REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: ADM.06001.H.2.B

Product name(s): Edaptis

Chemical active substance(s):

Mesosulfuron-methyl, 12 g/L
Pinoxaden, 60 g/L

Safener:
Mefenpyr-diethyl, 35 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Sponsor: ADAMA Agan Ltd.
Applicant: Country organisation / representative of ADAMA, as given in Part A

Submission date: June 2021 (updated in September 2022)

MS Finalisation date: May 2023 (initial Core Assessment)

September 2023, December 2023 (final Core Assessment)

Version history

When	What
June 2021	dRR version 1 submitted by applicant
September 2022	8.8 updated PECgw following comments of zRMS Poland 8.9 updated PECsw following comments of zRMS Poland
May 2023	Initial assessment by the zRMS The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are ~~struck through and shaded for transparency~~.
September 2023	Final report (Core Assessment updated following the commenting period). Additional information/assessments included by the zRMS in the report in response to comments received from the cMS and the Applicant are highlighted in yellow. Information no longer relevant is ~~struck through and shaded~~.
December 2023	Final report (Core Assessment updated following the second commenting period) No additional information or assessments after the second commenting period.

DATA PROTECTION CLAIM

Under Article 59, Regulation 1107/2009/EC, on behalf of the Sponsor Company the applicant claims data protection for these studies. The data protection status and corresponding justification as valid for the respective country will be confirmed in the respective PART A

STATEMENT FOR OWNERSHIP

The summaries and evaluations contained in this document may be based on unpublished proprietary data submitted for the purpose of the assessment undertaken by the regulatory authority that prepared it. Other registration authorities should not grant, amend, or renew a registration on the basis of the summaries and evaluation of unpublished proprietary data contained in this document unless they have received the data on which the summaries and evaluation are based, either –

- from the owner of the data, or
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- following expiry of any period of exclusive use, by offering – in certain jurisdictions – mandatory compensation, unless the period of protection of the proprietary data concerned has expired.

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8 Fate and behaviour in the environment (KCP 9)

zRMS comments:

Zonal evaluation of ADM.06001.H.2.B was based on the active substance (mesosulfuron-methyl and pinoxaden) data provided in the respective EFSA reports or evaluated as a part of the confirmatory data (pinoxaden). None of the substances is owned by ADAMA and the access to their protected data was granted via the LoA issued by Bayer AG CropScience Division (owner of mesosulfuron-methyl data) and Syngenta Crop Protection AG (owner of pinoxaden).

The LoA issued by Bayer AG CropScience Division is valid in all 27 EU countries and in the UK. No clear information on the countries where the LoA for pinoxaden is valid was indicated by Syngenta Crop Protection AG, but it is also not indicated that its validity is restricted to selected countries.

Nevertheless it should be noted that access to the data for both active compounds was given exclusively to ADAMA Polska Sp. z o.o and for this reason separate LoA has to be presented in case other subsidiary of ADAMA is applying for authorisation of ADM.06001.H.2.B in particular Member States.

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 mesosulfuron-methyl / pinoxaden 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~~	~~AT, DE, BE, NL, CZ, PL, HU, IE~~	~~Winter wheat, rye, triticale~~	~~F~~	~~ALOMY, APESV, AVESS, BROSS, POAAN, POATR, Broad-leaved weeds~~	~~Foliar, spraying, overall~~	~~BBCH 13-20 (spring)~~	~~a) 1 b) 1~~	~~-~~	~~a) 0.75 L/ha b) 0.75 L/ha~~	~~a) 9 / 45 g/ha b) 9 / 45 g/ha~~	~~80 / 300~~		~~Mefenpyr-diethyl applied as a safener at 26.3 g/ha~~	C
2	AT, DE, BE, NL, CZ, PL, HU, IE	Winter wheat, rye, triticale	F	ALOMY, APESV, AVESS, BROSS, POAAN, POATR, Broad-leaved weeds	Foliar, spraying, overall	BBCH 20-39 (spring)	a) 1 b) 1	-	a) 1 L/ha b) 1 L/ha	a) 12 / 60 g/ha b) 12 / 60 g/ha	80 / 300		Mefenpyr-diethyl applied as a safener at 35.0 g/ha	C
3	AT, DE, BE, NL, CZ, PL, HU, IE	Spring wheat	F	ALOMY, APESV, AVESS, BROSS, POAAN, POATR, Broad-leaved weeds	Foliar, spraying, overall	BBCH 13-39 (spring)	a) 1 b) 1	-	a) 1 L/ha b) 1 L/ha	a) 12 / 60 g/ha b) 12 / 60 g/ha	80 / 300		Mefenpyr-diethyl applied as a safener at 35.0 g/ha	C
3*	AT, DE, BE, NL, CZ, PL, HU, IE	Spring wheat	F	ALOMY, APESV, AVESS, BROSS, POAAN, POATR, Broad-leaved weeds	Foliar, spraying, overall	BBCH 13-39 (spring)	a) 1 b) 1	-	a) 0.75 L/ha b) 0.75 L/ha	a) 9 / 45 g/ha b) 9 / 45 g/ha	80 / 300		Mefenpyr-diethyl applied as a safener at 26.3 g/ha	C

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

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

Explanation for column 15 “Conclusion”

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

zRMS comments:

Originally the GAP table presented by the Applicant in the dRR included also spring uses in winter cereals at BBCH 13-20 (use no 1). However, in line with information available in AppDate ver. 3.06, BBCH 13-20 of winter cereals are developed before winter while the spring starting point is at BBCH 21. This was confirmed by the efficacy experts, who indicated that in the available efficacy data for ADM.06001.H.2.B nearly all efficacy trials for spring uses in winter cereals were performed at BBCH >21 and the available data do not cover spring application to winter cereals at BBCH 13-20. Taking this into account, the spring application to winter cereals at BBCH 13-20 has been struck through in Table 8.1-1 above.

During the commenting period Applicant modified the GAP table for use in spring cereals by considering the additional lower application rate of 0.75 L/ha of the product which was thus added in Table 8.1-1 above and considered in groundwater modelling for pinoxaden (additional simulations were not required for other compounds as acceptable groundwater exposure was concluded for the umbrella GAP).

Table 8.1-2: Assessed (critical) uses during approval of mesosulfuron-methyl 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)	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	Winter wheat	F	Grass and dicot. weed species	Broadcast	BBCH 20-32 end of winter, beginning of vegetation	1	n/a	1.5	0.015	100-400	n/a	
2	EU	Winter rye	F	Grass and dicot. weed species	Broadcast	BBCH 20-32 end of winter, beginning of vegetation	1	n/a	0.6	0.006	100-400	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

Table 8.1-3: Assessed (critical) uses during approval of pinoxaden 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)	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	North EU	Winter wheat	F	Grass weeds	Foliar broadcast	Up to BBCH 39	1	n/a	0.3-0.6	0.03-0.06	100-400	n/a	Up to 0.045 kg as/ha in autumn
2	North EU	Winter barley	F	Grass weeds	Foliar broadcast	Up to BBCH 39	1	n/a	0.3-0.6	0.03-0.06	100-400	n/a	Up to 0.045 kg as/ha in autumn
3	North EU	Spring barley	F	Grass weeds	Foliar broadcast	Up to BBCH 39	1	n/a	0.3-0.6	0.03-0.06	100-400	n/a	
4	North EU	Rye	F	Grass weeds	Foliar broadcast	Up to BBCH 39	1	n/a	0.3-0.6	0.03-0.06	100-400	n/a	Up to 0.045 kg as/ha in autumn
5	North EU	Triticale	F	Grass weeds	Foliar broadcast	Up to BBCH 39	1	n/a	0.3-0.6	0.03-0.06	100-400	n/a	Up to 0.045 kg as/ha in autumn
6	South EU	Winter wheat	F	Grass weeds	Foliar broadcast	Up to BBCH 39	1	n/a	0.3-0.6	0.03-0.06	100-400	n/a	
7	South EU	Winter barley	F	Grass weeds	Foliar broadcast	Up to BBCH 39	1	n/a	0.3-0.6	0.03-0.06	100-400	n/a	
8	South EU	Durum	F	Grass weeds	Foliar broadcast	Up to BBCH 39	1	n/a	0.3-0.45	0.03-0.045	100-400	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

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

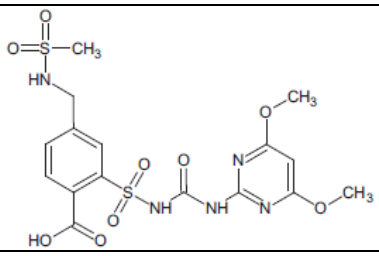
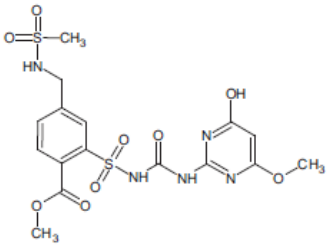
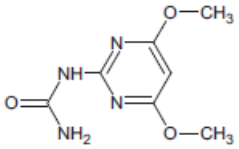
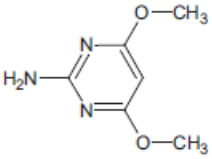
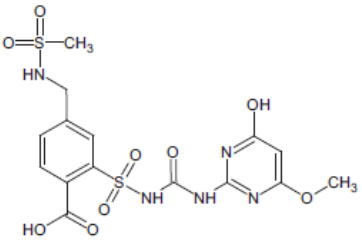
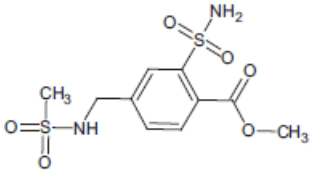
1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. *	**Member state(s)**	**Crop and/or situation (crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I ****	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**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)	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	Winter and spring cereals	F	Not applicable	Foliar broadcast	Up to BBCH 39	1	n/a		100	100-400	n/a	Safener
2	EU	Turf	F	Not applicable	Foliar broadcast	Up to BBCH 39	1	n/a		100	100-400	n/a	safener

* 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 mesosulfuron-methyl potentially relevant for exposure assessment

Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
Mesosulfuron	489.5		Soil: 16.2% (aerobic soil) Water/Sediment: 4.9% (total system)	PEC_{gw}: leaching potential to groundwater PEC_{soil}: > 10% of a.s. $PEC_{sw/sed}$: run-off/drainage potential to surface water
AE F160459	489.5		Soil: 8.9% (aerobic, > 5% in > 2 sequential measurements), 25.9% (anaerobic) Water/Sediment: 21.6% (total system)	PEC_{gw}: leaching potential to groundwater PEC_{soil}: > 5% of a.s. (> 2 sequential measurements) $PEC_{sw/sed}$: > 10% of a.s., run-off/drainage potential to surface water
AE F099095	198.2		Soil: 29.2% (aerobic) Water/Sediment: 0.9% (total system)	PEC_{gw}: potential formation from mesosulfuron PEC_{soil}: potential formation from mesosulfuron $PEC_{sw/sed}$: run-off/drainage potential to surface water
AE F092944	155.2		Soil: 10.1% (aerobic) Water/Sediment: 3.2% (total system)	PEC_{gw}: potential formation from AE F099095 PEC_{soil}: potential formation from AE F099095 $PEC_{sw/sed}$: run-off/drainage potential to surface water
AE F160460	475.5		Soil: 8.6% (aerobic, > 5% in > 2 sequential measurements) Water/Sediment: 8.4% (total system, > 5% in > 2 sequential measurements)	PEC_{gw}: potential formation from mesosulfuron and AE F160459 PEC_{soil}: potential formation from mesosulfuron and AE F160459 $PEC_{sw/sed}$: run-off/drainage potential to surface water, potential formation from mesosulfuron and AE F160459
AE F140584	322.4		Soil: 5.1% (aerobic, > 5% in 1 measurement only) Water/Sediment: 1.9% (total system)	PEC_{gw}: potential formation from AE F160459 PEC_{soil}: potential formation from AE F160459 $PEC_{sw/sed}$: run-off/drainage potential to surface water

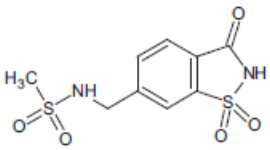
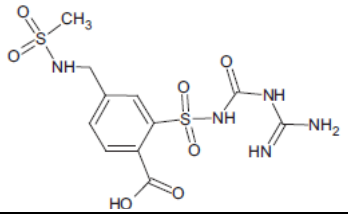
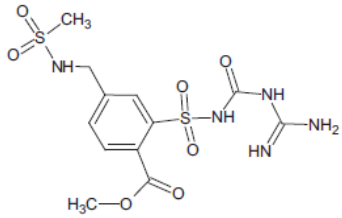
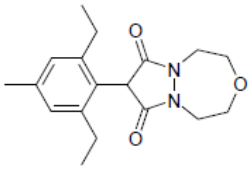
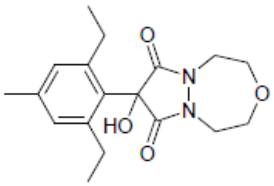
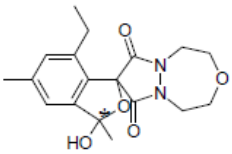
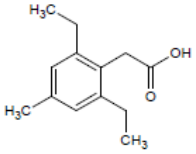
Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
AE F147447	290.3		Soil: 5.8% (aerobic, > 5% in > 2 sequential measurements), 6.5% (anaerobic, maximum of formation not yet reached at the end of the study) Water/Sediment: 10.9% (total system)	PEC_{gw}: potential formation from AE F140584 PEC_{soil}: potential formation from AE F140584 $PEC_{sw/sed}$: > 10% of a.s., run-off/drainage potential to surface water, potential formation from AE F140584 and AE F160460
BCS-CV14885	393.4		Water/Sediment: 22.0% (total system) Lysimeter: up to 0.481 µg/L	PEC_{gw}: potential formation from parent PEC_{soil}: potential formation from parent $PEC_{sw/sed}$: > 10% of a.s.
BCS-CO60720	407.4		Water/Sediment: 13.1% (total system)	PEC_{gw}: - PEC_{soil}: - $PEC_{sw/sed}$: > 10% of a.s.

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

Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartements	Exposure assessment required due to
NOA 407854 (M2)	316.4		Soil: 89.7% (aerobic), 94.4% (anaerobic) Water/Sediment: 98.8% (total system), 86.9% (water), 26.0% (sediment)	PEC_{gw}: leaching potential to groundwater PEC_{soil}: > 10% of a.s. $PEC_{sw/sed}$: > 10% of a.s.
NOA 447204 (M3)	332.4		Soil: 30.6% (aerobic) Water/Sediment: 9.7% (total system, > 5% in 2 sequential measurements, < 5% in water or sediment at all sample times) metabolite found in lysimeter studies Lysimeter leachate max: 0.206 µg/L (second year)	PEC_{gw}: potential formation from NOA 407854 PEC_{soil}: potential formation from NOA 407854 $PEC_{sw/sed}$: run-off/drainage potential to surface water, potential formation from NOA 407854
SYN 515622	-		Soil: 20.4% (soil photolysis)	Not required
NOA 437397	-		Soil: 6.7% (soil photolysis, maximum of formation not yet reached at the end of the study)	Not required.

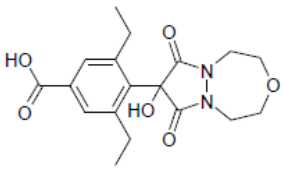
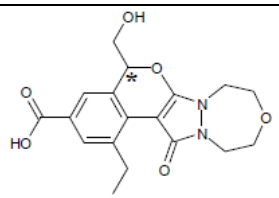
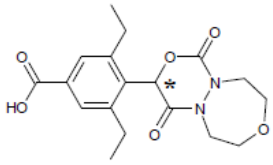
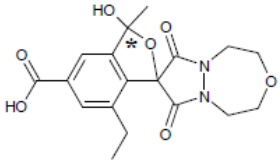
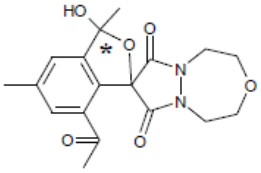
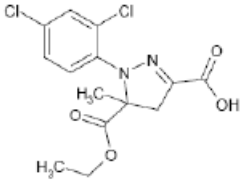
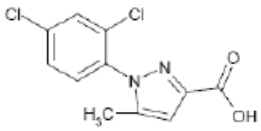
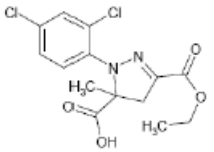
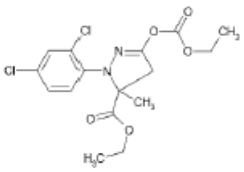
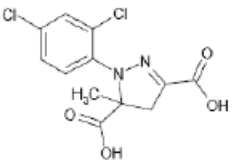
Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartements	Exposure assessment required due to
M11 (SYN504574)	362.4		metabolite found in lysimeter studies Lysimeter leachate max: 0.229 ~~0.06~~ µg/L (second year)	PEC_{gw}: leaching potential to groundwater PEC_{soil}: - $PEC_{sw/sed}$: -
M52 (SYN546105)	360.3		metabolite found in lysimeter studies Lysimeter leachate max: 0.130 µg/L (second year)	PEC_{gw}: leaching potential to groundwater PEC_{soil}: - $PEC_{sw/sed}$: -
M54 (SYN546106)	362.4		metabolite found in lysimeter studies Lysimeter leachate: 0.150 µg/L (second year)	PEC_{gw}: leaching potential to groundwater PEC_{soil}: - $PEC_{sw/sed}$: -
M55 (SYN546107)	376.4		metabolite found in lysimeter studies Lysimeter leachate max: 0.134 µg/L (second year)	PEC_{gw}: leaching potential to groundwater PEC_{soil}: - $PEC_{sw/sed}$: -
M56 (SYN546108)	360.4		metabolite found in lysimeter studies Lysimeter leachate max: 0.266 µg/L (third year)	PEC_{gw}: leaching potential to groundwater PEC_{soil}: - $PEC_{sw/sed}$: -

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

Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartements	Exposure assessment required due to
AE F113225	345.2		Soil: 44.1% (aerobic), 46.7% (anaerobic) Water/Sediment: 74.9% (water), 18.0% (sediment), 82.8% (total system)	PEC_{gw}: leaching potential to groundwater PEC_{soil}: > 10% of a.s. $PEC_{sw/sed}$: > 10% of a.s.
AE F094270	271.11		Soil: 72.2% (aerobic), 34.9% (anaerobic) Water/Sediment: 28.5% (water), 33.9% (sediment), 62.4% (total system)	PEC_{gw}: potential formation from F109453 PEC_{soil}: potential formation from F109453 $PEC_{sw/sed}$: > 10% of a.s.
AE F114952* *Metabolite AE F114952 is an isomer of metabolite AE F113225. It is considered that the assessment performed for AE F113225 for soil and groundwater covers the isomer AE F114952.	345.18		Soil: 11.5% (aerobic) Water/Sediment: 17.3% (water), 3.8% (sediment), 18.6% (total system)	PEC_{gw}: - PEC_{soil}: > 10% of a.s. $PEC_{sw/sed}$: > 10% of a.s.
AE 2211046	391.26		Soil: 11% (soil photolysis) Water/Sediment: 40.7% (aqueous photolysis)	PEC_{gw}: leaching potential to groundwater PEC_{soil}: > 10% of a.s. $PEC_{sw/sed}$: > 10% of a.s.
AE F109453	317.13		Water/Sediment: 42.0% (water), 5.6% (sediment, > 5% in 2 sequential measurements), 46.5% (total system)	PEC_{gw}: - PEC_{soil}: - $PEC_{sw/sed}$: > 10% of a.s.

zRMS comments:

Information regarding metabolites of mesosulfuron-methyl, pinoxaden and mefenpyr-diethyl provided in Tables 8.2-1 to 8.2-3 above is in general in line with EU agreed endpoints reported in:

- EFSA Journal 2016;14(10):4584 for mesosulfuron-methyl,
- EFSA Journal 2013;11(8):3269 for pinoxaden,
- Monograph (list of endpoints) voluntarily prepared by AGES and ANSES in the context of zonal authorisation of plant protection products containing safener mefenpyr-diethyl (October 2011)

Respective corrections were included by the zRMS where necessary.

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 Mesosulfuron-methyl and its metabolites

Table 8.3-1: Summary of aerobic degradation rates for mesosulfuron-methyl - laboratory studies (for modelling of parent alone)

Mesosufuron-methyl, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH [a]**	**t.oC**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi^2 (%)**	**Kinetic model**	**Evaluated on EU level y Reference**
CHL	Loamy sand	5.2	20	31.0	60.5	427	173.29	2.8	DFOP	EFSA Conclusion 4584/2016
SLI	Sandy loam	7.5	20	45.2	15.5	62.3	18.76	4.6	FOMC	EFSA Conclusion 4584/2016
SLV	Loamy sand	6.25	20	30.8	61.7	295.0	99.02	3.2	DFOP	EFSA Conclusion 4584/2016
CLF	Loam	7.3	20	47.5	15.98	53.1 ~~53.~~	15.44	2.0	SFO	EFSA Conclusion 4584/2016
FF	Loam	7.3	20	43.2	31.9	144.2	46.43	2.1	DFOP	EFSA Conclusion 4584/2016
SCL	Clay	7.3	20	59.8	67.7	822.4	242.77	5.7	DFOP	EFSA Conclusion 4584/2016
SLS	Silt loam	7.1	20	54.9	7.8	25.9	7.80	19.3	FOMC	EFSA Conclusion 4584/2016
LS 2.2, pyrimidyl label	Loamy sand	5.2	20	55.4	30.6	316.1	134.07	3.2	DFOP	EFSA Conclusion 4584/2016
LS 2.2, pheny label	Loamy sand	6.8	20	38.2	31.70	105.1	31.70	5.6	SFO	EFSA Conclusion 4584/2016
Geometric mean (n=9)							49.72			
pH-dependency: y/n							No			

[a] measured in calcium chloride solution

Table 8.3-2: Summary of aerobic degradation rates for mesosulfuron-methyl - laboratory studies (for modelling of parent with metabolites)

Mesosufuron-methyl, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH [a]**	**t.oC**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi^2 (%)**	**Kinetic model**	**Evaluated on EU level y Reference**
CHL	Loamy sand	5.2	20	31.0	77.3	256.9	77.3	9.1	SFO	EFSA Conclusion 4584/2016
SLI	Sandy loam	7.5	20	45.2	16.67	55.39	16.67	6.2	SFO	EFSA Conclusion 4584/2016
SLV	Loamy sand	6.25	20	30.8	71.6	238.0	71.6	7.2	SFO	EFSA Conclusion 4584/2016
CLF	Loam	7.3	20	47.5	16.0	53.0	15.46	2.0	SFO	EFSA Conclusion 4584/2016
FF	Loam	7.3	20	43.2	37.5	124.7	33.86	4.3	SFO	EFSA Conclusion 4584/2016
SCL	Clay	7.3	20	59.8	140.1	465.4	100.59	14.8	SFO	EFSA Conclusion 4584/2016
SLS	Silt loam	7.1	20	54.9	7.6	25.3	7.6	18.5	SFO	EFSA Conclusion 4584/2016

Mesosufuron-methyl, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH ([a])**	**t.oC**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi^2 (%)**	**Kinetic model**	**Evaluated on EU level y Reference**
LS 2.2, pyrimidyl label	Loamy sand	5.2	20	55.4	53.56	177.91	53.56	11.1	SFO	EFSA Conclusion 4584/2016
LS 2.2, pheny label	Loamy sand	6.8	20	38.2	31.44	104.44	31.44	5.6	SFO	EFSA Conclusion 4584/2016
Geometric mean (n=9)							34.09			
pH-dependency: y/n							No			

[a] measured in calcium chloride solution

Table 8.3-3: Summary of aerobic degradation rates for mesosulfuron (AE F154851) - laboratory studies

Mesosufuron (AE F154851), Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH ([a])**	**t.oC**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi^2 (%)**	**Kinetic model**	**Evaluated on EU level y Reference**
CHL	Loamy sand	5.2	20	31.0	76.74	254.91	76.74	9.3	SFO-SFO	EFSA Conclusion 4584/2016
SLI	Sandy loam	7.5	20	45.2	18.73	62.20	18.73	18.6	SFO-SFO	EFSA Conclusion 4584/2016
SLV	Loamy sand	6.25	20	30.8	38.52	127.95	38.52	15.7	SFO-SFO	EFSA Conclusion 4584/2016
CLF	Loam	7.3	20	47.5	46.35	153.97	44.77	13.4	SFO-SFO	EFSA Conclusion 4584/2016
FF	Loam	7.3	20	43.2	73.93	245.59	66.76	14.6	SFO-SFO	EFSA Conclusion 4584/2016
SCL	Clay	7.3	20	59.8	207.38	688.91	148.90	19.3	SFO-SFO	EFSA Conclusion 4584/2016
SLS	Silt loam	7.1	20	54.9	[b]	[b]	[b]	[b]	[b]	EFSA Conclusion 4584/2016
LS 2.2, pyrimidyl label	Loamy sand	5.2	20	55.4	21.52	71.49	21.52	26.1	SFO-SFO	EFSA Conclusion 4584/2016
LS 2.2, pheny label	Loamy sand	6.8	20	38.2	32.95	109.46	32.95	11.2	SFO-SFO	EFSA Conclusion 4584/2016
Geometric mean (n=8)							45.22			
pH-dependency: y/n							No			

[a] measured in calcium chloride solution
[b] no reliable value could be determined

Table 8.3-4: Summary of aerobic degradation rates for AE F160459 - laboratory studies

AE F160459 ~~AE F460459~~, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH ([a])**	**t.oC**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi^2 (%)**	**Kinetic model**	**Evaluated on EU level y Reference**
CHL	Loamy sand	5.2	20	31.0	[b]	[b]	[b]	[b]	[b]	EFSA Conclusion 4584/2016
SLI	Sandy loam	7.5	20	45.2	128.64	427.34	128.64	10.2	SFO-SFO	EFSA Conclusion 4584/2016
SLV	Loamy sand	6.25	20	30.8	[b]	[b]	[b]	[b]	[b]	EFSA Conclusion 4584/2016
CLF	Loam	7.3	20	47.5	38.6	128.23	32.29	14.3	SFO-	EFSA Conclusion

AE F160459 ~~AE F460459~~, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH (a)**	**t.oC**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi^2 (%)**	**Kinetic model**	**Evaluated on EU level y Reference**
									SFO	4584/2016
FF	Loam	7.3	20	43.2	76.0	252.47	68.63	9.9	SFO-SFO	EFSA Conclusion 4584/2016
SCL	Clay	7.3	20	59.8	129.8	431.0	93.20 ~~73.20~~	21.68	SFO-SFO	EFSA Conclusion 4584/2016
SLS	Silt loam	7.1	20	54.9	c	c	c	c	c	EFSA Conclusion 4584/2016
LS 2.2, pyrimidyl label	Loamy sand	5.2	20	55.4	c	c	c	c	c	EFSA Conclusion 4584/2016
LS 2.2, pheny label	Loamy sand	6.8	20	38.2	84.29	280.02	84.29	11.9	SFO-SFO	EFSA Conclusion 4584/2016
Geometric mean (n=5)							74.14			
pH-dependency: y/n							No			

[a] measured in calcium chloride solution
[b] not observed in this soil in amounts that would allow kinetic evaluation
[c] no reliable value could be determined

Table 8.3-5: Summary of aerobic degradation rates for AE F160460 - laboratory studies

AE F160460 ~~AE F460460~~, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH (a)**	**t.oC**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi^2 (%)**	**Kinetic model**	**Evaluated on EU level y Reference**
CHL	Loamy sand	5.2	20	31.0	b	b	b	b	b	EFSA Conclusion 4584/2016
SLI	Sandy loam	7.5	20	45.2	24.14	80.20	24.14	12.0	SFO-SFO	EFSA Conclusion 4584/2016
SLV	Loamy sand	6.25	20	30.8	b	b	b	b	b	EFSA Conclusion 4584/2016
CLF	Loam	7.3	20	47.5	37.07	123.15	35.81	30.3	SFO-SFO	EFSA Conclusion 4584/2016
FF	Loam	7.3	20	43.2	36.23	120.3	32.72	15.9	SFO-SFO	EFSA Conclusion 4584/2016
SCL	Clay	7.3	20	59.8	c	c	c	c	c	EFSA Conclusion 4584/2016
SLS	Silt loam	7.1	20	54.9	c	c	c	c	c	EFSA Conclusion 4584/2016
LS 2.2, pyrimidyl label	Loamy sand	5.2	20	55.4	44.22	196.9	44.22	29.9	Decline fit	EFSA Conclusion 4584/2016
LS 2.2, pheny label	Loamy sand	6.8	20	38.2	15.32	50.90	15.32	5.8	SFO-SFO	EFSA Conclusion 4584/2016
Geometric mean (n=5)							28.6			
pH-dependency: y/n							No			

[a] measured in calcium chloride solution
[b] not observed in this soil in amounts that would allow kinetic evaluation
[c] no reliable value could be determined

Table 8.3-6: Summary of aerobic degradation rates for AE F099095 - laboratory studies

AE F099095, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH ([a])**	**t.oC**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi^2 (%)**	**Kinetic model**	**Evaluated on EU level y Reference**
CHL	Loamy sand	5.2	20	31.0	185.52	616.28	185.52	4.5	SFO-SFO	EFSA Conclusion 4584/2016
SLI	Sandy loam	7.5	20	45.2	105.21	349.49	105.21	13.8	SFO-SFO	EFSA Conclusion 4584/2016
SLV	Loamy sand	6.25	20	30.8	[b]	[b]	[b]	[b]	[b]	EFSA Conclusion 4584/2016
CLF	Loam	7.3	20	47.5	80.16	266.29	77.43	18.4	SFO-SFO	EFSA Conclusion 4584/2016
FF	Loam	7.3	20	43.2	94.19	312.89	85.05	9.7	SFO-SFO	EFSA Conclusion 4584/2016
SCL	Clay	7.3	20	59.8	135.08	448.71	96.99	25.9	SFO-SFO	EFSA Conclusion 4584/2016
SLS	Silt loam	7.1	20	54.9	49.10	163.1	49.10	7.4	SFO-SFO	EFSA Conclusion 4584/2016
LS 2.2, pyrimidyl label	Loamy sand	5.2	20	55.4	27.90	92.68	27.90	16.28	SFO-SFO	EFSA Conclusion 4584/2016
LS 2.2, pheny label	Loamy sand	6.8	20	38.2	[c]	[c]	[c]	[c]	[c]	EFSA Conclusion 4584/2016
Not provided	Sandy loam	5.3	20	pF2	58.82	195.4	58.82	2.73	SFO	EFSA Conclusion 4584/2016
Not provided	Sandy clay loam	6.9	20	pF2	23.16	76.93	23.16	3.25	SFO	EFSA Conclusion 4584/2016
Not provided	Clay	7.2	20	pF2	12.2	40.51	12.2	4.68	SFO	EFSA Conclusion 4584/2016
Geometric mean (n=10)							55.6			
pH-dependency: y/n							No			

[a] measured in calcium chloride solution
[b] no reliable value could be determined
[c] not traced at this radiolabel position

Table 8.3-7: Summary of aerobic degradation rates for AE F140584 - laboratory studies

AE F140584, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH ([a])**	**t.oC**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi^2 (%)**	**Kinetic model**	**Evaluated on EU level y Reference**
CHL	Loamy sand	5.2	20	31.0	[b]	[b]	[b]	[b]	[b]	EFSA Conclusion 4584/2016
SLI	Sandy loam	7.5	20	45.2	[b]	[b]	[b]	[b]	[b]	EFSA Conclusion 4584/2016
SLV	Loamy sand	6.25	20	30.8	[b]	[b]	[b]	[b]	[b]	EFSA Conclusion 4584/2016
CLF	Loam	7.3	20	47.5	[b]	[b]	[b]	[b]	[b]	EFSA Conclusion 4584/2016
FF	Loam	7.3	20	43.2	[b]	[b]	[b]	[b]	[b]	EFSA Conclusion 4584/2016
SCL	Clay	7.3	20	59.8	[b]	[b]	[b]	[b]	[b]	EFSA Conclusion 4584/2016
SLS	Silt loam	7.1	20	54.9	[b]	[b]	[b]	[b]	[b]	EFSA Conclusion 4584/2016
LS 2.2, pyrimidyl label	Loamy sand	5.2	20	55.4	[b]	[b]	[b]	[b]	[b]	EFSA Conclusion 4584/2016

AE F140584, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH ([a])**	**t.oC**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi^2 (%)**	**Kinetic model**	**Evaluated on EU level y Reference**
LS 2.2, pheny label	Loamy sand	6.8	20	38.2	13.45	44.66	13.45	39.7	SFO-SFO	EFSA Conclusion 4584/2016
Not provided	Sandy loam	6.3	20	55	4.02	13.34	4.02	4.2	SFO	EFSA Conclusion 4584/2016
Not provided	Sand	5.8	20	55	7.04	23.38	7.04	2.1	SFO	EFSA Conclusion 4584/2016
Not provided	Silt loam	6.4	20	55	2.35	7.81	2.35	6.8	SFO	EFSA Conclusion 4584/2016
Not provided	Loam	7.2	20	55	1.49	4.94	1.49	5.4	SFO	EFSA Conclusion 4584/2016
Geometric mean (n=5)							4.22 ~~74.14~~			
pH-dependency: y/n							No			

[a] measured in calcium chloride solution
[b] not observed in this soil in amounts that would allow kinetic evaluation

Table 8.3-8: Summary of aerobic degradation rates for AE F147447 - laboratory studies

AE F147447, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH ([a])**	**t.oC**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi^2 (%)**	**Kinetic model**	**Evaluated on EU level y Reference**
CHL	Loamy sand	5.2	20	31.0	[b]	[b]	[b]	[b]	[b]	EFSA Conclusion 4584/2016
~~SLI~~	~~Sandy loam~~	~~7.5~~	~~20~~	~~45.2~~	~~128.64~~	~~427.34~~	~~128.64~~	~~10.2~~	~~SFO-SFO~~	~~EFSA Conclusion 4584/2016~~
SLV	Loamy sand	6.25	20	30.8	[b]	[b]	[b]	[b]	[b]	EFSA Conclusion 4584/2016
CLF	Loam	7.3	20	47.5	[b]	[b]	[b]	[b]	[b]	EFSA Conclusion 4584/2016
FF	Loam	7.3	20	43.2	[b]	[b]	[b]	[b]	[b]	EFSA Conclusion 4584/2016
SCL	Clay	7.3	20	59.8	[b]	[b]	[b]	[b]	[b]	EFSA Conclusion 4584/2016
SLS	Silt loam	7.1	20	54.9	[b]	[b]	[b]	[b]	[b]	EFSA Conclusion 4584/2016
LS 2.2, pyrimidyl label	Loamy sand	5.2	20	55.4	[b]	[b]	[b]	[b]	[b]	EFSA Conclusion 4584/2016
LS 2.2, pheny label	Loamy sand	6.8	20	38.2	157.14	522.0	157.14	11.9	SFO-SFO	EFSA Conclusion 4584/2016
Not provided	Loam	6.1	20	55	60.6	201.3	60.6	4.9	SFO	EFSA Conclusion 4584/2016
Not provided	Sandy loam	6.4	20	55	78.5	260.7	78.5	4.5	SFO	EFSA Conclusion 4584/2016
Not provided	Silt loam	6.3	20	55	54.76	526.0	202.97	3.9	HS	EFSA Conclusion 4584/2016
Not provided	Clay loam	7.1	20	55	31.12	201.2	73.32	3.0	DFOP	EFSA Conclusion 4584/2016
Geometric mean (n=5)							102.15 (162.8[c])			
pH-dependency: y/n							No			

[a] measured in calcium chloride solution
[b] not observed in this soil in amounts that would allow kinetic evaluation
[c] value used for PEC_{GW} and PEC_{SW} based on SFO, please refer to EFSA Conclusion 4584/2016

Table 8.3-9: Summary of aerobic degradation rates for AE F092944 - laboratory studies

AE F092944, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH ([a])**	**t.oC**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi^2 (%)**	**Kinetic model**	**Evaluated on EU level y Reference**
CHL	Loamy sand	5.2	20	31.0	13.97	46.39	13.97	23.8	SFO-SFO	EFSA Conclusion 4584/2016
SLI	Sandy loam	7.5	20	45.2	[c]	[c]	[c]	[c]	[c]	EFSA Conclusion 4584/2016
SLV	Loamy sand	6.25	20	30.8	[c]	[c]	[c]	[c]	[c]	EFSA Conclusion 4584/2016
CLF	Loam	7.3	20	47.5	62.55	207.77	60.42	21.3	SFO-SFO	EFSA Conclusion 4584/2016
FF	Loam	7.3	20	43.2	[c]	[c]	[c]	[c]	[c]	EFSA Conclusion 4584/2016
SCL	Clay	7.3	20	59.8	[b]	[b]	[b]	[b]	[b]	EFSA Conclusion 4584/2016
SLS	Silt loam	7.1	20	54.9	[b]	[b]	[b]	[b]	[b]	EFSA Conclusion 4584/2016
LS 2.2, pyrimidyl label	Loamy sand	5.2	20	55.4	80.52	267.49	80.52	27.1	SFO-SFO	EFSA Conclusion 4584/2016
LS 2.2, pheny label	Loamy sand	6.8	20	38.2	[c]	[c]	[c]	[c]	[c]	EFSA Conclusion 4584/2016
Collombey	Not provided	7.6	20	44.2	2.9	9.6	2.9	6.3	SFO	EFSA Conclusion 4584/2016
Speyer 2.2	Not provided	6.0	20	44.3	4.9	34.8	10.48	2.3	FOMC	EFSA Conclusion 4584/2016
Les Evouettes	Not provided	7.3	20	53.4	9.0	72.4	19.6	2.6	FOMC	EFSA Conclusion 4584/2016
Nambsheim	Sandy loam	8.0	20	50	8.9	116	30.8	6.0	FOMC	EFSA Conclusion 4584/2016
Pavia	Loamy sand	5.5	20	50	9.7	231.3	173.3	4.0	HS	EFSA Conclusion 4584/2016
Speyer 2.2	Sandy loam	6.7	20	50	2.5	12.0	3.6	4.0	FOMC	EFSA Conclusion 4584/2016
Vercelli	Silt loam	6.1	20	50	6.0	122.3	30.6	5.0	FOMC	EFSA Conclusion 4584/2016
Not provided	Sandy loam	7.3	20	40	6.4	30.3	8.0	5.1	FOMC	EFSA Conclusion 4584/2016
Uffholz	Loam	6.1	20	40	5.25	34.97	11.2	3.6	DFOP	EFSA Conclusion 4584/2016
Otzberg	Silt loam	7.4	20	40	5.9	19.6	4.4	5.7	SFO	EFSA Conclusion 4584/2016
Geometric mean (n=13)							16.93			
pH-dependency: y/n							No			

[a] measured in calcium chloride solution
[b] not observed in this soil in amounts that would allow kinetic evaluation
[c] no reliable value could be determined

Table 8.3-10: Summary of aerobic degradation rates for BCS CV14885 - laboratory studies

BCS CV14885, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH (a)**	**t.oC**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi^2 (%)**	**Kinetic model**	**Evaluated on EU level y Reference**
Not provided	Sandy loam	6.5	20	55	113.6	377.2	113.6	3.77	SFO	EFSA Conclusion 4584/2016
Not provided	Clay loam	7.3	20	55	125.7	417.5	125.7	3.01	SFO	EFSA Conclusion 4584/2016
Not provided	Silt loam	6.4	20	55	102.8	341.4	97.7	3.48	SFO	EFSA Conclusion 4584/2016
Not provided	Sandy loam	5.4	20	55	65.06	216.1	65.06	5.23	SFO	EFSA Conclusion 4584/2016
Geometric mean (n=4)							97.6			
pH-dependency: y/n							No			

[a] measured in calcium chloride solution

zRMS comments:

Soil laboratory degradation data for mesosulfuron-methyl and its metabolites are in general in line with EU agreed endpoints reported in EFSA Journal 2016;14(10):4584. Some corrections were introduced by the zRMS in Tables 8.3-1 and 8.3-4, 8.3-5, 8.3-7 and 8.3-8 so presented data are fully compliant with EFSA Journal 2016;14(10):4584.

