FINAL REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: SAE053H/01

Product name(s): KAGURA / GENKI

Chemical active substance(s):

Mesotrione, 80 g/L
Nicosulfuron, 30 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Document number - SAEDoc-00019 CEU

(authorization)

Applicant: Sumi Agro Europe Limited

Submission date: November 2019

Updated July 2021

MS Finalisation date: 18/02/2022

Version history

When	What
June 2020	dRR submitted by applicant
August 2020	Dossier sent for evaluation to Merit Mark (PL)
April 2021	dRR amended due to comments from RMS Poland. In brief, the Nicosulfuron parts required amendment using EFSA 2007 endpoints. In both the case of Nicosulfuron and Mesotrione, new calculations based on BBCH12 were performed, to bring in line with the intended GAP. In addition to amendments due to Poland comments, calculations for Mesotrione at pH7.9 used a DT50 of 0.54 d, instead of the incorrectly stated value of 5.4 d in EFSA 2016 conclusion. All calculations are now based on the application rate of 1.2L/ha, as stated in intended GAP. New information from the Nicosulfuron Renewal dossier has been deleted from the original dRR as no longer applicable for this application. Replacement text and values for both Mesotrione (as result of change to BBCH12 and DT50 of 0.54 d) and EFSA 2007 Nicosulfuron endpoints have been highlighted in green for ease of reference.
July 2021	dRR amended due to comments from RMS Poland. zRMS Poland requested that PEC_{GW} be simulated using a foliar application with the crop interception chosen internally by each model.
October 2021	zRMS finalised evaluation
January 2022	Final version prepared by zRMS after Commenting period
February 2022	Final version prepared by zRMS after Commenting period

Table of Contents

8 Fate and behaviour in the environment (KCP 9) 4
8.1 Critical GAP and overall conclusions 5
8.2 Metabolites considered in the assessment 7
8.3 Rate of degradation in soil (KCP 9.1.1) 9
8.3.1 Aerobic degradation in soil (KCP 9.1.1.1) 9
8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1) 9
8.4 Field studies (KCP 9.1.1.2) 10
8.4.1 Soil dissipation testing on a range of representative soils (KCP 9.1.1.2.1) 10
8.4.2 Soil accumulation testing (KCP 9.1.1.2.2) 10
8.5 Mobility in soil (KCP 9.1.2) 11
8.5.1 Column leaching (KCP 9.1.2.1) 12
8.5.2 Lysimeter studies (KCP 9.1.2.2) 12
8.5.3 Field leaching studies (KCP 9.1.2.3) 12
8.6 Degradation in the water/sediment systems (KCP 9.2, KCP 9.2.1, KCP 9.2.2, KCP 9.2.3) 13
8.7 Predicted Environmental Concentrations in soil (PEC_{soil}) (KCP 9.1.3) 16
8.7.1 Justification for new endpoints 17
8.7.2 Active substances and relevant metabolites 17
8.8 Predicted Environmental Concentrations in groundwater (PEC_{gw}) (KCP 9.2.4) 22
8.8.1 Justification for new endpoints 22
8.8.2 Active substances and relevant metabolites (KCP 9.2.4.1) 22
8.9 Predicted Environmental Concentrations in surface water (PECsw) (KCP 9.2.5) 34
8.9.1 Justification for new endpoints 37
8.9.2 Active substances, relevant metabolites and the formulation (KCP 9.2.5) 37
8.10 Fate and behaviour in air (KCP 9.3, KCP 9.3.1) 53

Appendix 1 Lists of data considered in support of the evaluation 54

Appendix 2 Detailed evaluation of the new active substance studies (MCA) 55

Appendix 3 Additional information provided by the applicant 56

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

8 Fate and behaviour in the environment (KCP 9)

The following section on fate and behaviour in the environment is based on the EFSA conclusion for mesotrione (EFSA 2016), the EFSA conclusion for nicosulfuron (EFSA 2007) The full citations for these documents are listed below.

The intended maximal application rate to be registered is 1.2 L product/ha, which is equivalent to 96 g mesotrione/ha and 36 g nicosulfuron/ha. All risk and exposure assessments presented have been performed with this application rate.

Mesotrione:

EFSA (2016) Peer review of the pesticide risk assessment of the active substance mesotrione. *EFSA Journal* 2016; 14(3):4419 http://dx.doi.org/10.2903/j.efsa.2016.4419

Nicosulfuron:

EFSA (2007) Conclusion regarding the peer review of the pesticide risk assessment of the active substance nicosulfuron. *EFSA Scientific Report* (2007) 120, 1-91 http://dx.doi.org/10.2903/j.efsa.2008.120r

8.1 Critical GAP and overall conclusions

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

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			PHI (days)	Remarks: e.g. g safener/ synergist per ha	**Conclusion groundwater**
					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			
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	SK, PL, RO, HU, CZ, UK, IE, DE, BE, NL, AT, SI	Maize	F	*Broadleaved weeds and grasses*	foliar spray	BBCH 12-18	a, b) 1	-	a, b) 1.2 L/ha	a, b) mesotrione: 96 g/ha nicosulfuron: 36 g/ha	200-400	n.a.		

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

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

Explanation for column 15 “Conclusion”

A	Safe use
R	Further refinement and/or risk mitigation measures required
C	To be confirmed by cMS
N	No safe use

The safe use can be concluded if formulation is applied every third year.

Table 8.1-2: Assessed (critical) uses during approval of mesotrione concerning the Section Environmental Fate (EFSA 2016, p. 32)

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			PHI (days)	Remarks: e.g. g safener/ synergist per ha
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
1	EU N&S	Maize	F	annual broad-leaved weeds and some annual grasses such as *Echinochloa crus-galli*	Foliar spray application using a hydraulic vehicle-mounted spray equipment	BBCH 12-18	1 application per crop/season	na		120 to 150 g as/ha	200-400 L/ha	na	

* 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 (EFSA 2007, p. 40)

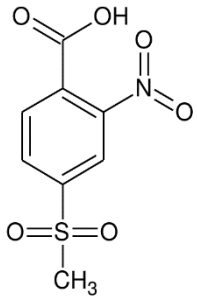
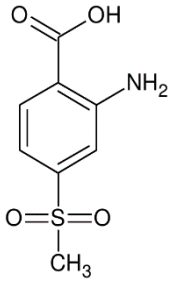
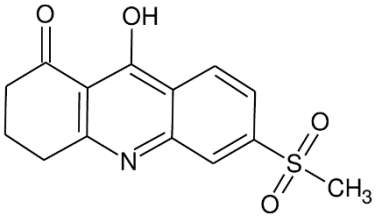
1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			PHI (days)	Remarks: 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	1	n.a.		60 g as/ha	200-400	n.r.	

* 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

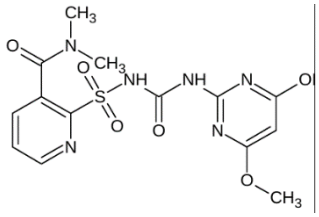
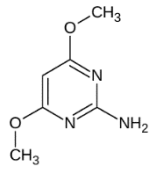
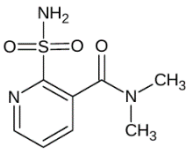
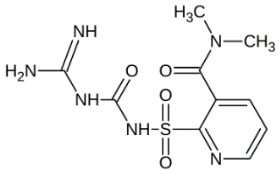
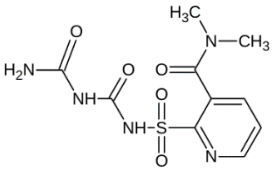
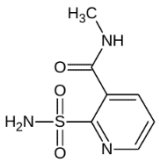
8.2 Metabolites considered in the assessment

Table 8.2-1: Metabolites of mesotrione potentially relevant for exposure assessment (EFSA 2016)

Metabolite	Molar mass	Chemical structure	Maximum observed occurence in compartments	Exposure assessment required due to
MNBA	245		Soil: 57.2% (p. 12, 54) Surface water: 7.4% (p. 65) Sediment: <1% (p. 65) Total system: 7.4% (p. 66)	PEC_{Soil}: different rate, increase accuracy of ecotox assessment PEC_{GW}: Not all PEC values below 0.1 µg/L in EU assessment (MNBA, pH 5.1, PELMO) $PEC_{SW/SED}$: different rate, increased accuracy of ecotox assessment
AMBA	215		Soil: 9.7% [a](p. 54) Water: 15.8% (p. 66) Sediment: 8.8% (p. 66) Total system: 24.6% (p. 66)	
SYN 546974	291		Surface water: 9.4% (p. 66) Sediment: 25.6% (p. 66) Total system: 33.0% (p. 66)	

[a] On page 12 of the EFSA conclusion, a value of 9.3% is given

Table 8.2-2: Metabolites of nicosulfuron potentially relevant for exposure assessment (EFSA 2007)

Metabolite	Molar mass [g/mol]	Chemical structure	Maximum observed occurence in compartments (%)	Exposure assessment required due to
HMUD	396.4		Soil: 14.4% Surface water: 14.1% (p. 64) Sediment: 5.7% (p. 64) Total system: 19.3% (p. 66)	Not covered in EU assessment
ADMP	155.2		Soil: 9.8% Surface water: 65.4% via hydrolysis (p. 62)	
ASDM	229.3		Soil: 63.4% Surface water: 6.9% (p. 64) Sediment: 4.4% (p. 64) Total system: 9.4% (p. 66) Aqueous photolysis: 61% (p. 62)	
AUSN	314.3		Soil: 26.8% Surface water: 9.1% (p. 64) Sediment: 2.4% (p. 64) Total system: 11.1% (p. 66)	
UCSN	315.3		Soil: 11.0% Surface water: 5.4% (p. 64) Sediment: 1.4% (p. 64) Total system: 6.5% (p. 66)	
MU-466	215.2		Soil: not relevant Water/sediment: not relevant	

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 substances.

8.3.1 Aerobic degradation in soil (KCP 9.1.1.1)

Mesotrione and its metabolites

The available data on the degradation of mesotrione and its metabolites in the laboratory has been reviewed during Annex I renewal (EFSA 2016, p. 55-57). For mesotrione, the peer review agreed to use a linear relationship between soil pH and modelling DT_{50} at reference conditions according to the following equation :

$$DT_{50}\ (20°C, pF2) = -\ 9.766\ days \times pH + 77.692\ days\ (r^2 = 0.4687)$$

For soil metabolites MNBA and AMBA, geometric mean of normalised (20°C, pF2) modelling DT_{50} values of 3.4 days (n=10) and 14.5 days (n=5, outlier) were reported. For detailed listings of soil properties and statistics of the kinetic evaluations please refer to the EFSA conclusion.

Nicosulfuron and its metabolites

The available data on the degradation of nicosulfuron and its metabolites in the laboratory has been reviewed during Annex I inclusion (EFSA 2007, p. 51-54).

Table 8.3-1: Geometric mean aerobic soil degradation rates for nicosulfuron and its metabolites

Compound	Annex I inclusion (EFSA 2007)	
	DT_{50} (d) 20°C[a] pF2/10kPa	**Remark**
Nicosulfuron	16.4	Geometric mean of laboratory studies, n=7
HMUD	23.8	Geometric mean of 2 values from 2 parent labels of laboratory studies in 1 soil, n=1
ADMP	4.5	Geometric mean of laboratory studies, n = 3
ASDM	236.6	Worst-case of laboratory studies, n = 3
AUSN	192.3	Worst-case of laboratory studies, n = 3
UCSN	271.0	Worst-case of laboratory studies, n = 3
MU-466	75.5	Worst-case of laboratory studies, n = 3

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

The anaerobic degradation data for both active substances has been reviewed (EFSA 2007, 2016). No additional studies have been performed and the resulting endpoints are not used in the risk assessment.

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)

Mesotrione and its metabolites

Field dissipation data for mesotrione were not relied upon during Annex I renewal of mesotrione (EFSA 2016, p. 12 and 57). These data are also not relied upon in this dossier.

Nicosulfuron and its metabolites

For Nicosulfuron, field dissipation from four sites were available for Annex I inclusion, but were not relied upon for the modelling (EFSA 2007, p. 54) apart from the maximum non-normalised DT_{50} of 63 days (Hünfelden, Germany), which was only used in PECsoil calculations. No normalised $DegT_{50}$ values were derived.

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

Soil accumulation testing was not considered to be triggered for mesotrione (EFSA 2016) and nicosulfuron (EFSA 2007).

