

REGISTRATION REPORT

Part A

Risk Management

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

NATIONAL ASSESSMENT Poland

(new authorization)

Applicant: BASF

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When	What
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01/2023	Version revised to take into account comments of cMSs and the applicant

Table of Contents

1	Details of the application	5
1.1	Application background	5
1.2	Letters of Access	6
1.3	Justification for submission of tests and studies	6
1.4	Data protection claims	6
2	Details of the authorization decision	7
2.1	Product identity	7
2.2	Conclusion	7
2.3	Substances of concern for national monitoring	7
2.4	Classification and labelling	7
2.4.1	Classification and labelling under Regulation (EC) No 1272/2008	7
2.4.2	Standard phrases under Regulation (EU) No 547/2011	9
2.4.3	Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)	9
2.5	Risk management	9
2.5.1	Restrictions linked to the PPP	9
2.5.2	Specific restrictions linked to the intended uses	9
2.6	Intended uses (only NATIONAL GAP)	10
3	Background of authorization decision and risk management	13
3.1	Physical and chemical properties (Part B, Section 2)	13
3.2	Efficacy (Part B, Section 3)	14
3.3	Efficacy data	14
3.3.1	Information on the occurrence or possible occurrence of the development of resistance	15
3.3.2	Adverse effects on treated crops	15
3.3.3	Observations on other undesirable or unintended side-effects	15
3.4	Methods of analysis (Part B, Section 5)	15
3.4.1	Analytical method for the formulation	15
3.4.2	Analytical methods for residues	16
3.5	Mammalian toxicology (Part B, Section 6)	18
3.5.1	Acute toxicity	19
3.5.2	Operator exposure	19
3.5.3	Worker exposure	20
3.5.4	Bystander and resident exposure	20
3.6	Residues and consumer exposure (Part B, Section 7)	21
3.6.1	Residues	21
3.6.2	Consumer exposure	22
3.7	Environmental fate and behaviour (Part B, Section 8)	22
3.7.1	Predicted environmental concentrations in soil (PEC _{soil})	23
3.7.2	Predicted environmental concentrations in groundwater (PEC _{gw})	23
3.7.3	Predicted environmental concentrations in surface water (PEC _{sw})	23
3.7.4	Predicted environmental concentrations in air (PEC _{air})	24
3.8	Ecotoxicology (Part B, Section 9)	24
3.8.1	Effects on terrestrial vertebrates	24

3.8.2	Effects on aquatic species	26
3.8.3	Effects on bees	26
3.8.4	Effects on other arthropod species other than bees.....	27
3.8.5	Effects on soil organisms	27
3.8.6	Effects on non-target terrestrial plants	28
3.8.7	Effects on other terrestrial organisms (Flora and Fauna).....	28
3.9	Relevance of metabolites (Part B, Section 10)	28
4	Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)	30
5	Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorization	31
Appendix 1	Copy of the product authorization	32
Appendix 2	Copy of the product label	33
Appendix 3	Letter of Access	34
Appendix 4	Lists of data considered for national authorization.....	35

PART A

RISK MANAGEMENT

1 Details of the application

This document describes the acceptable use conditions required for the national registration of BAS 736 00 F a new plant protection product containing 50 g/L of the active substance fluxapyroxad (BAS 700 F) and 75 g/L of the active substance azoxystrobin (BAS 9164 F) in Poland.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections B0-B10 and Part C and where appropriate in the national addendum. The information, data and assessments provided in Registration Report, Sections B includes assessment of further data or information as required at national level in accordance with the conclusions from the EU review of the active substances. It also includes assessment of data and information relating to BAS 736 00 F where that data has not been considered in the EU review. Assessments for the safe use of BAS 736 00 F have been made using endpoints agreed in the EU review of fluxapyroxad and azoxystrobin

Appendix 1 of this document provides a copy of the final product authorization in Poland.

Appendix 2 of this document is a copy of the approved product label for Poland.

Appendix 3 of this document contains copies of the letters of access to third party data that was needed for evaluation of the formulation.

Appendix 4 of this document contains the lists of data considered for national authorization.

1.1 Application background

This application was submitted by

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The application was submitted for the approval of BAS 736 00 F, a new EC formulation containing 50 g/L flupyroxad and 75 g/L azoxystrobin for use as a fungicide in cereals.

1.2 Letters of Access

Data on the active substance azoxystrobin are owned by Syngenta Crop Protection AG and a letter of access is included in this application (BASF DocID 2021/2051687).

1.3 Justification for submission of tests and studies

BAS 736 00 F is a new plant protection product.

Testing is conducted according to the data requirements for the authorisation of plant protection products and is conducted in compliance with national and international animal welfare regulations. The testing strategy takes into account methods compliant with the 3R concept for refinement, reduction and replacement of animal testing where applicable and acceptable.

Reasoning is provided in Section B documents.

Testing has been conducted in order to fulfil the data requirements for plant protection products and in order to demonstrate an acceptable use of the plant protection product.

1.4 Data protection claims

Data protection is claimed in accordance with Article 59 of Regulation (EC) No. 1107/2009 as provided for in the list of references in Appendix 4.

2 Details of the authorization decision

2.1 Product identity

Product code	BAS 736 00 F
Product name in MS	Miralon
Authorization number	Not applicable, new product
Function	fungicide
Applicant	BASF
Active substance(s) (incl. content)	Fluxapyroxad: 50 g/L Azoxystrobin: 75 g/L
Formulation type	formulation type [EC]
Packaging	0,15 – 15 L PA/PE (Coex) or f-HDPE, 20-50 L f-HDPE, professional user
Coformulants of concern for national authorizations	not applicable
Restrictions related to identity	not applicable
Mandatory tank mixtures	not applicable
Recommended tank mixtures	not applicable

2.2 Conclusion

The evaluation of the application for BAS 736 00 F (Miralon) resulted in the decision to grant the authorization of this product for diseases control in cereal crops.

All uses applied for were authorised.

2.3 Substances of concern for national monitoring

No further information is required.


2.4 Classification and labelling

2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard class(es), categories:	Acute Tox. 4 Skin Irrit. 2 Eye Dam. 1 Skin Sens. 1 Lact Aquatic chronic 1
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The following labelling information is derived from the classification and to be mentioned in the safety data sheet. The information which is determined for the **label is formatted bold**:

Hazard pictograms:	 GHS05, GHS07, GHS09
Signal word:	Danger
Hazard statement(s):	H302: Harmful if swallowed H332: Harmful if inhaled H315: Causes skin irritation H317: May cause an allergic skin reaction H318: Causes serious eye damage H362: May cause harm to breast-fed children H410: Very toxic to aquatic life with long lasting effects
Precautionary statement(s):	P101: If medical advice is needed, have product container or label at hand. P102: Keep out of reach of children. P103: Read carefully and follow the instructions - Prevention P201: Obtain special instructions before use P202: Do not handle until all safety precautions have been read and understood P260: Do not breathe mist/vapours/spray. P263: Avoid contact during pregnancy while nursing. P264: Wash contaminated body parts thoroughly after handling. P270: Do not eat, drink or smoke when using this product P271: Use only outdoors or in a well-ventilated area P272: Contaminated work clothing should not be allowed out of the workplace. P280: Wear protective gloves and eye or face protection. - Response P305+P351+P338, P310: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or physician P301 + P312, P330: IF SWALLOWED: Call a POISON CENTRE/doctor/ if you feel unwell. Rinse mouth P302 + P352: IF ON SKIN: Wash with plenty of water P304 + P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing P330: Rinse mouth P308 + P313: IF exposed or concerned: Get medical advice/attention P333 + P313: If skin irritation or rash occurs: Get medical advice/attention. P362 + P364: Take off contaminated clothing and wash it before reuse P391: Collect spillage - Disposal P501: Dispose of contents/container to hazardous or special waste collection point
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401] May produce an allergic reaction. Contains: Octabenzene [EUH208] Contains <i>Octabenzene and 2-Propenoic acid, 2-methyl-, polymer with tert-Bu acrylate, Me meth-acrylate, polyethylene glycol meth-acrylate C16-18-alkyl ethers and vinyl-pyrrolidone, tert-Bu 2-ethyl-hexane-peroxoate – initiated, compds. with 2-amino-2-methyl-1-propanol</i>

See Part C for justifications of the classification and labelling proposals.

2.4.2 Standard phrases under Regulation (EU) No 547/2011

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
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2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

None.

2.5 Risk management

2.5.1 Restrictions linked to the PPP

The authorization of the PPP is linked to the following conditions (mandatory labelling):
None proposed

The authorization of the PPP is linked to the following conditions (voluntary labelling):
None proposed

Statement recommended to include on the label: “Apply spray liquid under permanent agitation” (based on the results of emulsion stability test in Part B1,2&4).

2.5.2 Specific restrictions linked to the intended uses

None proposed.

2.6 Intended uses (only NATIONAL GAP)

PPP (product name/code):	Miralon (proposed) / BAS 736 00 F	Formulation type:	GAP rev. , date: year-month-day EC ^(a, b)
Active substance 1:	Fluxapyroxad	Conc. of as 1:	50 g/L ^(c)
Active substance 2:	Azoxystrobin	Conc. of as 2:	75 g/L ^(c)
Safener:	None	Conc. of safener:	Not relevant ^(c)
Synergist:	None	Conc. of synergist:	Not relevant ^(c)
Applicant:	BASF	Professional use:	<input checked="" type="checkbox"/>
Zone(s):	Central ^(d)	Non professional use:	<input type="checkbox"/>
Verified by MS:	yes/no		
Field of use:	fungicide		

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: develop- mental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha ⁽ⁱ⁾
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	PL	wheat TRZAW, TRZAS TRZDU, TRZSP	F	Zymoseptoria tritici - SEPTTR Puccinia triticina - PUCCRT Puccinia striiformis - PUC CST Pyrenophora tritici- repentis - PYRNTR	Spraying (SP)	30 - 69	a) 2 b) 2	21	a) 2.00 b) 4.00	a) 0.100 / 0.150 b) 0.200 / 0.300	100 - 300	35	
1a	PL	wheat, TRZAS	F	Puccinia striiformis - PUC CST Pyrenophora tritici- repentis - PYRNTR	Spraying (SP)	30 - 69	a) 2 b) 2	21	a) 2.00 b) 4.00	a) 0.100 / 0.150 b) 0.200 / 0.300	100 - 300	35	
6	PL	barley HORVW HORVS	F	Pyrenophora teres – PYRNTE R. secalis – RHYNSE Puccinia hordei - PUCCHD R. collo-cygni - RAMUCC	Spraying (SP)	30 - 69	a) 2 b) 2	21	a) 2.00 b) 4.00	a) 0.100 / 0.150 b) 0.200 / 0.300	100 - 300	35	
3	PL	rye SECCW SECCS SECCE	F	R. secalis - RHYNSE Puccinia recondita - PUC CRE	Spraying (SP)	30 - 69	a) 2 b) 2	21	a) 2.00 b) 4.00	a) 0.100 / 0.150 b) 0.200 / 0.300	100 - 300	35	
4	PL	triticales TTLWI TTL SO	F	Zymoseptoria sp. - SEPTSP Puccinia recondita - PUC CRE Puccinia striiformis - PUC CST	Spraying (SP)	30 - 69	a) 2 b) 2	21	a) 2.00 b) 4.00	a) 0.100 / 0.150 b) 0.200 / 0.300	100 - 300	35	

Remarks table heading:	(a)	e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(d)	Select relevant
	(b)	Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008	(e)	Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
	(c)	g/kg or g/l	(f)	No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.
Remarks columns:	1	Numeration necessary to allow references	7	Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
	2	Use official codes/nomenclatures of EU Member States	8	The maximum number of application possible under practical conditions of use must be provided.
	3	For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)	9	Minimum interval (in days) between applications of the same product
	4	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	10	For specific uses other specifications might be possible, e.g.: g/m ³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
	5	Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.	11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
	6	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench	12	If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
		Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.	13	PHI - minimum pre-harvest interval
			14	Remarks may include: Extent of use/economic importance/restrictions

3 Background of authorization decision and risk management

3.1 Physical and chemical properties (Part B, Section 2)

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. BAS 736 00 F is an emulsifiable concentrate containing 50 g/L of fluxapyroxad and 75 g/L of azoxystrobin. BAS 736 00 F was not a representative formulation and therefore has not been previously evaluated at EU level.

The appearance of the product is a dark yellow clear liquid, with a strong sweet odour. It is not explosive, has no oxidising properties. The product is not flammable and has a flash point of 96.5 °C. It has a self-ignition temperature of 425°C. In aqueous solution, it has a pH value around 6.1 at 1% dilution. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 14 days at 54 °C in F-HDPE bottles, neither the active substances content nor the technical properties were changed.

Since the relevant impurity of azoxystrobin and fluxapyroxad – toluene (used as solvent) cannot be formed upon storage of the formulation thus their determination in storage studies is not needed. Toluene content is controlled within the technical specifications of active substances. The analytical methods for the determination of the active substances and the relevant impurity – toluene, in the formulation BAS 736 00 F are available and validated.

An analytical method for the determination of the Z-isomer of azoxystrobin in the product BAS 736 00 F is ongoing.

The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in F-HDPE packaging. Its technical characteristics are acceptable for an EC formulation.

The investigations of the physical and chemical properties have shown that BAS 736 00 F meets the general requirements for an EC-formulation according to the FAO specifications. This indicates that no particular problems are to be expected if the preparation is used as recommended.

A minimum shelf life of 2 years would be expected for this product according to FAO specifications. However an ambient temperature shelf life study is required to support the proposed shelf life of 2 years for the product BAS 736 00 F.

The samples were stored, in their commercial packaging made from F-HDPE, however PA/PE (COEX) containers were additionally proposed (section 4.1). The PA/PE co-extruded packs are supported based on accelerated storage data for F-HDPE container (for details see findings of storage stability test KCP 2.7.1). The other study report BASF Ref. 2019/1039595 (see section 4.1) demonstrate that PA/PE co-extruded packaging material is stable after storage (8 weeks at 40°C) of product BAS 736 00 F.

A seepage study with BAS 736 00 F for the Coex PE/PA material (see section BASF DocID 2022/2027756) has been provided. Acceptable seepage data show that the formulation BAS 736 00 F is compatible with all tested packaging material. Therefore, for organic solvent based formulation type, like emulsifiable concentrate (EC), data can be extrapolated between packaging material of f-HDPE and coex-HDPE/PA, as acceptable seeping data is provided¹.

Implications for labelling: none for physical hazard classification (CLP)

Although the kinematic viscosity is lower than 20.5 mm²/sec, the formulation does not contain any substance classified as a category 1 for aspiration toxicity hazards (see composition in the confidential Part C).

Statement recommended to include on the label: “Apply spray liquid under permanent agitation” (based on the results of emulsion stability test in Part B1,2&4)

¹ SANCO/10473/2003 –rev.5; 21.10.2021

Compliance with FAO specifications:

The product BAS 736 00 F complies with FAO specifications

Compatibility of mixtures: The product BAS 736 00 F can be mixed in the tank together with Medax Max, Revysol, BAS 832 00 F, Actirob, Adigor, Atlantis and Axial 50. Studies regarding the combination with BAS 736 00 F were submitted and the application as tank mixture is acceptable.

However, no tank mixtures are recommended on the label of this product.

Nature and characteristics of the packaging: Information with regard to type, dimensions, capacity, size of opening, type of closure, strength, leakproofness, resistance to normal transport & handling, resistance to & compatibility with the contents of the packaging, have been submitted, evaluated and is considered to be acceptable.

Nature and characteristics of the protective clothing and equipment: Information regarding the required protective clothing and equipment for the safe handling of BAS 736 00 F has been provided and is considered to be acceptable.

3.2 Efficacy (Part B, Section 3)

The biological assessment dossier summarizes the biological activity of BAS 736 00 F against *Zymoseptoria tritici*, *Septoria spp.*, *Puccinia spp.*, *Pyrenophora tritici-repentis*, *Pyrenophora teres*, *Blumeria graminis*, *Rhynchosporium secalis* and *Ramularia collo-cygni* in cereals. It is intended for use in wheat, barley, rye, triticale and oats.

