FINAL REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: SHA 2619 A

Product name: KONARK

Chemical active substances:

Flufenacet, 60 g/L

Pendimethalin, 300 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

Submission date: March 2021

MS Finalisation date: March 2022; May 2023

Version history

When	What
March 2021	Original Sharda submission
November 2021	Applicant Update
March 2022	Draft assessment prepared by zRMS
May 2023	Aplicant update due to the comments made by German and Slovenian Authorities – final version of the RR

Table of Contents

8 Fate and behaviour in the environment (KCP 9)

8.1 Critical GAP and overall conclusions

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

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			PHI (days)	Remarks: e.g. g safener/ synergist per ha	**Conclusion**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	CEU	**Winter wheat**	F	Broadleaved and grass weeds	Foliar Spray	Pre emergence BBCH 00-09	a) 1 b) 1	NA	a) 4 b) 4	a) 0.24 flufenacet + 1.2 pendimethanil b) 0.24 flufenacet + 1.2 pendimethanil	200-400	-	Weeds at early stages	A
2	CEU	**Winter wheat**	F	Broadleaved and grass weeds	Foliar Spray	Post emergence BBCH 11-25	a) 1 b) 1	NA	a) 4 b) 4	a) 0.24 flufenacet + 1.2 pendimethanil b) 0.24 flufenacet + 1.2 pendimethanil	200-400	-	Weeds at early stages	A
3	CEU	**Winter barley**	F	Broadleaved and grass weeds	Foliar Spray	Pre emergence BBCH 00-09	a) 1 b) 1	NA	a) 4 b) 4	a) 0.24 flufenacet + 1.2 pendimethanil b) 0.24 flufenacet + 1.2 pendimethanil	200-400	-	Weeds at early stages	A

4	CEU	**Winter barley**	F	Broadleaved and grass weeds	Foliar Spray	Post emergence BBCH 11-25	a) 1 b) 1	NA	a) 4 b) 4	a) 0.24 flufenacet + 1.2 pendimethanil b) 0.24 flufenacet + 1.2 pendimethanil	200-400	-	Weeds at early stages	A
5	CEU	**Winter rye**	F	Broadleaved and grass weeds	Foliar Spray	Pre emergence BBCH 00-09	a) 1 b) 1	NA	a) 4 b) 4	a) 0.24 flufenacet + 1.2 pendimethanil b) 0.24 flufenacet + 1.2 pendimethanil	200-400	-	Weeds at early stages	A
6	CEU	**Winter rye**	F	Broadleaved and grass weeds	Foliar Spray	Post emergence BBCH 11-25	a) 1 b) 1	NA	a) 4 b) 4	a) 0.24 flufenacet + 1.2 pendimethanil b) 0.24 flufenacet + 1.2 pendimethanil	200-400	-	Weeds at early stages	A
7	CEU	**Triticale**	F	Broadleaved and grass weeds	Foliar Spray	Pre emergence BBCH 00-09	a) 1 b) 1	NA	a) 4 b) 4	a) 0.24 flufenacet + 1.2 pendimethanil b) 0.24 flufenacet + 1.2 pendimethanil	200-400	-	Weeds at early stages	A
8	CEU	**Triticale**	F	Broadleaved and grass weeds	Foliar Spray	Post emergence BBCH 11-25	a) 1 b) 1	NA	a) 4 b) 4	a) 0.24 flufenacet + 1.2 pendimethanil b) 0.24 flufenacet + 1.2 pendimethanil	200-400	-	Weeds at early stages	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

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

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			PHI (days)	Remarks: e.g. g safener/ synergist per ha
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
1	Northern and Southern European Countries	Corn	F	Annual grass weeds	Spray application with standard field sprayers	Pre-emergence	1	-	0.120 – 0.300	0.48 – 0.60	200 - 400	Pre-emergence	-
2	Southern European Countries	Soybean, Sunflower	F	Annual grass weeds	Spray application with standard field sprayers	Pre-emergence	1	-	0.120 – 0.300	0.48 – 0.60	200 - 400	Pre-emergence	-
3	Northern European Countries	Winter cereals (wheat, rye, barley, triticale)	F	Annual grass weeds	Spray application with standard field sprayers	Early post autumn at the 2nd leaf stage of the grass weeds	1	-	0.030 – 0.120	0.12 – 0.24	200 - 400	2nd leaf stage of the grass weeds	-

* 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 8.1-3: Assessed (critical) uses during approval of Pendimethalin 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: devel-opmental 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)	L product/ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
1	AT, BE, CZ, DK, DE, GR, IT, IE, LU, PT, SI, ES, UK	Wheat (repre-sents small grain cereals)	F	Broadleaved weeds and grasses	Spray	pre- or post-em (BBCH 00-29) autumn	1	-	a) 3.5 b) 3.5	1593	100 – 400	-	
2	AT, BE, CZ, DK, ET, DE, GR, IT, IE, LV, LT, LU, PO, PT, SI, ES, UK	Carrot	F	Broadleaved weeds and grasses	Spray	pre- or post-em (BBCH 00-14)	1	-	a) 3.5 b) 3.5	1593	100 – 600	42	
3	DE, SI	Carrot	F	Broadleaved weeds and grasses	Spray	pre- + post-em (BBCH 12-13)	2	14 – 35	a) 1.75 b) 3.5	796 + 796	200 – 400	42	Split application: 1.75 pre + 1.75 post at BBCH 12-13
4	DE, SI	Green bean	F	Broadleaved weeds and grasses	Spray	pre-em	1	-	a) 3.5 b) 3.5	1593	200 – 400	-	
5	AT, CZ, ET,DE, IT, LV, LU, PT, SI	Dry bean	F	Broadleaved weeds and grasses	Spray	pre- or post-em (BBCH 00-13)	1	-	a) 3.5 b) 3.5	1593	200 - 600	-	
6	AT, DK, DE	Green pea	F	Broadleaved weeds and grasses	Spray	pre- or post-em (BBCH 00-13)	1	-	a) Pre: 3.0 Post: 3.5 b) Pre: 3.0 Post: 3.5	Pre: 1365 Post: 1593	200 - 400	56	

7	DK	Green pea	F	Broadleaved weeds and grasses	Spray	BBCH 12 + BBCH 14	2	*	a) 1.0 b) 2.0	455	200 – 400	56	Total per crop/season: 910 g as/ha *In the current registration of this product in Denmark, no interval is mentioned
8	AT, BE, BG, CZ, DK, ET, DE, GR, IT, IE, LV, LT, LU, PO, PT, ES, UK	Dry pea	F	Broadleaved weeds and grasses	Spray	Pre-sowing, pre-em or post-em (BBCH 00-13)	1	-	a) 3.5 b) 3.5	1593	100 – 600	56	
9	DK	Dry pea	F	Broadleaved weeds and grasses	Spray	BBCH 12 + BBCH 14	2	*	a) 1.0 b) 2.0	455	200 - 400	56	Total per crop/season: 910 g as/ha *In the current registration of this product in Denmark, no interval is mentioned
10	All zones	Winter cereals (winter barley, winter wheat, winter rye and triticale)	F	Mono/ dicot annual weeds	Broad	BBCH 00-14 (sept-nov)	a) 1 b) 1	-	a) 4.0 b) 4.0	1600	200	-	The PHI is covered by the time remaining between application and harvest.

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

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

8.2 Metabolites considered in the assessment

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

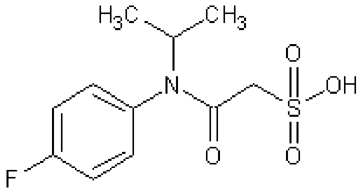
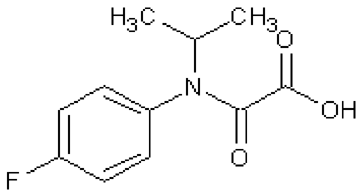
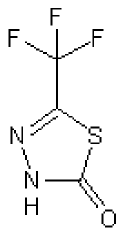
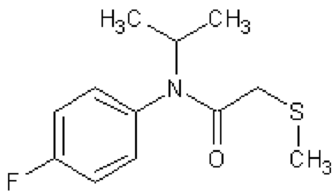
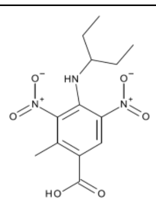
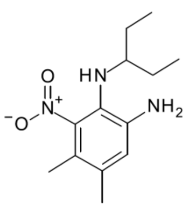
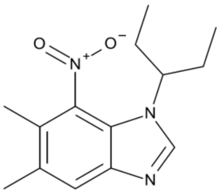
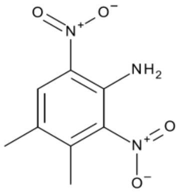
Metabolite	Molar mass	Chemical structure	Maximum observed oc-curence in compartements	Exposue assessment re-quired due to
FOE sulfonic acid (M2)	275.30		Soil: 26.3%	PEC_{soil} PEC_{gw}: leaching potential to groundwater
FOE oxalate (M1)	225.22		Soil: 15.6%	PEC_{soil} PEC_{gw}: leaching potential to groundwater
Thiadone (M9)	170.11		Water: 82% Sediment: <10%	$PEC_{sw/sed}$
FOE Methyl-sulfide (M5)	241.33		Water: 8% Sediment: 3.4%	$PEC_{sw/sed}$

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

Metabolite	Molar mass	Chemical structure	Maximum observed oc-curence in compartements	Exposue assessment required due to
M455H001	311.1		Soil: 6.9 % Water/sediment: 0.00001 %	PEC_{gw} / PEC_{soil} / $PEC_{sw/sed}$
P48 (M455H033)	251.3		Soil: 25.9 % Water/sediment: 12.1%	PEC_{gw} / PEC_{soil} / $PEC_{sw/sed}$

Metabolite	**Molar mass**	**Chemical structure**	**Maximum observed oc-curence in compartements**	**Exposue assessment required due to**
P36 (M455H029; M12)	261.3		Soil: 0.00001% Water/sediment: 23.4%	$PEC_{sw/sed}$
2,6-dinitro-3,4-dimethylaniline (aqueous photolysis metabolite)	211.2		Soil: 0.00001% Water/sediment: 14.2 %	$PEC_{sw/sed}$

8.3 Rate of degradation in soil (KCP 9.1.1)

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

8.3.1 Aerobic degradation in soil (KCP 9.1.1.1)

8.3.1.1 Flufenacet and its metabolites

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

Flufenacet, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH**	**T(ºC)**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa**	**Chi2 (%)**	**Kinetic model**	**Evaluated on EU level y Reference**
BBA 2.2	Loamy sand	6.2	20	40	39	130	24		1.5 order	DAR 1997 LoEP 7469/VI/98-Final – 03/07/2003 Flufenacet BD-C addendum fate, 2003-01
Laacherhof	Silt loam	7.3	20	40	15	52	13		1.5 order	
Höfchen i.Tal	Silt loam	5.8	20	40	27	92	14		First order	
Howe	Sandy loam	6.2	21	75	34-64 (mean 48)	-	-		First order	
Geometric mean (n=3)							16.5			
pH-dependency: y/n										

Table 8.3-2: Summary of aerobic degradation rates for FOE sulfonic acid (M2) - laboratory studies

FOE sulfonic acid (M2), Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH**	**T (ºC)**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa**	**Chi2 (%)**	**Kinetic model**	**Evaluated on EU level y Reference**
BBA 2.1	Sand	5.3	20	40	270		189			DAR 1997 LoEP 7469/VI/98-Final – 03/07/2003
BBA 2.2	Loamy sand	6.3	20	40	189		119			

FOE sulfonic acid (M2), Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH**	**T (ºC)**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa**	**Chi2 (%)**	**Kinetic model**	**Evaluated on EU level y Refer-ence**
Laacherhof	Silt loam	7.3	20	40	247		123			Flufenacet BD-C addendum fate, 2003-01
Geometric mean (n=3)							140.4			
pH-dependency: y/n										

Table 8.3-3: Summary of aerobic degradation rates for FOE oxalate (M1) - laboratory studies

FOE oxalate (M1), Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH**	**T (ºC)**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa**	**Chi2 (%)**	**Kinetic model**	**Evaluated on EU level y Refer-ence**
BBA 2.2	Loamy sand	6.2	20	40	5		4			DAR 1997 LoEP 7469/VI/98-Final – 03/07/2003 Flufenacet BD-C addendum fate, 2003-01
Laacherhof	Silt loam	7.3	20	40	17		10			
Höfchen i.Tal	Silt loam	5.8	20	40	12		7			
Geometric mean (n=3)							6.6			
pH-dependency: y/n										

8.3.1.2 Pendimethalin and its metabolites

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

Pendimethalin, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH (water)**	**t.oC**	**MWHC %**	**DT50 (d)***	**DT90 (d)***	**DT50 (d) 20°C pF2/10kPa**	**Chi2 (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
-	Sandy loam (USDA, North Carolina)	5.5	20	40 – 50	166.8	554	146	2.5	SFO	EFSA Journal 2016;14(3):4420

Pendimethalin, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH (water)**	**t.oC**	**MWHC %**	**DT50 (d)***	**DT90 (d)***	**DT50 (d) 20°C pF2/10kPa**	**Chi2 (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
-	Sandy loam	7.5	20	50	99.8	331.5	97	1.7	SFO	
-	Loamy sand	5.7	20	40	41	404.5**	201.1***	1.3	DFOP	
-	Silt loam (USDA, Louisiana)	5.1	20	40 – 50	301.6	1001.5	269.9	2.2	SFO	
-	Clay loam (USDA, Mississippi)	5.4	20	40 - 50	301.7	1002.4	261.8	1.8	SFO	
Geometric mean (n=5)							182.28***			
pH-dependency:							No			

*For the purpose of the application of Guidance on Information Requirements and Chemical Safety Assessment. Chapter R11: PBT/vPvB assessment (ECHA, November 2014) the range of half-lives in soil normalized to 12 °C is: 212–641 d.
**For a half-life trigger at 20 °C pseudo SFO DT50 (DT90/3.32) = 121.69 d
***Slow phase DFOP used for modelling; RMS calculated a slow phase DFOP DT50 of 177.7 days by exclusion of the last data point. The worst case value and corresponding geometric mean of the applicant is used for modelling.

Table 8.3-5: Summary of aerobic degradation rates for M455H001 - laboratory studies

M455H001, Laboratory studies, Dark aerobic conditions											
Soil name	**Soil type**	**pH (water)**	**t.oC**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**f. f. k_f / k_{dp}**	**DT50 (d) 20°C pF2/10kPa***	**Chi2 (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
-	Sandy loam	8.0	20	40	34.5	114.4	-	24.3	4.3	SFO	EFSA Journal 2016;14(3):4420
-	Loamy sand	6.5	20	40	11.2	100.7	-	31.2**	2.3	HS	
-	Loamy sand	6.6	20	40	37.9	336.3	-	47.9**	4.3	HS	
-	Sandy loam	7.5	20	50	72.2	239.9	0.231	70.2	11.3	SFO	
Geometric mean (n=4)								39.96**			
Arithmetic mean							0.231				
pH-dependency:							No				

*Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7
**Slow phase HS used as modelling endpoint

Table 8.3-6: Summary of aerobic degradation rates for M455H033 - laboratory studies

M455H033, Laboratory studies, Dark aerobic conditions											
Soil name	**Soil type**	**pH ($CaCl_2$)**	**t.oC**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**f. f. k_f / k_{dp}**	**DT50 (d) 20°C pF2/10kPa***	**Chi2 (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
-	Sandy loam	6.2	20	40	0.36	5.9	-	1.8**	2.5	FOMC	EFSA Journal 2016;14(3):4420
-	Loamy sand	7.3	20	40	1.46	12.7	-	3.8**	2.6	FOMC	
-	Loamy sand	7.4	20	40	0.48	4.9	-	1.5**	2.0	FOMC	
Geometric mean (n=3)								2.2 (0.09d***)			
Arithmetic mean							-****				
pH-dependency:							No				

*Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7
**Back-calculated: DT50 = DT90/3.32
***For modelling worst case anaerobic DT50 of 3.6 days is used
****For modelling conservative value 1 is used

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

8.3.2-1 Flufenacet and metabolites

Studies not submitted.

Justification from the DAR 1997: *"Due to the proposed use patterns (application pre or early post emergence herbicide in cereals) it can be justified that FOE 5043 will not be exposed to anaerobic conditions. Therefore, a study on the anaerobic rate of degradation is considered as being not relevant."*

8.3.2-2 Pendimethalin and metabolites

Table 8.3-7: Summary of anaerobic degradation rates for Pendimethalin - laboratory studies

Pendimethalin, Laboratory studies, Dark anaerobic conditions										
Soil name	**Soil type**	**pH ($CaCl_2$)**	**t.oC**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa***	**Chi2 (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
-	Sandy loam	7.0	20	40 - 100	11.7	38.8	11.7	3.8	HS	EFSA Journal 2016;14(3):4420
Geomean (n=1)							11.7			

* Normalised using a Q10 of 2.58

Table 8.3-7: Summary of anaerobic degradation rates for Pendimethalin metabolite M455H033 - laboratory studies

M455H033, Laboratory studies, Dark anaerobic conditions										
Soil name	**Soil type**	**pH ($CaCl_2$)**	**t.oC**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa***	**Chi2 (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
-	Sandy loam	7.4	20	40 - 100	0.4	7.4	3.6	3.6	DFOP	EFSA Journal 2016;14(3):4420
Geomean (n=1)							3.6			

* Normalised using a Q10 of 2.58

8.4 Field studies (KCP 9.1.1.2)

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

8.4.1.1 Flufenacet and its metabolites

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

Four studies in Germany, France (North and South) and Italy, covering 16 soils under spring and winter condition and different application rate were done.

