FINAL REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: CHR/H/PENDIF 599.5 SC

Product name(s): Cevino Trio 599.5 SC/ Trivino 599.5 SC

Chemical active substance(s):

Penoxsulam, 37.5 g/L
Diflufenican, 250 g/L
Flufenacet, 312 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Innvigo Sp. z o.o.

Submission date: October 2021

MS Finalisation date: 24/08/2022

Version history

When	What
February 2022	Dossier sent for evaluation
March 2022	Updates based on feedback from zRMS Poland
April 2022	Updates based on feedback from zRMS Poland
April 2022	Updates based on feedback from zRMS Poland
April 2022	Updates based on feedback from zRMS Poland
April 2022	zRMS evaluation of dRR
August 2022	Final version prepared by zRMS after Commenting period

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zRMS comments:
The text highlighted in grey was provided by the evaluator.

8 Fate and behaviour in the environment (KCP 9)

In the following document, data for active substances - penoxsulam, diflufenican and flufenacet - was described during its inclusion on Annex 1 process in respectively 2010, 2009 and 2004 . Were reference to active substance data in the current risk assessment has been made, it was based on the data which protection for expired 10 years from date of inclusion of active substances on Annex I

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: develop-mental stages of the pest or pest group)	**Application**				**Application rate**			PHI (days)	Remarks: e.g. g saf-ener/ synergist per ha	**Conclusion**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	PL	Winter wheat (TRZAW), Winter triticale (TTLWI),	F	dicotyledonous weeds	Spray, medium sprayer	autumn BBCH 11-25	a)1 b)1	n/a	a) 0.4 l/ha b) 0.4 l/ha	a) 0.2398 kg a.s./ha (0.1248 FLU + 0.1 D + 0.015 P) b) 0.2398 kg a.s./ha (0.1248 FLU + 0.1 D + 0.015 P)	200-400	n/a		
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)														
Minor uses according to Article 51 (zonal uses)														
Minor uses according to Article 51 (interzonal uses)														

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

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

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

The safe use is acceptable if product is used every other year.

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

Summary of intended uses (active substance)

Crop and/or situation	Member State or Country	Product Name	F G or I	Pests or Group of pests controlled	Formulation		Application			Application rate per treatment			PHI (days)	Remarks
(a)			(b)	(c)	Type (d-f)	Conc. of a.s. (i)	Method Kind (f-h)	Growth stage & season (j)	Number min max (k)	kg a.s./ha min max	water (L/ha) min max	kg a.s./hL min max	(l)	(m)
Rice	Italy	penoxsulam DE-638 (GF-657)	F	Echinochloa crus-galli, sedges and broad leaf weeds.	OD	20.4 g/L	Broadcast spray**	BBCH 11-31 May-June	1	0.03-0.04	200-400	0.0075-0.02	N.N*	[1]
Rice	Spain	penoxsulam DE-638 (GF-657)	F	Echinochloa crus-galli, sedges and broad leaf weeds.	OD	20.4 g/L	Broadcast spray**	BBCH 11-31 May-June	1	0.03-0.04	150-400	0.0075-0.027	N.N	[1]
Rice	Portugal	penoxsulam DE-638 (GF-657)	F	Echinochloa crus-galli, sedges and broad leaf weeds.	OD	20.4 g/L	Broadcast spray**	BBCH 11-31 May-June	1	0.03-0.04	150-400	0.0075-0.027	N.N	[1]
Rice	Greece	penoxsulam DE-638 (GF-657)	F	Echinochloa crus-galli, sedges and broad leaf weeds.	OD	20.4 g/L	Broadcast spray**	BBCH 11-31 May-June	1	0.03-0.04	300-500	0.006-0.013	N.N	[1]
Rice	France	penoxsulam DE-638 (GF-657)	F	Echinochloa crus-galli, sedges and broad leaf weeds.	OD	20.4 g/L	Broadcast spray**	BBCH 11-31 May-June	1	0.03-0.04	150-300	0.01-0.027	N.N	[1]

[1] The risk to aquatic plants has not been addressed
** The assessment covers only tractor application technology

Table 8.1-3: Assessed (critical) uses during approval of diflufenican concerning the Section Environmental Fate

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled I	Preparation Type (d-f)	Preparation Conc. Of as (i)	Application method kind (f-h)	Application growth stage & season (j)	Application number min/ max (k)	Application interval between applications (min)	Application rate per treatment g as/hL min – max (l)	Application rate per treatment water L/ha min – max	Application rate per treatment g as/ha min – max (l)	PHI (days) (m)	Remarks
Winter wheat Winter barley Winter rye	EU	Herold SC 600	F	Annual dicot weeds, ALOMY, APESV, POAAN	SC	1. 200 g/L 2. 400 g/L	Tractor mounted boom spraying	Pre-emergence; Post-emergence BBCH 10-13	1		1. 0.06 – 0.03 2. 0.12 – 0.06	200 – 400	1. 0.12 2. 0.24	#	0.6 L / ha product; Autumn use only

1 – active substance diflufenican, 2 – active substance flufenacet

* 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

Table 8.1-4: 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 or L product/ha a) max. rate per appl. b) max. total rate per crop/season	kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
	Northern and Southern Europeam Countries	Corn	F	Annual grass weeds	Spray application with standard field sprayers	Pre - Emergence	1	N/A	0.8-1 kg/ha	0.48 - 0.60	200 - 400	Not applicable	

	Southern Europeam Countries	Soybean, Sun-flower	F	Annual grass weeds	Spray applicati on with stand-ard field spray-ers	Pre - Emergence	1	N/A	0.8-1 kg/ha	0.48 - 0.60	200 - 400	Not applicable	
	Northern Europeam Countries	Winter cereals (wheat, rye, barley , triticale)	F	Annual grass weeds	Spray applicati on with stand-ard field spray-ers	Pre - Emergence	1	N/A	0.2-04 kg/ha	0.12-0.24	200 - 400	Not applicable	

* 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 penoxsulam potentially relevant for exposure assessment

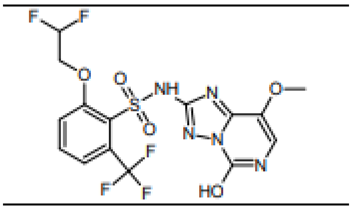
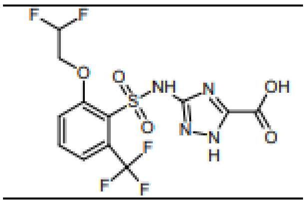
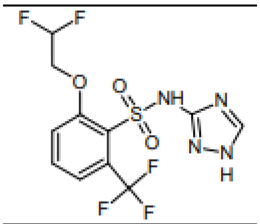
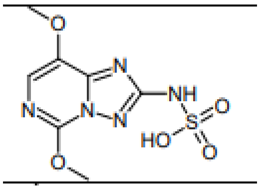
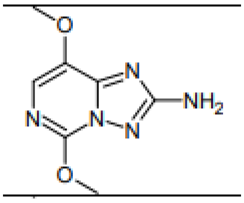
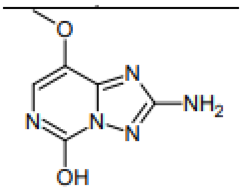
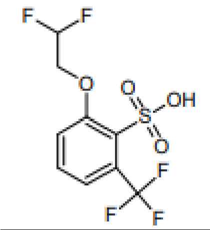
Metabolite	Molar mass	Chemical structure	Maximum observed occurence in compartements	Exposue assessment required due to
5-OH-penoxsulam			Soil/Water/Sediment: 41/-/19	PECs, PECgw, PECsw
BSTCA			Soil/Water/Sediment: 53/-/24	PECs, PECgw, PECsw
BST			Soil/Water/Sediment: 8/-/-	PECgw
TPSA			Soil/Water/Sediment: -/56/-	PECsw
2-amino-TP			Soil/Water/Sediment: -/18/-	PECsw
5-OH-2-amino-TP			Soil/Water/Sediment: -/23/-	PECsw
BSA			Soil/Water/Sediment: -/36/-	PECsw

Table 8.2-2: Metabolites of diflufenican potentially relevant for exposure assessment

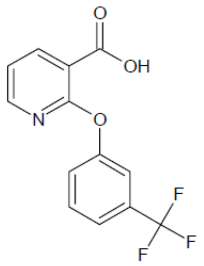
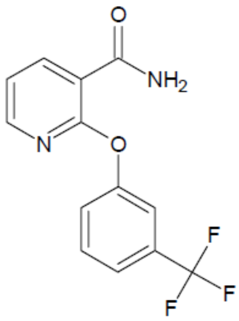
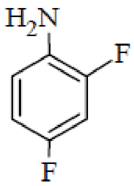
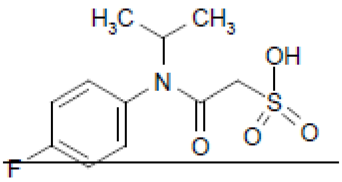
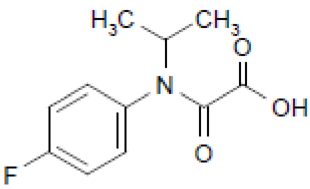
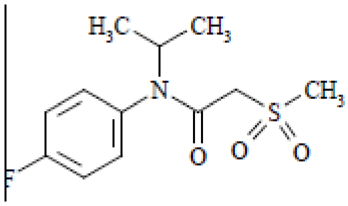
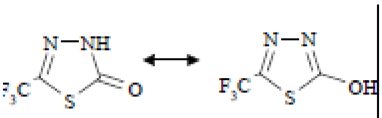
Metabolite	Molar mass	Chemical structure	Maximum observed occurence in compartements	Exposue assessment required due to
AE B107137	283		Soil: 16.8% Water: 32.6% Sed: 13.3%	AE PECsoil PECgw: leaching potential to groundwater PECsw/sed B107137
AE 0542291	282		Soil: 26.3% Water: 6.1% Sed: 1.0%	PECsoil PECgw: leaching potential to groundwater PECsw/sed
AE C522392	129.11		Soil: 26.3% Water: 6.1% Sed: 1.0%	PECsoil PECgw: leaching potential to groundwater PECsw/sed

Table 8.2-3: Metabolites of flufenacet potentially relevant for exposure assessment

Metabolite	Molar mass	Chemical structure	Maximum observed occurence in compartements	Exposue assessment required due to
FOE sulfonic acid	275.3g/mol		Soil (lab): max 26.3% AR	PEC_{gw}; PEC_{soil}
FOE oxalate	225.2g/mol		Soil (Lab): max 15.6 % AR	PECsoil PEC_{gw}
FOE methyl-sulfone	273.3g/mol		Water/sediment max. 8 % in water, 3.4 % in sediment on day 157	PEC sw

Metabolite	Molar mass	Chemical structure	Maximum observed oc-curence in compartements	Exposue assessment re-quired due to
FOE-thiazole	170.1g/mol		Maximum occurrence ob-served in sediment/ water studies: 82 % in water (55 d)	PECsw

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)

Studies on aerobic degradation in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance. EU approved endpoints were evaluated during Annex I inclusion for actives substances. All relevant data are presented in:

- **Penoxsulam -** EFSA Scientific Report (2009) 343, 59-90
- **Diflufenican -** EFSA Scientific Report (2007) 122, 1-84,
- **Flufenacet** – SANCO 7469/VI/98-Final 3 July 2003 and Flufenacet Addendum to the monograph of flufenacet-Annex B- B.7 Enviromental Fate and behaviour

8.3.1.1 Penoxsulam and its metabolites

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

Method of calculation	Linear first-order kinetics for parent compound. Non-linear first-order kinetics used for 5-OH-DE-638 and BSTCA metabolites.
Laboratory studies (range or median, with n value, with r^2 value)	DT_{50lab} (20 °C, aerobic): Average = 32 days (range 22 - 58 days, n = 4, r^2 = 0.96 - 0.99) 5-OH-DE-638 DT_{50lab} (20 °C, aerobic): Average = 26 days (range 19 - 37 days, n = 4, r^2 = 0.97 - 0.99) BSTCA DT_{50lab} (20 °C, aerobic): Average = 79 days (range 61 – 118 days, n = 4, r^2 = 0.97 - 0.99)
	DT_{90lab} (20 °C, aerobic): Average = 107 days (range 74 - 192 days, n = 4, r^2 = 0.96 - 0.99)
	DT_{50lab} (6 °C, aerobic): 137 days (n = 1, r^2 = 0.95)
	DT_{50lab} (20 °C, anaerobic): 6.6 days (total system, n = 1, r^2 = 0.98), 5.3 days (water only, n = 1, r^2 = 1.00), 8.8 days (soil only, n = 1, r^2 = 0.91) 5-OH-DE-638 DT_{50lab} (20 °C, anaerobic): 5.1days (total system, n = 1, r2 = 0.80)
	DT_{50lab} (photolysis on moist soil, 25 °C, 40 °N latitude, summer sunlight): 19 days (n = 1, r^2=0.90)
	Degradation in the saturated zone: Data not submitted, not required.

8.3.1.2 Diflufenican and its metabolites

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

Diflufenican	Aerobic conditions						
Soil type	X^{20}	pH ($CaCl_2$)	t. °C / % MWHC	DT_{50} / DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
Sandy loam		7.7 [(a)]	22°C/ 75 % of 0.33 bar	248.5/825.5	237.9	0.9980	SFO
Clay loam		6.6 [(a)]	22°C/ 75 % of 0.33 bar	139.5/463.4	119.9	0.9967	SFO
Clay loam		6.5	20°C/45 %	232.6/772.7	193.5	0.9954	SFO
Clay loam		6.5	20°C/45 %	206.0/684.3	172.1	0.9975	SFO
Clay loam		6.5	20°C/45 %	176.3/585.8	147.3	0.9967	SFO
Silty clay loam		7.5	20°C/45 %	44.3/147.2	44.3	0.9819	SFO
Sandy loam 1		5.5	20°C/45 %	129.3/429.5	129.3	0.9836	SFO
Sandy loam 2		6.9	20°C/45 %	89.8/298.3	89.8	0.9890	SFO
Sandy loam 2		6.9	10°C/45 %	204.4/679.0 [(b)]			SFO
Geometric mean/median					128 / 138.3		
Arithmetric mean					141.8		

Table 8.3-3: Summary of aerobic degradation rates for AE B107137 - laboratory studies

AE B107137	Aerobic conditions							
Soil type	X^1	pH ($CaCl_2$)	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f [(c)]	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
Silt loam 1		7.0	20 °C/45 %	9.1/30.2	1	7.5	0.9919	SFO
Sandy loam		6.2	20 °C/45 %	17.9/59.5	1	13.9	0.9868	SFO
Silt loam 2		7.4	20 °C/45 %	14.5/48.1	1	10.4	0.9959	SFO
Geometric mean/median						10.3 / 10.4		
Arithmetric mean						10.6		

Table 8.3-4: Summary of aerobic degradation rates for AE 0542291 - laboratory studies

AE 0542291	Aerobic conditions							
Soil type	X^1	pH ($CaCl_2$)	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f [(c)]	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
Silt loam 1		7.0	20 °C/45 %	13.6/45.2	1	11.1	0.987	SFO
Sandy loam		6.2	20 °C/45 %	58.7/194.9	1	45.7[d]	0.999	SFO

AE 0542291	Aerobic conditions							
Soil type	X[1]	pH ($CaCl_2$)	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f (c)	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
Silt loam 2		7.4	20 °C/45 %	33.2/110.2	1	23.8	0.991	SFO
Geometric mean/median						22.9 / 23.8		
Arithmetic mean						26.9		

8.3.1.3 Flufenacet and its metabolites

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

Soil type	pH	OC (%)	DT50 (days)
loamy sand	6.2	2.58	39
silt loam	7.3	0.9	15
silt loam	5.8	2.4	27
sandy loam*	6.2	0.32	34-64 (mean 48)
* 2 labels, 21° C, 75 % FC			Normalized DT 50 used for Focus calculations: 13-24d (**geometric mean 16.5d, n=3**)

Table 8.3-6: Summary of aerobic degradation rates for FOE sulfonic acid- laboratory studies

Soil type	pH	OC (%)	DT50 (days)
sand	5.3	0.57	270
loamy sand	6.3	2.48	189
silt loam	7.3	0.9	247
			Normalized DT 50 used for Focus calculations: 119-189d (**geometric mean 140 d, n=3)**

Table 8.3-7: Summary of aerobic degradation rates for FOE oxalate- laboratory studies

Soil type	pH	OC (%)	DT50 (days)
sand	6.2	2.58	5
loamy sand	7.3	0.9	17
silt loam	5.8	2.3	12
			Normalized DT 50 used for Focus calcu-lations: 4-10 d (**geometric mean 6.6 d, n=3**)

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

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

Annex I inclusion for active substances. All relevant data are presented in :

- **Penoxsulam** - EFSA Scientific Report (2009) 343, 59-90
- **Diflufenican** - EFSA Scientific Report (2007) 122, 1-84,
- **Flufenacet** – SANCO 7469/VI/98-Final 3 July 2003 and Flufenacet Addendum to the monograph of flufenacet-Annex B- B.7 Enviromental Fate and behaviour

8.3.2.1 Penoxsulam and its metabolites

Anaerobic degradation	Mineralization: ≤1% AR (120 days, both TP and PH radiolabels) NER: Average = 64.1% AR (120 days, 65.3% TP radiolabel, 62.9% PH radiolabel) Major metabolites: 5-OH-DE-638 (33.4% AR at 14 days), BSTCA (19.1% AR at 120 days)
Soil photolysis	Photolysis on moist soil, 25 °C, 40 °N latitude, summer sunlight Mineralization: <1% AR (37 days, both TP and PH radiolabels) NER: Average = 24.4% AR (37 days, 30.9% TP radiolabel, 17.9% PH radiolabel) Major metabolites: BSTCA (11.1% AR at 30 days), 2-amino-TP (10.4% AR at 37 days)

8.3.2.2 Diflufenican and its metabolites

Anaerobic degradation ‡	
Mineralization after 100 days	Not available for [^{14}C-2,4-difluorophenyl]-label Not available for [^{14}C-3-trifluoromethylphenyl]-label 4.0 % after 112 d, [^{14}C-2-pyridyl]-label (n=1)
Non-extractable residues after 100 days	16.6 % after 120 d, [^{14}C-2,4-difluorophenyl]-label (n=1) 11.2 % after 120 d, [^{14}C-3-trifluoromethylphenyl]-label (n=1) 4.0 % after 112 d, [^{14}C-2-pyridyl]-label (n=1)
Metabolites that may require further consideration for risk assessment – name and/or code, % of applied (range and maximum)	AE C522392[19] – 10.7 % at 90 d [^{14}C-2,4-difluorophenyl]-label (n=1) AE B107137 – 48.5 % at 272 d [^{14}C-3-trifluoromethylphenyl]-label (n=2)
Soil photolysis ‡	
Metabolites that may require further consideration for risk assessment – name and/or code, % of applied (range and maximum)	None. Diflufenican was stable during the 31 d study.