3.3 Efficacy data

The biological assessment dossier summarizes the biological activity of BAS 736 00 F against *Zymoseptoria tritici*, *Septoria spp.*, *Puccinia spp.*, *Pyrenophora tritici-repentis*, *Pyrenophora teres*, *Blumeria graminis*, *Rhynchosporium secalis* and *Ramularia collo-cygni* in cereals. It is intended for use in wheat, barley, rye, triticale and oats.

The efficacy of azoxystrobin and fluxapyroxad solo at the dose rates as used in BAS 736 00 F and the efficacy of their mixtures in different ratios were tested in comparison to a standard and the optimum ratio of both active ingredients has been justified.

The dose response of BAS 736 00 F is demonstrated with altogether 194 trials conducted in wheat (86 trials), barley (67 trials), rye (21 trials) and triticale (20 trials) in which the performances of the target dose rate and the reduced dose rate were compared. BAS 736 00 F at the target dose rate of 2.0 L/ha provided the optimum and most consistent control of the key diseases of important cereal crops and should be considered as the minimum effective dose rate in cereals under a wide range of environmental conditions.

A total dataset of 227 efficacy trials conducted between 2019 and 2020 is presented to support the efficacy on target diseases in the Central registration zone. The efficacy trials cover the following crops: winter wheat (104), spring wheat (2), winter barley (57), spring barley (2), rye (21), triticale (20) and oats (3). All efficacy trials were performed according to GEP and EPPO guidelines in force when the protocols were written. The data show very good effects on the target diseases and confirm that BAS 736 00 F is a highly effective fungicide, offering a valid opportunity for the control of important pathogens of cereals.

Beside the efficacy of the product, the results demonstrated a yield increase after application of BAS 736 00 F.

The submitted data support the registration of BAS 736 00 F (Miralon) for following diseases control: – in **wheat**: *Septoria* leaf blotch (*Zymoseptoria tritici*), brown rust (*Puccinia triticina*), yellow rust (*Puccinia striiformis*) and tan spot (*Pyrenophora tritici-repentis*); – in **barley**: net blotch (*Pyrenophora teres*), leaf scald (*Rhynchosporium secalis*), *Ramularia* leaf spot (*Ramularia collo-cygni*) and leaf rust (*Puccinia*

hordei); – in **rye**: leaf scald (*Rhynchosporium secalis*) and leaf rust (*Puccinia recondita*), – in **triticale**: powdery mildew (*Blumeria graminis*), Septoria leaf and glume blotch (*Zymoseptoria tritici* and *Parastagonospora nodorum*) and rusts (*Puccinia recondita* and *Puccinia striiformis*).

BAS 736 00 F can be use as foliar application, at the rate of 2.0 L/ha (fluxapyroxad – 100 g/ha + azoxystrobin – 150 g/ha) (in some countries lower rates) at a maximum of two treatments, at the growth stages between BBCH 30 and 69, with water volume from 100 to 300 L/ha.

3.3.1 Information on the occurrence or possible occurrence of the development of resistance

The analysis of the combined resistance risk showed that the risk is not acceptable for the medium-risk and high-risk pathogens under unrestricted use of BAS 736 00 F, therefore resistance management strategies need to be implemented. Management strategies are necessary to reduce the risk of resistance development. The key of the resistance management strategies is the reduction of selection pressure to a specific mode of action. Different modifiers that lead to such a reduction will be implemented in the resistance management strategy. BASF actively participates in the FRAC meetings for all presently established Working Groups. In this way every attempt is made to formulate and promote resistance management strategies and the rational use of its fungicides.

3.3.2 Adverse effects on treated crops

No phytotoxicity was observed in the efficacy trials after treatments with the maximum target dose rate 2.0 L/ha.

Altogether 16 trials without disease or with the disease symptoms below the threshold (7 in wheat, 5 in barley, 1 in triticale and 3 in oats) were presented and demonstrated no statistically significant negative impact on yield and qualitative parameters such as the thousand grain weight and the hectolitre weight.

Moreover foliar treatments with BAS 736 00 F do not have any impact on germination of harvested cereal seeds. Bread making and brewing studies confirmed no negative effect on transformation processes.

3.3.3 Observations on other undesirable or unintended side-effects

Result of the studies indicate that there is no necessity for restrictions in the choice of succeeding crops and adjacent crops after the application of BAS 736 00 F.

3.4 Methods of analysis (Part B, Section 5)

3.4.1 Analytical method for the formulation

An overview on the acceptable methods and possible data gaps for the analysis of the active substances, relevant impurities and relevance of CIPAC methods in BAS 736 00 F is provided within this submission. All relevant data are considered adequate.

For further information see Part B, Section 5 (KCP 5.1.1).

The analytical method AFL1000/01 has been developed for the determination of the active substances azoxystrobin and fluxapyroxad in the plant protection product BAS 736 00 F.

With respect to the conditions described in the analytical method AFL1000/01 all validation parameters (identity, specificity, linearity, accuracy and precision) are acceptable.

Therefore, this method is valid without restriction in the tested concentration range and is applicable to

determine the content of azoxystrobin and fluxapyroxad in the EC-formulation BAS 736 00 F. Azoxystrobin and fluxapyroxad both contain toluene as relevant impurity. The maximum allowed level in the technical material is 2 g/kg and 0.6 g/kg for azoxystrobin technical and fluxapyroxad technical respectively, which means 0.19 g/L in the formulation BAS 736 00 F.

The analytical method AFL1012/01 has been developed for the determination of toluene in the EC-formulation BAS 736 00 F. The validation data prove that the GC-MS method is suitable to the determination of the content of the relevant impurity toluene in the formulation BAS 736 00 F.

Since Z-isomer is identified as toxicologically relevant for azoxystrobin (according to Commission Implementing Regulation (EU) No 540/2011), an analytical method for the determination of the Z-isomer in plant protection product BAS 736 00 F is required and should be provided by the applicant. (According to the applicant's statement: analytical method for the z-isomer is in development; study will be provided as soon as available).

3.4.2 Analytical methods for residues

The analytical methods used for determination residues of fluxapyroxad (BAS 700 F) and azoxystrobin in plant matrices in the residue behaviour studies in wheat and barley (L0137/01 and L0435/01) were fully validated showing that they can be successfully used in cereals.

Fluxapyroxad

The analytical methods developed for fluxapyroxad (BAS 700 F) in plant and animal matrices were already EU reviewed and considered adequate. Analytical methods developed for determination of fluxapyroxad residues in the environmental matrices soil, water, and air were also already EU reviewed and considered adequate. New methods were developed for body fluids and bee-related matrices which are submitted with the current dossier.

Plant and plant products:

The analytical method for determination of fluxapyroxad residues and its metabolites in foodstuffs of plant origin (BASF Method No L0137/01) is based on LC-MS/MS (using HPLC or UPLC) with an LOQ of 0.01 mg/kg. It was sufficiently validated for a diverse range of representative plant matrices. This method is used for both data generation and enforcement purposes. An independent laboratory validation (ILV) for fluxapyroxad was carried out successfully. Therefore, this method can be used as enforcement method for fluxapyroxad in plant matrices. The EU residue definition for fluxapyroxad for monitoring purposes is parent only.

Food of animal origin:

The analytical methods for the determination of fluxapyroxad residues in foodstuffs of animal origin (BASF Method No L0140/02 and L0140/01) are based on LC-MS/MS. The LOQ for muscle, kidney, liver and fat is 0.01 mg/kg, while the LOQ for milk, skim milk, cream as well as egg is 0.001 mg/kg. These methods were sufficiently validated for animal matrices and an ILV for fluxapyroxad in animal matrices (BASF Method No L0140/02) was carried out successfully. Both methods are used for data generation and L0140/02 is also used as enforcement method. The EU residue definition for fluxapyroxad for monitoring purposes is parent only.

Soil:

An analytical LC-MS/MS method (BASF Method No L0092/03) was developed and validated, analyzing fluxapyroxad and its metabolites with an LOQ of 0.001 mg/kg. This method based on LC-MS/MS (using HPLC or UPLC) is suitable for enforcement purposes and data generation. The EU residue definition for fluxapyroxad for monitoring purposes is parent only.

Water:

Fluxapyroxad and its metabolites can be determined using BASF analytical method L0143/01 using LC/MS/MS with a limit of quantification of 30 ng/L. A new independent laboratory validation (ILV) was carried out successfully in pond water and submitted. The EU residue definition for fluxapyroxad for monitoring purposes is parent only.

Air:

Fluxapyroxad in air can be determined using BASF analytical method L0142/01 by sucking air through adsorption tubes for about 6 hours. The tube content is then extracted with methanol and water and analyzed by LC/MS-MS (using HPLC or UPLC). The limit of quantification corresponded to a concentration of 0.06 ng/L air. The EU residue definition for fluxapyroxad for monitoring purposes is parent only.

Bee-related matrices:

A new analytical method based on LC-MS/MS was developed and validated for the determination of fluxapyroxad in bee-related matrices flowers, nectar surrogate and pollen, (BASF Method No L0372/02) with a limit of quantification of 0.01 mg/kg. The new method was submitted.

Body Fluids and Tissues:

A new analytical method based on LC-MS/MS was developed and validated for the determination of fluxapyroxad in body fluids (BASF Method No L0352/01) with a limit of quantification of 0.01 mg/kg. The new method was submitted. The analytical method for the determination of fluxapyroxad in tissues (BASF analytical method L0140/02) is based on LC-MS/MS. The LOQ for muscle, kidney and liver is 0.01 mg/kg. This method was sufficiently validated for animal tissues and an ILV for fluxapyroxad (BASF Method No L0140/02) was carried out successfully.

Azoxystrobin

Adequate analytical methods are available to monitor all compounds given in the respective residue definition of azoxystrobin in food of plant origin, soil, water and air. Suitable methods for the determination of azoxystrobin in food of animal origin and body fluids and tissues are available as well.

The analytical methods developed for azoxystrobin were already EU reviewed and considered adequate, except for one new animal method (Syngenta method: RAM 399/01) with the related ILV and one new analytical method for azoxystrobin in water.

Food of plant origin

The analytical method for determination of azoxystrobin in foodstuffs of plant origin (Syngenta method: RAM 305/03 and BASF Method No L0435/01) is based on LC-MS/MS with an LOQ of 0.01 mg/kg. It was validated for a diverse range of representative plant matrices. This method is used for data generation purposes.

An analytical LC-MS/MS method (Syngenta method: RAM 305/02) is validated, analyzing the parent compound with an LOQ of 0.01 mg/kg. An independent laboratory validation (ILV) was carried out successfully and therefore, this method can be used as enforcement method for azoxystrobin in plant matrices. Further a DFG-S19 multi-method and the corresponding ILV is available. The EU residue definition for azoxystrobin for monitoring purposes is parent only in food of plant origin.

Food of animal origin:

An analytical GC-NPD method (Syngenta method: RAM 255/03) was developed and validated which analyzes azoxystrobin with an LOQ of 0.01 mg/kg for liver, muscle, fat, milk and egg and an LOQ of 0.001 mg/kg for milk. The corresponding ILV to the method was carried out successfully.

A new analytical LC-MS/MS method (Syngenta method: RAM 399/01) was developed and validated which analyzes azoxystrobin with an LOQ of 0.01 mg/kg, for liver, kidney, muscle, fat, milk and egg. The new corresponding ILV to the method is based on LC-MS/MS with an LOQ of 0.01 mg/kg for muscle and milk. These methods are suitable for enforcement and data generation purposes. The EU residue definition for azoxystrobin for monitoring purposes is parent only in food of animal origin.

Soil:

An analytical method (Syngenta method: RAM 269/03) was validated, analyzing azoxystrobin with an LOQ of 0.02 mg/kg. This method is based on LC-MS/MS, HPLC-UV and GC-MSD determination and is suitable for enforcement purposes and data generation. The EU residue definition for azoxystrobin for monitoring purposes is parent only in soil.

Water:

An analytical method based on GC-MSD was developed and validated for the determination of azoxystrobin in water (Syngenta method: RAM 358/01) with a limit of quantification of 0.1 µg/L. A new analytical method based on LC-MS/MS for the determination of azoxystrobin in water with a limit of quantification of 0.05 µg/L was developed and validated. The EU residue definition for azoxystrobin for monitoring purposes is parent only in water.

Air:

Azoxystrobin in air can be determined using an analytical GC-MSD method (Syngenta method: RAM 376/01). The limit of quantification corresponded to a concentration of 0.003 mg/m³ air. The EU residue definition for azoxystrobin for monitoring purposes is parent only in air.

Body Fluids and Body Tissues:

Azoxystrobin in body fluids can be determined using an analytical method (Hall 1999) with an LOQ of 0.05 µg/mL. The method is based on HPLC-UV and LC-MS detection. Azoxystrobin in body tissues can be determined by GC-NPD using the analytical animal method (Syngenta method: RAM 255/03) and by LC-MS/MS with the new analytical animal method (Syngenta method: RAM 399/01). Both methods have an LOQ of 0.01 mg/kg. The EU residue definition for azoxystrobin for monitoring purposes is parent only in body fluids and tissues.

3.5 Mammalian toxicology (Part B, Section 6)

BAS 736 00 F is an EC product containing the active ingredients fluxapyroxad and azoxystrobin at concentrations of 50 g/L and 75 g/L, respectively. It is intended to be used for tractor-mounted applications to cereal crops.

Based on hazard properties of the product or the ingredients contained in the formulation, BAS 736 00 F is classified for toxicological hazards as Lact, H362 (“May cause harm to breast-fed children”), Acute Tox. 4, H302+H332 (“Harmful if swallowed and inhaled”); Skin Irrit 2, H315 (“Causes skin irritation”); Eye Dam. 1, H318 (“Causes serious eye damage”), and Skin Sens.1, H317 (“May cause an allergic skin reaction”). Gloves, and eye protection should be worn when handling the undiluted product.

Toxicological evaluation of fluxapyroxad groundwater metabolites M700F001 and M700F002 and of the azoxystrobin metabolite R234886 revealed that the metabolites are not of toxicological relevance and less toxic than the parent molecule.

Studies with BAS 736 00 F to derive dermal absorption estimates for its active ingredients were not performed. Therefore, default dermal absorption estimates of 25% for the undiluted concentrate and 70% for the spray-strength dilutions of BAS 736 00 F were used to estimate non-dietary exposure to fluxapyroxad and azoxystrobin, in accordance to EFSA’s Guidance on Dermal absorption (EFSA Journal 2017; 15(6):4873).

The relevant reference values for the non-dietary risk assessment (AOEL) are 0.04 mg/kg bw/day for fluxapyroxad and 0.2 mg/kg bw/d for azoxystrobin, to be used for longer-term exposure scenarios. No AAoELs are currently assigned to fluxapyroxad and azoxystrobin for assessment of acute exposures.

3.5.1 Acute toxicity

The acute classification of BAS 736 00 F was derived considering the products composition, *in vitro* studies for assessment of skin and eye irritation, and acute oral and inhalation toxicity studies in rats carried out with the product.

BAS 736 00 F is assessed to be of low acute toxicity by the dermal route, but harmful if swallowed or inhaled. BAS 736 00 F is a skin irritant and may cause serious eye damage. BAS 736 00 F is classified as a skin sensitizer based on the product composition.

3.5.2 Operator exposure

Operator exposure and risk evaluations were performed following the EFSA guidance (2014) [European Food Safety Authority (2014) Guidance on the Assessment of Exposure for Operators, Workers, Residents and Bystanders in Risk Assessment for Plant Protection Products (EFSA Journal 2014;12(10):3874 [55 pp.]. doi:10.2903/j.efsa.2014.3874)]. The critical use of 2x 2.0 L/ha BAS 736 00 F applied with tractor operated application systems was investigated. Based on EFSA model assumptions safe uses could be shown for operators wearing work wear during all operations and gloves during mixing/loading.

