REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: GLOB2111F

Product name: Starinta

Chemical active substance(s):

Bixafen, 125 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorisation)

Applicant: Globachem NV

Submission date: December 2023

zRMS Assessment : 09/08/2024

Version after commenting : 15/11/2024

Version history

When	What
August 2024	zRMs has evaluated dRR submitted by Applicant
November 2024	Revised assessment after commenting period

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8 Fate and behaviour in the environment (KCP 9)

General comment zRMS
The following data and information were submitted by the applicant Globachem NV as a dRR. This document provides the results of the assessment of the zRMS. All comments and conclusions of the evaluator there are in the grey boxes. Additionally, minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information is struck through and shaded for transparency.

8.1 Critical GAP and overall conclusions

Table 8.1-1: Critical use pattern of the formulated product .

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			PHI (days)	Remarks: e.g. g safener/ synergist per ha	**Conclusion**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
Zonal uses (field or outdoor uses, certain types of protected crops)														
1-10, 21-30, 41, 42	PL, CZ, HU, RO	Winter cereals (wheat, barley, rye, triticale, oats, spelt)	F	*Puccinia recondite, Puccinia striiformis, Pyrenophora teres, Pyrenophora tritici-repentis, Rhynchosporium secalis, Zymoseptoria tritici, Puccinia triticina, Puccinia recondita , Fusarium sp.*	Normal down-ward spraying	BBCH 30 – 69	a) 1 b) 1	/	a) 1 L/ha b) 1 L/ha	a) ~~100~~ 125 b) ~~100~~ 125	100 - 300	/	/	A
11-20, 31-40	PL, CZ, HU, RO	Spring cereals (wheat, barley, rye, triticale, oats, spelt)	F	*Puccinia recondite, Puccinia striiformis, Pyrenophora teres, Pyrenophora tritici-repentis, Rhynchosporium secalis, Zymoseptoria tritici, Puccinia triticina, Puccinia recondita , Fusarium sp.*	Normal down-ward spraying	BBCH 30 – 69	a) 1 b) 1	/	a) 1 L/ha b) 1 L/ha	a) ~~100~~ 125 b) ~~100~~ 125	100 - 300	/	/	A

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

** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

Explanation for column 15 “Conclusion”

A	Safe use
R	Further refinement and/or risk mitigation measures required
C	To be confirmed by cMS
N	No safe use

Table 8.1-2: Assessed (critical) uses during approval of bixafen concerning the Section Environmental Fate

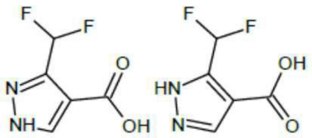
1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			PHI (days)	Remarks: e.g. g safener/ synergist per ha
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
1	EU	Wheat, rye , triticale	F	various	Foliar spray	25 – 69	a) 2 b) 2	14	a) 1 b) 2	a) 125 b) 125	100 – 300		
2	EU	Barley, oats	F	various	Foliar spray	25 – 61	a) 2 b) 2	14	a) 1 b) 2	a) 125 b) 125	100 – 300		

Representative formulation Bixafen EC 125
* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

General comment zRMS
Starinta (product code: GLOB2111F) is an emulsifiable concentrate (EC) containing 125 g/L of the active substance bixafen for use as a fungicide on winter and spring cereals. Bixafen (CAS No 581809-46-3) is recognised as approved for use in plant protection products under Regulation (EC) No 1107/2009 in Annex of Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 with the expiration of approval on 31 May 2025. The this assessment used end points evaluated on EU level in accordance with EFSA document "Conclusion on the peer review of the pesticide risk assessment of the active substance bixafen (EFSA Journal 2012;10(11):2917). The uses in Table 8.1-1 are consistent with the uses indicated in the GAP table in Part B0 of this documentation.

8.2 Metabolites considered in the assessment

Table 8.2-1: Metabolites of bixafen potentially relevant for exposure assessment

Metabolite	Molar mass	Chemical structure	Maximum observed occurence in comparte-ments	Exposue assessment required due to
M44 (3-(difluoromethyl)-1H-pyrazole-4-carboxylic acid)		162.1 g/mol	Soil Max. 2.9 % at the end of study	PECgw: leaching poten-tial to groundwater

zRMS comment

Information relating to bixafen metabolite: M44 is in line with EU agreed endpoints as reported in EFSA Journal 2012;10(11):2917 and have been considered in the exposure assessment presented in this report.

8.3 Rate of degradation in soil (KCP 9.1.1)

Studies on degradation in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

Evaluation by zRMS	**Rate of degradation in soil (KCP 9.1.1)**
Comments	No new data. Information in Section 8.3 is available in dossier of active substance bixafen and can be extrapolated to formulation. Therefore no studies have been conducted. EU agreed data were correctly reported. However, respective corrections were included by the zRMS where necessary.

8.3.1 Aerobic degradation in soil (KCP 9.1.1.1)

All information on bixafen and its metabolite M44 provided in this chapter was previously evaluated in the frame of the EU review of bixafen and were summarized from the EFSA Conclusion on the active substance (EFSA Journal 2012;10(11):2917).

Table 8.3-1: Summary of aerobic degradation rates for bixafen - laboratory studies

Bixafen, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH**	**t.°C**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi^2 (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Laacherhof AXXa	Sandy loam	6.0	20°C	55%	n.c. (>1y)	n.c. (>1y)	n.c.	-	Decline <10% over 120d	Y/Sneikus & Koehn (2005) UK, 2011 EFSA Journal 2012;10(11):2917
Laacherhof AIIIa	Silt loam	6.4	20°C	55%	n.c. (>1y)	n.c. (>1y)	n.c.	-	Decline <10% over 120d	
Laacherhof Wurmwiese	Loam	5.4	20°C	55%	n.c. (>1y)	n.c. (>1y)	n.c.	-	Decline <10% over 120d	
Hoefchen am Hohenseh	Silt loam	6.1	20°C	55%	n.c. (>1y)	n.c. (>1y)	n.c.	-	Decline <10% over 120d	
Geometric mean (n=4)							> 1 year			
pH-dependency: y/n							-			

