REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: GLOB2112dH

Product name: Walkover Trio

Chemical active substance:

Mesotrione, 375 g/L

Thiencarbazone-methyl, 75 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Globachem NV

Submission date: September 2024

zRMS Assessment : 31/03/2025

Version after commenting: 03/07/2025

List of references update: 10/07/2025

Version history

When	What
September 2024	Initial dossier submission by applicant for approval of new product.
March 2025	zRMs evaluated dRR submitted by Applicant
July 2025	zRMS – after first commenting round
July 2025	List of references update

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8 Fate and behaviour in the environment (KCP 9)

General comment
The following data and information were provided by the applicant Globachem NV and have been submitted as a dRR. This document provides the results of the assessment for product Walkover Trio(GLOB2112dH). All comments of the evaluator there are in the “greyboxes”.

8.1 Critical GAP and overall conclusions

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

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: develop-mental stages of the pest or pest group)	**Application**				**Application rate**			PHI (days)	Remarks: e.g. g safener/ synergist per ha	**Conclusion**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product/ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	PL, RO, HU, SK	Maize (ZEAMX)	F	*Annual dicotyledonous weed plants* (3ANDIT) *Annual grasses* (3ANMNT)	Downwards spraying – Broadcast application	BBCH 10-18	a) 1 b) 1	/	a) 0.2 b) 0.2	a) Thiencarba-zone-methyl: 15 + Mesotrione: 75 b) Thiencarba-zone-methyl 15 + Mesotrione: 75	100 – 300	N/A	Safener: 22.4 g/ha cyprosul-famide	A
2	PL, RO, HU, SK	Maize (ZEAMX)	F	*Annual dicotyledonous weed plants* (3ANDIT) *Annual grasses* (3ANMNT)	Downwards spraying – Broadcast application	BBCH 10-18	a) 1 b) 1	/	a) 0.13 b) 0.13	a) Thiencarbazone-methyl: 9.75 + Mesotrione: 48.75 b) Thiencarbazone-methyl 9.75 + Mesotrione: 48.75	100 – 300	N/A	Safener: 14.6 g/ha cyprosul-famide Optional lower rate as backup or dose range.	A
3	PL, RO, HU, SK	Maize (ZEAMX)	F	*Annual dicotyledonous weed plants* (3ANDIT) *Annual grasses* (3ANMNT)	Downwards spraying – Banded appli-cation (50% of field)	BBCH 10-18	a) 1 b) 1	/	a) 0.2 b) 0.2	a) Thiencarba-zone-methyl: 15 + Mesotrione: 75 b) Thiencarba-zone-methyl 15 + Mesotrione:	100 – 300	N/A	Safener: 22.4 g/ha cyprosul-famide Dose rate is concentration within the band.	A

										75				
4	PL, RO, HU, SK	Maize (ZEAMX)	F	*Annual dicotyledonous weed plants* (3ANDIT) *Annual grasses* (3ANMNT)	Downwards spraying – Banded application (50% of field)	BBCH 10-18	a) 1 b) 1	/	a) 0.13 b) 0.13	a) Thiencarbazone-methyl: 9.75 + Mesotrione: 48.75 b) Thiencarbazone-methyl 9.75 + Mesotrione: 48.75	100 – 300	N/A	Safener: 14.6 g/ha cyprosulfamide Optional lower rate as backup or dose range. Dose rate is concentration within the band.	A

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

Explanation for column 15 "Conclusion"

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

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

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			PHI (days)	Remarks: e.g. g safener/ synergist per ha
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
1	EU N&S	Maize	F	annual broadleaved weeds and some annual grasses such as *Echinochloa crus-galli*	Foliar spray application using a hydraulic vehicle-mounted spray equipment	BBCH 12-18	a) 1 b) 1	Not relevant	a) -	a) 150 b) 150	200- 400	N/A	

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

Table 8.1-3: Assessed (critical) uses during approval of thiencarbazone-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 destina-tion / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: devel-opmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/ synergist per ha
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product/ha a) max. rate per appl. b) max. total rate per crop/season	kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
1	EU	Maize	F	Weeds	Broadcast spray	BBCH 00-13	a) 1 b) 1	NA	a) 0.089-0.20 b) 0.089-0.20	Thiencarbazone-methyl: 0.02-0.045 AE0001789: 0.02-0.045	150-400	NA	

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

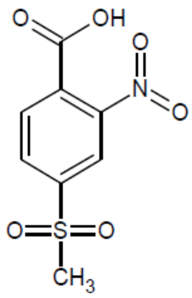
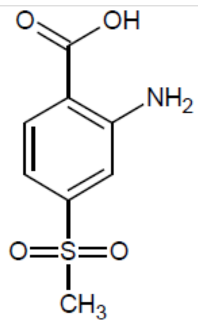
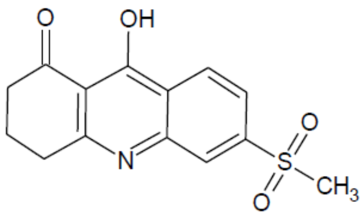
General comment zRMS
Walkover Trio (product code: GLOB2112dH) is suspension concentrate (SC) containing containing 75 g/L thiencarbazone-methyl, 375 g/L mesotrione and 112 g/L cyprosulfamide (safener) for use as an herbicide in maize in Central zone. Thiencarbazone-methyl: CAS No 317815-83-1 is recognised as approved for use in plant protection products under Regulation (EC) No 1107/2009 in Annex of Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 with the expiration of approval on 01 March 2027. Mesotrione: CAS No 104206-82-8 is recognised as approved for use in plant protection products under Regulation (EC) No 1107/2009 in Annex of Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 with the expiration of approval on 31 May 2032. In this assessment used endpoints evaluated on EU level in accordance with EFSA documents:

- The SANCO report for thiencarbazone-methyl (SANCO/12602/2013 rev 2 – 23/03/2018);
- "Conclusion on the peer review of the pesticide risk assessment of the active substance thiencarbazone-methyl" - EFSA Journal 2013;11(7):3270
- The SANCO report for mesotrione (SANTE/11654/2016 – 23/03/2017)
- "Peer review of the pesticide risk assessment of the active substance mesotrione" - EFSA Journal 2016;14(3):4419.

Cyprosulfamide (safener) has not been assessed.

8.2 Metabolites considered in the assessment

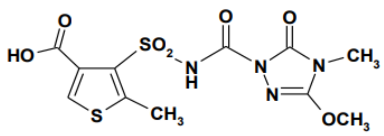
Table 8.2-1: Metabolites of mesotrione potentially relevant for exposure assessment

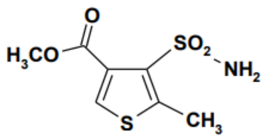
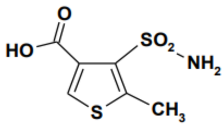
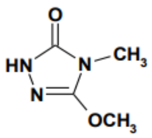
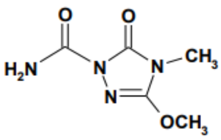
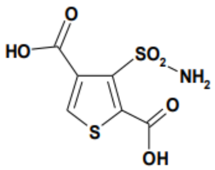
Metabolite	Molar mass	Chemical structure	Maximum observed oc-curence in compartements	Exposue assessment re-quired due to
MNBA	245 g/mol		Soil: 57.2% ~~> 10 % of a.s~~ Surface water: 7.4% Sediment: <1% Water/Sediment: Max. 7.4%	PEC_{gw}: leaching potential to groundwater PEC_{soil}: risk to soil organ-isms $PEC_{sw/sed}$: risk to aquatic organisms
AMBA	215 g/mol		Soil: Max. 9.7% Water: 15.8% Sediment: 8.8% Water/Sediment: 24.6% ~~> 10 % of a.s~~	PEC_{gw}: leaching potential to groundwater PEC_{soil}: risk to soil organ-isms $PEC_{sw/sed}$: risk to aquatic organisms
SYN546974	291 g/mol		Surface water: 9.4% Sediment: 25.6% Water/Sediment: 33% ~~> 10 % of a.s~~	$PEC_{sw/sed}$: risk to aquatic organisms

zRMS comment

Information relating to mesotrione metabolites is in line with EU agreed endpoints as reported in EFSA Journal 2016;14(3):4419 and have been considered in the exposure assessment presented in this report. However, respective corrections were included by the zRMS where necessary.

Table 8.2-2: Metabolites of thiencarbazone-methyl potentially relevant for exposure as-sessment

Metabolite	Molar mass	Chemical structure	Maximum observed occurence in comparte-ments	Exposue assessment required due to
BYH 18636- carboxylic acid / AE 1394083	376.4		Soil: 53.6% (aerobic), 32.8% (anaerobic) Water: 24.6% Sediment: ~~37.1%~~ 13% Water/sediment: 37.1%	PEC_{gw}: leaching poten-tial to groundwater PEC_{soil}: risk to soil organisms $PEC_{sw/sed}$: risk to aquat-ic organisms

Metabolite	Molar mass	Chemical structure	Maximum observed occurence in compartements	Exposue assessment required due to
BYH 18636- sulfonamide / AE 1364547	235.3		Soil: 15.6% (aerobic) Water: 4.3% 41% (hydrolysis) Sediment: 2.7% Water/sediment: 7.0%	PEC_{gw}: leaching potential to groundwater PEC_{soil}: risk to soil organisms $PEC_{sw/sed}$: risk to aquatic organisms
BYH 18636- sulfonamide carboxylic acid / AE 1395853	221.3		Soil: 21.2% (aerobic) Water: 45.6% Sediment: 21.3% Water/sediment: 66.9%	PEC_{gw}: leaching potential to groundwater PEC_{soil}: risk to soil organisms $PEC_{sw/sed}$: risk to aquatic organisms
BYH 18636- MMT / AE 1277106	129.1		Soil: 20.6% (aerobic) Water: 24.9% 41.5% (hydrolysis) Sediment: 7.8% Water/sediment: 30.7%	PEC_{gw}: leaching potential to groundwater PEC_{soil}: risk to soil organisms $PEC_{sw/sed}$: risk to aquatic organisms
BYH 18636- triazolinonecarboxamide / AE 1430601	172.1		Soil: 8.1% (photolysis)	PEC_{gw}: leaching potential to groundwater PEC_{soil}: risk to soil organisms ~~$PEC_{sw/sed}$: risk to aquatic organisms~~
BYH 18636- dicarboxysulfonamide / BCSAA10007	251.2		Water: 18.9% Sediment: - Water/sediment: 23.9%	$PEC_{sw/sed}$: risk to aquatic organisms

zRMS comment
Information relating to thiencarbazone-methyl metabolites is in line with EU agreed endpoints as reported in EFSA Journal 2013;11(7):3270 and have been considered in the exposure assessment presented in this report. However, 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.

Evaluation by zRMS	Rate of degradation in soil (KCP 9.1.1)
Comments	No new data. Information in Section 8.3 is available in dossiers of active substances: mesotrione and thiencarbazone-methyl and can be extrapolated to formulation. Therefore no studies have been conducted. EU agreed data were correctly reported.

8.3.1 Aerobic degradation in soil (KCP 9.1.1.1)

8.3.1.1 Mesotrione and its metabolites

Table 8.3-1: Summary of aerobic degradation rates for mesotrione - laboratory studies – best fit kinetic endpoints

Soil name	Soil type	Best fit kinetic	DT50 (d)	DT90 (d)	St. (χ^2)	Evaluated on EU level / Reference
ERTC	Sandy loam	SFO	11.6	38.5	18	Mesotrione Renewal Assessment Report, Volume 3 – B.8, 2015
Toulouse	Loam	FOMC	3.8	17.7	15.5	
Pickett Piece	Clay loam	SFO	5.3	17.7	6.5	
721	Clay loam	FOMC	18.8	-[a] (234)	1.0	
722	Silty clay loam	SFO	10.3	(34.2)	3.9	
723	Silt loam	SFO	17.6	(58.5)	3.4	
724	Loamy sand	FOMC	23.7	-[a]	1.3	
725	Loam	FOMC	5.0	25.3	1.0	
727	Clay loam	DFOP	18.0	-[b] (209)	1.7	
728	Sandy loam	FOMC	6.3	28.2	2.7	
729	Silt loam	FOMC	12.4	-[a] (45.1)	1.6	
730	Clay loam	FOMC	14.0	-[a]	6.7	
731	Silty clay loam	SFO	14.1	(46.9)	1.0	
732	Silty clay loam	FOMC	12.0	-[a]	1.5	
741	Silty clay loam	DFOP	(34.3)	(224)	1.0	
742	Silty clay loam	SFO	9.7	(32.1)	5.5	
Vispetto & Tovshteyn, 1997	Silt loam Richmond	DFOP	12.6	46.3	2.5	
Subba-Rao, 1996	Silt loam Richmond	DFOP	11.5	43.2	4.5	
Miller, 1997	Silt loam Richmond	DFOP	13.4	(67.7)	4.0	

(xx) indicates extrapolated beyond experimental period
[a] DT90 not valid, FOMC DT50/90 should not be extrapolated outside of the experimental period [EFSA, 2009]
[b] DT90 not valid, limited datapoints and k2 t-test not robust
[c] β contains zero
[d] both α and β contain zero.

Table 8.3-2: Summary of aerobic degradation rates for mesotrione - laboratory studies – modelling endpoints

Mesotrione, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH**	**t.°C**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa ***	**St. (χ^2)**	**Kinetic model**	**Evaluated on EU level / Reference**
ERTC	Sandy loam	6.4	20	19 [a]	11.6	38.5	8.2	18	SFO	EFSA, 2016
Toulouse	Loam	7.7	20	25 [a]	4.3	14.3	4.0	16.4	SFO	
Pickett Piece	Clay loam	7.1	20	28 [a]	5.3	17.7	5.3	6.5	SFO	
721	Clay loam	5.6	25	28 [a]	20.2	67.1	32.3	4.1	SFO	
722	Silty clay loam	5.7	25	30 [a]	10.3	34.2	16.5	3.9	SFO	
723	Silt loam	5.4	25	26 [a]	17.6	58.5	28.2	3.4	SFO	
724	Loamy sand	4.8	25	14 [a]	23.8	78.9	31.1	4.3	SFO	
725	Loam	5.8	25	25 [a]	6.1	20.3	9.5	7.6	SFO	
727	Clay loam	5.1	25	28 [a]	20.8	69.2	32.4	6.4	SFO	
728	Sandy loam	5.9	25	25 [a]	7.2	24	9.7	5.6	SFO	
729	Silt loam	5.6	25	26 [b]	12.7	42.2	20.3	1.6	SFO	
730	Clay loam	5.3	25	28 [a]	17.1	56.9	26.9	8.9	SFO	
731	Silty clay loam	6.1	25	30 [a]	14.1	46.9	22.6	1.0	SFO	
732	Silty clay loam	5.0	25	30 [a]	14.0	46.4	22.4	5.3	SFO	
741	Silty clay loam	5.7	25	30 [a]	28.7	95.3	44.3	4.5	SFO	
742	Silty clay loam	7.2	25	34.4 [a]	9.7	32.1	15.5	5.5	SFO	
Vispetto & Tovshteyn, 1997	Silt loam Richmond	6.2	25	32.04 [b]	13.2	44.0	14.68 (Average DT_{50}ref of 15.5 & 13.9 days given identical soil descriptions in these 2 studies).	3.1	SFO	
Subba-Rao, 1996	Silt loam Richmond	6.2	25	32.04 [b]	11.8	39.3		4.9	SFO	
Miller, 1997	Silt loam Richmond	6.1	20	32.04 [b]	14.2	47.2	11.5	4.6	SFO	
Geometric mean (if not pH dependent) (n=18)										
pH-dependency:							Yes – degradation increases with increasing pH. DT50 y= -9.766x pH + 77.692 R^2 0.4687			

Mesotrione, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH**	**t.°C**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa [*]**	**St. (χ²)**	**Kinetic model**	**Evaluated on EU level / Reference**
							(non-log)			

[a] FOCUS default;
[b] measured pF2
[*] Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

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

MNBA, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH**	**t.°C**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa [*]**	**St. (χ²)**	**Kinetic model**	**Evaluated on EU level / Reference**
722	Silty clay loam	5.7	25	30 [a]	0.6	1.89	1.0	10	SFO	EFSA, 2016
725	Loam	5.8	25	25 [a]	0.5	1.5	0.8	10.8	SFO	
728	Sandy loam	5.9	25	25 [a]	5.1	16.97	6.9	3.1	Decline from peak	
729	Silt loam	5.6	25	26 [b]	1.66	5.52	2.7	3.88	SFO	
730	Clay loam	5.3	25	28 [a]	2.81	9.35	4.4	14.17	SFO	
731	Silty clay loam	6.1	25	30 [a]	15.7	52.3	25.2	1.6	SFO	
ERTC	Sandy loam	6.4	20	19 [a]	6.2	20.7	4.4	21.89	Decline from peak	
Toulouse	Loam	7.7	20	25 [a]	5	16.65	4.6	13.08	Decline from peak	
Subba-Rao, 1996	Silt loam Richmond	6.2	25	32.04 [b]	1.1	3.67	1.3	11.2	SFO	
Miller, 1997	Silt loam Richmond	6.1	20	32.04 [b]	6.3	21.03	5.1	20.13	Decline from peak	
Geometric mean (n=10)							3.4			
pH-dependency:							No			

[a] FOCUS default;
[b] measured pF2
[*] Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

Table 8.3-4: Summary of aerobic degradation rates for AMBA - laboratory studies – best fit kinetic endpoints

	AMBA, Laboratory studies, aerobic conditions						
Soil name	**pH**	**Best fit kinetic**	**DT_{50} (days)**	**DT_{90} (days)**	**ffm (-)**	**St. (χ^2)**	**Evaluated on EU level / Reference**
Richmond	6.2	SFO	13.6	45.2 44.9	0.25 0.25	15.2	Mesotrione Renewal Assessment Report, Volume 3 – B.8, 2015
*Richmond**	6.1	SFO	*>1000*	*>1000*	*0.12* *0.11*	28	
Wisborough	4.9	DFOP overall	0.38	26	-	5.52	
Wisconsin	6.4	FOMC	5.87	441	-	6.58	
East Anglia	7.9	DFOP overall	2.84	67.6	-	3.66	
Spinks	6.7	DFOP overall	2.91	496	-	3.11	

*Outlier

Table 8.3-5: Summary of aerobic degradation rates for AMBA - laboratory studies – modelling endpoints

AMBA, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH**	**t.°C**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa**	**St. (χ^2)**	**Kinetic model**	**Evaluated on EU level / Reference**
Wisborough	-	4.9	20	-	7.8	-	3.7	5.52	DFOP DT90/3.32	EFSA, 2016
Wisconsin	-	6.4	20	-	33.0	109	23.5	7.98	DFOP k2	
East Anglia	-	7.9	20	-	58.7	195	47.4	3.66	DFOP k2	
Spinks	-	6.7	20	-	10.2	34	9.7	6.94	FOMC	
Richmond	-	6.2	25	-	13.6	45.2	16.0	14.8	SFO	
*Richmond**	-	*6.1*	*20*	-	*>1000*	-	*>1000*	*26.6*	*SFO*	
						Geometric mean (n=5)	14.5			
						pH-dependency:	No			

*Outlier

8.3.1.2 Thiencarbazone-methyl and its metabolites

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

Thiencarbazone-methyl, laboratory studies, dark aerobic conditions									
Soil	**pH ($CaCl_2$)**	**t (°C)**	**MWHC (%)**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa[a)]**	**Chi^2 (%)**	**Kinetic model**	**Evaluated on EU level**
AIII	6.8	20°C	44	23.1	76.7	15.0	8.5	SFO	Yes / EFSA (2013)
AXXa	6.3	20°C	50	12.9	42.9	10.2	5.0	SFO	Yes / EFSA (2013)
HCB	7.4	20°C	79% of 1/3 bar	53.2	176.7	38.8	3.8	SFO	Yes / EFSA (2013)
SLS	7.5	20°C	43	17.7	58.8	11.3	8.2	SFO	Yes / EFSA (2013)
Pikeville	5.0	25°C	75% of 1/3 bar	3.2	10.6	3.1	14.7	SFO	Yes / EFSA (2013)
Geometric mean (n=5)						11.6			

a) Normalised using a Q_{10} of 2.58 and Walker equation coefficient of 0.7.

Table 8.3-7: Summary of aerobic degradation rates for BYH 18636-carboxylic acid (M01) - laboratory studies

BYH 18636-carboxylic acid (M01), laboratory studies, dark aerobic conditions										
Soil type	**pH ($CaCl_2$)**	**t (°C)**	**MWHC (%)**	**DT_{50} (d)**	**DT_{90} (d)**	**Formation fraction k_f/k_{dp}**	**DT_{50} (d) 20°C pF2/10kPa[a)]**	**Chi^2 (%)**	**Kinetic model**	**Evaluated on EU level**
AIII	6.8	20°C	44	433.8	n.r.	0.194	- [b]	21.5	SFO	Yes / EFSA (2013)
AXXa	6.3	20°C	50	451.1	n.r.	0.136	- [b]	9.8	SFO	Yes / EFSA (2013)
HCB	7.4	20°C	79% of 1/3 bar	338.3	n.r.	0.748	- [b]	6.7	SFO	Yes / EFSA (2013)
SLS	7.5	20°C	43	477.6	n.r.	0.638	- [b]	10.0	SFO	Yes / EFSA (2013)
Pikeville	5.0	25°C	75% of 1/3 bar	51.3	n.r.	0.196	- [b]	4.7	SFO	Yes / EFSA (2013)
Geometric mean (n=5)				276.7	-		- [b]			
Arithmetic mean (n=5)				-	-	0.382	-			

a) Normalised using a Q_{10} of 2.58 and Walker equation coefficient of 0.7.
b) Normalised DT_{50} values were not used since the exposure assessment was based on field dissipation data.

