FINAL REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: **102000025743**

Product name(s): **Foramsulfuron + Thiencarbazone-methyl**
(Active substance(s)) **OD 80 (50+30 g/L)**

Central Zone
Zonal Rapporteur Member State: **Poland**

CORE ASSESSMENT

(Re-Authorisation)

Applicant: **Bayer Crop Science Division**

Submission date: **31/08/2020**

MS Finalisation date: **06.2021; 12.2021**

Version history

When	What
31/08/2020	Original Bayer Crop Science document (Regulation 1107/2009 - Art. 43) Foramsulfuron
14/06/2021	Draft assessment of dRR performed by RMS to commenting
December 2021	Final version prepared by zRMS after Commenting period

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8 Fate and behaviour in the environment (KCP 9)

Thiencarbazone-methyl (non-renewed active ingredient)

In agreement with the Guidance Document on the Renewal of Authorisations according to Article 43 of Regulation (EC) No 1107/2009 (SANCO/2010/13170), for products containing two or more active substances -and when the 1st substance is renewed- there is no need to evaluate data related to the 2nd substance.

Thiencarbazone-methyl (TCM) is the active ingredient not being renewed and therefore data pertaining to TCM should not be evaluated in this application unless they are required for mixture toxicity risk assessment.

The fate and behaviour of the **active substance foramsulfuron** in the environment has been evaluated on EU level according to the Commission Regulation (EU) N° 1107/2009, full details are provided in the EU renewal assessment report and related documents and are summarised in the EFSA conclusion (EFSA Journal 2016;14(3):4421).

The fate and behaviour of the **active substance thiencarbazone-methyl** in the environment has been evaluated on EU level according to the Commission Regulation (EU) N° 1107/2009, full details are provided in the EU draft assessment report and related documents and are summarised in the EFSA conclusion (from EFSA Journal 2013; 11(7): 3270).

For a better navigation through the document – due to the complexity of some of the tiered exposure assessments – it is recommended to use the “navigation pane” of Microsoft Word. Subheaders for each component at each step of the assessment are consistently used in each section of the document and can be quickly accessed via the navigation pane.

8.1 Critical GAP and overall conclusions

Please note: the following table is a subset of the uses listed in the GAP table of Appendix 1 in part B section 0 and contains only the critical GAPs with regard to Section 8 of the dossier.

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

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			PHI (days)	Remarks: e.g. g safener/ synergist per ha	**Conclusion**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	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)														
22	POL	Sugar beet (BEAVA) Fodder beet (BEAVC)***	F	AETCY, ECHCG, VIOAR, STEME, LAMPU, MATIN, CHEAL, GALAP, POLCO, POLAV, POLPE, BRSNN, VERPE, THLAR, POAAN, VERAR	spraying (broadcast, overall)	10-18	a) 1 b) 1	-	a) 1 b) 1	a) FSN 50 + TCM 30 b) FSN 50 + TCM 30	100-300	as per growth stage		A
32	POL	Sugar beet (BEAVA) Fodder beet (BEAVC)***	F	AETCY, ECHCG, VIOAR, STEME, LAMPU, MATIN, CHEAL, GALAP, POLCO, POLAV, POLPE, BRSNN, VERAR, THLAR, POAAN, VERPE	spraying (broadcast, overall)	10-18 B1: 10-12 B2: 12-18	a) B1: 1 B2: 1 b) 2	B1: - B2: - 10 d after B1	a) B1: 0.5 B2: 0.5 b) 1	a) FSN 25 + TCM 15 b) FSN 50 + TCM 30	100-300	as per growth stage		A

Active substance (1): Foramsulfuron [FSN]
Active substance (2): Thiencarbazone-methyl [TCM]

* 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

Fodder beet (BEAVC)*** The product is registered for only some countries (refer to B0 document for the countries having a registration for herbicide tolerant fodder beet use)

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 foramsulfuron concerning the Section Environmental Fate

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No.	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			PHI (days)	Remarks: e.g. g safener/ synergist per ha
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product/ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
1	EU	maize	F	Weeds	Spraying broadcast	BBCH 12-18	a) 1 b) same as a)	-	a) 2.66 b) same as a)	a) FSN: 60 b) same as a)	100-400	-	

** 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 destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			PHI (days)	Remarks: e.g. g safener/ synergist per ha
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product/ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
1	EU	maize	F	Weeds	Spraying broadcast	BBCH 00-13	a) 1 b) same as a)	-	a) 0.2 L/ha b) same as a)	a) TCM: 45 b) same as a)	150-400	-	

** 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

Risk envelope assessment for foramsulfuron

Due to its biological profile, foramsulfuron is used in maize, sugar beet and in nurseries. Application is made in early post-emergence development stage via spray treatment, with one or two applications per season. The overall maximum seasonal application rate for foramsulfuron is 60 g a.s./ha. The application timing varies from BBCH 10 (in sugar beet) to BBCH 34 (in nurseries).
In cases where the risk assessment is passed on screening or 1st tier level, exposure and risk characterisation for the active substance foramsulfuron is presented as a generic 'risk envelope' approach, which will cover all intended European uses across different products in which foramsulfuron may be implemented. **The overall maximum application rate considered for the risk envelope assessment is set to 60 g a.s./ha**.
Other crop or GAP dependent parameters relevant for the exposure assessment are all set to the worst case (0 % crop interception, no tillage, application all year round).

Even though for a particular product a lower use rate may be relevant, the risk envelope assessment will always analyse the environmental exposure situation for the maximum use rate at worst case environmental conditions, so that subsequent risk assessments in the different disciplines can address the overall worst case.

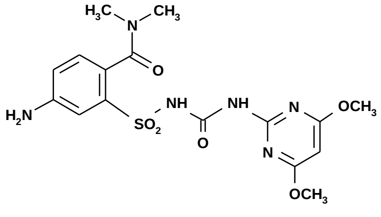
Risk envelope assessment for thiencarbazone-methyl

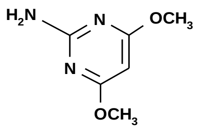
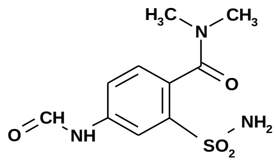
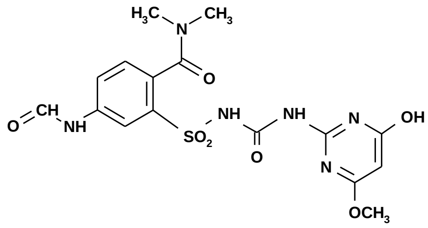
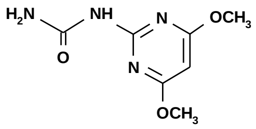
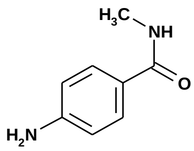
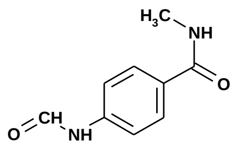
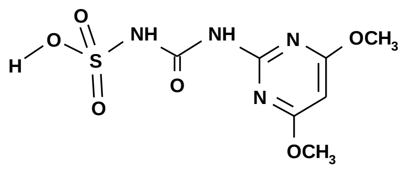
Due to its biological profile, thiencarbazone-methyl is used in cereal crops, maize, sugar beet and on non-cropped areas (bare soil). Application is made in early post-emergence development stage (crop and weeds) via spray treatment, with one or two applications per season. The overall maximum seasonal application rate for thiencarbazone-methyl is 40 g a.s./ha. The application timing varies from BBCH 00 (for bare soil application on non-cropped land) to BBCH 32 (in cereals).
In cases where the risk assessment is passed on screening or 1st tier level, exposure and risk characterisation for the active substance thiencarbazone-methyl is presented as a generic 'risk envelope' approach, which will cover all intended European uses across different products in which thiencarbazone-methyl may be implemented. **The overall maximum application rate considered for the risk envelope assessment is set to 40 g a.s./ha**.
Other crop or GAP dependent parameters relevant for the exposure assessment are all set to the worst case (0 % crop interception, no tillage, application all year round).

Even though for a particular product a lower use rate may be relevant, the risk envelope assessment will always analyse the environmental exposure situation for the maximum use rate at worst case environmental conditions, so that subsequent risk assessments in the different disciplines can address the overall worst case.

8.2 Metabolites considered in the assessment

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

Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
AE F130619	424.44		Soil: 29.1% (aerobic), 6.6% (anaerobic) Water: 5.7% Sediment: 1.4% Water/sediment: 7.0% Water: 10.7% (photolysis buffer)	PEC_{soil} PEC_{gw} $PEC_{sw/sed}$

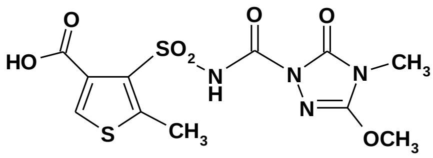
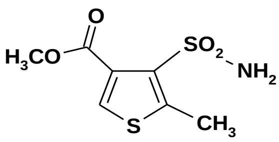
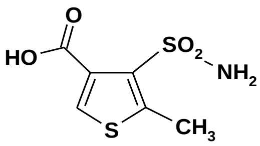
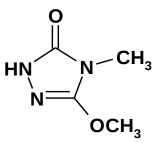
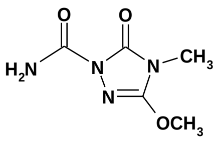
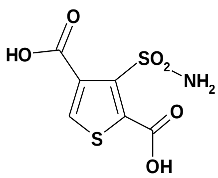
Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
AE F092944	155.16		Soil: 17.8% (aerobic) Water: 2.2% Sediment: 6.7% Water/sediment: 7.3% Water: 26.5% (photolysis buffer)	PEC_{soil} PEC_{gw} $PEC_{sw/sed}$
AE F153745	271.3		Soil: 7.8% (aerobic) Water: 12.3% Sediment: 13.6% Water/sediment: 24.6%	PEC_{soil} PEC_{gw} $PEC_{sw/sed}$
AE 0338795	438.42		Water: 17.0% Sediment: 6.8% Water/sediment: 23.7%	$PEC_{sw/sed}$
AE F099095	198.18		Water: 35.2% (photolysis buffer)	$PEC_{sw/sed}$
4-amino-N-methylbenzamide	150.18		Water: 10.2% (photolysis buffer)	$PEC_{sw/sed}$
4-formamido-N-methylbenzamide*	178.19		Water: 16.6% (photolysis buffer)	$PEC_{sw/sed}$
foramsulfuron-sulfamic acid	278.24		Water: 14.2% (photolysis buffer)	$PEC_{sw/sed}$

* also named as 4-formylamido-N-methylbenzamide

zRMS comments:

All relevant metabolites of foramsulfuron have been included in the risk assessment. They are in agreement with the EFSA Conclusion (EFSA Journal 2016;14(3):4421).

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

Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
BYH 18636-carboxylic acid / AE 1394083	376.4		Soil: 53.6% (aerobic), 32.8% (anaerobic) Water: 24.6% Sediment: 13.0% Water/sediment: 37.1%	PEC_{soil} PEC_{gw} $PEC_{sw/sed}$
BYH 18636-sulfonamide / AE 1364547	235.3		Soil: 15.6% (aerobic) Water: 4.3% 41% (hydrolysis) Sediment: 2.7% Water/sediment: 7.0%	PEC_{soil} PEC_{gw} $PEC_{sw/sed}$
BYH 18636-sulfonamide carboxylic acid / AE 1395853	221.3		Soil: 21.2% (aerobic) Water: 45.6% Sediment: 21.3% Water/sediment: 66.9%	PEC_{soil} PEC_{gw} $PEC_{sw/sed}$
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_{soil} PEC_{gw} $PEC_{sw/sed}$
BYH 18636-triazolinone-carboxamide / AE 1430601	172.1		Soil: 8.1% (photolysis)	PEC_{soil} PEC_{gw}
BYH 18636-dicarboxy-sulfonamide / BCS-AA10007	251.2		Water: 18.9% Sediment: - Water/sediment: 23.9%	$PEC_{sw/sed}$

zRMS comments:

All relevant metabolites of thiencarbazone-methyl have been included in the risk assessment. They are in agreement with the EFSA Conclusion (EFSA Journal 2013; 11(7): 3270).

8.3 Rate of degradation in soil (KCP 9.1.1)

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

8.3.1 Aerobic degradation in soil (KCP 9.1.1.1)

8.3.1.1 Foramsulfuron and its metabolites

The aerobic degradation of foramsulfuron has been evaluated, full details of studies and their data are provided in the respective EU reference and related documents and as summarised in the EFSA Conclusion (EFSA Journal 2016; 14(3): 4421); no additional studies have been performed.

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

Foramsulfuron, Laboratory studies, aerobic conditions										
Soil name	**Soil type (USDA)**	**pH ($CaCl_2$)**	**t.°C**	**MWHC %**	**DT_{50} (d) ***	**DT_{90} (d) ***	**DT_{50} (d) 20°C pF2/10kPa**	**Chi² (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Iowa-phenyl	silty clay loam	7.2	25	25**	7.1	143.8	53.0	5.1	FOMC (α = 0.6076; β = 3.3265)	Y/ EFSA Journal 2016;14(3): 4421
Iowa-pyrimidyl	silty clay loam	7.2	25	25**	9.2	222.4	82.0	8.0	FOMC (α = 0.5626; β = 3.7783)	Y/ EFSA Journal 2016;14(3): 4421
Geomean							65.9			
North Carolina-phenyl	loamy sand	6.2	25	9**	7.0	102.6	29.8	7.3	FOMC (α = 0.7143; β = 4.2577)	Y/ EFSA Journal 2016;14(3): 4421
North Carolina-pyrimidyl	loamy sand	6.2	25	9**	6.7	93.0	27.0	4.8	FOMC (α = 0.7405; β = 4.3436)	Y/ EFSA Journal 2016;14(3): 4421
Geomean							28.4			
Shuttleworth phenyl	sandy loam	5.0	20	27	7.3	51.9	10.5	8.5	FOMC (α = 1.2569; β = 9.8972)	Y/ EFSA Journal 2016;14(3): 4421
Shuttleworth pyrimidyl	sandy loam	5.0	20	27	11.5	65.3	13.1	11.0	FOMC (α =	Y/ EFSA Journal

Foramsulfuron, Laboratory studies, aerobic conditions										
Soil name	**Soil type (USDA)**	**pH ($CaCl_2$)**	**t.°C**	**MWHC %**	**DT_{50} (d) ***	**DT_{90} (d) ***	**DT_{50} (d) 20°C pF2/10kPa**	**Chi² (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
									1.7164; β = 23.0987)	2016;14(3): 4421
Shuttleworth phenyl	sandy loam	5.0	20	40.4	-	-	29.2***	13.1	DFOP	Y/ EFSA Journal 2016;14(3): 4421
Shuttleworth pyrimidyl	sandy loam	5.0	20	40.4	-	-	44.6***	11.0	DFOP	Y/ EFSA Journal 2016;14(3): 4421
Geomean							11.7			
Orainville-phenyl	clay loam	7.4	20	32	1.2	11.5	2.0	4.4	FOMC (α = 0.9824; β = 1.2194)	Y/ EFSA Journal 2016;14(3): 4421
Orainville-pyrimidyl	clay loam	7.4	20	32	1.0	10.3	1.8	3.9	FOMC (α = 0.8737; β = 0.7983)	Y/ EFSA Journal 2016;14(3): 4421
Geomean							1.9			
Chantepie-phenyl	clay loam	6.3	20	32	3.5	35.4	6.1	5.3	FOMC (α = 0.9068; β = 3.092)	Y/ EFSA Journal 2016;14(3): 4421
Chantepie-pyrimidyl	clay loam	6.3	20	32	3.5	34.8	6.1	5.8	FOMC (α = 0.9323; β = 3.2158)	Y/ EFSA Journal 2016;14(3): 4421
Geomean							6.1			
Geometric mean/Median (n=5)							**12.0** / n.c.			
pH-dependency: y/n							no			

* trigger endpoint; ** 0.33 bar moisture; *** values not used in calculation of modelling endpoint; n.c. = not calculated

Table 8.3-1: Summary of aerobic degradation rates for AE F130619 - laboratory studies

AE F130619, Laboratory studies, aerobic conditions										
Soil name	**Soil type (USDA)**	**pH ($CaCl_2$)**	**t.°C**	**MWHC %**	**DT_{50} (d) * (Formation from parent)**	**DT_{90} (d) ***	**DT_{50} (d) 20°C pF2/10kPa**	**Chi² (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Shuttleworth phenyl	sandy loam	5.0	20	27	6.5 (0.14)	21.6	4.4	25.8	SFO	Y/ EFSA Journal 2016;14(3): 4421
Shuttleworth pyrimidyl	sandy loam	5.0	20	27	-	-	-	80.2	SFO	Y/ EFSA Journal 2016;14(3): 4421
Worst case					6.5 (0.14)	21.6	4.4			
Shuttleworth phenyl/pyrimidyl	sandy loam	5.0	20	44.7	0.7 (-)	6.3	3.3	3.4	FOMC (α = 1.0112; β = 0.7247)	Y/ EFSA Journal 2016;14(3): 4421
Orainville-phenyl	clay loam	7.4	20	32	0.7 (1.0)	2.3	0.4	16.3	SFO	Y/ EFSA Journal 2016;14(3): 4421
Orainville-pyrimidyl	clay loam	7.4	20	32	0.9 (0.84)	3.0	0.5	24.0	SFO	Y/ EFSA Journal 2016;14(3): 4421
Geomean					0.8 (0.92)	2.6	0.4			
Orainville phenyl/pyrimidyl	clay loam	7.3	20	54.3	0.5 (-)	4.9	1.4	4.9	FOMC (α = 0.9021; β = 0.4116)	Y/ EFSA Journal 2016;14(3): 4421
Chantepie-phenyl	clay loam	6.3	20	32	0.2 (0.85)	0.7	0.1	30.7	SFO	Y/ EFSA Journal 2016;14(3): 4421
Chantepie-pyrimidyl	clay loam	6.3	20	32	-	-	-	82.4	SFO	Y/ EFSA Journal 2016;14(3): 4421
Worst case					0.2 (0.85)	0.7	0.1			
Chantepie phenyl/pyrimidyl	clay loam	6.3	20	57	0.5 (-)	5.1	1.4	7.5	FOMC (α = 0.9532; β = 0.4997)	Y/ EFSA Journal 2016;14(3): 4421
Geomean					0.5 (-)	5.1	1.4			

AE F130619, Laboratory studies, aerobic conditions										
Soil name	**Soil type (USDA)**	**pH ($CaCl_2$)**	**t.°C**	**MWHC %**	**DT_{50} (d) * (Formation from parent)**	**DT_{90} (d) ***	**DT_{50} (d) 20°C pF2/10kPa**	**Chi² (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Illinois phenyl/pyrimidyl	silty clay loam	7.2	20	52.3	1.4 (-)	24.8	13.3	1.1	DFOP (k_1 = 0.9898; k_2 = 0.05403; g = 0.619026)	Y/ EFSA Journal 2016;14(3): 4421
Geometric mean/Median (n=7)							**1.5** / n.c.			
pH-dependency: y/n							no			

* trigger endpoint; n.c. = not calculated

Table 8.3-2: **Summary of aerobic degradation rates for AE F092944 - laboratory studies**

AE F092944, Laboratory studies, aerobic conditions										
Soil name	**Soil type (USDA)**	**pH ($CaCl_2$)**	**t.°C**	**MWHC %**	**DT_{50} (d) * (Formation from parent)**	**DT_{90} (d) ***	**DT_{50} (d) 20°C pF2/10kPa**	**Chi² (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Shuttleworth	sandy loam	5.0	20	44.7	141.7 (0.22)	470.8	94.9	39.8	SFO	Y/ EFSA Journal 2016;14(3): 4421
Chantepie	clay loam	6.3	20	32	254.4 (0.07)	845.1	147.6	27.1	SFO	Y/ EFSA Journal 2016;14(3): 4421
Collombey	loamy sand	7.6**	20	44.2	2.9 (-)	9.6	3.4	6.3	SFO	Y/ EFSA Journal 2016;14(3): 4421
Speyer 2.2	loamy sand	6.0**	20	44.3	4.9 (-)	34.8	12.4	2.3	FOMC [a)]	Y/ EFSA Journal 2016;14(3): 4421
Les Evouettes	loam	7.3**	20	53.4	9.0 (-)	72.4	19.6	2.6	FOMC [a)]	Y/ EFSA Journal 2016;14(3): 4421
Nambsheim [b)]	sandy loam	8.0***	20	50	8.9 (-)	116	30.8	6	FOMC [a)] (α = 0.77; β = 6.09)	Y/ EFSA Journal 2014;12(11) :3881
Pavia [b)]	loamy sand	5.5***	20	50	9.7 (-)	231.3	173.3	4	HS [a)] (k_1 = 0.0711;	Y/ EFSA Journal 2014;12(11)

AE F092944, Laboratory studies, aerobic conditions										
Soil name	**Soil type (USDA)**	**pH ($CaCl_2$)**	**t.°C**	**MWHC %**	**DT_{50} (d) * (Formation from parent)**	**DT_{90} (d) ***	**DT_{50} (d) 20°C pF2/10kPa**	**Chi² (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
									k_2 = 0.004; Tb = 20.54)	:3881
Speyer 2.2 [b)]	sandy loam	6.7***	20	50	2.5 (-)	12	3.6	4	FOMC [a)] (α = 2.4; β = 7.44)	Y/ EFSA Journal 2014;12(11) :3881
Vercelli [b)]	silt loam	6.1***	20	50	6 (-)	122.3	30.6	5	FOMC [a)] (α = 0.61; β = 2.80)	Y/ EFSA Journal 2014;12(11) :3881
Pappelacker [c)]	sandy loam	7.3	20	40	6.4 (-)	30.3	8.0	5.1	FOMC [a)] (α = 2.5205; β = 20.289)	Y/ EFSA Journal 2014;12(7) :3764
Uffholz [c)]	loam	6.1	20	40	5.25 (-)	34.97	11.2	3.6	DFOP [a)] (k_1 = 0.5552; k_2 = 0.0528; g = 0.367)	Y/ EFSA Journal 2014;12(7) :3764
Otzberg [c)]	silt loam	7.4	20	40	5.9 (-)	19.6	4.4	5.7	SFO	Y/ EFSA Journal 2014;12(7) :3764
Geometric mean/Median (n=12)							**18.8** / n.c.			
pH-dependency: y/n							no			

* trigger endpoint; ** pH in KCl; *** pH in water; n.c. = not calculated

a) pseudo-SFO DT50: FOMC DT90 divided by 3.32 or slow phase rate constant
b) EFSA Journal 2014;12(11) = data from List of Endpoints, EFSA Conclusion flupyrsulfuron-methyl
c) EFSA Journal 2014;12(7) = data from List of Endpoints, EFSA Conclusion sulfosulfuron

Please note: Trigger and modelling endpoint evaluation for AE F092944 followed the actual List of Endpoints in EFSA, 2016. In the same reference (see page 18, point 9), a potential data gap was indicated to consider additional data from recent EU assessments of azimsulfuron, bensulfuron, flupyrsulfuron and sulfosulfuron. Following a detailed check, it is concluded that RMS Finland had considered this additional data on rate of degradation of AE F092944. Consequently, the actual foramsulfuron List of Endpoints is consolidated with no data gap regarding the consideration of other degradation data.

Table 8.3-3: Summary of aerobic degradation rates for AE F153745 - laboratory studies

AE F153745, Laboratory studies, aerobic conditions

Soil name	**Soil type (USDA)**	**pH ($CaCl_2$)**	**t.°C**	**MWHC %**	**DT_{50} (d) * (Formation from parent)**	**DT_{90} (d) ***	**DT_{50} (d) 20°C pF2/10kPa**	**Chi² (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Porterville	sandy loam	7.2	20	27.1	3.3 (-)	13.0	3.7	4.5	SFO	Y/ EFSA Journal 2016;14(3): 4421
Springfield	silt loam	6.4	20	46.8	0.12 (-)	0.54	0.2	1.3	SFO	Y/ EFSA Journal 2016;14(3): 4421
Pikeville	loamy sand	5.4	20	26.9	0.8 (-)	6.2	2.5	2.0	FOMC [a)] (α = 1.1436; β = 0.9619)	Y/ EFSA Journal 2016;14(3): 4421
Sanger	loamy sand	6.7	20	30.5	0.19 (-)	0.87	0.3	3.4	SFO	Y/ EFSA Journal 2016;14(3): 4421
Geometric mean/Median (n=4)							**0.87** / n.c.			
pH-dependency: y/n							no			

[a)] pseudo-SFO DT_{50}: FOMC DT_{90} divided by 3.32

* trigger endpoint; n.c. = not calculated

zRMS comments:

Laboratory data on aerobic soil degradation of foramsulfuron and metabolites are in accordance with the LoEP (EFSA Journal 2016; 14(3):4421).
Laboratory data on aerobic soil degradation of thiencarbazone- methyl and metabolites are in accordance with the LoEP (EFSA Journal 2013; 11(7):3270).

8.3.1.2 Thiencarbazone-methyl and its metabolites

The fate and behaviour of thiencarbazone-methyl in soil is discussed in detail in the corresponding document of the EU draft assessment report where the study references can be found; presented agreed endpoints were taken from EFSA Journal 2013; 11(7): 3270, if not otherwise stated. Data requirements according to Commission Regulation (EU) No. 544/2011 apply.

Under aerobic conditions, degradation of thiencarbazone-methyl resulted in the formation of metabolites, BYH 18636-carboxylic acid / AE 1394083 (maximum 53.6%), BYH 18636-sulfonamide / AE 1364547 (maximum 15.6%), BYH 18636-sulfonamide carboxylic acid / AE 1395853 (maximum 21.2%) and BYH 18636-MMT / AE 1277106 (maximum 20.6%). Metabolite BYH 18636-triazolinone-carboxamide / AE 1430601 was observed in soil photolysis only at 8.1% in maximum. The degradation pathway of thiencarbazone-methyl under aerobic conditions in soil is summarised in the Figure below.

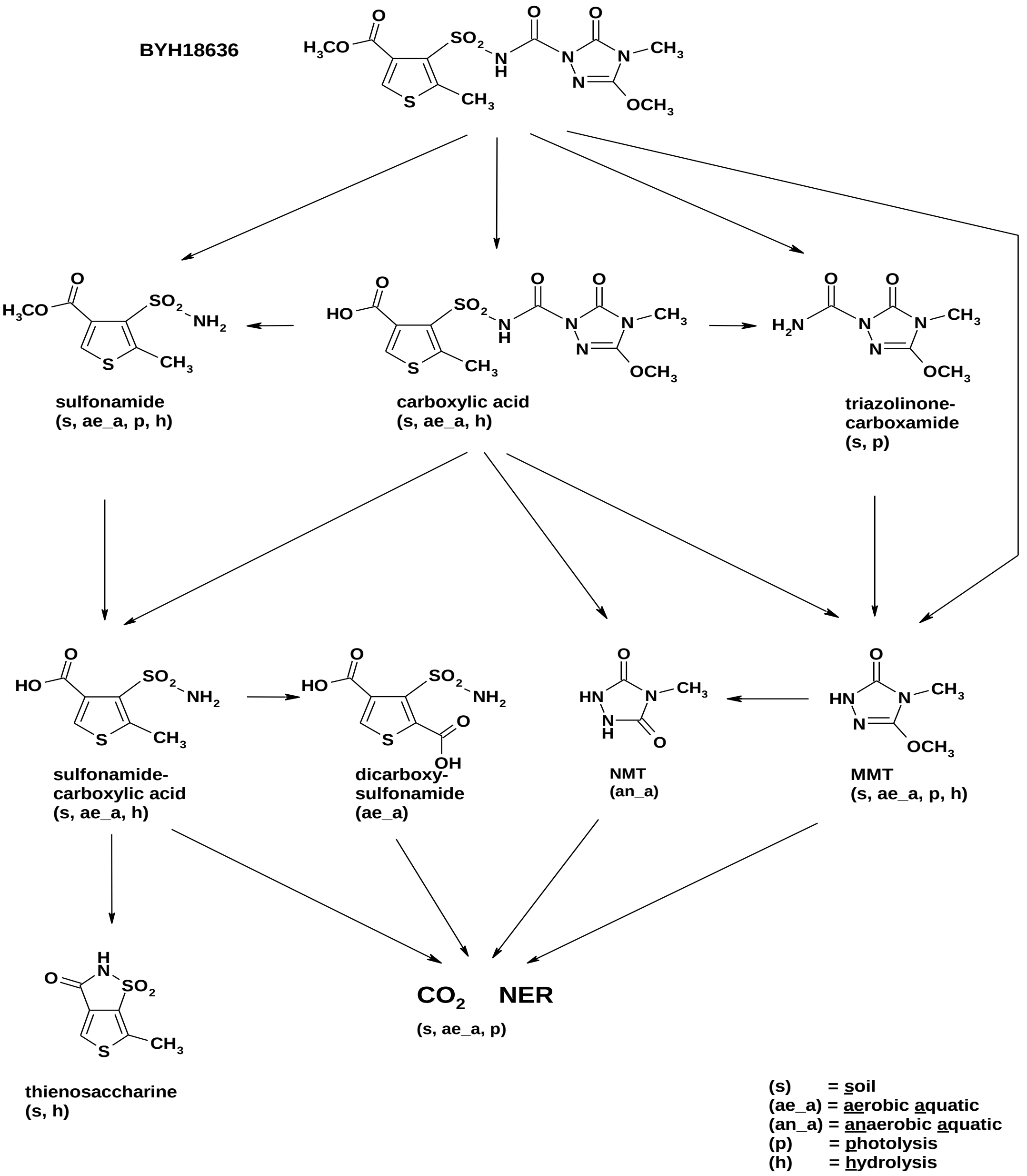


Figure 8.3-1: Proposed pathway of thiencarbazone-methyl in soil under aerobic conditions

The aerobic degradation of thiencarbazone-methyl has been evaluated, full details of studies and their data are provided in the respective EU reference and related documents and as summarised in the EFSA Conclusion (EFSA Journal 2013; 11(7): 3270); no additional studies are considered for this assessment.

Triggering and modelling endpoints were not specified in the EFSA conclusion (EFSA Journal 2013; 11(7): 3270).

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

Thiencarbazone-methyl, Laboratory studies, aerobic conditions										
Soil name	**Soil type (USDA)**	**pH ($CaCl_2$)**	**t.°C**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi² (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
AIII	silt loam	6.8	20	44	23.1	76.7	15.0	8.5	SFO	Y/ EFSA Journal 2013;11(7):3270
AXXa	sandy loam	6.3	20	50	12.9	42.9	10.2	5.0	SFO	Y/ EFSA Journal 2013;11(7):3270
HCB	silt loam	7.4	20	79% of 1/3 bar	53.2	176.7	38.8	3.8	SFO	Y/ EFSA Journal 2013;11(7):3270
SLS	silt loam	7.5	20	43	17.7	58.8	11.3	8.2	SFO	Y/ EFSA Journal 2013;11(7):3270
Pikeville	loamy sand	5.0	25	75% of 1/3 bar	3.2	10.6	3.1	14.7	SFO	Y/ EFSA Journal 2013;11(7):3270
						Geometric mean/Median (n=5)	**11.6**			
						pH-dependency: y/n	No			

Table 8.3-5: Summary of aerobic degradation rates for BYH 18636-carboxylic acid / AE 1394083 - laboratory studies

BYH 18636-carboxylic acid / AE 1394083, Laboratory studies, aerobic conditions										
Soil name	**Soil type (USDA)**	**pH ($CaCl_2$)**	**t.°C**	**MWHC %**	**DT_{50} (d) a) (Formation from parent)**	**DT_{90} (d) c)**	**DT_{50} (d)b) 20°C pF2/10kPa**	**Chi² (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
AIII		6.8	20	44	433.8 (0.194)	n.a.	-	21.5	SFO-SFO	Y/ EFSA Journal 2013;11(7):3270
AXXa		6.3	20	50	451.1 (0.136)	n.a.	-	9.8	SFO-SFO	Y/ EFSA Journal 2013;11(7):3270
HCB		7.4	20	79% of 1/3 bar	338.3 (0.748)	n.a.	-	6.7	SFO-SFO	Y/ EFSA Journal 2013;11(7):3270
SLS		7.5	20	43	477.6 (0.638)	n.a.	-	10.0	SFO-SFO	Y/ EFSA Journal 2013;11(7):3270
Pikeville		5.0	25	75% of 1/3 bar	51.3 (0.196)	n.a.	-	4.7	SFO-SFO	Y/ EFSA Journal 2013;11(7):3270
						Geometric mean/Median (n=0)	-			
						pH-dependency: y/n	No			

a) DT_{50} and DT_{90} extrapolated well beyond duration of the study for first four soils

b) Normalised DT_{50} values were not used since the exposure assesment was based on field dissipation data

BYH 18636-carboxylic acid / AE 1394083, Laboratory studies, aerobic conditions										
Soil name	**Soil type (USDA)**	**pH ($CaCl_2$)**	**t.°C**	**MWHC %**	**DT_{50} (d) [a] (Formation from parent)**	**DT_{90} (d) [c]**	**DT_{50} (d)[b] 20°C pF2/10kPa**	**Chi^2 (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**

[c] N.a. = not reported in List of Endpoints

Table 8.3-6: Summary of aerobic degradation rates for BYH 18636-sulfonamide / AE 1364547 - laboratory studies

BYH 18636-sulfonamide / AE 1364547, Laboratory studies, aerobic conditions										
Soil name	**Soil type (USDA)**	**pH ($CaCl_2$)**	**t.°C**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa (Formation from parent)**	**Chi^2 (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
AIII		6.8	20	44	48	159.5	31.2 (n.a.)	10.7	SFO-SFO [a]	Y/ EFSA Journal 2013;11(7):3270
AXXa		6.3	20	50	7.4	24.6	5.8 (0.571)	24.0	SFO-SFO	Y/ EFSA Journal 2013;11(7):3270
HCB		7.4	20	79% of 1/3 bar	25	83.0	18.3 (0.253)	50.1	SFO-SFO	Y/ EFSA Journal 2013;11(7):3270
SLS		7.5	20	43	16.4	54.5	10.5 (0.302)	30.5	SFO	Y/ EFSA Journal 2013;11(7):3270
Pikeville		5.0	25	75% of 1/3 bar	5.2	17.3	5.0 (n.a.)	3.2	SFO-FOMC [b]	Y/ EFSA Journal 2013;11(7):3270
Geometric mean/Median (n=5)							**11.2** (0.375 [c])			
pH-dependency: y/n							No			

n.a. = not applicable

[a] Decline from maximum
[b] Decline from maximum; DT_{50} calculated by dividing DT_{90} from fit by 3.32
[c] Arithmetic mean

Table 8.3-7: Summary of aerobic degradation rates for BYH 18636-sulfonamide carboxylic acid / AE 1395853 - laboratory studies

BYH 18636-sulfonamide carboxylic acid / AE 1395853, Laboratory studies, aerobic conditions										
Soil name	**Soil type (USDA)**	**pH ($CaCl_2$)**	**t.°C**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa (Formation from sulfonamide metabolite)**	**Chi^2 (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
AIII		6.8	20	44	26.6	88.4	17.3 (1)	20.6	SFO-SFO	Y/ EFSA Journal 2013;11(7):3270
AXXa		6.3	20	50	4.7	15.6	3.7 (1)	22.1	SFO-SFO	Y/ EFSA Journal 2013;11(7):3270
HCB		7.4	20	79% of 1/3 bar	-	-	-	-	-	Y/ EFSA Journal 2013;11(7):3270
SLS		7.5	20	43	26	86.4	16.7 (0.382)	35	SFO-SFO	Y/ EFSA Journal 2013;11(7):3270
Pikeville		5.0	25	75% of 1/3 bar	4.2	14.0	4.0 (n.a.)	14.7	SFO-FOMC a)	Y/ EFSA Journal 2013;11(7):3270
Geometric mean/Median (n=4)							**8.1** (0.794 b))			
pH-dependency: y/n							No			

n.a. = not applicable

a) Decline from maximum; DT_{50} calculated by dividing DT_{90} from fit by 3.32
b) Arithmetic mean

Table 8.3-8: Summary of aerobic degradation rates for BYH 18636-MMT / AE 1277106 - laboratory studies

BYH 18636-MMT / AE 1277106, Laboratory studies, aerobic conditions										
Soil name	**Soil type (USDA)**	**pH ($CaCl_2$)**	**t.°C**	**MWHC %**	**DT_{50} fast / DT_{50} slow (d)**	**DT_{90} (d)**	**DT_{50} fast / DT_{50} slow (d) 20°C pF2/10kPa (Formation from parent)**	**Chi^2 (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
AIII		6.8	20	44	2 / 58.2	-	1.3 / 37.9 (0.8081)	20.8	SFO-DFOP (g=0.8822)	Y/ EFSA Journal 2013;11(7):3270
AXXa		6.3	20	50	20.3 / -	-	16.0 / - (0.390)	20.1	SFO-DFOP	Y/ EFSA Journal

BYH 18636-MMT / AE 1277106, Laboratory studies, aerobic conditions										
Soil name	**Soil type (USDA)**	**pH ($CaCl_2$)**	**t.°C**	**MWHC %**	**DT_{50} fast / DT_{50} slow (d)**	**DT_{90} (d)**	**DT_{50} fast / DT_{50} slow (d) 20°C pF2/10kPa (Formation from parent)**	**Chi² (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
									(g=1)	2013;11(7):3270
HCB		7.4	20	79% of 1/3 bar	10.1 / 182.4	-	7.4 / 133.2 (0.3081)	25.7	SFO-DFOP (g=0.9001)	Y/ EFSA Journal 2013;11(7):3270
SLS		7.5	20	43	2.4 / 192.5	-	1.5 / 123.4 (0.3716)	33.4	SFO-DFOP (g=0.9439)	Y/ EFSA Journal 2013;11(7):3270
Pikeville		5.0	25	75% of 1/3 bar	-	-	-	-	-	Y/ EFSA Journal 2013;11(7):3270
Geometric mean/Median (n=4)							**3.9** / 85.4 (0.4695 a))			
pH-dependency: y/n							No			

a) Arithmetic mean

Table 8.3-9: Summary of aerobic degradation rates for BYH 18636-triazolinone-carboxamide / AE 1430601 - laboratory studies

BYH 18636-triazolinone-carboxamide / AE 1430601, Laboratory studies, aerobic conditions										
Soil name	**Soil type (USDA)**	**pH ($CaCl_2$)**	**t.°C**	**MWHC %**	**DT_{50} fast / DT_{50} slow (d)**	**DT_{90} (d)**	**DT_{50} (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	-	15.4	1.7	DFOP (trigger) SFO (modelling)	Y/ EFSA Journal 2013;11(7):3270
Wurmwiese		5.1	20	14.1	27.4 / 44.7	-	25.7	1.9	DFOP (trigger) SFO (modelling)	Y/ EFSA Journal 2013;11(7):3270
Hoefchen		6.4	20	21.7	11.3 / 11.3	-	8.4	2.0	DFOP (trigger) SFO (modelling)	Y/ EFSA Journal 2013;11(7):3270
Geometric mean/Median (n=3)							**14.9**			
pH-dependency: y/n							No			

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

8.3.2.1 Foramsulfuron and its metabolites

The anaerobic degradation of foramsulfuron had been evaluated, full details of the study were provided in the respective EU reference and related documents and summarised in the EFSA conclusion (EFSA Journal 2016;14(3):4421); no additional studies have been performed.

Table 8.3-10: Summary of anaerobic degradation rates for foramsulfuron in the laboratory

Foramsulfuron, Laboratory studies, anaerobic conditions										
Soil name	**Soil type (USDA)**	**pH ($CaCl_2$)**	**t.°C**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**St. (r^2)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Shuttleworth	sandy loam	5.0	20	40 / flooded	165	548	165	-	SFO	Y/ EFSA Journal 2016;14(3): 4421
Geometric mean/Median (n=1)							-			
pH-dependency: y/n							-			

8.3.2.2 Thiencarbazone-methyl and its metabolites

The anaerobic degradation of thiencarbazone-methyl has been evaluated, full details of the study were provided in the respective EU reference and related documents and summarised in the EFSA conclusion (EFSA Journal 2013;11(7):3270); no additional studies are considered for this assessment.

Degradation in soil under anaerobic conditions was poor to result in lower levels of metabolites formed. Degradation followed in principle the same pathways as under aerobic conditions.

Table 8.3-11: Summary of anaerobic degradation rates for of thiencarbazone-methyl - laboratory studies

Thiencarbazone-methyl, Laboratory studies, anaerobic conditions										
Soil name	**Soil type (USDA)**	**pH ($CaCl_2$)**	**t.°C**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**St. (r^2)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
AIIIa	sandy loam	6.5	20	flooded	109	362	-	0.991	SFO	Y/ EFSA Journal 2013;11(7):3270
Geometric mean/Median (n=1)							-			
pH-dependency: y/n							-			

8.4 Field studies (KCP 9.1.1.2)

Because of the fast degradation of **foramsulfuron** in aerobic soil, no field dissipation studies for parent substance were required in the EU. However, the degradation of foramsulfuron under field conditions was investigated in a study performed at sites in the US and Canada. Full details were provided in the respective EU reference and related documents and summarised in the EFSA conclusion (EFSA Journal 2016;14(3):4421). No additional studies have therefore been performed.

Because of the fast degradation of **thiencarbazone-methyl** in soil, no field dissipation studies for parent substance were required in the EU. However, degradation rates in the field were derived from US and Canadian field dissipation data. Full details are provided in the respective EU reference and related documents and summarised in the EFSA conclusion (EFSA Journal 2013;11(7):3270). No additional studies have been performed.

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

8.4.1.1 Foramsulfuron and its metabolites

Owing to the fast degradation of residues of foramsulfuron in soil under conditions of the laboratory, no need for the investigation in field dissipation studies was required for EU.

8.4.1.2 Thiencarbazone-methyl and its metabolites

Because of the fast degradation of thiencarbazone-methyl in soil, no field dissipation studies for parent substance were required in the EU. However, degradation rates in the field were derived from US and Canadian field dissipation data.

In addition, data on rate of degradation in the field were derived from a study conducted at four sites in the EU for metabolite BYH 18636-carboxylic acid. The field data was evaluated, full details of the study and its assessment are provided in the respective EU reference and related documents and summarised in the EFSA conclusion (EFSA Journal 2013;11(7):3270); no additional studies are considered for this assessment.

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)**	**DT_{50} (d) actual**	**DT_{90} (d) actual**	**DT_{50} (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	Y/ EFSA Journal 2013;11(7):3270
Clay loam	Manitoba, Canada	7.8 [a)]	0-45	26.0	86.3	27.2	12	SFO	Y/ EFSA Journal 2013;11(7):3270
Loam	California, US	7.7	0-61	3	9.9	9.6	43	HS	Y/ EFSA Journal 2013;11(7):3270
Silt loam	Illinois, US	4.5	0-61	6.9	22.9	3.6	11.5	SFO	Y/ EFSA Journal 2013;11(7):3270
Silt loam	Nebraska, US	6.2	0-61	44.6	148	38.6	9.4	SFO	Y/ EFSA Journal 2013;11(7):3270
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 10mm 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 for BYH 18636-carboxylic acid / AE 1394083 - field studies: Trigger and Modelling endpoints

BYH 18636-carboxylic acid / AE 1394083, Field studies									
Soil type	**Location**	**pH ($CaCl_2$)[a)]**	**Depth (cm)**	**DT_{50} (d) actual**	**DT_{90} (d) actual**	**DT_{50} (d) norm [b)]**	**St. (x^2)**	**Method of calc. [c)]**	**Evaluated on EU level y/n/ Reference**
Silt loam	Burscheid, Germany	6.4	0-100	5.4	81.3	22.7	11.1	DFOP	Y/ EFSA Journal 2013;11(7):3270
Clay loam	Vilobi d'Onyar, Spain	6.2	0-100	22.4	382.6	81.5	12.4	DFOP	Y/ EFSA Journal 2013;11(7):3270
Silt loam	Tarascon, S France	7.7	0-100	26.4	644.6	154.0	13.2	DFOP	Y/ EFSA Journal 2013;11(7):3270
Silt loam	Vatteville; N France	6.5	0-100	41.1	252.6	53.3	9.4	DFOP	Y/ EFSA Journal 2013;11(7):3270
Geometric mean (if not pH dependent)						**62.4**			

a) Top 30 cm

b) referenced to 20 °C and 100 % field capacity (FC)

c) derived from slow phase (i.e. k_2) of time-step normalised DFOP kinetic

zRMS comments:

No field dissipation studies for parent substance foramsulfurone were required in the EU but aerobic soil degradation of foramsulfuron from field studies (US and Canada) were included in EFSA Journal 2016;14(3):442.
Aerobic soil degradation of thiencarbazone-methyl from field studies are in accordance with LoEP (EFSA Journal 2013; 11(7):3270).

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

8.4.2.1 Foramsulfuron and its metabolites

The accumulation of **foramsulfuron** had been evaluated, full details are provided in the respective EU reference and related documents are summarised in the EFSA conclusion (EFSA Journal 2016;14(3):4421).

8.4.2.2 Thiencarbazone-methyl and its metabolites

The accumulation of **thiencarbazone-methyl** has been evaluated, full details are provided in the respective EU reference and related documents and summarised in the EFSA conclusion (EFSA Journal 2013;11(7):3270).
The maximum DT_{90} of metabolite BYH 18636-carboxylic acid in the laboratory and in the field exceeded 1 year. Therefore, its accumulation in soil was evaluated by calculating the plateau concentrations in soil as well as the maximum PEC_{soil} directly after the last of an infinite number of applications of the product. 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 thus 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.

8.5.1 Laboratory studies (KCP 9.1.2.1)

8.5.1.1 Foramsulfuron and its metabolites

Column leaching studies for foramsulfuron were not required for EU registration; no additional studies have been performed.

The soil adsorption/desorption of foramsulfuron and its metabolites has been evaluated; full details are provided in the respective EU reference and related documents and summarised in the EFSA conclusion (EFSA Journal 2016;14(3):4421); no additional studies have been performed.

Table 8.5-1: Summary of soil adsorption data for the active substance foramsulfuron

Foramsulfuron							
Soil name	**Soil type**	**OC (%)**	**pH ($CaCl_2$)**	**K_f (mL/g)**	**K_{foc} (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
Maquoketa (EFS-16)	silt loam	1.73	7.2	2.61	151	0.96	Y/ EFSA Journal 2016;14(3): 4421
Pikeville (EFS-21)	silty sand	0.47	6.2	0.42	89	0.82	Y/ EFSA Journal 2016;14(3): 4421
Muenster (EFS-22)	loamy sand	1.80	5.5	0.91	51	0.86	Y/ EFSA Journal 2016;14(3): 4421
Shuttleworth (EFS-24)	clayey sand	0.81	6.4	0.31	38	0.86	Y/ EFSA Journal 2016;14(3): 4421
Chantepie (EFS-25)	sandy clay loam	1.84	5.4	1.17	63	0.87	Y/ EFSA Journal 2016;14(3): 4421
Arithmetic mean (n=5)					**78.4**	**0.87**	
Geometric mean (n=5)					**69.7**	**-**	
pH-dependency y/n					no		

Table 8.5-2: Summary of soil adsorption data for metabolite AE F130619

AE F130619							
Soil Name	**Soil Type**	**OC (%)**	**pH ($CaCl_2$)**	**K_f (mL/g)**	**K_{foc} (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
Shuttleworth (EFS-24)	clayey sand	0.81	6.4	0.36	44	0.93	Y/ EFSA Journal 2016;14(3): 4421

AE F130619							
Soil Name	**Soil Type**	**OC (%)**	**pH ($CaCl_2$)**	**K_f (mL/g)**	**K_{foc} (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
Orainville (EFS-38)	sandy clay loam	1.99	7.4	0.79	40	0.90	Y/ EFSA Journal 2016;14(3): 4421
Wonderpark (EFS-11)	silty sand	3.0	7.2	1.90	63	0.93	Y/ EFSA Journal 2016;14(3): 4421
Pikeville sediment (EFS-54)	sandy loam	2.07	4.5	2.98	144	0.94	Y/ EFSA Journal 2016;14(3): 4421
Arithmetic mean (n=4)					**72.8**	**0.93**	
Geometric mean (n=5)					**63.2**	**-**	
pH-dependency y/n					no		

Table 8.5-3: Summary of soil adsorption data for metabolite AE F092944

AE F092944							
Soil Name	**Soil Type**	**OC (%)**	**pH ($CaCl_2$)**	**K_f (mL/g)**	**K_{foc} (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
S 2.1	loamy sand	1.17	5.0	2.47	211	0.69	Y/ EFSA Journal 2016;14(3): 4421
LS 2.2	loamy sand	2.91	5.0	2.59	89	0.86	Y/ EFSA Journal 2016;14(3): 4421
SL 2.3	sandy loam	1.32	4.7	8.25	625	0.65	Y/ EFSA Journal 2016;14(3): 4421
SLV	sandy loam	1.04	6.1	4.11	395	0.78	Y/ EFSA Journal 2016;14(3): 4421
SL 2	silt loam	0.72	5.6	81.3	11289	0.58	Y/ EFSA Journal 2016;14(3): 4421
Kanada	silty clay	1.80	7.7	16.5	917	0.62	Y/ EFSA Journal 2016;14(3): 4421
Speyer 2.2 [a)]	loamy sand	2.1	6.4*	1.22	58.1	0.85	Y/ EFSA Journal 2014;12(11):3881
Pavia [a)]	loamy sand	0.5	5.2*	2.26	452	0.81	Y/ EFSA Journal 2014;12(11):3881
Drummer [a)]	silt loam	3.1	5.5*	45.3	1460	0.71	Y/ EFSA Journal 2014;12(11):3881
Nambsheim [a)]	sandy loam	0.7	7.8*	0.859	123	0.79	Y/ EFSA Journal 2014;12(11):3881
Vercelli [a)]	silt loam	1.2	5.8*	2.35	196	0.82	Y/ EFSA Journal 2014;12(11):3881
Speyer 2.2 [b)]	loamy sand	2.29	7.0*	1.17	50.9	0.84	Y/ EFSA Conclusion 2007;120, 1-91

AE F092944							
Soil Name	**Soil Type**	**OC (%)**	**pH ($CaCl_2$)**	**K_f (mL/g)**	**K_{foc} (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
Collombey [b)]	loamy sand	1.17	7.7*	0.71	60.4	0.82	Y/ EFSA Conclusion 2007;120, 1-91
Sisseln [b)]	sandy loam	1.557	7.8*	0.83	52.8	0.92	Y/ EFSA Conclusion 2007;120, 1-91
Vetroz [b)]	silt loam	4.05	7.3*	1.70	42.0	0.91	Y/ EFSA Conclusion 2007;120, 1-91
Drummer [c)]	silt loam	1.78	6.9*	11.54	648.3	0.72	Y/ EFSA Journal 2014;12(7):3764
Sarpy [c)]	sandy loam	0.58	8.0*	1.92	331.0	0.68	Y/ EFSA Journal 2014;12(7):3764
Spinks [c)]	loamy sand	1.15	6.8*	2.59	225.2	0.79	Y/ EFSA Journal 2014;12(7):3764
Sable [c)]	silty clay loam	2.0	5.8*	32.23	1611.5	0.56	Y/ EFSA Journal 2014;12(7):3764
Arithmetic mean (n=19)					**991.4**	**0.76**	
Geometric mean (n=5)					**275.8**	**-**	
pH-dependency y/n					no		

* pH determined in water
a) EFSA Journal 2014;12(11):3881 = data from List of Endpoints, EFSA Conclusion flupyrsulfuron-methyl
b) EFSA Scientific Report (2007) 120, 1-91 = data from List of Endpoints, EFSA Conclusion nicosulfuron
c) EFSA Journal 2014;12(7):3764 = data from List of Endpoints, EFSA Conclusion sulfosulfuron
Please note: Adsorption data (i.e. values of adsorption K_{oc} and Freundlich exponent 1/n) to soil for AE F092944 followed the List of Endpoints in EFSA, 2016. In the same reference (see page 18, point 10), a potential data gap was indicated to consider additional data from recent EU assessments of azimsulfuron, bensulfuron, flupyrsulfuron and sulfosulfuron. Following a detailed check, it is concluded that RMS Finland had considered this additional adsorption data for AE F092944. Consequently, the actual foramsulfuron List of Endpoints is consolidated with no data gap regarding the consideration of other adsorption data.

