REGISTRATION REPORT
Part B
Section 8
Environmental Fate

Detailed summary of the risk assessment

Product code: RNB 072 A

Product name(s): **MATLAM**

Chemical active substance(s):

Florasulam, 50 g/l

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: XXXX

Submission date: June 2024

Evaluation date: February 2025

MS Finalisation date: May 2025

Version history

When	What
June 2024	dRR version 1 submitted by applicant
December 2024	Update by the applicant
February 2025	zRMS finalized dRR evaluation

Table of Contents

8 Fate and behaviour in the environment (KCP 9)

Review Comments:

MATLAM (RNB 072 A) is a suspension concentrate containing 50 g/L of florasulam and is used as a herbicide in cereals.

This Part B document only reviews data and additional information that has not previously been considered within the EU review process.

Since this document is based on the information provided by the applicant, all review comments, additions and corrections have been made using commenting boxes or highlighted in grey.

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)	L product/ha a) max. rate per appl. b) max. total rate per crop/season	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.	PL	**Winter wheat Winter spelt, Winter barley, Winter triticale, Winter rye**	F	dicotyledonous weeds (TTTDS)	Broadcast spray	BBCH 12-33 (spring application)	a) 1 b) 1	NA	a) 0.1 b) 0.1	a) 5.0 b) 5.0	200-400	60		A
2.	PL	**Spring barley Spring wheat Spring triticale, Spring oat**	F	dicotyledonous weeds (TTTDS)	Broadcast spray	BBCH 12-33 (spring application)	a) 1 b) 1	NA	a) 0.1 b) 0.1	a) 5.0 b) 5.0	200-400	55		A
Minor uses according to Article 51 (zonal uses)														
3	PL	Winter wheat durum	F	dicotyledonous weeds (TTTDS)	Broadcast spray	BBCH 12-33 (spring application)	a) 1 b) 1	NA	a) 0.1 b) 0.1	a) 5.0 b) 5.0	200-400	60		A
4	PL	Winter oat	F	dicotyledonous weeds (TTTDS)	Broadcast spray	BBCH 12-33 (spring application)	a) 1 b) 1	NA	a) 0.1 b) 0.1	a) 5.0 b) 5.0	200-400	60		A
5	PL	Spring wheat durum	F	dicotyledonous weeds (TTTDS)	Broadcast spray	BBCH 12-33 (spring application)	a) 1 b) 1	NA	a) 0.1 b) 0.1	a) 5.0 b) 5.0	200-400	55		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 Florasulam 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	**Winter cereals (wheat, barley, rye, triticale, oats, spelt)**	F	Broadleaved weeds	Tractor mounted or self-propelled hydraulic sprayer giving overall application.	BBCH 00-29 (1st September to end of December)	a) 1 b) 1	N.A	-	a) 3.75 b) 3.75	70-400	-	Autumn uses Max autumn rate is 3.75 g a.s./ha and the total rate per season is 6.25 g a.s./ha)
2	EU	**Winter cereals (wheat, barley, rye, triticale, oats, spelt)**	F	Broadleaved weeds	Tractor mounted or self-propelled hydraulic sprayer giving overall application.	BBCH 13-45 (1st January to early July)	a) 1 b) 1	N.A	-	a) 6.25 b) 6.25	70-400	-	Spring uses
3	EU	**Spring cereals (wheat, barley, rye, triticale, oats, spelt)**	F	Broadleaved weeds	Tractor mounted or self-propelled hydraulic sprayer giving overall application.	BBCH 12-45 (1st February to 15th July)	a) 1 b) 1	N.A	-	a) 6.25 b) 6.25	70-400	-	Spring uses
4	EU	**Maize**	F	Broadleaved weeds	Tractor mounted or self-propelled hydraulic sprayer giving overall application.	BBCH 11-20 (1st April to 30th June)	a) 1 b) 1	N.A	-	a) 5 b) 5	70-400	-	Spring uses

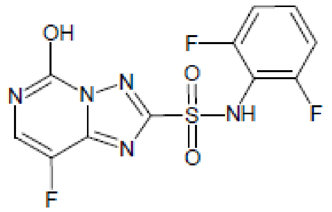
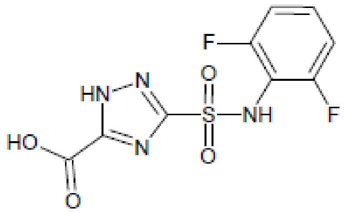
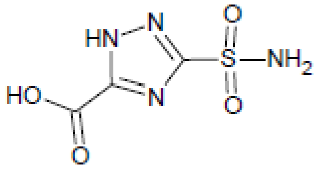
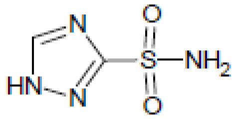
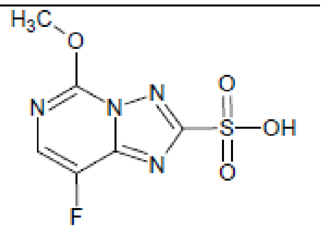
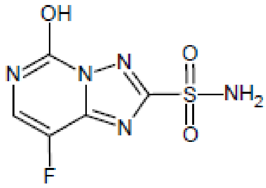
5	EU	**Permanent pasture**	F	Broadleaved weeds	Tractor mounted or self-propelled hydraulic sprayer giving overall application.	BBCH growth stage unspecified (15th February to 15th November)	a) 1 b) 1	N.A	-	a) 6.25 b) 6.25	70-400	-	Spring to Autumn uses
6	EU	**New Leys (one season pasture)**	F	Broadleaved weeds	Tractor mounted or self-propelled hydraulic sprayer giving overall application.	BBCH 12-39 (1st January to 31st August)	a) 1 b) 1	N.A	-	a) 6.25 b) 6.25	70-400	-	Spring to Summer uses
7	EU	**New Leys (one season pasture)**	F	Broadleaved weeds	Tractor mounted or self-propelled hydraulic sprayer giving overall application.	BBCH growth stage unspecified (1st September to 31st December)	a) 1 b) 1	N.A	-	a) 3.75 b) 3.75	70-400	-	Autumn uses

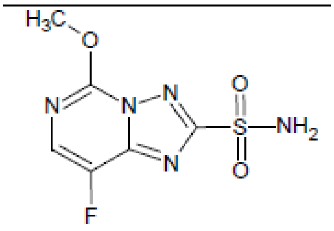
* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

** 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

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 occurence in compartements	Exposue assessment required due to
5-OH Florasulam	345.26		Soil: 71.6% Water/sediment: 99%	PEC_{soil}: not covered by EU assessment PEC_{gw}: leaching potential to groundwater $PEC_{sw/sed}$: not covered by EU assessment
DFP-ASTCA	304.20		Soil: 17.8% Water/sediment: 8.9%	PEC_{soil}: not covered by EU assessment PEC_{gw}: leaching potential to groundwater $PEC_{sw/sed}$: not covered by EU assessment
ASTCA	192.13		Soil: 40% Water/sediment: 53.8%	PEC_{soil}: not covered by EU assessment PEC_{gw}: leaching potential to groundwater $PEC_{sw/sed}$: not covered by EU assessment
TSA	148.14		Soil: 15.9% Water/sediment: 0.0001%	PEC_{soil}: not covered by EU assessment PEC_{gw}: leaching potential to groundwater $PEC_{sw/sed}$: not covered by EU assessment
TPSA	248.17		Soil: 0.0001% Water/sediment: 58.3%	$PEC_{sw/sed}$: not covered by EU assessment
5-OH ASTP	233.18		Soil: 0.0001% Water/sediment: 28.9%	$PEC_{sw/sed}$: not covered by EU assessment

Metabolite	Molar mass	Chemical structure	Maximum observed occurence in compartements	Exposue assessment required due to
ASTP	247.20		Soil: 0.0001% Water/sediment: 21.9%	$PEC_{sw/sed}$: not covered by EU assessment

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.