Table 8.3-8: Summary of aerobic degradation rates for BYH 18636-sulfonamide (M15) - laboratory studies

BYH 18636-sulfonamide (M15), laboratory studies, dark aerobic conditions										
Soil type	**pH ($CaCl_2$)**	**t (°C)**	**MWHC (%)**	**DT_{50} (d)**	**DT_{90} (d)**	**Formation fraction k_f/k_{dp}**	**DT_{50} (d) 20°C pF2/10kPa[a)]**	**Chi[2] (%)**	**Kinetic model**	**Evaluated on EU level**
AIII	6.8	20°C	44	48	159.5	-	31.2	10.7	SFO diss. from peak	Yes / EFSA (2013)
AXXa	6.3	20°C	50	7.4	24.6	0.571	5.8	24.0	SFO	Yes / EFSA (2013)
HCB	7.4	20°C	79% of 1/3 bar	25	83.0	0.253	18.3	50.1	SFO	Yes / EFSA (2013)
SLS	7.5	20°C	43	16.4	54.5	0.302	10.5	30.5	SFO	Yes / EFSA (2013)
Pikeville	5.0	25°C	75% of 1/3 bar	5.2	17.3	-	5.0	3.2	FOMC diss. from peak DT90/3.322	Yes / EFSA (2013)
Geometric mean (n=5)				15.0	49.8	-	11.2			
Arithmetic mean (n=5)				-	-	0.375	-			

a) Normalised using a Q_{10} of 2.58 and Walker equation coefficient of 0.7.

Table 8.3-9: Summary of aerobic degradation rates for BYH 18636-sulfonamide carboxylic acid (M03) - laboratory studies

BYH 18636-sulfonamide-carboxylic acid (M03), laboratory studies, dark aerobic conditions										
Soil type	**pH ($CaCl_2$)**	**t (°C)**	**MWHC (%)**	**DT_{50} (d)**	**DT_{90} (d)**	**Formation fraction k_f/k_{dp}**	**DT_{50} (d) 20°C pF2/10kPa[a)]**	**Chi[2] (%)**	**Kinetic model**	**Evaluated on EU level**
AIII	6.8	20°C	44	26.6	88.4	1	17.3	20.6	SFO	Yes / EFSA (2013)
AXXa	6.3	20°C	50	4.7	15.6	1	3.7	22.1	SFO	Yes / EFSA (2013)
SLS	7.5	20°C	43	26	86.4	0.382	16.7	35	SFO	Yes / EFSA (2013)
Pikeville	5.0	25°C	75% of 1/3 bar	4.2	14.0	-	4.0	14.7	FOMC diss. from peak DT90/3.322	Yes / EFSA (2013)
Geometric mean (n=5)				10.8	35.9	-	8.1			
Arithmetic mean (n=5)				-	-	0.794	-			

a) Normalised using a Q_{10} of 2.58 and Walker equation coefficient of 0.7.

Table 8.3-10: Summary of aerobic degradation rates for BYH 18636-MMT (M21) - laboratory studies

BYH 18636-MMT (M21), laboratory studies, dark aerobic conditions										
Soil type	**pH ($CaCl_2$)**	**t (°C)**	**MWHC (%)**	**$DT_{50, fast}$ (d)**	**$DT_{50, slow}$ (d)**	**Formation fraction k_f/k_{dp})**	**$DT_{50, fast}$ / $DT^{50, slow}$ (d) 20°C pF2/10kPa[a)]**	**Chi² (%)**	**Kinetic model**	**Evaluated on EU level**
AIII	6.8	20°C	44	2	58.2	0.8081	1.3 / 37.9	20.8	DFOP (g: 0.8822)	Yes / EFSA (2013)
AXXa	6.3	20°C	50	20.3	-	0.390	16.0 / -	20.1	SFO	Yes / EFSA (2013)
HCB	7.4	20°C	79% of 1/3 bar	10.1	182.4	0.3081	7.4 / 133.2	25.7	DFOP (g: 0.9001)	Yes / EFSA (2013)
SLS	7.5	20°C	43	2.4	192.5	0.3716	1.5 / 123.4	3.4	DFOP (g: 0.9439)	Yes / EFSA (2013)
Geometric mean (n=5)				5.6	126.9	-	3.9 / 85.4			
Arithmetic mean (n=5)				-	-	0.4695	-			

a) Normalised using a Q_{10} of 2.58 and Walker equation coefficient of 0.7.

Table 8.3-11: Summary of aerobic degradation rates for BYH 18636-triazolinonecarboxamide - laboratory studies

BYH 18636-triazolinone-carboxamide, Laboratory studies, aerobic conditions										
Soil name	**Soil type (USDA)**	**pH ($CaCl_2$)**	**t.°C**	**MWHC %**	**DT50 fast/DT50 slow (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa**	**Chi2 (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
AIIIa		6.5	20	14.5	18.5/23.4	-	~~15.7~~ 15.4	1.7	DFOP (trigger) SFO (modelling)	Yes / EFSA (2013)
Wurmwiese		5.1	20	14.1	27.4/44.7	-	25.7	1.9	DFOP (trigger) SFO (modelling)	Yes / EFSA (2013)
Hoefchen		6.4	20	21.7	11.3/11.3	-	8.4	2.0	DFOP (trigger) SFO (modelling)	Yes / EFSA (2013)
Geometric mean (n=3)							14.9			
pH-dependency: y/n							n			

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

8.3.2.1 Mesotrione and its metabolites

Mesotrione degradation in soil under anaerobic conditions was investigated in one study. Mesotrione was low persistent under these conditions. Metabolite AMBA reached 40.7% AR after 30 d. MNBA was not detected.

Table 8.3-12: Summary of anaerobic degradation rates for mesotrione - laboratory studies

Mesotrione, Laboratory studies, anaerobic conditions										
Soil name	**Soil type**	**pH**	**t.°C**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa**	**St. (χ^2)**	**Kinetic model**	**Evaluated on EU level / Reference**
Wisconsin silt loam cyclohexane-label Sandy loam		6.2	25	-	4 days	14 days	-	r^2 = 0.98	First order (linear least squares fit of natural log of concentration vs. Sampling interval).	EFSA, 2016
Wisconsin silt loam phenyl-label Loam		7.7	25	-	4 days	12 days	-	r^2 = 0.97	First order (linear least squares fit of natural log of concentration vs. Sampling interval).	
Geometric mean (if not pH dependent)							-			
pH-dependency:							-			

8.3.2.2 Thiencarbazone-methyl and its metabolites

Degradation of thiencarbazone-methyl in soil under dark anaerobic conditions was investigated in one soil. Degradation of parent and aerobic metabolites slowed under these conditions. No new metabolites were generated during the anaerobic phase of the study.

8.4 Field studies (KCP 9.1.1.2)

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

8.4.1.1 Mesotrione and its metabolites

Studies on the field dissipation rates of mesotrione are considered to be data provided in support of the active substance. All relevant detailed experimental information has been submitted for the EU review of mesotrione (EFSA Journal, 2016). These studies have not been re-evaluated at EU level according to the current guidance document in the context of the renewal of authorisation of mesotrione (EFSA, 2016).

These studies are not deemed necessary for the risk assessment of this dossier.

8.4.1.2 Thiencarbazone-methyl and its metabolites

Because of the fast degradation of BYH 18636 in soil, no field dissipation studies for parent substance were required in Europe.
However, degradation rates in US and Canadian field dissipation trials are available and were similar to those in EU laboratory soils. Results of five of these North American field trials (excluding three of the Canadian ones) were considered relevant to EU conditions. Normalized degradation rates calculated on the basis of these studies are in the upper range of the values observed in the laboratory studies. Laboratory studies half-lives were considered to be appropriate for modelling environmental exposure of thiencarbazone-methyl.
A European field dissipation study was also conducted for metabolite BYH 18636-carboxylic acid, to test the degradation behaviour under outdoor conditions. BYH 18636-carboxylic acid was degraded significantly faster in European field soils (trigger DT_{50}: 5.4–41.1 days) compared to laboratory conditions (trigger DT_{50}: 56.9 – 449.3 days). For use in environmental exposure models, a geometric mean normalised field DT_{50} of 62.4 days was derived for BYH 18636-carboxylic acid.

Table 8.4-1: Summary of aerobic degradation rates for thiencarbazone-methyl - field studies: Trigger and modelling endpoints

Thiencarbazone-methyl, Field studies									
Soil type	**Location**	**pH ($CaCl_2$)**	**Depth (cm)**	**DT50 (d) actual**	**DT90 (d) actual**	**DT50 (d) norm**	**St (X^2)**	**Method of calc.[b)]**	**Evaluated on EU level y/n/ Reference**
Sandy loam	Ontario, Canada	7.3	0+61	32.5	108	25.6	21	SFO	Yes / EFSA (2013)
Clay loam	Manitoba, Canada	7.8[a)]	0-45	26.0	86.3	27.2	12	SFO	Yes / EFSA (2013)
Loam	California, USA	7.7	0-61	3	9.9	9.6	43	HS	Yes / EFSA (2013)
Silt loam	Illinois, USA	4.5	0-61	6.9	22.9	3.6	11.5	SFO	Yes / EFSA (2013)
Silt loam	Nebraska, USA	6.2	0-61	44.6	148	38.6	9.4	SFO	Yes / EFSA (2013)
Geometric mean (if not PH dependent)						-			

a) pH in water
b) SFO based on values after exclusion of data points before 10 mm rainfall. Breakpoint for HS k2 occurring after 10 mm rainfall. North America studies not used in EU exposure assessment as within range of laboratory aerobic degradation rates.

Table 8.4-2: Summary of aerobic degradation rates BYH 18636-carboxylic acid (M01) - field studies: Trigger and modelling endpoints

BYH 18636-carboxylic acid (M01)										
Soil type	**Location**	**OC (%)**	**pH ($CaCl_2$)**	**Depth (cm)**	**DT_{50} (d) actual**	**DT_{90} (d) actual**	**DT_{50} (d) norm.**	**Chi² (%)**	**Kinetic model**	**Evaluated on EU level**
Silt loam	Burscheid (Germany)	0.89	6.4	100	5.4	81.3	22.7	11.1	DFOP	Yes / EFSA (2013)
Clay loam	Vilobi d'Onyar (Spain)	1.23	6.2	100	22.4	382.6	81.5	12.4	DFOP	Yes / EFSA (2013)
Silt loam	Tarascon (Southern France)	0.56	7.7	100	26.4	26.4	154.0	13.2	DFOP	Yes / EFSA (2013)
Silt loam	Vatteville (Northern France)	0.87	6.5	100	41.1	41.1	53.3	9.4	DFOP	Yes / EFSA (2013)
Geometric mean (n=4)					19.0	266.8	62.4			

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

8.4.2.1 Mesotrione and its metabolites

Following the proposed uses and given the rapid degradation observed in laboratory and field studies, only very low or negligible residues of mesotrione are expected following harvest or sowing of succeeding crops. Therefore, no soil accumulation testing is required.

8.4.2.2 Thiencarbazone-methyl and its metabolites

Due to fast degradation, residues thiencarbazone-methyl would not have potential to accumulate in soil. Therefore, no soil accumulation testing is required. The maximum DT90 of metabolite BYH 18636-carboxylic acid in the laboratory and in the field exceeds 1 year. Therefore, its accumulation in soil was evaluated by calculating the plateau concentrations in soil as well as the maximum PECsoil directly after the last of an infinite number of applications of the product; (cf. Section KIIIA 9.5/03). The calculation indicated that the background level in soil from carryover of previous uses will contribute less than 10 % of the actual soil concentration. Accumulation of BYH 18636-carboxylic acid can herewith be considered negligible.

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.

Evaluation by zRMS	**Mobility in soil (KCP 9.1.2)**
Comments	No new data. Information in Section 8.5 is available in dossiers of active substances: mesotrione and thiencarbazone-methyl and can be extrapolated to formulation. Therefore no studies have been conducted. EU agreed data were cor-

	rectly reported.

8.5.1 Mesotrione and its metabolites

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

Mesotrione							
Soil name	**Soil type**	**OC (%)**	**pH (-)**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Evaluated on EU level / Reference**
Wisborough Green	Silty clay loam	2.63	5.1	4.46	171	0.902	EFSA, 2016
Wisconsin	Silt loam	1.58	6.2	0.74	47	0.921	
Toulouse	Clay	1.79	6.5	1.25	70	0.915	
Garonne	Loam	1.03	7.8	0.15	14	0.971	
Visalia	Sandy loam	0.53	8.2	013	25	0.959	
Wisconsin	Silt loam	1.28	6.1	0.61	48	0.947	
ERTC	Sandy loam	0.58	6.4	0.33	57	0.950	
Pickett Piece	Clay loam	3.31	7.1	0.97	29	0.932	
Garonne	Loam	0.87	7.7	0.16	18	0.954	
Champaign (1:2 ratio)	Silty clay loam	3.0	4.4	6.16	354	0.94	
Arithmetic mean (n=10)					-	0.94	
Worst case					14	-	
pH-dependency					Yes, sorption decreases as pH increases. Kfoc y= 8583.4e^{-0785x} (log) r² 0.8977		

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

MNBA							
Soil Name	**Soil Type**	**OC (%)**	**pH (-)**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Evaluated on EU level / Reference**
Wisborough Green	Silty clay loam	2.63	5.1	0.16	6.1	0.32	EFSA, 2016
Wisconsin	Silt loam	1.58	6.2	0.05	3.2	0.61	
Worst case (n=2)					3.2	0.9 (FOCUS default)	EFSA, 2016
pH-dependency					No		

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

AMBA							
Soil Name	**Soil Type**	**OC (%)**	**pH (-)**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Evaluated on EU level / Reference**
Wisborough Green	Silty clay loam	2.63	5.1	3.2	122	0.83	EFSA, 2016
Wisconsin	Silt loam	1.58	6.2	0.71	44.9	0.85	
Toulouse	Clay	1.79	6.5	0.91	51.0	0.85	
Garonne	Loam	1.03	7.8	0.18	18.1	0.82	
Visalia	Sandy loam	0.53	8.2	0.12	23.9	0.90	
Arithmetic mean (n=5)					-	0.85	EFSA, 2016
Worst case					18.1	-	EFSA, 2016
pH-dependency					Yes, sorption decreases as pH increases. Kfoc $y = 1865e^{-0.563x}$ (log) r^2 0.9062		

Table 8.5-4: Summary of soil adsorption/desorption for SYN 546974

SYN 546974							
Soil Name	**Soil Type**	**OC (%)**	**pH (-)**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Evaluated on EU level / Reference**
Gartenacker	Loam	1.8	7.2	30.63	1702	0.82	EFSA, 2016
18 Acres	Sandy clay loam	2.2	5.7	220.07	10003	0.96	
Marysville	Clay loam	1.6	7.6	432.49	27031	0.96	
Sarpy	Silt loam	1.7	6.5	376.10	22124	0.88	
Seven Springs	Loamy sand	0.6	5.2	19.56	3260	0.84	
Arithmetic mean (n=5)					13000	0.89	EFSA, 2016
Geometric mean (n=5)					8021	-	
pH-dependency					No		

8.5.2 Thiencarbazone-methyl and its metabolites

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

Thiencarbazone-methyl						
Soil type	**OC (%)**	**pH ($CaCl_2$)**	**K_F (mL/g)**	**K_{Foc} (mL/g)**	**1/n (-)**	**Evaluated on EU level**
AXXa	1.47	6.3	0.64	43	0.899	Yes / EFSA (2013)
AIII	0.88	6.8	0.40	46	0.886	Yes / EFSA (2013)
SLS	1.30	7.5	0.88	68	0.917	Yes / EFSA (2013)
HCB	4.1	7.4	6.23	152	0.897	Yes / EFSA (2013)
SSC	1.15	4.8	2.18	190	0.932	Yes / EFSA (2013)
Arithmetic mean (n=5)				100	0.906	
Geometric mean (n=5)				82.8	-	
pH-dependency				No		

Table 8.5-6: Summary of soil adsorption/desorption for BYH 18636-carboxylic acid (M01)

BYH 18636-carboxylic acid (M01)						
Soil type	**OC (%)**	**pH ($CaCl_2$)**	**K_F (mL/g)**	**K_{Foc} (mL/g)**	**1/n (-)**	**Evaluated on EU level**
AXXa	2.7	6.2	0.129	4.8	0.917	Yes / EFSA (2013)
AIII	0.4	6.8	0.036	8.9	0.802	Yes / EFSA (2013)
SLS	0.9	6.9	0.116	12.9	0.980	Yes / EFSA (2013)
HCB	4.9	7.1	0.605	12.3	0.933	Yes / EFSA (2013)
SSC	1.2	4.8	0.376	32.7	0.965	Yes / EFSA (2013)
Arithmetic mean (n=5)				14.3	0.919	
Geometric mean (n=5)				11.7	-	
pH-dependency				No		

Table 8.5-7: Summary of soil adsorption/desorption for BYH 18636-sulfonamide (M15)

BYH 18636-sulfonamide (M15)						
Soil type	**OC (%)**	**pH ($CaCl_2$)**	**K_F (mL/g)**	**K_{Foc} (mL/g)**	**1/n (-)**	**Evaluated on EU level**
AXXa	2.7	6.2	0.88	33	0.91	Yes / EFSA (2013)
AIII	0.4	6.8	0.41	102	0.87	Yes / EFSA (2013)
SLS	0.9	6.9	0.86	95	0.90	Yes / EFSA (2013)
HCB	4.9	7.1	7.07	144	0.90	Yes / EFSA (2013)
SSC	1.15	4.8	2.54	221	0.91	Yes / EFSA (2013)
Arithmetic mean (n=5)				119	0.90	
Geometric mean (n=5)				100.4	-	
pH-dependency				No		

Table 8.5-8: Summary of soil adsorption/desorption for BYH 18636-sulfonamide carboxylic acid (M03)

BYH 18636-sulfonamide-carboxylic acid (M03)						
Soil type	**OC (%)**	**pH ($CaCl_2$)**	**K_F (mL/g)**	**K_{Foc} (mL/g)**	**1/n (-)**	**Evaluated on EU level**
AXXa	1.70	6.3	0.07	3.9	0.97	Yes / EFSA (2013)
AIII	0.91	6.7	0.06	6.5	0.72	Yes / EFSA (2013)
SLS	1.3	7.5	0.24	9.8	0.62	Yes / EFSA (2013)
HCB	4.1	7.0	0.46	11.3	0.58	Yes / EFSA (2013)
SSC	2.4	5.5	0.09	7.3	0.79	Yes / EFSA (2013)
Arithmetic mean (n=5)				7.8	0.74	
Geometric mean (n=5)				7.3	-	
pH-dependency				No		

Table 8.5-9: Summary of soil adsorption/desorption for BYH 18636-MMT (M21)

BYH 18636-MMT (M21))						
Soil type	**OC (%)**	**pH ($CaCl_2$)**	**K_F (mL/g)**	**K_{Foc} (mL/g)**	**1/n (-)**	**Evaluated on EU level**
AXXa	2.7	6.2	0.13	4.7	1.03	Yes / EFSA (2013)
AIII	0.4	6.8	0.07	17.8	1.01	Yes / EFSA (2013)
SLS	0.9	6.9	0.13	14.7	1.00	Yes / EFSA (2013)
HCB	4.9	7.1	0.76	15.5	0.97	Yes / EFSA (2013)
SSC	1.15	4.8	0.34	29.8	1.00	Yes / EFSA (2013)
Arithmetic mean (n=5)				16.4	1.00	
Geometric mean (n=5)				14.2	-	
pH-dependency				No		

Table 8.5-10: Summary of soil adsorption/desorption for BYH 18636-triazolinonecarboxamide

BYH 18636-triazolinone-carboxamide / AE 1430601							
Soil Name	**Soil Type**	**OC (%)**	**pH ($CaCl_2$)**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
Not applicable, HPLC method OECD 121					18	1	Yes / EFSA (2013)
Geometric mean (n = 1)					-	-	
Arithmetic mean (n=1)					-	-	
pH-dependency y/n					n		

8.5.3 Column leaching (KCP 9.1.2.1)

Column leaching studies were not required for the active substance mesotrione according to Regulation (EU) N° 283/2013 (reference to EFSA peer review mesotrione, 2016).

No column leaching studies were conducted with thiencarbazone-methyl.

8.5.4 Lysimeter studies (KCP 9.1.2.2)

Lysimeter studies were not required for the active substance mesotrione according to Regulation (EU) N° 283/2013 (reference to EFSA peer review mesotrione, 2016).

No lysimeter studies were conducted with thiencarbazone-methyl.

8.5.5 Field leaching studies (KCP 9.1.2.3)

Field leaching studies were not required for the active substance mesotrione according to Regulation (EU)

N° 283/2013 (reference to EFSA peer review mesotrione, 2016).

No field leaching studies were conducted with thiencarbazone-methyl.