8.5 Mobility in soil (KCP 9.1.2)

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

Mesotrione and its metabolites

Sorption of mesotrione and its metabolites to soil has been reviewed during Annex I renewal. For the active substance, sorption was found to be dependent on soil pH. The following exponential relationship between soil pH and $K_{f,oc}$ was agreed in the peer review (EFSA 2016, p. 12, 59)

$$K_{f,oc} = 8583.4 \text{ L/kg} \cdot e^{(-0.785 \text{ pH})}$$

From this relationship, modelling endpoints for different soil pH values can be obtained. From a GIS analysis, the 10th percentile, median and 90th percentile soil pH values for maize growing areas in Europe were determined to be pH 5.1, pH 6.5 and pH 7.9, respectively (EFSA 2016, p. 70). The corresponding modelling endpoints for $K_{f,oc}$ used in the ground- and surface water modelling were 156.7 L/kg, 52.2 L/kg and 17.4 L/kg, respectively.

For soil metabolite MNBA, sorption values from two soils were available, with a worst-case Kf,oc value of 3.2 L/kg agreed as conservative modelling endpoint, together with a 1/n value of 0.9 (FOCUS default, EFSA 2016, p. 60).

For soil metabolite AMBA, sorption data from five soils was available for Annex I renewal. The Kf,oc was found to be pH dependent and the following relationship was established (EFSA 2016, p. 60)

$$K_{f,oc} = 1865 \text{ L/kg} \cdot e^{(-0.563 \text{ pH})}$$

From this relationship, modelling endpoints for $K_{f,oc}$ used in the ground- and surface water modelling for pH 5.1, pH 6.5 and pH 7.9 were derived to be 105.6 L/kg, 48.0 L/kg and 21.8 L/kg, respectively (EFSA 2016, p. 70/71, p. 80/81).

For water/sediment metabolite SYN 546974, sorption values from five soils were available, with an arithmetic mean values for $K_{f,oc}$ and 1/n of 12824 L/kg and 0.89, respectively.

Nicosulfuron and its metabolites

During Annex I inclusion, a correlation of nicosulfuron sorption to soil with soil clay content was established (EFSA 2007).

For nicosulfuron metabolites, the soil sorption endpoints are summarised in Table 8.5-1.

Table 8.5-1: Soil sorption endpoints for nicosulfuron and its metabolites

Compound	Annex I inclusion (EFSA 2007)		
	$K_{f,oc}$ [mL/g]	**1/n [-]**	**Remark**
Nicosulfuron	20.7	0.93	Arithmetic mean (n=4, p. 55)

Compound	Annex I inclusion (EFSA 2007)		
	$K_{f,oc}$ [mL/g]	1/n [-]	Remark
HMUD	Only Koc values available, ranging from 0.88-10.75 mL/g. (n=5, p. 56)		
ADMP	51.5	0.87	Arithmetic mean (n=4, p. 55)
ASDM	5.7	0.91	Arithmetic mean (n=4, p. 55)
AUSN	27.5	0.96	Arithmetic mean (n=4, p. 56)
UCSN	Only Koc values available, ranging from 1.1-5.6 mL/g. (n=4, p. 56)		
MU-466	Only Koc values available, ranging from 1.32 -16.08 mL/g. (n=5, p. 57)		

8.5.1 Column leaching (KCP 9.1.2.1)

No column leaching studies were provided for Annex I renewal of mesotrione (EFSA 2016, p. 12).

Column leaching data for nicosulfuron were reviewed during Annex I inclusion of nicosulfuron (EFSA 2007, p. 19), but not used in the risk assessments.

8.5.2 Lysimeter studies (KCP 9.1.2.2)

No lysimeter studies were provided for Annex I renewal of mesotrione (EFSA 2016, p. 12).

Three lysimeter studies were reviewed during Annex I inclusion of nicosulfuron (EFSA 2007, p. 19/20).

In the lysimeters where two applications have been made at 60 g/ha, the two-year average stays below 0.15 µg/L, indicating that under conditions less prone for leaching (higher clay content and lower precipitation) and at the application rate (1 x 36 g/ha) used in the GAP for this product dossier, the trigger of 0.1 µg/L would not have been breached. In addition, the results obtained for 1 x 40 g/ha (maximum of 0.07 µg/L over two years), support the modelling conclusion that the trigger of 0.1 µg/L would not be breached in the Hamburg scenario for triennial application used in the GAP for this product dossier.

8.5.3 Field leaching studies (KCP 9.1.2.3)

No field leaching studies are reported in the EFSA conclusion on mesotrione, as they are not required (EFSA 2016, p. 61).

No field leaching studies are reported for nicosulfuron in the EFSA conclusion on nicosulfuron (EFSA 2007).

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.

Mesotrione and its metabolites

The available water/sediment studies were reviewed during Annex I renewal (EFSA 2016, p. 65-66). The results for parent compound mesotrione are summarised in Table 8.6-1. No kinetic evaluations are shown for the aquatic metabolites MNBA, AMBA and SYN546974 listed with their maximum occurrence values in
Table 8.6-2. Degradation in surface water studies without a sediment phase was either not observed or much slower (EFSA 2016, p. 63).

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

Mesotrione Distribution (max. water 98.7 % after 0 days, max. in sediment 4.3% after 1 day)									
Water/sediment system	**pH water**	**pH sed.**	**DegT50 whole syst. (d)**	**Kinetic/ χ^2 error level (%)**	**DissT50 water (d)**	**Kinetic/ χ^2 error level (%)**	**DissT50 sed. (d)**	**Kin.**	**Evaluated on EU level**
Basing (Phenyl)	7.86	-	2.6	SFO / 6.8	2.5	SFO / 6.2	-	-	yes
Basing (Cyclohexane)			4.2	SFO / 13.3	4.2	SFO / 13.3	-	-	yes
Virginia (Phenyl)	7.40		5.5	SFO / 12.3	5.3	SFO / 13.5	-	-	yes
Virginia (Cyclohexane)			7.2	SFO / 14.4	7.0	SFO / 13.4	-	-	yes
Calwich (Phenyl)	8.4/7.8 aerobic/anaerobic	7.6	6.6	SFO / 4.5	6.7	SFO / 3.4	-	-	yes
Swiss (Phenyl)	7.4/7.5 aerobic/anaerobic	6.1	11.1	SFO / 3.5	11.0	SFO / 3.3	-	-	yes
Geometric mean (n=4 systems)			5.6		5.5		-		yes

Table 8.6-2: Summary of observed metabolites

MNBA Water/sediment system	Maximum in water 7.4% after 3 days Maximum in sediment <1% Maximum in total system 7.4% after 3 days.	Evaluated on EU level: yes
AMBA Water/sediment system	Maximum in water 15.8% after 46 days Maximum in sediment 8.8% after 46 days Maximum in total system 24.6% after 46 days	

SYN546974 Water/sediment system	Maximum in water 9.4% after 29 days Maximum in sediment 25.6% after 102 days Maximum in total system 33% after 29 days	

Nicosulfuron and its metabolites

One water/sediment study with two systems was reviewed during Annex I inclusion of nicosulfuron (EFSA 2007).

Table 8.6-3 shows the kinetic endpoints from these systems for nicosulfuron. No kinetic evaluation of the aquatic metabolites was possible.

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

		Nicosulfuron Distribution (max. in sediment 24% after 14 days)								
Water/sediment system	**pH water**	**pH sed.**	**DegT50 whole syst. (d)**	**Kinetic fit**	**[a]DissT50 water (d)**	**[a]DissT90 water (d)**	**Kinetic/ χ^2 error level (%)**	**DissT50 Sed. (d)**	**Kinetic fit**	**Reference**
River(Rhine)	6.9	-	49.8	SFO	63.9	212.4	SFO	21.9	SFO	EFSA 2007, DAR 2005
Pond (Anwil)	6.9	-	33.2	SFO	66.2	219.9	SFO	8.8	SFO	
Geometric mean (n=2)					65.0			13.9		

a calculated using ModelMaker, r2 = 0.90-0.97

The maximum observed percentages of the aquatic nicosulfuron metabolites are summarised in Table 8.6-4 (EFSA 2007).

Table 8.6-4: Summary of observed nicosulfuron metabolites

HUMD Water/sediment system	Max. in water: 14.1 % after 62 d (pond, pyridine label) Max. in sediment: 5.7 % after 30 d (pond, pyridine label)	Evaluated on EU level Y Reference EFSA 2007, DAR, 2005
AUSN Water/sediment system	Max. in water: 9.1 % after 177 d (study end) (River, pyridine label) Max. in sediment: 2.4% after 105 d (pond, pyridine label)	Evaluated on EU level Y Reference EFSA 2007, DAR, 2005
UCSN Water/sediment system	Max. in water: 5.4 % after 177 d (pond, pyridine label) Max. in sediment: 1.4% after 105 d (River, pyridine label)	Evaluated on EU level Y

		Reference EFSA 2007, DAR, 2005
ASDM Water/sediment system	Max. in water: 6.9 % after 177 d (River, pyridine label) Max. in sediment: 4.4% after 62 d (pond, pyridine label)	Evaluated on EU level Y Reference EFSA 2007, DAR, 2005

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

zRMS Comments:

Calculations of PEC_S for active substances, their metabolites and formulation was accepted

In accordance with GAP table one application per season in maize was considered.
The active substances and their metabolites endpoints for PECs assessment were agreed at the EU level.
The interception of 25% and plateau concentration at depth of 20 cm at steady state were considered.

Mesotrione. Based on EFSA Conclusion, 2016 all relevant data were used. All relevant metabolites were taken into consideration.
The following PECs values were calculated

Crop	**Maize**	
Application rate g a.s/ha	96	
Compound	PECs ini mg/kg soil	PECs accum mg/kg soil
Mesotrione	0.096	nr
MNBA	0.040	nr
AMBA	0.006	nr

nr – not relevant

Nicosulfuron. The used DT_{50} and other input parameters for active substance and its metabolites were in accordance with EFSA *Scientific Report*, 2007.
The following PECs values were calculated

Crop	**Maize**	
Application rate g a.s/ha	~~96~~ 36	
Compound	PECs ini mg/kg soil	PECs accum mg/kg soil
Nicosulfuron	0.040	nr
HMUD	0.006	nr
ADMP	0.001	nr
ASDM	0.014	0.014
AUSN	0.008	0.008
UCSN	0.003	0.003

nr – not relevant

Formulation. The PECs for formulation was assessed; PECs = 1.18 mg formulation/~~ha~~ kg.

These values will be used in further risk assessment.

8.7.1 Justification for new endpoints

For mesotrione, endpoints for PEC soil calculations are shown in the EFSA conclusion (EFSA 2016, p. 68/69). These are also used in this dossier.

For nicosulfuron, endpoints for PEC soil calculations are shown in the EFSA conclusion (EFSA 2007, p. 58-61). These are also used in this dossier.

8.7.2 Active substances and relevant metabolites

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

Use No.	1
Crop	Maize
Application rate (g as/ha)	Mesotrione: 96 g/ha Nicosulfuron: 36 g/ha
Number of applications/interval	1
Crop interception (%)	25
Depth of soil layer (relevant for plateau concentration) (cm)	5/20 cm (no tillage/tillage)

The input parameters for both active substances and their metabolites are listed in Table 8.7-2. Long term PEC soil values (accumulation) are only relevant for the compounds with PEC soil modelling DT_{50} values > 100 days, *i.e.* for UCSN, ASDM and AUSN. All results are nevertheless shown.