8.3.1.2 Pinoxaden and its metabolites

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

Pinoxaden, Laboratory studies, aerobic conditions										
Soil name	**Soil type (USDA)**	**pH**	**t. (°C)**	**Moisture**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi^2 (%)**	**Kinetic model**	**Evaluated on EU level / Reference**
Gartenacker	Loam/Silt loam	7.23 (KCl)	20	40% MWHC	0.13	0.44	0.08	12.7	SFO	EFSA Conclusion 3269/2013
Gartenacker	Silt loam	7.32 (KCl)	20	40% MWHC	0.23	0.76	0.16	5.0	SFO	EFSA Conclusion 3269/2013
Plaza	Loamy sand	8.0 (not quoted)	25	75% FMC	0.15	0.48	0.21	8.9	SFO	EFSA Conclusion 3269/2013
Plaza	Loamy sand	7.7 (not quoted)	25	75% FMC	0.23	0.75	0.29	6.6	SFO	EFSA Conclusion 3269/2013
Plaza	Loamy sand	7.7 (not quoted)	25	75% FMC	0.19	0.62	0.24	4.4	SFO	EFSA Conclusion 3269/2013
Birkenheide	Sandy loam	6.04 ($CaCL_2$)	20	40% MWHC	1.05	3.48	0.70	10.0	SFO	EFSA Conclusion 3269/2013
Borstel	Loamy sand	5.1 (not quoted)	20	40% MWHC	2.30	7.63	-	17.1	SFO	EFSA Conclusion 3269/2013
Borstel	Weak loamy sand	6.70 ($CaCl_2$)	20	40% MWHC	0.43	1.43	-	19.2	SFO	EFSA Conclusion 3269/2013
Marsillargues	Silty clay loam	7.9 (not quoted)	20	40% MWHC	0.39	1.31	0.30	4.6	SFO	EFSA Conclusion 3269/2013
Marsillargues	Silty clay loam	7.00 ($CaCl_2$)	20	40% MWHC	0.37	1.21	0.27	12.8	SFO	EFSA Conclusion 3269/2013

Pinoxaden, Laboratory studies, aerobic conditions										
Soil name	**Soil type (USDA)**	**pH**	**t. (°C)**	**Moisture**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi^2 (%)**	**Kinetic model**	**Evaluated on EU level / Reference**
18 Acres	Sandy clay loam	5.8 (KCl)	20	40% MWHC	0.76	2.54	0.81	6.8	SFO	EFSA Conclusion 3269/2013
Pappelacker	Sand	6.70* ($CaCl_2$)	20	40% MWHC	0.10	0.33	-	24.4	SFO	EFSA Conclusion 3269/2013
Welver-Borgeln	Silt laom	6.70 ($CaCl_2$)	20	40% MWHC	0.24	0.80	-	18.6	SFO	EFSA Conclusion 3269/2013
Geometric mean (n=9)							0.34			
pH-dependency:							No			

* (mistakenly reported as 1.14 in EFSA conclusion)

Table 8.3-12: Summary of aerobic degradation rates for M2 (NOA407854) - laboratory studies

M2 (NOA407854), Laboratory studies, aerobic conditions										
Soil name	**Soil type (USDA)**	**pH**	**t. (°C)**	**Moisture**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi^2 (%)**	**Kinetic model**	**Evaluated on EU level / Reference**
Gartenacker	Loam/ Silt loam	7.23 (KCl)	20	40% MWHC	15.8	54.4	10.3	11.7	SFO	EFSA Conclusion 3269/2013
Gartenacker	Silt loam	7.32 (KCl)	20	40% MWHC	12.3	41.0	8.4	12.3	SFO	EFSA Conclusion 3269/2013
Plaza	Loamy sand	8.0 (not quoted)	25	75% FMC	6.1	20.2	8.4	9.6	SFO	EFSA Conclusion 3269/2013
Plaza	Loamy sand	7.7 (not quoted)	25	75% FMC	2.4	7.9	3.1	8.8	SFO	EFSA Conclusion 3269/2013
Plaza	Loamy sand	7.7 (not quoted)	25	75% FMC	3.0	10.0	3.8	5.9	SFO	EFSA Conclusion 3269/2013
Marsillargues	Silty clay loam	7.9 (H_20)	20	40% MWHC	42.2	140.1	32.9	4.5	SFO	EFSA Conclusion 3269/2013
Marsillargues	Silty clay loam	7.00 ($CaCl_2$)	20	40% MWHC	57.8	192.1	57.8	3.5	SFO	EFSA Conclusion 3269/2013
Geometric mean (n=7)							17.1			
pH-dependency:							No			

Table 8.3-13: Summary of aerobic degradation rates for M3 (NOA447204) - laboratory studies, alkaline conditions

M3 (NOA447204), Laboratory studies, aerobic conditions, alkaline conditions										
Soil name	**Soil type (USDA)**	**pH**	**t. (°C)**	**Moisture**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi^2 (%)**	**Kinetic model**	**Evaluated on EU level / Reference**
Plaza	Loamy sand	8.0 (not quoted)	25	75% FMC	36.9	122.6	50.9	16.9	SFO	EFSA Conclusion 3269/2013
Plaza	Loamy sand	7.7 (not quoted)	25	75% FMC	50.6	168.0	64.8	8.6	SFO	EFSA Conclusion 3269/2013
Plaza	Loamy sand	7.7 (not quoted)	25	75% FMC	39.6	131.6	50.7	17.5	SFO	EFSA Conclusion 3269/2013

M3 (NOA447204), Laboratory studies, aerobic conditions, alkaline conditions										
Soil name	**Soil type (USDA)**	**pH**	**t. (°C)**	**Moisture**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi^2 (%)**	**Kinetic model**	**Evaluated on EU level / Reference**
Marsillargues	Silty clay loam	7.90 (H_20)	20	40% MWHC	117.0	388.7	91.3	12.2	SFO	EFSA Conclusion 3269/2013
Marsillargues	Silty clay loam	7.00 ($CaCl_2$)	20	40% MWHC	103.4	343.4	74.6	8.2	SFO	EFSA Conclusion 3269/2013
Geometric mean (n=5)							67.4			
pH-dependency:							Yes			

Table 8.3-14: Summary of aerobic degradation rates for M3 (NOA447204) - laboratory studies, acidic conditions

M3 (NOA447204), Laboratory studies, aerobic conditions, acidic conditions										
Soil name	**Soil type (USDA)**	**pH ($CaCl_2$)**	**t. (°C)**	**Moisture at pF 2.0 (w/w%)**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi^2 (%)**	**Kinetic model**	**Evaluated on EU level / Reference**
Krone	Silt loam	6.0	20	41	387.2	1286.3	387.2	16.9	HS	EFSA Conclusion 3269/2013
18 Acres	Sandy clay loam	6.1	20	28.2	129.7	430.8	129.7	8.6	SFO	EFSA Conclusion 3269/2013
Borstel	Loamy sand	5.0	20	14.2	179.0	594.6	179.0	17.5	SFO	EFSA Conclusion 3269/2013
Geometric mean (n=3)							208			
pH-dependency:							Yes			

Table 8.3-15: Summary of aerobic degradation rates for M11 (SYN504574) - laboratory studies, acidic conditions

M11 (SYN504574), Laboratory studies, aerobic conditions										
Soil name	**Soil type (USDA)**	**pH (H_2O)**	**t. (°C)**	**Moisture at pF 2.0 (w/w%)**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi2 (%)**	**Kinetic model**	**Evaluated on EU level / Reference**
Gartenacker	Silt loam	7.53	20	39.0	7.7 ~~7.6~~	25.5 ~~25.2~~	7.7 ~~7.6~~	5.6 ~~6.1~~	SFO	Addendum 1 to pinoxaden RAR, Vol. 3CA, B.8 (May 2022) ~~No / Robinson, 2012aa~~
18 Acres	Sandy clay loam	6.10	20	26.8	9.6 ~~13.0~~	75.1 ~~43.3~~	22.6[b] ~~13.0~~	4.3 ~~9.8~~	FOMC ~~SFO~~	Addendum 1 to pinoxaden RAR, Vol. 3CA, B.8 (May 2022) ~~No / Robinson, 2012aa~~
Marsillargues	Silty clay loam	8.08	20	22.7	9.3 ~~9.2~~	30.8 ~~30.7~~	9.3 ~~9.2~~	2.7 ~~3.5~~	SFO	Addendum 1 to pinoxaden RAR, Vol. 3CA, B.8 (May 2022) ~~No / Robinson, 2012aa~~
Geometric mean (n=3)							11.7 ~~9.7~~			
pH-dependency:							No			

~~[a] Syngenta submitted data on aerobic degradation rates for metabolite M11 (SYN504574) as confirmatory data in the EU review of pinoxaden.~~

(b): Pseudo SFO-*DegT50*: FOMC-*DegT90* / 3.32

Table 8.3-16: Summary of aerobic degradation rates for M52 (SYN546105) - laboratory studies, acidic conditions

M52 (SYN546105), Laboratory studies, aerobic conditions										
Soil name	**Soil type (USDA)**	**pH (H_2O)**	**t. (°C)**	**Moisture at pF 2.0 (w/w%)**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi^2 (%)**	**Kinetic model**	**Evaluated on EU level / Reference**
Gartenacker	Silt loam	7.35	20	39.0	0.7 ~~0.8~~	28.1 ~~16.8~~	8.4[b] ~~0.8~~	6.2 ~~2.7~~	FOMC ~~HS~~	Addendum 1 to pinoxaden RAR, Vol. 3CA, B.8 (May 2022) ~~No / Völkel, 2012a[a]~~
18 Acres	Loam	6.49	20	26.8	1.1	18.7 ~~17.4~~	5.6[b] ~~1.1~~	5.9 ~~3.8~~	FOMC ~~DFOP~~	Addendum 1 to pinoxaden RAR, Vol. 3CA, B.8 (May 2022) ~~No / Völkel, 2012a[a]~~
Marsillargues	Silty clay loam	8.19	20	22.7	1.0	26.3	12.6[c] ~~1.0~~	2.5	HS	Addendum 1 to pinoxaden RAR, Vol. 3CA, B.8 (May 2022) ~~No / Völkel, 2012a[a]~~
Geometric mean (n=3)							8.4			
pH-dependency:							No			

~~[a] Syngenta submitted data on aerobic degradation rates for metabolite M52 (SYN546105) as confirmatory data in the EU review of pinoxaden.~~

(b): Pseudo SFO-*DegT50*: FOMC-*DegT90* / 3.32
(c): HS slow phase rate (k_2)

Table 8.3-17: Summary of aerobic degradation rates for M54 (SYN546106) - laboratory studies, acidic conditions

M54 (SYN546106), Laboratory studies, aerobic conditions										
Soil name	**Soil type (USDA)**	**pH (H_2O)**	**t. (°C)**	**Moisture at pF 2.0 (w/w%)**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi^2 (%)**	**Kinetic model**	**Evaluated on EU level / Reference**
Gartenacker	Silt loam	7.35	20	39.0	4.9	16.4	4.9 ~~5.4~~	5.4	SFO	Addendum 1 to pinoxaden RAR, Vol. 3CA, B.8 (May 2022) ~~No / Völkel, 2012b[a]~~
18 Acres	Loam	6.10	20	26.8	9.3	30.9 ~~30.8~~	9.3 ~~5.5~~	5.5	SFO	Addendum 1 to pinoxaden RAR, Vol. 3CA, B.8 (May 2022) ~~No / Völkel, 2012b[a]~~
Marsillargues	Silty clay loam	8.08	20	22.7	9.3 ~~9.2~~	30.9 ~~30.6~~	9.3 ~~8.8~~	7.0	SFO	Addendum 1 to pinoxaden RAR, Vol. 3CA, B.8 (May 2022) ~~No / Völkel, 2012b[a]~~
Geometric mean (n=3)							7.5			
pH-dependency:							No			

~~[a] Syngenta submitted data on aerobic degradation rates for metabolite M54 (SYN546106) as confirmatory data in the EU review of pinoxaden.~~

Table 8.3-18: Summary of aerobic degradation rates for M55 (SYN546107) - laboratory studies, acidic conditions

M55 (SYN546107), Laboratory studies, aerobic conditions										
Soil name	**Soil type (USDA)**	**pH (H_2O)**	**t.(°C)**	**Moisture at pF 2.0 (w/w%)**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi^2 (%)**	**Kinetic model**	**Evaluated on EU level / Reference**
Gartenacker	Silt loam	7.53	20	39.0	9.6	31.9	9.6	7.1	SFO	Addendum 1 to pinoxaden RAR, Vol. 3CA, B.8 (May 2022) ~~No / Robinson, 2012b[a]~~
18 Acres	Sandy clay loam	6.49	20	29.8	75.4 ~~86.3~~	321 ~~286.8~~	106[b]	1.1 ~~5.8~~	DFOP ~~SFO~~	Addendum 1 to pinoxaden RAR, Vol. 3CA, B.8 (May 2022) ~~No / Robinson, 2012b[a]~~
Marsillargues	Silty clay loam	8.19	20	22.7	5.3	17.5	5.3	8.6	SFO	Addendum 1 to pinoxaden RAR, Vol. 3CA, B.8 (May 2022) ~~No / Robinson, 2012b[a]~~
						Geometric mean ~~Worst case~~ (n=3)	17.5 ~~106~~			
						pH-dependency:	No			

~~[a] Syngenta submitted data on aerobic degradation rates for metabolite M55 (SYN546107) as confirmatory data in the EU review of pinoxaden. .~~

(b): DFOP slow phase (k_2)

Table 8.3-19: Summary of aerobic degradation rates for M56 (SYN546108) - laboratory studies, acidic conditions

M56 (SYN546108), Laboratory studies, aerobic conditions										
Soil name	**Soil type (USDA)**	**pH (H_2O)**	**t.(°C)**	**Moisture at pF 2.0 (w/w%)**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi^2 (%)**	**Kinetic model**	**Evaluated on EU level / Reference**
Gartenacker	Silt loam	7.44	20	38.95	39.1	129.7	39.1	7.5	SFO	Addendum 1 to pinoxaden RAR, Vol. 3CA, B.8 (May 2022) ~~No /Caviezel, 2013a[a]~~
18 Acres	Loam	6.40	20	29.78	110.3	366.4	110.3	4.7	SFO	Addendum 1 to pinoxaden RAR, Vol. 3CA, B.8 (May 2022) ~~No /Caviezel, 2013a[a]~~
Marsillargues	Silty clay laom	8.06	20	22.71	76.1 ~~91.3~~	375 ~~303.4~~	129[b] ~~91.3~~	2.7 ~~8.3~~	HS ~~SFO~~	Addendum 1 to pinoxaden RAR, Vol. 3CA, B.8 (May 2022) ~~No /Caviezel, 2013a[a]~~
						Geometric mean (n=3)	82.2 ~~73.3~~			
						pH-dependency:	No			

~~[a] Syngenta submitted data on aerobic degradation rates for metabolite M56 (SYN546108) as confirmatory data in the EU review of pinoxaden.~~

(b): HS slow phase (k_2)

zRMS comments:

Soil laboratory degradation data for pinoxaden and its metabolites M2 and M3 presented in Table 8.3-11 to 8.3-14 are in line with EU agreed endpoints reported in EFSA Journal 2013;11(8):3269.

The soil degradation data for metabolites M11 (SYN504574), M52 (SYN546105), M54 (SYN546106), M55 (SYN546107) and M56 (SYN546108) were obtained in new studies referred to by the Applicant. Although, in general, the product assessment should be carried out according to the currently agreed EU endpoints, the Working Document of the Central Zone in area of Section 8, identifies situation when new active substance data may be considered in the Core Assessments:

> *[...] Note that according to the guidance document on the evaluation of new active substance data post approval (SANCO/10328/2004– rev 8, 24.01.2012) new active substance/metabolite data should not be considered unless they are necessary in order to show a safe use, they are needed as additional uses/crops are applied for authorisation, or they are "adverse" data. [...]*

As for some pinoxaden metabolites the predicted concentrations in groundwater exceeded 10.0 µg/L at Tier 1 assessment based on EU agreed inputs, consideration of the new data was fully justified to enable refined groundwater modelling.

Before evaluation of the new studies, the zRMS checked if they were evaluated at the EU level in the course of the renewal process or as a part of the confirmatory data. It turned out that all these studies are presented in Addendum 1 to pinoxaden RAR (Vol. 3CA, B.8) issued by RMS (AT) in May 2022 and were considered in the exposure assessment in Addendum 1 to Vol. 3CP, B.8. It is noted that the Addendum 1 (May 2022) was not commented yet by MS and EFSA, however, there is no need to perform separate evaluation at the zonal level as the studies were already evaluated by the RMS (AT). Nevertheless, the zRMS reviewed the assessment performed by AT and in general agrees with the derived endpoints and does not expect that they will substantially change following the peer-review. Since the endpoints agreed by the RMS are different than values proposed by the Applicant, Tables 8.3-15 to 8.3-19 above were corrected accordingly to provide endpoints as agreed by the RMS.

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

8.3.1.3 Mefenpyr-diethyl and its metabolites

Table 8.3-20: Summary of aerobic degradation rates for Mefenpyr-diethyl - laboratory studies, acidic conditions

Mefenpyr-diethyl, Laboratory studies, aerobic conditions										
Soil name	**Soil type (USDA)**	**pH (H_2O)**	**t. (°C)**	**Moisture at pF 2.0 (w/w%)**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi^2 (%)**	**Kinetic model**	**Evaluated on EU level / Reference**
Not provided	Sandy loam	5.0	25	40	2.90	9.64	4.1	11.0	SFO	Proposed in Monograph (list of endpoints) Oct 2011[a]
Not provided	Loamy sand	6.1	25	40	1.54	5.12	2.4	15.1	SFO	Proposed in Monograph (list of endpoints) Oct 2011[a]
Not provided	Silt loam	6.1	20	40	2.32	7.69	1.7[b]	10.9	SFO	Proposed in Monograph (list of endpoints) Oct 2011[a]
Mefenpyr-diethyl, Laboratory studies, aerobic conditions										
Not provided	Silt loam	6.1	20	60	1.06	3.52	1.1 [b]	17.2	SFO	Proposed in Monograph (list of endpoints) Oct 2011[a]
Not provided	Loamy sand	7.1	20	40	2.44	8.11	2.3	18.4	SFO	Proposed in Monograph (list of endpoints) Oct 2011[a]
Geometric mean (n=4)							2.4			
pH-dependency:							No			

[a] Monograph has been voluntarily prepared by AGES and ANSES in the context of zonal authorisation of plant protection products containing safener mefenpyr-diethyl.
[b] Since there are 2 DT_{50} values from the same soils, the geometric mean of both values was calculated first (1.4 days) and used as on single value in the calculation of the overall geometric mean.

Table 8.3-21: Summary of aerobic degradation rates for AE F113225 - laboratory studies, acidic conditions

AE F113225, Laboratory studies, aerobic conditions										
Soil name	**Soil type (USDA)**	**pH (H_2O)**	**t. (°C)**	**Moisture at pF 2.0 (w/w%)**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi^2 (%)**	**Kinetic model**	**Evaluated on EU level / Reference**
Not provided	Sandy loam	5.0	25	40	5.68	18.89	7.9	20.4	SFO	Proposed in Monograph (list of endpoints) Oct 2011[a]
Not provided	Loamy sand	6.1	25	40	6.77	22.50	10.6	11.7	SFO	Proposed in Monograph (list of endpoints) Oct 2011[a]
Not provided	Silt loam	6.1	20	40	3.47	11.52	2.61[b]	7.4	SFO	Proposed in Monograph (list of endpoints) Oct 2011[a]
Not provided	Silt loam	6.1	20	60	4.56	15.17	4.55 [b]	2.5	SFO	Proposed in Monograph (list of endpoints) Oct 2011[a]
Not provided	Loamy sand	7.1	20	40	4.89	16.24	4.59	16.8	SFO	Proposed in Monograph (list of endpoints) Oct 2011[a]
Geometric mean (n=4)							6.1			
pH-dependency:							No			

[a] Monograph has been voluntarily prepared by AGES and ANSES in the context of zonal authorisation of plant protection products containing safener mefenpyr-diethyl.

[b] Since there are 2 DT_{50} values from the same soils, the geometric mean of both values was calculated first (3.5 days) and used as on single value in the calculation of the overall geometric mean.

Table 8.3-22: Summary of aerobic degradation rates for AE F094270 - laboratory studies, acidic conditions

AE F094270, Laboratory studies, aerobic conditions										
Soil name	**Soil type (USDA)**	**pH (H_2O)**	**t. (°C)**	**Moisture at pF 2.0 (w/w%)**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi^2 (%)**	**Kinetic model**	**Evaluated on EU level / Reference**
Not provided	Sandy loam	5.0	25	40	270.8	900	379	6.7	SFO	Proposed in Monograph (list of endpoints) Oct 2011[a]
Not provided	Loamy sand	6.1	25	40	258.7	859	406	4.6	SFO	Proposed in Monograph (list of endpoints) Oct 2011[a]
Not provided	Silt loam	6.1	20	40	91.2	303	68[b]	3.9	SFO	Proposed in Monograph (list of endpoints) Oct 2011[a]
Not provided	Silt loam	6.1	20	60	53.1	176	53 [b]	8.2	SFO	Proposed in Monograph (list of endpoints) Oct 2011[a]
Not provided	Loamy sand	7.1	20	40	266.2	884	250	8.1	SFO	Proposed in Monograph (list of endpoints) Oct 2011[a]
Not provided	Silt loam	6.8	20	50	126	418	126	4.0	SFO	Proposed in Monograph (list of endpoints) Oct 2011[a]
Not provided	Sandy loam	6.2	20	45	314	>1000	314	1.6	SFO	Proposed in Monograph (list of endpoints) Oct 2011a
Not provided	Clay loam	7.4	20	50	152	505	152	3.6	SFO	Proposed in Monograph (list of endpoints) Oct 2011[a]
Geometric mean (n=4)							202			
pH-dependency:							No			

[a] Monograph has been voluntarily prepared by AGES and ANSES in the context of zonal authorisation of plant protection products containing safener mefenpyr-diethyl.
[b] Since there are 2 DT_{50} values from the same soils, the geometric mean of both values was calculated first (60 days) and used as on single value in the calculation of the overall geometric mean.

zRMS comments:

Soil laboratory degradation data for mefenpyr-diethyl and its metabolites presented in tables above are in line with the Monograph (list of endpoints) prepared in October 2011 by ANSES and AGES in order to aid zonal evaluations of the products containing this safener.

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

8.3.2.1 Mesosulfuron-methyl and its metabolites

Table 8.3-23: Summary of anaerobic degradation rates for mesosulfuron-methyl - laboratory studies

Mesosufuron-methyl, Laboratory studies, anaerobic conditions										
Soil name	**Soil type**	**pH ([a])**	**t.oC**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi^2 (%)**	**Kinetic model**	**Evaluated on EU level y Reference**
n/p (pyrimidyl label)	Sandy loam	5.4	20	n/p	30.1	n/p	n/p	n/p	SFO	EFSA Conclusion 4584/2016
n/p (pheny label)	Sandy loam	5.4	20	n/p	30.5	n/p	n/p	n/p	SFO	EFSA Conclusion 4584/2016
Geometric mean (n=2)							n/p			
pH-dependency: y/n							n/p			

[a] measured in calcium chloride solution
n/p not provided

Table 8.3-24: Summary of anaerobic degradation rates for AE F160459 - laboratory studies

AE F160459, Laboratory studies, anaerobic conditions										
Soil name	**Soil type**	**pH ([a])**	**t.oC**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi^2 (%)**	**Kinetic model**	**Evaluated on EU level y Reference**
n/p (pyrimidyl label)	Sandy loam	5.4	20	n/p	70.2	n/p	n/p	n/p	SFO	EFSA Conclusion 4584/2016
n/p (pheny label)	Sandy loam	5.4	20	n/p	81.4	n/p	n/p	n/p	SFO	EFSA Conclusion 4584/2016
Geometric mean (n=2)							n/p			
pH-dependency: y/n							n/p			

[a] measured in calcium chloride solution
n/p not provided

zRMS comments:

Anaerobic soil degradation data for mesosulfuron-methyl and its metabolite presented in Tables 8.3-23 and 8.3-24 are in line with EU agreed endpoints reported in EFSA Journal 2016;14(10):4584.

8.3.2.2 Pinoxaden and its metabolites

Table 8.3-25: Summary of anaerobic degradation rates for pinoxaden - laboratory studies

Pinoxaden, Laboratory studies, anaerobic conditions										
Soil name	**Soil type**	**pH**	**t.oC**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi^2 (%)**	**Kinetic model**	**Evaluated on EU level y Reference**
Gartenacker	Loam/ Silt loam	7.23	20	40	0.2	0.6	n/p	n/p	SFO	EFSA Conclusion 3269/2013

n/p not provided

Table 8.3-26: Summary of anaerobic degradation rates for M2 (NOA407854) - laboratory studies

M2 (NOA407854), Laboratory studies, anaerobic conditions										
Soil name	**Soil type**	**pH**	**t.oC**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi^2 (%)**	**Kinetic model**	**Evaluated on EU level y Reference**
Gartenacker	Loam/ Silt loam	7.23	20	40	Stable	Stable	n/p	n/p	SFO	EFSA Conclusion 3269/2013

n/p not provided

zRMS comments:

Anaerobic soil degradation data for pinoxaden and its metabolite presented in tables above are in line with EU agreed endpoints reported in EFSA Journal 2013;11(8):3269.

8.3.2.3 Mefenpyr-diethyl and its metabolites

No soil degradation studies conducted under anaerobic conditions are available for mefenpyr-diethyl and its metabolites in the Monograph (list of endpoints) dated October 2011.

zRMS comments:

No EU agreed endpoints exist for mefenpyr-diethyl and its metabolites.

8.4 Field studies (KCP 9.1.1.2)

8.4.1.1 Mesosulfuron-methyl and its metabolites

Table 8.4-1: Summary of aerobic degradation rates for mesosulfuron-methyl – field soil dissipation studies

Mesosulfuron-methyl, field soil dissipation studies, anaerobic conditions										
Location	**Soil type**	**Application period**	**pH**	**Depth (cm)**	**$DissT_{50}$ (d)**	**$DissT_{90}$ (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi^2 (%)**	**Kinetic model**	**Evaluated on EU level y Reference**
Germany	Loamy silt	Spring	6.9	0-30	41.2	137	[a]	[a]	SFO	EFSA Conclusion 4584/2016
Germany	Loamy silt	Autumn	6.9	0-30	77.0 ~~770~~	256	[a]	[a]	SFO	EFSA Conclusion 4584/2016
Germany	Silty sand	Spring	5.8	0-30	62.0	206	[a]	[a]	SFO	EFSA Conclusion 4584/2016
Germany	Silty sand	Autumn	5.8	0-30	109	362	[a]	[a]	SFO	EFSA Conclusion 4584/2016
France	Silty sand	Spring	6.1	0-30	56.0	186	[a]	[a]	SFO	EFSA Conclusion 4584/2016
France	Silty sand	Autumn	6.1	0-30	97.0	322	[a]	[a]	SFO	EFSA Conclusion 4584/2016
UK	Sandy sit	Spring	4.7	0-30	29.3	97.0	[a]	[a]	SFO	EFSA Conclusion 4584/2016
UK	Sandy silt	Autumn	4.7	0-30	114	378	[a]	[a]	SFO	EFSA Conclusion 4584/2016
Italy	Sandy silt	Spring	7.5	0-30	72.9	242	[a]	[a]	SFO	EFSA Conclusion 4584/2016
Spain	Silty loam	Spring	7.4	0-30	72.0	239	[a]	[a]	SFO	EFSA Conclusion 4584/2016
Geometric mean (n= 10)							n/p			
pH-dependency: y/n							n/p			

[a] no reliable DT_{50} could be calculated
n/p not provided

zRMS comments:

Field degradation data for mesosulfuron-methyl presented above are in line with EU agreed endpoints reported in EFSA Journal 2016;14(10):4584. A typing error was corrected by the zRMS.

8.4.1.2 Pinoxaden and its metabolites

Please refer to section 8.4.2 below.

zRMS comments:

Please, refer to point 8.4.2 below.

8.4.1.3 Mefenpyr-diethyl and its metabolites

Table 8.4-2: Summary of aerobic degradation rates for mefenpyr-diethyl – field soil dissipation studies

Mesosulfuron-methyl, field soil dissipation studies, anaerobic conditions										
Location	**Soil type**	**Application period**	**pH**	**Depth (cm)**	**DissT$_{50}$ (d)**	**DissT$_{90}$ (d)**	**DT$_{50}$ (d) 20°C pF2/10kPa**	**Chi^2 (%)**	**Kinetic model**	**Evaluated on EU level y Reference**
Bornheim (Germany)	Sandy loam (bare soil)	n/p	7.1	40	[a]	[a]	[a] 13.4	[a]	[a]	Proposed in Monograph (list of endpoints) Oct 2011[b]
Gersthofen (Germany)	Sandy loam (bare soil)	n/p	6.3	40	23	76	12.8	9.0	SFO	Proposed in Monograph (list of endpoints) Oct 2011[b]
Schwanheim (Germany)	Sandy silt loam (bare soil)	n/p	5.7	40	79	263	43.8	9.0	SFO	Proposed in Monograph (list of endpoints) Oct 2011[b]
Geometric mean (n= 2)							19.6			
pH-dependency: y/n							No			

[a] ~~no reliable DT$_{50}$ could be calculated~~

[b] Monograph has been voluntarily prepared by AGES and ANSES in the context of zonal authorisation of plant protection products containing safener mefenpyr-diethyl.
n/p not provided

zRMS comments:

Field degradation data for mefenpyr-diethyl are in general in line with endpoints presented in the ANSES/AGES Monograph (2011). It is, however, noted that in the Monograph also DT$_{50}$ of 13.4 days for Bornheim is reported and is thus included by the zRMS in the table above. The derived geometric mean DT$_{50}$ of 19.6 days is correct, as it was calculated with consideration of the DT$_{50}$ for Bornheim.

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

8.4.2.1 Mesosulfuron-methyl and its metabolites

Please refer to section 8.4.1 above.

zRMS comments:

Please, refer to point 8.4.1 above.

8.4.2.2 Pinoxaden and its metabolites

Triggering endpoints

Table 8.4-3: Summary of aerobic degradation rates for M2 (NOA407854) field studies: Triggering endpoints

M2 (NOA407854), Field studies – Trigger endpoints									
Soil type (USDA)	Location	pH (KCl)	Depth (cm)	$DissT_{50}$ (d) Actual	$DissT_{90}$ (d) Actual	f.f.	Chi^2 (%)	Kinetic model	Evaluated on EU level / Reference
Silt loam	Rignano Scalo, Italy	7.02	0–30	2.02	6.69	1	11.1	SFO	EFSA Conclusion 3269/2013
Silt loam	Rignano Scalo, Italy	7.1	0–30	1.93	6.41	1	5.41	SFO	EFSA Conclusion 3269/2013
Silty clay loam	Bagnarola di Budrio, Italy	7.29	0–30	6.45	21.41	1	10.47	SFO	EFSA Conclusion 3269/2013
Silt loam	Tamarite de litera, Spain	7.30	0–30	3.81	12.65	1	15.5	SFO	EFSA Conclusion 3269/2013
Loam	Tamarite de litera, Spain	7.54	0–30	1.91	6.34	1	6.71	SFO	EFSA Conclusion 3269/2013
Loamy sand	Alcala de Guadaria	7.59	0–30	9.73	32.32	1	9.78	SFO	EFSA Conclusion 3269/2013
Clay loam	Rohlstorf, Germany, (sub-study 2)	7.00	0–30	1.19	3.96	1	13.0	SFO	EFSA Conclusion 3269/2013
Clay loam	Rohlstorf, Germany, (sub-study 4)	7.00	0–30	2.22	7.36	1	2.21	SFO	EFSA Conclusion 3269/2013
Clay loam	Stein, Switzerland	7.18	0–20	1.79	5.96	1	0.95	SFO	EFSA Conclusion 3269/2013
			Maximum (n=9)	9.73	32.32				

Table 8.4-4: Summary of aerobic degradation rates for M3 (NOA447204) – field studies: Triggering endpoints

M3 (NOA447204), Field studies – Trigger endpoints									
Soil type (USDA)	Location	pH (KCl)	Depth (cm)	$DissT_{50}$ (d) Actual	$DissT_{90}$ (d) Actual	f.f.	Chi^2 (%)	Kinetic model	Evaluated on EU level / Reference
Sandy loam	Xinzo de Limia (ES)	4.52	0–30	37.4	229	NA	17.5	FOMC	No / Finger, 2016a; Pietsch, 2016a
Loamy sand	Bossel (DE)	6.27	0–30	139	461	NA	25.2	SFO	No / Finger, 2016b; Pietsch, 2016a
Loam	Barry D'Islemade (S. FR)	5.43	0–30	24.3	80.8	NA	25.3	SFO	No / Finger, 2016c; Pietsch, 2016a
			Maximum (n=3)	139	461				

Modelling endpoints

Table 8.4-5: Summary of aerobic degradation rates for M2 (NOA407854) - field studies: Modelling endpoints

M2 (NOA407854), Field studies – Modelling endpoints								
Soil type (USDA)	**Location**	**pH (KCl)**	**Depth (cm)**	**DT_{50} (d) 20°C, pF2**	**f.f.**	**Chi^2 (%)**	**Kinetic model**	**Evaluated on EU level / Reference**
Silt loam	Rignano Scalo, Italy (Tribolet, 2003a)	7.02	-	0.85	1	11.1	SFO	Yes / EFSA, 2013
Silt loam	Rignana Scalo, Italy (Tribolet, 2003b)	7.1	-	2.04	1	5.41	SFO	Yes / EFSA, 2013
Silty clay loam	Bagnarola di Budrio, Italy (Tribolet, 2003d)	7.29	-	14.8	1	10.47	SFO	Yes / EFSA, 2013
Silt loam	Tamarite de litera, Spain (Tribolet, 2003e)	7.30	-	2.84	1	15.5	SFO	Yes / EFSA, 2013
Loam	Tamarite de litera, Spain (Tribolet, 2003f)	7.54	-	0.85	1	6.71	SFO	Yes / EFSA, 2013
Loamy sand	Alcala de Guadaria (Tribolet, 2003g)	7.59	-	7.24	1	9.78	SFO	Yes / EFSA, 2013
Clay loam	Rohlstorf, Germany, sub-study 2 (Stolze, 2003a)	7.00	-	0.99	1	13.0	SFO	Yes / EFSA, 2013
Clay loam	Rohlstorf, Germany, sub-study 4 (Stolze, 2003a)	7.00	-	2.37	1	2.21	SFO	Yes / EFSA, 2013
Clay loam	Stein, Switzerland (Sandmeier, 2001)	7.18	-	1.3	1	0.95	SFO	Yes / EFSA, 2013
Geometric mean (n=9)				2.23				
pH-dependency				No				

Table 8.4-6: Summary of aerobic degradation rates for M3 (NOA447204) - field studies: Modelling endpoints

M3 (NOA447204), Field studies – Modelling endpoints								
Soil type (USDA)	**Location**	**pH (KCl)**	**Depth (cm)**	**DT_{50} (d) 20°C, pF2**	**f.f.**	**Chi^2 (%)**	**Kinetic model**	**Evaluated on EU level / Reference**
Sandy loam	Xinzo de Limia (ES)	4.52	0-30	47.9 ~~42.6~~	NA	17.3 ~~17.8~~	FOMC	Addendum 1 to pinoxaden RAR, Vol. 3CA, B.8 (May 2022) ~~No / Finger, 2016a; Pietsch, 2016b~~
Loamy sand	Bossel (DE)	6.27	0-30	88.0 ~~84.6~~	NA	23.0 ~~23.6~~	SFO	Addendum 1 to pinoxaden RAR, Vol. 3CA, B.8 (May 2022) ~~No / Finger, 2016b; Pietsch, 2016b~~
Loam	Barry D'Islemade (S. FR)	5.43	0-30	28.6 ~~27.7~~	NA	24.3 ~~24.7~~	SFO	Addendum 1 to pinoxaden RAR, Vol. 3CA, B.8 (May 2022) ~~No / Finger, 2016c; Pietsch, 2016b~~
Geometric mean (n=3)				49.4 ~~46.4~~				
pH-dependency				Yes				

zRMS comments:

Metabolite M2

No triggering endpoints from field dissipation studies are reported in EFSA Journal 2013;11(8):3269 and for this reason information provided in Table 8.4-3 has been struck through. Modelling endpoints for M2 provided in Table 8.4-5 are in line with endpoints reported in the EFSA conclusion.

Metabolite M3

No EU agreed soil field dissipation data for metabolite M3 are available in EFSA Journal 2013;11(8):3269 and the Applicant considered results of the new studies, generated post-approval. Although, in general, the product

assessment should be carried out according to the currently agreed EU endpoints, the Working Document of the Central Zone in area of Section 8, identifies situation when new active substance data may be considered in the Core Assessments:

> *[...] Note that according to the guidance document on the evaluation of new active substance data post approval (SANCO/10328/2004– rev 8, 24.01.2012) new active substance/metabolite data should not be considered unless they are necessary in order to show a safe use, they are needed as additional uses/crops are applied for authorisation, or they are "adverse" data. [...]*

As for pinoxaden metabolite M3 the predicted concentrations in groundwater considerably exceeded 0.1 µg/L at Tier 1 assessment based on EU agreed inputs, consideration of the new field dissipation data was fully justified to enable refined groundwater exposure assessment.

Before evaluation of the new studies, the zRMS checked if they were evaluated at the EU level in the course of the renewal process or as a part of the confirmatory data. It turned out that all these studies are presented in Addendum 1 to pinoxaden RAR (Vol. 3CA, B.8) issued by RMS (AT) in May 2022 and were considered in the exposure assessment in Addendum 1 to Vol. 3CP, B.8. It is noted that the Addendum 1 (May 2022) was not commented yet by MS and EFSA, however as the studies were already evaluated by the RMS (AT), there is no need to perform separate evaluation at the zonal level. Nevertheless, the zRMS reviewed the assessment performed by AT and in general agrees with the derived endpoints and does not expect that they will substantially change following the peer-review. Since no triggering endpoints are reported in Addendum 1 to the RAR and modelling endpoints agreed by the RMS are different than values proposed by the Applicant, Table 8.4-4 above was struck through while Table 8.4-6 was corrected accordingly to provide endpoints as agreed by the RMS.

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

8.4.2.3 Mefenpyr-diethyl and its metabolites

Please refer to section 8.4.1 above.

zRMS comments:

Please, refer to point 8.4.1 above.

8.4.3 Soil accumulation testing (KCP 9.1.1.2.2)

No soil accumulation studies are required for any active substance.

zRMS comments:

No soil accumulation studies were performed with mesosulfuron-methyl, pinoxaden and mefenpyr-diethyl for purposes of the EU review. Potential for accumulation of active compounds and their metabolites has been considered by the zRMS in the course of the soil exposure assessment (see point 8.7 below).

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 Mesosulfuron-methyl and its metabolites

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

Mesosulfuron-methyl								
Soil name	**Soil type**	**OC (%)**	**pH (-)**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Evaluated on EU level y Reference**	
EFS-8	Sand	0.49	5.0	1.69	345	0.85	~~EFSA Conclusion 3269/2013~~	EFSA Conclusion 4584/2016
EFS-15	Sandy clay loam	2.70	7.4	3.71	137	0.93	~~EFSA Conclusion 3269/2013~~	
EFS-17	Loamy sand	1.13	5.2	0.41	37	0.93	~~EFSA Conclusion 3269/2013~~	
EFS-18	Loamy sand	2.34	5.2	0.71 ~~0.74~~	31	0.91	~~EFSA Conclusion 3269/2013~~	
EFS-19	Sandy loam	2.64	7.3	2.28	86	0.90	~~EFSA Conclusion 3269/2013~~	
EFS-20	Sandy loam	0.91	6.3	0.24	26	0.92	~~EFSA Conclusion 3269/2013~~	
EFS-28	Clay loam	1.68	7.5	0.60	36	0.93	~~EFSA Conclusion 3269/2013~~	
EFS-29	Loam	1.43	7.5	1.22	85	0.90	~~EFSA Conclusion 3269/2013~~	
EFS-30	Silt loam	1.16	7.3	0.56	48	0.93	~~EFSA Conclusion 3269/2013~~	
Geometric mean (n=9)					64			
Arithmetic mean (n=9)					92	0.91		
pH-dependency y/n					No			

Table 8.5-2: Summary of soil adsorption/desorption for mesosulfuron (AE F154851)

Mesosulfuron (AE F154851)								
Soil Name	**Soil Type**	**OC (%)**	**pH (-)**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Evaluated on EU level y Reference**	
Not provided	Clay loam	3.15	5.8	3.1	98	0.92	~~EFSA Conclusion 3269/2013~~	EFSA Conclusion 4584/2016
Not provided	Silt loam	1.3	7.4	0.79	61	0.94	~~EFSA Conclusion 3269/2013~~	
Not provided	Sandy loam	1.65	5.1	0.75	46	0.95	~~EFSA Conclusion 3269/2013~~	
Geometric mean (n=3)					65			
Arithmetic mean (n=3)					68	0.94		
pH-dependency y/n					No			

Table 8.5-3: Summary of soil adsorption/desorption for AE F160459

AE F160459								
Soil Name	**Soil Type**	**OC (%)**	**pH (-)**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Evaluated on EU level y Reference**	
Not provided	Loam	1.8	5.3	0.1978	11.2	0.9320	~~EFSA Conclusion 3269/2013~~	EFSA Conclusion 4584/2016
Not provided	Silt loam	2.4	6.6	0.3797	15.7	0.9388	~~EFSA Conclusion 3269/2013~~	
Not provided	Clay loam	7.42	7.3	0.7630	16.2	0.9267	~~EFSA Conclusion 3269/2013~~	
Not provided	Sandy loam	0.7	6.7	0.1475	21.1	0.9760	~~EFSA Conclusion 3269/2013~~	
Not provided	Silt loam	1.7	6.6	0.7590	44.6	0.9324	~~EFSA Conclusion 3269/2013~~	
Geometric mean (n=5)					19.3			
Arithmetic mean (n=5)					21.8	0.941		
pH-dependency y/n					No			

Table 8.5-4: Summary of soil adsorption/desorption for AE F099095

AE F099095								
Soil Name	**Soil Type**	**OC (%)**	**pH (-)**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Evaluated on EU level y Reference**	
Not provided	Clay loam	3.15	5.8	42.8	1360	0.83	~~EFSA Conclusion 3269/2013~~	EFSA Conclusion 4584/2016
Not provided	Silt loam	1.3	7.4	2.94	226	0.84	~~EFSA Conclusion 3269/2013~~	
Not provided	Sandy loam	1.65	5.1	2.33	141	0.86	~~EFSA Conclusion 3269/2013~~	
Not provided	Sandy loam	1.3	5.7	3.05	235	0.777	~~EFSA Conclusion 3269/2013~~	
Not provided	Sandy loam	4.3	5.3	4.81	112	0.737	~~EFSA Conclusion 3269/2013~~	
Not provided	Sandy clay loam	3.5	7.0	4.39	126	0.78	~~EFSA Conclusion 3269/2013~~	
Not provided	Clay	3.8	7.1	4.94	130	0.79	~~EFSA Conclusion 3269/2013~~	
Not provided	Sand	1.1	3.9	2.05	186	0.801	~~EFSA Conclusion 3269/2013~~	
Not provided	Loamy sand	14.42	3.38	126	874	0.817	~~EFSA Conclusion 3269/2013~~	
Not provided	Clay	0.89	7.55	33	3704	0.761	~~EFSA Conclusion 3269/2013~~	
Not provided	Silt loam	2.13	5.16	11	516	0.802	~~EFSA Conclusion 3269/2013~~	
Geometric mean (n=11)					334 ~~692~~			
Arithmetic mean (n=11)					692	0.80		
pH-dependency y/n					No			

Table 8.5-5: Summary of soil adsorption/desorption for AE F092944

AE F092944								
Soil Name	**Soil Type**	**OC (%)**	**pH (-)**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Evaluated on EU level**	**y Reference**
Not provided	Loamy sand	1.17	5.00	2.47	211	0.69	~~EFSA Conclusion 3269/2013~~	EFSA Conclusion 4584/2016
Not provided	Loamy sand	2.91	5.00	2.59	89	0.86	~~EFSA Conclusion 3269/2013~~	
Not provided	Sandy loam	1.32	4.70	8.25	625	0.65	~~EFSA Conclusion 3269/2013~~	
Not provided	Loamy sand	0.16	8.00	1.05 [a]	663[a]	0.52 [a]	~~EFSA Conclusion 3269/2013~~	
Not provided	Sandy loam	0.26	7.95	1.82 [a]	696 [a]	0.63 [a]	~~EFSA Conclusion 3269/2013~~	
Not provided	Sandy loam	1.04	6.10	4.11	395	0.78	~~EFSA Conclusion 3269/2013~~	
Not provided	Silt loam	0.72	5.60	81.3	11289	0.58	~~EFSA Conclusion 3269/2013~~	
Not provided	Silty clay	1.80	7.70	16.5	917	0.62	~~EFSA Conclusion 3269/2013~~	
Not provided	Loamy sand	2.1	6.4	1.22	58.1	0.85	~~EFSA Conclusion 3269/2013~~	
Not provided	Loamy sand	0.5	5.2	2.26	452	0.81	~~EFSA Conclusion 3269/2013~~	
Not provided	Silt loam	3.1	5.5	45.3	1460	0.71	~~EFSA Conclusion 3269/2013~~	
Not provided	Sandy loam	0.7	7.8	0.859	123	0.79	~~EFSA Conclusion 3269/2013~~	
Not provided	Silt loam	1.2	5.8	2.35	196	0.82	~~EFSA Conclusion 3269/2013~~	
Not provided	Loamy sand	2.29	7.0	1.17	50.9	0.84	~~EFSA Conclusion 3269/2013~~	
Not provided	Loamy sand	1.17	7.7	0.71	60.4	0.82	~~EFSA Conclusion 3269/2013~~	
Sisseln	Sandy loam	1.557	7.8	0.83	52.8	0.92	~~EFSA Conclusion 3269/2013~~	
Not provided	Silt loam	4.05	7.3	1.70	42.0	0.91	~~EFSA Conclusion 3269/2013~~	
Not provided	Silt loam	1.78	6.9	11.54	648.3	0.72	~~EFSA Conclusion 3269/2013~~	
Not provided	Sandy loam	0.58	8.0	1.92	331.0	0.68	~~EFSA Conclusion 3269/2013~~	
Not provided	Loamy sand	1.15	6.8	2.59	225.2	0.79	~~EFSA Conclusion 3269/2013~~	
Not provided	Silty clay loam	2.0	5.8	32.23	1611.5	0.56	~~EFSA Conclusion 3269/2013~~	

AE F092944								
Soil Name	**Soil Type**	**OC (%)**	**pH (-)**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Evaluated on EU level**	**y Reference**
Not provided	Sandy loam	1.1	4.9	13.77	1252.0	0.632	~~EFSA Conclusion 3269/2013~~	
Not provided	Sandy loam	1.4	6.2	5.53	395.0	0.695	~~EFSA Conclusion 3269/2013~~	
Not provided	Sandy clay loam	3.3	7.6	3.7	112.0	0.754	~~EFSA Conclusion 3269/2013~~	
Not provided	Clay loam	4.0	4.9	17.99	450.0	0.429	~~EFSA Conclusion 3269/2013~~	
Geometric mean (n=11)					293.9 ~~956.4~~			
Arithmetic mean (n=11)					956.4	0.74		
pH-dependency y/n					No			

[a] value excluded from the mean calculation

Table 8.5-6: Summary of soil adsorption/desorption for AE F160460

AE F160460								
Soil Name	**Soil Type**	**OC (%)**	**pH (-)**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Evaluated on EU level**	**y Reference**
Not provided	Loam	1.8	5.3	0.2069	11.5	0.9745	~~EFSA Conclusion 3269/2013~~	EFSA Conclusion 4584/2016
Not provided	Silt loam	2.4	6.6	0.2258	9.4	0.8692	~~EFSA Conclusion 3269/2013~~	
Not provided	Clay loam	7.42	7.3	0.3488	7.6	0.8387	~~EFSA Conclusion 3269/2013~~	
Not provided	Sandy loam	0.7	6.7	0.0743	10.6	0.9524	~~EFSA Conclusion 3269/2013~~	
Not provided	Silt loam	1.7	6.6	0.5329	31.3	0.8628	~~EFSA Conclusion 3269/2013~~	
Geometric mean (n=5)					12.2			
Arithmetic mean (n=5)					14.1	0.900		
pH-dependency y/n					No			

Table 8.5-7: Summary of soil adsorption/desorption for AE F147447

AE F147447								
Soil Name	**Soil Type**	**OC (%)**	**pH (-)**	**Kd (mL/g)**	**Kdoc (mL/g)**	**1/n (-)**	**Evaluated on EU level**	**y Reference**
Not provided	Loam	2.1	6.4	0.097	4.6	n/p	~~EFSA Conclusion 3269/2013~~	EFSA Conclusion 4584/2016
Not provided	Silt loam	2.5	6.8	0.096	3.8	n/p	~~EFSA Conclusion 3269/2013~~	
Not provided	Clay loam	1.3	6.8	0.086	6.6	n/p	~~EFSA Conclusion 3269/2013~~	
Not provided	Sandy loam	2.8	5.6	0.196	7.0	n/p	~~EFSA Conclusion 3269/2013~~	
Not provided	Silt loam	4.4	7.3	0.181	4.1	n/p	~~EFSA Conclusion 3269/2013~~	
Geometric mean (n=5)					5.1			
Arithmetic mean (n=5)					5.2	n/p		
pH-dependency y/n					No			

n/p not provided

Table 8.5-8: Summary of soil adsorption/desorption for BCS CV14885

BCS CV14885								
Soil Name	**Soil Type**	**OC (%)**	**pH (-)**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Evaluated on EU level y Reference**	
Not provided	Loamy sand	1.7	6.2	0.3	17.5	1.17	~~EFSA Conclusion 3269/2013~~	EFSA Conclusion 4584/2016
Not provided	Loam	5.1	7.0	0.96	18.8	1.07	~~EFSA Conclusion 3269/2013~~	
Not provided	Silt loam	2.0	6.1	0.27	13.6	1.18	~~EFSA Conclusion 3269/2013~~	
Not provided	Loam	1.9	5.3	0.41	21.7	1.43	~~EFSA Conclusion 3269/2013~~	
Geometric mean (n=4)					17.7			
Arithmetic mean (n=4)					17.8	1.21		
pH-dependency y/n					No			

n/p not provided

zRMS comments:

Soil mobility data for mesosulfuron-methyl and its metabolites presented in Tables 8.5-1 to 8.5-8 are in line with EU agreed endpoints reported in EFSA Journal 2016;14(10):4584. It is noted that the Applicant made mistake in reference to the EFSA conclusion, which was corrected by the zRMS.

Some minor corrections were introduced by the zRMS in tables above, so the data are fully in line with EFSA Journal 2016;14(10):4584. The EU agreed arithmetic mean K_{foc} values were also included, although the geometric mean values were calculated based on individual EU agreed data and are confirmed to be correct.

8.5.2 Pinoxaden and its metabolites

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

Pinoxaden							
Soil name	**Soil type (USDA)**	**OC (%)**	**pH ($CaCl_2$)**	**K_F (mL/g)**	**K_{FOC} (mL/g)**	**1/n (-)**	**Evaluated on EU level / Reference**
Borstel	Sandy loam	1.0	5.1	1.7	173	0.99	EFSA Conclusion 3269/2013
Marsillargues	Silty clay loam	1.4	7.3	4.4	323	1.025	EFSA Conclusion 3269/2013
Gartenacker	Silty loam	2.4	7.2	2.9	121	1.029	EFSA Conclusion 3269/2013
18 Acres	Sandy clay loam	2.5	5.8	4.6	180	1.054	EFSA Conclusion 3269/2013
Plaza	Loamy sand	1.2	7.0	4.9	403	0.93	EFSA Conclusion 3269/2013
Northwood	Loam	3.0	6.4	13.4	453	1.12	EFSA Conclusion 3269/2013
Ephrata	Sand	0.35	6.7	1.04	299	0.98	EFSA Conclusion 3269/2013
Minto	Loam	3.2	7.5	10.9	337	1.03	EFSA Conclusion 3269/2013
Larned	Silty clay loam	1.0	5.6	8.9	852	1.07	EFSA Conclusion 3269/2013
Geomean (n=9)					299		
Arithmetic mean (n=9)						1.03	
pH-dependency					No		

Table 8.5-10: Summary of soil adsorption/desorption for M2 (NOA407854)

M2 (NOA407854)							
Soil name	**Soil type (USDA)**	**OC (%)**	**pH ($CaCl_2$)**	**K_F (mL/g)**	**K_{FOC} (mL/g)**	**1/n (-)**	**Evaluated on EU level / Reference**
Wisborough Green	Silty clay loam	2.5	4.8	0.1	4	0.99	EFSA Conclusion 3269/2013
Borstel	Sandy loam	1.4	4.9	n.d.	0[a]	1	EFSA Conclusion 3269/2013
Marsillargues	Loam	0.58	7.8	n.d.	0 [a]	1	EFSA Conclusion 3269/2013
Gartenacker	Loam	2.3	7.1	n.d.	0 [a]	1	EFSA Conclusion 3269/2013
18 Acres	Sandy clay loam	2.9	5.9	0.32	11	0.79	EFSA Conclusion 3269/2013
Birkenheide	Sandy loam	0.9	6	0.47	51.9	0.96	EFSA Conclusion 3269/2013
Plaza	Loamy sand	1.2	7	0.06	5.2	1.019	EFSA Conclusion 3269/2013
Northwood	Loam	3	6.4	0.18	6	0.976	EFSA Conclusion 3269/2013
Ephrata	Sand	0.35	7	0.098	23	1.029	EFSA Conclusion 3269/2013
Larned	Silty clay loam	1	5.6	0.28	27	0.975	EFSA Conclusion 3269/2013
Minto	Loam	3.2	7.5	0.14	4.2	0.988	EFSA Conclusion 3269/2013
18 Acres	Sandy clay loam	2.9	5.9	0.49	17	0.9	EFSA Conclusion 3269/2013
Wisborough green	Silty clay loam	2.9	4.8	0.32	11	0.99	EFSA Conclusion 3269/2013
Maine	Clay loam	2.6	5	0.14	6	0.96	EFSA Conclusion 3269/2013
Pappelacker	Sand	1.14	6.7	n.d.	0 [a]	1	EFSA Conclusion 3269/2013
Welver-Borgeln	Silt loam	2.02	6.7	0.19	10	0.93	EFSA Conclusion 3269/2013
				Geomean (n=12)	10.6		
				Arithmetic mean (n=16)		0.97	
				pH-dependency	No		

[a] It was not possible to calculate Kfoc because little or no adsorption was observed during the study.

