FINAL REGISTRATION REPORT

Part B

Section 9

Ecotoxicology

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) art 43

Applicant: **Bayer Crop Science Division**

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

MS Finalisation date: **10/2021, 12/2021**

Version history

When	What
31/08/2020	Original Bayer Crop Science document (Regulation 1107/2009 - Art. 43) Foramsulfuron
October 2021	Finalisation of the assessment by zRMS
December 2021	Final version prepared by zRMS after Commenting period

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9 Ecotoxicology (KCP 10)

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 ecotoxicological properties of the active substance **foramsulfuron** have 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 ecotoxicological properties of the active substance **thiencarbazone-methyl** have 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 risk 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 but are not assigned to section numbers to avoid changing the official numbering system of the dRR format.

9.1 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 9 of the dossier.

Table 9.1-1: Table of critical GAPs

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
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: devel-opmental stages of the pest or pest group)	**Application**				**Application rate**			PHI (days)	Remarks: e.g. g saf-ener/ synergist per ha	**Conclusion**						
					Method / Kind	Timing / Growth stage of crop & season	Max. num-ber a) per use b) per crop/ season	Min. inter-val 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			Birds	Mammals	Aquatic organisms	Bees	Non-target arthro-	Soil organisms	Non-target plants
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								
32	POL	Sugar beet (BEAVA) Fodder beet (BEAVC)***	F	AETCY, ECHCG, VI-OAR, STEME, LAM-PU, MATIN, CHEAL, GALAP, POLCO, PO-LAV, 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								

FSN = Foramsulfuron; TCM = Thiencarbazone-methyl

* 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 in only some countries (refer to B0 document for the countries having a registration for herbicide tolerant fodder beet use)

Explanation for column 15 – 21 "Conclusion"

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

Remarks table:

(1) Numeration necessary to allow references
(2) Use official codes/nomenclatures of EU
(3) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(4) 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
(5) Scientific names and EPPO-Codes of target pests/diseases/ weeds or when relevant the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named
(6) Method, e.g. high-volume spraying, low volume spraying, spreading, dusting, drench
Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(7) Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(8) The maximum number of application possible under practical conditions of use must be provided
(9) Minimum interval (in days) between applications of the same product.
(10) For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products
(11) The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
(12) If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
(13) PHI - minimum pre-harvest interval
(14) Remarks may include: Extent of use/economic importance/restrictions

9.1.1 Overall conclusions

zRMS comment:

The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. The changes are introduced directly as text in blue. Not agreed or not relevant information is struck through and shaded for transparency.

In order to comply with the provisions of Regulation (EC) No 1107/2009 (Commission Implement-ing Regulation (EU) 2015/2033) and according to Art. 43 of Regulation (EC) No 1107/2009, and in accordance with the guidance document SANCO/2010/13170, this risk assessment report for the Ecotoxicology" only applies for the active substance foramsulfuron following its renewal of approval.

New data provided by the applicant for the other active substance (thiencarbazone-methyl) are not reviewed by zRMS. They are presented as informative data only. Provisions of the initial authorization remain.

9.1.2 Effects on birds (KCP 10.1.1), Effects on terrestrial vertebrates other than birds (KCP 10.1.2), Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3)

The risk assessments for birds and mammals meet the trigger criteria at screening level, for all intended uses of product FSN+TCM OD 80 (50+30). No unacceptable risk resulted also from the assessment of exposure via drinking water, and for secondary poisoning via prey like fish and earthworms. The above assessments do not raise specific concern for other terrestrial vertebrate wildlife such as reptiles and amphibians.

No measures for exposure mitigation need to be taken into account for the protection of birds, mammals, and other terrestrial vertebrate wildlife.

9.1.2.1 Effects on aquatic organisms (KCP 10.2)

Acceptable risk for all aquatic organisms other than macrophytes could be demonstrated in a screening-level risk assessment (FOCUS Steps 1-2) for the active substances contained in product FSN+TCM OD 80 (50+30), and their metabolites.

For macrophytes, refined assessments were presented for **the a.s. foramsulfuro**n ~~following the tiered approach of the EFSA Aquatic Guidance Document,~~ and resulted in overall conclusions as follows:

- **for use group B (rate 1.0 L prod/ha = 50 g/ha FSN + 30 g/ha TCM):** ~~the risk for aquatic organisms is considered acceptable without requiring measures for exposure mitigation.~~

- **for use group C (rate 2 x 0.5 L prod/ha = 2 x 25 g/ha FSN + 2 x 15 g/ha TCM):** ~~the risk for aquatic organisms is considered acceptable without requiring measures for exposure mitigation.~~

- **For use group B (rate 1.0 L prod/ha = 1 x 50 g/ha FSN):**

- D3 (ditch) -5 meter non spray buffer zone
- D4 (stream)- 5 meter non spray buffer zone
- R1 (stream) – 10 meter non spray buffer zone
- R3 (stream) - 20 meter non -spray buffer zone

- **For use group C - use on sugar beet / rate 2 × 25 g FSN/ha (2 × 0.5 L prod./ha)**

- D3 (ditch) -5 meter non spray buffer zone
- D4 (stream)- 5 meter non spray buffer zone
- R1 (stream) – 20 meter non spray buffer zone
- **R3 (stream) unresolved risk with 20 meter non spray buffer zone**

For **the second active substance -hiencarbazone-methyl to protect aquatic organism** the following risk mititagation measures are applied to surface water bodies:

Group B use on sugar beet / rate 1 × 30 g a.s./ha (1 × 1.0 L prod./ha)
- D3 scenario- 5 meter buffer non-spray zone
- R3 scenario – 10 meter non-spray zone

Group C - use on sugar beet / rate 2 × 15 g a.s./ha (2 × 0.5 L prod./ha)
- R1 scenario - 10 meter buffer non-spray zone
- R3 scenario – 20 meter non-spray zone

Combined risk assessment

Use group B (1 × 50 g /ha FSN + 1 × 30 g /ha TCM (1 × 1.0 L prod./ha)

The risk is considered acceptable for the following scenarios:
D3- 10 meter non-spray zone
D4 pond - resolved at STEP 3
D4 stream – 10 meter non spray zone
R1 pond –resolved at STEP 3
R1 stream – 20 meter non –spray buffer zone
R3 stream- unresolved with 20 meter non –spray buffer zone

Use group C (2 × 25 g /ha FSN + 2 × 15 g /ha TCM (2 × 0.5 L prod./ha)

D3- 5 meter non-spray zone
D4 pond - resolved at STEP 3
D4 stream – 5 meter non spray zone
R1 pond –resolved at STEP 3
R1 stream – unresolved with 20 meter non –spray buffer zone
R3 stream- unresolved with 20 meter non –spray buffer zone

Therefore, further refinement should be considered at MSs level for the following scenarios:

- R3 stream for use group B (1 × 50 g /ha FSN + 1 × 30 g /ha TCM (1 × 1.0 L prod./ha).
- R1 stream and R3 stream for use group C (2 × 25 g /ha FSN + 2 × 15 g /ha TCM (2 × 0.5 L prod./ha).

9.1.2.2 Effects on bees (KCP 10.3.1)

The risk to bees was demonstrated to be acceptable for all intended uses of product FSN+TCM OD 80 (50+30), based on assessments for the active substances, and the formulated product.
No measures for exposure mitigation need to be taken into account for the protection of bees.
According to Reg.284/2009 the chronic tests for adults bees and larve should be provided by the applicant.

9.1.2.3 Effects on arthropods other than bees (KCP 10.3.2)

The risk to arthropods other than bees is acceptable for all intended uses of product FSN+TCM OD 80 (50+30), based on the presented assessments for the in-field and the off-field exposure situations.
No measures for exposure mitigation need to be taken into account for the protection of arthropods other than bees.

9.1.2.4 Effects on non-target soil meso- and macrofauna (KCP 10.4), Effects on soil microbial activity (KCP 10.5)

No unacceptable risk to the soil meso- and macrofauna and to the soil microbial activity is concluded from the risk assessments presented, for all intended uses of the product FSN+TCM OD 80 (50+30).
No measures for exposure mitigation need to be taken into account for the protection of soil organisms.

9.1.2.5 Effects on non-target terrestrial plants (KCP 10.6)

Based on probabilistic risk assessment it is concluded that the use of the product will not produce unacceptable effects on terrestrial non-target plants growing near treated fields, when considering the following mitigation measures:

- a 10 m buffer zone, or alternatively 5 m buffer zone and 50% drift reducing spray nozzles, or alternatively 90% drift reducing spray nozzles for the application rate 1 x 1.0 L product/ha (use group B).
- a 5 m buffer zone, or alternatively 75% drift reducing spray nozzles for the application rate 2 x 0.5 L product/ha (use group C).

The position of the zRMS-PL is that the trigger value of 1 should be used in the probabilistic risk assessment with a HR5 value; however it is noted that this is not a Central Zone harmonised position and other member states may consider the use of a different trigger value at National Registration.
The risk migitation measures should be considered at MSs level depending on their national requirments.

Based on the deterministic risk assessment it is concluded that the use of the product will not produce unacceptable effects on terrestrial non-target plants growing near treated fields, when considering the following mitigation measures:

Use group B (1 x 1 L product/ha)

- 5 m in-crop buffer with 90% drift reducing nozzles or
- 10 m in-crop buffer with 75 % drift reducing nozzles

Use group C (2 x 0.5 L product/ha)
-5 m in-crop buffer with 50% drift reducing nozzles or
or

- **no buffer with 90** % drift reducing nozzles

The risk migitation measures should be considered at MSs level depending on their national requirments.

9.1.2.6 Effects on other terrestrial organisms (flora and fauna) (KCP 10.7)

No further information is available or considered to be necessary.

9.1.3 Grouping of intended uses for risk assessment

The following table documents the grouping of the intended uses to support application of the risk envelope approach (according to SANCO/11244/2011).

Table 9.1-2: Critical use pattern of FSN+TCM OD 80 (50+30) grouped according to application rate

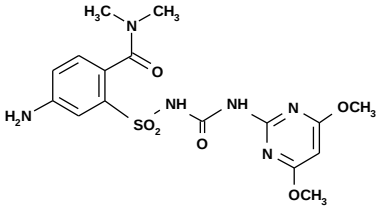
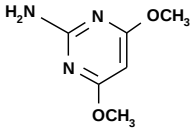
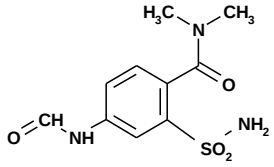
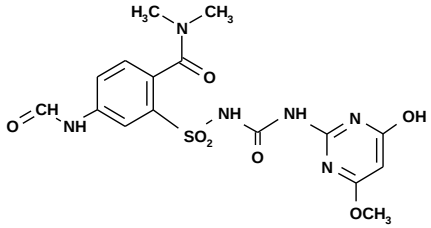
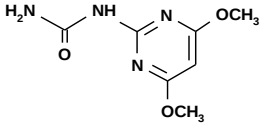
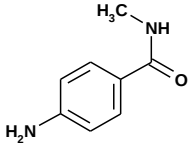
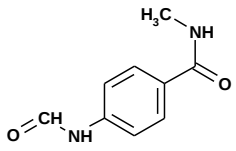
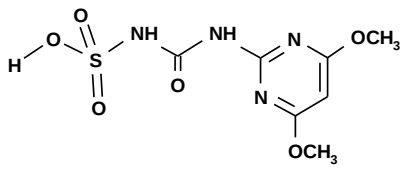
Grouping according to application pattern (number of application and application rate)			
Group	**Intended uses**	**relevant use parameters for grouping**	**relevant parameter or value for sorting**
A	Generic risk envelope covering all product uses of active substances FSN and TCM in Europe, see explanation below #)	Application patterns: 1 × 60 g FSN/ha 1 × 40 g TCM/ha BBCH < 20 [no crop interception], year round use	Maximum application rate per a.s. (covering all products and uses in Europe)
B	Sugar beet, single application use no. 22 [POL] use no. 23 [AUT] use no. 24 [BEL] use no. 25 [CZE] use no. 26 [HUN] use no. 27 [SVK] use no. 28 [GBR] use no. 29 [NLD] use no. 30 [ROU] use no. 31 [IRE]	Application rate: 1 x 1.0 L prod./ha (50 g FSN/ha; 30 g TCM/ha) BBCH 10-18	worst case single application rate for use on crop type sugar beet
C	Sugar beet, multiple application use no. 32 [POL] use no. 33 [AUT] use no. 34 [BEL] use no. 35 [CZE] use no. 36 [SVK] use no. 37 [NLD] use no. 39 [HUN] use no. 40 [IRE]	Application rate: 2 x 0.5 L prod./ha (25 g FSN/ha; 15 g TCM/ha) BBCH 10-18	worst case multiple application rate for use on crop type sugar beet

#) In cases where the risk assessment is passed with a wide margin of safety already on screening or 1st tier level, exposure and risk characterisations for the active substances foramsulfuron and thiencarbazone-methylare presented as a generic 'risk envelope' approach, which will cover all intended uses of these active substances accross products marketed by Bayer in Europe. **The European envelope rate considered for foramsulfuron is 60 g a.s./ha and for for thiencarbazone-methyl is 40 g a.s./ha.** Other crop or GAP dependent parameters relevant for the assessments are all set to the worst case (BBCH 00-39, 0 % crop interception, no tillage, application all year round). Even though for a particular product lower use rates or less critical application parameters may apply, this generic risk envelope provides a simple and efficient tool to conservatively cover many areas of the risk assessment.

9.1.4 Consideration of metabolites

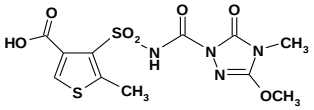
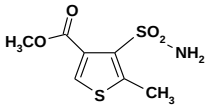
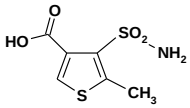
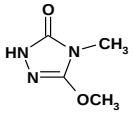
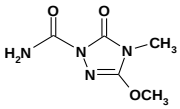
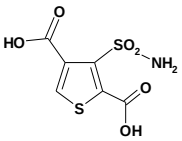
A list of metabolites found in environmental compartments is provided below.

Table 9.1-3: Metabolites of foramsulfuron

Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Risk assessment required?
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)	Yes, soil and aquatic organisms
AE F092944	155.16		Soil: 17.8% (aerobic) Water: 2.2% Sediment: 6.7% Water/sediment: 7.3% Water: 26.5% (photolysis buffer)	Yes, soil and aquatic organisms
AE F153745	271.3		Soil: 7.8% (aerobic) Water: 12.3% Sediment: 13.6% Water/sediment: 24.6%	Yes, soil and aquatic organisms
AE 0338795	438.42		Water: 17.0% Sediment: 6.8% Water/sediment: 23.7%	Yes, aquatic organisms
AE F099095	198.18		Water: 35.2% (photolysis buffer)	Yes, aquatic organisms
4-amino-N-methylbenzamide	150.18		Water: 10.2% (photolysis buffer)	Yes, aquatic organisms
4-formamido-N-methylbenzamide*	178.19		Water: 16.6% (photolysis buffer)	Yes, aquatic organisms
foramsulfuron-sulfamic acid	278.24		Water: 14.2% (photolysis buffer)	Yes, aquatic organisms

* also named as 4-formylamido-N-methylbenzamide

Table 9.1-4: Metabolites of thiencarbazone-methyl

Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Risk assessment required?
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%	Yes, soil and aquatic organisms
BYH 18636-sulfonamide / AE 1364547	235.3		Soil: 15.6% (aerobic) Water: 4.3% 41% (hydrolysis) Sediment: 2.7% Water/sediment: 7.0%	Yes, soil and aquatic organisms
BYH 18636-sulfonamide carboxylic acid / AE 1395853	221.3		Soil: 21.2% (aerobic) Water: 45.6% Sediment: 21.3% Water/sediment: 66.9%	Yes, soil and aquatic organisms
BYH 18636-MMT / AE 1277106	129.1		Soil: 20.6% (aerobic) Water: 24.9% 41.5% (hydrolysis) Sediment: 7.8% Water/sediment: 30.7%	Yes, soil and aquatic organisms
BYH 18636-triazolinone-carboxamide / AE 1430601	172.1		Soil: 8.1% (photolysis)	Yes, soil organisms
BYH 18636-dicarboxy-sulfonamide / BCS-AA10007	251.2		Water: 18.9% Sediment: - Water/sediment: 23.9%	Yes, aquatic organisms

9.2 Effects on birds (KCP 10.1.1)

9.2.1 Toxicity data

Foramsulfuron

Avian toxicity studies have been carried out with foramsulfuron. Full details of these studies are provided in the respective EU Renewal Assessment Report and related documents, presented agreed endpoints were taken from EFSA Journal 2016;14(3):4421.

Table 9.2-1: Endpoints and effect values relevant for the risk assessment for birds - Foramsulfuron

Species	Substance	Exposure System	Results	Reference
Bobwhite quail Mallard duck	Foramsulfuron	Oral Acute	LD_{50} > 2000 mg as/kg bw	EFSA Journal 2016;14(3):4421
Bobwhite quail	Foramsulfuron	Dietary Reproductive toxicity, 21 weeks	NOEL = 104 mg/kg bw/d	EFSA Journal 2016;14(3):4421

Thiencarbazone-methyl

Avian toxicity studies have been carried out with thiencarbazone-methyl. Full details of these studies are provided in the EU draft assessment Report and related documents; presented agreed endpoints were taken from EFSA Journal 2013; 11(7): 3270.

Table 9.2-2: Endpoints and effect values relevant for the risk assessment for birds - Thiencarbazone-methyl

Species	Substance	Exposure System	Results	Reference
Bobwhite quail	Thiencarbazone-methyl	Oral Acute	LD_{50} > 2000 mg as/kg bw	EFSA Journal 2013;11(7):3270
Mallard duck	Thiencarbazone-methyl	Dietary, reproductive toxicity, 21 weeks	NOEL = 24 mg/kg bw/d	EFSA Journal 2013;11(7):3270

FSN+TCM OD 80 (50+30)

Possible risk to birds exposed to the formulated product **FSN+TCM OD 80 (50+30)** can be predicted on the basis of data for the individual active substances in a combined toxicity assessment. Therefore, no toxicity data of a vertebrate study with the formulation is presented here.

zRMS comment:
zRMS agrees with the endpoint performed in the Tables above. We also agree that for formulated product FSN+TCM OD 80 (50+30) the toxicity can be predicted on the basis of data for the individual active substances in a combined toxicity assessment.

9.2.1.1 Justification for new endpoints

No deviation from the EU agreed endpoints.

9.2.2 Risk assessment for spray applications

The risk assessment is based on the methods presented in the Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438; hereafter referred to as EFSA/2009/1438).
To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group A covers the risk for birds from all intended uses (see 9.1.3).

9.2.2.1 First-tier assessment (screening/generic focal species)

Foramsulfuron

For the active substance foramsulfuron - as the risk assessment is passed on screening level - exposure and risk characterisation is presented as a generic 'risk envelope' approach: The risk assessment is based on worst case application rates which cover all intended European uses across different products in which foramsulfuron may be included.
The results of the acute and reproductive screening assessments for foramsulfuron are summarised in the following table.

Table 9.2-3: Screening assessment of the acute and long-term/reproductive risk for birds of foramsulfuron due to the use of FSN+TCM OD 80 (50+30) in sugar beet (use group A)

Intended use	**Risk envelope approach (use group A): maize, sugar beet, nursery (conifer), BBCH 10-34**				
Active substance/product	foramsulfuron				
Application rate (g/ha)	risk envelope approach: 1 × 60				
Acute toxicity (mg/kg bw)	>2000				
TER criterion	10				
GAP crop	**Indicator species for screening**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Maize, sugar beet *	Small omnivorous bird	158.8	1.0	9.5	>209.9
Reprod. toxicity (mg/kg bw/d)	104				
TER criterion	5				
GAP crop	**Indicator species for screening**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Maize, sugar beet *	Small omnivorous bird	64.8	1.0 x 0.53	2.1	50.5

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.
* covers also nurseries (conifer)

Thiencarbazone-methyl

For the active substance thiencarbazone-methyl - as the risk assessment is passed on screening level -

exposure and risk characterisation is presented as a generic 'risk envelope' approach: The risk assessment is based on worst case application rates which cover all intended European uses across different products in which thiencarbazone-methyl may be included.
The results of the acute and reproductive screening assessments for thiencarbazone-methyl are summarised in the following table.

Table 9.2-4: Screening assessment of the acute and long-term/reproductive risk for birds of thiencarbazone-methyl due to the use of FSN+TCM OD 80 (50+30) in sugar beet (use group A)

Intended use	**Risk envelope approach (use group A): cereals, maize, sugar beet, non-cropped area, BBCH 00-32**
Active substance/product	thiencarbazone-methyl
Application rate (g/ha)	risk envelope aproach 1 × 40
Acute toxicity (mg/kg bw)	>2000
TER criterion	10

GAP crop	**Indicator species for screening**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Cereals, maize, sugar beet *	Small omnivorous bird	158.8	1.0	6.4	>315

Reprod. toxicity (mg/kg bw/d)	24
TER criterion	5

GAP crop	**Indicator species for screening**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Cereals, maize, sugar beet *	Small omnivorous bird	64.8	1.0 x 0.53	1.4	17

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.
* covers also non-cropped areas

Birds - Assessment of combined toxicity
As requested by the Central Zone when a product contains more than one active substance, an additional assessment on combined toxicity risk has to be presented. It is considered that a quantitative toxicity risk assessment according to concentration addition is not needed if one of the following points applies:

- The risk assessment for all active substances in the product passes with a high margin of safety
- One active substance clearly drives the risk assessment

These conditions are assessed following a step-wise approach. A detailed description of this approach is presented in a separate document (Gladbach, A., Ebeling, M., Weyers, A., 2017, M-571377-02-1). Note that for the calculation only the scenario with the lowest TER values was considered (most critical scenario). This safely covers all other scenarios.

1st step: Margin of safety
Condition: all TER values are > Trigger x n (n = number active substances in the mixture)

2nd step: Risk per fraction
Condition: One a.s. contributes to ≥ 90% of the predicted combined toxicity of the product.
Assessment: The contribution of each individual a.s. to the combined toxicity (risk per fraction, rpf) is estimated based on the following equation:

$$rpf_{a.s.1} = \frac{1}{TER_{a.s.1}} / (\frac{1}{TER_{a.s.1}} + \frac{1}{TER_{a.s.2}} ... + \frac{1}{TER_{a.s.i}})$$

The estimation is based on TER values from the same refinement level to assure comparability.

3rd step: TER_{MIX} calculation

Condition: The combined toxicity is acceptable if $TER_{MIX} \geq 10$ (acute) or 5 (long-term)

Assessment: The combined toxicity risk (TER_{MIX}) with concentration-addition is estimated based on the following equation:

$$TER_{mix} = 1/(\frac{1}{TER_{a.s.1}} + \frac{1}{TER_{a.s.2}} ... + \frac{1}{TER_{a.s.i}})$$

As the notifier experienced differing preferences by national reviewers for one or the other step, results of all three steps are considered below:

Table 9.2-5: Combined toxicity assessment – birds

Intended use	Risk envelope approach covering all uses (use group A)					
Active substances	Foramsulfuron + thiencarbazone-methyl					
Application rate (g/ha)	1 × (60 g/ha + 40 g/ha)					
Scenario / Generic focal species	**TER values [1]**		**Trigger a.s.1/a.s.2/ a.s.3**	**1st step all TER ≥ trigger × n**	**2nd step Rpf_{max}**	**3rd step TER_{MIX}**
	FSN	**TCM**				
Acute / small omnivorous bird	>209.9	>315	10/10	Yes	not applicable[#]	not needed
Long-term / small omnivorous bird	50.5	17	5/5	Yes	not applicable[#]	not needed

[1)] Worst-case TER values as listed in point 9.2.2.1

[#] The rpf calculation is not meaningful if due to a risk envelope approach for one or more individual substances the ratio of the active substances in the assessed mixture differs from the ratio in the formulation.

In all cases the TER values are ≥ Trigger × n (n = number of active substances in the mixture), indicating no unacceptable risk from the use of the product.

zRMS comments:

The risk assessment at screening and Tier 1 is considered acceptable. The risk assessment is based on the methods presented in the Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438; hereafter referred to as EFSA/2009/1438). Safe use of active substances for birds were confirmed based on TER_A and TER_{LT} above the trigger values of 10 and 5, respectively , indicating the acute and long-term risk is acceptable.

According to the toxicity data of the two active substances (LD_{50} >2000 mg/kg bw for both active substances), zRMS considered that an increase of the toxicity of the product is not expected. In addition, the combined acute and long-term assessment of two active substances for birds was considered acceptable.

In reference to metabolites, for a.s. Foramsulfuron, it was stated in the EFSA conclusion (2016): "On the basis of the available data and risk assessments, a low acute and long-term risk to birds and wild mammals was concluded for all routes of exposure".

For a.s.-Thiencarbazone-methyl the risk was assessed as low at the first-tier level for birds and mammals in the EFSA conclusion (2013).

Therefore, and considering the high margins of safety calculated , it is assumed that the risk assessments for birds for the relevant metabolites are covered by the risk assessments of the active substances.

The combined risk assessment was considered as acceptable.

9.2.2.2 Higher-tier risk assessment

Not relevant.

9.2.2.3 Drinking water exposure

When necessary, the assessment of the risk for birds due to uptake of contaminated drinking water is conducted for a small granivorous bird with a body weight of 15.3 g (*Carduelis cannabina*) and a drinking water uptake rate of 0.46 L/kg bw/d (*cf.* Appendix K of EFSA/2009/1438).

Leaf scenario

Since the product is not intended to be applied on leafy vegetables forming heads or crop plants with comparable water collecting structures at principal growth stage 4 or later, the leaf scenario does not have to be considered.

Puddle scenario

Due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by animals, no specific calculations of exposure and TER are necessary when the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances (Koc < 500 L/kg) or 3000 in the case of more sorptive substances (Koc ≥ 500 L/kg).

Foramsulfuron

With a K(f)oc of 69.7, foramsulfuron belongs to the group of less sorptive substances.

Foramsulfuron				
Effective application rate (g/ha)	=	60		
Acute toxicity (mg/kg bw)	=	>2000	Quotient =	<0.03
Reprod. toxicity (mg/kg bw/d)	=	104	Quotient =	0.58

Thiencarbazone-methyl

With a K(f)oc of 100, thiencarbazone-methyl belong to the group of less sorptive substances.

Thiencarbazone-methyl				
Effective application rate (g/ha)	=	40		
Acute toxicity (mg/kg bw)	=	>2000	Quotient =	<0.02
Reprod. toxicity (mg/kg bw/d)	=	24	Quotient =	1.67

Conclusion: Since the ratios of effective application rates (in g/ha) to the relevant endpoints (in mg/kg bw/d) do not exceed the trigger, no further risk assessment is required.

zRMS comments:

We agree that hazard quotient for Puddle scenario for Foramsulfuron and Thiencarbazone-methyl are below trigger value 50, so no specific calculations of exposure and TER are necessary.

9.2.2.4 Effects of secondary poisoning

Foramsulfuron

The log P_{ow} of **foramsulfuron** amounts to 0.60 and does not exceed the trigger value of 3. The log P_{ow} values of the foramsulfuron metabolites AE F130619, AE F092944, AE F153745 and AE 0338795 are all below the trigger of 3 as stated in EFSA Journal 2016;14(3):4421. In accordance with the Guidance Document on Risk Assessment for Birds and Mammals, a risk assessment for effects due to secondary poisoning is not required.

Thiencarbazone-methyl

The log P_{ow} of **thiencarbazone-methyl** amounts to -1.98 and thus does not exceed the trigger value of 3. The log P_{ow} of all thiencarbazone-methyl metabolites are below the trigger value of 3 as stated in the EFSA Journal 2013;11(7):3270. In accordance with the Guidance Document on Risk Assessment for Birds and Mammals, a risk assessment for effects due to secondary poisoning is not required.

Risk assessment for earthworm-eating birds via secondary poisoning

Not required.

Risk assessment for fish-eating birds via secondary poisoning

Not required.

zRMS comments:

As both active substances have log Pow of less than 3, neither active substance is expected to bioaccumulate in the environment. It is therefore considered that secondary poisoning is not expected to occur from the proposed use of FSN+TCM OD 80 (50+30).

9.2.2.5 Biomagnification in terrestrial food chains

Not relevant.

9.2.3 Risk assessment for baits, pellets, granules, prills or treated seed

Not relevant.

9.2.4 Overall conclusions

Foramsulfuron

The acute and long-term risks of foramsulfuron to birds were assessed from toxicity exposure ratios between toxicity endpoints, estimated from studies on the active substance and maximum residues occurring on food items following applications according to the proposed use pattern. For foramsulfuron, the acute and long-term screening step TER values, calculated for the recommended scenario, were above the trigger value of 10 and 5, respectively, according to the proposed use pattern.

Furthermore, due to the k(f)oc and log P_{ow} values, the risk assessment for exposure via drinking water from puddles and risk of secondary poisoning was not considered necessary.

Thiencarbazone-methyl

The acute and long-term risks of thiencarbazone-methyl to birds were assessed from toxicity exposure ratios between toxicity endpoints, estimated from studies on the active substance and maximum residues occurring on food items following applications according to the proposed use pattern. For thiencarbazone-methyl, the acute and long-term screening step TER values, calculated for the recommended scenario, were above the trigger value of 10 and 5, respectively, according to the proposed use pattern.

Furthermore, due to the k(f)oc and log P_{ow} values, the risk assessment for exposure via drinking water from puddles and risk of secondary poisoning was not considered necessary.

Assessment of combined toxicity

The combined toxicity of the active substances was assessed. Both, the acute and the long-term assessment of combined toxicity revealed no unacceptable risk.

In overall conclusion, the risk for wild birds is acceptable for the use of FSN+TCM OD 80 (50+30) according to the intended use pattern.

9.3 Effects on terrestrial vertebrates other than birds (KCP 10.1.2)

9.3.1 Toxicity data

Foramsulfuron

Mammalian toxicity studies have been carried out with foramsulfuron. Full details of these studies are provided in the respective EU Renewal Assessment Report and related documents, presented agreed endpoints were taken from EFSA Journal 2016;14(3):4421.

Table 9.3-1: Endpoints and effect values relevant for the risk assessment for mammals - Foramsulfuron

Species	Substance	Exposure System	Results	Reference
Rat	Foramsulfuron	Oral Acute	LD_{50} > 5000 mg/kg bw	EFSA Journal 2016;14(3):4421
Rabbit	Foramsulfuron	Dietary developmental toxicity	NOEL = 500 mg/kg bw/d	EFSA Journal 2016;14(3):4421

Thiencarbazone-methyl

Mammalian toxicity studies have been carried out with thiencarbazone-methyl. Full details of these studies are provided in the respective EU DAR and related documents, presented agreed endpoints were taken from EFSA Journal 2013;11(7):3270.

Table 9.3-2: Endpoints and effect values relevant for the risk assessment for mammals - Thiencarbazone-methyl

Species	Substance	Exposure System	Results	Reference
Rat	Thiencarbazone-methyl	Oral Acute	LD_{50} >2000 mg/kg bw	EFSA Journal 2013;11(7):3270

Species	Substance	Exposure System	Results	Reference
Rat	Thiencarbazone-methyl	Dietary Reproductive toxicity Two-generation study	NOAEL = 946 mg/kg bw/d (reproductive effects)	EFSA Journal 2013;11(7):3270
Rat	FSN+TCM OD 80 (50+30)	Oral Acute	LD_{50} > 2000 mg/kg bw	xxx (2013) (See Toxicological)

FSN+TCM OD 80 (50+30)

Possible risk to mammals exposed to the formulated product **FSN+TCM OD 80 (50+30)** can be predicted on the basis of data for the individual active substances in a combined toxicity assessment. Therefore, no toxicity data of a vertebrate study with the formulation is presented here.

zRMS comment:

zRMS agrees with the endpoint performed in the Tables above. We also agree that for formulated product FSN+TCM OD 80 (50+30) the toxicity can be predicted on the basis of data for the individual active substances in a combined toxicity assessment.
Additionaly, available acute toxicity endpoint for mammals for product was considered by zRMS.
In reference to metabolites, for a.s. Foramsulfuron, it was stated in the EFSA conclusion (2016): "On the basis of the available data and risk assessments, a low acute and long-term risk to birds and wild mammals was concluded for all routes of exposure".
For a.s.-Thiencarbazone-methyl the risk was assessed as low at the first-tier level for birds and mammals in the EFSA conclusion (2013).
Therefore, considering the high margins of safety calculated below, it is assumed that the risk assessments for mammals for the relevant metabolites are covered by the risk assessments of the active substances.

9.3.1.1 Justification for new endpoints

No deviation to EU agreed endpoints.

9.3.2 Risk assessment for spray applications

The risk assessment is based on the methods presented in the Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438; hereafter referred to as EFSA/2009/1438).
To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group A covers the risk for mammals from all intended uses (see 9.1.3).

9.3.2.1 First-tier assessment (screening/generic focal species)

Foramsulfuron

For the active substance foramsulfuron - as the risk assessment is passed on screening level - exposure and risk characterisation is presented as a generic 'risk envelope' approach: The risk assessment is based on worst case application rates which cover all intended European uses across different products in which foramsulfuron may be included.

The results of the acute and reproductive screening assessments for foramsulfuron are summarised in the following table.

Table 9.3-3: Screening assessment of the acute and long-term/reproductive risk for mammals of foramsulfuron due to the use of FSN+TCM OD 80 (50+30) in sugar beet (use group A)

Intended use	**Risk envelope approach (use group A): maize, sugar beet, nursery (conifer), BBCH 10-34**				
Active substance/product	Foramsulfuron				
Application rate (g/ha)	risk envelope approach: 1 × 60				
Acute toxicity (mg/kg bw)	>5000				
TER criterion	10				
GAP crop	**Indicator species for screening**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Nursery*	Small herbivorous mammal	136.4	1.0	8.2	>611
Reprod. toxicity (mg/kg bw/d)	500				
TER criterion	5				
GAP crop	**Indicator species for screening**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Nursery*	Small herbivorous mammal	72.3	1 x 0.53	2.3	217

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.
* covers also maize and sugar beet

Thiencarbazone-methyl

For the active substance thiencarbazone-methyl - as the risk assessment is passed on screening level - exposure and risk characterisation is presented as a generic ‘risk envelope’ approach: The risk assessment is based on worst case application rates which cover all intended European uses across different products in which thiencarbazone-methyl may be included.
The results of the acute and reproductive screening assessments for thiencarbazone-methyl are summarised in the following table.

Table 9.3-4: Screening assessment of the acute and long-term/reproductive risk for mammals of thiencarbazone-methyl due to the use of FSN+TCM OD 80 (50+30) in sugar beet (use group A)

Intended use	**Risk envelope approach (use group A): cereals, maize, sugar beet, non-cropped area, BBCH 00-32**				
Active substance/product	thiencarbazone-methyl				
Application rate (g/ha)	risk envelope approach 1 × 40				
Acute toxicity (mg/kg bw)	>2000				
TER criterion	10				
GAP crop	**Indicator species for screening**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Cereals, maize, sugar beet *	Small herbivorous mammal	136.4	1.0	5.5	>367
Reprod. toxicity (mg/kg bw/d)	946				
TER criterion	5				
GAP crop	**Indicator species for screening**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Cereals, maize, sugar beet *	Small herbivorous mammal	72.3	1 x 0.53	1.5	617

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.
* covers also non-cropped areas

Mammals - Assessment of combined toxicity

As requested by the Central Zone when a product contains more than one active substance, an additional assessment on combined toxicity risk has to be presented. It is considered that a quantitative toxicity risk assessment according to concentration addition is not needed if one of the following points applies:

- The risk assessment for all active substances in the product passes with a high margin of safety
- One active substance clearly drives the risk assessment

These conditions are assessed following a step-wise approach. A detailed description of this approach is presented in a separate document (Gladbach, A., Ebeling, M., Weyers, A., 2017, M-571377-02-1). Note that for the calculation only the scenario with the lowest TER values was considered (most critical scenario). This safely covers all other scenarios.

1st step: Margin of safety

Condition: all TER values are > Trigger x n (n = number active substances in the mixture)

2nd step: Risk per fraction

Condition: One a.s. contributes to ≥ 90% of the predicted combined toxicity of the product.

Assessment: The contribution of each individual a.s. to the combined toxicity (risk per fraction, rpf) is estimated based on the following equation:

$$rpf_{a.s.1} = \frac{1}{TER_{a.s.1}} / (\frac{1}{TER_{a.s.1}} + \frac{1}{TER_{a.s.2}} ... + \frac{1}{TER_{a.s.i}})$$

The estimation is based on TER values from the same refinement level to assure comparability.

3rd step: TER_{MIX} calculation

Condition: The combined toxicity is acceptable if $TER_{MIX} \geq 10$ (acute) or 5 (long-term)

Assessment: The combined toxicity risk (TER_{MIX}) with concentration-addition is estimated based on the

following equation:

$$TER_{mix} = 1/(\frac{1}{TER_{a.s.1}} + \frac{1}{TER_{a.s.2}} ... + \frac{1}{TER_{a.s.i}})$$

As the notifier experienced differing preferences by national reviewers for one or the other step, results of all three steps are considered below:

Table 9.3-5: Combined toxicity assessment – mammals

Intended use	Risk envelope approach covering all uses (use group A)					
Active substances	Foramsulfuron + thiencarbazone-methyl					
Application rate (g/ha)	1 × (60 g/ha + 40 g/ha)					
Scenario / Generic focal species	**TER values [1]**		**Trigger a.s.1/a.s.2/a.s.3**	**1st step all TER ≥ trigger × n**	**2nd step Rpf$_{max}$**	**3rd step TER$_{MIX}$**
	FSN	**TCM**				
Acute / small herbivorous mammal	>611	>367	10/10	Yes	not applicable[#]	not needed
Long-term / small herbivorous mammal	217	617	5/5	Yes	not applicable[#]	not needed

[1)] Worst-case TER values as listed in point 9.2.2.1
[#] The rpf calculation is not meaningful if due to a risk envelope approach for one or more individual substances the ratio of the active substances in the assessed mixture differs from the ratio in the formulation.

For the acute and chronic assessment, all TER values are ≥ Trigger × n (n = number of active substances in the mixture), indicating no unacceptable risk from the use of the product.

FSN+TCM OD 80 (50+30)

GAP crop	Indicator species for screening	LD$_{50}$ [mg/kg bw]	DDD			DDD	TER$_A$
			Appl. rate [kg/ha]	SV$_{90}$	MAF$_{90}$		
Sugar beet	Small herbivorous mammal	>2000	0.1	136.4	1.0	13.64	>147

zRMS comment:

The risk assessment at screening and Tier 1 is considered acceptable. The risk assessment is based on the methods presented in the Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438; hereafter referred to as EFSA/2009/1438).
Safe use of active substances for mammals were confirmed based on TER$_A$ and TER$_{LT}$ above the trigger values of 10 and 5, respectively, indicating the acute and long-term risk is acceptable.
In addition, the TER$_A$ values for FSN+TCM OD 80 (50+30) is greater than the trigger values, indicating an acceptable acute risk to mammals from the product FSN+TCM OD 80 (50+30).
The combined for acute and chronic assessment indicated that all TER values are ≥ Trigger × n (n = number of active substances in the mixture). Therefore, no unacceptable risk from the use of the product was confirmed.

9.3.2.2 Higher-tier risk assessment

Not required.

9.3.2.3 Drinking water exposure

When necessary, the assessment of the risk for mammals due to uptake of contaminated drinking water is conducted for a small omnivorous mammal with a body weight of 21.7 g (*Apodemus sylvaticus*) and a drinking water uptake rate of 0.24 L/kg bw/d (*cf.* Appendix K of EFSA/2009/1438).

Leaf scenario

Since the product is not intended to be applied on leafy vegetables forming heads or crop plants with comparable water collecting structures at principal growth stage 4 or later, the leaf scenario does not have to be considered.

Puddle scenario

Due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by animals, no specific calculations of exposure and TER are necessary when the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances (Koc < 500 L/kg) or 3000 in the case of more sorptive substances (Koc ≥ 500 L/kg).

Foramsulfuron

With a K(f)oc of 69.7, foramsulfuron belongs to the group of less sorptive substances.

Foramsulfuron				
Effective application rate (g/ha)	=	60		
Acute toxicity (mg/kg bw)	=	>5000	Quotient =	<0.012
Reprod. toxicity (mg/kg bw/d)	=	500	Quotient =	0.12

Thiencarbazone-methyl

With a K(f)oc of 100, thiencarbazone-methyl belong to the group of less sorptive substances.

Thiencarbazone-methyl				
Effective application rate (g/ha)	=	40		
Acute toxicity (mg/kg bw)	=	>2000	Quotient =	<0.02
Reprod. toxicity (mg/kg bw/d)	=	946	Quotient =	0.04

Conclusion: Since the ratios of effective application rates (in g/ha) to the relevant endpoints (in mg/kg bw/d) do not exceed the trigger, no further risk assessment is required.

zRMS comments:

We agree that hazard quotient for Puddle scenario for Foramsulfuron and Thiencarbazone-methyl are below trigger value 50, so no specific calculations of exposure and TER are necessary.

9.3.2.4 Effects of secondary poisoning

Foramsulfuron

The log P_{ow} of **foramsulfuron** amounts to 0.60 and does not exceed the trigger value of 3. The log P_{ow} values of the foramsulfuron metabolites AE F130619, AE F092944, AE F153745 and AE 0338795 are all below the trigger of 3 as stated in EFSA Journal 2016;14(3):4421. In accordance with the Guidance Doc-

ument on Risk Assessment for Birds and Mammals, a risk assessment for effects due to secondary poisoning is not required.

Thiencarbazone-methyl

The log P_{ow} of **thiencarbazone-methyl** amounts to -1.98 and thus does not exceed the trigger value of 3. The log P_{ow} of all thiencarbazone-methyl metabolites are below the trigger value of 3 as stated in the EFSA Journal 2013;11(7):3270. In accordance with the Guidance Document on Risk Assessment for Birds and Mammals, a risk assessment for effects due to secondary poisoning is not required.

Risk assessment for earthworm-eating mammals via secondary poisoning

Not required.

Risk assessment for fish-eating mammals via secondary poisoning

Not required.

zRMS comments:

As both active substances have log Pow of less than 3, neither active substance is expected to bioaccumulate in the environment. It is therefore considered that secondary poisoning is not expected to occur from the proposed use of FSN+TCM OD 80 (50+30).

9.3.2.5 Biomagnification in terrestrial food chains

Not relevant.

9.3.3 Risk assessment for baits, pellets, granules, prills or treated seed

Not relevant.

9.3.4 Overall conclusions

Foramsulfuron

The acute and long-term risks of foramsulfuron to mammals were assessed from toxicity exposure ratios between toxicity endpoints, estimated from studies on the active substance and maximum residues occurring on food items following applications according to the proposed use pattern. For foramsulfuron, the acute and long-term screening step TER values, calculated for the recommended scenario, were above the trigger value of 10 and 5, respectively, according to the proposed use pattern.
Furthermore, due to the $k(f)_{oc}$ and log P_{ow} values, the risk assessment for exposure via drinking water from puddles and risk of secondary poisoning was not considered necessary.

Thiencarbazone-methyl

The acute and long-term risks of thiencarbazone-methyl to mammals were assessed from toxicity exposure ratios between toxicity endpoints, estimated from studies on the active substance and maximum residues occurring on food items following applications according to the proposed use pattern. For thiencarbazone-methyl, the acute and long-term screening step TER values, calculated for the recommended scenario, were above the trigger value of 10 and 5, respectively, according to the proposed use pattern.
Furthermore, due to the $k(f)_{oc}$ and log P_{ow} values, the risk assessment for exposure via drinking water

from puddles and risk of secondary poisoning was not considered necessary.

Assessment of combined toxicity

The combined toxicity of the active substances was assessed. Both, the acute and the long-term assessment of combined toxicity revealed no unacceptable risk.

In overall conclusion, the risk for wild mammals is acceptable for the use of FSN+TCM OD 80 (50+30) according to the intended use pattern.

9.4 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3)

The assessments on birds and terrestrial vertebrates other than birds presented in Sections 9.2 and 9.3 before do not raise particular concern for further terrestrial vertebrate wildlife such as reptiles and amphibians. Moreover, the ALS mode of action of all active substances in the present formulation is well known to be highly specific for plants. Therefore, no testing on other vertebrate organisms is deemed necessary.

9.5 Effects on aquatic organisms (KCP 10.2)

9.5.1 Toxicity data

Foramsulfuron

Studies on the toxicity to aquatic organisms have been carried out with foramsulfuron and its relevant metabolites. Full details of these studies are provided in the respective EU Renewal Assessment Report, as well as in Appendix 2 of this document (new studies). Presented agreed endpoints were taken from EFSA Journal 2016;14(3):4421, if not otherwise stated.

The selection of studies and endpoints for the risk assessment for foramsulfuron, is basically in line with the results of the EU review process (EFSA Journal 2016;14(3):4421). However, in some cases clarity is missing regarding the endpoints which should be chosen for others than the “representative” formulation, or regarding endpoints which should be used when the new aquatic guidance document (EFSA Journal 2013;11(7):3290) is applied. In these cases, justifications for the selection are provided below.

For the provision of "further information (is) required to address the risk to aquatic plants in areas represented by the R1, R2, R3 and R4 FOCUS surface water scenarios" (data gap acc. point 7 of EFSA conclusion), refined exposure type studies on the most sensitive macrophyte species *Lemna gibba* have been generated for the active substance and its metabolite AE F130619 after the EU review. The studies are presented as new data below and were used to establish refined risk assessments following options Tier 2C and Tier 3 of the EFSA Aquatic Guidance Document.

Table 9.5-1: Endpoints and effect values relevant for the risk assessment for aquatic organisms – foramsulfuron and relevant metabolites

Species	Substance	Exposure System	Results	Reference
Oncorhynchus mykiss, Lepomis	Foramsulfuron	96 h, s	**LC_{50} >100 mg a.s./L $_{nom}$**	EFSA Journal 2016;14(3):4421

Species	Substance	Exposure System	Results	Reference
macrochirus, Cyprinodon variegatus				
Pimephales promelas	Foramsulfuron	35 d, f	**NOEC = 10.5 mg a.s./L** $_{mm}$	EFSA Journal 2016;14(3):4421
Daphnia magna	Foramsulfuron	48 h, ss	**EC_{50} >100 mg a.s./L** $_{nom}$	EFSA Journal 2016;14(3):4421
Daphnia magna	Foramsulfuron	21 d, ss	**NOEC = 100 mg a.s./L** $_{nom}$	EFSA Journal 2016;14(3):4421
Pseudokirchneriella subcapitata	Foramsulfuron	72 h, s	E_rC_{50} = 75 mg a.s./L $_{nom}$ E_bC_{50} = 10.9 mg a.s./L $_{nom}$	EFSA Journal 2016;14(3):4421
Skeletonema costatum	Foramsulfuron	72 h / 96 h, s	Growth rate: E_rC_{50} > 105 mg a.s./L (mm)	EFSA Journal 2016;14(3):4421
			Biomass: E_bC_{50} > 105 mg a.s./L (mm)	EFSA Journal 2016;14(3):4421
Navicula pelliculosa	Foramsulfuron	72 h/96 h, s	E_rC_{50} > 112 mg a.s./L $_{nom}$ E_bC_{50} > 112 mg a.s./L $_{nom}$	EFSA Journal 2016;14(3):4421
Anabaena flos-aquae	Foramsulfuron	96 h, s	**E_rC_{50} = 8.1 mg a.s./L** $_{nom}$ E_bC_{50} = 3.3 mg a.s./L $_{nom}$	EFSA Journal 2016;14(3):4421
Lemna gibba	Foramsulfuron	7 d, s	**E_rC_{50} = 1.01 µg a.s./L** $_{nom}$ E_bC_{50} = 0.65 µg a.s./L $_{nom}$	EFSA Journal 2016;14(3):4421
Myriopyllum spicatum (aquatic plant)	Foramsulfuron	14 d, s	E_yC_{50} (shoot length, wet weight and dry weight) > 0.084 µg a.s./L (mm)	EFSA Journal 2016;14(3):4421
Lemna gibba	AE F130619	7 d, s	E_rC_{50} = 0.889 µg/L $_{nom}$	EFSA Journal 2016;14(3):4421
Oncorhynchus mykiss	AE F092944	96 h, s	**LC_{50} = 169.2 mg/L** $_{nom}$ [A]	xxxx M-131422-01-2 Appendix 2 xxxx M-549001-01-1 *New re-evaluation study; See justification*
Lemna gibba	AE F092944	7 d, ss	E_rC_{50} >100 mg/L $_{nom}$ E_bC_{50} >100 mg/L $_{nom}$	EFSA Journal 2016;14(3):4421
Lemna gibba	AE F153745	7 d, ss	**E_rC_{50} >100 mg/L** $_{nom}$ E_bC_{50} >100 mg/L $_{nom}$	EFSA Journal 2016;14(3):4421
Lemna gibba	AE 0338795	7 d, ss	**E_rC_{50} = 27.2 mg/L** $_{nom}$ E_bC_{50} = 14.8 mg/L $_{nom}$	EFSA Journal 2016;14(3):4421
Pseudokirchneriella subcapitata	AE F099095	72 h, s	**E_rC_{50} >100 mg/L** $_{nom}$ E_bC_{50} >100 mg/L $_{nom}$	EFSA Journal 2016;14(3):4421
Lemna gibba	AE F099095	7 d, s	E_rC_{50} >100 mg/L $_{nom}$	EFSA Journal 2016;14(3):4421
Lemna gibba	4-amino-N-methylbenzamide	7 d, s	**E_rC_{50} >10 mg/L** $_{nom}$	EFSA Journal 2016;14(3):4421

Species	Substance	Exposure System	Results	Reference
Lemna gibba	4-formamido-N-methylbenzamide[1)]	7 d, s	**E_rC_{50} >10 mg/L $_{nom}$**	EFSA Journal 2016;14(3):4421
Lemna gibba	Foramsulfuron-sulfamic acid	7 d, s	**E_rC_{50} >10 mg/L $_{nom}$**	EFSA Journal 2016;14(3):4421
Higher-tier studies				
Lemna gibba	Foramsulfuron	Design 1: 2 peaks lasting 24h on day 0 and 3. Test duration 7 d Design 2: 2 peaks lasting 24h on day 0 and 7. Test duration 14 d	E_rC_{50} = 0.0096 mg a.s./L $_{nom}$ (frond area) 1st week E_rC_{50} > 0.05 mg a.s./L $_{nom}$ (frond area and frond number) 2nd week E_rC_{50} >0.05 mg a.s./L $_{nom}$ (frond area and frond number)	Kuhl, K.; 2016 M-572386-03-1 *New study; See justification**
Lemna gibba	AE F130619	Design 1: 2 peaks lasting 24h on day 0 and 3. Test duration 7 d Design 2: 2 peaks lasting 24h on day 0 and 7. Test duration 14 d	E_rC_{50} = 0.0221 mg a.s./L $_{nom}$ (frond area) 1st week E_rC_{50} > 0.07 mg a.s./L $_{nom}$ (frond area and frond number) 2nd week E_rC_{50} >0.07 mg a.s./L $_{nom}$ (frond area and frond number)	Kuhl, K.; 2016 M-574191-01-1 *New study; See justification*.*
Endpoints used for metabolites risk assessment in case that no test data are available				
Fish acute *Oncorhynchus mykiss*	Metabolites of foramsulfuron[2)]	96 h, s	LC_{50} >100 mg/L $_{nom}$	from parent compound - see justification for new endpoints
Fish prolonged Pimephales promelas	Metabolites of foramsulfuron[3)]	35 d, f	NOEC = 10.5 mg/L $_{mm}$	from parent compound - see justification for new endpoints
Invertebrates acute *Daphnia magna*	Metabolites of foramsulfuron[3)]	48 h, ss	EC_{50} >100 mg/L $_{nom}$	from parent compound - see justification for new endpoints
Invertebrates prolonged *Daphnia magna*	Metabolites of foramsulfuron[3)]	21 d, ss	NOEC = 100 mg/L $_{nom}$	from parent compound - see justification for new endpoints
Algae *Anabaena flos-aquae*	Metabolites of foramsulfuron[4)]	96 h, s	E_rC_{50} = 8.1 mg/L $_{nom}$ E_bC_{50} = 3.3 mg/L $_{nom}$	from parent compound - see justification for new endpoints
Higher-tier studies (micro- or mesocosm studies)				
Lemna gibba (duck weed)	Foramsulfuron	7 d + 14 d (growth inhibition + recovery)	NOEC = 0.005 mg a.s./L	EFSA Journal 2016;14(3):4421
Lemna gibba	Foramsulfuron	1 d + 6 d	E_rC_{50} > 0.0567 mg a.s./L	EFSA Journal

Species	Substance	Exposure System	Results	Reference
(duck weed)		(growth inhibition, peak exposure)		2016;14(3):4421
Lemna gibba (duck weed)	Foramsulfuron	stepwise decreasing concentrations over 6 weeks	NOAEC < 0.0002 mg a.s./L (nom)	EFSA Journal 2016;14(3):4421
Outdoor growth inhibition and recovery multi-species study ('Foramsulfuron WG 50') 10 potted aquatic plant species in outdoor (4) replicated ponds. Nominal concentrations: 0.10, 0.25, 0.63, 1.6, 3.9, 9.7, 24 and 65 µg a.s./L(nom). Water control Monocotyledon species: *Elodea Canadensis, Stuckenia pectinata, Glyceria maxima, Sagittaria latifolia*. Diocotyledon species: *Nymphaea odorata, Ceratophyllum demersum, Myriophyllum heterophyllum, Mentha aquatic, Cabomba caroliniana, Salvinia minima*. Control plants were considered to be growing sufficiently. 6-week NOAEC figures (µg a.s./L) for nine aquatic macrophytes tested in the outdoor ponds based on initial measured concentrations Recalculated 6-week NOAEC values for nine aquatic macrophytes tested in the outdoor ponds on the basis of geometric mean concentrations using a factor of 0.564 (geomean of the percentage of the nominal concentrations which was 56.4%)				EFSA Journal 2016;14(3):4421

Species	Substance	Exposure System	Results	Reference

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1]
	Week 6 Mean Shoot Length	Week 6 Growth Rate Based on Mean Shoot Length	Week 6 Mean Shoot Dry Weight	Week 6 Growth Rate Based on Dry Weight
	NOAEC (µg a.s./L)	NOAEC (µg a.s./L)	NOAEC (µg a.s./L)	NOAEC (µg a.s./L)
Elodea canadensis	NC[a]	NC	0.10	0.10
Stuckenia pectinata	NC[a]	NC	3.9	3.9
Glyceria maxima	24	24	65	65
Sagittaria latifolia	1.6[b]	1.6	3.9	3.9
Ceratophyllum demersum	NC	NC	65	65
Myriophyllum heterophyllum	24	24	65	65
Mentha aquatica	65	65	65	65
Caaomba caroliniana	65	65	65	65
	Week 6 Mean Leaf Density	Week 6 Growth Rate Based on Leaf Density	Week 6 Mean Leaf Dry Weight	Week 6 Growth Rate Based on Leaf Dry Weight
	NOAEC (µg a.s./L)	NOAEC (µg a.s./L)	NOAEC (µg a.s./L)	NOAEC (µg a.s./L)
Salvinia minima	1.6[b]	1.6	1.6[b]	1.6[b]

(a): NC = Not calculated and not a required endpoint for this species. Due to the constant branching or the fact that stems could not be associated with an individual plant, plant lengths were not measured.
(b): Due to substantial % inhibition at the higher treatment levels, the 1.6 µg a.s./L treatment was used as a conservative NOEC value.
Note: Due to the inconsistency in emergence and growth, statistical analysis was not performed for *Nymphaea odorata*.

s: static; ss: semi-static; f: flow-through; nom: based on nominal concentrations; mm: based on mean measured concentrations; im: based on initial measured concentrations
[1)] also named as 4-formylamido-N-methylbenzamide
[2)] applicable for AE F153745, AE 0338795, AE F099095, 4-amino-N-methylbenzamide, 4-formamido-N-methylbenzamide and foramsulfuron-sulfamic acid
[3)] applicable for AEF092944, AE F153745, AE 0338795, AE F099095, 4-amino-N-methylbenzamide, 4-formamido-N-methylbenzamide and foramsulfuron-sulfamic acid
[4)] applicable for AEF092944, AE F153745, AE 0338795, 4-amino-N-methylbenzamide, 4-formamido-N-methylbenzamide and foramsulfuron-sulfamic acid
* The studies not used in the current risk assessment byzRMS.