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

Compound	Molecular weight (g/mol)	Max. occurrence (%)	DT_{50} (days)	Value in accordance to EU endpoint y/n/ Reference
Mesotrione	339.3	-	34.3 (representative worst-case from non-normalised laboratory data)	yes (EFSA 2016 p. 68/69)
MNBA	245	57.2	< 100	
AMBA	215	9.7	< 100	
Nicosulfuron	410.4	-	63 (Worst-case non-normalised field)	yes (EFSA 2007 p. 58-61)
HMUD	396.5	14.4	30.8 (Worst-case non-normalised lab)	
ADMP	155.2	9.8	11.3 (Worst-case non-normalised lab)	
ASDM	229.3	63.4	268.5 (Worst-case non-normalised lab)	
AUSN	314.3	26.8	218.2 (Worst-case non-normalised lab)	
UCSN	315.3	11	307.5 (Worst-case non-normalised lab)	

Mesotrione and its metabolites

Table 8.7-3: PEC_{soil} for mesotrione on maize

PEC_{soil} (mg/kg)		Maize			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.096	-	-	-
Short term	24h	0.094	0.095	-	-
	2d	0.092	0.094	-	-
	4d	0.089	0.092	-	-
Long term	7d	0.083	0.090	-	-
	14d	0.072	0.084	-	-
	21d	0.063	0.078	-	-
	28d	0.055	0.073	-	-
	50d	0.035	0.060	-	-
	100d	0.013	0.041	-	-
Plateau concentration (20 cm) at steady state		<0.001	-	-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		0.096	-	-	-

Table 8.7-4: PEC_{soil} for mesotrione metabolites on maize

Metabolite	PEC_{soil} (mg/kg)		
	Initial	Plateau concentration (20 cm) at steady state	$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)
MNBA	0.040	<0.001	0.040
AMBA	0.006	<0.001	0.006

Nicosulfuron and its metabolites

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

PEC_{soil} (mg/kg)		Maize			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.040	-	-	-
Short term	24h	0.040	0.040	-	-
	2d	0.039	0.040	-	-
	4d	0.038	0.039	-	-
Long term	7d	0.037	0.038	-	-
	14d	0.034	0.037	-	-
	21d	0.032	0.036	-	-
	28d	0.029	0.034	-	-
	50d	0.024	0.031	-	-
	100d	0.013	0.024	-	-
Plateau concentration (20 cm) at steady state		0.0002	-	-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		0.040	-	-	-

Table 8.7-6: PEC_{soil} for nicosulfuron metabolites on maize

Metabolite	PEC_{soil} (mg/kg)		
	Initial	Plateau concentration (20 cm) at steady state	$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)
HMUD	0.006	<0.001	0.006
ADMP	0.001	<0.001	0.001
ASDM	0.014	<0.001	0.014
AUSN	0.008	<0.001	0.008
UCSN	0.003	<0.001	0.003

PECsoil of SAE053H/01

For the conversion of the product application rate of 1.2 L/ha to g/ha, a density of 980 g/L was taken into account, as well as 25% interception. As the DT_{50} of the formulation is not defined, no weighted averages or plateau PEC values can be calculated for the formulation (Table 8.7-7).

Table 8.7-7: PEC_{soil} for SAE053H/01 on maize

Preparation	Application rate (g/ha)	PEC_{act} (mg/kg)
SAE053H/01	1176	1.18

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

zRMS Comments:	The submitted reports considering the PECgw assessment for active substances and their metabolites were accepted. Calculations of PEC_{GW} for active substances and their relevant metabolites were provided with tiered approach: in Tier 1 the ground application with 25% of interception and in Tier 2 – the foliar application and crop interception chosen by FOCUS models were considered. The annual and biennial application for mesotrione and trennial application for nicosulfuron were taken for modelling. The application dates were accepted. In accordance with GAP table one application per season was considered. The recommended FOCUS models were used: FOCUS PELMO, FOCUS PEARL and FOCUS MACRO. The plant uptake factor for both active substances and their metabolites of 0 was used in PECgw assessment. **Mesotrione.** All used endpoints were agreed at the EU level and were accepted. The acidic, neutral and alkaline soils were considered. **Tier 1**. The maximum PEC_{GW} values for active substance and its metabolites were below the trigger value of 0.1 µg/L. **Tier 2**. The maximum PEC_{GW} values for active substance and its metabolites were below the trigger value of 0.1 µg/L if applied every other year. **Nicosulfuron**. All used endpoints were agreed at the EU level and were accepted. **Tier 1 and Tier 2**. The maximum PEC_{GW} values for active substance and metabolite ADMP were below the trigger value of 0.1 µg/L if applied every third year. For metabolies AUSN, UCSN, ASDM, HMUD and MU-466 the PECgw values were above the trigger value of 0.1 µg/L if applied every third year, and their relevance will be discussed in Section 10. **The application in maize at BBCH 12 is acceptable if the formulation is used every third year.**

8.8.1 Justification for new endpoints

Endpoints for groundwater modelling of mesotrione were used exactly as documented in the EFSA conclusion (EFSA 2016, p. 69-71). Endpoints for groundwater modelling of nicosulfuron were taken from the EFSA conclusion (EFSA 2007, p. 68-70)

8.8.2 Active substances and relevant metabolites (KCP 9.2.4.1)

PEC groundwater calculations were simulated according to the FOCUS (2014) guidance and the Working

Document of the Central Zone in the Authorisation of Plant Protection Products (ver 1.1, June 2018) and are documented in detail in the following two reports.

Report	Worthington M. (2021a)
Title	Mesotrione – A leaching assessment for mesotrione and metabolites MNBA and AMBA using the PEARL 4.4.4, PELMO 5.5.3 and MACRO 5.5.4 groundwater models following spray application to maize in the EU
Document No	S21-01990-01/007-B
Guidelines	based on FOCUS (2003 and 2015)
GLP	not applicable

Report	Worthington M. (2021b)
Title	Nicosulfuron – A leaching assessment for nicosulfuron and metabolites HMUD, AUSN, UCSN, ASDM, ADMP and MU-466 using the PEARL 4.4.4, PELMO 5.5.3 and MACRO 5.5.4 groundwater models following spray application to maize in the EU
Document No	S21-01990-01/007-D
Guidelines	based on FOCUS (2003 and 2015)
GLP	not applicable

Following feedback from zRMS Poland, additional PEC groundwater calculations have also been conducted in order to address their requirements for the central zone. The specific changes requested for the additional modelling were:

- to match the application method in the modelling to that documented in the GAP table, i.e. foliar application in this case,
- using the crop interception chosen by the model (internal interception routines of each model), rather than defined consistently across models by the modeller.

These requirements were specifically advised by the zRMS as being necessary for submissions to the central zone. It should be noted that the FOCUS (2014) groundwater guidance document specifically advises against using this approach:

> *"Interception of the substance by the crop canopy should be determined by reference to the interception data provided in Tables 1.4 and 1.5 and a corrected application rate should be calculated. The substance should then be applied directly to the ground in all models, thus avoiding the internal interception routines in the models."*
>
> Generic Guidance for Tier 1 FOCUS Ground Water Assessments (2014 v2.2, p.23)

The Use No. 2 in Table 8.8-2 represents the requested additional modelling.

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

Use No.	**1 – (FOCUS Modelling)**	**2 – (Central Zone Modelling)**
Crop [-]	Maize	Maize
Application rate [g a.s./ha]	Mesotrione: 96 g/ha Nicosulfuron: 36 g/ha	Mesotrione: 96 g/ha Nicosulfuron: 36 g/ha
Number of applications / interval [d]	1 / -	1 / -
Frequency of application [-]	Mesotrione: Annual Nicosulfuron: Triennial	Mesotrione: Annual (+ biennial for Hamburg scenario only (PELMO)) Nicosulfuron: Triennial
Application method [-]	Ground application	Foliar application*
BBCH growth stage [-]	BBCH 12	BBCH 12

Crop interception [%]	25	Various / Chosen by model* (see next Table)
Models used for calculation	FOCUS PEARL v4.4.4, FOCUS PELMO v5.5.3, FOCUS MACRO v5.5.4	FOCUS PEARL v4.4.4, FOCUS PELMO v5.5.3**

* This is not the FOCUS-recommended approach. Use No. 2 was added as a results of feedback from zRMS Poland.
** Since MACRO 5.5.4 only permits soil applications, with the soil loading manually adjusted to account for crop interception, MACRO PECgw cannot be simulated for these uses.

Table 8.8-2 clearly demonstrates that the interception values calculated by the current model versions i.e. PEARL 4.4.4 (13 – 23 %) and PELMO 5.5.3 (8 – 10 %) are very different both to each other and to the recommended FOCUS value of 25% for the proposed use pattern. Full details are included in the two updated modelling reports referenced above.

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

Crop	Scenario	Application dates	Crop interception [%]		
		Absolute	PEARL 4.4.4	PELMO 5.5.3	MACRO 5.5.4
Maize ** Use No 1	Châteaudun	9 May	25		
	Hamburg	12 May			
	Kremsmünster	12 May			
	Okehampton	29 May			
	Piacenza	21 May			
	Porto	9 May			
	Sevilla*	15 March			
	Thiva*	25 April			
Maize *** Use No 2	Châteaudun	9 May	13	8	N/A
	Hamburg	12 May	13	8	N/A
	Kremsmünster	12 May	13	8	N/A
	Okehampton	29 May	23	9	N/A
	Piacenza	21 May	15	8	N/A
	Porto	9 May	13	8	N/A
	Sevilla*	15 March	18	8	N/A
	Thiva*	25 April	16	10	N/A

* According to the "Working document of the central zone in the Authorisation of plant protection products, Section 8 Environmental Fate and Behaviour, Version 1 rev. 1- June 2018", these scenarios are not relevant for the Central Zone.
** Use No. 1 was simulated using the FOCUS interception value for maize at BBCH 12 (FOCUS, 2014) and FOCUS-recommended application method (directly on soil).
*** Use No. 2 was not calculated using the FOCUS-recommended approach. Due to the application method being set as "foliar application", the crop interception values were chosen by the internal interception routines of each model, hence the inconsistent crop interception values.
N/A: Not available. Due to model-specific limitations, it is not possible to stay consistent with the selected application method of Use No. 2.

Mesotrione and its metabolites

Four different variants were calculated, one with worst-case values regarding metabolite formation and sorption, and three variants for three representative soil pH values (low, average and high) for maize cultivation.

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

Compound	Mesotrione	MNBA	AMBA	Value in accordance with EU endpoint y/n/ EFSA 2016, p. 69-71
Molecular weight (g/mol)	339.3	245	215	yes
Water solubility (mg/L):	160	160	160	yes (not listed for metabolites, parent value entered, irrelevant for the results)
Saturated vapour pressure (Pa):	0	0	0	yes
DT_{50} in soil (d)	4 (worst-case for metabolite formation) 27.88 (pH 5.1) 14.2 (pH 6.5) *0.54 (pH 7.9)	3.4	14.5	yes
Transformation rate (d^{-1})	to MNBA: 0.173287 (worst case) 0.024862 (pH 5.1) 0.048813 (pH 6.5) 1.2836 (pH 7.9)	to AMBA: 0.051 0.05010 to sink: 0.1529	to sink: 0.0478	yes
K_{foc} (mL/g)/K_{fom}	14 / 8.12 (worst case) 156.6 / 90.84 (pH 5.1) 52.2 / 30.28 (pH 6.5) 17.39 / 10.09 (pH 7.9)	3.2 / 1.86	18.1 / 10.50 (worst case) 105.61 / 61.26 (pH 5.1) 48.02 / 27.85 (pH 6.5) 21.8 / 12.65 (pH 7.9)	yes (K_{fom} for input in PEARL calculated by K_{foc} / 1.724)
1/n	0.97 (worst case soil) 0.94 (pH 5.1) 0.94** (pH 6.5) 0.94 (pH 7.9)	0.9	0.82 (worst case soil) 0.85 (pH 5.1) 0.85** (pH 6.5) 0.85 (pH 7.9)	Yes
Plant uptake factor	0	0	0	yes
Formation fraction	-	1 (from parent)	0.25 (from MNBA)	yes

* EFSA 2016 conclusion incorrectly states DT50 as 5.4 d which is not consistent with value used in surface water or linear regression equation (p. 56 of EFSA 2016)

** Not listed in EFSA conclusion, median used

PEC_{GW}– Results

Although both sets of values are presented below, the additional results are not in accordance with either FOCUS guidance or the current version of the central zone working document. Therefore, the applicant does not consider the PEC values calculated using the foliar application method (use no. 2) to be correct and suggests the original guideline-compliant modelling (use no. 1) be relied upon for risk assessment purposes.