Table 8.5-11: Summary of soil adsorption/desorption for M3 (NOA447204)

M3 (NOA447204)							
Soil name	**Soil type (USDA)**	**OC (%)**	**pH ($CaCl_2$)**	**K_F (mL/g)**	**K_{FOC} (mL/g)**	**1/n (-)**	**Evaluated on EU level / Reference**
Borstel	Sandy loam	1.0	5.1	0.38	37.8	1.046	EFSA Conclusion 3269/2013
Gartenacker	Silty loam	1.4	7.3	0.62	26.2	1.028	EFSA Conclusion 3269/2013
Marsillargues	Silty clay loam	2.4	7.2	0.59	43.5	1.07	EFSA Conclusion 3269/2013
Plaza	Loamy sand	2.5	5.8	0.28	23	0.904	EFSA Conclusion 3269/2013
Northwood	Loam	1.2	7.0	0.76	26	0.914	EFSA Conclusion 3269/2013
Ephrata	Sand	3.0	6.4	0.12	35	0.916	EFSA Conclusion 3269/2013
Minto	Loam	0.35	6.7	0.86	26	0.9	EFSA Conclusion 3269/2013
Larned	Silty clay loam	3.2	7.5	0.5	48	0.915	EFSA Conclusion 3269/2013
Geomean (n=8)					32.1		
Aruthmetic mean (n=8)						0.96	
pH-dependency					No		

Table 8.5-12: Summary of soil adsorption/desorption for M11 (SYN504574)

M11 (SYN504574)							
Soil name	**Soil type (USDA)**	**OC (%)**	**pH ($CaCl_2$)**	**K_f (mL/g)**	**K_{foc} (mL/g)**	**1/n (-)**	**Evaluated on EU level / Reference**
Gartenacker	Silty loam	1.71	7.13	0.041 ~~0.206~~	2.4 ~~12~~	0.97	Addendum 1 to pinoxaden RAR, Vol. 3CA, B.8 (May 2022) ~~No /Robinson, 2012c[a]~~
18 Acres	Sandy clay loam	3.09	5.96	0.143 ~~0.351~~	4.7 ~~11.4~~	0.98	Addendum 1 to pinoxaden RAR, Vol. 3CA, B.8 (May 2022) ~~No /Robinson, 2012c[a]~~
Marsillargues	Silty clay loam	0.83	7.55	0[b] ~~0.117~~	0[b] ~~14.1~~	0.99	Addendum 1 to pinoxaden RAR, Vol. 3CA, B.8 (May 2022) ~~No /Robinson, 2012c[a]~~
Geomean (n=3)					na[c] ~~12.4~~		
Arithmetic mean (n=3)					2.4[c]	0.980	
pH-dependency					No		

~~[a] Syngenta submitted data on soil adsorption/desorption for metabolite M11 (SYN504574) as confirmatory data in the EU review of pinoxaden~~. (b): Percentage 'adsorbed' (δ) = percentage 'loss' (f); no adsorption assumed
(c): Arithmetic mean used as data set includes zero

Table 8.5-13: Summary of soil adsorption/desorption for M52 (SYN546105)

M52 (SYN546105)							
Soil name	**Soil type (USDA)**	**OC (%)**	**pH ($CaCl_2$)**	**K_F (mL/g)**	**K_{FOC} (mL/g)**	**1/n (-)**	**Evaluated on EU level / Reference**
Gartenacker	Silty loam	1.96	7.10	1.06	54.1	0.97	Addendum 1 to pinoxaden RAR, Vol. 3CA, B.8 (May 2022) ~~No /Völkel, 2012c[a]~~
18 Acres	Sandy clay loam	2.88	5.58	2.36	81.9	0.96	Addendum 1 to pinoxaden RAR, Vol. 3CA, B.8 (May 2022) ~~No /Völkel, 2012c[a]~~
Marsillargues	Silty clay loam	1.05	7.46	0.49 ~~2.836~~	55.2 ~~270.1~~	1.00	Addendum 1 to pinoxaden RAR, Vol. 3CA, B.8 (May 2022) ~~No /Völkel, 2012c[a]~~
Geomean (n=3)					62.5 ~~135.4~~		
Arithmetic mean (n=3)						0.977	
pH-dependency					No		

~~[a] Syngenta submitted data on soil adsorption/desorption for metabolite M52 (SYN546105) as confirmatory data in the EU review of pinoxaden. .~~

Table 8.5-14: Summary of soil adsorption/desorption for M54 (SYN546106)

M54 (SYN546106)							
Soil name	**Soil type (USDA)**	**OC (%)**	**pH ($CaCl_2$)**	**K_F (mL/g)**	**K_{FOC} (mL/g)**	**1/n (-)**	**Evaluated on EU level / Reference**
Gartenacker	Silty loam	1.96	7.10	0.267	13.6	0.93	Addendum 1 to pinoxaden RAR, Vol. 3CA, B.8 (May 2022) ~~No /Völkel, 2012d[a]~~
18 Acres	Sandy clay loam	2.88	5.58	0.201 ~~0.321~~	6.9 ~~11.1~~	1.03	Addendum 1 to pinoxaden RAR, Vol. 3CA, B.8 (May 2022) ~~No /Völkel, 2012d[a]~~
Marsillargues	Silty clay loam	1.05	7.46	0.310	29.5	1.00	Addendum 1 to pinoxaden RAR, Vol. 3CA, B.8 (May 2022) ~~No /Völkel, 2012d[a]~~
Geomean (n=3)					14.1 ~~16.5~~		
Arithmetic mean (n=3)						0.987	
pH-dependency					No		

~~[a] Syngenta submitted data on soil adsorption/desorption for metabolite M54 (SYN546106) as confirmatory data in the EU review of pinoxaden.~~

Table 8.5-15: Summary of soil adsorption/desorption for M55 (SYN546107)

M55 (SYN546107)							
Soil name	**Soil type (USDA)**	**OC (%)**	**pH ($CaCl_2$)**	**K_F (mL/g)**	**K_{FOC} (mL/g)**	**1/n (-)**	**Evaluated on EU level / Reference**
Gartenacker	Silty loam	1.71	7.13	0.017 ~~0.195~~	1.0 ~~11.4~~	0.98	Addendum 1 to pinoxaden RAR, Vol. 3CA, B.8 (May 2022) ~~No /Robinson, 2012d[a]~~
18 Acres	Sandy clay loam	3.09	5.96	0.049 ~~0.153~~	1.6 ~~5.0~~	0.96	Addendum 1 to pinoxaden RAR, Vol. 3CA, B.8 (May 2022) ~~No /Robinson, 2012d[a]~~
Marsillargues	Silty clay loam	0.83	7.55	0.003 ~~0.143~~	0.3 ~~17.3~~	1.05	Addendum 1 to pinoxaden RAR, Vol. 3CA, B.8 (May 2022) ~~No /Robinson, 2012d[a]~~
Geomean (n=3)					0.8 ~~10.0~~		
Arithmetic mean (n=3)						0.997	
pH-dependency					No		

~~[a] Syngenta submitted data on soil adsorption/desorption for metabolite M55 (SYN546107) as confirmatory data in the EU review of pinoxaden.~~

Table 8.5-16: Summary of soil adsorption/desorption for M56 (SYN546108)

M56 (SYN546108)							
Soil name	**Soil type (USDA)**	**OC (%)**	**pH ($CaCl_2$)**	**K_F (mL/g)**	**K_{FOC} (mL/g)**	**1/n (-)**	**Evaluated on EU level / Reference**
Gartenacker	Loam	2.01	7.01	0.189	9.4	1.15	Addendum 1 to pinoxaden RAR, Vol. 3CA, B.8 (May 2022) ~~No /Caviezel, 2013b[a]~~
18 Acres	Clay loam	2.46	6.01	0.149 ~~0.222~~	6.0 ~~9.0~~	0.97	Addendum 1 to pinoxaden RAR, Vol. 3CA, B.8 (May 2022) ~~No /Caviezel, 2013b[a]~~
Marsillargues	Silty clay loam	0.83	7.55	nc ~~0.193~~	nc ~~23.2~~	1.29	Addendum 1 to pinoxaden RAR, Vol. 3CA, B.8 (May 2022) ~~No /Caviezel, 2013b[a]~~
Worst case ~~Geomean (n=3)~~					6.0 ~~12.5~~		
Arithmetic mean (n=3)						1.137	
pH-dependency					No		

~~[a] Syngenta submitted data on soil adsorption/desorption for metabolite M56 (SYN546108) as confirmatory data in the EU review of pinoxaden.~~

nc denotes not calculated (no reliable K_{fE}/K_f ratio available)
na denotes not applicable

zRMS comments:

Soil mobility data for pinoxaden and its metabolites: M2 (NOA407854) and M3 (NOA447204) presented in Tables 8.5-9 to 8.5-11 are in line with EU agreed endpoints reported in EFSA Journal 2013;11(8):3269.

The soil mobility data for metabolites: M11 (SYN504574), M52 (SYN546105), M54 (SYN546106), M55 (SYN546107) and M56 (SYN5461080) were obtained in new studies referred to by the Applicant. Although, in general, the product assessment should be carried out according to the currently agreed EU endpoints, the Working Document of the Central Zone in area of Section 8, identifies situation when new active substance data may be considered in the Core Assessments:

[...] Note that according to the guidance document on the evaluation of new active substance data post approval (SANCO/10328/2004– rev 8, 24.01.2012) new active substance/metabolite data should not be considered unless they are necessary in order to show a safe use, they are needed as additional uses/crops are applied for authorisation, or they are "adverse" data. [...]

As for some pinoxaden metabolites the predicted concentrations in groundwater exceeded 10.0 µg/L at Tier 1 assessment based on EU agreed inputs, consideration of the new data was fully justified to enable refined groundwater exposure assessment.

Before evaluation of the new studies, the zRMS checked if they were evaluated at the EU level in the course of the renewal process or as a part of the confirmatory data. It turned out that all these studies are presented in Addendum 1 to pinoxaden RAR (Vol. 3CA, B.8) issued by RMS (AT) in May 2022 and were considered in the exposure assessment in Addendum 1 to Vol. 3CP, B.8. It is noted that the Addendum 1 (May 2022) was not commented yet by MS and EFSA, however, there is no need to perform separate evaluation at the zonal level as the studies were already evaluated by the RMS (AT). Nevertheless, the zRMS reviewed the assessment performed by AT and in general agrees with the derived endpoints and does not expect that they will substantially change following the peer-review. Since the endpoints agreed by the RMS are different than values proposed by the Applicant, Tables 8.5-12 to 8.5-16 above were corrected accordingly to provide endpoints as agreed by the RMS.

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

8.5.3 Mefenpyr-diethyl and its metabolites

Table 8.5-17: Summary of soil adsorption/desorption for mefenpyr-diethyl

Mefenpyr-diethyl							
Soil name	**Soil type (USDA)**	**OC (%)**	**pH ($CaCl_2$)**	**K_F (mL/g)**	**K_{FOC} (mL/g)**	**1/n (-)**	**Evaluated on EU level / Reference**
SLH	Silt loam	1.10	6.2	7.08	644	0.99	Proposed in Monograph (list of endpoints) Oct 2011[a]
SLV	Loamy sand	1.13	5.8	6.71	593 ~~5.93~~	1.20	Proposed in Monograph (list of endpoints) Oct 2011[a]
S2.1	Silty sand	1.17	5.0	5.68	486	1.20	Proposed in Monograph (list of endpoints) Oct 2011[a]
SLN	Loamy sand	0.89	7.1	5.16	580	1.20	Proposed in Monograph (list of endpoints) Oct 2011[a]
EFS-8	Sand	0.49	4.98	3.16	648	0.96	Proposed in Monograph (list of endpoints) Oct 2011[a]
EFS-15	Sandy clay loam	2.70	7.9	19.9	738	0.96	Proposed in Monograph (list of endpoints) Oct 2011[a]
				Geomean (n=6)	610		
				Arithmetic mean (n=6)	615	1.085	
				pH-dependency	No		

[a] Monograph has been voluntarily prepared by AGES and ANSES in the context of zonal authorisation of plant protection products containing safener mefenpyr-diethyl.

Table 8.5-18: Summary of soil adsorption/desorption for AE F113225

AE F113225							
Soil name	**Soil type (USDA)**	**OC (%)**	**pH ($CaCl_2$)**	**K_F (mL/g)**	**K_{FOC} (mL/g)**	**1/n (-)**	**Evaluated on EU level / Reference**
Not provided	Loam	1.9	7.1	2.73	144	0.90	Proposed in Monograph (list of endpoints) Oct 2011[a]
Not provided	Sandy loam	2.1	7.3	1.83	76	0.93	Proposed in Monograph (list of endpoints) Oct 2011[a]
Not provided	Loam	3.0	5.2	3.6	120	0.93	Proposed in Monograph (list of endpoints) Oct 2011[a]
Geomean (n=3)					110		
Arithmetic mean (n=3)					113	0.92	
pH-dependency					No		

[a] Monograph has been voluntarily prepared by AGES and ANSES in the context of zonal authorisation of plant protection products containing safener mefenpyr-diethyl.

Table 8.5-19: Summary of soil adsorption/desorption for AE F094270

AE F094270							
Soil name	**Soil type (USDA)**	**OC (%)**	**pH ($CaCl_2$)**	**K_F (mL/g)**	**K_{FOC} (mL/g)**	**1/n (-)**	**Evaluated on EU level / Reference**
Not provided	Loamy sand	2.91	5.0	7.49	257	0.96	Proposed in Monograph (list of endpoints) Oct 2011[a]
Not provided	Sandy loam	1.15	5.0	4.57	397	0.80	Proposed in Monograph (list of endpoints) Oct 2011[a]
Not provided	Silt loam	1.33	6.8	1.57	118	1.02	Proposed in Monograph (list of endpoints) Oct 2011[a]
Not provided	Sandy loam	2.28	7.1	1.49	65	1.00	Proposed in Monograph (list of endpoints) Oct 2011[a]
Not provided	Loamy sand	1.17	5.0	2.58	221	0.86	Proposed in Monograph (list of endpoints) Oct 2011[a]
Geomean (n=5)					177		
Arithmetic mean (n=5)					212	0.928	
pH-dependency					No		

[a] Monograph has been voluntarily prepared by AGES and ANSES in the context of zonal authorisation of plant protection products containing safener mefenpyr-diethyl.

zRMS comments:

Soil mobility data for mefenpyr-diethyl and its metabolites presented in tables above are in general in line with the Monograph (list of endpoints) prepared in October 2011 by ANSES and AGES in order to aid zonal evaluations of the products containing this safener. Some minor corrections were introduced by the zRMS in tables above, so the values are fully in line with endpoints agreed by ANSES and AGES. Furthermore, the agreed arithmetic mean K_{foc} values were also included, although the geometric mean values were calculated based on individual EU agreed data and are confirmed to be correct.

8.5.4 Column leaching (KCP 9.1.2.1)

8.5.4.1 Mesosulfuron-methyl and its metabolites

No column leaching data required.

zRMS comments:

No column leaching studies were required at the EU level for mesosulfuron-methyl and none are required for this zonal assessment.

8.5.4.2 Pinoxaden and its metabolites

Aged residues column leaching data are presented in the EFSA conclusion for pinoxaden. Results are summarized in the table below.

Table 8.5-20: Summary of column leaching studies for Pinoxaden

Endpoint	Result	Evaluated on EU level / Reference
Aged residues leaching		
Elution (mm):	200	EFSA Conclusion 3269/2013
Ageing period (d):	7-9	EFSA Conclusion 3269/2013
Time period (d):	7-9	EFSA Conclusion 3269/2013
Soil residues (post-ageing/pre-leaching):		EFSA Conclusion 3269/2013
Pinoxaden (% total radioactivity):	Negligible	EFSA Conclusion 3269/2013
M2 (NOA407854) (% total radioactivity):	15.2	EFSA Conclusion 3269/2013
M3 (NOA447204) (% total radioactivity):	8.7	EFSA Conclusion 3269/2013
Leachate (% total radioactivity):	39.9	EFSA Conclusion 3269/2013
Pinoxaden (% total radioactivity):	Negligible	EFSA Conclusion 3269/2013
M2 (NOA407854) (% total radioactivity):	38.9	EFSA Conclusion 3269/2013
M3 (NOA447204) (% total radioactivity):	0.4	EFSA Conclusion 3269/2013
Residues retained in top 2cm soil (% total radioactivity):	63.9	EFSA Conclusion 3269/2013

zRMS comments:

Summary of column leaching studies for metabolites M2 and M3 presented in table above is in line with results reported in EFSA Journal 2013;11(8):3269.

8.5.4.3 Mefenpyr-diethyl and its metabolites

Column leaching and aged residues leaching data are provided for mefenpyr-diethyl in the Monograph list of endpoints dated October 2011. Results are summarised in the table below.

Table 8.5-21: Summary of column leaching studies for Mefenpyr-diethyl

Endpoint	Result	Evaluated on EU level / Reference
Column leaching		
Elution (mm):	200	Proposed in Monograph (list of endpoints) Oct 2011[a]
Time period (d):	2	Proposed in Monograph (list of endpoints) Oct 2011[a]
Leachate (% total radioactivity):	2.1-4.5	Proposed in Monograph (list of endpoints) Oct 2011[a]
Aged residues leaching		
Elution (mm):	200	Proposed in Monograph (list of endpoints) Oct 2011[a]
Ageing period (d):	3	Proposed in Monograph (list of endpoints) Oct 2011[a]

Endpoint	Result	Evaluated on EU level / Reference
Time period (d):	2	Proposed in Monograph (list of endpoints) Oct 2011[a]
Leachate (% total radioactivity):	14.5-15.7	Proposed in Monograph (list of endpoints) Oct 2011[a]
Mefenpyr-diethyl (% total radioactivity):	0-2.5	Proposed in Monograph (list of endpoints) Oct 2011[a]
AE F113225 (% total radioactivity):	13.2-14.5	Proposed in Monograph (list of endpoints) Oct 2011[a]

[a] Monograph has been voluntarily prepared by AGES and ANSES in the context of zonal authorisation of plant protection products containing safener mefenpyr-diethyl.

zRMS comments:

Summary of column leaching studies for mefenpyr-diethyl and its metabolites presented in table above is in line with results reported in the Monograph (list of endpoints) prepared in October 2011 by ANSES and AGES in order to aid zonal evaluations of the products containing this safener.

8.5.5 Lysimeter studies (KCP 9.1.2.2)

8.5.5.1 Mesosulfuron-methyl and its metabolites

Lysimeter studies were submitted as part of the active substance assessment of mesosulfuron-methyl. Two studies were carried out for 3 years in Germany. In one study the radiolabelled test substance was applied in spring, in the other study the radiolabelled test substance was applied in autumn. The results of both studies indicated that mesosulfuron-methyl degraded to average yearly concentrations below the drinking water limit of 0.1 µg/L. Metabolite BCS-CV14885 was detected in both studies at average yearly concentrations from below the drinking water limit of 0.1 µg/L up to 0.481 µg/L.

zRMS comments:

Summary regarding the lysimeter studies presented above is in agreement with information provided in EFSA Journal 2016;14(10):4584. Potential leaching of mesosulfuron-methyl and its metabolites to groundwater has been sufficiently addressed in the groundwater modelling. For details, please see point 8.8 of this document.

8.5.5.2 Pinoxaden and its metabolites

~~Lysimeter studies were submitted as part of the active substance assessment of pinoxaden. Three studies were carried out in Switzerland, two of which ran for two years and one for three years, and one study was carried out in Germany for three years. In the three year Swiss study pinoxaden was not detected in the leachate. All metabolites were detected at average yearly concentrations below the drinking water limit of 0.1 µg/L, with the exception of metabolite NOA447204 (M3) which was present in the first year at 0.07-0.15 µg/L, but reduced to 0.003-0.005 µg/L in year 3. In the three year German study pinoxaden was not analysed. All metabolites were detected at average yearly concentrations below the drinking water limit of 0.1 µg/L, with the exceptions of metabolite M54 which was present in the third year at 0.050–0.101 µg/L and metabolite M56 which was present in the third year at 0.097-0.266 µg/L. In the two two-year studies all annual average concentrations of all measured metabolites were below the drinking water limit of 0.1 µg/L, with the exception of NOA407854 (M2) with a calculated annual average of 0.5 µg/L at 0.8 m depth and 0.1 µg/L at 1.2 m depth.~~

zRMS comments:

Summary of the results of the lysimeter studies does not fully corresponds with information presented in EFSA Journal 2013;11(8):3269 (e.g. in 3-year study in Germany a number of metabolites exceeded 0.1 µg/L trigger during 2nd and/or 3rd year (M3, M52, M11, M54, M55 and M56), while the Applicant indicates that only metabolites M54 and M56 were detected at >0.1 µg/L. Taking this into account, the summary above was struck through, while results of the lysimeter studies in relation to the performed groundwater modelling are discussed in more detail in the zRMS commenting box in point 8.8.2.2.

~~Summary regarding the lysimeter studies presented above is in agreement with information provided in EFSA Journal 2013;11(8):3269. Potential leaching of pinoxaden and its metabolites to groundwater has been sufficiently addressed in the groundwater modelling. For details, please see point 8.8 of this document.~~

8.5.5.3 Mefenpyr-diethyl and its metabolites

A lysimeter study was summarised in the Monograph list of endpoints dated October 2011. The study was carried out for 3 years in Germany. Annual average concentrations for mefenpyr-diethyl, AE F094270 and AE F113225 were all below 0.03 µg/L. Unidentified substances accounted for up to 0.1 µg/L.

zRMS comments:

Summary regarding the lysimeter studies presented above is in agreement with information provided in in the Monograph (list of endpoints) prepared in October 2011 by ANSES and AGES in order to aid zonal evaluations of the products containing this safener. Potential leaching of mefenpyr-diethyl and its metabolites to groundwater has been sufficiently addressed in the groundwater modelling. For details, please see point 8.8 of this document.

8.5.6 Field leaching studies (KCP 9.1.2.3)

No field leaching studies are required for any active substance.

zRMS comments:

Potential leaching of the active substances and its metabolites to groundwater has been sufficiently addressed in the groundwater modelling. For details, please see point 8.8 of this document.

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

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

8.6.1 Mesosulfuron-methyl and its metabolites

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

Mesosulfuron-methyl Distribution (max. sediment 20.0 % after 7 days)											
Water/ sediment system	**pH water/ sed.**	**DegT50 whole syst. (d)**	**DegT90 whole syst. (d)**	**Kinetic, Fit**	**DissT50 water (d)**	**DissT90 water (d)**	**Kinetic, Fit**	**DissT50 sed. (d)**	**Kinetic, Fit**	**Evaluated on EU level y Reference**	
Kies (phenyl label)	7.2/ 7.2	81.15	269.6	SFO	72.7	241.5	SFO	[a]	[a]	~~EFSA Conclusion 3269/2013~~	EFSA Conclusion 4584/2016
Kies (pyrimidyl label)	7.2/7.2	68.93	228.98	SFO	61.65	204.8	SFO	62.83	SFO	~~EFSA Conclusion 3269/2013~~	
Nidda (phenyl label)	7.8/6.4	26.82	89.08	SFO	12.79	68.19	FOMC	79.32	SFO	~~EFSA Conclusion 3269/2013~~	
Nidda (pyrimidyl label)	7.8/6.4	22.81	75.78	SFO	14.42	47.9	SFO	44.45	SFO	~~EFSA Conclusion 3269/2013~~	
Geometric mean (n=4)		43.01	-		33.9	-		60.51			

[a] no reliable value could be derived

Table 8.6-2: Summary of observed metabolites

AE F154851 Water/sediment system	Max. in total system 4.9 % after 14 d (Nidda, phenyl)	~~EFSA Conclusion 3269/2013~~	EFSA Conclusion 4584/2016
AE F160459 Water/sediment system	Max. in total system 21.6 % after 112 d (Kies, pyrimidyl)	~~EFSA Conclusion 3269/2013~~	
AE F160460 Water/sediment system	Max. in total system 8.4 % after 28 d (Nidda, pyrimidyl)	~~EFSA Conclusion 3269/2013~~	
AE F147447 Water/sediment system	Max. in total system 10.9 % after 141 d (Kies, phenyl)	~~EFSA Conclusion 3269/2013~~	
AE F092944 Water/sediment system	Max. in total system 3.2 % after 112 d (Nidda, pyrimidyl)	~~EFSA Conclusion 3269/2013~~	
AE F099095 Water/sediment system	Max. in total system 0.9 % after 141 d (Kies, pyrimidyl)	~~EFSA Conclusion 3269/2013~~	
BCS CV14885 Water/sediment system	Max. in total system 22.0 % after 309 d (Kies, pyrimidyl)	~~EFSA Conclusion 3269/2013~~	
BCS CO60720 Water/sediment system	Max. in total system 13.1 % after 365 d (Kies, pyrimidyl)	~~EFSA Conclusion 3269/2013~~	

Table 8.6-3: Summary of degradation in water/sediment of AE F154851

AE F154851 Distribution (max. total system 4.9 % 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 Reference**	
Kies (phenyl label)	7.2/ 7.2	~~a~~ 1000	a	a	a	a	a	a	a	~~EFSA Conclusion 3269/2013~~	EFSA Conclusion 4584/2016
Kies (pyrimidyl label)	7.2/7.2	100.04	322.34	SFO	a	a	a	a	a	~~EFSA Conclusion 3269/2013~~	
Nidda (phenyl label)	7.8/6.4	11.03	36.64	SFO	33.11	110.0	SFO	a	a	~~EFSA Conclusion 3269/2013~~	
Nidda (pyrimidyl label)	7.8/6.4	8.12	26.98	SFO	25.29	84.02	SFO	a	a	~~EFSA Conclusion 3269/2013~~	
Geometric mean (n=4)		54.7 ~~56.4~~	-		-	-		-			

[a] no reliable value could be derived

Table 8.6-4: Summary of degradation in water/sediment of AE F160459

AE F160459 Distribution (max. total system 21.6 % after 112 days)											
Water/ sediment system	**pH water/ sed.**	**DegT50 whole syst. (d)**	**DegT90 whole syst. (d)**	**Kinetic, Fit**	**DissT50 water (d)**	**DissT90 water (d)**	**Kinetic, Fit**	**DissT50 sed. (d)**	**Kinetic, Fit**	**Evaluated on EU level y Reference**	
Kies (phenyl label)	7.2/ 7.2	> 1000	[a]	[a]	[a]	[a]	[a]	[a]	[a]	~~EFSA Conclusion 3269/2013~~	EFSA Conclusion 4584/2016
Kies (pyrimidyl label)	7.2/7.2	77.39	257.08	SFO	[a]	[a]	[a]	[a]	[a]	~~EFSA Conclusion 3269/2013~~	
Nidda (phenyl label)	7.8/6.4	43.98	146.11	SFO	83.85	278.5	SFO	[a]	[a]	~~EFSA Conclusion 3269/2013~~	
Nidda (pyrimidyl label)	7.8/6.4	17.45	57.98	SFO	51.43	170.8	SFO	[a]	[a]	~~EFSA Conclusion 3269/2013~~	
Geometric mean (n=4)		87.8 ~~87.9~~	-		-	-		-			

[a] no reliable value could be derived

Table 8.6-5: Summary of degradation in water/sediment of AE F160460

AE F160460 Distribution (max. total system 8.4 % after 28 days)											
Water/ sediment system	**pH water/ sed.**	**DegT50 whole syst. (d)**	**DegT90 whole syst. (d)**	**Kinetic, Fit**	**DissT50 water (d)**	**DissT90 water (d)**	**Kinetic, Fit**	**DissT50 sed. (d)**	**Kinetic, Fit**	**Evaluated on EU level y Reference**	
Kies (phenyl label)	7.2/ 7.2	> 1000	[a]	[a]	[a]	[a]	[a]	[a]	[a]	~~EFSA Conclusion 3269/2013~~	EFSA Conclusion 4584/2016
Kies (pyrimidyl label)	7.2/7.2	> 1000	[a]	[a]	[a]	[a]	[a]	[a]	[a]	~~EFSA Conclusion 3269/2013~~	
Nidda (phenyl label)	7.8/6.4	101.6	337.4 ~~33.74~~	Peak down	[a]	[a]	[a]	[a]	[a]	~~EFSA Conclusion 3269/2013~~	
Nidda (pyrimidyl label)	7.8/6.4	111.0	368.7	Peak down	70.59	234.5	Peak down	[a]	[a]	~~EFSA Conclusion 3269/2013~~	
Geometric mean (n=4)		325.9	-		-	-		-			

[a] no reliable value could be derived

No reliable DT_{50} values could be determined for any other metabolites. Worst-case DT_{50} values of 1000 days were used for PEC_{SW} calculations.

zRMS comments:

Information on degradation of mesosulfuron-methyl and its metabolites in water/sediment systems presented in Tables 8.6-1 to 8.6-5 above is in general in line with EU agreed endpoints reported in EFSA Journal 2016;14(10):4584. It is noted that the Applicant made mistake in reference to the EFSA conclusion, which was corrected by the zRMS.

Some minor corrections were introduced by the zRMS in tables above, so the data are fully in line with EFSA Journal 2016;14(10):4584. ~~The EU agreed arithmetic mean K_{foc} values were also included, although the geometric mean values were calculated based on individual EU agreed data and are confirmed to be correct.~~

8.6.2 Pinoxaden and its metabolites

Table 8.6-6: Summary of degradation in water/sediment of AE F160460

Pinoxaden – Distribution: max. in water 97.9% after 0 days; max. in sediment 0.2% after 1 day											
Water/sediment system	**pH water phase**	**pH sed**	**$DegT_{50}$ whole syst. (d)**	**$DegT_{90}$ whole syst. (d)**	**Kinetic model**	**$DissT_{50}$ water (d)**	**$DissT_{90}$ water (d)**	**Kinetic model**	**$DissT_{50}$ sed. (d)**	**Kinetic model**	**Evaluated on EU level / Reference**
River	8.3	7.4	0.28	0.95	SFO	0.26	-	SFO	3.4	SFO	EFSA Conclusion 3269/2013
Pond	8.1	7.2	0.28	0.93	SFO	0.28	-	SFO	1.7	SFO	EFSA Conclusion 3269/2013
Geometric mean (n=2)			0.28	-		0.27			-		

Table 8.6-7: Summary of observed metabolites

M2 (NOA407854)	Max. in water/sediment system: 86.9% after 7 days (pond system).	EFSA Conclusion 3269/2013
M3 (NOA447204)	Max. in water/sediment system: 9.7% after 70 days (pond system).	EFSA Conclusion 3269/2013

Table 8.6-8: Summary of degradation in water/sediment of M2 (NOA407854)

M2 (NOA407854) – Distribution: max. in water 86.9% after 7 days; max. in sediment 26% after 35 day, pond system											
Water/sediment system	**pH water phase**	**pH sed**	**$DegT_{50}$ whole syst. (d)**	**$DegT_{90}$ whole syst. (d)**	**Kinetic model**	**$DissT_{50}$ water (d)**	**$DissT_{90}$ water (d)**	**Kinetic model**	**$DissT_{50}$ sed. (d)**	**Kinetic model**	**Evaluated on EU level / Reference**
River	8.3	7.4	193	-	SFO	317	-	SFO	-	-	EFSA Conclusion 3269/2013
Pond	8.1	7.2	515	-	SFO	117	-	SFO	-	-	EFSA Conclusion 3269/2013
Geometric mean (n=2)			315	-		193			-		

Table 8.6-9: Summary of degradation in water/sediment of M3 (NOA447204)

M3 (NOA447204) – Distribution: max. in water/sediment 9.7% after 70 d, pond system; max. in water or sediment <5% at all sample times											
Water / sediment system	**pH water phase**	**pH sed**	**$DegT_{50}$ whole syst. (d)**	**$DegT_{90}$ whole syst. (d)**	**Kinetic model**	**$DissT_{50}$ water (d)**	**$DissT_{90}$ water (d)**	**Kinetic model**	**$DissT_{50}$ sed. (d)**	**Kinetic model**	**Evaluated on EU level / Reference**
River	8.3	7.4	37.7	-	SFO	41.8	-	SFO	-	-	EFSA Conclusion 3269/2013
Pond	8.1	7.2	34.1	-	SFO	31.8	-	SFO	-	-	EFSA Conclusion 3269/2013
Geometric mean (n=2)			35.9	-		36.4			-		

zRMS comments:

Information on degradation of pinoxaden and its metabolites in water/sediment systems presented in Tables 8.6-6 to 8.6-9 above is in line with EFSA Journal 2013;11(8):3269.

8.6.3 Mefenpyr-diethyl and its metabolites

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

Mefenpyr-diethyl Distribution (max. water 88% after 0 days, max. sediment 34 % after 0 days)										
Water/ sediment system	**pH water/ sed.**	**DegT50 whole syst. (d)**	**DegT90 whole syst. (d)**	**Kinetic, Fit**	**DissT50 water (d)**	**DissT90 water (d)**	**Kinetic, Fit**	**DissT50 sed. (d)**	**Kinetic, Fit**	**Evaluated on EU level y Reference**
Nidda	9.0/7.1	1.0	3.5	SFO	0.65	2.2	SFO	0.95	SFO	Proposed in Monograph (list of endpoints) Oct 2011[a]
Gravel Pit	7.7/6.9	1.1	3.6	SFO	0.92	3.0	SFO	1.5	SFO	Proposed in Monograph (list of endpoints) Oct 2011[a]
Geometric mean (n=2)		1.1	-		0.8	-		1.2		

[a] Monograph has been voluntarily prepared by AGES and ANSES in the context of zonal authorisation of plant protection products containing safener mefenpyr-diethyl.

Table 8.6-11: Summary of observed metabolites

AE F113225 Water/sediment system	Max. in water 75 % after 7 d (Gravel Pit), max. in sediment 18% after 14 d (Nidda)	Proposed in Monograph (list of endpoints) Oct 2011[a]
AE F114952 Water/sediment system	Max. in water 17 % after 7 d (Gravel Pit), max. in sediment 4 % after 101 d (Gravel Pit)	Proposed in Monograph (list of endpoints) Oct 2011[a]
AE F109453 Water/sediment system	Max. in water 42 % after 101 d (Gravel Pit), max. in sediment 5.6 % after 36 d (Nidda)	Proposed in Monograph (list of endpoints) Oct 2011[a]
AE F094270 Water/sediment system	Max. in water 29 % after 101 d (Nidda), max. in sediment 34 % after 101 d (Nidda)	Proposed in Monograph (list of endpoints) Oct 2011[a]

[a] Monograph has been voluntarily prepared by AGES and ANSES in the context of zonal authorisation of plant protection products containing safener mefenpyr-diethyl.

Table 8.6-12: Summary of degradation in water/sediment of AE F113225

AE F113225 Distribution (max. water 75% after 7 days, max. sediment 18 % 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 Reference**
Nidda	9.0/7.1	27	90	SFO	29	96	SFO	24	SFO	Proposed in Monograph (list of endpoints) Oct 2011[a]
Gravel Pit	7.7/6.9	67	222	SFO	57	190	SFO	37	SFO	Proposed in Monograph (list of endpoints) Oct 2011[a]
Geometric mean (n=2)		42.5	-		41	-		30		

[a] Monograph has been voluntarily prepared by AGES and ANSES in the context of zonal authorisation of plant protection products containing safener mefenpyr-diethyl.

Table 8.6-13: Summary of degradation in water/sediment of AE F114952

AE F114952 Distribution (max. water 17% after 7 days, max. sediment 4% after 101 days)										
Water/ sediment system	**pH water/ sed.**	**DegT50 whole syst. (d)**	**DegT90 whole syst. (d)**	**Kinetic, Fit**	**DissT50 water (d)**	**DissT90 water (d)**	**Kinetic, Fit**	**DissT50 sed. (d)**	**Kinetic, Fit**	**Evaluated on EU level y Reference**
Nidda	9.0/7.1	12	40	SFO	18	60	SFO	7	SFO	Proposed in Monograph (list of endpoints) Oct 2011[a]
Gravel Pit	7.7/6.9	24	79	SFO	18	60	SFO	[b]	[b]	Proposed in Monograph (list of endpoints) Oct 2011[a]
Geometric mean (n=2)		19.9	-		18	-		-		

[a] Monograph has been voluntarily prepared by AGES and ANSES in the context of zonal authorisation of plant protection products containing safener mefenpyr-diethyl.
[b] no reliable value could be derived

Table 8.6-14: Summary of degradation in water/sediment of AE F109453

AE F109453 Distribution (max. water 42% after 101 days, max. sediment 5.6% after 36 days)										
Water/ sediment system	**pH water/ sed.**	**DegT50 whole syst. (d)**	**DegT90 whole syst. (d)**	**Kinetic, Fit**	**DissT50 water (d)**	**DissT90 water (d)**	**Kinetic, Fit**	**DissT50 sed. (d)**	**Kinetic, Fit**	**Evaluated on EU level y Reference**
04/34	7.5/7.1	69	230	SFO	48	159	SFO	[b]	[b]	Proposed in Monograph (list of endpoints) Oct 2011[a]
04/35	6.6/5.3	8	27	SFO	8	27	SFO	[b]	[b]	Proposed in Monograph (list of endpoints) Oct 2011[a]
Geometric mean (n=2)		23	-		20	-		-		

[a] Monograph has been voluntarily prepared by AGES and ANSES in the context of zonal authorisation of plant protection products containing safener mefenpyr-diethyl.
[b] no reliable value could be derived

Table 8.6-15: Summary of degradation in water/sediment of AE F094270

AE F094270 Distribution (max. water 29% after 101 days, max. sediment 34% after 101 days)										
Water/ sediment system	**pH water/ sed.**	**DegT50 whole syst. (d)**	**DegT90 whole syst. (d)**	**Kinetic, Fit**	**DissT50 water (d)**	**DissT90 water (d)**	**Kinetic, Fit**	**DissT50 sed. (d)**	**Kinetic, Fit**	**Evaluated on EU level y Reference**
04/34	7.5/7.1	[b]	[b]	[b]	[b]	[b]	[b]	[b]	[b]	Proposed in Monograph (list of endpoints) Oct 2011[a]
04/35	6.6/5.3	112	372	SFO	92	306 ~~360~~	SFO	[b]	[b]	Proposed in Monograph (list of endpoints) Oct 2011[a]

AE F094270 Distribution (max. water 29% after 101 days, max. sediment 34% after 101 days)										
Water/ sediment system	**pH water/ sed.**	**DegT50 whole syst. (d)**	**DegT90 whole syst. (d)**	**Kinetic, Fit**	**DissT50 water (d)**	**DissT90 water (d)**	**Kinetic, Fit**	**DissT50 sed. (d)**	**Kinetic, Fit**	**Evaluated on EU level y Reference**
05/006	8.1/7.0	87	290	SFO	47	156	SFO			Proposed in Monograph (list of endpoints) Oct 2011[a]
Geometric mean (n=2)		109.2	-		66	-		-		

[a] Monograph has been voluntarily prepared by AGES and ANSES in the context of zonal authorisation of plant protection products containing safener mefenpyr-diethyl.
[b] no reliable value could be derived

zRMS comments:

Information on degradation of mefenpyr-diethyl and its metabolites presented in Tables 8.6-10 to 8.6-15 is in line with the Monograph (list of endpoints) prepared in October 2011 by ANSES and AGES in order to aid zonal evaluations of the products containing this safener. The typing error in Table 8.6-15 was corrected by the zRMS.

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

8.7.1 Justification for new endpoints

No new endpoints were used for PEC_{soil} calculations.

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.	3
Crop	Spring wheat
Application rate (g as/ha)	Mesosulfuron-methyl: 12 Pinoxaden: 60 Mefenpyr-diethyl: 35
Number of applications/interval	1
Crop interception (%)	0
Depth of soil layer (relevant for plateau concentration) (cm)	20 cm (tillage)

PEC_{soil} values were not calculated for GAP ~~uses 1~~ and 2. The risks from exposure in soil for all uses are covered by PEC_{soil} values for GAP use 3 because crop interception was not considered in any of the calculations and there are no differences between spring and winter cereals in the calculation tool.

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

Compound	Molecular weight (g/mol)	Max. occurrence (%)	DT_{50} (days)	Value in accordance to EU endpoint y/n/ Reference
Mesosulfuron-methyl	503.5	-	155 d (slow phase from DFOP model, worst-case laboratory tests)	EFSA Conclusion 4584/2016
Mesosulfuron (AE F154851)	489.5	16.2	207.4 (SFO, worst-case laboratory tests)	EFSA Conclusion 4584/2016
AE F160459	489.5	8.9	144.8 (SFO, worst-case laboratory tests)	EFSA Conclusion 4584/2016
AE F099095	198.2	29.2	261.2 (SFO, worst-case laboratory tests)	EFSA Conclusion 4584/2016
AE F092944	155.2	10.1	82.7 (SFO, worst-case laboratory tests)	EFSA Conclusion 4584/2016
AE F160460	475.5	8.6	44.2 (SFO, worst-case laboratory tests)	EFSA Conclusion 4584/2016
AE F140584	322.4	7.1	15.1 (SFO, worst-case laboratory tests)	EFSA Conclusion 4584/2016
AE F147447	290.3	6.5	833.1 (SFO, worst-case laboratory tests)	EFSA Conclusion 4584/2016
Pinoxaden	400.5	-	1.05 (SFO, worst-case laboratory tests)	EFSA Conclusion 3269/2013
NOA 407854 (M2)	316.4	100	57.8 (SFO, worst-case laboratory tests)	EFSA Conclusion 3269/2013
NOA 447204 (M3)	332.4	100	117/387 (alkaline/acid soils, SFO, worst-case laboratory tests)	EFSA Conclusion 3269/2013
Mefenpyr-diethyl	373.26	-	4.6 (SFO, worst-case laboratory tests)	Proposed in Monograph (list of endpoints) Oct 2011[a]
AE F113225	345.2	44.1	-	Proposed in Monograph (list of endpoints) Oct 2011[a]
AE F094270	271.11	72.2	425 (SFO, worst-case laboratory tests)	Proposed in Monograph (list of endpoints) Oct 2011[a]
AEF2211046/ AE 211046	391.26	11.0	-	Proposed in Monograph (list of endpoints) Oct 2011[a]

[a] Monograph has been voluntarily prepared by AGES and ANSES in the context of zonal authorisation of plant protection products containing safener mefenpyr-diethyl.

zRMS comments:

The application pattern considered in soil exposure assessment and presented in Table 8.7-1 is in line with the critical Central Zone GAP presented in Table 8.1-1. It is noted that the application to spring wheat was considered as a worst case, covering all intended zonal uses. Selected crop interception of 0% is in line with FOCUS groundwater guidance (2021) and is relevant for the earliest intended application timing.

Input parameters for ~~mesosulfuron-methyl,~~ pinoxaden, mefenpyr-diethyl and their metabolites presented in Table 8.7-2 are in line with EU agreed parameters reported in ~~EFSA Journal 2016;14(10):4584,~~ EFSA Journal 2013;11(8):3269, and in ANSES/AGES Monograph (list of endpoints) October 2011, respectively.

With regard to mesosulfuron-methyl and its metabolites it is noted that the degradation data given in Table 8.7-2 were taken by the Applicant from the part of EFSA Journal 2016;14(10):4584 where soil exposure is calculated (pages 51-53 in the LoEP), while the triggering endpoints that should be used in the soil exposure assessment (presented on pages 25-29 of the LoEP) were modified and for some compounds they do not correspond with inputs considered in the EU PEC_{SOIL} calculation. Furthermore, in chapter with PEC_{SOIL} calculations in the LoEP there is a following note: *Agreed trigger endpoints should be considered in further exposure calculations*. This note was clearly overlooked by the Applicant and the zRMS (it actually looks like the table title and not indication that other endpoints are now relevant). As a result of this mistake, the following deviations between endpoints considered by the Applicant and endpoints that should have been used are noted:

- Mesosulfuron-methyl: the correct DT_{50} is 140.1 d (calculations were performed for 155 d),
- AE F160459: the correct DT_{50} is 129.8 d (calculations were performed for 144.8 d),
- AE F099095: the correct DT_{50} is 185.5 d (calculations were performed for 261.2 d),
- AE F140584: the correct DT_{50} is 13.5 d (calculations were performed for 15.1 d),
- AE F147447: the correct DT_{50} is 203.0 d (calculations were performed for 833.1 d).

The differences in correct and used DT_{50} values will have no impact on the initial PEC_{SOIL} values, but they may have impact on $PEC_{SOIL,ACCU}$ as well as TWA PEC_{SOIL}. Nevertheless, as all correct triggering DT_{50} values are shorter than these used in soil exposure assessment for mesosulfuron-methyl and its metabolites following application of ADM.06001.H.2.B, the recalculation of $PEC_{SOIL,ACCU}$ and TWA PEC_{SOIL} would result with lower soil exposure. Therefore, the already performed calculations may be considered to represent worst case and new calculations are deemed not necessary as they would not change the outcome of the risk assessment for soil organisms. Nevertheless, in case of any future assessments of ADM.06001.H.2 (e.g. due to the label extension) the correct DT_{50} values should be used.

There were no deviations between used and correct DT_{50} values for mesosulfuron and metabolites AE F092944 and AE F160460.

