specimens

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Prothioconazole-desthio		
	(a)	(b)				(c)				(d)	(e)
S15-02629-06/ 50367 Retascón Spain/ SEU/ 2015	Winter wheat / Garcia	10 Nov 2014 N/A 08 Jul 2015	190.5 185.7	190 186	100.3 99.8	13 May 15 28 May 15	BBCH 47 BBCH 67-69	Grain Straw	**(0.003)** **0.875**	41* 41*	There were no residues above the LOQ in any of the untreated specimens
S15-02629-07/ 44492 Fonfría, Teruel Spain/ SEU/ 2015	Winter wheat / Marius	01 Nov 2014 N/A 30 Jul 2015	216.3 191.1	324 287	66.8 66.6	27 May 15 10 Jun 15	BBCH 57-61 BBCH 69	Grain Straw	**(0.004)** **1.122**	50* 50*	There were no residues above the LOQ in any of the untreated specimens
S15-02629-08/ NG34 8PE, Silk Willoughby, Lincolnshire, UK/ NEU/ 2015	Spring wheat / Mulika	12 Mar 2015 N/A 19 Aug 2015	216.7 215.0	217 215	99.9 100.0	16 Jun 15 29 Jun 15	BBCH 39 BBCH 69	Grain Straw Grain Straw Grain Straw Grain Straw	(0.004) 0.484 **ND** 0.53 ND 0.754 ND **0.87**	44 44 51* 51* 58 58 65 65	There were no residues above the LOQ in any of the untreated specimens
S15-02629-09/ LE12 5RQ, West Leake, Leicestershire UK/ NEU/ 2015	Spring wheat / Mulika	05 Mar 2015 N/A 24 Aug 2015	230.0 193.3	230 193	100.0 100.2	25 Jun 15 09 Jul 15	BBCH 61 BBCH 69	Grain Straw	**0.02** **0.851**	46* 46*	There were no residues above the LOQ in any of the untreated specimens
S15-02629-10/ 40057, Granarolo, Emilia-Romagna Italy/ SEU/ 2015	Spring wheat / Aquilante	10 Feb 2015 N/A 29 Jul 2015	218.2 217.8	327 327	66.7 66.6	08 May 15 20 May 15	BBCH 51 BBCH 69	Grain Straw Grain Straw Grain Straw Grain Straw	ND 0.145 **ND** **0.212** ND 0.205 ND ND	33 33 40* 40* 47 47 54 54	There were no residues above the LOQ in any of the untreated specimens

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Prothioconazole-desthio		
	(a)	(b)				(c)				(d)	(e)

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
N/A - Not applicable
ND - Not detected *=NCH (normal commercial harvest)
Residues of less than the LOQ of 0.01 mg/kg for prothioconazole-desthio but equal to or greater than the LOD are shown in parentheses.

~~-01566~~

A 2.1.3.1.3 Study S18-01566/ DAS 180126

Comments of zRMS:

Trials were conducted at 4 sites: 2 in N-EU and 2 in S-EU to determine residues of fenpicoxamid, X642188 and prothioconazole in wheat following one foliar application of GF-3307 (EC formulation containing nominal 100 g prothioconazole/L and nominal 50 g fenpicoxamid/L). Application was conducted at BBCH 55, outdoor.

In all trials specimens of the crop from the untreated and treated plots were taken at normal commercial harvest (NCH, BBCH 89).

The methods were validated for the determination of fenpicoxamid, X642188 and prothioconazole-desthio in specimens of wheat grain within this study.
The limit of detection (LOD) and limit of quantitation (LOQ) for all analytes were 0.003 mg/kg and 0.01 mg/kg respectively.
No analyte residues above the analytical method LOQ where detected in any of the untreated samples.
The maximum period of frozen storage for fenpicoxamid and its metabolite X642188 and prothioconazole-desthio in wheat grain was 260 days, which is supported by frozen storage stability studies.

The following residues of fenpicoxamid, X642188 and desthio-prothioconazole were detected in the untreated and treated specimens:

Sample Code	Crop part	Plot	Timing (Nominal)	Fenpicoxamid (mg/kg)	X642188 (mg/kg)	Prothioconazole-desthio (mg/kg)
S18-01566-01 (Northern France)						
S18-01566-01-001A	Grain	1	NCH	n.d.	n.d.	n.d.
S18-01566-01-002A	Grain	2	NCH	n.d.	n.d.	n.d.
S18-01566-01-003A	Grain	3	NCH	n.d.	n.d.	n.d.
S18-01566-01-004A	Grain	4	NCH	n.d.	n.d.	< LOQ (0.006)
S18-01566-01-005A	Grain	5	NCH	n.d.	n.d.	n.d.
S18-01566-02 (Germany)						
S18-01566-02-001A	Grain	1	NCH	n.d.	n.d.	n.d.
S18-01566-02-002A	Grain	2	NCH	n.d.	n.d.	n.d.
S18-01566-02-003A	Grain	3	NCH	n.d.	n.d.	n.d.
S18-01566-02-004A	Grain	4	NCH	n.d.	n.d.	n.d.
S18-01566-02-005A	Grain	5	NCH	n.d.	n.d.	n.d.
S18-01566-03 (Italy)						
S18-01566-03-001A	Grain	1	NCH	n.d.	n.d.	n.d.
S18-01566-03-002A	Grain	2	NCH	n.d.	n.d.	n.d.
S18-01566-03-003A	Grain	3	NCH	n.d.	n.d.	n.d.
S18-01566-03-004A	Grain	4	NCH	n.d.	n.d.	n.d.
S18-01566-03-005A	Grain	5	NCH	n.d.	n.d.	n.d.
S18-01566-04 (Spain)						
S18-01566-04-001A	Grain	1	NCH	n.d.	n.d.	n.d.
S18-01566-04-002A	Grain	2	NCH	n.d.	n.d.	n.d.
S18-01566-04-003A	Grain	3	NCH	n.d.	n.d.	n.d.
S18-01566-04-004A	Grain	4	NCH	0.01	n.d.	< LOQ (0.007)
S18-01566-04-005A	Grain	5	NCH	n.d.	n.d.	n.d.

n.d. = not detectable

The study is acceptable.

Reference:	KCA 6.3.1/05
Report	Residues of Fenpicoxamid and Prothioconazole in Wheat at Harvest Following One Application of GF-3307 – Southern and Northern Europe – 2018, Semrau J, Thomas B, 2019, Report No. S18-01566, DAS Study ID 180126
Guideline(s):	Regulation (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009

	Repealing Council Directives 79/117/EEC and 91/414/EEC EC guidance working document 7029/VI/95 rev. 5 (July 22, 1997) OECD Test Guideline 509 (Crop Field Trials) OECD Principles on Good Laboratory Practice (revised in 1997, issued 1998) The application of the GLP principles to field studies ENV/JM/MONO(99)22 The Application Of OECD Principles Of GLP To The Organisation And Management Of Multi-Site Studies ENV/JM/MONO(2002)/9 EU Guidance Document SANCO/3029/99 rev. 4 for generating and reporting methods of analysis in support of pre-registration data requirements
Deviations:	None with consequences.
GLP:	Yes
Acceptability:	Yes

The objective of the study is to determine residues of fenpicoxamid (also known as XDE-777) and prothioconazole in wheat following one foliar application of GF-3307.
Four residue trials were conducted on wheat (outdoor) during 2018 in northern France (S18-01566-01), in Germany (S18-01566-02), in Italy (S18-01566-03) and in Spain (S18-01566-04). All trials comprised five plots, one untreated and four treated with GF-3307 (EC formulation containing nominal 100 g prothioconazole/L and nominal 50 g fenpicoxamid/L).
In all trials one application of GF-3307 to each plot at a different growth stage was performed. Each application was applied at a target rate of 75 g a.i./ha (nominal, fenpicoxamid). The test item was diluted with water immediately prior to application to a spray volume of 300 L/ha (nominal).
In all trials specimens of the crop from the untreated and treated plots were taken at normal commercial harvest (NCH, BBCH 89).
The maximum period of frozen storage for fenpicoxamid and its metabolite X642188 and prothioconazole-desthio in wheat grain was 260 days. This period was deemed acceptable as residues of fenpicoxamid and X642188 in wheat grain have been shown to be stable under these conditions for 741 days (DAS Study ID 120749) and residues of prothioconazole-desthio in wheat grain have been shown to be stable under these conditions for 540 days (Bayer CropScience Report No. MR-282/00 – evaluated in addendum to 2006 DAR).
The specimens were analysed for residues of fenpicoxamid, its metabolite X642188, and for prothioconazole-desthio following the procedures described in the analytical phase report. The final determination of the analytes in the untreated and treated specimens was performed by single extraction and single injection with liquid chromatography and mass spectrometric detection (LC/MS/MS). The limit of detection (LOD) and limit of quantitation (LOQ) for all analytes were 0.003 mg/kg and 0.01 mg/kg respectively.
During analysis, numerous fortification experiments for wheat grain with fenpicoxamid, X642188 and desthio-prothioconazole were performed. No analyte residues above the analytical method LOQ where detected in any of the untreated samples. This indicates that untreated control plots and samples remained largely uncontaminated through the course of the analytical phase.
Samples of wheat were analysed for residues fenpicoxamid and X642188 using a method described and reported within the study no. S12-01537/ Dow AgroSciences study number 120615 [1]. Samples of wheat were analysed for residues prothioconazole-desthio using a method described and reported within the study no. P60293002 [2].
The methods were validated for the determination of fenpicoxamid, X642188 and prothioconazole-desthio in specimens of wheat grain within this study.
Details of recoveries per matrix, level of residues in field samples and examples of typical chromatograms per matrix are shown in analytical phase report.
The following residues of fenpicoxamid, X642188 and desthio-prothioconazole were detected in the untreated and treated specimens:

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	**prothioconazole**		
Crop group:	**wheat**	Commercial Product (name):	n/a
Crop EPPO code:	TRZAX	Other active substance in the formulation (common name and content):	fenpicoxamid
Responsible body for reporting (name, address)	Dow AgroSciences 3B Park Square, Milton Park, Abingdon Oxon, OX14 4RN, United Kingdom	Producer of commercial product:	Dow AgroSciences
		Study type:	Residue
Country	Northern France	Indoor/Glasshouse/Outdoor:	Outdoor
Trial location (region):	Bas-Rhin	Residues calculated as:	prothioconazole
Content of active substance nominal (g/L):	100 g/L	Residue method and LOQ :	DAS Study P60293002 LOQ = 0.01 mg/kg
Formulation number:	GF-3307	Procedural recovery (mean):	88 % (grain)
Formulation type	EC	Max frozen storage time prior to extraction	239 days

1 Trial No. Location (region)	2 Commodity / Variety (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 No. of trt(s)	6 Dates of treatment(s) (d)	7 Growth stage at last treatment (e)	8 Portion analysed (commodity) (a)	9 Residues (mg/kg) (*)	10 PHI (days) (f)	11 Remarks (g)
				kg as/hL	water (L/ha)	kg as/ha							
S18-01566-01 67230 Benfeld, Bas-Rhin, France	winter wheat, TRZAW, Dicemento	1) 18 Oct 2017 2) 15 May 2018 to 23 May 2018 3) 05 Jul 2018	broadcast foliar spray with boom sprayer with Teejet, DG 110 015 VS (flat fan)	0.0497 0.0497 0.0498 0.0497	316 318 317 320	0.1571 0.1581 0.1578 0.1589	1 1 1 1	02 May 2018 07 May 2018 09 May 2018 09 May 2018	39 45 51 55	grain grain grain grain	n.d. n.d. < LOQ n.d.	64 59 57 57	Plot 2 Plot 3 Plot 4 Plot 5

(a) According to EEC and Codex classifications (both) should be used.
(b) Only if relevant
(c) High or low volume spraying. spreading. dusting etc., overall, broadcast, type of equipment used must be indicated
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4
(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application
(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date
(*) Limit of quantification = 0.01 mg/kg; Limit of detection = 0.003 mg/kg

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	**fenpicoxamid**		
Crop group:	**wheat**	Commercial Product (name):	n/a
Crop EPPO code:	TRZAX	Other active substance in the formulation (common name and content):	prothioconazole
Responsible body for reporting (name, address)	Dow AgroSciences 3B Park Square, Milton Park, Abingdon Oxon, OX14 4RN, United Kingdom	Producer of commercial product:	Dow AgroSciences
		Study type:	Residue
Country	Northern France	Indoor/Glasshouse/Outdoor:	Outdoor
Trial location (region):	Bas-Rhin	Residues calculated as:	mg/kg fenpicoxamid (XDE-777) and X642188
Content of active substance nominal (g/L):	50 g/L	Residue method and LOQ :	DAS Study 120615 LOQ = 0.01 mg/kg
Formulation number:	GF-3307	Procedural recovery (mean):	99 % and 97 % (grain)
Formulation type	EC	Max frozen storage time prior to extraction	239 days

1 Trial No. Location (region)	2 Commodity / Variety (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 No. of trt(s)	6 Dates of treatment(s) (d)	7 Growth stage at last treatment (e)	8 Portion analysed (commodity) (a)	9 Residues (mg/kg) (*)		10 PHI (days) (f)	11 Remarks (g)
				kg as/hL	water (L/ha)	kg as/ha					fenpicoxamid (XDE-777)	X642188		
S18-01566-01 67230 Benfeld, Bas-Rhin, France	winter wheat, TRZAW, Dicemento	1) 18 Oct 2017 2) 15 May 2018 to 23 May 2018 3) 05 Jul 2018	broadcast foliar spray with boom sprayer with Teejet, DG 110 015 VS (flat fan)	0.0248 0.0248 0.0249 0.0248	316 318 317 320	0.0785 0.0790 0.0789 0.0795	1 1 1 1	02 May 2018 07 May 2018 09 May 2018 09 May 2018	39 45 51 55	grain grain grain grain	n.d. n.d. n.d. n.d.	n.d. n.d. n.d. n.d.	64 59 57 57	Plot 2 Plot 3 Plot 4 Plot 5

(a) According to EEC and Codex classifications (both) should be used.
(b) Only if relevant
(c) High or low volume spraying. spreading. dusting etc., overall, broadcast, type of equipment used must be indicated
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4
(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application
(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date
(*) Limit of quantification = 0.01 mg/kg; Limit of detection = 0.003 mg/kg

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	**prothioconazole**		
Crop group:	**wheat**	Commercial Product (name):	n/a
Crop EPPO code:	TRZAX	Other active substance in the formulation (common name and content):	fenpicoxamid
Responsible body for reporting (name, address)	Dow AgroSciences 3B Park Square, Milton Park, Abingdon Oxon, OX14 4RN, United Kingdom	Producer of commercial product:	Dow AgroSciences
		Study type:	Residue
Country	Germany	Indoor/Glasshouse/Outdoor:	Outdoor
Trial location (region):	Niedersachsen	Residues calculated as:	prothioconazole
Content of active substance nominal (g/L):	100 g/L	Residue method and LOQ :	DAS Study P60293002 LOQ = 0.01 mg/kg
Formulation number:	GF-3307	Procedural recovery (mean):	88 % (grain)
Formulation type	EC	Max frozen storage time prior to extraction	204 days

1 Trial No. Location (region)	2 Commodity / Variety (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 No. of trt(s)	6 Dates of treatment(s) (d)	7 Growth stage at last treatment (e)	8 Portion analysed (commodity) (a)	9 Residues (mg/kg) (*)	10 PHI (days) (f)	11 Remarks (g)
				kg as/hL	water (L/ha)	kg as/ha							
S18-01566-02 27449 Mulsum, Niedersachsen, Germany	spring wheat, TRZAS, Willow	1) 07 Apr 2018 2) 24 Jun 2018 to 30 Jun 2018 3) 09 Aug 2018	broadcast foliar spray with boom sprayer with Lechler, IDK 120-02 (reduced drift fan)	0.0500 0.0499 0.0501 0.0500	310 302 303 315	0.1550 0.1508 0.1517 0.1575	1 1 1 1	06 Jun 2018 11 Jun 2018 14 Jun 2018 20 Jun 2018	39 45 51 55	grain grain grain grain	n.d. n.d. n.d. n.d.	64 59 56 50	Plot 2 Plot 3 Plot 4 Plot 5

(a) According to EEC and Codex classifications (both) should be used.
(b) Only if relevant
(c) High or low volume spraying. spreading. dusting etc., overall, broadcast, type of equipment used must be indicated
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4
(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application
(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date
(*) Limit of quantification = 0.01 mg/kg; Limit of detection = 0.003 mg/kg

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	**fenpicoxamid**		
Crop group:	**wheat**	Commercial Product (name):	n/a
Crop EPPO code:	TRZAX	Other active substance in the formulation (common name and content):	prothioconazole
Responsible body for reporting (name, address)	Dow AgroSciences 3B Park Square, Milton Park, Abingdon Oxon, OX14 4RN, United Kingdom	Producer of commercial product:	Dow AgroSciences
		Study type:	Residue
Country	Germany	Indoor/Glasshouse/Outdoor:	Outdoor
Trial location (region):	Niedersachsen	Residues calculated as:	mg/kg fenpicoxamid (XDE-777) and X642188
Content of active substance nominal (g/L):	50 g/L	Residue method and LOQ :	DAS Study 120615 LOQ = 0.01 mg/kg
Formulation number:	GF-3307	Procedural recovery (mean):	99 % and 97 % (grain)
Formulation type	EC	Max frozen storage time prior to extraction	204 days

1 Trial No. Location (region)	2 Commodity / Variety (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 No. of trt(s)	6 Dates of treatment(s) (d)	7 Growth stage at last treatment (e)	8 Portion analysed (commodity) (a)	9 Residues (mg/kg) (*)		10 PHI (days) (f)	11 Remarks (g)
				kg as/hL	water (L/ha)	kg as/ha					fenpicoxamid (XDE-777)	X642188		
S18-01566-02 27449 Mulsum, Niedersachsen, Germany	spring wheat, TRZAS, Willow	1) 07 Apr 2018 2) 24 Jun 2018 to 30 Jun 2018 3) 09 Aug 2018	broadcast foliar spray with boom sprayer with Lechler, IDK 120-02 (reduced drift fan)	0.0250	310	0.0775	1	06 Jun 2018	39	grain	n.d.	n.d.	64	Plot 2
				0.0250	302	0.0754	1	11 Jun 2018	45	grain	n.d.	n.d.	59	Plot 3
				0.0250	303	0.0758	1	14 Jun 2018	51	grain	n.d.	n.d.	56	Plot 4
				0.0250	315	0.0787	1	20 Jun 2018	55	grain	n.d.	n.d.	50	Plot 5

(a) According to EEC and Codex classifications (both) should be used.
(b) Only if relevant
(c) High or low volume spraying. spreading. dusting etc., overall, broadcast, type of equipment used must be indicated
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4
(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application
(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date
(*) Limit of quantification = 0.01 mg/kg; Limit of detection = 0.003 mg/kg

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	**prothioconazole**		
Crop group:	**wheat**	Commercial Product (name):	n/a
Crop EPPO code:	TRZAX	Other active substance in the formulation (common name and content):	fenpicoxamid
Responsible body for reporting (name, address)	Dow AgroSciences 3B Park Square, Milton Park, Abingdon Oxon, OX14 4RN, United Kingdom	Producer of commercial product:	Dow AgroSciences
		Study type:	Residue
Country	Italy	Indoor/Glasshouse/Outdoor:	outdoor
Trial location (region):	Bologna	Residues calculated as:	prothioconazole
Content of active substance nominal (g/L):	100 g/L	Residue method and LOQ :	DAS Study P60293002 LOQ = 0.01 mg/kg
Formulation number:	GF-3307	Procedural recovery (mean):	88 % (grain)
Formulation type	EC	Max frozen storage time prior to extraction	245 days

1 Trial No. Location (region)	2 Commodity / Variety (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 No. of trt(s)	6 Dates of treatment(s) (d)	7 Growth stage at last treatment (e)	8 Portion analysed (commodity) (a)	9 Residues (mg/kg) (*)	10 PHI (days) (f)	11 Remarks (g)
				kg as/hL	water (L/ha)	kg as/ha							
S18-01566-03 40016 San Giorgio di Piano, Bologna, Italy	winter wheat, TRZAW, Genesi	1) 03 Dec 2017 2) 15 May 2018 to 25 May 2018 3) 28 Jun 2018	broadcast foliar spray with boom sprayer with AFC 11015 (flat fan)	0.0501 0.0499 0.0499 0.0499	293 307 297 287	0.1467 0.1533 0.1483 0.1433	1 1 1 1	24 Apr 2018 27 Apr 2018 04 May 2018 09 May 2018	39 45 51 55	grain grain grain grain	n.d. n.d. n.d. n.d.	65 62 55 50	Plot 2 Plot 3 Plot 4 Plot 5

(a) According to EEC and Codex classifications (both) should be used.
(b) Only if relevant
(c) High or low volume spraying. spreading. dusting etc., overall, broadcast, type of equipment used must be indicated
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4
(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application
(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date
(*) Limit of quantification = 0.01 mg/kg; Limit of detection = 0.003 mg/kg

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	**fenpicoxamid**		
Crop group:	**wheat**	Commercial Product (name):	n/a
Crop EPPO code:	TRZAX	Other active substance in the formulation (common name and content):	prothioconazole
Responsible body for reporting (name, address)	Dow AgroSciences 3B Park Square, Milton Park, Abingdon Oxon, OX14 4RN, United Kingdom	Producer of commercial product:	Dow AgroSciences
		Study type:	Residue
Country	Italy	Indoor/Glasshouse/Outdoor:	outdoor
Trial location (region):	Bologna	Residues calculated as:	mg/kg fenpicoxamid (XDE-777) and X642188
Content of active substance nominal (g/L):	50 g/L	Residue method and LOQ :	DAS Study 120615 LOQ = 0.01 mg/kg
Formulation number:	GF-3307	Procedural recovery (mean):	99 % and 97 % (grain)
Formulation type	EC	Max frozen storage time prior to extraction	245 days