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 substances.

Evaluation by zRMS	**Degradation in the water/sediment systems (KCP 9.2)**
Comments	No new data. Information in Section 8.6 is available in dossiers of active substances: mesotrione and thiencarbazone-methyl and can be extrapolated to formulation. Therefore no studies have been conducted. EU agreed data were correctly reported.

8.6.1 Mesotrione and its metabolites

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

Mesotrione Distribution (max. water 98.7 % after 0 d, max. sediment 4.3 % after 1 d)										
Water / sediment system (radiolabel)	**pH water**	**pH sed.**	**t.°C**	**$DegT_{50}$ whole syst. (d)**	**$DegT_{90}$ whole syst. (d) [b]**	**$DissT_{50}$ water (d)**	**$DissT_{90}$ water (d) [b]**	**$DissT_{50}$/ $DissT_{90}$ sed. (d)**	**Kinetic model**	**Evaluated on EU level / Reference**
Basing (Phenyl)	7.86	7.86	20	2.6	8.6	2.5	8.3	n.a.	SFO	Yes, EFSA (2016)
Basing (Cyclohexane)	7.86	7.86	20	4.2	13.8	4.2	13.8	n.a.	SFO	
Virginia (Phenyl)	7.40	7.40	20	5.5	18.3	5.3	17.5	n.a.	SFO	
Virginia (Cyclohexane)	7.40	7.40	20	7.2	24.1	7.0	23.2	n.a.	SFO	
Calwich (Phenyl)	8.4/7.8 (aerobic/ anaerobic)	7.6	20	6.6	21.8	6.7	22.2	n.a.	SFO	
Swiss (Phenyl)	7.4/7.5 (aerobic / anaerobic)	6.1	20	11.1	36.7	11.0	37.0	n.a.	SFO	
Geometric mean (n=6) at 20 °C [a]				5.6	18.6	5.5	18.4	-		

[a] normalized using a Q10 of 2.58
[b] values presented in the RAR of mesotrione (2015)

Table 8.6-2: Summary of observed metabolites

MNBA Water/sediment system	Max. in water 7.4% after 3 days. Max. in sediment <1%. Max. in total system 7.4% after 3 days.	Evaluated on EU level / EFSA, 2016

AMBA Water/sediment system	Max. in water 15.8% after 46 days. Max. in sediment 8.8% after 46 days. Max. in total system 24.6% after 46 days.	Evaluated on EU level / EFSA, 2016
SYN546974 Water/sediment system	Max. in water 9.4% after 29 days. Max. in sediment 25.6% after 102 days. Max. in total system 33% after 29 days.	Evaluated on EU level / EFSA, 2016

zRMS comment
Information on degradation mesotrione and its metabolites: MNBA, AMBA, SYN 546974 in water/sediment systems are in accordance with EU agreed endpoints as reported in EFSA Journal 2016;14(3):4419.

8.6.2 Thiencarbazone-methyl and its metabolites

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

Thiencarbazone-methyl (max. in sediment 26.0% after 14 d)											
Water / sediment system	**pH water phase**	**pH sediment a)**	**t (°C)**	**DT_{50} / DT_{90} whole syst. (d)**	**Chi² (χ^2)**	**$DissT_{50}$ / $DissT_{90}$ water (d)**	**Chi² (χ^2)**	**$DissT_{50}$ / $DissT_{90}$ sed. (d)**	**Chi² (χ^2)**	**Method of calc.**	**Evaluated on EU level**
Hoenniger sandy loam	6.7	5.0	20	21.9 / 72.7	2.5	11.7 / 58.8	5.8	21.5 / 71.4	10.1	SFO	Yes / EFSA (2013)
Clayton loamy sand	5.7	5.2	20	31.3 / 103.8	2.9	25.6 / 85.1	5.7	38.2 / 126.9	14.5	SFO	Yes / EFSA (2013)
Geometric mean (n=2)				26.2 b) / 86.9							

a) Measured in 0.01 M $CaCl_2$.
b) A value of 26.1 days was used in the risk assessment.

Table 8.6-4: Summary of degradation in water/sediment of BYH18636-carboxylic acid (M01)

BYH 18636-carboxylic acid (M01) (max. in water 25.7% after 14 d; max. in sediment 14.1% after 30 d)											
Water / sediment system	**pH water phase**	**pH sediment a)**	**t (°C)**	**DT_{50} / DT_{90} whole syst. (d)**	**Chi² (χ^2)**	**$DissT_{50}$ / $DissT_{90}$ water (d)**	**Chi² (χ^2)**	**$DissT_{50}$ / $DissT_{90}$ sed. (d)**	**Chi² (χ^2)**	**Method of calc.**	**Evaluated on EU level**
Hoenniger	6.7	5.0	20	29.1 /	12.9	79.5 /	11.8	62.9 /	9.1	SFO	Yes /

BYH 18636-carboxylic acid (M01) (max. in water 25.7% after 14 d; max. in sediment 14.1% after 30 d)											
Water / sediment system	**pH water phase**	**pH sedi-ment [a)]**	**t (°C)**	**DT_{50} / DT_{90} whole syst. (d)**	**Chi^2 (x^2)**	**$DissT_{50}$ / $DissT_{90}$ water (d)**	**Chi^2 (x^2)**	**$DissT_{50}$ / $DissT_{90}$ sed. (d)**	**Chi^2 (x^2)**	**Method of calc.**	**Evalua-ted on EU level**
sandy loam				96.6		264		208.9			EFSA (2013)
Clayton loamy sand	5.7	5.2	20	32.4 / 107.7	12.3	138.5 / 460.1	5.7	88.3 / 293.4	16.3	SFO	Yes / EFSA (2013)
Geometric mean (n=2)				30.7 / 102							

a) Measured in 0.01 M $CaCl_2$.

Table 8.6-5: Summary of degradation in water/sediment of BYH 18636-sulfonamide (M15)

BYH 18636-sulfonamide (M15) (max. in water 4.3% after 59 d; max. in sediment 2.7% after 59 d)											
Water / sediment system	**pH water phase**	**pH sedi-ment [a)]**	**t (°C)**	**DT_{50} / DT_{90} whole syst. (d)**	**Chi^2 (x^2)**	**$DissT_{50}$ / $DissT_{90}$ water (d)**	**Chi^2 (x^2)**	**$DissT_{50}$ / $DissT_{90}$ sed. (d)**	**Chi^2 (x^2)**	**Method of calc.**	**Evalua-ted on EU level**
Hoenniger sandy loam	6.7	5.0	20	23.3 / -	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	Yes / EFSA (2013)
Clayton loamy sand	5.7	5.2	20	6.5 / -	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	Yes / EFSA (2013)
Geometric mean (n=2)				12.3							

n.r.: not reported.
a) Measured in 0.01 M $CaCl_2$.

Table 8.6-6: Summary of observed metabolites

BYH18636-carboxylic acid	Max. in water/sediment: 37.1% after 14 d (Clayton) Max. in water: 24.6% after 30 d (Clayton) Max. in sediment: 13.0% after 14 d (Hoenniger)	Evaluated on EU level y/n/ Reference Y/EFSA, 2013
BYH 18636-sulfonamide carboxylic acid	Distribution (maximum in water 45.6% after 120 d; maximum in sediment 21.3 % after 120 d). No clear decline in residues therefore no degradation/dissipation rates were calculated. Default 1000 d used in exposure assessment. Max. in water/sediment: 66.9% after 120 d (Hoenniger) Max. in water: 45.6% after 120 d (Hoenniger) Max. in sediment: 21.3% after 120 d (Hoenniger)	
BYH 18636-MMT	Distribution (maximum in water 24.9% after 90 d; maximum in sediment 7.8 % after 120 d). No clear decline in residues therefore no degradation/dissipation rates were calculated. Default 1000 d used in exposure assessment. Max. in water/sediment: 30.7% after 92 d (Clayton) Max. in water: 24.9% after 92 d (Clayton)	

	Max. in sediment: 7.8% after 120 d (Clayton)	
BYH 18636-dicarboxy sulfonamide	Distribution (maximum in water 18.9% after 120 d; maximum in sediment 6.1 % after 120 d). No clear decline in residues therefore no degradation/dissipation rates were calculated. Default 1000 d used in exposure assessment. Max. in water/sediment: 23.9% after 120 d (Clayton) Max. in water: 18.9% after 120 d (Clayton) Max. in sediment: 0%	
BYH 18636-sulfonamide	Distribution (maximum in water 4.3% after 59 d; maximum in sediment 2.7 % after 59 d). Calculated SFO DT50 23.3 days (Hoenniger) and 6.5 days (Clayton), geomean 12.3 days. Max. in water/sediment: 7.0% after 59 d (Clayton) Max. in water: 4.3% after 59 d (Clayton) Max. in sediment: 2.7% after 59 d (Clayton)	
~~**AE 0001789-sulfamoyl benzoic acid**~~	~~Max. in water/sediment 5.7/1.8%~~	

zRMS comment
Information on degradation thiencarbazone-methyl and its metabolites in water/sediment systems are in accordance with EU agreed endpoints as reported in EFSA Journal 2013;11(7):3270.

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

8.7.1 Justification for new endpoints

/

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

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

Use No.	1 (covering 2, 3, 4)
Crop	Maize
Application rate (g as/ha)	Mesotrione: 75 Thiencarbazone-methyl: 15 Metabolites: AR_{parent}*MCF*MOS
Number of applications/interval	1/-
Crop interception (%)	25
Depth of soil layer (relevant for plateau concentration) (cm)	5 (no tillage)

AR = application rate, MCF = molar correction factor, MOS = maximum occurrence in soil.

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

Compound	Molecular weight (g/mol)	Max. occurrence (%)	DT50 (days)	Value in accordance to EU endpoint y/n/ Reference
Mesotrione	339	-	34.3 d (Kinetics: DFOP, Maximum (worst case) from laboratory studies)	Y, EFSA, 2016
MNBA	245	57.2	N/A	Y, EFSA, 2016
AMBA	215	9.7	N/A	Y, EFSA, 2016
Thiencarbazone-methyl	390.4	-	53.2 (SFO, worst-case unnormalized lab)	Y, EFSA, 2013
BYH 18636-carboxylic acid	376.4	53.6	g = 0.640 $DT_{50\ fast}$ = 13.1 (k1 = 0.0529 day^{-1}) $DT_{50\ slow}$ = 346.57 (k2 = 0.002 day^{-1}) (DFOP, worst-case unnormalized field)	Y, EFSA, 2013
BYH 18636-sulfonamide	235.3	15.6	48 (SFO, worst-case unnormalized lab)	Y, EFSA, 2013
BYH 18636-sulfonamide carboxylic acid	221.3	21.2	26.6 (SFO, worst-case unnormalized lab)	Y, EFSA, 2013
BYH 18636-MMT	129.1	20.6	20.3 (SFO, worst-case unnormalized lab)	Y, EFSA, 2013
BYH 18636-triazolinone-carboxamide	172.1	8.1	34.5(unnormalized)	~~From French RR of Adengo Xtra (Bayer, 2016)~~ Y/ DAR of Thiencarbazone-methyl April 2012

8.7.2.1 Mesotrione and its metabolites

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

PEC_{soil} (mg/kg)		Maize	
		Actual	TWA
Initial		0.0750	-
Short term	24h	0.0735	0.0742
	2d	0.0720	0.0735

	4d	0.0692	0.0720
Long term	7d	0.0651	0.0699
	14d	0.0565	0.0653
	21d	0.0491	0.0611
	28d	0.0426	0.0573
	50d	0.0273	0.0472
	100d	0.0099	0.0322
Plateau concentration		Not required	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		Not required	-

PEC_{soil} of metabolites

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

PEC_{soil} (mg/kg)	maize	
	Actual	TWA
Initial	0.0310	-
Plateau concentration	Not required	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)	Not required	-

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

PEC_{soil} (mg/kg)	maize	
	Actual	TWA
Initial	0.0046	-
Plateau concentration	Not required	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)	Not required	-

Evaluation by zRMS PL	**PECsoil (KCP 9.1.3)**
Modelling	The assumptions of calculations are acceptable. The predicted environmental concentrations in soil (PECsoil) of mesotrione and its metabolites: MNBA and AMBA were calculated according to recommendations of the FOCUS workgroup on degradation kinetics using: - the maximum application rate: 0.2l of Walkover Trio / GLOB2112dH/ha/per season i.e. 75 g mesotrione/ha, considering 25% interception for maize. It was assumed that the active substance were distributed in the top 5 cm soil layer with a soil bulk density of 1.5 g/mL.

	The calculated PECs values are presented in Tables from 8.7-3 to 8.7-5. The applicant correctly calculated the PECsoil for mesotrione and its metabolites: MNBA and AMBA. The results of PECsoil calculations are appropriate to be used for the subsequent risk assessment for soil organisms.
Agreed Endpoints	**Mesotrione:** Initial PEC_{soil}: 0.075 mg/kg **Metabolite of mesotrione:** **MNBA** Initial PEC_{soil}: 0.031 mg/kg **AMBA** Initial PEC_{soil}: 0.0046 mg/kg

8.7.2.2 Thiencarbazone-methyl and its metabolites

Table 8.7-6: PEC_{soil} for thiencarbazone-methyl on maize

PEC_{soil} (mg/kg)		Maize	
		Actual	TWA
Initial		0.0150	-
Short term	24h	0.0148	0.0149
	2d	0.0146	0.0148
	4d	0.0142	0.0146
Long term	7d	0.0137	0.0143
	14d	0.0125	0.0137
	21d	0.0114	0.0131
	28d	0.0104	0.0126
	50d	0.0078	0.0110
	100d	0.0041	0.0084
Plateau concentration (5 cm)		0.0001	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		0.0151	-

PEC_{soil} of metabolites

Table 8.7-7: PEC_{soil} for BYH 18636-carboxylic acid on maize

PEC_{soil} (mg/kg)	Maize	
	Actual	TWA
Initial	~~0.0030~~	-

		0.0078~~7~~	
Short term	24h	~~0.0030~~ 0.0075	~~0.0030~~ 0.0076
	2d	~~0.0030~~ 0.0072	~~0.0030~~ 0.0075
	4d	~~0.0030~~ 0.0068	~~0.0030~~ 0.0073
Long term	7d	~~0.0030~~ 0.0062	~~0.0030~~ 0.0069
	14d	~~0.0030~~ 0.0051	~~0.0030~~ 0.0063
	21d	~~0.0030~~ 0.0043	~~0.0030~~ 0.0057
	28d	~~0.0030~~ 0.0038	~~0.0030~~ 0.0053
	50d	0.0029	~~0.0030~~ 0.0044
	100d	~~0.0027~~ 0.0023	~~0.0030~~ 0.0035
Plateau concentration (5 cm) after year 10		~~0.0034~~ 0.0026	-
$PEC_{accumulation}$ (PEC_{act} + $PEC_{soil\ plateau}$)		~~0.0064~~ 0.0103	-

Table 8.7-8: PEC_{soil} for BYH 18636-sulfonamide on maize

PEC_{soil} (mg/kg)		Maize	
		Actual	TWA
Initial		0.0014	-
Short term	24h	0.0014	0.0014
	2d	0.0014	0.0014
	4d	0.0013	0.0014
Long term	7d	0.0013	0.0014
	14d	0.0012	0.0013
	21d	0.0011	0.0012
	28d	0.0009	0.0012
	50d	0.0007	0.0010
	100d	0.0003	0.0008

Table 8.7-9: PEC_{soil} for BYH 18636-sulfonamide carboxylic acid on maize

PEC_{soil} (mg/kg)		Maize	
		Actual	TWA
Initial		0.0018	-
Short term	24h	0.0018	0.0018

	2d	0.0017	0.0018
	4d	0.0016	0.0017
Long term	7d	0.0015	0.0017
	14d	0.0013	0.0015
	21d	0.0011	0.0014
	28d	0.0009	0.0013
	50d	0.0005	0.0010
	100d	0.0001	0.0006

Table 8.7-10: PEC$_{soil}$ for BYH 18636-MMT on maize

PEC$_{soil}$ (mg/kg)		Maize	
		Actual	TWA
Initial		0.0010	-
Short term	24h	0.0010	0.0010
	2d	0.0010	0.0010
	4d	0.0009	0.0010
Long term	7d	0.0008	0.0009
	14d	0.0006	0.0008
	21d	0.0005	0.0007
	28d	0.0004	0.0007
	50d	0.0002	0.0005
	100d	0.0000	0.0003

Table 8.7-11: PEC$_{soil}$ for BYH 18636-triazolinone-carboxamide on maize

PEC$_{soil}$ (mg/kg)		Maize	
		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	0.0004
	28d	0.0003	0.0004
	50d	0.0002	0.0003
	100d	0.0001	0.0002

8.7.2.3 PEC$_{soil}$ of GLOB2112dH

Table 8.7-12: PEC$_{soil}$ for GLOB2112dH on maize

Active substance/ reparation	Application rate (g/ha)	PEC$_{act}$ (mg/kg)
GLOB2112dH	243	0.2430

*based on a density of the formulation of 1.2153 g/mL

Evaluation by zRMS PL	**PECsoil (KCP 9.1.3)**
Modelling	The assumptions of calculations are acceptable. The predicted environmental concentrations in soil (PECsoil) of thiencarbazone-methyl and its metabolites: BYH 18636-carboxylic acid, BYH 18636-sulfonamide, BYH 18636-sulfonamide carboxylic acid, BYH 18636-MMT and BYH 18636-triazolinone-carboxamide were calculated according to recommendations of the FOCUS workgroup on degradation kinetics using: - the maximum application rate: 0.2l of Walkover Trio (GLOB2112dH)/ha/per season i.e. 15 g thiencarbazone-methyl /ha, considering 25% interception for maize. It was assumed that the active substance were distributed in the top 5 cm soil layer with a soil bulk density of 1.5 g/mL. The calculated PECs values are presented in Tables from 8.7-6 to 8.7-11. The applicant correctly calculated the PECsoil for thiencarbazone-methyl and its metabolites apart PECsoil for BYH 18636-carboxylic acid. zRMS recalculated these values. **Walkover Trio (GLOB2112dH)** The applicant properly calculated the PECsoil for the formulation Walkover Trio (GLOB2112dH). The results are shown in the Table 8.7-12. The calculated PECsoil values for the formulation Walkover Trio (GLOB2112dH), thiencarbazone-methyl and its metabolites are appropriate to be used for the subsequent risk assessment for soil organisms.
Agreed Endpoints	**Thiencarbazone-methyl:** Initial PEC$_{soil}$: 0.015 mg/kg **Metabolite of thiencarbazone-methyl:** **BYH 18636-carboxylic acid** Initial PEC$_{soil}$: 0.0078~~7~~ mg/kg PEC$_{accumulation}$ = 0.0103 mg/kg **BYH 18636-sulfonamide** Initial PEC$_{soil}$: 0.0014 mg/kg **BYH 18636-sulfonamide carboxylic acid**

	Initial PEC_{soil}: 0.0018 mg/kg **BYH 18636-MMT** Initial PECsoil: 0.0010 mg/kg **BYH 18636-triazolinone-carboxamide** Initial PECsoil: 0.0005 mg/kg **Formulation: Walkover Trio (GLOB2112dH)** PECact = 0.243 mg/kg

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

8.8.1 Justification for new endpoints

/

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

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

Use No.	1 (covering 2, 3, 4)
Crop	Maize
Application rate (g as/ha)	Mesotrione: 75 Thiencarbazone-methyl: 15
Number of applications/interval (d)	1/-
Relative application date	7 days after emergence
Absolute aplication date (MACRO)*	08.05 (128)
Crop interception (%)	25
Frequency of application	annual
Models used for calculation	FOCUS PEARL v5.5.5, FOCUS PELMO v6.6.4, MACRO 5.5.4

*Based on the emergence date for maize in the Chateaudun scenario as given by AppDate 3.06

Evaluation by zRMS	**PECgw (KCP 9.2.4)**
Comments	The Applicant did not provide detailed information on application dates used for groundwater exposure assessment so the evaluator supplemented this data in the table below.

Crop	Scenario	Application dates
Maize	Châteaudun	08 May
	Hamburg	12 May

		Kremsmünster	12 May
		Okehampton	01 Jun
		Piacenza	22 May
		Porto	08 May
		Sevilla	14 Mar
		Thiva	27 Apr

Metabolite BYH 18636-MMT – implementation in FOCUS PEARL
For consideration of the biphasic (DFOP) kinetics in the groundwater simulation, EFSA (2013) recommended a procedure as follows: for modelling purposes the parent application dose is doubled and parent degrades to a transient MMT compartment with formation fraction of 0.47 and the following modelling parameters: DT50 = 0.5 days, Kom = 100000 and 1/n = 1.
The transient MMT compartment degrades to fast degrading MMT compartment with formation fraction of 0.932, and to slow degrading compartment with formation fraction of 0.068. Resulting 80th percentile concentrations of MMT fast and MMT slow are added together and divided by 2.
In the presented simulation, the DFOP kinetics for metabolite BYH 18636-MMT will be implemented as recommended by EFSA (2013), however omitting the doubling step of the application rate and subsequent PEC division. Since BYH 18636-MMT exhibits concentration linear sorption (1/n = 1.0), in this particular case there is no need to compensate for concentration effects in soil adsorption. The fast and slow phase parts of BYH 18636-MMT were defined as individual compounds, and the resulting PECgw were summed.

