REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: GF-3308

Product name(s): Not yet defined

Chemical active substance:

XDE-777 (Fenpicoxamid), 50 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Corteva Agriscience

Submission date: May 2021

Finalisation date: February 2022 (initial Core Assessment)

August 2022 (final Core Assessment)

Version history

When	What
May 2021	New submission of GF-3308 in the Central Zone.
February 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~~.
August 2022	Final report (Core Assessment updated following the commenting period). Additional information/assessments included by the zRMS in the report in response to comments received from the cMS and the Applicant are highlighted in yellow. Information no longer relevant ~~is struck through and shaded~~.

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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 GF-3308 are presented in Table . They have been selected from the individual GAPs in the Central zone for wheat, rye, spelt and triticale. A list of all intended uses within the Central zone is given in Part B, Section 0.

The critical GAP proposed for GF-3308 results in a total maximum application rate of 1 x 100 g ai/ha with final application at BBCH 69 for Fenpicoxamid (XDE-777). This is less than the rate upon which the EU MRL is proposed (2 x 130 g ai/ha, final application also at BBCH 69).

Overall conclusion
An exceedance of the EFSA proposed MRL of 0.6 mg/kg for Fenpicoxamid on wheat, rye, spelt and triticale is not expected.
The chronic and the short-term intakes of Fenpicoxamid residues are unlikely to present a public health concern.
As far as consumer health protection is concerned, Poland, zRMS agrees with the authorization of the intended use(s).

Data gaps: None for GF-3308

However according to the EFSA Journal 2018;16(1):5146:
"*This is a list of data gaps identified during the peer review process, including those areas in which a study may have been made available during the peer review process but not considered for procedural reasons:*

- *Wheat processing residue trials for all processed commodities that undergoes in a heating step, representative of baking conditions (bread) conducted with sufficiently high residue levels in grain to allow determination of the magnitude of relevant identified metabolites X12019520, X12314005, X12335723, X12264475 (relevant for representative uses in wheat; submission date proposed by the applicant; see Section 3).*
- *Potential residue levels in pollen and bee products (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 3).”*

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**		
1-14	Winter wheat (TRZAW), Spring wheat (TRZAS), Durum wheat (TRZDU), Winter rye (SECCW), Spring rye (SECCS), Winter triticale (TTLWI), Spring triticale (TTLSO), Spelt (TRZSP)	CZ	GF-3308	F	SEPTTR, SEPTSP, PUCCRT, PUCCST, PUCCRE, RHYNSE	EC	50 g/L	Broadcast spraying	BBCH 30 to 69	1	-	2 L/ha	100-300 L/ha	100 g as/ha	PHI F **** (BBCH 69)	A

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
** Use also code numbers according to Annex I of Regulation (EU) No 396/2005
*** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
**** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

Explanation for Column 11 "Conclusion"

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

7.1.2 Summary of the evaluation

The preparation GF-3308 is composed of Fenpicoxamid (code = XDE-777).

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

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

7.1.2.1 Summary for Fenpicoxamid

Table 7.1-3: Summary for Fenpicoxamid

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?
1-14	Wheat, Rye, Triticale	Yes	Yes (min 8 trials per zone)	Yes (PHI F)	Yes	Yes	No	No

* Use number(s) in accordance with the list of all intended GAPs in Part B, **Uses 5 and 10 are covered by other uses**

Based on the metabolism studies, the proposed residue definition for enforcement and risk assessment in plants was proposed by EFSA to be fenpicoxamid (XDE-777) only, this residue definition covers all crop groups. In livestock commodities the residue definition for risk assessment and enforcement was derived as X12326349, expressed as parent. The residue definition is restricted to ruminants.

The effects of processing on the nature of active substance residues have been investigated. Data on effects of processing on the amount of residue have been submitted in the framework of the approval of fenpicoxamid.

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

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

No chronic and acute dietary risk has been identified for wheat, rye, spelt and triticale. The use of GF-3308 on wheat, rye, spelt and triticale is therefore acceptable.

7.1.2.2 Summary for GF-3308

Table 7.1-4: Information on GF-3308 (KCA 6.8)

Crop	PHI for GF-3308 proposed by applicant	PHI/ Withholding period* sufficiently supported for Fenpicoxamid	PHI for GF-3308 proposed by zRMS	zRMS Comments (if different PHI proposed)
Wheat, Rye, Triticale	BBCH 69 - F**	Yes	BBCH 69 - 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 7.1-5: Waiting periods before planting succeeding crops

Waiting period before planting succeeding crops		**Overall waiting period proposed by zRMS for GF-3308**
Crop group	**Led by fenpicoxamid**	
Leafy vegetables	Not Required	Not Required
Root vegetables	Not Required	Not Required
Cereal	Not Required	Not Required

NR: not relevant

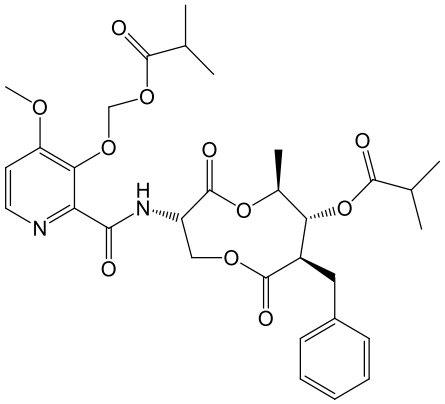
Assessment

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

7.2 Fenpicoxamid

General data on Fenpicoxamid 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/Corteva Agriscience
Rapporteur Member State (RMS)	UK
Approval status	Approved (Commission Implementing Regulation (EU) No 2018/1265
Restriction (e.g. is restricted to use as "...")	N/A
Review Report	20 July 2018 (SANTE/10319/2018 Rev. 2)
Current MRL regulation	COMMISSION REGULATION (EU) 2019/50 of 11 January 2019
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	31 January 2018 (EFSA Journal 2018;16(1):5146)
EFSA Journal: conclusion on article 12	New active substance
Current MRL applications on intended uses	N/A

7.2.1 Stability of Residues (KCA 6.1)

7.2.1.1 Stability of residues during storage of samples

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 supported the stability of the relevant residues in crop, processed fractions, and animal tissues under frozen conditions prior to sample 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.