8.3.2.3 Flufenacet and its metabolites

Data not provided

8.4 Field studies (KCP 9.1.1.2)

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

Studies on field degradation in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance. EU approved endpoints were evaluated during Annex I inclusion for active substances. All relevant data are presented in :

- **Penoxsulam** - EFSA Scientific Report (2009) 343, 59-90
- **Diflufenican** - EFSA Scientific Report (2007) 122, 1-84,
- **Flufenacet** – SANCO 7469/VI/98-Final 3 July 2003 and Flufenacet Addendum to the monograph of flufenacet-Annex B- B.7 Enviromental Fate and behaviour

8.4.1.1 Penoxsulam and its metabolites

Triggering endpoints

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

Field studies (state location, range or median with n value)	DT_{50f} (Italy, Spain, water): median 5.9 days (n = 2, range 5.6 - 6.1 days) DT_{50f} (Italy, Spain, soil): <1 day
	DT_{90f} (Italy, Spain, water): median 19.5 days (n = 2, range 19 - 20 days)

8.4.1.2 Diflufenican and its metabolites

Diflufenican	Aerobic conditions								
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	X[1]	pH	Depth (cm)	DT_{50} (d) actual	DT_{90}(d) actual	St. (r^2)	DT_{50} (d) 20°C / pF2	Method of calculation
Loamy sand (b)	UK		5.8	30	621	2063	0.493	282.0	SFO
Sandy silt loam I	France		7.1	30	241	801	0.796	130.0	SFO
Sandy loam (b)	Netherlands		6.3	30	389	1292	0.495	199.5	SFO
Clay (b)	Spain		7.6	30	236	784	0.728	122.2	SFO
Clay loam (b)	Italy		6.9	30	224	744	0.748	103.4	SFO
Geometric mean/median					315/241			156/130*	

*Note a Q10 of 2.2 was assumed during the normalization.

8.4.1.3 Flufenacet and its metabolites

Table 8.4-2: Summary of aerobic degradation rates for Flufenacet - field studies

Location	Application and timings	DT50*
Germany	Autumn (240 g a.s/ha) Spring (480-600 g/ha)	38-43 d 15-54-31-53d
N.France	Early spring (240 g a.s/ha) Spring (480-600 g/ha)	13-16 d 16-38 d
S.France	Spring (480-600 g/ha)	30-36-34-42 d
Italy	Spring (480-600 g/ha)	38-48 d

*DT50: Germany (4 sites, bare soils), N.France (2 sites,crop), S.France (2 sites,crop), Italy (2 sites,crop). LOD 10 µg/kg (<6%)

Metabolites not detected above LOD.

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

Studies on soil accumulation testing with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance. EU approved endpoints were evaluated during Annex I inclusion for active substances. All relevant data are presented in :

- **Penoxsulam** - EFSA Scientific Report (2009) 343, 59-90
- **Diflufenican** - EFSA Scientific Report (2007) 122, 1-84,
- **Flufenacet** – SANCO 7469/VI/98-Final 3 July 2003 and Flufenacet Addendum to the monograph of flufenacet-Annex B- B.7 Enviromental Fate and behaviour

8.4.2.1 Penoxsulam and its metabolites

Soil accumulation and plateau concentration	Data not submitted, not required.

8.4.2.2 Diflufenican and its metabolites

Soil accumulation and plateau concentration ‡	Maximum soil accumulation concentration of 0.405 mg/kg over top 5cm soil layer. Plateau concentration (i.e. the maximum amount of diflufenican remaining immediately prior to the following years application) would be 0.245 mg/kg. Maximum accumulation factor = 2.53

8.4.2.3 Flufenacet and its metabolites

Not relevant according with Flufenacet – SANCO 7469/VI/98-Final 3 July 2003 and Flufenacet Addendum to the monograph of flufenacet-Annex B- B.7 Enviromental Fate and behaviour (2003).

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. EU approved endpoints were evaluated during Annex I inclusion for active substances. All relevant data are presented in :

- **Penoxsulam -** EFSA Scientific Report (2009) 343, 59-90
- **Diflufenican -** EFSA Scientific Report (2007) 122, 1-84,
- **Flufenacet** – SANCO 7469/VI/98-Final 3 July 2003 and Flufenacet Addendum to the monograph of flufenacet-Annex B- B.7 Enviromental Fate and behaviour

8.5.1 Penoxsulam and its metabolites

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

K_f / K_{oc}
<u>K_d</u>
pH dependence (yes / no)
<u>(if yes type of dependence)</u>

	penoxsulam			
Soil	K_f	1/n	K_d (L/kg)	K_{doc} (L/kg)
Greggio (Italy)	1.96	0.90	2.50	253
Ottobaiano (Italy)	0.32	0.89	0.38	45
Charentilly (France)	0.48	0.88	0.63	65
Marcham (UK)	0.16	0.93	0.20	12
Average[1]	0.73	0.90	0.93	94
Median[1]	0.40	0.90	0.51	55
Supplemental Information				
Wagram-Troup (USA)	0.27	1.02	0.31	77
Amagon (USA)	0.30	0.91	0.39	40
Oswald (USA)	0.49	0.94	0.47	19
Glyndon-Tiffany (USA)	0.45	0.88	0.57	21
Chernozemic (Canada)	nm	nm	1.44	72
Ryerson (Canada)	nm	nm	0.67	19
Glu Humid (Brazil)	nm	nm	0.63	14
Red Latisoil (Brazil)	nm	nm	0.13	13
Purple Latisoil (Brazil)	nm	nm	0.50	35
Volcanic/Upland (Japan)	0.59	0.86	0.81	22
Non-Volcanic/Upland (Japan)	0.56	0.86	0.85	39
Volcanic/Rice (Japan)	4.69	0.80	10.40	305
Non-Volcanic/Rice (Japan)	1.55	0.83	2.49	194
Average[3]	0.99	0.89	1.38	73
Median[3]	0.49	0.89	0.63	39.5

[1] Average and median values for 4 European soils

[2] nm = Freundlich coefficients were not measured for these soils

[3] Average and median values for all reported soils

pH dependence: Yes. Sorption increases with decreasing pH. As soil pH decreases, sorption of penoxsulam is increasingly dependent on the soil organic carbon content.

Table 8.5-2: Summary of soil adsorption/desorption for 5-OH-DE-638

K_f / K_{oc}
K_d
pH dependence (yes / no)
(if yes type of dependence)

	5-OH-DE-638		
Soil	K_f	K_d (L/kg)	K_{doc} (L/kg)
Greggio (Italy)	nm[1]	1.42	144
Ottobaiano (Italy)	nm	0.40	41
Charentilly (France)	nm	0.28	17
Marcham (UK)	nm	0.30	34
Average[2]	n/a	0.60	59
Median[2]	n/a	0.35	37
Supplemental Information			
Wagram-Troup (USA)	nm	0.14	34
Amagon (USA)	nm	0.32	33
Oswald (USA)	nm	0.46	19
Glyndon-Tiffany (USA)	nm	1.03	38
Average[3]	n/a	0.54	45
Median[3]	n/a	0.36	34
[1] nm = Freundlich coefficients were not measured for these soils			
[2] Average and median values for 4 European soils			
[3] Average and median values for all reported soils			
pH dependence: No.			

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

K_f /K_{oc}
K_d
pH dependence (yes / no)
(if yes type of dependence)

	BSTCA		
Soil	K_f	K_d (L/kg)	K_{doc} (L/kg)
Greggio (Italy)	nm[1]	4.39	444
Ottobaiano (Italy)	nm	0.72	74
Charentilly (France)	nm	0.09	5
Average[2]	n/a	1.73	174
Median[2]	n/a	0.72	74
Supplemental Information			
Wagram-Troup (USA)	nm	0.18	46
Amagon (USA)	nm	1.52	156
Oswald (USA)	nm	0.60	25
Average[3]	n/a	1.25	125
Median[3]	n/a	0.66	60
[1] nm = Freundlich coefficients were not measured for these soils			
[2] Average and median values for 3 European soils			
[3] Average and median values for all reported soils			
pH dependence: No.			

8.5.2 Diflufenican and its metabolites

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

Diflufenican ‡								
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n	R^2
Sandy loam	2.09	7.7			33.9	1622	0.875	>0.988
Loamy sand	0.75	6.6			13.5	1800	0.917	>0.988
Clay loam	1.68	6.6			39.8	2369	0.934	>0.988
Silty clay loam	2.26	6.8			48.9	2164	0.923	>0.988
Clay loam (Shelley Field)	2.4	6.2			98.82	4118	0.901	0.998
Silt loam (Kissendorf)	1.4	6.7			46.28	3306	0.897	1.000
Sandy loam (Manningtree)	3.6	5.3			267.51	7431	0.991	0.998
Loam (Santilly)	0.9	7.0			39.86	4428	0.940	0.999
Clay loam (Lleida)	2.9	8.0			88.91	3066	0.917	0.999
Clay loam (Chazay)	1.9	6.6			73.49	3868	0.879	0.998
Arithmetic mean					75.1	3417	0.917	-
Median					47.6	3186	0.917	
pH dependence, Yes or No			No					

Table 8.5-5: Summary of soil adsorption/desorption for AE B107137

AE B107137 ‡							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Clay loam	1.9	7.0			0.22	12	0.72
Sand	1.6	5.8			0.11	7	0.99
Clay loam	4.7	7.6			0.38	8	0.54
Sandy loam	1.8	6.0			0.42	23	0.68
Arithmetic mean/median						13/10	0.73/0.70
pH dependence (yes or no)			No				

Table 8.5-6: Summary of soil adsorption/desorption for AE 0542291

AE 0542291							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Sandy loam	0.8	6.0			1.3	160	0.80
Sandy loam	1.2	5.3			1.5	127	0.84
Clay loam	2.6	7.0			3.6	137	0.77
Clay	3.9	6.0[a]			4.0	103	0.85
Arithmetic mean/median						132/132	0.81/0.82

8.5.3 Flufenacet and its metabolites

Table 8.5-7: Summary of soil adsorption/desorption for Flufenacet

Soil type	pH	OC (%)	Koc	slope
silt loam	5.9	1.68	190	0.84
clay loam	6.4	1.28	211	0.90
loamy sand	6.4	0.23	696	0.87
sand	5.0	0.17	588	0.98
sandy loam	6.4	1.4	354	0.89
loam	7.1	4.3	113	0.96
silt loam	7.3	2.8	144	0.86
			Mean: 202 (for OC>0.23%)	Art mean:0.89 (for OC>0.23%)

Table 8.5-8: Summary of soil adsorption/desorption for metabolite FOE-oxalate

Soil type	pH	OC (%)	Koc	slope
sand	5.8	0.27	23	1.42
sandy loam	6.3	0.75	13	0.93
silty clay loam	6.6	2.13	7	0.82
silty clay	6.0	1.21	13	0.98
			Mean: 11 (for OC>0.27%)	Art mean:0.91 (for OC>0.27%)

Table 8.5-9: Summary of soil adsorption/desorption for metabolite FOE Sulfonic acid

Soil type	pH	OC (%)	Koc	slope
sand	5.8	0.27	19	0.86
sandy loam	6.3	0.75	15	1.00
silty clay loam	6.6	2.13	10	0.93
silty clay	6.0	1.21	6	1.18
			Mean: 10 (for OC>0.27%)	Art mean:1.04 (for OC>0.27%)

8.5.4 Column leaching (KCP 9.1.2.1)

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

EU approved endpoints were evaluated during Annex I inclusion for active substances. All relevant data are presented in :

- **Penoxsulam -** EFSA Scientific Report (2009) 343, 59-90
- **Diflufenican -** EFSA Scientific Report (2007) 122, 1-84,
- **Flufenacet** – SANCO 7469/VI/98-Final 3 July 2003 and Flufenacet Addendum to the monograph of flufenacet-Annex B- B.7 Enviromental Fate and behaviour

8.5.4.1 Penoxsulam and its metabolites

Column leaching	Sandy loam soil (free draining), leached for 2 d at 10 cm water/d 9.7% 0-5 cm soil layer 95.8% total in soil (0-30 cm) 3.1% in leachate
	Sandy loam soil (saturated), leached for 2 d at 10 cm water/d 20.9% 0-5 cm soil layer 97.5% total in soil (0-30 cm) 0.2% in leachate
	Clay loam soil (free draining), leached for 2 d at 10 cm water/d 102.9% 0-5 cm soil layer 102.9% total in soil (0-30 cm) <LOD in leachate
	Clay loam soil (saturated), leached for 2 d at 10 cm water/d 35.7% 0-5 cm soil layer 97.1% total in soil (0-30 cm) 1.0% in leachate
	Sandy silt loam soil (free draining), leached for 2 d at 10 cm water/d 40.2% 0-5 cm soil layer 100.2% total in soil (0-30 cm) <LOD in leachate
	Silt loam soil (free draining), leached for 2 d at 20 cm water/d 86.1% 0-5 cm 98.2% total in soil (0-30 cm) <LOD in leachate

8.5.4.2 Diflufenican and its metabolites

Column leaching ‡	None submitted, none required

8.5.4.3 Flufenacet and its metabolites

No studies were provided according to the SANCO 7469/VI/98-Final 3 July 2003 and Flufenacet Addendum to the monograph of flufenacet-Annex B- B.7 Enviromental Fate and behaviour (2003).

8.5.5 Lysimeter studies (KCP 9.1.2.2)

Studies on lysimeters studies with the formulation were not performed, since it is possible to ex-trapolate from data obtained with the active substance.

EU approved endpoints were evaluated during Annex I inclusion for actives substances. All relevant data are presented in :

- **Penoxsulam -** EFSA Scientific Report (2009) 343, 59-90
- **Diflufenican -** EFSA Scientific Report (2007) 122, 1-84,
- **Flufenacet** – SANCO 7469/VI/98-Final 3 July 2003 and Flufenacet Addendum to the monograph of flufenacet-Annex B- B.7 Enviromental Fate and behaviour

8.5.5.1 Penoxsulam and its metabolites

Aged residues leaching	Data not submitted, not required.

8.5.5.2 Diflufenican and its metabolites

Aged residues leaching ‡	None submitted, none required

8.5.5.3 Flufenacet and its metabolites

8.5.5.1 Flufenacet and metabolites.

Lysimeter/ field leaching studies	Lysimeter (sandy loam soil, < 1.41 % OC) **corn/corn rotation (2 x 480 g a.s./ha)** Total mean 0.87-0.99 µg/l, max. 2.23 µg/l (y 1) mean 0.46-0.67 µg/l, max. 1.0 µg/l (y 2) mean 0.23-0.33 µg/l, max. 0.33 µg/l (y 3) a.s. < 0.035 µg/l FOE oxalate < 0.04 µg/l FOE thioglycolate < 0.08 µg/l FOE sulfonic acid mean 0.49-0.59 µg/l, max. 1.29 µg/l (y 1) mean 0.15-0.24 µg/l (y 2) **corn/wheat rotation (480 + 180 g a.s./ha)** Total mean 2.5 µg/l, max. 5 µg/l (year 1) mean 0.24 µg/l (year 2) a.s. not identified FOE oxalate and thioglycolate < 0.1 µg/l FOE sulfonic acid : mean 1.49 µg/l, max. 3.7 µg/l (year 1) mean 0.015 µg/l (year 2)

8.5.6 Field leaching studies (KCP 9.1.2.3)

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

EU approved endpoints were evaluated during Annex I inclusion for active substances. All relevant data are presented in :

- **Penoxsulam -** EFSA Scientific Report (2009) 343, 59-90
- **Diflufenican -** EFSA Scientific Report (2007) 122, 1-84,
- **Flufenacet** – SANCO 7469/VI/98-Final 3 July 2003 and Flufenacet Addendum to the monograph of flufenacet-Annex B- B.7 Enviromental Fate and behaviour

8.5.6.1 Penoxsulam and its metabolites

Lysimeter/ field leaching studies	Data not submitted, not required.

8.5.6.2 Diflufenican and its metabolites

Lysimeter/ field leaching studies ‡	Location: Germany (Bruhl, Schwemmlob) Study type (e.g. lysimeter, field): lysimeter Soil properties: pH = 7.2, OC= 1.05 Dates of application: 3rd December 1990 Crop: 1st year winter wheat, 2nd year winter barley, final green mustard Interception estimated: None (application pre-emergent) Number of applications: lysimeter 219 1 application each year, lysimeter 220 1 application 1st year Duration: 2 years Application rate: 185 g a.s./ha/year (nominal) Average annual rainfall and irrigation (mm): 853 mm Average annual leachate volume (mm): 325 mm %radioactivity in leachate (maximum/year): 0.014 % AR 1st year, 0.117 % AR 2nd year Individual annual average concentrations: 1st year 0.003 µg /L and 2nd year <0.003 µg /L active substance, <0.003 µg /L metabolites AE B107137 and AE 0542291. Unidentified radioactivity: total max 0.01 µg /L parent equivalents.

8.5.6.3 Flufenacet and its metabolites

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.
EU approved endpoints were evaluated during Annex I inclusion for active substances. All relevant data are presented in :

- **Penoxsulam** - EFSA Scientific Report (2009) 343, 59-90
- **Diflufenican** - EFSA Scientific Report (2007) 122, 1-84,
- **Flufenacet** – SANCO 7469/VI/98-Final 3 July 2003 and Flufenacet Addendum to the monograph of flufenacet-Annex B- B.7 Enviromental Fate and behaviour

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8.6.1 Penoxsulam and its metabolites

Table 8.6-1: Summary of degradation in water/sediment of penoxsulam and its metabolites

Hydrolysis of active substance and relevant metabolites (DT_{50}) (state pH and temperature)		pH 5, 25 °C: stable pH 7, 25 °C: stable pH 9, 25 °C: stable
Photolytic degradation of active substance and relevant metabolites		DT_{50} = 2 days (summer, 40 °N latitude, sterile pH 7 buffer and natural water) Major metabolites: TPSA: 56% AR at 1 day, DT_{50} = 4.7 days (buffer), 2.0 days (natural water) 2-amino-TP: 18% AR at 1 day, DT_{50} = 0.6 days (buffer), 0.6 days (natural water) 5-OH-2-amino-TP: 23% AR at 14 days (natural water) BSA: 36% at 1.5 days, DT_{50} = 0.9 days (buffer), 0.7 days (natural water)
Readily biodegradable (yes/no)		No
Degradation in water/sediment	DT_{50} water	Average = 15 days (n = 2, range 10 – 20 days, r^2 = 0.90 - 0.96)
	DT_{90} water	Average = 50 days (n = 2, range 34 – 65 days, r^2 = 0.90 - 0.96
	DT_{50} whole system	penoxsulam Average = 23 days (n = 2, range 11 – 34 days, r^2 = 0.78 - 0.91) 5-OH-DE-638 Average = 50 days (n = 2, range 24 – 75 days, r^2 = 0.89 - 0.93)
	DT_{90} whole system	Average = 76 days (n = 2, range 37 – 114 days, r^2 = 0.78 - 0.91
Mineralisation		Average = 1.6% AR (n = 2, range 0.8 – 2.4% AR, 99 days)
Non-extractable residues		Average = 39.4% AR (n = 2, range 20.8 – 57.9% AR, 99 days)
Distribution in water / sediment systems (active substance)		Water Phase: Maximum of 87.5 – 91.5% AR at 0 DAT (days after treatment) decreasing to 0.4 – 3.9% AR at 99 DAT Sediment Phase: 0% AR at 0 DAT, maximum of 2.5 – 20.9% AR at 4 DAT
Distribution in water / sediment systems (metabolites)		Major Metabolites (water): 5-OH-DE-638 (18.6% AR), BSTCA (23.7% AR) Major Metabolites (sediment): 5-OH-DE-638 (15.6% AR)

8.6.2 Diflufenican and its metabolites

Degradation in water / sediment

Diflufenican	Distribution (Max. in sed 74.4 % after 14 d)										
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50}-DT_{90} whole sys.	St. (r^2)	DT_{50}-DT_{90} water	St. (r^2)	DT_{50}- DT_{90} sed	St. (r^2)	Method of calculation
Unter Widdersheim	8.2	7.5	20	90	0.76	n.a.	n.a.	n.a.		SFO
Bickenbach	8.2	7.8	20	154	0.77	n.a.	n.a.	n.a.		SFO
Clay, UK	7.8	6.3	20	345	0.82	n.a.	n.a.	n.a.		SFO
Sand, UK	6.8	5.4	20	195	0.96	n.a.	n.a.	n.a.		SFO
Arithmetic mean (DT_{50})				196		n.a.		n.a.		
Geometric mean				175		n.a.		n.a.		

n.a. no reliable value available.

