FINAL REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: SHA 4307 A

Product name: PRIMARY MX

Chemical active substances:

Rimsulfuron, 30 g/kg

Nicosulfuron 120 g/kg

Mesotrione 360 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: SHARDA Cropchem España S.L.

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Version history

When	What
07.2021	Applicant update.
10.2021	Applicant update
10.2021	zRMS first assessment
11.2022	Applicant update
12.2022	zRMS assessment and corrected after commenting
03.2023	zRMS assessment and corrected after commenting II
27.03.2023	zRMS assessment and corrected after commenting II

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8 Fate and behaviour in the environment (KCP 9)

zRMS comments:
All comments and conclusions of the zRMS are presented in grey. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information is struck through and shaded for transparency. The new calculations performed by applicant for lower doses in yellow and green. The amendments after commenting are introduced in blue and pink.

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
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	SEU	**Maize**	F	Broadleaved and grass weeds	Foliar Spray	BBCH 12-18	a) 1 b) 1	NA	a) 0.25 b) 0.25 ~~a) 0.33~~ ~~b) 0.33~~	a) 0.0075 rimsulfuron + 0.03 nicosulfuron + 0.09 mesotrione b) 0.0075 rimsulfuron + 0.03 nicosulfuron + 0.09 mesotrione ~~a) 0.0099 rimsulfuron + 0.0396 nicosulfuron + 0.118 mesotrione~~ ~~b) 0.0099 rimsulfuron + 0.0396 nicosulfuron + 0.118 mesotrione~~	200-400	-	

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional

and non-professional greenhouse use, I: indoor application

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 Rimsulfuron 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 min - max	g or kg as/ha min - max	Water L/ha min/max		
1	N&S EU	**Maize**	F	Broadleaved weeds (BLW), grasses	Hydraulic sprayer overall	Up to GS 18 (8 leaves) Spring	1-2 splitting	7 days	N/A	5.0-20.0 (total 20.0)	150-500	-	+ Non-ionic surfactant at 0.1% application information covers worst-case use in EU. Max rate and latest timing vary between countries
2	N&S EU	**Potato**	F	Broadleaved weeds (BLW), grasses	Hydraulic sprayer overall	GS 30 (before closing of the rows) Spring	1-2 splitting	4-5 days	N/A	5.0-20.0 (total 20.0)	150-400	-	
3	SEU	**Tomato**	F	Broadleaved weeds (BLW), grasses	Hydraulic sprayer overall	GS 18 (8 leaves) Spring	1-2 splitting	7 days	N/A	5.0-20.0 (total 20.0)	200-500	-	

* 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 Nicosulfuron 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	various	**Maize**	F	weeds	Spray application	BBCH 12-18	a) 1 b) 1	N/A	N/A	a) 60 b) 60	200-400	-	-

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

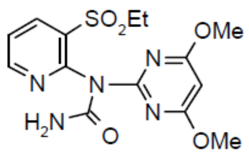
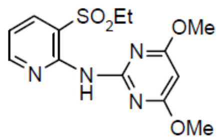
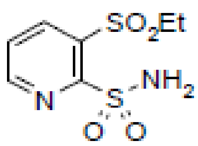
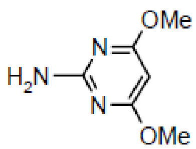
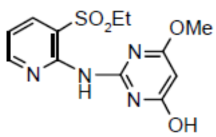
Table 8.1-4: Assessed (critical) uses during approval of Mesotrione concerning the Section Environmental Fate

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 as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
1	N & S-EU	**Maize**	F	Annual broadleaved weeds and some annual grasses such as *Echinochloa crus-galli*	Foliar spray application using hydraulic vehicle-mounted spray equipment	BBCH 12-18	a) 1 b) 1	N/A	N/A	a) 150 b) 150	200-400	-	-

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

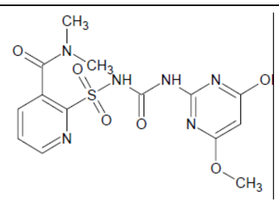
8.2 Metabolites considered in the assessment

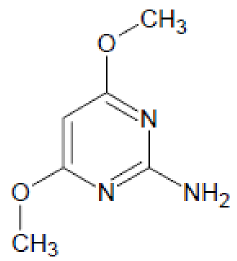
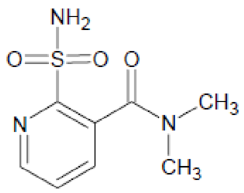
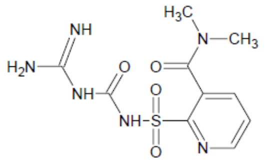
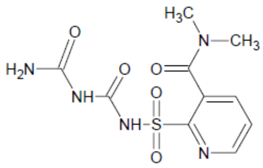
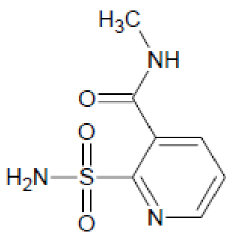
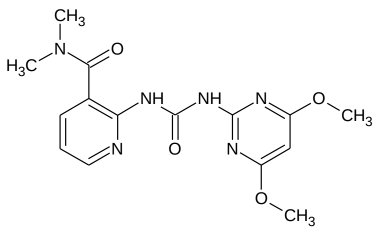
Table 8.2-1: Metabolites of Rimsulfuron potentially relevant for exposure assessment

Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
IN-70941 (N-(4.6-dimethoxy-2-pyrimidinyl)-N-[3-(ethylsuflonyl)-2-pyridinyl] urea)	367.4 g/mol		Soil: 54.5% Total system: 87.2%	PECgw PECsoil PECsw/sed
IN-70942 (N-[3-(ethylsulfuronyl)-2-pyridinyl]-4,6-dimethoxy-2-pyrimiinamine)	324.36 g/mol		Soil: 23.5% Total system: 83.8%*	PECgw PECsoil PECsw/sed
IN-E9260 (3-(ethylsulfuonyl)-2-pyridinesulfonamide)	250.30 g/mol		Soil: 18.9% Total system: 16.2%**	PECgw PECsoil PECsw/sed
IN-J0290 (4,6-dimethoxy-2-pyrimidinamine) a.k.a ADMP	155.20 g/mol		Soil: 12.7%*** Total system: 19.1%**	PECgw PECsoil PECsw/sed
IN-JF999 (2-[[3-ethylsulfonyl)-2-pyridinyl]amino]-6-methoxy-4(1H)-pyrimidinone)	310.33 g/mol		Soil: 1 x 10^{-10}% Total system: 24.5%	PECsw/sed

***From hydrolysis study**
****From photolysis study**
*****From soil photolysis study**

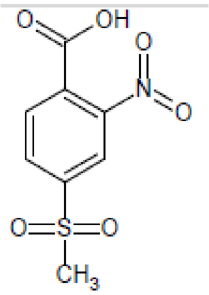
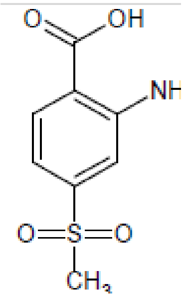
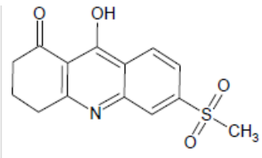
Table 8.2-2: Metabolites of Nicosulfuron potentially relevant for exposure assessment

Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
HMUD (2-{[(4-hydroxy-6-methoxypyrimidin-2-yl)carbamoyl]sulfamoyl}-N-N-dimethylpyridine-3-carboxamide)	396.4 g/mol		Soil:14.4% Water: 14.1% Sediment: 5.7% Water/sediment: 19.3%	PECgw PECsoil PECsw/sed

Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
ADMP (4,6-dimethoxypyrimidin-2-amine)	155.2 g/mol		Soil: 9.8% Water: 23.1%*	PEC_{gw} PEC_{soil} $PEC_{sw/sed}$
ASDM (N,N-dimethyl-2-sulfamoylpyridine-3-carboxmide)	229.2 g/mol		Soil: 63.4% Water: 61%* Sediment: 4.4% Water/sediment: 61%*	PEC_{gw} PEC_{soil} $PEC_{sw/sed}$
AUSN (2-[(carbamimidoylcarbamoyl)sulfamoyl]-N,N-dimethylpyridine-3-carboxamide	314.3 g/mol		Soil: 26.8% Water: 9.1% Sediment: 2.4% Water/sediment: 11.1%	PEC_{gw} PEC_{soil} $PEC_{sw/sed}$
UCSN (2-[(carbamoylcarbamoyl)sulfamoyl]-N,N-dimethylpyridine-3-carboxamide	315.3 g/mol		Soil: 11% Water: 5.4% Sediment: 1.4% Water/sediment: 6.5%	PEC_{gw} PEC_{soil} $PEC_{sw/sed}$
MU-466 (N-methyl-2-sulfamoylpyridine-3-carboxamide)	215.2 g/mol			PEC_{gw}
DUDN 2-{[(4,6-dimethoxypyrimidin-2-yl)carbamoyl]amino}-N,N-dimethylpyridine-3-carboxamide	346.3 g/mol		Soil: 1 x 10^{-10}% Water: 22.3%*	$PEC_{sw/sed}$

***From photolysis study**

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

Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
MNBA (4-(methylsulfonyl)-2-nitrobenzoic acid)	245 g/mol		Soil: 57.2 % Water: 7.9% Sediment: <1% Water/sediment: 7.9%	PEC_{gw} PEC_{soil} $PEC_{sw/sed}$
AMBA (2-amino-4-(methylsulfonyl)benzoic acid)	215 g/mol		Soil: 9.7% Water: 15.8% Sediment: 8.8% Water/sediment: 24.6%	PEC_{gw} PEC_{soil} $PEC_{sw/sed}$
SYN546974 (9-hydroxy-6-(methylsulfonyl)-3,4-dihydroacridin-1(2H)-one)	291 g/mol		Soil: <1 x 10^{-10}% Water: 9.4% Sediment: 25.6% Water/sediment: 33%	$PEC_{sw/sed}$

zRMS comments:

Information relating to rimsulfuron metabolites are in line with EU agreed endpoints as reported in EFSA Journal, EFSA Journal 2005; 45, 1-61 and have been considered in the exposure assessment presented in this report.
Information relating to nicosulfuron metabolites are in line with EU agreed endpoints as reported in EFSA Journal EFSA Scientific Report (2007) 120, 1-91 and have been considered in the exposure assessment presented in this report. Information relating to mesotrione metabolites are in line with EU agreed endpoints as reported in EFSA Journal 2016;14(3):4419 and have been considered in the exposure assessment presented in this report.

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 Rimsulfuron and its metabolites

EFSA Journal 2005; 45, 1-61 was used as agreed endpoints for Rimsulfuron.
Agreed EU endpoints used in the evaluation: Rimsulfuron (SANCO/10528/2005 rev 2, 27 January 2006).

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

Rimsulfuron, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH**	**t.ºC**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa***	**r^2**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Sassafras	Sandy loam	6.7	25	75	21.3		34.2	0.87[a]/0.94[b]	SFO	Y, EFSA Journal 2005; 45, 1-61
Speyer 2.2	Loamy sand	5.6	20	40	30		23	0.977		
Middlefield	Sandy loam	6.7		40	40		26.9	0.927		
Sion Hill	Loamy sand	7.0		40	25		19.2	0.977		
	Loamy sand	7.0		60	5		5	0.982		
Geometric mean (n=5)							**18.3** (22 for n=4)			
pH-dependency: y/n							n			

[a]: Pyridine
[b]: Pyrimidine
***Normalized using a Q10 of 2.58 by the UBA Excel™ spreadsheet Input_Decision v3.3**

Table 8.3-2: Summary of aerobic degradation rates for IN-70941 - laboratory studies

IN-70941, Laboratory studies, aerobic conditions										
Soil name	**Soil type (x)**	**pH (x)**	**t.ºC**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa***	**r^2**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Lynge	Sandy loam	5.4	20	40	359		241.6	0.913	SFO	Y, EFSA Journal 2005; 45, 1-61
San Pietro en Cerro	Clay	7.9			38		21.4	0.982		

IN-70941, Laboratory studies, aerobic conditions										
Soil name	**Soil type (x)**	**pH (x)**	**t.ºC**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa***	**r^2**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Handorf	Sandy loam	5.8			615		413.9	0.722		
Geometric mean (n=3)							**128.9** (140 for n=3)			
pH-dependency: y/n							n			

***Normalized using a Q10 of 2.58 by the UBA Excel™ spreadsheet Input_Decision v3.3**

Table 8.3-3: Summary of aerobic degradation rates for IN-70942 - laboratory studies

IN-70942, Laboratory studies, aerobic conditions										
Soil name	**Soil type (x)**	**pH (x)**	**t.ºC**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa***	**r^2**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Lynge	Sandy loam	5.4			214		144	0.928		
San Pietro en Cerro	Clay	7.9	20	40	101		57	~~0.982~~ 0.831	SFO	Y, EFSA Journal 2005; 45, 1-61
Handorf	Sandy loam	5.8			116		78.1	0.956		
Geometric mean (n=3)							**86.2** (94 for n=3)			
pH-dependency: y/n							n			

***Normalized using a Q10 of 2.58 by the UBA Excel™ spreadsheet Input_Decision v3.3**

Table 8.3-4: Summary of aerobic degradation rates for IN-E9260 - laboratory studies

IN-70942, Laboratory studies, aerobic conditions										
Soil name	**Soil type (x)**	**pH (x)**	**t.ºC**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa**	**r^2**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Lynge	Sandy loam	5.4			744		500.7	0.814		
San Pietro en Cerro	Clay	7.9	20	40	252		142.1	0.710	SFO	Y, EFSA Journal 2005; 45, 1-61
Handorf	Sandy loam	5.8			969		652.1	0.337		
Geometric mean (n=3)							**359.3** (390 for n=3)			

***Normalized using a Q10 of 2.58 by the UBA Excel™ spreadsheet Input_Decision v3.3**

Table 8.3-5: Summary of aerobic degradation rates for IN-J0290 (a.k.a ADMP) - laboratory studies

IN-J0290 (ADMP), Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH**	**t.oC**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa**	**St. (r^2)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Collombey	Loamy sand	7.6			2.9	9.5	2.4	0.995		EFSA Scientiic report nicosulfuron (2007) 120, 1-91
Speyer 2.2	Loamy sand	6.0	20	40	6.1	20.4	5.4	0.980	1st order non-linear	
Les Evouettes	Loam	7.3			11.3	37.7	7.3	0.970		
Geometric mean (n=3)							**4.5** (1000 worst-case DT_{50} of 1000 days)			
pH-dependency:							No			

8.3.1.2 Nicosulfuron and its metabolites

EFSA Scientific Report (2007) 120, 1-91 was used as agreed endpoints for Nicosulfuron.

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

Nicosulfuron, Laboratory studies, aerobic conditions										
Soil name (label)	**Soil type**	**pH**	**t.oC**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa**	**St. (r^2)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Le Noron (pyridine)	Loam	5.3	20	46.3	20.0	66.4*	13.3	0.986	1st order non-linear	
Le Noron (pyrimidine)	Loam	5.3	20	46.3	26.3	87.4*	17.4	0.901	1st order non-linear	
Mean							**15.3**			
Les Evouettes (pyridine)	Silt loam	6.1	20	54.6	40.5	134.4*	33.2	0.981	1st order non-linear	
Les Evouettes (pyrimidine)	Silt loam	6.1	20	54.6	33.1	110.1*	27.1	0.993	1st order non-linear	EFSA Scientific Report (2007) 120, 1-91
Mean							**30.1**			
Speyer 2.1 (pyridine)	Sand	6.0	20	21.1	35.1	116.6*	30.6	0.989	1st order non-linear	
Speyer 2.1 (pyrimidine)	Sand	6.0	20	21.1	46.3	154.0*	40.4	0.974	1st order non-linear	
Mean							**35.5**			
Speyer 2.3 (pyridine)	Sandy loam	6.6	20	31.4	26.7	88.8*	20.3	0.985	1st order non-linear	
Speyer 2.3 (pyrimidine)	Sandy loam	6.6	20	31.4	23.3	77.2*	17.7	0.992	1st order non-linear	

Nicosulfuron, Laboratory studies, aerobic conditions										
Soil name (label)	**Soil type**	**pH**	**t.oC**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa**	**St. (r^2)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
						Mean	**19.0**			
Pappelacker (pyrimidine)	Loamy sand	7.0	20	40	7.0	23.4**	**5.7**	0.960	SFO	
Karolinenhof (pyrimidine)	Sand	7.2	20	40	13.2	43.9**	**12.6**	0.992	SFO	
Otzberg (pyrimidine)	Silt loam	7.2	20	40	18.9	62.8**	**14.3**	0.991	SFO	
						Geometric mean (n=7)	**16.4**			
						pH-dependency:	No			

Values in bold used to calculated geometric mean DT_{50}
***: values from DAR (UK, 2005)**
****: values from report A39791 (Mamouni, 2006)**

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

HMUD, Laboratory studies, aerobic conditions										
Soil name (label)	**Soil type**	**pH**	**t.oC**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa**	**St (r^2)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Les Evouettes (pyridine)	Silt loam	6.1	20	54.6	30.8	102.2	25.2	0.983	ModelMaker based on SFO formation and decline from parent	EFSA Scientific report (2007) 120, 1-91
					27.4	90.0	22.4	0.930		
						Geometric mean (n=2)	**23.8**			
						pH-dependency:	No			
The DT_{50} for HMUD are 2 values from 2 parent labels for 1 soil. Whereas for the other metabolites more than 1 soil was tested. This was calculated using first-order kinetics in Modelmaker based on formation of HMUD and its subsequent degradation (HMUD formation fraction used was 0.00752 and 0.00786 respectively.										

Table 8.3-8: Summary of aerobic degradation rates for ADMP - laboratory studies

ADMP, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH**	**t.oC**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa**	**St. (r^2)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Collombey	Loamy sand	7.6	20	40	2.9	9.5	2.4	0.995	1st order non-linear	EFSA Scientiic report (2007) 120,
Speyer 2.2	Loamy sand	6.0			6.1	20.4	5.4	0.980		

ADMP, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH**	**t.oC**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa**	**St. (r^2)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Les Evouettes	Loam	7.3			11.3	37.7	7.3	0.970		1-91
Geometric mean (n=3)							**4.5**			
pH-dependency:							No			

Table 8.3-9: Summary of aerobic degradation rates for ASDM - laboratory studies

ASDM, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH**	**t.oC**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa**	**St. (r^2)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Collombey	Loamy sand	7.6	20	40	90.5	300.8	73.6	0.995	1st order non-linear	EFSA Scientiic report (2007) 120, 1-91
Speyer 2.2	Loamy sand	6.0	20	40	268.5	892.1	236.6	0.933		
Les Evouettes	Loam	7.3	20	40	114.8	381.4	73.8	0.992		
Geometric mean (n=3)							**108.7**			
pH-dependency:							No			

Table 8.3-10: Summary of aerobic degradation rates for AUSN - laboratory studies

AUSN, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH**	**t.oC**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa**	**St. (r^2)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Collombey	Loamy sand	7.6	20	40	73.9	245.1	60.0	0.894	1st order non-linear	EFSA Scientiic report (2007) 120, 1-91
Speyer 2.2	Loamy sand	6.0	20	40	218.2	724.8	192.3	0.907		
Les Evouettes	Loam	7.3	20	40	101.4	336.9	65.2	0.856		
Geometric mean (n=3)							**90.9**			
pH-dependency:							No			

Table 8.3-11: Summary of aerobic degradation rates for UCSN - laboratory studies

UCSN, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH**	**t.oC**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa**	**St. (r²)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Collombey	Loamy sand	7.6	20	40	126.2	419.3	102.6	0.993	1[st] order non-linear	EFSA Scientiic report (2007) 120, 1-91
Speyer 2.2	Loamy sand	6.0	20	40	307.5	1021.7	271.0	0.962		
Les Evouettes	Loam	7.3	20	40	229.3	761.7	147.5	0.942		
Geometric mean (n=3)							**160.1**			
pH-dependency:							No			

Table 8.3-12: Summary of aerobic degradation rates for MU-466 - laboratory studies

MU-466, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH**	**t.oC**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa**	**St. (r²)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Uffholtz	-	5.74	20	40	89.5	297	66.3	0.943	1[st] order non-linear	EFSA Scientiic report (2007) 120, 1-91
Speyer 2.1	Sand	6.2	20	40	84	279	75.5	0.975		
3A	-	7.1	20	40	67.9	225.5	59.1	1.000		
Geometric mean (n=3)							**66.6**			
pH-dependency:							No			

8.3.1.3 Mesotrione and its metabolites

EFSA Journal 2016;14(3):4419 was used as agreed endpoints for Mesotrione.