8.3.1 Aerobic degradation in soil (KCP 9.1.1.1)

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

Florasulam, Laboratory studies, aerobic conditions										
Soil name	**Soil type (USDA)**	**pH**	**t.oC**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa**	**X²**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Andover; TP-l labelled XDE-570	Silt loam	7.6	20	40	1.02	3.40	0.91	4.34	SFO k=0.7617	y/ EFSA Journal 2015;13(1):3984
Kenslow; TP-labelled XDE-570	Silt loam	5.6	20	40	0.58	1.92	0.58	4.14	SFO k=1.2006	
Marcham; TP-labelled XDE-570	Sandy clay loam	7.7	20	40	2.55	8.46	2.14	13.44	SFO k=0.3290	
Speyer 2.2; XDE-570, both labels	Sandy loam	7.3	20	40	0.71	5.38	1.62	7.48	Pseudo-SFO (back-calculated from FOMC) k=0.4279	
Cuckney; TP-labelled XDE-570	Sandy loam	6.9	25	40	0.94	3.11	1.11	3.81	SFO k=0.6245	
Cuckney; TP-labelled XDE-570	Sandy loam	6.9	20	Field capacity	2.86	9.49	2.86	15.28	SFO k=0.2427	
Cuckney; TP-labelled XDE-570; averaged geomean	Sandy loam	6.9	-	-	-	-	1.78	-	SFO	

Florasulam, Laboratory studies, aerobic conditions										
Soil name	**Soil type (USDA)**	**pH**	**t.oC**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa**	**X²**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Marcham; TP-labelled XDE-570	Sandy clay loam	7.6	20	Field capacity	4.29	14.24	4.29	12.78	SFO k=0.1617	
Geometric mean (n=8)							1.55			
pH-dependency							No			

Table 8.3-2: **Summary of aerobic degradation rates for 5-OH Florasulam - laboratory studies**

5-OH Florasulam, Laboratory studies, aerobic conditions										
Soil name	**Soil type (USDA)**	**pH**	**t.oC**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa**	**X²**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Andover; TP-labelled XDE-570	Silt loam	7.6	20	40	7.02	23.32	6.30	5.14	SFO k=0.1100	y/ EFSA Journal 2015; 13(1)3984
Kenslow; TP-labelled XDE-570	Silt loam	5.6	20	40	17.69	58.76	17.69	8.15	SFO k=0.0392	
Marcham; TP-labelled XDE-570	Sandy clay loam	7.7	20	40	14.56	48.36	12.22	15.52	SFO k=0.0567	
Speyer 2.2; XDE-570 both labels	Sandy loam	7.3	20	40	14.44	47.97	14.44	7.70	SFO k=0.0480	
Cuckney; TP-labelled XDE-570	Sandy loam	6.9	25	40	12.97	43.09	15.02	16.52	SFO k=0.0461	
Cuckney; TP-labelled XDE-570	Sandy loam	6.9	20	Field capacity	24.77	82.30	24.77	21.07	SFO k=0.0280	
Cuckney; TP-labelled XDE-570; averaged geomean	Sandy loam	6.9	-	-	-	-	19.29	-	SFO	
Marcham; TP-labelled XDE-570	Sandy clay loam	7.6	20	Field capacity	29.75	98.63	29.75	14.62	SFO k=0.0487	
Geometric mean (n=8)							14.98			
pH-dependency							No			

Table 8.3-3: Summary of aerobic degradation rates for DFP-ASTCA - laboratory studies

DFP-ASTCA, Laboratory studies, aerobic conditions										
Soil name	**Soil type (USDA)**	**pH**	**t.oC**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa**	**X²**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Andover; TP-labelled XDE-570	Silt loam	7.6	20	40	21.68	72.02	19.45	9.88	SFO, top-down k=0.0356	y/ EFSA Journal 2015; 13(1)3984
Kenslow; TP-labelled XDE-570	Silt loam	5.6	20	40	21.87	72.65	21.87	6.47	SFO, top-down k=0.0317	
Marcham; TP-labelled XDE-570	Sandy clay loam	7.7	20	40	55.02	182.75	46.16	6.73	SFO, top-down k=0.0150	
Cuckney; TP-labelled DFP-ASTCA	Loamy sand	7.2	20	40	15.82	52.55	15.27	9.95	SFO k=0.0454	
Marcham; TP-labbelled DFP-ASTCA	Sandy clay loam	7.9	20	40	4.23	14.06	4.23	7.51	SFO k=0.1637	
Geometric mean (n=5)							16.62			
pH-dependency							No			

Table 8.3-4: Summary of aerobic degradation rates for ASTCA - laboratory studies

ASTCA, Laboratory studies, aerobic conditions										
Soil name	**Soil type (USDA)**	**pH**	**t.oC**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa**	**X²**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Cuckney; TP-labelled DFP-ASTCA	Loamy sand	7.2	20	40	1000 (default)	1000 (default)	1000 (default)	Not determined	SFO k=-	y/ EFSA Journal 2015; 13(1)3984
Marcham; TP-labelled XDE-570	Sandy clay loam	7.9	20	40	214.11	711.24	214.11	4.40	SFO k=0.0032	
Cuckney; TP-labelled DFP-ASTCA	Loamy sand	7.2	20	40	268.45	891.76	259.05	4.52	SFO k=0.0027	
Marcham; TP-labbelled DFP-ASTCA	Sandy clay loam	7.9	20	40	141.18	469.00	141.18	7.12	SFO k=0.0049	
Geometric mean (n=4)							297.47			
pH-dependency							No			

Table 8.3-5: Summary of aerobic degradation rates for TSA - laboratory studies

TSA, Laboratory studies, aerobic conditions										
Soil name	**Soil type (USDA)**	**pH**	**t.oC**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa**	**X²**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Calke	Sandy loam	5.4	20	20	78.77	261.66	71.44	2.23	SFO (slow phase DFOP) K_2=0.0097	y/ EFSA Journal 2015; 13(1):3984
South Witham	Clay loam	3.83	20	25.7	101.93	338.62	94.39	2.11	SFO (slow phase DFOP) K_2=0.0073	
Lufa 5M	Sandy loam	0.93	20	14	230.14	764.52	171.68	4.44	SFO k=0.0040	
RefeSol 06-A	Clay loam	6.7	20	29	133.30	422.80	42.47	2.20	SFO k=0.0163	
Geometric mean (n=4)							83.74			
pH-dependency							No			

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

Table 8.3-6: Summary of dark anaerobic degradation rates for Florasulam - laboratory studies

Florasulam, Laboratory studies, dark anaerobic conditions								
Soil name	**Soil type**	**pH**	**t°C**	**DT50 (d)**	**DT90 (d)**	**X²**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Speyer 2.2; TP labelling	Sandy loam	7.3	20	18.49	61.43	8.66	SFO k = 0.0375	y/ EFSA Journal 2015; 13 (1):3984
Speyer 2.2; phenyl-labelling	Sandy loam	7.3	20	18.46	61.31	9.86	SFO k = 0.0376	
Geometric mean (n=2)				18.47				

Table 8.3-7: Summary of dark anaerobic degradation rates for 5-OH Florasulam - laboratory studies

5-OH Florasulam, Laboratory studies, dark anaerobic conditions								
Soil name	**Soil type**	**pH**	**t°C**	**DT50 (d)**	**DT90 (d)**	**X²**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Speyer 2.2; TP labelling	Sandy loam	7.3	20	1386.29	4605.17	7.75	SFO k = 5.0E-4	y/ EFSA Journal 2015; 13 (1):3984
Speyer 2.2; phenyl-labelling	Sandy loam	7.3	20	1083.04	3597.79	11.18	SFO k = 6.4E-4	
Geometric mean (n=2)				1225.32				

8.4 Field studies (KCP 9.1.1.2)

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

Florasulam	Aerobic conditions. Field dissipation of florasulam was examined in six field trials – four in Northern Europe (Germany, UK- two trials, and North France) and two in Southern Europe (south France and Greece). The results were kinetically re-examined following FOCUS Kinetics (2006), but are not reported due to the low reliability of the fitting.
5-OH Florasulam	Aerobic conditions metabolite formed from parent – Florasulam. Field dissipation of 5-OH florasulam was examined in six field trials – four in Northern Europe (Germany, UK- two trials, and North France) and two in Southern Europe (south France and Greece), in which florasulam was applied as parent compound. The results were kinetically re-examined following FOCUS Kinetics (2006), but are not reported due to the low reliability of the fitting.

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

No accumulation observed in the field studies.

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.

