REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: GLOB2111F

Product name(s): Starinta

Chemical active substance(s):

Bixafen, 125 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Globachem NV

Submission date: December 2023

zRMS Assessment : 09/08/2024

Version after commenting : 15/11/2024

Version history

When	What
August 2024	zRMS assessment
November 2024	After commenting period

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7 Metabolism and residue data (KCA section 6)

7.1 Summary and zRMS Conclusion

7.1.1 Critical GAP(s) and overall conclusion

Selection of critical uses and justification

The critical GAPs with respect to consumer intake and risk assessment for the preparation GLOB 2111F are presented in Table 7.1-1. They have been selected from the individual GAPs in the central zone EU for cereals. A list of all intended uses within the central zone EU is given in Part B, Section 0.

Overall conclusion

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

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

Data gaps

Noticed data gaps are: none

No new data has been submitted in the framework of this application. The evaluation is based on the data already evaluated in the peer-review (EFSA, 2012) and review (EFSA, 2020).

Storage stability

Bixafen and its metabolites M21, M43 and M44 are considered to be stable under freezer storage for at least 24 months in high water, high acid, high oil and in dry/high starch matrices. Degradation of residues during storage of the trial samples is not expected.

Metabolism in plants and animals

The metabolism of bixafen was sufficiently investigated in cereals. According to the results of the metabolism studies in plants, the residue definition for enforcement can be proposed as bixafen and for risk assessment as sum of bixafen and desmethyl-bixafen, expressed as bixafen.

According to the study results in animals the residue definitions for enforcement in livestock commodities was proposed as the sum of bixafen and desmethyl-bixafen (M21) expressed as bixafen equivalents and for risk assessment, the sum of bixafen and desmethyl-bixafen (M21), free and conjugated expressed as bixafen equivalents.

Magnitude of residues in plants

Comparison of EU and intended GAP in cereals:

Type of GAP	Method	Number of applications	Application rate per treatment (kg as/ha)	Interval between applications	Growth stage at las application	PHI (days)

GAP EU (SANCO/10357/2013 rev. 3, EFSA, 2020)	Spraying	2	0.125	14	BBCH 69	-
Intended GAP	Spraying	2	~~0.1~~ 0.125	-	BBCH 69	-

The reviewed residue data packages covers the intended uses of GLOB2111F. Available results show that the current MRL in cereals (Reg. (EU) 2023/1069) will not be exceeded.

The uses of GLOB2111F on barley, oats, wheat, rye, triticale and spelt can be considered as sufficiently supported.

Magnitude of residues in livestock

The available feeding data indicates that there is no risk for animal MRL to be exceeded.

Magnitude of residues in processed commodities

Bixafen remained stable under hydrolytic conditions representative of pasteurisation, baking, brewing, boiling and sterilization. Processing factors show that bixafen residues do not concentrate in processed commodities except slight concentration in brewer's grain and brewer's malt.

Magnitude of residues in representative succeeding crops

For the intended uses of bixafen on cereals, no residues are expected in rotational crops.

Other / special studies

Studies are not required.

Estimation of exposure through diet and other means

The proposed uses of bixafen in the product GLOB2111F do not represent unacceptable acute and chronic risks for the consumers.

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

1	2	3	4	5	6	7		8				9			10	11
GAP number (see part B.0)*	**Crop and/ or situation ****	**Zone**	**Product code**	**F, Fn, Fpn G, Gn, Gpn or I*****	**Pests or Group of pests controlled**	**Formulation**		**Application**				**Application rate per treatment**			**PHI (days)**	**Conclusion**
						Type	**Conc. of as**	**method kind**	**growth stage & season**	**number min max**	**interval between applications (min)**	**kg as/hL min max**	**water L/ha min max**	**g as/ha min max**		
1-10, 21-30, 41, 42	Winter cereals (wheat, barley, rye, triticale, oats, spelt)	Central	GLOB2111F	F	*Puccinia recondite, Puccinia striiformis, Pyrenophora teres, Pyrenophora tritici-repentis, Rhynchosporium secalis, Zymoseptoria tritici, Puccinia triticina, Puccinia recondita , Fusarium sp.*	EC	125 g/L	Normal downward spraying	BBCH 30 – 69	1	-	1	100-300	~~100~~ 125	-	A
11-20, 31-40	Spring cereals (wheat, barley, rye, triticale, oats, spelt)	Central	GLOB2111F	F	*Puccinia recondite, Puccinia striiformis, Pyrenophora teres, Pyrenophora tritici-repentis, Rhynchosporium secalis, Zymoseptoria tritici, Puccinia triticina, Puccinia recondita , Fusarium sp.*	EC	125 g/L	Normal downward spraying	BBCH 30 – 69	1	-	1	100-300	~~100~~ 125	-	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

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 GLOB2111F is composed of one active substance - bixafen.

Table 7.1-2: Toxicological reference values for the dietary risk assessment of bixafen

Reference value	Source	Year	Value	Study relied upon	Safety factor
ADI	EFSA Journal 2012; 10 (11): 2917	2012	0.02 mg/kg bw/day	rat – 2 year male feeding study	100
ARfD			0.2 mg/kg bw/day	rat - development study	100

7.1.2.1 Summary for bixafen

Table 7.1-3: Summary for bixafen

The residue data on bixafen are reported in the Review of the existing MRLs for bixafen (EFSA, 2020). Comparison of the northern zone GAP evaluated in the EU review (EFSA 2012 and 2020) and identified as critical GAP indicates that the GAP for the product GLOB2111F is less critical.

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?
1-10, 21-30, 41, 42	Barley (extrapolation to oat)	Yes	Yes (number of trials – 9, EFSA 2020)	Yes	Yes	Yes	No	No
11-20, 31-40	Wheat (extrapolation to rye, triticale and spelt)	Yes	Yes (number of trials – 10, EFSA 2020)					

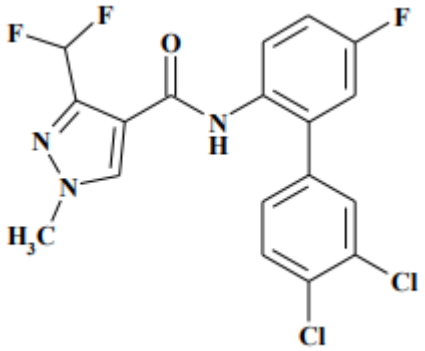
* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

7.2 Bixafen

General data on bixafen are summarized in the table below.

Table 7.2-1: General information on bixafen

Active substance (ISO Common Name)	Bixafen
IUPAC	*N*-(3',4'-dichloro-5-fluorobiphenyl-2-yl)-3- (difluoromethyl)-1-methyl-1*H*-pyrazole-4-carboxamide

Chemical structure	
Molecular formula	$C_{18}H_{12}Cl_2F_3N_3O$
Molar mass	414.21 g/mol
Chemical group	Pyrazole-4-carboxamides
Mode of action (if available)	Inhibition of the enzyme succinate dehydrogenase (complex II) within the fungal mitochondrial respiration chain. Its primary biological mode of action is the inhibition of spore germination and germ tube extension on the surface of the plant.
Systemic	Yes
Company (ies)	Bayer AG*
Rapporteur Member State (RMS)	United Kingdom Czech Republic
Approval status	Approved on 01/10/2013 Approval Reg. (EU) No. 350/2013, 17 April 2013
Restriction (e.g. is restricted to use as "...")	see Approval Directive / Regulation
Review Report	SANCO/10357/2013 rev 3, 15 March 2013
Current MRL regulation	Reg. (EU) 2023/1069
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes, EFSA Journal 2020;18(1):5998
EFSA Journal : Conclusion on the peer review	Yes, EFSA Journal 2012;10(11):2917
EFSA Journal: conclusion on article 12	Yes, EFSA Journal 2020;18(1):5998
Current MRL applications on intended uses	None

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

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 submitted in the framework of this application. The data evaluated during the Annex I inclusion of bixafen are sufficient to describe the behaviour of the formulated product, and no further studies are required.

The storage stability of bixafen and its metabolite desmethyl-bixafen (M21) was investigated in the framework of the EU review of the active substance (UK, 2011; EFSA, 2012) and showed bixafen and its

metabolite desmethyl-bixafen to be stable up to 12 months in commodities of high-water content (wheat green material and lettuce head), high-starch content (potato tuber, wheat grain), high-oil content (rape seed) and a dry matrix (straw).

EFSA (2020): The storage stability of bixafen and its metabolite M21 was investigated in the framework of the peer review (2012) and in new studies submitted under this review.
According to these studies, bixafen and its metabolite M21 are stable for at least 24 months in high water content (lettuce, wheat green material), high acid content (orange), high oil content (rapeseed) matrices and in dry/high starch (wheat grain and straw; potato tuber; dry bean) content commodities when stored at –18°C.
Additional storage stability data demonstrates the storage stability of metabolites M44 and M43 for a period of 24 months in high water content (tomato), high acid content (orange), high oil content (soybean seed) matrices and in dry/high starch (potato tuber; dry bean) content commodities when stored at –18°C.
Therefore, it can be concluded that bixafen, and its metabolites M21, M43 and M44 are stable for at least 24 months in all major matrices when stored at -18°C.