Table 8.3-13: Summary of aerobic degradation rates for Mesotrione - laboratory studies

Mesotrione, Laboratory studies, dark aerobic conditions										
Soil name	**Soil type**	**pH***	**t.oC**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa****	**St. (X²)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
ERTC	Sandy loam	6.4	20	19[a]	11.6	38.5	8.2	18	SFO	EFSA Journal 2016;14(3):4419
Toulouse	Loam	7.7	20	25[a]	4.3	14.3	4.0	16.4		
Pickett Piece	Clay loam	7.1	20	28[a]	5.3	17.7	5.3	6.5		
721	Clay loam	5.6	25	28[a]	20.2	67.1	32.3	4.1		
722	Silty clay loam	5.7	25	30[a]	10.3	34.2	16.5	3.9		
723	Silt loam	5.4	25	26[a]	17.6	58.5	28.2	3.4		

Mesotrione, Laboratory studies, dark aerobic conditions										
Soil name	**Soil type**	**pH***	**t.oC**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa****	**St. (X^2)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
724	Loamy sand	4.8	25	14[a]	23.8	78.9	31.1	4.3		
725	Loam	5.8	25	25[a]	6.1	20.3	9.5	7.6		
727	Clay loam	5.1	25	28[a]	20.8	69.2	32.4	6.4		
728	Sandy loam	5.9	25	25[a]	7.2	24	9.7	5.6		
729	Silt loam	5.6	25	26[b]	12.7	42.2	20.3	1.6		
730	Clay loam	5.3	25	28[a]	17.1	56.9	26.9	8.9		
731	Silty clay loam	6.1	25	30[a]	14.1	46.9	22.6	1.0		
732	Silty clay loam	5.0	25	30[a]	14.0	46.4	22.4	5.3		
741	Silty clay loam	5.7	25	30[a]	28.7	95.3	44.3	4.5		
742	Silty clay loam	7.2	25	34.4[a]	9.7	32.1	15.5	5.5		
Richmond	Silt loam	6.2	25	32.04[b]	13.2	44.0	14.68 (average DT_{50} of 15.5 & 13.9 d given identical soil description in these 2 studies)	3.1		
Richmond	Silt loam	6.2	25	32.04[b]	11.8	39.3		4.9		
Richmond	Silt loam	6.1	20	32.04[b]	14.2	47.2	11.5	4.6		
Geometric mean:							Not relevant as pH dependant			
pH-dependency:							Yes, degradation increases with increasing pH. DT_{50} y = -9.766x pH + 77.692 r^2 0.4687 (non-log)			

[a]: FOCUS default
[b]: measured pF2
***: measured in [medium to be stated, usually calcium chloride solution or water]**
****: normalized using Q_{10} of 2.58 and Walker equation coefficient of 0.7**

Table 8.3-14: Summary of aerobic degradation rates for MNBA - laboratory studies

MNBA, Laboratory studies, dark aerobic conditions										
Soil name	**Soil type**	**pH***	**t.oC**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa****	**St. (X^2)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
722	Silty clay loam	5.7	25	30[a]	0.6	1.89	1.0	10	SFO	EFSA Journal 2016;14(3):4419
725	Loam	5.8	25	25[a]	0.5	1.5	0.8	10.8	SFO	
728	Sandy loam	5.9	25	25[a]	5.1	16.97	6.9	3.1	Decline from peak	
729	Silt loam	5.6	25	26[b]	1.66	5.52	2.7	3.88	SFO	

MNBA, Laboratory studies, dark aerobic conditions										
Soil name	**Soil type**	**pH***	**t.oC**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa****	**St. (X^2)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
730	Clay loam	5.3	25	28[a]	2.81	9.35	4.4	14.17	SFO	
731	Silty clay loam	6.1	25	30[a]	15.7	52.3	25.2	1.6	SFO	
ERTC	Sandy loam	6.4	20	19[a]	6.2	20.7	4.4	21.89	Decline from peak	
Toulouse	Loam	7.7	20	25[a]	5	16.65	4.6	13.08	Decline from peak	
Richmond	Silt loam	6.2	25	32.04[b]	1.1	3.67	1.3	11.2	SFO	
Richmond	Silt loam	6.1	20	32.04[b]	6.3	21.03	5.1	20.13	Decline from peak	
Geometric mean (n=10)							**3.4**			
pH-dependency:							No			

[a]: FOCUS default
[b]: measured pF2
***: measured in [medium to be stated, usually calcium chloride solution or water]**
****: normalized using a Q_{10} of 2.58 and Walker equation coefficient of 0.7**

Table 8.3-15: Summary of aerobic degradation rates for AMBA - laboratory studies

AMBA, Laboratory studies, dark aerobic conditions										
Soil name	**Soil type**	**pH***	**t.oC**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa****	**St. (X^2)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Wisbourg	clay	4.9	20	41.26	7.8		3.7	5.52	DFOP DT_{90}/3.32	EFSA Journal 2016; 14(3):4419
Wisconsin	Silt loam	6.4	20	40.0	33	109	23.5	7.98	DFOP K2	
East Anglia	Sandy loam	7.9	20	34.94	58.7	195	47.4	3.66	DFOP K2	
Spinks	Loamy sand	6.7	20		10.2	34	9.7	6.94	FOMC	
Richmond	Silt loam	6.2	25	32.04	13.6	45.2	16.0	14.8	SFO	
Richmond	Silt loam	*6.1*	*20*	32.04	*> 1000*	*> 1000*	*> 1000*	*26.6*	*SFO*	
Geometric mean (n=5)							**14.5**			
pH-dependency:							No			

***: measured in [medium to be stated, usually calcium chloride solution or water]**
****: normalised using Q_{10} of 2.58 and Walker equation coefficient of 0.7**
***Italics* - outlier**

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

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

8.3.2.1 Rimsulfuron and metabolites

The degradation of rimsulfuron was also studied in sandy loam soil in the laboratory under flooded anaerobic conditions (25°C), the route and rate of degradation observed was comparable to that observed under aerobic conditions. The summary of anaerobic degradation rates obtained under anaerobic condition is presented in Table 8.3-16.

Table 8.3-16: Summary of anaerobic degradation rates for Rimsulfuron - laboratory studies

Soil type	pH	t. ºC	DT_{50} (d)	St. (r^2)
Sandy loam	6.7	25	18.1[1]/17.9[2]	0.99[1]/0.91[2]

[1]: Pyridine
[2]: Pyrimidine

8.3.2.2 Nicosulfuron and metabolites

Table 8.3-17: Summary of anaerobic degradation rates for Nicosulfuron - laboratory studies

Nicosulfuron, Laboratory studies, anaerobic conditions
Due to limited degradation observed under anaerobic conditions it was not possible to derive a DT_{50}/DT_{90} for this phase of the study. (Aerobic phase: 21.8, 24.4; r^2 0.909-0.998; n=2)

8.3.2.3 Mesotrione and metabolites

Table 8.3-17: Summary of anaerobic degradation rates for Mesotrione - laboratory studies

Mesotrione, Laboratory studies, dark anaerobic conditions										
Soil name	**Soil type**	**pH**	**t.oC**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa**	**St. (X^2)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Wisconsin	Silt loam	6.2	25	-	4	14	-	r^2=0.98	First order (linear least squares fit of natural lof of concentration vs. Sampling interval)	EFSA Journal 2016;14(3):4419
Wisconsin	Silt loam	6.2	25	-	4	12	-	r^2= 0.97		

8.4 Field studies (KCP 9.1.1.2)

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

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

8.4.1.1 Rimsulfuron and its metabolites

In European field studies (2 northern trial sites and 1 southern site) rimsulfuron was degraded with single first order DT_{50}'s ranging from 6 to 14 days and in US field studies (3 sites), single first order DT_{50}values from 8 to 18 days were determined. Rimsulfuron is considered to exhibit moderate persistence.

Table 8.4-1: Summary of field dissipation values of Rimsulfuron from studies performed in Europe and USA

Country	Location	% OC	pH	DT_{50} (d)	r^2
MS, USA	Greenv.	0.75	7.0	7.9[1]-9.6[2]	0.88[1]-0.96[2]
CA, USA	Madera	0.70	7.7	8.0[1]-8.2[2]	0.99[1]-0.99[2]
IL, USA	Rochelle	2.61	7.8	15.9[1]-17.7[2]	0.94[1]-0.95[2]
Spain	Palafolls	0.8	6.7	5.6	0.95
Germany	Lindenh.	1.1	6.5	10	0.94
Denmark	Middelf.	1.1	6.6	14	0.95
			Geomean (n=3)	**4***	

[1] **Pyridine**
[2] **Pyrimidine**
***Normalized value for the 3 European values (20ºC, Q10 = 2.2 and 100% relative moisture) according to Addendum to the DAR**

In the 3 field studies conducted in Europe where rimsulfuron was the applied test substance, single first order DT_{50}values for IN-70941 were 62 to 1100 days and for IN-E9620 were 25 to 294 days (calculated using a 2 compartment kinetic model, parent to metabolite, using the residues detected in all soil layers. This $DT_{50}$is therefore analogous to a degradation rate and does not represent the rate of the observed decline after the peak formation). As IN-70942 was not detected at levels greater than 10 % of the parent molar equivalence in any of the European field studies, it was not possible to estimate field $DT_{50}$for this metabolite. These data indicate that in the field, the metabolites IN-70941 and IN-E9620 have the potential to accumulate in soil when rimsulfuron applications are made every year.

Table 8.4-2: Summary of field dissipation values of IN-70941

Country	Location	% OC	pH	DT_{50} (d)	r^2
Spain	Palafolls	0.8	6.7	435	0.95
Germany	Lindenh.	1.1	6.5	62	0.94
Denmark	Middelf.	1.1	6.6	1100	0.95
			Geomean (n=3)	**201***	

***Normalized value for the 3 European values (20ºC, Q10 = 2.2 and 100% relative moisture) according to Addendum to the DAR**

Table 8.4-3: Summary of field dissipation values of IN-E9260

Country	Location	% OC	pH	DT_{50} (d)	r^2
Spain	Palafolls	0.8	6.7	294	0.95
Germany	Lindenh.	1.1	6.5	25	0.94
Denmark	Middelf.	1.1	6.6	82	0.95
			Geomean (n=3)	**56***	

***Normalized value for the 3 European values (20ºC, Q10 = 2.2 and 100% relative moisture) according to Addendum to the DAR**

8.4.1.2 Nicosulfuron and its metabolites

Triggering endpoints

Table 8.4-4: Summary of aerobic degradation rates for Nicosulfuron - field studies: Triggering endpoints

Nicosulfuron Field studies – Triggering endpoints								
Soil type	**Location**	**pH**	**Depth (cm)**	**DissT50 (d) actual**	**DT90 (d) actual**	**St. (χ^2)**	**Method of calculation**	**Evaluated on EU level y/n/ Reference**
Sand (bare soil)	Flackenhorst, Germany	5.7	0-10	20.7	68.8	0.869	1^{st} order non-linear	EFSA Scientific report (2007) 120, 1-91
Silty clay loam (bare soil)	Hünfelden, Germany	7.1	0-10	63.3	210	0.919		
Loam (bare soil)	St. Claire, N. France	5.3	0-5	12	40	0.949		
Clay loam (bare soil)	Lante, S. France	6.0	0-5	8.9	29.7	0.964		
Geometric mean (n=4)				**19.3**				
Cropped soil (maize): Niederhofen and Schifferstadt (Germany), <0.01 mg/kg after 27/28 days, Emilia Romagna (Italy) calculation of DT_{50} not possible; Lombardia and Veneto (Italy), DT_{50} uncertain due to non-validated LOQ.								

8.4.1.3 Mesotrione and its metabolites

Following studies came from original DAR, not relied on for renewal.

Table 8.4-5: Summary of aerobic degradation rates for Mesotrione - field studies: Triggering endpoints – From original DAR, not relied on for renewal

Mesotrione Field studies – Triggering endpoints								
Soil type	**Location**	**pH[a]**	**Depth (cm)**	**DissT50 (d) actual**	**DT90 (d) actual**	**St. (χ^2)**	**Method of calculation**	**Evaluated on EU level y/n/ Reference**
Clay loam (bare soil)	France	6.0	0-10	7	73	-	Sqrt 1^{st} order – linear regression	EFSA Journal 2016;1(3):4419
Clay loam (bare soil)	Italy	6.1		5	59	-		
Sandy loam (bare soil)	Italy	8.0		4	39	-		
Sandy loam (bare soil)	Germany	6.2		7	78	-		
Loam (bare soil)	Germany	5.8		/	/	-		
Loam (bare soil)	Germany	7.0		3	36	-		
Sandy clay loam (bare soil)	Germany	6.9		3	38	-		
Geometric mean (n=7)				**4.5**	51.2			
Maximum (n=7)				7	78			

[a]: measure in [medium to be stated, usually calcium chloride solution or water]

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

Rimsulfuron	Based on calculation for metabolites
Nicosulfuron	No studies provided or required.
Mesotrione	Not triggered. Same as initial PEC_{soil}.

8.5 Mobility in soil (KCP 9.1.2)

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

8.5.1 Rimsulfuron and its metabolites

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

Rimsulfuron							
Soil name	**Soil type**	**OC (%)**	**pH (-)**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
Cecil	Sandy loam	1.2	6.5	0.23	18.9	0.9	Y, EFSA Journal 2005; 45, 1-61
Fargo	Clay loam	2.5	7.7	1.4	54.4	0.97	
Sassafras	Sandy loam	0.6	6.3	0.35	50.1	1.22	
Flanagan	Silt loam	2.5	5.4	1.58	62.8	0.99	
Geomean (n=4)					**42.4**	-	
Arithmetic mean (n=4)					**47**	1.02	
pH-dependency y/n					n		

Table 8.5-2: Summary of soil adsorption/desorption for IN-70941

IN-70941							
Soil Name	**Soil Type**	**OC (%)**	**pH (-)**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
Lynge	Sandy loam	1.2	5.4	0.47	39	0.96	Y, EFSA Journal 2005; 45, 1-61
San Pietro	Clay	1.6	7.9	1.85	116*	0.94	
Handorf	Sandy loam	1.1	5.8	0.37	34	0.92	
Frederica	Sandy loam	0.5	6.3	0.27	54	0.92	
Geomean (n=3)					**41.5**	-	
Arithmetic mean (n=4)					-	0.94	
pH-dependency y/n					n		

***Not used for geomean calculation**

Table 8.5-3: Summary of soil adsorption/desorption for IN-70942

IN-70942							
Soil Name	**Soil Type**	**OC (%)**	**pH (-)**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
Lynge	Sandy loam	1.2	5.4	2.68	223	0.84	Y, EFSA Journal 2005; 45, 1-61
San Pietro	Clay	1.6	7.9	3.12	195	0.85	
Handorf	Sandy loam	1.1	5.8	1.59	145	0.84	
Frederica	Sandy loam	0.5	6.3	1.07	214	0.85	
Geomean (n=4)					**191.7**	-	
Arithmetic mean (n=4)					-	0.85	
pH-dependency y/n					n		

Table 8.5-4: Summary of soil adsorption/desorption for IN-E9260

IN-E9260							
Soil Name	**Soil Type**	**OC (%)**	**pH (-)**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
Lynge	Sandy loam	1.2	5.4	0.27	23	1.08	Y, EFSA Journal 2005; 45, 1-61
San Pietro	Clay	1.6	7.9	1.37	86*	0.96	
Handorf	Sandy loam	1.1	5.8	0.18	16	0.99	
Frederica	Sandy loam	0.5	6.3	0.17	34	0.93	
Geomean (n=3)					**23.2**	-	
Arithmetic mean (n=4)					-	0.99	
pH-dependency y/n					n		

***Not used for geomean calculation**

Table 8.5-5: Summary of soil adsorption/desorption for IN-J0290*

IN-J0290						
Soil Type	**OC (%)**	**pH (-)**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
Loamy sand	2.29	7.0 [b)]	1.17	50.9	0.84	Y, EFSA Journal 2018; 16(5):5258
Loamy sand	1.17	7.7 [b)]	0.71	60.4	0.82	
Sisseln, sandy loam	1.557	7.8 [b)]	0.83	52.8	0.92	

IN-J0290						
Soil Type	**OC (%)**	**pH (-)**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
Silt loam	4.05	7.3 [b)]	1.70	42.0	0.91	
Geomean (n=4)				**51.1**	-	
Arithmetic mean (n=4)				-	0.87	
pH-dependency y/n				n		

***Also known as ADPM, Voelkel, W. 1995 (accepted in the RAR for nicosulfuron; refer to the EFSA conclusion on the peer review of the active substance nicosulfuron, EFSA (2007))**

8.5.2 Nicosulfuron and its metabolites

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

Nicosulfuron							
Soil name	**Soil type**	**OC (%)**	**pH**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n**	**Evaluated on EU level y/n/ Reference**
Speyer 2.1	(loamy) sand	0.48	6.0	0.05	10.0	0.90	EFSA Scientific report (2007) 120, 1-91
Speyer 2.2	Loamy sand	2.55	6.0	0.20	7.9	0.92	
Itingen II	Silt loam	1.42	7.7	0.73	51.3	0.94	
Les Evouettes	Loam	1.40	6.1	0.19	13.7	1.01	
Geometric mean (n=4)					**15.4**	-	
Arithmetic mean (n=4)					-	0.94	
pH-dependency					No Clay dependence: Yes		

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

ADMP							
Soil Name	**Soil Type**	**OC (%)**	**pH**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n**	**Evaluated on EU level y/n/ Reference**
Speyer 2.2	Loamy sand	2.29	7.0	1.17	50.9	0.84	EFSA Scientific report (2007) 120, 1-91
Collombey	Loamy sand	1.17	7.7	0.71	60.4	0.82	
Sisseln	Sandy loam	1.557	7.8	0.83	52.8	0.92	
Vetroz	Silt loam	4.05	7.3	1.70	42.0	0.91	
Geometric mean (n=4)					**51.1**	-	
Arithmetic mean (n=4)					-	0.87	
pH-dependency					No		

Table 8.5-8: Summary of soil adsorption/desorption for ASDM

ASDM							
Soil Name	**Soil Type**	**OC (%)**	**pH**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n**	**Evaluated on EU level y/n/ Reference**
Speyer 2.2	Loamy sand	2.29	7.0	0.05	2.3	0.82	EFSA Scientific report (2007) 120, 1-91
Collombey	Loamy sand	1.17	7.7	0.08	6.7	0.81	
Sisseln	Sandy loam	1.554	7.8	0.12	7.7	1.07	
Vetroz	Silt loam	4.05	7.3	0.24	6.0	0.94	
Geometric mean (n=4)					**5.2**	-	
Arithmetic mean (n=4)					-	0.91	
pH-dependency					Could not be clearly established		

Table 8.5-9: Summary of soil adsorption/desorption for AUSN

AUSN							
Soil Name	**Soil Type**	**OC (%)**	**pH**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n**	**Evaluated on EU level y/n/ Reference**
Speyer 2.2	Loamy sand	2.29	7.0	0.30	13.0	0.98	EFSA Scientific report (2007) 120, 1-91
Collombey	Loamy sand	1.17	7.7	0.42	35.6	0.92	
Sisseln	Sandy loam	1.554	7.8	0.61	39.0	0.98	
Vetroz	Silt loam	4.05	7.3	0.90	22.3	0.96	
Geometric mean (n=4)					**25.2**	-	
Arithmetic mean (n=4)					-	0.96	
pH-dependency					Could not be clearly established		

Table 8.5-10: Summary of soil adsorption/desorption for UCSN

UCSN							
Soil Name	**Soil Type**	**OC (%)**	**pH**	**Kd (mL/g)**	**Koc (mL/g)**	**1/n**	**Evaluated on EU level y/n/ Reference**
Speyer 2.2	Loamy sand	2.29	7.0	0.02	1.1	-	EFSA Scientific report (2007) 120, 1-91
Collombey	Loamy sand	1.17	7.7	0.07	5.6	-	
Sisseln	Sandy loam	1.554	7.8	0.06	3.5	-	
Vetroz	Silt loam	4.05	7.3	0.09	2.1	-	
Geometric mean (n=4)				0.04	**2.6**		
pH-dependency				No			

Table 8.5-11: Summary of soil adsorption/desorption for HMUD

HMUD							
Soil Name	**Soil Type**	**OC (%)**	**pH (Ca)**	**Kd (mL/g)**	**Koc (mL/g)**	**1/n**	**Evaluated on EU level y/n/ Reference**
Speyer 2.2	Loamy sand	2.3	5.6	0.12	5.07	-	EFSA Scientific report (2007) 120, 1-91
Mechtildshausen	Loam	1.28	7.37	0.14	10.75	-	
Uffholtz	Silty clay loam	2.67	5.42	0.02	0.88	-	
Sawtry	Clay	2.94	7.23	0.19	6.98	-	
Bretagne 1	Silt loam	2.11	5.7	0.08	2.83	-	
Geometric mean (n=5)				0.09	**3.9**		
pH-dependenc				No			

Table 8.5-12: Summary of soil adsorption/desorption for MU-466

MU-466							
Soil Name	**Soil Type**	**OC (%)**	**pH (Ca)**	**Kd (mL/g)**	**Koc (mL/g)**	**1/n**	**Evaluated on EU level y/n/ Reference**
Speyer 2.2	Loamy sand	2.3	5.6	0.07	3.05	-	EFSA Scientific report (2007) 120, 1-91
Mechtildshausen	Loam	1.28	7.37	0.14	10.73	-	
Uffholtz	Silty clay loam	2.67	5.42	0.04	1.32	-	
Sawtry	Clay	2.94	7.23	0.43	16.08	-	
Bretagne 1	Silt loam	2.11	5.7	0.17	6.50	-	
Geomeatric mean (n=5)				0.12	**5.4**		
pH-dependency				Could not be clearly established			

8.5.3 Mesotrione and its metabolites

Table 8.5-13: Summary of soil adsorption/desorption for Mesotrione

Mesotrione							
Soil name	**Soil type**	**OC (%)**	**pH[a]**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n**	**Evaluated on EU level y/n/ Reference**
Wisborough Green	Silty clay loam	2.63	5.1	4.46	171	0.902	EFSA Journal 2016;14(3):4419
Wisconsin	Silt loam	1.58	6.2	0.74	47	0.921	
Toulouse	Clay	1.79	6.5	1.25	70	0.915	
Garonne	Loam	1.03	7.8	0.15	14	0.971	
Visalia	Sandy	0.53	8.2	0.13	25	0.959	

Mesotrione							
Soil name	**Soil type**	**OC (%)**	**pH[a]**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n**	**Evaluated on EU level y/n/ Reference**
	loam						
Wisconsin	Silt loam	1.28	6.1	0.61	48	0.947	
ERTC	Sandy loam	0.58	6.4	0.33	57	0.950	
Pickett Piece	Clay loam	3.31	7.1	0.97	29	0.932	
Garonne	Loam	0.87	7.7	0.16	18	0.954	
Champaign (1:2 ratio)	Silty clay loam	3.0	4.4	6.16	354	0.94	
Arithmetic mean (n=10)						0.94	
Worst-case					**14**		
pH-dependency					Yes, sorption decreases as pH increases. K_{foc} y= 8583.4e^{-0785x} (log) r² 0.8977		

[a]: measured in [medium to be stated, usually calcium chloride solution or water]

Table 8.5-14: Summary of soil adsorption/desorption for MNBA

MNBA							
Soil Name	**Soil Type**	**OC (%)**	**pH[a]**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n**	**Evaluated on EU level y/n/ Reference**
Wisborough Green	Silty clay loam	2.63	5.1	0.16	6.1	0.32	EFSA Journal 2016;14(3):4419
Wisconsin	Silt loam	1.58	6.2	0.05	3.2	0.61	
Worst case					**3.2**	0.9[b]	
pH-dependency					No		

[a]: Measured in [medium to be stated, usually calcium chloride solution or water]
[b]: FOCUS default (0.9) will be used

Table 8.5-15: Summary of soil adsorption/desorption for AMBA

AMBA							
Soil Name	**Soil Type**	**OC (%)**	**pH[a]**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n**	**Evaluated on EU level y/n/ Reference**
Wisborough reen	Silty clay loam	2.63	5.1	3.2	122	0.83	EFSA Journal 2016;14(3):4419
Wisconsin	Silt loam	1.58	6.2	0.71	44.9	0.85	
Toulouse	Clay	1.79	6.5	0.91	51.0	0.85	
Garonne	Loam	1.03	7.8	0.18	18.1	0.82	
Visalia	Sandy loam	0.53	8.2	0.12	23.9	0.90	