8.7.2.1 Mesosulfuron-methyl and its metabolites

Table 8.7-3: PEC_{soil} for Mesosulfuron-methyl on spring wheat

PEC_{soil} (mg/kg)		**Spring wheat**	
		Single application	
		Actual	**TWA**
Initial		0.016	-
Short term	24h	0.016	0.016
	2d	0.016	0.016
	4d	0.016	0.016
Long term	7d	0.016	0.016
	14d	0.015	0.016
	21d	0.015	0.015
	28d	0.014	0.015
	50d	0.013	0.014
	100d	0.010	0.013
Plateau concentration (20 cm)		0.001	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		0.017	

PEC_{soil} of metabolites

Table 8.7-4: PEC_{soil} for mesosulfuron (AE F154851) on spring wheat

PEC_{soil} (mg/kg)		**Spring wheat**	
		Single application	
		Actual	**TWA**
Initial		0.003	-
Short term	24h	0.003	0.003
	2d	0.003	0.003
	4d	0.002	0.003
Long term	7d	0.002	0.002
	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)		<0.001	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		0.003	

Table 8.7-5: PEC_{soil} for AE F160459 on spring wheat

PEC_{soil} (mg/kg)		**Spring wheat**	
		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)		<0.001	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		0.001	

Table 8.7-6: PEC_{soil} for AE F099095 on spring wheat

PEC_{soil} (mg/kg)		**Spring wheat**	
		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	0.002	0.002
	100d	0.001	0.002
Plateau concentration (20 cm)		<0.001	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		0.002	

Table 8.7-7: PEC_{soil} for AE F092944 on spring wheat

PEC_{soil} (mg/kg)		**Spring wheat**	
		Single application	
		Actual	**TWA**
Initial		0.0005	-
Short term	24h	0.0005	0.0005
	2d	0.0005	0.0005
	4d	0.0005	0.0005
Long term	7d	0.0005	0.0005
	14d	0.0004	0.0005
	21d	0.0004	0.0005
	28d	0.0004	0.0004
	50d	0.0003	0.0004
	100d	0.0002	0.0003
Plateau concentration (20 cm)		0.0005	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		0.001	

Table 8.7-8: PEC_{soil} for AE F160460 on spring wheat

PEC_{soil} (mg/kg)		**Spring wheat**	
		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)		-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		-	-

Table 8.7-9: PEC_{soil} for AE F140584 on spring wheat

PEC_{soil} (mg/kg)		**Spring wheat**	
		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)		-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		-	-

Table 8.7-10: PEC_{soil} for AE F147447 on spring wheat

PEC_{soil} (mg/kg)		**Spring wheat**	
		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)		-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		-	-

The above PEC_{soil} values calculated for Mesosulfuron-methyl and its metabolites can be used to perform the risk assessment for non-target organisms.

zRMS comments:

Endpoints considered by the Applicant in the soil exposure assessment for mesosulfuron-methyl and its metabolites were agreed by the zRMS despite some deviations (see commenting box in point 8.7.2 for more details). ~~and are in line with EU agreed parameters reported in EFSA Journal 2016;14(10):4584.~~

The soil exposure for mesosulfuron-methyl and its metabolites has been independently validated by the zRMS using FOCUS methods and EU agreed endpoints. The pseudo-application rates of metabolites were derived with consideration of the parent rate, molar ratio and peak occurrence in soil. Recalculation resulted with the same PEC_{SOIL} values, therefore results reported in Tables 8.7-3 to 8.7-10 may be used for the soil risk assessment purposes.

8.7.2.2 Pinoxaden and its metabolites

Table 8.7-11: PEC_{soil} for Pinoxaden on spring wheat

PEC_{soil} (mg/kg)		**Spring wheat**	
		Single application	
		Actual	**TWA**
Initial		0.080	-
Short term	24h	0.041	0.059
	2d	0.021	0.044
	4d	0.006	0.028
Long term	7d	0.001	0.017
	14d	<0.001	0.009
	21d	<0.001	0.006
	28d	<0.001	0.004
	50d	<0.001	0.002
	100d	<0.001	0.001
Plateau concentration (20 cm)		-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		-	-

PEC_{soil} of metabolites

Table 8.7-12: PEC_{soil} for NOA 407854 (M2) on spring wheat

PEC_{soil} (mg/kg)		**Spring wheat**	
		Single application	
		Actual	**TWA**
Initial		0.063	-
Short term	24h	0.062	0.063
	2d	0.062	0.062
	4d	0.060	0.062
Long term	7d	0.058	0.061
	14d	0.053	0.058
	21d	0.049	0.056
	28d	0.045	0.054
	50d	0.035	0.048
	100d	0.019	0.037
Plateau concentration (20 cm)		-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		-	-

Table 8.7-13: PEC_{soil} for NOA 447204 (M3) on spring wheat in alkaline soil

PEC_{soil} (mg/kg)		**Spring wheat**	
		Single application	
		Actual	**TWA**
Initial		0.066	-
Short term	24h	0.066	0.066
	2d	0.066	0.066
	4d	0.065	0.066
Long term	7d	0.064	0.065
	14d	0.061	0.064
	21d	0.059	0.062
	28d	0.056	0.061
	50d	0.049	0.057
	100d	0.037	0.050
Plateau concentration (20 cm)		0.003	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		0.069	-

Table 8.7-14: PEC_{soil} for NOA 447204 (M3) on spring wheat in acidic soil

PEC_{soil} (mg/kg)		**Spring wheat**	
		Single application	
		Actual	**TWA**
Initial		0.066	-
Short term	24h	0.066	0.066
	2d	0.066	0.066
	4d	0.066	0.066
Long term	7d	0.066	0.066
	14d	0.065	0.066
	21d	0.064	0.065
	28d	0.063	0.065
	50d	0.061	0.064
	100d	0.056	0.061
Plateau concentration (20 cm)		0.018	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		0.084	-

The above PEC_{soil} values calculated for Pinoxaden and its metabolites can be used to perform the risk assessment for non-target organisms.

zRMS comments:

Endpoints considered by the Applicant in the soil exposure assessment for pinoxaden and its metabolites were agreed by the zRMS and are in line with EU agreed parameters reported in EFSA Journal 2013;11(8):3269.

The soil exposure for pinoxaden and its metabolites has been independently validated by the zRMS using FOCUS methods and EU agreed endpoints. The pseudo-application rates of metabolites were derived with consideration of the parent rate, molar ratio and peak occurrence in soil. Recalculation resulted with the same PEC_{SOIL} values, therefore results reported in Tables 8.7-11 to 8.7-14 may be used for the soil risk assessment purposes.

8.7.2.3 Mefenpyr-diethyl and its metabolites

Table 8.7-15: PEC_{soil} for Mefenpyr-diethyl on spring wheat

PEC_{soil} (mg/kg)		**Spring wheat**	
		Single application	
		Actual	**TWA**
Initial		0.047	-
Short term	24h	0.040	0.043
	2d	0.035	0.040
	4d	0.026	0.035
Long term	7d	0.016	0.029
	14d	0.006	0.019
	21d	0.002	0.014
	28d	0.001	0.011
	50d	0.000	0.006
	100d	0.000	0.003
Plateau concentration (20 cm)		-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		-	-

PEC_{soil} of metabolites

Table 8.7-16: PEC_{soil} for AE F113225 on spring wheat

PEC_{soil} (mg/kg)		**Spring wheat**	
		Single application	
		Actual	**TWA**
Initial		0.019	-
Short term	24h	-	-
	2d	-	-
	4d	-	-
Long term	7d	-	-
	14d	-	-
	21d	-	-
	28d	-	-
	50d	-	-
	100d	-	-
Plateau concentration (20 cm)		-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		-	-

Table 8.7-17: PEC_{soil} for AE F113225 on spring wheat

PEC_{soil} (mg/kg)		**Spring wheat**	
		Single application	
		Actual	**TWA**
Initial		0.019	-
Short term	24h	-	-
	2d	-	-
	4d	-	-
Long term	7d	-	-
	14d	-	-
	21d	-	-
	28d	-	-
	50d	-	-
	100d	-	-
Plateau concentration (20 cm)		-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		-	-

Table 8.7-18: PEC_{soil} for AE F094270 on spring wheat

PEC_{soil} (mg/kg)		**Spring wheat**	
		Single application	
		Actual	**TWA**
Initial		0.024	-
Short term	24h	0.024	0.024
	2d	0.024	0.024
	4d	0.024	0.024
Long term	7d	0.024	0.024
	14d	0.024	0.024
	21d	0.024	0.024
	28d	0.023	0.024
	50d	0.023	0.024
	100d	0.021	0.023
Plateau concentration (20 cm)		0.008	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		0.032	-

Table 8.7-19: PEC_{soil} for AE F2211046/AE 2211046 on spring wheat

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

The above PEC_{soil} values calculated for Mefenpyr-diethyl and its metabolites can be used to perform the risk assessment for non-target organisms.

zRMS comments:

No EU agreed data exist for the safener mefenpyr-diethyl, however in 2011 ANSES and AGES prepared Monograph (List of Endpoints) in order to aid zonal evaluations of the products containing this safener. Considered input parameters were in line with this document.

The soil exposure for mefenpyr-diethyl and its metabolites has been independently validated by the zRMS using FOCUS methods and input parameters taken from the Monograph (2011). The pseudo-application rates of metabolites were derived with consideration of the parent rate, molar ratio and peak occurrence in soil. Recalculation resulted with the same PEC_{SOIL} values, therefore results reported in Tables 8.7-15 to 8.7-19 may be used for the soil risk assessment purposes.

8.7.2.4 PEC_{soil} of ADM.06001.H.2.B

The initial PECsoil value for the formulation ADM.06001.H.2.B has been calculated using the application rate of 1.0 L/ha and the formulation density of 0.97 g/ml. A worst-case crop interception of 0% was assumed.

Table 8.7-20: PEC_{soil} for ADM.06001.H.2.B on cereals

Active substance/ reparation	Application rate (g/ha)	PEC_{act} (mg/kg)	PEC_{twa}21 d (mg/kg)	Tillage depth (cm)	$PEC_{soil,plateau}$ (mg/kg)	PEC_{accu} = PEC_{act} + $PEC_{soil,plateau}$ (mg/kg)
ADM.06001.H.2.B	970.0	1.293	-	-	-	-

The above PEC_{soil} values can be used to perform the risk assessment for non-target organisms.

zRMS comments:

PEC_{SOIL} value calculated by the Applicant for the formulated product is agreed by the zRMS and may be used in the risk assessment for soil organisms.

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

zRMS comments:

After superficial review of the first version of the dRR submitted to the Polish authorities some of the assumptions taken by the Applicant were not agreed by the zRMS efate expert. The Applicant was thus requested to provide updated groundwater exposure assessment based on inputs selected in line with current requirements and agreed endpoints. The results based on the relevant inputs were included by the Applicant in the updated version of the dRR, but the parts not agreed already after the superficial zRMS review (i.e. before the actual detailed assessment) were retained. Since the document was updated by the Applicant and the values presented initially would not be accepted anyway, the updated version of the dRR could be treated as the initial version and the zRMS decided to remove not agreed data and results obtained on their basis in order to avoid excessive strikethroughs and to improve the transparency of the report, facilitating the cMS review without unnecessary confusion.

8.8.1 Justification for new endpoints

No new endpoints were used for PEC_{gw} calculations.

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.	2	3
Crop	Winter cereals	Spring cereals
Application rate (g as/ha)	Mesosulfuron-methyl: 12 Pinoxaden: 60 Mefenpyr-diethyl: 35	Mesosulfuron-methyl: 12 Pinoxaden: 60/(45[c]) Mefenpyr-diethyl: 35
Number of applications/interval (d)	1	1
Relative application date	Actual application dates used, see Table 8.8-2	
Crop interception (%)	0[a] 20[b]	0[a]
Frequency of application	annual	annual
Models used for calculation	FOCUS PEARL v4.4.4, FOCUS PELMO v5.5.3, FOCUS MACRO v5.5.4	

[a] Worst-case crop interception of 0% used for PEC_{gw} calculations of both winter and spring cereals,
[b] crop interception in accordance with EFSA Journal 2014; 12(5):3662 for winter cereals at BBCH 20-39,
[c] On request of the Applicant, following the commenting period additional simulations were performed for pinoxaden with consideration of the lower application rate of ADM.06001.H.2.B in spring cereals (0.75 L/ha, use No 3* in GAP table) in order to identify use giving acceptable exposure following annual application (for Hamburg scenario restriction to biennial application was deemed necessary for the higher application rate).

PEC_{gw} values have been provided using application dates determined with AppDate (v3.06). The new application dates are provided in the table below.

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

Crop	Scenario	Application dates (absolute)
Winter cereals (BBCH 20-39)	Châteaudun	06 April
	Hamburg	25 April
	Jokioinen	05 May
	Kremsmünster	15 April
	Okehampton	12 April
	Piacenza	10 March
	Porto	03 January
	Sevilla	21 December
	Thiva	27 December
Spring cereals (BBCH 13-39)	Châteaudun	16 March
	Hamburg	06 April
	Jokioinen	22 May
	Kremsmünster	06 April

Crop	Scenario	Application dates (absolute)
	Okehampton	05 May
	Porto	16 March

[a] revised application date used for PEARL calculation of mesosulfuron-methyl based on EFSA Conclusion 4584/2016

zRMS comments:

The input parameters related to the application pattern presented in Table 8.8-1 are agreed by the zRMS. The assumed crop interception of 20% for winter cereals at BBCH 20-39 and 0% for spring cereals at BBCH 13-39 is in line with the most recent version of the FOCUS Groundwater Guidance (2021).

On request of the Applicant, following the commenting period additional simulations were performed for pinoxaden with consideration of the lower application rate of ADM.06001.H.2.B in spring cereals (0.75 L/ha, use No 3* in GAP table) in order to identify use giving acceptable exposure following annual application (for Hamburg scenario restriction to biennial application was deemed necessary for the higher application rate). As additional simulations were not required for other substances in ADM.06001.H.2.B, the information on the lower rate was added only to pinoxaden in Table 8.8-1.

Application dates presented in Table 8.8-2 were checked by the zRMS using AppDate ver. 3.06 tool and are considered acceptable.

8.8.2.1 Mesosulfuron-methyl and its metabolites

There are 8 metabolites of Mesosulfuron-methyl which could potentially be detected in groundwater: AE F154851 (Mesosulfuron), AE F160459, AE F099095, AE F092944, AE F160460, AE F140584, AE F147447, BCS CV14885. In compliance with the Mesosulfuron-methyl RAR Volume 3 B.8 (PPP) document, calculations for mesosulfuron-methyl and its metabolites were carried out for various pathways as follows:

1. Parent only
2. Mesosulfuron-methyl → AE F154851 + AE F160459 + AE F099095 + AEF092944
3. Mesosulfuron-methyl → AE F140584 + AE F147447
4. Mesosulfuron-methyl → BCS CV14885

Test simulations (not provided) indicate that splitting the metabolic scheme in such a fashion does not affect the resultant PECgw values as it start from the active substance.

Please refer to report KCP 9.2.4.1/01, Hicks J. (2021a) for more details. For updated calculations please refer to reports KCP 9.2.4.1/04 Fragkoulis G. (2022a) and KCP 9.2.4.1/05 Hicks J. (2022a) for more details.

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

Compound	Mesosulfuron-methyl	AE F154851 (Mesosulfuron)	AE F160459	Value in accordance with EU endpoint y/n/ Reference
Molecular weight (g/mol)	503.5	489.5	489.5	EFSA Conclusion 4584/2016
Water solubility (g/mol):	483 at 20ºC	200000 at 20ºC	10000 at 20ºC	EFSA Conclusion 4584/2016
Saturated vapour pressure (Pa):	3.5×10^{-12} at 20ºC	1.7×10^{-8} at 20ºC	6.8×10^{-8} at 20ºC	EFSA Conclusion 4584/2016

DT_{50} in soil (d)	49.72 for calculations with active substance only (geomean, normalisation to 10 kPa or pF2, 20 °C with Q_{10} of 2.58, n = 9) 34.09 for calculations with metabolites (geomean, normalisation to 10 kPa or pF2, 20 °C with Q_{10} of 2.58, n =9)	45.22 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q_{10} of 2.58, n = 8)	74.14 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q_{10} of 2.58, n = 5)	EFSA Conclusion 4584/2016
Transformation rate	-	0.004270	0.002094	Calculated in PELMO
K_{foc}/K_{fom} (mL/g)	64/37.1 (geometric mean, n = 9)	65/37.7 (geometric mean, n = 3)	19.3/11.2 (geometric mean, n = 5)	EFSA Conclusion 4584/2016
1/n	0.91 (arithmetic mean, n = 9)	0.94 (arithmetic mean, n = 3)	0.941 (arithmetic mean, n = 5)	EFSA Conclusion 4584/2016
Plant uptake factor	0	0	0	Default value
Formation fraction	-	0.21 (from parent)	0.103 (from parent)	EFSA Conclusion 4584/2016
Compound	**AE F099095**	**AE F092944**	**AE F160460**	**Value in accordance with EU endpoint y/n/ Reference**
Molecular weight (g/mol)	198.2	155.2	475.5	EFSA Conclusion 4584/2016
Water solubility (g/mol):	190 at 20ºC	5200 at 20ºC	100000 at 20ºC	EFSA Conclusion 4584/2016
Saturated vapour pressure (Pa):	1.9×10^{-5} at 20ºC	2.6×10^{-2} at 20ºC	5.6×10^{-7} at 20ºC	EFSA Conclusion 4584/2016
DT_{50} in soil (d)	55.6 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q_{10} of 2.58, n = 10)	16.93 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q_{10} of 2.58, n = 13)	28.61 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q_{10} of 2.58, n = 5)	EFSA Conclusion 4584/2016
Transformation rate	0.000813	0.007259	0.009349	Calculated in PELMO
K_{foc}/K_{fom} (mL/g)	692/401.4 (geometric mean, n = 11)	956.4/554.8 (geometric mean, n = 23)	12.2/7.08 (geometric mean, n = 5)	EFSA Conclusion 4584/2016
1/n	0.8 (arithmetic mean, n = 11)	0.74 (arithmetic mean, n = 23)	0.9 (arithmetic mean, n = 5)	EFSA Conclusion 4584/2016
Plant uptake factor	0	0	0	Default value
Formation fraction	0.04 (from parent)	0.357 (from parent)	1 (from parent) 1 (from AE F160459)	EFSA Conclusion 4584/2016
Compound	**AE F140584**	**AE F147447**	**BCS CV14885**	**Value in accordance with EU endpoint y/n/ Reference**
Molecular weight (g/mol)	322.4	290.3	393.4	EFSA Conclusion 4584/2016
Water solubility (g/mol):	100 at 20ºC	15000 at 20ºC	2000 at 20ºC	EFSA Conclusion 4584/2016
Saturated vapour pressure (Pa):	1.3×10^{-6} at 20ºC	1.0×10^{-8} at 20ºC	0 (worst-case assumption)	EFSA Conclusion 4584/2016
DT_{50} in soil (d)	4.22 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q_{10} of 2.58, n = 5)	162.8 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q_{10} of 2.58, n = 5)	97.6 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q_{10} of 2.58, n = 4)	EFSA Conclusion 4584/2016

Transformation rate	0.004311	0.001789	0.001952	Calculated in PELMO
K_{foc}/K_{fom} (mL/g)	0/0 (default value)	5.1/2.96 (geometric mean, n = 5)	17.7/10.27 (geometric mean, n = 4)	EFSA Conclusion 4584/2016
1/n	1.0 (default value)	1.0 (default value)	1.21 (arithmetic mean, n = 4)	EFSA Conclusion 4584/2016
Plant uptake factor	0	0	0	Default value
Formation fraction	0.212 (from parent)	0.088 (from parent)	0.096 (from parent)	EFSA Conclusion 4584/2016

Table 8.8-4: Updated PEC_{gw} for mesosulfuron-methyl and metabolites on winter cereals (with FOCUS PEARL 4.4.4/PELMO 5.5.3/MACRO 5.5.4)

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)		
		Mesosulfuron-methyl[a]	**Mesosulfuron (AE F154851)**	**AE F160459**
Winter cereals	Châteaudun	0.009/0.006/0.009	0.007/0.004/0.006	0.076/0.069/0.066
	Hamburg	0.066/0.066	0.034/0.032	**0.141/0.140**
	Jokioinen	0.023/0.029	0.015/0.017	**0.142/0.134**
	Kremsmünster	0.050/0.053	0.025/0.026	0.090/**0.101**
	Okehampton	0.066/0.067	0.032/0.031	0.089/0.086
	Piacenza	0.031/0.035	0.016/0.019	0.062/0.077
	Porto	0.050/0.085	0.024/0.035	0.066/0.065
	Sevilla	<0.001/<0.001	<0.001/<0.001	0.022/0.024
	Thiva	0.006/0.003	0.004/0.003	0.080/0.053
		AE F099095	**AE F092944**	**AE F160460**
	Châteaudun	<0.001/<0.001/<0.001	<0.001/<0.001/<0.001	0.041/0.037/0.024
	Hamburg	<0.001/<0.001	<0.001/<0.001	0.066/0.065
	Jokioinen	<0.001/<0.001	<0.001/<0.001	0.073/0.063
	Kremsmünster	<0.001/<0.001	<0.001/<0.001	0.041/0.0.48
	Okehampton	<0.001/<0.001	<0.001/<0.001	0.038/0.037
	Piacenza	<0.001/<0.001	<0.001/<0.001	0.031/0.041
	Porto	<0.001/<0.001	<0.001/<0.001	0.033/0.030
	Sevilla	<0.001/<0.001	<0.001/<0.001	0.012/0.016
	Thiva	<0.001/<0.001	<0.001/<0.001	0.046/0.030
		AE F140584	**AE F147447**	**BCS CV14885**
	Châteaudun	<0.001/0.001/<0.001	**0.209/0.192/0.199**	**0.208/0.179/0.119**
	Hamburg	0.008/0.007	**0.206/0.175**	**0.263/0.219**
	Jokioinen	0.013/0.018	**0.320/0.230**	**0.401/0.306**
	Kremsmünster	0.002/0.003	**0.13/0.133**	**0.144/0.167**
	Okehampton	0.003/0.007	**0.106/0.105**	**0.136/0.131**
	Piacenza	0.001/0.004	**0.122/0.154**	**0.125/0.163**
	Porto	0.004/0.010	**0.103/0.103**	**0.119/0.118**
	Sevilla	<0.001/<0.001	**0.108**/0.098	0.088/0.088
	Thiva	<0.001/<0.001	**0.238/0.156**	**0.206/0.104**

[a] calculated as parent only, values in **bold** exceed drinking water limit of 0.1µg/L

Table 8.8-5: Updated PEC_{gw} for mesosulfuron-methyl and metabolites on spring cereals (with FOCUS PEARL 4.4.4/PELMO 5.5.3/MACRO 5.5.4)

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)		
		Mesosulfuron-methyl[a]	**Mesosulfuron (AE F154851)**	**AE F160459**
Spring cereals	Châteaudun	0.010/0.006/0.012	0.007/0.005/0.007	0.087/0.075/0.074
	Hamburg	0.093/0.078	0.046/0.039	**0.227/0.167**
	Jokioinen	0.034/0.031	0.021/0.019	**0.154/0.147**
	Kremsmünster	0.069/0.065	0.034/0.033	**0.124/0.128**
	Okehampton	0.077/0.076	0.038/0.037	**0.116/0.111**
	Porto	0.028/0.046	0.017/0.024	0.073/0.077
		AE F099095	**AE F092944**	**AE F160460**
	Châteaudun	<0.001/<0.001/<0.001	<0.001/<0.001/<0.001	0.046/0.041/0.026
	Hamburg	<0.001/<0.001	<0.001/<0.001	**0.105**/0.080
	Jokioinen	<0.001/<0.001	<0.001/<0.001	0.078/0.066
	Kremsmünster	<0.001/<0.001	<0.001/<0.001	0.056/0.060
	Okehampton	<0.001/<0.001	<0.001/<0.001	0.049/0.046
	Porto	<0.001/<0.001	<0.001/<0.001	0.035/0.034
		AE F140584	**AE F147447**	**BCS CV14885**
	Châteaudun	0.001/0.001/0.001	**0.207/0.178/0.171**	**0.200/0.173/0.169**
	Hamburg	0.012/0.009	**0.330/0.212**	**0.416/0.262**
	Jokioinen	0.019/0.025	**0.304/0.258**	**0.412/0.350**
	Kremsmünster	0.003/0.003	**0.159/0.165**	**0.194/0.205**
	Okehampton	0.004/0.005	**0.135/0.123**	**0.173/0.153**
	Porto	0.003/0.005	**0.122/0.113**	**0.142/0.128**

[a] calculated as parent only, values in **bold** exceed drinking water limit of 0.1µg/L

The drinking water limit of 0.1 µg/L was exceeded by metabolites AE F160459, AE F147447 and BCS CV14885 in most scenarios after application of ADM.06001.H.2.B to both winter and spring cereals. AE F160460 also exceeded 0.1 µg/L in only one scenario, Hamburg, following application to spring cereals, calculated with PEARL 4.4.4. The assessment of the relevance of metabolites in groundwater is presented in document Part B Section 10 of this dossier.

zRMS comments:

Input parameters used in the groundwater modelling for mesosulfuron-methyl and its metabolites presented in Table 8.8-3 are in line with EU agreed endpoints reported in EFSA Journal 2016;14(10):4584.

In simulations PUF value of 0 was assumed for all compounds, which is in line with recommendations of the most recent version of the FOCUS Groundwater Guidance (2021).

Results presented by the Applicant were independently validated by the zRMS in additional modelling with FOCUS PEARL 4.4.4, PELMO 5.5.3 and FOCUS MACRO 5.5.4 using the EU agreed input parameters and application dates as suggested by AppDate 3.06. Obtained PEC_{GW} values were in good agreement with Applicants' results presented in Tables 8.8-4 and 8.8-5.

Based on the results of performed simulations no unacceptable leaching of mesosulfuron-methyl and its metabolites AE F154851, AE F099095, AE F092944, and AE F140584 is expected following the intended Central Zone uses of ADM.06001.H.2.B in winter and spring cereals.
Mesosulfuron-methyl metabolites AE F160459, AE F160460, AE F147447 and BCS CV14885 may migrate to groundwater at concentrations >0.1 µg/L, however in line with EFSA Journal 2016;14(10):4584 they are toxicologically non-relevant and their predicted concentrations in groundwater have not exceeded 0.75 µg/L in any of the scenarios or crop. The zRMS performed additional simulations with consideration for metabolite AE F160460 a ff of 1 from mesosulfuron-methyl, the PECgw results remain below the threshold value of 0.75 µg/L. Therefore the groundwater exposure to these compounds is also considered acceptable.

Please note that additional groundwater modelling may be required by the concerned Member States that do not accept simulations performed according to FOCUS recommendations.

Since acceptable groundwater exposure to mesosulfuron-methyl and its metabolites could be concluded for application rate of 1.0 L product/ha, no additional simulations for lower application rate (0.75 L product/ha) were required.

8.8.2.2 Pinoxaden and its metabolites

There are 3 metabolites of Pinoxaden which could potentially be detected in groundwater: NOA407854 (M2), NOA447204 (M3) and MetX. MetX is representative of a combination of metabolites identified in a lysimeter study: SYN 504574 (M11), SYN546105 (M52), SYN 546106 (M54), SYN 546107 (M55) and SYN 546108 (M56). In accordance with EFSA conclusion 3269 of 2013, metabolite MetX has been modelled in three different ways:

1. MetXa: Using a high formation fraction (ff = 1) with a short DT_{50} (5 days)
2. MetXb: Using a low formation fraction (ff = 0.05) with a long DT_{50} (1000 days)
3. MetXc: Using a medium formation fraction (ff = 0.25) with a medium DT_{50} (200 days)

Further calculations have been provided using PEARL 4.4.4 for metabolites SYN 504574 (M11), SYN546105 (M52), SYN 546106 (M54), SYN 546107 (M55) and SYN 546108 (M56). These higher tier calculations have only been provided for winter cereals because the PEC_{gw} value for MetXc was >10 µg/L.

Please refer to report KCP 9.2.4.1/02, Hicks J. (2021b) for more details.

Updated PEC_{gw} calculations have been provided with consideration of Tier 1 input values from EFSA conclusion 3269 of 2013. For further details please refer to report KCP 9.2.4.1/10, Fragkoulis G. (2022j).

Further PECgw calculations have been provided with consideration of Tier 2 input values, i.e. measured DT_{50}, K_{foc} and 1/n values for the Pinoxaden lysimeter metabolites and the revised AppDate application dates. For updated calculations please refer to reports KCP 9.2.4.1/06, Fragkoulis G. (2022b) and KCP 9.2.4.1/07, Hicks J. (2022b) for more details. For updated winter cereal calculations, only PEC_{gw} values for NOA447204 (M3) under basic conditions were provided as a worst-case. Similarly, only PECgw values for MetX with medium formation fraction were provided for winter cereals use 2 and MACRO calculations.

Table 8.8-6: Input parameters related to active substance Pinoxaden and metabolites for Tier 1 PEC_{gw} calculations

Compound	Pinoxaden	NOA 407854 (M2)	NOA 447204 (M3)	Value in accordance with EU endpoint y/n/ Reference
Molecular weight (g/mol)	400.5	316.4	332.4	EFSA Conclusion 3269/2013
Water solubility (g/mol):	200 at 25ºC	380000 at 25ºC	370 at 25ºC	EFSA Conclusion 3269/2013
Saturated vapour pressure (Pa):	0 at 20ºC (default value)	0 at 20ºC (default value)	0 at 20ºC (default value)	EFSA Conclusion 3269/2013
DT_{50} in soil (d)	0.34 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q_{10} of 2.58, n = 9)	2.23 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q_{10} of 2.58, n = 9)	pH >7 (alkaline soils) 67.4 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q_{10} of 2.58, n = 2) pH <7 (acidic soils) 208[a] (geomean, normalisation to 10 kPa or pF2, 20 °C with Q_{10} of 2.58, n = 3) all pH 24.2[b] (geomean, normalisation to 10 kPa or pF2, 20 °C with Q_{10} of 2.58, n = 16) ~~Refined pH <7 (acidic field soils) 46.4[c]~~	EFSA Conclusion 3269/2013 [c] Pietsch 2016b

			~~(geomean, normalisation to 10 kPa or pF2, 20 °C with Q_{10} of 2.58, n = 3)~~	
Transformation rate	-	2.038668	0.310828	Calculated in PELMO
K_{foc}/K_{fom} (mL/g)	323/187.35 (median, n = 9)[r] ~~299/173.4 (geometric mean, n = 9)~~	10.6/6.1 (geometric mean, n = 12)	32.1/18.6 (geometric mean, n = 8)	EFSA Conclusion 3269/2013
1/n	1.0 (arithmetic mean, n = 9)	0.97 (arithmetic mean, n = 16)	0.96 (arithmetic mean, n = 8)	EFSA Conclusion 3269/2013
Plant uptake factor	0	0	0	Default value
Formation fraction	-	1 (from pinoxaden)	1 (from NOA 407854)	EFSA Conclusion 3269/2013
Compound	**MetXa (high ff)**	**MetXb (low ff)**	**MetXc (medium ff)**	**Value in accordance with EU endpoint y/n/ Reference**
Molecular weight (g/mol)	376.4	376.4	376.4	EFSA Conclusion 3269/2013
Water solubility (g/mol):	1000 at 25ºC	1000 at 25ºC	1000 at 25ºC	EFSA Conclusion 3269/2013
Saturated vapour pressure (Pa):	0 at 20ºC (default value)	0 at 20ºC (default value)	0 at 20ºC (default value)	EFSA Conclusion 3269/2013
DT_{50} in soil (d)	5	1000	200	EFSA Conclusion 3269/2013
Transformation rate	0.028642	0.001432	0.007161	Calculated in PELMO
K_{foc}/K_{fom} (mL/g)	0/0 (worst-case)	0/0 (worst-case)	0/0 (worst-case)	EFSA Conclusion 3269/2013
1/n	1 (worst-case)	1 (worst-case)	1 (worst-case)	EFSA Conclusion 3269/2013
Plant uptake factor	0	0	0	Default value
Formation fraction	1 (from NOA 447204)	0.05 (from NOA 447204)	0.25 (from NOA 447204)	EFSA Conclusion 3269/2013
~~**Compound**~~	~~**M11 (SYN5004574)**~~	~~**M52 (SYN546105)**~~	~~**M54 (SYN546106)**~~	~~**Value in accordance with EU endpoint y/n/ Reference**~~
~~Molecular weight (g/mol)~~	~~362.4~~	~~360.3~~	~~362.4~~	~~EFSA Conclusion 3269/2013~~
~~Water solubility (g/mol):~~	~~200 at 25ºC~~	~~200 at 25ºC~~	~~200 at 25ºC~~	~~EFSA Conclusion 3269/2013~~
~~Saturated vapour pressure (Pa):~~	~~0 at 20ºC~~	~~0 at 20ºC~~	~~0 at 20ºC~~	~~Default value~~
~~DT_{50} in soil (d)~~	~~9.7[dm] (geomean, lab study)~~	~~8.4[e] (geomean, lab study)~~	~~7.5[f] (geomean, lab study)~~	~~[d] Robinson 2012a [e] Völkel 2012a [f] Völkel 2012b~~
~~Transformation rate~~	~~Not required~~	~~Not required~~	~~Not required~~	~~Calculated in PELMO~~
~~K_{foc}/K_{fom}~~	~~12.4/7.2[g] (geometric mean, n=3)~~	~~106.2/61.6[h] (geometric mean, n=3)~~	~~16.5/9.5[i] (geometric mean, n=3)~~	~~[g] Robinson 2012c [h] Völkel 2012c [i] Völkel 2012d~~
~~1/n~~	~~0.98[g] (arithmetic mean, n=3)~~	~~0.977[h] (arithmetic mean, n=3)~~	~~0.987[i] (arithmetic mean, n=3)~~	~~[g] Robinson 2012c [h] Völkel 2012c [i] Völkel 2012d~~
~~Plant uptake factor~~	~~0~~	~~0~~	~~0~~	~~Default value~~
~~Formation fraction~~	~~pH >7 (alkaline soils) 0.49 pH <7 (acidic soils) 1.0 (from NOA 447204)~~	~~1.0 (from NOA 447204)~~	~~pH >7 (alkaline soils) 0.6 pH <7 (acidic soils) 1.0 (from NOA 447204)~~	~~EFSA Conclusion 3269/2013~~
~~**Compound**~~	~~**M55 (SYN546107)**~~	~~**M56 (SYN546108)**~~		~~**Value in accordance with EU endpoint y/n/ Reference**~~

Molecular weight (g/mol)	376.4	360.3	EFSA Conclusion 3269/2013
Water solubility (g/mol):	200 at 25ºC	200 at 25ºC	EFSA Conclusion 3269/2013
Saturated vapour pressure (Pa):	0 at 20ºC	0 at 20ºC	Default value
DT_{50} in soil (d)	106[j] (maximum, lab study)	73.3[k] (geometric mean, lab study)	[j] Robinson 2012b [k] Caviezel, 2013a
Transformation rate	Not required	Not required	Calculated in PELMO
K_{foc} (mL/g)/K_{fom}	10.0/5.8[l] (geometric mean, n=3)	12.5 /7.3[p] (geometric mean, n=3)	[l] Robinson 2012d [p] Caviezel, 2013b
1/n	0.997[l] (arithmetic mean, n=3)	1.137[p] (arithmetic mean, n=3)	[l] Robinson 2012d
Plant uptake factor	0	0	Default value
Formation fraction	pH >7 (alkaline soils) 0.12 pH <7 (acidic soils) 0.2 (from NOA 447204)	pH >7 (alkaline soils) 0.13[q] pH <7 (acidic soils) 0.25[q] (from NOA 447204)	EFSA Conclusion 3269/2013

[a] Refined DT_{50} value of 46.45 days was used for the calculations
[b] Geometric mean field DT_{50} used for MetX calculations
[c] The refined DT_{50} values of 46.4 days was used for winter and spring cereals PEC_{gw} calculations in acidic conditions.
[cdefghiljklm] Syngenta submitted data on aerobic degradation rates and adsorption/desorption for metabolite M11, M52, M45, M55 and M56 as confirmatory data in the EU review of pinoxaden.
[n] A DT_{50} of 11.9 days was used for the simulations. This represents a worst-case situation.
[o] A DT_{50} of 200 days was used for the simulations. This represents a worst-case situation.
[p] A K_{foc} of 0 L/Kg and a 1/n of 1 was used for the simulations. This represents a worst-case situation.
[q] As a worst-case only the ff of 0.25 was used for the simulations.
[r] Tier 1 values from EFSA Conclusion 3269/2013

Table 8.8-7: PEC_{gw} for pinoxaden and metabolites on winter cereals (with FOCUS PEARL 4.4.4/PELMO 5.5.3/MACRO 5.5.4) using Tier 1 values and updated application dates

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)		
		Pinoxaden	**NOA 407854 (M2)**	**NOA 447204 (M3) (alkaline soils)**
Winter cereals	Châteaudun	<0.001/<0.001/<0.001	<0.001/<0.001/<0.001	**1.849/1.672**/[a]
	Hamburg	<0.001/<0.001	0.005/<0.001	**3.637/3.533**
	Jokioinen	<0.001/<0.001	<0.001/<0.001	**3.391/3.479**
	Kremsmünster	<0.001/<0.001	<0.001/<0.001	**2.683/3.020**
	Okehampton	<0.001/<0.001	<0.001/<0.001	**2.742/2.866**
	Piacenza	<0.001/<0.001	<0.001/0.001	**1.815/2.524**
	Porto	<0.001/<0.001	0.011/0.092	**2.248/2.676**
	Sevilla	<0.001/<0.001	<0.001/0.004	**0.262/0.522**
	Thiva	<0.001/<0.001	<0.001/0.003	**2.193/1.737**
		NOA 447204 (M3) (acidic soils)	**MetXa (high ff)**	**MetXb (low ff)**
	Châteaudun	**10.965/10.395/9.290**	0.073/0.010/[a]	**2.171/1.859/**[a]
	Hamburg	**11.473/10.772**	**0.564/0.062**	**1.232/1.098**
	Jokioinen	**13.091/11.033**	**0.722/0.165**	**1.945/1.510**
	Kremsmünster	**7.246/8.969**	**0.213/0.088**	**0.707/0.814**
	Okehampton	**6.515/6.708**	**0.303/0.119**	**0.665/0.631**
	Piacenza	**8.139/10.455**	**0.123/0.120**	**1.173/1.256**
	Porto	**6.955/6.455**	**0.404/0.364**	**0.613/0.632**
	Sevilla	**5.306/6.253**	0.005/0.015	**2.971/1.355**
	Thiva	**15.367/10.978**	0.052/0.024	**3.674/1.666**
		MetXc (medium ff)		
	Châteaudun	**6.507/3.349/8.160**		
	Hamburg	**5.284/3.627**		

	Jokioinen	**8.299/5.089**
	Kremsmünster	**2.961/2.876**
	Okehampton	**2.801/2.160**
	Piacenza	**3.864/3.413**
	Porto	**2.484/2.149**
	Sevilla	**3.654/2.358**
	Thiva	**7.991/3.516**

[a] MACRO calculation for NOA 447204 only carried out for acidic soils and Met X medium formation fraction as the worst-case scenarios
Values in **bold** exceed the drinking water limit of 0.1 µg/L

~~**Table 8.8-8: Updated PECgw for pinoxaden and metabolites on winter cereals (with FOCUS PEARL 4.4.4/PELMO 5.5.3/MACRO 5.5.4) using Tier 2 values and updated application dates**~~

~~Crop~~	~~Scenario~~	~~80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)~~		
		~~Pinoxaden~~	~~NOA 407854 (M2)~~	~~NOA 447204 (alkaline soils)~~
~~Winter cereals~~	~~Châteaudun~~	~~<0.001/<0.001/<0.001~~	~~<0.001/<0.001/<0.001~~	~~1.849/1.627/1.41~~
	~~Hamburg~~	~~<0.001/<0.001~~	~~0.005/<0.001~~	~~3.637/3.533~~
	~~Jokioinen~~	~~<0.001/<0.001~~	~~<0.001/<0.001~~	~~3.391/3.479~~
	~~Kremsmünster~~	~~<0.001/<0.001~~	~~<0.001/<0.001~~	~~2.683/3.020~~
	~~Okehampton~~	~~<0.001/<0.001~~	~~<0.001/<0.001~~	~~2.742/2.866~~
	~~Piacenza~~	~~<0.001/<0.001~~	~~<0.001/0.001~~	~~12.815/2.524~~
	~~Porto~~	~~<0.001/<0.001~~	~~0.011/0.092~~	~~2.248/2.676~~
	~~Sevilla~~	~~<0.001/<0.001~~	~~<0.001/0.004~~	~~0.262/0.522~~
	~~Thiva~~	~~<0.001/<0.001~~	~~<0.001/0.003~~	~~2.193/1.737~~
		~~NOA 447204 (acidic soils)~~	~~MetXa (high ff)~~	~~MetXb (low ff)~~
	~~Châteaudun~~	~~n.c~~	~~n.c~~	~~n.c~~
	~~Hamburg~~	~~n.c~~	~~n.c~~	~~n.c~~
	~~Jokioinen~~	~~n.c~~	~~n.c~~	~~n.c~~
	~~Kremsmünster~~	~~n.c~~	~~n.c~~	~~n.c~~
	~~Okehampton~~	~~n.c~~	~~n.c~~	~~n.c~~
	~~Piacenza~~	~~n.c~~	~~n.c~~	~~n.c~~
	~~Porto~~	~~n.c~~	~~n.c~~	~~n.c~~
	~~Sevilla~~	~~n.c~~	~~n.c~~	~~n.c~~
	~~Thiva~~	~~n.c~~	~~n.c~~	~~n.c~~
		~~MetXc (medium ff)~~	~~M11 SYN504574[b]~~	~~M52 SYN546105[b]~~
	~~Châteaudun~~	~~6.507/3.349/8.160~~	~~0.215~~	~~<0.001~~
	~~Hamburg~~	~~5.284/3.627~~	~~1.104~~	~~<0.001~~
	~~Jokioinen~~	~~8.299/5.089~~	~~0.911~~	~~<0.001~~
	~~Kremsmünster~~	~~2.961/2.876~~	~~0.613~~	~~<0.001~~
	~~Okehampton~~	~~2.801/2.159~~	~~0.720~~	~~0.001~~
	~~Piacenza~~	~~3.864/3.413~~	~~0.335~~	~~<0.001~~
	~~Porto~~	~~2.484/2.149~~	~~0.700~~	~~0.009~~
	~~Sevilla~~	~~3.654/2.358~~	~~0.015~~	~~<0.001~~
	~~Thiva~~	~~7.991/3.516~~	~~0.147~~	~~<0.001~~
		~~M54 SYN546106[b]~~	~~M55 SYN546107[b]~~	~~M56 SYN546108[b]~~
	~~Châteaudun~~	~~0.077~~	~~2.412~~	~~6.229~~
	~~Hamburg~~	~~0.418~~	~~2.987~~	~~5.058~~
	~~Jokioinen~~	~~0.385~~	~~4.478~~	~~7.944~~
	~~Kremsmünster~~	~~0.265~~	~~1.731~~	~~2.834~~
	~~Okehampton~~	~~0.352~~	~~1.574~~	~~2.681~~
	~~Piacenza~~	~~0.142~~	~~1.544~~	~~3.698~~
	~~Porto~~	~~0.354~~	~~1.579~~	~~2.378~~
	~~Sevilla~~	~~0.005~~	~~1.095~~	~~3.497~~
	~~Thiva~~	~~0.055~~	~~2.796~~	~~7.649~~

~~[a] MACRO calculation for NOA 447204 only carried out for acidic soils as the worst-case scenario~~
~~[b] Only calculated in PEARL~~
~~Values in **bold** exceed the drinking water limit of 0.1 µg/L n.c. not calculated~~

Table 8.8-9: Updated PEC_{gw} for pinoxaden and metabolites on spring cereals (with FOCUS PEARL 4.4.4/PELMO 5.5.3/MACRO 5.5.4) using Tier 1 values ~~and updated application dates~~

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)		
		Pinoxaden	**NOA407854 (M2)**	**NOA 447204 (M3) (alkaline soils)**
Spring cereals	Châteaudun	<0.001/<0.001/<0.001	<0.001/<0.001/<0.001	**5.514/1.754/[a]**
	Hamburg	<0.001/<0.001	<0.001/<0.001	**2.068/4.107**
	Jokioinen	<0.001/<0.001	<0.001/<0.001	**3.776/3.714**
	Kremsmünster	<0.001/<0.001	<0.001/<0.001	**3.657/3.627**
	Okehampton	<0.001/<0.001	<0.001/<0.001	**3.326/3.297**
	Porto	<0.001/<0.001	<0.001/<0.001	**1.725/1.992**
		NOA 447204 (M3) (acidic soils)	**MetXa (high ff)**	**MetXb (low ff)**
	Châteaudun	**11.496/10.286/9.290**	**n.c**	**n.c**
	Hamburg	**18.075/12.642**	**n.c**	**n.c**
	Jokioinen	**13.212/11.708**	**n.c**	**n.c**
	Kremsmünster	**10.008/10.703**	**n.c**	**n.c**
	Okehampton	**8.342/7.561**	**n.c**	**n.c**
	Porto	**6.327/5.947**	**n.c**	**n.c**
		MetXc (medium ff)		
	Châteaudun	**6.298/3.310/6.620**		
	Hamburg	**8.469/4.290**		
	Jokioinen	**8.973/5.826**		
	Kremsmünster	**4.091/3.605**		
	Okehampton	**3.602/2.579**		
	Porto	**3.305/2.264**		

Values in **bold** exceed the drinking water limit of 0.1 µg/L
[a] MACRO calculation for NOA 447204 only carried out for acidic soils as the worst-case scenario
n.c. not calculated

~~Table 8.8-10: Updated PEC_{gw} for pinoxaden and metabolites on spring cereals (with FOCUS PEARL 4.4.4/PELMO 5.5.3/MACRO 5.5.4) using Tier 2 values and updated application dates~~

~~Crop~~	~~Scenario~~	~~80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)~~		
		~~Pinoxaden~~	~~NOA407854 (M2)~~	~~NOA 447204 (alkaline soils)~~
~~Spring cereals~~	~~Châteaudun~~	~~<0.001/<0.001/<0.001~~	~~<0.001/<0.001/<0.001~~	~~2.068/1.754/1.660~~
	~~Hamburg~~	~~<0.001/<0.001~~	~~<0.001/<0.001~~	~~5.515/4.107~~
	~~Jokioinen~~	~~<0.001/<0.001~~	~~<0.001/<0.001~~	~~3.776//3.714~~
	~~Kremsmünster~~	~~<0.001/<0.001~~	~~<0.001/<0.001~~	~~3.657/3.627~~
	~~Okehampton~~	~~<0.001/<0.001~~	~~<0.001/<0.001~~	~~3.402/3.328~~
	~~Porto~~	~~<0.001/<0.001~~	~~<0.001/<0.001~~	~~1.725/1.992~~
		~~NOA 447204 (acidic soils)~~	~~MetXa (high ff)~~	~~MetXb (low ff)~~
	~~Châteaudun~~	~~0.858/0.669/0.667~~	~~0.093/0.060/0.071~~	~~2.049/1.737/2.020~~
	~~Hamburg~~	~~2.997/2.088~~	~~0.809/0.434~~	~~1.990/1.405~~
	~~Jokioinen~~	~~2.003/2.032~~	~~1.061/1.251~~	~~2.070/1.719~~
	~~Kremsmünster~~	~~1.951/2.058~~	~~0.277/0.291~~	~~1.003/1.127~~
	~~Okehampton~~	~~2.003/1.977~~	~~0.334/0.354~~	~~0.851/0.782~~
	~~Porto~~	~~0.794/1.064~~	~~0.121/0.206~~	~~0.872/0.791~~
		~~MetXc (medium ff)~~		
	~~Châteaudun~~	~~6.298/5.180/6.300~~		
	~~Hamburg~~	~~8.469/5.819~~		
	~~Jokioinen~~	~~7.568/7.568~~		
	~~Kremsmünster~~	~~4.549/4.549~~		
	~~Okehampton~~	~~3.602/3.242~~		
	~~Porto~~	~~3.305/3.063~~		

~~Values in **bold** exceed the drinking water limit of 0.1 µg/L~~

The drinking water limit of 0.1 µg/L was exceeded by metabolites NOA 447204 (M3) and Metabolite X in the majority of scenarios following application of ADM.06001.H.2.B to both winter and spring cereals. The PEC_{gw} values for the component substances of Metabolite X were above 0.1 µg/L, with the exception of M52 (SYN546105). The assessment of the relevance of metabolites in groundwater is presented in document Part B Section 10 of this dossier.

zRMS comments:

Tier 1

Input parameters used for Tier 1 groundwater modelling for pinoxaden and its metabolites presented in Table 8.8-6 ~~Table 8.8-8~~ are in line with EU agreed endpoints presented in EFSA Journal 2013;11(8):3269.

