

# REGISTRATION REPORT

## **Part B**

### **Section 8**

#### **Environmental Fate**

Detailed summary of the risk assessment

Product code: FLORAS 50 SC

Product name(s): Floras 50 SC, HerbiFlo 50 SC

Chemical active substance:

Florasulam, 50 g/L

Central Zone

Zonal Rapporteur Member State: POLAND

#### **CORE ASSESSMENT**

(authorization)

Applicant: Elvita Sp. z o.o.

Submission date: 30/11/2023, updated March 2024

MS Finalisation date: April 2024 (initial Core Assessment)

June 2024 (final Core Assessment)

### Version history

When	What
November 2023	Initial dRR – Elvita Sp. z o.o.
March 2024	Applicants' update.
April 2024	Initial zRMS assessment The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and <b>highlighted in grey</b> . Not agreed or not relevant information are <del>struck through</del> and <b>shaded</b> for transparency.
June 2024	Final report (Core Assessment updated following the commenting period) No additional information or assessments after the commenting period.

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## 8 Fate and behaviour in the environment (KCP 9)

This document reviews the environmental fate and behaviour for the product Floras 50 SC containing Florasulam as active substance.

Florasulam was reviewed as part of the renewal of approval procedure by the Member States and the Commission and the Commission review report finalised on 14.08.2015 approved Florasulam in accordance with Regulation (EC) No. 1107/2009 (Regulation 2015/1397).

Where appropriate this document refers to the conclusions of the EU review of the active substance Florasulam. This will be where:

- the active substance data is relied upon in the risk assessment of the formulation; or when
- the EU review concluded that additional data/information should be considered at national re-registration.

Note: this Part B document only reviews data (Annex II or Annex III) and additional information that has not previously been considered within the EU review process, as part of the Annex I inclusion decision. New annex II data must only be included if they are considered essential for the evaluation and in this case a full study summary must be provided.

This product was not the representative formulation and has not been previously evaluated according to Uniform Principles.

The EFSA Report of Florasulam (EFSA Journal 2015; 13(1):3984) is considered to provide the relevant review information or a reference to where such information can be found. The following table provides the EU endpoints to be used in the evaluation.

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, shall be taken into account.

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

- the risk to aquatic organisms and non-target terrestrial plants. Conditions of use shall include risk mitigation measures, where appropriate.

This concern have been addressed within the current submission in the respective sections.

Appendix 1 of this document contains the list of references included in this document for support of the evaluation.

## 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 situa- tion  (crop destination / purpose of crop)	F, Fn, Fnp G, Gn, Gnp 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, other dose rate expres- sion, dose range (min- max)	zRMS Conclusion Groundwater (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. inter- val between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min / max			
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	Poland	Winter wheat	F	<i>Anthemis arvensis</i> , <i>Brachiaria nana</i> , <i>Brassica napus</i> , <i>Capsella bursa-pastoris</i> , <i>Descurainia sophia</i> , <i>Fallopia convolvulus</i> , <i>Galium aparine</i> , <i>Tripleurospermum inodorum</i> , <i>Myosotis arvensis</i> , <i>Papaver rhoeas</i> , <i>Fallopia convolvulus</i> , <i>Sinapis arvensis</i> , <i>Stellaria media</i> , <i>Thlaspi arvense</i> , <i>Veronica persica</i> .	Foliar spraying; small drops	BBCH 12-32	1	-	a) 0,1	Florasulam: 5.0	200- 400	-	Herbicide for use with field sprayers	A
2	Poland	Spring barley	F	<i>Anthemis arvensis</i> , <i>Amaranthus retroflexus</i> , <i>Brassica napus</i> , <i>Capsella bursa-pastoris</i> , <i>Chenopodium album</i> , <i>Descurainia sophia</i> , <i>Fallopia convolvulus</i> , <i>Galeopsis tetrahit</i> , <i>Galium aparine</i> , <i>Galinsoga parviflora</i> , <i>Tripleurospermum inodorum</i> , <i>Silene latifolia</i> subsp. <i>Alba</i> , <i>Myosotis arvensis</i> , <i>Polygonum aviculare</i> , <i>Fallopia convolvulus</i> , <i>Persicaria maculosa</i> , <i>Sinapis arvensis</i> , <i>Stellaria media</i> , <i>Thlaspi arvense</i> , <i>Veronica persica</i> .	Foliar spraying; small drops	BBCH 12-32	1	-	a) 0,1	Florasulam: 5.0	200- 400	-	Herbicide for use with field sprayers	A

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

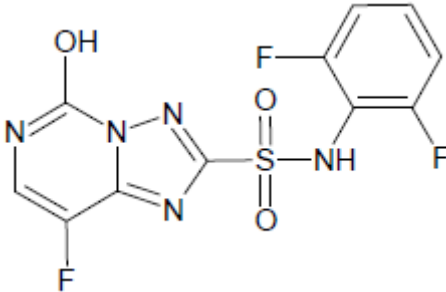
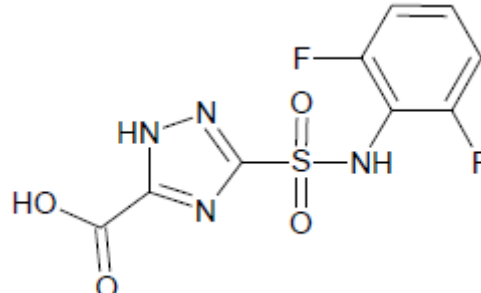
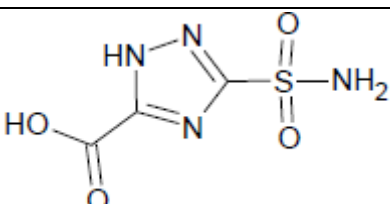
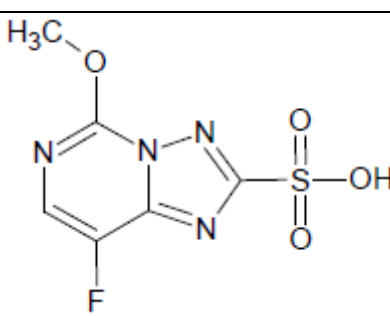
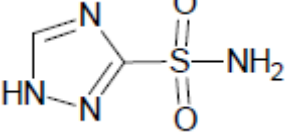
\*\* F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

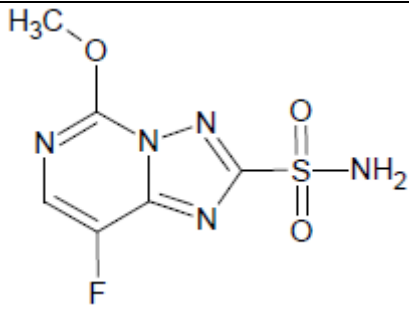
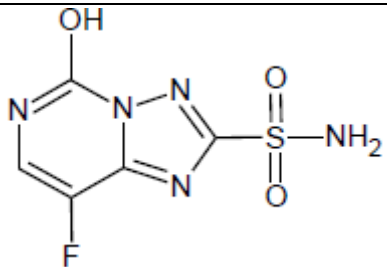
Explanation for column 15 “Conclusion”

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

## 8.2 Metabolites considered in the assessment

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

Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
<b>5-OH Florasulam;</b> N-(2,6-difluorophenyl)-8-fluoro-5-oxo-5,6-dihydro[1,2,4]triazolo[1,5-c]pyrimidine-2-sulfonamide	345.3		Soil: 71.6 % w/s system: 99.0 %	PEC <sub>soil</sub> PEC <sub>gw</sub> PEC <sub>sw</sub> PEC <sub>sed</sub> Soil Water/Sediment
<b>DFP-ASTCA;</b> 3-[(2,6-difluorophenyl)sulfamoyl]-1H-1,2,4-triazole-5-carboxylic acid	304.2		Soil: 17.8 % w/s system: 8.9 %	PEC <sub>soil</sub> PEC <sub>gw</sub> PEC <sub>sw</sub> PEC <sub>sed</sub> Soil Water/Sediment
<b>ASTCA;</b> 3-sulfamoyl-1H-1,2,4-triazole-5-carboxylic acid	192.1		Soil: 40 % w/s system: 53.8 %	PEC <sub>soil</sub> PEC <sub>gw</sub> PEC <sub>sw</sub> PEC <sub>sed</sub> Soil Water/Sediment
<b>TPSA;</b> 8-fluoro-5-methoxy[1,2,4]triazolo[1,5-c]pyrimidine-2-sulfonic acid	248.2		Soil: 0.001 % w/s system: 58 %	PEC <sub>sw</sub> PEC <sub>sed</sub> Soil Water/Sediment
<b>TSA;</b> 1H-1,2,4-triazole-3-sulfonamide	148.1		Soil: 15.9 % w/s system: 0.0001 %	PEC <sub>soil</sub> PEC <sub>gw</sub> PEC <sub>sw</sub> PEC <sub>sed</sub> Soil Water/Sediment

Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
<b>ASTP;</b> 8-fluoro-5-methoxy[1,2,4]triazolo[1,5-c]pyrimidine-2-sulfonamide	247.2		Soil: 0.001 % w/s system: 21.0%	PEC <sub>sw</sub> PEC <sub>sed</sub> Soil  Water/Sediment
<b>5-OH ASTP;</b> 8-fluoro-5-oxo-5,6-dihydro[1,2,4]triazolo[1,5-c]pyrimidine-2-sulfonamide	233.2		Soil: 0.001 % w/s system: 29.0 %	PEC <sub>sw</sub> PEC <sub>sed</sub> Soil  Water/Sediment

#### zRMS comments:

Information regarding florasulam and its metabolites presented in Table 8.2-1 above is in line with EU agreed data reported in EFSA Journal 2015;13(1):3984, minor corrections were introduced.