AMBA							
Soil Name	**Soil Type**	**OC (%)**	**pH[a]**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n**	**Evaluated on EU level y/n/ Reference**
				Arithmetic mean (n=5)	pH dependent (51.9)	0.85	
				Worts case	**18.1**	-	
				pH-dependency	Yes, sorption decreases as pH increaes. K_{foc} y=1865e$^{-0.563x}$ (log) r² 0.9062		

[a]: Measured in [medium to be stated, usually calcium chloride solution or water]

Table 8.5-16: Summary of soil adsorption/desorption for SYN546974

SYN546974							
Soil Name	**Soil Type**	**OC (%)**	**pH[a]**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n**	**Evaluated on EU level y/n/ Reference**
Gartenacker	Loam	1.8	7.2	30.63	1702	0.82	EFSA Journal 2016;14(3):4419
18 Acres	Sandy clay loam	2.2	5.7	220.07	10003	0.96	
Marysville	Clay loam	1.6	7.6	432.49	27031	0.96	
Sarpy	Silt loam	1.7	6.5	376.10	22124	0.88	
Seven Springs	Loamy sand	0.6	5.2	19.56	3260	0.84	
				Geometric mean (n=5)	**8021**	-	
				Arithmetic mean (n=5)	-	0.89	
				pH-dependency	No		

[a]: Measured in [medium to be stated, usually calcium chloride solution or water]

8.5.4 Column leaching (KCP 9.1.2.1)

Rimsulfuron	Column leaching studies showed a high leaching potential of Rimsulfuron with 47 - 93 % TAR in the leachate (mainly Rimsulfuron and metabolites IN-70941 and IN-70942). Radioactivity in leachate [%]:

	^{14}C	**Rimsulfuron**	**IN-70942**	**IN-70941**
Soil 1	97.9[1]/70.7[2]	50.7[1]/60.4	27.5[1]/6.4[2]	5.7[1]/0.9[2]
Soil 2	89.6/57.3[2]	49.9[1]/45.1[2]	6.9[1]/6.1[2]	2.8[1]/2.6[2]
Soil 3	76.0[1]/62.0[2]	5.8[1]/n.d.[2]	3.0[1]/n.d.[2]	60.8[1]/59.8[2]
Soil 4	89.5[1]/79.5[2]	61.3[1]/54.0[2]	11.8[1]/10.3[2]	11.4[1]/14.1[2]

IN-9260: 1.6-3.5% in leachate (Pyridine)

Soil 1 (Speyer 2.1): sand, 0.7% C_{org}, pH6.1
Soil 2 (Speyer 2.2): loamy sand, 2.3% C_{org}, pH 6.3
Soil 3 (Speyer 2.3): sandy loam, 1.3% C_{prg}, pH 6.7
Soil 4 (Sassafras): sandy loam, 1.3% Corg, pH 6.2

<table>
<tr><td></td><td><u>Aged residues leaching</u>
30 days ageing (20 °C, 40% MWHC, dark), radi-activity in leachate in soil [%]:
<table>
<tr><th>^{14}C</th><th>Rimsulfuron</th><th>IN-70942</th><th>IN-70941</th><th>IN-E9260</th></tr>
<tr><td>41.7[1]/29.1[2]</td><td>5.7[1]/3.0[2]</td><td>16.2[1]/7.4[2]</td><td>11.6[1]/18.7[2]</td><td>7.2[1]/n.d.</td></tr>
</table>
[1]: Pyridine
[2]: Pyrimidine</td></tr>
<tr><td>Nicosulfuron</td><td>Eluation: 508 mm
Time period: 4d
Leachate: 62.9-92.2% total residues/radioactivity in leachate
41.2-58.6% active substance, <0.5% ADMP, ≤1% DMPU
1.4-5.7% total residues/radioactivity retained in top 6 cm

<u>Aged residues leaching</u>
Aged for 28 d
Time period: 8 d
Eluation: 480 mm
Analysis of soil residues post ageing (soil residues pre-leaching): 43.2% active substance, 9.0% HMUD, 3.2% DMPU, 2.4% ADMP
Leachate: 54.8% total residue/radioactivity in leachate
49.6% Nicosulfuron, 5.2% others
28.5% AR retained in soil column (8.8% identified as Nicosulfuron)
3.5% AR as Nicosulfuron in the top 0-46.5 cm, and 5.3% AR in the bottom 16.5-34.5 cm of column</td></tr>
<tr><td>Mesotrione</td><td>Not required.</td></tr>
</table>

8.5.5 Lysimeter studies (KCP 9.1.2.2)

<table>
<tr><td>Rimsulfuron</td><td>No data provided, not required.</td></tr>
<tr><td>Nicosulfuron</td><td>3 Lysimeter studies, each with two lysimeters, 1 in Germany (Schmallenberg) and 2 in Switzerland (Itigen), each run for:
(i) 2 years, (ii) 3 years, (iii) 3 years

Maize was sown in the first two years and then wheat in the final year (ii & iii)
Application rates of:
(i) pyridine labelled Nicosulfuron: year 1 only – 1 x 40 g a.s./ha;
(ii) pyridine labelled Nicosulfuron: 1^{st} lysimeter 1 x 60 g a.s. /ha in year 1 only, 2^{nd} lysimeter 1 x 60 g a.s./HA in year 1&2 only
(iii) pyrimidine labelled Nicosulfuron: 1^{st} lysimeter 1 x 60 g a.s./ha in year 1 only, 2^{nd} lysimeter 1 x 60 g a.s./ha in year 1&2 only.

Average annual rainfall: (i) 600, 1039 mm; (ii & iii) 832. 1136.1118 mm
Average annual leachate volume: (i) 401-456 and 675-700 L; (ii) 334-335, 515-529, 522,538 L; (iii) 303-346, 485-543, 434-546 L

Annual average concentrations (µg/L)
(i) Nicosulfuron 0.03-0.07; ASDM 0.18-0.99; AUSN 0.24-0.59; UCSN 0.03-0.22; MU-466 0.002-0.04 (1x40 g s.a./ha)

(ii) (2^{nd} lysimeter with 2 applications) Nicosulfuron 0.03-0.13; ASDM 0.34-2.70; AUSN 0.68-1.62; UCSN 0.06-0.94; MU-466 0.07-0.14 (1x60 g as/ha)

(iii) (2^{nd} lysimeter with 2 applications) Nicosulfuron 0.01-0.17; HMUD 0.01-0.03.</td></tr>
</table>

Mesotrione	Not required.

8.5.6 Field leaching studies (KCP 9.1.2.3)

Rimsulfuron	No data provided, not required.
Nicosulfuron	Please refer to 8.5.5.
Mesotrione	Not required.

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 Rimsulfuron and its metabolites

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

Rimsulfuron Distribution (max. sediment 12.6 % after 14 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/n/ Reference**
Blackiston	4.3/4.8	1	3	1st order non-linear	1	3	1st order non-linear	12	1st order non-linear	Y, DAR and EFSA Journal 2005; 45, 1-61
Mills Lawn	6.7/5.7	11	35		7	26		9		
Geometric mean at 20ºC (n=2)		**3.3**	10.4		2.6	8.8		**10.4**		

Table 8.6-2: Summary of degradation in water/sediment of IN-70941

Distribution (max in water 74.9% after 3 d. Max. sed x 17.5 % after 7 d). Max in total system 87.2 % after 3 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/n/ Reference**
Blackiston	4.3/4.8	12	-	1st order non-linear	9	-	1st order non-linear	-	1st order non-linear	Y, DAR and EFSA Journal 2005; 45, 1-61
Mills Lawn	6.7/5.7	28	-		31	-		-		
Geometric mean at 20ºC (n=2)		**18.3**	-		**16.7**	-		-		

Table 8.6-3: Summary of degradation in water/sediment of IN-70942

Distribution (max in water 33.5% after 14 d. Max. sed 78.0 % after 100 d). Max in total system 79.1 % after 100 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/n/ Reference**
Blackiston	4.3/4.8	-	-	1st order non-linear	27	-	1st order non-linear	-	1st order non-linear	Y, DAR and EFSA Journal 2005; 45, 1-61
Mills Lawn	6.7/5.7	107	-		22	-		-		
Worst case at 20ºC (n=1)		**107**	-		-	-		-		

Table 8.6-7: Summary of observed metabolites in water/sediment systems

IN-70941	Max. in water/sediment 87.2 %	Y, DAR and EFSA Journal 2005; 45, 1-61
IN-70942	Max. in water/sediment 79.1%	
IN-E9260	Max. in water/sediment < 6%	
IN-JF999	Max. in water/sediment 24.5%	

8.6.2 Nicosulfuron and its metabolites

Table 8.6-8: Summary of degradation in water/sediment of Nicosulfuron

Nicosulfuron Distribution (max. water/max. in sediment 24% after 14 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/n/ Reference**
Pond (Anwil)	-/6.9	33.2	110.2	1st order non-linear	24.9	82.9	1st order non-linear	-	-	EFSA Scientific report (2007) 120, 1-91
River (Rhine)	-/6.9	49.8	165.4		32.0	106.2		-	-	
Geometric mean (n=2)		**40.7**	-		**28.2**	-		-		

Table 8.6-9: Summary of observed metabolites

HMUD Water/sediment system	Max. in water 14.1% after 62 d (pyridine) Max. in sediment 5.7 % after x 30 (pyridine) Max. in water/sediment 19.3%	Y, EFSA Journal 2007; 120, 1-91
AUSN Water/sediment system	Max. in water 9.1% after 177 d (pyridine) Max. in sediment 2.4 % after x 105 (pyridine) Max. in water/sediment 11.1%	
UCSN Water/sediment system	Max. in water 5.4% after 177 d (pyridine) Max. in sediment 1.4 % after x 105 (pyridine) Max. in water/sediment 6.5%	

ASMD Water/sediment system	Max. in water 6.9% after 177 d (pyridine) Max. in sediment 4.4 % after x 62 (pyridine) Max. in water/sediment 9.4%	

8.6.3 Mesotrione and its metabolites

Table 8.6-10: Summary of degradation in water/sediment of Mesotrione

Mesotrione Distribution (max. in water 98.7% after 0 d, max. in sediment 4.3% after 1 d)										
Water/sediment system	**pH wat.**	**pH sed.[a]**	**DegT50/90 whole syst. (d)**	**St. (X^2)**	**DissT50/90 water (d)**	**St. (X^2)**	**DissT50 sed. (d)**	**St. (X^2)**	**Method calculation**	**Evaluated on EU level y/n/ Reference**
Basing (Phenyl)	7.86		2.6	6.8	2.5	6.2	n/a	n/a	SFO	EFSA Journal 2016;14 (3):4419
Basing (Cyclohexane)			4.2	13.3	4.2	13.3	n/a	n/a		
Virginia (Phenyl)	7.40		5.5	12.3	5.3	13.5	n/a	n/a		
Virginia (Cyclohexane)			7.2	14.4	7.0	13.4	n/a	n/a		
Calwich (Phenyl)	8.4/7.8*	7.6	6.6	4.5	6.7	3.4	n/a	n/a		
Swiss (Phenyl)	7.4/7.5*	6.1	11.1	3.5	11.0	3.3	n/a	n/a		
Geometric mean at 20°C[b] (n=6)			**5.6**		**5.5**		n/a			

*: aerobic/anaerobic
[a]: measured in [medium to be stated, usually calcium chloride solution or water]
[b]: normalized using a Q_{10} of 2.58

Table 8.6-11: Summary of observed metabolites

NMBA Water/sediment system	Max. in water 7.4%* after 3 days, max. in sediment <1%* Max. in total system 7.4% after 3 days	EFSA Journal 2016;14(3):4419
AMBA Water/sediment system	Max. in water 15.8% after 46 days, max. in sediment 8.8% after 46 days Max. in total system 24.6% after 46 days	
SYN546974 Water/sediment system	Max. in water 9.4% after 29 days, max. in sediment 25.6% after 102 days Max. in total system 33% after 29 days	

*: detected in Cary., 1999. Not detected in Graham R, 2013

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

8.7.1 Justification for new endpoints

Not relevant as there is no deviation to EU agreed endpoints.

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

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

Use No.	1
Crop	**Maize**
Application rate (g as/ha)	Rimsulfuron: 7.5 ~~9.9~~ Nicosulfuron: 30 ~~39.6~~ Mesotrione: 90 ~~118~~
Number of applications/interval	1/-
Crop interception (%)	25%
Depth of soil layer (relevant for plateau concentration) (cm)	20 cm (Tillage)

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

Compound	Molecular weight (g/mol)	Max. occurrence (%)	DT50 (days)	Value in accordance to EU endpoint y/n/ Reference
Rimsulfuron	431.45	-	9.8 (field studies)	Y, EFSA Journal 2005; 45, 1-61
IN-70941	367.4	54.5	615 (Maximum non normalised, laboratory studies)	
IN-70942	324.36	23.5	214 (Maximum non normalised, laboratory studies)	
IN-E9260	250.3	18.9	969 (Maximum non normalised, laboratory studies)	
IN-J0290	155.2	12.7	11.3 (Maximum, non normalised laboratory studies)	
Nicosulfuron	410.4	-	63 d (longest value from field study, n=4)	EFSA Scientific report (2007) 120, 1-91
HMUD	396.4	14.4	30.8 (longest value from lab. study, n=2)	
ADMP	155.2	9.8	11.3 d (longest value from lab study, n=3)	

Compound	Molecular weight (g/mol)	Max. occurrence (%)	DT50 (days)	Value in accordance to EU endpoint y/n/ Reference
ASDM	229.3	63.4	268.5 (longest value from lab. study, n=3)	
AUSN	314.3	26.8	218.28 (longest value from lab. study, n=3)	
UCSN	315.3	11	307.5 d (longest value from lab. study, n=3)	
Mesotrione	339	-	43.4 d (DFOP, laboratory studies, ~~normalized)~~	EFSA Journal 2016;14(3):4419
MNBA	245	57.2	n.a	
AMBA	215	9.7		

8.7.2.1 Rimsulfuron and its metabolites

Table 8.7-3: PEC$_{soil}$ for Rimsulfuron on maize

PEC$_{soil}$ (mg/kg)		Maize	
		Single application	
		Actual	TWA
Initial		0.008	-
Short term	24h	0.007	0.007
	2d	0.007	0.007
	4d	0.006	0.007
Long term	7d	0.005	0.006
	14d	0.003	0.005
	21d	0.002	0.004
	28d	0.001	0.003
	50d	<0.001	0.002
	100d	<0.001	0.001
Plateau concentration (20 cm) after year 20		-	-
PEC$_{accumulation}$ (PEC$_{act}$ +PEC$_{soil\ plateau}$)		-	-

~~PEC$_{soil}$ (mg/kg)~~	~~Maize~~
	~~Single application~~

		Actual	TWA
~~Initial~~		~~0.010~~	~~-~~
~~Short term~~	~~24h~~	~~0.009~~	~~0.010~~
	~~2d~~	~~0.009~~	~~0.009~~
	~~4d~~	~~0.007~~	~~0.009~~
~~Long term~~	~~7d~~	~~0.006~~	~~0.008~~
	~~14d~~	~~0.004~~	~~0.006~~
	~~21d~~	~~0.002~~	~~0.005~~
	~~28d~~	~~0.001~~	~~0.004~~
	~~50d~~	~~<0.001~~	~~0.003~~
	~~100d~~	~~<0.001~~	~~0.001~~
~~Plateau concentration (20 cm) after year 20~~		~~-~~	~~-~~
~~$PEC_{accumulation}$ (PEC_{act} + $PEC_{soil\ plateau}$)~~		~~-~~	~~-~~

PEC_{soil} of metabolites

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

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

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

Table 8.7-4: Corrected application rates for the metabolites

Metabolite	Application rate of the parent (g/ha)	MW_{parent}	$MW_{metabolite}$	Maximum occurrence in soil (%)	Corrected application rate (g/ha)
IN-70941	7.5	431.45	367.4	54.5	3.480
IN-70942			324.36	23.5	1.325
IN-E9260			250.3	18.9	0.822
IN-J0290			155.2	12.7	0.342

~~Metabolite~~	~~Application rate of the parent (g/ha)~~	~~MW_{parent}~~	~~$MW_{metabolite}$~~	~~Maximum occurrence in soil (%)~~	~~Corrected application rate (g/ha)~~
~~IN-70941~~	~~9.9~~	~~431.45~~	~~367.4~~	~~54.5~~	~~4.595~~
~~IN-70942~~			~~324.36~~	~~23.5~~	~~1.749~~
~~IN-E9260~~			~~250.3~~	~~18.9~~	~~1.085~~
~~IN-J0290~~			~~155.2~~	~~12.7~~	~~0.452~~

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

Table 8.7-5: PEC_{soil} for IN-70941 on maize

PEC_{soil} (mg/kg)	Maize
	Single application

		Actual	TWA
Initial		0.003	-
Short term	24h	0.003	0.003
	2d	0.003	0.003
	4d	0.003	0.003
Long term	7d	0.003	0.003
	14d	0.003	0.003
	21d	0.003	0.003
	28d	0.003	0.003
	50d	0.003	0.003
	100d	0.003	0.003
Plateau concentration (20 cm) after year 7		0.002	-
$PEC_{accumulation}$ (PEC_{act} + $PEC_{soil\ plateau}$)		0.005	-

~~PEC_{soil} (mg/kg)~~		~~**Maize**~~	
		~~Single application~~	
		~~Actual~~	~~TWA~~
~~Initial~~		~~0.005~~	~~-~~
~~Short term~~	~~24h~~	~~0.005~~	~~0.005~~
	~~2d~~	~~0.005~~	~~0.005~~
	~~4d~~	~~0.005~~	~~0.005~~
~~Long term~~	~~7d~~	~~0.005~~	~~0.005~~
	~~14d~~	~~0.005~~	~~0.005~~
	~~21d~~	~~0.004~~	~~0.005~~
	~~28d~~	~~0.004~~	~~0.005~~
	~~50d~~	~~0.004~~	~~0.004~~
	~~100d~~	~~0.004~~	~~0.004~~
~~Plateau concentration (20 cm) after year 4~~		~~0.002~~	~~-~~
~~$PEC_{accumulation}$ (PEC_{act} + $PEC_{soil\ plateau}$)~~		~~0.006~~	~~-~~

Table 8.7-6: PEC_{soil} for IN-70942 on maize

PEC_{soil} (mg/kg)		**Maize**	
		Single application	
		Actual	TWA
Initial		0.001	-
Short term	24h	0.001	0.001

	2d	0.001	0.001
	4d	0.001	0.001
Long term	7d	0.001	0.001
	14d	0.001	0.001
	21d	0.001	0.001
	28d	0.001	0.001
	50d	0.001	0.001
	100d	0.001	0.001
Plateau concentration (20 cm) after year 1		<0.001	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		0.001	-

~~PEC_{soil} (mg/kg)~~		~~Maize~~	
		~~Single application~~	
		~~Actual~~	~~TWA~~
~~Initial~~		~~0.002~~	~~-~~
~~Short term~~	~~24h~~	~~0.002~~	~~0.002~~
	~~2d~~	~~0.002~~	~~0.002~~
	~~4d~~	~~0.002~~	~~0.002~~
~~Long term~~	~~7d~~	~~0.002~~	~~0.002~~
	~~14d~~	~~0.002~~	~~0.002~~
	~~21d~~	~~0.002~~	~~0.002~~
	~~28d~~	~~0.002~~	~~0.002~~
	~~50d~~	~~0.001~~	~~0.002~~
	~~100d~~	~~0.001~~	~~0.001~~
~~Plateau concentration (20 cm) after year 1~~		~~<0.001~~	~~-~~
~~$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)~~		~~0.002~~	~~-~~

Table 8.7-7: PEC_{soil} for IN-E9260 on maize

PEC_{soil} (mg/kg)		Maize	
		Single application	
		Actual	TWA
Initial		0.001	-
Short term	24h	0.001	0.001
	2d	0.001	0.001
	4d	0.001	0.001
Long term	7d	0.001	0.001

	14d	0.001	0.001
	21d	0.001	0.001
	28d	0.001	0.001
	50d	0.001	0.001
	100d	0.001	0.001
Plateau concentration (20 cm) after year 6		0.001	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		0.002	-

~~PEC_{soil} (mg/kg)~~		~~Maize~~	
		~~Single application~~	
		~~Actual~~	~~TWA~~
~~Initial~~		~~0.001~~	~~-~~
~~Short term~~	~~24h~~	~~0.001~~	~~0.001~~
	~~2d~~	~~0.001~~	~~0.001~~
	~~4d~~	~~0.001~~	~~0.001~~
~~Long term~~	~~7d~~	~~0.001~~	~~0.001~~
	~~14d~~	~~0.001~~	~~0.001~~
	~~21d~~	~~0.001~~	~~0.001~~
	~~28d~~	~~0.001~~	~~0.001~~
	~~50d~~	~~0.001~~	~~0.001~~
	~~100d~~	~~0.001~~	~~0.001~~
~~Plateau concentration (20 cm) after year 5~~		~~0.001~~	~~-~~
~~$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)~~		~~0.002~~	~~-~~

Table 8.7-8: PEC_{soil} for IN-J0290 on maize

PEC_{soil} (mg/kg)		**Maize**	
		Single application	
		Actual	TWA
Initial		<0.001	-
Short term	24h	<0.001	<0.001
	2d	<0.001	<0.001
	4d	<0.001	<0.001
Long term	7d	<0.001	<0.001
	14d	<0.001	<0.001
	21d	<0.001	<0.001
	28d	<0.001	<0.001
	50d	<0.001	<0.001

	100d	<0.001	<0.001
Plateau concentration (20 cm) after year 20		-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		-	-

~~PEC_{soil} (mg/kg)~~		~~Maize~~	
		~~Single application~~	
		~~Actual~~	~~TWA~~
~~Initial~~		~~<0.001~~	~~-~~
~~Short term~~	~~24h~~	~~<0.001~~	~~<0.001~~
	~~2d~~	~~<0.001~~	~~<0.001~~
	~~4d~~	~~<0.001~~	~~<0.001~~
~~Long term~~	~~7d~~	~~<0.001~~	~~<0.001~~
	~~14d~~	~~<0.001~~	~~<0.001~~
	~~21d~~	~~<0.001~~	~~<0.001~~
	~~28d~~	~~<0.001~~	~~<0.001~~
	~~50d~~	~~<0.001~~	~~<0.001~~
	~~100d~~	~~<0.001~~	~~<0.001~~
~~Plateau concentration (20 cm) after year 20~~		~~-~~	~~-~~
~~$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)~~		~~-~~	~~-~~

zRMS comments:

Rimsulfuron

PEC_{soil} calculations has been accepted for the active substance rimsulfuron and its metabolites IN-70941, IN-70942 and IN-E9260 and for the major metabolite from photolysis study IN-J0290.
The input parameters used in calculations were taken from the endpoints available in the EFSA conclusion on Scientific Report (EFSA Journal 2005; 45, 1-61. Interception is appropriate to the proposed BBCH of crops (guidance 2014).
The acceptable predicted environmental concentrations of rimsulfuron and its metabolites in soil are appropriate to be used for the subsequent risk assessment.