AE B107137	Distribution (max in water 32.6 % after 30 d, max in sed 13.3 % after 30 d)
AE C522392	Distribution (max in water 6.1 % after 30 d, max in sed 1.0 % after 59 d)

Mineralization and non extractable residues					
Water / sediment system	pH water phase	pH sed	Mineralization x % after n d. (end of the study).	Non-extractable residues in sed. Max x % after n d	Non-extractable residues in sed. Max x % after n d (end of the study)
Unter Widdersheim	8.2	7.5	0.6 % after 121 d	11.1 % after 121 d	11.1 % after 121 d
Bickenbach	8.2	7.8	0.2 % after 121 d	9.0 after 61 d	8.6 % after 121 d
Clay, UK	7.8	6.3	0.8 % after 365 d	35.2 % after 365 d	35.2 % after 365 d
Sand, UK	6.8	5.4	6.8 % after 365 d	27.4 % after 212 d	22.7 % after 365 d

8.6.3 Flufenacet and its metabolites

Table 8.6-2: Summary of degradation in water/sediment of Flufenacet

Degradation in water/sediment	(Days)
DT50 water	46.3-61.7d
DT90 water	154-205d
DT50 whole system	76.4-84.6 d(fluorophenyl), 20-31 d (thiadiazole)
DT90 whole system	254-281d (fluorophenyl), 67-104d (thiadiazole)

Table 8.6-3: Summary of observed metabolites

FOE methylsulfide	Max 8% in water and 3.4 % in sediment (157 d)
FOE-thiadone	Max 82 % in water (55d)

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

zRMS Comments:

The PECs assessment was accepted.
The worst case scenario of 0% interception was used in PECs assessment (active substance and formulation).
The endpoints used for soil exposure assessment are consistent with list of endpoints for both active substances and their metabolites.
The PECs accum of active substances/metabolites, if relevant, was assessed.

The density of formulation, based on Section 2: Physical and chemical properties, of 1.2233 g/mL should be used in further assessment of PECs formulation. The Applicant has used the density of 1.2243 g/mL. The difference does not affect the final conclusion (see Table 8.7-12).

Winter wheat

Compound	PECs	PECs accum
	mg/kg soil	
Penoxsulam	0.0200	nr
5-OH-penoxsulam	0.0064	nr
BSTCA	0.00912	nr
Diflufenican	0.1333	0.3985
AE B107137	0.0003	nr
AE 0542291	0.0010	nr
Flufenacet	0.1664	nr
FOE-sulfonic acid	0.0222	0.0412
FOE - oxalate	0.0030	nr
Formulation	0.6530	nr

The relevant PECs values will be used in further risk assessment.

8.7.1 Justification for new endpoints

EU approved endpoints were evaluated during Annex I inclusion for active substances. All relevant data are presented in :

- Penoxsulam - EFSA Scientific Report (2009) 343, 59-90
- Diflufenican - EFSA Scientific Report (2007) 122, 1-84,
- Flufenacet – SANCO 7469/VI/98-Final 3 July 2003 and Flufenacet Addendum to the monograph of flufenacet-Annex B- B.7 Enviromental Fate and behaviour

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

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

Use No.	1
Crop	Cereals
Application rate (~~g as/ha~~) (kg a.s./ha)	Penoxsulam: 0.015 Diflufenican: 0.1 Flufenacet: 0.1248
Number of applications/interval	1/-
Crop interception (%)	0
Depth of soil layer (relevant for plateau concentration) (cm)	5

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

Compound	Molecular weight (g/mol)	Max. occurrence (%)	DT50 (days)	Value in accordance to EU end-point y/n/ Reference
Penoxsulam	483.37	-	8.8	EFSA Scientific Report (2009) 343, 63-90
5-OH-penoxsulam	469	33	-	EFSA Scientific Report (2009) 343, 63-90
BSTCA	416	53	-	EFSA Scientific Report (2009) 343, 63-90
Diflufenican	394	-	621	LoEP EFSA 2007
AE B107137	283	16.8	10.6	LoEP EFSA 2007
AE 0542291	282	26.3	26.9	LoEP EFSA 2007
Flufenacet	363.34	-	DT50: 54 d Kinetics: Longest DT 50 from field studies	SANCO 7469/VI/98-Final 3 July 2003
FOE-sulfonic acid	275.3	26.3%	DT50:270 d Kinetics: SFO Field or Lab: representative worst case un-normalised values from lab studies	SANCO 7469/VI/98-Final 3 July 2003
FOE - oxalate	225.2	15.6%	DT50:17 d Kinetics: SFO	SANCO 7469/VI/98-Final

Compound	Molecular weight (g/mol)	Max. occurrence (%)	DT50 (days)	Value in accordance to EU endpoint y/n/ Reference
			using a fixed DT50 representative worst case un-normalised values from lab studies	3 July 2003

8.7.2.1 Penoxsulam and its metabolites

Table 8.7-3: PEC_{soil} for Penoxsulam on cereals

PEC_{soil} (mg/kg)		cereals	
		Single application	
		Actual	TWA
Initial		0.0200	-
Short term	24h	0.0185	0.0192
	2d	0.0171	0.0185
	4d	0.0146	0.0172
Long term	7d	0.0115	0.0154
	14d	0.0066	0.0121
	21d	0.0038	0.0098
	28d	0.0022	0.0081
	50d	0.0004	0.0050
	100d	<0.0001	0.0025
Plateau concentration (5 cm) after year 10		<0.0001	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		0.0200	-

PEC_{soil} of metabolites

The PECsoil immediately after the first application was calculated for metabolites as follows with corrected application rate. No time-dependent PECsoil values have been calculated for penoxsulam metabolites since these are not required for the risk assessment.

$$\text{Initial PECsoil (mg/kg)} = \frac{A\ (g/ha)}{100 \times d\ (cm) \times \rho\ (g/cm^3)}$$

where: A = application rate (corrected by max. occur. of metabolite and molar ratio metabolite and parent)

d = depth of soil layer (5 cm)
ρ = soil bulk density (1.5 g/cm3)

Table 8.7-4: PEC$_{soil}$ for 5-OH-penoxsulam on cereals (app.rate= 4.80 g/ha)

PEC$_{soil}$ (mg/kg)	cereals			
	Single application		Multiple applications	
	Actual	TWA	Actual	TWA
Initial	0.0064	-		-

Table 8.7-5: PEC$_{soil}$ for BSTCA on cereals (app.rate= 6.84 g/ha)

PEC$_{soil}$ (mg/kg)	cereals			
	Single application		Multiple applications	
	Actual	TWA	Actual	TWA
Initial	0.00912	-		-

8.7.2.2 Diflufenican and its metabolites

Table 8.7-6: PEC$_{soil}$ for Diflufenican on cereals

PEC$_{soil}$ (mg/kg)		cereals	
		Single application	
		Actual	TWA
Initial		0.1333	-
Short term	24h	0.1332	0.1333
	2d	0.1330	0.1332
	4d	0.1327	0.1330
Long term	7d	0.1323	0.1328
	14d	0.1313	0.1323
	21d	0.1302	0.1318
	28d	0.1292	0.1313
	50d	0.1261	0.1297
	100d	0.1193	0.1262
Plateau concentration (5 cm) after year 10		0.2651	-
PEC$_{accumulation}$ (PEC$_{act}$ +PEC$_{soil\ plateau}$)		0.3985	-

PEC_{soil} of metabolites

Table 8.7-7: PEC_{soil} for AE B107137 on cereals

PEC_{soil} (mg/kg)		cereals	
		Single application	
		Actual	TWA
Initial		0.0003	-
Short term	24h	0.0003	0.0003
	2d	0.0003	0.0003
	4d	0.0003	0.0003
Long term	7d	0.0003	0.0003
	14d	0.0003	0.0003
	21d	0.0003	0.0003
	28d	0.0003	0.0003
	50d	0.0003	0.0003
	100d	0.0002	0.0003
Plateau concentration (5 cm) after year 10		0.0005	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		0.0008	-

Table 8.7-8: PEC_{soil} for AE 0542291 on cereals

PEC_{soil} (mg/kg)		cereals	
		Single application	
		Actual	TWA
Initial		0.0010	-
Short term	24h	0.0010	0.0010
	2d	0.0010	0.0010
	4d	0.0010	0.0010
Long term	7d	0.0010	0.0010
	14d	0.0010	0.0010
	21d	0.0010	0.0010
	28d	0.0009	0.0010
	50d	0.0009	0.0010
	100d	0.0009	0.0009
Plateau concentration (5 cm) after year 10		0.0020	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		0.0030	-

8.7.2.3 Flufenacet and its metabolites

Table 8.7-9: PEC_{soil} for Flufenacet on winter cereals

PEC_{soil} (mg/kg)		Winter cereals	
		Single application	
		Actual	TWA
Initial		0.1664	-
Short term	24h	0.1643	0.1653
	2d	0.1622	0.1643
	4d	0.1581	0.1622
Long term	7d	0.1521	0.1591
	14d	0.1390	0.1523
	21d	0.1271	0.1459
	28d	0.1162	0.1398
	50d	0.0876	0.1228
	100d	0.0461	0.0937
Plateau concentration (5 cm) after year 10		0.0016	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		0.1680	-

PEC_{soil} of metabolites

Table 8.7-10: PEC_{soil} for FOE sulfonic acid on winter cereals

PEC_{soil} (mg/kg)		Winter cereals	
		Single application	
		Actual	TWA
Initial		0.0222	-
Short term	24h	0.0222	0.0222
	2d	0.0222	0.0222
	4d	0.0222	0.0222
Long term	7d	0.0222	0.0222
	14d	0.0221	0.0222
	21d	0.0221	0.0222
	28d	0.0219	0.0222
	50d	0.0215	0.0221
	100d	0.0199	0.0219
Plateau concentration (5 cm) after year 10		0.0190	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		0.0412	-

Table 8.7-11: PEC_{soil} for FOE oxalate on winter cereals

PEC_{soil} (mg/kg)		Winter cereals	
		Single application	
Initial		0.0030	-
Short term	24h	0.0030	0.0030
	2d	0.0030	0.0030
	4d	0.0030	0.0030
Long term	7d	0.0030	0.0030
	14d	0.0029	0.0030
	21d	0.0028	0.0030
	28d	0.0027	0.0030
	50d	0.0022	0.0029
	100d	0.0012	0.0025
Plateau concentration (5 cm) after year 10		<0.0001	-
$PEC_{accumulation}$ (PEC_{act} + $PEC_{soil\ plateau}$)		0.0031	-

8.7.2.4 PEC_{soil} of CHR/H/PENDIF 599.5 SC

The PECsoil immediately after the first application was calculated for formulation as follows:

$$\text{Initial PECsoil (mg/kg)} = \frac{\text{A (g/ha)}}{100 \times \text{d (cm)} \times \rho\ (\text{g/cm}^3)}$$

where: A = application rate (489.72 g formulation/ha)
d = depth of soil layer (5 cm)
ρ = soil bulk density (1.5 g/cm^3)

Table 8.7-12: PEC_{soil} for CHR/H/PENDIF 599.5 SC on cereals

Active substance/ reparation	Application rate (g/ha)	PEC_{act} (mg/kg)	PEC_{twa}21 d (mg/kg)	Tillage depth (cm)	$PEC_{soil,plateau}$ (mg/kg)	PEC_{accu} = PEC_{act} + $PEC_{soil,plateau}$ (mg/kg)
CHR/H/PENDIF 599.5 SC	489.72	0.6530	-	5	~~0.6530~~	~~0.6530~~
	489.32	0.6524				

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

Evaluator's Comments:	The submitted PECgw assessment was accepted. Calculations of PECgw for all active substances and its relevant metabolite were provided with PUF = 0. The recommended FOCUS models were used: FOCUS PELMO and FOCUS PEARL. All used endpoints were agreed at the EU level. **Penoxsulam**. The PECgw assessment for active substance and its metabolites was provided for acidic and alkaline soils. The tiered approach (Tier 1 based on DT50 laboratory and Tier 2 based on field studies) was considered. The PECgw values for active substance were below the trigger value of 0.1 µg/L. As PECgw for metabolite BSTCA was above trigger value of 0.75 µg/L (scenario Hamburg, alkaline soils) the additional assessment – for application every other year – was provided. For metabolites the following PECgw values in application every other year were obtained:

Compound	Acidic soils	Alkaline soils
	PECgw µg/L	
Penoxsulam	< 0.001	< 0.001
5-OH-penoxsulam	0.134	0.232
BSTCA	0.472	0.596
BST	0.196	0.218

Diflufenican. The PECgw values for active substance and its metabolites were below the trigger value of 0.1 µg/L.

Flufenacet. The PECgw values for active substance and its metabolite FOE oxalate were below the trigger value of 0.1 µg/L.
For metabolite FOE Sulfonic acid the PECgw values was higher than the trigger value of 10 µg/L in scenario Jokioinen; as this scenario is not relevant for Central Zone – was not taken into account.
For metabolites the following PECgw values were obtained:

Compound	PECgw
	µg/L
Flufenacet	< 0.001
FOE-sulfonic acid	9.0484

The relevant metabolites of active substances will be considered in Section 10.

8.8.1 Justification for new endpoints

EU approved endpoints were evaluated during Annex I inclusion for active substances. All relevant data

are presented in :
- Penoxsulam - EFSA Scientific Report (2009) 343, 59-90
- Diflufenican - EFSA Scientific Report (2007) 122, 1-84,
- Flufenacet – SANCO 7469/VI/98-Final 3 July 2003 and Flufenacet Addendum to the monograph of flufenacet-Annex B- B.7 Enviromental Fate and behaviour

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

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

Use No.	1
Crop	Winter Cereals
Application rate (g as/ha)	Penoxsulam: 15 Diflufenican: 100 Flufenacet: 124.8
Number of applications/interval (d)	1/-
Relative application date	2 day after evemt
Crop interception (%)	0
Frequency of application	annual
Models used for calculation	FOCUS PEARL v4.4.4, FOCUS PELMO v5.5.3, FOCUS MACRO v5.5.3

8.8.2.1 Penoxsulam and its metabolites

Table 8.8-2: Input parameters related to active substance penoxsulam and metabolite(s) for PEC_{gw} calculations

Compound	Penoxsualm	5-OH-penoxsulam	BSTCA	BST	Value in accordance with EU endpoint y/n/ Reference*
Molecular weight (g/mol)	483	469	416	372	From LoEP
Water solubility (g/mol):	408	90**	90**	90**	LOEP **default value
Saturated vapour pressure (Pa):	2.5E-14	1E-04**	1E-04**	1E-04**	From LoEP **default value
DT_{50} in soil (d)	29.6	25	~~76~~ 100	17	From LoEP
DT_{50} in soil (d) field	~~14.5~~ 5.3	-	-	-	**From LoEP**
Transformation rate	0.023417 per day to 5-OH-penoxsulam (lab DT50)	0.027726 per day to BSTCA (lab DT50)	~~0.00912~~ 0.006931 per day to BST	0.040773 per day to CO2	

Compound	Penoxsualm	5-OH-penoxsulam	BSTCA	BST	Value in accordance with EU endpoint y/n/ Reference*
	0.047803 per day to 5-OH-penoxsulam (field DT50)				
K_{foc} (mL/g)/K_{fom}	16 (pH > 6.5) 84 <pH<6.5)	59	174	52.5	From LoEP
1/n	0.90 (pH >6.5) 0.89 (pH <6.5)	1	1	1	From LoEP/ worst case
Plant uptake factor	0	0	0	0	Worst case
Formation fraction		1 from penoxsulam	1 from 5-OH-penoxsulam	1 from BSTCA	From LoEP

Table 8.8-3: ~~**PEC$_{gw}$ for penoxsulam and metabolite(s) on winter cereals (with FOCUS PEARL 4.4.4) – TIER 1 (lab DT50)**~~

~~Crop~~	~~Scenario~~	~~80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)~~			
		~~Penoxsulam~~	~~5-OH-Penoxsulam~~	~~BSTCA~~	~~BST~~
~~Winter cereals~~	~~Châteaudun~~	~~0.2463~~	~~0.3384~~	~~0.6518~~	~~0.3029~~
	~~Hamburg~~	~~0.003195~~	~~0.2112~~	~~0.5925~~	~~0.3246~~
	~~Jokioinen~~	~~0.000107~~	~~0.1188~~	~~0.3397~~	~~0.2669~~
	~~Kremsmünster~~	~~0.4601~~	~~0.4775~~	~~0.7402~~	~~0.2785~~
	~~Okehampton~~	~~0.005008~~	~~0.2079~~	~~0.5516~~	~~0.2616~~
	~~Piacenza~~	~~0.3054~~	~~0.3686~~	~~0.6520~~	~~0.2396~~
	~~Porto~~	~~0.001989~~	~~0.1359~~	~~0.3375~~	~~0.1971~~
	~~Sevilla~~	~~0.005331~~	~~0.004665~~	~~0.01055~~	~~0.02636~~
	~~Thiva~~	~~0.1130~~	~~0.1787~~	~~0.5520~~	~~0.3000~~

Table 8.8-4: ~~**PEC$_{gw}$ for penoxsulam and metabolite(s) on winter cereals (with FOCUS PEARL 4.4.4) – TIER 2 (field DT50)**~~

~~Crop~~	~~Scenario~~	~~80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)~~			
		~~Penoxsulam~~	~~5-OH-Penoxsulam~~	~~BSTCA~~	~~BST~~
~~Winter~~	~~Châteaudun~~	~~0.01977~~	~~0.1639~~	~~0.4837~~	~~0.2492~~