Table 8.3-2: Summary of aerobic degradation rates for M44 - laboratory studies

M44, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH**	**t.°C**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi² (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Li10 – pyrazole label	Loamy sand	6.3	20°C	40%	152 (0.968 fast; 178 slow)	567	**123** (0.786 fast; 145 slow)	0.4	DFOP	Y/Unold & Bayer (2009) UK, 2011 EFSA Journal 2012;10(11):2917
LUFA 2.2 – pyrazole label	Sand	5.9	20°C	40%	147	>1000	**147**	1.9	FOMC	
LUFA 2.2 – pyrazole label	Sand	5.9	20°C	40%	120 (4.86 fast; 193 slow)	567	123 (0.786 fast; 145 slow)	2.1	DFOP	
Wisconsin – pyrazole label	Loamy sand	5.9	20°C	40%	76.6	>1000	**70.4**	2.2	FOMC	
Wisconsin – pyrazole label	Loamy sand	5.9	20°C	40%	83.1 (5.06 fast; 161 slow)	454	76.3 (4.65 fast; 148 slow)	2.5	DFOP	
Bruch West – pyrazole label	Sandy loam	7.4	20°C	40%	197	>1000	**134**	2.0	FOMC	
Bruch West – pyrazole label	Sandy loam	7.4	20°C	40%	158 (9.94 fast; 204 slow)	636	108 (6.78 fast; 139 slow)	2.2	DFOP	
Geometric mean (n=4)							~~168.1~~ 114.3			
pH-dependency: y/n							No			

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

All information on anaerobic degradation of bixafen was previously evaluated in the frame of the EU review of bixafen and was summarized in the EFSA Conclusion on the active substance (EFSA Journal 2012;10(11):2917). No additional studies have been performed.

Bixafen was slowly degraded. Bixafen-pyrazole-4-carboxylic acid (M44) was only observed at one sampling date (day 181) and amounted to 9.0% AR. Anaerobic conditions are not expected to last such a long time under real environmental conditions; therefore the formation of M44 under anaerobic conditions is not considered further.

Table 8.3-3: Summary of anerobic degradation rates for bixafen - laboratory studies

Bixafen, Laboratory studies, anerobic conditions										
Soil name	**Soil type**	**pH**	**t.°C**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi² (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Laacherhof AIIIa	Loam	6.7	20°C	45%	612	1236	-	0.99	SFO (extrapolated beyond study duration)	Y/Simmonds (2006) UK, 2011 EFSA Journal 2012;10(11):2917

Bixafen, Laboratory studies, anerobic conditions										
Soil name	**Soil type**	**pH**	**t.°C**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi^2 (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Geometric mean (n=4)							> 1 year			
pH-dependency: y/n							-			

8.4 Field studies (KCP 9.1.1.2)

Studies on degradation in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

8.4.1 Soil dissipation testing on a range of representative soils (KCP 9.1.1.2.1)

The field dissipation rates of Bixafen and its metabolite M44 were evaluated during EU assessment. No additional studies have been performed. The DT_{50} values are summarized in Table 8.4-1.

Triggering endpoints

Table 8.4-1: Summary of aerobic degradation rates for Bixafen - field studies: Triggering endpoints

Bixafen, Field studies – Triggering endpoints									
Soil type	**Location**	**pH**	**Depth (cm)**	**$DissT_{50}$ (d) actual**	**DT_{90} (d) actual**	**St. (χ^2)**	**DT_{50} (d) 20°C pF2/10kPa**	**Method of calculation**	**Evaluated on EU level y/n/ Reference**
Silt loam	Germany	6.3	0 - 30	>1235	>1000	12.6	320.1	Actual – HS Norm. – SFO Q_{10} = 2.58	Y/Heinemann (2007) UK, 2011 EFSA Journal 2012;10(11):2917
Sandy loam	UK	7.4	0 - 30	316	>1000	10.2	196.8		
Silt loam	Sweden	7.4	0 - 30	541	>1000	12.0	247.8		
Silt loam	N. France	6.7	0 - 30	395	>1000	11.8	231.4		
Loam	Spain	6.1	0 - 30	105	>1000	18.7	145.6		
Silt loam	Italy	8.3	0 - 30	30.6	>1000	24.8	122.4		
~~Silt loam*~~	~~Germany~~	~~6.3~~	~~0 - 30~~	~~>1000~~	~~>1000~~	~~12.6~~	~~320.1~~		
Maximum (n=~~7~~ 6)				>1235	>1000		320.1		
Geometric Mean				>254	>1000		200.2		

*: Remark: By error the respective table of LoEP, page 38 of EFSA Journal 2012; 10(11): 2917, listed the results of soil Germany twice (compare 1st and 7th soil).

Table 8.4-2: Summary of aerobic degradation rates for M44 - field studies: Triggering endpoints

M44, Field studies – Triggering endpoints										
Soil type	**Location**	**pH**	**Depth (cm)**	**$DissT_{50}$ (d) actual**	**DT_{90} (d) actual**	**Kinetic parameters**	**DT_{50} (d) 20 °C, pF2**	**St. (χ^2)**	**Method of calc.**	**Evaluated on EU level y/n/ Reference**
Loamy sand – bare soil	Middelfart, Denmark	5.8	0 - 40	-	-	-	17.9	13.2	SFO	Y/Unold *et al.* (2009), Hardy (2009a and 2009b) UK, 2011 EFSA Journal 2012;10(11):2917
Silt Loam – bare soil	GochNierswalde, Germany	6.4	0 - 40	-	-	-	23.1	10.3	SFO	
Silt Loam – bare soil	Poggio Renatico, Italy	7.7	0 - 70	-	-	-	44.1	11.9	SFO	
Loam – bare soil	Meauzac. Southern France	5.5	0 - 60	-	-	-	24.6	9.1	SFO	
Maximum				-	-		44.1			
Geomean (n=4)				-	-		25.9			

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

All information on soil accumulation of bixafen and its metabolite M44 was previously evaluated in the frame of the EU review of bixafen and were summarized from the EFSA Conclusion on the active substance (EFSA Journal 2012;10(11):2917). No additional studies have been performed.

The results confirm the potential of accumulation of the active substance bixafen.

8.5 Mobility in soil (KCP 9.1.2)

Studies on mobility in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

All information on bixafen and its metabolite M44 provided in this chapter was previously evaluated in the frame of the EU review of bixafen and were summarized from the EFSA Conclusion on the active substance (EFSA Journal 2012;10(11):2917). No additional studies have been performed.

Evaluation by zRMS	**Mobility in soil (KCP 9.1.2)**
Comments	No new data. Information in Section 8.5 is available in dossier of active substance bixafen and can be extrapolated to formulation. Therefore no studies have been conducted. EU agreed data were correctly reported. However, respective corrections were included by the zRMS where necessary.