EFSA Conclusions 2016

"Several refinement options to address the risk to aquatic plants from foramsulfuron were discussed at the experts' meeting (the use of peak exposure study, the use of an outdoor multispecies modified exposure study together with a Lemna gibba bioassay to derive a HC5 value and linking the effect studies to the predicted exposure profiles). The RMS proposed to derive a HC5 value using ErC50 values, expressed in terms of the geometric mean of the measured concentrations from the outdoor multi-species modified exposure toxicity study and the accompanying Lemna gibba modified exposure bioassay. The experts

agreed it was appropriate to use the endpoints from the modified exposure toxicity studies in terms of geometric mean concentrations as it had not been demonstrated that the exposure in the studies cover the predicted FOCUS surface water exposure profiles. It was agreed that the HC5 value could be used together with an assessment factor of 3 in a refined risk assessment. However, subsequent to the meeting, a further concern has been raised regarding the appropriateness of expressing toxicity endpoints from a long-term study in terms of a 6-week EC50 where no endpoints for intermediate time periods were determined. In the absence of an assessment of intermediate effects it is not possible to determine whether recovery had occurred during the study in which case a 6 week EC50 value is not appropriate (i.e. an EC50 is true effect endpoint and shouldnot account for recovery). It was noted that intermediate measurements of effects were not performed in the outdoor multi-species study. Intermediate measurements were taken in the accompanying Lemna gibba bioassay and confirmed that during weeks 1 to 5 lower EC50 values were derived. This issue was discussed for another active substance, for which a similar study had been performed, at the Pesticides Peer Review Expert Meeting 139 (January, 2016). The experts at the meeting agreed with the concern and therefore proposed that a 6-week NOAEC should be calculated for each tested species (i.e. which accounts for any recovery which may have occurred). The experts discussed an appropriate assessment factor to be used with the lowest NOAEC value and decided that a value of 3 is appropriate given that the study is not a true mesocosm but also taking into consideration that the toxicity endpoint is a NOAEC value over 6 weeks rather than an EC_{50} value over a shorter time period and that a wide range of additional species had been tested.

In relation to the refined risk assessment for foramsulfuron, Lemna gibba was the most sensitive species tested in the modified exposure studies; no NOEAC value could be derived for Lemna gibba in the 6-week bioassay as effects were observed at the lowest tested concentration. Therefore, a refined RAC value based on the available higher tier data, using this approach, cannot currently be derived. It was therefore considered to conclude on the risk assessment for foramsulfuron using the tier 1 toxicity endpoint but noting that the available higher tier data may be used to refine the risk further if data giving a NOEAC for the most sensitive species is provided."

zRMS comment:

Based on these conclusions, zRMS considered appropriate to use worst case Tier 1 toxicity endpoint (*Lemna*) covering all macrophtytes, as concluded in EFSA journal. Risk assessment with this endpoint is used with corresponding PEC_{sw} including max mitigation measures necessary to conclude to an acceptable risk.

Thiencarbazone-methyl

Studies on the toxicity to aquatic organisms have been carried out with thiencarbazone-methyl and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents, as well as in Appendix 2 of this document (new studies). Presented agreed endpoints were taken from EFSA Journal 2013;11(7):3270, if not otherwise stated.

The selection of studies and endpoints for the risk assessment for thiencarbazone-methyl is basically in line with the results of the EU review process. However, in some cases information is missing regarding endpoints which should be used when the new Aquatic Guidance document is applied. In these cases, justifications for the selection are provided below.

In the EFSA conclusion on thiencarbazone-methyl, the risk assessment for some R-stream scenarios based on FOCUS Step 4 was even not passed considering the use of a no-spray buffer zone of 20 m. Therefore, refined exposure type studies on the most sensitive macrophyte species *Lemna gibba* and *Myriophyllum spicatum* have been generated for the active substance after the EU review. The studies are presented as new data below. The refined exposure studies with *Lemna gibba* were used to establish re-

fined risk assessments following options Tier 2C and Tier 3 of the EFSA Aquatic Guidance Document. The study with *M. spicatum* was not directly used in refined risk assessment but should be considered as confirmation for the applicability of Tier 2C also with rooted, more slowly growing macrophytes.

Table 9.5-2: Endpoints and effect values relevant for the risk assessment for aquatic organisms – thiencarbazone-methyl and relevant metabolites

Species	Substance	Exposure System	Results	Reference
Oncorhynchus mykiss	Thiencarbazone-methyl	96 h, s	**LC_{50} > 104 mg a.s./L_{mm}**	EFSA Journal 2013;11(7):3270
Oncorhynchus mykiss	Metabolite BYH 18636 – sulfonamide (M15)	96 h, s	**LC_{50} = 98.3** mg/L (mm)	EFSA Journal 2013;11(7):3270
Pimephales promelas	Thiencarbazone-methyl	35 d (ELS), f	**NOEC = 4.8 mg a.s./L_{mm}**	EFSA Journal 2013;11(7):3270
Daphnia magna	Thiencarbazone-methyl	48h, s	**EC_{50} > 98.6 mg a.s./L_{mm}**	EFSA Journal 2013;11(7):3270
Daphnia magna	Thiencarbazone-methyl	21 d, s	**NOEC = 3.54 mg a.s./L_{mm}**	EFSA Journal 2013;11(7):3270
Chironomus riparius (spiked water)	Thiencarbazone-methyl	48 h, s	**EC_{50} > 100 mg a.s./L_{nom}**	EFSA Journal 2013;11(7):3270
Americamysis bahia	Thiencarbazone-methyl	96 h, f	**LC_{50} > 94 mg a.s./L_{mm}**	EFSA Journal 2013;11(7):3270
Americamysis bahia	Thiencarbazone-methyl	28 d, f	NOEC = 5.9 mg a.s./L_{mm}	EFSA Journal 2013;11(7):3270
Pseudokirchneriella subcapitata	Thiencarbazone-methyl	72 h	**E_rC_{50} = 1.017 mg a.s./L_{mm}**	EFSA Journal 2013;11(7):3270
Navicula pelliculosa	Thiencarbazone-methyl	96 h, s	Biomass E_bC_{50} = 64.0 mg a.s./L (mm) Growth rate E_rC_{50} = 64.0 mg a.s./L (mm)	EFSA Journal 2013;11(7):3270
Anabaena flos-aquae	Thiencarbazone-methyl	96 h, s	Biomass E_bC_{50} = 4.25 mg a.s./L (mm) Growth rate E_rC_{50} = 8.92 mg a.s./L (mm)	EFSA Journal 2013;11(7):3270
Skeletonema costatum	Thiencarbazone-methyl	96 h, s	Biomass E_bC_{50} > 114 mg a.s./L (mm) Growth rate E_rC_{50} > 114 mg a.s./L (mm)	EFSA Journal 2013;11(7):3270
Lemna gibba	Thiencarbazone-methyl	7 d, ss	**E_rC_{50} = 1.31 µg a.s./L_{mm}**	EFSA Journal 2013;11(7):3270
Myriophyllum spicatum	Thiencarbazone-methyl	14 d, s	Length E_yC_{50} = 0.00058 mg a.s./L Length E_rC_{50} = 0.00094 mg a.s./L	EFSA Journal 2013;11(7):3270
Potamogeton pectinatus	Thiencarbazone-methyl	14 d, s	Length E_rC_{50} = 0.0053 mg a.s./L Dry weight E_rC_{50} > 0.010 mg a.s./L	EFSA Journal 2013;11(7):3270

Species	Substance	Exposure System	Results	Reference
			Length E_bC_{50} = 0.0083 mg a.s./L Dry weight E_bC_{50} > 0.010 mg a.s./L	
Chironomus riparius (spiked water)	BYH 18636 - carboxylic acid	48 h, s	EC_{50} > 100 mg/L_{nom}	EFSA Journal 2013;11(7):3270
Lemna gibba	BYH 18636 - carboxylic acid	7d, ss	**E_rC_{50} = 3.54 mg/L_{mm}**	EFSA Journal 2013;11(7):3270
Oncorhynchus mykiss	BYH 18636 - sulfonamide	96 h, s	LC_{50} = 98.3 mg /L_{mm}	EFSA Journal 2013;11(7):3270
Daphnia magna	BYH 18636 - sulfonamide	48h, s	EC_{50} > 100 mg/L_{nom}	EFSA Journal 2013;11(7):3270
Pseudokirchneriella subcapitata	BYH 18636 - sulfonamide	72 h, s	**E_rC_{50} = 1.61 mg/L_{mm}**	EFSA Journal 2013;11(7):3270
Lemna gibba	BYH 18636 - sulfonamide	7d, ss	**ErC_{50} = 90.5 mg/L_{mm}**	EFSA Journal 2013;11(7):3270
Chironomus riparius (spiked water)	BYH 18636 - sulfonamide-carboxylic acid	28 d, s	**EC_{50} > 100 mg/L_{nom}**	EFSA Journal 2013;11(7):3270
Lemna gibba	BYH 18636 - sulfonamide-carboxylic acid	7d, s	**E_rC_{50} >100 mg/L_{nom}**	EFSA Journal 2013;11(7):3270
Lemna gibba	BYH 18636 - MMT	7d,ss	**E_rC_{50} > 95.7 mg/L_{mm}**	EFSA Journal 2013;11(7):3270
Lemna gibba	BYH 18636 - dicarboxy-sulfonamide	7d, ss	**E_rC_{50} > 104 mg/L_{mm}**	EFSA Journal 2013;11(7):3270
Higher-tier studies				
Higher tier Aquatic macrophytes Geomean mean of 3 species*	Thiencarbazone-methyl	-	EC_{50} = 0.00135 mg a.s./L	EFSA Journal 2013;11(7):3270
Lemna gibba Pulsed exposure	Thiencarbazone-methyl	Design 1: 2 peaks lasting 24h on day 0 and 3. Test duration 7 d Design 2: 2 peaks lasting 24h on day 0 and 7. Test duration 14 d	Design 1: E_rC_{50} = 0.0031 mg a.s./L $_{nom}$ Design 2: 1st week E_rC_{50} = 0.0157 mg a.s./L $_{nom}$ 2nd week E_rC_{50} = 0.0128 mg a.s./L $_{nom}$	Kuhl, K.; 2016 M-568404-02-1 *New study; See justification.***
Lemna gibba Pulsed exposure	Thiencarbazone-methyl	2 peaks lasting 24h on day 0 and 9. Test duration 21 d	$NOE_rC \geq$ 0.0015 mg a.s./L $_{nom}$	Bruns, E.; 2013 M-462568-01-1 *New study; See justification***
Myriophyllum spi-	Thiencarbazone-			Banman, C. S. &

Species	Substance	Exposure System	Results	Reference
catum Pulsed exposure	methyl	24h peak test duration 14 d	E_rC_{50} = 0.0092 mg a.s./L $_{nom}$	Moore, S.; 2013 M-466233-01-1 *New study; See justification.***
Endpoints used for metabolites risk assessment in case that no test data are available				
Fish acute *Oncorhynchus mykiss*	Metabolites of thiencarbazone-methyl [1)]	96 h, s	LC_{50} > 104 mg a.s./L_{mm}	from parent compound - see justification for new endpoints
Fish prolonged *Pimephales promelas*	Metabolites of thiencarbazone-methyl [2)]	35 d (ELS), f	NOEC = 4.8 mg a.s./L_{mm}	from parent compound - see justification for new endpoints
Invertebrates acute *Daphnia magna*	Metabolites of thiencarbazone-methyl [1)]	48h, s	EC_{50} > 98.6 mg a.s./L_{mm}	from parent compound - see justification for new endpoints
Invertebr. prolonged *Daphnia magna*	Metabolites of thiencarbazone-methyl [2)]	21 d, s	NOEC = 3.54 mg a.s./L_{mm}	from parent compound - see justification for new endpoints
Sed. dwell. acute *Chironomus riparius* (spiked water)	Metabolites of thiencarbazone-methyl [3)]	48 h, s	EC_{50} > 100 mg a.s./L_{nom}	from parent compound - see justification for new endpoints
Crustacean acute *Americamysis bahia*	Metabolites of thiencarbazone-methyl [2)]	96 h, f	LC_{50} > 94 mg a.s./L_{mm}	from parent compound - see justification for new endpoints
Crustacean prolonged *Americamysis bahia*	Metabolites of thiencarbazone-methyl [2)]	28 d, f	NOEC = 5.9 mg a.s./L_{mm}	from parent compound - see justification for new endpoints
Algae *Pseudokirchneriella subcapitata*	Metabolites of thiencarbazone-methyl [1)]	72 h	E_rC_{50} = 1.017 mg a.s./L_{mm}	from parent compound - see justification for new endpoints

s: static; ss: semi-static; f: flow-through; nom: based on nominal concentrations; mm: based on mean measured concentrations; im: based on initial measured concentrations

* *L. gibba, M. spicatum, Potamogeton pectinatus*

[1)] applicable for BYH 18636 - carboxylic acid, BYH 18636 - sulfonamide-carboxylic acid, BYH 18636 – MMT, BYH 18636 - dicarboxy-sulfonamide

[2)] applicable for BYH 18636 - carboxylic acid, BYH 18636 – sulfonamide, BYH 18636 - sulfonamide-carboxylic acid, BYH 18636 – MMT, BYH 18636 - dicarboxy-sulfonamide

[3)] applicable for BYH 18636 - carboxylic acid, BYH 18636 – sulfonamide, BYH 18636 – MMT, BYH 18636 - dicarboxy-sulfonamide

****The new studies are not considered in the current dossier in the context of the Art 43 renewal assessment of foramsulfuron.**

FSN+TCM OD 80 (50+30)

According to the data requirements No. 284/2013, Section 10.2.1, tests with the formulated product are required for each group of aquatic organisms (fish, invertebrates, algae, macrophytes). However, where the available information permits to conclude that one of these groups is clearly more sensitive, tests on only the relevant group shall be performed. In case of products with two or more active substances, this criterion applies only if the most sensitive taxonomic groups for the individual active substances are the same.

For all active substances in the product **FSN+TCM OD 80 (50+30)** aquatic macrophytes are clearly more sensitive than fish, invertebrates or algae. Therefore, only data for aquatic macrophytes is presented here and used for risk assessment.

Effects on aquatic macrophytes of the formulation were not evaluated as part of the EU assessment of the active substances. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

Table 9.5-3: Endpoints and effect values relevant for the risk assessment for aquatic organisms – FSN+TCM OD 80 (50+30)

Species	Substance	Exposure System	Results	Reference
Lemna gibba	FSN + TCM OD 80	7 d, s	E_rC_{50} = 0.0134 mg/L $_{nom}$	Appendix 2 Bruns (2014) M-477103-01-1

s: static; ss: semi-static; f: flow-through; nom: based on nominal concentrations; mm: based on mean measured concentrations

9.5.1.1 Justification for new endpoints

Growth-rate-related endpoints (where available) are proposed to be used in risk assessment for algae and macrophytes according to the EFSA aquatic guidance document (2013) and the EFSA (2015) Technical report on the outcome of the pesticides peer review meeting on general recurring issues in ecotoxicology (EFSA supporting publication 2015:EN-924. 62 pp.).

Foramsulfuron

Table 9.5-4: Justification for new endpoints

Species	Substance	Exposure System	Justification
Lemna gibba	Foramsulfuron	Higher tier: refined exposure test Design 1: 2 peaks lasting 24h on day 0 and 3. Test duration 7 d Design 2: 2 peaks lasting 24h on day 0 and 7. Test duration 14 d	New peak-exposure studies on *Lemna gibba* were performed with foramsulfuron and its metabolite AE F130619 to support the refinement options presented in this dossier. The need for further information to address the risk to aquatic plants was stated in the EFSA conclusion on foramsulfuron (EFSA Journal 2016;14(3):4421).*

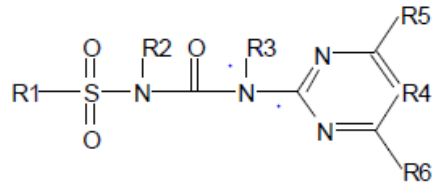
Species	Substance	Exposure System	Justification
Lemna gibba	Metabolite AE F130619	Higher tier: refined exposure test Design 1: 2 peaks lasting 24h on day 0 and 3. Test duration 7 d Design 2: 2 peaks lasting 24h on day 0 and 7. Test duration 14 d	

***The studies are not considered in the current risk assessment and they are left at MSs level, if necessary.**

Foramsulfuron metabolites, where no test data are available

The approach for metabolite risk assessment refers to part 10.2.4 decision scheme of the above mentioned Aquatic Guidance Document (EFSA:3290 (2013)). The decision scheme is followed step by step.

Step 1: none of the studies with the active substance is adequate for assessing the potential effect of the metabolites: ⇨ step 3.
Step 3: As mentioned in the Aquatic Guidance Document, toxophores for major classes of PPP have been identified ([1]Sinclair, 2009), for sulfonylureas, it is:



On this basis, it is considered that metabolites AE F130619, AE 0338795 and foramsulfuron sulfamic acid still contain the toxophore (⇨step 4). The other metabolites have lost it (⇨step 6).

Step 4: Identify the species or taxonomic group determining the lowest tier 1 $RAC_{sw,ac}$ for the active substance. Is the acute metabolite $L(E)C_{50}$ > 10 times the a.s. $L(E)C_{50}$ (on a molar basis)?
The active substance is not acutely toxic on fish and daphnia. Consequently, it is proposed to use the macrophyte endpoint to compare the level of effects of the parent and the metabolites even though it is not considered as an acute endpoint.
This approach shows that only AE F130619 EC_{50} is NOT greater than 10 times the a.s. EC_{50} (on a molar basis).

AE F130619 ⇨ step 5, i.e. risk assessment is performed with available data on macrophytes (*Lemna*) as the most sensitive organism.
All other metabolites ⇨ step 6, i.e. risk assessment will address all taxonomic groups with parent endpoints when no study was performed with the metabolite.

Acute fish endpoint for AE F092944
A study on rainbow trout with this metabolite (xxx, 1993) was submitted in the AIR dossier of foramsul-

[1] CJ Sinclair PhD Thesis University of York, Predicting the environmental fate and ecotoxicological and toxicological effects of pesticide transformation products https://www.researchgate.net/publication/235934684_Predicting_the_environmental_fate_and_ecotoxicological_and_toxicological_effects_of_pesticide_transformation_products - BCS documentation no. M-551653-01-1 - see Appendix **Błąd! Nie można odnaleźć źródła odwołania.**.

furon. It was evaluated and commented as follows:
"The end point for rainbow trout has been based on nominal concentrations even though the measured concentration in the highest treatment group is below 80 % of the nominal. Since the toxicity of AE F092944 is not driving the risk assessment there is no need for recalculation of the end point based on the measured concentrations. Therefore, the study is acceptable" (Foramsulfuron draft Renewal Assessment Report, January 2016).
However, the endpoint has been recalculated on the basis of mean measured concentration during the mesosulfuron review (xxx, 2016), providing a LC_{50} of 169.2 mg met./L. As this endpoint is available and the study was acceptable, the risk assessment will be performed with this new value.

Thiencarbazone-methyl

Table 9.5-5: Justification for new endpoints

Species	Substance	Exposure System	Justification
Lemna gibba	Thiencarbazone-methyl	Pulsed exposure: Design 1: 2 peaks lasting 24h on day 0 and 3. Test duration 7 d Design 2: 2 peaks lasting 24h on day 0 and 7. Test duration 14 d	Study needed to perform higher tier risk assessment according to Tier 2C of the EFSA Aquatic Guidance Document (EFSA, 2013)*
Lemna gibba	Thiencarbazone-methyl	Pulsed exposure: 2 peaks lasting 24h on day 0 and 9. Test duration 21 d	Study needed to perform higher tier risk assessment according to Tier 2C of the EFSA Aquatic Guidance Document (EFSA, 2013)*
Myriophyllum spicatum	Thiencarbazone-methyl	Pulsed exposure: 24h peak exposure conditions. Test duration 14 d	Study needed to perform higher tier risk assessment according to Tier 2C of the EFSA Aquatic Guidance Document (EFSA, 2013).*

*** The studies were not considered in the current dossier according in the context of the Art 43 renewal assessment of foramsulfuron and they are left at MSs level, if necessary.**

Thiencarbazone-methyl metabolites, where no test data are available

The approach for metabolite risk assessment refers to part 10.2.4 decision scheme of the above mentioned Aquatic Guidance Document (EFSA:3290 (2013)). The decision scheme is followed step by step.

Step 1: none of the studies with the active substance is adequate for assessing the potential effect of the metabolites: ⇨ step 3.
Step 3: No information is available to demonstrate that the toxophore is lost: ⇨ step 4.
Step 4: Identify the species or taxonomic group determining the lowest tier 1 RACsw,ac for the active substance. Is the acute metabolite $L(E)C_{50}$ > 10 times the a.s. $L(E)C_{50}$ (on a molar basis)?
The active substance is not acutely toxic on fish and daphnia. Consequently, it is proposed to use the macrophyte endpoint to compare the level of effects of the parent and the metabolites even though it is not considered as an acute endpoint.
This approach shows that metabolites are more than 10x less toxic to Lemna than the parent. **Therefore parent endpoints are used to demonstrate safe uses also for the metabolites, when test data are not available.**

9.5.2 Risk assessment

The evaluation of the risk for aquatic and sediment-dwelling organisms was performed in accordance with the recommendations of the "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.)

Following the Technical Guidelines on the format of the dRR (SANCO/6895/2009 rev 2.2) the risk envelope concept exploits the idea that the risk assessment for several use groups can be simplified by focusing on the group with worst-case characteristics as a representative for all other use groups.
This concept is also followed in the present submission – worst case critical uses are assessed to cover also less critical uses with similar characteristics. Refinements are performed to the level at which the assessment for the critical use is passed, while intermediate steps only relevant for less critical uses are not presented. However, in cases where a reviewer does not agree to refinement steps presented by the notifier, this might lead situations where unnecessarily severe risk mitigation measures are applied to less critical uses. In this case, adaptation of the risk assessment for less critical uses may be necessary.

Via stepwise procedure as follows, a comprehensive risk assessment was established for product FSN+TCM OD 80 (50+30) the different active substances contained therein, and their corresponding relevant metabolites. Each assessment of individual components is followed by a combined toxicity assessment, considering the active substances and the active metabolite AE F130619:

- As a first step of the assessment, a **spray-drift assessment for the formulated product** is presented, based on the measured formulation endpoints for each organism group.

- As an **MDR calculation** indicates concentration additive toxicity behaviour of the formulation, any further risk assessment considerations and refinements are made on the level of the individual active components.

- At a **screening level**, a "generic risk envelope approach" is presented for FOCUS steps 1 and 2. For the inactive metabolites, all risk assessments for aquatic organisms are passed at this stage without any refinement and even if worst case PECsw values are considered. Therefore, to simplify the assessment, only the maximum registered application rate and overall worst-case exposure situation (application all year round, no crop interception) relevant for the compound in any product supported by Bayer AG in Europe is addressed.

- An AGD **Tier 1** risk assessment is performed based on the accurate GAP and FOCUS Step 3 and Step 4, where risk assessment is not passed at the before screening level. For the present product and uses, this applies only for the group of aquatic macrophytes, on which all further risk assessments will concentrate.

  Tier 1 assessment based on FOCUS Step 3 could not resolve all critical use scenarios of the present product. Therefore, a further risk assessment with Tier 1 toxicity data was performed based on the accurate GAP and FOCUS Step 4 (with the use of drift-reducing nozzles or buffer strips as possible mitigation options). With regard to combined toxicity of the three active substances foramsulfuron, metabolite AE F130619 and thiencarbazone-methyl, even with the use of TWA for foramsulfuron not all critical FOCUS scenarios were resolved with maximum mitigation. Therefore, the notifier provides different higher tier level risk assessment options for demonstrating safe use of the product. The reason to provide multiple options is the current lack of agreed final guidance.

- Refinement based on AGD option **Tier 2C via experimental testing** of representative time-variable exposure patterns, and comparison of the FOCUSsw predicted exposure patterns vs. the tested representative patterns.

- Refinement based on AGD option **Tier 2C via *in-silico* virtual laboratory testing** of the time-variable exposure patterns predicted in FOCUSsw calculations.

- Refinement based on AGD option **Tier 3 via population effect modelling for macrophytes growing in exposed FOCUS surface water bodies.**

For these options relying on the timecourse output of the FOCUSsw model, additional simulations for an extended period (20 years instead of 1 year) of scenario weather are provided as a confirmatory information, taking into account specific recent reviewer's concerns.

The refined risk assessments by purpose follow a strategy of redundancy in procedures, aiming to clearly demonstrate safe use via the presentation of several alternative options leading to consistent conclusions. In recent product evaluations, the notifier experienced differing procedural preferences for refinements and acceptance criteria applied by national reviewers. As final clarification on the EFSA Aquatic Guidance Document is not yet available at the time of dossier authoring, a choice of options following state of the art science and addressing known concerns will therefore be presented.

A tabular overview of the tiered approach and the outcome of each risk assessment is presented at the end of this chapter, together with the overall conclusions (9.5.3).

Mechanistic background of population effect modelling: Adverse outcome pathway (AOP) for sulfonylurea herbicides

Extensive research over the last decades by industry and academia has led to a deep molecular level understanding of the biological effects of the active substances used in the present formulation, with both foramsulfuron and thiencarbazone-methyl being members of the sulfonylurea chemical class of herbicides.
Based on this detailed biochemical information and aiming to provide fundamental mechanistic insight into the aquatic macrophyte risk due to the present product, a pathway scheme [Figure 1] has been established that illustrates key events which interconnect the aquatic exposure with the assessment relevant effects on population level. Such approach is based on elements of the «Adverse Outcome Pathways (AOP) » concept[2] ,[3] and the scheme template of the AOP Wiki website[4], being amended for preceding exposure aspects:

(1) After a sulfonylurea substance enters surface water, as a first key event of relevance for possible effects, uptake will occur from the dissolved state into the macrophyte organism. Due to high polarity and water solubility, transport can be assumed as a diffusion-controlled equilibrium process. The rate constant for exchange between external and internal substance can be calculated from laboratory study data via TK modelling approaches.

(2) Once inside the organism, a specific Molecular Initiating Event [MIE] has been identified responsible for the component's biological activity: sulfonylurea-type herbicides form a highly selective,

[2] Ankley et al. (2010): ADVERSE OUTCOME PATHWAYS: A CONCEPTUAL FRAMEWORK TO SUPPORT ECOTOXICOLOGY RESEARCH AND RISK ASSESSMENT. Environmental Toxicology and Chemistry, Vol. 29, No. 3, pp. 730–741, 2010.

[3] OECD ENV/JM/MONO(2016)12: USERS' HANDBOOK SUPPLEMENT TO THE GUIDANCE DOCUMENT FOR DEVELOPING AND ASSESSING AOPs. Series on Testing & Assessment No. 233, Series on Adverse Outcome Pathways No. 1. Version 14 February 2018.
[available online free of charge at: https://one.oecd.org/document/ENV/JM/MONO(2016)12/en/pdf)

[4] Society for the Advancement of Adverse Outcome Pathways (SAAOP): Collaborative Adverse Outcome Pathway Wiki (AOP-Wiki) [accessible online free of charge at: https://aopwiki.org/]

non-covalent bonding to the anabolic enzyme *acetolactate synthase* (ALS, EC 2.2.1.6)[5]. This enzyme catalyzes a reaction step from pyruvate / 2-ketobutyrate to 2-acetolactate / 2-acetobutyrate, which are key intermediates within the synthesis pathways of the branched-chain amino acids valine, leucine, and isoleucine. Recently, high resolution crystal structures of exemplary enzyme-sulfonylurea complexes could be studied in detail[6]: As the binding site is located inside a molecular channel required for substrate transport to the enzyme active center, the presence of a sulfonylurea component results in a temporal non-competitive interruption of the enzyme operation.

(3) On cellular level, ALS blockage by the sulfonylurea component leads into an imbalance of enzyme substrates vs. downstream products. From the observation that plant growth inhibition of sulfonylurea herbicides can entirely be reversed by supplementation with branched-chain amino acids[7], it is concluded that the key event of relevance for adverse effects is to be seen in the development of intracellular deficiency of these particular downstream products. As amino acids are essential building blocks for anabolic protein synthesis, their shortage will slow down de-novo biosynthesis. On a macroscopic level, cell proliferation will hereby be impaired to a degree dependent on the severity and duration of the ALS enzyme blockage.

(4) Severity and duration of the ALS enzyme blockage will be a function of the concentration and timecourse of substance presence in the water body. Macrophyte internal substance concentration - and in consequence its enzyme-bound state equilibrium - will follow the external water phase concentration in both directions, as given by the exchange rate constant.

[Sulfonylurea substance detoxification via plant metabolism processes may represent an additional route of dissipation, which was identified of relevance in particular for herbicide tolerant crops varieties. In the present context of aquatic macrophyte risk assessment, however, such route can be conservatively ignored since risk assessment will focus on the most sensitive organism, likely not capable of a rapid substance detoxification.]

(5) On individual organism level, slowdown of de-novo protein synthesis shows expression as a slowdown of plant biomass generation, i.e. a reduction of growth and propagation rate compared to an unexposed organism. In consequence of the above mode of action, effects on organism level will only become manifest during phases of active growth with a prevailing high demand for anabolic building blocks[8].

(6) Adverse Outcome [AO] of relevance for risk assessment in case of macrophytes are negative effects on population level[9], i.e. a decrease in population growth rate leading into reduction of population biomass of an exposed vs. an unexposed population. Effect expression can be expected to dynamically follow the actual aquatic exposure. A short time delay will occur given by the rate of uptake/excretion into and out of the organism, and by the time until a deficiency in - or a reconstitution of - the cellular amino acid balance is developed.

[5] Acetolactate synthase (ALS, EC 2.2.1.6) is also known as acetohydroxy acid synthase (AHAS – former code EC 4.1.3.18c)

[6] McCourt et al. (2005): Elucidating the Specificity of Binding of Sulfonylurea Herbicides to Acetohydroxyacid Synthase. *Biochemistry* **2005,** *44,* 2330-2338

[7] e.g. Ray (1984): Site of Action of Chlorsulfuron. Plant Physiol. (1984) 75, 827-831

[8] This is a substance class property well-known also from agricultural practice, i.e. effective weed control requires the product to be used in a phase of active growth of the weeds to be controlled.

[9] See also EFSA Aquatic Guidance Document, Chapter 5.4 - Table 12: The aquatic key drivers and their ecological entity to be protected as proposed in EFSA PPR Panel (2010a) and the current standard aquatic test species related to these key drivers (Commission Regulation (EU) 283/2013)

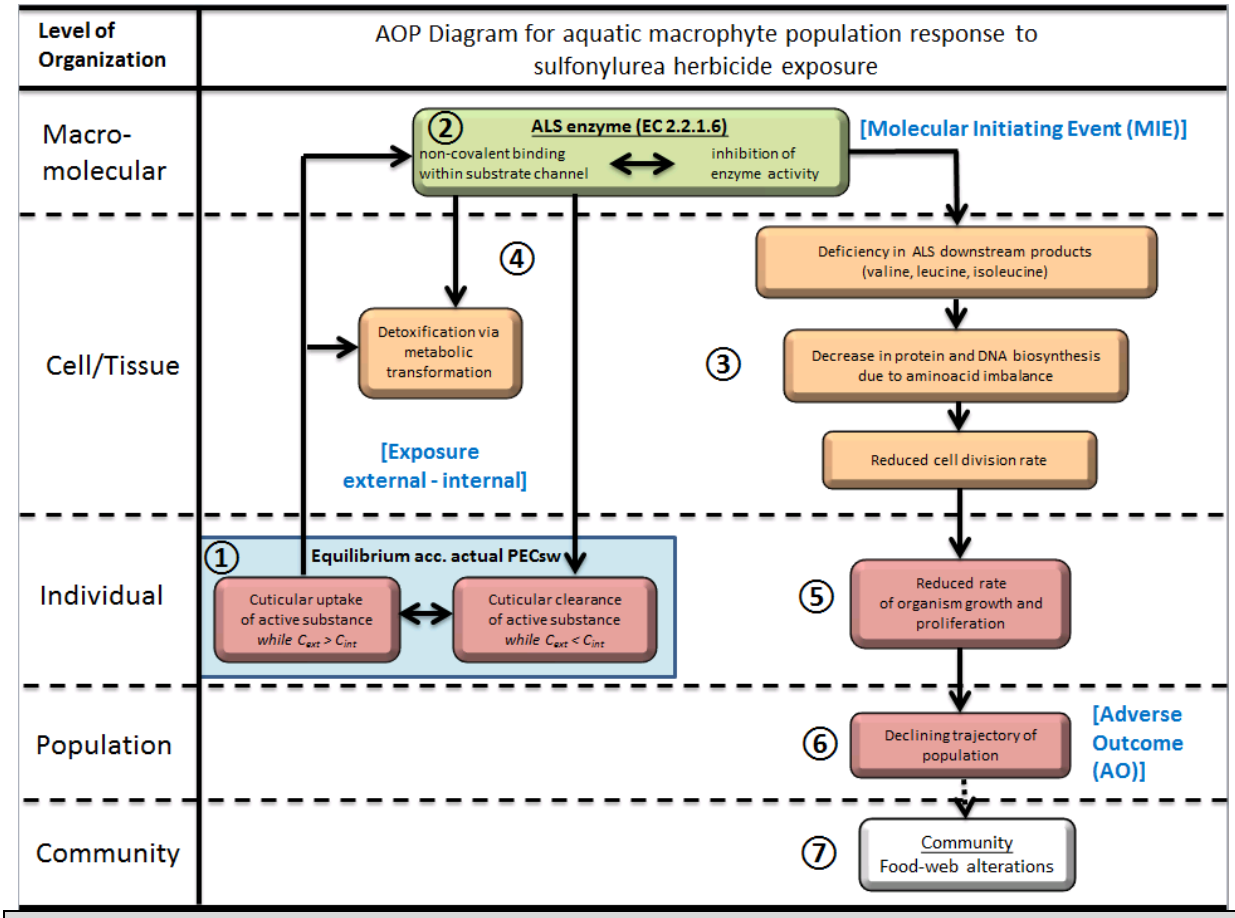
Such population growth effects can be directly assayed for defined exposure situations in the laboratory. The most sensitive macrophyte species for sulfonylurea herbicides is *Lemna* and standard tests with this organism are performed with populations that increase by vegetative reproduction. Since in the test system *Lemna* is maintained at conditions fostering optimum (exponential) growth, such test design will provoke maximized effects for the present mode of action (worst-case approach).

For more complex exposure patterns and / or for an additional consideration of modulating environmental factors leading to non-optimal growth conditions, population effect modelling systems are a valuable tool.

(7) Effects on community level could occur indirectly via food-web alterations, as a consequence of severe and long-lasting depression of macrophyte population growth. Due to the above mode of action, development of such effect would require a significant exposure over long time.

In summary, both the Molecular Initiating Event and the subsequent Adverse Outcome Pathway lead to the same conclusion regarding assessment relevant effects: Sulfonylurea class compounds do not produce an irreversible (lethal) threshold event. They just lead to temporary decrease of macrophyte growth and proliferation rate. The degree and duration of population level response will be a dynamic function of the exposure concentration over time.
Any evaluation based on laboratory study data will provide a most conservative risk assessment, since in these studies the test organisms are maintained under optimum growth conditions fostering most pronounced substance effect for this mode of action. Population effect modelling provides a valuable tool for investigation of population response on differing exposure situations. By considering variation of growth relevant environmental factors, it also enables to study population responses under non-optimal growing conditions (e.g. lower temperatures).

Figure 1: **ALS inhibition [Molecular Initiating Event - MIE] after exposure to sulfonylurea class herbicides leading to growth depression of aquatic macrophyte populations [Adverse Outcome - AO]**



zRMS comment:

zRMS summarised below some uncertainties with each tier of the risk assessment proposed by the Applicant in the current evaluation of the product Conviso One.

Using PEC_{twa} approach

It was agreed at EU level that until further guidance on reciprocity and latency of effects are available, then the use of TWA approaches are unlikely to be sufficiently robust to be used in regulatory risk assessment.' (EFSA Supporting publication 2015:EN-92). Therefore, using PECtwa vlues in refined risk assessment was not considered byzRMS in the current dossier.

Using Tier 2C – (Pulsed exposure studies)

Foramsulfuron

For the scenarios R3 and R1 stream the calculated PEC/RAC ratios did not indicate an acceptable risk at all at STEP 3 and **in case of R3 scenario also with mitigation measures such as buffer zones 10 and 20 meters calculated at STEP 4 (for application 2 x 25 g a.s./ha). In addition for R3 and R1 scenarios the PEC/RAC ratios did not indicate an acceptable risk in combitox exposure for application 2 x 25 g a.s./ha and 1 x50 g a.s./ha (onlyR3 scenario).**
The refined risk assessment proposed by the applicant with peak exposure studies for foramsulfruon only concerns the aquatic macrophyte *Lemna gibba* and, without justification, may not cover the risk to other aquatic macrophytes for which toxicity data were available at EU level and indicated sensitivity (not in Tier 1 lab study on *Myriophyllum*, but in the outdoor growth inhibition and recovery multi-

species study). However, it can be noted that in EFSA conclusions it is reported that "*Lemna gibba was the most sensitive species tested in the modified exposure studies and no NOEAC value could be derived for Lemna gibba in the 6-week bioassay as effects were observed at the lowest tested concentration and therefore, a refined RAC value based on the available higher tier data, using this approach, cannot currently be derived" […]* "*the available higher tier data may be used to refine the risk further if data giving a NOEAC for the most sensitive species is provided".*
Based on available summary in DAR volume 3CA B9.2.7.5 concerning 6 weeks outdoor multispecies modified exposure study, and more particularly based on comparison of NOAEC and E_rC_{50} values, *Lemna* is indeed one of the most sensitive species (6weeks NOA(E)C = 0.11 ug/L and 6weeks E_rC_{50}=0.67 ug/L in geomean concentration of 56% over 6 weeks), also with *Elodea canadensis* that is equally sensitive (6weeks NOAEC = 0.056 ug/L and 6weeks E_rC_{50}=0.85 ug/L in geomean concentration of 56% over 6 weeks) while other species are indeed less sensitive (6weeks NOAEC from 0.9 to 36.6 ug/L; and 6weeks E_rC_{50}=1.58 to >36.7 ug/L in geomean concentration of 56% over 6 weeks).
Based on these considerations that *Lemna* is the most sensitive species from these 6weeks NOAEC issued from studies included recovery, then refinement based on *Lemna* (peak studies) may be used in a weight of evidence approach to consider that recovery would also occur for other aquatic macrophytes following exposure to the corresponding scenario failing Tier 1 risk assessment .
However, as such lab modified exposures studies approach have not been conducted for other macrophytes species, zRMS considered appropriate to use Tier 1 endpoint and PEsw max (in accordance with EFSA conclusions) including max mitigation measures necessary up to an acceptable risk can be concluded.
The weight of evidence approach for scenario still failing with max mitigation measures – in this case R3 and R1 stream scenarios <u>should be considered at National level.</u>

It should be noted that the agreed outcome at the 4th Central Zone Harmonisation meeting (Sept 2018, Dessau, DE) - states the following in the meeting minutes that the Tier 2C approach should generally not be supported at zonal level, considering that implementation in ERA is complex and linked to high uncertainties.
Therefore, zRMS did not taken into consideration this refinement option in the current evaluation.
As in the EFSA conclusion for Foramsulfuron, zRMS conducted the risk assessment using PEC sw.max from FOCUS Step 4 calculations and the RAC based on the **<u>E_rC_{50} = 1.01 µg a.s./L</u>** for *L. gibba* and AF of 10.

Therefore, FOCUS PECsw STEP 4 was used by zRMS to refine the long-term risk assessment.

<u>Thiencarbazone-methyl</u>

For Thiencarbazone-methyl, the applicant presented a refined risk assessment with peak exposure studies with L. gibba and Myriophyllum spicantum species. The studies were not considered in the context of the Art 43 renewal assessment of foramsulfuron.
Therefore, the risk assessment for aquatic macropytes was based on the 7 **d E_rC_{50} 1.31 <u>µg a.s./L</u>** for *L. gibba* and AF of 10.

<u>Using Tier 3- TK-TD modelling</u>

The EFSA Opinion on TKTD modelling considers the conceptual and formal parts *Lemna* model to be suitable to use in a regulatory risk assessment but it also notes that there are several outstanding areas to address. TK/TD modelling based on L.gibba alone may not be appropriate for extrapolation to species with different life history strategies. As such, even if TK/TD modelling could be considered, it would only be suitable as refinement for L.gibba or plants of a similar sensitivity and life history strategy and not aquatic plants as a whole.

<u>zRMS's final conclusion conclusion:</u>

In the current evaluation of the product Conviso One the refinement presented by ZRMS-PL was based

on risk migitation measueres with $PEC_{sw\ max}$ STEP 1- 4 calculated by FOCUS program.

We would like to stress that if the other MSs are of a diffrent opinion refered to the uncertainties with each tier of the risk assessment proposed by the zRMS they can considered it further at National level (please see in Appendix 2 for detail).

9.5.2.1 Spray drift exposure assessment for the formulated product - FSN+TCM OD 80 (50+30)

As a first step of the assessment, a simple "spray-drift only"- assessment is presented for the formulated product, based on the measured endpoint for *Lemna gibba*, and exposure being calculated based on Rautmann drift values:

Table 9.5-6: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for FSN+TCM OD 80 (50+30) for aquatic macrophytes based on Screening level (drift only) calculations for the use in sugar beet – 1 × 1.0 L prod./ha (Use group B)

Group		**Aquatic macrophyte**
Test species		*Lemna gibba*
Endpoint (µg/L)		E_rC_{50} 13.4
AF		10
RAC (µg/L)		1.34
Drift only	**PEC $_{gl\text{-}max}$ (µg/L)**	
no buffer		
0 % drift reduction	9.492	**7.08**
50% drift reduction	4.746	**3.54**
75% drift reduction	2.373	**1.77**
90% drift reduction	0.949	0.71
5 meters buffer		
0 % drift reduction	1.953	**1.46**
50% drift reduction	0.977	0.73
10 meters buffer		
0 % drift reduction	0.994	0.74

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in **bold**

Conclusion: In a screening level risk assessment for 1.0 L product/ha (use group B), measures for drift exposure mitigation equivalent to a 10 m buffer zone, a 5 m

buffer zone and 50 % drift reducing spray equipment or a use of 90% drift reducing spray equipment would be required to pass the risk assessment for aquatic macrophytes.

zRMS comments:

zRMS agrees with the risk assessment for product Conviso One for most sensitive organism – Lemna gibba group from Spray drift exposure calculation for the formulated product – FSN+TCM OD 80 (50+30).
In a screening level risk assessment for 1.0 L product/ha (use group B), measures for drift exposure mitigation equivalent to a 10 m buffer zone, a 5 m buffer zone and 50 % drift reducing spray equipment or a use of 90% drift reducing spray equipment would be required to pass the risk assessment for aquatic macrophytes.

This simplistic screening conclusion is however subject to higher tiered assessments on the basis of the individual active substances, which allow for more detailed and sophisticated risk analysis and the consideration of further possible entry routes, presented in the subsequent sections here below.
In case higher tier assessments on the basis of individual active substances are not considered to overrule the conclusion of this screening assessment, formulation risk assessment should be expanded for the lower use rate, to avoid unnecessarily severe mitigation measures for these less critical uses.

9.5.2.2 MDR calculation for the formulated product – FSN+TCM OD 80 (50+30)

To check plausibility of the hypothesis that concentration-additive toxicity of the individual components applies for the present active substances and formulation, measured toxicity of the formulation on the most sensitive organism (driver of the risk assessment) is compared to the expected toxicity for this organism when predicted via concentration-addition (Finney calculation). This is performed using the MDR approach as defined in the EFSA Aquatic Guidance document (page 33):

Table 9.5-7: Calculation of the acute mixed toxicity of FSN+TCM OD 80 (50+30) to *Lemna* according to Finney additivity assumption

	Foramsulfuron	**Thiencarbazone-methyl**	**Formulation**	
Content within the product [%]	4.9	2.9	-	-
			Effects on aquatic plants	
EC_{50} [µg/L]	1.01	1.31	Expected	14.20
			Measured	13.40
			MDR	1.06

The MDR is 1.06, clearly falling into the threshold corridor between 0.2 and 5 defined in the Aquatic Guidance Document as criterion for the conclusion of concentration additive toxicity behaviour of a formulation.

In consequence, any further risk assessment considerations and refinements can safely be made on the level of the individual active components. Where required, toxicity of a mixture (e.g. the formulation, or a combination of substances simultaneously present in a surface water body) can be described as the arithmetic sum of individual toxicity contributions ($RQ_{mix} = \sum RQ_i$).

This approach will be applied in all subsequent assessments.

zRMS comments:

A model often used to estimate the toxicity of mixtures is the assumption of dose/concentration additivity of toxicity (Finney approach of concentration additivity of toxicity; Finney, D.J., 1948 and 1971).
Toxicity studies on acute and chronic effects of the active substances and Conviso One to aquatic organisms are available. For a more detailed assessment of mixture toxicity, a surrogate LC_{50} or EC_{50} can be calculated. However, reliable results can only be expected for combinations of EC_X values for the same biological endpoint. Moreover, the use of NOEC values, which are strongly depending on dose-spacing, would introduce additional bias in the calculations.

Calculated mixture toxicity

The default model of Concentration Addition (CA) is applied to calculate the toxicity of the formulated product (ECx_{mix}-CA) based on the toxicity of the active

substances using the following equation:

$$ECx_{mix-CA} = \left(\sum_{i=1}^{n} \frac{P_i}{ECx_i} \right)^{-1}$$

where:
n: number of mixture components
i: index from 1…n mixture components
P_i: the i^{th} component as a relative fraction of the mixture composition (note: Σ pi must be 1)
ECx_i: concentration of component i provoking x % effect (pragmatically, NOECi may be inserted, too).

For each endpoint, the calculated toxicity (ECx_{mix-CA}) for the various endpoints is compared to the measured toxicity of the formulation (ECx_{PPP}) as Model Deviation Ratio (MDR) as

$$MDR = \frac{ECx_{mix-CA}}{ECx_{PPP}}$$

The observed and calculated mixture toxicities are considered in agreement if the MDR is between 0.2 and 5. More-than additive (i.e. synergistic) mixture toxicity is indicated if the MDR is > 5. Less-than additive (i.e. antagonistic) mixture toxicity is indicated if the MDR is below 0.2.

The approach of the mixture risk assessment may be simplified if one active substance is driving the toxicity of the formulation. Relative Toxic Units ($\%TU_i$) as calculated for each active substance as

$$\%TU_i = \frac{TU_i}{\sum_{i=1}^{n} TU_i}$$

with TU_i being the concentration of substance i in the product divided by its ECx.

Decision making of deriving a surrogate EC_{50} for risk assessment of aquatic organisms based on mixture toxicity.

Substance	Concentration (C_i) in formulation (g a.s./L)	P_i	ECx_i (mg a.s./L)	relative Toxic Unit (%TU)	$ECx_{mix\text{-}CA}$ (mg /L)	ECx_{ppp} (mg sum of a.s./L)	MDR
Aquatic higher plants (*L. gibba*)							
Foramsulfuron	50	0.625	0.00101	68.4	0.00111	0.00107	1.03
Thiencarbazone-methyl	30	0.375	0.00131	31.6			

The MDR is 1.03. The toxicity of the formulation is similar to the expected one based on additivity.

9.5.2.3 Screening Level: Risk envelope assessment based on FOCUS Steps 1-2, all active substances and metabolites

In this step, the risk is assessed substance by substance including all metabolites which may potentially enter surface water, for all groups of organisms. The assessment considers all possible entry routes to surface water (drift, run-off, drainage), with exposure calculated on screening level (FOCUS Step 1-2) for the generic risk envelope use pattern (use group A) covering all possible uses.

Foramsulfuron and metabolites

Table 9.5-8: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for foramsulfuron for each organism group based on FOCUS Steps 1 and 2 calculations for the use of FSN+TCM OD 80 (50+30) in sugar beet (Use group A).

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic plants**
Test species		***Oncorhynchus mykiss***	***Pimephales promelas***	***Daphnia magna***	***Daphnia magna***	***Anabaena flos-aquae***	***Lemna gibba***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_rC_{50}/E_yC_{50}	E_rC_{50}
(µg/L)		>100000	10500	>100000	100000	8100	1.01
AF		100	10	100	10	10	10
RAC (µg/L)		>1000	1050	>1000	10000	810	0.101
FOCUS Scenario	**PEC gl-max (µg/L)**						
Step 1 (risk envelope approach: 60 g a.s./ha, year-round use, no crop interception)							
	18.851	< 0.0189	0.0180	< 0.0189	0.0019	0.0233	**186.644**
Step 2 (risk envelope approach: 60 g a.s./ha, year-round use, no crop interception)							
N-Europe	7.7397	< 0.0077	0.0074	< 0.0077	0.0008	0.0096	**76.631**
S-Europe	6.2873	< 0.0063	0.0060	< 0.0063	0.0006	0.0078	**62.250**

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

zRMS comments:

zRMS agrees with the risk assessment for a.s. foramsulfuron for each organism group based on FOCUS Steps 1 and 2 calculations for the use of FSN+TCM OD 80 (50+30) in sugar beet (Use group A). **Further refinment is required for Lemna sp.**

Table 9.5-9: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for foramsulfuron metabolite AE F130619 for the most sensitive organism group based on FOCUS Steps 1 and 2 calculations for the use of FSN+TCM OD 80 (50+30) in sugar beet (Use group A)

Note: according to EFSA aquatic guidance document, the risk assessment for metabolites with the toxophore of the parent substance has to be performed on the most sensitive organisms only (i.e. *Lemna* in this specific case)

Group		**Aquatic plants**
Test species		***Lemna gibba***
Endpoint (µg/L)		E_rC_{50} 0.889
AF		10
RAC (µg/L)		0.0889
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**	
Step 1 (risk envelope approach: 60 g a.s./ha, year-round use, no crop interception)		
	6.9417	**78.084**
Step 2 (risk envelope approach: 60 g a.s./ha, year-round use, no crop interception)		
N-Europe	1.1751	**13.218**
S-Europe	0.9489	**10.674**

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

zRMS comments:

zRMS agrees with the risk assessment for metabolite AE F130619 for Lemna gibba based on FOCUS Steps 1 and 2 calculations in sugar beet (Use group A).

Further redinment is required for Lemna sp.

Table 9.5-10: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for foramsulfuron metabolite AE F092944 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of FSN+TCM OD 80 (50+30) in sugar beet (Use group A)

Group		**Fish acute**	**Fish pro-longed**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic plants**
Test species		***Oncorhynchus mykiss***	***Pimephales promelas***	***Daphnia magna***	***Daphnia magna***	***Anabaena flos-aquae***	***Lemna gibba***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_rC_{50}/E_yC_{50}	E_rC_{50}
(µg/L)		169200	10500	>100000	100000	8100	>100000
AF		100	10	100	10	10	10
RAC (µg/L)		1692	1050	>1000	10000	810	>10000
FOCUS Scenario	**PEC gl-max (µg/L)**						
Step 1 (risk envelope approach: 60 g a.s./ha, year-round use, no crop interception)							
	2.2714	0.0013	0.0022	< 0.0023	0.0002	0.0028	< 0.0002

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

zRMS comment:

zRMS agrees with the risk assessment for metabolite AE F130619 for each organism group based on FOCUS Steps 1 and 2 calculations in sugar beet (Use group A).

Table 9.5-11: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for foramsulfuron metabolite AE F153745 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of FSN+TCM OD 80 (50+30)) in sugar beet (Use group A)

Group		**Fish acute**	**Fish pro-longed**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic plants**
Test species		***Oncorhynchus mykiss***	***Pimephales promelas***	***Daphnia magna***	***Daphnia magna***	***Anabaena flos-aquae***	***Lemna gibba***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_rC_{50}/E_yC_{50}	E_rC_{50}
(µg/L)		>100000	10500	>100000	100000	8100	>100000
AF		100	10	100	10	10	10
RAC (µg/L)		>1000	1050	>1000	10000	810	>10000
FOCUS Scenario	**PEC gl-max (µg/L)**						
Step 1 (risk envelope approach: 60 g a.s./ha, year-round use, no crop interception)							
	4.0259	< 0.0040	0.0038	< 0.0040	0.0004	0.0050	< 0.0004

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

zRMS comment:

zRMS agrees with the risk assessment for metabolite AE F153745 for each organism group based on FOCUS Steps 1 and 2 calculations in sugar beet (Use group A).

Table 9.5-12: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for foramsulfuron metabolite AE 0338795 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of FSN+TCM OD 80 (50+30) in sugar beet (Use group A)

Group		**Fish acute**	**Fish pro-longed**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic plants**
Test species		***Oncorhynchus mykiss***	***Pimephales promelas***	***Daphnia magna***	***Daphnia magna***	***Anabaena flos-aquae***	***Lemna gibba***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_rC_{50}/E_yC_{50}	E_rC_{50}
(µg/L)		>100000	10500	>100000	100000	8100	27200
AF		100	10	100	10	10	10
RAC (µg/L)		>1000	1050	>1000	10000	810	2720
FOCUS Scenario	**PEC gl-max (µg/L)**						
Step 1 (risk envelope approach: 60 g a.s./ha, year-round use, no crop interception)							
	4.6138	< 0.0046	0.0044	< 0.0046	0.0005	0.0057	0.0017

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

zRMS comment:

zRMS agrees with the risk assessment for metabolite AE 0338795 for each organism group based on FOCUS Steps 1 and 2 calculations in sugar beet (Use group A).

Table 9.5-13: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for foramsulfuron metabolite AE F099095 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of FSN+TCM OD 80 (50+30) in sugar beet (Use group A)

Group		**Fish acute**	**Fish pro-longed**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic plants**
Test species		***Oncorhynchus mykiss***	***Pimephales promelas***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchneriella subcapitata***	***Lemna gibba***
Endpoint (µg/L)		LC_{50} >100000	NOEC 10500	EC_{50} >100000	NOEC 100000	E_rC_{50}/E_yC_{50} >100000	E_rC_{50} >100000
AF		100	10	100	10	10	10
RAC (µg/L)		>1000	1050	>1000	10000	>10000	>10000
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**						
Step 1 (risk envelope approach: 60 g a.s./ha, year-round use, no crop interception)							
	2.1855	< 0.0022	0.0021	< 0.0022	0.0002	< 0.0002	< 0.0002

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

zRMS comments:

zRMS agrees with the risk assessment for metabolite AE F099095 for each organism group based on FOCUS Steps 1 and 2 calculations in sugar beet (Use group A).