~~cereals~~	~~Hamburg~~	~~0.000012~~	~~0.1694~~	~~0.5457~~	~~0.3105~~
	~~Jokioinen~~	~~<0.0001~~	~~0.09710~~	~~0.3056~~	~~0.2476~~
	~~Kremsmünster~~	~~0.08845~~	~~0.3541~~	~~0.6656~~	~~0.2776~~
	~~Okehampton~~	~~0.000023~~	~~0.1777~~	~~0.5322~~	~~0.2567~~
	~~Piacenza~~	~~0.05806~~	~~0.2524~~	~~0.6090~~	~~0.2325~~
	~~Porto~~	~~0.000004~~	~~0.1105~~	~~0.3391~~	~~0.1950~~
	~~Sevilla~~	~~0.000315~~	~~0.000666~~	~~0.005350~~	~~0.01413~~
	~~Thiva~~	~~0.005996~~	~~0.07386~~	~~0.3340~~	~~0.2099~~

Table 8.8-5: ~~**PEC$_{gw}$ for penoxsulam and metabolite(s) on winter cereals (with FOCUS PELMO 5.5.3) – TIER 1 (lab DT50)**~~

~~**Crop**~~	~~**Scenario**~~	~~**80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)**~~			
		~~**Penoxsulam**~~	~~**5-OH-Penoxsulam**~~	~~**BSTCA**~~	~~**BST**~~
~~Winter cereals~~	~~Châteaudun~~	~~0.226~~	~~0.290~~	~~0.651~~	~~0.308~~
	~~Hamburg~~	~~0.005~~	~~0.258~~	~~0.654~~	~~0.375~~
	~~Jokioinen~~	~~0.001~~	~~0.157~~	~~0.397~~	~~0.302~~
	~~Kremsmünster~~	~~0.563~~	~~0.579~~	~~0.860~~	~~0.340~~
	~~Okehampton~~	~~0.007~~	~~0.232~~	~~0.599~~	~~0.223~~
	~~Piacenza~~	~~0.543~~	~~0.488~~	~~0.750~~	~~0.305~~
	~~Porto~~	~~0.005~~	~~0.219~~	~~0.405~~	~~0.223~~
	~~Sevilla~~	~~0.078~~	~~0.059~~	~~0.109~~	~~0.082~~
	~~Thiva~~	~~0.114~~	~~0.160~~	~~0.432~~	~~0.230~~

Table 8.8-6: ~~**PEC$_{gw}$ for penoxsulam and metabolite(s) on winter cereals (with FOCUS PELMO4.4.4) – TIER 2 (field DT50)**~~

~~**Crop**~~	~~**Scenario**~~	~~**80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)**~~			
		~~**Penoxsulam**~~	~~**5-OH-Penoxsulam**~~	~~**BSTCA**~~	~~**BST**~~
~~Winter cereals~~	~~Châteaudun~~	~~0.014~~	~~0.129~~	~~0.445~~	~~0.247~~
	~~Hamburg~~	~~<0.001~~	~~0.203~~	~~0.617~~	~~0.364~~
	~~Jokioinen~~	~~<0.001~~	~~0.126~~	~~0.358~~	~~0.286~~
	~~Kremsmünster~~	~~0.107~~	~~0.449~~	~~0.797~~	~~0.331~~
	~~Okehampton~~	~~<0.001~~	~~0.198~~	~~0.583~~	~~0.281~~
	~~Piacenza~~	~~0.140~~	~~0.358~~	~~0.720~~	~~0.283~~
	~~Porto~~	~~<0.001~~	~~0.164~~	~~0.396~~	~~0.221~~
	~~Sevilla~~	~~0.017~~	~~0.032~~	~~0.078~~	~~0.055~~

	~~Thiva~~	~~0.012~~	~~0.068~~	~~0.267~~	~~0.167~~

Table 8.8-7: ~~**PEC_{gw} for penoxsulam and metabolite(s) on winter cereals (with FOCUS PELMO4.4.4) – TIER 2A (field DT50) – PUF 0.5**~~

~~Crop~~	~~Scenario~~	~~80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)~~			
		~~Penoxsulam~~	~~5-OH-Penoxsulam~~	~~BSTCA~~	~~BST~~
~~Winter cereals~~	~~Kremsmünster~~	~~0.075~~	~~0.359~~	~~0.676~~	~~0.288~~
	~~Piacenza~~	~~0.121~~	~~0.295~~	~~0.617~~	~~0.249~~

Table 8.8-8: ~~**PEC_{gw} for penoxsulam and metabolite(s) on winter cereals (with FOCUS PELMO4.4.4) – TIER 2A (field DT50) – PUF 0.5 – 11.25 g as/ha (0.3 L prod/ha)**~~

~~Crop~~	~~Scenario~~	~~80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)~~			
		~~Penoxsulam~~	~~5-OH-Penoxsulam~~	~~BSTCA~~	~~BST~~
~~Winter cereals~~	~~Piacenza~~	~~0.084~~	~~0.219~~	~~0.460~~	~~0.187~~

~~Only in Piacenza scenario calculated by FOCUS PELMO 5.5.4 the active substance no exceed the trigger value 0.1 µg/L when lower dose than maximum – 11.25 g penoxsulam/ha (0.3L prod/ha) is used, but this scenario is not relevant scenario in Poland and does not any impact on registration in Poland.~~

Calculations PECgw for penoxsulam was divied for Tier 1 and Tier 2. Tier 1 used DT50 value from laboratory studies and showed exceed trigger value 0.1 µg/L by penoxsulam in alcalic soil. Therefore, Tier 2 used DT50 from field studies as risk refinement to show realistic concentration of penoxsulam in groundwater

Table 8.8-9: PEC_{gw} for penoxsulam and metabolite(s) on winter cereals (with FOCUS PEARL 4.4.4) – TIER 1 (pH<6.5)

Crop	**Scenario**	**80th Percentile PE(pH<6.5)C_{gw} at 1 m Soil Depth (µg/L)**			
		Penoxsulam	**5-OH-Penoxsulam**	**BSTCA**	**BST**
Winter cereals	Châteaudun	<0.0001	0.0486	~~0.2521~~ 0.4214	~~0.1599~~ 0.1836
	Hamburg	0.0036	0.2140	~~0.5960~~ 0.8333	~~0.3257~~ 0.3296
	Jokioinen	0.0001	0.1203	~~0.3419~~ 0.5144	~~0.2686~~ 0.2880
	Kremsmünster	0.0013	0.1194	~~0.4169~~ 0.5847	~~0.2130~~ 0.2139
	Okehampton	0.0057	0.2108	~~0.5544~~ 0.7376	~~0.2623~~ 0.2581
	Piacenza	0.0021	0.0948	~~0.3341~~ 0.4938	~~0.1670~~ 0.1735
	Porto	0.0023	0.1388	~~0.3403~~ 0.4668	~~0.1979~~ 0.1990
	Sevilla	<0.0001	0.0009	~~0.0033~~ 0.0103	~~0.0096~~ 0.01531

	Thiva	<0.0001	0.0173	~~0.1603~~ 0.3185	~~0.09932~~ 0.1339

~~**Table 8.8-10: PEC$_{gw}$ for penoxsulam and metabolite(s) on winter cereals (with FOCUS PEARL 4.4.4) – TIER 2 (field DT50) (pH<6.5)**~~

~~**Crop**~~	~~**Scenario**~~	~~**80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)**~~			
		~~**Penoxsulam**~~	~~**5-OH-Penoxsulam**~~	~~**BSTCA**~~	~~**BST**~~
~~Winter cereals~~	~~Châteaudun~~	~~<0.0001~~	~~0.0450~~	~~0.2384 0.4031~~	~~0.1516 0.1755~~
	~~Hamburg~~	~~<0.0001~~	~~0.1767~~	~~0.5559 0.7946~~	~~0.3132 0.3234~~
	~~Jokioinen~~	~~<0.0001~~	~~0.0986~~	~~0.3211 0.4896~~	~~0.2520 0.2781~~
	~~Kremsmünster~~	~~<0.0001~~	~~0.0895~~	~~0.3801 0.5418~~	~~0.1995 0.2031~~
	~~Okehampton~~	~~<0.0001~~	~~0.1971~~	~~0.5432 0.7161~~	~~0.2550 0.2506~~
	~~Piacenza~~	~~<0.0001~~	~~0.0679~~	~~0.3279 0.4713~~	~~0.1621 0.1697~~
	~~Porto~~	~~<0.0001~~	~~0.1241~~	~~0.3600 0.4816~~	~~0.1993 0.1950~~
	~~Sevilla~~	~~<0.0001~~	~~0.0005~~	~~0.0016 0.0088~~	~~0.0079 0.0141~~
	~~Thiva~~	~~<0.0001~~	~~0.0155~~	~~0.1428 0.2919~~	~~0.0964 0.1302~~

Table 8.8-11: PEC$_{gw}$ for penoxsulam and metabolite(s) on winter cereals (with FOCUS PEARL 4.4.4) – TIER 2 (field DT50) (pH<6.5) every other year

Crop	**Scenario**	**80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)**			
		Penoxsulam	**5-OH-Penoxsulam**	**BSTCA**	**BST**
Winter cereals	Châteaudun	<0.0001	0.0212	0.1876	0.0837
	Hamburg	<0.0001	0.0873	0.4101	0.1684
	Jokioinen	<0.0001	0.0547	0.2524	0.1390
	Kremsmünster	<0.0001	0.0480	0.2740	0.1038
	Okehampton	<0.0001	0.1065	0.3690	0.1284
	Piacenza	<0.0001	0.0374	0.2791	0.0961
	Porto	<0.0001	0.0615	0.2525	0.1012
	Sevilla	<0.0001	0.0012	0.0057	0.0082
	Thiva	<0.0001	0.0074	0.1544	0.0663

Table 8.8-12: PEC$_{gw}$ for penoxsulam and metabolite(s) on winter cereals (with FOCUS PELMO 5.5.3) – TIER 1 (pH<6.5)

Crop	Scenario	80th Percentile PE(pH<6.5)C$_{gw}$ at 1 m Soil Depth (µg/L)			
		Penoxsulam	5-OH-Penoxsulam	BSTCA	BST
Winter cereals	Châteaudun	<0.001	0.037	~~0.226~~ 0.385	~~0.149~~ 0.178
	Hamburg	0.005	0.258	~~0.654~~ 0.895	~~0.375~~ 0.380
	Jokioinen	0.001	0.157	~~0.397~~ 0.582	~~0.302~~ 0.317
	Kremsmünster	0.002	0.134	~~0.501~~ 0.683	~~0.247~~ 0.247
	Okehampton	0.007	0.232	~~0.599~~ 0.791	~~0.287~~ 0.277
	Piacenza	0.003	0.130	~~0.407~~ 0.583	~~0.227~~ 0.228
	Porto	0.005	0.219	~~0.405~~ 0.544	~~0.223~~ 0.226
	Sevilla	<0.001	0.006	~~0.013~~ 0.029	~~0.021~~ 0.026
	Thiva	<0.001	0.015	~~0.092~~ 0.190	~~0.072~~ 0.096

~~**Table 8.8-13: PEC$_{gw}$ for penoxsulam and metabolite(s) on winter cereals (with FOCUS PELMO 5.5.3) – TIER 2 (field DT50) (pH<6.5)**~~

~~Crop~~	~~Scenario~~	~~80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)~~			
		~~Penoxsulam~~	~~5-OH-Penoxsulam~~	~~BSTCA~~	~~BST~~
~~Winter cereals~~	~~Châteaudun~~	~~<0.001~~	~~0.031~~	~~0.219 0.381~~	~~0.145 0.173~~
	~~Hamburg~~	~~<0.001~~	~~0.217~~	~~0.647 0.885~~	~~0.368 0.375~~
	~~Jokioinen~~	~~<0.001~~	~~0.131~~	~~0.369 0.553~~	~~0.290 0.306~~
	~~Kremsmünster~~	~~<0.001~~	~~0.113~~	~~0.474 0.658~~	~~0.238 0.239~~
	~~Okehampton~~	~~<0.001~~	~~0.224~~	~~0.581 0.774~~	~~0.277 0.271~~
	~~Piacenza~~	~~<0.001~~	~~0.090~~	~~0.422 0.592~~	~~0.217 0.220~~
	~~Porto~~	~~<0.001~~	~~0.182~~	~~0.408 0.541~~	~~0.222 0.221~~
	~~Sevilla~~	~~<0.001~~	~~0.003~~	~~0.015 0.030~~	~~0.018 0.024~~
	~~Thiva~~	~~<0.001~~	~~0.013~~	~~0.093 0.191~~	~~0.073 0.096~~

Table 8.8-14: PEC$_{gw}$ for penoxsulam and metabolite(s) on winter cereals (with FOCUS PELMO 5.5.3) – TIER 2 (field DT50) (pH<6.5) every other year

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)			
		Penoxsulam	5-OH-Penoxsulam	BSTCA	BST
Winter cereals	Châteaudun	<0.001	0.016	0.175	0.080
	Hamburg	<0.001	0.134	0.472	0.196

	Jokioinen	<0.001	0.067	0.286	0.158
	Kremsmünster	<0.001	0.061	0.336	0.122
	Okehampton	<0.001	0.112	0.389	0.139
	Piacenza	<0.001	0.051	0.324	0.123
	Porto	<0.001	0.089	0.277	0.107
	Sevilla	<0.001	0.002	0.014	0.015
	Thiva	<0.001	0.005	0.105	0.053

Table 8.8-15: PEC$_{gw}$ for penoxsulam and metabolite(s) on winter cereals (with FOCUS PEARL 4.4.4) – TIER 1 (pH>6.5)

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)			
		Penoxsulam	5-OH-Penoxsulam	BSTCA	BST
Winter cereals	Châteaudun	0.2473	0.3389	~~0.6524~~ 0.8844	~~0.3031~~ 0.3078
	Hamburg	0.9115	0.7671	~~0.9737~~ 1.2246	~~0.3989~~ 0.3807
	Jokioinen	0.5962	0.5155	~~0.6516~~ 0.8663	~~0.3723~~ 0.3709
	Kremsmünster	0.4613	0.4783	~~0.7407~~ 0.9468	~~0.2785~~ 0.2652
	Okehampton	0.7282	0.5714	~~0.6915~~ 0.8361	~~0.2541~~ 0.2333
	Piacenza	0.3062	0.3690	~~0.6523~~ 0.8393	~~0.2396~~ 0.2249
	Porto	0.5474	0.3524	~~0.4921~~ 0.6272	~~0.2420~~ 0.2281
	Sevilla	0.0054	0.0047	~~0.0106~~ 0.0326	~~0.0264~~ 0.0365
	Thiva	0.1134	0.1790	~~0.5527~~ 0.0326	~~0.3003~~ 0.0365

~~**Table 8.8-16: PEC$_{gw}$ for penoxsulam and metabolite(s) on winter cereals (with FOCUS PEARL 4.4.4) – TIER 2 (field DT50) (pH>6.5)**~~

~~Crop~~	~~Scenario~~	~~80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)~~			
		~~Penoxsulam~~	~~5-OH-Penoxsulam~~	~~BSTCA~~	~~BST~~
~~Winter cereals~~	~~Châteaudun~~	~~0.0001~~	~~0.0650~~	~~0.3084 0.4833~~	~~0.1829 0.2025~~
	~~Hamburg~~	~~0.0173~~	~~0.3711~~	~~0.7524 1.009~~	~~0.3776 0.3777~~
	~~Jokioinen~~	~~0.002584~~	~~0.1994~~	~~0.4471 0.6500~~	~~0.3162 0.3270~~
	~~Kremsmünster~~	~~0.0018~~	~~0.1843~~	~~0.5456 0.7206~~	~~0.2453 0.2481~~
	~~Okehampton~~	~~0.0110~~	~~0.3001~~	~~0.6284 0.8043~~	~~0.2760 0.2647~~
	~~Piacenza~~	~~0.0019~~	~~0.1278~~	~~0.5021 0.6649~~	~~0.2125 0.2081~~
	~~Porto~~	~~0.0188~~	~~0.2272~~	~~0.4269 0.5658~~	~~0.2253 0.2151~~
	~~Sevilla~~	~~<0.0001~~	~~0.0009~~	~~0.0028 0.0092~~	~~0.0079 0.01616~~
	~~Thiva~~	~~<0.0001~~	~~0.03197~~	~~0.2115 0.4016~~	~~0.1415 0.1803~~

Table 8.8-17: PEC$_{gw}$ for penoxsulam and metabolite(s) on winter cereals (with FOCUS PEARL 4.4.4) – TIER 2 (field DT50) (pH>6.5) every other year

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)			
		Penoxsulam	**5-OH-Penoxsulam**	**BSTCA**	**BST**
Winter cereals	Châteaudun	<0.0001	0.0287	0.2419	0.1039
	Hamburg	0.0109	~~0.1933~~ 0.1934	0.5487	0.1941
	Jokioinen	0.0011	0.1117	0.3265	0.1659
	Kremsmünster	0.0009	0.0951	0.3733	0.1240
	Okehampton	0.0053	0.1722	~~0.4128~~ 0.4127	0.1332
	Piacenza	0.0007	0.0675	0.3693	0.1131
	Porto	0.0093	0.1180	0.2891	~~0.1143~~ 0.1142
	Sevilla	<0.0001	0.0048	0.0224	0.0141
	Thiva	<0.0001	0.0133	0.2025	0.0886

Table 8.8-18: PEC$_{gw}$ for penoxsulam and metabolite(s) on winter cereals (with FOCUS PELMO 5.5.3) – TIER 1 (pH>6.5)

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)			
		Penoxsulam	**5-OH-Penoxsulam**	**BSTCA**	**BST**
Winter cereals	Châteaudun	0.226	0.290	~~0.651~~ 0.915	~~0.308~~ 0.314
	Hamburg	1.073	0.841	~~0.989~~ 1.238	~~0.417~~ 0.387
	Jokioinen	0.803	0.570	~~0.663~~ 0.875	~~0.400~~ 0.387
	Kremsmünster	0.563	0.579	~~0.860~~ 1.082	~~0.340~~ 0.328
	Okehampton	0.822	0.612	~~0.723~~ 0.867	~~0.265~~ 0.241
	Piacenza	0.543	0.488	~~0.750~~ 0.956	~~0.305~~ 0.316
	Porto	0.831	0.371	~~0.476~~ 0.606	~~0.230~~ 0.221
	Sevilla	0.078	0.059	~~0.109~~ 0.144	~~0.082~~ 0.082
	Thiva	0.114	0.160	~~0.432~~ 0.655	~~0.230~~ 0.250

Table 8.8-19: PEC$_{gw}$ for penoxsulam and metabolite(s) on winter cereals (with FOCUS PELMO 5.5.3) – TIER 2 (field DT50) (pH>6.5)