Table 8.5-1: Summary of soil adsorption/desorption for bixafen

Bixafen							
Soil name	**Soil type**	**OC (%)**	**pH**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
Laacher hof	sandy loam	1.3	6.5	42.8	3290	0.857	Y/Koehn & Haas (2005) UK, 2011 EFSA Journal 2012;10(11):2917
Hoefchen	silt loam	2.62	6.8	102.7	3920	0.876	
Laacher hof	Loam	2.07	6	72	3477	0.883	
Pikeville	loamy sand	1.1	5.4	40.5	3682	0.885	
Stanley	clay loam	1.1	6.3	54.7	4974	0.882	
Arithmetic mean (n=5)					3869	0.877	
Geometric mean (n=5)					3827	-	
pH-dependency y/n					No		

Table 8.5-2: Summary of soil adsorption/desorption for M44

M44							
Soil Name	**Soil Type**	**OC (%)**	**pH**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
LUFA 2.1	Sand	0.52	5.2	0.07	13.1	0.969	Y/Hassink & Stephan (2009) UK, 2011 EFSA Journal 2012;10(11):2917
Obihiro	Sandy Loam*	2.74	5.6	2.74	99.9	0.963	
Li 10	Loamy Sand	0.88	5.9	0.04	4.8	0.842	
New Jersey	Silt Loam	0.90	6.3	0.13	14.1	1.165	
Nierswalde	Silt Loam	1.63	6.5	0.15	9	0.937	
LUFA 2.3	Sandy Loam	1.09	6.9	0.06	5.6	1.078	
La Gironda	Silty Clay Loam	3.84	7.5	0.04	1.	0.99	
California	Sandy Loam	0.41	7.6	0.02	5.6	0.764	
Arithmetic mean (n= 8)					7.6	0.964	
Geometric mean (n=8)					5.9	-	
pH-dependency y/n					No		

*Volcanic ash - excluded from mean calculation

8.5.1 Column leaching (KCP 9.1.2.1)

No study was deemed necessary since Bixafen has little to no tendency for mobility, is therefore unlikely to contaminate groundwater by simply leaching through the soil profile, and no significant amount of radioactivity was observed in the leachate of the aged soil columns.

8.5.2 Lysimeter studies (KCP 9.1.2.2)

No data were submitted nor required as concluded in the Conclusion on the peer review of the pesticide risk assessment of the active substance bixafen (EFSA Journal 2012;10(11):2917). No additional studies have been performed.

8.5.3 Field leaching studies (KCP 9.1.2.3)

No data were submitted nor required as concluded in the Conclusion on the peer review of the pesticide risk assessment of the active substance bixafen (EFSA Journal 2012;10(11):2917). No additional studies have been performed.

8.6 Degradation in the water/sediment systems (KCP 9.2, KCP 9.2.1, KCP 9.2.2, KCP 9.2.3)

Studies on degradation in water/sediment systems with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

Evaluation by zRMS	Degradation in the water/sediment systems (KCP 9.2)
Comments	No new data. Information in Section 8.6 is available in dossier of active substance bixafen and can be extrapolated to the formulation. Therefore no studies have been conducted.

The exposure modelling is based on the results of the water/sediment study of Bixafen reviewed in the DAR/AR/Addendum. The DT_{50} values of the water/sediment study are summarized in Table 8.6-1below.

Table 8.6-1: Summary of degradation in water/sediment of bixafen

Bixafen Distribution (max. in water 97.6 % after 0d, max. /sediment 88.3% after 118d)										
Water/sediment system	**pH water/ sed.**	**DegT50 whole syst. (d)**	**DegT90 whole syst. (d)**	**Kinetic, Fit**	**DissT50 water (d)**	**DissT90 water (d)**	**Kinetic, Fit**	**DissT50 sed. (d)**	**Kinetic, Fit**	**Evaluated on EU level y/n/ Reference**
River Roding (clay)	7.58 / 7.5	n.c.	n.c.	-	27.4*	91.1	SFO*	n.c.	-	Y/Oddy & Doble, 2006 UK, 2011 EFSA Journal 2012;10(11):2917
Clayton (sand)	5.7 / 6.9	n.c.	n.c.	-	25.5	84.6	SFO	n.c.	-	

*FOMC gave best fit for River Roding DT_{50} in water (22.5 d), based on slightly lower % chi^2 error (7.4%) than for SFO kinetics (9.1%), but as SFO fit gave similar DT_{50} values with acceptable $\%chi^2$ error.

No major (>10%AR) metabolites were detected in water or sediment.

8.7 Predicted Environmental Concentrations in soil (PEC_{soil}) (KCP 9.1.3)

8.7.1 Justification for new endpoints

No other endpoints than those agreed during the EU review were used for the calculation of of predicted environmental concentrations in soil.

8.7.2 Active substance(s) and relevant metabolite(s)

Input parameters for the PEC_{soil} calculations related to the application of GLOB2111F are summarised in Table 8.7-1 below.

Table 8.7-1: Input parameters related to application for PEC_{soil} calculations

Use No.	1 (covers all the rest)
Crop	Cereals (winter and spring)
Application rate (g as/ha)	Bixafen: 125 g/ha
Number of applications/interval	1/-
Crop interception (%)	80%
Depth of soil layer (relevant for plateau concentration) (cm)	5 (20 for plateau)

The PEC_{soil} calculations were performed for a standard soil considering a dry soil bulk density of 1.5 g/cm^3 and 5 cm soil depth in agreement with the recommendation of the EU guideline FOCUS (1997) [1].

According to the EFSA Scientific Report 2010; 8(4) for bixafen, bixafen itself is the sole residue of potential relevance in soil.

A summary of the input parameters for bixafen is given in Table 8.7-2 below.

Table 8.7-2: Input parameter for active substance(s) and relevant metabolite(s) for PEC_{soil} calculation

Compound	Molecular weight (g/mol)	Max. occurrence (%)	DT50 (days)	Value in accordance to EU endpoint y/n/ Reference
Bixafen	Not required	-	1235d (bi-phasic degradation – kinetic parameters	Y/ EFSA Journal 2012; 10(11): 2917

[1] FOCUS (1997) Soil persistence models and EU Registration - The Final Report of the Soil Modelling Workgroup of FOCUS (Forum for the Co-ordination of Pesticide Fate Models and their Use) – 29 February 1997.

Compound	Molecular weight (g/mol)	Max. occurrence (%)	DT50 (days)	Value in accordance to EU endpoint y/n/ Reference
			obtained from HS kinetic model: k1 0.0081 day^{-1}, k2 2.3E^{-4} day^{-1}, (DT_{50}_fast = 86 d; DT_{50}_slow = 3014 d) breakpoint (tb) 53 days,worst-case, non-normalised DT_{50} from field dissipation studies)	

Results of the PEC_{soil} calculations are presented in Table 8.7-3 below.

Table 8.7-3: PEC_{soil} for bixafen on cereals (winter and spring)

PEC_{soil} (mg/kg)		Cereals			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0333	-		-
Short term	24h	0.0331	0.0332		
	2d	0.0328	0.0331		
	4d	0.0323	0.0328		
Long term	7d	0.0315	0.0324		
	14d	0.0298	0.0315		
	21d	0.0281	0.0307		
	28d	0.0266	0.0298		
	50d	0.0223	0.0274		
	100d	0.0215	0.0245		
Plateau concentration (20 cm) after year 10		0.0129	-		-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		0.0462			

PEC_{soil} of metabolites

Not relevant.