1 Trial No. Location (region)	2 Commodity / Variety (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 No. of trt(s)	6 Dates of treatment(s) (d)	7 Growth stage at last treatment (e)	8 Portion analysed (commodity) (a)	9 Residues (mg/kg) (*)		10 PHI (days) (f)	11 Remarks (g)
				kg as/hL	water (L/ha)	kg as/ha					fenpicoxamid (XDE-777)	X642188		
S18-01566-03 40016 San Giorgio di Piano, Bologna, Italy	winter wheat, TRZAW, Genesi	1) 03 Dec 2017 2) 15 May 2018 to 25 May 2018 3) 28 Jun 2018	broadcast foliar spray with boom sprayer with AFC 11015 (flat fan)	0.0250	293	0.0733	1	24 Apr 2018	39	grain	n.d.	n.d.	65	Plot 2
				0.0250	307	0.0767	1	27 Apr 2018	45	grain	n.d.	n.d.	62	Plot 3
				0.0250	297	0.0742	1	04 May 2018	51	grain	n.d.	n.d.	55	Plot 4
				0.0250	287	0.0717	1	09 May 2018	55	grain	n.d.	n.d.	50	Plot 5

(a) According to EEC and Codex classifications (both) should be used.
(b) Only if relevant
(c) High or low volume spraying. spreading. dusting etc., overall, broadcast, type of equipment used must be indicated
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4
(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application
(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date
(*) Limit of quantification = 0.01 mg/kg; Limit of detection = 0.003 mg/kg

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	**prothioconazole**		
Crop group:	**wheat**	Commercial Product (name):	n/a
Crop EPPO code:	TRZAX	Other active substance in the formulation (common name and content):	fenpicoxamid
Responsible body for reporting (name, address)	Dow AgroSciences 3B Park Square, Milton Park, Abingdon Oxon, OX14 4RN, United Kingdom	Producer of commercial product:	Dow AgroSciences
		Study type:	Residue
Country	Spain	Indoor/Glasshouse/Outdoor:	Outdoor
Trial location (region):	Seville	Residues calculated as:	prothioconazole
Content of active substance nominal (g/L):	100 g/L	Residue method and LOQ :	DAS Study P60293002 LOQ = 0.01 mg/kg
Formulation number:	GF-3307	Procedural recovery (mean):	88 % (grain)
Formulation type	EC	Max frozen storage time prior to extraction	260 days

1 Trial No. Location (region)	2 Commodity / Variety (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 No. of trt(s)	6 Dates of treatment(s) (d)	7 Growth stage at last treatment (e)	8 Portion analysed (commodity) (a)	9 Residues (mg/kg) (*)	10 PHI (days) (f)	11 Remarks (g)
				kg as/hL	water (L/ha)	kg as/ha							
S18-01566-04 41907 Valencina de la Concepción, Seville, Spain	winter wheat, TRZAW, Avispa	1) 15 Dec 2017 2) n/a 3) 14 Jun 2018	broadcast foliar spray with boom sprayer with Albuz, ADI 110 015 (flat fan)	0.0500 0.0500 0.0500 0.0499	316 308 284 275	0.1579 0.1540 0.1421 0.1373	1 1 1 1	28 Mar 2018 09 Apr 2018 16 Apr 2018 18 Apr 2018	39 45 53 55	grain grain grain grain	n.d. n.d. < LOQ n.d.	78 66 59 57	Plot 2 Plot 3 Plot 4 Plot 5

(a) According to EEC and Codex classifications (both) should be used.
(b) Only if relevant
(c) High or low volume spraying. spreading. dusting etc., overall, broadcast, type of equipment used must be indicated
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4
(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application
(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date
(*) Limit of quantification = 0.01 mg/kg; Limit of detection = 0.003 mg/kg

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	**fenpicoxamid**		
Crop group:	**wheat**	Commercial Product (name):	n/a
Crop EPPO code:	TRZAX	Other active substance in the formulation (common name and content):	prothioconazole
Responsible body for reporting (name, address)	Dow AgroSciences 3B Park Square, Milton Park, Abingdon Oxon, OX14 4RN, United Kingdom	Producer of commercial product:	Dow AgroSciences
		Study type:	Residue
Country	Spain	Indoor/Glasshouse/Outdoor:	Outdoor
Trial location (region):	Seville	Residues calculated as:	mg/kg fenpicoxamid (XDE-777) and X642188
Content of active substance nominal (g/L):	50 g/L	Residue method and LOQ :	DAS Study 120615 LOQ = 0.01 mg/kg
Formulation number:	GF-3307	Procedural recovery (mean):	99 % and 97 % (grain)
Formulation type	EC	Max frozen storage time prior to extraction	260 days

1 Trial No. Location (region)	2 Commodity / Variety (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 No. of trt(s)	6 Dates of treatment(s) (d)	7 Growth stage at last treatment (e)	8 Portion analysed (commodity) (a)	9 Residues (mg/kg) (*)		10 PHI (days) (f)	11 Remarks (g)
				kg as/hL	water (L/ha)	kg as/ha					fenpicoxamid (XDE-777)	X642188		
S18-01566-04 41907 Valencina de la Concepción, Seville, Spain	winter wheat, TRZAW, Avispa	1) 15 Dec 2017 2) n/a 3) 14 Jun 2018	broadcast foliar spray with boom sprayer with Albuz, ADI 110 015 (flat fan)	0.0250	316	0.0790	1	28 Mar 2018	39	grain	n.d.	n.d.	78	Plot 2
				0.0250	308	0.0770	1	09 Apr 2018	45	grain	n.d.	n.d.	66	Plot 3
				0.0250	284	0.0710	1	16 Apr 2018	53	grain	n.d.	n.d.	59	Plot 4
				0.0249	275	0.0686	1	18 Apr 2018	55	grain	n.d.	n.d.	57	Plot 5

(a) According to EEC and Codex classifications (both) should be used.
(b) Only if relevant
(c) High or low volume spraying. spreading. dusting etc., overall, broadcast, type of equipment used must be indicated
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4
(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application
(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date
(*) Limit of quantification = 0.01 mg/kg; Limit of detection = 0.003 mg/kg

A 2.1.3.2 Barley

Table A 6: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (EFSA 2018)	2	100 g XDE-777/ha	14 days	BBCH 69	N/A
cGAP EU (EFSA 2007) prothioconazole	1-2	200 g prothioconazole/ha	14 days	start 30 up to BBCH 61 (interval 14 -21 d)	35
Intended cGAP (1-6*)	1	75g XDE-777/ha	NA	BBCH 69	F
Intended cGAP (1-6*)	1	150 g prothioconazole/ha	NA	BBCH 69	F

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0
Uses 7-14 are covered by Uses 1-6

A 2.1.3.2.1 S17-01904/ 170191

Comments of zRMS:	Trials were conducted at 16 sites: 8 in N-EU and 8 in S-EU to determine residues of fenpicoxamid, X642188 and prothioconazole in barley following two foliar applications of GF-3307 at a target rate of 100 g a.i. (fenpicoxamid)/ha (nominal) and 200 g a.i. (prothioconazole)/ha (nominal), first application at 14±2 days before growth stage BBCH 69 and the second - at growth stage BBCH 69. In all trials specimens of the crop from the untreated and treated plots were taken at normal commercial harvest (NCH). The methods were validated for the determination of fenpicoxamid, X642188 and prothioconazole-desthio. 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 period of frozen storage from the day of sampling until extraction was 314 days. **Residues in grain (N-EU):** In seed specimens taken at normal commercial harvest residues of fenpicoxamid were between ND and 0.29 mg/kg. In seed specimens taken at normal commercial harvest residues of X642188 were between ND and 0.11 mg/kg. In seed specimens taken at normal commercial harvest residues of prothioconazole-desthio were between ND and 0.13 mg/kg. The study is acceptable.

Reference:	KCA 6.3.1/06
Report	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. Semrau, J., Thomas, B. 2019. Report no. S17-01904/ 170191.
Guideline(s):	Regulation (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 Repealing Council Directives 79/117/EEC and 91/414/EEC EC guidance working document 7029/VI/95 rev. 5 (July 22, 1997) OECD Test Guideline 509 (Crop Field Trials)

	OECD (2016) Guidance Document ENV/JM/MONO(2011)50/REV1 , Second Edition, on Crop Field Trials (Series on Testing and Assessment No. 164 and Series on Pesticides No. 66) OECD (2009) Guidance Document on Overview of Residue Chemistry Studies (Series on Testing and Assessment No. 64 and Series on Pesticides No. 32) OECD Principles on Good Laboratory Practice (OECD 1998) The application of the GLP principles to field studies ENV/JM/MONO(99)22 The Application Of OECD Principles Of GLP To The Organisation And Management Of Multi-Site Studies ENV/JM/MONO(2002)/9
Deviations:	None with impact on the study.
GLP:	Yes
Acceptability:	Yes

Materials and methods

The objective of the study is to determine residues of fenpicoxamid and prothioconazole in barley following two foliar applications of GF-3307.

Sixteen residue trials were conducted on barley (outdoor) during 2017 and 2018 in Northern France (S17-01904-01 and -09), in Poland (S17-01904-03), in UK (S17-01904-04), in Italy (S17-01904-06 and -14), in Spain (S17-01904-07 and -15), in Greece (S17-01904-08 and -13), in Germany (S17-01904-10 and -17), in Hungary (S17-01904-12), in Bulgaria (S17-01904-16), in Southern France (S17-01904-18) and in Austria (S17-01904-19). All trials comprised two plots, one untreated and one treated with GF-3307 (SL formulation containing 100 g prothioconazole /L and 50 g fenpicoxamid /L), nominal.

In all trials two applications of GF-3307 were performed. The 1st application was applied at a target rate of 100 g a.i. (fenpicoxamid)/ha (nominal) and 200 g a.i. (prothioconazole)/ha (nominal) to plot 2 at 14±2 days before growth stage BBCH 69 with broadcast foliar application to the crop. The 2nd application was applied again with 100 g a.i. (fenpicoxamid)/ha (nominal) and 200 g a.i. (prothioconazole)/ha (nominal) to plot 2 at growth stage BBCH 69 with broadcast foliar application to the crop. The test item was diluted with water immediately prior to application to a spray volume of 100 - 300 L/ha (nominal).

In trials S17-01904-01, -03, -04, -06, -07, -08, -17 and -18 samples of grain and straw from the untreated and treated plots were taken at normal commercial harvest (NCH).

In trials S17-01904-09, -10, -12 to -16 and-19 samples of whole plant from the untreated and treated plots were taken at 0, 7, 14±1 and 28±2 (except trial -14) days after the last application, while samples of grain and straw from the untreated and treated plots were taken at normal commercial harvest (NCH). At trial S17-01904-14 (Italy) NCH occurred at 27 days after the last application. Therefore whole plant samples at 28±2 DAA2 were not taken.

Treated samples taken from trial S17-01904-15 in Spain, have given substantially higher results for fenpicoxamid, X642188 and prothioconazole than the other 15 trials of this study. Poor crop development, due to periods of hot and dry weather conditions, was documented at all sampling timings. Crop growth and increase of biomass were adversely affected and not as expected of a commercially viable trial. As a consequence, no retain samples were collected at any sampling timings, even though plot size and drilling rate of trial S17-01904-15 were comparable to those of the other trials. The barley in this trial is not considered to be representative of conventional cereal development according to good agricultural practice, and is therefore not considered to be commercially acceptable to have been used as a trial site. Therefore, residues from trial S17-01904-15 are excluded from all discussions in the following paragraphs.

The maximum period of frozen storage from the day of sampling until extraction was 314 days, which is supported by frozen storage stability studies.

The field samples were analyzed for residues of fenpicoxamid (XDE-777), its metabolite X642188 and prothioconazole-desthio. A summary of the analytical methods is given below.

Analytical Method Summary for the Analysis of XDE-777 and X642188

Residues of fenpicoxamid (XDE-777) and X642188 were determined using the analytical method "Residue Method for the Determination of fenpicoxamid and X642188 in crops", Watson (2012) – Study number 120615. Residues of fenpicoxamid (XDE-777) and X642188 were extracted with acetonitrile/ultra-pure water. After homogenization, the extracts were diluted in acetonitrile/ultra-pure water/formic acid and then analyzed by liquid chromatography coupled with positive-ion electrospray tandem mass spectrometry (LC-MS/MS). The limit of detection (LOD) and limit of quantitation (LOQ) were 0.003 mg/kg and 0.01 mg/kg, respectively, for both analytes in barley grain, straw and whole plant.

The extraction efficiency of the XDE-777 residue method (Method Identifier No. 120615) for fenpicoxamid was evaluated using incurred radiolabeled wheat samples from the metabolism study. Fenpicoxamid residue levels determined using the manual extraction procedure outlined in the crop analytical method (acetonitrile/water (9/1, v/v)) were comparable (differed by no more than 30%) to residue levels determined using the accelerated solvent extraction (ASE) procedure outlined in the wheat nature of residue (NOR) study (Li, Q., Dixit, V., 2013).

Characteristics of the analytical method for the analysis of XDE-777 and X642188

	Fenpicoxamid (XDE-777)	**X642188**
Specificity	*m/z* 615/239 blank value <30% LOQ	*m/z* 515/239 blank value <30% LOQ
Calibration (type, number of data points)	linear regression with 1/x weighting $r^2 \geq 0.990$ 8 data points	linear regression with 1/x weighting $r^2 \geq 0.990$ 8 data points
Calibration range	Concentration range of 0.0075-1.00 ng/mL	Concentration range of 0.0075-1.00 ng/mL
Limit of quantification	LOQ = 0.01 mg/kg	LOQ = 0.01 mg/kg

Method performance was appropriately documented for the analytical set, with mean recovery values between 70-110% for all matrices and analytes. Additional procedural recovery details are summarized below. Relative standard deviations were all less than 20%.

Summary of Procedural Recoveries for XDE-777 and X642188

Matrix	**Analyte**	**Fortification level (mg/kg)**	**Recovery Range (%)**	**Recovery Mean (%)**
Barley grain	XDE-777	0.01	70-99	87
		1	84-94	89
		10	68-77	73
	X642188	0.01	93-105	97
		1	91-95	93
		10	89-96	93
Barley straw	XDE-777	0.01	72-108	89
		10	84-92	89
	X642188	0.01	89-108	99
		1	99-109	104
		10	96-100	98
Barley whole plant	XDE-777	0.01	79-110	94

Matrix	Analyte	Fortification level (mg/kg)	Recovery Range (%)	Recovery Mean (%)
		1	85-99	92
		10	97-107	103
	X642188	0.01	70-97	83
		1	73-96	82
		10	79-95	89

Analytical Method Summary for the analysis of prothioconazole-desthio

Residues of prothioconazole-desthio were determined using the analytical method "Residue Method for the Determination of prothioconazole-desthio in cereals", Heinemann, O. (2000) – Study number P60293002. Residues of prothioconazole-desthio were extracted from samples with acetonitrile/water. A liquid-liquid extraction was performed with hexane and two further liquid-liquid extractions were then performed with dichloromethane. The extract was taken and evaporated to dryness. The sample was dissolved in acetonitrile/water and then analyzed by liquid chromatography coupled with positive-ion electrospray tandem mass spectrometry (LC-MS/MS). The limit of detection (LOD) and limit of quantitation (LOQ) in barley straw and whole plant were 0.015 mg/kg and 0.05 mg/kg, respectively. The limit of detection (LOD) and limit of quantitation (LOQ) in barley grain were 0.003 mg/kg and 0.01 mg/kg, respectively.

The extraction efficiency of the prothioconazole-desthio residue method (Method Identifier No. P60293002) was evaluated using aged radioactive residues from the metabolism study following spray application of 14C-prothioconazole on wheat. The residue method extraction (using acetonitrile/water as solvent) and the amount extracted in the metabolism studies were in good agreement (Haas, M., 2001).

Characteristics of the analytical method for the analysis of prothioconazole-desthio

	Prothioconazole-desthio
Specificity	*m/z* 314/127 blank value <30% LOQ
Calibration (type, number of data points)	linear regression with 1/x weighting $r^2 \geq 0.990$ 8 data points
Calibration range	Barley grain: Concentration range of 0.05-100.00 ng/mL Barley straw and whole plant: Concentration range of 1.0-200.0 ng/mL
Limit of quantification	Barley grain: LOQ = 0.01 mg/kg Barley straw and whole plant: LOQ = 0.05 mg/kg

Method performance was appropriately documented for the analytical set, with mean recovery values between 70-110% for all matrices and analytes. Additional procedural recovery details are summarized below. Relative standard deviations were all less than 20%.

Summary of Procedural Recoveries for prothioconazole-desthio

Matrix	Analyte	Fortification level (mg/kg)	Recovery Range (%)	Recovery Mean (%)
Barley grain	Prothioconazole-desthio	0.01	75-93	87
		0.1	92-97	95
		1.0	90-109	99
Barley straw	Prothioconazole-desthio	0.05	76-115	90

Matrix	Analyte	Fortification level (mg/kg)	Recovery Range (%)	Recovery Mean (%)
		0.5	80-95	85
		50	104-105	105
Barley whole plant	Prothioconazole-desthio	0.05	69-126	98
		0.5	79-118	97
		5.0	92-94	93
		50	78-83	81

Results and discussions

Residue results can be observed in the following tables.

Table 3.1.2-1 Residue trials on Barley RACs.

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Active substance (common name):	**Fenpicoxamid and Prothioconazole**	Commercial Product (name):	N/A
Crop group:	**Barley**	Other active substance in the formulation (common name and content):	None
Crop EPPO code:	HORVX	Producer of commercial product:	Dow AgroSciences
Responsible body for reporting (name & address):	Dow AgroSciences. 3B Park Square, Milton Park, Abingdon Oxon, OX14 4RN, UK	Study type:	Residue
		Indoor/Glasshouse/Outdoor:	Outdoor
		Residues calculated as:	mg/kg Fenpicoxamid, X642188 and prothioconazole-desthio
Country:	France (North)	Residue method and LOQ :	S12-01537; P60293002 LOQ[a] = 0.01 mg/kg; LOQ[b] = 0.05 mg/kg
Trial location (region):	45160, Saint Hilaire Saint Mesmin, Loiret, France	Procedural recovery (mean):	See foot note
Content of active substance (g/kg or g/l):	50 g a.i./L (fenpicoxamid); 100 g a.i./L (prothioconazole)		
Formulation number:	GF-3307	Max frozen storage time prior to extraction	253 days
Formulation type (e.g. WP):	EC	Study no. / Report No.:	S17-01904

1	2	3	4	5			6		7	8	9			10	11
Trial No. Location (region)	Commodity/ Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treatments	Growth stage at treatment	Portion analysed (commod-ity)	Residues (mg/kg)			PHI	Re-marks:
	(a)	(b) – if relevant	(c)	kg a.i/hL	Water (L/ha)	kg a.i/ha		(d)	(e)	(a)	(h)			(days) (f)	(g)
											fenpico-xamid	X642188	prothio-conazole-desthio		
S17-01904-01: 45160, Saint Hilaire Saint Mesmin, Loiret, France	Spring barley / Planet	1) 31 Mar 2017 2) 28 May – 01 Jun 2017 3) 18 Jul 2017	Broadcast foliar application with boom sprayer, Hypro flat fan nozzle LD015 F110	fenpicoxamid						Grain Straw	ND 1.71	ND 0.11	ND 1.04	47 47	-
				0.0499 0.0449	212 214	0.1058 0.1068	1 2	17 May 2017 01 Jun 2017	37 69						
				prothioconazole											
				0.0998 0.0998	212 214	0.2116 0.2136	1 2	17 May 2017 01 Jun 2017	37 69						

(a) According to EEC and Codex classifications (both) should be used.
(b) Only if relevant.
(c) High or low volume spraying. spreading. dusting etc.. overall. broadcast. -type of equipment must be indicated.
(d) Year must be indicated.
(e) BBCH Monograph. Growth Stages of Plants. 1997. Blackwell. ISBN 3-8263-3152-4
(f) Minimum number of days after last application (Label pre-harvest interval. PHI. underline)
(g) Remarks may include: climatic conditions. references to analytical method. info concerning the metabolites Included. method of storage. storage stability. analysis date and analytical method.
(h) Limit of quantification[a] = 0.01 mg/kg; limit of detection = 0.003 mg/kg for fenpicoxamid (XDE-777) and X642188
Limit of quantification[b] = 0.05 mg/kg; limit of detection = 0.015 mg/kg for prothioconazole-desthio.
ND = not detectable
Procedural recovery (mean across fortification levels):

Fenpicoxamid	Grain	83%
	Straw	89%
	Whole plant	96%
X642188	Grain	94%
	Straw	100%
	Whole plant	85%
Prothioconazole-desthio	Grain	94%
	Straw	93%
	Whole plant	92%

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Active substance (common name):	**Fenpicoxamid and Prothioconazole**	Commercial Product (name):	N/A
Crop group:	**Barley**	Other active substance in the formulation (common name and content):	None
Crop EPPO code:	HORVX	Producer of commercial product:	Dow AgroSciences
Responsible body for reporting (name & address):	Dow AgroSciences. 3B Park Square, Milton Park, Abingdon Oxon, OX14 4RN, UK	Study type:	Residue
		Indoor/Glasshouse/Outdoor:	Outdoor
		Residues calculated as:	mg/kg Fenpicoxamid, X642188 and prothioconazole- desthio
Country:	Poland	Residue method and LOQ :	S12-01537; P60293002 LOQ[a] = 0.01 mg/kg; LOQ[b] = 0.05 mg/kg
Trial location (region):	64-606, Gorka, Wielkopolska, Poland	Procedural recovery (mean):	See foot note
Content of active substance (g/kg or g/l):	50 g a.i./L (fenpicoxamid); 100 g a.i./L (prothioconazole)		
Formulation number:	GF-3307	Max frozen storage time prior to extraction	254 days
Formulation type (e.g. WP):	EC	Study no. / Report No.:	S17-01904

1	2	3	4	5			6		7	8	9			10	11
Trial No. Location (region)	Commodity/ Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treatments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)			PHI	Re-marks:
	(a)	(b) – if relevant	(c)	kg a.i/hL	Water (L/ha)	kg a.i/ha		(d)	(e)	(a)	(h)			(days) (f)	(g)
											fenpico-xamid	X642188	prothio-conazole-desthio		
S17-01904-03: 64-606, Gorka, Wielkopolska, Poland	Winter barley / Meridian	1) 15 Sep 2016 2) 21 – 26 May 2017 3) 17 Jul 2017	Broadcast foliar application with boom sprayer, Lechler reduced drift fan nozzle IDK 120-04	fenpicoxamid						Grain Straw	0.06 0.48	ND 0.02	0.02 0.21	52 52	-
				0.0319 0.0319	307 303	0.0979 0.0968	1 2	11 May 2017 26 May 2017	37 69						
				prothioconazole											
				0.0638 0.0638	307 303	0.1958 0.1937	1 2	11 May 2017 26 May 2017	37 69						