Metabolite BYH 18636-MMT – implementation in FOCUS PELMO
In order to account for multiple metabolites, PELMO requires a split of the parent degradation rate by multiplying it with the formation fraction of the individual metabolite. For the present case, the sum of molar formation fractions from the parent to the direct metabolites BYH 18636-sulfonamide, BYH 18636-carboxylic acid and BYH 18636-MMT accounts with 0.375, 0.382 and 0.470, respectively, for more than 1. This cannot be implemented directly into PELMO. Therefore, the pathway was split and multiple runs were made.

8.8.2.1 Mesotrione and its metabolites

Table 8.8-2: Input parameters related to active substance mesotrione and metabolites for PEC_{gw} calculations

Compound	Mesotrione	MNBA	AMBA	Value in accordance with EU endpoint / Reference
Molecular weight (g/mol)	339	245	215	LoEP mesotrione Phys.-chem. Properties (EFSA, 2016)
Water solubility (mg/L):	160 at pH 7 and 20°C	32400 at 20°C	23000 at 20°C	LoEP mesotrione Phys.-chem. Properties (EFSA, 2016)
Saturated vapour pressure	0 Pa at 20°C			Worst-case estimate

Compound	Mesotrione	MNBA	AMBA	Value in accordance with EU end-point / Reference
(Pa):				
DT_{50} in soil (d)	Scenario 1: 4 Scenario 2: 27.88 Scenario 3: 0.54 Scenario 4: 14.2	3.4 (SFO, normalized, geometric mean $DT50_{lab}$)	14.5 (SFO, normalized, geometric mean $DT50_{lab}$)	LoEP mesotrione Fate and behavior (EFSA, 2016) mesotrione : 4 different scenarios because of pH dependency of degradation
Transformation rate	Scenario 1: 0.173287 Scenario 2: 0.024862 Scenario 3: 1.28361 Scenario 4: 0.048813 To MNBA	0.0509668 to AMBA 0.1529003 to CO_2	0.047803 to CO_2	Calculated by PELMO 6.6.4 from DT_{50} and formation fraction
K_{foc} (mL/g)/K_{fom}	Scenario 1: 14/8.12 Scenario 2: 156.6/90.84 Scenario 3: 17.39/10.12 Scenario 4: 52.2/30.28	3.2/1.86 (worst case)	Scenario 1: 18.1/10.50 Scenario 2: 105.61/61.26 Scenario 3: 21.8/12.65 Scenario 4: 48.02/27.85	LoEP mesotrione Fate and behavior (EFSA, 2016) 4 different scenarios due to pH dependency of sorption
1/n	Scenario 1: 0.97 (value from worst-case soil) Scenario 2, 3 and 4: 0.94 (median)	0.90 (FOCUS default)	Scenario 1: 0.82 (value from worst-case soil) Scenario 2, 3 and 4: 0.85 (arithmetic mean)	LoEP mesotrione Fate and behavior (EFSA, 2016) 4 different scenarios due to pH dependency of sorption
Plant uptake factor	0			FOCUS recommendation
Formation fraction	N/A	1 from parent mesotrione	0.25 from metabolite MNBA	LoEP mesotrione Fate and behavior (EFSA, 2016)

Table 8.8-3: PEC_{gw} for mesotrione and metabolites on maize with FOCUS PEARL 5.5.5

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)		
		Mesotrione	MNBA	AMBA
Maize Scenario 1	Châteaudun	< 0.001	< 0.001	< 0.001
	Hamburg	< 0.001	0.003	0.012
	Kremsmünster	< 0.001	0.001	0.011
	Okehampton	0.001	0.004	0.034
	Piacenza	< 0.001	< 0.001	0.002
	Porto	< 0.001	< 0.001	< 0.001

	Sevilla	< 0.001	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001	< 0.001
Maize Scenario 2	Châteaudun	< 0.001	0.003	< 0.001
	Hamburg	0.002	0.046	0.011
	Kremsmünster	0.001	0.008	0.001
	Okehampton	0.003	0.022	0.003
	Piacenza	0.002	0.007	0.002
	Porto	< 0.001	0.006	< 0.001
	Sevilla	< 0.001	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001	< 0.001
Maize Scenario 3	Châteaudun	< 0.001	< 0.001	< 0.001
	Hamburg	< 0.001	< 0.001	0.006
	Kremsmünster	< 0.001	< 0.001	0.007
	Okehampton	< 0.001	0.002	0.019
	Piacenza	< 0.001	< 0.001	0.001
	Porto	< 0.001	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001	< 0.001
Maize Scenario 4	Châteaudun	0.002	0.003	< 0.001
	Hamburg	0.010	0.030	0.012
	Kremsmünster	0.008	0.008	0.005
	Okehampton	0.018	0.023	0.009
	Piacenza	0.004	0.003	0.002
	Porto	< 0.001	0.001	< 0.001
	Sevilla	< 0.001	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001	< 0.001

Table 8.8-4: PEC$_{gw}$ for mesotrione and metabolites on maize with FOCUS PELMO 6.6.4

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)		
		Mesotrione	**MNBA**	**AMBA**
Maize Scenario 1	Châteaudun	< 0.001	< 0.001	< 0.001
	Hamburg	< 0.001	< 0.001	0.003
	Kremsmünster	< 0.001	0.001	0.011
	Okehampton	0.002	0.006	0.031
	Piacenza	< 0.001	< 0.001	0.002
	Porto	< 0.001	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001	< 0.001

Maize Scenario 2	Châteaudun	< 0.001	0.003	< 0.001
	Hamburg	0.002	0.057	0.007
	Kremsmünster	0.001	0.014	0.001
	Okehampton	0.003	0.035	0.003
	Piacenza	0.003	0.012	0.002
	Porto	0.001	0.013	< 0.001
	Sevilla	< 0.001	0.001	< 0.001
	Thiva	< 0.001	0.002	< 0.001
Maize Scenario 3	Châteaudun	< 0.001	< 0.001	< 0.001
	Hamburg	< 0.001	< 0.001	0.002
	Kremsmünster	< 0.001	< 0.001	0.007
	Okehampton	< 0.001	0.005	0.018
	Piacenza	< 0.001	< 0.001	0.002
	Porto	< 0.001	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001	< 0.001
Maize Scenario 4	Châteaudun	0.001	0.003	< 0.001
	Hamburg	0.007	0.023	0.007
	Kremsmünster	0.006	0.011	0.004
	Okehampton	0.020	0.027	0.008
	Piacenza	0.005	0.005	0.003
	Porto	0.001	0.002	< 0.001
	Sevilla	< 0.001	< 0.001	< 0.001
	Thiva	< 0.001	0.001	< 0.001

Table 8.8-5: PEC$_{gw}$ for mesotrione and metabolites on maize with MACRO 5.5.4

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)		
		Mesotrione	MNBA	AMBA
Maize Scenario 1	Châteaudun	< 0.001	0.000117	0.000114
Maize Scenario 2	Châteaudun	0.000164	0.00223	< 0.001
Maize Scenario 3	Châteaudun	0	< 0.001	0.000288
Maize Scenario 4	Châteaudun	0	< 0.001	< 0.001

The PECgw of mesotrione and its metabolites is below 0.1 µg/L in all scenarios. Therefore, the risk to groundwater with regard to mesotrione and its metabolites is acceptable for the intended use of GLOB2112dH.

Evaluation by zRMS	**PECgw (KCP 9.2.4)**
Modelling	For the active substance mesotrione and its metabolites MNBA, AMBA the calculations presented here are accepted. Input parameters used in FOCUS ground water modelling are correct. The applicant used appropriate models for ground water FOCUS-PEARL 5.5.5, FOCUS-PELMO 6.6.4 and FOCUS MACRO 5.5.4. PEC_{GW} values were calculated for intended use on maize.
PECgw	Results of modelling with FOCUS PELMO 6.6.4 and PEARL 5.5.5 show that the active substance mesotrione and its metabolites MNBA, AMBA are not expected to penetrate into groundwater at concentrations of ≥ 0.1 µg/L in the intended use for all scenarios. Moreover, PECgw values for active substance mesotrione and its metabolites MNBA, AMBA calculated by means the FOCUS MACRO 5.5.4. are below 0.1 µg/L for Châteaudun scenario.

8.8.2.2 Thiencarbazone-methy and its metabolites

Table 8.8-6: Input parameters related to active substance thiencarbazone-methyl and metabolites for PEC_{gw} calculations

Compound	Thiencarbazone-methyl	BYH 18636-carboxylic acid	BYH 18636-sulfonamide	BYH 18636-sulfonamide-carboxylic acid	BYH 18636-MMT	BYH 18636-triazolinone-carboxamide*	Value in accordance with EU end-point y/n/ Reference*
Molecular weight (g/mol)	390.4	376.4	235.3	221.3	129.1	172.1	Y, EFSA 2013
Water solubility (mg/L)	20°C: 436 30°C: 872	20°C: 10000 (default) 30°C: N/A	20°C: 10000 (default) 30°C: N/A	20°C: 10000 (default) 30°C: N/A	20°C: 10000 (default) 30°C: N/A	20°C: 10000 (default) 30°C: 20000	Y, EFSA 2013 30°C: value at 20°C x 2
Saturated vapour pressure (Pa):	20°C: 8.8×10^{-14} 30°C: 3.52×10^{-13}	20°C: 1×10^{-19} 30°C: N/A	20°C: 1×10^{-19} 30°C: N/A	20°C: 1×10^{-19} 30°C: N/A	20°C: 1×10^{-19} 30°C: N/A	20°C: 1×10^{-19} 30°C: 4×10^{-19}	Y, EFSA 2013 30°C: value at 20°C x 4
DT_{50} in soil (d)	11.6 (geomean, lab, 20°C pF2 Q10 2.58)	62.4 (geomean, field, 20°C pF2 Q10 2.58)	11.2 (geomean, lab, 20°C pF2 Q10 2.58)	8.1 (geomean, lab, 20°C pF2 Q10 2.58)	0.5 (transient) 3.9 (geomean, lab, fast phase, 20°C pF2 Q10 2.58) 85.4 (geomean, lab, slow phase, 20°C pF2 Q10 2.58)	14.9 (geomean, lab, 20°C pF2 Q10 2.58)	Y, EFSA 2013
K_{foc} (mL/g)/K_{fom}	82.8/48.0 (geomean, n=5)	11.7/6.8 (geomean, n=5)	100.4/58.2 (geomean, n=5)	7.3/4.2 (geomean, n=5)	Transient: 10000 Fast and slow: 14.2/8.2 (geomean, n=5)	18/10.4	Y, EFSA 2013 Geometric mean used in accordance with EFSA Journal 2014;12(5):3662.
1/n	0.906 (arithmetic	0.919	0.90 (arithmetic	0.74 (arithmetic	Transient: 1	1.00	Y, EFSA 2013

Compound	Thiencarbazone-methyl	BYH 18636-carboxylic acid	BYH 18636-sulfonamide	BYH 18636-sulfonamide-carboxylic acid	BYH 18636-MMT	BYH 18636-triazolinone-carboxamide*	Value in accordance with EU end-point y/n/ Reference*
	mean, n=4)	(arithmetic mean, n=5)	mean, n=5)	mean, n=5)	Fast and slow: 1.00 (arithmetic mean, n=1)		
Plant uptake factor	0	0	0	0	0	0	Y, EFSA 2013
Formation fraction	N/A	0.382 from parent	0.375 from parent	1 from BYH 18636-carboxylic acid 0.794 from BYH 18636-sulfonamide	0.47 from parent to MMT transient 0.932 from MMT transient to MMT fast 0.068 from MMT transient to MMT slow	N/A	Y, EFSA 2013
Rate constant	0.05976	0.01111	0.06189	0.08557	Transient: 1.38629 Fast: 0.17773 Slow: 0.00812	0.04652	Y, EFSA 2013 Calculated as $\ln 2/DT_{50}$
Transformation rate	Pathway 1: 0.02283 to BYH 18636-carboxylic acid 0.02241 to BYH 18636-sulfonamide 0.01452 to CO_2 Pathway 2: 0.02808 to transient MMT 0.03167 to CO_2	Pathway 1: 0.01111 to BYH 18636-sulfonamide-carboxylic acid	Pathway 1: 0.04914 to BYH 18636-sulfonamide-carboxylic acid 0.01275 to CO_2	Pathway 1: 0.08557 to CO_2	Pathway 2: 1.2920 from MMT transient to MMT fast 0.09427 from MMT transient to MMT slow 0.17773 from MMT fast to CO_2 0.00812 from MMT slow to CO_2	0.04652 to CO_2	Y, EFSA 2013 Calculated as $\ln 2/DT_{50}$*ff

*Modelled as applied substance with the application rate of parent adjusted for molecular weight ratio (172.1/390.4) and the maximum occurrence of 8.1% AR in the soil photolysis study

Table 8.8-7: PEC_{gw} for thiencarbazone-methyl and metabolites on maize with FOCUS PEARL 5.5.5

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)							
		Thiencarbazone-methyl	BYH 18636-carboxylic acid	BYH 18636-sulfonamide	BYH 18636-sulfonamide-carboxylic acid	BYH 18636-MMT transient	BYH 18636-MMT fast	BYH 18636-MMT slow	BYH 18636-triazolinone-carboxamide
Maize	Châteaudun	< 0.001	0.406	< 0.001	0.0154	< 0.001	< 0.001	0.0203	0.0010
	Hamburg	< 0.001	0.660	< 0.001	0.0251	< 0.001	< 0.001	0.0312	0.0037
	Kremsmünster	< 0.001	0.365	< 0.001	0.0150	< 0.001	< 0.001	0.0163	0.0019
	Okehampton	< 0.001	0.371	< 0.001	0.0125	< 0.001	< 0.001	0.0158	0.0030
	Piacenza	< 0.001	0.314	< 0.001	0.0178	< 0.001	< 0.001	0.0161	< 0.001
	Porto	< 0.001	0.190	< 0.001	0.0029	< 0.001	< 0.001	0.0093	< 0.001
	Sevilla	< 0.001	0.106	< 0.001	0.0027	< 0.001	< 0.001	0.0084	< 0.001
	Thiva	< 0.001	0.379	< 0.001	0.0161	< 0.001	< 0.001	0.0234	< 0.001

Table 8.8-8: PEC_{gw} for thiencarbazone-methyl and metabolites on maize with FOCUS PELMO 6.6.4

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)							
		Thiencarbazone-methyl	BYH 18636-carboxylic acid	BYH 18636-sulfonamide	BYH 18636-sulfonamide-carboxylic acid	BYH 18636-MMT transient	BYH 18636-MMT fast	BYH 18636-MMT slow	BYH 18636-triazolinone-carboxamide
Maize	Châteaudun	< 0.001	0.361	< 0.001	0.015	< 0.001	< 0.001	0.019	0.001
	Hamburg	< 0.001	0.537	< 0.001	0.019	< 0.001	< 0.001	0.025	0.002
	Kremsmünster	< 0.001	0.399	< 0.001	0.015	< 0.001	< 0.001	0.019	0.002
	Okehampton	< 0.001	0.358	< 0.001	0.011	< 0.001	< 0.001	0.015	0.003
	Piacenza	< 0.001	0.306	< 0.001	0.012	< 0.001	< 0.001	0.014	0.001
	Porto	< 0.001	0.184	< 0.001	0.003	< 0.001	< 0.001	0.009	< 0.001

	Sevilla	< 0.001	0.111	< 0.001	0.002	< 0.001	< 0.001	0.008	< 0.001
	Thiva	< 0.001	0.291	< 0.001	0.012	< 0.001	< 0.001	0.017	< 0.001

Table 8.8-9: PEC$_{gw}$ for thiencarbazone-methyl and metabolites on maize with MACRO 5.5.4

Crop	**Scenario**	**80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)**							
		Thiencarbazone-methyl	**BYH 18636-carboxylic acid**	**BYH 18636-sulfonamide**	**BYH 18636-sulfonamide-carboxylic acid**	**BYH 18636-MMT transient**	**BYH 18636-MMT fast**	**BYH 18636-MMT slow**	**BYH 18636-triazolinone-carboxamide**
Maize	Châteaudun	< 0.001	0.269	< 0.001	0.00785 + < 0.001 = 0.00885	< 0.001	< 0.001	0.0134	0.00041

The PECgw of thiencarbazone-methyl and its metabolites is below 0.1 µg/L in all scenarios, except for the metabolite BYH 18636-carboxylic acid. An assessment of metabolite relevance in groundwater of BYH 18636-carboxylix acid is presented in the dRR B10. The groundwater relevance of this compound has previously been evaluated in the EU peer review procedure, and the component was agreed to be non-relevant. Therefore, the risk to groundwater with regard to thiencarbazone-methyl and its metabolites is acceptable for the intended use of GLOB2112dH.

Evaluation by zRMS	**PECgw (KCP 9.2.4)**
Modelling	For the active substance thiencarbazone-methyl and its metabolites: BYH 18636-carboxylic acid, BYH 18636-sulfonamide, BYH 18636-sulfonamide-carboxylic acid, BYH 18636-MMT, BYH 18636-triazolinone-carboxamide the calculations presented here are accepted. Input parameters used in FOCUS ground water modelling for active substance and its metabolites are correct. The applicant applied appropriate models for ground water FOCUS-PEARL 5.5.5, FOCUS-PELMO 6.6.4 and FOCUS MACRO 5.5.4. PEC$_{GW}$ values were calculated for intended use on maize.
PECgw	Results of modelling with FOCUS PELMO 6.6.4 and PEARL 5.5.5 show that the active substance thiencarbazone-methyl and its metabolites are not expected to penetrate into groundwater at concentrations of ≥ 0.1 µg/L in the intended use for all scenarios, except BYH 18636-carboxylic acid. Additionally, only for this metabolite: BYH 18636-carboxylic acid the PECgw value for the Châteaudun scenario is above 0.1 µg/L (i.e. 0.269 µg/L) after calculations by means FOCUS MACRO model. Therefore, for component BYH 18636-carboxylic acid, an assessment of metabolite relevance in groundwater is triggered and accordingly presented in dRR Section 10. The relevance of the groundwater metabolite BYH 18636-carboxylic acid has already been assessed at EU level (EU DAR (2012) of thiencarbazone-methyl), and the corresponding

	EFSA peer review conclusion (EFSA Journal; 11(7): 3270, 2013). In accordance with this assessment BYH 18636-carboxylic acid is not considered relevant.

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

8.9.1 Justification for new endpoints

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

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

Plant protection product	GLOB2112dH	
Use No.	1+3	2+4
Crop	Maize	
Application rate (g as/ha)*	Mesotrione: 75 Thiencarbazone-methyl: 15	Mesotrione: 48.75 Thiencarbazone-methyl: 9.75
Number of applications/interval (d)	1/-	
Application window	March-May, June-Sept (relevant for STEP 1 and 2 only)	
Application method	Ground spray	
CAM (Chemical application method)	CAM 2 – foliar linear	
Soil depth (cm)	4	
Models used for calculation	FOCUS STEPS 1-2 v3.2, FOCUS SWASH v5.3, FOCUS PRZM v4.3.1, FOCUS MACRO v5.5.4, FOCUS TOXWA v5.5.3, SWAN v5.0.0, EPAT v1.2	

*For the banded application, calculations at FOCUS Step 3 and 4 for the input pathways runoff and drainage are performed considering the average field application rate. For spray drift the spray drift values in the TOXSWA input files ('.txw' files) are manually adjusted to represent drift loadings of the nominal application rate.

Table 8.9-2: FOCUS Step 3 Scenario related input parameters for $PEC_{sw/sed}$ calculations for the application of GLOB2112dH

Crop	Scenario	Application window used in modelling*
Maize	D3	06/05-05/06
	D4	11/05-10/06
	D5	11/05-10/06
	D6	21/04-21/05
	R1	04/05-03/06
	R2	02/05-01/06
	R3	02/05-01/06
	R4	11/04-11/05

*window proposed in AppDate v3.06 at BBCH10

8.9.2.1 Mesotrione and its metabolites

Table 8.9-3: Input parameters related to active substance mesotrione and metabolites for $PEC_{sw/sed}$ calculations STEP ½ and 3(/4) (if necessary)

Compound	Mesotrione	MNBA	AMBA	SYN 546974	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	339	245	215	291	Y, EFSA, 2013
Saturated vapour pressure (Pa)	1.0 x 10^{-10}	-	-	-	Y, EFSA, 2013
Water solubility (mg/L)	160	32400	23000	160	Y, EFSA, 2013
K_{foc} (mL/g)/K_{fom}	156.7/90.84 at pH=5.1 52.2/30.28 at pH=6.5 17.4/10.12 at pH=7.9	3.2/1.86 (worst case, n=2, pH independent)	101.5/105.6 (linear/log fit) at pH=5.1 59.7/48.0 (linear/log fit) at pH=6.5 18.0/21.8 (linear/log fit) at pH=7.9	8021/4653 (geometric mean, n=5)	Y, EFSA, 2013
Freundlich Exponent 1/n	0.94	-	-	-	Y, EFSA, 2013
Plant Uptake	0				Worst-case
Wash-Off factor from Crop (1/mm)	0.05 (MACRO) 0.50 (PRZM)				Default in FOCUS SWASH 5.3
$DT_{50,soil}$ (d)	27.88 at pH=5.1 14.2 at pH=6.5 0.54 at pH=7.9	3.4*	14.5	0.1	Y, EFSA, 2013
$DT_{50,water}$ (d)	5.5	1000	1000	1000	Y, EFSA, 2013
$DT_{50,sed}$ (d)	Step 1-2: 5.6 Step 3-4: 1000	1000	1000	1000	Y, EFSA, 2013
$DT_{50,whole\ system}$ (d)	5.6	1000	1000	1000	Y, EFSA, 2013
Maximum occurrence observed (% molar basis with respect to the parent)	-	Soil: 57.2 Water: 7.4 Sediment: < 1 Total system: 7.9	Soil: 9.7 Water: 15.8 Sediment: 8.8 Total system: 24.6	Soil: - Water: 9.4 Sediment: 25.6 Total system: 33	Y, EFSA, 2013
Formation fraction in soil:	-	N/A	N/A	N/A	Y, EFSA, 2013

* the correct value accroding to EFSA Journal 2016;14(3):4419 is 3.6d instead 3.4d.