Table 9.5-14: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for foramsulfuron metabolite 4-amino-N-methylbenzamide for each organism group based on FOCUS Steps 1 and 2 calculations for the use of FSN+TCM Od 80 (50+30) in sugar beet (Use group A)

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic plants**
Test species		***Oncorhynchus mykiss***	***Pimephales promelas***	***Daphnia magna***	***Daphnia magna***	***Anabaena flos-aquae***	***Lemna gibba***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_rC_{50}/E_yC_{50}	E_rC_{50}
(µg/L)		>100000	10500	>100000	100000	8100	>10000
AF		100	10	100	10	10	10
RAC (µg/L)		>1000	1050	>1000	10000	810	>1000
FOCUS Scenario	**PEC gl-max (µg/L)**						
Step 1 (risk envelope approach: 60 g a.s./ha, year-round use, no crop interception)							
	0.8732	< 0.0009	0.0008	< 0.0009	0.0001	0.0011	< 0.0009

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

zRMS comments:

zRMS agrees with the risk assessment for metabolite 4-amino-N-methylbenzamide for each organism group based on FOCUS Steps 1 and 2 calculations in sugar beet (Use group A).

Table 9.5-15: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for foramsulfuron metabolite 4-formylamido-N-methylbenzamide for each organism group based on FOCUS Steps 1 and 2 calculations for the use of FSN+TCM OD 80 (50+30)) in sugar beet (Use group A)

Group		**Fish acute**	**Fish pro-longed**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic plants**
Test species		***Oncorhynchus mykiss***	***Pimephales promelas***	***Daphnia magna***	***Daphnia magna***	***Anabaena flos-aquae***	***Lemna gibba***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_rC_{50}/E_yC_{50}	E_rC_{50}
(µg/L)		>100000	10500	>100000	100000	8100	>10000
AF		100	10	100	10	10	10
RAC (µg/L)		>1000	1050	>1000	10000	810	>1000
FOCUS Scenario	**PEC gl-max (µg/L)**						
Step 1 (risk envelope approach: 60 g a.s./ha, year-round use, no crop interception)							
	1.5945	< 0.0016	0.0015	< 0.0016	0.0002	0.0020	< 0.0016

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

zRMS comments:

zRMS agrees with the risk assessment for metabolite 4-formylamido-N-methylbenzamide for each organism group based on FOCUS Steps 1 and 2 calculations in sugar beet (Use group A).

Table 9.5-16: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for foramsulfuron metabolite foramsulfuron-sulfamic acid for each organism group based on FOCUS Steps 1 and 2 calculations for the use of FSN+TCM OD 80 (50+30) in sugar beet (Use group A)

Group		**Fish acute**	**Fish pro-longed**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic plants**
Test species		***Oncorhynchus mykiss***	***Pimephales promelas***	***Daphnia magna***	***Daphnia magna***	***Anabaena flos-aquae***	***Lemna gibba***
Endpoint (µg/L)		LC_{50} >100000	NOEC 10500	EC_{50} >100000	NOEC 100000	E_rC_{50}/E_yC_{50} 8100	E_rC_{50} >10000
AF		100	10	100	10	10	10
RAC (µg/L)		>1000	1050	>1000	10000	810	>1000
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**						
Step 1 (risk envelope approach: 60 g a.s./ha, year-round use, no crop interception)							
	2.2243	< 0.0022	0.0021	< 0.0022	0.0002	0.0027	< 0.0022

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

zRMS comments:

zRMS agrees with the risk assessment foramsulfuron metabolite foramsulfuron-sulfamic acid for each organism group based on FOCUS Steps 1 and 2 calculations in sugar beet (Use group A).

Thiencarbazone-methyl and metabolites

Table 9.5-17: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for thiencarbazone-methyl for each organism group based on FOCUS Steps 1 and 2 calculations for the use of FSN+TCM OD 80 (50+30) in sugar beet (Use group A)

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. Prolonged**	**Sed. dwell. acute**	**Crustacean acute**	**Crustacean prolonged**	**Algae**	**Aquatic macrophyte**
Test species		***Oncorhynchus mykiss***	***Oncorhynchus mykiss***	***Daphnia magna***	***Daphnia magna***	***Chironomus riparius***	***Americamysis bahia***	***Americamysis bahia***	***Pseudokirchn. subcapitata***	***Lemna gibba***
Endpoint (µg/L)		LC_{50} >104000	NOEC 4800	EC_{50} >98600	NOEC 3540	EC_{50} > 100000	EC_{50} > 94000	NOEC 5900	E_rC_{50} 1017	E_rC_{50} 1.31
AF		100	10	100	10	100	100	10	10	10
RAC (µg/L)		> 1040	480	> 986	354	> 1000	> 940	590	101.7	0.131
FOCUS Scenario	**PEC gl-max (µg/L)**									
Step 1 (risk envelope approach: 40 g/ha, year-round use, no crop interception)										
	12.133	< 0.012	0.025	< 0.012	0.034	< 0.012	< 0.013	0.021	0.119	**92.618**
Step 2 (risk envelope approach: 40 g/ha, year-round use, no crop interception)										
N-Europe	5.2228									**39.869**
S-Europe	4.2390									**32.359**

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

zRMS comments:

zRMS agrees with the risk assessment for a.s. thiencarbazone-methyl for each organism group based on FOCUS Steps 1 and 2 calculations for the use of FSN+TCM OD 80 (50+30) in sugar beet (Use group A). Further refinment is required for Lemna sp.

Table 9.5-18: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for thiencarbazone-methyl metabolite BYH 18636-carboxylic acid for each organism group based on FOCUS Step 1 calculations for the use of FSN+TCM OD 80 (50+30) in sugar beet (Use group A)

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Sed. dwell. acute**	**Crustacean acute**	**Crustacean prolonged**	**Algae**	**Aquatic macrophyte**
Test species		***Oncorhynchus mykiss***	***Oncorhynchus mykiss***	***Daphnia magna***	***Daphnia magna***	***Chironomus riparius***	***Americamysis bahia***	***Americamysis bahia***	***Pseudokirchn. subcapitata***	***Lemna gibba***
Endpoint (µg/L)		LC_{50} >104000	NOEC 4800	EC_{50} >98600	NOEC 3540	EC_{50} > 100000	EC_{50} > 94000	NOEC 5900	E_rC_{50} 1017	E_rC_{50} 3540
AF		100	10	100	10	100	100	10	10	10
RAC (µg/L)		> 1040	480	> 986	354	> 1000	> 940	590	101.7	354
FOCUS Scenario	**PEC gl-max (µg/L)**									
Step 1 (risk envelope approach: 40 g/ha, year-round use, no crop interception)										
	11.573	< 0.011	0.024	< 0.012	0.033	< 0.012	< 0.012	0.020	0.114	0.033

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

zRMS comments:

zRMS agrees with the risk assessment for thiencarbazone-methyl metabolite BYH 18636-carboxylic acid for each organism group based on FOCUS Steps 1 and 2 calculations in sugar beet (Use group A).

Table 9.5-19: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for thiencarbazone-methyl metabolite BYH 18636-sulfonamide for each organism group based on FOCUS Step 1 calculations for the use of FSN+TCM OD 80 (50+30) in sugar beet (Use group A)

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Sed. dwell. acute**	**Crustacean acute**	**Crustacean prolonged**	**Algae**	**Aquatic macrophyte**
Test species		***Oncorhynchus mykiss***	***Oncorhynchus mykiss***	***Daphnia magna***	***Daphnia magna***	***Chironomus riparius***	***Americamysis bahia***	***Americamysis bahia***	***Pseudokirchn. subcapitata***	***Lemna gibba***
Endpoint (µg/L)		LC_{50} 98300	NOEC 4800	EC_{50} > 100000	NOEC 3540	EC_{50} > 100000	EC_{50} > 94000	NOEC 5900	E_rC_{50} 1610	E_rC_{50} 90500
AF		100	10	100	10	100	100	10	10	10
RAC (µg/L)		983	480	> 1000	354	> 1000	> 940	590	161	9050
FOCUS Scenario	**PEC gl-max (µg/L)**									
Step 1 (risk envelope approach: 40 g/ha, year-round use, no crop interception)										
	1.583	0.002	0.003	< 0.002	0.004	< 0.002	< 0.002	0.003	0.010	<0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

zRMS comments:

zRMS agrees with the risk assessment for thiencarbazone-methyl metabolite BYH 18636-sulfonamide for each organism group based on FOCUS Steps 1 and 2 calculations in sugar beet (Use group A).

Table 9.5-20: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for thiencarbazone-methyl metabolite BYH 18636-sulfonamide-carboxylic acid for each organism group based on FOCUS Step 1 calculations for the use of FSN+TCM OD 80 (50+30) in sugar beet (Use group A)

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Sed. dwell. acute**	**Crustacean acute**	**Crustacean prolonged**	**Algae**	**Aquatic macrophyte**
Test species		***Oncorhynchus mykiss***	***Oncorhynchus mykiss***	***Daphnia magna***	***Daphnia magna***	***Chironomus riparius***	***Americamysis bahia***	***Americamysis bahia***	***Pseudokirchn. subcapitata***	***Lemna gibba***
Endpoint (µg/L)		LC_{50} >104000	NOEC 4800	EC_{50} >98600	NOEC 3540	EC_{50} > 100000	EC_{50} > 94000	NOEC 5900	E_rC_{50} 1017	E_rC_{50} > 100000
AF		100	10	100	10	100	100	10	10	10
RAC (µg/L)		> 1040	480	> 986	354	> 1000	> 940	590	101.7	> 10000
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**									
Step 1 (risk envelope approach: 40 g/ha, year-round use, no crop interception)										
	6.7296	< 0.006	0.014	< 0.007	0.019	< 0.007	< 0.007	0.011	0.066	< 0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

zRMS comments:

zRMS agrees with the risk assessment for thiencarbazone-methyl metabolite BYH 18636-sulfonamide-carboxylic acid for each organism group based on FOCUS Steps 1 and 2 calculations in sugar beet (Use group A).

Table 9.5-21: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for thiencarbazone-methyl metabolite BYH 18636-MMT for each organism group based on FOCUS Step 1 calculations for the use of FSN+TCM OD 80 (50+30) in sugar beet (Use group A)

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Sed. dwell. acute**	**Crustacean acute**	**Crustacean prolonged**	**Algae**	**Aquatic macrophyte**
Test species		***Oncorhynchus mykiss***	***Oncorhynchus mykiss***	***Daphnia magna***	***Daphnia magna***	***Chironomus riparius***	***Americamysis bahia***	***Americamysis bahia***	***Pseudokirchn. subcapitata***	***Lemna gibba***
Endpoint (µg/L)		LC_{50} >104000	NOEC 4800	EC_{50} >98600	NOEC 3540	EC_{50} > 100000	EC_{50} > 94000	NOEC 5900	E_rC_{50} 1017	E_rC_{50} > 95700
AF		100	10	100	10	100	100	10	10	10
RAC (µg/L)		> 1040	480	> 986	354	> 1000	> 940	590	101.7	> 9570
FOCUS Scenario	**$PEC_{gl\text{-}max}$ (µg/L)**									
Step 1 (risk envelope approach: 40 g/ha, year-round use, no crop interception)										
	2.2508	< 0.002	0.005	< 0.002	0.006	< 0.002	< 0.002	0.004	0.022	< 0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

zRMS comments:

zRMS agrees with the risk assessment for thiencarbazone-methyl l metabolite BYH 18636-MMT for each organism group based on FOCUS Steps 1 and 2 calculations in sugar beet (Use group A).

Table 9.5-22: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for thiencarbazone-methyl metabolite BYH 18636-dicarboxy-sulfonamide for each organism group based on FOCUS Step 1 calculations for the use of FSN+TCM OD 80 (50+30) in sugar beet (Use group A)

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Sed. dwell. acute**	**Crustacean acute**	**Crustacean prolonged**	**Algae**	**Aquatic macrophyte**
Test species		***Oncorhynchus mykiss***	***Oncorhynchus mykiss***	***Daphnia magna***	***Daphnia magna***	***Chironomus riparius***	***Americamysis bahia***	***Americamysis bahia***	***Pseudokirchn. subcapitata***	***Lemna gibba***
Endpoint (µg/L)		LC_{50} >104000	NOEC 4800	EC_{50} >98600	NOEC 3540	EC_{50} > 100000	EC_{50} > 94000	NOEC 5900	E_rC_{50} 1017	E_rC_{50} > 104000
AF		100	10	100	10	100	100	10	10	10
RAC (µg/L)		> 1040	480	> 986	354	> 1000	> 940	590	101.7	> 10400
FOCUS Scenario	**$PEC_{gl\text{-}max}$ (µg/L)**									
Step 1 (risk envelope approach: 40 g/ha, year-round use, no crop interception)										
	2.1070	< 0.002	0.004	< 0.002	0.006	< 0.002	< 0.002	0.004	0.021	< 0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

zRMS comments:

zRMS agrees with the risk assessment for thiencarbazone-methyl l for metabolite BYH 18636-dicarboxy-sulfonamide for each organism group based on FOCUS Steps 1 and 2 calculations in sugar beet (Use group A).

Combined toxicity risk assessment – Screening Tier level

zRMS comment:

The applicant proposes to conduct a co-exposure of active substances and AE F130619 in a combined risk assessment.
The MSs should consider this approach at national level.

Tier 1 – considering mitigation measures

According to current requirements when a product contains more than one active substance, an additional assessment on combined toxicity risk has to be presented. It is considered that a quantitative assessment according to concentration addition is however not needed if one of the following points applies:

- The risk assessment for all active substances in the product passes with a high margin of safety.
- One active substance clearly drives the risk assessment.

These conditions are assessed following a step-wise approach. A detailed description of this approach is presented in a separate document (Gladbach, A., Ebeling, M., Weyers, A., 2016, M-571377-02-1). The assessment is based on RQ values (risk quotient RQ = PEC/RAC). Note that RQ values which actually pass the risk assessment are used and if different mitigation measures result in an acceptable risk, the highest RQ value per individual substance is used.

1st step: Margin of safety
Condition: all RQ values are < 1/n (n = number active substances in the mixture).

2nd step: Risk per fraction
Condition: One a.s. contributes to ≥ 90% of the predicted combined toxicity of the product.
Assessment: The contribution of each individual a.s. to the combined toxicity (risk per fraction, rpf) is estimated based on the following equation:

$$rpf_{a.s.1} = RQ_{a..s.1} / (RQ_{a.s.1} + RQ_{a.s.2} \ldots + RQ_{a..s.i})$$

The estimation is based on RQ values from the same FOCUS Step to assure comparability.

3rd step: RQ_{MIX} calculation

Condition: The combined risk is acceptable when $RQ_{MIX} \leq 1$.
Assessment: The combined toxicity risk (RQ_{MIX}) with concentration-addition for aquatic organisms is estimated according to the following formula:

$$RQ_{mix} = \sum_{i=1}^{n} \frac{PEC_i}{RAC_i}$$

As the notifier experienced differing preferences by national reviewers for one or the other step, results of all three steps are considered below:

Table 9.5-23: Combined toxicity risk assessment for aquatic organisms – Screening Tier, FOCUS Step 1-2 for generic risk envelope (use group A)

Group		Fish, acute[1)]	Fish, prolonged[1)]	Invertebrates, acute[1)]	Invertebrates, prolonged[1)]	Algae[1)]	Aquatic macrophytes[2)]
RQ values[1)]	FSN	< 0.0189	0.0180	< 0.0189	0.0019	0.0233	**76.631**
	AE F130619	-	-	-	-	-	**13.218**
	TCM	< 0.012	0.025	< 0.012	0.034	0.119	**39.869**
Trigger		1	1	1	1	1	1
1/n		0.5	0.5	0.5	0.5	0.5	0.33
1st step: All RQ < 1/n		yes	yes	yes	yes	yes	Not profitable at screening level, as risk envelope assessment remained unresolved for individual substances FSN, its metabolite AE F130619, and TCM. Combined assessment for macrophytes is therefore presented at Tier 1, Tier 2, and Tier 3 for the accurate GAP below.
2nd step: RPF_{max}		not applicable[#]	not applicable[#]	not applicable[#]	not applicable[#]	not applicable[#]	
3rd step: RQ_{mix}		< 0.031	0.043	< 0.031	0.036	0.142	

FSN = Foramsulfuron, TCM = thiencarbazone-methyl
[1)] Based on step1 calculations
[2)] Based on step2 calculations
[#] The rpf calculation is not meaningful if due to a risk envelope approach for one or more individual substances the ratio of the active substances in the assessed mixture differs from the ratio in the formulation.

Combined toxicity risk is resolved for all aquatic organism groups other than macrophytes via a simple FOCUS Step 1-2 based screening level asessment for the generic risk envelope use pattern (use group A), covering all uses.

Overall conclusion from Screening Level risk assessment:

Assuming a highly conservative generic exposure situation (FOCUS Step 1-2 exposure simulations for risk envelope use pattern covering all uses, use group A), risk assessment including combination toxicity could be resolved for all groups of aquatic organisms other than macrophytes. Acceptable risk was also demonstrated for all biologically inactive metabolites (i.e. other than AE F130619), for all groups of organisms.
Subsequent assessment steps will therefore concentrate on the biologically active components of relevance for this formulation, i.e. foramsulfuron, metabolite AE F130619, and thiencarbazone-methyl.

9.5.2.4 Tier 1 – considering mitigation measures for FOCUS Step 4: Accurate GAP assessment based on FOCUS Step 3-4, all active substances and metabolite AE F130619

In the following section the risk assessment will focus on macrophytes, as only for this group of organisms the risk was left unresolved after the FOCUS Step 1-2 based screening level assessments presented before. Tier 1 level risk assessment will start from FOCUS step 3 exposure calculations for the two critical GAP situations of use groups B and C covering all intended product uses of FSN+TCM OD 80 (50+30) in countries requiring FOCUSsw calculations.
The scenarios which do not pass the risk assessment based on FOCUS Step 3 will be further addressed below considering FOCUS Step 4 PEC_{sw} values.

The Tier 1 risk assessment will follow the recommendations of the EFSA Aquatic Guidance Document for chronic risk assessment, as found visualised in "Decision scheme B" on guidance page 15, and further outlined in the subsequent text of pages 15-16. In the chronic risk assessment, the RAC_{sw} is, in the first instance, compared with the $PEC_{sw;max}$, and under certain conditions with a $PEC_{sw;twa}$ (the predicted time-weighted average (TWA) concentration in surface water). A decision scheme on when to use the $PEC_{sw;max}$ or the $PEC_{sw;twa}$ in the chronic RA is presented in the guidance and will be applied below. Note that the applicability of TWA can only be demonstrated for foramsulfuron but not for metabolite AE F130619 and for thiencarbazone-methyl.

Foramsulfuron

TWA applicability check and justification: The EFSA AGD proposes the use of a time weighted average (TWA) concentration in the risk assessment of aquatic organisms in order to address a possible discrepancy between the duration of an exposure event and the exposure period in the corresponding effect study. Specific prerequisites have to be fulfilled before the use of a TWA approach can be justified. In **Appendix A 3.1**, it is discussed for the active substance foramsulfuron and the test organism *Lemna gibba* whether the $PEC_{sw,twa}$ can be compared to the $RAC_{sw,ch}$ in the risk assessment using the TWA approach by (i) showing linear reciprocity for this species compound combination, (ii) using the decision scheme presented in the EFSA AGD and (iii) direct proof of conservatism of the TWA approach itself. All lines of evidence are supported by biological data derived from static exposure or peak exposure studies and/or by simulations (*in silico* experiments) using a mechanistic *Lemna* model. As a crucial first step, it is shown that linear reciprocity can be ascertained for the combination of *Lemna* and foramsulfuron, forming the basis of the TWA approach. Furthermore, the EFSA AGD decision scheme clearly allows for the use of TWA in the case presented here, putting a special focus on the evaluation of onset of effects and potential delayed effects. An additional alternative 'direct proof of conservatism' test presented by the notifier compares effect levels from short-term and long-term studies, and also confirms that the TWA approach in the case of *Lemna* and foramsulfuron can be regarded as conservative and therefore protective.

Table 9.5-24: Overview on methodologies used to demonstrate the applicability of the TWA approach: (for detailed assessment see Appendix A 3.1 (a): Solga, A.; Heine, S.; 2018; M-615294-02-1)

Criteria addressed / methodology		Analysis of biological data	*In silico* experiment
Reciprocity		X	-
Decision scheme	Generic parts	X	-
	Early onset of effects	X	X
	Delayed effects	X	X
Direct proof of conservatism		Graphical data comparison between constant exposure and pulse exposure studies.	

As an overall conclusion, it is considered justified to base the Tier 1 risk assessment for *Lemna gibba* and foramsulfuron on 7d time-weighted average concentrations ($PEC_{sw,\ 7d\text{-}twa}$).

Risk Assessment: In the following, therefore both, a risk assessment based on $PEC_{sw,max}$ and a risk assessment based on $PEC_{sw,\ 7d\text{-}twa}$ will be shown side-by-side, as they are considered to represent alternative Tier 1 approaches applicable for foramsulfuron.

Table 9.5-25: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for foramsulfuron for aquatic macrophytes based on FOCUS Step 3 calculations for the use of FSN+TCM OD 80 (50+30) in sugar beet

Group		**Aquatic plants**		~~**Aquatic plants**~~
Test species		***Lemna gibba***		~~***Lemna gibba***~~
Endpoint (µg/L)		E_rC_{50} 1.01		~~E_rC_{50} 1.01~~
AF		10		~~10~~
RAC (µg/L)		0.101		~~0.101~~
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**		~~**7 d PEC$_{twa}$ (µg/L)**~~	
Use group B – FOCUS Step 3 (use on sugarbeets / rate = 1 × 50 g a.s./ha ≡ 1 × 1.0 L prod./ha)				
D3/ditch	0.2624	**2.5980**	~~0.0447~~	~~0.4426~~
D4/pond	0.0111	0.1099	~~0.0103~~	~~0.1020~~
D4/stream	0.2146	**2.1248**	~~0.0021~~	~~0.0208~~
R1/pond	0.0151	0.1495	~~0.0141~~	~~0.1396~~
R1/stream	0.1813	**1.7950**	~~0.0150~~	~~0.1485~~
R3/stream	0.3644	**3.6079**	~~0.0515~~	~~0.5099~~
Use group C – FOCUS Step 3 (use on sugarbeet / rate = 2 × 25 g a.s./ha ≡ 2 × 0.5 L prod./ha)				
D3/ditch	0.1313	**1.3000**	~~0.0224~~	~~0.2218~~
D4/pond	0.0083	0.0822	~~0.0078~~	~~0.0772~~
D4/stream	0.1071	**1.0604**	~~0.0016~~	~~0.0158~~
R1/pond	0.0247	0.2446	~~0.0232~~	~~0.2297~~
R1/stream	0.4106	**4.0653**	~~0.0351~~	~~0.3475~~
R3/stream	0.8509	**8.4248**	~~0.1202~~	~~**1.1901**~~

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in **bold**

For foramsulfuron, risks are acceptable in the scenarios D4 pond and R1 pond for the two critical GAP situations of use groups B and C covering all intended product uses of FSN+TCM OD 80 (50+30). When risk assessment is based on $PEC_{sw, max}$, the scenarios D3 ditch, D4 stream, R1 stream and R3 stream remain unresolved in the FOCUS Step 3 based risk assessment.
Subsequently, the risk assessment was performed with a TWA PEC_{sw} approach. In these conditions, the risks are acceptable in all scenarios but R3 stream for the one critical GAP situation of use group C.
Therefore, for foramsulfuron further risk assessment based on FOCUS Step 4 is deemed necessary here and is presented in the following. A more in depth refined assessment of the potential risk for macrophytes posed by the scenario situations of D3, D4, R1 and R3 will be made later in Section 9.5.2.5 to Section 9.5.2.8 of this document, as part of the Tier 2C and Tier 3 level assessment.

zRMS comments:

It should be noted that the risk assessment based on PECsw twa at STEP 3 was not considered acceptable by zRMS -PL.
According to section 4.5 of EFSA (2013) for use of the PEC_{twa}, linear reciprocity must be demonstrated.
In the case of Foramsulfuron the check for linear reciprocity was based on the first 7 days of the Lemna study of Christ & Ruff (1998, M-147891-02-1) which also delivers the endpoint to be used in the Tier 1 risk assessment for aquatic plants (E_rC_{50} = 1.01 µg a.s./L). This endpoint was presented by EFSA in their conclusion on Foramsulfuron.
The currently the use of PECsw-twa is not accepted until further work is done to verify its suitability and under which circumstances it is appropriate to use.
This was discussed at a PRAPeR meeting (EFSA Supporting publication 2015:EN-924) where it was stated that 'It was agreed that until further guidance on reciprocity and latency of effects are.
However, the endpoint used to demonstrate linear reciprocity was based on yield for frond number, whereas the tier 1 endpoint is based on growth rate.
Inhibitions of yield for frond number were considered for the intervals 0-2, 0-4 days.
The Applicant stated that reciprocity based on growth rate is not meaningful. However, as stated by EFSA, reciprocity has to be demonstrated for the endpoint that is used for the risk assessment with the exception of the E_yC_{50} for taxa showing exponential growth (e.g. Lemna sp.). In this specific case, one possible option would be to demonstrate the reciprocity using E_rC_{50} and then using the E_yC_{50} in the risk assessment (corrigendum of the Aquatic Guidance Document (EFSA, 2016).
In this case, the Applicant has attempted to demonstrate reciprocity for yield and used the E_rC_{50} in the risk assessment.
It is unclear from EFSA (2016) if it is appropriate to take this approach available, then the use of TWA approaches are unlikely to be sufficiently robust to be used in regulatory risk assessment. The Applicant provided an alternative approach additionally, considering the conservatism of the TWA approach as justification for its use in the risk assessment. However, this is not an agreed Central Zone approach and as such has not been considered further by the ZRMS as justification for using the TWA. Furthermore, reference was made to proof of conservatism by considering the results from the pulsed dose studies.
zRMS did not consider the results of peak exposure study for active substance and its metabolite- Foramsulfuron metabolite AE F130619.
We considered the max PEC_{sw} values at STEP 3 instead of PEC_{twa} STEP 3 values proposed by the Applicant.
When risk assessment is based on $PEC_{sw, max}$, the scenarios D3 ditch, D4 stream, R1 stream and R3 stream remain unresolved in the FOCUS Step 3 based risk assessment. Therefore, for foramsulfuron further risk assessment based on FOCUS Step 4 is considered.

Table 9.5-26: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for <u>foramsulfuron</u> based on FOCUS Step 4 calculations and toxicity data for aquatic plants with mitigation of spray drift and run-off for the use of FSN+TCM OD 80 (50+30) in sugar beet – Use: sugar beet, 1 × 50 g foramsulfuron/ha

Sugar beet, 1 × 50 g a.s./ha	**Scenario**	**PECsw STEP 4 foramsulfuron**								**PECsw / RAC** RAC = 0.101 µg/L							
		PEC gl-max						**7-d PECtwa**		**PEC gl-max**						~~7-d PECtwa~~	
Nozzle red.	Vegetated strip (m)	None	None	None	None	10 m low*	20 m high*	10 m low*	20 m high*	None	None	None	None	10 m low*	20 m high*	~~10 m low*~~	~~20 m high*~~
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m	10 m	20 m	0 m	5 m	10 m	20 m	10 m	20 m	~~10 m~~	~~20 m~~
None	D3 Ditch	0.2624	0.0859	0.0458	0.0237	0.0458	0.0237	0.0078	0.004	**2.5980**	0.8505	0.4535	0.2347	0.4535	0.2347	~~0.0772~~	~~0.0396~~
50 %		0.1312	0.043	0.0229	0.0119	0.0229	0.0119	0.0039	0.002	**1.2990**	0.4257	0.2267	0.1178	0.2267	0.1178	~~0.0386~~	~~0.0198~~
75 %		0.0656	0.0215	0.0115	0.0059	0.0115	0.0059	0.0019	0.001	0.6495	0.2129	0.1139	0.0584	0.1139	0.0584	~~0.0188~~	~~0.0099~~
90 %		0.0262	0.0086	0.0046	0.0024	0.0046	0.0024	0.0008	0.0004	0.2594	0.0851	0.0455	0.0238	0.0455	0.0238	~~0.0079~~	~~0.0040~~
None	D4 Pond	0.0111	0.01	0.0073	0.005	0.0073	0.005	0.0068	0.0047	0.1099	0.0990	0.0723	0.0495	0.0723	0.0495	~~0.0673~~	~~0.0465~~
50 %		0.0058	0.0053	0.0039	0.0028	0.0039	0.0028	0.0037	0.0026	0.0574	0.0525	0.0386	0.0277	0.0386	0.0277	~~0.0366~~	~~0.0257~~
75 %		0.0032	0.0029	0.0022	0.0017	0.0022	0.0017	0.0021	0.0016	0.0317	0.0287	0.0218	0.0168	0.0218	0.0168	~~0.0208~~	~~0.0158~~
90 %		0.0016	0.0015	0.0012	0.001	0.0012	0.001	0.0011	0.001	0.0158	0.0149	0.0119	0.0099	0.0119	0.0099	~~0.0109~~	~~0.0099~~
None	D4 Stream	0.2146	0.0904	0.0482	0.0252	0.0482	0.0252	0.0008	0.0008	**2.1248**	0.8950	0.4772	0.2495	0.4772	0.2495	~~0.0079~~	~~0.0079~~
50 %		0.1075	0.0454	0.0243	0.0128	0.0243	0.0128	0.0008	0.0008	**1.0644**	0.4495	0.2406	0.1267	0.2406	0.1267	~~0.0079~~	~~0.0079~~
75 %		0.054	0.023	0.0124	0.0067	0.0124	0.0067	0.0008	0.0008	0.5347	0.2277	0.1228	0.0663	0.1228	0.0663	~~0.0079~~	~~0.0079~~
90 %		0.0219	0.0095	0.0052	0.0029	0.0052	0.0029	0.0008	0.0008	0.2168	0.0941	0.0515	0.0287	0.0515	0.0287	~~0.0079~~	~~0.0079~~
None	R1 Pond	0.0151	0.0144	0.0127	0.0112	0.0077	0.0045	0.0072	0.0043	0.1495	0.1426	0.1257	0.1109	0.0762	0.0446	~~0.0713~~	~~0.0426~~
50 %		0.0117	0.0114	0.0105	0.0098	0.0055	0.0031	0.0052	0.0029	0.1158	0.1129	0.1040	0.0970	0.0545	0.0307	~~0.0515~~	~~0.0287~~
75 %		0.01	0.0099	0.0094	0.0091	0.0044	0.0024	0.0041	0.0022	0.0990	0.0980	0.0931	0.0901	0.0436	0.0238	~~0.0406~~	~~0.0218~~
90 %		0.009	0.009	0.0088	0.0086	0.0038	0.002	0.0035	0.0018	0.0891	0.0891	0.0871	0.0851	0.0376	0.0198	~~0.0347~~	~~0.0178~~
None	R1 Stream	0.1813	0.1791	0.1791	0.1791	0.0812	0.0425	0.0068	0.0035	**1.7950**	**1.7733**	**1.7733**	**1.7733**	0.8040	0.4208	~~0.0673~~	~~0.0347~~
50 %		0.1791	0.1791	0.1791	0.1791	0.0812	0.0425	0.0068	0.0035	**1.7733**	**1.7733**	**1.7733**	**1.7733**	0.8040	0.4208	~~0.0673~~	~~0.0347~~
75 %		0.1791	0.1791	0.1791	0.1791	0.0812	0.0425	0.0068	0.0035	**1.7733**	**1.7733**	**1.7733**	**1.7733**	0.8040	0.4208	~~0.0673~~	~~0.0347~~
90 %		0.1791	0.1791	0.1791	0.1791	0.0812	0.0425	0.0068	0.0035	**1.7733**	**1.7733**	**1.7733**	**1.7733**	0.8040	0.4208	~~0.0673~~	~~0.0347~~

Sugar beet, 1 × 50 g a.s./ha	Scenario	PECsw STEP 4 foramsulfuron								PECsw / RAC RAC = 0.101 µg/L							
		PEC gl-max						7-d PECtwa		PEC gl-max						7-d PECtwa	
Nozzle red.	Vegetated strip (m)	None	None	None	None	10 m low*	20 m high*	10 m low*	20 m high*	None	None	None	None	10 m low*	20 m high*	10 m low*	20 m high*
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m	10 m	20 m	0 m	5 m	10 m	20 m	10 m	20 m	10 m	20 m
None	R3 Stream	0.3644	0.3644	0.3644	0.3644	0.1662	0.0872	0.0237	0.0125	**3.6079**	**3.6079**	**3.6079**	**3.6079**	**1.6455**	0.8634	0.2347	0.1238
50 %		0.3644	0.3644	0.3644	0.3644	0.1662	0.0872	0.0237	0.0125	**3.6079**	**3.6079**	**3.6079**	**3.6079**	**1.6455**	0.8634	0.2347	0.1238
75 %		0.3644	0.3644	0.3644	0.3644	0.1662	0.0872	0.0237	0.0125	**3.6079**	**3.6079**	**3.6079**	**3.6079**	**1.6455**	0.8634	0.2347	0.1238
90 %		0.3644	0.3644	0.3644	0.3644	0.1662	0.0872	0.0237	0.0125	**3.6079**	**3.6079**	**3.6079**	**3.6079**	**1.6455**	0.8634	0.2347	0.1238

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
* low and high fractional reduction in the runoff and erosion through volume, mass and flux

Table 9.5-27: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for <u>foramsulfuron</u> based on FOCUS Step 4 calculations and toxicity data for aquatic plants with mitigation of spray drift and run-off for the use of FSN+TCM OD 80 (50+30) in sugar beet – Use: sugar beet, 2 × 25 g foramsulfuron/ha

Sugar beet, 2 × 25 g a.s./ha	Scenario	PECsw STEP 4 foramsulfuron								PECsw / RAC RAC = 0.101 µg/L							
		PEC gl-max						7-d PECtwa		PEC gl-max						7-d PECtwa	
Nozzle red.	Vegetated strip (m)	None	None	None	None	10 m low*	20 m high*	10 m low*	20 m high*	None	None	None	None	10 m low*	20 m high*	10 m low*	20 m high*
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m	10 m	20 m	0 m	5 m	10 m	20 m	10 m	20 m	10 m	20 m
None	D3 Ditch	0.1313	0.0431	0.0227	0.0119	0.0227	0.0119	0.0039	0.002	**1.3000**	0.4267	0.2248	0.1178	0.2248	0.1178	0.0386	0.0198
50 %		0.0657	0.0216	0.0114	0.0059	0.0114	0.0059	0.0019	0.001	0.6505	0.2139	0.1129	0.0584	0.1129	0.0584	0.0188	0.0099
75 %		0.0329	0.0108	0.0057	0.003	0.0057	0.003	0.001	0.0005	0.3257	0.1069	0.0564	0.0297	0.0564	0.0297	0.0099	0.0050
90 %		0.0131	0.0043	0.0023	0.0012	0.0023	0.0012	0.0004	0.0002	0.1297	0.0426	0.0228	0.0119	0.0228	0.0119	0.0040	0.0020
None	D4 Pond	0.0083	0.0076	0.0055	0.0039	0.0055	0.0039	0.0052	0.0037	0.0822	0.0752	0.0545	0.0386	0.0545	0.0386	0.0515	0.0366
50 %		0.0045	0.0042	0.0031	0.0023	0.0031	0.0023	0.0029	0.0022	0.0446	0.0416	0.0307	0.0228	0.0307	0.0228	0.0287	0.0218
75 %		0.0026	0.0024	0.0019	0.0015	0.0019	0.0015	0.0018	0.0014	0.0257	0.0238	0.0188	0.0149	0.0188	0.0149	0.0178	0.0139
90 %		0.0014	0.0014	0.0013	0.0012	0.0013	0.0012	0.0013	0.0012	0.0139	0.0139	0.0129	0.0119	0.0129	0.0119	0.0129	0.0119

Sugar beet, 2 × 25 g a.s./ha	**Scenario**	**PECsw STEP 4 foramsulfuron**								**PECsw / RAC** RAC = 0.101 µg/L							
		PEC gl-max						**7-d PECtwa**		**PEC gl-max**						~~7-d PECtwa~~	
Nozzle red.	Vegetated strip (m)	None	None	None	None	10 m low*	20 m high*	10 m low*	20 m high*	None	None	None	None	10 m low*	20 m high*	~~10 m low*~~	~~20 m high*~~
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m	10 m	20 m	0 m	5 m	10 m	20 m	10 m	20 m	~~10 m~~	~~20 m~~
None	D4 Stream	0.1071	0.0453	0.0241	0.0126	0.0241	0.0126	0.0009	0.0009	**1.0604**	0.4485	0.2386	0.1248	0.2386	0.1248	~~0.0089~~	~~0.0089~~
50 %		0.0537	0.0228	0.0121	0.0064	0.0121	0.0064	0.0009	0.0009	0.5317	0.2257	0.1198	0.0634	0.1198	0.0634	~~0.0089~~	~~0.0089~~
75 %		0.0269	0.0115	0.0062	0.0033	0.0062	0.0033	0.0009	0.0009	0.2663	0.1139	0.0614	0.0327	0.0614	0.0327	~~0.0089~~	~~0.0089~~
90 %		0.0109	0.0047	0.0027	0.0017	0.0027	0.0017	0.0009	0.0009	0.1079	0.0465	0.0267	0.0168	0.0267	0.0168	~~0.0089~~	~~0.0089~~
None	R1 Pond	0.0247	0.0242	0.0225	0.0212	0.0113	0.0063	0.0106	0.0059	0.2446	0.2396	0.2228	0.2099	0.1119	0.0624	~~0.1050~~	~~0.0584~~
50 %		0.0217	0.0214	0.0205	0.0199	0.0094	0.005	0.0088	0.0047	0.2149	0.2119	0.2030	0.1970	0.0931	0.0495	~~0.0871~~	~~0.0465~~
75 %		0.0202	0.02	0.0196	0.0193	0.0084	0.0044	0.0079	0.0041	0.2000	0.1980	0.1941	0.1911	0.0832	0.0436	~~0.0782~~	~~0.0406~~
90 %		0.0192	0.0192	0.019	0.0189	0.0079	0.004	0.0073	0.0037	0.1901	0.1901	0.1881	0.1871	0.0782	0.0396	~~0.0723~~	~~0.0366~~
None	R1 Stream	0.4106	0.4106	0.4106	0.4106	0.1862	0.0974	0.0158	0.0083	**4.0653**	**4.0653**	**4.0653**	**4.0653**	**1.8436**	0.9644	~~0.1564~~	~~0.0822~~
50 %		0.4106	0.4106	0.4106	0.4106	0.1862	0.0974	0.0158	0.0083	**4.0653**	**4.0653**	**4.0653**	**4.0653**	**1.8436**	0.9644	~~0.1564~~	~~0.0822~~
75 %		0.4106	0.4106	0.4106	0.4106	0.1862	0.0974	0.0158	0.0083	**4.0653**	**4.0653**	**4.0653**	**4.0653**	**1.8436**	0.9644	~~0.1564~~	~~0.0822~~
90 %		0.4106	0.4106	0.4106	0.4106	0.1862	0.0974	0.0158	0.0083	**4.0653**	**4.0653**	**4.0653**	**4.0653**	**1.8436**	0.9644	~~0.1564~~	~~0.0822~~
None	R3 Stream	0.8509	0.8509	0.8509	0.8509	0.3881	0.2036	0.0553	0.0291	**8.4248**	**8.4248**	**8.4248**	**8.4248**	**3.8426**	**2.0158**	~~0.5475~~	~~0.2881~~
50 %		0.8509	0.8509	0.8509	0.8509	0.3881	0.2036	0.0553	0.0291	**8.4248**	**8.4248**	**8.4248**	**8.4248**	**3.8426**	**2.0158**	~~0.5475~~	~~0.2881~~
75 %		0.8509	0.8509	0.8509	0.8509	0.3881	0.2036	0.0553	0.0291	**8.4248**	**8.4248**	**8.4248**	**8.4248**	**3.8426**	**2.0158**	~~0.5475~~	~~0.2881~~
90 %		0.8509	0.8509	0.8509	0.8509	0.3881	0.2036	0.0553	0.0291	**8.4248**	**8.4248**	**8.4248**	**8.4248**	**3.8426**	**2.0158**	~~0.5475~~	~~0.2881~~

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
* low and high fractional reduction in the runoff and erosion through volume, mass and flux

Conclusion from Tier 1 Level risk assessment for foramsulfuron:

A detailed summary of the outcome of the Tier 1 risk assessment level per use group and FOCUS scenario is provided in the following tables.

Table 9.5-28: Summary table of the aquatic risk assessment for foramsulfuron: use group B - use on sugar beet / rate 1 × 50 g a.s./ha (1 × 1.0 L prod./ha)

RA Tier *(Section reference)*	**Approach**	**D3 ditch**	**D4 pond**	**D4 stream**	**R1 pond**	**R1 stream**	**R3 stream**
Tier 1 *(9.5.2.4)*	FOCUS Step 3 & 4, based on PEC_{max}	resolved 5 m buffer	resolved Step 3	resolved 5 m buffer	resolved Step 3	resolved 10 m buffer	resolved 20 m buffer
	~~FOCUS Step 3 & 4, based on PEC_{twa}~~	~~resolved Step 3~~	~~resolved Step 3~~	~~resolved Step 3~~	~~resolved Step 3~~	~~resolved Step 3~~	~~resolved Step 3~~

Table 9.5-29: Summary table of the aquatic risk assessment for foramsulfuron: use group C - use on sugar beet / rate 2 × 25 g a.s./ha (2 × 0.5 L prod./ha)

RA Tier *(Section reference)*	**Approach**	**D3 ditch**	**D4 pond**	**D4 stream**	**R1 pond**	**R1 stream**	**R3 stream**
Tier 1 *(9.5.2.4)*	FOCUS Step 3 & 4, based on PEC_{max}	resolved 5 m buffer	resolved Step 3	resolved 5 m buffer	resolved Step 3	resolved 20 m buffer	**failed 20 m buffer**
	~~FOCUS Step 3 & 4, based on PEC_{twa}~~	~~resolved Step 3~~	~~resolved Step 3~~	~~resolved Step 3~~	~~resolved Step 3~~	~~resolved Step 3~~	~~resolved 10 m buffer~~

zRMS comments:

The PEC/RAC ratio is below <1 **for foramsulfuron** for D3 (ditch), D4 (stream), R1 (stream) and R3 (stream) scenarios when following risk mititagation measures are applied to surface water bodies:

Use group B - use on sugar beet / rate 1 × 50 g a.s./ha (1 × 1.0 L prod./ha)

RA Tier	Approach	D3 ditch	D4 stream	R1 stream	R3 stream
Tier 1	FOCUS Step 4, based on PEC_{max}	resolved 5 m buffer	resolved 5 m buffer	resolved 10 m buffer	resolved 20 m buffer

Use group C - use on sugar beet / rate 2 × 25 g a.s./ha (2 × 0.5 L prod./ha)

RA Tier	Approach	D3 ditch	D4 stream	R1 stream	R3 stream
Tier 1	FOCUS Step 4, based on PEC_{max}	resolved 5 m buffer	resolved 5 m buffer	resolved 20 m buffer	**failed 20 m buffer**

Foramsulfuron metabolite AE F130619

Risk Assessment: In the following, a risk assessment based on $PEC_{sw,max}$ with associated RAC according EFSA will be shown to represent the Tier 1 approach applicable for metabolite AE F130619. Note that in contrast to foramsulfuron, for metabolite AE F130619 the applicability of TWA cannot be demonstrated.

Table 9.5-30: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for foramsulfuron metabolite AE F130619 for aquatic macrophytes based on FOCUS Step 3 calculations for the use of FSN+TCM OD 80 (50+30) in sugar beet

Group		**Aquatic plants**
Test species		***Lemna gibba***
Endpoint		E_rC_{50}
(µg/L)		0.889
AF		10
RAC (µg/L)		0.0889
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**	
Use group B – FOCUS Step 3 **(use on sugar beet / rate = 1 × 50 g a.s./ha ≡ 1 × 1.0 L prod./ha)**		
D3/ditch	0.0003	0.0034
D4/pond	0.0003	0.0034
D4/stream	0.0003	0.0034
R1/pond	0.0010	0.0112
R1/stream	0.0193	0.2171
R3/stream	0.0432	0.4859
Use group C – FOCUS Step 3 **(use on sugar beet / rate = 2 × 25 g a.s./ha ≡ 2 × 0.5 L prod./ha)**		
D3/ditch	0.0001	0.0011
D4/pond	0.0003	0.0034
D4/stream	0.0002	0.0022

Group		**Aquatic plants**
R1/pond	0.0017	0.0191
R1/stream	0.0364	0.4094
R3/stream	0.0833	0.9370

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in **bold**

When the risk assessment is based on $PEC_{sw, max}$ at FOCUS Step 3 level, risks are acceptable in all scenarios.

Overall, for the metabolite AE F130619 the risks are acceptable at Tier 1 level without mitigation measures in all FOCUS scenarios for all intended uses of the product.

Nevertheless, for the metabolite AE F130619 further risk assessment based on FOCUS Step 4 is presented in the following because the RQ values based on the FOCUS Step 4 risk assessment are needed for the assessment of combined toxicity on Tier 1 level presented at the end of this chapter.

zRMS comments:
We agree with the risk assessment provided for foramsulfuron metabolite AE F130619 for aquatic macrophytes.
When the risk assessment is based on $PEC_{sw, max}$ at FOCUS Step 3 level, risks are acceptable in all scenarios.
For the metabolite AE F130619 further risk assessment based on FOCUS Step 4 is presented because the RQ values based on the FOCUS Step 4 risk assessment are needed for the assessment of combined toxicity.

Table 9.5-31: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for foramsulfuron metabolite AE F130619 based on FOCUS Step 4 calculations and toxicity data for aquatic plants with mitigation of spray drift and run-off for the use of FSN+TCM OD 80 (50+30) in sugar beet – Use: sugar beet, 1 × 50 g foramsulfuron/ha

Sugar beet, 1 × 50 g a.s./ha	Scenario	PECsw STEP 4 AE F130619						PECsw / RAC RAC = 0.0889 µg/L					
		PEC gl-max						PEC gl-max					
Nozzle red.	Vegetated strip (m)	None	None	None	None	10 m low*	20 m high*	None	None	None	None	10 m low*	20 m high*
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 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	0.0034	0.0112	0.0112	0.0112	0.0112	0.0112
50 %		0.0001	0.001	0.001	0.001	0.001	0.001	0.0011	0.0112	0.0112	0.0112	0.0112	0.0112
75 %		0.001	0.001	0.001	0.001	0.001	0.001	0.0112	0.0112	0.0112	0.0112	0.0112	0.0112
90 %		0.001	0.001	0.001	0.001	0.001	0.001	0.0112	0.0112	0.0112	0.0112	0.0112	0.0112
None	D4 Pond	0.0003	0.0003	0.0002	0.0002	0.0002	0.0002	0.0034	0.0034	0.0022	0.0022	0.0022	0.0022
50 %		0.0002	0.0002	0.0002	0.0002	0.0002	0.0002	0.0022	0.0022	0.0022	0.0022	0.0022	0.0022
75 %		0.0002	0.0002	0.0002	0.0002	0.0002	0.0002	0.0022	0.0022	0.0022	0.0022	0.0022	0.0022
90 %		0.0002	0.0002	0.0002	0.0002	0.0002	0.0002	0.0022	0.0022	0.0022	0.0022	0.0022	0.0022
None	D4 Stream	0.0003	0.0002	0.0002	0.0002	0.0002	0.0002	0.0034	0.0022	0.0022	0.0022	0.0022	0.0022
50 %		0.0002	0.0002	0.0002	0.0002	0.0002	0.0002	0.0022	0.0022	0.0022	0.0022	0.0022	0.0022
75 %		0.0002	0.0002	0.0002	0.0002	0.0002	0.0002	0.0022	0.0022	0.0022	0.0022	0.0022	0.0022
90 %		0.0002	0.0002	0.0002	0.0002	0.0002	0.0002	0.0022	0.0022	0.0022	0.0022	0.0022	0.0022
None	R1 Pond	0.001	0.001	0.001	0.0009	0.0005	0.0002	0.0112	0.0112	0.0112	0.0101	0.0056	0.0022
50 %		0.0009	0.0009	0.0009	0.0009	0.0004	0.0002	0.0101	0.0101	0.0101	0.0101	0.0045	0.0022
75 %		0.0009	0.0009	0.0009	0.0009	0.0004	0.0002	0.0101	0.0101	0.0101	0.0101	0.0045	0.0022
90 %		0.0009	0.0009	0.0009	0.0009	0.0004	0.0002	0.0101	0.0101	0.0101	0.0101	0.0045	0.0022
None	R1 Stream	0.0193	0.0193	0.0193	0.0193	0.0088	0.0046	0.2171	0.2171	0.2171	0.2171	0.0990	0.0517
50 %		0.0193	0.0193	0.0193	0.0193	0.0088	0.0046	0.2171	0.2171	0.2171	0.2171	0.0990	0.0517
75 %		0.0193	0.0193	0.0193	0.0193	0.0088	0.0046	0.2171	0.2171	0.2171	0.2171	0.0990	0.0517
90 %		0.0193	0.0193	0.0193	0.0193	0.0088	0.0046	0.2171	0.2171	0.2171	0.2171	0.0990	0.0517
None	R3 Stream	0.0432	0.0432	0.0432	0.0432	0.0197	0.0103	0.4859	0.4859	0.4859	0.4859	0.2216	0.1159
50 %		0.0432	0.0432	0.0432	0.0432	0.0197	0.0103	0.4859	0.4859	0.4859	0.4859	0.2216	0.1159

Sugar beet, 1 × 50 g a.s./ha	Scenario	PECsw STEP 4 AE F130619						PECsw / RAC RAC = 0.0889 µg/L					
		PEC gl-max						PEC gl-max					
Nozzle red.	Vegetated strip (m)	None	None	None	None	10 m low*	20 m high*	None	None	None	None	10 m low*	20 m high*
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m	0 m	5 m	10 m	20 m	10 m	20 m
75 %		0.0432	0.0432	0.0432	0.0432	0.0197	0.0103	0.4859	0.4859	0.4859	0.4859	0.2216	0.1159
90 %		0.0432	0.0432	0.0432	0.0432	0.0197	0.0103	0.4859	0.4859	0.4859	0.4859	0.2216	0.1159

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
* low and high fractional reduction in the runoff and erosion through volume, mass and flux

Table 9.5-32: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for foramsulfuron metabolite AE F130619 based on FOCUS Step 4 calculations and toxicity data for aquatic plants with mitigation of spray drift and run-off for the use of FSN+TCM OD 80 (50+30) in sugar beet – Use: sugar beet, 2 × 25 g foramsulfuron/ha

Sugar beet, 2 × 25 g a.s./ha	Scenario	PECsw STEP 4 AE F130619						PECsw / RAC RAC = 0.0889 µg/L					
		PEC gl-max						PEC gl-max					
Nozzle red.	Vegetated strip (m)	None	None	None	None	10 m low*	20 m high*	None	None	None	None	10 m low*	20 m high*
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m	0 m	5 m	10 m	20 m	10 m	20 m
None	D3 Ditch	0.0001	0.001	0.001	0.001	0.001	0.001	0.0011	0.0112	0.0112	0.0112	0.0112	0.0112
50 %		0.001	0.001	0.001	0.001	0.001	0.001	0.0112	0.0112	0.0112	0.0112	0.0112	0.0112
75 %		0.001	0.001	0.001	0.001	0.001	0.001	0.0112	0.0112	0.0112	0.0112	0.0112	0.0112
90 %		0.001	0.001	0.001	0.001	0.001	0.001	0.0112	0.0112	0.0112	0.0112	0.0112	0.0112
None	D4 Pond	0.0003	0.0003	0.0002	0.0002	0.0002	0.0002	0.0034	0.0034	0.0022	0.0022	0.0022	0.0022
50 %		0.0002	0.0002	0.0002	0.0002	0.0002	0.0002	0.0022	0.0022	0.0022	0.0022	0.0022	0.0022
75 %		0.0002	0.0002	0.0002	0.0002	0.0002	0.0002	0.0022	0.0022	0.0022	0.0022	0.0022	0.0022
90 %		0.0002	0.0002	0.0002	0.0002	0.0002	0.0002	0.0022	0.0022	0.0022	0.0022	0.0022	0.0022
None	D4 Stream	0.0002	0.0002	0.0002	0.0002	0.0002	0.0002	0.0022	0.0022	0.0022	0.0022	0.0022	0.0022

Sugar beet, 2 × 25 g a.s./ha	**Scenario**	**PECsw STEP 4 AE F130619**						**PECsw / RAC** RAC = 0.0889 µg/L					
		PEC gl-max						**PEC gl-max**					
Nozzle red.	Vegetated strip (m)	None	None	None	None	10 m low*	20 m high*	None	None	None	None	10 m low*	20 m high*
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m	0 m	5 m	10 m	20 m	10 m	20 m
50 %		0.0002	0.0002	0.0002	0.0002	0.0002	0.0002	0.0022	0.0022	0.0022	0.0022	0.0022	0.0022
75 %		0.0002	0.0002	0.0002	0.0002	0.0002	0.0002	0.0022	0.0022	0.0022	0.0022	0.0022	0.0022
90 %		0.0002	0.0002	0.0002	0.0002	0.0002	0.0002	0.0022	0.0022	0.0022	0.0022	0.0022	0.0022
None	R1 Pond	0.0017	0.0017	0.0016	0.0016	0.0007	0.0004	0.0191	0.0191	0.0180	0.0180	0.0079	0.0045
50 %		0.0016	0.0016	0.0016	0.0016	0.0007	0.0003	0.0180	0.0180	0.0180	0.0180	0.0079	0.0034
75 %		0.0016	0.0016	0.0016	0.0016	0.0006	0.0003	0.0180	0.0180	0.0180	0.0180	0.0067	0.0034
90 %		0.0016	0.0016	0.0016	0.0016	0.0006	0.0003	0.0180	0.0180	0.0180	0.0180	0.0067	0.0034
None	R1 Stream	0.0364	0.0364	0.0364	0.0364	0.0165	0.0086	0.4094	0.4094	0.4094	0.4094	0.1856	0.0967
50 %		0.0364	0.0364	0.0364	0.0364	0.0165	0.0086	0.4094	0.4094	0.4094	0.4094	0.1856	0.0967
75 %		0.0364	0.0364	0.0364	0.0364	0.0165	0.0086	0.4094	0.4094	0.4094	0.4094	0.1856	0.0967
90 %		0.0364	0.0364	0.0364	0.0364	0.0165	0.0086	0.4094	0.4094	0.4094	0.4094	0.1856	0.0967
None	R3 Stream	0.0833	0.0833	0.0833	0.0833	0.038	0.0199	0.9370	0.9370	0.9370	0.9370	0.4274	0.2238
50 %		0.0833	0.0833	0.0833	0.0833	0.038	0.0199	0.9370	0.9370	0.9370	0.9370	0.4274	0.2238
75 %		0.0833	0.0833	0.0833	0.0833	0.038	0.0199	0.9370	0.9370	0.9370	0.9370	0.4274	0.2238
90 %		0.0833	0.0833	0.0833	0.0833	0.038	0.0199	0.9370	0.9370	0.9370	0.9370	0.4274	0.2238

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
* low and high fractional reduction in the runoff and erosion through volume, mass and flux

Conclusion from Tier 1 Level risk assessment for metabolite AE F130619

A detailed summary of the outcome of the Tier 1 risk assessment level per use group and FOCUS scenario is provided in the following tables.