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

Florasulam							
Soil Name	**Soil Type**	**OC (%)**	**pH**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n**	**Evaluated on EU level y/n/ Reference**
Kenslow	Loam	3.8	4.6	0.47	12.37	0.91	y/ EFSA Journal 2015; 13(1):3984
Fuquay (M444)	Sand	0.64	4.7	0.35	54.69	1.00	
RefeSol 01-A	Sandy loam	1.0	5.1	0.30	30.00	1.02	
Calke	Sandy loam	3.6	5.4	0.30	8.33	0.95	
Pewano (M445)	Clay	2.4	5.7	1.88	78.33	0.92	
Kenslow (94/16)	Silt loam	6.8	6.1	1.47	21.62	0.94	
Lufa 6S	Clay	1.8	6.6	0.04	2.22	1.04	
RefeSol 06-A	Clay loam	1.9	6.7	0.08	4.21	0.94	
Catlin (M 461)	Silty clay loam	2.2	7.0	0.89	40.45	0.88	
South Witham	Clay loam	3.8	7.1	0.10	2.63	0.98	
Longwoods	Sandy loam	1.5	7.2	0.03	2.00	0.89	
Lufa 5M	Sandy loam	1.0	7.3	0.03	3.00	0.95	

Florasulam							
Soil Name	**Soil Type**	**OC (%)**	**pH**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n**	**Evaluated on EU level y/n/ Reference**
Speyer 2.2 (94/14)	Sandy loam	3.9	7.3	0.13	3.33	0.95	
Hanford (M 466)	Sandy loam	1.0	7.4	0.22	22.00	0.86	
Geometric mean (n=14)					10.2		
Arithmetic mean (n=14)						**0.945**	
Median mean (n=14)					**10.35**		
pH-dependency					No		

Table 8.5-2: Summary of soil adsorption/desorption for 5-OH Florasulam

5-OH Florasulam							
Soil Name	**Soil Type**	**OC (%)**	**pH**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n**	**Evaluated on EU level y/n/ Reference**
Fuquay (M444)	Sand	0.64	4.7	0.24	37.50	0.98	y/ EFSA Journal 2015; 13(1):3984
Calke	Sandy loam	3.6	5.4	0.29	8.06	0.83	
Pewamo	Clay	2.4	5.7	1.73	72.08	0.90	
Kenslow (94/16)	Silt loam	6.8	6.1	1.55	22.79	0.90	
RefeSol 06-A	Clay loam	1.9	6.7	0.12	6.32	0.87	
Catlin (M461)	Silty clay loam	2.2	7.0	0.69	31.36	0.88	
South Witham	Clay loam	3.8	7.1	0.16	4.21	0.79	
Lufa 5M	Sandy loam	1.0	7.3	0.06	6.00	0.86	
Speyer 2.2 (94/14)	Sandy loam	3.9	7.3	0.07	1.79	1.01	
Hanford (M466)	Sandy loam	1.0	7.4	0.21	21.00	0.95	
Geometric mean (n=10)					12.5		
Arithmetic mean (n=10)						**0.91**	
Median mean (n=10)					**14.53**		
pH-dependency					No		

Table 8.5-3: Summary of soil adsorption/desorption for DFP-ASTCA

DFP-ASTCA							
Soil Name	**Soil Type**	**OC (%)**	**pH**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n**	**Evaluated on EU level y/n/ Reference**
Calke	Sandy loam	3.6	5.4	0.88	24.44	0.84	y/ EFSA Journal 2015; 13(1):3984
South Witham	Clay loam	3.8	7.1	0.63	16.58	0.80	
Lufa 5M	Sandy loam	1.0	7.3	2.36	236.00	0.91	
RefeSol 06-A	Clay loam	1.9	6.7	0.45	23.68	0.86	
Geometric mean (n=4)					38.8		
Arithmetic mean (n=4)					**75.18**	**0.85**	
pH-dependency					No		

Table 8.5-4: Summary of soil adsorption/desorption for ASTCA

ASTCA							
Soil Name	**Soil Type**	**OC (%)**	**pH**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n**	**Evaluated on EU level y/n/ Reference**
Calke	Sandy loam	3.6	5.4	1.34	37.22	0.91	y/ EFSA Journal 2015; 13(1):3984
South Witham	Clay loam	3.8	7.1	1.27	33.42	0.94	
Lufa 5M	Sandy loam	1.0	7.3	2.97	297.00	0.95	
RefeSol 06-A	Clay loam	1.9	6.7	0.98	51.58	0.94	
Geometric mean (n=4)					66.1		
Arithmetic mean (n=4)					**104.81**	**0.94**	
pH-dependency					No		

Table 8.5-5: Summary of soil adsorption/desorption for TSA

TSA							
Soil Name	**Soil Type**	**OC (%)**	**pH**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n**	**Evaluated on EU level y/n/ Reference**
Calke	Sandy loam	3.6	5.4	0.26	7.22	0.98	y/ EFSA Journal 2015; 13(1):3984
South Witham	Clay loam	3.8	7.1	0.36	9.47	0.94	
Lufa 5M	Sandy loam	1.0	7.3	0.64	64.00	0.87	
RefeSol 06-A	Clay loam	1.9	6.7	0.25	13.16	0.98	
Geometric mean (n=4)					15.5		
Arithmetic mean (n=4)					**23.46**	**0.94**	
pH-dependency					No		

Aqueous photoproducts of Florasulam – values determined theoretically using KocWin:
- for ASTP: Koc = 60.22 mL/g;
- for 5-OH ASTP: Koc = 77.74 mL/g;
- for TPSA: Koc = 41.52 mL/g.

8.5.1 Column leaching (KCP 9.1.2.1)

Column leaching	The examination of the column leaching of Florasulam was performed on columns filled with three different soils: - Loamy sand (Cuckney), having the pH = 6.6 and OC = 0.8%; - Sand (Elvendon), having the pH = 7.6 and OC = 1.1%; - Sandy clay loam (Marcham), having the pH = 7.7 and OC = 2.0%. The amount of the applied Florasulam corresponded to the application rate of 15 g/ha. Following application, the columns were leached for two days with 393 mL of 0.01M $CaCl_2$ solution (equivalent to 200 mm of rainfall) applied to the top of the column at a constant rate.
Aged residues leaching	Not performed, as the results of the other experiments provided sufficient information in this area.

8.5.2 Lysimeter studies (KCP 9.1.2.2)

Lysimeter studies	Location: Letcombe Regis, UK Study type: Lysimeter Soil properties: Lysimeter No. 25, 26, 27, 28, 29, 30: texture: sand, pH = 6.2, OC = 0.6, MWHC not determined (data for 0-29 cm layer) Lysimeters No. 31, 33: texture: sandy loam, pH = 6.5, OC = 2.49, MWHC not determined (data for 0-22 cm layer) Dates of application: Lysimeters No 28, 29, 33 – 19.04.1994 Lysimeters No. 27 and 31 – 19.04.1994 and 20.04.1995 Lysimeters No. 25 and 26 – 16.02.1995 Crop: Interception estimated: Year -1 crop: Winter cereals (winter wheat or winter barley), CI = 50% at application; Year -2 (following) crop: Winter cereals or Winter OSR; Year -3: fallow; Number of applications: Lysimeters No. 25, 26, 28, 29, 33: 1 year, application per year Lysimeters No. 27 and 31: 2 years, 1 application per year Duration: 2 years – lysimeters No. 25, 26, 28, 33; 3 years – lysimeters No. 27 and 31. Application rate: Lysimeters No. 25, 26, 27, 28, 31: 5 g/ha/year; Lysimeter No. 29: 25 g/ha/year Average annual rainfall (mm): Lysimeters No. 27-31: Year 1 (April 1994 – April 1995) 1006 mm (including irrigation), Year 2 (April 1995 - April 1996) 773 mm (including irrigation); Year 3 (April 1996 – March 1997) 510 mm (including irrigation) Lysimeters No. 25 and 26: Year 1 (February 1995 – March 1996) 792 mm, Year 2 (February 1996 – April 1997) 600 mm Average annual leachate volume (mm): Lysimeters No. 27-29: Year 1: 404-426 mm, Year 2: 274-296 mm, Year 3:

	126 mm Lysimeters No. 31 and 33: Year 1: 317-335 mm; Year 2: 718 mm, Year 3: 90 mm Lysimeters No. 25 and 26: Year 1: 312-325 mm; Year 2: 176-181 mm All remaining results presented in tables below

Table 8.5-6: Total recovery of the Applied Radioactivity from the Lysimeters treated with [14C]-Florasulam in Aril 1994