FOCUS Groundwater Modelling

Table 8.8-4: PEC_{gw} for mesotrione and metabolites, worst-case metabolite formation

Use No.	Model	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)		
			Mesotrione	MNBA	AMBA
1	FOCUS PEARL 4.4.4	Châteaudun	< 0.001	< 0.001	0.001
		Hamburg	< 0.001	0.004	0.017
		Kremsmünster	< 0.001	0.001	0.018
		Okehampton	0.001	0.005	0.040
		Piacenza	< 0.001	< 0.001	0.002
		Porto	< 0.001	< 0.001	< 0.001
		Sevilla	< 0.001	< 0.001	< 0.001
		Thiva	< 0.001	< 0.001	< 0.001
	FOCUS PELMO 5.5.3	Châteaudun	< 0.001	< 0.001	0.001
		Hamburg	< 0.001	0.001	0.005
		Kremsmünster	< 0.001	0.002	0.017
		Okehampton	0.002	0.009	0.041
		Piacenza	< 0.001	0.001	0.005
		Porto	< 0.001	< 0.001	0.001
		Sevilla	< 0.001	< 0.001	< 0.001
		Thiva	< 0.001	< 0.001	< 0.001
	MACRO 5.5.4	Châteaudun	<0.001	<0.001	<0.001

Table 8.8-5: PEC_{gw} for mesotrione and metabolites, soil pH 5.1

Use No.	Model	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)		
			Mesotrione	MNBA	AMBA
1	FOCUS PEARL 4.4.4	Châteaudun	< 0.001	0.004	< 0.001
		Hamburg	0.004	0.059	0.014
		Kremsmünster	0.002	0.012	0.002
		Okehampton	0.005	0.029	0.004
		Piacenza	0.002	0.008	0.002
		Porto	< 0.001	0.008	< 0.001
		Sevilla	< 0.001	< 0.001	< 0.001
		Thiva	< 0.001	0.001	< 0.001
	FOCUS PELMO 5.5.3	Châteaudun	0.002	0.003	0.001
		Hamburg	0.010	0.031	0.009
		Kremsmünster	0.009	0.015	0.006
		Okehampton	0.025	0.033	0.011
		Piacenza	0.007	0.007	0.005
		Porto	0.001	0.003	< 0.001
		Sevilla	< 0.001	< 0.001	< 0.001
		Thiva	0.001	0.001	< 0.001
	MACRO 5.5.4	Châteaudun	<0.001	0.003	<0.001

Table 8.8-6: PEC_{gw} for mesotrione and metabolites, soil pH 6.5

Use No.	Model	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)		
			Mesotrione	MNBA	AMBA
1	FOCUS PEARL 4.4.4	Châteaudun	0.003	0.005	0.001
		Hamburg	0.014	0.038	0.017
		Kremsmünster	0.010	0.010	0.007
		Okehampton	0.022	0.028	0.012
		Piacenza	0.005	0.003	0.002
		Porto	< 0.001	0.002	< 0.001
		Sevilla	< 0.001	< 0.001	< 0.001
		Thiva	< 0.001	< 0.001	< 0.001
	FOCUS PELMO 5.5.3	Châteaudun	0.002	0.003	0.001
		Hamburg	0.010	0.031	0.009
		Kremsmünster	0.009	0.015	0.006
		Okehampton	0.025	0.033	0.011
		Piacenza	0.007	0.007	0.005
		Porto	0.001	0.003	< 0.001
		Sevilla	< 0.001	< 0.001	< 0.001
		Thiva	0.001	0.001	< 0.001
	MACRO 5.5.4	Châteaudun	0.001	0.002	<0.001

Table 8.8-7: PEC_{gw} for mesotrione and metabolites, soil pH 7.9

Use No.	Model	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)		
			Mesotrione	MNBA	AMBA
1	FOCUS PEARL 4.4.4	Châteaudun	< 0.001	< 0.001	< 0.001
		Hamburg	< 0.001	< 0.001	0.009
		Kremsmünster	< 0.001	< 0.001	0.008
		Okehampton	< 0.001	0.002	0.019
		Piacenza	< 0.001	< 0.001	0.002
		Porto	< 0.001	< 0.001	< 0.001
		Sevilla	< 0.001	< 0.001	< 0.001
		Thiva	< 0.001	< 0.001	< 0.001
	FOCUS PELMO 5.5.3	Châteaudun	< 0.001	< 0.001	< 0.001
		Hamburg	< 0.001	< 0.001	0.003
		Kremsmünster	< 0.001	< 0.001	0.010
		Okehampton	< 0.001	0.005	0.020
		Piacenza	< 0.001	< 0.001	0.003
		Porto	< 0.001	< 0.001	0.001
		Sevilla	< 0.001	< 0.001	< 0.001
		Thiva	< 0.001	< 0.001	< 0.001
	MACRO 5.5.4	Châteaudun	<0.001	<0.001	<0.001

Predicted environmental concentrations in groundwater evaluated according to the FOCUS methodology were below 0.1 µg/L for mesotrione and its soil metabolites MNBA and AMBA in all simulations.

Central Zone Modelling Using Foliar Application Method

Table 8.8-8: PEC_{gw} for mesotrione and metabolites, worst-case metabolite formation

Use No.	Model	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)		
			Mesotrione	MNBA	AMBA
2	FOCUS PEARL 4.4.4	Châteaudun	< 0.001	< 0.001	0.002
		Hamburg	< 0.001	0.005	0.021
		Kremsmünster	< 0.001	0.001	0.022
		Okehampton	0.001	0.005	0.041
		Piacenza	< 0.001	< 0.001	0.003
		Porto	< 0.001	< 0.001	< 0.001
		Sevilla	< 0.001	< 0.001	< 0.001
		Thiva	< 0.001	< 0.001	< 0.001
	FOCUS PELMO 5.5.3	Châteaudun	< 0.001	< 0.001	0.001
		Hamburg	< 0.001	0.001	0.008
		Kremsmünster	< 0.001	0.002	0.025
		Okehampton	0.003	0.013	0.061
		Piacenza	< 0.001	0.001	0.007
		Porto	< 0.001	< 0.001	0.001
		Sevilla	< 0.001	< 0.001	< 0.001
		Thiva	< 0.001	< 0.001	< 0.001
	MACRO 5.5.4	Châteaudun	N/A	N/A	N/A

Table 8.8-9: PEC_{gw} for mesotrione and metabolites, soil pH 5.1

Use No.	Model	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)		
			Mesotrione	MNBA	AMBA
2	FOCUS PEARL 4.4.4	Châteaudun	< 0.001	0.005	< 0.001
		Hamburg	0.004	0.069	0.017
		Kremsmünster	0.002	0.014	0.002
		Okehampton	0.005	0.030	0.004
		Piacenza	0.003	0.010	0.002
		Porto	< 0.001	0.010	< 0.001
		Sevilla	< 0.001	< 0.001	< 0.001
		Thiva	< 0.001	0.001	< 0.001
	FOCUS PELMO 5.5.3	Châteaudun	< 0.001	0.005	< 0.001
		Hamburg	0.005	0.102	0.013
		Hamburg (biennial)	*0.002*	*0.043*	*0.005*
		Kremsmünster	0.003	0.025	0.003
		Okehampton	0.006	0.061	0.006
		Piacenza	0.007	0.022	0.004
		Porto	0.002	0.026	0.001
		Sevilla	< 0.001	0.002	< 0.001
		Thiva	< 0.001	0.003	< 0.001
	MACRO 5.5.4	Châteaudun	N/A	N/A	N/A

Table 8.8-10: PEC_{gw} for mesotrione and metabolites, soil pH 6.5

Use No.	Model	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)		
			Mesotrione	MNBA	AMBA
2	FOCUS PEARL 4.4.4	Châteaudun	0.004	0.006	0.001
		Hamburg	0.017	0.045	0.020
		Kremsmünster	0.012	0.012	0.008
		Okehampton	0.023	0.029	0.012
		Piacenza	0.006	0.003	0.003
		Porto	0.001	0.002	< 0.001
		Sevilla	< 0.001	< 0.001	< 0.001
		Thiva	< 0.001	< 0.001	< 0.001
	FOCUS PELMO 5.5.3	Châteaudun	0.002	0.005	0.001
		Hamburg	0.014	0.042	0.013
		Kremsmünster	0.013	0.021	0.009
		Okehampton	0.035	0.046	0.016
		Piacenza	0.010	0.009	0.006
		Porto	0.002	0.004	< 0.001
		Sevilla	< 0.001	< 0.001	< 0.001
		Thiva	0.001	0.001	< 0.001
	MACRO 5.5.4	Châteaudun	N/A	N/A	N/A

Table 8.8-11: PEC_{gw} for mesotrione and metabolites, soil pH 7.9

Use No.	Model	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)		
			Mesotrione	MNBA	AMBA
2	FOCUS PEARL 4.4.4	Châteaudun	< 0.001	< 0.001	0.001
		Hamburg	< 0.001	< 0.001	0.011
		Kremsmünster	< 0.001	< 0.001	0.010
		Okehampton	< 0.001	0.002	0.020
		Piacenza	< 0.001	< 0.001	0.002
		Porto	< 0.001	< 0.001	< 0.001
		Sevilla	< 0.001	< 0.001	< 0.001
		Thiva	< 0.001	< 0.001	< 0.001
	FOCUS PELMO 5.5.3	Châteaudun	< 0.001	< 0.001	0.001
		Hamburg	< 0.001	< 0.001	0.005
		Kremsmünster	< 0.001	0.001	0.015
		Okehampton	< 0.001	0.007	0.030
		Piacenza	< 0.001	< 0.001	0.005
		Porto	< 0.001	< 0.001	0.001
		Sevilla	< 0.001	< 0.001	< 0.001
		Thiva	< 0.001	< 0.001	< 0.001
	MACRO 5.5.4	Châteaudun	N/A	N/A	N/A

Predicted environmental concentrations in groundwater evaluated according to the FOCUS methodology were below 0.1 µg/L for mesotrione and its soil metabolites MNBA and AMBA in all simulations, except for metabolite MNBA in the Hamburg scenario for Use No. 2 simulated using PELMO. A biennial application was simulated for this scenario combination only and yielded a PEC_{GW} below 0.1 µg/L.

Nicosulfuron and its metabolites

Sorption of nicosulfuron to soil was modelled in accordance with EFSA 2007 approach.

Table 8.8-12: Input parameters related to active substance nicosulfuron for PEC_{gw} calculations at Tier 1

Compound	Nicosulfuron	HMUD	AUSN	UCSN	ASDM	ADMP	MU-466	Value in accordance with EU endpoint y/n/ EFSA 2007
Molar mass [g/mol]	410.4	396.4	314.3	315.3	229.2	155.2	215.1	Yes
Water solubility [mg/L]	9500	9500	9500	9500	9500	9500	9500	Yes
Saturated vapour pressure [Pa]	0	0	0	0	0	0	0	Yes
DT50 in soil [d] lab/field	16.4	23.8	192.3	271	236.6	4.5	75.5	Yes
Transformation rate [d-1]	0.0187 (to HMUD) 0.0090 (to ADMP) 0.0090 (to ASDM) 0.0055 (to CO2)	0.0200 (to AUSN) 0.0091 (to UCSN)	0.0036 (to CO2)	0.0026 (to CO2)	0.0008 (to MU-466) 0.0021 (to CO2)	0.1540 (to CO2)	0.0092 (to CO2)	Yes
Kfoc / Kfom [mL/g]	Clay-dependent (0.026 × %Clay)	5.3 / 3.1	13 / 7.5	3.1 / 1.8	2.3 / 1.3	51.5 / 29.9	3.62 / 2.1	Yes
1/n [-]	0.94	1	0.98	1	0.82	0.87	1	Yes
Plant uptake factor [-]	0	0	0	0	0	0	0	Yes
Formation fraction [-]	-	0.442 (from Nicosulfuron)	0.687 (from HMUD)	0.313 (from HMUD)	0.214 (from Nicosulfuron)	0.214 (from Nicosulfuron)	0.282 (from ASDM)	Yes

PEC_{GW}– Results

Although both sets of values are presented below, the additional results are not in accordance with either FOCUS guidance or the current version of the central zone working document. Therefore, the applicant does not consider the PEC values calculated using the foliar application method (use no. 2) to be correct and suggests the original guideline-compliant modelling (use no. 1) be relied upon for risk assessment purposes.