Table 9.5-33: Summary table of the aquatic risk assessment for foramsulfuron metabolite AE F130619: use group B - use on sugar beet / rate 1 × 50 g a.s./ha (1 × 1.0 L prod./ha)

RA Tier *(Section reference)*	**Approach**	**D3 ditch**	**D4 pond**	**D4 stream**	**R1 pond**	**R1 stream**	**R3 stream**
Tier 1 *(9.5.2.4)*	FOCUS Step 3 & 4, based on PEC_{max}	resolved Step 3	resolved Step 3	resolved Step 3	resolved Step 3	resolved Step 3	resolved Step 3

Table 9.5-34: Summary table of the aquatic risk assessment for foramsulfuron metabolite AE F130619: use group C - use on sugar beet / rate 2 × 25 g a.s./ha (2 × 0.5 L prod./ha)

RA Tier *(Section reference)*	**Approach**	**D3 ditch**	**D4 pond**	**D4 stream**	**R1 pond**	**R1 stream**	**R3 stream**
Tier 1 *(9.5.2.4)*	FOCUS Step 3 & 4, based on PEC_{max}	resolved Step 3	resolved Step 3	resolved Step 3	resolved Step 3	resolved Step 3	resolved Step 3

zRMS comments:

For foramsulfuron metabolite **AE F130619 t**risk assessment is based on $PEC_{sw,\ max}$ at FOCUS Step 3 level, risks are acceptable in all scenarios.

Thiencarbazone-methyl

According to the EFSA Conclusion on the active substance thiencarbazone-methyl[10] it would be possible to refine the risk assessment with the geometric mean EC_{50} of three macrophyte species which is 1.35 µg a.s./L. However, since this geometric mean is very similar to the Tier 1 endpoint for *Lemna gibba* (E_rC_{50} = 1.31 µg a.s./L), no Tier 2A risk assessment (geomean-AF approach according to the EFSA AGD) will be presented in this document.

Risk assessment: Therefore, a risk assessment based on *Lemna* standard endpoint (E_rC_{50} = 1.31 µg a.s./L) with associated RAC according to EFSA will be shown in the table below. Note that in contrast to foramsulfuron, for thiencarbazone-methyl the applicability of TWA cannot be demonstrated.

[10] European Food Safety Authority, 2013. Conclusion on the peer review of the pesticide risk assessment of the active substance thiencarbazone-methyl. EFSA Journal 2013;11(7):3270, 77 pp. doi:10.2903/j.efsa.2013.3270

Table 9.5-35: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for thiencarbazone-methyl for aquatic macrophytes based on FOCUS Step 3 calculations for the use of FSN+TCM OD 80 (50+30) in sugar beet.

Group		**Aquatic macrophyte**
Test species		***Lemna gibba***
Endpoint (µg/L)		E_rC_{50} 1.31
AF		10
RAC (µg/L)		0.131
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**	
Use group B – FOCUS Step 3 (use on sugar beet / rate = 1 × 30 g a.s./ha ≡ 1 × 1.0 L prod./ha)		
D3/ditch	0.1574	**1.2015**
D4/pond	0.0067	0.0511
D4/stream	0.1288	0.9832
R1/pond	0.0086	0.0656
R1/stream	0.1088	0.8305
R3/stream	0.2048	**1.5634**
Use group C – FOCUS Step 3 (use on sugar beet / rate = 2 × 15 g a.s./ha ≡ 2 × 0.5 L prod./ha)		
D3/ditch	0.0787	0.6008
D4/pond	0.0050	0.0382
D4/stream	0.0642	0.4901
R1/pond	0.0144	0.1099
R1/stream	0.2388	**1.8229**
R3/stream	0.4757	**3.6313**

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in **bold**

When risk assessment is based on $PEC_{sw, max}$ and the *Lemna* standard endpoint, risks are acceptable in all scenarios but D3 ditch and R3 stream for the critical GAP situation of use group B. For the application of 2 × 15 g a.s./ha (use group C), the risks are acceptable in all scenarios but R1 stream and R3 stream.

Therefore, for thiencarbazone-methyl further risk assessment based on FOCUS Step 4 is deemed necessary here and is presented in the following. A more in depth refined assessment of the potential risk for macrophytes posed by the scenario situations of D3, R1 and R3 will be made in Section 9.5.2.5 to Section 9.5.2.8 of this document, as part of the Tier 2C and Tier 3 level assessment.

zRMS comment:

It should be noted that zRMS did not consider the results of peak exposure studies with Lemna sp. and M.spicatum species for active substance - thiencarbazone-methyl to refine risk to aquatic macrophytes in the context of the Art 43 renewal assessment of foramsulfuron.
When risk assessment is based on $PEC_{sw, max}$, the scenarios:
R1 stream and D3 ditch, **in Use group B**
R1 stream , R3 stream in **Use group C** remained unresolved in the FOCUS Step 3 based risk assessment.
Therefore, for further risk assessment based on FOCUS Step 4 was considered considered.

Table 9.5-36: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for thiencarbazone-methyl based on FOCUS Step 4 calculations and toxicity data for aquatic plants with mitigation of spray drift and run-off for the use of FSN+TCM OD 80 (50+30) in sugar beet – Use: sugar beet, 1 × 30 g thiencarbazone-methyl/ha

Sugar beet, 1 × 30 g a.s./ha	**Scenario**	**PECsw STEP 4 thiencarbazone-methyl**						**PECsw / RAC** RAC = 0.131 µg/L					
		PEC gl-max						**PEC gl-max**					
Nozzle red.	Vegetated strip (m)	None	None	None	None	10 m low*	20 m high*	None	None	None	None	10 m low*	20 m high*
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 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	**1.2015**	0.3947	0.2084	0.1084	0.2084	0.1084
50 %		0.0787	0.0258	0.0137	0.0071	0.0137	0.0071	0.6008	0.1969	0.1046	0.0542	0.1046	0.0542
75 %		0.0393	0.0129	0.0068	0.0036	0.0068	0.0036	0.3000	0.0985	0.0519	0.0275	0.0519	0.0275
90 %		0.0157	0.0052	0.0027	0.0014	0.0027	0.0014	0.1198	0.0397	0.0206	0.0107	0.0206	0.0107
None	D4 Pond	0.0067	0.006	0.0044	0.003	0.0044	0.003	0.0511	0.0458	0.0336	0.0229	0.0336	0.0229
50 %		0.0035	0.0032	0.0024	0.0017	0.0024	0.0017	0.0267	0.0244	0.0183	0.0130	0.0183	0.0130
75 %		0.0019	0.0018	0.0014	0.001	0.0014	0.001	0.0145	0.0137	0.0107	0.0076	0.0107	0.0076
90 %		0.001	0.0009	0.0007	0.0006	0.0007	0.0006	0.0076	0.0069	0.0053	0.0046	0.0053	0.0046
None	D4 Stream	0.1288	0.0543	0.029	0.0153	0.029	0.0153	0.9832	0.4145	0.2214	0.1168	0.2214	0.1168
50 %		0.0645	0.0273	0.0147	0.0078	0.0147	0.0078	0.4924	0.2084	0.1122	0.0595	0.1122	0.0595
75 %		0.0324	0.0138	0.0075	0.004	0.0075	0.004	0.2473	0.1053	0.0573	0.0305	0.0573	0.0305
90 %		0.0132	0.0057	0.0032	0.0018	0.0032	0.0018	0.1008	0.0435	0.0244	0.0137	0.0244	0.0137
None	R1 Pond	0.0086	0.0082	0.0073	0.0064	0.0044	0.0027	0.0656	0.0626	0.0557	0.0489	0.0336	0.0206
50 %		0.0067	0.0065	0.006	0.0056	0.0032	0.0018	0.0511	0.0496	0.0458	0.0427	0.0244	0.0137
75 %		0.0058	0.0057	0.0054	0.0052	0.0025	0.0014	0.0443	0.0435	0.0412	0.0397	0.0191	0.0107
90 %		0.0052	0.0051	0.005	0.005	0.0022	0.0011	0.0397	0.0389	0.0382	0.0382	0.0168	0.0084
None	R1 Stream	0.1088	0.1032	0.1032	0.1032	0.0468	0.0245	0.8305	0.7878	0.7878	0.7878	0.3573	0.1870
50 %		0.1032	0.1032	0.1032	0.1032	0.0468	0.0245	0.7878	0.7878	0.7878	0.7878	0.3573	0.1870
75 %		0.1032	0.1032	0.1032	0.1032	0.0468	0.0245	0.7878	0.7878	0.7878	0.7878	0.3573	0.1870
90 %		0.1032	0.1032	0.1032	0.1032	0.0468	0.0245	0.7878	0.7878	0.7878	0.7878	0.3573	0.1870
None	R3 Stream	0.2048	0.2048	0.2048	0.2048	0.0934	0.049	**1.5634**	**1.5634**	**1.5634**	**1.5634**	0.7130	0.3740
50 %		0.2048	0.2048	0.2048	0.2048	0.0934	0.049	**1.5634**	**1.5634**	**1.5634**	**1.5634**	0.7130	0.3740

Sugar beet, 1 × 30 g a.s./ha	Scenario	PECsw STEP 4 thiencarbazone-methyl						PECsw / RAC RAC = 0.131 µg/L					
		PEC gl-max						PEC gl-max					
Nozzle red.	Vegetated strip (m)	None	None	None	None	10 m low*	20 m high*	None	None	None	None	10 m low*	20 m high*
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m	0 m	5 m	10 m	20 m	10 m	20 m
75 %		0.2048	0.2048	0.2048	0.2048	0.0934	0.049	**1.5634**	**1.5634**	**1.5634**	**1.5634**	0.7130	0.3740
90 %		0.2048	0.2048	0.2048	0.2048	0.0934	0.049	**1.5634**	**1.5634**	**1.5634**	**1.5634**	0.7130	0.3740

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
* low and high fractional reduction in the runoff and erosion through volume, mass and flux

Table 9.5-37: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for thiencarbazone-methyl based on FOCUS Step 4 calculations and toxicity data for aquatic plants with mitigation of spray drift and run-off for the use of FSN+TCM OD 80 (50+30) in sugar beet – Use: sugar beet, 2 × 15 g thiencarbazone-methyl/ha

Sugar beet, 2 × 15 g a.s./ha	Scenario	PECsw STEP 4 thiencarbazone-methyl						PECsw / RAC RAC = 0.131 µg/L					
		PEC gl-max						PEC gl-max					
Nozzle red.	Vegetated strip (m)	None	None	None	None	10 m low*	20 m high*	None	None	None	None	10 m low*	20 m high*
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m	0 m	5 m	10 m	20 m	10 m	20 m
None	D3 Ditch	0.0787	0.0257	0.0138	0.0072	0.0138	0.0072	0.6008	0.1962	0.1053	0.0550	0.1053	0.0550
50 %		0.0393	0.0128	0.0069	0.0036	0.0069	0.0036	0.3000	0.0977	0.0527	0.0275	0.0527	0.0275
75 %		0.0197	0.0064	0.0035	0.0018	0.0035	0.0018	0.1504	0.0489	0.0267	0.0137	0.0267	0.0137
90 %		0.0079	0.0026	0.0014	0.0007	0.0014	0.0007	0.0603	0.0198	0.0107	0.0053	0.0107	0.0053
None	D4 Pond	0.005	0.0045	0.0032	0.0023	0.0032	0.0023	0.0382	0.0344	0.0244	0.0176	0.0244	0.0176
50 %		0.0027	0.0024	0.0018	0.0014	0.0018	0.0014	0.0206	0.0183	0.0137	0.0107	0.0137	0.0107
75 %		0.0015	0.0014	0.0011	0.0009	0.0011	0.0009	0.0115	0.0107	0.0084	0.0069	0.0084	0.0069
90 %		0.0009	0.0008	0.0007	0.0007	0.0007	0.0007	0.0069	0.0061	0.0053	0.0053	0.0053	0.0053
None	D4 Stream	0.0642	0.0272	0.0145	0.0076	0.0145	0.0076	0.4901	0.2076	0.1107	0.0580	0.1107	0.0580
50 %		0.0322	0.0137	0.0073	0.0039	0.0073	0.0039	0.2458	0.1046	0.0557	0.0298	0.0557	0.0298

Sugar beet, 2 × 15 g a.s./ha	**Scenario**	**PECsw STEP 4 thiencarbazone-methyl**						**PECsw / RAC** RAC = 0.131 µg/L					
		PEC gl-max						**PEC gl-max**					
Nozzle red.	Vegetated strip (m)	None	None	None	None	10 m low*	20 m high*	None	None	None	None	10 m low*	20 m high*
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m	0 m	5 m	10 m	20 m	10 m	20 m
75 %		0.0162	0.0069	0.0037	0.002	0.0037	0.002	0.1237	0.0527	0.0282	0.0153	0.0282	0.0153
90 %		0.0066	0.0028	0.0016	0.001	0.0016	0.001	0.0504	0.0214	0.0122	0.0076	0.0122	0.0076
None	R1 Pond	0.0144	0.014	0.013	0.0123	0.0065	0.0037	0.1099	0.1069	0.0992	0.0939	0.0496	0.0282
50 %		0.0126	0.0124	0.0119	0.0116	0.0054	0.0029	0.0962	0.0947	0.0908	0.0885	0.0412	0.0221
75 %		0.0117	0.0116	0.0114	0.0112	0.0049	0.0026	0.0893	0.0885	0.0870	0.0855	0.0374	0.0198
90 %		0.0112	0.0111	0.011	0.011	0.0046	0.0023	0.0855	0.0847	0.0840	0.0840	0.0351	0.0176
None	R1 Stream	0.2388	0.2388	0.2388	0.2388	0.1083	0.0567	**1.8229**	**1.8229**	**1.8229**	**1.8229**	0.8267	0.4328
50 %		0.2388	0.2388	0.2388	0.2388	0.1083	0.0567	**1.8229**	**1.8229**	**1.8229**	**1.8229**	0.8267	0.4328
75 %		0.2388	0.2388	0.2388	0.2388	0.1083	0.0567	**1.8229**	**1.8229**	**1.8229**	**1.8229**	0.8267	0.4328
90 %		0.2388	0.2388	0.2388	0.2388	0.1083	0.0567	**1.8229**	**1.8229**	**1.8229**	**1.8229**	0.8267	0.4328
None	R3 Stream	0.4757	0.4757	0.4757	0.4757	0.217	0.1138	**3.6313**	**3.6313**	**3.6313**	**3.6313**	**1.6565**	0.8687
50 %		0.4757	0.4757	0.4757	0.4757	0.217	0.1138	**3.6313**	**3.6313**	**3.6313**	**3.6313**	**1.6565**	0.8687
75 %		0.4757	0.4757	0.4757	0.4757	0.217	0.1138	**3.6313**	**3.6313**	**3.6313**	**3.6313**	**1.6565**	0.8687
90 %		0.4757	0.4757	0.4757	0.4757	0.217	0.1138	**3.6313**	**3.6313**	**3.6313**	**3.6313**	**1.6565**	0.8687

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
* low and high fractional reduction in the runoff and erosion through volume, mass and flux

Conclusion from Tier 1 Level risk assessment for thiencarbazone-methyl:

A detailed summary of the outcome of the Tier 1 risk assessment level per use group and FOCUS scenario is provided in the following tables.

Table 9.5-38: Summary table of the aquatic risk assessment for thiencarbazone-methyl: use group B - use on sugar beet / rate 1 × 30 g a.s./ha (1 × 1.0 L prod./ha)

RA Tier *(Section reference)*	**Approach**	**D3 ditch**	**D4 pond**	**D4 stream**	**R1 pond**	**R1 stream**	**R3 stream**
Tier 1 *(9.5.2.4)*	FOCUS Step 3 & 4, based on PEC_{max}	resolved 5 m buffer	resolved Step 3	resolved Step 3	resolved Step 3	resolved Step 3	resolved 10 m buffer

Table 9.5-39: Summary table of the aquatic risk assessment for thiencarbazone-methyl: use group C - use on sugar beet / rate 2 × 15 g a.s./ha (2 × 0.5 L prod./ha)

RA Tier *(Section reference)*	**Approach**	**D3 ditch**	**D4 pond**	**D4 stream**	**R1 pond**	**R1 stream**	**R3 stream**
Tier 1 *(9.5.2.4)*	FOCUS Step 3 & 4, based on PEC_{max}	resolved Step 3	resolved Step 3	resolved Step 3	resolved Step 3	resolved 10 m buffer	resolved 20 m buffer

zRMS comments:

The PEC/RAC ratio is below <1 for **thiencarbazone-methyl** when following risk mititagation measures are applied to surface water bodies:

Group B use on sugar beet / rate 1 × 30 g a.s./ha (1 × 1.0 L prod./ha)

- D3 scenario- 5 meter buffer non-spray zone
- R3 scenario – 10 meter non-spray zone

Group C - use on sugar beet / rate 2 × 15 g a.s./ha (2 × 0.5 L prod./ha)

- R1 scenario- 10 meter buffer non-spray zone
- R3 scenario – 20 meter non-spray zone

Combined risk assessment - Tier 1 level

zRMS comment
The applicant proposes to conduct combined risk assessment of active substances and metabolite AE F130619.
The decion of using this approach is left for MSs level.

Tier 1 – considering mitigation measures

A combined toxicity risk assessment of biologically active components is presented here below, considering foramsulfuron, metabolite AE F130619, and thiencarbazone-methyl via the methodology of concentration addition, i.e. calculation of RQmix based on the above individual substance assessment results.

As before in the assessments on individual substance level both, a risk assessment based on $PEC_{sw,max}$ and a risk assessment based on $PEC_{sw,\ 7d\text{-}twa}$ (only for foramsulfuron) will be shown side-by-side, as these are considered justified alternative Tier 1 approaches with applicability for the present product demonstrated in details to fulfil respective AGD criteria.

Table 9.5-40: Tier 1: Combined toxicity assessment* based on FOCUS Step 4 calculations and toxicity data for aquatic plants with mitigation of spray drift and run-off for the use of FSN+TCM OD 80 (50+30) in sugar beet – Use group B: Use in sugar beet, 1 × 50 g /ha FSN + 1 × 30 g /ha TCM (1 × 1.0 L prod./ha)

Aquatic macrophytes	Scenario	RQ_{MIX} based on EU endpoints						RQ_{MIX} considering TWA applicability for foramsulfuron	
Nozzle red.	Vegetated strip (m)	None	None	None	None	10 m low*	20 m high*	10 m low*	20 m high*
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m	10 m	20 m
None	D3 Ditch	**3.8029**	**1.2564**	0.6731	0.3543	0.6731	0.3543	0.2968	0.1592
50 %		**1.9009**	0.6338	0.3425	0.1832	0.3425	0.1832	0.1544	0.0852
75 %		0.9607	0.3226	0.1770	0.0971	0.1770	0.0971	0.0819	0.0486
90 %		0.3904	0.1360	0.0773	0.0457	0.0773	0.0457	0.0397	0.0259
None	D4 Pond	0.1644	0.1482	0.1081	0.0746	0.1081	0.0746	0.1031	0.0716
50 %		0.0863	0.0791	0.0591	0.0429	0.0591	0.0429	0.0571	0.0409
75 %		0.0484	0.0446	0.0347	0.0266	0.0347	0.0266	0.0337	0.0256

Aquatic macrophytes	**Scenario**	**RQ_{MIX} based on EU endpoints**						**RQ_{MIX} considering TWA applicability for foramsulfuron**	
Nozzle red.	Vegetated strip (m)	None	None	None	None	10 m low*	20 m high*	10 m low*	20 m high*
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m	10 m	20 m
90 %		0.0256	0.0240	0.0194	0.0167	0.0194	0.0167	0.0184	0.0167
None	D4 Stream	**3.1114**	**1.3117**	0.7008	0.3685	0.7008	0.3685	0.2315	0.1269
50 %		**1.5590**	0.6601	0.3550	0.1884	0.3550	0.1884	0.1223	0.0696
75 %		0.7842	0.3352	0.1823	0.0990	0.1823	0.0990	0.0674	0.0406
90 %		0.3198	0.1398	0.0781	0.0446	0.0781	0.0446	0.0345	0.0238
None	R1 Pond	0.2263	0.2164	0.1926	0.1699	0.1154	0.0674	0.1105	0.0654
50 %		0.1770	0.1726	0.1599	0.1498	0.0834	0.0466	0.0804	0.0446
75 %		0.1534	0.1516	0.1444	0.1399	0.0672	0.0367	0.0642	0.0347
90 %		0.1389	0.1381	0.1354	0.1334	0.0589	0.0304	0.056	0.0284
None	R1 Stream	**2.8426**	**2.7782**	**2.7782**	**2.7782**	**1.2603**	0.6595	0.5236	0.2734
50 %		**2.7782**	**2.7782**	**2.7782**	**2.7782**	**1.2603**	0.6595	0.5236	0.2734
75 %		**2.7782**	**2.7782**	**2.7782**	**2.7782**	**1.2603**	0.6595	0.5236	0.2734
90 %		**2.7782**	**2.7782**	**2.7782**	**2.7782**	**1.2603**	0.6595	0.5236	0.2734
None	R3 Stream	**5.6572**	**5.6572**	**5.6572**	**5.6572**	**2.5801**	**1.3533**	**1.1693**	0.6137
50 %		**5.6572**	**5.6572**	**5.6572**	**5.6572**	**2.5801**	**1.3533**	**1.1693**	0.6137
75 %		**5.6572**	**5.6572**	**5.6572**	**5.6572**	**2.5801**	**1.3533**	**1.1693**	0.6137
90 %		**5.6572**	**5.6572**	**5.6572**	**5.6572**	**2.5801**	**1.3533**	**1.1693**	0.6137

* RQ_{MIX} based on summation of RQ values of foramsulfuron (Table 9.5-26), its metabolite AE F130619 (Table 9.5-31) and thiencarbazone-methyl (Table 9.5-36)

Table 9.5-41: Tier 1: Combined toxicity assessment* based on FOCUS Step 4 calculations and toxicity data for aquatic plants with mitigation of spray drift and run-off for the use of FSN+TCM OD 80 (50+30) in sugar beet – Use group C: Use in sugar beet, 2 × 25 g /ha FSN + 2 × 15 g /ha TCM (2 × 0.5 L prod./ha)

Aquatic macrophytes	Scenario	RQ_{MIX} based on EU endpoints						RQ_{MIX} considering TWA applicability for foramsulfuron	
Nozzle red.	Vegetated strip (m)	None	None	None	None	10 m low*	20 m high*	10 m low*	20 m high*
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m	10 m	20 m
None	D3 Ditch	**1.9019**	0.6341	0.3413	0.1840	0.3413	0.1840	0.1551	0.086
50 %		0.9617	0.3228	0.1768	0.0971	0.1768	0.0971	0.0827	0.0486
75 %		0.4873	0.1670	0.0943	0.0546	0.0943	0.0546	0.0478	0.0299
90 %		0.2012	0.0736	0.0447	0.0284	0.0447	0.0284	0.0259	0.0185
None	D4 Pond	0.1238	0.1130	0.0811	0.0584	0.0811	0.0584	0.0781	0.0564
50 %		0.0674	0.0621	0.0466	0.0357	0.0466	0.0357	0.0446	0.0347
75 %		0.0394	0.0367	0.0294	0.0240	0.0294	0.0240	0.0284	0.023
90 %		0.0230	0.0222	0.0204	0.0194	0.0204	0.0194	0.0204	0.0194
None	D4 Stream	**1.5527**	0.6583	0.3515	0.1850	0.3515	0.1850	0.1218	0.0691
50 %		0.7797	0.3325	0.1777	0.0954	0.1777	0.0954	0.0668	0.0409
75 %		0.3922	0.1688	0.0918	0.0502	0.0918	0.0502	0.0393	0.0264
90 %		0.1605	0.0701	0.0411	0.0266	0.0411	0.0266	0.0233	0.0187
None	R1 Pond	0.3736	0.3656	0.3400	0.3218	0.1694	0.0951	0.1625	0.0911
50 %		0.3291	0.3246	0.3118	0.3035	0.1422	0.0750	0.1362	0.072
75 %		0.3073	0.3045	0.2991	0.2946	0.1273	0.0668	0.1223	0.0638
90 %		0.2936	0.2928	0.2901	0.2891	0.1200	0.0606	0.1141	0.0576
None	R1 Stream	**6.2976**	**6.2976**	**6.2976**	**6.2976**	**2.8559**	**1.4939**	**1.1687**	0.6117
50 %		**6.2976**	**6.2976**	**6.2976**	**6.2976**	**2.8559**	**1.4939**	**1.1687**	0.6117
75 %		**6.2976**	**6.2976**	**6.2976**	**6.2976**	**2.8559**	**1.4939**	**1.1687**	0.6117
90 %		**6.2976**	**6.2976**	**6.2976**	**6.2976**	**2.8559**	**1.4939**	**1.1687**	0.6117
None	R3 Stream	**12.9931**	**12.9931**	**12.9931**	**12.9931**	**5.9265**	**3.1083**	**2.6314**	**1.3806**

Aquatic macrophytes	Scenario	RQ_{MIX} based on EU endpoints						RQ_{MIX} considering TWA applicability for foramsulfuron	
Nozzle red.	Vegetated strip (m)	None	None	None	None	10 m low*	20 m high*	10 m low*	20 m high*
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m	10 m	20 m
50 %		**12.9931**	**12.9931**	**12.9931**	**12.9931**	**5.9265**	**3.1083**	**2.6314**	**1.3806**
75 %		**12.9931**	**12.9931**	**12.9931**	**12.9931**	**5.9265**	**3.1083**	**2.6314**	**1.3806**
90 %		**12.9931**	**12.9931**	**12.9931**	**12.9931**	**5.9265**	**3.1083**	**2.6314**	**1.3806**

* RQ_{MIX} based on summation of RQ values of foramsulfuron (Table 9.5-27), its metabolite AE F130619 (Table 9.5-32) and thiencarbazone-methyl (Table 9.5-37)

zRMS comment:

Mixture toxicity:

For the intended use groups B and C, calculated PEC/RAC ratios indicate a risk to aquatic plants exposed to the single active substances Foramsulfuron, Thiencarbazone-methyl . The toxicity of the mixture concentration addition for the aquatic plants (most sensitive group) includinf metabolite was determined.
Therefore, a mixture risk assessment is performed for higher aquatic plants using the following formula yielding a risk quotient for the mixture (RQ_{mix}) (EFSA Journal 2013;11(7):3290):

$$RQ_{mix} = \sum_{i=1}^{n} \frac{PEC_i}{RAC_i}$$

If $RQ_{mix} < 1$, the risk is considered acceptable.

RQ_{mix} values for aquatic plants exposed to a combination of Foramsulfuron + Thiencarbazone-methyl + the Foramsulfuron metabolite AE F130619 were shown in the Tables below:

Overall conclusion from Tier 1 risk assessment:

A Tier 1 level risk assessment has been presented based on FOCUS exposure simulations and assessment versus Tier 1 RAC values derived from macrophyte standard studies. As the scientific appropriateness of considering 7d-TWA exposure values has been clearly demonstrated following EFSA decision scheme for foramsulfuron, the assessment has considered both alternative approaches for Tier 1 RQ calculation side-by-side.

Based on a combined assessment to consider the potential effect of concentration additive toxicity of the three biologically active components relevant to the present product (i.e. foramsulfuron, its metabolite AE F130619, and thiencarbazone-methyl), the following conclusions can be drawn from assessment at Tier 1:

Table 9.5-42: Summary table of the aquatic risk assessment for <u>combined toxicity</u>: use group B - use on sugar beet / rate 1 × 50 g /ha FSN + 1 × 30 g /ha TCM (1 × 1.0 L prod./ha)

RA Tier *(Section reference)*	**Approach**	**D3 ditch**	**D4 pond**	**D4 stream**	**R1 pond**	**R1 stream**	**R3 stream**
Tier 1 *(9.5.2.4)*	FOCUS Step 3 & 4, based on PEC_{max}	resolved 10 m buffer	resolved Step 3	resolved 10 m buffer	resolved Step 3	resolved 20 m buffer	**failed 20 m buffer**
	FOCUS Step 3 & 4, based on PEC_{twa} for foramsulfuron	-*	-*	-*	-*	resolved 10 m buffer	resolved 20 m buffer

* Risk assessment already resolved using FOCUS Step 3 & 4 PEC_{max} values

Table 9.5-43: Summary table of the aquatic risk assessment for <u>combined toxicity</u>: use group C - use on sugar beet / rate 2 × 25 g /ha FSN + 2 × 15 g /ha TCM (2 × 0.5 L prod./ha)

RA Tier *(Section reference)*	**Approach**	**D3 ditch**	**D4 pond**	**D4 stream**	**R1 pond**	**R1 stream**	**R3 stream**
Tier 1 *(9.5.2.4)*	FOCUS Step 3 & 4, based on PEC_{max}	resolved 5 m buffer	resolved Step 3	resolved 5 m buffer	resolved Step 3	**failed 20 m buffer**	**failed 20 m buffer**
	FOCUS Step 3 & 4, based on PEC_{twa} for foramsulfuron	-*	-*	-*	-*	resolved 20 m buffer	**failed 20 m buffer**

* Risk assessment already resolved using FOCUS Step 3 & 4 PEC_{max} values

For a registration in regions where the scenarios which did not pass the final combined assessment on Tier 1 level are deemed relevant, reference is made for deeper investigation at subsequent higher tier of the assessment following below.

In case that reviewers for formal reasons would not accept the proposed use of TWA approach for foramsulfuron, the scenario R3 stream would be left unresolved for the critical GAP situation of use group B at Tier 1. For the critical GAP situation of use group C, the scenarios R1 stream and R3 stream would be left unresolved at Tier 1. These scenarios will therefore proactively be further addressed in the following, applying Aquatic Guidance Document Tier 2C methodology. These higher tier assessments may in reverse conclusion be seen further confirmative evidence for correctness of the Tier 1 TWA approach assumptions.

zRMS comment:

Mixture toxicity:

Based on a combined assessment to consider the potential effect of concentration additive toxicity of the three biologically active components relevant to the present product (i.e. foramsulfuron, its metabolite AE F130619, and thiencarbazone-methyl), the following conclusions can be drawn from assessment at Tier 1:

Summary table of the aquatic risk assessment for combined toxicity:

Use group B - use on sugar beet / rate 1 × 50 g /ha FSN + 1 × 30 g /ha TCM (1 × 1.0 L prod./ha).

RA Tier	Approach	D3 ditch	D4 pond	D4 stream	R1 pond	R1 stream	R3 stream
Tier 1	FOCUS Step 3 & 4, based on PEC_{max}	resolved 10 m buffer	resolved Step 3	resolved 10 m buffer	resolved Step 3	resolved 20 m buffer	**failed 20 m buffer**

* Risk assessment already resolved using FOCUS Step 3 & 4 PEC_{max} values

Use group C - use on sugar beet / rate 2 × 25 g /ha FSN + 2 × 15 g /ha TCM (2 × 0.5 L prod./ha).

RA Tier	Approach	D3 ditch	D4 pond	D4 stream	R1 pond	R1 stream	R3 stream
Tier 1	FOCUS Step 3 & 4, based on PEC_{max}	resolved 5 m buffer	resolved Step 3	resolved 5 m buffer	resolved Step 3	**failed 20 m buffer**	**failed 20 m buffer**

Therefore, further refinement should be considered **at MSs level:**

- For scenario R3 stream for use group B
- For scenarios: R1 stream and R3 stream for use group C

The applicant proposed using the refined risk assessment based on the TIER 2C and Tier 3 which were left at MSs level.

9.5.2.5 Tier 2C: Higher-tier assessment based on refined exposure testing combined with exposure pattern analysis

This higher tier assessment addresses particularly those FOCUS scenarios that are characterized by pronounced time-variability of exposure, and short-lasting exposure events such as drift or run-off entry. The procedure is foreseen in the Aquatic Guidance Document as option Tier 2C, proposed by the PPR Panel of EFSA *"to explore a higher tier RAC derivation on the basis of the refined exposure laboratory-AF approach if predicted (modelled) exposure profiles for edge-of-field surface waters differ considerably from exposure regimes in standard toxicity studies and if the PECsw;twa cannot be used in the chronic RA."*

With regard to the present product, these characteristics apply in particular to the runoff-driven scenarios R1 stream and R3 stream failing combination toxicity assessment based on FOCUS Step 4 $PEC_{sw,max}$. Applying the TWA-based approach, the relevant runoff-driven scenarios R1 stream and R3 stream can be resolved for the use group B (1 x 1.0 L prod./ha). For the use group C (2 x 0.5 L prod./ha), the scenario R1 stream can be resolved but the scenario R3 stream still remains unresolved. The combination toxicity assessment for the drift-driven scenarios D3 ditch and D4 stream could be resolved for all critical uses when based on FOCUS Step 4 $PEC_{sw,max}$. However, to demonstrate the low risk from short-lasting drift exposure events, also these scenarios will be further addressed at Tier 2C level below.

Consequently, higher tier refinement options for the run-off driven scenarios R1 stream and R3 and the drift-driven scenarios D3 ditch and D4 stream are evaluated at Tier 2C level in this section, confirmative to - or alternative for - the Tier 1 TWA solutions presented before.

The Tier 2C refined exposure approach is based on the concentration-time profiles of those FOCUS step 3 and Step 4 PEC_{sw} simulations used for assessment at Tier 1 before, and the results of refined exposure type laboratory tests studying the effects of a pulsed exposure on the most sensitive organism, *Lemna gibba*.

For the assessment, an exposure pattern is characterized 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.

A peak event is identified as such when a concentration in the exposure profile exceeds the relevant Tier 1 RAC value which in the case of foramsulfuron is 0.101 µg a.s./L (EU agreed endpoint of 1.01 µg/L, divided by standard assessment factor 10), in the case of the foramsulfuron metabolite AE F130619 is 0.0889 µg a.s./L (EU agreed endpoint of 0.889 µg/L, divided by standard assessment factor 10), and in the case of thiencarbazone-methyl is 0.131 µg a.s./L (EU agreed endpoint of 1.31 µg/L, divided by standard assessment factor 10).

The exposure profiles for the entire FOCUS year of simulation are plotted graphically from the model output files and are amended with a numeric characterisation for event identification according to the above descriptors, extracted by the EPAT Exposure Profile Analysis Tool[11]. Please refer to Appendix A 3.2 for more details.

These characterised exposure patterns are then assessed versus the findings from refined exposure type

[11] 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.

tests, which studied the effects of two sequential pulse exposure events with different spacing intervals. Such tests were performed for foramsulfuron, for its metabolite AE F130619 and for thiencarbazone-methyl and were always done in the same test design. A description of the studies performed for the three active substances is given in the following paragraphs.

Foramsulfuron

The refined exposure type test with foramsulfuron studied the effects of two sequential pulse exposure events with different spacing intervals (new study: Kuhl, 2016; M-572386-03-1; detailed study summary see Appendix A 2.2.1.4; summary of study results see Table 9.5-44). As suggested in the EFSA Aquatic Guidance Document, Section 2.1.5, this test is performed with the tier 1 standard species that drives the aquatic risk (i.e. *Lemna*) and simulates a realistic worst-case exposure relative to that predicted for the edge-of-field. The RACs derived from the refined exposure toxicity tests should always be expressed in terms of peak exposure concentration in these tests, for comparison with the $PEC_{sw,max.}$ According to the EFSA Aquatic Guidance Document Table 7, for chronic risk assessment of plants, the EC_{50} is the relevant endpoint of the refined exposure toxicity test, and the RAC is calculated as $EC_{50}/10$.

The results of this study are suitable to address three different peak exposure situations as predicted by FOCUS:

1. A single peak exceeding the Tier 1 RAC: can be addressed with design 2, first week (study duration of 7 days with 24 h-exposure peak on d0) which delivered a peak-E_rC_{50} of > 50 µg/L, resulting in a peak-RAC of > 5.0 µg/L.
2. Two peak events with short interval (approx. 3 days): can be addressed with design 1 (study duration of 7 days with 24 h-exposure peaks on d0 and d3) which delivered a peak-E_rC_{50} of 9.60 µg /L, resulting in a peak-RAC of 0.96 µg/L. The stronger effects observed in this design compared to a single peak indicate that, for foramsulfuron, two peaks with short interval cannot be considered as being toxicologically independent.
3. Two peak events with longer interval (≥ 7 days): can be addressed with design 2 (study duration of 14 days with 24 h-exposure peaks on d0 and d7) which delivered a peak-E_rC_{50} of > 50 µg/L, resulting in a peak-RAC of > 5.0 µg/L. With this design, it was demonstrated that toxicological independence of peaks is given if the interval between peaks is sufficiently long. To verify this statistically, the similarity of effect patterns following each of the 2 peaks was compared. One-way repeated measures ANOVAs were conducted for all test concentrations and all biological parameters (i.e. frond number and frond area). For frond number, no statistically significant difference was found between the growth rates of the 1st and the 2nd week. For frond area, one statistically significant difference was obtained (treatment level 8.06 µg/L). However, since in this treatment group growth rates were slightly higher in week 2 than in week 1, it can be concluded that the 2nd peak did not further increase the level of growth rate inhibition.

Table 9.5-44: Derivation of peak-RACs from the *Lemna* 2-peak study with foramsulfuron

Test species	Test system	Test duration	Endpoint [µg a.s./L]	Peak-RAC [µg a.s./L]	Reference
Lemna gibba (duck weed)	growth inhibition, 2-peak exposure	7 d peaks on d0 & d3 [Design 1]	E_rC_{50} (days 0-7) 9.60 µg/L	0.96 µg/L	Kuhl, 2016, M-572386-03-1 (see Appendix A 2.2.1.4)
		14 d peaks on d0 & d7 [Design 2]	E_rC_{50} (days 0-7) > 50.0 µg/L E_rC_{50} (days 7-14) > 50.0 µg/L	> 5.0 µg/L > 5.0 µg/L	

Tier 2C refined assessment as described above is presented for D3 ditch, D4 stream, R1 stream and R3 stream FOCUS scenarios for use groups B and C, alternative to or confirmatory for the TWA approach previously used to resolve the most of these scenarios at Tier 1 level.
Graphs of the exposure profiles are taken from the FOCUSsw Step 3 and Step 4 calculations (see Part B - Section 8.9). Further and more detailed PECsw time course plots can be found provided in the respective modelling reports referenced in Part B - Section 8, Appendix 3.3.1.

AE F130619

A refined exposure type test in the same design as for foramsulfuron was also performed with the metabolite AE F130619 (new study: Kuhl, 2016; M-574191-01-1; detailed study summary see Appendix A 2.2.1.4). Since the risk assessment for AE F130619 was passed at Tier 1 level without mitigation, no Tier 2C refined assessment for this metabolite is needed. The results of the new study were also not needed for the assessment of combined toxicity at Tier 2C level presented at the end of this chapter. For the product under evaluation, the new study was only considered in the modelling approach presented in chapter 9.5.2.7 (*in-silico* time-variable exposure testing of *Lemna*). Therefore, no derivation of specific peak-RACs for AE F130619 is done here.

Thiencarbazone-methyl

The refined exposure type tests with thiencarbazone-methyl studied the effects of two sequential pulse exposure events with different spacing intervals (new study: Kuhl, 2016; M-568404-02-1; detailed study summary see Appendix A 2.2.1.4; summary of study results see Table 9.5-45). As suggested in the EFSA Aquatic Guidance Document, Section 2.1.5, this test is performed with the tier 1 standard species that drives the aquatic risk (i.e. *Lemna*) and simulates a realistic worst-case exposure relative to that predicted for the edge-of-field. The RACs derived from the refined exposure toxicity tests should always be expressed in terms of peak exposure concentration in these tests, for comparison with the $PEC_{sw,max.}$ According to the EFSA Aquatic Guidance Document Table 7, for chronic risk assessment of plants, the EC_{50} is the relevant endpoint of the refined exposure toxicity test, and the RAC is calculated as $EC_{50}/10$.

The results of this study are suitable to address three different peak exposure situations as predicted by FOCUS:

1. A single peak exceeding the Tier 1 RAC: can be addressed with design 2, first week (study duration of 7 days with 24 h-exposure peak on d0) which delivered a peak-E_rC_{50} of 15.7 µg/L, resulting in a peak-RAC of 1.57 µg/L.
2. Two peak events with short interval (approx. 3 days): can be addressed with design 1 (study duration of 7 days with 24 h-exposure peaks on d0 and d3) which delivered a peak-E_rC_{50} of 3.10 µg /L, resulting in a peak-RAC of 0.31 µg/L. The stronger effects observed in this design compared to a single peak indicate that, for thiencarbazone-methyl, two peaks with short interval cannot be considered as being toxicologically independent.
3. Two peak events with longer interval (≥ 7 days): can be addressed with design 2 (study duration of 14 days with 24 h-exposure peaks on d0 and d7) which delivered a peak-E_rC_{50} of 12.8 µg/L, resulting in a peak-RAC of 1.28 µg/L. With this design, it was demonstrated that toxicological independence of peaks is given if the interval between peaks is sufficiently long. To verify this statistically, the similarity of effect patterns following each of the 2 peaks was compared. One-way repeated measures ANOVAs were conducted for all test concentrations and all biological parameters (i.e. frond number and frond area). For frond number, no statistically significant difference was found between the growth rates of the 1st and the 2nd week. For frond area, a statistically significantly lower growth rate in week 2 compared to week 1 was obtained for the highest test level (50 µg/L). Thus, for concentrations above 22.4 µg/L (highest concentration without stat. sig. difference), the assumption of toxicological independence of peaks is not applicable. However, since risk assessment relevant endpoints and derived peak-RACs are clearly lower (see table below), this finding has no impact on the overall approach.

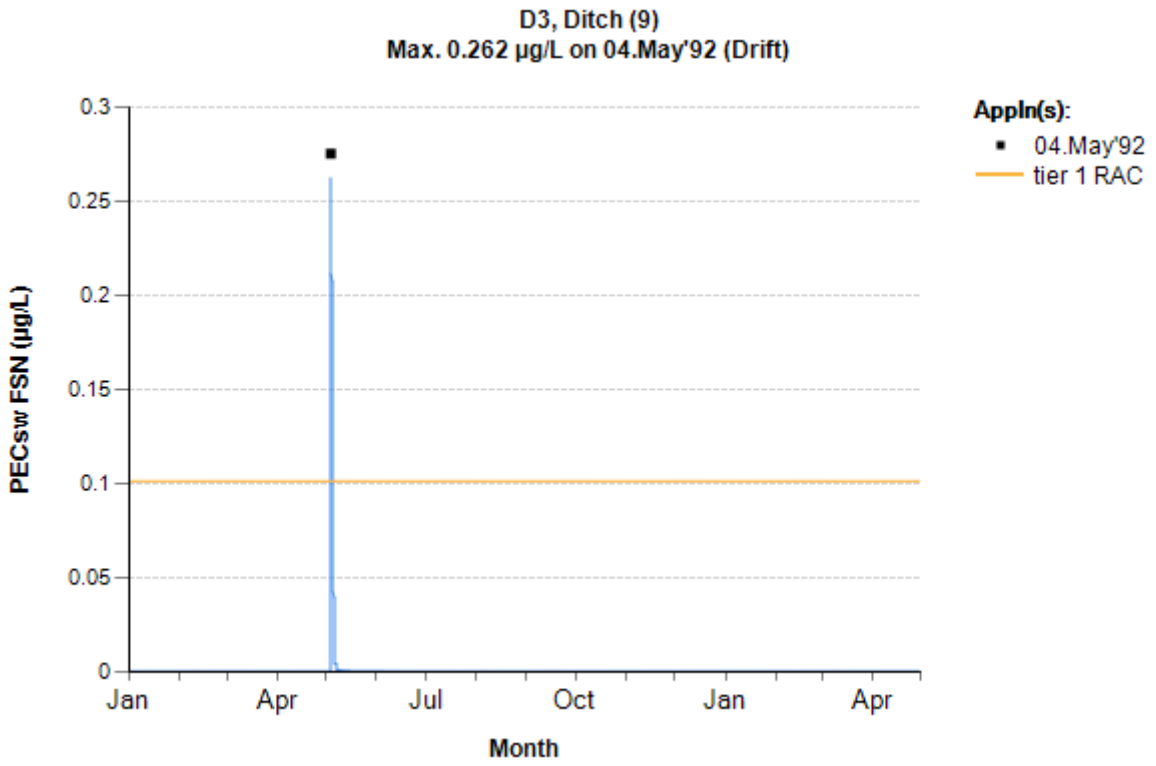
Table 9.5-45: Derivation of peak-RACs from the *Lemna* 2-peak study with thiencarbazone-methyl

Test species	Test system	Test duration	Endpoint [µg as/L]		Peak-RAC [µg as/L]	Reference
Lemna gibba (duck weed)	growth inhibition, 2-peak exposure	7 d peaks on d0 & d3 [Design 1]	E_rC_{50} (days 0-7)	3.10 µg/L	0.31 µg/L	Kuhl, 2016, M-568404-02-1 (see Appendix A 2.2.1.4)
		14 d peaks on d0 & d7 [Design 2]	E_rC_{50} (days 0-7)	15.7 µg/L	1.57 µg/L	
			E_rC_{50} (days 7-14)	12.8 µg/L	1.28 µg/L	

Tier 2C refined assessment as described above is presented for D3 ditch and R3 stream for use group B and for R1 stream and R3 stream FOCUS scenarios for use group C.
Graphs of the exposure profiles are taken from the FOCUSsw Step 3 and Step 4 calculations (see Part B - Section 8.9). Further and more detailed PECsw time course plots can be found provided in the respective modelling reports referenced in Part B - Section 8, Appendix 3.3.2.

Foramsulfuron – exposure pattern analysis

use group B – FOCUS Step 3, Scenario D3 ditch:
(use on sugar beet / rate = 1 × 50 g/ha FSN)



Tier 1-RAC = 0.101 µ/L

EPAT analysis:

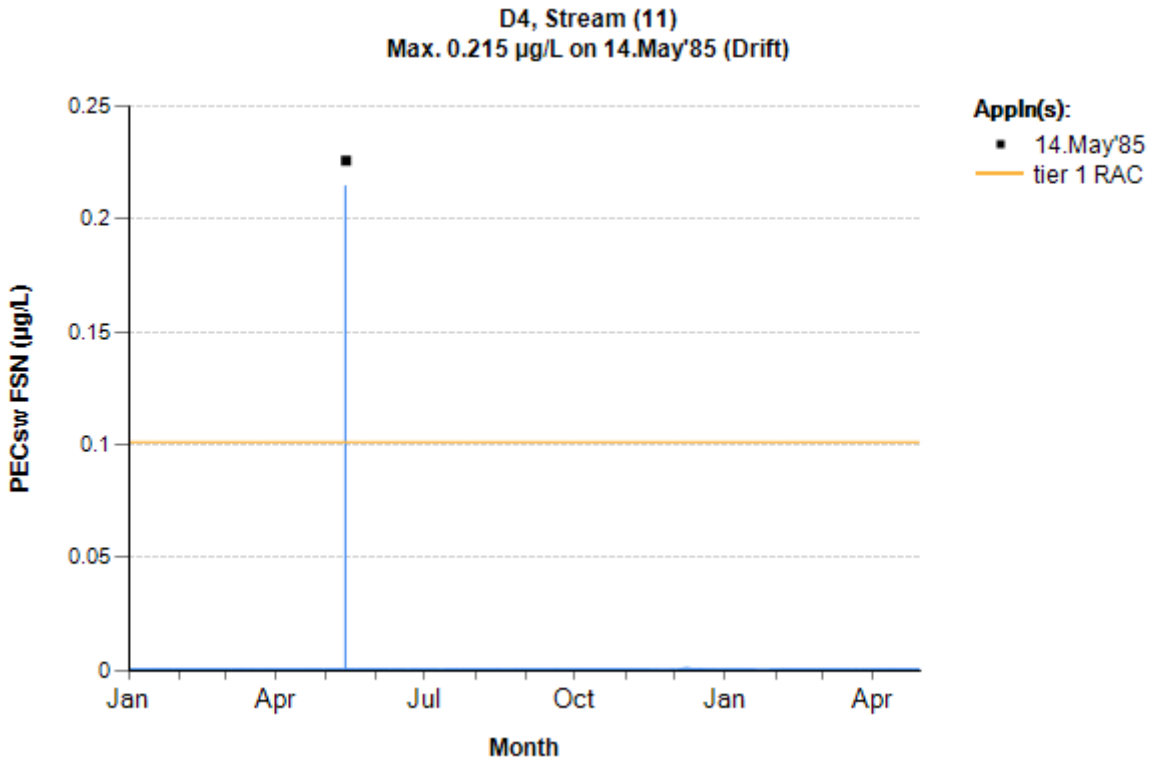
Compound	PECmax [µg/L]	events above Tier 1 RAC	event duration above Tier 1 RAC [d]	interval betw. events above Tier 1 RAC [d]	Relevant peak-RAC from Lemna 2-peak study		RQ = PECmax/ peakRAC
					Study duration	Peak-RAC [µg a.s./L]	
Foramsulfuron	0.2624	1 peak	1.333	not applicable	14 d peaks on d0 & d7	> 5.0 µg/L	< 0.05

[event recognition threshold: 0.101 µg/L = Tier 1 RAC of foramsulfuron]

The PEC pattern of the FOCUS year consists of 1 prominent peak that reaches a maximum concentration of 0.2624 µg a.s./L which is well below the peak-RAC of > 5.0 µg a.s./L applicable for single or independent peaks. With the duration of 1.333 days the peak is slightly longer than the exposure of 1 day tested in the underlying refined exposure experiment. However, the low RQ of < 0.05 indicates a wide additional margin of safety that should cover this minor discrepancy.

Consequently, the risk to aquatic macrophytes arising from this peak is considered to be low.

use group B – FOCUS Step 3, Scenario D4 stream:
(use on sugar beet / rate = 1 × 50 g/ha FSN)



Tier 1-RAC = 0.101 µ/L

EPAT analysis:

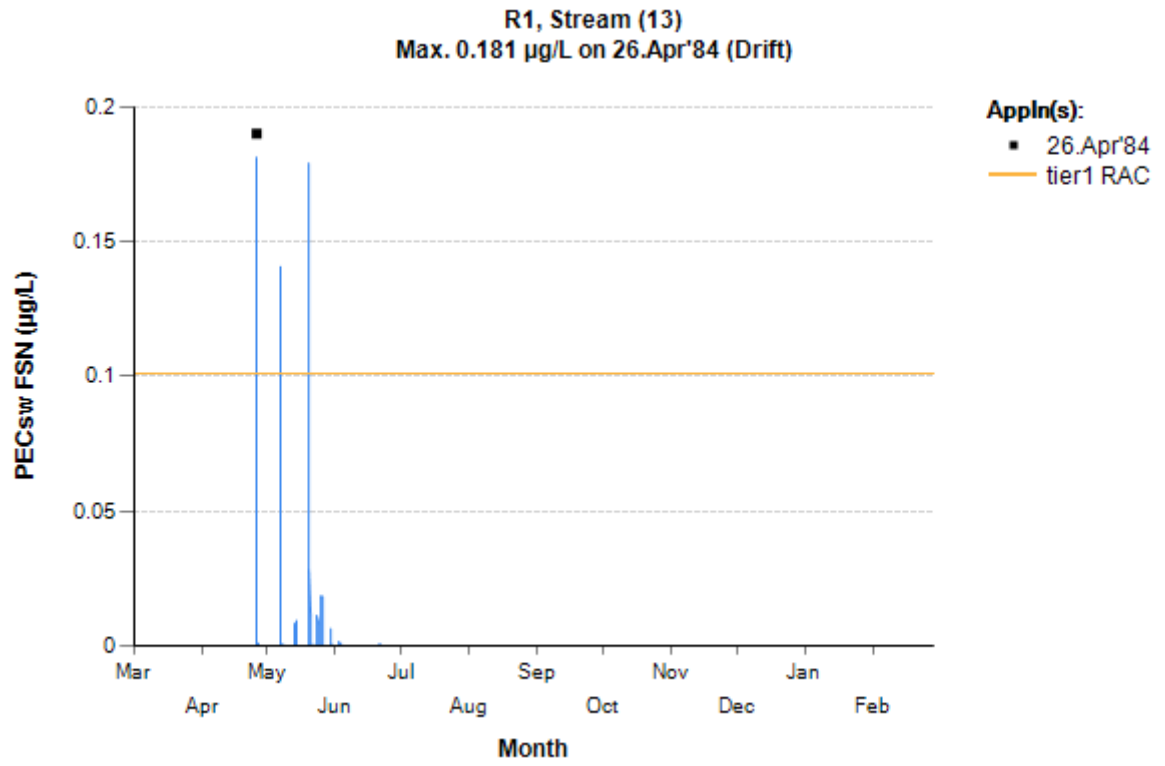
Compound	PECmax [µg/L]	events above Tier 1 RAC	event duration above Tier 1 RAC [d]	interval betw. events above Tier 1 RAC [d]	Relevant peak-RAC from Lemna 2-peak study		RQ = PECmax/ peakRAC
					Study duration	Peak-RAC [µg a.s./L]	
Foramsulfuron	0.2146	1 peak	0.083	not applicable	14 d peaks on d0 & d7	> 5.0 µg/L	< 0.04

[event recognition threshold: 0.101 µg/L = Tier 1 RAC of foramsulfuron]

The PEC pattern of the FOCUS year consists of 1 prominent peak that reaches a maximum concentration of 0.2146 µg a.s./L which is well below the peak-RAC of > 5.0 µg a.s./L applicable for single or independent peaks. With the duration of 0.083 days the peak is much shorter than the exposure of 1 day tested in the underlying refined exposure experiment.