There is no data on the relevant metabolites as not detected above the LOD (10 µg/kg).

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

Flufenacet, Field studies – Triggering endpoints									
Soil type	**Location**	**pH**	**Depth (cm)**	**DissT50 (d) actual**	**DT90 (d) actual**	**Kinetic parameters**	**St. (x^2)**	**Method of calculation**	**Evaluated on EU level y Reference**
Heavy loamy silt	Burscheid	6.5		38	125			1st order	DAR 1997 LoEP 7469/VI/98-Final – 03/07/2003
Loamy sand	Monheim	6.7		43	144				
Weak loamy silt	Saussay-la Cam-pagne	7.4		16	52				
Loamy silt	Fresne-L'Archeveque	6.6		13	43				
Silty sand	Breitenfelde	6.2		31	101				
Heavy sandy loam	Kirchlauter	7.1		53	177				
Loamy sand	Monheim	6.7		54	178				
Heavy loamy sand	Burscheid	6.5		15	51				

Flufenacet, Field studies – Triggering endpoints									
Soil type	**Location**	**pH**	**Depth (cm)**	**DissT50 (d) actual**	**DT90 (d) actual**	**Kinetic parameters**	**St. (x^2)**	**Method of calculation**	**Evaluated on EU level y Reference**
Loamy silt	Fresne-L'Archeveque	6.0		16	177			√1st order	
Loamy silt	Fresne-L'Archeveque	5.2		38	198			1.5th order	
Sandy loamy silt	Laudun	7.6		30	98			1st order	
Sandy loamy silt	St. Etienne du Gres	7.7		34	112				
Silty clay loam	Laudun	7.7		36	120				
Silty loam	St. Etienne du Gres	7.7		42	139				
Sandy loamy silt	Ravena	7.8		38	126				
Loamy clay	S. Romualdo	7.8		48	158				
Maximum (n=16)				54	198				

8.4.1.2 Pendimethalin and its metabolites

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

Pendimethalin, Field studies								
Soil type	**Location**	**pH ($CaCl_2$)**	**Depth (cm)**	**DissT50 (d) actual**	**DT90 (d) actual**	**St. (x^2)**	**Method of calculation**	**Evaluated on EU level y/n/ Reference**
Clay	Thermi, Greece (CS)	7.6	30	187.0*	621.3	20.8	SFO	EFSA Journal 2016;14(3):4420
Clay	Thermi, Greece (EC)	7.6	30	175.4	582.5	26.3		
Silty clay loam	Longara, Italy (CS)	7.2	30	108.9	361.6	24.6		
Silty clay loam	Longara, Italy (EC)	7.2	30	77.0	255.7	16.8		
Clay loam	Emmeloord, NL (CS)	7.0	30	54.2	1536	12.1		
Clay loam	Emmeloord, NL (SC)	7.0	30	65.6	476.8	8.9		
Clay loam	Idice, Italy (CS)	7.0	30	147.9	491.4	26.5		
Clay loam	Idice, Italy (EC)	7.0	30	117.3	389.7	18.7		
Loamy sand	Brunne,	4.9	40	166.2	552.1	8.2		

Pendimethalin, Field studies								
Soil type	**Location**	**pH ($CaCl_2$)**	**Depth (cm)**	**DissT50 (d) actual**	**DT90 (d) actual**	**St. (x^2)**	**Method of calculation**	**Evaluated on EU level y/n/ Reference**
	Germany (CS)							
Silty clay loam	Sermaises, France (WG)	6.8	30	56.2	186.7	15.8	HS	
Sandy clay loam	Melbourne, UK (WG)	6.6	30	59.1	196.3	10.1	DFOP	
Clay loam	Idice, Italy (WG)	7.5	30	87.1	289.2	29.8	SFO	
Clay loam	Barry d'Islemade, France (WG)	6.4	30	87.5	290.7	38.2		
Clay silt	Goch-Nierswalde, Germany (CS)	6.1-6.2	50	120.1	398.9	14.4		
Silty sand	Lentzke, Germany (CS)	5.9	50	43.3	144.0	10.0		
Sand	Utrera, Spain (CS)	6.6-7.4	50	39.8	132.3	5.7		
Loamy sand	Dugliolo, Italy (CS)	8.4-8.5	50	99.6	330.8	28.6		
pH dependence:				No				

*Normalization to derive modelling kinetic endpoints are meaningless when one of the processes involved in the dissipation is volatilization, therefore EFSA removed normalized endpoints from the LoEP and maximum DissT50 is used for PECsoil calculations.

Table 8.4-3: Summary of aerobic degradation rates for M455H001 - field studies

M455H001, Field studies										
Soil type	**Location**	**pH ($CaCl_2$)**	**Depth (cm)**	**DissT50 (d) actual**	**DT90 (d) actual**	**f.f.**	**DT50 (d) norm.***	**St. (x^2)**	**Method of calc.**	**Evaluated on EU level y/n/ Reference**
Loamy sand	Brunne, Germany	4.2	40	117.7	391	-	-*	11.1	SFO	EFSA Journal 2016;14(3):4420

*Normalization to derive modelling kinetic endpoints are meaningless when one of the processes involved in the dissipation is volatilization. Whereas no direct volatilization is expected for metabolite M455H001 therefore, EFSA removed normalized end point because are correlated with pendimethalin endpoints that are unreliable due to volatilization.

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

8.4.2.1 Flufenacet

According to the Review Report of flufenacet (7469/VI/98-Final – 03/07/2003), data is not relevant.

8.4.2.2 Pendimethalin

Soil accumulation and plateau concentration for Pendimethalin	Plateau concentration of 0.087 mg/kg reached after 5 years (based on calculation)

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 substances.

8.5.1 Flufenacet and its metabolites

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

Flufenacet							
Soil name	**Soil type**	**OC (%)**	**pH (-)**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Evaluated on EU level y Reference**
Stanley	Silt loam	1.68	5.9		190	0.84	DAR 1997 LoEP 7469/VI/98-Final – 03/07/2003
Hagerstown	Clay loam	1.28	6.4		211	0.90	
Howe	Loamy sand	0.23	6.4		696	0.87	
Vero Beach	Sand	0.17	5.0		588	0.98	
Monheim	Sandy loam	1.4	6.4		354	0.89	
Harriston	Loam	4.3	7.1		113	0.96	
St. George	Silt loam	2.8	7.3		144	0.86	
Geometric mean (n=5)					187.4 (for OC > 0.23%)	-	
Arithmetic mean (n=5)					-	0.89 (for OC > 0.23%)	
pH-dependency n							

Table 8.5-2: Summary of soil adsorption/desorption for FOE sulfonic acid (M2)

FOE sulfonic acid (M2)							
Soil Name	**Soil Type**	**OC (%)**	**pH (-)**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Evaluated on EU level y Reference**
Vero Beach	Sand	0.27	5.8		19	0.86	DAR 1997 LoEP 7469/VI/98-Final –
Howe	Sandy loam	0.75	6.3		15	1.00	
Champaign	Silty clay loam	2.13	6.6		10	0.93	

FOE sulfonic acid (M2)							
Soil Name	**Soil Type**	**OC (%)**	**pH (-)**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Evaluated on EU level y Reference**
Stilwell	Silty clay	1.21	6.0		6	1.18	03/07/2003
Geometric mean (n=3)					9.7 (for OC > 0.27%)	-	
Arithmetic mean (n=3)					-	1.04 (for OC > 0.27%)	
pH-dependency n							

Table 8.5-3: Summary of soil adsorption/desorption for FOE oxalate (M1)

FOE oxalate (M1)							
Soil Name	**Soil Type**	**OC (%)**	**pH (-)**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Evaluated on EU level y Reference**
Vero Beach	Sand	0.27	5.8		23	1.42	DAR 1997 LoEP 7469/VI/98-Final – 03/07/2003
Howe	Sandy loam	0.75	6.3		13	0.93	
Champaign	Silty clay loam	2.13	6.6		7	0.82	
Stilwell	Silty clay	1.21	6.0		13	0.98	
Geometric mean (n=3)					10.6 (for OC > 0.27%)	-	
Arithmetic mean (n=3)					-	0.91 (for OC > 0.27%)	
pH-dependency n							

8.5.2 Pendimethalin and its metabolites

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

Pendimethalin									
Soil name	**Soil type**	**OC (%)**	**pH ($CaCl_2$)**	**Kd (mL/g)**	**Kdoc (mL/g)**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
Borstel	Loamy sand	1.29	5.4	228.5	17710	159.7	12380	0.919	EFSA Journal 2016;14(3):4420
Rendzina Soest	Silty clay loam	4.10	7.3	420	10241	366.6	8942	0.980	
LUFA 2.2	Loamy sand	2.17	5.7	362.5	16699	273.4	12599	0.943	
Parabraunerde	Silt loam	1.26	6.9	169	13414	123.7	9814	0.941	

Pendimethalin									
Soil name	**Soil type**	**OC (%)**	**pH ($CaCl_2$)**	**Kd (mL/g)**	**Kdoc (mL/g)**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
Soest									
LUFA 2.1	Sand	0.60	5.6	120.74	20124	113.7	18954	0.993	
LUFA 2.3	Sandy loam	0.99	6.7	150.05	15156	110.5	11160	0.958	
Bruch West	Sandy loam	1.63	7.3	226.64	13905	202.8	12442	0.961	
Nierswalder Wildacker	Silt loam	1.85	5.7	677.16	36604	510.2	27578	0.960	
La Gironda	Sandy clay loam	1.22	7.4	165.51	13566	125.1	10258	0.931	
Geomean (n=9)							12943	-	
Arithmetic mean (n=9)							-	0.954	
pH-dependency							No		

Table 8.5-5: Summary of soil adsorption/desorption for M455H001

M455H001									
Soil Name	**Soil Type**	**OC (%)**	**pH ($CaCl_2$)**	**Kd (mL/g)**	**Kdoc (mL/g)**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
LUFA 2.1	Sand	0.60	5.6	1.4 - 2.2	232-366	1.896	316.0	1.01	EFSA Journal 2016;14(3):4420
LUFA 2.3	Sandy loam	1.85	5.7	5.4 - 6.7	294-362	4.840	261.6	0.97	
Li 10	Loamy sand	0.97	6.2	4.3 - 5.8	441-593	3.191	328.9	0.93	
La Gironda	Sandy clay loam	1.22	7.4	3.7 - 4.6	305-373	3.246	266.1	0.96	
Brunch West	Sandy loam	1.36	7.4	0.8 - 1.8	59.7-134	1.041	76.6	0.96	
Geomean (n=5)							223.2	-	
Arithmetic mean (n=5)							-	0.966	
pH-dependency							No		

Table 8.5-6: Summary of soil adsorption/desorption for M455H033

M455H033									
Soil Name	**Soil Type**	**OC (%)**	**pH ($CaCl_2$)**	**Kd (mL/g)**	**Kdoc (mL/g)**	**Kf* (mL/g)**	**Kfoc* (mL/g)**	**1/n* (-)**	**Evaluated on EU level y/n/ Reference**
LUFA 2.1	Sand	0.60	5.6	18	2921	-	-	-	EFSA Journal

M455H033									
Soil Name	**Soil Type**	**OC (%)**	**pH ($CaCl_2$)**	**Kd (mL/g)**	**Kdoc (mL/g)**	**Kf* (mL/g)**	**Kfoc* (mL/g)**	**1/n* (-)**	**Evaluated on EU level y/n/ Reference**
Brunch West	Sandy loam	1.36	7.4	23	1669	-	-	-	2016;14(3):4420 -
-	Silt loam	1.85	5.7	106	5747	-	-	-	
Li 10	Li 10	0.97	6.2	37	3861	-	-	-	
La Gironda	La Gironda	1.22	7.4	36	2974	-	-	-	
Geomean (n=5)					3173.2	-	-	1 (default)	
pH-dependency							No		

*Could not be determined due to transformation of M455H033

8.5.3 Column leaching (KCP 9.1.2.1)

8.5.3.1 Flufenacet

The study was done using two soils BBA 2.1 in Germany and Howe in The USA, in the table below only are represented maximum values from the two soils.

Table 8.5.7 Results from DAR 1997 on Aged residue column leaching study

Endpoint			
Column leaching	No data provided, not required		
Aged residues leaching	2 sand soils (pH 6-6.2, OC: 0.26-0.32 %) (BBA 2.1 and Howe)		
	Radioactivity in leachates: Incubation:	30 days	90days
	Total:	<30%	<44%
	Parent:	<16%	<0.3%
	FOE oxalate (M1)	<7%	<27%
	FOE sulfonic acid (M2)	<10.2%	<11%
	FOE thioglycolate sulfoxide (M4))	<6.2%	<3.6%
	Others:	<1.6%	<2.9%

8.5.3.2 Pendimethalin

No data was submitted during the EU peer review of Pendimethalin renewal as considered as not required.

Data from review report (SANCO 7477/VI/98-final 13th January 2003): Mobility was very low (less than 2% of applied dose).

8.5.4 Lysimeter studies (KCP 9.1.2.2)

8.5.4.1 Flufenacet and its metabolites

Two studies were done in corn-corn and corn-winter wheat both in pre-emergence, the application rate was 480 g a.i/ha each year for corn-corn study and 480 g a.i./ha and 180g a.i./ha for first and second year respectively in the corn-wheat study. After two years application the concentrations found are shown in the table below (LoEP 7469/VI/98-Final – 03/07/2003).

Table 8.5.8: Lysimeter/field leaching endpoints for Flufenacet and its metabolites

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

8.5.4.2 Pendimethalin and its metabolites

No data was submitted during the EU peer review of Pendimethalin renewal as considered as not required.

Data from review report (SANCO 7477/VI/98-final 13th January 2003): Pendimethalin was not observed in the leachate.

8.5.5 Field leaching studies (KCP 9.1.2.3)

Please refer to point 8.5.4.

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

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

8.6.1 Flufenacet and its metabolites

In table 8.6-1 are given the maximum values (fluorophenyl label) from the two water/sediment systems.

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

Flufenacet Distribution (max. water/sediment 34.2% in sediment after 30 days)										
Water/sediment system	**pH water/ sed.**	**DegT50 whole syst. (d)**	**DegT90 whole syst. (d)**	**Kinetic, Fit**	**DissT50 water (d)**	**DissT90 water (d)**	**Kinetic, Fit**	**DissT50 sed. (d)**	**Kinetic, Fit**	**Evaluated on EU level y Reference**
NESA	7.5/7.9	84.6	281		61.7	205	1st order			DAR 1997 LoEP 7489/VI/98 Final 03/07/2003
BRP	7.3/7.8	76.4	254		46.3	154	1st order			
Geometric mean (n=2)		80.4	267.2		53.5	177.7				

Table 8.6-2: Summary of Flufenacet observed metabolites

Thiadone (M9) Water/sediment system	Max. in water/sediment 82% (water) after 55 d (thiadiazole label)	Evaluated on EU level y Reference DAR 1997 LoEP 7489/VI/98 Final 03/07/2003 Flufenacet BD-C addendum fate, 2003-01
FOE methyl sulphide (M5) Water/sediment system	Max. in water/sediment 8 % and 3.4% respectively after 157 d (NESA, fluorophenyl label)	

8.6.2 Pendimethalin and its metabolites

In tables 8.6-3 to 8.6-5 are given the maximum values from water/sediment systems.

