REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: BAS 736 00 F

Product name(s): **Miralon**

Chemical active substance(s):

Fluxapyroxad, 50 g/L
Azoxystrobin, 75 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(new authorization)

Applicant: BASF

Submission date: 12/2021

Evaluation date: September 2022

Update: December 2022

MS Finalisation date: January 2023

Version history

When	What
12/2021	Initial dRR - BASF DocID 2021/2043974
09/2022	zRMS-PL evaluation
12/2022	Updated version - BASF DocID 2022/2060358
01/2023	zRMS-PL changes as result of MSs comments

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zRMS's comments or conclusions are highlighted in grey colour.

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 BAS 736 00 F are presented in Table 7.1-1. They have been selected from the individual GAPs in the Central zone for wheat, rye, barley, oat and triticale. A list of all intended uses within the Central zone is given in Part B, Section 0.

Overall conclusion

This dossier is prepared to support the authorisation of the plant protection product BAS 736 00 F (Miralon) in the Central zone of EU Member States to be used as fungicide in cereals. The product is a new EC formulation containing 75 g/L of azoxystrobin and 50 g /L of fluxapyroxad.
All parts of dRR for metabolism and residues submitted by the applicant are considered acceptable. The intended uses in cereals are adequately supported for both azoxystrobin and fluxapyroxad by the required information regarding primary metabolism in plants and live-stock, metabolism in rotational crops, impact of processing on the nature and magnitude of the residue, and magnitude of residues in food and feed commodities.
8 new residue trials in wheat and barley with identical GAP (table 7.1-1) conducted in the NEU have been submitted. The available residue data for the use BAS 736 00 F are considered sufficient to support the applied use on wheat with extrapolation to rye, triticale and on barley with extrapolation to oat in the central zone MSs.

The data available are considered sufficient for risk assessment. An exceedance of the current MRLs of 3 mg/kg (barley, oat) and 0.4 mg/kg (wheat, rye, triticale) for fluxapyroxad as laid down in Reg. (EU) 396/2005 (Reg. (EU) 2022/1324) is not expected.
The chronic and the short-term intakes of fluxapyroxad residues are unlikely to present a public health concern.
The data available are considered sufficient for risk assessment. An exceedance of the current MRLs of 1.5 mg/kg (barley, oat) and 0.5 mg/kg (wheat, rye, triticale) for azoxystrobin as laid down in Reg. (EU) 396/2005 (Reg. (EU) 2022/476) is not expected.
The chronic and the short-term intakes of azoxystrobin residues are unlikely to present a public health concern.

As far as consumer health protection is concerned, zRMS PL agrees with the authorization of the intended uses.

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

Data gaps

Noticed data gaps are: none

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

1	2	3	4	5	6	7		8				9			10	11
						Formulation		Application				Application rate			PHI (days)	
GAP number (see part B.0)*	Crop and/ or situation **	Zone	Product	F, Fn, Fpn G, Gn, Gpn or I***	Pests or Group of pests controlled	Type	Conc. of as	method kind	growth stage & season	number min max	interval between applications (min) (days)	kg as/hL min max	water L/ha min max	kg as/ha min max		Conclusion
1, 12	Wheat (TRZAW, TRZAS, TRZDU, TRZSP)	N-EU	BAS 736 00 F	F	Zymoseptoria tritici - SEPTTR Puccinia triticina - PUCCRT Puccinia striiformis - PUCCST P. tritici-repentis - PYRNTR Blumeria graminis - ERYSGR	SP	50 g/L BAS 700 F + 75 g/L Azoxystrobin	SP	BBCH 30-69	2	21	0.033–0.1 + 0.050-0.150	100 - 300	0.100 (a) + 0.150 (b)	35	A
2, 6, 13	Barley (HORVW, HORVS)	N-EU	BAS 736 00 F	F	Pyrenophora teres - PYRNTE R. secalis - RHYNSE R. collo-cygni - RAMUCC Puccinia hordei - PUCCHD Blumeria graminis - ERYSGR	SP	50 g/L BAS 700 F + 75 g/L Azoxystrobin	SP	BBCH 30-69	2	21	0.033–0.1 + 0.050-0.150	100 - 300	0.100 (a) + 0.150 (b)	35	A
3, 14	Rye (SECCW, SECCS, SECCE)	N-EU	BAS 736 00 F	F	R. secalis - RHYNSE Puccinia recondita - PUCCRE	SP	50 g/L BAS 700 F + 75 g/L Azoxystrobin	SP	BBCH 30-69	2	21	0.033–0.1 + 0.050-0.150	100 - 300	0.100 (a) + 0.150 (b)	35	A
4, 15	Triticale (TTLWI, TTLSO)	N-EU	BAS 736 00 F	F	Zymoseptoria sp. - SEPTSP Puccinia recondita - PUCCRE Puccinia striiformis - PUCCST Blumeria graminis - ERYSGR	SP	50 g/L BAS 700 F + 75 g/L Azoxystrobin	SP	BBCH 30-69	2	21	0.033–0.1 + 0.050-0.150	100 - 300	0.100 (a) + 0.150 (b)	35	A
5, 16	Oat (AVESA)	N-EU	BAS 736 00 F	F	Blumeria graminis - ERYSGR Puccinia coronata - PUCCCA	SP	50 g/L BAS 700 F + 75 g/L Azoxystrobin	SP	BBCH 30-69	2	21	0.033–0.1 + 0.050-0.150	100 - 300	0.100 (a) + 0.150 (b)	35	A
7	Wheat (TRZAW, TRZAS, TRZDU, TRZSP)	N-EU (CZ)	BAS 736 00 F	F	Zymoseptoria tritici - SEPTTR Puccinia triticina - PUCCRT Puccinia striiformis - PUCCST P. tritici-repentis - PYRNTR Blumeria graminis - ERYSGR	SP	50 g/L BAS 700 F + 75 g/L Azoxystrobin	SP	BBCH 30-69	1	N/A	0.033–0.1 + 0.050-0.150	100 - 300	0.100 (a) + 0.150 (b)	35	A

1	2	3	4	5	6	7		8				9			10	11
						Formulation		Application				Application rate			PHI (days)	
GAP number (see part B.0)*	**Crop and/ or situation ****	**Zone**	**Product**	**F, Fn, Fpn G, Gn, Gpn or I*****	**Pests or Group of pests controlled**	**Type**	**Conc. of as**	**method kind**	**growth stage & season**	**number min max**	**interval between applications (min) (days)**	**kg as/hL min max**	**water L/ha min max**	**kg as/ha min max**		**Conclusion**
8	Barley (HORVW, HORVS)	N-EU (CZ)	BAS 736 00 F	F	Pyrenophora teres – PYRNTE R. secalis – RHYNSE R. collo-cygni – RAMUCC Puccinia hordei – PUCCHD Blumeria graminis – ERYSGR	SP	50 g/L BAS 700 F + 75 g/L Azoxystrobin	SP	BBCH 30-69	1	N/A	0.033–0.1 + 0.050-0.150	100 – 300	0.100 (a) + 0.150 (b)	35	A
9	Rye (SECCW, SECCS, SECCE)	N-EU (CZ)	BAS 736 00 F	F	R. secalis - RHYNSE Puccinia recondita - PUCCRE	SP	50 g/L BAS 700 F + 75 g/L Azoxystrobin	SP	BBCH 30-69	1	N/A	0.033–0.1 + 0.050-0.150	100 - 300	0.100 (a) + 0.150 (b)	35	A
10	Triticale (TTLWI, TTLSO)	N-EU (CZ)	BAS 736 00 F	F	Zymoseptoria sp. – SEPTSP Puccinia 8econdite – PUCCRE Puccinia striiformis – PUCCST Blumeria graminis – ERYSGR	SP	50 g/L BAS 700 F + 75 g/L Azoxystrobin	SP	BBCH 30-69	1	N/A	0.033–0.1 + 0.050-0.150	100 – 300	0.100 (a) + 0.150 (b)	35	A
11	Oat (AVESA)	N-EU (CZ)	BAS 736 00 F	F	Blumeria graminis - ERYSGR Puccinia coronata - PUCCCA	SP	50 g/L BAS 700 F + 75 g/L Azoxystrobin	SP	BBCH 30-69	1	N/A	0.033–0.1 + 0.050-0.150	100 - 300	0.100 (a) + 0.150 (b)	35	A

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

** 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

(a) Fluxapyroxad (BAS 700 F)

(b) Azoxystrobin

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 BAS 736 00 F is composed of fluxapyroxad (BAS 700 F) and azoxystrobin.

Table 7.1-2: Toxicological reference values for the dietary risk assessment of fluxapyroxad and azoxystrobin

Reference value	Source	Year	Value	Study relied upon	Safety factor
Fluxapyroxad – Parent compound					
ADI	EFSA	2012	0.02 mg/kg bw per day	2-year rat	100
ARfD	EFSA	2012	0.25 mg/kg bw	developmental toxicity studies: developmental effects in rabbit maternal effects in rat	100
Azoxystrobin - Parent compound					
ADI	EFSA	2010	0.20 mg/kg bw/ day	2-year rat	100
ARfD	EFSA	2010	Not necessary	NA	NA

7.1.2.1 Summary for fluxapyroxad

Table 7.1-3: Summary for fluxapyroxad

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, 7, 12	Wheat	Yes	Yes (8 N-EU, 8 S-EU)	Yes	Yes	Yes	No	No
2, 6, 8, 13	Barley	Yes	Yes (8 N-EU, 8 S-EU)	Yes	Yes	Yes		No
3, 9, 14	Rye	Yes	Yes (8 N-EU, 8 S-EU) **	Yes	Yes	Yes		No
4, 10, 15	Triticale	Yes	Yes (8 N-EU, 8 S-EU) **	Yes	Yes	Yes		No
5, 11, 16	Oat	Yes	Yes (8 N-EU, 8 S-EU) **	Yes	Yes	Yes		No

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

The residue trials have been conducted in wheat and barley. No additional data are required for fluxapyroxad regarding metabolism, residues, industrial and/or household processing or succeeding crops. The available MRLs for fluxapyroxad in wheat, barley, rye, oat and triticale are sufficient to cover the intended uses.

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

The proposed uses of fluxapyroxad in the formulation BAS 736 00 F do not represent unacceptable acute and chronic risks for the consumer.

7.1.2.2 Summary for Axoxystrobin

Table 7.1-4: Summary for Azoxystrobin

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, 7, 12	Wheat	Yes	Yes (8 N-EU, 8 S-EU)	Yes	Yes	Yes	No	No
2, 6, 8, 13	Barley	Yes	Yes (8 N-EU, 8 S-EU)	Yes	Yes	Yes		No
3, 9, 14	Rye	Yes	Yes (8 N-EU, 8 S-EU) **	Yes	Yes	Yes		No
4, 10, 15	Triticale	Yes	Yes (8 N-EU, 8 S-EU) **	Yes	Yes	Yes		No
5, 11, 16	Oat	Yes	Yes (8 N-EU, 8 S-EU) **	Yes	Yes	Yes		No

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

The residue trials have been conducted in wheat and barley. No additional data are required for azoxystrobin regarding metabolism, residues, industrial and/or household processing or succeeding crops. The available MRLs for azoxystrobin in wheat, barley, rye, oat and triticale are sufficient to cover the intended uses.

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

The proposed uses of azoxystrobin in the formulation BAS 736 00 F do not represent unacceptable acute and chronic risks for the consumer.

7.1.2.3 Summary for BAS 736 00 F

Waiting periods prior to planting succeeding crops are not required. This is not relevant here since a pre-emergence use is not intended and application of BAS 736 00 F is directed to the crop only. Withholding period/PHI is detailed in the following table.

Table 7.1-5: Information on BAS 736 00 F (KCA 6.8)

Crop	PHI for BAS 736 00 F proposed by applicant	PHI/ Withholding period* sufficiently supported for		PHI for BAS 736 00 F proposed by zRMS	zRMS Comments (if different PHI proposed)
		Fluxapyroxad	Azoxystrobin		
Wheat	35 days	Yes	Yes	35	-
Barley	35 days	Yes	Yes	35	-
Rye	35 days	Yes	Yes	35	-
Triti-cale	35 days	Yes	Yes	35	-
Oat	35 days	Yes	Yes	35	-

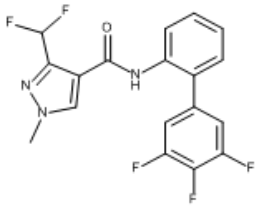
NR: not relevant
* Purpose of withholding period to be specified
** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

Assessment

7.2 Fluxapyroxad

General data on Fluxapyroxad are summarized in the table below (last updated 2021/08/23)

Table 7.2- 1: General information on fluxapyroxad

Active substance (ISO Common Name)	Fluxapyroxad
IUPAC	3-(difluoromethyl)-1-methyl-*N*-(3′,4′,5′-trifluorobi-phenyl-2-yl)pyrazole-4-carboxamide
Chemical structure	
Molecular formula	$C_{18}H_{12}F_5N_3O$
Molar mass	381.31 g/mol
Chemical group	Carboxamide
Mode of action (if available)	Inhibition of succinate dehydrogenase in complex II of the mitochondrial respiratory chain (inhibition of spore germination, germ tubes and mycelial growth within the fungus target species)
Systemic	Yes
Company (ies)	BASF SE*
Rapporteur Member State (RMS)	France (formerly United Kingdom)
Approval status	Approved 01/01/2013 Reg. (EU) No 2020/2007 Reg. (EU) No 589/2012 Dossier complete 2010/672/EU
Restriction	None
Review Report	SANCO/10692/2012 Rev 2, 25/03/2021
Current MRL regulation	Regulation (EU) 2020/856 New MRLs will apply from 10/11/2021 (Reg. (EU) 2021/644) New MRLs will apply from 18/08/2022 (Reg. (EU) 2022/1324)
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes**, EFSA 2020
EFSA Journal: Conclusion on the peer review	Yes**, EFSA 2012
EFSA Journal: conclusion on article 12	Yes**, EFSA 2020
Current MRL applications on intended uses	No current applications on cereals.

* Notifier in the EU process to whom the a.s. belong(s)
** If yes: EFSA, 2020, 2012 - 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.

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			
Cereal grain Wheat grain	High starch content	BAS 700 F: 737 M700F002: 824 M700F048: 733 M700F008: 725 M700F008: 1108	EFSA 2012, UK 2011a, JMPR, 2012, UK 2011b BASF DocIDs 2009/1072397 2010/7016724 2009/1072398 2010/1009625 2009/1072399 2011/1125600 2009/1072400 2011/1124183 2011/1141383
Apple, grape, tomato, potato tuber, Wheat forage	High water content	BAS 700 F: 737 M700F002: 824 M700F048: 733 M700F008: 1155	
Soybean seed Avocado fruit	High lipid content	BAS 700 F: 737 M700F002: 824 M700F048: 733 M700F008: 1149	
Dry pea seed	High protein content	BAS 700 F: 737 M700F002: 824 M700F048: 733	
Lemon fruit	High acid content	BAS 700 F: 737 M700F002: 824 M700F048: 733	
Wheat straw	Not assigned to group	M700F008: 725 M700F008: 1106	
Animal Products			
As far as residues in animal matrices (egg, milk, tissues) are concerned, freezer storage stability data is not required to support the submitted data packages as samples generally were stored frozen, not exceeding 30 days.			

Conclusion on stability of residues during storage

EFSA, 2020:

"The storage stability of fluxapyroxad was investigated in the framework of the peer review (United Kingdom, 2011a,b, EFSA, 2012). Fluxapyroxad was found to be stable in all plant matrices for a period of 737 days when stored at –20°C (EFSA, 2012). Moreover, when stored at –20°C, metabolite M700F002 was stable for 824 days in all plant matrices, metabolite M700F048 for 733 days in high starch, high acid, high oil and high water content matrices and in wheat straw and metabolite M700F008 was stable 725 days in high starch matrices and in wheat straw, and up to 133 days in high oil and high water content matrices (EFSA, 2012)."

Demonstration of storage stability of fluxapyroxad samples in animal matrices is not required as samples were analysed within 30 days.

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

Available data

For plant matrices, fortified samples were analyzed along with validation of analytical BASF Method No. L0137/01 (BASF DocID 2009/1074617, see chapter 5.2) to show the stability of the analytes fluxapyroxad, M700F002, M700F008 and M700F0048. In six representative plant extracts (wheat grain, pea seed, onion bulb, lemon fruit, tomato fruit, soybean oil) stability under refrigerator conditions (about 6°C, in the dark) was proven for time periods of at least 6 to 15 days (depending on matrix and analyte).

For animal matrices, fortified samples were analyzed along with validation of analytical BASF Method No. L0140/02 to show the stability of the analytes fluxapyroxad, M700F002, M700F008 and M700F0048 (BASF DocID 2009/1074613, see chapter 5.2). In two representative extracts (cow liver, hen egg) stability under refrigerator conditions (about 6°C, in the dark) was proven for time periods of at least 7 days.

Conclusion on stability of residues in sample extracts

The analytes fluxapyroxad and its metabolites M700F002, M700F008 and M700F048 were stable in the extracts used for analysis of residues samples treated with BAS 736 00 F.

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.

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)	Re-mark	
EU data								
Fruits and fruiting vegetable	Tomato	Aniline-U-^{14}C/ Pyrazole-4-^{14}C	Foliar treatment G	0.1	3	3		UK, 2011a EFSA, 2012 BASF DocID 2009/1017901
Pulses and oilseeds	Soya bean	Aniline-U-^{14}C/ Pyrazole-4-^{14}C	Foliar treatment G	0.6	3	Forage (0, 21 DAT 1st treatm.); Hay (22 DALA), straw, hull, seed (34 DALA)		UK, 2011a EFSA, 2012 BASF DocID 2009/1017387

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (kg a.s./ha)	No	Sampling (DAT)	Remark	
Cereals	Wheat	Aniline-U-^{14}C/ Pyrazole-4-^{14}C	Foliar treatment G	0.125	2	Wheat forage (36 DAT) Hay (4 DALA) grain, chaff, straw (34-35 DALA)		UK, 2011a EFSA, 2012 BASF DocID 2009/1048403

Summary of plant metabolism studies reported in the EU

The metabolism of fluxapyroxad (BAS 700 F) was investigated in tomatoes (fruit crops), soya bean (pulses and oilseed crops) and in wheat (cereals) under greenhouse conditions after foliar spray applications using the ^{14}C labelling on the aniline and the pyrazole moieties, respectively.
Fluxapyroxad was identified as the major component of the radioactive residues in the tomato and cereal plant parts investigated, accounting for 54% TRR up to more than 90% TRR and residue concentrations of 0.03 mg/kg in wheat grain and up to 0.16 mg/kg in tomato fruit. The metabolism was more extensive in soya bean seed where fluxapyroxad accounted for only 7% TRR up to 21% TRR, and the major metabolites were identified as M700F002 (33.5% TRR, pyrazole labelling) and M700F048 (20% TRR, aniline labelling). Minor metabolites were identified at very low levels, accounting for less than 2% of the TRR.

Based on these studies, the main routes of biotransformation of fluxapyroxad (BAS 700 F) in plants were proposed to consist of N-demethylation of the pyrazole moiety, and hydroxylation of the biphenyl moiety with further glycosidation of the molecule. A minor pathway consisted of the loss of a fluorine atom at the biphenyl ring. No cleavage of the molecule was foreseen and the presence of the metabolite M700F002 in soybean seeds resulting from the cleavage of the carboxamide bond was assumed to result from its uptake from the soil, where M700F002 was identified as a major soil metabolite. This statement is supported by the fact that the corresponding biphenyl counterpart metabolites were not detected in the primary crops when the labelling on the aniline moiety was used, and also by the higher total radioactive residues measured in soybean seeds in the ^{14}C-pyrazole study compared to the ^{14}C-aniline study (0.26 mg/kg vs. 0.12 mg/kg).

Conclusion on metabolism in primary crops

It can be concluded from the available metabolism studies that for the compound BAS 700 F a plant typical metabolic pathway exists. This has been shown in different crops.

EFSA, 2020:
The metabolic pathway of fluxapyroxad was similar in fruits, pulses and oilseeds and cereals following foliar application, and in cereals after seed treatment. The application of fluxapyroxad on witloofs is authorised for post-harvest treatment (dipping, drenching of roots, before forcing), for which no metabolism study was submitted. However, considering that the behaviour of fluxapyroxad is the same in three crop groups following foliar application and soil treatments (in rotational crops), it can be assumed that the metabolism following post-harvest treatment would also follow the same pathway. Therefore, no metabolism study following post-harvest treatment is required.
The application of fluxapyroxad on several root crops (e.g. potatoes) is in the form of soil treatment, for which no metabolism study was submitted. However, since the metabolism observed in rotational crops, following bare soil application, was similar to the primary crop metabolism […], further metabolism studies in primary roots following soil treatment are not required and deemed covered by the metabolism studies in rotational crops."

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

No new data submitted in the framework of this application.

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

Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G *	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Re-mark	
EU data								
Leafy vegetables	Spinach	Pyrazole 4-^{14}C	G	0.25	30 149 365	143 166 428		UK, 2011a EFSA, 2012 BASF DocID 2009/1074683 2009/1074684
	Spinach	Aniline U-^{14}C	G	0.25	30 120 365	83 180 422		
Root and tuber vegetables	Radish (White)	Pyrazole 4-^{14}C	G	0.25	30 149 365	- 215 447		
	Radish (White)	Aniline U-^{14}C	G	0.25	30 120 365	105 196 455		
Cereals	Wheat (Spring)	Pyrazole 4-^{14}C	G	0.25	30 149 365	162 223 527		
	Wheat (Spring)	Aniline U-^{14}C	G	0.25	30 120 365	161 253 519		

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

Summary of plant metabolism studies reported in the EU

In confined rotational crop studies, the soil was treated once at a dose rate of 250 g a.s./ha (1 N) with ^{14}C-fluxapyroxad labelled either on the pyrazole or the aniline moiety. Spinach, radish and spring wheat were planted at plant back intervals of 30, 149 and 365 days. A similar residue pattern as in the primary crops was observed in the edible parts of the rotated crops.

EFSA, 2020

"One confined rotational crop study with fluxapyroxad radiolabelled on the aniline and pyrazole rings of the molecule was available for this review (United Kingdom, 2011a; EFSA, 2012). Fluxapyroxad was applied once at a rate of 250 g a.s./ha onto bare soil. Spinach, white radish and spring wheat were planted at nominal plant back intervals (PBI) of 30, 120/149 and 365 days after treatment (DAT). Residues in wheat straw were up to 2.2 mg/kg (pyrazole label) and 2.65 mg/kg (aniline label), in spinach up to 0.18 mg/kg and 0.1 mg/kg for the pyrazole and aniline labels, respectively, and in roots up to 0.015 mg/kg for both labels (United Kingdom, 2011a). Residues in wheat grain accounted for 0.043 mg/kg and 0.02 mg/kg for the pyrazole and aniline labels, respectively (United Kingdom, 2011a). Fluxapyroxad was the major component in all matrices, while metabolite M700F002 was also present at relevant levels in all matrices."

Conclusion on metabolism in rotational crops

The metabolism found in rotational crop studies proved to be in accordance with the results from primary crops.

EFSA, 2020:
"Fluxapyroxad is authorised on crops that may be grown in rotation. The field DT_{90} reported in the soil degradation studies evaluated in the framework of the peer review was higher than 1000 days (EFSA, 2012).
... No specific compound for rotational crops was identified. The metabolism and distribution of fluxapyroxad in rotational crops are similar to the metabolic pathway observed in primary crops (EFSA, 2012)."

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.

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)	BAS 700 F (97.3%)	UK, 2011a EFSA, 2012 BASF DocID 2009/1049060
Baking, boiling, brewing (60 minutes, 100°C, pH 5)	BAS 700 F (101.6%)	
Sterilisation (20 minutes, 120°C, pH 6)	BAS 700 F (96.7%)	

Conclusion on nature of residues in processed commodities

Fluxapyroxad (BAS 700 F) was shown to remain stable under standard hydrolytic conditions representative of pasteurization, baking, boiling, brewing and sterilization.

EFSA, 2020:
"Studies investigating the nature of residues in processed commodities were assessed in the peer review (United Kingdom, 2011b; EFSA, 2012). Studies were conducted with radiolabelled fluxapyroxad on the ring simulating representative hydrolytic conditions for pasteurisation (20 min at 90°C, pH 4), boiling/brewing/baking (60 min at 100°C, pH 5) and sterilisation (20 min at 120°C, pH 6).
Fluxapyroxad is stable to hydrolysis under standard conditions of pasteurisation, baking/brewing/boiling and sterilisation (EFSA, 2012)."

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

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

Endpoints	
Plant groups covered	Cereals (wheat) Fruit (tomato) Pulses and oilseeds (soybean)
Rotational crops covered	Confined metabolism studies on leafy crops (spinach), root crops (radish) and cereals (wheat)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Fluxapyroxad is stable under standard hydrolysis conditions
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes
Plant residue definition for monitoring	Fluxapyroxad (BAS 700 F), all crop categories (EFSA 2012)
Plant residue definition for risk assessment	Fluxapyroxad (BAS 700 F), all crop categories (EFSA 2012)
Conversion factor from enforcement to RA	n/a

7.2.2.5 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 ani-mal**	**Application details**		**Sample details**		**Reference**
				Rate (mg/kg bw/d)	**Duration (days)**	**Commod-ity**	**Time of sampling**	
EU data								
Lactating rumi-nants	Goat	Aniline-U-^{14}C/ Pyrazole-4-^{14}C BAS 700 F	4	0.39 – 0.44 mg/kg bw/day	8	Milk	twice daily	UK, 2011a EFSA, 2012 BASF DocID 2009/1065024 2009/1074074
						Urine and faeces	daily	
						Tissues	at sacrifice	
Laying poultry	Hens	Aniline-U-^{14}C/ Pyrazole-4-^{14}C BAS 700 F	12	0.76 mg/kg bw/d	12	Eggs	twice daily	UK, 2011a EFSA, 2012 BASF DocID 2009/1065025 2009/1069223
						Excreta	daily	
						Tissues	at sacrifice	
Lactating rumi-nants	Goat	Aniline-U-^{14}C/ Pyrazole-4-^{14}C M700F002F	2	0.38 and 0.42 mg/kg bw/day	8	Milk	twice daily	UK, 2011a EFSA, 2012 BASF DocID 2009/1074682
						Urine and faeces	daily	
						Tissues	at sacrifice	

Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling	
Poultry	Laying hens	Pyrazole-4-^{14}C M700F002	10	0.84 mg/kg bw/day	10	Eggs	daily	UK, 2011b BASF DocID 2009/1083000 2009/1078621
						Excreta	daily	
						Tissues	at sacrifice	

Summary of animal metabolism studies reported in the EU

EFSA 2012:
Metabolism studies on lactating goats and laying hens were provided showing that besides the parent compound, the desmethyl metabolite M700F008 was found to be a significant compound of the total residues in all the ruminant and poultry matrices (17% to 83% TRR). Further minor metabolites were detected at a trace level (<0.01 mg/kg) and resulted from the hydroxylation of the biphenyl moiety with a further step of conjugation reactions with glucuronic acid, amino acids or sulfate. An additional metabolism study on poultry using the ^{14}C-labelled M700F002 was provided and evaluated in Addendum 2 to the DAR (UK, 2011). Unchanged M700F002 was the major component of the total residues identified in all matrices (30% to 90% TRR). The agreed residue definition for monitoring in animal matrices is the parent compound only, whereas for risk assessment it is proposed to include both the parent compound and the desmethyl metabolite M700F008 expressed as parent equivalent.

EFSA, 2020:
"The metabolism of fluxapyroxad residues in livestock was investigated in lactating goats and laying hens (United Kingdom, 2011a) at dose rates covering the maximum dietary burdens calculated in this review (2.5–10 N). These studies were assessed in the framework of the peer review (EFSA, 2012). In all studies, fluxapyroxad was radiolabelled in the aniline and/or pyrazole ring of the molecule. The study on lactating goats fed for 8 consecutive days with 0.4 mg/kg body weight (bw) per day showed that fluxapyroxad was rapidly excreted, with more than 80% of the TRR recovered in urine and faeces. Parent was the main constituent, while another predominant component was metabolite M700F008 present at relevant levels in ruminant matrices (EFSA, 2012).
The study performed on laying hens fed for 12 consecutive days with 11.5 mg/kg feed (equivalent to 0.4 mg/kg bw per day) showed that fluxapyroxad was extensively degraded in livestock matrix (<0.5% and 0.18% of the TRR in tissues and eggs, respectively). The parent and metabolite M700F008 were the main constituents of the residues in hens. In livestock, parent compound and metabolite M700F008 were the main constituents of the residues in all matrices. All other identified metabolites were present at more than 10% TRR but at levels lower than 0.003 mg/kg. Therefore, the metabolism of fluxapyroxad in livestock is adequately elucidated, and fluxapyroxad and metabolite M700F008 are the most relevant components of the residues in livestock commodities (EFSA, 2012). As the parent compound was found to be a sufficient marker in livestock commodities, the residue definition for enforcement is proposed as fluxapyroxad only. An analytical method using HPLC-MS/MS and its independent laboratory validation (ILV) have been provided and fully validated for the determination of fluxapyroxad in foodstuff of animal origin with an LOQ of 0.01 mg/kg for liver, kidney, fat and muscle and an LOQ of 0.001 mg/kg for milk, eggs and cream (EFSA, 2012)."

Conclusion on metabolism in livestock

Based on the available metabolism studies in livestock the following residue definitions were agreed: for monitoring in animal matrices it is the parent compound only, whereas for risk assessment it is proposed to include both the parent compound and the desmethyl metabolite M700F008 expressed as parent equivalent.

EFSA, 2020:
"In the framework of the peer review upon consideration of metabolism data and mammalian toxicology information, the residue for risk assessment was defined as sum of fluxapyroxad and metabolite M700F008, expressed as parent equivalent (EFSA, 2012). The same residue definition is proposed for the current review."

