REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: 102000007779

Product name: Flufenacet SC 508.8 G

Chemical active substances:

Flufenacet 508.8 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(Authorization)

Applicant: Bayer Crop Science Division

Submission date: 30 June 2021

Finalisation date: March 2023 (initial Core Assessment)

June 2023 (final Core Assessment)

Version history

When	What
June 2021	Original Bayer Crop Science Division submission
March 2023	Initial assessment by the zRMS 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 highlighted in grey. Not agreed or not relevant information are ~~struck through and shaded for transparency~~.
June 2023	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)

8.1 Critical GAP and overall conclusions

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

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use No *	**Member state(s)**	**Crop and/or situation (crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I ****	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/ synergist per ha	**Conclusion**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
Zonal uses (field or outdoor uses, certain types of protected crops)														
29, 33, 37, 89, 93, 129, 53, 57, 61, 97, 101, 133, 65, 69, 73, 105, 109, 137, 77, 81, 85, 113, 117, 141	PL, SVK, BEL, IRL	Winter cereals	F	Mono- and dicotyledonous weeds	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage		A
30, 34, 38, 90, 94, 130, 54, 58, 62, 98, 102, 134, 66, 70, 74, 106, 110, 138, 78, 82, 86, 114, 118, 142	PL, SVK, BEL, IRL	Winter cereals	F	Mono- and dicotyledonous weeds	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.48 b) 0.48	a) FFA 244.2 b) FFA 244.2	100-400	as per growth stage		A
31, 35, 39, 91, 95, 131, 55, 59, 63, 99, 103, 135,	PL, SVK, BEL, IRL	Winter cereals	F	Mono- and dicotyledonous weeds	spraying (broadcast, overall)	00-09	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage		A

67, 71, 75, 107, 111, 139, 79, 83, 87, 115, 119, 143														
32, 36, 40, 92, 96, 132, 56, 60, 64, 100, 104, 136, 68, 72, 76, 108, 112, 140, 80, 84, 88, 116, 120, 144	PL, SVK, BEL, IRL	Winter cereals	F	Mono- and dicotyledonous weeds	spraying (broadcast, overall)	10-13	a) 1 b) 1	-	a) 0.24 b) 0.24	a) FFA 122.1 b) FFA 122.1	100-400	as per growth stage		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

zRMS comments:

Originally the GAP table presented by the Applicant listed all intended uses of FFA SC 508.8 G in particular countries together with detailed information on the crop species/variety and weeds against which the product is intended to be used, giving almost 100 entries. However, zonal evaluation in area of environmental fate and behaviour has to cover all countries in the zone and is performed with consideration of the crop group, relevant BBCH stage, number of applications, interval and application rate, while the weeds against which the product is applied or species/variety of the crop are irrelevant. Taking this into account the original GAP table has been modified by the zRMS in order to construct the risk envelope GAP, which covers particular uses in each cMS. The detailed GAP for particular countries may be found in the Core Assessment, Part B, Section 0.

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

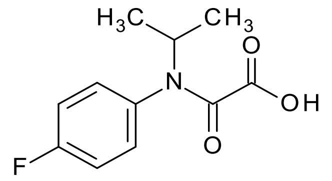
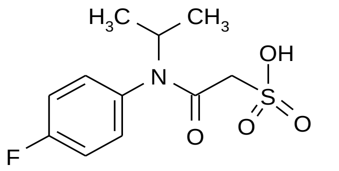
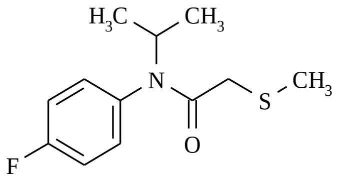
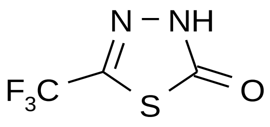
1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/or situation (crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I ****	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**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 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		
	EU-N EU-S	Corn	F	Annual grass weeds	Spray application with standard field sprayers	Pre-emergence	a) 1 b) 1	-	a) 1 b) 1	a) 0.60 b) 0.60	200 - 400	-	
	EU-S	Soybean, sunflower	F	Annual grass weeds	Spray application with standard field sprayers	Pre-emergence	a) 1 b) 1	-	a) 1 b) 1	a) 0.60 b) 0.60	200 - 400	-	
	EU-N EU-S	Winter cereals (wheat, rye, barley, triticale)	F	Annual grass weeds	Spray application with standard field sprayers	Early post autumn at the 2nd leaf stage of the grass weeds	a) 1 b) 1	-	a) 0.4 b) 0.4	a) 0.240 b) 0.240	200 - 400	-	

* 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 flufenacet potentially relevant for exposure assessment

Metabolite [1]	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
FOE oxalate (M1)	225.2 g/mol		Soil 15.6% (aerobic)	PEC_{soil} PEC_{gw} PEC_{sw} PEC_{sed}
FOE sulfonic acid (M2)	275.3 g/mol		Soil 26.3% (aerobic)	PEC_{soil} PEC_{gw} PEC_{sw} PEC_{sed}
FOE methylsulfide (M5)	241.3 g/mol		Water/sediment: 11.5% entire system	PEC_{sw} PEC_{sed}
FOE-thiadone (Thiadone, M9)	170.1 g/mol		Water/sediment: 84.3% entire system	PEC_{sw} PEC_{sed}

[1] The structures and report names of degradation products identified in e-fate studies reflect in general their neutral (uncharged) species. The degradation product FOE sulfonic acid has a pKa-value < 2 and hence, is deprotonated under environmental conditions. Therefore, the environmental relevant deprotonated species was used for all studies which were conducted to elucidate the toxicological and ecotoxicological properties of this degradation product as well as its fate in the environment, plants and animals.

zRMS comments:

Information regarding flufenacet metabolites FOE oxalate and FOE sulfonic acid is in line with endpoints reported in Review Report for flufenacet (7469/VI/98-Final – 3rd July 2003). Information regarding metabolite M9 is in line with DAR Addendum, 2003. Maximum observed occurrence of metabolite FOE methylsulfide (M5) in total water/sediment system is 11.4% (DAR Addendum, 2003).

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)

8.3.1.1 Flufenacet and its metabolites

The aerobic degradation of flufenacet has been evaluated, full details of these studies are provided in the respective EU monograph Annex B.7 (ECCO 73, August 1997) and related documents and summarised in the Review Report for flufenacet (7469/VI/98-Final – 3rd July 2003). Additional studies have been performed (updated kinetic evaluation Schaefer, H.; 1998; M-004479-02-1 that was evaluated but is not part of the EU monograph, time-dependent sorption study with the degradation product FOE sulfonic acid to derive the kinetic parameters) and are considered as necessary for the risk assessment, the studies are summarised in Appendix 2.

Table 8.3-1: Summary of aerobic degradation rates for flufenacet - laboratory studies, triggering endpoints

Flufenacet, laboratory studies, aerobic conditions, triggering endpoints										
Soil name	**Soil type (USDA)**	**pH ($CaCl_2$)**	**T (°C)**	**MWHC (%)**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20 °C pF2 / 10kPa**	**Chi² (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
BBA 2.2	Loamy sand	6.2	20	40	39		n/a			y / Review report 7469/VI/98-Final – 3rd July 2003
Laacherhof	Silt loam	7.3	20	40	15		n/a			
Höfchen i. Tal	Silt loam	5.8	20	40	27		n/a			
Geometric mean (n=3)					25.1					
pH-dependency: y/n					n					

n/a – not assessed

Table 8.3-2: Summary of aerobic degradation rates for flufenacet - laboratory studies, modelling endpoints

Flufenacet, laboratory studies, aerobic conditions, modelling endpoints										
Soil name	**Soil type (USDA)**	**pH ($CaCl_2$)**	**T (°C)**	**MWHC (%)**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20 °C pF2 / 10kPa**	**Chi² (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
BBA 2.2	Loamy sand	6.2	20	40	31.2		24.0		SFO	y / Review report 7469/VI/98-Final – 3rd July 2003 y / Appendix 2 kinetic evaluation Schaefer, H.; 1998; M-004479-02-1 [2]
Laacherhof	Silt loam	7.3	20	40	20.9		12.7		SFO	
Höfchen i. Tal	Silt loam	5.8	20	40	22.6		13.8		SFO	
Geometric mean (n=3)							16.1			
pH-dependency: y/n							n			

[1] conversion to 20 °C and 100% FC
[2] 1998 amendment evaluated but not in EU monograph Annex B.7 (ECCO 73, August 1997), therefore summarized in Appendix 2

Table 8.3-3: Summary of aerobic degradation rates for FOE oxalate - laboratory studies, triggering endpoints

FOE oxalate, Laboratory studies, aerobic conditions, triggering endpoints										
Soil name	**Soil type (USDA)**	**pH ($CaCl_2$)**	**T (°C)**	**MWHC (%)**	**DT_{50} (d)** [1]	**DT_{90} (d)**	**DT_{50} (d) 20 °C pF2 / 10kPa** [2]	**Chi² (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
BBA 2.2	Loamy sand	6.2	20	40	5		n/a			y / Review report 7469/VI/98-Final – 3rd July 2003
Laacherhof	Silt loam	7.3	20	40	17		n/a			
Höfchen i. Tal	Silt loam	5.8	20	40	12		n/a			
Geometric mean (n=3)							10.0			
pH-dependency: y/n							n			

[1] estimated from parent study
[2] conversion to 20 °C and 100% FC
n/a – not assessed

Table 8.3-4: Summary of aerobic degradation rates for FOE oxalate - laboratory studies, modelling endpoints

FOE oxalate, Laboratory studies, aerobic conditions, modelling endpoints										
Soil name	**Soil type (USDA)**	**pH ($CaCl_2$)**	**T (°C)**	**MWHC (%)**	**DT_{50} (d)** [1]	**DT_{90} (d)**	**DT_{50} (d) 20 °C pF2 / 10kPa** [2]	**Chi² (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
BBA 2.2	Loamy sand	6.2	20	40	5.1	-	3.9	-	-	y / Review report 7469/VI/98-Final – 3rd July 2003
Laacherhof	Silt loam	7.3	20	40	17.0	-	10.4	-	-	
Höfchen i. Tal	Silt loam	5.8	20	40	11.6	-	7.1	-	-	y / Appendix 2 kinetic evaluation Schaefer, H.; 1998; M-004479-02-1 [3]
Geometric mean (n=3)							6.6			
pH-dependency: y/n							n			

[1] estimated from parent study
[2] conversion to 20 °C and 100% FC
[3] 1998 amendment evaluated at EU level (Review Report 7469/VI/98-Final – 3rd July 2003) but not in EU monograph Annex B.7 (ECCO 73, August 1997), therefore summarized in Appendix 2.

Table 8.3-5: Summary of aerobic degradation rates for FOE sulfonic acid - laboratory studies, triggering endpoints and modelling endpoints

FOE sulfonic acid, Laboratory studies, aerobic conditions, triggering endpoints and modelling endpoints										
Soil name	**Soil type (USDA)**	**pH ($CaCl_2$)**	**T (°C)**	**MWHC (%)**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20 °C pF2 / 10kPa** [1]	**Chi² (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
BBA 2.1	Sand	5.3	20	75% of ⅓ bar	270		188.8		SFO	y / Review report 7469/VI/98-Final – 3rd July 2003
BBA 2.2	Loamy sand	6.3	20	75% of ⅓ bar	189		118.7		SFO	
Laacherhof	Silt loam	7.3	20	75% of ⅓ bar	247		123.0		SFO	
~~Laacher Hof AXXa~~	~~Sandy loam~~	~~6.3~~	~~20~~	~~40~~	~~61.8~~		~~41.6~~		~~SFO~~	~~n / Appendix 2 Hellpointner, E.; 2003; M-111445-01-1~~
~~Laacher Hof AIII~~	~~Silt loam~~	~~6.8~~	~~20~~	~~40~~	~~60.2~~		~~36.7~~		~~SFO~~	
Geometric mean (n=3 ~~n=5~~)							140 ~~136.2 or 84.1(20 °C, pF2)~~			
pH-dependency: y/n							n			

[1] conversion to 20 °C and 100% FC; modelling endpoints are given by the normalised DT_{50} values

zRMS comments:

Soil degradation data for flufenacet and its metabolites are in general in line with the Review Report for flufenacet (7469/VI/98-Final – 3rd July 2003) and Flufenacet Addendum (Volume 3, B.7, Environmental Fate) of January 2003 (14377/ECCO/BVL/03).

It is noted that information on degradation rates for FOE sulfonic acid presented in Table 8.3-5 are only partly reported in the Review Report for flufenacet (7469/VI/98-Final – 3rd July 2003). In support of evaluation for FFA SC 508.8 G the Applicant submitted additional soil degradation study (Hellpointner, 2003), which was, however, not evaluated by the zRMS since the available dataset was sufficient to finalise the exposure assessment and additional data for FOE sulfonic acid were not necessary to demonstrate safe uses. Taking this into account, only values reported in the Review Report or Addendum to the monograph (2003) should be used for exposure assessment, in line with indications of the Working Document of the Central Zone in area of Section 8 and results of the new study were struck thorugh in Table 8.3-5. Evaluation of the new data is expected during the ongoilg renewal process.

It is further noted that although in the above mentioned addendum for flufenacet the geometric mean normalised DT_{50} of 16.5 d is reported, the geometric mean of 16.1 d is actually calcualted from the individual values. Therefore the geometric mean reported in Table 8.3-2 is correct.

For relevant endpoints considered in exposure assessment, please refer to points 8.8 (groundwater) and 8.9 (surface water) of this document.

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

The anaerobic degradation of flufenacet has been evaluated, full details of these studies are provided in the respective EU monograph Annex B.7 (ECCO 73, August 1997) and related documents and summarised in the Review Report for flufenacet (7469/VI/98-Final – 3rd July 2003). No additional studies have been performed.

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

Flufenacet, Laboratory studies, anaerobic conditions										
Soil name	**Soil type (x)**	**pH (x)**	**T (°C)**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi^2 (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
No data provided, not required	-	-	-	-	-	-	-	-	-	y / Review report 7469/VI/98-Final – 3rd July 2003
Geometric mean/Median (n=x)							-			
pH-dependency: y/n							-			

zRMS comments:

Anaerobic soil degradation data for flufenacet has not been evaluated. No major metabolites were detected in soil anaerobic studies.

8.4 Field studies (KCP 9.1.1.2)

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

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

8.4.1.1 Flufenacet and its metabolites

The field dissipation of flufenacet has been evaluated, full details of these studies are provided in the respective EU monograph Annex B.7 (ECCO 73, August 1997) and related documents and summarised in the Review Report for flufenacet (7469/VI/98-Final – 3rd July 2003). ~~Additional studies have been performed to derive suitable modelling input from this data (kinetic evaluation according to Focus kinetics) and are considered as necessary for the risk assessment, the studies are summarised in Appendix 2.~~

Triggering endpoints

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

Flufenacet, Field studies – Triggering endpoints									
Soil type (0 – 30 cm depth)	**Location**	**pH ($CaCl_2$)**	**Depth (cm)**	**$DissT_{50}$ (d) actual**	**DT_{90} (d) actual**	**Kinetic parameters**	**St. (x^2)**	**Method of calculation**	**Evaluated on EU level y/n/ Reference**
sandy loam	Breitenfelde (Germany)	6.2		31					y / Review Report 7469/VI/98-Final – 3rd July 2003
sandy loam	Kirchlauter (Germany)	7.1		53					
sandy loam	Monheim (Germany)	6.7		54					
silt loam	Burscheid (Germany)	6.5		15					
silt loam	Fresne-L'Archeveque (France)	6.0		16					
silt loam	Fresne-L'Archeveque (France)	5.2		38					
loam	Laudun (France)	7.6		30					
loam	St. Etienne du Gres (France)	7.7		34					
silt loam	Saussay La Campagne (France)	7.4		16					
silt loam	Fresne-L'Archeveque (France)	6.6		13					
silt loam	Burscheid (Germany)	6.5		38					
sandy loam	Monheim (Germany)	6.7		43					
clay loam	Laudun (France)	7.7		36					
silt loam	St. Etienne du Gres (France)	7.7		42					
silt loam	Ravenna (Italy)	7.8		38					
silty clay	S. Romualdo (Italy)	7.8		48					
Maximum (n=16)				54					

Table 8.4-2: Summary of aerobic degradation rates for FOE sulfonic acid - field studies: Triggering endpoints

FOE sulfonic acid, Field studies – Triggering endpoints										
Soil type (x)	**Location**	**pH (x)**	**Depth (cm)**	**DissT$_{50}$ (d) actual**	**DT$_{90}$ (d) actual**	**f.f.**	**Kinetic parameters**	**St. (x^2)**	**Method of calculation**	**Evaluated on EU level y/n/ Reference**
-	-	-	-	- [A]	-	-	-	-	-	y / Review report 7469/VI/98-Final – 3rd July 2003
Maximum (n=x)				-	-	-	-			-

[A] error in list of endpoints “metabolites not detected above LOD”, see modelling endpoints below from kinetic evaluation FOE sulfonic acid, field studies.

Modelling endpoints

~~**Table 8.4-3: Summary of aerobic degradation rates for flufenacet - field studies: Modelling endpoints**~~

~~Flufenacet, Field studies – Modelling endpoints~~						
~~**Soil type (0 – 30 cm depth)**~~	~~**Location**~~	~~**pH (x)**~~	~~**Depth (cm)**~~	~~**DT$_{50}$ (d) 20°C, pF2**~~	~~**Fit, Kinetic**~~	~~**Evaluated on EU level y/n/ Reference**~~
~~sandy loam~~	~~Breitenfelde (Germany)~~	~~6.2~~		~~17.1~~		~~n / Appendix 2 Hammel, K.; 2008; M-306683-01-1~~
~~sandy loam~~	~~Kirchlauter (Germany)~~	~~7.1~~		~~33.3~~		
~~sandy loam~~	~~Monheim (Germany)~~	~~6.7~~		~~31.8~~		
~~silt loam~~	~~Burscheid (Germany)~~	~~6.5~~		~~11.4~~		
~~silt loam~~	~~Fresne-L'Archeveque (France)~~	~~6.0~~		~~31.4~~		
~~silt loam~~	~~Fresne-L'Archeveque (France)~~	~~5.2~~		~~32.9~~		
~~loam~~	~~Laudun (France)~~	~~7.6~~		~~24.7~~		
~~loam~~	~~St. Etienne du Gres (France)~~	~~7.7~~		~~37.6~~		
~~silt loam~~	~~Saussay La Campagne (France)~~	~~7.4~~		~~6.0~~		
~~silt loam~~	~~Fresne-L'Archeveque (France)~~	~~6.6~~		~~7.1~~		
~~silt loam~~	~~Burscheid (Germany)~~	~~6.5~~		~~8.5~~		
~~sandy loam~~	~~Monheim (Germany)~~	~~6.7~~		~~14.7~~		
~~clay loam~~	~~Laudun (France)~~	~~7.7~~		~~45.3~~		
~~silt loam~~	~~St. Etienne du Gres (France)~~	~~7.7~~		~~41.0~~		
~~silt loam~~	~~Ravenna (Italy)~~	~~7.8~~		~~36.2~~		
~~silty clay~~	~~S. Romualdo (Italy)~~	~~7.8~~		~~51.1~~		
~~Geometric mean (n=16)~~				~~22.3~~		
~~pH dependency y/n~~				~~n~~		

~~**Table 8.4-4: Summary of aerobic degradation rates for FOE sulfonic acid - field studies: Modelling endpoints**~~

~~FOE sulfonic acid, Field studies – Modelling endpoints~~						
~~**Soil type (x)**~~	~~**Location**~~	~~**pH (x)**~~	~~**Depth (cm)**~~	~~**DT$_{50}$ (d) 20°C, pF2**~~	~~**Fit, Kinetic**~~	~~**Evaluated on EU level y/n/ Reference**~~
~~sandy loam~~	~~Breitenfelde (Germany)~~	~~6.2~~		~~17.7~~		~~n / Appendix 2 Hammel, K.; 2008; M-306683-01-1~~
~~sandy loam~~	~~Kirchlauter (Germany)~~	~~7.1~~		~~19.8~~		
~~sandy loam~~	~~Monheim (Germany)~~	~~6.7~~		~~20.5~~		
~~silt loam~~	~~Burscheid (Germany)~~	~~6.5~~		~~n/a~~		
~~silt loam~~	~~Fresne-L'Archeveque (France)~~	~~6.0~~		~~18.1~~		
~~silt loam~~	~~Fresne-L'Archeveque (France)~~	~~5.2~~		~~20.8~~		
~~loam~~	~~Laudun (France)~~	~~7.6~~		~~n.a.~~		
~~loam~~	~~St. Etienne du Gres (France)~~	~~7.7~~		~~19.6~~		
~~silt loam~~	~~Saussay La Campagne (France)~~	~~7.4~~		~~n.a.~~		
~~silt loam~~	~~Fresne-L'Archeveque (France)~~	~~6.6~~		~~n.a.~~		
~~silt loam~~	~~Burscheid (Germany)~~	~~6.5~~		~~29.8~~		
~~sandy loam~~	~~Monheim (Germany)~~	~~6.7~~		~~n.a.~~		
~~clay loam~~	~~Laudun (France)~~	~~7.7~~		~~21.8~~		
~~silt loam~~	~~St. Etienne du Gres (France)~~	~~7.7~~		~~25.0~~		
~~silt loam~~	~~Ravenna (Italy)~~	~~7.8~~		~~41.4~~		
~~silty clay~~	~~S. Romualdo (Italy)~~	~~7.8~~		~~14.1~~		

FOE sulfonic acid, Field studies – Modelling endpoints						
Soil type (x)	Location	pH (x)	Depth (cm)	DT_{50} (d) 20°C, pF2	Fit, Kinetic	Evaluated on EU level y/n/ Reference
Geometric mean (n=11)				21.7		
pH-dependency y/n				n		

n/a – not assessed

zRMS comments:

Field degradation data for flufenacet presented in Table 8.4-1 are in general in line with the Review Report for flufenacet (7469/VI/98-Final – 3rd July 2003). The kinetic evaluation of soil field degradation data for flufenacet and its metabolite sulfonic acid performed by Hammel (2008) was already evaluated by the RMS in the course of the flufenacet EU renewal process and considered as unreliable. Taking this into account, its results also will not be considered in the assessment performed for FFA SC 508.8 G and the new field degradation data were struck through in Tables 8.4-3 and 8.4-4 above .

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

Flufenacet

The accumulation of flufenacet has been evaluated, full details of these studies are provided in the respective EU monograph Annex B.7 (ECCO 73, August 1997) and related documents and summarised in the Review Report for flufenacet (7469/VI/98-Final – 3rd July 2003). No additional studies have been performed.