According to the information presented in EFSA conclusion the metabolites: M11, M52, M54, M55 and M56 were modelled as MetX using following conservative input parameters:

- MetXa High formation fraction (ff = 1) DT_{50} = 5d,
- MetXb low formation fraction (ff=0.05) DT_{50} = 1000 days,
- MetXc medium formation fraction (ff = 0.25) DT_{50} = 200 days.

For each 'Met X' a Koc of 0 and 1/n of 1 were used and soil DT_{50} of 24.2 days was used for M3 which is in line with the EFSA conclusion. Results presented in Table 8.8-10 for winter cereals clearly show that the highest PEC_{GW} was obtained for MetXc, thus for the application to spring cereals only that metabolite was considered in the groundwater modelling, which is agreed by the zRMS.

In simulations PUF value of 0 was assumed for all compounds, which is in line with recommendations of the most recent version of the FOCUS Groundwater Guidance (2021).

Results presented by the Applicant were independently validated by the zRMS in additional modelling with FOCUS PEARL 4.4.4, PELMO 5.5.3 and FOCUS MACRO 5.5.4 using the EU agreed input parameters and application dates as suggested by AppDate 3.06. Obtained PEC_{GW} values were in good agreement with Applicants' results presented in Tables 8.8-7 and 8.8-9.

No unacceptable leaching of pinoxaden and metabolite M2 is expected following application of ADM.06001.H.2.B according to the intended Central Zone use pattern given in Table 8.1-1.

The PEC_{GW} values for MetX were above the threshold concentration of 0.75 µg/L for non-relevant metabolites, while PEC_{GW} values for metabolite M3 in acidic soils were above 10 µg/L in almost all scenarios in both winter and spring cereals. Although in line with SANCO/221/2000-rev.10-final of 25th February 2003 (version applicable for evaluation of ADM.06001.H.2.B) predicted concentrations of metabolites in groundwater at >10.0 µg/L are not cut-off criterion and carrying out the refined consumer risk assessment is possible, at the same time no clear guidance on how to deal with such a high concentrations is provided. Therefore, further modelling at Tier 2 was performed and is discussed by the zRMS below.

Tier 2

For purposes of the Tier 2 groundwater modelling the Applicant referred to the new studies on aerobic degradation rates and adsorption/desorption in soil of pinoxaden lysimeter metabolites M11, M52, M45, M55 and M56. Furthermore, results of studies on field dissipation of metabolite M3 in acidic soils were considered in order to refine the groundwater exposure to this compound.

Although generation of the new active substance data should be avoided at the zonal level, their consideration in the groundwater exposure assessment for pinoxaden metabolites from uses of ADM.06001.H.2.B is justified due to Tier 1 PEC_{GW} being above 0.75 µg/L for majority of metabolites and even exceeding 10.0 µg/L for metabolite M3 and other options for refinement. As already stated in the zRMS comments in points 8.3.1.2 (laboratory soil degradation data), 8.4.2.2 (field dissipation data) and 8.5.2 (soil sorption data), all studies with metabolites referred to by the Applicant were already evaluated and agreed by the RMS (AT) in Addendum 1 to Vol. 3CA, B.8 (May 2022) as a part of the confirmatory data. Although the Addendum was not yet commented by MS and EFSA experts, the zRMS reviewed the assessment performed by AT and in general agrees with the derived endpoints and does not expect that they will substantially change following the peer-review. Therefore no separate assessment of the new studies was carried out at the zonal level. Nevertheless it is noted that the endpoints agreed by the RMS (AT) are different than values reported by the Applicant in Table 8.8-6 above and for this reason all endpoints derived from new studies as well as results of Applicants' Tier 2 modelling were struck through and new Tier 2 modelling was performed by the

zRMS using endpoints agreed by AT in the course of evaluation of the confirmatory information with exception of PUF value for metabolite M3 (AT used refined PUF of 0.784 for M3, but PUF refinement is not accepted by all MS, so for purposes of simulations for ADM.06001.H.2.B the zRMS assumed PUF of 0 for all modelled compounds as a worst case). The application pattern and application dates assumed by the zRMS were the same as presented in Tables 8.8-1 and 8.8-2. Only scenarios relevant for the Central Zone (i.e. Châteaudun, Hamburg, Kremsmünster, Okehampton, Piacenza and Porto) were included in zRMS modelling.

In line with RMS (AT) suggestions, two separate runs were modelled:

1. Based on soil laboratory degradation data for all metabolites including M2 and M3.
2. 'Higher-tier' run for M2 and M3 metabolites using the field dissipation data.

The summary of input parameters for each run is presented in tables below.

Input parameters based on laboratory degradation data most reliable for PEC_{GW} values of M11, M52, M54, M55 and M56 (agreed by RMS AT)

Parameter	PXD	M2	M3	M11	M52	M54	M55	M56
Mol mass (g/mol)	400.5	316.4	332.4	362.4	360.3	362.4	376.4	360.4
Water solubility at 25 °C (mg/L)	200	380000	370	1000	1000	1000	1000	1000
Vapour pressure at 25 °C (Pa)	0	0	0	0	0	0	0	0
DT_{50} (d)	0.34[a]	17.1[a]	208 / 67.4[a]	11.7	8.4	7.5	17.5	82.2
K_{foc} (L/kg)	299[b]	7.97[b]	32.1[b]	2.4	62.5	14.1	0.8	6.0
K_{fom} (L/kg)	173	4.63	18.6	1.4	36.3	8.2	0.5	3.5
1/n (-)	1.0[c]	0.99[c]	0.92[c]	0.98	0.98	0.99	1.0	1.14
Plant uptake factor (-)	0	0	0	0	0	0	0	0
Formation fraction (-)	na	0.91[a] (from parent)	0.42[e] / 0.30[f] (from M2)	1.0 / 0.86 (from M3)	0.26 / 0.11 (from M2)	1.0 / 1.0 (from M3)	1.0 / 0.62 (from M3)	0.70 / 0.22 (from M3)

Values separated by an '/' refer to acidic and neutral/alkaline soil conditions, respectively
(a): EFSA conclusion on pinoxaden (EFSA, 2013)
(b): Geomean from soil data given in EFSA (2013), following the approach of Habib (2012) in case of M2 to address zeros in the data set (see applicant's study summary)
(c): Median values given in the EFSA conclusion on pinoxaden (EFSA, 2013)
(e): Manually adjusted to cover residues in acidic soils (refer to Vol. 3CA, section B.8.1.4)
(f): Deduced from the EFSA conclusion on pinoxaden (EFSA, 2013) on basis of data given for neutral/alkaline soils

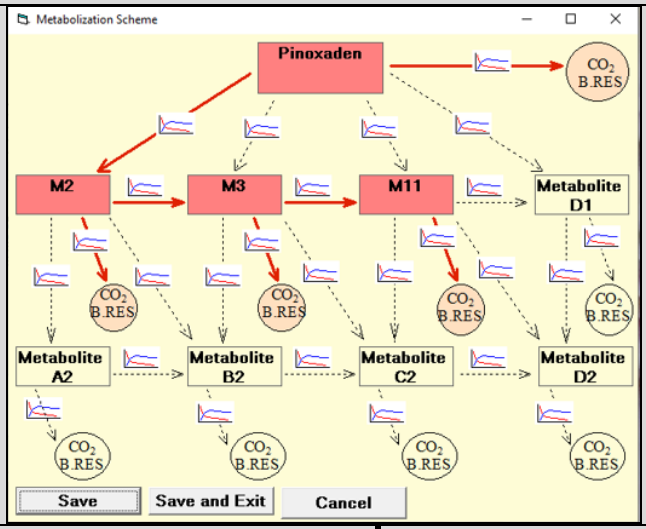
Input parameters for a 'higher-tier' modelling based on field dissipation data most reliable for PEC_{GW} values of M2 and M3 (agreed by RMS AT)

Parameter	PXD	M2	M3
Mol mass (g/mol)	400.5	316.4	332.4
Water solubility (mg/L)	200 (25 °C)	380000 (25 °C)	370 (25 °C)
Vapour pressure (Pa)	0 (25 °C)	0 (25 °C)	0 (25 °C)
DT_{50} (d)	0.34[a]	2.23[a]	49.4[b]
K_{foc} (L/kg)	299[c]	7.97[c]	32.1[c]
K_{fom} (L/kg)	173	4.63	18.6
1/n (-)	1.0[d]	0.99[d]	0.92[d]
Plant uptake factor (-)	0	0	0
Formation fraction (-)	na	0.91[a] (from parent)	0.42/ 0.30[g] (from M2)

Values separated by an '/' refer to acidic and neutral/alkaline soil conditions, respectively
(a): EFSA conclusion on pinoxaden (EFSA, 2013)
(b): The field *DegT50* of M3 under neutral/alkaline conditions in unknown; field *DegT50* under acidic conditions considered to also cover neutral/alkaline soils
(c): Geomean from soil data given in EFSA (2013), following the approach of Habib (2012) in case of M2 to address zeros in the data set
(d): Median values given in the EFSA conclusion on pinoxaden (EFSA, 2013)
(g): Deduced from the EFSA conclusion on pinoxaden (EFSA, 2013) on basis of data given for neutral/alkaline soils

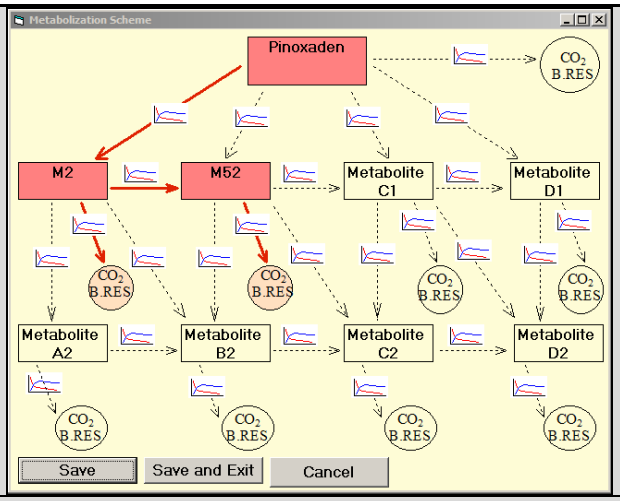
It is noted that the RMS (AT) performed simulations with FOCUS PEARL 4.4.4 only, however in line with indications of the Central Zone working document in area of Section 8 (2018)[1], modelling using both, FOCUS PEARL 4.4.4 and FOCUS PELMO 5.5.3, is required when PEC_{GW} simulated using one of these programs are >0.001 µg/L, which is the case for pinoxaden metabolites. Taking this into account, simulations using FOCUS PELMO 5.5.3 based on inputs agreed by the RMS (AT) were also performed by the zRMS. Due to multiple metabolites formed from pinoxaden and PELMO limitations, the metabolic scheme was divided into several separate runs in order to obtain PEC_{GW} for all compounds. Additional difficulty was that the sum of ff agreed by the RMS for metabolites formed from metabolite M3 was >1, thus it was possible to perform simulations with assumption of only one metabolite formed from M3. The metabolic schemes assumed by the zRMS in PELMO modelling together with respective k values based on DT_{50} and ff are presented below.

PELMO metabolic schemes based on laboratory data agreed by the RMS (AT)

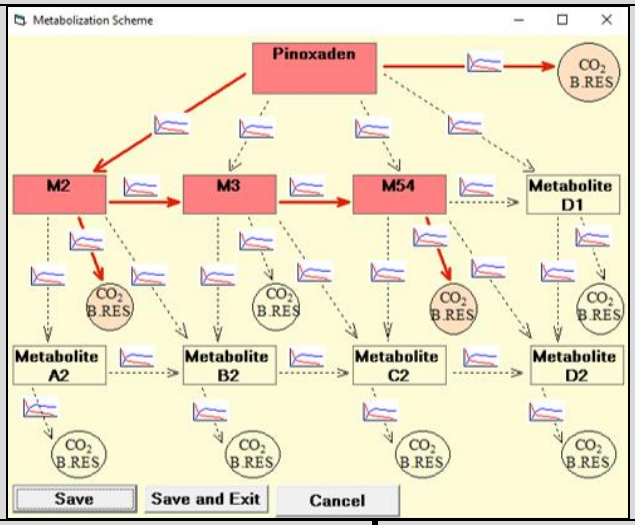


Substance	Acidic soils					Alkaline / neutral soils				
	DT_{50} [d]	k (ln2/DT_{50})	ff	transformation	Rate constant (k*ff)	DT_{50} [d]	k (ln2/DT_{50})	ff	transformation	Rate constant (k*ff)
Pinoxaden	0.34	2.03866	0.91	to M2	1.85519	0.34	2.038668	0.91	to M2	1.85519
			0.09	to sink	0.18348			0.09	to sink	0.18348
M2	17.1	0.040535	0.42	to M3	0.01703	17.1	0.040535	0.30	to M3	0.01216
			0.58	to sink	0.02351			0.70	to sink	0.02837
M3	208	0.003332	1.0	to M11	0.00333	67.4	0.010284	0.86	to M11	0.00884
								0.14	to sink	0.00144
M11	11.7	0.059243	1.0	to sink	0.05924	11.7	0.059243	1.0	to sink	0.05924

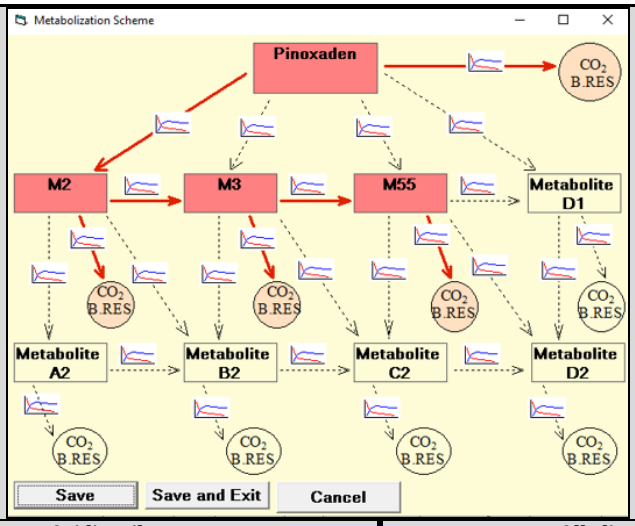
[1] Working Document of the Central Zone in the Authorisation of Plant Protection Products, Section 8, Environmental Fate and Behaviour, version 1 rev. 1, June 2018



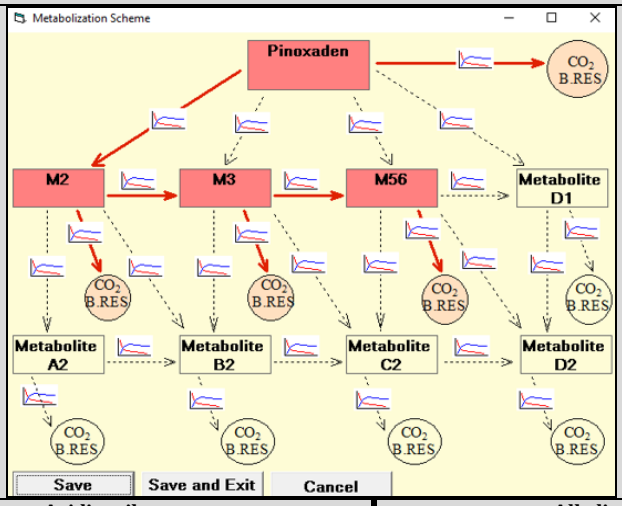
Substance	Acidic / alkaline / neutral soils				
	DT_{50} [d]	k (ln2/DT_{50})	ff	transformation	Rate constant (k*ff)
Pinoxaden	0.34	2.038668	0.91	to M2	1.85519
			0.09	to sink	0.18348
M2	17.1	0.040535	0.26	to M52	0.01054
			0.74	to sink	0.03000
M52	8.4	0.082518	1.0	to sink	0.08252



Substance	Acidic soils					Alkaline / neutral soils				
	DT_{50} [d]	k (ln2/DT_{50})	ff	transformation	Rate constant (k*ff)	DT_{50} [d]	k (ln2/DT_{50})	ff	transformation	Rate constant (k*ff)
Pinoxaden	0.34	2.038668	0.91	to M2	1.85519	0.34	2.038668	0.91	to M2	1.85519
			0.09	to sink	0.18348			0.09	to sink	0.18348
M2	17.1	0.040535	0.42	to M3	0.017025	17.1	0.040535	0.30	to M3	0.01216
			0.58	to sink	0.02351			0.70	to sink	0.02837
M3	208	0.003332	1.0	to M54	0.00333	67.4	0.010284	1.0	to M54	0.01028
M54	7.5	0.09242	1.0	to sink	0.09242	7.5	0.09242	1.0	to sink	0.09242

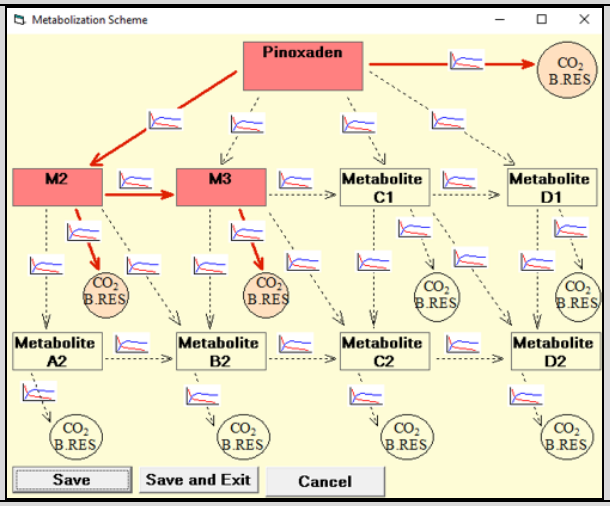


Substance	Acidic soils					Alkaline / neutral soils				
	DT_{50} [d]	k (ln2/DT_{50})	ff	transformation	Rate constant (k*ff)	DT_{50} [d]	k (ln2/DT_{50})	ff	transformation	Rate constant (k*ff)
Pinoxaden	0.34	2.038668	0.91	to M2	1.85519	0.34	2.038668	0.91	to M2	1.85519
			0.09	to sink	0.18348			0.09	to sink	0.18348
M2	17.1	0.040535	0.42	to M3	0.017025	17.1	0.040535	0.30	to M3	0.01216
			0.58	to sink	0.02351			0.70	to sink	0.02837
M3	208	0.003332	1.0	to M55	0.00333	67.4	0.010284	0.62	to M55	0.00638
								0.38	to sink	0.00391
M55	17.5	0.039608	1.0	to sink	0.03961	17.5	0.039608	1.0	to sink	0.03961



Substance	Acidic soils					Alkaline / neutral soils				
	DT_{50} [d]	k (ln2/DT_{50})	ff	transformation	Rate constant (k*ff)	DT_{50} [d]	k (ln2/DT_{50})	ff	transformation	Rate constant (k*ff)
Pinoxaden	0.34	2.038668	0.91	to M2	1.85519	0.34	2.038668	0.91	to M2	1.85519
			0.09	to sink	0.18348			0.09	to sink	0.18348
M2	17.1	0.040535	0.42	to M3	0.017025	17.1	0.040535	0.30	to M3	0.01216
			0.58	to sink	0.02351			0.70	to sink	0.02837
M3	208	0.003332	0.70	to M56	0.00233	67.4	0.010284	0.22	to M56	0.00226
			0.30	to sink	0.00100			0.78	to sink	0.00802
M56	82.2	0.008432	1.0	to sink	0.00843	82.2	0.008432	1.0	to sink	0.00843

PELMO metabolic scheme based on field data agreed by the RMS (AT), M2 and M3 in acidic soils



Substance	Acidic soils				
	DT50 [d]	k (ln2/DT50)	ff	transformation	Rate constant (k*ff)
Pinoxaden	0.34	2.038668	0.91	to M2	1.85519
			0.09	to sink	0.18348
M2	2.23	0.310828	0.42	to M3	0.13055
			0.58	to sink	0.18028
M3	49.4	0.014031	1.0	to sink	0.01403

Results of the groundwater modelling performed by the zRMS for uses of ADM.06001.H.2.B in winter and spring cereals on the basis of the detailed input parameters for each metabolite are presented in tables below. Simulations using MACRO were not carried out since only parent with a single metabolite may be simulated in MACRO, while in case of pinoxaden there is a single primary metabolite (M2), two secondary metabolites (M52 and M3) and multiple tertiary metabolites formed from M3. With such a metabolic scheme MACRO simulations were not possible.

PECGW for pinoxaden and its metabolites in winter and spring cereals calculated using laboratory degradation data

Crop	Scenario	80th Percentile PECGW at 1 m Soil Depth (µg/L), FOCUS PEARL 4.4.4							
		Pinoxaden	M2	M3	M11	M52	M54	M55	M56
winter cereals	Châteaudun	<0.001	**0.144**	**4.108**	**0.490**	0.014	**0.239**	**0.885**	**3.128**
	Hamburg	<0.001	**0.870**	**4.296**	**0.715**	0.075	**0.282**	**1.197**	**2.005**
acidic soils	Kremsmünster	<0.001	**0.554**	**2.883**	**0.309**	0.075	**0.155**	**0.515**	**1.085**
	Okehampton	<0.001	**0.612**	**2.583**	**0.312**	0.081	**0.152**	**0.499**	**0.821**
	Piacenza	< 0.001	**0.299**	**3.341**	**0.336**	0.033	**0.172**	**0.578**	**1.659**
	Porto	<0.001	**1.040**	**2.634**	**0.337**	0.048	**0.177**	**0.527**	**0.979**
winter cereals	Châteaudun	<0.001	**0.144**	**0.636**	**0.283**	0.006	**0.136**	**0.386**	**0.835**
	Hamburg	<0.001	**0.870**	**1.112**	**0.647**	0.031	**0.267**	**0.824**	**0.763**
alkaline / neutral soils	Kremsmünster	<0.001	**0.554**	**0.913**	**0.310**	0.031	**0.176**	**0.381**	**0.412**
	Okehampton	<0.001	**0.612**	**0.909**	**0.329**	0.034	**0.183**	**0.409**	**0.364**
	Piacenza	< 0.001	**0.299**	**0.690**	**0.227**	0.014	**0.130**	**0.287**	**0.486**
	Porto	<0.001	**1.040**	**0.721**	**0.317**	0.020	**0.181**	**0.362**	**0.354**
spring cereals	Châteaudun	<0.001	**0.145**	**4.366**	**0.524**	0.014	**0.254**	**0.945**	**3.037**
	Hamburg	<0.001	**1.149**	**6.693**	**1.072**	**0.106**	**0.445**	**1.785**	**3.108**
acidic soils	Kremsmünster	<0.001	**0.683**	**4.033**	**0.435**	0.089	**0.219**	**0.731**	**1.509**
	Okehampton	<0.001	**0.650**	**3.135**	**0.397**	0.072	**0.198**	**0.646**	**1.057**
	Porto	<0.001	**0.121**	**2.379**	**0.405**	0.010	**0.187**	**0.677**	**1.415**
spring cereals	Châteaudun	<0.001	**0.145**	**0.689**	**0.323**	0.006	**0.154**	**0.449**	**0.810**
	Hamburg	<0.001	**1.149**	**1.668**	**0.993**	0.044	**0.419**	**1.274**	**1.227**
alkaline / neutral soils	Kremsmünster	<0.001	**0.683**	**1.237**	**0.420**	0.037	**0.237**	**0.525**	**0.591**
	Okehampton	<0.001	**0.650**	**1.063**	**0.427**	0.030	**0.223**	**0.514**	**0.457**
	Porto	<0.001	**0.121**	**0.519**	**0.307**	0.004	**0.153**	**0.403**	**0.493**

		80th Percentile PEC_{GW} at 1 m Soil Depth (µg/L), FOCUS PELMO 5.5.3							
		Pinoxaden	**M2**	**M3**	**M11**	**M52**	**M54**	**M55**	**M56**
winter cereals acidic soils	Châteaudun	<0.001	**0.102**	**3.995**	**0.466**	0.009	**0.233**	**0.803**	**2.918**
	Hamburg	<0.001	**0.496**	**4.082**	**0.640**	0.044	**0.283**	**1.054**	**1.661**
	Kremsmünster	<0.001	**0.644**	**3.647**	**0.379**	0.080	**0.197**	**0.640**	**1.265**
	Okehampton	<0.001	**0.685**	**2.646**	**0.323**	0.083	**0.164**	**0.515**	**0.831**
	Piacenza	<0.001	**0.472**	**4.399**	**0.474**	0.049	**0.240**	**0.794**	**1.967**
	Porto	<0.001	**2.030**	**2.027**	**0.327**	0.047	**0.157**	**0.517**	**0.954**
winter cereals alkaline / neutral soils	Châteaudun	<0.001	**0.102**	**0.558**	**0.251**	0.004	**0.121**	**0.342**	**0.726**
	Hamburg	<0.001	**0.496**	**1.095**	**0.612**	0.018	**0.282**	**0.754**	**0.668**
	Kremsmünster	<0.001	**0.644**	**1.065**	**0.383**	0.033	**0.208**	**0.460**	**0.485**
	Okehampton	<0.001	**0.685**	**0.943**	**0.347**	0.035	**0.195**	**0.403**	**0.362**
	Piacenza	<0.001	**0.472**	**0.943**	**0.351**	0.021	**0.187**	**0.443**	**0.624**
	Porto	<0.001	**2.031**	**0.653**	**0.308**	0.020	**0.171**	**0.381**	**0.384**
spring cereals acidic soils	Châteaudun	<0.001	**0.109**	**3.787**	**0.463**	0.007	**0.217**	**0.809**	**2.634**
	Hamburg	<0.001	**0.497**	**4.857**	**0.786**	0.040	**0.340**	**1.296**	**2.139**
	Kremsmünster	<0.001	**0.641**	**4.377**	**0.484**	0.077	**0.241**	**0.809**	**1.607**
	Okehampton	<0.001	**0.657**	**2.974**	**0.395**	0.070	**0.187**	**0.611**	**0.985**
	Porto	<0.001	**0.185**	**2.260**	**0.374**	0.016	**0.170**	**0.582**	**1.289**
spring cereals alkaline / neutral soils	Châteaudun	<0.001	**0.109**	**0.547**	**0.268**	0.003	**0.126**	**0.364**	**0.684**
	Hamburg	<0.001	**0.497**	**1.214**	**0.735**	0.017	**0.328**	**0.920**	**0.842**
	Kremsmünster	<0.001	**0.642**	**1.234**	**0.466**	0.032	**0.245**	**0.577**	**0.606**
	Okehampton	<0.001	**0.658**	**1.039**	**0.407**	0.029	**0.225**	**0.491**	**0.430**
	Porto	<0.001	**0.185**	**0.593**	**0.314**	0.007	**0.170**	**0.379**	**0.467**

Values in **bold** exceed the drinking water limit of 0.1 µg/L
Value displayed in dark grey background is a maximum PEC_{GW} for each compound calculated using PEARL and PELMO, relevant for the toxicological relevance assessment

The zRMS groundwater modelling based on the laboratory degradation data for metabolites demonstrated that:

1. Following application to <u>winter cereals</u>:
   - i) All PEC_{GW} for pinoxaden and metabolite M52 are <0.1 µg/L, indicating that no unacceptable leaching of these compounds is expected following the intended uses of ADM.06001.H.2.B in winter cereals.
   - ii) PEC_{GW} for metabolite M54 are above 0.1 µg/L in all scenarios but <0.75 µg/L, which is the relevant threshold for toxicologically non-relevant compounds, such as metabolite M54 and no further assessment is thus necessary.
   - iii) PEC_{GW} for non-relevant metabolites M3, M11, M55 and M56 are above the threshold concentration of 0.75 µg/L in majority of scenarios but <10.0 µg/L. Based on the outcome of evaluation presented in the Core Assessment, Part B, Section 10, the consumer risk assessment demonstrates an acceptable risk for these metabolites.
   - iv) PEC_{GW} for metabolite M2 are above the threshold concentration of 0.1 µg/L in all scenarios. As based on the currently available data the toxicological relevance of this compound cannot be excluded, its predicted concentrations cannot exceed 0.1 µg/L. Therefore further evaluation based on field dissipation data has been performed and is presented below under' Higher tier' assessment.
2. Following application to <u>spring cereals</u>:
   - i) All PEC_{GW} for pinoxaden are <0.001 µg/L, indicating that no unacceptable leaching of the active substance is expected following the intended uses of ADM.06001.H.2.B in spring cereals.
   - ii) PEC_{GW} for metabolite M52 are <0.1 µg/L in all scenarios following application on alkaline/neutral soils. In case of application on acidic soils, PEC_{GW} are <0.1 µg/L in almost all scenarios, with exception of Hamburg scenario, in which the PEC_{GW} was slightly exceeded (0.106 µg/L) when simulations were run using PEARL (in PELMO all PEC_{GW} were <0.1 µg/L for this application pattern and soil pH). The data available in area of toxicology were insufficient to conclude on the toxicological relevance of this compound and for this reason its predicted concentration in groundwater cannot exceed 0.1 µg/L. Therefore, in order to further refine the M52 concentration in Hamburg scenario, additional modelling was performed by the zRMS using PEARL with assumption of biennial application of ADM.06001.H.2.B in spring cereals on acidic soils. Table below shows obtained results:

PEC_{GW} for metabolite M52 in spring ~~winter~~ cereals, scenario Hamburg, calculated using laboratory degradation data for biennial application

Crop	Scenario	80th Percentile PEC_{GW} at 1 m Soil Depth (µg/L), FOCUS PEARL 4.4.4
		M52
Spring cereals (1.0 L product/ha, biennial) Acidic soils	Hamburg	0.058

The additional modelling for metabolite M52 performed for biennial application of ADM.06001.H.2.B in spring cereals at rate corresponding to 1.0 L product/ha resulted with PEC_{GW} <0.1 µg/L indicating that this restriction is sufficient to protect groundwater for this application pattern and soil pH.

Due to restriction of the frequency of application of pinoxaden to spring cereals at rate corresponding to 1.0 L product/ha (biennial application), during the commenting period the Applicant proposed to consider also lower application rate in this crop (corresponding to 0.75 L product/ha, use No 3* in GAP table). Additional simulations for the lower application rate were thus performed for metabolite M52 in scenario Hamburg using FOCUS PEARL 4.4.4, as this combination resulted with exceedance of the threshold concentration. The same input parameters as discussed above were considered in this additional modelling. Table below shows obtained results:

PEC_{GW} for metabolite M52 in spring cereals, scenario Hamburg, calculated using laboratory degradation data for annual application (45 g a.s./ha)

Crop	Scenario	80th Percentile PEC_{GW} at 1 m Soil Depth (µg/L), FOCUS PEARL 4.4.4
		M52
Spring cereals (0.75 L product/ha, annual) Acidic soils	Hamburg	0.079

The additional modelling for metabolite M52 performed for annual application of ADM.06001.H.2.B in spring cereals at 0.75 L product/ha resulted with PEC_{GW} <0.1 µg/L indicating that no unacceptable leaching of M52 is expected following application of ADM.06001.H.2.B every year at the lower rate.

iii) PEC_{GW} for metabolite M54 in all scenarios are above 0.1 µg/L but <0.75 µg/L, which is the relevant threshold for toxicologically not relevant compound, such as metabolite M54 and no further assessment is thus necessary.

iv) PEC_{GW} for non-relevant metabolites M3, M11, M55 and M56 are above the threshold concentration of 0.75 µg/L in majority of scenarios but <10.0 µg/L. Based on the outcome of evaluation presented in the Core Assessment, Part B, Section 10, the consumer risk assessment demonstrates an acceptable risk for these metabolites.

v) PEC_{GW} for metabolite M2 are above the threshold concentration of 0.1 µg/L in all scenarios. As based on the currently available data the toxicological relevance of this compound cannot be excluded, its predicted concentrations cannot exceed 0.1 µg/L. Therefore further evaluation based on field dissipation data has been performed and is presented below under' Higher tier' assessment.

Since for metabolites M2 and M3 soil DT_{50} values derived from the field dissipation studies were available, it was possible to perform additional modelling to further refine the groundwater exposure to these compounds. Results are presented below.

'Higher tier' PEC_{GW} for metabolites M2 and M3 in winter and spring cereals, calculated using <u>field degradation data</u>

Crop	Scenario	80th Percentile PEC_{GW} at 1 m Soil Depth (µg/L), FOCUS PEARL 4.4.4	
		M2	M3
Winter cereals Acidic soils	Châteaudun	< 0.001	**0.215**
	Hamburg	< 0.001	**0.577**
	Kremsmünster	< 0.001	**0.462**
	Okehampton	< 0.001	**0.526**
	Piacenza	<0.001	**0.304**
	Porto	< 0.001	**0.440**
Winter cereals Alkaline/neutral soils	Châteaudun	< 0.001	**0.146**
	Hamburg	< 0.001	**0.397**
	Kremsmünster	< 0.001	**0.318**
	Okehampton	< 0.001	**0.365**
	Piacenza	<0.001	**0.212**
	Porto	< 0.001	**0.306**
Spring cereals Acidic soils	Châteaudun	< 0.001	**0.254**
	Hamburg	< 0.001	**0.873**
	Kremsmünster	< 0.001	**0.628**
	Okehampton	< 0.001	**0.667**
	Porto	< 0.001	**0.255**
Spring cereals Alkaline/neutral soils	Châteaudun	< 0.001	**0.173**
	Hamburg	< 0.001	**0.592**
	Kremsmünster	< 0.001	**0.433**
	Okehampton	< 0.001	**0.459**
	Porto	< 0.001	**0.175**
		80th Percentile PEC_{GW} at 1 m Soil Depth (µg/L), FOCUS PELMO 5.5.3	
		M2	**M3**
Winter cereals Acidic soils	Châteaudun	< 0.001	**0.181**
	Hamburg	< 0.001	**0.570**
	Kremsmünster	< 0.001	**0.550**
	Okehampton	< 0.001	**0.559**
	Piacenza	0.001	**0.391**
	Porto	**0.152**	**0.565**
Winter cereals Alkaline/neutral soils	Châteaudun	< 0.001	**0.122**
	Hamburg	< 0.001	**0.391**
	Kremsmünster	< 0.001	**0.382**
	Okehampton	< 0.001	**0.387**
	Piacenza	0.001	**0.265**
	Porto	**0.152**	**0.393**
Spring cereals Acidic soils	Châteaudun	< 0.001	**0.191**
	Hamburg	< 0.001	**0.636**
	Kremsmünster	< 0.001	**0.630**
	Okehampton	< 0.001	**0.644**
	Porto	0.001	**0.353**
Spring cereals Alkaline/neutral soils	Châteaudun	< 0.001	**0.130**
	Hamburg	< 0.001	**0.438**
	Kremsmünster	< 0.001	**0.431**
	Okehampton	< 0.001	**0.444**
	Porto	0.001	**0.243**

Values in **bold** exceed the drinking water limit of 0.1 µg/L
Value displayed in dark grey background is a maximum PEC_{GW} for each compound calculated using PEARL and PELMO, relevant for the toxicological relevance assessment

When soil field dissipation data are considered, the PEC_{GW} values for metabolite M3 derived using PELMO are >0.1 µg/L in all scenarios, but <0.75 µg/L, which is the relevant threshold for toxicologically non-relevant compounds, such as metabolite M3. Modelling performed using PEARL gave similar results with PEC_{GW} in range of 0.1-0.75 µg/L in majority of scenarios with exception of scenario Hamburg following application in spring cereals on acidic soils, for which PEC_{GW} of 0.873 µg/L has been calculated, which is above the threshold of 0.75 µg/L for non-relevant metabolites. For this reason the consumer risk assessment was performed in area of section B10, which demonstrated acceptable risk to consumers from this metabolite (for details, please refer to the Core Assessment, Part B, Section 10).
Additional modelling based on field data resulted with PEC_{GW} for metabolite M2 <0.001 µg/L in all scenarios following uses in spring cereals. In case of winter cereals the PEC_{GW} are <0.001 µg/L in majority scenarios with exception of Porto in which PEC_{GW} of 0.152 µg/L was calculated following application to winter cereals. The data available in area of toxicology were insufficient to conclude on the toxicological relevance of this compound and for this reason its predicted concentration in groundwater cannot exceed 0.1 µg/L. Therefore, in order to further refine the M2 concentration in Porto scenario, additional modelling was performed by the zRMS using PELMO with assumption of biennial application of ADM.06001.H.2.B in winter cereals. As PEC_{GW} derived for this compound with PEARL were <0.1 µg/L in all scenarios for annual applications, simulations using this model were not necessary. Results of additional PELMO modelling for winter cereals in Porto scenario are presented below.

'Higher tier' PEC_{GW} for metabolite M2 in winter cereals, scenario Porto, calculated using field degradation data for biennial application at 1.0 L product/ha

Crop	Soil type	Scenario	80th Percentile PEC_{GW} at 1 m Soil Depth (µg/L), FOCUS PELMO 5.5.3
			M2
Winter cereals (1.0 L/ha, biennial)	Acidic	Porto	0.080
	Alkaline / neutral		0.080

The additional modelling for metabolite M2 performed for biennial application of ADM.06001.H.2.B in winter cereals resulted with PEC_{GW} <0.1 µg/L indicating that this restriction is sufficient to protect groundwater.

In order to further refine the exposure of groundwater to metabolites M2 and M52, results of higher-tier studies could be considered. For purposes of the first EU authorisation of pinoxaden, several lysimeter studies were evaluated by the RMS. The studies were performed in Germany (1 study) and Switzerland (3 studies). One of the Switzerland studies is not relevant for assessment of ADM.06001.H.2.B since pinoxaden was applied at cereals BBCH 41-49, while ADM.06001.H.2.B is intended to be applied up to BBCH 39. Results of the remaining studies in the context of application of ADM.06001.H.2.B are discussed below:

1. **Germany (LoEP study ii):** study duration was three years with applications carried out over 2 first years with 2 treatments per year: at 49-51 g a.s./ha in autumn (winter wheat at BBCH 17-22) and at 66 g a.s./ha in spring (winter wheat at BBCH 31-32). The spring applications cover intended application of ADM.06001.H.2.B, while due additional applications in autumn the study represents worst case as only single application of ADM.06001.H.2.B is intended in the Central Zone. The growth stages correspond with the intended Central Zone uses of ADM.06001.H.2.B. In this study metabolite M2 was always detected <0.1 µg/L with maximum concentration of 0.05 µg/L in year 1. Metabolite M52 was found <0.1 µg/L (max 0.088 µg/L) in years 1 and 3, however in year 2 it was detected at maximum concentration of 0.130 µg/L.
2. **Switzerland (LoEP study iii):** study duration was 3 years. Applications were carried out over 2 first years with single treatment per year at 60 g a.s./ha to wheat at BBCH 21-23 (during spring). The application pattern covers intended uses of ADM.06001.H.2.B in the Central Zone. In this study metabolites M2 and M52 were always detected at <0.1 µg/L.
3. **Switzerland (LoEP study iv):** study duration was 2 years. Applications were carried out each year during spring to winter wheat at BBCH 13-14. The application rates were 45 g a.s./ha during first year and 60 g a.s./ha during second year. The application rate during first year was lower than this intended for ADM.06001.H.2.B and during the second year it was at the same level as intended for this product. The BBCH stages were in line with these intended for spring cereals, while they were earlier for winter cereals which represents worst case in terms of the crop interception. In this study metabolite M52 was not analysed, while metabolite M2 was detected at maximum concentration of 1.2 µg/L (no information on the year of detection given) with calculated annual average of 0.5 and 0.1 µg/L at 0.8 and 1.2 m, respectively.

Results of the available lysimeter studies demonstrate that at some conditions leaching of metabolites M2 and M52 to groundwater is possible when pinoxaden is applied every year.

In order to further investigate leaching of pinoxaden metabolites to groundwater, the Pan-European groundwater monitoring study was performed in 70 sites in 5 countries (France, Germany, Italy, Lithuania and the UK) in years 2015-2019 at vulnerable locations reflecting realistic pinoxaden use pattern in the EU cereal growing regions. The groundwater monitoring was evaluated by the RMS (AT) as a part of the confirmatory data and is presented in Addendum to pinoxaden RAR, Vol. 3CA, B.8 (May 2022). The following was concluded by the RMS:

The RMS AT agrees with the applicant that the overall monitoring results provided, obtained at 70 monitoring sites in the pan-EU targeted pinoxaden edge-of-field monitoring study, at 22 monitoring sites in the German National monitoring program and at 22 monitoring sites in the French National monitoring program, give strong evidence that the exposure of the pinoxaden metabolites to groundwater is low, and it is highly unlikely that pinoxaden metabolites will exceed the regulatory threshold of 0.1 µg/L under typical pinoxaden use conditions across the EU. However, the monitoring results also demonstrate that highly isolated exceedances of 0.1 µg/L of pinoxaden metabolites, particularly in shallow groundwater below or close to treated fields, may occur (albeit at concentrations much less than 0.75 µg/L).

In fact, among the 1933 groundwater samples collected from 90 wells metabolite M2 was always detected at concentrations <0.1 µg/L with maximum concentration of 0.064 µg/L. Concentration of metabolite M52 were <0.1 µg/L in 99.9% of groundwater samples and detections >0.1 µg/L were observed in 2 samples with maximum of 0.162 µg/L. Based on the obtained results it may be thus expected that metabolite M2 will not migrate to groundwater at concentrations exceeding the threshold concentration of 0.1 µg/L, while possibility of migration of metabolite M52 at concentrations exceeding 0.1 µg/L is negligible.

Nevertheless, it is also concluded by the RMS that:

All of these three monitoring programs have their flaws and limitations, particularly with respect to hydraulic connectivity between treated fields and sampling wells, leaching vulnerability estimates and application rates and frequencies of pinoxaden less than intended. In view of the RMS AT, there is a need to adequately address these limitations in the assessment of a monitoring study as far as possible. For now, there is only limited regulator guidance available on how to do so. […] On overall, the RMS AT highly recommends to develop more targeted regulatory guidance on how to conduct, evaluate and assess such monitoring studies at the level of the entire EU (for active substance approval) and at the level of Member States (for product registration

The zRMS for ADM.06001.H.2.B agrees with conclusions of the RMS that currently there are no clear criteria on how to interpret results of groundwater monitoring and how to treat the results in order to derive the final conclusion (consider annual average concentrations, 80th percentile, 90th percentile, maximum detections?). It is further noted that in order to conclude if the results of the available monitoring studies are representative for the intended uses of ADM.06001.H.2.B, respective analysis should be performed with comparison of the application rates, timing and environmental conditions in the study with the intended use pattern of ADM.06001.H.2.B and conditions in particular cMS. The zRMS would like to point out that it is the responsibility of the Applicant to perform such analyses, but none was submitted and for this reason the conclusion regarding the groundwater exposure following application of ADM.06001.H.2.B will be based on the results of the groundwater modelling performed by the zRMS.

Due to complex groundwater assessment for application of pinoxaden in ADM.06001.H.2.B, the zRMS prepared table presenting conclusions for each compound in each scenario and for various conditions of use (acidic vs alkaline/neutral soils, different application rates), in order to facilitate particular cMS the decision on authorisation of the product and identification of the respective mitigation measures. Scenarios where no restrictions were necessary are highlighted in green, while scenarios with mitigation measures are highlighted in yellow.

Conclusions on groundwater exposure to pinoxaden and its metabolites following application of ADM.06001.H.2.B in the Central Zone, based on results of the groundwater modelling performed for application rate of 1.0 L product/ha

Crop	Soil	Compound	Scenario					
			C	H	K	N	P	O
Winter cereals	Acidic	Pinoxaden						
		M2						Biennial application
		M3						
		M11						
		M52						
		M54						
		M55						
		M56						
	Alkaline / neutral	Pinoxaden						
		M2						Biennial application
		M3						
		M11						
		M52						
		M54						
		M55						
		M56						
Spring cereals	Acidic	Pinoxaden					X	
		M2						
		M3						
		M11						
		M52		Biennial application				
		M54						
		M55						
		M56						
	Alkaline / neutral	Pinoxaden					X	
		M2						
		M3						
		M11						
		M52						
		M54						
		M55						
		M56						

C: Châteaudun **H:** Hamburg **K:** Kremsmünster **N:** Okehampton **P:** Piacenza **O:** Porto
X: scenario not defined for this crop

Conclusions on groundwater exposure to pinoxaden and its metabolites following application of ADM.06001.H.2.B in the Central Zone, based on results of the additional groundwater modelling performed for application rate of 0.75 L product/ha in spring cereals

Crop	Soil	Compound	Scenario					
			C	H	K	N	P	O
Spring cereals	Acidic	Pinoxaden						
		M2						
		M3						
		M11						
		M52						
		M54						
		M55						
		M56						
	Alkaline / neutral	Pinoxaden						
		M2						
		M3						
		M11						
		M52						
		M54						
		M55						
		M56						

C: Châteaudun **H:** Hamburg **K:** Kremsmünster **N:** Okehampton **P:** Piacenza **O:** Porto
X: scenario not defined for this crop

At the product authorisation the concerned Member States must decide if any restrictions are required in their countries, since PEC_{GW} for M2 and M52 were exceeded only in single scenarios, which may be representative for only some Member States. Furthermore, particular cMS must decide whether they agree with the use of the new endpoints from the Addendum 1 to pinoxaden RAR (May 2022). Taking all this into account, conclusion in Table 8.1-1 has been highlighted in blue (to be confirmed by cMS).

Please note that additional groundwater modelling may be required by the concerned Member States that do not accept simulations performed according to FOCUS recommendations.

8.8.2.3 Mefenpyr-diethyl and its metabolites

There are 3 metabolites of Mefenpyr-diethyl which could potentially be detected in groundwater: AE F113225, AE E094270, AE F2211046. Groundwater concentrations for metabolite AE F2211046 were calculated as if AE F2211046 was the parent molecule. A pseudo-application rate was calculated considering relative molecular weights, the application rate of mefenpyr-diethyl and the maximum occurrence of AE F221046 of 11.5%. The resultant pseudo-application rate was 4.2 g met./ha.
For calculations please refer to reports KCP 9.2.4.1/08, Fragkoulis G. (2022c) and KCP 9.2.4.1/09, Hicks J. (2022c) for more details.