$PEC_{sw/sed}$

Table 8.9-4: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for mesotrione following single application of GLOB2112dH to maize – 75 g/ha

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)*	Max PEC_{sed} (µg/kg)
pH 5.1					
Step 1	---	21.37	-	7.57	32.40
Step 2					
Northern Europe	March-May	3.17	-	1.11	4.78
	June-Sept	3.17	-	1.11	4.78
Southern Europe	March-May	5.98	-	2.10	9.18
	June-Sept	4.58	-	1.61	6.98
Step 3					
Full dose rate					
D3	ditch	0.3935	Drift	0.02073	0.1037
D4	pond	0.04175	Drainage	0.03896	0.07975
D4	stream	0.3385	Drift	0.03378	0.06413
D5	pond	0.02331	Drainage	0.01881	0.04662
D5	stream	0.3437	Drift	0.01310	0.04935
D6	ditch	0.3954	Drift	0.02210	0.1143
R1	pond	0.05680	Run-off	0.03600	0.06392
R1	stream	1.201	Run-off	0.04953	0.2812
R2	stream	0.8774	Run-off	0.02785	0.2407
R3	stream	2.325	Run-off	0.09349	0.5126
R4	stream	2.672	Run-off	0.1306	0.7479
Banded application					
D3	ditch	0.3935	Drift	0.02073	0.1037
D4	pond	0.02081	Drainage	0.01939	0.04172
D4	stream	0.3377	Drift	0.01683	0.03256
D5	pond	0.01686	Drainage	0.009280	0.02556
D5	stream	0.3395	Drift	0.006232	0.02861
D6	ditch	0.3943	Drift	0.02078	0.1086
R1	pond	0.03216	Run-off	0.02027	0.03888
R1	stream	0.6013	Run-off	0.02560	0.1440
R2	stream	0.4248	Run-off	0.01440	0.1205
R3	stream	1.139	Run-off	0.04884	0.2612

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)*	Max PEC_{sed} (µg/kg)
R4	stream	1.318	Run-off	0.06609	0.3781
pH 6.5					
Step 1	---	24.06	-	8.56	12.20
Step 2					
Northern Europe	March-May	3.28	-	1.15	1.64
	June-Sept	3.28	-	1.15	1.64
Southern Europe	March-May	6.17	-	2.17	3.15
	June-Sept	4.72	-	1.66	2.40
Step 3					
Full dose rate					
D3	ditch	0.3936	Drift	0.02089	0.06434
D4	pond	0.01618	Drainage	0.008089	0.01004
D4	stream	0.3379	Drift	0.005844	0.01783
D5	pond	0.01692	Drainage	0.008646	0.01473
D5	stream	0.3393	Drift	0.008165	0.02045
D6	ditch	0.3947	Drift	0.02120	0.06798
R1	pond	0.03674	Run-off	0.02033	0.02334
R1	stream	0.8203	Run-off	0.03058	0.1106
R2	stream	1.605	Run-off	0.04912	0.2613
R3	stream	2.952	Run-off	0.1051	0.4031
R4	stream	3.116	Run-off	0.1329	0.5333
Banded application					
D3	ditch	0.3936	Drift	0.02082	0.06412
D4	pond	0.01603	Drainage	0.007988	0.008425
D4	stream	0.3374	Drift	0.002814	0.01617
D5	pond	0.01640	Drainage	0.008236	0.01120
D5	stream	0.3375	Drift	0.004027	0.01442
D6	ditch	0.3941	Drift	0.02050	0.06617
R1	pond	0.02259	Run-off	0.01422	0.01587
R1	stream	0.4078	Run-off	0.01637	0.05832
R2	stream	0.7863	Run-off	0.02498	0.1313
R3	stream	1.468	Run-off	0.05527	0.2072
R4	stream	1.551	Run-off	0.06753	0.2712
pH 7.9					
Step 1	---	25.12	-	8.94	4.25
Step 2					

Scenario **FOCUS**	**Waterbody**	**Max PEC_{sw} (µg/L)**	**Dominant entry route**	**21 d- $PEC_{sw,twa}$ (µg/L)***	**Max PEC_{sed} (µg/kg)**
Northern Europe	March-May	0.69	-	0.25	0.07
	June-Sept	0.69	-	0.25	0.07
Southern Europe	March-May	0.69	-	0.25	0.07
	June-Sept	0.69	-	0.25	0.07
Step 3					
Full dose rate					
D3	ditch	0.3935	Drift	0.02079	0.04191
D4	pond	0.01589	Drainage	0.007950	0.004986
D4	stream	0.3370	Drift	0.001430	0.01102
D5	pond	0.01589	Drainage	0.007883	0.004922
D5	stream	0.3358	Drift	0.000683	0.006945
D6	ditch	0.3935	Drift	0.01981	0.04212
R1	pond	0.01588	Run-off	0.009525	0.005981
R1	stream	0.2700	Run-off	0.006234	0.01959
R2	stream	0.3648	Run-off	0.003968	0.01269
R3	stream	0.3844	Run-off	0.01730	0.03984
R4	stream	0.2719	Run-off	0.01108	0.02850
Banded application					
D3	ditch	0.3935	Drift	0.02079	0.04191
D4	pond	0.01589	Drift	0.007950	0.004986
D4	stream	0.3370	Drift	0.001430	0.01102
D5	pond	0.01589	Drift	0.007883	0.004922
D5	stream	0.3358	Drift	0.000683	0.006945
D6	ditch	0.3935	Drift	0.01981	0.04212
R1	pond	0.01588	Drift	0.009078	0.005650
R1	stream	0.2675	Drift	0.003919	0.01083
R2	stream	0.3648	Drift	0.002853	0.01269
R3	stream	0.3828	Drift	0.01140	0.02367
R4	stream	0.2719	Drift	0.006738	0.01515

* twa-time as required by ecotox

Table 8.9-5: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for mesotrione following single application of GLOB2112dH to maize – 48.75 g/ha

Scenario **FOCUS**	**Waterbody**	**Max PEC_{sw} (µg/L)**	**Dominant entry route**	**21 d- $PEC_{sw,twa}$ (µg/L)***	**Max PEC_{sed} (µg/kg)**
pH 5.1					

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)*	Max PEC_{sed} (µg/kg)
Step 1	---	~~12.75~~ 13.89	-	~~4.52~~ 4.92	~~19.33~~ 21.06
Step 2					
Northern Europe	March-May	~~1.89~~ 2.06	-	~~0.66~~ 0.72	~~2.85~~ 3.11
	June-Sept	~~1.89~~ 2.06	-	~~0.66~~ 0.72	~~2.85~~ 3.11
Southern Europe	March-May	~~3.57~~ 3.89	-	~~1.25~~ 1.37	~~5.48~~ 5.97
	June-Sept	~~2.73~~ 2.98	-	~~0.96~~ 1.04	~~4.17~~ 4.54
Step 3					
Full dose rate					
D3	ditch	0.2558	Drift	0.01348	0.06820
D4	pond	0.02708	Drainage	0.02525	0.05222
D4	stream	0.2200	Drift	0.02190	0.04191
D5	pond	0.01504	Drainage	0.01213	0.03033
D5	stream	0.2232	Drift	0.008257	0.03134
D6	ditch	0.2569	Drift	0.01425	0.07463
R1	pond	0.03697	Run-off	0.02358	0.04240
R1	stream	0.7822	Run-off	0.03247	0.1849
R2	stream	0.5598	Run-off	0.01779	0.1555
R3	stream	1.494	Run-off	0.06025	0.3333
R4	stream	1.725	Run-off	0.08467	0.4885
Banded application					
D3	ditch	0.2558	Drift	0.01347	0.06819
D4	pond	0.01351	Drainage	0.01258	0.02735
D4	stream	0.2195	Drift	0.01092	0.02131
D5	pond	0.01093	Drainage	0.005977	0.01653
D5	stream	0.2205	Drift	0.003925	0.01823
D6	ditch	0.2563	Drift	0.01344	0.07113
R1	pond	0.02091	Run-off	0.01326	0.02574
R1	stream	0.3912	Run-off	0.01674	0.09463
R2	stream	0.2708	Run-off	0.009206	0.07782
R3	stream	0.7322	Run-off	0.03148	0.1698
R4	stream	0.8512	Run-off	0.04284	0.2470
pH 6.5					
Step 1	---	~~14.36~~	-	~~5.11~~	~~7.28~~

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)*	Max PEC_{sed} (µg/kg)
		15.64		5.56	7.93
Step 2					
Northern Europe	March-May	~~1.96~~ 2.13	-	~~0.69~~ 0.75	~~0.98~~ 1.07
	June-Sept	~~1.96~~ 2.13	-	~~0.69~~ 0.75	~~0.98~~ 1.07
Southern Europe	March-May	~~3.68~~ 4.01	-	~~1.29~~ 1.41	~~1.88~~ 2.05
	June-Sept	~~2.82~~ 3.07	-	~~0.99~~ 1.08	~~1.43~~ 1.56
Step 3					
Full dose rate					
D3	ditch	0.2559	Drift	0.01357	0.04224
D4	pond	0.01051	Drainage	0.005253	0.006476
D4	stream	0.2196	Drift	0.003710	0.01160
D5	pond	0.01099	Drainage	0.005617	0.009663
D5	stream	0.2205	Drift	0.005263	0.01338
D6	ditch	0.2566	Drift	0.01379	0.04469
R1	pond	0.02423	Run-off	0.01339	0.01554
R1	stream	0.5318	Run-off	0.02012	0.07388
R2	stream	1.032	Run-off	0.03159	0.1699
R3	stream	1.915	Run-off	0.06832	0.2644
R4	stream	2.021	Run-off	0.08633	0.3496
Banded application					
D3	ditch	0.2558	Drift	0.01353	0.04212
D4	pond	0.01042	Drainage	0.005190	0.005522
D4	stream	0.2193	Drift	0.001789	0.01054
D5	pond	0.01066	Drainage	0.005352	0.007350
D5	stream	0.2194	Drift	0.002594	0.009420
D6	ditch	0.2562	Drift	0.01333	0.04349
R1	pond	0.01487	Run-off	0.009310	0.01053
R1	stream	0.2644	Run-off	0.01077	0.03896
R2	stream	0.5052	Run-off	0.01606	0.08537
R3	stream	0.9528	Run-off	0.03593	0.1360
R4	stream	1.006	Run-off	0.04389	0.1779
pH 7.9					
Step 1	---	~~14.99~~ 16.33	-	~~5.34~~ 5.81	~~2.54~~ 2.76

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)*	Max PEC_{sed} (µg/kg)
Step 2					
Northern Europe	March-May	~~0.41~~ 0.45	-	~~0.15~~ 0.16	0.04
	June-Sept	~~0.41~~ 0.45	-	~~0.15~~ 0.16	0.04
Southern Europe	March-May	~~0.41~~ 0.45	-	~~0.15~~ 0.16	0.04
	June-Sept	~~0.41~~ 0.45	-	~~0.15~~ 0.16	0.04
Step 3					
Full dose rate					
D3	ditch	0.2558	Drift	0.01351	0.02748
D4	pond	0.01033	Drainage	0.005167	0.003271
D4	stream	0.2190	Drift	0.000929	0.007212
D5	pond	0.01033	Drainage	0.005123	0.003229
D5	stream	0.2183	Drift	0.000444	0.004536
D6	ditch	0.2558	Drift	0.01288	0.02762
R1	pond	0.01032	Run-off	0.006190	0.003924
R1	stream	0.1755	Run-off	0.004050	0.01284
R2	stream	0.2371	Run-off	0.002564	0.008305
R3	stream	0.2488	Run-off	0.01121	0.02603
R4	stream	0.1767	Run-off	0.007199	0.01867
Banded application					
D3	ditch	0.2558	Drift	0.01351	0.02748
D4	pond	0.01033	Drift	0.005167	0.003271
D4	stream	0.2190	Drift	0.000929	0.007212
D5	pond	0.01033	Drift	0.005123	0.003229
D5	stream	0.2183	Drift	0.000444	0.004536
D6	ditch	0.2558	Drift	0.01288	0.02762
R1	pond	0.01032	Drift	0.005900	0.003706
R1	stream	0.1739	Drift	0.002547	0.007096
R2	stream	0.2371	Drift	0.001847	0.008305
R3	stream	0.2488	Drift	0.007391	0.01551
R4	stream	0.1767	Drift	0.004375	0.009920

* twa-time as required by ecotox

FOCUS Step 4

Table 8.9-6: Global maximum PEC_{sw} values for mesotrione, following single application of GLOB2112dH to maize according to the EU GAP according to surface water Step 4 – 75 g/ha

PEC_{sw} (µg/L)	Scenario	STEP 4 Mesotrione		
Nozzle reduction	Vegetative strip (m)	10	10 vfsmod	20
	No spray buffer (m)	10	10	20
pH 5.1				
None	R1 stream	0.5437	0.05973	0.2843
None	R2 stream	0.3872	-	-
None	R3 stream	1.049	0.08547	0.5488
None	R4 stream	1.214	0.06070	0.6364
pH 6.5				
None	R1 stream	0.3366	-	-
None	R2 stream	0.7083	-	-
None	R3 stream	1.333	0.08548	0.6973
None	R4 stream	1.416	0.06071	0.7422
pH 7.9				
None	R2 stream	0.08146	-	-

Table 8.9-7: Global maximum PEC_{sw} values for mesotrione, following single application of GLOB2112dH to maize according to the EU GAP according to surface water Step 4 – 48.75 g/ha

PEC_{sw} (µg/L)	Scenario	STEP 4 Mesotrione		
Nozzle reduction	Vegetative strip (m)	10	10 vfsmod	20
	No spray buffer (m)	10	10 vfsmod	20
pH 5.1				
None	R1 stream	0.3540	-	-
None	R2 stream	0.2470	-	-
None	R3 stream	0.6739	0.05562	0.3526
None	R4 stream	0.7839	0.03950	0.4108
pH 6.5				
None	R1 stream	0.2182	-	-
None	R2 stream	0.4552	-	-
None	R3 stream	0.8648	0.05563	0.4523

PEC$_{sw}$ (µg/L)	Scenario	STEP 4 Mesotrione		
Nozzle reduction	Vegetative strip (m)	10	10 vfsmod	20
	No spray buffer (m)	10	10 vfsmod	20
None	R4 stream	0.9186	0.03951	0.4814

Table 8.9-8: Global maximum PEC$_{sw}$ values for mesotrione, following single application of GLOB2112dH to maize according to the EU GAP according to surface water Step 4 – 75 g/ha – banded application

PEC$_{sw}$ (µg/L)	Scenario	STEP 4 Mesotrione		
Nozzle reduction	Vegetative strip (m)	10	10 vfsmod	20
	No spray buffer (m)	10	10 vfsmod	20
pH 5.1				
None	R1 stream	0.2721	-	-
None	R3 stream	0.5141	0.04273	0.2689
None	R4 stream	0.5992	0.03035	0.3140
pH 6.5				
None	R2 stream	0.3470	-	-
None	R3 stream	0.6627	-	-
None	R4 stream	0.7048	-	-
pH 7.9				
None	R3 stream	0.08597	-	-

Table 8.9-9: Global maximum PEC$_{sw}$ values for mesotrione, following single application of GLOB2112dH to maize according to the EU GAP according to surface water Step 4 – 48.75 g/ha – banded application

PEC$_{sw}$ (µg/L)	Scenario	STEP 4 Mesotrione		
Nozzle reduction	Vegetative strip (m)	10	10 vfsmod	20
	No spray buffer (m)	10	10 vfsmod	20
pH 5.1				
None	R3 stream	0.3303	-	-
None	R4 stream	0.3869	-	-

PEC_{sw} (µg/L)	Scenario	STEP 4 Mesotrione		
Nozzle reduction	Vegetative strip (m)	10	10 vfsmod	20
	No spray buffer (m)	10	10 vfsmod	20
pH 6.5				
None	R3 stream	0.4302	-	-
None	R4 stream	0.4572	0.01975	0.2397

Metabolites of mesotrione

Table 8.9-10: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for MNBA following single application to maize

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)*	Max PEC_{sed} (µg/kg)
pH 5.1					
Step 1	---	11.75	-	11.67	0.38
Step 2					
Northern Europe	March-May	0.92	-	0.91	0.03
	June-Sept	0.92	-	0.91	0.03
Southern Europe	March-May	1.79	-	1.78	0.06
	June-Sept	1.35	-	1.34	0.04
pH 6.5					
Step 1	---	11.75	-	11.67	0.38
Step 2					
Northern Europe	March-May	0.90	-	0.89	0.03
	June-Sept	0.90	-	0.89	0.03
Southern Europe	March-May	1.76	-	1.74	0.06
	June-Sept	1.33	-	1.32	0.04
pH 7.9					
Step 1	---	11.75	-	11.67	0.38
Step 2					
Northern Europe	March-May	0.72	-	0.72	0.02
	June-Sept	0.72	-	0.72	0.02
Southern Europe	March-May	1.41	-	1.40	0.05
	June-Sept	1.07	-	1.06	0.03

* twa-time as required by ecotox

Table 8.9-11: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for AMBA following single application to maize

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)*	Max PEC_{sed} (µg/kg)
pH 5.1					
Step 1	---	4.90	-	4.85	4.95
Step 2					
Northern Europe	March-May	0.73	-	0.72	0.74
	June-Sept	0.73	-	0.72	0.74
Southern Europe	March-May	1.37	-	1.35	1.38
	June-Sept	1.05	-	1.04	1.06
pH 6.5					
Step 1	---	~~5.22~~ 5.15	-	~~5.17~~ 5.10	~~2.50~~ 3.01
Step 2					
Northern Europe	March-May	~~0.73~~ 0.72	-	~~0.73~~ 0.72	~~0.35~~ 0.43
	June-Sept	~~0.73~~ 0.72	-	~~0.73~~ 0.72	~~0.35~~ 0.43
Southern Europe	March-May	~~1.37~~ 1.35	-	~~1.35~~ 1.33	~~0.65~~ 0.80
	June-Sept	~~1.05~~ 1.04	-	~~1.04~~ 1.03	~~0.50~~ 0.62
pH 7.9					
Step 1	---	5.42	-	5.38	0.97
Step 2					
Northern Europe	March-May	0.30	-	0.29	0.05
	June-Sept	0.30	-	0.29	0.05
Southern Europe	March-May	0.48	-	0.48	0.09
	June-Sept	0.39	-	0.39	0.07

* twa-time as required by ecotox

Table 8.9-12: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for SYN 546974 following single application to maize

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)*	Max PEC_{sed} (µg/kg)
pH 5.1					
Step 1	---	0.80	-	0.62	49.88
Step 2					
Northern	March-May	0.20	-	0.09	7.93

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)*	Max PEC_{sed} (µg/kg)
Europe	June-Sept	0.20	-	0.09	7.93
Southern Europe	March-May	0.20	-	0.16	14.52
	June-Sept	0.20	-	0.13	11.22
pH 6.5					
Step 1	---	0.80	-	0.62	49.88
Step 2					
Northern Europe	March-May	0.20	-	0.09	7.32
	June-Sept	0.20	-	0.09	7.32
Southern Europe	March-May	0.20	-	0.15	13.31
	June-Sept	0.20	-	0.12	10.32
pH 7.9					
Step 1	---	0.80	-	0.62	49.88
Step 2					
Northern Europe	March-May	0.20	-	0.03	1.38
	June-Sept	0.20	-	0.03	1.38
Southern Europe	March-May	0.20	-	0.03	1.42
	June-Sept	0.20	-	0.03	1.40

* twa-time as required by ecotox

Evaluation by zRMS	PECsw (KCP 9.2.5)
Inputs for Modelling	For the active substance mesotrione and its metabolites MNBA, AMBA and SYN546974 the calculations presented here are accepted. Where needed, zRMS corrected the calculations. Predicted environmental concentrations in surface water (PEC_{sw}) and sediment (PEC_{sed}) have been calculated for mesotrione and its metabolites after the application of the product Walkover Trio (GLOB2112dH) on maize: - 1x 0.2l product Walkover Trio (GLOB2112dH)/ha; - 1x0.13l product Walkover Trio (GLOB2112dH)/ha considering the pathways spray drift, drainage and runoff. In addition, for the active substance, $PEC_{SW}/_{SED}$ values were calculated for a dose of 75g a.s./ha and 48.75g a.s/ha. In general input parameters used in FOCUS surface water/sediment modelling for active substance and its metabolites are correct. However, it should be noted that the $DT50_{soil}$ value of 3.6 days for metabolite MNBA should be used for PECsw calculations instead of the 3.4 d value. The applicant used inappropriate the value of 3.4 d and obtained PECsw values in step 2 slightly lower than when using DT_{50soil}=3.6d. However, since the correct PECsw values from step 1 were taken for the risk assessment as the worst case(PECsw=11.75 µg/L), there is no need to recalculate the PEC_{sw} values for MNBA metabolite because the risk assessment for it will not change.