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)			
		Penoxsulam	5-OH-Penoxsulam	BSTCA	BST
Winter cereals	Châteaudun	<0.001	0.049	0.275 0.459	0.173 0.200
	Hamburg	0.032	0.436	0.848 1.115	0.435 0.421
	Jokioinen	0.007	0.274	0.502 0.704	0.346 0.252
	Kremsmünster	0.003	0.225	0.648 0.857	0.289 0.288
	Okehampton	0.021	0.343	0.667 0.856	0.305 0.290
	Piacenza	0.013	0.207	0.599 0.786	0.268 0.263
	Porto	0.093	0.339	0.458 0.592	0.246 0.240
	Sevilla	0.001	0.018	0.037 0.063	0.035 0.041
	Thiva	0.001	0.028	0.166 0.305	0.117 0.144

Table 8.8-20: PEC$_{gw}$ for penoxsulam and metabolite(s) on winter cereals (with FOCUS PELMO 5.5.3) – TIER 2 (field DT50) (pH>6.5) every other year

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)			
		Penoxsulam	5-OH-Penoxsulam	BSTCA	BST
Winter cereals	Châteaudun	<0.001	0.021	0.216	0.096
	Hamburg	0.016	0.232	0.596	0.218
	Jokioinen	0.002	0.131	0.354	0.186
	Kremsmünster	0.002	0.125	0.423	0.147
	Okehampton	0.009	0.174	0.417	0.141
	Piacenza	0.008	0.129	0.437	0.149
	Porto	0.037	0.166	0.289	0.119
	Sevilla	<0.001	0.005	0.025	0.019
	Thiva	0.001	0.011	0.146	0.078

8.8.2.2 Diflufenican and its metabolites

Table 8.8-21: Input parameters related to active substance diflufenican and metabolite(s) for PEC_{gw} calculations

Compound	Diflufenican	AE B107137	AE 0542291	Value in accordance with EU endpoint y/n/ Reference*
Molecular weight (g/mol)	394	283	282	EFSA Scientific Report (2007) 122, 1-84
Water solubility (g/mol):	0.05	0.05	0.05	EFSA Scientific Report (2007) 122, 1-84
Saturated vapour pressure (Pa):	4.25 E-06	4.25E-06	4.24E-06	EFSA Scientific Report (2007) 122, 1-84
DT_{50} in soil (d)	141.8	10.6	45.7	EFSA Scientific Report (2007) 122, 1-84
DT_{50} in soil (d) field	-	-	-	EFSA Scientific Report (2007) 122, 1-84
Transformation rate	0.000821 per day to AE B107137 0.0012855 per day to AE 0542291 0.0021067 per day to CO2	0.065391 per day to CO2	0.025768 per day to CO_2@	EFSA Scientific Report (2007) 122, 1-84
K_{foc} (mL/g)/K_{fom}	1989/1154	13/7.5	132/76.6	EFSA Scientific Report (2007) 122, 1-84
1/n	0.91	0.73	0.81	EFSA Scientific Report (2007) 122, 1-84
Plant uptake factor	0	0	0	EFSA Scientific Report (0.5022007) 122, 1-840.648
Formation fraction		0.168 from diflufenican	0.263 from diflufenica	EFSA Scientific Report (2007) 122, 1-84

* Inputs used for Chateaudun, Kremsmunster, Piacenza, Sevilla and Thivia

Table 8.8-22: PEC_{gw} for diflufenican and metabolite(s) on winter cereals (with FOCUS PEARL 4.4.4) – TIER 1 (lab DT50)

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)		
		Diflufenican	AE B107137	AE 0542291
Winter cereals	Châteaudun	<0.0001	<0.0001	<0.0001
	Hamburg	<0.0001	<0.0001	<0.0001
	Jokioinen	<0.0001	<0.0001	<0.0001
	Kremsmünster	<0.0001	<0.0001	<0.0001
	Okehampton	<0.0001	<0.0001	<0.0001
	Piacenza	<0.0001	<0.0001	<0.0001
	Porto	<0.0001	<0.0001	<0.0001
	Sevilla	<0.0001	<0.0001	<0.0001
	Thiva	<0.0001	<0.0001	<0.0001

Table 8.8-23: PEC_{gw} for diflufenican and metabolite(s) on winter cereals (with FOCUS PELMO 5.5.3)

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)		
		Diflufenican	AE B107137	AE 0542291
Winter cereals	Châteaudun	<0.001	<0.001	<0.001
	Hamburg	<0.001	<0.001	<0.001
	Jokioinen	<0.001	<0.001	<0.001
	Kremsmünster	<0.001	<0.001	<0.001
	Okehampton	<0.001	<0.001	<0.001
	Piacenza	<0.001	<0.001	<0.001
	Porto	<0.001	<0.001	<0.001
	Sevilla	<0.001	<0.001	<0.001
	Thiva	<0.001	<0.001	<0.001

8.8.2.3 Flufenacet and its metabolites

Table 8.8-24: Input parameters related to active substance flufenacet and metabolite(s) for PEC_{gw} calculations

Compound	Flufenacet	FOE sulfonic acid	FOE oxalate	Value in accordance with EU endpoint y/n/ Reference*
Molecular weight	363.34	275.3	225.2	SANCO 7469/VI/98-Final 3 July

Compound	Flufenacet	FOE sulfonic acid	FOE oxalate	Value in accordance with EU endpoint y/n/ Reference*
(g/mol)				2003 and Flufenacet Addendum to the monograph of flufenacet- Annex B- B.7 Enviromental Fate and behaviour (2003).
Water solubility (mg/L):	56	56 from parent	56 from parent	SANCO 7469/VI/98-Final 3 July 2003 and Flufenacet Addendum to the monograph of flufenacet- Annex B- B.7 Enviromental Fate and behaviour (2003).
Saturated vapour pressure (Pa):	9E-5 Pa at 20°C	1E-8 default	1E-8 default	SANCO 7469/VI/98-Final 3 July 2003 and Flufenacet Addendum to the monograph of flufenacet- Annex B- B.7 Enviromental Fate and behaviour (2003).
DT_{50} in soil (d)	16.5 (geo mean normalised)	140 (geo mean normalised)	6.6 (geo mean normalised)	SANCO 7469/VI/98-Final 3 July 2003 and Flufenacet Addendum to the monograph of flufenacet- Annex B- B.7 Enviromental Fate and behaviour (2003).
Transformation rate	0.008359791to FOE Sulfonic acid 0.00042to FOE oxalate 0.0336072 to C02	0.004951 to CO2	0.105022 to CO2	**SANCO 7469/VI/98-Final 3 July 2003 and Flufenacet Addendum to the monograph of flufenacet- Annex B- B.7 Enviromental Fate and behaviour (2003).**
K_{foc} (mL/g)/K_{fom}	349 mL/g, arithmetic mean	12.5 arithmetic mean	14 arithmetic mean	SANCO 7469/VI/98-Final 3 July 2003 and Flufenacet Addendum to the monograph of flufenacet- Annex B- B.7 Enviromental Fate and behaviour (2003).
1/n	0.89	1.04	0.91	SANCO 7469/VI/98-Final 3 July 2003 and Flufenacet Addendum to the monograph of flufenacet- Annex B- B.7 Enviromental Fate and behaviour (2003).
Plant uptake factor	0	0	0	
Max occurance	-	26.2%	15.6 %	

* Inputs used for Chateaudun, Kremsmunster, Piacenza, Sevilla and Thivia

Table 8.8-25: PEC_{gw} for flufenacet and metabolite(s) on winter cereals (with FOCUS PEARL 4.4.4)

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)		
		Flufenacet	FOE Sulfonic acid	FOE oxalate
Winter cereals	Châteaudun	<0.0001	8.6327	0.0004
	Hamburg	<0.0001	8.5117	0.0111

	Jokioinen	<0.0001	14.045	0.007117
	Kremsmünster	<0.0001	5.2870	0.0019
	Okehampton	<0.0001	4.856	0.01817
	Piacenza	<0.0001	5.1420	0.0017
	Porto	<0.0001	4.2630	0.0135
	Sevilla	<0.0001	4.034	<0.0001
	Thiva	<0.0001	9.0484	~~14.045~~ <0.0001

Table 8.8-26: PEC$_{gw}$ for flufenacet and metabolite(s) on winter cereals (with FOCUS PELMO 5.5.3)

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)		
		Flufenacet	FOE Sulfonic acid	FOE oxalate
Winter cereals	Châteaudun	<0.001	5.973	<0.001
	Hamburg	<0.001	6.354	0.001
	Jokioinen	<0.001	7.677	<0.001
	Kremsmünster	<0.001	4.837	<0.001
	Okehampton	<0.001	3.731	0.001
	Piacenza	<0.001	5.466	<0.001
	Porto	<0.001	3.258	0.001
	Sevilla	<0.001	2.637	<0.001
	Thiva	<0.001	4.713	<0.001

~~Conclusions: No scenerio predicts to exceed 0.1 µg/L for active substance and FOE oxalate. However one of the metabolite FOE Sulfonic acid is exceeding 0.75 µg/L in all 9 scenarios. On Annex I inclusion were performed Lysimeter studies, which represents worst case of application. Results are summrized below:~~
~~Lysimeter (sandy loam soil, < 1.41 % OC)~~
~~corn/corn rotation (2 x 480 g a.s./ha)~~

~~Total mean 0.87-0.99 µg/l, max. 2.23 µg/l (y 1)~~
~~mean 0.46-0.67 µg/l, max. 1.0 µg/l (y 2)~~
~~mean 0.23-0.33 µg/l, max. 0.33 µg/l (y 3)~~
~~a.s. < 0.035 µg/l~~
~~FOE oxalate < 0.04 µg/l~~
~~FOE thioglycolate < 0.08 µg/l~~
~~FOE sulfonic acid~~
~~mean 0.49-0.59 µg/l, max. 1.29 µg/l (y 1)~~
~~mean 0.15-0.24 µg/l (y 2)~~

~~Conclusions: Under unfavourable conditions (sand soil, high rainfall), concentrations of flufenacet and of most of its degradation products are clearly < 0.1 µg/L in soil water at 1.3 m depth, for repeated applications to corn at 480 g as/ha with the exception of metabolite FOE-sulfonic acid. For this~~

compound, the maximum concentration is 1.29 µg/L (year 1) and annual mean concentrations are 0.49-0.59 µg/L (year 1) and 0.15-0.24 µg/L (year 2). This metabolit eis likely to present hazard to ground water wand this risk is similar for both single ans repeated applications. No accumulation in soi lis expected.

corn/wheat rotation (480 + 180 g a.s./ha)

Total mean 2.5 µg/l, max. 5 µg/l (year 1)
mean 0.24 µg/l (year 2)
a.s. not identified
FOE oxalate and thioglycolate < 0.1 µg/l
FOE sulfonic acid :
mean 1.49 µg/l, max. 3.7 µg/l (year 1)
mean 0.015 µg/l (year 2)
Conclusions: Th maximum concentration of FOE 5043 in single leachates were measured to be lower than 0.01 µg/l, however, a defined peak of the parent compound could not be observed. Therefore, FOE 5043 was not positively identified in the leachate. The same is true for FOE oxalate (M1, ≤0.04 µg/l). FOE alcohol (M3) was only positively identified in lysimeter #18, especially in the early leachates in maximum concentrations of 0.16 µg/l. Whereas FOE thioglycolate sulfoxide was only detected in amounts of 0.028 µg/l, the maximum residues of FOE sulfonic acid (M2) in the leachates of February 1994 were 3.4 µg/l (lys #17) and 3.7 µg/l (lys #18). Maximum concentrations of radioactivity remaining at the start and being spread over the whole TLC plate were 0.31 and 0.37 µg/l, respectively, and unknown single metabolites were below 0.08 µg/l.
The results of this study proved that even under worst case conditions a contamination of soil layers below 1.2 m depth by parent compound can be precluded with high probability. Most of ist relevant degradation products in soil showed a similar behaviour. Furthermore, the data confirmed that FOE 5043 is well degradable in soil.
Assessment of relevance of ground water metabolites is performed and presented in section b10 of dRR

Conclusions: No scenerio predicts to exceed 0.1 µg/L for active substance Penoxsulam, Diflufenican and Diflufenican. However metabolite BST, BSTCA, 5-OH Penoxsulam, DOE sulfonic acid exceed triger value 0.1 µg/L. Therfore, Assessment of relevance of ground water metabolites is performed and presented in section b10 of dRR

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

Evaluator's Comments:

The submitted PECsw and PECsed calculations were accepted.

All used endpoints for active substances and their metabolites were agreed at the EU level. The recommended FOCUS models were used: FOCUS Step 1 & 2, Step 3 and Step 4. The autumn application was taken into consideration.

D1 and D2 scenarios are not relevant for Central Zone and were not taken into consideration.

The max PECsw for Central zone and Poland with relevant mitigation measure are presented in the table below.

Penoxsulam. The PECsw and PECsed assessment for active substance and its metabolites was provided for acidic and alkaline soils.

Crop	Application rate g a.s./ha	Vegetative strip (m)	No spray buffer (m)	Central Zone Max PEC_{sw} (µg/L)
Winter cereals	15 alkaline soils	20	20	0.2583 R3 stream
	15 acidic soils	10	10	0.3179 R3 stream

Metabolites of penoxsulam. The relevant metabolites were taken into consideration; the Step 1 & 2 were used in PEC assessment. In the table below the higher values of PECsw and PECsed (from alkaline and acidic soils) are presented.

Step 1

Compound	PECsw µg/L	PECsed µg/kg
5-OH-penoxsulam	3.42	1.99
BSTCA	2.72	4.72
TPSA	1.60	1.04
BSA	1.15	0.36
2-amino-TP	0.37	0.24
for 5-OH-2-amino-TP	0.44	0.28

Diflufenican. The PECsw and PECsed values for active substance and its metabolites with relevant mitigation measures are presented in the table below.

Crop	Application rate g a.s./ha	Vegetative strip (m)	No spray buffer (m)	Max PEC_{sw} (µg/l)
Winter cereals	100	20	20	0.1656 D4 stream

Metabolites of diflufenican. The relevant metabolites were taken into consideration; the Step 1 & 2 were used in PEC assessment. In the table below the higher values of PECsw and PECsed (from alkaline and acidic soils) are presented.

Step 1

Compound	PECsw	PECsed
	µg/L	µg/kg
AE B107137	12.59	1.63
AE 0542291	5.34	7.04

Flufenacet. The PECsw and PECsed values for active substance and its metabolites with relevant mitigation measures are presented in the table below.

Crop	Application rate g a.s./ha	Vegetative strip (m)	No spray buffer (m)	Max PEC_{sw} (µg/l)
Winter cereals	124.8	20	20	0.4940 D5 stream

Metabolites of flufenacet. The relevant metabolites were taken into consideration; the Step 1 & 2 were used in PEC assessment. In the table below PECsw and PECsed are presented.

Step 1

Compound	PECsw	PECsed
	µg/L	µg/kg
FOE methylsulfide	3.67	0.00
FOE thiadone	16.41	0.00
FOE sulfonic acid	8.12	1.02

ZRMS is of the opinion, that relevant mitigation measures will be proposed at the Member State level.

The drift exposure was reassessed by evaluator using the Drift Calculator in SWASH model:

Crop	Application rate g product./ha	No spray buffer (m)	Max PEC_{sw} (µg/l)
Winter cereals	489.32	10 20 30	0.4523 0.2350 0.1593

	The relevant mitigation measure will be recommended in ecotoxicological section.

8.9.1 Justification for new endpoints

EU approved endpoints were evaluated during Annex I inclusion for active substances. All relevant data are presented in :

- Penoxsulam - EFSA Scientific Report (2009) 343, 59-90
- Diflufenican - EFSA Scientific Report (2007) 122, 1-84,
- Flufenacet – SANCO 7469/VI/98-Final 3 July 2003 and Flufenacet Addendum to the monograph of flufenacet-Annex B- B.7 Enviromental Fate and behaviour

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

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

Plant protection product	CHR/H/PENDIF 599.5 SC
Use No.	1
Crop	Winter cereals
Application rate (kg as/ha)	Penoxsulam: 0.015 Dilfufenican: 0.100 Flufenacet:0.1248
Number of applications/interval (d)	1/-
Application window	September - Febuary
Application method	annual
CAM (Chemical application method)	
Soil depth (cm)	
Models used for calculation	FOCUS SWASH v3.1, FOCUS PRZM v3.3.1, FOCUS MACRO v5.5.3, FOCUS TOXWA v3.3.1

Table 8.9-2: FOCUS Step 3 Scenario related input parameters for $PEC_{sw/sed}$ calculations for the application of CHR/H/PENDIF 599.5 SC

Crop	Scenario	Application window used in modelling
Winter cereals	D3	23 Nov – 23 Dec
	D4	24 Sep – 24 Oct
	D5	12 Nov – 12 Dec
	R1	14 Nov – 14 Dec
	R3	1 Dec – 31 Dec
	R4	15 Nov – 15 Dec

8.9.2.1 Penoxsualm and its metabolites

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

Compound	Penoxsulam	5-OH-Penoxsulam	BSTCA	TPSA	BSA	2-amino-TP	5-OH-2-amino-TP	Value in accordance to EU end-point y/n/ Reference
Molecular weight (g/mol)	483	469	416	275	306	195	183	EFSA Scientific Report (2009) 343
Saturated vapour pressure (Pa)	2.49E-014	Not required for Step 1+2	Not required for Step 1+2	-	-	-	-	EFSA Scientific Report (2009) 343
Water solubility (mg/L)	408	1000	1000	-	-	-	-	EFSA Scientific Report (2009) 343
Diffusion coefficient in water (m²/d)	4.3×10^{-5}	Not required for Step 1+2	Not required for Step 1+2	-	-	-	-	default
Diffusion coefficient in air (m²/d)	0.43	Not required for Step 1+2	Not required for Step 1+2	-	-	-	-	default
K_{foc} (mL/g)	16 (pH>6.5) 84 (pH<6.5)	59	174	-	-	-	-	EFSA Scientific Report (2009) 343
Freundlich Exponent 1/n	0.9 (pH>6.5) 0.89 (pH<6.5)	Not required for Step 1+2	Not required for Step 1+2	-	-	-	-	EFSA Scientific Report (2009) 343
Plant Uptake	0	Not required for Step 1+2	Not required for Step 1+2	-	-	-	-	EFSA Scientific Report (2009) 343
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	-	-	-	-	default
$DT_{50,soil}$ (d)	29.6	25	76	-	-	-	-	EFSA Scientific Report (2009) 343
$DT_{50,water}$ (d)	19.34	42.4	1000	-	-	-	-	EFSA Scientific Report

Compound	Penoxsulam	5-OH-Penoxsulam	BSTCA	TPSA	BSA	2-amino-TP	5-OH-2-amino-TP	Value in accordance to EU end-point y/n/ Reference
								(2009) 343
$DT_{50,sed}$ (d)	1000	1000	1000	-	-	-	-	EFSA Scientific Report (2009) 343
$DT_{50,whole\ system}$ (d)	19.34	42.4	1000	-	-	-	-	EFSA Scientific Report (2009) 343
Maximum occurrence observed (% molar basis with respect to the parent)	-	Soil: 41 Water/ Sediment: 34	Soil: 53 Water: Sediment: 24	Water: 56	Water: 36	Water: 18	Water: 23	EFSA Scientific Report (2009) 343