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	Milk: 5-7 days (feeding study); rapid depletion of the total radioactivity 1-day post dosing.
	Eggs: 10-12 days (metabolism study)
Animal residue definition for monitoring	Fluxapyroxad (BAS 700 F)
Animal residue definition for risk assessment	Fluxapyroxad (BAS 700 F) and metabolite M700F008 expressed as parent equivalent.
Conversion factor	N/A A feeding study analyzing fluxapyroxad (BAS 700 F), and metabolites M700F008 and M700F002 in poultry and ruminant matrices is available.
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	Yes Log P_{ow} at pH 7 = 3.13 Feeding studies indicate the highest residue level in ruminant fat (0.024 mg/kg).

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

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application. These studies are summarized in the Table below. The detailed assessment of these studies is presented in Appendix 2.

Table 7.2- 9: Summary of EU reported and new data supporting the intended uses of BAS 736 00 F 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)	Un-rounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Barley grains → extrapolation to oat grains	EFSA, 2020	Import (US&Canada) *(2010/7003693)*	Trials GAP: 2 x 0.100 kg as/ha, PHI 21d E/RA: <0.01, 0.41, 2x 0.42, 0.52, 2x 0.54, 0.55, 0.82, 0.88, 1.09, 1.65	N/A				
	New trials	N-EU	Trials GAP: 2 x 0.1 kg as/ha, PHI 35d E/RA: 0.024, 0.033, 0.044, 0.078, 0.098, 2x 0.12, 0.16					
	Overall supporting data for cGAP	N-EU	E/RA: 0.024, 0.033, 0.044, 0.078, 0.098, 2x 0.12, 0.16	E/RA: 0.088	E/RA: 0.16	0.278	3	Yes
	New trials	S-EU[1]	Trials GAP: 2 x 0.1 kg as/ha, PHI 35d E/RA: 0.015, 0.023, 0.034, 0.057, 0.082, 0.12, 0.17, 1.0	N/A				
	Overall supporting data for cGAP	S-EU[1]	E/RA: 0.015, 0.023, 0.034, 0.057, 0.082, 0.12, 0.17, 1.0	E/RA: 0.070	E/RA: 1.00	1.5	3	Yes

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)	Un-rounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Barley straw → extrapolation to oat straw	EFSA, 2011	Import (Canada)[2] *(2010/7003693)*	Trials GAP: 2 x 0.100 kg as/ha, PHI 21d E/RA: 0.78, 3.95, 4.11, 4.55, 5.96, 10.1	N/A				
	EFSA, 2012	N-EU[2]	Trials GAP: 2 x 0.125 kg as/ha, BBCH 25-69, PHI 35d E/RA: 0.11, 0.12, 0.44, 0.47, 0.64, 0.74, 1.79, 2.37					
	EFSA, 2020	N-EU[2]	Trials GAP: 2 x 0.125 kg as/ha, BBCH 25-69, PHI 35d E/RA: 0.47, 0.62, 0.64, 0.70, 0.74, 0.99, 1.30, 1.50, 1.54, 1.71, 1.79, 2.10, 2.37, 2.39, 2.45, 3.55					
	New trials	N-EU	Trials GAP: 2 x 0.1 kg as/ha, PHI 35d E/RA: 0.10, 0.28, 0.50, 0.84, 1.1, 1.2, 1.6, 3.8					
	Overall supporting data for cGAP	N-EU	E/RA: 0.10, 0.28, 0.50, 0.84, 1.1, 1.2, 1.6, 3.8	E/RA: 0.970	E/RA: 3.80	N/A	N/A	N/A
	EFSA, 2012	S-EU[1, 2]	Trials GAP: 2 x 0.125 kg as/ha, BBCH 25-69, PHI 35d E/RA: 0.11, 0.36, 0.45, 0.80, 0.96, 1.03, 1.29, 1.24	N/A				
	EFSA, 2020	S-EU[1, 2]	Trials GAP: 1-2 x 0.125 kg as/ha, PHI 35d E/RA: 0.11, 0.22, 0.45, 0.49, 0.76, 0.91, 2x0.96, 1.24, 1.29, 2x2.2, 2.68, 2.83, 2.89, 2.90, 2.95					
	New trials	S-EU[1]	Trials GAP: 2 x 0.1 kg as/ha, PHI 35d E/RA: 0.059, 0.14, 0.29, 0.71, 0.74, 1.3, 3.0, 3.2					

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)	Un-rounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
	Overall supporting data for cGAP	S-EU[1]	E/RA: 0.059, 0.14, 0.29, 0.71, 0.74, 1.3, 3.0, 3.2	E/RA: 0.725	E/RA: 3.20	N/A	N/A	N/A
Wheat grains → extrapolation to rye and triticale grains	EFSA, 2020	Import (Canada) *(2010/7003693)*	Trials GAP: 2 x 0.100 kg as/ha, PHI 21d E/RA: 2x 0.05, 0.07, 0.08, 0.11, 2x 0.12, 0.17, 0.19, 0.21	N/A				
	New trials	N-EU	Trials GAP: 2x 0.1 kg as/ha, PHI 35d E/RA: <0.010, 0.012, 2x 0.013, 0.016, 0.028, 0.032, 0.057					
	Overall supporting data for cGAP	N-EU	E/RA: <0.010, 0.012, 2x 0.013, 0.016, 0.028, 0.032, 0.057	E/RA: 0.015	E/RA: 0.057	0.087	0.4	Yes
	New trials	S-EU[1]	Trials GAP: 2 x 0.1 kg as/ha, PHI 35d E/RA: <0.010, 0.014, 0.015, 0.025, 0.027, 0.033, 0.058, 0.17	N/A				
	Overall supporting data for cGAP	S-EU[1]	E/RA: <0.010, 0.014, 0.015, 0.025, 0.027, 0.033, 0.058, 0.17	E/RA: 0.026	E/RA: 0.170	0.256	0.4	Yes
Wheat straw → extrapolation to rye and triticale straw	EFSA, 2011	Import (USA&Canada) [2] *(2010/7003693)*	Trials GAP: 2 x 0.100 kg as/ha, PHI 21d E/RA: 0.58, 0.81, 0.97, 1.00, 1.16, 1.19, 1.24, 1.29, 1.41, 1.52, 1.87, 2.00, 2.25, 2.50, 2.60, 2.85, 3.09, 3.46, 4.67, 5.39, 6.44, 7.00, 7.43, 8.32					
	EFSA, 2012	N-EU[2]	Trials GAP: 2 x 0.125 kg as/ha, BBCH 25-69, PHI 35d E/RA: 0.44, 1.0, 1.02, 1.80, 2.78, 6.05 (wheat) E/RA: 0.32, 1.55 (triticale)					

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)	Un-rounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
	EFSA, 2020	N-EU[2]	Trials GAP: 2 x 0.125 kg as/ha, PHI 35d E/RA: 0.41, 0.44, 0.52, 0.95, 1.0, 1.02, 1.04, 1.1, 1.17, 1.53, 1.56, 1.80, 2.78, 3.92, 4.58, 6.05					
	New trials	N-EU	Trials GAP: 2 x 0.1 kg as/ha, PHI 35d E/RA: 0.13, 0.29, 0.47, 0.95, 1.4, 1.5, 1.7, 2.0					
	Overall supporting data for cGAP	N-EU	E/RA: 0.13, 0.29, 0.47, 0.95, 1.4, 1.5, 1.7, 2.0	E/RA: 1.175	E/RA: 2.00	N/A	N/A	N/A
	EFSA, 2012	S-EU[1, 2]	Trials GAP: 2 x 0.125 kg as/ha, BBCH 25-69, PHI 35d E/RA: 0.46, 0.55, 0.64, 1.0, 1.19, 2.58 (wheat) E/RA: 0.49, 0.55 (triticale)	N/A				
	EFSA, 2020	S-EU[1, 2]	Trials GAP: 1-2 x 0.125 kg as/ha, PHI 35d E/RA: 0.11, 0.38, 0.46, 0.55, 0.63, 0.64, 0.71, 0.75, 1.0, 1.19, 1.76, 2.23, 2.58, 2.67, 5.83, 5.85					
	New trials	S-EU[1]	Trials GAP: 2 x 0.1 kg as/ha, PHI 35d E/RA: 0.41, 0.48, 0.50, 0.70, 0.85, 1.0, 1.6, 3.0					
	Overall supporting data for cGAP	S-EU[1]	E/RA: 0.41, 0.48, 0.50, 0.70, 0.85, 1.0, 1.6, 3.0	E/RA: 0.775	E/RA: 3.00	N/A	N/A	N/A

* Source of EU MRL: Reg. (EU) 2020/856 and Reg. (EU) 2022/1324 applicable from: 18/08/2022

1 S-EU data shown for information only. N-EU data used for further evaluation.

2 As no MRLs are derived from residue data on straw data is shown for the sake of completeness.

7.2.3.2 Conclusion on the magnitude of residues in plants

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

According to appendix D of EU guidelines, extrapolation to oat is possible with 8 trials on barley, which is the case here.

According to appendix D of EU guidelines, extrapolation to rye is possible with 8 trials on wheat, which is the case here.

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

The uses are considered acceptable.

zRMS:
In support of the use of BAS 736 00 F in the central zone MSs sufficient GAP compliant residue trials on cereals are available: 8 new trials with identical GAP conducted in the NEU on each crop - wheat and barley have been submitted by the applicant.
Residues of fluxapyroxad were also determined in wheat and barley straw.
The available residue data for the use BAS 736 00 F are considered sufficient to support the applied use on wheat with extrapolation to rye, triticale and on barley with extrapolation to oat in the central zone MSs.
The fluxapyroxad MRLs of 0.4 mg/kg for wheat, rye, triticale and 3 mg/kg for barley, oat (Reg. (EU) 2022/1324 applicable from: 18/08/2022) are not exceeded.

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

For calculation of the dietary burden the EFSA animal model 2017 was used. Input values are taken from the Article 12 evaluation (EFSA, 2020) and from the values calculated above for the newly submitted studies on barley, oat, wheat, rye and triticale.

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: fluxapyroxad					
Barley	straw	0.97	STMR	3.80	HR
Cabbage	heads	0.01	STMR (EFSA, 2020)	0.27	HR (EFSA, 2020)
Oat	straw	0.97	STMR (extrapolated from barely)	3.80	HR (extrapolated from barely)
Rye	straw	1.18	STMR (extrapolated from wheat)	2.00	HR(extrapolated from wheat)
Triticale	straw	1.18	STMR (wheat)	2.00	HR (wheat)

Feed Commodity		Median dietary burden		Maximum dietary burden	
		Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Turnip	top (leaves)	0.03	STMR (EFSA, 2020)	0.07	HR (EFSA, 2020)
Wheat	straw	1.18	STMR	2.00	HR
Carrot	culls	0.12	STMR (EFSA, 2020)	0.26	HR (EFSA, 2020)
Cassava	roots	0.03	STMR (EFSA, 2020)	0.08	HR (EFSA, 2020)
Potato	culls	0.09	STMR (EFSA, 2020)	0.12	HR (EFSA, 2020)
Swede	roots	0.12	STMR (EFSA, 2020)	0.26	HR (EFSA, 2020)
Turnip	roots	0.12	STMR (EFSA, 2020)	0.26	HR (EFSA, 2020)
Barley	grain	0.09	STMR	0.09	STMR
Oat	grain	0.09	STMR	0.09	STMR
Bean	seed (dry)	0.01	STMR (EFSA, 2020)	0.01	STMR (EFSA, 2020)
Corn, field (Maize)	grain	0.01	STMR (EFSA, 2020)	0.01	STMR (EFSA, 2020)
Corn, pop	grain	0.01	STMR (EFSA, 2020)	0.01	STMR (EFSA, 2020)
Cowpea	seed	0.01	STMR (EFSA, 2020)	0.01	STMR (EFSA, 2020)
Lupin	seed	0.01	STMR (EFSA, 2020)	0.01	STMR (EFSA, 2020)
Pea (Field pea)	seed (dry)	0.04	STMR (EFSA, 2020)	0.04	STMR (EFSA, 2020)
Sorghum	grain	0.19	STMR (EFSA, 2020)	0.19	STMR (EFSA, 2020)
Soybean	seed	0.01	STMR (EFSA, 2020)	0.01	STMR (EFSA, 2020)
Triticale	grain	0.02	STMR (wheat)	0.02	STMR (wheat)
Wheat	grain	0.02	STMR	0.02	STMR
Rye	grain	0.02	STMR (extrapolated from wheat)	0.02	STMR (extrapolated from wheat)
Apple	pomace, wet	0.254 × 4.6	STMR × PF (EFSA, 2020)	0.254 × 4.6	STMR × PF (EFSA, 2020)
Beet, sugar	dried pulp	0.121 × 1.7	STMR × PF (EFSA, 2020)	0.121 × 1.7	STMR × PF (EFSA, 2020)
Beet, sugar	ensiled pulp	0.121 × 0.4	STMR × PF (EFSA, 2020)	0.121 × 0.4	STMR × PF (EFSA, 2020)
Beet, sugar	molasses	0.121 × 0.8	STMR × PF (EFSA, 2020)	0.121 × 0.8	STMR × PF (EFSA, 2020)
Brewer's grain	dried	0.09 × 3.3	STMR × PF_d (EFSA, 2020)	0.09 × 3.3	STMR × PF_d (EFSA, 2020)
Canola (Rape seed)	meal	0.09 × 0.4	STMR × PF (EFSA, 2020)	0.09 × 0.4	STMR × PF (EFSA, 2020)
Citrus	dried pulp	0.1 × 0.1	STMR × PF (EFSA, 2020)	0.1 × 0.1	STMR × PF (EFSA, 2020)
Corn, field	milled by-pdts	0.01 × 1.0	STMR × PF_d (EFSA, 2020)	0.01 × 1.0	STMR × PF_d (EFSA, 2020)
Corn, field	hominy meal	0.01 × 6.0	STMR × PF_d (EFSA, 2020)	0.01 × 6.0	STMR × PF_d (EFSA, 2020)

Feed Commodity		Median dietary burden		Maximum dietary burden	
		Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Corn, field	gluten feed	0.01 × 2.5	STMR × PF_d (EFSA, 2020)	0.01 × 2.5	STMR × PF_d (EFSA, 2020)
Corn, field	gluten, meal	0.01 × 1.0	STMR × PF_d (EFSA, 2020)	0.01 × 1.0	STMR × PF_d (EFSA, 2020)
Distiller's grain	dried	0.02 × 3.3	STMR × PF_d (EFSA, 2020)	0.02 × 3.3	STMR × PF_d (EFSA, 2020)
Flaxseed/Linseed	meal	0.09 × 2	STMR × PF_d (EFSA, 2020)	0.09 × 2	STMR × PF_d (EFSA, 2020)
Lupin seed	meal	0.01 × 1.1	STMR × PF_d (EFSA, 2020)	0.01 × 1.1	STMR × PF_d (EFSA, 2020)
Peanut	meal	0.00 × 0.1	STMR × PF (EFSA, 2020)	0.00 × 0.1	STMR × PF (EFSA, 2020)
Potato	process waste	0.09 × 5.0	STMR × PF (EFSA, 2020)	0.09 × 5.0	STMR × PF (EFSA, 2020)
Potato	dried pulp	0.09 × 8.0	STMR × PF (EFSA, 2020)	0.09 × 8.0	STMR × PF (EFSA, 2020)
Rape	meal	0.09 × 0.4	STMR × PF (EFSA, 2020)	0.09 × 0.4	STMR × PF (EFSA, 2020)
Rice	bran/pollard	0.87 × 0.9	STMR × PF (EFSA, 2020)	0.87 × 0.9	STMR × PF (EFSA, 2020)
Safflower	meal	0.09 × 2	STMR × PF_d (EFSA, 2020)	0.09 × 2	STMR × PF_d (EFSA, 2020)
Soybean	meal	0.01 × 1.3	STMR × PF_d (EFSA, 2020)	0.01 × 1.3	STMR × PF_d (EFSA, 2020)
Soybean	hulls	0.01 × 13	STMR × PF_d (EFSA, 2020)	0.01 × 13	STMR × PF_d (EFSA, 2020)
Sugarcane	molasses	0.25 x 0.04	STMR x PF (EFSA, 2020)	0.25 x 0.04	STMR x PF (EFSA, 2020)
Sunflower	meal	~~0.07~~ 0.09 × 0.14	STMR × PF (EFSA, 2020)	~~0.07~~ 0.09 × 0.14	STMR × PF (EFSA, 2020)
Wheat gluten	meal	0.02 × 1.8	STMR × PF_d (EFSA, 2020)	0.02 × 1.8	STMR × PF_d (EFSA, 2020)
Wheat	milled by-pdts	0.02 × 7	STMR × PF_d (EFSA, 2020)	0.02 × 7	STMR × PF_d (EFSA, 2020)

PF_d Default processign factor

Table 7.2- 11: Results of the dietary burden calculation

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Enforement residue definition (fluxapyroxad)					
Beef cattle*	0.054	0.085	Barley, straw	3.6	Y
Dairy cattle*	0.067	0.114	Barley, straw	3.0	Y
Ram/ewe	0.075	0.135	Barley, straw	4.1	Y
Lamb	0.070	0.163	Barley, straw	3.8	Y
Breeding swine	0.0320	0.047	Potato, process waste	2.0	Y
Finishing swine*	0.022	0.039	Swede, roots	1.3	Y
Broiler poultry	0.031	0.041	Swede, roots	0.6	Y
Layer poultry*	0.036	0.052	Swede, roots	0.8	Y
Turkey	0.019	0.029	Swede, roots	0.4	Y

* These categories correspond to those (formerly) assessed at EU level.

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

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

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

Commodity	Dietary burden		Results of the livestock feeding study						Median residue (mg/kg)[a]	Highest residue (mg/kg)[b]	Calculated MRL (mg/kg)	CF for RA[c]
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level (mg/kg bw/d)	No	Result for enforcement		Result for RA					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
EU data (EFSA, 2011, 2020, BASF DocID 2009/1074798, 2009/1118922, 2009/1074799, 2010/1029664)												
Enforcement residue definition: fluxapyroxad parent												
Ruminant meat	0.075	0.163	0.086 / 3	3	<0.01	<0.01	0.02	0.02	0.01	0.01	0.01	2.0
			0.171 / 6	3	<0.01	<0.01	0.02	0.02				
			0.512 / 18	3	<0.01	<0.01	0.02	0.02				
			1.556 / 60	3	0.011	0.012	0.035	0.043				
Ruminant fat	0.075	0.163	0.086 / 3	3	0.011	0.011	0.021	0.021	0.01	0.02	0.02	1.9
			0.171 / 6	3	0.019	0.024	0.029	0.034				
			0.512 / 18	3	0.045	0.059	0.070	0.091				
			1.556 / 60	3	0.147	0.171	0.255	0.296				
Ruminant liver	0.075	0.163	0.086 / 3	3	<0.01	<0.01	0.033	0.042	0.01	0.01	0.015	3.3
			0.171 / 6	3	0.013	0.015	0.051	0.066				
			0.512 / 18	3	0.031	0.032	0.119	0.143				
			1.556 / 60	3	0.085	0.094	0.340	0.441				
Ruminant kidney	0.075	0.163	0.086 / 3	3	<0.01	<0.01	0.02	0.02	0.01	0.01	0.01	2.0
			0.171 / 6	3	<0.01	<0.01	0.021	0.021				
			0.512 / 18	3	<0.01	<0.01	0.027	0.031				
			1.556 / 60	10	0.014	0.019	0.064	0.095				

Commodity	Dietary burden		Results of the livestock feeding study						Median residue (mg/kg)[a]	Highest residue (mg/kg)[b]	Calculated MRL (mg/kg)	CF for RA[c]
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level (mg/kg bw/d)	No	Result for enforcement		Result for RA					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
Poultry meat	0.036	0.052	0.022 / 0.3	10	<0.01	<0.01	0.02	0.02	0.01	0.01	0.01	2.0
			0.047 / 0.6	10	<0.01	<0.01	0.02	0.02				
			0.133 / 1.8	10	<0.01	<0.01	0.02	0.02				
			0.443 / 6.0	10	<0.01	<0.01	0.02	0.02				
Poultry fat	0.036	0.052	0.022 / 0.3	10	<0.01	<0.01	0.02	0.02	0.01	0.01	0.01	2.0
			0.047 / 0.6	10	<0.01	<0.01	0.02	0.02				
			0.133 / 1.8	10	<0.01	<0.01	0.02	0.02				
			0.443 / 6.0	10	0.025	0.028	0.039	0.044				
Poultry liver	0.036	0.052	0.022 / 0.3	10	<0.01	<0.01	0.02	0.02	0.01	0.01	0.01	2.0
			0.047 / 0.6	10	<0.01	<0.01	0.02	0.02				
			0.133 / 1.8	10	<0.01	<0.01	0.02	0.02				
			0.443 / 6.0	10	<0.01	<0.01	0.024	0.028				
Milk	0.075	0.163	0.086 / 3	10	0.0011	0.0013	0.0026	0.0030	0.00	0.00	0.002	2.4
			0.171 / 6	10	0.0019	0.0032	0.0037	0.0059				
			0.512 / 18	10	0.0052	0.0063	0.0098	0.0116				
			1.556 / 60	10	0.0154	0.0374	0.0311	0.0664				
Eggs	0.036	0.052	0.022 / 0.3	3	0.0014	0.0021	0.0031	0.0031	0.00	0.00	0.004	2.0
			0.047 / 0.6	3	0.0017	0.0031	0.0034	0.0052				
			0.133 / 1.8	3	0.0028	0.0045	0.0078	0.0100				
			0.443 / 6.0	3	0.0065	0.0124	0.0192	0.0308				

N/A: Not applicable

(a): Median residue value according to the enforcement residue definition, derived by interpolation/extrapolation from the feeding study for the median dietary burden (FAO, 2009).
(b): Highest residue value (tissues, eggs) or mean residue value (milk) according to the enforcement residue definition, derived by interpolation/extrapolation of the maximum dietary burden between the relevant feeding groups of the study (FAO, 2009).
(c): The median conversion factor for enforcement to risk assessment.

Conclusion on feeding studies

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

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

Information on processing studies with barley and wheat were reviewed during the MRL Article 12 evaluation (EFSA 2020: EFSA Journal 2020; 18(1):5984).

7.2.5.1 Available data for all crops under consideration

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

Table 7.2- 13: Overview of the available processing studies

Processed commodity	Number of studies	Median PF *	Median CF **	Comments	Reference
EU data					
Enforcement residue definition: Fluxapyroxad					
Wheat, whole-meal flour	12	0.94	N/A	-	EFSA, 2020 BASF DocID 2009/7003065
Wheat, whole-meal bread	12	0.66	N/A	-	
Wheat, white flour	12	0.17	N/A	-	
Wheat, white bread	12	0.13	N/A	-	
Barley, brewing malt	4	0.01	N/A	-	EFSA, 2020 BASF DocID 2009/7003177
Barley, beer	4	0.02	N/A	-	
Barley, whole-meal flour	4	0.23	N/A	-	

* 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.

7.2.5.2 Conclusion on processing studies

Conclusion on processing studies

Processing studies in several crops were evaluated by EFSA in former reasoned opinions and additional data during the review of the existing MRLs according to Article 12 (EFSA, 2020).

EFSA, 2020:
"Further processing studies are not required as they are not expected to affect the outcome of the risk assessment".

7.2.6 Magnitude of residues in representative succeeding crops

Crops under consideration can be grown in rotation.

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 submitted in the framework of this application.

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

Primary crop	Rate (kg a.s./ha) (GS at appl. or PHI)	Residue levels in succeeding crops			
		Succeeding crop group	Succeeding crop	Sowing intervals (DAT)	Reference / Remarks
EU data					
n/a (bare soil)	0.250 (n/a)	Leafy vegetables	lettuce	30 120 365	UK, 2011a EFSA, 2012 BASF DocID 2010/1144335
		Root and tuber vegetables	carrot/radish	30 120 365	
		Brassica	cauliflower/ broccoli	30 120 365	
		Cereals	wheat	30 120 365	

Conclusion on rotational crops studies

Rotational field crop studies in wheat, cauliflower, broccoli, lettuce and carrots were assessed in the DAR (UK, 2011). The studies were performed by applying fluxapyroxad once to bare soil at 250 g a.s./ha.

The results of the rotational crop field study indicate that detected residues of fluxapyroxad were highest in wheat forage and straw and decreased with the extension of the plant back period. In wheat straw the residue level decreased from 0.43 mg/kg at 30 days plant back to 0.07-0.08 mg/kg at 120 days plant back.

The residues of parent compound in the edible parts of mature cauliflowers and broccoli inflorescences, lettuce head and in wheat grain were <0.01 mg/kg after 30, 120 and 365 days replant intervals. Residues at up to 0.03 mg/kg and 0.06 mg/kg respectively, were found in lettuce and cauliflower planted 30 DAT and harvested at immature stage. In carrot roots and tops the highest residue levels of 0.08 mg/kg and 0.07 mg/kg respectively were detected after a replant interval of 30 days. At a 120 day plant back interval residue decreased to 0.03 mg/kg in carrot roots.

In all plant and soil matrices parent compound represented the majority of the residues. Metabolites M700F048 and M700F008 appeared only to a very low extent; metabolite M700F002 was always below the LOQ of 0.01 mg/kg.
It is considered that under crop rotations at the proposed GAP (BAS 736 00 F: 2 x 100 g fluxapyroxad/ha there is no potential for residues occurring in succeeding crops such as carrots, lettuce and flowering brassica. In addition, MRLs are currently established for lettuce (4 mg/kg). New MRL values are ~~will be~~ applicable from 10/11/2021 for carrot (0.9 mg/kg), cauliflower (0.2 mg/kg) and broccoli (2 mg/kg).

It should be noted that according to the EFSA Review of the existing MRLs forfluxapyroxad (EFSA Journal 2020;18(1):5984), *the possible occurrence of residues of fluxapyroxad at levels higher than the MRLs derived for rotational crops on a tentative basis, following multiannual applications, cannot be excluded. Therefore, Member States granting an authorisation should request additional rotational crop field studies conducted with application rates that cover the plateau background concentrations for these crops. Pending the submission of these studies, Member States are recommended to implement appropriate mitigation measures or to reconsider these uses in order to avoid exceedances of the derived MRLs*.

7.2.7 Other / special studies (KCA 6.10, KCA 6.10.1)

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of BAS 736 00 F. Therefore, other special studies are not needed.

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

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

7.2.8.1 Input values for the consumer risk assessment

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

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: fluxapyroxad				
Barley, oat	0.088	STMR	0.160	HR
Wheat, rye	0.015	STMR	0.057	HR
Grapefruit	0.07	EFSA 2020	Acute risk assessment is performed only for the crops under consideration	
Oranges	0.01	EFSA 2020		
Tree nuts	0.01	EFSA 2020		
Pome fruit	0.3	JMPR 2011		
Apricot	0.03	EFSA 2020		
Cherries (sweet)	0.56	EFSA 2020		
Peaches	0.44	EFSA 2020		
Plums	0.44	EFSA 2011		
Table grapes	0.09	EFSA 2020		

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Wine grapes	0.15	EFSA 2020		
Strawberries	0.82	EFSA 2016a		
Blueberries	2.39	EFSA 2016a		
Bananas	0.06	EFSA 2016a		
Mangoes	0.18	EFSA 2016a		
Potatoes	0.09	EFSA 2020		
Tropical root & tuber vegetables	0.03	EFSA 2020		
Other root and tuber	0.12	EFSA 2020		
Bulb vegetables	0.03	EFSA 2020		
Spring onion	0.19	EFSA 2020		
Tomatoes	0.06	EFSA 2020		
Swett peppers/bell peppers	0.07	EFSA 2020		
Aubergines/eggplants	0.07	EFSA 2020		
Okra/lady’s fingers	0.07	EFSA 2020		
Cucurbits with edible peel	0.05	EFSA 2016a		
Cucurbits with inedible peel	0.02	EFSA 2020		
Sweet corn	0.01	JMPR, 2011		
Broccoli	0.28	EFSA 2016a		
Cauliflower	0.07	EFSA 2020		
Brussels sprouts	0.11	EFSA 2020		
Head cabbage	0.01	EFSA 2017		
Chinese cabbage	0.90	EFSA 2016a		
Kales	0.01	EFSA, 2020		
Kohlrabies	0.01	EFSA, 2020		
Lambs Lettuce/corn salad	0.25	EFSA 2017		
Lettuces	0.25	EFSA 2020		
Escaroles/broad-leaved endives	0.25	EFSA 2020		
Cress and other sprouts and shoots	0.06	EFSA 2020		
Land cress	0.06	EFSA 2020		
Roman rocket/rucola	0.25	EFSA 2020		
Red mustards	0.06	EFSA 2020		
Baby leaf crops (including brassica species)	0.06	EFSA 2020		
Spinach and similar leaves	0.06	EFSA 2017		
Witloof/Begian endives	1.95	EFSA 2017		
Herbs and edible flowers	0.06	EFSA 2017		
Beans, peas with pods	0.58	EFSA 2020		
Beans, peas without pods	0.03	JMPR, 2011		
Celery, cardoon, fennel, rhubarb	1.68	EFSA 2016a		

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Globe artichokes	0.08	EFSA 2020		
Leek	0.19	EFSA 2020		
Pulses (exc.beans, lupins)	0.04	JMPR, 2011		
Beans (dry)	0.01	EFSA 2020		
Lupins/lupini beans	0.01	JMPR, 2011		
Oilseeds exc. peanuts, soybean, cotton seeds	0.09	EFSA 2020		
Soybean	0.01	EFSA 2020		
Peanuts	0.01	EFSA 2020		
Cotton	0.30	JMPR, 2017		
Maize	0.01	EFSA 2011		
Rice	0.87	EFSA 2020		
Sorghum	0.19	EFSA 2011		
Herbal infusions (dried leaves)	0.55	EFSA 2020		
Herbal infusions from roots	0.32	EFSA 2020		
Sugar beet roots	0.12	EFSA 2020		
Sugar canes	0.26	EFSA 2016a		
Chicory roots	0.07	EFSA 2017		
Animal: Risk assessment residue definition: Fluxapyroxad and M700F008 expressed. as parent equivalent				
Meat	0.02	STMR	Acute risk assessment is performed only for the crops under consideration	
Fat	0.02	STMR		
Fat sheep, goat, swine	0.01	STMR		
Liver	0.03	STMR		
Liver sheep, goat	0.04	STMR		
Liver poultry	0.02	STMR		
Kidney	0.02	STMR		
Milk	0.001	STMR		
Egg	0.004	STMR		

7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Taking into account residues in food commodities of plant and animal origin, the TMDI calculation was performed with the current EFSA model (rev3.1) using an ADI of 0.02 mg/kg bw/day.

