REGISTRATION REPORT
Part A

Risk Management

Product code:	**AG-FB1-485 SC**
Active Substance:	**bifenox 480 g/L**
	florasulam 5 g/L

COUNTRY: Germany

Central Zone

Zonal Rapporteur Member State: Austria

NATIONAL ASSESSMENT

Applicant:	**ADAMA Deutschland GmbH**
Date:	**14/03/2016**

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PART A – Risk Management

This document describes the acceptable use conditions required for the registration of AG-FB1-485 SC containing bifenox and florasulam in Germany. This evaluation is required subsequent to the approval of bifenox and florasulam.

The risk assessment conclusions are based on the information, data and assessments provided in AG-FB1-485 SC Registration Report, Part B Sections 1-7 and Part C from Austria and where appropriate the addendum for Germany. The information, data and assessments provided in Registration Report, Parts B includes assessment of further data or information as required at national re-registration/registration by the EU review. It also includes assessment of data and information relating to AG-FB1-485-SC where that data has not been considered in the EU review. Otherwise assessments for the safe use of AG-FB1-485-SC have been made using endpoints agreed in the EU review of bifenox and florasulam.

This document describes the specific conditions of use and labelling required for Germany for the registration of AG-FB1-485-SC.

Appendix 1 of this document provides a copy of the final product authorisation in Germany.

Appendix 2: The submitted draft product label has been checked by the competent authority. The applicant is requested to amend the product label in accordance with the decisions made by the competent authority. The final version of the label has to fulfil the requirements according to Article 16 of Directive 91/414/EEC.

Appendix 3 of this document contains copies of the letters of access to the protected data / third party data that was needed for evaluation of the formulation.
Letter(s) of access is/are classified as confidential and, thus, are not attached to this document.

1 Details of the application

1.1 Application background

This application was submitted by ADAMA Deutschland GmbH on 17 December 2012.

The application was for approval of AG-FB1-485 SC, a suspension concentrate containing 5 g/L florasulam and 480 g/L bifenox for use in winter and spring cereals to control annual dicot weeds.

1.2 Annex I inclusion

Florasulam has been included into Annex I of Directive 91/414/EEC (repealed by Reg. EC No 1107/2011) with entry into force by 01 October 2002. The corresponding EU Commission Directive 2002/64/EC (repealed by Reg (EU) No 540/2011) for florasulam had been published in the Official Journal of the European Communities on 15 July 2002.

Bifenox has been included into Annex I of Directive 91/414/EEC with entry into force by 01 January 2009. The corresponding EU Commission Directive 2008/66/EC (repealed by Reg (EU) No 540/2011) for bifenox had been published in the Official Journal of the European Communities on 30 June 2008.

The Annex I Inclusion Directives for florasulam (2002/64/EC repealed by Reg (EU) No 540/2011) and for bifenox (2008/66/EC repealed by Reg (EU) No 540/2011) provide specific provisions under Part B which need to be considered by the applicant in the preparation of their submission and by the MS prior to granting an authorization.

According to commission implementing regulation (EU) No 546/2011, the conclusions of the review report on florasulam, and in particular Appendices I and II thereof, as finalized in the Standing Committee on the Food Chain and Animal Health on 19/04/2002 shall be taken into account.

In this overall assessment Member States should pay particular attention to the:

- potential for groundwater contamination, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of authorisation must include risk-mitigation measures, where appropriate.

According to commission implementing regulation (EU) No 546/2011, the conclusions of the review report on bifenox, and in particular Appendices I and II thereof, as finalized in the Standing Committee on the Food Chain and Animal Health on 14/03/2008, and the last revision of SANCO/3776/08-final rev 1– 24/01/2011 shall be taken into account.

In this overall assessment Member States should pay particular attention to:

- the operator safety and ensure that conditions of use prescribe the application of adequate personal protctive equipment where,
- the dietary exposure of consumers to bifenox residues in products of animal origin and in succeeding rotational crops.

The Member States concerned shall request the submission of:

- Information on residues of bifenox and its metabolite hydroxyl bifenox acid in food of animal origin and on residues of bifenox in rotational crops,
- Information to further address the long-term risk to herbivorous mammals arising from the use of bifenox.

These concerns have been addressed within the current submission.

1.3 Regulatory approach

To obtain approval the product AG-FB1-485 SC must meet the conditions of Annex I inclusion and be supported by dossiers satisfying the requirements of Annex II and Annex III, with an assessment to Uniform Principles, using Annex I agreed end-points.

This application was submitted in order to allow the first approval of this product/use in Germany in accordance with the above.

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of AG-FB1-485 SC, it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B, sections 1 - 8 and Part C.

1.5 Letters of Access

Letter of Access to the data produced by Dow AgroSciences in order to the EU-approval of the active substance florasulam.

2 Details of the authorisation

2.1 Product identity

Product Name	AG-FB1-485 SC
Authorization Number	007818-00/00
Function	herbicide
Applicant	ADAMA Deutschland GmbH
Composition	5 g/L florasulam and 480 g/L bifenox
Formulation type	suspension concentrate [Code: SC]
Packaging	1L, 5L and 10L HDPE canister

2.2 Classification and labelling

2.2.1 Classification and labelling under Directive 99/45/EC

The following labelling is proposed in accordance with Directive 1999/45/EC:

Symbol(s)/Indication(s) of danger:	
Risk phrases:	
Safety phrases:	
S36/37	Wear suitable protective clothing and gloves.
S2	Keep out of the reach of children
S24	Avoid contact with skin
Specific labelling requirement:	
To avoid risks to man and the environment, comply with the instructions for use.	
Contains 1,2-benzisothiazole-3(2H)-one. May produce allergic reactions.	

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

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

Hazard classes and categories: (kein Labelling-Requirement!)	
Hazard pictograms:	
GHS09	environment
Signal word:	
Warning	
Hazard statements:	
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
Precautionary statements:	
P501	Dispose of contents/container to ...

Special rule for labelling of PPP:	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.
Further labelling statements under Regulation (EC) No 1272/2008:	
EUH 208 - Contains 1,2-benzisothiazole-3(2H)-one. May produce allergic reactions.	

2.2.3 R and S phrases under Directive 2003/82/EC (Annex IV and V)

None

2.2.4 Other phrases

2.2.4.1 Restrictions linked to the PPP under Regulation (EC) No 547/2011

The authorization of the PPP is linked to the following conditions (mandatory labelling):

Human health protection	
SB001	Avoid any unnecessary contact with the product. Misuse can lead to health damage.
SB005	If medical advice is needed, have product container or label at hand.
SB010	Keep out of children’s reach.
SB110	The directive concerning requirements for personal protective gear in plant protection, "Personal protective gear for handling plant protection products" of the Federal Office of Consumer Protection and Food Safety must be observed.

SB166	Do not eat, drink or smoke when using this product.
SF245-01	Treated areas/crops may not be entered until the spray coating has dried.
SS206	Working clothes (if no specific protective suit is required) and sturdy footwear (e.g. rubber boots) must be worn when applying/handling plant protection products.
SS110	Wear standard protective gloves (plant protection) when handling the undiluted product.
SS2101	Wear a protective suit against pesticides and sturdy shoes (e.g. rubber boots) when handling the undiluted product.
SS530	Wear face protection when handling the undiluted product.
SS610	Wear a rubber apron when handling the undiluted product.
Integrated pest management (IPM)/sustainable use	
WME	Mode of action (HRAC-group): E
WMB	Mode of action (HRAC-group): B
WH951	The risk of resistance has to be indicated on the package and in the instructions for use. Particularly measures for an appropriate risk management have to be declared.
NN2001	The product is classified as slightly harmful for populations of relevant beneficial predatory mites and spiders.
NN3002	The product is classified as harmful for populations of relevant beneficial predatory mites and spiders.
NB6641	The product is classified as non-hazardous to bees, even when the maximum application rate, or concentration if no application rate is stipulated, as stated for authorisation is applied. (B4)
Ecosystem protection	
NW 262	The product is toxic for algae.
NW 264	The product is toxic for fish and aquatic invertebrates.
NW 265	The product is toxic for higher aquatic plants.

2.2.4.2 Specific restrictions linked to intended uses

Some of the authorised uses are linked to the following conditions (mandatory labelling):
See 2.3 (Product uses)

Integrated pest management (IPM)/sustainable use	
WH9161	The instructions for use must include a summary of weeds which can be controlled well, less well and insufficiently by the product, as well as a list of species and/or varieties showing which crops are tolerant of the intended application rate and which are not.
Ecosystem protection	

NW 468	Fluids left over from application and their remains, products and their remains, empty containers and packaging, and cleansing and rinsing fluids must not be dumped in water. This also applies to indirect entry via the urban or agrarian drainage system and to rain-water and sewage canals.
NW607-1	When applying the product on areas adjacent to surface waters - except only occasionally but including periodically water bearing surface waters - the product must be applied with equipment which is registered in the index of 'Loss Reducing Equipment' of 14 October 1993 ('Bundesanzeiger' [Federal Gazette] No 205, p. 9780) as amended. Depending on the drift reduction classes for the equipment stated below, the following buffer zones must be kept from surface waters. In addition to the minimum buffer zone from surface waters stipulated by state law, the ban on application in or in the immediate vicinity of waters must be observed at all times for drift reduction classes marked with "*". Violations may be punished by fines of up to 50 000 EUR. Drift reduction 90%, 20 m buffer
NT103	In a strip at least 20 m wide which is adjacent to other areas, the product must be applied using loss reducing equipment which is registered in the index of 'Loss Reducing Equipment' of 14 October 1993 (Federal Gazette No 205, p. 9780) as amended, and be registered in at least drift reducing class 90 % (except agriculturally or horticulturally used areas, roads, paths and public places). Loss reducing equipment is not required if the product is applied with portable plant protection equipment or if adjacent areas (field boundaries, hedges, groups of woody plants) are less than 3 m wide or the product is applied in an area which has been declared by the Biologische Bundesanstalt in the "Index of regional proportions of ecotones" of 7 February 2002 (Federal Gazette no. 70 a of 13 April 2002), as amended, as agrarian landscape with a sufficient proportion of natural and semi-natural structures
NT108	A buffer zone of at least 5 m must be kept from adjacent areas (except agriculturally or horticulturally used areas, roads, paths and public places). In addition, in an adjoining strip of at least 20 m, the product must be applied using loss reducing equipment which is registered in the index of 'Loss Reducing Equipment' of 14 October 1993 (Federal Gazette No 205, p. 9780) as amended, and be registered in at least drift reducing class 75 %. Neither loss reducing equipment nor a buffer zone of at least 5 m are required if the product is applied with portable plant protection equipment or if adjacent areas (field boundaries, hedges, groups of woody plants) are less than 3 m wide. A buffer zone of at least 5 m is also unnecessary if the product is applied in an area which has been declared by the Biologische Bundesanstalt in the "Index of regional proportions of ecotones" of 7 February 2002 (Federal Gazette no. 70 a of 13 April 2002), as amended, as agrarian landscape with a sufficient proportion of natural and semi-natural structures, or if evidence can be shown that adjacent areas (e.g. field boundaries, hedges, groups of woody plants) were planted on agriculturally or horticulturally used areas.

2.3 Product uses

GAP-Table of intended uses for Germany

GAP rev. (No 2), date: 2014-11-26

PPP (product name/code): **AG-FB1-485 SC**
Active substance 1: **Florasulam**
Active substance 2: **Bifenox**

Formulation type: **SC (suspension concentrate)**
Conc. of as 1: **5 g/ L**
Conc. of as 2: **480 g/ L**

Applicant : **Feinchemie Schwebda GmbH**
Zone(s) : **central/EU**

Professional use: ☒
Non-professional use: ☐

Verified by MS: **yes**

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**			**Application rate**			**PHI** (days)	**Remarks:** e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
001	DE	winter soft wheat (TRZAW), winter barley (HORVW), winter rye (SECCW), winter triticale (TTLWI), ~~winter oats~~ * ~~(AVESW)~~	F	Annual dicotyledonous weeds	spray	BBCH 13-29	1	a) 1.2 b) 1.2	a) Florasulam 0.006 kg as/ha Bifenox 0.576 kg as/ha b) Florasulam 0.006 kg as/ha	200 / 400	F	WH9161 NW607-1 NT108

									Bifenox 0.576 kg as/ha			
002	DE	spring soft wheat (TRZAS), spring barley (HORVS), ~~spring triticale~~ * ~~(TTLSO),~~ common oats (AVESA)	F	Annual dicotyledonous weeds	spray	BBCH 13-29	1	a) 1.0 b) 1.0	a) Florasulam 0.005 kg as/ha Bifenox 0.480 kg as/ha b) Florasulam 0.005 kg as/ha Bifenox 0.480 kg as/ha	200 / 400	F	WH9161 NW607-1 NT103

* crop canceled because missing data on phytotoxicity

Remarks:

(1) Numeration of uses in accordance with the application/as verified by MS
(2) Member State(s) or zone for which use is applied for
(3) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(4) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(5) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds, developmental stages
(6) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(7) Growth stage of treatment(s) (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(8) The maximum number of applications possible under practical conditions of use for each single application and per year (permanent crops) or crop (annual crops) must be provided
(8) Min. interval between applications (days) were relevant
(10) The application rate of the product a) max. rate per appl. and b) max. total rate per crop/season must be given in metric units (e.g. kg or L product / ha)
(11) The application rate of the active substance a) max. rate per appl. and b) max. total rate per crop/season must be given in metric units (e.g. g or kg / ha)
(12) The range (min/max) of water volume under practical conditions of use must be given (L/ha)
(13) PHI - minimum pre-harvest interval
(14) Remarks may include: Extent of use/economic importance/restrictions/minor use etc.

3 Risk management

3.1 Reasoned statement of the overall conclusions taken in accordance with the Uniform Principles

3.1.1 Physical and chemical properties (Part B, Section 1, Points 2 and 4)

Overall Summary:
The product is a homogenous off-white clear suspension, with a characteristic odour. The formulated product is not classified as explosive or as having oxidising properties. AG-FB1-485 SC is not highly flammable, auto-flammable and has no other inherently dangerous similar properties. The pH of the preparation was 6.1 pH units. The formulation is stable for at least 2 years in HDPE packaging. The technical characteristics are acceptable for a suspension concentrate formulation.

Implications for labelling: none

Compliance with FAO specifications:
There are no FAO specifications for bifenox or florasulam.

Compliance with FAO guidelines:
The product AG-FB1-485 SC complies with the general requirements according to the FAO/WHO manual (2010).

Compatibility of mixtures:
No tank mixes are applied for, but the physical and chemical compatibility of AG-FB1-485 SC with different formulations (SC, EC, SL and WG) and AHL has been examined.

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 AG-FB1-485 SC has been provided and is considered to be acceptable.

3.1.2 Methods of analysis (Part B, Section 2, Point 5)

3.1.2.1 Analytical method for the formulation (Part B, Section 2, Point 5.2)

The submitted HPLC method is validated and suitable for the determination of florasulam and bifenox in AG-FB1-485 SC according to SANCO/3030/99 rev. 4.
No CIPAC method is available for florasulam. The CIPAC method for bifenox in SC formulations is CIPAC 413/SC/M/3.
The submitted HPLC method is validated and suitable for the determination of the relevant impurities 2,4-Dichlorophenol and 2,4-Dichloroanisole in AG-FB1-485 SC according to SANCO/3030/99 rev. 4.

3.1.2.2 Analytical methods for residues (Part B, Section 2, Points 5.3 – 5.8)

The assessment of the zRMS is supported:
All provided analytical methods are acceptable.

Bifenox:

Crop / Matrix		Analyte	Method	LOQ	Reference
Plant commodities	All commodity groups	Bifenox	DFG S19, HPLC-MS/MS	0.01 mg/kg	Part B Section 2; IIIA 5.3.1.2 (Method, Validation and ILV)
Animal commodities	Milk, egg, meat, liver, fat, kidney	Bifenox	DFG S19, HPLC-MS/MS	0.01 mg/kg	Part B Section 2; IIIA 5.3.1.2 (Method, Validation and ILV)
Soil		Bifenox	GC-MS	0.02 mg/kg	EFSA Scientific Report (2007) 119
drinking water		Bifenox	GC-ECD conf. by GC-MS	0.05 µg/L	EFSA Scientific Report (2007) 119
surface water		Bifenox	GC-MS	0.1 µg/L	EFSA Scientific Report (2007) 119
		AminoBifenox acid	LC-MS/MS	0.1 µg/L	
Air		Bifenox	GC-ECD	10 µg/m³	EFSA Scientific Report (2007) 119

Florasulam:

Crop / Matrix		Analyte	Method	LOQ	Reference
Plant commodities	All commodity groups	Florasulam	QuEChERS HPLC-MS/MS	0.01 mg/kg	Part B Section 2; IIIA 5.3.1.1 (Method, Validation and ILV)
Animal commodities	Milk, egg, meat, liver, fat	Florasulam	QuEChERS HPLC-MS/MS	0.01 mg/kg	Part B Section 2; IIIA 5.3.1.1 (Method, Validation and ILV)
Soil		Florasulam 5-OH Florasulam	ESP LC-MS/MS	0.05 µg/kg	Monograph
		Florasulam	GC-MS	0.05 µg/kg	Monograph
		Florasulam 5-OH Florasulam	ESP LC-MS	0.05 µg/kg	Monograph
drinking water		Florasulam 5-OH Florasulam	HPLC-UV	0.05 µg/L 0.10 µg/L	Monograph
surface water		Florasulam 5-OH Florasulam	HPLC-UV	0.1 µg/L 0.2 µg/L	Monograph
Air		Florasulam	HPLC-UV	1.5 µg/m³	Monograph

3.1.3 Mammalian Toxicology (Part B, Section 3, Point 7)

If used properly and according to the intended conditions of use, adverse health effects for operators, workers, bystanders and residents will not be expected.

For further details please refer to the registration report of the zonal RMS AT.

3.1.3.1 Acute Toxicity (Part B, Section 3, Point 7.1)

Please refer to the registration report of the zonal RMS AT.

3.1.3.2 Operator Exposure (Part B, Section 3, Point 7.3)

Please refer to the registration report of the zonal RMS AT.

3.1.3.3 Bystander Exposure (Part B, Section 3, Point 7.4)

Please refer to the registration report of the zonal RMS AT.

3.1.3.4 Worker Exposure (Part B, Section 3, Point 7.5)

Please refer to the registration report of the zonal RMS AT.

Implications for labelling resulting from operator, worker, bystander assessments:
None.

3.1.3.5 Groundwater metabolites (Part B, Section 8)

In contrast to the zRMS AT Germany assessed the metabolite TSA it was found in concentrations above 0.1 µg/L. TSA is acceptable in concentrations between 0,1 µg/L and 0,75 µg/L.

3.1.4 Residues and Consumer Exposure (Part B, Section 4, Point 8)

The indended uses in cereals will not result in residues above the MRLs (LOQ) for bifenox and florasulam set in Regulation (EC) No 396/2005. A risk for consumers through the consumption of food possibly containing residues of these active substances is not expected.
For further details please refer to the registration report of the zonal RMS AT.

3.1.4.1 Residues (Part B, Section 4, Points 8.3 and 8.7)

Please refer to the registration report of the zonal RMS AT.

3.1.4.2 Consumer exposure (Part B, Section 4, Point 8.10)

Please refer to the registration report of the zonal RMS AT.

3.1.5 Environmental fate and behaviour (Part B, Section 5, Point 9)

A full exposure assessment for the plant protection product AG-FB1-485 SC in its intended uses in winter cereals is documented in detail in the core assessment of the plant protection product AG-FB1-485 SC dated from December 2013 performed by Austria.
The following chapters summarise specific exposure assessment for soil and surface water and the specific risk assessment for groundwater for the authorization of AG-FB1-485 SC in Germany according to its intended use in cereals (Use No. 00-001 and 00-002).

Metabolites

No new study on the fate and behaviour of florasulam and bifenox has been performed. Hence no potentially new metabolites need to be considered for environmental risk assessment.

Metabolites of florasulam

The risk assessment for the soil metabolites 5-OH-XDE-570, DFP-ASTCA, ASTCA, and TSA of florasulam has already been performed for EU approval (see SANCO/1406/2001-final). Therefore no new risk assessment hence no exposure assessment for these metabolites is necessary.
Potential ground water contamination by the soil metabolites 5-OH-XDE-570, DFP-ASTCA, and ASTCA was evaluated for EU approval of florasulam. PEC_{gw} modelled with FOCUS PELMO (version 3.0). The PEC_{gw} values were less than 0.1 µg/L for the metabolites 5-OH-XDE-570 and DFP-ASTCA and higher than 0.1 µg/L for the metabolite ASTCA in scenario Hamburg based on an application of 7.5 g as/ha (50 % crop interception) in winter wheat on 15th April.
However, the leaching potential into groundwater of the soil metabolites 5-OH-XDE-570, DFP-ASTCA, ASTCA, and TSA will be assessed for the application of the plant protection product and its intended uses.

Metabolites of bifenox

An assessment of the relevance of the metabolites of bifenox (bifenox-acid, aminobifenox and aminobifenox-acid) has been performed in the core assessment, section 6. They are all classified as not relevant. Hence an exposure assessment for national assessment in Germany is not required. However, for the soil metabolite bifenox-acid, occurring in soil at relevant concentrations, national groundwater risk assessment was performed.

3.1.5.1 Predicted Environmental Concentration in Soil (PEC_{soil}) (Part B, Section 5, Points 9.4 and 9.5)

For the intended use of the plant protection product AG-FB1-485 SC in cereals according to use No 00-001 and 00-002 PEC_{soil} was calculated for the active substances florasulam and bifenox considering a soil depth of 2.5 cm (florasulam) and 1 cm (bifenox).
Due to the fast degradation of florasulam and its soil metabolites 5-OH-XDE-570 and DFP-ASTCA in soil (DT90 < 365 d, SFO, laboratory data) their accumulation potential does not need to be considered. Due to the slow degradations of metabolites ASTCA and TSA in soil (DT90> 365 d, Kinetic, laboratory data) their accumulation potential needs to be considered. Therefore, for ASTCA and TSA an accumulated soil concentration (PEC_{accu}) is used for risk assessment that comprises background concentration in soil (PEC_{bkgd}) considering a tillage depth of 20 cm (arable crop) or 5 cm (permanent crops) and the maximum annual soil concentration PEC_{act} for a soil depth of 2.5 cm.
Due to the fast degradation of the active substance bifenox in soil (DT90 < 365 d, SFO, laboratory data) the accumulation potential of bifenox does not need to be considered. Due to the slow degradation of metabolite bifenox-acid in soil (DT90> 365 d, SFO Kinetic, laboratory data) its accumulation potential needs to be considered. Therefore, for bifenox-acid an accumulated soil concentration (PEC_{accu}) is used

for risk assessment that comprises background concentration in soil (PEC_{bkgd}) considering a tillage depth of 20 cm (arable crop) or 5 cm (permanent crops) and the maximum annual soil concentration PEC_{act} for a soil depth of 2.5 cm.
Details are given in Part B National Addendum-Germany, Section5, chapter 5.5.
The results for PEC soil for the active substance and its metabolites were used for the eco-toxicological risk assessment.

3.1.5.2 Predicted Environmental Concentration in Ground Water (PEC_{GW}) (Part B, Section 5, Point 9.6)

Direct leaching into groundwater

According to the results of the groundwater simulation with FOCUS-PELMO 5.5.3, a groundwater contamination of the active substances florasulam and bifenox in concentrations of ≥ 0.1 µg/L is not expected for the intended use in winter and spring cereals.
For the metabolites 5-OH-XDE-570, DFP-ASTCA and ASTCA of florasulam a groundwater concentration of ≥ 0.1 µg/L can be excluded for the application in winter and spring cereals according to the results of the groundwater simulation with FOCUS PELMO 5.5.3. For the metabolite TSA of florasulam a groundwater concentration of ≥ 0.1 µg/L cannot be excluded for the intended uses according to the results of the groundwater simulation with FOCUS PELMO 5.5.3.
For the metabolites bifenox-acid of bifenox a groundwater concentration of ≥ 0.1 µg/L cannot be excluded for the intended use in winter cereals (00-001) according to the results of the groundwater simulation with FOCUS PELMO 5.5.3.
For details see Part B, National Addendum-Germany, Section 5, chapter 5.7.1.

Consequences for authorization:

none

Ground water contamination by bank filtration due to surface water exposure via run-off and drainage

According modelling with EXPOSIT 3.01, groundwater contamination at concentrations ≥ 0.1 µg/L by the active substances florasulam and bifenox and its soil metabolites due to surface run-off and drainage into the adjacent ditch with subsequent bank filtration can be excluded for the intended use in cereals (00-001 and 00-002).
For details see Part B, National Addendum-Germany, Section 5, chapter 5.7.2.

Consequences for authorization:

none

3.1.5.3 Predicted Environmental Concentration in Surface Water (PEC_{SW}) (Part B, Section 5, Points 9.7 and 9.8)

For the intended use of the plant protection product AG-FB1-485 SC in cereals according to use No 00-001 and 00-002 PECsw was calculated for the active substances florasulam and bifenox considering the two routes of entry (i) spraydrift and volatilization with subsequent deposition and (ii) run-off, drainage separately.
The calculation of concentrations in surface water is based on spray drift data by Rautmann and Ganzelmeier. The vapour pressures at 20 °C of the active substances florasulam and bifenox are < 10^{-5} Pa. Hence the active substances florasulam and bifenox are regarded as non-volatile. Therefore exposure of surface water by the active substances florasulam and bifenox due to deposition following volatilization does not need to be considered.

The concentration of the active substances florasulam and bifenox in adjacent ditch due to surface runoff and drainage is calculated using the model EXPOSIT 3.01.
Details are given in Part B, National Addendum-Germany, Section5, chapter 5.6.
The results for PEC surface water for the active substance and its metabolites were used for the eco-toxicological risk assessment.

3.1.5.4 Predicted Environmental Concentration in Air (PEC_{Air}) (Part B, Section 5, Point 9.9)

Not calculated – due to low volatility and rapid photochemical oxidative degradation of florasulam and bifenox in air.

Implications for labelling resulting from environmental fate assessment

For the authorization of the plant protection product AG-FB1-485 SC following labeling and conditions of use are mandatory:

Classification and labelling

Based on the data on the active substances florasulam and bifenox the plant protection product AG-FB1-485 SC is considered to be not readily degradable in the sense of the CLP regulation.

Standard Phrases for special risks and safety precautions under Regulation (EU) 547/2011 Annex II and III / conditions of use

none

Further data requirements:

none

3.1.6 Ecotoxicology (Part B, Section 6, Point 10)

A full risk assessment according to Uniform Principles for the plant protection product AG-FB1-485 SC in its intended uses in winter and spring cereals is documented in detail in the core assessment of the plant protection product AG-FB1-485 SC dated from December 2013 performed by zRMS Austria. The intended use of AG-FB1-485 SC in Germany is generally covered by the uses evaluated in the course of the core assessment by Austria.
The following chapters summarise specific risk assessment for non-target organisms and hence risk mitigation measures for the authorization of AG-FB1-485 SC in Germany according to its intended use in winter and spring cereals (use No.00-001; 00-002).

3.1.6.1 Effects on Terrestrial Vertebrates (Part B, Section 6, Points 10.1 and 10.3)

The risk assessment for effects on birds and other terrestrial vertebrates was carried out according to the European Food Safety Authority Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438).
Based on the risk assessment by zRMS Austria, the calculated TER values for the acute and long-term risk resulting from an exposure of birds and mammals to the active substance bifenox and florasulam according to the intended use of the formulation AG-FB1-485 SC in cereals achieve the acceptability criteria TER ≥ 10 and TER ≥ 5, respectively, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for birds.
For details see Part B, National Addendum-Germany, Section 6, chapters 6.2 and 6.3.

Consequences for authorization:
None

3.1.6.2 Effects on Aquatic Species (Part B, Section 6, Point 10.2)

Results of aquatic risk assessment for the intended for uses of AG-FB1-485 SC in winter and spring based on FOCUS Surface Water PEC values is presented in the core assessment, Part B, Section 6, chapter 6.4.
For authorization in Germany, exposure assessment of surface water considers the two routes of entry (i) spraydrift and volatilization with subsequent deposition and (ii) run-off, drainage separately in order to allow risk mitigation measures separately for each entry route.

Exposure by spraydrift and deposition following volatilization

Based on the relevant toxicity of the AG-FB1-485 SC, the calculated TER values for the risk to aquatic organism resulting from an exposure of surface water by spraydrift to AG-FB1-485 SC according to the use No 00-001 does not achieve the acceptability criteria of TER ≥ 10, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. However, considering additional information from available mesocosm studies as well as additional considerations on the time dependence of effects and the exposure regime in experimental studies, the TER of 9.18 for Ind. 00-001 is considered acceptable and the risk is considered acceptable if appropriate risk mitigation measures (20 m buffer strip and 90 % drift reducing technique) are applied.
Regarding use No 00-002 the calculated TER values only achieve the acceptability criteria of TER ≥ 10, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2 if appropriate risk mitigation measures (20 m buffer strip and 90 % drift reducing technique) are applied.

For details see Part B, National Addendum-Germany, Section 6, chapters 6.4.3.

Exposure by surface run-off and drainage

The concentration of the active substances bifenox and florasulam in adjacent ditch due to surface runoff and drainage was calculated using the model EXPOSIT 3.01.
The calculated TER values for the risk to aquatic organisms resulting from an exposure of surface water by the active substances bifenox and florasulam due to run-off and drainage according to the use No 00-001 and 00-002 achieve the acceptability criteria of TER ≥ 2 or 10 respectively, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. Risk mitigation measures do not need to be applied.
For details see Part B, National Addendum-Germany, Section 6, chapters 6.4.4.

Consequences for authorization:

For the authorization of the plant protection product AG-FB1-485 SC the following labelling and conditions of use are mandatory:

Required Labelling

NW 262	AG-FB1-485 SC: *Pseudokirchneriella sub.* NOEC < 0.001mg/L
NW 264	Bifenox: z.B. *Oncorhynchus mykiss* LC50 = 0.67 mg/L *Daphnia magna* EC50 = 0.66 mg/L
NW 265	AG-FB1-485 SC: *Lemna gibba* NOEC = 0.001 mg/L

Safety precautions / Conditions of use

AG-FB1-485 SC	NW 468
All uses	NW607-1 (90% drift reduction, 20m buffer)

3.1.6.3 Effects on Bees and Other Arthropod Species (Part B, Section 6, Points 10.4 and 10.5)

Bees

Toxicity
Table 3.1.6.3-1 presents the LD50 values for honeybees.

Table 3.1.6.3-1: Toxicological data for honeybees

Test substance	Endpoint	Reference
Florasulam	48 h Oral LD_{50} > 100 µg a.s./bee 48 h Contact LD_{50} > 100 µg a.s./bee	SANCO/1406/2001 – final; 2002
Bifenox	72 h Oral LD_{50} > 200 µg a.s./bee 48 h Contact LD_{50} > 200 µg a.s./bee	EFSA Scientific Report 119, 2007
AG-FB1-485 SC	Oral LD_{50} > 285 µg product/bee Contact LD_{50} > 243 µg product/bee	Vergé, E. 2012; 90015378

Risk Assessment

Exposure

Applications of pesticides can potentially result in exposure of honeybees either through direct over-spray, or by contact with residues on plants whilst bees are foraging for food.

Hazard quotients for bees

The acute risk to honeybees from use of AG-FB1-485 SC was assessed using the maximum single application rate and the LD_{50} values to calculate hazard quotients (EPPO 2003) as follows:

$$Hazard\ Quotient = \frac{Maximum\ application\ rate\ [g\ product/ha]}{Acute\ LD_{50}\ [\mu g\ product/bee]}$$

Hazard quotients were calculated for oral exposure (QH_O) and contact exposure (QH_C) to AG-FB1-485 SC. A hazard quotient of less than 50 indicates a low risk to bees in the field.