$PEC_{sw/sed}$

~~Step 3 and 4 for parent was calculated only for high pH value as worst-case situation.~~

Table 8.9-4: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for penoxsulam following single/ multiple application(s) of CHR/H/PENDIF 599.5 SC to winter cereals

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1 – pH > 6.5	---	5.03	Drainage/run off	3.54	0.78
Step 1 – pH <6.5	---	4.63	Drainage/run off	3.25	3.78
Step 2					
Northern Europe – pH >6.5	Oct-Feb	2.35	Drainage/run off	1.66	0.38
Northern Europe – pH < 6.5	Oct - Feb	2.18	Drainage/runoff	1.56	1.81
Step 3 pH > 6.5					
D3	Ditch	0.1664	Drainage	0.08706	0.1648
D4	pond	0.2745	Drainage	0.2640	0.3218
D4	stream	0.2705	Drainage	0.1812	0.1671
D5	pond	0.2289	Drainage	0.2113	0.2255
D5	stream	0.1669	Drainage	0.09184	0.09520
R1	pond	0.009001	Run off	0.007572	0.007313

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
R1	stream	0.5833	Run off	0.01237	0.05258
R3	stream	1.095	Run off	0.03015	0.1052
R4	stream	0.2161	Run off	0.006695	0.02328
Step 3 pH < 6.5					
D3	Ditch	0.09474	Drainage	0.003475	0.02084
D4	pond	0.1022	Drainage	0.09807	0.2100
D4	stream	0.1419	Drainage	0.06878	0.1052
D5	pond	0.1020	Drainage	0.09262	0.2535
D5	stream	0.1573	Drainage	0.03731	0.09964
R1	pond	0.008377	Run off	0.006932	0.01556
R1	stream	0.5333	Run off	0.01138	0.09622
R3	stream	0.7044	Run off	0.02384	0.1398
R4	stream	0.4042	Run off	0.01367	0.08558
Step 4 pH > 6.5	10 meters buffer zone and 10 meters no-spray buffer zone				
D3	Ditch	0.08541	Drainage	0.08706	0.1647
D4	pond	0.2742	Drainage	0.2638	0.3214
D4	stream	0.2705	Drainage	0.1812	0.1670
D5	pond	0.2287	Drainage	0.2111	0.2251
D5	stream	0.1669	Drainage	0.09184	0.09500
R1	pond	0.004166	Run off	0.003507	0.003584
R1	stream	0.2616	Run off	0.005383	0.02411
R3	stream	0.4942	Run off	0.01340	0.04868
R4	stream	0.09756	Run off	0.002902	0.01074
Step 4 pH < 6.5	10 meters buffer zone and 10 meters no-spray buffer zone				
D3	Ditch	0.01377	Drainage	0.000505	0.003320
D4	pond	0.1019	Drainage	0.09782	0.2086
D4	stream	0.1419	Drainage	0.08728	0.1047
D5	pond	0.1018	Drainage	0.09241	0.2521
D5	stream	0.1573	Drainage	0.03731	0.09902
R1	pond	0.003899	Run off	0.003230	0.007706
R1	stream	0.2391	Run off	0.004940	0.04405
R3	stream	0.3179	Run off	0.01074	0.06458
R4	stream	0.1825	Run off	0.006032	0.03967
Step 4 >	20 meters vegetative buffer zone and 20 meters no-spray buffer zone – used only for mixture toxicity in				

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
6.5	aquatic species				
R3	stream	0.2583	Run off	0.006997	0.02604

* single applications should be marked.
** twa-time as required by ecotox

Metabolite(s) of penoxsulam

Metabolites was calculated in comparative with high pH value of parent like worst-case situation.

Table 8.9-5: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for 5-OH-Penoxsulam following single application(s) to winter cerelas

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominat entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1 (pH> 6.5)	---	3.42	Drainage/run off	2.89	1.99
Step 1 (pH< 6.5)		3.42	Drainage/run off	2.89	1.99
Step 2					
Northern Europe (pH> 6.5)	Oct-Feb	1.56	Dainage/run off	1.34	0.92
Northern Europe (pH< 6.5)	Oct-Feb	1.56	Drainage/run off	1.34	0.92

* single applications should be marked.
** twa-time as required by ecotox

Table 8.9-6: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for BSTCA following single application(s) to winter cerelas

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominat entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1 (pH> 6.5)	---	2.72	Drainage/run off	2.70	4.72
Step 1 (pH< 6.5)		2.72	Drainage/run off	2.70	4.72
Step 2					
Northern Europe (pH> 6.5)	Oct-Feb	1.30	Dainage/run off	1.29	2.26
Northern Europe	Oct-Feb	1.30	Drainage/run off	1.29	2.26

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominat entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
(pH< 6.5)					

Aqueous Photolysis Products
There are four major aqueous photolysis products of penoxsulam (TPSA-penoxsulam, BSA, 2-amino-TP and 5-OH-2-amino-TP).

The PECsw values for these photolysis products were calculated by taking the initial (maximum) PECsw value for the active substance and correcting for the maximum percent formed and the difference in molecular weights as follows.

Initial $PEC_{SW,metab}$ (µg/L) = $PEC_{initial,\ parent}$ x (max % met/100) x molar ratio

Table 8.9-7: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for TPSA following single application(s) to winter cerelas

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominat entry route	Max PEC_{sed} (µg/kg)*
Step 1 (pH> 6.5)	---	1.60	Drainage/run off	0.25
Step 1 (pH< 6.5)		1.47	Dainage/run off	1.04
Step 2				
Northern Europe (pH> 6.5)	Oct-Feb	0.75	Dainage/run off	0.12
Northern Europe (pH< 6.5)	Oct-Feb	0.69	Dainage/run off	0.50

Table 8.9-8: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for BSA following single application(s) to winter cerelas

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominat entry route	Max PEC_{sed} (µg/kg)*
Step 1 (pH> 6.5)	---	1.15	Drainage/run off	0.18
Step 1 (pH< 6.5)		1.06	Dainage/run off	0.36
Step 2				
Northern Europe	Oct-Feb	0.54	Dainage/run off	0.09

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominat entry route	Max PEC_{sed} (µg/kg)*
(pH> 6.5)				
Northern Europe (pH< 6.5)	Oct-Feb	0.5	Dainage/run off	0.36

Table 8.9-9: **FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for 2-amino-TP following single application(s) to winter cerelas**

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominat entry route	Max PEC_{sed} (µg/kg)*
Step 1 (pH> 6.5)	---	0.37	Drainage/run off	0.06
Step 1 (pH< 6.5)		0.34	Dainage/run off	0.24
Step 2				
Northern Europe (pH> 6.5)	Oct-Feb	0.17	Dainage/run off	0.03
Northern Europe (pH< 6.5)	Oct-Feb	0.16	Dainage/run off	0.11

Table 8.9-10: **FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for 5-OH-2-amino-TP following single application(s) to winter cerelas**

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominat entry route	Max PEC_{sed} (µg/kg)*
Step 1 (pH> 6.5)	---	0.44	Drainage/run off	0.07
Step 1 (pH< 6.5)		0.40	Dainage/run off	0.28
Step 2				
Northern Europe (pH> 6.5)	Oct-Feb	0.20	Dainage/run off	0.03
Northern Europe (pH< 6.5)	Oct-Feb	0.19	Dainage/run off	0.14

8.9.2.2 Diflufenican and its metabolites

Table 8.9-11: Input parameters related to active substance Diflufenican and metabolite(s) for $PEC_{sw/sed}$ calculations STEP 1/2 and 3(/4

Compound	Diflufenican	AE B107137	AE 0542291	Value in accordance to EU end-point y/n/ Reference
Molecular weight (g/mol)	394	283	282	EFSA Scientific Report (2007) 122,1-84, Conclusion on the peer review of Diflufenican, Appendix 1 – list of end points
Saturated vapour pressure (Pa)	0.425E-05	Not required for Step 1+2	Not required for Step 1+2	EFSA Scientific Report (2007) 122,1-84, Conclusion on the peer review of Diflufenican, Appendix 1 – list of end points
Water solubility (mg/L)	50	410	100	EFSA Scientific Report (2007) 122,1-84, Conclusion on the peer review of Diflufenican, Appendix 1 – list of end points
Diffusion coefficient in water (m²/d)	4.3×10^{-5}	Not required for Step 1+2	Not required for Step 1+2	default
Diffusion coefficient in air (m²/d)	0.43	Not required for Step 1+2	Not required for Step 1+2	default
K_{foc} (mL/g)	1989	13	131.9	EFSA Scientific Report (2007) 122,1-84, Conclusion on the peer review of Diflufenican, Appendix 1 – list of end points
Freundlich Exponent 1/n	0.91	0.73	0.81	EFSA Scientific Report (2007) 122,1-84, Conclusion on the peer review of Diflufenican, Appendix 1 – list of end points
Plant Uptake	0	Not required for Step 1+2	Not required for Step 1+2	EFSA Scientific Report (2007) 122,1-84, Conclusion on the peer review of Diflufenican,

Compound	**Diflufenican**	**AE B107137**	**AE 0542291**	**Value in accordance to EU end-point y/n/ Reference**
				Appendix 1 – list of end points
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	default
$DT_{50,soil}$ (d)	141.8	10.6	20.9	EFSA Scientific Report (2007) 122,1-84, Conclusion on the peer review of Diflufenican, Appendix 1 – list of end points
$DT_{50,water}$ (d)	31.7	730	730	EFSA Scientific Report (2007) 122,1-84, Conclusion on the peer review of Diflufenican, Appendix 1 – list of end points
$DT_{50,sed}$ (d)	338.7	730	730	EFSA Scientific Report (2007) 122,1-84, Conclusion on the peer review of Diflufenican, Appendix 1 – list of end points
$DT_{50,whole\ system}$ (d)	214	730	730	EFSA Scientific Report (2007) 122,1-84, Conclusion on the peer review of Diflufenican, Appendix 1 – list of end points
Maximum occurrence observed (% molar basis with respect to the parent)	-	Soil: 16.8 Water/ Sediment: 35.7	Soil: 26.3 Water: Sediment: 0.0001	EFSA Scientific Report (2007) 122,1-84, Conclusion on the peer review of Diflufenican, Appendix 1 – list of end points

$PEC_{sw/sed}$

Table 8.9-12: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for Diflufenican following single/ multiple application(s) of CHR/H/PENDIF 599.5 SC to winter cereals

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	10.05	Drainage/run off	9.08	185.95
Step 2					
Northern Europe	Oct-Feb	4.79	Drainage/run off	4.31	93.63
Step 3					
D3	Ditch	0.6299	Drainage	0.02287	0.3088
D4	pond	0.04667	Drainage	0.03718	0.3668
D4	stream	0.5464	Drainage	0.01610	0.1787
D5	pond	0.02189	Drainage	0.01679	0.1939
D5	stream	0.5896	Drainage	0.01078	0.1607
R1	pond	0.06265	Run off	0.04945	0.5696
R1	stream	0.4154	Run off	0.02002	0.5601
R3	stream	0.5829	Run off	0.02451	0.4198
R4	stream	0.5912	Run off	0.02899	0.5392
Step 4	10 meters vegetative buffer zone and 10 meters no-spray buffer zone				
D3	Ditch	0.09049	Drainage	0.003280	0.04528
D4	pond	0.04452	Drainage	0.03531	0.3258
D4	Stream	0.1656	Drainage	0.01610	0.1654
D5	pond	0.01363	Drainage	0.01054	0.1522
D5	stream	0.1140	Drainage	0.002155	0.03206
R1	pond	0.02718	Run off	0.02155	0.2619
R1	stream	0.1749	Run off	0.008953	0.1770
R3	stream	0.1949	Run off	0.009706	0.1375
R4	stream	0.2667	Run off	0.01228	0.1990
Step 4	20 meters vegetative buffer zone and 20 meters no-spray buffer zone (vfs mode) – used only for mixture toxicity in aquatic speciec				
D3	Ditch	0.04703	Drainage	0.001704	0.02368
D4	pond	0.04336	Drainage	0.03431	0.3034
D4	Stream	0.1656	Drainage	0.08817	0.1638
D5	pond	0.01229	Drainage	0.009766	0.1295
D5	stream	0.06354	Drainage	0.002155	0.02712
R1	pond	0.009043	Run off	0.006760	0.05747
R1	stream	0.04185	Run off	0.000350	0.005559

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
R3	stream	0.05872	Run off	0.000958	0.01546
R4	stream	0.04151	Run off	0.000312	0.005451

* single applications should be marked.
** twa-time as required by ecotox

Metabolite(s) of diflufenican

Table 8.9-13: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for AE B107137 following single application(s) to winter cereals

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominat entry route	21 d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	12.59	Drainage/runoff	12.46	1.63
Step 2					
Northern Europe	Oct-Feb	5.87	Drainage/runoff	5.81	0.76

* single applications should be marked.
** twa-time as required by ecotox

Table 8.9-14: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for AE 0542291 following single application(s) to winter cereals

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominat entry route	21 d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	5.34	Drainage/runoff	5.28	7.04
Step 2					
Northern Europe	Oct-Feb	2.34	Drainage/runoff	2.31	3.08

* single applications should be marked.
** twa-time as required by ecotox

8.9.2.3 Flufenacet and its metabolites

Table 8.9-15: Input parameters related to active substance flufenacet and metabolite(s) for $PEC_{sw/sed}$ calculations STEP 1/2 and 3(/4

Compound	Flufenacet	FOE methyl-sulfide	FOE thiadone	FOE Sulfonic acid	**Value in accord-ance to EU end-point y/n/ Reference**
Molecular weight (g/mol)	363.34	273.3 g/mol	170.1 g/mol	275.3 g/mol	SANCO 7469/VI/98-Final 3 July 2003 and Flufenacet Addendum to the monograph of flufenacet-Annex B-B.7 Enviromental Fate and behaviour (2003).
Saturated vapour pressure (Pa)	9E-5	9E-5	9E-5	9E-5	SANCO 7469/VI/98-Final 3 July 2003 and Flufenacet Addendum to the monograph of flufenacet-Annex B-B.7 Enviromental Fate and behaviour (2003).
Diffusion coefficient in water (m²/d)	4.3 x 10^{-5}	not required for Step 1+2/	not required for Step 1+2	not required for Step 1+2	default
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	default
Water solubility (mg/L)	56	56 from parent	56 from parent	56 from parent	SANCO 7469/VI/98-Final 3 July 2003 and Flufenacet Addendum to the monograph of flufenacet-Annex B- B.7 Enviromental Fate and behaviour (2003).
KOC	349	0	0	12.5	SANCO 7469/VI/98-Final 3 July 2003 and Flufenacet Addendum to the monograph of flufenacet-Annex B- B.7 Enviromental Fate and behaviour (2003).
Plant Uptake	0.5	not required for Step 1+2	not required for Step 1+2	not required for Step 1+2	default
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/	default
$DT_{50,soil}$ (d)	16.5 d	0.1 d	0.1 d	140	SANCO 7469/VI/98-Final 3 July 2003 and Flufenacet Addendum to the monograph of flufenacet-Annex B- B.7 Enviromental Fate and behaviour (2003).
$DT_{50,water}$ (d)	61.7 d	1000 d	1000 d	1000 d	SANCO 7469/VI/98-

Compound	Flufenacet	FOE methyl-sulfide	FOE thiadone	FOE Sulfonic acid	**Value in accordance to EU end-point y/n/ Reference**
$DT_{50,sed}$ (d)	1000 d	1000 d	1000 d	1000 d	Final 3 July 2003 and Flufenacet Addendum to the monograph of flufenacet-Annex B- B.7 Enviromental Fate and behaviour (2003).
$DT_{50,whole\ system}$ (d)	84.6 d (STEP 1-2)	1000 d	1000d	1000 d	
Maximum occurrence observed (% molar basis with respect to the parent)		Maximum occurrence observed in soil: 0.001% max. 8 % in water, 3.4 % in sediment	Maximum occurrence observed in soil: 0.001 % Max 82 % in water (55 d)	Maximum occurrence observed in soil: 26.2% Max 0.001% in water	SANCO 7469/VI/98-Final 3 July 2003 and Flufenacet Addendum to the monograph of flufenacet-Annex B- B.7 Enviromental Fate and behaviour (2003).