### 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 substances.

#### 8.3.1 Aerobic degradation in soil (KCP 9.1.1.1) of active substances and metabolites.

Summary of aerobic degradation rates for Florasulam – laboratory studies (EFSA Journal 2015; 13(1):3984.

Soil		Soil properties		Incubation conditions	Kinetic model	Evaluation of the fit		Kinetic parameters		Normalised kinetic endpoints <sup>3)</sup>	
Soil name	Soil type (USDA)	OC	pH			$\chi^2$ error	Visual fit <sup>1)/R<sup>2</sup></sup>	Param.	Value	DT <sub>50</sub> [days]	DT <sub>90</sub> [days]
<i>Andover; TP-labelling</i>	Silt loam	3.1	7.6	20°C; 40% MWHC	SFO)	4.34	V. G./ 0.999	<i>k</i>	0.7617	0.91	3.05
<i>Kenslow; TP-labelling</i>	Silt loam	6.8	5.6	20°C; 40% MWHC	SFO	4.14	V. G./ 0.999	<i>k</i>	1.2006	0.58	1.92
<i>Marcham; TP-labelling</i>	Sandy clay loam	2.0	7.7	20°C; 40% MWHC	SFO	13.44	V.G./ 0.985	<i>k</i>	0.3290	2.14	7.10
<i>Speyer 2.2; XDE-570, both labels</i>	Sandy loam	3.9	7.3	20°C; 40% MWHC	Pseudo-SFO (back-calculated from FOMC)	7.48	V.G./ 0.996	<i>k</i>	0.4279	1.62	5.38
<i>Cuckney; TP-labelling</i>	Sandy loam	1.4	6.9	25°C; 40% MWHC	SFO	3.81	V. G./ 0.999	<i>k</i>	0.6245	1.11	3.63
<i>Cuckney; TP-labelling</i>	Sandy loam	1.4	6.9	20°C; Field Capacity	SFO	15.28	G./0.982	<i>k</i>	0.2427	2.86	9.49
<i>Cuckney; TP-labelling; averaged - geomean</i>	Sandy loam	1.4	6.9	----	SFO	----	----	<i>k</i>	----	<b>1.78</b>	<b>5.87</b>
<i>Marcham; TP-labelling</i>	Sandy clay loam	1.4	7.6	20°C; Field Capacity	SFO	12.78	G./ 0.984	<i>k</i>	0.1617	4.29	14.24
<b>Geometric mean:<sup>2)</sup></b>										<b>1.55</b>	<b>5.15</b>

- 1) The abbreviations used to describe the visual fit: V. G. – very good, G. – good, I. – intermediate, P. – poor.
- 2) The values calculated using the geomean value determined for the experiments in Cuckney soil (individual results for this soil were not considered in calculating geomean, following the recommendation given by PRAS 117 Expert's Meeting);
- 3) Normalised, where necessary, using a Q10 of 2.58 and/or Walker equation coefficient of 0.7.



Soil		Soil properties		Incubation conditions	Kinetic model	Evaluation of the fit		Kinetic parameters		Normalised kinetic endpoints <sup>1)</sup>		
Soil name	Soil type (USDA)	OC	pH			$\chi^2$ error	Visual fit <sup>2)</sup> /R <sup>2</sup>	Param.	Value	DT <sub>50</sub> [days]	DT <sub>90</sub> [days]	Kinetic formation fraction <i>ff</i>
Andover; TP-labelled XDE-570	Silt loam	3.1	7.6	20°C; 40% MWHC	SFO	5.14	V, G./ 0.998	<i>k</i>	0.1100	6.30	20.92	0.747
Kenslow; TP-labelled XDE-570	Silt loam	6.8	5.6	20°C; 40% MWHC	SFO	8.15	G./ 0.984	<i>k</i>	0.0392	17.69	58.76	0.828
Marcham ; TP-labelled XDE-570	Sandy clay loam	2.0	7.7	20°C; 40% MWHC	SFO	15.52	G./ 0.939	<i>k</i>	0.0567	12.22	40.57	0.717
Speyer 2.2; XDE-570; both labels	Sandy loam	3.9	7.3	20°C; 40% MWHC	SFO	7.70	G./ 0.982	<i>k</i>	0.0480	14.44	47.97	0.863
Cuckney; TP-labelled XDE-570	Sandy loam	1.4	6.9	25°C; 40% MWHC	SFO	16.52	G./ 0.951	<i>k</i>	0.0461	15.02	50.02	0.933
Cuckney; TP-labelled XDE-570	Sandy loam	1.4	6.9	20°C; Field Capacity	SFO	21.07	G./ 0.903	<i>k</i>	0.0280	24.77	82.30	1.000
Cuckney; TP-labelled XDE-570; averaged - geomean	Sandy loam	1.4	6.9	----	SFO	----	----	<i>k</i>	----	19.29	64.16	0.967
Marcham TP-labelled XDE-570	Sandy clay loam	1.4	7.6	20°C; Field Capacity	SFO	14.62	G./ 0.961	<i>k</i>	0.0487	14.24 <sup>#</sup>	98.63	1.000
Geometric mean <sup>2)</sup> :										14.98	49.74	----
Arithmetic mean (for <i>ff</i> only) <sup>3)</sup> :										----	----	0.854

- 1) The abbreviations used to describe the visual fit: V, G. – very good, G. – good, I. – intermediate, P. – poor.
- 2) The values calculated using the geomean value determined for the experiments in Cuckney soil (individual results for this soil were not considered in calculating geomean, following the recommendation given by PRAS 117 Expert's Meeting);
- 3) The values calculated using the arithmetic mean value determined for the experiments in Cuckney soil (individual results for this soil were not considered in calculating the mean, following the recommendation given by PRAS 117 Expert's Meeting);
- 4) Normalised, where necessary, using a Q10 of 2.58 and/or Walker equation coefficient of 0.7.
- #) The DT50 = 14.24 was incorrectly transferred in tables B.8.1.2.1-84, -88, -89, -90, -91, -137 and -138 in the Addendum 2 (final) provided by the RMS (Poland, 2014). The correct DT50 value for metabolite 5-OH florasulam derived from the Marcham soil incubated at 20°C and Field Capacity is 29.75 days, because that is what results from the *k* = 0.0233 (the DT90 value and the final geometric mean of 14.98 are correct). The value of 29.75 days was properly reported in tables B.8.1.2.1-145 and B.8.3-1 of the same Addendum 2 (final) (Poland, 2014).

#### Summary of aerobic degradation rates for DFP-ASTCA- laboratory studies (EFSA Journal 2015; 13(1):3984)

Soil		Soil properties		Incubation conditions	Kinetic model	Evaluation of the fit		Kinetic parameters		Normalised kinetic endpoints		
Soil name	Soil type (USDA)	OC	pH			$\chi^2$ error	Visual fit <sup>2)</sup> /R <sup>2</sup>	Param.	Value	DT <sub>50</sub> [days]	DT <sub>90</sub> [days]	Kinetic formation fraction <i>ff</i> <sup>3)</sup>
Andover; TP-labelled XDE-570	Silt loam	3.1	7.6	20°C; 40% MWHC	SFO, top-down	9.88	G./ 0.979	<i>k</i>	0.0356	19.45	64.60	1.000 (default)
Kenslow; TP-labelled XDE-570	Silt loam	6.8	5.6	20°C; 40% MWHC	SFO, top-down	6.47	V, G./ 0.989	<i>k</i>	0.0317	21.87	72.65	1.000 (default)
Marcham ; TP-labelled XDE-570	Sandy clay loam	2.0	7.7	20°C; 40% MWHC	SFO, top-down	6.47	G./	<i>k</i>	0.0150	46.16	153.33	1.000 (default)
Cuckney; TP-labelled DFP-ASTCA	Loamy sand	1.5	7.2	20°C; 40% MWHC	SFO	9.95	G./ 0.985	<i>k</i>	0.0454	15.27	50.71	1.000 (default)
Marcham TP-labelled DFP-ASTCA	Sandy clay loam	3.4	7.9	20°C; 40% MWHC	SFO	7.51	V, G./ 0.991	<i>k</i>	0.1637	4.23	14.06	1.000 (default)
Geometric mean:										16.62	55.21	----
Arithmetic mean (for <i>ff</i> only):										----	----	1.000 (default)

- 1) The abbreviations used to describe the visual fit: V, G. – very good, G. – good, I. – intermediate, P. – poor.
- 2) Because the fitting was performed using either the top-down approach or for DFP-ASTCA applies as a parent compound, the *ff* values could not be determined experimentally; instead the default value of 1 was proposed.