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(a) According to EEC and Codex classifications (both) should be used.
(b) Only if relevant.
(c) High or low volume spraying. spreading. dusting etc.. overall. broadcast. -type of equipment must be indicated.
(d) Year must be indicated.
(e) BBCH Monograph. Growth Stages of Plants. 1997. Blackwell. ISBN 3-8263-3152-4
(f) Minimum number of days after last application (Label pre-harvest interval. PHI. underline)
(g) Remarks may include: climatic conditions. references to analytical method. info concerning the metabolites
Included. method of storage. storage stability. analysis date and analytical method.
(h) Limit of quantification[a] = 0.01 mg/kg; limit of detection = 0.003 mg/kg for fenpicoxamid (XDE-777) and X642188
Limit of quantification[b] = 0.05 mg/kg; limit of detection = 0.015 mg/kg for prothioconazole-desthio.
ND = not detectable

Procedural recovery (mean across fortification levels):

Fenpicoxamid	Grain	83%
	Straw	89%
	Whole plant	96%
X642188	Grain	94%
	Straw	100%
	Whole plant	85%
Prothioconazole-desthio	Grain	94%
	Straw	93%
	Whole plant	92%

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)			
(Application on agricultural and horticultural crops)			
Active substance (common name):	**Fenpicoxamid and Prothioconazole**	Commercial Product (name):	N/A
Crop group:	**Barley**	Other active substance in the formulation (common name and content):	None
Crop EPPO code:	HORVX	Producer of commercial product:	Dow AgroSciences
Responsible body for reporting (name & address):	Dow AgroSciences. 3B Park Square, Milton Park, Abingdon Oxon, OX14 4RN, UK	Study type:	Residue
		Indoor/Glasshouse/Outdoor:	Outdoor
		Residues calculated as:	mg/kg Fenpicoxamid, X642188 and prothioconazole- desthio
Country:	UK	Residue method and LOQ :	S12-01537; P60293002 LOQ[a] = 0.01 mg/kg; LOQ[b] = 0.05 mg/kg
Trial location (region):	LE11 3YA, Loughborough, Leicestershire, UK	Procedural recovery (mean):	See foot note
Content of active substance (g/kg or g/l):	50 g a.i./L (fenpicoxamid); 100 g a.i./L (prothioconazole)		
Formulation number:	GF-3307	Max frozen storage time prior to extraction	216 days
Formulation type (e.g. WP):	EC	Study no. / Report No.:	S17-01904

1	2	3	4	5			6		7	8	9			10	11
Trial No. Location (region)	Commodity/ Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treatments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)			PHI	Re-marks:
	(a)	(b) – if relevant	(c)	kg a.i/hL	Water (L/ha)	kg a.i/ha		(d)	(e)	(a)	(h)			(days) (f)	(g)
											fenpico-xamid	X642188	prothio-conazole-desthio		
S17-01904-04: LE11 3YA, Loughborough, Leicestershire, UK	Spring barley / Olympus	1) 23 Apr 2017 2) Late Jun 2017 3) 24 Aug 2017	Broadcast foliar application with boom sprayer, Hypro reduced drift fan nozzle LD110 015	fenpicoxamid						Grain Straw	0.02 0.99	ND 0.04	(0.004) 0.42	61 61	-
				0.0501 0.0501	213 233	0.1067 0.1167	1 2	13 Jun 2017 24 Jun 2017	43 69						
				prothioconazole											
				0.1002 0.1002	213 233	0.2134 0.2334	1 2	13 Jun 2017 24 Jun 2017	43 69						

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(a) According to EEC and Codex classifications (both) should be used.
(b) Only if relevant.
(c) High or low volume spraying. spreading. dusting etc.. overall. broadcast. -type of equipment must be indicated.
(d) Year must be indicated.
(e) BBCH Monograph. Growth Stages of Plants. 1997. Blackwell. ISBN 3-8263-3152-4
(f) Minimum number of days after last application (Label pre-harvest interval. PHI. underline)
(g) Remarks may include: climatic conditions. references to analytical method. info concerning the metabolites
Included. method of storage. storage stability. analysis date and analytical method.
(h) Limit of quantification[a] = 0.01 mg/kg; limit of detection = 0.003 mg/kg for fenpicoxamid (XDE-777) and X642188
Limit of quantification[b] = 0.05 mg/kg; limit of detection = 0.015 mg/kg for prothioconazole-desthio.
ND = not detectable

Procedural recovery (mean across fortification levels):

Fenpicoxamid	Grain	83%
	Straw	89%
	Whole plant	96%
X642188	Grain	94%
	Straw	100%
	Whole plant	85%
Prothioconazole-desthio	Grain	94%
	Straw	93%
	Whole plant	92%

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Active substance (common name):	**Fenpicoxamid and Prothioconazole**	Commercial Product (name):	N/A
Crop group:	**Barley**	Other active substance in the formulation (common name and content):	None
Crop EPPO code:	HORVX	Producer of commercial product:	Dow AgroSciences
Responsible body for reporting (name & address):	Dow AgroSciences. 3B Park Square, Milton Park, Abingdon Oxon, OX14 4RN, UK	Study type:	Residue
		Indoor/Glasshouse/Outdoor:	Outdoor
		Residues calculated as:	mg/kg Fenpicoxamid, X642188 and prothioconazole- desthio
Country:	Italy	Residue method and LOQ :	S12-01537; P60293002 LOQ[a] = 0.01 mg/kg; LOQ[b] = 0.05 mg/kg
Trial location (region):	40016, S. Giorgio di Piano, Bologna, Italy	Procedural recovery (mean):	See foot note
Content of active substance (g/kg or g/l):	50 g a.i./L (fenpicoxamid); 100 g a.i./L (prothioconazole)		
Formulation number:	GF-3307	Max frozen storage time prior to extraction	275 days
Formulation type (e.g. WP):	EC	Study no. / Report No.:	S17-01904

1	2	3	4	5			6		7	8	9			10	11
Trial No. Location (region)	Commodity/ Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treatments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)			PHI	Re-marks:
	(a)	(b) – if relevant	(c)	kg a.i/hL	Water (L/ha)	kg a.i/ha		(d)	(e)	(a)	(h)			(days) (f)	(g)
											fenpico-xamid	X642188	prothio-conazole-desthio		
S17-01904-06: 40016, S. Giorgio di Piano, Bologna, Italy	Spring barley / Meseta	1) 02 Feb 2017 2) 12 – 24 May 2017 3) 26 Jun 2017	Broadcast foliar application with boom sprayer, AFC flat fan nozzle AFC 110 015	fenpicoxamid						Grain Straw	0.26 1.94	ND 0.06	0.05 0.68	33 33	-
				0.0332	277	0.0922	1	10 May 2017	59						
				0.0333	297	0.0989	2	24 May 2017	69						
				prothioconazole											
				0.0666	277	0.1844	1	10 May 2017	59						
				0.0666	297	0.1978	2	24 May 2017	69						

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(a) According to EEC and Codex classifications (both) should be used.
(b) Only if relevant.
(c) High or low volume spraying. spreading. dusting etc.. overall. broadcast. -type of equipment must be indicated.
(d) Year must be indicated.
(e) BBCH Monograph. Growth Stages of Plants. 1997. Blackwell. ISBN 3-8263-3152-4
(f) Minimum number of days after last application (Label pre-harvest interval. PHI. underline)
(g) Remarks may include: climatic conditions. references to analytical method. info concerning the metabolites
Included. method of storage. storage stability. analysis date and analytical method.
(h) Limit of quantification[a] = 0.01 mg/kg; limit of detection = 0.003 mg/kg for fenpicoxamid (XDE-777) and X642188
Limit of quantification[b] = 0.05 mg/kg; limit of detection = 0.015 mg/kg for prothioconazole-desthio.
ND = not detectable

Procedural recovery (mean across fortification levels):

Fenpicoxamid	Grain	83%
	Straw	89%
	Whole plant	96%
X642188	Grain	94%
	Straw	100%
	Whole plant	85%
Prothioconazole-desthio	Grain	94%
	Straw	93%
	Whole plant	92%

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Active substance (common name):	**Fenpicoxamid and Prothioconazole**	Commercial Product (name):	N/A
Crop group:	**Barley**	Other active substance in the formulation (common name and content):	None
Crop EPPO code:	HORVX	Producer of commercial product:	Dow AgroSciences
Responsible body for reporting (name & address):	Dow AgroSciences. 3B Park Square, Milton Park, Abingdon Oxon, OX14 4RN, UK	Study type:	Residue
		Indoor/Glasshouse/Outdoor:	Outdoor
		Residues calculated as:	mg/kg Fenpicoxamid, X642188 and prothioconazole- desthio
Country:	Spain	Residue method and LOQ :	S12-01537; P60293002 LOQ[a] = 0.01 mg/kg; LOQ[b] = 0.05 mg/kg
Trial location (region):	50490, Villarreal de Huerva, Zaragoza, Spain	Procedural recovery (mean):	See foot note
Content of active substance (g/kg or g/l):	50 g a.i./L (fenpicoxamid); 100 g a.i./L (prothioconazole)		
Formulation number:	GF-3307	Max frozen storage time prior to extraction	273 days
Formulation type (e.g. WP):	EC	Study no. / Report No.:	S17-01904

1	2	3	4	5			6		7	8	9			10	11
Trial No. Location (region)	Commodity/ Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treatments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)			PHI	Re-marks:
	(a)	(b) – if relevant	(c)	kg a.i/hL	Water (L/ha)	kg a.i/ha		(d)	(e)	(a)	(h)			(days) (f)	(g)
											fenpico-xamid	X642188	prothio-conazole-desthio		
S17-01904-07: 50490, Villarreal de Huerva, Zaragoza, Spain	Spring barley / Volley	1) 14 Feb 2017 2) n/r 3) 28 Jun 2017	Broadcast foliar application with boom sprayer, Lurmark flat fan nozzle LD015 F110	fenpicoxamid						Grain Straw	0.18 3.67	ND 0.08	0.04 2.00	33 33	-
				0.0334 0.0333	302 310	0.1008 0.1032	1 2	11 May 2017 26 May 2017	59 - 61 69						
				prothioconazole											
				0.0668 0.0666	302 310	0.2016 0.2063	1 2	11 May 2017 26 May 2017	59 - 61 69						

Continued on next page

(a) According to EEC and Codex classifications (both) should be used.
(b) Only if relevant.
(c) High or low volume spraying. spreading. dusting etc.. overall. broadcast. -type of equipment must be indicated.
(d) Year must be indicated.
(e) BBCH Monograph. Growth Stages of Plants. 1997. Blackwell. ISBN 3-8263-3152-4
(f) Minimum number of days after last application (Label pre-harvest interval. PHI. underline)
(g) Remarks may include: climatic conditions. references to analytical method. info concerning the metabolites
Included. method of storage. storage stability. analysis date and analytical method.
(h) Limit of quantification[a] = 0.01 mg/kg; limit of detection = 0.003 mg/kg for fenpicoxamid (XDE-777) and X642188
Limit of quantification[b] = 0.05 mg/kg; limit of detection = 0.015 mg/kg for prothioconazole-desthio.
ND = not detectable

Procedural recovery (mean across fortification levels):

Fenpicoxamid	Grain	83%
	Straw	89%
	Whole plant	96%
X642188	Grain	94%
	Straw	100%
	Whole plant	85%
Prothioconazole-desthio	Grain	94%
	Straw	93%
	Whole plant	92%

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)			
(Application on agricultural and horticultural crops)			
Active substance (common name):	**Fenpicoxamid and Prothioconazole**	Commercial Product (name):	N/A
Crop group:	**Barley**	Other active substance in the formulation (common name and content):	None
Crop EPPO code:	HORVX	Producer of commercial product:	Dow AgroSciences
Responsible body for reporting (name & address):	Dow AgroSciences. 3B Park Square, Milton Park, Abingdon Oxon, OX14 4RN, UK	Study type:	Residue
		Indoor/Glasshouse/Outdoor:	Outdoor
		Residues calculated as:	mg/kg Fenpicoxamid, X642188 and prothioconazole- desthio
Country:	Greece	Residue method and LOQ :	S12-01537; P60293002 LOQ[a] = 0.01 mg/kg; LOQ[b] = 0.05 mg/kg
Trial location (region):	57018, Melissohori, Oreokastro, Greece	Procedural recovery (mean):	See foot note
Content of active substance (g/kg or g/l):	50 g a.i./L (fenpicoxamid); 100 g a.i./L (prothioconazole)		
Formulation number:	GF-3307	Max frozen storage time prior to extraction	278 days
Formulation type (e.g. WP):	EC	Study no. / Report No.:	S17-01904

1	2	3	4	5			6		7	8	9			10	11
Trial No. Location (region)	Commodity/ Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treatments	Growth stage at treatment	Portion analysed (comm-odity)	Residues (mg/kg)			PHI	Re-marks:
	(a)	(b) – if relevant	(c)	kg a.i/hL	Water (L/ha)	kg a.i/ha		(d)	(e)	(a)	(h)			(days) (f)	(g)
											fenpico-xamid	X642188	prothio-conazole-desthio		
S17-01904-08: 57018, Melissohori, Oreokastro, Greece	Barley / Thessaloniki	1) 07 Dec 2017 2) 08 – 18 May 2017 3) 23 Jun 2017	Broadcast foliar application with boom sprayer, TeeJet flat fan nozzle DG11002-VS	fenpicoxamid						Grain Straw	0.09 1.82	ND 0.07	0.02 1.10	36 36	-
				0.0333 0.0333	304 320	0.1013 0.1065	1 2	05 May 2017 18 May 2017	57 69						
				prothioconazole											
				0.0666 0.0666	304 320	0.2026 0.2131	1 2	05 May 2017 18 May 2017	57 69						

Continued on next page

(a) According to EEC and Codex classifications (both) should be used.
(b) Only if relevant.
(c) High or low volume spraying. spreading. dusting etc.. overall. broadcast. -type of equipment must be indicated.
(d) Year must be indicated.
(e) BBCH Monograph. Growth Stages of Plants. 1997. Blackwell. ISBN 3-8263-3152-4
(f) Minimum number of days after last application (Label pre-harvest interval. PHI. underline)
(g) Remarks may include: climatic conditions. references to analytical method. info concerning the metabolites
Included. method of storage. storage stability. analysis date and analytical method.
(h) Limit of quantification[a] = 0.01 mg/kg; limit of detection = 0.003 mg/kg for fenpicoxamid (XDE-777) and X642188
Limit of quantification[b] = 0.05 mg/kg; limit of detection = 0.015 mg/kg for prothioconazole-desthio.
ND = not detectable

Procedural recovery (mean across fortification levels):

Fenpicoxamid	Grain	83%
	Straw	89%
	Whole plant	96%
X642188	Grain	94%
	Straw	100%
	Whole plant	85%
Prothioconazole-desthio	Grain	94%
	Straw	93%
	Whole plant	92%

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)			
(Application on agricultural and horticultural crops)			
Active substance (common name):	**Fenpicoxamid and Prothioconazole**	Commercial Product (name):	N/A
Crop group:	**Barley**	Other active substance in the formulation (common name and content):	None
Crop EPPO code:	HORVX	Producer of commercial product:	Dow AgroSciences
Responsible body for reporting (name & address):	Dow AgroSciences. 3B Park Square, Milton Park, Abingdon Oxon, OX14 4RN, UK	Study type:	Residue
		Indoor/Glasshouse/Outdoor:	Outdoor
		Residues calculated as:	mg/kg Fenpicoxamid, X642188 and prothioconazole- desthio
Country:	France (North)	Residue method and LOQ :	S12-01537; P60293002 LOQ[a] = 0.01 mg/kg; LOQ[b] = 0.05 mg/kg
Trial location (region):	45300, Rouvres Saint Jean, Loiret, France	Procedural recovery (mean):	See foot note
Content of active substance (g/kg or g/l):	50 g a.i./L (fenpicoxamid); 100 g a.i./L (prothioconazole)		
Formulation number:	GF-3307	Max frozen storage time prior to extraction	293 days
Formulation type (e.g. WP):	EC	Study no. / Report No.:	S17-01904

1	2	3	4	5			6		7	8	9			10	11
Trial No. Location (region)	Commodity/ Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treatments	Growth stage at treatment	Portion analysed (commodi-ty)	Residues (mg/kg)			PHI	Re-marks:
	(a)	(b) – if relevant	(c)	kg a.i/hL	Water (L/ha)	kg a.i/ha		(d)	(e)	(a)	(h)			(days) (f)	(g)
											fenpico-xamid	X642188	prothio-conazole-desthio		
S17-01904-09: 45300, Rouvres Saint Jean, Loiret, France	Spring barley / Sebastian	1) 21 Feb 2017 2) 25 May – 01 Jun 2017 3) 17 Jul 2017	Broadcast foliar application with boom sprayer, TeeJet flat fan nozzle TT110 015	fenpicoxamid						Whole plant	0.36	0.14	0.99	< 0	-
				0.0501	203	0.1017	1	17 May 2017	37	Whole plant	2.98	0.09	3.42	0	
				0.0500	201	0.1006	2	01 Jun 2017	69	Whole plant	0.86	0.03	1.75	7	
				prothioconazole						Whole plant	0.69	0.02	1.22	14	
										Whole plant	0.55	0.05	0.96	28	
				0.1001	203	0.2033	1	17 May 2017	37	Grain	0.01	ND	0.01	46	
				0.1001	201	0.2012	2	01 Jun 2017	69	Straw	1.02	0.05	1.00	46	

Continued on next page

(a) According to EEC and Codex classifications (both) should be used.
(b) Only if relevant.
(c) High or low volume spraying. spreading. dusting etc.. overall. broadcast. -type of equipment must be indicated.
(d) Year must be indicated.
(e) BBCH Monograph. Growth Stages of Plants. 1997. Blackwell. ISBN 3-8263-3152-4
(f) Minimum number of days after last application (Label pre-harvest interval. PHI. underline)
(g) Remarks may include: climatic conditions. references to analytical method. info concerning the metabolites
Included. method of storage. storage stability. analysis date and analytical method.
(h) Limit of quantification[a] = 0.01 mg/kg; limit of detection = 0.003 mg/kg for fenpicoxamid (XDE-777) and X642188
Limit of quantification[b] = 0.05 mg/kg; limit of detection = 0.015 mg/kg for prothioconazole-desthio.
ND = not detectable

Procedural recovery (mean across fortification levels):

Fenpicoxamid	Grain	83%
	Straw	89%
	Whole plant	96%
X642188	Grain	94%
	Straw	100%
	Whole plant	85%
Prothioconazole-desthio	Grain	94%
	Straw	93%
	Whole plant	92%

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Active substance (common name):	**Fenpicoxamid and Prothioconazole**	Commercial Product (name):	N/A
Crop group:	**Barley**	Other active substance in the formulation (common name and content):	None
Crop EPPO code:	HORVX	Producer of commercial product:	Dow AgroSciences
Responsible body for reporting (name & address):	Dow AgroSciences. 3B Park Square, Milton Park, Abingdon Oxon, OX14 4RN, UK	Study type:	Residue
		Indoor/Glasshouse/Outdoor:	Outdoor
		Residues calculated as:	mg/kg Fenpicoxamid, X642188 and prothioconazole- desthio
Country:	Germany	Residue method and LOQ :	S12-01537; P60293002 LOQ[a] = 0.01 mg/kg; LOQ[b] = 0.05 mg/kg
Trial location (region):	71706, Markgröningen, Baden-Württemberg, Germany	Procedural recovery (mean):	See foot note
Content of active substance (g/kg or g/l):	50 g a.i./L (fenpicoxamid); 100 g a.i./L (prothioconazole)		
Formulation number:	GF-3307	Max frozen storage time prior to extraction	285 days
Formulation type (e.g. WP):	EC	Study no. / Report No.:	S17-01904

1	2	3	4	5			6		7	8	9			10	11
Trial No. Location (region)	Commodity/ Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treatments	Growth stage at treatment	Portion analysed (commodi-ty)	Residues (mg/kg)			PHI	Re-marks:
	(a)	(b) – if relevant	(c)	kg a.i/hL	Water (L/ha)	kg a.i/ha		(d)	(e)	(a)	(h)			(days) (f)	(g)
											fenpico-xamid	X642188	prothio-conazole-desthio		
S17-01904-10: 71706, Markgröningen, Baden-Württemberg, Germany	Winter barley / California	1) 01 Oct 2017 2) 25 May – 08 Jun 2017 3) 13 Jul 2017	Broadcast foliar application with boom sprayer, TeeJet reduced drift fan nozzle DG11002-VS	fenpicoxamid						Whole plant	0.30	0.01	0.31	< 0	-
				0.0333	316	0.1052	1	22 May 2017	59	Whole plant	2.29	0.09	1.48	0	
				0.0333	296	0.0985	2	08 Jun 2017	69	Whole plant	2.03	0.04	1.49	7	
				prothioconazole						Whole plant	2.11	0.02	0.92	13	
				0.0666	316	0.2104	1	22 May 2017	59	Whole plant	2.08	0.04	0.99	27	
				0.0666	296	0.1970	2	08 Jun 2017	69	Grain	0.29	0.01	0.13	35	
										Straw	0.18	0.13	1.41	35	

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(a) According to EEC and Codex classifications (both) should be used.
(b) Only if relevant.
(c) High or low volume spraying. spreading. dusting etc.. overall. broadcast. -type of equipment must be indicated.
(d) Year must be indicated.
(e) BBCH Monograph. Growth Stages of Plants. 1997. Blackwell. ISBN 3-8263-3152-4
(f) Minimum number of days after last application (Label pre-harvest interval. PHI. underline)
(g) Remarks may include: climatic conditions. references to analytical method. info concerning the metabolites
Included. method of storage. storage stability. analysis date and analytical method.
(h) Limit of quantification[a] = 0.01 mg/kg; limit of detection = 0.003 mg/kg for fenpicoxamid (XDE-777) and X642188
Limit of quantification[b] = 0.05 mg/kg; limit of detection = 0.015 mg/kg for prothioconazole-desthio.
ND = not detectable