Table 8.5-4: Summary of soil adsorption for metabolite AE F153745

AE F153745							
Soil Name	**Soil Type**	**OC (%)**	**pH ($CaCl_2$)**	**K_f (mL/g)**	**K_{foc} (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
Shuttleworth	sand	0.81	6.9	0.51	63	0.98	Y/ EFSA Journal 2016;14(3): 4421
Chantepie	clay loam	4.09	6.2	1.43	35	0.97	Y/ EFSA Journal 2016;14(3): 4421
Wonderpark	sandy loam	3.0	7.7	1.49	50	0.92	Y/ EFSA Journal 2016;14(3): 4421
Pikeville	loam	2.07	5.1	0.99	48	1.00	Y/ EFSA Journal 2016;14(3): 4421

AE F153745							
Soil Name	**Soil Type**	**OC (%)**	**pH ($CaCl_2$)**	**K_f (mL/g)**	**K_{foc} (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
Arithmetic mean (n=4)					**49**	**0.97**	
pH-dependency y/n					no		

zRMS comments:

The adsorption/desorption endpoints for foramsulfuron reflect the outcome of the EU peer-review and are in accordance with EFSA Conclusions 2016;14(3): 4421.

8.5.1.2 Thiencarbazone-methyl and its metabolites

The TSCF value that should be used in FOCUS modelling for thiencarbazone-methyl and its soil metabolites has been extensively discussed in Pesticides Peer Review Meeting 101 (see minuted in EFSA Peer Review Report on Thiencarbazone-methyl, PDF page 211). It was accepted that a TSCF value of 0.5 could be used for the parent compound on the basis of the results of the confined rotational crop study. As there was no good definitive evidence of systemicity for soil metabolites, the majority of experts considered that FOCUS modelling should use a TSCF factor of 0 for metabolites. These values are listed as the relevant EU Endpoints for modelling (cf. page 50 of EFSA Journal 2013;11(7):3270) and are used in the subsequent exposure simulations.

The soil adsorption/desorption of thiencarbazone-methyl and its metabolites has been evaluated; full details are provided in the respective EU reference and related documents and summarised in the EFSA conclusion (EFSA Journal 2013;11(7):3270); no additional studies are considered for this assessment.

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

Thiencarbazone-methyl							
Soil name	**Soil type**	**OC (%)**	**pH ($CaCl_2$)**	**K_f (mL/g)**	**K_{foc} (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
AXXa (Laacherhof AXXa)	Sandy loam	1.47	6.3	0.64	43	0.899	Y/ EFSA Journal 2013;11(7):3270
AIII (Laacherhof AIII)	Silt loam	0.88	6.8	0.40	46	0.886	Y/ EFSA Journal 2013;11(7):3270
SLS (Silt Loam Sarotti)	Silt loam	1.30	7.5	0.88	68	0.917	Y/ EFSA Journal 2013;11(7):3270
HCB (Horse Camp Bridge)	Silt loam	4.1	7.4	6.23	152	0.897	Y/ EFSA Journal 2013;11(7):3270
SSC (Stilwell Silty Clay)	Silty clay	1.15	4.8	2.18	190	0.932	Y/ EFSA Journal 2013;11(7):3270
Arithmetic mean (n=5)					**100**	0.906	
pH-dependency y/n					No		

Table 8.5-6: Summary of soil adsorption/desorption for BYH 18636-carboxylic acid / AE 1394083

BYH 18636-carboxylic acid / AE 1394083							
Soil Name	**Soil Type**	**OC (%)**	**pH ($CaCl_2$)**	**K_f (mL/g)**	**K_{foc} (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
AXXa (Laacherhof AXXa)	Sandy loam	2.7	6.2	0.129	4.8	0.917	Y/ EFSA Journal 2013;11(7):3270
AIII (Laacherhof AIII)	Silt loam	0.4	6.8	0.036	8.9	0.802	Y/ EFSA Journal 2013;11(7):3270
SLS (Silt Loam Sarotti)	Silt loam	0.9	6.9	0.116	12.9	0.980	Y/ EFSA Journal 2013;11(7):3270
HCB (Horse Camp Bridge)	Silt loam	4.9	7.1	0.605	12.3	0.933	Y/ EFSA Journal 2013;11(7):3270
SSC (Stilwell Silty Clay)	Silty clay	1.2	4.8	0.376	32.7	0.965	Y/ EFSA Journal 2013;11(7):3270
Arithmetic mean (n=5)					**14.3**	0.919	
pH-dependency y/n					No		

Table 8.5-7: Summary of soil adsorption/desorption for BYH 18636-sulfonamide / AE 1364547

BYH 18636-sulfonamide / AE 1364547							
Soil Name	**Soil Type**	**OC (%)**	**pH ($CaCl_2$)**	**K_f (mL/g)**	**K_{foc} (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
AXXa (Laacherhof AXXa)	Sandy loam	2.7	6.2	0.88	33	0.91	Y/ EFSA Journal 2013;11(7):3270
AIII (Laacherhof AIII)	Silt loam	0.4	6.8	0.41	102	0.87	Y/ EFSA Journal 2013;11(7):3270
SLS (Silt Loam Sarotti)	Silt loam	0.9	6.9	0.86	95	0.90	Y/ EFSA Journal 2013;11(7):3270
HCB (Horse Camp Bridge)	Silt loam	4.9	7.1	7.07	144	0.90	Y/ EFSA Journal 2013;11(7):3270
SSC (Stilwell Silty Clay)	Silty clay	1.15	4.8	2.54	221	0.91	Y/ EFSA Journal 2013;11(7):3270
Arithmetic mean (n=5)					**119**	0.90	
pH-dependency y/n					No		

Table 8.5-8: Summary of soil adsorption/desorption for BYH 18636-sulfonamide carboxylic acid / AE 1395853

BYH 18636-sulfonamide carboxylic acid / AE 1395853							
Soil Name	**Soil Type**	**OC (%)**	**pH ($CaCl_2$)**	**K_f (mL/g)**	**K_{foc} (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
AXXa (Laacherhof AXXa)	Sandy loam	1.70	6.3	0.07	3.9	0.97	Y/ EFSA Journal 2013;11(7):3270
AIII (Laacherhof AIII)	Silt loam	0.91	6.7	0.06	6.5	0.72	Y/ EFSA Journal 2013;11(7):3270
SLS (Silt Loam Sarotti)	Silt loam	1.3	7.5	0.24	9.8	0.62	Y/ EFSA Journal 2013;11(7):3270
HCB (Horse Camp Bridge)	Silt loam	4.1	7.0	0.46	11.3	0.58	Y/ EFSA Journal 2013;11(7):3270
SSC (Stilwell Silty Clay)	Silty clay	2.4	5.5	0.09	7.3	0.79	Y/ EFSA Journal 2013;11(7):3270
Arithmetic mean (n=5)					**7.8**	0.74	
pH-dependency y/n					No		

Table 8.5-9: Summary of soil adsorption/desorption for BYH 18636-MMT / AE 1277106

BYH 18636-MMT / AE 1277106							
Soil Name	**Soil Type**	**OC (%)**	**pH ($CaCl_2$)**	**K_f (mL/g)**	**K_{foc} (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
AXXa (Laacherhof AXXa)	Sandy loam	2.7	6.2	0.13	4.7	1.03	Y/ EFSA Journal 2013;11(7):3270
AIII (Laacherhof AIII)	Silt loam	0.4	6.8	0.07	17.8	1.01	Y/ EFSA Journal 2013;11(7):3270
SLS (Silt Loam Sarotti)	Silt loam	0.9	6.9	0.13	14.7	1.00	Y/ EFSA Journal 2013;11(7):3270
HCB (Horse Camp Bridge)	Silt loam	4.9	7.1	0.76	15.5	0.97	Y/ EFSA Journal 2013;11(7):3270
SSC (Stilwell Silty Clay)	Silty clay	1.15	4.8	0.34	29.8	1.00	Y/ EFSA Journal 2013;11(7):3270
Arithmetic mean (n=5)					**16.4**	1.00	
pH-dependency y/n					No		

Table 8.5-10: Summary of soil adsorption/desorption for BYH 18636-triazolinone-carboxamide / AE 1430601

BYH 18636-triazolinone-carboxamide / AE 1430601							
Soil Name	**Soil Type**	**OC (%)**	**pH ($CaCl_2$)**	**K_f (mL/g)**	**K_{foc} (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
Not applicable, HPLC method OECD 121					18	1	Y/ EFSA Journal 2013;11(7):3270
				Arithmetic mean (n=1)	-	-	
				pH-dependency y/n	No		

zRMS comments:

The adsorption/desorption endpoints for thiencarbazone-methyl reflect the outcome of the EU peer-review and are in accordance with EFSA Conclusions 2013;11(7):3270.

8.5.2 Lysimeter studies (KCP 9.1.2.2)

8.5.2.1 Foramsulfuron and its metabolites

Lysimeter studies for foramsulfuron have been evaluated, full details of these studies are provided in the respective EU reference and related documents and summarised in the EFSA conclusion (EFSA Journal 2016;14(3):4421). No additional studies have been performed.

8.5.2.2 Thiencarbazone-methyl and its metabolites

No lysimeter studies had been submitted for thiencarbazone-methyl, thus nothing regarding this study type was evaluated in the respective EU reference and related documents such as the EFSA conclusion (EFSA Journal 2013;11(7):3270). No additional studies are considered for this assessment.

8.5.3 Field leaching studies (KCP 9.1.2.3)

Field leaching studies for **foramsulfuron** or its metabolites were not required for EU registration as sufficient information can be derived from the existing data; no additional studies have been performed.

Field leaching studies for **thiencarbazone-methyl** were not required for EU registration as sufficient information can be derived from the existing studies; no additional studies are considered for this assessment.

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

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

8.6.1 Foramsulfuron and its metabolites

The degradation of foramsulfuron in water/sediment systems has been evaluated, full details of these studies are provided in the respective EU reference and related documents and summarised in the EFSA conclusion (EFSA Journal 2016;14(3):4421); no additional studies have been performed.

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

Foramsulfuron Distribution: maximum in sediment 24.8% after 14 d										
Water/sediment system	**pH water/ sed.**	**$DegT_{50}$ whole syst. (d)**	**$DegT_{90}$ whole syst. (d)**	**Kinetic, Fit**	**$DissT_{50}$ water (d)**	**$DissT_{90}$ water (d)**	**Kinetic, Fit**	**$DissT_{50}$ sed. (d)**	**Kinetic, Fit**	**Evaluated on EU level y/n/ Reference**
Pikeville	6.2 / 4.9 a)	27.3	90.7	SFO	14.8	49.2	SFO	45.0	SFO	Y/ EFSA Journal 2016;14(3): 4421
Hoechst sand	8.4 / 7.4 a)	39.6	131.6	SFO	42.8	123	SFO	46.3	SFO	Y/ EFSA Journal 2016;14(3): 4421
Geometric mean (n=2)		32.9	90.7		25.2	78.1		45.6		

a) measured in $CaCl_2$

Table 8.6-2: Summary of degradation in water/sediment of metabolite AE F130619

AE F130619: max. 7.0% total system (57 d), 5.7% water (57 d), 1.4% sediment (84 d) Formation fraction from parent active substance in total systems: 0.14 (geomean of two systems)										
Water/sediment system	**pH water/ sed.**	**$DegT_{50}$ whole syst. (d)**	**$DegT_{90}$ whole syst. (d)**	**Kinetic, Fit**	**$DissT_{50}$ water (d)**	**$DissT_{90}$ water (d)**	**Kinetic, Fit**	**$DissT_{50}$ sed. (d)**	**Kinetic, Fit**	**Evaluated on EU level y/n/ Reference**
Pikeville	6.2 / 4.9 a)	5.4	17.9	SFO	16.8	55.9	SFO	-	SFO	Y/ EFSA Journal 2016;14(3): 4421
Hoechst sand	8.4 / 7.4 a)	45.8	152.0	SFO	115	382.1	SFO	103	SFO	Y/ EFSA Journal 2016;14(3): 4421
Geometric mean (n=2)		15.7	52.2		44.0	146.1		103		

a) measured in $CaCl_2$

Table 8.6-3: Summary of degradation in water/sediment of metabolite AE 0338795

AE 0338795: max. 23.7% total system (57 d), 17.0% water (57 d), 6.8% sediment (57 d) Formation fraction from parent active substance in total systems: 0.32 (geomean of two systems)										
Water/sediment system	**pH water/ sed.**	**$DegT_{50}$ whole syst. (d)**	**$DegT_{90}$ whole syst. (d)**	**Kinetic, Fit**	**$DissT_{50}$ water (d)**	**$DissT_{90}$ water (d)**	**Kinetic, Fit**	**$DissT_{50}$ sed. (d)**	**Kinetic, Fit**	**Evaluated on EU level y/n/ Reference**

AE 0338795: max. 23.7% total system (57 d), 17.0% water (57 d), 6.8% sediment (57 d) Formation fraction from parent active substance in total systems: 0.32 (geomean of two systems)										
Water/sediment system	**pH water/ sed.**	**$DegT_{50}$ whole syst. (d)**	**$DegT_{90}$ whole syst. (d)**	**Kinetic, Fit**	**$DissT_{50}$ water (d)**	**$DissT_{90}$ water (d)**	**Kinetic, Fit**	**$DissT_{50}$ sed. (d)**	**Kinetic, Fit**	**Evaluated on EU level y/n/ Reference**
Pikeville	6.2 / 4.9 a)	n.d.	n.d.		8.0	26.4	SFO	27.9	SFO	Y/ EFSA Journal 2016;14(3): 4421
Hoechst sand	8.4 / 7.4 a)	65.4	217.5	SFO	104.0	345.7	SFO	89.0	SFO	Y/ EFSA Journal 2016;14(3): 4421
Geometric mean (n=2)		65.4	217.5		28.8	95.5		49.8		

a) measured in $CaCl_2$

Table 8.6-4: Summary of degradation in water/sediment of metabolite AE F153745

AE F153745: max. 24.6% total system (57 d), 12.3% water (119 d), 13.6% sediment (57 d) Formation fraction from parent active substance in total systems: 0.34 (geomean of two systems)										
Water/sediment system	**pH water/ sed.**	**$DegT_{50}$ whole syst. (d)**	**$DegT_{90}$ whole syst. (d)**	**Kinetic, Fit**	**$DissT_{50}$ water (d)**	**$DissT_{90}$ water (d)**	**Kinetic, Fit**	**$DissT_{50}$ sed. (d)**	**Kinetic, Fit**	**Evaluated on EU level y/n/ Reference**
Pikeville	6.2 / 5.7 a)	72.1	239.5	SFO	n.d.	n.d.	-	n.d.	-	Y/ EFSA Journal 2016;14(3): 4421
Hoechst sand	8.4 / 7.8 a)	n.d.	n.d.	-	31.2	103.7	SFO	n.d.	-	Y/ EFSA Journal 2016;14(3): 4421
Geometric mean (n=2)		72.1	239.5		31.2	103.7		-		

a) measured in $CaCl_2$

Table 8.6-5: Summary of degradation in water/sediment of metabolite AE F092944

AE F092944: max. 7.3% total system (57 d), 2.2% water (7 d), 6.7% sediment (84 d) Formation fraction from parent active substance in total systems: 0.11 (geomean of two systems)										
Water/sediment system	**pH water/ sed.**	**$DegT_{50}$ whole syst. (d)**	**$DegT_{90}$ whole syst. (d)**	**Kinetic, Fit**	**$DissT_{50}$ water (d)**	**$DissT_{90}$ water (d)**	**Kinetic, Fit**	**$DissT_{50}$ sed. (d)**	**Kinetic, Fit**	**Evaluated on EU level y/n/ Reference**
Pikeville	6.2 / 5.7 a	110.0	363.6	SFO	n.d.	n.d.	-	147	SFO	Y/ EFSA Journal 2016;14(3): 4421
Hoechst sand	8.4 / 7.8 a)	n.d.	n.d.	-	n.d.	n.d.	-	n.d.	-	Y/ EFSA Journal

AE F092944: max. 7.3% total system (57 d), 2.2% water (7 d), 6.7% sediment (84 d) Formation fraction from parent active substance in total systems: 0.11 (geomean of two systems)										
Water/sediment system	**pH water/ sed.**	**$DegT_{50}$ whole syst. (d)**	**$DegT_{90}$ whole syst. (d)**	**Kinetic, Fit**	**$DissT_{50}$ water (d)**	**$DissT_{90}$ water (d)**	**Kinetic, Fit**	**$DissT_{50}$ sed. (d)**	**Kinetic, Fit**	**Evaluated on EU level y/n/ Reference**
										2016;14(3): 4421
Geometric mean (n=2)		110.0	363.6		-	-		147		

[a)] measured in $CaCl_2$

Table 8.6-6: Summary of observed metabolites

AE F130619 Water/sediment system	Max. in water/sediment: 7.0% after 57 d (Hoechst sand) Max. in water: 5.7% after 57 d (Hoechst sand) Max. in sediment: 1.4% after 84 d (Hoechst sand)	Y/ EFSA Journal 2016;14(3): 4421
AE 0338795 Water/sediment system	Max. in water/sediment: 23.7% after 57 d (Hoechst sand) Max. in water: 17.0% after 57 d (Hoechst sand) Max. in sediment: 6.8% after 57 d (Hoechst sand)	Y/ EFSA Journal 2016;14(3): 4421
AE F153745 Water/sediment system	Max. in water/sediment: 24.6% after 57 d (Pikeville) Max. in water: 12.3% after 119 d (Hoechst sand) Max. in sediment: 13.6% after 57 d (Pikeville)	Y/ EFSA Journal 2016;14(3): 4421
AE F092944 Water/sediment system	Max. in water/sediment: 7.3% after 57 d (Pikeville) Max. in water: 2.2% after 7 d (Pikeville) Max. in sediment: 6.7% after 84 d (Pikeville)	Y/ EFSA Journal 2016;14(3): 4421
AE F099095 Sterile aqueous buffer photolysis	Max. in water: 35.2% after 6 d	Y/ EFSA Journal 2016;14(3): 4421
4-Amino-N-methylbenzamide Sterile aqueous buffer photolysis	Max. in water: 10.2% after 6 d	Y/ EFSA Journal 2016;14(3): 4421
4-Formylamido-N-methylbenzamide* Sterile aqueous buffer photolysis	Max. in water: 16.6% after 5 d	Y/ EFSA Journal 2016;14(3): 4421
Foramsulfuron-sulfamic acid Sterile aqueous buffer photolysis	Max. in water: 14.2% after 6-7 d	Y/ EFSA Journal 2016;14(3): 4421

* also named as 4-formamido-N-methylbenzamide

zRMS comments:

Aquatic degradation data of foramsulfuron and its metabolites are in accordance with EFSA Conclusions (EFSA Journal 2016; 14 (3):4421).

8.6.2 Thiencarbazone-methyl and its metabolites

The degradation of thiencarbazone-methyl in water/sediment systems has been evaluated, full details of these studies are provided in the respective EU reference and related documents and summarised in the EFSA conclusion (EFSA Journal 2013;11(7):3270); no additional studies are considered for this assessment.

Table 8.6-7: Summary of degradation in water/sediment of thiencarbazone-methyl

Thiencarbazone-methyl Distribution: maximum in sediment 26.0% after 14 d										
Water/sediment system	**pH water/ sed.**	**$DegT_{50}$ whole syst. (d)**	**$DegT_{90}$ whole syst. (d)**	**Kinetic, Fit**	**$DissT_{50}$ water (d)**	**$DissT_{90}$ water (d)**	**Kinetic, Fit**	**$DissT_{50}$ sed. (d)**	**Kinetic, Fit**	**Evaluated on EU level y/n/ Reference**
Hoenniger sandy loam	6.7 / 5.0 a)	21.9	72.7	SFO	17.7	58.8	SFO	21.5	SFO	Y/ EFSA Journal 2013;11(7):3270
Clayton loamy sand	5.7 / 5.2 a)	31.3	103.8	SFO	25.6	85.1	SFO	38.2	SFO	Y/ EFSA Journal 2013;11(7):3270
Geometric mean (n=2)		26.2	86.9		21.3	70.7		28.7		

a a) measured in $CaCl_2$

Table 8.6-8: Summary of degradation in water/sediment of BYH18636-carboxylic acid

BYH18636-carboxylic acid Distribution: max. 37.1% total system (14 d), 24.6% water (30 d), 13.0% sediment (14 d)										
Water/sediment system	**pH water/ sed.**	**$DegT_{50}$ whole syst. (d)**	**$DegT_{90}$ whole syst. (d)**	**Kinetic, Fit**	**$DissT_{50}$ water (d)**	**$DissT_{90}$ water (d)**	**Kinetic, Fit**	**$DissT_{50}$ sed. (d)**	**Kinetic, Fit**	**Evaluated on EU level y/n/ Reference**
Hoenniger	6.7 / 5.0 a)	29.1	96.6	SFO	79.5	264	SFO	62.9	SFO	Y/ EFSA Journal 2013;11(7):3270
Clayton	5.7 / 5.2 a)	32.4	107.7	SFO	138.5	460.1	SFO	88.3	SFO	Y/ EFSA Journal 2013;11(7):3270
Geometric mean (n=2)		30.7	102		104.9	348.5		74.5		

a) measured in $CaCl_2$

Table 8.6-9: Summary of degradation in water/sediment of BYH18636-sulfonamide, BYH18636-MMT and BYH18636-dicarboxy-sulfonamide

BYH18636-sulfonamide Distribution: max. 7.0% total system (59 d), 4.3% water (59 d), 2.7% sediment (59 d)

BYH18636-sulfonamide-carboxylic acid Distribution: max. 66.9% total system (120 d = study end), 45.6% water (120 d), 21.3% sediment (120 d)

BYH18636-MMT Distribution: max. 30.7% total system (92 d), 24.9% water (92 d), 7.8% sediment (120 d)

BYH18636-dicarboxy-sulfonamide Distribution: max. 23.9% total system (120 d = study end), 18.9% water (120 d), 0% sediment

Water/sediment system	pH water/ sed.	$DegT_{50}$ whole syst. (d)	$DegT_{90}$ whole syst. (d)	Kinetic, Fit	$DissT_{50}$ water (d)	$DissT_{90}$ water (d)	Kinetic, Fit	$DissT_{50}$ sed. (d)	Kinetic, Fit	Evaluated on EU level y/n/ Reference
Hoenniger	6.7 / 5.0 [a]	- [b]	- [b]	- [b]	- [b]	- [b]	- [b]	- [b]	- [b]	Y/ EFSA Journal 2013;11(7):3270
Clayton	5.7 / 5.2 [a]	- [b]	- [b]	- [b]	- [b]	- [b]	- [b]	- [b]	- [b]	Y/ EFSA Journal 2013;11(7):3270
Endpoint		- [b]	- [b]		- [b]	- [b]		- [b]		

[a] measured in $CaCl_2$

[b] no reliable value determinable

Table 8.6-10: Summary of observed metabolites

BYH18636-carboxylic acid Water/sediment system	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)	Y/ EFSA Journal 2013;11(7):3270
BYH18636-sulfonamide Water/sediment system	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)	Y/ EFSA Journal 2013;11(7):3270
BYH18636-sulfonamide-carboxylic acid Water/sediment system	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)	Y/ EFSA Journal 2013;11(7):3270
BYH18636-MMT Water/sediment system	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)	Y/ EFSA Journal 2013;11(7):3270
BYH18636-dicarboxy-sulfonamide Water/sediment system	Max. in water/sediment: 23.9% after 120 d (Clayton) Max. in water: 18.9% after 120 d (Clayton) Max. in sediment: 0%	Y/ EFSA Journal 2013;11(7):3270

zRMS comments:

Aquatic degradation data of thiencarbazone-methyl and its metabolites are in accordance with EFSA Conclusions EFSA Journal 2013;11(7):3270.

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

PEC_{soil} reports provided by the applicant are listed in Appendix 3.1.

8.7.1 Justification for new endpoints

Foramsulfuron and metabolites

Compound	Parameter	EU endpoint	Used endpoint	Justification
Metabolite AE F153745	Maximum occurrence observed (% molar basis with respect to the parent)	Soil: 7.8	Soil: 10.4	As a conservative assessment max. occurrence in soil from a soil photolysis study was taken for modelling.

Thiencarbazone-methyl
No new endpoints were used.

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

Input parameters related to application:

Foramsulfuron

For the active substance **foramsulfuron** and its metabolites risk assessments based on PEC_{soil} calculations are passed without any refinement, even if worst case PEC_{soil} values are considered.
Therefore, to simplify the assessment, PEC_{soil} for this compound is calculated in a “risk envelope approach”, addressing the maximum registered application rate and overall worst case exposure situation (no tillage, no crop interception) which is relevant for the compound in any product supported by Bayer AG in Europe.
The resulting PEC_{soil} calculations overestimate the actual exposure due to use of the product, and thus further increase the conservatism of the Tier 1 risk assessments.

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

Use No.	risk envelope covering all uses of foramsulfuron
Crop	maize, sugar beet, nursery (risk envelope)
Application rate (g as/ha)	60 g a.s./ha (risk envelope)
Number of applications/interval	1 / -
Crop interception (%)	0
Depth of soil layer (relevant for	10 cm (no tillage)

plateau concentration) (cm)	

Thiencarbazone-methyl

For the active substance **thiencarbazone-methyl** and its metabolites risk assessments based on PEC_{soil} calculations are passed without any refinement, even if worst case PEC_{soil} values are considered.
Therefore, to simplify the assessment, PEC_{soil} for this compound is calculated in a “risk envelope approach”, addressing the maximum registered application rate and overall worst case exposure situation (no tillage, no crop interception) which is relevant for the compound in any product supported by Bayer AG in Europe.
The resulting PEC_{soil} calculations overestimate the actual exposure due to use of the product, and thus further increase the conservatism of the Tier 1 risk assessments.

Table 8.7-2: Input parameters related to application for PEC_{soil} calculations

Use No.	risk envelope covering all uses of thiencarbazone-methyl
Crop	cereals, maize, sugar beet, non-cropped area (risk envelope)
Application rate (g as/ha)	40 g a.s./ha (risk envelope)
Number of applications/interval	1 / -
Crop interception (%)	0
Depth of soil layer (relevant for plateau concentration) (cm)	10 cm (no tillage)

Substance parameters for active substances and metabolites:

Table 8.7-3: Input parameter for foramsulfuron and relevant metabolite(s) for PEC_{soil} calculation

Compound	Molecular weight (g/mol)	Max. occurrence (%)	DT_{50} (days)	Value in accordance to EU endpoint y/n/ Reference
Foramsulfuron	452.49	100	82	Y/ EFSA Journal 2016;14(3): 4421
AE F130619	424.44	29.1	13.3	Y/ EFSA Journal 2016;14(3): 4421
AE F092944	155.16	17.8	254.4	Y/ EFSA Journal 2016;14(3): 4421
AE F153745	271.3	10.4*	3.7 (3.68)	Y/ EFSA Journal 2016;14(3): 4421 *N / justification is presented above

Table 8.7-4: Input parameter for thiencarbazone-methyl and relevant metabolites for PEC_{soil} calculation

Compound	Molecular weight (g/mol)	Max. occurrence (%)	DT_{50} (days)	Value in accordance to EU endpoint y/n/ Reference
thiencarbazone-methyl	390.4	100	53.2	Y/ EFSA Journal 2013;11(7):3270
BYH 18636-sulfonamide	235.3	15.6	48	Y/ EFSA Journal 2013;11(7):3270
BYH 18636-carboxylic acid	376.4	53.6	- * (Bi-phasic degradation)	Y/ EFSA Journal 2013;11(7):3270
BYH 18636-sulfonamide-carboxylic acid	221.3	21.2	26.6)	Y/ EFSA Journal 2013;11(7):3270
BYH 18636-MMT	129.1	20.6	- * (Bi-phasic degradation)	Y/ EFSA Journal 2013;11(7):3270
BYH 18636-triazolinone-carboxamide	172.1	8.1	34.5	Y/ EFSA Journal 2013;11(7):3270

* bi-phasic degradation – detailed kinetic parameters used for calculation are described in Appendix 3, A 3.1 - A 3.1; 8.7 - Predicted Environmental Concentrations in soil (PECsoil) (KCP 9.1.3): Thiencarbazone-methyl and relevant metabolites

8.7.2.1 Foramsulfuron and its metabolites

Table 8.7-5: PEC_{soil} for foramsulfuron

PEC_{soil} (mg/kg)		Risk envelope approach – maize, **sugar beet**, nursery (needle trees)			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		**0.080**	-	-	-
Short term	24h	0.079	0.080	-	-
	2d	0.079	0.079	-	-
	4d	0.077	0.079	-	-
Long term	7d	0.075	0.078	-	-
	14d	0.071	0.075	-	-
	21d	0.067	0.073	-	-
	28d	0.063	0.071	-	-
	42d	0.056	0.067	-	-
	50d	0.052	0.065	-	-
	100d	0.034	0.054	-	
Plateau concentration (10 cm) after year 1		0.002	-	-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		**0.082**	-	-	-

Table 8.7-6: PEC_{soil} for AE F130619

PEC_{soil} (mg/kg)		Risk envelope approach – maize, **sugar beet,** nursery (needle trees)			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		**0.022**	-	-	-
Short term	24h	0.021	0.021	-	-
	2d	0.020	0.021	-	-
	4d	0.018	0.020	-	-
Long term	7d	0.015	0.018	-	-
	14d	0.011	0.016	-	-
	21d	0.007	0.013	-	-
	28d	0.005	0.011	-	-
	42d	0.002	0.009	-	-
	50d	0.002	0.008	-	-
	100d	<0.001	0.004	-	-
Plateau concentration (10 cm) after year 0		<0.001	-	-	--
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		**0.022**	-	-	-

Table 8.7-7: PEC$_{soil}$ for AE F092944

PEC$_{soil}$ (mg/kg)		Risk envelope approach – maize, **sugar beet**, nursery (needle trees)			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		**0.005**	-	-	-
Short term	24h	0.005	0.005	-	-
	2d	0.005	0.005	-	-
	4d	0.005	0.005	-	-
Long term	7d	0.005	0.005	-	-
	14d	0.005	0.005	-	-
	21d	0.005	0.005	-	-
	28d	0.005	0.005	-	-
	42d	0.004	0.005	-	-
	50d	0.004	0.005	-	-
	100d	0.004	0.004	-	-
Plateau concentration (10 cm) after year 3		0.001	-	-	-
PEC$_{accumulation}$ (PEC$_{act}$ +PEC$_{soil\ plateau}$)		**0.006**	-	-	-

Table 8.7-8: PEC$_{soil}$ for AE F153745

PEC$_{soil}$ (mg/kg)		Risk envelope approach – maize, **sugar beet**, nursery (needle trees)			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		**0.005**	-	-	-
Short term	24h	0.004	0.005	-	-
	2d	0.003	0.004	-	-
	4d	0.002	0.004	-	-
Long term	7d	0.001	0.003	-	-
	14d	<0.001	0.002	-	-
	21d	<0.001	0.001	-	-
	28d	<0.001	< 0.001	-	-
	42d	<0.001	< 0.001	-	-
	50d	<0.001	< 0.001	-	-
	100d	<0.001	< 0.001	-	-
Plateau concentration (10 cm) after year 0		<0.001	-	-	-
PEC$_{accumulation}$ (PEC$_{act}$ +PEC$_{soil\ plateau}$)		**0.005**	-	-	-

8.7.2.2 Thiencarbazone-methyl and its metabolites

Table 8.7-9: PEC$_{soil}$ for thiencarbazone-methyl

PEC$_{soil}$ (mg/kg)		Risk envelope approach – cereals, maize, **sugar beet**, non-cropped area			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		**0.053**	-	-	-
Short term	24h	0.053	0.053	-	-
	2d	0.052	0.053	-	-
	4d	0.051	0.052	-	-
Long term	7d	0.049	0.051	-	-
	14d	0.044	0.049	-	-
	21d	0.041	0.047	-	-
	28d	0.037	0.045	-	-
	42 d	0.031	0.041	-	-
	50d	0.028	0.039	-	-
	100d	0.014	0.030	-	-

Table 8.7-10: PEC$_{soil}$ for BYH 18636-sulfonamide

PEC$_{soil}$ (mg/kg)		Risk envelope approach – Cereals, maize, **sugar beet**, non-cropped area			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		**0.005**	-	-	-
Short term	24h	0.005	0.005	-	-
	2d	0.005	0.005	-	-
	4d	0.005	0.005	-	-
Long term	7d	0.005	0.005	-	-
	14d	0.004	0.005	-	-
	21d	0.004	0.004	-	-
	28d	0.003	0.004	-	-
	42 d	0.003	0.004	-	-
	50d	0.002	0.004	-	-
	100d	0.001	0.003	-	-

Table 8.7-11: PEC$_{soil}$ for BYH 18636-carboxylic acid

PEC$_{soil}$ (mg/kg)		Risk envelope approach – Cereals, maize, **sugar beet**, non-cropped area			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		**0.028**	-	-	-
Short term	24h	0.027	0.027	-	-
	2d	0.026	0.027	-	-
	4d	0.024	0.026	-	-
Long term	7d	0.022	0.025	-	-
	14d	0.018	0.022	-	-
	21d	0.015	0.020	-	-
	28d	0.013	0.019	-	-
	42 d	0.011	0.017	-	-
	50d	0.010	0.016	-	-
	100d	0.008	0.012	-	-
Plateau concentration (10 cm)		0.004	-	-	-
PEC$_{accumulation}$ (PEC$_{act}$ +PEC$_{soil\ plateau}$)		**0.032**	-	-	-

Table 8.7-12: PEC$_{soil}$ for BYH 18636-sulfonamide-carboxylic acid

PEC$_{soil}$ (mg/kg)		Risk envelope approach – Cereals, maize, **sugar beet**, non-cropped area			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		**0.006**	-	-	-
Short term	24h	0.006	0.006	-	-
	2d	0.006	0.006	-	-
	4d	0.006	0.006	-	-
Long term	7d	0.005	0.006	-	-
	14d	0.004	0.005	-	-
	21d	0.004	0.005	-	-
	28d	0.003	0.005	-	-
	42 d	0.002	0.004	-	-
	50d	<0.002	0.004	-	-
	100d	<0.001	0.002	-	-

Table 8.7-13: PEC$_{soil}$ for BYH 18636-MMT

PEC$_{soil}$ (mg/kg)		Risk envelope approach – Cereals, maize, **sugar beet**, non-cropped area			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		**0.004**	-	-	-
Short term	24h	0.004	0.004	-	-
	2d	0.003	0.004	-	-
	4d	0.003	0.003	-	-
Long term	7d	0.003	0.003	-	-
	14d	0.002	0.003	-	-
	21d	0.002	0.003	-	-
	28d	0.001	0.002	-	-
	42 d	0.001	0.000	-	-
	50d	<0.001	0.002	-	-
	100d	<0.001	<0.001	-	-

Table 8.7-14: PEC$_{soil}$ for BYH 18636-triazolinone-carboxamide

PEC$_{soil}$ (mg/kg)		Risk envelope approach – Cereals, maize, **sugar beet**, non-cropped area			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		**0.002**	-	-	-
Short term	24h	0.002	0.002	-	-
	2d	0.002	0.002	-	-
	4d	0.002	0.002	-	-
Long term	7d	0.002	0.002	-	-
	14d	0.001	0.002	-	-
	21d	0.001	0.002	-	-
	28d	0.001	0.001	-	-
	42 d	<0.001	0.001	-	-
	50d	0.001	0.001	-	-
	100d	<0.001	<0.001	-	-

8.7.2.3 PECsoil of FSN+TCM OD 80 (50+30)

Table 8.7-15: PEC_{soil} for FSN+TCM OD 80 (50+30) on sugar beets

Active substance/ preparation	Application rate (g/ha)	PEC_{act} (mg/kg)	PEC_{twa}21 d (mg/kg)	Tillage depth (cm)	$PEC_{soil,plateau}$ (mg/kg)	PEC_{accu} = PEC_{act} + $PEC_{soil,plateau}$ (mg/kg)
FSN+TCM OD 80 (50+30)	1028#	1.371 *	-	5	-	-

Based on formulation density of 1.028 g/mL
* The PEC for the formulation was calculated with an interception rate of 0%

PEC_{soil} is calculated using a standard approach with 5 cm mixing depth and soil density of 1.5 kg/L. No degradation data is available for the product. Therefore, TWA, plateau, and accumulation concentrations are not calculated, and tillage depth is not relevant here.

zRMS comments:

The PECsoil of foramsulfuron and metabolites in soil have been assessed with the DT_{50} values established in the EU review (EFSA Journal 2016). DT_{50} in soil of 82 days (worst case of normalized laboratory studies) was used for calculation for foramsulfuron.

The PECsoil of thiencarbazone-methyl and metabolites in soil have been assessed with the DT50 values established in the EU review (EFSA Journal 2013). DT_{50} in soil of 53.2 days (representative worst case un-normalised value from lab studies.) was used for calculation for thiencarbazone-methyl.

The PECsoil calculations are accepted by the zRMS and the results can be used in the exposure and risk assessment.

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

PEC_{gw} reports provided by the applicant are listed in Appendix 3.2.

8.8.1 Justification for new endpoints

No new endpoints were used.

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.	POL:22 (critical GAP) covers other uses listed in B0 AUT: 23 BEL: 24 CZE: 25 HUN: 26 SVK: 27 GBR: 28 NLD: 29 ROU: 30 IRE: 31	POL: 32 (critical GAP) covers other uses listed in B0 AUT: 33 BEL: 34 CZE: 35 SVK: 36 NLD: 37 ROU: 38 HUN: 39 IRE: 40

Crop	Sugar beets	Sugar beets
Application rate (g as/ha)	Foramsulfuron: 50 g a.s./ha Thiencarbazone-methyl: 30 g a.s./ha	Foramsulfuron: 25 g a.s./ha Thiencarbazone-methyl: 15 g a.s./ha
Number of applications/interval (d)	1 / -	2 / 10
Relative application date	Absolute date setting based on AppDate tool Application window used for modelling: see Table 8.8-2	Absolute date setting based on AppDate tool Application window used for modelling: see Table 8.8-2
Crop interception (%)	20 %	20 %
Frequency of application	annual use	annual use
Models used for calculation	FOCUS PEARL v4.4.4, FOCUS PELMO v5.5.3, FOCUS MACRO v5.5.4	FOCUS PEARL v4.4.4, FOCUS PELMO v5.5.3, FOCUS MACRO v5.5.4

Table 8.8-2: Application dates used for groundwater exposure assessment – single and multiple applications in sugar beet

Crop	Scenario	Application dates (absolute)
Sugar beets	Châteaudun	17 Apr
	Hamburg	16 Apr
	Jokioinen	26 May
	Kremsmünster	16 Apr
	Okehampton	26 Apr
	Piacenza	21 Mar
	Porto	16 Mar
	Sevilla	11 Nov
	Thiva	02 May

8.8.2.1 Foramsulfuron and its metabolites

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

Compound	Foramsulfuron	AE F130619	AE F092944	AE F153745	Value in accordance with EU endpoint y/n/ Reference
Molecular weight (g/mol)	452.49	424.44	155.16	271.30	Y/ EFSA Journal 2016;14(3): 4421

Compound	Foramsulfuron	AE F130619	AE F092944	AE F153745	Value in accordance with EU endpoint y/n/ Reference
Water solubility (mg/L):	3293 (20°C, pH 6.9)	35.5 (20°C, pH 7)	5484 (20°C, pH 7)	5830 (20°C, pH 7)	Y/ EFSA Journal 2016;14(3): 4421
Saturated vapour pressure (Pa):	4.2×10^{-11} (20°C)	5.8×10^{-13} (20°C)	3.72×10^{-2} (20°C)	3.47×10^{-8} (20°C)	Y/ EFSA Journal 2016;14(3): 4421
DT_{50} in soil (d)	12.0 (geomean, lab., normalisation to 10 kPa or pF2, 20 °C with Q10 of 2.58, n = 10)	1.5 (geomean, lab., normalisation to 10 kPa or pF2, 20 °C with Q10 of 2.58, n = 7)	18.8 (geomean, lab., normalisation to 10 kPa or pF2, 20 °C with Q10 of 2.58, n = 12)	0.85 (geomean, lab., normalisation to 10 kPa or pF2, 20 °C with Q10 of 2.58, n = 4)	Y/ EFSA Journal 2016;14(3): 4421
Transformation rate (1/d)	0.05776	0.4621	0.03687	0.79672	Calculated as ln 2 / DT_{50}
K_{foc} (mL/g)/K_{fom}	69.7/40.4 (geometric mean, n =5)	63.2/36.7 (geometric mean, n =4)	275.8/160 (geometric mean, n =19)	48/27.8 (geometric mean, n =4)	Y/ EFSA Journal 2016;14(3): 4421
1/n	0.87 (arithmetic mean, n =5)	0.93 (arithmetic mean, n =4)	0.76 (arithmetic mean, n =19)	0.97 (arithmetic mean, n =4)	Y/ EFSA Journal 2016;14(3): 4421
Plant uptake factor	0.0	0.0	0.0	0.0	Y/ EFSA Journal 2016;14(3): 4421
Formation fraction	-	0.92	0.22	0.22	Y/ EFSA Journal 2016;14(3): 4421

Table 8.8-4: PEC$_{gw}$ for foramsulfuron and metabolites (with FOCUS PEARL, PELMO and MACRO)
- Use: Sugar beet, 1 × 50 g a.s./ha

Crop	Scenario	80th percentile PEC$_{gw}$ at 1 m soil depth (µg/L)							
		Foramsulfuron		AE F130619		AE F092944		AE F153745	
		PEARL[1)]	PELMO[1)]	PEARL[1)]	PELMO[1)]	PEARL[1)]	PELMO[1)]	PEARL[1)]	PELMO[1)]
Sugar beet, 1 × 50 g/ha ≡ 1 × 1.0L prod./ha	Châteaudun	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Hamburg	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Jokioinen	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Kremsmünster	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Okehampton	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Piacenza	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Porto	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Sevilla	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Thiva	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
		MACRO[1)]		MACRO[1)]		MACRO[1)]		MACRO[1)]	
	Châteaudun	<0.001		<0.001		<0.001		<0.001	

data origin (modelling report & crop no.): [1)] EnSa-16-0770, Sugar beets, 1×50 g a.s./ha.

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Table 8.8-5: PEC_{gw} for foramsulfuron and metabolites (with FOCUS PEARL, PELMO and MACRO)
- Use: Sugar beet, 2 × 25 g a.s./ha, 10 d interval

Crop	Scenario	80th percentile PEC_{gw} at 1 m soil depth (µg/L)							
		Foramsulfuron		**AE F130619**		**AE F092944**		**AE F153745**	
		PEARL[1)]	**PELMO[1)]**	**PEARL[1)]**	**PELMO[1)]**	**PEARL[1)]**	**PELMO[1)]**	**PEARL[1)]**	**PELMO[1)]**
Sugar beet, 2 × 25 g/ha ≡ 2 × 0.5L prod./ha	Châteaudun	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Hamburg	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Jokioinen	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Kremsmünster	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Okehampton	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Piacenza	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Porto	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Sevilla	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Thiva	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
		MACRO[1)]		**MACRO[1)]**		**MACRO[1)]**		**MACRO[1)]**	
	Châteaudun	<0.001		<0.001		<0.001		<0.001	

data origin (modelling report & crop no.): [1)] EnSa-16-0770, Sugar beets, 2×25 g a.s./ha..

Groundwater exposure assessment foramsulfuron – Overall Conclusion:
The active substance foramsulfuron and its metabolites do not breach the EU threshold value of 0.1 µg/L for the intended uses of the present formulation. The risk for groundwater is acceptable and no relevance assessment in Part B.10 for any of the assessed metabolites is required.

RMS comments:

<u>Foramsulfuron</u>
The PEC_{gw} calculations have been provided for the active substance foramsulfuron and its metabolites AE F130619, AE F092944, AE F153745. Input parameters used for calculations were appropriate. In opinion of zRMS interception is appropriate to the proposed BBCH of crops (guidance 2014). In simulations PUF value of 0 was assumed for all compounds, in line with recommendations of the most recent version of the FOCUS Groundwater Guidance.
According to the PEC_{gw} modelling a groundwater contamination of the active substance foramsulfuron at a concentration of ≥ 0.1 µg/L is not expected for the all FOCUS groundwater scenarios.
For the metabolites AE F130619, AE F092944 and AE F153745 a groundwater concentration of ≥ 0.1 µg/L can be excluded in all FOCUS groundwater scenarios.

8.8.2.2 Thiencarbazone-methyl 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	Value in accordance with EU endpoint y/n/ Reference*
Molecular weight (g/mol)	390.4	376.4	235.3	Y/ EFSA Journal 2013;11(7):3270

Compound	Thiencarbazone-methyl	BYH 18636-carboxylic acid	BYH 18636-sulfonamide	Value in accordance with EU endpoint y/n/ Reference*
Water solubility (mg/L):	436 (20°C)	10000 mg/L [a]	10000 mg/L [a]	Y/ EFSA Journal 2013;11(7):3270
Saturated vapour pressure (Pa):	8.8×10^{-14} # (20°C)	1×10^{-20} Pa [a]	1×10^{-20} Pa [a]	# Y/ EFSA Journal 2013;11(7):3270 N / Worst case assumption for metabolites
DT_{50} in soil (d)	11.6 (geomean, normalisation to pF2, 20 °C with Q_{10} of 2.58, n =5)	62.4 (geomean, normalisation to pF2, 20 °C with Q_{10} of 2.58, n =4)	11.2 (geomean, normalisation to pF2, 20 °C with Q_{10} of 2.58, n =5)	Y/ EFSA Journal 2013;11(7):3270
Transformation rate (Rate constant)	0.05976	0.01111	0.06189	Y/ EFSA Journal 2013;11(7):3270
K_{foc} (mL/g)/K_{fom}	83/ 48.1 (geomean, n = 5)	11.7/ 6.8 geomean, n = 5)	100/58.2 (geomean, n = 5)	Y/ EFSA Journal 2013;11(7):3270
1/n	0.906 (arithm. mean, n = 4)	0.919 (arithm. mean, n = 5)	0.90 (arithm. mean, n = 5)	Y/ EFSA Journal 2013;11(7):3270
Plant uptake factor	0.5 [b]	0 [b]	0 [b]	Y/ EFSA Journal 2013;11(7):3270
Formation fraction	-	0.382 (from TCM)	0.375 (from TCM)	Y/ EFSA Journal 2013;11(7):3270

[a] Not measured. Default value used
[b] The TSCF value that should be used in FOCUS modelling for thiencarbazone-methyl and its soil metabolites has been extensively discussed in Pesticides Peer Review Meeting 101 (see minuted in EFSA Peer Review Report on Thiencarbazone-methyl, PDF page 211). It was accepted that a TSCF value of 0.5 could be used for the parent compound on the basis of the results of the confined rotational crop study. As there was no good definitive evidence of systemicity for soil metabolites, the majority of experts considered that FOCUS modelling should use a TSCF factor of 0 for metabolites. These values are listed as the relevant EU Endpoints for modelling (cf. page 50 of EFSA Journal 2013;11(7):3270), and are used in the subsequent exposure simulation

Table 8.8-7: Input parameters related to thiencarbazone-methyl metabolites for PEC_{gw} calculations (continued)

Compound	BYH 18636- sulfonamide-carboxylic acid	BYH 18636-MMT	BYH 18636-triazolinone-carboxamide	Value in accordance with EU endpoint y/n/ Reference*
Molecular weight (g/mol)	221.3	129.1	172.1	Y/ EFSA Journal 2013;11(7):3270
Water solubility (mg/L):	10000 mg/L [a]	10000 mg/L [a]	10000 mg/L [a]	Y/ EFSA Journal 2013;11(7):3270
Saturated vapour pressure (Pa):	1×10^{-20} Pa [a]	1×10^{-20} Pa [a]	1×10^{-20} Pa [a]	N / Worst case assumption
DT_{50} in soil (d)	8.1 (geomean, lab.,	3.9/85.4 (geomean slow/fast	14.9 (geomean, lab.,	Y/ EFSA Journal 2013;11(7):3270

Compound	BYH 18636- sulfonamide-carboxylic acid	BYH 18636-MMT	BYH 18636-triazolinone-carboxamide	Value in accordance with EU endpoint y/n/ Reference*
	normalisation to pF2, 20 °C with Q_{10} of 2.58, n =5)	phase, normalisation to pF2, 20 °C with Q10 of 2.58, n =5)	normalisation to pF2, 20 °C with Q_{10} of 2.58, n =3)	
Transformation rate (Rate constant)	0.08557	transient: 1.38629 fast: 0.17773 slow:0.00812	0.04652	Y/ EFSA Journal 2013;11(7):3270
K_{foc} (mL/g)/K_{fom}	7.3/4.2 (geometric mean, n =5)	14.2/8.2 (geometric mean, n =5)	18/10.4	Y/ EFSA Journal 2013;11(7):3270
1/n	0.74 (arithmetic mean, n =5)	1.00 (arithmetic mean, n =1)	1.0	Y/ EFSA Journal 2013;11(7):3270
Plant uptake factor	0 [b]	0 [b]	0 [b]	N / Worst case assumption
Formation fraction	1 (from BYH18636-carboxylic acid) 0.794 (from BYH18636-sulfonamide)	0.932 (from MMT transient to MMTfast), 0.068 (from MMT transient to MMTslow)	-	Y/ EFSA Journal 2013;11(7):3270

[a] Not measured. Default value used
[b] The TSCF value that should be used in FOCUS modelling for thiencarbazone-methyl and its soil metabolites has been extensively discussed in Pesticides Peer Review Meeting 101 (see minuted in EFSA Peer Review Report on Thiencarbazone-methyl, PDF page 211). It was accepted that a TSCF value of 0.5 could be used for the parent compound on the basis of the results of the confined rotational crop study. As there was no good definitive evidence of systemicity for soil metabolites, the majority of experts considered that FOCUS modelling should use a TSCF factor of 0 for metabolites. These values are listed as the relevant EU Endpoints for modelling (cf. page 50 of EFSA Journal 2013;11(7):3270), and are used in the subsequent exposure simulation

Table 8.8-8: PEC_{gw} for thiencarbazone-methyl and metabolites: BYH 18636-sulfonamide, BYH 18636-carboxylic acid (with FOCUS PEARL, PELMO and MACRO) – Use: sugar beets, 1 × 30 g a.s./ha

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)					
		Thiencarbazone-methyl		BYH 18636-sulfonamide		BYH 18636-carboxylic acid1)	
		PEARL2)	PELMO2)	PEARL2)	PELMO2)	PEARL2)	PELMO2)
Sugar beet 1 × 30 g a.s./ha ≡ 1 × 1.0 L prod. /ha	Châteaudun	<0.001	<0.001	<0.001	<0.001	**1.152**	**1.051**
	Hamburg	<0.001	<0.001	<0.001	<0.001	**1.467**	**1.003**
	Jokioinen	<0.001	<0.001	<0.001	<0.001	**1.353**	**1.151**
	Kremsmünster	<0.001	<0.001	<0.001	<0.001	**0.800**	**0.790**
	Okehampton	<0.001	<0.001	<0.001	<0.001	**0.692**	**0.683**
	Piacenza	<0.001	<0.001	<0.001	<0.001	**0.589**	**0.665**
	Porto	<0.001	<0.001	<0.001	<0.001	**0.529**	**0.550**
	Sevilla	<0.001	<0.001	<0.001	<0.001	**0.543**	**0.682**
	Thiva	<0.001	<0.001	<0.001	<0.001	**1.109**	**0.663**

		MACRO[3)]	**MACRO[3)]**	**MACRO[3)]**
	Châteaudun	<0.001	<0.001	**0.616**

[1)] Metabolite non-relevance is demonstrated in Part B Section 10
data origin (modelling report & crop no.): [2)] EnSa-16-0806, Sugar beet I. / [3)] EnSa-18-0269, Sugar beet I.