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			
Lettuce head	High water content	12 months	Billian, 2008 UK, 2011 EFSA, 2012
Potato tuber	High starch content		
Oilseed rape seed	High oil content		
Wheat forage	High water content		
Wheat grain	High starch content		
Wheat straw	Dry commodity		

Conclusion on stability of residues during storage

Storage stability studies of bixafen and its metabolite desmethyl-bixafen assessed in this section cover the requested uses on cereals grain (high starch content commodity), forage (high water content commodity) and straw (dry commodity) for GLOB2111F.

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

Available data

No new data submitted in the framework of this application. The data evaluated during the Annex I inclusion of bixafen are sufficient to describe the behaviour of the formulated product, and no further studies are required.

The stability of residues of bixafen and its metabolite desmethyl-bixafen in sample extracts was assessed during the validation of the residue analytical methods for the determination of these analytes in plant material and animal extracts using fortified samples. In none of the extracts investigated any degradation was observed.

Additionally, the stability of residues of bixafen and its metabolite desmethyl-bixafen in sample extracts has been demonstrated in all of the presented trials as all procedural recoveries for bixafen and its me-

tabolite desmethyl-bixafen are within acceptable ranges (70-110%). As fortification occurs prior to extraction, it can be demonstrated that compounds remained stable during the analytical phase.

Conclusion on stability of residues in sample extracts

The stability of the residues in sample extracts is acceptable for the uses under consideration and in regard to the submitted residue trials.

7.2.2 Nature of residues in plants, livestock and processed commodities

7.2.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

No new data submitted in the framework of this application. The data evaluated during the Annex I inclusion of bixafen are sufficient to describe the behaviour of the formulated product, and no further studies are required.

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 (kg a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Cereals	Wheat	Pyrazole-^{14}C and Dichlorophenyl-^{14}C	Foliar treatment, G	0.125+0.150	2	forage and hay 9 d (hay after 1st appl.), grain and straw 50 d	Applications at BBCH 29-31 and 69	Miebach & Bongartz, 2007a and 2007b UK, 2011 EFSA, 2012
Pulses and oilseeds	Soybean	Pyrazole-^{14}C and Dichlorophenyl-^{14}C	Foliar treatment, G	0.06	3	forage 5 d (2nd appl.), hay 29 d (2nd appl.), seed and straw 26 d	Applications at BBCH 60, 69 and 88	Spiegel, 2007a and 2007b UK, 2011 EFSA, 2012

Summary of plant metabolism studies reported in the EU

The metabolism of bixafen was assessed after foliar treatment in pulses and oilseeds (soybeans) and in cereals (wheat grain and forage) in the framework of the peer-review of the active substance (EFSA, 2012).

Following two foliar applications of ~140 g a.s./ha, applied at BBCH growth stage 29-31 and 69, bixafen was the only major component identified of the total radioactive residues (TRR) in wheat grain and straw (90% to 93% TRR, up to 0.214 mg eq/kg and 22.3 mg eq/kg in grain and straw, respectively). In addition, desmethyl-bixafen (M21) resulting from the demethylation of the parent molecule on the pyrazole ring was observed at low levels (~ 2% TRR, <0.01 and 0.43 mg eq./kg in grain and straw, respectively) (UK, 2011).

After three foliar applications of 60 g a.s./ha, at BBCH 60, 69 and 88, TRR levels were low (0.024 and 0.005 mg eq/kg) in soybeans seeds, allowing characterisation only of the pyrazole labelled residues present at higher levels. The major metabolite identified was bixafen (30% TRR; 0.007 mg eq./kg), whilst metabolites desmethyl-pyrazole-4-carboxylic acid (M44) and pyrazolone-4-carboxylic acid (M47) constituted 19% and 12% of the TRR (0.005 mg eq/kg and 0.003 mg eq/kg), respectively. In soybean straw, bixafen constituted at least 90% of the TRR, while the metabolite M21 was 0.06% of the TRR (UK, 2011).

Additional studies were submitted in the present review investigating metabolism in fruits and fruiting vegetables (tomato) and in root and tuber vegetables (potato).The metabolism of bixafen in plants was investigated in primary and rotational crops. According to the results of the metabolism studies, the residue definition for enforcement can be proposed as bixafen and for risk assessment as sum of bixafen and desmethyl-bixafen, expressed as bixafen. These residue definitions are also applicable to processed commodities (EFSA, 2020).

Conclusion on metabolism in primary crops

The available European data are considered sufficient to support the intended uses of GLOB2111F on cereals and no additional metabolism studies are necessary.

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

No new data submitted in the framework of this application. The data evaluated during the Annex I inclusion of bixafen are sufficient to describe the behaviour of the formulated product, and no further studies are required.

Available data

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

Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G *	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks	
EU data								
Leafy vegetables	Swiss chards	Pyrazole-^{14}C	Bare soil G	0.790	30, 138 and 285d	maturity		Weber, Spiegel & Koehn, 2007a and
		Dichlorophenyl-^{14}C	Bare soil G	0.850	30, 138 and 285d	maturity		

Root and tuber vegetables	Turnips	Pyrazole-^{14}C	Bare soil G	0.790	30, 138 and 285d	maturity		2007b UK, 2011 EFSA, 2012
		Dichlorophenyl-^{14}C	Bare soil G	0.850	30, 138 and 285d	maturity		
Cereals	Wheat	Pyrazole-^{14}C	Bare soil G	0.790	30, 138 and 285d	hay and forage intermediate straw and grain maturity		
		Dichlorophenyl-^{14}C	Bare soil G	0.850	30, 138 and 285d	hay and forage intermediate straw and grain maturity		

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

Summary of plant metabolism studies reported in the EU

A confined rotational crop study with bixafen radiolabelled on both rings of the molecule conducted on wheat, turnips and Swiss chards was evaluated in the framework of the peer review of the active substance. Following bare soil treatment with pyrazole and dichlorophenyl ring radiolabelled bixafen, at a rate of 790-850 g a.s./ha, crops were planted 30, 138 and 285 days after application (UK, 2011).

Residues in all crops declined over time, with TRRs observed up to 0.06 mg eq/kg in food commodities, and up to 0.49 mg eq/kg in wheat straw. No residue was detected in wheat grain. Highest levels of bixafen in Swiss chards (26–70% TRR; 0.02 mg eq/kg), in turnip roots (59–78% TRR; 0.02–0.03 mg eq/kg) and in wheat straw (23–37% TRR; 0.1–0.18 mg eq/kg were observed at 30 DAT. M21 was a major metabolite in turnips roots (>10% TRR; but < 0.01 mg e.q/kg) and in wheat straw (up to 70% TRR, 0.18 mg eq/kg). Other major metabolites included M44 and pyrazolecarboxamide (M43) in Swiss chards (38–49% TRR, respectively; 0.02 mg eq/kg and turnip tops (14– 12% TRR respectively; 0.01 mg eq/kg, and hydroxy-glycoside-sulfate (M20) in Swiss chards (up to 38% TRR; 0.015 mg eq./kg).

The studies indicated that the bridge between the pyrazole ring and the dichlorophenyl ring had been broken, and only low levels of metabolites containing solely the pyrazole ring are taken up by succeeding crops (< 0.04 mg/kg). Overall, it was concluded that the metabolism and distribution of bixafen in rotational crops is similar to the metabolic pathway observed in primary crops.

Conclusion on metabolism in rotational crops

The available European data on the nature of residue in rotational crops has been sufficiently investigated to cover the intended uses of GLOB2111F on cereals.

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

No new data submitted in the framework of this application. The data evaluated during the Annex I inclusion of bixafen are sufficient to describe the behaviour of the formulated product, and no further studies are required.

Bixafen is stable under hydrolytic conditions representative of pasteurisation, baking, brewing, boiling and sterilisation.

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)	Bixafen (98.2%)	Justus & Kuhunke, 2008 UK, 2011 EFSA, 2012
Baking, boiling, brewing (60 minutes, 100°C, pH 5)	Bixafen (100.2%)	
Sterilisation (20 minutes, 120°C, pH 6)	Bixafen (98%)	

Conclusion on nature of residues in processed commodities

The nature of residues in processed commodities has been sufficiently investigated to cover the uses of GLOB2111F on cereals.
Bixafen remained stable under hydrolytic conditions representative of pasteurisation, baking, brewing, boiling and sterilization.