Table 8.6-3: Summary of degradation in water/sediment of Pendimethalin

Pendimethalin Distribution (max. water 89.8 % after 0 days, max in sediment 86.0% after 7 days)													
Water /sediment system	**pH water**	**pH sed. ($CaCl_2$)**	**t.°C**	**DegT 50 whole syst. (d)**	**DegT 90 whole syst. (d)**	**St. (X^2)**	**DissT 50 water (d)**	**DissT 90 water (d)**	**St. (X^2)**	**Diss T50 sed. (d)**	**Diss T90 sed. (d)**	**Method of calculation****	**Evaluated on EU level y/n/ Reference**
Wenne*	-	-	-	15.1	50.2	9.0	-	-	-	-	-	SFO	EFSA Journal 2016;14(3):4420
Mühlenteich*	-	-	-	9.3	31.0	5.0	-	-	-	-	-		
Berghäuser Altrhein (1)	8.15	7.2	20	27.5	91.4	13.4	1.1	4.9	-	31.3	96.9		

Pendimethalin Distribution (max. water 89.8 % after 0 days, max in sediment 86.0% after 7 days)													
Water /sediment system	**pH water**	**pH sed. ($CaCl_2$)**	**t.°C**	**DegT50 whole syst. (d)**	**DegT90 whole syst. (d)**	**St. (X^2)**	**DissT50 water (d)**	**DissT90 water (d)**	**St. (X^2)**	**DissT50 sed. (d)**	**DissT90 sed. (d)**	**Method of calculation****	**Evaluated on EU level y/n/ Reference**
Ranschgraben (1)	8.02	5.6	20	25.4	84.2	4.8	0.6	12.0	-	31.4	-		
Berghäuser Altrhein (2)	7.66	7.3	20	101.4	336.8	2.4	0.42	4.77	4.7	-	-		
Ranschgraben (2)	7.88	6.3	20	103.1	342.6	2.1	0.41	8.18	7.1	-	-		
Geometric mean at 20°C*** (n=6)				31.8	105.5								

*Old water sediment study evaluated in initial DAR not all data available. New kinetic evaluation available, study conducted at 20°C
**For whole system kinetics
***For the purpose of the application of Guidance on Information Requirements and Chemical Safety Assessment. Chapter R11: PBT/vPvB assessment (ECHA, November 2014) the range of half-lives in fresh water/sediment systems normalized at 12 °C is : 19.8 d - 219 d

Table 8.6-4: Summary of degradation in water/sediment of M455H033

P48 (M455H033) Distribution (max. water 1.48 % after 7 days, max in sediment 10.61% after 7 days)											
Water /sediment system	**pH water**	**pH sed. ($CaCl_2$)**	**t.°C**	**DegT50 whole syst. (d)**	**DegT90 whole syst. (d)**	**St. (X^2)**	**DissT50 / DissT90 water (d)**	**St. (X^2)**	**DissT50 / DissT90 sed. (d)**	**Method of calculation****	**Evaluated on EU level y/n/ Reference**
Schaephysen	7.3	-	20	5.02	74.2 (65.95*)	6.7	-	-	-	DFOP	EFSA Journal 2016;14(3):4420
Rückhaltebecken	7.1	-	20	5.9	19.5	9.2	-	-	-	SFO	
Geometric mean at 20°C** (n=2)				5.4	38 (19.7*)						

*Slow phase DFOP used for modelling
**Normalized using a Q10 of 2.58

Table 8.6-5: Summary of degradation in water/sediment of M455H029

P36 (M12; M455H029) Distribution (max. water 2.03% after 7 days, max in sediment 21.32% after 7 days)											
Water /sediment system	**pH water**	**pH sed. ($CaCl_2$)**	**t.°C**	**DegT50 whole syst. (d)**	**DegT90 whole syst. (d)**	**St. (X^2)**	**DissT50 / DissT90 water (d)**	**St. (X^2)**	**DissT50 / DissT90 sed. (d)**	**Method of calculation****	**Evaluated on EU level y/n/ Reference**
Schaephysen	7.3	-	20	3.9	12.9	6.7	-	-	-	SFO	EFSA Journal 2016;14(3):4420
Rückhaltebecken	7.1	-	20	3.1	10.4	9.2	-	-	-		
Geometric mean at 20°C* (n=2)				3.5	11.6						

*Normalized using a Q10 of 2.58

Table 8.6-6: Summary of observed metabolites

P48 (M455H033) Water/sediment system	Max. in water :1.48%/sediment: 10.61/whole system: 12.1 % after 7 d	EFSA Journal 2016;14(3):4420
P36 (M12, M455H029) Water/sediment system	Max. in water: 2.03%/sediment: 21.32/ whole system: 23.4 % after 7 d	

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

8.7.1 Justification for new endpoints

The same endpoints as the LoEP from SANCO 7469/VI/98-Final – 03/07/2003 and EFSA Journal 2016;14(3):4420 for Flufenacet and Pendimethalin respectively were used in cereals.

8.7.2 Active substances and relevant metabolites

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

Use No.	All uses
Crop	Cereals
Application rate (g as/ha)	Flufenacet: 240 Pendimethalin: 1200
Number of applications/interval	1
Crop interception (%)	0
Depth of soil layer (relevant for plateau concentration) (cm)	20 cm

Table 8.7-2: Input parameter for active substances and relevant metabolites for PEC_{soil} calculation

Compound	**Molecular weight (g/mol)**	**Max. occurrence (%)**	**DT50 (days)**	**Value in accordance to EU endpoint y/n/ Reference**
Flufenacet	363.34	-	54 (worst case field studies)	DAR 1997 LoEP 7469/VI/98-Final – 03/07/2003
FOE sulfonic acid (M2)	275.3	26.3	270 (wost case lab studies)	
FOE oxalte (M1)	225.22	15.6	17 (wost case lab studies)	
Pendimethalin	281.3	-	187 d (SFO, field studies, worst case)	EFSA Journal 2016;14(3):4420
M455H001	311.3	6.9	117.7 d (SFO, field studies, worst case)	

Compound	**Molecular weight (g/mol)**	**Max. occurrence (%)**	**DT50 (days)**	**Value in accordance to EU end-point y/n/ Reference**
M455H033	251.3	25.9	3.6 (SFO, anaerobic laboratory studies, worst case)	

8.7.2.1 Flufenacet and its metabolites

Table 8.7-3: PEC$_{soil}$ for Flufenacet on cereals

PEC$_{soil}$ (mg/kg)		Winter cereals			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.320	-	-	-
Short term	24h	0.316	0.318	-	-
	2d	0.312	0.316	-	-
	4d	0.304	0.312	-	-
Long term	7d	0.293	0.306	-	-
	14d	0.267	0.293	-	-
	21d	0.244	0.280	-	-
	28d	0.223	0.269	-	-
	50d	0.168	0.236	-	-
	100d	0.089	0.180	-	-
Plateau concentration (20 cm) after year x		-	-	-	-
PEC$_{accumulation}$ (PEC$_{act}$ +PEC$_{soil\ plateau}$)		-	-	-	-

PEC$_{soil}$ of metabolites

Table 8.7-4: PEC$_{soil}$ for FOE sulfonic (M2) on cereals

PEC$_{soil}$ (mg/kg)		Winter cereals			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.064	-	-	-
Short term	24h	0.064	0.064	-	-
	2d	0.063	0.064	-	-
	4d	0.063	0.063	-	-
Long term	7d	0.063	0.063	-	-

	14d	0.062	0.063	-	-
	21d	0.060	0.062	-	-
	28d	0.059	0.062	-	-
	50d	0.056	0.060	-	-
	100d	0.049	0.056	-	-
Plateau concentration (20 cm) after year 4		0.010	-	-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		0.074	-	-	-

Table 8.7-5: PEC_{soil} for FOE oxalate (M1) on cereals

PEC_{soil} (mg/kg)		Winter cereals			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.031	-	-	-
Short term	24h	0.030	0.030	-	-
	2d	0.029	0.030	-	-
	4d	0.026	0.029	-	-
Long term	7d	0.023	0.027	-	-
	14d	0.017	0.024	-	-
	21d	0.013	0.021	-	-
	28d	0.010	0.018	-	-
	50d	0.004	0.013	-	-
	100d	0.001	0.007	-	-
Plateau concentration (20 cm) after year		-	-	-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		-	-	-	-

8.7.2.2 Pendimethalin and its metabolites

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

PEC_{soil} (mg/kg)		Winter cereals			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		1.600	-	-	-
Short term	24h	1.594	1.597	-	-
	2d	1.588	1.594	-	-
	4d	1.576	1.588	-	-
Long term	7d	1.559	1.579	-	-
	14d	1.519	1.559	-	-

	21d	1.480	1.539	-	-
	28d	1.442	1.520	-	-
	50d	1.329	1.460	-	-
	100d	1.104	1.337	-	-
Plateau concentration (20 cm) after year 5		0.139	-	-	-
$PEC_{accumulation}$ (PEC_{act} + $PEC_{soil\ plateau}$)		1.739	-	-	-

PEC_{soil} of metabolites

Table 8.7-5: PEC_{soil} for M455H001 on cereals

PEC_{soil} (mg/kg)		Winter cereals			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.122	-	-	-
Short term	24h	0.121	0.122	-	-
	2d	0.121	0.121	-	-
	4d	0.119	0.121	-	-
Long term	7d	0.117	0.120	-	-
	14d	0.113	0.117	-	-
	21d	0.108	0.115	-	-
	28d	0.104	0.113		-
	50d	0.091	0.106	-	-
	100d	0.068	0.092	-	-
Plateau concentration (20 cm) after year 2		0.004	-	-	-
$PEC_{accumulation}$ (PEC_{act} + $PEC_{soil\ plateau}$)		0.126	-	-	-

Table 8.7-5: PEC_{soil} for M455H033 on cereals

PEC_{soil} (mg/kg)		Winter cereals			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.370	-	-	-
Short term	24h	0.305	0.337	-	-
	2d	0.252	0.307	-	-
	4d	0.171	0.258	-	-
Long term	7d	0.096	0.203	-	-
	14d	0.025	0.128	-	-
	21d	0.006	0.090	-	-

	28d	0.002	0.068	-	-
	50d	<0.001	0.038	-	-
	100d	<0.001	0.019	-	-
Plateau concentration (20 cm) after year x		-	-	-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		-	-	-	-

8.7.2.3 PEC_{soil} of KONARK

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

Active substance / preparation	Application rate (g/ha)	Interception (%)	PEC_{act} (mg/kg)
Flufenacet + Pendimethalin / KONARK	3954.4*	0	5.273
		25**	3.954

***Based on a density value of 0.9886 g/mL**
****Interception due to the weeds themselves**

zRMS comments:

Flufenacet
The calculation of values PECs for flufenacet and its metabolites are accepted by the ZRMS. Input parameters and application patterns are considered acceptable and in line with LoEP 7469/VI/98-Final – 03/07/2003 and the proposed GAP. Interception has been appropriate to the proposed BBCH of crops (EFSA guidance was published, (2014;12(5):3662).l

Maximum PECs for flufenacet: 0.320 mg/kg
FOE Oxalate (M1): 0.031 mg/kg
FOE Sulfonic acid (M2): 0.062 mg/kg (PECs acc: 0.074 mg/kg)
KONARK: 5.273mg/kg

Pendimethalin
The PECs calculations have been accepted.
The input parameters used in calculation was established in the EU review for pendimethalin EFSA Journal 2016;14(3):4420.
Interception has been appropriate to the proposed BBCH of crops (EFSA guidance was published, (2014;12(5):3662).l

Maximum PECs for pendimethalin: 1.600 mg/kg (PECs acc: 1.739 mg/kg)
M455H001: 0.122 mg/kg (PECs acc: 0.126 mg/kg)
M455H033: 0.370 mg/kg

The results initial PEC soil of the active substances flufenacet and pendimethalin and its metabolites in soil are appropriate to be used for the subsequent risk assessment.

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

8.8.1 Justification for new endpoints

The same endpoints as the LoEP from SANCO 7469/VI/98-Final – 03/07/2003 and EFSA Journal 2016;14(3):4420 for Flufenacet and Pendimethalin respectively were used in cereals.

8.8.2 Active substance and relevant metabolites (KCP 9.2.4.1)

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

Use No.	All uses	7,8
Crop	Winter cereals	Spring cereals
Application rate (g as/ha)	Flufenacet: 240 Pendimethalin: 1200	
Number of applications/interval (d)	1	
Crop interception (%)	0	
Frequency of application	annual	
Models used for calculation	FOCUS PEARL v4.4.4, FOCUS PELMO v5.5.3	

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

Scenario	Application dates *	
	Winter cereals	Spring cereals
Châteaudun	20/10	20/02
Hamburg	12/10	10/03
Jokioinen	10/09	07/05
Kremsmünster	25/10	10/03
Okehampton	07/10	25/03
Piacenza	25/11	-
Porto	15/11	20/02
Sevilla	15/11	-
Thiva	15/11	-

***According to AppDate v3.06 (28 June 2019)**

8.8.2.1 Flufenacet and its metabolites

Table 8.8-3: Input parameters related to active substance Flufenacet and its metabolites for PEC_{gw} calculations

Compound	Flufenacet	FOE sulfonic acid (ESA)	FOE oxalate (OXA)	Value in accordance with EU endpoint y Reference*
Molecular weight (g/mol)	363.34	275.3	225.22	LoEP from Sanco 7469/VI/98-Final – 03/07/2003
Water solubility (mg/L):	56 @ 20ºC	6709 @ 25ºC	1.84 @ 25ºC	LoEP from Sanco 7469/VI/98-Final – 03/07/2003 EPIWIN v4.1
Saturated vapour pressure (Pa):	9×10^{-5} @ 20ºC	0 @ 20ºC		LoEP from Sanco 7469/VI/98-Final – 03/07/2003 Worst case
DT_{50} in soil (d)	16.5 (geomean, normalized 20ºC, pF 2, n =3)	140.4 (geomean, normalized 20ºC, pF 2, n =3) 21.7 (field studies geomean, normalized to pF2, n=11)*	6.6 (geomean, normalized 20ºC, pF 2, n =3))	Flufenacet BD-C addendum fate, 2003-01
K_{foc} (mL/g)/K_{fom}	187.4/108.7 (geomean, n = 5, in soils > 0.23% OC)	9.7/5.6 (geomean, n = 3, in soils > 0.27% OC)	10.6/6.1 (geomean, n = 3, in soils > 0.27% OC)	LoEP from Sanco 7469/VI/98-Final – 03/07/2003
1/n	0.89 (arithmetic mean, n = 5, in soils > 0.23% OC)	1.04 (arithmetic mean, n = 3, in soils > 0.27% OC)	0.91 (arithmetic mean, n = 3, in soils > 0.27% OC)	LoEP from Sanco 7469/VI/98-Final – 03/07/2003
Plant uptake factor	0			default
Formation fraction	-	0.254 Parent → FOE sulfonic acid	0.471 Parent → FOE oxalate	Flufenacet BD-C addendum fate, 2003-01

***** In the addendum to the DAR of flufenacet (January 2003); the RMS used a Kfoc value of 349 mL/g indicating that this value may under-estimate flufenacet mobility. The value selected from the endpoints (202 mL/g) seems more representative since soils with very low organic content (i.e., 0.17 %) have been excluded.

The rate constants and DT_{50} for the metabolites FOE-sulfonic acid and FOE-oxalate were calculated based on the Kelley et al. study from 1995.

Formation fractions for FOE-sulfonic acid and FOE-oxalate (DAR addendum)

Reference	Test Soil	Transformation rate (k)	DT50 (calculated based on ln2/total transformation rate)	Formation fractions for FOE-sulfonic acid and FOE-oxalate (calculated based on individual transformation rate*DT50/ln2)

Kelley, I.; Wood, S. & McKinney, M. 1995	BBA 2.2 Loamy sand	Total = 0.022223 FOE-sulfonic acid = 0.006762 FOE-oxalate = 0.01158	31	FOE-sulfonic acid = 0.3024 FOE-oxalate = 0.5179
	Laacher-hof Silt loam	Total = 0.0331491 FOE-sulfonic acid = 0.009667 FOE-oxalate = 0.01563	21	FOE-sulfonic acid = 0.2929 FOE-oxalate = 0.4735
	Hofchen Silt loam	Total = 0.030683 FOE-sulfonic acid = 0.005565 FOE-oxalate = 0.01287	23	FOE-sulfonic acid = 0.1847 FOE-oxalate = 0.4271
Geometric mean				FOE-sulfonic acid = 0.254 FOE-oxalate = 0.471

Subsequently, the rate constant (k) for transformation of the active substance flufenacet into both metabolites, FOE-sulfonic acid and FOE-oxalate, is calculated based on the geomean normalised DT_{50} and the above calculated geomean formation fraction (ff) of both metabolites:

$$k_{FOE\text{-sulfonic acid}} = \ln 2/DT_{50} * ff_{FOE\text{-sulfonic acid}} = \ln 2/16.5 * 0.254 = 0.0107$$

$$k_{FOE\text{-oxalate}} = \ln 2/DT_{50} * ff_{FOE\text{-oxalate}} = \ln 2/16.5 * 0.471 = 0.0198$$

It is considered that flufenacet forms FOE-sulfonic acid and FOE-oxalate and that the remaining part of the active substance is converted into CO_2. Consequently, the formation fraction for flufenacet into CO_2 equals:

$$1 – 0.254 – 0.471 = 0.275$$

Thus, the transformation rate for the conversion of flufenacet into CO_2

$$= \ln 2/16.5 * 0.275 = 0.0116$$

Table 8.8-4: PEC_{gw} for Flufenacet and its metabolites on winter cereals (with FOCUS PEARL 4.4.4/PELMO 5.5.3) in pre emergence

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)					
		Flufenacet		FOE sulfonic acid (ESA)		FOE oxalate (OXA)	
		PEARL	PELMO	PEARL	PELMO	PEARL	PELMO
Winter cereals	Châteaudun	<0.001	<0.001	**17.492**	**14.832**	0.020	0.024
	Hamburg	<0.001	<0.001	**16.873**	**14.722**	**0.370**	**0.577**
	Jokioinen	<0.001	<0.001	**27.736**	**19.311**	**0.233**	**0.421**
	Kremsmünster	<0.001	<0.001	**10.302**	**11.906**	0.054	0.075
	Okehampton	<0.001	<0.001	**9.168**	**9.256**	0.316	0.423
	Piacenza	<0.001	<0.001	**10.077**	**13.000**	0.042	0.152
	Porto	<0.001	<0.001	**7.933**	**7.534**	0.357	0.862
	Sevilla	<0.001	<0.001	**8.641**	**5.905**	<0.001	0.054

	Thiva	<0.001	<0.001	**19.049**	**11.916**	0.006	0.036

Table 8.8-5: PEC_{gw} for Flufenacet and its metabolites on spring cereals (with FOCUS PEARL 4.4.4/PELMO 5.5.3) in pre emergence

Crop	Scenario	80th Percentile PEC_{Gw} at 1 m Soil Depth (µg/L)					
		Flufenacet		FOE sulfonic acid (ESA)		FOE oxalate (OXA)	
		PEARL	PELMO	PEARL	PELMO	PEARL	PELMO
Spring cereals	Châteaudun	<0.001	<0.001	**12.088**	**10.855**	0.001	0.001
	Hamburg	<0.001	<0.001	**21.863**	**14.273**	0.047	0.034
	Jokioinen	<0.001	<0.001	**19.779**	**16.657**	0.053	0.072
	Kremsmünster	<0.001	<0.001	**10.622**	**11.210**	0.017	0.017
	Okehampton	<0.001	<0.001	**8.900**	**8.133**	0.022	0.029
	Porto	<0.001	<0.001	**7.584**	**7.138**	0.005	0.016

The PEC_{GW} (Predicted Environmental Concentrations in Ground Water) of Flufenacet and its soil metabolites were calculated using the simulation models FOCUS-PELMO (version 5.5.3) and FOCUS-PEARL (version 4.4.4). Nine realistic worst-case standard weather, soil and crop scenarios that collectively represent major agricultural areas in the European Union were used as recommended by FOCUS (2000[1], 2009[2]). The concentrations were calculated for 26 years in consideration of the relevant FOCUS scenarios.