The PECs calculation for the lower dose 7.5 g/ha have been performed using the same parameters as made earlier and are therefore accepted by zRMS.

Agreed PECsoil:
Rimsulfuron:PECs = 0.008 mg/kg
IN-70491: PECs = 0.003 mg/kg; PECs acc = 0.005 mg/kg
IN-70942: PECs = 0.001 mg/kg; PECs acc = 0.001 mg/kg
IN-E9260: PECs = 0.001 mg/kg; PECs acc = 0.002 mg/kg
IN-J0290: PECs < 0.001mg/kg.

8.7.2.2 Nicosulfuron and its metabolites

Table 8.7-9: PEC_{soil} for Nicosulfuron on maize

PEC_{soil} (mg/kg)		**Maize**	
		Single application	
		Actual	TWA
Initial		0.030	-
Short term	24h	0.030	0.030
	2d	0.029	0.030
	4d	0.029	0.029
Long term	7d	0.028	0.029
	14d	0.026	0.028
	21d	0.024	0.027
	28d	0.022	0.026
	50d	0.017	0.023
	100d	0.010	0.018
Plateau concentration (20 cm) after year 1		<0.001	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		0.030	-

~~PEC_{soil} (mg/kg)~~		~~**Maize**~~	
		~~Single application~~	
		~~Actual~~	~~TWA~~
~~Initial~~		~~0.040~~	~~-~~
~~Short term~~	~~24h~~	~~0.039~~	~~0.039~~
	~~2d~~	~~0.039~~	~~0.039~~
	~~4d~~	~~0.038~~	~~0.039~~
~~Long term~~	~~7d~~	~~0.037~~	~~0.038~~
	~~14d~~	~~0.034~~	~~0.037~~
	~~21d~~	~~0.031~~	~~0.035~~
	~~28d~~	~~0.029~~	~~0.034~~
	~~50d~~	~~0.023~~	~~0.031~~
	~~100d~~	~~0.013~~	~~0.024~~
~~Plateau concentration (20 cm) after year 1~~		~~< 0.001~~	~~-~~
~~$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)~~		~~0.040~~	~~-~~

PEC_{soil} of metabolites

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

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

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

Table 8.7-10: Corrected application rates for the metabolites

Metabolite	Application rate of the parent (g/ha)	MW_{parent}	$MW_{metabolite}$	Maximum occurrence in soil (%)	Corrected application rate (g/ha)
HMUD	30	410.4	396.4	14.4	4.17
ADMP			155.2	9.8	1.11
ASDM			229.3	63.4	10.62
AUSN			314.3	26.8	6.15
UCSN			315.3	11.0	2.33

~~Metabolite~~	~~Application rate of the parent (g/ha)~~	~~MW_{parent}~~	~~$MW_{metabolite}$~~	~~Maximum occurrence in soil (%)~~	~~Corrected application rate (g/ha)~~
~~HMUD~~	~~39.6~~	~~410.4~~	~~396.4~~	~~14.4~~	~~5.51~~
~~ADMP~~			~~155.2~~	~~9.8~~	~~1.47~~
~~ASDM~~			~~229.3~~	~~63.4~~	~~14.03~~
~~AUSN~~			~~314.3~~	~~26.8~~	~~8.13~~
~~UCSN~~			~~315.3~~	~~11.0~~	~~3.35~~

Table 8.7-11: PEC_{soil} for HMUD on maize

PEC_{soil} (mg/kg)		Maize	
		Single application	
		Actual	TWA
Initial		0.004	-
Short term	24h	0.004	0.004
	2d	0.004	0.004
	4d	0.004	0.004
Long term	7d	0.004	0.004
	14d	0.003	0.004
	21d	0.003	0.003
	28d	0.002	0.003
	50d	0.001	0.003
	100d	<0.001	0.002
Plateau concentration (20 cm) after year		-	-
$PEC_{accumulation}$ (PEC_{act} + $PEC_{soil\ plateau}$)		-	-

~~PEC$_{soil}$ (mg/kg)~~		~~Maize~~	
		~~Single application~~	
		~~Actual~~	~~TWA~~
~~Initial~~		~~0.006~~	~~-~~
~~Short term~~	~~24h~~	~~0.005~~	~~0.005~~
	~~2d~~	~~0.005~~	~~0.005~~
	~~4d~~	~~0.005~~	~~0.005~~
~~Long term~~	~~7d~~	~~0.005~~	~~0.005~~
	~~14d~~	~~0.004~~	~~0.005~~
	~~21d~~	~~0.003~~	~~0.004~~
	~~28d~~	~~0.003~~	~~0.004~~
	~~50d~~	~~0.002~~	~~0.003~~
	~~100d~~	~~0.002~~	~~0.002~~
~~Plateau concentration (20 cm) after year~~		~~-~~	~~-~~
~~PEC$_{accumulation}$ (PEC$_{act}$ +PEC$_{soil\ plateau}$)~~		~~-~~	~~-~~

Table 8.7-12: PEC$_{soil}$ for ADMP on maize

PEC$_{soil}$ (mg/kg)		Maize	
		Single application	
		Actual	TWA
Initial		0.001	-
Short term	24h	0.001	0.001
	2d	0.001	0.001
	4d	0.001	0.001
Long term	7d	0.001	0.001
	14d	<0.001	0.001
	21d	<0.001	0.001
	28d	<0.001	0.001
	50d	<0.001	<0.001
	100d	<0.001	<0.001
Plateau concentration (20 cm) after year 20		-	-
PEC$_{accumulation}$ (PEC$_{act}$ +PEC$_{soil\ plateau}$)		-	-

~~PEC$_{soil}$ (mg/kg)~~	~~Maize~~
	~~Single application~~

		~~Actual~~	~~TWA~~
~~Initial~~		~~0.001~~	~~-~~
~~Short term~~	~~24h~~	~~0.001~~	~~0.001~~
	~~2d~~	~~0.001~~	~~0.001~~
	~~4d~~	~~0.001~~	~~0.001~~
~~Long term~~	~~7d~~	~~0.001~~	~~0.001~~
	~~14d~~	~~0.001~~	~~0.001~~
	~~21d~~	~~< 0.001~~	~~0.001~~
	~~28d~~	~~< 0.001~~	~~0.001~~
	~~50d~~	~~< 0.001~~	~~< 0.001~~
	~~100d~~	~~< 0.001~~	~~< 0.001~~
~~Plateau concentration (20 cm) after year 20~~		~~-~~	~~-~~
~~$PEC_{accumulation}$ (PEC_{act} + $PEC_{soil\ plateau}$)~~		~~-~~	~~-~~

Table 8.7-13: PEC_{soil} for ASDM on maize

PEC_{soil} (mg/kg)		**Maize**	
		Single application	
		Actual	TWA
Initial		0.011	-
Short term	24h	0.011	0.011
	2d	0.011	0.011
	4d	0.011	0.011
Long term	7d	0.010	0.011
	14d	0.010	0.010
	21d	0.010	0.010
	28d	0.010	0.010
	50d	0.009	0.010
	100d	0.008	0.009
Plateau concentration (20 cm) after year 4		0.002	-
$PEC_{accumulation}$ (PEC_{act} + $PEC_{soil\ plateau}$)		0.013	-

~~PEC_{soil} (mg/kg)~~		~~**Maize**~~	
		~~Single application~~	
		~~Actual~~	~~TWA~~
~~Initial~~		~~0.014~~	~~-~~
~~Short term~~	~~24h~~	~~0.014~~	~~0.014~~

	~~2d~~	~~0.014~~	~~0.014~~
	~~4d~~	~~0.014~~	~~0.014~~
~~Long term~~	~~7d~~	~~0.014~~	~~0.014~~
	~~14d~~	~~0.014~~	~~0.014~~
	~~21d~~	~~0.013~~	~~0.014~~
	~~28d~~	~~0.013~~	~~0.014~~
	~~50d~~	~~0.012~~	~~0.013~~
	~~100d~~	~~0.011~~	~~0.012~~
~~Plateau concentration (20 cm) after year 3~~		~~0.002~~	~~-~~
~~$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)~~		~~0.016~~	~~0.014~~

Table 8.7-14: PEC$_{soil}$ for AUSN on maize

PEC_{soil} (mg/kg)		**Maize**	
		Single application	
		Actual	TWA
Initial		0.006	-
Short term	24h	0.006	0.006
	2d	0.006	0.006
	4d	0.006	0.006
Long term	7d	0.006	0.006
	14d	0.006	0.006
	21d	0.006	0.006
	28d	0.006	0.006
	50d	0.005	0.006
	100d	0.004	0.005
Plateau concentration (20 cm) after year 3		0.001	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		0.007	-

~~PEC_{soil} (mg/kg)~~		~~**Maize**~~	
		~~Single application~~	
		~~Actual~~	~~TWA~~
~~Initial~~		~~0.008~~	~~-~~
~~Short term~~	~~24h~~	~~0.008~~	~~0.008~~
	~~2d~~	~~0.008~~	~~0.008~~
	~~4d~~	~~0.008~~	~~0.008~~

~~Long term~~	~~7d~~	~~0.008~~	~~0.008~~
	~~14d~~	~~0.008~~	~~0.008~~
	~~21d~~	~~0.008~~	~~0.008~~
	~~28d~~	~~0.007~~	~~0.008~~
	~~50d~~	~~0.007~~	~~0.008~~
	~~100d~~	~~0.006~~	~~0.007~~
~~Plateau concentration (20 cm) after year 2~~		~~0.001~~	~~-~~
~~$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)~~		~~0.009~~	~~-~~

Table 8.7-15: PEC$_{soil}$ for UCSN on maize

PEC$_{soil}$ (mg/kg)		Maize	
		Single application	
		Actual	TWA
Initial		0.003	-
Short term	24h	0.003	0.003
	2d	0.003	0.003
	4d	0.003	0.003
Long term	7d	0.002	0.003
	14d	0.002	0.002
	21d	0.002	0.002
	28d	0.002	0.002
	50d	0.002	0.002
	100d	0.002	0.002
Plateau concentration (20 cm) after year 1		<0.001	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		0.003	-

~~PEC$_{soil}$ (mg/kg)~~		~~Maize~~	
		~~Single application~~	
		~~Actual~~	~~TWA~~
~~Initial~~		~~0.003~~	~~-~~
~~Short term~~	~~24h~~	~~0.003~~	~~0.003~~
	~~2d~~	~~0.003~~	~~0.003~~
	~~4d~~	~~0.003~~	~~0.003~~
~~Long term~~	~~7d~~	~~0.003~~	~~0.003~~
	~~14d~~	~~0.003~~	~~0.003~~

	~~21d~~	~~0.003~~	~~0.003~~
	~~28d~~	~~0.003~~	~~0.003~~
	~~50d~~	~~0.003~~	~~0.003~~
	~~100d~~	~~0.003~~	~~0.003~~
~~Plateau concentration (20 cm) after year 3~~		~~0.001~~	~~-~~
~~$PEC_{accumulation}$ (PEC_{act} + $PEC_{soil\ plateau}$)~~		~~0.004~~	~~-~~

zRMS comments:

Nicosulfuron

PEC_{soil} calculations has been accepted for the active substance nicosulfuron and its metabolites HMUD, ADMP, ASDM, AUSN and UCSN.
The input parameters used in calculations were taken from the endpoints available in the EFSA conclusion on Scientific Report EFSA (2007) 120, 1-91. Interception is appropriate to the proposed BBCH of crops (guidance 2014).
The acceptable predicted environmental concentrations of nicosulfuron and its metabolites in soil are appropriate to be used for the subsequent risk assessment.

The PECs calculation of nicosulfuron for the lower dose 30 g/ha have been performed using the same parameters as made earlier and are therefore accepted by zRMS.
Nicosulfuron: PECs = 0.030 mg/kg; PECs, acc = 0.040 mg/kg
HMUD:PECs = 0.004 mg/kg
ADMP :PECs = 0.001 mg/kg
ASDM :PECs = 0.011 mg/kg; PECs, acc = 0.013 mg/kg
AUSN :PECs = 0.006 mg/kg; PECs, acc = 0.007 mg/kg
UCSN: PECs = 0.003 mg/kg; PECs, acc = 0.003 mg/kg

8.7.2.3 Mesotrione and its metabolites

Table 8.7-16: PEC_{soil} for Mesotrione on maize

PEC_{soil} (mg/kg)		Maize	
		Single application	
		Actual	TWA
Initial		0.090	-
Short term	24h	0.089	0.089
	2d	0.087	0.089
	4d	0.084	0.087
Long term	7d	0.080	0.085
	14d	0.072	0.081
	21d	0.064	0.076
	28d	0.058	0.073
	50d	0.040	0.062
	100d	0.018	0.045

Plateau concentration (20 cm) after year -	-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)	-	-

~~PEC_{soil} (mg/kg)~~		~~Maize~~	
		~~Single application~~	
		~~Actual~~	~~TWA~~
~~Initial~~		~~0.118~~	~~-~~
~~Short term~~	~~24h~~	~~0.116~~	~~0.117~~
	~~2d~~	~~0.114~~	~~0.116~~
	~~4d~~	~~0.111~~	~~0.114~~
~~Long term~~	~~7d~~	~~0.116~~	~~0.112~~
	~~14d~~	~~0.094~~	~~0.106~~
	~~21d~~	~~0.084~~	~~0.100~~
	~~28d~~	~~0.075~~	~~0.095~~
	~~50d~~	~~0.055~~	~~0.082~~
	~~100d~~	~~0.024~~	~~0.059~~
~~Plateau concentration (20 cm) after year -~~		~~-~~	~~-~~
~~$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)~~		~~-~~	~~-~~

PEC_{soil} of metabolites

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

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

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

Table 8.7-17: Corrected application rates for the metabolites

Metabolite	**Application rate of the parent (g/ha)**	**MW_{parent}**	**$MW_{metabolite}$**	**Maximum occurrence in soil (%)**	**Corrected application rate (g/ha)**
MNBA	90	339	245	57.2	37.20
AMBA			215	9.7	5.53

~~**Metabolite**~~	~~**Application rate of the parent (g/ha)**~~	~~**MW_{parent}**~~	~~**$MW_{metabolite}$**~~	~~**Maximum occurrence in soil (%)**~~	~~**Corrected application rate (g/ha)**~~
~~MNBA~~	~~118~~	~~339~~	~~245~~	~~57.2~~	~~48.78~~
~~AMBA~~			~~215~~	~~9.7~~	~~7.26~~

Table 8.7-18: PEC$_{soil}$ for MNBA on maize

PEC$_{soil}$ (mg/kg)	Maize	
	Single application	
	Actual	TWA
Initial	~~0.049~~ ~~0.049~~ 0.043	-

Table 8.7-99: PEC$_{soil}$ for AMBA on maize

PEC$_{soil}$ (mg/kg)	Maize	
	Single application	
	Actual	TWA
Initial	~~0.007~~ ~~0.007~~ 0.007	-

zRMS comments:

Mesotrione

PEC$_{soil}$ calculations has been accepted for the active substance mesotrione and its metabolites MNBA and AMBA. The input parameters used in calculations were taken from the endpoints available in the EFSA conclusion on Scientific EFSA Journal 2016;14 (3):4419. Interception is appropriate to the proposed BBCH of crops (guidance 2014). It is noted that for mesotrione the maximum non-normalised laboratory DT50 of 34.3 days was recommended for calculation of the soil exposure in EFSA report. However, DT50 used by the Applicant was accepted by zRMS because it does not affect the outcome of the PECs. Moreover, due to lack of potential mesotrione for accumulation in soil (DT50 <60 days) the soil risk assessment is based on initial PECsoil values. The acceptable predicted environmental concentrations of mesotrione and its metabolites in soil are appropriate to be used for the subsequent risk assessment.

The PECs calculation of mesotrione for the lower dose 90 g/ha have been performed using the same parameters as made earlier and are therefore accepted by zRMS.

Mesotrione: PECs = 0.09 mg/kg
MNBA: PECs = 0.043 mg/kg
AMBA: PECs = 0.007 mg/kg

8.7.2.4 PEC$_{soil}$ of PRIMARY MX

Since PRIMARY MX is rapidly broken down into its constituent parts on contact with soil and/or crop material, it is appropriate to calculate the PEC$_{Soil}$ following a single application only, using the following equation:

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

Table 0-1: PEC$_{soil}$ for PRIMARY MX on maize

Active substances/Preparation	Application rate (g/ha)	Crop interception (%)	PEC$_{act}$ (mg/kg)
Rimsulfuron + Nicosulfuron + Mesotrione / PRIMARY MX	250 ~~330~~	25	0.250 ~~0.330~~

zRMS comments: PECsoil value calculated by the Applicant for the formulated product may be used in the risk assessment. **PRIMARY MX** PECs, formulation = 0.250 mg/kg

8.8 Predicted Environmental Concentrations in groundwater (PEC$_{gw}$) (KCP 9.2.4)

8.8.1 Justification for new endpoints

Not relevant as there is no deviation to EU agreed endpoints.

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

Table 8.8-1: Input parameters related to application for PEC$_{gw}$ calculations

Use No.	1
Crop	Maize
Application rate (g as/ha)	Rimsulfuron: ~~9.9~~ / 7.5 Nicosulfuron: ~~39.6~~30 Mesotrione: ~~118~~ / 90
Number of applications/interval (d)	1/-
Crop interception (%)	25
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 (absolute)*
Châteaudun	09/05
Hamburg	12/05
Kremsmünster	12/05

Scenario	Application dates (absolute)*
Okehampton	29/05
Piacenza	21/05
Porto	09/05
Sevilla	15/03
Thiva	25/04

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

8.8.2.1 Rimsulfuron and its metabolites

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

Compound	Rimsulfuron	IN-70941	IN-70942	IN-E9260	IN-J0290	Value in accordance with EU endpoint y/n/ Reference*
Molecular weight (g/mol)	431.45	367.4	324.36	250.3	155.2	Y, EFSA Journal 2005; 45, 1-61
Water solubility (mg/L):	7300 @ 25ºC 6062 @ 20ºC*					
Saturated vapour pressure (Pa):	8.9×10^{-7} @ 20ºC					
DT_{50} in soil (d)	18.3 (geomean, lab studies n=5, normalized at 20°C, Q_{10} 2.58 and pF2)	128.9 (geomean, lab studies n=3, normalized at 20°C, Q_{10} 2.58 and pF2)	86.2 (geomean, lab studies n=3, normalized at 20°C, Q_{10} 2.58 and pF2)	359.3 (geomean, lab studies n=3, normalized at 20°C, Q_{10} 2.58 and pF2)	4.5 (geomean lab studies, n=3, normalized at 20 °C, Q_{10} 2.58 and pF2)	
K_{foc}/K_{fom} (mL/g)	42.4/24.6 (geomean, n=4)	41.5/24.1 (geomean, n=3, higher adsorption value from clay soil was excluded)	191.7/111.2 (geomean, n=4)	23.2/13.5 (geomean, n=3, higher adsorption value from clay soil was excluded)	51.1/29.6(geomean, n=4)	
1/n	1.02 (arithmetic mean, n =4)	0.94 (arithmethic mean, n=4)	0.85 (arithmethic mean, n=4)	0.99 (arithmethic mean, n=4)	0.87 (arithmetic mean, n= 4)	
Plant uptake factor	0 (default)					
Formation fraction	-	0.57 from parent	1 from IN-70941	0.18 from parent	0.03 from parent	

***Calcualted by UBA Excel™ spreadsheet EVA 3.0 rev 2h used in PELMO claulations.**

Table 8.8-4: PEC$_{gw}$ for Rimsulfuron and metabolites on maize with FOCUS PEARL 4.4.4 and FOCUS PELMO 5.5.3

Scenario	**80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)**									
	Rimsulfuron		**IN-70941**		**IN-70942**		**IN-E9260**		**IN-J0290**	
	PELMO	**PEARL**	**PELMO**	**PEARL**	**PELMO**	**PEARL**	**PELMO**	**PEARL**	**PELMO**	**PEARL**
Châteaudun	0.008	0.013	0.327	0.331	0.028	0.027	0.213	0.202	<0.001	<0.001
Hamburg	0.027	0.032	0.387	0.448	0.030	0.033	0.219	0.254	<0.001	<0.001
Kremsmünster	0.022	0.019	0.328	0.315	0.026	0.025	0.171	0.151	<0.001	<0.001
Okehampton	0.032	0.033	0.283	0.285	0.019	0.020	0.119	0.126	<0.001	<0.001
Piacenza	0.011	0.008	0.259	0.320	0.023	0.033	0.125	0.215	<0.001	<0.001
Porto	0.004	0.004	0.176	0.170	0.008	0.008	0.103	0.096	<0.001	<0.001
Sevilla	0.001	<0.001	0.135	0.148	0.008	0.010	0.192	0.236	<0.001	<0.001
Thiva	0.003	0.005	0.362	0.424	0.033	0.044	0.301	0.408	<0.001	<0.001

~~Scenario~~	~~80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)~~									
	~~Rimsulfuron~~		~~IN-70941~~		~~IN-70942~~		~~IN-E9260~~		~~IN-J0290~~	
	~~PELMO~~	~~PEARL~~	~~PELMO~~	~~PEARL~~	~~PELMO~~	~~PEARL~~	~~PELMO~~	~~PEARL~~	~~PELMO~~	~~PEARL~~
~~Châteaudun~~	~~0.010~~	~~0.017~~	~~0.434~~	~~0.444~~	~~0.038~~	~~0.037~~	~~0.279~~	~~0.267~~	~~<0.001~~	~~<0.001~~
~~Hamburg~~	~~0.033~~	~~0.042~~	~~0.508~~	~~0.600~~	~~0.040~~	~~0.045~~	~~0.285~~	~~0.336~~	~~<0.001~~	~~<0.001~~
~~Kremsmünster~~	~~0.027~~	~~0.025~~	~~0.430~~	~~0.423~~	~~0.035~~	~~0.035~~	~~0.223~~	~~0.200~~	~~<0.001~~	~~<0.001~~
~~Okehampton~~	~~0.040~~	~~0.044~~	~~0.372~~	~~0.378~~	~~0.026~~	~~0.028~~	~~0.156~~	~~0.166~~	~~<0.001~~	~~<0.001~~
~~Piacenza~~	~~0.015~~	~~0.010~~	~~0.348~~	~~0.428~~	~~0.031~~	~~0.045~~	~~0.166~~	~~0.284~~	~~<0.001~~	~~<0.001~~
~~Porto~~	~~0.006~~	~~0.005~~	~~0.234~~	~~0.227~~	~~0.010~~	~~0.011~~	~~0.135~~	~~0.127~~	~~<0.001~~	~~<0.001~~
~~Sevilla~~	~~0.001~~	~~0.001~~	~~0.182~~	~~0.200~~	~~0.010~~	~~0.014~~	~~0.252~~	~~0.313~~	~~<0.001~~	~~<0.001~~
~~Thiva~~	~~0.005~~	~~0.006~~	~~0.487~~	~~0.569~~	~~0.046~~	~~0.061~~	~~0.398~~	~~0.539~~	~~<0.001~~	~~<0.001~~

Conclusion

The Rimsulfuron, IN-70942 and IN-J0290 PECgw were below 0.1 µg/L. However, the non-relevant metabolites IN-70941 and IN-E9260 shown PECgw's greater than 0.1 but below 0.75 µg/L. The assessment relevance of the metabolites in ground water according to SANCO/221/2000 –rev.10 document will be done and reported in the dRR Part B10.

zRMS comments:

Rimsulfuron

The PEC$_{gw}$ calculations have been provided for the active substance rimsulfuron and its metabolites IN-70941, IN-70942 and IN-E9260. PEC$_{gw}$ has been provided also for the major metabolite, in the soil photolysis study IN-J0290. Input parameters used for calculations can be considered acceptable (Y, EFSA Journal 2005; 45, 1-61). In opinion of zRMS interception is appropriate to the proposed BBCH of crops (guidance 2014). 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 Rimsulfuron, and IN-70942 and IN-J0290 PECgw were below 0.1 µg/L. However, the non-relevant metabolites IN-70941 and IN-E9260 shown PEC_{gw} greater than 0.1 but below 0.75 µg/L. The assessment relevance of the metabolites in ground water according to SANCO/221/2000 –rev.10 document will be done and reported in the dRR Part B10.