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

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

Endpoints	
Plant groups covered	Cereals (wheat) Pulses and oilseeds (soybean) Fruit crops (tomatoes) Root crops (potatoes)
Rotational crops covered	Wheat (Cereals/small grains), turnips (Root/tuber crops) and Swiss chard (leafy crops)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes, only in rotated leafy crops more extensive degradation of bixafen into pyrazole derived metabolites.
Processed commodities	Bixafen is stable under standard hydrolysis conditions
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes
Plant residue definition for monitoring	Bixafen (Reg (EU) 2023/1069)
Plant residue definition for risk assessment	Sum of bixafen and desmethyl-bixafen (M21) expressed as bixafen (EFSA Journal 2020;18(1):5998)
Conversion factor from enforcement to RA	A CF of 1 was applied for all commodities where the metabolite M21 was found at or below the LOQ in all trials. CF of 1: Linseeds, rapeseeds, mustard seeds, wheat and rye grain CF of 1.1: Barley and oat straw CF of 1.2: Wheat and rye straw CF of 1.3: Barley and oat grains, wheat forage (EFSA Journal 2020;18(1):5998)

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

Available data

No new data were submitted in the framework of this application. The data evaluated during the Annex I inclusion of bixafen are sufficient to describe the behaviour of the formulated product, and no further studies are required

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	Pyrazole and dichlorophenyl ring labelled ^{14}C-bixafen	1	2 mg/kg bw/d (35-46 mg/kg DM)	5	Blood	0.5, 2, 4, 6, 8 hours after 1st administration Twice daily after 2nd administration	[redacted], 2007a and 2007b UK, 2011 EFSA, 2012
						Milk	twice daily	
						Urine and faeces	daily	
						Muscle, fat, liver and kidney	at sacrifice	
Laying poultry	Hens	Pyrazole and dichlorophenyl ring labelled ^{14}C-bixafen	1	2.04 mg/kg bw/d (26-32 mg/kg DM)	14	Egg	daily	[redacted], 2007a and 2007b UK, 2011 EFSA, 2012
						Urine and faeces	daily	
						Liver, muscle, fat and skin	at sacrifice	

Summary of animal metabolism studies reported in the EU

During the EU review of the active substance bixafen, the metabolism of bixafen residues in livestock was investigated in lactating goats (35–46 mg/kg DM in feed; 4.5N for sheep) and laying hens (26–32 mg/kg DM, 18N) fed for 5 and 14 days, respectively, at dose rates covering the maximum calculated dietary burdens (UK, 2011, EFSA 2012). In both studies bixafen was radiolabelled in the pyrazole and in the dichloro-phenyl ring of the molecule. Label dependent differences in uptake and distribution of radioactivity were not observed.

The studies performed on lactating goats and laying hens showed a similar pattern of uptake and metabolism. The majority of radioactivity was excreted (74–93%), with less than 0.3% in the milk, 1.2% TRR in the eggs and less than 1.1% and 0.3% in the tissues of ruminants and poultry, respectively. In goats, the highest residue levels were recovered in liver and fat (1.2 and 0.61 mg eq/kg), followed by kidney and milk (0.2 and 0.18 mg eq/kg). Bixafen and its metabolite desmethyl-bixafen (M21) were predominant; representing 52% TRR in liver, over 80% TRR in kidney, up to 100% TRR in muscle and fat, and above 90% TRR in milk. In addition, in liver and kidney the glucuronide conjugated form of M21 was also

found at significant levels (19% and 14% TRR, respectively).

In poultry, the highest residue levels were recovered in liver and eggs (up to 0.8 mg eq/kg). The sum of bixafen, its conjugate and M21 represented 64% (liver)–100% TRR (fat). In liver, the major form of bixafen was its conjugate (up to 27% TRR).

As preferential concentration in fat tissues is observed bixafen residues are considered as fat soluble. EFSA concluded that bixafen and its metabolite M21 are the most relevant components of the residues in livestock commodities.

Conclusion on metabolism in livestock

The available livestock metabolism studies are considered sufficient to support the intended uses of GLOB2111F and no additional metabolism studies are necessary.

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

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

	Endpoints
Animals covered	Lactating goats
	Laying hens
Time needed to reach a plateau concentration	3 days in milk
	7 days in eggs
Animal residue definition for monitoring	Sum of bixafen and desmethyl-bixafen (M21), expressed as bixafen (UK, 2012; EFSA, 2012) (Reg (EU) 2023/1069)
Animal residue definition for risk assessment	Sum of bixafen and desmethyl-bixafen (M21), free and conjugated expressed as bixafen equivalent (UK, 2012; EFSA, 2012 and 2020)
Conversion factor	Cattle, sheep and swine liver: 1.3 Cattle, sheep and swine kidney: 1.1 Other matrices: 1.0 (EFSA 2020)
Metabolism in rat and ruminant similar	Yes The metabolism in pig can be extrapolated from ruminants
Fat soluble residue	Yes

7.2.3 Magnitude of residues in plants (KCA 6.3)

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

No new data are submitted in the framework of this application. The residue data on cereals were evaluated during the EU review of bixafen are sufficient to describe the behaviour of the formulated product and no further studies are required. Reference to these studies can be made to support the intended use of GLOB2111F.

NEU residue data were considered for evaluation in Central zone.

During the EU Review, a total of twenty residue trials on wheat, ten in Northern Europe and ten in Southern Europe, and 19 trials on barley nine in Northern Europe and ten in Southern Europe, were caried out. These trials can be used in support of the GAP applied for in this submission as 2 treatments at up to 0.125 kg a.i./ha were described, with the last treatment performed at BBCH 69 for wheat and BBCH 61 in barley. This application scheme can therefore be considered more worst case than the GAP of GLOB2111F (single application) and it is therefore covered by the trials submitted during the EU review. Moreover, these trials show that residues in grain and straw following treatment at up to 0.125 kg a.i./ha were always below the current MRLs.

According to EU guidelines (SANTE/2019/12752) extrapolation of residue data from wheat to rye and from barley to oat is possible. Therefore sufficient residue trials are available to support the intended uses of GLOB2111F on wheat (including triticale and spelt) and barley in Northern Europe.

Table 7.2-9: Summary of EU reported and new data supporting the intended uses of GLOB2111F and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Wheat grain → extrapolated to Rye, Triticale, Spelt (grain)	Schoening, Raecker & Erler, 2007 Schoening & Reineke, 2008a UK, 2011	N-EU (10)	GAP on which MRL/EU a.s. assessment is based: 2 x 0.125 kg a.s./ha (int. 14d), last appl. BBCH 69, outdoor E: 6 x <0.01, 2 x 0.01, 2 x 0.03 RA: 6 x <0.02, 2 x 0.02, 2 x 0.04	N/A				

	EFSA, 2012 EFSA, 2020							
	Schoening, Raecker & Lorenz, 2007 Schoening & Reineke, 2008b UK, 2011 EFSA, 2012 EFSA, 2020	S-EU (10)	GAP on which MRL/EU a.s. assessment is based: 2 x 0.125 kg a.s./ha (int . 14d), last appl. BBCH 69, outdoor E: 6 x <0.01, 0.01, 2 x 0.02, 0.03 RA: 6 x <0.02, 0.02, 0.03, 0.03, 0.04	N/A				
	Overall supporting data for cGAP	N-EU (10)	E: 6 x <0.01, 2 x 0.01, 2 x 0.03 RA: 6 x <0.02, 2 x 0.02, 2 x 0.04	RA: 0.02 E: 0.01	RA: 0.04 E: 0.03	0.048	0.3	Yes
		S-EU (10)	E: 6 x <0.01, 0.01, 2 x 0.02, 0.03 RA: 6 x <0.02, 0.02, 0.03, 0.03, 0.04	RA: 0.02 E: 0.01	RA: 0.04 E: 0.03	0.042		
Wheat → extrapolated to Rye, Triticale, Spelt (straw)	Schoening, Raecker & Erler, 2007 Schoening & Reineke, 2008a UK, 2011 EFSA, 2012 EFSA, 2020	N-EU (10)	GAP on which MRL/EU a.s. assessment is based: 2 x 0.125 kg a.s./ha (int. 14d), last appl. BBCH 69, outdoor E: 0.52 ; 0.93 ; 0.95; 1.3; 1.8; 1.90 ; 3.6; 4.1; 8.4; 10 RA: 0.78, 1.2, 1.3, 1.5, 2.1, 2.5, 3.8, 4.4, 9.7, 11	N/A				
	Schoening, Raecker & Lorenz, 2007 Schoening & Reineke, 2008b UK, 2011 EFSA, 2012 EFSA, 2020	S-EU (10)	GAP on which MRL/EU a.s. assessment is based: 2 x 0.125 kg a.s./ha (int . 14d), last appl. BBCH 69, outdoor E: 0.79; 1.4; 1.7;1.8; 2.6; 3.2; 3.3; 3.6; 5.4; 5.7 RA: 1.2, 2 x 1.9, 2.2, 3.3, 3.7, 3.9, 4.1, 6.0, 6.2	N/A				
	Overall supporting	N-EU (10)	E: 0.52 ; 0.93 ; 0.95; 1.3; 1.8; 1.90 ; 3.6; 4.1; 8.4; 10 RA: 0.78, 1.2, 1.3, 1.5, 2.1, 2.5, 3.8, 4.4, 9.7, 11	RA: 2.3 E: 1.85	RA: 11 E:10.00	N/R	N/R	N/R