8.7.2.1 PEC_{soil} of GLOB2111F

An initial PEC_{soil} value for the formulation has also been calculated for the risk envelope assuming an application rate of 1.0 L/ha per ha and a formulation density of 1.006 g/mL (1006 g/ha formulation per ha). A minimum crop interception of 80% was considered, according to the intended GAP in winter and spring cereals.

Table 8.7-4 5: PEC_{soil} for GLOB2111F on cereals

Active substance/ reparation	Application rate (g/ha)	PEC_{act} (mg/kg)	PEC_{twa}21 d (mg/kg)	Tillage depth (cm)	$PEC_{soil,plateau}$ (mg/kg)	PEC_{accu} = PEC_{act} + $PEC_{soil,plateau}$ (mg/kg)
GLOB2111F	1006*	0.268	-	-	-	-

*based on an application rate of 1.0 L/ha and a relative density of 1.006 g/mL

Evaluation by zRMS PL	**PECsoil (KCP 9.1.3)**
Modelling	The assumptions of calculations are acceptable. The predicted environmental concentrations in soil (PECsoil) of bixafen were calculated according to recommendations of the FOCUS workgroup on degradation kinetics ((FOCUS (2006) “Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration” Report of the FOCUS Work Group on Degradation Kinetics, EC Document Reference Sanco/10058/2005 version 2.0, 434 pp) using: - the maximum application rate: 1L Starinta (GLOB2111F)/ha/per season i.e. 125 g bixafen/ha, considering 80% interception on cereals. It was assumed that the active substance were distributed in the top 5 cm soil layer with a soil bulk density of 1.5 g/mL. For the determination of the long term background concentration a mixing depth of 20 cm was assumed for normal tillage practices. Kinetic parameters obtained from HS kinetic model were used for the assessment (worst-case): k1 0.0081 days-1, k2 2.3E-4 days-1, tb 53 days. The calculated PECs values presented in Table 8.7-3 are accepteed by zRMS. No major metabolite requiring soil exposure assessment was triggered according to the EU Review and EFSA conclusion. The applicant correctly calculated the PECsoil for the formulation Starinta (GLOB2111F). The results are shown in the Table 8.7-4. Taking into account the above information, the calculated PECsoil values for Starinta (GLOB2111F) and bixafen are appropriate to be used in the subsequent risk assessment for soil organisms.
Agreed Endpoints	**Bixafen:** Initial PEC_{soil}: 0.0333 mg/kg PECaccumulation = 0.0462 mg/kg

	Formulation: Starinta (GLOB2111F) PECact = 0.268 mg/kg

8.8 Predicted Environmental Concentrations in groundwater (PEC_{gw}) (KCP 9.2.4)

8.8.1 Justification for new endpoints

For bixafen, no other endpoints than the ones agreed during the EU Review were used for the calculation of predicted environmental concentrations in ground water except for the K_{foc} of bixafen, for which the geomean was used (in accordance with the new EFSA guidance[2]). For the metabolite of bixafen M44, the endpoints as reported in the EFSA conclusion of the active substance fluxapyroxad were used in combination with a ffm value of 1 between bixafen and M44 as a worst case assumption.

8.8.2 Active substance(s) and relevant metabolite(s) (KCP 9.2.4.1)

The applicant submitted a report of first tier PEC_{gw} calculations:

Report:	**KCP 9.2.4 Fernandez D., 2023**
Title:	Estimation of the Predicted Environmental Concentration of bixafen in groundwater following the application of GLOB2111F to winter and spring cereals
Document No:	GLOB2111F-Bixf-GW
Guidelines:	SANCO/321/2000 rev.2: FOCUS groundwater scenarios in the EU review of active substances
GLP	No

Table 8.8-1: Input parameters related to application for PEC_{gw} calculations

Use No.	1 (covers 2-10, 21-30, 39, 40)	11 (covers 12-20, 31-38)
Crop	Winter cereals	Spring cereals
Application rate (g as/ha)	Bixafen: 125 g/ha	Bixafen: 125 g/ha
Number of applications/interval (d)	1/-	1/-
Relative application date	-	-
Crop interception (%)	80%	80%
Frequency of application	annual	annual
Models used for calculation	FOCUS PEARL v5.5.5, FOCUS PELMO v6.6.4	FOCUS PEARL v5.5.5, FOCUS PELMO v6.6.4

The absolute application dates used for the PEC_{GW} calculations were determined by using the software AppDate v3.06 for both winter & spring cereals. The following BBCH stages were used as input parame-

[2] "EFSA Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT50 values of active substances of plant protection products and transformation products of these active substances in soil", EFSA Journal 2014, 12(5): 3662

ters: first possible application at BBCH 30 with an 80% crop interception. The corresponding dates are presented in the table below.

Table 8.8-2: Application dates used for groundwater risk assessment

Crop	Scenario	Application dates (absolute)
Winter cereals	Châteaudun	15/04
	Hamburg	04/05
	Jokioinen	14/05
	Kremsmünster	24/04
	Okehampton	21/04
	Piacenza	19/03
	Porto	30/01
	Sevilla	06/01
	Thiva	18/01
Spring cereals	Châteaudun	16/04
	Hamburg	28/04
	Jokioinen	05/06
	Kremsmünster	27/04
	Okehampton	22/04
	Porto	16/04

Input parameters for the PEC_{gw} calculations related to the application of GLOB2111F are summarized in table 8.8-3 below.

Table 8.8-3: Input parameters related to active substance bixafen and metabolite(s) for PEC_{gw} calculations

Compound	Bixafen	M44	Value in accordance with EU endpoint y/n/ Reference*
Molecular weight (g/mol)	414.2	162.1	Y/EFSA Journal 2012;10(11):2917
Water solubility (g/mol):	0.49 (20°C) 0.98 (30°C)	31580 (20°C) 63160 (30°C)	Parent: Y/EFSA Journal 2012;10(11):2917 M44: EFSA Journal 2012;10(11):2917
Saturated vapour pressure (Pa):	4.6×10^{-8} (20°C) 1.84×10^{-7} (30°C)	5×10^{-6} (20°C) 2.0×10^{-5} (30°C)	Parent: Y/EFSA Journal 2012;10(11):2917 M44: EFSA Journal 2012;10(11):2917
DT_{50} in soil (d)	200.2 (geomean normalisation to 10 kPa or pF2, 20 °C with Q_{10} of 2.58, n =7)	25.9 (geomean normalisation to 10 kPa or pF2, 20 °C with Q_{10} of 2.58, n =4)	Y/EFSA Journal 2012;10(11):2917
Transformation rate	-	0.0034623	Worst case default

Compound	Bixafen	M44	Value in accordance with EU endpoint y/n/ Reference*
(Rate constant)			
K_{foc} (mL/g)/K_{fom}	3827/2220 (geometric mean, n = 5)	5.9/3.4 (geometric mean, n = 8)	Parent: Y/EFSA Journal 2012;10(11):2917 M44: EFSA Journal 2012;10(11):2917
1/n	0.877 (arithmetic mean, n = 5)	0.964 ~~0.877~~ (arithmetic mean, n = 8)	Parent: Y/EFSA Journal 2012;10(11):2917 M44: EFSA Journal 2012;10(11):2917
Plant uptake factor	0	0	Focus recommendation
Formation fraction	-	1 (from parent)	Worst case default

Results of the PEC_{gw} calculations are presented in Table 8.8-4 and Table 8.8-5 below.