$PEC_{sw/sed}$

Table 8.9-16: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for flufenacet following single/ multiple application(s) of CHR/H/PENDIF 599.5 SC to winter cereals

Scenario FOCUS	**Waterbody**	**Max PEC_{sw} (µg/L)***	**Dominant entry route**	**21 d- $PEC_{sw,twa}$ (µg/L)****	**Max PEC_{sed} (µg/kg)***
Step 1	---	29.54	Drainage/runoff	26.81	100.98
Step 2					
Northern Europe	Oct-Feb	12.84	Drainage/runoff	11.72	44.49
Step 3					
D3	Ditch	0.7881	Drainage	0.02892	0.2752
D4	pond	0.02724	Drainage	0.02216	0.1416
D4	stream	0.6839	Drainage	0.009442	0.1218
D5	pond	0.3578	Drainage	0.3279	1.457
D5	stream	0.7378	Drainage	0.1179	0.4872
R1	pond	0.08545	Run off	0.07424	0.3978
R1	stream	2.046	Run off	0.04604	0.5613
R3	stream	2.602	Run off	0.1100	0.8316
R4	stream	2.429	Run off	0.09891	0.9011
Step 4	10 meters vegetative buffer zone and 10 meters no-spray buffer zone				
D3	Ditch	0.1134	Drainage	0.004157	0.04227
D4	pond	0.01696	Drainage	0.01401	0.1163
D4	Stream	0.1325	Drainage	0.007759	0.03325
D5	pond	0.3550	Drainage	0.3253	1.431
D5	stream	0.4940	Drainage	0.1179	0.4765

Scenario **FOCUS**	**Waterbody**	**Max PEC_{sw} (µg/L)***	**Dominant entry route**	**21 d- $PEC_{sw,twa}$ (µg/L)****	**Max PEC_{sed} (µg/kg)***
R1	pond	0.03775	Run off	0.03284	0.1888
R1	stream	0.9162	Run off	0.01941	0.2453
R3	stream	1.173	Run off	0.04956	0.3677
R4	stream	1.096	Run off	0.04350	0.4099
Step 4	10 meters vegetative buffer zone and 10 meters no-spray buffer zone (vfs mode)				
D3	Ditch	0.1134	Drainage	0.004157	0.04227
D4	pond	0.01696	Drainage	0.01401	0.1163
D4	Stream	0.1325	Drainage	0.007759	0.03325
D5	pond	0.3550	Drainage	0.3253	1.431
D5	stream	0.4940	Drainage	0.1179	0.4765
R1	pond	0.03775	Run off	0.03284	0.1888
R1	stream	0.1007	Run off	0.001208	0.01735
R3	stream	0.1413	Run off	0.001715	0.02313
R4	stream	0.09989	Run off	0.000781	0.01010
Step 4	20 meters vegetative buffer zone and 20 meters no-spray buffer zone – used only for mixture toxicity in aquatic species				
R3	stream	0.6129	Run off	0.02587	0.1942
Step 4	20 meters vegetative buffer zone and 20 meters no-spray buffer zone (vfs mode) – used only for mixture toxicity in aquatic speciec				
D3	Ditch	0.05897	Drainage	0.002162	0.02245
D4	pond	0.01388	Drainage	0.01338	0.1026
D4	Stream	0.06895	Drainage	0.007759	0.03263
D5	pond	0.3535	Drainage	0.3239	1.416
D5	stream	0.4940	Drainage	0.1179	0.4752
R1	pond	0.01137	Run off	0.009455	0.04401
R1	stream	0.05242	Run off	0.000439	0.006412
R3	stream	0.07353	Run off	0.000892	0.01216
R4	stream	0.05199	Run off	0.000354	0.005288

* single applications should be marked.
** twa-time as required by ecotox

Metabolite(s) of flufenacet

Table 8.9-17: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for FOE methylsulfide following single application(s) to winter cereals

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominat entry route	21 d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	3.67	Drainage/runoff	3.64	0.00
Step 2					
Northern Europe	Oct-Feb	1.61	Drainage/run off	1.59	0.00

* single applications should be marked.
** twa-time as required by ecotox

Table 8.9-18: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for FOE thiadone following single application(s) to winter cereals

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominat entry route	21 d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	16.41	Drainage/runoff	16.29	0.00
Step 2					
Northern Europe	Oct-Feb	7.19	Drainage/run off	7.14	0.00

* single applications should be marked.
** twa-time as required by ecotox

Table 8.9-19: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for FOE sulfonic acid following single application(s) to winter cereals

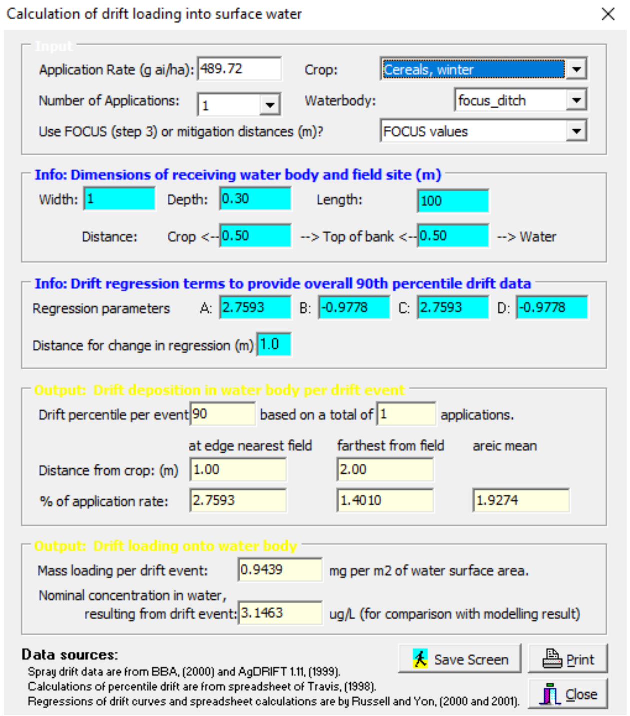
Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominat entry route	21 d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	8.12	Drainage/runoff	8.06	~~0.00~~ 1.02
Step 2					
Northern Europe	Oct-Feb	3.98	Drainage/run off	3.95	0.50

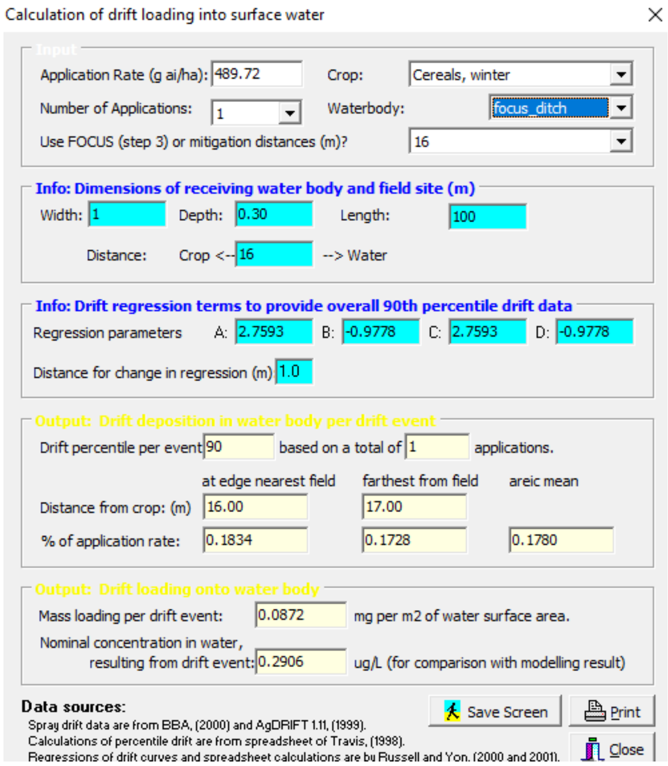
* single applications should be marked.
** twa-time as required by ecotox

8.9.2.4 PEC$_{sw/sed}$ of CHR/H/PENDIF 599.5 SC

Table 8.9-20: PEC$_{sw}$ of CHR/H/PENDIF 599.5 SC assuming application 489.72 g prod/ha (0.4L on winter cereals) in Drift calculator into surface water from SWASH ver 5.3

Intended use	Winter cereals
Formulation	CHR/H/PENDIF 599.5 SC
Application rate (g[prod]/ha)	1 X 489.72 g
Entry into surface water via spraydrift (Drift alculator from SWASH)	
Buffer zone (m)	**PECsw [µg prod/L**
1	3.1463
16	0.2906





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

Table 8.10-1 Summary of atmospheric degradation and behaviour

Compound	Penoxsulam		
Direct photolysis in air	Not evaluated		
Quantum yield of direct phototransformation	0.180 (measured in water)		
Photochemical oxidative degradation in air (DT_{50})	Latitude: N/A	Season: N/A	DT_{50}: 2.1 hours
Volatilisation from plant surfaces:	Not evaluated		
from soil:	Not evaluated		

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

Table 8.10-2 Summary of atmospheric degradation and behaviour

Compound	Diflufenican

Direct photolysis in air ‡	Not studied – no data requested
Quantum yield of direct phototransformation	Not studied – no data requested
Photochemical oxidative degradation in air ‡	DT_{50} of 5.0 d (EU), 3.3 d (USA) derived by the Atkinson method of calculation
Volatilisation ‡	From plant surfaces (BBA guideline): negligible (max. 0.3 %) after 24 hours
	from soil (BBA guideline): negligible (<0.01 %) after 24 hours
Metabolites	Metabolite AE C522392 was found to be volatile in an anaerobic soil degradation study (peak of 28.11% AR in volatile traps). However because its DT_{50} in air is 10.5 hours (via Atkinson calculation), it is unlikely to persist in the troposphere or be subject to long range transport.

The vapour pressure at 20 °C of the active substance diflufenican is < 10^{-5} Pa. Hence the active substance diflufenican is regarded as non-volatile. Therefore exposure of adjacent surface waters and terrestrial ecosystems by the active substance diflufenican due to volatilization with subsequent deposition should be considered.

Table 8.10-3 Summary of atmospheric degradation and behaviour

Compound	Flufenacet
Direct photolysis in air	No data provided, not required (no absorbance above 290 nm)
Quantum yield of direct phototransformation	Not studied - no data requested
Photochemical oxidative degradation in air	4.7 h (according to Atkinson)
Volatilisation	from plant surfaces: no data, not required from soil: up to 29 % within 1 day
Metabolites	None

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 should be considered.

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 (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.1.3	-	2021	CHR/H/PENDIF 599 SC Predicted environmental concentration of penoxsulam, diflufenican and flufenacet and their metabolites in soil, ground water and surface water. PUH Chemirol Sp. z o.o. Study code: CHR/H/PENDIF-B8 Non GLP Unpublished	N	Chemirol
KCP 9.2.4	-	2021	CHR/H/PENDIF 599 SC Predicted environmental concentration of penoxsulam, diflufenican and flufenacet and their metabolites in soil, ground water and surface water. PUH Chemirol Sp. z o.o. Study code: CHR/H/PENDIF-B8 Non GLP Unpublished	N	Chemirol
KCP 9.2.5	-	2021	CHR/H/PENDIF 599 SC Predicted environmental concentration of penoxsulam, diflufenican and flufenacet and their metabolites in soil, ground water and surface water. PUH Chemirol Sp. z o.o. Study code: CHR/H/PENDIF-B8 Non GLP Unpublished	N	Chemirol

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.1/01	Jackson, R.	2001	The Aerobic Degradation of XDE-638 in European Soils GHE-P-8899 Dow AgroSciences Letcombe Regis Wantage, UK GLP Unpublished	N	Dow AgroSciences
KCP 9.1/02	Krieger, M. S., Meitl, T. J., Balcer, J. L.	2002	Anaerobic Soil and Sediment Degradation of 14C-XDE-638 990052 Dow AgroSciences LLC Indianapolis, Indiana, USA GLP Unpublished	N	Dow AgroScience
KCP 9.1/03	Rutherford , L A, Yoder, R N, Balcer, J L.	2002	Photodegradation of XDE-638 on Aerobic Soil 000137 Dow AgroSciences LLC Indianapolis, Indiana, USA GLP Unpublished	N	Dow AgroSciences
KCP 9.1/04	Oxspring, S	2002	The Field Dissipation of XDE-638 in European Rice Paddies AF/5664/DE Agrisearch UK Ltd GLP Unpublished	N	Dow AgroSciences
KCP 9.1/05	Miller A M Lindsay D A Thomas A D	2002	Frozen Storage Stability of XDE-638, 5-Hydroxy-XDE-638, XDE-638 Sulfonic Acid (BSA), XDE-638 Sulfonamide, Triethylammonium of XDE-638 (BSTCA) and 5,8-Dimethoxy XDE-638 (2-amino-TP) in Soil—Interim Report GH-C 5501 Dow AgroSciences LLC Indianapolis, Indiana, USA GLP Unpublished	N	Dow AgroScience
KCP	Miller,	2002	Storage Stability of XDE-638, 5-hydroxy-XDE-638, XDE-638 sulfonic acid (BSA), XDE-638	N	Dow

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
9.2/01	A.M., Lindsay, D.A., Thomas, A.D		sulfonamide, triethylammonium of XDE-638 (BSTCA), XDE-638 TPSA, and 2-amino-8-methoxy (5-hydroxy-Amino- TP) in Water—Interim Report GH-C 5502 Dow AgroSciences LLC Indianapolis, Indiana, USA		AgroSciences
KCP 9.1/06	Yoder, R.N.	2000	Batch Equilibrium Adsorption/Desorption of XDE-638 on Seventeen Soils and One Sediment 990058 Dow AgroSciences, 9330 Zionsville Rd., Indianapolis, IN 46268 USA GLP Unpublished	N	Dow Agroscienes
KCP 9.1/07	Yoder, R.N.	2002	Batch Equilibrium Adsorption of XDE-638 Metabolites, 5-OH-XDE-638, RSTCA and BST 010092 Dow AgroSciences LLC Indianapolis, Indiana, USA GLP Unpublished	N	Dow AgroSciences
KCP 9.1/08	R Jackson J Massart	1999	The Soil Column Leaching Behaviour of XR-638 (Non-aged) GHE-P-7705 Dow AgroSciences Letcombe Regis Wantage, UK GLP Unpublished	N	Dow AgroScience
KCP 9.2/02	Simon, K. Smith, J.K.	2001	Hydrolysis of XDE-638 in Buffered and Natural Water as a Function of pH 000134 Dow AgroSciences LLC Indianapolis, Indiana, USA GLP Unpublished	N	Dow AgroSciences
KCP 9.2/03	Knowles, S., Portwood, D.	2000	Photolysis of XDE-638 in Sterile Aqueous Buffer and Natural Surface Water GHE-P-8084 Dow AgroSciences Letcombe Laboratories Letcombe Regis Wantage OX12 9JT. UK GLP	N	Dow Agrosciences

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
			Unpublished		
KCP 9.2/04	Lebertz, H. Heim, Lucas, G.	2002	Investigation on the “Ready Biodegradability” of XDE-638 according to the OECD-Test Guideline 301B GH-C 5474 Institut Fresenius, Chemische und Biologisch Laboratorien AG, Im Maisel 14, D- 65232 Taunustein GLP Unpublished	N	Dow AgroSciences
KCP 9.2/05	Cook, W.L; Smith, K.P.	2002	Aerobic Aquatic Degradation of XDE-638 in Six Matrices 990061 Dow AgroSciences LLC Indianapolis, Indiana, USA GLP Unpublished	N	Dow AgroSciences
KCP 9.2/06	Krieger, M.S.	2001	Estimation of the Photochemical Oxidation Rate of XDE-638 GH-C 5351 Dow AgroSciences Indianapolis, USA GLP Unpublished	N	Dow AgroSciences
KCP 9.1/09	Buys M., Chabassol Y.	1985	Diflufenican (MB38544) Aerobic soilmetabolism study. Generated by: Rhone-Poulenc; Rhone-Poulenc Secteur Agro, Lyon, France; Centre de Recherche de la Dargoire Document No: R008121 GLP / GEP: No unpublished	N	BCS
KCP 9.1/10	Slater B.J., McClenaghan I.	1987	Diflufenican - Structure of soil metabolite Generated by: Rhone-Poulenc; May & Baker Ltd., Dagenham, Essex, GBR; Radiochemistry & Analytical Chemistry Laboratories	N	BCS

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
			Document No: R008226 GLP / GEP: No unpublished		
KCP 9.1/11	Unsworth R.H., Clarke D.E.	2000	(2-pyridine-14C)-diflufenican: Route of aerobic degradation in one soil type at 20 degrees Celsius. Generated by: Rhone-Poulenc; Aventis CropScience U.K., Ltd.; Document No: R008059 GLP / GEP Yes unpublished	N	BCS
KCP 9.1/12	Mahay N., Lowden P.	2000	(14C)-Diflufenican: route of degradation in one soil (using (14C)-2,4-difluorophenyl ringlabelled and (14C)-3-trifluoromethylphenyl ring-labelled diflufenican) Code: AE F088657 Generated by: Aventis CropScience UK Limited, GBR; Aventis CropScience UK Limited, GBR; Document No: C010668 GLP / GEP Yes unpublished	N	BCS
KCP 9.1/13	Oddy A.M., Hatcher G.	2000	(14C)-diflufenican anaerobic soil degradation Generated by: Aventis CropScience UK Limited, GBR; Aventis CropScience UK Limited, GBR; Document No: C010707 GLP / GEP Yes unpublished	N	BCS
KCP 9.2/07	Chabassol Y.	1985	MB 38544 Anaerobic aquatic metabolism study. Generated by: Rhone-Poulenc; Rhone-Poulenc Agrochimie, Lyon, France; Centre de Recherche de La Dargoire Document No: R008125 GLP / GEP: No	N	BCS

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
			unpublished		
KCP 9.1/14	Hobbs D., Savage E.A.	1986	Herbicides: Diflufenican-14C:Photodegradation study on soil Generated by: Rhone-Poulenc; May & Baker Ltd., Ongar, Essex, GBR; Environmental Chemistry Document No: R008188 GLP / GEP: No unpublished	N	BCS
KCP 9.1/15	Chabassol Y.	1985	Diflufenican (MB38544) Rate of degradation in soil. Generated by: Rhone-Poulenc; Rhone-Poulenc Secteur Agro, Lyon, France; Centre de Recherche de la Dargoire Document No: R008123 GLP / GEP: No unpublished	N	BCS
KCP 9.1/16	Mahay N., Burr C.M.	2001	Rate of degradation in three soils at 20 degrees C and one at 10 degrees C (14C)-Diflufenican Generated by: Aventis CropScience UK Limited, GBR; Environmental Chemistry, Ongar Document No: C014862 GLP / GEP Yes unpublished	N	BCS
KCP 9.1/17	Fliege R.	2002	Rate of degradation of (pyridyl-2-14C)-AE 0650274 in three European soils at 20 degrees C under laboratory conditions Code: AE 0650274 (= AE B107137 = M&B 38181) Generated by: Aventis CropScience GmbH, DEU; Oekochemie, Frankfurt Document No: C022808 GLP / GEP Yes unpublished	N	BCS
KCP	Fliege R.	2002	Rate of degradation of (pyridyl-2-14C)-AE 0542291 in three European soils at 20 degrees C under	N	BCS

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
9.1/18			laboratory conditions Code: AE 0542291 (= M&B 43625) Generated by: Aventis CropScience GmbH, DEU; Oekochemie, Frankfurt Document No: C022809 GLP / GEP Yes unpublished		
KCP 9.1/19	Oddy A.M., Hatcher G.	2000	(14C)-diflufenican anaerobic soil degradation Generated by: Aventis CropScience UK Limited, GBR; Aventis CropScience UK Limited, GBR; Document No: C010707 GLP / GEP Yes unpublished	N	BCS
KCP 9.1/20	Lowden P., Mahay N.	1999	Anerobic soil degredation (14C)-M&B 38181 Generated by: Rhone-Poulenc Agriculture Ltd, Ongar, GBR; Rhone-Poulenc Agriculture Ltd, Ongar, GBR; Document No: C010709 GLP / GEP Yes unpublished	N	BCS
KCP 9.1/21	Hardy I.	2003	Kinetic evaluation of a laboratory anaerobic soil study with diflufenican using TopFit 2.0 to derive degradation data for the metabolite M&B40401 Code AE F088657 AE C522392 Generated by: Batelle AgriFood Ltd., Ongar, UK; BCS S.A., FRANCE; Environmental Chemistry Document No: C031450 GLP / GEP: Not required unpublished	N	BCS
KCP 9.1/22	Duncan P., Doran A.,	2004	Terrestrial field dissipation of diflufenican and its metabolites M&B 43625 and M&B 38181 at 4 Northern and 2 Southern European locations	N	BCS