Nevertheless, additional simulations may be required by the sMS that do not accept calculations performed using FOCUS models.

The PECs calculation of rimsulfuron for the lower dose 7.5 g/ha have been performed using the same parameters as made earlier and are therefore accepted by zRMS.

8.8.2.2 Nicosulfuron and its metabolites

Table 8.8-5: Input parameters related to active substance Nicosulfuron and metabolites for PEC_{gw} calculations

Compound	**Nicosulfuron**	**HMUD**	**ADMP**	**ASDM**	**AUSN**	**UCSN**	**MU-466**	**Value in accordance with EU endpoint y/n/ Reference***
Molecular weight (g/mol)	410.4	396.4	155.2	229.3	314.3	315.3	215.2	EFSA Scientific Report (2007) 120, 1-91
Water solubility (mg/L):	9500 at 19.7°C and pH 6.7 9508 at 20ºC pH 6.7*	1000 at 20ºC (default)						
Saturated vapour pressure (Pa):	8 x 10^{-10} at 25°C 4.16 x 10^{-10} at 20ºC*	0 at 20°C (default)						
DT_{50} in soil (d)	16.4 d (geomean, normalisation to 10 kPa or pF2, 20 °C, n =7)	23.8 (geomean normalisation to pF2, 20°C, n=2)	4.5 (geomean normalisation to pF2, 20°C, n=3)	108.7 (geomean normalisation to pF2, 20°C, n=3) ~~236.6 Worst case DT50 values, normalised to 20°C and pF2 (lab).~~	90.9 (geomean normalisation to pF2, 20°C, n=3) ~~192.3 Worst case DT50 values, normalised to 20°C and pF2 (lab).~~	160.1 (geomean normalisation to pF2, 20°C, n=3) ~~271.0 Worst case DT50 values, normalised to 20°C and pF2 (lab).~~	66.6 (geomean normalisation to pF2, 20°C, n=3) ~~75.50 Worst case DT50 values, normalised to 20°C and pF2 (lab).~~	
K_{foc} (mL/g)/K_{fom}	15.4 / 8.9 (geomean, n=4)	3.9 / 2.3 (geomean, n=5)	51.1 / 29.6 (geomean, n=4)	**	**	2.6 / 1.5 (geomean, n=4)	**	
1/n	0.94 (arithmetic mean, n=4)	0.9 (default)	0.87 (arithmetic mean, n=4)	**	**	0.9 (default)	0.9 (default)	
Plant uptake factor	0							

Compound	**Nicosulfuron**	**HMUD**	**ADMP**	**ASDM**	**AUSN**	**UCSN**	**MU-466**	**Value in accordance with EU endpoint y/n/ Reference***
Formation fraction	-	0.442 from parent	0.214 from parent	0.214 from parent	0.687 from HMUD	0.313 from HMUD	0.282 from ASDM	

***Calculated by UBA Excel™ spreadsheet EVA 3.0 rev 2h used on PELMO calculations**
****: cf. Table: Scenario specific adsorption values for PECgw modelling for metabolites**

Table 8.8-6: Scenario specific adsorption values for PEC_{gw} modelling for metabolites

Compound	DT_{50} (days)	**pH ≤ 6** Hamburg, Okehampton, Porto		**6 < pH < 7** Piacenza, Sevilla		**pH ≥ 7** Châteaudun, Krems-münster, Thiva	
		K_{oc}	1/n	K_{oc}	1/n	K_{oc}	1/n
AUSN	90.9[a]	13	0.98	P=13 S=22.3	P=0.98 S=0.96	37.3	0.95
ASDM	108.7[a]	2.3	0.82	P=2.3 S=6.0	P=0.82 S=0.94	7.2	0.94
MU-466	66.6[a]	3.62	0.9*	7.5	0.9*	13.41	0.9*

*: FOCUS default value
[a]: Geometric mean DT_{50} values, normalized to 20°C and pF2 (lab.)

ASDM and AUSN have pH dependant adsorption and tests were conducted at the same pH as the topsoil in these two scenarios: P= Piacenza, S= Sevilla. Although pH dependency on adsorption can not be clearly established, the introduction of the scenario specific adsorption values for AUSN, ASDM and MU-466 in $FOCUS_{gw}$ modelling will not affect the results.

Table 8.8-7: Adsorption data for Nicosulfuron used in the FOCUS modelling

Scenario	**Horizon**	**Depth (cm)**	**Clay content* (%)**	**Calculated $K_{F\ CLAY}^{+}$ (mL/g)**	**Degradation transformation factor**
Châteaudun	1	0-25	30	0.78	1.0
	2	25-50	31	0.81	0.5
	3	50-60	25	0.64	0.5
	4	60-100	26	0.68	0.3
	5	100-120	26	0.68	0.0
	6	120-190	24	0.62	0.0
	7	190-260	31	0.81	0.0
Hamburg	1	0-30	7.2	0.19	1.0
	2	30-60	6.7	0.17	0.5
	3	60-75	0.9	0.02	0.3
	4	75-90	0	0.00	0.3
	5	90-100	0	0.00	0.3
	6	100-200	0	0.00	0.0
Kremsmünster	1	0-30	14	0.36	1.0
	2	30-50	25	0.65	0.5
	3	50-60	27	0.70	0.5
	4	60-100	27	0.70	0.3
	5	100-200	27	0.70	0.0
Okehampton	1	0-25	18	0.47	1.0
	2	25-55	17	0.44	0.5
	3	55-85	14	0.36	0.3
	4	85-100	9	0.23	0.3
	5	100-150	9	0.23	0.0
Piacenza	1	0-30	15	0.39	1.0
	2	30-40	15	0.39	0.5
	3	40-60	7	0.18	0.5
	4	60-80	7	0.18	0.3
	5	80-100	0	0.00	0.3
	6	100-170	0	0.00	0.0
Porto	1	0-35	10	0.26	1.0
	2	35-60	8	0.21	0.5

	3	60-100	8	0.21	0.3
	4	100-120	8	0.21	0.0
Sevilla	1	0-10	14	0.36	1.0
	2	10-30	13	0.34	1.0
	3	30-60	15	0.39	0.5
	4	60-100	16	0.42	0.3
	5	100-120	16	0.42	0.0
	6	120-180	22	0.57	0.0
Thiva	1	0-30	25.3	0.66	1.0
	2	30-45	25.3	0.66	0.5
	3	45-60	29.6	0.77	0.5
	4	60-85	31.9	0.83	0.3
	5	85-100	32.9	0.86	0.3
	6	100-200	32.9	0.86	0.0

*: fraction < 2µm
+: calculated using the equation $K_{F\ CLAY} = 0.026 \times \%_{clay}$

Table 8.8-8: PEC$_{gw}$ for Nicosulfuron and metabolites on maize (with FOCUS PEARL v4.4.4)

Scenario	pH [KCl]	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)						
		Nicosulfuron	**HMUD**	**AUSN**	**ADMP**	**UCSN**	**ASDM**	**MU-466**
Châteaudun	7.3	<0.001	0.340	0.706	<0.001	0.773	0.639	0.071
Hamburg	5.7	0.226	0.990	1.526	0.002	0.947	0.986	0.097
Kremsmünster	7.0	0.004	0.431	0.651	<0.001	0.542	0.499	0.046
Okehampton	5.1	0.027	0.499	0.750	0.001	0.452	0.472	0.045
Piacenza	6.3	0.009	0.206	0.947	<0.001	0.711	0.509	0.082
Porto	4.2	0.009	0.145	0.538	<0.001	0.321	0.278	0.038
Sevilla	6.6	<0.001	0.032	0.399	<0.001	0.611	0.346	0.066
Thiva	7.0	<0.001	0.145	0.862	<0.001	1.298	0.824	0.130
Every other year								
Hamburg	5.7	0.118	-	-	-	-	-	-
Every 3rd year								
Hamburg	5.7	0.073	-	-	-	-	-	-

~~Scenario~~	~~pH [KCl]~~	~~80th Percentile PECgw at 1 m Soil Depth (µg/L)~~						
		~~**Nicosulfuron**~~	~~**HMUD**~~	~~**AUSN**~~	~~**ADMP**~~	~~**UCSN**~~	~~**ASDM**~~	~~**MU-466**~~
~~Châteaudun~~	~~7.3~~	~~<0.001~~	~~0.454~~	~~0.940~~	~~<0.001~~	~~1.020~~	~~0.846~~	~~0.094~~
~~Hamburg~~	~~5.7~~	~~0.306~~	~~1.319~~	~~2.015~~	~~0.003~~	~~1.248~~	~~1.311~~	~~0.127~~
~~Kremsmünster~~	~~7.0~~	~~0.005~~	~~0.576~~	~~0.865~~	~~<0.001~~	~~0.715~~	~~0.662~~	~~0.061~~
~~Okehampton~~	~~5.1~~	~~0.038~~	~~0.665~~	~~0.999~~	~~0.001~~	~~0.597~~	~~0.627~~	~~0.059~~
~~Piacenza~~	~~6.3~~	~~0.012~~	~~0.275~~	~~1.252~~	~~<0.001~~	~~0.941~~	~~0.678~~	~~0.108~~
~~Porto~~	~~4.2~~	~~0.012~~	~~0.194~~	~~0.710~~	~~<0.001~~	~~0.423~~	~~0.369~~	~~0.050~~

~~Sevilla~~	~~6.6~~	~~<0.001~~	~~0.043~~	~~0.531~~	~~<0.001~~	~~0.809~~	~~0.460~~	~~0.089~~
~~Thiva~~	~~7.0~~	~~<0.001~~	~~0.195~~	~~1.152~~	~~<0.001~~	~~1.717~~	~~1.092~~	~~0.173~~

Table 8.8-9: PEC$_{gw}$ for Nicosulfuron and metabolites on maize (with FOCUS PELMO v. 5.3.3)

Scenario	pH [KCl]	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)						
		Nicosulfuron	**HMUD**	**AUSN**	**ADMP**	**UCSN**	**ASDM**	**MU-466**
Châteaudun	7.3	<0.001	0.211	0.680	<0.001	0.876	0.598	0.076
Hamburg	5.7	0.117	0.335	1.041	<0.001	0.774	0.628	0.082
Kremsmünster	7.0	0.003	0.170	0.463	<0.001	0.569	0.404	0.050
Okehampton	5.1	0.026	0.192	0.630	<0.001	0.466	0.364	0.049
Piacenza	6.3	0.014	0.061	0.501	<0.001	0.428	0.281	0.046
Porto	4.2	0.009	0.043	0.397	<0.001	0.317	0.200	0.037
Sevilla	6.6	<0.001	0.007	0.137	<0.001	0.361	0.142	0.028
Thiva	7.0	<0.001	0.008	0.144	<0.001	0.452	0.196	0.039
Every other year								
Hamburg	5.7	0.072	-	-	-	-	-	-

~~Scenario~~	~~pH [KCl]~~	~~80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)~~						
		~~**Nicosulfuron**~~	~~**HMUD**~~	~~**AUSN**~~	~~**ADMP**~~	~~**UCSN**~~	~~**ASDM**~~	~~**MU-466**~~
~~Châteaudun~~	~~7.3~~	~~<0.001~~	~~0.284~~	~~0.906~~	~~<0.001~~	~~1.157~~	~~0.794~~	~~0.101~~
~~Hamburg~~	~~5.7~~	~~0.156~~	~~0.448~~	~~1.379~~	~~0.001~~	~~1.021~~	~~0.836~~	~~0.108~~
~~Kremsmünster~~	~~7.0~~	~~0.005~~	~~0.228~~	~~0.621~~	~~<0.001~~	~~0.749~~	~~0.535~~	~~0.066~~
~~Okehampton~~	~~5.1~~	~~0.036~~	~~0.258~~	~~0.832~~	~~<0.001~~	~~0.615~~	~~0.484~~	~~0.065~~
~~Piacenza~~	~~6.3~~	~~0.019~~	~~0.082~~	~~0.663~~	~~<0.001~~	~~0.565~~	~~0.373~~	~~0.061~~
~~Porto~~	~~4.2~~	~~0.012~~	~~0.058~~	~~0.525~~	~~<0.001~~	~~0.418~~	~~0.265~~	~~0.049~~
~~Sevilla~~	~~6.6~~	~~<0.001~~	~~0.010~~	~~0.183~~	~~<0.001~~	~~0.476~~	~~0.188~~	~~0.038~~
~~Thiva~~	~~7.0~~	~~<0.001~~	~~0.011~~	~~0.195~~	~~<0.001~~	~~0.597~~	~~0.260~~	~~0.052~~

Conclusion

The Nicosulfuron PECgw was below 0.1 µg/L with the exception of Hamburg scenario where the concentration was ~~0.306~~ 0.226 ug/L. Metabolites HMUD, AUSN, UCSN and ASDM shown PECgw greater than 0.75 but below 10 µg/L, metabolite MU-466 had PECgw greater than 0.1 but below 0.75 µg/L and metabolite ADMP reported PECgw's well below 0.1 µg/L.

The Applicant would like to mention the Sharda's monitoring study for Nicosulfuron and its metabolites HMUD, AUSN, UCSN and ASDM performed on Italy during almost 3 years (January 2016-November 2018), where all of the monitoring regions are typical for cultivation of maize in Italy. The monitoring regions were Piemonte, Lombardia, Veneto, Emilia-Romagna and Friuli-Venezia Giulia. Within these five selected regions, seven key maize-growing areas of Northern Italy were identified and the 23 wells were distributed throughout these areas. During the study, groundwater sampling was conducted 12 times for 240 samples (20 wells × 12 sampling events) were analyzed for Nicosulfuron and its four metabolites

(3 out 23 wells were used as backup samples). According to the study the Nicosulfuron application rate used in the maize crops were 40 g as/ha in all Italian regions.

The results of the study shown that the concentration of Nicosulfuron and its four metabolites were all < 0.1 µg/L except for UCSN which showed 4 detections at 1 location up to 0.111 µg/L, AUSN which showed 26 detections at 6 locations up to 0.657 µg/L and also ASDM which showed 4 detections at 1 location up to 0.447 µg/L. A summary of Nicosulfuron and metabolites (UCSN, HMUD, AUSN and ASDM) concentrations in groundwater (µg/L) detected during the study is presented below:

Nicosulfuron < 0.1 µg/L.
UCSN ranged from < 0.1 µg/L to 0.111 µg/L.
HMUD < 0.1 µg/L.
AUSN ranged from < 0.1 µg/L to 0.657 µg/L.
ASDM ranged from < 0.1 µg/L to 0.447 µg/L.

In the next table are given the range of concentrations for Nicosulfuron at its metabolites from FOCUS models *vs* monitoring stud.

Substance	**FOCUS models**		**Monitoring study**	
	PECgw min (µg/L)	**PECgw max (µg/L)**	**PECgw min (µg/L)**	**PECgw max (µg/L)**
Nicosulfuron	<0.001	0.226	-	<0.1
HMUD	0.007	0.990	-	<0.1
AUSN	0.137	1.526	<0.1	0.657
ADMP	<0.001	0.002	-	-
UCSN	0.317	1.298	<0.1	0.111
ASDM	0.142	0.986	<0.1	0.477
MU-466	0.028	0.130	-	-

~~**Substance**~~	~~**FOCUS models**~~		~~**Monitoring study**~~	
	~~**PECgw min (µg/L)**~~	~~**PECgw max (µg/L)**~~	~~**PECgw min (µg/L)**~~	~~**PECgw max (µg/L)**~~
~~Nicosulfuron~~	~~<0.001~~	~~0.306~~	~~-~~	~~<0.1~~
~~HMUD~~	~~0.010~~	~~1.319~~	~~-~~	~~<0.1~~
~~AUSN~~	~~0.183~~	~~2.015~~	~~<0.1~~	~~0.657~~
~~ADMP~~	~~<0.001~~	~~0.003~~	~~-~~	~~-~~
~~UCSN~~	~~0.418~~	~~1.717~~	~~<0.1~~	~~0.111~~
~~ASDM~~	~~0.188~~	~~1.311~~	~~<0.1~~	~~0.477~~
~~MU-466~~	~~0.038~~	~~0.173~~	~~-~~	~~-~~

The monitoring study results shown that the Nicosulfuron at its monitored metabolites concentrations are not in agreement with the model predicted values and it can be concluded that the use of Nicosulfuron in maize crops are safe and doesn't pose an unacceptable risk for ground water. Furthermore, the concentration of the monitored non-relevant metabolites was below 0.75 µg/L. The assessment relevance of the metabolites in ground water according to SANCO/221/2000 –rev.10 document will be done and reported in the dRR Part B10.

~~Due to Polish Authorities are asking for Nicosulfuron Hamburg refinements due to the Czech Authorities comments, new calculations are given in the tables above in blue. Therefore, the next mitigation measure proposed by the Applicant must be applied at National level only:~~

~~SPe2: To protect ground water apply this product every 3 years in sandy soils on maize crops~~

<u>Z RMS comments:</u>

<u>Nicosulfuron</u>

The PEC_{gw} calculations provided for the active substance nicosulfuron and its metabolites HMUD, AUSN and ASDM, ADMP has been accepted by zRMS.

Groundwater Guidance. The input parameters used in calculations were taken from the endpoints available in the EFSA conclusion on Scientific Report EFSA (2007) 120, 1-91. However, the calculations are not in line with the current FOCUS groundwater Guidance 2014 and that MS should check and recalculate PECgw on national level for the relevant scenarios with adapted endpoints if required.

In simulations PUF value of 0 was assumed for all compounds, in line with recommendations of the most recent version of the FOCUS Interception is appropriate to the proposed BBCH of crops (guidance 2014).

The results of the FOCUS PELMO and PEARL modelling show that the expected concentration of nicosulfuron was above the 0.1 µg/L in scenario Hamburg. Hamburg scenario is considered a relevant scenario for CZ so refinement of the assessment must be developed by the applicant in order to achieve PEG_{gw} values below 0.1 ug/L. In this way, leaching of nicosulfuron in above scenarios are linked to soil parameters, where Hamburg is the scenario with lowest clay content. Moreover, a soil refinement and development of different scenarios at member state level have to be carried out by the applicant.

The nicosulfuron PEC_{gw} was below 0.1 µg/L with the exception of Hamburg scenario where the concentration was > 0.1 ug/L. Metabolites HMUD, AUSN and ASDM and UCSM shown PEC_{gw} greater than greater than 0.1 µg L. The assessment relevance of the metabolites in ground water according to SANCO/221/2000 –rev.10 document is reported in the dRR Part B10. Three lysimeter studies were conducted in Germany and Switzerland with pyridine and pyrimidine labelled nicosulfuron. All lysimeters were cropped with maize in the first and second years and with rye in the third year. Applications were made at 60 and 40 g a.s./ ha. Level of nicosulfuron in the leachate of lysimeters treated at 40 g a.s./ha were <0.1 µg L (EFSA (2007) 120, 1-91). Lysimeter studies may be accepted as higher tier risk assessment. The assessment relevance of the metabolites in ground water according to SANCO/221/2000 –rev.10 document is reported in the dRR Part B10.

Additionale, the Applicant has submitted its own monitoring study for nicosulfuron and to the study the nicosulfuron application rate used in the maize crops were 40 g as/ha in all Italian regions. The results of monitoring study shown that the nicosulfuron and its metabolites concentrations are lower than the predicted values obtained from modelling. The monitoring study results shown that concentrations of nicosulfuron following single application in maize at a dose of 40 g / ha doesn't pose an unacceptable risk for ground water.
The monitoring study was accepted by RMS, however the other MS should decide whether the monitoring studies can be used to assess the $PEC_{gw.}$
Nevertheless, additional simulations may be required by the sMS that do not accept calculations performed using FOCUS models.