Considering the exposure data and toxicological properties of the product BAS 736 00 F, the following sentence regarding the use of PPE is recommended by the evaluator to be placed in the label:

„Stosować rękawice ochronne oraz odzież roboczą (kombinezon) w trakcie przygotowywania cieczy roboczej oraz odzież roboczą w trakcie wykonywania zabiegu”

“Wear protective gloves and work wear (coverall) during mixing/loading and work wear during application”.

zRMS:

The exposure to Fluxapyroxad (BAS 700 F) of operator wearing a work clothing (long sleeved shirt, long trousers) during mixing/loading and application but no PPE and applying a product BAS 736 00 F (Miralon) on cereals at maximal dose of 2.0 L product/ha (0.1 kg a.s./ha) using tractor-mounted/trailed boom sprayer, calculated with the EFSA AOEM amounted to 522 % of AOEL. In case the operator is using additionally protective gloves during mixing and loading the exposure to Fluxapyroxad (BAS 700 F) is reduced to 36.2% of AOEL..

The exposure to Azoxystrobin (BAS 9164 F) of operator wearing a work clothing (long sleeved shirt, long trousers) during mixing/loading and application but no PPE and applying a product BAS 736 00 F (Miralon) on cereals at maximal dose of 2.0 L product/ha (0.15 kg a.s./ha) using tractor-mounted/trailed boom sprayer, calculated with the EFSA AOEM amounted to 56 % of AOEL. In case the operator is using protective gloves during mixing and loading the exposure to Fluxapyroxad (BAS 700 F) is reduced to 8.2% of AOEL..

The sum of exposures of operator wearing a work clothing (long sleeved shirt, long trousers) and using protective gloves during mixing and loading to both active substance expressed as percentage of their AOELs is also below 100%, therefore the application of product BAS 736 00 F (Miralon) according to its intended use within good agricultural practice does not pose an unacceptable risk to the health of operator

Summing up the application of product BAS 736 00 F (Miralon) does not pose an unacceptable risk to the health of operator during its intended use within good agricultural practice providing that operator is wearing work wear covering arms, body and legs during mixing/loading and application and protective gloves during mixing and loading. Since the product classified as Skin Irrit. 2, Eye Dam. 1 and Skin Sens.1 the operator should wear protective gloves, eye protection/face protection during mixing/loading operations or when directly contacting surface of equipment contaminated with concentrated product.

3.5.3 Worker exposure

Worker exposure and risk evaluations were performed following the EFSA guidance (2014) [European Food Safety Authority (2014) Guidance on the Assessment of Exposure for Operators, Workers, Residents and Bystanders in Risk Assessment for Plant Protection Products (EFSA Journal 2014;12(10):3874 [55 pp.]. doi:10.2903/j.efsa.2014.3874)]. The critical use of 2x 2.0 L/ha BAS 736 00 F was investigated. The relevant re-entry scenario investigated was crop inspection. Based on EFSA model assumptions safe uses could be shown for workers wearing work wear.

Nevertheless, it is forbidden to re-enter area treated with BAS 736 00 F until spray deposit on plant surfaces has dried.

Bearing in minds the hygienic rules and the classification of the product (H317, including the risk to the most sensitive individuals and no dose-effect relationship in case of sensitization potential), the use of protective gloves is recommended by the evaluator during inspection of the treated area.

zRMS:

The exposure of worker to Fluxapyroxad (BAS 700 F), an active substance of a product BAS 736 00 F (Miralon) not wearing PPE (gloves) but wearing a work clothing (long sleeved shirt, long trousers) and entering for 2 hours for inspection a field of cereals treated with a product BAS 736 00 F (Miralon) at maximal dose of 2.0 L product/ha (0.1 kg a.s./ha) as foreseen in GAP, calculated with the EFSA AOEM amounted 40 % of respective AOEL.

The exposure to Azoxystrobin (BAS 9164 F), an active substance of a product BAS 736 00 F (Miralon), of worker not wearing PPE (gloves) but wearing a work clothing (long sleeved shirt, long trousers) and entering for 2 hours for inspection a field of cereals treated with a product BAS 736 00 F (Miralon) at maximal dose of 2.0 L product/ha (0.15 kg a.s./ha) as foreseen in GAP, calculated with the EFSA AOEM amounted 12 % of respective AOEL.

The sum of exposures of worker wearing a work clothing (long sleeved shirt, long trousers) to both active substance expressed as percentage of their AOELs is also below 100%, therefore the application of product BAS 736 00 F (Miralon) according to its intended use within good agricultural practice does not pose an unacceptable risk to the health of workerr

Thus, it is concluded that the application of a product BAS 736 00 F (Miralon) does not pose an unacceptable risk to the health of worker due to its intended use within good agricultural practice providing that the worker is wearing a work clothing (long sleeved shirt, long trousers).

3.5.4 Bystander and resident exposure

Resident and bystander exposure and risk evaluations were performed following the EFSA guidance (2014) [European Food Safety Authority (2014) Guidance on the Assessment of Exposure for Operators, Workers, Residents and Bystanders in Risk Assessment for Plant Protection Products. EFSA Journal 2014;12(10):3874 [55 pp.]. doi:10.2903/j.efsa.2014.3874]. The critical use of 2x 2.0 L/ha BAS 736 00 F was investigated. Based on EFSA model assumptions safe uses could be shown for residents and bystanders. The **incidental short-time exposure of bystander and resident (children and adult)** to fluxapyroxad and azoxystrobin contained in the formulation BAS 736 00 F **causes no risk** to human health if the product is used in accordance to the intended uses listed in the GAP Table.

zRMS:

The exposure estimates of resident (adult and child) to both active substances of a product BAS 736 00 F (Miralon) applied on a field of cereals at dose of 2.0 L product/ha, using tractor-mounted/trailed boom sprayer, calculated with the EFSA AOEM demonstrates that such a exposure for adult and child resident is equal respectively to 29% and to 70% of AOEL for Fluxapyroxad (BAS 700 F), and to 8.5% and to 21% of AOEL for Azoxystrobin (BAS 9164 F) and a sum of exposures of adult or child resident to both

active substance expressed as percentage of their AOELs is also below 100%, therefore the application of product BAS 736 00 F (Miralon) does not pose an unacceptable risk to the health of adult and child resident for its intended use within good agricultural practice.

No bystander acute exposure estimation for Fluxapyroxad (BAS 700 F) and for Azoxystrobin (BAS 9164 F) is required since no acute acceptable operator exposure value (AAOEL) has been set for any of this active substance. Therefore, as indicated in the EU guidance (SANTE-10832-2015 rev. 1.7; 24 January 2017), no unacceptable risk is expected for bystanders due to short-term single exposure to Fluxapyroxad (BAS 700 F) and to Azoxystrobin (BAS 9164 F) as a result of application of a product BAS 736 00 F (Miralon) with accordance with intended use within good agricultural practice.

Summing up application of a product BAS 736 00 F (Miralon) on a field of cereals at dose of 2.0 L product/ha, using tractor-mounted/trailed boom sprayer in line with GAP does not pose an unacceptable health risk for residents and bystanders.

3.6 Residues and consumer exposure (Part B, Section 7)

3.6.1 Residues

8 new residue trials in wheat and barley with identical GAP (table in section 2.6) 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.

Fluxapyroxad

The metabolism and residue studies of fluxapyroxad (BAS 700 F) have been evaluated by the formerly Rapporteur Member State (United Kingdom) and the EFSA in context of the Annex I inclusion/Approval procedure (DAR and EFSA conclusion).

BAS 736 00 F was not the representative formulation in the EU dossier of BAS 700 F. Therefore, additional studies in cereals (barley, wheat) are submitted to support the registration of the formulated product BAS 736 00 F.

No new MRL is proposed for BAS 700 F for cereals in this document. The current MRLs for fluxapyroxad are published in Regulation (EU) 2021/644.

Azoxystrobin

The metabolism and residue studies of azoxystrobin (BAS 9164 F) have been evaluated by the former

Rapporteur Member State (United Kingdom) and the EFSA in context of the Annex I inclusion/Approval procedure (DAR and EFSA conclusion).

BAS 736 00 F was not the representative formulation in the EU dossier of azoxystrobin. Therefore, additional studies in cereals (barley, wheat) are submitted to support the registration of the formulated product BAS 736 00 F.

No new MRLs have been proposed for azoxystrobin for cereals in this document. The current MRLs for azoxystrobin are published in Regulation (EU) 2019/552.

3.6.2 Consumer exposure

Fluxapyroxad

No new MRLs are proposed for wheat, barley, rye, oat and triticale in this document. Dietary risk assessments for fluxapyroxad were carried out based on the EFSA PRIMo_rev3.1.

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 rev.3.1 model uses the respective STMR values which results in a utilisation of the ADI of 49%, with the NL toddler being the population group with the highest value (contributors: apples with 16%).

A long-term consumer intake concern was not identified for any of the European diets incorporated in the EFSA PRIMo_rev3.1.

An acute consumer risk assessment was performed for wheat, barley, rye, oats and triticale only using the HR value. The maximum ARfD utilization was 0.3% barley / beer - based on NL general population), showing that there is no acute risk for consumers.

Azoxystrobin

No new MRLs are proposed for wheat, barley, rye, oat and triticale in this document. Dietary risk assessments for azoxystrobin were carried out based on the EFSA PRIMo_rev3.1.

The assessment with the PRIMo rev.3.1 model uses the respective STMR values which results in a utilisation of the ADI of 19%, with the DE child being the population group with the highest value (contributors: oranges with 10%, potatoes with 3% and mandarins with 1%).

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_rev3.1.

An acute consumer risk assessment was not performed for wheat, barley, rye, oats, and triticale as no ARfD has been established for azoxystrobin.

3.7 Environmental fate and behaviour (Part B, Section 8)

The results of the peer review on fluxapyroxad are available in the the EFSA Conclusion on the active substance [EFSA (European Food Safety Authority), 2012. *Conclusion on the peer review of the pesticide risk assessment of the active substance fluxapyroxad (BAS 700 F)*. EFSA Journal 2012;10(1):2522, 90 pp. doi:10.2903/j.efsa.2012.2522]. All parameters and procedures relevant for the exposure assessment are provided in Part B of the Core Dossier.

The results of the peer review for azoxystrobin are available and in the EFSA conclusion (EFSA Journal

2010; 8(4): 1542 or DAR, 2014). All parameters and procedures relevant for the exposure assessment are provided in Part B of the Core Dossier.

For fluxapyroxad, studies were re-evaluated according to current guidelines, where necessary. This ensures that all model input parameters comply with latest FOCUS and EFSA guidance documents. Details are presented in Part B of the Core Dossier. No further explanations are provided below.

All exposure calculations for both active ingredients and their metabolites were carried out in considering zonal and national requirements for exposure assessment and under consideration of an appropriate worst-case application scenario.

3.7.1 Predicted environmental concentrations in soil (PEC_{soil})

The PEC in soil have been assessed following the latest guidance of the FOCUS working groups on degradation kinetics, soil persistence models and groundwater scenarios. A soil bulk density of 1.5 g cm⁻³ and a soil layer depth of 5 cm were assumed for the calculations. PEC values were derived with Excel. Additionally, PEC_{soil} were calculated for the formulated product.

The results of the calculations are presented in Part B, Section 8 of the Core Dossier. The obtained PEC_{soil} values are suitable for subsequent ecotoxicological risk assessment.

3.7.2 Predicted environmental concentrations in groundwater (PEC_{gw})

Calculations for fluxapyroxad and for azoxystrobin and their representative metabolites were based on the latest guidance of the FOCUS groundwater working group. The simulations were performed with the models FOCUS-PEARL 4.4.4, FOCUS-PELMO 5.5.3 and FOCUS-MACRO 5.5.4, assuming worst-case application scenarios for all national relevant FOCUS scenarios parameterized for the use in spring and winter cereals. Further details on the assessment, and detailed results are presented in Section 8 of the Core Dossier.

The groundwater risk assessment showed that the leaching of unacceptable amounts of the parent substances or the metabolites following application of fluxapyroxad or azoxystrobin to the crops intended in the GAP is highly unlikely.

3.7.3 Predicted environmental concentrations in surface water (PEC_{sw})

The calculations for PEC in surface water (PEC_{sw}) and sediment (PEC_{sed}) were performed for worst-case application scenarios at Step 1 to 4 for both parent compounds and at Step 1 to 2 for their metabolites according to the latest guidance of the FOCUS working group on surface water scenarios in a stepwise approach considering the pathways spray drift, drainage and runoff.

The software packages STEPS1-2 (version 3.2) for Step 1 and Step 2, SWASH 5.3 in combination with MACRO 5.5.4, PRZM 4.3.1 and TOXSWA 4.4.3 for Step 3 and SWAN 4.0.1 in combination with TOXSWA 4.4.3 for Step 4 were used for the calculations.

Additionally, PEC_{sw} were calculated for the formulated product assuming drift as entry pathway.

Further details on the assessment, and detailed results for all relevant scenarios are presented in Part B, Section 8 of the Core Dossier. Obtained PEC_{sw} and PEC_{sed} values are suitable for subsequent ecotoxicological risk assessment.

3.7.4 Predicted environmental concentrations in air (PEC_{air})

Air is not a relevant exposure pathway either for fluxapyroxad (*EFSA Journal* 2012;10(1):2522) or for azoxystrobin (*EFSA Journal* 2010; 8(4): 1542).

The vapour pressure at 20 °C of both active substances is $< 10^{-5}$ Pa. Hence, fluxapyroxad and azoxystrobin are regarded as non-volatile.

3.8 Ecotoxicology (Part B, Section 9)

Following application of BAS 736 00 F no risk or unacceptable effects are expected for birds, mammals, non-target aquatic organisms, honeybees, non-target arthropods others than bees, non-target meso- and macrofauna, non-target higher plants and soil nitrogen transformation processes without the need for additional mitigation measures.

3.8.1 Effects on terrestrial vertebrates

The risk assessment for birds and mammals is carried out following the latest guidance document by EFSA (*Anonymous 2009: Guidance Document on risk assessment for Birds & Mammals on request from EFSA. EFSA Journal* 2009; 7(12):1438. European Food Safety Authority).

Effects on birds

Dietary risk assessment

Exposure to active substances separately

In the screening step all TER_A values and all TER_{LT} values for fluxapyroxad and azoxystrobin exceed the trigger values set by Commission Regulation (EU) 546/2011 for acceptability of effects.

Exposure to combined active substances and to the formulation

The two acute risk assessment approaches carried out (combined toxicity of the active substances as virtual compound and formulation toxicity) have resulted in TER values at the screening and/or tier 1 acute risk assessment above the trigger of 10 for acceptability of effects. The reproductive risk assessment using the concentration addition model resulted in TER value above the trigger of 5 for acceptability of effects in screening step.

Therefore, the acute and reproductive dietary risk to birds from BAS 736 00 F according to the proposed use pattern is acceptable.

Drinking water risk assessment

Following EFSA/2009/1438, the puddle scenario is considered relevant for applications of BAS 736 00 F according to the proposed use pattern. Since the ratio of the effective application rate to the relevant toxicity endpoints is below the values of 3000 and 50 for fluxapyroxad and azoxystrobin, respectively, a quantitative risk assessment for the proposed use pattern of BAS 736 00 F is not necessary.

Secondary poisoning and biomagnification

The log P_{ow} of the active substance fluxapyroxad is > 3 , which triggers an assessment of the potential risk from secondary poisoning. According to the tier 1 risk assessment for earthworm- and fish-eating birds, the TER values for fluxapyroxad are above the trigger value of 5, indicating an acceptable risk for the intended use of BAS 736 00 F. The log P_{ow} of the active substance azoxystrobin is < 3 , thus, a risk assessment for

effects due to secondary poisoning is not required. Low potential for accumulation of fluxapyroxad and azoxystrobin in animal tissue was concluded in the respective EU reviews and therefore further evaluation of biomagnification is not necessary.

Overall conclusion

It can be concluded that the risk to birds from the application of BAS 736 00 F according to good agricultural practice is acceptable.

Effects on terrestrial vertebrates other than birds

Dietary risk assessment

Exposure to active substances separately

In the screening step and/or tier 1 risk assessment, all TER_A values and all TER_{LT} values for fluxapyroxad and azoxystrobin exceed the trigger values set by Commission regulation (EU) 546/2011 for acceptability of effects.