Compartment	Sample detail		Results obtained for the lysimeter No.				
			27	28	29	31	33
			Sandy soil; 2 x 5 g/ha	Sandy soil; 1 x 5 g/ha	Sandy soil; 1 x 25 g/ha	Loamy soil; 2 x 5 g/ha	Loamy soil; 1 x 5 g/ha
			% AR	% AR	% AR	% AR	% AR
Soil	Horizon [cm]	0 – 10	26.1	24.9	30.0	33.6	25.5
		10 – 20	18.0	11.7	14.1	29.8	30.9
		20 – 30	9.7	6.4	5.7	7.1	9.7
		0 – 30 (cumulative)	53.8	43.0	19.8	70.5	66.1
		30 – 40	3.3	3.4	5.5	1.4	3.3
		40 – 50	3.1	2.8	3.9	0.8	1.2
		50 – 60	3.2	2.9	2.4	<0.5	<0.5
		60 – 70	2.7	2.2	2.3	<0.5	<0.5
		70 – 80	2.2	1.7	2.1	<0.5	<0.5
		80 – 90	1.1	1.3	1.8	<0.5	<0.5
		90 - 100	1.5	1.1	1.9	<0.5	<0.5
	Soil – sub-total		**70.7**	**58.5**	**69.7**	**72.9**	**70.6**
Leachate	**Year 1**		4.4[1)]	3.9	4.4	1.0[1)]	0.8
	Year 2		1.5	1.8	2.4	0.3	0.8
	Year 3[2)]		0.4	---	---	0.1	---
	Leachate sub-total		**4.0**	**5.7**	**6.8**	**0.9**	**1.6**
Crops	**Year 1**		0.8[1)]	0.5	0.9	0.7[1)]	0.6
	Year 2		1.1	0.5	0.1	1.5	0.1
	Crop sub-total		1.4	1.0	1.0	1.7	0.7
Total AR recovered [%]			**76.1**	**65.2**	**77.5**	**75.5**	**72.9**

1) These results are expressed as% of radioactivity applied the Year 1, all other results for these two lysimeters are expressed as % of cumulative radioactivity from the two applications.
2) Year 3 leachates were analysed for only two lysimeters, receiving double treatment with Florasulam at two consecutive years – lysimeters No. 27 and 31

Table 8.5-7: Total recovery of the Applied Radioactivity from the Lysimeters treated with [14C]-Florasulam in February 1995

Compartment	Sample detail		Results obtained for the lysimeter No.	
			25	26
			Sandy soil; 1 x 5 g/ha	Sandy soil; 1 x 5 g/ha
			% AR	% AR
Soil	Horizon [cm]	0 – 10	13.2	13.0
		10 – 20	14.7	10.1
		20 – 30	15.0	8.9
		0 – 30 (cumulative)	42.9	32.0
		30 – 40	6.4	10.8
		40 – 50	5.4	4.3
		50 – 60	5.5	3.0
		60 – 70	4.3	2.5
		70 – 80	3.7	1.9

Compartment	Sample detail		Results obtained for the lysimeter No. 25 Sandy soil; 1 x 5 g/ha % AR	26 Sandy soil; 1 x 5 g/ha % AR
		80 – 90	2.9	1.4
		90 - 100	1.2	1.7
	Soil – sub-total		**58.9**	**44.7**
Leachate	**Year 1**		2.5	2.5
	Year 2		1.0	1.1
	Leachate sub-total		**3.5**	**3.6**
Crops	**Year 1**		9.4	0.5
	Year 2		0.1	0.1
	Crop sub-total		0.5	0.6
Total AR recovered [%]			**62.9**	**48.9**

Table 8.5-8: The total radioactivity in the leachates from the test lysimeters

Experimental year	Type of value		Results obtained for the lysimeter 27 Sandy soil; 2 x 5 g/ha	28 Sandy soil; 1 x 5 g/ha	29 Sandy soil; 1 x 25 g/ha	31 Loamy soil; 2 x 5 g/ha	33 Loamy soil; 1 x 5 g/ha	25 Sandy soil; 1 x 5 g/ha	26 Sandy soil; 1 x 5 g/ha
Year 1 [1]	**Annual average**	µg/L [4]	**0.05**	**0.04**	**0.27**	**0.01**	**0.01**	**0.04**	**0.004**
		%AR	**4.389**	**3.897**	**4.433**	**12.043**	**0.753**	**2.466**	**2.457**
	Minimum	µg/L [4]	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
		%AR	<0.001	<0.001	<0.001	<0.001	0.001	<0.001	<0.001
	Maximum	µg/L [4]	0.08	0.07	0.41	0.03	0.01	0.006	0.007
		%AR	0.735	0.726	0.741	0.256	0.141	0.458	0.468
Year 2 [2]	**Annual average**	µg/L [4]	**0.05**	**0.03**	**0.21**	**0.01**	**0.01**	**0.003**	**0.003**
		%AR	**1.519**	**1.790**	**2.388**	**0.268**	**0.758**	**0.982**	**1.076**
	Minimum	µg/L [4]	0.03	0.02	0.18	0.01	0.01	0.002	0.002
		%AR	0.005	0.034	0.005	0.003	0.004	0.0014	0.020
	Maximum	µg/L [4]	0.06	0.03	0.24	0.01	0.01	0.005	0.004
		%AR	0.234	0.298	0.359	0.044	0.132	0.109	0.160
Year 3 [3]	**Annual average**	µg/L [4]	**0.04**	**n.e. [5]**	**n.e. [5]**	**<0.01**	**n.e. [5]**	**n.e. [5]**	**n.e. [5]**
		%AR	**0.440**	**n.e. [5]**	**n.e. [5]**	**0.078**	**n.e. [5]**	**n.e. [5]**	**n.e. [5]**
	Minimum	µg/L [4]	0.03	n.e. [5]	n.e. [5]	<0.01	n.e. [5]	n.e. [5]	n.e. [5]
		%AR	0.007	n.e. [5]	n.e. [5]	<0.01	n.e. [5]	n.e. [5]	n.e. [5]
	Maximum	µg/L [4]	0.05	n.e. [5]	n.e. [5]	0.01	n.e. [5]	n.e. [5]	n.e. [5]
		%AR	0.124	n.e. [5]	n.e. [5]	0.028	n.e. [5]	n.e. [5]	n.e. [5]

1) Year 1: April 1994 – March 1995 for the lysimeters No. 27-33 and February 1995 – February 1996 for lysimeters No. 25 and 26
2) Year 2: April 1995 – March 1996 for the lysimeters No. 27-33 and February 1996 – April 1997
3) Year 3: April 1996 – April 1997, only for the lysimeters No. 27 and 31
4) Expressed as parent equivalent
5) n.e. – not examined, leachates not collected

8.5.3 Field leaching studies (KCP 9.1.2.3)

Please refer to point 8.5.2 (above).

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.

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

Florasulam Distribution										
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**
Sandy loam sediment system [14C]-phenyl Florasulam	7.6/5.4	6.74	22.38	SFO; X^2 err = 4.45; r^2 = 0.994	6.12	20.32	SFO; X^2 err = 5.27; r^2 = 0.992	0.54	n.r.	y/ EFSA Journal 2015; 13(1):3984
Sandy loam sediment system; [14C]-TP Florasulam	7.6/5.4	11.29	37.49	SFO; X^2 err = 5.44; r^2 = 0.986	10.51	34.91	SFO; X^2 err = 5.65; r^2 = 0.987	1.37	n.r.	
Clay loam sediment system; [14C]-phenyl Florasulam	6.6/5.9	26.89	89.34	SFO; X^2 err = 9.58; r^2 = 0.964	23.29	77.38	SFO; X^2 err = 7.97; r^2 = 0.971	4.31	n.r.	
Clay loam sediment system; [14C]-TP Florasulam	6.6/5.9	24.42	81.13	SFO; X^2 err = 5.46; r^2 = 0.988	22.07	73.31	DFOP; X^2 err = 4.28; r^2 = 0.992	3.82	n.r.	
Calwich Abbey Lake water/sediment system; [14C]-phenyl Florasulam	7.9/7.3	8.25	27.41	SFO; X^2 err = 4.76; r^2 = 0.995	7.98	26.53	SFO; X^2 err = 3.28; r^2 = 0.997	0.41	n.r.	
Calwich Abbey Lake water/sediment system; [14C]-TP Florasulam	7.9/7.3	9.89	32.85	SFO; X^2 err = 4.50, r^2 = 0.995	9.98	33.15	SFO; X^2 err = 4.08, r^2 = 0.996	0.42	n.r.	
Swiss Lake water/sediment system; [14C]-phenyl Florasulam	6.7/5.2	25.05	89.19	SFO; X^2 err = 4.71; r^2 = 0.988	24.01	79.76	SFO; X^2 err = 3.97; r^2 = 0.992	1.85	n.r.	
Swiss Lake water/sediment system; [14C]-TP Florasulam	6.7/5.2	25.49	84.66	SFO; X^2 err = 5.45, r^2 = 0.985	24.30	80.72	SFO; X^2 err = 4.30; r^2 = 0.991	4.56	n.r.	
Geometric mean (n=3)		15.03	50.36		14.05	46.74		1.44		

Table 8.6-2: Summary of observed metabolites

5-OH Florasulam water/sediment system	Max. in water/sediment 99%	y/ EFSA Journal 2015; 13(1):3984
DFP-ASTCA water/sediment system	Max. in water/sediment 8.9%	y/ EFSA Journal 2015; 13(1):3984
ASTCA water/sediment system	Max. in water/sediment 53.8%	y/ EFSA Journal 2015; 13(1):3984
TPSA water/sediment system	Max. in water/sediment 58.3%	y/ EFSA Journal 2015; 13(1):3984
ASTP water/sediment system	Max. in water/sediment 21.9%	y/ EFSA Journal 2015; 13(1):3984
5-OH ASTP water/sediment system	Max. in water/sediment 28.9%	y/ EFSA Journal 2015; 13(1):3984

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

Review Comments:

The PEC_{soil} calculations for florasulam, its metabolites and for formulation were provided by the Applicant and are considered acceptable. The EU agreed endpoints were used for PEC_{soil} calculations.