Table 8.8-4: PEC_{gw} for bixafen and its metabolite M44 on winter and spring cereals (with FOCUS PEARL 5.5.5)

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)	
		Bixafen	M44
Winter cereals	Châteaudun	< 0.001	0.268
	Hamburg	< 0.001	0.856
	Jokioinen	< 0.001	1.134
	Kremsmünster	< 0.001	0.437
	Okehampton	< 0.001	0.485
	Porto	< 0.001	0.263
	Piacenza	< 0.001	0.265
	Sevilla	< 0.001	0.094
	Thiva	< 0.001	0.176
Spring cereals	Châteaudun	< 0.001	0.256
	Hamburg	< 0.001	1.077
	Jokioinen	< 0.001	0.968
	Kremsmünster	< 0.001	0.471
	Okehampton	< 0.001	0.490
	Porto	< 0.001	0.301

Table 8.8-5: PEC_{gw} for bixafen and its metabolite M44 on winter and spring cereals (with FOCUS PELMO 6.6.4)

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)	
		Bixafen	M44
Winter cereals	Châteaudun	< 0.001	0.234
	Hamburg	< 0.001	0.751

	Jokioinen	< 0.001	1.026
	Kremsmünster	< 0.001	0.460
	Okehampton	< 0.001	0.495
	Porto	< 0.001	0.351
	Piacenza	< 0.001	0.324
	Sevilla	< 0.001	0.115
	Thiva	< 0.001	0.157
Spring cereals	Châteaudun	< 0.001	0.201
	Hamburg	< 0.001	0.769
	Jokioinen	< 0.001	0.970
	Kremsmünster	< 0.001	0.469
	Okehampton	< 0.001	0.476
	Porto	< 0.001	0.332

Evaluation by zRMS	**PECgw (KCP 9.2.4)**
Modelling	For the active substance bixafen and its metabolite M44 the calculations presented here are accepted. The applicant has used appropriate models for groundwater FOCUS-PEARL 5.5.5 and FOCUS-PELMO 6.6.4. Calculations using the FOCUS MACRO 5.5.4 model were not presented, therefore zRMS calculated PECgw values for the Châteaudun scenario and reported the results in the tables below. PEC_{GW} values were calculated for the growth stage: BBCH 30-69 on winter and spring cereals.

PECgw for bixafen and metabolite M44 on winter cereals (1 x 125 g/ha)

Crop	**Scenario**	**80th percentile PECgw at 1 m soil depth (µg/L)**	
		Bixafen	**M44**
		MACRO	**MACRO**
Winter cereals	Chateaudun	<0.001	0.225

PECgw for bixafen and metabolite M44 on spring cereals (1 x 125 g/ha)

Crop	**Scenario**	**80th percentile PECgw at 1 m soil depth (µg/L)**	
		Bixafen	**M44**
		MACRO	**MACRO**
Spring cereals	Chateaudun	<0.001	0.225

Input parameters used in the groundwater modelling for bixafen and its metabolite M44 presented in Table 8.8-3 are in line with EU agreed endpoints reported in EFSA Journal 2012;10(11):2917 apart the value of 1/n for metabolite M44. ~~However, this does not affect the risk assessment.~~ Despite the fact that the appli-

	cant reported an incorrect value of 1/n for the metabolite M44, the modelling calculations provided by the applicant were performed with the correct 1/n value (0.964). Obtained PEC_{GW} values are presented in Tables 8.8-4 and 8.8-5.
PECgw	Based on the results of performed simulations no unacceptable leaching of bixafen is expected following the intended Central Zone uses of Starinta (GLOB2111F) on winter and spring cereals. PECgw of bixafen is well below the trigger value of 0.1 µg/L for the FOCUS crops winter and spring cereals in all available FOCUS scenarios. The metabolite of bixafen M44 may migrate to groundwater at concentrations >0.1 µg/L (max. PEC_{GW} =1.134 µg/L for Jokioinen scenario), however in accordance with the assessment of the relevance of this metabolite, it is not considered as relevant.
Conclusion	In accordance with the assessment of the relevance of the metabolite of bixafen M44, it is not considered as relevant. An assessment of the metabolite of bixafen M44 regarding their relevance for groundwater was done. For the assessment of relevance please refer to Part B, Section 10 of this dRR.

8.9 Predicted Environmental Concentrations in surface water (PEC_{SW}) (KCP 9.2.5)

8.9.1 Justification for new endpoints

For bixafen, no other endpoints than the ones agreed during the EU Review were used for the calculation of predicted environmental concentrations in surface water, except for the K_{foc} of bixafen, for which the geomean was used (in accordance with the new EFSA guidance[3]).

8.9.2 Active substance(s), relevant metabolite(s) and the formulation (KCP 9.2.5)

The applicant submitted a report of first tier PEC_{sw} calculations:

Report:	KCP 9.2.5 Fernandez D., 2023
Title:	Estimation of the Predicted Environmental Concentration of bixafen in surface water following application of GLOB2111F to winter and spring cereals
Document No:	GLOB2111F-Bixf-SW
Guidelines:	SANCO/321/2000 rev.2: FOCUS groundwater scenarios in the EU review of active substances
GLP	No

Table 8.9-1: Input parameters related to application for $PEC_{SW/SED}$ calculations

Plant protection product	GLOB2111F	
Use No.	1 (covers 2-10, 21-30, 39, 40)	11 (covers 12-20, 31-38)

[3] "EFSA Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT50 values of active substances of plant protection products and transformation products of these active substances in soil", EFSA Journal 2014, 12(5): 3662

Crop	Winter cereals	Spring cereals
Application rate (kg as/ha)	Bixafen: 125 g/ha	Bixafen: 125 g/ha
Number of applications/interval (d)	1/-	1/-
Application window / Crop intercep-tion (Step 2)	Mar. – May (Spring) / Average crop cover Jun. – Sep. (Summer) / Full canopy	Mar. – May (Spring) / Average crop cover Jun. – Sep. (Summer) / Full canopy
Application method	Ground spray	Ground spray
CAM (Chemical application method)	2	2
Soil depth (cm)	4	4
Models used for calculation	FOCUS STEP 1-2, v3.2, FOCUS SWASH v5.3, FOCUS PRZM v4.3.1, FOCUS MACRO v5.5.4, FOCUS TOXWA v5.5.3, FOCUS SWAN 5.0.1	FOCUS STEP 1-2, v3.2, FOCUS SWASH v5.3, FOCUS PRZM v4.3.1, FOCUS MACRO v5.5.4, FOCUS TOXWA v5.5.3, FOCUS SWAN 5.0.1

Absolute application dates are used in Step 3 and are shown in the table 8.9-2 below. The absolute application dates are chosen by using the software AppDate v3.06 and the following BBCH stages were used as input parameters: first possible application at BBCH 30.