The PECgw calculation of nicosulfuron for the lower dose 30 g/ha have been performed using the same parameters as made earlier and are therefore accepted by zRMS.
The calculation PECgw it is suitable for using of nicosulfuron at the lower dose of 30 g/ha

8.8.2.1 Mesotrione and its metabolites

Table 8.8-10: Input parameters related to active substance Mesotrione and metabolites for PEC_{gw} calculations

Compound	**Mesotrione**	**MNBA**	**AMBA**	**Value in accordance with EU endpoint y/n/ Reference***
Molecular weight (g/mol)	339	245	215	EFSA Journal 2016;14(3):4419
Water solubility (mg/L):	160 at pH 7 and 20°C			
Saturated vapour pressure (Pa):	0 at 20°C			
DT_{50} in soil (d)*	4 ~~(Worst case)~~ (shortest normalised laboratory DT50) 27.88 (linear fit, pH 5.1 value) 14.2 (linear fit, pH 6.5 value) 0.54 (linear fit, pH 7.9 value) (normalisation to 10 kPa or pF2, 20 °C with Q_{10} of 2.58)	3.4 (geomean of normalised lab value, pF2, 10 kPa, Q_{10} 2.58, n=10	14.5 (geomean of normalised lab value, pF2, 10 kPa, Q_{10} 2.58, n=5)	
K_{foc} (mL/g)/K_{fom}*	14 / 8.12 (Worst case) 156.7 / 90.9 (log fit, pH 5.1 value) 52.2 / 30.3 (log fit, pH 6.5 value) 17.4 / 10.1 (log fit, pH 7.9 value)	3.2 / 1.86 (worst case)	18.1 / 10.5 (Worst case) 105.61 / 61.3 (log fit, pH 5.1) 48.02 / 27.9 (log fit, pH 6.5) 21.8 / 12.7 (log fit, pH 7.9)	
1/n	0.97 (worst case) 0.94 (arithmetic mean, n=10)	0.90 (default)	0.82 (Worst case) 0.85 (arithmetic mean, n=5)	
Plant uptake factor	0			
Formation fraction		1 from parent	0.25 from MNBA	

*: cf. Table: Scenario specific adsorption values for PECgw modelling

~~**Table 8.8-11: Scenario specific adsorption values for PECgw modelling**~~

~~Compound~~	~~pH ~ 5.1 Hamburg, Okehampton, Porto~~		~~pH ~ 6.5 Kremsmünster, Piacenza, Sevilla, Thiva~~		~~pH ~ 7.9 Châteaudun~~	
	~~DT_{50}~~	~~K_{oc}~~	~~DT_{50}~~	~~K_{oc}~~	~~DT_{50}~~	~~K_{oc}~~
~~Mesotrione~~	~~27.88~~	~~156.7~~	~~14.2~~	~~52.2~~	~~0.54~~	~~17.4~~
~~AMBA~~	~~14.5~~	~~105.61~~	~~14.5~~	~~48.02~~	~~14.5~~	~~21.8~~

Table 8.8-12: **PEC$_{gw}$ for Mesotrione and metabolites on maize using worst case (Mesotrione DT$_{50}$ of 4 days, Kfoc value for Mesotrione 14 l/kg, Kfoc value for AMBA 18.1 L/kg, with the corresponding 1/n values 0.97 and 0.82) with FOCUS PEARL 4.4.4/PELMO 5.5.3**

Scenario	**80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)**					
	Mesotrione		**MNBA**		**AMBA**	
	PEARL	**PELMO**	**PEARL**	**PELMO**	**PEARL**	**PELMO**
Châteaudun	<0.001	<0.001	<0.001	<0.001	0.001	0.001
Hamburg	<0.001	<0.001	0.004	0.001	0.016	0.006
Kremsmünster	<0.001	<0.001	0.001	0.002	0.016	0.018
Okehampton	0.001	0.002	0.004	0.013	0.037	0.042
Piacenza	<0.001	<0.001	<0.001	0.001	0.002	0.005
Porto	<0.001	<0.001	<0.001	0.001	<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

~~Scenario~~	~~80th Percentile PECgw at 1 m Soil Depth (µg/L)~~					
	~~Mesotrione~~		~~MNBA~~		~~AMBA~~	
	~~PEARL~~	~~PELMO~~	~~PEARL~~	~~PELMO~~	~~PEARL~~	~~PELMO~~
~~Châteaudun~~	~~<0.001~~	~~<0.001~~	~~<0.001~~	~~<0.001~~	~~0.002~~	~~0.001~~
~~Hamburg~~	~~0.001~~	~~<0.001~~	~~0.005~~	~~0.001~~	~~0.023~~	~~0.009~~
~~Kremsmünster~~	~~<0.001~~	~~<0.001~~	~~0.002~~	~~0.003~~	~~0.024~~	~~0.026~~
~~Okehampton~~	~~0.001~~	~~0.003~~	~~0.006~~	~~0.017~~	~~0.053~~	~~0.061~~
~~Piacenza~~	~~<0.001~~	~~<0.001~~	~~<0.001~~	~~0.001~~	~~0.003~~	~~0.007~~
~~Porto~~	~~<0.001~~	~~<0.001~~	~~<0.001~~	~~0.001~~	~~<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 8.8-3: **PEC$_{gw}$ for Mesotrione and metabolites on maize with FOCUS PEARL v4.4.4, FOCUS PELMO v5.5.3**

Scenario	**pH (KCl)**	**80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)**					
		Mesotrione		**MNBA**		**AMBA**	
		PEARL	**PELMO**	**PEARL**	**PELMO**	**PEARL**	**PELMO**
Châteaudun	7.3	<0.001	<0.001	<0.001	<0.001	0.001	0.001
Hamburg	5.7	0.003	0.003	0.056	0.102	0.013	0.013
Kremsmünster	7.0	0.009	0.008	0.010	0.019	0.006	0.007

Okehampton	5.1	0.004	0.004	0.027	0.061	0.004	0.006
Piacenza	6.3	0.005	0.007	0.003	0.008	0.002	0.005
Porto	4.2	<0.001	0.001	0.008	0.023	<0.001	0.001
Sevilla	6.6	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
Thiva	7.0	0.001	<0.001	0.001	0.001	<0.001	<0.001

~~Scenario~~	~~pH (KCl)~~	~~80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)~~					
		~~Mesotrione~~		~~MNBA~~		~~AMBA~~	
		~~PEARL~~	~~PELMO~~	~~PEARL~~	~~PELMO~~	~~PEARL~~	~~PELMO~~
~~Châteaudun~~	~~7.3~~	~~<0.001~~	~~<0.001~~	~~<0.001~~	~~<0.001~~	~~0.001~~	~~0.001~~
~~Hamburg~~	~~5.7~~	~~0.005~~	~~0.005~~	~~0.076~~	~~0.134~~	~~0.019~~	~~0.017~~
~~Kremsmünster~~	~~7.0~~	~~0.014~~	~~0.011~~	~~0.013~~	~~0.025~~	~~0.009~~	~~0.010~~
~~Okehampton~~	~~5.1~~	~~0.006~~	~~0.005~~	~~0.036~~	~~0.081~~	~~0.006~~	~~0.008~~
~~Piacenza~~	~~6.3~~	~~0.006~~	~~0.009~~	~~0.003~~	~~0.011~~	~~0.003~~	~~0.006~~
~~Porto~~	~~4.2~~	~~0.001~~	~~0.001~~	~~0.011~~	~~0.031~~	~~<0.001~~	~~0.001~~
~~Sevilla~~	~~6.6~~	~~<0.001~~	~~<0.001~~	~~<0.001~~	~~<0.001~~	~~<0.001~~	~~<0.001~~
~~Thiva~~	~~7.0~~	~~0.001~~	~~0.001~~	~~0.001~~	~~0.002~~	~~<0.001~~	~~<0.001~~

Conclusion

The PECgw of Mesotrione, MNBA and AMBA were below 0.1 µg/L, although the PECgw of toxicological non-relevant metabolite MNBA in Hamburg scenario was ~~0.134~~ 0.102 ug/L for FOCUS PELMO model and pH specific endpoints. However, using the worst case endpoints the PECgw for MNBA in Hamburg was 0.001 µg/L for the same FOCUS model~~. The assessment relevance of the metabolites in ground water according to SANCO/221/2000 –rev.10 document will be done and reported in the dRR Part B10.~~

FINAL CONCLUSIONS

Rimsulfuron and its metabolites

The Rimsulfuron, IN-70942 and IN-J0290 PECgw were below 0.1 µg/L. However, the non-relevant metabolites IN-70941 and IN-E9260 shown PECgw's greater than 0.1 but below 0.75 µg/L. The assessment relevance of the metabolites in ground water according to SANCO/221/2000 –rev.10 document will be done and reported in the dRR Part B10.

Nicosulfuron and its metabolites

The Nicosulfuron PECgw was below 0.1 µg/L with the exception of Hamburg scenario where the concentration was ~~0.306~~ 0.226 ug/L. Metabolites HMUD, AUSN, UCSN and ASDM shown PECgw greater than 0.75 but below 10 µg/L, metabolite MU-466 had PECgw greater than 0.1 but below 0.75 µg/L and metabolite ADMP reported PECgw's well below 0.1 µg/L.

The Applicant would like to mention the Sharda's monitoring study for Nicosulfuron and its metabolites HMUD, AUSN, UCSN and ASDM performed on Italy during almost 3 years (January 2016-November 2018), where all of the monitoring regions are typical for cultivation of maize in Italy. The monitoring regions were Piemonte, Lombardia, Veneto, Emilia-Romagna and Friuli-Venezia Giulia. Within these five selected regions, seven key maize-growing areas of Northern Italy were identified and the 23 wells were distributed throughout these areas. During the study, groundwater sampling was conducted 12 times for 240 samples (20 wells × 12 sampling events) were analyzed for Nicosulfuron and its four metabolites (3 out 23 wells were used as backup samples). According to the study the Nicosulfuron application rate used in the maize crops were 40 g as/ha in all Italian regions.

The results of the study shown that the concentration of Nicosulfuron and its four metabolites were all < 0.1 µg/L except for UCSN which showed 4 detections at 1 location up to 0.111 µg/L, AUSN which showed 26 detections at 6 locations up to 0.657 µg/L and also ASDM which showed 4 detections at 1 location up to 0.447 µg/L. A summary of Nicosulfuron and metabolites (UCSN, HMUD, AUSN and ASDM) concentrations in groundwater (µg/L) detected during the study is presented below:

Nicosulfuron < 0.1 µg/L.
UCSN ranged from < 0.1 µg/L to 0.111 µg/L.
HMUD < 0.1 µg/L.
AUSN ranged from < 0.1 µg/L to 0.657 µg/L.
ASDM ranged from < 0.1 µg/L to 0.447 µg/L.

In the next table are given the range of concentrations for Nicosulfuron at its metabolites from FOCUS models *vs* monitoring stud.

Substance	**FOCUS models**		**Monitoring study**	
	PECgw min (µg/L)	**PECgw max (µg/L)**	**PECgw min (µg/L)**	**PECgw max (µg/L)**
Nicosulfuron	<0.001	0.226	-	<0.1
HMUD	0.007	0.990	-	<0.1
AUSN	0.137	1.526	<0.1	0.657
ADMP	<0.001	0.002	-	-
UCSN	0.317	1.298	<0.1	0.111
ASDM	0.142	0.986	<0.1	0.477
MU-466	0.028	0.130	-	-

~~**Substance**~~	~~**FOCUS models**~~		~~**Monitoring study**~~	
	~~**PECgw min (µg/L)**~~	~~**PECgw max (µg/L)**~~	~~**PECgw min (µg/L)**~~	~~**PECgw max (µg/L)**~~
~~Nicosulfuron~~	~~<0.001~~	~~0.306~~	~~-~~	~~<0.1~~
~~HMUD~~	~~0.010~~	~~1.319~~	~~-~~	~~<0.1~~
~~AUSN~~	~~0.183~~	~~2.015~~	~~<0.1~~	~~0.657~~
~~ADMP~~	~~<0.001~~	~~0.003~~	~~-~~	~~-~~
~~UCSN~~	~~0.418~~	~~1.717~~	~~<0.1~~	~~0.111~~
~~ASDM~~	~~0.188~~	~~1.311~~	~~<0.1~~	~~0.477~~
~~MU-466~~	~~0.038~~	~~0.173~~	~~-~~	~~-~~

The monitoring study results shown that the Nicosulfuron at its monitored metabolites concentrations are not in agreement with the model predicted values and it can be concluded that the use of Nicosulfuron in maize crops are safe and doesn't pose an unacceptable risk for ground water. Furthermore, the concentration of the monitored non-relevant metabolites was below 0.75 µg/L. The assessment relevance of the metabolites in ground water according to SANCO/221/2000 –rev.10 document will be done and reported in the dRR Part B10.

~~Due to Polish Authorities are asking for Nicosulfuron Hamburg refinements due to the Czech Authorities comments, new calculations are given in the tables above in blue. Therefore, the next mitigation measure proposed by the Applicant must be applied at National level only:~~

~~SPe2: To protect ground water apply this product every 3 years in sandy soils on maize crops~~

Mesotrione and its metabolites

The PECgw of Mesotrione, MNBA and AMBA were below 0.1 µg/L, although the PECgw of toxicological non-relevant metabolite MNBA in Hamburg scenario was ~~0.134~~ 0.102 ug/L for FOCUS PELMO model and pH specific endpoints. However, using the worst case endpoints the PECgw for MNBA in Hamburg was 0.001 µg/L for the same FOCUS model.

As above mentioned it can be concluded that the use of PRYMARY MX in maize crops is safe and doesn't pose an unacceptable risk for ground water. The assessment relevance of the all non-relevant metabolites in ground water according to SANCO/221/2000 –rev.10 document will be done and reported in the dRR Part B10.

~~Due to Polish Authorities are asking for Nicosulfuron Hamburg refinements due to the Czech Authorities comments, new calculations are given in the tables above in blue. Therefore, the next mitigation measure proposed by the Applicant must be applied at National level only:~~

~~SPe2: To protect ground water apply this product every 3 years in sandy soils on maize crops~~

zRMS comments:

Mesotrione

The modelling results PEC_{gw} are acceptable to describe predicted environmental concentrations of mesotrione and its metabolites in groundwater. All input parameters considered in the groundwater modelling for mesotrione and its metabolites were EU agreed values (EFSA Scientific Report (2007) 120, 1-91). In simulations PUF value of 0 was assumed for all compounds is in line with recommendations of the most recent version of the FOCUS Groundwater Guidance.

PEC_{gw} for mesotrione and its metabolites AMBA and MNBA are below 0.1 µg/L for all modelled scenarios.

Therefore, no unacceptable risk of groundwater contamination is expected for the formulated product according to GAP.

and for all application rate except PECgw for MNBA in Hamburg scenario.

~~As regards MNBA metabolite exceeds the threshold 0.1 µg/L in cases written above. Overall, on the basis of the available data it could be concluded that metabolite MNBA is not toxicologically relevant intended us~~

~~The assessment relevance of the all non-relevant metabolites in ground water according to SANCO/221/2000 –rev.10 document was reported in the dRR Part B10.~~

Nevertheless, additional simulations may be required by the sMS that do not accept calculations performed using FOCUS models.

The PECgw calculation of mesotrione for the lower dose 90 g/ha have been performed using the same parameters as made earlier calculations and are therefore accepted by zRMS.

The calculation PECgw it is suitable for using of ~~nicosulfuron~~ mesotrione at the lower dose of 90 g/ha

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

8.9.1 Justification for new endpoints

Not relevant as there is no deviation to EU agreed endpoints.

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

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

Plant protection product	PRIMARY MX
Use No.	1
Crop	**Maize**
Application rate (kg as/ha)	Rimsulfuron: ~~0.0099~~ / 0.0075 Nicosulfuron: ~~0.0396~~ / 0.03 Mesotrione: ~~0.118 /~~ 0.09
Number of applications/interval (d)	1/-
Application window	March-May Minimal crop canopy
Application method	Foliar spray
CAM (Chemical application method)	CAM 2
Soil depth (cm)	4 cm
Models used for calculation	FOCUS STEPS 1-2 v3.2, FOCUS SWASH v5.3, FOCUS PRZM v4.3.1, FOCUS MACRO v5.5.4, FOCUS TOXWA v5.5.3, SWAN v 5.0.0

Table 8.9-1: FOCUS Step 3 Scenario related input parameters for $PEC_{sw/sed}$ calculations for the application of PRIMARY MX

Scenario	Application window used in modelling*
D3	12/05
D4	18/05
D5	15/05
D6	25/04
R1	10/05
R2	09/05
R3	08/05
R4	15/04

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

8.9.2.1 Rimsulfuron and its metabolites

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

Compound	Rimsulfuron	IN-70941	IN-70942	IN-E9260	IN-JF999	IN-J0290 a.ka. ADMP	Value in accordance to EU end-point y/n/ Reference
Molecular weight (g/mol)	431.45	367.4	324.36	250.3	310.33	155.2	Y, EFSA Journal 2005; 45, 1-61 EFSA Scientific report (2007) 120, 1-91
Saturated vapour pressure (Pa)	8.9×10^{-7} (20°C)	not required for Step 1+2					
Water solubility (mg/L)	7300 (25°C)						
Diffusion coefficient in water (m²/d)	4.3 x 10^{-5}	not required for Step 1+2					
Diffusion coefficient in air (m²/d)	0.43						
K_{foc} (mL/g)	42.4/24.6 (geomean, n = 4)	41.5/24.1 (geomean (n=3) higher adsorption value from clay soil was excluded)	191.7/111.2 (geomean, n=4)	23.2/13.5 (geomean (n=3) higher adsorption value from clay soil was excluded)	34/19.7 Calculated from $\log K_{OW}$=0.95 14 due to SRC $\log K_{OW}$ v.1.66 for chemical class 4	51.1/29.6(geomean, n=4)	
Freundlich Exponent 1/n	1.02 (arithmetic mean, n= 4)	not required for Step 1+2					
Plant Uptake	0						
Wash-Off factor from Crop (1/mm)	0.05 (MACRO) 0.50 (PRZM)						
$DT_{50,soil}$ (d)	18.3 (geomean, lab studies n=5, normalized at 20°C, Q_{10} 2.58 and pF2)	128.9 (geomean, lab studies n=3, normalized at 20°C, Q_{10} 2.58 and pF2)	86.2 (geomean, lab studies n=3, normalized at 20°C, Q_{10} 2.58 and pF2)	359.3 (geomean, lab studies n=3, normalized at 20°C, Q_{10} 2.58 and pF2)	1000 (default)	4.5 (geomean lab studies, n=3, normalized at 20 °C, Q_{10} 2.58 and pF2)	
$DT_{50,water}$ (d)	11 (Max. value, n = 2)	28 (Max. value, n = 2)	107 (Max. value, n = 2)	1000 (default)	86 (Max. value, n = 2	1000 (default)	
$DT_{50,sed}$ (d)	1000 (default)						
$DT_{50,whole\ system}$ (d)	11 (Max. value, n = 2)	28 (Max. value, n = 2)	107 (Max. value, n = 2)	1000 (default)	86 (Max. value, n = 2	1000 (default)	
Maximum occurrence observed (% molar basis with respect to the	Sediment: 12.6	Soil: 54.5 Total system: 82.7	Soil: 23.5 Total system: 83.8*	Soil: 18.9 Total system: 16.2**	Soil: 1x 10^{-10} Total system: 24.5	Soil: 12.7*** Total system: 19.1%**	

Compound	Rimsulfuron	IN-70941	IN-70942	IN-E9260	IN-JF999	IN-J0290 a.ka. ADMP	Value in accordance to EU end-point y/n/ Reference
parent)							
Formation fraction in soil:	-	0.57 from parent	1 from IN-70941	0.18 from parent	-	0.03 from parent	

***From hydrolysis study**
****From photolysis study**
*****From soil photolysis study**

PEC$_{sw/sed}$

Table 8.9-4: FOCUS Step 1, 2 and 3 PEC$_{sw}$ and PEC$_{sed}$ for Rimsulfuron following single application of PRIMARY MX to maize

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	---	2.44	Drainage/Runoff	1.35	1.00
Step 2					
Southern Europe	March-May	0.66	Drainage/Runoff	0.38	0.28
Northern Europe		0.36	Drainage/Runoff	0.20	0.15
Step 3					
D3	ditch	0.042	Drainage	0.005	0.008
D4	pond	0.007		0.007	0.007
D4	stream	0.035		0.005	0.005
D5	pond	0.003		0.003	0.003
D5	stream	0.036		0.002	0.003
D6	ditch	0.040		0.002	0.005
R1	pond	0.003	Runoff	0.002	0.002
R1	stream	0.087		0.003	0.006
R2	stream	0.209		0.006	0.025
R3	stream	0.310		0.011	0.031
R4	stream	0.313		0.012	0.040

~~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~~	~~---~~	~~3.21~~	~~Drainage/Runoff~~	~~1.78~~	~~1.32~~
~~Step 2~~					
~~Southern Europe~~	~~March-May~~	~~0.87~~	~~Drainage/Runoff~~	~~0.50~~	~~0.37~~

~~Scenario FOCUS~~	~~Waterbody~~	~~Max PEC$_{sw}$ (µg/L)~~	~~Dominant entry route~~	~~21 d- PEC$_{sw,twa}$ (µg/L)~~	~~Max PEC$_{sed}$ (µg/kg)~~
~~Northern Europe~~		~~0.47~~	~~Drainage/Runoff~~	~~0.27~~	~~0.20~~
~~Step 3~~					
~~D3~~	~~ditch~~	~~0.055~~	~~Drainage~~	~~0.006~~	~~0.011~~
~~D4~~	~~pond~~	~~0.009~~		~~0.008~~	~~0.009~~
~~D4~~	~~stream~~	~~0.046~~		~~0.006~~	~~0.007~~
~~D5~~	~~pond~~	~~0.004~~		~~0.004~~	~~0.004~~
~~D5~~	~~stream~~	~~0.048~~		~~0.003~~	~~0.004~~
~~D6~~	~~ditch~~	~~0.052~~		~~0.003~~	~~0.006~~
~~R1~~	~~pond~~	~~0.005~~	~~Runoff~~	~~0.003~~	~~0.002~~
~~R1~~	~~stream~~	~~0.115~~		~~0.004~~	~~0.009~~
~~R2~~	~~stream~~	~~0.276~~		~~0.008~~	~~0.033~~
~~R3~~	~~stream~~	~~0.409~~		~~0.014~~	~~0.042~~
~~R4~~	~~stream~~	~~0.413~~		~~0.017~~	~~0.053~~

~~FOCUS Step 4~~

~~Due to requirements on B9 by the ecotox expert step 4 calculations have been done. Furthermore, VFSMOD calculations have been done as refinement for all R scenarios, with the exception of R1 pond scenario. The results are given below.~~

~~Table 8.9-4 bis: Global maximum PEC$_{sw}$ values for Rimsulfuron, following single application of PRIMARY MX to maize according to the southern central EU zone GAP according to surface water Step 4~~