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
	Livingstone K.		Generated by: Bayer CropScience GmbH, DEU Inveresk Research, Tranent, Scotland; Document No: C031887 GLP / GEP Yes unpublished		
KCP 9.1/23	Brumhard B.	2004	Determination of the storage stability of diflufenican and its metabolites M&B38181 and M&B43625 in soil from the dissipation study Generated by: Bayer CropScience AG, Monheim, DEU Document No: C031487 GLP / GEP Yes unpublished	N	BCS
KCP 9.1/24	Hardy I.A.J.	2004	Diflufenican: Kinetic modelling analysis of data from field soil dissipation studies conducted at ten locations in Europe Generated by: Battelle AgriFood Ltd., Ongar, UK; Bayer CropScience AG, DEU Document No: C031888 GLP / GEP: Not required Unpublished	N	BCS
KCP 9.1/25	Maycey P.A., Savage E.A.	1990	Herbicides: Diflufenican - Investigation of behaviour under field conditions after treatment with Fenikan, West Germany, 1987/ 89 Generated by: Rhone-Poulenc; Rhone-Poulenc Agriculture, Essex, England; Analytical Chemistry Department Document No: R007601 GLP / GEP: No unpublished	N	BCS
KCP 9.1/26	Cooper I., Hardy I.	2003	Kinetic evaluation of data from a diflufenican field dissipation study in Germany. Generated by: Batelle Agrifood Ltd, Ongar, UK;	N	BCS

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
			Bayer Crop Science, Lyon,FRA; Batelle Agrifood Ltd, Ongar, UK; Document No: C031449 GLP / GEP: Not required unpublished		
KCP 9.1/27	Brockelsby C.H., Maycey P.A., Savage E.A.	1990	Herbicides: Diflufenican - Determination of M&B38181 in soil after treatment with Fenikan, West Germany, 1987 / 89. Generated by: Rhone-Poulenc; Rhone-Poulenc Agriculture, Ongar, Essex, GBR; Analytical Chemistry Department Document No: R008141 GLP / GEP Yes unpublished	N	BCS
KCP 9.1/28	Imbroglini G.	1997	Long term field dissipation studydiflufenican Generated by: Inst. Sperimentale per la patologia vegetale, ITA ; Rhone-Poulenc AGRO Italy; Document No: C010715 GLP / GEP Yes unpublished	N	BCS
KCP 9.1/29	Maycey P.A., Savage E.A.	1991	Herbicides: Diflufenican - Behaviour in soil under field conditions: A five year study, United Kingdom, 1985 - 1990. Generated by: Rhone-Poulenc; Rhone-Poulenc Agriculture Ltd., Ongar, Essex, GBR; Analytical Chemistry Department Document No: R008167 GLP / GEP Yes unpublished	N	BCS
KCP	Parsons R.G.	1991	Herbicides: Diflufenican - Long term soil residue study: Methods used and effect on following rape and	N	BCS

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
9.1/30			beet crops U.K., 1985 - 90 Generated by: Rhone-Poulenc; Rhone-Poulenc Agriculture Ltd., Essex, U.K.; Aldhams Farm, Manningtree Document No: R008165 GLP / GEP Yes unpublished		
KCP 9.1/31	Giraud J.P., Plewa A.	1984	Diflufenican (MB 38544): Soil sorption study. Generated by: Rhone-Poulenc; Rhone-Poulenc Agrochimie, Lyon; Centre de Recherche de la Dargoire Document No: R006369 GLP / GEP: No Unpublished	N	BCS
KCP 9.1/32	Burr C.M.	2000	(14C)-M&B38181 adsoption to and from four soils Generated by: Aventis CropScience UK Limited, GBR; Aventis CropScience UK Limited, GBR; Document No: C010711 GLP / GEP Yes unpublished	N	BCS
KCP 9.1/33	Unsworth R., McGhee I.	2002	[14C]-M&B 43625: Adsorption / Desorption on Soil Generated by: Huntingdon Life Sciences Ltd.; Document No: C023990 GLP / GEP Yes unpublished	N	BCS
KCP 9.2/08	Hardy I.A.J.	2003	Predicted environmental concentrations in groundwater (PECgw) of diflufenican, M&B38181 and M&B43625 for the use of the formulation Fenikan using the FOCUS groundwater scenarios Generated by: Battelle AgriFood Ltd., Ongar, UK; BCS S.A., FRANCE; Environmental	N	BCS

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
			Chemistry Document No: C031460 GLP / GEP: Not required unpublished		
KCP 9.2/09	Stork A., Fuehr F.	1994	Verhalten von (Pyridin-2-14C) Diflufenican in einer Parabraunerde nach Vorauflaufspritzungen zu Winterweizen und Wintergerste - Abschlußbericht. Generated by: Rhone-Poulenc; Forschungszentrum Juelich GmbH, DEU; Institut fuer Radioagronomie Rhone-Poulenc Secteur Agro, Lyon, France; Document No: R008229 GLP / GEP Yes unpublished	N	BCS
KCP 9.2/10	Stork A., Fuehr F.	1994	The behaviour or (pyridine-2-14C)diflufenican in parabrown earth following pre-emergence application to winter wheat and winter barley, definitive report Generated by: Rhone-Poulenc; Forschungszentrum Juelich GmbH, DEU; Institut fuer Radioagronomie Rhone-Poulenc Secteur Agro, Lyon, France; Document No: C036280 GLP / GEP: No unpublished	N	BCS
KCP 9.2/11	Reeves G.L., Savage E.A.	1986	Diflufenican-14C: Hydrolysis in aqueous conditions at 22 degrees Celsius. Generated by: Rhone-Poulenc; May & Baker Ltd., GBR; Environmental Chemistry Document No: R008078 GLP / GEP: No (QA statement included) unpublished	N	BCS
KCP	Reeves G.L.,	1986	Diflufenican-14C: Hydrolysis in aqueous conditions at 50 degrees and 70 degrees Celsius.	N	BCS

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
9.2/12	Savage E.A.		Generated by: Rhone-Poulenc; May & Baker Ltd., England; Environmental Chemistry Document No: R008080 GLP / GEP: No (QA statement included) unpublished		
KCP 9.2/13	Simmonds M.B., Burr C.M.	1999	(14C)-M&B38181: Aqueous hydrolysis Generated by: Rhone-Poulenc; Rhone-Poulenc Agriculture Ltd., Ongar, UK; Document No: R015177 GLP / GEP Yes Unpublished	N	BCS
KCP 9.2/14	SimmondsM.B., Mills E.A.M	2002	(14C)-Diflufenican: Aqueous photolysis and quantum yield at pH7 Generated by: BCS S.A., FRA; Battelle-AgriFood Ltd., Essex, GBR; Document No: C026217 GLP / GEP Yes unpublished	N	BCS
KCP 9.2/15	Simmonds M.B., Mills E.A.M.	2003	(14C)-Diflufenican: Aqueous photolysis and quantum yield at pH7 (amendment) Generated by: BCS S.A., FRA; Environmental Chemistry, Lyon Battelle-AgriFood Ltd., Essex, GBR; Document No: C029716 GLP / GEP Yes unpublished	N	BCS
KCP 9.2/16	Buntain I.G.	2003	Diflufenican: Estimation of environmental photolytic half-life in water Model calculation according to Frank and Kloepffer Generated by: Battelle AgriFood Ltd., Essex, GBR; BCS S.A., FRA; Environmental Chmiestry, Lyon Document No: C030899	N	BCS

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
			GLP / GEP: Not required unpublished		
KCP 9.2/17	McGhee I.	2000	(14C)-M&B 38181: Photodegradation in water Generated by: Aventis CropScience UK Limited, GBR; Aventis CropScience UK Limited, GBR; Document No: C010713 GLP / GEP Yes unpublished	N	BCS
KCP 9.2/18	Lebertz H.	1989	Diflufenican: Biodegradability according to closed bottle test, (OECD guideline 301D for testing chemicals) Generated by: Rhone-Poulenc; Battelle Europe, Frankfurt; Rhone-Poulenc Agro GmbH, Kerpen, Germany; Document No: R003371 GLP / GEP: yes unpublished	N	BCS
KCP 9.2/19	Knoch E.	1996	Degradation and metabolism of diflufenican in water / sediment systems Generated by: Rhone-Poulenc; Rhone-Poulenc Secteur Agro; Analytical Chemistry ORS Institut Fresenius Chem.und Biolog. Lab. GmbH; Document No: R000436 GLP / GEP Yes unpublished	N	BCS
KCP 9.2/20	Hardy I.	2002	Kinetic evaluation of a water / sediment study with diflufenican using Topfit 2.0 Generated by: BCS S.A., FRANCE; Battelle AgriFood Ltd, UK; Document No: C023585 GLP / GEP: Not required	N	BCS

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
			unpublished		
KCP 9.2/21	Crowe A.	2003	Diflufenican: Degradability and fate in the water/sediment system Generated by: Huntingdon Life Sciences Ltd., Suffolk, GBR; Eye Research Centre Huntingdon Life Sciences Ltd., Suffolk, GBR; Eye Research Centre BCS; Document No: C031677 GLP / GEP Yes unpublished	N	BCS
KCP 9.2/22	Hardy I.	2003	Kinetic modelling evaluation of a diflufenican water sediment study. Generated by: Battelle AgriFood Ltd, Ongar, UK; Battelle AgriFood Ltd, Ongar, UK; BCS, Monheim, DEU; Document No: C031461 GLP / GEP: Not required unpublished	N	BCS
KCP 9.3/01	Maurer T.	2002	Estimation of the reaction with photochemically produced hydroxyl radicals in the atmosphere Diflufenican Code: AE F088657 Generated by: Aventis CropScience GmbH, DEU; Environmental Chemistry, Frankfurt Document No: C019306 GLP / GEP: Not required unpublished	N	BCS
KCP 9.3/02	Kubiak R.	1994	Investigation of the volatilization of 14Cdiflufenican formulated according to EXP30052 (RPA30052H) with a total amount of 21 g/l diflufenican from plant surfaces under laboratory conditions. Generated by: Rhone-Poulenc; SLFA, FB Phytomedizin, Neustadt, DEU; Rhone-Poulenc Secteur Agro, Lyon, France; Document No: R008194	N	BCS

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
			GLP / GEP Yes unpublished		
KCP 9.3/03	Jendrzejczak N.H., Turier G.P., Maestracci M.P.	1992	Soil surface volatility study of diflufenican formulated as EXP30052 (official German Ref.No. RPA30052H). Generated by: Rhone-Poulenc; Rhone-Poulenc Secteur Agro, Lyon, France; Analytical Department Document No: R008180 GLP / GEP Yes unpublished	N	BCS
KCP 9.3/04	Jendrzejczak N.H., Turier G.P., Maestracci M.P.	1992	Soil surface volatility study of diflufenican formulated as EXP04072 (official German Ref.No. RPA40720H). Generated by: Rhone-Poulenc; Rhone-Poulenc Secteur Agro, Lyon, France; Analytical Department Document No: R008178 GLP / GEP Yes unpublished	N	BCS
KCP 9.3/05	Buntain I.G.	2003	2,4-difluoroaniline (AE C522392 = M&B 40401) Estimation of degradation by photooxidation in air Model calculation according to Atkinson Generated by: BCS, Monheim, Germany; Battelle AgriFood Ltd, UK; Document No: C032943 GLP / GEP: Not required unpublished	N	BCS
KCP 9.2/23	Parsons R.G.	1999	Diflufenican: Residues in drainage sediment - Monitoring study Generated by: Rhone-Poulenc; Rhone-Poulenc Agriculture Ltd., Essex, U.K.; Rhone-Poulenc Secteur Agro; Document No: R006364	N	BCS

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
			GLP / GEP Yes unpublished		
KCP 9.1/34	Pangilinan, N. C.; Smith, D. M.	1994	Aerobic soil metabolism of [Phenyl-U-14C]FOE 5043 Miles Inc., Agriculture Division, Stilwell, KS, USA Bayer CropScience, Date: 1994-05-12 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.1/35	Pangilinan, N. C.; Smith, D. M..	1994	Aerobic soil metabolism of [Thiadiazole-2-14C]FOE 5043 Miles Inc., Agriculture Division, Stilwell, KS, USA Bayer CropScience, GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.1/36	Kelley, I. V.; Wood, S.; McKinney, M.	1995	Degradation of [Phenyl-UL-14C]FOE 5043 in three soil types Bayer Corporation, Stilwell, KS, USA Bayer CropScience, GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.1/37	Kasper, A. M.; Shadrick, B. A.	1995	Photolysis of [Phenyl-U-14C]FOE 5043 on sandy loam Bayer Corporation, Stilwell, KS, USA Bayer CropScience, Report No.: MR106247, GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.1/38	Hellpointner, E.	1995	Evolution of the microbial biomass in the biometer flask system (supportive to study no. F3042102 (MR106408), aerobic soil metabolism of FOE 5043) Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: PF4066, GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.1/39	Pangilinan, N. C.; Smith, D. M.	1994	Aerobic soil metabolism of [Phenyl-U-14C]FOE 5043 Miles Inc., Agriculture Division, Stilwell, KS, USA Bayer CropScience, Report No.: MR106408, GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.1/40	Pangilinan, N. C.; Smith, D. M.	1994	Aerobic soil metabolism of [Thiadiazole-2-14C]FOE 5043 Miles Inc., Agriculture Division, Stilwell, KS, USA Bayer CropScience,	N	Bayer CropScience

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
			Report No.: MR106420, GLP/GEP: yes, unpublished		
KCP 9.1/41	Kelley, I. V.; Wood, S.; McKinney, M..	1995	Degradation of [Phenyl-UL-14C]FOE 5043 in three soil types Bayer Corporation, Stilwell, KS, USA Bayer CropScience, Report No.: MR106664, GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.1/42	Hellpointner, E.	1996	Degradation of [phenyl-UL-14C]FOE 5043-sulfonic acid in three soils Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: 107515, GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.1/43	Schaefer, H.	1995	Calculation of DT-50 values of two metabolites of FOE 5043 in soil under aerobic conditions Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: MR-037/98, GLP/GEP: no, unpublished	N	Bayer CropScience
KCP 9.1/44	Sommer, H.	1995	Dissipation of FOE 5043 in soil under field conditions (France, Italy) Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: 107721, Report includes Trial Nos.: 40163/3 40164/1 40494/2 40495/0 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.1/45	Sommer, H.	1995	Dissipation of FOE 5043 in soil under field conditions (Germany) Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: 107722, Report includes Trial Nos.: 30499/9	N	Bayer CropScience

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
			30500/6 GLP/GEP: yes, unpublished		
KCP 9.1/46	Sommer, H.	1995	Dissipation of FOE 5043 in soil under field conditions (France) Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: 107723, Report includes Trial Nos.: 30254/6 30455/7 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.1/47	Sommer, H.	1995	Dissipation of FOE 5043 in soil under field conditions (Germany, France) Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: 107724, Report includes Trial Nos.: 30159/0 30162/0 30163/9 30164/7 30248/1 30250/3 30251/1 30253/8 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.1/48	Kelley, I. V.; Wood, S.	1992	Adsorption/desorption of FOE 5043 to soil - Addendum to Miles report no. 103903 - Adsorption/desorption of FOE 5043 to soil Miles Inc., Agriculture Division, Stilwell, KS, USA Bayer CropScience, Report No.: MR103903, GEP: yes, unpublished	N	Bayer CropScience
KCP 9.1/49	Christensen, K. P.; Yen, P. Y.	1994	FOE 5043 - Determination of the adsorption and desorption properties in Canadian soils Springborn Laboratories, Inc., Wareham, MA, USA Bayer CropScience, Report No.: MR106578,	N	Bayer CropScience

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
			GLP/GEP: yes, unpublished		
KCP 9.1/50	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 EPL Bio-Analytical Service, Inc., Harristown, IL, USA Bayer CropScience, Report No.: MR106598, GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.1/51	Kelley, I. V.; Wood, S.	1993	Leaching of aged FOE 5043 through soil columns Miles Inc., Agriculture Division, Stilwell, KS, USA Bayer CropScience, Report No.: MR105018, GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.1/52	Kelley, I. V.; Wood, S.	1993	Leaching of aged FOE 5043 through soil columns Miles Inc., Agriculture Division, Stilwell, KS, USA Bayer CropScience, Report No.: MR105018, GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.1/53	Hellpointner, E.	1996	Lysimeter study on the translocation of FOE 5043 into the subsoil after use as pre-emergence herbicide in a maize/winter wheat crop rotation Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: 107688, GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.1/54	Hellpointner, E.	1995	Lysimeter study on the translocation of FOE 5043 into the underground after 2-year application as pre-emergence herbicide in corn Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: 107728, GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.1/55	Hellpointner, E.	1995	Lysimeter study on the translocation of FOE 5043 into the underground after 2-year application as pre-emergence herbicide in corn Bayer AG, Leverkusen, Germany Bayer CropScience,	N	Bayer CropScience

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
			Report No.: PF4024, GLP/GEP: yes, unpublished		
KCP 9.1/56	Hellpointner, E.	1995	Lysimeter study on the translocation of FOE 5043 into the underground after the use as pre-emergence herbicide in a corn/winter wheat crop rotation Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: PF4025, GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.1/57	Hellpointner, E..	1997	Lysimeter study on the translocation of FOE 5043 into the subsoil after 2-year use as pre-emergence herbicide in corn Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: PF4188, GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.2/24	Kasper, A. M.; Shadrick, B. A.	1995	Aqueous photolysis of [Phenyl-U-14C]FOE 5043 Bayer Corporation, Stilwell, KS, USA Bayer CropScience, Report No.: MR106246, GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.2/25	Hellpointner, E.	1993	Determination of the quantum yield and assessment of the environmental half-life of the direct photodegradation of FOE 5043 in water Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: PF3919, GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.2/26	Pangilinan, N. C.; Smith, D. M.	1995	Anaerobic aquatic metabolism of [Thiadiazole-2-14C]FOE 5043 Miles Inc., Agriculture Division, Stilwell, KS, USA Bayer CropScience, Report No.: MR106440, GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.2/27	Kelley, I. V.; Wood, S.; McKinney, M.	1995	Degradability and fate of [Phenyl-UL-14C]FOE 5043 in two sediment/water systems Bayer Corporation, Stilwell, KS, USA Bayer CropScience,	N	Bayer CropScience

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
			Report No.: MR106928, GLP/GEP: yes, unpublished		
KCP 9.2/28	Halarnkar, P. P.; Irwin, D. W.	1997	Aerobic aquatic metabolism of [Thiadiazole-2-14C]FOE 5043 in two water/sediment systems Bayer Corporation, Stilwell, KS, USA Bayer CropScience, Report No.: 107822, GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.3/06	Hellpointner, E.	1995	Determination of the volatilisation behavior of FOE 5043 (60 WG) in a field trial Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: 107281, GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 9.3/07	Hellpointner, E.	1995	Calculation of the chemical lifetime of thiafluamide (FOE 5043) in the troposphere Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: PF4069, GLP/GEP: no, unpublished	N	Bayer CropScience

Appendix 2 Detailed evaluation of the new Annex II studies

A 2.1 Study 1

Reference:	Data point
Report	Title, author(s), year, report No, document No, Authority registration No
Guideline(s):	Yes/No (If yes, give guidelines; If no, give justification, e.g., " no guidelines available" or " methods used comparable to guideline(s) xxx")
Deviations:	Yes/No (If yes, describe deviations from test guidelines)
GLP:	Yes/No (If no, give justification, e.g., state that GLP was not compulsory at the time the study was performed)
Acceptability:	Yes/No/Supplementary

Materials and methods

Results and discussions

Conclusion

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