### Summary of aerobic degradation rates for ASTCA - laboratory studies (EFSA Journal 2015; 13(1):3984)

Soil		Soil properties		Incubation conditions	Kinetic model	Evaluation of the fit		Kinetic parameters		Normalised kinetic endpoints		
Soil name	Soil type (USDA)	OC	pH			$\chi^2$ error	Visual fit <sup>1)</sup> /R <sup>2</sup>	Param.	Value	DT <sub>50</sub> [days]	DT <sub>90</sub> [days]	Kinetic formation fraction <i>ff</i>
Cuckney; TP-labelled DFP-ASTCA	Loamy sand	1.5	7.2	20°C; 40% MWHC	SFO	n. d. <sup>2)</sup>	n. d. <sup>2)</sup>	<i>k</i>	n. d. <sup>2)</sup>	1000 <sup>3)</sup>	>1000 <sup>3)</sup>	Not determined
Marcham TP-labelled DFP-ASTCA	Sandy clay loam	3.4	7.9	20°C; 40% MWHC	SFO	4.40	V. G./0.992	<i>k</i>	0.0032	214.11	711.24	0.781
Cuckney; TP-labelled ASTCA	Loamy sand	1.5	7.2	20°C; 40% MWHC	SFO	4.52	I./0.718	<i>k</i>	0.0027	259.05	860.55	Not determined
Marcham TP-labelled ASTCA	Sandy clay loam	3.4	7.9	20°C; 40% MWHC	SFO	7.12	G./0.809	<i>k</i>	0.0049	141.18	469.00	Not determined
Geometric mean:										297.47	659.66 <sub>4)</sub>	----
Arithmetic mean (for <i>ff</i> only):										----	----	0.781

1) The abbreviations used to describe the visual fit: V. G. – very good, G. – good, I. – intermediate, P. – poor.

2) n. d. – not determined;

3) A default value, DT50 not to be used in soil exposure assessment;

4) Calculated excluding the default values.

### Summary of aerobic degradation rates for TSA - laboratory studies (EFSA Journal 2015; 13(1):3984)

Soil		Soil properties		Incubation conditions	Kinetic model	Evaluation of the fit		Kinetic parameters		Normalised kinetic endpoints		
Soil name	Soil type (USDA)	OC	pH			$\chi^2$ error	Visual fit <sup>1)</sup>	Param.	Value	DT <sub>50</sub> [days]	DT <sub>90</sub> [days]	Kinetic formation fraction ff <sup>2)</sup>
Calke	Sandy loam	3.54	5.4	20°C, 20% v/v	SFO (slow phase DFOP)	2.23	V. G.	k <sub>2</sub>	0.0097	71.44	237.33	1.000 from ASTCA
												0.219 from DFP-ASTCA
South Witham	Clay loam	3.83	7.1	20°C, 25.7% v/v	SFO (slow phase DFOP)	2.11	V. G.	k <sub>2</sub>	0.0073	94.39	313.56	1.000 from ASTCA
												0.219 from DFP-ASTCA
Lufa 5M	Sandy loam	0.93	7.3	20°C, 14% v/v	SFO	4.44	G.	k	0.0040	171.68	570.33	1.000 from ASTCA
												0.219 from DFP-ASTCA
RefeSol 06-A	Clay loam	1.97	6.7	20°C, 29% v/v	SFO	12.87	G.	k	0.0163	42.47	141.07	1.000 from ASTCA
												0.219 from DFP-ASTCA
Geometric mean:										83.74	278.17	----
Arithmetic mean (for ff only):										---	---	1.000 from ASTCA 0.219 from DFP-ASTCA

1) The abbreviations used to describe the visual fit: V. G. – very good, G. – good, I. – intermediate, P. – poor.

2) The reported *ff* values are the default values derived from the analysis of the postulated transformation scheme and the appropriate experimentally-derived *ff* values

**Table 8.3-1: Summary of aerobic degradation rates - Florasulam.**

Endpoint	Florasulam	5-OH Florasulam	DFP-ASTCA	ASTCA	TSA
DT <sub>50</sub> (20 °C, pF2) for ground- and surface water modelling	1.55 (geomean lab)	14.98 (geomean lab)	16.62 (geomean lab)	297.47 (geomean lab)	83.74 (geomean lab)
DT <sub>50</sub> for modelling soil concentrations	4.29 (worst-case lab)	29.75 (worst-case lab)	46.16 (worst-case lab)	259.05 (worst-case lab)	171.68 (worst-case lab)
Maximum occurrence	-	71.6	17.8	40.0	15.9
Molar formation fractions	-	0.854 from Florasulam	1.0 from 5-OH	0.781 from DFP-ASTCA	1.0 from ASTCA 0.219 from DFP-ASTCA

**zRMS comments:**

Soil degradation data for florasulam and its metabolites are in line with EU agreed endpoints reported in EFSA Journal 2015;13(1):3984.

### 8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

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

The degradation half-life of Florasulam was slightly higher than under aerobic conditions. In addition to the soil metabolites Florasulam 5-OH that also occurred as major metabolite in the aerobic soil metabolism study (see above) a second metabolite, tentatively identified as triazolo-methyl carboxylic acid, occurred at 8.2% of applied radioactivity. However this was only after 368 days and is not relevant for the assessment. Florasulam 5-OH underwent almost no degradation.

**Table 8.3-2: Summary of anaerobic degradation rates for Florasulam**

EU endpoint	Florasulam	5-OH Florasulam
DT <sub>50,lab</sub>	18.47 days (mean of two radiolabels in one soil)	1235 days (mean of two radiolabels in one soil)

**zRMS comments:**

Information on anaerobic soil degradation of florasulam is in line with EU agreed data reported EFSA Journal 2015;13(1):3984.

### 8.4 Field studies (KCP 9.1.1.2)

Please refer to Conclusion on the peer review of the pesticide risk assessment of the active substances:

- Florasulam (EFSA Journal 2015; 13(1):3984) and Draft Assessment Report for Florasulam.

#### 8.4.1 Soil dissipation testing on a range of representative soils (KCP 9.1.1.2.1) of active substances and its metabolites

Studies on field dissipation rates with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

One field dissipation test of Florasulam and Florasulam 5-OH was performed following a single application of EF-1343 (SC formulation containing 50 g a.s./L). Six sites, Northern France, Germany, UK, UK, Southern France and Greece were included. Florasulam and Florasulam 5-OH were recovered in deeper horizons.

The field dissipation rates of Florasulam were evaluated during the Annex I Inclusion and used for PEC soil calculations. During Annex I renewal, these data were not used due to the low reliability of the fitting (EFSA 2015, p. 47). Instead, laboratory DT<sub>50</sub> values were used for PEC soil calculations (see IIIA 9.4).

**zRMS comments:**

Soil field degradation studies of florasulam and its metabolites according to EFSA Journal 2015;13(1):3984 were performed for six field trials but data were not reported due to the low reliability of the fitting.

#### 8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

Based on the results obtained with the active substances in the field residue trials, soil accumulation testing with the formulation is not required.

**zRMS comments:**

No EU agreed data from soil accumulation studies with florasulam are available in EFSA Journal 2015;13(1):3984. Potential for soil accumulation is thus addressed in calculation of soil exposure in point 8.7 of this report.

## **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.

### **8.5.1 Active substances and its metabolites**

As it is possible to extrapolate from data provided for the active substances, no further data are provided on the preparation.

The mobility in soil of Florasulam and its soil metabolites 5-OH Florasulam, DFP-ASTCA, ASTCA and TSA was evaluated during the Annex I renewal. No additional studies have been performed on these compounds.