The PEC_{soil} reported below can be used for the risk assessment of the non-target organisms. Please refer to Section B9.

8.7.1 Justification for new endpoints

No deviation from the EU agreed endpoints.

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

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

Use No.	1, 3	2, 4
Crop	Winter cereals	Spring cereals
Application rate (g as/ha)	5.0	
Number of applications/interval	1	
Crop interception (%)	0	
Depth of soil layer (relevant for plateau concentration) (cm)	20 cm	

***Worst cases for PECsoil calculations**

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 (%)	Worst case normalised DT50 (days)	Value in accordance to EU endpoint y/n/ Reference
Florasulam	359.29	-	4.29 (worst case from lab. studies, normalised)	y/ EFSA Journal 2015; 13(1):3984
5-OH Florasulam	345.26	71.6	29.75 (worst case from lab. studies, normalised)	
DFP-ASTCA	304.20	17.8	46.16 (worst case from lab. studies, normalised)	
ASTCA	192.13	40.0	259.05 (worst case from lab. studies, normalised)	
TSA	148.14	15.9	171.68 (worst case from lab. studies, normalised)	

8.7.2.1 Florasulam and its metabolites

8.7.2.2 Florasulam and its metabolites

Table 8.7-3: PECsoil for Florasulam on cereals

PEC_{soil} (mg/kg)		Winter 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	<0.001	0.002	-	-
	28d	<0.001	0.001	-	-
	50d	<0.001	0.001	-	-
	100d	<0.001	<0.001	-	-
Plateau concentration (5 cm) after year 10		<0.001	-	-	-
$PEC_{accumulation}$ (PEC_{act} + $PEC_{soil\ plateau}$)		0.007	-	-	-

PEC_{soil} of metabolites

PEC_{soil} values for the metabolites were determined as for the parent with an application rate corrected taking into account the molecular weights (MW) and the maximum occurrence of the metabolite in soil as following:

Application $rate_{metabolite} = (MW_{metabolite}/ MW_{parent})$ x (% maximum occurrence/100) x application $rate_{parent}$

The corresponding application rates for each metabolite are summarized in the table below.

Table 8.7-3: Corrected application rates for the metabolites

Metabolite	Application rate of the parent (g/ha)	MW_{parent}	$MW_{metabolite}$	Maximum occurrence in soil (%)	Corrected application rate (g/ha)
5-OH Florasulam	5	359.29	345.26	71.6	3.4
DFP-ASTCA			304.20	17.8	0.8
ASTCA			192.13	40.0	1.1
TSA			148.14	15.9	0.3

The results of PEC_{soil} calculations are presented in the tables below.

Table 8.7-5: PEC_{soil} for 5-OH Florasulam on cereals

PEC_{soil} (mg/kg)		Winter cereals			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.005	-	-	-
Short term	24h	0.004	0.004	-	-
	2d	0.004	0.004	-	-
	4d	0.004	0.004	-	-
Long term	7d	0.004	0.004	-	-
	14d	0.003	0.004	-	-
	21d	0.003	0.004	-	-
	28d	0.002	0.003	-	-
	50d	0.001	0.003	-	-
	100d	0.004	0.002	-	-
Plateau concentration (5 cm) after year 10		<0.001	-	-	-
$PEC_{accumulation}$ (PEC_{act} + $PEC_{soil\ plateau}$)		0.005	-	-	-

Table 8.7-6: PEC_{soil} for DFP-ASTCA on cereals

PEC_{soil} (mg/kg)		Winter cereals			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.001	-	-	-
Short term	24h	0.001	0.001	-	-
	2d	0.001	0.001	-	-
	4d	0.001	0.001	-	-
Long term	7d	0.001	0.001	-	-
	14d	0.001	0.001	-	-
	21d	0.001	0.001	-	-
	28d	0.001	0.001	-	-
	50d	0.001	0.001	-	-
	100d	0.001	0.001	-	-
Plateau concentration (5 cm) after year 10		<0.001	-	-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		0.001	-	-	-

Table 8.7-7: PEC_{soil} for ASTCA on cereals

PEC_{soil} (mg/kg)		Winter cereals			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.001	-	-	-
Short term	24h	0.001	0.001	-	-
	2d	0.001	0.001	-	-
	4d	0.001	0.001	-	-
Long term	7d	0.001	0.001	-	-
	14d	0.001	0.001	-	-
	21d	0.001	0.001	-	-
	28d	0.001	0.001	-	-
	50d	0.001	0.001	-	-
	100d	0.001	0.001	-	-
Plateau concentration (5 cm) after year 10		0.001	-	-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		0.002	-	-	-

Table 8.7-8: PEC_{soil} for TSA on cereals

PEC_{soil} (mg/kg)		Winter cereals			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		<0.001	-	-	-
Short term	24h	<0.001	<0.001	-	-
	2d	<0.001	<0.001	-	-
	4d	<0.001	<0.001	-	-
Long term	7d	<0.001	<0.001	-	-
	14d	<0.001	<0.001	-	-
	21d	<0.001	<0.001	-	-
	28d	<0.001	<0.001	-	-
	50d	<0.001	<0.001	-	-
	100d	<0.001	<0.001	-	-
Plateau concentration (5 cm) after year 10		<0.001		-	-
$PEC_{accumulation}$ (PEC_{act} + $PEC_{soil\ plateau}$)		<0.001		-	-

8.7.2.3 PEC_{soil} of MATLAM

Since MATLAM is rapidly broken down into its constituent parts on contact with soil and/or crop material, it is appropriate to calculate the PEC_S following a single application only, using the following equation:

$$PEC_S\,(mg/kg) = \frac{\text{Application rate (g/ha)} \times (1 - F)}{100 \times \text{Soil depth (cm)} \times \text{Soil dry bulk density (g/cm}^3)}$$

Table 8.7-4: PEC_{soil} for MATLAM on winter cereals (worst case)

Active substance/ reparation	Application rate (g/ha)	Crop interception (%)	PEC_{act} (mg/kg)
MATLAM	104 (0.1 l/ha, density: 1.040 g/mL)	0	0.139

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

Review Comments:

For florasulam and its relevant metabolites PEC_{GW} calculations were performed with models: FOCUS PEARL 5.5.5, FOCUS PELMO 6.6.4 and FOCUS MACRO 5.5.4. The EU agreed endpoints, derived from the datasets presented in the EFSA Journal 2015;13(1):3984, were used. Application dates used in modeling are LoEP compliant. Therefore, submitted calculations of PEC_{GW} were accepted.

The PEC_{GW} of florasulam, 5-OH florasulam and DFP-ASTCA (80th percentile) at 1 m depth following uses on cereals, are less than 0.1 µg/L in all scenarios of three models. The potential for the metabolites ASTCA and TSA to leach to groundwater has been identified. The PEC_{GW} for those metabolites are above the trigger value of 0.1 µg/L, but below the trigger value of 0.75 µg/L. The metabolites are not toxicologically relevant (please refer to dRR Part B10).

In conclusion, the results demonstrate that MATLAM can be applied safely according to the recommended use patterns without risk of florasulam and its metabolites exceeding acceptable levels in groundwater.

8.8.1 Justification for new endpoints

No deviation from the EU agreed endpoints.