	The PEC_{SW} and PEC_{sed} were calculated in compliance with relevant FOCUS scenarios in stepwise procedure (Steps 1, 2, 3 and 4). The calculations were carried out at Step 1 to Step 4 for mesotrione for two doses. For the metabolites, the values of the PEC_{SW} and PEC_{sed} were calculated at Step 1 and 2. Presented calculations of $PEC_{sw/sed}$ may be used for risk assessment.
Agreed endpoints	Please refer to Tables from 8.9-4 to 8.9-12.
Implication for risk assessment	Please refer to Part B, Section 9 of this dRR.

8.9.2.2 Thiencarbazone-methyl and its metabolites

Table 8.9-13: Input parameters related to active substance thiencarbazone-methyl and metabolites for $PEC_{sw/sed}$ calculations STEP 1/2 and 3(/4) (if necessary)

Compound	Thiencarbazone-methyl	BYH 18636-carboxylic acid (M01)	BYH 18636-sulfonamide (M15)	BYH 18636-sulfonamide-carboxylic acid (M03)	BYH 18636-MMT (M21)	BYH 18636-dicarboxy-sulfonamide (M25)	BYH 18636-triazolinone carboxamide	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	390.4	376.4	235.3	221.3	129.1	251.2	172.1	Y, EFSA, 2013
Saturated vapour pressure (Pa)	8.8×10^{-14}	1×10^{-19}	1×10^{-19}	1×10^{-19}	1×10^{-19}	1×10^{-19}	1×10^{-19}	Y, EFSA, 2013
Water solubility (mg/L)	436	10000 (default)	10000 (default)	10000 (default)	10000 (default)	10000 (default)	10000 (default)	Y, EFSA, 2013
Diffusion coefficient in water (m^2/d)	not required for Step 1+2/ 4.3×10^{-5}							default
Diffusion coefficient in air (m^2/d)	not required for Step 1+2/0.43							default
K_{foc} (mL/g)/ K_{fom}	82.8/48.0 (geomean, n=5)	11.7/6.8 (geomean, n=5)	100.4/58.2 (geomean, n=5)	7.3/4.2 (geomean, n=5)	14.2/8.2 (geomean, n=5)	0 (default)*	18/10.4	Y, EFSA 2013 Geometric mean used in accordance with EFSA Journal 2014;12(5):3662.
Freundlich Exponent 1/n	0.906 (arithmetic mean, n=5)	0.919 (arithmetic mean, n=5)	0.90 (arithmetic mean, n=5)	0.74 (arithmetic mean, n=5)	1.00 (arithmetic mean, n=1)	1 (default)*	1.00	Y, EFSA 2013
Plant Uptake	0	0	0	0	0	0	0	Y, EFSA, 2013
Wash-Off factor from Crop (1/mm)	not required for Step 1+2/ 0.05 (MACRO) 0.50 (PRZM)							default

Compound	Thiencarbazone-methyl	BYH 18636-carboxylic acid (M01)	BYH 18636-sulfonamide (M15)	BYH 18636-sulfonamide-carboxylic acid (M03)	BYH 18636-MMT (M21)	BYH 18636-dicarboxy-sulfonamide (M25)	BYH 18636-triazolinone carboxamide	Value in accordance to EU endpoint y/n/ Reference
$DT_{50,soil}$ (d)	11.6 (geomean, lab, 20°C pF2 Q10 2.58, n=5)	62.4 (geomean, field, 20°C pF2 Q10 2.58)	11.2 (geomean, lab, 20°C pF2 Q10 2.58)	8.1 (geomean, lab, 20°C pF2 Q10 2.58)	85.4 (geomean, lab, slow phase, 20°C pF2 Q10 2.58)	0.0001 (default)*	14.9 (geomean, lab, 20°C pF2 Q10 2.58)	Y, EFSA, 2013
$DT_{50,water}$ (d)	26.1 (geomean from whole system)	30.7 (geomean from whole system)	12.3 (geomean from whole system)	1000 (default)	1000 (default)	1000 (default)	1000 (default)	Y, EFSA, 2013
$DT_{50,sed}$ (d)	1000 (default)	30.7 (geomean from whole system)	12.3 (geomean from whole system)	1000 (default)	1000 (default)	1000 (default)	1000 (default)	Y, EFSA, 2013
$DT_{50,whole\ system}$ (d)	26.1 (geomean water/sediment studies, n = 2)	30.7 (geomean water/sediment studies, n = 2)	12.3 (geomean water/sediment studies, n = 2)	1000 (default)	1000 (default)	1000 (default)	1000 (default)	Y, EFSA, 2013
Maximum occurrence observed (% molar basis with respect to the parent)	-	Soil: 53.6 Water-sediment: 37.1	Soil: 15.6 Water-sediment: 7.0	Soil: 21.2 Water-sediment: 66.9	Soil: 20.6 Water-sediment: 30.7	Soil: 0* Water-sediment: 23.9	Soil: 8.1 Water-sediment: 0	Y, EFSA, 2013

*not a soil metabolite

Table 8.9-14: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for thiencarbazone-methyl following single application of GLOB2112dH to maize – 15 g/ha

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)*	Max PEC_{sed} (µg/kg)
Step 1	---	4.64	-	3.55	3.73
Step 2					
Northern Europe	March-May	0.65	-	0.51	0.53
	June-Sep	0.65	-	0.51	0.53
Southern Europe	March-May	1.18	-	0.92	0.97
	June-Sep	0.91	-	0.71	0.75
Step 3					
Full dose rate					
D3	ditch	0.07870	Drift	0.004364	0.01979
D4	pond	0.003202	Drift	0.002526	0.004664
D4	stream	0.06741	Drift	0.000309	0.003789
D5	pond	0.003417	Drift	0.002709	0.005762
D5	stream	0.06730	Drift	0.000312	0.002828
D6	ditch	0.07881	Drift	0.004256	0.02029
R1	pond	0.01057	Run-off	0.008958	0.01628
R1	stream	0.1930	Run-off	0.007753	0.04244
R2	stream	0.2037	Run-off	0.006396	0.04932
R3	stream	0.4951	Run-off	0.01881	0.09789
R4	stream	0.5472	Run-off	0.02460	0.1350
Banded application					
D3	ditch	0.07870	Drift	0.004364	0.01979
D4	pond	0.003188	Drift	0.002513	0.004599
D4	stream	0.06740	Drift	0.000295	0.003712
D5	pond	0.003284	Drift	0.002590	0.005098
D5	stream	0.06722	Drift	0.000200	0.002340
D6	ditch	0.07875	Drift	0.004179	0.01998
R1	pond	0.006583	Run-off	0.005562	0.1064
R1	stream	0.09855	Run-off	0.004117	0.02238
R2	stream	0.09740	Run-off	0.003245	0.02464
R3	stream	0.2423	Run-off	0.009834	0.05030
R4	stream	0.2698	Run-off	0.01246	0.06898

* twa-time as required by ecotox

Table 8.9-15: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for thiencarbazone-methyl following single application of GLOB2112dH to maize – 9.75 g/ha

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)*	Max PEC_{sed} (µg/kg)
Step 1	---	3.02	-	2.31	2.43
Step 2					
Northern Europe	March-May	0.42	-	0.33	0.35
	June-Sep	0.42	-	0.33	0.35
Southern Europe	March-May	0.77	-	0.60	0.63
	June-Sep	0.59	-	0.46	0.49
Step 3					
Full dose rate					
D3	ditch	0.05115	Drift	0.002837	0.01310
D4	pond	0.002080	Drift	0.001639	0.003081
D4	stream	0.04382	Drift	0.000199	0.002473
D5	pond	0.002210	Drift	0.001750	0.003763
D5	stream	0.04374	Drift	0.000188	0.001817
D6	ditch	0.05122	Drift	0.002758	0.01340
R1	pond	0.006911	Run-off	0.005880	0.01090
R1	stream	0.1265	Run-off	0.005080	0.02823
R2	stream	0.1281	Run-off	0.004030	0.03164
R3	stream	0.3160	Run-off	0.01206	0.06362
R4	stream	0.3507	Run-off	0.01584	0.08820
Banded application					
D3	ditch	0.05115	Drift	0.002837	0.01310
D4	pond	0.002071	Drift	0.001632	0.003041
D4	stream	0.04381	Drift	0.000191	0.002427
D5	pond	0.002130	Drift	0.001678	0.003351
D5	stream	0.04369	Drift	0.000127	0.001515
D6	ditch	0.05118	Drift	0.002713	0.01321
R1	pond	0.004319	Run-off	0.003664	0.007146
R1	stream	0.06511	Run-off	0.002719	0.01499
R2	stream	0.06186	Run-off	0.002067	0.01596
R3	stream	0.1561	Run-off	0.006361	0.03299
R4	stream	0.1747	Run-off	0.008104	0.04550

* twa-time as required by ecotox

FOCUS Step 4

Table 8.9-16: Global maximum PEC$_{sw}$ values for thiencarbazone-methyl, following single application(s) of GLOB2112dH to maize according to surface water Step 4 – 15 g/ha

PEC$_{sw}$ (µg/L)	Scenario	STEP 4 thiencarbazone-methyl		
Nozzle reduction	Vegetative strip (m)	10	10 m VFSmod	20
	No spray buffer (m)	10	10 m VFSmod	20
None	R1 stream	0.08737	0.01194	0.04569
None	R2 stream	0.08990	-	-
None	R3 stream	0.2237	0.01709	0.1170
None	R4 stream	0.2487	0.01214	0.1304

Table 8.9-17: Global maximum PEC$_{sw}$ values for thiencarbazone-methyl, following single application(s) of GLOB2112dH to maize according to surface water Step 4 – 15 g/ha – banded application

PEC$_{sw}$ (µg/L)	Scenario	STEP 4 thiencarbazone-methyl		
Nozzle reduction	Vegetative strip (m)	10	10 m VFSmod	20
	No spray buffer (m)	10	10 m VFSmod	20
None	R1 stream	0.04461	-	-
None	R2 stream	0.04299	-	-
None	R3 stream	0.1095	0.008547	0.05726
None	R4 stream	0.1227	0.006070	0.06426

Table 8.9-18: Global maximum PEC$_{sw}$ values for thiencarbazone-methyl, following single application(s) of GLOB2112dH to maize according to surface water Step 4 – 9.75 g/ha

PEC$_{sw}$ (µg/L)	Scenario	STEP 4 thiencarbazone-methyl		
Nozzle reduction	Vegetative strip (m)	10	10 m VFSmod	20
	No spray buffer (m)	10	10 m VFSmod	20
None	R1 stream	0.05728	-	-
None	R2 stream	0.05651	-	-
None	R3 stream	0.1428	0.01105	0.07466

PEC_{sw} (µg/L)	**Scenario**	**STEP 4 thiencarbazone-methyl**		
Nozzle reduction	Vegetative strip (m)	10	10 m VFSmod	20
	No spray buffer (m)	10	10 m VFSmod	20
None	R4 stream	0.1595	0.007849	0.08354

Table 8.9-19: Global maximum PEC_{sw} values for thiencarbazone-methyl, following single application(s) of GLOB2112dH to maize according to surface water Step 4 – 9.75 g/ha – banded application

PEC_{sw} (µg/L)	**Scenario**	**STEP 4 thiencarbazone-methyl**		
Nozzle reduction	Vegetative strip (m)	10	10 m VFSmod	20
	No spray buffer (m)	10	10 m VFSmod	20
None	R3 stream	0.07053	-	-
None	R4 stream	0.07941	0.003965	0.04162

EPAT analyses

Since macrophyte peak exposure studies are available for thiencarbazone-methyl, FOCUS profiles of selected STEP 3 and STEP 4 simulations were anlysed using EPAT v1.2.

Table 8.9-20: Peak event summary for FOCUS scenarios exceeding the Tier 1 RAC at Step 3

Application	**Scenario**	**PECmax (µg/L)**	**Number of events above Tier 1 RAC**	**Duration of event above Tier 1 RAC (d)**	**Interval between events above Tier 1 RAC (d)**
STEP 3					
15 g/ha	R1 stream	0.1930	1	0.375	-
	R2 stream	0.2037	1	0.542	-
	R3 stream	0.4951	1	0.625	-
	R4 stream	0.5472	1	0.833	-
9.75 g/ha	R3 stream	0.3160	1	0.542	-
	R4 stream	0.3507	1	0.791	-
15 g/ha, banded	R3 stream	0.2423	1	0.459	-
	R4 stream	0.2698	1	0.750	-

Metabolites of thiencarbazone-methyl

Table 8.9-21: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for BYH 18363-carboxylic acid following single application to maize

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)*	Max PEC_{sed} (µg/kg)
Step 1	---	4.35	-	3.47	0.50
Step 2					
Northern Europe	March-May	0.62	-	0.49	0.07
	June-Sept	0.62	-	0.49	0.07
Southern Europe	March-May	1.19	-	0.95	0.14
	June-Sept	0.90	-	0.72	0.10

* twa-time as required by ecotox

Table 8.9-22: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for BYH 18363-sulfonamide following single application to maize

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)*	Max PEC_{sed} (µg/kg)
Step 1	---	0.61	-	0.36	0.60
Step 2					
Northern Europe	March-May	0.07	-	0.04	0.07
	June-Sept	0.07	-	0.04	0.07
Southern Europe	March-May	0.15	-	0.09	0.14
	June-Sept	0.11	-	0.06	0.11

* twa-time as required by ecotox

Table 8.9-23: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for BYH 18363-sulfonamide carboxylic acid following single application to maize

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)*	Max PEC_{sed} (µg/kg)
Step 1	---	2.53	-	2.51	0.18
Step 2					
Northern Europe	March-May	0.34	-	0.33	0.02
	June-Sept	0.34	-	0.33	0.02
Southern Europe	March-May	0.62	-	0.62	0.05
	June-Sept	0.48	-	0.48	0.03

* twa-time as required by ecotox

Table 8.9-24: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for BYH 18363-MMT following single application to maize

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)*	Max PEC_{sed} (µg/kg)
Step 1	---	0.85	-	0.84	0.12
Step 2					
Northern Europe	March-May	0.12	-	0.12	0.02
	June-Sept	0.12	-	0.12	0.02
Southern Europe	March-May	0.23	-	0.23	0.03
	June-Sept	0.17	-	0.17	0.02

* twa-time as required by ecotox

Table 8.9-25: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for BYH 18363- dicarboxysulfonamide following single application to maize

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)*	Max PEC_{sed} (µg/kg)
Step 1	---	0.79	-	0.78	0.00
Step 2					
Northern Europe	March-May	0.11	-	0.11	0.00
	June-Sept	0.11	-	0.11	0.00
Southern Europe	March-May	0.20	-	0.20	0.00
	June-Sept	0.16	-	0.16	0.00

* twa-time as required by ecotox

Table 8.9-26: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for BYH 18363-triazolinone carboxamide following single application to maize

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)*	Max PEC_{sed} (µg/kg)
Step 1	---	0.17	-	0.17	0.03
Step 2					
Northern Europe	March-May	0.02	-	0.02	0.00
	June-Sept	0.02	-	0.02	0.00
Southern Europe	March-May	0.04	-	0.04	0.01
	June-Sept	0.03	-	0.03	0.01

* twa-time as required by ecotox

Evaluation by zRMS	**PECsw (KCP 9.2.5)**
Inputs for Modelling	For the active substance thiencarbazone-methyl and its metabolites BYH 18636-

carboxylic acid, BYH 18636-sulfonamide, BYH 18636-sulfonamide-carboxylic acid, BYH 18636-MMT, BYH 18363- dicarboxysulfonamide, BYH 18636-triazolinone-carboxamide the calculations presented here are accepted.

Predicted environmental concentrations in surface water (PEC_{sw}) and sediment (PEC_{sed}) have been calculated for thiencarbazone-methyl and its metabolites after the application of the product Walkover Trio (GLOB2112dH) on maize:

- 1x 0.2l product Walkover Trio (GLOB2112dH)/ha;
- 1x0.13l product Walkover Trio (GLOB2112dH)/ha

considering the pathways spray drift, drainage and runoff. In addition, for the active substance, $PEC_{SW/SED}$ values were calculated for a dose of 15g a.s./ha and 9.75g a.s/ha.

In general input parameters used in FOCUS surface water/sediment modelling for active substance and its metabolites are correct. However, it should be noted that the applicant for calculations of $PEC_{sw/sed}$ for metabolites: BYH 18636-carboxylic acid, BYH 18636-sulfonamide, BYH 18636-sulfonamide-carboxylic acid, BYH 18636-MMT at Step 1and 2 used DT_{50soil} (geomean, normalised) values instead DT50soil values (geomean, not normalised) as provided in EFSA Journal 2013;11(7):3270.This is summarized in the table below.

Compound	DT50,soil (d), as used for PEC_{SW} and PEC_{SED} calculations by the Applicant	DT50,soil (d), as listed in the LoEP (EFSA, 2013)
BYH 18636-carboxylic acid	62.4 (geomean, field, 20°C pF2 Q10 2.58)	112.3 (geomean, non-normalised, n =4)
BYH 18636-sulfonamide	11.2 (geomean, lab, 20°C pF2 Q10 2.58)	15.0 (geomean, non-normalised, n =5)
BYH 18636- sulfonamide-carboxylic acid	8.1 (geomean, lab, 20°C pF2 Q10 2.58)	10.8 (geomean, non-normalised, n =5)
BYH 18636-MMT	85.4 (geomean, lab, slow phase, 20°C pF2 Q10 2.58)	126.9 (geomean, non-normalised, n =5)

However, zRMS checked what the calculations would differ for these metabolites after using the geomean, non-normalised DT_{50} value. It turned out that in step 1 there were no differences in the results while in step 2 the $PEC_{sw/sed}$ values were in some cases minimally higher by about 0.01, as shown in the example of the BYH 18636-carboxylic acid metabolite (Table below). The differences in the calculations are minimal that they do not affect the risk assessment. Thus, the zRMS agrees with the $PEC_{sw/sed}$ calculations presented by the applicant for the metabolites: BYH 18636-carboxylic acid, BYH 18636-sulfonamide, BYH 18636-sulfonamide-carboxylic acid, BYH 18636-MMT in steps 1 and 2.

Table 8.9-27: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for BYH 18363-carboxylic acid following single application to maize

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	21 d-$PEC_{sw,twa}$ (µg/L)*	Max PEC_{sed} (µg/kg)
Step 1	---	4.35/**4.35**#	-	3.47/**3.47**#	0.50/**0.5**#
Step 2					
Norther	March-May	0.62/**0.62**#	-	0.49/**0.50**#	0.07/**0.07**#

n Europe	June-Sept	0.62/**0.62**#	-	0.49/**0.50**#	0.07/**0.07**#
Southern Europe	March-May	1.19/**1.2**#	-	0.95/**0.96**#	0.14/**0.14**#
	June-Sept	0.90/**0.92**#	-	0.72/**0.73**#	0.10/**0.11**#

* twa-time as required by ecotox
# for calculation zRMS used DT50soil (geomean, non-normalised)=112.3d, as recommended in the LoEP (EFSA, 2013).

The PEC_{SW} and PEC_{sed} were calculated in compliance with relevant FOCUS scenarios in stepwise procedure (Steps 1, 2, 3 and 4). The calculations were carried out at Step 1 to Step 4 for thiencarbazone-methyl for two doses. For the metabolites, the values of the PEC_{SW} and PEC_{sed} were calculated at Step 1 and 2.

Presented calculations of $PEC_{sw/sed}$ may be used for risk assessment.

Agreed endpoints	Please refer to Tables from 8.9-14 to 8.9-26.
Implication for risk assessment	Please refer to Part B, Section 9 of this dRR.

8.9.2.3 $PEC_{sw/sed}$ of GLOB2112dH

The PEC_{sw} of the formulation GLOB2112dH was also calculated based on a relative density of 1.22 kg/L for the product and one application at 0.2 L/ha or 0.13 L/ha. The calculator tool from the FOCUS SWASH model was used for this purpose. These PEC_{sw} were calculated for the ditch, pond and stream scenarios. On top, to allow for the 20% spray drift contribution from the upstream catchment in the case of streams, the drift values of the calculator have been multiplied with a factor 1.2 for the stream scenario. The results of these calculations are provided in the table below.

Table 8.9-28: Maximum PEC_{sw} for GLOB2112dH

Cropping scenario	FOCUS scenario	1 m		2 m	
		% drift	Max. PECsw (µg/L)	% drift	Max. PECsw (µg/L)
Maize, 0.2 L/ha	Ditch	1.9274	1.5676	1.1413	0.9282
	Pond	0.3282	0.0801	0.2671	0.0652
	Stream	1.9274	1.5676	1.1413	0.9282
		-	1.8811*	-	1.1138*
Maize, 0.13 L/ha	Ditch	1.9274	1.0189	-	-
	Pond	0.3282	0.0521	-	-
	Stream	1.9274	1.0189	-	-
		-	1.2227*	-	*

*taking into account the 20% contribution from the upstream catchment

Evaluation by zRMS	PECsw (KCP 9.2.5)
Inputs for Modelling	**Walkover Trio (GLOB2112dH)** The applicant properly calculated the PEC_{sw} values for the formulation Walkover Trio (GLOB2112dH). The results are shown in the Table 8.9-27. Presented calculations of PEC_{sw} may be used for risk assessment.
Agreed endpoints	Please refer to Table from 8.9-27.
Implication for risk assessment	Please refer to Part B, Section 9 of this dRR.