The endpoints given in the EU review report are listed in the table below. The  $K_{FOC}$  for Florasulam and 5-OH Florasulam are median values, and arithmetic mean values for DFP-ASTCA, ASTCA and TSA as given in EFSA (2015).

## Adsorption

Soil name	Soil properties			Adsorption distribution coefficients		Freundlich adsorption isotherm parameters			
	Soil type (USDA)	pH	OC [%]	$K_d$ [mL/g]	$K_{dOC}$ [mL/g]	$K_f$ [mL/g]	$K_{fOC}$ [mL/g]	1/n	$R^2$
<i>Kenslow</i>	Loam	4.6	3.8	----	----	0.47	12.37	0.91	1.000
<i>Fuquay (M 444)</i>	Sand	4.7	0.64	0.35	54	0.35	54.69	1.00	0.978
<i>RefeSol 01-A</i>	Sandy loam	5.1	1.0	----	----	0.30	30.00	1.02	0.996
<i>Calke</i>	Sandy loam	5.4	3.6	----	----	0.30	8.33	0.95	1.000
<i>Pewamo (M 445)</i>	Clay	5.7	2.4	0.94	38	1.88	78.33	0.92	0.995
<i>Kenslow (94/16)</i>	Silt loam	6.1	6.8	0.90	13	1.47	21.62	0.94	0.998
<i>Lufa 6S</i>	Clay	6.6	1.8	----	----	0.04	2.22	1.04	0.996
<i>RefeSol 06-A</i>	Clay loam	6.7	1.9	----	----	0.08	4.21	0.94	0.998
<i>Catlin (M 461)</i>	Silty clay loam	7.0	2.2	0.33	15	0.89	40.45	0.88	0.992
<i>South Witham</i>	Clay loam	7.1	3.8	----	----	0.10	2.63	0.98	0.995
<i>Longwoods</i>	Sandy loam	7.2	1.5	----	----	0.03	2.00	0.89	0.989
<i>Lufa 5M</i>	Sandy loam	7.3	1.0	----	----	0.03	3.00	0.95	0.994
<i>Speyer 2.2 (94/14)</i>	Sandy loam	7.3	3.9	0.14	4	0.13	3.33	0.95	0.810
<i>Hanford (M 466)</i>	Sandy loam	7.4	1.0	0.08	8	0.22	22.00	0.86	0.943
Arithmetic mean values for the whole data set (n = 14)						0.45	20.37	<b>0.945</b>	----
Median values for the whole data set (n = 14)						0.26	<b>10.35</b>	----	----

## Desorption

Soil name	Soil properties			Adsorption distribution coefficients		Freundlich adsorption isotherm parameters			
	Soil type (USDA)	pH	OC [%]	$K_d$ [mL/g]	$K_{dOC}$ [mL/g]	$K_f$ [mL/g]	$K_{fOC}$ [mL/g]	1/n	$R^2$
<i>Kenslow</i>	Loam	4.6	3.8	----	----	0.77	20.26	0.92	0.999
<i>Fuquay (M 444)</i>	Sand	4.7	0.64	1.24	194	1.31	204.69	0.96	0.89
<i>RefeSol 01-A</i>	Sandy loam	5.1	1.0	----	----	0.51	51.00	1.05	0.993
<i>Calke</i>	Sandy loam	5.4	3.6	----	----	0.37	10.27	0.95	0.999
<i>Pewamo (M 445)</i>	Clay	5.7	2.4	2.00	82	4.25	177.08	0.89	0.98
<i>Kenslow (94/16)</i>	Silt loam	6.1	6.8	1.45	21	2.33	34.26	0.94	0.99
<i>Lufa 6S</i>	Clay	6.6	1.8	----	----	0.53	29.44	0.97	0.999
<i>RefeSol 06-A</i>	Clay loam	6.7	1.9	----	----	0.15	7.89	0.93	0.997
<i>Catlin (M 461)</i>	Silty clay loam	7.0	2.2	1.05	49	2.19	99.54	0.88	0.97
<i>South Witham</i>	Clay loam	7.1	3.8	----	----	0.35	9.21	0.94	0.962
<i>Longwoods</i>	Sandy loam	7.2	1.5	----	----	0.10	6.67	1.08	0.989
<i>Lufa 5M</i>	Sandy loam	7.3	1.0	----	----	0.04	4.00	0.93	0.953
<i>Speyer 2.2 (94/14)</i>	Sandy loam	7.3	3.9	0.50	13	3.94	101.03	0.64	0.78
<i>Hanford (M 466)</i>	Sandy loam	7.4	1.0	0.49	50	3.18	318.00	0.64	0.79

pH dependence, Yes or No

No

**Table 8.5-2: Summary of soil adsorption/desorption for 5-OH Florasulam (EFSA Journal 2015; 13(1):3984)**

Soil name	Soil properties			Adsorption distribution coefficients		Freundlich adsorption isotherm parameters			
	Soil type (USDA)	pH	OC [%]	$K_d$ [mL/g]	$K_{dOC}$ [mL/g]	$K_f$ [mL/g]	$K_{fOC}$ [mL/g]	1/n	$R^2$
<i>Fuquay (M 444)</i>	Sand	4.7	0.64	0.20	32	0.24	37.50	0.98	0.986
<i>Calke</i>	Sandy loam	5.4	3.6	----	----	0.29	8.06	0.83	0.997
<i>Pewamo (M 445)</i>	Clay	5.7	2.4	0.72	30	1.73	72.08	0.90	0.998
<i>Kenslow (94/16)</i>	Silt loam	6.1	6.8	0.66	10	1.55	22.79	0.90	0.999
<i>RefeSol 06-A</i>	Clay loam	6.7	1.9	----	----	0.12	6.32	0.87	0.999
<i>Catlin (M 461)</i>	Silty clay loam	7.0	2.2	0.23	11	0.69	31.36	0.88	0.994
<i>South Witham</i>	Clay loam	7.1	3.8	----	----	0.16	4.21	0.79	0.997
<i>Lufa 5M</i>	Sandy loam	7.3	1.0	----	----	0.06	6.00	0.86	0.994
<i>Speyer 2.2 (94/14)</i>	Sandy loam	7.3	3.9	0.28	7	0.07	1.79	1.01	0.827
<i>Hanford (M 466)</i>	Sandy loam	7.4	1.0	0.16	16	0.21	21.00	0.95	0.892
Arithmetic mean values for the whole data set (n = 10)						0.51	21.11	0.91	----
Median values for the whole data set (n = 10)						0.225	14.53	----	----

pH dependence, Yes or No	No
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**Table 8.5-3: Summary of soil adsorption/desorption for DFP-ASTCA (EFSA Journal 2015; 13(1):3984)**

Soil name	Soil properties			Freundlich adsorption isotherm parameters			
	Soil type (USDA)	pH	OC [%]	$K_f$ [mL/g]	$K_{fOC}$ [mL/g]	1/n	$R^2$
<i>Calke</i>	Sandy loam	5.4	3.6	0.88	24.44	0.84	0.999
<i>South Witham</i>	Clay loam	7.1	3.8	0.63	16.58	0.80	0.999
<i>Lufa 5M</i>	Sandy loam	7.3	1.0	2.36	236.00	0.91	0.999
<i>RefeSol 06-A</i>	Clay loam	6.7	1.9	0.45	23.68	0.86	1.000
Average values (n = 4)				1.08	75.18	0.85	----

pH dependence (yes or no)	No
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**Table 8.5-1: EU endpoints for Florasulam**

End-point	Florasulam	5-OH Florasulam	DFP-ASTCA	ASTCA	TSA
$K_{fOC}$	10.35	14.53	75.18	104.81	23.46
1/n	0.945	0.91	0.85	0.94	0.94

In addition,  $K_{OC}$  values for TPSA, ASTP and 5-OH ASTP were estimated using PCKOCWIN v1.66 to be 41.52, 60.22 L/kg and 77.74 L/kg, respectively (EFSA, 2015 p. 51).

#### zRMS comments:

Soil mobility data for florasulam and its metabolites presented in tables above are in line with EU agreed endpoints as reported in EFSA Journal 2015;13(1):3984.

## 8.5.2 Column leaching (KCP 9.1.2.1)

Please refer to Conclusion on the peer review of the pesticide risk assessment of the active sub-stances:

- Florasulam (EFSA Journal 2015; 13(1):3984) and Draft Assessment Report for Florasulam.

The mobility of Florasulam in soil was evaluated during the Annex I Inclusion. No additional studies have been performed. The available column leaching study confirms the results observed in the batch tests. Please refer to IIIA 9.3

The column leaching data available for Florasulam was included as supporting information in the EFSA conclusion prepared for Annex I renewal (EFSA, 2015).