Exposure to combined active substances and to formulation

For the acute risk assessment addressing combined toxicity of the active substances as virtual compound the TER_A value for the screening step is above the trigger of 10.

For the acute risk assessment addressing combined toxicity of the active substances in the formulation the tier 1 risk assessment resulted in TER_A values above the trigger of 10 for acceptability of effects for all scenarios, except for the small herbivorous mammal “vole” scenario at $BBCH \geq 40$.

The two different refinement approaches are presented. In the first approach the acute higher tier risk assessment for the formulation is based on the refinement of the deposition factor, whereas the second approach is based on the interpolated LD_{50} value for BAS 736 00 F as refinement parameter. Both approaches resulted in refined TER_A values for the formulation toxicity of BAS 736 00 F that are above the trigger of 10 for acceptability of effects for the small herbivorous mammal “vole” scenario at $BBCH \geq 40$.

The reproductive risk assessment using the concentration addition model resulted in an acceptable risk for all scenarios, except for the small herbivorous mammal “vole” scenario at $BBCH \geq 40$. Based on the higher tier risk assessment considering the refinement of the deposition factor an acceptable combined reproductive risk to small herbivorous mammal “vole” could be identified.

Therefore, the acute and reproductive dietary risk to mammals from BAS 736 00 F according to the proposed use pattern is acceptable.

Drinking water risk assessment

Following EFSA/2009/1438, the puddle scenario is the one relevant for mammals. Since the ratio of the effective application rate to the relevant toxicity endpoints is below the values of 3000 and 50 for fluxapyroxad and azoxystrobin, respectively, a quantitative risk assessment for the proposed use pattern of BAS 736 00 F is not necessary.

Secondary poisoning and biomagnification

The $\log P_{ow}$ of the active substance fluxapyroxad is > 3 , which triggers an assessment of the potential risk from secondary poisoning. According to the tier 1 risk assessment for earthworm- and fish-eating mammals, the TER values for fluxapyroxad are above the trigger value of 5, indicating an acceptable risk for the intended use of BAS 736 00 F. The $\log P_{ow}$ of the active substance azoxystrobin is < 3 , thus, a risk assessment for effects due to secondary poisoning is not required. Low potential for accumulation of fluxapyroxad

and azoxystrobin in animal tissue was concluded in the respective EU reviews and therefore further evaluation of biomagnification is not necessary.

Overall conclusion

It can be concluded that the risk to mammals from the application of BAS 736 00 F according to good agricultural practice is acceptable.

Effects on other terrestrial vertebrate wildlife (reptiles and amphibians)

In the EU, there is no requirement to test terrestrial amphibians or reptiles and there is also no guidance available on how to conduct risk assessments for these groups.

In the absence of toxicity data on fluxapyroxad and azoxystrobin, the active substances in the formulation BAS 736 00 F, and considering the lack of guidance for risk assessment, it is assumed that the risk assessments for birds and mammals are protective for terrestrial life stages of amphibians and reptiles, an approach that is also used by US EPA (2004).

References

US EPA 2004. Overview of the ecological risk assessment process in the Office of Pesticide Programs, U.S. Environmental Protection Agency. Endangered and Threatened Species Effects Determinations. Office of Prevention, Pesticides and Toxic Substances; Office of Pesticide Programs, Washington, D.C. 92 pp.

3.8.2 Effects on aquatic species

The following risk assessment is based on more detailed information given in the core dossier (Section B09, chapter 9.5), considering in the addition the national requirements relevant for Poland.

The standard risk assessment for the active substances fluxapyroxad and azoxystrobin indicate an acceptable risk for all groups of aquatic organisms following the intended uses of BAS 736 00 F with no need for additional any mitigation measures.

The PEC/RAC ratios for the relevant metabolites of fluxapyroxad and azoxystrobin are significantly below the trigger of 1 based on standard worst-case assumptions; they are thus considered not to be of ecotoxicological relevance.

The formulation risk assessment revealed an acceptable risk to aquatic organisms following the intended uses of BAS 736 00 F in 'winter and spring cereals' with no need for any mitigation measures (scenarios D3, D4 and R1).

The standard risk assessment for the fungicidal product BAS 736 00 F, the active substances fluxapyroxad and azoxystrobin as well as their major metabolites demonstrates that the application of BAS 736 00 F in 'winter and spring cereals' according to good agricultural practice is of low risk to aquatic ecosystems.

3.8.3 Effects on bees

The risk to honey bees from the use of fluxapyroxad, azoxystrobin and BAS 736 00 F was assessed using the maximum single application rate and the LD₅₀ values to calculate hazard quotients (HQ) for oral exposure (Q_{HO}) and contact exposure (Q_{HC}) [OEPP/EPPO, 2010: Environmental risk assessment scheme for plant protection products, Chapter 10: Honeybees (PP 3/10 (3), Bulletin OEPP/EPPO Bulletin 40, 323–331]. Furthermore, under Regulation (EC) No 1107/2009, no risk assessment scheme exists currently for

chronic honey bee or honey bee larvae studies. In the absence of clear guidance (noted and agreed by member states) a preliminary risk assessment according to the current legal requirements (SANCO/10329/2002 and EPPO 2010) has been conducted.

The hazard quotients for BAS 736 00 F and the active substances fluxapyroxad and azoxystrobin for acute oral and acute contact exposure of honey bees are considerably below the Commission Regulation (EU) 546/2011 trigger value of 50. Additionally, the chronic TER for larvae and adult bees exceed the suggested trigger. Considering the very protective assumptions the risk can be considered acceptable.

Based on these results it can be concluded that low risk to honey bees is expected from applications of BAS 736 00 F according to the proposed uses. This is confirmed by a worst-case assessment following EPPO (2010) for chronic adult and honey bee larvae.

3.8.4 Effects on other arthropod species other than bees

The testing and risk assessment strategy used here follow the approach recommended in the ESCORT 2 guidance document, ESCORT 3, and the EC Guidance Document on Terrestrial Ecotoxicology (SANCO/10329, 17 October 2002). The risk assessment for BAS 736 00 F is based on Tier I tests with the standard test species *T. pyri* and *A. rhopalosiphi* and Tier II tests on *T. pyri*, *A. rhopalosiphi* and *C. carnea*. The risk assessment is based on the worst-case application rate according to the proposed use pattern.

Based on the results of the conducted first and higher tier risk assessments it can be concluded that low risk for non-target arthropods is expected from the use of BAS 736 00 F according to the proposed use pattern. No unacceptable effects on non-target arthropods are expected in in-field and off-field habitats.

3.8.5 Effects on soil organisms

The evaluation of the risk for earthworms and other non-target soil organisms (meso- and macrofauna), as well as for soil microorganisms was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).

Effects on non-target soil meso- and macrofauna

The potential risk of BAS 736 00 F, fluxapyroxad, azoxystrobin and the relevant metabolites to earthworms and other non-target soil macro-organisms was assessed by comparing the maximum PEC_{soil} values with NOEC or EC_{10} values, to generate TER values.

All TER values for BAS 736 00 F, fluxapyroxad, azoxystrobin and the relevant metabolites for chronic exposure of earthworms and other non-target soil organisms (meso- and macrofauna) are considerably higher than the relevant trigger value. This indicates that BAS 736 00 F poses no unacceptable risk to earthworms and other non-target soil organisms (meso- and macrofauna) when applied according to the proposed use rate.

Effects on soil microbial activity

The potential risk of BAS 736 00 F, fluxapyroxad, azoxystrobin and the relevant metabolites to soil microorganisms was assessed by comparing the maximum PEC_{soil} values with the maximum concentration with effects $\leq 25\%$.

For the formulation BAS 736 00 F, the active substances fluxapyroxad and azoxystrobin as well as their relevant metabolites, the maximum concentration with effects $< 25\%$ (SANCO/10329/2002 trigger) are all above the maximum PEC_{soil} values. Therefore, it is concluded that the use of BAS 736 00 F

will not pose an unacceptable risk to non-target soil micro-organisms, if applied according to good agricultural practice.

3.8.6 Effects on non-target terrestrial plants

The toxicity of BAS 736 00 F to non-target terrestrial plants has been investigated by carrying out vegetative vigor and seedling emergence studies with up to six dicotyledonous and four monocotyledonous non-target plant species. Plants showed similar/higher sensitivity to pre-emergence exposure than to post-emergence exposure. The risk assessment is thus carried out with the respective most sensitive endpoints obtained from the vegetative vigor tests.

The risk assessment is based on the “Guidance Document on Terrestrial Ecotoxicology”, (SANCO/10329/2002 rev.2 final, 2002). It is restricted to off-field areas, as non-target plants are non-crop plants located outside the treated area. The amount of spray drift reaching off-crop habitats is calculated using the 90th percentile estimates in Appendix IV of ESCORT 2. For a single application to field crops and vegetables < 50 cm, 2.77% of the application rate was assumed to reach areas at 1 m from the edge of the crop (worst-case scenario). The highest single application rate of BAS 736 00 F is used to calculate the maximum off-field predicted environmental rate (PER_{off-field}). The potential risk of BAS 736 00 F to non-target plants was assessed by comparing the calculated PER value to the ER₅₀ values in order to generate TER values (TER).

Based on the results of the greenhouse trials, all the TER values were above the standard trigger of 5.

Based on the risk assessment it can be concluded that BAS 736 00 F poses no unacceptable risk to non-target plants, if applied according to the recommended use pattern. Particular precautions to reduce the environmental concentrations resulting from BAS 736 00 F applications are not required for the protection of terrestrial non-target plants.

3.8.7 Effects on other terrestrial organisms (Flora and Fauna)

Not relevant.

3.9 Relevance of metabolites (Part B, Section 10)

Fluxapyroxad

The fluxapyroxad metabolites M700F001 and M700F002 are predicted to occur in groundwater at concentrations above 0.1 µg L⁻¹ (see Part B, Chapter 8.8.2). The relevance of M700F001 and M700F002 has already been assessed at EU level (EFSA conclusion, 2012). The relevance assessment is applicable for the GAP and groundwater scenarios considered in this dRR (i.e., the conclusions reached at Step 4 and 5 of the relevance assessment made at the EU-level are valid also with regard to the PEC_{gw} calculated for the GAP and groundwater scenarios considered in this dRR).

The metabolites M700F001 and M700F002 are considered not relevant in terms of toxicological properties according to EC guidance document SANCO/221/2000 –rev.10.

Azoxystrobin

The azoxystrobin metabolite R234886 is predicted to occur in groundwater at concentrations above 0.1 µg L⁻¹ (see Part B, Chapter 8.8.2). The relevance of R234886 has already been assessed at EU level (EFSA Journal (2010) 8(4), 1542). The relevance assessment is applicable for the GAP and groundwater scenarios considered in this dRR (i.e., the conclusions reached at Step 4 and 5 of the relevance assessment made at the EU-level are valid also with regard to the PEC_{gw} calculated for the GAP and groundwater scenarios considered in this dRR).

The metabolite R234886 is considered not relevant in terms of toxicological properties according to EC guidance document SANCO/221/2000 –rev.10.

4 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)

Fluxapyroxad and azoxystrobin are not listed as candidates for substitution according to Regulation (EU) 2015/408, hence a comparative assessment is not required.

5 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorization

Insert any data that the notifier needs to submit following authorization. As a rule, this is restricted to storage stability and monitoring data.

Insert the data that is still required for the evaluation of the product in the case where the product authorization is not granted.

Appendix 1 Copy of the product authorization

MS assessor to insert details of the product authorization for MS country.
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Appendix 2 Copy of the product label

MS assessor to present a copy of the approved product label for MS country.

Appendix 3 Letter of Access

Letters of access for azoxystrobin have been submitted together with this application (see BASF DocID 2021/2051687)

Appendix 4 Lists of data considered for national authorization

Tables considered not relevant can be deleted as appropriate.

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

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protec- tion is claimed	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	Yes	Data/study report never submitted before to Poland	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	Yes	Data/study report never submitted before to Poland	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	Yes	Data/study report never submitted before to Poland	BASF

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	Data protection claimed Y/N	Justification if data protec- tion is claimed	Owner
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	Yes	Data/study report never submitted before to Poland	BASF
KCP 2.1/1	Keller, M.	2020	Physical and chemical properties of BAS 736 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C) 2020/2079771 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before to Poland	BASF
KCP 2.1/2	Keller, M.	2021	Amendment 1: Physical and chemical properties of formula BAS 736 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C) 2021/2041812 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before to Poland	BASF
KCP 2.2.1/1	Dreisch, S.	2019	BAS 736 00 F - Determination of physico-chemical properties according to UN Transport Regulation and Directive 94/37/EC (Regulation (EC) No. 440/2008) 2019/1039592 consilab Gesellschaft fuer Anlagensicherheit mbH, Frankfurt/Main, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before to Poland	BASF

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KCP 2.2.2/1	Dreisch, S.	2019	BAS 736 00 F - Determination of physico-chemical prop- erties according to UN Transport Regulation and Directive 94/37/EC (Regulation (EC) No. 440/2008) 2019/1039592 consilab Gesellschaft fuer Anlagensicherheit mbH, Frank- furt/Main, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never sub- mitted before to Poland	BASF
KCP 2.3.1/1	Dreisch, S.	2019	BAS 736 00 F - Determination of physico-chemical prop- erties according to UN Transport Regulation and Directive 94/37/EC (Regulation (EC) No. 440/2008) 2019/1039592 consilab Gesellschaft fuer Anlagensicherheit mbH, Frank- furt/Main, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never sub- mitted before to Poland	BASF
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KCP 2.3.3/1	Dreisch, S.	2019	BAS 736 00 F - Determination of physico-chemical prop- erties according to UN Transport Regulation and Directive 94/37/EC (Regulation (EC) No. 440/2008) 2019/1039592 consilab Gesellschaft fuer Anlagensicherheit mbH, Frank- furt/Main, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never sub- mitted before to Poland	BASF
KCP 2.4.2/1	Keller, M.	2020	Physical and chemical properties of BAS 736 00 F includ- ing Low temperature stability (7 days at 0°C) and Acceler- ated storage stability (14 days at 54°C) 2020/2079771 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never sub- mitted before to Poland	BASF

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	Data protection claimed Y/N	Justification if data protec- tion is claimed	Owner
KCP 2.4.2/2	Keller, M.	2021	Amendment 1: Physical and chemical properties of formula BAS 736 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C) 2021/2041812 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before to Poland	BASF
KCP 2.5.1/1	Keller, M.	2020	Physical and chemical properties of BAS 736 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C) 2020/2079771 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before to Poland	BASF
KCP 2.5.1/2	Keller, M.	2021	Amendment 1: Physical and chemical properties of formula BAS 736 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C) 2021/2041812 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before to Poland	BASF
KCP 2.5.2/1	Keller, M.	2020	Physical and chemical properties of BAS 736 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C) 2020/2079771 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before to Poland	BASF
KCP 2.5.2/2	Keller, M.	2021	Amendment 1: Physical and chemical properties of formula BAS 736 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C) 2021/2041812 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before to Poland	BASF

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	Data protection claimed Y/N	Justification if data protec- tion is claimed	Owner
KCP 2.6.1/1	Keller, M.	2020	Physical and chemical properties of BAS 736 00 F includ- ing Low temperature stability (7 days at 0°C) and Acceler- ated storage stability (14 days at 54°C) 2020/2079771 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never sub- mitted before to Poland	BASF
KCP 2.6.1/2	Keller, M.	2021	Amendment 1: Physical and chemical properties of for- mula BAS 736 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C) 2021/2041812 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never sub- mitted before to Poland	BASF
KCP 2.7.1/1	Keller, M.	2020	Physical and chemical properties of BAS 736 00 F includ- ing Low temperature stability (7 days at 0°C) and Acceler- ated storage stability (14 days at 54°C) 2020/2079771 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never sub- mitted before to Poland	BASF
KCP 2.7.1/2	Keller, M.	2021	Amendment 1: Physical and chemical properties of for- mula BAS 736 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C) 2021/2041812 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never sub- mitted before to Poland	BASF
KCP 2.7.4/1	Keller, M.	2020	Physical and chemical properties of BAS 736 00 F includ- ing Low temperature stability (7 days at 0°C) and Acceler- ated storage stability (14 days at 54°C) 2020/2079771 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never sub- mitted before to Poland	BASF