FOCUS Groundwater Modelling

Table 8.8-13 PECgw for nicosulfuron and metabolites on maize, triennial application

Use No.	Model	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)						
			Nicosulfuron	HMUD	AUSN	UCSN	ASDM	ADMP	MU-466
1	FOCUS PEARL 4.4.4	Châteaudun	< 0.001	0.142	0.631	0.326	0.357	< 0.001	0.022
		Hamburg	0.064	0.331	0.655	0.366	0.416	< 0.001	0.023
		Kremsmünster	< 0.001	0.186	0.532	0.290	0.314	< 0.001	0.019
		Okehampton	0.009	0.210	0.352	0.177	0.218	< 0.001	0.010
		Piacenza	0.005	0.099	0.571	0.331	0.315	< 0.001	0.026
		Porto	0.003	0.058	0.254	0.136	0.141	< 0.001	0.009
	FOCUS PELMO 5.5.3	Châteaudun	< 0.001	0.099	0.656	0.375	0.377	< 0.001	0.029
		Hamburg	0.040	0.266	0.605	0.330	0.368	< 0.001	0.021
		Kremsmünster	0.001	0.215	0.556	0.322	0.329	< 0.001	0.021
		Okehampton	0.008	0.223	0.334	0.169	0.208	< 0.001	0.010
		Piacenza	0.007	0.112	0.381	0.199	0.209	< 0.001	0.013
		Porto	0.003	0.049	0.255	0.135	0.140	< 0.001	0.010
	FOCUS MACRO 5.5.4	Châteaudun	<0.001	0.216	1.54	0.974	0.954	<0.001	0.119

Predicted environmental concentrations in groundwater determined according to the FOCUS guidance were below 0.1 µg/L for nicosulfuron.

PEC groundwater values for AUSN, UCSN and ASDM were below 2 µg/L. For HMUD and MU-466 they were below 0.5 µg/L. For ADMP, they stayed below 0.1 µg/L.

Central Zone Modelling Using Foliar Application Method

Table 8.8-14 PECgw for nicosulfuron and its metabolites on maize, triennial application

Use No.	Model	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)						
			Nicosulfuron	HMUD	AUSN	UCSN	ASDM	ADMP	MU-466
2	FOCUS PEARL 4.4.4	Châteaudun	< 0.001	0.165	0.735	0.380	0.416	< 0.001	0.025
		Hamburg	0.075	0.385	0.760	0.424	0.484	< 0.001	0.027
		Kremsmünster	< 0.001	0.216	0.617	0.337	0.365	< 0.001	0.022
		Okehampton	0.009	0.216	0.362	0.182	0.225	< 0.001	0.010
		Piacenza	0.005	0.112	0.646	0.374	0.357	< 0.001	0.029
		Porto	0.003	0.067	0.295	0.159	0.164	< 0.001	0.011
		Sevilla	< 0.001	0.017	0.683	0.642	0.481	< 0.001	0.058
		Thiva	< 0.001	0.088	1.70	1.10	0.991	< 0.001	0.095
	FOCUS PELMO 5.5.3	Châteaudun	< 0.001	0.133	0.875	0.500	0.506	< 0.001	0.038
		Hamburg	0.054	0.356	0.807	0.440	0.492	0.001	0.028
		Kremsmünster	0.001	0.288	0.742	0.429	0.440	< 0.001	0.028
		Okehampton	0.011	0.298	0.445	0.226	0.278	< 0.001	0.013
		Piacenza	0.010	0.150	0.508	0.265	0.280	< 0.001	0.017
		Porto	0.004	0.066	0.339	0.180	0.187	< 0.001	0.013
		Sevilla	< 0.001	0.029	0.642	0.497	0.404	< 0.001	0.046
		Thiva	< 0.001	0.073	1.34	0.861	0.778	< 0.001	0.075
	FOCUS MACRO 5.5.4	Châteaudun	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Predicted environmental concentrations in groundwater were below 0.1 µg/L for nicosulfuron.

PEC groundwater values for AUSN, UCSN and ASDM were below 2 µg/L.

For HMUD and MU-466 they were below 0.5 µg/L.

For ADMP, they stayed below 0.1 µg/L.

8.9 Predicted Environmental Concentrations in surface water (PECsw) (KCP 9.2.5)

zRMS Comments:

The submitted reports with PECsw and PECsed calculations were accepted.

The recommended FOCUS models were used: FOCUS Step 1 & 2 and Step 3 and Step 4. The SWAN and VFSmod models were used in Step 4 and the mitigation measures were proposed: vegetative and non-spray buffer zones.
The relevant mitigation measure will be choosen in ecotox section at Member State level.

All used endpoints for active substance and its metabolites were agreed at the EU level.

The application dates were accepted. The AppDate tool was used in selection of application dates.

Mesotrione. In Step 2 the minimal cover and the application time March-May and Jun-Sep were considered.
In Step 3 and Step 4 the acidic (pH 5.1), neutral (pH 6.5), alkaline (pH 7.9) soil condition were taken into consideration.

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

SWAN model. Application rate 1 x 96 g a.s./ha in maize

Crop	Application rate g a.s./ha	Central Zone Max PEC_{sw} (µg/L)		
		acidic	neutral	alkaline
Maize	1 x 96	20 m vegetative strip and 20 m non-spray buffer strip	20 m vegetative strip and 20 m non-spray buffer strip	5 non-spray buffer strip.
		0.773 R4 stream	0.895 R4 stream	0.494 R3 stream

VFSmod model. Application rate 1 x 96 g a.s./ha in maize

Crop	Application rate g a.s./ha	Central Zone Max PEC_{sw} (µg/L)		
		acidic	neutral	alkaline
Maize	1 x 96	5 m vegetative strip and 5 m non-spray buffer strip	5 m vegetative strip and 5 m non-spray buffer strip	5 m vegetative strip and 5 m non-spray buffer strip.
		0.206 R3 stream	0.206 R3 stream	0.206 R3 stream

Metabolites of mesotrione. The Step 1 max PECsw and PECsed in alkaline, neutral and acidic soils are presented in the table below:

Metabolites of mesotrione, Application rate 1 x 96 g a.s./ha in maize

Compound	Step 1 Max PEC_{sw} (µg/L)	Step 1 Max PEC_{SED} (µg/kg)
	acidic/neutral/alkaline	acidic/neutral/alkaline
MNBA	15.029	0.913
AMBA	6.234 /6.674 /6.896	6.561 /3.197 /1.501
SYN546974	0.750	65.897

Nicosulfuron. PECsw and PECsed were determined at Steps 1 to 4 for the active substance nicosulfuron and Steps 1 and 2 for its relevant metabolites.
The max PECsw and relevant mitigation measure for Central zone are presented in the table below.

Nicosulfuron. Application rate 1 x 36 g a.s./ha in maize

Crop	Application rate g a.s./ha	Central Zone Max PEC_{sw} (µg/L)	
		SWAN	VFSmod
Maize	1 x 36	20 m vegetative strip and 20 m non-spray buffer strip	5 m vegetative strip and 5 m non-spray buffer strip
		0.364 R4 stream	0.077 R3 stream

Metabolites of nicosulfuron. The Step ~~1~~ 2 max PECsw and PECsed are presented in the table below:

Metabolites of nicosulfuron, Application rate 1 x 36 g a.s./ha in maize

Compound	Step ~~1~~ 2 Max PEC_{sw} (µg/L)	Step ~~1~~ 2 Max PEC_{SED} (µg/kg)
HMUD	0.569	0.005
AUSN	0.513	0.067
UCSN	0.243	0.003
ASDM	2.250	0.052
ADMP	0.466	0.195

Formulation. The PECsw of formulation submitted by the Applicant was not accepted, as mass of 1.2 L of product is 1176 g, not 1140 g. The drift exposure was assessed by evaluator using the Drift Calculator in SWASH model and is presented below.

Crop	Application rate (g prod/ha)	No spray buffer (m)	Max PEC_{sw} (µg/L)
Maize	1176	1	7.555
		5	2.048
		10	1.086
		15	0.698
		20	0.564

The relevant PECsw and PECsed values will be used in further risk assessment at national level.

The relevant mitigation measure will be recommended in ecotoxicological section.

National Assessment, Poland
In accordance with national requirements, only D3, D4 and R1 scenarios were taken into consideration. The max PECsw and proposed mitigation measures are presented in the table below:

SWAN model. Application rate 1 x 96 g mesotrione/ha in maize

Crop	Application rate g a.s./ha	Poland Max PEC_{sw} (µg/L)		
		acidic	**neutral**	**alkaline**
Maize	1 x 96	10 m vegetative strip and 10 m non-spray buffer strip	5 m non-spray buffer strip	5 non-spray buffer strip
		0.705 R1 stream	1.070 R1 stream	0.473 R1 stream

VFSmod model. Application rate 1 x 96 g mesotrione/ha in maize

Crop	Application rate g a.s./ha	Central Zone Max PEC_{sw} (µg/L)		
		acidic	neutral	alkaline
Maize	1 x 96	5 m vegetative strip and 5 m non-spray buffer strip	5 m vegetative strip and 5 m non-spray buffer strip	5 m vegetative strip and 5 m non-spray buffer strip
		0.184 D4 stream	0.183 D4 stream	0.182 D4 stream

Nicosulfuron. Application rate 1 x 36 g a.s./ha in maize

Crop	Application rate g a.s./ha	Central Zone Max PEC_{sw} (µg/L)	
		SWAN	VFSmod
Maize	1 x 36	10 m vegetative strip and 10 m non-spray buffer strip	5 m vegetative strip and 5 m non-spray buffer strip
		0.167 R1 stream	0.072 D4 stream

The relevant mitigation measure for Poland will be recommended in ecotoxicological section.

8.9.1 Justification for new endpoints

EU agreed endpoints were used for PEC_{SW} and PEC_{SED} modelling of mesotrione (EFSA 2016), nicosulfuron (EFSA 2007) and their respective metabolites.

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

PEC surface water calculations at Steps 1 to 4 are described in this document and are documented in detail in the following two modelling reports. Calculations were performed for a product use rate of 1.2 L/ha and first date of application windows are based on BBCH 12 using AppDate (v3.06).

Report	Fortin-McCuaig M. (2021a)
Title	Mesotrione – A European Environmental Fate Assessment for Mesotrione and its metabolites MNBA, AMBA and SYN546974 Using the FOCUS Surface Water Models at Steps 1 to 4 Following Spray Application to Maize in Central Europe
Document No	S21-01990-01-003-A
Guidelines	FOCUS (2003 and 2015)
GLP	not applicable

Report	Fortin-McCuaig M. (2021b)

Title	Nicosulfuron – A European Environmental Fate Assessment for Nicosulfuron and its metabolites HMUD, AUSN, UCSN, ASDM and ADMP Using the FOCUS Surface Water Models at Steps 1 to 4 Following Spray Application to Maize in Central Europe
Document No	S21-01990-01-003-C
Guidelines	FOCUS (2003 and 2015)
GLP	not applicable

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

Use No.	1
FOCUS Crop	Maize
Application rate [g a.s./ha]	Mesotrione: 96 Nicosulfuron: 36
Number of applications / interval [days]	1 / -
Application date/BBCH growth stage	BBCH 12-18
Steps 1-2:	
Region / Season	N-EU / Mar-May + Jun-Sep S-EU / Mar-May + Jun-Sep
Interception	Minimal crop cover – 25 %
Models used for calculation	STEPS 1+2 in FOCUS v3.2
Steps 3-4:	
Application method	Spray
CAM (Chemical Application Method)	2 (foliar linear)
Soil depth [cm]	4 (default)
Models used for calculation	FOCUS SWASH v5.3 (comprising MACRO v5.5.4, PRZM v4.3.1, TOXSWA v5.5.3), ECPA SWAN v5.0.1

Table 8.9-2: FOCUS Step 3 Scenario related input parameters for $PEC_{SW/SED}$ calculations for the application of SAE053H/01

Use	Scenario	Application window	Julian days	Application date
Maize	D3	12-May – 11-Jun	132-162	14-May-92
	D4	18-May – 17-Jun	138-168	30-May-85
	D5	15-May – 14-Jun	135-165	27-May-78
	R1	10-May – 09-Jun	130-160	10-May-84
	R3	08-May – 07-Jun	128-158	18-May-80
	R4	15-Apr – 15-May	105-135	20-Apr-84

Mesotrione and its metabolites

The input parameters of mesotrione and its metabolites used in modelling were taken from the EFSA conclusion (EFSA, 2016). All other input values were set at the FOCUS default values unless otherwise stated.