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

Table 8.10-1 Summary of atmospheric degradation and behaviour

Compound	Mesotrione
Direct photolysis in air	Not studied – no data requested
Quantum yield of direct phototransformation	Not studied – no data requested
Photochemical oxidative degradation in air	DT50 of 17.635 hours (1.5 days) derived by the Atkinson model (AOP version 18). OH (12h) concentration assumed = 1.5×10^6 OH/cm³
Volatilisation	Vapour pressure (Pa): <5.7×10^{-6} Pa at 20°C (99.7% pure)

	Henry's Law Constant ($Pa.m^3/mol$): <5.1 x 10^{-7} Pa m^3/mol at 20°C From plant surfaces: <10% volatilisation over 24 hours From soil: <10% volatilisation over 24 hours
Metabolites	Not applicable

The vapour pressure at 20°C of the active substance mesotrione is < 10^{-5} Pa. Hence the active substance mesotrione is regarded as non-volatile. Therefore exposure of adjacent surface waters and terrestrial ecosystems by the active substance mesotrione due to volatilization with subsequent deposition should not be considered.
Mesotrione has low volatility (<5.7 x 10^{-6} Pa at 20°C) and is shown to have insignificant volatilisation from soil and plants. The photochemical oxidative degradation of mesotrione in air is rapid (Half-life 1.5days calculated using Atkinson method, 12 hour day, 1.5 x 10^6 OH/cm^3). Therefore long-range transport is not considered to be of relevance. The predicted environmental concentration in air (PEC_{air}) is therefore predicted to be negligible (RAR Mesotrione, 2015).

Table 8.10-2 Summary of atmospheric degradation and behaviour

Compound	Thiencarbazone-methyl
Direct photolysis in air	Not studied – no data requested
Quantum yield of direct phototransformation	Not studied – no data requested
Photochemical oxidative degradation in air	DT50 (h): 24.2 derived by the Atkinson model OH (12h) concentration assumed = 1.5 x $10^6/cm^3$
Volatilisation	Not studied – no data requested Vapour pressure (Pa): 8.8 x 10^{-14}
Metabolites	None

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

Evaluation by zRMS	**Fate and behaviour in air (KCP 9.3)**
Comments	The data on the atmospheric degradation and behaviour for the active substances of Walkover Trio (GLOB2112dH) follow the EU assessment and is therefore agreed by the zRMS.
Conclusion for exposure assessment	The vapour pressure at 20°C of the active substances: mesotrione is < 5.7x10^{-6} Pa and thiencarbazone-methyl is determined to be 8.8 x 10^{-14} Pa. Hence both active substances are regarded as non-volatile and the environmental concentrations in air and the transport through air are considered negligible.

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.2.4	Truyens S.	2024	Estimations of the PECgw of mesotrione, thiencarbazone-methyl and metabolites in maize GLOB2112dHGW Globachem NV non GLP Unpublished	N	Globachem NV
KCP 9.2.5	Truyens S.	2024	Estimations of the PECsw of mesotrione, thiencarbazone-methyl and metabolites in maize GLOB2112dHSW Globachem NV non GLP Unpublished	N	Globachem NV

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
KCA 7.1.1.3	Graham R., Gilbert J.	2013	Mesotrione - Soil Photolysis of [14C]-Mesotrione Smithers Viscient (ESG) Ltd. Covance Laboratories Limited GLP, not published	N	Syngenta *Matching data provided*
KCA 7.1.1.3	Miner P. & Grcar M.	2016	Soil Photolysis of 14C Mesotrione Ricerca Biosciences, LLC Study No. 034223 GLP, not published	N	Globachem NV *Matching data*
KCA 7.1.2	Hardy I.	2013	Mesotrione – Kinetic Modelling Analysis of Data from Aerobic Soil Degradation Studies to Derive Modelling and Persistence Endpoint DT_{50} Values Syngenta Battelle UK Ltd. Not GLP, not published	N	Syngenta *No data protection claimed*
KCA 7.1.2	Graham D.G. et al	1997	Field Soil Dissipation Study Carried Out in France During 1995-1996. Zeneca Agrochemicals Report No: RR97-026B	N	Syngenta *No data protection claimed*
KCA 7.1.2	Graham D.G. et al	1997	Field Dissipation Study Carried Out in Italy During 1995- 1996. Zeneca Agrochemicals Report No: RR97-025B	N	Syngenta *No data protection claimed*
KCA 7.1.2	Graham D.G. et al	1997	Field Dissipation Study Carried Out in Germany During 1995- 1996. Zeneca Agrochemicals Report No: RR97-051B	N	Syngenta *No data protection claimed*

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
KCA 7.1.2	Graham D.G. et al	1998	Field Dissipation Study Carried Out in Germany During 1996- 1997. Zeneca Agrochemicals Report No: RR97-067B	N	Syngenta *No data protection claimed*
KCA 7.1.2	Graham D.G. et al	1998	Field Dissipation Study Carried Out in Italy During 1996- 1997. Zeneca Agrochemicals Report No: RR97-070B	N	Syngenta *No data protection claimed*
KCA 7.1.2	Wiebe L.A., Yeh S.M.	1999	ZA 1296: Stability of ZA 1296 and the Metabolites MNBA and AMBA in Frozen Soil (WRC-98- 158). (WINO 2775). Zeneca Agrochemicals Report No: RR98-065B	N	Syngenta *No data protection claimed*
KCA 7.1.2	Carley S.E.	1996	[phenyl-U-14C]ZA 1296 Anaerobic Aquatic Soil Metabolism Zeneca Agrochemicals Report No: RR96-033B GLP, not published	N	Syngenta *No data protection claimed*
KCA 7.1.2	Marth J.L.	1997	[14C]AMBA, a Metabolite of ZA 1296: Rate of Degradation in Soil Under Aerobic Laboratory Conditions. Zeneca Agrochemicals Report No: RR97-032	N	Syngenta *No data protection claimed*
KCA 7.1.1 & 7.1.2	Miller M.M	1997	[Phenyl-U- 14C]ZA 1296: Route and Rate of Degradation in Wisconsin Silt Loam Soil Under Aerobic Laboratory Conditions. Zeneca Agrochemicals Report No: RR97-033B	N	Syngenta *No data protection claimed*

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
KCA 7.1.2	Miller M.M, Wilson W.R.	1997	[phenyl-U- 14C]ZA 1296. Rate of Degradation in Three Soils Under Aerobic Laboratory Condition. Zeneca Agrochemicals Report No: RR96-099B	N	Syngenta *No data protection claimed*
KCA 7.1.2	Subba-Rao R.V.	1996	[Phenyl 14C-ZA 1296. Aerobic soil metabolism study. Zeneca Agrochemicals Report No: RR95-082B	N	Syngenta *No data protection claimed*
KCA 7.1.2	Tarr J.B.	1997	[phenyl-U- 14C]ZA 1296. Metabolism in Thirteen Soils Under Aerobic Conditions. Zeneca Agrochemicals Report No: RR93-092B	N	Syngenta *No data protection claimed*
KCA 7.1.2	Vispetto A.R., Tovshteyn M.	1996	[cyclohexane-2- 14C]ZA 1296. Anaerobic Aquatic Soil Metabolism. Zeneca Agrochemicals Report No: RR95-048B GLP	N	Syngenta *No data protection claimed*
KCA 7.1.2	Vispetto A.R., Tovshteyn M.	1997	Addendum to: [Cyclohexane-2- 14C]ZA 1296. Aerobic soil metabolism study. Zeneca Agrochemicals Report No: RR95-047B ADD	N	Syngenta *No data protection claimed*
KCA 7.1.2	Lay M.M.	2000	[Phenyl-U-14C] AMBA : Rate of Degradation in Soil under Aerobic Laboratory Conditions Zeneca Ag products Western Research Center Report No RR 99-096B	N	Syngenta *No data protection claimed*

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
KCA 7.1.2	Fliege R.	2006	[Dihydrotriazole-3-14C] and [thiophene-4-14C] BYH 18636: Aerobic soil metabolism in four soils MEF-05/532 Bayer CropScience AG GLP Unpublished	N	Bayer CropScience *Data out of protection*
KCA 7.1.2	Fliege R.	2006	[Dihydrotriazole-3-14C] and [thiophene-4-14C]BYH 18636: Aerobic soil metabolism in one US soil MEF-05/224 Bayer CropScience AG GLP Unpublished	N	Bayer CropScience *Data out of protection*
KCA 7.1.2	Heinemann O.	2006	BYH18636-triazolinone carboxamide: Aerobic soil degradation in 3 EU soils MEF-05/519 Bayer CropScience AG GLP Unpublished	N	Bayer CropScience *Data out of protection*
KCA 7.1.2	Fliege R.	2006	[Dihydrotriazole-3-14C] and [thiophene-4-14C] BYH 18636: Anaerobic soil metabolism MEF-05/490 Bayer CropScience AG GLP Unpublished	N	Bayer CropScience *Data out of protection*
KCA 7.1.2	Stupp H.P.	2006	BYH 18636: Phototransformation on soil MEF-04/561 Bayer CropScience AG GLP Unpublished	N	Bayer CropScience *Data out of protection*
KCA 7.1.2	Hammel K.	2007	Kinetic evaluation of the aerobic metabolism of BYH 18636, BYH 18636-carboxylic acid, BYH 18636-sulfonamide, BYH 18636-sulfonamide-carboxylic acid and BYH 18636 MMT in soil for comparison with triggers MEF-07/109 Bayer CropScience AG	N	Bayer CropScience *Not protected (not GLP)*

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
			Not GLP Unpublished		
KCA 7.1.2	Hammel K.	2007	Kinetic evaluation of the aerobic metabolism of BYH 18636, BYH 18636-carboxylic acid, BYH 18636-sulfonamide, BYH 18636-sulfonamide-carboxylic acid and BYH 18636 MMT in soil for modelling purposes MEF-07/024 Bayer CropScience AG Not GLP Unpublished	N	Bayer CropScience *Not protected (not GLP)*
KCA 7.1.2	Wyatt D.R.	2007	Terrestrial field dissipation of BYH18636 in Nebraska soil, 2005 MEGSP002 Bayer CropScience GLP Unpublished	N	Bayer CropScience *Data out of protection*
KCA 7.1.2	Wyatt D.R.	2007	Terrestrial field dissipation of BYH18636 in Illinois soil, 2005 MEGSP004 Bayer CropScience GLP Unpublished	N	Bayer CropScience *Data out of protection*
KCA 7.1.2	Wyatt D.R.	2007	Terrestrial field dissipation of BYH18636 in California soil, 2005 MEGSP013 Bayer CropScience GLP Unpublished	N	Bayer CropScience *Data out of protection*
KCA 7.1.2	Wyatt D.R.	2007	Terrestrial field dissipation of BYH18636 in Ontario, Canada soil, 2005 MEGSP003 Bayer CropScience GLP Unpublished	N	Bayer CropScience *Data out of protection*

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
KCA 7.1.2	Couckel G.	2007	Field dissipation of BYH18636 in three Canadian soils MEGSP019 Bayer CropScience AG GLP Unpublished	N	Bayer CropScience *Data out of protection*
KCA 7.1.2	Heinemann O.	2006	Determination of the residues of AE 1394083 in/on soil after spraying of AE 1394083 00 WP10 A1 (10 WP) in the field in France, Germany and Spain RA-2146/04 Bayer CropScience AG GLP Unpublished	N	Bayer CropScience *Data out of protection*
KCA 7.1.2	Heinemann O.	2006	Determination of the residues of AE 1394083 in/on soil after spraying of AE 1394083 00 WP10 A1 (10 WP) in the field in France RA-2048/05 Bayer CropScience AG GLP Unpublished	N	Bayer CropScience *Data out of protection*
KCA 7.1.2	Hammel K.	2007	Kinetic Evaluation of the dissipation of BYH 18636-carboxylic acid in soil based on field studies MEF-07/067 Bayer CropScience AG Not GLP Unpublished	N	Bayer CropScience *Not protected (not GLP)*
KCA 7.1.3	Diaz D.G.	1995	[14C]ZA 1296. Adsorption and Desorption Properties in Soil Zeneca Agrochemicals Report No: RR95-070B GLP, not published	N	Syngenta *Out of data protection*
KCA 7.1.3	Rowe D., Lane M.C.G.	1997	ZA 1296: Adsorption and Desorption properties of ZA 1296 in 4 soils. Zeneca Agrochemicals Report No: RJ2340B GLP, not published	N	Syngenta *Out of data protection*

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
KCA 7.1.3	Diaz D.G.	1995	[14C]ZA 1296. Adsorption and Desorption Properties in Soil. Zeneca Agrochemicals Report No: RR95-070B	N	Syngenta *No data protection claimed*
KCA 7.1.3	Diaz D.G.	1996	[14C]MNBA. Adsorption and Desorption Properties in Soil of a ZA 1296 Metabolite. Zeneca Agrochemicals Report No: RR96-008B	N	Syngenta *No data protection claimed*
KCA 7.1.3	Diaz D.G.	1996	[14C]AMBA. Adsorption and Desorption Properties in Soil of a ZA 1296 Metabolite. Zeneca Agrochemicals Report No: RR96-009B	N	Syngenta *No data protection claimed*
KCA 7.1.3	Hand L.H.	1999	MNBA (R169649) : Absorption Properties in Four Soils Zeneca Agrochemicals Jealott's Hill Research Station Report No RJ2885B	N	Syngenta *No data protection claimed*
KCA 7.1.3	Fliege R.	2006	Adsorption/desorption of BYH 18636 on five soils MEF-191/03 Bayer CropScience AG GLP Unpublished	N	Bayer CropScience *Data out of protection*
KCA 7.1.3	Stupp H.P.	2006	GSE28226: Adsorption/desorption in five soils MEF-191/04 Bayer CropScience AG GLP Unpublished	N	Bayer CropScience *Data out of protection*

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
KCA 7.1.3	Fliege R.	2006	GSE 18448: Adsorption/desorption on five soils MEF-085/04 Bayer CropScience AG GLP Unpublished	N	Bayer CropScience *Data out of protection*
KCA 7.1.3	Simmonds M., Early E.	2006	[14C]-BYH18636-sulfonamide-carboxylic acid: Adsorption to and desorption from five soils CX/04/069 Battelle AgriFood Ltd. GLP Unpublished	N	Bayer CropScience *Data out of protection*
KCA 7.1.3	Henk F., Haas M., Sneikus J.	2007	GSE12201: Adsorption/desorption on five soils MEF-027/04 Bayer CropScience AG GLP Unpublished	N	Bayer CropScience *Data out of protection*
KCA 7.1.3	Koenig H., Fliege R.	2006	BYH 18636-triazolinone-carboxamide (AE 1430601): Estimation of the adsorption coefficient (Koc) MEF-05/417 Bayer CropScience AG GLP Unpublished	N	Bayer CropScience *Data out of protection*
KCA 7.2.1.3	Eya B.K.	1995	[Carbonyl-^{13}C][phenyl-U-^{14}C]ZA 1296 and [cyclohexane-2-^{14}C]ZA 1296 – Aqueous photolysis. Zeneca Agrochemicals Report No: RR94-071B	N	Syngenta *Out of data protection*
KCA 7.2.1.3	Eya B.K.	1997	Calculation of the Water Photolysis Half Life at 50°N. Zeneca Agrochemicals Report No: 6439	N	Syngenta *Out of data protection*
KCA	Graham R., Yeomans	2013	Aerobic Mineralisation of 14C-Phenyl Labelled ZA1296 in Surface Water	N	Syngenta

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
7.2.2.2	P.		Syngenta Smithers Viscient (ESG) Ltd GLP, not published		*Matching data provided*
KCA 7.2.2.2	Miner P.	2016	Aerobic Mineralisation of 14C-Mesotrione in Surface Water. AgChem Product Development Ricerca Biosciences, LLC, USA Study No. 034269-1 GLP, not published	N	Globachem NV *Matching data*
KCA 7.2.2.3	Graham R., Gilbert J.	2013	Mesotrione - Aerobic and Anaerobic Aquatic Sediment Metabolism of [Phenyl-14C]- Mesotrione Syngenta Smithers Viscient (ESG) Ltd Covance Laboratories Limited GLP, not published	N	Syngenta *Matching data provided*
KCA 7.2.2.3	Miner P.	2016	Aerobic Aquatic Metabolism of [14C]Mesotrione. AgChem Product Development Ricerca Biosciences, LLC, USA Study No. 034270-1 GLP, not published	N	Globachem NV *Matching data*
KCA 7.2.2.3	Hardy I.	2013	Mesotrione – Kinetic Modelling Analysis of Data from Water Sediment Studies to Derive Modelling and Persistence Endpoint DT_{50} Values Syngenta Battelle UK Ltd. Not GLP, not published	N	Syngenta *No data protection claimed*
KCA 7.2.2.3	Henk F., Haas M.	2006	BYH18636: Aerobic aquatic metabolism MEF-05/008 Bayer CropScience AG GLP Unpublished	N	Bayer CropScience *Data out of protection*
KCA 7.2.2.3	Sneikus L.	2007	BYH18636-MMT: Aerobic aquatic degradation MEF-06/500 Bayer CropScience AG GLP	N	Bayer CropScience *Data out of*

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Unpublished		*protection*
KCA 7.2.2.3	Hammel K.	2007	Kinetic evaluation of the aerobic aquatic metabolism of BYH 18636, BYH 18636-carboxylic acid, BYH 18636-sulfonamide, BYH 18636-sulfonamide-carboxylic acid, BYH 18636-MMT and BYH 18636-dicarboxy-sulfonamide MEF-06/489 Bayer CropScience AG Not GLP Unpublished	N	Bayer CropScience *Not protected (not GLP)*
KCA 7.3	Patel A., Benner K.	1997	ZA 1296: Volatilisation from Soil and Leaf Surfaces Following Application as a Suspension concentrate Formulation Containing a Build in Wetter. Zeneca Agrochemicals Report No: RJ2374B	N	Syngenta *No data protection claimed*
KCA 7.3	Fliege R.	2007	BYH 18636 (AE 1162464): Calculation of the chemical lifetime in the troposphere MEF-05/299 Bayer CropScience AG GLP Unpublished	N	Bayer CropScience *Data out of protection*

The following tables are to be completed by MS

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
KCP XX	Author	YYYY	Title Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

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
KCP XX	Author	YYYY	Title Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

Appendix 2 Detailed evaluation of the new Annex II studies

No new studies were submitted.