The risk assessments are presented in Table 3.1.6.3-2.

Table 3.1.6.3-2: Risk to honeybees from exposure to **Fehler! Verweisquelle konnte nicht gefunden werden.**, bifenox and AG-FB1-485 SC

Test substance	Application rate [g a.s./ha]	LD_{50} [µg a.s./bee]		Hazard quotient
Florasulam	6	Oral	> 100	< 0.06
		Contact	> 100	< 0.06
Bifenox	576	Oral	> 200	< 2.88
		Contact	> 200	< 2.88
AG-FB1-485 SC	1419.6 g product/ha[a)]	Oral	> 285 product/bee	< 4.98
		Contact	> 243 product/b	< 5.84

[a)] based on a max. application rate of 1.2 L product/ha and a product density of 1.183 g/mL

Conclusions

All hazard quotients are considerably less than 50, indicating an acceptable risk to bees from the application of AG-FB1-485 SC in accordance with the intended worst-case uses.
Label NB6641 will be assigned to the product.

Other non-target arthropods

Based on the calculated rates of AG-FB1-485 SC in off-field areas under the implementation of 1 m vegetated buffer strip and 90 % drift reduction, the calculated TER values describing the risk resulting from an exposure of non-target arthropods to AG-FB1-485 SC according to the GAP of the formulation AG-FB1-485 SC achieve the acceptability criteria TER ≥ 10, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for non-target arthropods due to the intended use of AG-FB1-485 SC in winter and spring cereals according to the label.
For details please refer to the core assessment Part B, section 6, chapter 6.6.

Consequences for authorization:

For the authorization of the plant protection product AG-FB1-485 SC the following labelling and conditions of use are mandatory:

Safety precautions / Conditions of use

All uses	NT103 (90 % drift reduction)

3.1.6.4 Effects on Earthworms and Other Soil Macro-organisms (Part B, Section 6, Point 10.6)

Based on the predicted concentrations of AG-FB1-485 SC in soils, the TER values describing the acute and longterm risk for earthworms and other non-target soil organisms following exposure to AG-FB1-485 SC according to the GAP of the formulation AG-FB1-485 SC achieve the acceptability criteria TER ≥ 10 resp. TER ≥ 5 according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for soil organisms due to the intended use of AG-FB1-485 SC in winter and spring according to the label.
For details please refer to the core assessment Part B, section 6, chapter 6.7.

Consequences for authorization:

None

3.1.6.5 Effects on organic matter breakdown (Part B, Section 6, Point 10.6)

Since no risk was identified for soil fauna, soil micro-organisms and non-target arthropods from the use of AG-FB1-485 SC in winter and spring cereals, data on the effects on organic matter breakdown (litterbag) is not required.
For details please refer to the core assessment Part B, section 6, chapter 6.7.

Consequences for authorization:

None

3.1.6.6 Effects on Soil Non-target Micro-organisms (Part B, Section 6, Point 10.7)

Based on the predicted concentrations of AG-FB1-485 SC in soils, the risk to soil microbial processes following exposure to AG-FB1-485 SC according to the GAP of the formulation AG-FB1-485 SC is considered to be acceptable/ not acceptable according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2.
For details please refer to the core assessment Part B, section 6, chapter 6.8.

Consequences for authorization:

None

3.1.6.7 Assessment of Potential for Effects on Other Non-target Organisms (Flora and Fauna) (Part B, Section 6, Point 10.8)

Non-Target Plants

Based on the predicted rates of AG-FB1-485 SC in off-field areas, the TER values describing the risk for non-target plants following exposure to AG-FB1-485 SC according to the GAP of the formulation AG-FB1-485 SC achieve the acceptability criteria TER ≥ 10 according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. The results of the

assessment indicate an acceptable risk for non-target terrestrial plants due to the intended use of AG-FB1-485 SC in winter and spring cereals according to the label.
For details please refer to the core assessment Part B, section 6, chapter 6.9.

Consequences for authorization

For the authorization of the plant protection product AG-FB1-485 SC following labelling and conditions of use are mandatory:

Safety precautions / Conditions of use

Use No. 00-001	NT 108 (75% drift reduction technique and 5 m)
Use No. 00-002	NT 103 (90% drift reduction technique)

Implications for labelling resulting from ecotoxicological assessment:

For the authorization of the plant protection product AG-FB1-485 SC the following labelling and conditions of use are mandatory:

Classification and labelling

Relevant toxicity	AG-FB1-485 SC EyC50 = 0.00065 mg product/L (*Lemna gibba*) NOEC = 0.00016 mg product/L
Classification and labelling according to Regulation 1272/2008	
Hazard sysmbol	GHS09
Signal word	Warning
Hazard statement	H400, H410

Standard Phrases for special risks and safety precautions under Regulation (EU) 547/2011 Annex II and III / conditions of use

All uses:

NW 468 — Fluids left over from application and their remains, products and their remains, empty containers and packaging, and cleansing and rinsing fluids must not be dumped in water. This also applies to indirect entry via the urban or agrarian drainage system and to rain-water and sewage canals.

NW607-1 — When applying the product on areas adjacent to surface waters - except only occasionally but including periodically water bearing surface waters - the product must be applied with equipment which is registered in the index of 'Loss Reducing Equipment' of 14 October 1993 ('Bundesanzeiger' [Federal Gazette] No 205, p. 9780) as amended. Depending on the drift reduction classes for the equipment stated below, the following buffer zones must be kept from surface waters. In addition to the minimum buffer zone from surface waters stipulated by state law, the ban on application in or in the immediate vicinity of waters must be observed at all times for drift reduction classes marked with "*". Violations may be punished by fines of up to 50 000 EUR.

Drift reduction 90%, 20 m buffer

Use No. 00-001:

NT 108 — A buffer zone of at least 5 m must be kept from adjacent areas (except agriculturally or horticulturally used areas, roads, paths and public places). In addition, in an adjoining strip of at least 20 m, the product must be applied using loss reducing equipment which is registered in the index of 'Loss Reducing Equipment' of 14 October 1993 (Federal Gazette No 205, p. 9780) as amended, and be registered in at least drift reducing class 75 %. Neither loss reducing equipment nor a buffer zone of at least 5 m are required if the product is applied with portable plant protection equipment or if adjacent areas (field boundaries, hedges, groups of woody plants) are less than 3 m wide. A buffer zone of at least 5 m is also unnecessary if the product is applied in an area which has been declared by the Biologische Bundesanstalt in the "Index of regional proportions of ecotones" of 7 February 2002 (Federal Gazette no. 70 a of 13 April 2002), as amended, as agrarian landscape with a sufficient proportion of natural and semi-natural structures, or if evidence can be shown that adjacent areas (e.g. field boundaries, hedges, groups of woody plants) were planted on agriculturally or horticulturally used areas.

Use No. 00-002:

NT 103	In a strip at least 20 m wide which is adjacent to other areas, the product must be applied using loss reducing equipment which is registered in the index of 'Loss Reducing Equipment' of 14 October 1993 (Federal Gazette No 205, p. 9780) as amended, and be registered in at least drift reducing class 90 % (except agriculturally or horticulturally used areas, roads, paths and public places). Loss reducing equipment is not required if the product is applied with portable plant protection equipment or if adjacent areas (field boundaries, hedges, groups of woody plants) are less than 3 m wide or the product is applied in an area which has been declared by the Biologische Bundesanstalt in the "Index of regional proportions of ecotones" of 7 February 2002 (Federal Gazette no. 70 a of 13 April 2002), as amended, as agrarian landscape with a sufficient proportion of natural and semi-natural structures.

Other labels:

NW262	The product is toxic for algae.
NW264	The product is toxic for fish and aquatic invertebrates.
NW265	The product is toxic for higher aquatic plants.

3.1.7 Efficacy (Part B, Section 7, Point 8)

Information on the active substances

Bifenox is a selective herbicide to be used mainly in small grain cereals and oil seed rape for the control of dicotyledonous weeds. Bifenox belongs to the chemical group of dichlorphenoxybenzoeacid derivates and diphenyl-ethers. It is absorbed by foliage, emerging shoots and roots, with limited translocation from roots and foliage to shoots. Susceptible weed seedlings become necrotic and finally get withered. Bifenox is selective in cereals and oil seed rape. It provides limited residual activity only. Bifenox acts as an inhibitor of protoporphyrinogen oxidase (HRAC Group: E).
Label applied: WME

Florasulam is a selective herbicide to be used in small grain cereals for the control of broad-leaved weeds. Florasulam is primarily adsorbed by shoots but in part also by roots. It is acropetally and basipetally translocated to meristems and stops cell division and plant growth. Florasulam belongs to the chemical group of triazolopyrimidine herbicides also called sulfonamide herbicides. It acts as an inhibitor of the acetolactate synthetase, inhibiting the essential amino acids valine and isoleucine (HRAC Group: B).
Label applied: WMB

Efficacy

Based on results achieved in 19 trials in winter cereals and in 11 trials in spring cereals, it can be concluded that for the control of annual broad-leaved weeds the intended dose rates of 1.2 L/ha AG-FB1-485 SC in winter cereals and 1.0 L/ha in spring cereals are sufficiently effective and are required for the provision of a most consistent control of susceptible annual broad-leaved weed species.
For some annual dicotyledonous weeds, which are described on the label as being controlled well, only a few or no efficacy results have been submitted, so that a reliable evaluation of these weed species is not possible.
Therefore and due to the fact that cereals respond sensitively to herbicides, the restriction WH9161 (The instructions for use must include a summary of weeds which can be controlled well, less well and insufficiently by the product, as well as a list of species and/or varieties showing which crops are tolerant of the intended application rate and which are not.) is assigned to the product.

Phytotoxicity

Overall 25 selectivity trials in winter cereals and 15 trials in spring cereals including yield were carried out in Germany. The values revealed no detrimental effects on yield.
All tested winter cereals were selective to AG-FB1-485 SC applied at 1.2 L/ha and the double rate of 2.4 L/ha. For winter rye in one trial high max values of 10% were assessed.
In spring cereals AG-FB1-485 SC caused plant injuries immediate after application (<14 DA-A) in spring barley and oats (chlorosis and bleaching effects). These effects were transient and later on symptoms were no longer visible. Spring wheat was fully selective to AG-FB1-485 SC applied at 1.2 L/ha and 2.4 L/ha.
Results of winter oat and spring triticale are not available. Consequently, selectivity of AG-FB1-485 SC in these crops was not assessed. Because of the missing data, winter oat and spring triticale are not listed in the GAP-table.

Succeeding crops

Regarding possible negative impacts of AG-FB1-485 SC on succeeding crops, the applicant provided an EC_{10} study (soil mix test) conducted with AG-FB1-485 SC. In addition an estimation of the degradation of the product was performed. Based on both data, TER values > 1 demonstrate that all crops can be sown safely 30 DA-A.

Adjacent crops

The applicant provided two studies, vegetative vigour test and seedling emergence test, to prove if there are no detrimental effects on adjacent crops. The values which were presented in the BAD revealed no damages on the neighbouring crops (TER >1). All crops are safe with the intended doses of 1.2 L/ha (winter cereals) and 1.0 L/ha (spring cereals).

Resistance

Taking into consideration inherent and agronomic risks, the risk for the development of resistant biotypes is considered medium to high. Due to that, the restriction WH951 (The risk of resistance has to be indicated on the package and in the instructions of use. Particularly measures for an appropriate risk management have to be declared.) is assigned to the product.

Beneficial arthropods

On the basis of the results of an aged residue test, the test product can be considered as harmful for the predatory mite *Typhlodromus pyri*. Further, a *Typhlodromus pyri* aged residue study did not show recovery to < 50% effect at the higher rate of 1500 mL/ha within 49 days (corrected mortality 79.9%). The results for this sensitive indicator species indicate that the test product is potentially harmful for relevant predatory mites and spiders.
The test product had no lethal effect on the parasitoid wasp *Aphidius rhopalosiphi*. However, sublethal effects were not investigated. For the insect species *Chrysoperla carnea* the results of an aged residue test showed effects < 25% on fresh residues of the product. However for the rove beetle *Aleochara bilineata* AG-FB1-485 SC caused a statistically significant reduction on the reproductive capacity compared to control at rates of 500 mL and 1500 mL product/ha (Dunnett's t- Test, one-sided, $\alpha = 0.05$).
Consequently, labels NN2001 and NN3002 are assigned to the product.

3.2 Conclusions

With respect to physical, chemical and technical properties of the formulation an authorisation can be granted.

With respect to analytical methods (formulation and residues) an authorisation can be granted.
Regards efficacy/IPM and sustainable use an authorization can be granted for AG-FB1-485 SC, a suspension concentrate containing 5 g/L florasulam and 480 g/L bifenox, for use in winter and spring cereals to control annual dicot weeds. However, transient in-field effects on beneficial arthropods may occur.

With respect to toxicology, residues and consumer protection an authorisation can be granted.

With respect to fate and ecotoxicology assessment, an authorisation can be granted. Considering an application in accordance with the evaluated use pattern and good agricultural practice as well as strict observance of the conditions of use no harmful effects on groundwater or adverse effects on the ecosystem are to be apprehended.

An authorisation can be granted.

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

No further information required.

Appendix 1 – Copy of the product authorisation

See below.

Appendix 2 – Copy of the product label

The submitted draft product label has been checked by the competent authority. The applicant is requested to amend the product label in accordance with the decisions made by the competent authority. The final version of the label has to fulfil the requirements according to Article 16 of Directive 91/414/EEC.

Appendix 3 – Letter of Access

Letter(s) of access is/are classified as confidential and, thus, are not attached to this document.

Bundesamt für
Verbraucherschutz und
Lebensmittelsicherheit

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit
Dienstsitz Braunschweig • Postfach 15 64 • 38005 Braunschweig

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IHR ZEICHEN
IHRE NACHRICHT VOM

AKTENZEICHEN (bitte bei Antwort angeben) 200.22100.007818-00/00.76995

DATUM 11. April 2016

ZV3 007818-00/00

AG-FB1-485 SC

Zulassungsverfahren für Pflanzenschutzmittel

Bescheid

Das oben genannte Pflanzenschutzmittel

mit den Wirkstoffen:	480 g/l 5 g/l	Bifenox Florasulam
Zulassungsnummer:	007818-00	
Versuchsbezeichnungen:	ADD-03781-H-0-SC	
Antrag vom:	17. Dezember 2012	

wird auf der Grundlage von Art. 29 der Verordnung (EG) Nr. 1107/2009 des Europäischen Parlaments und des Rates vom 21. Oktober 2009 über das Inverkehrbringen von Pflanzenschutzmitteln und zur Aufhebung der Richtlinien 79/117/EWG und 91/414/EWG des Rates (ABl. L 309 vom 24.11.2009, S. 1), wie folgt zugelassen:

Zulassungsende

Die Zulassung endet am 31. Dezember 2019.

Festgesetzte Anwendungsgebiete bzw. Anwendungen

Es werden folgende Anwendungsgebiete bzw. Anwendungen festgesetzt (siehe Anlage 1):

BVL_FO_05_2437_200_V1.7

Anwendungs-nummer	Schadorganismus/ Zweckbestimmung	Pflanzen/-erzeugnisse/ Objekte	Verwendungszweck
007818-00/00-002	Einjährige zweikeim-blättrige Unkräuter	Sommerweichweizen, Sommergerste, Sommerhafer	
007818-00/00-001	Einjährige zweikeim-blättrige Unkräuter	Winterweichweizen, Wintergerste, Winterroggen, Wintertriticale	

Festgesetzte Anwendungsbestimmungen

Es werden folgende Anwendungsbestimmungen gemäß § 36 Abs. 1 S. 1 des Gesetzes zum Schutz der Kulturpflanzen (Pflanzenschutzgesetz - PflSchG) vom 6. Februar 2012 (BGBl. I S. 148, 1281), zuletzt geändert durch Artikel 375 der Verordnung vom 31. August 2015 (BGBl. I S. 1474), festgesetzt:

(NW468)
Anwendungsflüssigkeiten und deren Reste, Mittel und dessen Reste, entleerte Behältnisse oder Packungen sowie Reinigungs- und Spülflüssigkeiten nicht in Gewässer gelangen lassen. Dies gilt auch für indirekte Einträge über die Kanalisation, Hof- und Straßenabläufe sowie Regen- und Abwasserkanäle.
Begründung:
Aufgrund der Auswirkungen der Wirkstoffe Bifenox und Florasulam gegenüber aquatischen Organismen besitzt das Pflanzenschutzmittel "AG-FB1-485 SC" einen den Naturhaushalt schädigenden Charakter, so dass jeder weitergehende, d.h. den als Folge der sachgerechten und bestimmungsgemäßen Anwendung des o.g. Pflanzenschutzmittels übersteigende Eintrag von Rückständen in Gewässer zu einer erheblichen Gefährdung des Naturhaushaltes führen würde. Angesichts der Umstände, dass ein erheblicher Anteil an Pflanzenschutzmittelfrachten im einzelnen Gewässer auf Einträge aus kommunalen Kläranlagen zurückzuführen ist (vgl. Umweltpolitik - Wasserwirtschaft in Deutschland, 10.5.2 Pestizide, S. 156 ff., BMU, Februar 1998 und Fischer, Bach, Frede: Abschlussbericht zum DBU-Projekt 09931, April 1998), ist es unverzichtbar, der Gefahr, die eine Verbringung von Pflanzenschutzmitteln in Gewässer mit sich bringt, durch die bußgeldbewehrte Anwendungsbestimmung im Sinne der Zweckbestimmung des Pflanzenschutzgesetzes durchsetzbar zu begegnen.

Siehe anwendungsbezogene Anwendungsbestimmungen in Anlage 1, jeweils unter Nr. 3.

Verpackungen

Gemäß § 36 Abs. 1 S. 2 Nr. 1 PflSchG sind für das Pflanzenschutzmittel die nachfolgend näher beschriebenen Verpackungen für den beruflichen Anwender zugelassen:

Verpackungs-art	Verpackungs-material	Anzahl		Inhalt		
		von	bis	von	bis	Einheit
Kanister	HDPE	1		1,00	10,00	l

Die Verpackungen für den beruflichen Anwender sind wie folgt zu kennzeichnen:
Anwendung nur durch berufliche Anwender zulässig.

Auflagen

Die Zulassung wird mit folgenden Auflagen gemäß § 36 Abs. 3 S. 1 PflSchG verbunden:

Kennzeichnungsauflagen:

(NN2001)
Das Mittel wird als schwach schädigend für Populationen relevanter Nutzinsekten eingestuft.

(NN3002)
Das Mittel wird als schädigend für Populationen relevanter Raubmilben und Spinnen eingestuft.

(NW262)
Das Mittel ist giftig für Algen.

(NW264)
Das Mittel ist giftig für Fische und Fischnährtiere.

(NW265)
Das Mittel ist giftig für höhere Wasserpflanzen.

(SB001)
Jeden unnötigen Kontakt mit dem Mittel vermeiden. Missbrauch kann zu Gesundheitsschäden führen.

(SB005)
Ist ärztlicher Rat erforderlich, Verpackung oder Etikett des Produktes bereithalten.

(SB010)
Für Kinder unzugänglich aufbewahren.

(SB110)
Die Richtlinie für die Anforderungen an die persönliche Schutzausrüstung im Pflanzenschutz

"Persönliche Schutzausrüstung beim Umgang mit Pflanzenschutzmitteln" des Bundesamtes für Verbraucherschutz und Lebensmittelsicherheit ist zu beachten.

(SB166)
Beim Umgang mit dem Produkt nicht essen, trinken oder rauchen.

(SF245-01)
Behandelte Flächen/Kulturen erst nach dem Abtrocknen des Spritzbelages wieder betreten.

(SS110)
Universal-Schutzhandschuhe (Pflanzenschutz) tragen beim Umgang mit dem unverdünnten Mittel.

(SS206)
Arbeitskleidung (wenn keine spezifische Schutzkleidung erforderlich ist) und festes Schuhwerk (z.B. Gummistiefel) tragen bei der Ausbringung/Handhabung von Pflanzenschutzmitteln.

(SS2101)
Schutzanzug gegen Pflanzenschutzmittel und festes Schuhwerk (z.B. Gummistiefel) tragen beim Umgang mit dem unverdünnten Mittel.

(SS530)
Gesichtsschutz tragen beim Umgang mit dem unverdünnten Mittel.

(SS610)
Gummischürze tragen beim Umgang mit dem unverdünnten Mittel.

(WMB)
Wirkungsmechanismus (HRAC-Gruppe): B

(WME)
Wirkungsmechanismus (HRAC-Gruppe): E

Siehe anwendungsbezogene Kennzeichnungsauflagen in Anlage 1, jeweils unter Nr. 2.

Sonstige Auflagen:
(WH951)

Auf der Verpackung und in der Gebrauchsanleitung ist auf das Resistenzrisiko hinzuweisen. Insbesondere sind Maßnahmen für ein geeignetes Resistenzmanagement anzugeben.

Vorbehalt

Dieser Bescheid wird mit dem Vorbehalt der nachträglichen Aufnahme, Änderung oder Ergänzung von Anwendungsbestimmungen und Auflagen verbunden.

Angaben zur Einstufung und Kennzeichnung gemäß Verordnung (EG) Nr. 1272/2008

Signalwort:

(S1) Achtung

Gefahrenpiktogramme:

(GHS09) Umwelt

Gefahrenhinweise (H-Sätze):

(EUH 208-0098)

Enthält 1,2-Benzisothiazol-3(2H)-on. Kann allergische Reaktionen hervorrufen.

(EUH 401)

Zur Vermeidung von Risiken für Mensch und Umwelt die Gebrauchsanleitung einhalten.

(H400)

Sehr giftig für Wasserorganismen.

(H410)

Sehr giftig für Wasserorganismen mit langfristiger Wirkung.

Sicherheitshinweise (P-Sätze):

(P501)

Inhalt/Behälter ... zuführen.

Abgelehnte Anwendungsgebiete bzw. Anwendungen

Für folgende Anwendungsgebiete bzw. Anwendungen lehne ich Ihren Antrag ab (siehe Anlage 2):

- keine -

Hinweise

Auf dem Etikett und in der Gebrauchsanleitung kann angegeben werden:

(NB6641)

Das Mittel wird bis zu der höchsten durch die Zulassung festgelegten Aufwandmenge oder Anwendungskonzentration, falls eine Aufwandmenge nicht vorgesehen ist, als nicht bienengefährlich eingestuft (B4).

Weitere Hinweise und Bemerkungen

Zu KIIA 1.11, KIIA 4.2.3, KIIIA1 5.2.4

Spätestens mit der nächsten Beantragung eines Mittels mit dem Wirkstoff Florasulam sind folgende Unterlagen vorzulegen:

- Eine 5-Batchanalyse, in der auch die relevante Verunreinigung 2,6-DFA (2,6-Difluoranilin) untersucht wird.
- Eine validierte Analysemethode zur Bestimmung von 2,6-DFA im technischen Material
- Eine validierte Analysemethode zur Bestimmung von 2,6-DFA im Mittel

Begründung:

Mit der Verordnung (EU) 2015/1397 wurde für die relevante Verunreinigung 2,6-DFA (2,6-Difluoranilin) ein Maximalgehalt von 2 g/kg festgesetzt. Entsprechende Unterlagen wurden bisher nicht vorgelegt.

Zu KIIIA1 6.2.8:

Hinweis und Begründung für die Kennzeichnungsauflage zum Wirkungsmechanismus (WME: Bifenox; WMB: Florasulam):

Die HRAC-Klassifizierung ist als neutrale Information direkt jedem einzelnen Wirkstoff (hier: Bifenox und Florasulam) zuzuordnen. Die Kennzeichnung erleichtert der Praxis die Bestimmung des Wirkungsmechanismus von Herbiziden und ermöglicht so ein gezieltes Wirkstoffmanagement.

Vorsorglich weise ich darauf hin, dass bisher mitgeteilte Forderungen bestehen bleiben, soweit sie noch nicht erfüllt sind.

Unterbleibt eine Beanstandung der vorgelegten Gebrauchsanleitung, so ist daraus nicht zu schließen, dass sie als ordnungsgemäß angesehen wird. Die Verantwortung des Zulassungsinhabers für die Übereinstimmung mit dem Zulassungsbescheid bleibt bestehen.

Hinsichtlich der Gebühren erhalten Sie einen gesonderten Bescheid.

Rechtsbehelfsbelehrung

Gegen diesen Bescheid kann innerhalb eines Monats nach Bekanntgabe Widerspruch erhoben werden. Der Widerspruch ist bei dem Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Messeweg 11/12, 38104 Braunschweig, schriftlich oder zur Niederschrift einzulegen.

Mit freundlichen Grüßen
im Auftrag

gez. Dr. Martin Streloke
Abteilungsleiter

Dieses Schreiben wurde maschinell erstellt und ist daher ohne Unterschrift gültig.

Anlage

Anlage 1 zugelassene Anwendung: 007818-00/00-001

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung:	Einjährige zweikeimblättrige Unkräuter
Pflanzen/-erzeugnisse/Objekte:	Winterweichweizen, Wintergerste, Winterroggen, Wintertriticale
Verwendungszweck:	

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Ackerbau
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Nein
Stadium der Kultur:	13 bis 29
Anwendungszeitpunkt:	Nach dem Auflaufen, Frühjahr
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	1
- für die Kultur bzw. je Jahr:	1
Anwendungstechnik:	spritzen
Aufwand:	
-	1,2 l/ha in 200 bis 400 l Wasser/ha

2.2 Sonstige Kennzeichnungsauflagen

(WH9161)
In die Gebrauchsanleitung ist eine Zusammenstellung der Unkräuter aufzunehmen, die durch die Anwendung des Mittels gut, weniger gut und nicht ausreichend bekämpft werden, sowie eine Arten- und/oder Sortenliste der Kulturpflanzen, für die der vorgesehene Mittelaufwand verträglich oder unverträglich ist.

2.3 Wartezeiten

(F)	Freiland: Winterweichweizen Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

(F)	Freiland: Wintergerste Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.
(F)	Freiland: Winterroggen Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.
(F)	Freiland: Wintertriticale Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

3 Anwendungsbezogene Anwendungsbestimmungen

(NT108)
Bei der Anwendung des Mittels muss ein Abstand von mindestens 5 m zu angrenzenden Flächen (ausgenommen landwirtschaftlich oder gärtnerisch genutzte Flächen, Straßen, Wege und Plätze) eingehalten werden. Zusätzlich muss die Anwendung in einer darauf folgenden Breite von mindestens 20 m mit einem verlustmindernden Gerät erfolgen, das in das Verzeichnis "Verlustmindernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung, mindestens in die Abdriftminderungsklasse 75 % eingetragen ist.
Bei der Anwendung des Mittels ist weder der Einsatz verlustmindernder Technik noch die Einhaltung eines Abstandes von mindestens 5 m erforderlich, wenn die Anwendung mit tragbaren Pflanzenschutzgeräten erfolgt oder angrenzende Flächen (z. B. Feldraine, Hecken, Gehölzinseln) weniger als 3 m breit sind. Bei der Anwendung des Mittels ist ferner die Einhaltung eines Abstandes von mindestens 5 m nicht erforderlich, wenn die Anwendung des Mittels in einem Gebiet erfolgt, das von der Biologischen Bundesanstalt im "Verzeichnis der regionalisierten Kleinstrukturanteile" vom 7. Februar 2002 (Bundesanzeiger Nr. 70a vom 13. April 2002) in der jeweils geltenden Fassung, als Agrarlandschaft mit einem ausreichenden Anteil an Kleinstrukturen ausgewiesen worden ist oder angrenzende Flächen (z. B. Feldraine, Hecken, Gehölzinseln) nachweislich auf landwirtschaftlich oder gärtnerisch genutzten Flächen angelegt worden sind.
Begründung:
Das o.g. Pflanzenschutzmittel weist ein hohes Gefährdungspotenzial für terrestrische Nichtzielpflanzen auf. Bewertungsbestimmend ist hier die ER50 von 29,9 mL Produkt/ha für Tomaten (Lycopersicon esculentum) im Vegetative Vigour Test. Ausgehend von den geltenden

Modellen zur Abdrift und einem Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnisse die o.g. Anwendungsbestimmung erforderlich, um einen ausreichenden Schutz von terrestrischen Nichtzielpflanzen in Saumbiotopen zu gewährleisten. Weitere Informationen hierzu sind dem nationalen Addendum zum Part B des Draft Registration Report zu entnehmen.

(NW607-1)
Die Anwendung des Mittels auf Flächen in Nachbarschaft von Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - muss mit einem Gerät erfolgen, das in das Verzeichnis "Verlustmindernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung eingetragen ist. Dabei sind, in Abhängigkeit von den unten aufgeführten Abdriftminderungsklassen der verwendeten Geräte, die im Folgenden genannten Abstände zu Oberflächengewässern einzuhalten. Für die mit "*" gekennzeichneten Abdriftminderungsklassen ist, neben dem gemäß Länderrecht verbindlich vorgegebenen Mindestabstand zu Oberflächengewässern, das Verbot der Anwendung in oder unmittelbar an Gewässern in jedem Fall zu beachten. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.
reduzierter Abstand: 90 % 20 m
<u>Begründung:</u>
Das o.g. Pflanzenschutzmittel weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Algen und aquatische Wasserpflanzen auf. Bewertungsbestimmend ist hier die EC50 für aquatische Wasserpflanzen (Lemna gibba) von 0,65 µg Produkt/L. Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnisse die o.g. Anwendungsbestimmung erforderlich, um einen ausreichenden Schutz von Gewässerorganismen zu gewährleisten. Weitere Informationen hierzu sind dem nationalen Addendum zum Part B des Draft Registration Report zu entnehmen.

Anlage 1 zugelassene Anwendung: 007818-00/00-002

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung:	Einjährige zweikeimblättrige Unkräuter
Pflanzen/-erzeugnisse/Objekte:	Sommerweichweizen, Sommergerste, Sommerhafer
Verwendungszweck:	

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Ackerbau
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Nein
Stadium der Kultur:	13 bis 29
Anwendungszeitpunkt:	Nach dem Auflaufen, Frühjahr
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	1
- für die Kultur bzw. je Jahr:	1
Anwendungstechnik:	spritzen
Aufwand:	
-	1 l/ha in 200 bis 400 l Wasser/ha

2.2 Sonstige Kennzeichnungsauflagen

(WH9161)
In die Gebrauchsanleitung ist eine Zusammenstellung der Unkräuter aufzunehmen, die durch die Anwendung des Mittels gut, weniger gut und nicht ausreichend bekämpft werden, sowie eine Arten- und/oder Sortenliste der Kulturpflanzen, für die der vorgesehene Mittelaufwand verträglich oder unverträglich ist.

2.3 Wartezeiten

(F)	Freiland: Sommerweichweizen Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

(F) Freiland: Sommergerste
Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

(F) Freiland: Sommerhafer
Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

3 Anwendungsbezogene Anwendungsbestimmungen

(NT103)
Die Anwendung des Mittels muss in einer Breite von mindestens 20 m zu angrenzenden Flächen (ausgenommen landwirtschaftlich oder gärtnerisch genutzte Flächen, Straßen, Wege und Plätze) mit einem verlustmindernden Gerät erfolgen, das in das Verzeichnis "Verlustmindernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung, mindestens in die Abdriftminderungsklasse 90 % eingetragen ist. Bei der Anwendung des Mittels ist der Einsatz verlustmindernder Technik nicht erforderlich, wenn die Anwendung mit tragbaren Pflanzenschutzgeräten erfolgt oder angrenzende Flächen (z. B. Feldraine, Hecken, Gehölzinseln) weniger als 3 m breit sind oder die Anwendung des Mittels in einem Gebiet erfolgt, das von der Biologischen Bundesanstalt im "Verzeichnis der regionalisierten Kleinstrukturanteile" vom 7. Februar 2002 (Bundesanzeiger Nr. 70a vom 13. April 2002) in der jeweils geltenden Fassung, als Agrarlandschaft mit einem ausreichenden Anteil an Kleinstrukturen ausgewiesen worden ist.
Begründung:
Das o.g. Pflanzenschutzmittel weist ein hohes Gefährdungspotenzial für terrestrische Nichtzielpflanzen auf. Bewertungsbestimmend ist hier die ER50 von 29,9 mL Produkt/ha für Tomaten (Lycopersicon esculentum) im Vegetative Vigour Test. Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnisse die o.g. Anwendungsbestimmung erforderlich, um einen ausreichenden Schutz von terrestrischen Nichtzielpflanzen in Saumbiotopen zu gewährleisten. Weitere Informationen hierzu sind dem nationalen Addendum zum Part B des Draft Registration Report zu entnehmen.