**zRMS comments:**

Information on column leaching is in line with conclusions derived at the EU level.

### 8.5.3 Lysimeter studies (KCP 9.1.2.2)

Please refer to Conclusion on the peer review of the pesticide risk assessment of the active sub-stances:

- Florasulam (EFSA Journal 2015; 13(1):3984) and Draft Assessment Report for Florasulam.

A lysimeter study for Florasulam was evaluated during the Annex I renewal. No annual average leachate concentration greater than 0.1 µg/L parent equivalents was observed in this study when 5 g/ha Florasulam were applied. With the exception of a single sampling following application of an exaggerated rate, the parent compound was not detected in the leachate. No additional studies have been performed by the applicant.

**zRMS comments:**

The lysimeter studies were not required during the EU review. The leaching potential of florasulam and their metabolites following application of Floras 50 SC is addressed in groundwater modelling presented in point 8.8 of this document.

### 8.5.4 Field leaching studies (KCP 9.1.2.3)

Please refer to Conclusion on the peer review of the pesticide risk assessment of the active sub-stances:

- Florasulam (EFSA Journal 2015; 13(1):3984) and Draft Assessment Report for Florasulam.

No such studies are required.

**zRMS comments:**

The field leaching studies were not required during the EU review. The leaching potential of florasulam and their metabolites following application of Floras 50 SC is addressed in groundwater modelling presented in point 8.8 of this document.

## 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.

### 8.6.1 Active substances and its metabolites

**Table 8.6-1: Summary of degradation in water/sediment of Florasulam and metabolites**

Compound	Maximum detected in aquatic environment	Kinetic endpoints – DT50 [days] to be used in SW modelling		
		Whole system	Water phase	Sediment Phase
<i>Florasulam</i>	Not applicable – parent compound	15.03	15.03	15.03
<i>5-OH Florasulam</i>	99.0%	1000	1000	1000
<i>DFP-ASTCA</i>	8.9%	1000	1000	1000
<i>ASTCA</i>	53.8%	1000	1000	1000
<i>TPSA</i>	58.3%	1000	1000	1000
<i>ASTP</i>	21.9	1000	1000	1000
<i>5-OH ASTP</i>	28.9%	1000	1000	1000

**zRMS comments:**

Information on degradation of florasulam and its metabolites in water/sediment systems is in line with EU agreed data reported in EFSA Journal 2015;13(1):3984.

## 8.7 Predicted Environmental Concentrations in soil (PEC<sub>soil</sub>) (KCP 9.1.3)

### 8.7.1 Justification for new endpoints

Floras 50 SC wasn't assessed as representative formulation.  
PEC<sub>soil</sub> was calculated according to endpoints for Florasulam and submitted for Floras 50 SC.

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

The PECs of Floras 50 SC in soil has been assessed assuming that active substance Florasulam are evenly distributed in the top 5 cm soil horizon with a soil bulk density 1.5 g/cm<sup>3</sup>.

**Table 8.7-1: Input parameters related to application for PEC<sub>soil</sub> calculations**

Substance	Florasulam
Crop	Winter and Spring Cereals
Application rate (g as/ha)	5
Number of applications/interval	1/0
Crop interception (%)	0
Depth of soil layer (relevant for plateau concentration) (cm)	5 cm 5/20/x cm (no tillage/tillage)

**Table 8.7-2: Input parameter for active substance(s) and relevant metabolite(s) for PEC<sub>soil</sub> calculation**

Compound	Molecular weight (g/mol)	Max. occurrence (%)	pseudo application Rate (g/ha)	DT50 (days)	Value in accordance to EU endpoint y/n/ Reference
Florasulam	359.29	-	5	4.29	Y
5-OH Florasulam	345.26	71.6	3.44 <del>3.58</del>	29.75	Y
DFP-ASTCA	304.20	17.8	0.75 <del>0.89</del>	46.16	Y
ASTCA	192.13	40	1.07 <del>2</del>	259.05	Y
TSA	148.14	15.9	0.33 <del>0.795</del>	171.68	Y

#### 8.7.2.1 Active substances and its metabolites

**Table 8.7-3: PEC<sub>soil</sub> for Florasulam**

		Florasulam			
PEC <sub>soil</sub> (mg/kg)		Cereals			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.007	-	-	-
Short term	24h	0.006	0.006	-	-
	2d	0.005	0.006	-	-
	4d	0.003	0.005	-	-
Long term	7d	0.002	0.004	-	-
	14d	0.001	0.003	-	-
	21d	0.000	0.002	-	-
	28d	0.000	0.001	-	-
	48d	0.000	0.001	-	-
	100d	0.000	0.000	-	-
Plateau concentration (5/20 cm) after year x		not required			
PEC <sub>accumulation</sub> (PEC <sub>act</sub> + PEC <sub>soil plateau</sub> )		0.007	-	-	-



## PEC<sub>soil</sub> of metabolites

**Table 8.7-4: PEC<sub>soil</sub> for metabolites**

PEC <sub>soil</sub> (mg/kg)	Cereals			
	Single application		Multiple applications	
	Actual	21-d TWA	Actual	TWA
5-OH Florasulam	0.0046 0.0048	0.0048	-	-
DFP-ASTCA	0.0010 0.0012	0.0012	-	-
ASTCA	0.0014 0.0027	0.001 0.0027	-	-
TSA	0.0004 0.0011	0.0004 0.0011	-	-
Plateau concentration (5/20 cm) after year x	not calculated			

### zRMS comments:

The application pattern presented in Table 8.7-1 and assumed in the soil exposure assessment is in line with the critical Central Zone GAP presented in Table 8.1-1.

Input parameters presented in Table 8.7-2 for florasulam are in line with EU agreed parameters reported in EFSA Journal 2015;13(1):3984. Relevant crop interception of 0% for winter and spring cereals in line with FOCUS groundwater guidance (2023) has been selected.

It is noted that the Applicant calculated pseudo application rates for metabolites only considering maximum occurrence, since the pseudo application rates should be calculated from the parent rate corrected for molar ratio and maximum occurrence, respective changes thus are introduced in the Table 8.7-2. The soil exposure for florasulam and its metabolites has been independently validated by the zRMS using ESCAPE ver. 2. Obtained results for parent were in good agreement with PEC<sub>SOIL</sub> values reported in Table 8.7-3, whereas new calculation of PEC<sub>SOIL</sub> values for metabolites were different comparing to Applicant's results, thus respective changes are presented in the Table 8.7-4.

## 8.7.2.2 PEC<sub>soil</sub> of Floras 50 SC

**Table 8.7-5: PEC<sub>soil</sub> for Floras 50 SC (Cereals)**

Active substance/ reparation	Application rate (g/ha)	PEC <sub>act</sub> (mg/kg)	PEC <sub>twa21 d</sub> (mg/kg)	Tillage depth (cm)	PEC <sub>soil,plateau</sub> (mg/kg)	PEC <sub>accu</sub> = PE- C <sub>act</sub> + PEC <sub>soil,plateau</sub> (mg/kg)
Florasulam	104 5.0	0.139 0.0073	0.0021	5	-	0.007
Density of formulation – Floras 50 SC = 1.040 g/ml (dRR Seccion 1)						

### zRMS comments:

PEC<sub>soil</sub> value for the formulated product Floras 50 SC was independently validated by the zRMS based on the application rate of 0.1 L product per ha and the density of Floras 50 SC of 1.040 g/mL. The initial PEC<sub>SOIL</sub> of 0.139 mg product per kg dry soil was obtained, since the result differ from the Applicant's result respective changes are presented in table above.

## 8.8 Predicted Environmental Concentrations in groundwater (PEC<sub>gw</sub>) (KCP 9.2.4)

### 8.8.1 Justification for new endpoints

Floras 50 SC was not assessed as representative formulation.

PEC<sub>gw</sub> was calculated according to endpoints for active substances and submitted for Floras 50 SC.

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

**Table 8.8-1: Input parameters related to application for PEC<sub>gw</sub> calculations**

Use No.	1	2
Crop	Spring Cereals	Winter Cereals
Application rate (g as/ha)	Florasulam	5
Number of applications/interval (d)	1/0	1/0
Relative application date	5 days after emergence: Châteaudun, Porto 4 days after emergence: Hamburg, Kremsmünster 3 days after emergence: Jokioinen, Okehampton	4 days after emergence: Châteaudun, Hamburg, Jokioinen, Kremsmünster, Okehampton, Piacenza 5 days after emergence: Sevilla 6 days after emergence: Thiva 7 days after emergence: Porto
Crop interception (%)	% Calculated by model	0% Calculated by model
Frequency of application	Annual	Annual
Models used for calculation	FOCUS PEARL 5.5.5 FOCUS PELMO 6.6.4. FOCUS MACRO 5.5.4.	FOCUS PEARL 5.5.5 FOCUS PELMO 6.6.4. FOCUS MACRO 5.5.4.