Table 8.9-3: Summary of modelling input parameters used for $PEC_{SW/SED}$ calculations of active substance mesotrione at FOCUS Steps 1 to 4

Parameter	Value	Value in accordance to EU endpoint Y/N / Reference
Molar mass [g/mol]	339.3	Y / EFSA (2016)
Water solubility at 20°C [mg/L]	160	Y / EFSA (2016)
Saturated vapour pressure at 20°C [Pa]	1.00×10^{-10}	Y / EFSA (2016)
Diffusion coefficient in water (m^2/d)	4.3×10^{-5}	Default
Diffusion coefficient in air (m^2/d)	0.43	Default
$DT_{50,soil}$ [days]	27.88 (pH 5.1) 14.2 (pH 6.5) 0.54 (pH 7.9)	Y / EFSA (2016)
K_{FOC} / K_{FOM} [mL/g]	156.7 / 90.9 (pH 5.1) 52.2 / 30.3 (pH 6.5) 17.4 / 10.1 (pH 7.9)	Y / EFSA (2016)
1/n [-]	0.94	Y / EFSA (2016)
Plant uptake factor [-]	0	Y / EFSA (2016)
Crop wash-off factor [m^{-1}]	50	Default
$DT_{50,water}$ [days]	5.5 (Steps 1-2) 5.6 (Steps 3-4)	Y / EFSA (2016)
$DT_{50,sediment}$ [days]	5.6 (Steps 1-2) 1000 (Steps 3-4)	Y / EFSA (2016)
$DT_{50,whole\ system}$ [days]	5.6	Y / EFSA (2016)
Q_{10} factor [-]	2.58	Y / EFSA (2016)

Table 8.9-4: Summary of modelling input parameters used for $PEC_{SW/SED}$ calculations of metabolites at FOCUS Steps 1-2

Parameter	MNBA	AMBA	SYN546974	Value in accordance to EU endpoint Y/N / Reference
Molar mass [g/mol]	245	215	291	Y / EFSA (2016)
Water solubility at 20°C [mg/L]	160	160	160	Y / Parent value
$DT_{50,soil}$ [days]	3.4	14.5	0.1 [b]	Y / EFSA (2016)
K_{FOC} [mL/g]	3.2 / 6.1 (PEC_{SW}/PEC_{SED}) (lowest/highest value, n=2)	Linear fit:[a] 101.5 (pH 5.1) 59.7 (pH 6.5) 18.0 (pH 7.9) Log fit:[a] 105.6 (pH 5.1) 48.0 (pH 6.5) 21.8 (pH 7.9)	12824 [c]	Y / EFSA (2016)
$DT_{50,water}$ [days]	1000	1000	1000	Y / FOCUS default
$DT_{50,sediment}$ [days]	1000	1000	1000	Y / FOCUS default
$DT_{50,whole\ system}$ [days]	1000	1000	1000	Y / FOCUS default
Maximum occurrence in soil [%]	57.2	9.7	1E-10 [b]	Y / EFSA (2016)
Maximum occurrence in water/sediment [%]	7.9	24.6	33.0	Y / EFSA (2016)

[a] As the worst-case $PEC_{SW/SED}$ values were obtained with the log fit (EFSA p. 82), no results with the linear fit are shown.
[b] Metabolite is not observed in soil. Value is lowest/default model input value.
[c] In EFSA conclusion (p. 81), a K_{FOC} value of 27031 mL/g is given, which is the highest K_{FOC} value listed in the sorption section (p. 61) and therefore appears to be erroneous. The correct arithmetic mean K_{FOC} value 12824 mL/g.

$PEC_{SW/SED}$ – Steps 1 and 2

Table 8.9-5: FOCUS Steps 1-2 PEC_{SW} and PEC_{SED} for active substance mesotrione (pH 5.1)

Use	No. of appl.	Step	Region	Season	Mesotrione (pH 5.1)		
					Maximum PEC_{SW} [µg/L]	21-d TWA PEC_{SW} [µg/L]	Maximum PEC_{SED} [µg/kg]
Maize 1 × 96 g a.s./ha BBCH 12-18	1	1	-	-	27.352	9.692	41.478
		2	N-EU	Mar-May	4.067	1.441	6.126
				Jun-Sep	4.067	1.441	6.126
			S-EU	Mar-May	7.662	2.723	11.759
				Jun-Sep	5.864	2.082	8.943

Table 8.9-6: FOCUS Steps 1-2 PEC_{SW} and PEC_{SED} for active substance mesotrione (pH 6.5)

Use	No. of appl.	Step	Region	Season	Mesotrione (pH 6.5)		
					Maximum PEC_{SW} [µg/L]	21-d TWA PEC_{SW} [µg/L]	Maximum PEC_{SED} [µg/kg]
Maize 1 × 96 g a.s./ha BBCH 12-18	1	1	-	-	30.801	10.952	15.617
		2	N-EU	Mar-May	4.206	1.496	2.106
				Jun-Sep	4.206	1.496	2.106
			S-EU	Mar-May	7.898	2.812	4.033
				Jun-Sep	6.052	2.154	3.070

Table 8.9-7: FOCUS Steps 1-2 PEC_{SW} and PEC_{SED} for active substance mesotrione (pH 7.9)

Use	No. of appl.	Step	Region	Season	Mesotrione (pH 7.9)		
					Maximum PEC_{SW} [µg/L]	21-d TWA PEC_{SW} [µg/L]	Maximum PEC_{SED} [µg/kg]
Maize 1 × 96 g a.s./ha BBCH 12-18	1	1	-	-	32.157	11.447	5.442
		2	N-EU	Mar-May	0.883	0.319	0.088
				Jun-Sep	0.883	0.319	0.088
			S-EU	Mar-May	0.883	0.329	0.089
				Jun-Sep	0.883	0.324	0.088

Table 8.9-8: FOCUS Steps 1-2 PEC_{SW} and PEC_{SED} for metabolites at soil pH 5.1

Use	Metabolite	Step	Region	Season	pH 5.1		
					Maximum PEC_{SW} [µg/L]	21-day $PEC_{SW,TWA}$ [µg/L]	Maximum PEC_{SED} [µg/kg]
Maize 1 × 96 g a.s./ha BBCH 12-18	MNBA	1	-	-	15.029	14.920	0.913
		2	N-EU	Mar-May	1.170	1.162	0.071
				Jun-Sep	1.170	1.162	0.071
			S-EU	Mar-May	2.291	2.274	0.139
				Jun-Sep	1.730	1.718	0.105
	AMBA	1	-	-	6.234	6.173	6.561
		2	N-EU	Mar-May	0.933	0.921	0.979
				Jun-Sep	0.933	0.921	0.979
			S-EU	Mar-May	1.740	1.723	1.831
				Jun-Sep	1.337	1.322	1.405
	SYN546974	1	-	-	0.750	0.516	65.897
		2	N-EU	Mar-May	0.250	0.082	10.473
				Jun-Sep	0.250	0.082	10.473
			S-EU	Mar-May	0.250	0.138	19.182
				Jun-Sep	0.250	0.110	14.827

Table 8.9-9: FOCUS Steps 1 and 2 PEC_{SW} and PEC_{SED} for metabolites at soil pH 6.5

Use	Metabolite	Step	Region	Season	pH 6.5		
					Maximum PEC_{SW} [µg/L]	21-day $PEC_{SW,TWA}$ [µg/L]	Maximum PEC_{SED} [µg/kg]
Maize 1 × 96 g a.s./ha BBCH 12-18	MNBA	1	-	-	15.029	14.920	0.913
		2	N-EU	Mar-May	1.148	1.139	0.070
				Jun-Sep	1.148	1.139	0.070
			S-EU	Mar-May	2.245	2.229	0.136
				Jun-Sep	1.697	1.684	0.103
	AMBA	1	-	-	6.674	6.618	3.197
		2	N-EU	Mar-May	0.939	0.930	0.449
				Jun-Sep	0.939	0.930	0.449
			S-EU	Mar-May	1.747	1.731	0.837
				Jun-Sep	1.343	1.331	0.643
	SYN546974	1	-	-	0.750	0.516	65.897
		2	N-EU	Mar-May	0.250	0.077	9.677
				Jun-Sep	0.250	0.077	9.677
			S-EU	Mar-May	0.250	0.128	17.590
				Jun-Sep	0.250	0.102	13.634

Table 8.9-10: FOCUS Steps 1 and 2 PEC_{SW} and PEC_{SED} for metabolites at soil pH 7.9

Use	Metabolite	Step	Region	Season	pH 7.9		
					Maximum PEC_{SW} [µg/L]	21-day $PEC_{SW,TWA}$ [µg/L]	Maximum PEC_{SED} [µg/kg]
Maize 1 × 96 g a.s./ha BBCH 12-18	MNBA	1	-	-	15.029	14.920	0.913
		2	N-EU	Mar-May	0.925	0.918	0.056
				Jun-Sep	0.925	0.918	0.056
			S-EU	Mar-May	1.800	1.787	0.109
				Jun-Sep	1.363	1.353	0.083
	AMBA	1	-	-	6.896	6.842	1.501
		2	N-EU	Mar-May	0.376	0.372	0.082
				Jun-Sep	0.376	0.372	0.082
			S-EU	Mar-May	0.617	0.611	0.134
				Jun-Sep	0.496	0.491	0.108
	SYN546974	1	-	-	0.750	0.516	65.897
		2	N-EU	Mar-May	0.250	0.026	1.821
				Jun-Sep	0.250	0.026	1.821
			S-EU	Mar-May	0.250	0.026	1.878
				Jun-Sep	0.250	0.026	1.849

$PEC_{SW/SED}$ – FOCUS Step 3

Table 8.9-11: FOCUS Step 3 Global Maximum PEC_{SW} and PEC_{SED} for mesotrione (pH 5.1)

Use	Scenario	Application date	Date of maximum PEC_{SW}	Global maximum		Main Entry Route	$PEC_{SW,TWA}$ [µg/L]		
				PEC_{SW} [µg/L]	PEC_{SED} [µg/kg]		7-d	21-d	28-d
Maize 1 × 96 g a.s./ha BBCH 12-18	D3 Ditch	14-May-92	14-May-92	0.504	0.134	Drift	0.081	0.027	0.020
	D4 Pond	30-May-85	17-Dec-85	0.055	0.106	Drainage	0.055	0.051	0.049
	D4 Stream	30-May-85	30-May-85	0.434	0.086	Drift	0.068	0.045	0.037
	D5 Pond	27-May-78	13-Feb-79	0.037	0.070	Drainage	0.036	0.030	0.027
	D5 Stream	27-May-78	27-May-78	0.459	0.071	Drift	0.028	0.017	0.017
	R1 Pond	10-May-84	20-May-84	0.074	0.083	Run-off	0.061	0.047	0.040
	R1 Stream	10-May-84	20-May-84	1.560	0.363	Run-off	0.145	0.066	0.050
	R3 Stream	18-May-80	23-May-80	3.000	0.656	Run-off	0.339	0.120	0.090
	R4 Stream	20-Apr-84	27-Apr-84	3.250	0.904	Run-off	0.360	0.153	0.118

Table 8.9-12: FOCUS Step 3 Global Maximum PEC_{SW} and PEC_{SED} for mesotrione (pH 6.5)

Use	Scenario	Application date	Date of maximum PEC_{SW}	Global maximum		Main Entry Route	$PEC_{SW,TWA}$ [µg/L]		
				PEC_{SW} [µg/L]	PEC_{SED} [µg/kg]		7-d	21-d	28-d
Maize 1 × 96 g a.s./ha BBCH 12-18	D3 Ditch	14-May-92	14-May-92	0.504	0.083	Drift	0.082	0.028	0.021
	D4 Pond	30-May-85	30-May-85	0.021	0.014	Drift	0.017	0.011	0.009
	D4 Stream	30-May-85	30-May-85	0.433	0.025	Drift	0.011	0.008	0.007
	D5 Pond	27-May-78	27-May-78	0.021	0.018	Drift	0.016	0.010	0.008
	D5 Stream	27-May-78	27-May-78	0.454	0.031	Drift	0.011	0.011	0.009
	R1 Pond	10-May-84	20-May-84	0.048	0.030	Run-off	0.039	0.027	0.025
	R1 Stream	10-May-84	14-May-84	1.070	0.143	Run-off	0.109	0.040	0.030
	R3 Stream	18-May-80	23-May-80	3.780	0.514	Run-off	0.382	0.135	0.101
	R4 Stream	20-Apr-84	27-Apr-84	3.760	0.641	Run-off	0.416	0.153	0.116

Table 8.9-13: FOCUS Step 3 Global Maximum PEC_{SW} and PEC_{SED} for mesotrione (pH 7.9)