(NW607-1)
Die Anwendung des Mittels auf Flächen in Nachbarschaft von Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - muss mit einem Gerät erfolgen, das in das Verzeichnis "Verlustmindernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung eingetragen ist. Dabei sind, in Abhängigkeit von den unten aufgeführten Abdriftminderungsklassen der verwendeten Geräte, die im Folgenden genannten Abstände

zu Oberflächengewässern einzuhalten. Für die mit "*" gekennzeichneten Abdriftminderungsklassen ist, neben dem gemäß Länderrecht verbindlich vorgegebenen Mindestabstand zu Oberflächengewässern, das Verbot der Anwendung in oder unmittelbar an Gewässern in jedem Fall zu beachten. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.
reduzierter Abstand: 90 % 20 m
Begründung:
Das o.g. Pflanzenschutzmittel weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Algen und aquatische Wasserpflanzen auf. Bewertungsbestimmend ist hier die EC50 für aquatische Wasserpflanzen (Lemna gibba) von 0,65 µg Produkt/L. Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnisse die o.g. Anwendungsbestimmung erforderlich, um einen ausreichenden Schutz von Gewässerorganismen zu gewährleisten. Weitere Informationen hierzu sind dem nationalen Addendum zum Part B des Draft Registration Report zu entnehmen.

REGISTRATION REPORT
Part B

Section 5 Environmental Fate
Detailed summary of the risk assessment

Product code: **AG-FB1-485 SC**

Active Substance(s):	**Florasulam**	**5 g/L**
	Bifenox	**480 g/L**

COUNTRY: Germany
Central Zone
Zonal Rapporteur Member State: Austria

NATIONAL ADDENDUM – Germany

Sponsor:	**Agan Chemical Manufacturers Ltd.**
Applicant:	**ADAMA Deutschland GmbH**
Date:	**14/03/2016**

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Sec 5 FATE AND BEHAVIOUR IN THE ENVIRONMENT (KIIIA 9)

The exposure assessment of the plant protection product AG-FB1-485 SC in its intended uses in winter cerels is documented in detail in the core assessment, part B,section 5 of the plant protection product AG-FB1-485 SC dated from December 2013 performed by Austria.

This document comprises the risk assessment for groundwater and the exposure assessment of surface water and soil for authorization of the plant protection product AG-FB1-485 SC in Germany according to uses listed in Table 5.2-1

Regarding PECgw relevant risk mitigation measures, if necessary, are documented in this document. PECsoil, PECsw are used for risk assessment to derive specific risk mitigation measures if necessary (see National addendum Germany, part B, section 6 and part A).

5.1 General Information on the formulation

Table 5.1-1: General information on the formulation AG-FB1-485 SC

Code	07818-00-00	
plant protection product	AG-FB1-485 SC	
sponsor	Agan Chemical Manufacturers Ltd	
applicant	Country organisation/representative of MAI as specified in Part A	
date of application	17.12.2012	
Formulation type (WP, EC, SC, …; density)	SC, relative density 1.189	
active substances (as)	Florasulam	Bifenox
Concentration of as	5 g/L	480 g/L

Data pool/task force	-
letter of access/cross reference	Letter of Access to the data produced by Dow AgroSciences in order to the EU-approval of the active substance florasulam

5.2 Proposed use pattern

The intended uses in Germany classified according the soil effective application rate (cumulative, disregarding degradation in soil) is presented in Table 5.2-1.

The intended uses in Germany (use No.00-001 and 00-002) are covered by the core assessment (December 2013), part B, section 5 performed by zRMS Austria.

Table 5.2-1: Classification of intended uses in Germany for AG-FB1-485 SC

Group/ use No*	Crop/growth stage	Application method Drift scenario	Number of applications, Minimum application interval, application time, interception	Application rate, cumulative (g as/ha)	Soil effective application rate (g as/ha)
00-001	Winter cereals , BBCH 13-29	spraying	1 x 25 % interception	1.2 L/ha: Florasulam: 6 Bifenox:576	Florasulam: 4.5 g as/ha Bifenox: 432 g as(ha

00-002	Spring cereals, BBCH 13-29	spraying	1x 25 % interception	1 L/ha: Florasulam: 5 Bifenox:480	Florasulam: 3.75 g as/ha Bifenox: 360 g as(ha

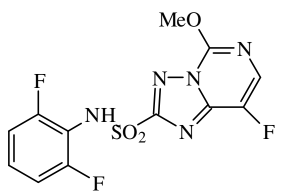
* For administrative purposes, each intended use of a plant protection product in Germany is assigned with an individual use number from the German Federal Office of Consumer Protection and Food Safety (BVL). A complete list of the individual GAPs in Germany together with their assigned use numbers is given in Appendix 3 of this Addendum.

5.3 Information on the active substances

5.3.1 Florasulam

5.3.1.1 Identity, further information of florasulam

Table 5.3-1: Identity, further information on florasulam

Active substance (ISO common name)	florasulam
IUPAC	2',6',8'-Trifluor-5-methoxy-[1,2,4]-triazolo[1,5-c]pyrimidin-2-sulfonanilid
Function (e.g. fungicide)	herbicide
Status under Reg. (EC) No 1107/2009	approved
Date of approval	01/10/2002
Conditions of approval	Only uses as herbicide may be authorised. For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on florasulam, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 19 April 2002 shall be taken into account. In this overall assessment Member States: should pay particular attention to the potential for ground water contamination, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of authorisation must include risk mitigation measures, where appropriate.
Confirmatory data	None
RMS	Belgium
Minimum purity of the active substance as manufactured (g/kg)	970
Molecular formula	$C_{12}H_8F_3N_5O_3S$
Molecular mass	359.3
Structural formula	

5.3.1.2 Physical and chemical properties of florasulam

Physical and chemical properties of florasulam as agreed at EU level (see SANCO/1406/2001-final) and considered relevant for the exposure assessment are listed in Table 5.3-2.

Table 5.3-2: EU agreed physical chemical properties of florasulam relevant for exposure assessment

	Value	Reference
Vapour pressure (at 20 °C) (Pa)	1 x 10^{-5} Pa at 25°C 1 x 10^{-6} Pa at 20°C	Appendix 1 (LoEP) of SANCO/1406/2001
Henry's law constant (Pa × m³ × mol^{-1})	3.29 x 10^{-5} Pa· m^3/mol (pH 5) at 20°C 4.35 x 10^{-7} Pa· m^3/mol (pH 7) at 20°C 2.94 x 10^{-8} Pa· m^3/mol (pH 9) at 20°C	
Solubility in water (at 25 °C in mg/L)	solubility in: purified water (pH 5.6-5.8) : 0.121 g/L pH 5.0 buffer : 0.084 g/L pH 7.0 buffer : 6.36 g/L pH 9.0 buffer : 94.2 g/L	
Partition co-efficient (at 25 °), log P_{OW}	pH 4.0: log P_{ow} = 1.00 pH 7.0: log P_{ow} = -1.22 pH 10.0: log P_{ow} = -2.06	
Dissociation constant, pKa	pKa = 4.54 (determined at 22-23°C)	
Hydrolytic degradation	50°C: pH 4 and 7: less than 5% degradation after 7d 50°C: pH 9: k = 0.378 d^{-1}; $t_{1/2}$ = 2 d (triazole-label) 25°C: pH 5: no degradation observed after 30 d 25°C: pH 7: no degradation observed after 30 d 25°C: pH 9: k = 0.00692 d^{-1}; $t_{1/2}$ = 100 d (phenyllabel) k = 0.00706 d^{-1}; $t_{1/2}$ = 98 d (triazole-label)	
Direct photolysis in water	pH 5, 25 °C, natural sunlight 40°N, June and May; $t_{1/2}$ = 88-223 d	
Quantum yield of direct phototransformation in water > 290 nm	Φ = 0.074	
Photochemical oxidative degradation in air (calculation according to Atkinson)	DT_{50} =1.82 d k = 70.4 x 10^{-12} cm^3 s^{-1} (1.5 × 10^6 radicals/cm³, 12 h day)	

5.3.1.3 Metabolites of florasulam

Environmental occurring metabolites of florasulam requiring further assessment according to the results of the assessment of florasulam for EU approval are summarized in **Fehler! Verweisquelle konnte nicht gefunden werden.**.

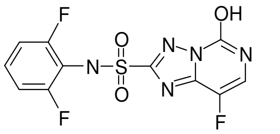
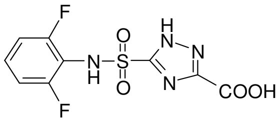
No new study on the fate and behaviour of florasulam has been performed. Hence no potentially new metabolites need to be considered.

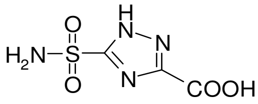
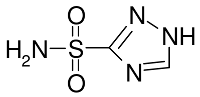
The risk assessment for the soil metabolites 5-OH-XDE-570, DFP-ASTCA, ASTCA, and TSA of florasulam has already been performed for EU approval (see SANCO/1406/2001-final). Therefore no new risk assessment hence no exposure assessment for these metabolites is necessary.

Potential ground water contamination by the soil metabolites 5-OH-XDE-570, DFP-ASTCA, and ASTCA was evaluated for EU approval of florasulam. PECgw modelled with FOCUS PELMO (version 3.0) was less than 0.1 µg/L for the metabolites 5-OH-XDE-570 and DFP-ASTCA and higher than 0.1 µg/L for the metabolite ASTCA in scenario Hamburg based on an application of 7.5 g as/ha (50 % crop interception) in winter wheat on 15th April.

However, the leaching potential into groundwater of the soil metabolites 5-OH-XDE-570, DFP-ASTCA, ASTCA, and TSA will be assessed for the application of the plant protection product and its intended uses. The metabolites are summarized in the table below.

Table 5.3-3: Metabolites of florasulam potentially relevant for exposure assessment

> 10 % of as or > 5 % of as in 2 sequential measurements or > 5 % of as and maximum of formation not yet reached at the end of the study			
Metabolite	**Structural formula/Molecular formula**	**occurrence in compartments (Max. at day/ 2 x > 5 %)**	**Status of Relevance according to the core assessment by zRMS Austria**
5-OH-XDE-570 (XDE-570 5-hydroxy) N-(2,6-difluorophenyl)-8-fluoro-5-hydroxyl (1,2,4) triazolo(1,5c) pyrimidine-2-sulphonamide	 M = 345.26 g/mol	Soil, aerob: max. 71.6 % after 3 d Water: max. 64 % after 60 d Sediment: max. 35 % after 60 d (Soil photolysis: 60%)	Aquatic organism: Water: not relevant Sediment: not relevant Terrestrial organism: not relevant Groundwater: not relevant (Step 2)[1)]
DFP-ASTCA (M3) N-(2,6-difluorophenyl)-5-aminosulphonyl-1H-1,2,4)triazole-3-carboxylic acid	 M = 304.2 g/mol	Soil, aerob: max. 17.8 % after 28 d Water: max. 15 % after 100 d Sediment: max. 9.15 % after 182 d	Aquatic organism: Water: not relevant Sediment: not applicable Terrestrial organism: not relevant Groundwater: not relevant (Step 2)[1)]

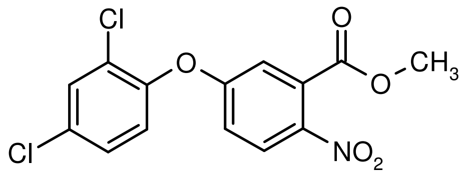
ASTCA (M4) 5-(aminosulphonyl)-1H-1,2,4-triazole-3-carboxylic acid	 M = 192.2 g/mol	Soil, aerob: max. 40.0 % after 59 d	Aquatic organism: Water: not relevant Sediment: not applicable Terrestrial organism: not relevant Groundwater: relevant (Step 2)[1)] not relevant (Step 3 and 4)[1)],[2)]
TSA M6 1H-1,2,4-triazole-3-sulphonamide	 M = 148.14 g/mol	Soil, aerob: max. 15.9 % at d 100	Aquatic organism: Water: not assessed Sediment: not assessed Terrestrial organism: not assessed Groundwater: not assessed

[1)] According to Guidance Document on the assessment of the relevance of metabolites in groundwater of substances regulated under council directive 91/414/EEC (SANCO/221/2000 –rev.10- final - 25 February 2003)

5.3.2 Bifenox

5.3.2.1 Identity, further information of bifenox

Active substance (ISO common name)	Bifenox
IUPAC	Methyl 5-(2,4-dichlorophenoxy)-2-nitrobenzoate
Function (e.g. fungicide)	Herbicide
Status under Reg. (EC) No 1107/2009	approved
Date of approval	01/01/2009
Conditions of approval	PART A Only uses as herbicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on bifenox, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 14 March 2008 shall be taken into account. In this overall assessment Member States shall pay particular attention to: (c) the environmental conditions leading to the potential formation of nitrofen. Member States shall impose restrictions as regards the conditions of use, where appropriate in view of point (c).'
Confirmatory data	none
RMS	Belgium
Minimum purity of the active substance as manufactured (g/kg)	970 g/kg (commercial plant)
Molecular formula	$C_{14}H_9Cl_2NO_5$
Molecular mass	342.14

Structural formula	 **Bifenox**

5.3.2.2 Physical and chemical properties of bifenox

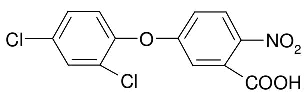
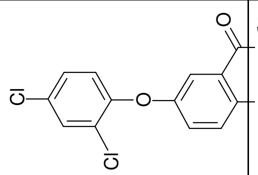
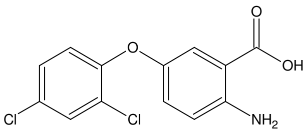
Table 5.3-4: EU agreed physical chemical properties of bifenox relevant for exposure assessment

	Value	**Reference**
Vapour pressure (at 20 °C) (Pa)	4.74 x 10^{-8} Pa at 20°C (99.9%)	SANCO/3776/08-final rev 1– 24/01/2011
Henry's law constant (Pa × m^3 × mol^{-1})	> 1.62 x 10^{-4} $Pa.m^3.mol^{-1}$ at 20°C (98.4% - 99.9%)	
Solubility in water (at 25 °C in mg/L)	pH 4, 20°C: < 0.1 mg/L (98.4%)	
Partition co-efficient (at 25 °), log Pow	pH unadjusted, 20-25°C: log Pow = 3.64 (range 3.55 to 3.73) (99.9%)	
Dissociation constant, pKa	Not relevant (no acidic of basic function or other substituent included in the molecule which could be dissociated in water)	
Hydrolytic degradation	Stable at 25°C at pH 4 and 7, At pH 9 : DT50 = 4 d	
Direct photolysis in water	pH 5, 20°C: DT50 = 24.4 hrs (continuous artificial light) (99.2% radiochemical purity) DT50 was ca. 2.18 days when equated to natural summer sunlight at 40°N. 2,4-dichlorophenol accounted for 79% AR after 72 hours	
Quantum yield of direct phototransformation in water > 290 nm	1.25 x 10^{-3} molecules $degraded.photon^{-1}$	
Photochemical oxidative degradation in air (calculation according to Atkinson)	OVERALL OH Rate Constant = 1.0495 E-12 cm3/molecule-sec Half-Life = 15.287 d (24-hr day; 0.5E6 OH/cm3), (AOP version 1.91)	calculated by evaluator

5.3.2.3 Metabolites of bifenox

Please refer to the core assessment (December 2013), part B, section 5, Table IIIA 9-2.

Table 5.3-5: Metabolites of bifenox potentially relevant for exposure assessment

Metabolite	**Structural formula/Molecular formula**	**occurrence in compartments (Max. at day/ 2 x > 5 %)**	**Status of Relevance according to the core assessment by zRMS Austria**
Bifenox-acid	 $C_{14}H_{11}Cl_2N_2O_3$ 328 g/mol	Soil, aerob: max. 78.7 % at day 10	Aquatic organism: Water: not relevant Sediment: not relevant Terrestrial organism: not relevant Groundwater: not relevant (Step 3)[1)]
Aminobifenox	 $C_6H_4Cl_2O$ 312 g/mol	Sediment: 66.7 % at day	Aquatic organism: Water: not relevant Sediment: not relevant Terrestrial organism: not relevant Groundwater: not assessed
Aminobifenox-acid	 $C_{13}H_7C_{12}NO_5$ 298 g/mol	Water phase: 12.7 % at day	Aquatic organism: Water: not relevant Sediment: not relevant Terrestrial organism: not relevant Groundwater: not assessed

5.4 Summary on input parameters for environmental exposure assessment

5.4.1 Rate of degradation in soil

5.4.1.1 Laboratory studies

Florasulam

No new studies have been submitted regarding route and rate of degradation in soil of its soil metabolites 5-OH-XDE-570, DFP-ASTCA, and ASTCA. However, a new evalulations of the degradation kinetics of florasulam for the study Jackson and evaluated in the EU assessment together with temperature and moisture recalculated DT_{50} values has been submitted (Jackson, 2010). The study was the new DRAR submitted for renewal of EU approval, where the study summary study was considered only partly acceptable by the RMS and a new kinetic according to FOCUS guidance (2006). The recalculated and/or normalized DT_{50} florasulam are summarized in

Table 5.4-1. The recalculated and/or normalized DT_{50} and DT_{90} values for 5-OH-XDE-570, DFP-ASTCA, and ASTCA are presented in Table 5.4-2,

Table 5.4-3 and Table 5.4-4. A new study (Simmonds, 2012) on the soil degradation of the florasulam soil metabolite TSA has been submitted for renewal of EU approval and is summarized in the new DRAR for Florasulam. The DT_{50} and DT_{90} values for TSA are summarized and Table 5.4-5.

The DT_{50} values of florasulam and its soil metabolites 5-OH-XDE-570, DFP-ASTCA, ASTCA and TSA listed in the core assessment, part B, section 5, point AIII 9.1 were analyzed according to Holdt et al. 2011 (Holdt et al: Recommendations for simulations to predict environmental concentrations of active substances of plant protection products and their metabolites in groundwater (PEC_{GW}) in the national assessment for authorization in Germany, Texte Umweltbundesamt 56, 2011). The recommendations of the Excel tool Input Decision 3.3 are used for the national groundwater assessment.

The degradation of florasulam in soil is not pH-dependent and the coefficient of variation is ≤ 100 %. Thus, the geometric mean of all DT_{50} values can be used for groundwater risk assessment.

The degradation of the metabolites 5-OH-XDE-570, DFP-ASTCA and TSA in soil is not pH-dependent and the coefficient of variations are ≤ 100 %. Thus, the geometric mean of all DT_{50} values can be used for groundwater risk assessment.

Table 5.4-1: Summary of aerobic degradation rates for florasulam - laboratory studies

Soil type	pH (H_2O)	T (°C)	moisture	DT_{50} (d)	DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa		Method of calculation	Reference
Andover, silt loam	7.6	20	40 % MWHC	1.01	3.94	-		DFOP, chi^2: 2.07%	Jackson & Gosh (1997), DRAR (2013)
				0.91	-	0.82		DFOP, fast phase	
Marcham sandy clay loam	8.0	20	40 % MWHC	1.92	16.59	-		DFOP, chi2: 5.64%	
				8.27	-	6.94		DFOP, slow phase	
Kenslow, humus silt loam	6.3	20	40 % MWHC	0.57	1.88	0.57		SFO; chi2: 4.94%	
Speyer 2.2, loamy sand, TP-labelled	7.7	20	40 % MWHC	0.46	5.68	2.29	2.25 *	DFOP, chi^2: 4.84%	
Speyer 2.2, loamy sand, Phenyl- labelled	7.7	20	40 % MWHC	0.72	5.12	2.21		DFOP, chi^2: 4.39%	
Marcham, Sandy clay loam	8.8	25	40 % MWHC	1.16	13.38	-	2.43 *	DFOP, chi^2: 15.74%	Pillar, (1997a), DRAR (2013)
				0.92	-	1.38		DFOP, fast phase	
		20	pF2	4.29	14.24	4.29		SFO, chi^2: 12.78%	Pillar, (1997b), DRAR (2013)

Cuckney, sand	8.0	25	40 % MWHC	4.29	14.24	4.29	3.39 *	SFO, chi^2: 12.78	Pillar, (1997a), DRAR (2013)
		20	pF2	2.86	9.49	2.86		SFO, chi^2: 15.28	Pillar, (1997b), DRAR (2013)
Aggregated DT_{50} (n=6)		**Coefficient of variation (%)**				85		No pH-dependency of degradation according to non-parametrical Kendall test	
		Geomean (d)				2.0			
		90th percentile (d)				5.2			

* geomean

Metabolites of florasulam

Table 5.4-2 Summary of aerobic degradation rates for metabolite 5-OH-XDE-570 - laboratory studies

Soil type	**pH (H_2O)**	**T (°C)**	**Mois-ture**	**DT_{50}/ DT_{90} (d)**	**f.f.**		**DT_{50} (d) 20 °C pF2/10kPa**		**Kinetic, Fit**	**Reference**
Andover, silt loam	7.9	20	40 % MWHC	6.99/ 23.22	0.786		6.27		DFOP-SFO, chi^2: 5.34%	Jackson & Gosh (1997), DRAR (2013)
Marcham, sandy clay loam	8.0	20	40 % MWHC	14.73/ 48.93	0.795		12.36		DFOP-SFO, chi^2: 10.85	
Kenslow, humous silt loam	6.3	20	40 % MWHC	18.03/ 59.89	0.871		18.03		SFO- SFO, chi^2: 9.18%	
Speyer 2.2, loamy sand, TP-labelled	7.7	20	40 % MWHC	13.72/ 45.58	0.902	0.92 **	13.72	13.42*	DFOP-SFO, chi^2: 10.4%	
Speyer 2.2, loamy sand, phenyl-labelled				13.12/ 43.58	0.939		13.12		DFOP-SFO, chi^2: 7.05%	
Marcham, sandy clay loam	7.6	25	40 % MWHC	11.59/ 38.49	0.885	0.94 **	17.89	15.96*	SFO- SFO, chi^2: 18.37%	Pillar, (1997a), DRAR (2013)
		20	FC	14.24 / 98.63	1.000		14.24		SFO- SFO, chi^2: 14.62%	Pillar, (1997b), DRAR (2013)

Cuckney, sand	8.0	25	40 % MWHC	12.97/ 43.09	0.933	0.97 **	15.02	19.29*	SFO- SFO, chi^2: 16.52	Pillar, (1997a), DRAR (2013)
		20	pF2 (= 0.05 bar)	24.77/ 82.30	1.000		24.77		SFO- SFO, chi^2: 21.07%	Pillar, (1997b), DRAR (2013)
Aggregated DT_{50} (n = 6)		**Coefficient of variation (%)**					33		No pH-dependency of degradation according to non-parametrical Kendall test	
		Geomean (d)					13.4			
		90th percentile					18.7			
Formation Fraction ai → 5-OH-XDE-570 (n = 6)		**Arithmetic mean**					0.88			

* geomean
** arithmetic mean

Table 5.4-3 Summary of aerobic degradation rates for metabolite DFP-ASTCA - laboratory studies

Soil type	pH (H_2O)	T (°C)	Moisture	DT_{50}/ DT_{90} (d)	f.f.**		DT_{50} (d) 20 °C pF2/10kPa	Kinetic, Fit	Reference
Andover, silt loam, treated with TP-labelled XDE-570	7.6	20	40 % MWHC	(2.46/ 8.18)*	0.743		-	DFOP-SFO , chi^2: 46.33%	Jackson & Gosh (1997), DRAR (2013)
Marcham, sandy clay loam, treated with TP-labelled XDE-570	8.0	20	40 % MWHC	(4.29/ 14.24) *	0.851		-	DFOP-SFO , chi^2: 30.91%	
Kenslow, humus silt loam, treated with TP-labelled XDE-570	6.3	20	40 % MWHC	(2.71/ 9.00)*	0.777		-	SFO- SFO , chi^2: 32.03%	
Speyer 2.2, loamy sand, treated with TP-labelled XDE-570	7.7	20	40 % MWHC	37.33/ 124.01	0.439	0.404 ***	37.33	DFOP-SFO , chi^2: 11.9%	

Speyer 2.2, loamy sand, treated with phenyl-labelled XDE-570				61.89/ 205.59	0.369		61.89	SFO-SFO, chi^2: 9.89	
Cuckney, sand, treated with TP- labelled DFP-ASTCA	7.2	20	40 % MWHC	15.82/ 52.55	n.a.		15.27	SFO, chi^2: 9.95%	Jackson and Massart, (1998), DRAR (2013)
Marcham, sandy clay loam, treated with TP- labelled DFP-ASTCA	7.9	20	40 % MWHC	4.23/ 14.06	n.a.		4.23	SFO, chi^2: 7.51%	
Aggregated DT_{50} (n = 3)	**Coefficient of variation (%)**						89	No pH-dependency of degradation according to non-parametrical Kendall test	
	Geomean (d)						13.4		
	90th percentile						32.9		
Formation Fraction 5-OH-XDE-570 → DFP-ASTCA (n = 4)	**Arithmetic mean**						0.69		

* no statistically reliable fit could be obtained
** formation fractiion from 5-OH-XDE-570 to DFP-ASTCA
*** arithmetic mean

Table 5.4-4 Summary of aerobic degradation rates for metabolite ASTCA - laboratory studies

Soil type	pH (H_2O)	T (°C)	Moisture	DT_{50}/ DT_{90} (d)	f.f.**	DT_{50} (d) 20 °C pF2/10kPa		Kinetic, Fit	Reference
Cuckney, Sand, treated with DFP-ASTCA	7.2	20	40% MWHC	(170.7/ 567)	0.571	-*		SFO, chi^2: 18.84%	Jackson and Massart (1998), DRAR (2013)
Cuckney, Sand, treated with ASTCA				268.5/ 892	-	259		SFO, chi^2: 4.25%	
Marcham, sandy clay loam, treated with DFP-ASTCA	7.9	20	40% MWHC	214/ 711	0.781	214	254 ***	SFO, chi^2: 4.40%	
Marcham, sandy clay loam, treated with ASTCA				158.5/ 863	-	-		DFOP, chi^2: 2.19%	
				301.4	-	301.4		DFOP, slow phase	

Aggregated DT50 (n = 2)	**Maximum**	259	
Formation Fraction DFP-ASTCA → ASTCA (n = 2)	**Maximum**	0.781	

* the fit after direct application of ASTCA is more robust, thus only the formation fraction after direct application of DFP-ASTCA was used
** Formation Fraction from DFP-ASTCA to ASTCA
*** geomean

Table 5.4-5 Summary of aerobic degradation rates for metabolite TSA - laboratory studies

Soil type	pH	T (°C)	Moisture	DT_{50} (d)	DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa	Fit, Kinetic	Reference
Calke, Sandy Loam	5.9	20	pF2-2.5	8.1	166.9	-	DFOP, chi^2: 2.2	Simmonds (2012)/ DRAR (2013)
				78.77	-	71.44	DFOP, slow phase	
S-Witham, Clay Loam	7.6	20	pF2-2.5	10.6	155.3	-	DFOP, chi2: 2.1	
				101.93	-	94.39	DFOP, slow phase	
Lufa 5M, Sandy Loam	7.7	20	pF2-2.5	230	765	172	SFO, chi^2: 4.4	
RefeSol 06-A, Clay Loam	7.6	20	pF2-2.5	24.87	622.96	-	FOMC, chi^2: 1.99	
				187.64	-	172.44		
Aggregated DT_{50} (n = 4)		**Coefficient of variation (%)**				41	No pH-dependency of degradation according to non-parametrical Kendall test	
		Geomean (d)				118.9		
		90th percentile				172.2		
Formation Fraction ASTCA→ TSA		**Default**				1.0		
Formation Fraction DFP-ASTCA→ TSA		Calculated by the difference of 1.000 – the mean ff value for the formation of ASTCA from DFP-ASTCA (0.781)				0.219		

Bifenox

No new studies have been submitted regarding route and rate of degradation in soil of bifenox. The environmental exposure assessment is based on the EU agreed DT_{50} values from the laboratory as summarized in the in Table IIIA 9.1.1.-1 of the core assessment, part B, section 5. and in the table below.

Table 5.4-6: Summary of aerobic degradation rates for bifenox - laboratory studies

Soil type	pH (H_2O)	T (°C)	moisture	DT_{50} (d)	DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa	Method of calculation	Reference
Loam, Label 1	6.5	20	45 % MWHC	7.5	24.3	7.2 (average of 2 labels)	SFO	Simmonds (1999) SANCO/3776 /08-final rev 1– 24/01/2011
Loam, Label 2				6.9	23.4		SFO	
Sandy loam 99/13	6.1	20	45 % MWHC	17.7	58.7	17.7	SFO	Simmonds (2000) SANCO/3776 /08-final rev 1– 24/01/2011
Clay loam 99/16	7.6	20	45 % MWHC	4.0	13.3	4.0	SFO	
Sandy loam 99/17	6.0	20	45 % MWHC	9.5	31.4	9.5	SFO	
Aggregated DT50 (n=4)	Coefficient of variation (%)					61	According to Input Decision (3.3): No pH-dependence, use geometric mean for PECgw	
	Geomean (d)					8.3		
	90th percentile (d)					15.2		

Metabolites of bifenox

No new studies have been submitted regarding route and rate of degradation in soil of the metabolite bifenox-acid. The DT_{50} values of the metabolite bifenox-acid are summarized in table IIIA 9.1.1-2 of the core assessment, part B, section 5 and in the table below.

Table 5.4-7: Summary of aerobic degradation rates for metabolite bifenox-acid - laboratory studies

Soil type	pH (H_2O)	T (°C)	moisture	DT_{50} (d) Recalculation EFSA	ff	DT_{50} (d) 20 °C pF2/10 kPa	Fit % chi²	Kinetic	Reference SANCO/3776/08-final rev 1–24/01/2011
Clay loam 99/02		20	45% MWHC	48.9	1	48.2		SFO	Simmonds (1999),
Sandy loam 99/13		20	45% MWHC	58.1	1	58.1		SFO	Simmonds (2000),
Clay loam 99/16		20	45% MWHC	86.2	1	86.2		SFO	

Sandy loam 99/17		20	45% MWHC	156.2	1	156.2		SFO	
Loamy sand BBA 2.2	5.7	20	45% MWHC	24.3	-	24.3	5.6	SFO	Heintze (2003),
Sandy loam BBA 2.3	6.1	20	45% MWHC	88.4	-	80.0	9.3	SFO	
Loam BBA 3A	7.2	20	45% MWHC	25.1	-	24.5	8.3	SFO	
Aggregated DT_{50} (n=7)		**Coefficient of variation (%)**				67	According to Input Decision (3.3): No pH-dependence, use geometric mean for PECgw		
		Geometric mean (d)				56.3			
		90th Percentil				114.2			

5.4.1.2 Field studies

Florasulam

No new studies have been submitted on the soil degradation of florasulam and its metabolite 5-OH-XDE-570 under field conditions. However, a new kinetic evaluation according to FOCUS guidance (2006) of the field studies with FLorasulam was performed in the DRAR of Florasulam submitted for renewal of EU assessment. The recalculated DT_{50} and DT_{90} values for florasulam are summarized in Table 5.4-8.