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KCP 2.7.4/2	Keller, M.	2021	Amendment 1: Physical and chemical properties of formula BAS 736 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C) 2021/2041812 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before to Poland	BASF
KCP 2.8.2/1	Keller, M.	2020	Physical and chemical properties of BAS 736 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C) 2020/2079771 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before to Poland	BASF
KCP 2.8.2/2	Keller, M.	2021	Amendment 1: Physical and chemical properties of formula BAS 736 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C) 2021/2041812 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before to Poland	BASF
KCP 2.8.6.2/1	Keller, M.	2020	Physical and chemical properties of BAS 736 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C) 2020/2079771 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before to Poland	BASF
KCP 2.8.6.2/2	Keller, M.	2021	Amendment 1: Physical and chemical properties of formula BAS 736 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C) 2021/2041812 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before to Poland	BASF

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	Data protection claimed Y/N	Justification if data protec- tion is claimed	Owner
KCP 2.8.6.3/1	Keller, M.	2020	Physical and chemical properties of BAS 736 00 F includ- ing Low temperature stability (7 days at 0°C) and Acceler- ated storage stability (14 days at 54°C) 2020/2079771 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never sub- mitted before to Poland	BASF
KCP 2.8.6.3/2	Keller, M.	2021	Amendment 1: Physical and chemical properties of for- mula BAS 736 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C) 2021/2041812 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No		Data/study report never sub- mitted before to Poland	BASF
KCP 2.9.1/1	Schlotterbeck, U.	2019	Physical and Chemical Compatibility in aqueous tank mix- tures of BAS 736 00 F 2021/2004054 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	No	N/A	BASF
KCP 2.9.2/1	Schlotterbeck, U.	2019	Physical and Chemical Compatibility in aqueous tank mix- tures of BAS 736 00 F 2021/2004054 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	No	N/A	BASF
KCP 2.11/1	Keller, M.	2020	Physical and chemical properties of BAS 736 00 F includ- ing Low temperature stability (7 days at 0°C) and Acceler- ated storage stability (14 days at 54°C) 2020/2079771 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never sub- mitted before to Poland	BASF

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	Data protection claimed Y/N	Justification if data protec- tion is claimed	Owner
KCP 2.11/2	Keller, M.	2021	Amendment 1: Physical and chemical properties of formula BAS 736 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C) 2021/2041812 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before to Poland	BASF
KCP 4.2/1	Nord, S.	2020	Effectiveness of Procedures for Cleaning Application Equipment and Protective Clothing BAS 736 00 F 2020/2036309 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	No	N/A	BASF
KCP 4.3/1	Anonymous	2021	Safety Data Sheet - Miralon 2021/2047854 BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep. no Unpublished	No	No	N/A	BASF
KCP 4.4/1	Maurer M.	2019	BAS 736 00 F - EU Performance Test in COEX 2019/1039595 BASF SE no Unpublished	No	No	N/A	BASF
KCP 4.4/2	Maurer M.	2019	BAS 736 00 F EU Performance Test in HDPE, fluoriert 2019/1039594 BASF SE no Unpublished	No	No	N/A	BASF
KCP 4.4/3	Keller, M.	2020	Physical and chemical properties of BAS 736 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C) 2020/2079771 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before to Poland	BASF

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	Data protection claimed Y/N	Justification if data protec- tion is claimed	Owner
KCP 4.4/4	Keller, M.	2021	Amendment 1: Physical and chemical properties of formula BAS 736 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C) 2021/2041812 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before to Poland	BASF
KCP 4.5/1	Anonymous	2021	Safety Data Sheet - Miralon 2021/2047854 BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep. no Unpublished	No	No	N/A	BASF
KCP 5.1.1/1	Frohn, D.	2020	Determination of the Active Ingredients Fluxapyroxad and Azoxystrobin in BAS 736 00 F and Aqueous Solutions of BAS 736 00 F by HPLC and UHPLC 2020/2002656 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before to Poland	BASF
KCP 5.1.1/2	Schubring, M.	2020	Validation of the Analytical Method AFL1012/01: "Determination of Toluene in BAS 736 00 F containing Fluxapyroxad and Azoxystrobin by GC-MS" 2020/2033569 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before to Poland	BASF
KCP 5.1.1/3	Schubring, M.	2021	Additional Validation of the Analytical Method AFL1012/01: "Determination of Toluene in BAS 736 00 F containing Fluxapyroxad and Azoxystrobin by GC-MS" 2021/2022815 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before to Poland	BASF

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	Data protection claimed Y/N	Justification if data protec- tion is claimed	Owner
KCP 5.1.2/1	Obermann, M.	2020	Validation of Analytical Method L0372/02 for the determi- nation of BAS 750 F (Reg.No.5834378), BAS 500 F (Reg.No.304428) and BAS 700 F (Reg.No.5094351) in bee-related matrices by HPLC-MS/MS 2020/2000481 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never sub- mitted before to Poland	BASF
KCP 5.2/1	Perez, R., Perez, S.	2011	Independent laboratory validation of BASF analytical method L0143/01: Validation of analytical method L0143/01: Determination of BAS 700 F and its metabo- lites M700F001, M700F002 and M700F007 in water by HPLC/MS-MS 2011/7001254 ADPEN Laboratories Inc., Jacksonville FL, United States of America yes Unpublished	No	Yes	Data protection started with BAS 734 00 F (Inovor) sub- mitted 23.06.2016; first reg- istration 21.11.2017 + last renewal 09.01.2019; RegNo.: R-233/2017	BASF
KCP 5.2/2	Richter, S., Djedovic, S.	2016	Validation of BASF analytical method L0352/01 for the determination of BAS 700 F (Fluxapyroxad) in body fluids 2016/1217548 PTRL Europe, Ulm, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with BAS 717 00 F (Dagonis) submitted 05.12.2018; first registration 12.02.2019 + last renewal 29.03.2021; RegNo.: R-36/2019	BASF
KCP 6/1	Neradova, D.	2021	Biological Assessment Dossier - BAS 736 00 F - Central Zone - zRMS: Poland 2021/2015967 BASF spol. s.r.o., Prague, Czech Republic no Unpublished	No	No	N/A	BASF
KCP 6.1/1	Neradova, D.	2021	Justification of the co-formulated mixture BAS 736 00 F for cereals 2021/2036686 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	No	N/A	BASF

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	Data protection claimed Y/N	Justification if data protec- tion is claimed	Owner
KCP 6.2/1	Anonymous	2021	Dossier Trial Data Reports: BAS 736 00 F - Efficacy trials in wheat (113 trials) 2021/2042887 <none> yes Unpublished	No	Yes	Data/study report never sub- mitted before to Poland	BASF
KCP 6.2/2	Anonymous	2021	Dossier Trial Data Reports: BAS 736 00 F - Efficacy trials in barley (82 trials) 2021/2042888 <none> yes Unpublished	No	Yes	Data/study report never sub- mitted before to Poland	BASF
KCP 6.2/3	Anonymous	2021	Dossier Trial Data Reports: BAS 736 00 F - Efficacy trials in rye (21 trials) 2021/2042890 <none> yes Unpublished	No	Yes	Data/study report never sub- mitted before to Poland	BASF
KCP 6.2/4	Anonymous	2021	Dossier Trial Data Reports: BAS 736 00 F - Efficacy trials in triticale (21 trials) 2021/2042891 <none> yes Unpublished	No	Yes	Data/study report never sub- mitted before to Poland	BASF
KCP 6.2/5	Anonymous	2021	Dossier Trial Data Reports: BAS 736 00 F - Efficacy trials in oats (6 trials) 2021/2042892 <none> yes Unpublished	No	Yes	Data/study report never sub- mitted before to Poland	BASF
KCP 6.3/1	Stammeler, G.	2021	BAS 736 00 F - Resistance Risk Analysis 2021/2031889 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	No	N/A	BASF

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	Data protection claimed Y/N	Justification if data protec- tion is claimed	Owner
KCP 6.4.5/1	Schuster, A.	2021	Germination trials with harvested grains from Wheat and Barley treated with BAS 736 00 F 2021/2004014 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	No	N/A	BASF
KCP 6.5.1/1	Brahm, L.	2019	Cultivation of different crops in substrate treated with BAS 736 00 F (Succeeding crops study) 2019/1067468 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	No	N/A	BASF
KCP 6.5.2/1	Maleck, A.	2019	Effect of BAS 736 00 F on vegetative vigour of ten species of terrestrial plants under greenhouse conditions 2019/1061112 Agro-Check Dr. Teresiak & Erdmann GbR, Lentzke, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before to Poland	BASF
KCP 6.6/1	Nord, S.	2020	Effectiveness of Procedures for Cleaning Application Equipment and Protective Clothing BAS 736 00 F 2020/2036309 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	No	N/A	BASF
KCP 6.6/2	Schlotterbeck, U.	2019	Physical and Chemical Compatibility in aqueous tank mixtures of BAS 736 00 F 2021/2004054 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	No	N/A	BASF
KCP 6.6/3	Anonymous	2021	BAS 736 00 F: Summary report on comparison of regions 2021/2042893 <none> no Unpublished	No	No	N/A	BASF

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KCP 6.6/4	Lopatka, A., Koza, P., Sie- bielec, G., Ly- siak, M.	2012	Expert report regarding division of Europe into regions characterized by homogenous soil and climatic conditions, within the boundaries of which the results of efficacy eval- uation of pesticides can be relevant for the entire region 2012/1368202 IUNG - Institute of Soil Science and Plant Cultivation - State Research Institute, Pulawy, Poland no Unpublished	No	No	N/A	BASF
KCP 6.6/5	Anonymous	2015	GEP Certificate: Eurofins Agroscience Services EOOD, Letnitsa, Bulgaria - 2015 2015/1143221 Eurofins Agroscience Services EOOD, Letnitsa, Bulgaria no Unpublished	No	No	N/A	BASF
KCP 6.6/6	Anonymous	2016	GEP Certificate: BASF spol. s r.o., Praha, Czech Republic 2016/1351528 BASF spol. s.r.o., Prague, Czech Republic no Unpublished	No	No	N/A	BASF
KCP 6.6/7	Anonymous	2018	GEP Certificate - ADW Agro As Krahulov Czech Repub- lic - 2018 2019/2046744 ADW Agro A.s., Krahulov, Czech Republic no Unpublished	No	No	N/A	BASF
KCP 6.6/8	Anonymous	2018	Rozhodnuti InTec Agro Trials spol sro, Uhersky Ostroh, Czech Republic 2019/2055093 InTec Agro Trials spol sro, Uhersky Ostroh, Czech Repub- lic no Unpublished	No	No	N/A	BASF

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KCP 6.6/9	Anonymous	2016	GEP Certificate: Zemservis zkusebni stanice Domaninek s.r.o., Bystrice nad Pernštejnem, Czech Republic - 2016 2016/1350607 Zemservis zkusebni stanice Domaninek s.r.o, Bystrice nad Pernštejnem, Czech Republic no Unpublished	No	No	N/A	BASF
KCP 6.6/10	Anonymous	2016	GEP Certificate: Zkusebni stanice Nechanice, s.r.o., Nechanice, Czech Republic - 2016 2020/2095629 Zkusebni stanice Nechanice s.r.o., Nechanice, Czech Republic no Unpublished	No	No	N/A	BASF
KCP 6.6/11	Anonymous	2016	GEP Certificate - Zkusebni Stanice Trutnov s.r.o, Trutnov, Czech Republic - 2017 2017/1156065 ZST - Zkusebni Stanice Trutnov s.r.o, Trutnov, Czech Republic no Unpublished	No	No	N/A	BASF
KCP 6.6/12	Anonymous	2013	GEP Certificate: BASF SE Agrarzentrum Limburgerhof, Germany, 2013 2013/1412362 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	No	N/A	BASF
KCP 6.6/13	Anonymous	2018	GEP Certificate - BASF SE Agrarzentrum Limburgerhof Germany - 2018 2018/1238674 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	No	N/A	BASF
KCP 6.6/14	Anonymous	2019	GEP Certificate - Hetterich Fieldwork GbR Schwarzach - Germany 2019/2041586 Hetterich Fieldwork GbR, Schwarzach, Germany Fed.Rep. no Unpublished	No	No	N/A	BASF

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KCP 6.6/15	Anonymous	2013	GEP Certificate - Aarhus University (diseases and pests), Slagelse, Denmark 2014-2019 2014/1321454 University of Aarhus, Slagelse, Denmark no Unpublished	No	No	N/A	BASF
KCP 6.6/16	Anonymous	2020	GEP Certificate - Aarhus University - Department of Agroecology (diseases and pests), Flakkebjerg, Denmark - 2020 2020/2104176 Aarhus University, Aarhus, Denmark no Unpublished	No	No	N/A	BASF
KCP 6.6/17	Anonymous	2013	GEP Certificate: Agrolab A/S, Field Trials, Middelfart, Denmark, 2014 2014/1327634 Agrolab A/S, Middelfart, Denmark no Unpublished	No	No	N/A	BASF
KCP 6.6/18	Anonymous	2014	GEP Certificate: BASF A/S, Copenhagen, Denmark, 2014 2014/1048395 BASF Denmark A/S, Copenhagen, Denmark no Unpublished	No	No	N/A	BASF
KCP 6.6/19	Anonymous	2020	GEP certificate BASF A/S Kobenhavn Denmark 2020 2020/2079424 BASF Denmark A/S, Copenhagen, Denmark no Unpublished	No	No	N/A	BASF
KCP 6.6/20	Anonymous	2017	GEP Certificate - Luke Jokionen Finland - 2016-2023 2017/1229043 Natural Resources Institute Finland (Luke), Jokioinen, Fin- land no Unpublished	No	No	N/A	BASF

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KCP 6.6/21	Anonymous	2017	GEP Certificate - Nylands Svenska Lantbrukssällskap (NSL) Finland 2016-2023 2020/2100984 Nylands Svenska Lantbrukssällskap (NSL), Helsingfors, Finland no Unpublished	No	No	N/A	BASF
KCP 6.6/22	Anonymous	2017	GEP Certificate - BASF France SAS Ecully France - 2017 2017/1023856 BASF Agro SAS, Ecully, France no Unpublished	No	No	N/A	BASF
KCP 6.6/23	Anonymous	2019	GEP Certificate: BASF France SAS, Ecully, France, 2019 2019/1054949 BASF France SAS, Ecully, France no Unpublished	No	No	N/A	BASF
KCP 6.6/24	Anonymous	2017	GEP Certificate - BASF Hungaria Kft - Budapest - Hunga- ria - 2017 2017/1077283 BASF Hungaria Kft., Budapest, Hungary no Unpublished	No	No	N/A	BASF
KCP 6.6/25	Anonymous	2019	Trials permit certificate - Crop-Plot Trials C/O Buck Leary's Cross, Ballinaperson, Glanmire, Co. Cork, Ireland - 2019 2019/2050392 <none> no Unpublished	No	No	N/A	BASF
KCP 6.6/26	Anonymous	2020	Trials permit certificate - Teagasc Carlow Ireland - re- newal 2020 2020/2099299 Teagasc, Carlow, Ireland no Unpublished	No	No	N/A	BASF