7.2.2 Stability of residues in sample extracts (KCA 6.1)

Available data
In residue studies for the fenpicoxamid and its metabolites, batch recoveries were carried out in parallel with the analytical batches for the crop and animal residue studies. 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.

7.2.3 Nature of residues in plants, livestock and processed commodities

7.2.3.1 Nature of residue in primary crops (KCA 6.2.1)

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

Table 7.2-3: Summary of plant metabolism studies

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

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

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

Summary of plant metabolism studies reported in the EU

The results from the plant metabolism studies showed that fenpicoxamid 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-3308.

7.2.3.2 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 crop 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 plant 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-3308.

7.2.3.3 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, fenpicoxamid 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-3308.

7.2.3.4 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 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. However, in a Magnitude of Residue processing study, the only instance in which one of the hydrolysis degradates was found at ≥0.01 mg/kg was for X12264475 in gluten.
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)

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

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

Table 7.2-7: Summary of animal metabolism studies

Group	**Species**	**Label position**	**No of animal**	**Application details**		**Sample details**		**Reference**
				Rate ~~(mg/kg bw/d)~~	**Duration (days)**	**Commodity**	**Time of sampling**	
EU data								
Lactating ruminants	Goat	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 (xxx, 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 fenpicoxamid 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-3308.

7.2.3.6 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

7.2.4 Magnitude of residues in plants (KCA 6.3)

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

The EFSA proposed MRL for fenpicoxamid (XDE-777) in wheat, rye and triticale is based on a critical GAP 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-3308 proposed in this submission.

The GAP proposed for GF-3308 results in a total maximum application rate for fenpicoxamid that is lower than the rate upon which the EU MRL is based (1 x 100 g ai/ha vs 2 x 130 g ai/ha). Both GAPs (GAP for GF-3308 vs GAP for representative use for EU approval) foresee the final application no later than BBCH 69. Consequently, the existing proposed EU MRL of 0.60 mg/kg for fenpicoxamid in wheat and rye covers the GAP proposed for GF-3308 uses in this submission . Intended uses of GF-3308 will not lead to residues exceeding the proposed EU MRL.

New magnitude of residue studies conducted with GF-3308 and other 3 Emulsifiable Concentrate formulations comparable to GF-3308 are submitted in the framework of this application (Study S16-03318, Studies S15-02628, S14-01569, and S14-01568 & S15-02629, conducted on GF-3308, GF-3309, GF-3312, and GF-3307, respectively). These studies are summarized in the Table below and the detailed assessment is presented in Appendix 2. . Even being a higher total rate than the proposed cGAP for GF-3308, results show that this GAP will not lead to residues exceeding the proposed EU MRL.

GF-3312, GF-3309 and GF-3307 are all EC formulations and are similar to GF-3308. These formulations have the same coformulants and a fenpicoxamid content similar to GF-3308. Detailed comparison between GF-3312, GF-3309, GF-3307 and GF-3308 is provided in dRR Part C.

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 7.2-1.

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

Table 7.2-9: Summary of EU reported and new data supporting the intended uses of GF-3308 and conformity to existing MRL

Commodity	Source	Residue zone	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Wheat grain	EFSA 2018*	N-EU (16)	Trials GAP: 2 x 130 g as/ha, Appl. interval 14 d, 2nd appl. at BBCH 69, outdoor E = RA: 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 (a)	0.60	Yes
	New Trials on GF-3312 (Study S14-01569), GF-3309 (Study S15-02628) and GF-3307 (Study S14-01568 and S15-02629) (b)	N-EU (10)	Trials GAP: 2 x 100 g as/ha, Appl. interval 14 d, 2nd appl. at BBCH 69, outdoor E = RA: 2x<0.01; 2 x 0.011; 2 x 0.014; 0.015; 0.021; 0.029; 0.064	0.014	0.064	0.09	0.60	Yes
	New Trials on GF-3308 (Study S16-03318/ DAS 160393)	N-EU (4)	Trials GAP: 1 x 75 g as/ha + 1 x 150 g as/ha, Appl. interval 14 d, 2nd appl. at BBCH 69, outdoor E: 2x <0.01, 0.066, 0.107 RA: 2x <0.01, 0.066, 0.107	E: 0.04 RA: 0.04	E: 0.11 RA: 0.11	E: 0.30 RA: 0.30	E: 0.60 RA: 0.60	Yes
	EFSA 2018	S-EU (16)	Trials GAP: 2 x 130 g as/ha, Appl. interval 14 d, 2nd appl. at BBCH 69, outdoor E = RA: 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	0.60	Yes
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 E = RA: 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	6.32	15.94	-	-	-
	New Trials on GF-3312 (Study S14-01569), GF-3309 (Study S15-02628) and GF-3307, (Study S14-01568 and S15-02629)	N-EU (10)	Trials GAP: 2 x 100 g as/ha, Appl. interval 14 d, 2nd appl. at BBCH 69, outdoor E = RA: 0.80; 0.96; 1.33; 1.51; 1.52; 1.92; 2.62; 2.64; 4.05; 5.72	1.72	5.72	-	-	-

Commodity	Source	Residue zone	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
	New Trials on GF-3308 (Study S16-03318/ DAS 160393)	N-EU (4)	Trials GAP: 1 x 75 g as/ha + 1 x 150 g as/ha, Appl. interval 14 d, 2nd appl. at BBCH 69, outdoor E = RA: 0.537, 0.720, 1.702, 10.364	0.90	10.36	-	-	-
	EFSA 2018	S-EU (16)	Trials GAP: 2 x 130 g as/ha, Appl. interval 14 d, 2nd appl. at BBCH 69, outdoor E = RA: 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	-	-	-

* Source of EU MRL: EFSA Journal 2018;16(1):5146 [27 pp.], Reg. (EU) 2019/50

(a) According to EFSA 2018 document, wheat grain MRL in the NEU was set as 0.4 mg/kg due to the inputs from Risk assessment considering the previous residue definition (sum of fenpicoxamid and X642188, expressed as fenpicoxamid equivalents). The residue definition proposed for enforcement and risk assessment is now fenpicoxamid only, thus the MRL proposed in NEU for wheat grain is 0.3 mg/kg.

(b) 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).

7.2.4.2 Conclusion on the magnitude of residues in plants

According to the available data, the intended use on wheat 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-3308, while the EFSA proposed[2] MRL for Fenpicoxamid in wheat, rye and triticale was based on a SC formulaton. 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 MRL will occur and the intended uses are considered acceptable on wheat and triticale.