Accumulation has been found: "not relevant"

zRMS comments:

Studies on accumulation of flufenacet in soil were not required in the course of the EU review in 2003 and are also deemed not necessary for this zonal evaluation.

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 Laboratory studies (KCP 9.1.2.1)

8.5.1.1 Flufenacet and its metabolites

Column leaching studies for flufenacet were not required for EU registration; no additional studies have been performed.

The soil adsorption/desorption of flufenacet and its metabolites has been evaluated, full details of these studies are provided in the respective EU monograph Annex B.7 (ECCO 73, August 1997) and related documents and summarised in the Review Report for flufenacet (7469/VI/98-Final – 3rd July 2003).
Additional studies have been performed (time dependent sorption of FOE sulfonic acid and adsorption/desorption data for FOE thiadone) and are considered as necessary for the risk assessment, the studies are summarised in Appendix 2.

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

flufenacet							
Soil name	**Soil type**	**OC (%)**	**pH (-)**	**K_f (mL/g)**	**K_{foc} (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
Stanley	Silt loam	1.68	5.9		190	0.84	y / Review report 7469/VI/98-Final – 3rd July 2003
Hagerstown	Clay loam	1.28	6.4		211	0.90	
Howe_1	Loamysand	0.23	6.4		696	0.87	
Vero Beach_1	sand	0.17	5.0		588	0.98	
Monheim	Sandy loam	1.4	6.4		354	0.89	
Harriston	Loam	4.3	7.1		113	0.96	
Brantford	Silt loam	2.8	7.3		144	0.86	
Geometric mean (n=5) Arithmetic mean (n=5)					187 [1] 202 [1]	0.890	
pH-dependency y/n					no		

[1] for OC >0.23%

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

FOE oxalate							
Soil Name	**Soil Type**	**OC (%)**	**pH (-)**	**K_f (mL/g)**	**K_{foc} (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
Vero Beach_2	sand	0.27	5.8		23	1.42	y / Review report 7469/VI/98-Final – 3rd July 2003
Howe_2	Sandy loam	0.75	6.3		13	0.93	
Champaign	Silty clay loam	2.13	6.6		7	0.82	
Stilwell	Silty clay	1.21	6.0		13	0.98	
Geometric mean (n=3) Arithmetic mean (n=3)					11 [1] 11 [1]	0.910	
pH-dependency y/n					n		

[1] for OC >0.27%
~~for OC >0.23%~~

Table 8.5-3: Summary of soil adsorption/desorption for FOE sulfonic acid

FOE sulfonic acid							
Soil Name	**Soil Type**	**OC (%)**	**pH (-)**	**K_f (mL/g)**	**K_{foc} (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
Vero Beach_2	sand	0.27	5.8		19	0.86	y / Review report 7469/VI/98-Final – 3rd July 2003
Howe_2	Sandy loam	0.75	6.3		15	1.00	
Champaign	Silty clay loam	2.13	6.6		10	0.93	
Stilwell	Silty clay	1.21	6.0		6	1.18	
Geometric mean (n=3) Arithmetic mean (n=3)					10 [1] 10 [1]	1.040	
pH-dependency y/n					n		

[1] for OC >0.27%
~~[1] for OC >0.23%~~

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

FOE thiadone							
Soil Name	**Soil Type**	**OC (%)**	**pH (-)**	**K_f (mL/g)**	**K_{foc} (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
Vero Beach, USA	sand	0.27	5.8	0.12	43	0.782	n / Appendix 2 Blumhorst, M. R.; Yen, P. Y.; Marlow, V. A.; 1994; M-002185-01-1
Howe, USA	Sandy loam	0.75	6.3	0.33	44	0.807	
Champaign, USA	Silty clay loam	2.13	6.6	0.61	29	0.673	
Stilwell, USA	Silty clay	1.21	6.0	0.71	58	0.798	
Geometric mean (n=3) Arithmetic mean (n=3)					42.0 43.7 [1]	0.759 [1]	
pH-dependency y/n					n		

[1] for OC >0.27%
~~[1] for OC >0.23%~~

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

FOE methylsulfide							
Soil Name	**Soil Type**	**OC (%)**	**pH (-)**	**K_f (mL/g)**	**K_{foc} (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
-	-	-	-	-	850.5	-	n / the K_{foc} was estimated using PCKOCWIN™ (version 1.66) EPA 2000
-	-	-	-	-	-	0.9	Default FOCUS (2001)

zRMS comments:

Soil adsorption/desorption study for flufenacet and its metabolites (with exception of FOE thiadone and FOE methylsulfide) presented in Tables 8.5-1 to 8.5-3 above are in line with Review Report for flufenacet (7469/VI/98-Final – 3rd July 2003). The geometric mean Kfoc values were included by the zRMS in tables above as they were used for modelling purposes.

It is noted that according to the Review Report, 2003 the mean Kfoc values were calculated from soil types with organic carbon content higher than 0.27% and not 0.23% as it is stated in tables above. The information has been amended accordingly.

For metabolite FOE thiadone the Applicant provided new soil adsorption study which was not previously evaluated. Its submission is justified since no EU agreed sorption data exist for this compound. Nevertheless, the study was not evaluated by the zRMS since it was already considered in the course of the ongoing flufenacet EU renewal process and agreed by the RMS. Since the process is already at the late stage, the Kfoc values reported in the LoEP (version of November 2018) may be considered as peer-reviewed and accepted. It is noted that the geometric mean Kfoc agreed by the RMS is slightly lower (42.1 mL/g), which is a result of rounding procedure. The difference is not expected to have any impact on the modelling results.

No EU agreed sorption data exist for the aquatic metabolite FOE methylsulfide and the Applicant submitted the PCKOCWIN estimation. In the course of the flufenacet renewal process also no study was available and Kfoc was estimated using QSAR. The obtained value (598 mL/g) is lower than this reported in Table 8.5-5 above, however given the low maximum occurrence in the water column (8%) the impact on the calculated PEC_{SW} is expected to be marginal. Furthermore, acceptable risk with large margin of safety could be concluded for this compound already at Step 1 PEC_{SW}, therefore it was decided by the zRMS to accept Kfoc reported in Table 8.5-5 for purposes of evaluation of surface water exposure following the intended uses of FFA SC 508.8 G.

8.5.2 Lysimeter studies (KCP 9.1.2.2)

Flufenacet

Lysimeter studies for flufenacet have been evaluated, full details of these studies are provided in the respective EU monograph Annex B.7 (ECCO 73, August 1997) and related documents and summarised in the Review Report for flufenacet (7469/VI/98-Final – 3rd July 2003). No additional studies have been performed. A brief summary of the studies is presented below.

Results from two lysimeter studies (a corn-corn rotation and a corn-winter wheat rotation) demonstrate that flufenacet will not leach to shallow groundwater at concentrations > 0.1 µg/L. Only one degradation product, FOE sulfonic acid, was found in lysimeter leachate at annual average concentrations of > 0.1 µg/L. However, it could be demonstrated that, the radioactivity in the leachate rapidly declined, after the peak concentration was reached. In the corn-corn rotation the mean concentration of FOE sulfonic acid reached levels of 0.57 µg/L (first year) and 0.24 µg/L (second year), while in the corn-winter wheat rotation maximum annual average levels of 1.49 µg/L (first year) and 0.015 µg/L (second year) were measured.

A comparison of the groundwater modelling and the results of the lysimeter studies shows, that the leaching potential of degradation products of flufenacet is significantly overestimated by simulation runs. The degradation product FOE sulfonic acid has been shown to be non-relevant in groundwater in terms of efficacy and toxicity.

zRMS comments:
Information on results of the lysimeter studies performed with flufenacet is in line with data reported in Review Report for flufenacet (7469/VI/98-Final – 3rd July 2003). Nevertheless, results of the lysimeter studies were not used in evaluation of the leaching potential of flufenacet and its metabolites following intended uses of FFA SC 508.8 G, which was sufficiently addressed in the groundwater modelling presented in point 8.8 of this document.

8.5.3 Field leaching studies (KCP 9.1.2.3)

Flufenacet

Field leaching studies for flufenacet were not required for EU registration; no additional studies have been performed.

zRMS comments:
Potential leaching of the active substance and its metabolites to groundwater has been sufficiently addressed in the groundwater modelling. For details, please see 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 Flufenacet and its metabolites

The degradation of flufenacet in water/sediment systems has been evaluated, full details of these studies are provided in the respective EU monograph Annex B.7 (ECCO 73, August 1997) and related documents and summarised in the Review Report for flufenacet (7469/VI/98-Final – 3rd July 2003). No additional studies have been performed.

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

Flufenacet Distribution (max. water 100% at time zero, max. sediment 34.2% after 30 days)										
Water/ sediment system	**pH water/ sed.**	**$DegT_{50}$ whole syst. (d)**	**$DegT_{90}$ whole syst. (d)**	**Kinetic, Fit**	**$DissT_{50}$ water (d)**	**$DissT_{90}$ water (d)**	**Kinetic, Fit**	**$DissT_{50}$sed. (d)**	**Kinetic, Fit**	**Evaluated on EU level y/n/ Reference**
NESA	7.5/7.9	84.6	281	SFO	61.7	205				y / Review report 7469/VI/98-Final – 3rd July 2003
BRP	7.3/7.8	76.4	254	SFO	46.3	154				
NESA	7.2/7.8	20	67							
BRP	6.9/7.8	31	104							
Geometric mean (n=4)		44.7								

Table 8.6-2: Summary of observed metabolites

FOE methylsulfide Water/sediment system	Max. in water 8% after 157 d /sediment 3.4% after 157 d (fluorophenyl)	y / review report 7469/VI/98-Final – 3rd July 2003
FOE thiadone Water/sediment system	Max. in water 82% after 55 d (thiadiazole)	y / review report 7469/VI/98-Final – 3rd July 2003

zRMS comments:

Information on degradation of flufenacet and its metabolites in water/sediment systems presented in Tables 8.6-1 and 8.6-2 above is in line with Review Report for flufenacet (7469/VI/98-Final – 3rd July 2003).

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

8.7.1 Justification for new endpoints

No deviation from the EU agreed endpoints for flufenacet and its relevant metabolites.

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

PEC_{soil} reports provided by the applicant are listed in Appendix 3.1.

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

Use No.	29;30;33;34;37;38;89;90;93;94;129;130; 53;54;57;58;61;62;97;98;101;102;133;134; 65;66;69;70;73;74;105;106;109;110;137; 138;77;78;81;82;85;86;113;114;117;118;141;142	31;32;35;36;39;40;91;92;95;96;131;132; 55;56;59;60;63;64;99;100;103;104;135; 136;67;68;71;72;75;76;107;108;111;112; 139;140;79;80;83;84;87;88;115;116;119; 120;143;144
Crop	Winter cereals I	Winter cereals II
Application rate (g as/ha)	Flufenacet: 244.2	Flufenacet: 122.1
Number of applications/interval	1 / -	1 / -
Crop interception (%)	0	0
Depth of soil layer (relevant for plateau concentration) (cm)	5 cm (no tillage)/ 20 cm (tillage)	5 cm (no tillage)/ 20 cm (tillage)

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 (%)	DT_{50} (days)	Value in accordance to EU endpoint y/n/ Reference
Flufenacet	363.30	100	54.0 (SFO, maximum, field studies, non-normalised, n=16)	Y / Review Report 7469/VI/98-Final -3rd July 2003
Flufenacet sulfonic acid	275.30	26.3	270 (SFO, maximum, lab studies, non-normalised, n=5)	
Flufenacet oxalate	225.20	15.6	17 (SFO, maximum, lab studies, non-normalised, n=3)	

8.7.2.1 Flufenacet and its metabolites

PEC_{soil} of flufenacet

Table 8.7-3: PEC_{soil} for flufenacet on Winter Cereals I, 1×244.2 g a.s./ha, 0% interception

PEC_{soil} (mg/kg)		Winter Cereals I			
		Single application		~~Multiple applications~~	
		Actual	TWA	~~Actual~~	~~TWA~~
Initial		0.326	-	~~0.326~~	-
Short term	24h	0.321	0.324	~~0.321~~	~~0.324~~
	2d	0.317	0.321	~~0.317~~	~~0.321~~
	4d	0.309	0.317	~~0.309~~	~~0.317~~
Long term	7d	0.298	0.311	~~0.298~~	~~0.311~~
	14d	0.272	0.298	~~0.272~~	~~0.298~~
	21d	0.249	0.285	~~0.249~~	~~0.285~~
	28d	0.227	0.274	~~0.227~~	~~0.274~~
	42d	0.190	0.252	~~0.190~~	~~0.252~~
	50d	0.171	0.240	~~0.171~~	~~0.240~~
	100d	0.090	0.183	~~0.090~~	~~0.183~~
Plateau concentration (20 cm) after year 1		<0.001	-	~~<0.001~~	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		0.326		~~0.326~~	

Table 8.7-4: PEC_{soil} for flufenacet on Winter Cereals II, 1×122.1 g a.s./ha, 0% interception

PEC_{soil} (mg/kg)		Winter Cereals II			
		Single application		~~Multiple applications~~	
		Actual	TWA	~~Actual~~	~~TWA~~
Initial		0.163	-	~~0.163~~	-
Short term	24h	0.161	0.162	~~0.161~~	~~0.162~~
	2d	0.159	0.161	~~0.159~~	~~0.161~~
	4d	0.155	0.159	~~0.155~~	~~0.159~~
Long term	7d	0.149	0.156	~~0.149~~	~~0.156~~
	14d	0.136	0.149	~~0.136~~	~~0.149~~
	21d	0.124	0.143	~~0.124~~	~~0.143~~
	28d	0.114	0.137	~~0.114~~	~~0.137~~
	42d	0.095	0.126	~~0.095~~	~~0.126~~
	50d	0.086	0.120	~~0.086~~	~~0.120~~
	100d	0.045	0.092	~~0.045~~	~~0.092~~
Plateau concentration (20 cm) after year 1		<0.001	-	~~<0.001~~	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		0.163		~~0.163~~	

PEC_{soil} of metabolites

FOE sulfonic acid

Table 8.7-5: PEC_{soil} for FOE sulfonic acid on Winter Cereals I, 1×244.2 g a.s./ha, 0% interception

PEC_{soil} (mg/kg)		Winter Cereals I			
		Single application		~~Multiple applications~~	
		Actual	TWA	~~Actual~~	~~TWA~~
Initial		0.065	-	~~0.065~~	~~-~~
Short term	24h	0.065	0.065	~~0.065~~	~~0.065~~
	2d	0.065	0.065	~~0.065~~	~~0.065~~
	4d	0.064	0.065	~~0.064~~	~~0.065~~
Long term	7d	0.064	0.064	~~0.064~~	~~0.064~~
	14d	0.063	0.064	~~0.063~~	~~0.064~~
	21d	0.061	0.063	~~0.061~~	~~0.063~~
	28d	0.060	0.063	~~0.060~~	~~0.063~~
	42d	0.058	0.062	~~0.058~~	~~0.062~~
	50d	0.057	0.061	~~0.057~~	~~0.061~~
	100d	0.050	0.057	~~0.050~~	~~0.057~~
Plateau concentration (20 cm) after year 3		0.010	-	~~0.010~~	~~-~~
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		0.075		~~0.075~~	

Table 8.7-6: PEC_{soil} for FOE sulfonic acid on Winter Cereals II, 1×122.1 g a.s./ha, 0% interception

PEC_{soil} (mg/kg)		Winter Cereals II			
		Single application		~~Multiple applications~~	
		Actual	TWA	~~Actual~~	~~TWA~~
Initial		0.032	-	~~0.032~~	~~-~~
Short term	24h	0.032	0.032	~~0.032~~	~~0.032~~
	2d	0.032	0.032	~~0.032~~	~~0.032~~
	4d	0.032	0.032	~~0.032~~	~~0.032~~
Long term	7d	0.032	0.032	~~0.032~~	~~0.032~~
	14d	0.031	0.032	~~0.031~~	~~0.032~~
	21d	0.031	0.032	~~0.031~~	~~0.032~~
	28d	0.030	0.031	~~0.030~~	~~0.031~~
	42d	0.029	0.031	~~0.029~~	~~0.031~~
	50d	0.029	0.030	~~0.029~~	~~0.030~~
	100d	0.025	0.029	~~0.025~~	~~0.029~~
Plateau concentration (20 cm) after year 3		0.005	-	~~0.005~~	~~-~~
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		0.038		~~0.038~~	

FOE oxalate

Table 8.7-7: PEC$_{soil}$ for FOE oxalate on Winter Cereals I, 1×244.2 g a.s./ha, 0% interception

PEC$_{soil}$ (mg/kg)		**Winter Cereals I**			
		Single application		~~**Multiple applications**~~	
		Actual	**TWA**	~~**Actual**~~	~~**TWA**~~
Initial		0.031	-	~~0.031~~	~~-~~
Short term	24h	0.030	0.031	~~0.030~~	~~0.031~~
	2d	0.029	0.030	~~0.029~~	~~0.030~~
	4d	0.027	0.029	~~0.027~~	~~0.029~~
Long term	7d	0.024	0.027	~~0.024~~	~~0.027~~
	14d	0.018	0.024	~~0.018~~	~~0.024~~
	21d	0.013	0.021	~~0.013~~	~~0.021~~
	28d	0.010	0.019	~~0.010~~	~~0.019~~
	42d	0.006	0.015	~~0.006~~	~~0.015~~
	50d	0.004	0.013	~~0.004~~	~~0.013~~
	100d	<0.001	0.008	~~<0.001~~	~~0.008~~
Plateau concentration (20 cm) after year 0		<0.001	-	~~<0.001~~	~~-~~
PEC$_{accumulation}$ (PEC$_{act}$ +PEC$_{soil\ plateau}$)		0.031		~~0.031~~	

Table 8.7-8: PEC$_{soil}$ for FOE oxalate on Winter Cereals II, 1×122.1 g a.s./ha, 0% interception

PEC$_{soil}$ (mg/kg)		**Winter Cereals II**			
		Single application		~~**Multiple applications**~~	
		Actual	**TWA**	~~**Actual**~~	~~**TWA**~~
Initial		0.016	-	~~0.016~~	~~-~~
Short term	24h	0.015	0.015	~~0.015~~	~~0.015~~
	2d	0.015	0.015	~~0.015~~	~~0.015~~
	4d	0.013	0.015	~~0.013~~	~~0.015~~
Long term	7d	0.012	0.014	~~0.012~~	~~0.014~~
	14d	0.009	0.012	~~0.009~~	~~0.012~~
	21d	0.007	0.011	~~0.007~~	~~0.011~~
	28d	0.005	0.009	~~0.005~~	~~0.009~~
	42d	0.003	0.008	~~0.003~~	~~0.008~~
	50d	0.002	0.007	~~0.002~~	~~0.007~~
	100d	<0.001	0.004	~~<0.001~~	~~0.004~~
Plateau concentration (20 cm) after year 0		<0.001	-	~~<0.001~~	~~-~~
PEC$_{accumulation}$ (PEC$_{act}$ +PEC$_{soil\ plateau}$)		0.016		~~0.016~~	

zRMS comments:

The application pattern considered in soil exposure assessment and presented in Table 8.7-1 is in line with the critical Central Zone GAP and it is thus agreed by the zRMS.

Input parameters for flufenacet and its metabolites presented in Table 8.7-2 are in line with parameters reported in Review Report for flufenacet (7469/VI/98-Final – 3rd July 2003).

The soil exposure for flufenacet and its metabolites has been independently validated by the zRMS using FOCUS methods. The pseudo-application rates of metabolite were derived with consideration of the parent rate, molar ratio and peak occurrence in soil. The calculated PEC$_{SOIL}$ values for the parent and metabolites were in good agreement with these obtained by the Applicant. Therefore, results reported in tables above may be used for the soil risk assessment purposes.

The results for multiple applications were struck through in tables above since only single application is intended for FFA SC 508.8 G.

8.7.2.2 PEC_{soil} of FFA SC 508.8

PEC_{soil} is calculated using a standard approach with 5 cm mixing depth and soil density of 1.5 kg/L. All loadings are considered to occur in a single pseudo-application. No degradation data is available for the product. Therefore, TWA, plateau, and accumulation concentrations are not calculated, and tillage depth is not relevant here.

Table 8.7-9: PEC_{soil} for FFA SC 508.8 on Winter Cereals

Active substance/ reparation	Application rate (g/ha)	PEC_{act} (mg/kg)	PEC_{twa}21 d (mg/kg)	Tillage depth (cm)	$PEC_{soil,plateau}$ (mg/kg)	PEC_{accu} = PEC_{act} + $PEC_{soil,plateau}$ (mg/kg)
FFA SC 508.8 1)	0.48	0.776	-	-	-	-
	0.24	0.388	-	-	-	-

- = Not applicable
1) the PEC for the formulation was based on a specific density of 1.213 g/mL with maximum applications of 0.24 and 0.48 L/ha and an interception rate of 0% representing the maximum use in GAP.

zRMS comments:

Soil exposure calculated by the Applicant for the formulated product is agreed by the zRMS.

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

8.8.1 Justification for new endpoints

Table 8.8-1: Justification for new endpoints (flufenacet and metabolites)

Compound	Parameter	EU endpoint	Used endpoint	Justification
Flufenacet	DT_{50} in soil (d)	16.5 (geometric mean DT_{50} lab, normalised to pF2, 20 °C with Q_{10} of 2.2, n=3) ~~No value stated for modelling input value~~	16.5 (geometric mean DT_{50} lab, normalised to pF2, 20 °C with Q_{10} of 2.2, n=3)	y / DAR Addendum 2003
	K_{foc} (mL/g) / K_{fom}	202.0 / 117.2 (arith. mean, n=5)	187.0 / 109.0 (geomean, n=5)	Geometric mean to replace arithmetic mean following actual EFSA Guidance (EFSA Journal 2014; 12(5):3662). Soils with an OC content < 0.3% were excluded from the calculation.
	Plant uptake factor	No value stated	0.0	Application of FOCUS gw guidance (SANCO/321/2000 rev.2, Nov 2000): default of zero or 0.5 for systemic substances; zero in case of field DT_{50} (Tier 2)
FOE sulfonic acid	-	-	-	Adoption of the guidance document on the relevance of metabolites (Sanco/221/2000 –rev.10- final 25 February 2003) made the refinement of the FOE sulfonic acid soil half-life necessary to address the risk assessment.
	DT_{50} in soil (d)	232.7 (SFO, geomean, lab, n=3)	Tier 1: 140 (geomean, lab normalisation to pF2, 20 °C with Q_{10} of 2.2, n =3) Tier 2: 31.62 (geomean, lab normalisation to pF2, 20 °C with Q_{10} of 2.2, n =18) ~~Tier 2: 21.7 (geomean, field normalisation to pF2, 20 °C with Q_{10} of 2.2, n =11)~~	Tier 1: DAR Addendum 2003 ~~Tier 1 is based only on Hellpointer (1996) ;~~ Tier 2: LoEP, November 2018 (not yet issued as an official document, but already after EFSA correction for drawing a conclusion) ~~Tier 2: The technique of inverse modelling made it possible to use the 1995 field study data to derive meaningful half lives for FOE sulfonic acid to refine the groundwater leaching risk assessment.~~ ~~According to recommendations from EFSA DegT50 guidance (EFSA 2014), the geometric mean DT50 values of 21.7 days instead of the median value of 20.5 days is used in Tier 2 for metabolite FOE sulfonic acid.~~
	K_{foc} (mL/g) / K_{fom}	10 / 5.8 (arith. mean, n=3)	10 / 5.8 (geomean, n=3)	Geometric mean to replace arithmetic mean following actual EFSA Guidance (EFSA Journal 2014; 12(5):3662). Soils with an OC content < 0.3% were excluded from the calculation. Geometric mean and arithmetic mean result in the same values.