Table 8.9-2: FOCUS Step 3 Scenario related input parameters for $PEC_{sw/sed}$ calculations for the application of GLOB2111F

Crop	Scenario	Application window used in modelling
Winter cereals	D1 Ditch/Stream	25/03 – 24/04
	D2 Ditch/Stream	04/04 – 04/05
	D3 Ditch	16/04 – 16/05
	D4 Pond/Stream	18/03 – 17/04
	D5 Pond/Stream	15/03 – 14/04
	D6 Ditch	16/02 – 18/03
	R1 Pond/Stream	24/04 – 24/05
	R3 Stream	19/03 – 18/04
	R4 Stream	24/01 – 23/02
Spring cereals	D1 Ditch/Stream	27/05 – 26/06
	D3 Ditch	28/04 – 28/05
	D4 Pond/Stream	18/05 – 17/06
	D5 Pond/Stream	09/04 – 09/05
	R4 Stream	09/04 – 09/05

Table 8.9-3: Input parameters related to active substance bixafen for $PEC_{sw/sed}$ calculations STEP 1/2 and 3/4

Compound	Bixafen	Value in accordance to EU end-point y/n/ Reference
Molecular weight (g/mol)	414.2	Y/EFSA Journal 2012;10(11):2917
Saturated vapour pressure (Pa)	4.6×10^{-8} (20°C)	Y/EFSA Journal 2012;10(11):2917
Water solubility (mg/L)	0.49 (20°C)	Y/EFSA Journal 2012;10(11):2917
Diffusion coefficient in water (m²/d)	4.3×10^{-5}	default
Diffusion coefficient in air (m²/d)	0.43	default
K_{foc} (mL/g)/K_{fom}	3827/2220 (geomean, n=5)	Geomean in accordance with EFSA guidance (2014)
Freundlich Exponent 1/n	0.877 (mean, n=5)	Y/EFSA Journal 2012;10(11):2917
Plant Uptake	0	FOCUS recommendation
Wash-Off factor from Crop (1/mm)	0.05 (MACRO) 0.50 (PRZM)	default
$DT_{50,soil}$ (d)	200.2 (geomean, field, 20°C pF2)	Y/EFSA Journal 2012;10(11):2917
$DT_{50,water}$ (d)	1000	Conservative assumption
$DT_{50,sed}$ (d)	1000	Conservative assumption
$DT_{50,whole\ system}$ (d)	1000	Conservative assumption

$PEC_{sw/sed}$

As the DT_{50} of bixafen in sediment amounts to 1000 days, the active substance have the potential to bio-accumulate in the sediment.

The following equation is used to calculate $PEC_{sed,\ accu}$ based on FOCUS Step 1 and 2 values:

maximum PEC_s accumulation = Initial PEC_s for 1 application / $(1 - e^{-ki})$
Where: $k = \ln 2 / DT_{50} = \ln 2 / 315.5$
i = interval between the applications = 365

To calculate $PEC_{sed,\ accu}$ based on FOCUS Step 3 and 4 values, following approach is used:

The pragmatic approach outlined in the EFSA Scientific Opinion on the effect assessment for pesticides on sediment organisms in edge-of-field surface water (EFSA Journal 2015;13(7):4176) was used. It is similar to the methodology commonly used for soil concentrations. Accumulation was calculated as follows:

$$PEC_{SED,ACCU} = PEC_{SED,FOCUS} + PEC_{SED,MAX,FOCUS}\frac{X}{1-X}$$

$$X = \exp\left(-\frac{365\ln(2)f}{DegT50}\right)$$

$$f = \left(\frac{-E}{R}\left[\frac{1}{T_{arr,scen}+273.15} - \frac{1}{T_0+273.15}\right]\right)$$

$PEC_{SED,ACCU}$:	predicted sediment concentration including accumulation (µg/kg)
$PEC_{SED,FOCUS}$:	predicted concentration in sediment according to FOCUS (µg/kg)
$PEC_{SED,MAX,FOCUS}$:	maximum concentration in sediment according to FOCUS (µg/kg)
f:	temperature correction factor (–)
DegT50:	degradation in water/sediment at reference temperature (days)
$T_{arr,scen}$:	Arrhenius-weighted average concentration of the scenario (°C)
T_0:	Reference temperature during the degradation study (20 °C)
E:	Arrhenius activation energy, (kJ/mol)
R:	Gas constant (kJ/mol/K)

EFSA (2015) explains that $PEC_{SED,FOCUS}$ represents the standard environmental concentrations as provided by FOCUS at the different steps. It could alternatively be a maximum concentration or an actual concentration sometime after the maximum or a TWA. The maximum PEC_{SED} from the FOCUS Step 3 and 4 simulations was used in the calculations presented in this dRR. Temperature correction factors for the 10 FOCUS surface water scenarios have been provided by EFSA and repeated here in the following table:

Table 8.9-4: Temperature correction factor for the FOCUS surface water scenarios (EFSA 2015)

Scenario	Correction factor f
D1	0.366
D2	0.424
D3	0.483
D4	0.400
D5	0.526
D6	0.841
R1	0.483
R2	0.660
R3	0.679
R4	0.662

Results of the PEC_{sw} and PEC_{sed} calculations are reported below.