Table 8.8-11: Input parameters related to active substance Mefenpyr-diethyl and metabolites for PEC_{gw} calculations

Compound	**Mefenpyr-diethyl**	**AE F113225**	**AE F094270**	**Value in accordance with EU endpoint y/n/ Reference**
Molecular weight (g/mol)	373.26	345.2	271.11	Proposed in Monograph (list of endpoints) Oct 2011[a]
Water solubility (g/mol):	20 at 20ºC	14 at 20ºC	50 at 20ºC	Proposed in Monograph (list of endpoints) Oct 2011[a]
Saturated vapour pressure (Pa):	6.3×10^{-6} at 20ºC	0 at 20ºC (worst-case)	0 at 20ºC (worst-case)	Proposed in Monograph (list of endpoints) Oct 2011[a]
DT_{50} in soil (d)	2.4 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q_{10} of 2.58, n = 4)	6.1 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q_{10} of 2.58, n = 4)	19.6 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q_{10} of 2.58, n = 3)	Proposed in Monograph (list of endpoints) Oct 2011[a]
Transformation rate	-	0.219497	0.113631	Calculated in PELMO
K_{foc}/K_{fom} (mL/g)	610/353.8 (geometric mean, n=6)	110/63.8 (geometric mean, n=3)	177/102.7 (geometric mean, n=5)	Proposed in Monograph (list of endpoints) Oct 2011[a]
1/n	1.085 (arithmetic mean, n=6)	0.92 (arithmetic mean, n=3)	0.928 (arithmetic mean, n=5)	Proposed in Monograph (list of endpoints) Oct 2011[a]
Plant uptake factor	0	0	0	Default value
Formation fraction	-	0.76 (from parent)	1 (from AE F113225)	Proposed in Monograph (list of endpoints) Oct 2011[a]

Compound	**AE F2211046**	**Value in accordance with EU endpoint y/n/ Reference**
Molecular weight (g/mol)	391.26	Proposed in Monograph (list of endpoints) Oct 2011[a]
Water solubility (g/mol):	1000 at 20ºC	Proposed in Monograph (list of endpoints) Oct 2011[a]
Saturated vapour pressure (Pa):	1.0×10^{-9} at 20ºC	Proposed in Monograph (list of endpoints) Oct 2011[a]
DT_{50} in soil (d)	1000	Proposed in Monograph (list of endpoints) Oct 2011[a] for the deeper horizons; the 1st horizon DT_{50} of 35.5 days (from photodegradation) was not used in the current calculations
Transformation rate	-	Run as parent

K_{foc} (mL/g)/K_{fom}	1320/765.7 (QSAR)	Proposed in Monograph (list of endpoints) Oct 2011[a]
1/n	1	Default value
Plant uptake factor	0	Default value
Formation fraction	-	Run as parent

[a] Monograph has been voluntarily prepared by AGES and ANSES in the context of zonal authorisation of plant protection products containing safener mefenpyr-diethyl.

Table 8.8-12: PEC_{gw} for mefenpyr-diethyl and metabolites on winter cereals (with FOCUS PEARL 4.4.4/PELMO 5.5.3/MACRO 5.5.4)

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)		
		Mefenpyr-diethyl	**AE F113225**	**AE F094270**
Winter cereals	Châteaudun	<0.001/<0.001/<0.001	<0.001/<0.001/<0.001	<0.001/<0.001/<0.001
	Hamburg	<0.001/<0.001	<0.001/<0.001	<0.001/<0.001
	Jokioinen	<0.001/<0.001	<0.001/<0.001	<0.001/<0.001
	Kremsmünster	<0.001/<0.001	<0.001/<0.001	<0.001/<0.001
	Okehampton	<0.001/<0.001	<0.001/<0.001	<0.001/<0.001
	Piacenza	<0.001/<0.001	<0.001/<0.001	<0.001/<0.001
	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
		AE F2211046		
	Châteaudun	0.005/0.001		
	Hamburg	0.062/0.036		
	Jokioinen	<0.001/<0.001		
	Kremsmünster	0.044/0.038		
	Okehampton	0.085/0.083		
	Piacenza	0.082/0.074		
	Porto	0.063/0.060		
	Sevilla	<0.001/<0.001		
	Thiva	<0.001/<0.001		

Values in **bold** exceed the drinking water limit of 0.1 µg/L

Table 8.8-13: PEC_{gw} for mefenpyr-diethyl and metabolites on spring cereals (with FOCUS PEARL 4.4.4/PELMO 5.5.3/MACRO 5.5.4)

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)		
		Mefenpyr-diethyl	**AE F113225**	**AE F094270**
Spring cereals	Châteaudun	<0.001/<0.001/<0.001	<0.001/<0.001/<0.001	<0.001/<0.001/<0.001
	Hamburg	<0.001/<0.001	<0.001/<0.001	<0.001/<0.001
	Jokioinen	<0.001/<0.001	<0.001/<0.001	<0.001/<0.001
	Kremsmünster	<0.001/<0.001	<0.001/<0.001	<0.001/<0.001
	Okehampton	<0.001/<0.001	<0.001/<0.001	<0.001/<0.001
	Porto	<0.001/<0.001	<0.001/<0.001	<0.001/<0.001
		AE F2211046		
	Châteaudun	0.004/0.001/0.005		
	Hamburg	0.085/0.034		
	Jokioinen	<0.001/<0.001		
	Kremsmünster	0.053/0.035		
	Okehampton	0.089/0.082		
	Porto	0.056/0.063		

Values in **bold** exceed the drinking water limit of 0.1 µg/L

The drinking water limit of 0.1µg/L was not exceed for any metabolite following application of ADM.06001.H.2.B to winter or spring cereals.

zRMS comments:

No EU agreed data exist for the safener mefenpyr-diethyl, however in 2011 ANSES and AGES prepared Monograph (List of Endpoints) in order to aid zonal evaluations of the products containing this safener. Considered input parameters presented n Table 8.8-11 were in general in line with this document with exception of the Kfoc values. The Applicant considered the geometric mean values instead of the agreed arithmetic means, which is in line with the current EFSA requirements. This deviation is agreed by the zRMS since the geometric mean values are lower comparing to arithmetic means and represent thus worst case. The geometric mean Kfoc values were calculated on the basis of individual values agreed in ANSES/AGES Monograph and are confirmed to be correct.

In simulations PUF value of 0 was assumed for all compounds, which is in line with recommendations of the most recent version of the FOCUS Groundwater Guidance (2021).

Results presented by the Applicant were independently validated by the zRMS in additional modelling with FOCUS PEARL 4.4.4, PELMO 5.5.3 and FOCUS MACRO 5.5.4 using the input parameters from the Monograph (2011) and application dates as suggested by AppDate 3.06. Obtained PEC_{GW} values were in good agreement with Applicants' results presented in Tables 8.8-12 and 8.8-13.

Based on the results of performed simulations no unacceptable leaching of mefenpyr-diethyl and its metabolites is expected following the intended Central Zone uses of ADM.06001.H.2.B in winter and spring cereals

Please note that additional groundwater modelling may be required by the concerned Member States that do not accept simulations performed according to FOCUS recommendations.

Since acceptable groundwater exposure to mefenpyr-diethyl could be concluded for application rate of 1.0 L product/ha, no additional simulations for lower application rate (0.75 L product/ha) were required.

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

zRMS comments:

After superficial review of the first version of the dRR submitted to the Polish authorities some of the assumptions taken by the Applicant were not agreed by the zRMS efate expert. The Applicant was thus requested to provide updated surface water exposure assessment based on inputs selected in line with current requirements and agreed endpoints. The results based on the relevant inputs were included by the Applicant in the updated version of the dRR, but the parts not agreed already after the superficial zRMS review (i.e. before the actual detailed assessment) were retained. Since the document was updated by the Applicant and the values presented initially would not be accepted anyway, the updated version of the dRR could be treated as the initial version and the zRMS decided to remove not agreed data and results obtained on their basis in order to avoid excessive strikethroughs and to improve the transparency of the report, facilitating the cMS review without unnecessary confusion.

8.9.1 Justification for new endpoints

No new endpoints were used for $PEC_{sw/sed}$ calculations.

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	ADM.06001.H.2.B	
Use No.	2	3
Crop	Winter cereals	Spring cereals
Application rate (kg as/ha)	Mesosulfuron-methyl: 12 Pinoxaden: 60 Mefenpyr-diethyl: 35	Mesosulfuron-methyl: 12 Pinoxaden: 60 Mefenpyr-diethyl: 35
Number of applications/interval (d)	1	1
Application window	Mar – May (NEU) Mar – May (SEU) Minimal crop cover (relevant for STEP 1 and 2 only)	Mar – May (NEU) Mar – May (SEU) Minimal crop cover (relevant for STEP 1 and 2 only)
Application method	Ground spray	Ground spray
CAM (Chemical application method)	2 – appln foliar linear	2 – appln foliar linear
Soil depth (cm)	4 (default PRZM input)	4 (default PRZM input)
Models used for calculation	FOCUS Steps 1 and 2 v3.2, FOCUS SWASH v5.3, FOCUS PRZM v4.3.1, FOCUS MACRO v5.5.4, FOCUS TOXWA v4.4.3, SWAN v5.0.0	

PECsw calculations are provided for winter cereals at BBCH 20-39, spring cereals BBCH 13-39 and both winter and spring cereals at BBCH 35-39. All application dates were determined using AppDate (v3.06) and are provided in the table below.

Table 8.9-2: FOCUS Step 3 Scenario related input parameters for $PEC_{sw/sed}$ calculations for the application of ADM.06001.H.2.B

Crop	Scenario	Start of application window
Winter cereals (BBCH 20**-39)	D1	16 March
	D2	26 March
	D3	07 April
	D4	09 March
	D5	06 March
	D6	21 December*
	R1	15 April
	R3	10 March
	R4	22 December

Crop	Scenario	Start of application window
Winter cereals (BBCH 35-39)	D1	09 April
	D2	19 April
	D3	03 May
	D4	03 April
	D5	25 March
	D6	23 February
	R1	02 May
	R3	28 March
	R4	12 February
Spring cereals (BBCH 13-39)	D1	09 May
	D3	06 April
	D4	30 April
	D5	20 March
	R4	20 March
Spring cereals (BBCH 35-39)	D1	02 June
	D3	04 May
	D4	24 May
	D5	15 April
	R4	15 April

* The application date for D6 is not in accordance with the intended GAP (spring application). See table 8.8-12 for further consideration
** BBCH 21 was used to be more in line with the intended GAP (spring application)

zRMS comments:

The input parameters related to the application pattern presented in Table 8.9-1 are agreed by the zRMS. The crop cover (minimal) assumed at Step 1&2 is in line with indications of the FOCUS surface water guidance (2014) for the earliest possible application timing (cereal, BBCH 10-19). At Step 3 CAM 2 was correctly assumed, while the crop interception was calculated internally by the model.

In line with zRMS recommendations, two sets of simulations were performed:

1. for application at the earliest possible application timing,
2. for application at the later BBCH stages (>30) in order to check if different weather conditions (e.g. higher precipitation) do not increase the exposure of surface water bodies to the modelled substance (the zRMS experience show that for some compounds $PEC_{SW/SED}$ are higher for later BBCH stages with the most pronounced differences observed between BBCH stages 10-29 and 30-39).

Start of the application windows presented in Table 8.9-2 for each scenario was checked by the zRMS using AppDate ver. 3.06 tool and is considered acceptable.

8.9.2.1 Mesosulfuron-methyl and its metabolites

Please refer to report KCP 9.2.5/01, Hicks J. (2021d) for more details on Step 1&2 calculations. For Step 3&4 calculations please refer to reports KCP 9.2.5/04, Fragkoulis G. (2022d), KCP 9.2.5/05, Hicks J. (2022d) and KCP 9.2.5/10, Fragkoulis G. (2022g) for more details.

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

Compound	Mesosulfuron-methyl	AE F154851 (Mesosulfuron)	AE F160459	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	503.5	489.5	489.5	EFSA Conclusion 4584/2016
Saturated vapour pressure (Pa)	3.5 x $x10^{-12}$ at 20ºC	Not required	Not required	EFSA Conclusion 4584/2016
Water solubility (mg/L)	483 at 20ºC	200000 at 20ºC	10000 at 20ºC	EFSA Conclusion 4584/2016
Diffusion coefficient in water (m²/d)	not required for Step 1+2/4.3 x 10^{-5}			default
Diffusion coefficient in air (m²/d)	not required for Step 1+2/0.43			default
K_{foc} (mL/g)	64 (geomean, n = 9)	65 (geomean, n=8)	19.3 (geomean, n=5)	EFSA Conclusion 4584/2016
Freundlich Exponent 1/n	0.91 (arithmetic mean, n = 9)	Not required ~~0.94 (arithmetic mean, n=3)~~	Not required	EFSA Conclusion 4584/2016
Plant Uptake	not required for Step 1+2/ 0			EFSA Conclusion 4584/2016
Wash-Off factor from Crop (1/mm)	not required for Step 1+2/0.05 (MACRO), 0.50 (PRZM)			default
$DT_{50,soil}$ (d)	49.72 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q_{10} of 2.58, n =9)	45.22 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q_{10} of 2.58, n =8)	74.14 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q_{10} of 2.58, n =5)	EFSA Conclusion 4584/2016
$DT_{50,water}$ (d)	43 (geomean, n=4)	56.4 (geomean, n=4)	87.9 (geomean, n=4)	EFSA Conclusion 4584/2016
$DT_{50,sed}$ (d)	1000 (default at both Step 1/2 and Step 3/4)	56.4 (geomean, n=4)	87.9 (geomean, n=4)	EFSA Conclusion 4584/2016
$DT_{50,whole\ system}$ (d)	43 (geomean, n=4)	56.4 (geomean, n=4)	87.9 (geomean, n=4)	EFSA Conclusion 4584/2016
Maximum occurrence observed (% molar basis with respect to the parent)	-	Soil: 16.2 Total system: 4.9	Soil: 8.9 Total system: 21.6	EFSA Conclusion 4584/2016
Compound	**AE F099095**	**AE F092944**	**AE F160460**	**Value in accordance to EU endpoint y/n/ Reference**
Molecular weight (g/mol)	198.2	155.2	475.5	EFSA Conclusion 4584/2016
Saturated vapour pressure (Pa)	Not required	Not required	Not required	EFSA Conclusion 4584/2016
Water solubility (mg/L)	190 at 20ºC	5200 at 20ºC	100000 at 20ºC	EFSA Conclusion 4584/2016
Diffusion coefficient in water (m²/d)	not required for Step 1+2/4.3 x 10^{-5}			default
Diffusion coefficient in air (m²/d)	not required for Step 1+2/0.43			default
K_{foc} (mL/g)	692 (arithmetic mean, n=11)	956.4 (arithmetic mean, n=23)	12.2 (geometric mean, n=5)	EFSA Conclusion 4584/2016
Freundlich Exponent 1/n	Not required	Not required	Not required	EFSA Conclusion 4584/2016
Plant Uptake	not required for Step 1+2/ 0			EFSA Conclusion 4584/2016

Wash-Off factor from Crop (1/mm)	not required for Step 1+2/0.05 (MACRO), 0.50 (PRZM)			default
$DT_{50,soil}$ (d)	1000 (default)	1000 (default)	28.61 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q_{10} of 2.58, n =5)	EFSA Conclusion 4584/2016
$DT_{50,water}$ (d)	1000 (default)	1000 (default)	325.9 (geomean, n=4)	EFSA Conclusion 4584/2016
$DT_{50,sed}$ (d)	1000 (default)	1000 (default)	325.9 (geomean, n=4)	EFSA Conclusion 4584/2016
$DT_{50,whole\ system}$ (d)	1000 (default)	1000 (default)	325.9 (geomean, n=4)	EFSA Conclusion 4584/2016
Maximum occurrence observed (% molar basis with respect to the parent)	Soil: 29.2 Total system: 0.9	Soil: 10.1 Total system: 3.2	Soil: 8.6 Total system: 8.4	EFSA Conclusion 4584/2016
Compound	**AE F140584**	**AE F147447**	**BCS CV14885 1)**	**Value in accordance to EU endpoint y/n/ Reference**
Molecular weight (g/mol)	322.4	290.3	393.4	EFSA Conclusion 4584/2016
Saturated vapour pressure (Pa)	Not required	Not required	Not required	EFSA Conclusion 4584/2016
Water solubility (mg/L)	100 at 20ºC	15000 at 20ºC	2000 at 20ºC	EFSA Conclusion 4584/2016
Diffusion coefficient in water (m²/d)	not required for Step 1+2/4.3 x 10^{-5}			default
Diffusion coefficient in air (m²/d)	not required for Step 1+2/0.43			default
K_{foc} (mL/g)	0 (default)	5.1 (geomean, n=5)	17.7 (geomean, n=4)	EFSA Conclusion 4584/2016
Freundlich Exponent 1/n	Not required	Not required	1.21 ~~Not required~~	EFSA Conclusion 4584/2016
Plant Uptake	not required for Step 1+2/ 0			EFSA Conclusion 4584/2016
Wash-Off factor from Crop (1/mm)	not required for Step 1+2/0.05 (MACRO), 0.50 (PRZM)			default
$DT_{50,soil}$ (d)	4.22 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q_{10} of 2.58, n =5)	162.8 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q_{10} of 2.58, n =4)	151.2 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q_{10} of 2.58, n =4)	EFSA Conclusion 4584/2016
$DT_{50,water}$ (d)	1000 (default)	1000 (default)	1000 (default)	EFSA Conclusion 4584/2016
$DT_{50,sed}$ (d)	1000 (default)	1000 (default)	1000 (default)	EFSA Conclusion 4584/2016
$DT_{50,whole\ system}$ (d)	1000 (default)	1000 (default)	1000 (default)	EFSA Conclusion 4584/2016
Maximum occurrence observed (% molar basis with respect to the parent)	Soil: 7.1 Total system: 1.9	Soil: 5.8 Total system: 10.9	Soil: 5.0 Total system: 22.0	EFSA Conclusion 4584/2016

Compound	**BCS CO60720**	**Value in accordance to EU endpoint y/n/ Reference**
Molecular weight (g/mol)	407.4	EFSA Conclusion 4584/2016
Saturated vapour pressure (Pa)	Not required	EFSA Conclusion 4584/2016
Water solubility (mg/L)	1000 at 20ºC	EFSA Conclusion 4584/2016
Diffusion coefficient in water (m²/d)	not required for Step 1+2/4.3 x 10^{-5}	default
Diffusion coefficient in air (m²/d)	not required for Step 1+2/0.43	default

K_{foc} (mL/g)	0	default
Freundlich Exponent 1/n	Not required	
Plant Uptake	not required for Step 1+2/ 0	EFSA Conclusion 4584/2016
Wash-Off factor from Crop (1/mm)	not required for Step 1+2/0.05 (MACRO), 0.50 (PRZM)	default
$DT_{50,soil}$ (d)	0.001	default
$DT_{50,water}$ (d)	1000	default
$DT_{50,sed}$ (d)	1000	default
$DT_{50,whole\ system}$ (d)	1000	default
Maximum occurrence observed (% molar basis with respect to the parent)	Soil: 0.001 Total system: 13.1	EFSA Conclusion 4584/2016

[1)] Metabolite BCS CV14885 was implemented in the degradation scheme for the Step 3 simulations with a formulation fraction in soil of 0.096 (based on LoEP, EFSA 2016, page 60), a formation fraction in water of 1 as default worst-case value and no formation to the sediment compartment. Additionally, a 1/n of 1.21 (based on LoEP, EFSA 2016, page 60) and a vapour pressure value of 7.4 x 10-4 Pa (based on RAR 2016, page 54) was used.

$PEC_{sw/sed}$

Table 8.9-4: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for mesosulfuron-methyl following application of ADM.06001.H.2.B to winter cereals

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	3.796	Runoff/drainage	**	2.359
Step 2					
Northern Europe	March-May	0.795	Runoff/drainage	**	0.499
Southern Europe	March-May	1.492	Runoff/drainage	**	0.938

* single applications should be marked.
** twa-time as required by ecotox – not required

Table 8.9-5: FOCUS Step 3 PEC_{sw} and PEC_{sed} for mesosulfuron-methyl following application of ADM.06001.H.2.B to winter cereals BBCH 20-39

Scenario FOCUS	Waterbody		Max PEC_{sw} (µg/L)*	Dominant entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
D1	ditch		0.508	Drainage	**	0.684
D1	stream		0.318	Drainage	**	0.349
D2	ditch		1.432	Drainage	**	0.850
D2	stream		0.900	Drainage	**	0.479
D3	ditch		0.078	Drift	**	0.023
D4	pond		0.032	Drift	**	0.081
D4	stream		0.059	Drift	**	0.032
D5	pond		0.016	Drift	**	0.041
D5	stream		0.066	Drift	**	0.019
D6	ditch		0.462	Drainage	**	0.158
R1	pond		0.005	Drift	**	0.008
R1	stream		0.080	Run-off	**	0.015
R3	stream		0.209	Run-off	**	0.037
R4	stream		0.050	Drift	**	0.004

* single applications should be marked. ** twa-time as required by ecotox – not required

Table 8.9-6: FOCUS Step 3 PEC_{sw} and PEC_{sed} for mesosulfuron-methyl following application of ADM.06001.H.2.B to winter cereals BBCH 35-39

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
D1	ditch	0.176	Drift	**	0.313
D1	stream	0.114	Drift	**	0.183
D2	ditch	2.099	Drainage	**	0.905
D2	stream	1.345	Drainage	**	0.480
D3	ditch	0.078	Drift	**	0.026
D4	pond	0.032	Drift	**	0.082
D4	stream	0.062	Drift	**	0.033
D5	pond	0.014	Drift	**	0.043
D5	stream	0.066	Drift	**	0.037
D6	ditch	0.086	Drift	**	0.035
R1	pond	0.006	Drift	**	0.010
R1	stream	0.100	Drift	**	0.019
R3	stream	0.137	Drift	**	0.035
R4	stream	0.213	Drift	**	0.046

* single applications should be marked.
** twa-time as required by ecotox – not required

Table 8.9-7: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for mesosulfuron-methyl following application of ADM.06001.H.2.B to spring cereals

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	3.796	Runoff/drainage	**	2.359
Step 2					
Northern Europe	March-May	0.795	Runoff/drainage	**	0.499
Southern Europe	March-May	1.492	Runoff/drainage	**	0.938

* single applications should be marked.
** twa-time as required by ecotox – not required

Table 8.9-8: FOCUS Step 3 PEC_{sw} and PEC_{sed} for mesosulfuron-methyl following application of ADM.06001.H.2.B to spring cereals BBCH 13-39

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
D1	ditch	0.249	Drainage	**	0.401
D1	stream	0.207	Drainage	**	0.222
D3	ditch	0.079	Drainage	**	0.025
D4	pond	0.036	Drainage	**	0.095
D4	stream	0.065	Drainage	**	0.041
D5	pond	0.014	Drainage	**	0.043
D5	stream	0.065	Drainage	**	0.017
R4	stream	0.050	Drift	**	0.004

* single applications should be marked.
** twa-time as required by ecotox – not required

Table 8.9-9: FOCUS Step 3 PEC_{sw} and PEC_{sed} for mesosulfuron-methyl following application of ADM.06001.H.2.B to spring cereals BBCH 35-39

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
D1	ditch	0.242	Drift	**	0.412
D1	stream	0.207	Drift	**	0.213
D3	ditch	0.078	Drift	**	0.026
D4	pond	0.033	Drift	**	0.085
D4	stream	0.065	Drift	**	0.037
D5	pond	0.014	Drift	**	0.043
D5	stream	0.070	Drift	**	0.019
R4	stream	0.321	Drift	**	0.064

* single applications should be marked.
** twa-time as required by ecotox – not required

FOCUS Step 4

Table 8.9-10: Global maximum PEC_{sw} values for mesosulfuron-methyl, following application of ADM.06001.H.2.H to winter cereals BBCH 20-39 according to the central ~~southern~~ EU zone GAP according to surface water Step 4

PEC_{sw} (µg/L)	Scenario	STEP 4
Nozzle reduction	Vegetative strip (m)	10
	No spray buffer (m)	10
None	D1 ditch	0.508
None	D1 stream	0.318
None	D2 ditch	1.432
None	D2 stream	0.900
None	D3 ditch	Passes at Step3
None	D4 pond	Passes at Step3
None	D4 stream	Passes at Step3
None	D5 pond	Passes at Step3
None	D5 stream	Passes at Step3
None	D6 ditch	0.462
None	R1 pond	Passes at Step3
None	R1 stream	Passes at Step3
None	R3 stream	0.094
None	R4 stream	Passes at Step3

Further refinement is required for drainage scenarios since the introduction of vegetated buffer zones only reduces risk from spray drift and surface runoff and a 20 meter buffer zone will not change PECs.

Table 8.9-11: Global maximum PEC_{sw} values for mesosulfuron-methyl, following application of ADM.06001.H.2.H to spring cereals BBCH 13-39 according to the central ~~southern~~ EU zone GAP according to surface water Step 4

PEC_{sw} (µg/L)	Scenario	STEP 4		
Nozzle reduction	Vegetative strip (m)	5m (includes 5m VFS-mod)	10	20
	No spray buffer (m)	5m	10	20
None	D1 ditch	0.249	0.249	0.249
None	D1 stream	0.207	0.207	0.207
None	D3 ditch	0.024	0.014	0.009
None	D4 pond	0.036	0.036	0.036
None	D4 stream	0.033	0.033	0.033
None	D5 pond	0.014	0.014	0.014
None	D5 stream	0.027	0.016	0.015
None	R4 stream	0.018	0.010	0.005

Metabolites of mesosulfuron-methyl

Table 8.9-12: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for AE F154851 following application to winter cereals

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	0.760	Not applicable	**	0.491

* single applications should be marked.
** twa-time as required by ecotox – not required

Table 8.9-13: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for AE F154851 following application to spring cereals

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	0.760	Not applicable	**	0.491

* single applications should be marked.
** twa-time as required by ecotox – not required

Table 8.9-14: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for AE F160459 following application to winter cereals

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	1.180	Not applicable	**	0.223

* single applications should be marked.
** twa-time as required by ecotox – not required

Table 8.9-15: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for AE F160459 following application to spring cereals

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	1.180	Not applicable	**	0.223

* single applications should be marked.
** twa-time as required by ecotox – not required

Table 8.9-16: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for AE F099095 following application to winter cereals

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	0.247	Not applicable	**	1.706

* single applications should be marked.
** twa-time as required by ecotox – not required

Table 8.9-17: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for AE F099095 following application to spring cereals

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	0.247	Not applicable	**	1.706

* single applications should be marked.
** twa-time as required by ecotox – not required

Table 8.9-18: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for AE F092944 following application to winter cereals

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	0.073	Not applicable	**	0.689

* single applications should be marked.
** twa-time as required by ecotox – not required

Table 8.9-19: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for AE F092944 following application to spring cereals

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	0.073	Not applicable	**	0.689

* single applications should be marked.
** twa-time as required by ecotox – not required

Table 8.9-20: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for AE F160460 following application to winter cereals

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	0.641	Not applicable	**	0.077

* single applications should be marked.
** twa-time as required by ecotox – not required

Table 8.9-21: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for AE F160460 following application to spring cereals

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	0.641	Not applicable	**	0.077

* single applications should be marked.
** twa-time as required by ecotox – not required

Table 8.9-22: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for AE F140584 following application to winter cereals

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	0.232	Not applicable	**	<0.001

* single applications should be marked.
** twa-time as required by ecotox – not required

Table 8.9-23: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for AE F140584 following application to spring cereals

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	0.232	Not applicable	**	<0.001

* single applications should be marked.
** twa-time as required by ecotox – not required

Table 8.9-24: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for AE F147447 following application to winter cereals

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	0.390	Not applicable	**	0.020

* single applications should be marked.
** twa-time as required by ecotox – not required

Table 8.9-25: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for AE F147447 following application to spring cereals

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	0.390	Not applicable	**	0.020

* single applications should be marked.
** twa-time as required by ecotox – not required

Table 8.9-26: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for BCS CV14885 following application to winter cereals

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	0.843	Not applicable	**	0.146
Step 2					
Northern Europe	March-May	0.176	Not applicable	**	0.031
Southern Europe	March-May	0.333	Not applicable	**	0.059

* single applications should be marked.
** twa-time as required by ecotox – not required

Table 8.9-27: FOCUS Step 3 PECsw and PECsed for BCS CV14885 following application to winter cereals BBCH 20-39

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
D1	ditch	0.057	Not applicable	**	0.033
D1	stream	0.051	Not applicable	**	0.348
D2	ditch	0.077	Not applicable	**	0.045
D2	stream	0.279	Not applicable	**	0.050
D3	ditch	0.060	Not applicable	**	0.043
D4	pond	0.123	Not applicable	**	0.086
D4	stream	0.054	Not applicable	**	0.031
D5	pond	0.099	Not applicable	**	0.071
D5	stream	0.038	Not applicable	**	0.019
D6	ditch	0.034	Not applicable	**	0.019
R1	pond	0.002	Not applicable	**	0.001
R1	stream	0.002	Not applicable	**	<0.001
R3	stream	0.014	Not applicable	**	0.001
R4	stream	<0.001	Not applicable	**	<0.001

* single applications should be marked.
** twa-time as required by ecotox – not required

Table 8.9-28: FOCUS Step 3 PEC_{sw} and PEC_{sed} for BCS CV14885 following application to winter cereals BBCH 35-39

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
D1	ditch	0.056	Not applicable	**	0.031
D1	stream	0.039	Not applicable	**	0.021
D2	ditch	0.151	Not applicable	**	0.085
D2	stream	0.414	Not applicable	**	0.066
D3	ditch	0.060	Not applicable	**	0.043
D4	pond	0.119	Not applicable	**	0.083
D4	stream	0.052	Not applicable	**	0.030
D5	pond	0.094	Not applicable	**	0.068
D5	stream	0.037	Not applicable	**	0.019
D6	ditch	0.025	Not applicable	**	0.013
R1	pond	0.002	Not applicable	**	0.001
R1	stream	0.003	Not applicable	**	<0.001
R3	stream	0.010	Not applicable	**	0.001
R4	stream	0.007	Not applicable	**	0.001

* single applications should be marked.
** twa-time as required by ecotox – not required

Table 8.9-29: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for BCS CV14885 following application to spring cereals

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	0.843	Not applicable	**	0.146
Step 2					
Northern Europe	March-May	0.176	Not applicable	**	0.031
Southern Europe	March-May	0.333	Not applicable	**	0.059

* single applications should be marked.
** twa-time as required by ecotox – not required

Table 8.9-30: FOCUS Step 3 PEC_{sw} and PEC_{sed} for BCS CV14885 following application to spring cereals BBCH 13-39

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
D1	ditch	0.006	Not applicable	**	0.003
D1	stream	0.017	Not applicable	**	0.004
D3	ditch	<0.001	Not applicable	**	<0.001
D4	pond	0.007	Not applicable	**	0.005
D4	stream	0.001	Not applicable	**	<0.001
D5	pond	0.007	Not applicable	**	0.004
D5	stream	0.001	Not applicable	**	<0.001
R4	stream	0.001	Not applicable	**	<0.001

* single applications should be marked.
** twa-time as required by ecotox – not required

Table 8.9-31: FOCUS Step 3 PEC_{sw} and PEC_{sed} for BCS CV14885 following application to spring cereals BBCH 35-39

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
D1	ditch	0.036	Not applicable	**	0.023
D1	stream	0.033	Not applicable	**	0.015
D3	ditch	0.055	Not applicable	**	0.041
D4	pond	0.097	Not applicable	**	0.068
D4	stream	0.038	Not applicable	**	0.024
D5	pond	0.084	Not applicable	**	0.061
D5	stream	0.032	Not applicable	**	0.016
R4	stream	0.011	Not applicable	**	0.001

* single applications should be marked.
** twa-time as required by ecotox – not required

Table 8.9-32: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for BCS CO60720 following application to winter cereals

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	0.436	Not applicable	**	<0.001

* single applications should be marked.
** twa-time as required by ecotox – not required

Table 8.9-33: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for BCS CO60720 following application to spring cereals

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	0.436	Not applicable	**	<0.001

* single applications should be marked.
** twa-time as required by ecotox – not required

The above PEC values for mesosulfuron-methyl and its metabolite can be used to perform the risk assessment for non-target organisms.

zRMS comments:

The input parameters used for surface water modelling for mesosulfuron-methyl and its metabolites presented in Table 8.9-3 are in line with EU agreed endpoints presented in EFSA Journal 2016;14(10):4584. At Step 3 PUF value of 0 was assumed for mesosulfuron-methyl is in line with current recommendations.

The surface water exposure was independently validated by the zRMS in additional simulations using the same EU agreed input parameters. Results obtained by the zRMS at Step 1-4 for mesosulfuron-methyl and its metabolites were in good agreement with values obtained by the Applicant.

Step 4 simulations were performed according to recommendations of the FOCUS working group on landscape and mitigation factors. An additional set of calculations was performed using VFSmod and has been retained since some Member States (e.g. Poland) accept this tool for determination of surface water exposure in run-off scenarios.

Surface water modelling at Step 4 was independently validated by the zRMS using the same EU agreed input parameters. Obtained $PEC_{SW/SED}$ values for mesosulfuron-methyl at BBCH stages were in good agreement with those obtained by the Applicant and therefore surface water exposure reported in Tables 8.9-10 and 8.9-11 may be used in the aquatic risk assessment. It was, however, noted that Step 4 calculations provided by the Applicant have not included application to cereals at later BBCH stages (BBCH 35-39), although at Step 3 this application timing resulted with higher surface water exposure in some scenarios. Therefore additional modelling was performed by the zRMS in order to determine respective RMM relevant for application at later BBCH stages. Only scenarios failing the aquatic risk assessment at Step 3 were considered. The zRMS results are presented in tables below.

PEC_{sw} (µg/L)	**Scenario**	**STEP 4**	
		winter cereals BBCH 35-39	
Nozzle reduction	Vegetative strip (m)	10	
	No spray buffer (m)	10	
None	D1 ditch	0.160	
None	D1 stream	0.103	
None	D2 ditch	2.074	
None	D2 stream	1.329	
None	R3 stream	0.066	
None	R4 stream	0.099	
		spring cereals BBCH 35-39	
Nozzle reduction	Vegetative strip (m)	10	20
	No spray buffer (m)	10	20
None	D1 ditch	0.231	0.231
None	D1 stream	0.199	0.199
None	R4 stream	0.147	0.077

Overall, the surface water exposure of mesosulfuron-methyl presented in: Tables 8.9-4 to 8.9-11, zRMS tables above, and its metabolites presented in Tables 8.9-12 to 8.9-33 may be used in the aquatic risk assessment.

Please note that additional surface water modelling may be required by the concerned Member States that do not accept simulations performed according to FOCUS recommendations.

8.9.2.2 Pinoxaden and its metabolites

Please refer to report KCP 9.2.5/02, Hicks J. (2021e) for more details on Step 1&2 calculations. For Step 3&4 calculations please refer to reports KCP 9.2.5/06, Fragkoulis G. (2022e) and KCP 9.2.5/07, Hicks J. (2022e) and KCP 9.2.5/11, Fragkoulis G. (2022h) for more details.

Table 8.9-34: Input parameters related to active substance pinoxaden and metabolites for $PEC_{sw/sed}$ calculations STEP 1/2 and 3(/4)

Compound	Pinoxaden	NOA 407854 (M2)	NOA 447204 (M3)	Value in accordance with EU endpoint y/n/ Reference
Molecular weight (g/mol)	400.5	316.4	332.4	EFSA Conclusion 3269/2013
Saturated vapour pressure (Pa)	0 (default)	Not required	Not required	EFSA Conclusion 3269/2013
Water solubility (mg/L)	200 at 25ºC	380000 at 25ºC	370 at 25ºC	EFSA Conclusion 3269/2013
Diffusion coefficient in water (m²/d)	not required for Step 1+2/4.3 x 10^{-5}			default
Diffusion coefficient in air (m²/d)	not required for Step 1+2/0.43			default
K_{foc} (mL/g)	299 (geomean, n=9)	10.6 (geomean, n=12)	32.1 (geomean, n=8)	EFSA Conclusion 3269/2013
Freundlich Exponent 1/n	1.0 (arithmetic mean, n=9)	Not required	Not required	EFSA Conclusion 3269/2013
Plant Uptake	not required for Step 1+2/ 0			EFSA Conclusion 3269/2013
Wash-Off factor from Crop (1/mm)	not required for Step 1+2/0.05 (MACRO), 0.50 (PRZM)			default
$DT_{50,soil}$ (d)	0.34 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q_{10} of 2.58, n =5)	17.1 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q_{10} of 2.58, n =5)	67.4 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q_{10} of 2.58, n =5)	EFSA Conclusion 3269/2013
$DT_{50,water}$ (d)	0.28 (geomean, n=2)	315 (geomean, n=2)	35.9 (geomean, n=2)	EFSA Conclusion 3269/2013
$DT_{50,sed}$ (d)	0.28 (Step 1-2) 1000 (default) (Step 3)	315 (geomean, n=2)	35.9 (geomean, n=2)	EFSA Conclusion 3269/2013
$DT_{50,whole\ system}$ (d)	0.28 (geomean, n=2)	315 (geomean, n=2)	35.9 (geomean, n=2)	EFSA Conclusion 3269/2013
Maximum occurrence observed (% molar basis with respect to the parent)	-	Soil: 100 Total system: 100 (worst-case)	Soil: 100 Total system: 100 (worst-case)	EFSA Conclusion 3269/2013

$PEC_{sw/sed}$

Table 8.9-35: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for pinoxaden following application of ADM.06001.H.2.B to winter cereals

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	14.851	Runoff/drainage	**	43.904
Step 2					
Northern Europe	March-May	0.552	Drift	**	0.066
Southern Europe	March-May	0.552	Drift	**	0.066

* single applications should be marked.
** twa-time as required by ecotox – not required

Table 8.9-36: FOCUS Step 3 PEC_{sw} and PEC_{sed} for pinoxaden following application of ADM.06001.H.2.B to winter cereals BBCH 20-39

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
D1	ditch	0.381	Drift	**	0.092
D1	stream	0.297	Drift	**	0.011
D2	ditch	0.383	Drift	**	0.094
D2	stream	0.317	Drift	**	0.022
D3	ditch	0.380	Drift	**	0.069
D4	pond	0.013	Drift	**	0.004
D4	stream	0.281	Drift	**	0.007
D5	pond	0.013	Drift	**	0.003
D5	stream	0.300	Drift	**	0.007
D6	ditch	0.373	Drift	**	0.045
R1	pond	0.013	Drift	**	0.003
R1	stream	0.251	Drift	**	0.024
R3	stream	0.352	Drift	**	0.042
R4	stream	0.248	Drift	**	0.020

* single applications should be marked.
** twa-time as required by ecotox – not required

Table 8.9-37: FOCUS Step 3 PEC_{sw} and PEC_{sed} for pinoxaden following application of ADM.06001.H.2.B to winter cereals BBCH 35-39

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
D1	ditch	0.384	Drift	**	0.102
D1	stream	0.328	Drift	**	0.038
D2	ditch	0.385	Drift	**	0.078
D2	stream	0.340	Drift	**	0.069
D3	ditch	0.380	Drift	**	0.055
D4	pond	0.013	Drift	**	0.004
D4	stream	0.291	Drift	**	0.009
D5	pond	0.013	Drift	**	0.003
D5	stream	0.303	Drift	**	0.008
D6	ditch	0.376	Drift	**	0.052
R1	pond	0.013	Drift	**	0.003
R1	stream	0.250	Drift	**	0.021
R3	stream	0.352	Drift	**	0.042
R4	stream	0.252	Drift	**	0.039

* single applications should be marked.
** twa-time as required by ecotox – not required

Table 8.9-38: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for pinoxaden following application of ADM.06001.H.2.B to spring cereals

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	14.851	Runoff/drainage	**	43.904
Step 2					
Northern Europe	March-May	0.552	Drift	**	0.066
Southern Europe	March-May	0.552	Drift	**	0.066

* single applications should be marked.
** twa-time as required by ecotox – not required

Table 8.9-39: FOCUS Step 3 PEC_{sw} and PEC_{sed} for pinoxaden following application of ADM.06001.H.2.B to spring cereals BBCH 13-39

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
D1	ditch	0.382	Drift	**	0.078
D1	stream	0.306	Drift	**	0.014
D3	ditch	0.380	Drift	**	0.070
D4	pond	0.013	Drift	**	0.003
D4	stream	0.311	Drift	**	0.017
D5	pond	0.013	Drift	**	0.003
D5	stream	0.302	Drift	**	0.007
R4	stream	0.250	Drift	**	0.023

* single applications should be marked.
** twa-time as required by ecotox – not required

Table 8.9-40: FOCUS Step 3 PEC_{sw} and PEC_{sed} for pinoxaden following application of ADM.06001.H.2.B to spring cereals BBCH 35-39

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
D1	ditch	0.385	Drift	**	0.075
D1	stream	0.337	Drift	**	0.061
D3	ditch	0.380	Drift	**	0.056
D4	pond	0.013	Drift	**	0.003
D4	stream	0.311	Drift	**	0.017
D5	pond	0.013	Drift	**	0.003
D5	stream	0.331	Drift	**	0.016
R4	stream	0.349	Drift	**	0.097

* single applications should be marked.
** twa-time as required by ecotox – not required

Metabolites of pinoxaden

Table 8.9-41: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for NOA 407854 (M2) following application to winter cereals

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	31.596	Not applicable	**	3.341
Step 2					
Northern Europe	March-May	3.079	Not applicable	**	0.325
Southern Europe	March-May	5.729	Not applicable	**	0.606

* single applications should be marked.
** twa-time as required by ecotox – not required

Table 8.9-42: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for NOA 407854 (M2) following application to spring cereals

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	31.596	Not applicable	**	3.341
Step 2					
Northern Europe	March-May	3.079	Not applicable	**	0.325
Southern Europe	March-May	5.729	Not applicable	**	0.606

* single applications should be marked.
** twa-time as required by ecotox – not required

Table 8.9-43: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for NOA 447204 (M3) following application to winter cereals

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	32.339	Not applicable	**	10.219
Step 2					
Northern Europe	March-May	3.470	Not applicable	**	1.090
Southern Europe	March-May	6.530	Not applicable	**	2.053

* single applications should be marked.** twa-time as required by ecotox – not required

Table 8.9-44: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for NOA 447204 (M3) following application to spring cereals

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	32.339	Not applicable	**	10.219
Step 2					
Northern Europe	March-May	3.470	Not applicable	**	1.090
Southern Europe	March-May	6.530	Not applicable	**	2.053

* single applications should be marked.
** twa-time as required by ecotox – not required

The above PEC values for pinoxaden and its metabolite can be used to perform the risk assessment for non-target organisms.

zRMS comments:

The input parameters used for surface water modelling for pinoxaden and its metabolites presented in Table 8.9-34 are in general in line with EU agreed endpoints presented in EFSA Journal 2013;11(8):3269 with following exceptions:

- For pinoxaden the geometric mean instead of the EU agreed median Kfoc value was used. This deviations is agreed by the zRMS as the geometric mean Kfoc for pinoxaden is lower than the median value and represents thus worst case in terms of the water column exposure (relevant for aquatic organisms exposed to pinoxaden). Moreover, consideration of the geometric mean Kfoc values is in line with current EFSA recommendations. The geometric mean value calculated by the Applicant was based on the EU agreed individual values and is confirmed to be correct.
- In Table 8.9-34 it was indicated that in Step 1&2 simulations for pinoxaden the sediment DT_{50} of 1000 days was considered. However, in line with EFSA Journal 2013;11(8):3269 for Step 1&2 sediment DT_{50} of 0.28 days is relevant. It seems, however, that this is a typing error in Table 8.9-34, as in the modelling report by Hicks (2021e, KCP 9.2.5/02) the correct value of 0.28 days is indicated as being used at this step of exposure assessment. Respective information has been added in Table 8.9-34.
- For pinoxaden metabolites NOA 407854 (M2) and NOA 447204 (M3) geometric Kfoc values were considered in Applicants' modelling (10.6 and 32.1 mL/g, respectively) instead of the EU agreed median values of 10.5 and 31 mg/L, respectively). Although EU agreed median values are higher than geometric mean values used in simulations, the difference is marginal and is not expected to have impact on the obtained $PEC_{SW/SED}$ values. Therefore this deviation has been agreed by the zRMS. As the difference is very small and has not impact on the PECsw results, this deviations is agreed by the zRMS. It should be also noted that consideration of the geometric mean Kfoc values is in line with current EFSA recommendations. The geometric mean values calculated by the Applicant were based on the EU agreed individual values and are confirmed to be correct.

At Step 3 PUF value of 0 was assumed for pinoxaden, in line with current recommendations.

The combination of DT_{50} for water (0.28 d) and sediment (1000 d) considered for pinoxaden at Step 3 followed approach taken during the EU review of this compound. However, during the commenting period it was pointed out

that in line with the current FOCUS kinetic guidance, also reversed combination with water DT_{50} of 1000 d and sediment DT_{50} of 0.28 d should have been simulated due to pinoxaden Kfoc being between 100 and 2000 mL/g. Nevertheless, as for sediment worst case DT_{50} was considered, while the DT_{50} considered for water column will have no impact on the initial PEC_{SW} used in the aquatic risk assessment, additional simulations were not performed.

The surface water exposure was independently validated by the zRMS in additional simulations using the EU agreed input parameters. Results obtained by the zRMS at Step 1-3 for pinoxaden and its metabolites were in good agreement with values obtained by the Applicant.

Overall, the surface water exposure for pinoxaden presented in Tables 8.9-35 to 8.9-40 and its metabolites presented in Tables 8.9-41 to 8.9-44 may be used in the aquatic risk assessment.

Please note that additional surface water modelling may be required by the concerned Member States that do not accept simulations performed according to FOCUS recommendations.

8.9.2.3 Mefenpyr-diethyl and its metabolites

Please refer to report KCP 9.2.5/03, Hicks J. (2021f) for more details on Step 1&2 calculations. For Step 3&4 calculations please refer to reports KCP 9.2.5/08, Fragkoulis G. (2022f) and KCP 9.2.5/09, Hicks J. (2022f) and KCP 9.2.5/12, Fragkoulis G. (2022i) for more details.