Compound	Parameter	EU endpoint	Used endpoint	Justification
FOE oxalate	DT_{50} in soil (d)	10.0 (SFO, geomean, lab., n=3)	6.6 (SFO, geomean, lab, normalised to pF2, 20 °C with Q_{10} of 2.2, n=3)	Application of Focus gw guidance (SANCO/321/2000 rev.2, Nov 2000): modelling endpoint based on kinetic evaluation of Schaefer, H.; 1998; M-004479-02-1 [1].
	K_{foc} (mL/g) / K_{fom}	11.0 / 6.4 (arith. mean, n=3)	11.0 / 6.4 (geomean, n=3)	Geometric mean to replace arithmetic mean following actual EFSA Guidance (EFSA Journal 2014; 12(5):3662). Soils with an OC content < 0.3% were excluded from the calculation. Geometric mean and arithmetic mean result in the same values.

[1] 1998 amendment evaluated at EU level (Review Report 7469/VI/98-Final – 3rd July 2003). but not in EU monograph Annex B.7 (ECCO 73, August 1997), therefore summarized in Appendix 2

zRMS comments:

The zRMS has following comments regarding the new endpoint proposed by the Applicant for flufenacet and its metabolites:

- Soil DT_{50} of 16.5 days proposed by the Applicant for flufenacet is actually EU agreed value reported in Flufenacet Addendum (Volume 3, B.7, Environmental Fate) of January 2003 (14377/ECCO/BVL/03). Respective information has been included in Table 8.8-1 above.
- For flufenacet and its metabolites the geometric mean instead of the arithmetic Kfoc values reported in the Review Report (7469/VI/98-Final – 3rd July 2003) were used. This deviations is agreed by the zRMS as the geometric mean Kfoc values are lower than arithmetic mean and represent thus worst case in terms of the leaching potential. Moreover consideration of geometric mean Kfoc values is in line with current EFSA recommendations. The geometric mean values calculated by the Applicant were based on the currently EU agreed individual values and are confirmed to be correct.
- For FOE sulfonic acid the Applicant proposed to use soil DT_{50} of 21.7 d at Tier 2 which is not agreed by the RMS (see commenting box in point 8.8.2 below for more details). The zRMS proposes to use the DT_{50} of 31.62 d, agreed in the course of the flufenacet EU renewal process, being is already at the final stage. Therefore the value proposed by the zRMS may be considered as peer-reviewed and agreed, especially it is reported in the LoEP (November 2018), already corrected by EFSA for drawing the final conclusions.
- The soil DT_{50} of 6.6 days proposed by the Applicant for FOE oxalate is taken from the Flufenacet Addendum (Volume 3, B.7, Environmental Fate) of January 2003 (14377/ECCO/BVL/03) and is thus agreed by the zRMS.

Not agreed new input values were struck through in Table 8.8-1 above.

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

PEC_{gw} reports provided by the applicant are listed in Appendix 3.2.

Table 8.8-2: Input parameters related to application for PEC_{gw} calculations

Use No.	29;33;37;89;93;129;53; 57;61;97;101;133;65; 69;73;105;109137;77;81; 85;113;117;141	30;34;38;90;94;130; 54;58;62;98;102;134; 66;70;74;106;110; 138;78;82;86;114; 118;142	31;35;39;91;95;131; 55;59;63;99;103; 135;67;71;75;107; 111;139;79;83;87; 115;119;143	32:36:40:92:96:132; 56;60;64;100;104;136; 68;72;76;108;112;140; 80;84;88;116;120;144
Crop	Winter cereals I (pre-emg.)	Winter cereals II (early post-emg.)	Winter cereals III (pre-emg.)	Winter cereals IV (early post-emg.)
Application rate (g as/ha)	Flufenacet: 244.2	Flufenacet: 244.2	Flufenacet: 122.1	Flufenacet: 122.1
Number of applications/interval (d)	1 / -	1 / -	1 / -	1 / -
Relative application date	Absolute dates are given in table below	Absolute dates are given in table below	Absolute dates are given in table below	Absolute dates are given in table below

Crop interception (%)	0	0 ~~20~~	0	0
Frequency of application	annual	annual	annual	annual
Models used for calculation	FOCUS PEARL v4.4.4, FOCUS PELMO v5.5.3, FOCUS MACRO v5.5.4	FOCUS PEARL v4.4.4, FOCUS PELMO v5.5.3, FOCUS MACRO v5.5.4	FOCUS PEARL v4.4.4, FOCUS PELMO v5.5.3, FOCUS MACRO v5.5.4	FOCUS PEARL v4.4.4, FOCUS PELMO v5.5.3, FOCUS MACRO v5.5.4

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

Crop	Scenario	Application dates (absolute) 1)
Winter cereals I (pre-emg.) Flufenacet: 1×244.2 g a.s./ha BBCH: 00-09	Châteaudun	19 Oct (292)
	Hamburg	25 Oct (298)
	Jokioinen	13 Sep (256)
	Kremsmünster	29 Oct (302)
	Okehampton	10 Oct (283)
	Piacenza	24 Nov (328)
	Porto	23 Nov (327)
	Sevilla	23 Nov (327)
	Thiva	23 Nov (327)
Winter cereals II (early post-emg.) Flufenacet: 1×244.2 g a.s./ha BBCH: 10-13	Châteaudun	02 Nov (306)
	Hamburg	08 Nov (312)
	Jokioinen	27 Sep (270)
	Kremsmünster	12 Nov (316)
	Okehampton	24 Oct (297)
	Piacenza	08 Dec (342)
	Porto	07 Dec (341)
	Sevilla	07 Dec (341)
	Thiva	07 Dec (341)
Winter cereals III (pre-emg.) Flufenacet: 1×122.1 g a.s./ha BBCH: 00-09	Châteaudun	19 Oct (292)
	Hamburg	25 Oct (298)
	Jokioinen	13 Sep (256)
	Kremsmünster	29 Oct (302)
	Okehampton	10 Oct (283)
	Piacenza	24 Nov (328)
	Porto	23 Nov (327)
	Sevilla	23 Nov (327)
	Thiva	23 Nov (327)
Winter cereals IV (early post-emg.) Flufenacet: 1×122.1 g a.s./ha BBCH: 10-13	Châteaudun	02 Nov (306)
	Hamburg	08 Nov (312)
	Jokioinen	27 Sep (270)
	Kremsmünster	12 Nov (316)
	Okehampton	24 Oct (297)
	Piacenza	08 Dec (342)
	Porto	07 Dec (341)
	Sevilla	07 Dec (341)
	Thiva	07 Dec (341)

1) Value in brackets indicate "Julian Day"

zRMS comments:

The input parameters related to the application pattern presented in Table 8.8-2 are in general agreed by the zRMS.

It is, however, noted that for all intended application timing the crop interception of 0% should be assumed in line with indication of the FOCUS groundwater guidance (2021). to 0%. Therefore, information in Table 8.8-2 was amended accordingly. Nevertheless, this seems to by a typing error, as according to the modelling reports the PEC_{GW} values were calculated with consideration of 0% crop interception.

It is noted that the application dates presented in Table 8.8-3 differ from dates suggested by the last version of AppDate (Version 3.06 of 28 June 2019). Since the dates considered by the Applicant are also possible, they are retained for information of the cMS while dates suggested by AppDate are reported below. The cMS may chose the dates most relevant for their countries.

Crop	Scenario	Application dates (absolute) [1)]
Winter cereals (pre-emg.) Flufenacet: 1×244.2 g a.s./ha and 1×122.1 g a.s./ha BBCH: 00-09	Châteaudun	20 Oct (293)
	Hamburg	12 Oct (285)
	Jokioinen	10 Sep (253)
	Kremsmünster	25 Oct (298)
	Okehampton	7 Oct (280)
	Piacenza	25 Nov (329)
	Porto	15 Nov (319)
	Sevilla	15 Nov (319)
	Thiva	15 Nov (319)
Winter cereals (early post-emg.) Flufenacet: 1×244.2 g a.s./ha and 1×122.1 g a.s./ha BBCH: 10-13	Châteaudun	27 Oct (300)
	Hamburg	2 Nov (306)
	Jokioinen	21 Sep (264)
	Kremsmünster	6 Nov (310)
	Okehampton	18 Oct (291)
	Piacenza	2 Dec (336)
	Porto	1 Dec (335)
	Sevilla	1 Dec (335)
	Thiva	1 Dec (335)

[1)] Values in brackets indicate "Julian Day"

8.8.2.1 Flufenacet and its metabolites

Table 8.8-4: Input parameters related to active substance flufenacet and metabolites for PEC_{gw} calculations

Compound	Flufenacet	Flufenacet sulfonic acid	Flufenacet oxalate	Value in accordance with EU endpoint y/n/ Reference
Molecular weight (g/mol)	363.3	275.3	225.2	Y / Review Report 2003
Water solubility (mg/L)	56.0 (20 °C in PEARL, 20 & 30°C in PELMO [b])	1000 (20 °C)	1000 (20 °C)	
Saturated vapour pressure (Pa)	9.0×10^{-5} (20 °C in PEARL, 20 & 30°C in PELMO [b])	0.0 (20 °C)	0.0 (20 °C)	

Compound	Flufenacet	Flufenacet sulfonic acid	Flufenacet oxalate	Value in accordance with EU endpoint y/n/ Reference
DT_{50} in soil (d)	16.5 (geomean, lab, normalisation to pF2, 20 °C with Q_{10} of 2.2, n=3)	Tier 1a: 140 (geomean, lab normalisation to pF2, 20 °C with Q_{10} of 2.2, n =3) Tier 2: 31.62 (geomean, lab normalisation to pF2, 20 °C with Q_{10} of 2.2, n =18) ~~Tier 2: 21.7 (geomean, field normalisation to pF2, 20 °C with Q10 of 2.2, n =11)~~	6.6 (geomean, lab, normalisation to pF2, 20 °C with Q_{10} of 2.2, n=3)	Tier 1a: Y / Review Report 2003 LoEP, November 2018 (not yet issued as an official document, but already after EFSA correction for drawing a conclusion) ~~Tier 2: N / KCA 7.1.2.2/01 Hammel 2008, see Appendix 2.3~~
K_{foc} (mL/g)/K_{fom}	187.0 / 109.0 [a] (geometic mean, n=5)	10 / 5.8 [a] (geometic mean, n=3)	11.0 / 6.4 [a] (geometic mean, n=3)	Y / Review Report 2003
1/n	0.890 (arithmetic mean, n=5)	1.040 (arithmetic mean, n=3)	0.910 (arithmetic mean, n=3)	
Plant uptake factor	0.0	0.0	0.0	
Formation fraction	-	0.26 from parent	0.47 from parent	

* Parameters not reported were left to their FOCUS default values

[a] According to FOCUS GW 2014 and EFSA 2014, geometric mean Kfoc of 187 mL/g for flufenacet should have been used. For metabolites, geometric mean and arithmetic mean result in the same values.

[b] Using the same values at both temperatures is not a conservative approach. However, in this case no significant impact on the outcome of the risk assessment is expected.

Tier 1a – PECgw for flufenacet and metabolites

Table 8.8-5: PEC_{gw} for flufenacet and its metabolites on winter cereals I (pre-emg.) (with FOCUS PEARL/PELMO/MACRO) – 1×244.2 g a.s./ha, 0% interception

Crop	Scenario	80th percentile PEC_{gw} at 1 m soil depth (µg/L)					
		Flufenacet		FOE sulfonic acid		FOE oxalate	
		PEARL	PELMO	PEARL	PELMO	PEARL	PELMO
Winter Cereals I (pre-emg.)	Chateaudun	<0.001	<0.001	18.06	15.45	0.018	0.021
	Hamburg	<0.001	<0.001	17.23	16.60	0.280	0.462
	Jokioinen	<0.001	<0.001	28.63	20.07	0.205	0.389
	Kremsmuenster	<0.001	<0.001	10.67	12.35	0.047	0.062
	Okehampton	<0.001	<0.001	9.531	9.536	0.299	0.414
	Piacenza	<0.001	<0.001	10.40	13.36	0.041	0.143
	Porto	<0.001	<0.001	8.218	7.539	0.270	0.745
	Sevilla	<0.001	<0.001	8.647	6.279	<0.001	0.052
	Thiva	<0.001	<0.001	19.23	11.77	0.003	0.017
		MACRO		MACRO		MACRO	
	Châteaudun	<0.001		16.18		0.028	

Table 8.8-6: PEC_{gw} for flufenacet and its metabolites on winter cereals II (early post-emg.) (with FOCUS PEARL/PELMO/MACRO) – 1×244.2 g a.s./ha, 0% interception

Crop	Scenario	80th percentile PEC_{gw} at 1 m soil depth (µg/L)					
		Flufenacet		FOE sulfonic acid		FOE oxalate	
		PEARL	PELMO	PEARL	PELMO	PEARL	PELMO
Winter Cereals II (early post-emg.)	Chateaudun	<0.001	<0.001	17.74	15.49	0.012	0.015
	Hamburg	<0.001	<0.001	17.20	16.35	0.206	0.336
	Jokioinen	<0.001	<0.001	28.41	19.88	0.188	0.373
	Kremsmuenster	<0.001	<0.001	10.60	12.58	0.036	0.051
	Okehampton	<0.001	<0.001	9.712	8.993	0.249	0.380
	Piacenza	<0.001	<0.001	10.33	13.09	0.029	0.130
	Porto	<0.001	<0.001	8.488	7.870	0.182	0.508
	Sevilla	<0.001	<0.001	8.111	5.695	<0.001	0.006
	Thiva	<0.001	<0.001	18.45	11.38	0.001	0.009
		MACRO		MACRO		MACRO	
	Châteaudun	<0.001		15.49		0.019	

Table 8.8-7: PEC_{gw} for flufenacet and its metabolites on winter cereals III (pre-emg.) (with FOCUS PEARL/PELMO/MACRO) – 1×122.1 g a.s./ha, 0% interception

Crop	Scenario	80th percentile PEC_{gw} at 1 m soil depth (µg/L)					
		Flufenacet		FOE sulfonic acid		FOE oxalate	
		PEARL	PELMO	PEARL	PELMO	PEARL	PELMO
Winter Cereals III (pre-emg.)	Chateaudun	<0.001	<0.001	9.075	7.788	0.007	0.009
	Hamburg	<0.001	<0.001	8.645	8.325	0.119	0.198
	Jokioinen	<0.001	<0.001	14.37	10.10	0.084	0.163
	Kremsmuenster	<0.001	<0.001	5.345	6.229	0.020	0.027
	Okehampton	<0.001	<0.001	4.771	4.792	0.133	0.188
	Piacenza	<0.001	<0.001	5.229	6.732	0.018	0.063
	Porto	<0.001	<0.001	4.109	3.819	0.119	0.332
	Sevilla	<0.001	<0.001	4.347	3.191	<0.001	0.023
	Thiva	<0.001	<0.001	9.643	5.934	0.001	0.007
		MACRO		MACRO		MACRO	
	Châteaudun	<0.001		8.135		0.012	

Table 8.8-8: PEC_{gw} for flufenacet and its metabolites on winter cereals IV (early post-emg.) (with FOCUS PEARL/PELMO/MACRO) – 1×122.1 g a.s./ha, 0% interception

Crop	Scenario	80th percentile PEC_{gw} at 1 m soil depth (µg/L)					
		Flufenacet		FOE sulfonic acid		FOE oxalate	
		PEARL	PELMO	PEARL	PELMO	PEARL	PELMO
Winter Cereals IV (early post-emg.)	Chateaudun	<0.001	<0.001	8.914	7.799	0.005	0.006
	Hamburg	<0.001	<0.001	8.630	8.219	0.087	0.145
	Jokioinen	<0.001	<0.001	14.26	10.01	0.077	0.156
	Kremsmuenster	<0.001	<0.001	5.313	6.312	0.015	0.022
	Okehampton	<0.001	<0.001	4.864	4.516	0.111	0.168
	Piacenza	<0.001	<0.001	5.173	6.573	0.012	0.056
	Porto	<0.001	<0.001	4.245	3.968	0.080	0.226
	Sevilla	<0.001	<0.001	4.077	2.877	<0.001	0.002
	Thiva	<0.001	<0.001	9.247	5.745	<0.001	0.004
		MACRO		MACRO		MACRO	
	Châteaudun	<0.001		7.790		0.008	

Tier 2 – PECgw for flufenacet and metabolites

Table 8.8-9: PEC$_{gw}$ for flufenacet and its metabolites on winter cereals i (pre-emg.) (with FOCUS PEARL/PELMO/MACRO) – 1×244.2 g a.s./ha, 0% interception

Crop	Scenario	80th percentile PEC$_{gw}$ at 1 m soil depth (µg/L)					
		Flufenacet		FOE sulfonic acid		FOE oxalate	
		PEARL	PELMO	PEARL	PELMO	PEARL	PELMO
Winter Cereals I (pre-emg.)	Chateaudun	<0.001	<0.001	1.169	0.895	0.018	0.021
	Hamburg	<0.001	<0.001	3.447	3.711	0.280	0.462
	Jokioinen	<0.001	<0.001	5.241	5.241	0.205	0.389
	Kremsmuenster	<0.001	<0.001	1.697	1.861	0.047	0.062
	Okehampton	<0.001	<0.001	2.821	2.980	0.299	0.414
	Piacenza	<0.001	<0.001	1.022	1.391	0.041	0.143
	Porto	<0.001	<0.001	1.962	2.665	0.270	0.745
	Sevilla	<0.001	<0.001	0.056	0.411	<0.001	0.052
	Thiva	<0.001	<0.001	0.401	0.421	0.003	0.017
		MACRO		MACRO		MACRO	
	Châteaudun	<0.001		1.154		0.028	

Table 8.8-10: PEC$_{gw}$ for flufenacet and its metabolites on winter cereals ii (early post-emg.) (with FOCUS PEARL/PELMO/MACRO) – 1×244.2 g a.s./ha, 0% interception

Crop	Scenario	80th percentile PEC$_{gw}$ at 1 m soil depth (µg/L)					
		Flufenacet		FOE sulfonic acid		FOE oxalate	
		PEARL	PELMO	PEARL	PELMO	PEARL	PELMO
Winter Cereals II (early post-emg.)	Chateaudun	<0.001	<0.001	1.027	0.761	0.012	0.015
	Hamburg	<0.001	<0.001	3.065	3.479	0.206	0.336
	Jokioinen	<0.001	<0.001	4.781	4.889	0.188	0.373
	Kremsmuenster	<0.001	<0.001	1.598	1.821	0.036	0.051
	Okehampton	<0.001	<0.001	2.588	2.778	0.249	0.380
	Piacenza	<0.001	<0.001	0.922	1.211	0.029	0.130
	Porto	<0.001	<0.001	1.551	2.389	0.182	0.508
	Sevilla	<0.001	<0.001	0.037	0.105	<0.001	0.006
	Thiva	<0.001	<0.001	0.293	0.295	0.001	0.009
		MACRO		MACRO		MACRO	
	Châteaudun	<0.001		0.871		0.019	

Table 8.8-11: PEC$_{gw}$ for flufenacet and its metabolites on winter cereals iii (pre-emg.) (with FOCUS PEARL/PELMO/MACRO) – 1×122.1 g a.s./ha, 0% interception

Crop	Scenario	80th percentile PEC$_{gw}$ at 1 m soil depth (µg/L)					
		Flufenacet		FOE sulfonic acid		FOE oxalate	
		PEARL	PELMO	PEARL	PELMO	PEARL	PELMO
Winter Cereals III (pre-emg.)	Chateaudun	<0.001	<0.001	0.590	0.454	0.007	0.009
	Hamburg	<0.001	<0.001	1.737	1.872	0.119	0.198
	Jokioinen	<0.001	<0.001	2.687	2.671	0.084	0.163
	Kremsmuenster	<0.001	<0.001	0.854	0.947	0.020	0.027
	Okehampton	<0.001	<0.001	1.424	1.504	0.133	0.188
	Piacenza	<0.001	<0.001	0.512	0.707	0.018	0.063
	Porto	<0.001	<0.001	0.983	1.336	0.119	0.332
	Sevilla	<0.001	<0.001	0.028	0.208	<0.001	0.023
	Thiva	<0.001	<0.001	0.201	0.214	0.001	0.007
		MACRO		MACRO		MACRO	
	Châteaudun	<0.001		0.579		0.012	

Table 8.8-12: PEC_{gw} for flufenacet and its metabolites on winter cereals iv (early post-emg.) (with FOCUS PEARL/PELMO/MACRO) – 1×122.1 g a.s./ha, 0% interception

Crop	Scenario	80[th] percentile PEC_{gw} at 1 m soil depth (µg/L)					
		Flufenacet		FOE sulfonic acid		FOE oxalate	
		PEARL	PELMO	PEARL	PELMO	PEARL	PELMO
Winter Cereals IV (early post-emg.)	Chateaudun	<0.001	<0.001	0.518	0.387	0.005	0.006
	Hamburg	<0.001	<0.001	1.542	1.755	0.087	0.145
	Jokioinen	<0.001	<0.001	2.453	2.484	0.077	0.156
	Kremsmuenster	<0.001	<0.001	0.803	0.917	0.015	0.022
	Okehampton	<0.001	<0.001	1.302	1.401	0.111	0.168
	Piacenza	<0.001	<0.001	0.463	0.611	0.012	0.056
	Porto	<0.001	<0.001	0.776	1.201	0.080	0.226
	Sevilla	<0.001	<0.001	0.019	0.054	<0.001	0.002
	Thiva	<0.001	<0.001	0.147	0.149	<0.001	0.004
		MACRO		MACRO		MACRO	
	Châteaudun	<0.001		0.439		0.008	

Based on Tier 2:
- PEC_{gw} for flufenacet are below 0.1 µg/L in all scenarios;
- PEC_{gw} for flufenacet sulfonic acid exceed 0.1 µg/L in most scenarios (max. 5.241 µg/L);
- PEC_{gw} for flufenacet oxalate exceed 0.1 µg/L in some scenarios (max. 0.745 µg/L).