Table 5.4-8: Field degradation studies of florasulam

soil / location	**pH**	**depth (cm)**	**DT_{50} (d)**	**DT_{90} (d)**	**Fit, Kinetic**	**DT_{50} (d) 20 °C, pF2**	**Fit, Kinetic**	**Reference**
silty clay loam , Tours, North-France	7.4	0-50	12.20	40.54	SFO, chi^2: 30.88	-	-	Maycock (1997a–f)/ DRAR (2013)
silty loam , Wetterfeld, Germany	6.1	0-50	17.66	58.67	SFO, chi^2: 20.42%	-	-	
sandy clay loam , Marcham, UK	7.7	0-50	16.25	53.99	SFO, chi^2: 26.42	-	-	
Sand, Elvedon, UK	7.6	0-50	25.48	84.65	SFO, chi^2: 17.03	-	-	
clay loam, St. Livrade, South-France	8.2	0-50	8.93	29.68	SFO, chi^2: 23.06	-	-	
sandy silt loam , Valtohori, Greece	8.5	0-50	5.84	19.41	SFO, chi^2: 19.56	-	-	

Bifenox

Field studies of bifenox as evaluated in the EU review are presented in the core assessment in table IIIA 9.2-2 and in table below.

Table 5.4-9: Field degradation studies of bifenox

soil / location	pH	depth (cm)	DT_{50} (d)	DT_{90} (d)	Fit, Kinetic, Parameters	DT_{50} (d) 20 °C, pF2	Fit, Kinetic	Reference
Florida, USA, Sandy loam		0-15	8.3	27.7	1st order			Bowman, (1982), SANCO/3776/08-final rev 1– 24/01/2011
Nebraska, USA, Loam		0-15	12.2	40.6	1st order			
Virginia, USA, Sandy loam		0-15	16.7	55.4	1st order			
New Jersey, USA, Loam		0-8	32.1	106.6	1st order			

5.4.2 Adsorption/desorption

Florasulam

New studies on the adsorption of florasulam and its soil metabolites 5-OH-XDE-570, DFP-ASTCA, ASTCA, and TSA have been submitted for the renewal of the EU approval of florasulam. The studies are summarized in the new DRAR of florasulam from July 2013. The K_{foc} values of the new studies together with those values from the previous EU assessment are summarized in Table 5.4-10, Table 5.4-12, Table 5.4-14, Table 5.4-16 and Table 5.4-18.

The K_{foc} values of florasulam and its soil metabolites were analysed according to Holdt et al. 2011 (Holdt et al: Recommendations for simulations to predict environmental concentrations of active substances of plant protection products and their metabolites in groundwater (PEC_{GW}) in the National assessment for authorization in Germany, Texte Umweltbundesamt 56, 2011).

Table 5.4-10: K_f, K_{foc} and 1/n (Freundlich exponent) values for florasulam

Soil Type	OC [%]	pH (H_2O)	K_f [mL g^{-1}]	K_{foc} [mL g^{-1}]	1/n [-]	Reference
Catlin, Silty clay loam	2.2	7.4*	0.89	40	0.88	Ostrander, 1996 (see DAR)
Hanford, Sandy loam	1.0	7.6*	0.22	22	0.86	
Pewamo, clay	2.4	6.4*	1.88	78	0.92	
Fuquay, sand	0.64	5.5*	0.35	55	1.00	
Kenslow, Silt loam	6.8	6.7*	1.47	22	0.94	
Speyer, Sandy loam	3.9	7.7*	0.13	3	0.95	
Calke, Sandy Loam	3.6	5.9	0.30	8.3	0.949	Simmonds, 2011 (YR/11/005)
S-Witham, Clay Loam	3.8	7.6	0.10	2.7	0.983	
Longwoods, Sandy Loam	1.5	7.7	0.03	1.7	0.885	
Kenslow, Loam	3.8	5.3	0.47	12.3	0.914	
Lufa 6S, Clay	1.8	7.3	0.04	2.5	1.041	
Lufa 5M, Sandy Loam	1.0	7.7	0.03	2.6	0.947	
RefeSol 06-A, Clay Loam	1.9	7.6	0.08	4.2	0.938	

RefeSol 01-A, Sandy Loam	1.0	6.0	0.30	29.9	1.018	
Arithmetic mean (n=14)				20.0	0.945	
10th percentile				2	-	

*calculated from measured pH values in KCl

For the dissociating active substance florasulam a significant negative correlation was found between the K_{foc} / K_f values and pH of the soils (n=14). Since the visual fit of the sigmoidale curve K_{foc} and pH was not acceptable, for PEC_{GW} calculations according to Input Decision 3.3 the arithmetic mean of the K_f values together with the Freundlich exponents 1/n of the alkaline soils with pH ≥ 7 was used for the FOCUS scenario Kremsmünster. Additionally the arithmetic mean of the K_f values and the Freundlich exponents 1/n of all soils was used for the FOCUS scenario Hamburg. The results are summarized in Table 5.4-11.

Table 5.4-11: Statistic values according to INPUT DECISION 3.3 for florasulam for PEC_{GW} modelling

Does the active substance dissociate ?	yes, pKs = 4.54	
correlation K_{foc} and pH	Kendall-τ: -0.536 p-value: 0.010	negativ significant (expected for acid), but visual fit of the sigmoidale curve is not acceptable
correlation K_f and pH	Kendall-τ: -0.644 p-value: 0.002	negativ significant (expected for acid)
correlation K_f and oc	Kendall-τ: 0.261 p-value: 0.112	not positive significant (p-Wert > significance level)
coefficient of variation K_{foc}	117 %	not relevant
coefficient of variation Kf	127 %	not relevant
correlation K_f and other soil parameters (clay, CEC)	-	not relevant
K_f for PEC_{GW}	At pH < 7: 0.795 At pH ≥ 7: 0.190 All soils: 0.45	1st run: Kremsmünster scenario with Kf = 0.190 (arithmetic mean at pH ≥ 7) for1st – 5th horizon 2nd run: Hamburg scenario with Kf = 0.449 (arithmetic mean all soils) for 1st-3rd horizon and K_f=0 (default) for 4th- 6th horizon
Kfoc for runoff	20	arithmetic mean all soils (n=14)
Kfoc for mobility class	2	10th percentil all soils (n=14)
1/n PEC_{GW}	at pH ≥ 7: 0.936 all soils: 0.945	1st run: Kremsmünster scenario: arithmetic mean for neutral and alkaline soils at pH ≥ 7 2nd run: Hamburg scenario: arithmetic mean all soils

Metabolites of Florasulam

Table 5.4-12: K_f, K_{foc} and 1/n (Freundlich exponent) values for metabolite 5-OH-XDE-570

Soil Type	OC [%]	pH (H_2O)	K_f [mL g^{-1}]	K_{foc} [mL g^{-1}]	1/n [-]	Reference
Catlin ,Silty clay loam	2.2	7.4*	0.69	31	0.88	Ostrander, 1996 (see DAR)
Hanford, Sandy loam	1.0	7.6*	0.21	21	0.95	
Pewamo, clay	2.4	6.4*	1.73	72	0.90	
Fuquay, sand	0.64	5.5*	0.24	4	0.98	
Kenslow, Silt loam	6.8	6.7*	1.55	23	0.90	
Speyer, Sandy loam	3.9	7.7*	0.07	2	1.10	
Calke, Sandy Loam	3.6	5.9	0.29	8.0	0.832	Simmonds, 2011 (YR/11/006)
S-Witham, Clay Loam	3.8	7.6	0.16	4.1	0.792	
Lufa 5M, Sandy Loam	1.0	7.7	0.06	6.1	0.864	
RefeSol 06-A, Clay Loam	1.9	7.6	0.12	6.1	0.866	
Arithmetic mean			**0.51**	**21.0**	**0.906**	

*calculated from measured pH values in KCl

For the metabolite 5-OH-XDE-570, a significant negative correlation was found between the K_f values and pH of the soils (n=14). According to Input Decision 3.3 for PEC_{GW} calculations the arithmetic mean of the K_f values together with the Freundlich exponents 1/n of the alkaline soils with pH ≥ 7 was used for the FOCUS scenario Kremsmünster. Additionally the arithmetic mean of the K_f values and the Freundlich exponents 1/n of all soils was used for the FOCUS scenario Hamburg.The results are summarized in Table 5.4-13.

Table 5.4-13: Statistic values according to INPUT DECISION 3.3 for metabolite 5-OH-XDE-570 for PEC_{GW} modelling

correlation K_f and oc	Kendall-τ: 0.135 p-value: 0.025	not positiv significant (p-Wert > significance level)
coefficient of variation K_{foc}	103%	too high (> 60%)
correlation K_f and pH	Kendall-τ: -0.584 p-value: 0.018	significant (p-Wert < significance level)
correlation K_f and other soil parameters (clay, CEC)	-	not relevant
K_f for PEC_{GW}	at pH ≥ 7: 0.218 all soils : 0.512	1st run: Kremsmünster scenario: Kf = 0.218 for1st – 5th horizon (arithmetic mean of neutral and alkaline soils at pH ≥ 7) 2nd run: Hamburg scenario: Kf = 0.512 for 1st-3rd horizon (arithmetic mean all soils)
1/n PEC_{GW}	at pH ≥ 7: 0.909 all soils: 0.906	1st run: Kremsmünster scenario: arithmetic mean for neutral and alkaline soils at pH ≥ 7 2nd run: Hamburg scenario: arithmetic mean all soils

Table 5.4-14: Kf, Kfoc and 1/n (Freundlich exponent) values for the metabolite DFP-ASTCA

Soil Type	OC (%)	pH (-)	K_d	$K_{d,OC}$	K_f (mL g^{-1})	K_{foc} (mL g^{-1})	1/n (-)	Reference
Marcham, Sandy clay loam	3.40	7.90	0.940	28	n.a.	n.a.	n.a.	Jackson und Massart, 1999
Cuckney, Sand	1.50	7.20	0.390	26	n.a.	n.a.	n.a.	
Sutton, Sandy clay loam	2.10	7.50	0.680	32	n.a.	n.a.	n.a.	
Thessaloniki, Sandy silt loam	0.90	8.50	0.900	100	n.a.	n.a.	n.a.	
Elvedon, Sand	1.10	7.60	0.260	24	n.a.	n.a.	n.a.	
Toulouse, Clay	1.20	8.20	0.640	53	n.a.	n.a.	n.a.	
Tours, Silty clay	1.20	7.40	0.650	54	n.a.	n.a.	n.a.	
Wetterfeld, Silty clay loam	1.20	6.10	0.630	53	n.a.	n.a.	n.a.	
Catlin, Silty loam	1.70	6.50	0.880	52	n.a.	n.a.	n.a.	
Hanford, Sandy loam	1.00	7.40	1.100	110	n.a.	n.a.	n.a.	
Calke, Sandy Loam	3.6	5.9	n.a.	n.a.	0.88	24.4	0.84	Burgess und Simmonds, 2011a
S-Witham, Clay Loam	3.8	7.6	n.a.	n.a.	0.63	16.6	0.80	
Lufa 5M, Sandy Loam	1.0	7.7	n.a.	n.a.	2.36	236.0	0.91	
RefeSol 06-A, Clay Loam	1.9	7.6	n.a.	n.a.	0.45	23.6	0.88	
Arithmetic mean					1.08	75.00	0.858	

n.a. not available

For the metabolite DFP-ASTCA, no siginificant correlation was found with the oc-content or the pH of the soils. Besides, the coefficient of variation of the K_{foc} values was > 60 %. However, the coefficient of variation of the K_f values was with < 100 % sufficiently low. Thus, K_f values were used together with the FOCUS scenarios Hamburg and Kremsmünster. The results are summarized in Table 5.4-15.

Table 5.4-15: Statistic values according to INPUT DECISION 3.3 for metabolite DFP-ASTCA for PEC_{GW} modelling

correlation K_f and oc	Kendall-τ: -0.333 p-value: 0.367	not positiv significant (p-Wert > significance level)
coefficient of variation K_{foc}	143 %	too high (> 60%)
coefficient of variation K_f	81 %	Sufficiently low (<60%)
correlation K_f and pH	Kendall-τ: 0.183 p-value: 1.0	Not significant (p-Wert > significance level)
correlation K_f and other soil parameters (clay, CEC)	-	not relevant

K_f for PEC_{GW}	1.08	arithmetic mean of K_f values all soils (n= 4)
1/n PEC_{GW}	0.858	arithmetic mean all soils (n = 4)

Table 5.4-16: Kf, Kfoc and 1/n (Freundlich exponent) values for the metabolite ASTCA

Soil Type	OC (%)	pH (-)	K_d	$K_{d,OC}$	K_f (mL g^{-1})	K_{foc} (mL g^{-1})	1/n (-)	Reference
Marcham, Sandy clay loam	3.40	7.90	1.65	49	n.a.	n.a.	n.a.	Jackson und Massart, 1999
Cuckney, Sand	1.50	7.20	0.42	28	n.a.	n.a.	n.a.	
Sutton, Sandy clay loam	2.10	7.50	1.87	89	n.a.	n.a.	n.a.	
Thessaloniki, Sandy silt loam	0.90	8.50	1.00	111	n.a.	n.a.	n.a.	
Elvedon, Sand	1.10	7.60	0.30	27	n.a.	n.a.	n.a.	
Toulouse, Clay	1.20	8.20	0.89	74	n.a.	n.a.	n.a.	
Tours, Silty clay	1.20	7.40	1.78	148	n.a.	n.a.	n.a.	
Wetterfeld, Silty clay loam	1.20	6.10	0.60	50	n.a.	n.a.	n.a.	
Catlin, Silty loam	1.70	6.50	1.62	95	n.a.	n.a.	n.a.	
Hanford, Sandy loam	1.00	7.40	1.59	159	n.a.	n.a.	n.a.	
Calke, Sandy Loam	3.6	5.9	n.a.	n.a.	1.34	37.2	0.91	Burgess und Simmonds, 2011a
S-Witham, Clay Loam	3.8	7.6	n.a.	n.a.	1.27	33.4	0.94	
Lufa 5M, Sandy Loam	1.0	7.7	n.a.	n.a.	2.97	297.1	0.95	
RefeSol 06-A, Clay Loam	1.9	7.6	n.a.	n.a.	0.98	51.8	0.94	
Arithmetic mean					1.64	105	0.935	

n.a. not available

For the metabolite ASTCA, no siginificant correlation was found with the oc-content or the pH of the soils. Besides, the coefficient of variation of the K_{foc} values was > 60%. However, the coefficient of variation of the K_f values was with < 100% sufficiently low. Thus, horizon-specific K_f values were used together with the scenarios Hamburg and Kremsmünster. The results are summarized in Table 5.4-17.

Table 5.4-17: Statistic values according to INPUT DECISION 3.3 for metabolite ASTCA for PEC_{GW} modelling

correlation K_f and oc	Kendall-τ: -0.333 p-value: 0.367	not significant (p-Wert > significance level)
coefficient of variation K_{foc}	122 %	too high (> 60%)
coefficient of variation K_f	55 %	Sufficiently low (<60%)

correlation K_f and pH	Kendall-τ: 0.183 p-value: 1.0	Not significant (p-Wert > significance level)
correlation K_f and other soil parameters (clay, CEC)	-	not relevant
K_{foc}	1.64	arithmetic mean of K_f values all soils (n= 4)
1/n PEC_{GW}	0.935	arithmetic mean all soils (n= 4)

Table 5.4-18 K_f, K_{foc} and 1/n (Freundlich exponent) values for the metabolite TSA

Soil Type	OC (%)	pH (-)	K_d	$K_{d,OC}$	K_f (mL g^{-1})	K_{foc} (mL g^{-1})	1/n (-)	Reference
Calke, Sandy Loam	3.6	5.9	n.a.	n.a.	0.26	7.3	0.98	Burgess und Simmonds, 2011c
S-Witham, Clay Loam	3.8	7.6	n.a.	n.a.	0.36	9.5	0.94	
Lufa 5M, Sandy Loam	1.0	7.7	n.a.	n.a.	0.64	63.6	0.87	
RefeSol 06-A, Clay Loam	1.9	7.6	n.a.	n.a.	0.25	13.1	0.98	
Arithmetic mean					0.38	23.0	0.943	

n.a. not available

For the metabolite TSA, no siginificant correlation was found with the oc-content or the pH of the soils. Besides, the coefficient of variation of the K_{foc} values was > 60%. However, the coefficient of variation of the K_f values was with < 100% sufficiently low. Thus, horizon-specific K_f values were used together with the scenarios Hamburg and Kremsmünster. The results are summarized in Table 5.4-19.

Table 5.4-19: Statistic values according to INPUT DECISION 3.3 for metabolite TSA for PEC_{GW} modelling

Does the active substance dissociate ?	yes, pKs = 4.54	
correlation K_f and oc	Kendall-τ: 0.000 p-value: 0.500	not positiv significant (p-Wert > significance level)
coefficient of variation K_{foc}	118%	too high (> 60%)
coefficient of variation K_f	47%	Sufficiently low (<60%)
correlation K_f and pH	Kendall-τ: 0.548 p-value: 0.470	Not significant (p-Wert > significance level)
correlation K_f and other soil parameters (clay, CEC)	-	not relevant
K_f	0.38	arithmetic mean of K_f values all soils (n= 4)
1/n PEC_{GW}	0.943	arithmetic mean all soils (n= 4)

Bifenox

In the core assessment, part B, section 5, table IIIA 9.3-7 to table IIIA 9.3-10 Kfoc values from the EU assessment were considered.

The K_{foc} values were analysed according to Holdt et al. 2011 (Holdt et al: Recommendations for simulations to predict environmental concentrations of active substances of plant protection products and their metabolites in groundwater (PEC_{GW}) in the National assessment for authorization in Germany, Texte Umweltbundesamt 56, 2011).

Table 5.4-20: K_f, K_{foc} and 1/n (Freundlich exponent) values for bifenox

Soil Type	OC (%)	pH (-)	K_f (mL g^{-1}	K_{foc} *** (mL $g^{-1)}$	1/n (-)	Reference
12, Sandy loam	2.09	5.3 (in water)	169	8086	1.117	Giraud (1983)
34, Loamy sand	0.75	6.6 (in water)	33.6	4480	1.055	
67, Clay loam	1.51	7.6 (in water)	73.3	4854	1.113	
Sand	0.17*	7.5	0.925	544*	0.7657	Spare (1984)
Burtonsville Maryland, Sandy loam	0.81	6.9	36.1	4457	0.8900	
Laurel, Maryland, Silt loam	1.16	7.4	54	4655	0.7707	
Wheaton, Maryland, Sandy clay loam	0.64	7.3	146	22813	0.9938	
Matagorda, Texas, Aquatic sediment (Loam)	2.26	6.7	41	1814**	1.03	
Arithmetic mean (n=6)				8224	0.99	

* low content organic carbon (< 0.3 %), therefore soil not used
**sediment , therefore soil not used
*** K_{foc} values are slightly different from the Kfoc values of the LoEP, because they were calculated with Input decision 3.3

Table 5.4-21: Statistic values according to INPUT DECISION 3.3 for bifenox for PEC_{GW} modelling

Does the active substance dissociate ?	no	
correlation K_f and oc	Kendall-τ: 0.467 p-value: 0.130	not positive significant (p-Wert > significance level)
coefficient of variation K_{foc}	89 %	too high (> 60%)
coefficient of variation K_f	68 %	sufficiently low (≤ 100%)
Correlation K_f and pH	-	not significant
Correlation K_f and other soil parameters (clay, CEC)	-	not significant
K_{foc} for runoff and drainage	8224	Arithmetic mean (n= 6)
K_{foc} for mobility class	4468	10th percentil (n=6)

K_f for PEC_{GW}	85.3	arithmetic mean K_f-values for soil horizons (n= 6)
1/n PEC_{GW}	0.99	arithmetic mean all soils (n=6)

Metabolites of bifenox

Table 5.4-22: K_f, K_{foc} and 1/n (Freundlich exponent) values for bifenox-acid

Soil Type	OC (%)	pH (-)	K_f (mL g^{-1}	K_{foc} (mL $g^{-1)}$	1/n (-)	Reference
Humic sand	2.50	5.7	3.62	145	0.89	Malt, Vonk (1992)
Loam soil	0.81	7.3	1.26	156	0.85	
BBA 2.1	0.52	5.6	0.68	131	0.79	
Arithmetic mean				144	0.84	

Table 5.4-23: Statistic values according to INPUT DECISION 3.3 for bifenox-acid for PEC_{GW} modelling

correlation K_f and oc	-	not positive significant
coefficient of variation K_{foc}	9 %	sufficiently low (≤ 60%)
coefficient of variation K_f	-	Not relevant
Correlation K_f and other soil parameters (clay, CEC)	-	not relevant
K_{foc} for PEC_{GW} (and runoff, drainage and for mobility class)	144	Arithmetic mean (n=3)
1/n PEC_{GW}	0.84	arithmetic mean all soils (n=3)

Table 5.4-24: K_f, K_{foc} and 1/n (Freundlich exponent) values for Aminobifenox

Soil Type	OC (%)	pH (-)	K_f (mL g^{-1}	K_{foc} (mL $g^{-1)}$	1/n (-)	Reference
Humic sand	2.50	5.7	115	4611	0.77	Malt, Vonk (1992)
Loam soil	0.81	7.3	40.8	5024	0.74	
BBA 2.1	0.52	5.6	19.3	3697	0.70	
Arithmetic mean				4444	0.74	

5.4.3 Rate of degradation in water/sediment

Florasulam

A new water/sediment study with florasulam has been submitted for the renewal of the EU approval of Florasulam (Lewis & Gilbert, 2011). The study is summarized in the new DRAR of Florasulam from July 2013. Besides, a new kinetic evaluation according to FOCUS guidance (2006) of the water/sediment study with florasulam already evaluated for the previous EU approval was performed for the DRAR of Florasulam. The DT_{50} and DT_{90} values for florasulam of the two water/ sediment studies are summarized in Table 5.4-25 and

Table 5.4-26.

Table 5.4-25: Degradation in water/sediment of florasulam

Water / sediment system	$DegT_{50}$/ $DegT_{90}$ whole system	Kinetic/ Fit	$DissT_{50}$/ $DissT_{90}$ water	Kinetic/ Fit	$DissT_{50}$/ $DissT_{90}$ sed.	Kinetic / Fit	Reference
Brown Carrick Hill, phenyl-labelled	6.74/ 22.38	SFO, chi^2: 4.45	6.12/ 20.3	SFO, chi^2: 5.27	-	-	Phillips, (1997)/ DRAR (2013)
Brown Carrick Hill, TP-labelled	811.3/ 39.5	SFO, chi^2: 5.44	10.51/ 34.9	SFO, chi^2: 5.65	-	-	
Auchingilsie system, phenyl-labelled	26.89/ 89.34	SFO, chi^2: 9.58	23.29/ 77.4	SFO, chi^2: 7.97	-	-	
Auchingilsie system, TP-labelled	24.42/ 81.13	SFO, chi^2: 5.46	22.07/ 73.3	SFO, chi^2: 4.28	-	-	
Calwich Abbey lake, phenyl-labelled	8.25/ 27.41	SFO, chi^2: 4.76	7.98/ 26.53	SFO, chi^2: 3.28	-	-	Lewis & Gilbert (2011)
Calwich Abbey lake, TP-labelled	9.89/ 32.85	SFO, chi^2: 4.5	9.98/ 33.15	SFO, chi^2: 4.08	-	-	
Swiss Lake, phenyl-labelled	25.05/ 89.19	SFO, chi^2: 4.71	24.01/.79.8	SFO, chi^2: 3.97	-	-	
Swiss Lake, TP-labelled	25.49/ 84.66	SFO, chi^2: 5.45	24.30/ 80.7	SFO, chi^2: 4.3	-	-	
Geomean DT_{50} values (n=4)	**15.03**		**14.07**				

Table 5.4-26: Degradation in water/sediment of the metabolite 5-OH-XDE 570

Water / sediment system	$DegT_{50}$/ $DegT_{90}$ whole system	Kinetic/ Fit	$DegT_{50}$ water	Kinetic/ Fit	$DegT_{50}$ sed.	Kinetic/ Fit	Reference
Brown Carrick Hill, phenyl-labelled	117.5/ 390	SFO, chi^2: 15.38	-	-	-	-	Phillips, (1997), DRAR (2013)
Brown Carrick Hill, TP-labelled	332.0/ 1097	SFO, chi^2: 7.71	-	-	-	-	

Table 5.4-27 Accumulation of active substance and relevant metabolites in the sediment

active substance	Florasulam
accumulation potential in sediment	no ($DT_{90,\text{whole system}}$ < 1 year, see core assessment, part B, section 5, chapter IIIA 9.7)
accumulation factor (SFO) $f_{accu} = e^{-kt}/(1 - e^{-kt})$	-

Bifenox

Please refer to the EU LoEP and core assessment (December 2013), part B, section 5, chapter IIIA 9.7.

Accumulation of active substance and relevant metabolites in the sediment

active substance	bifenox
accumulation potential in sediment	no ($DT_{90,\text{whole system}}$ < 1 year, see core assessment, part B, section 5, chapter IIIA 9.7)
accumulation factor (SFO) $f_{accu} = e^{-kt}/(1 - e^{-kt})$	-

5.5 Estimation of concentrations in soil (KIIIA1 9.4)

Results of PECsoil calculation for AG-FB1-485 SC according to EU assessment considering 5 cm soil depth are given in the core assessment (December 2013), part B, section 5, chapter IIIA 9.4 and IIIA 9.5.

For German exposure assessment the applied soil depth is based on experimental data (Fent, Löffler, Kubiak: Ermittlung der Eindringtiefe und Konzentrationsverteilung gesprühter Pflanzenschutzmittelwirkstoffe in den Boden zur Berechnung des PEC-Boden. Abschlussbericht zum Forschungsvorhaben FKZ 360 03 018, UBA, Berlin 1999). Generally for active substances with a $K_{f,oc}$ < 500 a soil depth of 2.5 cm is applied whereas for active substances with a $K_{f,oc}$ > 500 a soil depth of 1 cm is applied. As soil bulk density 1.5 g cm^{-3} is assumed.

Due to the fast degradation of florasulam and its soil metabolites 5-OH-XDE-570 and DFP-ASTCA in soil (DT_{90} < 365 d, SFO, laboratory data) their accumulation potential does not need to be considered. Due to the slow degradations of metabolites ASTCA and TSA in soil (DT_{90}> 365 d, Kinetic, laboratory data) their accumulation potential needs to be considered. Therefore, for ASTCA and TSA an accumulated soil concentration (PEC_{accu}) is used for risk assessment that comprises background concentration in soil (PEC_{bkgd}) considering a tillage depth of 20 cm (arable crop) or 5 cm (permanent crops) and the maximum annual soil concentration PEC_{act} for a soil depth of 2.5 cm.

Due to the fast degradation of the active substance bifenox in soil (DT_{90} < 365 d, SFO, laboratory data) the accumulation potential of bifenox does not need to be considered. Due to the slow degradation of metabolite bifenox-acid in soil (DT_{90}> 365 d, SFO Kinetic, laboratory data) its accumulation potential needs to be considered. Therefore, for bifenox-acid an accumulated soil concentration (PEC_{accu}) is used for risk assessment that comprises background concentration in soil (PEC_{bkgd}) considering a tillage depth of 20 cm (arable crop) or 5 cm (permanent crops) and the maximum annual soil concentration PEC_{act} for a soil depth of 2.5 cm.

The PEC_{soil} calculations were performed with ESCAPE 2.0 based on the input parameters as presented in Table 5.5-1.

Table 5.5-1: Input parameters related to application for PEC_{soil} calculation

Plant protection product	AG-FB1-485 SC
Use No.:	00-001, 00-002
Crop:	Winter and spring cereals
Application rate:	1.2 L/ha (00-001) 1 L/ha (00-002)
Number of application/interval:	1
Crop interception:	25 %

*formulation density: 1.189 g/mL

Table 5.5-2: DT_{50} values of florasulam and bifenox and its metabolites for PEC_{soil} calculation

Active substance	**DT_{50}**
florasulam	25.5 d (SFO, maximum field studies representative for German climate conditions, see point 5.4.1.2)
metabolite 5-OH-XDE-570	18.7 d (SFO, 90th percentile, laboratory study, see point 5.4.1.1)
metabolite DFP-ASTCA	32.9 d (SFO, 90th percentile, laboratory study, see point 5.4.1.1)
metabolite ASTCA	259 d (SFO, Maximum, laboratory study, see point 5.4.1.1)
metabolite TSA	172.2 d (SFO, 90th percentile, laboratory study, see point 5.4.1.1)
bifenox	15.2 d (SFO, 90th percentile, laboratory study, see point 5.4.1.1)
metabolite bifenox-acid	269.7 d (SFO, estimated rate of decline from day 56 in sandy loam 99/17 soil laboratory study, used for long term maximum (PEC plateau), see core assessment, part B, section 5, table IIIA 9.4.3)

Additional $PEC_{soil,act}$ was calculated for the formulation AG-FB1-485 SC for a soil depth of 2.5 cm.

No short-term and long-term PEC_{soil} were calculated since $PEC_{soil,act}$ is considered sufficient for German risk assessment.

The calculated PEC_{soil} used for German risk assessment for florasulam, bifenox and its metabolites and for the formulation AG-FB1-485 SC are summarised in

Table 5.5-3.

Table 5.5-3: Results of PEC_{soil} calculation for the intended use in winter cereals used for German risk assessment

plant protection product:		AG-FB1-485 SC				
use:		00-001				
Number of applications/intervall		1				
application rate:		1.2 L/ha				
crop interception:		25 %				
active substance/ formulation	**soil relevant application rate (g/ha)**	**soil depth$_{act}$ (cm)**	**PEC_{act} (mg/kg)**	**tillage depth (cm)**	**PEC_{bkgd} (mg/kg)**	**PEC_{accu} = PEC_{act} + PEC_{bkgd} (mg/kg)**
florasulam	4.5	2.5	0.01	-	-	-
metabolite 5-OH-XDE-570 [a)]	3.1	2.5	0.008	-	-	-
metabolite DFP-ASTCA [b)]	0.61	2.5	0.002	-	-	-
metabolite ASTCA [c)]	0.81	2.5	0.0018	20	0.0001	0.0020
metabolite TSA [d)]	0.30	2.5	0.0008	20	< 0.0001	0.0008
Bifenox	432	1	1.15	-	.	.
metabolite bifenox-acid [e)]	325.93	2.5	0.87	20	0.07	0.94
Formulation AG-FB1-485 SC	1070.1	2.5	2.85	-	-	-

a) maximum occurrence: 71.6 %, molecular correction: 0.96
b) maximum occurrence: 17.8 %, molecular correction: 0.76
c) maximum occurrence: 40.0 %, molecular correction: 0.45
d) maximum occurrence: 15.9 %, molecular correction: 0.41
e) maximum occurrence: 78.7 %, molecular correction: 0.96

Table 5.5-4: Results of PEC_{soil} calculation for the intended use in spring cereals used for German risk assessment

plant protection product:		AG-FB1-485 SC				
use:		00-002				
Number of applications/intervall		1				
application rate:		1 L/ha				
crop interception:		25 %				
active substance/ formulation	**soil relevant application rate (g/ha)**	**soil depth$_{act}$ (cm)**	**PEC_{act} (mg/kg)**	**tillage depth (cm)**	**PEC_{bkgd} (mg/kg)**	**PEC_{accu} = PEC_{act} + PEC_{bkgd} (mg/kg)**
florasulam	3.75	2.5	0.008	-	-	-
metabolite 5-OH-XDE-570 [a)]	2.58	2.5	0.007	-	-	-

metabolite DFP-ASTCA [b)]	0.51	2.5	0.0014	-	-	-
metabolite ASTCA [c)]	0.68	2.5	0.0018	20	0.0001	0.002
metabolite TSA [d)]	0.25	2.5	0.0007	20	< 0.0001	0.0007
Bifenox	360.0	1	0.96	-	-	-
metabolite bifenox-acid [e)]	271.6	2.5	0.72	20	0.058	0.783
Formulation AG-FB1-485 SC	891.8	2.5	2.38	-	-	-

[a)] maximum occurrence: 71.6 %, molecular correction: 0.96
[b)] maximum occurrence: 17.8 %, molecular correction: 0.76
[c)] maximum occurrence: 40.0 %, molecular correction: 0.45
[d)] maximum occurrence: 15.9 %, molecular correction: 0.41
[e)] maximum occurrence: 78.7 %, molecular correction: 0.96

5.6 Estimation of concentrations in surface water and sediment (KIIIA1 9.7)

Results of PECsw calculation of florasulam and bifenox for the intended uses of AG-FB1-485 SC in winter cereals using FOCUS Surface Water are given in the core assessment (December 2013), part B, section 5, chapter 9.7.