Consequently, the risk to aquatic macrophytes arising from this peak is considered to be low, with a resulting RQ of < 0.04.

use group B – FOCUS Step 3, Scenario R1 stream:
(use on sugar beet / rate = 1 × 50 g/ha FSN)



Tier 1-RAC = 0.101 µ/L

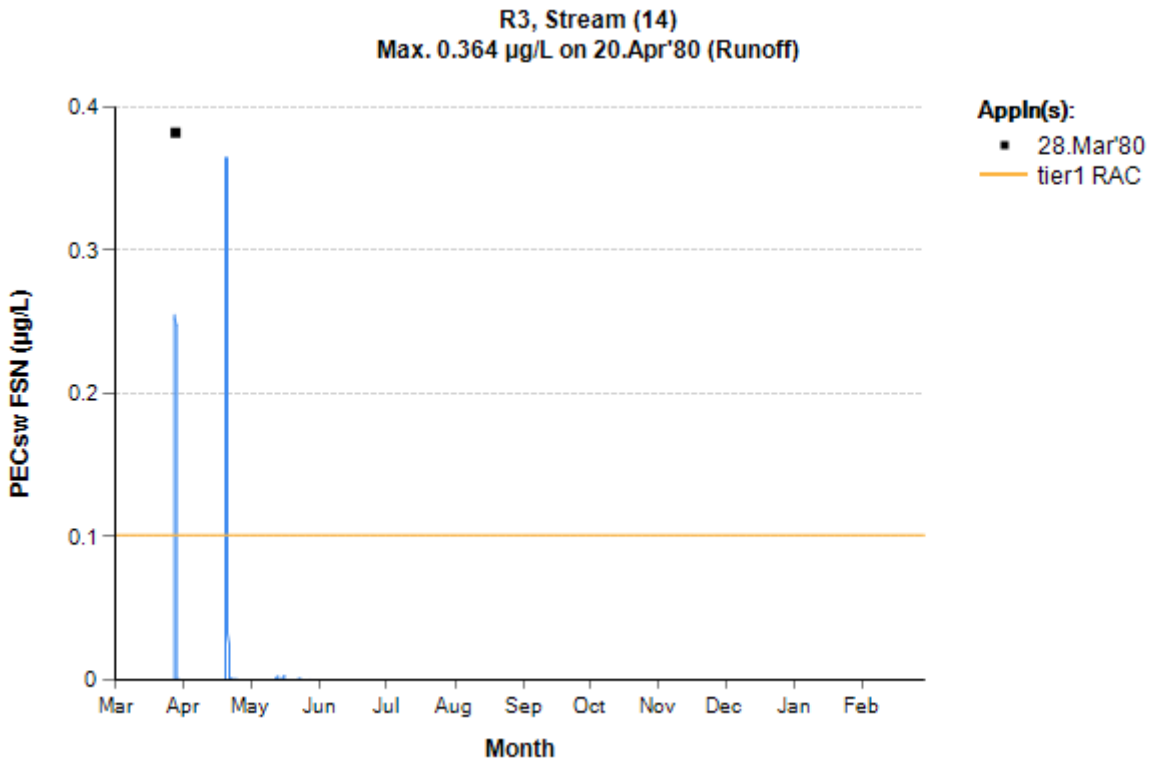
EPAT analysis:

Compound	PECmax [µg/L]	events above Tier 1 RAC	event duration above Tier 1 RAC [d]	interval betw. events above Tier 1 RAC [d]	Relevant peak-RAC from Lemna 2-peak study		RQ = PECmax/ peakRAC
					Study duration	Peak-RAC [µg a.s./L]	
Foramsulfuron	0.1813 0.1407 0.1791	3 peaks	0.208 0.334 0.541	- 10.625 12.5	14 d peaks on d0 & d7	> 5.0 µg/L	<0.04 <0.03 <0.04

[event recognition threshold: 0.101 µg/L = Tier 1 RAC of foramsulfuron]

The PEC pattern of the FOCUS year consists of 3 prominent peaks with a maximum concentration of 0.1813 µg a.s./L. Since the intervals between peaks are clearly longer than 7 days, the pattern can be addressed with the results of design 2, week 2 in the underlying refined exposure experiment (independent peaks). All calculated RQ values are clearly <1 and therefore the risk to aquatic macrophytes arising from this pattern is considered to be low.

use group B – FOCUS Step 3, Scenario R3 stream:
(use on sugar beet / rate = 1 × 50 g/ha FSN)



Tier 1-RAC = 0.101 µ/L

EPAT analysis:

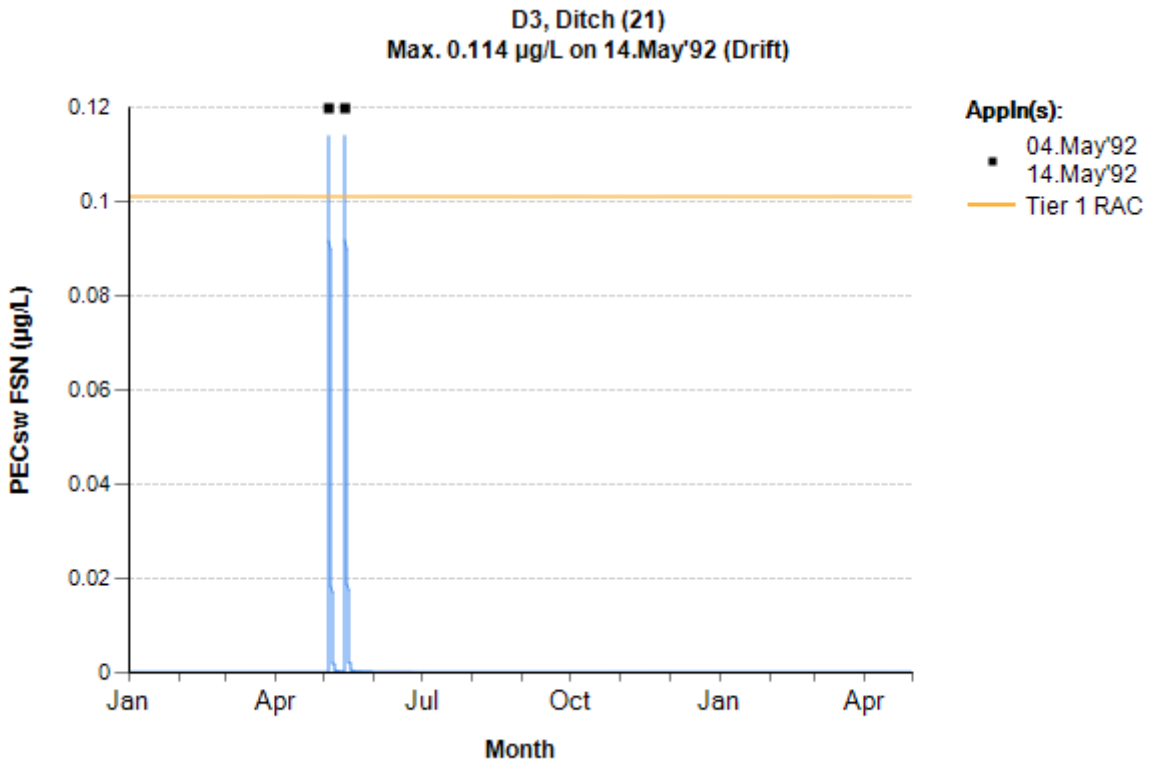
Compound	PECmax [µg/L]	events above Tier 1 RAC	event duration above Tier 1 RAC [d]	interval betw. events above Tier 1 RAC [d]	Relevant peak-RAC from Lemna 2-peak study		RQ = PECmax/ peakRAC
					Study duration	Peak-RAC [µg a.s./L]	
Foramsulfuron	0.2551 0.3644	2 peaks	0.333 1.083	- 22.334	7 d peaks on d0 & d7	> 5.0 µg/L	<0.05 <0.07

[event recognition threshold: 0.101 µg/L = Tier 1 RAC of foramsulfuron]

The PEC pattern of the FOCUS year consists of 2 prominent peaks that reach maximum concentrations of 0.3644 µg a.s./L and 0.2551 µg a.s./L which are below the peak-RAC of > 5.0 µg a.s./L applicable for two peaks with longer interval. With the duration of 1.083 days the 2nd peak is negligibly longer than the exposure of 1 day tested in the underlying refined exposure experiment. However, the low RQ values of <0.05 and <0.07 indicate a wide additional margin of safety that should cover this minor discrepancy.

Consequently, the risk to aquatic macrophytes arising from this peak is considered to be low.

use group C – FOCUS Step 3, Scenario D3 ditch:
(use on sugar beet / rate = 2 × 25 g/ha FSN)



Tier 1-RAC = 0.101 µ/L

EPAT analysis:

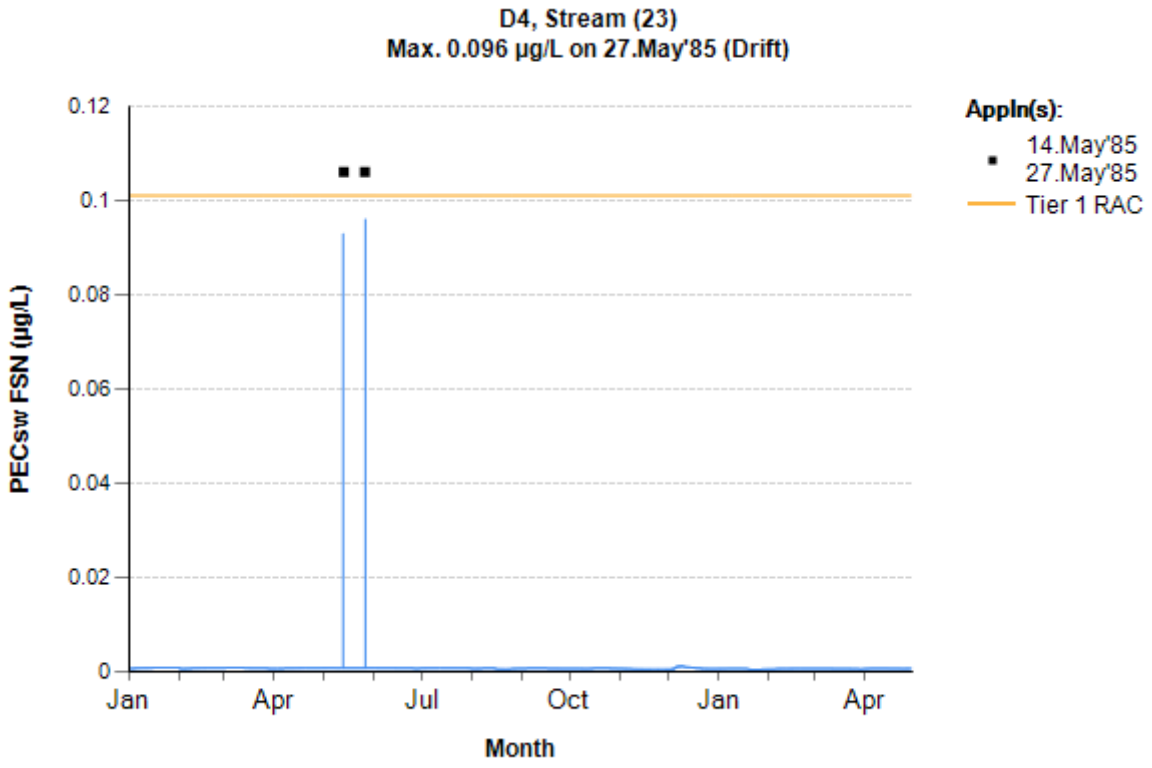
Compound	PECmax [µg/L]	events above Tier 1 RAC	event duration above Tier 1 RAC [d]	interval betw. events above Tier 1 RAC [d]	Relevant peak-RAC from Lemna 2-peak study		RQ = PECmax/ peakRAC
					Study duration	Peak-RAC [µg a.s./L]	
Foramsulfuron	0.1139 0.1140	2 peaks	0.375 0.375	- 9.625	7 d peaks on d0 & d7	> 5.0 µg/L	< 0.02 < 0.02

[event recognition threshold: 0.101 µg/L = Tier 1 RAC of foramsulfuron]

The PEC pattern of the FOCUS year consists of 2 prominent peaks that reach maximum concentrations of 0.1139 µg a.s./L and 0.1140 µg a.s./L which are below the peak-RAC of > 5.0 µg a.s./L applicable for two peaks with longer interval. With the durations of 0.375 days the peaks are much shorter than the two exposures of 1 day tested in the underlying refined exposure experiment.

Consequently, the risk to aquatic macrophytes arising from this peak is considered to be low, with a resulting RQ values of < 0.02.

use group C – FOCUS Step 3, Scenario D4 stream:
(use on sugar beet / rate = 2 × 25 g/ha FSN)



Tier 1-RAC = 0.101 µ/L

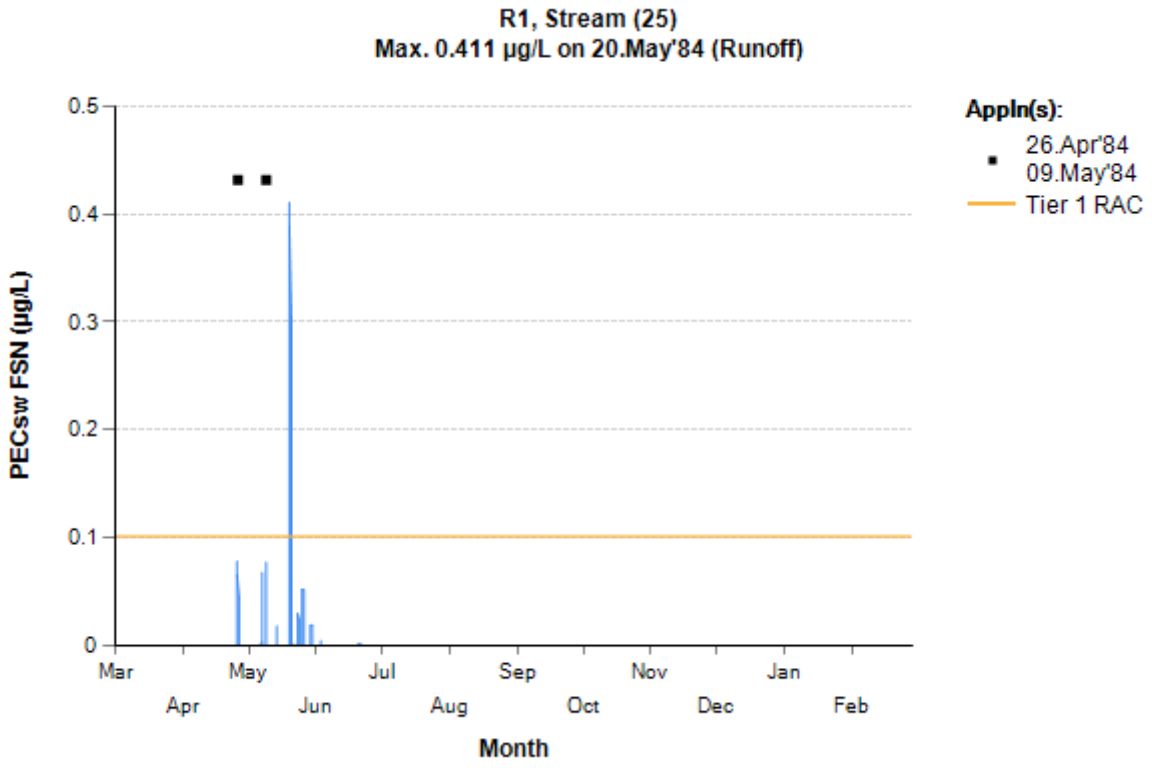
EPAT analysis:

Compound	PECmax [µg/L]	events above Tier 1 RAC	event duration above Tier 1 RAC [d]	interval betw. events above Tier 1 RAC [d]	Relevant peak-RAC from Lemna 2-peak study		RQ = PECmax/ peakRAC
					Study duration	Peak-RAC [µg a.s./L]	
Foramsulfuron	0.0960	0 peaks	-	-	-	-	-

[event recognition threshold: 0.101 µg/L = Tier 1 RAC of foramsulfuron]

With two applications, the PEC_{max} (using the real PEC_{max} for two applications instead the worst case PEC_{max} of single and multiple applications) does not exceed the Tier 1 RAC of foramsulfuron in this scenario. A detailed exposure pattern analysis therefore is not needed.

use group C – FOCUS Step 3, Scenario R1 stream:
(use on sugar beet / rate = 2 × 25 g/ha FSN)



Tier 1-RAC = 0.101 µ/L

EPAT analysis:

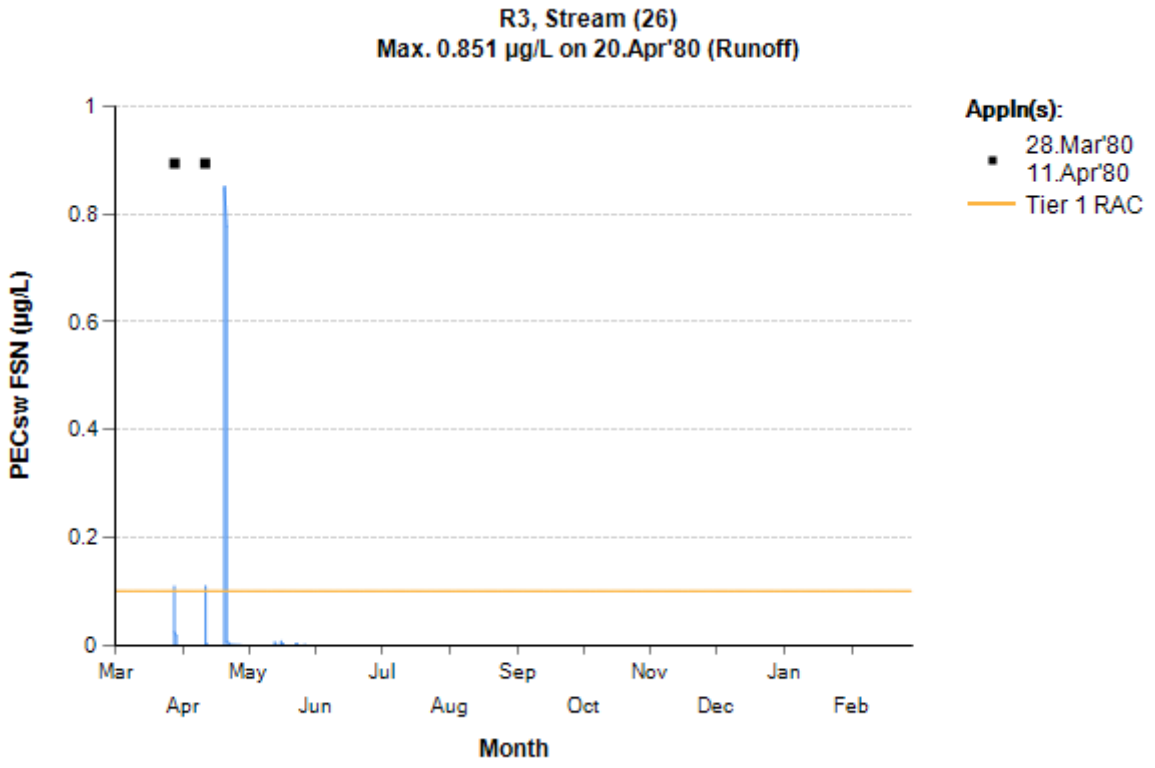
Compound	PECmax [µg/L]	events above Tier 1 RAC	event duration above Tier 1 RAC [d]	interval betw. events above Tier 1 RAC [d]	Relevant peak-RAC from Lemna 2-peak study		RQ = PECmax/ peakRAC
					Study duration	Peak-RAC [µg a.s./L]	
Foramsulfuron	0.4106	1 peak	0.583	not applicable	14 d peaks on d0 & d7	> 5.0 µg/L	< 0.08

[event recognition threshold: 0.101 µg/L = Tier 1 RAC of foramsulfuron]

The PEC pattern of the FOCUS year consists of 1 prominent peak that reaches a maximum concentration of 0.4106 µg a.s./L which is well below the peak-RAC of > 5.0 µg a.s./L applicable for single or independent peaks. With the duration of 0.583 days the peak is shorter than the exposure of 1 day tested in the underlying refined exposure experiment.

Consequently, the risk to aquatic macrophytes arising from this peak is considered to be low, with a resulting RQ of < 0.08.

use group C – FOCUS Step 3, Scenario R3 stream:
(use on sugar beet / rate = 2 × 25 g/ha FSN)



Tier 1-RAC = 0.101 µ/L

EPAT analysis:

Compound	PECmax [µg/L]	events above Tier 1 RAC	event duration above Tier 1 RAC [d]	interval betw. events above Tier 1 RAC [d]	Relevant peak-RAC from Lemna 2-peak study		RQ = PECmax/ peakRAC
					Study duration	Peak-RAC [µg a.s./L]	
Foramsulfuron	0.1099 0.1103 0.8509	3 peaks	0.167 0.208 1.250	- 13.833 8.459	14 d peaks on d0 & d7	> 5.0 µg/L	< 0.02 < 0.02 < 0.17

[event recognition threshold: 0.101 µg/L = Tier 1 RAC of foramsulfuron]

The PEC pattern of the FOCUS year consists of 3 prominent peaks with a maximum concentration of 0.8509 µg a.s./L. The pattern can be addressed with the results of design 2, week 2 in the underlying refined exposure experiment (independent peaks). One of the three predicted peaks (event duration 1.25 days) slightly exceeds the tested exposure duration of one day. However, with 0.167 and 0.208 days, respectively, the other two peaks are much shorter than one day. In addition, all calculated RQ values are clearly <1 and therefore the risk to aquatic macrophytes arising from this pattern is considered to be low.

Conclusion from Tier 2C Level risk assessment:

A detailed summary of the outcome of the Tier 2C risk assessment level per use group and FOCUS scenario is provided in the following tables.

Table 9.5-46: Summary table of the exposure pattern analysis for foramsulfuron: use group B - use on sugar beet / rate 1 × 50 g a.s./ha (1 × 1.0 L prod./ha)

RA Tier *(Section reference)*	**Approach**	**D3 ditch**	**D4 pond**	**D4 stream**	**R1 pond**	**R1 stream**	**R3 stream**
Tier 2C (via testing) *(9.5.2.5)*	FOCUS Step 3, refined exposure testing	resolved Step 3	-*	resolved Step 3	-*	resolved Step 3	resolved Step 3

* risk assessment already resolved at Tier 1 level

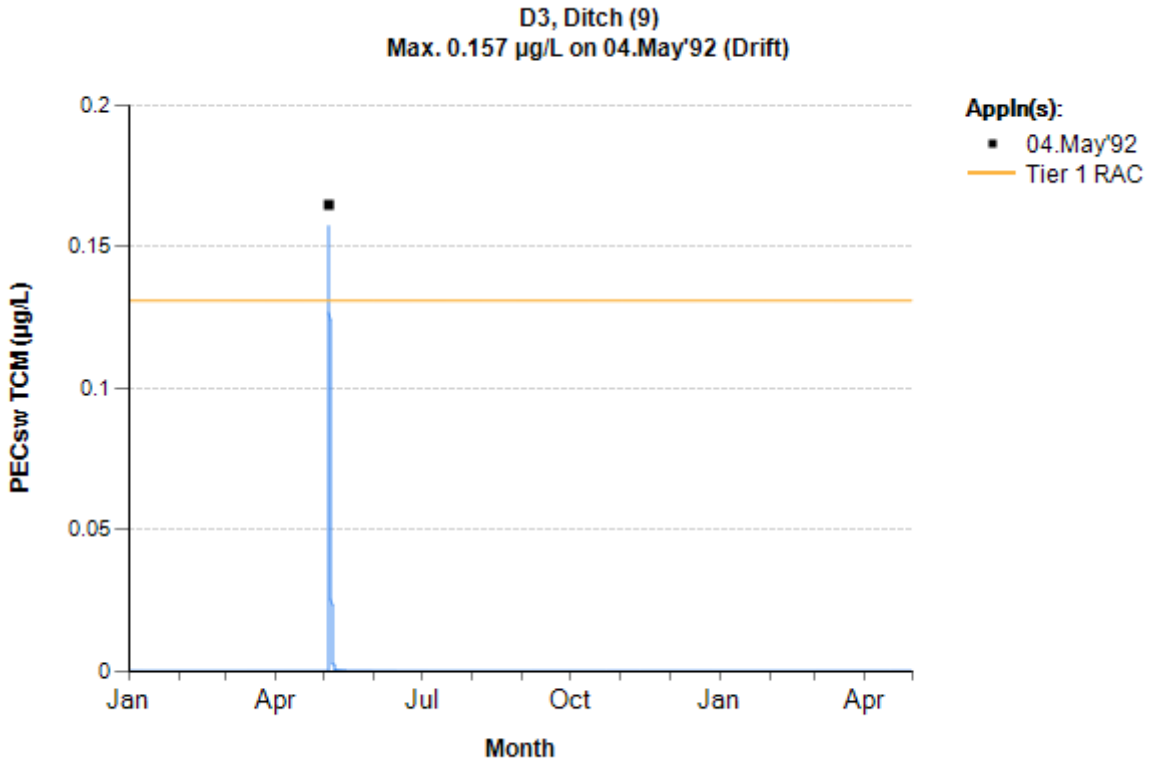
Table 9.5-47: Summary table of the exposure pattern analysis for foramsulfuron: use group C - use on sugar beet / rate 2 × 25 g a.s./ha (2 × 0.5 L prod./ha)

RA Tier *(Section reference)*	**Approach**	**D3 ditch**	**D4 pond**	**D4 stream**	**R1 pond**	**R1 stream**	**R3 stream**
Tier 2C (via testing) *(9.5.2.5)*	FOCUS Step 3, refined exposure testing	resolved Step 3	-*	resolved Step 3	-*	resolved Step 3	resolved Step 3

* risk assessment already resolved at Tier 1 level

Thiencarbazone-methyl – exposure pattern analysis

use group B – FOCUS Step 3, Scenario D3 ditch:
(use on sugar beet / rate = 1 × 30 g/ha TCM)



Tier 1-RAC = 0.131 µ/L

EPAT analysis:

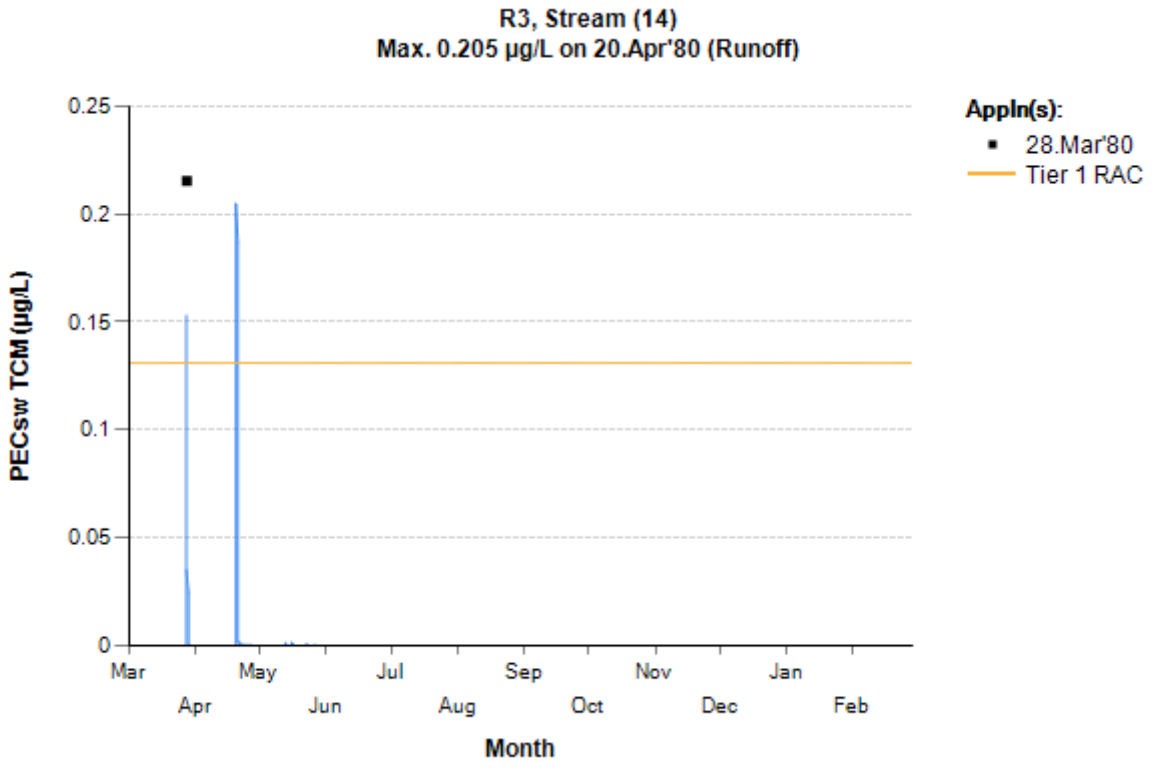
Compound	PECmax [µg/L]	events above Tier 1 RAC	event duration above Tier 1 RAC [d]	interval betw. events above Tier 1 RAC [d]	Relevant peak-RAC from Lemna 2-peak study		RQ = PECmax/ peakRAC
					Study duration	Peak-RAC [µg a.s./L]	
Thiencarbazone-methyl	0.1574	1 peak	0.542	not applicable	14 d peaks on d0 & d7	1.57 µg/L	0.10

[event recognition threshold: 0.131 µg/L = Tier 1 RAC of thiencarbazone-methyl]

The PEC pattern of the FOCUS year consists of 1 prominent peak that reaches a maximum concentration of 0.1574 µg a.s./L which is below the peak-RAC of 1.57 µg a.s./L applicable for a single peak. With the duration of 0.542 days the peak is shorter than the exposure of 1 day tested in the underlying refined exposure experiment.

Consequently, the risk to aquatic macrophytes arising from this peak is considered to be low, with a resulting RQ of 0.10.

use group B – FOCUS Step 3, Scenario R3 stream:
(use on sugar beet / rate = 1 × 30 g/ha TCM)



Tier 1-RAC = 0.131 µ/L

EPAT analysis:

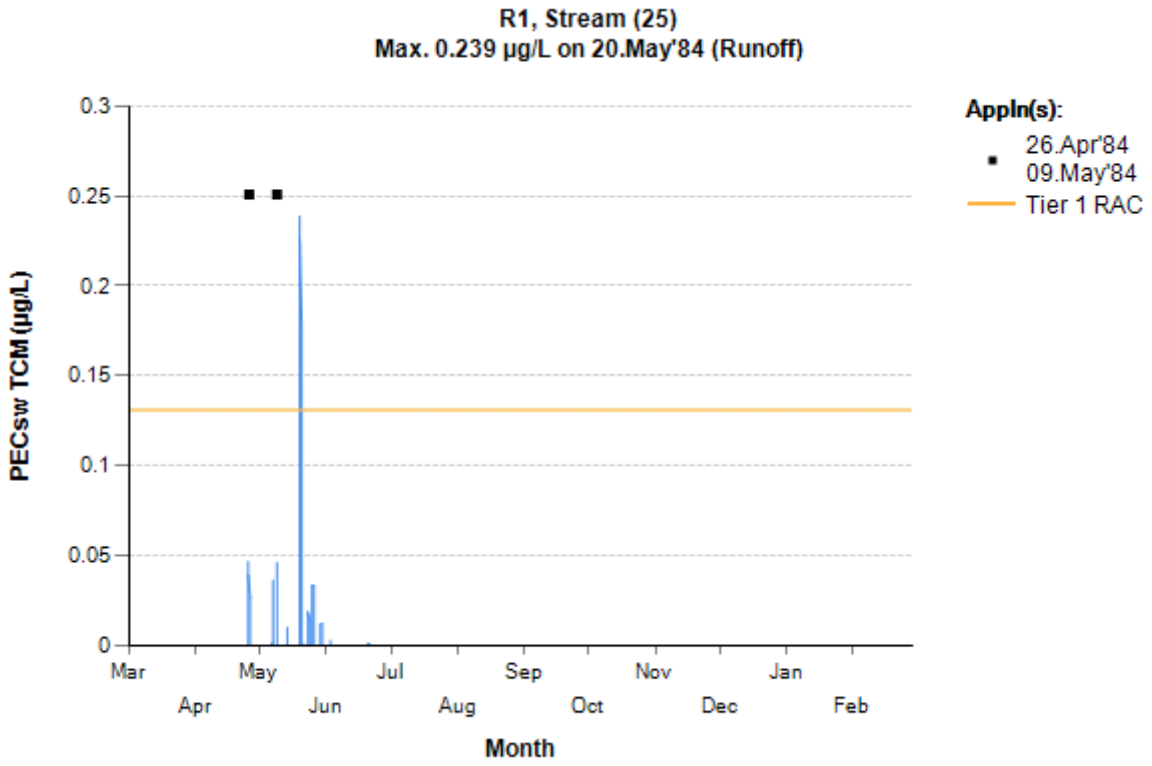
Compound	PECmax [µg/L]	events above Tier 1 RAC	event duration above Tier 1 RAC [d]	interval betw. events above Tier 1 RAC [d]	Relevant peak-RAC from Lemna 2-peak study		RQ = PECmax/ peakRAC
					Study duration	Peak-RAC [µg a.s./L]	
Thiencarbazone-methyl	0.1530 0.2048	2 peaks	0.208 0.791	- 22.459	14 d peaks on d0 & d7	1.28 µg/L	0.12 0.16

[event recognition threshold: 0.131 µg/L = Tier 1 RAC of thiencarbazone-methyl]

The PEC pattern of the FOCUS year consists of 2 prominent peaks that reach maximum concentrations of 0.1530 µg a.s./L and 0.2048 µg a.s./L which are below the peak-RAC of 1.28 µg a.s./L applicable for two peaks with longer interval. With the durations of 0.208 days and 0.791 days the peaks are shorter than the exposure of 2 × 1 day tested in the underlying refined exposure experiment.

Consequently, the risk to aquatic macrophytes arising from this peak is considered to be low, with resulting RQ values of 0.12 and 0.16.

use group C – FOCUS Step 3, Scenario R1 stream:
(use on sugar beet / rate = 2 × 15 g/ha TCM)



Tier 1-RAC = 0.131µ/L

EPAT analysis:

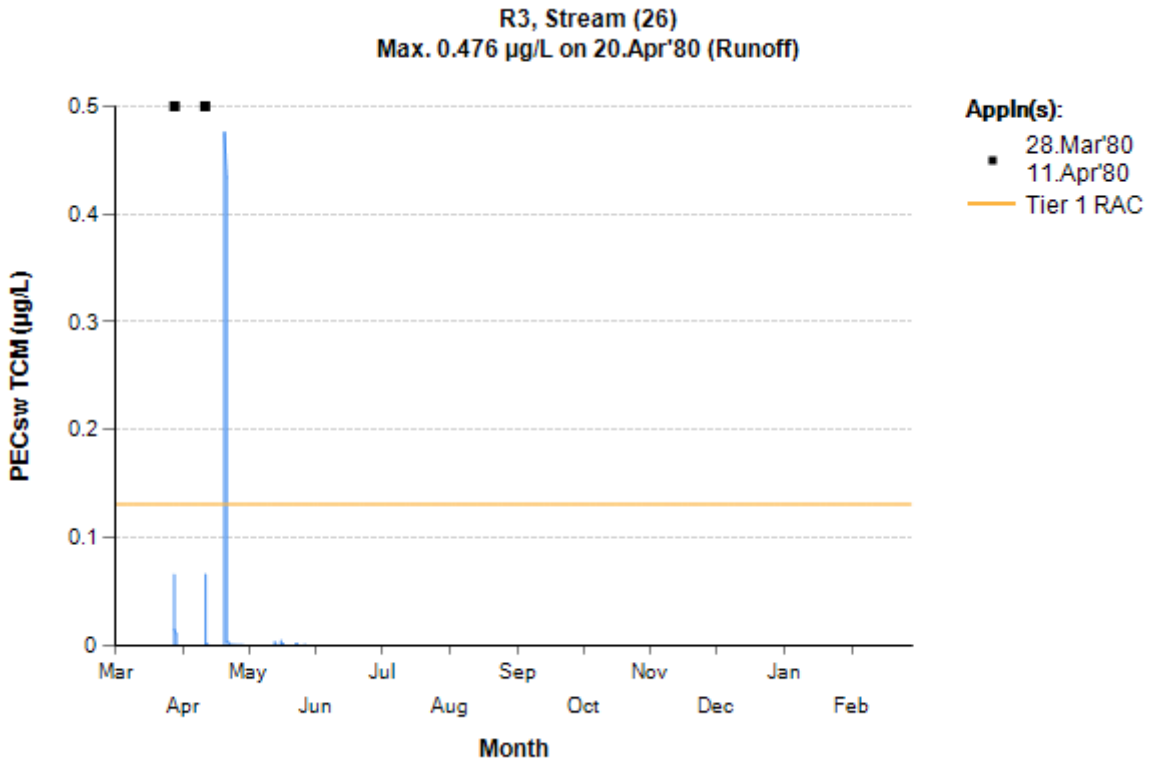
Compound	PECmax [µg/L]	events above Tier 1 RAC	event duration above Tier 1 RAC [d]	interval betw. events above Tier 1 RAC [d]	Relevant peak-RAC from Lemna 2-peak study		RQ = PECmax/ peakRAC
					Study duration	Peak-RAC [µg a.s./L]	
Thiencarbazone-methyl	0.2388	1 peak	0.541	not applicable	14 d peaks on d0 & d7	1.57 µg/L	0.15

[event recognition threshold: 0.131 µg/L = Tier 1 RAC of thiencarbazone-methyl]

The PEC pattern of the FOCUS year consists of 1 prominent peak that reaches a maximum concentration of 0.2388 µg a.s./L which is well below the peak-RAC of 1.57 µg a.s./L applicable for a single peak. With the duration of 0.541 days the peak is shorter than the exposure of 1 day tested in the underlying refined exposure experiment.

Consequently, the risk to aquatic macrophytes arising from this peak is considered to be low, with a resulting RQ of 0.15.

use group D – FOCUS Step 3, Scenario R3 stream:
(use on sugar beet / rate = 2 × 15 g/ha TCM)



Tier 1-RAC = 0.131µ/L

EPAT analysis:

Compound	PECmax [µg/L]	events above Tier 1 RAC	event duration above Tier 1 RAC [d]	interval betw. events above Tier 1 RAC [d]	Relevant peak-RAC from Lemna 2-peak study		RQ = PECmax/ peakRAC
					Study duration	Peak-RAC [µg a.s./L]	
Thiencarbazone-methyl	0.4757	1 peak	1.125	not applicable	14 d peaks on d0 & d7	1.57 µg/L	0.30

[event recognition threshold: 0.131 µg/L = Tier 1 RAC of thiencarbazone-methyl]

The PEC pattern of the FOCUS year consists of 1 prominent peak that reaches a maximum concentration of 0.4757 µg a.s./L which is well below the peak-RAC of 1.57 µg a.s./L applicable for single or independent peaks. With the duration of 1.125 days the peak is slightly longer than the exposure of 1 day tested in the underlying refined exposure experiment. However, the low RQ of 0.30 indicates a wide additional margin of safety that should cover this minor discrepancy.

Consequently, the risk to aquatic macrophytes arising from this peak is considered to be low.

Conclusion from Tier 2C Level risk assessment:

A detailed summary of the outcome of the Tier 2C risk assessment level per use group and FOCUS scenario is provided in the following tables.

Table 9.5-48: Summary table of the exposure pattern analysis for thiencarbazone-methyl: use group B - use on sugar beet / rate 1 × 30 g a.s./ha (1 × 1.0 L prod./ha)

RA Tier *(Section reference)*	Approach	D3 ditch	D4 pond	D4 stream	R1 pond	R1 stream	R3 stream
Tier 2C (via testing) *(9.5.2.5)*	FOCUS Step 3, refined exposure testing	resolved Step 3	-*	-*	-*	-*	resolved Step 3

* risk assessment already resolved at Tier 1 level

Table 9.5-49: Summary table of the exposure pattern analysis for thiencarbazone-methyl: use group C - use on sugar beet / rate 2 × 15 g a.s./ha (2 × 0.5 L prod./ha)

RA Tier *(Section reference)*	Approach	D3 ditch	D4 pond	D4 stream	R1 pond	R1 stream	R3 stream
Tier 2C (via testing) *(9.5.2.5)*	FOCUS Step 3, refined exposure testing	-*	-*	-*	-*	resolved Step 3	resolved Step 3

* risk assessment already resolved at Tier 1 level

The analysis of concentration over time patterns for the use groups B and C revealed that the exposure situation experienced by macrophytes in the water bodies represented by scenarios D3, D4, R1 and R3 is characterised by peak-shaped and short-term exposure events. For both uses and scenarios, this predicted exposure situation could be addressed by the results of refined exposure laboratory tests. Accordingly, the peak PECsw can be compared to matching peak-RAC values, clearly showing that the risk for macrophytes is acceptable.

Combined risk assessment - Tier 2C level

To present a combined toxicity risk assessment according to the concept of Tier 2C, it is necessary to review the concentration profiles of all considered components in time relation to each other, in order to investigate if the cumulated substance exposure would still follow a time-course falling into the boundaries of the available refined exposure test designs. To enable such analysis, graphical plots have been generated from the modelling data showing exposure time-course per the individual substance for foramsulfuron, metabolite AE F130619, and thiencarbazone-methyl in parallel, as well as their arithmetic curve addition yielding an exposure profile for the 'sum of sulfonylurea substances'.

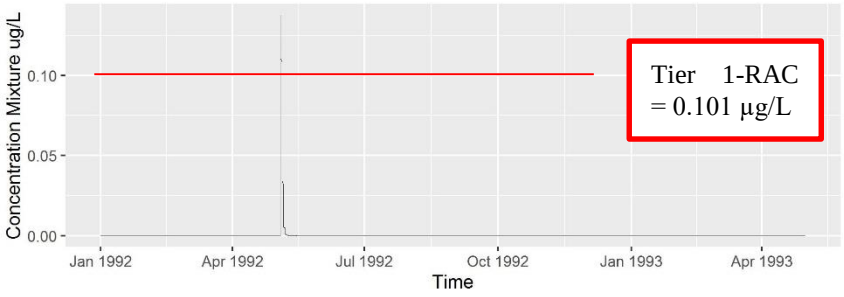
The procedure clearly illustrates that for the concerned substances and water bodies of relevance for assessment here, the exposure events occur simultaneously for all biologically active components, with the sum line still following a time evolution pattern that can be addressed via the dosing regimes tested in the higher tier pulsed exposure studies. No qualitatively new and / or more complex exposure patterns resulted from the curve addition.

Moreover, the graphs reveal that the exposure is dominated by the active substance foramsulfuron, with clearly lower contribution of thiencarbazone-methyl and very small amounts of its metabolite AE F130619. Therefore, even though experimental information would allow for a detailed assessment considering all three components, to avoid unnecessary complexity a simplified procedure is proposed, using:

- the Tier 1-RAC value of foramsulfuron (0.101 µg/L) as 'event' threshold for the evaluation via the EPAT tool. The use of this RAC rather than the Tier 1-RAC of thiencarbazone-methyl (0.131 µg/L) is considered appropriate because a) it is lower and thus more conservative, and b) foramsulfuron is dominating in the mixture. The Tier 1-RAC of metabolite AE F130619 (0.0889 µg/L) as 'event' threshold would be even more conservative, but since it is similar to the RAC of foramsulfuron and the contribution of the metabolite to the mixture is negligible, the focus should be on foramsulfuron.
- the peak-RAC values of thiencarbazone-methyl for final assessment of the 'sum of sulfonylurea substances' exposure profiles. As shown at the beginning of section 9.5.2.5, the refined exposure study with thiencarbazone-methyl delivered overall lower peak-RAC values than the studies on foramsulfuron and metabolite AE F130619. Thus, even though the mixture is dominated by foramsulfuron, the following sum patterns are compared to the results of the thiencarbazone-methyl study to be conservative and protective.

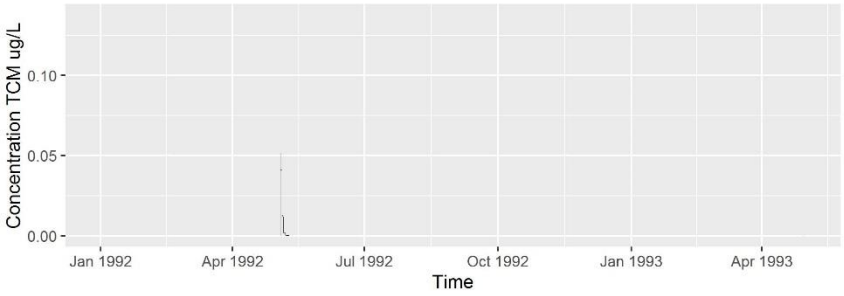
Combined risk assessment at Tier 2C level as described above is presented for those FOCUS scenarios where combined toxicity assessment at Tier 1 level required the acceptance of TWA approaches to pass, and which are dominated by drift or run-off entry route: D3 ditch, D4 stream, R1 stream and R3 stream.

use group B – FOCUS Step 4, 5 m buffer, 0% drift reduction, Scenario D3 ditch*:
(use on sugar beet / **rate = 1 × 50 g/ha FSN + 1 × 30 g/ha TCM)**

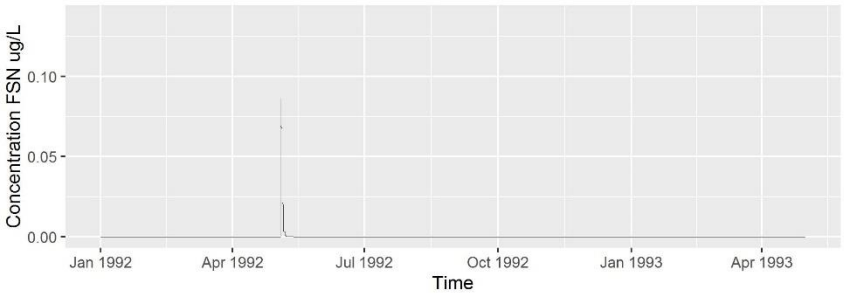


Curve addition

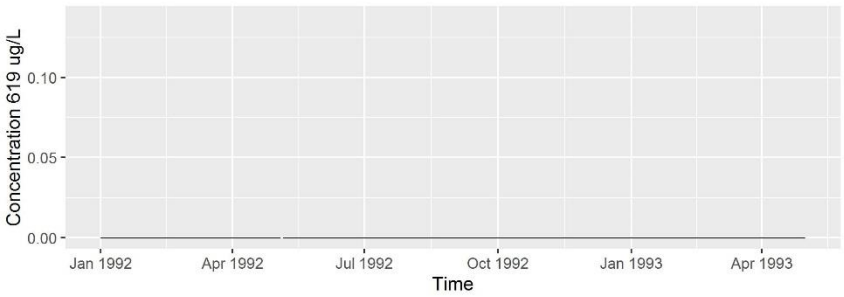
"sum of sulfonylurea compounds"



Thiencarbazone -methyl



Foramsulfuron



Metabolite AE F130619

EPAT analysis for "sum of sulfonylurea compounds"
for use group B – FOCUS Step 4, 5 m buffer, 0% drift reduction, Scenario D3 ditch
(use on sugar beet / **rate = 1 × 50 g/ha FSN + 1 × 30 g/ha TCM)**:

Compound	PECmax [µg/L]	events above Tier 1 RAC	event duration above Tier 1 RAC [d]	interval betw. events above Tier 1 RAC [d]	Relevant peak-RAC from Lemna 2-peak study		RQ = PECmax/ peakRAC
					Study duration	Peak-RAC [µg a.s./L]	
sum of sulfonyl-urea compounds	0.1376	1 peak	0.750	not applicable	14 d peaks on d0 & d7	1.57 µg/L	0.09
Thiencarbazone-	0.0517	-	-	-			

methyl [Step 4, 5 m buffer, 0% drift reduction]					
Foramsulfuron [Step 4, 5 m buffer, 0% drift reduction]	0.0859	-	-	-	
AE F130619 [Step 4, 5 m buffer, 0% drift reduction]	<0.001	-	-	-	

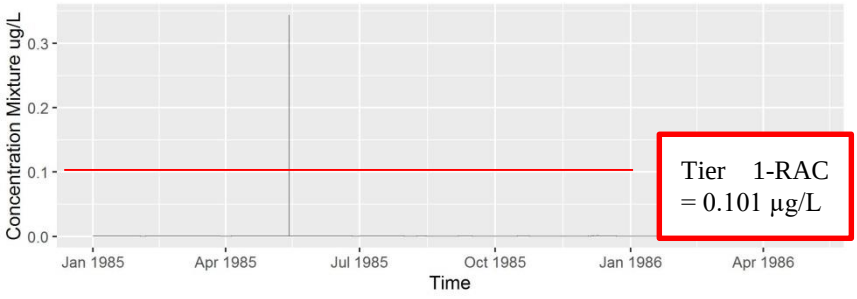
[event recognition threshold: 0.101 µg/L = Tier 1 RAC of foramsulfuron]

The PEC pattern for "sum of sulfonylurea substances" of the FOCUS year consists of 1 prominent peak that has a concentration of 0.1376 µg a.s./L. This is well below the peak-RAC of 1.57 µg a.s./L for a single peak of the substance thiencarbazone-methyl used for comparison. With the duration of 0.75 days the peak is shorter than the exposure of 1 day in the peak study.

Consequently, the risk to aquatic macrophytes arising from this exposure pattern is considered to be low.

* The available refined exposure studies does not cover the PEC pattern at FOCUS Step 3 level. Therefore the pattern of FOCUS Step 4 considering risk mitigation measures is presented.

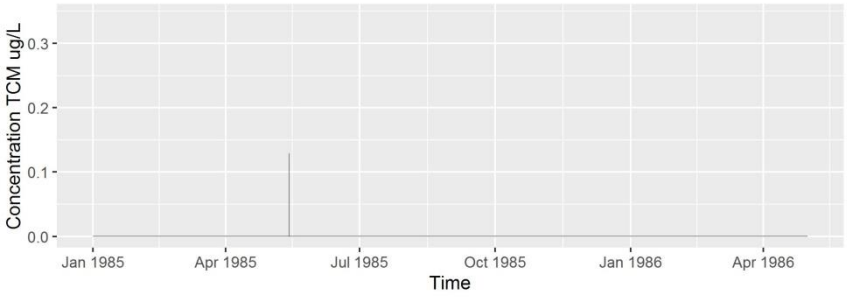
use group B – FOCUS Step 3, Scenario D4 stream:
(use on sugar beet / **rate = 1 × 50 g/ha FSN + 1 × 30 g/ha TCM)**



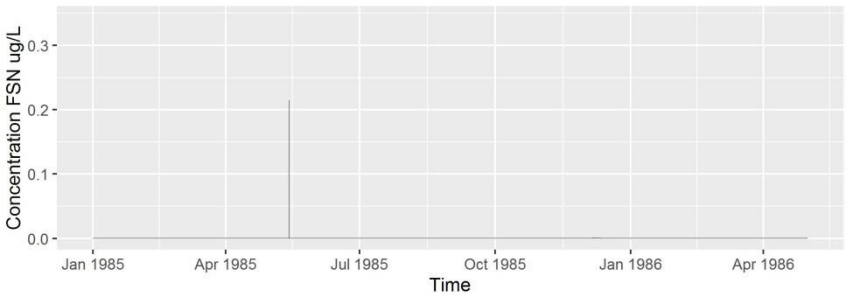
Tier 1-RAC = 0.101 µg/L

Curve addition

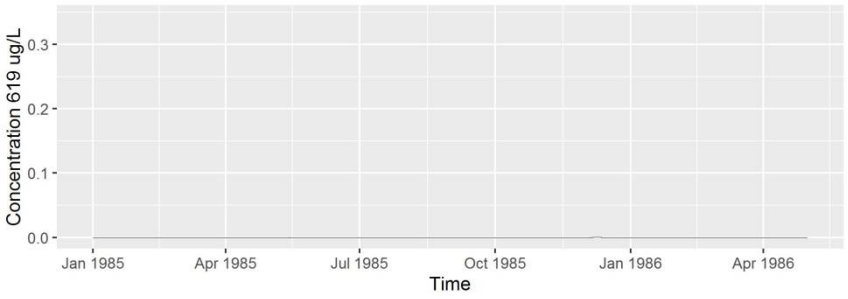
"sum of sulfonylurea compounds"



Thiencarbazone -methyl



Foramsulfuron



Metabolite AE F130619

EPAT analysis for "sum of sulfonylurea compounds"
for use group B – FOCUS Step 3, Scenario D4 stream
(use on sugar beet / **rate = 1 × 50 g/ha FSN + 1 × 30 g/ha TCM)**:

Compound	PECmax [µg/L]	events above Tier 1 RAC	event duration above Tier 1 RAC [d]	interval betw. events above Tier 1 RAC [d]	Relevant peak-RAC from Lemna 2-peak study		RQ = PECmax/ peakRAC
					Study duration	Peak-RAC [µg a.s./L]	
sum of sulfonyl-urea compounds	0.3436	1 peak	0.083	not applicable	14 d peaks on d0 & d7	1.57 µg/L	0.22
Thiencarbazone-methyl	0.1288	-	-	-			

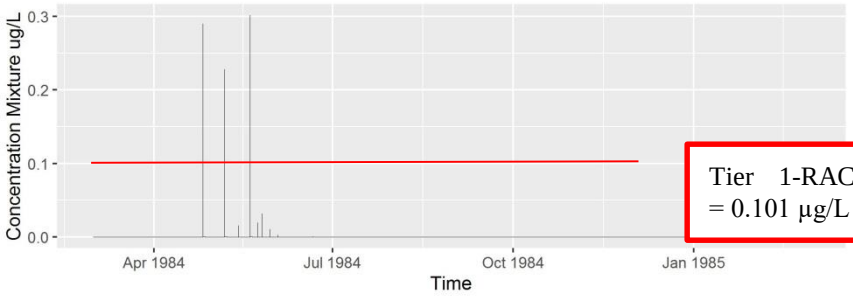
Foramsulfuron	0.2146	1 peak	0.083	not applicable	
AE F130619	0.0003	-	-	-	

[event recognition threshold: 0.101 µg/L = Tier 1 RAC of foramsulfuron]

The PEC pattern for "sum of sulfonylurea substances" of the FOCUS year consists of 1 prominent peak that has a concentration of 0.3436 µg a.s./L. This is well below the peak-RAC of 1.57 µg a.s./L for a single peak of the substance thiencarbazone-methyl used for comparison. With the duration of 0.083 days the peak is much shorter than the exposure of 1 day in the peak study.

Consequently, the risk to aquatic macrophytes arising from this exposure pattern is considered to be low.

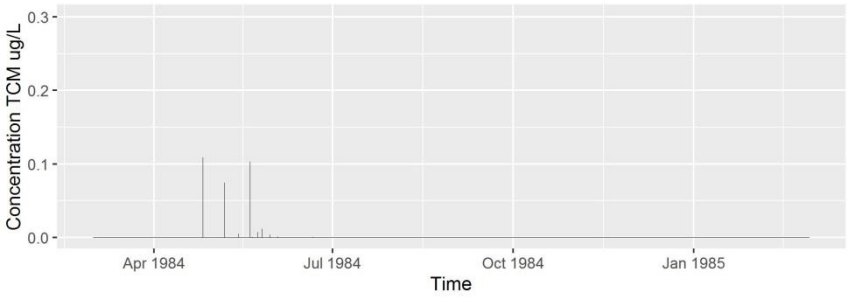
use group B – FOCUS Step 3, Scenario R1 stream:
(use on sugar beet / **rate = 1 × 50 g/ha FSN + 1 × 30 g/ha TCM)**



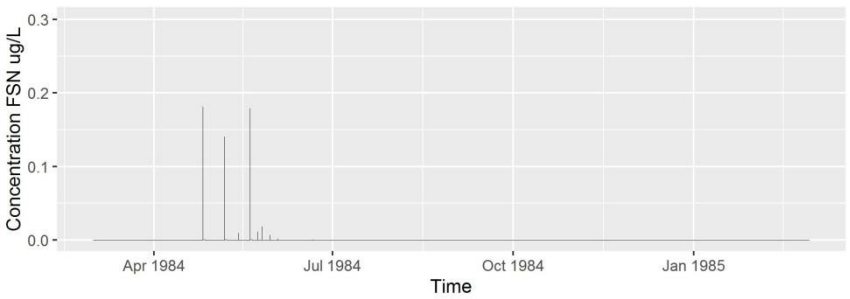
Tier 1-RAC = 0.101 µg/L

Curve addition

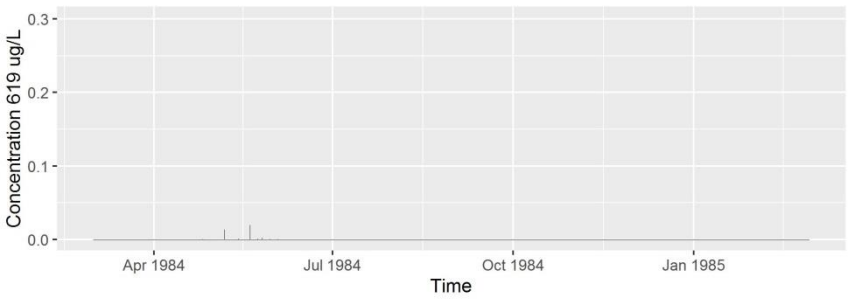
"sum of sulfonylurea compounds"



Thiencarbazone -methyl



Foramsulfuron



Metabolite AE F130619

EPAT analysis for "sum of sulfonylurea compounds"
for use group B – FOCUS Step 3, Scenario R1 stream
(use on sugar beet / **rate = 1 × 50 g/ha FSN + 1 × 30 g/ha TCM)**:

Compound	PECmax [µg/L]	events above Tier 1 RAC	event duration above Tier 1 RAC [d]	interval betw. events above Tier 1 RAC [d]	Relevant peak-RAC from Lemna 2-peak study		RQ = PECmax/ peakRAC
					Study duration	Peak-RAC [µg a.s./L]	
sum of sulfonyl-urea compounds	0.2903 0.2281 0.3017	3 peaks	0.208 0.375 0.583	- 10.584 12.5	14 d peaks on d0 & d7	1.28 µg/L	0.23 0.18 0.24
Thiencarbazone-methyl	0.1088#	-	-	-			

Foramsulfuron	0.1813 0.1407 0.1791	3 peaks	0.208 0.334 0.541	- 10.625 12.5	
AE F130619	0.0193	-	-	-	

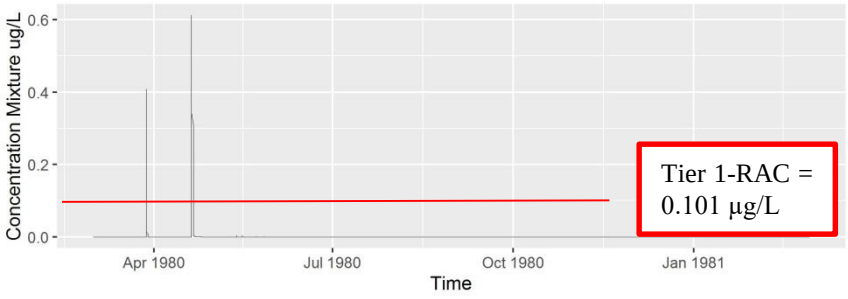
[event recognition threshold: 0.101 µg/L = Tier 1 RAC of foramsulfuron]

The PEC pattern for "sum of sulfonylurea substances" of the FOCUS year consists of 3 prominent peaks with a maximum concentration of 0.3017 µg a.s./L. Three peaks were not directly tested in the underlying refined exposure experiment. However, with intervals of about 10.6 days between peak 1 and peak 2 and 12.5 days between peak 2 and 3, these peaks are considered as independent and can be addressed with scenario 2, week 2 of the underlying refined exposure experiment, leading to a peak-RAC of 1.28 µg/L (thiencarbazone-methyl used for comparison).