Appendix 3 Modelling data provided by the applicant

Calculations with ESAPE 2.0 for the metabolite BYH 18636-carboxylic acid

E S C A P E

Estimation of Soil Concentrations After PEsticide Applications

developed by Michael Klein

Program version:	2.0 (5 September 2017)
Date of this simulation:	16/04/2024, 12:20:56
Calculation problem:	Programcheck

PROGRAM SETTINGS

Calculation mode:	Residues from different applications are considered separately over one year
Application mode:	Iteration of annual application pattern over 10 years

SCENARIO DATA USED IN THE CALCULATION

Name of the scenario:	Programcheck
Name of the soil:	Borstel
Soil density (kg/L):	1.5
Soil depth (cm):	5
Tillage depth (cm)*:	5
Organic carbon content (%):	1.5
Field capacity (Vol%):	29.2
Wilting point (Vol%):	6.4
Climatic conditions:	20 °C constant

(* for calculation of background concentrations)

APPLICATION PATTERN USED IN THE CALCULATION

Crop rotation:	every year
Application date:	1 May
Application rate (g/ha):	15
Crop interception (%):	0

COMPOUNDS CONSIDERED IN THE CALCULATION

Metabolism scheme: Active compound and a single metabolite

Compound	Molecular mass(g/mol)	Formation (%)
Thiencarbazone-methyl	390.4	
Carboxylic acid	376.4	11.753.6

DEGRADATION KINETICS PARAMETERS CONSIDERED FOR THE CALCULATION

Soil study: soil study 1

Metabolism scheme: Active compound and a single metabolite

Kinetics for Thiencarbazone-methyl: Single First order (SFO)
DT50 (d): 53.2
Rate constant (1/d): 0.013
Q10-factor: 2.2
Walker-exponent: 0.7
Ref. temperature (°C): 20

Kinetics for Carboxylic acid: Double First Order in Parallel (DFOP)
DT50 1(d): 13.1
DT50 2(d): 346.57
Rate constant 1 (1/d): 0.0529
Rate constant 2 (1/d): 0.002
Parameter g: 0.64
Q10-factor: 2.2
Walker-exponent: 0.7
Ref. temperature (°C): 20

RESULTS OF THE CALCULATION

Metabolism scheme: Active compound and a single metabolite

RESULTS FOR: Thiencarbazone-methyl

Calculations over one year

Maximum annual total soil concentration for Thiencarbazone-methyl over 5 cm(mg/kg): 0.0200 occurring on day 0

Calculated time dependent total soil concentrations over 5 cm for Thiencarbazone-methyl after one year (mg/kg)

Time(d)	PECact*	PECtwa	Begin TWAframe(d)	End TWAframe(d)
1	0.0197	0.0199	0	1
2	0.0195	0.0197	0	2
4	0.0190	0.0195	0	4
7	0.0183	0.0191	0	7
14	0.0167	0.0183	0	14
21	0.0152	0.0175	0	21
28	0.0139	0.0168	0	28
42	0.0116	0.0154	0	42
50	0.0104	0.0147	0	50
100	0.0054	0.0112	0	100

(* PECact values are related to the time after the first application)

Calculation of background concentrations after many years

Final Background concentration in total soil for Thiencarbazone-methyl over 5 cm(mg/kg)*:
0.0002**

(* estimated to occur within 10 years without crop rotation)
(** according to the estimation 100% of the final plateau was reached after 10 years without crop rotation)

Reduction factor to account for crop rotation: 1

Final Background concentration in total soil including crop rotation(mg/kg): 0.0002

Calculations of concentrations considering accumulation after many years of application

Maximum total soil concentration for Thiencarbazone-methyl over 5 cm considering accumulation* (mg/kg) 0.0202
(* a tillage depth of 5 cm was considered for calculating the background concentration)

Calculated time dependent total soil concentrations over 5 cm for Thiencarbazone-methyl(mg/kg) considering accumulation*

Time(d)	PECact**	PECtwa	Begin TWAframe(d)	End TWAframe(d)
1	0.0199	0.0200	0	1
2	0.0197	0.0199	0	2
4	0.0192	0.0197	0	4
7	0.0184	0.0193	0	7
14	0.0168	0.0185	0	14
21	0.0154	0.0177	0	21
28	0.0141	0.0169	0	28
42	0.0117	0.0156	0	42
50	0.0106	0.0149	0	50
100	0.0056	0.0114	0	100

(* a tillage depth of 5 cm was considered for calculating the background concentration)
(** PECact values are related to the time after the first application)

RESULTS FOR: Carboxylic acid

Calculations over one year

Maximum annual total soil concentration for Carboxylic acid over 5 cm(mg/kg): 0.0030 occurring on day 111^
(^ This is 15.58 % of the theoretical maximum concentration of the metabolite)

Calculated time dependent total soil concentrations over 5 cm for Carboxylic acid after one year (mg/kg)

Time(d)	PECact*	PECtwa	Begin TWAframe(d)	End TWAframe(d)
1	0.0030	0.0030	110	111
2	0.0030	0.0030	110	112
4	0.0030	0.0030	109	113
7	0.0030	0.0030	107	114
14	0.0030	0.0030	104	118
21	0.0030	0.0030	101	122
28	0.0030	0.0030	97	125
42	0.0029	0.0030	91	133
50	0.0029	0.0030	88	138
100	0.0027	0.0030	70	170

(* PECact values are related to the time after the maximum concentration)

Calculation of background concentrations after many years

Final Background concentration in total soil for Carboxylic acid over 5 cm(mg/kg)*: 0.0034**

(* estimated to occur after 10 years without crop rotation)
(** according to the estimation 100% of the final plateau was reached after 10 years without crop rotation)

Reduction factor to account for crop rotation: 1

Final Background concentration in total soil including crop rotation(mg/kg): 0.0034

Calculations of concentrations considering accumulation after many years of application

Maximum total soil concentration for Carboxylic acid over 5 cm considering accumulation* (mg/kg) 0.0064

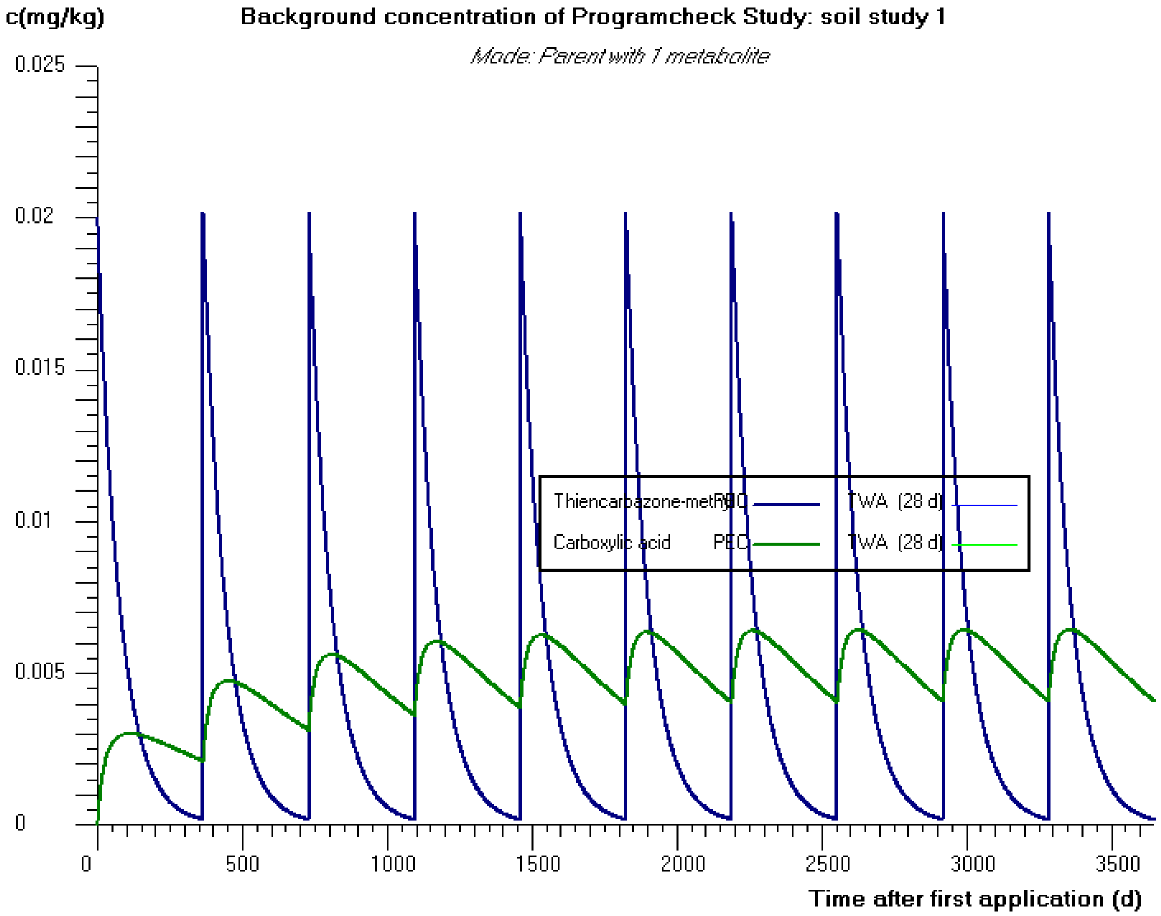
(* a tillage depth of 5 cm was considered for calculating the background concentration)

Calculated time dependent total soil concentrations over 5 cm for Carboxylic acid(mg/kg) considering accumulation*

Time(d)	PECact**	PECtwa	Begin TWAframe(d)	End TWAframe(d)
1	0.0064	0.0064	110	111
2	0.0064	0.0064	110	112
4	0.0064	0.0064	109	113
7	0.0064	0.0064	107	114
14	0.0064	0.0064	104	118
21	0.0064	0.0064	101	122
28	0.0064	0.0064	97	125
42	0.0064	0.0064	91	133
50	0.0064	0.0064	88	138
100	0.0062	0.0064	70	170

(* a tillage depth of 5 cm was considered for calculating the background concentration)
(** PECact values are related to the time after the maximum concentration)'

GRAPHIC REPRESENTATION OF THE CALCULATION

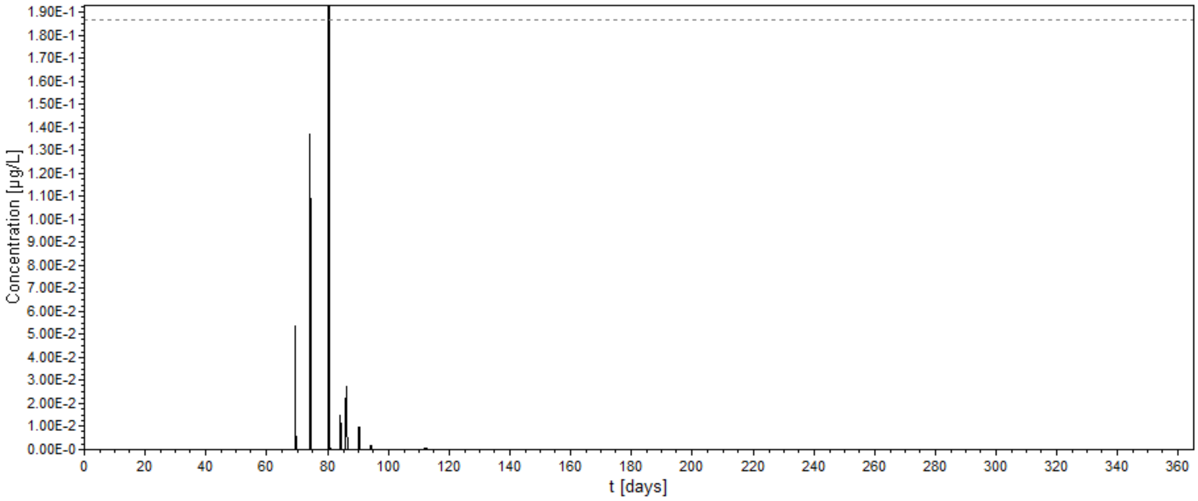


Graphs of the EPAT Analyses

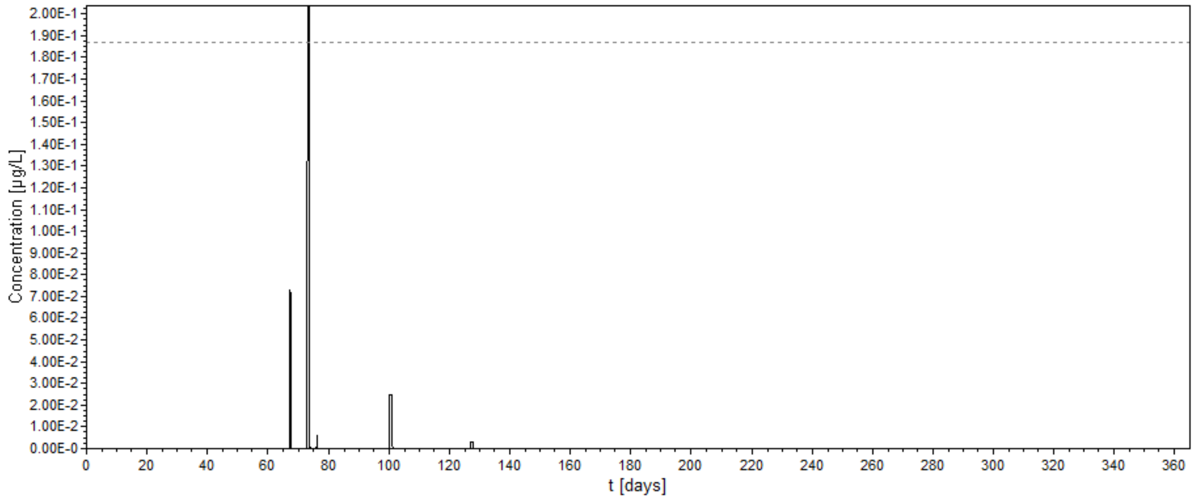
STEP 3

15 g/ha

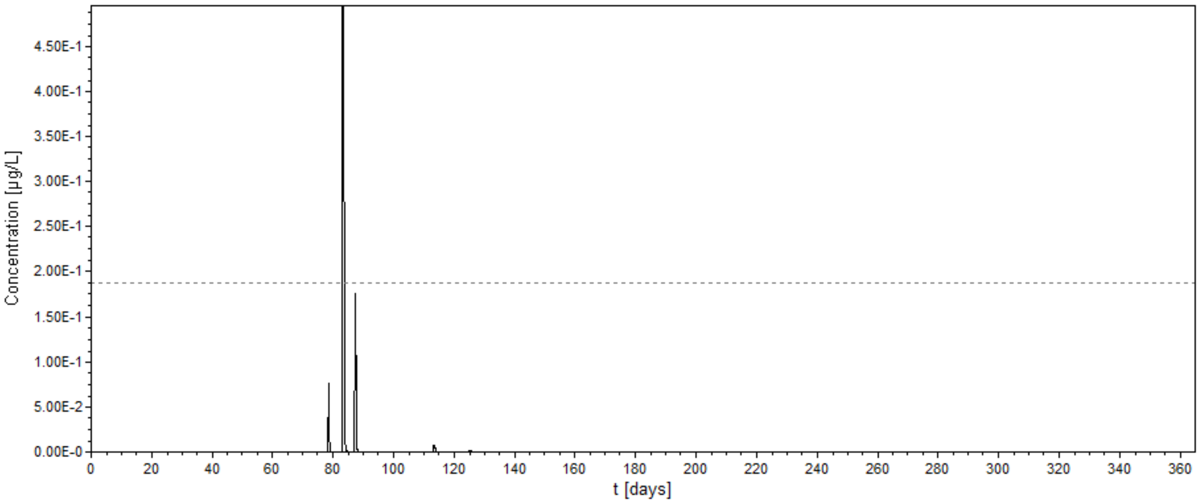
R1 stream



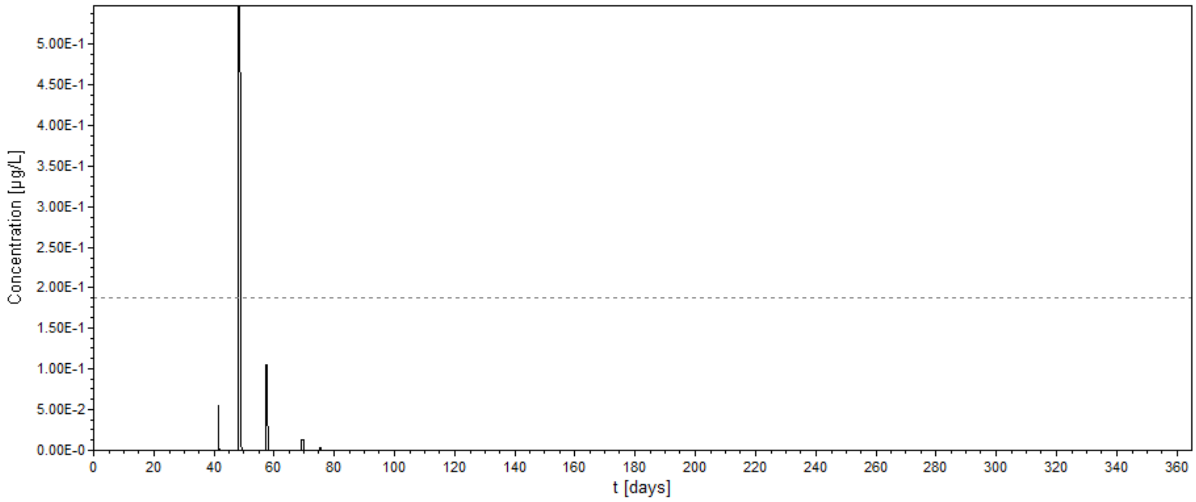
R2 stream



R3 stream

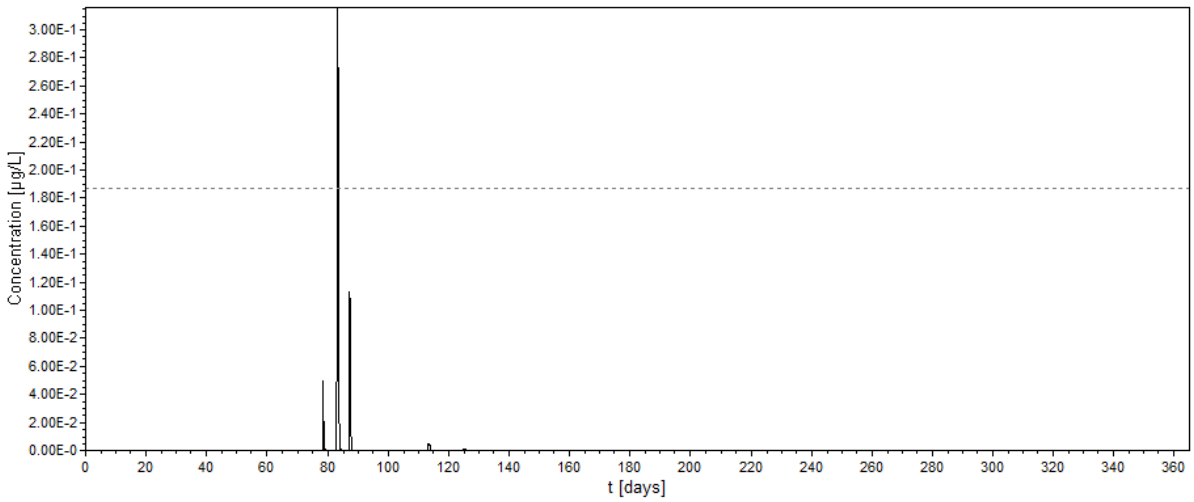


R4 stream

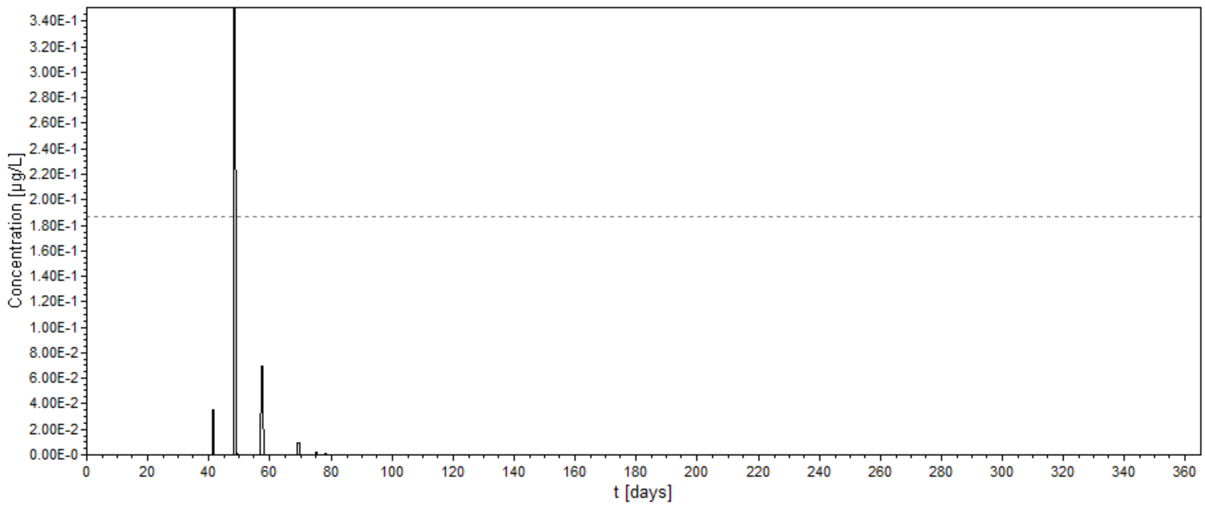


10 g/ha

R3 stream

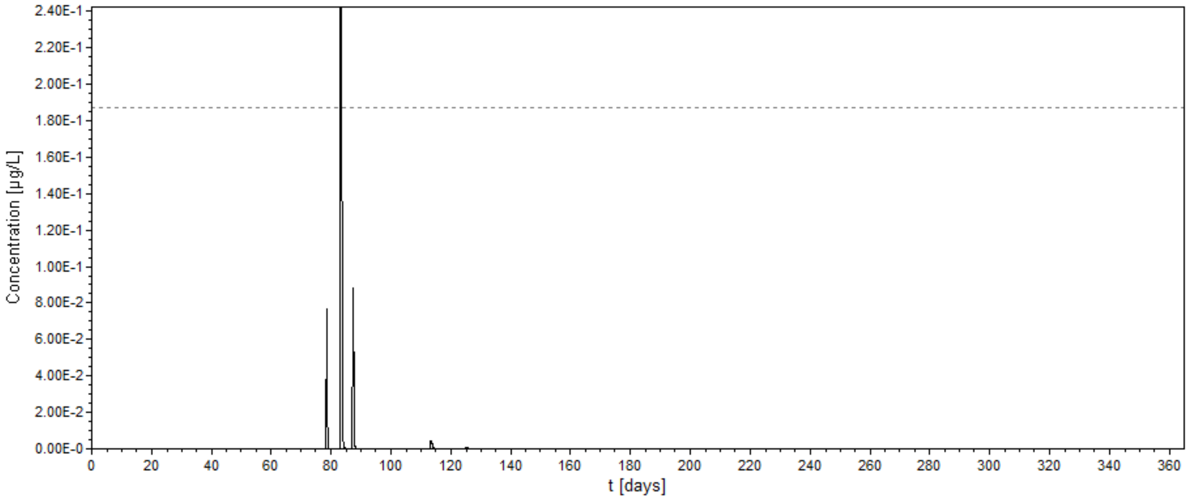


R4 stream



15 g/ha banded application

R3 stream



R4 stream