**Table 8.8-2: Input parameters related to active substance Florasulam and metabolite(s) for PEC<sub>gw</sub> calculations**

Compound	Florasulam	5-OH Florasulam	DFP-ASTCA	ASTCA	TSA
Molecular weight (g/mol)	359.29	345.26	304.2	192.13	148.14
Water solubility (mg/L):	6360	354	87400	250000	10900
Saturated vapour pressure (Pa):	0.000001	0.0000027	0.000003	0.000002	0.0001
DT <sub>50</sub> in soil (d)	1.55	14.98	16.62	297.47	83.47
Transformation rate	0.381902 to 5-OH 0.065290 to CO <sub>2</sub>	0.046272 to DFP-ASCTA	0.032572 to ASTCA 0.009134 to TSA	0.0233 to TSA	0.008304 to CO <sub>2</sub>
K <sub>fom</sub> (mL/g)	6	8.43	43.61	60.79	13.61
1/n	0.945	0.91	0.85	0.94	0.94
Plant uptake factor	0	0	0	0	0
Transformation scheme	-	0.854 from parent	1.0 from 5-OH Florasulam	0.781 from DFP-ASTCA	0.219 from DFP-ASTCA 1.0 from ASTCA

**Table 8.8-3: PEC<sub>gw</sub> for Florasulam and metabolite(s) on Winter wheat (with FOCUS PEARL 5.5.5)**

Crop	Scenario	80 <sup>th</sup> Percentile PEC <sub>gw</sub> at 1 m Soil Depth (µg/L)				
		Florasulam	5-OH Florasulam	DFP-ASTCA	ASCTA	TSA
Winter Cereals	Châteaudun	0.000000	0.008950	0.003234	0.286106	0.233316
	Hamburg	0.000470	0.101812	0.041143	0.347265	0.250852
	Jokioinen	0.000074	0.046666	0.010996	0.293697	0.283919
	Kremsmünster	0.000055	0.037027	0.013690	0.272996	0.160370
	Okehampton	0.000137	0.083662	0.024600	0.226548	0.126230
	Piacenza	0.000083	0.022967	0.014171	0.258092	0.177208
	Porto	0.000351	0.059971	0.008990	0.163024	0.128257
	Sevilla	0.000000	0.000000	0.000000	0.042756	0.090034
	Thiva	0.000000	0.001348	0.000262	0.358483	0.293602

**Table 8.8-4: PEC<sub>gw</sub> for Florasulam and metabolite(s) on Spring Barley (with FOCUS PEARL 5.5.5)**

Crop	Scenario	80 <sup>th</sup> Percentile PEC <sub>gw</sub> at 1 m Soil Depth (µg/L)				
		Florasulam	5-OH Florasulam	DFP-ASTCA	ASCTA	TSA
Spring Cereals	Châteaudun	0.000000	0.001590	0.000234	0.193567	0.172174
	Hamburg	0.000000	0.014821	0.004033	0.306025	0.291644
	Jokioinen	0.000000	0.007254	0.000861	0.181197	0.198496
	Kremsmünster	0.000000	0.011788	0.003480	0.228297	0.165247
	Okehampton	0.000000	0.012443	0.002696	0.203014	0.128161
	Porto	0.000000	0.001655	0.000106	0.123079	0.106419

**Table 8.8-5: PEC<sub>gw</sub> for Florasulam and metabolite(s) on Winter Wheat (with FOCUS PELMO 6.6.4)**

Crop	Scenario	80 <sup>th</sup> Percentile PEC <sub>gw</sub> at 1 m Soil Depth (µg/L)				
		Florasulam	5-OH Florasulam	DFP-ASTCA	ASCTA	TSA
Winter Cereals	Châteaudun	0.000	0.006	0.001	0.006	0.226
	Hamburg	0.002	0.100	0.035	0.038	0.320
	Jokioinen	0.001	0.055	0.009	0.021	0.294
	Kremsmünster	0.000	0.033	0.011	0.027	0.240
	Okehampton	0.000	0.101	0.023	0.032	0.194
	Piacenza	0.001	0.043	0.017	0.030	0.193
	Porto	0.002	0.119	0.009	0.020	0.161
	Sevilla	0.000	0.001	0.000	0.000	0.087
	Thiva	0.000	0.003	0.000	0.003	0.183

**Table 8.8-6:  $PEC_{gw}$  for Florasulam and metabolite(s) on Spring Barley (with FOCUS PELMO 6.6.4)**

Crop	Scenario	80 <sup>th</sup> Percentile $PEC_{gw}$ at 1 m Soil Depth (µg/L)				
		Florasulam	5-OH Florasulam	DFP-ASTCA	ASCTA	TSA
Spring Cereals	Châteaudun	0.000	0.001	0.000	0.001	0.150
	Hamburg	0.000	0.008	0.002	0.005	0.282
	Jokioinen	0.000	0.010	0.001	0.003	0.232
	Kremsmünster	0.000	0.011	0.002	0.010	0.218
	Okehampton	0.000	0.014	0.003	0.011	0.186
	Porto	0.000	0.004	0.000	0.004	0.138

**Table 8.8-7:  $PEC_{gw}$  for Florasulam and metabolite(s) on cereals Spring-Barley (with FOCUS MACRO v.5.5.4 PELMO 6.6.4)**

Scenario	80 <sup>th</sup> Percentile $PEC_{gw}$ at 1 m Soil Depth (µg/L)				
	Florasulam	5-OH Florasulam	DFP-ASTCA	ASCTA	TSA
	Winter Wheat				
Châteaudun	0.000000	0.005280	0.000000	0.464000	0.383000
	Spring Barley				
Châteaudun	0.000000	0.001210	0.000000	0.367000	0.229000

**zRMS comments:**

The application pattern assumed by the Applicant in simulations is in line with the Central Zone GAP presented in Table 8.1-1. Relative application dates are in line with these suggested by the AppDate v. 3.06. Crop interception of 0% was assumed in simulations and it is in line with indication of the FOCUS groundwater guidance (2023).

Input parameters presented in Tables 8.8-2 are in line with EU agreed endpoints reported in EFSA Journal 2015;13(1):3984.

For all compounds PUF values of 0 was assumed, in line with current recommendations of the most recent version of FOCUS groundwater guidance.

Results of Applicant's modelling were independently validated by the zRMS in additional simulations based on the same input parameters and application dates. The obtained  $PEC_{gw}$  values were the same and lower from these presented in Tables 8.8-3 to 8.8-7.

Performed simulations indicate that unacceptable leaching of florasulam and its metabolite DFP-ASTCA is expected following application of Floras 50 SC according to the intended use pattern. The  $PEC_{gw}$  values for metabolites: 5-OH Florasulam, ASCTA and TSA were above 0.1 µg/L in almost all scenarios with the maximum value of 0.320 µg/L in the Hamburg scenario (PELMO model) following application to winter cereals. According to EFSA Journal 2015;13(1):3984 metabolites: 5-OH Florasulam, ASCTA and TSA are toxicologically not relevant. Any of the  $PEC_{gw}$  values do not exceeded the threshold concentration of 0.75 µg/L for non-relevant metabolites.

Overall, based on the results of the groundwater modelling performed by the Applicant and the zRMS, no unacceptable leaching of florasulam and its metabolites is expected when Floras 50 SC is used according to the Central Zone GAP.

Please note that additional groundwater modelling may be required by the concerned Member States that do not accept simulations performed according to FOCUS recommendations.

## 8.9 Predicted Environmental Concentrations in surface water (PEC<sub>sw</sub>) (KCP 9.2.5)

### 8.9.1 Justification for new endpoints

Floras 50 SC was not assessed as representative formulation.

PEC<sub>sw</sub> was calculated according to endpoints for active substances and submitted for Floras 50 SC.