Consequently, the risk to aquatic macrophytes arising from this exposure pattern is considered to be low.

PECmax. acc. to FOCUS calculations presented in Section 8. Only single value given as no EPAT analysis performed for the compound (PEC < compound specific event recognition threshold of 0.131 µg/L)

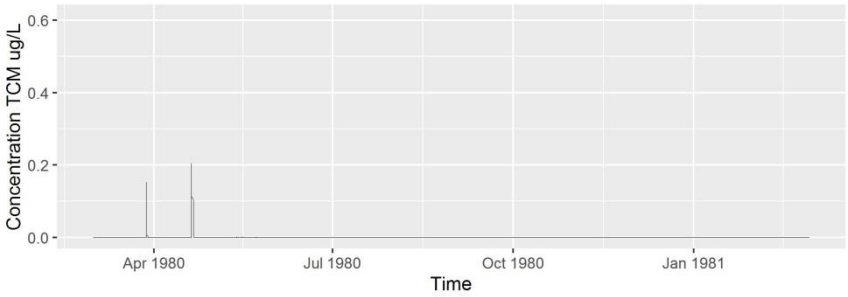
use group B – FOCUS Step 3, Scenario R3 stream:
(use on sugar beet / **rate = 1 × 50 g/ha FSN + 1 × 30 g/ha TCM)**



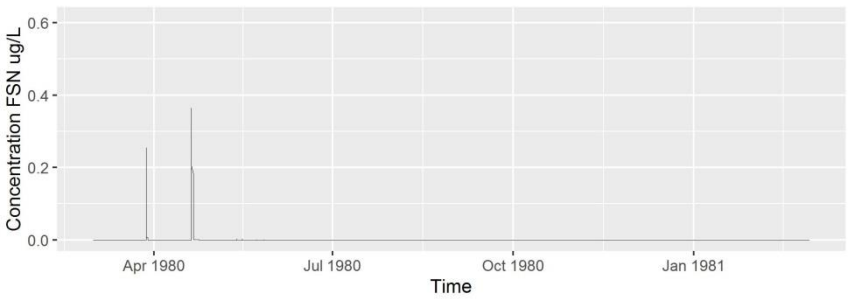
Tier 1-RAC = 0.101 µg/L

Curve addition

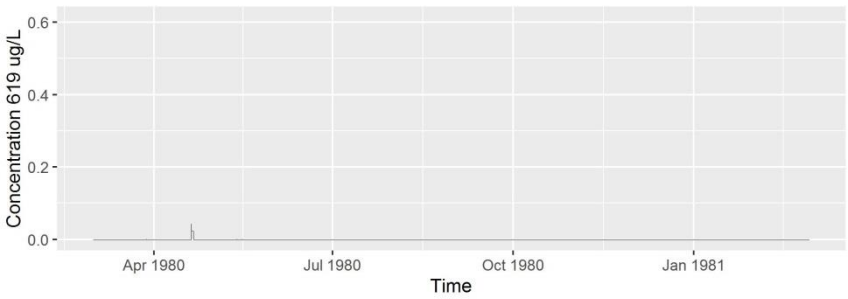
"sum of sulfonylurea compounds"



Thiencarbazone -methyl



Foramsulfuron



Metabolite AE F130619

EPAT analysis for "sum of sulfonylurea compounds"
for use group B – FOCUS Step 3, Scenario R3 stream
(use on sugar beet / **rate = 1 × 50 g/ha FSN + 1 × 30 g/ha TCM)**:

Compound	PECmax [µg/L]	events above Tier 1 RAC	event duration above Tier 1 RAC [d]	interval betw. events above Tier 1 RAC [d]	Relevant peak-RAC from Lemna 2-peak study		RQ = PECmax/ peakRAC
					Study duration	Peak-RAC [µg a.s./L]	
sum of sulfonyl-urea compounds	0.4086 0.6124	2 peaks	0.375 1.166	- 22.292	14 d peaks on d0 & d7	1.28 µg/L	0.32 0.48
Thiencarbazone-methyl	0.1530 0.2048	2 peaks	0.208 0.791	- 22.459			

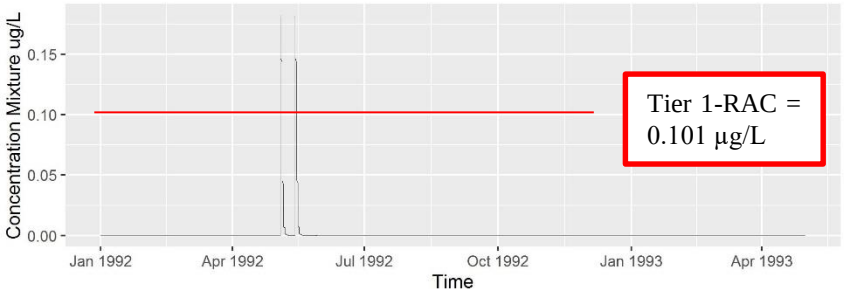
Foramsulfuron	0.2551 0.3644	2 peaks	0.333 1.083	- 22.334	
AE F130619	0.0432	-	-	-	

[event recognition threshold: 0.101 µg/L = Tier 1 RAC of foramsulfuron]

The PEC pattern for "sum of sulfonylurea substances" of the FOCUS year consists of 2 prominent peaks with a maximum concentration of 0.6124 µg a.s./L. Both peaks are below the peak-RAC of 1.28 µg a.s./L applicable for two peaks with a longer interval (thiencarbazone-methyl used for comparison). With the duration of 0.375 and 1.166 days the peaks are shorter than and slightly longer than the exposure of 1 day tested in the underlying refined exposure experiment. However, the low RQ values of 0.32 and 0.48 indicate an additional margin of safety that should cover this minor discrepancy.

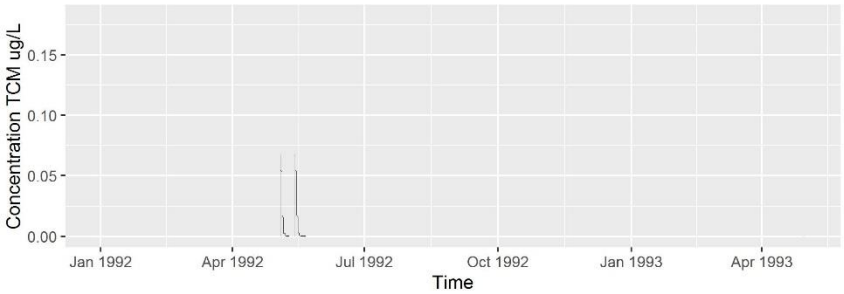
Consequently, the risk to aquatic macrophytes arising from this exposure pattern is considered to be low.

use group C – FOCUS Step 3, Scenario D3 ditch:
(use on sugar beet / **rate = 2 × 25 g/ha FSN + 2 × 15 g/ha TCM)**

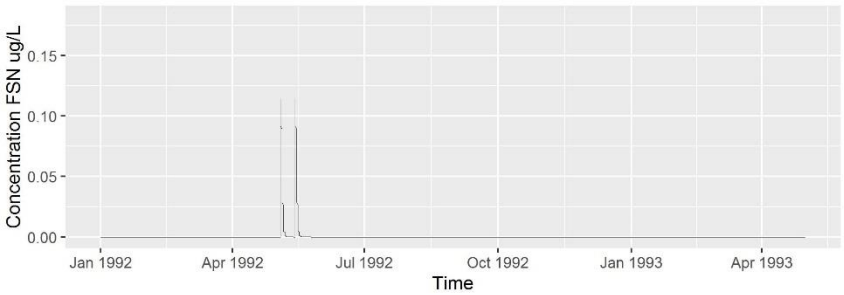


Curve addition

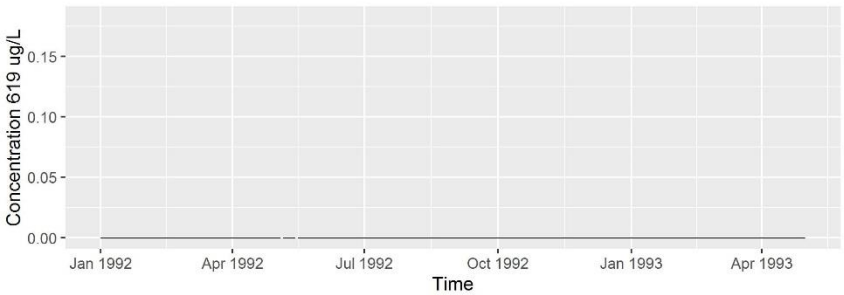
"sum of sulfonylurea compounds"



Thiencarbazone -methyl



Foramsulfuron



Metabolite AE F130619

EPAT analysis for "sum of sulfonylurea compounds" for use group C – FOCUS Step 3, Scenario D3 ditch
(use on sugar beet / **rate = 2 × 25 g/ha FSN + 2 × 15 g/ha TCM)**:

Compound	PECmax [µg/L]	events above Tier 1 RAC	event duration above Tier 1 RAC [d]	interval betw. events above Tier 1 RAC [d]	Relevant peak-RAC from Lemna 2-peak study		RQ = PECmax/ peakRAC
					Study duration	Peak-RAC [µg a.s./L]	
sum of sulfonyl-urea compounds	0.1820 0.1821	2 peaks	1.042 1.083	- 8.958	14 d peaks on d0 & d7	1.28 µg/L	0.14 0.14
Thiencarbazone-methyl	0.0682#	-	-	-			

Foramsulfuron	0.1139 0.1140	2 peaks	0.375 0.375	- 9.625	
AE F130619	0.0001#	-	-	-	

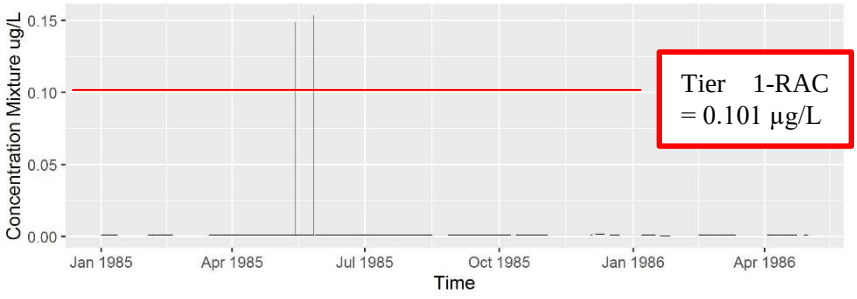
[event recognition threshold: 0.101 µg/L = Tier 1 RAC of foramsulfuron]

The PEC pattern for "sum of sulfonylurea substances" of the FOCUS year consists of 2 prominent peaks with a maximum concentration of 0.1821 µg a.s./L. Both peaks are below the peak-RAC of 1.28 µg a.s./L applicable for two peaks with a longer interval (thiencarbazone-methyl used for comparison). With the durations of 1.042 days and 1.083 days the peaks are slightly longer than the exposure of 2 × 1 day in the peak study. However, the low RQ values of 0.14 provide a large additional margin of safety.

Consequently, the risk to aquatic macrophytes arising from this exposure pattern is considered to be low.

PECmax. acc. to FOCUS calculations presented in Section 8. Only single value given as no EPAT analysis performed for the compound (PEC < compound specific event recognition threshold of 0.0889 µg/L)

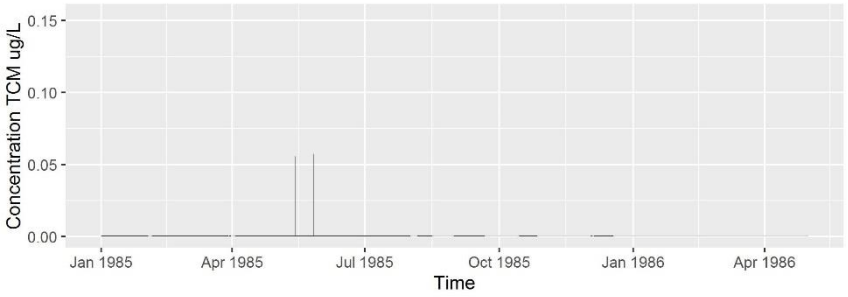
use group C – FOCUS Step 3, Scenario D4 stream:
(use on sugar beet / **rate = 2 × 25 g/ha FSN + 2 × 15 g/ha TCM)**



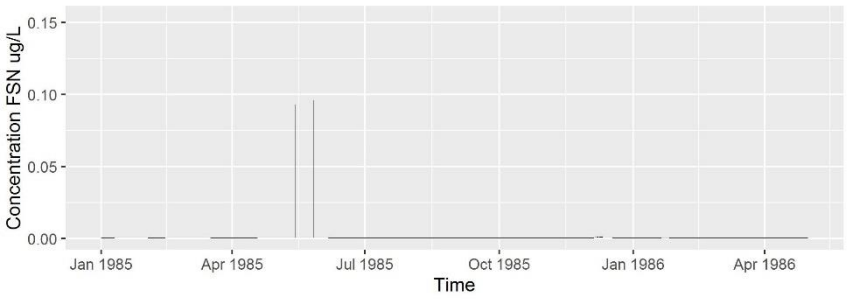
Tier 1-RAC = 0.101 µg/L

Curve addition

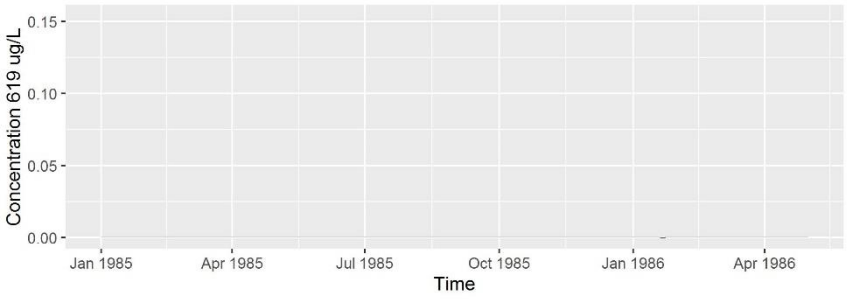
"sum of sulfonylurea compounds"



Thiencarbazone -methyl



Foramsulfuron



Metabolite AE F130619

EPAT analysis for "sum of sulfonylurea compounds"
for use group C – FOCUS Step 3, Scenario D4 stream
(use on sugar beet / **rate = 2 × 25 g/ha FSN + 2 × 15 g/ha TCM)**:

Compound	PECmax [µg/L]	events above Tier 1 RAC	event duration above Tier 1 RAC [d]	interval betw. events above Tier 1 RAC [d]	Relevant peak-RAC from Lemna 2-peak study		RQ = PECmax/ peakRAC
					Study duration	Peak-RAC [µg a.s./L]	
sum of sulfonyl-urea compounds	0.1487 0.1536	2 peaks	0.083 0.083	- 12.917	14 d peaks on d0 & d7	1.28 µg/L	0.12 0.12
Thiencarbazone-methyl	0.0574#	-	-	-			

Foramsulfuron	0.0960#	-	-	-	
AE F130619	0.0002#	-	-	-	

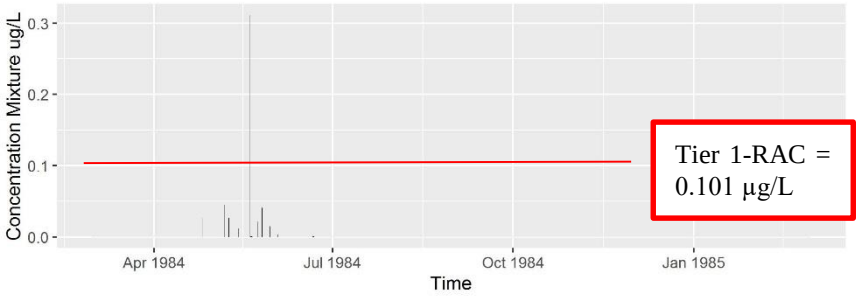
[event recognition threshold: 0.101 µg/L = Tier 1 RAC of foramsulfuron]

The PEC pattern for "sum of sulfonylurea substances" of the FOCUS year consists of 2 prominent peaks with a maximum concentration of 0.1536 µg a.s./L. Both peaks are below the peak-RAC of 1.28 µg a.s./L applicable for two peaks with a longer interval (thiencarbazone-methyl used for comparison). With the durations of 0.083 days the peaks are shorter than the exposure of 2 × 1 day tested in the underlying refined exposure experiment.

Consequently, the risk to aquatic macrophytes arising from this exposure pattern is considered to be low.

PECmax. acc. to FOCUS calculations presented in Section 8. Only single value given as no EPAT analysis performed for the compound (PEC < compound specific event recognition threshold of 0.131 µg/L)

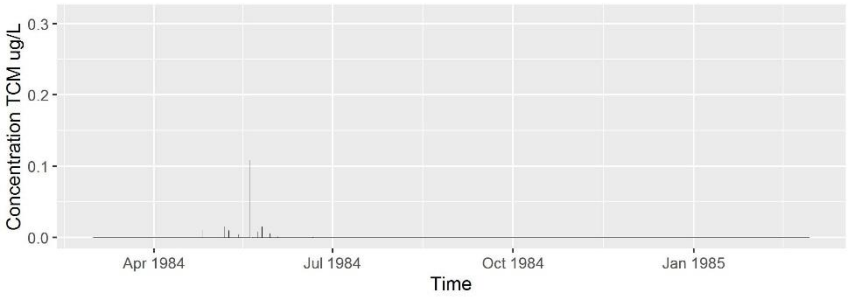
use group C – FOCUS Step 4, 10 m buffer, Scenario R1 stream*:
(use on sugar beet / **rate = 2 × 25 g/ha FSN + 2 × 15 g/ha TCM)**



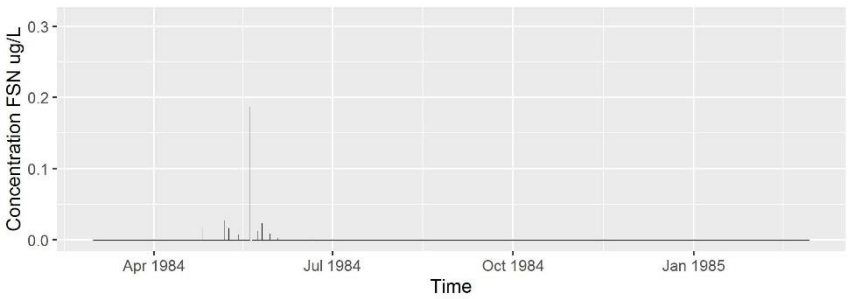
Tier 1-RAC = 0.101 µg/L

Curve addition

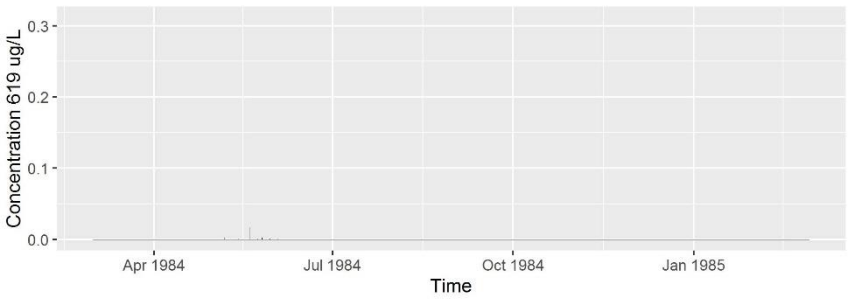
"sum of sulfonylurea compounds"



Thiencarbazone -methyl



Foramsulfuron



Metabolite AE F130619

EPAT analysis for "sum of sulfonylurea compounds"
for use group C – FOCUS Step 4, 10 m buffer, Scenario R1 stream
(use on sugar beet / **rate = 2 × 25 g/ha FSN + 2 × 15 g/ha TCM)**:

Compound	PECmax [µg/L]	events above Tier 1 RAC	event duration above Tier 1 RAC [d]	interval betw. events above Tier 1 RAC [d]	Relevant peak-RAC from Lemna 2-peak study		RQ = PECmax/ peakRAC
					Study duration	Peak-RAC [µg a.s./L]	
sum of sulfonyl-urea compounds	0.3110	1 peak	0.583	not applicable	14 d peaks on d0 & d7	1.57 µg/L	0.20
Thiencarbazone-methyl	0.1083	-	-	-			

[Step 4, 10 m buffer]					
Foramsulfuron [Step 4, 10 m buffer]	0.1862	1 peaks	0.541	not applicable	
AE F130619 [Step 4, 10 m buffer]	0.0165	-	-	-	

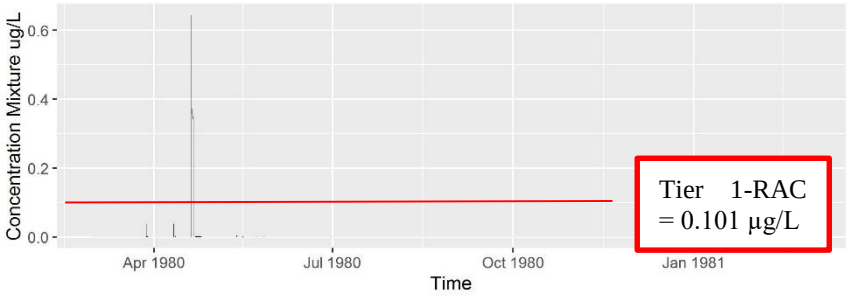
[event recognition threshold: 0.101 µg/L = Tier 1 RAC of foramsulfuron]

The PEC pattern for "sum of sulfonylurea substances" of the FOCUS year consists of 1 prominent peak that has a concentration of 0.311 µg a.s./L. This is well below the peak-RAC of 1.57 µg a.s./L for a single peak of the substance thiencarbazone-methyl used for comparison. With the duration of 0.583 days the peak is shorter than the exposure of 1 day in the peak study.

Consequently, the risk to aquatic macrophytes arising from this exposure pattern is considered to be low.

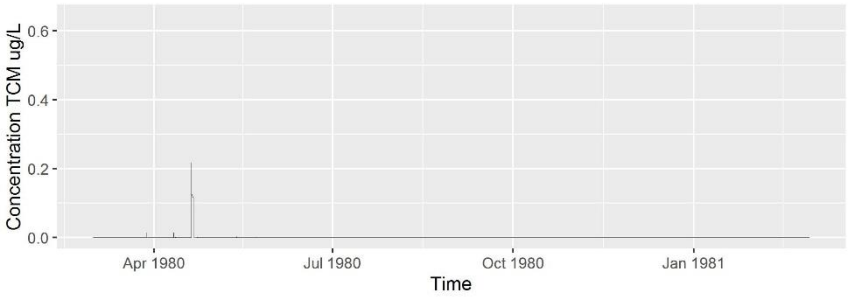
* The available refined exposure study does not cover the PEC pattern at FOCUS Step 3 level. Therefore the pattern of FOCUS Step 4 considering risk mitigation measures is presented.

use group C – FOCUS Step 4, 10 m buffer, Scenario R3 stream*:
(use on sugar beet / **rate = 2 × 25 g/ha FSN + 2 × 15 g/ha TCM)**

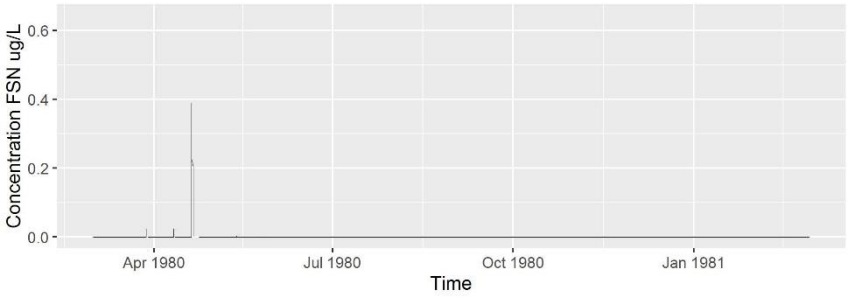


Curve addition

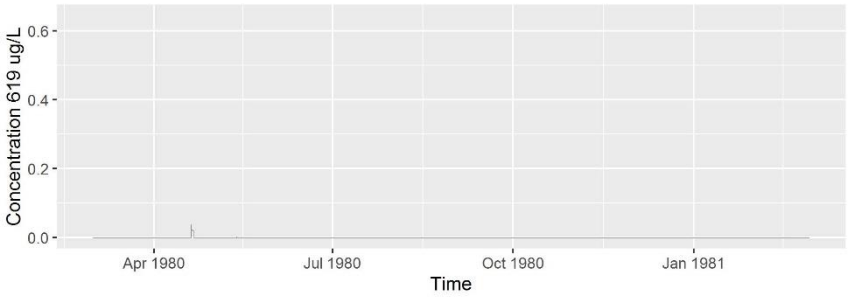
"sum of sulfonylurea compounds"



Thiencarbazone -methyl



Foramsulfuron



Metabolite AE F130619

EPAT analysis for "sum of sulfonylurea compounds"
for use group C – FOCUS Step 4, 10 m buffer, Scenario R3 stream
(use on sugar beet / **rate = 2 × 25 g/ha FSN + 2 × 15 g/ha TCM)**:

Compound	PECmax [µg/L]	events above Tier 1 RAC	event duration above Tier 1 RAC [d]	interval betw. events above Tier 1 RAC [d]	Relevant peak-RAC from Lemna 2-peak study		RQ = PECmax/ peakRAC
					Study duration	Peak-RAC [µg a.s./L]	
sum of sulfonyl-urea compounds	0.6431	1 peak	1.208	not applicable	14 d peaks on d0 & d7	1.57 µg/L	0.41
Thiencarbazone-methyl	0.2170	1 peak	0.916	not applicable			

[Step 4, 10 m buffer]					
Foramsulfuron [Step 4, 10 m buffer]	0.3881	1 peak	1.125	not applicable	
AE F130619 [Step 4, 10 m buffer]	0.0380	-	-	-	

[event recognition threshold: 0.101 µg/L = Tier 1 RAC of foramsulfuron]

The PEC pattern for "sum of sulfonylurea substances" of the FOCUS year consists of 1 prominent peak that has a concentration of 0.6431 µg a.s./L. This is well below the peak-RAC of 1.57 µg a.s./L for a single peak of the substance thiencarbazone-methyl used for comparison. With the duration of 1.208 days the peak is slightly longer than the exposure of 1 day in the peak study. However, the low RQ of 0.41 provides an additional margin of safety.

Consequently, the risk to aquatic macrophytes arising from this exposure pattern is considered to be low.

* The available refined exposure studies does not cover the PEC pattern at FOCUS Step 3 level. Therefore the pattern of FOCUS Step 4 considering risk mitigation measures is presented.

Overall conclusion from Tier 2C risk assessment:

A Tier 2C level risk assessment has been presented based on FOCUS exposure simulations and assessment versus peak RAC values derived from macrophyte 2-peak studies.

Based on a combined assessment to consider the potential effect of concentration additive toxicity of the three biologically active components relevant to the present product (i.e. foramsulfuron, its metabolite AE F130619, and thiencarbazone-methyl), the following conclusions can be drawn from assessment at Tier 2C:

Table 9.5-50: Summary table of the aquatic risk assessment for combined toxicity: use group B - use on sugar beet / rate 1 × 50 g /ha FSN + 1 × 30 g /ha TCM (1 × 1.0 L prod./ha)

RA Tier *(Section reference)*	Approach	D3 ditch	D4 pond	D4 stream	R1 pond	R1 stream	R3 stream
Tier 2C (via testing) *(9.5.2.5)*	FOCUS Step 3 & 4, refined exposure testing	resolved 5 m buffer 0% drift red.	-*	resolved Step 3	-*	resolved Step 3	resolved Step 3

* Risk assessment already resolved at Tier 1 level

Table 9.5-51: Summary table of the aquatic risk assessment for combined toxicity: use group C - use on sugar beet / rate 2 × 25 g /ha FSN + 2 × 15 g /ha TCM (2 × 0.5 L prod./ha)

RA Tier *(Section reference)*	Approach	D3 ditch	D4 pond	D4 stream	R1 pond	R1 stream	R3 stream
Tier 2C (via testing) *(9.5.2.5))*	FOCUS Step 3 & 4, refined exposure testing	resolved Step 3	-*	resolved Step 3	-*	resolved 10 m buffer	resolved 10 m buffer

* Risk assessment already resolved at Tier 1 level

For a registration in regions where the scenarios which did not pass the final combined assessment on Tier 2C level are **not** deemed relevant, reference is made to the assessment according to national requirements of the respective National Addendum.

The Tier 2C approach has been applied to refine the risk assessment for foramsulfuron, thiencarbazone-methyl and for the combination of active components relevant to the product, for FOCUS scenarios D3 ditch, D4 stream, R1 stream and R3 stream that are characterised by a pronounced peak-shaped time variability in their aquatic exposure profiles. In all these situations, it was possible to clearly demonstrate no unacceptable risks for aquatic macrophytes, with $RQ_{(mix)}$ values below the trigger of 1.

Overall, the assessment provides a mechanistic understanding of the conclusions previously drawn via TWA approach at Tier 1 level. Formally, as the notifier in previous submissions experienced no consistent acceptance of TWA approaches by countries, Tier 2C is presented here as the next level of risk assessment being proposed by EFSA PPR panel for cases where the $PEC_{sw,twa}$ cannot be used in the chronic risk assessment (Aquatic Guidance Document, Section 2.1.5).

9.5.2.6 Tier 2C: Higher-tier assessment based on refined exposure testing combined with exposure pattern analysis - considering multi-year exposure simulations

In previous submissions the notifier had experienced eventual reviewer's concerns over the representativeness of current FOCUS calculations for exposure time-course interpretation, based risk assessments. The approach has been challenged due to the model's limitation in weather data (single weather year). Multi-year FOCUS calculations are a possible way to overcome this concern. However, no guidance is available yet on the way to perform these calculations. Nevertheless, a methodology has been established by the notifier enabling the simulation of product uses over a period of 20 years in the FOCUSsw scenarios. From these 20 years simulations a surrogate exposure pattern is derived, describing the 90th percentile worst case exposure pattern for a respective FOCUS scenario. Please refer to **Appendix A 3.3** for more details.

As this matter and novel approaches are expected to be of interest only for specific national reviewers, no detailed explanation is provided here in the dRR main part and the methodology is fully described in the Appendix (A3.3):

Foramsulfuron – exposure pattern analysis

Table 9.5-52: Tier 2C risk assessment for aquatic macrophytes for foramsulfuron, based on refined exposure testing and 90th percentile worst case exposure patterns derived from multi-year (20 years) exposure simulations – Use group B

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]	Relevant peak-RAC from Lemna 2-peak study		RQ = PECmax/ peakRAC
					Study duration	Peak-RAC [µg a.s./L]	
Use group B (use on sugar beet / rate = 1 × 50 g/ha FSN)							
D3 ditch (Step 3)	0.2625	1 peak	1.4	not relevant	14 d peaks on d0 & d7	> 5.0 µg/L	< 0.053
D4 stream (Step 3)	0.2307	1 peak	0.3	not relevant	14 d peaks on d0 & d7	> 5.0 µg/L	< 0.046
R1 stream (Step 3)	0.6438	3 peaks	0.5	6.6	14 d peaks on d0 & d7	> 5.0 µg/L	< 0.13
R3 stream (Step 4, 10 m buffer)	0.5795	2 peaks	1.0[1)]	3.9[1)]	7 d peaks on d0 & d3	0.96 µg/L	0.60

[1)] To reduce complexity of the multi-year exposure simulations, only FOCUS step 3 level results were used to quantify the duration of and the interval between events, which is a conservative simplification.

Table 9.5-53: Tier 2C risk assessment for aquatic macrophytes for foramsulfuron, based on refined exposure testing and 90th percentile worst case exposure patterns derived from multi-year (20 years) exposure simulations – Use group C

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]	Relevant peak-RAC from Lemna 2-peak study		RQ = PECmax/ peakRAC
					Study duration	Peak-RAC [µg a.s./L]	
Use group C (use on sugar beet / rate = 2 × 25 g/ha FSN)							
D3 ditch (Step 3)	0.1140	2 peaks	0.4	11.8	14 d peaks on d0 & d7	> 5.0 µg/L	< 0.023
D4 stream (Step 3)	0.1318	1 peak	**5.8**[1)]	not relevant	- [1)]	- [1)]	- [1)]
R1 stream (Step 3)	0.6877	2 peaks	**1.375**[2)]	32.333[2)]	7 d peak on d0 & d3	> 5.0 µg/L	< 0.138
R3 stream (Step 4, 20 m buffer)	0.2481	2 peaks	0.9[3)]	3.5[3)]	7 d peaks on d0 & d3	0.96 µg/L	0.26

[1)] The peak duration is calculated to be 5.8 days which makes it impossible to address the multi-year pattern by either of the foramsulfuron peak studies where exposures to individual peaks did not last longer than 1 day. However, the PECmax of 0.1318 µg a.s./L is only slightly higher than the tier-1 RAC = 0.101 µg a.s./L which was derived from the standard *Lemna* study with 7 days constant exposure. It is therefore reasonable to assume that the risk to aquatic macrophytes arising from a peak with a slightly higher concentration but a shorter duration is covered by the *Lemna* tier-1 study. Additional information supporting this conclusion is provided in Appendix 3.3.

[2)] The combined duration of the two peaks is 1.375 days which is slightly longer than the exposure of 1 day tested in the underlying peak study. However, there is a large additional margin of safety that can be considered to cover this minor discrepancy. Additional information on the combination of the two peaks and the drawn conclusions is provided in Appendix 3.3.

[3)] To reduce complexity of the multi-year exposure simulations, only FOCUS step 3 level results were used to quantify the duration of and the interval between events, which is a conservative simplification.

Conclusion from Tier 2C Level risk assessment considering multi-year exposure simulations:

A summary of the outcome of the Tier 2C risk assessment level per use group and FOCUS scenario is provided in the following tables for the use groups B and C.

Table 9.5-54: Summary table of the exposure pattern analysis for foramsulfuron (multi-year): use group B - use on sugar beet / rate 1 × 50 g a.s./ha (1 × 1.0 L prod/ha)

RA Tier *(Section reference)*	Approach	D3 ditch	D4 pond	D4 stream	R1 pond	R1 stream	R3 stream
Tier 2C (via testing) *(9.5.2.6)*	FOCUS Step 3 & 4, refined exposure testing *supportive 20 yr simulation*	resolved Step 3	-*	resolved Step 3	-*	resolved 5 m buffer	resolved 10 m buffer

* risk assessment already resolved at Tier 1 level

Table 9.5-55: Summary table of the exposure pattern analysis for foramsulfuron (multi-year): use group C - use on sugar beet / rate 2 × 25 g a.s./ha (2 × 0.5 L prod/ha)

RA Tier *(Section reference)*	Approach	D3 ditch	D4 pond	D4 stream	R1 pond	R1 stream	R3 stream
Tier 2C (via testing) *(9.5.2.6)*	FOCUS Step 3 & 4, refined exposure testing *supportive 20 yr simulation*	resolved Step 3	-*	resolved Step 3	-*	resolved Step 3	resolved 20 m buffer

* risk assessment already resolved at Tier 1 level

Thiencarbazone-methyl – exposure pattern analysis

Table 9.5-56: Tier 2C risk assessment for aquatic macrophytes for thiencarbazone-methyl, based on refined exposure testing and 90th percentile worst case exposure patterns derived from multi-year (20 years) exposure simulations – Use group B

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]	Relevant peak-RAC from Lemna 2-peak study		RQ = PECmax/ peakRAC
					Study duration	Peak-RAC [µg a.s./L]	
Use group B (use on sugar beet / rate = 1 × 30 g/ha TCM)							
D3 ditch (Step 3)	0.1574	1 peak	0.5	not relevant	14 d peaks on d0 & d7	1.57 µg/L	0.10
R3 stream (Step 4, 10 m buffer)	0.3304	1 peak	0.8[1)]	not relevant	14 d peaks on d0 & d7	1.57 µg/L	0.21

[1)] To reduce complexity of the multi-year exposure simulations, only FOCUS step 3 level results were used to quantify the duration of and the interval between events, which is a conservative simplification.

Table 9.5-57: Tier 2C risk assessment for aquatic macrophytes for thiencarbazone-methyl, based on refined exposure testing and 90th percentile worst case exposure patterns derived from multi-year (20 years) exposure simulations – Use group C

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]	Relevant peak-RAC from Lemna 2-peak study		RQ = PECmax/ peakRAC
					Study duration	Peak-RAC [µg a.s./L]	
Use group C (use on sugar beet / rate = 2 × 15 g/ha TCM)							
R1 stream (Step 4, 10 m buffer)	0.1733	1 peak	0.7[1)]	not relevant	14 d peaks on d0 & d7	1.57 µg/L	0.11
R3 stream (Step 4, 10 m buffer)	0.2716	2 peaks	1.0[1)]	4.0[1)]	7 d peaks on d0 & d3	0.31 µg/L	0.88

[1)] To reduce complexity of the multi-year exposure simulations, only FOCUS step 3 level results were used to quantify the duration of and the interval between events, which is a conservative simplification.

Conclusion from Tier 2C Level risk assessment considering multi-year exposure simulations:

A summary of the outcome of the Tier 2C risk assessment level per use group and FOCUS scenario is provided in the following tables for the use groups B and C.

Table 9.5-58: Summary table of the exposure pattern analysis for thiencarbazone-methyl (multi-year): use group B - use on sugar beet / rate 1 × 30 g a.s./ha (1 × 1.0 L prod/ha)

RA Tier *(Section reference)*	Approach	D3 ditch	D4 pond	D4 stream	R1 pond	R1 stream	R3 stream
Tier 2C (via testing) *(9.5.2.6)*	FOCUS Step 3 & 4, refined exposure testing *supportive 20 yr simulation*	resolved Step 3	-*	-*	-*	-*	resolved 10 m buffer

* risk assessment already resolved at Tier 1 level

Table 9.5-59: Summary table of the exposure pattern analysis for thiencarbazone-methyl (multi-year): use group C - use on maize / rate 2 × 15 g a.s./ha (2 × 0.5 L prod/ha)

RA Tier *(Section reference)*	Approach	D3 ditch	D4 pond	D4 stream	R1 pond	R1 stream	R3 stream
Tier 2C (via testing) *(9.5.2.6)*	FOCUS Step 3 & 4, refined exposure testing *supportive 20 yr simulation*	-*	-*	-*	-*	resolved 10 m buffer	resolved 10 m buffer

* risk assessment already resolved at Tier 1 level

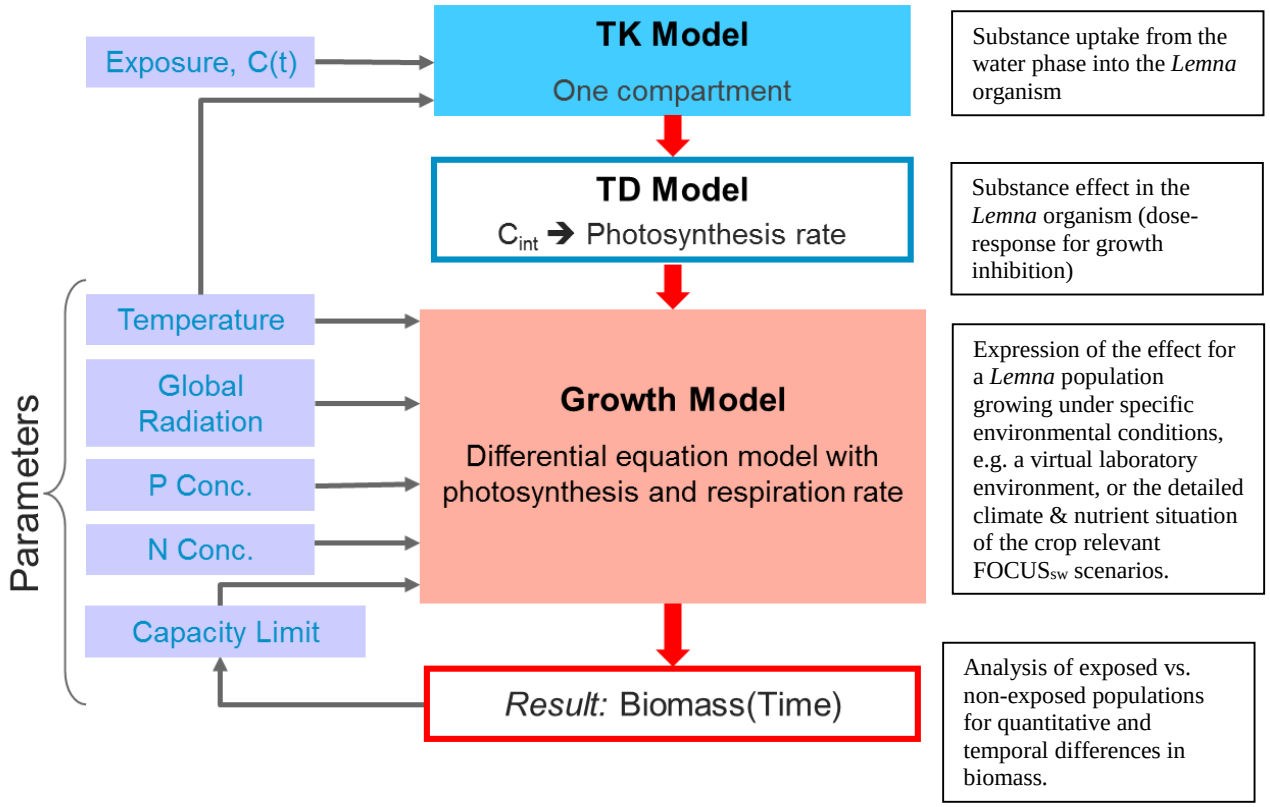
9.5.2.7 Tier 2C and Tier 3: Ecological modelling approaches, and their use in higher-tier risk assessments for the present product

Testing of exposure patterns, Tier 2C as described before, is an option to generate and consider information on the effects of time-variable aquatic exposure situations. As experimental testing will in practice be limited in regard to the number of different exposure patterns that can be studied, the combination with ecological modelling is a promising tool. Once established based on a set of measured experimental information, a modelling approach allows for a transfer to and mechanistic understanding of realistic exposure scenarios, which would not be possible to that level of detail via laboratory tests.

According to the EFSA Aquatic Guidance Document (EFSA, 2013), *"to better address risks of time-variable exposures the tier 2 assessment may be complemented with toxicokinetic/toxicodynamic (TK/TD) models."* This assessment which aims to combine experimental data and modelling is part of the Tier 2 assessment level (Tier 2C). It may further on lead to prediction of responses at population-level which are defined as Tier 3 level.

The here presented approach used a previously published TK/TD population model of *Lemna* (Schmitt et al. 2013) to link $FOCUS_{sw}$ exposure patterns to predicted effects on populations. The model comprises of a toxicokinetic, a toxicodynamic, and a growth sub-model, together enabling simulations for a comparative analysis of the growth of exposed vs. non-exposed populations for quantitative and temporal differences in biomass. Hereby, the model can also consider the influence of environmental conditions such as e.g. temperature, radiation and nutrients.

A schematic of the model principle is shown in the Figure here below, for a detailed description reference is made to **Appendix A 3.4** of the present document.



Before the model was used to address the risk assessment relevant questions, substance specific parameters were *calibrated* for each compound using experimental information from standard studies. The calibrated substance models were then *validated* by a check of the model's predictive power: Effects independently predicted for certain time-variable exposure patterns were compared with measured results of experimental studies for those exposure patterns. Details on the specific parameters including their calibration and validation are reported in Heine 2017a (M-591817-01-1) for foramsulfuron and its metabolite AE F130619, and in Heine 2017b (M-591850-01-1) for thiencarbazone-methyl. Summaries of these reports including the validation graphs and model efficiency information are presented in Appendix A 3.4 of the present dRR, clearly demonstrating the model fitness for a prediction of effects from complex exposure situations.

The successfully calibrated and validated *Lemna* models were then applied in two ways in order to address the present product risk assessment, referring to AGD levels Tier 2C and Tier 3:

Concept of model application for risk assessment Tier 2C
***In-silico* time-variable exposure testing of *Lemna*:** 'Virtual laboratory tests' on *Lemna* were performed to address FOCUSsw exposure patterns of particular interest, applying the model as a confirmation to the assessments made before at Tier 2C (Section 9.5.2.5). Starting from the condensed exposure pattern representations previously derived via EPAT tool analysis of the FOCUSsw output (number, duration, maximum concentration, and interval of events exceeding the Tier 1 RAC), the biological effect of such patterns was simulated for a *Lemna* population assumed to grow under constant environmental conditions representing an 'in-silico laboratory'. To investigate the dose-response relationship, the simulation was repeated multiple times with arbitrarily scaled concentration dimension of the exposure pattern, while keeping constant all other parameters. Based on the so generated data set, an $EC_{50pattern}$ could be derived in analogy to the procedures of a standard laboratory experiment. This $EC_{50pattern}$ is a descriptor which specifically reflects macrophyte sensitivity for the exposure time course experienced in the regarded FOCUSsw scenario of interest, and can be compared to the PECsw,max predicted for this scenario.

Concept of model application for risk assessment Tier 3
Population effect modelling for outdoor FOCUSsw water bodies: Dynamics of a *Lemna* population growing outdoors in an edge-of-field surface water body were simulated for each of the crop relevant $FOCUS_{sw}$ exposure scenarios, for the critical GAP situations of the present product. To realistically simulate the biological impact of the predicted exposure patterns, the model environmental scenarios were constructed to reflect the properties of each associated FOCUS surface water body[12]. Additionally, to generate information on the margin of safety, *Lemna* population dynamics were simulated as well for exaggerated exposure situations, generated via a multiplication of the concentration dimension of the exposure patterns with exemplary scaling factors of either 10 or 100. Scaling the exposure supports the assessment and is intended to demonstrate that the model is able to predict considerable inhibitions of population dynamics. Following the standard concept of concentration addition, the population modelling approach can consider and combine the effect contributions of all biologically active components relevant to a product, i.e. can directly provide a combined risk assessment for the detailed and potentially complex exposure situation of macrophytes in surface water bodies.

[12] In order to account for the uncertainty resp. natural variation in some model relevant parameters, e.g. waterbody nutrient concentrations, a stochastic simulation was performed varying those parameters in a Monte-Carlo approach. Therefore, actually 100 model runs were made per scenario, yielding output ranges.

Results of model application for risk assessment:

(a) Tier 2C: *In-silico* time-variable exposure testing of *Lemna*

For the present product, as discussed before in Section 9.5.2.5, in particular scenarios D3 ditch, D4 stream, R1 stream and R3 stream were of interest for confirmatory or complementary activity at Tier 2C.

An overview of the results is provided below; more detailed information including dose-effect curves can be found in **Appendix A 3.4**. Note that the *In-silico* time-variable exposure testing was not done for the individual substances separately but directly for the mixture of all active components, i.e. for foramsulfuron, metabolite AE F130619 and thiencarbazone-methyl in combination.

Table 9.5-60: Assessing exposure patterns for the sum of foramsulfuron, thiencarbazone-methyl and the metabolite AE F130619 derived from FOCUSsw calculations to determine the corresponding exposure pattern that causes 50% effect by increasing the event concentration and keeping all other pattern characteristics - Use group B

FOCUS Scenario	Pattern mixture toxicity				Scaling factor	$EC_{50\ pattern\ mix}$ [µg/L]	$RAC_{pattern\ mix}$ [µg/L]	$RQ_{mix} = PEC_{max\ sum}/RAC_{pattern\ mix}$
	PECmax [µg/L] FSN	PECmax [µg/L] AE F130619	PECmax [µg/L] TCM	PECmax [µg/L] Sum				
Use group B (use on sugar beet / rate = 1 × 1.0 L prod./ha)								
D3 ditch (Step 3)	0.2624	3.00E-04	0.1574	0.42	32.7	13.73	1.37	0.306
D4 stream (Step 3)	0.2146	3.00E-04	0.1288	0.3436	701.4	241	24.1	0.014
R1 stream (Step 3)	0.1791	0.0193	0.1032	0.3017	115.9	34.97	3.5	0.086
R3 stream (Step 3)	0.3644	0.0432	0.2048	0.6124	44.2	27.09	2.71	0.226

Table 9.5-61: Assessing exposure patterns for the sum of foramsulfuron, thiencarbazone-methyl and the metabolite AE F130619 derived from FOCUSsw calculations to determine the corresponding exposure pattern that causes 50% effect by increasing the event concentration and keeping all other pattern characteristics - Use group C

FOCUS Scenario	Pattern mixture toxicity				Scaling factor	$EC_{50\ pattern\ mix}$ [µg/L]	$RAC_{pattern\ mix}$ [µg/L]	$RQ_{mix} = PEC_{max\ sum}/RAC_{pattern\ mix}$
	PECmax [µg/L] FSN	PECmax [µg/L] AE F130619	PECmax [µg/L] TCM	PECmax [µg/L] Sum				
Use group C (use on sugar beet / rate = 2 × 0.5 L prod./ha)								
D3 ditch (Step 3)	0.114	1.00E-04	0.0682	0.1823	73.3	13.36	1.34	0.136
D4 stream (Step 3)	0.096	2.00E-04	0.0574	0.1536	537.3	82.53	8.25	0.019
R1 stream (Step 3)	0.4106	0.0364	0.2388	0.6859	47.4	32.52	3.25	0.211
R3 stream (Step 3)	0.8509	0.0833	0.4757	1.41	19.2	27.01	2.7	0.522

The Tier 2C risk assessment based on *In-silico* time-variable exposure testing of *Lemna* is passed at FOCUS Step 3 level for both use groups and all investigated scenarios.

(b) Tier 3: Population effect modelling for FOCUSsw water bodies

Dynamics of *Lemna* populations growing in edge-of-field FOCUS surface water bodies were simulated for all crop relevant $FOCUS_{sw}$ scenarios, for the two critical GAP situations of the present product: use group B and C. These simulations considered the effect contributions by all three biologically active components of relevance to the product, i.e. represent a combined toxicity assessment for foramsulfuron, its metabolite AE F130619, and thiencarbazone-methyl.

An overview of the results is provided in condensed tabular form here below. For detailed information including a higher resolved presentation of effect classes and ranges, reference is made to **Appendix A 3.4**.

Table 9.5-62: Effect magnitude and duration caused by FOCUSsw exposure patterns from use group B and C. Columns highlighted in grey are results for the original FOCUS predicted exposure patterns, other columns represent simulations for exaggerated exposure.

Level ►	Step3					
Scaling factor ►	1	10	100	1	10	100
Scenario ▼	Use group B (use on sugar beet, 1 × 50 g/ha FSN with consideration of metabolite AE F130619 & 1 × 30 g/ha TCM)			Use group C (use on sugar beet, 2 × 25 g/ha FSN with consideration of metabolite AE F130619 & 2 × 15 g/ha TCM)		
D3 (Ditch)	Neg.	Neg.	**>10%<20% (9d)**	Neg.	Neg.	**>20%<30% (16d)**
D4 (Pond)	Neg.	Neg.	**>70%<80% (61d)**	Neg.	Neg.	**>50%<60% (52d)**
D4 (Stream)	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
R1 (Pond)	Neg.	Neg.	**>70%<80% (87d)**	Neg.	Neg.	**>80%<90% (99d)**
R1 (Stream)	Neg.	Neg.	**>10%<20% (5d)**	Neg.	Neg.	**>10%<20% (15d)**
R3 (Stream)	Neg.	Neg.	**>10%<20% (7d)**	Neg.	Neg.	**>10%<20% (11d)**

Neg. = negligible (i.e. ≤ 10% effects);
d = days with predicted effects >10%.

The population simulations showed that adverse effects on *Lemna* are not to be expected for any scenario. Even a 10-fold increase of the exposure patterns did

not inhibit population dynamics for use group B and use group C, respectively. The intention of increasing the exposure patterns is to demonstrate that the model is able to predict considerable inhibitions of population dynamics.