The calculation of the TMDI using all MRLs according to Reg EU 2021/644 would lead to an exceedance of the ADI. Therefore, the PRIMo_rev3.1 model uses the respective STMR values which results in a utilisation of the ADI of 48%, with the NL toddler being the population group with the highest value (contributors: apples 16%).

A long-term consumer intake concern was not identified for any of the European diets incorporated in the

EFSA PRIMo_rev 3.1.

An acute consumer risk assessment was performed with barley, wheat, oat and rye only. EFSA PRIMo_rev 3.1 calculates no exceedance of the ARfD.

Table 7.2- 16: Consumer risk assessment

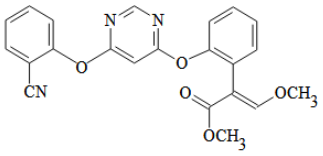
TMDI (% ADI) according to EFSA PRIMo_rev 3.1	>100%
IEDI (% ADI) according to EFSA PRIMo_rev 3.1	48% (based on NL toddler)
IESTI (% ARfD) according to EFSA PRIMo_rev 3.1	Only the highest values for unprocessed and processed commodities considering the GAPs under assessment are given below. Barley: 0.2% (based on UK 7-10 years) Barely / beer: 0.3% (based on NL general population)

The proposed uses of fluxapyroxad in the formulation BAS 736 00 F do not represent unacceptable acute and chronic risks for the consumer.

7.3 Azoxystrobin

General data on Azoxystrobin are summarized in the table below (last updated 2021/08/31)

Table 7.3- 1: General information on Azoxystrobin

Active substance (ISO Common Name)	Azoxystrobin
IUPAC	methyl (2E)-2-{2-[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl}-3-methoxyacrylate
Chemical structure	
Molecular formula	$C_{22}H_{17}N_3O_5$
Molar mass	403.39
Chemical group	Strobilurin
Mode of action (if available)	Fungicide. Inhibition of electron transport and mitochondrial respiration
Systemic	Yes
Company (ies)	Syngenta*
Rapporteur Member State (RMS)	Poland
Approval status	Approved Date: 01/01/2012 Reg. (EU) No. 540/2011 Reg. (EU) No. 703/2011 Reg. (EU) No. 2019/291 Reg. (EU) No. 2018/155
Restriction	No
Review Report	SANCO/11027/2011 – rev. 3 20/03/2015
Current MRL regulation	~~Regulation (EU) No 2019/552~~ Regulation (EU) No 2022/476 Regulation (EU) No. 2022/1363 will apply from 25/02/2023
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes
EFSA Journal : Conclusion on the peer review	Yes EFSA Journal 2010; 8(4):1542
EFSA Journal: conclusion on article 12	Yes EFSA Journal 2013;11(12):3497
Current MRL applications on intended uses	No current MRL applications

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

7.3.1 Stability of Residues (KCA 6.1)

7.3.1.1 Stability of residues during storage of samples

Available data

Data has been previously evaluated at EU level and is described in detail in the DAR (2009) and in EFSA's Conclusion on the peer review (EFSA, 2010).

No new data submitted in the framework of this application.

Table 7.3- 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			
Grain, Wheat	High starch content	24 Months	UK RMS, 2009a
Carrot Root*	High starch content	24 Months	UK RMS, 2009a
Corn Grits*	High starch content	24 months	UK RMS, 2009a
Grapes	High acid content	24 Months	UK RMS, 2009a
Wine	High acid content	24 Months	UK RMS, 2009a
Orange Pulp*	High acid content	24 Months	UK RMS, 2009a
Orange Juice*	High acid content	24 Months	UK RMS, 2009a
Soybean Meal*	High protein content	24 Months	UK RMS, 2009a
Wheat Bran	High protein content	24 Months	UK RMS, 2009a
Peanut Meal	High protein content	24 Months	UK RMS, 2009a
Leaf Lettuce	High water content	24 Months	UK RMS, 2009a
Forage, Wheat	High water content	24 Months	UK RMS, 2009a
Straw, Wheat	High water content	24 Months	UK RMS, 2009a
Tomato, fruit	High water content	24 Months	UK RMS, 2009a
Tomato, juice	High water content	24 Months	UK RMS, 2009a
Tomato, paste	High water content	24 Months	UK RMS, 2009a
Apples	High water content	24 Months	UK RMS, 2009a
Bananas	High water content	24 Months	UK RMS, 2009a
Cucumbers	High water content	24 Months	UK RMS, 2009a
Peaches	High water content	24 Months	UK RMS, 2009a
Oilseed rape	High oil content	24 Months	UK RMS, 2009a
Peanuts	High oil content	24 Months	UK RMS, 2009a
Peanut, oil	High oil content	24 Months	UK RMS, 2009a
Pecans	High oil content	24 Months	UK RMS, 2009a
Orange Oil*	High oil content	24 Months	UK RMS, 2009a

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Animal Products			
Ruminant	Muscle	10 Months	UK RMS, 2009a
Ruminant	Liver	10 Months	UK RMS, 2009a
Ruminant	Kidney	10 Months	UK RMS, 2009a
Ruminant	Fat	10 Months	UK RMS, 2009a
Ruminant	Milk	10 Months	UK RMS, 2009a
Poultry	Egg	10 Months	UK RMS, 2009a

* Stored at –15°C

Conclusion on stability of residues during storage

Azoxystrobin was shown to be stable in freezer storage at approximately –18°C in wheat (straw), wheat (grain), grapes, wine, peanuts, pecans, tomatoes, apples, bananas, cucumbers, peaches and oilseed rape, wheat (bran), tomato (juice and paste) and peanut (oil and nut meat) after storage for up to two years. Azoxystrobin was shown to be stable in freezer storage at approximately –15°C in soybean meal, corn grits, carrot root, leaf lettuce, wheat forage, orange oil, orange juice and orange pulp after storage for up to two years

7.3.1.2 Stability of residues in sample extracts (KCA 6.1)

Available data

In residue studies for the determination of azoxystrobin in this submission, procedural recoveries were conducted in parallel with the sample analysis for the residue studies. Acceptable recoveries were achieved, thereby demonstrating stability of residue in sample extracts between extraction and injection.

7.3.2 Nature of residues in plants, livestock and processed commodities

7.3.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

No new data submitted in the framework of this application.

Table 7.3- 3: Summary of plant metabolism studies (UK 2009a B.7.1.1)

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	Grape	14-C- Pyrimidinyl 14-C-cyanophenyl 14C- phenylacrylate	Foliar	250 g as/ha + 1000 g as/ha	2 + 2	21 days		UK RMS, 2009a
Pulses and oilseeds	Peanut	14-C- Pyrimidinyl 14-C-cyanophenyl 14C- phenylacrylate	Foliar	850 g as/ha + 300 g as/ha	2 + 1	10		UK RMS, 2009a
Cereals	Wheat	14-C- Pyrimidinyl 14-C-cyanophenyl 14C- phenylacrylate	Foliar	~~200~~ 500 g as/ha	2	13 days (forage), 61 days (straw and grain)		UK RMS, 2009a
New data – No new data submitted								

Summary of plant metabolism studies reported in the EU

The metabolism of azoxystrobin has been reviewed in the framework of the peer review (EFSA, 2013) and it can be concluded that the residue of concern for enforcement and risk assessment from both foliar, soil and post-harvest uses can be defined as parent azoxystrobin only."

Summary of new plant metabolism studies

No new studies submitted.

Conclusion on metabolism in primary crops

Primary crop metabolism of azoxystrobin was investigated in three different crop groups following foliar applications. Metabolic patterns in the different studies were shown to be similar and the relevant residue for enforcement and risk assessment in all crops supported in the framework of this review is proposed as parent azoxystrobin. No studies investigating the metabolism of azoxystrobin following post-harvest and soil treatments are available. However, azoxystrobin was applied close to harvest in the foliar metabolism studies and also in the rotational crop studies azoxystrobin was found to be the main component of the residue. The relevant residue following soil application or post-harvest treatment can therefore also be defined as parent azoxystrobin. (EFSA RO 2013)

7.3.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

No new data submitted in the framework of this application.

Table 7.3- 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	Lettuce	14C- phenylacrylate	G	2.2 kg as/ha	30, 200 & 365 days			UK RMS, 2009
Root and tuber vegetables	Radish	14C- phenylacrylate	G	2.2 kg as/ha	30, 200 & 365 days			UK RMS, 2009
Cereals	Wheat	14C- phenylacrylate	G	2.2 kg as/ha	30, 200 & 365 days			UK RMS, 2009
Leafy vegetables	Lettuce	14-C- Pyrimidinyl	G	2.21 kg as/ha	30, 200 & 365 days			UK RMS, 2009
Root and tuber vegetables	Radish	14-C- Pyrimidinyl	G	2.21 kg as/ha	30, 200 & 365 days			UK RMS, 2009
Cereals	Wheat	14-C- Pyrimidinyl	G	2.21 kg as/ha	30, 200 & 365 days			UK RMS, 2009
Leafy vegetables	Lettuce	14-C-cyanophenyl	G	2.21 kg as/ha	30, 200 & 365 days			UK RMS, 2009
Root and tuber vegetables	Radish	14-C-cyanophenyl	G	2.21 kg as/ha	30, 200 & 365 days			UK RMS, 2009
Cereals	Wheat	14-C-cyanophenyl	G	2.21 kg as/ha	30, 200 & 365 days			UK RMS, 2009
New data – No new data								

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

Summary of plant metabolism studies reported in the EU

The metabolism of azoxystrobin in rotational crops – radish, lettuce and wheat – has been evaluated (United Kingdom, 2009a). The peer-review concluded that the metabolism of azoxystrobin in succeeding crops is almost similar for all the analysed crops and also similar to that observed in the primary crops.

Summary of new plant metabolism studies

No new data submitted.

Conclusion on metabolism in rotational crops

The metabolism of azoxystrobin in succeeding crops is almost similar for all the analysed crops and is also similar to that observed in the primary crops. The metabolism of azoxystrobin in rotational crops is more extensive with more metabolites being formed than in the primary crops but the metabolites in succeeding crops are produced in low concentrations. The residue of concern for rotational crops is parent – azoxystrobin. (EFSA RO 2013)

7.3.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

No new data submitted in the framework of this application.

Table 7.3- 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 (100.9%), remainder (2.2%)*	UK, 2009a
Baking, boiling, brewing (60 minutes, 100°C, pH 5)	Parent (96.2%), remainder (2.2%)*	UK, 2009a
Sterilisation (20 minutes, 120°C, pH 6)	Parent (97.3%), remainder (2.3%)*	UK, 2009a
New data – No new data submitted		

* Average of duplicate results.

Conclusion on nature of residues in processed commodities

The effect of processing on the nature of azoxystrobin was investigated in the framework of the peer review (EFSA, 2013). The relevant residue for enforcement and risk assessment in processed commodities is therefore expected to be the same as for primary crops

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

Under conditions designed to mimic pasteurisation, baking, brewing, boiling and sterilization there was no significant hydrolysis of azoxystrobin following incubation at different pH values and temperatures. Azoxystrobin is stable under conditions representative of pasteurisation, baking, brewing, boiling and sterilisation, and no additional metabolites are formed in processed commodities as compared to raw agricultural commodities. The definition of the residue in processed crop commodities is azoxystrobin only.

Table 7.3- 6: Summary of the nature of residues in commodities of plant origin

Endpoints	
Plant groups covered	Fruits and Fruiting Vegetables (Grapes) Pulses and Oilseeds (Peanut) Cereals (Wheat)
Rotational crops covered	Yes
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Azoxystrobin is stable under standard hydrolysis conditions
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes
Plant residue definition for monitoring	Parent (Azoxystrobin) (EFSA RO 2013) **
Plant residue definition for risk assessment	Parent (Azoxystrobin) (EFSA RO 2013)***
Conversion factor from enforcement to RA	NA

* If residue pattern in processed commodities is not similar to that in raw commodities
** A more recent proposal by EFSA may be provided as additional information (EFSA RO XXXX).
*** If no EFSA proposal is available, a proposal should be made by the applicant/zRMS.

7.3.2.5 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 7.3- 7: Summary of animal metabolism studies

Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate (mg/kg diet /d)	Duration (days)	Commodity	Time of sampling	
EU data								
Lactating ruminants	Goat	^{14}-C- Pyrimidinyl or ^{14}-C-cyanophenyl or 14C- phenylacrylate	n.r	23.2-32.7	7	Milk	twice daily	UK, 2009a; EFSA, 2013
						Urine and faeces	daily	
						Tissues	at sacrifice	
		^{14}-C-cyanophenyl	1	25	7	Milk	twice daily	UK, 2009a; EFSA, 2013
						Urine and faeces	daily	
						Tissues	at sacrifice	
Laying poultry	Hens	^{14}C- Pyrimidinyl or ^{14}-C-cyanophenyl or ^{14}C- phenylacrylate	n.r.	11	10	Eggs	Daily	UK, 2009a; EFSA, 2013
						Excreta	Daily	
						Tissues	After sacrifice	
			10	12.5	10	Eggs	Daily	UK, 2009a; EFSA, 2013
						Excreta	Daily	
						Tissues	After sacrifice	
New data – No new data submitted								

n.r: not reported

Summary of animal metabolism studies reported in the EU

Lactating goats were dosed with approximately 25 mg/kg in the diet of azoxystrobin, corresponding to approximately 1.2 times the exposure of meat ruminant. Laying hens were dosed with 11 - 12.5 mg/kg in the diet of azoxystrobin, corresponding to approximately 7 - 8 times the exposure of poultry. All studies showed that azoxystrobin was rapidly excreted in both lactating goats and laying hens. The transfer in tissues was limited, the TRRs in muscle, fat, milk and egg white being <0.02 mg/kg. Thus, characterization of residues was only performed in goat liver and kidney, and in poultry liver and egg yolk, where the TRRs were in the range of 0.05 to 1.19 mg/kg. In these matrices, the metabolism was shown to be very extensive,

more than 20 compounds being identified/characterized, each accounting mostly for less than 5 % of the TRR.

Summary of new animal metabolism studies

No new studies submitted.

Conclusion on metabolism in livestock

The general metabolic pathways in rodents and ruminants were found to be comparable; the findings in ruminants can therefore be extrapolated to pigs. The conclusions reached by EFSA reflect the views of the RMS and are also in line with those of the JMPR (FAO, 2008). In the framework of the peer review, the proposed residue was not considered to be fat soluble based on the fact that the log $P_{o/w}$ of azoxystrobin is lower than 3.

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

Table 7.3- 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	n.r.
	6 days
Animal residue definition for monitoring	Parent (Azoxystrobin) (EFSA RO 2013 and EFSA Journal 2020;18(8):6)
Animal residue definition for risk assessment	Parent (Azoxystrobin) (EFSA RO 2013) Azoxystrobin (tentative, EFSA, 2010, 2013) [genotoxicity of metabolites L1, L4 and L9 can be ruled out but general toxicity of these metabolites was not addressed] (EFSA Journal 2020;18(8):6)
Conversion factor	None
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	No

7.3.3 Magnitude of residues in plants (KCA 6.3)

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

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application. These studies are summarized in the Table below. The detailed assessment of these studies is presented in Appendix 2.

Table 7.3- 9: Summary of EU reported and new data supporting the intended uses of BAS 736 00 F 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 and triticale grain	EFSA, 2013, UK, 2009a	NEU	Alternative GAP: 3 x 0.25 kg as/ha, until BBCH 71, PHI 35d, outdoor E: 4x <0.01; 0.01; 0.013; 0.022; 0.028 RA: 4x <0.01; 0.01; 0.013; 0.022; 0.028	N/A				
		SEU*	GAP on which MRL/EU a.s. assessment is based: 2 x 0.25 kg as/ha, from BBCH 31 until BBCH 71, PHI 35d, outdoor E: <0.01; 0.02; 0.03; 0.05; 0.10; 0.13; 0.20; 0.27 RA: <0.01; 0.02; 0.03; 0.05; 0.10; 0.13; 0.20; 0.27					
	New trials BAS 736 00 F BASF 2020/2006184 & ~~2020/2022810~~ 2021/2022810	NEU	BAS 736 00 F GAP: 2 x 0.15 kg as/ha, at BBCH 49 and BBCH 69, PHI ~~40~~35d, outdoor E: 8x <0.01 RA: 8x<0.01					
		SEU	BAS 736 00 F GAP: 2 x 0.15 kg as/ha, at BBCH 49 and BBCH 69, PHI ~~40~~35d, outdoor E: ~~7~~8x <0.01~~, 0.16~~ RA: ~~7~~8x<0.01~~, 0.016~~					

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
	Data summary for new GAP	NEU	E: 8x <0.01 RA: 8x <0.01	E: 0.01 RA: 0.01	E: 0.01 RA: 0.01	0.01	0.50	Yes
		SEU	E: ~~7~~8x <0.01~~, 0.16~~ RA: ~~7~~8x<0.01~~, 0.016~~	E: 0.01 RA: 0.01	E: ~~0.016~~ 0.01 RA: ~~0.016~~ 0.01	0.019	0.50	Yes
Barley grain → extrapolated to oat grain	EFSA, 2013, UK, 2009a	NEU	GAP on which EU a.s. assessment is based: 3 x 0.25 kg as/ha, at BBCH 49 nad BBCH 71, PHI 35d, outdoor E: <0.01; 0.01; 0.02; 2x 0.04; 0.08; 0.20; 0.43 RA: <0.01; 0.01; 0.02; 2x 0.04; 0.08; 0.20; 0.43	N/A				
		SEU	GAP on which EU a.s. assessment is based: 2 x 0.25 kg as/ha, at BBCH 31 and BBCH 69, PHI 35d, outdoor E: 0.01; 0.03; 0.04; 0.08; 2x 0.10; 0.11; 0.13; 0.28 RA: 0.01; 0.03; 0.04; 0.08; 2x 0.10; 0.11; 0.13; 0.28					
	Supporting data for cGAP FAO, 2014, Reg. (EU) 2015/845**	US	GAP on which EU MRL is based: 2 x 0.15 kg as/ha at BBCH 35 and BBCH 85, 14 d PHI, outdoor. Combines barley and oat grain data into one dataset. E : 0.013, 0.014, 0.019, 3x 0.028, 0.037, 0.048, 0.049, 0.05, 0.053, 0.058, 0.06, 2x 0.12, 0.19, 0.31, 0.63 and 0.99 mg/kg. RA: 0.013, 0.014, 0.019, 3x 0.028, 0.037, 0.048, 0.049, 0.05, 0.053, 0.058, 0.06, 2x 0.12, 0.19, 0.31, 0.63 and 0.99 mg/kg.					
	New trials BAS 736 00 F BASF: 2020/2006183 & ~~2020/2023846~~ 2021/2020010	NEU	BAS 736 00 F GAP: 2 x 0.15 kg as/ha, at BBCH 49 and BBCH 69, PHI ~~40~~35d, outdoor E: 7x <0.01, 0.016 RA: 7x <0.01, 0.016					
		SEU	BAS 736 00 F GAP: 2 x 0.15 kg as/ha, at BBCH 49 and BBCH 69, PHI ~~40~~35d, outdoor E: 7x <0.01, 0.11 RA: 7x <0.01, 0.11					

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
	Data summary for new GAP	NEU	E: 7x <0.01, 0.016 RA: 7x <0.01, 0.016	E: 0.01 RA: 0.01	E: 0.016 RA: 0.016	0.019	1.5	Yes
		SEU	E: 7x <0.01, 0.11 RA: 7x <0.01, 0.11	E: 0.01 RA: 0.01	E: 0.11 RA: 0.11	0.164	1.5	Yes
Wheat straw → Extrapolated to rye and triticale straw	EFSA, 2013, UK, 2009a	NEU	Alternative GAP: 3 x 0.25 kg as/ha, until BBCH 71, PHI 35d, outdoor E: 0.41; 1.2; 1.5; 1.7; 2x 2.02; 2.29; 10.1 RA: 0.41; 1.2; 1.5; 1.7; 2x 2.02; 2.29; 10.1	N/A				
		SEU	GAP on which MRL/EU a.s. assessment is based: 2 x 0.25 kg as/ha, from BBCH 31 until BBCH 71, PHI 35d, outdoor E: 0.81; 1.0; 2.4; 2.6; 5.1; 6.8; 7.3; 7.4 RA: 0.81; 1.0; 2.4; 2.6; 5.1; 6.8; 7.3; 7.4					
	New trials BAS 736 00 F BASF 2020/2006184 & ~~2020/2022810~~ 2021/2022810	NEU	BAS 736 00 F GAP: 2 x 0.15 kg as/ha, at BBCH 49 and BBCH 69, PHI ~~40~~ 35d, outdoor E: ~~2x~~ 0.01; 2x 0.05; ~~0.16~~ 0.13, 0.25, 0.28, 0.30; ~~0.31~~ 0.55 RA: ~~2x~~ 0.01; 2x 0.05; ~~0.16~~ 0.13, 0.25, 0.28, 0.30; ~~0.31~~ 0.55					
		SEU	BAS 736 00 F GAP: 2 x 0.15 kg as/ha, at BBCH 49 and BBCH 69, PHI ~~40~~ 35d, outdoor E: 0.02; 0.05; 2x 0.07; 0.08, 0.09, 0.23 RA: 0.02; 0.05; 2x 0.07; 0.08, 0.09, 0.23					
	Data summary for new GAP	NEU	E: ~~2x~~ 0.01; 2x 0.05; ~~0.16~~ 0.13, 0.25, 0.28, 0.30; ~~0.31~~ 0.55 RA: ~~2x~~ 0.01; 2x 0.05; ~~0.16~~ 0.13, 0.25, 0.28, 0.30; ~~0.31~~ 0.55	E: ~~0.11~~ 0.19 RA: : ~~0.11~~ 0.19	E: ~~0.31~~ 0.55 RA: ~~0.31~~ 0.55	N/A	N/A	N/A
		SEU	E: 0.02; 3x 0.05; 0.06; ~~2x~~ 0.07; ~~0.08, 0.09;~~ 0.20; 0.21 ~~0.23~~ RA: 0.02; 3x 0.05; 0.06; ~~2x~~ 0.07; ~~0.08, 0.09;~~ 0.20; 0.21 ~~0.23~~	E: ~~0.07~~ 0.06 RA: ~~0.07~~ 0.06	E: ~~0.23~~ 0.21 RA: ~~0.23~~ 0.21	N/A	N/A	N/A

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
Barley straw → Extrapolated to oat straw	EFSA, 2013, UK, 2009a	NEU	Alternative GAP: 3 x 0.25 kg as/ha, until BBCH 71, PHI 35d, outdoor E: 0.11; 0.39; 0.48; 0.91; 1.3; 1.5; 2.7; 5.1 RA: 0.11; 0.39; 0.48; 0.91; 1.3; 1.5; 2.7; 5.11	N/A				
		SEU	GAP on which MRL/EU a.s. assessment is based: 2 x 0.25 kg as/ha, from BBCH 31 until BBCH 71, PHI 35d, outdoor E: 0.65; 1.2; 1.3; 2.3; 2.3; 2.5; 2.9; 4.8; 5.5 RA: 0.65; 1.2; 1.3; 2.3; 2.3; 2.5; 2.9; 4.8; 5.5					
	New trials BAS 736 00 F BASF ~~2020/2006184~~ 2020/2006183 & ~~2020/2022810~~ 2021/2020010	NEU	BAS 736 00 F GAP: 2 x 0.15 kg as/ha, at BBCH 49 and BBCH 69, PHI ~~40~~35d, outdoor E: ~~0.02~~0.01; 0.03, 0.08; 0.11; 0.12; 0.13; 0.17; 0.20~~; 0.29~~ RA: ~~E:~~ ~~0.02~~0.01; 0.03, 0.08; 0.11; 0.12; 0.13; 0.17; 0.20~~; 0.29~~					
		SEU	BAS 736 00 F GAP: 2 x 0.15 kg as/ha, at BBCH 49 and BBCH 69, PHI ~~40~~35d, outdoor E: 0.01; 0.02; 0.03; 0.07; (2x) 0.08; ~~0.18~~0.15; 0.32 RA: 0.01; 0.02; 0.03; 0.07;(2x) 0.08; ~~0.18~~0.15; 0.32					
	Data summary for new GAP	NEU	E: ~~0.02~~0.01; 0.03, 0.08; 0.11; 0.12; 0.13; 0.17; 0.20~~; 0.29~~ RA: ~~E:~~ ~~0.02~~0.01; 0.03, 0.08; 0.11; 0.12; 0.13; 0.17; 0.20~~; 0.29~~	E: 0.12 RA: 0.12	E: ~~0.29~~0.20 RA: ~~0.29~~0.20	N/A	N/A	N/A
		SEU	E: 0.01; 0.02; 0.03; 0.07; (2x) 0.08 ; ~~0.18~~0.15 ; 0.32 RA: 0.01; 0.02; 0.03; 0.07; (2x) 0.08; ~~0.18~~0.15; 0.32	E: 0.07 RA: 0.07	E: 0.32 RA: 0.32	N/A	N/A	N/A

* Source of wheat, rye and triticale grain EU MRL, Reg. (EU) 2015/1040 (in accordance with Reg. (EU) 2022/1363 applicable from 25/02/2023)
** Source of barely & oat grain EU MRL, Reg. (EU) 2015/845 (in accordance with Reg. (EU) 2022/1363 applicable from 25/02/2023)

7.3.3.2 Conclusion on the magnitude of residues in plants

The residues in wheat and barley are not expected to exceed established tolerances for azoxystrobin based on the proposed uses of BAS 736 00F (Reg, (EU) 2022/476 (current) or Reg. (EU) 2022/1363 (not yet applicable)).

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

According to appendix D of EU guidelines, extrapolation to rye and triticale is possible with 16 trials on wheat and extrapolation to oats is possible with 16 trials on barley, which are the cases here.
The data submitted show that no exceedance of the MRL will occur.
The uses are considered acceptable.

zRMS:
In support of the use of BAS 736 00 F in the central zone MSs sufficient GAP compliant residue trials on cereals are available: 8 new trials with identical GAP conducted in the NEU on each crop - wheat and barley have been submitted by the applicant.
Residues of azoxystrobin were also determined in wheat and barley straw.
The available residue data for the use BAS 736 00 F are considered sufficient to support the applied use on wheat with extrapolation to rye, triticale and on barley with extrapolation to oat in the central zone MSs.
The azoxystrobin MRLs of 0.5 mg/kg for wheat, rye, triticale grain and 1.5 mg/kg for barley, oat (current Reg. (EU) 2022/476, Reg. (EU) 2022/1363 applicable from: 25/02/2023) are not exceeded.

7.3.4 Magnitude of residues in livestock

7.3.4.1 Dietary burden calculation

Table 7.3- 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: Azoxystrobin				
Head cabbage	0.03	Median residue	0.17	Highest residue
Kale	1.04	Median residue	3.50	Highest residue
Sugar beet leaves	0.21	Median residue	0.38	Highest residue
Orange pomace	11.88	Median residue x 2.5	11.88	Median residue x 2.5
Other citrus fruit pomace	0.73	Median residue x 2.5	0.73	Median residue x 2.5
Maize grain	0.01	Median residue	0.01	Median residue
Wheat, rye grain**	~~0.08~~0.01	Median residue	~~0.08~~0.01	Median residue
Barley, oat grain**	~~0.10~~0.01	Median residue	~~0.10~~0.01	Median residue
Wheat, ~~rye~~ milled by-pdts ~~bran~~**	~~0.13~~0.07	Median residue x PF	~~0.13~~0.07	Median residue x PF
Wheat, rye straw**	~~3.85~~0.19	Median residue	~~10.1~~0.55	Highest residue
Barley, oat straw**	~~2.30~~0.12	Median residue	~~5.50~~0.32	Highest residue
Beans (dry)	0.01	Median residue	0.01	Median residue
Peas (dry)	0.01	Median residue	0.01	Median residue
Lupins (dry)	0.01	Median residue	0.01	Median residue

Feed Commodity	Median Dietary Burden		Maximum Dietary Burden	
	Input value (mg/kg)	Comment*	Input value (mg/kg)	Comment*
Potatoes	0.02	Median residue	0.03	Highest residue
Turnips	0.06	Median residue	0.11	Highest residue
Swedes	0.05	Median residue	0.10	Highest residue
Sugar beet roots	0.01	Median residue	0.13	Highest residue
Rape seed meal	0.11	Median residue x 2	0.11	Median residue x 2
Sunflower seed meal	0.02	Median residue x 2	0.02	Median residue x 2
Soya bean	0.05	Median residue	0.05	Median residue
Soya bean meal	0.07	Median residue x 1.3	0.07	Median residue x 1.3

* EFSA, 2013
** From uses under consideration

Table 7.3- 11: Results of the dietary burden calculation (EFSA Animal Model 2017)

* These categories correspond to those (formerly) assessed at EU level (EFSA, 2013)

Animal Species	Median dietary burden (mg/kg bw per d)	Maximum dietary burden (mg/kg bw per d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Risk assessment residue definition: azoxystrobin					
Dairy ruminants	~~0.229~~0.459	~~0.416~~0.589	~~Kale~~Citrus, dried pulp	~~11.56~~15.31	Y
Meat ruminants	~~0.765~~0.101	~~0.925~~0.184	~~Orange pomace~~ Citrus, dried pulp	~~21.51~~7.68	Y
Poultry, Layer	~~0.037~~0.016	~~0.098~~0.022	~~Kale~~Beet, sugar, tops	~~1.56~~0.32	Y
Poultry, Broiler	0.017	0.020	Swede, roots	0.28	Y
~~Pigs~~Swine, Breeding	~~0.060~~0.201	~~0.178~~0.244	~~Kale~~Citrus, dried pulp	~~4.44~~10.57	Y
Swine, Finishing	0.016	0.022	Beet, sugar, top	0.72	Y

7.3.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Data has been previously evaluated at the EU level and is described in detail in the DAR in EFSA's conclusion on the peer review (EFSA 2013). The dietary burden estimates referenced above are driven by uses other than barley and wheat and since the residues from the proposed new uses in barley and wheat are less than the established critical GAPs~~, the residues in cereals from the proposed new GAPs will not change the established dietary burdens in livestock~~.