For authorization in Germany, exposure assessment of surface water considers the two routes of entry (i) spraydrift and volatilisation with subsequent deposition and (ii) run-off, drainage separately in order to allow risk mitigation measures separately for each entry route.

Surface water exposure via spray drift and volatilization with subsequent deposition is estimated with the models EVA 2.1. Surface water exposure via surface run-off and drainage is estimated using the model EXPOSIT 3.0.

The German surface water exposure assessment is outlined in the following chapters.

5.6.1 PECsw after exposure by spraydrift and volatilization with subsequent deposition

The calculation of concentrations in surface water is based on spray drift data by Rautmann and Ganzelmeier. The vapour pressures at 20 °C of the active substances florasulam and bifenox are $< 10^{-5}$ Pa. Hence the active substances florasulam and bifenox are regarded as non-volatile. Therefore exposure of surface water by the active substances florasulam and bifenox due to deposition following volatilization does not need to be considered.

The calculation of PECsw after exposure via spray drift is performed using the model EVA 3.0. For a single application, the exposure assessment via spray drift is based on the application rate in conjunction with the 90th percentile of the drift values.

The calculated PECsw values after exposure via spray drift for the active substances florasulam and bifenox for the intended use of AG-FB1-485 SC in winter and spring cereals according to use No.00-001 and 00-002 are presented in the National addendum Germany, part B, section 6, chapter 6.5.

5.6.2 PECsw after exposure by surface run-off and drainage

The concentration of the active substances florasulam and bifenox in adjacent ditch due to surface runoff and drainage is calculated using the model EXPOSIT 3.01.

The endpoints for florasulam and bifenox used for modelling surface water exposure via run-off and drainage in an adjacent ditch with EXPOSIT 3.01 are summarized in Table 5.6-1.

Table 5.6-1 Input parameters for florasulam used for PEC_{SW} calculations with EXPOSIT 3.01

Parameter	florasulam	Reference
$K_{foc, Runoff}$	20	arithm. mean (see chapter 5.4.2)
$K_{foc, mobility\ class}$	2	10th percentil (see chapter 5.4.2)
DT_{50} soil (d)	25.5	SFO, maximum field studies representative for German climate conditions, see point 5.4.1.2)
Solubility in water (mg/L)	6360	see point 5.3.1.2
Mobility class	3	
Reduction by bank filtration (only relevant for PECgw see 5.7.2)	90 %	

Table 5.6-2 Input parameters for bifenox used for PEC_{SW} calculations with EXPOSIT 3.01

Parameter	bifenox	Reference
$K_{foc, Runoff}$	8224	arithm. mean (see chapter 5.4.2)
$K_{foc, mobility\ class}$	4468	10th percentile (see chapter 5.4.2)
DT_{50} soil (d)	15.2	90th percentil (see point 5.4.1.1)
Solubility in water (mg/L)	< 0.1	see core assessment, section 5, point 5.3.1.1
Mobility class	1	
Reduction by bank filtration (only relevant for PECgw see 5.7.2)	100 %	

The calculated PEC_{SW} in an adjacent ditch due to surface run-off and drainage for the active substance florasulam for the intended use of AG-FB1-485 SC in winter and spring cereals according to use No. 00-001 and 00-002 are presented in the National addendum Germany, part B, section 6, chapter 6.5.

Table 5.6-3: Risk assessment for groundwater (KIIIA1 9.6)

Results of PECgw calculation of florasulam and bifenox for the intended uses of AG-FB1-485 SC in winter cereals according to EU assessment using FOCUS-PELMO 4.4.3 and FOCUS-PEARL 4.4.4 are given in the core assessment (December 2013), part B, section 5, chapter IIIA 9.6.

For authorization in Germany, risk assessment for groundwater considers two pathways, (i) direct leaching of the active substance into the groundwater after soil passage and (ii) surface run-off and drainage of the active substance into an adjacent ditch with subsequent bank filtration into the groundwater.

Direct leaching after soil passage is assessed following the recommendations of the publication of Holdt et al. 2011 (Holdt et al: Recommendations for simulations to predict environmental concentrations of active substances of plant protection products and their metabolites in groundwater (PEC_{GW}) in the National assessment for authorization in Germany, Texte Umweltbundesamt 56, 2011) for tier 1 and tier 2 risk assessment. According to Holdt et al, 2011, endpoints for groundwater modelling are derived with the program INPUT DECISION 3.3 and subsequent simulations are performed for the groundwater scenarios “Hamburg” or with the scenarios “Hamburg” and “Kremsmünster” of FOCUS PELMO 5.5.3.

In tier 3 risk assessment, results of experimental studies (lysimeter studies and/or field leaching studies) can also be considered in German groundwater risk assessment.

Surface run-off and drainage into an adjacent ditch with subsequent bank filtration into the groundwater are estimated using the model EXPOSIT 3.

The German risk assessment for groundwater is given in the following chapters.

5.7 Direct leaching into groundwater

5.7.1 PEC$_{GW}$ modelling

The worst case scenario used for PECgw modelling is summarized in Table 5.7-1. It covers the intended uses of AG-FB1-485 SC in winter and spring cereals according to Table 5.2-1.

Table 5.7-1 Input parameters related to application for PEC$_{GW}$ modelling with FOCUS PELMO 5.5.3

use evaluated	1. 00-001 (winter cereals) 2. 00-002 (spring cerals)
application rate (g as/ha)	1. florasulam: 6; bifenox: 576 2. florasulam: 5; bifenox: 480
crop (crop rotation)	1. winter cereals 2. spring cereals
date of application	6th of april (spring application in winter and spring cereals)
interception (%)	25 %
soil effective application rate (g as/ha)	1. florasulam: 4.5; bifenox: 432 2. florasulam: 3.75; bifenox: 360
soil moisture	100 % FC
Q10-factor	2.58
moisture exponent	0.7
plant uptake	0
simulation period (years)	26

Florasulam

The endpoints used for groundwater modelling for florasulam and its metabolites 5-OH-XDE-570, DFP-ASTCA, ASTCA and TSA according to INPUT DECISION 3.3 are summarized in Table 5.7-2.

Table 5.7-2 Input parameters related to florasulam for PEC$_{GW}$ modelling

Parent	florasulam	Remarks/Reference to core assessment, part B, section 5
molecular weight (g/mol)	359.3	-
DT$_{50}$ in soil (d)	2.0	geomean, all soils for scenario Hamburg and Kremsmünster
Transformation rates	parent → 5-OH-XDE-570: 0.3050 Parent → sink: 0.0416	-
K$_f$	pH ≥ 7: 1.90 all soils: 0.449	1st run: Kremsmünster scenario: Kf = 0.190 for1st – 5th horizon (arithmetic mean of neutral and alklaine soils at pH ≥ 7) for1st – 5th horizon

		2nd run: Hamburg scenario with Kf = 0.449 for 1st-3rd horizon (arithmetic mean all soils)
1/n	at pH ≥ 7: 0.936 all soils: 0.945	1st run: Kremsmünster scenario: arithmetic mean for neutral and alkaline soils at pH ≥ 7 2nd run: Hamburg scenario: arithmetic mean all soils
Plant uptake	0	default
metabolite	**5-OH-XDE-570**	
molecular weight (g/mol)	345.3	
Formation fraction	0.88 (from parent)	arithmetic mean
DT_{50} in soil (d)	13.4	geomean, laboratory studies at pF2 and 20°C
Transformation rates	5-OH-XDE-570→DFP-ASTCA : 0.69 5-OH-XDE-570→ sink: 0.31	-
K_f	at pH ≥ 7: 0.218 all soils : 0.512	1st run: Kremsmünster scenario: Kf = 0.218 for1st – 5th horizon (arithmetic mean of neutral and alkaline soils at pH ≥ 7) 2nd run: Hamburg scenario: Kf = 0.512 for 1st-3rd horizon (arithmetic mean all soils)
1/n	at pH ≥ 7: 0.909 all soils: 0.906	1st run: Kremsmünster scenario: arithmetic mean for neutral and alkaline soils at pH ≥ 7 2nd run: Hamburg scenario: arithmetic mean all soils
Plant uptake	0	default
metabolite	**DFP-ASTCA**	
molecular weight (g/mol)	304.2	
Formation fraction (5-OH-XDE-570→ DFP-ASTCA)	0.69	arithmetic mean, laboratory studies at pF2 and 20°C
DT_{50} in soil (d)	13.4	geomean, laboratory studies at pF2 and 20°C
Transformation rates	DFP-ASTCA → ASTCA: 0.0404 DFP-ASTCA → TSA: 0.0113	-
K_f	1.08	arithmetic mean of K_f values all soils (n= 4)
1/n	0.858	arithmetic mean all soils (n = 4)
Plant uptake	0	default
metabolite	**ASTCA**	
molecular weight (g/mol)	192.2	
Formation fraction (DFP-ASTCA→ASTCA)	0.781	maximum, laboratory studies at pF2 and 20°C
DT_{50} in soil (d)	259	maximum, laboratory studies at pF2 and 20°C
Transformation rates	ASTCA → TSA: 0.002676	-

K_f	1.64	arithmetic mean of K_f values all soils (n= 4)
1/n	0.935	arithmetic mean all soils (n= 4)
Plant uptake	0	default
metabolite	**TSA**	
molecular weight (g/mol)	148.1	
Formation fraction	ASTCA→TSA: 1.0	-
	DFP-ASTCA→ TSA: 0.219	calculated by the difference of 1.000 – the mean ff value for the formation of ASTCA from DFP-ASTCA (0.781)
DT_{50} in soil (d)	118.9	
K_{foc}	0.38	arithmetic mean of K_f values all soils (n= 4)
1/n	0.943	arithmetic mean all soils (n= 4)
Plant uptake	0	default

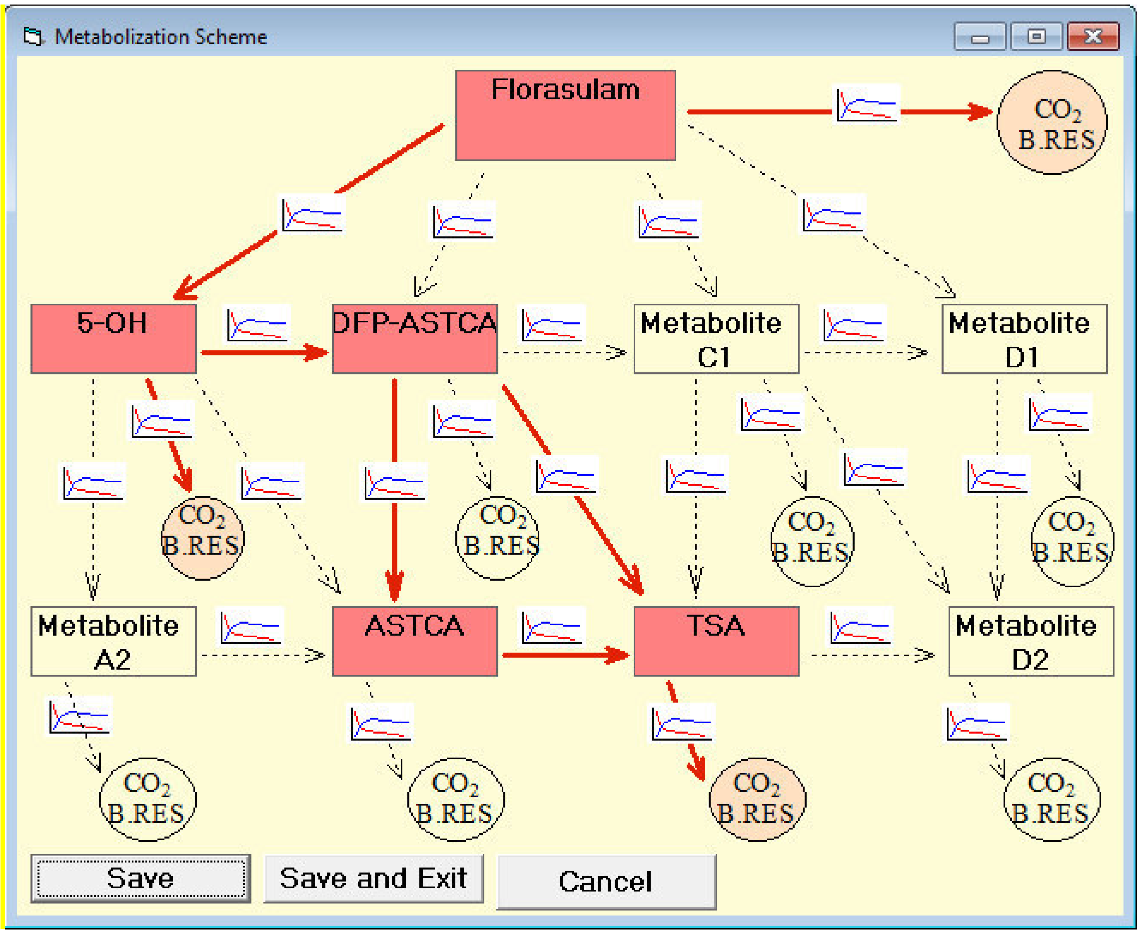


Figure 5.7-1: Metabolization scheme for florasulam used in calculations with FOCUS PELMO 5.5.3

The results of the groundwater simulation are presented in Table 5.7-3.

Table 5.7-3 PEC_{GW} at 1 m soil depth of florasulam and its metabolites considered relevant for German exposure assessment

Use No.	Szenario	80th Percentile PEC_{GW} at 1 m Soil Depth (µg L^{-1}) modeled by FOCUS PELMO 5.5.3				
		florasulam	metabolite 5-OH	metabolite DFP-ASTCA	metabolite ASTCA	metabolite TSA
00-001 winter cereal	Hamburg	0.000	0.000	0.000	0.088	**0.188**
	Krems-münster	0.000	0.000	0.000	0.055	**0.144**
00-002 spring cereals	Hamburg	0.000	0.000	0.000	0.072	**0.156**
	Krems-münster	0.000	0.000	0.000	0.051	**0.138**

Bifenox

Table 5.7-4 Input parameters related to bifenox for PEC_{GW} modelling

Parent	Bifenox	Remarks/Reference to core assessment, part B, section 5
molecular weight (g/mol)	342.1	-
DT_{50} in soil (d)	8.3	geometric mean (n = 4)
K_f	85.3	arithmetic mean K_f – values for soil horizons (n= 6)
1/n	0.99	arithmetic mean all soils (n=6)
Plant uptake	0	Default
Metabolite	**Bifenox-acid**	
molecular weight (g/mol)	328	-
DT_{50} in soil (d)	56.3	geometric mean (n = 7)
Foramtion fraction	1	default
K_{foc}	144	arithmetic mean (n= 3)
1/n	0.84	arithmetic mean all soils (n=3)
Plant uptake	0	Default

Table 5.7-5 PEC_{GW} at 1 m soil depth of bifenox and its metabolite considered relevant for German exposure assessment

Use No.	Szenario	80th Percentile PEC_{GW} at 1 m Soil Depth (µg L^{-1}) modeled by FOCUS PELMO 5.5.3	
		bifenox	**Metabolite bifenox-acid**
00-001 winter cereals	Hamburg	0.000	**0.110**
00-002, spring cereals	Hamburg	0.000	0.073

According to the results of the groundwater simulation with FOCUS-PELMO 5.5.3, a groundwater contamination of the active substances florasulam and bifenox in concentrations of ≥ 0.1 µg/L is not expected for the intended use in winter and spring cereals.

For the metabolites 5-OH-XDE-570, DFP-ASTCA and ASTCA of florasulam a groundwater concentration of ≥ 0.1 µg/L can be excluded for the application in winter and spring cereals according to the results of the groundwater simulation with FOCUS PELMO 5.5.3. For the metabolite TSA of florasulam a groundwater concentration of ≥ 0.1 µg/L cannot be excluded for the intended uses according to the results of the groundwater simulation with FOCUS PELMO 5.5.3.

For the metabolites bifenox-acid of bifenox a groundwater concentration of ≥ 0.1 µg/L cannot be excluded for the intended use in winter cereals (00-001) according to the results of the groundwater simulation with FOCUS PELMO 5.5.3.

In addition to the PEC_{GW} modelling experimental data from lysimeter studies are available to assess the leaching behaviour of the active substance florasulam.

5.7.2 Experimental data to the leaching behaviour of the active aubstance florasulam

In case of the active substance florasulam exposure assessment is based additionally on results of two lysimeter studies. The study Jackson and Paterson (1997) was reviewd in the EU assessment.

Jackson, R. and Paterson, G, (1997)

active substance:	Florasulam
author:	Jackson, R. and Paterson, G.
report:	The dissipation of XDE-570 in soil and crops using field lysimeters
study date:	17/12/1997
study code:	GHE-P-6751
reference:	see DAR for a detailed description of the study

The experimental data on the leaching behaviour of the active substance florasulam show that florasulam and its metabolite 5-OH are not expected to penetrate into groundwater at concentrations of ≥ 0.1µg/L in the intended for uses in winter and spring cereals after application in spring at locations for which the climate conditions of the UK (51.5°N latitude) are considered a worst case scenario.

Additionally, a second lysimeter study with florasulam (Pillar, 2001) was submitted within the national authorization of other florasulam-containing formulations, which was not evaluated during the EU assessment.

Pillar (2001)

active substance:	Florasulam
author:	Pillar, F.
report:	The dissipation of DE-570 in field lysimeters following autumn application
study date:	19.7.2001
study code:	GEH-P-9281

In the study, the leaching behaviour of florasulam was tested in the UK (51.5°N latitude) for a single application of 4 g as/ha to winter cereals at BBCH stage 12-16 in autumn at a location. Due to the smaller application rate, it is thus not considered relevant for estimating possible groundwater entries of the active substance florasulam and its metabolites for this exposure assessment. Thus, no detailed description of the study is presented here.

5.7.3 Summary on risk assessment for groundwater after direct leaching

According to the results of the groundwater simulation with FOCUS-PELMO 5.5.3, a groundwater contamination of the active substances florasulam and bifenox in concentrations of ≥ 0.1 µg/L is not expected for the intended use in winter and spring cereals.

For the metabolites 5-OH-XDE-570, DFP-ASTCA and ASTCA of florasulam a groundwater concentration of ≥ 0.1 µg/L can be excluded for the application in winter and spring cereals according to the results of the groundwater simulation with FOCUS PELMO 5.5.3. For the metabolite TSA of florasulam a groundwater concentration of ≥ 0.1 µg/L cannot be excluded for the intended uses according to the results of the groundwater simulation with FOCUS PELMO 5.5.3.

For the metabolites bifenox-acid of bifenox a groundwater concentration of ≥ 0.1 µg/L cannot be excluded for the intended use in winter cereals (00-001) according to the results of the groundwater simulation with FOCUS PELMO 5.5.3.

However the metabolite TSA are classified as not relevant for groundwater (see part B, section 8, national addendum).

Consequences for authorization:

none

5.7.4 Ground water contamination by bank filtration due to surface water exposure via run-off and drainage

The input parameters for florasulam used for modelling surface water exposure via run-off and drainage in an adjacent ditch with subsequent bank filtration into the groundwater with EXPOSIT 3.0 are summarized in Table 5.7-6.

Table 5.7-6 Input parameters for florasulam used for PEC_{GW} calculations with EXPOSIT 3.0

Parameter	florasulam	Reference
$K_{foc, Runoff}$	20	arithm. mean (see chapter 5.4.2)
$K_{foc, mobility class}$	2	10th percentil (see chapter 5.4.2)
DT_{50} soil (d)	25.5	SFO, maximum field studies representative for German climate conditions, see point 5.4.1.2)
Solubility in water (mg/L)	6360	See chapter 5.3.1.2
Mobility class	3	
Reduction by bank filtration	60 %	default

Table 5.7-7 Input parameters for bifenox used for PEC_{GW} calculations with EXPOSIT 3.0

Parameter	bifenox	Reference
$K_{foc, Runoff}$	8224	arithm. mean (see chapter 5.4.2)
$K_{foc, mobility class}$	4468	10th percentile (see chapter 5.4.2)
DT_{50} soil (d)	15.2	90th percentil, lab data (see point 5.4.1.1)
Solubility in water (mg/L)	< 0.1	see core assessment, section 5, point 5.3.1.1
Mobility class	1	
Reduction by bank filtration	100 %	default

Table 5.7-8 Input parameters for the metabolite bifenox-acid used for PEC_{GW} calculations with EXPOSIT 3.0

Parameter	Metabolite bifenox-acid	Reference
$K_{foc, Runoff}$	144	arithm. mean (see chapter 5.4.2)
$K_{foc, mobility class}$	144	arithm. mean (see chapter 5.4.2)

DT_{50} soil (d)	114.2	90th percentil (see point 5.4.1.1)
Solubility in water (mg/L)	-	-
Mobility class	2	
Reduction by bank filtration	%	default

The calculated PECgw for florasulam and bifenox after surface run-off and drainage with subsequent bank filtration are summarized in Table 5.7-9.

Table 5.7-9 PEC_{gw} for florasulam after surface run-off and drainage with subsequent bank filtration (modelled with EXPOSIT 3.01)

Active substance		**florasulam**			
Use No.	**application rate interception**	**PECgw due to**			
		run-off		**drainage**	
		vegetated buffer strip (m)	**bank filtrate (µg/L)**	**Time of application**	**bank filtrate (µg/L)**
00-001 (covers 00-002)	1 x 6, 25 %	0	0.000	autumn/winter/ early spring	0.00
		5	-		
		10	-	spring/summer	0.00
		20	-		
required labelling		none			

Table 5.7-10 PEC_{gw} for bifenox after surface run-off and drainage with subsequent bank filtration (modelled with EXPOSIT 3.01)

Active substance		**bifenox**			
Use No.	**application rate interception**	**PECgw due to**			
		run-off		**drainage**	
		vegetated buffer strip (m)	**bank filtrate (µg/L)**	**Time of application**	**bank filtrate (µg/L)**
00-001 (covers 00-002)	1 x 576, 25 %	0	0.000	autumn/winter/ early spring	0.00
		5	-		
		10	-	spring/summer	0.00
		20	-		
required labelling		none			

According modelling with EXPOSIT 3.01, groundwater contamination at concentrations ≥ 0.1 µg/L by the active substances florasulam and bifenox due to surface run-off and drainage into the adjacent ditch with subsequent bank filtration can be excluded.

Metabolites

The soil metabolites 5-OH, DFP-ASTCA, ASTCA and TSA of florasulam (see point 5.3.1) are potentially relevant. Therefore potential ground water contamination due to bank filtration via surface water exposure by run-off and drainage needs to be assessed using EXPOSIT 3.01. However, EXPOSIT 3.01 calculations for the active substances florasulam resulted in concentrations <0.001 ug/L in the groundwater due to surface run-off and drainage into the adjacent ditch with subsequent bank filtration. Since the metabolites are expected in even lower concentrations in the surface water than the active substance, no groundwater contamination due to surface run-off and drainage into the adjacent ditch with subsequent bank filtration of the metabolites is expected. Calculations with EXPOSIT 3.01 are therefore not considered necessary for these metabolites.

The soil metabolite bifenox-acid (see point 5.3.2) are formed > 10 % in soil. Therefore potential ground water contamination due to bank filtration via surface water exposure by run-off and drainage needs to be assessed using EXPOSIT 3.01.

The input parameter for the model EXPOSIT 3.01 are summarized in Table 5.7-11, the results are given in

Table 5.7-12.

Table 5.7-11: Input parameter for soil metabolite of bifenox for EXPOSIT 3.01

Parameter	**Metabolite bifenox-acid**
Molecular weight (g/mol)	328
Correction factor molecular weight	0.96
Maximum occurrence in soil (%)	78.7 %
$K_{foc, Runoff}$	144
$K_{foc, mobility class}$	144
DT_{50} soil (d)[1)]	114.2
Solubility in water (mg/L)	Not available
Mobility class	2

[1)] only relevant for mobility class

Table 5.7-12: PEC_{gw} for soil metabolites of bifenox after surface run-off and drainage with subsequent bank filtration (modelled with EXPOSIT 3.01)

<table>
<tr><td colspan="2">Metabolit</td><td colspan="4">Bifenox-acid</td></tr>
<tr><td rowspan="3">Use No.</td><td rowspan="3">application rate interception</td><td colspan="4">PECgw due to</td></tr>
<tr><td colspan="2">run-off</td><td colspan="2">drainage</td></tr>
<tr><td>vegetated buffer strip (m)</td><td>bank filtrate (µg/L)</td><td>Time of application</td><td>bank filtrate (µg/L)</td></tr>
<tr><td rowspan="4">00-001 (covers 00-002)</td><td rowspan="4">434.6, 25 %</td><td>0</td><td>0.061</td><td rowspan="2">autumn/winter/ early spring</td><td rowspan="2">0.062</td></tr>
<tr><td>5</td><td>-</td></tr>
<tr><td>10</td><td>-</td><td rowspan="2">spring/summer</td><td rowspan="2">0.020</td></tr>
<tr><td>20</td><td>-</td></tr>
<tr><td colspan="2">required labelling</td><td colspan="4">none</td></tr>
</table>

According to modelling with EXPOSIT 3, groundwater contamination at concentrations ≥ 0.1 µg/L by the soil metabolite of bifenox due to surface run-off and drainage into the adjacent ditch with subsequent bank filtration can be excluded.

Consequences for authorization:

None.

Appendix 1 List of data submitted in support of the evaluation

No additional data for national assessment submitted.

DRAFT REGISTRATION REPORT
Part B

Section 6: Ecotoxicological studies
Detailed summary of the risk assessment

Product code: **AG-FB1-485 SC**
Active Substance(s): **Florasulam 5 g/L**
Bifenox 480 g/L

COUNTRY: Germany
Central Zone
Zonal Rapporteur Member State: Austria

NATIONAL ADDENDUM

Applicant: **ADAMA Deutschland GmbH**
Date: **14/03/2016**

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Sec 6 ECOTOXICOLOGICAL STUDIES (MIIIA 10)

A full risk assessment according to Uniform Principles for the plant protection product AG-FB1-485 SC in its intended uses in winter and spring cereals is documented in detail in the core assessment of the plant protection product AG-FB1-485 SCdated from September 2013 performed by zRMS Austria.

This document comprises specific risk assessment for some annex points for authorization of the plant protection product AG-FB1-485 SC in Germany according to the uses listed in Appendix 2.

General information on the formulation AG-FB1-485 SC can be found in Table 5.1-1of Section 5 of the National addendum Germany (April 2013).

6.1 Proposed use pattern and considered metabolites

6.1.1 Grouping of intended uses for risk assessment

Full details of the proposed use pattern of the formulation AG-FB1-485 SC that will be assessed are presented in **Fehler! Verweisquelle konnte nicht gefunden werden.** and summarized in the table below. The intended uses in Germany are covered by the core assessment performed by zRMS Austria.

The following table lists the grouping of the intended uses in order to perform a risk envelope approach.

Intended uses may be grouped according to soil relevant application rate, drift rate and maximum daily dose for birds and mammals. The soil relevant application rate is based on the effective cumulative application rate including interception. For drift rate, the intended uses are grouped according to the application rate and the relevant drift scenario. For birds and mammals the application rate, minimum interval, number of applications and the relevant crop scenario are considered.

Table 6.1-1: Critical use pattern of AG-FB1-485 SC

Group/ use No*	Crop/growth stage	Application method Drift scenario	Number of applications, Minimum application interval, application time, interception	Application rate, cumulative (g as/ha)	Soil effective application rate (g as/ha)
00-001	Winter cereals , BBCH 13-29	spraying	1	1.2 L/ha: Florasulam: 6 Bifenox:576	
00-002	Spring cereals, BBCH 13-29	spraying	1	1 L/ha: Florasulam: 5 Bifenox:480	

6.1.2 Consideration of metabolites

Please refer to the core assessment as well as NA, Section B5.

6.2 Effects on birds (MIIIA 10.1, KPC 10.1, KPC 10.1.1)

Please refer to the core assessment.

Consequences for authorization:

none

6.3 Effects on Terrestrial Vertebrates Other Than Birds (MIIIA 10.3, KPC 10.1, KPC 10.1.2)

Please refer to the core assessment.

Consequences for authorization:

none

6.4 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KPC 10.1.3)

Please refer to the core assessment.

Consequences for authorization:

none

6.5 Effects on aquatic organisms (MIIIA 10.2, KPC 10.2, KPC 10.2.1)

6.5.1 Overview

Results of aquatic risk assessment for the intended for uses of AG-FB1-485 SC in winter and spring cereals based on FOCUS Surface Water PEC values is presented in the Core assessment, Part B, Section 6, chapter 10.2.

For authorization in Germany, exposure assessment of surface water considers the two routes of entry (i) spraydrift and volatilisation with subsequent deposition and (ii) run-off, drainage separately in order to allow risk mitigation measures separately for each entry route. Hence, aquatic risk assessment differs from those in the core assessment.

The risk assessment for aquatic organism for authorization of AG-FB1-485 SC is outlined in the following chapters.

6.5.2 Toxicity

The following studies were used for risk assessment.