Please refer to Section 10 for the assessment of the relevance of flufenacet metabolites.

zRMS comments:

Input parameters used for groundwater modelling for flufenacet and its metabolites presented in Tables 8.8-4 are in general in line with Review Report for flufenacet (7469/VI/98-Final – 3[rd] July 2003) with some exceptions described already in the zRMS commenting box in point 8.8.1 above. In simulations PUF value of 0 was assumed for all compounds, which is in line with recommendations of the most recent version of the FOCUS Groundwater Guidance (2021).

Tier 1a

Results at Tier 1a presented by the Applicant were independently validated by the zRMS in additional modelling using the same parameters as indicated in Table 8.8-4 and application dates presented in Table 8.8-3. The same PEC_{GW} values were obtained as presented in Tables 8.8-5 to 8.8-8.

Based on Tier 1a no unacceptable leaching of flufenacet is expected following the intended use pattern.

Metabolite FOE oxalate may migrate to groundwater at concentrations >0.1 µg/L, but it is considered as toxicologically not relevant and PEC_{GW} have not exceeded 0.75 µg/L, so groundwater exposure to this compound is also considered acceptable.

At Tier 1a the predicted concentrations of FOE sulfonic acid in groundwater were >10 µg/L in some scenarios and for this reason the Applicant performed Tier 2 simulations, which are discussed by the zRMS below.

Tier 2

At Tier 2 groundwater modelling for FOE sulfonic acid the Applicant used the soil DT_{50} of 21.7 days, based on results of the kinetic evaluation by Hammel (2008). However, as already indicated in the zRMS comment in point 8.4.1.1 of this document, the kinetic evaluation by Hammel (2008) was rejected by the RMS in the course of the flufenacet renewal process and should be thus not used in the zonal evaluations. Nevertheless, as already noted in point 8.8.1 above, the laboratory soil DT_{50} of 31.62 d, agreed during the renewal, is considerably shorter than value used for FOE sulfonic acid at Tier 1a and may be considered as a refinement option, as being already agreed by the MS experts and EFSA (the value is reported in the LoEP of November 2018, corrected by EFSA for drawing the final conclusion).

Taking this into account, the results of the Tier 2 modelling performed by the Applicant were struck through in Tables 8.8-9 to 8.8-12 and new Tier 2 groundwater modelling was carried out by the zRMS using DT_{50} of 31.62 days for FOE sulfonic acid. Remaining input parameters were the same as reported in Table 8.8-4. The application dates as suggested by AppDate ver. 3.06 were assumed, as being most relevant in line with the Central Zone agreements in area of efate. However, for illustrative purposes, additional set of simulations was performed with assumption of application dates proposed by the Applicant in Table 8.8-3. Nevertheless, in order to reduce the workload this modelling was limited to the worst case use pattern, i.e. pre-emergence application to winter cereals at 244.2 and 122.1 g a.s./ha which is also protective for the intended early post-emergence uses. Results are presented in tables below and concerned Member States may choose the results most suitable for the application dates in their countries.

PEC_{GW} for flufenacet and its metabolites on winter cereals I (pre-emg.) (with FOCUS PEARL 4.4.4 and FOCUS PELMO 5.5.3) – 1×244.2 g a.s./ha, 0% interception

Crop	Scenario	80th percentile PEC_{gw} at 1 m soil depth (µg/L)					
		Flufenacet		FOE sulfonic acid		FOE oxalate	
		PEARL	PELMO	PEARL	PELMO	PEARL	PELMO
Winter cereals (BBCH 00-09)	Chateaudun	<0.001	<0.001	2.447 2.452*	2.048 2.033*	0.018 0.018*	0.022 0.021*
	Hamburg	<0.001	<0.001	5.776 5.389*	5.934 6.009*	0.343 0.279*	0.528 0.462*
	Jokioinen	<0.001	<0.001	**8.800** 8.670*	8.187 8.164*	0.208 0.205*	0.389 0.389*
	Kremsmuenster	<0.001	<0.001	3.177 3.108*	3.510 3.381*	0.049 0.047*	0.070 0.062*
	Okehampton	<0.001	<0.001	4.185 4.155*	4.393 4.230*	0.298 0.299*	0.410 0.414*
	Piacenza	<0.001	<0.001	1.817 1.832*	2.329 2.352*	0.039 0.041*	0.144 0.143*
	Porto	<0.001	<0.001	2.846 2.737*	3.536 3.397*	0.338 0.270*	**0.832** 0.745*
	Sevilla	<0.001	<0.001	0.216 0.223*	0.965 0.743*	<0.001 <0.001*	0.051 0.052*
	Thiva	<0.001	<0.001	1.401 1.154*	1.360 1.053*	0.005 0.003	0.033 0.017*

* values calculated with consideration of application dates presented in Table 8.8-3

PEC_{GW} for flufenacet and its metabolites on winter cereals II (early post-emg.) (with FOCUS PEARL 4.4.4 and FOCUS PELMO 5.5.3) – 1×244.2 g a.s./ha, 0% interception

Crop	Scenario	80th percentile PEC_{gw} at 1 m soil depth (µg/L)					
		Flufenacet		FOE sulfonic acid		FOE oxalate	
		PEARL	PELMO	PEARL	PELMO	PEARL	PELMO
Winter cereals (BBCH 10-13)	Chateaudun	<0.001	<0.001	2.38	1.983	0.013	0.018
	Hamburg	<0.001	<0.001	5.24	5.701	0.239	0.358
	Jokioinen	<0.001	<0.001	8.36	8.043	0.198	0.379
	Kremsmuenster	<0.001	<0.001	3.01	3.283	0.040	0.055
	Okehampton	<0.001	<0.001	4.06	4.203	0.286	0.400
	Piacenza	<0.001	<0.001	1.71	2.259	0.032	0.129
	Porto	<0.001	<0.001	2.53	2.982	0.238	0.603
	Sevilla	<0.001	<0.001	0.206	0.360	<0.001	0.011
	Thiva	<0.001	<0.001	1.06	0.853	0.002	0.012

PEC_{GW} for flufenacet and its metabolites on winter cereals III (pre-emg.) (with FOCUS PEARL 4.4.4 and FOCUS PELMO 5.5.3) – 1×122.1 g a.s./ha, 0% interception

Crop	Scenario	80th percentile PEC_{gw} at 1 m soil depth (µg/L)					
		Flufenacet		FOE sulfonic acid		FOE oxalate	
		PEARL	PELMO	PEARL	PELMO	PEARL	PELMO
Winter cereals (BBCH 00-09)	Chateaudun	<0.001	<0.001	1.232 1.235*	1.033 1.026*	0.007 0.007*	0.009 0.009*
	Hamburg	<0.001	<0.001	2.910 2.723*	3.010 3.037*	0.148 0.119*	0.230 0.198*
	Jokioinen	<0.001	<0.001	4.470 4.404*	4.160 4.154*	0.086 0.084*	0.163 0.163*

	Kremsmuenster	<0.001	<0.001	1.598 1.563*	1.772 1.716*	0.021 0.020*	0.030 0.027*
	Okehampton	<0.001	<0.001	2.101 2.086*	2.211 2.135*	0.132 0.132*	0.186 0.188*
	Piacenza	<0.001	<0.001	0.910 0.918*	1.177 1.189*	0.017 0.017*	0.063 0.063*
	Porto	<0.001	<0.001	1.419 1.368*	1.776 1.701*	0.149 0.119*	0.374 0.332*
	Sevilla	<0.001	<0.001	0.109 0.113*	0.499 0.377*	<0.001 <0.001*	0.023 0.023*
	Thiva	<0.001	<0.001	0.701 0.577*	0.685 0.537*	0.002 <0.001*	0.014 0.007*

*values calculated with consideration of application dates presented in Table 8.8-3

PEC_{GW} for flufenacet and its metabolites on winter cereals IV (early post-emg.) (with FOCUS PEARL 4.4.4 and FOCUS PELMO 5.5.3) – 1×122.1 g a.s./ha, 0% interception

Crop	Scenario	80th percentile PEC_{gw} at 1 m soil depth (µg/L)					
		Flufenacet		FOE sulfonic acid		FOE oxalate	
		PEARL	PELMO	PEARL	PELMO	PEARL	PELMO
Winter cereals (BBCH 10-13)	Chateaudun	<0.001	<0.001	1.200	1.000	0.005	0.007
	Hamburg	<0.001	<0.001	2.646	2.886	0.102	0.155
	Jokioinen	<0.001	<0.001	4.246	4.078	0.081	0.159
	Kremsmuenster	<0.001	<0.001	1.517	1.655	0.017	0.023
	Okehampton	<0.001	<0.001	2.036	2.116	0.127	0.180
	Piacenza	<0.001	<0.001	0.858	1.141	0.013	0.056
	Porto	<0.001	<0.001	1.262	1.498	0.105	0.268
	Sevilla	<0.001	<0.001	0.104	0.181	<0.001	0.005
	Thiva	<0.001	<0.001	0.533	0.429	<0.001	0.005

On the basis of the additional Tier 2 modelling performed by the zRMS the following conclusions regarding the groundwater exposure may be drawn:

1. All PEC_{GW} for flufenacet are <0.001 µg/L, indicating that no unacceptable leaching of the active substance is expected following the intended uses of FFA SC 508.8 G.
2. PEC_{GW} for metabolite FOE oxalate are above 0.1 µg/L in most of scenarios but below 0.75 µg/L, which is the relevant threshold for toxicologically not relevant compound, such as FOE oxalate. The only exception is scenario Porto in which maximum PEC_{GW} of 0.832 µg/L was obtained using PELMO for the pre-emergence application of the higher rate (244.2 g a.s./ha). Based on the outcome of evaluation presented in the Core Assessment, Part B, Section 10, acceptable risk to the consumer may be, however, concluded for PEC_{GW} exceeding threshold of 0.75 µg/L in this single scenario.
3. Majority of PEC_{GW} for toxicologically not relevant metabolite FOE sulfonic acid were above the threshold concentration of 0.75 µg/L with maximum PEC_{GW} of 8.8 µg/L calculated using PEARL in Jokioinen scenario following pre-emergence application at 244.2 g a.s./ha. at pre-emergence application). Based on the outcome of evaluation presented in the Core Assessment, Part B, Section 10, acceptable risk to the consumer may be, however, concluded for this compound for this maximum concentration, covering all remaining scenarios and uses where PEC_{GW} is >0.75 µg/L.

Additional MACRO simulations for flufenacet were not performed by the zRMS since in line with indications of the *Working Document of the Central Zone in the Authorisation of Plant Protection Products* (Section 8, Environmental Fate and Behaviour, version 1 rev. 1, June 2018) no MACRO modelling is required when PEC_{GW} modelled using PELMO and PEARL were <0.001 µg/L. Based on Tier 1 results for metabolites, the maximum PEC_{GW} obtained using PELMO/PEARL were clearly higher than these obtained with MACRO and for this reason additional simulations were deemed not necessary as PEC_{GW} from MACRO are considered to be covered in PELMO/PERL modelling.

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_{sw}) (KCP 9.2.5)

8.9.1 Justification for new endpoints

Table 8.9-1: Justification for new endpoints (flufenacet and metabolites)

Compound	Parameter	EU endpoint	Used endpoint	Justification
Flufenacet	K_{foc} (mL/g)	202.0 (arith. mean, n=5)	187 (geometric mean, n=5)	Geometric mean to replace arithmetic mean following actual EFSA Guidance, (EFSA Journal 2014; 12(5):3662). Soils with an OC content < 0.3% were excluded from the calculation.
	DT_{50} in soil (d)	16.5 (geometric mean, lab. normalisation to pF2, 20 °C with Q_{10} of 2.2, n =3) ~~No value stated for modelling input value~~	16.5 (geometric mean, lab. normalisation to pF2, 20 °C with Q_{10} of 2.2, n =3)	y / DAR Addendum 2003
FOE sulfonic acid	K_{foc} (mL/g)	10 (arithmetic mean, n=3)	10 (geometric mean, n=3)	Geometric mean to replace arithmetic mean following actual EFSA Guidance (EFSA Journal 2014; 12(5):3662). Soils with an OC content < 0.3% were excluded from the calculation. Geometric mean and arithmetic mean result in the same values.
	DT_{50} in soil (d)	140 (geometric mean, lab. normalisation to pF2, 20 °C with Q_{10} of 2.2, n =3) ~~No value stated~~	~~136.2 (SFO, geomean, lab, non-normalised, n=5)~~	y / DAR Addendum 2003 ~~Application of FOCUS gw guidance (SANCO/321/2000 rev.2, Nov 2000) made the refinement of the FOE sulfonic acid soil half-life necessary to address the risk assessment.~~
FOE oxalate	K_{foc} (mL/g)	11.0 (arithmetic mean, n=3)	11 (geometric mean, n=3)	Geometric mean to replace arithmetic mean following actual EFSA Guidance, (EFSA Journal 2014; 12(5):3662). Soils with an OC content < 0.3% were excluded from the calculation. Geometric mean and arithmetic mean result in the same values.
FOE methylsulfide	K_{foc} (mL/g)	No value stated	850.5 (calc)	Application of FOCUS sw guidance (SANCO/4802/2001-rev.2 final (May 2003) requires information on the mobility of aquatic metabolites, the K_{foc} was estimated using PCKOCWIN™ (version 1.66) EPA 2000
FOE thiadone	K_{foc} (mL/g)	No value stated	42.0 (geometric mean, n=3)	Application of FOCUS sw guidance (SANCO/4802/2001-rev.2 final (May 2003) requires information on the mobility of aquatic metabolites. Soils with an OC content < 0.3% were excluded from the calculation.

zRMS comments:

The zRMS has following comments regarding the new endpoint proposed by the Applicant for flufenacet and its metabolites:

- Soil DT_{50} of 16.5 days proposed by the Applicant for flufenacet is actually EU agreed value reported in the Flufenacet Addendum (Volume 3, B.7, Environmental Fate) of January 2003 (14377/ECCO/BVL/03). Respective information has been included in Table 8.9-1 above.

- For metabolite FOE sulfonic acid the Applicant proposed to use soil DT_{50} of 136.2 days derived in the new kinetic evaluation by Hellpointner (2003). However, for this compound EU agreed soil DT_{50} of 140 days exist and is reported in the Flufenacet Addendum (Volume 3, B.7, Environmental Fate) of January 2003 (14377/ECCO/BVL/03). Respective information has been included in Table 8.9-1 above.
- For flufenacet and its metabolites the geometric mean instead of the arithmetic Kfoc values reported in the Review Report (7469/VI/98-Final – 3rd July 2003) were used. This deviations is agreed by the zRMS as the geometric mean Kfoc values are lower than arithmetic mean and represent thus worst case in terms of the water column exposure (relevant for aquatic organisms exposed to flufenacet and its metabolites). Moreover consideration of geometric mean Kfoc values is in line with current EFSA recommendations. The geometric mean values calculated by the Applicant were based on the currently EU agreed individual values and are confirmed to be correct.
- Although geometric mean Kfoc of 11 mL/g for FOE oxalate is indicated as a new endpoint, the same value is reported in the Review Report for flufenacet (7469/VI/98-Final – 3rd July 2003) and for this reason no new endpoint is used for this compound.
- Currently no EU agreed soil sorption data exist for metabolites FOE methylsulfide and FOE thiadone and the Applicant provided value calculated using PCKOCWIN (FOE methylsulfide) and ne sorption study (FOE thiadone). Both values reported in Table 8.9-1 were agreed by the zRMS (for details, please refer to the zRMS commenting box in point 8.5.1.1).

Not agreed new input values were struck through in Table 8.9-1 above.

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

PEC_{sw} reports provided by the applicant are listed in Appendix 3.3.

Table 8.9-2: Input parameters related to application for $PEC_{SW/SED}$ calculations

Plant protection product	FFA SC 508.8	FFA SC 508.8	FFA SC 508.8	FFA SC 508.
Use No.	29;33;37;89;93;129;53;57;61;97;101;133;65;69;73;105;109137;77;81;85;113;117;141	30;34;38;90;94;130;54;58;62;98;102;134;66;70;74;106;110;138;78;82;86;114;118;142	31;35;39;91;95;131;55;59;63;99;103;135;67;71;75;107;111;139;79;83;87;115;119;143	32:36:40:92:96:132;56;60;64;100;104;136;68;72;76;108;112;140;80;84;88;116;120;144
Crop	Winter cereals I Pre-emg.	Winter cereals I Early post-emg.	Winter cereals II Pre-emg.	Winter cereals II Early post-emg.
Application rate (kg as/ha)	0.2442	0.2442	0.1221	0.1221
Number of applications/interval (d)	1 / -	1 / -	1 / -	1 / -
Application window	Autumn (October – February)	Autumn (October – February)	Autumn (October – February)	Autumn (October – February)
Application method	Ground spray	Ground spray	Ground spray	Ground spray
CAM (Chemical application method)	1 – appln. soil linear	2 – appln. foliar linear	1 – appln. soil linear	2 – appln. foliar linear
Soil depth (cm)	4	4	4	4
Models used for calculation	FOCUS SWASH v5.3, FOCUS PRZM v4.3.1, FOCUS MACRO v5.5.4, FOCUS TOXWA v5.5.3	FOCUS SWASH v5.3, FOCUS PRZM v4.3.1, FOCUS MACRO v5.5.4, FOCUS TOXWA v5.5.3	FOCUS SWASH v5.3, FOCUS PRZM v4.3.1, FOCUS MACRO v5.5.4, FOCUS TOXWA v5.5.3	FOCUS SWASH v5.3, FOCUS PRZM v4.3.1, FOCUS MACRO v5.5.4, FOCUS TOXWA v5.5.3

Table 8.9-3: FOCUS Step 3 Scenario related input parameters for $PEC_{sw/sed}$ calculations for the application of FFA SC 508.8 G

Crop	Scenario	Application window used in modelling
Winter cereals Pre-emergence	D1	26-Aug - 25-Sep
	D2	25-Sep - 25-Oct
	D3	22-Oct - 21-Nov
	D4	23-Aug - 22-Sep
	D5	11-Oct - 10-Nov
	D6	31-Oct - 30-Nov
	R1	13-Oct - 12-Nov
	R3	01-Nov - 01-Dec
	R4	11-Oct - 10-Nov
Winter cereals Early post-emergence	D1	25-Sep - 25-Oct
	D2	25-Oct - 24-Nov
	D3	21-Nov - 21-Dec
	D4	22-Sep - 22-Oct
	D5	10-Nov - 10-Dec
	D6	30-Nov - 30-Dec
	R1	12-Nov - 12-Dec
	R3	01-Dec - 31-Dec
	R4	10-Nov - 10-Dec

zRMS comments:

The application pattern assumed in surface water simulations is in line with Central Zone GAP as presented in Table 8.1-1.

The application windows presented in Table 8.9-3 were checked by the zRMS using the last version of AppDate (Version 3.06 of 28 June 2019). The application window for pre-emergence application was set by the Applicant to 30 days before emergence, which is agreed by the zRMS. The assumed application window for early post-emergence is relevant for BBCH 09, which corresponds to date of emergence and it is in line with Central Zone GAP presented in Table 8.1-1. Thus, application dates presented in table above and used for Step 3 and 4 simulations are considered acceptable.

8.9.2.1 Flufenacet and its metabolites

Table 8.9-4: Input parameters related to active substance flufenacet and metabolites for $PEC_{sw/sed}$ calculations STEP 1/2 and ¾

Compound	Flufenacet	FOE sulfonic acid	FOE oxalate	FOE methylsulfide	FOE thiadone	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	363.3	275.3	225.2	241.3	170.1	y / Review Report 7469/VI/98-Final – 3rd July 2003 # n / a justification is presented above
Saturated vapour pressure (Pa)	9×10^{-5} (20°C)	not required for Step 1+2	not required for Step 1+2	not required for Step 1+2	not required for Step 1+2	
Water solubility (mg/L)	56.0	1.84	6709	113.3	5904	
Diffusion coefficient in water (m²/d)	4.3×10^{-5}	not required for Step 1+2	not required for Step 1+2	not required for Step 1+2	not required for Step 1+2	
Diffusion coefficient in air (m²/d)	0.43	not required for Step 1+2	not required for Step 1+2	not required for Step 1+2	not required for Step 1+2	

Compound	**Flufenacet**	**FOE sulfonic acid**	**FOE oxalate**	**FOE methylsulfide**	**FOE thiadone**	**Value in accordance to EU endpoint y/n/ Reference**
K_{foc} (mL/g)	Step 1+2: 187 # (geometric mean, n=5) Step 3+4: 187.92	10 # (geometric mean, n=3) [a]	11 # (geometric mean, n=3) [a]	850.5 # (calc)	42 # (geometric mean, n=3) [a]	
Freundlich Exponent 1/n	0.89 (arithmetic mean, n=5)	not required for Step 1+2	not required for Step 1+2	not required for Step 1+2	not required for Step 1+2	
Plant Uptake	0.0	not required for Step 1+2	not required for Step 1+2	not required for Step 1+2	not required for Step 1+2	
Wash-Off factor from Crop (1/mm)	0.05 (MACRO) 0.50 (PRZM)	not required for Step 1+2	not required for Step 1+2	not required for Step 1+2	not required for Step 1+2	
$DT_{50,soil}$ (d)	16.5 # (normalised lab, normalisation to pF2, 20 °C with Q10 of 2.2, n =3)	140 (geometric mean, lab. normalisation to pF2, 20 °C with Q_{10} of 2.2, n =3) ~~136.2 # (geometric mean, lab, n=5)~~	10.0 (geometric mean, lab, n=3)	1000 [1]	1000 [1]	
$DT_{50,water}$ (d)	44.7 (geomean, 20 °C, n=4)	1000 [1]	1000 [1]	1000 [1]	1000 [1]	
$DT_{50,sed}$ (d)	Step 1+2: 44.7 (geomean, 20 °C, n=4) Step 3+4: 1000 [1]	1000 [1]	1000 [1]	1000 [1]	1000 [1]	
$DT_{50,whole\ system}$ (d)	44.7 (geomean, 20 °C, n=4)	1000 [1]	1000 [1]	1000 [1]	1000 [1]	
Maximum occurrence observed (% molar basis with respect to the parent)	Soil: 100 Total system: 100	Soil: 26.3 Total system: 0	Soil: 15.6 Total system: 0	Soil: 0 Total system: 11.5	Soil: 0 Total system: 84.3	
Formation fraction in soil:	-	not required for Step 1+2	not required for Step 1+2	not required for Step 1+2	not required for Step 1+2	

[1] Parameters not reported were left to their FOCUS default values
[a] According to FOCUS SW 2015 and EFSA 2014, geometric mean Kfoc of 187 mL/g for flufenacet should have been used.