Procedural recovery (mean across fortification levels):

Fenpicoxamid	Grain	83%
	Straw	89%
	Whole plant	96%
X642188	Grain	94%
	Straw	100%
	Whole plant	85%
Prothioconazole-desthio	Grain	94%
	Straw	93%
	Whole plant	92%

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Active substance (common name):	**Fenpicoxamid and Prothioconazole**	Commercial Product (name):	N/A
Crop group:	**Barley**	Other active substance in the formulation (common name and content):	None
Crop EPPO code:	HORVX	Producer of commercial product:	Dow AgroSciences
Responsible body for reporting (name & address):	Dow AgroSciences. 3B Park Square, Milton Park, Abingdon Oxon, OX14 4RN, UK	Study type:	Residue
		Indoor/Glasshouse/Outdoor:	Outdoor
		Residues calculated as:	mg/kg Fenpicoxamid, X642188 and prothioconazole- desthio
Country:	Hungary	Residue method and LOQ :	S12-01537; P60293002 LOQ[a] = 0.01 mg/kg; LOQ[b] = 0.05 mg/kg
Trial location (region):	5000, Szolnok, Hungary	Procedural recovery (mean):	See foot note
Content of active substance (g/kg or g/l):	50 g a.i./L (fenpicoxamid); 100 g a.i./L (prothioconazole)		
Formulation number:	GF-3307	Max frozen storage time prior to extraction	296 days
Formulation type (e.g. WP):	EC	Study no. / Report No.:	S17-01904

1	2	3	4	5			6		7	8	9			10	11
Trial No. Location (region)	Commodity/ Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treatments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)			PHI	Re-marks:
	(a)	(b) – if relevant	(c)	kg a.i/hL	Water (L/ha)	kg a.i/ha		(d)	(e)	(a)	(h)			(days) (f)	(g)
											fenpico-xamid	X642188	prothio-conazole-desthio		
S17-01904-12: 5000, Szolnok, Hungary	Winter barley / Vanessa	1) 14 Oct 2016 2) n/r 3) 04 Jul 2017	Broadcast foliar application with boom sprayer, TeeJet flat fan nozzle AI11003	fenpicoxamid						Whole plant	0.68	0.02	0.45	< 0	-
				0.05	194	0.0970	1	15 May 2017	55 - 61	Whole plant	2.77	0.09	2.11	0	
				0.05	200	0.1000	2	29 May 2017	69	Whole plant	1.66	0.04	0.90	7	
				prothioconazole						Whole plant	2.23	0.04	0.93	14	
										Whole plant	2.10	0.15	0.63	29	
				0.1	194	0.1940	1	15 May 2017	55 - 61	Grain	0.20	(0.006)	0.07	36	
				0.1	200	0.2000	2	29 May 2017	69	Straw	0.30	0.14	1.57	36	

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(a) According to EEC and Codex classifications (both) should be used.
(b) Only if relevant.
(c) High or low volume spraying. spreading. dusting etc.. overall. broadcast. -type of equipment must be indicated.
(d) Year must be indicated.
(e) BBCH Monograph. Growth Stages of Plants. 1997. Blackwell. ISBN 3-8263-3152-4
(f) Minimum number of days after last application (Label pre-harvest interval. PHI. underline)
(g) Remarks may include: climatic conditions. references to analytical method. info concerning the metabolites
Included. method of storage. storage stability. analysis date and analytical method.
(h) Limit of quantification[a] = 0.01 mg/kg; limit of detection = 0.003 mg/kg for fenpicoxamid (XDE-777) and X642188
Limit of quantification[b] = 0.05 mg/kg; limit of detection = 0.015 mg/kg for prothioconazole-desthio.
ND = not detectable

Procedural recovery (mean across fortification levels):

Fenpicoxamid	Grain	83%
	Straw	89%
	Whole plant	96%
X642188	Grain	94%
	Straw	100%
	Whole plant	85%
Prothioconazole-desthio	Grain	94%
	Straw	93%
	Whole plant	92%

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)			
(Application on agricultural and horticultural crops)			
Active substance (common name):	**Fenpicoxamid and Prothioconazole**	Commercial Product (name):	N/A
Crop group:	**Barley**	Other active substance in the formulation (common name and content):	None
Crop EPPO code:	HORVX	Producer of commercial product:	Dow AgroSciences
Responsible body for reporting (name & address):	Dow AgroSciences. 3B Park Square, Milton Park, Abingdon Oxon, OX14 4RN, UK	Study type:	Residue
		Indoor/Glasshouse/Outdoor:	Outdoor
		Residues calculated as:	mg/kg Fenpicoxamid, X642188 and prothioconazole- desthio
Country:	Greece	Residue method and LOQ :	S12-01537; P60293002 LOQ[a] = 0.01 mg/kg; LOQ[b] = 0.05 mg/kg
Trial location (region):	53100, Tripotamos, Florina, Greece	Procedural recovery (mean):	See foot note
Content of active substance (g/kg or g/l):	50 g a.i./L (fenpicoxamid); 100 g a.i./L (prothioconazole)		
Formulation number:	GF-3307	Max frozen storage time prior to extraction	282 days
Formulation type (e.g. WP):	EC	Study no. / Report No.:	S17-01904

1	2	3	4	5			6		7	8	9			10	11
Trial No. Location (region)	Commodity/ Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treatments	Growth stage at treatment	Portion analysed (commod-ity)	Residues (mg/kg)			PHI	Re-marks:
	(a)	(b) – if relevant	(c)	kg a.i/hL	Water (L/ha)	kg a.i/ha		(d)	(e)	(a)	(h)			(days) (f)	(g)
											fenpico-xamid	X642188	prothio-conazole-desthio		
S17-01904-13: 53100, Tripotamos, Florina, Greece	Barley / Persefoni	1) 29 Dec 2016 2) 02 – 13 Jun 2017 3) 16 Jul 2017	Broadcast foliar application with boom sprayer, TeeJet flat fan nozzle XR11002-VS	fenpicoxamid						Whole plant	0.92	0.05	0.57	< 0	-
				0.0334	304	0.1015	1	29 May 2017	57	Whole plant	3.09	0.12	2.11	0	
				0.0334	302	0.1007	2	13 Jun 2017	69	Whole plant	1.55	0.05	1.13	7	
				prothioconazole						Whole plant	1.20	0.02	0.69	13	
										Whole plant	0.17	(0.004)	0.11	26	
				0.0668	304	0.2030	1	29 May 2017	57	Grain	0.10	ND	0.04	33	
				0.0668	302	0.2015	2	13 Jun 2017	69	Straw	0.09	0.06	1.57	33	

(a) According to EEC and Codex classifications (both) should be used.
(b) Only if relevant.
(c) High or low volume spraying. spreading. dusting etc.. overall. broadcast. -type of equipment must be indicated.
(d) Year must be indicated.
(e) BBCH Monograph. Growth Stages of Plants. 1997. Blackwell. ISBN 3-8263-3152-4
(f) Minimum number of days after last application (Label pre-harvest interval. PHI. underline)
(g) Remarks may include: climatic conditions. references to analytical method. info concerning the metabolites
Included. method of storage. storage stability. analysis date and analytical method.
(h) Limit of quantification[a] = 0.01 mg/kg; limit of detection = 0.003 mg/kg for fenpicoxamid (XDE-777) and X642188
Limit of quantification[b] = 0.05 mg/kg; limit of detection = 0.015 mg/kg for prothioconazole-desthio.
ND = not detectable
Procedural recovery (mean across fortification levels):

Fenpicoxamid	Grain	83%
	Straw	89%
	Whole plant	96%
X642188	Grain	94%
	Straw	100%
	Whole plant	85%
Prothioconazole-desthio	Grain	94%
	Straw	93%
	Whole plant	92%

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)			
(Application on agricultural and horticultural crops)			
Active substance (common name):	**Fenpicoxamid and Prothioconazole**	Commercial Product (name):	N/A
Crop group:	**Barley**	Other active substance in the formulation (common name and content):	None
Crop EPPO code:	HORVX	Producer of commercial product:	Dow AgroSciences
Responsible body for reporting (name & address):	Dow AgroSciences. 3B Park Square, Milton Park, Abingdon Oxon, OX14 4RN, UK	Study type:	Residue
		Indoor/Glasshouse/Outdoor:	Outdoor
		Residues calculated as:	mg/kg Fenpicoxamid, X642188 and prothioconazole- desthio
Country:	Italy	Residue method and LOQ :	S12-01537; P60293002 LOQ[a] = 0.01 mg/kg; LOQ[b] = 0.05 mg/kg
Trial location (region):	48025, Riolo Terme, Ravenna, Italy	Procedural recovery (mean):	See foot note
Content of active substance (g/kg or g/l):	50 g a.i./L (fenpicoxamid); 100 g a.i./L (prothioconazole)		
Formulation number:	GF-3307	Max frozen storage time prior to extraction	312 days
Formulation type (e.g. WP):	EC	Study no. / Report No.:	S17-01904

1	2	3	4	5			6		7	8	9			10	11
Trial No. Location (region)	Commodity/ Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treatments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)			PHI	Re-marks:
	(a)	(b) – if relevant	(c)	kg a.i/hL	Water (L/ha)	kg a.i/ha		(d)	(e)	(a)	(h)			(days) (f)	(g)
											fenpico-xamid	X642188	prothio-conazole-desthio		
S17-01904-14: 48025, Riolo Terme, Ravenna, Italy	Winter barley / Atomo	1) 21 Nov 2016 2) 05 – 18 May 2017 3) 14 Jun 2017	Broadcast foliar application with boom sprayer, AFC flat fan nozzle AFC 110 015	fenpicoxamid						Whole plant	0.01	ND	0.13	< 0	-
				0.0333	316	0.1052	1	05 May 2017	61	Whole plant	1.49	0.08	0.99	0	
				0.0334	324	0.1081	2	18 May 2017	69	Whole plant	1.23	0.03	0.55	7	
				prothioconazole						Whole plant	1.15	0.02	0.32	15	
										Whole plant	-	-	-	Not taken	
				0.0666	316	0.2104	1	05 May 2017	61	Grain	0.31	(0.005)	0.09	27	
				0.0668	324	0.2163	2	18 May 2017	69	Straw	0.11	0.02	0.81	27	

(a) According to EEC and Codex classifications (both) should be used.
(b) Only if relevant.
(c) High or low volume spraying. spreading. dusting etc.. overall. broadcast. -type of equipment must be indicated.
(d) Year must be indicated.
(e) BBCH Monograph. Growth Stages of Plants. 1997. Blackwell. ISBN 3-8263-3152-4
(f) Minimum number of days after last application (Label pre-harvest interval. PHI. underline)
(g) Remarks may include: climatic conditions. references to analytical method. info concerning the metabolites
Included. method of storage. storage stability. analysis date and analytical method.
(h) Limit of quantification[a] = 0.01 mg/kg; limit of detection = 0.003 mg/kg for fenpicoxamid (XDE-777) and X642188
Limit of quantification[b] = 0.05 mg/kg; limit of detection = 0.015 mg/kg for prothioconazole-desthio.
ND = not detectable
Procedural recovery (mean across fortification levels):

Fenpicoxamid	Grain	83%
	Straw	89%
	Whole plant	96%
X642188	Grain	94%
	Straw	100%
	Whole plant	85%
Prothioconazole-desthio	Grain	94%
	Straw	93%
	Whole plant	92%

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Active substance (common name):	**Fenpicoxamid and Prothioconazole**	Commercial Product (name):	N/A
Crop group:	**Barley**	Other active substance in the formulation (common name and content):	None
Crop EPPO code:	HORVX	Producer of commercial product:	Dow AgroSciences
Responsible body for reporting (name & address):	Dow AgroSciences. 3B Park Square, Milton Park, Abingdon Oxon, OX14 4RN, UK	Study type:	Residue
		Indoor/Glasshouse/Outdoor:	Outdoor
		Residues calculated as:	mg/kg Fenpicoxamid, X642188 and prothioconazole- desthio
Country:	Spain	Residue method and LOQ :	S12-01537; P60293002 LOQ[a] = 0.01 mg/kg; LOQ[b] = 0.05 mg/kg
Trial location (region):	50374, Torralba de los Frailes, Aragon, Spain	Procedural recovery (mean):	See foot note
Content of active substance (g/kg or g/l):	50 g a.i./L (fenpicoxamid); 100 g a.i./L (prothioconazole)		
Formulation number:	GF-3307	Max frozen storage time prior to extraction	279 days
Formulation type (e.g. WP):	EC	Study no. / Report No.:	S17-01904

1	2	3	4	5			6		7	8	9			10	11
Trial No. Location (region)	Commodity/ Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treatments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)			PHI	Re-marks:
	(a)	(b) – if relevant	(c)	kg a.i/hL	Water (L/ha)	kg a.i/ha		(d)	(e)	(a)	(h)			(days) (f)	(g)
											fenpico-xamid	X642188	prothio-conazole-desthio		
S17-01904-15 #: 50374, Torralba de los Frailes, Aragon, Spain	Spring barley / Unia	1) 10 Feb 2017 2) May – Jun 2017 3) 11 Jul 2017	Broadcast foliar application with boom sprayer, Lurmark flat fan nozzle LD015 F110	fenpicoxamid						Whole plant	0.27	0.10	0.22	< 0	-
				0.0333	303	0.1010	1	31 May 2017	59 - 61	Whole plant	8.96	0.20	4.33	0	
				0.0333	291	0.0969	2	12 Jun 2017	69	Whole plant	6.02	0.08	3.20	8	
				prothioconazole						Whole plant	5.71	0.06	3.34	14	
				0.0667	303	0.2021	1	31 May 2017	59 - 61	Whole plant	7.09	0.10	4.08	28	
				0.0666	291	0.1938	2	12 Jun 2017	69	Grain	0.55	0.01	0.47	29	
										Straw	0.33	0.18	4.68	29	

(a) According to EEC and Codex classifications (both) should be used.
(b) Only if relevant.
(c) High or low volume spraying. spreading. dusting etc.. overall. broadcast. -type of equipment must be indicated.
(d) Year must be indicated.
(e) BBCH Monograph. Growth Stages of Plants. 1997. Blackwell. ISBN 3-8263-3152-4
(f) Minimum number of days after last application (Label pre-harvest interval. PHI. underline)
(g) Remarks may include: climatic conditions. references to analytical method. info concerning the metabolites Included. method of storage. storage stability. analysis date and analytical method.
(h) Limit of quantification[a] = 0.01 mg/kg; limit of detection = 0.003 mg/kg for fenpicoxamid (XDE-777) and X642188
Limit of quantification[b] = 0.05 mg/kg; limit of detection = 0.015 mg/kg for prothioconazole-desthio.
ND = not detectable
Procedural recovery (mean across fortification levels):

Fenpicoxamid	Grain	83%
	Straw	89%
	Whole plant	96%
X642188	Grain	94%
	Straw	100%
	Whole plant	85%
Prothioconazole-desthio	Grain	94%
	Straw	93%
	Whole plant	92%

The barley in trial S17-01904-15 is not considered to be representative for a conventional cereal development and the generated results are not considered representative for normal agronomical practice.

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Active substance (common name):	**Fenpicoxamid and Prothioconazole**	Commercial Product (name):	N/A
Crop group:	**Barley**	Other active substance in the formulation (common name and content):	None
Crop EPPO code:	HORVX	Producer of commercial product:	Dow AgroSciences
Responsible body for reporting (name & address):	Dow AgroSciences. 3B Park Square, Milton Park, Abingdon Oxon, OX14 4RN, UK	Study type:	Residue
		Indoor/Glasshouse/Outdoor:	Outdoor
		Residues calculated as:	mg/kg Fenpicoxamid, X642188 and prothioconazole- desthio
Country:	Bulgaria	Residue method and LOQ :	S12-01537; P60293002 LOQ[a] = 0.01 mg/kg; LOQ[b] = 0.05 mg/kg
Trial location (region):	5570, Letnitsa, Lovech, Bulgaria	Procedural recovery (mean):	See foot note
Content of active substance (g/kg or g/l):	50 g a.i./L (fenpicoxamid); 100 g a.i./L (prothioconazole)		
Formulation number:	GF-3307	Max frozen storage time prior to extraction	314 days
Formulation type (e.g. WP):	EC	Study no. / Report No.:	S17-01904

1	2	3	4	5			6		7	8	9			10	11
Trial No. Location (region)	Commodity/ Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treatments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)			PHI	Re-marks:
	(a)	(b) – if relevant	(c)	kg a.i/hL	Water (L/ha)	kg a.i/ha		(d)	(e)	(a)	(h)			(days) (f)	(g)
											fenpico-xamid	X642188	prothio-conazole-desthio		
S17-01904-16: 5570, Letnitsa, Lovech, Bulgaria	Winter barley / Kazanova	1) 10 Oct 2016 2) 11 – 24 May 2017 3) 26 Jun 2017	Broadcast foliar application with boom sprayer, Teejet flat fan nozzle 0.02/110°	fenpicoxamid						Whole plant	0.53	0.01	0.30	< 0	-
				0.0333	295	0.0982	1	11 May 2017	61	Whole plant	2.88	0.09	1.86	0	
				0.0333	305	0.1016	2	24 May 2017	69	Whole plant	0.68	0.02	0.48	7	
				prothioconazole						Whole plant	0.37	0.02	0.20	15	
										Whole plant	0.37	0.02	0.12	28	
				0.0666	295	0.1964	1	11 May 2017	61	Grain	0.10	ND	0.05	33	
				0.0666	305	0.2031	2	24 May 2017	69	Straw	0.02	0.03	0.31	33	

(a) According to EEC and Codex classifications (both) should be used.
(b) Only if relevant.
(c) High or low volume spraying. spreading. dusting etc.. overall. broadcast. -type of equipment must be indicated.
(d) Year must be indicated.
(e) BBCH Monograph. Growth Stages of Plants. 1997. Blackwell. ISBN 3-8263-3152-4
(f) Minimum number of days after last application (Label pre-harvest interval. PHI. underline)
(g) Remarks may include: climatic conditions. references to analytical method. info concerning the metabolites Included. method of storage. storage stability. analysis date and analytical method.
(h) Limit of quantification[a] = 0.01 mg/kg; limit of detection = 0.003 mg/kg for fenpicoxamid (XDE-777) and X642188
Limit of quantification[b] = 0.05 mg/kg; limit of detection = 0.015 mg/kg for prothioconazole-desthio.
ND = not detectable
Procedural recovery (mean across fortification levels):

Fenpicoxamid	Grain	83%
	Straw	89%
	Whole plant	96%
X642188	Grain	94%
	Straw	100%
	Whole plant	85%
Prothioconazole-desthio	Grain	94%
	Straw	93%
	Whole plant	92%

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Active substance (common name):	**Fenpicoxamid and Prothioconazole**	Commercial Product (name):	N/A
Crop group:	**Barley**	Other active substance in the formulation (common name and content):	None
Crop EPPO code:	HORVX	Producer of commercial product:	Dow AgroSciences
Responsible body for reporting (name & address):	Dow AgroSciences. 3B Park Square, Milton Park, Abingdon Oxon, OX14 4RN, UK	Study type:	Residue
		Indoor/Glasshouse/Outdoor:	Outdoor
		Residues calculated as:	mg/kg Fenpicoxamid, X642188 and prothioconazole- desthio
Country:	Germany	Residue method and LOQ :	S12-01537; P60293002 LOQ[a] = 0.01 mg/kg; LOQ[b] = 0.05 mg/kg
Trial location (region):	21698, Ohrensen, Lower Saxony, Germany	Procedural recovery (mean):	See foot note
Content of active substance (g/kg or g/l):	50 g a.i./L (fenpicoxamid); 100 g a.i./L (prothioconazole)		
Formulation number:	GF-3307	Max frozen storage time prior to extraction	114 days
Formulation type (e.g. WP):	EC	Study no. / Report No.:	S17-01904

1	2	3	4	5			6		7	8	9			10	11
Trial No. Location (region)	Commodity/ Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treatments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)			PHI	Re-marks:
	(a)	(b) – if relevant	(c)	kg a.i/hL	Water (L/ha)	kg a.i/ha		(d)	(e)	(a)	(h)			(days) (f)	(g)
											fenpico-xamid	X642188	prothio-conazole-desthio		
S17-01904-17: 21698, Ohrensen, Lower Saxony, Germany	Barley / Planet	1) 30 Apr 2018 2) 20 Jun 2018 to 28 Jun 2018 3) 25 Jul 2018	Broadcast foliar application with boom sprayer, Lechler reduced drift fan nozzle IDK 120 02	fenpicoxamid						Grain Straw	0.04 2.28	(0.001) 0.07	(0.009) 1.58	28 28	-
				0.0333	300	0.1000	1	15 Jun 2018	59						
				0.0333	310	0.1033	2	27 Jun 2018	69						
				prothioconazole											
				0.0666	300	0.2000	1	15 Jun 2018	59						
				0.0666	310	0.2067	2	27 Jun 2018	69						

(a) According to EEC and Codex classifications (both) should be used.
(b) Only if relevant.
(c) High or low volume spraying. spreading. dusting etc.. overall. broadcast. -type of equipment must be indicated.
(d) Year must be indicated.
(e) BBCH Monograph. Growth Stages of Plants. 1997. Blackwell. ISBN 3-8263-3152-4
(f) Minimum number of days after last application (Label pre-harvest interval. PHI. underline)
(g) Remarks may include: climatic conditions. references to analytical method. info concerning the metabolites Included. method of storage. storage stability. analysis date and analytical method.
(h) Limit of quantification[a] = 0.01 mg/kg; limit of detection = 0.003 mg/kg for fenpicoxamid (XDE-777) and X642188
Limit of quantification[b] = 0.05 mg/kg; limit of detection = 0.015 mg/kg for prothioconazole-desthio.
ND = not detectable

Procedural recovery (mean across fortification levels):