Table 8.8-9: PEC_{gw} for thiencarbazone-methyl and metabolites: BYH 18636-sulfonamide-carboxylic acid, BYH 18636-MMT, BYH 18636-triazolinone-carboxamide (with FOCUS PEARL, PELMO and MACRO) (continued) Use: sugar beets, 1 × 30 g a.s./ha

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)					
		BYH 18636-sulfonamide-carboxylic acid		BYH 18636 -MMT [1)]		BYH 18636-triazolinone-carboxamide	
		PEARL[2)]	**PELMO[2)]**	**PEARL[2)]**	**PELMO[2)]**	**PEARL[2)]**	**PELMO[2)]**
Sugar beet 1 × 30 g a.s./ha ≡ 1 × 1.0 L prod. /ha	Châteaudun	0.052	0.050	0.050	0.048	0.007	0.003
	Hamburg	0.057	0.039	0.067	0.045	0.006	0.003
	Jokioinen	0.037	0.026	0.069	0.057	0.006	0.006
	Kremsmünster	0.037	0.032	0.036	0.037	0.004	0.004
	Okehampton	0.027	0.025	0.030	0.028	0.004	0.005
	Piacenza	0.033	0.032	0.029	0.034	0.002	0.003
	Porto	0.011	0.014	0.027	0.027	0.002	0.004
	Sevilla	0.016	0.020	0.031	0.038	0.006	0.010
	Thiva	0.054	0.030	0.064	0.039	<0.001	<0.001
		MACRO[3)]		**MACRO[3)]**		**MACRO[3)]**	
	Châteaudun	<0.001		0.060		0.002	

[1)] sum of PEC_{gw} for DFOP fast & slow phase simulations
data origin (modelling report & crop no.): [2)] EnSa-16-0806, Sugar beet I. / [3)] EnSa-18-0269, Sugar beet I.

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Table 8.8-10: PEC_{gw} for thiencarbazone-methyl and metabolites: BYH 18636-sulfonamide, BYH 18636-carboxylic acid (with FOCUS PEARL, PELMO and MACRO) – Use: sugar beets, 2 × 15 g a.s./ha, 10 d app. interval

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)					
		Thiencarbazone-methyl		BYH 18636-sulfonamide		BYH 18636-carboxylic acid[1)]	
		PEARL[2)]	**PELMO[2)]**	**PEARL[2)]**	**PELMO[2)]**	**PEARL[2)]**	**PELMO[2)]**
Sugar beet 2 × 15 g a.s./ha ≡ 2 × 0.5 L prod. /ha	Châteaudun	<0.001	<0.001	<0.001	<0.001	**1.166**	**1.061**
	Hamburg	<0.001	<0.001	<0.001	<0.001	**1.486**	**1.016**
	Jokioinen	<0.001	<0.001	<0.001	<0.001	**1.377**	**1.158**
	Kremsmünster	<0.001	<0.001	<0.001	<0.001	**0.805**	**0.795**
	Okehampton	<0.001	<0.001	<0.001	<0.001	**0.699**	**0.689**

	Piacenza	<0.001	<0.001	<0.001	<0.001	**0.589**	**0.659**
	Porto	<0.001	<0.001	<0.001	<0.001	**0.525**	**0.544**
	Sevilla	<0.001	<0.001	<0.001	<0.001	**0.505**	**0.640**
	Thiva	<0.001	<0.001	<0.001	<0.001	**1.130**	**0.670**
		MACRO[3)]		**MACRO[3)]**		**MACRO[3)]**	
	Châteaudun	<0.001		<0.001		**0.617**	

[1)] Metabolite non-relevance is demonstrated in Part B Section 10
data origin (modelling report & crop no.): [2)] EnSa-16-0806, Sugar beet II. / [3)] EnSa-18-0269, Sugar beet II.

Table 8.8-11: PEC_{gw} for thiencarbazone-methyl and metabolites: BYH 18636-sulfonamide-carboxylic acid, BYH 18636-MMT, BYH 18636-triazolinone-carboxamide (with FOCUS PEARL, PELMO and MACRO) (continued) – Use: sugar beets, 2 × 15 g a.s./ha, 10 d app. interval

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)					
		BYH 18636-sulfonamide-carboxylic acid		BYH 18636 -MMT [1)]		BYH 18636-triazolinone-carboxamide	
		PEARL[2)]	PELMO[2)]	PEARL[2)]	PELMO[2)]	PEARL[2)]	PELMO[2)]
Sugar beet 2 × 15 g a.s./ha ≡ 2 × 0.5 L prod. /ha	Châteaudun	0.053	0.051	0.050	0.048	0.007	0.003
	Hamburg	0.058	0.039	0.068	0.046	0.006	0.003
	Jokioinen	0.038	0.026	0.070	0.058	0.006	0.007
	Kremsmünster	0.038	0.033	0.036	0.037	0.004	0.004
	Okehampton	0.027	0.025	0.030	0.028	0.003	0.005
	Piacenza	0.032	0.031	0.029	0.034	0.002	0.003
	Porto	0.011	0.013	0.027	0.026	0.002	0.004
	Sevilla	0.015	0.019	0.031	0.037	0.006	0.011
	Thiva	0.056	0.031	0.065	0.039	<0.001	0.001
		MACRO[3)]		**MACRO[3)]**		**MACRO[3)]**	
	Châteaudun	<0.001		0.060		0.002	

[1)] sum of PEC_{gw} for DFOP fast & slow phase simulations
data origin (modelling report & crop no.): [2)] EnSa-16-0806, Sugar beet II. / [3)] EnSa-18-0269, Sugar beet II.

Groundwater exposure thiencarbazone-methyl – Overall Conclusion:
The active substance thiencarbazone-methyl and its metabolites other than BYH 18636-carboxylic acid do not breach the EU threshold value of 0.1 µg/L for the intended uses of the present formulation.
For component BYH 18636-carboxylic acid, an assessment of metabolite relevance in groundwater is triggered and accordingly presented in dRR Section 10. The assessment demonstrates no groundwater relevance. Therefore, the risk to groundwater with regard to thiencarbazone-methyl and its metabolites is acceptable for the intended uses of the present formulation.

RMS comments:

Thiencarbazone-methyl
The PECgw calculations have been provided 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. Input parameters used for calculations were appropriate. In opinion of zRMS interception is appropriate to the proposed BBCH of crops (guidance 2014). In simulations PUF value of 0 was assumed for all compounds, in line with recommendations of the most recent version of the FOCUS Groundwater Guidance.
The active substance foramsulfuron and its metabolites do not breach the EU threshold value of 0.1 µg/L except BYH 18636-carboxylic acid. For component BYH 18636-carboxylic acid, an assessment of metabolite relevance in groundwater is triggered and accordingly presented in dRR Section 10.

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

PEC_{sw} reports provided by the applicant are listed in Appendix 3.3.

8.9.1 Justification for new endpoints

Foramsulfuron and metabolites

Compound	**Parameter**	**EU endpoint**	**Used endpoint**	**Justification**
Metabolites AE 0338795 AE F099095 4-amino-N-methylbenzamide 4-formamido-N-methylbenzamide* Sulfamic acid	Saturated vapour pressure (Pa)	Not stated	1×10^{-10} (20°C)	Value not stated in LoEP, therefore, a default value was used.
Metabolite AE 0338795	Water solubility (mg/L)	Not stated	200000 (20°C)	Value not stated in EU agreed endpoint list and is based on Reary and Bright (2000, M-194905-01-1)
Metabolites AE F099095 4-amino-N-methylbenzamide 4-formamido-N-methylbenzamide* Sulfamic acid	Water solubility (mg/L)	Not stated	1000 (20°C)	Value not stated in LoEP, therefore, a default value was used.
Metabolite AE F153745	Maximum occurrence observed (% molar basis with respect to the parent)	Soil: 7.8	Soil: 10.4	As a conservative assessment max. occurrence in soil from a soil photolysis study was taken for modelling.

* also named as 4-formylamido-N-methylbenzamide

Thiencarbazone-methyl and metabolites

No new endpoints were used for the other active substance thiencarbazone-methyl and its metabolites.

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

Structure of PEC_{sw} presentation

To enable a stepwise ecotoxicological risk assessment according the tiered approaches of the EFSA Aquatic Guidance Document (AGD)[1], a comprehensive set of exposure calculations and supportive information for exposure description is presented here in dRR Part B.8, in an order consistent with the later data use for risk assessment in dRR Part B Section 9:

As a first step, a **spray-drift exposure calculation for the formulated product** is made, based on Ganzelmeier tabulated standard drift values.

Thereafter, **exposure calculations for the individual components (active substances and metabolites) via the $FOCUS_{sw}$ approach** are made, in a structure as follows:

(a) FOCUS Steps 1-2 - $PEC_{sw/sed}$ for a generic risk envelope use pattern covering all uses
to enable a simplified screening level assessment for components and organisms characterised by a wide margin of safety even when based on highly conservative exposure assumptions.

(b) FOCUS Step 3 – $PEC_{sw/sed}$ (maximum and TWA) for the critical GAPs
to enable Tier 1 risk assessment based on the accurate GAP and standard FOCUS Step 3 exposure description, where assessment was not resolved at the before screening level. For the present product and uses, this applies only for the herbicidally active components foramsulfuron, metabolite AE F130619, and thiencarbazone-methyl on which all further risk assessments will concentrate.

(c) FOCUS Step 4 – PECsw/sed (maximum and TWA) for the critical GAPs
to enable consideration of exposure mitigation measures, where required.

(d) FOCUS Step 3-4 - Time course plots (FOCUS year) and exposure pattern analysis to selected scenarios
to enable a refined risk assessment considering time-variability of the exposure based on AGD option Tier 2C.

(e) FOCUS Step 3-4 - Time course plots (multi-year simulation) and exposure pattern analysis to selected scenarios
to provide confirmative information on multi-annual representativeness of the preceding assessments.

The same headline structure (a) to (e) is followed for each substance in the subsequent sections, and is found mirrored in Appendix 3.3, where references to the respective modelling reports and additional summary information are provided.

Methodology information

(a) FOCUS Step 1-2 – Risk envelope $PEC_{sw/sed}$ [for screening level assessment]

Risk envelope approach for foramsulfuron: For foramsulfuron and its metabolites, risk assessment for most aquatic organisms is resolved with a wide margin of safety even when based on highly conservative

[1] "Guidance document on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters in the context of Regulation (EC) No 1107/2009", as provided by the Commission Services (SANTE-2015-00080, 15 January 2015). (Cited as "EFSA Aquatic Guidance Document" or "AGD" in the following pages.)

exposure assumptions. For dossier simplicity, a screening level assessment will therefore be presented first as a “risk envelope" approach, based on a generic FOCUS Step 1-2 exposure simulation for the maximum registered application rate and overall worst-case exposure situation across all foramsulfuron containing products supported by Bayer AG in Europe.

FOCUS Step 3-4 calculations are performed for the critical product GAP(s). These calculations are only provided for those components which are failing the risk assessment at screening level, i.e. for the parent active substance and its relevant metabolite AE F130619.

Table 8.9-1: <u>Risk envelope assessment (FOCUS Step 1, 2):</u> Input parameters related to application for $PEC_{sw/sed}$ calculations - foramsulfuron

Plant protection product	risk envelope for active substance foramsulfuron and its metabolites
Use No.	covers all uses
Crop	arable crops, no interception
Application rate (kg as/ha)	60 g a.s./L
Number of applications/interval (d)	- 1 / -
Application window	year-round: October – February, March – May, June – September (Step 2)
Application method	Spray application
CAM (Chemical application method)	not relevant for FOCUS Steps 1, 2
Soil depth (cm)	not relevant for FOCUS Steps 1, 2
Models used for calculation	FOCUS STEPS 1-2 v3.2

Risk envelope approach for thiencarbazone-methyl: For thiencarbazone-methyl and its metabolites, risk assessment for most aquatic organisms is resolved with a wide margin of safety even when based on highly conservative exposure assumptions. For dossier simplicity, a screening level assessment will therefore be presented first as a “risk envelope" approach, based on a generic FOCUS Step 1-2 exposure simulation for the maximum registered application rate and overall worst-case exposure situation across all thiencarbazone-methyl containing products supported by Bayer AG in Europe.

FOCUS Step 3-4 calculations are performed for the critical product GAP(s). These calculations are only provided for those components which are failing the risk assessment at screening level, i.e. for the parent active substance.

Table 8.9-2: <u>Risk envelope assessment (FOCUS Step 1, 2):</u> Input parameters related to application for $PEC_{SW/SED}$ calculations - thiencarbazone-methyl

Plant protection product	risk envelope for active substance thiencarbazone-methyl and its metabolites
Use No.	covers all uses
Crop	arable crops, no interception
Application rate (kg as/ha)	40 g a.s./ha
Number of applications/interval (d)	1 / -
Application window	year-round: October – February, March – May, June – September (Step 2)
Application method	Spray application

CAM (Chemical application method)	not relevant for FOCUS Steps 1, 2
Soil depth (cm)	not relevant for FOCUS Steps 1, 2
Models used for calculation	FOCUS STEPS 1-2 v3.2

(b) FOCUS Step 3 – PECsw/sed (maximum and TWA) [for Tier 1 assessment]

Table 8.9-3: Input parameters related to application for $PEC_{sw/sed}$ calculations – foramsulfuron, thiencarbazone-methyl

Plant protection product	FSN+ TCM OD 80	FSN+ TCM OD 80
Use No.	POL: 22 (critical GAP) covers other uses listed in B0 AUT: 23 BEL: 24 CZE: 25 HUN: 26 SVK: 27 GBR: 28 NLD: 29 ROM: 30 IRE: 31	POL: 32(critical GAP) covers other uses listed in B0 AUT: 33 BEL: 34 CZE: 35 SVK: 36 NLD: 37 ROM: 38 HUN: 39 IRE: 40
Crop	Sugar beet (arable crops)	Sugar beet (arable crops)
Application rate (kg as/ha)	Foramsulfuron: 50 g a.s./ha Thiencarbazone-methyl: 30 g a.s./ha	Foramsulfuron: 25 g a.s./ha Thiencarbazone-methyl: 15 g a.s./ha
Number of applications/interval (d)	1 / -	2 / 10
Application window	Foramsulfuron: relative, 1 day after emergence of sugar beet Thiencarbazone-methyl: absolute Application window used for modelling: see Table 8.9-4	Foramsulfuron: relative, 1 day after emergence of sugar beet Thiencarbazone-methyl: absolute Application window used for modelling: see Table 8.9-4
Application method	Spray application	Spray application
CAM (Chemical application method)	2 (application foliar linear)	2 (application foliar linear)
Soil depth (cm)	4 (default)	4 (default)
Models used for calculation	FOCUS SWASH v5.3 (FOCUS PRZM v4.3.1, FOCUS MACRO v5.5.4, FOCUS TOXWA v4.4.3)	FOCUS SWASH v5.3 (FOCUS PRZM v4.3.1, FOCUS MACRO v5.5.4, FOCUS TOXWA v4.4.3)

Table 8.9-4: FOCUS Step 3 Scenario related input parameters for $PEC_{sw/sed}$ calculations for the application of FSN+TCM OD 80

Crop	Scenario	Application window used in modelling
Sugar beets 1 × 1.0 L product/ha	D3 Ditch D4 Pond/Stream R1 Pond/Stream R3 Stream	26-Apr - 26-May 05-May - 04-Jun 17-Apr - 17-May 21-Mar - 20-Apr
Sugar beets 2 × 0.5 L product/ha	D3 Ditch D4 Pond/Stream R1 Pond/Stream R3 Stream	26-Apr - 05-Jun 05-May - 14-Jun 17-Apr - 27-May 21-Mar - 30-Apr

(c) FOCUS Step 4 – $PEC_{sw/sed}$ (maximum and TWA) [for Tier 1 assessment considering mitigation options]

Exposure simulations considering options for exposure mitigation according FOCUS Step 4 methodology[2] were conducted for all components of biological relevance, based on the same substance and timing parameters previously used at Step 3.

(d) FOCUS Step 3 – Timecourse of PEC_{sw} (FOCUS year) [for Tier 2C and Tier 3 assessment]

In dRR Part B Section 9, a refined risk assessment is presented based on an ecotoxicological interpretation of the evolution of surface concentration over time (EFSA Aquatic Guidance Document: Tier 2C). Therefore, plots of the exposure pattern were generated from the FOCUS Step 3 simulation output data for some exposure scenarios of relevance and are shown for the complete time frame simulated by the FOCUS model (1 year). For data interpretation, a numeric pattern description is made via the EPAT tool[3], to characterise each exposure pattern by four properties which are

- the PEC_{max},
- the number of peak events above the Tier 1 RAC,
- the duration of these peak events, and
- the interval between these peak events.

Moreover, the full detailed electronic information of hourly exposure values over the simulated FOCUS year period for all FOCUS scenarios serves as basis for ecological modelling approaches (TK/TD population effect simulation), which are described in dRR Part B Section 9.

(e) FOCUS Step 3-4 – Timecourse of PEC_{sw} (multi-year simulation) [for Tier 2C and Tier 3 assessment]

In response to concerns expressed by some regulators on the representativeness of the FOCUS model's single weather year in the context of a refined risk assessment based on exposure pattern analysis, additional FOCUS calculations have been conducted for an extended time period of 20 years (multi-year calculations). From this large data set, a statistically justified 90th percentile realistic worst case exposure

[2] FOCUS (2007). “Landscape And Mitigation Factors In Aquatic Risk Assessment. Volume 2. Detailed Technical Reviews”. Report of the FOCUS Working Group on Landscape and Mitigation Factors in Ecological Risk Assessment, EC Document Reference SANCO/10422/2005 v2.0. 436 pp.

[3] Bastiansen, F., Nickisch, D., Wang, M. (2016): EPAT v. 1.1 – Exposure Pattern Analysis Tool. European Crop Protection Association (ECPA), Brussels. Program Manual: RIFCON GmbH Report No. R1520392. Program download: https://www.rifcon.de/files/downloads/EPAT_1.1.1_setup.exe.

pattern was derived for use in ecotoxicological risk assessment Tier 2C, based again on the above four exposure pattern descriptors.

Moreover, the full detailed electronic information of hourly exposure values over the simulated 20-years period for all FOCUS scenarios served as basis for a multiyear-extended ecological modelling (TK/TD population effect simulation), which is described in dRR Part B Section 9.

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8.9.2.1 Spray drift exposure calculation for the formulated product – FSN+TCM OD 80 (50+30)

The PEC_{sw} of the formulation was calculated according to the following formula:

$$PEC_{sw}\ [\mu g/L] = \frac{\%\ \text{drift (90}^{th}\text{ percentile)} \times \text{application rate [g/ha]}}{\text{water depth (30 cm)} \times 10}$$

Application rate & frequency / Crop	1 × 1.0 L/ha to sugar beets 2 × 0.5 L/ha to sugar beets	1 × 1028 g/ha [1] / sugar beet 2 × 514 g/ha [2] / sugar beet
Scenario / Drift percentile	Arable crops / 90th percentile (for 1 x application), 82nd percentile (for 2 x applications)	
Entry pathways considered	Drift: yes Volatilisation: no	

[1] Assuming density of 1.028 g/mL and application rate of 1 x 1.0 L product/ha.
[2] Assuming density of 1.028 g/mL and application rate of 2 x 0.5 L product/ha.

PEC_{sw} for formulations are based on Ganzelmeier data covering the respective crop (arable crops) and the number of applications. All loadings are considered to occur in a single pseudo-application reaching the standard static ditch (width 1 m, depth 30 cm, sediment depth 5 cm, and sediment density 0.8 kg/L). Since no degradation data is available for the product, no TWA concentrations can be calculated.

Table 8.9-5: PEC_{sw} via spray drift for FSN+ TCM OD 80 (50+30) following applications to sugar beet, 1 × 1.0 L/ha

PEC_{sw} (µg/L)*	distance (m) / drift (%)				
	1 m / 2.77%	**5 m / 0.57%**	**10 m / 0.29%**	**15 m / 0.20%**	**20 m / 0.15%**
0 % drift reduction	9.492	1.953	0.994	0.685	0.514
50% drift reduction	4.746	0.977	0.497	0.343	0.257
75% drift reduction	2.373	0.488	0.248	0.171	0.129
90% drift reduction	0.949	0.195	0.099	0.069	0.051

*considered density of 1.028 g/mL

Table 8.9-6: PEC_{sw} via spray drift for FSN+ TCM OD 80 (50+30) following applications to sugar beet, 2 × 0.5 L/ha

PEC_{sw} (µg/L)*	distance (m) / drift (%)				
	1 m / 2.38%	**5 m / 0.47%**	**10 m / 0.24%**	**15 m / 0.16%**	**20 m / 0.12%**
0 % drift reduction	8.155	1.611	0.822	0.548	0.411
50% drift reduction	4.078	0.805	0.411	0.274	0.206
75% drift reduction	2.039	0.403	0.206	0.137	0.103
90% drift reduction	0.816	0.161	0.082	0.055	0.041

* considered density of 1.028 g/mL

8.9.2.2 Foramsulfuron and its metabolites

For foramsulfuron, agreed endpoints were used as input to exposure modelling as follows:

Table 8.9-7: Input parameters related to active substance foramsulfuron and metabolites for $PEC_{sw/sed}$ calculations STEP 1/2 and 3/4

Compound	Foramsulfuron	AE F130619	AE F092944	AE F153745	AE 0338795	Value in accordance to EU end-point y/n/ Reference
Molecular weight (g/mol)	452.49	424.44	155.16	271.3	438.42	Y/ EFSA 2016;14(3): 4421
Saturated vapour pressure (Pa)	4.2×10^{-11} # (20°C)	5.8×10^{-13} # (20°C)	3.72×10^{-2} # (20°C)	3.47×10^{-8} # (20°C)	1×10^{-10} a (20°C)	# Y/ EFSA 2016;14(3): 4421 N / justification is presented above
Water solubility (mg/L)	3293# (20°C, pH 6.9)	35.5# (20°C, pH 7)	5484# (20°C, pH 7)	5830# (20°C, pH 7)	200000 (20°C)	# Y/ EFSA 2016;14(3): 4421 N/ justification is presented above
Diffusion coefficient in water (m^2/d)	not required for Step 1+2/ 4.3×10^{-5}	not required for Step 1+2	not required for Step 1+2	not required for Step 1+2	not required for Step 1+2	default
Diffusion coefficient in air (m^2/d)	not required for Step 1+2/ 0.43	not required for Step 1+2	not required for Step 1+2	not required for Step 1+2	not required for Step 1+2	default
K_{foc} (mL/g)	69.7 (geometric mean, n =5)	63.2 (geometric mean, n =4)	275.8 (geometric mean, n =19)	48 (geometric mean, n =4)	17.67 (est. By Kocwin US EPA 2000)	Y/ EFSA 2016;14(3): 4421
Freundlich Exponent 1/n	0.87 (arithmetic mean, n =5)	0.93 (arithmetic mean, n =4)	not required for Step 1+2	not required for Step 1+2	not required for Step 1+2	Y/ EFSA 2016;14(3): 4421
Plant Uptake	0.0	0.0	not required for Step 1+2	not required for Step 1+2	not required for Step 1+2	Y/ EFSA 2016;14(3): 4421
Wash-Off factor from Crop (1/m)	not required for Step 1+2/ 50	not required for Step 1+2/ 50	not required for Step 1+2	not required for Step 1+2	not required for Step 1+2	default
$DT_{50,soil}$ (d)	12.0	1.5	18.8	0.87 (0.9)	1000 (default)	Y/ EFSA

Compound	**Foramsulfuron**	**AE F130619**	**AE F092944**	**AE F153745**	**AE 0338795**	**Value in accordance to EU end-point y/n/ Reference**
	(geomean, lab., normalisation to 10 kPa or pF2, 20 °C with Q10 of 2.58, n = 10)	(geomean, lab., normalisation to 10 kPa or pF2, 20 °C with Q10 of 2.58, n = 7)	(geomean, lab., normalisation to 10 kPa or pF2, 20 °C with Q10 of 2.58, n = 12)	(geomean, lab., normalisation to 10 kPa or pF2, 20 °C with Q10 of 2.58, n = 4)		2016;14(3): 4421
$DT_{50,water}$ (d)	32.9 (geomean, total system, n=4)	15.7 (geomean, total system, n=3)	110 (total system, n=1)	72.1 (total system, n=1)	65.4 (geomean, total system, n=2)	Y/ EFSA 2016;14(3): 4421
$DT_{50,sed}$ (d)	32.9 (geomean, total system, n=4, Step 1+2) 1000 (default, Step 3+4)	15.7 (geomean, total system, n=3, Step 1+2) 1000 (default, Step 3+4)	110 (total system, n=1)	72.1 (total system, n=1)	65.4 (geomean, total system, n=2)	Y/ EFSA 2016;14(3): 4421
$DT_{50,whole\ system}$ (d)	32.9 (geomean, total system, n=4)	15.7 (geomean, total system, n=3)	110 (total system, n=1)	72.1 (total system, n=1)	65.4 (geomean, total system, n=2)	Y/ EFSA 2016;14(3): 4421
Maximum occurrence observed (% molar basis with respect to the parent)	-	Soil: 29.1 Water/sediment: 10.7	Soil: 17.8 Water/sediment: 26.5	Soil: 10.4* Water/sediment: 24.6	Soil: 0.001 Water/sediment: 23.7	Y/ EFSA 2016;14(3): 4421 *N / justification is presented above
Formation fraction in soil:	-	not required for Step 1+2 0.92 (Step 3+4)	not required for Step 1+2	not required for Step 1+2	not required for Step 1+2	

[a] Not measured. Default value used.

Table 8.9-8: Input parameters related to foramsulfuron metabolites for $PECs_{w/sed}$ calculations STEP 1/2 (continued)

Compound	AE F099095	4-amino-N-methylbenzamide	4-formamido-N-methylbenzamide	Sulfamic acid	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	198.18	150.18	178.19	278.24	Y/ EFSA 2016;14(3): 4421
Saturated vapour pressure (Pa)	1×10^{-10} [a] (20°C)	1×10^{-10} [a] (20°C)	1×10^{-10} [a] (20°C)	1×10^{-10} [a] (20°C)	N / Worst case assumption
Water solubility (mg/L)	not required for Step 1+2/ 1000[a] (20°C)	not required for Step 1+2/ 1000[a] (20°C)	not required for Step 1+2/ 1000[a] (20°C)	not required for Step 1+2/ 1000[a] (20°C)	N / justification is presented above
Diffusion coefficient in water (m²/d)	not required for Step 1+2	not required for Step 1+2	not required for Step 1+2	not required for Step 1+2	default
Diffusion coefficient in air (m²/d)	not required for Step 1+2	not required for Step 1+2	not required for Step 1+2	not required for Step 1+2	default
K_{foc} (mL/g)	351 (geometric mean, n =3)	1×10^{-10} [a]	1×10^{-10} [a]	1×10^{-10} [a]	Y/ EFSA 2016;14(3): 4421
Freundlich Exponent 1/n	not required for Step 1+2	not required for Step 1+2	not required for Step 1+2	not required for Step 1+2	
Plant Uptake	not required for Step 1+2	not required for Step 1+2	not required for Step 1+2	not required for Step 1+2	
Wash-Off factor from Crop (1/m)	not required for Step 1+2	not required for Step 1+2	not required for Step 1+2	not required for Step 1+2	
$DT_{50,soil}$ (d)	1000 (default)	1000 (defaul)	1000 (default)	1000 (default)	Y/ EFSA 2016;14(3): 4421
$DT_{50,water}$ (d)	1000 (default)	1000 (default)	1000 (default)	1000 (default)	Y/ EFSA 2016;14(3): 4421
$DT_{50,sed}$ (d)	1000 (default)	1000 (default)	1000 (default)	1000 (default)	Y/ EFSA 2016;14(3): 4421
$DT_{50,whole\ system}$ (d)	1000 (default)	1000 (default)	1000 (default)	1000 (default)	Y/ EFSA 2016;14(3): 4421
Maximum occurrence observed (% molar basis with respect to the parent)	Soil: 0.001 Water/sediment: 35.2	Soil: 0.001 Water/sediment: 12.8	Soil: 0.001 Water/sediment: 19.7	Soil: 0.001 Water/sediment: 17.6	Y/ EFSA 2016;14(3): 4421
Formation fraction in soil:	not required for Step 1+2	not required for Step 1+2	not required for Step 1+2	not required for Step 1+2	

[a] Not measured. Default value used.

(a) FOCUS Steps 1-2 – Risk envelope PECsw/sed of foramsulfuron and all metabolites [for screening level assessment]

Table 8.9-9: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for <u>foramsulfuron</u> following single application to sugar beet - for generic risk envelope covering all uses

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	7d-$PEC_{sw,twa}$ (µg/L)**	21d-$PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	18.851 -	RunOff/Drain.	17.487	15.197	12.833 -
Step 2						
N-Europe S-Europe	Mar. - May (Spring)	3.3825 * 6.2873 *	RunOff/Drain. RunOff/Drain.	3.1334 5.8343	2.7228 5.0703	2.2992 * 4.2817 *
N-Europe S-Europe	Jun. - Sep. (Summer)	3.3825 * 4.8349 *	RunOff/Drain. RunOff/Drain.	3.1334 4.4838	2.7228 3.8966	2.2992 * 3.2904 *
N-Europe S-Europe	Oct. - Feb. (Autumn)	7.7397 * 6.2873 *	RunOff/Drain. RunOff/Drain.	7.1847 5.8343	6.2441 5.0703	5.2836 * 4.2817 *

* Single applications marked
** TWA-interval as required by ecotox

Table 8.9-10: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for <u>AE F130619</u> following single application to sugar beet - for generic risk envelope covering all uses

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	7d-$PEC_{sw,twa}$ (µg/L)**	21d-$PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	6.9417 -	RunOff/Drain.	5.9682	4.5220	4.3521 -
Step 2						
N-Europe S-Europe	Mar. - May (Spring)	0.4964 * 0.9489 *	RunOff/Drain. RunOff/Drain.	0.4262 0.8155	0.3229 0.6179	0.3045 * 0.5904 *
N-Europe S-Europe	Jun. - Sep. (Summer)	0.4964 * 0.7227 *	RunOff/Drain. RunOff/Drain.	0.4262 0.6209	0.3229 0.4704	0.3045 * 0.4475 *
N-Europe S-Europe	Oct. - Feb. (Autumn)	1.1751 * 0.9489 *	RunOff/Drain. RunOff/Drain.	1.0102 0.8155	0.7654 0.6179	0.7334 * 0.5904 *

* Single applications marked
** TWA-interval as required by ecotox

Table 8.9-11: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for <u>AE F092944</u> following single application to sugar beet - for generic risk envelope covering all uses

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	7d-$PEC_{sw,twa}$ (µg/L)**	21d-$PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	2.2714 -	RunOff/Drain.	2.2098	2.1152	6.1883 -
Step 2						
N-Europe S-Europe	Mar. - May (Spring)	0.4042 * 0.7692 *	RunOff/Drain. RunOff/Drain.	0.3923 0.7493	0.3754 0.7173	1.0982 * 2.0984 *
N-Europe	Jun. - Sep.	0.4042 *	RunOff/Drain.	0.3923	0.3754	1.0982 *

Scenario **FOCUS**	**Waterbody**	**Max PEC_{sw} (µg/L)***		**Dominant entry route**	**7d-$PEC_{sw,twa}$ (µg/L)****	**21d-$PEC_{sw,twa}$ (µg/L)****	**Max PEC_{sed} (µg/kg)***	
S-Europe	(Summer)	0.5867	*	RunOff/Drain.	0.5708	0.5463	1.5983	*
N-Europe S-Europe	Oct. - Feb. (Autumn)	0.9517 0.7692	* *	RunOff/Drain. RunOff/Drain.	0.9278 0.7493	0.8882 0.7173	2.5985 2.0984	* *
Step 3	Not required							

* Single applications marked
** TWA-interval as required by ecotox

Table 8.9-12: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for <u>AE F153745</u> following single application to sugar beet - for generic risk envelope covering all uses

Scenario **FOCUS**	**Waterbody**	**Max PEC_{sw} (µg/L)***		**Dominant entry route**	**7d-$PEC_{sw,twa}$ (µg/L)****	**21d-$PEC_{sw,twa}$ (µg/L)****	**Max PEC_{sed} (µg/kg)***	
Step 1	---	4.0259	-	RunOff/Drain.	3.8891	3.6412	1.9116	-
Step 2								
N-Europe S-Europe	Mar. - May (Spring)	0.5249 0.9747	* *	RunOff/Drain. RunOff/Drain.	0.5063 0.9413	0.4740 0.8813	0.2488 0.4627	* *
N-Europe S-Europe	Jun. - Sep. (Summer)	0.5249 0.7498	* *	RunOff/Drain. RunOff/Drain.	0.5063 0.7238	0.4740 0.6776	0.2488 0.3557	* *
N-Europe S-Europe	Oct. - Feb. (Autumn)	1.1996 0.9747	* *	RunOff/Drain. RunOff/Drain.	1.1588 0.9413	1.0849 0.8813	0.5696 0.4627	* *

* Single applications marked
** TWA-interval as required by ecotox

Table 8.9-13: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for <u>AE 0338795</u> following single application to sugar beet - for generic risk envelope covering all uses

Scenario **FOCUS**	**Waterbody**	**Max PEC_{sw} (µg/L)***		**Dominant entry route**	**7d-$PEC_{sw,twa}$ (µg/L)****	**21d-$PEC_{sw,twa}$ (µg/L)****	**Max PEC_{sed} (µg/kg)***	
Step 1	---	4.6138	-	RunOff/Drain.	4.4442	4.1339	0.8062	-
Step 2								
N-Europe S-Europe	Mar. - May (Spring)	0.8319 1.5442	* *	RunOff/Drain. RunOff/Drain.	0.8009 1.4875	0.7450 1.3836	0.1453 0.2698	* *
N-Europe S-Europe	Jun. - Sep. (Summer)	0.8319 1.1880	* *	RunOff/Drain. RunOff/Drain.	0.8009 1.1442	0.7450 1.0643	0.1453 0.2076	* *
N-Europe S-Europe	Oct. - Feb. (Autumn)	1.9003 1.5442	* *	RunOff/Drain. RunOff/Drain.	1.8307 1.4875	1.7029 1.3836	0.3321 0.2698	* *

* Single applications marked
** TWA-interval as required by ecotox

Table 8.9-14: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for <u>AE F099095</u> following single application to sugar beet - for generic risk envelope covering all uses

Scenario **FOCUS**	**Waterbody**	**Max PEC_{sw} (µg/L)***	**Dominant entry route**	**7d-$PEC_{sw,twa}$ (µg/L)****	**21d-$PEC_{sw,twa}$ (µg/L)****	**Max PEC_{sed} (µg/kg)***
Step 1	---	2.1855 -	RunOff/Drain.	2.1551	2.1434	7.5707 -
Step 2						
N-Europe S-Europe	Mar. - May (Spring)	0.3981 * 0.7315 *	RunOff/Drain. RunOff/Drain.	0.3908 0.7234	0.3886 0.7196	1.3722 * 2.5417 *
N-Europe S-Europe	Jun. - Sep. (Summer)	0.3981 * 0.5648 *	RunOff/Drain. RunOff/Drain.	0.3908 0.5571	0.3886 0.5541	1.3722 * 1.9570 *
N-Europe S-Europe	Oct. - Feb. (Autumn)	0.8982 * 0.7315 *	RunOff/Drain. RunOff/Drain.	0.8897 0.7234	0.8851 0.7196	3.1265 * 2.5417 *

* Single applications marked
** TWA-interval as required by ecotox

Table 8.9-15: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for <u>4-amino-N-methylbenzamide</u> following single application to sugar beet - for generic risk envelope covering all uses

Scenario **FOCUS**	**Waterbody**	**Max PEC_{sw} (µg/L)***	**Dominant entry route**	**7d-$PEC_{sw,twa}$ (µg/L)****	**21d-$PEC_{sw,twa}$ (µg/L)****	**Max PEC_{sed} (µg/kg)***
Step 1	---	0.8732 -	RunOff/Drain.	0.8710	0.8668	<0.001 -
Step 2						
N-Europe S-Europe	Mar. - May (Spring)	0.1583 * 0.2932 *	RunOff/Drain. RunOff/Drain.	0.1579 0.2924	0.1571 0.2910	<0.0001 * <0.0001 *
N-Europe S-Europe	Jun. - Sep. (Summer)	0.1583 * 0.2257 *	RunOff/Drain. RunOff/Drain.	0.1579 0.2252	0.1571 0.2241	<0.0001 * <0.0001 *
N-Europe S-Europe	Oct. - Feb. (Autumn)	0.3606 * 0.2932 *	RunOff/Drain. RunOff/Drain.	0.3597 0.2924	0.3580 0.2910	<0.0001 * <0.0001 *

* Single applications marked
** TWA-interval as required by ecotox

Table 8.9-16: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for <u>4-formamido-N-methylbenzamide</u> following single application to sugar beet - for generic risk envelope covering all uses

Scenario **FOCUS**	**Waterbody**	**Max PEC_{sw} (µg/L)***	**Dominant entry route**	**7d-$PEC_{sw,twa}$ (µg/L)****	**21d-$PEC_{sw,twa}$ (µg/L)****	**Max PEC_{sed} (µg/kg)***
Step 1	---	1.5945 -	RunOff/Drain.	1.5906	1.5829	<0.001 -
Step 2						
N-Europe S-Europe	Mar. - May (Spring)	0.2890 * 0.5353 *	RunOff/Drain. RunOff/Drain.	0.2883 0.5340	0.2869 0.5314	<0.0001 * <0.0001 *
N-Europe S-Europe	Jun. - Sep. (Summer)	0.2890 * 0.4122 *	RunOff/Drain. RunOff/Drain.	0.2883 0.4112	0.2869 0.4092	<0.0001 * <0.0001 *
N-Europe S-Europe	Oct. - Feb. (Autumn)	0.6585 * 0.5353 *	RunOff/Drain. RunOff/Drain.	0.6569 0.5340	0.6537 0.5314	<0.0001 * <0.0001 *

Scenario **FOCUS**	**Waterbody**	**Max PEC_{sw} (µg/L)***	**Dominant entry route**	**7d-$PEC_{sw,twa}$ (µg/L)****	**21d-$PEC_{sw,twa}$ (µg/L)****	**Max PEC_{sed} (µg/kg)***

* Single applications marked
** TWA-interval as required by ecotox

Table 8.9-17: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for <u>sulfamic acid</u> following single application to sugar beet - for generic risk envelope covering all uses

Scenario **FOCUS**	**Waterbody**	**Max PEC_{sw} (µg/L)***	**Dominant entry route**	**7d-$PEC_{sw,twa}$ (µg/L)****	**21d-$PEC_{sw,twa}$ (µg/L)****	**Max PEC_{sed} (µg/kg)***
Step 1	---	2.2243 -	RunOff/Drain.	2.2189	2.2082	<0.001 -
Step 2						
N-Europe S-Europe	Mar. - May (Spring)	0.4032 * 0.7468 *	RunOff/Drain. RunOff/Drain.	0.4022 0.7450	0.4003 0.7414	<0.0001 * <0.0001 *
N-Europe S-Europe	Jun. - Sep. (Summer)	0.4032 * 0.5750 *	RunOff/Drain. RunOff/Drain.	0.4022 0.5736	0.4003 0.5708	<0.0001 * <0.0001 *
N-Europe S-Europe	Oct. - Feb. (Autumn)	0.9186 * 0.7468 *	RunOff/Drain. RunOff/Drain.	0.9164 0.7450	0.9119 0.7414	<0.0001 * <0.0001 *

* Single applications marked
** TWA-interval as required by ecotox

(b) FOCUS Step 3 – $PEC_{sw/sed}$ (maximum and TWA) of foramsulfuron and metabolite AE F130619 [for Tier 1 assessment]

Table 8.9-18: FOCUS Step 3 PEC_{sw} and PEC_{sed} for <u>foramsulfuron</u> following application of FSN+TCM OD 80 (50+30)
- Use: sugar beet, 1 × 50 g foramsulfuron/ha, BBCH 10–18

Scenario **FOCUS**	**Waterbody**	**Max PEC_{sw} (µg/L)***	**Dominant entry route**	**7 d- $PEC_{sw,twa}$ (µg/L)****	**21 d- $PEC_{sw,twa}$ (µg/L)****	**Max PEC_{sed} (µg/kg)***
Step 3: Sugar beets, 1 × 50 g foramsulfuron/ha [1)]						
D3	ditch	0.2624 *	Spray drift	0.0447	0.0150	0.0681 *
D4	pond	0.0111 *	Spray drift	0.0103	0.0092	0.0204 *
D4	stream	0.2146 *	Spray drift	0.0021	0.0010	0.0104 *
R1	pond	0.0151 *	Runoff	0.0141	0.0127	0.0309 *
R1	stream	0.1813 *	Spray drift	0.0150	0.0077	0.0441 *
R3	stream	0.3644 *	Runoff	0.0515	0.0172	0.1069 *

* Single applications marked
** TWA-interval as required by ecotox
data origin (modelling report & crop no.): [1)] EnSa-16-0765, Sugar beet I

Table 8.9-19: FOCUS Step 3 PEC_{sw} and PEC_{sed} for <u>foramsulfuron</u> following application of FSN+TCM OD 80 (50+30)
- Use: sugar beet, 2 × 25 g foramsulfuron/ha, BBCH 10–18

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*		Dominant entry route	7 d- $PEC_{sw,twa}$ (µg/L)**	21 d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*	
Step 3: Sugar beets, 2 × 25 g foramsulfuron/ha [1)] ***Maximum values (max PEC_{sw} and 7 d-$PEC_{sw,twa}$) out of single and multiple application are marked in bold***								
Single application								
D3	ditch	**0.1313**	*	Spray drift	0.0224	0.0075	0.0355	*
D4	pond	0.0055	*	Spray drift	0.0051	0.0046	0.0105	*
D4	stream	**0.1071**	*	Spray drift	0.0010	0.0005	0.0052	*
R1	pond	0.0079	*	Runoff	0.0074	0.0067	0.0169	*
R1	stream	0.0990	*	Runoff	0.0084	0.0041	0.0248	*
R3	stream	0.1903	*	Runoff	0.0269	0.0090	0.0578	*
Multiple applications								
D3	ditch	0.1140		Spray drift	0.0196	0.0130	0.0399	
D4	pond	**0.0083**		Spray drift	0.0078	0.0069	0.0177	
D4	stream	0.0960		Spray drift	0.0016	0.0012	0.0084	
R1	pond	**0.0247**		Runoff	0.0232	0.0212	0.0443	
R1	stream	**0.4106**		Runoff	0.0351	0.0137	0.0899	
R3	stream	**0.8509**		Runoff	0.1202	0.0419	0.2414	

* Single applications marked
** TWA-interval as required by ecotox
data origin (modelling report & crop no.): [1)] EnSa-16-0765, Sugar beet II

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Table 8.9-20: FOCUS Step 3 PEC_{sw} and PEC_{sed} for <u>AE F130619</u> following application of FSN+TCM OD 80 (50+30)
- Use: sugar beet, 1 × 50 g foramsulfuron/ha, BBCH 10–18

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*		Dominant entry route	7 d- $PEC_{sw,twa}$ (µg/L)**	21 d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*	
metabolite AE F130619 **Step 3: Sugar beet, 1 × 50 g foramsulfuron/ha [1)]**								
D3	ditch	0.0003	*	-	<0.001	<0.001	<0.001	*
D4	pond	0.0003	*	-	0.0003	0.0003	0.0010	*
D4	stream	0.0003	*	-	0.0002	0.0001	0.0005	*
R1	pond	0.0010	*	-	0.0010	0.0009	0.0016	*
R1	stream	0.0193	*	-	0.0016	0.0008	0.0037	*
R3	stream	0.0432	*	-	0.0061	0.0020	0.0101	*

* Single applications marked
** TWA-interval as required by ecotox
data origin (modelling report & crop no.): 1) EnSa-16-0765, Sugar beets I

Table 8.9-21: FOCUS Step 3 PEC_{sw} and PEC_{sed} for <u>AE F130619</u> following application of FSN+TCM OD 80 (50+30))
- Use: sugar beet, 2 × 25 g foramsulfuron/ha, BBCH 10–18

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	7 d- $PEC_{sw,twa}$ (µg/L)**	21 d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
metabolite AE F130619 **Step 3: Sugar beet, 2 × 25 g foramsulfuron/ha 1)** ***Maximum values (max PEC_{sw} and 7 d-$PEC_{sw,twa}$) out of single and multiple application are marked in bold***						
Single application						
D3	ditch	**0.0001** *	-	<0.001	<0.001	<0.001 *
D4	pond	0.0001 *	-	0.0001	0.0001	0.0005 *
D4	stream	0.0001 *	-	<0.001	<0.001	0.0002 *
R1	pond	0.0006 *	-	0.0005	0.0005	0.0009 *
R1	stream	0.0108 *	-	0.0009	0.0004	0.0021 *
R3	stream	0.0229 *	-	0.0032	0.0011	0.0054 *
Multiple applications						
D3	ditch	**0.0001**	-	<0.001	<0.001	<0.001
D4	pond	**0.0003**	-	0.0003	0.0003	0.0010
D4	stream	**0.0002**	-	0.0002	0.0001	0.0006
R1	pond	**0.0017**	-	0.0016	0.0016	0.0026
R1	stream	**0.0364**	-	0.0031	0.0012	0.0065
R3	stream	**0.0833**	-	0.0118	0.0039	0.0195

* Single applications marked
** TWA-interval as required by ecotox
data origin (modelling report & crop no.): 1) EnSa-16-0765, Sugar beet II

(c) FOCUS Step 4 – $PEC_{sw/sed}$ (single/multiple applications and TWA) of foramsulfuron [for Tier 1 assessment considering mitigation options]

FOCUS Step 4 exposure values are available from the same set of modelling reports referenced under point (b) before.