FOCUS Step 1/2 - $PEC_{sw/sed}$ for flufenacet and metabolites

Table 8.9-5: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for flufenacet following single application(s) of FFA SC 508.8 G to Winter Cereals (modelling use winter cereals I -- autumn -- 1×244.2g a.s./ha)

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	21d-$PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	-	67.4	RunOff	57.2	123
Step 2					
Northern Europe	Oct. - Feb. (Autumn)	29.3 *	RunOff	25.0	53.8 *
Southern Europe	Oct. - Feb. (Autumn)	23.8 *	RunOff	20.2	43.7 *

* Single applications are marked.
** TWA interval as required by ecotox

Table 8.9-6: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for flufenacet following single application(s) of FFA SC 508.8 G to Winter Cereals (modelling use winter cereals II -- autumn -- 1×122.1g a.s./ha)

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	21d-$PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	-	33.7	RunOff	28.6	61.6
Step 2					
Northern Europe	Oct. - Feb. (Autumn)	14.7 *	RunOff	12.5	26.9 *
Southern Europe	Oct. - Feb. (Autumn)	11.9 *	RunOff	10.1	21.8 *

* Single applications are marked.
** TWA interval as required by ecotox

FOCUS Step 3 - $PEC_{sw/sed}$ for flufenacet

Table 8.9-7: FOCUS Step 3 PEC_{sw} and PEC_{sed} for flufenacet following single application(s) of FFA SC 508.8 G to Winter Cereals (modelling use winter cereals I -- pre-emg. -- 0.2442 kg a.s./ha)

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	7d-$PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 3					
D1	Ditch	5.75 *	Drainage	5.47	14.6 *
D1	Stream	3.67 *	Drainage	3.48	8.16 *
D2	Ditch	17.0 *	Drainage	9.21	14.9 *
D2	Stream	10.9 *	Drainage	5.31	8.97 *
D3	Ditch	1.54 *	Spray drift	0.186	0.441 *
D4	Pond	0.484 *	Drainage	0.479	1.50 *
D4	Stream	1.34 *	Spray drift	0.471	0.656 *
D5	Pond	0.542 *	Drainage	0.534	1.86 *
D5	Stream	1.44 *	Spray drift	0.368	0.556 *
D6	Ditch	4.42 *	Drainage	1.93	2.63 *
R1	Pond	0.163 *	RunOff	0.152	0.502 *
R1	Stream	5.55 *	RunOff	0.315	1.15 *
R3	Stream	8.54 *	RunOff	1.58	7.18 *
R4	Stream	9.79 *	RunOff	1.02	2.33 *

* Single applications are marked.
** TWA interval as required by ecotox

Table 8.9-8: FOCUS Step 3 PEC_{sw} and PEC_{sed} for flufenacet following single application(s) of FFA SC 508.8 G to Winter Cereals (modelling use winter cereals I -- early post-emg. -- 0.2442 kg a.s./ha)

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*		Dominant entry route	7d-$PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*	
Step 3							
D1	Ditch	9.87	*	Drainage	9.15	23.5	*
D1	Stream	6.18	*	Drainage	5.70	13.4	*
D2	Ditch	21.0	*	Drainage	7.85	19.3	*
D2	Stream	13.3	*	Drainage	4.60	11.6	*
D3	Ditch	1.54	*	Spray drift	0.170	0.419	*
D4	Pond	1.20	*	Drainage	1.19	3.43	*
D4	Stream	1.51	*	Drainage	1.22	1.53	*
D5	Pond	1.30	*	Drainage	1.28	4.06	*
D5	Stream	1.72	*	Drainage	0.915	1.27	*
D6	Ditch	6.51	*	Drainage	3.74	5.66	*
R1	Pond	0.115	*	RunOff	0.109	0.372	*
R1	Stream	6.57	*	RunOff	0.402	1.44	*
R3	Stream	8.56	*	RunOff	0.661	2.11	*
R4	Stream	2.38	*	RunOff	0.245	0.634	*

* Single applications are marked.
** TWA interval as required by ecotox

Table 8.9-9: FOCUS Step 3 PEC_{sw} and PEC_{sed} for flufenacet following single application(s) of FFA SC 508.8 G to Winter Cereals (modelling use winter cereals II -- pre-emg. -- 0.1221 kg a.s./ha)

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*		Dominant entry route	7d-$PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*	
Step 3							
D1	Ditch	2.84	*	Drainage	2.74	7.81	*
D1	Stream	1.82	*	Drainage	1.73	4.35	*
D2	Ditch	7.88	*	Drainage	4.32	7.36	*
D2	Stream	5.07	*	Drainage	2.44	4.49	*
D3	Ditch	0.772	*	Spray drift	0.093	0.228	*
D4	Pond	0.239	*	Drainage	0.236	0.770	*
D4	Stream	0.669	*	Spray drift	0.224	0.340	*
D5	Pond	0.263	*	Drainage	0.259	0.911	*
D5	Stream	0.722	*	Spray drift	0.174	0.277	*
D6	Ditch	1.82	*	Drainage	0.944	1.32	*
R1	Pond	0.079	*	RunOff	0.074	0.258	*
R1	Stream	2.69	*	RunOff	0.153	0.572	*
R3	Stream	4.06	*	RunOff	0.770	3.87	*
R4	Stream	4.71	*	RunOff	0.513	1.15	*

* Single applications are marked.
** TWA interval as required by ecotox

Table 8.9-10: FOCUS Step 3 PEC_{sw} and PEC_{sed} for flufenacet following single application(s) of FFA SC 508.8 G to Winter Cereals (modelling use winter cereals II -- early post-emg. -- 0.1221 kg a.s./ha)

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*		Dominant entry route	7d-$PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*	
Step 3							
D1	Ditch	4.32	*	Drainage	4.09	12.2	*
D1	Stream	2.69	*	Drainage	2.55	6.93	*
D2	Ditch	10.1	*	Drainage	4.01	9.61	*
D2	Stream	6.29	*	Drainage	2.34	5.73	*
D3	Ditch	0.771	*	Spray drift	0.085	0.216	*
D4	Pond	0.591	*	Drainage	0.586	1.76	*
D4	Stream	0.722	*	Drainage	0.584	0.796	*
D5	Pond	0.659	*	Drainage	0.648	2.06	*
D5	Stream	0.873	*	Drainage	0.470	0.651	*
D6	Ditch	3.37	*	Drainage	1.73	2.77	*
R1	Pond	0.056	*	RunOff	0.053	0.197	*
R1	Stream	3.14	*	RunOff	0.192	0.705	*
R3	Stream	4.07	*	RunOff	0.314	1.03	*
R4	Stream	1.23	*	RunOff	0.129	0.336	*

* Single applications are marked.
** TWA interval as required by ecotox

FOCUS Step 4 PEC_{sw} for flufenacet

For run-off, the mitigation factors as reported in the FOCUS Landscape and Mitigation guidance document were used (for 10 m vegetated strip: 60/85% for aqueous/sediment phase; for 20 m vegetated strip: 80/95% for aqueous/sediment phase).

Table 8.9-11: PECsw values for flufenacet, following single application of FFA SC 508.8 G to Winter Cereals according to the Central EU zone GAP according to surface water Step 4 (modelling use winter cereals I -- pre-emg. -- 0.2442 kg a.s./ha)

PECsw (µg/L)	Scenario	Step 4 flufenacet							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	None	10 m	20 m	
	No spray buffer (m)	0 m	2 m	5 m	10 m	20 m	10 m	20 m	
None	D1 Ditch	5.75	5.75	5.75	5.75	5.75	5.75	5.75	
50 %		5.75	5.75	5.75	5.75	5.75	5.75	5.75	
75 %		5.75	5.75	5.75	5.75	5.75	5.75	5.75	
90 %		5.75	5.75	5.75	5.75	5.75	5.75	5.75	
None	D1 Stream	3.67	3.67	3.67	3.67	3.67	3.67	3.67	
50 %		3.67	3.67	3.67	3.67	3.67	3.67	3.67	
75 %		3.67	3.67	3.67	3.67	3.67	3.67	3.67	
90 %		3.67	3.67	3.67	3.67	3.67	3.67	3.67	
None	D2 Ditch	17.0	17.0	17.0	17.0	17.0	17.0	17.0	
50 %		17.0	17.0	17.0	17.0	17.0	17.0	17.0	
75 %		17.0	17.0	17.0	17.0	17.0	17.0	17.0	
90 %		17.0	17.0	17.0	17.0	17.0	17.0	17.0	
None	D2 Stream	10.9	10.9	10.9	10.9	10.9	10.9	10.9	
50 %		10.9	10.9	10.9	10.9	10.9	10.9	10.9	
75 %		10.9	10.9	10.9	10.9	10.9	10.9	10.9	

PECsw (µg/L)	Scenario	Step 4 flufenacet							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	None	10 m	20 m	
	No spray buffer (m)	0 m	2 m	5 m	10 m	20 m	10 m	20 m	
90 %		10.9	10.9	10.9	10.9	10.9	10.9	10.9	
None	D3 Ditch	1.54	0.914	0.419	0.222	0.115	0.222	0.115	
50 %		0.772	0.457	0.209	0.111	0.058	0.111	0.058	
75 %		0.386	0.229	0.105	0.056	0.029	0.056	0.029	
90 %		0.154	0.091	0.042	0.022	0.012	0.022	0.012	
None	D4 Pond	0.484	0.486	0.482	0.480	0.477	0.480	0.477	
50 %		0.478	0.479	0.477	0.476	0.475	0.476	0.475	
75 %		0.475	0.476	0.475	0.474	0.474	0.474	0.474	
90 %		0.474	0.474	0.474	0.473	0.473	0.473	0.473	
None	D4 Stream	1.34	1.07	0.586	0.586	0.586	0.586	0.586	
50 %		0.669	0.586	0.586	0.586	0.586	0.586	0.586	
75 %		0.586	0.586	0.586	0.586	0.586	0.586	0.586	
90 %		0.586	0.586	0.586	0.586	0.586	0.586	0.586	
None	D5 Pond	0.542	0.544	0.541	0.539	0.537	0.539	0.537	
50 %		0.538	0.539	0.537	0.536	0.535	0.536	0.535	
75 %		0.535	0.536	0.535	0.535	0.534	0.535	0.534	
90 %		0.534	0.534	0.534	0.534	0.533	0.534	0.533	
None	D5 Stream	1.44	1.15	0.674	0.674	0.674	0.674	0.674	
50 %		0.722	0.674	0.674	0.674	0.674	0.674	0.674	
75 %		0.674	0.674	0.674	0.674	0.674	0.674	0.674	
90 %		0.674	0.674	0.674	0.674	0.674	0.674	0.674	
None	D6 Ditch	4.42	4.42	4.42	4.42	4.42	4.42	4.42	
50 %		4.42	4.42	4.42	4.42	4.42	4.42	4.42	
75 %		4.42	4.42	4.42	4.42	4.42	4.42	4.42	
90 %		4.42	4.42	4.42	4.42	4.42	4.42	4.42	
None	R1 Pond	0.163	0.172	0.157	0.146	0.138	0.075	0.042	
50 %		0.141	0.146	0.138	0.133	0.129	0.061	0.033	
75 %		0.131	0.133	0.129	0.126	0.124	0.055	0.029	
90 %		0.124	0.125	0.124	0.123	0.122	0.051	0.026	
None	R1 Stream	5.55	5.55	5.55	5.55	5.55	2.52	1.32	
50 %		5.55	5.55	5.55	5.55	5.55	2.52	1.32	
75 %		5.55	5.55	5.55	5.55	5.55	2.52	1.32	
90 %		5.55	5.55	5.55	5.55	5.55	2.52	1.32	
None	R3 Stream	8.54	8.54	8.54	8.54	8.54	3.89	2.04	
50 %		8.54	8.54	8.54	8.54	8.54	3.89	2.04	
75 %		8.54	8.54	8.54	8.54	8.54	3.89	2.04	
90 %		8.54	8.54	8.54	8.54	8.54	3.89	2.04	
None	R4 Stream	9.79	9.79	9.79	9.79	9.79	4.40	2.29	
50 %		9.79	9.79	9.79	9.79	9.79	4.40	2.29	
75 %		9.79	9.79	9.79	9.79	9.79	4.40	2.29	
90 %		9.79	9.79	9.79	9.79	9.79	4.40	2.29	

Table 8.9-12: PECsw values for flufenacet, following single application of FFA SC 508.8 G to Winter Cereals according to the Central EU zone GAP according to surface water Step 4 (modelling use winter cereals I -- early post-emg. -- 0.2442 kg a.s./ha)

PECsw (µg/L)	Scenario	Step 4 flufenacet							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	None	10 m	20 m	
	No spray buffer (m)	0 m	2 m	5 m	10 m	20 m	10 m	20 m	
None	D1 Ditch	9.87	9.87	9.87	9.87	9.87	9.87	9.87	
50 %		9.87	9.87	9.87	9.87	9.87	9.87	9.87	
75 %		9.87	9.87	9.87	9.87	9.87	9.87	9.87	
90 %		9.87	9.87	9.87	9.87	9.87	9.87	9.87	
None	D1 Stream	6.18	6.18	6.18	6.18	6.18	6.18	6.18	
50 %		6.18	6.18	6.18	6.18	6.18	6.18	6.18	
75 %		6.18	6.18	6.18	6.18	6.18	6.18	6.18	
90 %		6.18	6.18	6.18	6.18	6.18	6.18	6.18	
None	D2 Ditch	21.0	21.0	21.0	21.0	21.0	21.0	21.0	
50 %		21.0	21.0	21.0	21.0	21.0	21.0	21.0	
75 %		21.0	21.0	21.0	21.0	21.0	21.0	21.0	
90 %		21.0	21.0	21.0	21.0	21.0	21.0	21.0	
None	D2 Stream	13.3	13.3	13.3	13.3	13.3	13.3	13.3	
50 %		13.3	13.3	13.3	13.3	13.3	13.3	13.3	
75 %		13.3	13.3	13.3	13.3	13.3	13.3	13.3	
90 %		13.3	13.3	13.3	13.3	13.3	13.3	13.3	
None	D3 Ditch	1.54	0.914	0.418	0.222	0.115	0.222	0.115	
50 %		0.771	0.457	0.209	0.111	0.058	0.111	0.058	
75 %		0.386	0.228	0.105	0.056	0.029	0.056	0.029	
90 %		0.154	0.091	0.042	0.022	0.012	0.022	0.012	
None	D4 Pond	1.20	1.20	1.19	1.19	1.19	1.19	1.19	
50 %		1.19	1.19	1.19	1.19	1.18	1.19	1.18	
75 %		1.18	1.19	1.18	1.18	1.18	1.18	1.18	
90 %		1.18	1.18	1.18	1.18	1.18	1.18	1.18	
None	D4 Stream	1.51	1.51	1.51	1.51	1.51	1.51	1.51	
50 %		1.51	1.51	1.51	1.51	1.51	1.51	1.51	
75 %		1.51	1.51	1.51	1.51	1.51	1.51	1.51	
90 %		1.51	1.51	1.51	1.51	1.51	1.51	1.51	
None	D5 Pond	1.30	1.31	1.30	1.30	1.29	1.30	1.29	
50 %		1.30	1.30	1.29	1.29	1.29	1.29	1.29	
75 %		1.29	1.29	1.29	1.29	1.29	1.29	1.29	
90 %		1.29	1.29	1.29	1.29	1.29	1.29	1.29	
None	D5 Stream	1.72	1.72	1.72	1.72	1.72	1.72	1.72	
50 %		1.72	1.72	1.72	1.72	1.72	1.72	1.72	
75 %		1.72	1.72	1.72	1.72	1.72	1.72	1.72	
90 %		1.72	1.72	1.72	1.72	1.72	1.72	1.72	
None	D6 Ditch	6.51	6.51	6.51	6.51	6.51	6.51	6.51	
50 %		6.51	6.51	6.51	6.51	6.51	6.51	6.51	
75 %		6.51	6.51	6.51	6.51	6.51	6.51	6.51	

PECsw (µg/L)	Scenario	Step 4 flufenacet							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	None	10 m	20 m	
	No spray buffer (m)	0 m	2 m	5 m	10 m	20 m	10 m	20 m	
90 %		6.51	6.51	6.51	6.51	6.51	6.51	6.51	
None	R1 Pond	0.115	0.125	0.109	0.098	0.089	0.056	0.033	
50 %		0.093	0.098	0.090	0.084	0.080	0.042	0.023	
75 %		0.082	0.084	0.080	0.078	0.075	0.035	0.019	
90 %		0.075	0.076	0.074	0.073	0.072	0.031	0.016	
None	R1 Stream	6.57	6.57	6.57	6.57	6.57	2.95	1.53	
50 %		6.57	6.57	6.57	6.57	6.57	2.95	1.53	
75 %		6.57	6.57	6.57	6.57	6.57	2.95	1.53	
90 %		6.57	6.57	6.57	6.57	6.57	2.95	1.53	
None	R3 Stream	8.56	8.56	8.56	8.56	8.56	3.86	2.02	
50 %		8.56	8.56	8.56	8.56	8.56	3.86	2.02	
75 %		8.56	8.56	8.56	8.56	8.56	3.86	2.02	
90 %		8.56	8.56	8.56	8.56	8.56	3.86	2.02	
None	R4 Stream	2.38	2.38	2.38	2.38	2.38	1.07	0.561	
50 %		2.38	2.38	2.38	2.38	2.38	1.07	0.561	
75 %		2.38	2.38	2.38	2.38	2.38	1.07	0.561	
90 %		2.38	2.38	2.38	2.38	2.38	1.07	0.561	

Table 8.9-13: PECsw values for flufenacet, following single application of FFA SC 508.8 G to Winter Cereals according to the Central EU zone GAP according to surface water Step 4 (modelling use winter cereals II -- pre-emg. -- 0.1221 kg a.s./ha)

PECsw (µg/L)	Scenario	Step 4 flufenacet							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	None	10 m	20 m	
	No spray buffer (m)	0 m	2 m	5 m	10 m	20 m	10 m	20 m	
None	D1 Ditch	2.84	2.84	2.84	2.84	2.84	2.84	2.84	
50 %		2.84	2.84	2.84	2.84	2.84	2.84	2.84	
75 %		2.84	2.84	2.84	2.84	2.84	2.84	2.84	
90 %		2.84	2.84	2.84	2.84	2.84	2.84	2.84	
None	D1 Stream	1.82	1.82	1.82	1.82	1.82	1.82	1.82	
50 %		1.82	1.82	1.82	1.82	1.82	1.82	1.82	
75 %		1.82	1.82	1.82	1.82	1.82	1.82	1.82	
90 %		1.82	1.82	1.82	1.82	1.82	1.82	1.82	
None	D2 Ditch	7.88	7.88	7.88	7.88	7.88	7.88	7.88	
50 %		7.88	7.88	7.88	7.88	7.88	7.88	7.88	
75 %		7.88	7.88	7.88	7.88	7.88	7.88	7.88	
90 %		7.88	7.88	7.88	7.88	7.88	7.88	7.88	
None	D2 Stream	5.07	5.07	5.07	5.07	5.07	5.07	5.07	
50 %		5.07	5.07	5.07	5.07	5.07	5.07	5.07	
75 %		5.07	5.07	5.07	5.07	5.07	5.07	5.07	
90 %		5.07	5.07	5.07	5.07	5.07	5.07	5.07	

PECsw (µg/L)	Scenario	Step 4 flufenacet							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	None	10 m	20 m	
	No spray buffer (m)	0 m	2 m	5 m	10 m	20 m	10 m	20 m	
None	D3 Ditch	0.772	0.457	0.209	0.111	0.058	0.111	0.058	
50 %		0.386	0.229	0.105	0.056	0.029	0.056	0.029	
75 %		0.193	0.114	0.052	0.028	0.014	0.028	0.014	
90 %		0.077	0.046	0.021	0.011	0.006	0.011	0.006	
None	D4 Pond	0.239	0.240	0.238	0.237	0.235	0.237	0.235	
50 %		0.236	0.237	0.236	0.235	0.234	0.235	0.234	
75 %		0.235	0.235	0.234	0.234	0.234	0.234	0.234	
90 %		0.234	0.234	0.234	0.234	0.233	0.234	0.233	
None	D4 Stream	0.669	0.534	0.281	0.281	0.281	0.281	0.281	
50 %		0.335	0.281	0.281	0.281	0.281	0.281	0.281	
75 %		0.281	0.281	0.281	0.281	0.281	0.281	0.281	
90 %		0.281	0.281	0.281	0.281	0.281	0.281	0.281	
None	D5 Pond	0.263	0.264	0.263	0.262	0.261	0.262	0.261	
50 %		0.261	0.262	0.261	0.260	0.260	0.260	0.260	
75 %		0.260	0.260	0.260	0.259	0.259	0.259	0.259	
90 %		0.259	0.259	0.259	0.259	0.259	0.259	0.259	
None	D5 Stream	0.722	0.576	0.315	0.315	0.315	0.315	0.315	
50 %		0.361	0.315	0.315	0.315	0.315	0.315	0.315	
75 %		0.315	0.315	0.315	0.315	0.315	0.315	0.315	
90 %		0.315	0.315	0.315	0.315	0.315	0.315	0.315	
None	D6 Ditch	1.82	1.82	1.82	1.82	1.82	1.82	1.82	
50 %		1.82	1.82	1.82	1.82	1.82	1.82	1.82	
75 %		1.82	1.82	1.82	1.82	1.82	1.82	1.82	
90 %		1.82	1.82	1.82	1.82	1.82	1.82	1.82	
None	R1 Pond	0.079	0.084	0.077	0.071	0.067	0.037	0.021	
50 %		0.069	0.071	0.067	0.065	0.062	0.030	0.016	
75 %		0.063	0.065	0.063	0.061	0.060	0.027	0.014	
90 %		0.060	0.061	0.060	0.059	0.059	0.025	0.013	
None	R1 Stream	2.69	2.69	2.69	2.69	2.69	1.22	0.638	
50 %		2.69	2.69	2.69	2.69	2.69	1.22	0.638	
75 %		2.69	2.69	2.69	2.69	2.69	1.22	0.638	
90 %		2.69	2.69	2.69	2.69	2.69	1.22	0.638	
None	R3 Stream	4.06	4.06	4.06	4.06	4.06	1.85	0.973	
50 %		4.06	4.06	4.06	4.06	4.06	1.85	0.973	
75 %		4.06	4.06	4.06	4.06	4.06	1.85	0.973	
90 %		4.06	4.06	4.06	4.06	4.06	1.85	0.973	
None	R4 Stream	4.71	4.71	4.71	4.71	4.71	2.12	1.10	
50 %		4.71	4.71	4.71	4.71	4.71	2.12	1.10	
75 %		4.71	4.71	4.71	4.71	4.71	2.12	1.10	
90 %		4.71	4.71	4.71	4.71	4.71	2.12	1.10	