Available data

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

Table 7.3- 12: Overview of the values derived from livestock feeding studies (EFSA, 2013)

Commodity	Dietary burden		Results of the livestock feeding study						Median residue (mg/kg)[b]	Highest residue (mg/kg)[c]	MRL proposal (mg/kg)[d]	CF for RA
					Result for enf.		Result for RA					
	Med. (mg/kg bw per d)	Max. (mg/kg bw per d)	Dose Level (mg/kg bw per d)[a]	No	Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
Enforcement residue definition: azoxystrobin												
Pig muscle	0.060	0.178	0.18	4	<0.01	<0.01	See results for enforcement		0.01	0.01	0.01* (tentative)	1.00
			0.91	4	<0.01	<0.01						
			9.09	4	<0.01	<0.01						
Pig fat			0.18	4	<0.01	<0.01			0.01	0.01	0.01* (tentative)	1.00
			0.91	4	<0.01	<0.01						
			9.09	4	0.02	0.02						
Pig liver			0.18	4	<0.01	<0.01			0.01	0.01	0.01* (tentative)	1.00
			0.91	4	0.01	0.01						
			9.09	4	0.05	0.05						
Pig kidney			0.18	4	<0.01	<0.01			0.01	0.01	0.01* (tentative)	1.00
			0.91	4	<0.01	<0.01						
			9.09	4	0.02	0.02						
Ruminant muscle	0.765	0.925	0.18	4	<0.01	<0.01	See results for enforcement		0.01	0.01	0.01* (tentative)	1.00
			0.91	4	<0.01	<0.01						
			9.09	4	<0.01	<0.01						
Ruminant fat			0.18	4	<0.01	<0.01			0.01	0.01	0.01* (tentative)	1.00
			0.91	4	<0.01	<0.01						
			9.09	4	0.02	0.02						
Ruminant liver			0.18	4	<0.01	<0.01			0.01	0.01	0.01* (tentative)	1.00
			0.91	4	0.01	0.01						
			9.09	4	0.05	0.05						
Ruminant kidney			0.18	4	<0.01	<0.01			0.01	0.01	0.01* (tentative)	1.00
			0.91	4	<0.01	<0.01						
			9.09	4	0.02	0.02						

Commodity	Dietary burden		Results of the livestock feeding study						Median residue (mg/kg)[b]	Highest residue (mg/kg)[c]	MRL proposal (mg/kg)[d]	CF for RA
					Result for enf.		Result for RA					
	Med. (mg/kg bw per d)	Max. (mg/kg bw per d)	Dose Level (mg/kg bw per d)[a]	No	Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
Milk	0.229	0.416	0.18	39	0.003 [e]	n.a.			0.003	0.003	0.005 (tentative)	1.00
			0.91	40	0.003 [f]	n.a.						
			9.09	40	0.006 [f]	n.a.						
Poultry muscle	0.037	0.098	0.39	3	<0.01	<0.01	See results for enforcement		0.01	0.01	0.01* (tentative)	1.00
			1.20	3	<0.01	<0.01						
			3.90	3	<0.01	<0.01						
Poultry fat			0.39	3	<0.01	<0.01			0.01	0.01	0.01* (tentative)	1.00
			1.20	3	<0.01	<0.01						
			3.90	3	<0.01	<0.01						
Poultry liver			0.39	3	<0.01	<0.01			0.01	0.01	0.01* (tentative)	1.00
			1.20	3	<0.01	<0.01						
			3.90	3	<0.01	<0.01						
Eggs			0.39	n.r.	<0.01	<0.01			0.01	0.01	0.01* (tentative)	1.00
			1.20	n.r.	<0.01	<0.01						
			3.90	n.r.	<0.01	<0.01						

n.a.: Not applicable – only the mean values are considered for calculating MRLs in milk.
n.r.: Not reported.
(a) Based on a 412.5 kg/bw cow consuming 15 kg feed DM/day and based on a 1.83 kg/bw laying hen consuming 0.12 kg feed DM/day.
(b) Median residue value according to the enforcement residue definition, derived by interpolation/extrapolation from the feeding study for the median dietary burden (FAO, 2009).
(c) Highest residue value (tissues, eggs) or mean residue value (milk) according to the enforcement residue definition, derived by interpolation/extrapolation of the maximum dietary burden between the relevant feeding groups of the study (FAO, 2009).
(d) The median conversion factor for enforcement to risk assessment.
(e) mean residue level from day 1 until day 30 (4 cows, 9 sampling days).
(f) mean residue level from day 1 until day 30 (4 cows, 10 sampling days).
(*): Indicates that the MRL is set at the limit of analytical quantification.

Conclusion on feeding studies

The requested uses do not modify the theoretical maximum daily intake for animals; consequently, there is no risk for the animal MRLs to be exceeded.

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

7.3.5.1 Available data for all crops under consideration

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

Table 7.3- 13: Overview of the available processing studies

Processed commodity	Number	Median PF [(a)]	Median CF [(b)]	Comments	Reference
Enforcement residue definition: azoxystrobin					
Processing factors recommended (sufficiently supported by data)					
Bananas, peeled	6	0.04	1.00	PROFile	EFSA, 2013
Wine grapes, must	6	0.51	1.00		U.K. 2009a EFSA, 2013
Wine grapes, white wine	6	0.52	1.00		
Wine grapes, juice	4	0.34	1.00		
Wine grapes, dry pomace	4	4.79	1.00		
Wine grapes, wet pomace	4	3.16	1.00		
Barley, brewing malt	4	0.19	1.00	Processing factor for malt, beer and pot are actually lower than the value reported as residues were below the LOQ (worst case assumption)	EFSA, 2013
Barley, beer	4	0.23	1.00		EFSA, 2013
Barley, pot/pearl	4	0.25	1.00		EFSA, 2013
Barley, bran	4	3.25	1.00		U.K. 2009a EFSA, 2013
Wheat/rye, whole-meal flour	4	0.68	1.00		U.K. 2009a EFSA, 2013
Wheat/rye, whole-meal bread	4	0.51	1.00		
Wheat/rye, white flour	4	0.45	1.00		
Wheat/rye, bran	4	1.67	1.00		
Beans (fresh, with pods), cooked	3	0.29	1.00	Processing factor for cooked beans is lower than 0.29 as residues were below the LOQ (worst case assumption). DAR	U.K. 2009a EFSA, 2013
Beans (fresh, with pods), canned	3	0.42	1.00		
Hops, beer	3	0.00	1.00	Additional PF: spent hops: 0,053; wort: 0,005; spent yeast: 0,016 (PROFile).	EFSA, 2013
Indicative processing factors (limited dataset)					
Oranges, juice	1	0.08	1.00	PROFile	EFSA, 2013
Oranges, dry pomace	1	0.42	1.00		EFSA, 2013
Strawberries, jam	2	0.36	1.00	PROFile	EFSA, 2013
Strawberries, canned	2	0.90	1.00	PROFile	EFSA, 2013
Tomatoes, peeled and canned	2	0.12	1.00	Canned/peeled tomatoes: no residues in processed product (PROFile).	EFSA, 2013
Tomatoes, paste	2	0.99	1.00		EFSA, 2013
Tomatoes, ketchup	2	0.48	1.00		EFSA, 2013
Tomatoes, juice	2	0.32	1.00		EFSA, 2013
Beans (fresh, without pods), cooked	2	0.05	1.00	PROFile	EFSA, 2013

Processed commodity	Number	Median PF [a]	Median CF [b]	Comments	Reference
Beans (fresh, without pods), canned	2	0.30	1.00		EFSA, 2013
Wheat/rye, white bread	2	0.57	1.00		U.K. 2009a EFSA, 2013
Rice, polished	1	0.09	1.00	PROFile	EFSA, 2013
Rice, bran	1	1.18	1.00		EFSA, 2013
New Data – No new data submitted in the context of this submission					

* 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.

7.3.5.2 Conclusion on processing studies

The effects of processing were reviewed in the framework of the peer review (EFSA, 2013). No additional processing studies were required for this application. As the residues from the uses under consideration were significantly lower than the previously reviewed studies used to establish the processing factors in wheat and barley, no additional studies were required for this submission. The established processing factors were used in the consumer risk assessment.

7.3.6 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.

7.3.6.1 Field rotational crop studies (KCA 6.6.2)

Available data

Several rotational crop field trials were evaluated in the framework of the peer review (U K, 2009a and UK, 2009b). At harvest, azoxystrobin residues were expected to be below the LOQ (0.01 mg/kg) in all mature plant parts except in wheat forage and wheat straw where the highest residues were expected to be 0.05 mg/kg and 0.04 mg/kg, respectively. However, no impact on the residue level in products of animal origin is expected (EFSA, 2013).

No new data submitted in the framework of this application.

Table 7.3- 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
US data					
Winter Wheat	2 x 0.896 kg a.s./ha (Total seasonal 1.792 kg a.s./ha)	Leafy vegetables	Mustard Greens	29 & 34	UK, 2009a UK, 2009b EFSA, 2013
		Root and tuber vegetables	Radish (tops and roots)	19 & 34	

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
		Cereal Grains	Millet Forage, hay, straw and grain	29, 34 & 45	
Cucumbers	8 x 0.224 kg a.s./ha Or 6 x 0.224 kg a.s./ha + 0.448 kg a.s./ha (Total seasonal 1.792 kg a.s./ha)	Leafy Vegetables	Mustard Greens	30 & 36	
		Root and tuber vegetables	Turnip (tops and roots)	30 & 36	
		Cereal Grains	Wheat (forage, hay, straw and grain)	30, 36, 45, 51, 59 & 61	
Leaf Lettuce	6 x 0.373 kg a.s./ha (Total seasonal rate 2.238 kg a.s./ha)	Leafy Vegetables	Leaf Lettuce	30 & 60	
		Root and tuber vegetables	Beetroot (tops and roots)	30 & 60	
		Cereals	Wheat (forage, hay, straw and grain)	30 & 60	

Conclusion on rotational crops studies

The RMS (UK, 2009a) concluded that the field rotational crop studies provide sufficient evidence to demonstrate that relevant residues will not be present and none of the already established MRLs will be exceeded as a result of the cultivation of rotational crops.

7.3.7 Other / special studies (KCA 6.10, KCA 6.10.1)

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of BAS 736 00 F. Therefore, other special studies are not needed.

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

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

As ARfD was not deemed necessary, acute risk assessment is not relevant.

7.3.8.1 Input values for the consumer risk assessment

The current MRLs (Reg. (EU) No 2022/476) were used for the input values for the consumer risk assessment.

Table 7.3- 15: Input values for the consumer risk assessment

	Chronic risk assessment	
Commodity	Input value (mg/kg)	Comment
Risk assessment residue definition: azoxystrobin		
Grapefruits	4.9	STMR (EFSA, 2013)
Oranges	4.75	STMR (EFSA, 2013)
Lemons	4.9	STMR (EFSA, 2013)
Limes	4.9	STMR (EFSA, 2013)
Mandarins	4.9	STMR (EFSA, 2013)
Almonds	0.01	STMR (EFSA, 2013)
Brazil nuts	0.01	STMR (EFSA, 2013)
Cashew nuts	0.01	STMR (EFSA, 2013)
Chestnuts	0.01	STMR (EFSA, 2013)
Coconuts	0.01	STMR (EFSA, 2013)
Hazelnuts/cobnuts	0.01	STMR (EFSA, 2013)
Macadamia	0.01	STMR (EFSA, 2013)
Pecans	0.01	STMR (EFSA, 2013)
Pine nut kernels	0.01	STMR (EFSA, 2013)
Pistachios	0.44	STMR (EFSA, 2013)
Walnuts	0.01	STMR (EFSA, 2013)
Apricots	0.74	STMR (EFSA, 2013)
Cherries (sweet)	0.74	STMR (EFSA, 2013)
Peaches	0.74	STMR (EFSA, 2013)
Plums	0.74	STMR (EFSA, 2013)
Table grapes	0.72	STMR (EFSA, 2016a)
Wine grapes	0.72	STMR (EFSA, 2016a)
Strawberries	1.3	STMR (EFSA, 2013)
Blackberries	1.03	STMR (EFSA, 2013)
Dewberries	1.03	STMR (EFSA, 2013)
Raspberries (red and yellow)	1.03	STMR (EFSA, 2013)
Blueberries	1.03	STMR (EFSA, 2013)
Cranberries	0.23	STMR (EFSA, 2013)
Currants (red, black and white)	1.03	STMR (EFSA, 2013)
Gooseberries (green, red and yellow)	1.03	STMR (EFSA, 2013)
Rose hips	1.03	STMR (EFSA, 2013)
Mulberries (black and white)	1.03	STMR (EFSA, 2013)
Azarole/Mediterranean medlar	1.03	STMR (EFSA, 2013)
Elderberries	1.03	STMR (EFSA, 2013)
Carambolas	0.023	STMR (EFSA, 2013)

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Passion fruits/maracujas	1.1	STMR (EFSA, 2013)
Prickly pears/cactus fruits	0.041	STMR (FAO, 2017)
Bananas	0.0326	STMR * PeF (EFSA, 2013)
Mangoes	0.28	STMR (EFSA, 2013)
Papayas	0.1	STMR (EFSA, 2013)
Potatoes	2.3	STMR (FAO, 2013)
Cassava roots/manioc	0.23	STMR (EFSA, 2013)
Sweet potatoes	0.23	STMR (EFSA, 2013)
Yams	0.23	STMR (EFSA, 2013)
Arrowroots	0.23	STMR (EFSA, 2013)
Beetroots	0.23	STMR (EFSA, 2013)
Carrots	0.23	STMR (EFSA, 2013)
Celeriacs/turnip rooted celeries	0.23	STMR (EFSA, 2013)
Horseradishes	0.23	STMR (EFSA, 2013)
Jerusalem artichokes	0.23	STMR (EFSA, 2013)
Parsnips	0.23	STMR (EFSA, 2013)
Parsley roots/Hamburg roots parsley	0.23	STMR (EFSA, 2013)
Radishes	0.295	STMR (EFSA, 2013)
Salsifies	0.23	STMR (EFSA, 2013)
Swedes/rutabagas	0.23	STMR (EFSA, 2013)
Turnips	0.23	STMR (EFSA, 2013)
Garlic	2.2	STMR (EFSA, 2013)
Onions	2.2	STMR (EFSA, 2013)
Shallots	2.2	STMR (EFSA, 2013)
Spring onions/green onions and Welsh onions	2.2	STMR (EFSA, 2013)
Tomatoes	0.35	STMR (EFSA, 2013)
Sweet peppers/bell peppers	0.71	STMR (EFSA, 2013)
Aubergines/egg plants	0.35	STMR (EFSA, 2013)
Okra/lady's fingers	0.35	STMR (EFSA, 2013)
Cucumbers	0.17	STMR (EFSA, 2013)
Gherkins	0.17	STMR (EFSA, 2013)
Courgettes	0.17	STMR (EFSA, 2013)
Melons	0.17	STMR (EFSA, 2013)
Pumpkins	0.17	STMR (EFSA, 2013)
Watermelons	1	MRL (EFSA, 2013)
Broccoli	1.2	STMR (EFSA, 2013)
Cauliflowers	1.2	STMR (EFSA, 2013)
Brussels sprouts	1.2	STMR (EFSA, 2013)
Head cabbages	1.2	STMR (EFSA, 2013)
Chinese cabbages/pe-tsai	1.04	STMR (EFSA, 2013)
Kales	1.04	STMR (EFSA, 2013)
Kohlrabies	1.2	STMR (EFSA, 2013)
Lamb's lettuce/corn salads	3.4	STMR (EFSA, 2020)
Lettuces	3.4	STMR (EFSA, 2020)
Escaroles/broad-leaved endives	3.4	STMR (EFSA, 2020)
Cress and other sprouts and shoots	3.4	STMR (EFSA, 2020)
Land cress	3.4	STMR (EFSA, 2020)
Roman rocket/rucola	3.4	STMR (EFSA, 2020)
Red mustards	3.4	STMR (EFSA, 2020)
Baby leaf crops (including brassica species)	3.4	STMR (EFSA, 2020)

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Spinaches	3.9	STMR (EFSA, 2013)
Purslanes	3.9	STMR (EFSA, 2013)
Chards/beet leaves	3.9	STMR (EFSA, 2013)
Witloofs/Belgian endives	0.05	STMR (EFSA, 2013)
Chervil	23	STMR (EFSA, 2013)
Chives	23	STMR (EFSA, 2013)
Celery leaves	23	STMR (EFSA, 2013)
Parsley	23	STMR (EFSA, 2013)
Sage	23	STMR (EFSA, 2013)
Rosemary	23	STMR (EFSA, 2013)
Thyme	23	STMR (EFSA, 2013)
Basil and edible flowers	23	STMR (EFSA, 2013)
Laurel/bay leaves	23	STMR (EFSA, 2013)
Tarragon	23	STMR (EFSA, 2013)
Beans (with pods)	1.04	STMR (EFSA, 2013)
Beans (without pods)	1.04	STMR (EFSA, 2013)
Peas (with pods)	1.04	STMR (EFSA, 2013)
Peas (without pods)	1.04	STMR (EFSA, 2013)
Lentils (fresh)	1.04	STMR (EFSA, 2013)
Asparagus	0.01	STMR (EFSA, 2013)
Cardoons	1.98	STMR (EFSA, 2013)
Celeries	1.98	STMR (EFSA, 2013)
Florence fennels	2.2	STMR (EFSA, 2013)
Globe artichokes	1.8	STMR (EFSA, 2013)
Leeks	2.2	STMR (EFSA, 2013)
Rhubarbs	0.1	STMR (EFSA, 2013)
Beans	0.01	STMR (EFSA, 2013)
Lentils	0.01	STMR (EFSA, 2013)
Peas	0.01	STMR (EFSA, 2013)
Lupins/lupini beans	0.01	STMR (EFSA, 2013)
Linseeds	0.02	STMR (EFSA, 2016b)
Peanuts/groundnuts	0.01	STMR (EFSA, 2013)
Poppy seeds	0.06	STMR (EFSA, 2013)
Sunflower seeds	0.04	STMR (EFSA, 2013)
Rapeseeds/canola seeds	0.06	STMR (EFSA, 2013)
Soyabeans	0.05	STMR (EFSA, 2013)
Mustard seeds	0.06	STMR (EFSA, 2013)
Cotton seeds	0.01	STMR (EFSA, 2013)
Safflower seeds	0.02	STMR (EFSA, 2016b)
Borage seeds	0.02	STMR (EFSA, 2016b)
Gold of pleasure seeds	0.06	STMR (EFSA, 2013)
Barley	0.05	STMR (FAO, 2013)
Maize/corn	0.01	STMR (EFSA, 2013)
Oat	0.05	STMR (FAO, 2013)
Rice	0.52	STMR (EFSA, 2013)
Rye	0.08	STMR (EFSA, 2013)
Sorghum	1.85	STMR (FAO, 2013)
Wheat	0.08	STMR (EFSA, 2013)
Coffee beans	0.01	STMR (FAO, 2013)
Hops (dried)	3.93	STMR (EFSA, 2013)

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Sugar beet roots	0.01	STMR (EFSA, 2013)
Sugar canes	0.02	STMR (FAO, 2017)
Chicory roots	0.03	STMR (EFSA, 2013)
Swine: Muscle/meat	0.01	STMR (EFSA, 2013 based on CXL)
Swine: Fat tissue	0.01	STMR (EFSA, 2013 based on CXL)
Swine: Liver	0.01	STMR (EFSA, 2013 based on CXL)
Swine: Kidney	0.01	STMR (EFSA, 2013 based on CXL)
Bovine: Muscle/meat	0.01	STMR (EFSA, 2013 based on CXL)
Bovine: Fat tissue	0.01	STMR (EFSA, 2013 based on CXL)
Bovine: Liver	0.01	STMR (EFSA, 2013 based on CXL)
Bovine: Kidney	0.01	STMR (EFSA, 2013 based on CXL)
Sheep: Muscle/meat	0.01	STMR (EFSA, 2013 based on CXL)
Sheep: Fat tissue	0.01	STMR (EFSA, 2013 based on CXL)
Sheep: Liver	0.01	STMR (EFSA, 2013 based on CXL)
Sheep: Kidney	0.01	STMR (EFSA, 2013 based on CXL)
Goat: Muscle/meat	0.01	STMR (EFSA, 2013 based on CXL)
Goat: Fat tissue	0.01	STMR (EFSA, 2013 based on CXL)
Goat: Liver	0.01	STMR (EFSA, 2013 based on CXL)
Goat: Kidney	0.01	STMR (EFSA, 2013 based on CXL)
Poultry: Muscle/meat	0.01	STMR (EFSA, 2013 based on CXL)
Poultry: Fat tissue	0.01	STMR (EFSA, 2013 based on CXL)
Poultry: Liver	0.01	STMR (EFSA, 2013 based on CXL)
Milk: Cattle	0.01	STMR (EFSA, 2013 based on CXL)
Milk: Sheep	0.01	STMR (EFSA, 2013 based on CXL)
Milk: Goat	0.01	STMR (EFSA, 2013 based on CXL)
Eggs: Chicken	0.01	STMR (EFSA, 2013 based on CXL)

Commodity	Chronic Risk Assessment	
	Input Value (mg/kg)	Comment
Risk assessment residue definition: azoxystrobin		
Grapefruits	15	EU MRL
Oranges	15	EU MRL
Lemons	15	EU MRL
Limes	15	EU MRL
Mandarins	15	EU MRL
Almonds	0.01	EU MRL
Brazil nuts	0.01	EU MRL
Cashew nuts	0.01	EU MRL
Chestnuts	0.01	EU MRL
Coconuts	0.01	EU MRL
Hazelnuts/cobnuts	0.01	EU MRL
Macadamia	0.01	EU MRL
Pecans	0.01	EU MRL
Pine nut kernels	0.01	EU MRL
Pistachios	1	EU MRL
Walnuts	0.01	EU MRL
Apples	0.01	EU MRL
Pears	0.01	EU MRL

Commodity	Chronic Risk Assessment	
	Input Value (mg/kg)	Comment
Quinces	0.01	EU MRL
Medlar	0.01	EU MRL
Loquats/Japanese medlars	0.01	EU MRL
Apricots	2	EU MRL
Cherries (sweet)	2	EU MRL
Peaches	2	EU MRL
Plums	2	EU MRL
Table grapes	3	EU MRL
Wine grapes	3	EU MRL
Strawberries	10	EU MRL
Blackberries	5	EU MRL
Dewberries	5	EU MRL
Raspberries (red and yellow)	5	EU MRL
Blueberries	5	EU MRL
Cranberries	0.5	EU MRL
Currants (red, black and white)	5	EU MRL
Gooseberries (green, red and yellow)	5	EU MRL
Rose hips	5	EU MRL
Mulberries (black and white)	5	EU MRL
Azarole/Mediteranean medlar	5	EU MRL
Elderberries	5	EU MRL
Dates	0.01	EU MRL
Figs	0.01	EU MRL
Table olives	0.01	EU MRL
Kumquats	0.01	EU MRL
Carambolas	0.1	EU MRL
Kaki/Japanese persimmons	0.01	EU MRL
Jambuls/jambolans	0.01	EU MRL
Kiwi fruits (green, red, yellow)	0.01	EU MRL
Litchis/lychees	0.01	EU MRL
Passionfruits/maracujas	4	EU MRL
Prickly pears/cactus fruits	0.3	EU MRL
Star apples/cainitos	0.01	EU MRL
American persimmon/Virginia kaki	0.01	EU MRL
Avocados	0.01	EU MRL
Bananas	2	EU MRL
Mangoes	4	EU MRL
Papayas	0.3	EU MRL
Granate apples/pomegranates	0.01	EU MRL
Cherimoyas	0.01	EU MRL
Guavas	0.01	EU MRL
Pineapples	0.01	EU MRL
Breadfruits	0.01	EU MRL
Durians	0.01	EU MRL
Soursops/guanabanas	0.01	EU MRL
Potatoes	7	EU MRL
Cassava roots/manioc	1	EU MRL

Commodity	Chronic Risk Assessment	
	Input Value (mg/kg)	Comment
Sweet potatoes	1	EU MRL
Yams	1	EU MRL
Arrowroots	1	EU MRL
Beetroots	1	EU MRL
Carrots	1	EU MRL
Celeriacs/turnip rooted celeries	1	EU MRL
Horseradishes	1	EU MRL
Jerusalem artichokes	1	EU MRL
Parsnips	1	EU MRL
Parsley roots/Hamburg roots parsley	1	EU MRL
Radishes	1.5	EU MRL
Salsifies	1	EU MRL
Swedes/rutabagas	1	EU MRL
Turnips	1	EU MRL
Garlic	10	EU MRL
Onions	10	EU MRL
Shallots	10	EU MRL
Spring onions/green onions and Welsh onions	10	EU MRL
Tomatoes	3	EU MRL
Sweet peppers/bell peppers	3	EU MRL
Aubergines/egg plants	3	EU MRL
Okra/lady’s fingers	3	EU MRL
Cucumbers	1	EU MRL
Gherkins	1	EU MRL
Courgettes	1	EU MRL
Melons	1	EU MRL
Pumpkins	1	EU MRL
Watermelons	1	EU MRL
Sweet corn	0.01	EU MRL
Broccoli	5	EU MRL
Cauliflowers	5	EU MRL
Brussels sprouts	5	EU MRL
Head cabbages	5	EU MRL
Chinese cabbages/pe-tsai	6	EU MRL
Kales	6	EU MRL
Kohlrabies	5	EU MRL
Lamb's lettuce/corn salads	15	EU MRL
Lettuces	15	EU MRL
Escaroles/broad-leaved endives	15	EU MRL
Cress and other sprouts and shoots	15	EU MRL
Land cress	15	EU MRL
Roman rocket/rucola	15	EU MRL
Red mustards	15	EU MRL
Baby leaf crops (including brassica species)	15	EU MRL
Other lettuce and other salad plants	15	EU MRL
Spinaches	15	EU MRL
Purslanes	15	EU MRL

Commodity	Chronic Risk Assessment	
	Input Value (mg/kg)	Comment
Chards/beet leaves	15	EU MRL
Other spinach and similar	15	EU MRL
Grape leaves and similar species	0.01	EU MRL
Watercress	0.01	EU MRL
Witloofs/Belgian endives	0.3	EU MRL
Chervil	70	EU MRL
Chives	70	EU MRL
Celery leaves	70	EU MRL
Parsley	70	EU MRL
Sage	70	EU MRL
Rosemary	70	EU MRL
Thyme	70	EU MRL
Basil and edible flowers	70	EU MRL
Laurel/bay leaves	70	EU MRL
Tarragon	70	EU MRL
Other herbs	70	EU MRL
Beans (with pods)	3	EU MRL
Beans (without pods)	3	EU MRL
Peas (with pods)	3	EU MRL
Peas (without pods)	3	EU MRL
Lentils (fresh)	3	EU MRL
Asparagus	0.01	EU MRL
Cardoons	15	EU MRL
Celeries	15	EU MRL
Florence fennels	10	EU MRL
Globe artichokes	5	EU MRL
Leeks	10	EU MRL
Rhubarbs	0.6	EU MRL
Bamboo shoots	0.01	EU MRL
Palm hearts	0.01	EU MRL
Cultivated fungi	0.01	EU MRL
Wild fungi	0.01	EU MRL
Beans	0.15	EU MRL
Lentils	0.15	EU MRL
Peas	0.15	EU MRL
Lupins/lupini beans	0.15	EU MRL
Linseeds	0.4	EU MRL
Peanuts/groundnuts	0.2	EU MRL
Poppy seeds	0.5	EU MRL
Sesame seeds	0.01	EU MRL
Sunflower seeds	0.5	EU MRL
Rapeseeds/canola seeds	0.5	EU MRL
Soyabeans	0.5	EU MRL
Mustard seeds	0.5	EU MRL
Cotton seeds	0.7	EU MRL
Pumpkin seeds	0.01	EU MRL
Safflower seeds	0.4	EU MRL

Commodity	Chronic Risk Assessment	
	Input Value (mg/kg)	Comment
Borage seeds	0.4	EU MRL
Gold of pleasure seeds	0.5	EU MRL
Hemp seeds	0.01	EU MRL
Castor beans	0.01	EU MRL
Olives for oil production	0.01	EU MRL
Oil palm kernels	0.01	EU MRL
Oil palm fruits	0.03	EU MRL
Kapok	0.01	EU MRL
Barley	1.5	EU MRL
Buckwheat and other pseudo-cereals	0.01	EU MRL
Maize/corn	0.02	EU MRL
Common millet/proso millet	0.01	EU MRL
Oat	1.5	EU MRL
Rice	5	EU MRL
Rye	0.5	EU MRL
Sorghum	10	EU MRL
Wheat	0.5	EU MRL
Tea (dried leaves of Camellia sinensis)	0.05	EU MRL
Coffee beans	0.03	EU MRL
Chamomille	60	EU MRL
Hybiscus/roselle	60	EU MRL
Rose	60	EU MRL
Jasmine	60	EU MRL
Lime/linden	60	EU MRL
Strawberry leaves	60	EU MRL
Rooibos	60	EU MRL
Mate/maté	60	EU MRL
Valerian root	0.3	EU MRL
Ginseng root	0.3	EU MRL
Cocoa beans	0.05	EU MRL
Carobs/Saint John's bread	0.05	EU MRL
HOPS (dried)	30	EU MRL
Spices (seeds)	0.3	EU MRL
Spices (fruits)	0.3	EU MRL
Spices (bark)	0.05	EU MRL
Liquorice	0.05	EU MRL
Turmeric/curcuma	0.05	EU MRL
Horseradish, root spices	7	EU MRL
Other spices (roots)	0.05	EU MRL
Spices (buds)	0.05	EU MRL
Spices (flower stigma)	0.05	EU MRL
Mace	0.05	EU MRL
Sugar beet roots	5	EU MRL
Sugar canes	0.05	EU MRL
Chicory roots	0.09	EU MRL
Other sugar plants	0.01	EU MRL
Swine: Muscle/meat	0.01	EU MRL

Commodity	Chronic Risk Assessment	
	Input Value (mg/kg)	Comment
Swine: Fat tissue	0.05	EU MRL
Swine: Liver	0.07	EU MRL
Swine: Kidney	0.07	EU MRL
Swine: Edible offals (other than liver and kidney)	0.07	EU MRL
Bovine: Muscle/meat	0.01	EU MRL
Bovine: Fat tissue	0.05	EU MRL
Bovine: Liver	0.07	EU MRL
Bovine: Kidney	0.07	EU MRL
Bovine: Edible offals (other than liver and kidney)	0.07	EU MRL
Sheep: Muscle/meat	0.01	EU MRL
Sheep: Fat tissue	0.05	EU MRL
Sheep: Liver	0.07	EU MRL
Sheep: Kidney	0.07	EU MRL
Sheep: Edible offals (other than liver and kidney)	0.07	EU MRL
Goat: Muscle/meat	0.01	EU MRL
Goat: Fat tissue	0.05	EU MRL
Goat: Liver	0.07	EU MRL
Goat: Kidney	0.07	EU MRL
Goat: Edible offals (other than liver and kidney)	0.07	EU MRL
Equine: Muscle/meat	0.01	EU MRL
Equine: Fat tissue	0.05	EU MRL
Equine: Liver	0.07	EU MRL
Equine: Kidney	0.07	EU MRL
Equine: Edible offals (other than liver and kidney)	0.07	EU MRL
Poultry: Muscle/meat	0.01	EU MRL
Poultry: Fat tissue	0.01	EU MRL
Poultry: Liver	0.01	EU MRL
Poultry: Kidney	0.01	EU MRL
Poultry: Edible offals (other than liver and kidney)	0.01	EU MRL
Milk: Cattle	0.01	EU MRL
Milk: Sheep	0.01	EU MRL
Milk: Goat	0.01	EU MRL
Birds eggs	0.01	EU MRL
Eggs: Chicken	0.01	EU MRL

7.3.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

~~The proposed uses of azoxystrobin in the formulation BAS 736 00 F do not represent the critical GAP in barley and wheat and therefore, the residues from the proposed use do not change the most recent risk assessment (EFSA, 2020).~~ The calculation of the TMDI using all the MRLs according to Reg. (EU) No 2022/476 does not lead to an exceedance of the ADI in any population group. Therefore, no additional refinements were used to calculate the risk in EFSA PRIMo rev. 3.1 which results in a utilization of the

ADI of 83% with the NL toddler being the population group with the highest exposure with oranges as the highest contributor to the diet (17%).