According to appendix D of EU guidelines, extrapolation to rye (0500070) is possible with 8 trials on wheat (0500090), which is the case here. So the uses are also considered acceptable on rye.

zRMS comments:

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

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 5 new magnitude of residue studies conducted with GF-3308 and other 3 Emulsifiable Concentrate formulations comparable to GF-3308 were submitted in the framework of this application (Study S16-03318, Studies S15-02628, S14-01569, and S14-01568 & S15-02629, conducted on GF-3308, GF-3309, GF-3312, and GF-3307, respectively) with a higher total rate than the proposed cGAP for GF-3308.
Summary is presented below.

Wheat, rye, triticale and spelt

Table 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)	2	130 g XDE-777/ha	14 days	BBCH 69	N/A
Intended cGAP	1	100 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 100 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 100 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 100 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 100 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).

5. Report No. S16-3318, DAS Study ID 160393
Four N-EU trials were conducted in accordance with the following GAP: 1 x 75 + 1 x 150 g a.s. /ha, instead of 1 x 100 g a.s./ha; application interval - 14 days, 2nd application. at BBCH 69, outdoor.
Residues of XDE-777 in grain taken at normal commercial harvest ranged from ND (not detected, <0.003 mg/kg) to 0.107 mg/kg (2x <0.01 mg/kg, 0.066 mg/kg, 0.107 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 7.2-9).
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 100 g a.s./ha; application interval - 14 days, 2nd application. at BBCH 65-71, outdoor. This can be considered the worst case.

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 are considered acceptable.

7.2.5 Magnitude of residues in livestock

7.2.5.1 Dietary burden calculation

Available data – EFSA, 2018
The use under consideration can be fed to livestock. Residue values used for dietary burden calculation are reported in table B.7.2-10. Processing factors on bran (wheat milled by-products) and wheat gluten meal have been used according to the studies submitted, in order to correspond to the feed items according to the EFSA 2017 calculator spread sheet.

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

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Residue definition: fenpicoxamid only				

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
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)	-	-

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

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

Table 7.2-11: Results of the dietary burden calculation

Relevant groups	Dietary burden expressed in				Most critical diet (a)	Most critical commodity (b)		Trigger exceeded (Yes/No)
	mg/kg bw per day		mg/kg DM					0.004
	Median	Maximum	Median	Maximum				mg/kg bw
Cattle (all diets)	0.159	0.159	4.12	4.12	Dairy cattle	Wheat	straw	**Yes**
Cattle (dairy only)	0.159	0.159	4.12	4.12	Dairy cattle	Wheat	straw	**Yes**
Sheep (all diets)	0.348	0.348	8.19	8.19	Lamb	Wheat	straw	**Yes**
Sheep (ewe only)	0.273	0.273	8.19	8.19	Ram/Ewe	Wheat	straw	**Yes**
Swine (all diets)	0.003	0.003	0.09	0.09	Swine (finishing)	Distiller's grain	dried	No
Poultry (all diets)	0.143	0.143	2.09	2.09	Poultry layer	Wheat	straw	**Yes**
Poultry (layer only)	0.143	0.143	2.09	2.09	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 intented uses for GF-3308 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 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.

7.2.5.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Available data
No new data are submitted in the framework of this application. The intended uses are covered by the representative use(s) of fenpicoxamide (EFSA, 2018).

Poultry:
Dietary burden for fenpicoxamid in poultry based on available residue data in wheat, rye and triticale cereal grain, straw, and bran, resulted in estimated values of 0.143 mg/kg bw/d / 2.09 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 and bran resulted in estimated values of 0.159 mg/kg bw/d / 4.12 mg/kg DM for all diets and dairy only; 0.348 mg/kg bw/d / 8.19 mg/kg DM for sheep all diets and 0.273 mg/kg bw/d / 8.19 mg/kg DM for sheep ewe only.
The trigger value (0.004 mg/kg bw/day) for ruminant is exceeded and a feeding study (Rawle, 2013, 130949) was perfomed 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 7.2-12: Overview of the values derived from livestock feeding studies

Animal commodity	**Residues at the closet feeding level** (mg/kg)		**Estimated value at 1N level**		**MRL proposal** (mg/kg)	**CF**	**STMR** (mg/kg)	**HR** (mg/kg)
	Mean	Highest	STMRMo (mg/kg)	HRMo (mg/kg)				
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.	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).
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 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.

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

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, Tandy, 2014, 120435) and 0.06 mg/kg (analysed for all hydrolysis metabolites X12019520, X12314005, X12335723 and X12264475 – Study S14-02186, Eversfield, 2015, 140696). 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-3308 is less intensive than the GAP for the EU representative use (1 x 100 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-3308 and presented in §7.2.3 (new trials on GF-3312, GF-3309, and GF-3307 at 2 x 100 g a.s./ha – Study S14-01569, S15-02628, S14-01568 and S15-02629) the STMR for fenpicoxamid is 0.01 mg/kg and the highest residue is 0.03 mg/kg. In the processing study S14-02186 the fenpicoxamid residue levels in the grain samples collected just before processing began (substrate "Grain, not cleaned (from the processor)") ranged 0.034-0.05 mg/kg therefore this processing study can be used to support this application.

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, <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

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

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-3308 and no further data are needed on these metabolites**.

Processed commodity	Number of studies	Median PF *	Median CF **	Comments	Reference
EFSA, 2018					
Enforcement residue definition – Fenpicoxamid (XDE-777)					
Total bran	12	0.84	-	-	EFSA, 2018
Refined flour	12	0.315	-	-	EFSA, 2018
Wholemeal flour	12	0.455	-	-	EFSA, 2018

Available data – United Kingdom, 2017
No new data are submitted in the framework of this application.