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_{gw} calculations

Use No.	1, 3	2, 4
Crop	Winter cereals	Spring cereals
Application rate (g as/ha)	5.0	
Number of applications/interval (d)	1	
Absolutive/Relative application date	15.03 for Châteaudun, Piacenza, Porto, Sevilla, Thiva 01.04 for Hamburg, Kremsmünster, Okehampton 15.05 for Jokioinen	5 days after emergence
Crop interception (%)	0	
Frequency of application	annual	
Models used for calculation	FOCUS PEARL v5.5.5, FOCUS PELMO v6.6.4, FOCUS MACRO v5.5.4*	

*** MACRO can only handle one parent compound and one metabolite in a single simulation. Hence, additional simulations are required. The degradation pathway includes a chain of degradation where a metabolite is formed from another metabolite, the PECgw for the metabolite of concern is simulated by using its precursor metabolite as "parent". In this cases, the applied dose in MACRO was adjusted to represent the occurrence of the precursor metabolite in soil according to following: Applied dose= Dose parent x (1-i) x ff_{met} x (Mw_{met} / Mw_{par}).**

Table 8.8-2: Input parameters related to active substance Florasulam and metabolites for PEC_{gw} calculations

Compound	Florasulam	5-OH Florasulam	DFP-ASTCA	ASTCA	TSA	Value in accordance with EU endpoint y/n/ Reference*
Molecular weight (g/mol)	359.29	345.26	304.20	192.13	148.14	y/ EFSA Journal 2015; 13(1):3984
Water solubility (mg/L):	6360 (20°C)	354 (20°C)	87400 (20°C)	250000 (20°C)	10900 (20°C)	
Saturated vapour pressure (Pa):	$1.0E^{-5}$ (25°C) (for PEARL) $1.0E^{-6}$(20°C) (for PELMO)	$2.7E^{-6}$ (20°C)	$3.0E^{-6}$ (20°C)	$2.0E^{-6}$ (20°C)	$1.0E^{-4}$ (20°C)	
DT_{50} in soil (d)	1.55 (geomean, normalisation to pF2, 20 °C with Q_{10} of 2.58, n=8)	14.98 (geomean, normalisation to pF2, 20 °C with Q_{10} of 2.58, n=8)	16.62 (geomean, normalisation to pF2, 20 °C with Q_{10} of 2.58, n=5)	297.47 (geomean, normalisation to pF2, 20 °C with Q_{10} of 2.58, n=4)	83.74 (geomean, normalisation to pF2, 20 °C with Q_{10} of 2.58, n=4)	
K_{foc} (mL/g) K_{fom}	10.35 / 6.00 (median, n=14)	14.53 /8.43 (median, n=10)	75.18 /43.61 (arithmetic mean, n=4)	104.81 /60.79 (arithmetic mean, n=4)	23.46 /13.61 (arithmetic mean, n=4)	
1/n	0.945 (arithetic mean, n=14)	0.91 (arithmetic mean, n=10)	0.85 (arithmetic mean, n=4)	0.94 (arithmetic mean, n=4)	0.94 (arithmetic mean, n=4)	
Plant uptake factor	0	0	0	0	0	
Formation fraction	-	0.854 from parent	1.00 from 5-OH Florasulam	0.781 from DFP-ASTCA	0.219 from DFP-ASTCA 1.00 from ASTCA	

Table 8.8-3: Application dates used for groundwater risk assessment

Scenario	Application dates (absolute)	
	Winter cereals (application in spring)*	Spring cereals**
Châteaudun	15.03	5 days after emergence ***
Hamburg	01.04	5 days after emergence
Jokioinen	15.05	5 days after emergence
Kremsmünster	01.04	5 days after emergence
Okehampton	01.04	5 days after emergence
Piacenza	15.03	5 days after emergence
Porto	15.03	5 days after emergence

Scenario	**Application dates (absolute)**	
	Winter cereals (application in spring)*	**Spring cereals****
Sevilla	15.03	5 days after emergence
Thiva	15.03	5 days after emergence

***Application dates based on EFSA Journal 2015;13(1):3984 for florasulam on winter cereals spring application**
****First application is set as an absolute application date – 5 days after emergence, which is in line with BBCH 12 according to AppDate v3.06 (28/06/2019)**
*****for MACRO calculation the date was set to 15/03 for Chateudun scenario which is in line with 5 days after emergence date**

Table 8.8-4: PEC$_{gw}$ for Florasulam and metabolites on winter cereals (with FOCUS PELMO 6.6.4)

Crop	**Scenario**	**80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)**				
		Florasulam	**5-OH Florasulam**	**DFP-ASTCA**	**ASTCA**	**TSA**
Winter cereals	Châteaudun	<0.001	0.002	<0.001	0.262	0.220
	Hamburg	<0.001	0.008	0.002	0.266	0.232
	Jokioinen	<0.001	0.013	0.001	0.205	0.232
	Kremsmünster	<0.001	0.011	0.003	0.240	0.181
	Okehampton	<0.001	0.015	0.004	0.217	0.138
	Piacenza	<0.001	0.007	0.003	0.244	0.183
	Porto	<0.001	0.006	0.001	0.149	0.129
	Sevilla	<0.001	<0.001	<0.001	0.054	0.107
	Thiva	<0.001	<0.001	<0.001	0.191	0.195

Table 8.8-5: PEC$_{gw}$ for Florasulam and metabolites on winter cereals (with FOCUS PEARL 5.5.5)

Crop	**Scenario**	**80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)**				
		Florasulam	**5-OH Florasulam**	**DFP-ASTCA**	**ASTCA**	**TSA**
Winter cereals	Châteaudun	<0.001	0.003	<0.001	0.246	0.223
	Hamburg	<0.001	0.013	0.003	0.280	0.259
	Jokioinen	<0.001	0.013	0.001	0.234	0.275
	Kremsmünster	<0.001	0.012	0.004	0.229	0.161
	Okehampton	<0.001	0.017	0.005	0.213	0.136
	Piacenza	<0.001	0.008	0.004	0.235	0.184
	Porto	<0.001	0.004	0.001	0.150	0.138
	Sevilla	<0.001	<0.001	<0.001	0.032	0.088
	Thiva	<0.001	<0.001	<0.001	0.306	0.283

Table 8.8-6: PEC$_{gw}$ for Florasulam and metabolites on winter cereals (spring application) with FOCUS MACRO v5.5.4

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)				
		Florasulam	5-OH Florasulam	DFP-ASTCA	ASTCA	TSA
Winter cereals	Châteaudun	<0.001	0.002	0.001	0.295	0.163

Table 8.8-6: PEC$_{gw}$ for Florasulam and metabolites on spring cereals (with FOCUS PELMO 6.6.4)

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)				
		Florasulam	5-OH Florasulam	DFP-ASTCA	ASTCA	TSA
Spring cereals	Châteaudun	<0.001	0.001	<0.001	0.192	0.175
	Hamburg	<0.001	0.008	0.002	0.277	0.231
	Jokioinen	<0.001	0.010	0.001	0.194	0.213
	Kremsmünster	<0.001	0.012	0.002	0.249	0.189
	Okehampton	<0.001	0.014	0.002	0.210	0.129
	Porto	<0.001	0.004	<0.001	0.135	0.108

Table 8.8-7: PEC$_{gw}$ for Florasulam and metabolites on spring cereals (with FOCUS PEARL 5.5.5)

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)				
		Florasulam	5-OH Florasulam	DFP-ASTCA	ASTCA	TSA
Spring cereals	Châteaudun	<0.001	0.002	<0.001	0.213	0.189
	Hamburg	<0.001	0.016	0.004	0.336	0.320
	Jokioinen	<0.001	0.008	0.001	0.206	0.225
	Kremsmünster	<0.001	0.013	0.004	0.249	0.180
	Okehampton	<0.001	0.013	0.003	0.221	0.139
	Porto	<0.001	0.002	<0.001	0.133	0.115

Table 8.8-9: PEC$_{gw}$ for Florasulam and metabolites on spring cereals with FOCUS MACRO v5.5.4

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)				
		Florasulam	5-OH Florasulam	DFP-ASTCA	ASTCA	TSA
Spring cereals	Châteaudun	<0.001	0.002	0.001	0.257	0.130

Conclusion

For use in Winter Cereals:

In case of Florasulam and 2 metabolites, 5-OF florasulam and DFP-ASTCA, the PEC$_{GW}$ < 0.1 µg/L were obtained in all scenarios and for both models used.
In case of ASTCA the PEC$_{GW}$ > 0.1 µg/L were recorded in all scenarios for FOCUS PELMO (except Sevilla) being in range 0.054 µg/L (Sevilla) – 0.266 µg/L (Hamburg) and in all scenarios for FOCUS PEARL (again, except Sevilla), being in range 0.032 µg/L (Sevilla) – 0.306µg/L (Thiva).
For TSA, PEC$_{GW}$ > 0.1 µg/L were obtained for all scenarios (except Sevilla in PEARL) for both models, being in range 0.088 µg/L (Sevilla) – 0.283 µg/L (Hamburg, Jokioinen) for FOCUS PELMO and 0.107 µg/L (Sevilla) – 0.232 µg/L (Thiva) for FOCUS PEARL.