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

Table 7.3- 16: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo revision 3.1	~~66~~83% (based on ~~DE Child~~ NL Toddler)
IEDI (% ADI) according to EFSA PRIMo revisoin 3.1	~~19 % (based on DE Child)~~ Not required
IESTI (% ARfD) according to EFSA PRIMo revision 3.1*	Not relevant
NESTI (% ARfD) **	Not relevant

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

The proposed uses of Azoxystrobin in the formulation BAS 736 00 F do not represent unacceptable chronic risks for the consumer.

7.4 Combined exposure and risk assessment

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

zRMS:
The uses under consideration provide only a minor contribution to the overall exposure of consumers to pesticide residues. A harmonised approach is not yet available, and currently no specific consideration is warranted in the scope of this evaluation.

7.5 References

Fluxapyroxad

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United Kingdom, 2011a. Draft assessment report (DAR) on the active substance BAS 700 F (fluxapyroxad) prepared by the rapporteur Member State the United Kingdom in the framework of Council Directive 91/414/EEC, January 2011.

United Kingdom, 2011b. Final Addendum to the draft assessment report on BAS 700 F (fluxapyroxad) compiled by EFSA, October 2011.

Azoxystrobin

EFSA (European Food Safety Authority), 2010. Peer Review Report to the conclusion regarding the peer review of the pesticide risk assessment of the active substance azoxystrobin. EFSA Journal 2010; 8(4):1542.

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EFSA (European Food Safety Authority), 2016a. Reasoned opinion on the Modification of the existing maximum residue levels for azoxystrobin in grapes. EFSA-Q-2015-00492. EFSA Journal 2016a;14(2):4415

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Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.3.1/1	Erdmann, H.	2021	Study on the residue behaviour of BAS 700 F (Fluxapyroxad) and BAS 9164 F (Azoxystrobin) in wheat after application of BAS 736 00 F under field conditions in Northern and Southern Europe, 2019 2020/2006184 Agro-Check Dr. Teresiak & Erdmann GbR, Lentzke, Germany Fed.Rep. yes Unpublished	No	BASF
KCA 6.3.1/2	Gabriel, E.	2021	Residues of Azoxystrobin (BAS 9164 F) and Fluxapyroxad (BAS 700 F) in Wheat after Treatment with BAS 736 00 F under Field Conditions in Northern and Southern Europe, 2020 2021/2022810 SGS Institut Fresenius GmbH, Taunusstein, Germany Fed.Rep. yes Unpublished	No	BASF
KCA 6.3.2/1	Erdmann, H.	2020	Study on the residue behaviour of BAS 700 F (Fluxapyroxad) and BAS 9164 F (Azoxystrobin) in barley after application of BAS 736 00 F under field conditions in Northern and Southern Europe, 2019 2020/2006183 Agro-Check Dr. Teresiak & Erdmann GbR, Lentzke, Germany Fed.Rep. yes Unpublished	No	BASF
KCA 6.3.2/2	Mahlo, C.	2021	Residues of Azoxystrobin (BAS 9164 F) and Fluxapyroxad (BAS 700 F) in Barley after Treatment with BAS 736 00 F under Field Conditions in Northern and Southern Europe, 2020 2021/2020010 SGS Institut Fresenius GmbH, Taunusstein, Germany Fed.Rep. yes Unpublished	No	BASF

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

BAS 736 00 F is a new product, no product data have been evaluated previously.

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	Verte-brate 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	Verte-brate study Y/N	Owner
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1 FLUXAPYROXAD

A 2.1.1 Stability of residues

No new data was submitted.

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

No new data was submitted.

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/US import (Art. 12, EFSA, 2020)	2	0.100 kg/ha	-	-	21
Intended cGAP (1, 12*)	2	0.100 kg/ha	21 days	69	35

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

A 2.1.3.1.1 Study 1 – BASF DocID 2020/2006184

Reference:	CA 6.3.1/1
Report	Study on the residue behaviour of BAS 700 F (Fluxapyroxad) and BAS 9164 F (Azoxystrobin) in wheat after application of BAS 736 00 F under field conditions in Northern and Southern Europe, 2019 Erdmann H.-P., 2021 report No 851042 BASF DocID 2020/2006184 Authority registration No
Guideline(s):	EC 1107/2009 of the European Parliament and of the Council of 21 Oct

	2009, EEC 7029/VI/95 rev. 5 (July 22 1997), EEC SANCO 7525/VI/95 Rev. 10.3 (June 2017), OECD 509 Crop Field Trial (2009)
Deviations:	No
GLP:	Yes (certified by Land Brandenburg Ministerium der Justiz und fuer Europa und Verbraucherschutz, Potsdam, Germany)
Acceptability:	Yes

zRMS:
Four field trials (L190173, L190174, L190175 and L190176) were conducted during the growing season of 2019 in order to determine the magnitude of residues of BAS 700 F (Fluxapyroxad) in wheat after treatment with BAS 736 00 F under field conditions in Germany, Belgium, Poland, Hungary. Data for four field trials conducted in southern zone was shown for information only. N-EU data was used for evaluation. Wheat specimens were analysed for BAS 700 F (Fluxapyroxad) and its metabolites using the BASF Method L0137/01, accepted at EU level. The method has a limit of quantitation of 0.010 mg/kg.

The study is considered acceptable to support the use of BAS 736 00 F in the central zone MSs. The GAP on wheat is deemed adequately supported by data on the magnitude of residues of fluxapyroxad resulted from the intended uses.

Table A 2: Summary of recoveries of FLUXAPYROXAD and its metabolites in wheat

Matrix	Fortification Levels [mg/kg]	Summary Recoveries					
		n	Mean [%]	RSD [%]	n	Mean [%]	RSD [%]
Method No. L0137/01*		**FLUXAPYROXAD**			**M700F002**		
Whole plant no roots	0.01, 0.10, and 6.0[1]	7	94.1	8.8	6	91.2	6.9
Ears	0.01, 0.10, and 4.0[1]	9	83.5	15	6	96.3	3.4
Rest of plants without roots	0.01, 0.10, and 4.0[1]	7	96.7	7.9	6	87.6	11
Grain	0.010 and 0.10	6	93.3	8.8	6	89.1	14
Straw	0.01, 0.10, and 4.0[1]	7	85.4	6.6	6	104	8.4
Overall:		**36**	**90.1**	**11**	**30**	**93.7**	**11**
Method No. L0137/01*		**M700F008**			**M700F048**		
Whole plant no roots	0.01 and 0.10	6	89.5	13	6	107	7.4
Ears	0.01 and 0.10	6	93.4	11	6	106	5.6
Rest of plants without roots	0.01 and 0.10	6	87.2	9.8	6	94.0	7.4
Grain	0.01 and 0.10	6	92.6	12	6	102	8.3
Straw	0.01, 0.10 and 0.80[2]	9	77.1	12	6	89.4	10
Overall:		**33**	**87.0**	**13**	**30**	**99.7**	**10**

1 Only for FLUXAPYROXAD
2 Only for M700F008
n Number of recoveries
RSD Coefficient of variation
* LOQ 0.01 mg/kg for FLUXAPYROXAD, M700F002 and M700F008 (as parent equivalent, conversation factor 1.038), and LOQ 0.007 mg/kg for M700F048 (as parent equivalent, conversation factor 0.720)

Table A 3: Residues of FLUXAPYROXAD and metabolites in wheat (treated samples)

Trial No./ DocID/ Location/ EU zone, Year	Commodity/ Variety (a)	Date of 1. Sowing or planting 2. Flowering 3. Harvest (b)	Application rate per treatm. kg as/hL	Water L/ha	kg as/ha	Dates of treatment or no. of treatments and last date (c)	Growth stage at last date	Portion analyzed	Residues (mg/kg) BAS 700 F	M700F008 (e)	M700F048 (f)	M700F002	PHI (days) (d)	Details on trial (g)
L190173 2020/2006184 16833 Lentzke Brandenburg, Germany (N) 2019	Wheat GC 0654 Boregar	1. 02.11.2018 2. 29.05.-07.06.2019 3. 11.07.-25.07.2019	0.050	200	0.100	07.06.2019 2	69	Whole plant no roots	1.7	0.026	<0.007	<0.010	0	**BAS 736 00 F EC** **BAS 700 F 50 g/L** BAS 9164 F 75 g/L BASF method L0137/01 LOQ: 0.01 mg/kg (parent, M700F008 (e), M700F002), 0.007 mg/kg (M700F048 (f)) No residues above LOQ in any untreated specimen Storage time for all commodities <315 days
								Grain	0.012	<0.010	<0.007	<0.010	34	
								Straw	1.7	0.081	0.015	<0.010	34	
								Grain	0.013	<0.010	<0.007	<0.010	41	
								Straw	2.0	0.085	0.018	<0.010	41	
								Grain	0.012	<0.010	<0.007	<0.010	48	
								Straw	1.5	0.13	0.026	<0.010	48	
L190174 2020/2006184 6221 Saint-Amand, Wallonia, Belgium (N) 2019	Wheat GC 0654 Talent	1. 05.11.2018 2. 05.06.-14.06.2019 3. 01.08.2019	0.050	200	0.100	14.06.2019 2	69	Whole plants no roots	1.5	0.023	<0.007	<0.010	0	
								Ears	0.10	0.021	<0.007	<0.010	34	
								Rest of plants [1]	0.52	0.037	<0.007	<0.010	34	
								Grain	<0.010	<0.010	<0.007	<0.010	42	
								Straw	0.29	0.043	<0.007	<0.010	42	
								Grain	<0.010	<0.010	<0.007	<0.010	48	
								Straw	<0.010	<0.010	<0.007	<0.010	48	
L190175 2020/2006184 64-000 Spytkówki, Wielkoposka, Poland (N) 2019	Wheat GC 0654 Toras	1. 28.09.2018 2. 04.06.-14.06.2019 3. 29.07.2019	0.050	200	0.100	10.06.2019 2	69	Whole plant no roots	2.0	0.017	<0.007	<0.010	0	
								Grain	0.047	0.010	<0.007	<0.010	35	
								Straw	0.40	0.11	0.013	<0.010	35	
								Grain	0.047	0.010	<0.007	<0.010	43	
								Straw	1.5	0.064	<0.007	<0.010	43	
								Grain	0.057	0.012	<0.007	<0.010	49	
								Straw	1.1	0.062	<0.007	<0.010	49	
L190176 2020/2006184 8781 Bókaháza, Zala County, Hungary (N) 2019	Wheat GC 0654 CH Combine	1. 24.09.2018 2. 24.05.-03.06.2019 3. 18.07.2019	0.050	200	0.100	01.06.2019 2	69	Whole plants no roots	1.3	<0.010	<0.007	<0.010	0	
								Ears	0.15	0.019	<0.007	<0.010	35	
								Rest of plants [1]	0.49	0.014	<0.007	<0.010	35	
								Grain	0.027	<0.010	<0.007	<0.010	41	
								Straw	0.47	0.024	<0.007	<0.010	41	
								Grain	0.028	<0.010	<0.007	<0.010	48	
								Straw	0.46	0.020	<0.007	<0.010	48	

Trial No./ DocID/ Location/ EU zone, Year	Commodity/ Variety	Date of 1. Sowing or planting 2. Flowering 3. Harvest	Application rate per treatm.			Dates of treat-ment or no. of treat-ments and last date	Growth stage at last date	Portion analyzed	Residues (mg/kg)				PHI (days)	Details on trial
			kg as/hL	Water L/ha	kg as/ha				BAS 700 F	M700F008	M700F048	M700F002		
L190177 2020/2006184 32220 Garravet, Occitanie, France (S) 2019	Wheat GC 0654 Oregrain	1. 18.11.2018 2. 15.05.-21.05.2019 3. 13.07.2019	0.050	200	0.100	21.05.2019 2	69	Whole plants no roots	1.6	0.013	<0.007	<0.010	0	
								Ears	0.11	0.021	<0.007	<0.010	34	
								Rest of plants [1]	0.45	0.028	0.008	<0.010	34	
								Ears	0.14	0.029	<0.007	<0.010	42	
								Rest of plants [1]	0.53	0.037	0.011	<0.010	42	
								Grain	0.025	<0.010	<0.007	<0.010	48	
								Straw	0.48	0.062	0.015	<0.010	48	
L190178 2020/2006184 57100 Koufalia, Central Mezadonia, Greece (S) 2019	Wheat GC 0654 Gibraltar	1. 25.11.2018 2. 26.04.-02.05.2019 3.20.06.2019	0.050	200	0.100	02.05.2019 2	69	Whole plants no roots	2.8	0.037	<0.007	<0.010	0	
								Ears	0.13	0.020	<0.007	<0.010	35	
								Rest of plants [1]	0.78	0.071	0.011	<0.010	35	
								Grain	<0.010	<0.010	<0.007	<0.010	42	
								Straw	0.50	0.052	0.008	<0.010	42	
								Grain	<0.010	<0.010	<0.007	<0.010	48	
								Straw	0.29	0.041	0.007	<0.010	48	
L190179 2020/2006184 12050 Magliano Alfieri, Piedmont, Italy (S) 2019	Wheat GC 0654 Solehio	1. 15.10.2018 2. 21.05.-04.06.2019 3. 10.07.2019	0.050	200	0.100	04.06.2019 2	69	Whole plant no roots	1.3	0.014	<0.007	<0.010	0	
								Grain	0.033	<0.010	<0.007	<0.010	36	
								Straw	0.85	0.016	<0.007	<0.010	36	
								Grain	0.016	<0.010	<0.007	<0.010	42	
								Straw	0.47	<0.010	<0.007	<0.010	42	
								Grain	0.016	<0.010	<0.007	<0.010	50	
								Straw	0.82	<0.010	<0.007	<0.010	50	
L190180 2020/2006184 41200 Alcalá del Rio, Andalusia, Spain (S) 2019	Wheat GC 0654 Tejada	1. 10.12.2018 2. 26.03.-07.04.2019 3. 06.06.-07.06.2019	0.050	200	0.100	10.04.2019 2	69	Whole plants no roots	1.9	0.017	<0.007	<0.010	0	
								Ears	0.63	0.049	0.007	<0.010	34	
								Rest of plants [1]	0.61	0.057	0.014	<0.010	34	
								Ears	0.82	0.064	0.009	<0.010	42	
								Rest of plants [1]	1.1	0.098	0.027	<0.010	42	
								Grain	0.027	<0.010	<0.007	<0.010	50	
								Straw	1.0	0.063	0.017	<0.010	50	

(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)
(e) Expressed as parent equivalent, conversion factor for calculation of M700F008 to parent equivalent is 1.038
(f) Expressed as parent equivalent, conversion factor for calculation of M700F048 to parent equivalent is 0.720
(g) Reference to analytical method
1 Without roots
The underlined values (e.g. 0.010) are used in the assessment of residues in wheat (section 7.3.3.1).

A 2.1.3.1.2 Study 2 – BASF DocID 2021/2022810

Reference:	CA 6.3.1/2
Report	Residues of Azoxystrobin (BAS 9164 F) and Fluxapyroxad (BAS 700 F) in Wheat after Treatment with BAS 736 00 F under Field Conditions in Northern and Southern Europe, 2020 Gabriel E.J., Thirkell C., 2021 report No 851043 BASF DocID 2021/2022810 Authority registration No
Guideline(s):	EC 1107/2009 of the European Parliament and of the Council of 21 Oct 2009, EEC 7029/VI/95 rev. 5 (July 22 1997), EEC SANCO 7525/VI/95 Rev. 10.3 (June 2017), OECD 509 Crop Field Trial (2009)
Deviations:	No
GLP:	Yes (certified by Hess. Ministerium fuer Umwelt, Klimaschutz, Landwirtschaft und Verbraucherschutz, Wiesbaden, Germany)
Acceptability:	Yes

zRMS:
During the growing season of 2020 four field trials in wheat (L200132, L200133, L200134 and L200135) were conducted in Germany, the Netherlands, United Kingdom and Hungary in order to determine the magnitude of residues of fluxapyroxad (BAS 700 F) in wheat after treatment with BAS 736 00 F under field conditions. Data for four field trials conducted in southern zone was shown for information only. N-EU data was used for evaluation.
Wheat specimens were analysed for BAS 700 F (Fluxapyroxad) and its metabolites using the BASF Method L0137/01, accepted at EU level. The method has a limit of quantitation of 0.010 mg/kg.

The study is considered acceptable to support the use of BAS 736 00 F in the central zone MSs. The GAP on wheat is deemed adequately supported by data on the magnitude of residues of fluxapyroxad resulted from the intended uses.

Table A 4: Summary of recoveries of FLUXAPYROXAD and its metabolites in wheat

Matrix	Fortification Levels [mg/kg]	Summary Recoveries					
		n	Mean [%]	RSD [%]	n	Mean [%]	RSD [%]
Method No. L0137/01*		**FLUXAPYROXAD**			**M700F002**		
Whole plant no roots	0.01, 0.10, and 5.0	9	101	9.2	9	98.4	3.7
Ears	0.01, 0.10, and 5.0	7	92.1	7.6	7	92.9	1.5
Rest of plants without roots	0.01, 0.10, and 5.0	9	90.5	3.1	9	94.4	6.5
Grain	0.010, 0.10 and 1.0	9	92.2	3.1	9	91.4	2.9
Straw	0.01, 0.10, and 5.0	13	84.6	6.9	11	84.9	13
Overall:		**47**	**91.5**	**8.9**	**45**	**92.1**	**8.6**
Method No. L0137/01*		**M700F008**			**M700F048**		
Whole plant no roots	0.01, 0.10 and 5.0[1]	9	100	9.8	8	100	6.5
Ears	0.01, 0.10 and 5.0	7	90.3	4.4	7	93.5	3.5
Rest of plants without roots	0.01, 0.10 and 5.0	9	88.2	7.3	9	89.3	6.0
Grain	0.010, 0.10 and 1.0	9	90.0	4.6	9	96.5	9.8
Straw	0.01, 0.10, and 5.0	11	81.5	8.3	11	89.0	14
Overall:		**45**	**89.6**	**9.9**	**44**	**93.4**	**9.9**

1 Only for M700F008
n Number of recoveries
RSD Coefficient of variation
* LOQ 0.01 mg/kg for FLUXAPYROXAD, M700F002 and M700F008 (as parent equivalent, conversation factor 1.038), and LOQ 0.007 mg/kg for M700F048 (as parent equivalent, conversation factor 0.720)

Table A 5: Residues of FLUXAPYROXAD and metabolites in wheat (treated samples)

Trial No./ DocID/ Location/ EU zone, Year (a)	Commodity/ Variety (a)	Date of 1. Sowing or planting 2. Flowering 3. Harvest (b)	Application rate per treatm. kg as/hL	Water L/ha	kg as/ha	Dates of treatment or no. of treatments and last date (c)	Growth stage at last date	Portion analyzed	Residues (mg/kg) BAS 700 F	M700F008 (e)	M700F048 (f)	M700F002	PHI (days) (d)	Details on trial (g)
L200132 2021/2022810 79353 Bahlingen am Kaiserstuhl, Germany (N) 2020	Wheat GC 0654 Turandot	1. 18.09.2019 2. 12.05.-29.05.2020 3. 13.07.2020	0.050	200	0.100	25.05.2020 2	69	Whole plant no roots	3.9	0.040	<0.007	<0.010	0	**BAS 736 00 F EC BAS 700 F 50 g/L** BAS 9164 F 75 g/L BASF method L0137/01 LOQ: 0.01 mg/kg (parent, M700F008 (e), M700F002), 0.007 mg/kg (M700F048 (f)) No residues above LOQ in any untreated specimen Storage time for all commodities <106 days
								Ears	0.34	0.051	<0.007	<0.010	35	
								Rest of plants[1]	0.80	0.081	0.0076	<0.010	35	
								Ears	0.38	0.063	<0.007	<0.010	42	
								Rest of plants[1]	0.75	0.094	0.0085	<0.010	42	
								Grain	0.013	<0.010	<0.007	<0.010	49	
								Straw	1.4	0.19	0.025	<0.010	49	
L200133 2021/2022810 9695 Bellingwolde, Netherlands (N) 2020	Wheat GC 0654 Licamero	1. 07.04.2020 2. 30.06.-03.07.2020 3. 20.08.2020	0.050	200	0.100	03.07.2020 2	69	Whole plant no roots	4.4	0.082	<0.007	<0.010	0	
								Ears	0.23	0.034	<0.007	<0.010	34	
								Rest of plants[1]	0.41	0.040	0.0076	<0.010	34	
								Ears	0.23	0.032	<0.007	<0.010	41	
								Rest of plants[1]	0.51	0.051	0.010	<0.010	41	
								Grain	0.032	<0.010	<0.007	<0.010	48	
								Straw	0.95	0.14	<0.007	<0.010	48	
L200134 2021/2022810 OX15 6EP Banbury, United Kingdom (N) 2020	Wheat GC 0654 Skyfall	1. 12.11.2019 2. 04.06.-15.06.2020 3. 03.08.-12.08.2020	0.050	200	0.100	15.06.2020 2	69	Whole plant no roots	3.1	0.042	<0.007	<0.010	0	
								Ears	0.35	0.044	<0.007	<0.010	35	
								Rest of plants[1]	1.4	0.13	<0.007	<0.010	35	
								Grain	0.016	<0.010	<0.007	<0.010	43	
								Straw	1.7	0.14	<0.007	<0.010	43	
								Grain	0.016	<0.010	<0.007	<0.010	50	
								Straw	1.7	0.14	<0.007	<0.010	50	
L200135 2021/2022810 H-4461 Nyirtelek-Ferenltanya, Hungary (N) 2020	Wheat GC 0654 GK Csillag	1. 12.10.2019 2. 20.05.-30.05.2020 3.09.07.-10.07.2020	0.050	200	0.100	28.05.2020 2	69	Whole plant no roots	4.2	0.035	<0.007	<0.010	0	
								Ears	0.17	0.027	<0.007	<0.010	35	
								Rest of plants[1]	0.14	0.021	<0.007	<0.010	35	
								Grain	0.012	<0.010	<0.007	<0.010	42	
								Straw	0.13	0.019	<0.007	<0.010	42	
								Grain	<0.010	<0.010	<0.007	<0.010	48	
								Straw	0.061	<0.010	<0.007	<0.010	48	

Trial No./ DocID/ Location/ EU zone, Year	Commodity/ Variety	Date of 1. Sowing or planting 2. Flowering 3. Harvest	Application rate per treatm.			Dates of treatment or no. of treat-ments and last date	Growth stage at last date	Portion analyzed	Residues (mg/kg)				PHI (days)	Details on trial
			kg as/hL	Water L/ha	kg as/ha				BAS 700 F	M700F008	M700F048	M700F002		
L200136 2021/2022810 84500 Bollène, France (S) 2020	Wheat GC 0654 RGT Aven-tadur	1. 10.01.2020 2. 10.05.-13.05.2020 3. 03.07.2020	0.050	200	0.100	22.05.2020 2	69	Whole plant no roots	4.1	0.043	<0.007	<0.010	0	
								Grain	0.17	<0.010	<0.007	<0.010	35	
								Straw	3.0	0.16	0.027	<0.010	35	
								Grain	0.036	<0.010	<0.007	<0.010	42	
								Straw	2.7	0.12	0.022	<0.010	42	
								Grain	0.15	<0.010	<0.007	<0.010	49	
								Straw	2.9	0.12	0.021	<0.010	49	
L200137 2021/2022810 57006 Thessalo-niki, Greece (S) 2020	Wheat GC 0654 Grekale	1. 09.12.2019 2. 25.04.-05.05.2020 3. 20.06.2020	0.050	200	0.100	05.05.2020 2	69	Whole plant no roots	2.4	0.036	<0.007	<0.010	0	
								Ears	0.23	0.032	<0.007	<0.010	35	
								Rest of plants[1]	0.71	0.065	0.0094	<0.010	35	
								Grain	0.013	<0.010	<0.007	<0.010	41	
								Straw	1.4	0.17	0.015	<0.010	41	
								Grain	0.015	<0.010	<0.007	<0.010	49	
								Straw	1.6	0.17	0.019	<0.010	49	
L200138 2021/2022810 13040 Borgo D'Ale, Italy (S) 2020	Wheat GC 0654 Vespucci	1. 16.03.2020 2. 15.05.-25.05.2020 3. 07.07.2020	0.050	200	0.100	19.05.2020 2	69	Whole plant no roots	4.2	0.045	<0.007	<0.010	0	
								Grain	0.030	<0.010	<0.007	<0.010	35	
								Straw	0.36	0.062	0.0090	<0.010	35	
								Grain	0.058	0.014	<0.007	<0.010	41	
								Straw	0.66	0.11	0.016	<0.010	41	
								Grain	0.033	<0.010	<0.007	<0.010	49	
								Straw	0.70	0.11	0.014	<0.010	49	
L200139 2021/2022810 18128 Zafarraya, Spain (S) 2020	Wheat GC 0654 Marius	1. 21.10.2019 2. 01.05.-10.05.2020 3. 26.06.2020	0.050	200	0.100	08.05.2020 2	69	Whole plant no roots	1.9	0.037	<0.007	<0.010	0	
								Ears	0.14	0.017	<0.007	<0.010	35	
								Rest of plants[1]	0.54	0.029	<0.007	<0.010	35	
								Grain	0.014	<0.010	<0.007	<0.010	41	
								Straw	0.37	0.028	<0.007	<0.010	41	
								Grain	<0.010	<0.010	<0.007	<0.010	49	
								Straw	0.41	0.026	<0.007	<0.010	49	

(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)
(e) Expressed as parent equivalent, conversion factor for calculation of M700F008 to parent equivalent is 1.038
(f) Expressed as parent equivalent, conversion factor for calculation of M700F048 to parent equivalent is 0.720
(g) Reference to analytical method
1 Without roots
The underlined values (e.g. 0.010) are used in the assessment of residues in wheat (section 7.3.3.1).

A 2.1.3.2 Barley

Table A 6: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU/US import (Art. 12, EFSA, 2020)	2	0.100 kg/ha	-	-	21
Intended cGAP (2, 6, 13*)	2	0.100 kg/ha	21 days	69	35

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

A 2.1.3.2.1 Study 1 – BASF DocID 2020/2006183

Reference:	CA 6.3.2/1
Report	Study on the residue behaviour of BAS 700 F (Fluxapyroxad) and BAS 9164 F (Azoxystrobin) in barley after application of BAS 736 00 F under field conditions in Northern and Southern Europe, 2019 Erdmann H.P., 2020 report No 851044 BASF DocID 2020/2006183 Authority registration No
Guideline(s):	EC 1107/2009 of the European Parliament and of the Council of 21 Oct 2009, EEC 7029/VI/95 rev. 5 (July 22 1997), EEC SANCO 7525/VI/95 Rev. 10.3 (June 2017), OECD 509 Crop Field Trial (2009)
Deviations:	No
GLP:	Yes (certified by Land Brandenburg Ministerium der Justiz und fuer Europa und Verbraucherschutz, Potsdam, Germany)
Acceptability:	Yes

zRMS:
Four field trials (L190165, L190166, L190167 and L190168) were conducted during the growing season of 2019 in order to determine the magnitude of residues of BAS 700 F (Fluxapyroxad) in barley after treatment with BAS 736 00 F under field conditions in Germany, The Netherlands, Poland, Northern France. Data for four field trials conducted in southern zone was shown for information only. N-EU data was used for evaluation.
Barley specimens were analysed for BAS 700 F (Fluxapyroxad) and its metabolites using the BASF Method L0137/01, accepted at EU level. The method has a limit of quantitation of 0.010 mg/kg.