7.2.6.1 Available data for all crops under consideration

Table 7.2-13: Overview of the available processing studies

Processed commodity	Number of studies	Median PF *	Median CF **	Comments	Reference
EU data					
Enforcement residue definition – Fenpicoxamid (XDE-777)					
Fine bran	8	0.290	-	-	United Kingdom, 2017
Coarse bran	8	1.290	-	-	United Kingdom, 2017
Total bran	8	0.870	-	-	United Kingdom, 2017
Refined flour (Type 550)	8	0.285	-	-	United Kingdom, 2017
White bread	8	0.130	-	-	United Kingdom, 2017
Wholemeal flour	8	0.405	-	-	United Kingdom, 2017
Wholemeal bread	8	0.195	-	-	United Kingdom, 2017
Dried starch	8	0.045	-	-	United Kingdom, 2017
Dried gluten	8	0.170	-	-	United Kingdom, 2017
Gluten feed meal	8	0.115	-	-	United Kingdom, 2017
Wheat germ	8	0.165	-	-	United Kingdom, 2017
EU data					
Risk assessment residue definition - Total Fenpicoxamid (XDE-777) Equivalents (the sum of fenpicoxamid and X642188, expressed as fenpicoxamid equivalents)					
Fine bran	8	0.305	-	-	United Kingdom, 2017
Coarse bran	8	1.365	-	-	United Kingdom, 2017
Total bran	8	0.915	-	-	United Kingdom, 2017
Refined flour (Type 550)	8	0.315	-	-	United Kingdom, 2017
White bread	8	0.175	-	-	United Kingdom, 2017

Processed commodity	Number of studies	Median PF *	Median CF **	Comments	Reference
Wholemeal flour	8	0.455	-	-	United Kingdom, 2017
Wholemeal bread	8	0.245	-	-	United Kingdom, 2017
Dried starch	8	0.090	-	-	United Kingdom, 2017
Dried gluten	8	0.265	-	-	United Kingdom, 2017
Gluten feed meal	8	0.175	-	-	United Kingdom, 2017
Wheat germ	8	0.470	-	-	United Kingdom, 2017

* The median processing factor is obtained by calculating the median of the individual processing factors of each processing study.

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

7.2.6.2 Conclusion on processing studies

The proposed uses for GF-3308 are covered by sufficient processing studies and no further data are required for this application. Processing factors derived during the peer review can be used for risk assessment and no further data are demed necessary for this dossier, considering the less critical GAP situation.

zRMS comments:
Information given by the Applicant is sufficient and accepted. The intended uses is less critical than the representative use (application rate of 100 g a.s./ha instead of 130 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-3308 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 100 g a.s./ha is 0.06 mg/kg, which is covered by the available processing data. Therefore, the derived processing factors can be used and no further data are demed necessary.

7.2.7 Magnitude of residues in representative succeeding crops

Considering available data dealing with nature of residues (see 7.2.3.2), 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.

7.2.7.1 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 requested.

7.2.8 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-3308. Therefore, other special studies are not needed.

Effect on the residue level in pollen and bee product

Wheat, Rye and Triticale are primarily self-pollinated plants and are not bee-attractive crops. Therefore, the proposed use of GF-3308 in these crops is expected to have little potential for contributing residues to bee products. Additionally, there are currently no final, approved test guidelines for assessing the magnitude of residues in pollen and bee products.

zRMS comments:
Information given by the Applicant is sufficient.
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 reasonabily 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)."*
In our opinion no further data is necessary to suport the uses of GF-3308.

7.2.9 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).

7.2.9.1 Input values for the consumer risk assessment

Table 7.2-14: 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: Fenpicoxamid (XDE-777)				
All commodities	MRL	Regulation (EU) 2019/50	-	-
Wheat, Rye, Triticale			0.064	HR current dossier

As results of the PRIMo rev. 3.1 calculations using MRL for all commodities (=TMDI) do not result in chronic exposure above 100% of the ADI, no refined data is deemed necessary. No acute exposure above 100% ARfD for the intended uses on wheat and rye have been observed.

7.2.9.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.2-15: Consumer risk assessment

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-3308 do not represent unacceptable acute and chronic risks for the consumer.

Evaluator comment:
Information given by the Applicant is sufficient.
The calculation of the TMDI using EFSA model (version 3.1) and MRLs 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 References

European Commission (EC), 2017. Appendix D. Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. 7525/VI/95-rev.10.3, 13 June 2017

EC, 2018. Final Review report for the active substance fenpicoxamid finalised in the Standing Com-mittee on Plants, Animals, Food and Feed at its meeting on 20 July 2018 in view of the approval of fenpicoxamid in accordance with Regulation (EC) No 1107/2009. SANTE/10319/2018 Rev. 2, 20 July 2018

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

EFSA (European Food Safety Authority), 2018. Conclusion on the Peer Review of the Pesticide Risk Assessment of the Active Substance Fenpicoxamid. EFSA Journal 2018;16(1):5146.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	Vertebrate study Y/N	Owner
KCA 6.3.1/01	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/Corteva Agriscience
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/Corteva Agriscience
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/Corteva Agriscience
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/Corteva Agriscience
KCA 6.3.1/05	White, T.	2017	Ddetermination of Residues of Fenpicoxamid (XDE-777) after Two Application of Gf-3308 to Spring And Winter Wheat, at 4 Sites in Northern Europe and 4 sites in Southern Europe, 2016. Report No: S16-03318, DAS Study ID 160393 Eurofins Agroscience Services Ltd GLP, Unpublished	N	DAS/Corteva Agriscience