Fenpicoxamid	Grain	83%
	Straw	89%

	Whole plant	96%
X642188	Grain	94%
	Straw	100%
	Whole plant	85%
Prothioconazole-desthio	Grain	94%
	Straw	93%
	Whole plant	92%

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Active substance (common name):	**Fenpicoxamid and Prothioconazole**	Commercial Product (name):	N/A
Crop group:	**Barley**	Other active substance in the formulation (common name and content):	None
Crop EPPO code:	HORVX	Producer of commercial product:	Dow AgroSciences
Responsible body for reporting (name & address):	Dow AgroSciences. 3B Park Square, Milton Park, Abingdon Oxon, OX14 4RN, UK	Study type:	Residue
		Indoor/Glasshouse/Outdoor:	Outdoor
		Residues calculated as:	mg/kg Fenpicoxamid, X642188 and prothioconazole- desthio
Country:	France	Residue method and LOQ :	S12-01537; P60293002 LOQ[a] = 0.01 mg/kg; LOQ[b] = 0.05 mg/kg
Trial location (region):	82130, Lafrancaise, , Tarn et Garonne, France	Procedural recovery (mean):	See foot note
Content of active substance (g/kg or g/l):	50 g a.i./L (fenpicoxamid); 100 g a.i./L (prothioconazole)		
Formulation number:	GF-3307	Max frozen storage time prior to extraction	130 days
Formulation type (e.g. WP):	EC	Study no. / Report No.:	S17-01904

1	2	3	4	5			6		7	8	9			10	11
Trial No. Location (region)	Commodity/ Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treatments	Growth stage at treatment	Portion analysed (commod-ity)	Residues (mg/kg)			PHI	Re-marks:
	(a)	(b) – if relevant	(c)	kg a.i/hL	Water (L/ha)	kg a.i/ha		(d)	(e)	(a)	(h)			(days) (f)	(g)
											fenpico-xamid	X642188	prothio-conazole-desthio		
S17-01904-18: 82130, Lafrancaise, Tarn et Garonne, France	Barley / Laureate	1) 28 Feb 2018 2) Mar to May 2018 3) 09 Jul 2018	Broadcast foliar application with boom sprayer, Teejet flat fan nozzle TT 110 015	fenpicoxamid						Grain Straw	0.01 0.70	(0.001) 0.02	0.03 1.04	31 31	-
				0.0499 0.0499	188 214	0.0938 0.1068	1 2	16 May 2018 08 Jun 2018	43 69						
				prothioconazole											
				0.0999 0.0999	188 214	0.1877 0.2137	1 2	16 May 2018 08 Jun 2018	43 69						

(a) According to EEC and Codex classifications (both) should be used.
(b) Only if relevant.
(c) High or low volume spraying. spreading. dusting etc.. overall. broadcast. -type of equipment must be indicated.
(d) Year must be indicated.
(e) BBCH Monograph. Growth Stages of Plants. 1997. Blackwell. ISBN 3-8263-3152-4
(f) Minimum number of days after last application (Label pre-harvest interval. PHI. underline)
(g) Remarks may include: climatic conditions. references to analytical method. info concerning the metabolites
Included. method of storage. storage stability. analysis date and analytical method.
(h) Limit of quantification[a] = 0.01 mg/kg; limit of detection = 0.003 mg/kg for fenpicoxamid (XDE-777) and X642188
Limit of quantification[b] = 0.05 mg/kg; limit of detection = 0.015 mg/kg for prothioconazole-desthio.
ND = not detectable

Procedural recovery (mean across fortification levels):

Fenpicoxamid	Grain	83%
	Straw	89%
	Whole plant	96%
X642188	Grain	94%
	Straw	100%
	Whole plant	85%
Prothioconazole-desthio	Grain	94%
	Straw	93%
	Whole plant	92%

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Active substance (common name):	**Fenpicoxamid and Prothioconazole**	Commercial Product (name):	N/A
Crop group:	**Barley**	Other active substance in the formulation (common name and content):	None
Crop EPPO code:	HORVX	Producer of commercial product:	Dow AgroSciences
Responsible body for reporting (name & address):	Dow AgroSciences. 3B Park Square, Milton Park, Abingdon Oxon, OX14 4RN, UK	Study type:	Residue
		Indoor/Glasshouse/Outdoor:	Outdoor
		Residues calculated as:	mg/kg Fenpicoxamid, X642188 and prothioconazole- desthio
Country:	Austria	Residue method and LOQ :	S12-01537; P60293002 LOQ[a] = 0.01 mg/kg; LOQ[b] = 0.05 mg/kg
Trial location (region):	8181, Oberdorf, Styria, Austria	Procedural recovery (mean):	See foot note
Content of active substance (g/kg or g/l):	50 g a.i./L (fenpicoxamid); 100 g a.i./L (prothioconazole)		
Formulation number:	GF-3307	Max frozen storage time prior to extraction	148 days
Formulation type (e.g. WP):	EC	Study no. / Report No.:	S17-01904

1	2	3	4	5			6		7	8	9			10	11
Trial No. Location (region)	Commodity/ Variety	Date of 1) Sowing or Planting 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			No. of trt(s)	Dates of treatments	Growth stage at treatment	Portion analysed (commodity)	Residues (mg/kg)			PHI	Re-marks:
	(a)	(b) – if relevant	(c)	kg a.i/hL	Water (L/ha)	kg a.i/ha		(d)	(e)	(a)	(h)			(days) (f)	(g)
											fenpico-xamid	X642188	prothio-conazole-desthio		
S17-01904-19: 8181, Oberdorf, Styria, Austria	Barley / Christelle	1) 20 Oct 2017 2) May 2018 3) 03 Jul 2018	Broadcast foliar application with boom sprayer, DG Teejet flat fan nozzle 02 110 VS	fenpicoxamid						Whole plant	0.11	(0.005)	0.12	< 0	-
				0.0335	328	0.11	1	02 May 2018	45	Whole plant	2.37	0.13	1.53	0	
				0.0336	312	0.1047	2	16 May 2018	65-69	Whole plant	0.88	0.03	0.60	7	
				prothioconazole						Whole plant	0.69	0.03	0.41	14	
										Whole plant	0.26	0.01	0.10	28	
				0.0671	328	0.22	1	02 May 2018	45	Grain	0.03	(0.001)	(0.005)	48	
				0.0671	312	0.2095	2	16 May 2018	65-69	Straw	0.23	(0.01)	0.08	48	

(a) According to EEC and Codex classifications (both) should be used.
(b) Only if relevant.
(c) High or low volume spraying. spreading. dusting etc.. overall. broadcast. -type of equipment must be indicated.
(d) Year must be indicated.
(e) BBCH Monograph. Growth Stages of Plants. 1997. Blackwell. ISBN 3-8263-3152-4
(f) Minimum number of days after last application (Label pre-harvest interval. PHI. underline)
(g) Remarks may include: climatic conditions. references to analytical method. info concerning the metabolites
Included. method of storage. storage stability. analysis date and analytical method.
(h) Limit of quantification[a] = 0.01 mg/kg; limit of detection = 0.003 mg/kg for fenpicoxamid (XDE-777) and X642188
Limit of quantification[b] = 0.05 mg/kg; limit of detection = 0.015 mg/kg for prothioconazole-desthio.
ND = not detectable
Procedural recovery (mean across fortification levels):
Fenpicoxamid Grain 83%

	Straw	89%
	Whole plant	96%
X642188	Grain	94%
	Straw	100%
	Whole plant	85%
Prothioconazole-desthio	Grain	94%
	Straw	93%
	Whole plant	92%

A 2.1.3.2.2 S18-01567/ 180128

Comments of zRMS:	Trials were conducted at 4 sites: 2 in N-EU and 2 in S-EU to determine residues of fenpicoxamid, X642188 and prothioconazole in barley following one foliar application of GF-3307 at a target rate of 75 g a.i. (fenpicoxamid)/ha (nominal) and 150 g a.i. (prothioconazole)/ha (nominal) at a different growth stage (Plot 2 was applied at BBCH 32, Plot 3 at BBCH 37-39, Plot 4 at BBCH 45, plot 5 at BBCH 51-61 and plot 6 at BBCH 55-65). In all trials specimens of the crop from the untreated and treated plots were taken at normal commercial harvest (NCH). The methods were validated for the determination of fenpicoxamid, X642188 and prothioconazole-desthio. 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 period of frozen storage from the day of sampling until extraction was 245 days. **Residues in grain (N-EU):** In seed specimens taken at normal commercial harvest residues of fenpicoxamid and prothioconazole-desthio were <LOQ. In seed specimens taken at normal commercial harvest residues of X642188 were not detectable. Straw matrices were not analysed in the frame of this study. The study is acceptable.

Reference:	KCA 6.3.1/07
Report	Residues of Fenpicoxamid and Prothioconazole in Barley at Harvest Following One Application of GF-3307 – Southern and Northern Europe – 2018. Semrau, J., Kühnel S. 2019. Report no. S18-01567/ 180128.
Guideline(s):	Regulation (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 Repealing Council Directives 79/117/EEC and 91/414/EEC EC guidance working document 7029/VI/95 rev. 5 (July 22, 1997) OECD Test Guideline 509 (Crop Field Trials) OECD Principles on Good Laboratory Practice (revised in 1997, issued 1998) The application of the GLP principles to field studies ENV/JM/MONO(99)22 The Application Of OECD Principles Of GLP To The Organisation And Management Of Multi-Site Studies ENV/JM/MONO(2002)/9 EU Guidance Document SANCO/3029/99 rev. 4 for generating and reporting methods of analysis in support of pre-registration data requirements
Deviations:	None with impact on the study.
GLP:	Yes
Acceptability:	Yes

The objective of the study is to determine residues of fenpicoxamid (also known as XDE-777) and prothioconazole in barley following one foliar application of GF-3307.
Four residue trials were conducted on barley (outdoor) during 2018 in northern France (S18-01567-01), in Germany (S18-01567-02), in Italy (S18-01567-03) and in Spain (S18-01567-04). All trials comprised six plots, one untreated and five treated with GF-3307 (EC formulation containing nominal 100 g prothioconazole/L and nominal 50 g fenpicoxamid/L).
In all trials one application of GF-3307 to each plot at a different growth stage was performed. Plot 2 was applied at BBCH 32, Plot 3 at BBCH 37-39, Plot 4 at BBCH 45, plot 5 at BBCH 51-61 and plot 6 at BBCH 55-65. Each application was applied at a target rate of 75 g a.i./ha (nominal, fenpicoxamid). The test item was diluted with water immediately prior to application to a spray volume of 200 - 300 L/ha (nominal).

In all trials specimens of the crop from the untreated and treated plots were taken at normal commercial harvest (NCH, BBCH 89).
The maximum period of frozen storage for fenpicoxamid and its metabolite X642188 and prothioconazole-desthio in barley grain was 245 days. This period was deemed acceptable as residues of fenpicoxamid and X642188 in high starch/protein content have been shown to be stable under these conditions for 741 days. (DAS Study ID 120749) and residues of prothioconazole-desthio in high starch/protein content have been shown to be stable under these conditions for 540 days (Bayer CropScience Report No. MR-282/00 – evaluated in addendum to 2006 DAR).
The specimens were analysed for residues of fenpicoxamid, its metabolite X642188, and for prothioconazole-desthio following the procedures described in the analytical phase report. The final determination of the analytes in the untreated and treated specimens was performed by single extraction and single injection with liquid chromatography and mass spectrometric detection (LC/MS/MS). The limit of detection (LOD) and limit of quantitation (LOQ) for all analytes were 0.003 mg/kg and 0.01 mg/kg respectively.
During analysis, numerous fortification experiments for barley grain with fenpicoxamid, X642188 and prothioconazole-desthio were performed. No analyte residues above the analytical method LOQ where detected in any of the untreated samples. This indicates that untreated control plots and samples remained largely uncontaminated through the course of the analytical phase.
Samples of barley were analysed for residues fenpicoxamid and X642188 using a method described and reported within this study no. S12-01537/ Dow AgroSciences study number 120615. Samples of barley were analysed for residues prothioconazole-desthio using a method described and reported within the study no. P60293002 [2].
The methods were validated for the determination of fenpicoxamid, X642188 and prothioconazole-desthio in specimens of barley grain within this study.
Details of recoveries per matrix, level of residues in field samples and examples of typical chromatograms per matrix are shown in analytical phase report.
The residues of fenpicoxamid, X642188 and prothioconazole-desthio are presented in the following tables.

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	**prothioconazole**		
Crop group:	**barley**	Commercial Product (name):	n/a
Crop EPPO code:	HORVX	Other active substance in the formulation (common name and content):	fenpicoxamid
Responsible body for reporting (name, address)	Dow AgroSciences 3B Park Square, Milton Park, Abingdon Oxon, OX14 4RN, United Kingdom	Producer of commercial product:	Dow AgroSciences
		Study type:	Residue
Country	northern France	Indoor/Glasshouse/Outdoor:	Outdoor
Trial location (region):	Loiret	Residues calculated as:	prothioconazole
Content of active substance nominal (g/L):	100 g/L	Residue method and LOQ :	DAS Study P60293002 LOQ = 0.01 mg/kg
Formulation number:	GF-3307	Procedural recovery (mean):	85 % (grain)
Formulation type	EC	Max frozen storage time prior to extraction	209 days

1 Trial No. Location (region)	2 Commodity / Variety (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 No. of trt(s)	6 Dates of treatment(s) (d)	7 Growth stage at last treatment (e)	8 Portion analysed (commodity) (a)	9 Residues (mg/kg) (*)	10 PHI (days) (f)	11 Remarks (g)
				kg as/hL	water (L/ha)	kg as/ha							
S18-01567-01	spring	1) 21 Mar 2018	broadcast foliar	0.0748	202	0.1511	1	03 May 2018	32	grain	n.d.	77	Plot 2
45300 Yèvre-la-	barley,	2) 28 May 2018	spray with boom	0.0745	200	0.1490	1	18 May 2018	37 - 39	grain	n.d.	62	Plot 3
Ville, Loiret,	HORVS,	to 04 Jun 2018	sprayer with	0.0748	206	0.1541	1	23 May 2018	45	grain	n.d.	57	Plot 4
northern France	Planet	3) 19 Jul 2018	Teejet, TT 110	0.0747	203	0.1516	1	28 May 2018	51 - 61	grain	< LOQ	52	Plot 5
			015 (flat fan)	0.0745	200	0.1490	1	30 May 2018	55 - 65	grain	< LOQ	50	Plot 6

(a) According to EEC and Codex classifications (both) should be used.
(b) Only if relevant
(c) High or low volume spraying. spreading. dusting etc., overall, broadcast, type of equipment used must be indicated
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4
(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application
(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date
(*) Limit of quantification = 0.01 mg/kg; Limit of detection = 0.003 mg/kg

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	**fenpicoxamid**		
Crop group:	**barley**	Commercial Product (name):	n/a
Crop EPPO code:	HORVX	Other active substance in the formulation (common name and content):	prothioconazole
Responsible body for reporting (name, address)	Dow AgroSciences 3B Park Square, Milton Park, Abingdon Oxon, OX14 4RN, United Kingdom	Producer of commercial product:	Dow AgroSciences
		Study type:	Residue
Country	northern France	Indoor/Glasshouse/Outdoor:	Outdoor
Trial location (region):	Loiret	Residues calculated as:	mg/kg fenpicoxamid (XDE-777) and X642188
Content of active substance nominal (g/L):	50 g/L	Residue method and LOQ :	DAS Study 120615 LOQ = 0.01 mg/kg
Formulation number:	GF-3307	Procedural recovery (mean):	96 % and 95 % (grain)
Formulation type	EC	Max frozen storage time prior to extraction	209 days

1 Trial No. Location (region)	2 Commodity / Variety (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 No. of trt(s)	6 Dates of treatment(s) (d)	7 Growth stage at last treatment (e)	8 Portion analysed (commodity) (a)	9 Residues (mg/kg) (*)		10 PHI (days) (f)	11 Remarks (g)
				kg as/hL	water (L/ha)	kg as/ha					fenpicoxamid (XDE-777)	X642188		
S18-01567-01 45300 Yèvre-la-Ville, Loiret, northern France	spring barley, HORVS, Planet	1) 21 Mar 2018 2) 28 May 2018 to 04 Jun 2018 3) 19 Jul 2018	broadcast foliar spray with boom sprayer with Teejet, TT 110 015 (flat fan)	0.0374 0.0373 0.0374 0.0373 0.0373	202 200 206 203 200	0.0756 0.0745 0.0771 0.0758 0.0745	1 1 1 1 1	03 May 2018 18 May 2018 23 May 2018 28 May 2018 30 May 2018	32 37 - 39 45 51 - 61 55 - 65	grain grain grain grain grain	n.d. n.d. n.d. < LOQ < LOQ	n.d. n.d. n.d. n.d. n.d.	77 62 57 52 50	Plot 2 Plot 3 Plot 4 Plot 5 Plot 6

(a) According to EEC and Codex classifications (both) should be used.
(b) Only if relevant
(c) High or low volume spraying. spreading. dusting etc., overall, broadcast, type of equipment used must be indicated
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4
(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application
(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date
(*) Limit of quantification = 0.01 mg/kg; Limit of detection = 0.003 mg/kg

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name): **prothioconazole**
Crop group: **barley**

Crop EPPO code: HORVX

Responsible body for reporting (name, address): Dow AgroSciences, 3B Park Square, Milton Park, Abingdon, Oxon, OX14 4RN, United Kingdom

Country: Germany
Trial location (region): Brandenburg

Content of active substance nominal (g/L): 100 g/L

Formulation number: GF-3307

Formulation type: EC

Commercial Product (name): n/a

Other active substance in the formulation (common name and content): fenpicoxamid

Producer of commercial product: Dow AgroSciences

Study type: Residue

Indoor/Glasshouse/Outdoor: Outdoor
Residues calculated as: prothioconazole

Residue method and LOQ : DAS Study P60293002, LOQ = 0.01 mg/kg

Procedural recovery (mean): 85 % (grain)

Max frozen storage time prior to extraction: 205 days

1 Trial No. Location (region)	2 Commodity / Variety (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 No. of trt(s)	6 Dates of treatment(s) (d)	7 Growth stage at last treatment (e)	8 Portion analysed (commodity) (a)	9 Residues (mg/kg) (*)	10 PHI (days) (f)	11 Remarks (g)
				kg as/hL	water (L/ha)	kg as/ha							
S18-01567-02 16356 Ahrensfelde OT Trappenfelde, Brandenburg, Germany	spring barley, HORVS, Solist	1) 11 Apr 2018 2) 05 Jun 2018 to 10 Jun 2018 3) 23 Jul 2018	broadcast foliar spray with boom sprayer with Lechler, IDK 120-02 (reduced drift fan)	0.0500	311	0.1555	1	17 May 2018	32	grain	n.d.	67	Plot 2
				0.0500	318	0.1590	1	25 May2018	39	grain	n.d.	59	Plot 3
				0.0499	325	0.1623	1	28 May 2018	45	grain	n.d.	56	Plot 4
				0.0501	288	0.1442	1	30 May 2018	51	grain	n.d.	54	Plot 5
				0.0499	297	0.1483	1	01 Jun 2018	55	grain	n.d.	52	Plot 6

(a) According to EEC and Codex classifications (both) should be used.
(b) Only if relevant
(c) High or low volume spraying. spreading. dusting etc., overall, broadcast, type of equipment used must be indicated
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4
(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application
(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date
(*) Limit of quantification = 0.01 mg/kg; Limit of detection = 0.003 mg/kg

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	**fenpicoxamid**		
Crop group:	**barley**	Commercial Product (name):	n/a
Crop EPPO code:	HORVX	Other active substance in the formulation (common name and content):	prothioconazole
Responsible body for reporting (name, address)	Dow AgroSciences 3B Park Square, Milton Park, Abingdon Oxon, OX14 4RN, United Kingdom	Producer of commercial product:	Dow AgroSciences
		Study type:	Residue
Country	Germany	Indoor/Glasshouse/Outdoor:	Outdoor
Trial location (region):	Brandenburg	Residues calculated as:	mg/kg fenpicoxamid (XDE-777) and X642188
Content of active substance nominal (g/L):	50 g/L	Residue method and LOQ :	DAS Study 120615 LOQ = 0.01 mg/kg
Formulation number:	GF-3307	Procedural recovery (mean):	96 % and 95 % (grain)
Formulation type	EC	Max frozen storage time prior to extraction	205days

1 Trial No. Location (region)	2 Commodity / Variety (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 No. of trt(s)	6 Dates of treatment(s) (d)	7 Growth stage at last treatment (e)	8 Portion analysed (commodity) (a)	9 Residues (mg/kg) (*)		10 PHI (days) (f)	11 Remarks (g)
				kg as/hL	water (L/ha)	kg as/ha					fenpicoxamid (XDE-777)	X642188		
S18-01567-02	spring	1) 11 Apr 2018	broadcast foliar	0.0250	311	0.0777	1	17 May 2018	32	grain	n.d.	n.d.	67	Plot 2
16356	barley,	2) 05 Jun 2018 to	spray with boom	0.0250	318	0.0795	1	25 May2018	39	grain	n.d.	n.d.	59	Plot 3
Ahrensfelde OT	HORVS,	10 Jun 2018	sprayer with	0.0250	325	0.0812	1	28 May 2018	45	grain	n.d.	n.d.	56	Plot 4
Trappenfelde,	Solist	3) 23 Jul 2018	Lechler, IDK	0.0250	288	0.0721	1	30 May 2018	51	grain	n.d.	n.d.	54	Plot 5
Brandenburg,			120-02 (reduced	0.0250	297	0.0742	1	01 Jun 2018	55	grain	n.d.	n.d.	52	Plot 6
Germany			drift fan)											

(a) According to EEC and Codex classifications (both) should be used.
(b) Only if relevant
(c) High or low volume spraying. spreading. dusting etc., overall, broadcast, type of equipment used must be indicated
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4
(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application
(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date
(*) Limit of quantification = 0.01 mg/kg; Limit of detection = 0.003 mg/kg