Table 8.9-14: PECsw values for flufenacet, following single application of FFA SC 508.8 G to Winter Cereals according to the Central EU zone GAP according to surface water Step 4 (modelling use winter cereals II -- early post-emg. -- 0.1221 kg a.s./ha)

PECsw (µg/L)	**Scenario**	**Step 4 flufenacet**							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	None	10 m	20 m	
	No spray buffer (m)	0 m	2 m	5 m	10 m	20 m	10 m	20 m	
None	D1 Ditch	4.32	4.32	4.32	4.32	4.32	4.32	4.32	
50 %		4.32	4.32	4.32	4.32	4.32	4.32	4.32	
75 %		4.32	4.32	4.32	4.32	4.32	4.32	4.32	
90 %		4.32	4.32	4.32	4.32	4.32	4.32	4.32	
None	D1 Stream	2.69	2.69	2.69	2.69	2.69	2.69	2.69	
50 %		2.69	2.69	2.69	2.69	2.69	2.69	2.69	
75 %		2.69	2.69	2.69	2.69	2.69	2.69	2.69	
90 %		2.69	2.69	2.69	2.69	2.69	2.69	2.69	
None	D2 Ditch	10.1	10.1	10.1	10.1	10.1	10.1	10.1	
50 %		10.1	10.1	10.1	10.1	10.1	10.1	10.1	
75 %		10.1	10.1	10.1	10.1	10.1	10.1	10.1	
90 %		10.1	10.1	10.1	10.1	10.1	10.1	10.1	
None	D2 Stream	6.29	6.29	6.29	6.29	6.29	6.29	6.29	
50 %		6.29	6.29	6.29	6.29	6.29	6.29	6.29	
75 %		6.29	6.29	6.29	6.29	6.29	6.29	6.29	
90 %		6.29	6.29	6.29	6.29	6.29	6.29	6.29	
None	D3 Ditch	0.771	0.457	0.209	0.111	0.058	0.111	0.058	
50 %		0.386	0.228	0.105	0.056	0.029	0.056	0.029	
75 %		0.193	0.114	0.052	0.028	0.014	0.028	0.014	
90 %		0.077	0.046	0.021	0.011	0.006	0.011	0.006	
None	D4 Pond	0.591	0.593	0.590	0.588	0.586	0.588	0.586	
50 %		0.587	0.588	0.586	0.585	0.584	0.585	0.584	
75 %		0.585	0.585	0.585	0.584	0.584	0.584	0.584	
90 %		0.584	0.584	0.583	0.583	0.583	0.583	0.583	
None	D4 Stream	0.722	0.722	0.722	0.722	0.722	0.722	0.722	
50 %		0.722	0.722	0.722	0.722	0.722	0.722	0.722	
75 %		0.722	0.722	0.722	0.722	0.722	0.722	0.722	
90 %		0.722	0.722	0.722	0.722	0.722	0.722	0.722	
None	D5 Pond	0.659	0.660	0.658	0.656	0.655	0.656	0.655	
50 %		0.655	0.656	0.655	0.654	0.653	0.654	0.653	
75 %		0.653	0.654	0.653	0.653	0.652	0.653	0.652	
90 %		0.652	0.652	0.652	0.652	0.652	0.652	0.652	
None	D5 Stream	0.873	0.873	0.873	0.873	0.873	0.873	0.873	
50 %		0.873	0.873	0.873	0.873	0.873	0.873	0.873	
75 %		0.873	0.873	0.873	0.873	0.873	0.873	0.873	
90 %		0.873	0.873	0.873	0.873	0.873	0.873	0.873	
None	D6 Ditch	3.37	3.37	3.37	3.37	3.37	3.37	3.37	
50 %		3.37	3.37	3.37	3.37	3.37	3.37	3.37	
75 %		3.37	3.37	3.37	3.37	3.37	3.37	3.37	

PECsw (µg/L)	**Scenario**	**Step 4 flufenacet**							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	None	10 m	20 m	
	No spray buffer (m)	0 m	2 m	5 m	10 m	20 m	10 m	20 m	
90 %		3.37	3.37	3.37	3.37	3.37	3.37	3.37	
None	R1 Pond	0.056	0.061	0.053	0.048	0.043	0.027	0.016	
50 %		0.045	0.047	0.043	0.041	0.039	0.020	0.011	
75 %		0.039	0.040	0.039	0.038	0.037	0.017	0.009	
90 %		0.037	0.037	0.037	0.037	0.036	0.015	0.008	
None	R1 Stream	3.14	3.14	3.14	3.14	3.14	1.41	0.732	
50 %		3.14	3.14	3.14	3.14	3.14	1.41	0.732	
75 %		3.14	3.14	3.14	3.14	3.14	1.41	0.732	
90 %		3.14	3.14	3.14	3.14	3.14	1.41	0.732	
None	R3 Stream	4.07	4.07	4.07	4.07	4.07	1.84	0.958	
50 %		4.07	4.07	4.07	4.07	4.07	1.84	0.958	
75 %		4.07	4.07	4.07	4.07	4.07	1.84	0.958	
90 %		4.07	4.07	4.07	4.07	4.07	1.84	0.958	
None	R4 Stream	1.23	1.23	1.23	1.23	1.23	0.556	0.290	
50 %		1.23	1.23	1.23	1.23	1.23	0.556	0.290	
75 %		1.23	1.23	1.23	1.23	1.23	0.556	0.290	
90 %		1.23	1.23	1.23	1.23	1.23	0.556	0.290	

Metabolites of flufenacet

PEC_{sw} were provided by the applicant for metabolites flufenacet sulfonic acid, flufenacet oxalate, flufenacet methylsulfide and flufenacet thiadone. PEC_{sw} values for flufenacet methylsulfide are not needed since this metabolite is not major in water or sediment. PEC_{sw} for other metabolites are not reported since they are not needed to finalise the risk assessment for non-target organisms (see Section 9).

<u>Metabolite FOE sulfonic acid</u>

Table 8.9-15: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for FOE sulfonic acid following single application(s) of FFA SC 508.8 G to Winter Cereals (modelling use winter cereals I -- autumn -- 1×244.2g a.s./ha)

Scenario FOCUS	**Waterbody**	**Max PEC_{sw} (µg/L)***	**Dominant entry route**	**21d-$PEC_{sw,twa}$ (µg/L)****	**Max PEC_{sed} (µg/kg)***
Step 1	-	16.0	-	15.9	1.60
Step 2					
Northern Europe	Oct. - Feb. (Autumn)	7.84 *	-	7.79	0.784 *
Southern Europe	Oct. - Feb. (Autumn)	6.27 *	-	6.23	0.628 *

* Single applications are marked.
** TWA interval as required by ecotox

Table 8.9-16: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for FOE sulfonic acid following single application(s) of FFA SC 508.8 G to Winter Cereals (modelling use winter cereals II -- autumn -- 1×122.1g a.s./ha)

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	21d-$PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	-	8.00	-	7.95	0.801
Step 2					
Northern Europe	Oct. - Feb. (Autumn)	3.92 *	-	3.89	0.392 *
Southern Europe	Oct. - Feb. (Autumn)	3.14 *	-	3.11	0.314 *

* Single applications are marked.
** TWA interval as required by ecotox

Metabolite FOE oxalate

Table 8.9-17: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for FOE oxalate following single application(s) of FFA SC 508.8 G to Winter Cereals (modelling use winter cereals I -- autumn -- 1×244.2g a.s./ha)

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	21d-$PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	-	7.76	-	7.70	0.853
Step 2					
Northern Europe	Oct. - Feb. (Autumn)	2.94 *	-	2.92	0.323 *
Southern Europe	Oct. - Feb. (Autumn)	2.35 *	-	2.33	0.259 *

* Single applications are marked.
** TWA interval as required by ecotox

Table 8.9-18: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for FOE oxalate following single application(s) of FFA SC 508.8 G to Winter Cereals (modelling use winter cereals II -- autumn -- 1×122.1g a.s./ha)

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	21d-$PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	-	3.88	-	3.85	0.427
Step 2					
Northern Europe	Oct. - Feb. (Autumn)	1.47 *	-	1.46	0.162 *
Southern Europe	Oct. - Feb. (Autumn)	1.18 *	-	1.17	0.129 *

* Single applications are marked.
** TWA interval as required by ecotox

Metabolite FOE methylsulfide

Table 8.9-19: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for FOE methylsulfide following single application(s) of FFA SC 508.8 G to Winter Cereals (modelling use winter cereals I -- autumn -- 1×244.2g a.s./ha)

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	21d-$PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	-	3.09	-	2.97	25.4
Step 2					
Northern Europe	Oct. - Feb. (Autumn)	1.33 *	-	1.30	11.1 *
Southern Europe	Oct. - Feb. (Autumn)	1.08 *	-	1.06	9.05 *

* Single applications are marked.
** TWA interval as required by ecotox

Table 8.9-20: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for FOE methylsulfide following single application(s) of FFA SC 508.8 G to Winter Cereals (modelling use winter cereals II -- autumn -- 1×122.1g a.s./ha)

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	21d-$PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	-	1.54	-	1.49	12.7
Step 2					
Northern Europe	Oct. - Feb. (Autumn)	0.665 *	-	0.651	5.57 *
Southern Europe	Oct. - Feb. (Autumn)	0.541 *	-	0.529	4.53 *

* Single applications are marked.
** TWA interval as required by ecotox

Metabolite FOE thiadone

Table 8.9-21: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for FOE thiadone following single application(s) of FFA SC 508.8 G to Winter Cereals (modelling use winter cereals I -- autumn -- 1×244.2g a.s./ha)

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	21d-$PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	-	31.3	-	31.0	13.1
Step 2					
Northern Europe	Oct. - Feb. (Autumn)	13.7 *	-	13.6	5.75 *
Southern Europe	Oct. - Feb. (Autumn)	11.1 *	-	11.0	4.67 *

* Single applications are marked.
** TWA interval as required by ecotox

Table 8.9-22: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for FOE thiadone following single application(s) of FFA SC 508.8 G to Winter Cereals (modelling use winter cereals II -- autumn -- 1×122.1g a.s./ha)

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	21d-$PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	-	15.7	-	15.5	6.56
Step 2					
Northern Europe	Oct. - Feb. (Autumn)	6.86 *	-	6.80	2.87 *
Southern Europe	Oct. - Feb. (Autumn)	5.57 *	-	5.52	2.33 *

* Single applications are marked.
** TWA interval as required by ecotox

zRMS comments:

Input parameters used for surface water modelling for flufenacet and its metabolites presented in Table 8.9-4 are in general in line with Review Report for flufenacet (7469/VI/98-Final – 3rd July 2003) with some exceptions described already in the zRMS commenting box in point 8.9.1 above. Table 8.9-4 was amended accordingly.

It is noted that for the metabolite FOE oxalate the soil un-normalised geometric mean DT_{50} of 10 days was used, although in line with the Flufenacet Addendum (Volume 3, B.7, Environmental Fate) of January 2003 (14377/ECCO/BVL/03) DT_{50} of 6.6 days should be used. Nevertheless, consideration of the longer value was agreed as representing worst case.

In simulations at Step 3/4 PUF value of 0 was assumed for flufenacet, which is in line with recommendations of the most recent version of respective guidance.

Step 4 simulations were performed according to recommendations of the FOCUS work group on landscape and mitigation factors and were validated by the zRMS for convenience of the concerned Member States that consider FOCUS simulations as Step 4 at the national level.

Surface water modelling for flufenacet and its metabolites was independently validated by the zRMS using the fully agreed EU agreed input parameters (with exception of Kfoc for FOE methylsulfide and FOE thiadone, for which in absence of EU agreed endpoints values reported in Table 8.9-4 were used). Obtained values were in good agreement with those calculated by the Applicant and therefore surface water exposure for flufenacet reported in Tables 8.9-5 to 8.9-22 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 $PEC_{sw/sed}$ of FFA SC 508.8 G

Table 8.9-23: Initial PEC_{SW} for the formulation following the single application on winter cereals with mitigation of spray drift

Formulation / compounds	No. of Applications	Maximum use rate (g product/ha) [1]	Drift [2]	PEC_{sw} (µg product/L)
FFA SC 508.8 / flufenacet	1	582.24	1 m (2.77%)	5.376
			5 m (0.57%)	1.106
			10 m (0.29%)	0.563
		291.12	1 m (2.77%)	2.688
			5 m (0.57%)	0.553
			10 m (0.29%)	0.281

1 The PEC for the formulation was based on a specific density of 1.213 g/mL with the maximum application rates of 0.48 and 0.24 L/ha and an interception rate of 0% representing the maximum use in GAP.
2 drift value according to Rautmann *et al*. (2001)[1]

zRMS comments:

Recalculation of the surface water exposure to the formulated product performed by the zRMS using Spray Drift Calculator resulted with lower PEC_{SW} values. Taking this into account, values obtained by the Applicant represent worst case and may be used in the aquatic risk assessment for the formulation.

[1] D. Rautmann, M. Streloke, M. Winkler (2001). New basic drift values in the authorisation procedure for plant protection products. In: R. Forster, M. Streloke: Workshop on Risk Assessment and Risk Mitigation Measures in the Context of the Authorization of Plant Protection Products (WORMM). Mitt. Biol. Bundesanst. Land-Forstwirtsch, Berlin-Dahlem, Heft 381.

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

Fate and behaviour of flufenacet in air

The fate of flufenacet in air has been evaluated, full details are provided in the respective EU monograph Annex B.7 (ECCO 73, August 1997) and related documents and summarised in the Review Report for flufenacet (7469/VI/98-Final – 3rd July 2003). No additional studies have been performed.

Table 8.10-1: Summary of atmospheric degradation and behaviour

Compound	flufenacet
Direct photolysis in air	not studied – no data required (no absorbance above 290 nm)
Quantum yield of direct phototransformation	not studied – no data required
Photochemical oxidative degradation in air	DT_{50} (h): 4.7 derived by the Atkinson model OH (12h) concentration assumed = 1.5×10^{6} radicals/cm^3
Volatilisation	Vapour pressure (Pa): 9 x 10^{-5} Pa (20 °C) (N-isomer)* (Krohn, 1994, M-004730-01-1) Henry's Law Constant 9 x 10^{-4} ($Pa.m^3/mol$) (Krohn, 1994, M-004737-01-1)
Metabolites	No data available

* Isomerization of flufenacet to its N-isomer during the determination. The vapor pressure of the N-isomer is assumed to be also applicable to the active substance flufenacet.

The vapour pressure at 20 °C of the active substance flufenacet is between 10^{-5} and 10^{-4} Pa. Hence the active substance flufenacet is regarded as semivolatile (volatilisation only from plant surfaces). Therefore, exposure of adjacent surface waters and terrestrial ecosystems by the active substance flufenacet due to volatilization with subsequent deposition is not expected.

zRMS comments:

Although the vapour pressure is above the trigger of 10^{-5} Pa and EU agreed data indicate potential volatilisation from soil surfaces (up to 29% within 1 day), due to the rapid degradation in the atmosphere (DT_{50} of 4.7 hours) flufenacet is not expected to be subject of short- or long-range transport.

Taking this into account, the contamination of the atmosphere with flufenacet from the intended uses of FFA SC 508.8 G is considered to be negligible.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Owner
KCP 9.1.3 / 01	Reinken, G.; Porschewski, R.	2017	Flufenacet (FFA) core PECsoil EUR - Modelling core info document for soil risk assessment in Europe Report No.: EnSa-16-0744, Edition Number: M-577701-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: No unpublished	No	Bayer
KCP 9.1.3 / 02	Reinken, G.; Serode, R.	2020	Flufenacet (FFA) and metabolites: PECsoil EUR - Use in winter cereals in Europe Report No.: EnSa-20-0760, Edition Number: M-765638-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: No unpublished	No	Bayer
KCP 9.2.4.1 / 01	Reinken, G.; Tamazashvili, A.	2017	Flufenacet (FFA) core PECgw FRA - Modelling core info document for groundwater risk assessment in France Report No.: EnSa-17-0044, Edition Number: M-579316-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: No unpublished	No	Bayer
KCP 9.2.4.1 / 02	Reinken, G.; Serode, R.	2020	Flufenacet (FFA) and metabolites: PECgw FOCUS PEARL, PELMO, MACRO EUR (Tier 1a) - Use in winter cereals in Europe Report No.: EnSa-20-0761, Edition Number: M-765637-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: No unpublished	No	Bayer
KCP 9.2.5 / 01	Reinken, G.; Porschewski, R.	2017	Flufenacet (FFA) core PECsw EUR - Modelling core info document for surface water risk assessment in Europe Report No.: EnSa-16-0743, Edition Number: M-577700-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: No unpublished	No	Bayer
KCP 9.2.5 / 02	Reinken, G.; Serode, R.	2020	Flufenacet (FFA) and metabolites: PECsw,sed FOCUS EUR - Use in winter cereals in Europe Report No.: EnSa-20-0749, Edition Number: M-765640-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: No unpublished	No	Bayer

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Owner
KCA 7.1.2.1.1 / 01	Schaefer, H.	1998	Calculation of DT-50 values of two metabolites of FOE 5043 in soil under aerobic conditions Report No.: MR-037/98, Edition Number: M-004479-02-1 Bayer AG, Leverkusen, Germany ... amended: 1998-01-15 GLP/GEP: No unpublished	No	Bayer
KCA 7.1.3.1.2 / 02	Blumhorst, M. R.; Yen, P. Y.; Marlow, V. A.	1994	Soil adsorption/desorption of FOE 5043 degradates: FOE Sulfonic Acid, FOE Methyl Sulfoxide, FOE Oxalate, FOE Alcohol, and Thiadone Report No.: MR106598, Edition Number: M-002185-01-1 EPL Bio-Analytical Service, Inc., Harristown, IL, USA GLP/GEP: Yes unpublished	No	Bayer

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

Please note that all data mentioned as part of DAR, RAR, or EFSA journals are considered as 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
As most of endpoints for flufenacet and its relevant metabolites was taken from the EU review, for the list of respective studies please refer to Volume 2 of the monograph.					

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	Reason for rejection
KCP 9.2.4.1 / 03	Reinken, G.; Serode, R.	2021	Flufenacet (FFA) and metabolites: PECgw FOCUS PEARL, PELMO, MACRO EUR (Tier 2) - Use in winter cereals in Europe Report No.: EnSa-21-0150, Edition Number: M-765725-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: No unpublished	No	Bayer	Not agreed input parameters
KCA 7.1.2.1.2 / 01 ... also filed: KCA 7.1.3.1.2 / 01	Hellpointner, E.	2003	Time-dependent sorption of FOE5043-sulfonic acid in soil Report No.: MEF-229/03, Edition Number: M-111445-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer	Study not evaluated, not used in the presented exposure evaluation for FFA SC 508.8 G
KCA 7.1.2.2.1 / 01	Hammel, K.	2008	Kinetic evaluation of the dissipation of flufenacet and its metabolite flufenacet - sulfonic acid in soil based on field studies Report No.: MEF-08/266, Edition Number: M-306683-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: No unpublished	No	Bayer	Study not evaluated, not used in the presented exposure evaluation for FFA SC 508.8 G
KCA 7.1.3.1.2 / 01 ... also filed: KCA 7.1.2.1.2 / 01	Hellpointner, E.	2003	Time-dependent sorption of FOE5043-sulfonic acid in soil Report No.: MEF-229/03, Edition Number: M-111445-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer	Study not evaluated, not used in the presented exposure evaluation for FFA SC 508.8 G

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
There were no data relied on and not submitted by the Applicant.					

Appendix 2 Detailed evaluation of the new Annex II studies

A 2.1 KCA 7.1 Fate and behaviour in soil

A 2.1.1 KCA 7.1.1 Route of degradation in soil

No new or additional studies have been submitted.

A 2.1.1.1 KCA 7.1.1.1 Aerobic degradation

A 2.1.1.2 KCA 7.1.1.2 Anaerobic degradation

A 2.1.1.3 KCA 7.1.1.3 Soil photolysis

A 2.1.2 KCA 7.1.2 Rate of degradation in soil

A 2.1.2.1 KCA 7.1.2.1 Laboratory studies

A 2.1.2.1.1 KCA 7.1.2.1.1 Aerobic degradation of the active substance

Comments of zRMS:	The study was already evaluated and agreed by the RMS in the Flufenacet Addendum (Volume 3, B.7, Environmental Fate) of January 2003 (14377/ECCO/BVL/03) and no additional assessment is thus deemed necessary. Endpoints obtained at the EU level were used in the exposure assessment presented in points 8.7, 8.8 and 8.9. Since the study was not evaluated by the zRMS, its summary is struck through below for clarity.

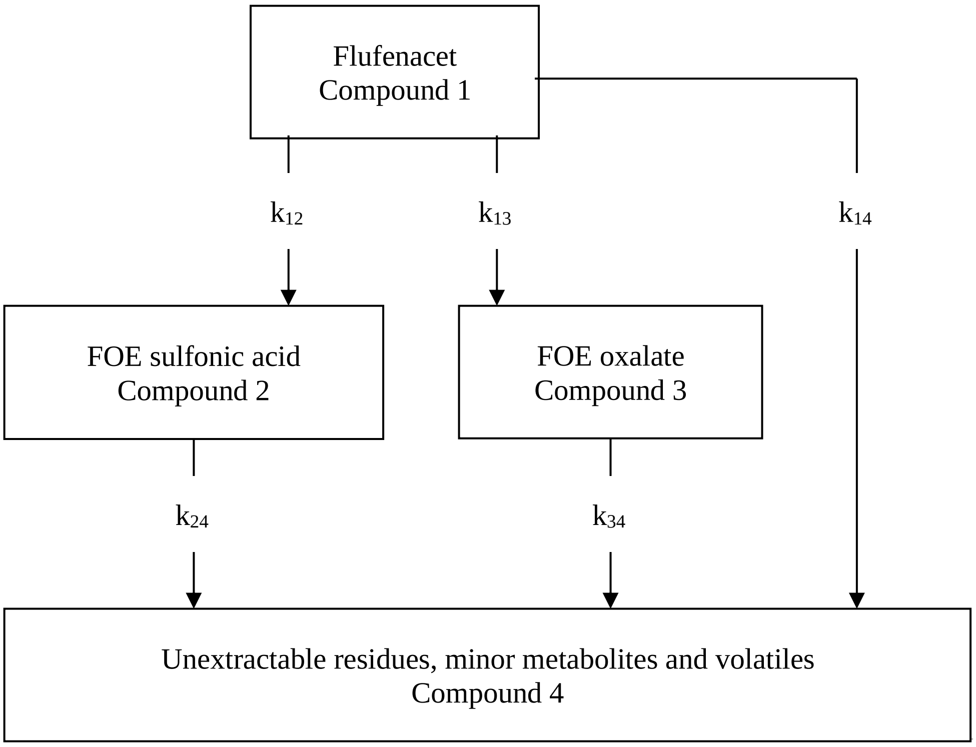
Reference:	**KCA 7.1.2.1.1/01**
Title:	Calculation of DT-50 values of two metabolites of FOE 5043 in soil under aerobic conditions
Report:	Schaefer, H.; 1998; MR-037/98; M-004479-02-1
Guideline(s):	--
Deviations:	--
GLP/GEP:	no
Acceptability:	Accepted at the EU level (Flufenacet Addendum, Volume 3, B.7, Environmental Fate, January 2003 (14377/ECCO/BVL/03)).