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KCP 6.6/27	Anonymous	2013	GEP certificate - Lithuanian Institute of Agriculture, Akademija Lithuania - 2013-2019 2013/1418041 Lithuanian Institute of Agriculture, Akademija, Lithuania no Unpublished	No	No	N/A	BASF
KCP 6.6/28	Anonymous	2019	GEP certificates for Institute of Agriculture - LAMMC- Lithuania 2020/2105312 Department of Soil and Crop Management - Institut of Ag- riculture, LAMMC, Akademija, Lithuania no Unpublished	No	No	N/A	BASF
KCP 6.6/29	Anonymous	2017	GEP Certificate: UAB Agrolab Baltic, Vilnius, Lithuania, 2017 2017/1014490 UAB Agrolab Baltic, Vilnius, Lithuania no Unpublished	No	No	N/A	BASF
KCP 6.6/30	Anonymous	2016	GEP Certificate - Latvijas Augu aizsardzibas petniecias centrs, Riga, LV 2016/1350437 Latvian State Centre of Plant Protection, Riga, Latvia no Unpublished	No	No	N/A	BASF
KCP 6.6/31	Anonymous	2019	GEP Certificate: SIA Baltic Trial Station, Riga, Latvia, 2019 - 2024 2020/2079667 SIA Agrolab Baltic, Riga, Latvia no Unpublished	No	No	N/A	BASF
KCP 6.6/32	Anonymous	2019	GEP Certificate - BASF Nederland BV Arnhem 2019 2019/2047841 BASF Nederland BV, Arnhem, Netherlands no Unpublished	No	No	N/A	BASF

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KCP 6.6/33	Anonymous	2010	GEP Certificate - Uniwersytet Technologiczno - Przyrod- niczy im. Jana i Jędrzeja Śniadeckich - Wydział Rolnictwa i Biotechnologii - Katedra Fitopatologii i Mikologii Mole- kularnej, Bydgoszcz, Poland 2010/1226832 <none> no Unpublished	No	No	N/A	BASF
KCP 6.6/34	Anonymous	2010	GEP Certificate - Institute of Plant Protection - National Research Institute in Poznań - Sosnowice Branch - Pesti- cide Efficacy Testing Department, Poland 2010/1226834 <none> no Unpublished	No	No	N/A	BASF
KCP 6.6/35	Anonymous	2011	GEP Certificate - Institut of Plant Protection - National Re- search Institute - Department of Plant Protection Products - Team for Fungicide Investigation, Poznań, Poland 2011/1269209 Institute of Plant Protection - National Research Institute, Poznań, Poland no Unpublished	No	No	N/A	BASF
KCP 6.6/36	Anonymous	2011	GEP Certificate - Agrostat Sp. z o.o., Poland 2011/1269203 Agrostat Sp. z o.o., Poznań, Poland no Unpublished	No	No	N/A	BASF
KCP 6.6/37	Anonymous	2011	GEP Certificate - BASF Polska Sp. z o.o., Warsaw, Poland 2011/1269204 BASF Polska Sp. z o.o., Warsaw, Poland no Unpublished	No	No	N/A	BASF
KCP 6.6/38	Anonymous	2021	GEP Certificate - BASF Polska Spółka z o.o. Warszawa - Poland - 2021 2021/2012841 BASF Polska Sp. z o.o., Warsaw, Poland no Unpublished	No	No	N/A	BASF

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KCP 6.6/39	Anonymous	2016	GEP Certificate - Eurofins Agroscience Service GmbH 2016 2016/1318743 Eurofins Agroscience Services GmbH, Stade, Germany Fed.Rep. no Unpublished	No	No	N/A	BASF
KCP 6.6/40	Laczynski, T.	2016	GEP Certificate - SGS Polska Sp. zo.o Warswa Poland - Translation 2016/1350127 SGS Polska Sp. zo.o., Warsaw, Poland no Unpublished	No	No	N/A	BASF
KCP 6.6/41	Anonymous	2018	GEP Certificate: AGRECO Sp. z o.o., Wroclaw, Poland 2018 2018/1181238 AGRECO Sp. z o.o., Wroclaw, Poland no Unpublished	No	No	N/A	BASF
KCP 6.6/42	Anonymous	2013	GEP Certificate - SC AgroProspect SRL Brasov, Romania, 2013 2013/1399864 SC AgroProspect Srl, Brasov, Romania no Unpublished	No	No	N/A	BASF
KCP 6.6/43	Anonymous	2018	GEP Certificate - SGS Romania SA - AFL seed & Crop - 2018 2019/2038531 SGS Romania SA - AFL seed & Crop, Timisoara, Romania no Unpublished	No	No	N/A	SGS
KCP 6.6/44	Anonymous	2016	GEP Certificate - S.C. BASF SRL Calarasi Romania - 2016 2016/1135081 S.C. BASF SRL, Calarasi, Romania no Unpublished	No	No	N/A	BASF

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KCP 6.6/45	Anonymous	2016	GEP Certificate - Agrolab Sverige AB - Eslov - Sweden - 2016 2016/1354368 Agrolab Sverige AB, Eslov, Sweden no Unpublished	No	No	N/A	BASF
KCP 6.6/46	Anonymous	2016	GEP Certificate: Blumeria consulting sro, Nitra, Slovakia, 2016-2021 2016/1352169 Blumeria consulting s.r.o., Nitra, Slovakia no Unpublished	No	No	N/A	BASF
KCP 6.6/47	Anonymous	2017	GEP Certificate - Berberis s.r.o., Boliarov, Slovakia 2017/1224930 Berberis s.r.o., Boliarov, Slovakia no Unpublished	No	No	N/A	BASF
KCP 6.6/48	Anonymous	2017	GEP Certificate - NPPC - Vyskumny ustav rastlinnej vy- roby Piestany, Piestany, Slovakia 2017 2017/1226421 VURV - Vyskumny Ustav Rastlinnej Vyroby Piestany, Piestany, Slovakia no Unpublished	No	No	N/A	BASF
KCP 6.6/49	Anonymous	2018	GEP Certificate: BASF plc, United Kingdom, 2018 2018/1015310 BASF plc, Cheadle Cheshire SK8 6QG, United Kingdom no Unpublished	No	No	N/A	BASF
KCP 6.6/50	Anonymous	2018	GEP Certificate - Eurofins Agroscience Services Ltd. - United Kingdom - 2018-2022 2018/1103451 Eurofins Agroscience Services Ltd., Melbourne Derby- shire DE73 8AG, United Kingdom no Unpublished	No	No	N/A	BASF

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KCP 6.6/51	Anonymous	2020	GEP Certificate - Cropworks Limited, UK, April 2020 - Feb 2025 2020/2036579 Cropworks Ltd., Bankfoot Perth PH1 4AQ, United Kingdom no Unpublished	No	No	N/A	BASF
KCP 7.1.1/1	xxx	2020	BAS 736 00 F - Acute oral toxicity study in rats 2020/2080214 xxx	Yes	Yes	Data/study report never submitted before to Poland	BASF
KCP 7.1.3/1	xxx	2021	BAS 736 00 F - Acute Inhalation toxicity study in Wistar rats 4-hour liquid Aerosol exposure (nose only) 2021/2000826 xxx	Yes	Yes	Data/study report never submitted before to Poland	BASF
KCP 7.1.4/1	Remmele, M.	2020	BAS 736 00 F - In vitro Skin Irritation and corrosion turn-key testing strategy 2020/2028460 BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before to Poland	BASF
KCP 7.1.5/1	Remmele, M.	2020	BAS 736 00 F - In Vitro Eye Irritation Test (EIT) in Reconstructed Human Cornea 2020/2027869 BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before to Poland	BASF
KCP 9.1.3/1	Mendez Gutierrez, A.	2018	Predicted environmental concentrations of BAS 700 F – Fluxapyroxad and its metabolites in soil, groundwater, surface water and sediment following application to cereals in Europe considering endpoints according to Focus 2018/1099939 Dr. Knoell Consult GmbH, Mannheim, Germany Fed.Rep. no Unpublished	No	No	N/A	BASF

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KCP 9.2.4.1/1	Mendez Gutierrez, A.	2018	Predicted environmental concentrations of BAS 700 F – Fluxapyroxad and its metabolites in soil, groundwater, sur- face water and sediment following application to cereals in Europe considering endpoints according to Focus 2018/1099939 Dr. Knoell Consult GmbH, Mannheim, Germany Fed.Rep. no Unpublished	No	No	N/A	BASF
KCP 9.2.5/1	Mendez Gutierrez, A.	2018	Predicted environmental concentrations of BAS 700 F – Fluxapyroxad and its metabolites in soil, groundwater, sur- face water and sediment following application to cereals in Europe considering endpoints according to Focus 2018/1099939 Dr. Knoell Consult GmbH, Mannheim, Germany Fed.Rep. no Unpublished	No	No	N/A	BASF
KCP 10.1.1.1/1	xxx	2009	BAS 700 F - Acute toxicity in the Zebra finch (<i>Taeniopy- gia guttata</i>) after single oral administration (LD50) xxx	Yes	Yes	Data protection started with BAS 728 00 F (Real Plus) submitted 15.04.2016; first registration 01.07.2019 + last renewal 30.09.2021; RegNo.: R-110/2019 and submitted with BAS 728 00 F (Premis Plus) 15.04.2016, first registration 01.07.2019 + last renewal 20.09.2019; RegNo.: R-109/2019	BASF
KCP 10.1.1.1/2	xxx	2020	BAS 736 00 F: An acute oral toxicity study with the north- ern bobwhite using a sequential testing procedure 2020/2095640 xxx	Yes	Yes	Data/study report never sub- mitted before to Poland	BASF
KCP 10.2.1/1	Mingo, V.	2020	BAS 736 00 F: Toxicity to the Rainbow Trout <i>Oncorhyn- chus mykiss</i> under Laboratory Conditions (Acute Toxicity Test – Static) 2019/2039621 Eurofins Agrosience Services GmbH, Niefern-Oeschel- bronn, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never sub- mitted before to Poland	BASF

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KCP 10.2.1/2	Lang, C.	2020	BAS 736 00 F: Toxicity to the water flea Daphnia magna Straus under laboratory conditions (Acute Immobilisation test - static) 2019/2039622 Eurofins Agroscience Services Ecotox GmbH, Niefern-Oeschelbronn, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before to Poland	BASF
KCP 10.2.1/3	Obert-Rauser, P.	2020	BAS 736 00 F: Toxicity to the Single Cell Green Alga Pseudokirchneriella subcapitata Hindák under Laboratory Conditions 2019/2039623 Eurofins Agroscience Services Ecotox GmbH, Niefern-Oeschelbronn, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before to Poland	BASF
KCP 10.3.1.1.1/1	Wendling, K.	2019	BAS 736 00 F: Acute Oral and Contact Toxicity to the Honey Bee, Apis mellifera L. under Laboratory Conditions 2019/1061095 Eurofins Agroscience Services GmbH, Niefern-Oeschelbronn, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before to Poland	BASF
KCP 10.3.1.1.1/2	Verge, E.	2014	BAS 700 04 F - Acute oral and contact toxicity to the bumble bee, Bombus terrestris L. under laboratory conditions 2014/1135445 Eurofins Agroscience Services EcoChem GmbH, Niefern-Oeschelbronn, Germany Fed.Rep. yes Unpublished	No	Yes	Submitted with BAS 700 04 F (Allstar/Sercadis) on 25.03.2021, evaluation ongoing	BASF
KCP 10.3.1.1.2/1	Wendling, K.	2019	BAS 736 00 F: Acute Oral and Contact Toxicity to the Honey Bee, Apis mellifera L. under Laboratory Conditions 2019/1061095 Eurofins Agroscience Services GmbH, Niefern-Oeschelbronn, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before to Poland	BASF

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KCP 10.3.1.1.2/2	Verge, E.	2014	BAS 700 04 F - Acute oral and contact toxicity to the bumble bee, <i>Bombus terrestris</i> L. under laboratory condi- tions 2014/1135445 Eurofins Agrosience Services EcoChem GmbH, Niefern- Oeschelbronn, Germany Fed.Rep. yes Unpublished	No	Yes	Submitted with BAS 700 04 F on 25.03.2021, evaluation ongoing	BASF
KCP 10.3.1.2/1	Dressler, K.	2021	Chronic toxicity of BAS 700 F tested as BAS 700 04 F to the honey bee <i>Apis mellifera</i> L. under laboratory condi- tions 2020/2083866 BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Machern OT Gerichshain, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never sub- mitted before to Poland	BASF
KCP 10.3.1.2/2	Haeuser, R.	2021	BAS 736 00 F - Honey Bee (<i>Apis mellifera</i> L.) Chronic Oral Toxicity Test - 10 Day Feeding Test in the Labora- tory 2020/2080999 Eurofins Agrosience Services Ecotox GmbH, Niefern- Oeschelbronn, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never sub- mitted before to Poland	BASF
KCP 10.3.1.3/1	Kleebaum, K.	2018	Repeated exposure of honey bee (<i>Apis mellifera</i>) larvae to BAS 700 F (Fluxapyroxad) under laboratory conditions (in vitro) 2017/1036679 BioChem agrar GmbH, Gerichshain, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with BAS 717 00 F (Dagonis) submitted 05.12.2018; first registration 12.02.2019 + last renewal 29.03.2021; RegNo.: R-36/2019	BASF
KCP 10.3.1.3/2	Haeuser, R.	2021	Repeated exposure of honey bee (<i>Apis mellifera</i> L.) larvae to BAS 736 00 F under laboratory conditions 2020/2081000 Eurofins Agrosience Services Ecotox GmbH, Niefern- Oeschelbronn, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never sub- mitted before to Poland	BASF

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KCP 10.3.2.1/1	Roehlig, U.	2019	Effects of BAS 736 00 F on the predatory mite Typhlodromus pyri SCHEUTEN in a laboratory test 2019/1061102 BioChem agrar GmbH, Gerichshain, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before to Poland	BASF
KCP 10.3.2.1/2	Roehlig, U.	2019	Effects of BAS 736 00 F on the parasitic wasp Aphidius rhopalosiphi (DESTEFANI-PEREZ) in a laboratory test 2019/1061100 BioChem agrar GmbH, Gerichshain, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before to Poland	BASF
KCP 10.3.2.2/1	Roehlig, U.	2019	Effects of BAS 736 00 F on the predatory mite Typhlodromus pyri Scheuten in an extended laboratory test 2019/1061104 BioChem agrar GmbH, Gerichshain, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before to Poland	BASF
KCP 10.3.2.2/2	Roehlig, U.	2019	Effects of BAS 736 00 F on the parasitic wasp Aphidius rhopalosiphi (Destefani-Perez) in an Extended laboratory test 2019/1061101 BioChem agrar GmbH, Gerichshain, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before to Poland	BASF
KCP 10.3.2.2/3	Roehlig, U.	2020	Effects of BAS 736 00 F on the green lacewing Chrysoperla carnea STEPH. in an (extended laboratory test) 2019/2054735 BioChem agrar GmbH, Gerichshain, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before to Poland	BASF

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KCP 10.4.1.1/1	Witte, B.	2014	Effects of BAS 700 F (Fluxapyroxad) on reproduction and growth of earthworms <i>Eisenia fetida</i> in artificial soil 2014/1135449 Institut fuer Biologische Analytik und Consulting IBA-CON GmbH, Rossdorf, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with BAS 728 00 F (Real Plus) submitted 15.04.2016; first registration 01.07.2019 + last renewal 30.09.2021; RegNo.: R-110/2019 and submitted with BAS 728 00 F (Premis Plus) 15.04.2016, first registration 01.07.2019 + last renewal 20.09.2019; RegNo.: R-109/2019	BASF
KCP 10.4.1.1/2	Friedrich, S.	2019	Effects of BAS 736 00 F on the reproduction of the earthworm <i>Eisenia andrei</i> in artificial soil 2019/1061096 BioChem agrar GmbH, Gerichshain, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before to Poland	BASF
KCP 10.4.2.1/1	Friedrich, S.	2014	Effects of BAS 700 F (Fluxapyroxad) on the reproduction of the collembolan <i>Folsomia candida</i> 2014/1135433 BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with BAS 728 00 F (Real Plus) submitted 15.04.2016; first registration 01.07.2019 + last renewal 30.09.2021; RegNo.: R-110/2019 and submitted with BAS 728 00 F (Premis Plus) 15.04.2016, first registration 01.07.2019 + last renewal 20.09.2019; RegNo.: R-109/2019	BASF
KCP 10.4.2.1/2	Schulz, L.	2016	Effects of BAS 700 F (Fluxapyroxad) on the reproduction of the predatory mite <i>Hypoaspis aculeifer</i> 2016/1122885 BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with BAS 717 00 F (Dagonis) submitted 05.12.2018; first registration 12.02.2019 + last renewal 29.03.2021; RegNo.: R-36/2019	BASF