All leaching simulation run with FOCUS PELMO and PEARL resulted in PEC_{GW} values highly below 0.1 µg/L for flufenacet for all FOCUS scenarios.

For the non relevant metabolites PECgw values exceed 0.1 µg/L for some scenarios. PEC_{gw} is ranged between < 0.001 to 0.577 µg/L for FOE oxalate, and from 5.905 to 27.736 µg/L for FOE sulfonic acid. The maximum value for FOE sulfonic acid was reported in winter cereals in Jokioinen scenario (27.736 µg/L) for FOCUS PEARL model.

Like explained in the DAR of Flufenacet (Annex B.7, 1997) in the lysimeter studies (see point CP9.3.2): the levels of FOE oxalate were < 0.1 µg/L and the level of FOE sulfonic acid were 3.7 µg/L (max. value - 1st year) and 0.015 µg/L (mean value - 2nd year). It can be noted that the level of FOE sulfonic acid in the lysimeter studies are significantly lower than the values of the FOCUS models, therefore, the models can be considered as not being representative.

Therefore, a refinement has been proposed using the FOE sulfonic acid DT_{50} geomean derived from field studies.

TIER 1

According to Maltese Authorities a new DT_{50} geomean value for FOE sulfonic acid is available. It is derived from a new kinetic evaluation of the Annex I Flufenacet field studies, therefore non protected. This refinement consists in a different DT_{50} in soil for FOE-sulfonic acid and 21.7 days was the geometric mean value (normalized to pF2, n=11). As it concerns a re-evaluation of existing unprotected data and not new data, this study is therefore not protected and the DT_{50} value of 21.7 days from this study can thus be used in support of KONARK use.

[1] FOCUS (2000) "FOCUS groundwater scenarios in the EU review of active substances" Report of the FOCUS Groundwater Scenarios Workgroup, EC Document Reference Sanco/321/2000 rev. 2
[2] FOCUS (2009) "Assessing Potential for Movement of Active Substances and their Metabolites to Groundwater in the EU Final Report of the Groundwater Workgroup of FOCUS, amending FOCUS (2000), EC Document Reference Sanco/13144/2010, 604 pp.

Table 8.8-6: PEC$_{gw}$ for Flufenacet and its metabolites on winter cereals (with FOCUS PEARL 4.4.4/PELMO 5.5.3) in pre emergence

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)					
		Flufenacet		FOE sulfonic acid (ESA)		FOE oxalate (OXA)	
		PEARL	PELMO	PEARL	PELMO	PEARL	PELMO
Winter cereals	Châteaudun	<0.001	<0.001	**1.137**	**0.873**	-	-
	Hamburg	<0.001	<0.001	**3.562**	**3.880**	-	-
	Jokioinen	<0.001	<0.001	**5.297**	**5.171**	-	-
	Kremsmünster	<0.001	<0.001	**1.682**	**1.863**	-	-
	Piacenza	<0.001	<0.001	**0.966**	**1.350**	-	-
	Thiva	<0.001	<0.001	**0.534**	**0.648**	-	-

Table 8.8-7: PEC$_{gw}$ for Flufenacet and its metabolites on spring cereals (with FOCUS PEARL 4.4.4/PELMO 5.5.3) in pre emergence

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)					
		Flufenacet		FOE sulfonic acid (ESA)		FOE oxalate (OXA)	
		PEARL	PELMO	PEARL	PELMO	PEARL	PELMO
Spring cereals	Châteaudun	<0.001	<0.001	**0.511**	**0.315**	-	-
	Hamburg	<0.001	<0.001	**2.948**	**1.694**	-	-
	Jokioinen	<0.001	<0.001	**2.887**	**2.783**	-	-
	Kremsmünster	<0.001	<0.001	**1.376**	**1.437**	-	-

The TIER 1 refinement shown the FOE sulfonic acid maximum concentrations in winter cereals in Jokioinen scenario (5.297µg/L), for FOCUS PEARL model that is in the range of field studies.

Summary of PECgw simulations for Flufenacet

The PEC$_{GW}$ (Predicted Environmental Concentrations in Ground Water) of Flufenacet and its soil metabolites were calculated using the simulation models FOCUS-PELMO (version 5.5.3) and FOCUS-PEARL (version 4.4.4). Nine realistic worst-case standard weather, soil and crop scenarios that collectively represent major agricultural areas in the European Union were used as recommended by FOCUS (2000[3], 2009[4]). The concentrations were calculated for 26 years in consideration of the relevant FOCUS scenarios.

All leaching simulation run with FOCUS PELMO and PEARL resulted in PEC$_{GW}$ values highly below 0.1 µg/L for flufenacet for all FOCUS scenarios.

For the non relevant metabolites PECgw values exceed 0.1 µg/L for some scenarios. PEC$_{gw}$ is ranged between < 0.001 to 0.577 µg/L for FOE oxalate, and from 5.905 to 27.736 µg/L for FOE sulfonic acid.

[3] FOCUS (2000) "FOCUS groundwater scenarios in the EU review of active substances" Report of the FOCUS Groundwater Scenarios Workgroup, EC Document Reference Sanco/321/2000 rev. 2

[4] FOCUS (2009) "Assessing Potential for Movement of Active Substances and their Metabolites to Groundwater in the EU Final Report of the Groundwater Workgroup of FOCUS, amending FOCUS (2000), EC Document Reference Sanco/13144/2010, 604 pp.

The maximum value for FOE sulfonic acid was reported in winter cereals in Jokioinen scenario (27.736 µg/L) for FOCUS PEARL model.

Like explained in the DAR of Flufenacet (Annex B.7, 1997) in the lysimeter studies (see point CP9.3.2): the levels of FOE oxalate were < 0.1 µg/L and the level of FOE sulfonic acid were 3.7 µg/L (max. value - 1st year) and 0.015 µg/L (mean value - 2nd year). It can be noted that the level of FOE sulfonic acid in the lysimeter studies are significantly lower than the values of the FOCUS models, therefore, the models can be considered as not being representative.

Therefore, a refinement has been proposed using the FOE sulfonic acid DT_{50} geomean derived from field studies.

The TIER 1 refinement shown the FOE sulfonic acid maximum concentrations in winter cereals in Jokioinen scenario (5.297µg/L), for FOCUS PEARL model that is in the range of field studies.

Furthermore, based on the additional information provided by the notifier[5], both metabolites FOE sulfonic acid and FOE oxalate have been screened for their biological activity, genotoxicity and toxicity. It has been concluded that both metabolites are not of toxicological relevance. For more details, please refer to Section 10.

8.8.2.2 Pnedimethalin and its metabolites

Table 8.8-8: Input parameters related to active substance Pendimethalin and for the non-relevant metabolites M455H001 and M455H033 for PEC_{gw} calculations

Compound	Pendimethalin	M455H001	M455H033	Value in accordance with EU endpoint y/n/ Reference
Molecular weight (g/mol)	281.3	311.3	251.3	EFSA Journal 2016;14(3):4420
Water solubility (mg/L):	0.330 (20°C)	100 (20°C)	100 (20°C)	
Saturated vapour pressure (Pa):	3.34×10^{-3} (25°C) 1.74×10^{-3} (20°C)*	1×10^{-10} (20°C)	1×10^{-10} (20°C)	
DT50 in soil (d)	182.28 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q10 of 2.58, n = 5)	39.96 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q10 of 2.58, n = 4)	3.6 (worst case, anaerobic DT_{50})	
K_{foc}/K_{fom} (mL/g)	12943/7508 (geomean, n = 9)	223.2/129.5 (Geomean, n = 5)	3173.2/1841 (Geomean, n = 5)	
1/n	0.954 (arithmetic mean, n = 9)	0.966 (arithmetic mean, n = 5)	1.0 (default)	
Plant uptake factor	0			
Formation fraction	-	0.231 from parent	1 from parent	

***Derived from EVA 3.0 and used on PELMO calculations**

[5] Information provided during the risk assessment performed for the preparation TROOPER (containing flufenacet and pendimethalin (see http://e-phy.agriculture.gouv.fr/)), and based on document Sanco/221/2000

Table 8.8-9: PEC$_{gw}$ for active Pendimethalin and its non-relevant metabolites M455H001 and M455H033 on winter cereals with FOCUS PEARL 4.4.4/PELMO 5.5.3 (pre-emergence)

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)					
		Pendimethalin		M455H001		M455H033	
		PEARL	PELMO	PEARL	PELMO	PEARL	PELMO
Winter cereals	Châteaudun	<0.001	<0.001	0.004	<0.001	<0.001	<0.001
	Hamburg	<0.001	<0.001	0.086	0.002	<0.001	<0.001
	Jokioinen	<0.001	<0.001	0.012	0.001	<0.001	<0.001
	Kremsmünster	<0.001	<0.001	0.055	0.002	<0.001	<0.001
	Okehampton	<0.001	<0.001	**0.119**	0.007	<0.001	<0.001
	Piacenza	<0.001	<0.001	0.054	0.003	<0.001	<0.001
	Porto	<0.001	<0.001	0.037	0.002	<0.001	<0.001
	Sevilla	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Thiva	<0.001	<0.001	0.001	<0.001	<0.001	<0.001

Table 8.8-10: PEC$_{gw}$ for active Pendimethalin and its non-relevant metabolites M455H001 and M455H033 on spring cereals with FOCUS PEARL 4.4.4/PELMO 5.5.3 (pre-emergence)

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)					
		Pendimethalin		M455H001		M455H033	
		PEARL	PELMO	PEARL	PELMO	PEARL	PELMO
Spring cereals	Châteaudun	<0.001	<0.001	0.003	<0.001	<0.001	<0.001
	Hamburg	<0.001	<0.001	**0.102**	0.004	<0.001	<0.001
	Jokioinen	<0.001	<0.001	0.012	<0.001	<0.001	<0.001
	Kremsmünster	<0.001	<0.001	0.057	0.002	<0.001	<0.001
	Okehampton	<0.001	<0.001	0.096	0.007	<0.001	<0.001
	Porto	<0.001	<0.001	0.038	0.003	<0.001	<0.001

Summary of PECgw simulations for Pendimethalin and its metabolites

A groundwater leaching risk assessment was performed for Pendimethalin and its metabolites, for all relevant FOCUS GW scenarios for winter cereals, using the latest FOCUS PELMO and PEARL model.

According to the simulations, the maximum predicted concentrations in leachate water at 1m depth were high below 0.1 µg/L for Pendimethalin and its non relevant metabolites M455H001 and M455H033 with the exception in winter and spring cereals preemergence PEARL Okehampton and Hamburg scenarios respectively where non relevant metabolite M455H001 exceed the trigger value with a maximum of 0.119 µg/L. Therefore, assessment of the relevance of metabolite M455H001 according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.10 is therefore required.

Summary of PECgw simulations

<u>Flufenacet and its metabolites</u>

The PEC_{GW} (Predicted Environmental Concentrations in Ground Water) of Flufenacet and its soil metabolites were calculated using the simulation models FOCUS-PELMO (version 5.5.3) and FOCUS-PEARL (version 4.4.4). Nine realistic worst-case standard weather, soil and crop scenarios that collectively represent major agricultural areas in the European Union were used as recommended by FOCUS (2000, 2009). The concentrations were calculated for 26 years in consideration of the relevant FOCUS scenarios.

All leaching simulation run with FOCUS PELMO and PEARL resulted in PEC_{GW} values highly below 0.1 µg/L for flufenacet for all FOCUS scenarios.

For the non relevant metabolites PECgw values exceed 0.1 µg/L for some scenarios. PEC_{gw} is ranged between < 0.001 to 0.577 µg/L for FOE oxalate, and from 5.905 to 27.736 µg/L for FOE sulfonic acid. The maximum value for FOE sulfonic acid was reported in winter cereals in Jokioinen scenario (27.736 µg/L) for FOCUS PEARL model.

Like explained in the DAR of Flufenacet (Annex B.7, 1997) in the lysimeter studies (see point CP9.3.2): the levels of FOE oxalate were < 0.1 µg/L and the level of FOE sulfonic acid were 3.7 µg/L (max. value - 1st year) and 0.015 µg/L (mean value - 2nd year). It can be noted that the level of FOE sulfonic acid in the lysimeter studies are significantly lower than the values of the FOCUS models, therefore, the models can be considered as not being representative.

Therefore, a refinement has been proposed using the FOE sulfonic acid DT_{50} geomean derived from field studies.

The TIER 1 refinement shown the FOE sulfonic acid maximum concentrations in winter cereals in Jokioinen scenario (5.297µg/L), for FOCUS PEARL model that is in the range of field studies.

Furthermore, based on the additional information provided by the notifier, both metabolites FOE sulfonic acid and FOE oxalate have been screened for their biological activity, genotoxicity and toxicity. It has been concluded that both metabolites are not of toxicological relevance. For more details, please refer to Section 10.

Pendimethalin and its metabolites

A groundwater leaching risk assessment was performed for Pendimethalin and its metabolites, for all relevant FOCUS GW scenarios for winter cereals, using the latest FOCUS PELMO and PEARL model.

According to the simulations, the maximum predicted concentrations in leachate water at 1m depth were high below 0.1 µg/L for Pendimethalin and its non relevant metabolites M455H001 and M455H033 with the exception in winter and spring cereals preemergence PEARL Okehampton and Hamburg scenarios respectively where non relevant metabolite M455H001 exceed the trigger value with a maximum of 0.119 µg/L. Therefore, assessment of the relevance of metabolite M455H001 according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.10 is therefore required.

Regarding the comments made by the German and Slovenian Authorities even taking into account that the Pendimethalin classification will come into force in November 2023, thus at this moment M455H001 metabolite is considered as non toxicologically relevant the Applicant has been done refinements for the non toxicologically relevant metabolite M455H001 in the scenarios where the PECgw exceed the trigger value of 0.1 µg/L. These proposed refinements are as follow:

TIER 1: a 25% of interception due to the weeds themselves. This percentage is the same percentage applied in the dry deposition calculations used in Step 4 mitigation measures.

TIER 2: application every other year.

The TIER 1 results are given below:

Table 8.8-11: PEC$_{gw}$ for active Pendimethalin and its non-relevant metabolite M455H001 on winter cereals with FOCUS PEARL 4.4.4 (pre-emergence, 25% interception)

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)	
		Pendimethalin	M455H001
Winter cereals	Okehampton	<0.001	0.085

Table 8.8-12: PEC$_{gw}$ for active Pendimethalin and its non-relevant metabolite M455H001 on spring cereals with FOCUS PEARL 4.4.4 (pre-emergence, 25% interception)

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)	
		Pendimethalin	M455H001
Spring cereals	Hamburg	<0.001	0.073

The TIER 2 outcomes are given in the next tables:

Table 8.8-13: PEC$_{gw}$ for active Pendimethalin and its non-relevant metabolite M455H001 on winter cereals with FOCUS PEARL 4.4.4 (pre-emergence, every other year)

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)	
		Pendimethalin	M455H001
Winter cereals	Okehampton	<0.001	0.052

Table 8.8-14: PEC$_{gw}$ for active Pendimethalin and its non-relevant metabolite M455H001 on spring cereals with FOCUS PEARL 4.4.4 (pre-emergence, every other year)

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)	
		Pendimethalin	M455H001
Spring cereals	Hamburg	<0.001	0.052

Conclusions

After the refinements the PECgw of the non toxicologically relevant metabolite M455H001 is below the trigger value of 0.1 µg/L. For TIER 1 no restrictions are needed, however for TIER 2 the applicant proposes the next restrictions phrases that must be applied only at national level:

For Slovenia:

SPe 2: To protect the groundwater apply this product every 2 years in cereal crops in sandy soils.

SPe 2: To protect the groundwater apply this product every 2 years in cereal crops in acid loam soils with a %OM content greater than 3.8%.

For Germany:

The applicant would like to mention that in German national requirements only the FOCUS model considered for GW calculations is PELMO, therefore the Applicant is wondering if the restriction below should be applied because the refinements were done using FOCUS PEARL model.

SPe 2: To protect the groundwater apply this product every 2 years in spring cereal crops in sandy soils.