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

**Table 8.9-1: Input parameters related to application for PEC<sub>sw/SED</sub> calculations**

Plant protection product	Floras 50 SC	
Use No.	1	2
Crop	Spring Cereals	Winter Cereals
Application rate (kg as/ha) for Florasulam	0.005	
Number of applications/interval (d)	1/0	1/0
Application window	BBCH 12-32	BBCH 12-32
Application method	Ground spray <small>Air blast</small>	Ground spray <small>Air blast</small>
CAM (Chemical application method)	2 (foliar)	2 (foliar)
Soil depth (cm)	4	4
Models used for calculation	STEPS1-2 ver.3.2, SWASH 5.3, MACRO 5.5.4, PRZM 4.3.1., TOXSWA 5.5.3, SWAN 5	STEPS1-2 ver.3.2, SWASH 5.3, MACRO 5.5.4, PRZM 4.3.1., TOXSWA 5.5.3, SWAN 5

### 8.9.2.1 Active substances and metabolites

**Table 8.9-2: Input parameters related to active substance Florasulam and metabolite(s) for PEC<sub>sw/SED</sub> calculations STEP 1/2 and 3(4)**

Compound	Florasulam	5-OH Florasulam	DFP-ASTCA	ASTCA	TSA	TPSA	ASTP	5-OH ASTP
Molecular weight (g/mol)	359.29	345.26	304.2	192.13	148.14	248.17	247.2	233.18
Saturated vapour pressure (Pa)	1.0 * 10 <sup>-5</sup>	Not required in Step1-2	Not required in Step1-2	Not required in Step1-2	Not required in Step1-2	Not required in Step1-2	Not required in Step1-2	Not required in Step1-2
Water solubility (mg/L)	6360	354	87400	250000	10900	250000	2790	8920
Diffusion coefficient in water (m <sup>2</sup> /d)	4.3 x 10 <sup>-5</sup> (default)	Not required in Step1-2	Not required in Step1-2	Not required in Step1-2	Not required in Step1-2	Not required in Step1-2	Not required in Step1-2	Not required in Step1-2
Diffusion coefficient in air (m <sup>2</sup> /d)	0.43 (default)	Not required in Step1-2	Not required in Step1-2	Not required in Step1-2	Not required in Step1-2	Not required in Step1-2	Not required in Step1-2	Not required in Step1-2
K <sub>foc</sub> (mL/g)	10.53	14.53	78.15	104.81	23.46	41.52	60.22	77.74
Freundlich Exponent 1/n	0.945	Not required in Step1-2	Not required in Step1-2	Not required in Step1-2	Not required in Step1-2	Not required in Step1-2	Not required in Step1-2	Not required in Step1-2
Plant Uptake	0	0	0	0	0	0	0	0
Wash-Off factor from Crop (1/mm)	0.05 (MACRO) 0.50 (PRZM) (default)	Not required in Step1-2	Not required in Step1-2	Not required in Step1-2	Not required in Step1-2	Not required in Step1-2	Not required in Step1-2	Not required in Step1-2
DT <sub>50,soil</sub> (d)	1.55	14.98	16.62	297.47	83.74	365	365	365

Compound	Florasulam	5-OH Florasulam	DFP-ASTCA	ASTCA	TSA	TPSA	ASTP	5-OH ASTP
DT <sub>50,water</sub> (d)	15.03	1000	1000	1000	1000	1000	1000	1000
DT <sub>50,sed</sub> (d)	15.03	1000	1000	1000	1000	1000	1000	1000
DT <sub>50,whole system</sub> (d)	15.03	1000	1000	1000	1000	1000	1000	1000
Maximum occurrence observed (% molar basis with respect to the parent)	-	Total system: 99 % Soil: 71.6 %	Total system: 8.9 % Soil: 17.8 %	Total system: 53.8 % Soil: 40 %	Total system: 0.0001 % Soil: 15.9 %	Total system: 58 % Soil: 0.0001 %	Total system: 21 % Soil: 0.0001 %	Total system: 29 % Soil: 0.0001 %

## PEC<sub>sw/sed</sub>

**Table 8.9-3-1: FOCUS Step 1,2 PEC<sub>sw</sub> and PEC<sub>sed</sub> for .following application of Floras 50 SC to Winter wheat**

Scenario FOCUS	Waterbody	Max PEC <sub>sw</sub> (µg/L)	21 d- PEC <sub>sw, twa</sub> (µg/L)	Max PEC <sub>sed</sub> (µg/kg)
Step 1				
Northern Europe	March-May	1.69	1.08	0.17
Northern Europe	Oct-Feb	1.69	1.08	0.17
Step 2				
Northern Europe	March-May	0.09 0.08	0.05	0.01
Northern Europe	Oct-Feb	0.18 0.15	0.09	0.02 0.01
Step 3				
D3	Ditch	0.031590	0.001069	0.002292
D4	Pond	0.001094	0.000255	0.000135
D4	Stream	0.027410	0.000365	0.001392
R1	Pond	0.0023 0.001749	0.002 0.000856	0.001 0.000378
R1	Stream	0.130 0.126500	0.003 0.002733	0.009 0.008966
Step 4	10 m no-spray buffer zone			
R1	Stream	0.05666	0.001174	0.04195

**Table 8.9-3-2: FOCUS Step 1,2 PEC<sub>sw</sub> and PEC<sub>sed</sub> for Florasulam following application of Floras 50 SC to Spring Barley**

Scenario FOCUS	Waterbody	Max PEC <sub>sw</sub> (µg/L)	21 d- PEC <sub>sw, twa</sub> (µg/L)	Max PEC <sub>sed</sub> (µg/kg)
Step 1				
Northern Europe	March-May	1.69	1.08	0.17
Step 2				
Northern Europe	March-May	0.09 0.08	0.05	0.01

### Metabolite(s) of Floras 50 SC active substances

**Table 8.9-3-3: FOCUS Step 1,2 PEC<sub>sw</sub> and PEC<sub>sed</sub> for metabolites of Florasulam following application to Winter cereals**

Scenario FOCUS		Max PEC <sub>sw</sub> (µg/L)	21 d- PEC <sub>sw, twa</sub> (µg/L)	Max PEC <sub>sed</sub> (µg/kg)
<b>5-OH Florasulam</b>				
Step 1 - Northern Europe	March-May	2.72	2.70	0.40
	Oct-Feb	2.72	2.70	0.40
Step 2 - Northern Europe	March-May	0.28 0.23	0.28 0.23	0.04 0.03
	Oct-Feb	0.64 0.52	0.63 0.52	0.09 0.08
<b>DFP-ASTCA</b>				
Step 1 - Northern Europe	March-May	0.34	0.34	0.27
	Oct-Feb	0.34	0.34	0.27
Step 2 - Northern Europe	March-May	0.04	0.04	0.03
	Oct-Feb	0.09	0.09	0.07
<b>ASTCA</b>				
Step 1 - Northern Europe	March-May	0.75	0.74	0.78
	Oct-Feb	0.75	0.74	0.78
Step 2 - Northern Europe	March-May	0.09 0.07	0.09 0.07	0.09 0.08
	Oct-Feb	0.20 0.16	0.20 0.16	0.21 0.17
<b>TSA</b>				
Step 1 - Northern Europe	March-May	0.11	0.11	0.02
	Oct-Feb	0.11	0.11	0.02
Step 2 - Northern Europe	March-May	0.02	0.02	0.00
	Oct-Feb	0.05 0.04	0.05 0.04	0.01
<b>TPSA</b>				
Step 1 - Northern Europe	March-May	0.65 0.63	0.64 0.63	0.27 0.26
	Oct-Feb	0.65 0.63	0.64 0.63	0.27 0.26
Step 2 - Northern Europe	March-May	0.04 0.10	0.04 0.10	0.02 0.04
	Oct-Feb	0.07 0.25	0.07 0.25	0.03 0.10
<b>ASTP</b>				
Step 1 - Northern Europe	March-May	0.22	0.22	0.13
	Oct-Feb	0.22	0.22	0.13
Step 2 - Northern Europe	March-May	0.01 0.04	0.01 0.04	0.01 0.02

Scenario FOCUS		Max PEC <sub>sw</sub> (µg/L)	21 d- PEC <sub>sw, twa</sub> (µg/L)	Max PEC <sub>sed</sub> (µg/kg)
<b>5-OH Florasulam</b>				
	Oct-Feb	0.02 0.09	0.02 0.09	0.01 0.05
<b>5-OH ASTP</b>				
Step 1 - Northern Europe	March-May	0.28	0.28	0.22
	Oct-Feb	0.28	0.28	0.22
Step 2 - Northern Europe	March-May	0.02 0.05	0.02 0.05	0.01 0.04
	Oct-Feb	0.03 0.11	0.03 0.11	0.02 0.09

**Table 8.9-3-4: FOCUS Step 1,2 PEC<sub>sw</sub> and PEC<sub>sed</sub> for metabolites of Florasulam following application to Spring cereals**