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/Corteva Agriscience
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/Corteva Agriscience
KCA 6.1/4	Ma, M.	2016	Frozen Storage Stability of XDE-777 and Its Metabolites in Soil – Final Report DAS Report No. 141045 Dow AgroSciences LLC GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS/Corteva Agriscience
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/Corteva Agriscience
KCA 6.2.1/2	Wu, S	2013a	A Nature of the Residue Study with [^{14}C]-XDE-777 Applied to Tomatoes Symbiotice Research, LLC Research For Hire (RFH) DAS Report No.: 121003 GLP/GEP (Y/N): Y Published (Y/N): N	N	DAS/Corteva Agriscience
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	N	DAS/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
			GLP/GEP (Y/N): Y Published (Y/N): N		
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/Corteva Agriscience
KCA 6.2.3	xxx	2013	A NATURE OF THE RESIDUE STUDY IN THE RUMINANT WITH [14C]-XR-777 xxx DAS Report No.: 110766 GLP/GEP (Y/N): Y Published (Y/N): N	Y	DAS/Corteva Agriscience
KCA 6.3.1/06	Oxspring, S	2013	DETERMINATION OF RESIDUES OF XDE-777 AFTER TWO APPLICATI ONS OF GF-2807 IN WINTER WHEAT AND SPRING WHEAT AT 6 SITES IN NORTHERN EUROPE AND 6 SITES IN SOUTHERN EUROPE 2011 Eurofins Agroscience Services Ltd DAS Report No.: 110414 GLP/GEP (Y/N): Y Published (Y/N): N	N	DAS/Corteva Agriscience
KCA 6.3.1/07	Eversfield, S	2013	DETERMINATION OF RESIDUES OF XDE-777 AFTER TWO APPLICATI ONS OF GF-2925 IN WINTER WHEAT, SPRING WHEAT AND DURUM WHEAT AT 6 SITES IN NORTHERN EUROPE AND 6 SITES IN SOUTHERN EUROPE IN 2012 Eurofins Agroscience Services Ltd DASReport No.: 120434 GLP/GEP (Y/N): Y Published (Y/N): N	N	DAS/Corteva Agriscience
KCA 6.3.1/08	Eversfield, S	2015	DETERMINATION OF RESIDUES OF XDE-777 AFTER TWO APPLICATI ONS OF GF-2925 IN WINTER WHEAT AND SPRING WHEAT AT 4 SITES IN NORTHERN EUROPE AND 4 SITES IN SOUTHERN EUROPE IN 2014 Eurofins Agroscience Services Ltd DAS Report No.: 140650 GLP/GEP (Y/N): Y Published (Y/N): N	N	DAS/Corteva Agriscience
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.	N	DAS/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.: 130949 GLP/GEP (Y/N): Y Published (Y/N): N		
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/Corteva Agriscience
KCA 6.5.3/1	~~Eversfield, S~~ Tandy, R	2014	Determination of Residues of XDE-777 in Grain and Processed Products After Two Applications of GF-2925 in Winter Wheat on 2 Sites in Northern Europe and 2 Sites in Southern Europe in 2012 Eurofins Agroscience Services Ltd DAS Report No.: 120435 GLP/GEP (Y/N): Y Published (Y/N): N	N	DAS/Corteva Agriscience
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 GLP/GEP (Y/N): Y Published (Y/N): N	N	DAS/Corteva Agriscience
KCA 6.5.3/2	Eversfield, S.	2015	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 Eurofins Agroscience Services Ltd DAS Report No.: 140696 GLP/GEP (Y/N): Y Published (Y/N): N	N	DAS/Corteva Agriscience
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/Corteva Agriscience

List of data submitted by the applicant and not relied on

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

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

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

Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1 Fenpicoxamid

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)	2	130 g XDE-777/ha	14 days	BBCH 69	N/A
Intended cGAP (1-10)	1	100 g XDE-777/ha	NA	BBCH 69	F

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

A 2.1.3.1.1 Study S14-01568 & S14-01569

Comments of zRMS:	Study Number: S14-01568, DAS Study ID 140649 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. 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 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. Recoveries in wheat straw averaged 109.4% for XDE-777 and 98.3% for X642188. The maximum period of frozen storage for XDE-777 and X642188 were 247 daya and 246 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 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 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. Some devations 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 ~~were 527 days and 527 days respectively~~ 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 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 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 devations 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 7.2-9).**

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 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,	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 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

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 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 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

	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

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

N° Trial		1	2	3	4	5	6	7	8
North/South/Indoor		N	N	N	N	S	S	S	N
Decline (D)/Harvest (H) trial?		D	D	H	H	D	D	H	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 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

N° Trial		1	2	3	4	5	6	7	8
North/South/Indoor		N	N	N	~~N~~S	S	S	S	~~N~~ S
Decline (D)/Harvest (H) trial?		D	D	H	H	D	D	H	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 **<u><0.01</u>** **<u>1.586</u>**	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 **<u><0.01</u>** **<u>1.250</u>** <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)	

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			
S14-01569-01/ 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 Straw	0.347 1.482 0.400 0.281 0.220 <0.01 0.729 **<u><0.01</u>** 0.879 <0.01 **<u>1.160</u>** ND 0.972	0.016 0.084 0.016 <0.01 <0.01 ND 0.065 ND 0.049 ND 0.035 ND 0.013	-0 0 8 14 28 43 43 50* 50* 57 57 64 64	Plot2 : formulation GF-3312 (EC)	Cf previous line
			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)

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			
S14-01568-02/ 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 Straw	0.152 1.171 0.731 0.448 0.416 0.021 2.094 <0.01 **1.729** **0.012** 1.457 <0.01 1.312	0.012 0.147 0.057 0.060 0.067 ND 0.109 ND 0.094 ND 0.072 ND 0.085	-0 0 7 14 28 28 28 35* 35* 42 42 49 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			
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 BBCH 69	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				**<0.01** **2.038**	ND 0.065	45* 45*	Plot 3: GF-3310 (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			
S14-01569-03/ DE73 7FW, Twyford, Derbyshire UK/NEU/2014	Winter wheat / KWS Santiago	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)	
			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)

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			
S14-01568-04/ 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 BBCH 69	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			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

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			
			33.4 33.3	292 310	33.4 33.3			Whole plant Whole plant Whole plant Whole plant Whole plant Grain Straw Grain Straw Grain Straw (032A) Straw (032R1) Grain Straw (038A) Straw (038R1)	0.506 1.868 0.874 0.524 0.502 0.018 1.815 **0.035** **1.683** 0.010 0.711 <0.01 ND 0.056 ND	0.015 0.079 0.019 0.010 (0.006) ND 0.015 ND 0.013 ND 0.053 ND ND ND ND	-0 0 6 14 28 49 49 55* 55* 62 62 62 67 67 67	Plot 3: GF-3310 (EC)	See previous line
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

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			
			103.0	309	33.3			Whole plant	1.026	0.022	-0	Plot3 : formulation GF-2925 (SC)	(not retained, SC formulation)
			97.0	291	33.3			Whole plant	1.995	0.046	0		
								Whole plant	1.225	0.030	6		
								Whole plant	1.062	0.029	14		
								Whole plant	0.766	0.015	28		
								Grain	0.027	ND	49		
								Straw	2.563	0.035	49		
								Grain	**0.040**	ND	55*		
								Straw	**1.409**	0.020	55*		
								Grain	0.012	ND	62		
								Straw	0.425	<0.01	62		
								Grain	ND	ND	67		
								Straw	0.143	<0.01	67		