The Applicant would also like to mention that after these refinements **no relevance assessment** according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.10 is required for Pendimethalin metabolite M455H001 because all PECgw for all crops and scenarios are below 0.1 µg/L and B10 has been amended accordingly although it is the core dossier not a national addendum.

zRMS comments:

Flufenacet

Evaluator agrees with modelling carried out by applicant.
The input parameters for groundwater calculation were established in the EU reviews Flufenacet 7469/VI/98-Final 3 July 2003.
Interception was appropriate to the proposed BBCH of crops (EFSA guidance was published, (2014;12(5):3662).
In simulations PUF value of 0 was assumed for all compounds, in line with recommendations of the most recent version of the FOCUS Groundwater Guidance. The geomean of the DT50 and Kfoc values were used in modelling.
The results of both leaching models PELMO 5.5.3 and PEARL 4.4.4 show that when used according to the intended use in winter and spring cereals flufenacet leaches in acceptable amounts to groundwater in every European scenario since all PECgw were found to be under the limit of 0.1 µg/L.
Regarding the metabolite FOE oxalate, it was found to exceed 0.1 µg/L in several scenarios with a maximum of 0.577 µg/L µg/L. However, since this metabolite was found to be not toxicologically relevant during the EU review of flufenacet, this higher value is acceptable as also confirmed in the Part B section 10.

Regarding FOE-sulfonic acid, it was found to exceed 0.1 µg/L in all scenarios with a maximum of 27.736 µg/L. The refinement expose consists in a different DT_{50} in soil for FOE-sulfonic acid, 21.7 days (geometric mean, normalized to pF2, n=11) instead of 140.4 days was accepted by zRMS. This metabolite was found to be not relevant during the EU review of flufenacet as is confirmed in Part B Section 10..

The metabolites FOA oxalate (M01) and FOE sulfonic acid (M02) are predicted to occur in groundwater at concentrations above 0.1 µg/L. Assessment of the relevance of these metabolites according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.10 is therefore required (refer to dRR Part B10 – Assessment of relevance of metabolites in groundwater).

Pendimethalin

Evaluator agrees with modelling carried out by applicant.
The input parameters for groundwater calculation were established in the EU reviews (EFSA Journal EFSA Journal 2016;14(3):4420).
Interception was appropriate to the proposed BBCH of crops (EFSA guidance was published, (2014;12(5):3662).
In simulations PUF value of 0 was assumed for all compounds, in line with recommendations of the most recent version of the FOCUS Groundwater Guidance. The geomean of the DT50 and Kfoc values were used in modelling.

The results of the leaching models PEARL 4.4.4 and PELMO 5.5.3 show that when used according to the intended use of pendimethalin and its metabolites leach in acceptable amounts to groundwater in every European scenario, since all PECgw were found to be under the limit of 0.1 µg/L except metabolite M455H001 for winter cereals for Okehampton scenario and Hamburg scenario for spring cereals.

The assessment relevance of the metabolite M455H001 in ground water according to SANCO/221/2000 –rev.10 document was performed and reported in the dRR Part B10.

The mitigation measure can be considered at national level if scenario Hamburg or Okehampton are relevant for country.

Applicant submitted new PECgw for German and Slovenian Authorities but this calculations should be assessed.

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

8.9.1 Justification for new endpoints

The same endpoints as the LoEP from SANCO 7469/VI/98-Final – 03/07/2003 and EFSA Journal 2016;14(3):4420 for Flufenacet and Pendimethalin respectively were used in winter cereals.

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

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

Plant protection product	KONARK	
Use No.	All	7,8
Crop	Winter cereals (pre-emergence worst case)	Springcereals (pre-emergence worst case)
Application rate (kg as/ha)	Flufenacet: 0.24 Pendimethalin: 1.2	
Number of applications/interval (d)	1	
Application window	Oct-Feb (relevant for STEP 1 and 2 only)	March-May (relevant for STEP 1 and 2 only)
Application method	Ground spray	
CAM (Chemical application method)	1 pre-emergence	
	2 post-emergence	
Models used for calculation	STEPS 1-2 in FOCUS v3.2 FOCUS SWASH v5.3, FOCUS PRZM v 4.3.1, FOCUS MACRO v5.5.4, FOCUS TOXWA v5.5, SWAN 5.0.0	

Table 8.9-2: FOCUS Step 3 Scenario related input parameters for $PEC_{sw/sed}$ calculations for the application of KONARK on ~~winter~~ cereals ~~(the dates are SWASH default for14 days before the emergence as worst case)~~

Scenario	Application window used in modelling*					
	Winter cereals			Spring cereals		
	BBCH 00	BBCH 11[a)]	BBCH 21	BBCH 00	BBCH 11[a)]	BBCH 21
D1	15/09	27/09	16/03	25/04	07/05	18/05
D2	15/10	27/10	26/03	-	-	-
D3	11/11	23/11	07/04	22/03	03/04	16/04

Scenario	Application window used in modelling*					
D4	12/09	24/09	09/03	16/04	28/04	09/05
D5	31/10	12/11	06/03	05/03	17/03	29/03
D6	20/11	02/12	21/12	-	-	-
R1	02/11	14/11	15/04	31/03**	12/04**	27/04**
R3	21/11	03/12	10/03	-	-	-
R4	31/10	15/11	22/12	05/03	17/03	29/03

***According to AppDate v3.06 (28 June 2019)**
****Spring oilseed rape has been calculated for this scenario**

[a)] According to the Polish Authorities requirements calculations in post emergence for Pendimethalin have been done.

8.9.2.1 Flufenacet and its metabolites

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

Compound	Flufenacet	FOE Sulfonic acid (M2)	FOE Oxalate (M1)	FOE Methylsulfide (M5)	Thiadone (M9)	Value in accordance to EU endpoint y Reference
Molecular weight (g/mol)	363.3	275.3	225.22	241	170	LoEP from Sanco 7469/VI/98-Final – 03/07/2003 Flufenacet BD-C addendum fate, 1999-01
Saturated vapour pressure (Pa)	9 x 10^{-5} @ 20°C	-				
Water solubility (mg/L)	56 (20°C)	1000 (default)				
Diffusion coefficient in water (m²/d)	4.3 x 10^{-5}	-				
Diffusion coefficient in air (m²/d)	0.43					
K_{foc}/K_{om} (mL/g)	187.4/108.7 (geomean, n = 5, in soils > 0.23% OC)	9.7 (geomean, n = 3, in soils > 0.27% OC)	10.6 (geomean, n = 3, in soils > 0.27% OC)	1 (default)		
Freundlich Exponent 1/n	0.89 (arithmetic mean, n = 5, in soils > 0.23% OC)	-				
Plant Uptake	0					
Wash-Off factor from Crop (1/mm)	0.05 (MACRO) 0.50 (PRZM)					
$DT_{50,soil}$ (d)	16.5 (geomean, normalized	140.4 (geomean, normalized	6.6 (geomean, normalized	1000 (default)		

Compound	**Flufenacet**	**FOE Sulfonic acid (M2)**	**FOE Oxalate (M1)**	**FOE Methylsulfide (M5)**	**Thiadone (M9)**	**Value in accordance to EU end-point y Reference**
	20ºC, pF 2, n =3)	20ºC, pF 2, n =3)	20ºC, pF 2, n =3))			
$DT_{50,water}$ (d)	1000 (default)	1000 (default)				
$DT_{50,sed}$ (d)	44.7(geomean (n=4))					
$DT_{50,whole\ system}$ (d)	44.7 (geomean (n=4))					
Maximum occurrence observed (% molar basis with respect to the parent)	Sed: 34.2	Soil: 26.3 Water: 3 Whole system: 3.2	Soil:15.6 Water: 4.8 Whole system: 5.4	Soil:0.00001 * Water: 8 Whole system: 11.4	Soil:0.00001 * Water:82 Sediment: < 10 Whole system: 92 (worst case)	
Formation fraction in soil:		0.254	0.471	-	-	

***No soil metabolites, default value**

$PEC_{sw/sed}$

Table 8.9-4: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for Flufenacet following single application of KONARK to winter cereals pre-emergence

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		66.21	-	56.15	121.36
Step 2					
Southern Europe	Oct-Feb	23.43	-	20.45	43.66
Northern Europe		28.84		25.19	53.80
Step 3					
D1	ditch	10.17	Drainage	7.460	18.08
D1	stream	6.476	Drainage	4.880	9.192
D2	ditch	20.54	Drainage	8.484	15.55
D2	stream	13.12	Drainage	4.813	9.204
D3	ditch	1.517	Drainage	0.059	0.423
D4	pond	0.806	Drainage	0.774	2.342

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
D4	stream	1.316	Drainage	0.490	0.989
D5	pond	1.326	Drainage	1.254	3.625
D5	stream	1.688	Drainage	0.496	1.146
D6	ditch	6.399	Drainage	2.011	5.254
R1	pond	0.115	Run off	0.102	0.377
R1	stream	6.516	Run off	0.141	1.421
R3	stream	9.128	Run off	0.597	8.317
R4	stream	2.104	Run off	0.073	0.560

Table 8.9-5: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for Flufenacet following single application of KONARK to spring cereals pre-emergence

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		66.21	-	56.15	121.36
Step 2					
Southern Europe	March-May	23.43	-	20.45	43.66
Northern Europe		12.61		10.96	23.40
Step 3					
D1	ditch	1.642	Drainage	0.442	1.687
D1	stream	1.343	Drainage	0.244	0.591
D3	ditch	1.520	Drainage	0.070	0.466
D4	pond	0.053	Drainage	0.047	0.138
D4	stream	1.161	Drainage	0.011	0.042
D5	pond	0.055	Drainage	0.049	0.152
D5	stream	1.207	Drainage	0.003	0.037
R1	pond	0.132	Run off	0.122	0.356
R1	stream	1.946	Run off	0.073	0.534
R4	stream	1.001	Run off	0.013	0.110

FOCUS Step 4

As the PECSW values of flufenacet derived from FOCUS step 3 calculations indicated a possible risk for at least one aquatic species, a calculation of PECSW values based on higher tier modelling (FOCUS step 4) was necessary.

To evaluate the effect of risk mitigation measures on the predicted environmental concentration flufenacet in surface water, the effect of unsprayed buffer zone was investigated.

Step 4 PECsw were calculated using the SWAN program, version 5.0.0. Where necessary and applicable, the calculations were conducted with protective buffer zones for spray drift reduction. Where the contamination of surface water was dominated by run-off events, vegetated buffer zones for the reduction of run-off were introduced as recommended in the FOCUS landscape mitigation guidance document[6].

FOCUS (2005) recommends the use of the SWAN software to determine Step 4 PEC values using particular mitigation approaches. In the current work 20 m spray drift buffer zones were specified with SWAN and this internally selected appropriate drift values from the FOCUS drift calculator plus 90% of nozzles. The run-off reduction was consistent with a vegetative buffer of 10, 15 and 20m without nozlzes.

The dry deposition was applied to step 4 calculations although Flufenacet was considered as semivolatile only from plants by EVA 3 and the interception considered for ground water according to EFSA Guidance 3662 and FOCUS Step 1/2 was 0. An interception of 25% (from weeds) was considered because in the preemergence herbicides particular cases this interception sometimes is used as default for refinements on soil and ground water calculations, the dry deposition as worst results are given below.

Table 8.9-6: EVA 3.0 rev 2h 29/09/2017 dry deposition calculations for Flufenacet

		dist. (m)	1	5	10	15	20
	v/d per h	v/d in 24 h					
time (h)	arable crop	no dissip.	0.022%	0.018%	0.014%	0.010%	0.008%
0 - 1	9.09%		0.0005	0.0004	0.0003	0.0002	0.0002
1 - 2	9.09%		0.0005	0.0004	0.0003	0.0002	0.0002
2 - 3	9.09%		0.0005	0.0004	0.0003	0.0002	0.0002
3 - 4	9.09%		0.0005	0.0004	0.0003	0.0002	0.0002
4 - 5	4.55%		0.0002	0.0002	0.0001	0.0001	0.0001
5 - 6	4.55%		0.0002	0.0002	0.0001	0.0001	0.0001
6 - 7	4.55%		0.0002	0.0002	0.0001	0.0001	0.0001
7 - 8	4.55%		0.0002	0.0002	0.0001	0.0001	0.0001
8 - 9	4.55%		0.0002	0.0002	0.0001	0.0001	0.0001
9 - 10	4.55%		0.0002	0.0002	0.0001	0.0001	0.0001
10 - 11	4.55%		0.0002	0.0002	0.0001	0.0001	0.0001
11 - 12	4.55%		0.0002	0.0002	0.0001	0.0001	0.0001
12 - 13	2.27%		0.0001	0.0001	0.0001	0.0001	0.0000
13 - 14	2.27%		0.0001	0.0001	0.0001	0.0001	0.0000
14 - 15	2.27%		0.0001	0.0001	0.0001	0.0001	0.0000
15 - 16	2.27%		0.0001	0.0001	0.0001	0.0001	0.0000
16 - 17	2.27%		0.0001	0.0001	0.0001	0.0001	0.0000
17 - 18	2.27%		0.0001	0.0001	0.0001	0.0001	0.0000
18 - 19	2.27%		0.0001	0.0001	0.0001	0.0001	0.0000
19 - 20	2.27%		0.0001	0.0001	0.0001	0.0001	0.0000
20 - 21	2.27%		0.0001	0.0001	0.0001	0.0001	0.0000
21 - 22	2.27%		0.0001	0.0001	0.0001	0.0001	0.0000
22 - 23	2.27%		0.0001	0.0001	0.0001	0.0001	0.0000
23 - 24	2.27%		0.0001	0.0001	0.0001	0.0001	0.0000
0 - 24	100.00%		0.0053	0.0043	0.0033	0.0025	0.0019

Table 8.9-7: Global maximum PEC_{sw} values for Flufenacet following single application of KONARK to winter cereals in pre-emergence according to the central ~~south~~ EU zone GAP according to surface water Step 4

PEC_{sw} (µg/L)	Scenario	STEP 4 Flufenacet			
Nozzle reduction	Vegetative strip (m)	None	10	15*	20
	No spray buffer (m)	5	10	15	20
90%	D1 ditch	10.16	-	-	-
	D1 stream	6.476	-	-	-

[6] SANCO/10422/2005 version 1.0, May 2005 (p.30) and SANCO/10422/2005 version 2.0, Sept 2007(p. 32)

PEC_{sw} (µg/L)	**Scenario**	**STEP 4 Flufenacet**			
Nozzle reduction	Vegetative strip (m)	None	10	15*	20
	No spray buffer (m)	5	10	15	20
	D2 ditch	20.54	-	-	-
	D2 stream	13.12	-	-	-
	D6 ditch	6.398	-	-	-
None	R1 stream	-	2.920	-	-
90%		6.514	-	-	-
None	R3 stream	-	4.167	3.199	2.186
90%		9.128	-	-	-

****0.7 and 09 for Fractional reduction in run-off volume and flux and Fractional reduction in erosion mass and flux were respectively used for strip vegetative simulation, according to the Austrian Environmental Agency AGES.**

Metabolites of Flufenacet

Table 8.9-8: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for FOE Oxalate (M1) following single application to winter cereals in pre-emergence

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	---	10.34	-	10.27	1.10
Step 2					
Southern Europe	Oct-Feb	2.97	-	2.95	0.31
Northern Europe		3.70		3.67	0.39

Table 8.9-9: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for FOE Oxalate (M1) following single application to spring cereals in pre-emergence

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	---	10.34	-	10.27	1.10
Step 2					
Southern Europe	March-May	2.97	-	2.95	0.31
Northern Europe		1.52		1.51	0.16

Table 8.9-10: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for FOE Sulfonic acid (M2) following single application to winter in cereals pre-emergence

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	---	17.71	-	17.58	1.72
Southern Europe	Oct-Feb	6.87	-	6.82	0.67
Northern Europe		8.58		8.52	0.83

Table 8.9-11: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for FOE Sulfonic acid (M2) following single application to spring in cereals pre-emergence

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	---	17.71	-	17.58	1.72
Southern Europe	Oct-Feb	6.87	-	6.82	0.67
Northern Europe		3.46		3.44	0.34

Table 8.9-12: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for FOE methylsulfide (M5) following single application to winter cereals in pre-emergence

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	---	6.21	-	6.16	0.06
Step 2					
Southern Europe	Oct-Feb	2.21	-	2.19	0.02
Northern Europe		2.72		2.70	0.03

Table 8.9-13: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for FOE methylsulfide (M5) following single application to spring cereals in pre-emergence

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	---	6.21	-	6.16	0.06
Step 2					

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Southern Europe	Oct-Feb	2.21	-	2.19	0.02
Northern Europe		1.19		1.18	0.01

Table 8.9-14: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for Thiadone (M9) following single application to winter cereals in pre-emergence

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	---	35.34	-	35.09	0.35
Step 2					
Southern Europe	Oct-Feb	12.58	-	12.48	0.13
Northern Europe		15.48		15.37	0.15

Table 8.9-15: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for Thiadone (M9) following single application to spring cereals in pre-emergence

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	---	35.34	-	35.09	0.35
Step 2					
Southern Europe	Oct-Feb	12.58	-	12.48	0.13
Northern Europe		6.76		6.71	0.07

8.9.2.2 Pendimethalin and its metabolites

Table 8.9-16: Input parameters related to active substance Pendimethalin and metabolites for $PEC_{sw/sed}$ calculations STEP 1/2 and 3(/4) (if necessary)

Compound	Pendimethalin	P44 (M455H001)	P48 (M455H033)	2,6-dinitro-3,4-dimethylaniline (M455H032)	P36 (M455H029)	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	281.3	311.3	251.3	211.2	261.3	EFSA Journal 2016;14(3):4420
Saturated vapour pressure	3.34×10^{-3} (25°C)	-	1×10^{-10} (20°C)			Pendmethalin RAR Volume 3