Table 8.9-5: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for bixafen following single application of GLOB2111F to winter cereals

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	21 d-$PEC_{sw,twa}$ (µg/L)*	Max PEC_{sed} (µg/kg)*	Max $PEC_{sed,accu}$ (µg/kg)
Step 1	---	7.9772	RunOff/Drain.	6.9881	268.3159	1200.35
Step 2						
Northern	March-May	1.3432	RunOff/Drain.	1.2579	48.3874	216.47

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	21 d-$PEC_{sw,twa}$ (µg/L)*	Max PEC_{sed} (µg/kg)*	Max $PEC_{sed,accu}$ (µg/kg)
Europe	June-Sept	1.1496	RunOff/Drain.	0.5747	22.6354	101.26
Southern Europe	March-May	2.4206	RunOff/Drain.	2.3275	89.5907	400.80
	June-Sept	1.1496	RunOff/Drain.	0.7421	30.3610	135.82
Step 3						
D1	ditch	0.7892	Drift	0.06625	0.8636	9.765
D1	stream	0.6136	Drift	0.001684	0.03065	0.347
D2	ditch	0.8	Drift	0.1142	2.179	21.422
D2	stream	0.6753	Drift	0.03259	0.9029	8.876
D3	ditch	0.7864	Drift	0.03795	0.5472	4.757
D4	pond	0.02703	Drift	0.01981	0.3499	3.635
D4	stream	0.5811	Drift	0.002925	0.04501	0.468
D5	pond	0.02724	Drift	0.02061	0.3479	2.792
D5	stream	0.6276	Drift	0.001116	0.01889	0.152
D6	ditch	0.7774	Drift	0.01729	0.2648	1.382
R1	pond	0.03769	Run-off	0.03404	1.115	9.693
R1	stream	0.5179	Drift	0.01519	2.408	20.934
R3	stream	0.7277	Drift	0.01404	2.605	16.504
R4	stream	0.5202	Drift	0.02657	3.34	21.659

Table 8.9-6: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for bixafen following single application of GLOB2111F to spring cereals

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	21 d-$PEC_{sw,twa}$ (µg/L)	Max PEC_{sed} (µg/kg)	Max $PEC_{sed,accu}$ (µg/kg)
Step 1	---	7.9772	RunOff/Drain.	6.9881	268.3159	1200.35
Step 2						
Northern Europe	March-May	1.3432	RunOff/Drain.	1.2579	48.3874	216.47
	June-Sept	1.1496	RunOff/Drain.	0.5747	22.6354	101.26
Southern Europe	March-May	2.4206	RunOff/Drain.	2.3275	89.5907	400.80
	June-Sept	1.1496	RunOff/Drain.	0.7421	30.3610	135.82
Step 3						
D1	ditch	0.7961	Drift	0.4177	3.841	43.431
D1	stream	0.6961	Drift	0.02966	0.4442	5.023
D3	ditch	0.7872	Drift	0.04254	0.6054	5.263

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	21 d-$PEC_{sw,twa}$ (µg/L)	Max PEC_{sed} (µg/kg)	Max $PEC_{sed,accu}$ (µg/kg)
D4	pond	0.02705	Drift	0.02047	0.3759	3.906
D4	stream	0.6434	Drift	0.002943	0.05006	0.520
D5	pond	0.02724	Drift	0.02073	0.3466	2.782
D5	stream	0.6608	Drift	0.001747	0.0291	0.234
R4	stream	0.5202	Drift	0.04873	5.907	38.305

FOCUS Step 4

Table 8.9-7: Global maximum PEC_{sw} values for bixafen, following single application(s) of GLOB2111F to winter cereals according to the central EU zone GAP according to surface water Step 4

PEC_{sw} (µg/L)	Scenario	STEP 4 bixafen	
Nozzle reduction	Vegetative strip (m)	None	None
	No spray buffer (m)	1/3	5
None	D1 ditch	0.7892	0.2137
50 %		0.3945	-
75 %		0.1971	-
90 %		-	-
None	D1 stream	0.6136	0.224
50 %		0.4135	-
75 %		0.2065	-
90 %		-	-
None	D2 ditch	0.8	0.3551
50 %		0.4029	-
75 %		0.3551	-
90 %		-	-
None	D2/stream	0.6753	0.2471
50 %		0.4554	-
75 %		0.228	-
90 %		-	-
None	D3/ditch	0.7864	0.2129
50 %		0.3931	-
75 %		0.1964	-
90 %		0	-

PEC_{sw} (µg/L)	**Scenario**	**STEP 4 bixafen**	
Nozzle reduction	Vegetative strip (m)	None	None
	No spray buffer (m)	1/3	5
None	D4/stream	0.5811	0.2121
50 %		0.3916	-
75 %		0.1956	-
90 %		-	-
None	D5/stream	0.6276	0.2291
50 %		0.4229	-
75 %		0.2113	-
90 %		-	-
None	D6/ditch	0.7774	0.2105
50 %		0.3886	-
75 %		0.1941	-
90 %		-	-
None	R1/stream	0.5179	0.189
50 %		0.349	-
75 %		0.1864	-
90 %		-	-
None	R3/stream	0.7277	0.2656
50 %		0.4904	-
75 %		0.245	-
90 %		-	-
None	R4/stream	0.5202	0.3145
50 %		0.3506	-
75 %		0.3145	-
90 %		-	-

Table 8.9-8: **Global maximum PEC_{sw} values for bixafen, following single application(s) of GLOB2111F to spring cereals according to the central EU zone GAP according to surface water Step 4**

PEC_{sw} (µg/L)	**Scenario**	**STEP 4 bixafen**	
Nozzle reduction	Vegetative strip (m)	None	None
	No spray buffer (m)	1/3	5

PEC$_{sw}$ (µg/L)	**Scenario**	**STEP 4 bixafen**	
Nozzle reduction	Vegetative strip (m)	None	None
	No spray buffer (m)	1/3	5
None	D1 ditch	0.7961	0.2156
50 %		0.398	-
75 %		0.1988	-
90 %		-	-
None	D1 stream	0.6961	0.2541
50 %		0.4691	-
75 %		0.2343	-
90 %		-	-
None	D3 ditch	0.7872	0.2131
50 %		0.3935	-
75 %		0.1966	-
90 %		-	-
None	D4 stream	0.6434	0.2348
50 %		0.4335	-
75 %		0.2166	-
90 %		-	-
None	D5 stream	0.6608	0.2412
50 %		0.4453	-
75 %		0.2224	-
90 %		-	-
None	R4 stream	0.5202	0.2957
50 %		0.3505	-
75 %		0.2957	-
90 %		-	-

8.9.2.1 PEC$_{sw/sed}$ of GLOB2111F

The PEC$_{sw}$ of the formulation GLOB2111F following drift events were also calculated using the calculator tool from the FOCUS SWASH model. The density of the product is 1.01 kg/L so the application rate of the formulation is 1010 g/ha for 1 L/ha. These PEC$_{sw}$ were calculated for the ditch, pond and stream scenarios for the use of GLOB2111F in cereals. The results of these calculations are provided below in ~~table~~ Table 8.9-9.