Table 8.9-45: Input parameters related to active substance mefenpyr-diethyl and metabolites for $PEC_{sw/sed}$ calculations STEP 1/2 and 3(/4)

Compound	Mefenpyr-diethyl	AE F113225	AE F094270	Value in accordance with EU endpoint y/n/ Reference
Molecular weight (g/mol)	373.26	345.2	271.11	Proposed in Monograph (list of endpoints) Oct 2011[a]
Saturated vapour pressure (Pa)	6.3×10^{-6} at 20ºC	Not required	Not required	Proposed in Monograph (list of endpoints) Oct 2011[a]
Water solubility (mg/L)	20 at 20ºC	14 at 20ºC	50 at 20ºC	Proposed in Monograph (list of endpoints) Oct 2011[a]
Diffusion coefficient in water (m²/d)	not required for Step 1+2/4.3×10^{-5}			default
Diffusion coefficient in air (m²/d)	not required for Step 1+2/0.43			default
K_{foc} (mL/g)	610 (geomean, n = 6)	110 (geomean, n=3)	177 (geomean, n=5)	Proposed in Monograph (list of endpoints) Oct 2011[a]
Freundlich Exponent 1/n	1.085 (arithmetic mean, n = 6)	Not required	Not required	Proposed in Monograph (list of endpoints) Oct 2011[a]
Plant Uptake	not required for Step 1+2/ 0			Proposed in Monograph (list of endpoints) Oct 2011[a]
Wash-Off factor from Crop (1/mm)	not required for Step 1+2/0.05 (MACRO), 0.50 (PRZM)			default
$DT_{50,soil}$ (d)	2.4 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q_{10} of 2.58, n =4)	6.1 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q_{10} of 2.58, n =4)	19.6 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q_{10} of 2.58, n =3)	Proposed in Monograph (list of endpoints) Oct 2011[a]

$DT_{50,water}$ (d)	1.1 (geomean, n=2)	42.5 (geomean, n=2)	109.2 (geomean, n=2)	Proposed in Monograph (list of endpoints) Oct 2011[a]
$DT_{50,sed}$ (d)	1.1 (geomean, n=2)	42.5 (geomean, n=2)	109.2 (geomean, n=2)	Proposed in Monograph (list of endpoints) Oct 2011[a]
$DT_{50,whole\ system}$ (d)	1.1 (geomean, n=2)	42.5 (geomean, n=2)	109.2 (geomean, n=2)	Proposed in Monograph (list of endpoints) Oct 2011[a]
Maximum occurrence observed (% molar basis with respect to the parent)	-	Soil: 44.1 Total system: 82.8	Soil: 72.2 ~~19.6~~ Total system: 62.4	Proposed in Monograph (list of endpoints) Oct 2011[a]
Compound	**AE F109453**	**AE F2211046**	**AE F114952**	**Value in accordance with EU endpoint y/n/** Reference
Molecular weight (g/mol)	317.13	391.26	345.18	Proposed in Monograph (list of endpoints) Oct 2011[a]
Saturated vapour pressure (Pa)	Not required	Not required	Not required	
Water solubility (mg/L)	1173	1000	563	Proposed in Monograph (list of endpoints) Oct 2011[a]
Diffusion coefficient in water (m^2/d)	not required for Step 1+2/4.3 x 10^{-5}			default
Diffusion coefficient in air (m^2/d)	not required for Step 1+2/0.43			default
K_{foc} (mL/g)	10 (default)	1320 (QSAR)	10 (default)	Proposed in Monograph (list of endpoints) Oct 2011[a]
Freundlich Exponent 1/n	Not required	Not required	Not required	
Plant Uptake	not required for Step 1+2/ 0			Proposed in Monograph (list of endpoints) Oct 2011[a]
Wash-Off factor from Crop (1/mm)	not required for Step 1+2/0.05 (MACRO), 0.50 (PRZM)			default
$DT_{50,soil}$ (d)	1000 (default)	35.5 (from soil photolysis study)	1000 (default)	Proposed in Monograph (list of endpoints) Oct 2011[a]
$DT_{50,water}$ (d)	23 (geomean, n=2)	1000 (default)	19.9 (geomean, n=2)	Proposed in Monograph (list of endpoints) Oct 2011[a]
$DT_{50,sed}$ (d)	23 (geomean, n=2)	1000 (default)	19.9 (geomean, n=2)	Proposed in Monograph (list of endpoints) Oct 2011[a]
$DT_{50,whole\ system}$ (d)	23 (geomean, n=2)	1000 (default)	19.9 (geomean, n=2)	Proposed in Monograph (list of endpoints) Oct 2011[a]
Maximum occurrence observed (% molar basis with respect to the parent)	Soil: 0.001 (default) Total system: 46.5	Soil: 11 Total system: 0.001 (default)	Soil: 11.5 Total system: 18.6	Proposed in Monograph (list of endpoints) Oct 2011[a]

$PEC_{sw/sed}$

Table 8.9-46: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for mefenpyr-diethyl following application of ADM.06001.H.2.B to winter cereals

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	6.756	Runoff/drainage	**	39.246
Step 2					
Northern Europe	March-May	0.422	Runoff/drainage	**	2.541
Southern Europe	March-May	0.827	Runoff/drainage	**	5.013

* single applications should be marked.
** twa-time as required by ecotox – not required

Table 8.9-47: FOCUS Step 3 PEC_{sw} and PEC_{sed} for mefenpyr-diethyl following application of ADM.06001.H.2.B to winter cereals BBCH 20-39

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
D1	ditch	0.222	Drift	**	0.063
D1	stream	0.173	Drift	**	0.006
D2	ditch	0.223	Drift	**	0.074
D2	stream	0.185	Drift	**	0.013
D3	ditch	0.221	Drift	**	0.047
D4	pond	0.008	Drift	**	0.003
D4	stream	0.164	Drift	**	0.004
D5	pond	0.008	Drift	**	0.002
D5	stream	0.175	Drift	**	0.004
D6	ditch	0.218	Drift	**	0.036
R1	pond	0.008	Drift	**	0.002
R1	stream	0.146	Drift	**	0.014
R3	stream	0.232	Drift	**	0.050
R4	stream	0.145	Drift	**	0.011

* single applications should be marked.
** twa-time as required by ecotox – not required

Table 8.9-48: FOCUS Step 3 PEC_{sw} and PEC_{sed} for mefenpyr-diethyl following application of ADM.06001.H.2.B to winter cereals BBCH 35-39

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
D1	ditch	0.224	Drift	**	0.084
D1	stream	0.191	Drift	**	0.022
D2	ditch	0.244	Drift	**	0.066
D2	stream	0.199	Drift	**	0.058
D3	ditch	0.222	Drift	**	0.042
D4	pond	0.008	Drift	**	0.003
D4	stream	0.170	Drift	**	0.005
D5	pond	0.008	Drift	**	0.002
D5	stream	0.177	Drift	**	0.004
D6	ditch	0.219	Drift	**	0.032
R1	pond	0.008	Drift	**	0.002
R1	stream	0.146	Drift	**	0.019
R3	stream	0.205	Drift	**	0.025
R4	stream	0.256	Drift	**	0.072

* single applications should be marked.
** twa-time as required by ecotox – not required

Table 8.9-49: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for mefenpyr-diethyl following application of ADM.06001.H.2.B to spring cereals

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	6.756	Runoff/drainage	**	39.246
Step 2					
Northern Europe	March-May	0.422	Runoff/drainage	**	2.541
Southern Europe	March-May	0.827	Runoff/drainage	**	5.013

* single applications should be marked.
** twa-time as required by ecotox – not required

Table 8.9-50: FOCUS Step 3 PEC_{sw} and PEC_{sed} for mefenpyr-diethyl following application of ADM.06001.H.2.B to spring cereals BBCH 13-39

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
D1	ditch	0.223	Drift	**	0.061
D1	stream	0.179	Drift	**	0.008
D3	ditch	0.222	Drift	**	0.047
D4	pond	0.008	Drift	**	0.002
D4	stream	0.181	Drift	**	0.010
D5	pond	0.008	Drift	**	0.002
D5	stream	0.176	Drift	**	0.004
R4	stream	0.146	Drift	**	0.013

* single applications should be marked.
** twa-time as required by ecotox – not required

Table 8.9-51: FOCUS Step 3 PEC_{sw} and PEC_{sed} for mefenpyr-diethyl following application of ADM.06001.H.2.B to spring cereals BBCH 35-39 ~~13-39~~

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
D1	ditch	0.224	Drift	**	0.062
D1	stream	0.196	Drift	**	0.042
D3	ditch	0.222	Drift	**	0.042
D4	pond	0.008	Drift	**	0.002
D4	stream	0.182	Drift	**	0.010
D5	pond	0.008	Drift	**	0.002
D5	stream	0.193	Drift	**	0.009
R4	stream	0.380	Drift	**	0.095

* single applications should be marked.
** twa-time as required by ecotox – not required

Metabolites of mefenpyr-diethyl

Table 8.9-52: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for AE F113225 following application to winter cereals

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	12.187	Not applicable	**	13.135
Step 2					
Northern Europe	March-May	1.228	Not applicable	**	1.319
Southern Europe	March-May	2.246	Not applicable	**	2.420

* single applications should be marked.
** twa-time as required by ecotox – not required

Table 8.9-53: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for AE F113225 following application to spring cereals

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	12.187	Not applicable	**	13.135
Step 2					
Northern Europe	March-May	1.228	Not applicable	**	1.319
Southern Europe	March-May	2.246	Not applicable	**	2.420

* single applications should be marked.
** twa-time as required by ecotox – not required

Table 8.9-54: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for AE F109453 following application to winter cereals

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	4.676	Not applicable	**	0.455
Step 2					
Northern Europe	March-May	0.398	Not applicable	**	0.039
Southern Europe	March-May	0.685	Not applicable	**	0.066

* single applications should be marked.
** twa-time as required by ecotox – not required

Table 8.9-55: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for AE F109453 following application to spring cereals

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	4.676	Not applicable	**	0.455
Step 2					
Northern Europe	March-May	0.398	Not applicable	**	0.039
Southern Europe	March-May	0.685	Not applicable	**	0.066

* single applications should be marked.
** twa-time as required by ecotox – not required

Table 8.9-56: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for AE F094270 following application to winter cereals

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	9.374	Not applicable	**	16.334
Step 2					
Northern Europe	March-May	1.252	Not applicable	**	2.188
Southern Europe	March-May	2.381	Not applicable	**	4.173

* single applications should be marked.
** twa-time as required by ecotox – not required

Table 8.9-57: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for AE F094270 following application to spring cereals

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	9.374	Not applicable	**	16.334
Step 2					
Northern Europe	March-May	1.252	Not applicable	**	2.188
Southern Europe	March-May	2.381	Not applicable	**	4.173

* single applications should be marked.
** twa-time as required by ecotox – not required

Table 8.9-58: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for AE F2211046 following application to winter cereals

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	0.487	Not applicable	**	6.434
Step 2					
Northern Europe	March-May	0.090	Not applicable	**	1.190
Southern Europe	March-May	0.180	Not applicable	**	2.380

* single applications should be marked.
** twa-time as required by ecotox – not required

Table 8.9-59: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for AE F2211046 following application to spring cereals

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	0.487	Not applicable	**	6.434
Step 2					
Northern Europe	March-May	0.090	Not applicable	**	1.190
Southern Europe	March-May	0.180	Not applicable	**	2.380

* single applications should be marked.
** twa-time as required by ecotox – not required

Table 8.9-60: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for AE F114952 following application to winter cereals

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	3.260	Not applicable	**	0.321
Step 2					
Northern Europe	March-May	0.417	Not applicable	**	0.040
Southern Europe	March-May	0.786	Not applicable	**	0.077

* single applications should be marked.
** twa-time as required by ecotox – not required

Table 8.9-61: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for AE F114952 following application to spring cereals

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	3.260	Not applicable	**	0.321
Step 2					
Northern Europe	March-May	0.417	Not applicable	**	0.040
Southern Europe	March-May	0.786	Not applicable	**	0.077

* single applications should be marked.
** twa-time as required by ecotox – not required

The above PEC values for mefenpyr-diethyl and its metabolite can be used to perform the risk assessment for non-target organisms.

zRMS comments:

No EU agreed data exist for the safener mefenpyr-diethyl, however in 2011 ANSES and AGES prepared Monograph (List of Endpoints) in order to aid zonal evaluations of the products containing this safener. Input parameters given in Table 8.9-45 and used in simulations are in general in line with this document with following exceptions:

- For mefenpyr-diethyl and metabolites AE F113225 and AE F094270 the geometric mean instead of the EU agreed arithmetic mean Kfoc values were used. This deviations is agreed by the zRMS as the geometric mean Kfoc values for compounds mentioned are lower than the arithmetic mean values and represents thus worst case in terms of the water column exposure (relevant for aquatic organisms exposed to mefenpyr-diethyl and its metabolites). Moreover, consideration of the geometric mean Kfoc values is in line with current EFSA recommendations. The geometric mean values calculated by the Applicant were based on the individual values reported in the Monograph (2011) and are confirmed to be correct.
- For metabolite AE F094270 the maximum occurrence in soil of 19.6% is indicated in Table 8.9-45, but according to the Monograph (2011) the peak occurrence in soil is 72.2%. It seems, however, that this is a typing error in Table 8.9-45, as in the modelling report by Hicks (2021f, KCP 9.2.5/03) the correct value of 72.2% is indicated as being used at this step of exposure assessment. Respective information has been added in Table 8.9-45.

In Step 3 simulations PUF value of 0 was assumed, in line with current recommendations.

The surface water exposure was independently validated by the zRMS in additional simulations using the input parameters taken from the Monograph (2011). Results obtained by the zRMS at Step 1-3 for mefenpyr-diethyl and its metabolites were in good agreement with values obtained by the Applicant.

Overall, the surface water exposure for mefenpyr-diethyl presented in Tables 8.9-46 to 8.9-51 and its metabolites presented in Tables 8.9-52 to 8.9-61 may be used in the aquatic risk assessment.

Please note that additional surface water modelling may be required by the concerned Member States that do not accept simulations performed according to FOCUS recommendations.

8.9.2.4 $PEC_{sw/sed}$ of ADM.06001.H.2.B

PEC_{SW} values were calculated for formulation ADM.06001.H.2.B following application to cereals, based on a standard FOCUS ditch scenario and Ganzelmeier drift values.

Table 8.9-10: PECsw values for formulation ADM.06001.H2.B following application to cereals

Buffer [m]	PECsw [µg/L]
FOCUS default	7.7899
5	2.1115
10	1.1198
16	0.7195
20	0.5818

The above PECsw values can be used to perform the risk assessment for non-target organisms.

zRMS comments:

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

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

Table 8.10-1 Summary of atmospheric degradation and behaviour of mesosulfuron-methyl and metabolites

Compound	Mesosulfuron-methyl
Direct photolysis in air	No data
Quantum yield of direct phototransformation	No data
Photochemical oxidative degradation in air	Mesosulfuron-methyl DT_{50} (h): 0.05 days derived by the Atkinson model OH (12h) concentration assumed = 1.5×10^6 OH/cm^3 AE F099095 DT_{50} (h): 0.053 days derived by the Atkinson model OH (12h) concentration assumed = 1.5×10^6 OH/cm^3 AE F092944 DT_{50} (h): 0.053 days derived by the Atkinson model OH (12h) concentration assumed = 1.5×10^6 OH/cm^3
Volatilisation	Vapour pressure (Pa): 3.5×10^{-12} at 20ºC Henry's Law Constant (Pa.m3/mol): 3.649×10^{-12} at pH7 and 20ºC
Metabolites	None

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

Table 8.10-2 Summary of atmospheric degradation and behaviour of pinoxaden

Compound	Pinoxaden
Direct photolysis in air	No data
Quantum yield of direct phototransformation	$\phi = 0.0117 \pm 0.0005$
Photochemical oxidative degradation in air	Pinoxaden DT_{50} (h): 1.1 hours derived by the Atkinson model OH (12h) concentration assumed = 1.5×10^6 OH/cm^3 M2 (NOA407854 DT_{50} (h): 1.1-1.4 hours derived by the Atkinson model OH (12h) concentration assumed = 1.5×10^6 OH/cm^3
Volatilisation	Vapour pressure (Pa): 2.0×10^{-7} at 20ºC Henry's Law Constant (Pa.m3/mol): 9.2×10^{-7} at 25ºC
Metabolites	None

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

Table 8.10-3 Summary of atmospheric degradation and behaviour of mefenpyr-diethyl

Compound	Mefenpyr-diethyl
Direct photolysis in air	No data
Quantum yield of direct phototransformation	$2.45 \times 10^{-5} – 2.53 \times 10^{-5}$
Photochemical oxidative degradation in air	DT_{50} (h): 2 days derived by the Atkinson model OH (12h) concentration assumed = 1.5×10^6 OH/cm^3
Volatilisation	Vapour pressure (Pa): 6.3×10^{-6} at 20ºC Henry's Law Constant (Pa.m3/mol): 1.18×10^{-4} at 20ºC
Metabolites	None

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

zRMS comments:

Information regarding fate and behaviour of mesosulfuron-methyl and its metabolites in the air presented in Table 8.10-1 is in line with EU agreed data reported in EFSA Journal 2016;14(10):4584 for mesosulfuron-methyl.
Taking into account the low vapour pressure ($<10^{-5}$ Pa) and DT_{50} in air <2 days, mesosulfuron-methyl is not expected to be subject to volatilisation and the long- or short-range transport.

Information regarding fate and behaviour of pinoxaden and its metabolite in the air presented in Table 8.10-2 is in line with the EU agreed data reported in EFSA Journal 2013;11(8):3269 for pinoxaden.
Taking into account the low vapour pressure ($<10^{-5}$ Pa) and DT_{50} in air <2 days, pinoxaden is not expected to be subject to volatilisation and the long- or short-range transport.

No EU agreed data exist for the safener mefenpyr-diethyl, however in 2011 ANSES and AGES prepared Monograph (List of Endpoints) in order to aid zonal evaluations of the products containing this safener. Information on fate and behaviour of mefenpyr-diethyl provided in Table 8.10-3 is in line with this document.
The DT_{50} in air of mefenpyr-diethyl was calculated to be 2 days based on the Atkinson method. It does not exceed the trigger of 2 days defined in the FOCUS Air guidance document and in conjunction with the low vapour pressure ($<10^{-5}$ Pa) indicates that mefenpyr-diethyl will not be subject to volatilisation and the long- or short-range transport.

Taking into account the above data, the contamination of the atmosphere from the intended uses of ADM.06001.H.2.B is considered to be negligible.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner	zRMS remarks
KCP 9.2.4.1/04	Fragkoulis G.	2022a	Updated Predicted Environmental Concentrations in groundwater (PECgw) following application of Mesosulfuron-methyl to winter cereals Adama Report No. 000111758 Aeiforia Report No. AEI_HELLAS_0010/2022 Aeiforia Hellas Ltd., Sandanski, Bulgaria non GLP Unpublished	N	ADAMA	
KCP 9.2.4.1/05	Hicks J.	2022a	Updated PECgroundwater Calculations for Mesosulfuron-methyl and Metabolites Following Application to Spring Cereals For Submission to Southern EU Regulatory Zone Adama Report No. 000111752 Agrexis Report No. MSU/EFA/03 Agrexis AG, Basel, Switzerland non GLP Unpublished	N	ADAMA	
KCP 9.2.4.1/08	Fragkoulis G.	2022c	Updated Predicted Environmental Concentrations in groundwater (PECgw) following application of Mefenpyr-diethyl to winter cereals Adama Report No. 000111756 Aeiforia Report No. AEI_HELLAS_0012/2022 Aeiforia Hellas Ltd., Sandanski, Bulgaria non GLP Unpublished	N	ADAMA	
KCP 9.2.4.1/09	Hicks J.	2022c	Updated PECgroundwater Calculations for Mefenpyr-diethyl and Metabolites Following Application to Spring Cereals For Submission to Southern EU Regulatory Zone Adama Report No. 000111750 Agrexis Report No. MPD/EFA/03 Agrexis AG, Basel, Switzerland non GLP Unpublished	N	ADAMA	

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	zRMS remarks
KCP 9.2.4.1/10	Fragkoulis G.	2022j	Updated Predicted Environmental Concentrations in groundwater (PECgw) following application of pinoxaden to winter and spring cereals Adama Report No. 000112243 Aeiforia Report No. AEI_HELLAS_0020/2022 Aeiforia Hellas Ltd., Sandanski, Bulgaria non GLP Unpublished	N	ADAMA	
KCP 9.2.5/01	Hicks J.	2021d	PECsurfacewater and PECsediment calculations for Mesosulfuron-methyl and Metabolites – FOCUS Steps 1, 2, 3 and 4 For Submission to Central and Southern EU Regulatory Zones Adama Report No. 000107913 Agrexis Report No. MSU/EFA/02 Agrexis AG, Basel, Switzerland non GLP Unpublished	N	ADAMA	Only Step 1&2 simulations accepted, Step 3&4 replaced by modelling report by Fragkoulis (2022d,g) and Hicks (2022d)
KCP 9.2.5/02	Hicks J.	2021e	PECsurfacewater and PECsediment calculations for Pinoxaden and Metabolites – FOCUS Steps 1, 2, 3 and 4 For Submission to Central and Southern EU Regulatory Zones Adama Report No. 000107912 Agrexis Report No. PXD/EFA/02 Agrexis AG, Basel, Switzerland non GLP Unpublished	N	ADAMA	Only Step 1&2 simulations accepted, Step 3&4 replaced by modelling report by Fragkoulis (2022e,h) and Hicks (2022e)
KCP 9.2.5/03	Hicks J.	2021f	PECsurfacewater and PECsediment calculations for Mefenpyr-diethyl and Metabolites – FOCUS Steps 1, 2, 3 and 4 For Submission to Central and Southern EU Regulatory Zones Adama Report No. 000107915 Agrexis Report No. MPR/EFA/02 Agrexis AG, Basel, Switzerland non GLP Unpublished	N	ADAMA	Only Step 1&2 simulations accepted, Step 3&4 replaced by modelling report by Fragkoulis (2022f,i) and Hicks (2022f)
KCP 9.2.5/04	Fragkoulis G.	2022d	Updated Predicted Environmental Concentrations in surface water (PECsw) following application of mesosulfuron-methyl to winter cereals Adama Report No. 000111759 Aeiforia Report No. AEI_HELLAS_0013/2022 Aeiforia Hellas Ltd., Sandanski, Bulgaria non GLP Unpublished	N	ADAMA	

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	zRMS remarks
KCP 9.2.5/05	Hicks J.	2022d	Updated PECsurfacewater and PECsediment calculations for Mesosulfuron-methyl and Metabolites Following Application to Spring Cereals – FOCUS Steps 1, 2, 3 and 4 For Submission to Southern EU Regulatory Zone Adama Report No. 000111753 Agrexis Report No. MSU/EFA/04 Agrexis AG, Basel, Switzerland non GLP Unpublished	N	ADAMA	
KCP 9.2.5/06	Fragkoulis G.	2022e	Updated Predicted Environmental Concentrations in surface water (PECsw) following application of pinoxaden to winter cereals Adama Report No. 000111761 Aeiforia Report No. AEI_HELLAS_0014/2022 Aeiforia Hellas Ltd., Sandanski, Bulgaria non GLP Unpublished	N	ADAMA	
KCP 9.2.5/07	Hicks J.	2022e	Updated PECsurfacewater and PECsediment calculations for Pinoxaden and Metabolites Following Application to Spring Cereals – FOCUS Step 3 For Submission to Southern EU Regulatory Zone Adama Report No. 000111755 Agrexis Report No. PXD/EFA/04 Agrexis AG, Basel, Switzerland non GLP Unpublished	N	ADAMA	
KCP 9.2.5/08	Fragkoulis G.	2022f	Updated Predicted Environmental Concentrations in surface water (PECsw) following application of mefenpyr-diethyl to winter cereals Adama Report No. 000111757 Aeiforia Report No. AEI_HELLAS_0015/2022 Aeiforia Hellas Ltd., Sandanski, Bulgaria non GLP Unpublished	N	ADAMA	
KCP 9.2.5/09	Hicks J.	2022f	Updated PECsurfacewater and PECsediment calculations for Mefenpyr-diethyl and Metabolites Following Application to Spring Cereals – FOCUS Step 3 For Submission to Southern EU Regulatory Zone Adama Report No. 000111751 Agrexis Report No. MPD/EFA/04 Agrexis AG, Basel, Switzerland non GLP Unpublished	N	ADAMA	

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	zRMS remarks
KCP 9.2.5/10	Fragkoulis G.	2022g	Updated Predicted Environmental Concentrations in surface water (PECsw) following application of mesosulfuron-methyl to winter and spring cereals Adama Report No. 000112245 Aeiforia Report No. AEI_HELLAS_0017/2022 Aeiforia Hellas Ltd., Sandanski, Bulgaria non GLP Unpublished	N	ADAMA	
KCP 9.2.5/11	Fragkoulis G.	2022h	Updated Predicted Environmental Concentrations in surface water (PECsw) following application of pinoxaden to winter cereals and spring cereals Adama Report No. 000112246 Aeiforia Report No. AEI_HELLAS_0018/2022 Aeiforia Hellas Ltd., Sandanski, Bulgaria non GLP Unpublished	N	ADAMA	
KCP 9.2.5/12	Fragkoulis G.	2022i	Updated Predicted Environmental Concentrations in surface water (PECsw) following application of mefenpyr-diethyl to winter cereals and spring cereals Adama Report No. 000112244 Aeiforia Report No. AEI_HELLAS_0019/2022 Aeiforia Hellas Ltd., Sandanski, Bulgaria non GLP Unpublished	N	ADAMA	

List of data referred to by the applicant and relied on, but not evaluated at EU peer review

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner	zRMS remarks
KCP 9.1.1/01	Robinson, N.	2012a	Pinoxaden - Rate of Degradation of Metabolite SYN504574 (M11) under Aerobic Laboratory Conditions, in Three Soils, at 20 °C Report Number 115 18 023. (Syngenta file No. SYN504574/10004) Innovative Environmental Services (IES) Ltd / Benkenstrasse 260, CH-4108 Witterswil/Switzerland GLP Unpublished	N	Syngenta	Studies evaluated and agreed by the RMS (AT) in the course of evaluation of the confirmatory data for pinoxaden (Addendum 1 to RAR, Vol. 3CA and CP, B.8, May 2022, not yet peer-reviewed) Applicant access via LoA from Syngenta
KCP 9.1.1/02	Völkel, W.	2012a	Pinoxaden - Rate of Degradation of Metabolite SYN546105 (M52) under Aerobic Laboratory Conditions, in Three Soils, at 20 °C Report Number 115 20 023. (Syngenta file No. SYN546105_10003) Innovative Environmental Services (IES) Ltd / Benkenstrasse 260, 4108 Witterswil, Switzerland GLP Unpublished	N	Syngenta	
KCP 9.1.1/03	Völkel, W.	2012b	Pinoxaden - Rate of Degradation of Metabolite SYN546106 (M54) under Aerobic Laboratory Conditions, in Three Soils, at 20 °C Report Number 115 19 023. (Syngenta file No. SYN546106_10004) Innovative Environmental Services (IES) Ltd / Benkenstrasse 260, 4108 Witterswil, Switzerland GLP Unpublished	N	Syngenta	
KCP 9.1.1/04	Robinson, N.	2012b	Pinoxaden - Rate of Degradation of Metabolite SYN546107 (M55) under Aerobic Laboratory Conditions, in Three Soils, at 20 °C Report Number 115 21 023. (Syngenta file No. SYN546107_10004) Innovative Environmental Services (IES) Ltd / Benkenstrasse 260, 4108 Witterswil, Switzerland GLP Unpublished	N	Syngenta	
KCP 9.1.1/05	Caviezel, A.	2013a	Pinoxaden - Rate of Degradation of Metabolite SYN546108 (M56) under Aerobic Conditions in Three Soils Report Number 20120126. (Syngenta file No. SYN546108_10004) Innovative Environmental Services (IES) Ltd / Benkenstrasse 260, 4108 Witterswil, Switzerland GLP Unpublished	N	Syngenta	
KCP 9.1.1.2.1/01	Finger N.	2016a	NOA447204 - Bare Soil Plot Soil Dissipation Study in Spain in 2014-2015 Syngenta File No A21118A_10000, report num S13-05207-FINAL Eurofins Agroscience Services GmbH, Stade, Germany, GLP Unpublished	N	Syngenta	

KCP 9.1.1.2.1/02	Finger N.	2016b	NOA447204 - Bare Soil Plot Soil Dissipation Study in Germany in 2014-2015 Syngenta File No A21118A_10002, report num S13-05211-FINAL Eurofins Agroscience Services GmbH, Stade, Germany, GLP Unpublished	N	Syngenta	
KCP 9.1.1.2.1/03	Finger N.	2016c	NOA447204 - Bare Soil Plot Soil Dissipation Study in Southern France in 2014-2015 Syngenta File No A21118A_10001, report num S13-05198-FINAL Eurofins Agroscience Services GmbH, Stade, Germany, GLP Unpublished	N	Syngenta	
KCP 9.1.1.2.1/04	Pietsch K.	2016a	NOA447204 - Field Soil Dissipation Kinetics for Persistence Endpoints Syngenta File No NOA447204_10023, report num105060-1 Dr Knoell Consult GmbH, Mannheim, Germany, Non GLP Unpublished	N	Syngenta	
KCP 9.1.1.2.1/05	Pietsch K.	2016b	NOA447204 - Field Soil Dissipation Kinetics for Modelling Endpoints Syngenta File No NOA447204_10023, report num105060-2 Dr Knoell Consult GmbH, Mannheim, Germany, Non GLP Unpublished	N	Syngenta	
KCP 9.1.2/01	Robinson N.	2012c	Pinoxaden - Adsorption/Desorption Properties of Metabolite SYN504574 (M11) in Three Soils Report Number 115 17 013. (Syngenta file No. SYN504574_10003) Innovative Environmental Services (IES) Ltd / Benkenstrasse 260, 4108 Witterswil, Switzerland GLP Unpublished	N	Syngenta	
KCP 9.1.2/02	Völkel, W.	2012c	Pinoxaden - Adsorption/Desorption properties of Metabolite SYN546105 (M52) in Three Soils Report Number 115 19 013. (Syngenta file No. SYN546105_10004) Innovative Environmental Services (IES) Ltd / Benkenstrasse 260, 4108 Witterswil, Switzerland GLP Unpublished	N	Syngenta	
KCP 9.1.2/03	Völkel, W.	2012d	Pinoxaden - Adsorption/Desorption properties of Metabolite SYN546106 (M54) in Three Soils Report Number 115 18 013 (Syngenta File No SYN546106_10003) Innovative Environmental Services (IES) Ltd / Benkenstrasse 260, 4108 Witterswil, Switzerland GLP Unpublished	N	Syngenta	
KCP 9.1.2/04	Robinson N.	2012d	Pinoxaden - Adsorption/Desorption properties of Metabolite SYN546105 (M55) in Three Soils Report Number 115 20 013. (Syngenta file No.SYN546107_10005) Innovative Environmental Services (IES) Ltd / Benkenstrasse 260, 4108 Witterswil, Switzerland GLP Unpublished	N	Syngenta	

KCP 9.1.2/05	Caviezel, A.	2013b	Pinoxaden - Adsorption/Desorption Properties of Metabolite SYN546108 (M56) in Three Soils Report Number 20120125. (Syngenta file No.SYN546108_10003) Innovative Environmental Services (IES) Ltd / Benkenstrasse 260, 4108 Witterswil, Switzerland GLP Unpublished	N	Syngenta	

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
As most of endpoints for particular active compounds were taken from the EU review, for list of respective studies, please refer to Vol. 2 of the monograph for individual substances.					

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner	Reason for rejection
KCP 9.2.4.1/01	Hicks J.	2021a	PECgroundwater Calculations for Mesosulfuron-methyl and Metabolites For Submission to Central and Southern EU Regulatory Zones Adama Report No. 000107914 Agrexis Report No. MSU/EFA/01 Agrexis AG, Basel, Switzerland non GLP Unpublished	N	ADAMA	Not agreed application dates
KCP 9.2.4.1/02	Hicks J.	2021b	PECgroundwater Calculations for Pinoxaden and Metabolites For Submission to Central and Southern EU Regulatory Zones Adama Report No. 000108000 Agrexis Report No. PXD/EFA/01 Agrexis AG, Basel, Switzerland non GLP Unpublished	N	ADAMA	Not agreed application dates

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner	Reason for rejection
KCP 9.2.4.1/03	Hicks J.	2021c	PECgroundwater Calculations for Mefenpyr-diethyl and Metabolites For Submission to Central and Southern EU Regulatory Zones Adama Report No. 000107911 Agrexis Report No. MPR/EFA/01 Agrexis AG, Basel, Switzerland non GLP Unpublished	N	ADAMA	Not agreed application dates
KCP 9.2.4.1/06	Fragkoulis G.	2022b	Updated Predicted Environmental Concentrations in groundwater (PECgw) following application of Pinoxaden to winter cereals Adama Report No. 000111760 Aeiforia Report No. AEI_HELLAS_0011/2022 Aeiforia Hellas Ltd., Sandanski, Bulgaria non GLP Unpublished	N	ADAMA	Not agreed input parameters
KCP 9.2.4.1/07	Hicks J.	2022b	Updated PECgroundwater Calculations for Pinoxaden and Metabolites Following Application to Spring Cereals For Submission to Southern EU Regulatory Zone Adama Report No. 000111754 Agrexis Report No. PXD/EFA/03 Agrexis AG, Basel, Switzerland non GLP Unpublished	N	ADAMA	Not agreed assumptions made for the Tier 2 groundwater modelling

List of data relied on not submitted by the applicant but necessary for evaluation

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
There were no data relied on and not submitted by the Applicant.					

Appendix 2 Detailed evaluation of the new Annex II studies

New reports are summaries of environmental fate modelling, please see Appendix 3.

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

A 3.1 KCP 9.2.4.1/01

Comments of zRMS:	The groundwater modelling for mesosulfuron-methyl and its metabolites presented in Hicks (2021a) was not agreed by the zRMS due to not appropriate application dates assumed in simulations. For discussion on input parameters and obtained results, please refer to point 8.8 of this document. The summary below was struck through as not agreed.

Reference:	KCP 9.2.4.1/01
Report	PECgroundwater Calculations for Mesosulfuron-methyl and Metabolites For Submission to Central and Southern EU Regulatory Zones, Hicks J., 2021a, Adama Report No. 000107914
Guideline(s):	Yes: SANCO/13144/2010 v. 3, 10 October 2014
Deviations:	Not applicable
GLP:	No: not applicable
Acceptability:	Not accepted (for details, please refer to point 8.8 of this report)

~~**Materials and methods**~~

~~Predicted environmental concentrations of mesosulfuron-methyl and metabolites were calculated in accordance with SANCO/13144/2010 v.3 using the following modelling software:~~

- ~~FOCUS PEARL version 4.4.4~~
- ~~FOCUS PELMO version 5.5.3~~
- ~~FOCUS MACRO version 5.5.4~~

~~There are 8 metabolites of Mesosulfuron-methyl which could potentially be detected in groundwater: AE F154851 (Mesosulfuron), AE F160459, AE F099095, AE F092944, AE F160460, AE F140584, AE F147447, BCS CV14885.~~

~~Input parameters were taken from EFSA Journal 2016;14(10):4584 and are presented in section 8.8.2.1 of this document.~~

~~The critical GAPs presented in section 8.1 of this document were assessed, with crop interception values in accordance with EFSA Journal 2014;12(5):3662.~~

~~The actual dates for field application differ according to the crop development in the different European regions and from year to year. For winter cereals, the sole treatment was considered to take place at 15th April in Northern Zone (attributed to the FOCUS scenario Jokioinen), at 15th March in Central Zone (attributed to the FOCUS scenarios Hamburg, Kremsmünster and Okehampton) and at 15th February in Southern Europe (attributed to the FOCUS scenarios Châteaudun, Piacenza, Porto, Sevilla and Thiva). For spring cereals, the sole application was timed to 15th June in Northern Zone (attributed to the FOCUS scenario Jokioinen), to 15th May in Central Zone (attributed to the FOCUS scenarios Hamburg, Kremsmünster and Okehampton) and to 15th April in Southern Zone (attributed to the FOCUS scenarios Châteaudun and Porto).~~

~~In compliance with the Mesosulfuron-methyl RAR Volume 3 B.8 (PPP) document, calculations for mesosulfuron-methyl and its metabolites were carried out for various pathways as follows:~~

~~1. Parent only~~
~~2. Mesosulfuron-methyl → AE F154851 + AE F160459 + AE F099095 + AEF092944~~
~~3. Mesosulfuron-methyl → AE F140584 + AE F147447~~
~~4. Mesosulfuron-methyl → BCS CV14885~~

~~For MACRO calculations only one metabolite could be modelled at a time. Separate calculations were carried out for Mesosulfuron-methyl → each metabolite. A further calculation was carried out for AE F160459 → AE F160460 with a pseudo-application rate of 1.038 g metab./ha. This was calculated with consideration of a molecular weight conversion factor of 0.972 and a maximum occurrence of 0.089.~~

~~Results and discussions~~

~~All PECgw values are presented in section 8.8.2.1 of this document.~~

~~Conclusion~~

~~All PECgw values are presented in section 8.8.2.1 of this document. Discussion of the relevance of metabolites with PECgw values above the drinking water limit is provided in this dossier document dRR Part B10.~~

A 3.2 KCP 9.2.4.1/02

Comments of zRMS:	The groundwater modelling for pinoxaden and its metabolites presented in Hicks (2021b) was not agreed by the zRMS due to not appropriate application dates assumed in simulations. For discussion on input parameters and obtained results, please refer to point 8.8 of this document. The summary below was struck through as not agreed.

Reference:	KCP 9.2.4.1/02
Report	PECgroundwater Calculations for Pinoxaden and Metabolites For Submission to Central and Southern EU Regulatory Zones, Hicks J., 2021b, Adama Report No. 000108000
Guideline(s):	Yes: SANCO/13144/2010 v. 3, 10 October 2014
Deviations:	Not applicable
GLP:	No: not applicable
Acceptability:	Not accepted (for details, please refer to point 8.8 of this report)

~~Materials and methods~~

~~Predicted environmental concentrations of pinoxaden and metabolites were calculated in accordance with SANCO/13144/2010 v.3 using the following modelling software:~~

- ~~FOCUS PEARL version 4.4.4~~
- ~~FOCUS PELMO version 5.5.3~~
- ~~FOCUS MACRO version 5.5.4~~

~~There are 3 metabolites of Pinoxaden which could potentially be detected in groundwater: NOA407854 (M2), NOA447204 (M3) and MetX. MetX is representative of a combination of metabolites identified in a lysimeter study: SYN 504574 (M11), SYN546105 (M52), SYN 546106 (M54), SYN 546107 (M55) and SYN 546108 (M56). In accordance with EFSA conclusion 3269 of 2013, metabolite MetX has been modelled in three different ways:~~

~~1. MetXa: Using a high formation fraction (ff = 1) with a short DT_{50} (5 days)~~
~~2. MetXb: Using a low formation fraction (ff = 0.05) with a long DT_{50} (1000 days)~~
~~3. MetXc: Using a medium formation fraction (ff = 0.25) with a medium DT_{50} (200 days)~~

~~Input parameters were taken from EFSA Journal 2013;11(8):3269 and are presented in section 8.8.2.2 of this document.~~

~~The critical GAPs presented in section 8.1 of this document were assessed, with crop interception values in accordance with EFSA Journal 2014;12(5):3662.~~

The actual dates for field application differ according to the crop development in the different European regions and from year to year. For winter cereals, the sole treatment was considered to take place at 15th April in Northern Zone (attributed to the FOCUS scenario Jokioinen), at 15th March in Central Zone (attributed to the FOCUS scenarios Hamburg, Kremsmünster and Okehampton) and at 15th February in Southern Europe (attributed to the FOCUS scenarios Châteaudun, Piacenza, Porto, Sevilla and Thiva). For spring cereals, the sole application was timed to 15th June in Northern Zone (attributed to the FOCUS scenario Jokioinen), to 15th May in Central Zone (attributed to the FOCUS scenarios Hamburg, Kremsmünster and Okehampton) and to 15th April in Southern Zone (attributed to the FOCUS scenarios Châteaudun and Porto).

For MACRO calculations only one metabolite could be modelled at a time. Separate calculations were carried out for Mesosulfuron methyl → NOA407854, NOA407854 → NOA447204 and NOA447204 → MetX. Pseudo application rates were calculated with consideration of a molecular weight conversion factors and a maximum occurrence percentages resulting in a pseudo application rate for NOA407854 of 47.4 g metab./ha and for NOA447204 of 60 g metab./ha.

Results and discussions

All PECgw values are presented in section 8.8.2.2 of this document.

Conclusion

All PECgw values are presented in section 8.8.2.2 of this document. Discussion of the relevance of metabolites with PECgw values above the drinking water limit is provided in this dossier document dRR Part B10.

A 3.3 KCP 9.2.4.1/03

Comments of zRMS:	The groundwater modelling for mefenpyr-diethyl and its metabolites presented in Hicks (2021c) was not agreed by the zRMS due to not appropriate application dates assumed in simulations. For discussion on input parameters and obtained results, please refer to point 8.8 of this document. The summary below was struck through as not agreed.

Reference:	KCP 9.2.4.1/03
Report	PECgroundwater Calculations for Mefenpyr-diethyl and Metabolites For Submission to Central and Southern EU Regulatory Zones, Hicks J., 2021c, Adama Report No. 000107911
Guideline(s):	Yes: SANCO/13144/2010 v. 3, 10 October 2014
Deviations:	Not applicable
GLP:	No: not applicable
Acceptability:	Not accepted (for details, please refer to point 8.8.1 of this report)

Materials and methods

Predicted environmental concentrations of mefenpyr-diethyl and metabolites were calculated in accordance with SANCO/13144/2010 v.3 using the following modelling software:

- FOCUS PEARL version 4.4.4
- FOCUS PELMO version 5.5.3
- FOCUS MACRO version 5.5.4

There are 3 metabolites of Mefenpyr-diethyl which could potentially be detected in groundwater: AE F113225, AE F094270, AE F2211046.

Input parameters were taken from Monograph list of endpoints, dated October 2011, which has been voluntarily prepared by AGES and ANSES in the context of zonal authorisation of plant protection products containing safener mefenpyr-diethyl, and are presented in section 8.8.2.3 of this document.

~~The critical GAPs presented in section 8.1 of this document were assessed, with crop interception values in accordance with EFSA Journal 2014;12(5):3662.~~

~~The actual dates for field application differ according to the crop development in the different European regions and from year to year. For winter cereals, the sole treatment was considered to take place at 15th April in Northern Zone (attributed to the FOCUS scenario Jokioinen), at 15th March in Central Zone (attributed to the FOCUS scenarios Hamburg, Kremsmünster and Okehampton) and at 15th February in Southern Europe (attributed to the FOCUS scenarios Châteaudun, Piacenza, Porto, Sevilla and Thiva). For spring cereals, the sole application was timed to 15th June in Northern Zone (attributed to the FOCUS scenario Jokioinen), to 15th May in Central Zone (attributed to the FOCUS scenarios Hamburg, Kremsmünster and Okehampton) and to 15th April in Southern Zone (attributed to the FOCUS scenarios Châteaudun and Porto).~~

~~PECgw calculations for metabolite AE F2211046 were calculated as if AE F2211046 was the parent molecule. A pseudo-application rate was calculated considering relative molecular weights, the application rate of mefenpyr diethyl and the maximum occurrence of AE F221046 of 11.5%. The resultant pseudo-application rate was 4.2 g met./ha.~~

~~MACRO PECgw calculations for metabolite AE F064270 were calculated as if metabolite AE F113225 was the parent molecule. A pseudo-application rate was calculated considering relative molecular weights, the application rate of mefenpyr diethyl and the maximum occurrence of AE F113225 of 44.1%. The resultant pseudo-application rate was 14.3 g met./ha.~~

~~Results and discussions~~

~~All PECgw values are presented in section 8.8.2.3 of this document.~~

~~Conclusion~~

~~All PECgw values are presented in section 8.8.2.3 of this document. Discussion of the relevance of metabolites with PECgw values above the drinking water limit is provided in this dossier document dRR Part B10.~~

A 3.4 KCP 9.2.4.1/04

Comments of zRMS:	The groundwater modelling for mesosulfuron-methyl and its metabolites presented in Fragkoulis (2022a) was accepted by the zRMS. For discussion on input parameters and obtained results, please refer to point 8.8 of this document.

Reference:	KCP 9.2.4.1/04
Report	Updated Predicted Environmental Concentrations in groundwater (PECgw) following application of Mesosulfuron-methyl to winter cereals, Fragkoulis G., 2022a, Adama Report No. 000111758
Guideline(s):	Yes: SANCO/13144/2010 v. 3, 10 October 2014
Deviations:	Not applicable
GLP:	No: not applicable
Acceptability:	Acceptable

Materials and methods

Predicted environmental concentrations of mesosulfuron-methyl and metabolites were calculated in accordance with SANCO/13144/2010 v.3 using the following modelling software:

- FOCUS PEARL version 4.4.4
- FOCUS PELMO version 5.5.3
- FOCUS MACRO version 5.5.4

There are 8 metabolites of Mesosulfuron-methyl which could potentially be detected in groundwater: AE F154851 (Mesosulfuron), AE F160459, AE F099095, AE F092944, AE F160460, AE F140584, AE F147447, BCS CV14885.

Input parameters were taken from EFSA Journal 2016;14(10):4584 and are presented in section 8.8.2.1 of this document. Following assessment of the dRR by RMS Malta, further calculations were requested using updated geometric mean Koc values for metabolites AE F092944 and AE F099095 and revised application dates dates. Two winter cereal uses were considered. The application dates for use 1, with application at BBCH 13-20, were determined with consideration of the soil moisture requirements and harvest times of previous crops in Maritime and Mediterranean climatic zones. The application dates for use 2, with application at BBCH 20-39, were determined using AppDate v.3.06.

The critical GAPs presented in section 8.1 of this document were assessed, with crop interception values in accordance with EFSA Journal 2014;12(5):3662. Due to time constraints the GAP was divided into winter and spring cereals. The calculations for the two different crops were carried out by two different people and presented in separate reports. This report contains calculations for winter cereals.

In compliance with the Mesosulfuron-methyl RAR Volume 3 B.8 (PPP) document, calculations for mesosulfuron-methyl and its metabolites were carried out for various pathways as follows:

1. Parent only
2. Mesosulfuron-methyl → AE F154851 + AE F160459 + AE F099095 + AEF092944
3. Mesosulfuron-methyl → AE F140584 + AE F147447
4. Mesosulfuron-methyl → BCS CV14885

For MACRO calculations only one metabolite could be modelled at a time. Separate calculations were carried out for Mesosulfuron-methyl → each metabolite. A further calculation was carried out for AE F160459 → AE F160460 with a pseudo-application rate of 1.038 g metab./ha. This was calculated with consideration of a molecular weight conversion factor of 0.972 and a maximum occurrence of 0.089.

Results and discussions

All PECgw values are presented in section 8.8.2.1 of this document.

Conclusion

All PECgw values are presented in section 8.8.2.1 of this document. Discussion of the relevance of metabolites with PECgw values above the drinking water limit is provided in this dossier document dRR Part B10.