For a graphical illustration, exposure concentration profile, effects curve and population biomass development over the simulated year is shown exemplarily for scenario R1 pond for use group B here below:

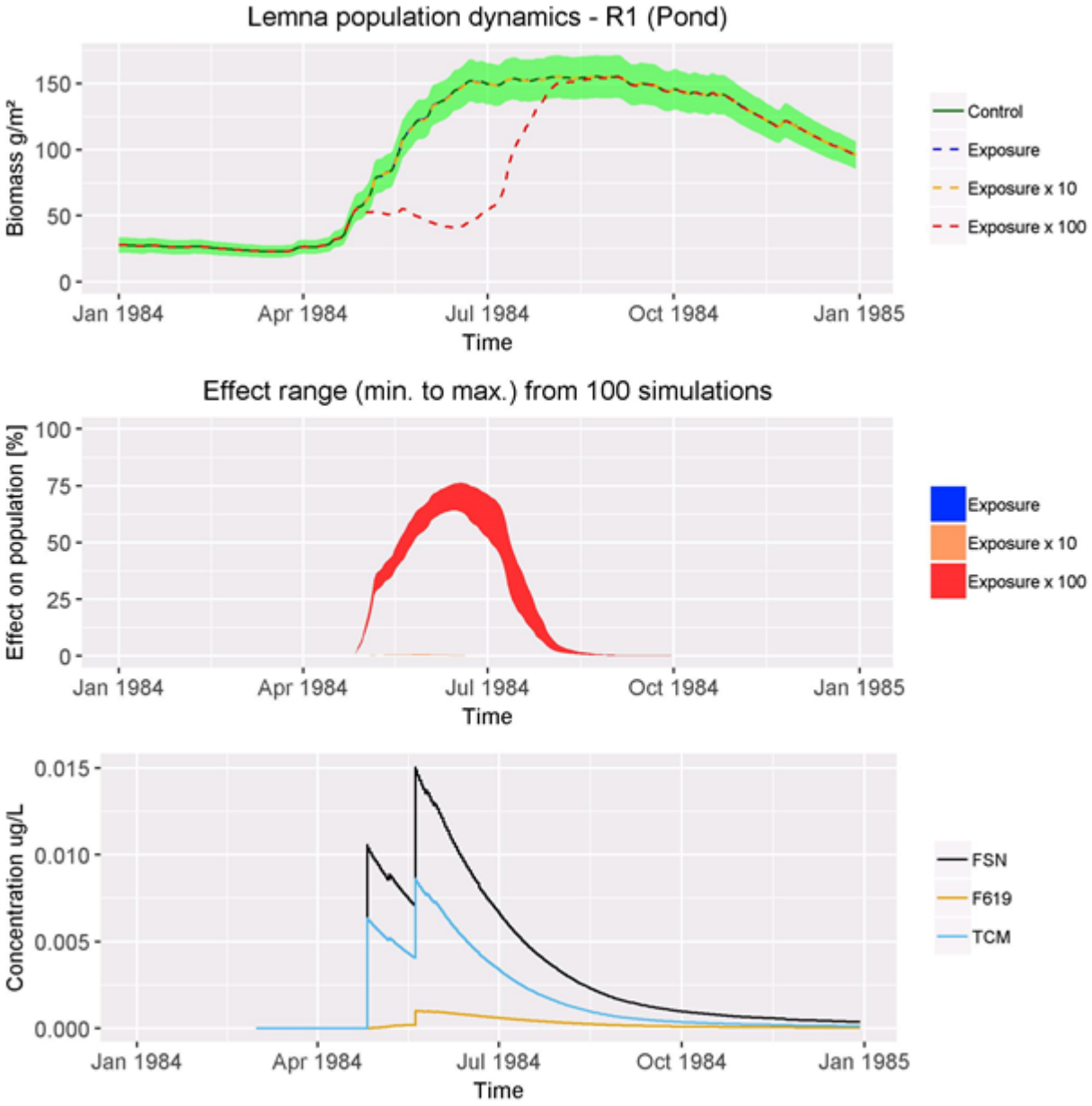


Figure 2: Inhibition of *Lemna* population dynamics caused by product FSN+TCM OD 80 (50+30), exposure pattern D4 stream, for use group B.

top: Population dynamics exposed vs. non-exposed, with the green area representing the range of undisturbed population dynamics.

middle: Predicted impact on the *Lemna* population with the areas representing minimum and maximum effects caused.

bottom: Exposure patterns of the two active ingredients, and relevant metabolite AE F130619 on which simulations of population dynamics were based.

(c) Overall conclusion from Tier 2C and Tier 3 risk assessment (ecological modelling approach):

Effect modelling approaches were established to generate a more in-depth understanding of the potential risk for macrophytes and aiming to provide alternative risk assessment routes for countries that might reject the initially proposed Tier 1 -TWA approaches.

The Tier 2C and Tier 3 level risk assessments based on *Lemna* TK/TD-population modelling were conducted for the critical GAP situations of the present product (use groups B and C).

Based on a combined assessment to consider the potential effect of the additive toxicity of the sum of the three biologically active components relevant to the present product (i.e. foramsulfuron, its metabolite AE F130619, and thiencarbazone-methyl), the following conclusions can be drawn from assessment at Tier 2C and Tier 3:

Table 9.5-63: Summary table of the aquatic risk assessment for combined toxicity (modelling approach): use group B - use on sugar beet / rate 1 × 50 g /ha FSN + 1 × 30 g /ha TCM (1 × 1.0 L prod./ha)

RA Tier *(Section reference)*	Approach	D3 ditch	D4 pond	D4 stream	R1 pond	R1 stream	R3 stream
Tier 2C & Tier 3 (via modelling) *(9.5.2.7)*	FOCUS Step 3, refined exp. *in-silico* virtual testing[1)]	resolved Step 3	-[2)]	resolved Step 3	-[2)]	resolved Step 3	resolved Step 3
	FOCUS Step 3, population effect modelling[1)]	resolved negligible effects	resolved negligible effects	resolved negligible effects	resolved negligible effects	resolved negligible effects	resolved negligible effects

[1)] At this risk assessment level assessment was not done for individual substances but for combined toxicity of all biologically active substances.
[2)] Risk assessment already resolved at Tier 1 level

Table 9.5-64: Summary table of the aquatic risk assessment for combined toxicity (modelling approach): use group C - use on sugar beet / rate 2 × 25 g /ha FSN + 2 × 15 g /ha TCM (2 × 0.5 L prod./ha)

RA Tier *(Section reference)*	Approach	D3 ditch	D4 pond	D4 stream	R1 pond	R1 stream	R3 stream
Tier 2C & Tier 3 (via modelling) *(9.5.2.7)*	FOCUS Step 3, refined exp. *in-silico* virtual testing[1)]	resolved Step 3	-[2)]	resolved Step 3	-[2)]	resolved Step 3	resolved Step 3
	FOCUS Step 3, population effect modelling[1)]	resolved negligible effects	resolved negligible effects	resolved negligible effects	resolved negligible effects	resolved negligible effects	resolved negligible effects

[1)] At this risk assessment level assessment was not done for individual substances but for combined toxicity of all biologically active substances.
[2)] Risk assessment already resolved at Tier 1 level

For a registration in regions where the scenarios which did not pass the final combined assessment on Tier 2C and Tier 3 level are **not** deemed relevant, reference is made to the assessment according to national requirements of the respective National Addendum.

9.5.2.8 Tier 2C and Tier 3: Ecological modelling approaches, and their use in higher-tier risk assessments for the present product – considering multiyear exposure simulations

As previously explained under point 9.5.2.6, the representativeness of current FOCUS calculations has been challenged and multi-year FOCUS calculations are a possible way to overcome this concern but are not laid down in agreed guidance documents yet. Nevertheless, for reviewers with deeper interest in this matter, the notifier has applied the novel 20 year-simulation methodology for the FOCUS scenarios as well to generate a more representative exposure data base for the *Lemna* population modelling. Please refer to Appendix A 3.5 for more details.

As this matter and novel approaches are expected to be of interest only for specific national reviewers, no detailed explanation is provided in this dRR main part, but it is worth noting that the conclusions drawn from the *Lemna* population modelling based on FOCUS step 3 one-year calculations were overall confirmed by the 20 years calculations.

(a) Tier 2C: In-silico time-variable exposure testing of *Lemna* – considering multiyear exposure simulations

For the present product, as discussed before in Section 9.5.2.5, in particular scenarios D3 ditch, D4 stream, R1 stream and R3 stream were of interest for confirmatory or complementary activity at Tier 2C.

An overview summary of the results is provided below; more detailed information can be found in **Appendix A 3.5**.

Table 9.5-65: Assessing exposure patterns for the sum of foramsulfuron, its metabolite AE F130619 and thiencarbazone-methyl from FOCUSsw multi-year calculations to determine the corresponding exposure pattern that causes 50% effect by increasing the event concentration and keeping all other pattern characteristics - Use group B

FOCUS Scenario	Pattern mixture toxicity				Scaling factor	$EC_{50\ pattern\ mix}$ [µg/L]	$RAC_{pattern\ mix}$ [µg/L]	80th percentile RQ_{mix} = $PEC_{max\ (sum)}$/ $RAC_{patternmix}$
	PECmax [µg/L] FSN	PECmax [µg/L] AE F130619	PECmax [µg/L] TCM	PECmax [µg/L] Sum				
Use group B (use on sugar beet / rate = 1 × 1.0 L prod./ha)								
D3 ditch (Step 3)	0.2625	3.00E-04	0.1574	0.4202	29.9	12.56	1.26	0.335
D4 stream (Step 3)	0.1147	0.0192	0.0642	0.1981	8.4	1.67	0.17	**1.186**
R1 stream (Step 3)	0.5267	0.0583	0.2977	0.8827	40.8	36.03	3.6	0.245
R3 stream (Step 3)	1.4385	0.1519	0.7879	2.3783	10	23.87	2.39	0.997

RQ_{mix} values above the relevant trigger of 1 are shown in **bold**

Table 9.5-66: Assessing exposure patterns for the sum of foramsulfuron, its metabolite AE F130619 and thiencarbazone-methyl from FOCUSsw multi-year calculations to determine the corresponding exposure pattern that causes 50% effect by increasing the event concentration and keeping all other pattern characteristics - Use group C

FOCUS Scenario	Pattern mixture toxicity				Scaling factor	$EC_{50\ pattern\ mix}$ [µg/L]	$RAC_{pattern\ mix}$ [µg/L]	80th percentile RQ_{mix} = $PEC_{max\ (sum)}$/ $RAC_{patternmix}$
	PECmax [µg/L] FSN	PECmax [µg/L] AE F130619	PECmax [µg/L] TCM	PECmax [µg/L] Sum				
Use group C (use on sugar beet / rate = 2 × 0.5 L prod./ha)								
D3 ditch (Step 3)	0.114	1.00E-04	0.1574	0.2715	40.4	10.96	1.1	0.248
D4 stream (Step 3)	0.1445	0.0236	0.0642	0.2322	7	1.63	0.16	**1.426**
R1 stream (Step 3)	0.3787	0.0397	0.4136	0.832	45.5	37.83	3.78	0.22
R3 stream (Step 3)	0.9414	0.0779	1.1095	2.1288	13.1	27.96	2.8	0.761

RQ_{mix} values above the relevant trigger of 1 are shown in **bold**

For both use groups RQ_{mix} values (multiyear 80th percentile) of < 1 were obtained for all scenarios at FOCUS Step 3 level except for scenario D4 stream. The pattern characteristics of scenario D4 stream inhibit growth the strongest in terms of having the smallest scaling factor to achieve a growth inhibition of 50%. Scenario D4 stream remains unresolved when risk assessment is based on $RAC_{pattern}$ and FOCUS Step 3. Since entry via drainage is driving the environmental concentrations in this scenario, FOCUS step 4 concentrations were not considered for refinements.

(b) Tier 3: Population effect modelling for FOCUSsw water bodies – considering multi-year exposure simulations

The results of the population effect modelling over 20 years for a combined assessment of all active components of the product based on the FOCUSsw multi-year step 3 showed that adverse effects on *Lemna* are not to be expected for any scenario (see Appendix A 3.5).

(c) Overall conclusion from Tier 2C and Tier 3 risk assessment (ecological modelling approach) – considering multi-year exposure simulations:

Overall, *Lemna* effect modelling for a 20-year extended period of exposure prediction confirmed the regulatory conclusions drawn in the assessment previously based on the standard FOCUS year period.
The Tier 2C and Tier 3 level risk assessments based on *Lemna* TK/TD-population modelling and considering FOCUSsw multi-year calculations were conducted for the critical GAP situations of the present product (use groups B and C).

Based on a combined assessment to consider the potential effect of the additive toxicity of the sum of the three biologically active components relevant to the present product (i.e. foramsulfuron, its metabolite AE F130619, and thiencarbazone-methyl), the following conclusions can be drawn from assessment at Tier 2C and Tier 3:

Table 9.5-67: Summary table of the aquatic risk assessment for combined toxicity (modelling approach, multi-year): use group B - use on sugar beet / rate 1 × 50 g /ha FSN + 1 × 30 g /ha TCM (1 × 1.0 L prod./ha)

RA Tier *(Section reference)*	Approach	D3 ditch	D4 pond	D4 stream	R1 pond	R1 stream	R3 stream
Tier 2C & Tier 3 (via modelling) *(9.5.2.8)*	FOCUS Step 3, refined exp. *in-silico* virtual testing[1] *supportive 20 yr simulation*	resolved Step 3	-[2]	**failed Step 3**	-[2]	resolved Step 3	resolved Step 3
	FOCUS Step 3, population effect modelling[1] *supportive 20 yr simulation*	resolved negligible effects	resolved negligible effects	resolved negligible effects	resolved negligible effects	resolved negligible effects	resolved negligible effects

[1] At this risk assessment level assessment was not done for individual substances but for combined toxicity of all biologically active substances.
[2] Risk assessment already resolved at Tier 1 level

Table 9.5-68: Summary table of the aquatic risk assessment for combined toxicity (modelling approach, multi-year): use group C - use on sugar beet / rate 2 × 25 g /ha FSN + 2 × 15 g /ha TCM (2 × 0.5 L prod./ha)

RA Tier *(Section reference)*	Approach	D3 ditch	D4 pond	D4 stream	R1 pond	R1 stream	R3 stream
Tier 2C & Tier 3 (via modelling) *(9.5.2.8)*	FOCUS Step 3 refined exp. *in-silico* virtual testing[1] *supportive 20 yr simulation*	resolved Step 3	-[2]	**failed Step 3**	-[2]	resolved Step 3	resolved Step 3
	FOCUS Step 3, population effect modelling[1] *supportive 20 yr simulation*	resolved negligible effects	resolved negligible effects	resolved negligible effects	resolved negligible effects	resolved negligible effects	resolved negligible effects

[1] At this risk assessment level assessment was not done for individual substances but for combined toxicity of all biologically active substances.
[2] Risk assessment already resolved at Tier 1 level

9.5.3 Overall conclusions

In overall conclusion of the above tiered assessments,

- **for use group B (use on sugar beet, rate 1 × 1.0 L prod/ha = 1 × 50 g/ha FSN + 1 × 30 g/ha TCM):** the risk for aquatic organisms is considered acceptable without requiring measures for exposure mitigation.
- **for use group C (use on sugar beet, rate 2 × 0.5 L prod/ha = 2 × 25 g/ha FSN + 2 × 15 g/ha TCM):** the risk for aquatic organisms is considered acceptable without requiring measures for exposure mitigation.

The presented tiered exposure and risk assessments provide a deep mechanistic understanding of the effects of time-variable exposure of aquatic macrophytes to the active components of the product **FSN+TCM OD 80 (50+30)** and allow for a detailed analysis of potential growth effects for exposure situations arising from the intended product uses.

The various assessments consistently describe that the effect of the active components of the product on aquatic macrophytes is a reversible growth inhibition, lasting not significantly longer than the exposure phase. Therefore, short periods of exposure will translate into effects notably smaller than implied by a standard risk assessment based on PECsw,max and standard long-term exposure effect endpoint.

This fundamental behaviour – time limited exposure leads to time-limited, reversible effects - can be expressed in risk assessments at different levels of complexity. In the more realistic higher tier approaches (Tier 2C and Tier 3), the effect endpoint is selected according to the actual exposure pattern. This enables very detailed assessments, including the consideration of high temporal resolution of both environmental conditions and development of the population, if required. At a lower Tier level, the same mechanistic background can be translated to a Tier 1 approach via adapting the exposure value into a 7d-TWA-PEC and comparing to the standard long-term exposure effect endpoint. Despite of the granularity and simplification inherent to this Tier 1 approach, the final outcome of the risk assessment is very similar (although slightly more conservative) to that of the more complex approaches.

A detailed summary of the outcome of each risk assessment level per use and FOCUS scenario is provided in the following tables.

Table 9.5-69: Summary table of the aquatic risk assessment for individual substances: use group B - use on sugar beet / rate 1 × 1.0 L prod/ha = 1 × 50 g/ha FSN + 1 × 30 g/ha TCM

RA Tier *(Section reference)*	Approach	Drift only	FOCUS step 1/2	FOCUS step 3/4					
				D3 ditch	D4 pond	D4 stream	R1 pond	R1 stream	R3 stream
Screening level *(9.5.2.1)*	Drift-only *(for formulated product)*	resolved (10 m drift buffer)							
Screening level *(9.5.2.3)*	FOCUS Step 1/2, generic envelope		resolved for all species except for macrophytes						
Tier 1 *(9.5.2.4)*	FOCUS Step 3 & 4, based on PEC_{max}			resolved 5 m buffer	resolved Step 3	resolved 5 m buffer	resolved Step 3	resolved 10 m buffer	resolved 20 m buffer
	FOCUS Step 3 & 4, based on PEC_{twa} for foramsulfuron			resolved Step 3	resolved Step 3	resolved Step 3	resolved Step 3	resolved Step 3	resolved Step 3
Tier 2C (via testing) *(9.5.2.5 & 9.5.2.6)*	FOCUS Step 3 & 4, refined exposure testing			resolved Step 3	-[1)]	resolved Step 3	-[1)]	resolved Step 3	resolved Step 3
	supportive 20 yr simulation			resolved Step 3	-[1)]	resolved Step 3	-[1)]	resolved Step 3	resolved 10 m buffer
Tier 2C (via modelling) *(9.5.2.7 & 9.5.2.8)*	FOCUS Step 3, refined exp. *in-silico* virtual testing			-[2)]	-[1)]	-[2)]	-[1)]	-[2)]	-[2)]
	supportive 20 yr simulation			-[2)]	-[1)]	-[2)]	-[1)]	-[2)]	-[2)]
Tier 3 *(9.5.2.7 & 9.5.2.8)*	FOCUS Step 3, population effect modelling			-[2)]	-[2)]	-[2)]	-[2)]	-[2)]	-[2)]
	supportive 20 yr simulation			-[2)]	-[2)]	-[2)]	-[2)]	-[2)]	-[2)]

[1)] risk assessment already resolved at Tier 1 level
[2)] At this risk assessment level assessment was done for combined toxicity driving the risk assessment, but not for the individual active substances.

Table 9.5-70: Summary table of the aquatic risk assessment for combined toxicity: use group B - use on sugar beet / rate 1 × 1.0 L prod/ha = 1 × 50 g/ha FSN + 1 × 30 g/ha TCM

RA Tier *(Section reference)*	Approach	Drift only	FOCUS step 1/2	FOCUS step 3/4					
				D3 ditch	D4 pond	D4 stream	R1 pond	R1 stream	R3 stream
Screening level *(9.5.2.1)*	Drift-only (for formulated product)	resolved (10 m drift buffer)							
Screening level *(9.5.2.3)*	FOCUS Step 1/2, generic envelope		resolved for all species except for macrophytes						
Tier 1 *(9.5.2.4)*	FOCUS Step 3 & 4, based on PEC_{max}			resolved 10 m buffer	resolved Step 3	resolved 10 m buffer	resolved Step 3	resolved 20 m buffer	**failed 20 m buffer**
	FOCUS Step 3 & 4, based on PEC_{twa} for foramsulfuron			-[1)]	-[1)]	-[1)]	-[1)]	resolved 10 m buffer	resolved 20 m buffer
Tier 2C (via testing) *(9.5.2.5 & 9.5.2.6)*	FOCUS Step 3 & 4, refined exposure testing			resolved 5 m buffer 0% drift red.	-[2)]	resolved Step 3	-[2)]	resolved Step 3	resolved Step 3
	supportive 20 yr simulation			-[3)]	-[2)]	-[3)]	-[2)]	-[3)]	-[3)]
Tier 2C (via modelling) *(9.5.2.7 & 9.5.2.8)*	FOCUS Step 3, refined exp. *in-silico* virtual testing			resolved Step 3	-[2)]	resolved Step 3	-[2)]	resolved Step 3	resolved Step 3
	supportive 20 yr simulation			resolved Step 3	-[2)]	**failed Step 3**	-[2)]	resolved Step 3	resolved Step 3
Tier 3 *(9.5.2.7 & 9.5.2.8)*	FOCUS Step 3, population effect modelling			resolved negligible effects	resolved negligible effects	resolved negligible effects	resolved negligible effects	resolved negligible effects	resolved negligible effects
	supportive 20 yr simulation			resolved negligible effects	resolved negligible effects	resolved negligible effects	resolved negligible effects	resolved negligible effects	resolved negligible effects

[1)] Risk assessment already resolved using FOCUS Step 3 & 4 PECmax values
[2)] Risk assessment already resolved at Tier 1 level
[3)] At this risk assessment level assessment was done for the individual substance driving the risk assessment, but not for combined toxicity.

Table 9.5-71: Summary table of the aquatic risk assessment for individual substances: use group C - use on sugar beet / rate 2 × 0.5 L prod/ha = 2 × 25 g/ha FSN + 2 × 15 g/ha TCM

RA Tier *(Section reference)*	Approach	Drift only	FOCUS step 1/2	FOCUS step 3/4					
				D3 ditch	D4 pond	D4 stream	R1 pond	R1 stream	R3 stream
Screening level *(9.5.2.1)*	Drift-only *(for formulated product)*	resolved (10 m drift buffer)							
Screening level *(9.5.2.3)*	FOCUS Step 1/2, generic envelope		resolved for all species except for macrophytes						
Tier 1 *(9.5.2.4)*	FOCUS Step 3 & 4, based on PEC_{max}			resolved 5 m buffer	resolved Step 3	resolved 5 m buffer	resolved Step 3	resolved 20 m buffer	**failed 20 m buffer**
	FOCUS Step 3 & 4, based on PEC_{twa} for foramsulfuron			resolved Step 3	resolved Step 3	resolved Step 3	resolved Step 3	resolved Step 3	resolved 10 m buffer
Tier 2C (via testing) *(9.5.2.5 & 9.5.2.6)*	FOCUS Step 3 & 4, refined exposure testing			resolved Step 3	-[1)]	resolved Step 3	-[1)]	resolved Step 3	resolved Step 3
	supportive 20 yr simulation			resolved Step 3	-[1)]	resolved Step 3	-[1)]	resolved Step 3	resolved 20 m buffer
Tier 2C (via modelling) *(9.5.2.7 & 9.5.2.8)*	FOCUS Step 3, refined exp. *in-silico* virtual testing			-[2)]	-[1)]	-[2)]	-[1)]	-[2)]	-[2)]
	supportive 20 yr simulation			-[2)]	-[1)]	-[2)]	-[1)]	-[2)]	-[2)]
Tier 3 *(9.5.2.7 & 9.5.2.8)*	FOCUS Step 3, population effect modelling			-[2)]	-[2)]	-[2)]	-[2)]	-[2)]	-[2)]
	supportive 20 yr simulation			-[2)]	-[2)]	-[2)]	-[2)]	-[2)]	-[2)]

[1)] risk assessment already resolved at Tier 1 level
[2)] At this risk assessment level assessment was done for combined toxicity driving the risk assessment, but not for the individual active substances.

Table 9.5-72: Summary table of the aquatic risk assessment for combined toxicity: use group C - use on sugar beet / rate 2 × 0.5 L prod/ha = 2 × 25 g/ha FSN + 2 × 15 g/ha TCM

RA Tier *(Section reference)*	Approach	Drift only	FOCUS step 1/2	FOCUS step 3/4					
				D3 ditch	D4 pond	D4 stream	R1 pond	R1 stream	R3 stream
Screening level *(9.5.2.1)*	Drift-only (for formulated product)	resolved (10 m drift buffer)							
Screening level *(9.5.2.3)*	FOCUS Step 1/2, generic envelope		resolved for all species except for macrophytes						
Tier 1 *(9.5.2.4)*	FOCUS Step 3 & 4, based on PEC_{max}			resolved 5 m buffer	resolved Step 3	resolved 5 m buffer	resolved Step 3	**failed 20 m buffer**	**failed 20 m buffer**
	FOCUS Step 3 & 4, based on PEC_{twa} for foramsulfuron			-[1)]	-[1)]	-[1)]	-[1)]	resolved 20 m buffer	**failed 20 m buffer**
Tier 2C (via testing) *(9.5.2.5 & 9.5.2.6)*	FOCUS Step 3 & 4, refined exposure testing			resolved Step 3	-[2)]	resolved Step 3	-[2)]	resolved 10 m buffer	resolved 10 m buffer
	supportive 20 yr simulation			-[3)]	-[2)]	-[3)]	-[2)]	-[3)]	-[3)]
Tier 2C (via modelling) *(9.5.2.7 & 9.5.2.8)*	FOCUS Step 3, refined exp. *in-silico* virtual testing			resolved Step 3	-[2)]	resolved Step 3	-[2)]	resolved Step 3	resolved Step 3
	supportive 20 yr simulation			resolved Step 3	-[2)]	**failed step 3**	-[2)]	resolved Step 3	resolved Step 3
Tier 3 *(9.5.2.7 & 9.5.2.8)*	FOCUS Step 3, population effect modelling			resolved negligible effects	resolved negligible effects	resolved negligible effects	resolved negligible effects	resolved negligible effects	resolved negligible effects
	supportive 20 yr simulation			resolved negligible effects	resolved negligible effects	resolved negligible effects	resolved negligible effects	resolved negligible effects	resolved negligible effects

[1)] Risk assessment already resolved using FOCUS Step 3 & 4 PECmax values
[2)] Risk assessment already resolved at Tier 1 level
[3)] At this risk assessment level assessment was done for the individual substance driving the risk assessment, but not for combined toxicity.

9.6 Effects on bees (KCP 10.3.1)

9.6.1 Toxicity data

Foramsulfuron

Studies on the toxicity to bees have been carried out with foramsulfuron and with a formulated product. Full details of these studies are provided in the corresponding document of the EU renewal assessment report where the study references can be found; presented agreed endpoints were taken from EFSA Journal 2016;14(3):4421.

Table 9.6-1: Endpoints and effect values relevant for the risk assessment for bees - foramsulfuron

Species	Substance	Exposure System	Results	Reference
Laboratory test				
Apis mellifera	Foramsulfuron, techn.	Adult, acute, oral	LD_{50} > 110.1 µg a.s./bee	EFSA Journal 2016;14(3):4421
Apis mellifera	Foramsulfuron, techn.	Adult, acute, contact	LD_{50} > 100.0 µg a.s./bee	EFSA Journal 2016;14(3):4421
Apis mellifera	Foramsulfuron WG 50	Adult, 10-day oral feeding test	LC_{50} > 120 mg a.s./kg LDD_{50} > 5.2 µg a.s./bee/day*	EFSA Journal 2016;14(3):4421
Apis mellifera	Foramsulfuron WG 50	Larva, acute, single dose	LD_{50} > 100 µg a.s./larva NOED = 100.0 µg a.s./larva	EFSA Journal 2016;14(3):4421
Higher-tier studies (tunnel test)				
Apis mellifera	Foramsulfuron+Isoxadifen-ethyl OD 45 (22.5+22.5 g/L)	Semi-field honey bee brood study (acc. to OECD 75; forced exposure conditions) in *Phacelia*; application during full-bloom and bees actively foraging	No statistically significant difference in brood termination rate. No adverse effects on mortality, flight intensity, behaviour, brood index, compensation index as well as on colony vitality at maximum application rate (2.67 L product/ha, corresponding to 60 g a.s./ha)	EFSA Journal 2016;14(3):4421

* There was no relevant mortality at the LDD_{50}.

Table 9.6-2: Endpoints of bee studies performed after publication of the recent list of end-points - foramsulfuron

Species	Substance	Exposure System	Results	Reference
Apis mellifera	Foramsulfuron, techn.	22-day repeated feeding larva exposure test	NOEC ≥ 163 mg a.s./kg diet NOED ≥ 25.1 µg a.s./larva	Un-reviewed data – can be submitted up on request Tier 2 summary in Appendix A 2.3.1.3, (M-604343-01-1)

Thiencarbazone-methyl

Studies on the toxicity to bees have been carried out with thiencarbazone-methyl. Full details of these studies are provided in the EU Draft Assessment Report and related documents; presented agreed end-points were taken from EFSA Journal 2013;11(7):3270.

Table 9.6-3: Endpoints and effect values relevant for the risk assessment for bees - thien-carbazone-methyl

Species	Substance	Exposure System	Results	Reference
Laboratory test				
Apis mellifera	Thiencarbazone-methyl, techn.	Adult, acute, oral	LD_{50} > 199 µg a.s./bee	EFSA Journal 2013;11(7):3270
Apis mellifera	Thiencarbazone-methyl, techn.	Adult, acute, contact	LD_{50} > 200 µg a.s./bee	EFSA Journal 2013;11(7):3270

Table 9.6-4: Endpoints of bee studies performed after publication of the recent list of end-points - thiencarbazone-methyl

Species	Substance	Exposure System	Results	Reference
Apis mellifera	Thiencarbazone-methyl + cyprosulfamide SC 450 (225 + 225)	Adult, 10d oral feeding test	LC_{50} = 2101.2 mg a.s./kg LDD_{50} = 24.5 µg a.s./bee/day	Un-reviewed data – can be submitted upon request , Tier 2 summary in Appendix A 2.3.1.2, (M-576217-01-1)
Apis mellifera	Thiencarbazone-methyl + cyprosulfamide SC 450 (225 + 225)	Larva, 22-day repeated feeding test	NOEC ≥ 129.9 mg a.s./kg diet NOED ≥ 20.0 µg a.s./larva	Un-reviewed data – can be submitted upon request, Tier 2 summary in Appendix A 2.3.1.3, (M-615921-01-1)
Apis mellifera	Thiencarbazone-methyl + cyprosulfamide SC 450 (225 + 225)	Semi-field honey bee brood study (according to OECD 75; forced exposure conditions) in *Phacelia*;	No adverse effects on mortality, foraging activity, behaviour, nectar and pollen storage, colony strength, brood development (brood termination rate, brood index,	Un-reviewed data – can be submitted upon request Tier 2 summary in Appendix A 2.3.1.5, (M-571235-01-1)

		application during full-bloom and bees actively foraging:	compensation index) at the application rate of 40 g a.s./ha	

FSN+TCM OD 80 (50+30)

The effects of the formulation on bees were not evaluated as part of the EU assessment neither for foramsulfuron nor for thiencarbazone-methyl. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

Table 9.6-5: Endpoints and effect values relevant for the risk assessment for bees – FSN+TCM OD 80 (50+30)

Species	Substance	Exposure System	Results	Reference
Apis mellifera	Foramsulfuron + Thiencarbazone-methyl OD 80	Adult, acute oral, 48 h	LD_{50} > 215.6 µg/bee	Appendix 2 Sekine (2013) M-461860-01-1
Apis mellifera	Foramsulfuron + Thiencarbazone-methyl OD 80	Adult, acute contact 48 h	LD_{50} > 200 µg/bee	Appendix 2 Sekine (2013) M-461860-01-1

9.6.1.1 Justification for new endpoints

In order to complete the dataset and the knowledge on effects on developmental stages of honey bees and chronic toxicity to adult honey bees further studies have been performed with the active substances. Since this data has not been part of the renewal process of the individual active substances, an overview is presented in the tables above and the detailed reports can be made available upon request.

9.6.2 Risk assessment

The evaluation of the risk for bees was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002).

To achieve a concise risk assessment, the risk envelope approach is applied. For the active substances foramsulfuron and thiencarbazone-methyl the assessment for use group A covers the risk for bees from all intended uses (see 9.1.3). For the formulation FSN+TCM OD 80 (50+30), the assessment for the use group B covers the risk for bees from all intended uses (see 9.1.3).

9.6.2.1 Hazard quotients for bees

Foramsulfuron

Table 9.6-6: First-tier assessment of the risk of foramsulfuron for bees due to the use of FSN+TCM OD 80 (50+30) in sugar beet (use group A)

Intended use	**Risk envelope approach (use group A): maize, sugar beet, nursery (conifer), BBCH 10-34**

Active substance	Foramsulfuron		
Application rate (g/ha)	1 × 60		
Test design	**LD_{50} (lab.) (µg/bee)**	**Single application rate (g/ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	> 110.1	60	< 0.5
Contact toxicity	> 100.0		< 0.6

Q_{HO}, Q_{HC}: Hazard quotients for oral and contact exposure. Q_H values shown in bold breach the relevant trigger.

Thiencarbazone-methyl

Table 9.6-7: First-tier assessment of the risk of thiencarbazone-methyl for bees due to the use of FSN+TCM OD 80 (50+30) in sugar beet (use group A)

Intended use	**Risk envelope approach (use group A): cereals, BBCH 00-32 [maize, sugar beet, non-cropped area]**		
Active substance	thiencarbazone-methyl		
Application rate (g/ha)	1 × 40		
Test design	**LD_{50} (lab.) (µg/bee)**	**Single application rate (g/ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	> 199	40	< 0.2
Contact toxicity	> 200		< 0.2

Q_{HO}, Q_{HC}: Hazard quotients for oral and contact exposure. Q_H values shown in bold breach the relevant trigger.

FSN+TCM OD 80 (50+30)

Table 9.6-8: First-tier assessment of the risk of FSN+TCM OD 80 (50+30) in sugar beet (use group B)

Intended use	Sugar beet, 1 × 1.0 L prod./ha (use group B)		
Product	FSN+TCM OD 80 (50+30)		
Application rate (L/ha)	1 × 1.0 L/ha		
Test design	**LD_{50} (lab.) (µg/bee)**	**Single application rate (g/ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	> 215.6	1028[1)]	< 4.8
Contact toxicity	> 200		< 5.1

Q_{HO}, Q_{HC}: Hazard quotients for oral and contact exposure. Q_H values shown in bold breach the relevant trigger.
[1)] calculated as follows: 1000 mL prod./ha × density of the formulation FSN+TCM OD 80 (1.028 g/mL at 20°C) = 1028 g prod./ha

According to the data requirements No. 284/2013 chronic toxicity to bees, effects on honey bee development and other honey bee life stages and sub-lethal effects should be addressed, whereby it is specifically pointed out that "Pending the validation and adoption of new studies and of a new risk assessment scheme, existing protocols shall be used to address the acute and chronic risk to bees, including those on colony survival and development, and the identification and measurement of relevant sub-lethal effects in the risk assessment".

While laboratory level test method development has progressed, only very recently agreed test methods became available. For example, only in July 2016 the OECD TG 239 to assess larval toxicity after repeated feeding and in October 2017 the OECD GL 245 to investigate chronic toxicity in adult honeybees were published. However, such laboratory testing of plant protection products is not yet performed on a routine

basis. The test methods that were available at the time of the active substance renewal process, which are still considered suitable to address the above described data requirements, include the study design OECD TG 75. Therefore, the study information and data that had been generated based on all available methods for the respective active substance is presented below.

For **Foramsulfuron** WG 50 a study was performed to determine the effects of the test substance on honey bee adults in a 10-day chronic feeding test in the laboratory. Adult honey bees were exposed to 50% (w/v) aqueous sucrose feeding solutions nominally 120 mg a.s./kg of the test item Foramsulfuron WG 50 by continuous and *ad libitum* feeding. Mortality, sub-lethal effects and behavioural observations were assessed daily throughout the 10-day exposure period. Furthermore, the daily food uptake of test item was measured. The study was performed as a limit test and the feeding of 120 mg foramsulfuron/kg diet resulted in a LC_{50} > 120 mg a.s./kg and a NOEC > 120 mg a.s./kg based on 2% mortality being observed at the tested dose. After 10 days of continuous exposure, by considering the actual food consumption of the honey bees, the accumulated nominal intake of the test item at the treatment level of 120 mg a.s./kg was 52.44 µg a.s./bee, the corresponding average daily dose was therefore 5.2 µg a.s./bee/day. The result of the study indicates that there are no delayed or cumulative toxicity effects when exposure takes place chronically compared with acute testing, i.e. daily dosing with 5.2 µg a.s./bee of foramsulfuron over 10 days (total dose = 52.44 µg a.s./bee) did not give higher mortality than a single acute oral exposure at 110.1 µg a.s./bee.

In order to investigate whether foramsulfuron would pose a risk to immature honeybee life stages an acute study on honeybee larvae had already been assessed at EU level that resulted in an LD_{50} > 100 µg a.s./larvae and a NOED = 100 µg a.s./larva, indicating that foramsulfuron is of low toxicity.
Furthermore, a repeated feeding test on honeybee larvae under laboratory conditions has been conducted after finalization of the Annex I Renewal process. The new study data did not result in adverse findings. Since this data has not yet been evaluated at EU level, it is described in more detail below. The related study report is not included in this submission but can be made available to the zRMS upon request.

In this laboratory test foramsulfuron tech was mixed into larval diet at concentrations of 163, 74.1, 33.7, 15.3 and 6.96 mg a.s./kg diet, together with a parallel running untreated control and a toxic reference item known to cause effects. The volume of the diet fed was increased over the four feeding events to account for higher demands at increasing age of the organisms. The cumulative dose levels of the test item over the entire feeding period amounted to 25.1, 11.4, 5.19, 2.36 and 1.07 µg a.s. per larva. In this test larval and pupal mortality as well as emergence success were assessed and consequently a 22-day NOED (emergence) of ≥ 25.1 µg foramsulfuron/larva has been determined, which indicates that this test item does not pose a risk to honeybee development under these laboratory severe exposure conditions.

In addition to the chronic laboratory data a higher tier study conducted with Foramsulfuron + Isoxadifen-ethyl OD 45 (22.5+22.5 g/L) is available. In this study the tested formulation was directly sprayed onto the highly bee-attractive flowering crop *Phacelia tanacetifolia* during bee activity. For the application of 60 g foramsulfuron/ha and a 4-day exposure period inside tunnels followed by a 22-day observation period outside tunnels no adverse effects were found regarding mortality (adult and pupae), foraging activity, behaviour and brood development. Since isoxadifen-ethyl was applied at 60 g/ha as part of the tested formulation, the findings from this study is equally relevant for the safener. Therefore, this study provides information on chronic adult and brood exposure and indicates that a low risk is posed to bees by foramsulfuron and isoxadifen-ethyl.

The EU review process for **thiencarbazone-methyl** was based on data requirements as set out under EU Directive 91/414/EEC and therefore at present only contains acute oral and contact toxicity data.
Additional information covering chronic toxicity to adult bees and bee brood has been generated. Since this data has not yet been evaluated at EU level, it is presented in the current document. The new study data did not result in adverse findings and is described in more detail below. Since cyprosulfamide was part of the tested formulation, the findings from these studies are equally relevant for toxicity assessment of the safener.
A study was performed to determine the effects of Thiencarbazone-methyl + cyprosulfamide SC 450 (225

+ 225) on honey bee adults in a 10-day chronic feeding test in the laboratory. Adult honey bees were exposed to 50% (w/v) aqueous sucrose feeding solutions by continuous *ad libitum* feeding. Mortality and sub-lethal effects were assessed daily throughout the 10-day exposure period. Furthermore, the daily consumption, the mean uptake of test item and the accumulated mean uptake of test item were measured so that a daily dose per bee could be determined. The study was performed as a dose-response-test and the feeding of 2101.2 mg a.s./kg diet resulted in a LDD_{50} 24.5 µg a.s./bee/day and a NOEDD of 23.5 µg a.s./bee/day based on 10% mortality being observed at this dose. The result of the study indicates that there are no delayed or cumulative toxicity effects when exposure takes place chronically compared with acute testing, i.e. daily dosing with 23.5 µg a.s./bee of thiencarbazone-methyl over 10 days (total dose = 235 µg a.s./bee) did not give higher mortality than a single acute oral exposure at 199 µg a.s./bee.

In order to investigate whether thiencarbazone-methyl would pose a risk to immature honey bee life stages, a repeated feeding test on honeybee larvae under laboratory conditions a honeybee exposure study to spray residues in a highly bee attractive flowering crop under semi-field conditions have been conducted.

In the laboratory test Thiencarbazone-methyl + cyprosulfamide SC 450 (225+225) was mixed into larval diet at concentrations of 129.9, 54.1, 22.5, 9.4 and 3.9 mg thiencarbazone-methyl/kg diet, together with a parallel running untreated control and a toxic reference item known to cause effects. The volume of the diet fed was increased over the four feeding events to account for higher demands at increasing age of the organisms. The cumulative dose levels of the test item over the entire feeding period amounted to 20.0, 8.33, 3.47, 1.45 and 0.60 µg thiencarbazone-methyl per larva. In this test larval and pupal mortality as well as emergence success were assessed and consequently a 22-day NOED (emergence) of ≥ 20.0 µg thiencarbazone-methyl/larva has been determined, which indicates that this test item does not pose a risk to honeybee development under these laboratory severe exposure conditions.

In order to clarify whether thiencarbazone-methyl poses a risk to honey bee brood and colony development in particular as well as on honey bees in general under realistic worst-case conditions, a higher tier semi-field honey bee brood study was conducted with Thiencarbazone-methyl + cyprosulfamide SC 450 (225 + 225). In this study the tested formulation was directly sprayed onto the highly bee-attractive flowering crop *Phacelia tanacetifolia* during bee activity. After 3.5 days of exposure inside tunnels followed by a 21-day observation period outside tunnels, the study NOEC was set to 40 g thiencarbazone-methyl/ha for mortality (adult and pupae), foraging activity, behaviour, food storage, colony strength and brood development. Since cyprosulfamide was applied at 40 g/ha as part of the tested formulation, the findings from this study is equally relevant for the safener. Therefore, this study provides information on chronic adult and brood exposure and indicates that a low risk is posed to bees by thiencarbazone-methyl and cyprosulfamide.

All in all, it can be concluded from the acute laboratory studies in honey bees the chronic laboratory studies in adult honey bees and honeybee larvae as well as from the bee brood studies investigating side-effects on immature honey bee life stages, that foramsulfuron and thiencarbazone-methyl are of low general intrinsic toxicity to honey bees.

When considering that the risk assessment can already be passed based on data originating from tier 1 laboratory studies, there is no need for higher tier test data. Furthermore, considering the available data on chronic effects on different bee life stages generated with the straight active substances, further chronic tests with the present mixture product would not be expected to provide any additional relevant information. Furthermore, considering the available data on chronic effects on different bee life stages generated with the straight active substances, further chronic tests with the present mixture product would not be expected to provide any additional relevant information.

Exposure to the active substances and especially to the product (even acute exposure) is unlikely for honeybees when considering the use of a herbicide at BBCH 10-18 (leaf development) in sugar beets. This crop is not considered to be attractive for bees and harvest takes place before flowering starts.

Exposure of honeybees to flowering weeds is also considered as low. A recent publication (Maynard *et al.*, 2015[13], M-542146-01-1) showed that the availability of flowering weeds in sugar beet fields at relevant application times for herbicides is minimal. It was demonstrated here that less than 2% of all weeds recorded in arable crop trials are at a flowering growth stage. For sugar beet a value of 0.12% was determined based on 156 trials that included 5006 weed recordings.

Generally, the presence of flowering plants is considered to be low. When conservatively assuming a theoretical exposure situation during which some bee-attractive plants would be present at the flowering stage and when treatment is performed, then the findings from the semi-field studies presented above (application scenario onto full flowering and bee-attractive *Phacelia*) provide sufficient evidence that neither adults nor bee brood would be at risk after application of foramsulfuron at application rates up to 60 g a.s./ha nor after application of thiencarbazone-methyl at application rates up to 40 g a.s./ha.

Therefore, a safe use to bees can be demonstrated based on the low toxicity of foramsulfuron and thiencarbazone-methyl, the outcome of the tier 1 risk assessment (HQ calculation), the additional information on chronic adult toxicity and brood development, as well as based on the use pattern for the product and the exposure situation in a non-bee-attractive crop.

zRMS comments:

The Q_{HO} and Q_{HC} values for both active substaces and the formulation Conviso One are all below the trigger of 50 indicating as acceptable acute risk to adult bees based on the maximum intended use of product.
No chronic adult or larval study with the formulation was provided, despite being required under (EU) No. 284/2013 points 10.3.1.2 and 10.3.1.3. Whilst this is noted as a data gap, this is not a barrier to authorization and is noted for procedural correctness in the context of the applicable regulation and data requirements.

9.6.2.2 Higher-tier risk assessment for bees (tunnel test, field studies)

Not required.

9.6.3 Effects on bumble bees

No EU reviewed data available, and not required.

9.6.4 Effects on solitary bees

Not required.

9.6.5 Overall conclusions

The acute risk of the active substances and of the formulated product **FSN+TCM OD 80 (50+30)** to honeybees was assessed by calculation of hazard quotients between the maximum single application rate

[13] Maynard S., Albuquerque R., Weber C.,Merey G., Geiger M., Becker R., Keppler J., Masche J., Brougham K., & Coulson M. 2015. Weeds in the treated field - a realistic scenario for pollinator risk assessment? Hazards of pesticides to bees - 12th International Symposium of the ICP-PR Bee Protection Group, Ghent (Belgium), September 15-17, Julius-Kühn-Archiv, 450, 2015 – BCS documentation No. M-542146-01-1 – see Appendix 2, A 2.3.1.

(covering also the split applications), and the respective toxicity endpoints determined as LD_{50} values following oral and contact exposure.
All hazard quotients calculated are lower than 50, indicating that the acute oral and contact risk to bees is acceptable following the use according to the proposed use pattern.

A safe use to bees can be demonstrated based on the low toxicity of the active substances, the outcome of the tier 1 risk assessment (HQ calculation), ~~the additional information from laboratory, semi-field and field testing, as well as based on the use pattern and the exposure situation.~~
No chronic adult or larval study with the formulation was provided, despite being required under (EU) No. 284/2013 points 10.3.1.2 and 10.3.1.3. Whilst this is noted as a data gap, this is not a barrier to authorization and is noted for procedural correctness in the context of the applicable regulation and data requirements.

9.7 Effects on arthropods other than bees (KCP 10.3.2)

9.7.1 Toxicity data

Effects on non-target arthropods of **FSN+TCM OD 80** were not evaluated as part of the EU assessment of active substances. Studies performed with this formulation are submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

Table 9.7-1: Endpoints and effect values relevant for the risk assessment for non-target arthropods

Species	Substance	Exposure System	Results	Reference
Typhlodromus pyri (protonymphs)	FSN+TCM OD 80 (50+30)	Extended laboratory test spray deposits on detached apple leaves (2D)	LR_{50} > 1000 mL/ha	Appendix 2 Waibel (2013) M-457257-01-1
Aphidius rhopalosiphi (adults)	FSN+TCM OD 80 (50+30)	Extended laboratory test spray deposits on barley seedlings (3D)	LR_{50} > 1000 mL/ha	Appendix 2 Waibel (2013) M-469970-01-1
Chrysoperla carnea	FSN+TCM OD 80 (50+30)	Extended laboratory test spray deposits on detached apple leaves (2D)	LR_{50} > 1000 mL/ha	Appendix 2 Waibel (2013) M-469943-01-1
Aleochara bilineata	FSN+TCM OD 80 (50+30)	Extended laboratory test spray deposits on soil (2D)	LR_{50} > 1000 mL/ha	Appendix 2 Schmitzer (2014) M-461869-01-1

9.7.1.1 Justification for new endpoints

Not relevant.

9.7.2 Risk assessment

The evaluation of the risk for non-target arthropods was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002), and in consideration of the recommendations of the guidance document ESCORT 2.

9.7.2.1 Risk assessment for in-field exposure

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group B covers the risk for non-target arthropods from all intended uses (see 9.1.3).

Please note: since a full set of four extended lab studies is available, the Tier 1 assessment is omitted, and the risk assessment starts directly with the higher tier assessment.

Table 9.7-2: First- and higher-tier assessment of the in-field risk for non-target arthropods due to the use of FSN+TCM OD 80 in sugar beet (use group B)

Intended use	Sugar beet, 1 x 1.0 L prod./ha (use group B)		
Active substance/product	FSN+TCM OD 80		
Application rate (mL/ha)	1 × 1000		
MAF	1.0		
Test species Tier I	**LR_{50} (lab.) (mL/ha)**	**$PER_{in\text{-}field}$ (mL/ha)**	**$HQ_{in\text{-}field}$ criterion: HQ ≤ 2**
-	-	-	-
Test species Higher-tier	**LR_{50} ; ER_{50} (mL/ha)**	**$PER_{in\text{-}field}$ (mL/ha)**	**$PER_{in\text{-}field}$ below rate with ≤ 50 % effect?**
Aphidius rhopalosiphi	> 1000	1000	yes
Typhlodromus pyri	> 1000	1000	yes
Chrysoperla carnea	> 1000	1000	yes
Aleochara bilineata	> 1000	1000	yes

MAF: Multiple application factor; PER: Predicted environmental rate; HQ: Hazard quotient; Criteria values shown in bold breach the relevant trigger.

9.7.2.2 Risk assessment for off-field exposure

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group B covers the risk for non-target arthropods from all intended uses (see 9.1.3).

Table 9.7-3: First- and higher-tier assessment of the off-field risk for non-target arthropods due to the use of FSN+TCM OD 80 (50+30) in sugar beet (use group B)

Intended use	Sugar beet, 1 × 1.0 L prod./ha (use group B)
Active substance/product	FSN+TCM OD 80 (50+30)
Application rate (mL/ha)	1 × 1000
MAF	1.0
vdf	10 (2D) / 1 (3D)
CF	5 (higher tier)

Test species Tier I	**LR_{50} (lab.) (mL/ha)**	**Drift rate**	**$PER_{off\text{-}field}$ (mL/ha)**	**CF**	**$HQ_{off\text{-}field}$ criterion: HQ ≤ 2**
-	-	-	-	-	-
Test species Higher-tier	**LR_{50} ; ER_{50} (g/ha**	**Drift rate**	**$PER_{off\text{-}field}$ (g/ha)**	**CF**	**corr. $PER_{off\text{-}field}$ below rate with ≤ 50 % effect?**
Aphidius rhopalosiphi	> 1000	2.77	138.5	5	yes
Typhlodromus pyri	> 1000	2.77	13.85	5	yes
Chrysoperla carnea	> 1000	2.77	13.85	5	yes
Aleochara bilineata	> 1000	2.77	13.85	5	yes

MAF: Multiple application factor; vdf: Vegetation distribution factor; (corr.) PER: (corrected) Predicted environmental rate; CF: Correction factor; HQ: Hazard quotient. Criteria values shown in bold breach the relevant trigger.

zRMS comments:

We agree with the risk assessment provided by the applicant. No unacceptable risk to non-target arthropods in the in-field and the off-field based on the extended labolatory studies for 4 species and PERin-field and PERoff-field is to be expected from the use of **FSN+TCM OD 80 (50+30)** according to the intended use pattern.

9.7.2.3 Additional higher-tier risk assessment

Not relevant.

9.7.2.4 Risk mitigation measures

No risk mitigation needed.

9.7.3 Overall conclusions

It can be concluded that no unacceptable risk to non-target arthropods in the in-field and the off-field is to be expected from the use of **FSN+TCM OD 80 (50+30)** according to the intended use pattern.

9.8 Effects on non-target soil meso- and macrofauna (KCP 10.4)

9.8.1 Toxicity data

Foramsulfuron

Studies on the toxicity to earthworms and other non-target soil organisms (meso- and macrofauna) have been carried out with foramsulfuron and its relevant metabolites. Full details of these studies are provided in the EU Renewal Assessment Report and related documents; presented agreed endpoints were taken from EFSA Journal 2016;14(3):4421.

Table 9.8-1: Endpoints and effect values relevant for the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna) - foramsulfuron

Species	Substance	Exposure System	Results	Reference
Eisenia fetida	Foramsulfuron	Sprayed onto substrate 56 d, chronic 10 % peat content	NOEC = 2.75 mg a.s./kg dw	Sowig & Gosch, 2000, M-193508-01-1 In: EFSA Journal 2016;14(3):4421 See justification
Folsomia candida	Foramsulfuron	Mixed into substrate 28 d, chronic 5 % peat content	NOEC = 100 mg a.s./kg dw	EFSA Journal 2016;14(3):4421
Hypoaspis aculeifer	Foramsulfuron	Mixed into substrate 14 d, chronic 5 % peat content	NOEC = 1000 mg a.s./kg dw	EFSA Journal 2016;14(3):4421
Eisenia fetida	AE F130619	Mixed into substrate 56 d, chronic 10 % peat content	NOEC = 56 mg/kg dw	EFSA Journal 2016;14(3):4421
Folsomia candida	AE F130619	Mixed into substrate 28 d, chronic 5 % peat content	NOEC = 100 mg/kg dw	EFSA Journal 2016;14(3):4421
Hypoaspis aculeifer	AE F130619	Mixed into substrate 14 d, chronic 5 % peat content	NOEC = 100 mg/kg dw	EFSA Journal 2016;14(3):4421
Eisenia fetida	AE F092944	Mixed into substrate 56 d, chronic 10 % peat content	NOEC = 10 mg/kg dw	EFSA Journal 2016;14(3):4421
Folsomia candida	AE F092944	Mixed into substrate 28 d, chronic 5 % peat content	NOEC = 100 mg/kg dw	EFSA Journal 2016;14(3):4421
Hypoaspis aculeifer	AE F092944	Mixed into substrate 14 d, chronic 5 % peat content	NOEC = 100 mg/kg dw	EFSA Journal 2016;14(3):4421
Eisenia fetida	AE F153745	Mixed into substrate 56 d, chronic 10 % peat content	NOEC = 100 mg/kg dw	EFSA Journal 2016;14(3):4421
Folsomia candida	AE F153745	Mixed into substrate 28 d, chronic 5 % peat content	NOEC = 100 mg /kg dw	EFSA Journal 2016;14(3):4421
Hypoaspis aculeifer	AE F153745	Mixed into substrate 14 d, chronic 5 % peat content	NOEC = 100 mg/kg dw	EFSA Journal 2016;14(3):4421

Thiencarbazone-methyl

Studies on the toxicity to earthworms and other non-target soil organisms (meso- and macrofauna) have been carried out with thiencarbazone-methyl and its relevant metabolites. Full details of these studies are provided in the respective EU Draft Assessment Report and related documents; presented agreed end-points were taken from EFSA Journal 2013;11(7):3270.

Studies on the toxicity to the soil mite *Hypoaspis aculeifer* are available for thiencarbazone-methyl, the initial metabolite carboxylic acid and the terminal metabolite sulphonamide-carboxylic acid and MMT. However, these studies have been performed after Annex I-listing of the active substance and, thus, have not been peer-reviewed in an EU evaluation process. If needed, these studies could be submitted upon request.

Table 9.8-2: Endpoints and effect values relevant for the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna) - thiencarbazone-methyl

Species	Substance	Exposure System	Results	Reference
Eisenia fetida	Thiencarbazone-methyl	Mixed into substrate 14 d, acute 10% peat content	LC_{50} > 1000 mg a.s./kg dws	EFSA Journal 2013;11(7):3270
Folsomia candida	Thiencarbazone-methyl	Mixed into substrate 28 d, chronic 10 % peat content	NOEC = 1000 mg a.s./kg dw	EFSA Journal 2013;11(7):3270
Eisenia fetida	BYH 18636-carboxylic acid	Mixed into substrate 56 d, reproduction 10% peat content	NOEC = 1000 mg /kg dws	EFSA Journal 2013;11(7):3270
Folsomia candida	BYH 18636-carboxylic acid	Mixed into substrate 28 d, chronic 10 % peat content	NOEC = 1000 mg/kg dw	EFSA Journal 2013;11(7):3270
Eisenia fetida	BYH 18636-sulfonamide	Mixed into substrate 56 d, reproduction 10% peat content	NOEC = 100 mg /kg dws	EFSA Journal 2013;11(7):3270
Eisenia fetida	BYH 18636-sulfonamide-carboxylic acid	Mixed into substrate 56 d, reproduction 10% peat content	NOEC = 100 mg /kg dws	EFSA Journal 2013;11(7):3270
Folsomia candida	BYH 18636-sulfonamide-carboxylic acid	Mixed into substrate 28 d, chronic 10 % peat content	NOEC = 1000 mg/kg dw	EFSA Journal 2013;11(7):3270
Eisenia fetida	BYH 18636-MMT	Mixed into substrate 56 d, reproduction 10% peat content	NOEC = 316 mg /kg dws	EFSA Journal 2013;11(7):3270
Folsomia candida	BYH 18636-MMT	Mixed into substrate 28 d, chronic 10 % peat content	NOEC = 1000 mg/kg dw	EFSA Journal 2013;11(7):3270
Folsomia candida	BYH 18636-triazolinone-carboxamide	Mixed into substrate 28 d, chronic 10 % peat content	NOEC = 1000 mg/kg dw	EFSA Journal 2013;11(7):3270

FSN+TCM OD 80 (50+30)

Effects on earthworms and other non-target soil organisms of **FSN+TCM OD 80 (50+30)** were not evaluated as part of the EU assessment of the active substances. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

Table 9.8-3: Endpoints and effect values for FSN+TCM OD 80 (50+30) relevant for the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna)

Species	Substance	Exposure System	Results	Reference
Eisenia fetida	FSN+TCM OD 80 (50+30)	Mixed into substrate 56 d, reproduction 10% peat content	NOEC = 178 mg/kg dw	Appendix 2 Kratz (2013) M-468316-01-1
Folsomia candida	FSN+TCM OD 80 (50+30)	Mixed into substrate 28 d, reproduction 5% peat content	NOEC = 31 mg/kg dw	Appendix 2 Frommholz (2013) M-459537-01-1
Hypoaspis aculeifer	FSN+TCM OD 80 (50+30)	Mixed into substrate 14 d, chronic 5 % peat content	NOEC = 178 mg/kg dw	Appendix 2 Kratz (2013) M-462709-01-1

9.8.1.1 Justification for new endpoints

Foramsulfuron

Table 9.8-4: Justification for new endpoints

Species	Substance	Exposure System	Justification
Eisenia fetida	Foramsulfuron	Sprayed onto substrate 56 d, chronic 10 % peat content	In the list of endpoint the more recent formulation study for FSN+IDF OD 45 is listed. It would be possible to calculate an active substance endpoint with this study based on the information that the formulation FSN+IDF OD 45 is containing 22.5 g/L foramsulfuron. Nevertheless, for the active substance no endpoint is listed in the List of endpoint. Therefore, in the presented risk assessment the NOEC value of 2.75 mg a.s./kg dws from the older study by Sowig & Gosch will be used. The study was conducted with the active ingredient itself and is based on the information given in the study report (test area of 283.4 cm² and containing 628 g dws).