Table 8.9-9: Maximum PEC_{sw} for GLOB2111F following single application to cereals (winter/spring)

Cropping scenario	FOCUS scenario	Step 3 value		50%		5m	
		% drift	Max. PEC_{sw} (µg/L)	% drift	Max. PEC_{sw} (µg/L)	% drift	Max. PEC_{sw} (µg/L)
Cereals, 1 x 1 L/ha	Ditch	1.9274	6.4889	0.9637	3.24445	0.5224	1.7589
	Pond	0.3282	0.3315	0.1641	0.16575	0.1896	0.1914
	Stream	1.9274	6.4889	0.9637	3.24445	0.5224	1.7589

Evaluation by zRMS	PECsw (KCP 9.2.5)
Inputs for Modelling	For the active substance bixafen the calculations presented here are accepted. Predicted environmental concentrations in surface water (PEC_{sw}) and sediment (PEC_{sed}) have been calculated for bixafen after the application of the product Starinta (GLOB2111F) on winter and spring cereals: - 1x 1l product Starinta (GLOB2111F)/ha; considering the pathways spray drift, drainage and runoff. Input parameters used in FOCUS surface water/sediment modelling for active substance are correct. The PEC_{SW} and PEC_{sed} were calculated in compliance with relevant FOCUS scenarios in stepwise procedure (Steps 1, 2, 3 and 4). The calculations were carried out at Step 1 to Step 4 for bixafen. **Starinta (GLOB2111F)** Calculations of PEC_{SW} values for formulation are appropriate. The obtained results of PECsw are accepted by zRMS. Presented calculations of $PEC_{sw/sed}$ may be used for risk assessment.
Agreed endpoints	Please refer to Tables from 8.9-5 to 8.9-9.
Implication for risk assessment	Please refer to Part B, Section 9 of this dRR.

8.10 Fate and behaviour in air (KCP 9.3, KCP 9.3.1)

Table 8.10-1 Summary of atmospheric degradation and behaviour

Compound	Bixafen
Direct photolysis in air	Not studied – no data requested
Quantum yield of direct phototransformation	Active substance: 0.0000218 (aqueous solution)
Photochemical oxidative degradation in air	DT_{50} (h): 10.4 derived by the Atkinson model (version 1.91). OH (12h) concentration assumed = 1.5 x 10^6
Volatilisation	Vapour pressure (Pa): 4.6 x 10^{-8} at 20°C Henry's Law Constant (Pa.m3/mol): 3.89 x 10^{-5} at 20°C

Metabolites	None

The vapour pressure at 20 °C of the active substance bixafen is < 10^{-5} Pa. Hence the active substance bixafen is regarded as non-volatile. Therefore exposure of adjacent surface waters and terrestrial ecosystems by the active substance bixafen due to volatilization with subsequent deposition should not be considered.

Evaluation by zRMS	**Fate and behaviour in air (KCP 9.3)**
Comments	The data on the atmospheric degradation and behaviour for the active substance follows the EU assessment and is therefore agreed by the zRMS.
Conclusion for exposure assessment	The vapour pressure at 20 °C of the active substance bixafen is 4.6×10^{-8} Pa. Hence bixafen is regarded as non-volatile and the environmental concentrations in air and the transport through air are considered negligible.

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

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

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.2.4	Fernandez D.	2023	Estimation of the Predicted Environmental Concentration of bixafen in groundwater following the application of GLOB2111F to winter and spring cereals GLOB2111F-Bixf-GW Globachem NV Non-GLP Unpublished	N	Globachem NV
KCP 9.2.5	Fernandez D.	2023	Estimation of the Predicted Environmental Concentration of bixafen in surface water following the application of GLOB2111F to winter and spring cereals GLOB2111F-Bixf-SW Globachem NV Non-GLP Unpublished	N	Globachem NV

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.1.1.1	Sneikus, J. ; Koehn, D.	2005	[Pyrazole-5-14C] and [dichlorophenyl-UL14C]BYF00587: Aerobic soil metabolism in 4 EU soils Bayer Crop Science AG Report No.: MEF-05/172 GLP Unpublished	N	BCS
KCP 9.1.1.1	Unold, M.; Bayer, H.	2009	Rate of degradation of M700F002 (metabolite of BAS 700 F) in aerobic soil. BASF SE 2009/1070322 GLP Unpublished	N	BASF
KCP 9.1.1.1	Simmonds, M.; Lowden, P.	2006	[Dichlorophenyl-UL-14C] and [pyrazole-5-14C]-BYF00587: Anaerobic soil degradation Battelle UK Ltd. / Bayer Crop Science AG Report No.: CX/05/045 GLP Unpublished	N	BCS
KCP 9.1.1.2	Heinemann, O.	2007	Determination of the residues of BYF 00587 and BYF 00587- desmethyl in/on soil after spraying of BYF 00587 (450 SC) in the field in Germany, United Kingdom, Sweden, France, Spain and Italy Bayer Crop Science AG, Report No.: RA-2056/05 GLP Unpublished	N	BCS
KCP 9.1.1.2	Unold, M.; *et al.*	2009	Field soil dissipation study of M700F002 (metabolite of BAS 700 F) in the formulation EXP 5435595 on bare soil at four different locations in Europe, 2008-2009. BASF SE; 2009/1070325 GLP Unpublished	N	BASF
KCP 9.1.1.2	Hardy, I.A.J.	2009a	BAS 700 F: Kinetic modelling analysis of M700F002 data from field soil residue studies conducted in Europe.	N	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Battelle UK Ltd Non-GLP Unpublished		
KCP 9.1.1.2	Hardy, I.A.J.	2009b	BAS 700 F: Timestep normalisation analysis of M700F002 data from field soil residue studies conducted in Europe. Battelle UK Ltd 2009/1093281 Non-GLP Unpublished	N	BASF
KCP 9.1.2.1	Koehn, D.; Haas, M	2005	BYF00587: Adsorption/desorption on five soils Bayer Crop Science AG Report No.: MEF-04/455, GLP Unpublished	N	BCS
KCP 9.1.2.1	Hassink, J.; Stephan, A.	2009	Determination of the adsorption/desorption behaviour of M700F002 (metabolite of BAS 700 F) on different soils BASF SE 2009/1070296 GLP Unpublished	N	BASF
KCP 9.2, KCP 9.2.1, KCP 9.2.2, KCP 9.2.3	Oddy, A.; Doble, M.	2006	[Dichlorophenyl-UL-14C] and [pyrazole-5-14C]-BYF 00587: Degradation and retention in two water/sediment systems Battelle UK Ltd. / Bayer Crop Science AG Report No.: CX/05/060 GLP Unpublished	N	BCS

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

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

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

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

Appendix 2 Detailed evaluation of the new Annex II studies

No new Annex II studies were submitted in support of the evaluation of the fate and behaviour of GLOB2111F.

Appendix 3 Additional information provided by the applicant (e.g. detailed modelling data)

None.