Tabular results for the uses assessed with the present formulation are provided here below:

Foramsulfuron

Table 8.9-22: FOCUS Step 4 PEC$_{sw}$ for <u>foramsulfuron</u>, following single application of FSN+TCM OD 80 (50+30)
- Use: Sugar beet, 1 × 50 g foramsulfuron/ha, BBCH 10-18

Sugar beet 1×50 g a.s./ha, single appl.[1)]	**Scenario**	**STEP 4 - foramsulfuron**					
		PEC$_{sw}$, max (µg/L)					
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10m low*	20m high*
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m
None	D3 Ditch	0.2624	0.0859	0.0458	0.0237	0.0458	0.0237
50 %		0.1312	0.0430	0.0229	0.0119	0.0229	0.0119
75 %		0.0656	0.0215	0.0115	0.0059	0.0115	0.0059
90 %		0.0262	0.0086	0.0046	0.0024	0.0046	0.0024
None	D4 Pond	0.0111	0.0100	0.0073	0.0050	0.0073	0.0050
50 %		0.0058	0.0053	0.0039	0.0028	0.0039	0.0028
75 %		0.0032	0.0029	0.0022	0.0017	0.0022	0.0017
90 %		0.0016	0.0015	0.0012	0.0010	0.0012	0.0010
None	D4 Stream	0.2146	0.0904	0.0482	0.0252	0.0482	0.0252
50 %		0.1075	0.0454	0.0243	0.0128	0.0243	0.0128
75 %		0.0540	0.0230	0.0124	0.0067	0.0124	0.0067
90 %		0.0219	0.0095	0.0052	0.0029	0.0052	0.0029
None	R1 Pond	0.0151	0.0144	0.0127	0.0112	0.0077	0.0045
50 %		0.0117	0.0114	0.0105	0.0098	0.0055	0.0031
75 %		0.0100	0.0099	0.0094	0.0091	0.0044	0.0024
90 %		0.0090	0.0090	0.0088	0.0086	0.0038	0.0020
None	R1 Stream	0.1813	0.1791	0.1791	0.1791	0.0812	0.0425
50 %		0.1791	0.1791	0.1791	0.1791	0.0812	0.0425
75 %		0.1791	0.1791	0.1791	0.1791	0.0812	0.0425
90 %		0.1791	0.1791	0.1791	0.1791	0.0812	0.0425
None	R3 Stream	0.3644	0.3644	0.3644	0.3644	0.1662	0.0872
50 %		0.3644	0.3644	0.3644	0.3644	0.1662	0.0872
75 %		0.3644	0.3644	0.3644	0.3644	0.1662	0.0872
90 %		0.3644	0.3644	0.3644	0.3644	0.1662	0.0872

* low and high fractional reduction in the runoff and erosion through volume, mass and flux
data origin (modelling report & crop no.): [1)] EnSa-16-0765, Sugar beet I, 1 × 50 g a.s./ha

Table 8.9-23: FOCUS Step 4 TWAC$_{sw}$ at Day 7 for foramsulfuron, following single application of FSN+TCM OD 80 (50+30)
- Use: Sugar beet, 1 × 50 g foramsulfuron/ha, BBCH 10-18

Sugar beet 1×50 g a.s./ha, single appl.[1)]	**Scenario**	**STEP 4 - foramsulfuron**					
		7 d- PEC$_{sw,twa}$ (µg/L)					
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10m low*	20m high*
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m
None	D3 Ditch	0.0447	0.0146	0.0078	0.0040	0.0078	0.0040
50 %		0.0223	0.0073	0.0039	0.0020	0.0039	0.0020
75 %		0.0112	0.0037	0.0019	0.0010	0.0019	0.0010
90 %		0.0045	0.0015	0.0008	0.0004	0.0008	0.0004
None	D4 Pond	0.0103	0.0093	0.0068	0.0047	0.0068	0.0047
50 %		0.0054	0.0049	0.0037	0.0026	0.0037	0.0026
75 %		0.0030	0.0027	0.0021	0.0016	0.0021	0.0016
90 %		0.0015	0.0014	0.0011	0.0010	0.0011	0.0010
None	D4 Stream	0.0021	0.0012	0.0008	0.0008	0.0008	0.0008
50 %		0.0013	0.0008	0.0008	0.0008	0.0008	0.0008
75 %		0.0009	0.0008	0.0008	0.0008	0.0008	0.0008
90 %		0.0008	0.0008	0.0008	0.0008	0.0008	0.0008
None	R1 Pond	0.0141	0.0135	0.0119	0.0105	0.0072	0.0043
50 %		0.0110	0.0106	0.0098	0.0091	0.0052	0.0029
75 %		0.0094	0.0092	0.0088	0.0085	0.0041	0.0022
90 %		0.0084	0.0084	0.0082	0.0081	0.0035	0.0018
None	R1 Stream	0.0150	0.0150	0.0150	0.0150	0.0068	0.0035
50 %		0.0150	0.0150	0.0150	0.0150	0.0068	0.0035
75 %		0.0150	0.0150	0.0150	0.0150	0.0068	0.0035
90 %		0.0150	0.0150	0.0150	0.0150	0.0068	0.0035
None	R3 Stream	0.0515	0.0515	0.0515	0.0515	0.0237	0.0125
50 %		0.0515	0.0515	0.0515	0.0515	0.0237	0.0125
75 %		0.0515	0.0515	0.0515	0.0515	0.0237	0.0125
90 %		0.0515	0.0515	0.0515	0.0515	0.0237	0.0125

* low and high fractional reduction in the runoff and erosion through volume, mass and flux
data origin (modelling report & crop no.): [1)] EnSa-16-0765, Sugar beet I, 1 × 50 g a.s./ha

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Table 8.9-24: FOCUS Step 4 PEC_{sw} for foramsulfuron, following single application of FSN+TCM OD 80 (50+30)
- Use: Sugar beet, 2 × 25 g foramsulfuron/ha, BBCH 10-18

Sugar beet 2×25 g a.s./ha, single appl.[1)]	**Scenario**	**STEP 4 - foramsulfuron**					
		PEC_{sw}, max (µg/L)					
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10m low*	20m high*
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m
Maximum PEC_{sw} values out of single and multiple application are marked in bold							
None	D3 Ditch	**0.1313**	**0.0431**	**0.0227**	**0.0119**	**0.0227**	**0.0119**
50 %		**0.0657**	**0.0216**	**0.0114**	**0.0059**	**0.0114**	**0.0059**
75 %		**0.0329**	**0.0108**	**0.0057**	**0.0030**	**0.0057**	**0.0030**
90 %		**0.0131**	**0.0043**	**0.0023**	**0.0012**	**0.0023**	**0.0012**
None	D4 Pond	0.0055	0.0049	0.0036	0.0025	0.0036	0.0025
50 %		0.0029	0.0026	0.0019	0.0014	0.0019	0.0014
75 %		0.0016	0.0014	0.0011	0.0008	0.0011	0.0008
90 %		0.0008	0.0007	0.0006	0.0005	0.0006	0.0005
None	D4 Stream	**0.1071**	**0.0453**	**0.0241**	**0.0126**	**0.0241**	**0.0126**
50 %		**0.0537**	**0.0228**	**0.0121**	**0.0064**	**0.0121**	**0.0064**
75 %		**0.0269**	**0.0115**	**0.0062**	**0.0033#**	**0.0062**	**0.0033#**
90 %		**0.0109**	**0.0047**	0.0026	0.0015	0.0026	0.0015
None	R1 Pond	0.0079	0.0076	0.0067	0.0060	0.0040	0.0024
50 %		0.0063	0.0061	0.0057	0.0053	0.0029	0.0016
75 %		0.0054	0.0053	0.0051	0.0050	0.0024	0.0013
90 %		0.0049	0.0049	0.0048	0.0047	0.0021	0.0011
None	R1 Stream	0.0990	0.0990	0.0990	0.0990	0.0449	0.0235
50 %		0.0990	0.0990	0.0990	0.0990	0.0449	0.0235
75 %		0.0990	0.0990	0.0990	0.0990	0.0449	0.0235
90 %		0.0990	0.0990	0.0990	0.0990	0.0449	0.0235
None	R3 Stream	0.1903	0.1903	0.1903	0.1903	0.0868	0.0455
50 %		0.1903	0.1903	0.1903	0.1903	0.0868	0.0455
75 %		0.1903	0.1903	0.1903	0.1903	0.0868	0.0455
90 %		0.1903	0.1903	0.1903	0.1903	0.0868	0.0455

* low and high fractional reduction in the runoff and erosion through volume, mass and flux
#results from single and multiple application are identical
data origin (modelling report & crop no.): 1) EnSa-16-0765, Sugar beet II, 2 × 25 g a.s./ha

Table 8.9-25: FOCUS Step 4 TWAC$_{sw}$ at Day 7 for foramsulfuron, following single applications of FSN+TCM OD 80 (50+30)
- Use: Sugar beet, 2 × 25 g foramsulfuron/ha, BBCH 10-18

Sugar beet 2×25 g a.s./ha, single appl.[1)]	**Scenario**	**Step 4 foramsulfuron 7 d- PEC$_{sw,twa}$ (µg/L)**					
Nozzle reduction	**Vegetated strip (m)**	**None**	**None**	**None**	**None**	**10m low***	**10m low***
	No spray buffer (m)	**0 m**	**5 m**	**10 m**	**20 m**	**10 m**	**20 m**
Maximum PECsw values out of single and multiple application are marked in bold							
None	D3 Ditch	**0.0224**	**0.0073**	**0.0039**	**0.0020**	**0.0039**	**0.0020**
50 %		**0.0112**	**0.0037**	**0.0019**	**0.0010**	**0.0019**	**0.0010**
75 %		**0.0056**	**0.0018**	**0.0010**	**0.0005**	**0.0010**	**0.0005**
90 %		**0.0022**	**0.0007**	**0.0004**	**0.0002#**	**0.0004**	**0.0002#**
None	D4 Pond	0.0051	0.0046	0.0034	0.0024	0.0034	0.0024
50 %		0.0027	0.0024	0.0018	0.0013	0.0018	0.0013
75 %		0.0015	0.0013	0.0010	0.0008	0.0010	0.0008
90 %		0.0007	0.0007	0.0005	0.0005	0.0005	0.0005
None	D4 Stream	0.0010	0.0006	0.0004	0.0004	0.0004	0.0004
50 %		0.0006	0.0004	0.0004	0.0004	0.0004	0.0004
75 %		0.0004	0.0004	0.0004	0.0004	0.0004	0.0004
90 %		0.0004	0.0004	0.0004	0.0004	0.0004	0.0004
None	R1 Pond	0.0074	0.0071	0.0063	0.0057	0.0037	0.0022
50 %		0.0059	0.0057	0.0053	0.0050	0.0027	0.0015
75 %		0.0051	0.0050	0.0048	0.0046	0.0022	0.0012
90 %		0.0046	0.0046	0.0045	0.0044	0.0019	0.0010
None	R1 Stream	0.0084	0.0084	0.0084	0.0084	0.0038	0.0020
50 %		0.0084	0.0084	0.0084	0.0084	0.0038	0.0020
75 %		0.0084	0.0084	0.0084	0.0084	0.0038	0.0020
90 %		0.0084	0.0084	0.0084	0.0084	0.0038	0.0020
None	R3 Stream	0.0269	0.0269	0.0269	0.0269	0.0124	0.0065
50 %		0.0269	0.0269	0.0269	0.0269	0.0124	0.0065
75 %		0.0269	0.0269	0.0269	0.0269	0.0124	0.0065
90 %		0.0269	0.0269	0.0269	0.0269	0.0124	0.0065

* low and high fractional reduction in the runoff and erosion through volume, mass and flux
#results from single and multiple application are identical
data origin (modelling report & crop no.): [1)] EnSa-16-0765, Sugar beet II, 2 × 25 g a.s./ha.

Table 8.9-26: FOCUS Step 4 PEC_{sw} for foramsulfuron, following multiple applications of FSN+TCM OD 80 (50+30) - Use: Sugar beet, 2 × 25 g foramsulfuron/ha, BBCH 10-18

Sugar beet, 2×25 g a.s./ha, multiple appl.[1)]	**Scenario**	**STEP 4 - foramsulfuron** **PEC_{sw}, max (µg/L)**					
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10m low*	20m high*
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m
Maximum PEC_{sw} values out of single and multiple application are marked in bold							
None	D3 Ditch	0.1140	0.0359	0.0188	0.0096	0.0188	0.0096
50 %		0.0570	0.0180	0.0094	0.0048	0.0094	0.0048
75 %		0.0285	0.0090	0.0047	0.0024	0.0047	0.0024
90 %		0.0114	0.0036	0.0019	0.0010	0.0019	0.0010
None	D4 Pond	**0.0083**	**0.0076**	**0.0055**	**0.0039**	**0.0055**	**0.0039**
50 %		**0.0045**	**0.0042**	**0.0031**	**0.0023**	**0.0031**	**0.0023**
75 %		**0.0026**	**0.0024**	**0.0019**	**0.0015**	**0.0019**	**0.0015**
90 %		**0.0014**	**0.0014**	**0.0013**	**0.0012**	**0.0013**	**0.0012**
None	D4 Stream	0.0960	0.0396	0.0208	0.0110	0.0208	0.0110
50 %		0.0483	0.0201	0.0107	0.0058	0.0107	0.0058
75 %		0.0245	0.0104	0.0057	**0.0033#**	0.0057	**0.0033#**
90 %		0.0102	0.0045	**0.0027**	**0.0017**	**0.0027**	**0.0017**
None	R1 Pond	**0.0247**	**0.0242**	**0.0225**	**0.0212**	**0.0113**	**0.0063**
50 %		**0.0217**	**0.0214**	**0.0205**	**0.0199**	**0.0094**	**0.0050**
75 %		**0.0202**	**0.0200**	**0.0196**	**0.0193**	**0.0084**	**0.0044**
90 %		**0.0192**	**0.0192**	**0.0190**	**0.0189**	**0.0079**	**0.0040**
None	R1 Stream	**0.4106**	**0.4106**	**0.4106**	**0.4106**	**0.1862**	**0.0974**
50 %		**0.4106**	**0.4106**	**0.4106**	**0.4106**	**0.1862**	**0.0974**
75 %		**0.4106**	**0.4106**	**0.4106**	**0.4106**	**0.1862**	**0.0974**
90 %		**0.4106**	**0.4106**	**0.4106**	**0.4106**	**0.1862**	**0.0974**
None	R3 Stream	**0.8509**	**0.8509**	**0.8509**	**0.8509**	**0.3881**	**0.2036**
50 %		**0.8509**	**0.8509**	**0.8509**	**0.8509**	**0.3881**	**0.2036**
75 %		**0.8509**	**0.8509**	**0.8509**	**0.8509**	**0.3881**	**0.2036**
90 %		**0.8509**	**0.8509**	**0.8509**	**0.8509**	**0.3881**	**0.2036**

* low and high fractional reduction in the runoff and erosion through volume, mass and flux
#results from single and multiple application are identical
data origin (modelling report & crop no.): 1) EnSa-16-0765, Sugar beet II, 2 × 25 g a.s./ha

Table 8.9-27: FOCUS Step 4 TWAC$_{sw}$ at Day 7 for foramsulfuron, following multiple applications of FSN+TCM OD 80 (50+30)
- Use: Sugar beet, 2 × 25 g foramsulfuron/ha, BBCH 10-18

Sugar beet, 2×25 g a.s./ha, multiple appl.[1)]	**Scenario**	**Step 4 foramsulfuron 7 d- PEC$_{sw,twa}$ (µg/L)**					
Nozzle reduction	**Vegetated strip (m)**	**None**	**None**	**None**	**None**	**10m low***	**10m low***
	No spray buffer (m)	**0 m**	**5 m**	**10 m**	**20 m**	**10 m**	**20 m**
Maximum PEC$_{sw}$ values out of single and multiple application are marked in bold							
None	D3 Ditch	0.0196	0.0062	0.0032	0.0016	0.0032	0.0016
50 %		0.0098	0.0031	0.0016	0.0008	0.0016	0.0008
75 %		0.0049	0.0015	0.0008	0.0004	0.0008	0.0004
90 %		0.0020	0.0006	0.0003	**0.0002#**	0.0003	**0.0002#**
None	D4 Pond	**0.0078**	**0.0072**	**0.0052**	**0.0037**	**0.0052**	**0.0037**
50 %		**0.0042**	**0.0039**	**0.0029**	**0.0022**	**0.0029**	**0.0022**
75 %		**0.0025**	**0.0023**	**0.0018**	**0.0014**	**0.0018**	**0.0014**
90 %		**0.0014**	**0.0013**	**0.0013**	**0.0012**	**0.0013**	**0.0012**
None	D4 Stream	**0.0016**	**0.0011**	**0.0009**	**0.0009**	**0.0009**	**0.0009**
50 %		**0.0011**	**0.0009**	**0.0009**	**0.0009**	**0.0009**	**0.0009**
75 %		**0.0009**	**0.0009**	**0.0009**	**0.0009**	**0.0009**	**0.0009**
90 %		**0.0009**	**0.0009**	**0.0009**	**0.0009**	**0.0009**	**0.0009**
None	R1 Pond	**0.0232**	**0.0226**	**0.0210**	**0.0198**	**0.0106**	**0.0059**
50 %		**0.0203**	**0.0200**	**0.0192**	**0.0186**	**0.0088**	**0.0047**
75 %		**0.0189**	**0.0187**	**0.0183**	**0.0180**	**0.0079**	**0.0041**
90 %		**0.0180**	**0.0179**	**0.0178**	**0.0177**	**0.0073**	**0.0037**
None	R1 Stream	**0.0351**	**0.0351**	**0.0351**	**0.0351**	**0.0158**	**0.0083**
50 %		**0.0351**	**0.0351**	**0.0351**	**0.0351**	**0.0158**	**0.0083**
75 %		**0.0351**	**0.0351**	**0.0351**	**0.0351**	**0.0158**	**0.0083**
90 %		**0.0351**	**0.0351**	**0.0351**	**0.0351**	**0.0158**	**0.0083**
None	R3 Stream	**0.1202**	**0.1202**	**0.1202**	**0.1202**	**0.0553**	**0.0291**
50 %		**0.1202**	**0.1202**	**0.1202**	**0.1202**	**0.0553**	**0.0291**
75 %		**0.1202**	**0.1202**	**0.1202**	**0.1202**	**0.0553**	**0.0291**
90 %		**0.1202**	**0.1202**	**0.1202**	**0.1202**	**0.0553**	**0.0291**

* low and high fractional reduction in the runoff and erosion through volume, mass and flux
#results from single and multiple application are identical
data origin (modelling report & crop no.): [1)] EnSa-16-0765, Sugar beet II, 2 × 25 g a.s./ha.

AE F130619

**Table 8.9-28: FOCUS Step 4 PEC_{sw} for AE F130619, following single application of FSN+TCM OD 80 (50+30)
- Use: Sugar beet, 1 × 50 g foramsulfuron/ha, BBCH 10-18**

Sugar beet 1×50 g a.s./ha, single appl.[1)]	**Scenario**	**STEP 4 - AE F130619**					
		PEC_{sw}, max (µg/L)					
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10m low*	20m high*
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m
None	D3 Ditch	0.0003	<0.001	<0.001	<0.001	<0.001	<0.001
50 %		0.0001	<0.001	<0.001	<0.001	<0.001	<0.001
75 %		<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
90 %		<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
None	D4 Pond	0.0003	0.0002	0.0002	0.0002	0.0002	0.0002
50 %		0.0002	0.0002	0.0002	0.0002	0.0002	0.0002
75 %		0.0002	0.0002	0.0002	0.0002	0.0002	0.0002
90 %		0.0002	0.0002	0.0002	0.0002	0.0002	0.0002
None	D4 Stream	0.0003	0.0002	0.0002	0.0002	0.0002	0.0002
50 %		0.0002	0.0002	0.0002	0.0002	0.0002	0.0002
75 %		0.0002	0.0002	0.0002	0.0002	0.0002	0.0002
90 %		0.0002	0.0002	0.0002	0.0002	0.0002	0.0002
None	R1 Pond	0.0010	0.0010	0.0010	0.0009	0.0005	0.0002
50 %		0.0009	0.0009	0.0009	0.0009	0.0004	0.0002
75 %		0.0009	0.0009	0.0009	0.0009	0.0004	0.0002
90 %		0.0009	0.0009	0.0009	0.0009	0.0004	0.0002
None	R1 Stream	0.0193	0.0193	0.0193	0.0193	0.0088	0.0046
50 %		0.0193	0.0193	0.0193	0.0193	0.0088	0.0046
75 %		0.0193	0.0193	0.0193	0.0193	0.0088	0.0046
90 %		0.0193	0.0193	0.0193	0.0193	0.0088	0.0046
None	R3 Stream	0.0432	0.0432	0.0432	0.0432	0.0197	0.0103
50 %		0.0432	0.0432	0.0432	0.0432	0.0197	0.0103
75 %		0.0432	0.0432	0.0432	0.0432	0.0197	0.0103
90 %		0.0432	0.0432	0.0432	0.0432	0.0197	0.0103

* low and high fractional reduction in the runoff and erosion through volume, mass and flux
data origin (modelling report & crop no.): [1)] EnSa-16-0765, Sugar beet I, 1 × 50 g a.s./ha

Table 8.9-29: FOCUS Step 4 PEC_{sw} for <u>AE F130619</u>, following <u>single</u> application of FSN+TCM OD 80 (50+30)
- Use: Sugar beet, 2 × 25 g foramsulfuron/ha, BBCH 10-18

Sugar beet, 2×25 g a.s./ha, single appl.[1)]	**Scenario**	**STEP 4 - AE F130619**					
		PEC_{sw}, max (µg/L)					
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10m low*	20m high*
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m
Maximum PEC_{sw} values out of single and multiple application are marked in bold							
None	D3 Ditch	**0.0001#**	**<0.001#**	**<0.001#**	**<0.001#**	**<0.001#**	**<0.001#**
50 %		**<0.001#**	**<0.001#**	**<0.001#**	**<0.001#**	**<0.001#**	**<0.001#**
75 %		**<0.001#**	**<0.001#**	**<0.001#**	**<0.001#**	**<0.001#**	**<0.001#**
90 %		**<0.001#**	**<0.001#**	**<0.001#**	**<0.001#**	**<0.001#**	**<0.001#**
None	D4 Pond	0.0001	0.0001	0.0001	<0.001	0.0001	<0.001
50 %		<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
75 %		<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
90 %		<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
None	D4 Stream	0.0001	<0.001	<0.001	<0.001	<0.001	<0.001
50 %		<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
75 %		<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
90 %		<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
None	R1 Pond	0.0006	0.0006	0.0005	0.0005	0.0002	0.0001
50 %		0.0005	0.0005	0.0005	0.0005	0.0002	0.0001
75 %		0.0005	0.0005	0.0005	0.0005	0.0002	0.0001
90 %		0.0005	0.0005	0.0005	0.0005	0.0002	0.0001
None	R1 Stream	0.0108	0.0108	0.0108	0.0108	0.0049	0.0026
50 %		0.0108	0.0108	0.0108	0.0108	0.0049	0.0026
75 %		0.0108	0.0108	0.0108	0.0108	0.0049	0.0026
90 %		0.0108	0.0108	0.0108	0.0108	0.0049	0.0026
None	R3 Stream	0.0229	0.0229	0.0229	0.0229	0.0104	0.0055
50 %		0.0229	0.0229	0.0229	0.0229	0.0104	0.0055
75 %		0.0229	0.0229	0.0229	0.0229	0.0104	0.0055
90 %		0.0229	0.0229	0.0229	0.0229	0.0104	0.0055

* low and high fractional reduction in the runoff and erosion through volume, mass and flux
#results from single and multiple application are identical
data origin (modelling report & crop no.): [1)] EnSa-16-0765, Sugar beet II, 2 × 25 g a.s./ha

**Table 8.9-30: FOCUS Step 4 PEC_{sw} for <u>AE F130619</u>, following <u>multiple</u> applications of FSN+TCM OD 80 (50+30)
- Use: Sugar beet, 2 × 25 g foramsulfuron/ha, BBCH 10-18**

Sugar beet, 2×25 g a.s./ha, multiple appl.[1)]	**Scenario**	**STEP 4 - AE F130619**					
		PEC_{sw}, max (µg/L)					
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10m low*	20m high*
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m
Maximum PEC_{sw} values out of single and multiple application are marked in bold							
None	D3 Ditch	**0.0001#**	**<0.001#**	**<0.001#**	**<0.001#**	**<0.001#**	**<0.001#**
50 %		**<0.001#**	**<0.001#**	**<0.001#**	**<0.001#**	**<0.001#**	**<0.001#**
75 %		**<0.001#**	**<0.001#**	**<0.001#**	**<0.001#**	**<0.001#**	**<0.001#**
90 %		**<0.001#**	**<0.001#**	**<0.001#**	**<0.001#**	**<0.001#**	**<0.001#**
None	D4 Pond	**0.0003**	**0.0003**	**0.0002**	**0.0002**	**0.0002**	**0.0002**
50 %		**0.0002**	**0.0002**	**0.0002**	**0.0002**	**0.0002**	**0.0002**
75 %		**0.0002**	**0.0002**	**0.0002**	**0.0002**	**0.0002**	**0.0002**
90 %		**0.0002**	**0.0002**	**0.0002**	**0.0002**	**0.0002**	**0.0002**
None	D4 Stream	**0.0002**	**0.0002**	**0.0002**	**0.0002**	**0.0002**	**0.0002**
50 %		**0.0002**	**0.0002**	**0.0002**	**0.0002**	**0.0002**	**0.0002**
75 %		**0.0002**	**0.0002**	**0.0002**	**0.0002**	**0.0002**	**0.0002**
90 %		**0.0002**	**0.0002**	**0.0002**	**0.0002**	**0.0002**	**0.0002**
None	R1 Pond	**0.0017**	**0.0017**	**0.0016**	**0.0016**	**0.0007**	**0.0004**
50 %		**0.0016**	**0.0016**	**0.0016**	**0.0016**	**0.0007**	**0.0003**
75 %		**0.0016**	**0.0016**	**0.0016**	**0.0016**	**0.0006**	**0.0003**
90 %		**0.0016**	**0.0016**	**0.0016**	**0.0016**	**0.0006**	**0.0003**
None	R1 Stream	**0.0364**	**0.0364**	**0.0364**	**0.0364**	**0.0165**	**0.0086**
50 %		**0.0364**	**0.0364**	**0.0364**	**0.0364**	**0.0165**	**0.0086**
75 %		**0.0364**	**0.0364**	**0.0364**	**0.0364**	**0.0165**	**0.0086**
90 %		**0.0364**	**0.0364**	**0.0364**	**0.0364**	**0.0165**	**0.0086**
None	R3 Stream	**0.0833**	**0.0833**	**0.0833**	**0.0833**	**0.0380**	**0.0199**
50 %		**0.0833**	**0.0833**	**0.0833**	**0.0833**	**0.0380**	**0.0199**
75 %		**0.0833**	**0.0833**	**0.0833**	**0.0833**	**0.0380**	**0.0199**
90 %		**0.0833**	**0.0833**	**0.0833**	**0.0833**	**0.0380**	**0.0199**

* low and high fractional reduction in the runoff and erosion through volume, mass and flux
#results from single and multiple application are identical
data origin (modelling report & crop no.): [1)] EnSa-16-0765, Sugar beet II, 2 × 25 g a.s./ha

zRMS comments

<u>Foramsulfurone</u>
The PECsw/sed calculations for foramsulfurone have been approved for applications proposed in GAP. Used input parameters were in line EFSA Conclusion (2016;14(3): 4421)
PECsw and PECsed calculations were carried out according to the FOCUS recommendations.

The Applicant has been used FOCUS models: STEPS1-2 and Step 3. $PEC_{sw/sed}$ were also carried out at Step 4 according to FOCUS L&M Guidance for 10m and 20m vegetative buffer zone.
The Applicant used the geometric mean value. In opinion of the zRMS this is acceptable, as being in line with current requirements concerning selection of Kfoc and DT50 to be used for modelling purposes.

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

Member States should decide on the applicability timecourse of PEC_{sw} (FOCUS year) of thiencarbazone-methyl for Tier 2C and Tier 3 assessment

Thiencarbazone

MS should identify risk reduction measures at the national level.

(d) FOCUS Step 3 – Timecourse of PEC_{sw} (FOCUS year) of foramsulfuron [for Tier 2C and Tier 3 assessment]

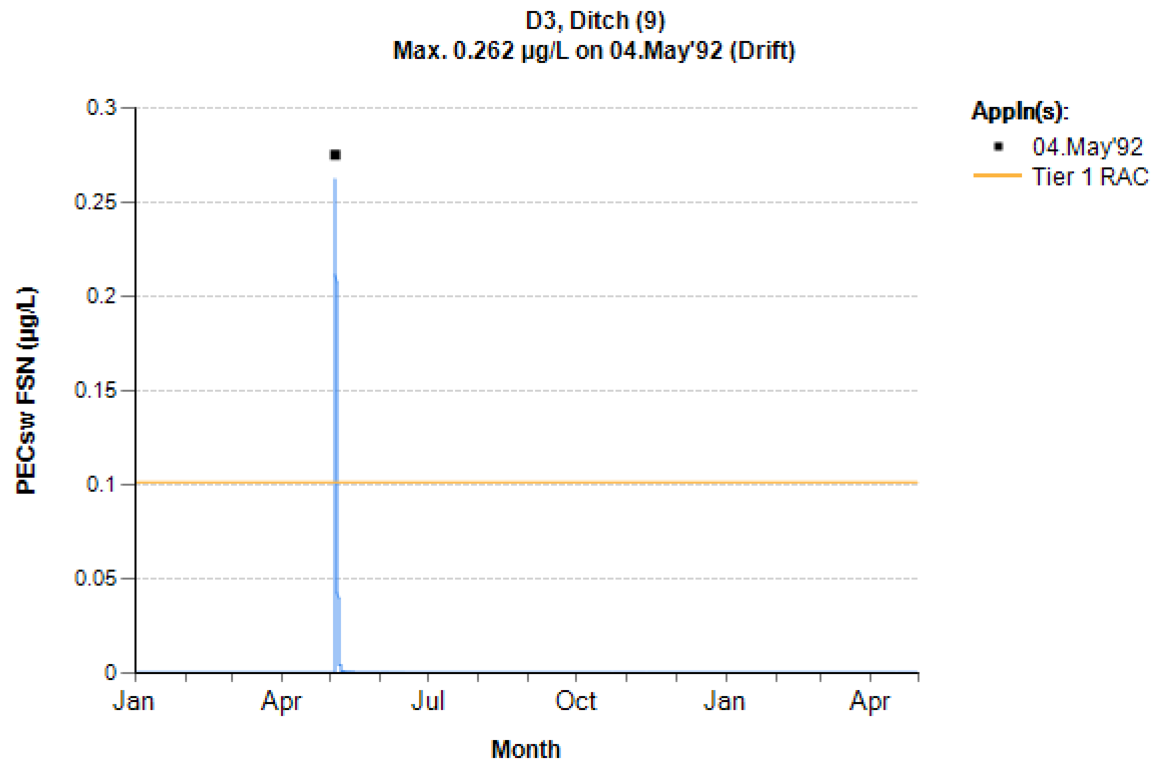
For the present formulation, a higher tier / refined risk assessment is presented for exposure of foramsulfuron in selected FOCUS surface water scenarios in dRR Part B Section 9, based on an ecotoxicological interpretation of the evolution of surface concentration over time. As prerequisite, time-course plots were generated from the FOCUS Step 3 model output, and numerically characterised via EPAT tool analysis for the following parameters:

- the PEC_{max},
- the number of peak events above the Tier 1 RAC,
- the duration of these peak events, and
- the interval between these peak events.

Moreover, the modelling output files containing full detailed information on exposure over the simulated FOCUS year period in hourly resolution for all FOCUS scenarios were transferred electronically into ecological modelling approaches (TK/TD population effect simulation), which are described in dRR Part B Section 9.

Table 8.9-31: Timecourse of FOCUS Step 3 PEC_{sw} for foramsulfuron following single application of FSN+TCM OD 80 (50+30) – Use: sugar beet, 1 × 50 g foramsulfuron/ha, BBCH 10–18

Scenario D3 ditch, FOCUS Step 3



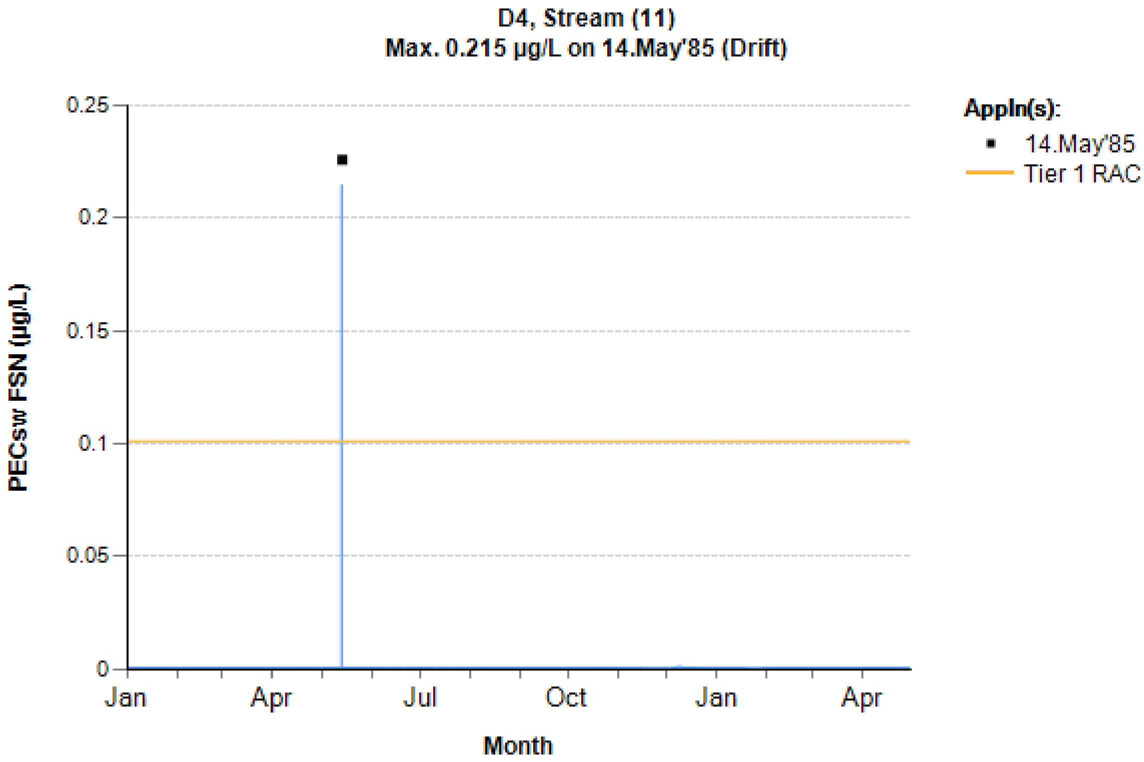
Tier 1-RAC = 0.101 µ/L

EPAT analysis:

PEC_{max} [µg a.s./L]	No. of events > Tier 1-RAC	Duration of event [days]	Interval between events [days]
0.2624	1	1.333	Not relevant

[event recognition threshold: 0.101 µg/L]

Scenario D4 stream, FOCUS Step 3



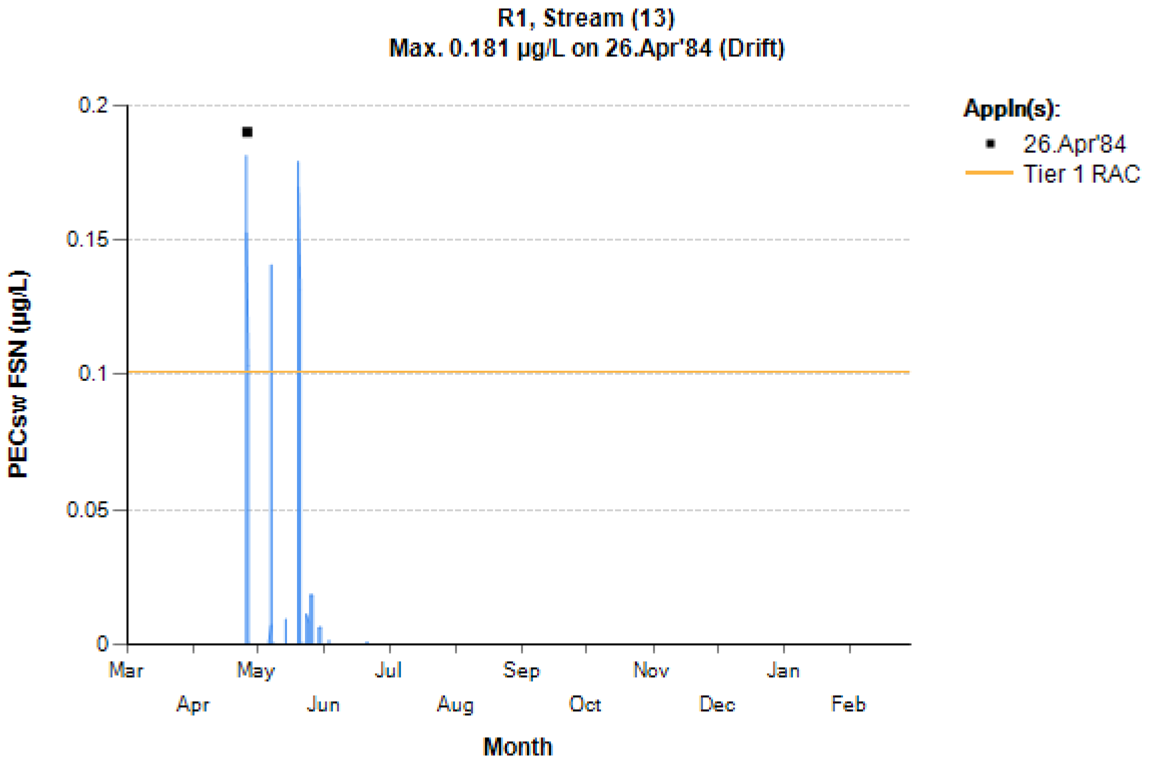
Tier 1-RAC = 0.101 µ/L

EPAT analysis:

PEC_{max} [µg a.s./L]	No. of events > Tier 1-RAC	Duration of event [days]	Interval between events [days]
0.2146	1	0.083	Not relevant

[event recognition threshold: 0.101 µg/L]

Scenario R1 stream, FOCUS Step 3



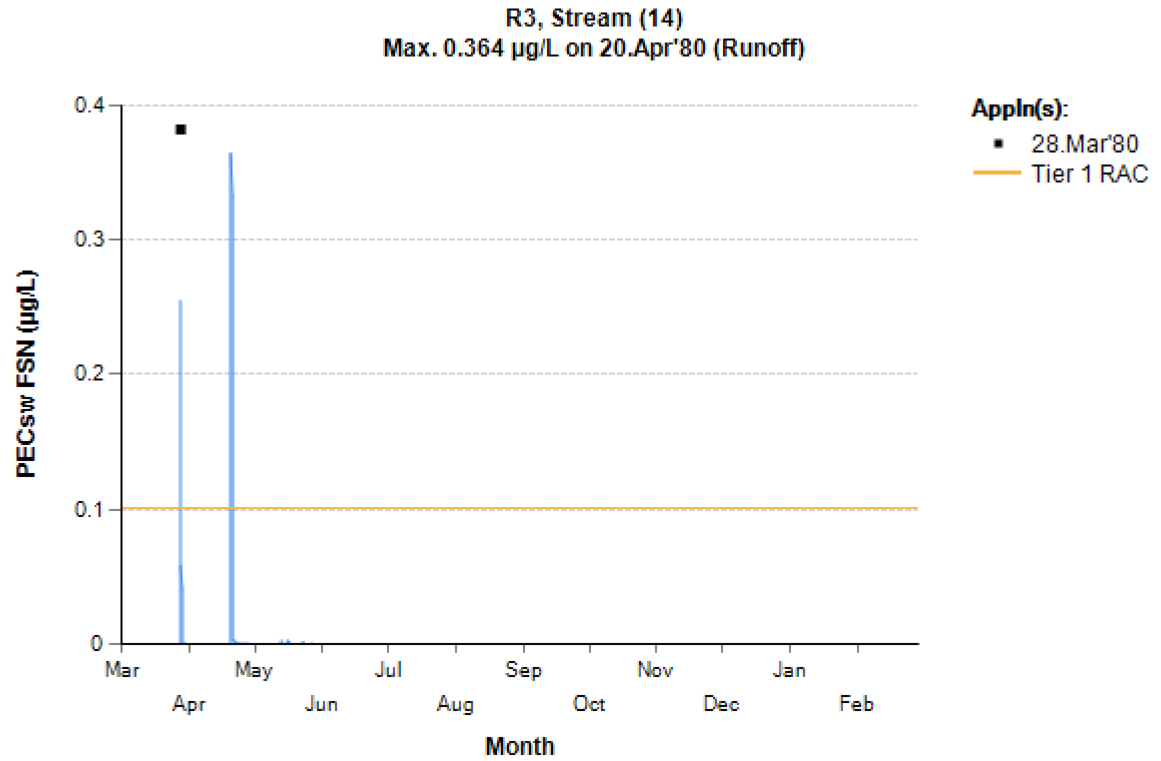
Tier 1-RAC = 0.101 µ/L

EPAT analysis:

PEC_{max} [µg a.s./L]	No. of events > Tier 1-RAC	Duration of event [days]	Interval between events [days]
0.1813 0.1407 0.1791	3	0.208 0.334 0.541	- 10.625 12.500

[event recognition threshold: 0.101 µg/L]

Scenario R3 stream, FOCUS Step 3



Tier 1-RAC = 0.101 µ/L

EPAT analysis:

PEC_{max} [µg a.s./L]	No. of events > Tier 1-RAC	Duration of event [days]	Interval between events [days]
0.2551 0.3644	2	0.333 1.083	- 22.334

[event recognition threshold: 0.101 µg/L]

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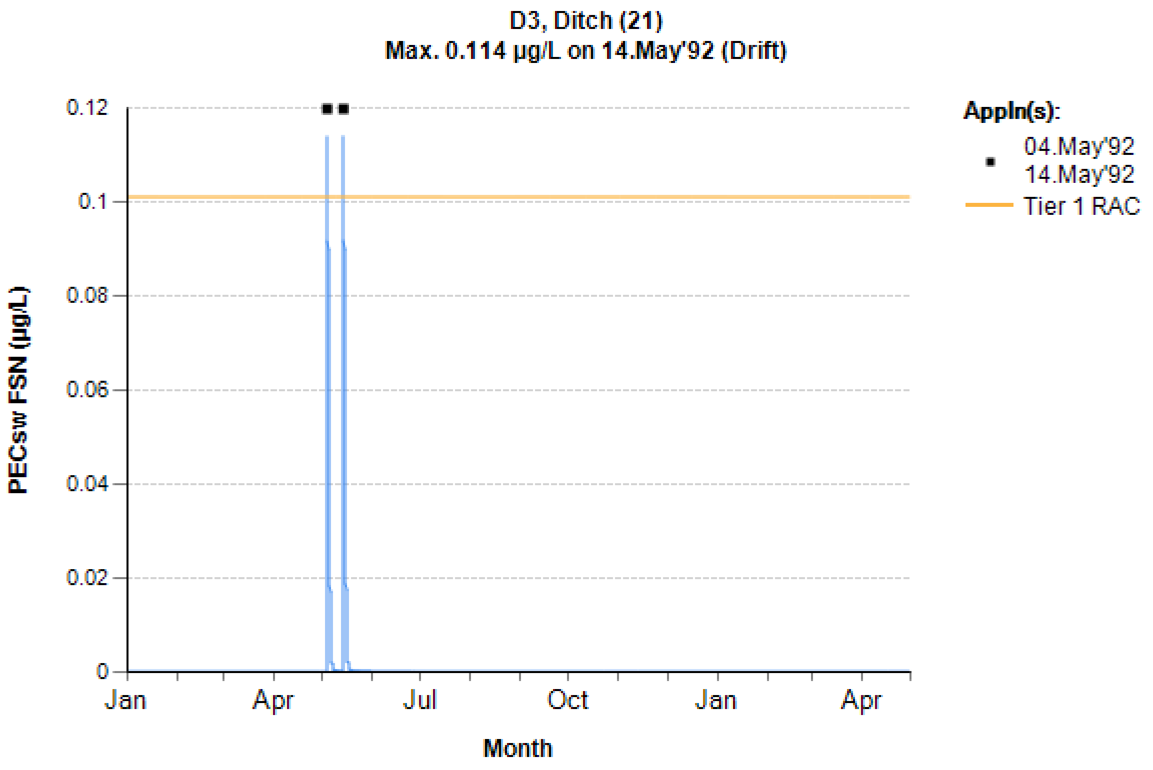
Table 8.9-32: Timecourse of FOCUS Step 3 PEC_{sw} for <u>foramsulfuron</u> following multiple applications of FSN+TCM OD 80 (50+30) – Use: sugar beet, 2 × 25 g foramsulfuron/ha, BBCH 10–18

Scenario D3 ditch, FOCUS Step 3



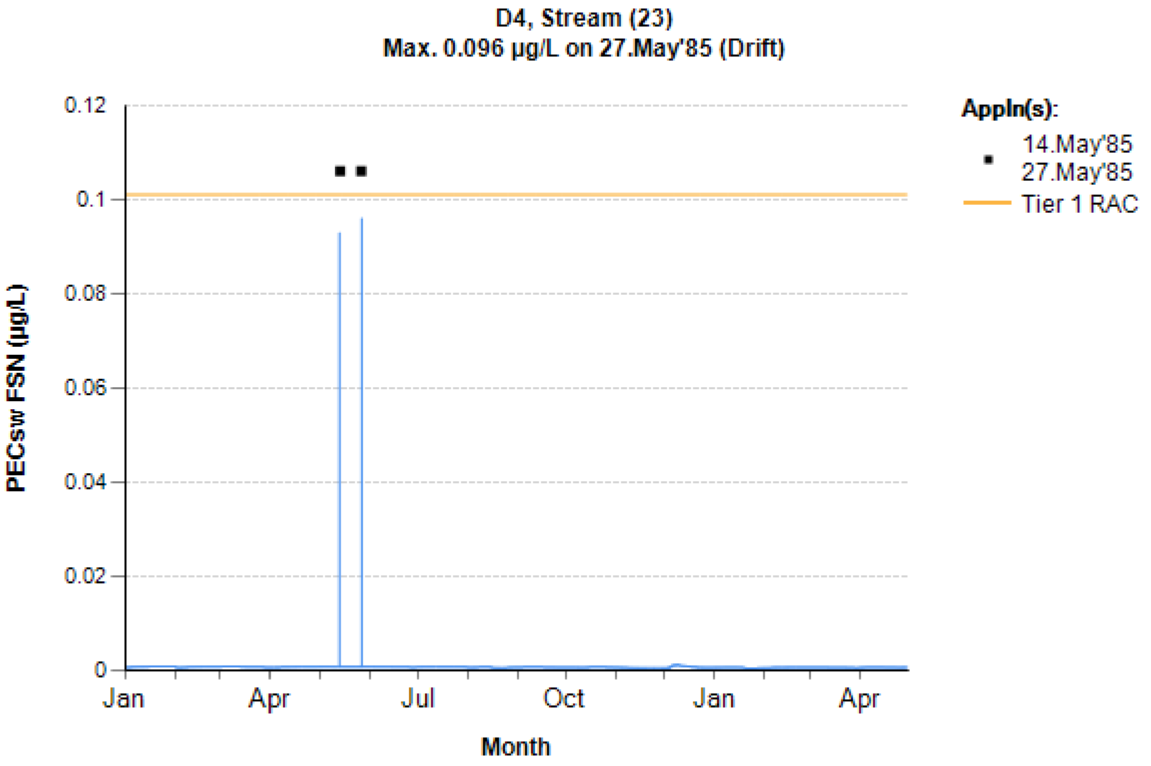
Tier 1-RAC = 0.101 µ/L

EPAT analysis:

PEC_{max} [µg a.s./L]	No. of events > Tier 1-RAC	Duration of event [days]	Interval between events [days]
0.1139 0.1140	2	0.375 0.375	- 9.625

[event recognition threshold: 0.101 µg/L]

Scenario D4 stream, FOCUS Step 3



Tier 1-RAC = 0.101 µ/L

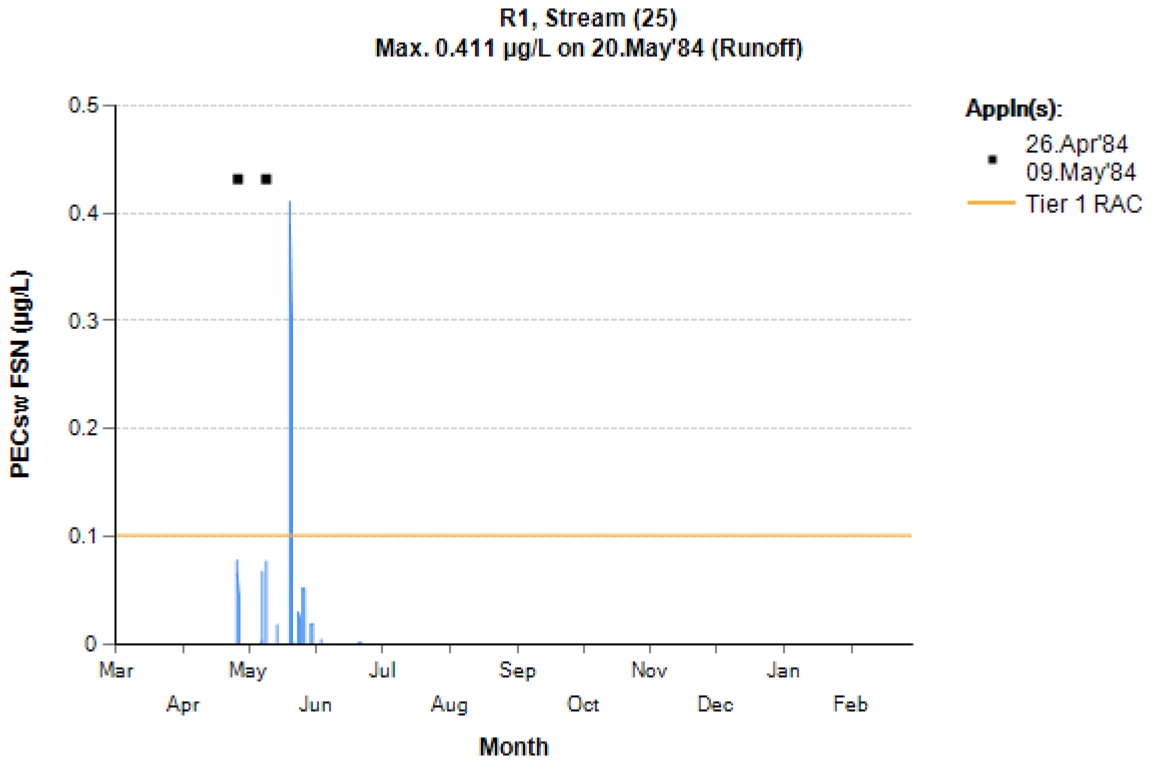
EPAT analysis:

PEC_{max} [µg a.s./L]	No. of events > Tier 1-RAC	Duration of event [days]	Interval between events [days]
0.0960	0	N/A	N/A

[event recognition threshold: 0.101 µg/L]

Exposure in this scenario situation does NOT exceed the Tier 1 RAC, however analysis of timecourse was triggered by combined toxicity assessment of all active substances. Visual assessment of the plotted time course clearly shows a peak exposure profile for this drift-driven scenario.

Scenario R1 stream, FOCUS Step 3



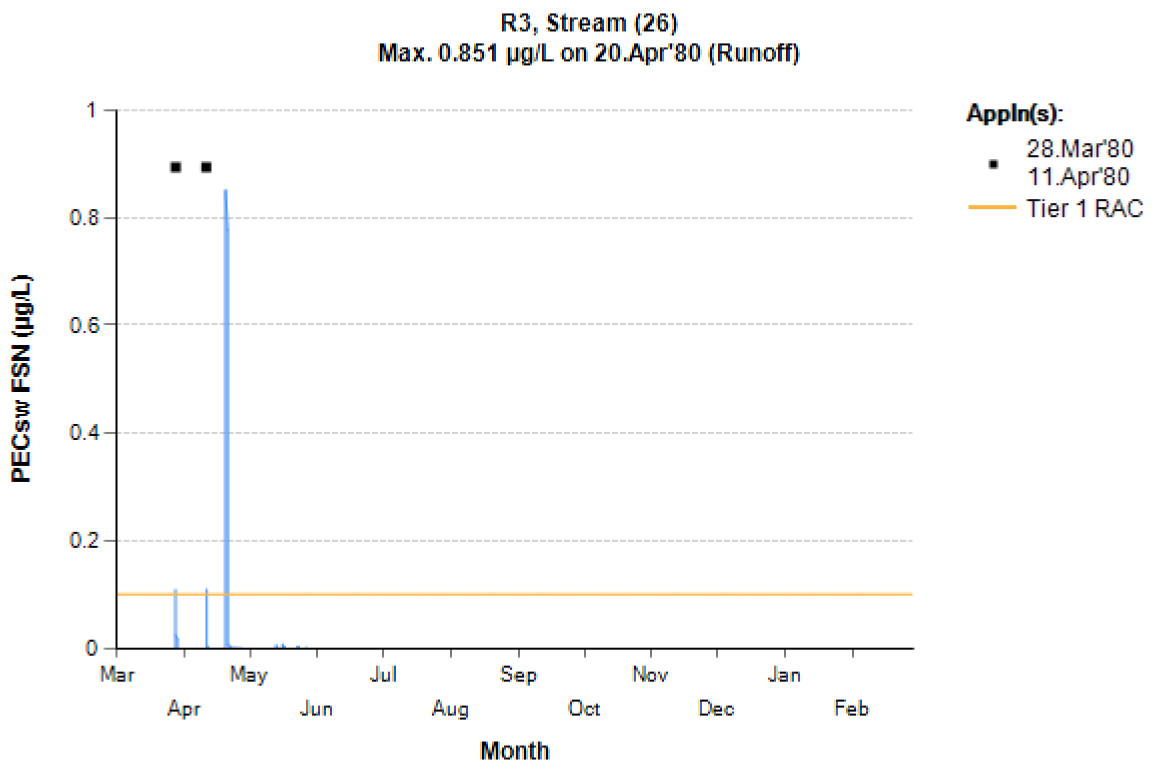
Tier 1-RAC = 0.101 µ/L

EPAT analysis:

PEC_{max} [µg a.s./L]	No. of events > Tier 1-RAC	Duration of event [days]	Interval between events [days]
0.4106	1	0.583	Not relevant

[event recognition threshold: 0.101 µg/L]

Scenario R3 stream, FOCUS Step 3



Tier 1-RAC = 0.101 µ/L

EPAT analysis:

PEC_{max} [µg a.s./L]	No. of events > Tier 1-RAC	Duration of event [days]	Interval between events [days]
0.1099 0.1103 0.8509	3	0.167 0.208 1.250	- 13.833 8.4590

[event recognition threshold: 0.101 µg/L]

(e) FOCUS Step 3-4 – Timecourse of PECsw (multi-year simulation) for foramsulfuron [for Tier 2C and Tier 3 assessment]

In response to concerns expressed by some regulators on the representativeness of the FOCUS model's single weather year in the context of a refined risk assessment based on exposure pattern analysis, additional calculations have been run for foramsulfuron over a period of 20 years (multi-year calculations). From this large data set, 90th percentile realistic worst-case exposure patterns were derived for those critical GAP situations previously addressed for the FOCUS medium year under point (c) above.