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			
S14-01568-06/ 44492 Fonfría, Teruel, Spain/ SEU/2014	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 BBCH 69	Whole plant Whole plant Whole plant Whole plant Whole plant Grain Straw Grain Straw Grain Straw Grain Straw	0.815 2.822 2.488 1.878 0.989 0.017 5.147 0.021 **5.692** **0.027** 4.077 0.014 5.089	0.031 0.073 0.077 0.029 0.020 ND 0.051 ND 0.063 ND 0.035 ND 0.040	-0 0 6 14 26 53 53 60* 60* 67 67 74 74	Plot 2: GF-3307 (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 0.020 mg/kg XDE-777 was found.	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			
			96.1 101.9	288 306	33.4 33.3			Whole plant Whole plant	0.874 2.444	0.021 0.075	-0 0	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 0.020 mg/kg XDE-777 was found.	See previous line
								Whole plant	2.227	0.059	6		
								Whole plant	1.598	0.025	14		
								Whole plant	0.772	0.010	26		
								Grain	0.012	ND	53		
								Straw	3.874	0.035	53		
								Grain	**0.017**	ND	60*		
								Straw	**4.903**	0.042	60*		
								Grain	0.016	ND	67		
								Straw	4.493	0.035	67		
								Grain	0.015	ND	74		
								Straw	3.267	0.033	74		

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			
S14-01569-06/ 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

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			
			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/ 66750, Saint-Cyprien, Pyrénées-Orientales France/ SEU/ 2014	Winter wheat / Babylone	30 Nov 2013 N/A	94.2 100.0	188 200	50.1 50.0	23 Apr 14 06 May 14	BBCH 61 BBCH 69	Grain Straw	**<u>0.066</u>** **<u>11.967</u>**	ND 0.125	36* 36*	Plot 2: GF-3307 (EC)	Grain: 0.06 Straw: 8.31
			50.0 50.1	190 208	95.0 104.2			Grain Straw	**<u>0.051</u>** **<u>8.308</u>**	ND (0.004)	36* 36*	Plot 3: GF-3310 (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			
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.	

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			
			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)
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 BBCH 69	Grain Straw	**<u>0.020</u>** **<u>7.095</u>**	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			Grain Straw	**<u>0.022</u>** **<u>5.811</u>**	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	**<u>0.013</u>** **<u>3.583</u>**	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.

A 2.1.3.1.2 Studies S15-02628 & S15-02629

Comments of zRMS:	Study Number: S15-02628; DAS Study ID 150650 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 devations have been identified, but do not affect the study. The study is acceptable. Report No. S15-02629, DAS Study ID 150649 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. Recoveries in wheat whole plant averaged 97% for XDE-777 and 94% for X642188. Recoveries in wheat grain averaged 104% for XDE-777 and 109% for X642188. Recoveries in wheat straw averaged 110% for XDE-777 and 110% for X642188. The maximum period of frozen storage for XDE-777 and X642188 were 204 days and 204 days respectively. With one exception, analyte residues were not detected above the analytical method LOQ in untreated samples. The exception is specimens L15-02629-01-011A where a residue of XDE-777 at 0.016 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 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). 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 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. Some devations have been identified, but do not affect the study. The study is acceptable. **Remark:** **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).**

Reference:	KCA 6.3.1/01	KCA 6.3.1/04
Report	Determination of Residues Of XDE-777	Determination of Residues of XDE-777 and

	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	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. 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	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 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.

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 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%

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 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.

	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	
GLP:	Yes	Yes
Acceptability:	Yes	Yes

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

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.

Table A 3: Summary of the study S15-02628 and S15-02629 trials on GF-3309 and GF-3307 – 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

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			
S15-02629-05/ 71290 Simandre, Saône-et-Loire, France/ ~~SEU~~NEU/2015	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 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).	

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			
S15-02628-10/ 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 **0.013** 0.892 <0.01 1.193 0.004 0.722 0.006 **1.265**	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/ SEU/2015	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 Grain Straw Grain Straw Grain Straw Grain Straw	0.872 2.548 0.448 0.682 0.308 **0.031** 0.979 <0.01 1.579 <0.01 1.75 0.02 **4.728**	0.024 0.089 0.028 0.023 0.017 ND 0.05 ND 0.047 ND 0.026 ND 0.084	-0 0 7 14 28 33 33 40* 40* 47 47 54 54	There were no residues above the LOQ 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

A 2.1.3.1.3 Study S16-3318

Comments of zRMS:	The magnitude of residues of XDE-777 in winter and spring wheat was determined following two post emergent broadcast applications of GF-3308 fungicide to wheat. To determine maximum XDE-777 residue levels in wheat, field trials were established in which two postemergent foliar applications of GF-3308, an emulsifiable concentrate (EC) formulation containing XDE-777 at a nominal concentration of 50 g /L, were applied in a nominal 14-day interval (actual interval ranged from 14 to 15 days) between applications and the last application at BBCH growth stage 69. Trials were conducted at 8 sites: 2 in Hungry (S16-03318-01/-03), 2 in the UK (S16-03318-02/-04), 1 in Greece (S16-03318-05), 1 in Spain (S16-03318-06), 1 in Bulgaria (S16-03318-07) and 1 in Southern France (S16-03318-08). Each site had a control plot and a treated plot. Two applications of GF-3308 were applied at target rates of 1.5 L product/ha (75 g ai/ha XDE-777) and 3.0 L product/ha (150 g ai/ha XDE-777) to plot 2, for a seasonal total of 4.5 L product/ha. At the four harvest trials, grain and straw specimens were taken at BBCH growth stage 89-99, 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), 6/7, 13/14 and 26/28/29 days after the final applications to plot 2. Grain and straw specimens were taken at normal commercial harvest (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 108% for XDE-777 and 107% for X642188, recoveries in wheat grain averaged 103% for XDE-777 and 98% for X642188 and recoveries in wheat straw averaged 85% for XDE-777 and 86% for X642188. The maximum period of frozen storage for XDE-777 and X642188 were 236 days, 170 days and 171 days respectively. No analyte residues above the analytical method LOD where detected in any of the untreated samples. 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 0.107 mg/kg. Residues of X642188 in grain taken at normal commercial harvest for plot / treatment 2 ranged from ND (not detected, <0.003 mg/kg) to <0.01 (0.0061). Residues of XDE-777 in straw taken at normal commercial harvest for plot / treatment 2 ranged from 0.537 to 10.364 mg/kg. Residues of X642188 in straw taken at normal commercial harvest for plot / treatment 2 ranged from 0.013 to 0.246 mg/kg. The study is acceptable.