	data for cGAP	S-EU (10)	E: 0.79; 1.4; 1.7;1.8; 2.6; 3.2; 3.3; 3.6; 5.4; 5.7 RA: 1.2, 2 x 1.9, 2.2, 3.3, 3.7, 3.9, 4.1, 6.0, 6.2	RA: 3.5 E: 2.9	RA: 6.2 E: 5.7	N/R		
Barley → extrapolated to oat (grain)	Schoening & Raecker, 2007 Schoening & Reineke, 2008 UK, 2011 EFSA, 2012 EFSA, 2020	N-EU (9)	GAP on which MRL/EU a.s. assessment is based: 2 x 0.125 kg a.s./ha, last appl. BBCH 61, outdoor E: 0.02, 3 x 0.04, 0.07, 0.08, 2 x 0.09, 0.10 RA: 0.03, 3 x 0.05, 0.08, 3 x 0.10, 0.11	N/A				
	Schoening, Raecker & Erler, 2007 Schoening & Reineke, 2007 UK, 2011 EFSA, 2012	S-EU (10)	GAP on which MRL/EU a.s. assessment is based: 2 x 125 g a.s./ha (int . 14d), last appl. BBCH 61, no PHI stated/last application based on growth stage E: 0.03, 2 x 0.04, 2 x 0.06, 0.08, 0.10, 0.14, 0.25, 0.34 RA: 0.04, 2 x 0.05,. 2 x 0.08, 0.10, 0.11, 0.16, 0.30, 0.38	N/A				
	Overall supporting data for cGAP	N-EU (9)	E: 0.02, 3 x 0.04, 0.07, 0.08, 2 x 0.09, 0.10 RA: 0.03, 3 x 0.05, 0.08, 3 x 0.10, 0.11	RA: 0.08 E: 0.07	RA: 0.11 E: 0.1	0.19	1.5	Yes
		S-EU (10)	E: 0.03, 2 x 0.04, 2 x 0.06, 0.08, 0.10, 0.14, 0.25, 0.34 RA: 0.04, 2 x 0.05,. 2 x 0.08, 0.10, 0.11, 0.16, 0.30, 0.38	RA: 0.09 E: 0.07	RA: 0.38 E: 0.34	0.526		
Barley → extrapolated to oat (straw)	Schoening & Raecker, 2007 Schoening & Reineke, 2008 2008 UK, 2011 EFSA, 2012 EFSA, 2020	N-EU (9)	GAP on which MRL/EU a.s. assessment is based: 2 x 0.125 kg as/ha, last appl. BBCH 61, outdoor E: 0.64, 0.7, 0.77, 0.86, 1.1, 3.7, 4.8, 5.4, 10 RA: 0.73, 0.74, 0.84, 1.0, 1.2, 3.9, 5.2, 5.6, 12	N/A				
	Schoening, Raecker & Erler, 2007 Schoening & Reineke, 2007 UK, 2011	S-EU (10)	GAP on which MRL/EU a.s. assessment is based: 2 x 125 g a.s./ha (int . 14d), last appl. BBCH 61, outdoor E: 0.46, 0.75, 1.2, 1.5, 1.9, 3.1, 3.7, 5.2, 5.7, 6.2 RA: 0.5, 1.0, 1.3, 1.7, 2.1, 3.3, 4.1, 5.6, 6.2, 6.7	N/A				

	EFSA, 2012 EFSA, 2020							
	Overall supporting data for cGAP	N-EU (9)	E: 0.64, 0.7, 0.77, 0.86, 1.1, 3.7, 4.8, 5.4, 10 RA: 0.73, 0.74, 0.84, 1.0, 1.2, 3.9, 5.2, 5.6, 12	RA: 1.2 E: 1.1	RA: 12 E: 1.0	N/R	N/R	N/R
		S-EU (10)	E: 0.46, 0.75, 1.2, 1.5, 1.9, 3.1, 3.7, 5.2, 5.7, 6.2 RA: 0.5, 1.0, 1.3, 1.7, 2.1, 3.3, 4.1, 5.6, 6.2, 6.7	RA: 2.7 E: 2.5	RA: 6.7 E: 6.2	N/R		

* Source of EU MRL: Reg (EU) 2023/1069

7.2.3.2 Conclusion on the magnitude of residues in plants

According to the available data, the intended uses on wheat (including triticale and spelt) and barley are considered acceptable.

According to appendix D of EU guidelines, extrapolation to rye is possible with the trials available on wheat, and to oats with the trials available in barley.

The data submitted show that no exceedance of the MRL will occur.

The uses are considered acceptable.

zRMS comment: Comparison of EU and intended GAP in cereals:

Type of GAP	Method	Number of applications	Application rate per treatment (kg as/ha)	Interval between application (days)	Growth stage at last application	PHI (days)
GAP EU (SANCO/10357/2013 rev 3, EFSA, 2020)	Spraying	2	0.125	14	BBCH 69	-
Intended GAP	Spraying	1	~~0.1~~ 0.125	-	BBCH 69	-

The applicant relied upon 10 NEU and 10 SEU (included as supportive data) trials that have been previously evaluated at EU level, with application rates higher than those in proposed GAP. Therefore these reviewed residue data packages fully cover the intended uses of GLOB2111F. Available results show that the current MRL in cereals (Reg. (EU) 2023/1069) will not be exceeded.
According to Technical Guidelines SANTE/2019/12752 Rev01, the supported extrapolation from barley to oats and from wheat to rye triticale and spelt is acceptable.
As a conclusion, the uses of GLOB2111F on barley, oats, wheat, rye, triticale and spelt can be considered as sufficiently supported.

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

Bixafen is authorised for use on several crops that might be fed to livestock. The median and maximum dietary burdens were therefore calculated using Animal Model 2017 for different groups of livestock using the input values according to the MRL review of Bixafen (EFSA, 2012, EFSA, 2020).

The input values are summarised in Table 7.2-10 below.

Table 7.2-10: Input values for the dietary burden calculation (considering the uses evaluated in Art. 12 procedure and the uses under consideration)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: Sum of bixafen and desmethyl-bixafen (M21) expressed as bixafen				

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Carrot, culls	0.03	STMR (rotational crops)	0.05	HR (rotational crops)
Swede, roots	0.03	STMR (rotational crops)	0.05	HR (rotational crops)
Turnip, roots	0.03	STMR (rotational crops)	0.05	HR (rotational crops)
Flaxseed/Linseed, meal	0.02	STMR x default PF[(a)] (2)	0.02	STMR x default PF[(a)] (2)
Canola (Rape seed), meal	0.01	STMR x PF (0.7) x CF (1.5)	0.01	STMR x PF (0.7) x CF (1.5)
Rape, meal	0.01	STMR x PF (0.7) x CF (1.5)	0.01	STMR x PF (0.7) x CF (1.5)
Barley, grain	0.09	STMR x CF (1.3)	0.09	STMR x CF (1.3)
Brewer's grain, dried	0.08	STMR x PF (1) x CF (1.1)	0.08	STMR x PF (1) x CF (1.1)
Oat, grain	0.09	STMR x CF (1.3)	0.09	STMR x CF (1.3)
Rye, grain	0.01	STMR	0.01	STMR
Triticale, grain	0.01	STMR	0.01	STMR
Wheat, grain	0.01	STMR	0.01	STMR
Wheat, distiller's grain (dry)	0.03	STMR x default PF[(a)] (3.3)	0.03	STMR x default PF[(a)] (3.3)
Wheat gluten, meal	0.02	STMR x default PF[(a)] (1.8)	0.02	STMR x default PF[(a)] (1.8)
Wheat, milled by-pdts	0.07	STMR x default PF[(a)] (7)	0.07	STMR x default PF[(a)] (7)
Beet, sugar, dried pulp	0.54	STMR x default PF (18) (rotational crops)	0.54	STMR x default PF (18) (rotational crops)
Beet, sugar, ensiled pulp	0.09	STMR x default PF (3) (rotational crops)	0.09	STMR x default PF (3) (rotational crops)
Beet, sugar, molasses	0.84	STMR x default PF (28) (rotational crops)	0.84	STMR x default PF (28) (rotational crops)
Triticale, forage	0.62	STMR x CF (1.3)	0.85	HR x CF (1.3)
Triticale, hay	1.81	STMR x default PF[(a)] (2.9) x CF (1.3)	2.45	HR x default PF[(a)] (2.9) x CF (1.3)
Wheat, forage	0.62	STMR x CF (1.3)	0.85	HR x CF (1.3)
Wheat, hay (fodder dry)	2.18	STMR x default PF[(a)] (3.5) x CF (1.3)	2.96	HR x default PF[(a)] (3.5) x CF (1.3)
Barley, straw	2.10	STMR x CF (1.1)	11	HR x CF (1.1)
Oat, straw	2.10	STMR x CF (1.1)	11	HR x CF (1.1)
Rye, straw	3.48	STMR x CF (1.2)	12	HR x CF (1.2)
Triticale, straw	3.48	STMR x CF (1.2)	12	HR x CF (1.2)
Wheat, straw	3.48	STMR x CF (1.2)	12	HR x CF (1.2)

STMR: supervised trials median residue; HR: highest residue; PF: processing factor.
(a): In the absence of processing factors supported by data, default processing factors were included in the calculation to consider the potential concentration of residues in the relevant commodities.

The results of the calculations are reported in Table 7.2-11. The calculated dietary burden for all groups of livestock were found to be above the maximum dietary burden trigger of 0.004 mg/kg bw per d and thus livestock feeding studies are triggered.