~~This kinetic evaluation is based on the data of Kelley, I. V.; Wood, S.; McKinney, M.; 1995; M-002146-01-1. Compared with the kinetic evaluation cited in EU monograph Annex B.7 (ECCO 73, August 1997) Schaefer, H.; 1995; M-004479-01-1 this amended version from 1998 also takes into account the experimental DT_{50} values of FOE sulfonic acid from Hellpointner, E.; 1996; M-004098-01-1. This kinetic evaluation was previously evaluated and the results on FOE oxalate are part of the Review Report for flufenacet (7469/VI/98-Final – 3rd July 2003). The data are summarised here as the 1998 amendment supersedes the version in the EU monograph Annex B.7 (ECCO 73, August 1997).~~

~~Note: using the submitted kinetic evaluation that led to optimised rate constants (k) for flufenacet the single first order modelling end-points (DT_{50} values) are calculated using DT_{50} = ln (2) / k.~~

Materials and methods

Simplified metabolic pathway of flufenacet based on the study of Kelley *et al.* (1995).



The naming of the rate constants was changed for this summary: k_{12} and k_{13} previously named k1 and k2, resp. k_{14} sum of previously named k3 and k4, k_{24} and k_{34} previously named kM1 and kM2, resp.

Results and discussions

The study reports the rate constants for flufenacet. The half-life of flufenacet is then calculated from rate constants k as $DT_{50} = \ln(2) / k$. K is calculated for each soil as sum of 3 rate constants (k12 + k13 + k14) presented in the table below.

Table A 1 Rate constants and non-normalised modelling half-lives (DT_{50}) for flufenacet

Soil	Texture	k_{12}	k_{13}	k_{14}	total k	DT50
-	-	**(days^{-1})**	**(days^{-1})**	**(days^{-1})**	**(days^{-1})**	**(d)**
BBA2.2_1	Loamy sand	0.00676	0.01158	0.00388	0.02222	**31.2**
Laacherhof Axxa_1	Silt loam	0.00967	0.01563	0.00787	0.03317	**20.9**
Höfchen am H.	Silt loam	0.00556	0.01287	0.01225	0.03068	**22.6**

A 2.1.2.1.2 KCA 7.1.2.1.2 Aerobic degradation of metabolites, breakdown and reaction products

Comments of zRMS:	The summarised below study was not evaluated by the zRMS since the available dataset was sufficient to finalise the exposure assessment and additional data for the flufenacet metabolite FOE sulfonic acid were not necessary to demonstrate the safe uses while evaluation of the new data is expexted during the ongoilg renewal process Summary below was thus struck through and shaded as being not validated.

Reference:	**KCA 7.1.2.1.2/01**
Title:	Time-dependent sorption of FOE5043-sulfonic acid in soil
Report:	Hellpointner, E.; 2003; MEF-229/03; M-111445-01-1
Guideline(s):	EC: Official Journal of the EC No. L 172 (EN), July 22, 95 Commission Directive 95/36/EC, amending Council Directive 91/414/EEC Annex II, Fate and Behaviour in the Environment, 7171/VI/94-EN, Section 7.1.2 according to OECD 106 (2000)
Deviations:	not applicable
GLP/GEP:	yes
Acceptability:	Not evaluated, not necessary to finalise the exposure assessment

~~**Materials and methods**~~

~~Test Item~~

~~[phenyl-UL-^{14}C]FOE5043-sulfonic acid ammonium salt (report name FOE sulfonic acid)~~

~~Batch No~~	~~#C-606B~~
~~Specific activity~~	~~2.66 MBq/mg~~
~~Radiochemical purity~~	~~> 98% HPLC with radioactivity detector~~

~~Test Soils~~

~~The soils were sampled fresh from the field (upper horizon of 0 to 20 cm) and sieved to a particle size of ≤ 2 mm. The soils were taken from agricultural areas representing different geographical origins and different soil properties as required by the guidelines.~~

~~**Table A 2 Physico-chemical properties of test soils**~~

~~Parameter~~		~~Results / Units~~	
~~Soil Designation~~		~~Laacherhof AXXa~~	~~Laacherhof AIII~~
~~Geographic Location~~ ~~City~~ ~~State~~ ~~Country~~		 ~~Monheim~~ ~~North-Rhine Westphalia~~ ~~Germany~~	 ~~Monheim~~ ~~North-Rhine Westphalia~~ ~~Germany~~
~~Soil Taxonomic Classification (USDA)~~		~~sandy, mixed, mesic typic Cambudolls~~	~~loamy, mixed, mesic typic Agrudalfs~~
~~Soil Series~~		~~no information available~~	
~~Textural Class (USDA)~~		~~sandy loam~~	~~silt loam~~
~~Sand [%]~~	~~[50 µm – 2 mm]~~	~~72.4~~	~~36.9~~
~~Silt [%]~~	~~[2 µm – 50 µm]~~	~~22.6~~	~~51.1~~
~~Clay [%]~~	~~[< 2 µm]~~	~~5.0~~	~~12.0~~
~~pH~~ ~~– in $CaCl_2$ (soil/$CaCl_2$ 1/2)~~ ~~– in water (soil/water 1/1)~~ ~~– in KCl~~		 ~~6.3~~ ~~6.9~~ ~~6.3~~	 ~~6.8~~ ~~7.6~~ ~~7.2~~
~~Organic Carbon [%]~~ ~~Organic Matter [%] [1]~~		~~1.47~~ ~~2.53~~	~~0.88~~ ~~1.51~~
~~Cation Exchange Capacity [meq/100 g]~~		~~10.3~~	~~9.8~~
~~Water Holding Capacity maximum [g H_2O *ad* 100 g soil DW]~~		~~34.42~~	~~36.40~~

Bulk Density (disturbed) [g/cm³]	2.5	2.55
Microbial Biomass [mg microbial carbon / kg soil DW] DAT-0 DAT-100	 242 209	 275 195

[1] calculated as: OM [%] = OC [%] / 1.724
DAT: days after treatment DW: dry weight
USDA: United States Department of Agriculture

B. Study design

1. Experimental Conditions

Static test systems were used, consisting of centrifuge tubes filled with soil and closed with cotton wool. 100 g of the sieved soil (dry weight equivalents) were weighed into each tube and the soil moisture was adjusted to 40% of the maximum water holding capacity (MWHC) by addition of deionized water. The untreated test systems were closed with cotton wool and equilibrated to study conditions for at least 1 week days prior to application.

The study application rate (SAR) was orientated on the lowest concentration of FOE sulfonic acid used in the former batch equilibrium study (M-002185-01-1), i.e. 0.04 µg/mL FOE sulfonic acid × 20 mL/6 g soil (DW) = 0.133 µg/g soil (DW).

The application solution was prepared in acetonitrile/water (1:20, *v/v*). 73 µL of the application solution were applied drop wise onto the soil surface of the respective test systems using a pipette. After application the soil moisture was re-adjusted to the initial value of 40% MWHC using deionized water and the test vessels were closed with cotton wool.

The test systems (except DAT-0) were incubated under aerobic conditions in the dark for 100 days at 20 °C and a soil moisture of 40% of the maximum water holding capacity in a walk-in climatic chamber.

2. Sampling

Seven sampling intervals were distributed over the entire incubation period of 100 days. Duplicate test systems were processed and analyzed 0, 3, 7, 14, 28, 56 and 100 days after treatment (DAT).

Microbial soil biomass was determined at DAT-0 and DAT-100.

3. Analytical Procedures

At each sampling interval, a so-called batch equilibrium shaking test was performed firstly to determine the time-dependent sorption of FOE sulfonic acid. Therefore, the soils were supplemented with 100 mL 0.01M $CaCl_2$ solution (soil/solution ratio = 1:1) and agitated for 24 h in the dark at 20 °C. Afterwards, supernatant and soil were separated by centrifugation and decantation.

Following, the soils were extracted four times at ambient temperature using 0.01M $CaCl_2$ solution (1×), acetonitrile/water (1×; 1:1, *v/v*) or acetonitrile containing 0.01M HCl (2×). After each extraction step, supernatant and soil were separated by centrifugation and decantation.

The desorption solution of the batch equilibrium shaking test as well as the $CaCl_2$ extract and the combined organic soil extracts were characterized separately by liquid scintillation counting and TLC/radio-detection. The limit of detection (LOD) for the TLC/radio-detection method was 0.5% AR. The amount of non-extractable residues was determined by combustion/ liquid scintillation counting.

The identity of the test item was elucidated by HPLC-MS(/MS) and assigned by comparison of the R_f values with those of reference items.

4. Kinetic Evaluation

The degradation kinetics of the test item was determined using the software ModelManager and the Single First Order kinetic model. Model input datasets were the residual amounts of FOE sulfonic acid found in each replicate test system at each sampling interval. DT_{50} and DT_{90} values were calculated from the resulting kinetic parameters.

Results and discussions

A. Extraction and quantitation of radioactivity in soil samples

The tables below summarize the degradation of [phenyl-UL-^{14}C]FOE sulfonic acid as a function of time.

Table A 3: Distribution of radioactivity in soil Laacherhof AXXa under aerobic conditions (expressed in as percent of applied radioactivity; mean value of duplicates)

Compartment	DAT 0	3	7	14	28	56	100
Carbon dioxide	not analyzed						
Volatile Organic Compounds							
Total Extractable Residues	97.9	96.9	93.4	87.2	74.6	58.6	29.4
Non-extractable Residues	2.1	3.0	5.0	7.2	13.5	20.2	30.7
Material Balance	**100.0**	**99.9**	**98.4**	**94.4**	**88.1**	**78.8**	**60.1**

n.d.: not detected, n.a.: not analyzed, DAT: days after treatment

Table A 4: Degradation of FOE sulfonic acid in soil Laacherhof AXXa under aerobic conditions (expressed in µg; single values and mean values)

Compound (replicate)		DAT 0	3	7	14	28	56	100
FOE sulfonic acid	(A1)	12.2	12.2	11.9	11.1	9.3	7.1	3.5
	(A2)	12.3	12.2	11.7	11.0	9.5	7.5	3.5
	mean	**12.2**	**12.2**	**11.8**	**11.0**	**9.4**	**7.3**	**3.5**

DAT: days after treatment

Table A 5: Distribution of Radioactivity in Soil Laacherhof AIII under Aerobic Conditions (expressed in as percent of applied radioactivity; mean value of duplicates)

Compound	DAT 0	3	7	14	28	56	100
Carbon dioxide	not analyzed						
Organic Volatiles							
Total Extractable Residues	97.8	94.4	90.6	86.1	74.1	55.9	27.8
Non-extractable Residues	2.2	3.4	5.2	6.5	11.9	18.4	28.4
Material Balance	**100.0**	**97.9**	**95.8**	**92.6**	**86.1**	**74.3**	**56.2**

n.d.: not detected, n.a.: not analyzed, DAT: days after treatment

Table A 6: Degradation of FOE sulfonic acid in soil Laacherhof AIII under aerobic conditions (expressed in µg; single values and mean values)

Compound (replicate)		DAT 0	3	7	14	28	56	100
FOE sulfonic acid	(A1)	12.6	12.2	11.9	11.2	9.7	7.2	3.4
	(A2)	12.2	11.9	11.6	11.0	9.4	6.9	3.3
	mean	**12.4**	**12.1**	**11.7**	**11.1**	**9.6**	**7.1**	**3.3**

DAT: days after treatment

B. Material balance

As the study design was not intended to determine total material balances, e.g. no volatiles were determined, the recovered radioactivity decreased to approx. 60% of the applied radioactivity [% AR] in soil Laacherhof AXXa and to approx. 56% AR in soil Laacherhof AIII.

C. Extractable and non-extractable residues

Extractable residues decreased from DAT-0 to DAT-100 from 97.9 to 29.4% AR in soil Laacherhof AXXa and from 97.8 to 27.8% AR in soil Laacherhof AIII.

Non-extractable residues increased from DAT-0 to DAT-100 from 2.1 to 30.7% AR in soil Laacherhof AXXa and from 2.2 to 28.4% AR in soil Laacherhof AIII.

D. Volatalization

No volatiles were determined within this study.

E. Degradation of test item

The amount of [phenyl-UL-^{14}C]FOE sulfonic acid decreased from DAT-0 to DAT-100 from 12.23 to 3.46 µg in soil Laacherhof AXXa and from 12.4 to 3.34 µg in soil Laacherhof AIII.

The experimental data were kinetically evaluated according to the Single First Order kinetic model in order

~~to derive half-lives for FOE sulfonic acid.~~

~~**Table A 7: Single First Order degradation kinetics of FOE sulfonic acid in soil under aerobic conditions for trigger evaluation**~~

~~Soil~~	~~DT_{50} [d]~~	~~DT_{90} [d]~~	~~k [d^{-1}]~~	~~Correlation Coefficient (R^2)~~
~~Laacherhof AXXa~~	~~61.8~~	~~205~~	~~0.0112~~	~~0.985~~
~~Laacherhof AIII~~	~~60.2~~	~~200~~	~~0.0115~~	~~0.986~~

~~**Conclusion**~~

~~[Phenyl-UL-^{14}C]FOE sulfonic acid was well degraded in soil under aerobic conditions in the dark in the laboratory. The calculated half-lives were between 60 and 62 days in the tested soils.~~
~~It is concluded that FOE sulfonic acid has no potential for accumulation in the environment.~~
~~These half-lives are significantly shorter than those found in an earlier study (Hellpointner, E.; 1996; M-004098-01-2), where only weak degradation of FOE sulfonic acid was found in three soils after 100 days (DT_{50} between 189 and 270 days). However, in that former study it was recognized that the soil moisture during test was too low and that an approx. 3-fold higher application rate was used.~~
~~Thus, these results clearly indicate that not a time-dependent sorption behaviour of FOE sulfonic acid, but rather shorter half-lives under aerobic condition in soil are the most plausible reason for measuring much lower peak concentrations of test item in the leachates of the lysimeter studies than that expected by modelling calculations with the earlier input parameters (longer half-lives).~~

A 2.1.2.1.3 KCA 7.1.2.1.3 Anaerobic degradation of the active substance

No new or additional studies have been submitted.

A 2.1.2.1.4 KCA 7.1.2.1.4 Anaerobic degradation of metabolites, breakdown and reaction products

No new or additional studies have been submitted.

A 2.1.2.2 KCA 7.1.2.2 Field studies

A 2.1.2.2.1 KCA 7.1.2.2.1 Soil dissipation studies

Comments of zRMS:	The summarised below study was not validated by the zRMS since peer-reviewed degradation data for FOE sulfonic acid are available from the ongoing flufenacet renewal process and were used by the zRMS as being agreed by EFSA and MS experts (taken from LoEP of November 2018, corrected by EFSA to draw final conclusion). For details, please refer to point 8.8. Summary below was thus struck through and shaded as being not validated.

Reference:	**KCA 7.1.2.2.1/01**
Title:	Kinetic evaluation of the dissipation of flufenacet and its metabolite flufenacet - sulfonic acid in soil based on field studies
Report:	Hammel, K.; 2008; MEF-08/266; M-306683-01-1
Guideline(s):	not applicable
Deviations:	not applicable
GLP/GEP:	no
Acceptability:	Not evaluated, additional already peer-reviewed data were taken from the LoEP of November 2018 (corrected by EFSA to draw the final conclusion).

Materials and methods

Soil residue data from the field dissipation studies M-002175-01-2, M-002171-01-2, M-002169-01-2 and M-002172-01-2 provided in the respective EU monograph Annex B.7 (ECCO 73, August 1997) and related documents and summarised in the Review Report for flufenacet (7469/VI/98-Final – 3rd July 2003) were used. In these studies, the degradation of flufenacet, was studied at sites Breitenfelde (Germany), Kirchlauter (Germany), Monheim (Germany), Burscheid (Germany), Fresne-L'Archeveque (France), Fresne-L'Archeveque (France), Laudun (France), St. Etienne du Gres (France), Saussay La Campagne (France), Fresne-L'Archeveque (France), Ravenna (Italy) and S. Romualdo (Italy) under field conditions covering a period of at least 231 days up to 303 days after treatment. 14 trials were applied in spring and two in autumn, using application rates of 240, 480 and 600 g/ha. Thereof, seven trials were applied on bare soil and nine trials were cropped with maize, sunflower, winter wheat and soybean. For the cropped trials application was performed from pre-emergence to early post-emergence.

The mathematical evaluation of the experimental data was done with the optimization code PEST and the transport model PEARL. The kinetic analysis was performed according to FOCUS kinetics (2005) thus, in principle, four kinetic models are to be considered: The single first-order (SFO), first-order multiple-compartment (FOMC), the hockey-stick model (HS) and the double first-order in parallel (DFOP). However, as FOE sulfonic acid is relatively mobile an inverse modelling approach was taken to separately account for leaching. Due to the application of this inverse modelling with an exposure model (PEARL) the kinetic model considered is exclusively Single First Order. No weighting of the data was performed in the kinetic analysis. In inverse modelling a model is made to best fit a given set of observations by varying the values of a given set of model input parameters. The parameters to be fitted here were restricted to the following kinetic parameters: the half-lives (DT_{50}) of flufenacet and FOE sulfonic acid, the formation fraction of FOE sulfonic acid and the mass applied. This is equivalent to the parameter set optimized in a normal evaluation with a compartment model as described in FOCUS. Because of the low level of measured FOE sulfonic acid residues it was not possible to fit its half-life and formation fraction simultaneously. Thus, independent information was used from former laboratory studies M-002146-01-1 (Kelley *et al.*, 1995, provided in the respective EU monograph Annex B.7 (ECCO 73, August 1997) and related documents and summarised in the Review Report for flufenacet (7469/VI/98-Final – 3rd July 2003)) to fix the formation fraction to 0.26 and thereby to improve the reliability of the calculated half-life. Additionally, the conservative nature of the finally selected estimates was assessed by comparison with independent data from two lysimeter experiments. For this purpose the experimental conditions at the lysimeters were closely reproduced, combined with the kinetic parameters derived here and implemented in PEARL.

All DT_{50} used by PEARL are referenced with respect to temperature and soil moisture which were set to 20 °C and 100% FC (field capacity). The dependence of degradation on temperature was considered using a molar activation energy of 65.4 kJ mol^{-1} (corresponding to Q_{10} = 2.58).

Field residue data were pre-processed as follows: at DAT-0 values < LOD in deep horizons were set to 0. Values between LOD and LOQ were set to 0.5 × (LOD + LOQ). Values < LOD were set to 0.5 × LOD for samples after, before or deeper as a value > LOD, or for samples between values > LOQ. The curve was cut off after the first non-detect (< LOD), if no later value > LOQ followed. As an additional conservatism, all depths were considered for FOE sulfonic acid during practically the whole experimental period (from the second sampling on for the 10 - 20 cm soil layer and from the third on for the 20 - 30 cm soil layer), i.e. all values < LOD were set to 0.5 LOD irrespective of the fact that below or after all values are also < LOD. By this procedure residues can hardly be underestimated, but are likely to be overestimated. Finally, the concentrations for each depth increment were summed to represent to concentration in a 10 cm thick soil layer containing all mass found in the 0 – 30 cm layer and were used for the kinetic evaluation. As a last step this concentration was transformed to mass per area in 0 - 30 cm using the same estimated site specific bulk density employed for the inverse modelling. This last transformation was made because the mass per area down to a given soil depth is a direct output of PEARL and thus technically simplifies the inverse modelling.

Because daily soil temperature and moisture data which are necessary to normalize the degradation parameters were not measured on-field corresponding values were generated by employing a suitable simulation model. Necessary driving variables for such a model are rainfall and potential evapotranspiration. In the field dissipation studies, rainfall and temperature data are reported as weekly, ten day or monthly sums and averages. Because continuous daily weather data are required for a normalized

~~evaluation, the MARS weather database[2] was employed to provide the daily variation of these variables. The weather data given in the field dissipation studies were used to calibrate the MARS data.~~

~~Results and discussions~~

~~Single first order (SFO) was used as kinetic model to describe the degradation of flufenacet and FOE sulfonic acid for modelling purpose at all sites. The fixed formation fraction of FOE sulfonic acid did hardly change the results for flufenacet but produces much more reliable and consistent results for FOE sulfonic acid. Additionally, this formation fraction is similar to the mean value of 0.18 obtained from the fitting to the field data. The conservative nature of the finally selected estimates was assessed by comparison with independent data from two lysimeter experiments, demonstrating that the measured maximum annual concentrations of FOE sulfonic acid in the leachate were substantially lower than the calculated ones in both cases. Thus, the half-lives obtained from the field studies enable a much more realistic, but still conservative assessment of the predicted environmental concentrations of FOE sulfonic acid. The table below summarizes the results of the kinetic analysis.~~

~~Table A 8: SFO of flufenacet ($DT50_{FFA}$) and FOE sulfonic acid ($DT50_{FOE\ SA}$) referenced to 20 °C and 100% field capacity~~

~~Trial number~~	~~Site~~	~~Texture (0 – 30 cm depth)~~	~~$DT_{50\ FFA}$ [days]~~	~~$DT_{50\ FOE\ SA}$ [days]~~
~~30159/0~~	~~Breitenfelde (Germany)~~	~~sandy loam~~	~~17.1~~	~~17.7~~
~~30162/0~~	~~Kirchlauter (Germany)~~	~~sandy loam~~	~~33.3~~	~~19.8~~
~~30163/9~~	~~Monheim (Germany)~~	~~sandy loam~~	~~31.8~~	~~20.5~~
~~30164/7~~	~~Burscheid (Germany)~~	~~silt loam~~	~~11.4~~	~~n.a.~~
~~30248/1~~	~~Fresne-L'Archeveque (France)~~	~~silt loam~~	~~31.4~~	~~18.1~~
~~30250/3~~	~~Fresne-L'Archeveque (France)~~	~~silt loam~~	~~32.9~~	~~20.8~~
~~30251/1~~	~~Laudun (France)~~	~~loam~~	~~24.7~~	~~n.a.~~
~~30253/8~~	~~St. Etienne du Gres (France)~~	~~loam~~	~~37.6~~	~~19.6~~
~~30254/6~~	~~Saussay La Campagne (France)~~	~~silt loam~~	~~6.0~~	~~n.a.~~
~~30455/7~~	~~Fresne-L'Archeveque (France)~~	~~silt loam~~	~~7.1~~	~~n.a.~~
~~30499/9~~	~~Burscheid (Germany)~~	~~silt loam~~	~~8.5~~	~~29.8~~
~~30500/6~~	~~Monheim (Germany)~~	~~sandy loam~~	~~14.7~~	~~n.a.~~
~~40163/3~~	~~Laudun (France)~~	~~clay loam~~	~~45.3~~	~~21.8~~
~~40164/1~~	~~St. Etienne du Gres (France)~~	~~silt loam~~	~~41.0~~	~~25.0~~
~~40494/2~~	~~Ravenna (Italy)~~	~~silt loam~~	~~36.2~~	~~41.4~~
~~40495/0~~	~~S. Romualdo (Italy)~~	~~silty clay~~	~~51.1~~	~~14.1~~
~~Geometric mean~~			~~22.3~~	~~21.7~~

~~n.a.: not applicable~~

~~Conclusion~~

~~The calculated normalized half lives (20 °C and 100% field capacity) for modelling purpose for the degradation in soil under field conditions ranged from 6.0 to 51.1 days (geometric mean 22.3 d) for flufenacet and from 14.1 to 41.4 days (geometric mean 21.7 d) for FOE sulfonic acid.~~

A 2.1.2.2.2 KCA 7.1.2.2.2 Soil accumulation studies

No new or additional studies have been submitted.