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	Data protection claimed Y/N	Justification if data protec- tion is claimed	Owner
KCP 10.4.2.1/3	Friedrich, S.	2019	Effects of BAS 736 00 F on the reproduction of the col- lembolan Folsomia candida 2019/1061097 BioChem agrar GmbH, Gerichshain, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never sub- mitted before to Poland	BASF
KCP 10.4.2.1/4	Schulz, L.	2021	Effects of BAS 736 00 F on the reproduction of the preda- tory mite Hypoaspis aculeifer 2019/1061098 BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Machern OT Gerichshain, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never sub- mitted before to Poland	BASF
KCP 10.5/1	Persdorf, M.	2019	Effects of BAS 736 00 F on the activity of soil microflora (Nitrogen transformation test) 2019/1061099 BioChem agrar GmbH, Gerichshain, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never sub- mitted before to Poland	BASF
KCP 10.6.2/1	Maleck, A.	2019	Effect of BAS 736 00 F on vegetative vigour of ten species of terrestrial plants under greenhouse conditions 2019/1061112 Agro-Check Dr. Teresiak & Erdmann GbR, Lentzke, Ger- many Fed.Rep. yes Unpublished	No	Yes	Data/study report never sub- mitted before to Poland	BASF
KCP 10.6.2/2	Maleck, A.	2019	Effect of BAS 736 00 F on seedling emergence and seed- ling growth of ten species of terrestrial plants under green- house conditions 2019/1061110 Agro-Check Dr. Teresiak & Erdmann GbR, Lentzke, Ger- many Fed.Rep. yes Unpublished	No	Yes	Data/study report never sub- mitted before to Poland	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

BAS 700 F

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	Data protection claimed Y/N	Justification if data protec- tion is claimed	Owner
KCA 6.1/1	Mackenroth, C., Radzom, M.	2009	Investigation of the storage stability of BAS 700 F in plant matrices 2009/1072397 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCA 6.1/2	Mackenroth, C., Radzom, M.	2010	Investigation of the storage stability of BAS 700 F in plant matrices (Including amendment no. 1) 2010/7016724 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCA 6.1/3	Mackenroth, C., Radzom, M.	2009	Investigation of the storage stability of the BAS 700 F metabolite M700F002 in plant matrices 2009/1072398 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCA 6.1/4	Mackenroth, C., Radzom, M.	2010	Investigation of the storage stability of the BAS 700 F metabolite M700F002 in plant matrices 2010/1009625 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF

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	Data protection claimed Y/N	Justification if data protec- tion is claimed	Owner
KCA 6.1/5	Mackenroth, C., Radzom, M.	2009	Investigation of the storage stability of the BAS 700 F me- tabolite M700F048 in plant matrices and processed com- modities 2009/1072399 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapy- roxad under Article 80. The study has been used un- der Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCA 6.1/6	Richter, M.	2011	Investigation of the storage stability of the BAS 700 F me- tabolite M700F048 in plant matrices and processed com- modities 2011/1125600 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapy- roxad under Article 80. The study has been used un- der Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCA 6.1/7	Lehmann, A., Mackenroth, C.	2009	Investigation of the storage stability of M700F008 in plant matrices 2009/1072400 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapy- roxad under Article 80. The study has been used un- der Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCA 6.1/8	Lehmann, A., Mackenroth, C.	2011	Investigation of the storage stability of M700F008 in plant matrices 2011/1124183 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapy- roxad under Article 80. The study has been used un- der Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF

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	Data protection claimed Y/N	Justification if data protec- tion is claimed	Owner
KCA 6.1/9	Deppermann, N., Schreiner, D.	2011	Re-analysis of samples which were generated during wheat and soybean metabolism studies with 14C-BAS 700 F (BASF DocID 2009/1048403 and BASF DocID 2009/1017387) 2011/1141383 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapy- roxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCA 6.2.1/1	Rabe, U.	2009	Metabolism of BAS 700 F in tomatoes 2009/1017901 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapy- roxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCA 6.2.1/2	Bretz, M.	2009	Metabolism of BAS 700 F in soybean 2009/1017387 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapy- roxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCA 6.2.1/3	Bross, M.	2009	Metabolism of 14C-BAS 700 F in wheat after foliar treat- ment 2009/1048403 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapy- roxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF

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	Data protection claimed Y/N	Justification if data protec- tion is claimed	Owner
KCA 6.2.2/1	xxx	2009	14C-BAS 700 F: Absorption, distribution and excretion after repeated oral administration in laying hens 2009/1065025 xxx	Yes	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCA 6.2.2/2	xxx	2009	The metabolism of 14C-BAS 700 F in laying hens 2009/1069223 xxx	Yes	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCA 6.2.2/3	xxx	2010	14C-Reg.No. 5435595 (metabolite of BAS 700 F) - Absorption, distribution and excretion after repeated oral administration in laying hens 2009/1083000 xxx	Yes	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCA 6.2.2/4	xxx	2010	The metabolism of 14C-M700F002 (metabolite of BAS 700 F) in laying hens 2009/1078621 xxx	Yes	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF

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KCA 6.2.3/1	xxx	2009	14C-BAS 700 F - Absorption, distribution and excretion after repeated oral administration in lactating goats 2009/1065024 xxx	Yes	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCA 6.2.3/2	xxx	2009	Metabolism of 14C-BAS 700 F (14C-Reg.No. 5094351) in lactating goat 2009/1074074 xxx	Yes	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCA 6.2.3/3	xxx	2009	The metabolism of 14C-M700F002 (metabolite of BAS 700 F) in lactating goats 2009/1074682 xxx	Yes	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCA 6.3.1/1	Erdmann, H.	2009	Study on the residue behaviour of BAS 700 F in wheat and triticale after application of BAS 700 00 F, under field condition in France, Italy, Spain, UK and Germany, 2008 2009/1012126 Agro-Check Dr. Teresiak & Erdmann GbR, Lentzke, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF

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	Data protection claimed Y/N	Justification if data protec- tion is claimed	Owner
KCA 6.3.1/2	Erdmann, H.	2009	Study on the residue behaviour of BAS 700 F in wheat and triticale after application of Fa 5094351 18 F under field condition in France, UK, Spain and Germany, 2007 2007/1050092 Agro-Check Dr. Teresiak & Erdmann GbR, Lentzke, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCA 6.3.2/1	Erdmann, H.	2009	Study on the residue behaviour of BAS 700 F in barley after application of BAS 700 00 F, under field condition in France, Italy, Spain, UK, Greece, Netherlands and Germany, 2008 2009/1012125 Agro-Check Dr. Teresiak & Erdmann GbR, Lentzke, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCA 6.3.2/2	Erdmann, H.	2009	Study on the residue behaviour of BAS 700 F in barley after application of Fa 5094351 18F under field condition in France, UK, Spain and Germany, 2007 2007/1050093 Agro-Check Dr. Teresiak & Erdmann GbR, Lentzke, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCA 6.4/1	xxx	2009	Magnitude of residues in milk and tissues of dairy cows following multiple oral administrations of BAS 700 F and metabolite M700F002 2009/1074798 xxx	Yes	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF

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	Data protection claimed Y/N	Justification if data protec- tion is claimed	Owner
KCA 6.4/2	xxx	2010	Report Amendment 1: Magnitude of residues in milk and tissues of dairy cows following multiple oral administrations of BAS 700 F and metabolite M700F002 2009/1118922 xxx	Yes	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCA 6.4.1/1	xxx	2009	Magnitude of residues in eggs and tissues of laying hens following multiple oral administration of BAS 700 F and M700F002 2009/1074799 xxx	Yes	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCA 6.4.1/2	xxx	2010	Amendment 1: Magnitude of residues in eggs and tissues of laying hens following multiple oral administration of BAS 700 F and M700F002 2010/1029664 xxx	Yes	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCA 6.4.2/1	xxx	2009	Magnitude of residues in milk and tissues of dairy cows following multiple oral administrations of BAS 700 F and metabolite M700F002 2009/1074798 xxx	Yes	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF

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	Data protection claimed Y/N	Justification if data protec- tion is claimed	Owner
KCA 6.4.2/2	xxx	2010	Report Amendment 1: Magnitude of residues in milk and tissues of dairy cows following multiple oral administrations of BAS 700 F and metabolite M700F002 2009/1118922 xxx	Yes	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCA 6.5.1/1	Hassink, J.	2009	BAS 700 F: Hydrolysis at 90°C, 100°C and 120°C 2009/1049060 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCA 6.5.3/1	Johnston, R., Saha, M.	2009	Magnitude of BAS 700 F residues in processed fractions and/or aspirated grain fractions of the cereal grain wheat following applications of BAS 700 AE F 2009/7003065 BASF Corp., Research Triangle Park NC, United States of America yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCA 6.5.3/2	Johnston, R., Saha, M.	2009	Magnitude of BAS 700 F residues in processed fractions of the cereal grain barley following applications of BAS 700 AE F 2009/7003177 BASF Corp., Research Triangle Park NC, United States of America yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF

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	Data protection claimed Y/N	Justification if data protec- tion is claimed	Owner
KCA 6.6.1/1	Schopfer, C.	2009	Confined rotational crop study with 14C-BAS 700 F (Py- razole label) 2009/1074683 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapy- roxad under Article 80. The study has been used un- der Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCA 6.6.1/2	Schopfer, C.	2009	Confined rotational crop study with 14C-BAS 700 F (Ani- line label) 2009/1074684 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapy- roxad under Article 80. The study has been used un- der Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCA 6.6.2/1	Erdmann, H.	2011	Field rotational crop study with BAS 700 00 F, containing 62.5 g/L Reg.No. 5094351, applied to bare soil at 365, 120 and 30 days prior to planting of four rotational crops in Spain, Italy, Greece and Germany, 2008-2009 2010/1144335 Agro-Check Dr. Teresiak & Erdmann GbR, Lentzke, Ger- many Fed.Rep. yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapy- roxad under Article 80. The study has been used un- der Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCP 5.1.2/1	Lehmann, A., Mackenroth, C.	2009	Validation of BASF Method No. L0137/01 in plant matri- ces 2009/1074617 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapy- roxad under Article 80. The study has been used un- der Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF

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	Data protection claimed Y/N	Justification if data protec- tion is claimed	Owner
KCP 5.1.2/2	Jooß, S., Class, T.	2009	BAS 700 F: Independent laboratory validation (ILV) of BASF method number L0137/01 and L0140/02 for the determination of BAS 700 F in plant materials and animal matrices by LC/MS/MS 2009/1074618 PTRL Europe GmbH, Ulm, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCP 5.1.2/3	Jooß, S., Class, T.	2009	M700F002 (Reg.No. 5435595, metabolite of BAS 700 F): Independent laboratory validation (ILV) of BASF method numbers L0137/01 and L0140/02 for the determination of M700F002 in plant materials and animal matrices by LC/MS/MS 2009/1074614 PTRL Europe GmbH, Ulm, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCP 5.1.2/4	Mackenroth, C.	2009	Validation of the analytical method L0140/02: Method for the determination of BAS 700 F (Reg.No. 5094351) and its metabolites M700F002 (Reg.No. 5435595), M700F008 (Reg.No. 5566402) and M700F048 (Reg.No. 5570265) in animal matrices 2009/1074613 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCP 5.1.2/5	Macdougall J.	2009	Independent laboratory validation of analytical method No. L0140/01 for the determination of BAS 700 F, M700F048, M700F008 and M700F002 in eggs, bovine, milk, liver and muscle by HPLC-MS/MS 2009/1074797 Charles River Laboratories, Tranent East Lothian EH33 2NE, United Kingdom yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF

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	Data protection claimed Y/N	Justification if data protec- tion is claimed	Owner
KCP 5.1.2/6	Zangmeister, W.	2009	Validation of analytical method L0092: Determination of Reg.No. 5094351 and its metabolites Reg.No. 5069089, Reg.No. 5410775 and Reg.No. 5435595 in soil by HPLC/MS-MS 2008/1063799 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapy- roxad under Article 80. The study has been used un- der Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCP 5.1.2/7	Zangmeister, W.	2010	Report amendment No. 1 - Validation of analytical method L0092: Determination of Reg.No. 5094351 and its metabo- lites Reg.No. 5069089, Reg.No. 5410775 and Reg.No. 5435595 in soil by HPLC/MS-MS 2010/1043659 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapy- roxad under Article 80. The study has been used un- der Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCP 5.1.2/8	Zangmeister, W.	2009	Validation of analytical method L0143/01: Determination of BAS 700 F and its metabolites M700F001, M700F002 and M700F007 in water by HPLC/MS-MS 2009/1069396 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapy- roxad under Article 80. The study has been used un- der Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCP 5.1.2/9	Zangmeister, W.	2009	Validation of BASF method L0142/01: Determination of BAS 700 F in air 2009/1069395 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapy- roxad under Article 80. The study has been used un- der Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF

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	Data protection claimed Y/N	Justification if data protec- tion is claimed	Owner
KCP 5.2/1	Lehmann, A., Mackenroth, C.	2009	Validation of BASF Method No. L0137/01 in plant matri- ces 2009/1074617 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapy- roxad under Article 80. The study has been used un- der Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCP 5.2/2	Jooß, S., Class, T.	2009	BAS 700 F: Independent laboratory validation (ILV) of BASF method number L0137/01 and L0140/02 for the de- termination of BAS 700 F in plant materials and animal matrices by LC/MS/MS 2009/1074618 PTRL Europe GmbH, Ulm, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapy- roxad under Article 80. The study has been used un- der Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCP 5.2/3	Mackenroth, C.	2009	Validation of the analytical method L0140/02: Method for the determination of BAS 700 F (Reg.No. 5094351) and its metabolites M700F002 (Reg.No. 5435595), M700F008 (Reg.No. 5566402) and M700F048 (Reg.No. 5570265) in animal matrices 2009/1074613 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapy- roxad under Article 80. The study has been used un- der Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCP 5.2/4	Zangmeister, W.	2009	Validation of analytical method L0092: Determination of Reg.No. 5094351 and its metabolites Reg.No. 5069089, Reg.No. 5410775 and Reg.No. 5435595 in soil by HPLC/MS-MS 2008/1063799 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapy- roxad under Article 80. The study has been used un- der Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF

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	Data protection claimed Y/N	Justification if data protec- tion is claimed	Owner
KCP 5.2/5	Zangmeister, W.	2010	Report amendment No. 1 - Validation of analytical method L0092: Determination of Reg.No. 5094351 and its metabolites Reg.No. 5069089, Reg.No. 5410775 and Reg.No. 5435595 in soil by HPLC/MS-MS 2010/1043659 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCP 5.2/6	Zangmeister, W.	2009	Validation of analytical method L0143/01: Determination of BAS 700 F and its metabolites M700F001, M700F002 and M700F007 in water by HPLC/MS-MS 2009/1069396 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCP 5.2/7	Zangmeister, W.	2009	Validation of BASF method L0142/01: Determination of BAS 700 F in air 2009/1069395 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCP 7/1	xxx	2009	Reg.No. 5069089 (metabolite of BAS 700 F) - Acute oral toxicity study in rats 2009/1072502 xxx	Yes	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF

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KCP 7/2	xxx	2009	Reg.No. 5069089 (metabolite of BAS 700 F) - Repeated dose 90-day oral toxicity study in Wistar rats; administration in the diet 2009/1072503 xxx	Yes	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCP 7/3	Landsiedel, R., Schulz, M.	2009	Reg.No. 5069089 (metabolite of BAS 700 F) - Salmonella typhimurium/Escherichia coli reverse mutation assay (standard plate test and preincubation test) 2009/1072504 BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCP 7/4	Landsiedel, R., Schulz, M.	2009	Reg.No. 5069089 (metabolite of BAS 700 F) - In vitro chromosome aberration assay in V79 cells 2009/1072505 BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCP 7/5	Landsiedel, R., Schulz, M.	2009	Reg.No. 5069089 (metabolite of 700 F) - In vitro gene mutation test in CHO cells (HPRT locus assay) 2009/1072392 BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF

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	Data protection claimed Y/N	Justification if data protec- tion is claimed	Owner
KCP 7/6	Schulz, M.	2009	Amendment No. 1 to the report: Reg.No. 5069089 (metabolite of 700 F) - In vitro gene mutation test in CHO cells (HPRT locus assay) 2009/1081058 BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCP 7/7	xxx	2009	Reg.No. 5069089 (metabolite of BAS 700 F) - Micronucleus test in bone marrow cells of the mouse 2009/1072506 xxx	Yes	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCP 7/8	xxx	2009	Reg.No. 5069089 (metabolite of BAS 700 F) - Prenatal developmental toxicity study in New Zealand white rabbits - Oral administration (gavage) 2009/1072507 xxx	Yes	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCP 7/9	xxx	2009	Reg.No. 5435595 (metabolite of BAS 700 F) - Acute oral toxicity study in rats 2009/1018501 xxx	Yes	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF

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KCP 7/10	xxx	2008	Reg.No. 5435595 (metabolite of BAS 700 F) - Repeated dose 28-day oral toxicity study in Wistar rats; Administration in the diet 2008/1052054 xxx	Yes	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCP 7/11	xxx	2009	Reg.No. 5435595 (metabolite of BAS 700 F) - Repeated dose 90-day oral toxicity study in Wistar rats; Administration in the diet 2009/1012026 xxx	Yes	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCP 7/12	Landsiedel, R., Schulz, M.	2007	Reg.No. 5435595 (metabolite of BAS 700 F) - Salmonella typhimurium / Escherichia coli reverse mutation assay (standard plate test and preincubation test) 2007/1051931 BASF AG, Ludwigshafen/Rhein, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCP 7/13	Landsiedel, R., Schulz, M.	2008	Reg.No. 5435595 (metabolite of BAS 700 F) - In vitro chromosome aberration assay in V79 cells 2008/1002741 BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF

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KCP 7/14	Landsiedel, R., Schulz, M.	2008	Reg.No. 5435595 (metabolite of BAS 700 F) - In vitro gene mutation test in CHO cells (HPRT locus assay) 2008/1014199 BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapy- roxad under Article 80. The study has been used un- der Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCP 7/15	xxx	2008	Reg.No. 5425764 (technical impurity of BAS 700 F) - Mi- cronucleus test in bone marrow cells of the mouse 2008/1002421 xxx	Yes	Yes	Data protection started with the EU approval of Fluxapy- roxad under Article 80. The study has been used un- der Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCP 7/16	xxx	2009	Reg.No. 5435595 (metabolite of BAS 700 F) - Prenatal de- velopmental toxicity study in New Zealand white rabbits - Oral administration (gavage) 2009/1072509 xxx	Yes	Yes	Data protection started with the EU approval of Fluxapy- roxad under Article 80. The study has been used un- der Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCP 10.1.1/1	xxx	2008	BAS 700 F - Acute toxicity in the bobwhite quail (Colinus virginianus) after single oral administration (LD50) 2007/1054365 xxx	Yes	Yes	Data protection started with the EU approval of Fluxapy- roxad under Article 80. The study has been used un- der Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF

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KCP 10.1.1/2	xxx	2008	BAS 700 F - Acute toxicity in the mallard duck (Anas platyrhynchos) after single oral administration (LD50) 2008/1003797 xxx	Yes	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCP 10.1.1/3	xxx	2009	BAS 700 F - 1-Generation reproduction study on the bobwhite quail (Colinus virginianus) by administration in the diet 2008/1023021 xxx	Yes	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCP 10.1.1/4	xxx	2009	Amendment No. 1: BAS 700 F - 1-Generation reproduction study on the bobwhite quail (Colinus virginianus) by administration in the diet 2009/1079886 xxx	Yes	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCP 10.1.1/5	xxx	2009	Amendment No. 2: BAS 700 F - 1-Generation reproduction study on the bobwhite quail (Colinus virginianus) by administration in the diet 2009/1099679 xxx	Yes	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF

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KCP 10.1.1/6	xxx	2008	BAS 700 F - 1-Generation reproduction study on the mal- lard duck (Anas platyrhynchos) by administration in the diet 2008/1055153 xxx	Yes	Yes	Data protection started with the EU approval of Fluxapy- roxad under Article 80. The study has been used un- der Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCP 10.1.1/7	xxx	2009	Amendment No. 1: BAS 700 F - 1-Generation reproduc- tion study on the mallard duck (Anas platyrhynchos) by administration in the diet 2009/1079887 xxx	Yes	Yes	Data protection started with the EU approval of Fluxapy- roxad under Article 80. The study has been used un- der Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCP 10.1.2/1	xxx	2008	BAS 700 F: Acute oral toxicity in rats - Acute toxic class method 2008/1002441 xxx	Yes	Yes	Data protection started with the EU approval of Fluxapy- roxad under Article 80. The study has been used un- der Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCP 10.1.2/2	xxx	2009	BAS 700 F - Two-generation reproduction toxicity study in Wistar rats - Administration via the diet 2009/1072491 xxx	Yes	Yes	Data protection started with the EU approval of Fluxapy- roxad under Article 80. The study has been used un- der Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF

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KCP 10.1.2/3	xxx	2009	BAS 700 F - Prenatal developmental toxicity study in Wistar rats - Oral administration (gavage) 2009/1072492 xxx	Yes	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCP 10.1.2/4	xxx	2009	BAS 700 F - Prenatal developmental toxicity study in Himalayan rabbits - Oral administration (gavage) 2009/1072493 xxx	Yes	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCP 10.2/1	xxx	2007	BAS 700 F - Acute toxicity study on the rainbow trout (Oncorhynchus mykiss) in a static system over 96 hours 2007/1057974 xxx	Yes	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCP 10.2/2	xxx	2008	BAS 700 F - Acute toxicity study with the bluegill sunfish (Lepomis macrochirus) 2008/1010605 xxx	Yes	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF

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KCP 10.2/3	xxx	2009	BAS 700 F - Acute toxicity study with the fathead minnow (Pimephales promelas) 2009/1025414 xxx	Yes	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCP 10.2/4	xxx	2008	Acute toxicity study of Reg.No. 5094351 to carp (Cypri- nus carpio) 2008/1064998 xxx	Yes	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCP 10.2/5	xxx	2009	BAS 700 F: A 96-hour static acute toxicity test with the Sheepshead minnow (Cyprinodon variegatus) 2008/7015417 xxx	Yes	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCP 10.2/6	xxx	2009	BAS 700 F - Early life-stage toxicity test on the fathead minnow (Pimephales promelas) in a flow through system 2008/1090791 xxx	Yes	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF

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KCP 10.2/7	xxx	2009	Bioconcentration and metabolism of BAS 700 F (Reg.No. 5094351, 14C) in bluegill sunfish (<i>Lepomis macrochirus</i>) 2009/1012801 xxx	Yes	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCP 10.2/8	Janson, G.	2009	Acute toxicity of BAS 700 F (Reg. No. 5094351) to <i>Daphnia magna</i> STRAUS in a 48 hour static test 2008/1028252 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCP 10.2/9	Gallagher, S.	2009	BAS 700 F: A 96-hour static acute toxicity test with the saltwater mysid (<i>Americamysis bahia</i>) 2009/7000069 Wildlife International Ltd., Easton MD, United States of America yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCP 10.2/10	Gallagher, S.	2009	BAS 700 F: A 96-hour shell deposition test with the eastern oyster (<i>Crassostrea virginica</i>) 2009/7000165 Wildlife International Ltd., Easton MD, United States of America yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF

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	Data protection claimed Y/N	Justification if data protec- tion is claimed	Owner
KCP 10.2/11	Janson, G.	2009	Chronic toxicity of BAS 700 F (Reg.No. 5094351) to Daphnia magna STRAUS in a 21 day semi-static test 2008/1055084 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCP 10.2/12	Backfisch, K., Weltje, L.	2009	Chronic toxicity of BAS 700 F to the non-biting midge Chironomus riparius - A spiked sediment study 2009/1037085 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCP 10.2/13	Hoffmann, F.	2008	Effect of BAS 700 F (Reg.No. 5094351) on the growth of the green alga Pseudokirchneriella subcapitata 2008/1022788 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCP 10.2/14	Hoffmann, F.	2009	Report amendment No. 1: Effect of BAS 700 F (Reg.No. 5094351) on the growth of the green alga Pseudokirchneriella subcapitata 2009/1015272 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF

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KCP 10.2/15	Hoffmann, F.	2010	Amendment No. 2 - Effect of BAS 700 F (Reg.No. 5094351) on the growth of the green alga <i>Pseudokirchneriella subcapitata</i> 2010/1016358 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCP 10.2/16	Hoffmann, F.	2009	Effect of BAS 700 F (Reg.No. 5094351) on the growth of the blue-green alga <i>Anabaena flos-aquae</i> 2009/1079883 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCP 10.2/17	Hoffmann, F.	2009	Effect of BAS 700 F (Reg.No. 5094351) on the growth of the fresh water diatom <i>Navicula pelliculosa</i> 2009/1079885 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCP 10.2/18	Hoffmann, F.	2009	Effect of BAS 700 F (Reg.No. 5094351) on the growth of <i>Lemna gibba</i> 2009/1086122 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF

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	Data protection claimed Y/N	Justification if data protec- tion is claimed	Owner
KCP 10.2/19	xxx	2009	M700F001 (Metabolite of BAS 700 F): Acute toxicity for rainbow trout 2009/1021591 xxx	Yes	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCP 10.2/20	xxx	2009	M700F002 (Metabolite of BAS 700 F): Acute toxicity for rainbow trout 2009/1021595 xxx	Yes	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCP 10.2/21	xxx	2009	M700F007 (Metabolite of BAS 700 F): Acute toxicity for rainbow trout 2009/1026001 xxx	Yes	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCP 10.2/22	Nierzedzka, E.	2009	M700F001 (Metabolite of BAS 700 F): Daphnia magna, acute immobilization test 2009/1021592 Institute of Industrial Organic Chemistry, Pszczyna, Poland yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF

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KCP 10.2/23	Zmijowski, G.	2009	M700F002 (Metabolite of BAS 700 F): Daphnia magna, acute immobilisation test 2009/1021596 Institute of Industrial Organic Chemistry, Pszczyna, Po- land yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCP 10.2/24	Rzodeczko, H.	2009	M700F007 (Metabolite of BAS 700 F): Daphnia magna, acute immobilisation test 2009/1026002 Institute of Industrial Organic Chemistry, Pszczyna, Po- land yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCP 10.2/25	Nierzedzka, E.	2009	M700F001 (Metabolite of BAS 700 F): Pseudokirchneriella subcapitata SAG.61.81 - Growth inhibition test 2009/1021593 Institute of Industrial Organic Chemistry, Pszczyna, Po- land yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCP 10.2/26	Nierzedzka, E.	2009	Amendment to the final report: M700F001 (Metabolite of BAS 700 F): Pseudokirchneriella subcapitata SAG.61.81 - Growth inhibition test 2009/1102103 Institute of Industrial Organic Chemistry, Pszczyna, Po- land yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF

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	Data protection claimed Y/N	Justification if data protec- tion is claimed	Owner
KCP 10.2/27	Zmijowski, G.	2009	M700F002 (Metabolite of BAS 700 F): Pseudokirchneriella subcapitata SAG.61.81 growth inhibition test 2009/1021597 Institute of Industrial Organic Chemistry, Pszczyna, Poland yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCP 10.2/28	Rzodeczko, H.	2009	M700F007 (Metabolite of BAS 700 F): Pseudokirchneriella subcapitata SAG.61.81 - Growth inhibition test 2009/1026003 Institute of Industrial Organic Chemistry, Pszczyna, Poland yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCP 10.2/29	Rzodeczko, H.	2009	Amendment to the final report: M700F007 (Metabolite of BAS 700 F): Pseudokirchneriella subcapitata SAG.61.81 - Growth inhibition test 2009/1102104 Institute of Industrial Organic Chemistry, Pszczyna, Poland yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCP 10.3/1	Schmitzer, S.	2008	Effects of BAS 700 F (acute contact and oral) on honey bees (Apis mellifera L.) in the laboratory 2008/1010703 Institut fuer Biologische Analytik und Consulting IBA-CON GmbH, Rossdorf, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF

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	Data protection claimed Y/N	Justification if data protec- tion is claimed	Owner
KCP 10.4/1	Friedrich, S.	2009	Acute toxicity of BAS 700 F (Reg.No. 5094351) to the earthworm <i>Eisenia fetida</i> in artificial soil with 5% peat 2009/1072245 BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCP 10.4/2	Witte, B.	2009	Acute toxicity (14 days) of Reg.No. 5435595 (metabolite of BAS 700 F, M700F002) to the earthworm <i>Eisenia fetida</i> in artificial soil 2009/1072244 Institut fuer Biologische Analytik und Consulting IBA-CON GmbH, Rossdorf, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCP 10.4/3	Wolf, A.	2008	Effects of Reg.No. 5069089 (M700F001, metabolite of BAS 700 F) on growth and reproduction of earthworms (<i>Eisenia fetida</i>) in artificial soil 2008/1033932 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCP 10.4/4	Wolf, A.	2008	Effects of Reg.No. 5435595 (M700F002, metabolite of BAS 700 F) on growth and reproduction of earthworms (<i>Eisenia fetida</i>) in artificial soil 2008/1017010 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF

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	Data protection claimed Y/N	Justification if data protec- tion is claimed	Owner
KCP 10.4/5	Royer, S.	2009	Effect of Reg.No. 5435595 (metabolite of BAS 700 F, M700F002) on the reproduction of the collembola Folso-mia candida in artificial soil with 5% peat 2009/1045472 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCP 10.5/1	Schulz, L.	2008	Effects of BAS 700 F (Reg.No. 5094351) on the activity of soil microflora (Nitrogen transformation test) 2008/1065108 BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCP 10.5/2	Schulz, L.	2009	Effects of Reg.No. 5435595 (metabolite of BAS 700 F, M700F002) on the activity of soil microflora (Nitrogen transformation test) 2009/1004145 BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCP 10.5/3	Schulz, L.	2008	Effects of BAS 700 F (Reg.No. 5094351) on the activity of soil microflora (Carbon transformation test) 2008/1065107 BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF

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	Data protection claimed Y/N	Justification if data protec- tion is claimed	Owner
KCP 10.5/4	Schulz, L.	2009	Effects of Reg.No. 5435595 (metabolite of BAS 700 F, M700F002) on the activity of soil microflora (carbon transformation test) 2009/1004144 BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCP 10.5/5	Schulz, L.	2009	Effects of Reg.No. 5069089 (Metabolite of BAS 700 F, M700F001) on the activity of soil microflora (Carbon transformation test) 2008/1065120 BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF
KCP 10.5/6	Schulz, L.	2009	Effects of Reg.No. 5069089 (Metabolite of BAS 700 F, M700F001) on the activity of soil microflora (Nitrogen transformation test) 2008/1065121 BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with the EU approval of Fluxapyroxad under Article 80. The study has been used under Article 80 in Regulation (EC) No. 1107/2009 in MS, approved with BAS 700 F on 01.01.2013.	BASF

Azoxystrobin

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	Data protection claimed Y/N	Justification if data protec- tion is claimed	Owner
KCP 9.2.4.1/1	Anonymous	2021	Azoxystrobin - Metabolite R234886: Evaluation of intrinsic fungicidal activity TMJ5077B <none> No Unpublished	No	No	N/A	Syngenta
KCP 13/1	Anonymous	2021	Azoxystrobin - Metabolite R234886: Evaluation of intrinsic fungicidal activity TMJ5077B <none> No Unpublished	No	No	N/A	Syngenta

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Y/N	Data/study report never submitted before to <insert MS> If previously submitted in this MS: Data protection started with: <insert authorization number of first authorization>	Owner

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Y/N	Data/study report never submitted before to <insert MS> If previously submitted in this MS: Data protection started with: <insert authorization number of first authorization>	Owner