A 3.5 KCP 9.2.4.1/05

Comments of zRMS:	The groundwater modelling for mesosulfuron-methyl and its metabolites presented in Hicks (2022a) was accepted by the zRMS. For discussion on input parameters and obtained results, please refer to point 8.8 of this document.

Reference:	KCP 9.2.4.1/05
Report	Updated PECgroundwater Calculations for Mesosulfuron-methyl and Metabolites Following Application to Spring Cereals For Submission to Southern EU Regulatory Zone. Hicks J., 2022a, Adama Report No. 000111752
Guideline(s):	Yes: SANCO/13144/2010 v. 3, 10 October 2014
Deviations:	Not applicable
GLP:	No: not applicable
Acceptability:	Acceptable

Materials and methods

Predicted environmental concentrations of mesosulfuron-methyl and metabolites were calculated in accordance with SANCO/13144/2010 v.3 using the following modelling software:

- FOCUS PEARL version 4.4.4
- FOCUS PELMO version 5.5.3
- FOCUS MACRO version 5.5.4

There are 8 metabolites of Mesosulfuron-methyl which could potentially be detected in groundwater: AE F154851 (Mesosulfuron), AE F160459, AE F099095, AE F092944, AE F160460, AE F140584, AE F147447, BCS CV14885.

Input parameters were taken from EFSA Journal 2016;14(10):4584 and are presented in section 8.8.2.1 of this document. Following assessment of the dRR by RMS Malta, further calculations were requested using updated geometric mean Koc values for metabolites AE F092944 and AE F099095 and revised application dates determined using AppDate.

The critical GAPs presented in section 8.1 of this document were assessed, with crop interception values in accordance with EFSA Journal 2014;12(5):3662. Due to time constraints the GAP was divided into winter and spring cereals. The calculations for the two different crops were carried out by two different people and presented in separate reports. This report contains calculations for spring cereals.

In compliance with the Mesosulfuron-methyl RAR Volume 3 B.8 (PPP) document, calculations for mesosulfuron-methyl and its metabolites were carried out for various pathways as follows:

1. Parent only

2. Mesosulfuron-methyl → AE F154851 + AE F160459 + AE F099095 + AEF092944

3. Mesosulfuron-methyl → AE F140584 + AE F147447

4. Mesosulfuron-methyl → BCS CV14885

For MACRO calculations only one metabolite could be modelled at a time. Separate calculations were carried out for Mesosulfuron-methyl → each metabolite. A further calculation was carried out for AE F160459 → AE F160460 with a pseudo-application rate of 1.038 g metab./ha. This was calculated with consideration of a molecular weight conversion factor of 0.972 and a maximum occurrence of 0.089.

Results and discussions

All PECgw values are presented in section 8.8.2.1 of this document.

Conclusion

All PECgw values are presented in section 8.8.2.1 of this document. Discussion of the relevance of metabolites with PECgw values above the drinking water limit is provided in this dossier document dRR Part B10.

A 3.6 KCP 9.2.4.1/06

Comments of zRMS:	The Tier 2 groundwater modelling for pinoxaden and metabolites presented in Fragkoulis (2022b) was based on input parameters not agreed by the zRMS. In consequence, the modelling was not accepted and the summary below is struck through. For discussion on input parameters and obtained results, please refer to point 8.8 of this document.

Reference:	KCP 9.2.4.1/06
Report	Updated Predicted Environmental Concentrations in groundwater (PECgw) following application of Pinoxaden to winter cereals, Fragkoulis G., 2022b, Adama Report No. 000111760
Guideline(s):	Yes: SANCO/13144/2010 v. 3, 10 October 2014
Deviations:	Not applicable
GLP:	No: not applicable
Acceptability:	Not accepted (for details, please refer to point 8.8 of this report)

~~**Materials and methods**~~

~~Predicted environmental concentrations of pinoxaden and metabolites were calculated in accordance with SANCO/13144/2010 v.3 using the following modelling software:~~

- ~~FOCUS PEARL version 4.4.4~~
- ~~FOCUS PELMO version 5.5.3~~
- ~~FOCUS MACRO version 5.5.4~~

~~There are 3 metabolites of Pinoxaden which could potentially be detected in groundwater: NOA407854 (M2), NOA447204 (M3) and MetX. MetX is representative of a combination of metabolites identified in a lysimeter study: SYN 504574 (M11), SYN546105 (M52), SYN 546106 (M54), SYN 546107 (M55) and SYN 546108 (M56). In accordance with EFSA conclusion 3269 of 2013, metabolite MetX has been modelled in three different ways:~~

~~1. MetXa: Using a high formation fraction (ff = 1) with a short DT_{50} (5 days)~~

~~2. MetXb: Using a low formation fraction (ff = 0.05) with a long DT_{50} (1000 days)~~

~~3. MetXc: Using a medium formation fraction (ff = 0.25) with a medium DT_{50} (200 days)~~

~~Input parameters were taken from EFSA Journal 2013;11(8):3269 and are presented in section 8.8.2.2 of this document. Following assessment of the dRR by RMS Malta, further calculations were requested using revised application dates. Two winter cereal uses were considered. The application dates for use 1, with application at BBCH 13-20, were determined with consideration of the soil moisture requirements and harvest times of previous crops in Maritime and Mediterranean climatic zones. The application dates for use 2, with application at BBCH 20-39, were determined using AppDate v.3.06.~~

~~The critical GAPs presented in section 8.1 of this document were assessed, with crop interception values in accordance with EFSA Journal 2014;12(5):3662. Due to time constraints the GAP was divided into winter and spring cereals. The calculations for the two different crops were carried out by two different people and presented in separate reports. This report contains calculations for winter cereals.~~

~~For MACRO calculations only one metabolite could be modelled at a time. Separate calculations were carried out for Mesosulfuron methyl → NOA407854, NOA407854 → NOA447204 and NOA447204 → MetX. Pseudo-application rates were calculated with consideration of a molecular weight conversion factors and a maximum occurrence percentages resulting in a pseudo application rate for NOA407854 of 47.4 g metab./ha and for NOA447204 of 60 g metab./ha.~~

Results and discussions

All PECgw values are presented in section 8.8.2.2 of this document.

Conclusion

All PECgw values are presented in section 8.8.2.2 of this document. Discussion of the relevance of metabolites with PECgw values above the drinking water limit is provided in this dossier document dRR Part B10.

A 3.7 KCP 9.2.4.1/07

Comments of zRMS:	The Tier 2 groundwater modelling for pinoxaden and metabolites presented in Hicks (2022b) was based on assumptions not agreed by the zRMS. In consequence, the modelling was not accepted and the summary below is struck through. For discussion on input parameters and obtained results, please refer to point 8.8 of this document.

Reference:	KCP 9.2.4.1/07
Report	Updated PECgroundwater Calculations for Pinoxaden and Metabolites Following Application to Spring Cereals For Submission to Southern EU Regulatory Zone. Hicks J., 2022b, Adama Report No. 000111754
Guideline(s):	Yes: SANCO/13144/2010 v. 3, 10 October 2014
Deviations:	Not applicable
GLP:	No: not applicable
Acceptability:	Not accepted (for details, please refer to point 8.8 of this report)

Materials and methods

Predicted environmental concentrations of pinoxaden and metabolites were calculated in accordance with SANCO/13144/2010 v.3 using the following modelling software:

- FOCUS PEARL version 4.4.4
- FOCUS PELMO version 5.5.3
- FOCUS MACRO version 5.5.4

There are 3 metabolites of Pinoxaden which could potentially be detected in groundwater: NOA407854 (M2), NOA447204 (M3) and MetX. MetX is representative of a combination of metabolites identified in a lysimeter study: SYN 504574 (M11), SYN546105 (M52), SYN 546106 (M54), SYN 546107 (M55) and SYN 546108 (M56). In accordance with EFSA conclusion 3269 of 2013, metabolite MetX has been modelled in three different ways:

1. MetXa: Using a high formation fraction (ff = 1) with a short DT_{50} (5 days)

2. MetXb: Using a low formation fraction (ff = 0.05) with a long DT_{50} (1000 days)

3. MetXc: Using a medium formation fraction (ff = 0.25) with a medium DT_{50} (200 days)

Input parameters were taken from EFSA Journal 2013;11(8):3269 and are presented in section 8.8.2.2 of this document. Following assessment of the dRR by RMS Malta, further calculations were requested using revised application dates determined using AppDate.

The critical GAPs presented in section 8.1 of this document were assessed, with crop interception values in accordance with EFSA Journal 2014;12(5):3662. Due to time constraints the GAP was divided into winter and spring cereals. The calculations for the two different crops were carried out by two different people and presented in separate reports. This report contains calculations for spring cereals.

~~For MACRO calculations only one metabolite could be modelled at a time. Separate calculations were carried out for Mesosulfuron-methyl → NOA407854, NOA407854 → NOA447204 and NOA447204 → MetX. Pseudo-application rates were calculated with consideration of a molecular weight conversion factors and a maximum occurrence percentages resulting in a pseudo application rate for NOA407854 of 47.4 g metab./ha and for NOA447204 of 60 g metab./ha.~~

~~**Results and discussions**~~

~~All PECgw values are presented in section 8.8.2.2 of this document.~~

~~**Conclusion**~~

~~All PECgw values are presented in section 8.8.2.2 of this document. Discussion of the relevance of metabolites with PECgw values above the drinking water limit is provided in this dossier document dRR Part B10.~~

A 3.8 KCP 9.2.4.1/08

Comments of zRMS:	The groundwater modelling for mefenpyr-diethyl and its metabolites presented in Fragkoulis (2022c) was accepted by the zRMS. For discussion on input parameters and obtained results, please refer to point 8.8 of this document.

Reference:	KCP 9.2.4.1/08
Report	Updated Predicted Environmental Concentrations in groundwater (PECgw) following application of Mefenpyr-diethyl to winter cereals, Fragkoulis G., 2022c, Adama Report No. 000111756
Guideline(s):	Yes: SANCO/13144/2010 v. 3, 10 October 2014
Deviations:	Not applicable
GLP:	No: not applicable
Acceptability:	Acceptable

Materials and methods

Predicted environmental concentrations of mefenpyr-diethyl and metabolites were calculated in accordance with SANCO/13144/2010 v.3 using the following modelling software:

- FOCUS PEARL version 4.4.4
- FOCUS PELMO version 5.5.3
- FOCUS MACRO version 5.5.4

There are 3 metabolites of Mefenpyr-diethyl which could potentially be detected in groundwater: AE F113225, AE F094270, AE F2211046.

Input parameters were taken from Monograph list of endpoints, dated October 2011, which has been voluntarily prepared by AGES and ANSES in the context of zonal authorisation of plant protection products containing safener mefenpyr-diethyl, and are presented in section 8.8.2.3 of this document. Following assessment of the dRR by RMS Malta, further calculations were requested using revised application dates. Two winter cereal uses were considered. The application dates for use 1, with application at BBCH 13-20, were determined with consideration of the soil moisture requirements and harvest times of previous crops in Maritime and Mediterranean climatic zones. The application dates for use 2, with application at BBCH 20-39, were determined using AppDate v.3.06.

The critical GAPs presented in section 8.1 of this document were assessed, with crop interception values in accordance with EFSA Journal 2014;12(5):3662. Due to time constraints the GAP was divided into winter and spring cereals. The calculations for the two different crops were carried out by two different people and presented in separate reports. This report contains calculations for winter cereals.

PECgw calculations for metabolite AE F2211046 were calculated as if AE F2211046 was the parent molecule. A pseudo-application rate was calculated considering relative molecular weights, the application rate of mefenpyr-diethyl and the maximum occurrence of AE F221046 of 11.5%. The resultant pseudo-application rate was 4.2 g met./ha.

MACRO PECgw calculations for metabolite AE F064270 were calculated as if metabolite AE F113225 was the parent molecule. A pseudo-application rate was calculated considering relative molecular weights, the application rate of mefenpyr-diethyl and the maximum occurrence of AE F113225 of 44.1%. The resultant pseudo-application rate was 14.3 g met./ha.

Results and discussions

All PECgw values are presented in section 8.8.2.3 of this document.

Conclusion

All PECgw values are presented in section 8.8.2.3 of this document. Discussion of the relevance of metabolites with PECgw values above the drinking water limit is provided in this dossier document dRR Part B10.

A 3.9 KCP 9.2.4.1/09

Comments of zRMS:	The groundwater modelling for mefenpyr-diethyl and its metabolites presented in Hicks (2022c) was accepted by the zRMS. For discussion on input parameters and obtained results, please refer to point 8.8 of this document.

Reference:	KCP 9.2.4.1/09
Report	Updated PECgroundwater Calculations for Mefenpyr-diethyl and Metabolites Following Application to Spring Cereals For Submission to Southern EU Regulatory Zone. Hicks J., 2022c, Adama Report No. 000111750
Guideline(s):	Yes: SANCO/13144/2010 v. 3, 10 October 2014
Deviations:	Not applicable
GLP:	No: not applicable
Acceptability:	Acceptable

Materials and methods

Predicted environmental concentrations of mefenpyr-diethyl and metabolites were calculated in accordance with SANCO/13144/2010 v.3 using the following modelling software:

- FOCUS PEARL version 4.4.4
- FOCUS PELMO version 5.5.3
- FOCUS MACRO version 5.5.4

There are 3 metabolites of Mefenpyr-diethyl which could potentially be detected in groundwater: AE F113225, AE F094270, AE F2211046.

Input parameters were taken from Monograph list of endpoints, dated October 2011, which has been voluntarily prepared by AGES and ANSES in the context of zonal authorisation of plant protection products containing safener mefenpyr-diethyl, and are presented in section 8.8.2.3 of this document. Following assessment of the dRR by RMS Malta, further calculations were requested using revised application dates determined using AppDate.

The critical GAPs presented in section 8.1 of this document were assessed, with crop interception values in accordance with EFSA Journal 2014;12(5):3662. Due to time constraints the GAP was divided into winter and spring cereals. The calculations for the two different crops were carried out by two different people and presented in separate reports. This report contains calculations for spring cereals.

PECgw calculations for metabolite AE F2211046 were calculated as if AE F2211046 was the parent molecule. A pseudo-application rate was calculated considering relative molecular weights, the application rate of mefenpyr-diethyl and the maximum occurrence of AE F221046 of 11.5%. The resultant pseudo-application rate was 4.2 g met./ha.

MACRO PECgw calculations for metabolite AE F064270 were calculated as if metabolite AE F113225 was the parent molecule. A pseudo-application rate was calculated considering relative molecular weights, the application rate of mefenpyr-diethyl and the maximum occurrence of AE F113225 of 44.1%. The resultant pseudo-application rate was 14.3 g met./ha.

Results and discussions

All PECgw values are presented in section 8.8.2.3 of this document.

Conclusion

All PECgw values are presented in section 8.8.2.3 of this document. Discussion of the relevance of metabolites with PECgw values above the drinking water limit is provided in this dossier document dRR Part B10.

A 3.10 KCP 9.2.4.1/10

Comments of zRMS:	The Tier 1 groundwater modelling for pinoxaden and its metabolites presented in Fragkoulis (2022j) was accepted by the zRMS. For discussion on input parameters and obtained results, please refer to point 8.8 of this document.

Reference:	KCP 9.2.4.1/10
Report	Updated Predicted Environmental Concentrations in groundwater (PECgw) following application of Pinoxaden to winter and spring cereals, Fragkoulis G., 2022j, Adama Report No. 000112243
Guideline(s):	Yes: SANCO/13144/2010 v. 3, 10 October 2014
Deviations:	Not applicable
GLP:	No: not applicable
Acceptability:	Acceptable

Materials and methods

Predicted environmental concentrations of pinoxaden and metabolites were calculated in accordance with SANCO/13144/2010 v.3 using the following modelling software:

- FOCUS PEARL version 4.4.4
- FOCUS PELMO version 5.5.3
- FOCUS MACRO version 5.5.4

There are 3 metabolites of Pinoxaden which could potentially be detected in groundwater: NOA407854 (M2), NOA447204 (M3) and MetX. MetX is representative of a combination of metabolites identified in a lysimeter study: SYN 504574 (M11), SYN546105 (M52), SYN 546106 (M54), SYN 546107 (M55) and SYN 546108 (M56). In accordance with EFSA conclusion 3269 of 2013, metabolite MetX has been modelled in three different ways:

1. MetXa: Using a high formation fraction (ff = 1) with a short DT_{50} (5 days)

2. MetXb: Using a low formation fraction (ff = 0.05) with a long DT_{50} (1000 days)

3. MetXc: Using a medium formation fraction (ff = 0.25) with a medium DT_{50} (200 days)

Input parameters were taken from EFSA Journal 2013;11(8):3269 and are presented in section 8.8.2.2 of this document. Following assessment of the dRR by RMS Poland, further calculations were requested

using revised application dates, determined using AppDate v.3.06. Furthermore, it was requested that only "tier 1" values from EFSA Journal 2013;11(8):3269 and no updated values should be included.

The critical GAPs presented in section 8.1 of this document were assessed, with crop interception values in accordance with EFSA Journal 2014;12(5):3662.

For MACRO calculations only one metabolite could be modelled at a time. Separate calculations were carried out for Mesosulfuron-methyl → NOA407854, NOA407854 → NOA447204 and NOA447204 → MetX. Pseudo-application rates were calculated with consideration of a molecular weight conversion factors and a maximum occurrence percentages resulting in the following pseudo-application rates:

Degradation pathway	**Pseudo application rate Winter cereals (g met./ha)**	**Pseudo application rate Spring cereals (g met./ha) Use 2**
NOA407854 → NOA447204	37.92	47.40
NOA447204 → MetX	50.43	63.03

Results and discussions

All PECgw values are presented in section 8.8.2.2 of this document.

Conclusion

All PECgw values are presented in section 8.8.2.2 of this document. Discussion of the relevance of metabolites with PECgw values above the drinking water limit is provided in this dossier document dRR Part B10.

A 3.11 KCP 9.2.5/01

Comments of zRMS:	The Step 1&2 surface water modelling for mesosulfuron-methyl and its metabolites presented in Hicks (2021d) was accepted by the zRMS while this performed at Step 3 and 4 was not agreed due to not correct application windows assumed for the modelled uses in winter and spring cereals. Parts of the summary referring to Step 3&4 simulations were struck through as not agreed. For discussion on input parameters and obtained results, please refer to point 8.9 of this document.

Reference:	KCP 9.2.5/01
Report	PECsurfacewater and PECsediment calculations for Mesosulfuron-methyl and Metabolites – FOCUS Steps 1, 2, 3 and 4 For Submission to Central and Southern EU Regulatory Zones, Hicks J., 2021d, Adama Report No. 000107913
Guideline(s):	Yes: Generic guidance for FOCUS surface water Scenarios v. 1.4, May 2015
Deviations:	No
GLP:	No: not applicable
Acceptability:	Partially accepted (for details, please refer to point 8.9 of this report)

Materials and methods

Predicted environmental concentrations of mesosulfuron-methyl and its metabolites were calculated in accordance with Generic guidance for FOCUS surface water Scenarios v. 1.4 using the following modelling software:

- FOCUS steps 1 and 2 version 3.2
- ~~FOCUS SWASH version 5.3~~
- ~~FOCUS MACRO version 5.5.4~~
- ~~FOCUS PRZM version 4.3.1~~
- ~~FOCUS TOXSWA version 4.4.3~~

- SWAN version 5.0.0

There are 9 metabolites of Mesosulfuron-methyl which could potentially be detected in surface water and sediment: AE F154851 (Mesosulfuron), AE F160459, AE F099095, AE F092944, AE F160460, AE F140584, AE F147447, BCS CV14885 and BCS-CO60720.

Input parameters were taken from EFSA Journal 2016;14(10):4584 and are presented in section 8.9.2.1 of this document.

The critical GAPs presented in section 8.1 of this document were assessed, with crop interception values in accordance with EFSA Journal 2014;12(5):3662.

For Step 1 and 2 calculations the regions "North Europe" and "South Europe" and minimal crop cover was considered. The application period "Mar – May" was selected based on the earliest possible application date.

For Step 3 calculations the actual dates for field application differ according to the crop development in the different European regions and from year to year. For winter cereals, the sole treatment was considered to take place at 15th April in Northern Zone (attributed to the FOCUS scenarios D1 and D4), at 15th March in Central Zone (attributed to the FOCUS scenarios D2, D3 and R1) and at 15th February in Southern Europe (attributed to the FOCUS scenarios D5, D6, R3 and R4). For spring cereals, the sole application was timed to 15th June in Northern Zone (attributed to the FOCUS scenarios D1 and D4), to 15th May in Central Zone (attributed to the FOCUS scenario D3) and to 15th April in Southern Zone (attributed to the FOCUS scenarios D5 and R4).

In the SWASH shell the application method was set to "ground spray", describing a spray application. The CAM (chemical application method) was set to 2 (appln foliar linear) for the R scenarios.

Results and discussions

All PECsw/sed values are presented in section 8.9.2.1 of this document.

Conclusion

The PECsw and PECsed calculations were considered acceptable and used in the aquatic risk assessment.

A 3.12 KCP 9.2.5/02

Comments of zRMS:	The Step 1&2 surface water modelling for pinoxaden and its metabolites presented in Hicks (2021e) was accepted by the zRMS while this performed at Step 3 and 4 was not agreed due to not correct application windows assumed for the modelled uses in winter and spring cereals. Parts of the summary referring to Step 3&4 simulations were struck through as not agreed. For discussion on input parameters and obtained results, please refer to point 8.9 of this document.

Reference:	KCP 9.2.5/02
Report	PECsurfacewater and PECsediment Calculations for Pinoxaden and Metabolites – FOCUS Steps 1, 2, 3 and 4 For Submission to Central and Southern EU Regulatory Zones, Hicks J., 2021e, Adama Report No. 000107912
Guideline(s):	Yes: Generic guidance for FOCUS surface water Scenarios v. 1.4, May 2015
Deviations:	No
GLP:	No: not applicable
Acceptability:	Partially accepted (for details, please refer to point 8.9 of this report)

Materials and methods

Predicted environmental concentrations of pinoxaden and its metabolites were calculated in accordance with Generic guidance for FOCUS surface water Scenarios v. 1.4 using the following modelling software:

- FOCUS steps 1 and 2 version 3.2
- ~~FOCUS SWASH version 5.3~~
- ~~FOCUS MACRO version 5.5.4~~
- ~~FOCUS PRZM version 4.3.1~~
- ~~FOCUS TOXSWA version 4.4.3~~
- ~~SWAN version 5.0.0~~

There are 2 metabolites of Pinoxaden which could potentially be detected in surface water and sediment: NOA407854 (M2) and NOA447204 (M3).

Input parameters were taken from EFSA Journal 2013;11(8):3269and are presented in section 8.9.2.2 of this document.

The critical GAPs presented in section 8.1 of this document were assessed, with crop interception values in accordance with EFSA Journal 2014;12(5):3662.

For Step 1 and 2 calculations the regions “North Europe” and “South Europe” and minimal crop cover was considered. The application period “Mar – May” was selected based on the earliest possible application date.

~~For Step 3 calculations the actual dates for field application differ according to the crop development in the different European regions and from year to year. For winter cereals, the sole treatment was considered to take place at 15th April in Northern Zone (attributed to the FOCUS scenarios D1 and D4), at 15th March in Central Zone (attributed to the FOCUS scenarios D2, D3 and R1) and at 15th February in Southern Europe (attributed to the FOCUS scenarios D5, D6, R3 and R4). For spring cereals, the sole application was timed to 15th June in Northern Zone (attributed to the FOCUS scenarios D1 and D4), to 15th May in Central Zone (attributed to the FOCUS scenario D3) and to 15th April in Southern Zone (attributed to the FOCUS scenarios D5 and R4).~~

~~In the SWASH shell the application method was set to “ground spray”, describing a spray application. The CAM (chemical application method) was set to 2 (appln foliar linear) for the R scenarios.~~

Results and discussions

All PECsw/sed values are presented in section 8.9.2.2 of this document.

Conclusion

The PECsw and PECsed calculations were considered acceptable and used in the aquatic risk assessment.

A 3.13 KCP 9.2.5/03

Comments of zRMS:	The Step 1&2 surface water modelling for mefenpyr-diethyl and its metabolites presented in Hicks (2021f) was accepted by the zRMS while this performed at Step 3 and 4 was not agreed due to not correct application windows assumed for the modelled uses in winter and spring cereals. Parts of the summary referring to Step 3&4 simulations were struck through as not agreed. For discussion on input parameters and obtained results, please refer to point 8.9 of this document.

Reference:	KCP 9.2.5/03
Report	Mefenpyr-diethyl and Metabolites – FOCUS Steps 1, 2, 3 and 4 For Submission to Central

	and Southern EU Regulatory Zones, Hicks J., 2021f, Adama Report No. 000107915
Guideline(s):	Yes: Generic guidance for FOCUS surface water Scenarios v. 1.4, May 2015
Deviations:	No
GLP:	No: not applicable
Acceptability:	Partially accepted (for details, please refer to point 8.9 of this report)

Materials and methods

Predicted environmental concentrations of mefenpyr-diethyl and its metabolites were calculated in accordance with Generic guidance for FOCUS surface water Scenarios v. 1.4 using the following modelling software:

- FOCUS steps 1 and 2 version 3.2
- ~~FOCUS SWASH version 5.3~~
- ~~FOCUS MACRO version 5.5.4~~
- ~~FOCUS PRZM version 4.3.1~~
- ~~FOCUS TOXSWA version 4.4.3~~
- ~~SWAN version 5.0.0~~

There are 5 metabolites of Mefenpyr-diethyl which could potentially be detected in surface water and sediment: AE F113225, AE F109453, AE F094270, AE F2211046 and AE F114952.

Input parameters were taken from Monograph list of endpoints, dated October 2011, which has been voluntarily prepared by AGES and ANSES in the context of zonal authorisation of plant protection products containing safener mefenpyr-diethyl, and are presented in section 8.9.2.3 of this document.

The critical GAPs presented in section 8.1 of this document were assessed, with crop interception values in accordance with EFSA Journal 2014;12(5):3662.

For Step 1 and 2 calculations the regions “North Europe” and “South Europe” and minimal crop cover was considered. The application period “Mar – May” was selected based on the earliest possible application date.

~~For Step 3 calculations the actual dates for field application differ according to the crop development in the different European regions and from year to year. For winter cereals, the sole treatment was considered to take place at 15th April in Northern Zone (attributed to the FOCUS scenarios D1 and D4), at 15th March in Central Zone (attributed to the FOCUS scenarios D2, D3 and R1) and at 15th February in Southern Europe (attributed to the FOCUS scenarios D5, D6, R3 and R4). For spring cereals, the sole application was timed to 15th June in Northern Zone (attributed to the FOCUS scenarios D1 and D4), to 15th May in Central Zone (attributed to the FOCUS scenario D3) and to 15th April in Southern Zone (attributed to the FOCUS scenarios D5 and R4).~~

~~In the SWASH shell the application method was set to “ground spray”, describing a spray application. The CAM (chemical application method) was set to 2 (appln foliar linear) for the R scenarios.~~

Results and discussions

All PECsw/sed values are presented in section 8.9.2.3 of this document.

Conclusion

The PECsw and PECsed calculations were considered acceptable and used in the aquatic risk assessment.

A 3.14 KCP 9.2.5/04

Comments of zRMS:	The surface water modelling for mesosulfuron-methyl and its metabolites presented in Fragkoulis (2022d) was agreed by the zRMS. For discussion on input parameters and obtained results, please refer to point 8.9 of this document.

Reference:	KCP 9.2.5/04
Report	Updated Predicted Environmental Concentrations in surface water (PECsw) following application of mesosulfuron-methyl to winter cereals, Fragkoulis G., 2022d, Adama Report No. 000111759
Guideline(s):	Yes: Generic guidance for FOCUS surface water Scenarios v. 1.4, May 2015
Deviations:	No
GLP:	No: not applicable
Acceptability:	Acceptable

Materials and methods

Predicted environmental concentrations of mesosulfuron-methyl and its metabolites were calculated in accordance with Generic guidance for FOCUS surface water Scenarios v. 1.4 using the following modelling software:

- FOCUS steps 1 and 2 version 3.2
- FOCUS SWASH version 5.3
- FOCUS MACRO version 5.5.4
- FOCUS PRZM version 4.3.1
- FOCUS TOXSWA version 4.4.3
- SWAN version 5.0.0

There are 9 metabolites of Mesosulfuron-methyl which could potentially be detected in surface water and sediment: AE F154851 (Mesosulfuron), AE F160459, AE F099095, AE F092944, AE F160460, AE F140584, AE F147447, BCS CV14885 and BCS-CO60720.

Input parameters were taken from EFSA Journal 2016;14(10):4584 and are presented in section 8.9.2.1 of this document. Following assessment of the dRR by RMS Malta, further calculations were requested using updated geometric mean Koc values for metabolites AE F092944 and AE F099095 and revised application dates. Two winter cereal uses were considered. The application dates for use 1, with application at BBCH 13-20, were determined with consideration of the soil moisture requirements and harvest times of previous crops in Maritime and Mediterranean climatic zones. The application dates for use 2, with application at BBCH 20-39, were determined using AppDate v.3.06.

The critical GAPs presented in section 8.1 of this document were assessed, with crop interception values in accordance with EFSA Journal 2014;12(5):3662. Due to time constraints the GAP was divided into winter and spring cereals. The calculations for the two different crops were carried out by two different people and presented in separate reports. This report contains calculations for winter cereals.

In the SWASH shell the application method was set to “ground spray”, describing a spray application. The CAM (chemical application method) was set to 2 (appln foliar linear) for the R scenarios.

Results and discussions

All PECsw/sed values are presented in section 8.9.2.1 of this document.

Conclusion

The PECsw and PECsed calculations were considered acceptable and used in the aquatic risk assessment.

A 3.15 KCP 9.2.5/05

Comments of zRMS:	The surface water modelling for mesosulfuron-methyl and its metabolites presented in Hicks (2022d) was agreed by the zRMS. For discussion on input parameters and obtained results, please refer to point 8.9 of this document.

Reference:	KCP 9.2.5/05
Report	Updated PECsurfacewater and PECsediment calculations for Mesosulfuron-methyl and Metabolites Following Application to Spring Cereals – FOCUS Steps 1, 2, 3 and 4 For Submission to Southern EU Regulatory Zone. Hicks J., 2022d, Adama Report No. 000111753
Guideline(s):	Yes: Generic guidance for FOCUS surface water Scenarios v. 1.4, May 2015
Deviations:	No
GLP:	No: not applicable
Acceptability:	Acceptable

Materials and methods

Predicted environmental concentrations of mesosulfuron-methyl and its metabolites were calculated in accordance with Generic guidance for FOCUS surface water Scenarios v. 1.4 using the following modelling software:

- FOCUS steps 1 and 2 version 3.2
- FOCUS SWASH version 5.3
- FOCUS MACRO version 5.5.4
- FOCUS PRZM version 4.3.1
- FOCUS TOXSWA version 4.4.3
- SWAN version 5.0.0

There are 9 metabolites of Mesosulfuron-methyl which could potentially be detected in surface water and sediment: AE F154851 (Mesosulfuron), AE F160459, AE F099095, AE F092944, AE F160460, AE F140584, AE F147447, BCS CV14885 and BCS-CO60720.

Input parameters were taken from EFSA Journal 2016;14(10):4584 and are presented in section 8.9.2.1 of this document. Following assessment of the dRR by RMS Malta, further calculations were requested using updated geometric mean Koc values for metabolites AE F092944 and AE F099095 and revised application dates determined using AppDate.

The critical GAPs presented in section 8.1 of this document were assessed, with crop interception values in accordance with EFSA Journal 2014;12(5):3662. Due to time constraints the GAP was divided into winter and spring cereals. The calculations for the two different crops were carried out by two different people and presented in separate reports. This report contains calculations for spring cereals.

In the SWASH shell the application method was set to “ground spray”, describing a spray application. The CAM (chemical application method) was set to 2 (appln foliar linear) for the R scenarios.

Results and discussions

All PECsw/sed values are presented in section 8.9.2.1 of this document.

Conclusion

The PECsw and PECsed calculations were considered acceptable and used in the aquatic risk assessment.

A 3.16 KCP 9.2.5/06

Comments of zRMS:	The surface water modelling for pinoxaden and its metabolites presented in Fragkoulis (2022e) was agreed by the zRMS. For discussion on input parameters and obtained results, please refer to point 8.9 of this document.

Reference:	KCP 9.2.5/06
Report	Updated Predicted Environmental Concentrations in surface water (PECsw) following application of pinoxaden to winter cereals, Fragkoulis G., 2022e, Adama Report No. 000111761
Guideline(s):	Yes: Generic guidance for FOCUS surface water Scenarios v. 1.4, May 2015
Deviations:	No
GLP:	No: not applicable
Acceptability:	Acceptable

Materials and methods

Predicted environmental concentrations of pinoxaden and its metabolites were calculated in accordance with Generic guidance for FOCUS surface water Scenarios v. 1.4 using the following modelling software:

- FOCUS SWASH version 5.3
- FOCUS MACRO version 5.5.4
- FOCUS PRZM version 4.3.1
- FOCUS TOXSWA version 4.4.3

There are 2 metabolites of Pinoxaden which could potentially be detected in surface water and sediment: NOA407854 (M2) and NOA447204 (M3).

Input parameters were taken from EFSA Journal 2013;11(8):3269and are presented in section 8.9.2.2 of this document. Following assessment of the dRR by RMS Malta, further calculations were requested using revised application dates. Two winter cereal uses were considered. The application dates for use 1, with application at BBCH 13-20, were determined with consideration of the soil moisture requirements and harvest times of previous crops in Maritime and Mediterranean climatic zones. The application dates for use 2, with application at BBCH 20-39, were determined using AppDate v.3.06.

The critical GAPs presented in section 8.1 of this document were assessed, with crop interception values in accordance with EFSA Journal 2014;12(5):3662. Due to time constraints the GAP was divided into winter and spring cereals. The calculations for the two different crops were carried out by two different people and presented in separate reports. This report contains calculations for winter cereals

In the SWASH shell the application method was set to “ground spray”, describing a spray application. The CAM (chemical application method) was set to 2 (appln foliar linear) for the R scenarios.

Results and discussions

All PECsw/sed values are presented in section 8.9.2.2 of this document.

Conclusion

The PECsw and PECsed calculations were considered acceptable and used in the aquatic risk assessment.

A 3.17 KCP 9.2.5/07

Comments of zRMS:	The surface water modelling for pinoxaden and its metabolites presented in Hicks (2022e) was agreed by the zRMS. For discussion on input parameters and obtained results, please refer to point 8.9 of this document.

Reference:	KCP 9.2.5/07
Report	Updated PECsurfacewater and PECsediment calculations for Pinoxaden and Metabolites Following Application to Spring Cereals – FOCUS Step 3 For Submission to Southern EU Regulatory Zone. Hicks J., 2022e, Adama Report No. 000111755
Guideline(s):	Yes: Generic guidance for FOCUS surface water Scenarios v. 1.4, May 2015
Deviations:	No
GLP:	No: not applicable
Acceptability:	Acceptable

Materials and methods

Predicted environmental concentrations of pinoxaden and its metabolites were calculated in accordance with Generic guidance for FOCUS surface water Scenarios v. 1.4 using the following modelling software:

- FOCUS SWASH version 5.3
- FOCUS MACRO version 5.5.4
- FOCUS PRZM version 4.3.1
- FOCUS TOXSWA version 4.4.3

There are 2 metabolites of Pinoxaden which could potentially be detected in surface water and sediment: NOA407854 (M2) and NOA447204 (M3).

Input parameters were taken from EFSA Journal 2013;11(8):3269and are presented in section 8.9.2.2 of this document. Following assessment of the dRR by RMS Malta, further calculations were requested using revised application dates determined using AppDate.

The critical GAPs presented in section 8.1 of this document were assessed, with crop interception values in accordance with EFSA Journal 2014;12(5):3662. Due to time constraints the GAP was divided into winter and spring cereals. The calculations for the two different crops were carried out by two different people and presented in separate reports. This report contains calculations for spring cereals

In the SWASH shell the application method was set to “ground spray”, describing a spray application. The CAM (chemical application method) was set to 2 (appln foliar linear) for the R scenarios.

Results and discussions

All PECsw/sed values are presented in section 8.9.2.2 of this document.

Conclusion

The PECsw and PECsed calculations were considered acceptable and used in the aquatic risk assessment.

A 3.18 KCP 9.2.5/08

Comments of zRMS:	The surface water modelling for mefenpyr-diethyl and its metabolites presented in Fragkoulis (2022f) was agreed by the zRMS. For discussion on input parameters and obtained results, please refer to point 8.9 of this document.

Reference:	KCP 9.2.5/08
Report	Updated Predicted Environmental Concentrations in surface water (PECsw) following application of mefenpyr-diethyl to winter cereals, Fragkoulis G., 2022f, Adama Report No. 000111757
Guideline(s):	Yes: Generic guidance for FOCUS surface water Scenarios v. 1.4, May 2015
Deviations:	No
GLP:	No: not applicable
Acceptability:	Acceptable

Materials and methods

Predicted environmental concentrations of mefenpyr-diethyl and its metabolites were calculated in accordance with Generic guidance for FOCUS surface water Scenarios v. 1.4 using the following modelling software:

- FOCUS SWASH version 5.3
- FOCUS MACRO version 5.5.4
- FOCUS PRZM version 4.3.1
- FOCUS TOXSWA version 4.4.3

There are 5 metabolites of Mefenpyr-diethyl which could potentially be detected in surface water and sediment: AE F113225, AE F109453, AE F094270, AE F2211046 and AE F114952.

Input parameters were taken from Monograph list of endpoints, dated October 2011, which has been voluntarily prepared by AGES and ANSES in the context of zonal authorisation of plant protection products containing safener mefenpyr-diethyl, and are presented in section 8.9.2.3 of this document. Following assessment of the dRR by RMS Malta, further calculations were requested using revised application dates. Two winter cereal uses were considered. The application dates for use 1, with application at BBCH 13-20, were determined with consideration of the soil moisture requirements and harvest times of previous crops in Maritime and Mediterranean climatic zones. The application dates for use 2, with application at BBCH 20-39, were determined using AppDate v.3.06.

The critical GAPs presented in section 8.1 of this document were assessed, with crop interception values in accordance with EFSA Journal 2014;12(5):3662. Due to time constraints the GAP was divided into winter and spring cereals. The calculations for the two different crops were carried out by two different people and presented in separate reports. This report contains calculations for winter cereals.

In the SWASH shell the application method was set to “ground spray”, describing a spray application. The CAM (chemical application method) was set to 2 (appln foliar linear) for the R scenarios.

Results and discussions

All PECsw/sed values are presented in section 8.9.2.3 of this document.

Conclusion

The PECsw and PECsed calculations were considered acceptable and used in the aquatic risk assessment.

A 3.19 KCP 9.2.5/09

Comments of zRMS:	The surface water modelling for mefenpyr-diethyl and its metabolites presented in Hicks (2022f) was agreed by the zRMS. For discussion on input parameters and obtained results, please refer to point 8.9 of this document.

Reference:	KCP 9.2.5/09
Report	Updated PECsurfacewater and PECsediment calculations for Mefenpyr-diethyl and Metabolites Following Application to Spring Cereals – FOCUS Step 3 For Submission to Southern EU Regulatory Zone. Hicks J., 2022f, Adama Report No. 000111751
Guideline(s):	Yes: Generic guidance for FOCUS surface water Scenarios v. 1.4, May 2015
Deviations:	No
GLP:	No: not applicable
Acceptability:	Acceptable

Materials and methods

Predicted environmental concentrations of mefenpyr-diethyl and its metabolites were calculated in accordance with Generic guidance for FOCUS surface water Scenarios v. 1.4 using the following modelling software:

- FOCUS SWASH version 5.3
- FOCUS MACRO version 5.5.4
- FOCUS PRZM version 4.3.1
- FOCUS TOXSWA version 4.4.3

There are 5 metabolites of Mefenpyr-diethyl which could potentially be detected in surface water and sediment: AE F113225, AE F109453, AE F094270, AE F2211046 and AE F114952.

Input parameters were taken from Monograph list of endpoints, dated October 2011, which has been voluntarily prepared by AGES and ANSES in the context of zonal authorisation of plant protection products containing safener mefenpyr-diethyl, and are presented in section 8.9.2.3 of this document. Following assessment of the dRR by RMS Malta, further calculations were requested using revised application dates determined using AppDate.

The critical GAPs presented in section 8.1 of this document were assessed, with crop interception values in accordance with EFSA Journal 2014;12(5):3662. Due to time constraints the GAP was divided into winter and spring cereals. The calculations for the two different crops were carried out by two different people and presented in separate reports. This report contains calculations for spring cereals.

In the SWASH shell the application method was set to “ground spray”, describing a spray application. The CAM (chemical application method) was set to 2 (appln foliar linear) for the R scenarios.

Results and discussions

All PECsw/sed values are presented in section 8.9.2.3 of this document.

Conclusion

The PECsw and PECsed calculations were considered acceptable and used in the aquatic risk assessment.

A 3.20 KCP 9.2.5/10

Comments of zRMS:	The surface water modelling for mesosulfuron-methyl and its metabolites presented in Fragkoulis (2022g) was agreed by the zRMS. For discussion on input parameters and obtained results, please refer to point 8.9 of this document.

Reference:	KCP 9.2.5/10
Report	Updated Predicted Environmental Concentrations in surface water (PECsw) following application of mesosulfuron-methyl to winter and spring cereals, Fragkoulis G., 2022g, Adama Report No. 000112245
Guideline(s):	Yes: Generic guidance for FOCUS surface water Scenarios v. 1.4, May 2015
Deviations:	No
GLP:	No: not applicable
Acceptability:	Acceptable

Materials and methods

Predicted environmental concentrations of mesosulfuron-methyl and its metabolite BCS CV14885 were calculated in accordance with Generic guidance for FOCUS surface water Scenarios v. 1.4 using the following modelling software:

- FOCUS SWASH version 5.3
- FOCUS MACRO version 5.5.4
- FOCUS PRZM version 4.3.1
- FOCUS TOXSWA version 4.4.3

There are 9 metabolites of Mesosulfuron-methyl which could potentially be detected in surface water and sediment: AE F154851 (Mesosulfuron), AE F160459, AE F099095, AE F092944, AE F160460, AE F140584, AE F147447, BCS CV14885 and BCS-CO60720. Only step 3 calculations are provided in this document. Step 3 PECsw values are only required for metabolite BCS CV14885.

Input parameters were taken from EFSA Journal 2016;14(10):4584 and are presented in section 8.9.2.1 of this document. Winter and spring cereal applications at BBCH 35-39 were considered. The application dates were determined using AppDate v.3.06.

The critical GAPs presented in section 8.1 of this document were assessed, with crop interception values in accordance with EFSA Journal 2014;12(5):3662.

In the SWASH shell the application method was set to “ground spray”, describing a spray application. The CAM (chemical application method) was set to 2 (appln foliar linear) for the R scenarios.

Results and discussions

All PECsw/sed values are presented in section 8.9.2.1 of this document.

Conclusion

The PECsw and PECsed calculations were considered acceptable and used in the aquatic risk assessment.

A 3.21 KCP 9.2.5/11

Comments of zRMS:	The surface water modelling for pinoxaden and its metabolites presented in Fragkoulis (2022h) was agreed by the zRMS. For discussion on input parameters and obtained results, please refer to point 8.9 of this document.

Reference:	KCP 9.2.5/11
Report	Updated Predicted Environmental Concentrations in surface water (PECsw) following application of pinoxaden to winter and spring cereals, Fragkoulis G., 2022h, Adama Report No. 000112246
Guideline(s):	Yes: Generic guidance for FOCUS surface water Scenarios v. 1.4, May 2015
Deviations:	No
GLP:	No: not applicable
Acceptability:	Acceptable

Materials and methods

Predicted environmental concentrations of pinoxaden were calculated in accordance with Generic guidance for FOCUS surface water Scenarios v. 1.4 using the following modelling software:

- FOCUS SWASH version 5.3
- FOCUS MACRO version 5.5.4
- FOCUS PRZM version 4.3.1
- FOCUS TOXSWA version 4.4.3

There are 2 metabolites of Pinoxaden which could potentially be detected in surface water and sediment: NOA407854 (M2) and NOA447204 (M3). Step 3 PECsw values for metabolites of pinoxaden are not required.

Input parameters were taken from EFSA Journal 2013;11(8):3269 and are presented in section 8.9.2.2 of this document. Winter and spring cereal applications at BBCH 35-39 were considered. The application dates were determined using AppDate v.3.06.

The critical GAPs presented in section 8.1 of this document were assessed, with crop interception values in accordance with EFSA Journal 2014;12(5):3662.

In the SWASH shell the application method was set to “ground spray”, describing a spray application. The CAM (chemical application method) was set to 2 (appln foliar linear) for the R scenarios.

Results and discussions

All PECsw/sed values are presented in section 8.9.2.2 of this document.

Conclusion

The PECsw and PECsed calculations were considered acceptable and used in the aquatic risk assessment.

A 3.22 KCP 9.2.5/12

Comments of zRMS:	The surface water modelling for mefenpyr-diethyl and its metabolites presented in Fragkoulis (2022i) was agreed by the zRMS. For discussion on input parameters and obtained results, please refer to point 8.9 of this document.

Reference:	KCP 9.2.5/12
Report	Updated Predicted Environmental Concentrations in surface water (PECsw) following application of mefenpyr-diethyl to winter and spring cereals, Fragkoulis G., 2022i, Adama Report No. 000112244
Guideline(s):	Yes: Generic guidance for FOCUS surface water Scenarios v. 1.4, May 2015
Deviations:	No
GLP:	No: not applicable
Acceptability:	Acceptable

Materials and methods

Predicted environmental concentrations of mefenpyr-diethyl were calculated in accordance with Generic guidance for FOCUS surface water Scenarios v. 1.4 using the following modelling software:

- FOCUS SWASH version 5.3
- FOCUS MACRO version 5.5.4
- FOCUS PRZM version 4.3.1
- FOCUS TOXSWA version 4.4.3

There are 5 metabolites of Mefenpyr-diethyl which could potentially be detected in surface water and sediment: AE F113225, AE F109453, AE F094270, AE F2211046 and AE F114952. Step 3 PECsw values for metabolites of mefenpyr-diethyl are not required.

Input parameters were taken from Monograph list of endpoints, dated October 2011, which has been voluntarily prepared by AGES and ANSES in the context of zonal authorisation of plant protection products containing safener mefenpyr-diethyl, and are presented in section 8.9.2.3 of this document. Winter and spring cereal applications at BBCH 35-39 were considered. The application dates were determined using AppDate v.3.06.

The critical GAPs presented in section 8.1 of this document were assessed, with crop interception values in accordance with EFSA Journal 2014;12(5):3662.

In the SWASH shell the application method was set to “ground spray”, describing a spray application. The CAM (chemical application method) was set to 2 (appln foliar linear) for the R scenarios.

Results and discussions

All PECsw/sed values are presented in section 8.9.2.3 of this document.

Conclusion

The PECsw and PECsed calculations were considered acceptable and used in the aquatic risk assessment.