Moreover, the full detailed electronic information of hourly exposure values over the simulated 20-year period for all FOCUS scenarios served as basis for ecological modelling approaches (TK/TD population effect simulation), which are described in dRR Part B Section 9.

Due to its confirmatory character, the detailed methodology and results of the multi-year approach are presented only in the Appendix section (A 3.3.1 (e)) of the present dRR, for the interested reader.

8.9.2.3 Thiencarbazone-methyl and its metabolites

For thiencarbazone-methyl, agreed endpoints were used as input to exposure modelling as follows:

Table 8.9-33: Input parameters related to active substance thiencarbazone-methyl and metabolites for $PEC_{sw/sed}$ calculations STEP 1/2 and 3/4

Compound	thiencarbazone-methyl	BYH 18636-carboxylic acid	BYH 18636-sulfonamide	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	390.4	376.4	235.3	Y/ EFSA Journal 2013;11(7):3270
Saturated vapour pressure (Pa)	8.8×10^{-14} # (20°C)	1×10^{-10} Pa [b]	1×10^{-10} Pa [b]	# Y/ EFSA Journal 2013;11(7):3270 N / Worst case assumption
Water solubility (mg/L)	436 (20°C)	10000 mg/L [b]	10000 mg/L [b]	Y/ EFSA Journal 2013;11(7):3270
Diffusion coefficient in water (m²/d)	4.3×10^{-5}	-[a]	-[a]	default
Diffusion coefficient in air (m²/d)	0.43	-[a]	-[a]	default
K_{foc} (mL/g)	83 (geometric mean, n = 5)	11.7 (geometric mean, n = 5)	100 (geometric mean, n = 5)	Y/ EFSA Journal 2013;11(7):3270
Freundlich Exponent 1/n	0.906 (arithmetic mean, n = 5)	0.919 (arithmetic mean, n = 5)	0.90 (arithmetic mean, n = 5)	Y/ EFSA Journal 2013;11(7):3270
Plant Uptake	0.5 [c]	0 [c]	0 [c]	Y/ EFSA Journal 2013;11(7):3270
Wash-Off factor from Crop	0.05 mm^{-1} (MACRO) 0.50 cm^{-1} (PRZM)	-[a]	-[a]	Default
$DT_{50,soil}$ (d)	STEP 1/2 : 15.5 (geomean, non-normalised, n=5) STEP 3/4: 11.6 (geomean normalisation to pF2, 20 °C with Q_{10} of 2.58, n =5)	112.3 (geomean, non-normalised, n =4)	15.0 (geomean, non-normalised, n =5)	Y/ EFSA Journal 2013;11(7):3270
$DT_{50,water}$ (d)	26.2	30.7	12.3	Y/ EFSA Journal 2013;11(7):3270
$DT_{50,sed}$ (d)	STEP 1/2: 26.2 (geomean, n = 2) STEP 3/4: 1000	30.7	12.3	Y/ EFSA Journal 2013;11(7):3270
$DT_{50,whole\ system}$ (d)	26.2 (geomean, n = 2)	30.7 (geomean, n = 2)	12.3 (geomean, n = 2)	Y/ EFSA Journal 2013;11(7):3270
Maximum occurrence observed (% molar basis with respect to the	Soil: 100 Water/Sediment:	Soil: 53.6 Water/Sediment:	Soil: 15.6 Water/Sediment:	Y/ EFSA Journal 2013;11(7):3270

Compound	**thiencarbazone-methyl**	**BYH 18636-carboxylic acid**	**BYH 18636-sulfonamide**	**Value in accordance to EU endpoint y/n/ Reference**
parent)	100	37.1	7	
Formation fraction in soil:	-	0.382 (from TCM)	0.375 (from TCM)	Y/ EFSA Journal 2013;11(7):3270

[a] not required for Steps 1-2 simulations
[b] Not measured. Default value used
[c] The TSCF value that should be used in FOCUS modelling for thiencarbazone-methyl and its soil metabolites has been extensively discussed in Pesticides Peer Review Meeting 101 (see minuted in EFSA Peer Review Report on Thiencarbazone-methyl, PDF page 211). It was accepted that a TSCF value of 0.5 could be used for the parent compound on the basis of the results of the confined rotational crop study. As there was no good definitive evidence of systemicity for soil metabolites, the majority of experts considered that FOCUS modelling should use a TSCF factor of 0 for metabolites. These values are listed as the relevant EU Endpoints for modelling (cf. page 50 of EFSA Journal 2013;11(7):3270), and are used in the subsequent exposure simulation

Table 8.9-34: Input parameters related to thiencarbazone-methyl metabolites for PECsw/sed calculations STEP 1/2 (continued)

Compound	**BYH 18636- sulfonamide-carboxylic acid**	**BYH 18636-MMT**	**BYH 18636-dicarboxy-sulfonamide**	**Value in accordance to EU endpoint y/n/ Reference**
Molecular weight (g/mol)	221.3	129.1	251.2	Y/ EFSA Journal 2013;11(7):3270
Saturated vapour pressure (Pa)	1×10^{-10} Pa [b]	1×10^{-10} Pa [b]	1×10^{-10} Pa [b]	N / Worst case assumption
Water solubility (mg/L)	10000 mg/L [b]	10000 mg/L [b]	10000 mg/L [b]	Y/ EFSA Journal 2013;11(7):3270
Diffusion coefficient in water (m²/d)	-[a]	-[a]	-[a]	-
Diffusion coefficient in air (m²/d)	-[a]	-[a]	-[a]	-
K_{foc} (mL/g)	7.3 (geometric mean, n =5)	14.2 (geometric mean, n =5)	0.001	Y/ EFSA Journal 2013;11(7):3270
Freundlich Exponent 1/n	0.74 (arithmetic mean, n =5)	1.00 (arithmetic mean, n =5)	1.0	Y/ EFSA Journal 2013;11(7):3270
Plant Uptake	0 [c]	0 [c]	0 [c]	Y/ EFSA Journal 2013;11(7):3270
Wash-Off factor from Crop (1/mm)	-[a]	-[a]	-[a]	Default
$DT_{50,soil}$ (d)	10.8 (geomean, non-normalised, n =5)	126.9 (geomean, non-normalised, n =5)	(geomean, normalisation to pF2, 20 °C with Q0.0001[d]	Y/ EFSA Journal 2013;11(7):3270
$DT_{50,water}$ (d)	1000	1000	1000	Y/ EFSA Journal 2013;11(7):3270
$DT_{50,sed}$ (d)	1000	1000	1000	Y/ EFSA Journal 2013;11(7):3270
$DT_{50,whole\ system}$ (d)	1000 (default)	1000 (default)	1000 (default)	Y/ EFSA Journal 2013;11(7):3270
Maximum occurrence observed (%	Soil: 21.2	Soil: 20.6	Soil: 0.001	Y/ EFSA Journal

Compound	BYH 18636- sulfonamide-carboxylic acid	BYH 18636-MMT	BYH 18636-dicarboxy-sulfonamide	Value in accordance to EU endpoint y/n/ Reference
molar basis with respect to the parent)	Water/Sediment: 66.9	Water/Sediment: 30.7	Water/Sediment: 23.9	2013;11(7):3270
Formation fraction in soil:	1 (from BYH18636-carboxylic acid) 0.794 (from BYH18636-sulfonamide)	0.932 (from MMT transient to MMTfast), 0.068 (from MMT transient to MMTslow)	-	Y/ EFSA Journal 2013;11(7):3270

[a] not required for Steps 1-2 simulations
[b] Not measured. Default value used
[c] The TSCF value that should be used in FOCUS modelling for thiencarbazone-methyl and its soil metabolites has been extensively discussed in Pesticides Peer Review Meeting 101 (see minuted in EFSA Peer Review Report on Thiencarbazone-methyl, PDF page 211). It was accepted that a TSCF value of 0.5 could be used for the parent compound on the basis of the results of the confined rotational crop study. As there was no good definitive evidence of systemicity for soil metabolites, the majority of experts considered that FOCUS modelling should use a TSCF factor of 0 for metabolites. These values are listed as the relevant EU Endpoints for modelling (cf. page 50 of EFSA Journal 2013;11(7):3270), and are used in the subsequent exposure simulation
[d] default value as BYH 18636-dicarboxy-sulfonamide is no soil metabolite

(a) FOCUS Steps 1-2 – Risk envelope $PEC_{sw/sed}$ of thiencarbazone-methyl and all metabolites [for screening level assessment]

Table 8.9-35: FOCUS Step 1, 2 PECsw and PECsed for thiencarbazone-methyl following single application to sugar beet - for generic risk envelope covering all uses

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	7-d- $PEC_{sw,twa}$ (µg/L)**	21-d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	12.133	Run-off/Drain	11.039	9.2764	11.774
Step 2						
Northern Europe	March-May	2.2715*	Run-off/Drain	2.0636**	1.7340**	2.2005*
	June-Sept.	2.2715*	Run-off/Drain	2.0636**	1.7340**	2.2005*
	Oct-Feb	5.2228*	Run-off/Drain	4.7579**	3.9985**	5.1215*
Southern Europe	March-May	4.2390*	Run-off/Drain	3.8598**	3.2437**	4.1377*
	June-Sept.	3.2552*	Run-off/Drain	2.9617**	2.4888**	3.1586*
	Oct-Feb	4.2390*	Run-off/Drain	3.8598**	3.2437**	4.1377*
Step 3 – not relevant						

* single applications should be marked.
** twa-time as required by ecotox

Table 8.9-36: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for BYH 18636-carboxylic acid following single application to sugar beet - for generic risk envelope covering all uses

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	7-d- $PEC_{sw,twa}$ (µg/L)**	21 d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	11.573	Run-off/Drain	10.703	9.2143	1.6361
Step						
Northern Europe	March-May	2.2207*	Run-off/Drain	2.0536**	1.7680**	0.3119*
	June - Sept	2.2207*	Run-off/Drain	2.0536**	1.7680**	0.3119*
	Oct-Feb	5.3737*	Run-off/Drain	4.9702**	4.2790**	0.7628*
Southern Europe	March-May	4.3227*	Run-off/Drain	3.9980**	3.4420**	0.6125*
	June - Sept	3.2717*	Run-off/Drain	3.0258**	2.6050**	0.4622*
	Oct-Feb	4.3227*	Run-off/Drain	3.9980**	3.4420**	0.6125*

* single applications should be marked.
** twa-time as required by ecotox

Table 8.9-37: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for BYH 18636-sulfonamide following single application to sugar beet - for generic risk envelope covering all uses

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	7-d- $PEC_{sw,twa}$ (µg/L)**	21 d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	1.5830	Run-off/Drain	1.3065	0.9268	1.8653
Step 2						
Northern Europe	March-May	0.2723*	Run-off/Drain	0.2247**	0.1594**	0.3196*
	June - Sept	0.2723*	Run-off/Drain	0.2247**	0.1594**	0.3196*
	Oct-Feb	0.6639*	Run-off/Drain	0.5483**	0.3890**	0.7856*
Southern Europe	March-May	0.5334*	Run-off/Drain	0.4405**	0.3125**	0.6302*
	June - Sept	0.4028*	Run-off/Drain	0.3326**	0.2359**	0.4749*
	Oct-Feb	0.5334*	Run-off/Drain	0.4405**	0.3125**	0.6302*

* single applications should be marked.
** twa-time as required by ecotox

Table 8.9-38: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for BYH 18636-sulfonamide-carboxylic acid following single application to sugar beet - for generic risk envelope covering all uses

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	7-d- $PEC_{sw,twa}$ (µg/L)**	21 d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	6.7296	Run-off/Drain	6.7120	6.6795	0.5244
Step 2						
Northern	March-May	1.2204*	Run-off/Drain	1.2170**	1.2111**	0.0951*

Scenario **FOCUS**	**Waterbody**	**Max PEC$_{sw}$ (µg/L)***	**Dominant entry route**	**7-d- PEC$_{sw,twa}$ (µg/L)****	**21 d- PEC$_{sw,twa}$ (µg/L)****	**Max PEC$_{sed}$ (µg/kg)***
Europe	June - Sept	1.2204*	Run-off/Drain	1.2170**	1.2111**	0.0951*
	Oct-Feb	2.8439*	Run-off/Drain	2.8365**	2.8228**	0.2216*
Southern Europe	March-May	2.3027*	Run-off/Drain	2.2967**	2.2856**	0.1795*
	June - Sept	1.7616*	Run-off/Drain	1.7569**	1.7484**	0.1373*
	Oct-Feb	2.3027*	Run-off/Drain	2.2967**	2.2856**	0.1795*

* single applications should be marked.
** twa-time as required by ecotox

Table 8.9-39: FOCUS Step 1, 2 PEC$_{sw}$ and PEC$_{sed}$ for <u>BYH 18636-MMT</u> following single application to sugar beet - for generic risk envelope covering all uses

Scenario **FOCUS**	**Waterbody**	**Max PEC$_{sw}$ (µg/L)***	**Dominant entry route**	**7-d- PEC$_{sw,twa}$ (µg/L)****	**21 d- PEC$_{sw,twa}$ (µg/L)****	**Max PEC$_{sed}$ (µg/kg)***
Step 1	---	2.2508	Run-off/Drain	2.2446	2.2338	0.3688
Step 2						
Northern Europe	March-May	0.4322*	Run-off/Drain	0.4309**	0.4288**	0.0708*
	June - Sept	0.4322*	Run-off/Drain	0.4309**	0.4288**	0.0708*
	Oct-Feb	1.0254*	Run-off/Drain	1.0226**	1.0177**	0.1680*
Southern Europe	March-May	0.8276*	Run-off/Drain	0.8254**	0.8214**	0.1356*
	June - Sept	0.6299*	Run-off/Drain	0.6281**	0.6251**	0.1032*
	Oct-Feb	0.8276*	Run-off/Drain	0.8254**	0.8214**	0.1356*

* single applications should be marked.
** twa-time as required by ecotox

Table 8.9-40: FOCUS Step 1, 2 PEC$_{sw}$ and PEC$_{sed}$ for <u>BYH 18636-dicarboxy-sulfonamide</u> following single application to sugar beet - for generic risk envelope covering all uses

Scenario **FOCUS**	**Waterbody**	**Max PEC$_{sw}$ (µg/L)***	**Dominant entry route**	**7-d- PEC$_{sw,twa}$ (µg/L)****	**21 d- PEC$_{sw,twa}$ (µg/L)****	**Max PEC$_{sed}$ (µg/kg)***
Step 1	---	2.1070	Run-off/Drain	2.1019	2.0918	<0.001
Step 2						
Northern Europe	March-May	0.3993*	Run-off/Drain	0.3984**	0.3964**	<0.0001*
	June - Sept	0.3993*	Run-off/Drain	0.3984**	0.3964**	<0.0001*
	Oct-Feb	0.9137*	Run-off/Drain	0.9115**	0.9071**	<0.0001*
Southern Europe	March-May	0.7423*	Run-off/Drain	0.7405**	0.7369**	<0.0001*
	June - Sept	0.5708*	Run-off/Drain	0.5694**	0.5667**	<0.0001*
	Oct-Feb	0.7423*	Run-off/Drain	0.7405**	0.7369**	<0.0001*

* single applications should be marked.
** twa-time as required by ecotox

(b) FOCUS Step 3 – $PEC_{sw/sed}$ (maximum and TWA) of thiencarbazone-methyl [for Tier 1 assessment]

Table 8.9-41: FOCUS Step 3 PEC_{sw} and PEC_{sed} for <u>thiencarbazone-methyl</u> following application of FSN+TCM OD 80 (50+30) – Use: sugar beet, 1 × 30 g thiencarbazone-methyl/ha, BBCH 10–18

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	7 d- $PEC_{sw,twa}$ (µg/L)**	21 d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 3: sugar beet, 1 × 30 g thiencarbazone-methyl/ha [1)]						
D3	ditch	0.1574 *	Spray drift	0.0268	0.0089	0.0389 *
D4	pond	0.0067 *	Spray drift	0.0062	0.0055	0.0105 *
D4	stream	0.1288 *	Spray drift	0.0013	0.0006	0.0060 *
R1	pond	0.0086 *	Runoff	0.0081	0.0072	0.0157 *
R1	stream	0.1088 *	Spray drift	0.0087	0.0043	0.0240 *
R3	stream	0.2048 *	Runoff	0.0289	0.0097	0.0582 *

* single applications should be marked.
** twa-time as required by ecotox
data origin (modelling report & crop no.): [1)] EnSa-16-0807, Sugar beet I.

Table 8.9-42: FOCUS Step 3 PEC_{sw} and PEC_{sed} for <u>thiencarbazone-methyl</u> following application of FSN+TCM OD 80 (50+30) – Use: sugar beet, 2 × 15 g thiencarbazone-methyl/ha, BBCH 10–18

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	7 d- $PEC_{sw,twa}$ (µg/L)**	21 d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 3: sugar beet, 2 × 15 g thiencarbazone-methyl/ha [1)] *Maximum values (max PEC_{sw} and 7 d-$PEC_{sw,twa}$) out of single and multiple application are marked in bold*						
Single application						
D3	ditch	**0.0787** *	Spray drift	**0.0134**	0.0045	0.0201 *
D4	pond	0.0033 *	Spray drift	0.0031	0.0027	0.0054 *
D4	stream	**0.0642** *	Spray drift	0.0006	0.0003	0.0030 *
R1	pond	0.0045 *	Runoff	0.0042	0.0037	0.0083 *
R1	stream	0.0553 *	Runoff	0.0047	0.0023	0.0131 *
R3	stream	0.1055 *	Runoff	0.0149	0.0050	0.0308 *
Multiple applications						
D3	ditch	0.0682	Spray drift	0.0117	**0.0078**	**0.0223**
D4	pond	**0.0050**	Spray drift	**0.0046**	**0.0040**	**0.0091**
D4	stream	0.0574	Spray drift	**0.0010**	**0.0007**	**0.0048**
R1	pond	**0.0144**	Runoff	**0.0134**	**0.0122**	**0.0226**

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	7 d- $PEC_{sw,twa}$ (µg/L)**	21 d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
R1	stream	**0.2388**	Runoff	**0.0207**	**0.0080**	**0.0504**
R3	stream	**0.4757**	Runoff	**0.0672**	**0.0235**	**0.1333**

* single applications should be marked.
** twa-time as required by ecotox
data origin (modelling report & crop no.): [1)] EnSa-16-0807, Sugar beet II.

(c) FOCUS Step 4 – PECsw/sed (single/multiple applications and TWA) of thiencarbazone-methyl [for Tier 1 assessment considering mitigation options]

FOCUS Step 4 exposure values are available from the same set of modelling reports referenced under point (b) before.

Tabular results for the uses assessed with the present formulation are provided here below:

Table 8.9-43: FOCUS Step 4 PEC_{sw} for thiencarbazone-methyl, following single application of FSN+TCM OD 80 (50+30)
- Use: Sugar beet, 1 × 30 g thiencarbazone-methyl/ha, BBCH 10-18

Sugar beet 1×30 g a.s./ha, single appl.[1)]	**Scenario**	**STEP 4 - thiencarbazone-methyl**					
		PEC_{sw}, max (µg/L)					
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10m low*	20m high*
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m
None	D3 Ditch	0.1574	0.0517	0.0273	0.0142	0.0273	0.0142
50 %		0.0787	0.0258	0.0137	0.0071	0.0137	0.0071
75 %		0.0393	0.0129	0.0068	0.0036	0.0068	0.0036
90 %		0.0157	0.0052	0.0027	0.0014	0.0027	0.0014
None	D4 Pond	0.0067	0.0060	0.0044	0.0030	0.0044	0.0030
50 %		0.0035	0.0032	0.0024	0.0017	0.0024	0.0017
75 %		0.0019	0.0018	0.0014	0.0010	0.0014	0.0010
90 %		0.0010	0.0009	0.0007	0.0006	0.0007	0.0006
None	D4 Stream	0.1288	0.0543	0.0290	0.0153	0.0290	0.0153
50 %		0.0645	0.0273	0.0147	0.0078	0.0147	0.0078
75 %		0.0324	0.0138	0.0075	0.0040	0.0075	0.0040
90 %		0.0132	0.0057	0.0032	0.0018	0.0032	0.0018
None	R1 Pond	0.0086	0.0082	0.0073	0.0064	0.0044	0.0027
50 %		0.0067	0.0065	0.0060	0.0056	0.0032	0.0018
75 %		0.0058	0.0057	0.0054	0.0052	0.0025	0.0014
90 %		0.0052	0.0051	0.0050	0.0050	0.0022	0.0011
None	R1 Stream	0.1088	0.1032	0.1032	0.1032	0.0468	0.0245
50 %		0.1032	0.1032	0.1032	0.1032	0.0468	0.0245
75 %		0.1032	0.1032	0.1032	0.1032	0.0468	0.0245
90 %		0.1032	0.1032	0.1032	0.1032	0.0468	0.0245
None	R3 Stream	0.2048	0.2048	0.2048	0.2048	0.0934	0.0490
50 %		0.2048	0.2048	0.2048	0.2048	0.0934	0.0490
75 %		0.2048	0.2048	0.2048	0.2048	0.0934	0.0490
90 %		0.2048	0.2048	0.2048	0.2048	0.0934	0.0490

* low and high fractional reduction in the runoff and erosion through volume, mass and flux
data origin (modelling report & crop no.): [1)] EnSa-16-0807, Sugar beet I, 1 × 0.030 kg a.s./ha

Table 8.9-44: FOCUS Step 4 PEC_{sw} for thiencarbazone-methyl, following single application of FSN+TCM OD 80 (50+30) - Use: Sugar beet, 2 × 15 g thiencarbazone-methyl/ha, BBCH 10-18

Sugar beet 2×15 g a.s./ha, single appl.[1)]	**Scenario**	**STEP 4 - thiencarbazone-methyl**					
		PEC_{sw}, max (µg/L)					
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10m low*	20m high*
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m
Maximum PEC_{sw} values out of single and multiple application are marked in bold							
None	D3 Ditch	**0.0787**	**0.0257**	**0.0138**	**0.0072**	**0.0138**	**0.0072**
50 %		**0.0393**	**0.0128**	**0.0069**	**0.0036**	**0.0069**	**0.0036**
75 %		**0.0197**	**0.0064**	**0.0035**	**0.0018**	**0.0035**	**0.0018**
90 %		**0.0079**	**0.0026**	**0.0014**	**0.0007**	**0.0014**	**0.0007**
None	D4 Pond	0.0033	0.0029	0.0021	0.0016	0.0021	0.0016
50 %		0.0018	0.0016	0.0012	0.0009	0.0012	0.0009
75 %		0.0010	0.0009	0.0007	0.0005	0.0007	0.0005
90 %		0.0005	0.0004	0.0004	0.0003	0.0004	0.0003
None	D4 Stream	**0.0642**	**0.0272**	**0.0145**	**0.0076**	**0.0145**	**0.0076**
50 %		**0.0322**	**0.0137**	**0.0073**	**0.0039**	**0.0073**	**0.0039**
75 %		**0.0162**	**0.0069**	**0.0037**	**0.0020**#	**0.0037**	**0.0020**#
90 %		**0.0066**	**0.0028**#	**0.0016**#	0.0009	**0.0016**#	0.0009
None	R1 Pond	0.0045	0.0042	0.0038	0.0034	0.0022	0.0014
50 %		0.0035	0.0034	0.0032	0.0030	0.0016	0.0009
75 %		0.0030	0.0030	0.0029	0.0028	0.0013	0.0007
90 %		0.0028	0.0027	0.0027	0.0026	0.0012	0.0006
None	R1 Stream	0.0553	0.0553	0.0553	0.0553	0.0251	0.0131
50 %		0.0553	0.0553	0.0553	0.0553	0.0251	0.0131
75 %		0.0553	0.0553	0.0553	0.0553	0.0251	0.0131
90 %		0.0553	0.0553	0.0553	0.0553	0.0251	0.0131
None	R3 Stream	0.1055	0.1055	0.1055	0.1055	0.0481	0.0253
50 %		0.1055	0.1055	0.1055	0.1055	0.0481	0.0253
75 %		0.1055	0.1055	0.1055	0.1055	0.0481	0.0253
90 %		0.1055	0.1055	0.1055	0.1055	0.0481	0.0253

* low and high fractional reduction in the runoff and erosion through volume, mass and flux
#results from single and multiple application are identical
data origin (modelling report & crop no.): [1)] EnSa-16-0807, Sugar beet II, 2 × 0.015 kg a.s./ha

Table 8.9-45: FOCUS Step 4 PEC_{sw} for thiencarbazone-methyl, following multiple applications of FSN+TCM OD 80 (50+30)
- Use: Sugar beet, 2 × 15 g thiencarbazone-methyl/ha, BBCH 10-18

Sugar beet 2×15 g a.s./ha, multiple appl.[1)]	**Scenario**	**STEP 4 - thiencarbazone-methyl**					
		PEC_{sw}, max (µg/L)					
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10m low*	20m high*
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m
Maximum PEC_{sw} values out of single and multiple application are marked in bold							
None	D3 Ditch	0.0682	0.0217	0.0112	0.0056	0.0112	0.0056
50 %		0.0341	0.0109	0.0056	0.0028	0.0056	0.0028
75 %		0.0171	0.0054	0.0028	0.0014	0.0028	0.0014
90 %		0.0068	0.0022	0.0011	0.0006	0.0011	0.0006
None	D4 Pond	**0.0050**	**0.0045**	**0.0032**	**0.0023**	**0.0032**	**0.0023**
50 %		**0.0027**	**0.0024**	**0.0018**	**0.0014**	**0.0018**	**0.0014**
75 %		**0.0015**	**0.0014**	**0.0011**	**0.0009**	**0.0011**	**0.0009**
90 %		**0.0009**	**0.0008**	**0.0007**	**0.0007**	**0.0007**	**0.0007**
None	D4 Stream	0.0574	0.0239	0.0126	0.0066	0.0126	0.0066
50 %		0.0289	0.0121	0.0065	0.0035	0.0065	0.0035
75 %		0.0147	0.0063	0.0035	**0.0020**#	0.0035	**0.0020**#
90 %		0.0061	**0.0028**#	**0.0016**#	**0.0010**	**0.0016**#	**0.0010**
None	R1 Pond	**0.0144**	**0.0140**	**0.0130**	**0.0123**	**0.0065**	**0.0037**
50 %		**0.0126**	**0.0124**	**0.0119**	**0.0116**	**0.0054**	**0.0029**
75 %		**0.0117**	**0.0116**	**0.0114**	**0.0112**	**0.0049**	**0.0026**
90 %		**0.0112**	**0.0111**	**0.0110**	**0.0110**	**0.0046**	**0.0023**
None	R1 Stream	**0.2388**	**0.2388**	**0.2388**	**0.2388**	**0.1083**	**0.0567**
50 %		**0.2388**	**0.2388**	**0.2388**	**0.2388**	**0.1083**	**0.0567**
75 %		**0.2388**	**0.2388**	**0.2388**	**0.2388**	**0.1083**	**0.0567**
90 %		**0.2388**	**0.2388**	**0.2388**	**0.2388**	**0.1083**	**0.0567**
None	R3 Stream	**0.4757**	**0.4757**	**0.4757**	**0.4757**	**0.2170**	**0.1138**
50 %		**0.4757**	**0.4757**	**0.4757**	**0.4757**	**0.2170**	**0.1138**
75 %		**0.4757**	**0.4757**	**0.4757**	**0.4757**	**0.2170**	**0.1138**
90 %		**0.4757**	**0.4757**	**0.4757**	**0.4757**	**0.2170**	**0.1138**

* low and high fractional reduction in the runoff and erosion through volume, mass and flux
#results from single and multiple application are identical
data origin (modelling report & crop no.): [1)] EnSa-16-0807, Sugar beet II, 2 × 0.015 kg a.s./ha

(d) FOCUS Step 3 – Timecourse of PEC_{sw} (FOCUS year) of thiencarbazone-methyl [for Tier 2C and Tier 3 assessment]

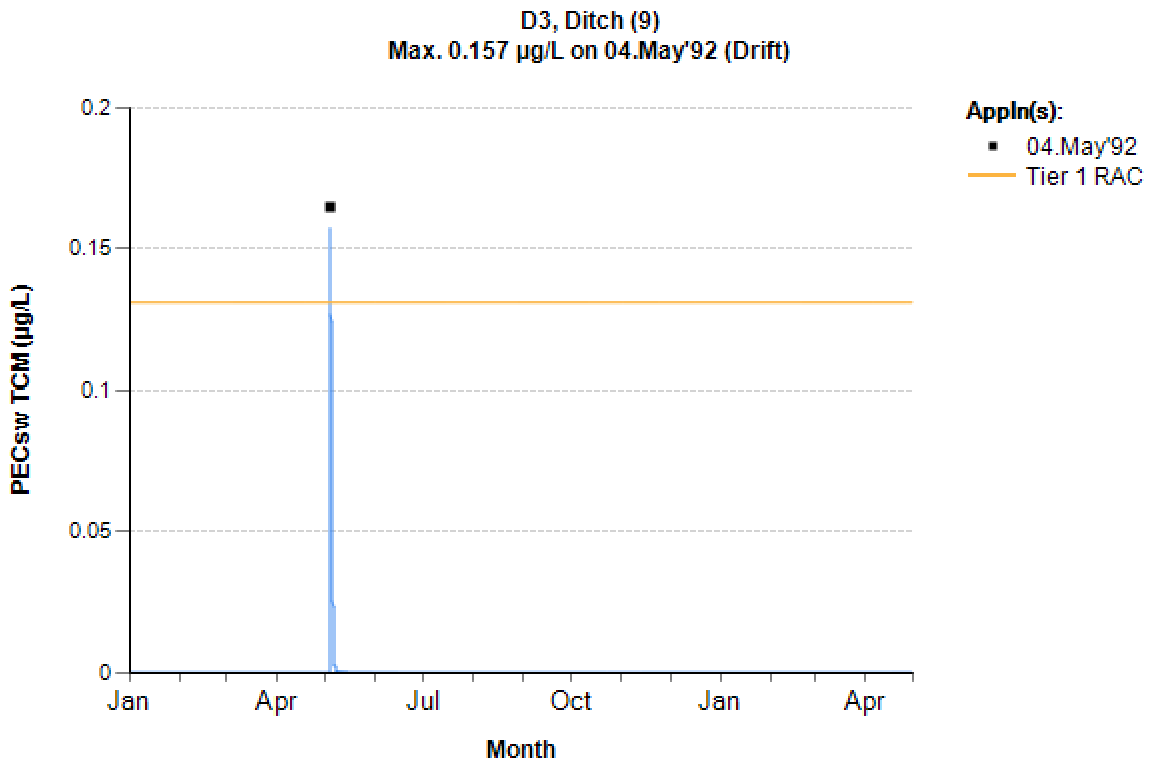
For the present formulation, a higher tier / refined risk assessment is presented for thiencarbazone-methyl exposure in selected FOCUS surface water scenarios in dRR Part B Section 9, based on an ecotoxicological interpretation of the evolution of surface concentration over time. As prerequisite, time-course plots were generated from the FOCUS Step 3 model output, and numerically characterised via EPAT tool analysis for the following parameters:

- the PEC_{max},
- the number of peak events above the Tier 1 RAC,
- the duration of these peak events, and
- the interval between these peak events.

Moreover, the modelling output files containing full detailed information on exposure over the simulated FOCUS year period in hourly resolution for all FOCUS scenarios were transferred electronically into ecological modelling approaches (TK/TD population effect simulation), which are described in dRR Part B Section 9.

Table 8.9-46: Timecourse of FOCUS Step 3 PEC_{sw} for <u>thiencarbazone-methyl</u> following single application of FSN+TCM OD 80 (50+30) – Use: sugar beet, 1 × 30 g thiencarbazone-methyl/ha, BBCH 10–18

Scenario D3 ditch, FOCUS Step 3



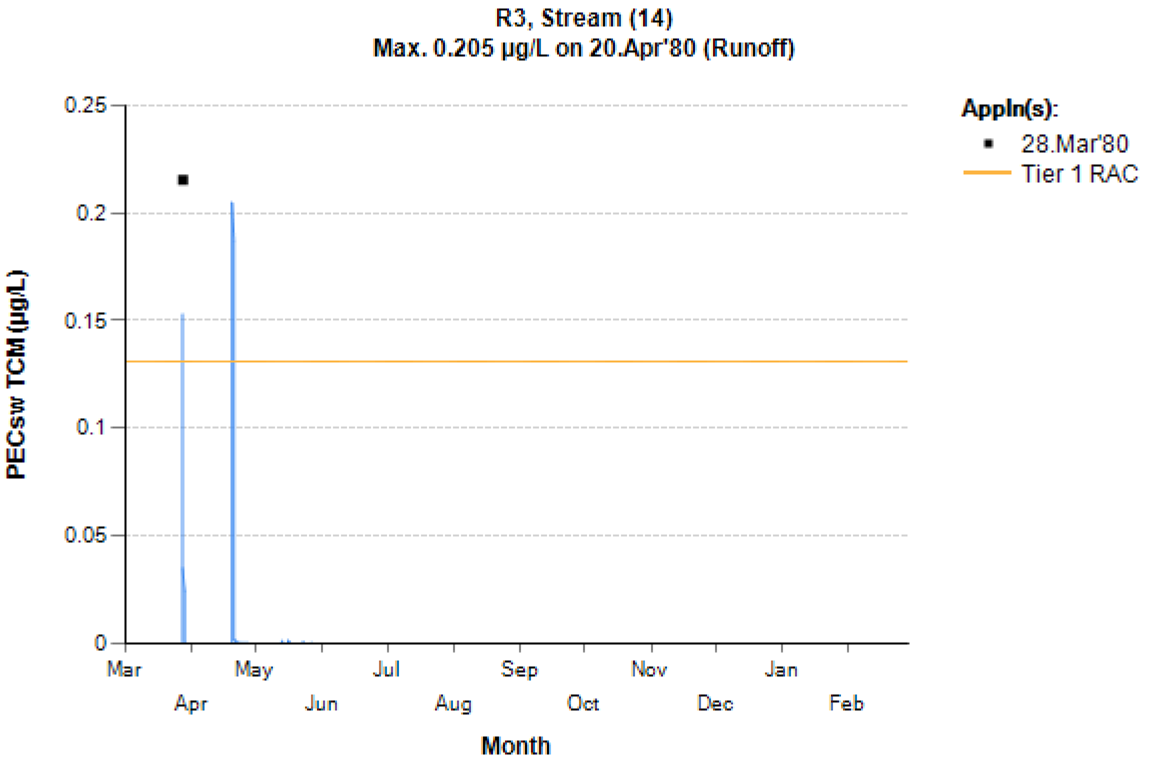
Tier 1-RAC = 0.131 µ/L

EPAT analysis:

PEC_{max} [µg a.s./L]	No. of events > Tier 1-RAC	Duration of event [days]	Interval between events [days]
0.1574	1	0.542	Not relevant

[event recognition threshold: 0.131 µg/L]

Scenario R3 stream, FOCUS Step 3



Tier 1-RAC = 0.131 µ/L

EPAT analysis:

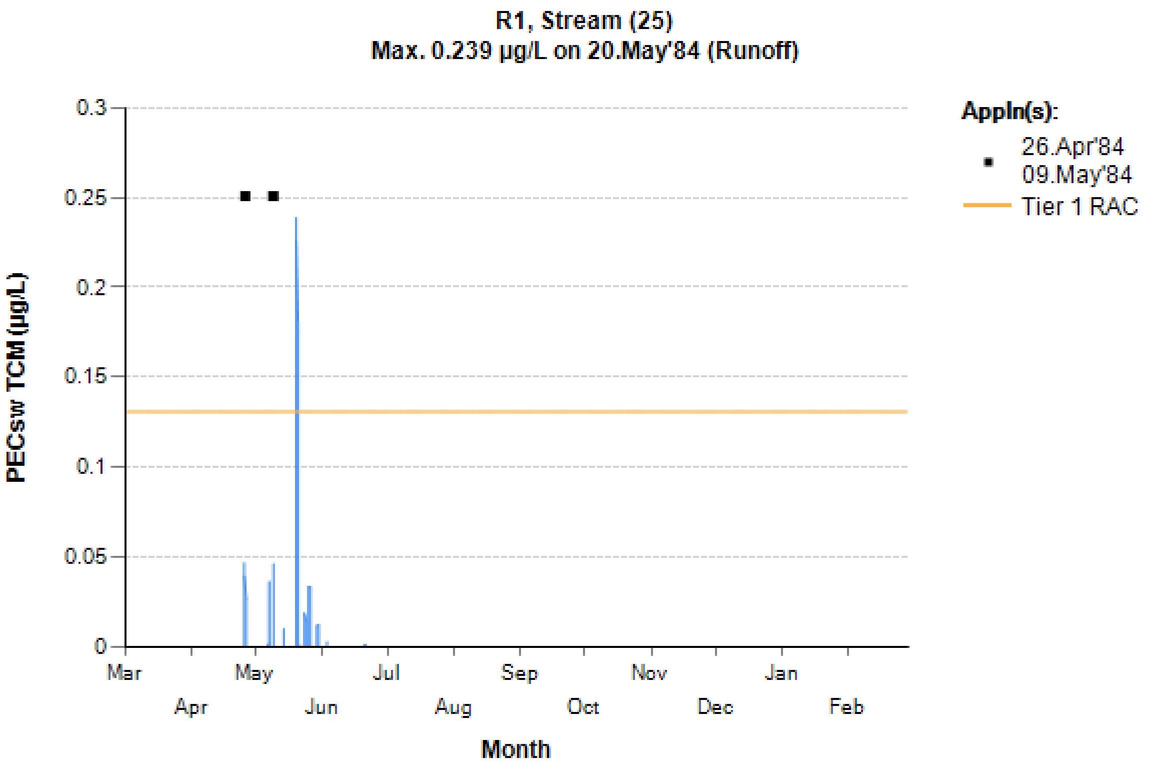
PEC_{max} [µg a.s./L]	No. of events > Tier 1-RAC	Duration of event [days]	Interval between events [days]
0.1530 0.2048	2	0.208 0.791	- 22.459

[event recognition threshold: 0.131 µg/L]

*****

Table 8.9-47: Timecourse of FOCUS Step 3 PEC_{sw} for thiencarbazone-methyl following mutiple applications of FSN+TCM OD 80 (50+30) – Use: sugar beet, 2 × 15 g thiencarbazone-methyl/ha, BBCH 10–18

Scenario R1 stream, FOCUS Step 3



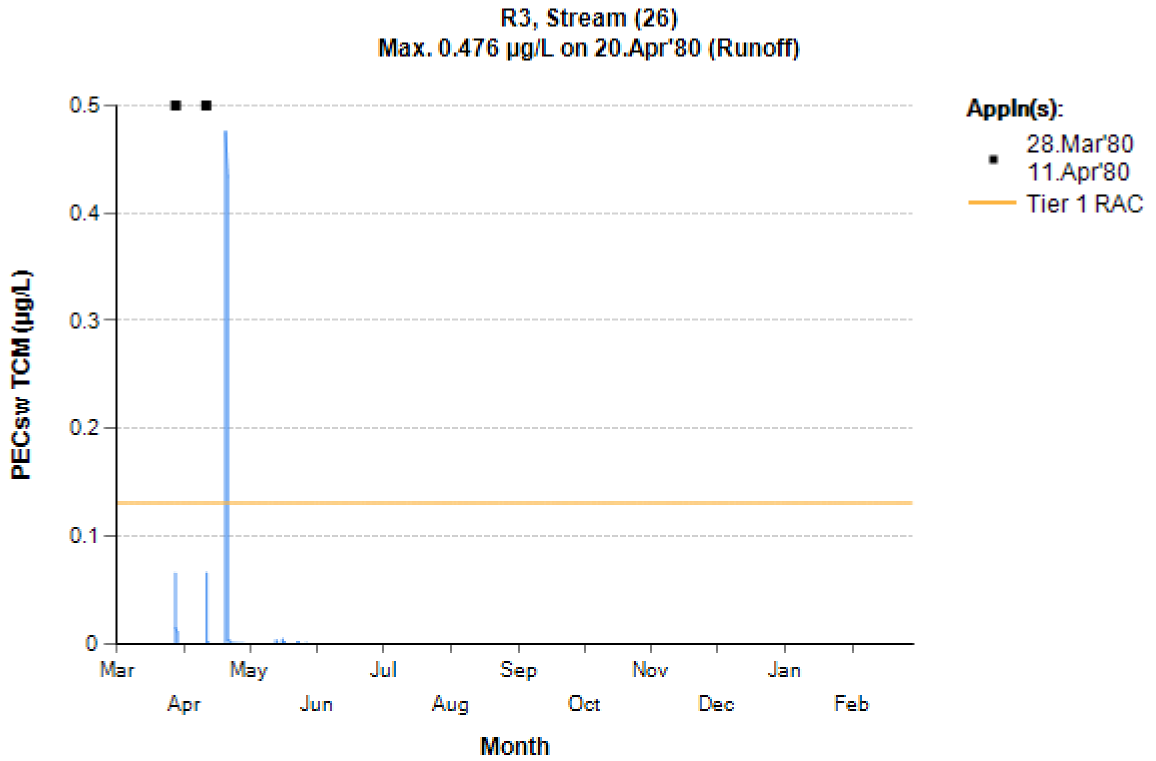
Tier 1-RAC = 0.131 µ/L

EPAT analysis:

PEC_{max} [µg a.s./L]	No. of events > Tier 1-RAC	Duration of event [days]	Interval between events [days]
0.2388	1	0.541	Not relevant

[event recognition threshold: 0.131 µg/L]

Scenario R3 stream, FOCUS Step 3



Tier 1-RAC = 0.131 µ/L

EPAT analysis:

PEC_{max} [µg a.s./L]	No. of events > Tier 1-RAC	Duration of event [days]	Interval between events [days]
0.4757	1	1.125	Not relevant

[event recognition threshold: 0.131 µg/L]

(e) FOCUS Step 3-4 – Timecourse of PEC_{sw} (multi-year simulation) for thiencarbazone-methyl [for Tier 2C and Tier 3 assessment]

In response to concerns expressed by some regulators on the representativeness of the FOCUS model's single weather year in the context of a refined risk assessment based on exposure pattern analysis, additional calculations have been run for thiencarbazone-methyl over a period of 20 years (multi-year calculations). From this large data set, 90th percentile realistic worst-case exposure patterns were derived for those critical GAP situations previously addressed for the FOCUS medium year under point (c) above.

Moreover, the full detailed electronic information of hourly exposure values over the simulated 20-year period for all FOCUS scenarios served as basis for ecological modelling approaches (TK/TD population effect simulation), which are described in dRR Part B Section 9.

Due to its confirmatory character, the detailed methodology and results of the multi-year approach are presented only in the Appendix section (A 3.3.2 (e)) of the present dRR, for the interested reader.

zRMS comments:

The modelling input parameters are in agreement with the EU evaluation (LoEP, 2013) or corresponded to standard default values and are thus acceptable. The PEC_{SW} and PEC_{SED} of Thiencarbazone-methyl and its metabolites have been assessed with the FOCUS surface water models (FOCUS STEPS 1-2, and FOCUS SWASH 3). Step 4 simulations were also provided.
Maximum PECsw for Thiencarbazone-methyl and its metabolites can be used for ecotoxicogical risk assessments.

Member States should decide on the applicability timecourse of PEC_{sw} (FOCUS year) of thiencarbazone-methyl for Tier 2C and Tier 3 assessment.

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

8.10.1 Fate and behaviour of foramsulfuron in air

The fate of foramsulfuron in air has been evaluated, full details are provided in the respective EU reference and related documents and summarised in the EFSA conclusion (EFSA Journal 2016;14(3): 4421). No additional studies have been performed.

Table 8.10-1 Summary of atmospheric degradation and behaviour: foramsulfuron

Compound	Foramsulfuron
Direct photolysis in air	Not studied, no data required
Quantum yield of direct phototransformation	-
Photochemical oxidative degradation in air	DT_{50}: 0.07 days derived by the Atkinson model OH (12 h) concentration assumed = 1.5 × 10^6 OH/cm^3
Volatilisation	From plant surfaces (BBA Guideline): Anticipated to be minimal due to low vapour pressure From soil surfaces (BBA Guideline): Anticipated to be minimal due to low vapour pressure
Metabolites	None

The vapour pressure at 20 °C of the active substance foramsulfuron is 4.2 × 10^{-11} Pa at 20°C. Hence the active substance foramsulfuron is regarded as non-volatile. Therefore, exposure of adjacent surface waters and terrestrial ecosystems by the active substance foramsulfuron from volatilization followed by subsequent deposition is not expected.

8.10.2 Fate and behaviour of thiencarbazone-methyl in air

The fate of thiencarbazone-methyl in air has been evaluated, full details are provided in the respective EU reference and related documents and summarised in the EFSA conclusion (EFSA Journal 2013;11(7)); 3270 and the Thiencarbazone-methyl; Addendum –Confirmatory Data; RMS: United Kingdom; July 2016 (EFSA-Q-2016-00485; Report No. EN-1083). No additional studies have been performed.

Table 8.10-2 Summary of atmospheric degradation and behaviour: thiencarbazone-methyl

Compound	Thiencarbazone-methyl
Direct photolysis in air	Not studied, no data required
Quantum yield of direct phototransformation	-
Photochemical oxidative degradation in air	DT_{50} (h): 2.02 days (24.2 hours) derived by the Atkinson model OH (12 h) concentration assumed = 1.5 x 10^6 OH/cm^3 refined DT_{50} in air considering as well degradation via

	nitrate radical reaction: 1.89 days (22.7 hours) NO_3 (12 h) concentration assumed = 5 x 10^8 NO_3/cm^3
Volatilisation	Not available, not requested
Metabolites	Not available, not requested

The vapour pressure of the active substance thiencarbazone-methyl at 20 °C is 8.8 x 10^{-14} 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 is not expected to occur, and any residues would not accumulate due to their degradability.

zRMS comments:
Foramsulfuron has a very low vapour pressure of 4.2x10-11 Pa (20°C) and it therefore can be concluded that no significant volatilisation would occur.

The vapour pressure of thiencarbazone-methyl was determined to be 8.8 × 10^{-14} Pa at 20°C. Compared to the indicator values for notable volatilisation (≥ 10^{-4} Pa for soil and ≥ 10^{-5} Pa for plant surfaces) as specified in Regulation (EU) No 283/2013 and FOCUS Air Report, the active substance is clearly non-volatile and hence would not enter the atmosphere via evaporation.

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 GLP or GEP status published or not	Vertebrate study Y/N	Owner
KCP 9.1.3 / 01	Heine, S.	2017	Foramsulfuron (FSN) and metabolites: PECsoil EUR - Use in arable crops in Europe Report No.: EnSa-16-0693, Edition Number: M-570502-02-1 Bayer AG, Crop Science Division, Monheim, Germany ... amended: 2017-01-16 GLP/GEP: No unpublished	No	Bayer
KCP 9.1.3 / 02	Bolekhan, A.	2016	Thiencarbazone-methyl (TCM) and metabolites: PECsoil EUR - Use in various crops in Europe Report No.: EnSa-16-0780, Edition Number: M-569933-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: No unpublished	No	Bayer
KCP 9.2.4.1 / 01	Heine, S.; Srinivasan, P.	2016	Foramsulfuron (FSN) and metabolites: PECgw FOCUS PEARL, PELMO, MACRO EUR - Use in sugar beets in Europe Report No.: EnSa-16-0770, Edition Number: M-576932-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: No unpublished	No	Bayer
KCP 9.2.4.1 / 02	Bolekhan, A.; Hoerold, C.	2016	Thiencarbazone-methyl (TCM) and metabolites: PECgw FOCUS PEARL, PELMO EUR - Use in sugarbeet and maize in Europe Report No.: EnSa-16-0806, Edition Number: M-577187-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: No unpublished	No	Bayer

Data Point	**Author(s)**	**Year**	**Title** **Company Report No.** **Source** **GLP or GEP status** **published or not**	**Vertebrate study Y/N**	**Owner**
KCP 9.2.4.1 / 03	Bolekhan, A.; Hoerold, C.	2018	Thiencarbazone-methyl (TCM) and metabolites: PECgw FOCUS MACRO EUR - Use in sugarbeet and maize in Europe Report No.: EnSa-18-0269, Edition Number: M-620310-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: No unpublished	No	Bayer
KCP 9.2.5 / 01	Heine, S.	2016	Foramsulfuron (FSN) and metabolites: PECsw,sed FOCUS EUR - Use in arable crops in Europe Report No.: EnSa-16-0746, Edition Number: M-570503-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: No unpublished	No	Bayer
KCP 9.2.5 / 02	Heine, S.; Srinivasan, P	2016	Foramsulfuron (FSN) and metabolites: PECsw,sed FOCUS EUR - Use in sugar beets in Europe Report No.: EnSa-16-0765, Edition Number: M-582622-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: No unpublished	No	Bayer
KCP 9.2.5 / 03	Bolekhan, A.	2017	Multi-year PECsw calculations for sulfonylurea herbicides in Europe: Description of methodology Report No.: EnSa-17-0541, Edition Number: M-602115-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: No unpublished	No	Bayer
KCP 9.2.5 / 04	Heine, S.; Hammel, K.; Bolekhan, A.	2018	Foramsulfuron (FSN) and metabolite AE F130619: PECsw FOCUS EUR (multi-year) - Use in maize and sugar beets in Europe Report No.: EnSa-17-0353, Edition Number: M-592861-02-1 Bayer AG, Crop Science Division, Monheim, Germany ... amended: 2018-03-08 GLP/GEP: No unpublished	No	Bayer

Data Point	**Author(s)**	**Year**	**Title** **Company Report No.** **Source** **GLP or GEP status** **published or not**	**Vertebrate study Y/N**	**Owner**
KCP 9.2.5 / 05	Bolekhan, A.; Porschewski, R.	2017	Thiencarbazone-methyl (TCM) core PECsw EUR - Modelling core info document for surface water risk assessment in Europe Report No.: EnSa-16-0916, Edition Number: M-600279-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: No unpublished	No	Bayer
KCP 9.2.5 / 06	Bolekhan, A.	2017	Thiencarbazone-methyl (TCM) and metabolites: PECsw,sed FOCUS EUR - Use in arable crops in Europe Report No.: EnSa-17-0557, Edition Number: M-600622-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: No unpublished	No	Bayer
KCP 9.2.5 / 07	Bolekhan, A.; Hoerold, C.	2016	Thiencarbazone-methyl (TCM): PECsw,sed FOCUS EUR - Use in sugar beet in Europe Report No.: EnSa-16-0807, Edition Number: M-582854-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: No unpublished	No	Bayer
KCP 9.2.5 / 08	Heine, S.; Hammel, K.; Bolekhan, A.	2017	Thiencarbazone-methyl (TCM): PECsw FOCUS EUR (multi-year) - Use in maize and sugar beets in Europe Report No.: EnSa-17-0354, Edition Number: M-592862-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: No unpublished	No	Bayer

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

Please note that all data mentioned as part of DAR, RAR, or EFSA journals are considered as relied upon.
Bayer is the owner of the data package peer-reviewed for the EU re-approval of the active substance **foramsulfuron** and the EU approval of **thiencarbazone-methyl.**

Data protection will be requested when relevant at MS level in the Part A.