Use	Scenario	Application date	Date of maximum PEC_{SW}	Global maximum		Main Entry Route	$PEC_{SW,TWA}$ [µg/L]		
				PEC_{SW} [µg/L]	PEC_{SED} [µg/kg]		7-d	21-d	28-d
Maize 1 × 96 g a.s./ha BBCH 12-18	D3 Ditch	14-May-92	14-May-92	0.504	0.054	Drift	0.082	0.027	0.021
	D4 Pond	30-May-85	30-May-85	0.020	0.006	Drift	0.016	0.010	0.009
	D4 Stream	30-May-85	30-May-85	0.431	0.014	Drift	0.005	0.002	0.001
	D5 Pond	27-May-78	27-May-78	0.020	0.006	Drift	0.016	0.010	0.008
	D5 Stream	27-May-78	27-May-78	0.450	0.011	Drift	0.004	0.001	0.001
	R1 Pond	10-May-84	10-May-84	0.020	0.008	Drift	0.017	0.013	0.011
	R1 Stream	10-May-84	14-May-84	0.473	0.034	Run-off	0.025	0.010	0.007
	R3 Stream	18-May-80	23-May-80	0.494	0.051	Run-off	0.063	0.022	0.017
	R4 Stream	20-Apr-84	27-Apr-84	0.458	0.056	Run-off	0.051	0.021	0.016

$PEC_{SW/SED}$ – FOCUS Step 4

Table 8.9-14: FOCUS Step 4 global maximum PEC_{SW} for mesotrione (pH 5.1)

Mitigation options							
VFSmod (m)		**No**		**No**		**No**	
No-spray buffer strip (m)		**5**		**10**		**20**	
Vegetated buffer strip (m)		**-**		**10**		**20**	
Drift reduction nozzle (%)		**-**		**-**		**-**	
Use	**Scenario**	**Global max PEC_{SW} [µg/L]**	**Main Entry Route**	**Global max PEC_{SW} [µg/L]**	**Main Entry Route**	**Global max PEC_{SW} [µg/L]**	**Main Entry Route**
Maize 1 × 96 g a.s./ha BBCH 12-18	D3 Ditch	0.165	Drift	0.088	Drift	0.046	Drift
	D4 Pond	0.055	Drainage	0.055	Drainage	0.055	Drainage
	D4 Stream	0.184	Drift	0.099	Drift	0.088	Drainage
	D5 Pond	0.037	Drainage	0.037	Drainage	0.037	Drainage
	D5 Stream	0.198	Drift	0.109	Drift	0.061	Drift
	R1 Pond	0.073	Run-off	0.032	Run-off	0.017	Run-off
	R1 Stream	1.560	Run-off	0.705	Run-off	0.369	Run-off
	R3 Stream	3.000	Run-off	1.350	Run-off	0.707	Run-off
	R4 Stream	3.250	Run-off	1.480	Run-off	0.773	Run-off
Mitigation options							
VFSmod		**Yes**		**Yes**			
No-spray buffer (m)		**5**		**10**			
Vegetated buffer strip (m)		**5**		**10**			
Drift reduction nozzle (%)		**-**		**-**			
Use	**Scenario**	**Global max PEC_{SW} [µg/L]**	**Main Entry Route**	**Global max PEC_{SW} [µg/L]**	**Main Entry Route**		
Maize 1 × 96 g a.s./ha BBCH 12-18	D3 Ditch	0.165	Drift	0.088	Drift		
	D4 Pond	0.055	Drainage	0.055	Drainage		
	D4 Stream	0.184	Drift	0.099	Drift		
	D5 Pond	0.037	Drainage	0.037	Drainage		
	D5 Stream	0.198	Drift	0.109	Drift		
	R1 Pond	0.018	Drift	0.013	Drift		
	R1 Stream	0.144	Drift	0.077	Drift		
	R3 Stream	0.206	Drift	0.109	Drift		
	R4 Stream	0.147	Drift	0.078	Drift		

Table 8.9-15: FOCUS Step 4 global maximum PEC_{SW} for mesotrione (pH 6.5)

Mitigation options							
VFSmod (m)		**No**		**No**		**No**	
No-spray buffer strip (m)		**5**		**10**		**20**	
Vegetated buffer strip (m)		**-**		**10**		**20**	
Drift reduction nozzle (%)		**-**		**-**		**-**	
Use	**Scenario**	**Global max PEC_{SW} [µg/L]**	**Main Entry Route**	**Global max PEC_{SW} [µg/L]**	**Main Entry Route**	**Global max PEC_{SW} [µg/L]**	**Main Entry Route**
Maize 1 × 96 g a.s./ha BBCH 12-18	D3 Ditch	0.165	Drift	0.088	Drift	0.046	Drift
	D4 Pond	0.019	Drift	0.014	Drift	0.010	Drainage
	D4 Stream	0.183	Drift	0.098	Drift	0.052	Drift
	D5 Pond	0.019	Drift	0.014	Drift	0.010	Drift
	D5 Stream	0.193	Drift	0.104	Drift	0.056	Drift
	R1 Pond	0.047	Run-off	0.022	Run-off	0.012	Run-off
	R1 Stream	1.070	Run-off	0.438	Run-off	0.221	Run-off
	R3 Stream	3.780	Run-off	1.710	Run-off	0.894	Run-off
	R4 Stream	3.760	Run-off	1.710	Run-off	0.895	Run-off
Mitigation options							
VFSmod		**Yes**		**Yes**			
No-spray buffer (m)		**5**		**10**			
Vegetated buffer strip (m)		**5**		**10**			
Drift reduction nozzle (%)		**-**		**-**			
Use	**Scenario**	**Global max PEC_{SW} [µg/L]**	**Main Entry Route**	**Global max PEC_{SW} [µg/L]**	**Main Entry Route**		
Maize 1 × 96 g a.s./ha BBCH 12-18	D3 Ditch	0.165	Drift	0.088	Drift		
	D4 Pond	0.019	Drift	0.014	Drift		
	D4 Stream	0.183	Drift	0.098	Drift		
	D5 Pond	0.019	Drift	0.014	Drift		
	D5 Stream	0.193	Drift	0.104	Drift		
	R1 Pond	0.018	Drift	0.013	Drift		
	R1 Stream	0.144	Drift	0.077	Drift		
	R3 Stream	0.206	Drift	0.109	Drift		
	R4 Stream	0.147	Drift	0.078	Drift		

Table 8.9-16: FOCUS Step 4 global maximum PEC_{SW} for mesotrione (pH 7.9)

Mitigation options							
VFSmod (m)		**No**		**No**		**No**	
No-spray buffer strip (m)		**5**		**10**		**20**	
Vegetated buffer strip (m)		**-**		**10**		**20**	
Drift reduction nozzle (%)		**-**		**-**		**-**	
Use	**Scenario**	**Global max PEC_{SW} [µg/L]**	**Main Entry Route**	**Global max PEC_{SW} [µg/L]**	**Main Entry Route**	**Global max PEC_{SW} [µg/L]**	**Main Entry Route**
Maize 1 × 96 g a.s./ha BBCH 12-18	D3 Ditch	0.165	Drift	0.088	Drift	0.046	Drift
	D4 Pond	0.018	Drift	0.013	Drift	0.009	Drift
	D4 Stream	0.182	Drift	0.096	Drift	0.050	Drift
	D5 Pond	0.018	Drift	0.013	Drift	0.009	Drift
	D5 Stream	0.190	Drift	0.101	Drift	0.052	Drift
	R1 Pond	0.018	Drift	0.013	Drift	0.009	Drift
	R1 Stream	0.473	Run-off	0.194	Run-off	0.098	Run-off
	R3 Stream	0.494	Run-off	0.223	Run-off	0.117	Run-off
	R4 Stream	0.458	Run-off	0.208	Run-off	0.109	Run-off
Mitigation options							
VFSmod		**Yes**		**Yes**			
No-spray buffer (m)		**5**		**10**			
Vegetated buffer strip (m)		**5**		**10**			
Drift reduction nozzle (%)		**-**		**-**			
Use	**Scenario**	**Global max PEC_{SW} [µg/L]**	**Main Entry Route**	**Global max PEC_{SW} [µg/L]**	**Main Entry Route**		
Maize 1 × 96 g a.s./ha BBCH 12-18	D3 Ditch	0.165	Drift	0.088	Drift		
	D4 Pond	0.018	Drift	0.013	Drift		
	D4 Stream	0.182	Drift	0.096	Drift		
	D5 Pond	0.018	Drift	0.013	Drift		
	D5 Stream	0.190	Drift	0.101	Drift		
	R1 Pond	0.018	Drift	0.013	Drift		
	R1 Stream	0.144	Drift	0.077	Drift		
	R3 Stream	0.206	Drift	0.109	Drift		
	R4 Stream	0.147	Drift	0.078	Drift		

Nicosulfuron and its metabolites

Table 8.9-17: Summary of modelling input parameters used for $PEC_{SW/SED}$ calculations of active substance nicosulfuron at FOCUS Steps 1 to 4

Parameter	Value	Value in accordance to EU endpoint Y/N / Reference
Molecular weight [g/mol]	410.4	Y / EFSA (2007)
Water solubility [mg/L]	9500 (19.7°C, pH 6.7)	Y / EFSA (2007)
Saturated vapour pressure [Pa]	8.00×10^{-10} (25°C)	Y / EFSA (2007)
$DT_{50,soil}$ [days]	16.4 (Geomean lab. studies, normalised, 20°C, pF2, n=7)	Y / EFSA (2007)
K_{FOC} / K_{FOM} [L/kg]	20.7 / 12.0 (Arithmetic mean, n=4)	Y / EFSA (2007)
1/n [-]	0.94 (Arithmetic mean, n=4)	Y / EFSA (2007)
Steps 1 and 2		
$DT_{50,water}$ [days]	42.3 (Whole system value)	Y / EFSA (2007)
$DT_{50,sediment}$ [days]	42.3 (Whole system value)	Y / EFSA (2007)
$DT_{50,whole\ system}$ [days]	42.3 (Representative worst-case, n=2)	Y / EFSA (2007)
Steps 3 and 4		
$DT_{50,water}$ [days]	65.0 (geomean, n=2)	Y / EFSA (2007)
$DT_{50,sediment}$ [days]	13.9 (geomean, n=2)	Y / EFSA (2007)
Q_{10} factor [-]	2.2	Y / EFSA (2016)

Table 8.9-18: Summary of modelling input parameters used for $PEC_{SW/SED}$ calculations of metabolites at FOCUS Steps 1 and 2

Compound	HMUD	AUSN	UCSN	ASDM	ADMP	Value in accordance to EU endpoint Y/N / Reference
Molecular weight [g/mol]	396.4	314.3	315.3	229.2 [a]	155.2	Y / EFSA (2007)
Water solubility [mg/L]	9500 (parent value)	9500 (parent value)	9500 (parent value)	9500 (parent value)	9500 (parent value)	Y / EFSA (2007)
$DT_{50,soil}$ [days]	25.2 (Worst-case lab. studies, normalised, 20°C and pF2, n=2)	192.3 (Worst-case lab. studies, normalised, 20°C and pF2, n=3)	271.0 (Worst-case lab. studies, normalised, 20°C and pF2, n=3)	236.6 (Worst-case lab. studies, normalised, 20°C and pF2, n=3)	7.3 (Worst-case lab. studies, normalised, 20°C and pF2, n=3)	Y / EFSA (2007)
K_{FOC} [mL/g]	0.88 (lowest value, n=5)	13.0 (lowest value, n=4)	1.1 (lowest value, n=4)	2.3 (lowest value, n=4)	42.0 (lowest value, n=4)	Y / EFSA (2007)
$DT_{50,water}$ [days]	1000	1000	1000	1000	1000	Y / EFSA (2007)
$DT_{50,sediment}$ [days]	1000	1000	1000	1000	1000	Y / EFSA (2007)
$DT_{50,whole\ system}$ [days]	1000	1000	1000	1000	1000	Y / FOCUS default
Maximum occurrence in soil [%]	14.4	26.8	11.0	63.4 [a]	7.2	Y / EFSA (2007)
Maximum occurrence in water/sediment [%]	19.3	11.1	6.5	61 (photolysis)	65.4 (hydrolysis)	Y / EFSA (2007)

[a] Since the highest conc. was found in a field dissipation study, the molecular weight ratio does not need to be considered (the same value (410.4 g/mol) as for nicosulfuron was input into the model)

$PEC_{SW/SED}$ – FOCUS Steps 1 and 2

Table 8.9-19: FOCUS Step 1 and 2 PEC_{SW} and PEC_{SED} for the active substance nicosulfuron