~~PEC$_{sw}$ (µg/L)~~	~~Scenario~~	~~STEP 4 Rimsulfuron~~			
~~Nozzle reduction~~	~~Vegetative strip (m)~~	~~5*~~	~~10~~	~~15**~~	~~20~~
	~~No spray buffer (m)~~	~~5~~	~~10~~	~~15~~	~~20~~
~~None~~	~~R1 stream~~	~~0.053~~	~~0.036~~	~~-~~	~~-~~
	~~R2 stream~~	~~0.134~~	~~0.092~~	~~0.071~~	~~0.048~~
	~~R3 stream~~	~~0.201~~	~~0.140~~	~~0.107~~	~~0.073~~
	~~R4 stream~~	~~0.204~~	~~0.142~~	~~0.109~~	~~0.075~~

~~*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 8.9-4 bis bis: Global maximum PEC_{sw} values for Rimsulfuron, following single application of COREY PRIMARY to maize according to the southern central EU zone GAP according to surface water VFSMOD Step 4**~~

~~PEC_{sw} (µg/L)~~	~~Scenario~~	~~VFSMOD STEP 4 Rimsulfuron~~
~~Nozzle reduction~~	~~Vegetative strip (m)~~	~~5~~
	~~No spray buffer (m)~~	~~5~~
~~None~~	~~R1 stream~~	~~0.011~~
	~~R2 stream~~	~~0.015~~
	~~R3 stream~~	~~0.016~~
	~~R4 stream~~	~~0.011~~

Metabolites of Rimsulfuron

Table 8.9-5: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for IN-70941 following single application to maize

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	---	2.82	Drainage/Runoff	2.19	1.15
Step 2					
Southern Europe	March-May	0.80	Drainage/Runoff	0.63	0.33
Northern Europe		0.42		0.33	0.17

~~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~~	~~---~~	~~3.72~~	~~Drainage/Runoff~~	~~2.90~~	~~1.52~~
~~Step 2~~					
~~Southern Europe~~	~~March-May~~	~~1.05~~	~~Drainage/Runoff~~	~~0.83~~	~~0.44~~
~~Northern Europe~~		~~0.55~~		~~0.44~~	~~0.23~~

Table 8.9-6: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for IN-70942 following single application to maize

Scenario FOCUS	**Waterbody**	**Max PEC_{sw} (µg/L)**	**Dominant entry route**	**21 d- $PEC_{sw,twa}$ (µg/L)**	**Max PEC_{sed} (µg/kg)**
Step 1	---	1.65	Drainage/Runoff	1.53	3.13

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	March-May	0.46	Drainage/Runoff	0.43	0.88
Northern Europe		0.25		0.23	0.47

~~**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~~	~~---~~	~~2.18~~	~~Drainage/Runoff~~	~~2.03~~	~~4.13~~
~~Step 2~~					
~~Southern Europe~~	~~March-May~~	~~0.61~~	~~Drainage/Runoff~~	~~0.57~~	~~1.16~~
~~Northern Europe~~		~~0.33~~		~~0.31~~	~~0.62~~

Table 8.9-7: FOCUS Step 1 and 2 PEC$_{sw}$ and PEC$_{sed}$ for IN-E9260 following single application to maize

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	---	0.50	Drainage/Runoff	0.50	0.12
Step 2					
Southern Europe	March-May	0.14	Drainage/Runoff	0.14	0.03
Northern Europe		0.08		0.07	0.02

~~**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~~	~~---~~	~~0.66~~	~~Drainage/Runoff~~	~~0.66~~	~~0.15~~
~~Step 2~~					
~~Southern Europe~~	~~March-May~~	~~0.19~~	~~Drainage/Runoff~~	~~0.19~~	~~0.04~~
~~Northern Europe~~		~~0.10~~		~~0.10~~	~~0.02~~

Table 8.9-8: FOCUS Step 1 and 2 PEC$_{sw}$ and PEC$_{sed}$ for IN-JF999 following single application to maize

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	---	0.43	Drainage/Runoff	0.40	0.15

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	March-May	0.12	Drainage/Runoff	0.11	0.04
Northern Europe		0.07		0.06	0.02

~~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~~	~~—~~	~~0.57~~	~~Drainage/Runoff~~	~~0.53~~	~~0.19~~
~~Step 2~~					
~~Southern Europe~~	~~March-May~~	~~0.16~~	~~Drainage/Runoff~~	~~0.15~~	~~0.05~~
~~Northern Europe~~		~~0.09~~		~~0.08~~	~~0.03~~

Table 8.9-9: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for IN-J0290 following single application to maize

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	---	0.27	Drainage/Runoff	0.27	0.14
Step 2					
Southern Europe	March-May	0.06	Drainage/Runoff	0.06	0.03
Northern Europe		0.03		0.03	0.02

~~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~~	~~—~~	~~0.36~~	~~Drainage/Runoff~~	~~0.36~~	~~0.18~~
~~Step 2~~					
~~Southern Europe~~	~~March-May~~	~~0.08~~	~~Drainage/Runoff~~	~~0.08~~	~~0.04~~
~~Northern Europe~~		~~0.04~~		~~0.04~~	~~0.02~~

zRMS comments:

<u>Rimsulfuron</u>

$PEC_{sw/sed}$ calculations performed at Step 1-2 and Step 3 for the active substance rimsulfuron and at Step 1-2 and for its relevant metabolites IN-70941, IN-70942 and IN-E9260 and soil photolysis metabolite IN-J0290. $PEC_{sw/sed}$ have been accepted. Input parameters and $PEC_{sw/sed}$ calculations can be considered acceptable.

The PECsw calculations have been approved for applications proposed in GAP. PECsw and PECsed calculations were carried out according to the FOCUS guidance recommendations.

The Applicant has been used FOCUS models: STEPS1-2 and Step3. Nevertheless, additional simulations may be required by the cMS that do not accept calculations performed using FOCUS models.

The acceptable predicted environmental concentrations of rimsulfuron and its metabolites are appropriate to be used for the subsequent risk assessment

The PECgw calculation of rimsulfuron for the lower dose 7.5 g/ha have been performed using the same parameters as made earlier and are therefore accepted by zRMS.

~~The VFSMOD calculations have been done as refinement for all R scenarios and are acceptable.~~

The calculation ~~PECsw~~ is suitable for using of nicosulfuron at the lower dose of 7.5 g/ha.

8.9.2.2 Nicosulfuron and its metabolites

Table 8.9-10: Input parameters related to active substance Nicosulfuron and metabolites for $PEC_{sw/sed}$ calculations STEP 1/2 and 3/4

Compound	Nicosulfuron	HMUD	ASDM	AUSN	UCSN	ADMP	DUDN	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	410.4	396.4	229.3	314.3	315.3	155.2	346.3	EFSA Scientific report (2007) 120, 1-91
Saturated vapour pressure (Pa)	8 x 10^{-10} at 25°C	not required for Step 1+2						
Water solubility (mg/L)	9500 at 19.7°C and pH 6.7	1000 at 20ºC (default)						
Diffusion coefficient in water (m²/d)	4.3 x 10^{-5}	not required for Step 1+2						default
Diffusion coefficient in air (m²/d)	0.43							
K_{foc} (mL/g)	15.4 (geomean, n=4)	3.9 (geomean, n=5)	5.2 (geomean, n=4)	25.2 (geomean, n=4)	2.6 (geomean, n=4)	51.1 (geomean, n=4)	1 (default)	EFSA Scientific report (2007) 120, 1-91
Freundlich Exponent 1/n	0.94 (arithmetic mean, n=4)	not required for Step 1+2						
Plant Uptake	0	not required for Step 1+2						default
Wash-Off factor from Crop (1/mm)	0.05 (MACRO) 0.50 (PRZM)	not required for Step 1+2						default

Compound	**Nicosulfu-ron**	**HMUD**	**ASDM**	**AUSN**	**UCSN**	**ADMP**	**DUDN**	**Value in accord-ance to EU end-point y/n/ Refer-ence**
$DT_{50,soil}$ (d)	16.4 (geomean, normalisation to 10 kPa or pF2, 20 °C, n=7)	23.8 (geomean, normalisation to 10 kPa or pF2, 20 °C, n=2)	108.7 (geomean, normalisation to 10 kPa or pF2, 20 °C, n=3)	90.9 (geomean, normalisation to 10 kPa or pF2, 20 °C, n=3)	160.1 (geomean, normalisation to 10 kPa or pF2, 20 °C, n=3)	4.5 (geomean normalisation to 10 kPa or pF2, 20 °C, n=3)	1000 (default)	EFSA Scientific report (2007) 120, 1-91
$DT_{50,water}$ (d)	40.7 (geomean, n=2)	1000 (default)						
$DT_{50,sed}$ (d)	1000 (default)							
$DT_{50,whole\ system}$ (d)	40.7 (geomean, n=2)	1000 (default)						
Maximum occurrence observed (% molar basis with respect to the parent)	Sediment: 24	Soil: 14.4 Water: 14.1 Sediment: 5.7 Total system: 19.3	Soil: 63.4 Water: 61* Sediment: 4.4 Total system: 61*	Soil: 26.8 Water: 9.1 Sediment: 2.4 Total system: 11.1	Soil: 11 Water: 5.4 Sediment:1.4 Total system: 6.5	Soil: 9.8 Total system: 23.1	Soil: 1 x 10^{-10} (no soil metabolite) Total system: 22.3*	

***Worst case from photolysis study**

$PEC_{sw/sed}$

Table 8.9-11: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for Nicosulfuron following single application of Rimsulfuron 3% + Nicosulfuron12% + Mesotrione 36% WG to maize

Scenario FOCUS	**Waterbody**	**Max PEC_{sw} (µg/L)**	**Dominant entry route**	**7 d- $PEC_{sw,twa}$ (µg/L)**	**Max PEC_{sed} (µg/kg)**
Step 1	---	10.07	Drainage/Runoff	8.47	1.52
Step 2					
Southern Europe	March-May	2.74	Drainage/Runoff	2.31	0.42
Northern Europe		1.50		1.26	0.23
Step 3					
D3	ditch	0.170	Drainage	0.022	0.035
D4	pond	0.032		0.032	0.043
D4	stream	0.143		0.018	0.021
D5	pond	0.014		0.012	0.015

Scenario **FOCUS**	**Waterbody**	**Max PEC_{sw} (µg/L)**	**Dominant entry route**	**7 d- $PEC_{sw,twa}$ (µg/L)**	**Max PEC_{sed} (µg/kg)**
D5	stream	0.144		0.008	0.009
D6	ditch	0.159		0.008	0.017
R1	pond	0.011	Runoff	0.009	0.007
R1	stream	0.334		0.008	0.022
R2	stream	1.015		0.030	0.105
R3	stream	1.215		0.040	0.108
R4	Stream	1.296		0.051	0.144

~~**Scenario**~~ ~~**FOCUS**~~	~~**Waterbody**~~	~~**Max PEC_{sw} (µg/L)**~~	~~**Dominant entry route**~~	~~**7 d- $PEC_{sw,twa}$ (µg/L)**~~	~~**Max PEC_{sed} (µg/kg)**~~
~~Step 1~~	~~—~~	~~13.30~~	~~Drainage/Runoff~~	~~11.17~~	~~2.01~~
~~Step 2~~					
~~Southern Europe~~	~~March-May~~	~~1.43~~	~~Drainage/Runoff~~	~~1.20~~	~~0.22~~
~~Northern Europe~~		~~2.52~~		~~2.12~~	~~0.39~~
~~Step 3~~					
~~D3~~	~~ditch~~	~~0.226~~	~~Drainage~~	~~0.053~~	~~0.047~~
~~D4~~	~~pond~~	~~0.044~~		~~0.044~~	~~0.057~~
~~D4~~	~~stream~~	~~0.189~~		~~0.029~~	~~0.028~~
~~D5~~	~~pond~~	~~0.018~~		~~0.017~~	~~0.020~~
~~D5~~	~~stream~~	~~0.190~~		~~0.011~~	~~0.012~~
~~D6~~	~~ditch~~	~~0.209~~		~~0.031~~	~~0.023~~
~~R1~~	~~pond~~	~~0.014~~	~~Runoff~~	~~0.014~~	~~0.010~~
~~R1~~	~~stream~~	~~0.440~~		~~0.029~~	~~0.029~~
~~R2~~	~~stream~~	~~1.344~~		~~0.121~~	~~0.138~~
~~R3~~	~~stream~~	~~1.603~~		~~0.153~~	~~0.142~~
~~R4~~	~~Stream~~	~~1.713~~		~~0.190~~	~~0.190~~

FOCUS Step 4

Table 8.9-12: **Global maximum PEC_{sw} values for Nicosulfuron, following single application of PRIMARY MX to maize according to the central EU zone GAP according to surface water Step 4**

PEC_{sw} (µg/L)	**Scenario**	**STEP 4 Nicosulfuron**				
Nozzle reduction	Vegetative strip (m)	None	5*	10	15**	20

	No spray buffer (m)	5	5	10	15	20
None	D3 ditch	0.065	-	-	-	-
	D4 stream	0.065	-	-	-	-
	D5 stream	0.062	-	-	-	-
	D6 ditch	0.052	-	-	-	-
	R1 stream	-	0.204	0.137	-	-
	R2 stream	-	0.649	0.448	0.341	0.232
	R3 stream	-	0.789	0.550	0.421	0.287
	R4 stream	-	0.846	0.590	0.452	0.309

***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.**

~~PEC_{sw} (µg/L)~~	~~Scenario~~	~~STEP 4 Nicosulfuron~~				
~~Nozzle reduction~~	~~Vegetative strip (m)~~	~~None~~	~~5*~~	~~10~~	~~15**~~	~~20~~
	~~No spray buffer (m)~~	~~5~~	~~5~~	~~10~~	~~15~~	~~20~~
~~None~~	~~D3 ditch~~	~~0.086~~	~~-~~	~~-~~	~~-~~	~~-~~
	~~D4 stream~~	~~0.086~~	~~-~~	~~-~~	~~-~~	~~-~~
	~~D5 stream~~	~~0.082~~	~~-~~	~~-~~	~~-~~	~~-~~
	~~D6 ditch~~	~~0.069~~	~~-~~	~~-~~	~~-~~	~~-~~
	~~R1 stream~~	~~-~~	~~0.269~~	~~0.181~~	~~0.136~~	~~-~~
	~~R2 stream~~	~~-~~	~~0.860~~	~~0.593~~	~~0.453~~	~~0.307~~
	~~R3 stream~~	~~-~~	~~1.041~~	~~0.725~~	~~0.556~~	~~0.379~~
	~~R4 stream~~	~~-~~	~~1.117~~	~~0.779~~	~~0.598~~	~~0.408~~

~~Due to requirements on B9 by the ecotox expert VFSMOD calculations have been done as refinement for all R scenarios, with the exception of R1 pond scenario. The results are performed for PL and CZ and given below.~~

~~Table 8.9-12 bis: Global maximum PEC_{sw} values for Nicosulfuron, following single application of COREY to maize according to the southern EU zone GAP according to surface water VFSMOD Step 4~~

~~PEC_{sw} (µg/L)~~	~~Scenario~~	~~VFSMOD STEP 4 Nicosulfuron~~
~~Nozzle reduction~~	~~Vegetative strip (m)~~	~~5~~

	~~No spray buffer (m)~~	~~5~~
~~None~~	~~R1 stream~~	~~0.045~~
	~~R2 stream~~	~~0.061~~
	~~R3 stream~~	~~0.064~~
	~~R4 stream~~	~~0.046~~

Metabolites of Nicosulfuron

Table 8.9-13: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for HMUD following single application to maize

Scenario FOCUS	**Waterbody**	**Max PEC_{sw} (µg/L)**	**Dominat entry route**	**21 d- $PEC_{sw,twa}$ (µg/L)**	**Max PEC_{sed} (µg/kg)**
Step 1	---	3.29	Drainage/Runoff	3.27	0.13
Step 2					
Southern Europe	March-May	0.89	Drainage/Runoff	0.88	0.03
Northern Europe		0.47		0.47	0.02

~~**Scenario FOCUS**~~	~~**Waterbody**~~	~~**Max PEC_{sw} (µg/L)**~~	~~**Dominat entry route**~~	~~**21 d- $PEC_{sw,twa}$ (µg/L)**~~	~~**Max PEC_{sed} (µg/kg)**~~
~~Step 1~~	~~---~~	~~4.34~~	~~Drainage/Runoff~~	~~4.31~~	~~0.17~~
~~Step 2~~					
~~Southern Europe~~	~~March-May~~	~~0.81~~	~~Drainage/Runoff~~	~~0.80~~	~~0.03~~
~~Northern Europe~~		~~0.44~~		~~0.43~~	~~0.02~~

Table 8.9-14: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for ASDM following single application to maize

Scenario FOCUS	**Waterbody**	**Max PEC_{sw} (µg/L)**	**Dominat entry route**	**21 d- $PEC_{sw,twa}$ (µg/L)**	**Max PEC_{sed} (µg/kg)**
Step 1	---	7.00	Drainage/Runoff	6.95	0.36
Step 2					
Southern Europe	March-May	1.98	Drainage/Runoff	1.97	0.10
Northern Europe		1.04		1.03	0.005

~~Scenario FOCUS~~	~~Waterbody~~	~~Max PEC_{sw} (µg/L)~~	~~Dominat entry route~~	~~21 d- $PEC_{sw,twa}$ (µg/L)~~	~~Max PEC_{sed} (µg/kg)~~
~~Step 1~~	~~---~~	~~9.24~~	~~Drainage/Runoff~~	~~9.17~~	~~0.48~~
~~Step 2~~					
~~Southern Europe~~	~~March-May~~	~~2.61~~	~~Drainage/Runoff~~	~~2.59~~	~~0.14~~
~~Northern Europe~~		~~1.37~~		~~1.36~~	~~0.07~~

Table 8.9-15: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for AUSN following single application to maize

Scenario FOCUS	**Waterbody**	**Max PEC_{sw} (µg/L)**	**Dominat entry route**	**21 d- $PEC_{sw,twa}$ (µg/L)**	**Max PEC_{sed} (µg/kg)**
Step 1	---	2.83	Drainage/Runoff	2.81	0.71
Step 2					
Southern Europe	March-May	0.81	Drainage/Runoff	0.80	0.20
Northern Europe		0.42		0.41	0.10

~~Scenario FOCUS~~	~~Waterbody~~	~~Max PEC_{sw} (µg/L)~~	~~Dominat entry route~~	~~21 d- $PEC_{sw,twa}$ (µg/L)~~	~~Max PEC_{sed} (µg/kg)~~
~~Step 1~~	~~---~~	~~3.74~~	~~Drainage/Runoff~~	~~3.71~~	~~0.94~~
~~Step 2~~					
~~Southern Europe~~	~~March-May~~	~~0.72~~	~~Drainage/Runoff~~	~~0.72~~	~~0.18~~
~~Northern Europe~~		~~0.38~~		~~0.37~~	~~0.10~~

Table 8.9-16: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for UCSN following single application to maize

Scenario FOCUS	**Waterbody**	**Max PEC_{sw} (µg/L)**	**Dominat entry route**	**21 d- $PEC_{sw,twa}$ (µg/L)**	**Max PEC_{sed} (µg/kg)**
Step 1	---	1.35	Drainage/Runoff	1.34	0.04
Step 2					
Southern Europe	March-May	0.39	Drainage/Runoff	0.39	0.01
Northern Europe		0.20		0.20	

~~Scenario FOCUS~~	~~Waterbody~~	~~Max PEC_{sw} (µg/L)~~	~~Dominat entry route~~	~~21 d- $PEC_{sw,twa}$ (µg/L)~~	~~Max PEC_{sed} (µg/kg)~~
~~Step 1~~	~~---~~	~~1.79~~	~~Drainage/Runoff~~	~~1.77~~	~~0.05~~
~~Step 2~~					
~~Southern Europe~~	~~March-May~~	~~0.35~~	~~Drainage/Runoff~~	~~0.35~~	~~0.01~~
~~Northern Europe~~					

Table 8.9-17: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for ADMP following single application to maize

Scenario FOCUS	**Waterbody**	**Max PEC_{sw} (µg/L)**	**Dominat entry route**	**21 d- $PEC_{sw,twa}$ (µg/L)**	**Max PEC_{sed} (µg/kg)**
Step 1	---	1.19	Drainage/Runoff	1.18	0.61
Step 2					
Southern Europe	March-May	0.29	Drainage/Runoff	0.28	0.15
Northern Europe		0.15		0.15	0.08

~~Scenario FOCUS~~	~~Waterbody~~	~~Max PEC_{sw} (µg/L)~~	~~Dominat entry route~~	~~21 d- $PEC_{sw,twa}$ (µg/L)~~	~~Max PEC_{sed} (µg/kg)~~
~~Step 1~~	~~---~~	~~1.57~~	~~Drainage/Runoff~~	~~1.56~~	~~0.79~~
~~Step 2~~					
~~Southern Europe~~	~~March-May~~	~~0.26~~	~~Drainage/Runoff~~	~~0.26~~	~~0.13~~
~~Northern Europe~~		~~0.15~~		~~0.15~~	~~0.07~~

Table 8.9-18: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for DUDN following single application to maize

Scenario FOCUS	**Waterbody**	**Max PEC_{sw} (µg/L)**	**Dominat entry route**	**21 d- $PEC_{sw,twa}$ (µg/L)**	**Max PEC_{sed} (µg/kg)**
Step 1	---	1.93	Drainage/Runoff	1.92	0.02
Step 2					
Southern Europe	March-May	0.53	Drainage/Runoff	0.52	0.01
Northern Europe		0.29		0.29	<0.01

~~Scenario FOCUS~~	~~Waterbody~~	~~Max PEC$_{sw}$ (µg/L)~~	~~Dominat entry route~~	~~21 d- PEC$_{sw,twa}$ (µg/L)~~	~~Max PEC$_{sed}$ (µg/kg)~~
~~Step 1~~	~~—~~	~~2.55~~	~~Drainage/Runoff~~	~~2.53~~	~~0.03~~
~~Step 2~~					
~~Southern Europe~~	~~March-May~~	~~0.70~~	~~Drainage/Runoff~~	~~0.069~~	~~0.01~~
~~Northern Europe~~		~~0.38~~		~~0.38~~	~~<0.01~~

zRMS comments:

Nicosulfuron

The submitted by Applicant calculations were accepted. The input parameters for active substance were used in accordance with the List of Endpoints. The PEC$_{SW}$ and PEC$_{SED}$ of nicosulfuron have been assessed with standard FOCUS scenarios at Step 1-2 and Step 3 and Step 4 for the active substance nicosulfuron and at Step 1-2 and for its relevant metabolites. Input parameters and PEC$_{sw/sed}$ calculations can be considered acceptable. The PEC$_{sw/sed}$ for nicosulfuron were also carried out at Step 4 according to FOCUS L&M Guidance for 10m and 20m buffer zone. The simulation, according to the Austrian Environmental Agency AGES were carried out for 5m and 15m buffer zone.
Nevertheless, additional simulations may be required by the cMS that do not accept calculations performed using FOCUS models.
The acceptable predicted environmental concentrations of nicosulfuron and its metabolites are appropriate to be used for the subsequent risk assessment
MS should identify risk reduction measures at the national level.