Table 6.5-1: Ecotoxicological endpoints for aquatic species exposed to bifenox, florasulam and AG-FB1-485 SC

Species	Substance	Exposition Duration System	Results Toxicity	Reference Date author Report No.	ICS-No.
Acute toxicity to fish					
Oncorhynchus mykiss	Bifenox	4 d, flow through	LC_{50} = 0.67 mg a.s./L 1a)	XXX et al. 1993 Report Nr.282/388	24763
Lepomis macrochirus	Bifenox	4 d, flow through	LC_{50} > 0.27 mg a.s./L 1a)	XXX et al. 1985 BW-85-10-1867	24761
Oncorhynchus mykiss	Aminobifenox acid	4 d	LC_{50} = 3.12 mg/L 1a)	XXX 2003 FAR88782	51879
Oncorhynchus mykiss	Bifenox acid	4 d	LC_{50} > 100 mg/L 1a)	XXX 2005 FAR84131	56740
Oncorhynchus mykiss	Florasulam (XDE-570)	4 d, static	LC_{50} > 100 mg/L 1b) nom	XXX et al., 26.01.1995, DECO-ES-2940	39400
Lepomis macrochirus	Florasulam (XDE-570)	4 d, static	LC_{50} > 100 mg/L 4) nom	XXX et al., 26.01.1995, DECO-ES-2939	39402
Oncorhynchus mykiss	5-OH-XDE-570 (metabolite of Florasulam)	4 d, static	LC_{50} > 91 mg/L 4)	XXX 23.08.1996, DECO-ES-3118	25427
Oncorhynchus mykiss	Florasulam + Bifenox 5/480 SC (AG-FB1-485 SC)	4 d, static	LC50 > 68 mg/L 2) mm	XXX 2011 D21638	85045
Chronic toxicity to fish					
Oncorhynchus mykiss	Bifenox	21 d, flow-through	NOEC = 0.0091 mg a.s./L 1a)	XXX. 1991 282/113	24770
Oncorhynchus mykiss	Florasulam (XDE-570)	28 d, prolonged flow-	NOEC > = 119 mg/L 1b) mm	XXX 02.01.1996,	39406

		through toxicity test (OECD 204)		DECO-ES-2973	
Pimephales promelas	Florasulam (XDE-570)	28 d, flow-through ELS	**NOEC = 2.9 mg/L mm [5)]**	XXX. 2011 101334 379A-138	80024
Aquatic invertebrates, acute					
Daphnia magna	Bifenox	2 d	EC_{50} = 0.66 mg a.s./L[1a)]	Surprenant, D.C et al. 1985 BW-85-10-1871	24755
Daphnia magna	Aminobifenox acid	2 d	EC_{50} = 3.38 mg a.s./L[1a)]	Noack, M 2003 DAI88781	51820
Daphnia magna	Florasulam (XDE-570)	2 d, static	EC_{50} > 292 mg/L – real [1b)]	Kirk, H. D. et al., 22.05.1995, DECO-ES-2938	39395
Daphnia magna	5-OH-XDE-570 (metabolite of Florasulam)	2 d, static	EC_{50} > 96.7 mg/L – real [1b)]	Kirk, H. D., Landre, A. M., Hugo, J. M., 23.08.1996, DECO-ES-3117	39397
Daphnia magna	Florasulam + Bifenox 5/480 SC (AG-FB1-485 SC)	2 d, static	EC50 > 18.8 mg/L[2)] mm	Kimmel, S. 2011 D21640	84925
Aquatic invertebrates, chronic					
Daphnia magna	Bifenox	21 d, semistatic	NOEC = 0.00015 mg a.s./L [1a)]	Young, B.M. 1990 38461	24757
Daphnia magna	Florasulam (XDE-570)	21 d, semistatic	NOEC = 38.9 mg/L nom (weight) [1b)] NOEC = 64.8 mg/L nom (reproduction)	Kirk, H.D., Landre, A.M., Hugo, J.M. and Stahl, D.C.	39398
Sediment dwelling organisms					
Chironomus riparius	Bifenox	28 d, static	NOEC = 0.015 mg a.s./L[1a)]	McElligott, A. 1996 SA 95480	34401

Chironomus riparius	Aminobifenox	28 d,	NOEC = 0.1 mg/L[1a)]	Scheerbaum, D. 2003 IZA84142	51915
Chironomus riparius	Florasulam (XDE-570)	28 d static spiked water	NOEC = 4.6 mg/L (nominal) (development) NOEC = 10 mg/L (nominal) (hatching) [1b)]	Kelly, C., 05.12.1997, GEHE-T-838	27644
Algae					
Desmodesmus subspicatus	Bifenox	4 d, static	**EbC50 = 0.000175 mg a.s./L** ErC50 = 0.000190 mg a.s./L[1a)]	Handley, J.W. et al. 1993 282/387	24750
Navicula pelliculosa	Bifenox	3 d, static	EbC50 = 0.0049 mg a.s./L ErC50 = 0.038 mg a.s./L[1a)]	Hoberg, J.R. 1999 10566.6577	43650
Desmodesmus subspicatus	Aminobifenox acid	3 d, static	E_bC_{50} = 11 mg/L E_rC_{50} = 19 mg/L[1a)]	Scheerbaum, D. 2003 SSO88781	51900
Desmodesmus subspicatus	Bifenox acid	3 d, static	E_bC_{50} = 2.22 mg/L E_rC_{50} = 2.88 mg/L[1a)]	Scheerbaum, D. 2005 SSO84131	56741
Navicula pelliculosa	Florasulam (XDE-570)	3 d, static	E_bC_{50} = 0.00942 mg/L mm E_rC_{50} = 0.00894 mg/L mm [1b)] NOEC < 0.000788 mg/L mm	Milazzo, D. P. et al., 1995 DECO-ES-2946	25425
Selenastrum capricornutum	5-OH-XDE-570 (metabolite of Florasulam)	4 d, static	E_bC_{50} = 21.32 mg/L mm [1b)] (biomass) EC_{50} = 21.57 mg/L (cell growth)	Milazzo, D. P., Hugo, J. M., McFadden, L., 19.08.1996, ES-3115	39392
Pseudokirchneriella subcapitata	DFP-ASTCA (N-(2,6-difluorophenyl)-5-amino-sulphonyl-1H-	3 d, static	E_bC_{50} > 100 mg/L E_yC_{50} = 96 mg/L NOEC = 50 mg/L [5)]	Rebstock, M., 27.09.2011 110046; 67000	79757

	1,2,4-triazole-3-carboxylic acid) (metabolite of Florasulam)				
Pseudokirchneriella subcapitata	ASTCA (5-(aminosulfonyl)-1H-1,2,4-triazole-3-carboxylic acid) (metabolite of Florasulam)	3 d, static	EC_{50} > 9.2 mg/L (growth) [5)]	Kirk, H. D. et al., 09.08.2000 001019	77675
Pseudokirchneriella subcapitata	TSA (metabolite of Florasulam)	3 d static	EC50 > 94 mg/L [5)]	Rebstock, M. 11.10.2011 110043	80504
Pseudokirchneriella subcapitata	5-OH-ASTP (metabolite of Florasulam)	3 d static	EC50 > 100 mg/L [5)]	Rebstock, M. 27.09.2011 110044	80506
Pseudokirchneriella subcapitata	ASTP (metabolite of Florasulam)	3 d static	EC50 > 100 mg/L [5)]	Rebstock, M. 28.09.2011 110045	80507
Pseudokirchneriella subcapitata	Florasulam + Bifenox 5/480 SC (AG-FB1-485 SC)	3 d, static	EyC50 = 0.001 mg/L mm [2,6)]	Kimmel, S. 2012 D21651	84907
Higher plant					
Lemna gibba	Bifenox	14 d	EC50 = 0.0021 mg a.s./L[1a)]	Hoberg, J.R. 1998 98-10-7499	38919
Lemna gibba	Bifenox acid	7 d	E_rC_{50} = 3.76 mg a.s./L[1a)]	Scheerbaum, D. 2005 TLA84131	56742
Lemna gibba	Florasulam (XDE-570)	14 d, static	**EC_{50} = 0.00118 mg/L [1b)]** NOEC = 0.00062 mg/L	Milazzo et al., 20.11.1995, ES-2988	39414
Lemna gibba	5-OH-XDE-570 (metabolite of Florasulam)	7 d, static	E_yC_{50} = 0.108 mg/L E_rC_{50} = 0.823 mg/L (dry weight) [5)] E_yC_{50} = 0.0378 mg/L [5)] E_rC_{50} = 0.0695 mg/L (number of fronds)	Hancock, G. A. et al., 11.07.2007, 071032	77665

			NOEC = 0.021 mg/L		
Lemna gibba	DFP-ASTCA (N-(2,6-difluorophenyl)-5-aminosulphonyl-1H-1,2,4-triazole-3-carboxylic acid) (metabolite of Florasulam)	7 d, semistatic	E_rC_{50} > 100 mg/L – (nominal) [5)] E_yC_{50} > 100 mg/L – (nominal) (biomass) E_rC_{50} > 100 mg/L – (nominal). E_yC_{50} > 100 mg/L – (nominal) (number of fronds)	Rebstock, M., 26.09.2011, 110039; 66997	79758
Lemna gibba	ASTCA (5-(aminosulphonyl)-1H-1,2,4-triazole-3-carboxylic acid) (metabolite of Florasulam)	7 d, static	EC_{50} > 10.2 mg/L – (nominal) [5)] (number of fronds)	Kirk, H. D. et al., 03.08.2000, 001021; 76666	77888
Lemna gibba	TSA (metabolite of Florasulam)	7 d semistatic	EC50 > 100 mg a.i./L [5)]	Rebstock, M. 07.10.2011 110040	80509
Lemna gibba	AG-FB1-485 SC	7 d, static	E_yC_{50} = 0.00065 mg/L mm[2,6)]	Weber, B. 2012 D21662	84909
Higher tier					
Algae, macrophyte and invertebrate communi-ties	Foxtril super (SC formulation con-taining 237.3 g bife-nox/L, 75.0 g ioxynil/L and 297.0 g mecoprop-P/L)	87 d	87 **d NOAEC = 0.004 mg bife-nox/L agreed assessment factor: 3** i.e. RAC = 0.00133 mg a.s./L[1a)]	Schäfers et al. 2006a	--
Algae, macrophyte and invertebrate communi-ties	Bifenix N (168 g bifenox/L, 341 g isoproturon/L)	3 m	NOEAEC = 0.004 mg/L[1a)]	Schäfers et al. 2006b FEI-011/4-52	65791

Mm: mean measured concentration

1a) EFSA Scientific Report 119; 2007

1b) SANCO/1406/2001

2) New study submitted by the applicant

3) new study known to UBA from another notifier (not submitted by the applicant) - most sensitive or only available endpoint

4) study evaluated in DAR (1999) for florasulam

5) study is part of Renewal DAR (2013) for florasulam

6) based on the assumption that the concentration of bifenxo decreased to < LOQ by the end of the test

6.5.3 Justification for new endpoints

Please refer to the core assessment.

6.5.4 Toxicity to exposure ratios for aquatic species (MIIIA 10.2.1)

The evaluation of the risk for aquatic and sediment-dwelling organisms was performed in accordance with the recommendations of the "Guidance Document on Aquatic Ecotoxicology", as provided by the Commission Services (SANCO/3268/2001 rev.4 (final), 17 October 2002).

Mixture Toxicity

A model often used to estimate the toxicity of mixtures is the assumption of dose/concentration additivity of toxicity (Finney approach of concentration additivity of toxicity; Finney, D.J., 1948 and 1971).

Toxicity studies on acute and chronic effects of the active substances and AG-FB1-485 SC to aquatic organisms are available. For a more detailed assessment of mixture toxicity, a surrogate LC_{50} or EC_{50} can be calculated. However, reliable results can only be expected for combinations of EC_X values for the same biological endpoint. Moreover, the use of NOEC values, which are strongly depending on dose-spacing, would introduce additional bias in the calculations.

The following formula is used to derive a surrogate LC_{50} or EC_{50} for the mixture of active substances with known toxicity assuming concentration additivity:

$$LC_{50}(mix) = \left(\sum_i \frac{X(a.s._i)}{LC_{50}(a.s._i)} \right)^{-1}$$

where:

X(a.s. *i*) = fraction of active substance (i) in the mixture expressed as:

X(Bifenox) = 480 g bifenox/L/(5 g florasulam/L + 480 g bifenox/L)

X(Florasulam) = 5 g florasulam/L/(480 g bifenox/L + 5 g florasulam/L)

LC_{50}(a.s. *i*) = acute toxicity value for active substance (*i*)

Because of the direct proportionality of the calculated TER to the LC_{50}, it is possible to calculate a TER(mix) with the following formula:

$$\mathrm{TER(mix)} = \left(\sum_i \frac{1}{\mathrm{TER(a.s._{\mathit{i}})}} \right)^{-1}$$

where:

$TER_{(a.s.i)}$= calculated TER for the active substance *i*

The results of the mixture calculation are presented in the following table:

Table 6.5-2: Mixture toxicity calculation for the most sensitive organism group

	Bifenox	Florasulam	AG-FB1-485 SC1	AG-FB1-485 SC, calculated mixture toxicity
Algae	E_bC_{50} = 0.175 µg a.s./L	E_bC_{50} = 9.42 µg/L	E_yC_{50} = 0,42 µg cumulative a.s./L (0.412 µg bifenox/L; 0.00456 µg florasulam/L)*	EC_{50} = 0.177 µg cumulative a.s./L
Aquatic higher plants	EC_{50} = 2.1 µg a.s./L	EC_{50} = 1.18 µg/L	E_yC_{50} = 0.27 µg cumulative a.s./L (0.267 µg bifenox/L; 0.002963 µg florasulam/L)*	EC_{50} = 2.081 µg cumulative a.s./L

*Calculated using density of AG-FB1-485 SC1 of 1.1846 g/cm³ and analyzed content of 5.4 g/L florasulam, 488 g/L bifenox as reported in the CA of AT

It can be seen that predicted mixture toxicity is clearly driven by the active substance bifenox. For Algae based on biomass endpoints, toxicity is by a factor of ca 2,4 lower in tests with the formulated product than predicted (mainly by the toxicity of the a.s. bifenox).

Evaluation of statement by the applicant on the RA by zRMS AT

In the study Weber (2012b), for *Lemna*, toxicity increased based on the E_yC_{50} (*Lemna*) = 0.00065 mg product/L calculated based on a linear degradation to the LOQ over the duration of the test. The statement that the product is 10 times more toxic than predicted was an error in the German dRR. However, the reported comparison of predicted vs. measured mixture toxicity was also erroneous. When comparing EC_{50} of the formulated product to the calculated mixture EC_{50}, the toxicity of the formulation should have been expressed as cumulative amount of a.s. and not as amount of formulation to achieve comparable values to the result of the mixture calculation. Therefore the estimate reported by DE underestimated the increase of toxicity of the formulation. The corrected calculation presented above shows a 7.7-fold increase of toxicity of the product.

It is stated by the zRMS that the concentration of bifenox in Weber (2012b) was analyzed but the results were not reliable and therefore not enclosed into the study report. Even if some of the results may not be considered valid by the applicant, they should be included for reasons of transparency. As bifenox is the active substance degrading much faster than florasulam, more toxic for aquatic organisms than florasulam. Whether results ultimately can be considered reliable is a decision made by the evaluation member state. That the applicant disclosed information regarding such a crucial point strongly undermines the credibility of the study results.

In the additional argumentation sent to UBA (Eck, 2014, DocID: ERA-0209), the applicant argues that the value calculated by the zRMS AT presents a rather conservative estimate in terms of mean measured concentration. Germany agreed to the estimate by AT since it the result of this calculation was considered to approximately reflect our own calculations of the mean measured concentrations of bifenox in the test.

The approach of assuming linear degradation over the test duration to the LOQ at test termination as suggested by Austria in general, may however either under or overestimate the mean measured concentration in a semi-static test. This is influenced by the number and frequency of renewals of the test medium as well as the degradation of the active substance.

Since the number and frequency of renewal intervals in the study is known, if it is assumed that

- the concentration of bifenox after each renewal of the test medium is the nominal concentration
- the degradation of bifenox follows a first-order kinetic

The mean measured concentration during the test can be estimated using the DT_{50} of the active substance in the test medium.

As a worst-case estimate of the DT_{50} of bifenox in the experimental study, water and sediment DT_{50} of 0.11 days agreed upon during peer-review (please refer to EFSA Scientific Report (2007) 119, 1-84) could be used. Since it was derived from studies containing sediment, this may present an unrealistic worst-case for experimental systems.

Reference	Test organism, design	Test item	Minimum test item recovery	Estimated DT_{50} [d]
Young, B.M. 1990 38461	*Daphnia magna* 21d, semistatic Renewal every 2-3d	Bifenox	55 - 76 % of nominal conc. Assuming 76% as initial an 55% as 2d recovery, ca **72% of the initial concentration remains after 2 days**	4,2
Handley, J.W. et al. 1993 282/387 24750	*Desmodesmus subspicatus* 4d, static	Bifenox	86 - 126 % of nominal conc. **Ca 68% of the initial concentration remains after 2 days.**	3,6
Hoberg, J.R. 1999 10566.6577 43650	*Navicula pelliculosa* 3d, static	Bifenox	90 - 100 % of nominal conc. **90% of the initial concentration remains after 2 days.**	13,2
Hoberg, J.R. 1998	*Lemna gibba* 14d semi-static	Bifenox	71 – 96 % of nominal conc	6,9

98-10-7499 38919	Renewal every 3d		Assuming 96% as initial an 71% as 3d recovery, ca **74% of the initial concentration remains after 3 days**	
Kimmel, S. 2011 D21640 84925	*Daphnia magna* 2d, static	Florasulam + bifenox 5/480 SC (AG-FB1-485 SC)	105 of the nominal concentration initially, 19% on day 2 **18% of the initial concentration remains after 2 days.**	0,81

In the table above it can be seen that according to back-calculation from available studies with the a.s., no considerable difference in degradation could be seen between test media of standard laboratory studies testing algae, *Lemna* and *Daphnia*. It should be noted that for the semi-static experiments with the active substance, only the minimum and maximum recovery of test item concentrations over the entire test duration are reported in the DAR. The actual recovery of the test item before and after the renewals of the test medium were not available. Using the minimum and maximum recovered concentrations may lead to an over or underestimation of the DT_{50} from these studies increasing the uncertainty around the derived DT_{50} values.

The only study with the product formulation AG-FB1-485 SC including analytical verification of bifenox concentrations in the test medium indicates a DT_{50} of 0.81d. Using this realistic DT_{50} of 0.81d and the above default assumptions to calculate mean measured concentrations for bifenox from the study with *Lemna* testing the formulation AG-FB1-485 SC yields a mean measured concentration of 0.427µg formulation/L, which is lower than the concentration of 0.65µg formulation/L calculated by the zRMS. This indicates that the calculated endpoint calculated by the zRMS presents rather a realistic estimate of the mean measured concentration during the test than a worst-case estimate.

An uncertainty when extrapolating mean measured concentrations of bifenox in the test is the solubility of bifenox, which is rather low. Some of the studies testing the a.s. showed rather low concentrations depending on the solvent used and the concentration of the a.s. However, the product AG-FB1-485 SC contains solvents and in the *Daphnia* study with the product (Kimmel, 2011) an initial bifenox levels analyzed were rather high (105% of nominal concentrations) indicating a good solubility of bifenox formulated as AG-FB1-485 SC. Furthermore there is only one study testing the product AG-FB1-485 SC from which a DT_{50} is derived.

Overall, we agree to use the endpoint of 0.65µg/L calculated by the zRMS in the risk assessment. As discussed above, this value is considered to represent rather a realistic estimate of the mean measured concentration during the test than a worst-case estimate. Consequently, the product formulation is considered to be at least 7,7 times more toxic than predicted by the mixture of active substances towards the most sensitive organism *Lemna*. Risk assessment therefore will be based on the toxicity of the product formulation.

We partly agree to the applicant´s statement (Eck, 2014, DocID: ERA-0209), section 2.6, that it is likely that the growth inhibitory effects of bifenox likely depend on the height of peaks and time of exposure. However, the comparison of exposure in FOCUS scenarios and in experimental studies presented by the applicant in section 2.5 is considered rather uncertain. To quantitatively link predicted exposure patterns and exposure in the experimental studies via AUC, the presented indications of time-dependency of effects are not sufficient. To do so the criteria discussed by the new aquatic GD for applying twa approach should be checked, e.g. the time to onset of effects needs to be determined, linear reciprocity needs to be shown and latency of effects needs to be excluded. The presented experimental study does not allow to check whether all these criteria are fulfilled. It is also increases uncertainty that both exposure in the experiment and the exposure scenario are not constant.

Another uncertainty in this comparison is presented by the FOCUS scenarios used in this comparison. It should be noted that the exposure profiles resulting from current FOCUS scenarios are highly artificial since 1) some processes such as photolysis are not considered and 2) each scenario has fixed dates for rainfall events reflecting one specific climatic year. This makes an evaluation based on exposure profiles resulting from current FOCUS Surface Water Scenarios questionable since climatic conditions including rainfall do not reflect all possible conditions within the EU. This problem has been recognised at the 18th meeting of the Pesticide Steering Network held on 10.02.2015 by EU MS and EFSA and EFSA plans to establish a working group (“repair action” of the FOCUS surface water scenarios) that should revise FOCUS scenarios by extending the assessment period to 20 climatic years.

Apart from the mesocosm study considered for EU review (Schäfers et al. 2006a; see addendum to the DAR) conducted with Foxtril super (a formulation containing 237.3 g bifenox/L, 75.0 g ioxynil/L and 297.0 g mecoprop-P/L), another mesocosm study conducted with Bifenix N (a formulation containing 341.3 g isoproturon/L and 168.2 g bifenox/L) is available (Schäfers et al. 2006b) as well as an indoor microcosm study (Klein & Fliedner 2006) conducted with the formulated product Fox (solo-formulation containing 476 g bifenox/L). Both studies were submitted during the Peer Review. The microcosm, however, was disregarded due to the lack of a clear dose-response relationship for the relevant effects and was finally considered to be superseded by the outdoor mesocosm study with Foxtril super (see addendum to the DAR). Also the second mesocosm with bifenox N was provided during the Peer Review. However, it was not evaluated and reference was made to evaluations to be done on Member State level (see addendum to the DAR).

Since the product formulation, as discussed above, is clearly >7.7-fold more toxic than expected by the mixture of active substances, the risk assessment will however be based on toxicity of the formulation. Information from mesocosms as well as additional information on the time dependence of effects and the exposure regime in experimental studies will however be taken account in the decision making.

The applicant argues that growth rate endpoints should be used tier 1 in risk assessment for aquatic primary producers according to the most recent guidance for aquatic organisms (EFSA, 2013). However, this guidance only applies to applications submitted from 1 January 2015 onwards (please refer to SANTE-2015-00080 15 January 2015) and in the light of current scientific and technical knowledge the immediate use of E_rC_{50} in product assessments is not considered necessary. It should be noted that a recent joint evaluation of a large regulatory dataset by several of the participating MS (Swarowsky et al., 2015) indicated that using the E_rC_{50} with the same AF instead of the lowest EP will lower the level of protection on average by a factor approx. three compared to the previous assessment where the E_bC_{50} was used.

References

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EFSA, PPR. "Panel (European Food Safety Authority Panel on Plant Protection Products and their Residues). (2013) Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters." EFSA Journal 11: 3290-3567.

6.5.4.1 TER values for the entry into surface water via spraydrift and deposition following volatilization

The calculation of concentrations in surface water is based on spray drift data by Rautmann and Ganzelmeier. Bifenox and florasulam have a vapour pressure of 4.74×10^{-8} and 1×10^{-5}, respectively, and are therefore classified as non-volatile. Hence, deposition following volatilization has not been considered. The input parameters for bifenox and florasulam are given in Section 5

Several ecotoxicological endpoints are available to assess the risk of the active substances bifenox and florasulam and the formulation AG-FB1-485 SC (see chapter 6.5.2). The choice of the relevant scenario is based on the ratio of endpoint to the highest PEC for each active substance and the formulation, related to the relevant trigger TER value.

Table 6.5-3: Decision making of the relevant scenario for risk assessment of aquatic organisms based on the lowest ratio of TER to safety factor

Substance	**Max. application rate** [g/ha]	**Drift factor** %	**Max. PEC (act)** [µg/L]	**Endpoint, Species, safety factor** [µg/L]	**TER**	**TER/SF**
Bifenox	1 x 576	2.77	5.3184	EC50 = 2.1 µg/L (*Lemna gibba*), 10	0.39	0.039
Florasulam	1 x 6	2.77	0.0554	EC50 = 1.18 µg/L (*Lemna gibba*), 10	21.2996	2.22
AG-FB1-485 SC	1 x 1200	2.77	13.07444	EC50 = 0.65 µg product/L (*Lemna gibba*), 10	0.05	0.005

PEC: predicted environmenral concentration; TER: Toxicity exposure ratio; SF: Safety factor

Based on the table above, *Lemna gibba* provides for AG-FB1-485 SC the lowest TER/SF ratio and is therefore the relevant scenario for risk assessment.

Table 6.5-4: Risk assessment for bifenox for aquatic organisms for the entry route via spraydrift and deposition following volatilization under the implementation of different risk mitigation measures

Compound:			AG-FB1-485 SC					
Crop/Application rate:			1 x 1200 mL product/ha (1416 g product/ha, density 1.18)					
Growth stage and season			BBCH 13-29					
Intended use:			00-001, winter cereals					
DT$_{50}$ water (SFO):			0.11 d					
PEC-selection:			actual					
Drift-Percentile:			90. percentile					
Buffer zone	**Entry via spraydrift**		**Entry via deposition following volatilization**		**PECsw; conventional and drift reducing technique**			
					0% conv.	**50% red.**	**75% red.**	**90% red.**
[m]	**[%]**	**[g/ha]**	**[%]**	**[µg/L]**	**[µg /L]**			
1	2.77	13.0744	-/-	-/-	13.0744	6.54	3.27	1.31
5	0.57	2.6904	-/-	-/-	2.6904	1.35	0.67	0.27
10	0.29	1.3688	-/-	-/-	1.3688	0.68	0.34	0.14
15	0.20	0.9440	-/-	-/-	0.9440	0.47	0.24	0.09
20	0.15	0.7080	-/-	-/-	0.7080	0.35	0.18	0.07
Relevant toxicity endpoint: EC$_{50}$ = 0.65 µg prod/L (*Lemna gibba*) Relevant TER: 10								
Buffer zone [m]					**TER**			
1					**0.05**	**0.10**	**0.20**	**0.50**
5					**0.24**	**0.48**	**0.97**	**2.42**
10					**0.47**	**0.95**	**1.90**	**4.75**
15					**0.69**	**1.38**	**2.75**	**6.89**
20					**0.92**	**1.84**	**3.67**	**9.18***
Risk mitigation measures			NW 607 (90% - 20m)					

PEC: predicted environmenral concentration; TER: Toxicity exposure ratio. TER values in bold fall below the relevant trigger.

* Considering additional information from available mesocosm studies as well as additional considerations on the time dependence of effects and the exposure regime in experimental studies, the TER of 9.18 for Ind. 00-001 is considered acceptable and the risk is considered acceptable if appropriate risk mitigation measures (20 m buffer strip and 90 % drift reducing technique) are applied.

Compound:	AG-FB1-485 SC
Crop/Application rate:	1 x 1000 mL product/ha (1180 g product/ha, density 1.18)1 x 480 g a.s./ha
Growth stage and season	BBCH 13-29
Intended use:	00-002, spring cereals
DT$_{50}$ water (SFO):	0.11 d
PEC-selection:	actual
Drift-Percentile:	90. percentile

Buffer zone	Entry via spraydrift		Entry via deposition following volatilization		PECsw; conventional and drift reducing technique			
					0% conv.	50% red.	75% red.	90% red.
[m]	[%]	[g/ha]	[%]	[µg/L]	[µg /L]			
1	2.77	10.8953	-/-	-/-	10.8953	5.45	2.72	1.09
5	0.57	2.2420	-/-	-/-	2.2420	1.12	0.56	0.22
10	0.29	1.1407	-/-	-/-	1.1407	0.57	0.29	0.11
15	0.20	0.7867	-/-	-/-	0.7867	0.39	0.20	0.08
20	0.15	0.5900	-/-	-/-	0.5900	0.30	0.15	0.06
Relevant toxicity endpoint: EC_{50} = 0.65 µg prod/L (*Lemna gibba*) Relevant TER: 10								
Buffer zone [m]					**TER**			
1					**0.06**	**0.12**	**0.24**	**0.60**
5					**0.29**	**0.58**	**1.16**	**2.90**
10					**0.57**	**1.14**	**2.28**	**5.70**
15					**0.83**	**1.65**	**3.31**	**8.26**
20					**1.10**	**2.20**	**4.41**	11.02
Risk mitigation measures			NW607-1 (90% - 20m)					

PEC: predicted environmenral concentration; TER: Toxicity exposure ratio. TER values in bold fall below the relevant trigger.

6.5.4.2 TER values for the entry into surface water via run-off and drainage

The concentration of the active substances bifenox and florasulam in adjacent ditch due to surface runoff and drainage is calculated using the model EXPOSIT 3.01. The input parameters for bifenox and florasulam for exposure modelling with EXPOSIT 3.01 are given in the German National Addendum Section 5, chapter 5.6.2.

For risk assessment purposes, a risk envelope approach was used. Hence, intended use no. 00-001 covers the risk for aquatic organisms from intended use no. 00-002 (see Table 6.1-1).

When calculating the exposure vie run-off and drainage, the formulation is not regarded complete, moreover the active substances in their single parts are regarded. Therefore the toxicity studies with the active substances are relevant for risk assessment. For bifenox the most sensitive endpoint is EC50 of 2.1 µg/L (*Lemna gibba*). However as refinement higher tier studies with bifenox are available.

A higher tier mesocosm study on aquatic organisms has been conducted with the representative formulation in the EU review for bifenox (Foxtril super; Schäfers et al. 2006a). The EU accepted endpoint from the higher tier study on Foxtril super which is applicable for algae, macrophyte and invertebrate communities is a NOAEC of 0.004 mg bifenox/L with an agreed assessment factor of 3. A second mesocoms study was submitted but not evaluated in the EU review for bifenox (Bifenix, Schäfers et al 2006). This second mesocosm study was conducted with the product Bifenix N, which contains 168 g bifenox/L and 341 g isoproturon/L. Since this is not in line with applied formulation AG-FB1-485 SC, e.g. the active substance isoproturon is not part of the current formulation, the study is not suitable for higher tier risk assessment in this case. Furthermore, also submitted during the Peer Review, an indoor microcosm study (Klein & Fliedner 2006) conducted with the formulated product Fox (solo-formulation containing 476 g bifenox/L) is available. The microcosm, however, was disregarded due to the lack of a clear dose-response relationship for the relevant effects and was finally considered to be superseded by the outdoor mesocosm study with Foxtril super (see addendum to the DAR).

In conclusion only the mesocosm study with the mono-formulation Foxtril super is relevant for a refined risk assessment. The agreed NOAEC of 0.004 mg bifenox/L with an assessment factor of 3 is used.

Table 6.5-5: Risk assessment for bifenox and florasulam for aquatic organisms for the entry route via run-off and drainage under the implementation of different risk mitigation measures

Compound:	bifenox	
Application rate:	1 x 576 g a.s./ha	
Intended use	00-001 (covers 00-002)	
Relevant toxicity endpoint:	NOAEC = 0.004 mg a.s./L (mesososm)	
Relevant TER:	3	
Run-off		
Buffer zone	**PEC**	**TER**
[m]	**[µg/L]**	
0	0.54	7.46
Drainage		
Time of application	**PEC**	**TER**
	[µg/L]	
Autumn/winter/early spring	0.18	22.08
Spring/summer	0.06	67.95
Risk mitigation measures	none	

PEC: predicted environmenral concentration; TER: Toxicity exposure ratio. TER values in bold fall below the relevant trigger.

Compound:	florasulam	
Application rate:	1 x 6 g/ha	
Intended use	00-001 (covers 00-002)	
Relevant toxicity endpoint:	*L. gibba* EC50 = 1.18 µg/L	
Relevant TER:	10	
Run-off		
Buffer zone	**PEC**	**TER**
[m]	**[µg/L]**	

0	0.02	67.25
Drainage		
Time of application	**PEC**	**TER**
	[µg/L]	
Autumn/winter/early spring	0.04	29.59
Spring/summer	0.01	91.04
Risk mitigation measures	none	

PEC: predicted environmenral concentration; TER: Toxicity exposure ratio. TER values in bold fall below the relevant trigger.

6.5.4.3 Consideration of Metabolites

Florasulam forms two major metabolites in surface water: 5-OH-florasulam (max. 64 %) and DFP-ASTCA (max. 15 %).

5-OH-florasulam and DFP-ASTCA are also formed in sediment (5-OH-florasulam: max. 35 %, DFP-ASTCA: max. 9,15 %) and soil (5-OH-florasulam: max.71,6 %, DFP-ASTCA: max.18 %).

Moreover, the florasulam metabolites ASTCA and TSA are formed in soil with 40 % and 16 %, respectively.

Contamination via run-off and drainage cannot be excluded. Ecotoxicological studies on fish, invertebrates, algae and aquatic plants are available for the metabolite 5-OH-florasulam. For both, the parent compound florasulam and the metabolite 5-OH-florasulam, algae and aquatic plants have been most sensitive. For these sensitive species (algae and aquatic plants) ecotoxicological studies are available for the florasulam metabolites DFP-ASTCA, TSA and ASTCA.

The comparison of the study results for the metabolites 5-OH-florsulam, DFP-ASTCA and ASTCA as well as TSA with the results of studies performed with florasulam shows florasualm is more toxic for aquatic organisms than its metabolites. Thus the risk assessment for the active substance covers also the metabolites. It is predicted that the risk for aquatic organisms exposed to florasulam metabolites according to the intended use of AG-FB1-485 SC will be low.