Foramsulfuron
The following studies are considered as already evaluated at EU peer review as they are referenced in the document entitled ("Renewal under Regulation (EC) 1107/2009. Foramsulfuron - List of information, tests and studies which are considered as relied upon by the RMS for the evaluation with a view to approval of the active substance and for which the main data submitter has claimed data protection RMS: Finland Co-RMS: Slovakia. April 2016)

Annex point/ reference number	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Owner
KCA 7.1.1.3 /02	Hall, L. R.	2012	[Phenyl-UL-14C]foramsulfuron: Phototransformation on soil Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: MEFSL009, Edition Number: M-422619-01-1 Date: 2012-01-17 GLP/GEP: yes, unpublished	N	Bayer Crop Science
KCA 7.1.2.1.2 /06	Shepherd, J. J.; Rip-perger, R. J.	2012	[Phenyl-UL-14C]foramsulfuron sulfonamide: Aerobic soil metabolism in four US soils Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: MEFSL008, Edition Number: M-425904-01-1 Date: 2012-02-23 GLP/GEP: yes, unpublished	N	Bayer Crop Science

Annex point/ reference number	**Author(s)**	**Year**	**Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not**	**Verte-brate study Y/N**	**Owner**
KCA 7.1.4.2 /02	Burr, C. M.; Ma-ckenzie, E.	2001	(2-14C-pyrimidyl)-AE F130360 leaching in outdoor lysimeter Aventis CropScience UK Ltd., United Kingdom Report No.: C014861, Edition Number: M-207434-01-1 Date: 2001-09-20 GLP/GEP: yes, unpublished	N	Bayer Crop Science
KCA 7.2.1.2 /02	Hall, L. R.	2012	Phototransformation of [14C]foramsulfuron in aqueous pH 7 buffer Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: MEFSL011, Edition Number: M-425561-01-1 Date: 2012-02-22 GLP/GEP: yes, unpublished	N	Bayer Crop Science
KCA 7.2.1.2 /03	Heine-mann, O.	2013	Foramsulfuron: Determination of the quantum yield and assessment of the environmental half-life of the direct photo-degradation in water Bayer CropScience, Report No.: EnSa-13-0305, Edition Number: M-460124-01-1 Date: 2013-07-16 GLP/GEP: yes, unpublished	N	Bayer Crop Science
KCA 7.2.1.3 /01	Meyer, B. N.	2009	[Phenyl-UL-14C]foramsulfuron: Phototransformation in natural water Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: MEFSU004, Edition Number: M-346695-01-1 Date: 2009-05-04 GLP/GEP: yes, unpublished	N	Bayer Crop Science
KCA 7.2.1.3 /02	Meyer, B. N.	2008	[Pyrimidine-2-14C] foramsulfuron: Phototransformation in natural water Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: MEFSU001, Edition Number: M-327230-01-1 Date: 2008-12-23 GLP/GEP: yes, unpublished	N	Bayer Crop Science

Annex point/ reference number	**Author(s)**	**Year**	**Title** **Compagny Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	**Verte-brate study Y/N**	**Owner**
KCA 7.2.2.2 /01	Fahrbach, M.	2013	[phenyl-UL-14C]Foramsulfuron: Aerobic Mineralization in surface water Harlan Laboratories Ltd., Itingen, Switzerland Bayer CropScience, Report No.: D62860, Edition Number: M-453421-01-1 Date: 2013-04-22 GLP/GEP: yes, unpublished	N	Bayer Crop Science

Thiencarbazone-methyl

The following studies are considered as already evaluated at EU peer review as they are referenced in the document entitled ("Council Directive 91/414/EEC. Thiencarbazone-methyl (BYH 18636) - Volume 2 - Annex A to the Draft Report and Proposed Decision - List of tests and studies submitted and information available (by Annex point). 2012)

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not	Vertebrate Y/N	Owner
KIIA 7.1.1 /01	Fliege, R.	2006	[Dihydrotriazole-3-14C] and [thiophene-4-14C] BYH 18636: Aerobic soil metabolism in four soils Bayer CropScience AG, Report No.: MEF-05/532, Edition Number: M-276687-01-2 Date: 04.07.2006 GLP, unpublished ***also filed: KIIA 7.2.1 /01***	N	Bayer
KIIA 7.1.1 /02	Fliege, R.	2005	[Dihydrotriazole-3-14C] and [thiophene-4-14C]BYH 18636: Aerobic soil metabolism in one US soil Bayer CropScience AG, Report No.: MEF-05/224, Edition Number: M-263213-01-2 Date: 31.08.2005 GLP, unpublished	N	Bayer
KIIA 7.1.2 /01	Fliege, R.	2006	[Dihydrotriazole-3-14C] and [thiophene-4-14C] BYH 18636: Anaerobic soil metabolism Bayer CropScience AG, Report No.: MEF-05/490, Edition Number: M-274584-01-2 Date: 27.04.2006 GLP, unpublished ***also filed: KIIA 7.2.4 /01***	N	Bayer

Annex point/ reference number	**Author(s)**	**Year**	**Title** **Source (where different from company)** **Company name, Report No., Date,** **GLP status (where relevant), published or not**	**Vertebrate Y/N**	**Owner**
KIIA 7.1.3 /01	Stupp, H. P.	2005	BYH 18636: Phototransformation on soil Bayer CropScience AG, Report No.: MEF-04/561, Edition Number: M-259443-01-2 Date: 11.08.2005 GLP, unpublished	N	Bayer

Annex point/ reference number	**Author(s)**	**Year**	**Title** **Source (where different from company)** **Company name, Report No., Date,** **GLP status (where relevant), published or not**	**Vertebrate Y/N**	**Owner**
KIIA 7.2.1 /01	Fliege, R.	2006	[Dihydrotriazole-3-14C] and [thiophene-4-14C] BYH 18636: Aerobic soil metabolism in four soils Bayer CropScience AG, Report No.: MEF-05/532, Edition Number: M-276687-01-2 Date: 04.07.2006 GLP, unpublished ***also filed: KIIA 7.1.1 /01***	N	Bayer
KIIA 7.2.1 /02	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 Bayer CropScience AG, Report No.: MEF-07/109, Edition Number: M-284746-01-1 Date: 28.02.2007 Non GLP, unpublished ***also filed: KIIA 7.2.3 /01***	N	Bayer
KIIA 7.2.1 /03	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 Bayer CropScience AG, Report No.: MEF-07/024, Edition Number: M-284770-01-1 Date: 28.02.2007 Non GLP, unpublished ***also filed: KIIA 7.2.3 /02***	N	Bayer

Annex point/ reference number	**Author(s)**	**Year**	**Title** **Source (where different from company)** **Company name, Report No., Date,** **GLP status (where relevant), published or not**	**Vertebrate Y/N**	**Owner**
KIIA 7.2.3 /01	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 Bayer CropScience AG, Report No.: MEF-07/109, Edition Number: M-284746-01-1 Date: 28.02.2007 Non GLP, unpublished ***also filed: KIIA 7.2.1 /02***	N	Bayer
KIIA 7.2.3 /02	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 Bayer CropScience AG, Report No.: MEF-07/024, Edition Number: M-284770-01-1 Date: 28.02.2007 Non GLP, unpublished ***also filed: KIIA 7.2.1 /03***	N	Bayer
KIIA 7.2.3 /03	Heinemann, O.	2006	BYH18636-triazolinone carboxamide: Aerobic soil degradation in 3 EU soils Bayer CropScience AG, Report No.: MEF-05/519, Edition Number: M-276814-01-2 Date: 02.08.2006 GLP, unpublished	N	Bayer

Annex point/ reference number	**Author(s)**	**Year**	**Title** **Source (where different from company)** **Company name, Report No., Date,** **GLP status (where relevant), published or not**	**Vertebrate Y/N**	**Owner**
KIIA 7.2.4 /01	Fliege, R.	2006	[Dihydrotriazole-3-14C] and [thiophene-4-14C] BYH 18636: Anaerobic soil metabolism Bayer CropScience AG, Report No.: MEF-05/490, Edition Number: M-274584-01-2 Date: 27.04.2006 GLP, unpublished ***also filed: KIIA 7.1.2 /01***	N	Bayer
KIIA 7.3.1 /01	Wyatt, D. R.	2007	Terrestrial field dissipation of BYH18636 in Nebraska soil, 2005 Bayer CropScience, Stilwell, KS, USA Bayer CropScience AG, Report No.: MEGSP002, Edition Number: M-285681-01-1 Date: 15.03.2007 GLP, unpublished	N	Bayer
KIIA 7.3.1 /02	Wyatt, D. R.	2007	Terrestrial field dissipation of BYH18636 in Illinois soil, 2005 Bayer CropScience, Stilwell, KS, USA Bayer CropScience AG, Report No.: MEGSP004, Edition Number: M-285673-01-1 Date: 15.03.2007 GLP, unpublished	N	Bayer
KIIA 7.3.1 /03	Wyatt, D. R.	2007	Terrestrial field dissipation of BYH18636 in California soil, 2005 Bayer CropScience, Stilwell, KS, USA Bayer CropScience AG, Report No.: MEGSM013, Edition Number: M-285682-01-1 Date: 15.03.2007 GLP, unpublished	N	Bayer

Annex point/ reference number	**Author(s)**	**Year**	**Title** **Source (where different from company)** **Company name, Report No., Date,** **GLP status (where relevant), published or not**	**Vertebrate Y/N**	**Owner**
KIIA 7.3.1 /04	Wyatt, D. R.	2007	Terrestrial field dissipation of BYH18636 in Ontario, Canada soil, 2005 Bayer CropScience, Stilwell, KS, USA Bayer CropScience AG, Report No.: MEGSP003, Edition Number: M-285678-01-1 Date: 15.03.2007 GLP, unpublished	N	Bayer
KIIA 7.3.1 /05	Coukell, G.	2007	Field dissipation of BYH18636 in three Canadian soils Bayer CropScience, Stilwell, KS, USA Bayer CropScience AG, Report No.: MEGSP019, Edition Number: M-285968-01-2 Date: 26.03.2007 GLP, unpublished	N	Bayer
KIIA 7.3.1 /06	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 Bayer CropScience AG, Report No.: RA-2146/04, Report includes Trial Nos.: R 2004 0920/6 R 2004 0921/4 R 2004 0922/2 Edition Number: M-279196-01-1 Date: 19.10.2006 GLP, unpublished	N	Bayer

Annex point/ reference number	**Author(s)**	**Year**	**Title** **Source (where different from company)** **Company name, Report No., Date,** **GLP status (where relevant), published or not**	**Vertebrate Y/N**	**Owner**
KIIA 7.3.1 /07	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 Bayer CropScience AG, Report No.: RA-2048/05, Report includes Trial Nos.: 0286-9 R 2005 0286/9 Edition Number: M-278040-01-1 Date: 26.09.2006 GLP, unpublished	N	Bayer
KIIA 7.3.1 /08	Hammel, K.	2007	KineticeEvaluation of the dissipation of BYH 18636-carboxylic acid in soil based on field studies Bayer CropScience AG, Report No.: MEF-07/067, Edition Number: M-284723-01-1 Date: 28.02.2007 Non GLP, unpublished	N	Bayer
KIIA 7.3.3 /01	Hammel, K.	2007	Predicted environmental concentrations of BYH 18636, BYH 18636-carboxylic acid, BYH 18636-sulfonamide, BYH 18636-sulfonamide carboxylic acid, BYH 18636-MMT and BYH 18636-triazolinone-carboxamide in soil Use in maize in the EU Bayer CropScience AG, Report No.: MEF-07/072, Edition Number: M-284827-01-1 Date: 28.02.2007 Non GLP, unpublished	N	Bayer

Annex point/ reference number	**Author(s)**	**Year**	**Title** **Source (where different from company)** **Company name, Report No., Date,** **GLP status (where relevant), published or not**	**Vertebrate Y/N**	**Owner**
KIIA 7.4.1 /01	Fliege, R.	2003	Adsorption/desorption of BYH 18636 on five soils Bayer CropScience AG, Report No.: MEF-191/03, Edition Number: M-110732-01-2 Date: 24.09.2003 GLP, unpublished	N	Bayer
KIIA 7.4.2 /01	Stupp, H. P.	2004	GSE28226: Adsorption/desorption in five soils Bayer CropScience AG, Report No.: MEF-191/04, Edition Number: M-086868-01-2 Date: 26.08.2004 GLP, unpublished	N	Bayer
KIIA 7.4.2 /02	Fliege, R.	2004	GSE 18448: Adsorption/desorption on five soils Bayer CropScience AG, Report No.: MEF-085/04, Edition Number: M-082278-01-2 Date: 27.05.2004 GLP, unpublished	N	Bayer
KIIA 7.4.2 /03	Simmonds, M.; Early, E.	2005	[14C]-BYH18636-sulfonamide-carboxylic acid: Adsorption to and desorption from five soils Battelle UK Ltd., Ongar, United Kingdom Bayer CropScience AG, Report No.: CX/04/069, Edition Number: M-263558-01-2 Date: 07.09.2005 GLP, unpublished	N	Bayer

Annex point/ reference number	**Author(s)**	**Year**	**Title** **Source (where different from company)** **Company name, Report No., Date,** **GLP status (where relevant), published or not**	**Vertebrate Y/N**	**Owner**
KIIA 7.4.2 /04	Henk, F.; Haas, M.	2004	GSE12201: Adsorption/desorption on five soils Bayer CropScience AG, Report No.: MEF-027/04, Edition Number: M-081509-01-2 Date: 08.06.2004 GLP, unpublished	N	Bayer
KIIA 7.4.2 /05	Koenig, H.; Fliege, R.	2006	BYH 18636-triazolinone-carboxamide (AE 1430601): Estimation of the adsorption coefficient (Koc) on soil using high performance liquid chromatography Bayer CropScience AG, Report No.: MEF-05/417, Edition Number: M-268082-01-2 Date: 23.01.2006 GLP, unpublished	N	Bayer
KIIA 7.5 /01	Haas, M.	2005	BYH18636: Hydrolytic degradation Bayer CropScience AG, Report No.: MEF-04/183, Edition Number: M-259661-01-2 Date: 10.08.2005 GLP, unpublished ***also filed: KIIA 2.9.1 /01***	N	Bayer
KIIA 7.5 /02	Hammel, K.	2007	Kinetic evaluation of the hydrolytic degradation of BYH 18636 (25 °C, pH 9) Bayer CropScience AG, Report No.: MEF-07/137, Edition Number: M-286045-01-1 Date: 26.03.2007 Non GLP, unpublished	N	Bayer

Annex point/ reference number	**Author(s)**	**Year**	**Title** **Source (where different from company)** **Company name, Report No., Date,** **GLP status (where relevant), published or not**	**Vertebrate Y/N**	**Owner**
KIIA 7.6 /01	Sneikus, J.	2005	BYH18636: Phototransformation in water Bayer CropScience AG, Report No.: MEF-04/381, Edition Number: M-244065-02-2 Date: 06.01.2005 GLP, unpublished	N	Bayer
KIIA 7.6 /02	Heinemann, O.	2004	BYH18636: Determination of the quantum yield and assessment of the environmental half-life of the direct photodegradation in water Bayer CropScience AG, Report No.: MEF-04/200, Edition Number: M-093045-02-1 Date: 01.10.2004***, Amended: 30.03.2007*** GLP, unpublished	N	Bayer
KIIA 7.6 /03	Heinemann, O.	2006	BYH18636-carboxylic acid: Determination of the quantum yield and assessment of the environmental half-life of the direct photodegradation in water Bayer CropScience AG, Report No.: MEF-06/101, Edition Number: M-274264-01-1 Date: 27.02.2006 GLP, unpublished	N	Bayer
KIIA 7.6 /04	xxx	2006	BYH18636-sulfonamide: Determination of the quantum yield and assessment of the environmental half-life of the direct photodegradation in water xxx Report No.: MEF-06/138, Edition Number: M-274454-01-1 Date: 20.04.2006 GLP, unpublished	Yes	BCS

Annex point/ reference number	**Author(s)**	**Year**	**Title** **Source (where different from company)** **Company name, Report No., Date,** **GLP status (where relevant), published or not**	**Vertebrate Y/N**	**Owner**
KIIA 7.6 /05	Heinemann, O.	2006	BYH18636-sulfonamide-carboxylic acid: Determination of the quantum yield and assessment of the environmental half-life of the direct photodegradation in water Bayer CropScience AG, Report No.: MEF-06/177, Edition Number: M-274499-01-1 Date: 04.05.2006 GLP, unpublished	N	Bayer
KIIA 7.6 /06	Heinemann, O.	2006	BYH18636-dicarboxy-sulfonamide: Determination of the quantum yield and assessment of the environmental half-life of the direct photodegradation in water Bayer CropScience AG, Report No.: MEF-06/167, Edition Number: M-274439-01-1 Date: 11.04.2006 GLP, unpublished	N	Bayer
KIIA 7.6 /07	Heinemann, O.	2006	BYH18636-MMT: Determination of the quantum yield and assessment of the environmental half-life of the direct photodegradation in water Bayer CropScience AG, Report No.: MEF-06/140, Edition Number: M-274491-01-1 Date: 04.05.2006 GLP, unpublished	N	Bayer
KIIA 7.7 /01	Weyers, A.	2006	BYH 18636 - Biodegradation Bayer Industry Services GmbH, Leverkusen, Germany Bayer CropScience AG, Report No.: 2005/0059/02, Edition Number: M-266049-01-1 Date: 10.02.2006 GLP, unpublished	N	Bayer

Annex point/ reference number	**Author(s)**	**Year**	**Title** **Source (where different from company)** **Company name, Report No., Date,** **GLP status (where relevant), published or not**	**Vertebrate Y/N**	**Owner**
KIIA 7.7 /02	Weyers, A.	2006	BYH 18636-Sulfonamide - Biodegradation Bayer Industry Services GmbH, Leverkusen, Germany Bayer CropScience AG, Report No.: 2005/0123/01, Edition Number: M-266051-01-1 Date: 13.02.2006 GLP, unpublished	N	Bayer
KIIA 7.8.2 /01	Arthur, E. L.; Sheperd, J.; Ripperger, R. J.; Dominic, A. R.	2007	[Dihydrotriazole-3-14C and thiophene-4-14C]BYH18636: Anaerobic aquatic metabolism Bayer CropScience, Stilwell, KS, USA Bayer CropScience AG, Report No.: MEGSM012, Edition Number: M-285668-01-1 Date: 15.03.2007 GLP, unpublished	N	Bayer
KIIA 7.8.3 /01	Henk, F.; Haas, M.	2005	BYH18636: Aerobic aquatic metabolism Bayer CropScience AG, Report No.: MEF-05/008, Edition Number: M-262178-01-2 Date: 19.08.2005 GLP, unpublished	N	Bayer
KIIA 7.8.3 /02	Sneikus, J.	2006	BYH18636-MMT: Aerobic aquatic degradation Bayer CropScience AG, Report No.: MEF-06/500, Edition Number: M-281546-01-2 Date: 23.11.2006 GLP, unpublished	N	Bayer

Annex point/ reference number	**Author(s)**	**Year**	**Title** **Source (where different from company)** **Company name, Report No., Date,** **GLP status (where relevant), published or not**	**Vertebrate Y/N**	**Owner**
KIIA 7.8.3 /03	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 Bayer CropScience AG, Report No.: MEF-06/489, Edition Number: M-284750-01-1 Date: 28.02.2007 Non GLP, unpublished	N	Bayer
KIIA 7.10 /01	Fliege, R.	2005	BYH 18636 (AE 1162464): Calculation of the chemical lifetime in the troposphere Bayer CropScience AG, Report No.: MEF-05/299, Edition Number: M-267793-01-2 Date: 17.10.2005 Non GLP, unpublished	N	Bayer
KIIA 7.13 /01	Iyengar; S.; Schumacher, G.; Kaune, A.; Lasserre-Bigot, D.; Ecker, U.	2007	The non-relevance of the BYH 18636 carboxylic acid (thiencarbazone-methyl-carboxylic acid) Bayer CropScience AG, Report No.: M-285847-01-2, Edition Number: M-285847-01-2 Date: 30.03.2007 Non GLP, unpublished ***also filed: KIIA 5.10 /01***	N	Bayer

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

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

Appendix 2 Detailed evaluation of the new Annex II studies

No new Annex II studies were required in context of the present submission. The fate and behaviour of the active substances has been evaluated on EU level according to the Commission Regulation (EU) N° 1107/2009, full details are provided in the EU renewal assessment reports and related documents.

A 2.1 KCA 7.1 Fate and behaviour in soil

A 2.1.1 KCA 7.1.1 Route of degradation in soil

A 2.1.1.1 KCA 7.1.1.1 Aerobic degradation

A 2.1.1.2 KCA 7.1.1.2 Anaerobic degradation

A 2.1.1.3 KCA 7.1.1.3 Soil photolysis

A 2.1.2 KCA 7.1.2 Rate of degradation in soil

A 2.1.2.1 KCA 7.1.2.1 Laboratory studies

A 2.1.2.1.1 KCA 7.1.2.1.1 Aerobic degradation of the active substance

A 2.1.2.1.2 KCA 7.1.2.1.2 Aerobic degradation of metabolites, breakdown and reaction products

A 2.1.2.1.3 KCA 7.1.2.1.3 Anaerobic degradation of the active substance

A 2.1.2.1.4 KCA 7.1.2.1.4 Anaerobic degradation of metabolites, breakdown and reaction products

A 2.1.2.2 KCA 7.1.2.2 Field studies

A 2.1.2.2.1 KCA 7.1.2.2.1 Soil dissipation studies

A 2.1.2.2.2 KCA 7.1.2.2.2 Soil accumulation studies

A 2.1.3 KCA 7.1.3 Adsorption and desorption in soil

A 2.1.3.1 KCA 7.1.3.1 Adsorption and desorption

A 2.1.3.1.1 KCA 7.1.3.1.1 Adsorption and desorption of the active substance

A 2.1.3.1.2 KCA 7.1.3.1.2 Adsorption and desorption of metabolites, breakdown and reaction products

A 2.1.3.2 KCA 7.1.3.2 Aged sorption

A 2.1.4 KCA 7.1.4 Mobility in soil

A 2.1.4.1 KCA 7.1.4.1 Column leaching studies

A 2.1.4.1.1 KCA 7.1.4.1.1 Column leaching of the active substance

A 2.1.4.1.2 KCA 7.1.4.1.2 Column leaching of metabolites, breakdown and reaction products

A 2.1.4.2 KCA 7.1.4.2. Lysimeter studies

A 2.1.4.3 KCA 7.1.4.3 Field leaching studies

A 2.2 KCA 7.2 Fate and behaviour in water and sediment

A 2.2.1 KCA 7.2.1 Route and rate of degradation in aquatic systems (chemical and photochemical degradation)

A 2.2.1.1 KCA 7.2.1.1 Hydrolytic degradation

A 2.2.1.2 KCA 7.2.1.2 Direct photochemical degradation

A 2.2.1.3 KCA 7.2.1.3 Indirect photochemical degradation

A 2.2.2 KCA 7.2.2 Route and rate of biological degradation in aquatic systems

A 2.2.2.1 KCA 7.2.2.1 "Ready biodegradability"

A 2.2.2.2 KCA 7.2.2.2 Aerobic mineralisation in surface water

A 2.2.2.3 KCA 7.2.2.3 Water/sediment study

A 2.2.2.4 KCA 7.2.2.4 Irradiated water/sediment study

A 2.2.3 KCA 7.2.3 Degradation in the saturated zone

A 2.3 KCA 7.3 Fate and behaviour in air

A 2.3.1 KCA 7.3.1 Route and rate of degradation in air

A 2.3.2 KCA 7.3.2 Transport via air

A 2.3.3 KCA 7.3.3 Local and global effects

A 2.4 KCA 7.4 Definition of the residue

A 2.4.1 KCA 7.4.1 Definition of the residue for risk assessment

A 2.4.2 KCA 7.4.2 Definition of the residue for monitoring

A 2.5 KCA 7.5 Monitoring data

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

A 3.1 8.7 Predicted Environmental Concentrations in soil (PECsoil) (KCP 9.1.3)

A 3.1.1 Foramsulfuron and metabolites relevant for risk assessment

Comments of zRMS:	Aceptable. Used in evaluation.

Reference:	**KCP 9.1.3/01**
Title:	Foramsulfuron (FSN) and metabolites: PECsoil EUR - Use in arable crops in Europe
Report:	Heine, S.; 2017; EnSa-16-0693; M-570502-02-1
Authority registration No:	
Guideline(s):	not applicable
Deviations:	not applicable
GLP/GEP:	no
Acceptability:	
Duplication (if vertebrate study):	

Notifier comment: Generic PEC_{soil} calculation for risk envelope use pattern.

A 3.1.2 Thiencarbazone-methyl and metabolites relevant for risk assessment

Comments of zRMS:	Aceptable. Used in evaluation.

Reference:	**KCP 9.1.3/02**
Title:	Thiencarbazone-methyl (TCM) and metabolites: PECsoil EUR - Use in various crops in Europe
Report:	Bolekhan, A.; 2016; EnSa-16-0780; M-569933-01-1
Authority registration No:	
Guideline(s):	not applicable
Deviations:	none
GLP/GEP:	no
Acceptability:	
Duplication (if vertebrate study):	

Notifier comment: Generic PEC_{soil} calculation for risk envelope use pattern.

Degradation parameters used in PEC_{soil} calculations to describe the bi-phasic degradation of Thiencarbazone-methyl metabolites cannot be reduced to one DT_{50} value. Therefore, these parameters are presented here.

BYH 18636-carboxylic acid
The degradation kinetics of BYH 18636-carboxylic acid was taken from EFSA (2013) – see respective Table in Chapter 8.4.1 on field soil degradation studies on four sites in Germany (1), France (2) and Spain (1).

The kinetic evaluation made in the above studies aimed on persistence endpoints (see also OECD (2008)).

The kinetic model chosen for all four trials was the Double-First-Order in Parallel (DFOP) model. The kinetic parameters obtained without referencing to soil moisture and temperature are shown in the Table below:

Table A 1: Unreferenced kinetic parameters (DFOP) of BYH 18636-carboxylic acid. The worst-case field site is given in bold

Site	g	k [1/days]		DT50 [days]	
		fast phase	slow phase	fast phase	slow phase
Burscheid, Germany	0.439	4.36	0.0212	0.2	32.7
Tarascon, France	**0.640**	**0.0529**	**0.0020**	**13.1**	**346.6**
Vatteville, France	0.316	10.08	0.0076	0.1	91.2
Vilobi, Spain	0.448	0.709	0.0045	1.0	154.0

The site Tarascon with the overall slowest degradation (DT50 = 26.4 days, DT90 = 644.6 days) was selected as worst case.

BYH 18636-MMT

The degradation kinetics of BYH 18636-MMT was taken from EFSA (2013) – see respective Table in Chapter 8.3.1 - Summary of aerobic degradation rates for BYH 18636-MMT / AE 1277106 - laboratory studies.
With the exception of AXXa soil, BYH 18636-MMT showed a pronounced bi-phasic behaviour and was evaluated with the DFOP (double first order in parallel) kinetic model. The experimental simple first order half-lives (DT_{50}) for the fast and the slow phase are shown in the table below:

Table A 2: Experimental fast phase fraction (g) and first order half-lives (DT_{50}) of BYH 18636-MMT for DFOP model

Soil	Texture	g	k [1/days]		DT_{50} [days]	
			fast phase	slow phase	fast phase	slow phase
AIII	Silt loam	0.882	0.3466	0.0119	2.0	58.2
AXXa	Sandy loam	1.000	0.0341	n.a.	20.3	n.a.
HCB	Silt loam	0.900	0.0686	0.0038	10.1	182.4
Pikeville	Loamy sand	n.a.	n.a.	n.a.	n.a.	n.a.
SLS	Silt loam	0.944	0.2888	0.0036	2.4	192.5

As no worst case degradation half-life could be derived clearly from the data, the residues of MMT in soil after a given time were calculated for all soils and the maximum was selected.

Employing the DFOP model

$$R(t) = R(0)\ \{g \cdot \exp(-k_{fast} \cdot t + (1 - g) \cdot \exp(-k_{slow} \cdot t)\}$$

and the parameters given in the Table above, the BYH 18636-MMT residues R can be calculated as relative values for the four soils considered (see Figure below).

Relative time-weighted average residues (TWAR) were calculated numerically as

$$TWAR(n) = 1/n\ \{0.5\ [R(0) + R(n)] + \Sigma_{i=1,\ n-1} R(i)\}$$

using a fixed time step of 1 day. These values can be combined with arbitrary application rates.

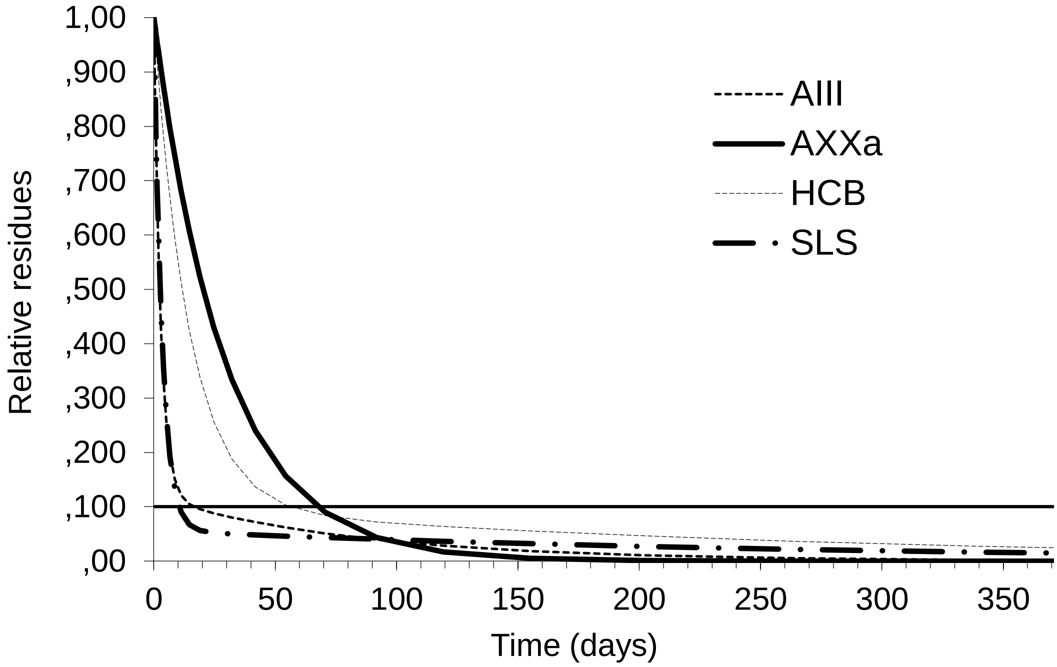


Figure A 1: Relative BYH 18636-MMT residue values using DFOP kinetics

The numerical values for selected times after application are given in the next Table for the residues and in the overnext Table for the TWAR.

Table A 3: Relative BYH 18636-MMT residues using DFOP kinetics. DAA is days after application. The maximum values are given in bold.

	Soil			
DAA	AIII	AXXa	HCB	SLS
0	1.000	**1.000**	1.000	1.000
1	0.740	**0.966**	0.940	0.763
2	0.556	**0.934**	0.884	0.585
4	0.333	**0.872**	0.782	0.353
7	0.187	**0.787**	0.654	0.180
14	0.107	**0.620**	0.439	0.070
21	0.092	**0.488**	0.305	0.054
28	0.085	**0.384**	0.222	0.051
50	0.065	**0.181**	0.112	0.047
100	0.036	0.033	**0.069**	0.039
365	0.002	0.000	**0.025**	0.015

Table A 4: Relative BYH 18636-MMT TWAR using DFOP kinetics. DAA is days after application. The maximum values are given in bold.

DAA	Soil AIII	AXXa	HCB	SLS
1	0.870	**0.983**	0.970	0.881
2	0.759	**0.967**	0.941	0.778
4	0.597	**0.935**	0.887	0.619
7	0.448	**0.890**	0.814	0.463
14	0.291	**0.795**	0.676	0.286
21	0.227	**0.714**	0.573	0.210
28	0.192	**0.644**	0.495	0.171
50	0.140	**0.480**	0.345	0.117
100	0.095	**0.283**	0.214	0.080

A 3.2 8.8 Predicted Environmental Concentrations in groundwater (PEC_{gw}) (KCP 9.2.4.1)

A 3.2.1 Foramsulfuron and metabolites relevant for risk assessment

Comments of zRMS:	Aceptable. Used in evaluation.

Reference:	**KCP 9.2.4.1/01**
Title:	Foramsulfuron (FSN) and metabolites: PECgw FOCUS PEARL, PELMO, MACRO EUR - Use in sugar beets in Europe
Report:	Heine, S.; Srinivasan, P.; 2016; EnSa-16-0770; M-576932-01-1
Authority registration No:	
Guideline(s):	not applicable
Deviations:	not applicable
GLP/GEP:	no
Acceptability:	
Duplication (if vertebrate study):	

Notifier comment: Tier 1 simulation for parent and metabolites via PEARL, PELMO and MACRO.

Report covers the use scenarios relevant to present product:
- "Sugar beets" = sugar beet, BBCH 10-18, 1×50 g a.s./ha, 20 % plant interception
- "Sugar beets" = sugar beet, BBCH 10-18, 2×25 g a.s./ha, 10 d interval, 20 % plant interception

A 3.2.1 Thiencarbazone-methyl and metabolites relevant for risk assessment

Comments of zRMS:	Aceptable. Used in evaluation.

Reference:	**KCP 9.2.4.1/02**
Title:	Thiencarbazone-methyl (TCM) and metabolites: PECgw FOCUS PEARL, PELMO EUR - Use in sugarbeet and maize in Europe
Report:	Bolekhan, A.; Hoerold, C.; 2016; EnSa-16-0806; M-577187-01-1
Authority registration No:	
Guideline(s):	not applicable
Deviations:	not applicable
GLP/GEP:	no
Acceptability:	
Duplication (if vertebrate study):	

Notifier comment: Tier 1 simulation for parent and metabolites via PEARL and PELMO.

Report covers several use scenarios – thereof relevant to present product:
- "Sugar beet I" = Sugar beet, BBCH 10-18, 1×30 g a.s./ha, 20 % plant interception
- "Sugar beet II" = Sugar beet, BBCH 10-14 and BBCH 12-18, 2×15 g a.s./ha, 10 d interval, 20 % plant interception

Reference:	**KCP 9.2.4.1/03**
Title:	Thiencarbazone-methyl (TCM) and metabolites: PECgw FOCUS MACRO EUR - Use in sugarbeet and maize in Europe
Report:	Bolekhan, A.; Hoerold, C.; 2018; EnSa-18-0269; M-620310-01-1
Authority registration No:	
Guideline(s):	none
Deviations:	none
GLP/GEP:	no
Acceptability:	
Duplication (if vertebrate study):	

Notifier comment: Tier 1 simulation for parent and metabolites via MACRO.

Report covers several use scenarios – thereof relevant to present product:

- "Sugar beet I" = Sugar beet, BBCH 10-18, 1×30 g a.s./ha, 20 % plant interception
- "Sugar beet II" = Sugar beet, BBCH 10-14 and BBCH 12-18, 2×15 g a.s./ha, 10 d interval, 20 % plant interception

A 3.3 8.9 Predicted Environmental Concentrations in surface water (PEC_{sw}) (KCP 9.2.5)

A 3.3.1 Foramsulfuron and metabolites relevant for risk assessment

(a) FOCUS Step 1-2 – Risk envelope PECsw/sed of foramsulfuron and all metabolites [for screening level assessment]

Comments of zRMS:	Aceptable. Used in evaluation.

Reference:	**KCP 9.2.5/01**
Title:	Foramsulfuron (FSN) and metabolites: PECsw,sed FOCUS EUR - Use in arable crops in Europe
Report:	Heine, S.; 2016; EnSa-16-0746; M-570503-01-1
Authority registration No:	
Guideline(s):	not applicable
Deviations:	none
GLP/GEP:	no
Acceptability:	
Duplication (if vertebrate study):	

Notifier comment: FOCUS Step 1/2 exposure calculation for generic risk envelope use, parent and all metabolites.

(b) FOCUS Step 3 – PECsw/sed (maximum and TWA) of foramsulfuron and metabolite AE F130619 [for Tier 1 assessment]

Comments of zRMS:	Aceptable. Used in evaluation.

Reference:	**KCP 9.2.5/02**
Title:	Foramsulfuron (FSN) and metabolites: PECsw,sed FOCUS EUR - Use in sugar beets in Europe
Report:	Heine, S.; Srinivasan, P; 2016; EnSa-16-0765; M-582622-01-1
Authority registration No:	
Guideline(s):	not applicable
Deviations:	not applicable
GLP/GEP:	no
Acceptability:	
Duplication (if vertebrate study):	

Notifier comment: FOCUS Step 3 simulation for parent active substance and metabolite AE F130619.

Report covers the use scenarios relevant to present product:

- DGR I "sugar beets I" = Sugar beet, BBCH 10-18, 1×50 g a.s./ha.
- DGR II "sugar beets II" = Sugar beet, BBCH 10-18, 2×25 g a.s./ha, 10 days interval.

(c) FOCUS Step 4 – PECsw (maximum and TWA) of foramsulfuron and metabolite AE F130619 [for Tier 1 assessment considering mitigation options]

FOCUS Step 4 exposure values are available for the active substance foramsulfuron and its metabolite AE F130619 from the same set of modelling reports referenced under point (b) before.

(d) FOCUS Step 3 – Timecourse of PECsw (FOCUS year) of foramsulfuron [for Tier 2C and Tier 3 assessment]

Comments of zRMS:	Only as additional information. No evaluated in core assessment.

In the FOCUS Step 3 simulations, the FOCUS model TOXSWA (TOXic substances in Surface WAters) calculates the pesticide distribution and concentrations in the water body that results for the various scenarios from the different routes of entry, in dependency of the substance parameters. The model version TOXSWA 4.4.3 provides detailed output files (*.out) which list surface water concentrations for the whole evaluation period of one year, in an hourly resolution. This data can be used for a refined exposure assessment and analysis of time-variable exposure patterns.

In order to obtain a meaningful description of these extensive data an evaluation tool (EPAT, Exposure Pattern Analysis Tool) was developed by Bastiansen et al. (2016), on behalf of the European Crop Protection Association (ECPA). EPAT uses the TOXSWA *.out files as its input together with a user-defined threshold concentration (here: RAC of substance) and scans the concentration time series in the *.out file for the exceedances of that given threshold value.

According to the program manual EPAT analyses and presents statistics on "events", which are defined as periods during which pesticide concentrations exceed the defined threshold. For each event EPAT calculates its maximum concentration, duration, number of peaks (local maxima) and interval from the last event to the current event, as well as time weighted average concentration (TWAC) and area under the curve (AUC) for individual events and for moving window analysis. EPAT produces three output files per analysis, one containing a detailed description of exposure events (*_events.txt), one containing a summary of exposure events (*_event summary.txt) and one containing results of the moving window analysis (*_moving window summary.txt). The here presented exposure discussion is based on the results presented in the *_event summary.txt files on the number of events, their duration and interval between events if relevant. Other parameters were not used for the analysis.

The TOXSWA output files (*.out) to the simulation runs of the present assessments are submitted electronically as supplemental modelling information. The EPAT Tool and its Manual are available for download free of charge at the developer's website (RIFCON GmbH): Program download: https://www.rifcon.de/files/downloads/EPAT_1.1.1_setup.exe, Manual: Report No. R1520392.

(e) FOCUS Step 3-4 – Timecourse of PECsw (multi-year simulation) foramsulfuron [for Tier 2C and Tier 3 assessment]

In response to concerns expressed by some regulators on the representativeness of the FOCUS model's single weather year in the context of refined risk assessment based on exposure pattern analysis, additional FOCUS calculations have been conducted for a period of 20 years (multi-year calculations). From this large data set, a statistically justified 90th percentile realistic worst case exposure pattern was derived for use in ecotoxicological risk assessment. As currently no official guidance is yet in place on such procedure, the simulation and risk assessment based here upon is intended to serve as supportive information only, confirming for the present product intended use pattern an adequate reliability of the standard assessment established on the official FOCUS medium year data. Due to its confirmatory character, methodology and results of the multi-year approach will be presented here in the Appendix section of the present dRR, for the interested reader.

Comments of zRMS:	Only as additional information. No evaluated in core assessment.

Reference:	**KCP 9.2.5/03**
Title:	Multi-year PECsw calculations for sulfonylurea herbicides in Europe: Description of methodology
Report:	Bolekhan, A.; 2017; EnSa-17-0541; M-602115-01-1
Authority registration No:	
Guideline(s):	not applicable
Deviations:	none
GLP/GEP:	no
Acceptability:	
Duplication (if vertebrate study):	

Backgrounds and general methodology: European surface water exposure assessment is performed with the FOCUS Surface Water Scenarios Help tool using a set of realistic worst case scenarios representative for agricultural conditions in Europe. The assessments are based on simulation results of a one year period selected according to 50th percentile annual (for drainage) or seasonal (for runoff) water balances (FOCUS, 2001).

However, this "single year" approach to the surface water exposure assessment has come under scrutiny in the scientific and regulatory community. Multiple publications examine various critical aspects in the current procedure and the effects that those may have on the risk assessment. One of the main questions is that the exposure of surface water bodies due to drainage and especially runoff of pesticides is strongly driven by individual rainfall events, whereas the FOCUS medium year was chosen based on annual or seasonal rainfall. Thus an evaluation based on this single, pre-selected year might not necessarily be an adequate realistic worst-case representation of pesticide exposure. Moreover, the appropriateness of the single year time-variable exposure patterns for use in the higher tier risk assessment is also questioned.

In order to reduce the uncertainty of the FOCUS surface water exposure and risk assessments it has been proposed to extend the assessment period for running the model simulations to 20 years, and choosing the appropriate endpoints for further use in the risk assessment, as it is performed in the current FOCUS Groundwater modelling (FOCUS, 2014).

A detailed description of the multi-year modelling procedure employed for use in the surface water exposure assessment at Step 3 and Step 4 is given in the present document. The assessment process was in general based on the standard FOCUS Surface Water modelling using SWASH, with the exception of an extended simulation period. No changes to scenario parametrisation were performed.

Weather data – principles applied: Extended weather data sets were required in order to perform the multi-year simulations. For this purpose it was decided to use the original FOCUS weather files with 20 years of data. The FOCUS working group obtained this data from the MARS 50 meteorological database. The most relevant grid cell was identified for each of the scenarios based on the selected representative field sites. In case of the PRZM model, i.e. for the run-off scenarios, the weather files implemented in the model already included the full 20 year period necessary for the multi-year simulations.

In case of the MACRO model, i.e. for the drainage scenarios, the weather files implemented in the model included only the selected 16-month evaluation period ("FOCUS" year) and the preceding 6 years of "warm-up" period. This "warm-up" period consists of the years 1988-1993 from the original weather files, which are re-numerated to match the numeration of the pre-selected "FOCUS" year.

For the multi-year drainage calculations, the MACRO weather files were extended using the original FOCUS weather files, and an additional six years of the “warm-up” period were added similarly to the standard FOCUS MACRO calculation procedure. The same “warm-up” data was used as in the weather files with 16-month evaluation period (years 1988-1993).

As the original weather files of the scenarios D1 and D6 included only 14 and 18 years respectively (plus the added 6 years for “warm-up”), it was decided for technical reasons, as well as for simpler comparison of results, to amend the two weather datasets to be of the same length as the rest of the files. These files were extended to 26 years by duplicating the first five and the last one year in case of the scenario D1, and by duplicating the first two years for the scenario D6, so that all final weather datasets comprise 26 years.

For the model TOXSWA, weather files also contained the whole 20-year periods. For the scenarios D1 and D6, which contained only 14 and 18 years, respectively, the weather files were amended in the same manner as for the MACRO model.

As defined in the FOCUS Surface Water Scenarios Report (FOCUS, 2015) some of the crop and scenario combinations represent agricultural systems that typically supplement rainfall with irrigation water. Irrigated crops are present in scenarios D3, D4, D6, R1, R3 and R4. For such scenario/crop combinations the models require additional “irrigated” weather files. During the development of FOCUS SW scenarios the FOCUS working group has introduced the required irrigation data by calculations with the irrigation-scheduling model ISAREG, assuming no water supply restrictions and a fixed irrigation depth of 30 mm. The ISAREG model then calculated a set of irrigation dates, and the pre-defined standard irrigation amount of 30 mm at each irrigation date was added to the rainfall amounts on the respective days.

A reasonable irrigation schedule for the extended 20-year time period was generated by distributing the average annual amounts of irrigation based on the weather pattern, and considering the general distribution of irrigation in the 7 year MACRO “weather plus irrigation” files. The distribution was performed taking into account rainfall amounts and number of irrigation events per month and per growing season, and respecting the minimal intervals between irrigation events and the earliest and latest possible irrigation dates as defined in the 7 year MACRO files.

Numeric details to the setup of all required multi-year weather files, and their technical implementation, are given in the original method report.

Pesticide application timer: In the same manner as in the standard FOCUS procedure a pesticide application timing calculator was used in order to reduce the influence of individual choice of application dates on the result of the exposure assessment (FOCUS, 2015). In the case of multi-year calculations the PAT is run over the whole period to identify suitable application dates for each year.

PAT rules were implemented in the same way as in the standard FOCUS models. The list of application dates for each year is presented for each of the calculation projects.

Simulation methods and tools: FOCUS Step 3 calculations are performed with the software tool FOCUS-SWASH (Surface Water Scenarios Help), developed by the FOCUS Surface Water Scenarios Group. FOCUS-SWASH consists of a database holding all information on substances, applications and scenarios, and of a software shell that controls and starts the deterministic simulation models MACRO, PRZM and TOXSWA.

The drain flow fluxes from the treated field to the water body are calculated with the one-dimensional leaching model MACRO, assuming a tile drain system. The flow to the drains is implemented as sink term in the vertical flow equation, using seepage potential theory. As MACRO also considers macro pores, the flow to the drains may originate from matrix and macropore flow. Similarly to the standard procedure MACRO considers a six-year warm-up period and a subsequent 20-year assessment period with annual applications. The calculated drainage volumes and drainage mass fluxes of the pesticide for the assessment period are exported to an “m2t” file that is used as input file for TOXSWA when running the drain flow scenarios.

The runoff and erosion loadings to the water body are calculated by the 1D leaching model PRZM, based on USDA curve number methodology and on a watershed-scale variant of the Universal Soil Loss Equation. Chemical Application Method (CAM) values are used in order to specify initial soil distribution resulting from the application method. PRZM automatically runs a 20-year simulation with annual applications. The calculated runoff volumes, the mass of eroded particles, and the mass fluxes of the pesticide with runoff and erosion for the whole 20 years are transformed into a “p2t” file that is used as input file for TOXSWA when simulating the aquatic fate of pesticides in runoff scenarios.

Presentation of results: The results of each calculation projects are presented as PEC_{max} and TWA values for water compartment and PECmax for sediment compartment for each individual year, as well as additional statistics on the surface water exposure pattern (number of exceedance peaks per year, peak duration and intervals between the peaks). The additional statistics is performed using the EPAT tool (Bastiansen et al., 2016).

More details on the interpretation of the results will be presented in the individual exposure assessment reports.

Comments of zRMS:	Only as additional information. No evaluated in core assessment.

Reference:	**KCP 9.2.5/04**
Title:	Foramsulfuron (FSN) and metabolite AE F130619: PECsw FOCUS EUR (multi-year) - Use in maize and sugar beets in Europe
Report:	Heine, S.; Hammel, K.; Bolekhan, A.; 2018; EnSa-17-0353; M-592861-02-1
Authority registration No:	
Guideline(s):	none
Deviations:	none
GLP/GEP:	no
Acceptability:	
Duplication (if vertebrate study):	

Based on a multi-year extended FOCUS PECsw approach, exposure patterns were calculated for foramsulfuron and metabolite AE F130619 use in sugar beet over a period of 20 years, with an hourly resolution. To enable a direct use in ecotoxicological risk assessments, the data was statistically processed and characterised via the following descriptors:

- Predicted environmental concentrations in surface water,
- Annual number of exposure events exceeding the RAC,
- Duration of these events,
- Interval between these events

Moreover, the full output data depth (TOXSWA *.out files) was transferred electronically for use in subsequent models, i.e. served as exposure information base for ecological effect modelling (cf. dRR Part B Section 9).