Compound	**Pendimethalin**	**P44 (M455H001)**	**P48 (M455H033)**	**2,6-dinitro-3,4-dimethylaniline (M455H032)**	**P36 (M455H029)**	**Value in accordance to EU endpoint y/n/ Reference**
(Pa)						and EFSA Journal 2016;14(3):4420
Water solubility (mg/L)	0.330 (pH 7, 20°C)	100 (20°C)	100 (20°C)	100 (20°C)	100 (20°C)	EFSA Journal 2016;14(3):4420
Diffusion coefficient in water (m²/d)	4.3 x 10^{-5}	-	4.3 x 10^{-5}			default
Diffusion coefficient in air (m²/d)	0.43	-	0.43			default
K_{foc}/K_{fom} (mL/g)	12943/7508 (geomean, n = 9)	223.2/129.5 (Geomean, n = 5)	3173.2/1841 (Geomean, n = 5)	0	10000/5800	EFSA Journal 2016;14(3):4420
Freundlich Exponent 1/n	0.954 (arithmetic mean, n = 9)	-	1.0 (default)			
Plant Uptake	0	-	0			
Wash-Off factor from Crop (1/mm)	0.05 (MACRO) 0.50 (PRZM)	-	0.05 (MACRO) 0.50 (PRZM)			default
DT50,soil (d)	182.28 (geomean/median, normalisation to 10 kPa or pF2, 20 °C with Q10 of 2.58, n =5)	39.96 (geomean/median, normalisation to 10 kPa or pF2, 20 °C with Q10 of 2.58, n =4)	3.6 (worst case)	1	1000	EFSA Journal 2016;14(3):4420
DT50,water (d)	1000 (default)	1000 (no data)	1000 (default)	6.6*	1000 (default)	
DT50,sed (d)	31.8	1000 (no data)	19.7	1000 (default)	3.5	
DT50,whole system (d)	31.8 (geomean, n=6)	1000 (no data)	19.7 (geomean, n=2)	6.6*	3.5 (geomean, n=2)	
Maximum occurrence observed	Sed: 86.0	Soil: 6.9 Total system: 0.00001	Soil: 25.9 Water: 1.48 Sed: 10.61 Total system: 12.1	Soil: 0.00001 Water: 14.2 Total system: 14.2	Soil: 0.00001 Water: 2.03 Sed: 21.32 Total system: 23.4	

***From Direct photolysis study**

Table 8.9-17: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for Pendimethalin following single application of KONARK to winter cereals in pre-emergence

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	---	32.95	-	18.31	2850

Scenario FOCUS	**Waterbody**	**Max PEC$_{sw}$ (µg/L)**	**Dominant entry route**	**21 d- PEC$_{sw,twa}$ (µg/L)**	**Max PEC$_{sed}$ (µg/kg)**
Step 2					
Southern Europe	Oct-Feb	11.04	-	7.24	1190
Northern Europe		11.73		9.40	1470
Step 3					
D1	ditch	7.601	Drainage	1.541	15.70
D1	stream	6.732	Drainage	0.259	3.891
D2	ditch	7.705	Drainage	0.947	13.18
D2	stream	6.855	Drainage	0.800	11.61
D3	ditch	7.585	Drainage	0.266	4.012
D4	pond	0.263	Drainage	0.125	1.210
D4	stream	6.579	Drainage	0.087	1.375
D5	pond	0.263	Drainage	0.147	1.530
D5	stream	7.097	Drainage	0.124	1.947
D6	ditch	7.671	Drainage	1.312	15.83
R1	pond	0.267	Run off	0.168	3.223
R1	stream	5.001	Run off	0.085	10.36
R3	stream	6.943	Run off	0.216	408.3
R4	stream	5.032	Run off	0.140	3.823

Table 8.9-18: FOCUS Step 3 PEC$_{sw}$ and PEC$_{sed}$ for Pendimethalin following single application of KONARK to winter cereals in post-emergence BBCH 11

Scenario FOCUS	**Waterbody**	**Max PEC$_{sw}$ (µg/L)**	**Dominant entry route**	**21 d- PEC$_{sw,twa}$ (µg/L)**	**Max PEC$_{sed}$ (µg/kg)**
Step 3					
D1	ditch	7.601	Drainage	1.991	19.780
D1	stream	6.647	Drainage	0.267	4.021
D2	ditch	7.557	Drainage	0.876	12.380
D2	stream	3.132	Drainage	0.028	0.426
D3	ditch	7.487	Drainage	0.255	3.847
D4	pond	0.259	Drainage	0.133	1.333
D4	stream	6.496	Drainage	0.086	1.375
D5	pond	0.259	Drainage	0.147	1.530
D5	stream	7.008	Drainage	0.124	1.947
D6	ditch	7.575	Drainage	1.312	15.830

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	0.263	Run off	0.168	3.216
R1	stream	4.937	Run off	0.085	10.300
R3	stream	6.928	Run off	0.132	3.460
R4	stream	4.897	Run off	0.135	4.867

Table 8.9-19: FOCUS Step 3 PEC_{sw} and PEC_{sed} for Pendimethalin following single application of KONARK to winter cereals in post-emergence BBCH 21

Scenario FOCUS	**Waterbody**	**Max PEC_{sw} (µg/L)**	**Dominant entry route**	**21 d- $PEC_{sw,twa}$ (µg/L)**	**Max PEC_{sed} (µg/kg)**
Step 3					
D1	ditch	7.535	Drainage	0.567	7.782
D1	stream	5.859	Drainage	0.015	0.249
D2	ditch	7.567	Drainage	1.032	13.970
D2	stream	6.260	Drainage	0.037	0.595
D3	ditch	7.502	Drainage	0.306	4.535
D4	pond	0.259	Drainage	0.153	1.657
D4	stream	5.549	Drainage	0.010	0.164
D5	pond	0.259	Drainage	0.141	1.448
D5	stream	5.932	Drainage	0.010	0.162
D6	ditch	7.376	Drainage	0.111	1.719
R1	pond	0.260	Run off	0.135	1.569
R1	stream	4.946	Run off	0.068	4.676
R3	stream	6.948	Run off	0.118	3.284
R4	stream	4.968	Run off	0.138	3.735

Table 8.9-20: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for Pendimethalin following single application of KONARK to spring cereals in pre-emergence

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		32.95	-	18.31	2850
Step 2					
Southern Europe	Oct-Feb	11.04	-	7.24	1190
Northern Europe				4.13	628.56
Step 3					
D1	ditch	7.669	Drainage	1.147	14.69

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
D1	stream	6.398	Drainage	0.042	0.678
D3	ditch	7.599	Drainage	0.312	4.620
D4	pond	0.262	Drainage	0.151	1.542
D4	stream	5.805	Drainage	0.013	0.207
D5	pond	0.263	Drainage	0.141	1.449
D5	stream	6.028	Drainage	0.010	0.166
R1	pond	0.273	Run off	0.140	2.936
R1	stream	5.010	Run off	0.098	5.976
R4	stream	5.005	Run off	0.245	5.401

Table 8.9-21: FOCUS Step 3 PEC_{sw} and PEC_{sed} for Pendimethalin following single application of KONARK to spring cereals in post-emergence BBCH 11

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Step 3					
D1	ditch	7.550	Drainage	0.744	9.722
D1	stream	6.045	Drainage	0.021	0.343
D3	ditch	7.504	Drainage	0.312	4.620
D4	pond	0.259	Drainage	0.138	1.368
D4	stream	5.949	Drainage	0.018	0.290
D5	pond	0.259	Drainage	0.141	1.444
D5	stream	5.966	Drainage	0.010	0.169
R1	pond	0.268	Run off	0.140	2.643
R1	stream	4.946	Run off	0.088	5.286
R4	stream	4.941	Run off	0.244	5.386

Table 8.9-22: FOCUS Step 3 PEC_{sw} and PEC_{sed} for Pendimethalin following single application of KONARK to spring cereals in post-emergence BBCH 21

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Step 3					
D1	ditch	7.601	Drainage	1.474	15.360
D1	stream	6.647	Drainage	0.258	3.877
D3	ditch	7.509	Drainage	0.336	4.940
D4	pond	0.259	Drainage	0.119	1.134
D4	stream	6.143	Drainage	0.026	0.427
D5	pond	0.259	Drainage	0.141	1.444

Scenario FOCUS	**Waterbody**	**Max PEC_{sw} (µg/L)**	**Dominant entry route**	**21 d- $PEC_{sw,twa}$ (µg/L)**	**Max PEC_{sed} (µg/kg)**
D5	stream	5.966	Drainage	0.010	0.169
R1	pond	0.268	Run off	0.138	2.605
R1	stream	4.946	Run off	0.087	5.440
R4	stream	4.941	Run off	0.232	5.159

<u>Step 4 calculations</u>

As the PECSW values of Pendimethalin derived from FOCUS step 3 calculations indicated a possible risk for at least one aquatic species, a calculation of PECSW values based on higher tier modelling (FOCUS step 4) was necessary.

To evaluate the effect of risk mitigation measures on the predicted environmental concentration Pendimethalin in surface water, the effect of unsprayed buffer zone was investigated.

Step 4 PECsw were calculated using the SWAN program, version 5.0.0. Where necessary and applicable, the calculations were conducted with protective buffer zones for spray drift reduction. Where the contamination of surface water was dominated by run-off events, vegetated buffer zones for the reduction of run-off were introduced as recommended in the FOCUS landscape mitigation guidance document[7].

FOCUS (2005) recommends the use of the SWAN software to determine Step 4 PEC values using particular mitigation approaches. In the current work 5, 10, 15 and 20m spray drift buffer zones were specified with SWAN and this internally selected appropriate drift values from the FOCUS drift calculator plus nozzles. The run-off reduction was consistent with a vegetative buffer of 5, 10, 15 and 20m (by reducing mass of eroded sediment by 40, 85, 90 and 95% and mass of pesticide in water phase by 40, 60 70 and 80% for 5, 10, 15 and 20m respectively) plus nozzles.

As for Flufenacet, the dry deposition calculated by EVA 3 was applied to step 4 calculations for Pendimethalin using an interception of 25% as worst case although the interception considered for ground water according to EFSA Guidance 3662 and FOCUS Step 1/2 was 0. This interception value was chosen because sometimes is used as default for refinements on soil and ground water calculations, the dry deposition as worst results are given below.

[7] SANCO/10422/2005 version 1.0, May 2005 (p.30) and SANCO/10422/2005 version 2.0, Sept 2007(p. 32)

Table 8.9-23: EVA 3.0 rev 2h 29/09/2017 dry deposition calculations for Pendimethalin

		dist. (m)	1	5	10	15	20
	v/d per h	v/d in 24 h					
time (h)	arable crop	no dissip.	0.074%	0.059%	0.045%	0.034%	0.026%
0 - 1	9.09%		0.0080	0.0064	0.0049	0.0037	0.0028
1 - 2	9.09%		0.0080	0.0064	0.0049	0.0037	0.0028
2 - 3	9.09%		0.0080	0.0064	0.0049	0.0037	0.0028
3 - 4	9.09%		0.0080	0.0064	0.0049	0.0037	0.0028
4 - 5	4.55%		0.0040	0.0032	0.0025	0.0019	0.0014
5 - 6	4.55%		0.0040	0.0032	0.0025	0.0019	0.0014
6 - 7	4.55%		0.0040	0.0032	0.0025	0.0019	0.0014
7 - 8	4.55%		0.0040	0.0032	0.0025	0.0019	0.0014
8 - 9	4.55%		0.0040	0.0032	0.0025	0.0019	0.0014
9 - 10	4.55%		0.0040	0.0032	0.0025	0.0019	0.0014
10 - 11	4.55%		0.0040	0.0032	0.0025	0.0019	0.0014
11 - 12	4.55%		0.0040	0.0032	0.0025	0.0019	0.0014
12 - 13	2.27%		0.0020	0.0016	0.0012	0.0009	0.0007
13 - 14	2.27%		0.0020	0.0016	0.0012	0.0009	0.0007
14 - 15	2.27%		0.0020	0.0016	0.0012	0.0009	0.0007
15 - 16	2.27%		0.0020	0.0016	0.0012	0.0009	0.0007
16 - 17	2.27%		0.0020	0.0016	0.0012	0.0009	0.0007
17 - 18	2.27%		0.0020	0.0016	0.0012	0.0009	0.0007
18 - 19	2.27%		0.0020	0.0016	0.0012	0.0009	0.0007
19 - 20	2.27%		0.0020	0.0016	0.0012	0.0009	0.0007
20 - 21	2.27%		0.0020	0.0016	0.0012	0.0009	0.0007
21 - 22	2.27%		0.0020	0.0016	0.0012	0.0009	0.0007
22 - 23	2.27%		0.0020	0.0016	0.0012	0.0009	0.0007
23 - 24	2.27%		0.0020	0.0016	0.0012	0.0009	0.0007
0 - 24	100.00%		0.0882	0.0709	0.0540	0.0411	0.0313

Table 8.9-24: **Global maximum PEC_{sw} values for Pendimethalin, following single application of KONARK to winter cereals in pre-emergence according to the ~~south~~ central EU zone GAP according to surface water Step 4**

PEC_{sw} (µg/L)	**Scenario**	**STEP 4 Pendimethalin**							
Nozzle reduction	Vegetative strip (m)	None				5*	10	15*	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
None	D1 ditch	2.087	1.112	0.764	0.573	-	-	-	-
50%		1.072	0.599	0.412	0.312	-	-	-	-
75%		0.607	0.354	0.252	0.191	-	-	-	-
90%		0.346	0.228	0.166	-	-	-	-	-
None	D1 stream	2.462	1.307	0.893	0.669	-	-	-	-
50%		1.233	0.654	0.441	0.335	-	-	-	-
75%		0.618	0.324	0.224	0.170	-	-	-	-
90%		0.288	0.188	-	-	-	-	-	-
None	D2 ditch	2.089	1.116	0.767	0.575	-	-	-	-
50%		1.076	0.603	0.415	0.314	-	-	-	-
75%		0.611	0.358	0.255	0.219	-	-	-	-
90%		0.350	0.230	0.219	-	-	-	-	-
None	D2 stream	2.507	1.330	0.909	0.682	-	-	-	-
50%		1.255	0.666	0.449	0.342	-	-	-	-
75%		0.629	0.329	0.225	0.171	-	-	-	-
90%		0.250	0.142	-	-	-	-	-	-
None	D3 ditch	2.056	1.091	0.745	0.559	-	-	-	-
50%		1.028	0.545	0.370	0.281	-	-	-	-
75%		0.533	0.298	0.209	0.158	-	-	-	-
90%		0.271	0.175	-	-	-	-	-	-
None	D4 pond	0.238	0.172	-	-	-	-	-	-
50%		0.134	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	2.407	1.277	0.873	0.655	-	-	-	-
50%		1.205	0.647	0.439	0.334	-	-	-	-
75%		0.626	0.340	0.235	0.197	-	-	-	-
90%		0.282	0.197	0.197	-	-	-	-	-
None	D5 pond	0.242	0.175	-	-	-	-	-	-
50%		0.137	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-

PEC_{sw} (µg/L)	**Scenario**	**STEP 4 Pendimethalin**							
Nozzle reduction	Vegetative strip (m)	None				5*	10	15*	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
90%		-	-	-	-	-	-	-	-
None	D5 stream	2.596	1.378	0.941	~~0.716~~ 0.706	-	-	-	-
50%		1.300	0.693	0.475	0.356	-	-	-	-
75%		0.667	0.362	0.250	0.190	-	-	-	-
90%		0.306	0.184	0.131	-	-	-	-	-
None	D6 ditch	2.080	1.115	0.766	0.575	-	-	-	-
50%		1.075	0.597	0.417	0.322	-	-	-	-
75%		0.613	0.362	0.322	0.322	-	-	-	-
90%		0.353	0.322	0.322	-	-	-	-	-
None	R1 pond	0.263	0.253	0.248	0.244	0.246	0.178	-	-
50%		0.248	0.242	0.239	0.237	0.158	-	-	-
75%		0.240	0.237	0.235	-	-	-	-	-
90%		0.236	0.234	0.232	-	-	-	-	-
None	R1 stream	1.864	1.366	1.366	-	1.864	1.000	0.686	0.522
50%		1.366	1.366	-	-	0.956	0.617	0.467	0.318
75%		1.366	-	-	-	0.886	0.609	0.467	0.318
90%		-	-	-	-	0.874	0.609	-	-
None	R3 stream	2.574	1.380	1.324	-	2.574	1.380	0.946	0.720
50%		1.324	1.324	-	-	1.319	0.715	~~0.492~~ 0.485	0.369
75%		1.324	-	-	-	0.854	0.596	0.458	0.313
90%		-	-	-	-	0.854	0.596	0.458	0.313
None	R4 stream	1.866	1.672	1.672	-	1.866	1.004	0.689	0.524
50%		1.672	1.672	-	-	1.086	0.755	0.570	0.389
75%		1.672	-	-	-	1.086	0.744	0.570	0.389
90%		-	-	-	-	1.071	0.744	-	-

***0.4 for Fractional reduction in run-off volume and flux and Fractional reduction in erosion mass and flux were used for strip vegetative simulation, according to the Austrian Environmental Agency AGES.**
****0.7 and 09 for Fractional reduction in run-off volume and flux and Fractional reduction in erosion mass and flux were respectively used for strip vegetative simulation, according to the Austrian Environmental Agency AGES.**

Table 8.9-25: Global maximum PEC_{sw} values for Pendimethalin, following single application of KONARK to winter cereals in pre-emergence according to the central EU zone GAP according to surface water VFSMOD Step 4