Reference:	KCA 6.3.1/05
Report	Determination of Residues of Fenpicoxamid (XDE-777) After Two Application of GF-3308 to Spring and Winter Wheat, at 4 Sites in Northern Europe and 4 Sites in Southern Europe, 2016. S. Eversfield, 2017, Report No. S16-3318, DAS Study ID 160393
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
Deviations:	No
GLP:	Yes

Acceptability: Yes

Summary of global information on study 1

Comparative trials (between formulations, with and adjuvant/safener/synergist)	N
Number of applications	2
Dose (g as/ha)	Appl1: 75 g a.s./ha; Appl2: 150 g a.s./ha
Mode of application	Foliar spray
PHI (days) and/or growth stage (BBCH)	BBCH 69; PHI: 35-54 days
Analytical method (Code +Type)	S12-01537 / Dow AgroSciences study code 120615 LC-MS/MS
LoQ (mg/kg)	0.01 mg/kg

Summary of the study 1 trials

N° Trial		1	2	3	4	5	6	7	8
North/South/Indoor		N	N	N	N	S	S	S	S
Decline (D)/Harvest (H) trial?		D	D	H	H	D	D	H	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		N[(a)]							
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	236							
	Extract	16 (frozen); 3 (refrigerated)[(b)]							
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		N	N	N	N	N	N	N	N

(a): the trials were conducted in accordance with the following GAP: 1 x 75 + 1 x 150 g a.s. /ha, instead of 2 x 100 g a.s./ha.
(b): Recoveries were conducted concurrently to analysis of untreated and treated samples (recoveries in wheat whole plant averaged 107 % for XDE-777 and 107 % for X642188, recoveries in wheat grain averaged 103 % for XDE-777 and 98 % for X642188 and recoveries in wheat straw averaged 85 % for XDE-777 and 86 % for X642188.), therefore the storage of extracts for more than 24 hours is deemed acceptable.

Table A 4: Summary of the study S16-3318 trials on GF-3308 – Residues of XDE-777 and X642188

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				XDE-777	X642188		
	(a)	(b)				(c)					(d)	(e)
S16-03318-01/ Vizpart KRT 32, Szolnok, Hungary/ NEU/ 2016	Winter wheat / G.K. Petur	02 Nov 2015 N/A 06 Jul 2016	37.1 74.4	185 193	68.7 143.6	17 May 16 31 May 16	59-61 69	Whole plant Whole plant Whole plant Whole plant Whole plant Grain Straw	0.153 2.024 0.715 0.362 0.375 <0.01 (0.0094) 0.720	<0.01 (0.0072) 0.152 0.022 0.016 0.017 ND 0.039	-0 0 7 14 28 36* 36*	There were no residues above the LOQ (0.01 mg/kg) in any of the untreated specimens
S16-03318-02/ PE15 0DN, Doddington, Cambridgshire UK NEU/ 2016	Spring wheat / Mulika	14 Mar 2016 N/A 23 Aug 2016	37.5 74.8	190 219	71.3 163.8	07 Jul 16 21 Jul 16	54 69	Whole plant Whole plant Whole plant Whole plant Whole plant Grain Straw	0.134 2.241 1.393 0.759 1.202 0.107 1.702	0.020 0.280 0.146 0.134 0.071 <0.01 (0.0061) 0.125	-0 0 6 13 29 33* 33*	There were no residues above the LOQ (0.01 mg/kg) in any of the untreated specimens
S16-03318-03 ADY Endre U, 18, Jászberény, Hungary/ NEU/ 2016	Winter wheat / G.K. Petur	06 Oct 2015 N/A 04 Jul 2016	36.9 75	217 210	80.0 157.5	17 May 16 01 Jun 16	57-61 69	Grain Straw	ND 0.537	ND 0.013	34* 34*	There were no residues above the LOQ (0.01 mg/kg) in any of the untreated specimens
S16-03318-04 LS24 9DD, Kirby Wharfe, North Yorkshire, UK NEU/ 2016	Spring wheat / KWS Alderon	02 Apr 2016 N/A 12 Sep 2016	93.9 187.8	213 193	200 362.5	06 Jul 16 20 Jul 16	59 69	Grain Straw	0.066 10.364	ND 0.246	54* 54*	There were no residues above the LOQ (0.01 mg/kg) in any of the untreated specimens
S16-03318-05 501 00 Kilada, Kozani, Greece/ SEU/ 2016	Winter wheat / Claudio	13 Nov 2015 N/A 06 Jul 2016	24.7 49.5	302 300	74.7 148.6	04 May 16 18 May 16	65 69	Whole plant Whole plant Whole plant Whole plant Whole plant Grain	0.199 1.452 0.619 0.356 0.433 <0.01	<0.01 0.055 0.020 0.014 0.013 ND	-0 0 7 14 28 49*	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	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				XDE-777	X642188		
	(a)	(b)				(c)					(d)	(e)
								Straw	1.133	0.049	49*	
S16-03318-06 44492, Fonfria, Aragon, Spain/ SEU/ 2016	Spring wheat / Arthur Nick	15 Jan 2016 N/A 27 Jul 2016	37.5 74.8	204 211	76.4 157.9	03 Jun 16 18 Jun 16	55-59 69	Whole plant Whole plant Whole plant Whole plant Whole plant Grain Straw	1.368 5.622 6.201 8.582 4.830 0.061 7.673	0.033 0.112 0.176 0.175 0.127 ND 0.135	-0 0 6 13 26 39* 39*	There were no residues above the LOQ (0.01 mg/kg) in any of the untreated specimens
S16-03318-07 4531, Smilets, Pazardzhik, Bulgaria/ SEU/ 2016	Winter wheat / Miryana	16 Nov 2015 N/A 07 Jul 2016	25.0 50.0	286 309	71.5 154.4	13 May 16 27 May 16	61 69	Grain Straw	0.041 4.255	ND 0.074	41* 41*	There were no residues above the LOQ (0.01 mg/kg) in any of the untreated specimens
S16-03318-08 82700, St Porquier, Tarn Et Garonne, France/ SEU/ 2016	Spring wheat / Turiso	22 Mar 2016 N/A 27 Jul 2016	37.4 75.1	208 211	77.8 158.5	02 Jun 16 17 Jun 16	47 69	Grain Straw	0.031 1.960	ND 0.135	40* 40*	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

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

No new studies presented.