[2] MARS, Interpolated meteorological data – JRC/MARS Database. European Commission, Joint Research Center (JRC). Ispra, 2004.

A 2.1.3 KCA 7.1.3 Adsorption and desorption in soil

A 2.1.3.1 KCA 7.1.3.1 Adsorption and desorption

A 2.1.3.1.1 KCA 7.1.3.1.1 Adsorption and desorption of the active substance

No new or additional studies have been submitted.

A 2.1.3.1.2 KCA 7.1.3.1.2 Adsorption and desorption of metabolites, breakdown and reaction products

Comments of zRMS:	The summarised below study was not evaluated by the zRMS since the available dataset was sufficient to finalise the exposure assessment and additional data for the flufenacet metabolite FOE sulfonic acid were not necessary to demonstrate the safe uses while evaluation of the new data is expexted during the ongoilg renewal process Summary below was thus struck through and shaded as being not validated.

Reference:	**KCA 7.1.3.1.2/01**
Title:	Time-dependent sorption of FOE5043-sulfonic acid in soil
Report:	Hellpointner, E.; 2003; MEF-229/03; M-111445-01-1
Guideline(s):	EC: Official Journal of the EC No. L 172 (EN), July 22, 95 Commission Directive 95/36/EC, amending Council Directive 91/414/EEC Annex II, Fate and Behaviour in the Environment, 7171/VI/94-EN, Section 7.1.2 according to OECD 106 (2000)
Deviations:	not applicable
GLP/GEP:	yes
Acceptability:	Not evaluated, not necessary to finalise the exposure assessment

Materials and methods

Details on the study conduct and its results are summarized under A 2.1.2.1.
The results were used to calculate the sorption constants (K_d) based on the amount of test item adsorbed to soil (sum of recovered FOE sulfonic acid in ambient soil extracts) in relation to the amount of FOE sulfonic acid desorbed during the so-called batch equilibrium shaking test by the 0.01M $CaCl_2$ solution.

Results and discussions

The tables below summarize the time-dependent sorption behaviour of [phenyl-UL-^{14}C]-FOE sulfonic acid as a function of time.

Table A 9: Time dependent sorption of FOE sulfonic acid in soil Laacherhof AXXa

Parameter	Replicate	DAT 0	3	7	14	28	56	100
$c_{desorbed}$ [µg/mL] [1]	1	0.110	0.104	0.103	0.094	0.077	0.059	0.029
	2	0.108	0.105	0.101	0.095	0.080	0.064	0.028
$c_{extracted}$ [µg/g] [2]	1	0.0120	0.0177	0.0159	0.0166	0.0161	0.0111	0.0061
	2	0.0145	0.0166	0.0160	0.0150	0.0146	0.0110	0.0068
K_d [mL/g]	mean	0.12	0.16	0.16	0.17	0.20	0.18	0.23
K_{OC} [mL/g]	mean	8	11	11	11	13	12	16
Time-dependent sorption factor [3]	mean	2						

[1] Concentration of test item in desorption solution from soil batch equilibrium shaking test
[2] Concentration of test item in soil after 24 h desorption phase (sum of test item in ambient soil extracts)
[3] Time-dependent sorption factor K_d (DAT 100) / K_d (DAT 0) = 2

~~Table A 10: Time Dependent Sorption of FOE sulfonic acid in Soil Laacherhof AIII~~

~~Parameter~~	~~Replicate~~	~~DAT 0~~	~~3~~	~~7~~	~~14~~	~~28~~	~~56~~	~~100~~
~~$c_{desorbed}$ [µg/mL] [1]~~	~~1~~	~~0.113~~	~~0.107~~	~~0.104~~	~~0.099~~	~~0.084~~	~~0.062~~	~~0.027~~
	~~2~~	~~0.109~~	~~0.105~~	~~0.102~~	~~0.095~~	~~0.081~~	~~0.060~~	~~0.030~~
~~$c_{extracted}$ [µg/g] [2]~~	~~1~~	~~0.0125~~	~~0.0152~~	~~0.0145~~	~~0.0131~~	~~0.0129~~	~~0.0096~~	~~0.0069~~
	~~2~~	~~0.0137~~	~~0.0149~~	~~0.0145~~	~~0.0151~~	~~0.0125~~	~~0.0093~~	~~0.0028~~
~~K_d [mL/g]~~	~~mean~~	~~0.12~~	~~0.14~~	~~0.14~~	~~0.15~~	~~0.15~~	~~0.15~~	~~0.18~~
~~K_{OC} [mL/g]~~	~~mean~~	~~13~~	~~16~~	~~16~~	~~17~~	~~17~~	~~18~~	~~20~~
~~Time-dependent sorption factor [3]~~	~~mean~~	~~1.5~~						

~~[1] Concentration of test item in desorption solution from soil batch equilibrium shaking test~~
~~[2] Concentration of test item in soil after 24 h desorption phase (sum of test item in ambient soil extracts)~~
~~[3] Time-dependent sorption factor K_d (DAT-100) / K_d (DAT-0) = 2~~

~~Conclusion~~

~~During the entire ageing period of 100 days the sorption values (Kd) increased by a factor of 2 (0.12 to 0.23 mL/g) and 1.5 (0.12 to 0.18 mL/g) in soils Laacherhof AXXa and Laacherhof AIII, respectively. However, the overall results of this results clearly indicate that not a time-dependent sorption behaviour of FOE sulfonic acid, but rather shorter half-lives under aerobic condition in soil are the most plausible reason for measuring much lower peak concentrations of test item in the leachates of the lysimeter studies than that expected by modelling calculations with the earlier input parameters (longer half-lives).~~

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Comments of zRMS:	Its submission is justified since no EU agreed sorption data exist for this compound. Nevertheless, the study was not evaluated by the zRMS since it was already considered in the course of the ongoing flufenacet EU renewal process and agreed by the RMS. Since the process is already at the late stage, the Kfoc values reported in the LoEP (version of November 2018) may be considered as peer-reviewed and accepted. It is noted that the geometric mean Kfoc agreed by the RMS is slightly lower (42.1 mL/g), which is a result of rounding procedure. The difference is not expected to have any impact on the modelling results. Since the study was not evaluated by the zRMS, its summary is struck through below for clarity.

Reference:	**KCA 7.1.3.1.2/02**
Title:	Soil adsorption/desorption of FOE 5043 degradates: FOE Sulfonic Acid, FOE Methyl Sulfoxide, FOE Oxalate, FOE Alcohol, and Thiadone
Report:	Blumhorst, M. R.; Yen, P. Y.; Marlow, V. A.; 1994; MR106598; M-002185-01-1
Guideline(s):	EPARef: 163-1, Adsorption/desorption
Deviations:	none
GLP/GEP:	yes
Acceptability:	Accepted by the RMS, EFSA and MS experts in the course of the ongoing flufenacet EU renewal process.

~~Materials and methods~~

~~1. Test Item~~

~~FOE-thiadone~~	
~~BAS No~~	~~94-503~~
~~Specific activity~~	~~12.40 MBq/mg (≙ 57 mCi/mmol = 335 µCi/mg)~~
~~Radiochemical purity~~	~~99.7%~~

2. Test Soils

The soils were sieved to a particle size of ≤ 2 mm. The soils were taken from agricultural areas representing different geographical origins and different soil properties as required by the guidelines.

Table A 11: Physico-chemical properties of test soils

Parameter		Results / Units			
Soil Designation		Winder	Shipshe	Drummer	Oska-Martin
Geographic Location City State Country		 Vero Beach Florida USA	 Howe Indiana USA	 Champaign Illinois USA	 Stilwell Kansas USA
Soil Series		no information available			
Textural Class (USDA)		sand	sandy loam	silty clay loam	silty clay
Sand [%]	[50 µm – 2 mm]	92.5	68.5	11.1	3.1
Silt [%]	[2 µm – 50 µm]	1.3	17.6	54.1	47.1
Clay [%]	[< 2 µm]	6.3	13.9	34.8	49.8
pH in water (soil/water 1/1)		5.8	6.3	6.6	6.0
Organic Carbon [%]		0.27	0.75	2.13	1.21
Organic Matter [%] [1]		0.5	1.3	3.7	2.1
Cation Exchange Capacity [meq/100 g]		3.3	7.9	22.4	29.3
Water Holding Capacity at 0.33 bar (pF 2.5) [%]		5.0	8.3	24.8	28.1

[1] calculated as: OM [%] = OC [%] / 1.724 USDA: United States Department of Agriculture

The test system for adsorption and desorption in batch equilibrium experiments consisted of glass centrifuge tubes closed with Teflon® lined caps. The experiments were performed in triplicate.
In preliminary tests, the adsorption of the test item to the test system surface, the optimal soil-to-solution ratio, the appropriate adsorption and desorption equilibration times and the stability of the test item were determined.
The adsorption phase was carried out using air-dried soils and aqueous 0.01M $CaCl_2$ solution with a soil-to-solution ratio of 3:10 (6 g soil $_{\text{dry weight}}$/20 mL solution). FOE-thiadone was applied at nominal concentrations of 5.0, 1.0, 0.2 and 0.04 mg/L in aqueous 0.01M $CaCl_2$ solution (containing max. 0.5% acetonitrile). The desorption phase was performed by supplying pre-adsorbed soil samples with fresh aqueous 0.01M $CaCl_2$ for all test concentrations. For the highest test concentration (5.0 mg/L) two additional desorption cycles were performed likewise. The adsorption and desorption steps were carried out each for 24 hours in the dark at 23.5 ± 1.5 °C under continuous agitation.

Analytical Procedures
After each adsorption and desorption step the aqueous supernatant was separated from the soil by centrifugation and the amount of FOE-thiadone in the supernatants was analysed by liquid scintillation counting (LSC).
The stability of the test item was demonstrated by HPLC/radio-detection analysis of the adsorption and desorption solutions of the highest test concentration of the definitive test. The limit of detection (LOD) for HPLC/radio-detection analysis corresponds to 1.2% of the applied radioactivity.
The partition of the test item in the adsorption and desorption batch equilibrium experiment was determined based on the radioactivity content in the supernatant only due to the stability of the test item demonstrated by the parental mass balance. After the desorption steps, the soil was air-dried and the radioactivity content determined by combustion/LSC to establish the material balance.
Adsorption and desorption isotherms were calculated by linear regression analysis of the adsorption or desorption data according to the Freundlich equation.

Results and discussions

A. Material Balance
Mean material balances were 96.5, 92.1, 84.6 and 84.8% of applied radioactivity [% AR] for soil Winder, Shipshe, Drummer and Oska-Martin, respectively.

B. Degradation of Test Item

FOE-thiadone was sufficient stable throughout the study, as demonstrated by HPLC/radio-detection analysis. The amount of FOE-thiadone ranged from 95.4 to 100.0% in all adsorption and desorption solutions of the highest test concentration of the definitive test.

C. Findings

At the end of the adsorption phase, 1.6 to 7.8% AR was adsorbed to soil Winder, 6.7 to 16.6% AR to soil Shipshe, 8.6 to 36.7% AR to soil Drummer and 11.3 to 28.6% AR to soil Oska-Martin. The adsorption constants $K_{F(ads)}$ of FOE-thiadone calculated based on the Freundlich isotherms of the four test soils ranged from 0.12 to 0.71 mL/g and the normalized adsorption constants $K_{OC(ads)}$ (normalized to organic carbon content) ranged from 29 and 58 mL/g. The Freundlich exponents 1/n were in the range of 0.673 to 0.807, indicating that the concentration of the test item affects its adsorption behaviour in the examined concentration range.

At the end of the first desorption phase, 13.4 to 62.2% (single sample up to 116.4%), 15.5 to 36.0%, 1.5 to 24.5% and 15.4 to 22.4% (highest test concentration up to - 8.7%) of the initially adsorbed amount were desorbed from soil Winder, Shipshe, Drummer and Oska-Martin, respectively. The desorption constants $K_{F(des)}$ (range from 0.35 to 2.10 mL/g) and the normalized desorption constants $K_{OC(des)}$ (range from 73 to 189 mL/g) were 2 to 4 times higher than the adsorption coefficients $K_{d(ads)}$ / $K_{OC(ads)}$.

Table A 12: Percentage of adsorbed and desorbed FOE-thiadone in soils (ranges of triplicates)

	Test Concentration [mg/L]							
	Adsorption [1]				Desorption [2]			
Soil	5.0	1.0	0.2	0.04	5.0	1.0	0.2	0.04
Winder	2.1 – 3.7	1.6 – 4.4	2.8 – 5.3	6.2 – 7.8	47.6 – 62.2	23.0 – 28.7[3]	24.5 – 50.4	13.4 – 28.8
Shipshe	6.7 – 6.9	8.5 – 10.0	11.0 – 12.7	15.2 – 16.6	15.5 – 26.8	25.3 – 30.0	27.5 – 36.0	27.8 – 29.5
Drummer	8.6 – 10.3	15.9 – 16.2	25.5 – 26.2	35.5 – 36.7	10.4 – 24.5	13.8 – 17.1	1.5 – 4.0	6.0 – 10.1
Oska-Martin	11.3 – 13.3	19.4 – 20.0	24.2 – 25.5	27.2 – 28.6	-5.6 – 8.7	15.6 – 22.4	15.4 – 17.6	14.9 – 19.0

[1] end of adsorption phase, mean values expressed as percentage of applied radioactivity
[2] end of first desorption phase, mean values expressed as percentage of the initially adsorbed amount
[3] single value of 116.4%

Table A 13: Adsorption/desorption constants and correlation coefficients of FOE-thiadone in soil at 20 °C

Soil	Adsorption K_F [mL/g]	1/n	R^2	K_{OC} [mL/g]	Desorption K_F [mL/g]	1/n	R^2	K_{OC} [mL/g]
Winder	0.12	0.782	0.975	43	0.35	0.705	0.958	128
Shipshe	0.33	0.807	0.999	44	1.42	0.876	0.998	189
Drummer	0.61	0.673	0.999	29	1.56	0.654	0.995	73
Oska-Martin	0.71	0.798	0.998	58	2.10	0.888	0.998	174

Conclusion

The adsorption constants KF(ads) of FOE-thiadone ranged from 0.12 to 0.71 mL/g, the respective normalized adsorption constants KOC(ads) ranged from 29 and 58 mL/g. The Freundlich exponents 1/n were in the range of 0.673 to 0.807, indicating that the concentration of the test item affects its adsorption behaviour in the examined concentration range. The results indicate that the adsorption behaviour of FOE-thiadone is dependent on the soil organic content.

A 2.1.3.2 KCA 7.1.3.2 Aged sorption

No new or additional studies have been submitted.

A 2.1.4 KCA 7.1.4 Mobility in soil

No new or additional studies have been submitted.

A 2.1.4.1 KCA 7.1.4.1 Column leaching studies

A 2.1.4.1.1 KCA 7.1.4.1.1 Column leaching of the active substance

A 2.1.4.1.2 KCA 7.1.4.1.2 Column leaching of metabolites, breakdown and reaction products

A 2.1.4.2 KCA 7.1.4.2. Lysimeter studies

A 2.1.4.3 KCA 7.1.4.3 Field leaching studies

A 2.2 KCA 7.2 Fate and behaviour in water and sediment

No new or additional studies have been submitted.

A 2.2.1 KCA 7.2.1 Route and rate of degradation in aquatic systems (chemical and photochemical degradation)

A 2.2.1.1 KCA 7.2.1.1 Hydrolytic degradation

A 2.2.1.2 KCA 7.2.1.2 Direct photochemical degradation

A 2.2.1.3 KCA 7.2.1.3 Indirect photochemical degradation

A 2.2.2 KCA 7.2.2 Route and rate of biological degradation in aquatic systems

A 2.2.2.1 KCA 7.2.2.1 "Ready biodegradability"

A 2.2.2.2 KCA 7.2.2.2 Aerobic mineralisation in surface water

A 2.2.2.3 KCA 7.2.2.3 Water/sediment study

A 2.2.2.4 KCA 7.2.2.4 Irradiated water/sediment study

A 2.2.3 KCA 7.2.3 Degradation in the saturated zone

A 2.3 KCA 7.3 Fate and behaviour in air

No new or additional studies have been submitted.

A 2.3.1 KCA 7.3.1 Route and rate of degradation in air

A 2.3.2 KCA 7.3.2 Transport via air

A 2.3.3 KCA 7.3.3 Local and global effects

A 2.4 KCA 7.4 Definition of the residue

No new or additional studies have been submitted.

A 2.4.1 KCA 7.4.1 Definition of the residue for risk assessment

A 2.4.2 KCA 7.4.2 Definition of the residue for monitoring

A 2.5 KCA 7.5 Monitoring data

No new or additional studies have been submitted.

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

A 3.1 8.7 Predicted Environmental Concentrations in soil (PEC_{soil}) (KCP 9.1.3)

Flufenacet and relevant metabolites

Comments of zRMS:	The soil exposure calculated by the Applicant was agreed by the zRMS. For discussion on input parameters and obtained results, please refer to point 8.7 of this document.

Reference:	**KCP 9.1.3/01**
Title:	Flufenacet (FFA) core PECsoil EUR - Modelling core info document for soil risk assessment in Europe
Report:	Reinken, G.; Porschewski, R.; 2017; EnSa-16-0744; M-577701-01-1
Guideline(s):	not applicable
Deviations:	not applicable
GLP/GEP:	no
Acceptability:	Acceptable

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Comments of zRMS:	The soil exposure calculated by the Applicant was agreed by the zRMS. For discussion on input parameters and obtained results, please refer to point 8.7 of this document.

Reference:	**KCP 9.1.3/02**
Title:	Flufenacet (FFA) and metabolites: PECsoil EUR - Use in winter cereals in Europe
Report:	Reinken, G.; Serode, R.; 2020; EnSa-20-0760; M-765638-01-1
Guideline(s):	none
Deviations:	None
GLP/GEP:	no
Acceptability:	Acceptable

A 3.2 8.8 Predicted Environmental Concentrations in groundwater (PEC_{gw}) (KCP 9.2.4.1)

Flufenacet and relevant metabolites

Comments of zRMS:	The input parameters for flufenacet and its metabolites were partially agreed by the zRMS. The groundwater modelling performed by the Applicant at Tier 1a was accepted by the zRMS while this performed at Tier 2 was not agreed due to not accepted soil degradation data considered by the Applicant for FOE sulfonic acid. In consequence, additional simulation were performed by the zRMS and used for derivation of the conclusion. For discussion on input parameters and obtained results, please refer to point 8.8.2 of this document.

Reference:	**KCP 9.2.4.1/01**
Title:	Flufenacet (FFA) core PECgw FRA - Modelling core info document for groundwater risk assessment in France
Report:	Reinken, G.; Tamazashvili, A.; 2017; EnSa-17-0044; M-579316-01-1
Guideline(s):	not applicable
Deviations:	not applicable
GLP/GEP:	no
Acceptability:	Partially accepted (for details, please refer to point 8.8 of this report)

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Comments of zRMS:	The groundwater modelling performed by the Applicant at Tier 1a was agreed by the zRMS. For discussion on input parameters and obtained results, please refer to point 8.8.2 of this document.

Reference:	**KCP 9.2.4.1/02**
Title:	Flufenacet (FFA) and metabolites: PECgw FOCUS PEARL, PELMO, MACRO EUR (Tier 1a) - Use in winter cereals in Europe
Report:	Reinken, G.; Serode, R.; 2020; EnSa-20-0761; M-765637-01-1
Guideline(s):	none
Deviations:	None
GLP/GEP:	no
Acceptability:	Acceptable

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Comments of zRMS:	The groundwater modelling performed by the Applicant at Tier 2 was not agreed by the zRMS. For discussion on input parameters and obtained results, please refer to point 8.8.2 of this document.

Reference:	**KCP 9.2.4.1/03**
Title:	Flufenacet (FFA) and metabolites: PECgw FOCUS PEARL, PELMO, MACRO EUR (Tier 2) - Use in winter cereals in Europe
Report:	Reinken, G.; Serode, R.; 2021; EnSa-21-0150; M-765725-01-1
Guideline(s):	none
Deviations:	None
GLP/GEP:	no
Acceptability:	Not accepted (for details, please refer to point 8.8.2.2 of this report)

A 3.3 8.9 Predicted Environmental Concentrations in surface water (PEC_{sw}) (KCP 9.2.5)

Flufenacet and relevant metabolites

Comments of zRMS:	The surface water modelling performed by the Applicant was agreed by the zRMS. For discussion on input parameters and obtained results, please refer to point 8.9 of this document.

Reference:	**KCP 9.2.5/01**
Title:	Flufenacet (FFA) core PECsw EUR - Modelling core info document for surface water risk assessment in Europe
Report:	Reinken, G.; Porschewski, R.; 2017; EnSa-16-0743; M-577700-01-1
Guideline(s):	not applicable
Deviations:	not applicable
GLP/GEP:	no
Acceptability:	Acceptable

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Comments of zRMS:	The surface water modelling performed by the Applicant was agreed by the zRMS. For discussion on input parameters and obtained results, please refer to point 8.9 of this document.

Reference:	**KCP 9.2.5/02**
Title:	Flufenacet (FFA) and metabolites: PECsw,sed FOCUS EUR - Use in winter cereals in Europe
Report:	Reinken, G.; Serode, R.; 2020; EnSa-20-0749; M-765640-01-1
Guideline(s):	none
Deviations:	None
GLP/GEP:	no
Acceptability:	Acceptable