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	**prothioconazole**		
Crop group:	**barley**	Commercial Product (name):	n/a
Crop EPPO code:	HORVX	Other active substance in the formulation (common name and content):	fenpicoxamid
Responsible body for reporting (name, address)	Dow AgroSciences 3B Park Square, Milton Park, Abingdon Oxon, OX14 4RN, United Kingdom	Producer of commercial product:	Dow AgroSciences
		Study type:	Residue
Country	Italy	Indoor/Glasshouse/Outdoor:	Outdoor
Trial location (region):	Bologna	Residues calculated as:	prothioconazole
Content of active substance nominal (g/L):	100 g/L	Residue method and LOQ :	DAS Study P60293002 LOQ = 0.01 mg/kg
Formulation number:	GF-3307	Procedural recovery (mean):	85 % (grain)
Formulation type	EC	Max frozen storage time prior to extraction	245 days

1 Trial No. Location (region)	2 Commodity / Variety (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 No. of trt(s)	6 Dates of treatment(s) (d)	7 Growth stage at last treatment (e)	8 Portion analysed (commodity) (a)	9 Residues (mg/kg) (*)	10 PHI (days) (f)	11 Remarks (g)
				kg as/hL	water (L/ha)	kg as/ha							
S18-01567-03	winter	1) 20 Nov 2017	broadcast foliar	0.0500	303	0.1517	1	28 Mar 2018	32	grain	n.d.	83	Plot 2
40064 Ozzano	barley,	2) 10 May 2018	spray with boom	0.0499	287	0.1433	1	09 Apr 2018	39	grain	n.d.	71	Plot 3
Emilia,	HORVW,	to 20 May 2018	sprayer with AFC	0.0501	323	0.1617	1	19 Apr 2018	45	grain	n.d.	61	Plot 4
Bologna, Italy	Atomo	3) 20 Jun 2018	110 015 (flat fan)	0.0501	313	0.1567	1	26 Apr 2018	51	grain	n.d.	54	Plot 5
				0.0500	280	0.1400	1	04 May 2018	55	grain	< LOQ	47	Plot 6

(a) According to EEC and Codex classifications (both) should be used.
(b) Only if relevant
(c) High or low volume spraying. spreading. dusting etc., overall, broadcast, type of equipment used must be indicated
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4
(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application
(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date
(*) Limit of quantification = 0.01 mg/kg; Limit of detection = 0.003 mg/kg

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	**fenpicoxamid**		
Crop group:	**barley**	Commercial Product (name):	n/a
Crop EPPO code:	HORVX	Other active substance in the formulation (common name and content):	prothioconazole
Responsible body for reporting (name, address)	Dow AgroSciences 3B Park Square, Milton Park, Abingdon Oxon, OX14 4RN, United Kingdom	Producer of commercial product:	Dow AgroSciences
		Study type:	Residue
Country	Italy	Indoor/Glasshouse/Outdoor:	Outdoor
Trial location (region):	Bologna	Residues calculated as:	mg/kg fenpicoxamid (XDE-777) and X642188
Content of active substance nominal (g/L):	50 g/L	Residue method and LOQ :	DAS Study 120615 LOQ = 0.01 mg/kg
Formulation number:	GF-3307	Procedural recovery (mean):	96 % and 95 % (grain)
Formulation type	EC	Max frozen storage time prior to extraction	245 days

1 Trial No. Location (region)	2 Commodity / Variety (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 No. of trt(s)	6 Dates of treatment(s) (d)	7 Growth stage at last treatment (e)	8 Portion analysed (commodity) (a)	9 Residues (mg/kg) (*)		10 PHI (days) (f)	11 Remarks (g)
				kg as/hL	water (L/ha)	kg as/ha					fenpicoxamid (XDE-777)	X642188		
S18-01567-03 40064 Ozzano Emilia, Bologna, Italy	winter barley, HORVW, Atomo	1) 20 Nov 2017 2) 10 May 2018 to 20 May 2018 3) 20 Jun 2018	broadcast foliar spray with boom sprayer with AFC 110 015 (flat fan)	0.0250	303	0.0758	1	28 Mar 2018	32	grain	n.d.	n.d.	83	Plot 2
				0.0250	287	0.0717	1	09 Apr 2018	39	grain	n.d.	n.d.	71	Plot 3
				0.0250	323	0.0808	1	19 Apr 2018	45	grain	n.d.	n.d.	61	Plot 4
				0.0250	313	0.0783	1	26 Apr 2018	51	grain	n.d.	n.d.	54	Plot 5
				0.0250	280	0.0700	1	04 May 2018	55	grain	< LOQ	n.d.	47	Plot 6

(a) According to EEC and Codex classifications (both) should be used.
(b) Only if relevant
(c) High or low volume spraying. spreading. dusting etc., overall, broadcast, type of equipment used must be indicated
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4
(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application
(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date
(*) Limit of quantification = 0.01 mg/kg; Limit of detection = 0.003 mg/kg

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	**prothioconazole**		
Crop group:	**barley**	Commercial Product (name):	n/a
Crop EPPO code:	HORVX	Other active substance in the formulation (common name and content):	fenpicoxamid
Responsible body for reporting (name, address)	Dow AgroSciences 3B Park Square, Milton Park, Abingdon Oxon, OX14 4RN, United Kingdom	Producer of commercial product:	Dow AgroSciences
		Study type:	Residue
Country	Spain	Indoor/Glasshouse/Outdoor:	Outdoor
Trial location (region):	Aragon	Residues calculated as:	prothioconazole
Content of active substance nominal (g/L):	100 g/L	Residue method and LOQ :	DAS Study P60293002 LOQ = 0.01 mg/kg
Formulation number:	GF-3307	Procedural recovery (mean):	85 % (grain)
Formulation type	EC	Max frozen storage time prior to extraction	209 days

1 Trial No. Location (region)	2 Commodity / Variety (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 No. of trt(s)	6 Dates of treatment(s) (d)	7 Growth stage at last treatment (e)	8 Portion analysed (commodity) (a)	9 Residues (mg/kg) (*)	10 PHI (days) (f)	11 Remarks (g)
				kg as/hL	water (L/ha)	kg as/ha							
S18-01567-04 44492 Fonfria, Aragon, Spain	winter barley, HORVW, Volley	1) 04 Dec 2017 2) n/r 3) 26 Jul 2018	broadcast foliar spray with boom sprayer with Lurmark, LD015 F110 (flat fan, reduced drift fan)	0.0745	192	0.1431	1	15 May 2018	32	grain	n.d.	72	Plot 2
				0.0745	188	0.1400	1	21 May 2018	39	grain	n.d.	66	Plot 3
				0.0746	196	0.1463	1	25 May 2018	45	grain	n.d.	62	Plot 4
				0.0746	196	0.1463	1	01 Jun 2018	51	grain	n.d.	55	Plot 5
				0.0748	183	0.1369	1	08 Jun 2018	55	grain	< LOQ	48	Plot 6

(a) According to EEC and Codex classifications (both) should be used.
(b) Only if relevant
(c) High or low volume spraying. spreading. dusting etc., overall, broadcast, type of equipment used must be indicated
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4
(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application
(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date
(*) Limit of quantification = 0.01 mg/kg; Limit of detection = 0.003 mg/kg

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	**fenpicoxamid**		
Crop group:	**barley**	Commercial Product (name):	n/a
Crop EPPO code:	HORVX	Other active substance in the formulation (common name and content):	prothioconazole
Responsible body for reporting (name, address)	Dow AgroSciences 3B Park Square, Milton Park, Abingdon Oxon, OX14 4RN, United Kingdom	Producer of commercial product:	Dow AgroSciences
		Study type:	Residue
Country	Spain	Indoor/Glasshouse/Outdoor:	Outdoor
Trial location (region):	Aragon	Residues calculated as:	mg/kg fenpicoxamid (XDE-777) and X642188
Content of active substance nominal (g/L):	50 g/L	Residue method and LOQ :	DAS Study 120615 LOQ = 0.01 mg/kg
Formulation number:	GF-3307	Procedural recovery (mean):	96 % and 95 % (grain)
Formulation type	EC	Max frozen storage time prior to extraction	209 days / 230* days

1 Trial No. Location (region)	2 Commodity / Variety (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 No. of trt(s)	6 Dates of treatment(s) (d)	7 Growth stage at last treatment (e)	8 Portion analysed (commodity) (a)	9 Residues (mg/kg) (*)		10 PHI (days) (f)	11 Remarks (g)
				kg as/hL	water (L/ha)	kg as/ha					fenpicoxamid (XDE-777)	X642188		
S18-01567-04 44492 Fonfria, Aragon, Spain	winter barley, HORVW, Volley	1) 04 Dec 2017 2) n/r 3) 26 Jul 2018	broadcast foliar spray with boom sprayer with Lurmark, LD015 F110 (flat fan, reduced drift fan)	0.0373	192	0.0716	1	15 May 2018	32	grain	n.d.	n.d.	72	Plot 2
				0.0372	188	0.0700	1	21 May 2018	39	grain	n.d.	n.d.	66	Plot 3
				0.0373	196	0.0731	1	25 May 2018	45	grain	< LOQ	n.d.	62	Plot 4
				0.0373	196	0.0731	1	01 Jun 2018	51	grain	< LOQ	n.d.	55	Plot 5
				0.0374	183	0.0685	1	08 Jun 2018	55	grain	0.08 / 0.07*	n.d.	48	Plot 6

*Following first analysis of S18-01567-04-006A, 0.08 mg/kg was found in XDE-777. The retain sample was then analysed on Sponsor's request to confirm the first analysis, similar result was found.

(a) According to EEC and Codex classifications (both) should be used.
(b) Only if relevant
(c) High or low volume spraying. spreading. dusting etc., overall, broadcast, type of equipment used must be indicated
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4
(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application
(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date
(*) Limit of quantification = 0.01 mg/kg; Limit of detection = 0.003 mg/kg

A 2.1.4 Magnitude of residues in livestock

A 2.1.4.1 Livestock feeding studies

No new studies presented.

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

A 2.1.5.1 Distribution of the residue in peel/pulp

A 2.1.5.1.1 S18-00056/ 170192

Comments of zRMS:	The residues of fenpicoxamid in barley and its processed commodities following two foliar applications of GF-3307 have been determined in this study. The maximum frozen storage interval for grain and its processed fractions from sampling to analysis was 267 days. The limit of detection (LOD) and limit of quantitation (LOQ) for fenpicoxamid and its X642188 metabolite as well as the hydrolysis degradates X12019520, X12314005, X12264475 and X12335723 was 0.003 mg/kg and 0.01 mg/kg, respectively. **Residues:** Residues of fenpicoxamid in grain (residue) and its processed fractions (RAC grain (prior to processing), cleaned grain, malt sprouts, brewing malt, spent grain, flocs, brewer's yeast, beer, pot barley, barley bran, barley flour and bread) taken at normal commercial harvest for plot / treatment 2 were found to be between ND (not detected, <0.003 mg/kg) and 1.6 mg/kg . Residues of X642188 in grain (residue) and its processed fractions (RAC grain (prior to processing), cleaned grain, malt sprouts, brewing malt, spent grain, flocs, brewer's yeast, beer, pot barley, barley bran, barley flour and bread) taken at normal commercial harvest for plot / treatment 2 were found to be between ND (not detected, <0.003 mg/kg) and 0.25 mg/kg. Residues of X12019520 in grain (residue) and its processed fractions (RAC grain (prior to processing), cleaned grain, malt sprouts, brewing malt, spent grain, flocs, brewer's yeast, beer, pot barley, barley bran, barley flour and bread) taken at normal commercial harvest for plot / treatment 2 were found to be between <LOQ (0.005 mg/kg) and 0.078 mg/kg. Residues of X12314005 in grain (residue) and its processed fractions (RAC grain (prior to processing), cleaned grain, malt sprouts, brewing malt, spent grain, flocs, brewer's yeast, beer, pot barley, barley bran, barley flour and bread) taken at normal commercial harvest for plot / treatment 2 were found to be between ND (not detected, <0.003 mg/kg) and 0.062 mg/kg. Residues of X12264475 in grain (residue) and its processed fractions (RAC grain (prior to processing), cleaned grain, malt sprouts, brewing malt, spent grain, flocs, brewer's yeast, beer, pot barley, barley bran, barley flour and bread) taken at normal commercial harvest for plot / treatment 2 were found to be between ND (not detected, <0.003 mg/kg) and 0.21 mg/kg. Residues of X1235723 in grain (residue) and its processed fractions (RAC grain (prior to processing), cleaned grain, malt sprouts, brewing malt, spent grain, flocs, brewer's yeast, beer, pot barley, barley bran, barley flour and bread) taken at normal commercial harvest for plot / treatment 2 were found to be between ND (not detected, <0.003 mg/kg) and 0.16 mg/kg. Calculated processing factors don't show concentration of fenpicoxamid and its metabolites after all processing steps, PF<1. The study is acceptable.

Reference:	KCA 6.3.1/08
Report	Residues of Fenpicoxamid in Barley and its Processed Commodities at Harvest Following Two Applications of GF-3307 – Europe - 2018.

	Eversfield, S. 2019. Report no. S18-00056/ 170192.
Guideline(s):	OECD (2009) Guidance document on Overview of Residues Chemistry Studies OECD Test Guideline 508: Magnitude of the pesticide residues in processed commodities OECD (2011) Guidance document on Crop Field trials EC (1997) Guidance document 7029/VI/95 rev. 5 SANCO/3029/99 rev. 4 Guideline 7029/VI/95 (REV. 5) to Directive 91/414/EEC and Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009
Deviations:	None with impact on the study.
GLP:	Yes
Acceptability:	Yes

Materials and methods

The magnitude of residues of fenpicoxamid in barley was determined following two post emergent broadcast applications of GF-3307 to barley. To determine maximum fenpicoxamid residue levels in barley, three field trials were established in which two post-emergent foliar applications of GF-3307, an emulsifiable concentrate (EC) formulation containing fenpicoxamid at a nominal concentration of 50 g/L and propiconazole at a nominal concentration of 100 g/L, applied in a nominal 14-day interval (actual interval was 14 days) between applications and the last application at BBCH growth stage 69 to 71.

Three trials were conducted in France (S18-00056-01), Germany (S18-00056-02) and the UK (S18-00056-03). Each site had a control plot and a treated plot. No analyte residues above the analytical method LOQ where detected in any of the untreated samples, except for barley flour samples no. S18-00056-L2-011A and S18-00056-L2-059A and bread sample S18-00056-L2-060A. This indicates that untreated control plots and samples remained largely uncontaminated through the course of the analytical phase.

For trials S18-00056-01 and 03, two applications of GF-3307 were applied at target rates of 10 L product/ha (500 g ai/ha fenpicoxamid and 1000 g ai/ha propiconazole). Treatment applications ranged from 97.88 % to 104.4 % of the target rates, and spray volumes ranged from 196 to 209 L/ha. There were no deviations greater than ± 10 %. For trial S18-00056-02 two applications were applied at rates of 5 L product/ha (252-266 g ai/ha fenpicoxamid and 504-532 g ai/ha propiconazole) and spray volume ranged from 251 to 264 L/ha.

At each trial, grain specimens were taken at BBCH growth stage 89 at normal commercial harvest (NCH). The maximum period of frozen storage between sampling and extraction for fenpicoxamid, X642188, X12019520, X12314005, X12264475 and X12335723 in barley grain and its processed commodities was 242 267 days.

The specimens were analysed for residues of fenpicoxamid, its metabolite X642188 as well as the hydrolysis degradates X12019520, X12314005, X12264475 and X12335723 following the procedure described in the analytical method described in the analytical phase report (Appendix B). A summary of the analytical method is given below.

Analytical Method Summary

Residues of fenpicoxamid and its X642188 metabolite as well as the hydrolysis degradates X12019520, X12314005, X12264475 and X12335723 were determined using the analytical method validated within "Determination of Residues of XDE-777 in Grain and Processed Products after Two Applications of GF-2925 in Winter Wheat at 2 sites in Northern Europe and 2 sites in Southern Europe in 2014", Eversfield (2014) – Study number 140696.

For fenpicoxamid, X642188, X12019520 and X12314005, the method involves extraction by homogenisation and shaking with acetonitrile/water/phosphorus acid (90/10/0.1, v/v/v) followed by dilution with acetonitrile/water/formic acid (90/10/0.1, v/v/v). For X12264475 and X12335723, the method involves extraction by homogenisation and shaking with acetonitrile/water/phosphorus acid (90/10/0.1, v/v/v) from which an aliquot is taken and the pH adjusted to < 4, followed by the addition of water/glycerine (8/2, v/v) prior to the concentration step. Ammonium acetate and ammonia solution is then added to bring

the pH to 5-6.5 prior to extraction of the aqueous solution with ethyl acetate. The final determination for all analytes was performed by single extraction and single injection with liquid chromatography and mass spectrometric detection (LC/MS/MS). The limit of detection (LOD) and limit of quantitation (LOQ) were 0.003 mg/kg and 0.01 mg/kg, respectively, for all analytes in all matrices.

Characteristics of the analytical method

	XDE-777	**X642188**	**X12019520**	**X12314005**	**X12264475**	**X12335723**
Specificity	*m/z* 615/239 blank value <30% LOQ	*m/z* 515/239 blank value <30% LOQ	*m/z* 189/143 blank value <30% LOQ	*m/z* 277/189 blank value <30% LOQ	*m/z* 257/124 blank value <30% LOQ	*m/z* 257/152 blank value <30% LOQ
Calibration (type, number of data points)	linear regression with 1/x weighting $r^2 \geq 0.980$ 5-8 data points					
Calibration range	Concentration range of 0.075-5.0 ng/mL				Concentration range of 0.15-10.0 ng/mL	
Limit of quantification	LOQ = 0.01 mg/kg					

During analysis, fortification experiments for barley grain and its processed fractions with fenpicoxamid, X642188, X12019520, X12314005, X12264475 and X12335723 were performed. Method performance was appropriately documented for the analytical set, with mean recovery values between 70-110% for all matrices and analytes. Additional procedural recovery details are summarized below. Relative standard deviations were all less than 20%.
Residues of fenpicoxamid (XDE-777), X642188, X12019520, X12314005, X12264475 and X12335723 were quantified in samples of barley grain (residue samples) and its processed fractions (RAC grain (grain prior to processing), cleaned grain, malt sprouts, brewing malt, spent grain, flocs, brewer's yeast, beer, pot barley, barley bran, barley flour and bread). The residues in treated and untreated samples are summarized in the "Results and Discussion" section of this phase report.

Results and discussions

Table C.3.2.2.1-1. Processing study on barley grain with fenpicoxamid

	Residues (mg/kg)		**PF**[(a)]	**CF**[(b)]	**Comments/Reference**
	RD-Mo	RD-RA			
RAC – Barley grain	Fenpicoxamid	Fenpicoxamid	-	-	
Barley/ Cleaned grain	Fenpicoxamid	Fenpicoxamid	0.74	-	
Barley/ Malt sprouts	Fenpicoxamid	Fenpicoxamid	0.72	-	
Barley/ Brewing malt	Fenpicoxamid	Fenpicoxamid	0.32	-	
Barley/ Spent grain	Fenpicoxamid	Fenpicoxamid	0.06	-	
Barley/ Flocs	Fenpicoxamid	Fenpicoxamid	NA	-	
Barley/ Brewer's yeast	Fenpicoxamid	Fenpicoxamid	NA	-	
Barley/ Beer	Fenpicoxamid	Fenpicoxamid	NA	-	
Barley/ Pot barley	Fenpicoxamid	Fenpicoxamid	0.18	-	
Barley/ Barley bran	Fenpicoxamid	Fenpicoxamid	0.60	-	
Barley/ Barley flour	Fenpicoxamid	Fenpicoxamid	0.79	-	
Barley/ Bread	Fenpicoxamid	Fenpicoxamid	0.42	-	

a: Processing Factor
b: Conversion factor for risk assessment

Residue data for the treated specimens are summarised in the following tables:

S18-00056-01, FRANCE

Sample Code	Commodity	Plot	Fenpicoxamid Application Rate (g ai/ha)	Spray Volume (L/ha)	BBCH at Application	Interval (days) (DALA)	Fenpicoxamid (mg/kg)	X642188 (mg/kg)	X12019520 (mg/kg)
S18-00056-01-002A	Grain (residue)	2	494 / 489	198 / 196	41 / 69	44	0.83	<LOQ (0.009)	0.044
S18-00056-L2-013A	RAC Grain (prior to processing)						0.76	0.011	0.044
S18-00056-L2-014A	Cleaned grain						0.73	<LOQ (0.01)	0.044
S18-00056-L2-015A	Malt sprouts						0.34	0.15	0.032
S18-00056-L2-016A	Brewing malt						0.23	0.13	0.019
S18-00056-L2-017A	Spent grain						0.053	0.056	0.013
S18-00056-L2-018A	Flocs						ND	ND	0.012
S18-00056-L2-019A	Brewer's yeast						ND	ND	0.014
S18-00056-L2-020A	Beer						ND	ND	<LOQ (0.005)
S18-00056-L2-021A	Pot barley						0.20	<LOQ (0.009)	0.026
S18-00056-L2-022A	Barley bran						0.48	0.012	0.042
S18-00056-L2-023A	Barley flour						0.68	<LOQ (0.009)	<LOQ (0.01)
S18-00056-L2-024A	Bread						0.32	<LOQ (0.008)	0.014

NCH = Normal commercial harvest
ND = Not detected, less than the LOD (<0.003 mg/kg)
Residues of less than the LOQ of 0.01 mg/kg but equal to or greater than the LOD are shown in parentheses.

S18-00056-01, FRANCE continued

Sample Code	Commodity	Plot	fenpicoxamid Application Rate (g ai/ha)	Spray Volume (L/ha)	BBCH at Application	Interval (days) (DALA)	X12314005 (mg/kg)	X12264475 (mg/kg)	X1235723 (mg/kg)
S18-00056-01-002A	Grain (residue)	2	494 / 489	198 / 196	41 / 69	44	<LOQ (0.008)	0.044	0.022
S18-00056-L2-013A	RAC Grain (prior to processing)						<LOQ (0.009)	0.043	0.024
S18-00056-L2-014A	Cleaned grain						<LOQ (0.007)	ND	<LOQ (0.007)
S18-00056-L2-015A	Malt sprouts						0.021	0.082	0.012
S18-00056-L2-016A	Brewing malt						0.013	0.049	<LOQ (0.008)
S18-00056-L2-017A	Spent grain						0.020	0.022	<LOQ (0.008)
S18-00056-L2-018A	Flocs						ND	0.025	ND
S18-00056-L2-019A	Brewer's yeast						ND	0.023	<LOQ (0.005)
S18-00056-L2-020A	Beer						ND	<LOQ (0.007)	ND
S18-00056-L2-021A	Pot barley						<LOQ (0.006)	0.068	<LOQ (0.004)
S18-00056-L2-022A	Barley bran						0.010	0.046	0.011
S18-00056-L2-023A	Barley flour						<LOQ (0.007)	<LOQ (0.01)	0.016
S18-00056-L2-024A	Bread						0.015	<LOQ (0.01)	0.033

NCH = Normal commercial harvest
ND = Not detected, less than the LOD (<0.003 mg/kg)
Residues of less than the LOQ of 0.01 mg/kg but equal to or greater than the LOD are shown in parentheses.