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

No new studies presented.

Appendix 3 Pesticide Residue Intake Model (PRIMo)

A 3.1 TMDI calculations

European Food Safety Authority
EFSA PRIMo revision 3.1; 2019/03/19

Fenpicoxamide

LOQs (mg/kg) range from:	0,01	to:	0,05
Toxicological reference values			
ADI (mg/kg bw/day):	0,05	ARfD (mg/kg bw):	1,8
Source of ADI:		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	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)
	13%	DK child	6,42	7%	Rye	5%	Wheat	0,3%	Bananas	0,6%	
	9%	GEMS/Food G06	4,72	9%	Wheat	0,1%	Bananas	0,1%	Tomatoes	0,6%	
	9%	NL toddler	4,56	5%	Wheat	2%	Bananas	1%	Milk: Cattle	2%	
	8%	IT toddler	4,16	8%	Wheat	0,2%	Bananas	0,0%	Other cereals	0,2%	
	8%	DE child	3,81	5%	Wheat	1,0%	Rye	0,5%	Bananas	1%	
	7%	NL child	3,46	5%	Wheat	0,6%	Bananas	0,5%	Milk: Cattle	1%	
	7%	RO general	3,40	6%	Wheat	0,2%	Milk: Cattle	0,1%	Potatoes	0,6%	
	7%	FR child 3 15 yr	3,36	6%	Wheat	0,5%	Milk: Cattle	0,2%	Bananas	1,0%	
	7%	GEMS/Food G15	3,26	5%	Wheat	0,3%	Rye	0,1%	Milk: Cattle	0,7%	
	6%	GEMS/Food G08	3,19	5%	Wheat	0,7%	Rye	0,1%	Bananas	0,7%	
	6%	ES child	3,13	5%	Wheat	0,3%	Bananas	0,2%	Milk: Cattle	0,6%	
	6%	GEMS/Food G07	2,96	5%	Wheat	0,1%	Milk: Cattle	0,1%	Bananas	0,7%	
	6%	UK toddler	2,91	5%	Wheat	0,4%	Milk: Cattle	0,3%	Bananas	0,8%	
	6%	GEMS/Food G10	2,80	5%	Wheat	0,1%	Rye	0,1%	Bananas	0,6%	
	5%	SE general	2,69	4%	Wheat	0,5%	Bananas	0,4%	Rye	0,6%	
	5%	PT general	2,65	5%	Wheat	0,2%	Rye	0,1%	Potatoes	0,3%	
	5%	GEMS/Food G11	2,60	4%	Wheat	0,2%	Milk: Cattle	0,1%	Bananas	0,8%	
	5%	IT adult	2,59	5%	Wheat	0,1%	Bananas	0,0%	Tomatoes	0,2%	
	5%	FR toddler 2 3 yr	2,46	4%	Wheat	0,6%	Milk: Cattle	0,2%	Bananas	1%	
	5%	UK infant	2,36	3%	Wheat	0,8%	Milk: Cattle	0,4%	Bananas	1%	
	4%	DE women 14-50 yr	1,97	3%	Wheat	0,6%	Rye	0,2%	Milk: Cattle	0,7%	
	4%	IE adult	1,88	3%	Wheat	0,2%	Bananas	0,2%	Rye	0,6%	
	4%	DE general	1,86	2%	Wheat	0,7%	Rye	0,2%	Milk: Cattle	0,7%	
	3%	ES adult	1,64	3%	Wheat	0,1%	Bananas	0,1%	Milk: Cattle	0,4%	
	3%	FR adult	1,55	3%	Wheat	0,1%	Milk: Cattle	0,0%	Wine grapes	0,4%	
	3%	NL general	1,52	2%	Wheat	0,2%	Milk: Cattle	0,1%	Bananas	0,6%	
	3%	FI 3 yr	1,45	1%	Wheat	0,8%	Rye	0,4%	Bananas	0,3%	
	3%	LT adult	1,43	1%	Rye	1%	Wheat	0,1%	Milk: Cattle	0,3%	
	3%	UK vegetarian	1,42	2%	Wheat	0,1%	Bananas	0,1%	Milk: Cattle	0,2%	
	2%	DK adult	1,20	1%	Wheat	0,6%	Rye	0,1%	Bananas	0,3%	
	2%	FI 6 yr	1,19	1%	Wheat	0,7%	Rye	0,2%	Bananas	0,2%	
	2%	UK adult	1,18	2%	Wheat	0,1%	Bananas	0,1%	Milk: Cattle	0,2%	
	2%	FI adult	1,00	0,8%	Rye	0,6%	Coffee beans	0,4%	Wheat	0,7%	
	2%	IE child	0,79	1%	Wheat	0,1%	Milk: Cattle	0,1%	Bananas	0,1%	
	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 Fenpicoxamide is unlikely to present a public health concern.

A 3.2 IEDI calculations

TMDI does not exceed ADI, therefore further refined assessment is not required.

A 3.3 IESTI calculations - Raw commodities

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.

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)
0,05%	Wheat	0,6 / 0,06	0,87
0,02%	Rye	0,6 / 0,06	0,38

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)
0,03%	Wheat	0,6 / 0,06	0,50
0,02%	Rye	0,6 / 0,06	0,29

A 3.4 IESTI calculations - Processed commodities

Fenpicoxamid:

Acute risk assessment /children	Acute risk assessment / adults / general population		
Details - acute risk assessment /children	Details - acute risk assessment/adults	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
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0,4%	Wheat / milling (flour)	0,6 / 0,6	7,3
0,2%	Wheat / milling (wholemea	0,6 / 0,6	3,3
0,1%	Rye / boiled	0,6 / 0,6	2,2
0,1%	Rye / milling (wholemeal)-	0,6 / 0,6	2,1

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0,1%	Wheat / bread/pizza	0,6 / 0,6	2,6
0,1%	Wheat / pasta	0,6 / 0,6	2,3
0,1%	Wheat / bread	0,6 / 0,6	2,1
#NOMBRE!	#NOMBRE!	#NOMBRE!	#NOMBRE!