Table 7.2-11: Results of the dietary burden calculation

Relevant groups	Dietary burden expressed in				Most critical diet	Most critical commodity	Trigger exceeded (Yes/No)
	mg/kg bw per day		mg/kg DM				
	Median	Maximum	Median	Maximum			
Cattle (all diets)	0.043	0.158	1.11	4.16	Cattle (dairy)	Barley, straw	Yes
Cattle (dairy only)	0.043	0.158	1.11	4.11	Cattle (dairy)	Barley, straw	Yes
Sheep (all diets)	0.08	0.328	1.89	7.71	Sheep (lamb)	Barley, straw	Yes
Sheep (ewe only)	0.057	0.257	1.70	7.71	Sheep (ram/ewe)	Barley, straw	Yes
Swine (all diets)	0.018	0.025	0.76	1.10	Swine (breeding)	Wheat, forage	Yes
Poultry (all diets)	0.035	0.104	0.51	1.52	Poultry (layer)	Wheat, straw	Yes
Poultry (layer only)	0.035	0.104	0.51	1.52	Poultry (layer)	Wheat, straw	Yes

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Available data

No new data were submitted in the framework of this application. The data evaluated during the Annex I inclusion of bixafen are sufficient to describe the behaviour of the formulated product, and no further studies are required.

During the EU Review, feeding studies performed with dairy cows ([redacted], 2008) and laying hens ([redacted], 2007) were assessed during the peer review (UK, 2011; EFSA, 2012). In the ruminant feeding study, bixafen was administered to cows using different dosing levels ranging from 0.15 to 1.5 mg/kg bw per day (0.5–4.7N) and a separate group to investigate depuration of bixafen residues at a dose rate of 1.5 mg/kg bw per day during feeding phase. In the poultry feeding study, bixafen was administered at dosing levels ranging from 0.092 to 1.007 mg/kg bw per day (0.9–10N).

The studies performed on cows and hens were used to derive MRL and risk assessment values in milk, eggs, and tissues of ruminants and poultry. Since extrapolation from ruminants to pigs is acceptable, results of the livestock feeding study on ruminants were relied upon to derive the MRL and risk assessment values in pigs. All tissue, milk and eggs samples were analysed within 30 days of collection and stored ≤ -18°C thus decline of residues during storage of the trial samples is not expected.

Based on the available metabolism studies, the peer review also derived a conversion factor (CF) for risk assessment of 1.3 and 1.1 in liver and kidney, respectively (EFSA, 2012).

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

Commodity	Dietary burden		Results of the livestock feeding study						Median residue (mg/kg)[b]	Highest residue (mg/kg)[c]	Calculated MRL (mg/kg)	CF for RA[d]
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level (mg/kg bw/d)	No	Result for enforce-ment		Result for RA					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
EU data (UK, 2011; EFSA, 2012; EFSA 2020)												
Enforcement residue definition: sum of bixafen and desmethyl-bixafen, expressed as bixafen Risk assessment residue definition: sum of bixafen and desmethyl-bixafen, free and conjugated, expressed as bixafen												
Pig meat[a]	0.018	0.025	0.15	3	0.05	0.07	0.05	0.07	0.01	0.01	0.02*	1
			0.45	3	0.16	0.26	0.16	0.26				
			1.5	3	0.82	1.0	0.82	1.0				
Pig fat[a]	0.018	0.025	0.15	3	0.15	0.21	0.15	0.21	0.02	0.03	0.04	1
			0.45	3	0.22	0.48	0.22	0.48				
			1.5	3	1.2	1.9	1.2	1.9				
Pig liver[a]	0.018	0.025	0.15	3	0.57	0.69	0.57	0.69	0.06	0.11	0.15	1.3
			0.45	3	1.4	1.7	1.4	1.7				
			1.5	3	5.0	5.4	5.0	5.4				
Pig kidney[a]	0.018	0.025	0.15	3	0.14	0.15	0.14	0.15	0.02	0.02	0.03	1.1
			0.45	3	0.35	0.37	0.35	0.37				
			1.5	3	1.2	1.3	1.2	1.3				
Ruminant meat	0.043	0.158	0.15	3	0.05	0.07	0.05	0.07	0.02	0.07	0.08	1
			0.45	3	0.16	0.26	0.16	0.26				
			1.5	3	0.82	1.0	0.82	1.0				
Ruminant fat	0.043	0.158	0.15	3	0.15	0.21	0.15	0.21	0.04	0.22	0.3	1

			0.45	3	0.22	0.48	0.22	0.48				
			1.5	3	1.2	1.9	1.2	1.9				
Ruminant liver	0.043	0.158	0.15	3	0.57	0.69	0.57	0.69	0.21	0.7	0.8	1.3
			0.45	3	1.4	1.7	1.4	1.7				
			1.5	3	5.0	5.4	5.0	5.4				
Ruminant kidney	0.043	0.158	0.15	3	0.14	0.15	0.14	0.15	0.04	0.17	0.2	1.1
			0.45	3	0.35	0.37	0.35	0.37				
			1.5	3	1.2	1.3	1.2	1.3				
Poultry meat	0.035	0.104	0.09	12	<0.02	<0.02	<0.02	<0.02	0.02	0.02	0.02*	1
			0.28	12	<0.02	<0.02	<0.02	<0.02				
			1.01	12	<0.02	<0.02	<0.02	<0.02				
Poultry fat	0.035	0.104	0.09	12	<0.02	<0.02	<0.02	<0.02	0.02	0.02	0.02*	1
			0.28	12	0.06	0.06	0.06	0.06				
			1.01	12	0.08	0.10	0.08	0.10				
Poultry liver	0.035	0.104	0.09	12	<0.02	<0.02	<0.02	<0.02	0.02	0.02	0.02*	1
			0.28	12	0.03	0.04	0.03	0.04				
			1.01	12	0.04	0.05	0.04	0.05				
Milk (cattle, dairy only)[(e)]	0.043	0.158	0.15	3	0.03	0.05	0.03	0.05	0.01	0.04	0.04	1
			0.45	3	0.07	0.12	0.07	0.12				
			1.5	3	0.22	0.36	0.22	0.36				
Eggs[(f)]	0.035	0.104	0.09	12	<0.02	0.02	<0.02	0.02	0.03	0.01	0.02*	1
			0.28	12	0.06	0.07	0.06	0.07				
			1.01	12	0.16	0.22	0.16	0.22				
Sheep meat[(a)]	0.08	0.328	0.15	3	0.05	0.07	0.05	0.07	0.03	0.19	0.2	1
			0.45	3	0.16	0.26	0.16	0.26				

			1.5	3	0.82	1.0	0.82	1.0				
Sheep fat[(a)]	0.08	0.328	0.15	3	0.15	0.21	0.15	0.21	0.08	0.39	0.4	1
			0.45	3	0.22	0.48	0.22	0.48				
			1.5	3	1.2	1.9	1.2	1.9				
Sheep liver[(a)]	0.08	0.328	0.15	3	0.57	0.69	0.57	0.69	0.31	1.30	1.5	1.3
			0.45	3	1.4	1.7	1.4	1.7				
			1.5	3	5.0	5.4	5.0	5.4				
Sheep kidney[(a)]	0.08	0.328	0.15	3	0.14	0.15	0.14	0.15	0.08	0.29	0.3	1.1
			0.45	3	0.35	0.37	0.35	0.37				
			1.5	3	1.2	1.3	1.2	1.3				
Milk (Sheep, ewe only) [(a) (e)]	0.057	0.257	0.15	3	0.03	0.05	0.03	0.05	0.01	0.05	0.05	1
			0.45	3	0.07	0.12	0.07	0.12				
			1.5	3	0.22	0.36	0.22	0.36				

N/A: Not applicable – only the mean values are considered for calculating MRLs in milk.
n.r.: Not reported
(*): Indicates that the MRL is set at the limit of analytical quantification.
(F): MRL is expressed as mg/kg of fat contained in the whole product.
(a): Since extrapolation from cattle to other ruminants and swine is acceptable, results of the livestock feeding study on ruminants were relied upon to derive risk assessment values in sheep and swine.
(b): Median residues expressed according to the residue definition for monitoring, recalculated at the 1N rate for the median dietary burden.
(c): Highest residues expressed according to the residue definition for monitoring, recalculated at the 1N rate for the maximum dietary burden.
(d): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment. The conversion factor was based on the livestock metabolism study and not the feeding study, as derived by the peer review (EFSA, 2011).
(e): For milk, mean was derived from samplings performed from day 4 to day 29 (daily mean of 3 cows).
(f): For eggs, mean and highest residues were derived from samplings performed from day 7 to day 28 (daily mean or daily highest of 12 laying hens).

Conclusion on feeding studies

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

Data on livestock feeding studies were reviewed during the MRL setting process and later in the EU peer review and were considered to be acceptable (EFSA, 2012) and in the MRL review according to Art 12 (EFSA, 2020).
EFSA 2020:
"In the framework of the peer review, feeding studies performed with dairy cows and laying hens were assessed (United Kingdom, 2011; EFSA, 2012b). In the ruminant feeding study, bixafen was administered to cows using different dosing levels ranging from 0.15 to 1.5 mg/kg bw per day (0.5–4.7N) and a separate group to investigate depuration of bixafen residues at a dose rate of 1.5 mg/kg bw per day during feeding phase. In the poultry feeding study, bixafen was administered at dosing levels ranging from 0.092 to 1.007 mg/kg bw per day (0.9–10N).
The studies performed on cows and hens were used to derive MRL and risk assessment values in milk, eggs, and tissues of ruminants and poultry. Since extrapolation from ruminants to pigs is ac-ceptable, results of the livestock feeding study on ruminants were relied upon to derive the MRL and risk assessment values in pigs. All tissue, milk and eggs samples were analysed within 30 days of collection and stored ≤ _18°C thus decline of residues during storage of the trial samples is not expected.
MRL and risk assessment values were derived for all commodities of ruminants, pigs and poultry in compliance with the latest recommendations on this matter (FAO, 2009)."