S17-00056-02, GERMANY

Sample Code	Commodity	Plot	fenpicoxamid Application Rate (g ai/ha)	Spray Volume (L/ha)	BBCH at Application	Interval (days) (DALA)	fenpicoxamid (mg/kg)	X642188 (mg/kg)	X12019520 (mg/kg)
S18-00056-02-002A	Grain (residue)	2	266 / 252	264 / 251	59 / 69	42	1.1	0.015	0.065
S18-00056-L2-037A	RAC Grain (prior to processing)						1.3	0.022	0.078
S18-00056-L2-038A	Cleaned grain						0.45	0.013	0.056
S18-00056-L2-039A	Malt sprouts						0.69	0.023	0.037
S18-00056-L2-040A	Brewing malt						0.27	0.14	0.032
S18-00056-L2-041A	Spent grain						0.056	0.061	0.012
S18-00056-L2-042A	Flocs						ND	ND	0.013
S18-00056-L2-043A	Brewer's yeast						ND	<LOQ (0.004)	0.014
S18-00056-L2-044A	Beer						ND	ND	<LOQ (0.009)
S18-00056-L2-045A	Pot barley						0.12	0.011	0.042
S18-00056-L2-046A	Barley bran						0.39	0.013	0.043
S18-00056-L2-047A	Barley flour						0.63	0.011	0.012
S18-00056-L2-048A	Bread						0.33	0.011	0.017

NCH = Normal commercial harvest
ND = Not detected, less than the LOD (<0.003 mg/kg)
Residues of less than the LOQ of 0.01 mg/kg but equal to or greater than the LOD are shown in parentheses.

S17-00056-02, GERMANY continued

Sample Code	Commodity	Plot	fenpicoxamid Application Rate (g ai/ha)	Spray Volume (L/ha)	BBCH at Application	Interval (days) (DALA)	X12314005 (mg/kg)	X12264475 (mg/kg)	X1235723 (mg/kg)
S18-00056-02-002A	Grain (residue)	2	266 / 252	264 / 251	59 / 69	42	0.017	0.088	0.031
S18-00056-L2-037A	RAC Grain (prior to processing)						0.062	0.090	0.035
S18-00056-L2-038A	Cleaned grain						<LOQ (0.009)	0.082	0.021
S18-00056-L2-039A	Malt sprouts						0.018	0.092	0.017
S18-00056-L2-040A	Brewing malt						0.013	0.055	0.010
S18-00056-L2-041A	Spent grain						0.017	0.030	<LOQ (0.005)
S18-00056-L2-042A	Flocs						ND	0.028	<LOQ (0.006)
S18-00056-L2-043A	Brewer's yeast						ND	0.023	<LOQ (0.005)
S18-00056-L2-044A	Beer						ND	0.014	<LOQ (0.004)
S18-00056-L2-045A	Pot barley						<LOQ (0.009)	0.062	<LOQ (0.006)
S18-00056-L2-046A	Barley bran						0.012	0.053	0.071
S18-00056-L2-047A	Barley flour						<LOQ (0.007)	0.017	0.038
S18-00056-L2-048A	Bread						0.017	0.019	0.033

NCH = Normal commercial harvest
ND = Not detected, less than the LOD (<0.003 mg/kg)
Residues of less than the LOQ of 0.01 mg/kg but equal to or greater than the LOD are shown in parentheses.

S17-00056-03, UK

Sample Code	Commodity	Plot	fenpicoxamid Application Rate (g ai/ha)	Spray Volume (L/ha)	BBCH at Application	Interval (days) (DALA)	fenpicoxamid (mg/kg)	X642188 (mg/kg)	X12019520 (mg/kg)
S18-00056-03-002A	Grain (residue)	2	510 / 522	204 / 209	51-55 / 69-71	56	1.6	0.030	0.059
S18-00056-L2-061A	RAC Grain (prior to processing)						1.1	0.030	0.055
S18-00056-L2-062A	Cleaned grain						1.0	0.029	0.056
S18-00056-L2-063A	Malt sprouts						1.3	0.051	0.068
S18-00056-L2-064A	Brewing malt						0.51	0.25	0.051
S18-00056-L2-065A	Spent grain						0.078	0.064	0.033
S18-00056-L2-066A	Flocs						ND	ND	0.025
S18-00056-L2-067A	Brewer's yeast						ND	ND	0.027
S18-00056-L2-068A	Beer						ND	ND	0.016
S18-00056-L2-069A	Pot barley						0.21	0.012	0.038
S18-00056-L2-070A	Barley bran						0.94	0.029	0.051
S18-00056-L2-071A	Barley flour						1.1	0.015	0.013
S18-00056-L2-072	Bread						0.63	0.024	0.014

NCH = Normal commercial harvest
ND = Not detected, less than the LOD (<0.003 mg/kg)
Residues of less than the LOQ of 0.01 mg/kg but equal to or greater than the LOD are shown in parentheses.

S17-00056-03, UK continued

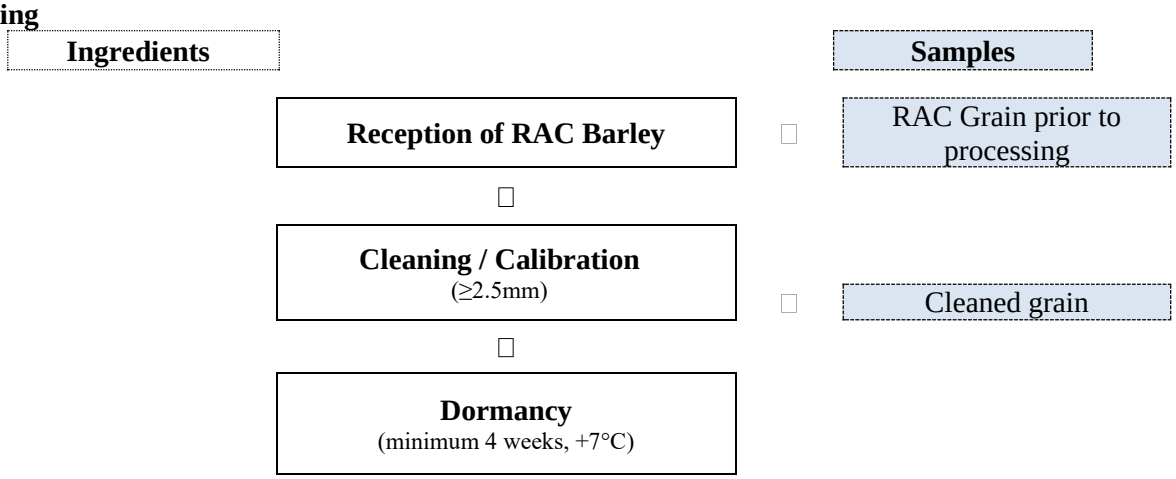
Sample Code	Commodity	Plot	fenpicoxamid Application Rate (g ai/ha)	Spray Volume (L/ha)	BBCH at Application	Interval (days) (DALA)	X12314005 (mg/kg)	X12264475 (mg/kg)	X1235723 (mg/kg)
S18-00056-03-002A	Grain (residue)	2	510 / 522	204 / 209	51-55 / 69-71	56	0.026	0.12	0.035
S18-00056-L2-061A	RAC Grain (prior to processing)						0.021	0.12	0.028
S18-00056-L2-062A	Cleaned grain						0.019	0.11	0.031
S18-00056-L2-063A	Malt sprouts						0.037	0.21	0.022
S18-00056-L2-064A	Brewing malt						0.023	0.10	0.018
S18-00056-L2-065A	Spent grain						0.032	0.083	0.022
S18-00056-L2-066A	Flocs						ND	0.055	0.013
S18-00056-L2-067A	Brewer's yeast						ND	0.041	0.012
S18-00056-L2-068A	Beer						ND	0.032	<LOQ (0.01)
S18-00056-L2-069A	Pot barley						0.013	0.057	<LOQ (0.005)
S18-00056-L2-070A	Barley bran						0.022	0.088	0.16
S18-00056-L2-071A	Barley flour						<LOQ (0.006)	0.023	0.040
S18-00056-L2-072	Bread						0.023	0.021	0.043

NCH = Normal commercial harvest
ND = Not detected, less than the LOD (<0.003 mg/kg)
Residues of less than the LOQ of 0.01 mg/kg but equal to or greater than the LOD are shown in parentheses.

Figure C.3.2.2 Processing flowchart for Barley processed fractions

Reception
At reception, the barley grains were in breathable bags at ambient temperature.
All specimens were verified for number, state, weight and temperature conditions. Each lot was classified by treatments (Untreated 1, Treatment 2).
After reception and before processing, the samples were stored in ambient condition.
All anomalies were reported to the PI and/or SD concerned, and/or sender and recorded in the raw data or reception documents.

Cleaning

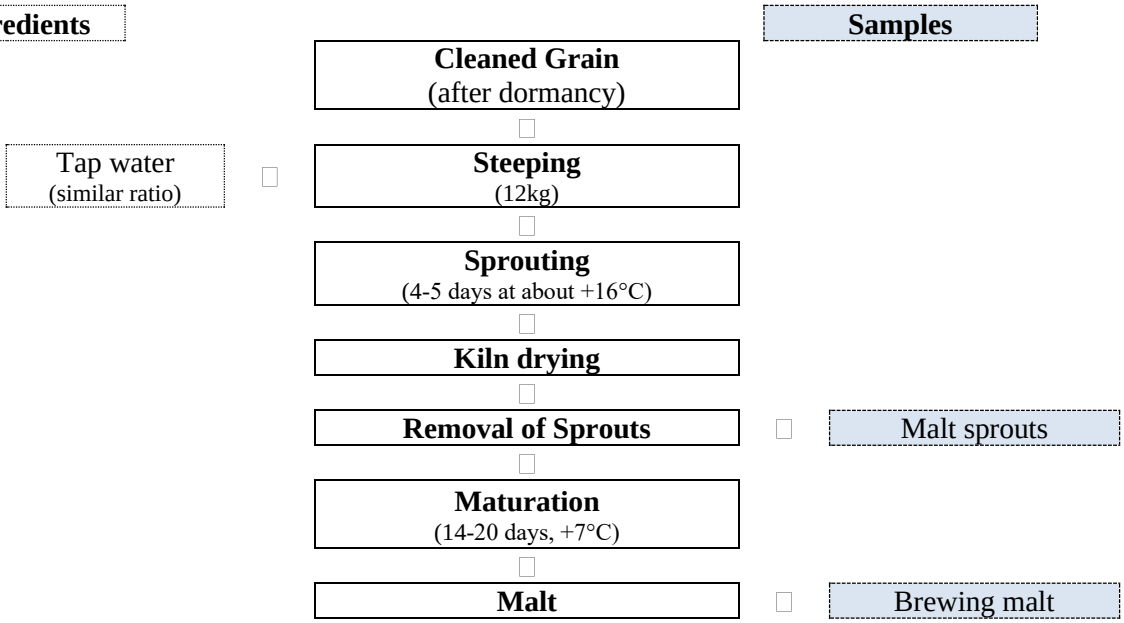


The cleaning process was done on a laboratory scale, but fully comparable to industrial cleaning.
Before start, the moisture content was measured for each sample; as it was inferior to 15%, no drying was necessary.
All the available grains were cleaned.

Cleaning / Calibration: the barley grains were cleaned using suitable cleaning equipment (Rationel Kornservice sample cleaner *SLN3*). At last the grains were sorted by size grading and only the grains with a size ≥ 2.5 mm were kept and used for the processing.
All the cleaned grains were stored in the cold room at target +7°C until the next process.

Dormancy: the grains used for beer processing were stored at target temperature +7°C for minimum 4 weeks.

Malting



Steeping: 12 kg of cleaned barley after dormancy were used for steeping.
The steeping stage consists in alternating sub-water period and sub-air period.

Stage	Spring barley	
	T°C	Time
1st wet stage	≈16°C	≈5h
1st air rest stage	≈16°C	≈15h
2nd wet stage	≈16°C	≈7h
2nd air rest stage	≈16°C	≈16h
3rd wet stage	≈16°C	≈1h

During the sub-water period, the grain was covered with tap water, about 1 kg of water per 1 kg of barley.

Sprouting: All the grains available after the steeping step were used.
The grains were put 4 or 5 days at a target temperature of about 16°C.

Kilning: the kilning step was done in a drying oven and following this table for duration and temperatures**.**

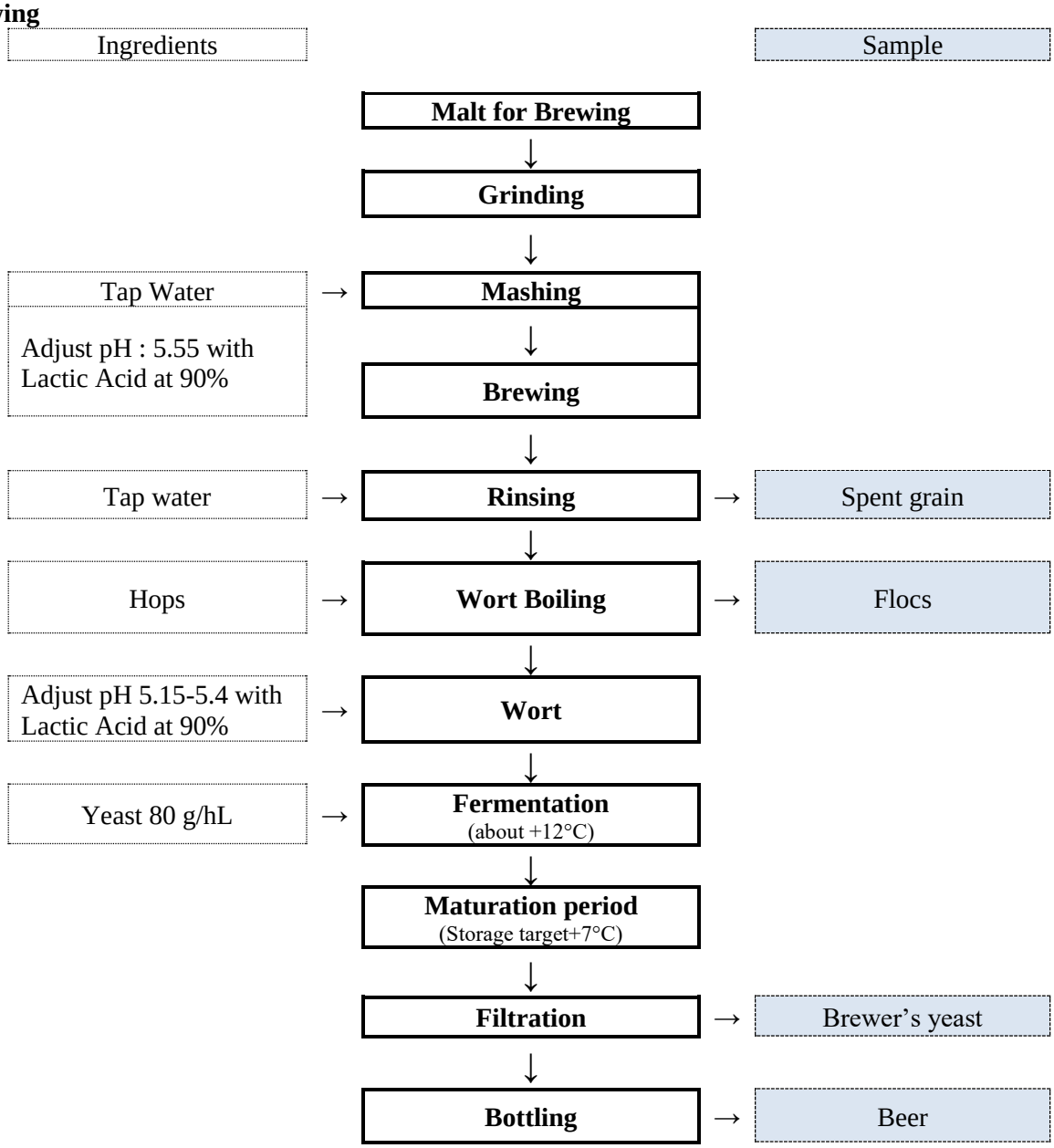
KILNING STAGE	TEMPERATURE (°C)	DURATION (h)
1st	≈50°C	≈8h
2nd	≈64°C	≈11h
3rd	≈80°C	≈5h
4th	≈30°C	≈2h

At the end of this step, the moisture content of the dried germinated grains was between 1.3% and 4.1%.

Sprouts removal: The sprouts were removed manually from the dried germinated grains.
The whole quantity of malt produced was used for the maturation.

Maturation: The malt was stored in chilled conditions (target +7°C) for 14 to 20 days before brewing.

Brewing



Malt grinding:

6 kg of malt were ground using a mill to generate about 28-30 L of wort.

Mashing: 18 L of water were used.

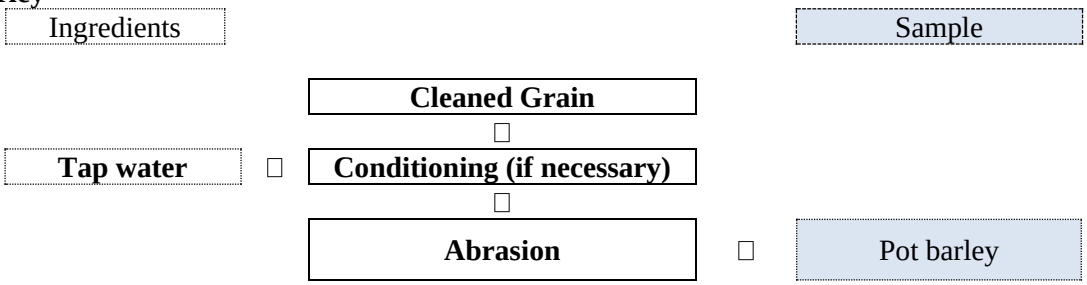
A brewer machine was used for brewing. Once the water reached 45°C, the ground malt was introduced in the malt tube.

Step	Step N°	Type of Step	Temperature (°C)	Duration (minutes)
Mashing	1	Rest	≈45 °C	≈ 20 min
Brewing	2	Ramp	≈45 - 52 °C	≈ 10 min
	3	Ramp	≈52 - 64 °C	≈ 10 min
	4	Rest	≈64 ± 2 °C	≈ 20 min

	5	Ramp	≈64 - 74 °C	≈ 10 min
	6	Rest	≈ 74 ± 2 °C	≈ 30 min
Wort Boiling	7	Ramp	≈74 - 100 °C	≈ 30 min
	8	Rest	≈ 100 ± 2 °C	≈ 90 min

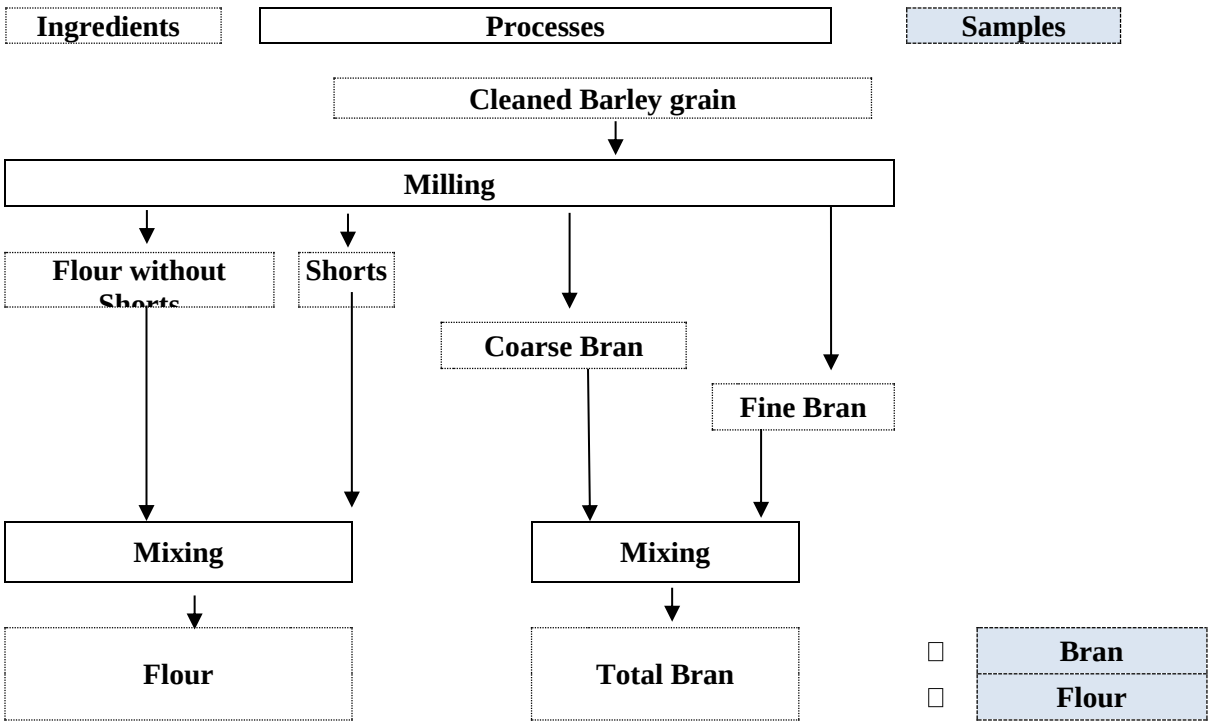
Brewing: As soon as mashing is completed, the pH was measured and adjusted to 5.55 using lactic acid.
Rinsing: The malt tube was rinsed above the wort 3 times with 5 L of water at about 74°C for 5 minutes. The malt tube was removed once the wort reaches about 30 L.
Wort boiling: 1.5 g of hops / 30 L wort was used (hops extract in CO_2 at 50% in α-acid). The hops were added when the first cooking step reached boiling.
The pH was measured and adjusted with lactic acid to 5.15 - 5.4.
After adjustment, the wort was stirred and left a few minutes for decantation.
After cooling of the wort, the deposited trub / flocs (hops draff) were removed and the wort then transferred to an open fermenting tank.
Fermentation:
The wort was inoculated with brewing yeasts at the rate of 80 g/hl, and then placed in a stainless tank and covered, at about +12 °C, until the sucrose by mass (°Plato) was stabilized.
Maturation: After the fermentation step, the stainless tank was moved in the cold room (target temperature +7°C) for 20 to 27 days**.**
Filtration: After the maturation period, the beer was filtered using filter sheets K900.
Bottling: The “Beer” specimen was taken and deep frozen.