Bifenox forms one major metabolite in surface water: Aminobifenox-acid (max. 12.7 %).

The bifenox-metabolite aminobifenox is formed in sediment (max. 66.7 %).

Moreover, the bifenox metabolite bifenox-acid is formed in soil with 78.7 %.

Based on the available ecotoxicological data and the assessment CA by zRMS Austria, the metabolites bifenox-acid and aminobifenox-acid are less toxic than the parent compound and therefore not relevant regarding a risk to aquatic organism.

For the metabolite aminobifenox, which was found in sediment, studies with *Chironomus riparius* are available for both bifenox and the metabolite. According to the risk assessment performed by zRMS Austria (see CA, section 6), the TER_{LT} values for the metabolite aminobifenox acid are well above the trigger based on worst-case FOCUS Step 1 PECSW values for the proposed use patterns indicating that there is an acceptable chronic risk to sediment-dwelling aquatic invertebrates.

6.5.5 Overall conclusions

Based on the calculated concentrations of bifenox and florasulam in surface water (EVA 2.1, EXPOSIT 3.0.1), the calculated TER values for the acute and long-term risk resulting from an exposure of aquatic organisms to bifenox according to the GAP of the formulation AG-FB1-485 SC achieve the acceptability criteria TER ≥ 10, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. for long-term effects regarding the use no. 00-002. For the intended use no. 00-001 the calculated TER values do not achieve the trigger of 10 and indicate an unacceptable risk for aquatic organisms due to the intended use 00-001 of AG-FB1-485 SC in winter cereals according to the label.

Consequences for authorization:

For the authorization of the plant protection product AG-FB1-485 SC following labeling and conditions of use are mandatory:

Required Labelling

NW 262	AG-FB1-485 SC: *Pseudokirchneriella sub.* NOEC < 0.001mg/L
NW 264	Bifenox: z.B. *Oncorhynchus mykiss* LC50 = 0.67 mg/L *Daphnia magna* EC50 = 0.66 mg/L
NW 265	AG-FB1-485 SC: *Lemna gibba* NOEC = 0.001 mg/L

Conditions for use

AG-FB1-485 SC	NW 468
All uses	NW607-1 (90% - 20m)

6.6 Effects on bees (MIIIA 10.4, KPC 10.3.1)

Please refer to the core assessment.

Consequences for authorization:

none

6.7 Effects on arthropods other than bees (MIIIA 10.5, KPC 10.3.2)

6.7.1 Toxicity

Please refer to the core assessment.

Table 6.7-1: Ecotoxicological endpoints for arthropods following exposure to AG-FB1-485 SC

Species	Substance	Exposition Duration Test type	Results Toxicity	Reference Author Date Report No.	ICS-No.

Aphidius rhopalosiphi	AG-FB1-485 SC	Standard laboratory (2D)	LR50 = 3 L product/ha 1)		
Typhlodromus pyri	AG-FB1-485 SC	Standard laboratory (2D)	LR50 = 0.011 L product/ha 1)		
Typhlodromus pyri	AG-FB1-485 SC	Extended/Aged residues (3D)2)	**0.0416 L product/ha** corr. Mortality[%] 0 DAA: 31.9 **14 DAA: 69.2** 21 DAA: 32.2 35 DAA: 47 49 DAA: 7.5 Reproduction reduction [%] 0 DAA: -23.2 14 DAA: n.d. 21 DAA: 20.7 35 DAA: 0.0 49 DAA: -4.3 **1.5 L product/ha** corr. Mortality[%] 0 DAA: 100.0 **14 DAA: 100.0** 21 DAA: 100.0 35 DAA: 94.6 49 DAA: 79.6 Reproduction reduction [%] Not determined 1)		
Chrysoperla carnea	AG-FB1-485 SC	Extended/Aged residues (3D)	ER50 > 1.5 (fresh and aged residues) L product/ha 1)		
Aleochara bilineata	AG-FB1-485 SC	Standard laboratory (2D)	LR50 > 1.5 L product/ha 1)		

1) New study submitted by the applicant

2) aged residue study → not suitable for off-field risk assessment

6.7.2 Justification for new endpoints

Please refer to the core assessment.

6.7.3 Risk assessment

The evaluation of the risk for non-target arthropods 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), and in consideration of the recommendations of the guidance document ESCORT 2.

Exposure

Exposure of non-target arthropods living in non-target off-field areas to AG-FB1-485 SC will mainly be due to spray drift from field applications. Off-field predicted environmental rates (PER-values) were calculated from in-field PERs in conjunction with drift values published by the BBA (2000[1]) as shown in the following equation:

$$Off-field\ PER = \frac{Maximum\ in-field\ PER\ x \left({drift\ percentile}/{100} \right)}{vegetation\ distribution\ factor\ (vdf)}$$

where:

vdf = vegetation distribution factor used in combination with test results derived from 2-dimensional exposure set-ups

To account for interception and dilution by three-dimensional vegetation in off-crop areas, a vegetation distribution or dilution factor (vdf, see above) is incorporated into the equation when calculating off-field exposure in conjunction with toxicity endpoints derived from two-dimensional studies (e.g. glass plate or leaf discs). A dilution factor of 10 is recommended by the Guidance Document, but has been questioned. The risk assessment procedure here considers a dilution factor of 5 more appropriated. For endpoint resulting from 3-dimensional studies, i.e. where spray treatment is applied onto whole plants, the dilution factor is not used.

The vapour pressure at 20 °C of the active substance florasulam is < 10^{-5} Pa. Hence the active substance florasulam is regarded as non-volatile. Therefore exposure of surface water by the active substance florasulam due to deposition following volatilization does not need to be considered.

Bifenox has a vapour pressure of 4.74×10^{-8} and is therefore classified as non-volatile. Hence, deposition following volatilization has not to be considered.

For the results of study with *T. pyri* exposed to AG-FB1-485 SC, a vegetation distribution factor has to be considered (study conducted in 2D environment).

Risk assessment

The assessment of the risk to non-target arthropods due to an exposure to AG-FB1-485 SC was performed on basis of the calculation of toxicity-exposure ratios (TER values) according the following formula:

[1] BBA (Biologische Bundesanstalt für Land- und Forstwirtschaft) (2000): Abdrifteckwerte für Flächen- und Raumkulturen sowie für den gewerblichen Gemüse-, Zierpflanzen- und Beerenobstanbau. Bundesanzeiger 100, 26. Mai 2000, Köln, pp. 9879.

$$TER = \frac{L(E)R50\,(L\ product/\,ha)}{Off-field\ PER\,(L\ product/\,ha)}$$

The risk is considered acceptable if the values obtained are TER off-field > 10 when the ecotoxicological data resulted from Tier 1 tests on glass plates or TER off-field > 5 when the data were obtained in higher tier test (extended lab or field tests).

The results of the risk assessment are summarized in the following table.

Table 6.7-2: Risk assessment for AG-FB1-485 SC for non-target arthropods for the entry route via spraydrift and deposition following volatilization under the implementation of different risk mitigation measures

Compound:			AG-FB1-485 SC					
Intended use group:			00-001, 1 x 1200 mL prod/ha					
Drift-Percentile:			90th Percentile; cereals					
Buffer zone	**Entry via spraydrift**		**Entry via deposition following volatilization**		**PER$_{off-field}$; conventional and drift reducing technique**			
					0% conv.	**90% red.**	**75% red.**	**50% red.**
[m]	**[%]**	**[g/ha]**	**[%]**	**[g/ha]**	**[g/ha]**			
0	100	1200			240	24.00	60.00	120.00
1	2.77	33.24			6.65	0.66	1.66	3.32
5	0.57	6.84			1.37	0.14	0.34	0.68
Relevant toxicity endpoint: ER_{50} = 11 mL prod./ha (*Typhlodromus pyri*) Relevant TER: 10								
Buffer zone [m]					**TER**			
0					**0.046**	**0.458**	**0.183**	**0.092**
1					**1.655**	16.546	**6.619**	**3.309**
5					**8.041**	80.409	32.164	16.082
Risk mitigation measures			NT 103					

PER: predicted environmenral rate; TER: Toxicity exposure ratio. TER values in bold fall below the relevant trigger.

Compound:			AG-FB1-485 SC					
Intended use group:			00-002, 1 x 1000 mL prod/ha					
Drift-Percentile:			90th Percentile; cereals					
Buffer zone	**Entry via spraydrift**		**Entry via deposition following volatilization**		**PER$_{off-field}$; conventional and drift reducing technique**			
					0% conv.	**90% red.**	**75% red.**	**50% red.**
[m]	**[%]**	**[g/ha]**	**[%]**	**[g/ha]**	**[g/ha]**			
0	100	1200			200.00	20.00	50.00	100.00
1	2.77	33.24			5.54	0.55	1.39	2.77
5	0.57	6.84			1.14	0.11	0.29	0.57
Relevant toxicity endpoint: ER_{50} = 11 mL prod./ha (*Typhlodromus pyri*) Relevant TER: 10								
Buffer zone [m]					**TER**			
0					**0.06**	**0.55**	**0.22**	**0.11**

1		**1.99**	19.86	**7.94**	**3.97**
5		**9.65**	96.49	38.60	19.30
Risk mitigation measures	NT 103				

PER: predicted environmental rate; TER: Toxicity exposure ratio. TER values in bold fall below the relevant trigger.

6.7.4 Conclusion

Based on the calculated rates of AG-FB1-485 SC in off-field areas under the implementation of 1 m vegetated buffer strip and 90 % drift reduction, the calculated TER values describing the risk resulting from an exposure of non-target arthropods to AG-FB1-485 SC according to the GAP of the formulation AG-FB1-485 SC achieve the acceptability criteria TER ≥ 10, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for non-target arthropods due to the intended use of AG-FB1-485 SC in winter and spring cereals according to the label.

Consequences for authorization:

None

Conditions for use

use No. 00-001/00-002 NT 103 (common: 1 m – 90 % drift reduction)

6.8 Effects on non-target soil meso- and macrofauna (MIIIA 10.6, KPC 10.4, KPC 10.4.1, KPC 10.4.2)

The following studies were used for risk assessment:

Table 6.8-1: Ecotoxicological endpoints for terrestrial non-target soil fauna following exposure to fluroxypyr, florasulam and AG-FB1-485 SC

Species	Substance	Exposition Duration System	Results Toxicity	Reference Author Date Report No.	ICS-No.
Earthworm, acute					
Eisenia fetida	Bifenox	acute 14d	LC50corr. > 500 mg a.s./kg soil dw [1a)*]	EFSA Scientific Report (2007) 119, 1-84	--
Eisenia fetida	Bifenox acid	acute 14d	LC50corr > 500 mg a.s./kg d.w.soil [1a)*]	EFSA Scientific Report (2007) 119, 1-84	--
Eisenia fetida	florasulam (XDE-570)	acute 14d	LC_{50} > 1320 mg/kg soil d.w. [1b)]	Boeri, R. L., Magazu, J. P., Ward, T. J., 05.07.1994, 464-DO	39384

Eisenia fetida	5-OH-XDE-570 (Florasulam metabolite)	acute 14d	LC50 > 1120 mg/kg soil d.w. 3)	Ward, T. J., Magazu, J. P., Boeri, R. L., 12.12.1996, DECO-ES-3120	25426
Eisenia fetida	ASTCA (5-(aminosulphonyl)-1H-1,2,4-triazole-3-carboxylic acid) (Florasulam metabolite)	acute 14d	LC50 > 100 mg/kg soil d.w. 4)	Lührs, U., 09.06.2008, 40981021 080037	77671
Eisenia foetida	DFP-ASTCA	acute 14d 10% peat	LC50 >0.1 mg/kg TS 4)	Ward, T.J., Magazu, J.P., Boeri, R.L. 1998 1488-DO, 980271 (R), 66907	77670
Eisenia foetida	TSA	acute 14d	LC50 >0.1 mg/kg TS 4)	Ward, T.J., Magazu, J.P., Boeri, R.L. 1998 1488-DO, 980271 (R), 66907	77670
Earthworm, chronic					
Eisenia fetida	5-OH-Florasulam (98.1%)	chronic 56 d mixed into soil,	NOEC > 0.14 mg Met./kg soil dw 4) Reproduction	Witte, B. 2010 57033022	72968
Eisenia fetida	ASTCA (5-(aminosulfonyl)-1H-1,2,4-triazole-3-carboxylic acid) (Florasulam metabolite)	chronic 56 d mixed into soil,	NOEC > 1 mg/kg soil d.w. 4)	Lührs, U., 07.08.2008, 40982022 080038	77672
Eisenia fetida	DFP-ASTCA (Florasulam Metabolitee)	56 d, chronic mixed into soil, 5 % Peat	NOEC > 0.0304 mg/kg soil dw Reproduction 4)	Witte, B. 2011 57042022	72977
Eisenia fetida	TSA (Florasulam metabolite)	chronic 56 d mixed into soil,	NOEC > 10 mg/kg soil dw Reproduction 4)	Witte, B. 2011 110132	72974
Eisenia fetida	Florasulam + Bifenox 5/480 SC (AG-FB1-485 SC)	chronic 56 d,	NOEC = 1214 mg/kg soil dw 2)	Schmidt, T. 2011 D21706	84930

			$NOEC_{corr}$ = 607 mg/kg soil dw		
Soil macro-organisms					
Hypoaspis aculeifer	5-OH-Florasulam	14 d, chronic 5 % peat	EC50 >2.5 mg ai/kg soil dw 45% Effect NOEC = 1.25 mg ai/kg soil dw Reproduction [4)]	Witte, B. 2010 101347; 57031089	79762
Hypoaspis aculeifer	ASTCA	14 d, chronic 5 % peat	NOEC = 100 mg a.s./kg soil dw[4)]	Witte, B. 2010 101349; 57051089	79764
Hypoaspis aculeifer	DFP-ASTCA	14 d, chronic 5 % Torf	NOEC = 10 mg a.s./kg soil dw[4)]	Lührs, U. 2011 101348; 57041089	79763
Hypoaspis aculeifer	TSA (Florasulam metabolite)	14 d, chronic 5 % Torf	NOEC = 50 mg a.s./kg soil dw[4)]	Lührs, U. 2011 64512016	72973
Folsomia candida	5-OH-Florasulam (Florasulam metabolite)	28 d chronic	NOEC = 2.5 mg ai/kg soil dw Reproduction, Mortality [4)]	Witte, B. 2010 101344; 57032016	79759
Folsomia candida	DFP-ASTCA (Florasulam metabolite)	28 d chronic	NOEC = 10 mg ai/kg soil dw Reproduction, Mortality [4)]	Lührs, U. 2011 101345; 57043016	79760
Folsomia candida	ASTCA (Florasulam metabolite)	28 d chronic	NOEC = 12.5 mg ai/kg soil dw Reproduction, Mortality [4)]	Witte, B. 2010 101346; 57052016	79761
Folsomia candida	TSA (Florasulam metabolite)	28 d Chronic, 5% Peat	NOEC = 50 mg/kg soil dw Mortality, reproduction [4)]	Lührs, U. 2011 64512016	72973
Folsomia candida	Florasulam + Bifenox 5/480 SC (AG-FB1-485 SC)	28 d 10 % peat	NOER > 7768 mg/kg soil dw [2)] $NOEC_{corr}$ > 3884 mg/kg soil dw *	Schmidt, T. 2012 D21695	84922

1a) EFSA Scientific Report (2007) 119, 1-84

1b) SANCO/1406/2001

2) New study submitted by the applicant

3) study evaluated in DAR (1999) for florasulam

4) study is part of Renewal DAR (2013) for florasulam

* divided by 2, as log pow > 2, (10 % peat)

6.8.1 Justification for new endpoints

Please refer to the core assessment.

6.8.2 Toxicity exposure ratios for earthworms and other soil macro- and mesofauna, TER_A and TER_{LT} (MIIIA 10.6.1)

The evaluation of the risk for earthworms and other soil macro-organisms 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).

For the calculations of predicted environmental concentrations in soils (PEC soil), reference is made to the environmental fate section (Part B, Section 5) of this submission. The resulting maximum PECsoil values for the active substances florasulam and bifenox and the major soil degradation products are presented in the table below.

For German exposure assessment the applied soil depth is based on experimental data (Fent, Löffler, Kubiak: Ermittlung der Eindringtiefe und Konzentrationsverteilung gesprühter Pflanzenschutzmittel-wirkstoffe in den Boden zur Berechnung des PEC-Boden. Abschlussbericht zum Forschungsvorhaben FKZ 360 03 018, UBA, Berlin 1999). Generally for active substances with a $K_{f,oc} < 500$ a soil depth of 2.5 cm is applied whereas for active substances with a $K_{f,oc} > 500$ a soil depth of 1 cm is applied. As soil bulk density 1.5 g $cm^{-3}$is assumed.

For risk assessment purposes, a risk envelope approach was used. Hence, intended use no 00-001 covers the risk for earthworms and other soil macro- and mesofauna from intended uses no. 00-002 (see Table 6.1 1).

The acute risk for earthworms and other non-target soil macro- and mesofauna resulting from an exposure to AG-FB1-485 SC as well as the major soil degradation products of florasulam and bifenox was assessed by comparing the maximum PEC_{SOIL} with the 14-day LC_{50} value to generate acute TER values. The TER_A was calculated as follows:

$$TER_A = \frac{LC_{50}\ (mg/kg)}{PEC_{soil}\ (mg/kg)}$$

The chronic risk for earthworms, other non-target soil macro- and mesofauna and organic matter breackdown resulting from an exposure to AG-FB1-485 SC as well as the major soil degradation products of florasulam and bifenox was assessed by comparing the maximum PEC_{SOIL} with the NOEC value to generate chronic TER values. The TER_{LT} was calculated as follows:

$$TER_{LT} = \frac{NOEC\ (mg/kg)}{PEC_{soil}\ (mg/kg)}$$

The results of the risk assessment are summarized in the following table.

Table 6.8-2: TER values for earthworms and other soil macro- and mesofauna (Tier-1) for the use in winter cereals, use-no. 00-001

Species	Test item	Time scale	Endpoint [mg/kg soil dw]	Max. PEC_{SOIL} [mg/kg soil dw]	TER
Eisenia fetida	florasulam	Acute	LC_{50} > 1320	0.01	>>1000
	5-OH-XDE-570	Acute	LC50 > 1120	0.008	>>1000
		Chronic	NOEC > 0.14	0.008	>17.5
	DFP-ASTCA	Acute	LC50 >0.1	0.002	>50
		Chronic	NOEC > 0.0304	0.002	15.2
	ASTCA	Acute	LC50 > 100	0.0020	>125
		Chronic	NOEC > 1	0.0020	>500
	TSA	Acute	LC50 >0.1	0.0008	>125
		Chronic	NOEC > 10	0.0008	>>1000
	Bifenox	Acute	LC50corr. > 500	1.15	>435
	bifenox-acid	Acute	LC50corr. > 500	0.94	>532
	Florasulam + Bifenox 5/480 SC (AG-FB1-485 SC)	Chronic	NOEC = 1214	2.85	426
Folsomia candida	5-OH-Florasulam	Chronic	NOEC = 2.5	0.008	312.5
	DFP-ASTCA	Chronic	NOEC = 10	0.002	>1000
	ASTCA	Chronic	NOEC = 12.5	0.002	>1000
	TSA	Chronic	NOEC = 50	0.0008	>>1000
	Florasulam + Bifenox 5/480 SC (AG-FB1-485 SC)	Chronic	$NOEC_{corr}$ > 3884	2.85	>1363
Hypoaspis aculeifer	5-OH-Florasulam	Chronic	NOEC = 1.25	0.008	156
	ASTCA	Chronic	NOEC = 100	0.002	>>1000
	DFP-ASTCA	Chronic	NOEC = 10	0.002	>1000
	TSA	Chronic	NOEC = 50	0.0008	>>1000

TER values shown in bold fall below the relevant trigger.

The bifenox metabolite bifenox acid has a DT_{90} > 365 d (labour). According to the terrestrial guidance document (SANCO/10329/2002 rev2 final) a $DT_{90,field}$ triggers a chronic study with earthworms a data for other soil non-target macroorganism. However, only an acute study with *Eisenia fetida* is available. The results of this study do not indicate a higher toxicity of the metabolite compared to the parent compound. Accroding to the final addendum of bifenox (November 2007), the risk was addressed in a weight of evidence approach. The acute TER values for the active substance and the metabolite bifenox acid were based on the highest dose tested and resulted TER values clearly higher than the trigger of 10.

The long-term TER value for the formulation resulted in a value of 426. Since the metabolite is formed max. The reproduction study with the formulation and earthworm and collembolan covers also the risk of the metabolite bifenox acid, since the metabolite bifenox acid will be rapidly formed in soil (max. at day 10) and therefore we can conclude that it was present in the reproduction study with the formulation. It was demonstrated that the active substance bifenox and its metabolite bifenox acid pose no acute and long-term risk to earthworms. Therefore, it can reasonably be concluded that the metabolite bifenox acid will not lead to an unacceptable long-term risk to earthworms.

6.8.3 Higher tier risk assessment

Not relevant.

6.8.4 Overall conclusions

Based on the predicted concentrations of AG-FB1-485 SC in soils, the TER values describing the acute and longterm risk for earthworms and other non-target soil organisms following exposure to AG-FB1-485 SC according to the GAP of the formulation AG-FB1-485 SC achieve the acceptability criteria TER ≥ 10 resp. TER ≥ 5 according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for soil organisms due to the intended use of AG-FB1-485 SC in winter and spring according to the label.

Consequences for authorization:

none

6.9 Effects on soil microbial activity (MIIIA 10.7, KPC 10.5)

The following studies were used for risk assessment:

Table 6.9-1: Ecotoxicological endpoints for soil microbial activity following exposure to bifenox, florasulam and AG-FB1-485 SC

Process	Substance	Exposition Duration System	Results Toxicity	Reference Author Date Report No.	ICS-No.
N-transformation	Bifenox	--	<25% effect at 3.1 mg/kg dry soil [1a)]	EFSA Scientific Report 119; 2007	--
N-transformation	Bifenox acid	--	<25% effect at 4.793 mg/kg dry soil [1a)]	EFSA Scientific Report 119; 2007	--

N-transformation	Florasulam (XDE-570)	28 d	<25% effect at 0.01 mg/kg dry soil <25% effect at 0.05 mg/kg dry soil [1b)]	Forster, J. 1997 ELL/1186	72218
N-transformation	5-OH-Florasulam (Lot No.: DECO-393-053)	28 d	<25% effect at 0.007 mg/kg soil dw <25% effect at 0.036 mg/kg soil dw [3)]	Feil, N. 2010 57034080	80513
N-transformation	DFP-ASTCA	28 d	<25% effect at 0.00152 mg/kg soil dw <25% effect at 0.00760 mg/kg soil dw [3)]	Feil, N. 2011 57044080	80512
N-transformation	ASTCA	28 d	<25% effect at 1.0 mg ai/kg TS [3)]	Feil, N. 2008 40983080	77673
N-transformation	TSA	28 d	<25% effect at 0.01 mg/kg soil dw <25% effect at 0.05 mg/kg soil dw [3)]	Feil, N. 2011 64514080	80511
N-transformation	Florasulam + Bifenox 5/480 SC (AG-FB1-485 SC)	28 d	<25% effect at 10 mg prod /kg soil dw [2)]	Weber, B. 2012 D21717	84926
C-transformation	Bifenox	--	<25% effect at 3.1 mg/kg dry soil [1a)]	EFSA Scientific Report 119; 2007	--
C-transformation	Bifenox acid	--	<25% effect at 4.793 mg/kg dry soil [1a)]	EFSA Scientific Report 119; 2007	--
C-transformation	Florasulam (XDE-570)	28 d 60 d	<25% effect at 0.01 mg/kg (Soil 1) <25% effect at 0.05 mg/kg (Soil 1) [1b)]	Forster, J. 1997 ELL/1186	72218
C-transformation	5-OH-Florasulam (Lot No.: DECO-393-053)	28 d	<25% effect at 0.007 mg/kg soil dw <25% effect at 0.036 mg/kg soil dw [3)]	Feil, N. 2010 57034080	80513
C-transformation	DFP-ASTCA	28 d	<25% effect at 0.00152 mg/kg soil dw <25% effect at 0.00760 mg/kg soil dw [3)]	Feil, N. 2011 57044080	80512
C-transformation	ASTCA	28 d	<25% effect at 1.0 mg ai/kg TS [3)]	Feil, N. 2008 40983080	77673
C-transformation	TSA	28 d	<25% effect at 0.01 mg/kg soil dw <25% effect at 0.05 mg/kg soil dw [3)]	Feil, N. 2011 64514080	80511

1a) EFSA Scientific Report 119; 2007

1b) SANCO/1406/2001

2) New study submitted by the applicant

3) study is part of Renewal DAR (2013) for florasulam

The notifier has only submitted a study investigating the N-transformation for the product, a study investigating the C-transformation for the product AG-FB1-485 SC is missing. However, based on the available data with the active substances and in line with the CA by zRMS Austria, in this case no study on C-transformation is regarded necessary.

6.9.1 Justification for new endpoints

Please refer to the core assessment.

6.9.2 Risk assessment

The evaluation of the risk for earthworms 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).

Please refer to above for the predicted environmental concentrations in soil (PEC_{SOIL}) of florasulam, bifenox and AG-FB1-485 SC.

The results of the risk assessment are summarized in the following table.

Table 6.9-2: Risk assessment for effects on soil micro-organisms

Test substance	Test concentration (adverse effects < 25%) [mg/kg]	PEC_{SOIL} [mg/kg]	Risk acceptable [yes/no]
Bifenox	3.1	1.15	yes
Bifenoc acid	4.793	0.94	Yes
Florasulam (XDE-570)	0.05	0.01	Yes
5-OH-Florasulam	0,036	0.008	Yes
DFP-ASTCA	0.0076	0.002	Yes
ASTCA	1	0.002	Yes
TSA	0.05	0.0008	Yes
AG-FB1-485 SC	10	2.85	yes

6.9.3 Overall conclusions

Based on the predicted concentrations of AG-FB1-485 SC in soils, the risk to soil microbial processes following exposure to AG-FB1-485 SC according to the GAP of the formulation AG-FB1-485 SC is considered to be acceptable/ not acceptable according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2.

Consequences for authorization:

None

6.10 Effects on non-target plants (MIIIA 10.8, KPC 10.6)

6.10.1 Effects on non-target terrestrial plants (MIIIA 10.8.1)

6.10.2 Toxicity

Please refer to the core assessment.

Table 6.10-1: Ecotoxicological endpoints for non-target plants following exposure to AG-FB1-485 SC

Species	Substance	Exposition Duration System	Results Toxicity	Reference Author Date Report No.	ICS-No.
Seedling emergence					
Onion (*Allium cepa*)	AG-FB1-485 SC	Seedling emergence, 23 d, 10 species	ER50 = 0.63L prod/ha fresh weight [1)] NOER < 125 mL/ha	Fiebig, S. 2012 TNK14728	84928
Vegetative vigour					
Tomato (Lycopersicon esculentum)	AG-FB1-485 SC	Vegetative vigour, 21d, 10 species	ER50 = 0.0299 prodL/ha Fresh weight [1)]	Fiebig, S. 2012 TNW14728	84929

1) New study submitted by the applicant

6.10.3 Justification for new endpoints

Please refer to the core assessment.

Both product studies investigating vegetative vigour and seedling emergence were not carried out according to the OECD guidelines 208 and 227. The OECD guidelines state that for the plant species with large seeds only 1 to 2 seeds should be sown in a 15 cm² pot. However, in the present study, 5 seeds were sown in a 12 cm² pot. Hence, the growth of the plants in the controls may have been influenced due to competition. The study can be used for the risk assessment but due to the remaining uncertainties the safety factor will not be reduced.

In the CA by zRMS Austria, also a probabilistic approach is provided based on the vegetative vigour median HC_5. The vegetative vigour is the more sensitive endpoint, with the assessment for seedling emergence and growth not resulting in risk mitigation requirements. Therefore, only the risk assessment for vegetative vigour is presented and no SSD over the seedling emergence and growth data is required. It is noted that the median HC_5 estimate of 0.0209 L product/ha (calculation see CA) is below the endpoint for the most sensitive species of the tested plants (i.e. tomato with an ER_{50} of 0.0299 L product/ha) supporting the conclusion that the HC_5 is sufficiently protective for the community of terrestrial non-target plants. However since the HC_5 is nearly the same as the ER_{50}¸ it is considered not necessary to provide a risk assessment in this NA.

6.10.4 Risk assessment

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 situations, as non-target plants are non-crop plants located outside the treated area. Spray drift from the treated areas may lead to residues of a product in off-crop areas.

Exposure

Effects on non-target plants are of concern in the off-field environment, where they may be exposed to spray drift. The amount of spray drift reaching off-crop habitats is calculated using the 90th percentile estimates derived by the BBA (2000) from the spray-drift predictions of Ganzelmeier & Rautmann (2000). Any dilution over the 3-dimensional vegetation surface is accounted for in the study design. Therefore, in contrast to the assessment of risks to arthropods from standard laboratory tests, no vegetation distribution factor is considered here.

$PER_{off\text{-}field}$= Maximum $PER_{in\text{-}field}$ (including MAF) x %drift

The vapour pressure at 20 °C of the active substance florasulam is < 10^{-5} Pa. Hence the active substance florasulam is regarded as non-volatile. Therefore exposure of surface water by the active substance florasulam due to deposition following volatilization does not need to be considered.

Bifenox has a vapour pressure of 4.74×10^{-8} and is therefore classified as non volatile. Hence, deposition following volatilization has not to be considered.

Tier 1 assessment

The assessment of the risk to non-target arthropods due to an exposure to AG-FB1-485 SC is performed on basis of the calculation of toxicity-exposure ratios (TER values) according the following formula:

$$TER = \frac{ER50\ (L\ product/ha)}{Off-field\ PER\ (L\ product/ha)}$$

The results of the risk assessment are summarized in the following table.

Table 6.10-2: Risk assessment for AG-FB1-485 SC for non-target arthropods for the entry route via spraydrift and deposition following volatilization under the implementation of different risk mitigation measures

Compound:					AG-FB1-485 SC			
Intended use group:					00-001, 1 x 1200 mL prod/ha			
Drift-Percentile:					90^{th} Percentile; cereals			
Buffer zone	**Entry via spraydrift**		**Entry via deposition following volatilization**		**PER$_{off-field}$; conventional and drift reducing technique**			
					0% conv.	**90% red.**	**75% red.**	**50% red.**
[m]	**[%]**	**[g/ha]**	**[%]**	**[g/ha]**	**[g/ha]**			
0	100	1200	-	-	1200	120	300	600
1	2.77	33.24	-	-	33.24	3.324	8.31	16.62
5	0.57	6.84	-	-	6.84	0.684	1.71	3.42
Relevant toxicity endpoint: ER_{50} = 29.9 mL prod/ha (*Tomato*) Relevant TER: 10								
Buffer zone [m]					**TER**			
0					**0.025**	**0.249**	**0.100**	**0.050**
1					**0.900**	**8.995**	**3.598**	**1.799**
5					**4.371**	43.713	17.485	**8.743**
Risk mitigation measures			NT 108					

PER: predicted environmenral rate; TER: Toxicity exposure ratio. TER values in bold fall below the relevant trigger.

Compound:					AG-FB1-485 SC			
Intended use group:					00-002, 1 x 1000 mL prod/ha			
Drift-Percentile:					90^{th} Percentile; cereals			
Buffer zone	**Entry via spraydrift**		**Entry via deposition following volatilization**		**PER$_{off-field}$; conventional and drift reducing technique**			
					0% conv.	**90% red.**	**75% red.**	**50% red.**
[m]	**[%]**	**[g/ha]**	**[%]**	**[g/ha]**	**[g/ha]**			
0	100	1000.00	-	-	1000.00	100.00	250.00	500.00
1	2.77	27.70	-	-	27.70	2.77	6.93	13.85
5	0.57	5.70	-	-	5.70	0.57	1.43	2.85
Relevant toxicity endpoint: ER_{50} = 29.9 mL prod/ha (*Tomato*) Relevant TER: 10								
Buffer zone [m]					**TER**			
0					**0.03**	**0.30**	**0.12**	**0.06**
1					**1.08**	10.79	**4.32**	**2.16**
5					**5.25**	52.46	20.98	10.49
Risk mitigation measures			NT 103					

PER: predicted environmenral rate; TER: Toxicity exposure ratio. TER values in bold fall below the relevant trigger.