No risk for consumer was identified in the framework of the MRL review. No MRL exceedances are anticipated arising from the supported uses of GLOB2111F.

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

7.2.5.1 Available data for all crops under consideration

No new data were submitted in the framework of this application. The data evaluated during the Annex I inclusion of bixafen are sufficient to describe the behaviour of the formulated product, and no further studies are required.

Table 7.2-13: Overview of the available processing studies

Processed commodity	Number of studies	Median PF *	Median CF **	Comments	Reference
EU data					
Barley/Pearl barley	4	0.2	1	-	Schoning, Billian & Wolters, 2007 UK, 2011 EFSA, 2012
Barley, Brewers malt	4	0.85	1.25	-	
Barley, Brewer's grain (dry)	3	1	1.1	-	
Barley, beer	4	< 0.1	1	-	

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

For reason of completeness, the data on wheat is present in the table below (EFSA, 2020):

Processed commodity	Number of valid studies[a]	Processing Factor (PF)		CF_P[b]		Comment/Source
		Individual values	Median PF	Individual values	Median CF	
Wheat, white flour	3	0.2, 0.25, 0.5	0.25	3 × 1	1	Czech Republic (2019)
Wheat, white bread	3	< 0.2, < 0.5, < 0.25	< 0.25	3 × 1	1	Czech Republic (2019)
Wheat, wholemeal bread	3	0.5, 0.5, 0.5	0.5	3 × 1	1	Czech Republic (2019)

PF: processing Factor (=Residue level in processed commodity expressed according to RD-Mo/Residue level in raw commodity expressed according to RD-Mo); CF_P: Conversion factor for risk assessment in processed commodity (=Residue level in processed commodity expressed according to RD-RA/Residue level in processed commodity expressed according to RD-Mo). If metabolite M21 < LOQ in processed commodity, CF is considered 1; LOQ: limit of quantification.
(a): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur)
(b): Median of the individual conversion factors for each processing residues trial.

7.2.5.2 Conclusion on processing studies

Intended uses under consideration are covered by sufficient processing studies. Calculated PF values have been used for the risk assessment.

Processing factors show that bixafen residues do not concentrate in processed commodities except slight concentration in brewer's grain (PF 1) and brewer's malt (PF 1.25).

7.2.6 Magnitude of residues in representative succeeding crops

Data dealing with magnitude of residues in succeeding crops are available/have been submitted and are summarized hereafter.

7.2.6.1 Field rotational crop studies (KCA 6.6.2)

Available data

No new data were submitted in the framework of this application. The data evaluated during the Annex I inclusion of bixafen are sufficient to describe the behaviour of the formulated product, and no further studies are required

Table 7.2-14: Summary of available studies in field rotational crops

Primary crop	Rate (kg a.s./ha) (GS at application or PHI)	Residue levels in succeeding crops			
		Succeeding crop group	Succeeding crop	Sowing intervals (DAT)	Reference / Remarks
EU data					
Bare soil	1 x 0.281	Leafy vegetables	Lettuce	1st rotation: 27-32	Schoening, R.; Erler, S., 2008a, 2008b, 2008c and 2008d UK, 2011
		Root and tuber vegetables	Turnip (N-EU)/ carrot (S-EU)	1st rotation: 30-32	

Primary crop	Rate (kg a.s./ha) (GS at application or PHI)	Residue levels in succeeding crops			
		Succeeding crop group	Succeeding crop	Sowing intervals (DAT)	Reference / Remarks
		Cereals	Winter wheat	1st rotation: 28-32	EFSA, 2012
Barley	1 x 0.156 (BBCH 47-49) 1x 0.125 (BBCH 69-71) (13-15 day interval)	Leafy vegetables	Lettuce	2nd rotation: 60-70 3rd rotation: 298-331	
		Root and tuber vegetables	Turnip (N-EU)/ carrot (S-EU)	2nd rotation: 60-70 3rd rotation: 302-331	
		Cereals	Winter wheat	2nd rotation: 120-184 3rd rotation: 278-304	

During the EU Review, four residue trials were conducted to investigate the magnitude of residues in succeeding or rotational crops. Winter/spring wheat, lettuce, and turnip/carrots were grown in soil which had been treated at an application rate of 0.28 kg as/ha (1.1N) and aged for 30 days and in soil which had been previously used to grow barley (treated with 2 foliar applications of bixafen at a combined rate of 0.28 as/ha (1.1N)). The barley crop was harvested at maturity 52 to 73 days after the last application and the soil cultivated ready for planting following crops. Rotational crops were planted into the soil at 60 to 70 and 298 to 331 days after the last application to simulate winter and spring rotations. Rotational crop samples were taken at set intervals up to maturity and analysed for bixafen and desmethyl-bixafen. In all samples bixafen and desmethyl-bixafen residues were below the LOQ of 0.01 mg/kg, with the exception of one sample of lettuce (sampled at an immature growth stage) which contained 0.05 mg/kg of bixafen and one sample of wheat straw in which desmethyl-bixafen residues were found at a concentration of 0.02 mg/kg. On the basis of the studies presented in the evaluation report, EFSA concluded that the probability of bixafen related residues in succeeding crops is low. However, bixafen being a compound with long soil half-lives (field DT_{50} 30.6 - 1235 days), EFSA identified the need to provide additional rotational crop field trials on cereals, leafy vegetables and root vegetables at a dose rate representative of the plateau concentration of bixafen in soil, as studies conducted with the maximum annual application rate over a single year, might not be appropriate to address the actual residues in rotational crops after repeated use of the active substance.

In consequence, new rotational crop studies were submitted and assessed in the framework of MRL review of Bixafen (EFSA, 2020).
Based on the assessment of these new studies (conducted at a more critical gap than the intended one), a plant back interval of 120 days was proposed for pulses and of 365 days for tuber vegetables in order to avoid bixafen residues in these crops following treatment of cereals.
zRMS comment: Nine studies, with several rotational crop field trials conducted in Europe were submitted. In all these trials, bixafen was applied on bare soil, at the dose rate of 930 or 1,130 g a.s./ha, which corresponded to a theoretical soil concentration of 0.31 mg/kg (equivalent to 1N plateau background) or 0.377 mg/kg (equivalent to ~1.1N PEC soil total at 20 cm), respectively. In the rotational field trials, at the nominal plateau concentration of 1N compared to that of the most critical authorised GAP, bixafen residues were observed at or above the LOQ of 0.01 mg/kg in pulses and root and tuber vegetables planted 30 days after the last application (EFSA, 2020).
It should be noted, however, that the trials were performed following application bixafen at the doses of 930-1130 g/ha resulting in soil concentration of 0.31-0.377 mg/kg. The application rate in the present dossier is much lower – 100 g/ha. Therefore the exceedance of MRLs for crops planted as rotational is not expected.

Conclusion on rotational crops studies

The available European data are considered sufficient to support the intended uses of GLOB2111F on cereals and no additional metabolism studies are necessary.

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

7.2.7.1 Residue level in pollen and bee products (KCA 6.10.1)

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

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

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

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

Residues in honey can occur:

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

Therefore, as Cereals are not recognized as melliferous crops, studies considering residues in honey are not required.

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

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

7.2.8.1 Input values for the consumer risk assessment

Consumer risk assessment calculations were performed taking into account all the crops for which an MRL has been set for bixafen under Reg (EU) 2023/1069. In order to account for the fact that the residue definitions for risk assessment in plant and animal commodities are different than the ones for enforcement, EU agreed conversion factors (CF) were used.

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

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition 1: Sum of bixafen and desmethyl-bixafen (M21) expressed as bixafen				
Barley	1.95	EU MRL Reg (EU) 2023/1069 x CF (1.3)	0.08	$STMR_{RA}$
Oat	0.52	EU MRL Reg (EU) 2023/1069 + CF (1.3)	0.08	$STMR_{RA}$
Rye	0.05	EU MRL Reg (EU) 2023/1069 + CF (1)	0.02	$STMR_{RA}$
Wheat	0.3	EU MRL Reg (EU) 2023/1069 + CF (1)	0.02	$STMR_{RA}$
All other commodities	EU MRLs	EU MRL Reg (EU) 2023/1069 + CF (1)	Acute risk assessment performed only considering intended uses	
Risk assessment residue definition 2: Sum of bixafen and desmethyl-bixafen (M21), free and conjugated expressed as bixafen equivalent				
Swine/Bovine/Sheep/Goat: Liver	5.2	EU MRL Reg (EU) 2023/1069 (4) x CF (1.3)	Acute risk assessment performed only considering intended uses	
Swine/Bovine/Sheep/Goat: Kidney	4.4	EU MRL Reg (EU) 2023/1069 (4) x CF (1.1)		
All other commodities	EU MRLs	EU MRL Reg (EU) 2023/1069 + CF (1)		

7.2.8.2 Conclusion on consumer risk assessment

Chronic and acute exposure calculations for all crops were performed using revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo). Results are shown in table Table 7.2-16 below. Extensive calculation sheets are presented in Appendix 3.