Pot barley



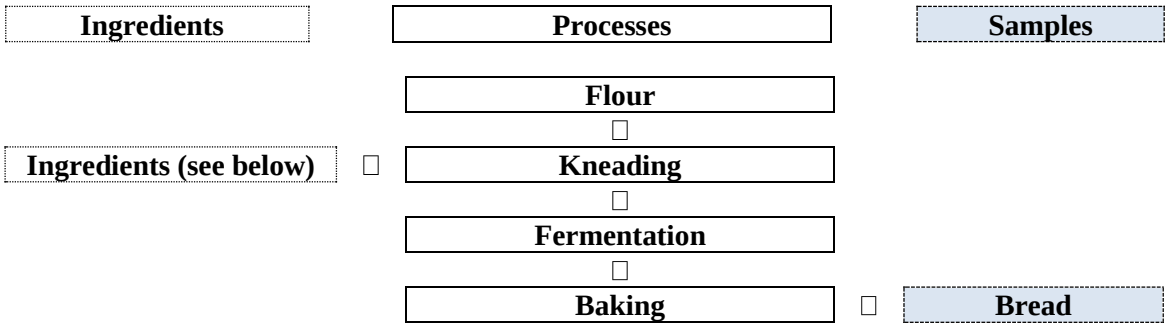
5 kg or 6 kg of cleaned grains were used for this processing to pot barley.
Conditioning: The grains were moistened with tap water at room temperature, until the moisture content reached to 10.9% - 14.1%.
Abrasion: The grains were filled in a suitable decorticator (e.g. *Vertikalschäler Fa. Schule)* until the range of abrasion was about 20% (19.6% to 20.5%).

Milling



About 25-28 kg of cleaned grain were used for this step.
Milling: For milling, a rolling mill type "Bühler Mahlautomat MLU-202" was used. First 0.5kg of the wheat sample was milled to clean the mill and to get normal milling conditions at the correct working temperature of the mill. This material was discarded.
The flour fractions 'Flour without Shorts' and the remaining 'Shorts' were mixed together to get the flour.
Parts of Fine Bran and Coarse Bran were mixed (ratio 1:1) to get the specimen "Bran".

Bread processing



Kneading: All ingredients were placed in the kneading machine. Mixing and kneading were performed for 10 minutes.

Ingredients	Dough
Flour	1.49 – 2.12 kg
Salt	29.8 – 42.4 g
Bread yeast	29.8 – 42.4 g
Water	745 – 1060 g

Fermentation: The dough was placed with moistened towels over the bowl or forms in environmental cabinets with a controlled climate at 25°C for in total 60 - 65 minutes. The time is divided into three fermentation steps.
Baking: The forms were placed in the preheated oven with steam injection and baked at target 210°C for 20-25 minutes.

Conclusion
Quantifiable residues were observed in the RACs and its processed fractions following use of the pesticide at maximum seasonal application rates and timings. However the processing factors calculated between three trials don't show concentration of fenpicoxamid and its metabolites after all processing steps.

A 2.1.5.2 Processing studies on a core set of representative processes

No new studies presented.

A 2.1.6 Magnitude of residues in representative succeeding crops

No new studies presented.

A 2.1.7 Other/Special Studies

A 2.1.7.1 Magnitude of residues in Pollen and Nectar

Comments of zRMS:	The residues of fenpicoxamid, prothioconazole and prothioconazole-desthio were determined in nectar, pollen and plants of winter oilseed rape after one application of GF-3307 under semi-field conditions. The study below was not evaluated by the zRMS. In our opinion, the data is not necessary to support the uses of GF-3307.

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
Acceptability:	Not evaluated, not required to support the uses of GF-3307 and finalise the evaluation for PPP.

~~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

Sampling Code	Timing	Treatment	Sample Code L20-01926-	Sample Type	Residues [mg/kg]		
					Fenpicoxamid	Prothioconazole	Prothioconazole-desthio
Trial S20-01926-01 (Germany)							
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

Sampling Code	Timing	Treatment	Sample Code L20-01926-	Sample Type	Residues [mg/kg]		
					Fenpicoxamid	Prothioconazole	Prothioconazole-desthio
Trial S20-01926-02 (Germany)							
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

A 2.2 Prothioconazole
A 2.2.1 Stability of residues
A 2.2.1.1 Stability of residues during storage of samples
A 2.2.1.1.1 Storage stability of residues in plant products

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 and

sprayed 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 or levels 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	
	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
Wheat	121	1.86, 1.57, 1.55 **(1.66)**	**103**	100
Forage	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
	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
Wheat	197	0.250, 0.237, 0.191 **(0.23)**	**98**	84
Grain	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
	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
Wheat	120	2.13, 2.15, 2.34 **(2.21)**	**114**	93
Straw	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.

A 2.2.1.1.2 Storage stability of residues in animal products

No new studies presented.

A 2.2.1.1.2.1 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 "*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 cereals.

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~~ Not validated
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).

A 2.2.1.1.2.2 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 "*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 cereals.

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~~ Not validated
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).

A 2.2.1.1.2.3 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 "*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 cereals.

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~~ Not validated
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).

A 2.2.2 Magnitude of residues in plants

A 2.2.2.1 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 cereals.

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~~ Not validated
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 G 2019	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

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

Table A-7. Fenpicoxamid

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Fenpicoxamid

LOQs (mg/kg) range from: 0.01 to: 0.80

Toxicological reference values

ADI (mg/kg bw/day):	0.05	ARfD (mg/kg bw):	1.8
Source of ADI:		Source of ARfD:	
Year of evaluation:		Year of evaluation:	

Input values

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
13%	DK child	6.73	7%	Rye	5%	Wheat	0.6%	Oat	1%	
10%	NL toddler	4.90	5%	Wheat	2%	Bananas	1%	Milk: Cattle	3%	
10%	GEMS/Food G06	4.77	9%	Wheat	0.1%	Barley	0.1%	Bananas	0.7%	
8%	IT toddler	4.17	8%	Wheat	0.2%	Bananas	0.0%	Other cereals	0.2%	
8%	DE child	4.03	5%	Wheat	1.0%	Rye	0.5%	Bananas	2%	
8%	GEMS/Food G08	3.99	5%	Wheat	1%	Barley	0.7%	Rye	2%	
8%	GEMS/Food G15	3.91	5%	Wheat	1%	Barley	0.3%	Rye	2%	
7%	GEMS/Food G07	3.56	5%	Wheat	1.0%	Barley	0.2%	Oat	2%	
7%	NL child	3.53	5%	Wheat	0.6%	Bananas	0.5%	Milk: Cattle	1%	
7%	FR child 3 15 yr	3.45	6%	Wheat	0.5%	Milk: Cattle	0.2%	Bananas	1%	
7%	RO general	3.40	6%	Wheat	0.2%	Milk: Cattle	0.1%	Potatoes	0.7%	
7%	GEMS/Food G10	3.34	5%	Wheat	0.9%	Barley	0.1%	Rye	2%	
7%	GEMS/Food G11	3.26	4%	Wheat	1%	Barley	0.2%	Milk: Cattle	2%	
6%	ES child	3.14	5%	Wheat	0.3%	Bananas	0.2%	Milk: Cattle	0.7%	
6%	UK toddler	2.98	5%	Wheat	0.4%	Milk: Cattle	0.3%	Bananas	0.9%	
5%	SE general	2.71	4%	Wheat	0.5%	Bananas	0.4%	Rye	0.7%	
5%	PT general	2.70	5%	Wheat	0.2%	Rye	0.1%	Potatoes	0.4%	
5%	IT adult	2.60	5%	Wheat	0.1%	Bananas	0.0%	Tomatoes	0.2%	
5%	UK infant	2.58	3%	Wheat	0.8%	Milk: Cattle	0.4%	Bananas	2%	
5%	FR toddler 2 3 yr	2.52	4%	Wheat	0.6%	Milk: Cattle	0.2%	Bananas	1%	
5%	DE general	2.36	2%	Wheat	0.8%	Barley	0.7%	Rye	2%	
4%	DE women 14-50 yr	2.21	3%	Wheat	0.6%	Rye	0.3%	Barley	1%	
4%	IE adult	2.04	3%	Wheat	0.3%	Oat	0.2%	Bananas	0.9%	
4%	ES adult	2.04	3%	Wheat	0.8%	Barley	0.1%	Bananas	1%	
4%	FI 3 yr	1.97	1%	Wheat	0.9%	Oat	0.8%	Rye	1%	
4%	NL general	1.80	2%	Wheat	0.5%	Barley	0.2%	Milk: Cattle	1%	
3%	FR adult	1.58	3%	Wheat	0.1%	Milk: Cattle	0.0%	Wine grapes	0.4%	
3%	LT adult	1.54	1%	Rye	1%	Wheat	0.1%	Oat	0.5%	
3%	FI 6 yr	1.49	1%	Wheat	0.7%	Rye	0.5%	Oat	0.8%	
3%	UK vegetarian	1.47	2%	Wheat	0.1%	Bananas	0.1%	Oat	0.4%	
2%	UK adult	1.22	2%	Wheat	0.1%	Bananas	0.1%	Milk: Cattle	0.3%	
2%	DK adult	1.20	1%	Wheat	0.6%	Rye	0.1%	Bananas	0.3%	
2%	FI adult	1.12	0.8%	Rye	0.6%	Coffee beans	0.4%	Wheat	0.9%	
2%	IE child	0.81	1%	Wheat	0.1%	Milk: Cattle	0.1%	Bananas	0.2%	
2%	FR infant	0.79	0.9%	Wheat	0.3%	Milk: Cattle	0.1%	Bananas	0.6%	
0.2%	PL general	0.12	0.1%	Potatoes	0.1%	Bananas	0.0%	Apples	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.

Table A-8. Prothioconazole-desthio

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Prothioconazole-desthio

LOQs (mg/kg) range from: 0.01 to: 0.50

Toxicological reference values

ADI (mg/kg bw/day):	0.01	ARfD (mg/kg bw):	0.01
Source of ADI:		Source of ARfD:	
Year of evaluation:		Year of evaluation:	

Input values

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

	Calculated exposure (% of ADI)	MS Diet	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)	40%	NL toddler	4.03	8%	Wheat	7%	Maize/corn	6%	Milk: Cattle	11%	
	35%	GEMS/Food G11	3.52	15%	Soyabeans	7%	Wheat	3%	Barley	3%	
	35%	GEMS/Food G10	3.46	13%	Soyabeans	8%	Wheat	2%	Barley	3%	
	34%	GEMS/Food G15	3.36	9%	Wheat	7%	Soyabeans	3%	Barley	3%	
	33%	GEMS/Food G07	3.32	8%	Wheat	7%	Soyabeans	2%	Barley	3%	
	33%	GEMS/Food G06	3.30	14%	Wheat	5%	Soyabeans	2%	Peas	3%	
	33%	GEMS/Food G08	3.28	8%	Wheat	8%	Soyabeans	4%	Barley	3%	
	24%	IE adult	2.40	6%	Peas	5%	Wheat	3%	Lentils	3%	
	23%	FR child 3 15 yr	2.33	9%	Wheat	4%	Lentils	2%	Milk: Cattle	5%	
	23%	NL child	2.26	8%	Wheat	2%	Milk: Cattle	1%	Sunflower seeds	6%	
	22%	DK child	2.24	9%	Wheat	6%	Rye	3%	Carrots	3%	
	22%	ES child	2.20	9%	Wheat	5%	Lentils	2%	Peas	3%	
	21%	RO general	2.15	10%	Wheat	3%	Sunflower seeds	3%	Head cabbages	3%	
	20%	DE child	1.99	8%	Wheat	2%	Carrots	2%	Milk: Cattle	6%	
	20%	UK infant	1.97	5%	Wheat	4%	Milk: Cattle	3%	Carrots	6%	
	19%	FR toddler 2 3 yr	1.85	6%	Wheat	3%	Milk: Cattle	2%	Lentils	5%	
	17%	UK toddler	1.66	8%	Wheat	2%	Milk: Cattle	1%	Carrots	4%	
	16%	IT toddler	1.60	13%	Wheat	0.7%	Lentils	0.4%	Carrots	1%	
	15%	PT general	1.50	8%	Wheat	1%	Carrots	1%	Soyabeans	2%	
	15%	SE general	1.47	6%	Wheat	2%	Carrots	1%	Milk: Cattle	3%	
	14%	ES adult	1.35	5%	Wheat	2%	Lentils	2%	Barley	2%	
	13%	NL general	1.29	4%	Wheat	1%	Barley	0.8%	Milk: Cattle	3%	
	12%	DE general	1.25	4%	Wheat	2%	Barley	1%	Milk: Cattle	3%	
	12%	DE women 14-50 yr	1.16	4%	Wheat	1%	Milk: Cattle	0.8%	Barley	3%	
	11%	FR adult	1.09	4%	Wheat	1%	Lentils	0.4%	Milk: Cattle	2%	
	10%	IT adult	1.04	8%	Wheat	0.4%	Lentils	0.3%	Carrots	0.8%	
	10%	FI 3 yr	0.97	2%	Wheat	2%	Carrots	0.9%	Potatoes	2%	
	9%	FR infant	0.90	2%	Carrots	2%	Milk: Cattle	2%	Wheat	3%	
	9%	UK vegetarian	0.85	4%	Wheat	0.8%	Lentils	0.6%	Peas	1%	
	8%	FI 6 yr	0.84	2%	Wheat	1%	Peas	1%	Carrots	2%	
	7%	FI adult	0.71	3%	Coffee beans	0.7%	Peas	0.7%	Rye	3%	
	7%	LT adult	0.70	2%	Wheat	1%	Rye	0.7%	Head cabbages	1%	
	7%	UK adult	0.68	3%	Wheat	0.4%	Carrots	0.3%	Milk: Cattle	1%	
	6%	DK adult	0.63	2%	Wheat	1.0%	Carrots	0.5%	Milk: Cattle	1%	
	4%	PL general	0.40	0.7%	Potatoes	0.7%	Head cabbages	0.6%	Carrots	1%	
	4%	IE child	0.38	2%	Wheat	0.4%	Milk: Cattle	0.3%	Carrots	0.7%	

A 3.2 IEDI calculations

TMDI does not exceed the ADI for fenpicoxamid or prothiconazole-desthio, therefore further refined assessments are not required.

A 3.3 IESTI calculations - Raw commodities

Table A-9. 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.
The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

Unprocessed commodities

Results for children				**Results for adults**			
No. of commodities for which ARfD/ADI is exceeded (IESTI):			---	No. of commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				**IESTI**			
Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.5%	Wheat	0.6 / 0.6	8.7	0.3%	Wheat	0.6 / 0.6	5.0
0.2%	Barley	0.8 / 0.8	4.5	0.2%	Barley	0.8 / 0.8	3.9
0.2%	Rye	0.6 / 0.6	3.8	0.2%	Rye	0.6 / 0.6	2.9
Expand/collapse list							
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)							

Table A-10. 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.
The calculation is based on the large portion of the most critical consumer group.

Show results of IESTI calculation only for crops with GAPs under assessment

Unprocessed commodities

Results for children				**Results for adults**			
No. of commodities for which ARfD/ADI is exceeded (IESTI):			---	No. of commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				**IESTI**			
Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
2%	Barley	0,2 / 0,04	0,22	2%	Barley	0,2 / 0,04	0,19
Expand/collapse list							
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)							

Acute risk assessment /children	Acute risk assessment / adults / general population	Acute risk assessment /children	Acute risk assessment / adults / general population
Details - acute risk assessment /children	Details - acute risk assessment/adults	Hide IESTI new calculations	Show IESTI new calculations

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

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

Show results of IESTI calculation only for crops with GAPs under assessment

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
3%	Wheat	0,1 / 0,02	0,29
1%	Rye	0,05 / 0,02	0,13

Expand/collapse list

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

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
2%	Wheat	0,1 / 0,02	0,17
1,0%	Rye	0,05 / 0,02	0,10

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

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
29%	Wheat	0,1 / 0,2	2,9

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

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

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
17%	Wheat	0,1 / 0,2	1,7
5%	Rye	0,05 / 0,1	0,49

A 3.4 IESTI calculations - Processed commodities

Table A-11. Fenpicoxamid:

Acute risk assessment /children	Acute risk assessment / adults / general population	Acute risk assessment /children	Acute risk assessment / adults / general population
Details - acute risk assessment /children	Details - acute risk assessment/adults	Hide IESTI new calculations	Show IESTI new calculations

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

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)
0,4%	Wheat / milling (flour)	0,6 / 0,6	7,3	0,1%	Wheat / bread/pizza	0,6 / 0,6	2,6
0,2%	Wheat / milling (wholemea	0,6 / 0,6	3,3	0,1%	Wheat / pasta	0,6 / 0,6	2,3
0,1%	Rye / boiled	0,6 / 0,6	2,2	0,1%	Wheat / bread	0,6 / 0,6	2,1
0,1%	Rye / milling (wholemeal)-	0,6 / 0,6	2,1	#NOMBRE!	#NOMBRE!	#NOMBRE!	#NOMBRE!

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)
0.2%	Barley / cooked	0.8 / 0.8	2.9	0.3%	Barley / beer	0.8 / 0.16	5.8
0.1%	Barley / milling (flour)	0.8 / 0.8	1.4				
Expand/collapse list							

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short term intake of residues of Fenpicoxamid is unlikely to present a public health risk.

For processed commodities, no exceedance of the ARfD/ADI was identified.

Table A-12. Prothioconazole-desthio

Processed commodities

Results for children				**Results for adults**			
No of processed commodities for which ARfD/ADI is exceeded (IESTI):			4	No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				**IESTI**			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
1%	Barley / cooked	0.2 / 0.04	0.15				
0.7%	Barley / milling (flour)	0.2 / 0.04	0.07	3%	Barley / beer	0.2 / 0.01	0.29

Conclusion:

No exceedance of the toxicological reference value was identified for unprocessed commodity

A short term intake of residues of prothioconazole-desthio is unlikely to present a public health risk

For processed commodities, no exceedance of the ARfD/ADI was identified.

Processed commodities

Results for children				**Results for adults**				**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):			---	No of processed commodities for which ARfD/ADI is exceeded (IESTI new):			---	No of processed commodities for which ARfD/ADI is exceeded (IESTI new):			---
IESTI				**IESTI**				**IESTI new**				**IESTI new**			
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)	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)
2%	Wheat / milling (flour)	0,1 / 0,02	0,24	0,9%	Wheat / bread/pizza	0,1 / 0,02	0,09	24%	Wheat / milling (flour)	0,1 / 0,2	2,4	9%	Wheat / bread/pizza	0,1 / 0,2	0,88
1%	Wheat / milling (wholemea	0,1 / 0,02	0,11	0,8%	Wheat / pasta	0,1 / 0,02	0,08	11%	Wheat / milling	0,1 / 0,2	1,1	8%	Wheat / pasta	0,1 / 0,2	0,76
0,7%	Rye / boiled	0,05 / 0,02	0,07	0,3%	Wheat / bread	0,1 / 0,02	0,03	4%	Rye / boiled	0,05 / 0,1	0,36	3%	Wheat / bread (wholemeal)	0,1 / 0,2	0,34
0,7%	Rye / milling (wholemeal)-I	0,05 / 0,02	0,07					4%	Rye / milling (wholemeal)-	0,05 / 0,1	0,35				

A 3.5 IESTI calculations-TDMs

1,2,4 Triazole

Show results of IESTI calculation only for crops with GAPs under assessment

Unprocessed commodities

Results for children				Results for adults			
No. of commodities for which ARfD/ADI is exceeded (IESTI):			---	No. of commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				**IESTI**			
Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0,3%	Barley	0 / 0,05	0,28	0,2%	Barley	0 / 0,05	0,24
Expand/collapse list							
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)							

Show results of IESTI calculation only for crops with GAPs under assessment

Unprocessed commodities

Results for children				Results for adults			
No. of commodities for which ARfD/ADI is exceeded (IESTI):			---	No. of commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				**IESTI**			
Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0,7%	Wheat	0 / 0,05	0,72	0,4%	Wheat	0 / 0,05	0,42
0,3%	Rye	0 / 0,05	0,32	0,2%	Rye	0 / 0,05	0,24

Triazole alanine and triazole lactic acid

Show results of IESTI calculation only for crops with GAPs under assessment

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
1%	Barley	0 / 0,64	3,6

Expand/collapse list

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

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
1%	Barley	0 / 0,64	3,1

Show results of IESTI calculation only for crops with GAPs under assessment

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
3%	Wheat	0 / 0,64	9,3
1%	Rye	0 / 0,64	4,1

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
2%	Wheat	0 / 0,64	5,4
1%	Rye	0 / 0,64	3,1

Triazole acetic acid (PRIMo rev.3.1)

Show results of IESTI calculation only for crops with GAPs under assessment

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0,4%	Barley	0 / 0,79	4,4

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0,4%	Barley	0 / 0,79	3,8

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

Show results of IESTI calculation only for crops with GAPs under assessment

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
1%	Wheat	0 / 0,79	11
0,5%	Rye	0 / 0,79	5,0

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0,7%	Wheat	0 / 0,79	6,6
0,4%	Rye	0 / 0,79	3,8