6.10.5 Conclusion

Based on the predicted rates of AG-FB1-485 SC in off-field areas, the TER values describing the risk for non-target plants following exposure to AG-FB1-485 SC according to the GAP of the formulation

AG-FB1-485 SC achieve the acceptability criteria TER ≥ 10 according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for non-target terrestrial plants due to the intended use of AG-FB1-485 SC in winter and spring cereals according to the label.

Consequences for authorization:

None

Conditions for use

Use No. 00-001	NT 108 (75% drift reduction technique and 5 m)
Use No. 00-002	NT 103 (90% drift reduction technique and 1 m)

REGISTRATION REPORT

Part B

Section 7: Efficacy Data and Information

Detailed Summary

Product code:	**AG-FB1-485 SC**
Active Substance:	**bifenox 480 g/L**
	florasulam 5 g/L

COUNTRY: Germany

Central Zone

Zonal Rapporteur Member State: Austria

National Addendum Germany

Applicant:	**ADAMA Deutschland GmbH**
Date:	**14/03/2016**

Table of Contents

IIIA1 6 Efficacy Data and Information on the Plant Protection Product

General information

Refer to Registration Report for further information.

Recent registration situation/history of the PPP

Refer to Registration Report for further information.

Information on the active ingredients (Uptake and mode of action)

Refer to Registration Report for further information.

Information on crops and pests

Refer to Registration Report for further information.

Information on the intended uses

2014-04-30	**AG-FB1-485 SC**
Use No.	**007818-00/00-001**
Field of use	Agriculture (field crops)
Crop(s)/object(s)	winter soft wheat (TRZAW), winter barley (HORVW), winter rye (SECCW), winter triticale (TTLWI), ~~winter oats (AVESW)*~~
Crop stage(s) (BBCH)	13 to 29
Pest(s)/target(s)	annual dicotyledonous weeds (TTTDS)
Area of application	Outdoors
Timing of application	After emergence, spring
Max. number of treatments for the use	1
Max. number of treatments per crop or season	1
Application method/kind of treatment	spraying
Application rate(s)	1.2 l/ha in 200 to 400 l water/ha
----------------------------	----------------------------
Use No.	**007818-00/00-002**
Field of use	Agriculture (field crops)
Crop(s)/object(s)	spring soft wheat (TRZAS), spring barley (HORVS), ~~spring triticale (TTLSO),~~* common oats (AVESA)
Crop stage(s) (BBCH)	13 to 29
Pest(s)/target(s)	annual dicotyledonous weeds (TTTDS)
Area of application	Outdoors
Timing of application	After emergence, spring
Max. number of treatments for the use	1
Max. number of treatments per crop or season	1
Application method/kind of	spraying

treatment	
Application rate(s)	1 l/ha in 200 to 400 l water/ha
----------------------------	

* crop should be deleted

IIIA1 6.1 Efficacy data

Refer to Registration Report for further information.

IIIA1 6.1.1 Preliminary range-finding tests

Refer to Registration Report for further information.

IIIA1 6.1.2 Minimum effective dose tests

Refer to Registration Report for further information.

IIIA1 6.1.3 Efficacy tests

For some annual dicotyledonous weeds, which are described on the label as being controlled well, only a few or no efficacy results have been submitted, which entails that a reliable evaluation of these weed species is not possible.
Therefore and due to the fact that cereals respond sensitively to herbicides, the restriction WH9161 (The instructions for use must include a summary of weeds which can be controlled well, less well and insufficiently by the product, as well as a list of species and/or varieties showing which crops are tolerant of the intended application rate and which are not.) is proposed.

Refer to Registration Report for further information.

IIIA1 6.1.4 Effects on yield and quality

Refer to Registration Report for further information.

IIIA1 6.1.4.1 Impact on the quality of plants and plant products

Refer to Registration Report for further information.

IIIA1 6.1.4.2 Effects on the processing procedure

Refer to Registration Report for further information.

IIIA1 6.1.4.3 Effects on the yield of treated plants and plant products

Refer to Registration Report for further information.

IIIA1 6.2 Adverse effects

Refer to Registration Report for further information.

IIIA1 6.2.1 Phytotoxicity to host crop

Results of winter oat and spring triticale are missing. Selectivity of AG-FB1-485 SC in these crops is not proved. In case of phytotoxicity extrapolation is not possible.
Because of the missing results, winter oat and spring triticale should be deleted from the uses.

IIIA1 6.2.2 Adverse effects on health of host animals

Refer to Registration Report for further information.

IIIA1 6.2.3 Adverse effects on site of application

Refer to Registration Report for further information.

IIIA1 6.2.4 Adverse effects on beneficial organisms (other than bees)

The herbicide AG-FB1-485 SC (480 g/L Bifenox + 5 g/L Florasulam, SC) has been proposed for a single post-emergence treatment per crop and season in cereals at a maximum application rate of 1.2 L/ha.

No observations about effects of AG-FB1-485 SC on beneficial organisms were reported in the efficacy trials.

Results on the potential adverse effects of the test product on beneficial arthropods were available from Registration Report Part B, Section 6, Annex Point IIIA 10.5 (Effects on Arthropods Other Than Bees).

The toxicity has been investigated by carrying out laboratory tests with the two indicator species *Typhlodromus pyri* and *Aphidius rhopalosiphi* and with the soil dwelling predator *Aleochara bilineata* using the formulated product Florasulam + Bifenox 5/480 SC, which is equivalent to the test product. Additionally aged residue tests were carried out with *Typhlodromus pyri* and the leaf dwelling predator *Chrysoperla carnea* (Table 6.2.4-1).

In a laboratory test on an artificial substrate, the predatory mite *Typhlodromus pyri* showed 100% mortality at 12% of the proposed rate already. The LR_{50} was calculated to be 0.011 L product/ha (D21673).
In an aged residue test with potted maize plant 1.25fold the proposed application rate still caused a nearly 80% mortality after 7 weeks of ageing (S12-03563).

In a laboratory test on an artificial substrate using the parasitic wasp *Aphidius rhopalosiphi,* the test product caused no mortality at 2.5fold the proposed rate. Sublethal effects were not investigated (D21684).
Although results from the EU Review Report SANCO/1406/2001 – final; 2002 (tests with a SC formulation containing 50 g Florasulam/L) and EFSA Scientific Report 119; 2007 (tests with a SC formulation containing 480 g Bifenox/L) did not reveal sublethal effects >30% in the range of the proposed rates of the single active substances, effects >30% on the parasitization rate cannot be excluded for the combined product.

In an aged residue test with potted maize plant using the lacewing species *Chrysoperla carnea* even fresh residues of 1.25fold the proposed application rate caused no mortality and only marginal sublethal effects <25% (S12-03564).

In a laboratory test on an artificial substrate using the soil dwelling predator *Aleochara bilineata,* the test product caused a reduction of the reproduction by 41% at 1.25fold the proposed application rate (S12-03565).

Table 6.2.4-1: Effects of Florasulam + Bifenox 5/480 SC (488 g/L Bifenox + 5.4 g/L Florasulam)

Species (Exposed Stage)	Substrate	Rate Product [L/ha]	Corrected Mortality [%]	Sublethal Effect (Re) [%]	Reference
T. pyri (PN)	Glass	0.009375	48		D21673
		0.01875	60		
		0.0375	90		
		0.075	92		
		0.15	100		
	Maize (0 DAT)	0.0416	31.9	-23.2	S12-03563
	Maize (0 DAT)	1.5	91.2		
	Maize (7 DAT)	0.0416			
	Maize (7 DAT)	1.5			
	Maize (14 DAT)	0.0416	69.2		
	Maize (14 DAT)	1.5	100		
	Maize (21 DAT)	0.0416	32.2	20.7	
	Maize (21 DAT)	1.5	100		
	Maize (35 DAT)	0.0416	47	0	
	Maize (35 DAT)	1.5	94.6		
	Maize (49 DAT)	0.0416	7.5	-4.3	
	Maize (49 DAT)	1.5	79.6		
A. rhopalosiphi (A)	Glass	3	-1.7		D21684
C. carnea (La)	Maize (0 DAT)	1.5	-7.2	3	S12-03564
	Maize (7 DAT)	1.5	3.5	10	
	Maize (14 DAT)	1.5	0	0	
	Maize (21 DAT)	1.5	-3.4	2	
A. bilineata (DC)	Quartz sand	0.019		4	S12-03565
		0.056		8	
		0.167		9	
		0.5		29	
		1.5		41	

PN = protonymphs, A = adults, La = larvae, DC = developmental cycle,
Re = reproduction
DAT = days after treatment (aged residue test)
The validity criteria were fulfilled.

Conclusion

On the basis of the results of an aged residue test, the test product can be considered as harmful for the predatory mite *Typhlodromus pyri.* No substantial recovery can be expected within 7 weeks after treatment.
As *Typhlodromus pyri* is not a relevant antagonist for the proposed crops, no classification is proposed for this species. However the results for this sensitive indicator species indicate that the test product can be harmful for other, relevant predatory mites and spiders.

The test product had no lethal effect on the parasitoid wasp *Aphidius rhopalosiphi*. As sublethal effects were not investigated and cannot be excluded, no classification is proposed.

On the basis of the results of an aged residue test with effects < 25% at fresh residues, the test product can be classified as not harmful for the insect species *Chrysoperla carnea*.

On the basis of the results of a laboratory test, the test product is to be classified as slightly harmful for the rove beetle *Aleochara bilineata*.

Classification according to IOBC:
Laboratory tests on artificial substrates

< 30%	= not harmful
30 – 79%	= slightly harmful
≥ 80%	= harmful

Extended laboratory tests on natural substrates

< 25%	= not harmful
25 - 50%	= slightly harmful
> 50%	= harmful

Adverse effects on soil quality indicators (e. g. microorganisms, earthworms) are considered in Section 6 Ecotoxicological Studies in the Registration Report.

IIIA1 6.2.5 Adverse effects on parts of plant used for propagating purposes

Refer to Registration Report for further information.

IIIA1 6.2.6 Impact on succeeding crops

Refer to Registration Report for further information.

IIIA1 6.2.7 Impact on other plants including adjacent crops

Refer to Registration Report for further information.

IIIA1 6.2.8 Possible development of resistance or cross-resistance

Due to a medium to high resistance risk, the restriction WH951 (The risk of resistance has to be indicated on the package and in the instructions of use. Particularly measures for an appropriate risk management have to be declared.) is required.

Refer to Registration Report for further information.

IIIA1 6.3 Economics

Refer to Registration Report for further information.

IIIA1 6.4 Benefits

Refer to Registration Report for further information.

IIIA1 6.4.1 Survey of alternative pest control measures

This is not an EC data requirement.

IIIA1 6.4.2 Compatibility with current management practices including IPM

This is not an EC data requirement.

IIIA1 6.4.3 Contribution to risk reduction

This is not an EC data requirement.

IIIA1 6.5 Other/special studies

Refer to Registration Report for further information.

IIIA1 6.6 Summary and assessment of data according to points 6.1 to 6.5

Refer to Registration Report for further information.

IIIA1 6.7 List of test facilities including the corresponding certificates

Refer to Registration Report for further information.

Appendix 1: List of data submitted in support of the evaluation

No additional studies submitted.

Appendix 2: GAP table

PPP (product name/code)	**AG-FB1-485 SC**	**Formulation type:**	**SC (suspension concentrate)**
active substance 1	**Florasulam**	**Conc. of as 1:**	**5 g/ L**
active substance 2	**Bifenox**	**Conc. of as 2:**	**480 g/ L**
active substance		**Conc. of as:**	
safener-		**Conc. of safener:**	**-**
synergist	**-**	**Conc. of synergist:**	**-**
Applicant:	**Feinchemie Schwebda GmbH**	**professional use**	☒
Zone(s):	**central/EU**	**non professional use**	☐

Verified by MS: **j/n**

Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**			**Application rate**			**PHI** (days)	**Remarks:** e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
001	DE	winter soft wheat (TRZAW), winter barley (HORVW), winter rye (SECCW), winter triticale (TTLWI), ~~winter oats (AVESW)~~	F	Annual dicotyledonous weeds	spray	BBCH 13-29	1	a) 1.2 b) 1.2	a) Florasulam: 0.006 Bifenox: 0.576 b) Florasulam: 0.006 Bifenox: 0.576	200 / 400	no PHI expected	
002	DE	spring soft wheat (TRZAS), spring barley (HORVS), ~~spring triticale (TTLSO),~~ common * oats (AVESA)	F	Annual dicotyledonous weeds	spray	BBCH 13-29	1	a) 1.0 b) 1.0	a) Florasulam: 0.005 Bifenox: 0.480	200 / 400	no PHI expected	

Use-No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F G or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application			Application rate			PHI (days)	Remarks: e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
									b) Florasulam: 0.005 Bifenox: 0.480			

* crop should be deleted

REGISTRATION REPORT
Part B

Section 8 Assessment of the relevance of metabolites in groundwater
Detailed summary of the risk assessment

Product code: **AG-FB1-485 SC**
Active Substances: **bifenox 480 g/L**
florasulam 5 g/L

COUNTRY: Germany
Central Zone
Zonal Rapporteur Member State: Austria

NATIONAL ASSESSMENT

Applicant: **ADAMA Deutschland GmbH**
Date: **14/03/2016**

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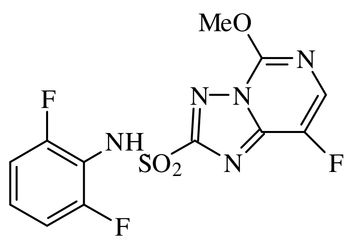
Sec 8 ASSESSMENT OF THE RELEVANCE OF METABOLITES IN GROUNDWATER

8.1 Introduction

8.1.1 Florasulam

The active substance florasulam has been approved according to Regulation (EC) No 1107/2009.

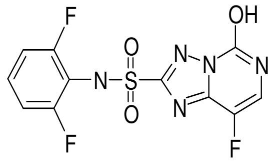
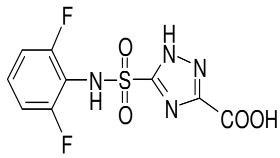
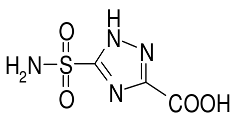
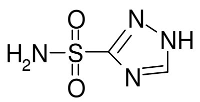
Table 8.1-1: Identity, further information on florasulam

Active substance (ISO common name)	Florasulam
IUPAC	2', 6', 8-Trifluoro-5-methoxy-[1,2,4]-triazolo [1,5-c] pyrimidine-2-sulfonanilide
Function (e.g. fungicide)	herbizide
Status under Reg. (EC) No 1107/2009	approved
Date of approval	01/10/2002
Conditions of approval	Only uses as herbicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on florasulam, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 19 April 2002 shall be taken into account. In this overall assessment Member States: - should pay particular attention to the potential for groundwater contamination, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of authorisation must include risk mitigation measures, where appropriate.
Confirmatory data	None
RMS	Belgium
Minimum purity of the active substance as manufactured (g/kg)	970
Molecular formula	$C_{12}H_8O_3N_5F_3S$
Molecular mass	359.3
Structural formula	

Environmental occurring metabolites of florasulam are summarized in Part B, National Addendum, Section 5, Table 5.3-3.

The soil metabolites of florasulam for wich the leaching potentials into groundwater was assessed are summarised in Table 8.1-2.

Table 8.1-2: Metabolites of florasulam relevant for groundwater exposure assessment

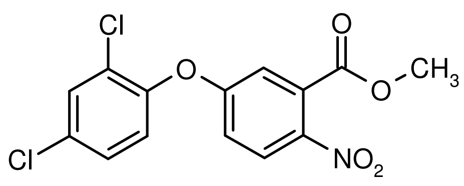
Metabolite	**Structural formula/ Molecular weight**	**Maximum occurence in compartements**	**Status of relevance (see SANCO/1406/2001 - 18 September 2002)**
5-OH-XDE-570 XDE-570 5-hydroxy, N-(2,6-difluorophenyl)-8-fluoro-5-hydroxyl (1,2,4) triazolo(1,5c) pyrimidine-2-sulphonamide	 M = 345.26 g/mol	Soil, aerob: max. 71.6 % at d 3 Water: max. 64 % at d 60 Sediment: max. 35 % at d 60 (Soil photolysis: 60 %)	Aquatic organism: Water: not relevant Sediment: not relevant Terrestrial organism: not assessed Groundwater: not relevant (Step 2)[1)]
DFP-ASTCA M3 N-(2,6-difluorophenyl)-5-aminosulphonyl-1H-1,2,4)triazole-3-carboxylic acid	 M = 274.25 g/mol	Soil, aerob: max. 17.8 % at d 28 Water: max. 15 % at d 100 Sediment: max. 9.15 % at d 182	Aquatic organism: Water: not assessed Sediment: not assessed Terrestrial organism: not assessed Groundwater: not relevant (Step 2)[1)]
ASTCA M4 5-(aminosulphonyl)-1H-1,2,4-triazole-3-carboxylic acid	 M = 162.17g/mol	Soil, aerob: max. 40.0 % at d 59	Aquatic organism: Water: not assessed Sediment: not assessed Terrestrial organism: not assessed Groundwater: not relevant (Step 3-4)[1)]
TSA M6 1H-1,2,4-triazole-3-sulphonamide	 M = 148.14 g/mol	Soil, aerob: max. 15.9 % at d 100	Aquatic organism: Water: not assessed Sediment: not assessed Terrestrial organism: not assessed Groundwater: not assessed

[1)] According to Guidance Document on the assessment of the relevance of metabolites in groundwater of substances regulated under council directive 91/414/EEC (SANCO/221/2000 –rev.10- final - 25 February 2003)

8.1.2 Bifenox

The active substance bifenox has been approved according to Regulation (EC) No 1107/2009.

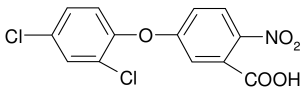
Table 8.1-3: Identity, further information of bifenox

Active substance (ISO common name)	Bifenox
IUPAC	Methyl 5-(2,4-dichlorophenoxy)-2-nitrobenzoate
Function (e.g. fungicide)	Herbicide
Status under Reg. (EC) No 1107/2009	approved
Date of approval	01/01/2009
Conditions of approval	PART A Only uses as herbicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on bifenox, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 14 March 2008 shall be taken into account. In this overall assessment Member States shall pay particular attention to: (c) the environmental conditions leading to the potential formation of nitrofen. Member States shall impose restrictions as regards the conditions of use, where appropriate in view of point (c).'
Confirmatory data	none
RMS	Belgium
Minimum purity of the active substance as manufactured (g/kg)	970 g/kg (commercial plant)
Molecular formula	$C_{14}H_9Cl_2NO_5$
Molecular mass	342.14
Structural formula	 **Bifenox**

Environmental occurring metabolites of bifenox are summarized in Part B, National Addendum, Section 5, Table 5.3-5.

The soil metabolites of bifenox for wich the leaching potentials into groundwater was assessed are summarised in Table 8.1-4.

Table 8.1-4: Metabolites of bifenox potentially relevant for exposure assessment

Metabolite	Structural formula/Molecular formula	occurrence in compartments (Max. at day/ 2 x > 5 %)	Status of Relevance according to the core assessment by zRMS Austria
Bifenox-acid	 $C_{14}H_{11}Cl_2N_2O_3$ 328 g/mol	Soil, aerob: max. 78.7 % at day 10	Aquatic organism: Water: not relevant Sediment: not relevant Terrestrial organism: not relevant Groundwater: not relevant (Step 3)[1)]

8.2 Exclusion of degradation products of no concern

8.2.1 Florasulam

None.

8.2.2 Bifenox

None.

8.3 Quantification of potential groundwater contamination (Step 2)

8.3.1 Florasulam

8.3.1.1 Exposure assessment for Germany

PEC_{GW} calculations after leaching from soil for florasulam its metabolites (see Table 8.1-2) were performed using the simulation model FOCUS PELMO 5.5.3 (see Part B, National Addendum, Section 5.7.1).

The following uses of AG-FB1-485 SC were considered.

Table 8.3-1: Input parameters related to application for PEC_{GW} modelling with FOCUS PELMO 5.5.3

use evaluated	1. 00-001 (winter cereals) 2. 00-002 (spring cerals)
application rate (g as/ha)	1. florasulam: 6 2. florasulam: 5
crop (crop rotation)	1. winter cereals 2. spring cereals
date of application	6th of april (spring application in winter and spring cereals)
interception (%)	25 %
soil effective application rate (g as/ha)	1. florasulam: 4.5 2. florasulam: 3.75
soil moisture	100 % FC
Q10-factor	2.58
moisture exponent	0.7
plant uptake	0

simulation period (years)	26

The result of the PECgw calculation with FOCUS PELMO 5.5.3 for the intended use of for the intended use of AG-FB1-485 SC in spring and winter cereals in Germany are summarised in Table 8.3-2.

Table 8.3-2 PEC_{GW} at 1 m soil depth of florasulam and its metabolites considered relevant for German exposure assessment

Use No.	Szenario	80th Percentile PEC_{GW} at 1 m Soil Depth (µg L^{-1}) modeled by FOCUS PELMO 5.5.3				
		florasulam	**metabolite 5-OH**	**metabolite DFP-ASTCA**	**metabolite ASTCA**	**metabolite TSA**
00-001 winter cereal	Hamburg	0.000	0.000	0.000	0.088	**0.188**
	Krems-münster	0.000	0.000	0.000	0.055	**0.144**
00-002 spring cereals	Hamburg	0.000	0.000	0.000	0.072	**0.156**
	Krems-münster	0.000	0.000	0.000	0.051	**0.138**

For the metabolites 5-OH-XDE-570, DFP-ASTCA and ASTCA of florasulam a groundwater concentration of ≥ 0.1 µg/L can be excluded for the application in winter and spring cereals according to the results of the groundwater simulation with FOCUS PELMO 5.5.3. For the metabolite TSA of florasulam a groundwater concentration of ≥ 0.1 µg/L cannot be excluded for the intended uses according to the results of the groundwater simulation with FOCUS PELMO 5.5.3.

8.3.1.2 <u>Conclusions</u>

The metabolites that are relevant according to Step 2 of this assessment are summarized in Table 8.3-3.

Table 8.3-3: Summary of PECgw of the soil metabolites of florasulam for the intended uses AG-FB1-485 SCin spring and winter cereals (simulation with FOCUS PELMO 5.5.3)

Metabolite	PEC gw	Maximum concentration in ground water	Status of relevance (see SANCO/1406/2001 - 18 September 2002)
TSA	National Addendum Germany: > 0.1 µg/L in the scenario Hamburg	Nationales Addendum Germany: 0.188 µg/L	Not assessed

A relevance assessment for the metabolite TSA is required.

8.3.2 Bifenox

8.3.2.1 Exposure assessment for Germany

PEC_{GW} calculations after leaching from soil for befenox its metabolite bifenox-acid (see Table 8.1-3) were performed using the simulation model FOCUS PELMO 5.5.3 (see Part B, National Addendum, Section 5.7.1).

The following uses of AG-FB1-485 SC were considered.

Table 8.3-4: Input parameters related to application for PEC_{GW} modelling with FOCUS PELMO 5.5.3

use evaluated	1. 00-001 (winter cereals) 2. 00-002 (spring cerals)
application rate (g as/ha)	1.bifenox: 576 2.bifenox: 480
crop (crop rotation)	1. winter cereals 2. spring cereals
date of application	6th of april (spring application in winter and spring cereals)
interception (%)	25 %
soil effective application rate (g as/ha)	1. bifenox: 432 2. bifenox: 360
soil moisture	100 % FC
Q10-factor	2.58
moisture exponent	0.7
plant uptake	0
simulation period (years)	26

The result of the PECgw calculation with FOCUS PELMO 5.5.3 for the intended use of for the intended use of AG-FB1-485 SC in spring and winter cereals in Germany are summarised in Table 8.3-5.

Table 8.3-5 PEC_{GW} at 1 m soil depth of bifenox and its metabolite considered relevant for German exposure assessment

Use No.	Szenario	80th Percentile PEC_{GW} at 1 m Soil Depth (µg L^{-1}) modeled by FOCUS PELMO 5.5.3	
		bifenox	**Metabolite bifenox-acid**
00-001 winter cereals	Hamburg	0.000	**0.110**
00-002, spring cereals	Hamburg	0.000	0.073

For the metabolites bifenox-acid a groundwater concentration of ≥ 0.1 µg/L cannot be excluded for the intended use in winter cereals (00-001) according to the results of the groundwater simulation with FOCUS PELMO 5.5.3.

8.3.2.2 *Conclusions*

The metabolites that are relevant according to Step 2 of this assessment are summarized in Table 8.3-6.

Table 8.3-6: Summary of PECgw of the soil metabolite of bifenox for the intended uses AG-FB1-485 SC in winter cereals (simulation with FOCUS PELMO 5.5.3)

Metabolite	PEC gw	Maximum concentration in ground water	Status of relevance (see SANCO/1406/2001 - 18 September 2002)
Bifenox-acid	National Addendum Germany: > 0.1 µg/L in the scenario Hamburg	Nationales Addendum Germany: 0.110 µg/L	Not assessed

A relevance assessment for the metabolite bifenox-acid is required.

8.4 Hazard Assessment: Identification of relevant metabolites (Step 3)

8.4.1 Screening for biological activity

8.4.1.1 *Bifenox-metabolites*

The comparison of the aquatic plants and algae study results for the metabolites with the results of studies performed with Bifenox show that Bifenox is several orders of magnitude more toxic to aquatic organisms than the metabolite bifenox-acid.

8.4.1.2 *Florasulam-metabolites*

The comparison of the aquatic plants and algae study results for the metabolites with the results of studies performed with Florasulam show that Florasulam is several orders of magnitude more toxic to aquatic organisms than the metabolites.

8.4.2 Screening for genotoxicity

For the bifenox metabolite bifenox-acid please refer to the RR Part B Section 8 core assessment of the zRMS AT.

TSA has been subjected to genotoxicity screening in the following tests: in vitro mutagenicity in bacteria, gene mutation assay, in vitro chromosomal aberration assay (*DRAR Florasulam - Volume 3, Annex B.6: Toxicology and Metabolism, Poland, June 2014*).

Table 8.4-2: Summary of toxicity studies on TSA

Type of test	Result	Purity, batch n°	References
Bacterial Reverse Mutation Test using Salmonella typhimurium (strains: TA1537, TA1535, TA98, TA100 and TA102)	negative	Test Substance No. GLCDAG-070211 99%	Nagane, R.M. (2011) * ASB2013-1486
In vitro Mammalian Cell Gene Forward Mutation Test at the HGPRT Locus of the Chinese Hamster Ovary (CHO)-K1 Cell	negative	Test Substance No. GLCDAG-070211	Nagane, R.M. (2011) *

Line		99%	ASB2013-1487
In vitro Mammalian Chromosome Aberration Test in Human Peripheral Blood Lymphocytes	negative	99%	Nagane, R. M. (2011) * ASB2013-1488

* Test is reported in the DRAR Florasulam - Volume 3, Annex B.6: Toxicology and Metabolism, Poland, June 2014

In summary TSA is regarded as non-genotoxic, therefore TSA has successfully passed the genotoxicity screening criteria.

8.4.3 Screening for toxicity

For the bifenox metabolite bifenox-acid please refer to the RR Part B Section 8 core assessment of the zRMS AT.

This screening stage is designed to determine whether metabolites have certain toxicological properties which would qualify them as being considered 'relevant' according to EC guidance document SANCO/221/2000 –rev.10 (SANCO, 2003). The starting point for this assessment involves considering the classification of the parent active substance, florasulam, under Regulation (EC) 1272/2008 (or earlier directives, e.g., Directive 67/548/EEC). The active substance, florasulam, is not classified as "toxic" or "very toxic" (symbols T and T+, respectively), nor is it classified as a carcinogen, genotoxic, or a developmental/ reproductive toxin.

Independent of the classification of the parent active substance, there is no reason to expect that the groundwater metabolite TSA may be toxic or highly toxic. Therefore no targeted testing is necessary.

8.5 Exposure assessment – threshold of concern approach (Step 4)

For the bifenox metabolite bifenox-acid please refer to the RR Part B Section 8 core assessment of the zRMS AT.

The metabolite TSA has a lower biological activity than the parent, is not genotoxic, and is not defined as toxic. Therefore TSA has not been identified as being relevant according to the hazard screening outlined in Step 3 according to EC guidance document SANCO/221/2000 –rev.10 (SANCO, 2003). A threshold of 0.75 µg/L can be considered acceptable for the groundwater metabolite TSA.

8.6 Refined risk assessment for non-relevant metabolites (Step 5)

8.6.1 Refined toxicological risk assessment for non-relevant metabolites

For the bifenox metabolite bifenox-acid please refer to the RR Part B Section 8 core assessment of the zRMS AT.

No further consideration of its potential risk is required in step 5 because the groundwater metabolite TSA does not exceed groundwater concentrations of 0.75 µg/L (threshold of concern).

8.6.2 Refined ecotoxicological risk assessment for non-relevant metabolites

8.6.2.1 Bifenox and Florasulam-metabolites

The refined risk assessment is presented in the following tables:

Table 8.6-1: Refined risk assessment for non-relevant Bifenox and Florasulam metabolites for Germany

Substance	PEC_{GW}	$PEC_{GW}/10$	Most sensitive	$TER_{(SW)}$

	[µg/L]	(“PEC$_{(SW)}$”) [µg/L]	aquatic toxicity endpoint [µg/L]	
Bifenox-acid	0.11	0.011	2220	201818
TSA	0.188	0.0188	>100000	>5000000

(SW) : ground water becoming surface water

TER values well achieve the acceptability criterium of TER ≥ 100 respectively TER ≥ 10.

8.6.2.2 Conclusion

The calculated TER values for the metabolites bifenox acid and TSA are far above the trigger value of 10 indicating no risk for ground water ecosystems by exposure of the metabolites in groundwater. Based on these results a risk assessment for aquatic organism in surface water that is linked to ground water is not required.

Appendix 1. Reference list

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
IIA 5.8	Nagane, R. M.	2011	In vitro mammalian cell gene forward mutation test at the hgprt locus of the chinese hamster ovary (CHO)-K1 cell line using TSA metabolite of Florasulam 110430 GLP: Yes Published: No BVL-2382321, BVL-2382321, ASB2013-1487	Yes (1) Open (1)	DOW	Add
IIA 5.8	Nagane, R. M.	2011	In vitro mammalian chromosome aberration test of TSA metabolite of Florasulam in human peripheral blood lymphocytes 110431 GLP: Yes Published: No) BVL-2382355, BVL-2382355, ASB2013-1488	Yes (1) Open (1)	DOW	Add
IIA 5.8	Nagane, R. M.	2011	Bacterial reverse mutation test of TSA metabolite of Florasulam using Salmonella Typhimurium 110432 ! 481-1-06-2308 GLP: Yes Published: No BVL-2382320, BVL-2382320, ASB2013-1486	Yes (1) Open (1)	DOW	Add
IIA 5.8	Poland	2014	Renewal Draft Assessment Report and Proposed Decision of the Poland prepared in the context of the re-authorisation procedures of florasulam in Annex I of Regulation (EC) No 1107/2009 (Reviewed) Rapporteur Member State: Poland Florasulam - Volume 3, Annex B.6: Toxicology and Metabolism			Add

* Y: Yes, relied on
N: No, not relied on
Add: Relied on, study not submitted by applicant but necessary for evaluation