The study is considered acceptable to support the use of BAS 736 00 F in the central zone MSs. The GAP on barley is deemed adequately supported by data on the magnitude of residues of fluxapyroxad resulted from the intended uses.

Table A 7: Summary of recoveries of FLUXAPYROXAD and its metabolites in barley

Matrix	Fortification Levels [mg/kg]	Summary Recoveries					
		n	Mean [%]	RSD [%]	n	Mean [%]	RSD [%]
Method No. L0137/01*		**FLUXAPYROXAD**			**M700F002**		
Whole plant no roots	0.01, 0.10, and 3.2[1]	9	92.7	9.2	7	77.6	11
Ears	0.01, 0.10, and 4.0[1]	7	97.8	6.2	6	82.5	5.5
Rest of plants without roots	0.01, 0.10, and 5.2[1]	7	104	6.6	6	76.8	17
Grain	0.010, 0.10 and 0.50[1]	7	97.5	2.4	6	86.6	16
Straw	0.01, 0.10, and 5.2[1]	7	90.4	12	6	92.7	15
Overall:		**37**	**96.3**	**8.8**	**31**	**83.0**	**15**
Method No. L0137/01*		**M700F008**			**M700F048**		
Whole plant no roots	0.01 and 0.10	6	76.4	9.1	6	86.1	11
Ears	0.01 and 0.10	6	82.8	6.1	6	95.5	4.5
Rest of plants without roots	0.01 and 0.10	6	92.8	11	6	97.9	11
Grain	0.01 and 0.10	6	86.6	6.0	6	101	2.6
Straw	0.01, 0.10, and 0.80[2]	9	88.5	11	6	99.7	13
Overall:		**33**	**85.7**	**11**	**30**	**96.0**	**10**

1 Only for FLUXAPYROXAD
2 Only for M700F008
n Number of recoveries
RSD Coefficient of variation
* LOQ 0.01 mg/kg for FLUXAPYROXAD, M700F002 and M700F008 (as parent equivalent, conversation factor 1.038), and LOQ 0.007 mg/kg for M700F048 (as parent equivalent, conversation factor 0.720)

Table A 8: Residues of FLUXAPYROXAD and metabolites in barley (treated samples)

Trial No./ DocID/ Location/ EU zone, Year	Commodity/ Variety	Date of 1. Sowing or planting 2. Flowering 3. Harvest	Application rate per treatm.			Dates of treatment or no. of treatments and last date	Growth stage at last date	Portion analyzed	Residues (mg/kg)				PHI (days)	Details on trial
			kg as/hL	Water L/ha	kg as/ha				BAS 700 F	M700F008	M700F048	M700F002		
	(a)	(b)				(c)				(e)	(f)		(d)	(g)
L190165 2020/2006183 16833 Brunne, Brandenburg, Germany (N) 2019	Barley GC 0640 KWS Cassia	1. 26.09.2018 2. 10.05.-17.05.2019 3. 27.06.-01.07.2019	0.050	200	0.100	17.05.2019 2	69	Whole plant no roots	2.2	<0.010	<0.007	<0.010	0	**BAS 736 00 F EC** **BAS 700 F 50 g/L** BAS 9164 F 75 g/L BASF method L0137/01 LOQ: 0.01 mg/kg (parent, M700F008 (e), M700F002), 0.007 mg/kg (M700F048 (f)) No residues above LOQ in any untreated specimen Storage time for all commodities <424 days
								Ears	0.22	0.015	<0.007	<0.010	28	
								Rest of plants[1]	1.4	0.065	<0.007	<0.010	28	
								Ears	0.27	0.020	<0.007	<0.010	35	
								Rest of plants[1]	1.8	0.081	<0.007	<0.010	35	
								Grain	0.078	<0.010	<0.007	<0.010	41	
								Straw	1.2	0.049	<0.007	<0.010	41	
L190166 2020/2006183 6599 AV Ven-Zelderheide, Limburg, The Netherlands (N) 2019	Barley GC 0640 Nure	1. 10.10.2018 2. 12.05.-23.05.2019 3. 04.07.2019	0.050	200	0.100	23.05.2019 2	69	Whole plant no roots	2.5	0.015	<0.007	<0.010	0	
								Ears	0.15	0.012	<0.007	<0.010	27	
								Rest of plants[1]	0.40	0.031	<0.007	<0.010	27	
								Ears	0.39	0.026	<0.007	<0.010	34	
								Rest of plants[1]	0.48	0.029	<0.007	<0.010	34	
								Grain	0.098	<0.010	<0.007	<0.010	42	
								Straw	0.50	0.025	<0.007	<0.010	42	
L190167 2020/2006183 64000 Spytkówki, Wielkopolska, Poland (N) 2019	Barley GC 0640 Lutece	1. 14.09.2018 2. 12.05.-27.05.2019 3. 04.07.2019	0.050	200	0.100	24.05.2019 2	69	Whole plant no roots	1.5	<0.010	<0.007	<0.010	0	
								Ears	0.49	0.033	<0.007	<0.010	29	
								Rest of plants[1]	1.0	0.041	<0.007	<0.010	29	
								Grain	0.11	<0.010	<0.007	<0.010	34	
								Straw	1.1	0.057	0.009	<0.010	34	
								Grain	0.12	<0.010	<0.007	<0.010	41	
								Straw	1.1	0.019	<0.007	<0.010	41	
L190168 2020/2006183 59189 Steenbecque, Hauts-de-France, France (N) 2019	Barley GC 0640 Meseta	1. 02.11.2018 2. 16.05.-03.06.2019 3. 19.07.2019	0.050	200	0.100	03.06.2019 2	69	Whole plant no roots	1.6	<0.010	<0.007	<0.010	0	
								Ears	0.27	0.013	<0.007	<0.010	28	
								Rest of plants[1]	0.61	0.034	<0.007	<0.010	28	
								Ears	0.35	0.014	<0.007	<0.010	35	
								Rest of plants[1]	0.80	0.037	<0.007	<0.010	35	
								Grain	0.12	<0.010	<0.007	<0.010	42	
								Straw	0.84	0.045	<0.007	<0.010	42	

Trial No./ DocID/ Location/ EU zone, Year	Commodity/ Variety	Date of 1. Sowing or planting 2. Flowering 3. Harvest	Application rate per treatm.			Dates of treatment or no. of treat-ments and last date	Growth stage at last date	Portion analyzed	Residues (mg/kg)				PHI (days)	Details on trial
			kg as/hL	Water L/ha	kg as/ha				BAS 700 F	M700F008	M700F048	M700F002		
L190169 2020/2006183 31620 Bouloc, Occitanie, France (S) 2019	Barley GC 0640 Jule	1. 25.10.2018 2. 27.04.-04.05.2019 3. 25.06.-26.06.2019	0.050	200	0.100	02.05.2019 2	69	Whole plant no roots	1.8	0.013	<0.007	<0.010	0	
								Ears	0.14	0.015	<0.007	<0.010	27	
								Rest of plants[1]	0.20	0.014	<0.007	<0.010	27	
								Ears	0.11	0.012	<0.007	<0.010	35	
								Rest of plants[1]	0.29	0.023	<0.007	<0.010	35	
								Ears	0.094	0.011	<0.007	<0.010	42	
								Rest of plants[1]	0.26	0.023	<0.007	<0.010	42	
								Grain	0.034	<0.010	<0.007	<0.010	54	
								Straw	0.29	0.021	<0.007	<0.010	54	
L190170 2020/2006183 57400 Sindos, Central Macedonia, Greece (S) 2019	Barley GC 0640 Domino	1. 12.12.2018 2. 15.04.-26.04.2019 3. 04.06.2019	0.050	200	0.100	24.04.2019 2	69	Whole plant no roots	2.2	0.012	<0.007	<0.010	0	
								Ears	2.2	0.083	<0.007	<0.010	28	
								Rest of plants[1]	3.4	0.094	<0.007	<0.010	28	
								Grain	0.095	<0.010	<0.007	<0.010	35	
								Straw	1.7	0.047	<0.007	<0.010	35	
								Grain	0.17	<0.010	<0.007	<0.010	41	
								Straw	3.0	0.12	<0.007	<0.010	41	
L190171 2020/2006183 40052 Baricella, Emilia-Romagna, Italy (S) 2019	Barley GC 0640 KWS Ariane	1. 12.12.2018 2. 30.04.-10.05.2019 3. 21.06.2019	0.050	200	0.100	11.05.2019 2	69	Whole plant no roots	1.7	0.022	<0.007	<0.010	0	
								Ears	0.062	<0.010	<0.007	<0.010	28	
								Rest of plants[1]	0.094	<0.010	<0.007	<0.010	28	
								Ears	0.062	<0.010	<0.007	<0.010	34	
								Rest of plants[1]	0.10	<0.010	<0.007	<0.010	34	
								Grain	0.023	<0.010	<0.007	<0.010	41	
								Straw	0.059	<0.010	<0.007	<0.010	41	
L190172 2020/2006183 31390 Olite, Andalusia, Spain (S) 2019	Barley GC 0640 Touareg	1. 30.11.2018 2. 25.04.-03.05.2019 3. 13.06.2019	0.050	200	0.100	03.05.2019 2	69	Whole plant no roots	1.5	0.024	<0.007	<0.010	0	
								Ears	0.23	0.015	<0.007	<0.010	28	
								Rest of plants[1]	0.48	0.041	<0.007	<0.010	28	
								Ears	0.28	0.016	<0.007	<0.010	35	
								Rest of plants[1]	0.91	0.069	<0.007	<0.010	35	
								Grain	0.082	<0.010	<0.007	<0.010	41	
								Straw	0.71	0.051	<0.007	<0.010	41	

(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)
(e) Expressed as parent equivalent, conversion factor for calculation of M700F008 to parent equivalent is 1.038
(f) Expressed as parent equivalent, conversion factor for calculation of M700F048 to parent equivalent is 0.720
(g) Reference to analytical method
1 Without roots
The underlined values (e.g. 0.010) are used in the assessment of residues in wheat (section 7.3.3.1).

A 2.1.3.2.2 Study 2 – BASF DocID 2021/2020010

Reference:	CA 6.3.2/2
Report	Residues of Azoxystrobin (BAS 9164 F) and Fluxapyroxad (BAS 700 F) in Barley after Treatment with BAS 736 00 F under Field Conditions in Northern and Southern Europe, 2020 Mahlo C., 2021 report No 851045 BASF DocID 2021/2020010 Authority registration No
Guideline(s):	EC 1107/2009 of the European Parliament and of the Council of 21 Oct 2009, EEC 7029/VI/95 rev. 5 (July 22 1997), EEC SANCO 7525/VI/95 Rev. 10.3 (June 2017), OECD 509 Crop Field Trial (2009)
Deviations:	No
GLP:	Yes (certified by Hess. Ministerium fuer Umwelt, Klimaschutz, Landwirtschaft und Verbraucherschutz, Wiesbaden, Germany)
Acceptability:	Yes

zRMS:
Four field trials (L 200140, L 200141, L 200142 and L 200143) were conducted during the growing season of 2020 in order to determine the magnitude of residues of BAS 700 F (Fluxapyroxad) in barley after treatment with BAS 736 00 F under field conditions in Germany, Belgium, Hungary, Northern France. Data for four field trials conducted in southern zone was shown for information only. N-EU data was used for evaluation.
Barley specimens were analysed for BAS 700 F (Fluxapyroxad) and its metabolites using the BASF Method L0137/01, accepted at EU level. The method has a limit of quantitation of 0.010 mg/kg.

The study is considered acceptable to support the use of BAS 736 00 F in the central zone MSs. The GAP on barley is deemed adequately supported by data on the magnitude of residues of fluxapyroxad resulted from the intended uses.

Table A 9: Summary of recoveries of FLUXAPYROXAD and its metabolites in barley

Matrix	Fortification Levels [mg/kg]	Summary Recoveries					
		n	Mean [%]	RSD [%]	n	Mean [%]	RSD [%]
Method No. L0137/01*		**FLUXAPYROXAD**			**M700F002**		
Whole plant no roots	0.01, 0.10, and 5.0	9	94.1	3.5	9	98.6	5.3
Ears	0.01, 0.10, and 5.0	7	95.8	10	7	95.8	5.0
Rest of plants without roots	0.01, 0.10, 5.0 and 10	14	93.6	5.2	14	91.8	11
Grain	0.010, 0.10 and 1.0	7	87.9	9.5	7	91.4	4.7
Straw	0.01, 0.10, and 5.0	9	84.2	11	12	82.6	8.4
Overall:		**46**	**91.3**	**8.7**	**49**	**91.3**	**9.7**
Method No. L0137/01*		**M700F008**			**M700F048**		
Whole plant no roots	0.01, 0.10, and 5.0	9	91.2	4.6	9	95.5	3.5
Ears	0.01, 0.10, and 5.0	7	90.3	4.0	7	96.1	6.9
Rest of plants without roots	0.01, 0.10, 5.0 and 10	14	91.4	4.0	14	93.8	7.4
Grain	0.010, 0.10 and 1.0	7	86.0	9.6	7	90.2	7.1
Straw	0.01, 0.10, and 5.0	12	84.2	9.3	12	84.2	10
Overall:		**49**	**88.7**	**7.2**	**49**	**91.6**	**91.6**

n Number of recoveries
RSD Coefficient of variation
* LOQ 0.01 mg/kg for FLUXAPYROXAD, M700F002 and M700F008 (as parent equivalent, conversation factor 1.038), and LOQ 0.007 mg/kg for M700F048 (as parent equivalent, conversation factor 0.720)

Table A 10: Residues of FLUXAPYROXAD and metabolites in barley (treated samples)

Trial No./ DocID/ Location/ EU zone, Year	Commodity/ Variety (a)	Date of 1. Sowing or planting 2. Flowering 3. Harvest (b)	Application rate per treatm.			Dates of treatment or no. of treat-ments and last date (c)	Growth stage at last date	Portion analyzed	Residues (mg/kg)				PHI (days) (d)	Details on trial (g)
			kg as/hL	Water L/ha	kg as/ha				BAS 700 F	M700F008 (e)	M700F048 (f)	M700F002		
L200140 2021/2020010 67294 Mauchen-heim, Germany (N) 2020	Barley GC 0640 Avalon	1. 2020 (h) 2. 28.05.-09.06.2020 (h) 3. 18.-22.07.2020 (h)	0.050	200	0.100	09.06.2020 2	69	Whole plant no roots Ears Rest of plants[1] Grain Straw Grain Straw	2.7 0.22 0.98 0.037 0.83 0.044 1.6	0.070 0.034 0.098 <0.010 0.072 <0.010 0.15	<0.007 <0.007 <0.007 <0.007 <0.007 <0.007 0.0078	<0.010 <0.010 <0.010 <0.010 <0.010 <0.010 <0.010	0 29 29 35 35 41 41	**BAS 736 00 F EC** **BAS 700 F 50 g/L** BAS 9164 F 75 g/L BASF method L0137/01 LOQ: 0.01 mg/kg (parent, M700F008 (e), M700F002), 0.007 mg/kg (M700F048 (f))
L200141 2021/2020010 6221 Saint-Amand, Belgium (N) 2020	Barley GC 0640 RGT Planet	1. 2020 (h) 2. 01.-08.06.2020 (h) 3. 20.-29.07.2020 (h)	0.050	200	0.100	08.06.2020 2	69	Whole plant no roots Ears Rest of plants[1] Grain Straw Grain Straw Grain Straw	2.4 0.095 0.85 0.021 0.28 0.024 0.25 0.021 0.23	0.076 0.014 0.12 <0.010 0.037 <0.010 0.028 <0.010 0.027	<0.007 <0.007 <0.007 <0.007 <0.007 <0.007 <0.007 <0.007 <0.007	<0.010 <0.010 <0.010 <0.010 <0.010 <0.010 <0.010 <0.010 <0.010	0 28 28 35 35 42 42 51 51	
L200142 2021/2020010 3905 Monok, Hungary (N) 2020	Barley GC 0640 Malz	1. 2019 (h) 2. 05.-15.06.2020 (h) 3.15.-18.07.2020 (h)	0.050	200	0.100	12.06.2020 2	69	Whole plant no roots Grain Straw Grain Straw Grain Straw	1.9 0.030 0.082 0.031 0.073 0.033 0.10	0.016 0.023 <0.010 <0.010 <0.010 <0.010 0.011	<0.007 <0.007 <0.007 <0.007 <0.007 <0.007 <0.007	<0.010 <0.010 <0.010 <0.010 <0.010 <0.010 <0.010	0 27 27 34 34 42 42	No residues above LOQ in any un-treated specimen Storage time for all commodities <118 days

Trial No./ DocID/ Location/ EU zone, Year	Commodity/ Variety	Date of 1. Sowing or planting 2. Flowering 3. Harvest	Application rate per treatm.			Dates of treatment or no. of treat-ments and last date	Growth stage at last date	Portion analyzed	Residues (mg/kg)				PHI (days)	Details on trial
			kg as/hL	Water L/ha	kg as/ha				BAS 700 F	M700F008	M700F048	M700F002		
L200143 2021/2020010 02190 Juvincourt, France (N) 2020	Barley GC 0640 KWS Fantex	1. 2020 (h) 2. 21.-29.05.2020 (h) 3.12.07.2020 (h)	0.050	200	0.100	29.05.2020 2	69	Whole plant no roots	3.5	0.084	<0.007	<0.010	0	
								Ears	1.4	0.077	<0.007	<0.010	27	
								Rest of plants[1]	6.4	0.32	0.019	<0.010	27	
								Grain	0.14	<0.010	<0.007	<0.010	34	
								Straw	3.1	0.21	0.0079	<0.010	34	
								Grain	0.16	<0.010	<0.007	<0.010	42	
								Straw	3.8	0.26	0.010	<0.010	42	
L200144 2021/2020010 30840 Meynes, France (S) 2020	Barley GC 0640 KWS Fantex	1. 2020 (h) 2. 10.-28.05.2020 (h) 3.29.06.2020 (h)	0.050	200	0.100	25.05.2020 2	69	Whole plant no roots	2.3	0.045	<0.007	<0.010	0	
								Grain	0.51	0.016	<0.007	<0.010	29	
								Straw	2.0	0.082	<0.007	<0.010	29	
								Grain	0.53	0.020	<0.007	<0.010	35	
								Straw	2.5	0.10	<0.007	<0.010	35	
								Grain	1.0	0.034	<0.007	<0.010	42	
								Straw	3.2	0.14	<0.007	<0.010	42	
L200145 2021/2020010 57006 Thessalo-niki, Greece (S) 2020	Barley GC 0640 Barke	1. 2019 (h) 2. 15.-25.04.2020 (h) 3.11.06.2020 (h)	0.050	200	0.100	24.04.2020 2	69	Whole plant no roots	2.0	0.030	<0.007	<0.010	0	
								Ears	0.49	0.041	<0.007	<0.010	28	
								Rest of plants[1]	2.0	0.12	<0.007	<0.010	28	
								Ears	<0.010	<0.010	<0.007	<0.010	35	
								Rest of plants[1]	<0.010	<0.010	<0.007	<0.010	35	
								Grain	0.12	<0.010	<0.007	<0.010	41	
								Straw	1.2	0.081	<0.007	<0.010	41	
								Grain	0.12	<0.010	<0.007	<0.010	47	
								Straw	1.3	0.092	<0.007	<0.010	47	

Trial No./ DocID/ Location/ EU zone, Year	Commodity/ Variety	Date of 1. Sowing or planting 2. Flowering 3. Harvest	Application rate per treatm.			Dates of treatment or no. of treat-ments and last date	Growth stage at last date	Portion analyzed	Residues (mg/kg)				PHI (days)	Details on trial
			kg as/hL	Water L/ha	kg as/ha				BAS 700 F	M700F008	M700F048	M700F002		
L200146 2021/2020010 20090 Caleppio di Settala, Italy (S) 2020	Barley GC 0640 Futura	1. 2020 (h) 2. 03.-11.05.2020 (h) 3.22.06.2020 (h)	0.050	200	0.100	11.05.2020 2	69	Whole plant no roots	1.3	0.021	<0.007	<0.010	0	
								Ears	0.029	<0.010	<0.007	<0.010	28	
								Rest of plants[1]	0.11	0.014	<0.007	<0.010	28	
								Grain	<u>0.015</u>	<0.010	<0.007	<0.010	36	
								Straw	0.084	0.016	<0.007	<0.010	36	
								Grain	0.015	<0.010	<0.007	<0.010	42	
								Straw	0.14	0.024	<0.007	<0.010	42	
L200147 2021/2020010 18128 Zafarraya, Granada, Spain (S) 2020	Barley GC 0640 Yuriko	1. 2020 (h) 2. 30.04.-10.05.2020 (h) 3.03.07.2020 (h)	0.050	200	0.100	08.05.2020 2	69	Whole plant no roots	2.9	0.067	<0.007	<0.010	0	
								Ears	0.19	0.021	<0.007	<0.010	28	
								Rest of plants[1]	0.63	0.045	<0.007	<0.010	28	
								Ears	0.13	0.015	<0.007	<0.010	35	
								Rest of plants[1]	1.0	0.066	<0.007	<0.010	35	
								Ears	0.13	0.014	<0.007	<0.010	41	
								Rest of plants[1]	1.2	0.074	<0.007	<0.010	41	
								Grain	<u>0.057</u>	<0.010	<0.007	<0.010	56	
								Straw	0.74	0.050	<0.007	<0.010	56	

(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)
(e) Expressed as parent equivalent, conversion factor for calculation of M700F008 to parent equivalent is 1.038
(f) Expressed as parent equivalent, conversion factor for calculation of M700F048 to parent equivalent is 0.720
(g) Reference to analytical method
(h) Non-GLP data
1 Without roots
The underlined values (e.g. 0.010) are used in the assessment of residues in wheat (section 7.3.3.1).

A 2.1.4 Magnitude of residues in livestock

A 2.1.4.1 Livestock feeding studies

No new studies submitted.

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

No new studies submitted.

A 2.1.5.1 Distribution of the residue in peel/pulp

No new studies submitted.

A 2.1.5.2 Processing studies on a core set of representative processes

No new studies submitted.

A 2.1.6 Magnitude of residues in representative succeeding crops

No new studies submitted.

A 2.1.7 Other/Special Studies (KCA 6.10, KCA 6.10.1)

No new studies submitted. A study, assessing residues in honey is not required for cereals according to SANTE/11956/2016 rev.9.

A 2.2 Azoxystrobin

A 2.2.1 Stability of residues

No new data was submitted in the context of this submission.

A 2.2.2 Nature of residues in plants, livestock and processed commodities

No new data was submitted in the context of this submission

A 2.2.3 Magnitude of residues in plants

A 2.2.3.1 Wheat

Table A 11: 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 (UK, 2009a; EFSA, 2010; EFSA, 2013)	2	0.250 kg/ha	14 days	69	35
Intended cGAP (1, 12*)	2	0.150 kg/ha	21 days	69	35

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

A 2.2.3.1.1 Study 1 – BASF DocID 2020/2006184

Reference:	CA 6.3.1/1
Report	Study on the residue behaviour of BAS 700 F (Fluxapyroxad) and BAS 9164 F (Azoxystrobin) in wheat after application of BAS 736 00 F under field conditions in Northern and Southern Europe, 2019 Erdmann H.-P., 2021 report No 851042 BASF DocID 2020/2006184 Authority registration No
Guideline(s):	EC 1107/2009 of the European Parliament and of the Council of 21 Oct 2009, EEC 7029/VI/95 rev. 5 (July 22 1997), EEC SANCO 7525/VI/95 Rev. 10.3 (June 2017), OECD 509 Crop Field Trial (2009)
Deviations:	No
GLP:	Yes (certified by Land Brandenburg Ministerium der Justiz und fuer Europa und Verbraucherschutz, Potsdam, Germany)

Acceptability: Yes

zRMS:
Four field trials (L190173, L190174, L190175 and L190176) were conducted during the growing season of 2019 in order to determine the magnitude of residues of BAS 9194 F (Azoxystrobin) in wheat after treatment with BAS 736 00 F under field conditions in Germany, Belgium, Poland, Hungary. Data for four field trials conducted in southern zone was shown for information only. N-EU data was used for evaluation.

Wheat specimens were analysed for BAS 9164 F (Azoxystrobin) using the BASF analytical method no. L0435/01[1]. The method has a limit of quantitation of 0.010 mg/kg. In this study, for azoxystrobin (BAS 9164 F) in wheat (whole plant no roots, ears, rest of plant without roots, grain and straw) the effect of matrix on the LC-MS/MS response was assessed by comparing peak areas of matrix-matched standards of at least 90 % matrix amount with solvent standards at equivalent concentrations. Matrix effects were <20% for azoxystrobin (BAS 9164F) in all matrices.
All dilutions were performed by using matrix extract. Matrix-matched standards were used for the determination of the analytes in all diluted sample extracts. In case of using diluted sample extracts, high level fortification samples were diluted accordingly to show that no significant matrix effect was present after dilution.
No residues of the analytes at or above 30 % of the limit of quantitation (0.010 mg/kg) were detected in the control samples used for the fortification experiments, which proves that no interferences of the specimen material with the analytical procedure occurred.
Furthermore, control samples were fortified with the analytes at concentration levels equivalent to LOQ and 10x LOQ and analysed simultaneously with the treated samples, in order to determine the efficiency of the method. An additional fortifications were performed at 6.0 mg/kg for wheat (whole plant no roots), at 1.0 mg/kg for wheat (ears) and wheat (rest of plant without roots) and at 2.0 mg/kg for wheat (straw) (Table A 12). Overall and average recoveries were all in the range of 70 – 110 % and relative standard deviations (RSD) were <20%.

The study is considered acceptable for determination magnitude of azoxystrobin residues in plant matrices (wheat).

In treated grain specimens taken at 34-36, 41-43 and 48-50 DALA (BBCH 89) the residues of BAS 9164 F were < LOQ (0.010 mg/kg).

The study is considered acceptable to support the use of BAS 736 00 F in the central zone MSs. The GAP on wheat is deemed adequately supported by data on the magnitude of residues of azoxystrobin resulted from the intended uses.

Table A 12: Summary of recoveries of AZOXYSTROBIN in wheat

Matrix	Fortification Levels [mg/kg]	Summary Recoveries		
		n	Mean [%]	RSD [%]
Method No. L0435/01		**Azoxystrobin (BAS 9164)**		
Whole plant no roots	0.01, 0.10, and 6	7	101	9.2
Ears	0.01, 0.10, and 1.0	7	85.7	6.2
Rest of plants without roots	0.01, 0.10, and 1.0	9	95.0	6.6
Grain	0.010 and 0.10	6	91.2	2.4
Straw	0.01, 0.10, and 2.0	7	90.7	12
Overall:		**36**	**92.9**	**13**

n Number of recoveries
RSD Coefficient of variation

[1] Melanie Kissel, Dr. Christian Spangler; "Technical Procedure: Analytical method for the determination of BAS 9164 F (Reg.No. 300254) and R230310 in plant matrices by LCMS/MS"; BASF Method Number L0435/01; 05 July 2019.