For use in Spring Cereals:

In case of Florasulam, 5-OH Florasulam and DFP-ASTCA, PEC$_{GW}$ < 0.1 µg/L were obtained in all scenarios and for both models used.
In case of ASTCA PEC$_{GW}$ > 0.1 µg/L were recorded in all scenarios for both models, being in range 0.135 µg/L (Porto) – 0.277 µg/L (Hamburg) for FOCUS PELMO and in range 0.133 µg/L (Porto) – 0.336 µg/L (Hamburg) for FOCUS PEARL.
For TSA, PEC$_{GW}$ > 0.1 µg/L were recorded in all scenarios for both models, being in range 0.108 µg/L (Porto) – 0.231 µg/L (Hamburg) for FOCUS PELMO and in range 0.115 µg/L (Porto) – 0.320 µg/L (Hamburg) for FOCUS PEARL.

8.9 Predicted Environmental Concentrations in surface water (PEC$_{sw}$) (KCP 9.2.5)

Review Comments:

The PECS$_{SW/SED}$ calculations for florasulam and its relevant metabolites were provided by the Applicant and are considered acceptable. The EU agreed endpoints, derived from the datasets presented in the EFSA Journal 2015;13(1):3984, were used. For FOCUS STEPS 3-4, application dates for winter cereals, spring application, used in modeling are LoEP compliant. Selected application dates for spring cereals (STEP 3) are according to AppDate.

For active substances and relevant metabolites PEC$_{SW}$ calculations were performed with FOCUS STEPS 1-2 (active substance and metabolites), STEP 3 (active substance, all scenarios) and STEP 4 (active substance, D1 and D2 scenarios).

Calculations for the formulation were not required.

The PEC$_{sw}$ reported below can be used for the risk assessment for aquatic organisms. Please refer to section 9.

8.9.1 Justification for new endpoints

No deviation from the EU agreed endpoints.

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

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

Plant protection product	MATLAM	
Use No.	1, 3	2, 4
Crop	Winter cereals	Spring cereals
Application rate (g as/ha)	5.0	
Number of applications/interval (d)	1	
Application window	Step 1-2: March-May (no interception) Step3- 4: Table 8.9-2	Step 1-2: March-May (no interception) Step3- 4: Table 8.9-3
Application method	Ground spray	
CAM (Chemical application method)	CAM 2	
Soil depth (cm)	Water body: 30cm Sediment: 5cm	
Models used for calculation	FOCUS STEPS 1-2 v3.2 FOCUS SWASH v5.3 FOCUS PRZM v4.3.1 FOCUS MACRO v5.5.4 FOCUS TOXWA v5.5.3	

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

Crop	Scenario	Application window used in modelling
Winter cereals	D1 ditch	25.03-24.04
	D1 stream	
	D2 ditch	04.04-04.05
	D2 stream	
	D3 ditch	02.04-02.05
	D4 pond	01.03-31.03
	D4 stream	
	D5 pond	01.03-31.03
	D5 stream	
	D6 ditch	16.02-17.03
	R1 pond	11.04-11.05
	R1 stream	
	R3 stream	11.03-10.04
	R4 stream	16.03-16.04

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

Crop	Scenario	Application window used in modelling
Spring cereals	D1 ditch	08.05-07.06
	D1 stream	
	D3 ditch	05.04-05.05
	D4 pond	29.04-29.05
	D4 stream	
	D5 pond	18.03-17.04
	D5 stream	
	R1 pond*	14.04-14.05
	R1 stream*	
	R4 stream	18.03-17.04

*** National scenarios relevant for Poland are D3, D4 and R1. Due to fact that drainage scenario R1 is not available for spring cereals in programs used for modelling, the surrogate crop was proposed. Presented calculation was done for spring oilseed rape, for scenario R1 considering all input data as for spring oilseed rape.**

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

Compound	Florasulam	5-OH Florasulam	DFP-ASTCA	ASTCA	TSA	TPSA	5-OH ASTP	ASTP	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	359.29	345.26	304.20	192.13	148.14	248.17	233.18	247.20	y/ EFSA Journal 2015; 13(1):3984
Saturated vapour pressure (Pa)	1.0×10^{-5} at 25°C	-	-	-	-	-	-	-	
Water solubility (mg/L)	6360 at 20°C	354 at 20°C	87400 at 20°C	250000 at 20°C	10900 at 20°C	250000 (20°C)*	8920 (20°C) *	2790 (20°C) *	
Diffusion coefficient in water (m²/d)	4.3×10^{-5}	-	-	-	-	-	-	-	
Diffusion coefficient in air (m²/d)	0.43	-	-	-	-	-	-	-	
K_{foc} (mL/g)	10.35 (median, n=14)	14.53 (median, n=10)	75.18 (arithmetic mean, n=4)	104.81 (arithmetic mean, n=4)	23.46 (arithmetic mean, n=4)	41.52 (KOCWIN (EPIsuite v4.1 estimatio	77.74 (KOCWIN (EPIsuite v4.1 estimatio	60.22 (KOCWIN (EPIsuite v4.1 estimatio	

Compound	**Florasulam**	**5-OH Florasulam**	**DFP-ASTCA**	**ASTCA**	**TSA**	**TPSA**	**5-OH ASTP**	**ASTP**	**Value in accordance to EU endpoint y/n/ Reference**
						n))	n))	n))	
Freundlich Exponent 1/n	0.95 (arithmetic mean, n=14)	-	-	-	-	-	-	-	
Plant Uptake	0	-	-	-	-	-	-	-	
General value	Q10=2.58, Walker equation coefficient 0.7								
Wash-Off factor from Crop (1/mm)	0.05 (MACRO) 0.50 (PRZM)	not required for Step 1+2/							
DT$_{50,soil}$ (d)	1.55 (geomean, normalisation to pF2, 20 °C with Q$_{10}$ of 2.58, n=8)	14.98 (geomean, normalisation to pF2, 20 °C with Q$_{10}$ of 2.58, n=8)	16.62 (geomean, normalisation to pF2, 20 °C with Q$_{10}$ of 2.58, n=5)	297.47 (geomean, normalisation to pF2, 20 °C with Q$_{10}$ of 2.58, n=4)	83.74 (geomean, normalisation to pF2, 20 °C with Q$_{10}$ of 2.58, n=4)	1000 (default)	1000 (default)	1000 (default)	
DT$_{50,water}$ (d)	15.03 (geomean whole system, n=8)	1000 (default)	1000 (default)	1000 (default)	1000 (default)	1000 (default)	1000 (default)	1000 (default)	
DT$_{50,sed}$ (d)	15.03 (geomean whole system, n=8)	1000 (default)	1000 (default)	1000 (default)	1000 (default)	1000 (default)	1000 (default)	1000 (default)	
DT$_{50,whole\ system}$ (d)	15.03 (geomean whole system, n=8)	1000 (default)	1000 (default)	1000 (default)	1000 (default)	1000 (default)	1000 (default)	1000 (default)	
Maximum occurrence observed (% molar basis with respect to the parent)	Sediment : 38.94	Soil: 71.6 Total system: 99	Soil: 17.8 Total system: 8.9	Soil 40 Total system: 53.8	Soil: 15.9 Total system:0.0001	Soil:0.0001 Total system: 58.3	Soil:0.0001 Total system: 28.9	Soil:0.0001 Total system: 21.9	

* Final Addendum to the RAR, Nov. 2014

$PEC_{sw/sed}$

Table 8.9-5: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for Florasulam following single application of MATLAM 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)
Step 1	---	1.69	Runoff/drainage	1.08	0.17
Step 2					
Northern Europe	March-May	0.09	Runoff/drainage	0.06	0.01
Southern Europe	March-May	0.15	Runoff/drainage	0.09	0.01
Step 3					
D1	ditch	0.353	Drainage	0.140	0.097
D1	stream	0.221	Drainage	0.124	0.057
D2	ditch	0.671	Drainage	0.185	0.095
D2	stream	0.469	Drainage	0.098	0.052
D3	ditch	0.032	Spray drift	0.001	0.003
D4	pond	0.001	Spray drift	0.001	0.001
D4	stream	0.025	Spray drift	<0.001	0.001
D5	pond	0.001	Drainage	0.001	<0.001
D5	stream	0.025	Drainage	<0.001	<0.001
D6	ditch	0.032	Drainage	0.001	0.002
R1	pond	0.001	Spray drift	0.001	<0.001
R1	stream	0.025	Runoff	0.001	0.002
R3	stream	0.029	Runoff	0.001	0.001
R4	stream	0.021	Runoff	<0.001	0.001