Table 7.2-16: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo	98 % (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo	No IEDI calculations were performed as the TMDI calculations were already acceptable. No refinement of the chronic risk assessment is required.
IESTI (% ARfD) according to EFSA PRIMo*	Unprocessed commodities 0.2 % Barley (based on children) 0.1 % Wheat (based on children) Processed commodities

	0.3 % Barley / beer (based on adult) 0.1 % Oat / boiled (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 bixafen in the formulation GLOB2111F do not represent unacceptable acute and chronic risks for the consumer.

No long-term and acute intake concern was identified when bixafen is used according to the proposed GAP.

7.3 Combined exposure and risk assessment

Not relevant. The product contains only one active substance.

7.4 References

EFSA (European Food Safety Authority), 2012. Conclusion on the peer review of the pesticide risk assessment of the active substance bixafen. EFSA Journal 2012; 10(11): 2917. 87 pp.] doi:10.2903/j.efsa.2012.2917.

EFSA (European Food Safety Authority), 2020. Reasoned opinion on the review of the existing maximum residue levels for bixafen according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2020;18(1):5998, 2654 pp. doi:10.2903/j.efsa.2020.5998. 48 pp. https://doi.org/10.2903/j.efsa.2020.5998

EC (European Commission), 2013: Review report for the active substance Bixafen. Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 15 March 2013 in view of the inclusion of Bixafen in Annex I of Council Directive 91/414/EEC. SANCO/10357/2013-Final, 15 March 2013.

United Kingdom, 2011. Draft assessment report on the active substance bixafen prepared by the rapporteur Member State the United Kingdom for the new active substance Bixafen made to the European Commission under Article 11 of Commission Regulation 1107/2009, July 2011.

United Kingdom, 2012. Draft assessment report on the active substance bixafen prepared by the rapporteur Member State the United Kingdom for the new active substance Bixafen made to the European Commission under Article 11 of Commission Regulation 1107/2009, July 2012.

Commission Regulation (EU) 2023/1069.

Final Review report for the active substance bixafen. SANCO/10357/2013 rev 3, 15 March 2013

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

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

List of data submitted by the applicant and relied on

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

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	Billian, P.	2008	Storage stability of BYF 00587 and its metabolite BYF00587-desmethyl in/on wheat (grain, straw, green material), potato tuber, lettuce head and oil seed rape for 24 months. Report No.: MR-06/141 Bayer CropScience AG GLP Unpublished	N	BCS
KCA 6.2.1	Miebach, D.; Bongartz, R.	2007a	Metabolism of [pyrazole-5-^{14}C]BYF00587 in wheat after spray application Report No.: MEF-06/347 Bayer CropScience AG	N	BCS

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GLP Unpublished		
KCA 6.2.1	Miebach, D.; Bongartz, R.	2007b	Metabolism of [dichlorophenyl-UL-^{14}C]BYF00587 in wheat after spray application Report No.: MEF-06/348 Bayer CropScience AG GLP Unpublished	N	BCS
KCA 6.2.1	Spiegel, K.	2007a	Metabolism of [pyrazole-5-^{14}C]BYF00587 in soybeans after spray application Report No.: MEF-07/069 Bayer CropScience AG GLP Unpublished	N	BCS
KCA 6.2.1	Spiegel, K.	2007b	Metabolism of [dichlorophenyl-UL-^{14}C]BYF00587 in soybeans after spray application Report No.: MEF-07/068 Bayer CropScience AG GLP Unpublished	N	BCS
KCA 6.2.2	Koester, J.	2007a	Metabolism of [pyrazole-5-^{14}C]BYF 00587 in the laying hen Report No.: MEF-06/460 Bayer CropScience AG GLP Unpublished	Y	BCS
KCA 6.2.2	[redacted]	2007b	Metabolism of [dichlorophenyl-UL-^{14}C]BYF 00587 in the laying hen [redacted] GLP Unpublished	Y	BCS
KCA 6.2.3	[redacted]	2007a	Metabolism of [pyrazole-5-^{14}C]BYF 00587 in the lactating goat [redacted]	Y	BCS

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			[redacted] GLP Unpublished		
KCA 6.2.3	[redacted]	2007b	Metabolism of [dichlorophenyl-UL-^{14}C]BYF 00587 in the lactating goat [redacted] GLP Unpublished	Y	BCS
KCA 6.3.1	Schoening, R.; Raecker, T.; Erler, S.	2007	Determination of the residues of BYF 00587 in/on spring wheat and winter wheat after spraying of BYF 00587 (125 EC) in the field in Northern France, Sweden, the United Kingdom and Germany Report No.: RA-2320/06 Bayer CropScience AG GLP Unpublished	N	BCS
KCA 6.3.1	Schoening, R.; Reineke, A.	2008a	Determination of the residues of BYF 00587 in/on winter wheat and spring wheat after spraying of BYF 00587 (125 EC) in the field in Northern France, the United Kingdom, Sweden and Germany Report No.: RA-2006/07 Bayer CropScience AG GLP Unpublished	N	BCS
KCA 6.3.1	Schoening, R.; Raecker, T.; Lorenz, S.	2007	Determination of the residues of BYF 00587 in/on winter wheat, wheat, durum and spring wheat after spraying of BYF 00587 (125 EC) in the field in Greece, Italy, Southern France and Spain Report No.: RA-2321/06 Bayer CropScience AG GLP Unpublished	N	BCS
KCA 6.3.1	Schoening, R.; Reineke, A.	2008b	Determination of the residues of BYF 00587 in/on spring wheat, wheat, durum and winter wheat after spraying of BYF 00587 (125 EC) in the field in Southern France, Italy, Spain and Portugal Report No.: RA-2005/07 Bayer CropScience AG	N	BCS

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	**Vertebrate study Y/N**	**Owner**
			GLP Unpublished		
KCA 6.3.2	Schoening, R.; Raecker, T.	2007	Determination of the residues of BYF 00587 in/on spring barley and winter barley after spraying of BYF 00587 (125 EC) in the field in Northern France, Sweden, the United Kingdom and Germany Report No.: RA-2322/06 Bayer CropScience AG GLP Unpublished	N	BCS
KCA 6.3.2	Schoening, R.; Reineke, A.	2008	Determination of the residues of BYF 00587 in/on spring barley after spraying of BYF 00587 (125 EC) in the field in Northern France, Germany, the United Kingdom and Belgium Report No.: RA-2003/07 Bayer CropScience AG GLP Unpublished	N	BCS
KCA 6.3.2	Schoening, R.; Raecker, T.; Erler, S	2007	Determination of the residues of BYF 00587 in/on spring barley and winter barley after spraying of BYF 00587 (125 EC) in the field in Southern France, Italy, Spain and Portugal Report No.: RA-2323/06 Bayer CropScience AG GLP Unpublished	N	BCS
KCA 6.3.2	Schoening, R.; Reineke, A.	2007	Determination of the residues of BYF 00587 in/on spring barley and winter barley after spraying of BYF 00587 (125 EC) in the field in Southern France, Italy and Spain Report No.: RA-2004/07 Bayer CropScience AG GLP Unpublished	N	BCS
KCA 6.4.1	[redacted]	2007	Bixafen: Feeding study laying hens (*Gallus gallus domesticus*) [redacted] GLP Unpublished	Y	BCS

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	**Vertebrate study Y/N**	**Owner**
KCA 6.4.2	[redacted]	2008	Bixafen: Feeding study with dairy cows [redacted] GLP Unpublished	Y	BCS
KCA 6.5.1	Justus, K.; Kuhnke, G.	2008	BYF 00587: Aqueous hydrolysis under conditions of processing studies Report No.: MEF-07/437 Bayer CropScience AG GLP Unpublished	N	BCS
KCA 6.5.3	Schoening, R.; Billian, P.; Wolters, A.	2007	Determination of the residues of BYF 00587 in/on spring barley grain and the processed fractions (brewers's malt; malt culms; ...) after spraying of BYF 00587 (125 EC) in the field in Sweden, Germany and Northern France. Report No.: RA-3324/06 Bayer CropScience AG GLP Unpublished	N	BCS
KCA 6.6.2	Weber, E.; Spiegel, K.; Koehn, D.	2007a	Metabolism of [pyrazole-5-^{14}C]BYF 00587 in confined rotational crops Report No.: MEF-07/071 Bayer CropScience AG GLP Unpublished	N	BCS
KCA 6.6.2	Weber, E.; Spiegel, K.; Koehn, D.	2007b	Metabolism of [dichlorophenyl-UL-^{14}C]BYF 00587 in confined rotational crops Report No.: MEF-07/070 Bayer CropScience AG GLP Unpublished	N	BCS
KCA 6.6.3	Schoening, R.; Erler, S	2008a	Determination of the residues of BYF 00587 in/on the field rotational crops turnip, lettuce, winter wheat and spring wheat after spraying of BYF 00587 (125 EC) in the field in Germany Report No.: RA-2139/06	N	BCS

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	**Vertebrate study Y/N**	**Owner**
			Bayer CropScience AG GLP Unpublished		
KCA 6.6.3	Schoening, R.; Erler, S.	2008b	Determination of the residues of BYF 00587 in/on the field rotational crops turnip, lettuce, winter wheat and spring wheat after spraying of BYF 00587 (125 EC) in the field in Northern France Report No.: RA-2143/06 Bayer CropScience AG GLP Unpublished	N	BCS
KCA 6.6.3	Schoening, R.; Erler, S.	2008c	Determination of the residues of BYF 00587 in/on the field rotational crops turnip, lettuce, winter wheat and spring wheat after spraying of BYF 00587 (125 EC) in the field in Germany Report No.: RA-2144/06 Bayer CropScience AG GLP unpublished	N	BCS
KCA 6.6.3	Schoening, R.; Erler, S.	2008d	Determination of the residues of BYF 00587 in/on the field rotational crops carrot, lettuce and winter wheat after spraying of BYF 00587 (125 EC) in the field in Spain Report No.: RA-2145/06 Bayer CropScience AG GLP Unpublished	N	BCS

The following tables are to be completed by MS.