Table A 13: Residues of AZOXYSTROBIN in wheat (Treated samples)

Trial No./ DocID/ 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 date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			kg as/hL	Water L/ha	kg as/ha				Azoxystrobin (BAS 9164)		
L190173 2020/2006184 16833 Lentzke Brandenburg, Germany (N) 2019	Wheat GC 0654 Boregar	1. 02.11.2018 2. 29.05.-07.06.2019 3. 11.07.-25.07.2019	0.075	200	0.150	07.06.2019 2	69	Whole plant no roots Grain Straw Grain Straw Grain Straw	2.6 <0.010 0.28 <u><0.010</u> 0.24 <0.010 0.16	0 34 34 41 41 48 48	
L190174 2020/2006184 6221 Saint-Amand, Wallonia, Belgium (N) 2019	Wheat GC 0654 Talent	1. 05.11.2018 2. 05.06.-14.06.2019 3. 01.08.2019	0.075	200	0.150	14.06.2019 2	69	Whole plants no roots Ears Rest of plants [1] Grain Straw Grain Straw	2.0 0.013 0.14 <u><0.010</u> 0.13 <0.010 <0.010	0 34 34 42 42 48 48	**BAS 736 00 F EC** BAS 700 F 50 g/L BAS 9164 F 75 g/L BASF method L0435/01 LOQ: 0.01 mg/kg (parent - azoxystrobin) No residues above LOQ in any untreated specimen Storage time for all commodities <315 days
L190175 2020/2006184 64-000 Spytkówki, Wielkoposka, Poland (N) 2019	Wheat GC 0654 Toras	1. 28.09.2018 2. 04.06.-14.06.2019 3. 29.07.2019	0.075	200	0.150	10.06.2019 2	69	Whole plant no roots Grain Straw Grain Straw Grain Straw	3.0 <0.010 0.55 <0.010 0.32 <u><0.010</u> 0.31	0 35 35 43 43 49 49	
L190176 2020/2006184 8781 Bókaháza, Zala County, Hungary (N) 2019	Wheat GC 0654 CH Combine	1. 24.09.2018 2. 24.05.-03.06.2019 3. 18.07.2019	0.075	200	0.15	01.06.2019 2	69	Whole plants no roots Ears Rest of plants [1] Grain Straw Grain Straw	2.2 <0.010 0.049 <0.010 0.046 <u><0.010</u> 0.051	0 35 35 41 41 48 48	

Trial No./ DocID/ 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 date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			kg as/hL	Water L/ha	kg as/ha				Azoxystrobin (BAS 9164)		
L190177 2020/2006184 32220 Garravet, Occitanie, France (S) 2019	Wheat GC 0654 Oregrain	1. 18.11.2018 2. 15.05.-21.05.2019 3. 13.07.2019	0.075	200	0.150	21.05.2019 2	69	Whole plants no roots Ears Rest of plants [1] Ears Rest of plants [1] Grain Straw	2.4 <0.010 0.036 0.011 0.051 <u><0.010</u> 0.073	0 34 34 42 42 48 48	
L190178 2020/2006184 57100 Koufalia, Central Mezadonia, Greece (S) 2019	Wheat GC 0654 Gibraltar	1. 25.11.2018 2. 26.04.-02.05.2019 3.20.06.2019	0.075	200	0.150	02.05.2019 2	69	Whole plants no roots Ears Rest of plants [1] Grain Straw Grain Straw	3.2 <0.010 0.040 <u><0.010</u> 0.023 <0.010 0.022	0 35 35 42 42 48 48	
L190179 2020/2006184 12050 Magliano Alfieri, Piedmont, Italy (S) 2019	Wheat GC 0654 Solehio	1. 15.10.2018 2. 21.05.-04.06.2019 3. 10.07.2019	0.075	200	0.150	04.06.2019 2	69	Whole plant no roots Grain Straw Grain Straw Grain Straw	2.0 <0.010 0.20 <u><0.010</u> 0.072 <0.010 0.082	0 36 36 42 42 50 50	
L190180 2020/2006184 41200 Alcalá del Rio, Andalusia, Spain (S) 2019	Wheat GC 0654 Tejada	1. 10.12.2018 2. 26.03.-07.04.2019 3. 06.06.-07.06.2019	0.075	200	0.150	10.04.2019 2	69	Whole plants no roots Ears Rest of plants [1] Ears Rest of plants [1] Grain Straw	2.4 <0.010 0.021 <0.010 0.038 <u><0.010</u> 0.045	0 34 34 42 42 50 50	

(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) Reference to analytical method
1 Without roots
The underlined values (e.g. 0.010) are used in the assessment of residues in wheat (section 7.3.3.1).

A 2.2.3.1.2 Study 2 – BASF DocID 2021/2022810

Reference:	CA 6.3.1/2
Report	Residues of Azoxystrobin (BAS 9164 F) and Fluxapyroxad (BAS 700 F) in Wheat after Treatment with BAS 736 00 F under Field Conditions in Northern and Southern Europe, 2020 Gabriel E.J., Thirkell C., 2021 report No 851043 BASF DocID 2021/2022810 Authority registration No
Guideline(s):	EC 1107/2009 of the European Parliament and of the Council of 21 Oct 2009, EEC 7029/VI/95 rev. 5 (July 22 1997), EEC SANCO 7525/VI/95 Rev. 10.3 (June 2017), OECD 509 Crop Field Trial (2009)
Deviations:	No
GLP:	Yes (certified by Hess. Ministerium fuer Umwelt, Klimaschutz, Landwirtschaft und Verbraucherschutz, Wiesbaden, Germany)
Acceptability:	Yes

zRMS:
During the growing season of 2020 four field trials in wheat (L200132, L200133, L200134 and L200135) were conducted in Germany, the Netherlands, United Kingdom and Hungary in order to determine the magnitude of residues of azoxystrobin (BAS 9164 F) in wheat after treatment with BAS 736 00 F under field conditions. Data for four field trials conducted in southern zone was shown for information only. N-EU data was used for evaluation.
Wheat specimens were analysed for azoxystrobin using the BASF Method L0435/01. The method has a limit of quantitation of 0.010 mg/kg. This analytical method is considered acceptable for determination magnitude of azoxystrobin residues in plant matrices (wheat).

In treated grain specimens taken at 41-43 DALA (BBCH 85-89) the residues of BAS 9164 F were < LOQ (0.010 mg/kg).

The study is considered acceptable to support the use of BAS 736 00 F in the central zone MSs. The GAP on wheat is deemed adequately supported by data on the magnitude of residues of azoxystrobin resulted from the intended uses.

Table A 14: Summary of recoveries of AZOXYSTROBIN in wheat

Matrix	Fortification Levels [mg/kg]	Summary Recoveries		
		n	Mean [%]	RSD [%]
Method No. L0435/01		**Azoxystrobin (BAS 9164)**		
Whole plant no roots	0.01, 0.10, and 10	7	92.5	8.3
Ears	0.01, 0.10, and 1.0	7	94.3	5.9
Rest of plants without roots	0.01, 0.10, and 10	7	89.6	4.7
Grain	0.010, 0.10 and 1.0	11	100	6.3

Straw	0.01, 0.10, and 2.0	7	93.5	9.1
	Overall:	**39**	**94.7**	**7.8**

n Number of recoveries
RSD Coefficient of variation

Table A 15: Residues of AZOXYSTROBIN in wheat (Treated samples)

Trial No./ DocID/ Location/ EU zone, Year	Commodity/ Variety (a)	Date of 1. Sowing or planting 2. Flowering 3. Harvest (b)	Application rate per treatment. kg as/hL	Water L/ha	kg as/ha	Dates of treatment or no. of treatments and last date (c)	Growth stage at last date	Portion analyzed	Residues (mg/kg) Azoxystrobin (BAS 9164)	PHI (days) (d)	Details on trial (e)
L200132 2021/2022810 79353 Bahlingen am Kaiserstuhl, Germany (N) 2020	Wheat GC 0654 Turandot	1. 18.09.2019 2. 12.05.-29.05.2020 3. 13.07.2020	0.075	200	0.150	25.05.2020 2	69	Whole plant no roots Ears Rest of plants[1] Ears Rest of plants[1] Grain Straw	2.4 <0.010 0.061 <0.010 0.066 <u><0.010</u> 0.052	0 35 35 42 42 49 49	**BAS 736 00 F EC** BAS 700 F 50 g/L BAS 9164 F 75 g/L BASF method L0435/01 LOQ: 0.01 mg/kg (parent, azoxystrobin) No residues above LOQ in any untreated specimen Storage time for all commodities <117 days
L200133 2021/2022810 9695 Bellingwolde, Netherlands (N) 2020	Wheat GC 0654 Licamero	1. 07.04.2020 2. 30.06.-03.07.2020 3. 20.08.2020	0.075	200	0.150	03.07.2020 2	69	Whole plant no roots Ears Rest of plants[1] Ears Rest of plants[1] Grain Straw	3.5 0.034 0.089 0.040 0.11 <u><0.010</u> 0.25	0 34 34 41 41 48 48	
L200134 2021/2022810 OX15 6EP Banbury, United Kingdom (N) 2020	Wheat GC 0654 Skyfall	1. 12.11.2019 2. 04.06.-15.06.2020 3. 03.08.-12.08.2020	0.075	200	0.150	15.06.2020 2	69	Whole plant no roots Ears Rest of plants[1] Grain Straw Grain Straw	2.4 0.031 0.23 <u><0.010</u> 0.28 <0.010 0.30	0 35 35 43 43 50 50	
L200135 2021/2022810 H-4461 Nyirtelek-Ferenltanya, Hungary (N) 2020	Wheat GC 0654 GK Csillag	1. 12.10.2019 2. 20.05.-30.05.2020 3.09.07.-10.07.2020	0.075	200	0.150	28.05.2020 2	69	Whole plant no roots Ears Rest of plants[1] Grain Straw Grain Straw	2.3 <0.010 0.018 <u><0.010</u> 0.013 <0.010 <0.010	0 35 35 42 42 48 48	

Trial No./ DocID/ Location/ EU zone, Year	Commodity/ Variety (a)	Date of 1. Sowing or planting 2. Flowering 3. Harvest (b)	Application rate per treatment. kg as/hL	Water L/ha	kg as/ha	Dates of treatment or no. of treatments and last date (c)	Growth stage at last date	Portion analyzed	Residues (mg/kg) Azoxystrobin (BAS 9164)	PHI (days) (d)	Details on trial (e)
L200136 2021/2022810 84500 Bollène, France (S) 2020	Wheat GC 0654 RGT Aventa-dur	1. 10.01.2020 2. 10.05.-13.05.2020 3. 03.07.2020	0.075	200	0.150	22.05.2020 2	69	Whole plant no roots Grain Straw Grain Straw Grain Straw	2.5 0.011 0.21 <0.010 0.21 0.016 0.23	0 35 35 42 42 49 49	
L200137 2021/2022810 57006 Thessaloniki, Greece (S) 2020	Wheat GC 0654 Grekale	1. 09.12.2019 2. 25.04.-05.05.2020 3. 20.06.2020	0.075	200	0.150	05.05.2020 2	69	Whole plant no roots Ears Rest of plants[1] Grain Straw Grain Straw	1.7 <0.010 0.03 <0.010 0.054 <0.010 0.074	0 35 35 41 41 49 49	
L200138 2021/2022810 13040 Borgo D'Ale, Italy (S) 2020	Wheat GC 0654 Vespucci	1. 16.03.2020 2. 15.05.-25.05.2020 3. 07.07.2020	0.075	200	0.150	19.05.2020 2	69	Whole plant no roots Grain Straw Grain Straw Grain Straw	2.9 <0.010 0.058 <0.010 0.096 <0.010 0.086	0 35 35 41 41 49 49	
L200139 2021/2022810 18128 Zafarraya, Spain (S) 2020	Wheat GC 0654 Marius	1. 21.10.2019 2. 01.05.-10.05.2020 3. 26.06.2020	0.075	200	0.150	08.05.2020 2	69	Whole plant no roots Ears Rest of plants[1] Grain Straw Grain Straw	1.8 0.015 0.076 <0.010 0.048 <0.010 0.066	0 35 35 41 41 49 49	

(b) According to CODEX Classification / Guide
(b) Only if relevant.

(c) Year must be indicated.
(d) Days after last application (Label pre-harvest interval, PHI)
(e) Reference to analytical method
1 Without roots
The underlined values (e.g. 0.010) are used in the assessment of residues in wheat (section 7.3.3.1).

A 2.2.3.2 Barley

Table A 16 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 (UK, 2009a; EFSA, 2010; EFSA, 2013)	2	0.250 kg/ha	14 days	69	35
Intended cGAP (2, 6, 13*)	2	0.150 kg/ha	21 days	69	35

A 2.2.3.2.1 Study 1 - BASF DocID 2020/2006183

Reference:	CA 6.3.2/1
Report	Study on the residue behaviour of BAS 700 F (Fluxapyroxad) and BAS 9164 F (Azoxystrobin) in barley after application of BAS 736 00 F under field conditions in Northern and Southern Europe, 2019 Erdmann H.P., 2020 report No 851044 BASF DocID 2020/2006183 Authority registration No
Guideline(s):	EC 1107/2009 of the European Parliament and of the Council of 21 Oct 2009, EEC 7029/VI/95 rev. 5 (July 22 1997), EEC SANCO 7525/VI/95 Rev. 10.3 (June 2017), OECD 509 Crop Field Trial (2009)
Deviations:	No
GLP:	Yes (certified by Land Brandenburg Ministerium der Justiz und fuer Europa und Verbraucherschutz, Potsdam, Germany)
Acceptability:	Yes

zRMS:
Four field trials (L190165, L190166, L190167 and L190168) were conducted during the growing season of 2019 in order to determine the magnitude of residues of azoxystrobin in barley after treatment with BAS 736 00 F under field conditions in Germany, The Netherlands, Poland, Northern France. Data for four field trials conducted in southern zone was shown for information only. N-EU data was used for evaluation.
Barley specimens were analysed for BAS 9164 F (Azoxystrobin) using the BASF analytical method no. L0435/01. The method has a limit of quantitation of 0.010 mg/kg. This analytical method is considered acceptable for determination magnitude of azoxystrobin residues in plant matrices (barley).

The study is considered acceptable to support the use of BAS 736 00 F in the central zone MSs. The GAP on barley is deemed adequately supported by data on the magnitude of residues of azoxystrobin resulted from the intended uses.

Table A 17: Summary of recoveries of AZOXYSTROBIN in Barley

Matrix	Fortification Levels [mg/kg]	Summary Recoveries		
		n	Mean [%]	RSD [%]
Method No. L0435/01		**Azoxystrobin (BAS 9164)**		
Whole plant no roots	0.01, 0.10, and 6	13	91.1	16
Ears	0.01, 0.10, and 0.60	7	91.9	21
Rest of plants without roots	0.01, 0.10, and 1.0	9	96.6	13
Grain	0.010 and 0.10	10	97.1	11
Straw	0.01, 0.10, and 2.0	9	89.9	14
	Overall:	**48**	**93.3**	**14**

n Number of recoveries
RSD Coefficient of variation

Table A 18: Residues of AZOXYSTROBIN in barley (Treated samples)

Trial No./ DocID/ Location/ EU zone, Year	Commodity/ Variety (a)	Date of 1. Sowing or planting 2. Flowering 3. Harvest (b)	Application rate per treatm. kg as/hL	Water L/ha	kg as/ha	Dates of treatment or no. of treatments and last date (c)	Growth stage at last date	Portion analyzed	Residues (mg/kg) Azoxystrobin (BAS 9164)	PHI (days) (d)	Details on trial (e)
L190165 2020/2006183 16833 Brunne, Brandenburg, Germany (N) 2019	Barley GC 0640 KWS Cassia	1. 26.09.2018 2. 10.05.-17.05.2019 3. 27.06.-01.07.2019	0.007	200	0.150	17.05.2019 2	69	Whole plant no roots Ears Rest of plants[1] Ears Rest of plants[1] Grain Straw	2.4 0.032 0.086 0.033 0.10 <0.010 0.12	0 28 28 35 35 41 41	**BAS 736 00 F EC** BAS 700 F 50 g/L BAS 9164 F 75 g/L BASF method L0435/01 LOQ: 0.01 mg/kg (parent, azoxystrobin) No residues above LOQ in any untreated specimen Storage time for all commodities <424 days
L190166 2020/2006183 6599 AV Ven-Zelderheide, Limburg, The Netherlands (N) 2019	Barley GC 0640 Nure	1. 10.10.2018 2. 12.05.-23.05.2019 3. 04.07.2019	0.075	200	0.150	23.05.2019 2	69	Whole plant no roots Ears Rest of plants[1] Ears Rest of plants[1] Grain Straw	2.5 0.016 0.067 0.042 .10 <0.010 0.11	0 27 27 34 34 42 42	
L190167 2020/2006183 64000 Spytkówki, Wielkopolska, Poland (N) 2019	Barley GC 0640 Lutece	1. 14.09.2018 2. 12.05.-27.05.2019 3. 04.07.2019	0.075	200	0.150	24.05.2019 2	69	Whole plant no roots Ears Rest of plants[1] Grain Straw Grain Straw	2.5 0.042 0.18 <0.010 0.17 <0.010 0.29	0 29 29 34 34 41 41	
L190168 2020/2006183 59189 Steenbecque, Hauts-de-France, France (N) 2019	Barley GC 0640 Meseta	1. 02.11.2018 2. 16.05.-03.06.2019 3. 19.07.2019	0.075	200	0.150	03.06.2019 2	69	Whole plant no roots Ears Rest of plants[1] Ears Rest of plants[1] Grain Straw	2.4 0.071 0.18 0.071 0.23 0.016 0.20	0 28 28 35 35 42 42	

Trial No./ DocID/ Location/ EU zone, Year	Commodity/ Variety (a)	Date of 1. Sowing or planting 2. Flowering 3. Harvest (b)	Application rate per treatm.			Dates of treat-ment or no. of treat-ments and last date (c)	Growth stage at last date	Portion analyzed	Residues (mg/kg)	PHI (days)	Details on trial
			kg as/hL	Water L/ha	kg as/ha				Azoxystrobin (BAS 9164)	(d)	(e)
L190169 2020/2006183 31620 Bouloc, Occitanie, France (S) 2019	Barley GC 0640 Jule	1. 25.10.2018 2. 27.04.-04.05.2019 3. 25.06.-26.06.2019	0.075	200	0.150	02.05.2019 2	69	Whole plant no roots Ears Rest of plants[1] Ears Rest of plants[1] Ears Rest of plants[1] Grain Straw	2.7 0.012 0.017 <0.010 0.018 <0.010 0.019 <0.010 0.030	0 27 27 35 35 42 42 54 54	
L190170 2020/2006183 57400 Sindos, Central Macedo-nia, Greece (S) 2019	Barley GC 0640 Domino	1. 12.12.2018 2. 15.04.-26.04.2019 3. 04.06.2019	0.075	200	0.150	24.04.2019 2	69	Whole plant no roots Ears Rest of plants[1] Grain Straw Grain Straw	3.6 0.16 0.35 <0.010 0.15 <0.010 0.18	0 28 28 35 35 41 41	
L190171 2020/2006183 40052 Baricella, Emilia-Romagna, Italy (S) 2019	Barley GC 0640 KWS Ariane	1. 12.12.2018 2. 30.04.-10.05.2019 3. 21.06.2019	0.075	200	0.150	11.05.2019 2	69	Whole plant no roots Ears Rest of plants[1] Ears Rest of plants[1] Grain Straw	3.1 <0.010 0.017 0.011 0.016 <0.010 0.013	0 28 28 34 34 41 41	
L190172 2020/2006183 31390 Olite, Anda-lusia, Spain (S) 2019	Barley GC 0640 Touareg	1. 30.11.2018 2. 25.04.-03.05.2019 3. 13.06.2019	0.075	200	0.150	03.05.2019 2	69	Whole plant no roots Ears Rest of plants[1] Ears Rest of plants[1] Grain Straw	2.4 0.030 0.11 0.025 0.092 <0.010 0.080	0 28 28 35 35 41 41	

(b) According to CODEX Classification / Guide
(b) Only if relevant.
(c) Year must be indicated.
(d) Days after last application (Label pre-harvest interval, PHI)
(e) Reference to analytical method
1 Without roots
The underlined values (e.g. 0.010) are used in the assessment of residues in wheat (section 7.3.3.1).

A 2.2.3.2.2 Study 2 - BASF DocID 2021/2020010

Reference:	CA 6.3.2/2
Report	Residues of Azoxystrobin (BAS 9164 F) and Fluxapyroxad (BAS 700 F) in Barley after Treatment with BAS 736 00 F under Field Conditions in Northern and Southern Europe, 2020 Mahlo C., 2021 report No 851045 BASF DocID 2021/2020010 Authority registration No
Guideline(s):	EC 1107/2009 of the European Parliament and of the Council of 21 Oct 2009, EEC 7029/VI/95 rev. 5 (July 22 1997), EEC SANCO 7525/VI/95 Rev. 10.3 (June 2017), OECD 509 Crop Field Trial (2009)
Deviations:	No
GLP:	Yes (certified by Hess. Ministerium fuer Umwelt, Klimaschutz, Landwirtschaft und Verbraucherschutz, Wiesbaden, Germany)
Acceptability:	Yes

zRMS:
Four field trials (L 200140, L 200141, L 200142 and L 200143) were conducted during the growing season of 2020 in order to determine the magnitude of residues of azoxystrobin (BAS 9164 F) in barley after treatment with BAS 736 00 F under field conditions in Germany, Belgium, Hungary, Northern France. Data for four field trials conducted in southern zone was shown for information only. N-EU data was used for evaluation.
Barley specimens were analysed for azoxystrobin using the BASF Method L0435/01. The method has a limit of quantitation of 0.010 mg/kg. This analytical method is considered acceptable for determination magnitude of azoxystrobin residues in plant matrices (wheat).

The study is considered acceptable to support the use of BAS 736 00 F in the central zone MSs. The GAP on barley is deemed adequately supported by data on the magnitude of residues of azoxystrobin resulted from the intended uses.

Table A 19: Summary of recoveries of AZOXYSTROBIN in barley

Matrix	Fortification Levels [mg/kg]	Summary Recoveries		
		n	Mean [%]	RSD [%]
Method No. L0435/01		**Azoxystrobin (BAS 9164)**		
Whole plant no roots	0.01, 0.10, and 10	9	92.4	6.0
Ears	0.01, 0.10, and 1.0	7	96.8	4.7
Rest of plants without roots	0.01, 0.10, and 5.0	7	94.1	10
Grain	0.010, 0.10 and 1.0	7	94.9	13
Straw	0.010, 0.10 and 1.0	7	94.7	6.9
	Overall:	**37**	**94.4**	**8.3**

n Number of recoveries
RSD Coefficient of variation

Table A 20: Residues of AZOXYSTROBIN in barley (Treated samples)

Trial No./ DocID/ Location/ EU zone, Year	Commodity/ Variety (a)	Date of 1. Sowing or planting 2. Flowering 3. Harvest (b)	Application rate per treatm. kg as/hL	Water L/ha	kg as/ha	Dates of treatment or no. of treatments and last date (c)	Growth stage at last date	Portion analyzed	Residues (mg/kg) Azoxystrobin (BAS 9164)	PHI (days) (d)	Details on trial (e)
L200140 2021/2020010 67294 Mauchenheim, Germany (N) 2020	Barley GC 0640 Avalon	1. 2020 (f) 2. 28.05.-09.06.2020 (f) 3. 18.-22.07.2020 (f)	0.075	200	0.150	09.06.2020 2	69	Whole plant no roots Ears Rest of plants[1] Grain Straw Grain Straw	2.5 0.015 0.044 <0.010 0.077 <0.010 0.081	0 29 29 35 35 41 41	
L200141 2021/2020010 6221 Saint-Amand, Belgium (N) 2020	Barley GC 0640 RGT Planet	1. 2020 (f) 2. 01.-08.06.2020 (f) 3. 20.-29.07.2020 (f)	0.075	200	0.150	08.06.2020 2	69	Whole plant no roots Ears Rest of plants[1] Grain Straw Grain Straw Grain Straw	1.4 <0.010 0.051 <0.010 0.043 <0.010 0.025 <0.010 0.030	0 28 28 35 35 42 42 51 51	**BAS 736 00 F EC** BAS 700 F 50 g/L BAS 9164 F 75 g/L BASF method L0435/01 LOQ: 0.01 mg/kg (parent, azoxystrobin) No residues above LOQ in any untreated specimen
L200142 2021/2020010 3905 Monok, Hungary (N) 2020	Barley GC 0640 Malz	1. 2019 (f) 2. 05.-15.06.2020 (f) 3.15.-18.07.2020 (f)	0.075	200	0.150	12.06.2020 2	69	Whole plant no roots Grain Straw Grain Straw Grain Straw	2.2 <0.010 0.013 <0.010 0.012 <0.010 0.015	0 27 27 34 34 42 42	Storage time for all commodities ≤118 days

Trial No./ DocID/ Location/ EU zone, Year	Commodity/ Variety (a)	Date of 1. Sowing or planting 2. Flowering 3. Harvest (b)	Application rate per treatm.			Dates of treat-ment or no. of treat-ments and last date (c)	Growth stage at last date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			kg as/hL	Water L/ha	kg as/ha				Azoxystrobin (BAS 9164)		
L200143 2021/2020010 02190 Juvincourt, France (N) 2020	Barley GC 0640 KWS Fantex	1. 2020 (f) 2. 21.-29.05.2020 (f) 3.12.07.2020 (f)	0.075	200	0.150	29.05.2020 2	69	Whole plant no roots Ears Rest of plants[1] Grain Straw Grain Straw	3.3 0.15 0.32 <0.010 0.15 <0.010 0.13	0 27 27 34 34 42 42	
L200144 2021/2020010 30840 Meynes, France (S) 2020	Barley GC 0640 KWS Fantex	1. 2020 (f) 2. 10.-28.05.2020 (f) 3.29.06.2020 (f)	0.075	200	0.150	25.05.2020 2	69	Whole plant no roots Grain Straw Grain Straw Grain Straw	2.4 0.034 0.24 0.064 0.29 0.11 0.32	0 29 29 35 35 42 42	
L200145 2021/2020010 57006 Thessaloniki, Greece (S) 2020	Barley GC 0640 Barke	1. 2019 (f) 2. 15.-25.04.2020 (f) 3.11.06.2020 (f)	0.075	200	0.150	24.04.2020 2	69	Whole plant no roots Ears Rest of plants[1] Ears Rest of plants[1] Grain Straw Grain Straw	1.7 0.026 0.10 <0.010 <0.010 <0.010 0.044 <0.010 0.073	0 28 28 35 35 41 41 47 47	

Trial No./ DocID/ Location/ EU zone, Year	Commodity/ Variety (a)	Date of 1. Sowing or planting 2. Flowering 3. Harvest (b)	Application rate per treatm. kg as/hL	Water L/ha	kg as/ha	Dates of treatment or no. of treatments and last date (c)	Growth stage at last date	Portion analyzed	Residues (mg/kg) Azoxystrobin (BAS 9164)	PHI (days) (d)	Details on trial (e)
L200146 2021/2020010 20090 Caleppio di Settala, Italy (S) 2020	Barley GC 0640 Futura	1. 2020 (f) 2. 03.-11.05.2020 (f) 3.22.06.2020 (f)	0.075	200	0.150	11.05.2020 2	69	Whole plant no roots Ears Rest of plants[1] Grain Straw Grain Straw	1.5 <0.010 0.017 <u><0.010</u> 0.015 <0.010 0.016	0 28 28 36 36 42 42	
L200147 2021/2020010 18128 Zafarraya, Granada, Spain (S) 2020	Barley GC 0640 Yuriko	1. 2020 (f) 2. 30.04.-10.05.2020 (f) 3.03.07.2020 (f)	0.075	200	0.150	08.05.2020 2	69	Whole plant no roots Ears Rest of plants[1] Ears Rest of plants[1] Ears Rest of plants[1] Grain Straw	2.2 0.043 0.069 0.030 0.10 0.020 0.11 <u><0.010</u> 0.075	0 28 28 35 35 41 41 56 56	

(b) According to CODEX Classification / Guide
(b) Only if relevant.
(c) Year must be indicated.
(d) Days after last application (Label pre-harvest interval, PHI)
(e) Reference to analytical method
(f) Non-GLP data
1 Without roots
The underlined values (e.g. 0.010) are used in the assessment of residues in wheat (section 7.3.3.1).

A 2.2.4 Magnitude of residues in livestock

No new data was submitted in the context of this submission.

A 2.2.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)

No new data was submitted in the context of this submission.

A 2.2.5.1 Distribution of the residue in peel/pulp

No new data was submitted in the context of this submission.

A 2.2.5.2 Processing studies on a core set of representative processes

No new data was submitted in the context of this submission.

A 2.2.6 Magnitude of residues in representative succeeding crops

No new data was submitted in the context of this submission.

A 2.2.7 Other/Special Studies (KCA 6.10, KCA 6.10.1)

No new data was submitted in the context of this submission. A study, assessing residues in honey is not required for serials according to SANTE/11956/2016 rev.9.