Details of the substance and general GAP parameters used in the calculations have been summarised in Section 8.9 before. Actual application dates were determined by the PAT (pesticide application timer) included within SWASH. For the multiyear calculations the PAT was running over the whole simulation period to identify suitable application dates for each year. The date settings per scenario and simulation year are presented in the following:

Table A 1: Multi-year exposure pattern analysis: FOCUS Scenario related input parameters for PEC_{sw} calculations for the application of FSN+TCM OD 80 (50+30) - Use in sugar beet, 1 × 50 g foramsulfuron/ha

	FOCUS model crop (crop group)			Sugar beets (arable crops)		
	Use pattern			50 g a.s./ha		
	Appl. method (Run off CAM, depth inc.)			Ground spray (2 - appln foliar linear, 4 cm)		
	PAT start date (relative to crop event or absolute)			Absolute		
	PAT window range			30 days for all scenarios (min = 30 days)		
Drainage scenario	**Year**	**PAT start/end date (Julian day)**	**Application date**	**Drainage scenario**	**PAT start/end date (Julian day)**	**Application date**
D3 Stream	1975	26-Apr/26-May	26-Apr	D4 Pond/Stream	05-May/04-Jun	08-May
	1976	26-Apr/26-May	29-Apr		05-May/04-Jun	07-May
	1977	26-Apr/26-May	24-May		05-May/04-Jun	15-May
	1978	26-Apr/26-May	16-May		05-May/04-Jun	07-May
	1979	26-Apr/26-May	19-May		05-May/04-Jun	05-May
	1980	26-Apr/26-May	29-Apr		05-May/04-Jun	10-May
	1981	26-Apr/26-May	26-Apr		05-May/04-Jun	05-May
	1982	26-Apr/26-May	26-Apr		05-May/04-Jun	10-May
	1983	26-Apr/26-May	19-May		05-May/04-Jun	05-May
	1984	26-Apr/26-May	25-Apr		05-May/04-Jun	05-May
	1985	26-Apr/26-May	06-May		05-May/04-Jun	14-May
	1986	26-Apr/26-May	30-Apr		05-May/04-Jun	18-May
	1987	26-Apr/26-May	28-Apr		05-May/04-Jun	24-May
	1988	26-Apr/26-May	25-Apr		05-May/04-Jun	07-May
	1989	26-Apr/26-May	09-May		05-May/04-Jun	16-May
	1990	26-Apr/26-May	30-Apr		05-May/04-Jun	07-May
	1991	26-Apr/26-May	27-Apr		05-May/04-Jun	21-May
	1992	26-Apr/26-May	04-May		05-May/04-Jun	14-May
	1993	26-Apr/26-May	26-Apr		05-May/04-Jun	05-May
	1994	26-Apr/26-May	27-Apr		05-May/04-Jun	07-May

	FOCUS model crop (crop group)			Sugar beet (arable crops)		
	Use pattern			50 g a.s./ha		
	Appl. method (Run off CAM, depth inc.)			Ground spray (2 - appln foliar linear, 4 cm)		
	PAT start date (relative to crop event or absolute)			Absolute		
	PAT window range			30 days for all scenarios (min = 30 days)		
Runoff scenarios	**Year**	**PAT start/end date (Julian day)**	**Application date**	**Runoff scenarios**	**PAT start/end date (Julian day)**	**Application date**
R1 Pond/Stream	1975	17-Apr/17-May	24-Apr	R3 Stream	21-Mar/20-Apr	21-Mar
	1976	17-Apr/17-May	17-Apr		21-Mar/20-Apr	03-Apr
	1977	17-Apr/17-May	17-Apr		21-Mar/20-Apr	21-Mar
	1978	17-Apr/17-May	17-Apr		21-Mar/20-Apr	25-Mar
	1979	17-Apr/17-May	07-May		21-Mar/20-Apr	25-Mar
	1980	17-Apr/17-May	28-Apr		21-Mar/20-Apr	28-Mar
	1981	17-Apr/17-May	17-Apr		21-Mar/20-Apr	21-Mar
	1982	17-Apr/17-May	18-Apr		21-Mar/20-Apr	22-Mar
	1983	17-Apr/17-May	21-Mar		21-Mar/20-Apr	21-Mar
	1984	17-Apr/17-May	26-Apr		21-Mar/20-Apr	21-Mar
	1985	17-Apr/17-May	18-Apr		21-Mar/20-Apr	01-Apr
	1986	17-Apr/17-May	30-Apr		21-Mar/20-Apr	28-Mar
	1987	17-Apr/17-May	22-Apr		21-Mar/20-Apr	27-Mar
	1988	17-Apr/17-May	22-Apr		21-Mar/20-Apr	25-Mar
	1989	17-Apr/17-May	23-Mar		21-Mar/20-Apr	23-Mar
	1990	17-Apr/17-May	17-Apr		21-Mar/20-Apr	21-Mar
	1991	17-Apr/17-May	19-Apr		21-Mar/20-Apr	25-Mar
	1992	17-Apr/17-May	17-Apr		21-Mar/20-Apr	17-Apr
	1993	17-Apr/17-May	20-Apr		21-Mar/20-Apr	06-Apr
	1994	17-Apr/17-May	11-May		21-Mar/20-Apr	21-Mar

Table A 2: Multi-year exposure pattern analysis: FOCUS Scenario related input parameters for PEC_{sw} calculations for the application of FSN+TCM OD 80 (50+30) - Use in sugar beet, 2 × 25 g foramsulfuron/ha

	FOCUS model crop (crop group)			Sugar beet (arable crops)		
	Use pattern			2 × 25 g a.s./ha		
	Appl. method (Run off CAM, depth inc.)			Ground spray (2 - appln foliar linear, 4 cm)		
	PAT start date (relative to crop event or absolute)			Absolute		
	PAT window range			30 days for all scenarios (min = 30 days)		
Drainage scenario	**Year**	**PAT start/end date (Julian day)**	**Application date**	**Drainage scenario**	**PAT start/end date (Julian day)**	**Application date**
D3 Stream	1975	26-Apr/05-Jun	26-Apr 08-May	D4 Pond/Stream	05-May/14-Jun	08-May 22-May
	1976	26-Apr/05-Jun	29-Apr 16-May		05-May/14-Jun	07-May 07-Jun
	1977	26-Apr/05-Jun	24-May 03-Jun		05-May/14-Jun	15-May 28-May
	1978	26-Apr/05-Jun	16-May 31-May		05-May/14-Jun	07-May 17-May
	1979	26-Apr/05-Jun	19-May 02-Jun		05-May/14-Jun	05-May 03-Jun
	1980	26-Apr/05-Jun	29-Apr 09-May		05-May/14-Jun	10-May 21-May
	1981	26-Apr/05-Jun	26-Apr 15-May		05-May/14-Jun	05-May 15-May
	1982	26-Apr/05-Jun	26-Apr 14-May		05-May/14-Jun	10-May 26-May
	1983	26-Apr/05-Jun	19-May 01-Jun		05-May/14-Jun	05-May 19-May
	1984	26-Apr/05-Jun	25-Apr 10-May		05-May/14-Jun	05-May 21-May
	1985	26-Apr/05-Jun	06-May 17-May		05-May/14-Jun	14-May 27-May
	1986	26-Apr/05-Jun	30-Apr 01-Jun		05-May/14-Jun	18-May 28-May
	1987	26-Apr/05-Jun	28-Apr 26-May		05-May/14-Jun	24-May 06-Jun
	1988	26-Apr/05-Jun	25-Apr 13-May		05-May/14-Jun	07-May 23-May
	1989	26-Apr/05-Jun	09-May 22-May		05-May/14-Jun	16-May 26-May
	1990	26-Apr/05-Jun	30-Apr 19-May		05-May/14-Jun	07-May 20-May
	1991	26-Apr/05-Jun	27-Apr 08-May		05-May/14-Jun	21-May 01-Jun
	1992	26-Apr/05-Jun	04-May 14-May		05-May/14-Jun	14-May 27-May
	1993	26-Apr/05-Jun	26-Apr 06-May		05-May/14-Jun	05-May 15-May
	1994	26-Apr/05-Jun	27-Apr 09-May		05-May/14-Jun	07-May 20-May

	FOCUS model crop (crop group)			Sugar beet (arable crops)		
	Use pattern			2 × 25 g a.s./ha		
	Appl. method (Run off CAM, depth inc.)			Ground spray (2 - appln foliar linear, 4 cm)		
	PAT start date (relative to crop event or absolute)			Absolute		
	PAT window range			30 days for all scenarios (min = 30 days)		
Runoff scenarios	**Year**	**PAT start/end date (Julian day)**	**Application date**	**Runoff scenarios**	**PAT start/end date (Julian day)**	**Application date**
R1 Pond/Stream	1975	17-Apr/27-May	24-Apr 11-May	R3 Stream	21-Mar/30-Apr	21-Mar 01-Apr
	1976	17-Apr/27-May	17-Apr 01-May		21-Mar/30-Apr	03-Apr 13-Apr
	1977	17-Apr/27-May	17-Apr 01-May		21-Mar/30-Apr	21-Mar 07-Apr
	1978	17-Apr/27-May	17-Apr 09-May		21-Mar/30-Apr	25-Mar 08-Apr
	1979	17-Apr/27-May	07-May 20-May		21-Mar/30-Apr	25-Mar 07-Apr
	1980	17-Apr/27-May	28-Apr 19-May		21-Mar/30-Apr	28-Mar 11-Apr
	1981	17-Apr/27-May	17-Apr 03-May		21-Mar/30-Apr	21-Mar 07-Apr
	1982	17-Apr/27-May	18-Apr 13-May		21-Mar/30-Apr	22-Mar 02-Apr
	1983	17-Apr/27-May	20-Apr 19-May		21-Mar/30-Apr	21-Mar 22-Apr
	1984	17-Apr/27-May	26-Apr 09-May		21-Mar/30-Apr	21-Mar 19-Apr
	1985	17-Apr/27-May	18-Apr 03-May		21-Mar/30-Apr	01-Apr 15-Apr
	1986	17-Apr/27-May	30-Apr 18-May		21-Mar/30-Apr	28-Mar 22-Apr
	1987	17-Apr/27-May	22-Apr 23-May		21-Mar/30-Apr	27-Mar 23-Apr
	1988	17-Apr/27-May	22-Apr 06-May		21-Mar/30-Apr	25-Mar 13-Apr
	1989	17-Apr/27-May	18-Apr 29-Apr		21-Mar/30-Apr	23-Mar 07-Apr
	1990	17-Apr/27-May	17-Apr 29-Apr		21-Mar/30-Apr	21-Mar 31-Mar
	1991	17-Apr/27-May	19-Apr 02-May		21-Mar/30-Apr	25-Mar 10-Apr
	1992	17-Apr/27-May	17-Apr 23-May		21-Mar/30-Apr	21-Mar 02-Apr
	1993	17-Apr/27-May	20-Apr 22-May		21-Mar/30-Apr	06-Apr 18-Apr
	1994	17-Apr/27-May	11-May 26-May		21-Mar/30-Apr	21-Mar 12-Apr

EPAT exposure pattern analysis of FOCUS multi-year calculations was used to define representative exposure patterns for those surface water scenarios where $PEC_{sw,max}$ exceeded the regulatory acceptable concentration (RAC) at Step 3 in the standard FOCUS assessment. The multi-year exposure analysis was always based on the results at Step 3, except for the parameter 'number of events' that was determined also at Step 4 level. The RACs were set to 0.101 µg/L (derived from E_rC_{50} of 1.01 µg/L for *Lemna gibba*, considering an assessment factor of 10) and 0.0889 µg/L (derived from E_rC_{50} of 0.889 µg/L for *Lemna gibba*, considering an assessment factor of 10), according to the EU agreed Tier 1 endpoints for foramsulfuron and metabolite AE F130619 relevant for aquatic macrophyte risk assessment.

The following table shows the FOCUS scenarios which did not pass the risk assessment for the active substance foramsulfuron and its metabolite AE F130619 based on FOCUS Step 3 PEC_{sw} values for the present product (presented in Section 9 of this core document) and for which an exposure pattern analysis was conducted.

Table A 3: Overview of FOCUS scenarios (multi-year) for which an exposure pattern analysis is used for the present product

Scenario	Sugar beet, 1×50 g a.s./ha		Sugar beet, 2×25 g a.s./ha	
	FSN	AE F130619	FSN	AE F130619
D3 (Ditch)	X	-	X	-
D4 (Pond)	-	-	-	-
D4 (Stream)	X	-	X	-
R1 (Pond)	-	-	-	-
R1 (Stream)	X	-	X	-
R3 (Stream)	X	-	X	-

FSN = foramsulfuron

Several properties were identified that are important to evaluate the representativeness of exposure patterns. Representativeness was defined as being a realistic worst-case pattern that covers the majority of the 20 annual exposure patterns. The following properties were quantified for each of the entire FOCUS multi-year scenarios.

Table A 4: Exposure pattern properties that were quantified for each of the entire FOCUS multi-year scenarios

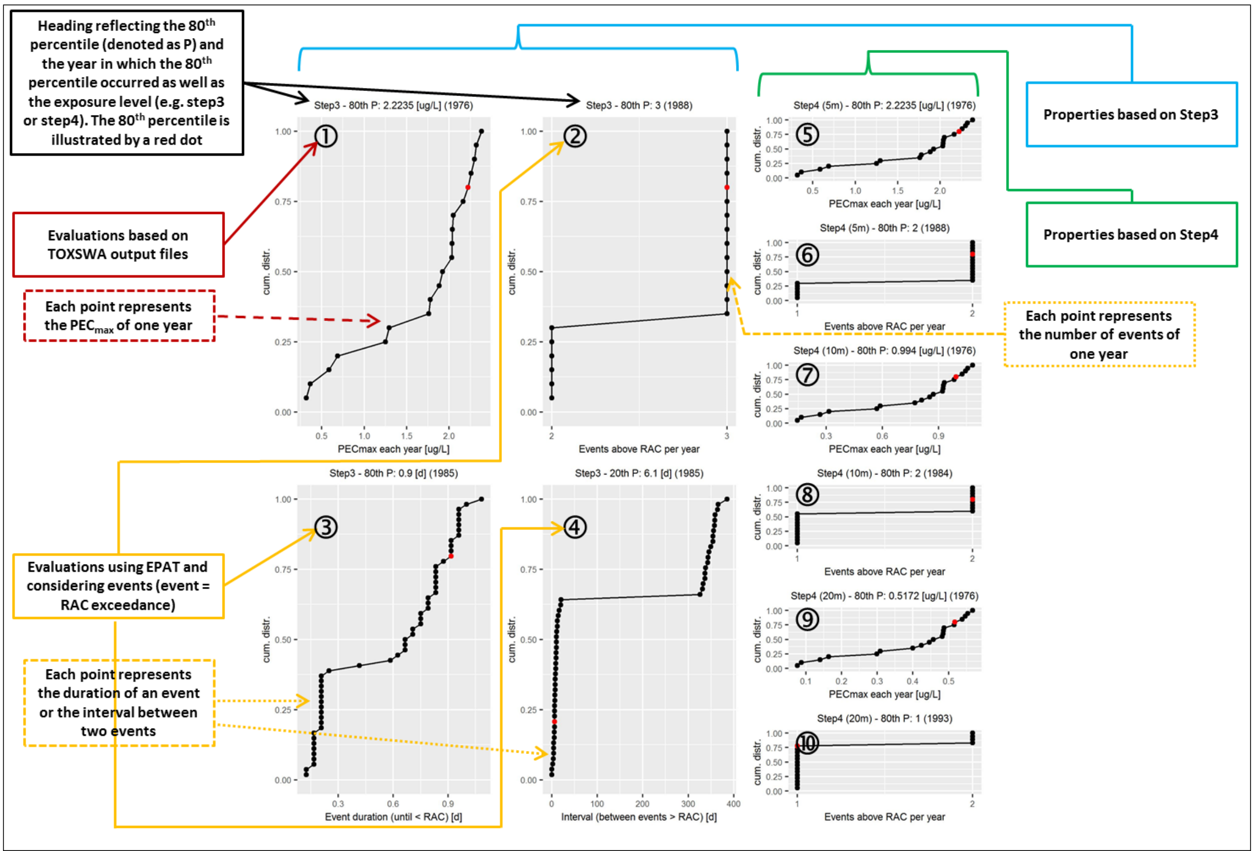
Number	PECmax	No. of events	Duration of events	Interval between events	FOCUS step
1	X				Step 3
2		X			Step 3
3			X		Step 3
4				X	Step 3
5	X				Step 4 (5m)
6		X			Step 4 (5m)
7	X				Step 4 (10m)
8		X			Step 4 (10m)
9	X				Step 4 (20m)
10		X			Step 4 (20m)

The PEC_{max} values for each year were directly obtained from the TOXSWA output files. The other properties describing the exposure patterns (number of events, duration of events, interval between events) were based on the analysis of EPAT (Bastiansen et al., 2016) and the entire (20 years) TOXSWA output files. EPAT considers the regulatory acceptable concentration (RAC) of a compound and scans the exposure pattern for events that exceed the RAC. Subsequently, an event is defined as a continuous time series of concentrations exceeding the RAC. PEC_{max} and the number of peak events (i.e. concentrations above the RAC) have been analysed individually for Step 3 and Step 4 (with 5m, 10m and 20m buffer). To reduce complexity, only FOCUS step 3 level results were used to quantify the duration of and the interval between events, which is a conservative simplification.

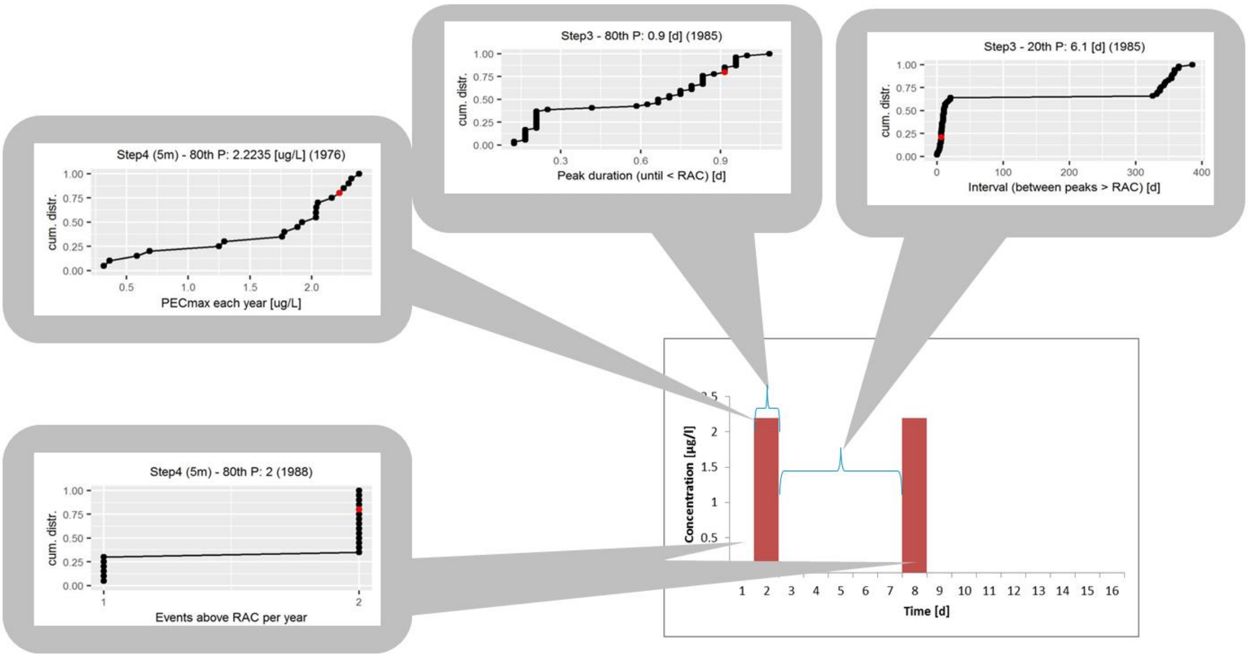
For each FOCUS multiyear scenario of relevance for further ecotoxicological assessment, ten cumulative distribution figures were generated illustrating the properties of the exposure pattern (as listed in the table above). To gain a representative exposure pattern that describes a realistic worst-case annual exposure situation, an artificial pattern was created by combining the 80th percentile PECsw,max, 80th percentile number of events and 80th percentile duration of events with the 20th percentile interval between peak events of the individual exposure pattern properties. Such approach will consolidate the 20-year-data generated into a single representative worst case exposure pattern usable for conservative risk assessment.

In the illustrated example (Figure A 1), at FOCUS Step 3 three events were identified. However, in the ecological tests used for risk assessment only exposure situations up to two events were experimentally addressed. Risk mitigation (Step 4, 5 m drift buffer) could therefore be applied to reduce the number of peak events (i.e. concentrations above the RAC) from three to two, so that the exposure situation could be compared to the ecological tests.

Figure A 1: Example figure describing the exposure pattern of a multi-year FOCUS scenario, and illustration of its use for synthesis of a conservative representative exposure pattern for ecological risk assessment



Synthesis of a 20-year characteristic and conservative exposure pattern:
(example case for Step 4 – 5 m):



FOCUS multiyear Scenario	**80th perc. PECmax [µg/L]**	**80th perc. events above Tier 1 RAC**	**80th perc. event duration above Tier 1 RAC [d]**	**20th per. interval betw. events above Tier 1 RAC [d]**
Example from **Figure A 1** – Step 3	2.2235	3 peaks	0.9	6.1
Example from **Figure A 1** – Step 4 (5 m)	2.2235	2 peaks	0.9	6.1
Remarks:	*taken from Step 4#*	*taken from Step 4*	*Step 3 value as conservative simplification*	*Step 3 value as conservative simplification*
	80th perc. PECmax assumed for both peaks, as conservative simplification			

In this example, PECmax is driven by run-off entry, and therefore not mitigated by 5 m drift buffer. However, one peak at Step 3 is a drift-peak, which is mitigated at Step 4. This reduces the number of events from 3 to 2 peaks.

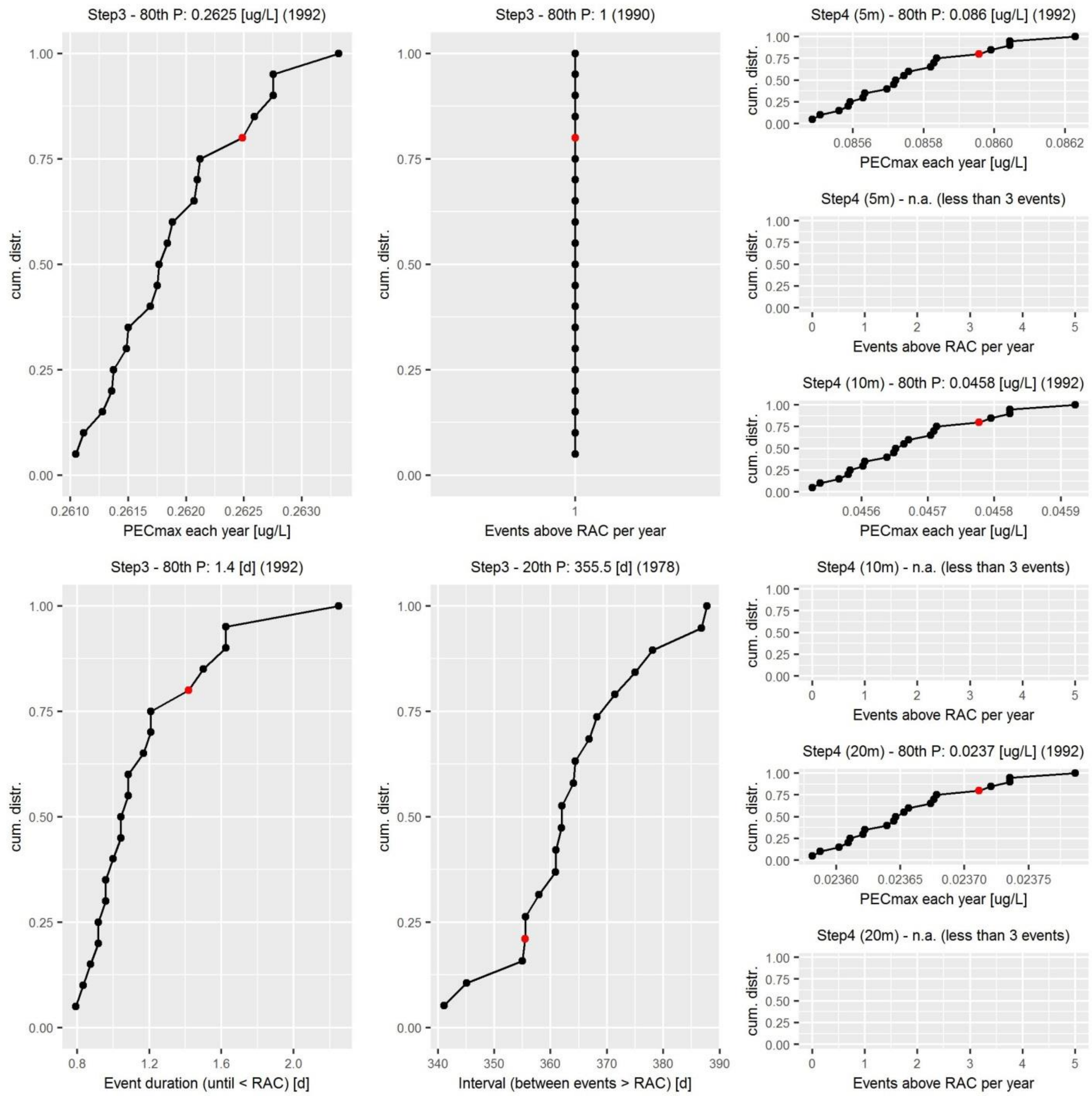
All properties mentioned above are considered important when comparing a representative FOCUS exposure pattern with the exposure regime of an ecotoxicological study.

Detailed further information on the approach is found provided in the original modelling document, also including statistical justifications for all selections made.

Results of the exposure pattern analysis:

The representative exposure pattern properties from each of the relevant FOCUS scenario multiyear simulations derive as presented in the following; for ecotoxicological interpretation to these patterns reference is made to dRR Section 9.5.

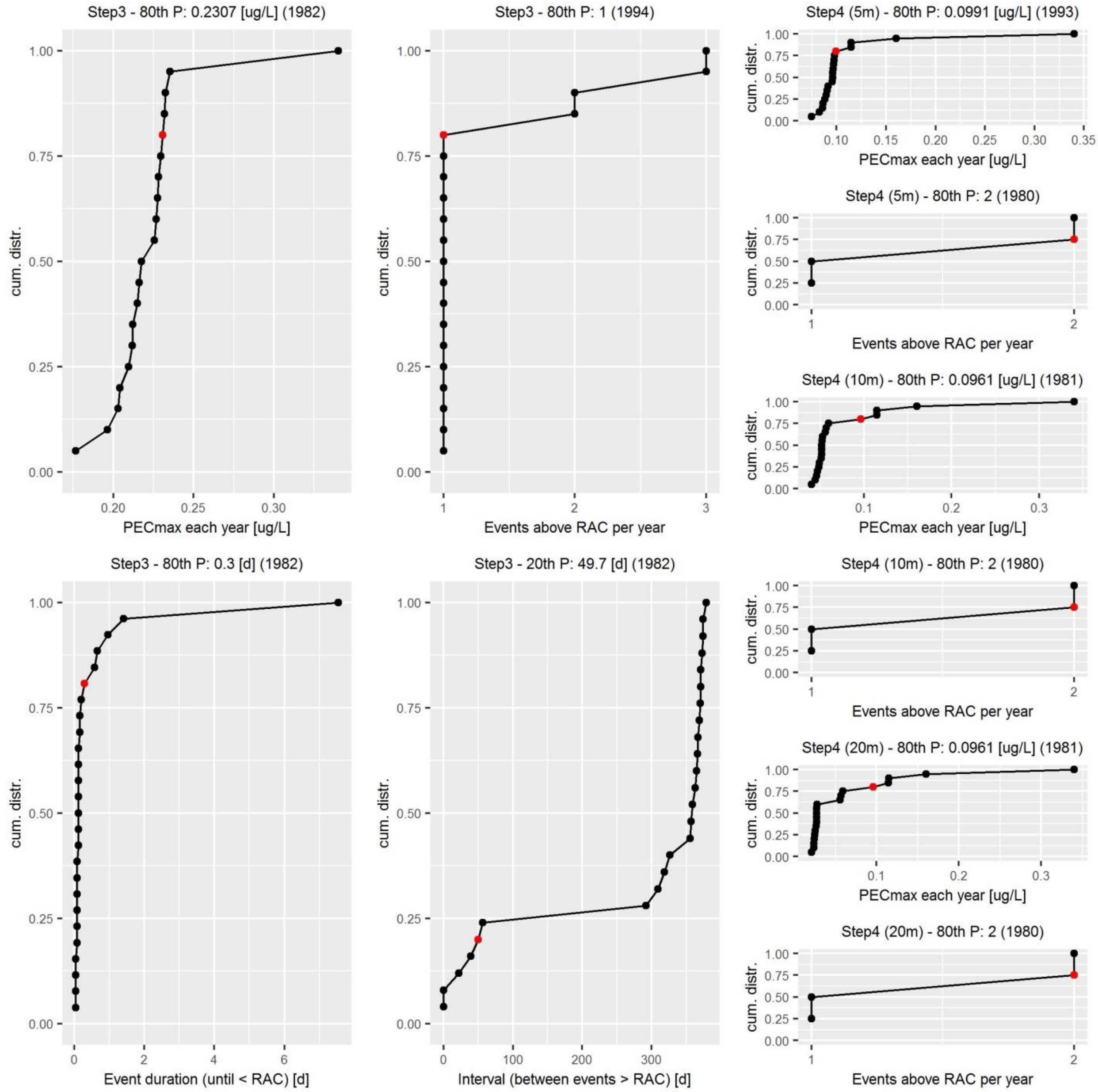
Figure A 2: **D3 ditch - results of multi-year exposure pattern analysis for foramsulfuron Use: Sugar beet, 1×50 g a.s./ha**



20-year characteristic exposure pattern:

FOCUS multiyear Scenario	80th perc. PECmax [µg/L]	80th perc. events above Tier 1 RAC	80th perc. event duration above Tier 1 RAC [d]	20th per. interval betw. events above Tier 1 RAC [d]
D3 ditch (Step 3)	0.2625	1 peak	1.4	Not relevant

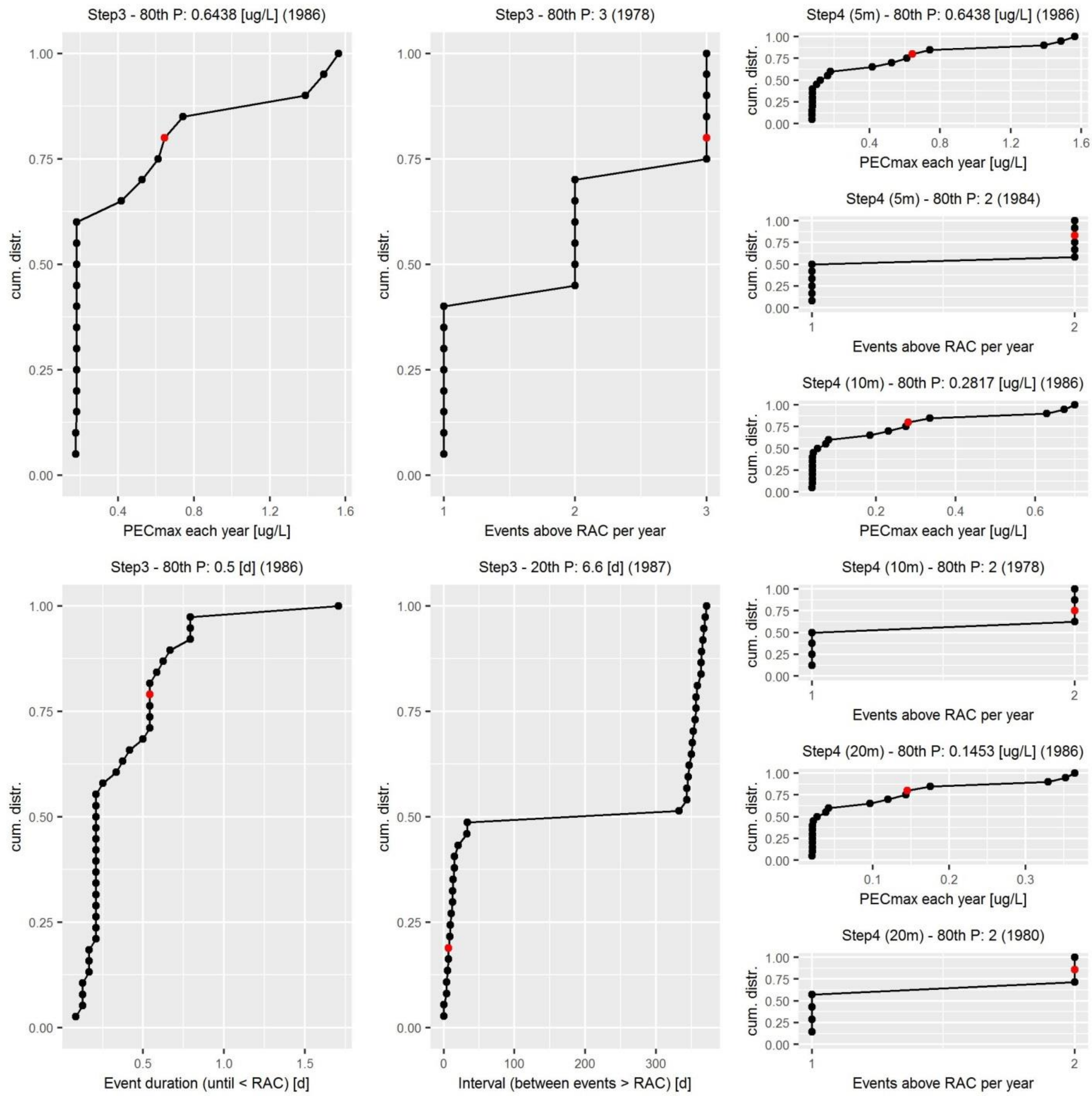
Figure A 3: **D4 stream - results of multi-year exposure pattern analysis for foramsulfuron Use: Sugar beet, 1×50 g a.s./ha**



20-year characteristic exposure pattern:

FOCUS multiyear Scenario	80th perc. PECmax [µg/L]	80th perc. events above Tier 1 RAC	80th perc. event duration above Tier 1 RAC [d]	20th per. interval betw. events above Tier 1 RAC [d]
D4 stream (Step 3)	0.2307	1 peak	0.3	Not relevant

Figure A 4: R1 stream - results of multi-year exposure pattern analysis for foramsulfuron
Use: Sugar beet, 1×50 g a.s./ha

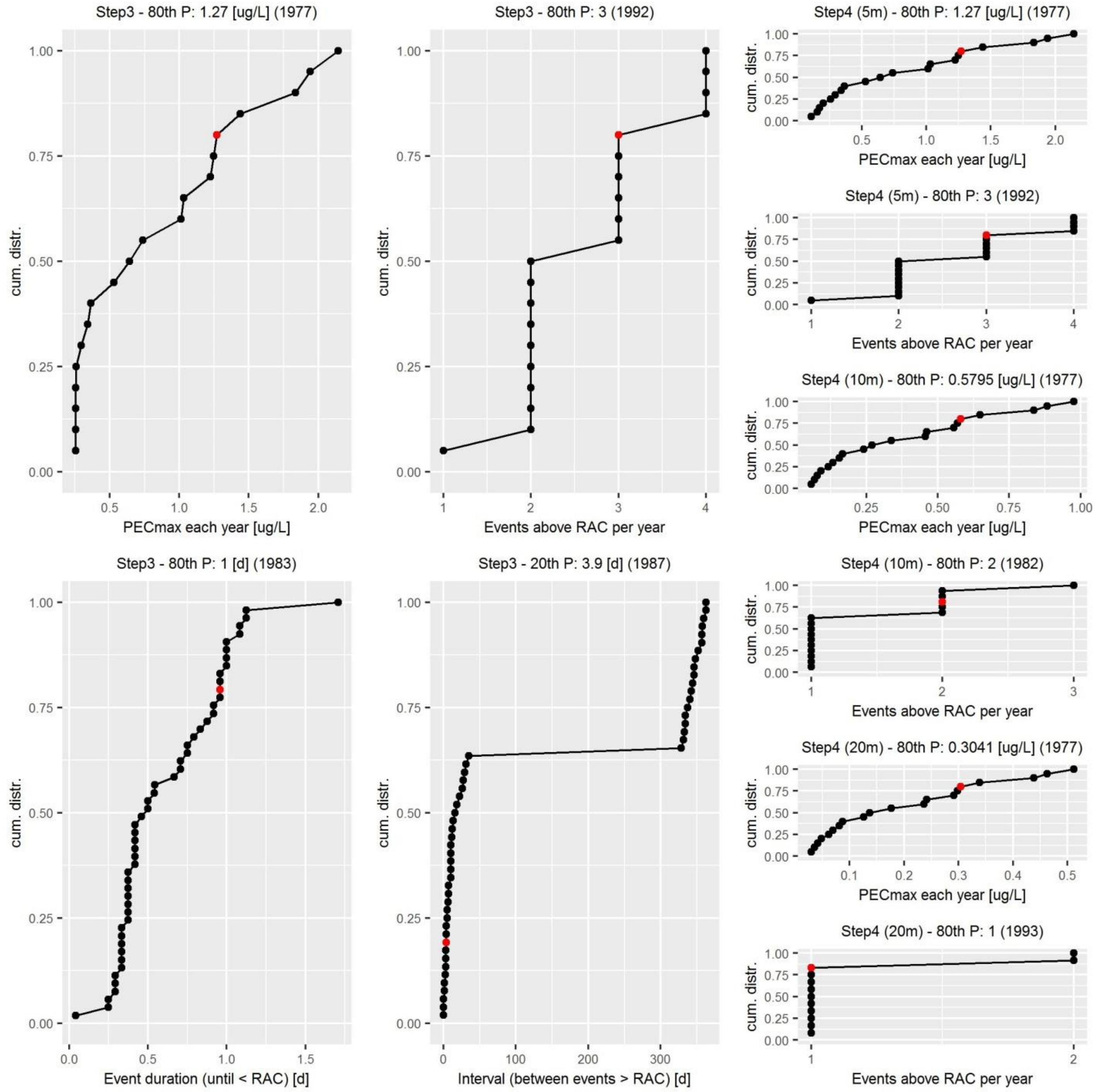


20-year characteristic exposure pattern:

FOCUS multiyear Scenario	80th perc. PECmax [µg/L]	80th perc. events above Tier 1 RAC	80th perc. event duration above Tier 1 RAC [d]	20th per. interval betw. events above Tier 1 RAC [d]
R1 stream (Step 3)	0.6438	3 peaks	0.5	6.6
R1 stream (Step 4 (5 m))	0.6438	2 peaks	-*	-*

* not quantified

Figure A 5: **R3 stream - results of multi-year exposure pattern analysis for foramsulfuron Use: Sugar beet, 1×50 g a.s./ha**



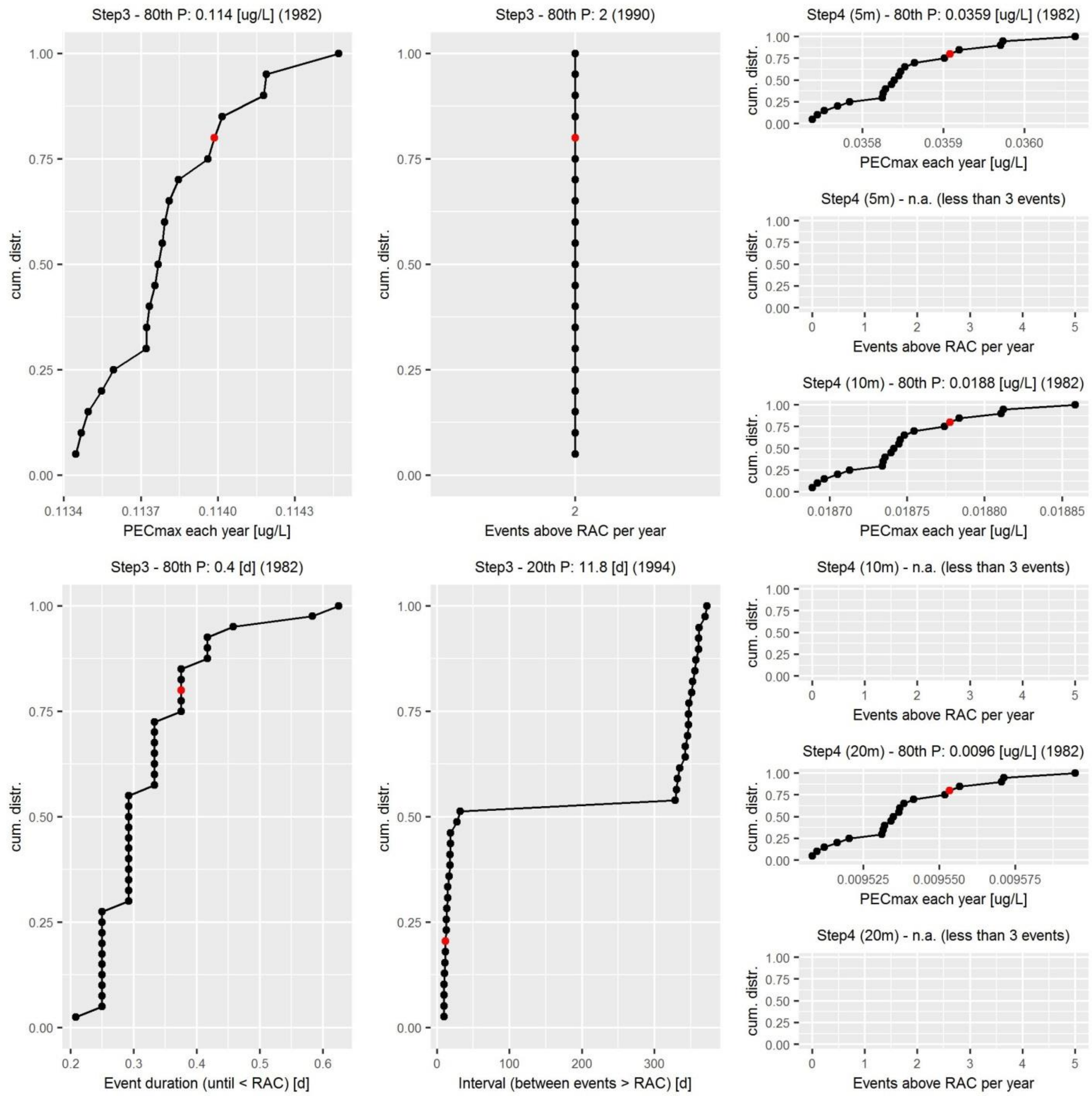
20-year characteristic exposure pattern:

FOCUS multiyear Scenario	80th perc. PECmax [µg/L]	80th perc. events above Tier 1 RAC	80th perc. event duration above Tier 1 RAC [d]	20th per. interval betw. events above Tier 1 RAC [d]
R3 stream (Step 3)	1.270	3 peaks	1.0	3.9
R3 stream (Step 4 (10 m)	0.5795	2 peaks	-*	-*

* not quantified

*****

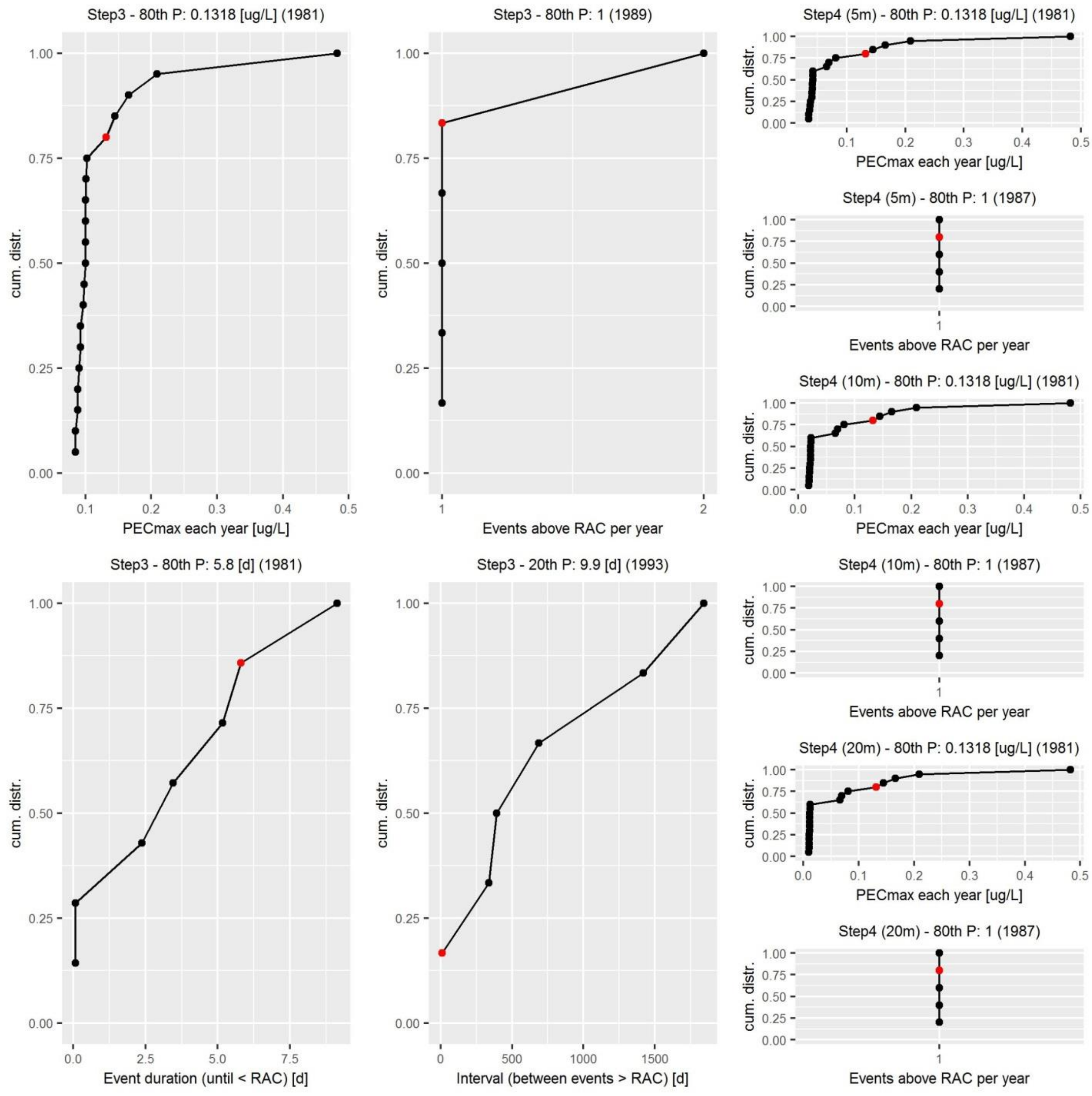
Figure A 6: D3 ditch - results of multi-year exposure pattern analysis for foramsulfuron Use: Sugar beet, 2×25 g a.s./ha



20-year characteristic exposure pattern:

FOCUS multiyear Scenario	80th perc. PECmax [µg/L]	80th perc. events above Tier 1 RAC	80th perc. event duration above Tier 1 RAC [d]	20th per. interval betw. events above Tier 1 RAC [d]
D3 ditch (Step 3)	0.114	2 peaks	0.4	11.8

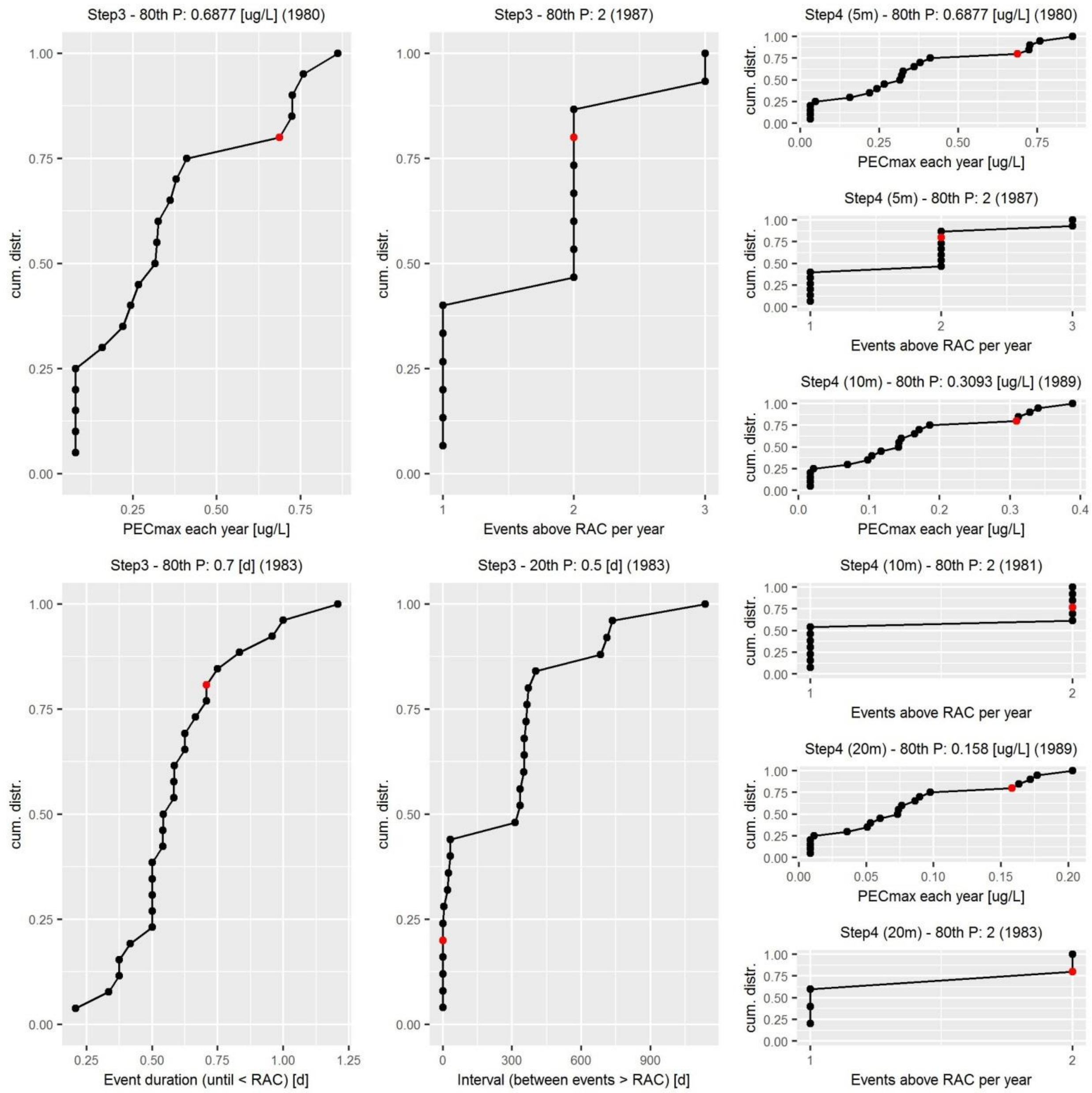
Figure A 7: D4 stream - results of multi-year exposure pattern analysis for foramsulfuron Use: Sugar beet, 2×25 g a.s./ha



20-year characteristic exposure pattern:

FOCUS multiyear Scenario	80th perc. PECmax [µg/L]	80th perc. events above Tier 1 RAC	80th perc. event duration above Tier 1 RAC [d]	20th per. interval betw. events above Tier 1 RAC [d]
D4 stream (Step 3)	0.1318	1 peak	5.8	Not relevant

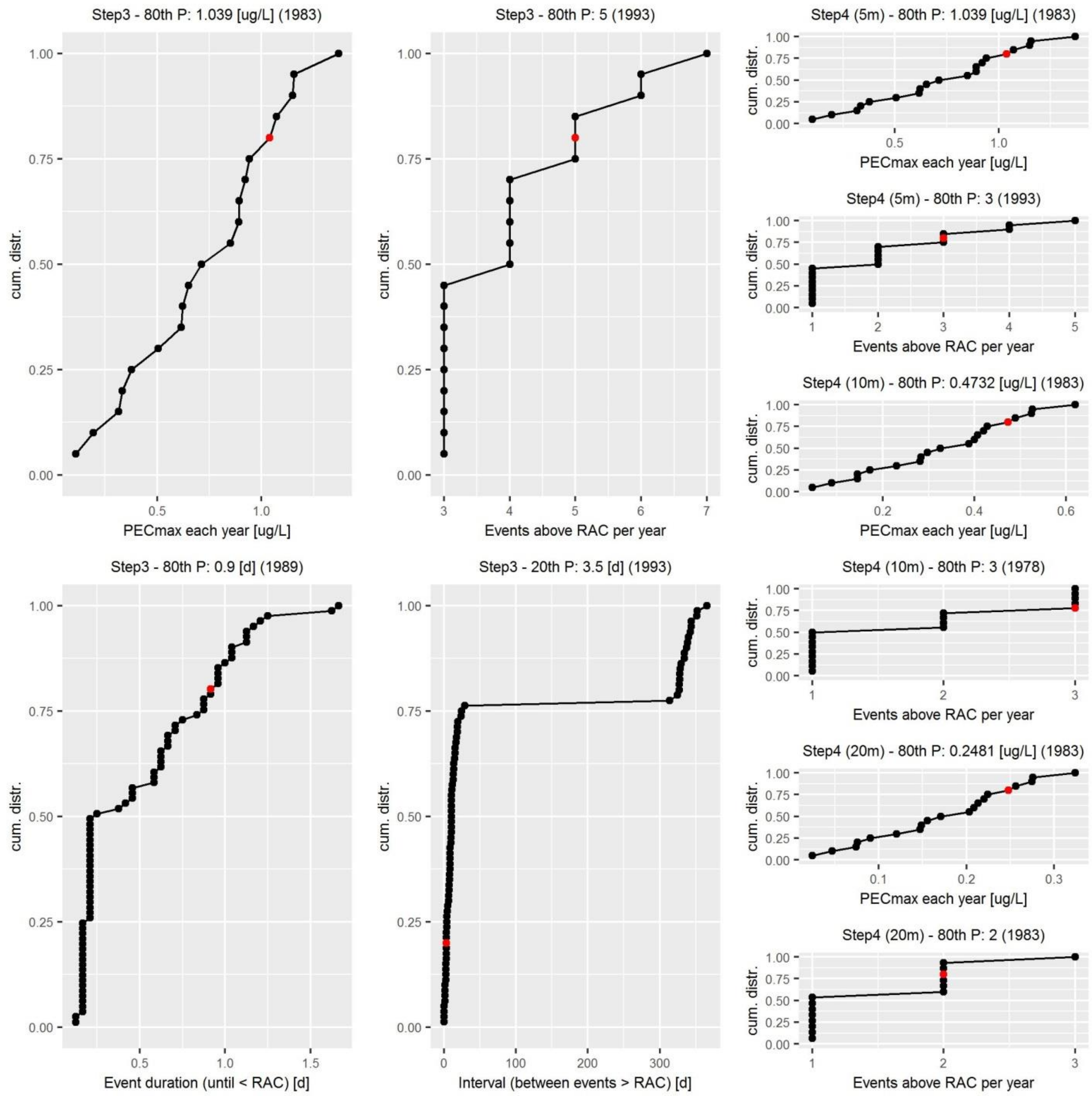
Figure A 8: **R1 stream - results of multi-year exposure pattern analysis for foramsulfuron Use: Sugar beet, 2×25 g a.s./ha**



20-year characteristic exposure pattern:

FOCUS multiyear Scenario	80th perc. PECmax [µg/L]	80th perc. events above Tier 1 RAC	80th perc. event duration above Tier 1 RAC [d]	20th per. interval betw. events above Tier 1 RAC [d]
R1 stream (Step 3)	0.6877	2 peaks	0.7	0.5

Figure A 9: **R3 stream - results of multi-year exposure pattern analysis for foramsulfuron Use: Sugar beet, 2×25 g a.s./ha**



20-year characteristic exposure pattern:

FOCUS multiyear Scenario	80th perc. PECmax [µg/L]	80th perc. events above Tier 1 RAC	80th perc. event duration above Tier 1 RAC [d]	20th per. interval betw. events above Tier 1 RAC [d]
R3 stream (Step 3)	1.039	5 peaks	0.9	3.5
R3 stream (Step 4 (20 m))	0.2481	2 peaks	-*	-*

* not quantified

A 3.3.2 Thiencarbazone-methyl and metabolites relevant for assessment

(a) FOCUS Step 1-2 – Risk envelope PECsw/sed of thiencarbazone-methyl and all metabolites [for screening level assessment]

Comments of zRMS:	Acceptable.