Scenario FOCUS	Max PEC <sub>sw</sub> (µg/L)	21 d- PEC <sub>sw, twa</sub> (µg/L)	Max PEC <sub>sed</sub> (µg/kg)
<b>5-OH Florasulam</b>			
Step 1 - Northern Europe	2.72	2.70	0.40
Step 2 - Northern Europe	0.28 0.23	0.28 0.23	0.04 0.03
<b>DFP-ASTCA</b>			
Step 1 - Northern Europe	0.34	0.34	0.27
Step 2 - Northern Europe	0.04	0.04	0.03
<b>ASTCA</b>			
Step 1 - Northern Europe	0.75	0.74	0.78
Step 2 - Northern Europe	0.09 0.07	0.09 0.07	0.09 0.08
<b>TSA</b>			
Step 1 - Northern Europe	0.11	0.11	0.02
Step 2 - Northern Europe	0.02	0.02	0.00
<b>TPSA</b>			
Step 1 - Northern Europe	0.65 0.63	0.64 0.63	0.27 0.26
Step 2 - Northern Europe	0.04 0.10	0.04 0.10	0.02 0.04
<b>ASTP</b>			
Step 1 - Northern Europe	0.22	0.22	0.13
Step 2 - Northern Europe	0.01 0.04	0.01 0.04	0.01 0.02
<b>5-OH ASTP</b>			
Step 1 - Northern Europe	0.28	0.28	0.22
Step 2 - Northern Europe	0.02 0.05	0.02 0.05	0.01 0.04

**zRMS comments:**

The application pattern assumed by the Applicant in simulations is in line with the Central Zone GAP presented in Table 8.1-1.

Input parameters presented in Tables 8.9-2 are in line with endpoints agreed in the course of the EU review of florasulam and reported in EFSA Journal 2015;13(1):3984.

It is noted that the Applicant used the crop interception at Step 1-2 as an average crop cover, whereas in line with FOCUS surface water generic guidance (2015) for winter and spring cereals at BBCH 12 (the earliest time for application Floras 50 SC) assumption of a minimal crop cover should be applied.



Step 3 simulations for florasulam were performed with consideration of PUF of 0, in line with current FOCUS recommendations.

Since there are no information provided in dRR for application window used for surface water modelling for use in winter cereals at Step 3, application dates related for each scenario are listed below:

#### Application dates used for PEC<sub>sw</sub>/sed

FOCUS SW scenario	Appn. date (absolute) (BBCH 12)
	Winter Cereals
D3	25 Nov – 25 Dec
D4	26 Sep – 26 Oct
D5	14 Nov -14 Dec
R1	16 Nov – 16 Dec
R3	05 Dec -04 Jan
R4	18 Nov – 18 Dec

The Step 1-3 surface water exposure was independently validated by the zRMS in additional simulations using the same input parameters, correct crop interception of minimal crop cover at Step 1-2 and application dates as presented in table above.

Although observed differences in the obtained PEC<sub>SW</sub> and PEC<sub>SED</sub> results seem to be minor, they may have significant impact on the outcome of the aquatic risk assessment, especially in scenarios in which PEC/RAC ratios are very close to the trigger. In such case even slight difference may decide on acceptability or non-acceptability of the risk.

At Step 1-2 for florasulam and its metabolites results of PEC<sub>SW</sub> and PEC<sub>SED</sub> calculated by the zRMS were higher comparing to these obtained by the Applicant, since assumption of minimal crop cover was applied according to the FOCUS surface water generic guidance (2015). Thus, values reported in Tables 8.9.3-1 to 8.9.3-4 were corrected by the zRMS and may be used for purposes of the aquatic risk assessment.

At Step 3 obtained PEC<sub>SW</sub> and PEC<sub>SED</sub> values for D3 and D4 scenarios for florasulam were in good agreement with values obtained by the Applicant, for R1 scenario obtained results were slightly higher from values obtained by the Applicant and were corrected by the zRMS in Table 8.9.3-1.

In addition to that it is noted that scenarios D5, R3 and R4 were not included in Applicant's simulations for winter cereals, although this scenarios are indicated as relevant for the Central Zone in the guidance for evaluation in area of environmental fate and behaviour<sup>1</sup>. Accordingly, respective simulations were performed by the zRMS for missing scenarios and obtained results are presented in table below.

#### FOCUS Step 3 and Step 4 Max PEC<sub>sw</sub> (µg/L) for florasulam considering application of 5 g a.s./ha

FOCUS scenario	Use no. 1 (winter cereals)			
	Step 3		Step 4	
	Max PEC <sub>sw</sub> (µg/L)	Max PEC <sub>SED</sub> (µg/kg)	Max PEC <sub>sw</sub> (µg/L)	Max PEC <sub>sw</sub> (µg/L)
			10m VFS	20m VFS
D5 pond	0.001	0.001	-	-
D5 stream	0.029	0.001	-	-
R1 pond	0.002	0.001	-	-
R1 stream	<b>0.130</b>	0.009	0.058	-
R3 stream	<b>0.319</b>	0.025	<b>0.144</b>	0.075
R4 stream	0.028	0.002	-	-

Maximum PEC<sub>sw</sub> values highlighted in **bold** exceed the lowest RAC of 0.118 µg a.s./L

At Step 3 the maximum PEC<sub>sw</sub> values of 0.130 µg/L and 0.319 µg/L were obtained in the run-off scenarios R1 stream and R3 stream, respectively. Since values are above the RAC value of 0.118 µg/L, further calculation at Step 4 were required for R1 and R3 scenarios. The application of run-off mitigation in the form of a vegetated filter strip according to the values proposed in the FOCUS Landscape and Mitigation report leads to a reduction of these maximum PEC values to around 0.058 µg/L and 0.075 µg/L, occurring in the R1 stream and R3 stream scenario.

<sup>1</sup> Working Document of the Central Zone in the Authorisation of Plant Protection Products - Part B section 8 - Environmental fate and behaviour, Version 1 rev. 1, June 2018

It is noted that for spring cereals Step 3 was not necessary.

Overall, surface water exposure of florasulam and its metabolites presented in Tables 8.9.3-1 to 8.9.3-4 and in the table above may be used in the aquatic risk assessment.

Please note that additional surface water modelling may be required by the concerned Member States that do not accept simulations performed according to FOCUS recommendations.

### 8.9.2.2 PEC<sub>sw/sed</sub> of Floras 50 SC

Floras 50 SC is formulation containing one active substance that quite quickly dissipate in soil and water hence PEC<sub>sw</sub> for formulation was calculated using Drift Calculator (embedded in SWASH v5.3). Results of modelling are included in table 8.9-4.

**Table 8.9-4: PEC<sub>sw</sub> for Floras 50 SC on Winter and Spring Cereals.**

Waterbody	Application rate * (g/ha)	% drift	PEC <sub>sw</sub> (µg/L)
Spring Cereals, application rate: 0.1 L/ha			
Ditch	104	1.9274	0.6682
Pond	104	0.2191	0.0228
Stream	104	1.4304	0.4959
Winter Cereals, application rate: 0.1 L/ha			
Ditch	104	1.9274	0.6682
Pond	104	0.2191	0.0228
Stream	104	1.4304	0.4959

\* Application rate calculated on the basis of density 1.04 g/ml.

#### **zRMS comments:**

The surface water exposure to formulation was validated by the zRMS using Spray Drift Calculator. Obtained PEC<sub>sw</sub> were in agreement with these reported in Table 8.9-4 and may be used in the aquatic risk assessment.

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

**Table 8.10-1 Summary of atmospheric degradation and behaviour - Florasulam**

Compound	Florasulam
Direct photolysis in air	Not studied - no data requested
Quantum yield of direct phototransformation	Not determined
Photochemical oxidative degradation in air	DT50 of 1.706 days hours derived by the Atkinson model (version 1.92). OH (12-h ) concentration assumed = 1.6 E-6
Volatilisation	from plant surfaces (BBA guideline): 1.7 % after 24 hours
Metabolites	None

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

PECa is assumed to be negligible.

#### **zRMS comments:**

Information regarding fate and behaviour of florasulam in the air presented in Table 8.10-1 is in line with EU agreed data reported in EFSA Journal 2015;13(1):3984.

Taking into account the low vapour pressure (<10<sup>-5</sup> Pa) and DT<sub>50</sub> in air <2 days, florasulam is not expected to be subject to volatilisation and the long- or short-range transport.

## Appendix 1 Lists of data considered in support of the evaluation

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
KCP 9.2.4.1	Janus, K.	2023	PECgw calculation for Floras 50 SC. Report No.: 1/2023 non GLP Unpublished	N	Elvita Sp. z o.o.
KCP 9.2.5	Janus, K.	2023	PECsw calculation for Floras 50 SC. Report No.: 2/2023 non GLP Unpublished	N	Elvita Sp. z o.o.

## **Appendix 2 Detailed evaluation of the new Annex II studies**

No studies submitted.

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

No additional information submitted.