Table 8.9-6: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for Florasulam following single application of MATLAM 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)
Step 1	---	1.69	Runoff/drainage	1.08	0.17
Step 2					
Northern Europe	March-May	0.09	Runoff/drainage	0.06	0.01
Southern Europe	March-May	0.15	Runoff/drainage	0.09	0.01
Step 3					
D1	ditch	0.045	Drainage	0.034	0.016

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
D1	stream	0.030	Drainage	0.016	0.009
D3	ditch	0.032	Spray drift	0.001	0.003
D4	pond	0.001	Spray drift	0.001	<0.001
D4	stream	0.024	Spray drift	<0.001	<0.001
D5	pond	0.001	Spray drift	0.001	<0.001
D5	stream	0.025	Spray drift	<0.001	<0.001
R1*	pond	0.001	Spray drift	0.001	<0.001
R1*	Stream	0.021	Spray drift	<0.001	0.001
R4	stream	0.021	Spray drift	<0.001	0.001

*** National scenarios relevant for Poland are D3, D4 and R1. Due to fact that drainage scenario R1 is not available for spring cereals in programs used for modelling, the surrogate crop was proposed. Presented calculation was done for spring oilseed rape, for scenario R1 considering all input data as for spring oilseed rape.**

FOCUS Step 4

Table 8.9-7: Global maximum PEC_{SW} values for Florasulam, following single application of MATLAM to winter cereals according to the central EU zone GAP according to surface water Step 4

PEC_{SW} (µg/L)	Scenario	STEP 4 Florasulam	
Nozzle reduction	Vegetative strip (m)	None	None
	No spray buffer (m)	5	10
None	D1 ditch	0.353	0.353
50%		0.353	-
None	D1 stream	0.221	0.221
50%		0.221	-
None	D2 ditch	0.671	0.671
50%		0.671	-
None	D2 stream	0.469	0.469
50%		0.469	-

Conclusion

Since the dominant entry route for the scenarios D1 and D2 is drainage, risk mitigation measures such as buffer zone and nozzle reduction have no impact on the outcome of the results of the PECsw. However, since the scenarios D1 and D2 are not considered in the risk assessment in all the members states across Europe, further refinement will be necessary at national level when relevant and necessary.

The scenarios D1 and D2 are not relevant for ZRMS Poland, therefore the obtained results of the PECsw are considered sufficient.

Metabolites of Florasulam

Table 8.9-8: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for 5-OH Florasulam following single application to winter and spring cereals

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominat entry route	Max PEC_{sed} (µg/kg)
Step 1	---	2.72	Runoff/drainage	0.40
Step 2				
Northern Europe	March-May	0.28	Runoff/drainage	0.04
Southern Europe	March-May	0.52	Runoff/drainage	0.08

Table 8.9-9: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for DFP-ASTCA following single application to winter and spring cereals

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominat entry route	Max PEC_{sed} (µg/kg)
Step 1	---	0.34	Runoff/drainage	0.27
Step 2				
Northern Europe	March-May	0.05	Runoff/drainage	0.04
Southern Europe	March-May	0.09	Runoff/drainage	0.07

Table 8.9-9: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for ASTCA following single application to winter and spring cereals

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominat entry route	Max PEC_{sed} (µg/kg)
Step 1	---	0.75	Runoff/drainage	0.78
Step 2				
Northern Europe	March-May	0.09	Runoff/drainage	0.09
Southern Europe	March-May	0.16	Runoff/drainage	0.17

Table 8.9-10: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for TSA following single application to winter and spring cereals

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominat entry route	Max PEC_{sed} (µg/kg)
Step 1	---	0.11	Runoff/drainage	0.02
Step 2				
Northern Europe	March-May	0.02	Runoff/drainage	<0.01
Southern Europe	March-May	0.04	Runoff/drainage	0.01

Table 8.9-11: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for TPSA following single application to winter and spring cereals

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominat entry route	Max PEC_{sed} (µg/kg)
Step 1	---	0.65	Runoff/drainage	0.27
Step 2				
Northern Europe	March-May	0.04	Runoff/drainage	0.02
Southern Europe	March-May	0.06	Runoff/drainage	0.02

Table 8.9-12: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for 5-OH-ASTP following single application to winter and spring cereals

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominat entry route	Max PEC_{sed} (µg/kg)
Step 1	---	0.29	Runoff/drainage	0.23
Step 2				
Northern Europe	March-May	0.02	Runoff/drainage	0.01
Southern Europe	March-May	0.03	Runoff/drainage	0.02

Table 8.9-14: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for ASTP following single application to winter and spring cereals

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominat entry route	Max PEC_{sed} (µg/kg)
Step 1	---	0.23	Runoff/drainage	0.14
Step 2				
Northern Europe	March-May	0.01	Runoff/drainage	0.01
Southern Europe	March-May	0.02	Runoff/drainage	0.01

8.9.2.1 $PEC_{sw/sed}$ of MATLAM

The PEC_{SW} for MATLAM was calculated using the following equation:

$$PEC_{SW}\,(\mu g/L) = \frac{\%Drift_{90th\,\%ile} \times Application\,rate\,(g/ha)}{Water\ depth\,(cm) \times 10}$$

The application of MATLAM is 0.1 L/ha, corresponding to 104 g/ha (taking into account a density of 1.04 g/mL) for spring and winter cereals. The depth of the static water body was assumed to be 30 cm. The resulting maximum instantaneous PEC_{SW} value is presented in the table 8.9-30.

Table 8.9-30: PEC$_{sw}$ for MATLAM following single application

Crop/uses	Distance (m)	Drift (%)	Max PEC$_{sw}$ (µg/l)
Spring cereals, winter cereals	1	2.77	0.960

The PEC$_{sed}$ for MATLAM was calculated using the following equation:

$$PEC_{sed}\,(\mu g/kg\,dw) = \frac{\%Drift_{90th\ \%ile} \times Application\ rate\ (g/ha) \times \%Active\ substance\ in\ sediment}{1000 \times sediment\ density\ (g/cm^3) \times sediment\ height\ (cm)}$$

The application of MATLAM is 0.1 L/ha, corresponding to 104 g/ha (taking into account a density of 1.04 g/mL) for spring and winter cereals. The maximum percentage of Florasulam in the sediment is 38.94 %. The height of the sediment was assumed to be 5 cm and the sediment density was assumed to be 1.3 g/cm^3. The resulting maximum instantaneous PEC$_{sed}$ value is presented in the table 8.9-31.

Table 8.9-31: PEC$_{sed}$ for MATLAM following single application

Crop	Distance (m)	Drift (%)	% of active substance	Max PEC$_{sed}$ (µg/l) (based on maximum occurrence)
Spring cereals, winter cereal	1	2.77	38.94	1.726

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

Review Comments:

The data on atmospheric degradation and behaviour in air for florasulam provided by the Applicant are considered acceptable. The justification for non-assessment via volatilization is accepted. Exposure of adjacent surface waters and terrestrial ecosystems by florasulam due to volatilization with subsequent deposition is not expected.

Table 8.10-1 Summary of atmospheric degradation and behaviour

Compound	Florasulam
Direct photolysis in air	No data requested
Quantum yield of direct phototransformation	Not determined
Photochemical oxidative degradation in air	DT$_{50}$: 1.706 days hours derived by the Atkinson model (version 1.92). OH (12-h) concentration assumed = 1.6 E-6
Volatilisation	Vapour pressure: 1 x 10^{-5} Pa at 25°C (99.7 %) Henry's Law Constant (Pa.m^3/mol): 3.29 x 10^{-5} (pH 5) at 20°C 4.35 x 10^{-7} (pH 7) at 20°C 2.94 x 10^{-8} (pH 9) at 20°C From plant surfaces (BBA guideline): 1.7 % after 24 hours From soil surfaces (BBA guideline): negligible after 24

	hours
Metabolites	Not examined

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

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

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

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

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

Appendix 2 Detailed evaluation of the new Annex II studies

Not relevant. No new Annex II study.

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