PEC_{sw} (µg/L)	Scenario	VFSMOD STEP 4 Pendimethalin		
Nozzle reduction	Vegetative strip (m)	10	15	20
	No spray buffer (m)	10	15	20
50 %	R1 stream	-	-	0.268
75 %		0.278	0.193	0.147
90 %		0.139	-	-
50 %	R3 stream	-	-	-
75 %		0.470	0.377	0.297
90 %		0.471	0.377	0.297
50 %	R4 stream	-	-	0.271
75 %		0.280	0.195	0.148
90 %		0.149	-	-

Table 8.9-26: Global maximum PEC_{sw} values for Pendimethalin, following single application of KONARK to winter cereals in post-emergence (BBCH 11) according to the central EU zone GAP according to surface water Step 4

PEC_{sw} (µg/L)	Scenario	STEP 4 Pendimethalin							
Nozzle reduction	Vegetative strip (m)	None				5*	10	15*	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
None	D1 ditch	2.059	1.110	0.763	0.580	-	-	-	-
50%		1.077	0.608	0.424	0.321	-	-	-	-
75%		0.615	0.372	0.265	0.201	-	-	-	-
90%		0.363	0.239	0.174	-	-	-	-	-
None	D1 stream	2.430	1.289	0.880	0.669	-	-	-	-
50%		1.216	0.645	0.441	0.335	-	-	-	-
75%		0.609	0.331	0.231	0.176	-	-	-	-
90%		0.299	0.196	0.143	-	-	-	-	-
None	D2 ditch	2.047	1.085	0.741	0.564	-	-	-	-
50%		1.038	0.574	0.400	0.303	-	-	-	-
75%		0.581	0.345	0.244	0.195	-	-	-	-
90%		0.336	0.226	0.195	-	-	-	-	-

PEC_{sw} (µg/L)	**Scenario**	**STEP 4 Pendimethalin**							
Nozzle reduction	Vegetative strip (m)	None				5*	10	15*	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
None	D2 stream	2.273	1.213	0.830	0.632	-	-	-	-
50%		1.154	0.620	0.425	0.323	-	-	-	-
75%		0.594	0.323	0.222	0.169	-	-	-	-
90%		0.259	0.148	-	-	-	-	-	-
None	D3 ditch	2.028	1.075	0.734	0.559	-	-	-	-
50%		1.014	0.537	0.368	0.280	-	-	-	-
75%		0.524	0.297	0.207	0.157	-	-	-	-
90%		0.267	0.172	-	-	-	-	-	-
None	D4 pond	0.238	0.172	-	-	-	-	-	-
50%		0.134	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	2.375	1.260	0.861	0.655	-	-	-	-
50%		1.189	0.368	0.439	0.334	-	-	-	-
75%		0.617	0.340	0.235	0.182	-	-	-	-
90%		0.282	0.182	0.182	-	-	-	-	-
None	D5 pond	0.242	0.175	-	-	-	-	-	-
50%		0.137	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D5 stream	2.562	1.359	0.928	0.706	-	-	-	-
50%		1.282	0.683	0.468	0.356	-	-	-	-
75%		0.658	0.362	0.250	0.190	-	-	-	-
90%		0.306	0.184	0.131	-	-	-	-	-
None	D6 ditch	2.052	1.100	0.756	0.575	-	-	-	-
50%		1.060	0.597	0.417	0.326	-	-	-	-
75%		0.605	0.362	0.326	0.326	-	-	-	-
90%		0.353	0.326	0.326	-	-	-	-	-
None	R1 pond	0.262	0.252	0.247	0.244	0.246	0.178	-	-
50%		0.247	0.242	0.239	0.237	0.157	-	-	-
75%		0.240	0.236	0.234	0.233	-	-	-	-
90%		0.235	0.233	0.232	0.231	-	-	-	-
None	R1 stream	1.839	1.343	1.343	-	1.839	0.986	0.676	0.514

PEC_{sw} (µg/L)	**Scenario**	**STEP 4 Pendimethalin**							
Nozzle reduction	Vegetative strip (m)	None				5*	10	15*	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
50%		1.343	1.343	-	-	0.943	0.607	0.466	0.318
75%		1.343	-	-	-	0.872	0.607	0.466	0.318
90%		-	-	-	-	0.872	-	-	-
None	R3 stream	2.553	1.370	1.179	1.179	2.553	1.370	0.939	0.714
50%		1.312	1.179	1.179	-	1.311	0.712	0.490	0.373
75%		1.179	1.179	-	-	0.762	0.530	0.406	0.277
90%		1.179	-	-	-	0.762	0.530	0.406	0.277
None	R4 stream	1.825	1.740	1.740	-	1.825	0.979	0.671	0.510
50%		1.740	1.740	-	-	1.130	0.785	0.601	0.410
75%		1.740	-	-	-	1.130	0.785	0.601	0.410
90%		-	-	-	-	-	-	-	-

***0.4 for Fractional reduction in run-off volume and flux and Fractional reduction in erosion mass and flux were used for strip vegetative simulation, according to the Austrian Environmental Agency AGES.**
****0.7 and 09 for Fractional reduction in run-off volume and flux and Fractional reduction in erosion mass and flux were respectively used for strip vegetative simulation, according to the Austrian Environmental Agency AGES.**

Table 8.9-27: Global maximum PEC_{sw} values for Pendimethalin, following single application of KONARK to winter cereals in post-emergence (BBCH 11) according to the central EU zone GAP according to surface water <u>VFSMOD Step 4</u>

PEC_{sw} (µg/L)	**Scenario**	**VFSMOD STEP 4 Pendimethalin**		
Nozzle reduction	Vegetative strip (m)	10	15	20
	No spray buffer (m)	10	15	20
50 %	R1 stream	-	-	0.268
75 %		0.278	0.193	0.147
90 %		0.139	-	-
50 %	R3 stream	-	-	0.373
75 %		0.383	0.265	0.202
90 %		0.195	-	-
50 %	R4 stream	-	-	0.266
75 %		0.273	0.189	0.144
90 %		0.147	-	-

Table 8.9-28: Global maximum PEC_{sw} values for Pendimethalin, following single application of KONARK to winter cereals in post-emergence (BBCH 21) according to the central EU zone GAP according to surface water Step 4

PEC_{sw} (µg/L)	**Scenario**	**STEP 4 Pendimethalin**							
Nozzle reduction	Vegetative strip (m)	None				5*	10	15*	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
None	D1 ditch	2.041	1.082	0.739	0.562	-	-	-	-
50%		1.027	0.564	0.390	0.296	-	-	-	-
75%		0.566	0.336	0.238	0.180	-	-	-	-
90%		0.315	0.208	0.150	-	-	-	-	-
None	D1 stream	2.166	1.155	0.790	0.601	-	-	-	-
50%		1.096	0.588	0.403	0.306	-	-	-	-
75%		0.561	0.304	0.209	0.159	-	-	-	-
90%		0.241	0.134	-	-	-	-	-	-
None	D2 ditch	2.050	1.089	0.748	0.569	-	-	-	-
50%		1.050	0.585	0.408	0.309	-	-	-	-
75%		0.592	0.351	0.250	0.189	-	-	-	-
90%		0.343	0.226	0.165	-	-	-	-	-
None	D2 stream	2.314	1.233	0.844	0.642	-	-	-	-
50%		1.175	0.634	0.436	0.332	-	-	-	-
75%		0.611	0.335	0.232	0.176	-	-	-	-
90%		0.273	0.156	0.109	-	-	-	-	-
None	D3 ditch	2.032	1.077	0.736	0.560	-	-	-	-
50%		1.016	0.540	0.373	0.284	-	-	-	-
75%		0.531	0.302	0.213	0.161	-	-	-	-
90%		0.281	0.182	-	-	-	-	-	-
None	D4 pond	0.243	0.176	-	-	-	-	-	-
50%		0.138	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	2.045	1.088	0.744	0.566	-	-	-	-
50%		1.031	0.551	0.377	0.287	-	-	-	-
75%		0.525	0.283	0.194	0.147	-	-	-	-
90%		0.221	0.121	-	-	-	-	-	-
None	D5 pond	0.240	0.174	-	-	-	-	-	-
50%		0.136	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-

PEC_{sw} (µg/L)	**Scenario**	**STEP 4 Pendimethalin**							
Nozzle reduction	Vegetative strip (m)	None				5*	10	15*	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
90%		-	-	-	-	-	-	-	-
None	D5 stream	2.184	1.162	0.795	0.604	-	-	-	-
50%		1.101	0.588	0.403	0.306	-	-	-	-
75%		0.559	0.301	0.206	0.157	-	-	-	-
90%		0.234	0.129	-	-	-	-	-	-
None	D6 ditch	1.998	1.059	0.723	0.550	-	-	-	-
50%		0.999	0.529	0.362	0.298	-	-	-	-
75%		0.499	0.298	0.298	0.298	-	-	-	-
90%		0.298	0.298	0.298	-	-	-	-	-
None	R1 pond	0.243	0.176	-	-	-	-	-	-
50%		0.138	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	1.839	0.986	0.830	-	1.839	0.986	0.676	0.514
50%		0.942	0.830	-	-	0.942	0.513	0.354	0.269
75%		0.830	0.830	-	-	0.541	0.377	0.289	0.197
90%		0.830	-	-	-	0.541	0.377	0.289	-
None	R3 stream	2.552	1.366	0.936	0.918	2.552	1.365	0.936	0.712
50%		1.305	0.918	0.918	-	1.305	0.707	0.486	0.370
75%		0.918	0.918	-	-	0.686	0.412	0.316	0.215
90%		0.918	-	-	-	0.594	0.412	0.316	-
None	R4 stream	1.841	1.639	1.639	-	1.841	0.990	0.679	0.516
50%		1.639	1.639	-	-	1.064	0.740	0.567	0.386
75%		1.639	-	-	-	1.064	0.740	0.567	0.386
90%		-	-	-	-	-	-	-	-

***0.4 for Fractional reduction in run-off volume and flux and Fractional reduction in erosion mass and flux were used for strip vegetative simulation, according to the Austrian Environmental Agency AGES.**
****0.7 and 09 for Fractional reduction in run-off volume and flux and Fractional reduction in erosion mass and flux were respectively used for strip vegetative simulation, according to the Austrian Environmental Agency AGES.**

Table 8.9-29: Global maximum PEC_{sw} values for Pendimethalin, following single application of KONARK to winter cereals in post-emergence (BBCH 21) according to the central EU zone GAP according to surface water VFSMOD Step 4

PEC_{sw} (µg/L)	Scenario	VFSMOD STEP 4 Pendimethalin		
Nozzle reduction	Vegetative strip (m)	10	15	20
	No spray buffer (m)	10	15	20
50 %	R1 stream	-	-	0.269
75 %		0.279	0.194	0.148
90 %		0.140	-	-
50 %	R3 stream	-	-	0.370
75 %		0.384	0.267	0.203
90 %		0.194	-	-
50 %	R4 stream	-	-	0.271
75 %		0.281	0.195	0.148
90 %		0.145	-	-

Table 8.9-30: Global maximum PEC_{sw} values for Pendimethalin, following single application of KONARK to spring cereals in pre-emergence according to the ~~south~~ central EU zone GAP according to surface water Step 4

PEC_{sw} (µg/L)	Scenario	STEP 4 Pendimethalin							
Nozzle Reduction	Vegetative strip (m)	None				5*	10	15*	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
None	D1 ditch	2.079	1.112	0.764	0.573	-	-	-	-
50%		1.072	0.602	0.414	0.314	-	-	-	-
75%		0.610	0.359	0.256	0.194	-	-	-	-
90%		0.351	0.231	0.168	-	-	-	-	-
None	D1 stream	2.360	1.263	0.865	0.649	-	-	-	-
50%		1.204	0.650	0.440	0.335	-	-	-	-
75%		0.626	0.338	0.233	0.177	-	-	-	-
90%		0.274	0.156	0.109	-				
None	D3 ditch	2.060	1.093	0.746	0.560	-	-	-	-
50%		1.030	0.549	0.374	0.284	-	-	-	-
75%		0.540	0.303	0.214	0.162	-	-	-	-
90%		0.283	0.183	-	-	-	-	-	-

PECsw (µg/L)	**Scenario**	**STEP 4 Pendimethalin**							
Nozzle Reduction	Vegetative strip (m)	None				5*	10	15*	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
None	D4 pond	0.243	0.176	-	-	-	-	-	-
50%		0.138	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	2.144	1.143	0.782	0.586	-	-	-	-
50%		1.084	0.580	0.392	0.298	-	-	-	-
75%		0.554	0.295	0.203	0.154	-	-	-	-
90%		0.232	0.143	-	-	-	-	-	-
None	D5 pond	0.240	0.174	-	-	-	-	-	-
50%		0.136	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D5 stream	2.221	1.183	0.809	0.607	-	-	-	-
50%		1.120	0.599	0.404	0.307	-	-	-	-
75%		0.570	0.302	0.207	0.158	-	-	-	-
90%		0.236	0.129	-	-	-	-	-	-
None	R1 pond	0.251	0.200	-	-	-	-	-	-
50%		0.200	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	1.864	1.288	1.288	-	1.864	0.848	0.676	0.514
50%		1.288	1.288	-	-	0.955	0.577	0.442	0.302
75%		1.288	-	-	-	0.840	0.577	0.442	0.302
90%		-	-	-	-	0.828	-	-	-
None	R4 stream	1.863	1.569	1.569	-	1.863	0.999	0.685	0.521
50%		1.569	1.569	-	-	1.024	0.714	0.540	0.369
75%		1.569	-	-	-	1.010	0.704	0.540	0.369
90%		-	-	-	-	1.010	0.704	-	-

***0.4 for Fractional reduction in run-off volume and flux and Fractional reduction in erosion mass and flux were used for strip vegetative simulation, according to the Austrian Environmental Agency AGES.**
****0.7 and 09 for Fractional reduction in run-off volume and flux and Fractional reduction in erosion mass and flux were respectively used for strip vegetative simulation, according to the Austrian Environmental Agency AGES.**

Table 8.9-31: Global maximum PEC$_{sw}$ values for Pendimethalin, following single application of KONARK to spring cereals in pre-emergence according to the central EU zone GAP according to surface water VFSMOD Step 4

PEC$_{sw}$ (µg/L)	Scenario	VFSMOD STEP 4 Pendimethalin		
Nozzle reduction	Vegetative strip (m)	10	15	20
	No spray buffer (m)	10	15	20
50 %	R1 stream	-	-	0.473
75 %		0.473	0.473	-
90 %		0.473	-	-
50 %	R4 stream	0.511	0.352	0.268
75 %		0.279	0.194	0.147
90 %		0.268	-	-

Table 8.9-32: Global maximum PEC$_{sw}$ values for Pendimethalin, following single application of KONARK to spring cereals in post-emergence (BBCH 11) according to the central EU zone GAP according to surface water Step 4

PEC$_{sw}$ (µg/L)	Scenario	STEP 4 Pendimethalin							
Nozzle Reduction	Vegetative strip (m)	None				5*	10	15*	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
None	D1 ditch	2.045	1.084	0.740	0.563	-	-	-	-
50%		1.029	0.565	0.392	0.297	-	-	-	-
75%		0.568	0.337	0.239	0.180	-	-	-	-
90%		0.319	0.211	0.154	-	-	-	-	-
None	D1 stream	2.240	1.195	0.818	0.622	-	-	-	-
50%		1.136	0.610	0.418	0.318	-	-	-	-
75%		0.584	0.317	0.219	0.166	-	-	-	-
90%		0.253	0.142	-	-	-	-	-	-
None	D3 ditch	2.033	1.078	0.736	0.560	-	-	-	-
50%		1.016	0.541	0.374	0.284	-	-	-	-
75%		0.532	0.303	0.214	0.162	-	-	-	-
90%		0.283	0.183	-	-	-	-	-	-
None	D4 pond	0.243	0.176	-	-	-	-	-	-
50%		0.138	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-

PEC_{sw} (µg/L)	**Scenario**	**STEP 4 Pendimethalin**							
Nozzle Reduction	Vegetative strip (m)	None				5*	10	15*	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
90%		-	-	-	-	-	-	-	-
None	D4 stream	2.202	1.175	0.804	0.611	-	-	-	-
50%		1.116	0.599	0.411	0.312	-	-	-	-
75%		0.573	0.311	0.214	0.163	-	-	-	-
90%		0.247	0.138	-	-	-	-	-	-
None	D5 pond	0.240	0.174	-	-	-	-	-	-
50%		0.136	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D5 stream	2.197	1.169	0.799	0.608	-	-	-	-
50%		1.108	0.592	0.405	0.308	-	-	-	-
75%		0.563	0.303	0.208	0.158	-	-	-	-
90%		0.236	0.130	-	-	-	-	-	-
None	R1 pond	0.250	0.184	-	-	-	-	-	-
50%		0.180	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	1.839	1.132	1.132	-	1.839	0.986	0.676	0.514
50%		1.132	1.132	-	-	0.942	0.514	0.394	0.269
75%		1.132	-	-	-	0.738	0.514	0.394	0.269
90%		-	-	-	-	0.738	-	-	-
None	R4 stream	1.838	1.544	1.544	-	1.838	0.986	0.676	0.514
50%		1.544	1.544	-	-	1.007	0.702	0.539	0.368
75%		1.544	-	-	-	1.007	0.702	0.539	0.368
90%		-	-	-	-	-		-	-