Use	No. of appl.	Step	Region	Season	Maximum PEC_{SW} [µg/L]	21-d TWA PEC_{SW} [µg/L]	Maximum PEC_{SED} [µg/kg]
Maize 1 × 36 g a.s./ha BBCH 12-18	1	1	-	-	12.009	10.153	2.444
		2	N-EU	Mar-May	1.784	1.507	0.363
				Jun-Sep	1.784	1.507	0.363
			S-EU	Mar-May	3.263	2.759	0.664
				Jun-Sep	2.523	2.133	0.513

Table 8.9-20: FOCUS Step 1 and 2 PEC_{SW} and PEC_{SED} for metabolite HMUD

Use	No. of appl.	Step	Region	Season	Maximum PEC_{SW} [µg/L]	21-d TWA PEC_{SW} [µg/L]	Maximum PEC_{SED} [µg/kg]
Maize 1 × 36 g a.s./ha BBCH 12-18	1	1	-	-	3.963	3.934	0.035
		2	N-EU	Mar-May	0.569	0.564	0.005
				Jun-Sep	0.569	0.564	0.005
			S-EU	Mar-May	1.076	1.068	0.009
				Jun-Sep	0.822	0.816	0.007

Table 8.9-21: FOCUS Step 1 and 2 PEC_{SW} and PEC_{SED} for metabolite AUSN

Use	No. of appl.	Step	Region	Season	Maximum PEC_{SW} [µg/L]	21-d TWA PEC_{SW} [µg/L]	Maximum PEC_{SED} [µg/kg]
Maize 1 × 36 g a.s./ha BBCH 12-18	1	1	-	-	3.452	3.426	0.448
		2	N-EU	Mar-May	0.513	0.509	0.067
				Jun-Sep	0.513	0.509	0.067
			S-EU	Mar-May	0.998	0.990	0.130
				Jun-Sep	0.755	0.750	0.098

Table 8.9-22: FOCUS Step 1 and 2 PEC_{SW} and PEC_{SED} for metabolite UCSN

Use	No. of appl.	Step	Region	Season	Maximum PEC_{SW} [µg/L]	21-d TWA PEC_{SW} [µg/L]	Maximum PEC_{SED} [µg/kg]
Maize 1 × 36 g a.s./ha BBCH 12-18	1	1	-	-	1.628	1.616	0.018
		2	N-EU	Mar-May	0.243	0.241	0.003
				Jun-Sep	0.243	0.241	0.003
			S-EU	Mar-May	0.469	0.465	0.005
				Jun-Sep	0.356	0.353	0.004

Table 8.9-23: FOCUS Step 1 and 2 PEC_{SW} and PEC_{SED} for metabolite ASDM

Use	No. of appl.	Step	Region	Season	Maximum PEC_{SW} [µg/L]	21-d TWA PEC_{SW} [µg/L]	Maximum PEC_{SED} [µg/kg]
Maize 1 × 36 g a.s./ha BBCH 12-18	1	1	-	-	15.084	14.974	0.347
		2	N-EU	Mar-May	2.250	2.233	0.052
				Jun-Sep	2.250	2.233	0.052
			S-EU	Mar-May	4.299	4.267	0.099
				Jun-Sep	3.274	3.250	0.075

Table 8.9-24: FOCUS Step 1 and 2 PEC_{SW} and PEC_{SED} for metabolite ADMP

Use	No. of appl.	Step	Region	Season	Maximum PEC_{SW} [µg/L]	21-d TWA PEC_{SW} [µg/L]	Maximum PEC_{SED} [µg/kg]
Maize 1 × 36 g a.s./ha BBCH 12-18	1	1	-	-	3.202	3.174	1.342
		2	N-EU	Mar-May	0.466	0.462	0.195
				Jun-Sep	0.466	0.462	0.195
			S-EU	Mar-May	0.854	0.847	0.358
				Jun-Sep	0.660	0.654	0.277

$PEC_{SW/SED}$ – FOCUS Step 3

Table 8.9-25: FOCUS Step 3 Global Maximum PEC_{SW} and PEC_{SED} for nicosulfuron

Use	Scenario	Application date	Date of maximum PEC_{SW}	Global maximum		Main Entry Route	$PEC_{SW, TWA}$ [µg/L]		
				PEC_{SW} [µg/L]	PEC_{SED} [µg/kg]		7-d	21-d	28-d
Maize 1 × 36 g a.s./ha BBCH 12-18	D3 Ditch	14-May-92	14-May-92	0.195	0.028	Drift	0.038	0.017	0.014
	D4 Pond	30-May-85	30-Dec-85	0.019	0.020	Drainage	0.019	0.019	0.019
	D4 Stream	30-May-85	30-May-85	0.166	0.011	Drift	0.012	0.010	0.010
	D5 Pond	27-May-78	27-May-78	0.014	0.010	Drift	0.014	0.013	0.012
	D5 Stream	27-May-78	27-May-78	0.171	0.007	Drift	0.007	0.007	0.006
	R1 Pond	10-May-84	20-May-84	0.015	0.008	Run-off	0.014	0.013	0.012
	R1 Stream	10-May-84	14-May-84	0.407	0.030	Run-off	0.029	0.011	0.008
	R3 Stream	18-May-80	23-May-80	1.470	0.143	Run-off	0.142	0.050	0.038
	R4 Stream	20-Apr-84	27-Apr-84	1.530	0.186	Run-off	0.169	0.060	0.045

$PEC_{SW/SED}$ – FOCUS Step 4

Table 8.9-26: FOCUS Step 4 global maximum PEC_{SW} for nicosulfuron

Mitigation options							
VFSmod (m)		**No**		**No**		**No**	
No-spray buffer strip (m)		**5**		**10**		**20**	
Vegetated buffer strip (m)		**-**		**10**		**20**	
Drift reduction nozzle (%)		**-**		**-**		**-**	
Use	**Scenario**	**Global max PEC_{SW} [µg/L]**	**Main Entry Route**	**Global max PEC_{SW} [µg/L]**	**Main Entry Route**	**Global max PEC_{SW} [µg/L]**	**Main Entry Route**
Maize 1 × 36 g a.s./ha BBCH 12-18	D3 Ditch	0.068	Spray drift	0.039	Spray drift	0.023	Spray drift
	D4 Pond	0.019	Drainage	0.019	Drainage	0.019	Drainage
	D4 Stream	0.072	Spray drift	0.040	Spray drift	0.023	Spray drift
	D5 Pond	0.013	Spray drift	0.012	Spray drift	0.010	Spray drift
	D5 Stream	0.073	Spray drift	0.040	Spray drift	0.022	Spray drift
	R1 Pond	0.014	Run-off	0.007	Run-off	0.004	Run-off
	R1 Stream	0.407	Run-off	0.167	Run-off	0.084	Run-off
	R3 Stream	1.470	Run-off	0.666	Run-off	0.349	Run-off
	R4 Stream	1.530	Run-off	0.694	Run-off	0.364	Run-off
Mitigation options							
VFSmod		**Yes**		**Yes**			
No-spray buffer (m)		**5**		**10**			
Vegetated buffer strip (m)		**5**		**10**			
Drift reduction nozzle (%)		**-**		**-**			
Use	**Scenario**	**Global max PEC_{SW} [µg/L]**	**Main Entry Route**	**Global max PEC_{SW} [µg/L]**	**Main Entry Route**		
Maize 1 × 36 g a.s./ha BBCH 12-18	D3 Ditch	0.068	Spray drift	0.039	Spray drift		
	D4 Pond	0.019	Drainage	0.019	Drainage		
	D4 Stream	0.072	Spray drift	0.040	Spray drift		
	D5 Pond	0.013	Spray drift	0.012	Spray drift		
	D5 Stream	0.073	Spray drift	0.040	Spray drift		
	R1 Pond	0.007	Spray drift	0.005	Spray drift		
	R1 Stream	0.054	Spray drift	0.029	Spray drift		
	R3 Stream	0.077	Spray drift	0.041	Spray drift		
	R4 Stream	0.055	Spray drift	0.029	Spray drift		

Product PEC_{sw} of SAE053H/01

Surface water PEC values were calculated for the formulation for the FOCUS waterbodies using the FOCUS drift calculator (Table 8.9-27). The application rate of 1.2 L/ha was converted to ~~1140~~ 1176 g/ha based on a product density of 980 g/L.

Table 8.9-27: PEC surface water for the formulated product SAE053H/01 (drift only)

~~Waterbody~~	~~Default distance to field edge~~	~~$PEC_{sw,drift}$ (µg/L)~~				
		~~Default distance (no buffer)~~	~~3 m~~	~~5 m~~	~~10 m~~	~~20 m~~
~~FOCUS ditch~~	~~1.3 m~~	~~6.06~~	~~3.10~~	~~1.99~~	~~1.05~~	~~0.55~~
~~FOCUS stream~~	~~1.8 m~~	~~4.72~~				
~~FOCUS pond~~	~~3.8 m~~	~~0.24~~	~~-~~	~~0.22~~	~~0.155~~	~~0.104~~

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

The fate and behaviour of mesotrione in air were reviewed during Annex I renewal (EFSA 2016, p. 31, 66/67). Mesotrione has low vapour pressure ($<5.7 \cdot 10^{-10}$ Pa at 25°C). Furthermore, photochemical oxidative degradation in air was estimated to be 17.6 hours and therefore, significant long-range transport and accumulation in the stratosphere is unlikely (see FOCUS working group report: Pesticides in Air: Considerations for exposure assessment, SANCO/10553/2006, June 2008).

The fate and behaviour of nicosulfuron in air were reviewed during Annex I inclusion (EFSA 2007). Nicosulfuron has low vapour pressure ($<8.0 \cdot 10^{-10}$ Pa at 25°C). Furthermore, the photochemical oxidative degradation in air was estimated to be 0.587 hours and therefore, significant long-range transport and accumulation in the stratosphere is unlikely.

Table 8.10-1 Summary of atmospheric degradation and behaviour

Compound	**Mesotrione**	**Nicosulfuron**
Vapour pressure	$<5.7 \cdot 10^{-6}$ Pa at ~~25~~ 20°C	$<8.0 \cdot 10^{-10}$ Pa at 25°C
Direct photolysis in air	No data	No data
Quantum yield of direct phototransformation	No data	No data
Photochemical oxidative degradation in air	DT_{50} (h): 17.6 h derived by the Atkinson model OH (12h) concentration assumed: 1.5×10^6 OH/cm^3	DT_{50} (h): 0.587 h
Volatilisation	From plant surfaces (BBA guideline): <10% after 24 h From soil surfaces (BBA guideline): <10% after 24 h	from plant: 8.3% after 24 hours, (measured as % loss) from soil: 6.2% after 24 hours, (measured as % loss)

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Owner
KCP 9.2.4.1/01	Worthington, Mark	2021a	Mesotrione – A leaching assessment for mesotrione and metabolites MNBA and AMBA using the PEARL 4.4.4, PELMO 5.5.3 and MACRO 5.5.4 groundwater models following spray application to maize in the EU S21-01990-01/007-B non GLP Unpublished	N	Sumi Agro
KCP 9.2.4.1/02	Worthington, Mark	2021b	Nicosulfuron – A leaching assessment for nicosulfuron and metabolites HMUD, AUSN, UCSN, ASDM, ADMP and MU-466 using the PEARL 4.4.4, PELMO 5.5.3 and MACRO 5.5.4 groundwater models following spray application to maize in the EU S21-01990-01/007-D non GLP Unpublished	N	Sumi Agro
KCP 9.2.5.1/01	Fortin-McCuaig, M.	2021a	Mesotrione – A European Environmental Fate Assessment for Mesotrione and its metabolites MNBA, AMBA and SYN546974 Using the FOCUS Surface Water Models at Steps 1 to 4 Following Spray Application to Maize in Central Europe S21-01990-01-003-A Non GLP Unpublished	N	Sumi Agro

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Owner
KCP 9.2.5.1/02	Fortin-McCuaig, M.	2021b	Nicosulfuron – A European Environmental Fate Assessment for Nicosulfuron and its metabolites HMUD, AUSN, UCSN, ASDM and ADMP Using the FOCUS Surface Water Models at Steps 1 to 4 Following Spray Application to Maize in Central Europe S21-01990-01-003-C Non GLP Unpublished	N	Sumi Agro

Appendix 2 Detailed evaluation of the new active substance studies (MCA)

Not relevant.

Appendix 3 Additional information provided by the applicant

None.