Reference:	**KCP 9.2.5/05**
Title:	Thiencarbazone-methyl (TCM) core PECsw EUR - Modelling core info document for surface water risk assessment in Europe
Report:	Bolekhan, A.; Porschewski, R.; 2017; EnSa-16-0916; M-600279-01-1
Authority registration No:	
Guideline(s):	not applicable
Deviations:	none
GLP/GEP:	no
Acceptability:	
Duplication (if vertebrate study):	

Notifier Comment: Core Info document, to explain origin and derivation of substance specific parameters used as input to subsequent surface water exposure simulations.

Reference:	**KCP 9.2.5/06**
Title:	Thiencarbazone-methyl (TCM) and metabolites: PECsw,sed FOCUS EUR - Use in arable crops in Europe
Report:	Bolekhan, A.; 2017; EnSa-17-0557; M-600622-01-1
Authority registration No:	
Guideline(s):	not applicable
Deviations:	none
GLP/GEP:	no
Acceptability:	
Duplication (if vertebrate study):	

Notifier comment: FOCUS Step 1/2 exposure calculation for generic risk envelope use, parent and all metabolites

(b) FOCUS Step 3 – PECsw/sed (maximum and TWA) of thiencarbazone-methyl [for Tier 1 assessment]

Comments of zRMS:	Acceptable.

Reference:	**KCP 9.2.5/07**
Title:	Thiencarbazone-methyl (TCM): PECsw,sed FOCUS EUR - Use in sugar beet in Europe
Report:	Bolekhan, A.; Hoerold, C.; 2016; EnSa-16-0807; M-582854-01-1
Authority registration No:	
Guideline(s):	not applicable
Deviations:	not applicable
GLP/GEP:	no
Acceptability:	
Duplication (if vertebrate study):	

Notifier comment: FOCUS Step 3-4 simulation for parent substance.

Report covers several use scenarios – thereof relevant to present product:

- DGR I "Sugar beet I" = Sugar beet, BBCH 10-18, 1×0.030 kg a.s./ha
- DGR II "Sugar beet II" = Sugar beet, BBCH 10-18, 2×0.015 kg a.s./ha, 10 d interval

(c) FOCUS Step 4 – PECsw (maximum and TWA) of thiencarbazone-methyl [for Tier 1 assessment considering mitigation options]

Comments of zRMS:	Acceptable.

FOCUS Step 4 exposure values are available from the same set of modelling reports referenced under point (b) before.

(d) FOCUS Step 3 – Timecourse of PECsw (FOCUS year) of thiencarbazone-methyl [for Tier 2C and Tier 3 assessment]

Comments of zRMS:	Only as additional information. No evaluated in core assessment.

In the FOCUS Step 3 simulations, the FOCUS model TOXSWA (TOXic substances in Surface WAters) calculates the pesticide distribution and concentrations in the water body that results for the various scenarios from the different routes of entry, in dependency of the substance parameters. The model version TOXSWA 4.4.3 provides detailed output files (*.out) which list surface water concentrations for the whole evaluation period of one year, in an hourly resolution. This data can be used for a refined exposure assessment and analysis of time-variable exposure patterns.

In order to obtain a meaningful description of these extensive data an evaluation tool (EPAT, Exposure Pattern Analysis Tool) was developed by Bastiansen et al. (2016), on behalf of the European Crop Protection Association (ECPA). EPAT uses the TOXSWA *.out files as its input together with a user-defined threshold concentration (here: RAC of substance) and scans the concentration time series in the *.out file for the exceedances of that given threshold value.

According to the program manual EPAT analyses and presents statistics on “events”, which are defined as periods during which pesticide concentrations exceed the defined threshold. For each event EPAT calculates its maximum concentration, duration, number of peaks (local maxima) and interval from the last event to the current event, as well as time weighted average concentration (TWAC) and area under the curve (AUC) for individual events and for moving window analysis. EPAT produces three output files per analysis, one containing a detailed description of exposure events (*_events.txt), one containing a summary of exposure events (*_event summary.txt) and one containing results of the moving window analysis (*_moving window summary.txt). The here presented exposure discussion is based on the results presented in the *_event summary.txt files on the number of events, their duration and interval between events if relevant. Other parameters were not used for the analysis.

The TOXSWA output files (*.out) to the simulation runs of the present assessments are submitted electronically as supplemental modelling information. The EPAT Tool and its Manual are available for download free of charge at the developer's website (RIFCON GmbH): Program download: https://www.rifcon.de/files/downloads/EPAT_1.1.1_setup.exe, Manual: Report No. R1520392.

(e) FOCUS Step 3-4 – Timecourse of PECsw (multi-year simulation) for thiencarbazone-methyl [for Tier 2C and Tier 3 assessment]

In response to concerns expressed by some regulators on the representativeness of the FOCUS model's single weather year in the context of refined risk assessment based on exposure pattern analysis, additional FOCUS calculations have been conducted for a period of 20 years (multi-year calculations). From this large data set, a statistically justified 90th percentile realistic worst case exposure pattern was derived for use in ecotoxicological risk assessment. As currently no official guidance is yet in place on such procedure, the simulation and risk assessment based here upon is intended to serve as supportive information only, confirming for the present product intended use pattern an adequate reliability of the standard assessment established on the official FOCUS medium year data. Due to its confirmatory character, methodology and results of the multi-year approach are presented here in the Appendix section of the present dRR, for the interested reader.

Comments of zRMS:	Only as additional information. No evaluated in core assessment.

Reference:	**KCP 9.2.5/03**
Title:	Multi-year PECsw calculations for sulfonylurea herbicides in Europe: Description of methodology
Report:	Bolekhan, A.; 2017; EnSa-17-0541; M-602115-01-1
Authority registration No:	
Guideline(s):	not applicable
Deviations:	none
GLP/GEP:	no
Acceptability:	
Duplication (if vertebrate study):	

This report outlines the methodology of multi-year simulations, and their output data interpretation. The document summary is presented in the corresponding chapter on the first active substance foramsulfuron, please refer to Appendix A 3.3.1 (e).

Comments of zRMS:	Only as additional information. No evaluated in core assessment.

Reference:	**KCP 9.2.5/08**
Title:	Thiencarbazone-methyl (TCM): PECsw FOCUS EUR (multi-year) - Use in maize and sugar beets in Europe
Report:	Heine, S.; Hammel, K.; Bolekhan, A.; 2017; EnSa-17-0354; M-592862-01-1
Authority registration No:	
Guideline(s):	not applicable
Deviations:	not applicable
GLP/GEP:	no
Acceptability:	
Duplication (if vertebrate study):	

Based on a multi-year extended FOCUS PEC_{sw} approach, representative exposure patterns were calculated for thiencarbazone-methyl use in sugar beet over 20 years, with an hourly resolution. To enable a direct use in ecotoxicological risk assessments, the data was statistically processed and characterised via the following descriptors:

- Predicted environmental concentrations in surface water,
- Annual number of exposure events exceeding the RAC,
- Duration of these events,
- Interval between these events

Moreover, the full output data depth (TOXSWA *.out files) was transferred electronically for use in subsequent models, i.e. served as exposure information base for ecological effect modelling (cf. dRR Part B Section 9).

Details of the substance and general GAP parameters used in the calculations have been summarised in Section 8.9 before. Actual application dates were determined by the PAT (pesticide application timer) included within SWASH. For the multiyear calculations the PAT was running over the whole simulation period to identify suitable application dates for each year. The date settings per scenario and simulation year are presented in the following:

Table A 5: Multi-year exposure pattern analysis: FOCUS Scenario related input parameters for PEC_{sw} calculations for the application of FSN+TCM OD 80 (50+30) - Use in sugar beet, 1 × 30 g thiencarbazone-methyl/ha

	FOCUS model crop (crop group)	Sugar beets (arable crops)
	Use pattern	30 g a.s./ha
	Appl. method (Run off CAM, depth inc.)	Ground spray (2 - appln foliar linear, 4 cm)
	PAT start date (relative to crop event or absolute)	Absolute
	PAT window range	30 days for all scenarios (min = 30 days)

Drainage scenario	Year	PAT start/end date (Julian day)	Application date	Drainage scenario	PAT start/end date (Julian day)	Application date
D3 Stream	1975	26-Apr/26-May	26-Apr	D4 Pond/Stream	05-May/04-Jun	08-May
	1976	26-Apr/26-May	29-Apr		05-May/04-Jun	07-May
	1977	26-Apr/26-May	24-May		05-May/04-Jun	15-May
	1978	26-Apr/26-May	16-May		05-May/04-Jun	07-May
	1979	26-Apr/26-May	19-May		05-May/04-Jun	05-May
	1980	26-Apr/26-May	29-Apr		05-May/04-Jun	10-May
	1981	26-Apr/26-May	26-Apr		05-May/04-Jun	05-May
	1982	26-Apr/26-May	26-Apr		05-May/04-Jun	10-May
	1983	26-Apr/26-May	19-May		05-May/04-Jun	05-May
	1984	26-Apr/26-May	25-Apr		05-May/04-Jun	05-May
	1985	26-Apr/26-May	06-May		05-May/04-Jun	14-May
	1986	26-Apr/26-May	30-Apr		05-May/04-Jun	18-May
	1987	26-Apr/26-May	28-Apr		05-May/04-Jun	24-May
	1988	26-Apr/26-May	25-Apr		05-May/04-Jun	07-May
	1989	26-Apr/26-May	09-May		05-May/04-Jun	16-May
	1990	26-Apr/26-May	30-Apr		05-May/04-Jun	07-May
	1991	26-Apr/26-May	27-Apr		05-May/04-Jun	21-May
	1992	26-Apr/26-May	04-May		05-May/04-Jun	14-May
	1993	26-Apr/26-May	26-Apr		05-May/04-Jun	05-May
	1994	26-Apr/26-May	27-Apr		05-May/04-Jun	07-May

	FOCUS model crop (crop group)			Sugar beet (arable crops)		
	Use pattern			30 g a.s./ha		
	Appl. method (Run off CAM, depth inc.)			Ground spray (2 - appln foliar linear, 4 cm)		
	PAT start date (relative to crop event or absolute)			Absolute		
	PAT window range			30 days for all scenarios (min = 30 days)		
Runoff scenarios	**Year**	**PAT start/end date (Julian day)**	**Application date**	**Runoff scenarios**	**PAT start/end date (Julian day)**	**Application date**
R1 Pond/Stream	1975	17-Apr/17-May	24-Apr	R3 Stream	21-Mar/20-Apr	21-Mar
	1976	17-Apr/17-May	17-Apr		21-Mar/20-Apr	03-Apr
	1977	17-Apr/17-May	17-Apr		21-Mar/20-Apr	21-Mar
	1978	17-Apr/17-May	17-Apr		21-Mar/20-Apr	25-Mar
	1979	17-Apr/17-May	07-May		21-Mar/20-Apr	25-Mar
	1980	17-Apr/17-May	28-Apr		21-Mar/20-Apr	28-Mar
	1981	17-Apr/17-May	17-Apr		21-Mar/20-Apr	21-Mar
	1982	17-Apr/17-May	18-Apr		21-Mar/20-Apr	22-Mar
	1983	17-Apr/17-May	21-Mar		21-Mar/20-Apr	21-Mar
	1984	17-Apr/17-May	26-Apr		21-Mar/20-Apr	21-Mar
	1985	17-Apr/17-May	18-Apr		21-Mar/20-Apr	01-Apr
	1986	17-Apr/17-May	30-Apr		21-Mar/20-Apr	28-Mar
	1987	17-Apr/17-May	22-Apr		21-Mar/20-Apr	27-Mar
	1988	17-Apr/17-May	22-Apr		21-Mar/20-Apr	25-Mar
	1989	17-Apr/17-May	23-Mar		21-Mar/20-Apr	23-Mar
	1990	17-Apr/17-May	17-Apr		21-Mar/20-Apr	21-Mar
	1991	17-Apr/17-May	19-Apr		21-Mar/20-Apr	25-Mar
	1992	17-Apr/17-May	17-Apr		21-Mar/20-Apr	17-Apr
	1993	17-Apr/17-May	20-Apr		21-Mar/20-Apr	06-Apr
	1994	17-Apr/17-May	11-May		21-Mar/20-Apr	21-Mar

Table A 6: Multi-year exposure pattern analysis: FOCUS Scenario related input parameters for PEC_{sw} calculations for the application of FSN+TCM OD 80 (50+30) - Use in sugar beet, 2 × 15 g thiencarbazone-methyl/ha

	FOCUS model crop (crop group)	Sugar beet (arable crops)
	Use pattern	2 × 15 g a.s./ha
	Appl. method (Run off CAM, depth inc.)	Ground spray (2 - appln foliar linear, 4 cm)
	PAT start date (relative to crop event or absolute)	Absolute
	PAT window range	30 days for all scenarios (min = 30 days)

Drainage scenario	**Year**	**PAT start/end date (Julian day)**	**Application date**	**Drainage scenario**	**PAT start/end date (Julian day)**	**Application date**
D3 Stream	1975	26-Apr/05-Jun	26-Apr 08-May	D4 Pond/Stream	05-May/14-Jun	08-May 22-May
	1976	26-Apr/05-Jun	29-Apr 16-May		05-May/14-Jun	07-May 07-Jun
	1977	26-Apr/05-Jun	24-May 03-Jun		05-May/14-Jun	15-May 28-May
	1978	26-Apr/05-Jun	16-May 31-May		05-May/14-Jun	07-May 17-May
	1979	26-Apr/05-Jun	19-May 02-Jun		05-May/14-Jun	05-May 03-Jun
	1980	26-Apr/05-Jun	29-Apr 09-May		05-May/14-Jun	10-May 21-May
	1981	26-Apr/05-Jun	26-Apr 15-May		05-May/14-Jun	05-May 15-May
	1982	26-Apr/05-Jun	26-Apr 14-May		05-May/14-Jun	10-May 26-May
	1983	26-Apr/05-Jun	19-May 01-Jun		05-May/14-Jun	05-May 19-May
	1984	26-Apr/05-Jun	25-Apr 10-May		05-May/14-Jun	05-May 21-May
	1985	26-Apr/05-Jun	06-May 17-May		05-May/14-Jun	14-May 27-May
	1986	26-Apr/05-Jun	30-Apr 01-Jun		05-May/14-Jun	18-May 28-May
	1987	26-Apr/05-Jun	28-Apr 26-May		05-May/14-Jun	24-May 06-Jun
	1988	26-Apr/05-Jun	25-Apr 13-May		05-May/14-Jun	07-May 23-May
	1989	26-Apr/05-Jun	09-May 22-May		05-May/14-Jun	16-May 26-May
	1990	26-Apr/05-Jun	30-Apr 19-May		05-May/14-Jun	07-May 20-May
	1991	26-Apr/05-Jun	27-Apr 08-May		05-May/14-Jun	21-May 01-Jun
	1992	26-Apr/05-Jun	04-May 14-May		05-May/14-Jun	14-May 27-May
	1993	26-Apr/05-Jun	26-Apr 06-May		05-May/14-Jun	05-May 15-May
	1994	26-Apr/05-Jun	27-Apr 09-May		05-May/14-Jun	07-May 20-May

	FOCUS model crop (crop group)			Sugar beet (arable crops)		
	Use pattern			2 × 15 g a.s./ha		
	Appl. method (Run off CAM, depth inc.)			Ground spray (2 - appln foliar linear, 4 cm)		
	PAT start date (relative to crop event or absolute)			Absolute		
	PAT window range			30 days for all scenarios (min = 30 days)		
Runoff scenarios	**Year**	**PAT start/end date (Julian day)**	**Application date**	**Runoff scenarios**	**PAT start/end date (Julian day)**	**Application date**
R1 Pond/Stream	1975	17-Apr/27-May	24-Apr 11-May	R3 Stream	21-Mar/30-Apr	21-Mar 01-Apr
	1976	17-Apr/27-May	17-Apr 01-May		21-Mar/30-Apr	03-Apr 13-Apr
	1977	17-Apr/27-May	17-Apr 01-May		21-Mar/30-Apr	21-Mar 07-Apr
	1978	17-Apr/27-May	17-Apr 09-May		21-Mar/30-Apr	25-Mar 08-Apr
	1979	17-Apr/27-May	07-May 20-May		21-Mar/30-Apr	25-Mar 07-Apr
	1980	17-Apr/27-May	28-Apr 19-May		21-Mar/30-Apr	28-Mar 11-Apr
	1981	17-Apr/27-May	17-Apr 03-May		21-Mar/30-Apr	21-Mar 07-Apr
	1982	17-Apr/27-May	18-Apr 13-May		21-Mar/30-Apr	22-Mar 02-Apr
	1983	17-Apr/27-May	20-Apr 19-May		21-Mar/30-Apr	21-Mar 22-Apr
	1984	17-Apr/27-May	26-Apr 09-May		21-Mar/30-Apr	21-Mar 19-Apr
	1985	17-Apr/27-May	18-Apr 03-May		21-Mar/30-Apr	01-Apr 15-Apr
	1986	17-Apr/27-May	30-Apr 18-May		21-Mar/30-Apr	28-Mar 22-Apr
	1987	17-Apr/27-May	22-Apr 23-May		21-Mar/30-Apr	27-Mar 23-Apr
	1988	17-Apr/27-May	22-Apr 06-May		21-Mar/30-Apr	25-Mar 13-Apr
	1989	17-Apr/27-May	18-Apr 29-Apr		21-Mar/30-Apr	23-Mar 07-Apr
	1990	17-Apr/27-May	17-Apr 29-Apr		21-Mar/30-Apr	21-Mar 31-Mar
	1991	17-Apr/27-May	19-Apr 02-May		21-Mar/30-Apr	25-Mar 10-Apr
	1992	17-Apr/27-May	17-Apr 23-May		21-Mar/30-Apr	21-Mar 02-Apr
	1993	17-Apr/27-May	20-Apr 22-May		21-Mar/30-Apr	06-Apr 18-Apr
	1994	17-Apr/27-May	11-May 26-May		21-Mar/30-Apr	21-Mar 12-Apr

EPAT exposure pattern analysis of FOCUS multi-year calculations was used to define representative exposure patterns for those surface water scenarios where $PEC_{sw,max}$ exceeded the regulatory acceptable concentration (RAC) at Step 3 in the standard FOCUS assessment. The multi-year exposure analysis was always based on the results at Step 3, except for the parameter 'number of events' that was determined also at Step 4 level. The RACs were set to 0.135 µg/L (derived from geometric mean EC_{50} of 1.35 µg/L for three aquatic macrophyte species, considering an assessment factor of 10), according to the EU agreed higher tier endpoint for thiencarbazone-methyl relevant for aquatic macrophyte risk assessment.

The following table shows the FOCUS scenarios which did not pass the risk assessment for the active substance thiencarbazone-methyl based on FOCUS Step 3 PEC_{sw} values for the present product (presented in Section 9 of this core document) and for which an exposure pattern analysis was conducted.

Table A 7: Overview of FOCUS scenarios (multi-year) for which an exposure pattern analysis is used for the present product

Scenario	Sugar beet, 1×30 g a.s./ha	Sugar beet, 2×15 g a.s./ha
D3 (Ditch)	X	-
D4 (Pond)	-	-
D4 (Stream)	-	-
R1 (Pond)	-	-
R1 (Stream)	-	X
R3 (Stream)	X	X

Several properties were identified that are important to evaluate the representativeness of exposure patterns. Representativeness was defined as being a realistic worst-case pattern that covers the majority of the 20 annual exposure patterns. The following properties were quantified for each of the entire FOCUS multi-year scenarios.

Table A 8: Exposure pattern properties that were quantified for each of the entire FOCUS multi-year scenarios

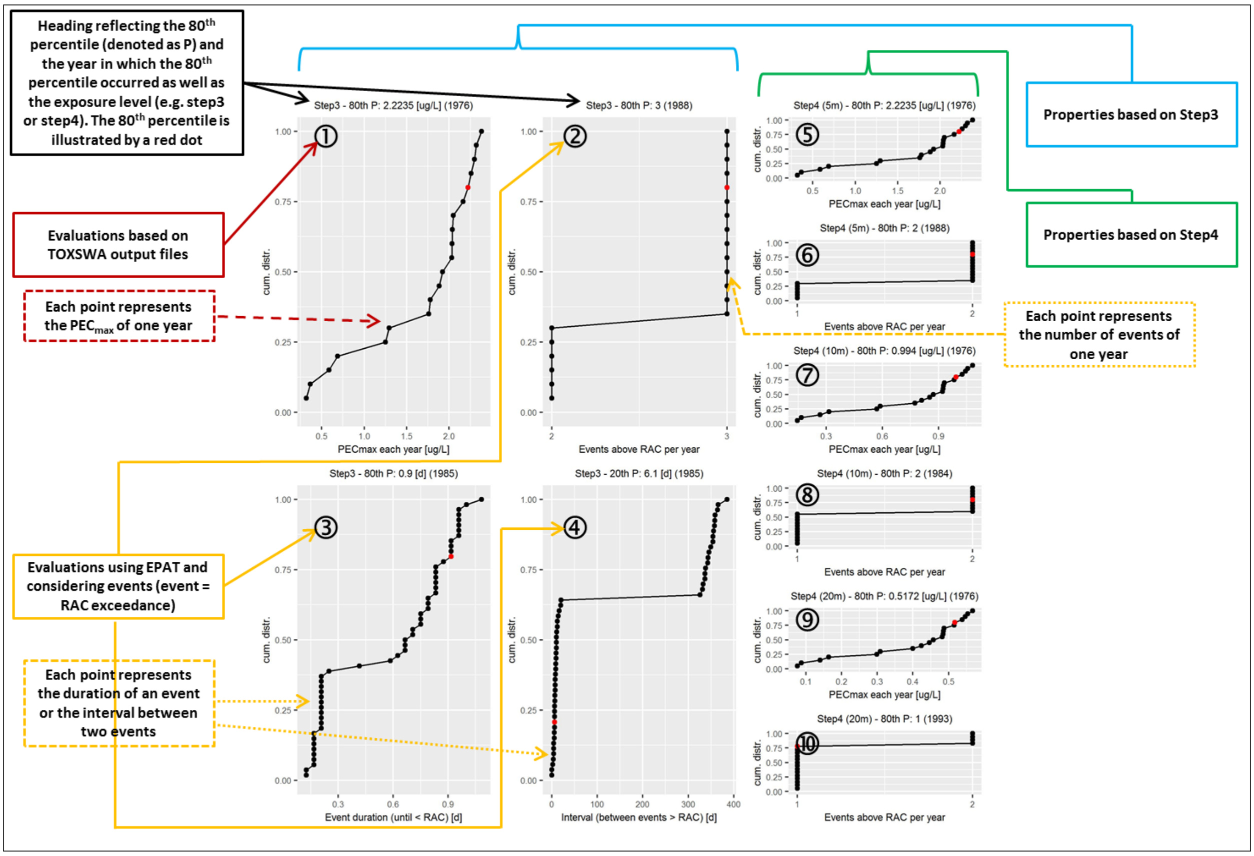
Number	PECmax	No. of events	Duration of events	Interval between events	FOCUS step
1	X				Step 3
2		X			Step 3
3			X		Step 3
4				X	Step 3
5	X				Step 4 (5m)
6		X			Step 4 (5m)
7	X				Step 4 (10m)
8		X			Step 4 (10m)
9	X				Step 4 (20m)
10		X			Step 4 (20m)

The PEC_{max} values for each year were directly obtained from the TOXSWA output files. The other properties describing the exposure patterns (number of events, duration of events, interval between events) were based on the analysis of EPAT (Bastiansen et al., 2016) and the entire (20 years) TOXSWA output files. EPAT considers the regulatory acceptable concentration (RAC) of a compound and scans the exposure pattern for events that exceed the RAC. Subsequently, an event is defined as a continuous time series of concentrations exceeding the RAC. PEC_{max} and the number of peak events (i.e. concentrations above the RAC) have been analysed individually for Step 3 and Step 4 (with 5m, 10m and 20m buffer). To reduce complexity, only FOCUS step 3 level results were used to quantify the duration of and the interval between events, which is a conservative simplification.

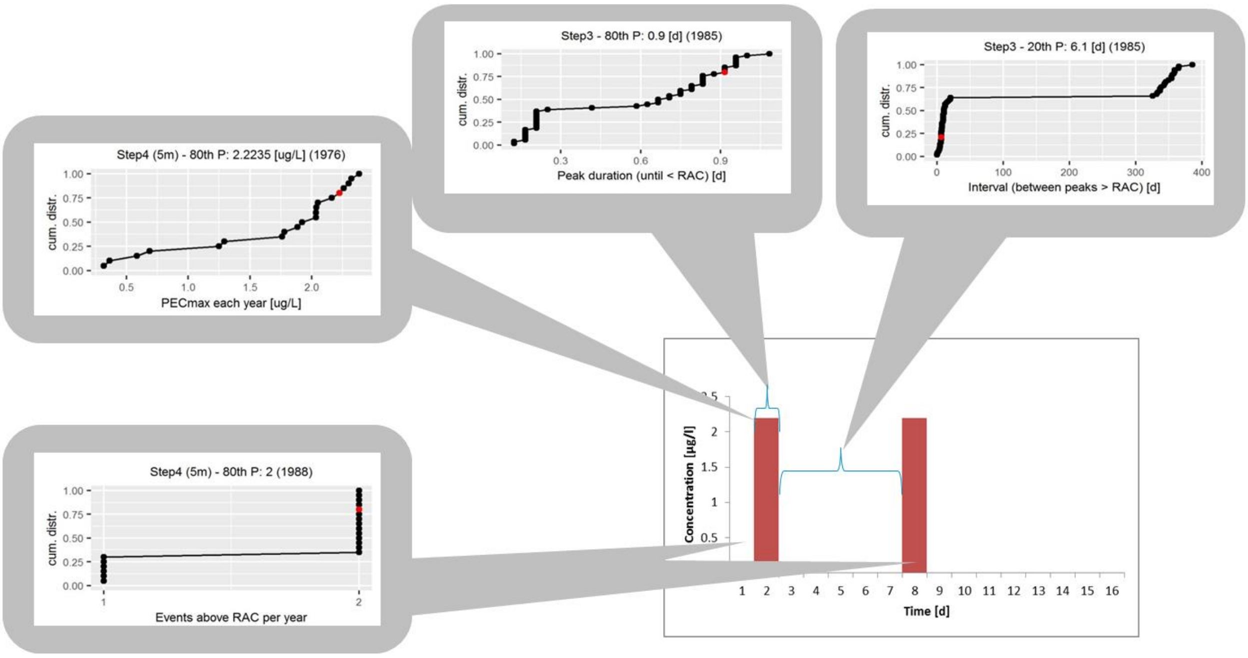
For each FOCUS multiyear scenario of relevance for further ecotoxicological assessment, ten cumulative distribution figures were generated illustrating the properties of the exposure pattern (as listed in the table above). To gain a representative exposure pattern that describes a realistic worst-case annual exposure situation, an artificial pattern was created by combining the 80th percentile PECsw,max, 80th percentile number of events and 80th percentile duration of events with the 20th percentile interval between peak events of the individual exposure pattern properties. Such approach will consolidate the 20-year-data generated into a single representative worst case exposure pattern usable for conservative risk assessment.

In the illustrated example (Figure A 10), at FOCUS Step 3 three events were identified. However, in the ecological tests used for risk assessment only exposure situations up to two events were experimentally addressed. Risk mitigation (Step 4, 5 m drift buffer) could therefore be applied to reduce the number of peak events (i.e. concentrations above the RAC) from three to two, so that the exposure situation could be compared to the ecological tests.

Figure A 10: Example figure describing the exposure pattern of a multi-year FOCUS scenario



Synthesis of a 20-year characteristic and conservative exposure pattern:
(example case for Step 4 – 5 m):



FOCUS multiyear Scenario	80th perc. PECmax [µg/L]	80th perc. events above Tier 1 RAC	80th perc. event duration above Tier 1 RAC [d]	20th per. interval betw. events above Tier 1 RAC [d]
Example from Figure A 10 – Step 3	2.2235	3 peaks	0.9	6.1
Example from Figure A 10 – Step 4 (5 m)	2.2235	2 peaks	0.9	6.1
Remarks:	*taken from Step 4#*	*taken from Step 4*	*Step 3 value as conservative simplification*	*Step 3 value as conservative simplification*
	80th perc. PECmax assumed for both peaks, as conservative simplification			

In this example, PECmax is driven by run-off entry, and therefore not mitigated by 5 m drift buffer. However, one peak at Step 3 is a drift-peak, which is mitigated at Step 4. This reduces the number of events from 3 to 2 peaks.

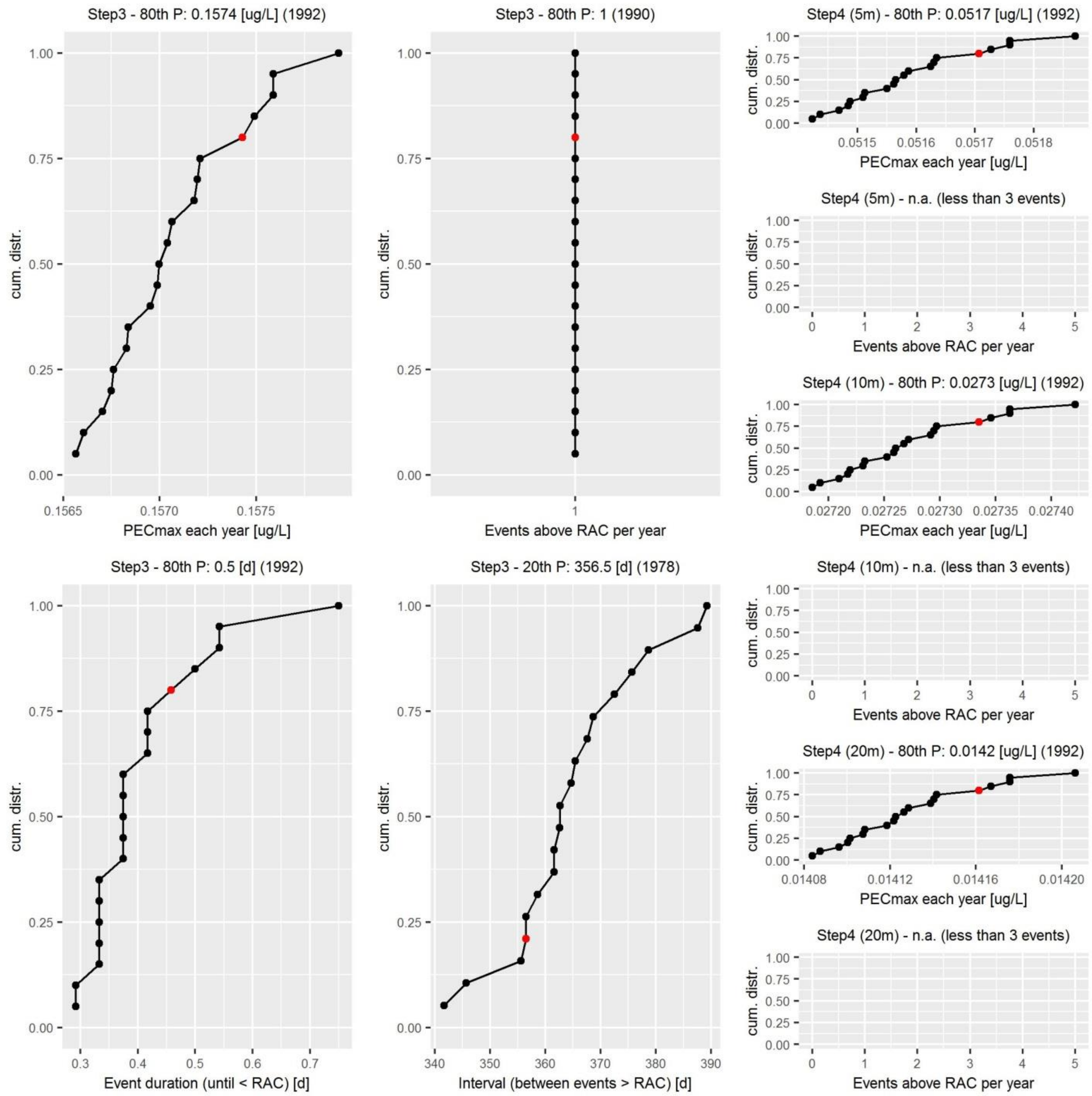
All properties mentioned above are considered important when comparing a representative FOCUS exposure pattern with the exposure regime of an ecotoxicological study.

Detailed further information on the approach is found provided in the original modelling document, also including statistical justifications for all selections made.

Results of the exposure pattern analysis:

The representative exposure pattern properties from each of the relevant FOCUS scenario multiyear simulations derive as presented in the following; for ecotoxicological interpretation to these patterns reference is made to dRR Section 9.5.

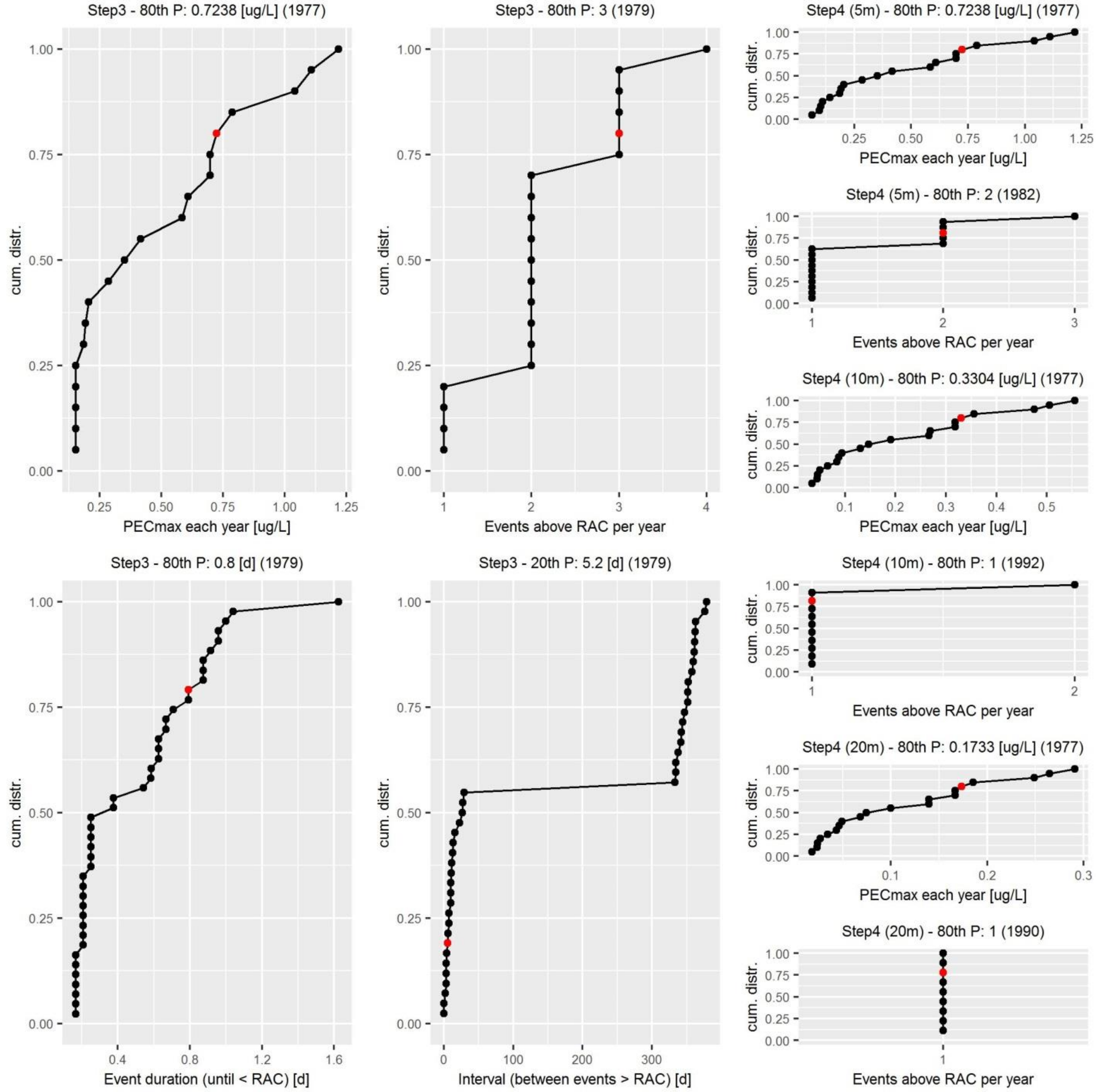
Figure A 11: D3 ditch - results of multi-year exposure pattern analysis for thiencarbazone-methyl
Use: Sugar beet, 1×30 g a.s./ha



20-year characteristic exposure pattern:

FOCUS multiyear Scenario	80th perc. PECmax [µg/L]	80th perc. events above Tier 1 RAC	80th perc. event duration above Tier 1 RAC [d]	20th per. interval betw. events above Tier 1 RAC [d]
D3 ditch (Step 3)	0.1574	1 peak	0.5	Not relevant

Figure A 12: **R3 stream - results of multi-year exposure pattern analysis for thiencarbazone-methyl**
Use: Sugar beet, 1×30 g a.s./ha



20-year characteristic exposure pattern:

FOCUS multiyear Scenario	80th perc. PECmax [µg/L]	80th perc. events above Tier 1 RAC	80th perc. event duration above Tier 1 RAC [d]	20th per. interval betw. events above Tier 1 RAC [d]
R3 stream (Step 3)	0.7238	3 peaks	0.8	5.2
R3 stream (Step 4 (10 m))	0.3304	1 peak	-*	-*

* not quantified

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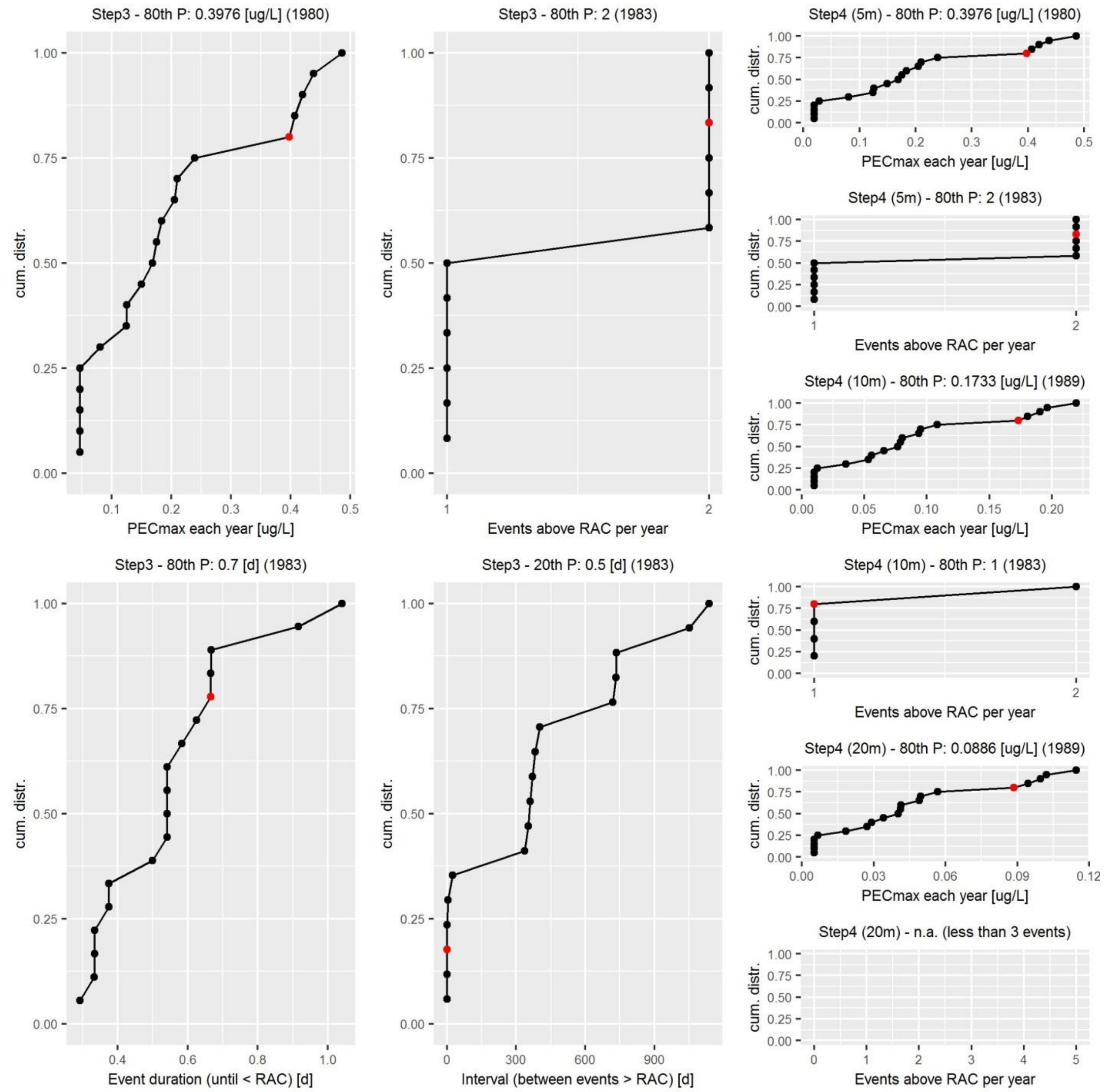
Figure A 13: **R1 stream - results of multi-year exposure pattern analysis for thiencarbazone-methyl**
Use: Sugar beet, 2×15 g a.s./ha

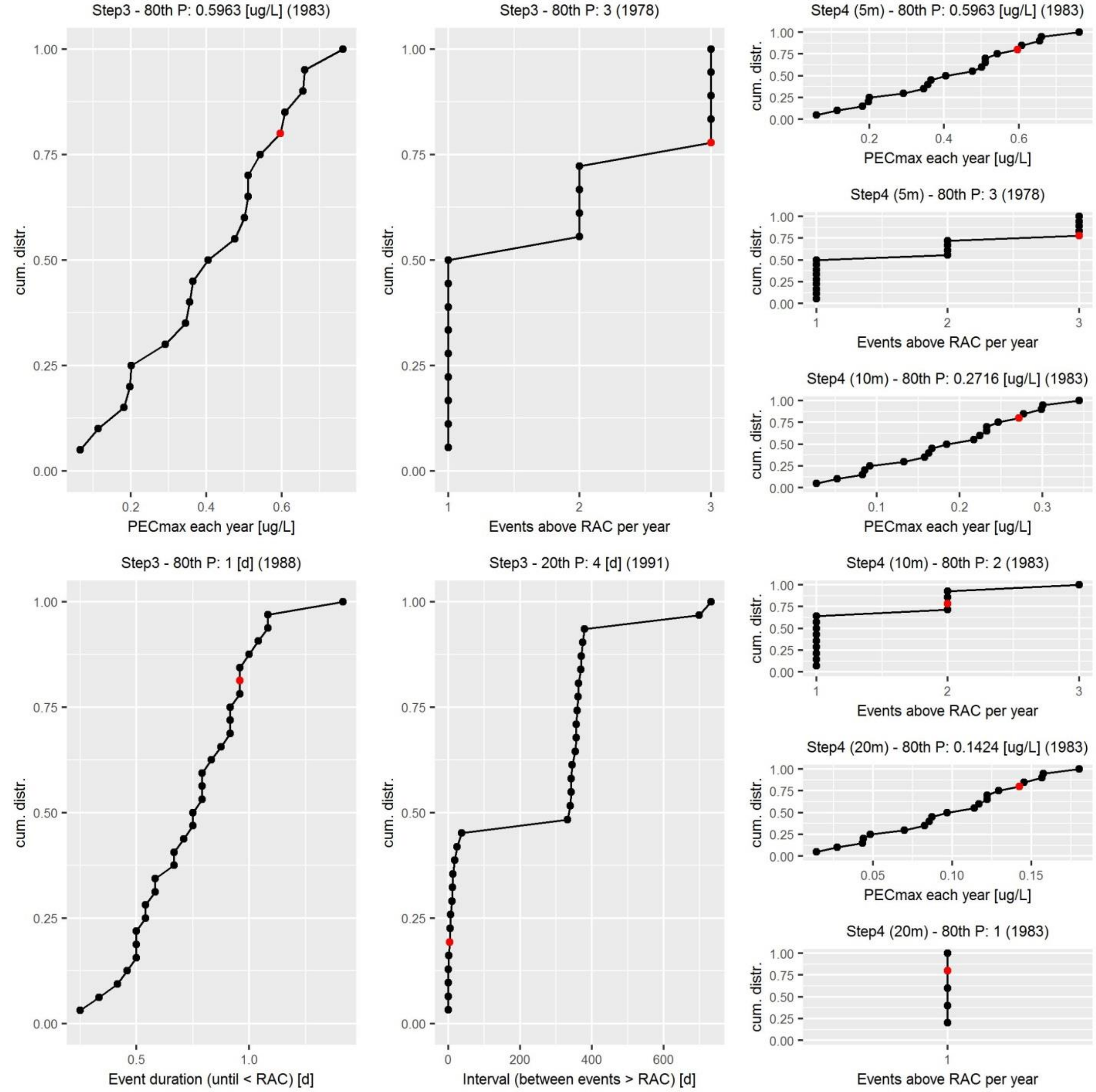


20-year characteristic exposure pattern:

FOCUS multiyear Scenario	80th perc. PECmax [µg/L]	80th perc. events above Tier 1 RAC	80th perc. event duration above Tier 1 RAC [d]	20th per. interval betw. events above Tier 1 RAC [d]
R1 stream (Step 3)	0.3976	2 peaks	0.7	0.5
R1 stream (Step 4 10 m))	0.1733	1 peak	-*	-*

* not quantified

Figure A 14: R3 stream - results of multi-year exposure pattern analysis for thiencarbazone-methyl
Use: Sugar beet, 2×15 g a.s./ha



20-year characteristic exposure pattern:

FOCUS multiyear Scenario	80th perc. PECmax [µg/L]	80th perc. events above Tier 1 RAC	80th perc. event duration above Tier 1 RAC [d]	20th per. interval betw. events above Tier 1 RAC [d]
R3 stream (Step 3)	0.5963	3 peaks	1.0	4.0
R3 stream (Step 4 10 m)	0.2716	2 peaks	-*	-*

* not quantified