***0.4 for Fractional reduction in run-off volume and flux and Fractional reduction in erosion mass and flux were used for strip vegetative simulation, according to the Austrian Environmental Agency AGES.**
****0.7 and 09 for Fractional reduction in run-off volume and flux and Fractional reduction in erosion mass and flux were respectively used for strip vegetative simulation, according to the Austrian Environmental Agency AGES.**

Table 8.9-33: Global maximum PEC_{sw} values for Pendimethalin, following single application of KONARK to spring cereals in post-emergence (BBCH 11) according to the central EU zone GAP according to surface water VFSMOD Step 4

PEC_{sw} (µg/L)	Scenario	VFSMOD STEP 4 Pendimethalin		
Nozzle reduction	Vegetative strip (m)	10	15	20
	No spray buffer (m)	10	15	20
50 %	R1 stream	-	-	0.425
75 %		0.425	0.425	0.425
90 %		0.425	-	-
50 %	R4 stream	-	-	0.268
75 %		0.279	0.194	0.147
90 %		0.215	-	-

Table 8.9-34: Global maximum PEC_{sw} values for Pendimethalin, following single application of KONARK to spring cereals in post-emergence (BBCH 21) according to the central EU zone GAP according to surface water Step 4

PEC_{sw} (µg/L)	Scenario	STEP 4 Pendimethalin							
Nozzle Reduction	Vegetative strip (m)	None				5*	10	15*	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
None	D1 ditch	2.059	1.095	0.753	0.572	-	-	-	-
50%		1.056	0.589	0.411	0.311	-	-	-	-
75%		0.596	0.353	0.251	0.190	-	-	-	-
90%		0.344	0.227	0.165	-	-	-	-	-
None	D1 stream	2.430	1.289	0.880	0.669	-	-	-	-
50%		1.216	0.645	0.441	0.335	-	-	-	-
75%		0.609	0.324	0.224	0.170	-	-	-	-
90%		0.287	0.187	-	-	-	-	-	-
None	D3 ditch	2.034	1.078	0.736	0.560	-	-	-	-
50%		1.017	0.544	0.376	0.286	-	-	-	-
75%		0.535	0.307	0.217	0.164	-	-	-	-
90%		0.287	0.186	-	-	-	-	-	-
None	D4 pond	0.239	0.173	-	-	-	-	-	-
50%		0.135	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-

PEC_{sw} (µg/L)	**Scenario**	**STEP 4 Pendimethalin**							
Nozzle Reduction	Vegetative strip (m)	None				5*	10	15*	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
90%		-	-	-	-	-	-	-	-
None	D4 stream	2.277	1.215	0.831	0.632	-	-	-	-
50%		1.155	0.620	0.425	0.324	-	-	-	-
75%		0.594	0.323	0.222	0.169	-	-	-	-
90%		0.260	0.148	-	-	-	-	-	-
None	D5 pond	0.240	0.174	-	-	-	-	-	-
50%		0.136	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D5 stream	2.197	1.169	0.799	0.608	-	-	-	-
50%		1.108	0.592	0.405	0.308	-	-	-	-
75%		0.563	0.303	0.208	0.158	-	-	-	-
90%		0.236	0.130	-	-	-	-	-	-
None	R1 pond	0.250	0.183	-	-	-	-	-	-
50%		0.177	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	1.839	1.118	1.118	-	1.839	0.986	0.676	0.514
50%		1.118	1.118	-	-	0.942	0.513	0.389	0.269
75%		1.118	-	-	-	0.729	0.507	0.389	0.266
90%		-	-	-	-	0.729	0.507	-	-
None	R4 stream	1.838	1.470	1.470	-	1.838	0.986	0.676	0.514
50%		1.470	1.470	-	-	0.959	0.668	0.513	0.350
75%		1.470	-	-	-	0.959	0.668	0.513	0.350
90%		-	-	-	-	-	-	-	-

***0.4 for Fractional reduction in run-off volume and flux and Fractional reduction in erosion mass and flux were used for strip vegetative simulation, according to the Austrian Environmental Agency AGES.**
****0.7 and 09 for Fractional reduction in run-off volume and flux and Fractional reduction in erosion mass and flux were respectively used for strip vegetative simulation, according to the Austrian Environmental Agency AGES.**

Table 8.9-35: Global maximum PEC_{sw} values for Pendimethalin, following single application of KONARK to spring cereals in post-emergence (BBCH 21) according to the central EU zone GAP according to surface water VFSMOD Step 4

PEC_{sw} (µg/L)	Scenario	VFSMOD STEP 4 Pendimethalin		
Nozzle reduction	Vegetative strip (m)	10	15	20
	No spray buffer (m)	10	15	20
50 %	R1 stream	-	-	0.419
75 %		0.419	0.419	0.419
90 %		0.419	-	-
50 %	R4 stream	-	-	0.268
75 %		0.279	0.194	0.147
90 %		0.203	-	-

Metabolites of Pendimethalin

Table 8.9-36: FOCUS Steps 1 and 2 PEC_{sw} and PEC_{sed} for M455H001 following single application to winter cereals in pre-emergence

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	---	23.54	-	23.37	52.54
Step 2					
Southern Europe	Oct-Feb March-May	8.78	-	8.72	19.61
Northern Europe		10.98		10.98	24.51

Table 8.9-37: FOCUS Steps 1 and 2 PEC_{sw} and PEC_{sed} for M455H001 following single application to spring cereals in pre-emergence

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	---	23.54	-	23.37	52.54
Step 2					
Southern Europe	March-May	8.78	-	8.72	19.61
Northern Europe		4.39		4.36	9.80

Table 8.9-38: FOCUS Steps 1, 2 and 3 PEC_{sw} and PEC_{sed} for M455H033 following single application to winter cereals in pre-emergence

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	---	27.15	-	18.54	823.73
Step 2					
Southern Europe	Oct-Feb	6.83	-	5.21	213.20
Northern Europe		8.46		6.48	265.02
Step 3					
D1	ditch	0.015	Drainage	0.015	0.204
D1	stream	<0.001	Drainage	<0.001	0.017
D2	ditch	0.009	Drainage	0.001	0.064
D2	stream	0.006	Drainage	<0.001	0.050

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
D3	ditch	<0.001	Drainage	<0.001	0.015
D4	pond	0.002	Drainage	0.002	0.023
D4	stream	0.008	Drainage	<0.001	0.009
D5	pond	0.001	Drainage	0.001	0.021
D5	stream	0.002	Drainage	<0.001	0.007
D6	ditch	0.018	Drainage	0.001	0.094
R1	pond	0.005	Run off	0.005	0.087
R1	stream	0.023	Run off	0.001	0.223
R3	stream	0.018	Run off	0.002	7.977
R4	stream	0.032	Run off	0.002	0.092

Table 8.9-39: FOCUS Steps 1, 2 and 3 PEC_{sw} and PEC_{sed} for M455H033 following single application to spring cereals in pre-emergence

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	---	27.15	-	18.54	823.73
Step 2					
Southern Europe	Oct-Feb	6.83	-	5.21	213.20
Northern Europe	Oct-Feb	3.56	-	2.69	109.55
Step 3					
D1	ditch	0.005	Drainage	0.005	0.112
D1	stream	<0.001	Drainage	<0.001	0.003
D3	ditch	<0.001	Drainage	<0.001	0.026
D4	pond	0.001	Drainage	0.001	0.024
D4	stream	0.006	Drainage	<0.001	0.003
D5	pond	0.001	Drainage	0.001	0.023
D5	stream	0.001	Drainage	<0.001	0.001
R1	pond	0.009	Run off	0.008	0.114
R1	stream	0.027	Run off	0.002	0.165
R4	stream	0.031	Run off	0.005	0.124

Table 8.9-40: FOCUS Steps 1, 2 and 3 PEC_{sw} and PEC_{sed} for M455H029 following single application to winter cereals in pre-emergence

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	---	8.46	-	1.53	606.59
Step 2					
Southern Europe	Oct-Feb	2.58	-	0.75	247.31
Northern Europe		3.18		0.93	307.06
Step 3					
D1	ditch	0.011	Drainage	0.011	0.221
D1	stream	<0.001	Drainage	<0.001	0.034
D2	ditch	0.002	Drainage	0.001	0.120
D2	stream	0.001	Drainage	<0.001	0.099
D3	ditch	<0.001	Drainage	<0.001	0.029
D4	pond	0.001	Drainage	0.001	0.019
D4	stream	<0.001	Drainage	<0.001	0.012
D5	pond	0.001	Drainage	0.001	0.022
D5	stream	<0.001	Drainage	<0.001	0.014
D6	ditch	0.003	Drainage	0.001	0.152
R1	pond	0.001	Run off	0.001	0.055
R1	stream	<0.001	Run off	<0.001	0.160
R3	stream	0.001	Run off	0.001	6.051
R4	stream	<0.001	Run off	<0.001	0.061

Table 8.9-41: FOCUS Steps 1, 2 and 3 PEC_{sw} and PEC_{sed} for M455H029 following single application to spring cereals in pre-emergence

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	---	8.46	-	1.53	606.59
Step 2					
Southern Europe	Oct-Feb	2.58	-	0.75	247.31
Northern Europe		2.40		0.55	127.83
Step 3					
D1	ditch	0.002	Drainage	0.002	0.131
D1	stream	<0.001	Drainage	<0.001	0.005

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
D3	ditch	<0.001	Drainage	<0.001	0.036
D4	pond	0.001	Drainage	0.001	0.023
D4	stream	<0.001	Drainage	<0.001	0.001
D5	pond	0.001	Drainage	0.001	0.021
D5	stream	<0.001	Drainage	<0.001	0.001
R1	pond	0.001	Run off	0.001	0.048
R1	stream	<0.001	Run off	<0.001	0.102
R4	stream	<0.001	Run off	<0.001	0.087

Table 8.9-42: FOCUS Steps 1, 2 and 3 PEC_{sw} and PEC_{sed} for M455H032 following single application to winter cereals in pre-emergence

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	---	43.82	-	17.68	<0.01
Step 2					
Southern Europe	Oct-Feb	17.57	-	7.10	<0.01
Northern Europe	Oct-Feb	21.77	-	8.79	<0.01
Step 3					
D1	ditch	0.001	Drainage	0.001	<0.001
D1	stream	0.001	Drainage	<0.001	<0.001
D2	ditch	0.001	Drainage	<0.001	<0.001
D2	stream	0.001	Drainage	<0.001	<0.001
D3	ditch	<0.001	Drainage	<0.001	<0.001
D4	pond	<0.001	Drainage	<0.001	<0.001
D4	stream	<0.001	Drainage	<0.001	<0.001
D5	pond	<0.001	Drainage	<0.001	<0.001
D5	stream	<0.001	Drainage	<0.001	<0.001
D6	ditch	<0.001	Drainage	<0.001	<0.001
R1	pond	<0.001	Run off	<0.001	<0.001
R1	stream	<0.001	Run off	<0.001	<0.001
R3	stream	<0.001	Run off	<0.001	<0.001
R4	stream	<0.001	Run off	<0.001	<0.001

Table 8.9-43: FOCUS Steps 1, 2 and 3 PEC_{sw} and PEC_{sed} for M455H032 following single application to spring cereals in pre-emergence

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	---	43.82	-	17.68	<0.01
Step 2					
Southern Europe	Oct-Feb	17.57	-	7.10	<0.01
Northern Europe		9.17		3.70	
Step 3					
D1	ditch	<0.001	Drainage	<0.001	<0.001
D1	stream	<0.001	Drainage	<0.001	<0.001
D3	ditch	<0.001	Drainage	<0.001	<0.001
D4	pond	<0.001	Drainage	<0.001	<0.001
D4	stream	<0.001	Drainage	<0.001	<0.001
D5	pond	<0.001	Drainage	<0.001	<0.001
D5	stream	<0.001	Drainage	<0.001	<0.001
R1	pond	<0.001	Run off	<0.001	<0.001
R1	stream	<0.001	Run off	<0.001	<0.001
R4	stream	<0.001	Run off	<0.001	<0.001

8.9.2.3 $PEC_{sw/sed}$ of KONARK

The calculations used to estimate the maximum PEC_{sw} of KONARK on cereals are:

KONARK density = 0.9886 g/mL
Application rate = 4000 mL/ha

$$PEC_{sw/sed}\,(\mu g/L) = \frac{\%Drift_{90^{th}\%ile} \times \text{Application rate (g/ha)}}{\text{Water depth (base value: 30cm)} \times 10}$$

Where:

$\%Drift_{90^{th}\%ile}$ = 1.9274 (according to FOCUS Swash Drift Calculator v1.1)
Application rate = 3954.4 g/ha

The maximum PEC_{sw} of KONARK is equal to 25.406 µg/L.

Table 8.9-30: Mitigation measures for KONARK following single application to cereals pre-emergence according to FOCUS Swash Drift Calculator v1.1

Distance (m)	PECsw (µg/L)	Nozzles (%)		
		50	75	90
5	6.886	3.443	-	-
10	3.652	-	-	-

The PEC_{sed} calculation is in agreement with the following equation:

$$PEC_{sed}\ (\mu g/kg\ dw) = \frac{\%Drift\ _{90}{}^{th}{}_{\%ile} \times Application\ rate\ (g/ha) \times \%\ of\ KONARK\ in\ sediment}{1000 \times Sediment\ density\ (g/cm3) \times Sediment\ height\ (cm)}$$

Where:

$\%Drift_{90}{}^{th}{}_{\%ile}$ = 1.9274 (according to FOCUS Swash Drift Calculator v1.1)
Application rate = 3954.4 g/ha
% of KONARK in sediment = 2.08 (F) + 26.1 (D) = 28.18%*
Sediment density = 1.3 g/cm^3
Sediment height = 5 cm

The maximum PEC_{sed} of KONARK is equal to 33.043 µg/kg dw.

*The calculation of the KONARK sediment percentage has been done as follow:

The percentages of Flufenacet and Pendimethalin in KONARK are 6% and 30% (w/v) and 6.07% and 30.35% (w/w) respectively, according to the Flufenacet and Pendimethalin EU reports their respective percentages on sediment are a 34.2% and 86%, therefore the final percentages on sediment are:

% Flufenacet = 6.07 x 34.2/100 = 2.08%

% Pendimethalin = 30.35 x 86/100 = 26.10%

zRMS comments:

Flufenacet

The calculated PECsw/sed values from the applicant are considered conservative and acceptable.
The input parameters for groundwater calculation were established in the EU reviews Flufenacet 7469/VI/98-Final 3 July 2003.
Interception was appropriate to the proposed BBCH of crops (EFSA guidance was published, (2014;12(5):3662).
In simulations PUF value of 0 was assumed for all compounds, in line with recommendations of the most recent version of the FOCUS Groundwater Guidance. The geomean of the DT50 and Kfoc values were used in modelling.

Pendimethalin

Evaluator agrees with modelling carried out by applicant.
The input parameters for surface water calculation were established in the EU reviews (EFSA Journal EFSA Journal 2016;14(3):4420)
Interception was appropriate to the proposed BBCH of crops (EFSA guidance was published, (2014;12(5):3662).
In simulations PUF value of 0 was assumed for all compounds, in line with recommendations of the most recent version of the FOCUS Groundwater Guidance. The geomean of the DT_{50} and Kfoc values were used in modelling.

The calculations PECsw/sed at STEP 4 according to the Austrian Environmental Agency (AGES) for 5 and 15 meters of vegetative buffer strip and the calculations PECsw/sed at STEP 4 according VFSMOD should be considered at national level.
Nevertheless, additional simulations may be required by the sMS that do not accept calculations performed using Focus models.

The predicted concentrations in surface water and sediment of flufenacet and pendimethalin and its metabolites are appropriate to be used for the subsequent risk assessment for aquatic organisms.

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

Table 8.10-1: Summary of Flufenacet 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	Very low
Photochemical oxidative degradation in air	DT50 (h): 4.7 h by the Atkinson model OH (12h) concentration assumed = no information
Volatilisation	Vapour pressure (Pa): 9 x 10^{-5} Henry's Law Constant (Pa.m3/mol): 9 x 10^{-4}
Metabolites	

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 not be considered due to the rapid degradation in air (DT_{50} = 4.7h) estimated.

Table 8.10-2: Summary of atmospheric degradation and behaviour for Pendimethalin

Compound	Pendimethalin
Direct photolysis in air	Not required
Quantum yield of direct phototransformation	-
Photochemical oxidative degradation in air	DT50 (h): 4.2 derived by the Atkinson model (APOWIN version 1.88) OH (12h) concentration assumed = 1.5 x 10^{6} mol/cm^{3}
Volatilisation	From plant surfaces (BBA guideline): < 4% after 24h From soil surfaces (BBA guideline): < 6% after 24h Vapour pressure (Pa): 1.39 x 10^{-3} (20°C) Henry's Law Constant (Pa.m3/mol): 1.27 x 10^{-3} (25°C)
Metabolites	None

The vapour pressure at 20 °C of the active substance Pendimethalin is > 10^{-4} Pa. Hence the active substance Pendimethalin is regarded as volatile (volatilisation from soil and plant surfaces). Therefore, exposure of adjacent surface waters and terrestrial ecosystems by the active substance Pendimethalin due to volatilization with subsequent deposition should be considered.

zRMS comments:

Accepted.

Appendix 1 Lists of data considered in support of the evaluation

Appendix 2 Detailed evaluation of the new Annex II studies

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