List of data submitted by the applicant and not relied on

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

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

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

Appendix 2 Detailed evaluation of the additional studies relied upon

No new studies submitted.

Appendix 3 Pesticide Residue Intake Model (PRIMo)

A 3.1 TMDI calculations

Chronic risk assessment: JMPR methodology (IEDI/TMDI)												
				No of diets exceeding the ADI :	---						Exposure resulting from	
	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	MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	98%	NL toddler	19.63	60%	Milk: Cattle	6%	Wheat	5%	Bovine: Muscle/meat	2%	
	59%	UK infant	11.86	39%	Milk: Cattle	6%	Bovine: Muscle/meat	4%	Wheat	0.4%	
	59%	NL child	11.75	24%	Milk: Cattle	6%	Wheat	6%	Swine: Muscle/meat	1.0%	
	57%	FR child 3 15 yr	11.34	23%	Milk: Cattle	8%	Bovine: Muscle/meat	8%	Swine: Muscle/meat	0.8%	
	54%	FR toddler 2 3 yr	10.86	29%	Milk: Cattle	6%	Bovine: Muscle/meat	6%	Swine: Muscle/meat	0.7%	
	51%	GEMS/Food G15	10.20	8%	Sunflower seeds	8%	Barley	7%	Swine: Muscle/meat	0.8%	
	49%	GEMS/Food G08	9.88	10%	Swine: Muscle/meat	9%	Barley	7%	Sunflower seeds	0.8%	
	48%	GEMS/Food G07	9.67	6%	Milk: Cattle	6%	Wheat	6%	Swine: Muscle/meat	0.8%	
	46%	DK child	9.18	13%	Milk: Cattle	12%	Swine: Muscle/meat	7%	Bovine: Muscle/meat	0.4%	
	43%	SE general	8.55	23%	Bovine: Muscle/meat	12%	Milk: Cattle	5%	Wheat	0.4%	
	42%	GEMS/Food G11	8.43	8%	Milk: Cattle	8%	Barley	6%	Swine: Muscle/meat	0.9%	
	41%	ES child	8.24	12%	Milk: Cattle	7%	Bovine: Muscle/meat	7%	Wheat	0.7%	
	40%	RO general	8.03	12%	Milk: Cattle	10%	Sunflower seeds	8%	Wheat	0.6%	
	40%	UK toddler	7.96	21%	Milk: Cattle	7%	Bovine: Muscle/meat	6%	Wheat	0.5%	
	39%	GEMS/Food G10	7.77	6%	Wheat	6%	Barley	5%	Milk: Cattle	0.8%	
	36%	DE child	7.28	20%	Milk: Cattle	6%	Wheat	3%	Swine: Muscle/meat	2%	
	34%	DE general	6.86	12%	Milk: Cattle	6%	Swine: Muscle/meat	5%	Barley	0.6%	
	31%	NL general	6.21	8%	Milk: Cattle	5%	Swine: Muscle/meat	4%	Bovine: Muscle/meat	0.5%	
	30%	IE adult	6.05	6%	Sheep: Liver	4%	Milk: Cattle	3%	Wheat	0.7%	
	30%	DE women 14-50 yr	6.01	12%	Milk: Cattle	5%	Swine: Muscle/meat	3%	Wheat	0.7%	
	27%	GEMS/Food G06	5.37	11%	Wheat	3%	Sunflower seeds	2%	Milk: Cattle	1.0%	
	26%	ES adult	5.26	5%	Milk: Cattle	5%	Barley	4%	Bovine: Muscle/meat	0.4%	
	25%	FR infant	5.01	17%	Milk: Cattle	2%	Swine: Muscle/meat	2%	Bovine: Muscle/meat	0.3%	
	20%	FR adult	4.09	4%	Milk: Cattle	3%	Swine: Muscle/meat	3%	Wheat	0.5%	
	20%	DK adult	3.97	5%	Milk: Cattle	5%	Swine: Muscle/meat	3%	Bovine: Muscle/meat	0.3%	
	17%	LT adult	3.46	5%	Swine: Muscle/meat	4%	Milk: Cattle	2%	Wheat	0.3%	
	13%	PT general	2.64	6%	Wheat	4%	Sunflower seeds	2%	Potatoes	0.4%	
	11%	UK adult	2.24	3%	Bovine: Muscle/meat	3%	Milk: Cattle	3%	Wheat	0.3%	
	11%	IT toddler	2.23	10%	Wheat	0.3%	Potatoes	0.2%	Sunflower seeds	0.4%	
	9%	IE child	1.70	4%	Milk: Cattle	2%	Wheat	1%	Swine: Fat tissue	0.1%	
	8%	UK vegetarian	1.64	3%	Milk: Cattle	3%	Wheat	0.4%	Potatoes	0.3%	
	7%	IT adult	1.41	6%	Wheat	0.2%	Potatoes	0.1%	Sunflower seeds	0.3%	
	7%	FI 3 yr	1.32	2%	Wheat	2%	Oat	1%	Potatoes	0.4%	
	5%	FI 6 yr	1.01	1%	Wheat	1%	Potatoes	0.8%	Oat	0.3%	
	3%	FI adult	0.70	1%	Coffee beans	0.5%	Wheat	0.4%	Potatoes	2%	
	2%	PL general	0.35	1%	Potatoes	0.1%	Carrots	0.1%	Sunflower seeds	0.3%	
	Conclusion: The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI. The long-term intake of residues of Bixafen (R) (F) Reg (EU) 2023/1069 Annex II (F) is unlikely to present a public health concern.											

A 3.2 IEDI calculations

No IEDI calculations were performed as the TMDI calculations were already acceptable.

A 3.3 IESTI calculations - Raw commodities

Unprocessed commodities

Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI): ---				**Results for adults** No. of commodities for which ARfD/ADI is exceeded (IESTI): ---			
IESTI				**IESTI**			
Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.2%	Barley	1.5 / 0.08	0.45	0.2%	Barley	1.5 / 0.08	0.39
0.1%	Wheat	0.3 / 0.02	0.29	0.08%	Wheat	0.3 / 0.02	0.17
0.06%	Rye	0.05 / 0.02	0.13	0.05%	Rye	0.05 / 0.02	0.10
0.04%	Oat	0.4 / 0.08	0.09	0.03%	Oat	0.4 / 0.08	0.05
Expand/collapse list							
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)							

IESTI calculations - Processed commodities

Processed commodities

Results for children				**Results for adults**			
No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---	No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				**IESTI**			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.1%	Oat / boiled	0.4 / 0.08	0.29	0.3%	Barley / beer	1.5 / 0.02	0.58
0.1%	Barley / cooked	1.5 / 0.08	0.29	0.06%	Oat / boiled	0.4 / 0.08	0.12
0.1%	Wheat / milling (flour)	0.3 / 0.02	0.24	0.04%	Wheat / bread/pizza	0.3 / 0.02	0.09
0.1%	Oat / milling (flakes)	0.4 / 0.08	0.24	0.04%	Wheat / pasta	0.3 / 0.02	0.08
0.1%	Barley / milling (flour)	1.5 / 0.08	0.14	0.03%	Wheat / bread (wholemeal)	0.3 / 0.02	0.07
0.1%	Wheat / milling (wholemeal)-I	0.3 / 0.02	0.11	#GETAL!	#GETAL!	#GETAL!	#GETAL!
0.0%	Rye / boiled	0.05 / 0.02	0.07	#GETAL!	#GETAL!	#GETAL!	#GETAL!
0.0%	Rye / milling (wholemeal)-	0.05 / 0.02	0.07	#GETAL!	#GETAL!	#GETAL!	#GETAL!
#GETAL!	#GETAL!	#GETAL!	#GETAL!	#GETAL!	#GETAL!	#GETAL!	#GETAL!
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#GETAL!	#GETAL!	#GETAL!	#GETAL!	#GETAL!	#GETAL!	#GETAL!	#GETAL!
Expand/collapse list							

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short term intake of residues of Bixafen (R) (F)

Appendix 4 Additional information provided by the applicant

No additional data submitted.