The PECsw calculation of nicosulfuron for the lower dose 30 g/ha have been performed using the same parameters as made earlier and are therefore accepted by zRMS.
The calculation PECsw is suitable for using of nicosulfuron at the lower dose of 30 g/ha.

~~The VFSMOD calculations have been done as refinement for R scenarios and are acceptable for PL and CZ.~~

8.9.2.3 Mesotrione and its metabolites

Table 8.9-19: Input parameters related to active substance Mesotrione and metabolites for PEC$_{sw/sed}$ calculations STEP 1/2 and 3/4

Compound	**Mesotrione**	**MNBA**	**AMBA**	**SYN546974**	**Value in accordance to EU endpoint y/n/ Reference**
Molecular weight (g/mol)	339	245	215	291	EFSA Journal 2016;14(3):4419
Saturated vapour pressure (Pa)	1.0 x 10^{-10} at 20°C	not required for Step 1+2			
Water solubility (mg/L)	160 at pH 7 and 20°C				
Diffusion coefficient in water (m²/d)	4.3 x 10^{-5}	not required for Step 1+2			default
Diffusion coefficient in air (m²/d)	0.43				
K$_{foc}$ (mL/g)	~~Linear fit: 190.92 (pH 5.1)~~	3.2 (worst case)	~~Linear fit: 101.5 (pH 5.1)~~	8021 (geomean,	EFSA Journal 2016;14(3):4419

Compound	Mesotrione	MNBA	AMBA	SYN546974	Value in accordance to EU endpoint y/n/ Reference
	~~87.01 (pH 6.5)~~ ~~0 (pH 7.9)~~ Log fit: 156.7 (pH 5.1) 52.2 (pH 6.5) 17.4 (pH 7.9)		~~59.7 (pH 6.5)~~ ~~18.0 (pH 7.9)~~ Log fit: 105.6 (pH 5.1) 48.0 (pH 6.5) 21.8 (pH 7.9)	n=5)	
Freundlich Exponent 1/n	0.94 (arithmetic mean, n=10)	not required for Step 1+2			
Plant Uptake	0				
Wash-Off factor from Crop (1/mm)	0.05 (MACRO) 0.50 (PRZM)				
$DT_{50,soil}$ (d)	Linear fit: 27.88 (pH 5.1) 14.2 (pH 6.5) 0.54 (pH 7.9) (normalisation to 10 kPa or pF2, 20 °C with Q_{10} of 2.58)	3.4 (geomean of normalised lab values, pF2, 10 kPa, Q_{10} 2.58, n=10)	14.5 (geomean of normalised lab values, pF2, 10 kPa, Q_{10} 2.58, n=5)	0.1 (default value for Step 1/2, not observed in soil)	
$DT_{50,water}$ (d)	5.6 (geomean, n=6)	1000 (default)			
$DT_{50,sed}$ (d)	1000 (default)	1000 (default)			
$DT_{50,whole\ system}$ (d)	5.6 (geomean, n=6)	1000 (default)			
Maximum occurrence observed (% molar basis with respect to the parent)	Sediment: 4.3	Soil: 57.2 Total system: 7.9	Soil: 9.7 Total system: 24.6	Soil: 1×10^{-10} Total system: 33	

Table 8.9-20: SWASH pH scenarios

Scenario	pH
D3	5.3
D4	6.9
D5	6.5
D6	7.5
R1	7.3
R2	4.5
R3	7.9
R4	8.4

$PEC_{sw/sed}$

Only calculations using the logarithmic Kfoc equation have been done according to the expert agreement, since the relation for adsorption is logarithmic instead of linear.

Table 8.9-3: FOCUS Step 1, 2 and 3 PEC$_{sw}$ for Mesotrione following single application of PRIMARY MX to maize

Scenario FOCUS		Period (Step 2) Waterbody (Step 3)	Max PEC$_{sw}$ (µg/L)			Dominant entry route
			pH 5.1	pH 6.5	pH 7.9	
Step 1		March - May	25.62	28.88	30.15	Runoff + drainage
Step 2	Southern Europe	March - May	7.20	7.41	0.83	Runoff + drainage
	Northern Europe		3.83	3.95		
Step 3	D3	Ditch	0.472	-	-	Drainage
	D4	Pond	-	0.020	-	Drainage
	D4	Stream	-	0.460	-	Drainage
	D5	Pond	-	0.020	-	Drainage
	D5	Stream	-	0.426	-	Drainage
	D6	Ditch	-	-		Drainage
	R1	Pond	-	-		Runoff and erosion
	R1	Stream	-	-		Runoff and erosion
	R2	Stream	**1.095**	-	-	Runoff and erosion
	R3	Stream	-	-		Runoff and erosion
	R4	Stream	-	-		Runoff and erosion

~~Scenario FOCUS~~		~~Period (Step 2) Waterbody (Step 3)~~	~~Max PEC$_{sw}$ (µg/L)*~~						~~Dominant entry route~~
			~~pH 5.1~~		~~pH 6.5~~		~~pH 7.9~~		
			~~Log~~	~~Linear~~	~~Log~~	~~Linear~~	~~Log~~	~~Linear~~	
~~Step 1~~		~~March – May~~	~~33.62~~	~~32.44~~	~~37.86~~	~~36.33~~	~~39.53~~	~~40.42~~	~~Runoff + drainage~~
~~Step 2~~	~~Southern Europe~~	~~March – May~~	~~6.50~~	~~6.27~~	~~6.69~~	~~6.43~~	~~1.09~~		~~Runoff + drainage~~
	~~Northern Europe~~		~~3.55~~	~~3.44~~	~~3.67~~	~~3.53~~			
~~Step 3~~	~~D3~~	~~Ditch~~	~~0.619~~	~~0.619~~	-	-	-	-	~~Drainage~~
	~~D4~~	~~Pond~~	-	-	~~0.025~~	~~0.026~~	-	-	~~Drainage~~
	~~D4~~	~~Stream~~	-	-	~~0.531~~	~~0.532~~	-	-	~~Drainage~~

~~Scenario FOCUS~~		~~Period (Step 2) Waterbody (Step 3)~~	~~Max PEC$_{sw}$ (µg/L)*~~						~~Dominant entry route~~
	~~D5~~	~~Pond~~	~~-~~	~~-~~	~~0.026~~	~~0.026~~	~~-~~	~~-~~	~~Drainage~~
	~~D5~~	~~Stream~~	~~-~~	~~-~~	~~0.577~~	~~0.558~~	~~-~~	~~-~~	~~Drainage~~
	~~D6~~	~~Ditch~~	~~-~~	~~-~~	~~-~~	~~-~~	~~0.618~~	~~0.618~~	~~Drainage~~
	~~R1~~	~~Pond~~	~~-~~	~~-~~	~~-~~	~~-~~	~~0.025~~	~~0.025~~	~~Runoff and erosion~~
	~~R1~~	~~Stream~~	~~-~~	~~-~~	~~-~~	~~-~~	~~0.547~~	~~0.581~~	~~Runoff and erosion~~
	~~R2~~	~~Stream~~	~~1.243~~	~~1.454~~	~~-~~	~~-~~	~~-~~	~~-~~	~~Runoff and erosion~~
	~~R3~~	~~Stream~~	~~-~~	~~-~~	~~-~~	~~-~~	~~0.752~~	~~0.608~~	~~Runoff and erosion~~
	~~R4~~	~~Stream~~	~~-~~	~~-~~	~~-~~	~~-~~	~~0.639~~	~~0.564~~	~~Runoff and erosion~~

Table 8.9-4: **FOCUS Step 1, 2 and 3 PEC$_{sed}$ for Mesotrione following single application of PRIMARY MX to maize**

Scenario FOCUS		**Period (Step 2) Waterbody (Step 3)**	**Max PEC$_{sed}$ (µg/kg)**			**Dominant entry route**
			pH 5.1	**pH 6.5**	**pH 7.9**	
Step 1		March - May	39.07	14.64	5.10	Runoff + drainage
Step 2	Southern Europe	March - May	11.30	3.86	0.10	Runoff + drainage
	Northern Europe		6.00	2.06	0.09	
Step 3	D3	Ditch	0.125	-	-	Drainage
	D4	Pond	-	0.013	-	Drainage
	D4	Stream	-	0.024	-	Drainage
	D5	Pond	-	0.017	-	Drainage
	D5	Stream	-	0.029	-	Drainage
	D6	Ditch	-	-	0.047	Drainage
	R1	Pond	-	-	0.007	Runoff and erosion
	R1	Stream	-	-	0.031	Runoff and erosion
	R2	Stream	0.299	-	-	Runoff and erosion
	R3	Stream	-	-	0.048	Runoff and erosion
	R4	Stream	-	-	0.052	Runoff and erosion

Scenario FOCUS		Period (Step 2) Waterbody (Step 3)	Max PEC_{sed} (µg/kg)						Dominant entry route
			pH 5.1		pH 6.5		pH 7.9		
			Log	Linear	Log	Linear	Log	Linear	
Step 1		March – May	50.983	59.86	19.20	30.67	6.69	<0.01	Runoff + drainage
Step 2	Southern Europe	March – May	10.14	11.91	3.49	5.58	0.12	<0.01	Runoff + drainage
	Northern Europe		5.52	6.50	1.91	3.06			
Step 3	D3	Ditch	0.178	0.163	-	-	-	-	Drainage
	D4	Pond	-	-	0.018	0.018	-	-	Drainage
	D4	Stream	-	-	0.031	0.031	-	-	Drainage
	D5	Pond	-	-	0.025	0.022	-	-	Drainage
	D5	Stream	-	-	0.040	0.037	-	-	Drainage
	D6	Ditch	-	-	-	-	0.036	0.062	Drainage
	R1	Pond	-	-	-	-	0.005	0.010	Runoff and erosion
	R1	Stream	-	-	-	-	0.022	0.041	Runoff and erosion
	R2	Stream	0.372	0.394	-	-	-	-	Runoff and erosion
	R3	Stream	-	-	-	-	0.043	0.062	Runoff and erosion
	R4	Stream	-	-	-	-	0.045	0.068	Runoff and erosion

FOCUS Step 4

~~The scenarios chosen for step 4 calculations are according to the worst case linear or logarithm Kfoc equation used and their respective pH's (Table 8.9-4 (Generic guidance for FOCUS surface water scenarios v1.4 May 2015)).~~

Table 8.9-23: Global maximum PEC_{sw} values for Mesotrione, following single application of PRIMARY MX to maize according to the central EU zone GAP according to surface water Step 4

PEC_{sw} (µg/L)	Scenario	STEP 4 Mesotrione
Nozzle reduction	**Vegetative strip (m)**	**5***
	No spray buffer (m)	**5**
None	R2 stream (pH 5.1)	0.701

***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.**

~~PEC$_{sw}$ (µg/L)~~	~~Scenario~~	~~STEP 3 Mesotrione~~	~~STEP 4 Mesotrione~~	
~~Nozzle reduction~~	~~Vegetative strip (m)~~	~~None~~	~~5**~~	~~10~~
	~~No spray buffer (m)~~	~~None~~	~~5~~	~~10~~
~~None~~	~~R2 stream (pH 5.1) Log*~~	~~1.454~~	~~0.930~~	~~0.642~~

~~*Worst case~~

Metabolites of Mesotrione

Table 8.9-24: FOCUS Step 1 and 2 PEC$_{sw}$ and PEC$_{sed}$ for MNBA following single application to maize

Scenario FOCUS		Season	Max PEC$_{sw}$(µg/L)			Max PEC$_{sed}$ (µg/kg)		
			pH 5.1	pH 6.5	pH 7.9	pH 5.1	pH 6.5	pH 7.9
Step 1		Mar– May	14.10			0.45		
Step 2	SEU		2.15	2.11	1.69	0.07		0.05
	NEU		1.10	1.08	0.87	0.04	0.03	

~~Scenario FOCUS~~		~~Season~~	~~Max PEC$_{sw}$(µg/L)~~						~~Max PEC$_{sed}$ (µg/kg)~~					
			~~pH 5.1 log~~	~~pH 5.1 linear~~	~~pH 6.5 log~~	~~pH 6.5 linear~~	~~pH 7.9 log~~	~~pH 7.9 linear~~	~~pH 5.1 log~~	~~pH 5.1 linear~~	~~pH 6.5 log~~	~~pH 6.5 linear~~	~~pH 7.9 log~~	~~pH 7.9 linear~~
~~Step 1~~			~~18.49~~						~~0.59~~					
~~Step 2~~	~~SEU~~	~~Mar– May~~	~~1.90~~		~~1.86~~		~~1.48~~		~~0.06~~				~~0.05~~	
	~~NEU~~		~~0.98~~		~~0.96~~		~~0.78~~		~~0.03~~				~~0.03~~	

Table 8.9-25: FOCUS Step 1 and 2 PEC$_{sw}$ and PEC$_{sed}$ for AMBA following single application to maize

Scenario FOCUS		Season	Max PEC$_{sw}$(µg/L)			Max PEC$_{sed}$ (µg/kg)		
			pH 5.1	pH 6.5	pH 7.9	pH 5.1	pH 6.5	pH 7.9
Step 1		Mar– May	5.85	6.26	6.47	6.16	3.00	1.41
Step 2	SEU		1.63	1.64	0.58	1.72	0.78	0.13
	NEU		0.88		0.35	0.92	0.42	0.08

Scenario FOCUS		Season	Max PEC$_{sw}$(µg/L)						Max PEC$_{sed}$ (µg/kg)					
			pH 5.1 log	pH 5.1 linear	pH 6.5 log	pH 6.5 linear	pH 7.9 log	pH 7.9 linear	pH 5.1 log	pH 5.1 linear	pH 6.5 log	pH 6.5 linear	pH 7.9 log	pH 7.9 linear
Step 1			11.24	11.29	12.03	11.86	12.43	12.49	11.60	11.21	5.66	6.93	2.66	2.20
Step 2	SEU	Mar– May	2.17	2.18	2.18	2.15	0.82	0.83	2.28	2.20	1.04	1.28	0.18	0.15

Scenario		**Season**	**Max PEC$_{sw}$(µg/L)**					**Max PEC$_{sed}$ (µg/kg)**					
	NEU		1.20	1.21	1.19	0.53	0.54	1.25	1.21	0.58	0.71	0.12	0.10

Table 8.9-26: **FOCUS Step 1 and 2 PEC$_{sw}$ and PEC$_{sed}$ for SYN546974 following single application to maize**

Scenario FOCUS		**Season**	**Max PEC$_{sw}$(µg/L)**			**Max PEC$_{sed}$ (µg/kg)**		
			pH 5.1	pH 6.5	pH 7.9	pH 5.1	pH 6.5	pH 7.9
Step 1		Mar– May	0.96			59.85		
Step 2	SEU		0.23			17.42	15.98	1.71
	NEU					9.51	8.79	1.65

~~Scenario FOCUS~~		~~Season~~	~~Max PEC$_{sw}$(µg/L)~~						~~Max PEC$_{sed}$ (µg/kg)~~					
			~~pH 5.1 log~~	~~pH 5.1 linear~~	~~pH 6.5 log~~	~~pH 6.5 linear~~	~~pH 7.9 log~~	~~pH 7.9 linear~~	~~pH 5.1 log~~	~~pH 5.1 linear~~	~~pH 6.5 log~~	~~pH 6.5 linear~~	~~pH 7.9 log~~	~~pH 7.9 linear~~
~~Step 1~~			~~1.26~~						~~76.42~~					
~~Step 2~~	~~SEU~~	~~Mar–May~~	~~0.31~~						~~15.93~~		~~14.67~~		~~2.19~~	
	~~NEU~~								~~9.02~~		~~8.38~~		~~2.15~~	

zRMS comments:

Mesotrione

The PECsw calculations for mesotrone have been approved for applications proposed in GAP. PEC$_{sw}$ and PEC$_{sed}$ calculations were carried out according to the FOCUS recommendations. The Applicant has been used FOCUS models: STEPS1-2 and Step 3. PEC$_{sw/sed}$ were also carried out at Step 4 according to FOCUS L&M Guidance for 10m and 20m buffer zone. Simulation, according to the Austrian Environmental Agency AGES were carried out for 5m and 15m buffer zone. The Applicant used the geometric mean value. In opinion of the zRMS this is acceptable, as being in line with current requirements concerning selection of Kfoc to be used for modelling purposes.

PECs$_{w/sed}$ are acceptable to describe predicted environmental concentrations of mesotrione and its metabolites in surface water and sediment and are appropriate to be used for the subsequent risk assessment for aquatic and sediment organisms.

MS should identify risk reduction measures at the national level.

The PECsw calculation of mesotrione for the lower dose 90 g/ha have been performed using the same parameters as made earlier and are therefore accepted by zRMS.
The calculation PECsw is suitable for using of mesotrione at the lower dose of 90 g/ha.

8.9.2.4 PEC$_{sw/sed}$ of PRIMARY MX

The PEC$_{SW}$ for PRIMARY MX was calculated using the following equation:

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

The application of PRIMARY MX is 1 x 250 ~~330~~ g/ha. The depth of the static water body was assumed to be 30 cm. The resulting maximum instantaneous PEC$_{SW}$ value is presented in the table 8.9-27.

Table 8.9-27: PEC$_{sw}$ PRIMARY MX following single application to maize

Crop	Distance (m)	Drift (%)	Max PEC$_{SW}$ (µg/L)
Maize	1	2.77	2.308 ~~3.047~~

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

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

The application of PRIMARY MX is 1 x 250 ~~330~~ g/ha, for all crops included in the GAP. The maximum percentages of Rimsulfuron, Nicosulfuron and Mesotrione in the sediment are 12.6, 24 and 4.3 % respectively. But the content in the formulated product is 3, 12 and 36% for Rimsulfuron, Nicosulfuron and Mesotrione respectively, thus the actual percentage is 12.6 x 0.03 = 0.38%, 24 x 0.12 =2.88% and 4.3 x 0.36 = 1.55% for Rimsulfuron, Nicosulfuron and Mesotrione respectively.
The height of the sediment was assumed to be 5 cm and the sediment density was assumed to be 1.3 g/cm^3. The resulting maximum instantaneous PEC$_{sed}$ value is presented in the table 8.9-28.

Table 8.9-28: PEC$_{sed}$ for PRIMARY MX following single application to maize

Crop	Distance (m)	Drift (%)	% of a.s. in sediment	Max PEC$_{sed}$ (µg/kg) (based on maximum occurrence)
Maize	1	2.77	Rimsulfuron: 0.38 ~~12.6~~	0.040 ~~1.772~~
			Nicosulfuron: 2.88 ~~24~~	0.307 ~~4.781~~
			Mesotrione: 1.55 ~~4.3~~	0.165 ~~0.605~~

zRMS comments:
The PEC$_{SW/}$sed for PRIMARY MX was accepted.

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

Table 8.10-1: Rimsulfuron summary of atmospheric degradation and behaviour

Compound	Rimsulfuron
Direct photolysis in air	No data, not required.
Quantum yield of direct phototransformation	Rimsulfuron: Φ = 0.0047 IN-70942: Φ = 0.00072
Photochemical oxidative degradation in air	DT50 0.611 h (12 hour day, Atkinston calculation)
Volatilisation	From plant surface: 0.3-3.5% in 24 h From soil: 0-2.2% in 24 h Vapour pressure (Pa): 3.8 x 10^{-11} @ 20ºC Henry's Law Constant (Pa.m3/mol): 4.5 x 10^{-10} Pa.m^3.mol^{-1} (pH 5, 25°C) 8.3 x 10^{-12} Pa.m^3.mol^{-1} (pH 7, 25°C) 1.1 x 10^{-11} Pa.m^3.mol^{-1} (pH 9, 25°C)
Metabolites	None.

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

Table 8.10-2: Nicosulfuron summary of atmospheric degradation and behaviour

Compound	Nicosulfuron
Direct photolysis in air	Not studies – no data requested
Quantum yield of direct phototransformation	No data submitted – not rquired.
Photochemical oxidative degradation in air	Atkinson (1988) method used, assuming a rate constant of 1.5 x 10^6 OH radicals/cm^3 photochemical produced during a 12 hour-photo phase day with temperature and solar light intensity typically found at sea level gave an atmospheric DT_{50} of 0.587 hours.
Volatilisation	From plant surface: 8.3% over 24 hours From soil: 6.2% over 24 hours Vapour pressure (Pa): < 8 x 10^{-10} Pa at 25°C (99.8%) Henry's Law Constant (Pa.m3/mol): 1.48 x 10^{-11} Pa.m^3.mol^{-1} at 20°C
Metabolites	None.

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

Table 8.10-3: Mesotrione summary of atmospheric degradation and behaviour

Compound	Mesotrione
Direct photolysis in air	Not studies – no data requested.
Quantum yield of direct phototransformation	Not reported.
Photochemical oxidative degradation in air	DT50 of 17.635 hours (1.5 days) derived by the Atkinston model (AOP version 1.8) OH (12h) concentration assumed = 1.5 x 10^6 OH/cm^3

Volatilisation	From plant surfaces (BBA guideline): < 10% after 24 hours From soil surfaces (BBA guideline): < 10% after 24 hours Vapour pressure (Pa): < 5.7 x 10^{-6} Pa at 20°C (99.7% pure) Henry's Law Constant (Pa.m3/mol): < 5.1 x 10^{-7} m^3/mol at 20°C
Metabolites	Not applicable.

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

zRMS comments

The atmospheric degradation and behaviour for rimsulfuron, nicosulfuron and mesotrione are in line with EU agreed endpoints.

Appendix 1 Lists of data considered in support of the evaluation

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 8.8-01	Ferrari, F.	2019	Title: Groundwater Monitoring for Nicosulfuron and 4 Metabolites in Maize Growing Regions of Italy. Company Report No 37/2016 Source Sharda Cropchem Ltd. GLP Unpublished	N	Sharda Cropchem Ltd.

Appendix 2 List of data submitted by the applicant and relied on

Appendix 3 Detailed evaluation of the new Annex II studies