Appendix 3 Pesticide Residue Intake Model (PRIMo v. 3.1)

Fluxapyroxad

A 3.1 Fluxapyroxad TMDI calculations

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Fluxapyroxad

LOQs (mg/kg) range from: 0.01 to: 0.05

Toxicological reference values

ADI (mg/kg bw/day):	0.02	ARfD (mg/kg bw):	0.25
Source of ADI:	EFSA, 2012	Source of ARfD:	EFSA, 2012
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 : 12

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

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
301%	NL toddler	60.22	81%	Bananas	49%	Apples	23%	Table grapes	0.2%	14%
184%	DE child	36.84	56%	Apples	24%	Bananas	21%	Table grapes	0.2%	13%
156%	NL child	31.12	29%	Bananas	26%	Apples	17%	Sugar beet roots	0.2%	9%
154%	GEMS/Food G06	30.76	39%	Rice	25%	Sugar canes	16%	Table grapes	0.1%	16%
147%	GEMS/Food G11	29.44	29%	Sugar canes	15%	Wine grapes	13%	Celeries	0.1%	20%
140%	GEMS/Food G07	28.03	23%	Sugar canes	22%	Wine grapes	9%	Barley	0.1%	19%
140%	GEMS/Food G10	27.92	31%	Rice	19%	Sugar canes	9%	Barley	0.1%	18%
134%	GEMS/Food G08	26.83	24%	Sugar canes	16%	Wine grapes	13%	Barley	0.1%	24%
125%	GEMS/Food G15	24.92	20%	Sugar canes	15%	Wine grapes	12%	Barley	0.1%	22%
114%	IE adult	22.75	19%	Wine grapes	12%	Bananas	11%	Rhubarbs	0.2%	8%
106%	PT general	21.25	37%	Wine grapes	20%	Rice	8%	Potatoes	0.0%	9%
100%	FR child 3 15 yr	20.07	11%	Rice	10%	Bananas	9%	Wheat	0.2%	11%
96%	SE general	19.25	27%	Bananas	10%	Rice	8%	Lettuces	0.1%	7%
92%	FR toddler 2 3 yr	18.41	15%	Rice	14%	Apples	8%	Bananas	0.2%	7%
92%	DK child	18.37	17%	Bananas	11%	Rye	10%	Apples	0.0%	26%
90%	RO general	17.98	25%	Wine grapes	10%	Wheat	6%	Apples	0.0%	10%
89%	UK infant	17.86	22%	Bananas	16%	Rice	7%	Apples	0.0%	9%
86%	FI 3 yr	17.10	20%	Bananas	14%	Rice	9%	Oat	0.1%	13%
85%	UK toddler	17.04	16%	Bananas	14%	Rice	8%	Wheat	0.1%	9%
80%	DE women 14-50 y	16.10	13%	Wine grapes	12%	Apples	9%	Sugar beet roots	0.1%	10%
80%	DE general	16.00	12%	Wine grapes	11%	Apples	8%	Sugar beet roots	0.1%	14%
77%	ES child	15.49	15%	Bananas	12%	Rice	9%	Wheat	0.2%	9%
77%	FR adult	15.37	35%	Wine grapes	4%	Wheat	4%	Rice	0.1%	5%
76%	NL general	15.20	9%	Wine grapes	7%	Apples	6%	Sugar beet roots	0.1%	9%
67%	IT toddler	13.43	13%	Wheat	8%	Bananas	6%	Lettuces	0.1%	13%
66%	ES adult	13.17	11%	Lettuces	7%	Barley	6%	Wine grapes	0.1%	12%
62%	FI 6 yr	12.36	12%	Bananas	11%	Rice	6%	Potatoes	0.1%	9%
58%	IT adult	11.70	8%	Wheat	8%	Lettuces	4%	Rice	0.1%	8%
56%	UK vegetarian	11.21	12%	Wine grapes	10%	Rice	6%	Bananas	0.0%	5%
52%	UK adult	10.40	16%	Wine grapes	9%	Rice	5%	Bananas	0.0%	4%
51%	FR infant	10.14	8%	Apples	5%	Carrots	5%	Beans (with pods)	0.0%	2%
49%	DK adult	9.73	14%	Wine grapes	7%	Bananas	4%	Apples	0.0%	3%
41%	FI adult	8.19	6%	Coffee beans	5%	Wine grapes	5%	Bananas	0.0%	4%
36%	PL general	7.10	9%	Apples	5%	Potatoes	5%	Table grapes	0.0%	
35%	LT adult	7.06	8%	Apples	5%	Rice	5%	Potatoes	0.0%	7%
21%	IE child	4.19	7%	Rice	3%	Bananas	2%	Wheat	0.0%	3%

Conclusion:
The estimated TMDI/NEDI/IEDI was in the range of 0 % to 301.1 % of the ADI.
For 12 diet(s) the ADI is exceeded.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

A 3.2 IEDI calculations

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Fluxapyroxad

LOQs (mg/kg) range from: 0.01 to: 0.05

Toxicological reference values

ADI (mg/kg bw/day):	0.02	ARfD (mg/kg bw):	0.25
Source of ADI:	EFSA, 2012	Source of ARfD:	EFSA, 2012
Year of evaluation:		Year of evaluation:	

Input values

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

Comments :

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : --

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

	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
	48%	NL toddler	9.67	16%	Apples	7%	Pears	3%	Sugar beet roots	0.2%	0.5%
	32%	DE child	6.36	19%	Apples	2%	Strawberries	1%	Rice	0.2%	0.5%
	29%	NL child	5.75	9%	Apples	5%	Sugar beet roots	3%	Oil palm fruits	0.2%	0.3%
	21%	GEMS/Food G06	4.15	7%	Rice	2%	Sugar canes	1%	Apples	0.1%	0.6%
	19%	GEMS/Food G11	3.82	3%	Sugar canes	2%	Celeries	2%	Apples	0.1%	0.6%
	18%	GEMS/Food G10	3.64	5%	Rice	2%	Sugar canes	1%	Potatoes	0.1%	0.6%
	18%	FR toddler 2 3 yr	3.55	5%	Apples	3%	Rice	2%	Beans (with pods)	0.2%	0.3%
	17%	FR child 3 15 yr	3.47	3%	Apples	2%	Sugar beet roots	2%	Other lettuce and other salad plan	0.2%	0.4%
	17%	GEMS/Food G07	3.32	2%	Sugar canes	2%	Potatoes	2%	Apples	0.1%	0.6%
	16%	IE adult	3.13	2%	Rhubarbs	1%	Celeries	1%	Apples	0.2%	0.3%
	15%	GEMS/Food G08	3.06	2%	Sugar canes	2%	Apples	2%	Potatoes	0.1%	0.8%
	14%	GEMS/Food G15	2.88	2%	Sugar canes	2%	Apples	2%	Potatoes	0.1%	0.7%
	14%	NL general	2.72	2%	Apples	2%	Oil palm fruits	2%	Sugar beet roots	0.1%	0.3%
	13%	PT general	2.55	3%	Rice	2%	Potatoes	2%	Wine grapes	0.0%	0.3%
	13%	SE general	2.52	2%	Potatoes	2%	Rice	2%	Apples	0.1%	0.3%
	13%	UK toddler	2.52	3%	Apples	3%	Rice	2%	Sugar beet roots	0.1%	0.3%
	12%	DE women 14-50 yr	2.47	4%	Apples	3%	Sugar beet roots	0.6%	Wine grapes	0.1%	0.3%
	12%	UK infant	2.46	3%	Rice	2%	Apples	1%	Potatoes	0.0%	0.3%
	12%	FR adult	2.41	3%	Other lettuce and other salad plants	2%	Wine grapes	1%	Apples	0.1%	0.2%
	12%	DK child	2.37	3%	Apples	1%	Rice	1%	Potatoes	0.0%	0.9%
	12%	DE general	2.37	4%	Apples	3%	Sugar beet roots	0.6%	Wine grapes	0.1%	0.5%
	12%	IT adult	2.33	3%	Other lettuce and other salad plants	1%	Apples	1.0%	Other spinach and similar	0.1%	0.3%
	11%	RO general	2.27	2%	Apples	2%	Potatoes	1%	Wine grapes	0.0%	0.4%
	11%	IT toddler	2.24	2%	Other lettuce and other salad plants	1%	Apples	0.8%	Rice	0.1%	0.5%
	11%	FI 3 yr	2.19	2%	Rice	2%	Potatoes	1%	Strawberries	0.1%	0.4%
	10%	ES child	2.05	2%	Rice	2%	Apples	0.8%	Potatoes	0.2%	0.3%
	10%	FI adult	1.97	6%	Coffee beans	0.9%	Apples	0.6%	Strawberries	0.0%	0.1%
	10%	FR infant	1.97	3%	Apples	1%	Beans (with pods)	0.9%	Potatoes	0.0%	0.1%
	8%	FI 6 yr	1.69	2%	Rice	2%	Potatoes	1%	Strawberries	0.1%	0.3%
	8%	ES adult	1.55	1%	Apples	1%	Rice	0.7%	Beans (with pods)	0.1%	0.4%
	7%	PL general	1.43	3%	Apples	2%	Potatoes	0.4%	Pears	0.0%	
	7%	LT adult	1.35	3%	Apples	1%	Potatoes	0.9%	Rice	0.0%	0.2%
	7%	UK vegetarian	1.31	2%	Rice	0.9%	Apples	0.6%	Potatoes	0.0%	0.2%
	6%	UK adult	1.16	2%	Rice	0.8%	Wine grapes	0.6%	Potatoes	0.0%	0.1%
	6%	DK adult	1.14	1%	Apples	0.7%	Wine grapes	0.6%	Potatoes	0.0%	0.1%
	3%	IE child	0.60	1%	Rice	0.5%	Apples	0.3%	Potatoes	0.0%	0.1%

Conclusion :
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Fluxapyroxad is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

A 3.3 IESTI calculations - Raw commodities

The acute risk assessment is based on the ARfD.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

Unprocessed commoditi

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)
0.2%	Barley	3 / 0.09	0.49
0.09%	Wheat	0.4 / 0.02	0.22
0.04%	Oat	3 / 0.09	0.10
0.04%	Rye	0.4 / 0.02	0.09

Expand/collapse list

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

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.2%	Barley	3 / 0.09	0.43
0.05%	Wheat	0.4 / 0.02	0.13
0.03%	Rye	0.4 / 0.02	0.07
0.02%	Oat	3 / 0.09	0.06

A 3.4 IESTI calculations - Processed commodities

Processed commoditie

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	3 / 0.09	0.32	0.3%	Barley / beer	3 / 0.02	0.63
0.1%	Barley / cooked	3 / 0.09	0.32	0.05%	Oat / boiled	3 / 0.09	0.13
0.1%	Oat / milling (flakes)	3 / 0.09	0.26	0.03%	Wheat / bread/pizza	0.4 / 0.02	0.07
0.1%	Wheat / milling (flour)	0.4 / 0.02	0.18	0.02%	Wheat / pasta	0.4 / 0.02	0.06
0.1%	Barley / milling (flour)	3 / 0.09	0.16	0.02%	Wheat / bread	0.4 / 0.02	0.05
0.0%	Wheat / milling (wholemea	0.4 / 0.02	0.08	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
0.0%	Rye / boiled	0.4 / 0.02	0.05	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
0.0%	Rye / milling (wholemeal)-	0.4 / 0.02	0.05	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
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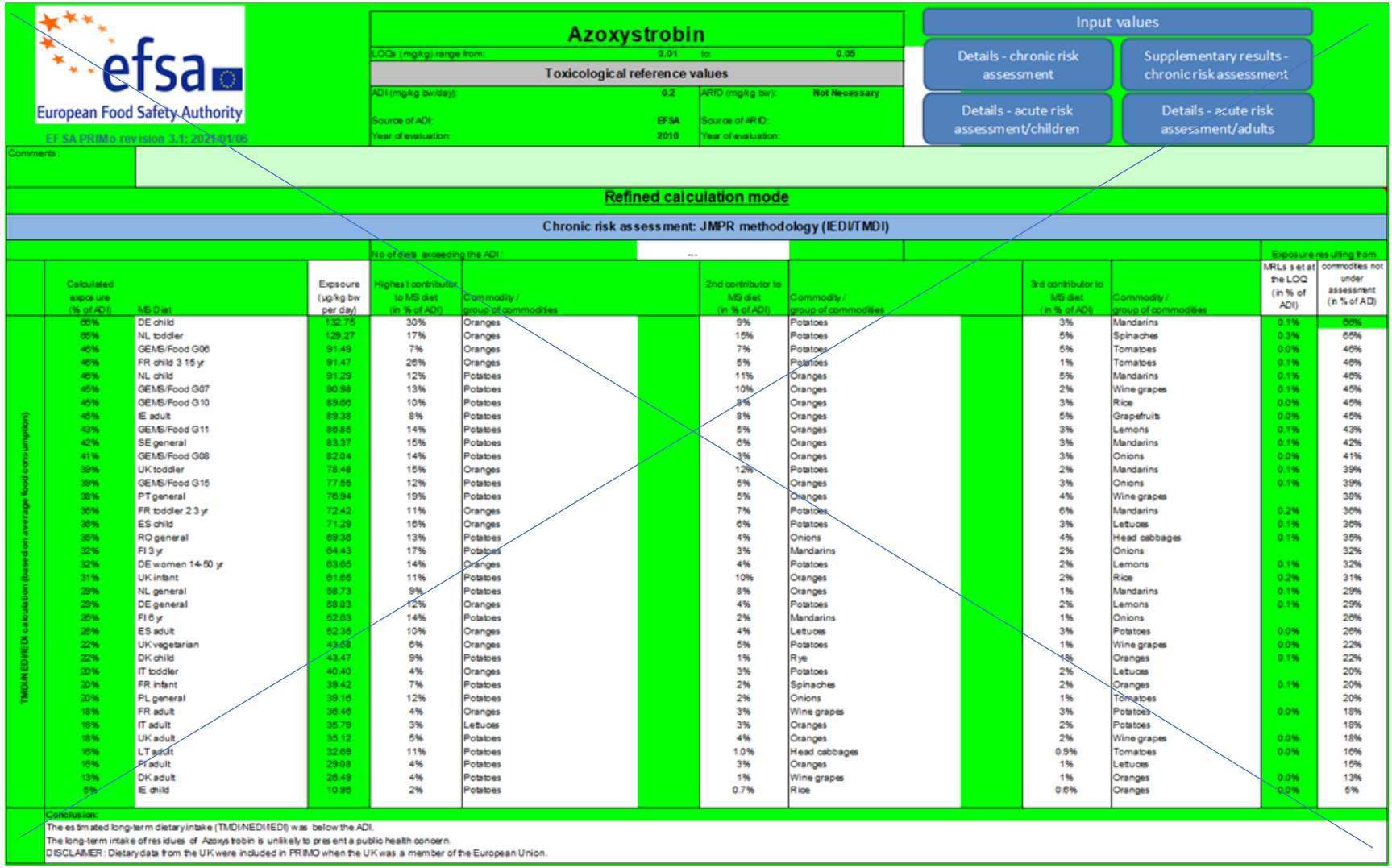
Expand/collapse list							

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

Azoxystrobin

A 3.5 Azoxystrobin TMDI calculations



European Food Safety Authority

EFSA PRIMo revision 3.1; 2024/01/08

Azoxystrobin

LOQs (mg/kg) range from: 0.01 to: 0.05

Toxicological reference values

ADI (mg/kg bw/day):	0.2	ARfD (mg/kg bw):	Not Necessary
Source of ADI:	EFSA	Source of ARfD:	
Year of evaluation:	2010	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 :

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
66%	DE child	132.75	30%	Oranges	9%	Potatoes	3%	Mandarins	0.1%	66%
65%	NL toddler	129.27	17%	Oranges	15%	Potatoes	5%	Spinaches	0.3%	65%
46%	GEMS/Food G06	91.49	7%	Oranges	7%	Potatoes	5%	Tomatoes	0.0%	46%
46%	FR child 3 15 yr	91.47	26%	Oranges	5%	Potatoes	1%	Tomatoes	0.1%	46%
46%	NL child	91.29	12%	Potatoes	11%	Oranges	5%	Mandarins	0.1%	46%
45%	GEMS/Food G07	90.98	13%	Potatoes	10%	Oranges	2%	Wine grapes	0.1%	45%
45%	GEMS/Food G10	89.66	10%	Potatoes	8%	Oranges	3%	Rice	0.0%	45%
45%	IE adult	89.38	8%	Potatoes	8%	Oranges	5%	Grapefruits	0.0%	45%
43%	GEMS/Food G11	86.85	14%	Potatoes	5%	Oranges	3%	Lemons	0.1%	43%
42%	SE general	83.37	15%	Potatoes	6%	Oranges	3%	Mandarins	0.1%	42%
41%	GEMS/Food G08	82.04	14%	Potatoes	3%	Oranges	3%	Onions	0.0%	41%
39%	UK toddler	78.48	15%	Oranges	12%	Potatoes	2%	Mandarins	0.1%	39%
39%	GEMS/Food G15	77.55	12%	Potatoes	5%	Oranges	3%	Onions	0.1%	39%
38%	PT general	76.94	19%	Potatoes	5%	Oranges	4%	Wine grapes		38%
36%	FR toddler 2 3 yr	72.42	11%	Oranges	7%	Potatoes	6%	Mandarins	0.2%	36%
36%	ES child	71.29	16%	Oranges	6%	Potatoes	3%	Lettuces	0.1%	36%
35%	RO general	69.36	13%	Potatoes	4%	Onions	4%	Head cabbages	0.1%	35%
32%	FI 3 yr	64.43	17%	Potatoes	3%	Mandarins	2%	Onions		32%
32%	DE women 14-50 yr	63.65	14%	Oranges	4%	Potatoes	2%	Lemons	0.1%	32%
31%	UK infant	61.65	11%	Potatoes	10%	Oranges	2%	Rice	0.2%	31%
29%	NL general	58.73	9%	Potatoes	8%	Oranges	1%	Mandarins	0.1%	29%
29%	DE general	58.03	12%	Oranges	4%	Potatoes	2%	Lemons	0.1%	29%
26%	FI 6 yr	52.63	14%	Potatoes	2%	Mandarins	1%	Onions		26%
26%	ES adult	52.35	10%	Oranges	4%	Lettuces	3%	Potatoes	0.0%	26%
22%	UK vegetarian	43.58	6%	Oranges	5%	Potatoes	1%	Wine grapes	0.0%	22%
22%	DK child	43.47	9%	Potatoes	1%	Rye	1%	Oranges	0.1%	22%
20%	IT toddler	40.40	4%	Oranges	3%	Potatoes	2%	Lettuces		20%
20%	FR infant	39.42	7%	Potatoes	2%	Spinaches	2%	Oranges	0.1%	20%
20%	PL general	39.16	12%	Potatoes	2%	Onions	1%	Tomatoes		20%
18%	FR adult	36.46	4%	Oranges	3%	Wine grapes	3%	Potatoes	0.0%	18%
18%	IT adult	35.79	3%	Lettuces	3%	Oranges	2%	Potatoes		18%
18%	UK adult	35.12	5%	Potatoes	4%	Oranges	2%	Wine grapes	0.0%	18%
16%	LT adult	32.69	11%	Potatoes	1.0%	Head cabbages	0.9%	Tomatoes	0.0%	16%
15%	FI adult	29.08	4%	Potatoes	3%	Oranges	1%	Lettuces		15%
13%	DK adult	26.49	4%	Potatoes	1%	Wine grapes	1%	Oranges	0.0%	13%
5%	IE child	10.95	2%	Potatoes	0.7%	Rice	0.6%	Oranges	0.0%	5%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Azoxystrobin is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Azoxystrobin Reg. (EU) 2022/476

LOQs [mg/kg] range from: 0.01 to: 0.05

Toxicological reference values

ADI [mg/kg bw/day]:	0.2	ARfD [mg/kg bw]:	Not needed
Source of ADI:	EFSA	Source of ARfD:	
Year of evaluation:	2018	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: ...

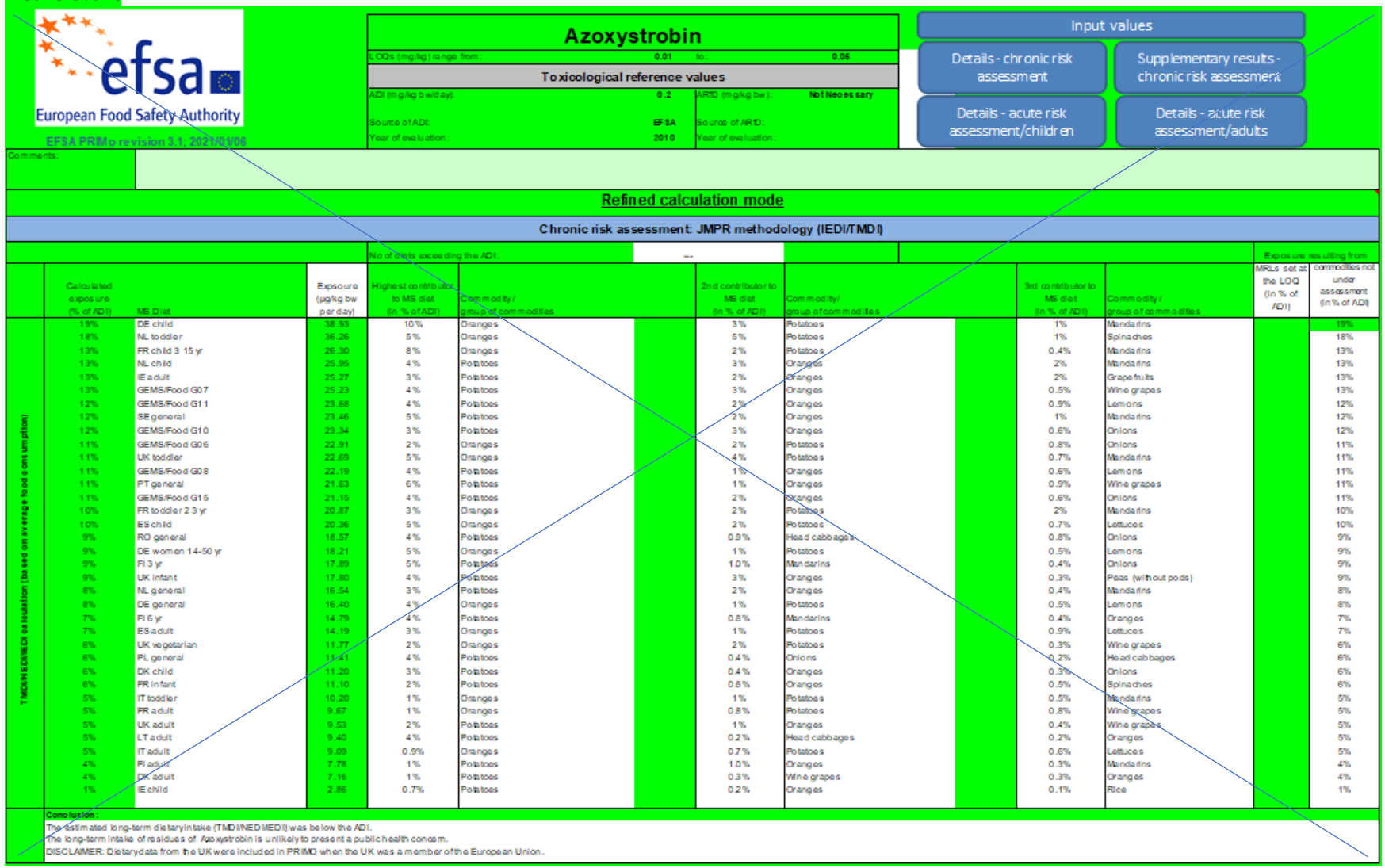
TMDI/MEDI/IEDI calculation (based on average food consumption)

Calculated exposure [% of ADI]	MS Diet	Exposure [µg/kg bw per day]	Highest contributor in MS diet [in % of ADI]	Commodity / group of commodities	2nd contributor in MS diet [in % of ADI]	Commodity / group of commodities	3rd contributor in 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]
85%	NL toddler	165.46	17%	Oranges	15%	Potatoes	13%	Sugar beet roots	0.4%	
69%	DE child	138.25	38%	Oranges	9%	Potatoes	9%	Mandarins	0.2%	
68%	NL child	135.83	24%	Sugar beet roots	12%	Potatoes	11%	Oranges	0.2%	
57%	FR child 3-15 yr	113.14	26%	Oranges	9%	Sugar beet roots	5%	Potatoes	0.2%	
50%	GEMS/Food G05	99.65	7%	Oranges	7%	Potatoes	5%	Tomatoes	0.8%	
48%	UK toddler	95.97	15%	Oranges	12%	Potatoes	8%	Sugar beet roots	0.1%	
47%	IE adult	94.82	8%	Potatoes	8%	Oranges	5%	Grapefruits	0.1%	
46%	GEMS/Food G07	92.33	13%	Potatoes	10%	Oranges	2%	Wine grapes	0.1%	
45%	GEMS/Food G10	90.58	10%	Potatoes	8%	Oranges	5%	Rice	0.1%	
44%	FR toddler 2-3 yr	88.23	11%	Oranges	7%	Sugar beet roots	7%	Potatoes	0.2%	
44%	GEMS/Food G11	87.73	14%	Potatoes	5%	Oranges	5%	Lemons	0.1%	
44%	DE women 14-50 yr	87.52	14%	Oranges	11%	Sugar beet roots	4%	Potatoes	0.1%	
43%	SE general	86.92	15%	Potatoes	6%	Oranges	5%	Mandarins	0.1%	
41%	GEMS/Food G08	82.57	14%	Potatoes	5%	Oranges	5%	Onions	0.1%	
40%	DE general	79.76	12%	Oranges	11%	Sugar beet roots	4%	Potatoes	0.1%	
39%	GEMS/Food G15	78.51	12%	Potatoes	5%	Oranges	5%	Onions	0.1%	
39%	PT general	77.61	13%	Potatoes	5%	Oranges	4%	Wine grapes	0.8%	
38%	RO general	76.13	13%	Potatoes	4%	Onions	4%	Head cabbages	0.1%	
37%	ES child	74.38	16%	Oranges	6%	Potatoes	5%	Lettuces	0.1%	
37%	NL general	73.14	5%	Potatoes	8%	Oranges	7%	Sugar beet roots	0.1%	
36%	UK infant	71.27	11%	Potatoes	10%	Oranges	4%	Sugar beet roots	0.2%	
34%	FI 3 yr	67.85	17%	Potatoes	5%	Mandarins	2%	Onions	0.8%	
27%	FI 6 yr	54.14	14%	Potatoes	2%	Mandarins	1%	Onions	0.8%	
27%	ES adult	53.88	10%	Oranges	4%	Lettuces	3%	Potatoes	0.1%	
25%	UK vegetarian	49.88	6%	Oranges	5%	Potatoes	1%	Sugar beet roots	0.8%	
23%	FR infant	46.41	7%	Potatoes	5%	Sugar beet roots	2%	Spinaches	0.1%	
23%	DK child	45.73	5%	Potatoes	1%	Rye	1%	Oranges	0.1%	
22%	IT toddler	44.58	4%	Oranges	5%	Potatoes	2%	Lettuces	0.8%	
22%	FR adult	43.23	4%	Oranges	3%	Wine grapes	3%	Potatoes	0.8%	
20%	IT adult	40.84	3%	Lettuces	3%	Oranges	2%	Potatoes	0.8%	
20%	PL general	39.56	12%	Potatoes	2%	Onions	1%	Tomatoes	0.8%	
19%	UK adult	38.51	5%	Potatoes	4%	Oranges	2%	Wine grapes	0.8%	
16%	LT adult	32.82	11%	Potatoes	1.8%	Head cabbages	0.5%	Tomatoes	0.8%	
15%	FI adult	29.58	4%	Potatoes	3%	Oranges	1%	Lettuces	0.8%	
14%	DK adult	27.48	4%	Potatoes	1%	Wine grapes	1%	Oranges	0.8%	
6%	IE child	11.54	2%	Potatoes	0.7%	Rice	0.6%	Oranges	0.8%	

Conclusion:
The estimated long-term dietary intake (TMDI/MEDI/IEDI) was below the ADI.
The long-term intake of residues of Azoxystrobin Reg. (EU) 2022/476 is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMo when the UK was a member of the European Union.

A 3.6 IEDI calculations

Not relevant



European Food Safety Authority

EFSA PRIMo revision 3.1: 2021(V3)

Azoxystrobin

LOQs (mg/kg) range from: 0.01 to: 0.05

Toxicological reference values

ADI (mg/kg bw/day): 0.2 ARfD (mg/kg bw): Not Necessary

Source of ADI: EFSA Source of ARfD:

Year of evaluation: 2010 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:

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI: ---

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

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
19%	DE child	38.93	10%	Oranges	3%	Potatoes	1%	Mandarins		19%
18%	NL toddler	36.26	5%	Oranges	5%	Potatoes	1%	Spinaches		18%
13%	FR child 3 15 yr	26.30	8%	Oranges	2%	Potatoes	0.4%	Mandarins		13%
13%	NL child	25.95	4%	Potatoes	3%	Oranges	2%	Mandarins		13%
13%	IE adult	25.27	3%	Potatoes	2%	Oranges	2%	Grapefruits		13%
13%	GEMS/Food G07	25.23	4%	Potatoes	3%	Oranges	0.5%	Wine grapes		13%
12%	GEMS/Food G11	23.68	4%	Potatoes	2%	Oranges	0.9%	Lemons		12%
12%	SE general	23.46	5%	Potatoes	2%	Oranges	1%	Mandarins		12%
12%	GEMS/Food G10	23.34	3%	Potatoes	3%	Oranges	0.6%	Onions		12%
11%	GEMS/Food G06	22.91	2%	Oranges	2%	Potatoes	0.8%	Onions		11%
11%	UK toddler	22.69	5%	Oranges	4%	Potatoes	0.7%	Mandarins		11%
11%	GEMS/Food G08	22.19	4%	Potatoes	1%	Oranges	0.6%	Lemons		11%
11%	PT general	21.63	6%	Potatoes	1%	Oranges	0.9%	Wine grapes		11%
11%	GEMS/Food G15	21.15	4%	Potatoes	2%	Oranges	0.6%	Onions		11%
10%	FR toddler 2 3 yr	20.87	3%	Oranges	2%	Potatoes	2%	Mandarins		10%
10%	ES child	20.36	5%	Oranges	2%	Potatoes	0.7%	Lettuces		10%
9%	RO general	18.57	4%	Potatoes	0.9%	Head cabbages	0.8%	Onions		9%
9%	DE women 14-50 yr	18.21	5%	Oranges	1%	Potatoes	0.5%	Lemons		9%
9%	FI 3 yr	17.89	5%	Potatoes	1.0%	Mandarins	0.4%	Onions		9%
9%	UK infant	17.80	4%	Potatoes	3%	Oranges	0.3%	Peas (without pods)		9%
8%	NL general	16.54	3%	Potatoes	2%	Oranges	0.4%	Mandarins		8%
8%	DE general	16.40	4%	Oranges	1%	Potatoes	0.5%	Lemons		8%
7%	FI 6 yr	14.79	4%	Potatoes	0.8%	Mandarins	0.4%	Oranges		7%
7%	ES adult	14.19	3%	Oranges	1%	Potatoes	0.9%	Lettuces		7%
6%	UK vegetarian	11.77	2%	Oranges	2%	Potatoes	0.3%	Wine grapes		6%
6%	PL general	11.41	4%	Potatoes	0.4%	Onions	0.2%	Head cabbages		6%
6%	DK child	11.20	3%	Potatoes	0.4%	Oranges	0.3%	Onions		6%
6%	FR infant	11.10	2%	Potatoes	0.6%	Oranges	0.5%	Spinaches		6%
5%	IT toddler	10.20	1%	Oranges	1%	Potatoes	0.5%	Mandarins		5%
5%	FR adult	9.67	1%	Oranges	0.8%	Potatoes	0.8%	Wine grapes		5%
5%	UK adult	9.53	2%	Potatoes	1%	Oranges	0.4%	Wine grapes		5%
5%	LT adult	9.40	4%	Potatoes	0.2%	Head cabbages	0.2%	Oranges		5%
5%	IT adult	9.09	0.9%	Oranges	0.7%	Potatoes	0.6%	Lettuces		5%
4%	FI adult	7.78	1%	Potatoes	1.0%	Oranges	0.3%	Mandarins		4%
4%	DK adult	7.16	1%	Potatoes	0.3%	Wine grapes	0.3%	Oranges		4%
1%	IE child	2.86	0.7%	Potatoes	0.2%	Oranges	0.1%	Rice		1%

Conclusion:

The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.

The long-term intake of residues of Azoxystrobin is unlikely to present a public health concern.

DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

A 3.7 IESTI calculations - Raw commodities

Not relevant, no ARfD has been set for Azoxystrobin.

A 3.8 IESTI calculations - Processed commodities

Not relevant, no ARfD has been set for azoxystrobin,

Appendix 4 Additional information provided by the applicant

Not relevant.