Thiencarbazone-methyl

No deviation from the EU agreed endpoints.

zRMS comment:

According to the EFSA Journal 2016;14(3):4421, the available chronic earthworm study performed with the active substance (Sowig & Gosch, 2000) was not considered suitable for risk assessment as the test item has not been incorporated into the test soil which is required according to Regulation (EU) No 283/2013. Therefore, the NOEC value of **2.75** mg a.s./kg dws is not used in the present risk assessment.

In the EFSA journal 2016;14(3):4421, the chronic earthworm risk assessment was therefore performed with the endpoint from the toxicity study performed with the representative formulation (FSN+IDF OD 45). Therefore, the same approach is considered relevant and the risk assessment conducted with the toxicity data from the formulation FSN+TCM OD 80 (50+30) is considered as sufficient to address the risk for the active substance foramsulfuron.

9.8.2 Risk assessment

The evaluation of the risk for earthworms and other non-target soil organisms (meso- and macrofauna) was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).

9.8.2.1 First-tier risk assessment

The relevant PEC_{soil} for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2. According to the assessment of environmental-fate data, multi-annual accumulation in soil is considered where relevant.

Foramsulfuron

For the active substance foramsulfuron (and metabolites) risk assessments are passed without any refinement, even if worst case PEC_{soil} values are considered. Therefore, to further simplify the assessment, PEC_{soil} for these compounds is calculated in an additional "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 9.8-5: First-tier assessment of the chronic risk of foramsulfuron for earthworms due to the use of FSN+TCM OD 80 (50+30) in sugar beet (use group A)

Intended use	Risk envelope approach: maize, sugar beet, nursery (conifer), 60 g a.s./ha, BBCH 10-34		
Chronic effects on earthworms			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
Foramsulfuron	2.75	0.080	34
AE F130619	56	0.022	2545
AE F092944	10	0.006	1667
AE F153745	100	0.005	20000

Table 9.8-6: First-tier assessment of the chronic risk of foramsulfuron for other non-target soil organisms (meso- and macrofauna) due to the use of FSN+TCM OD 80 (50+30) in sugar beet (use group A)

Intended use	Risk envelope approach: maize, sugar beet, nursery (conifer), 60 g a.s./ha, BBCH 10-34		
Chronic effects on other soil macro- and mesofauna			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
Foramsulfuron (*F. candida*)	100	0.080	1250
AE F130619 (*F. candida*)	100	0.022	4545

AE F092944 (*F. candida*)	100	0.006	16667
AE F153745 (*F. candida*)	100	0.005	20000
Foramsulfuron (*H. aculeifer*)	1000	0.080	12500
AE F130619 (*H. aculeifer*)	100	0.022	4545
AE F092944 (*H. aculeifer*)	100	0.006	16667
AE F153745 (*H. aculeifer*)	100	0.005	20000

Thiencarbazone-methyl

For the active substance thiencarbazone-methyl (and metabolites) risk assessments are passed without any refinement, even if worst case PEC_{soil} values are considered. Therefore, to further simplify the assessment, PEC_{soil} for these compounds is calculated in an additional "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 may overestimate the actual exposure due to use of the present product, and thus further increase the conservatism of the Tier 1 risk assessments.

Table 9.8-7: First-tier assessment of the chronic risk of thiencarbazone-methyl for earthworms due to the use of FSN+TCM OD 80 (50+30) in sugar beet (use group A)

Intended use	Risk envelope approach: Cereals, maize, sugar beet, non-cropped area, 40 g a.s./ha, BBCH 00-32		
Chronic effects on earthworms			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
BYH 18636-carboxylic acid	1000	0.032	30303
BYH 18636-sulfonamide	100	0.005	20000
BYH 18636-sulfonamide-carboxylic acid	100	0.006	16667
BYH 18636-MMT	316	0.004	79000

TER values shown in bold fall below the relevant trigger.

Table 9.8-8: First-tier assessment of the chronic risk of thiencarbazone-methyl for other non-target soil organisms (meso- and macrofauna) due to the use of FSN+TCM OD 80 (50+30) in sugar beet (use group A)

Intended use	Risk envelope approach – Cereals, maize, sugar beet, non-cropped area, 40 g a.s./ha, BBCH 00-32		
Chronic effects on other soil macro- and mesofauna			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
Thiencarbazone-methyl (*F. candida*)	1000	0.053	18868

BYH 18636-carboxylic acid (*F. candida*)	1000	0.032	31250
BYH 18636-sulfonamide-carboxylic acid (*F. candida*)	1000	0.006	166667
BYH 18636-MMT (*F. candida*)	1000	0.004	250000
BYH 18636-triazolinone-carboxamide (*F. candida*)	1000	0.002	500000

TER values shown in bold fall below the relevant trigger.

FSN+TCM OD 80 (50+30)

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group B also covers the risk for non-target soil organisms (meso- and macrofauna) from all other intended use groups (see 9.1.2).

Table 9.8-9: First-tier assessment of the chronic risk of FSN+TCM OD 80 (50+30) for earthworms and other non-target soil organisms (meso- and macrofauna) due to the use in sugar beet (use group B)

Intended use	**Sugar beet, 1 × 1.0 L prod./ha, 0 % crop interception**		
Chronic effects on earthworms			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
FSN+TCM OD 80 (50+30)	178	1.371[1)]	130
Chronic effects on other soil macro- and mesofauna			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
FSN+TCM OD 80 (50+30) (*F. candida*)	31	1.371[1)]	22.6
FSN+TCM OD 80 (50+30) (*H. aculeifer*)	178	1.371[1)]	130

TER values shown in bold fall below the relevant trigger.

1) Based on formulation density of 1.028 g/mL (20°C), application rate of 1 × 1.0 L product/ha and crop interception of 0%.

zRMS comments:

The risk assessment for earthworms and other soil macro-organism was accepted by zRMS.
The risk assessment provided by the zRMS considered PECs agreed at Section 8 by e-fate expert.
All TER_{LT} values for both active substances and their metabolites and also for the product Conviso One are above trigger of 5, indicting acceptable long-term risk assessment.

9.8.2.2 Higher-tier risk assessment

Not relevant.

9.8.3 Overall conclusions

The long-term risk of the active substances and their relevant metabolites and of the formulated product was assessed, based on maximum PEC_{soil} values. All TER values for earthworms and other soil macro-organisms are greater than the relevant triggers indicating acceptable risk for the use of **FSN+TCM OD 80 (50+30)** in sugar beet.

9.9 Effects on soil microbial activity (KCP 10.5)

9.9.1 Toxicity data

Foramsulfuron

Studies on effects on soil microorganisms have been carried out with foramsulfuron and its relevant metabolites. Full details of these studies are provided in the corresponding document of the EU renewal assessment report where the study references can be found; presented agreed endpoints were taken from EFSA Journal 2016;14(3):4421.

Table 9.9-1: Endpoints and effect values relevant for the risk assessment for soil microorganisms – foramsulfuron

Endpoint	Substance	Exposure System	Results	Reference
N-mineralisation	Foramsulfuron	28 d, aerobic loamy sand and loamy silt	No unacceptable effects on N-transformations at 0.3 mg/kg soil dw	EFSA Journal 2016;14(3):4421
N-mineralisation	AE F130619	28 d, aerobic loamy sand	No unacceptable effects on N-transformations at 0.375 mg/kg soil dw	EFSA Journal 2016;14(3):4421
N-mineralisation	AE F092944	28 d, aerobic loamy sand	No unacceptable effects on N-transformations at 0.137 mg/kg soil dw	EFSA Journal 2016;14(3):4421
N-mineralisation	AE F153745	28 d, aerobic loamy sand	No unacceptable effects on N-transformations at 0.240 mg/kg soil dw	EFSA Journal 2016;14(3):4421

Thiencarbazone-methyl

Studies on effects on soil microorganisms have been carried out with thiencarbazone-methyl and the relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents, presented agreed endpoints were taken from EFSA Journal 2013;11(7):3270.

Table 9.9-2: Endpoints and effect values relevant for the risk assessment for soil microorganisms – thiencarbazone-methyl

Endpoint	Substance	Exposure System	Results	Reference
N-mineralisation	Thiencarbazone-methyl	28 d, aerobic loamy sand	No unacceptable effects on N-transformations at 0.3 mg/kg soil dw	EFSA Journal 2013;11(7):3270
N-mineralisation	BYH 18636-carboxylic acid	28 d, aerobic loamy sand	No unacceptable effects on N-transformations at 0.29 mg/kg soil dw	EFSA Journal 2013;11(7):3270
N-mineralisation	BYH 18636-sulfonamide-carboxylic acid	28 d, aerobic loamy sand	No unacceptable effects on N-transformations at 0.17 mg/kg soil dw	EFSA Journal 2013;11(7):3270
N-mineralisation	BYH 18636-sulfonamide	28 d, aerobic loamy sand	No unacceptable effects on N-transformations at 0.18 mg/kg soil dw	EFSA Journal 2013;11(7):3270
N-mineralisation	BYH 18636-MMT	28 d, aerobic loamy sand	No unacceptable effects on N-transformations at 0.10 mg/kg soil dw	EFSA Journal 2013;11(7):3270

FSN+TCM OD 80 (50+30)

Effects on soil microorganisms of the formulation were not evaluated as part of the EU assessment of the active substances. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

Table 9.9-3: Endpoints and effect values for FSN+TCM OD 80 (50+30) relevant for the risk assessment for soil microorganisms

Endpoint	Substance	Exposure System	Results	Reference
N-mineralisation	FSN+TCM OD 80 (50+30)	28 d, aerobic loamy sand soil	No unacceptable effects on N-transformations at 6.85 mg/kg soil dw, equivalent to 5.0 L prod./ha	Appendix 2 Schulz (2013) M-460665-01-1

9.9.1.1 Justification for new endpoints

No deviation from the EU agreed endpoints.

9.9.2 Risk assessment

The evaluation of the risk for soil microorganisms was performed in accordance with the recommenda-

tions of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).
The relevant PEC_{soil} for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2, and were already used in the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna) (see 9.8).

Foramsulfuron

For the active substance foramsulfuron (and metabolites) risk assessments are passed without any refinement, even if worst case PEC_{soil} values are considered. Therefore, to further simplify the assessment, PEC_{soil} for these compounds is calculated in an additional "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 may overestimate the actual exposure due to use of the present product, and thus further increase the conservatism of the Tier 1 risk assessments.

Table 9.9-4: Assessment of the risk of foramsulfuron for effects on soil micro-organisms due to the use of FSN+TCM OD 80 (50+30) in sugar beet (use group A)

Intended use	Risk envelope approach: maize, sugar beet, nursery (conifer), 60 g a.s./ha, BBCH 10-34		
N-mineralisation			
Product/active substance	**Max. conc. with effects ≤ 25 % (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**Risk acceptable?**
Foramsulfuron	0.3 (at 28 d)	0.080	yes
AE F130619	0.375 (at 28 d)	0.022	yes
AE F092944	0.137 (at 28 d)	0.006	yes
AE F153745	0.240 (at 28 d)	0.005	yes

dw = dry weight

Thiencarbazone-methyl

For the active substance thiencarbazone-methyl (and metabolites) risk assessments are passed without any refinement, even if worst case PEC_{soil} values are considered. Therefore, to further simplify the assessment, PEC_{soil} for these compounds is calculated in an additional "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 may overestimate the actual exposure due to use of the present product, and thus further increase the conservatism of the Tier 1 risk assessments.

Table 9.9-5: Assessment of the risk for effects of thiencarbazone-methyl on soil micro-organisms due to the use of FSN+TCM OD 80 (50+30) in sugar beet (use group A)

Intended use	Risk envelope approach – Cereals, maize, sugarbeet, non-cropped area, 40 g a.s./ha, BBCH 00-32		
N-mineralisation			
Product/active substance	**Max. conc. with effects ≤ 25 % (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**Risk acceptable?**
Thiencarbazone-methyl	0.3 (at 28 d)	0.053	yes
BYH 18636-carboxylic acid	0.29 (at 28 d)	0.032	yes
BYH 18636-sulfonamide-carboxylic acid	0.17 (at 28 d)	0.006	yes
BYH 18636-sulfonamide	0.18 (at 28 d)	0.005	yes
BYH 18636-MMT	0.10 (at 28 d)	0.004	yes

dw = dry weight

FSN+TCM OD 80 (50+30)

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group B covers the risk for soil microorganisms from all intended uses (see 9.1.2).

Table 9.9-6: Assessment of the risk for effects of FSN+TCM OD 80 (50+30) on soil micro-organisms due to the use in sugar beet (use group B)

Intended use	**Sugar beet, 1 × 1.0 L prod./ha, 0 % crop interception**		
N-mineralisation			
Product/active substance	**Max. conc. with effects ≤ 25 % (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**Risk acceptable?**
FSN+TCM OD 80 (50+30)	6.85 (at 28 d)	1.371[1)]	yes

1) Based on formulation density of 1.028 g/mL (20°C), application rate of 1 × 1.0 L product/ha and crop interception of 0%.

ZRMS comments:

The risk assessment for soil micro-organism after exposure of both active substances and their metabolites was verified by the zRMS with considertation PECs values agreed by e-fate experts in Section 8. The effects on the nitrogen transformations are acceptable (<25%) at concentration which is higher than the maximum relevant PECs soil for the maximum application rate of active substances their metabolites and the product Conviso One.

9.9.3 Overall conclusions

The risk of the active substances, their relevant metabolites, and of the formulated product was assessed based on maximum PEC_{soil} values and indicated acceptable for the use of **FSN+TCM OD 80 (50+30)** in sugar beet.

9.10 Effects on non-target terrestrial plants (KCP 10.6)

9.10.1 Toxicity data

Effects on non-target terrestrial plants of FSN+TCM OD 80 (50+30) were not evaluated as part of the EU assessment of the active substances. Studies performed with this formulation are submitted with this application as listed in Appendix 1 and summarised in Appendix 2.

Table 9.10-1: Endpoints and effect values relevant for the risk assessment for non-target terrestrial plants

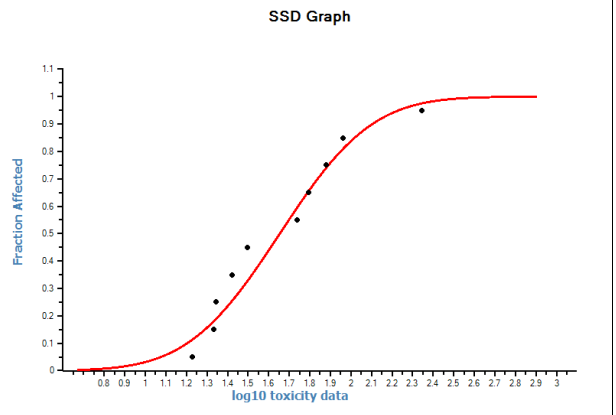
Species	Substance	Exposure System	Results	Reference
Beta vulgaris d [1)] *Brassica napus* d [2)] *Cucumis sativus* d [3)] *Fagopyrum esculentum* d [4)] *Glycine max* d [5)] *Helianthus annuus* d [6)] *Lycopersicon esculentum* d [7)] *Allium cepa* m [8)] *Avena sativa* m [9)] *Sorghum vulgare* m [10)]	FSN+TCM OD 80 (50+30)	21 d Seedling emergence, Tier 2	[1)] ER_{50} shoot dry weight = 31.36 mL product/ha [2)] ER_{50} shoot dry weight = 54.74 mL product/ha [3)] ER_{50} shoot dry weight = 75.53 mL product/ha [4)] ER_{50} shoot dry weight = 91.79 mL product/ha [5)] ER_{50} shoot dry weight = 221.48 mL product/ha [6)] ER_{50} shoot dry weight = 62.14 mL product/ha [7)] ER_{50} shoot dry weight = 21.45 mL product/ha [8)] ER_{50} shoot dry weight = 26.35 mL product/ha [9)] ER_{50} shoot dry weight = 22.12 mL product/ha **[10)] ER_{50} shoot dry weight = 16.91 mL product/ha** **HR_5 shoot dry weight = 11.383 mL product/ha** (calculated with ETX 2.2)	Appendix 2 Koehler (2013) M-467676-01-1 & additional calculations
Beta vulgaris d [1)] *Brassica napus* d [2)] *Cucumis sativus* d [3)] *Fagopyrum esculentum* d [4)] *Glycine max* d [5)] *Helianthus annuus* d [6)] *Lycopersicon esculentum* d [7)] *Allium cepa* m [8)] *Avena sativa* m [9)] *Sorghum vulgare* m [10)]	FSN+TCM OD 80 (50+30)	21 d Vegetative vigour, Tier 2	[1)] ER_{50} shoot dry weight = 14.44 mL product/ha [2)] ER_{50} shoot dry weight = 22.90 mL product /ha **[3)] ER_{50} shoot dry weight = 6.92 mL product/ha** [4)] ER_{50} shoot dry weight = 7.92 mL product/ha [5)] ER_{50} shoot dry weight = 62.94 mL product/ha [6)] ER_{50} shoot dry weight = 31.46 mL product/ha [7)] ER_{50} shoot dry weight = 20.49 mL product/ha [8)] ER_{50} shoot dry weight = 339.82 mL product/ha [9)] ER_{50} shoot dry weight = 57.44 mL product/ha [10)] ER_{50} shoot dry weight = 47.88 mL product/ha **HR_5 shoot dry weight = 4.355 mL product/ha** (calculated with ETX 2.2)	Appendix 2 Koehler (2014) M-491267-01-1 & additional calculations
Beta vulgaris d [1)] *Brassica napus* d [2)] *Cucumis sativus* d [3)] *Fagopyrum esculentum* d [4)] *Glycine max* d [5)] *Helianthus annuus* d [6)] *Lycopersicon esculentum* d [7)] *Allium cepa* m [8)] *Avena sativa* m [9)]	FSN+TCM OD 80 (50+30)	21 d Vegetative vigour, Tier 2	[1)] ER_{50} shoot dry weight = 6.97 mL product/ha [2)] ER_{50} shoot dry weight = 25.33 mL product/ha **[3)] ER_{50} shoot dry weight = 6.92 mL product/ha** [4)] ER_{50} shoot dry weight = 11.33 mL product/ha [5)] ER_{50} shoot dry weight = 38.36 mL product/ha [6)] ER_{50} shoot dry weight = 28.75 mL product/ha [7)] ER_{50} shoot dry weight = 10.53 mL product/ha [8)] ER_{50} shoot dry weight = 138.72 mL product/ha [9)] ER_{50} shoot dry weight > 62.5 mL product/ha [10)] ER_{50} shoot dry weight = 33.48 mL product/ha HR_5 shoot dry weight = 4.382 mL product/ha (calculated with ETX 2.2) HR_{50} shoot dry weight= 3.949 mL/ha*	Appendix 2 Koehler (2014) M-496996-01-1 & additional calculations

Species	Substance	Exposure System	Results	Reference
Sorghum vulgare m [10)]				
Higher-tier studies (semi-field studies)				
Beta vulgaris d [1)] *Brassica napus* d [2)] *Cucumis sativus* d [3)] *Fagopyrum esculentum* d [4)] *Helianthus annuus* d [5)] *Lycopersicon esculentum* d [6)] *Sorghum vulgare* m [7)]	FSN+TCM OD 80 (50+30)	21 d Vegetative vigour, Higher tier semi-field	[1)] ER_{50} shoot dry weight = 37.30 mL product/ha [2)] ER_{50} shoot dry weight = 53.20 mL product/ha **[3)] ER_{50} shoot dry weight = 8.90 mL product/ha** [4)] ER_{50} shoot dry weight = 63.79 mL product/ha [5)] ER_{50} shoot dry weight = 63.39 mL product/ha [6)] ER_{50} shoot dry weight = 62.50 mL product/ha [7)] ER_{50} shoot dry weight = 26.27 mL product/ha **HR_5 shoot dry weight = 10.907 mL product/ha** (calculated with ETX 2.2)**	Appendix 2 Koehler (2014) M-502816-01-1 & additional calculations

m: monocotyledonous; d: dicotyledonous
*The recalculated by zRMS with excluded value of ER_{50} shoot dry weight > 62.5 mL product/ha
**The study not used in the risk assessment

Details on the calculations of the species sensitivity distribution (SSD) for the three tier-2 greenhouse studies and the higher tier semi-field study are provided below:

Seedling emergence tier-2 study (M-467676-01-1)
HR_5 = 11.383 mL prod./ha based on shoot dry weight



Anderson-Darling test for normality

Sign. level	Critical	Normal?
0,1	0,631	Accepted
0,05	0,752	Accepted
0,025	0,873	Accepted
0,01	1,035	Accepted

AD Statistic: 3,36E-1
n: 10

Kolmogorov-Smirnov test for normality

Sign. level	Critical	Normal?
0,1	0,819	Accepted
0,05	0,895	Accepted
0,025	0,995	Accepted
0,01	1,035	Accepted

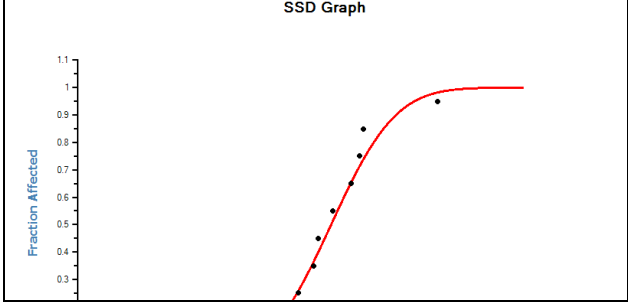
KS Statistic: 5,92E-1
n: 10

Cramer von Mises test for normality

Sign. level	Critical	Normal?
0,1	0,104	Accepted
0,05	0,126	Accepted
0,025	0,148	Accepted
0,01	0,179	Accepted

CM Statistic: 3,92E-2
n: 10

~~**Vegetative vigour tier-2 study (M-491267-01-1)**~~
~~**HR_5 = 4.355 mL prod./ha based on shoot dry weight**~~



Anderson-Darling test for normality

Sign. level	Critical	Normal?
0,1	0,631	Accepted
0,05	0,752	Accepted
0,025	0,873	Accepted
0,01	1,035	Accepted

AD Statistic: 2,80E-1
n: 10

Kolmogorov-Smirnov test for normality

Sign. level	Critical	Normal?
0,1	0,819	Accepted
0,05	0,895	Accepted
0,025	0,995	Accepted
0,01	1,035	Accepted

KS Statistic: 5,57E-1
n: 10

Cramer von Mises test for normality

Sign. level	Critical	Normal?
0,1	0,104	Accepted
0,05	0,126	Accepted
0,025	0,148	Accepted
0,01	0,179	Accepted

CM Statistic: 2,38E-2
n: 10

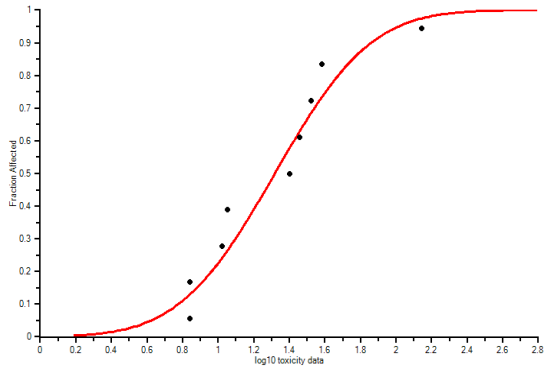
~~**Vegetative vigour tier-2 study (M-496996-01-1)**~~
~~**HR_5 = 4.382 mL prod./ha based on shoot dry weight**~~

~~In order to adequately cover the range of sensitivities found in the different species tested, the endpoint for oat (ER_{50} > 62.5 mL prod./ha) has been included in the SSD calculation as ER_{50} = 62.5 mL prod./ha. A reduction of dry weight of 39.4% has been measured in oat at the highest rate tested (62.5 mL prod./ha). As it can be assumed that the 50% effect level will be close but somewhat higher than this rate, it is a conservative approach to use 62.5 mL prod./ha as a surrogate ER_{50}.~~

Vegetative vigour tier-2 study (M-496996-01-1)

HR_5 = 3.949 mL prod./ha based on shoot dry weight calculated by zRMS.

SSD Graph



Anderson-Darling test for normality					
Sign. leve	Critical	Normal?			
0,1	0,631	Accepted			
0,05	0,752	Accepted		AD Statistic:	0,385353433
0,025	0,873	Accepted		n:	9
0,01	1,035	Accepted			
Kolmogorov-Smirnov test for normality					
Sign. leve	Critical	Normal?			
0,1	0,819	Accepted			
0,05	0,895	Accepted		KS Statistic:	0,585966999
0,025	0,995	Accepted		n:	9
0,01	1,035	Accepted			
Cramer von Mises test for normality					
Sign. leve	Critical	Normal?			
0,1	0,104	Accepted			
0,05	0,126	Accepted		CM Statistic:	0,044104995
0,025	0,148	Accepted		n:	9
0,01	0,179	Accepted			

HC5 results			
Name	Value	log10 (Val	Description
LL HC5	1,090043	0,037444	lower estimate of the HC5
HC5	3,949467	0,596539	median estimate of the HC5
UL HC5	7,955229	0,900653	upper estimate of the HC5
sprHC5	7,298089	0,863209	spread of the HC5 estimate

SSD Graph

Anderson-Darling test for normality

Sign. level	Critical	Normal?
0.1	0.631	Accepted
0.05	0.752	Accepted
0.025	0.873	Accepted
0.01	1.035	Accepted

AD Statistic: 2.98E-1
n: 10

Kolmogorov-Smirnov test for normality

Sign. level	Critical	Normal?
0.1	0.819	Accepted
0.05	0.895	Accepted
0.025	0.995	Accepted
0.01	1.035	Accepted

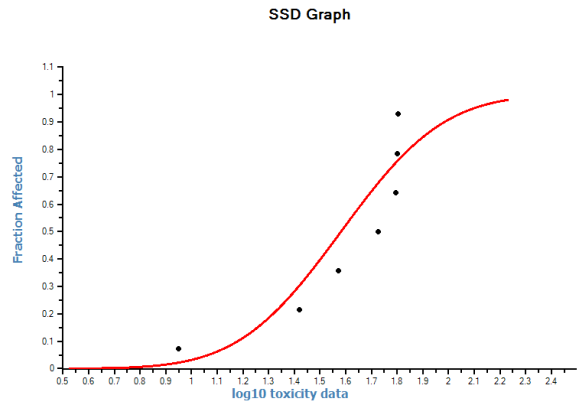
KS Statistic: 5.76E-1
n: 10

Cramer von Mises test for normality

Sign. level	Critical	Normal?
0.1	0.104	Accepted
0.05	0.126	Accepted
0.025	0.148	Accepted
0.01	0.179	Accepted

CM Statistic: 3.40E-2
n: 10

Vegetative vigour higher tier study (M-502816-01-1)
HR_5 = 10.907 mL prod./ha based on shoot dry weight *



Anderson-Darling test for normality

Sign. level	Critical	Normal?
0,1	0,631	Rejected
0,05	0,752	Rejected
0,025	0,873	Accepted
0,01	1,035	Accepted

AD Statistic: 7,80E-1
n: 7

Kolmogorov-Smirnov test for normality

Sign. level	Critical	Normal?
0,1	0,819	Accepted
0,05	0,895	Accepted
0,025	0,995	Accepted
0,01	1,035	Accepted

KS Statistic: 7,36E-1
n: 7

Cramer von Mises test for normality

Sign. level	Critical	Normal?
0,1	0,104	Rejected
0,05	0,126	Accepted
0,025	0,148	Accepted
0,01	0,179	Accepted

CM Statistic: 1,07E-1
n: 7

Figure 9.10-1: SSD graphs and results from the tests for normality of ER_{50}-figures from the tier-2 seedling emergence and vegetative vigour studies and the higher tier vegetative vigour study.

***The calculations were not considered by zRMS in the risk assessment.**

Not relevant.

9.10.2 Risk assessment

9.10.2.1 Tier-1 risk assessment (based screening data)

Not relevant, as not useful for a herbicide.

9.10.2.2 Tier-2 risk assessment (based on dose-response data)

The risk assessment is based on the "Guidance Document on Terrestrial Ecotoxicology", (SANCO/10329/2002 rev.2 final, 2002). It is restricted to off-field situations, as non-target plants are non-crop plants located outside the treated area.
The quantitative risk assessment presented here follows a step-wise approach: First step is a **deterministic risk assessment** based on the lowest endpoints of the Tier-2 greenhouse studies. Second step is a **probabilistic risk assessment** based on the HR_5 which is derived from the species sensitivity distribution (SSD) analysis of the various species tested in the Tier-2 greenhouse studies.
As the product is used on sugar beet at BBCH 10 to 18 (spring) interception of drift by the off-field vegetation can be assumed. For the exposure of seeds in the soil (as simulated in seedling emergence studies) an interception value of 40% can be assumed for applications taking place in April or later (cf. ctgb Evaluation manual PPP EU part Chapter 7 Non targets arthropods and plants. Version 2.1; October 2016).

a) Deterministic risk assessment

According to the Terrestrial Guidance Document, the risk to non-target plants is evaluated by comparing the lowest ER_{50} with the calculated Predicted Environmental Rates ($PER_{off\text{-}field}$) from spray-drift exposure. According to the Guidance Document on Terrestrial Ecotoxicology a trigger of 5 is considered appropriate if at least six plant species have been tested.

Table 9.10-2: Deterministic assessment of the risk for non-target plants due to the use of FSN+TCM OD 80 (50+30) in sugar beet

Intended use	**Sugar beet, 1 × 1.0 L prod./ha (use group B)**			
Active substance/product	FSN+TCM OD 80 (50+30)			
Application rate (mL/ha)	1 × 1000			
MAF	1.0 (single application)			
Test species	**ER_{50} (mL/ha)**	**Drift rate (%)**	**$PER_{off\text{-}field}$ (mL/ha)**	**TER[1)] criterion: TER ≥ 5***
Sorghum vulgare - seedling emergence	16.91	2.77	16.62 [3)]	**1.02**
Cucumis sativus - vegetative vigour	6.92	2.77	27.70	**0.25**
Intended use	**Sugar beet, 2 × 0.5 L prod./ha (use group C)**			
Active substance/product	FSN+TCM OD 80 (50+30)			
Application rate (mL/ha)	2 × 500			
MAF	1.0 Justification: At the recent Pesticide Peer Review Meeting 133 [2)] in Sept. 2015 "it was agreed that for the risk assessment of active substances, no MAF values should be used by default, until a guidance document is developed." This approach is in line with the "Guidance Document on Terrestrial Ecotoxicology" currently in use which does not require the use of a MAF value in the context of NTTP risk assessment. Thus, it is not deemed necessary to apply a MAF when calculating the PER.			
Test species	**ER_{50} (mL/ha)**	**Drift rate (%)**	**$PER_{off\text{-}field}$ (mL/ha)**	**TER[1)] criterion: TER ≥ 5***
Sorghum vulgare - seedling emergence	16.91	2.38	7.14 [3)]	**2.37**
Cucumis sativus - vegetative vigour	6.92	2.38	11.90	**0.58**

MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

* TER ≥ 5 for deterministic risk assessment based on ER_{50}

1) TER values were calculated using unrounded PER values

2) EFSA (European Food Safety Authority), 2015. Technical report on the outcome of the pesticides peer review meeting on general recurring issues in ecotoxicology. EFSA supporting publication 2015:EN-924. 62 pp.

3) For applications in April or later an interception of 40% by field boundary vegetation can be assumed in the case of soil exposure

Conclusion: The trigger is not met for both, seedling emergence and vegetative vigour, for the single and the multiple application rates intended for the product. As next step, a probabilistic assessment is therefore provided below.

zRMS comments:

Based on the deterministic risk assessment the trigger is not met for both, seedling emergence and veg-

etative vigour, for the single and the multiple application rates intended for the product.
As next step, the risk mitigation measures are required. In addition, as a refinement option the applicant provide the propabilistic risk assessment.

b) Probabilistic risk assessment

According to the Guidance Document on Terrestrial Ecotoxicology, the probabilistic method makes use of the species sensitivity distribution (SSD) in order to calculate an HR_5. The HR_5 is the concentration below which less than 5% of the species will be harmed above the ER_{50} level and can be calculated from the data sets of ER_{50} growth inhibition levels. If the HR_5 is below the highest predicted exposure level, the risk for terrestrial plants is deemed to be acceptable. The EU guidance document for terrestrial ecotoxicology states: ”*If the ED50 for less than 5 % of the species is below the highest predicted exposure level, the risk for terrestrial plants is assumed to be acceptable. Thus, the HC_5 itself (TER =1) can be regarded to be protective.”*
A probabilistic approach is considered more suitable than the deterministic one to achieve the environmental protection goal, since sensitivity data of several species are taken into account. However, it is applicable only if data of at least 6 species are available and requires that log-normal or another defined type of distribution of the data has been shown to fit the data adequately. The HR_5 in the present risk assessment was calculated using the ETX2.2 program.

For the present product FSN+TCM OD 80 (50+30), details of the HR_5 calculation are provided in Section 9.10.1 including SSD graph analysis.

Table 9.10-3: Probabilistic assessment of the risk for non-target plants due to the use of FSN+TCM OD 80 (50+30) in sugar beet

Intended use	**Sugar beet, 1 × 1.0 L prod./ha (use group B)**			
Active substance/product	FSN+TCM OD 80 (50+30)			
Application rate (mL/ha)	1 × 1000			
MAF	1.0 (single application)			
Test species	**HR_5 (mL/ha)**	**Drift rate (%)**	**$PER_{off\text{-}field}$ (mL/ha)**	**TER[1)] criterion: TER ≥ 1***
HR_5 – seedling emergence	11.383	2.77	16.62 [3)]	**0.68**
HR_5 – vegetative vigour	~~4.355~~ 3.949	2.77	27.70	~~**0.16**~~ **0.14**

Intended use	**Sugar beet, 2 × 0.5 L prod./ha (use group C)**
Active substance/product	FSN+TCM OD 80 (50+30)
Application rate (mL/ha)	2 × 500
MAF	1.0 Justification: At the recent Pesticide Peer Review Meeting 133 [2)] in Sept. 2015 "it was agreed that for the risk assessment of active substances, no MAF values should be used by default, until a guidance document is developed." This approach is in line with the "Guidance Document on Terrestrial Ecotoxicology" currently in use which does not require the use of a MAF value in the context of NTTP risk assessment. Thus, it is not deemed necessary to apply a MAF when calculating the PER.

Test species	**HR_5 (mL/ha)**	**Drift rate (%)**	**$PER_{off\text{-}field}$ (mL/ha)**	**TER[1)] criterion: TER ≥ 1***
HR_5 – seedling emergence	11.383	2.38	7.14[3)]	1.59
HR_5 – vegetative vigour	~~4.355~~ 3.949	2.38	11.90	~~**0.37**~~ **0.28**

MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

* TER ≥ 1 for probabilistic risk assessment based on HR_5

1) TER values were calculated using unrounded PER values

2) EFSA (European Food Safety Authority), 2015. Technical report on the outcome of the pesticides peer review meeting on general recurring issues in ecotoxicology. EFSA supporting publication 2015:EN-924. 62 pp.

3) For applications in April or later an interception of 40% by field boundary vegetation can be assumed in the case of soil exposure

Conclusion: For the multiple application rate, the trigger is met for seedling emergence, however is not reached for vegetative vigour. For the single application rate, the trigger is not met for both, seedling emergence and vegetative vigour. Accordingly, further analysis is required and will be presented for vegetative vigour as worst case, considering the results of a higher tier semi-field study.

9.10.2.3 Higher-tier risk assessment

As it had been established in tier-2 greenhouse studies that vegetative vigour, i.e. the overspray of young seedlings, represents the more sensitive exposure path for FSN+TCM OD 80 (50+30), a vegetative vigour higher tier semi-field study was performed with the product including the seven most sensitive species of the Tier 2 vegetative vigour greenhouse test. In this study, species were tested up to 250 mL product/ha. This higher tier vegetative vigour study still provided a lowest ER_{50} that is less than half of the lowest ER_{50} found in the seedling emergence study. Thus, the latter study type would also be covered by the higher tier risk assessment based on vegetative vigour.

The quantitative higher risk assessment presented here follows the same step-wise approach as presented for the Tier 2 risk assessment in Point 9.10.2.2: First step is a **deterministic risk assessment** based on the lowest endpoints of the higher tier semi-field study. Second step is a **probabilistic risk assessment** based on the HR_5 which is derived from the species sensitivity distribution (SSD) analysis of the various species tested in the higher tier semi-field study.

a) Deterministic risk assessment

Table 9.10-4: Deterministic assessment of the risk for non-target plants due to the use of FSN+TCM OD 80 (50+30) in sugar beet – Risk assessment based on higher tier semi-field study

Intended use	**Sugar beet, 1 × 1.0 L prod./ha (use group B)**			
Active substance/product	FSN+TCM OD 80 (50+30)			
Application rate (mL/ha)	1 × 1000			
MAF	1.0 (single application)			
Test species	**ER_{50} (mL/ha)**	**Drift rate (%)**	**$PER_{off\text{-}field}$ (mL/ha)**	**TER[1] criterion: TER ≥ 5***
Cucumis sativus - vegetative vigour	8.90	2.77	27.70	**0.32**
Intended use	**Sugar beet, 2 × 0. 5 L prod./ha (use group C)**			
Active substance/product	FSN+TCM OD 80 (50+30)			
Application rate (mL/ha)	2 × 500			
MAF	1.0 Justification: At the recent Pesticide Peer Review Meeting 133 [2] in Sept. 2015 "it was agreed that for the risk assessment of active substances, no MAF values should be used by default, until a guidance document is developed." This approach is in line with the "Guidance Document on Terrestrial Ecotoxicology" currently in use which does not require the use of a MAF value in the context of NTTP risk assessment. Thus, it is not deemed necessary to apply a MAF when calculating the PER.			
Test species	**ER_{50} (mL/ha)**	**Drift rate (%)**	**$PER_{off\text{-}field}$ (mL/ha)**	**TER[1] criterion: TER ≥ 5***
Cucumis sativus - vegetative vigour	8.90	2.38	11.90	**0.75**

MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

* TER ≥ 5 for deterministic risk assessment based on ER_{50}

[1] TER values were calculated using unrounded PER values

[2] EFSA (European Food Safety Authority), 2015. Technical report on the outcome of the pesticides peer review meeting on general recurring issues in ecotoxicology. EFSA supporting publication 2015:EN-924. 62 pp.

Conclusion: The trigger is not met for vegetative vigour, for the single and the multiple application rates intended for the product. As next step, a probabilistic assessment is therefore provided below.

b) Probabilistic risk assessment

Table 9.10-5: Probabilistic assessment of the risk for non-target plants due to the use of FSN+TCM OD 80 (50+30) in sugar beet – Risk assessment based on higher tier semi-field study

Intended use	**Sugar beet, 1 × 1.0 L prod./ha (use group B)**			
Active substance/product	FSN+TCM OD 80 (50+30)			
Application rate (mL/ha)	1 × 1000			
MAF	1.0 (single application)			
Test species	**HR_5 (mL/ha)**	**Drift rate (%)**	**$PER_{off\text{-}field}$ (mL/ha)**	**TER[1] criterion: TER ≥ 1***

HR_5 – vegetative vigour	10.907	2.77	27.70	**0.39**

Intended use	**Sugar beet, 2 × 0. 5 L prod./ha (use group C)**
Active substance/product	FSN+TCM OD 80 (50+30)
Application rate (mL/ha)	2 × 500
MAF	1.0 Justification: At the recent Pesticide Peer Review Meeting 133 [2)] in Sept. 2015 "it was agreed that for the risk assessment of active substances, no MAF values should be used by default, until a guidance document is developed." This approach is in line with the "Guidance Document on Terrestrial Ecotoxicology" currently in use which does not require the use of a MAF value in the context of NTTP risk assessment. Thus, it is not deemed necessary to apply a MAF when calculating the PER.

Test species	**HR_5 (mL/ha)**	**Drift rate (%)**	**$PER_{off\text{-}field}$ (mL/ha)**	**TER[1)] criterion: TER ≥ 1***
HR_5 – vegetative vigour	10.907	2.38	11.9	**0.92**

MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

* TER ≥ 1 for probabilistic risk assessment based on HR_5

1) TER values were calculated using unrounded PER values

2) EFSA (European Food Safety Authority), 2015. Technical report on the outcome of the pesticides peer review meeting on general recurring issues in ecotoxicology. EFSA supporting publication 2015:EN-924. 62 pp.

Conclusion: For both intended rates, the trigger is not met for vegetative vigour. Accordingly, further analysis is required and will be presented, considering possible options for exposure mitigation.

zRMS comments:

A higher tier study under semi-field condition (Koehler 2014c, see KIIIA 10.8.1.4/01) was conducted to further refined risk assessment based on these data.
However, the results of the study are considered not sufficiently reliable for a deterministic risk assessment (confidence intervals around the EC_{50} are quite large for some species such as *Beta vulgaris* and *Helianthus annus*).
Taking into account the propabilistic risk assessment it should be noted that some statistics tests are rejected, more particularly normality (p=0.05) from Anderson-Darling test. Then, regarding to the graphic results presented above, it is considered that the shape of the curve doesn't fit well the points, and the lowest endpoint (ER_{50} = 8.90 mL product/ha) is above the curve and lower than the HR_5 (10.907 mL product).
This HR_5 calculated by the notifier resulted in a relatively large interval of confidence leading to uncertainties on the conservatism of the value (HR_5 = 10.907 mL product/ha with a range between : 3.267 mL product/ha and 19.61 mL product/ha). Based on all these observations, SSD does not seem to be robust enough to be used in the risk assessment.
Therefore, the study was considered byzRMS as supplemental information.
In addition it should be noted that according to the recommendation in the EU guidance document for terrestrial ecotoxicology "[…] field or semi-field studies are not required if the risk based on the tier 2 assessment could be managed by risk mitigation measures which could be dealt with on a Member State level."
The probabilistic approach based on HR_5 derived from the tier 2 study shows that the risk of the product CONVISO ONE can be managed by risk mitigation measures.

9.10.2.4 Risk mitigation measures

In order to reduce the off-field exposure, risk mitigation measures can be implemented. These correspond to unsprayed in-field buffer strips of a given width and/or the usage of drift reducing nozzles. The results of the risk assessment using the lowest HR_5 (vegetative vigour) from the tier-2 studies as well as typical mitigation measures (no-spray buffer zones of 5 or 10 m; drift-reducing nozzles with reduction by 50 %, 75 %, or 90 %) are summarised in the following tables.

Table 9.10-6: Risk assessment for non-target terrestrial plants considering risk mitigation (in-field no-spray buffer zones, and drift-reducing nozzles) based on the lowest HR_5 from the vegetative vigour tier-2 studies - use of FSN+TCM OD 80 (50+30) in sugar beet: use group B

Intended use		**Sugar beet, 1 × 1.0 L prod./ha (use group B)**			
Active substance/product		FSN+TCM OD 80 (50+30)			
Application rate (mL/ha)		1 × 1000			
MAF		1.0			
Buffer strip (m)	**Drift rate (%)**	**$PER_{off\text{-}field}$ (g/ha)**	**$PER_{off\text{-}field}$ 50 % drift red. (g/ha)**	**$PER_{off\text{-}field}$ 75 % drift red. (g/ha)**	**$PER_{off\text{-}field}$ 90 % drift red. (g/ha)**
no buffer	2.77	27.70	13.85	6.93	2.77
5 m	0.57	5.70	2.85	1.43	0.57
10 m	0.29	2.90	1.45	0.73	0.29
~~**Toxicity value**~~ ~~HR_5 = 4.355 mL prod./ha (vegetative vigor)~~		~~**TER[1)]**~~ ~~**criterion: TER ≥ 1**~~			
~~no buffer~~		~~**0.16**~~	~~**0.31**~~	~~**0.63**~~	~~1.57~~
~~5 m~~		~~**0.76**~~	~~1.53~~	~~3.06~~	~~7.64~~
~~10 m~~		~~1.50~~	~~3.00~~	~~6.01~~	~~15.02~~
Toxicity value HR_5 = 3.949 mL prod./ha (vegetative vigor)		**TER[1)]** **criterion: TER ≥ 1**			
no buffer		**0.14**	**0.29**	**0.57**	1.43
5 m		**0.69**	1.39	2.76	6.93
10 m		1.36	2.72	5.41	13.62

MAF: Multiple application factor; PER: Predicted environmental rates; TER: toxicity to exposure ratio. TER values shown in bold breach the relevant trigger fo 1.

[1)] TER values were calculated using unrounded PER values

Table 9.10-7: Risk assessment for non-target terrestrial plants considering risk mitigation (in-field no-spray buffer zones, and drift-reducing nozzles) based on the lowest HR_5 from the vegetative vigour tier-2 studies - use of FSN+TCM OD 80 (50+30) in sugar beet: use group C

Intended use		**Sugar beet, 2 × 0.5 L prod./ha (use group C)**			
Active substance/product		FSN+TCM OD 80 (50+30)			
Application rate (mL/ha)		2 × 500			
MAF		1.0			
Buffer strip (m)	**Drift rate (%)**	**$PER_{off-field}$ (g/ha)**	**$PER_{off-field}$ 50 % drift red. (g/ha)**	**$PER_{off-field}$ 75 % drift red. (g/ha)**	**$PER_{off-field}$ 90 % drift red. (g/ha)**
no buffer	2.38	11.90	5.95	2.98	1.19
5 m	0.47	2.35	1.18	0.59	0.24
~~**Toxicity value**~~ ~~HR_5 = 4.355 mL prod./ha (vegetative vigor)~~		~~**TER**[1)]~~ ~~**criterion: TER ≥ 1**~~			
~~no buffer~~		~~**0.37**~~	~~**0.73**~~	~~1.46~~	~~3.66~~
~~5 m~~		~~1.85~~	~~3.71~~	~~7.41~~	~~18.53~~
Toxicity value HR_5 = 3.949 mL prod./ha (vegetative vigor)		**TER**[1)] **criterion: TER ≥ 1**			
no buffer		**0.33**	**0.66**	1.33	3.32
5 m		1.68	3.35	6.69	16.45

MAF: Multiple application factor; PER: Predicted environmental rates; TER: toxicity to exposure ratio. TER values shown in bold breach the relevant trigger fo 1.

1) TER values were calculated using unrounded PER values

zRMS comments:

According to the results of the **propabilistic a**pproach in use group B (1 x 1 L product/ha) involving the most sensitive endpoint from the vegetative vigour study with HR_{50} = 3.949 ml/ha) the risk for non-target terrestrial plants is considered acceptable with one of the following mitigation options:

- 5 m in-crop buffer with 50% drift reducing nozzles or
- 1 m in-crop with 90% drift reduction nozzels
- 10 m in-crop buffer

According to the results of the **propabilistic** approach in use group C (2 x 0.5 L product/ha) involving the most sensitive endpoint from the vegetative vigour study with HR_{50} = 3.949 the risk for non-target terrestrial plants is considered acceptable with one of the following mitigation options:

- 5 m in-crop buffer or
- 1 m in-crop buffer with 75 % drift reducing nozzles

Table 9.10-8: Deterministic assessment of the risk for non-target plants due to the use of FSN+TCM OD 80 (50+30) in sugar beetb based on the lowest value from labo-latory studies use group B.

Intended use		**Sugar beet, 1 × 1.0 L prod./ha (use group B)**			
Active substance/product		FSN+TCM OD 80 (50+30)			
Application rate (mL/ha)		1 × 1000			
MAF		1.0			
Buffer strip (m)	**Drift rate (%)**	**$PER_{off-field}$ (g/ha)**	**$PER_{off-field}$ 50 % drift red. (g/ha)**	**$PER_{off-field}$ 75 % drift red. (g/ha)**	**$PER_{off-field}$ 90 % drift red. (g/ha)**
no buffer	2.77	27.70	13.85	6.93	2.77
5 m	0.57	5.70	2.85	1.43	0.57
10 m	0.29	2.90	1.45	0.73	0.29
Toxicity value ER_5 = 6.92 mL prod./ha (vegetative vigor)		**TER[1)] criterion: TER ≥ 5**			
no buffer		**0.25**	**0.50**	**1.00**	**2.50**
5 m		**1.21**	**2.43**	**4.84**	12.14
10 m		**2.39**	**4.77**	9.48	23.86

MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.
* TER ≥ 5 for deterministic risk assessment based on ER_{50}

Deterministic assessment of the risk for non-target plants due to the use of FSN+TCM OD 80 (50+30) in sugar beetb based on the lowes value from labolatory studies-use group C.

Intended use		**Sugar beet, 2 × 0.5 L prod./ha (use group C)**			
Active substance/product		FSN+TCM OD 80 (50+30)			
Application rate (mL/ha)		2 × 500			
MAF		1.0			
Buffer strip (m)	**Drift rate (%)**	**$PER_{off-field}$ (g/ha)**	**$PER_{off-field}$ 50 % drift red. (g/ha)**	**$PER_{off-field}$ 75 % drift red. (g/ha)**	**$PER_{off-field}$ 90 % drift red. (g/ha)**
no buffer	2.38	11.90	5.95	2.98	1.19
5 m	0.47	2.35	1.18	0.59	0.24
Toxicity value ER_5 = 6.92 mL prod./ha (vegetative vigor)		**TER[1)] criterion: TER ≥ 5**			
no buffer		**0.58**	**1.16**	**2.32**	5.82
5 m		**2.94**	5.86	11.73	28.83

MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.
* TER ≥ 5 for deterministic risk assessment based on ER_{50}

zRMS comments:

According to the results of the deterministic approach in use group B (1 x 1 L product/ha) involving the most sensitive endpoint from the vegetative vigour study (biomass with cucumber with ERC50 = 6.92 ml/ha) the risk for non-target terrestrial plants is considered acceptable with one of the following mitigation options:

- 5 m in-crop buffer with 90% drift reducing nozzles or
- 10 m in-crop buffer with 75 % drift reducing nozzles

According to the results of the deterministic approach in use group C 2 x 0.5 L product/ha) involving the most sensitive endpoint from the vegetative vigour study (biomass with cucumber) the risk for non-target terrestrial plants is considered acceptable with one of the following mitigation options:

- 5 m in-crop buffer with 50% drift reducing nozzles or
- no buffer with 90 % drift reducing nozzles

9.10.3 Overall conclusions

Based on the probabilistic risk assessment it is concluded that the use of the product will not produce unacceptable effects on terrestrial non-target plants growing near treated fields, when considering the following mitigation measures:

- a 10 m buffer zone, or alternatively 5 m buffer zone and 50% drift reducing spray nozzles, or alternatively 90% drift reducing spray nozzles for the application rate 1 x 1.0 L product/ha (use group B).
- a 5 m buffer zone, or alternatively 75% drift reducing spray nozzles for the application rate 2 x 0.5 L product/ha (use group C).

Overall zRMS's comments:

Deterministic risk assessment conclusion:

Based on the deterministic risk assessment it is concluded that the use of the product will not produce unacceptable effects on terrestrial non-target plants growing near treated fields, when considering the following mitigation measures:
Use group B (1 x 1 L product/ha)

- 5 m in-crop buffer with 90% drift reducing nozzles or
- 10 m in-crop buffer with 75 % drift reducing nozzles

Use group C 2 x 0.5 L product/ha)
-5 m in-crop buffer with 50% drift reducing nozzles or
- no buffer with 90 % drift reducing nozzles

The risk migitation measures should be considered at MSs level depending on their national requirments.

Probabilistic risk assessment conclusion:

The position of the ZRMS-PL is that the trigger value of 1 should be used in the probabilistic risk assessment with a HR_5 value; however it is noted that this is not a Central Zone harmonised position and other member states may consider the use of a different trigger value at National Registration.
Based on the probabilistic risk assessment wtth trigger value of 1 it is concluded that the use of the product will not produce unacceptable effects on terrestrial non-target plants growing near treated fields, when considering the following mitigation measures:

According to the results of the propabilistic approach in **use group B (1 x 1 L product/ha**) the risk for non-target terrestrial plants is considered acceptable with one of the following mitigation options:
- 5 m in-crop buffer with 50% drift reducing nozzles or
- 1 m in-crop with 90% drift reduction nozzels
- 10 m in-crop buffer

According to the results of the propabilistic approach in use group **C (2 x 0.5 L product/ha)** the risk for non-target terrestrial plants is considered acceptable with one of the following mitigation options:
- 5 m in-crop buffer or
- 1 m in-crop buffer with 75 % drift reducing nozzles

The risk migitation measures should be considered at MSs level depending on their national requirments.

9.11 Effects on other terrestrial organisms **(flora and fauna) (KCP 10.7)**

No further information is available or considered to be necessary.

9.12 Monitoring data (KCP 10.8)

No further information is available or considered to be necessary.

9.13 Classification and Labelling

Acute aquatic toxicity: Category 1
H400 Very toxic to aquatic life.

Chronic aquatic toxicity: Category 1
H410 Very toxic to aquatic life with long lasting effects.

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

Please note that all data mentioned as part of DAR, RAR, or EFSA journals are considered as relied upon.

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Owner
KCP 10.2 / 01	Sinclair, C. J.	2009	Predicting the environmental fate and ecotoxicological and toxicological effects of pesticide transformation products Publisher: unknown Journal: unknown Year: 2009 Report No.: M-551653-01-1 GLP/GEP: n.a. published	No	published
KCP 10.2.1 / 01	xxx	2016	Re-evaluation of acute fish study with metabolite AE F092944 (M-131422-01-1) in context of mesosulfuron approval renewal (EFSA request, Point 33) Report No.: M-549001-01-1 xxx GLP/GEP: No unpublished	Yes	Bayer
KCP 10.2.1 / 02	Kuhl, K.	2017	Amendment no. 2: Lemna gibba G3 - Growth inhibition test with foramsulfuron tech. (BCS-AH47624) under peak exposure conditions Report No.: EBFS0001, Edition Number: M-572386-03-1 Bayer AG, Crop Science Division, Monheim, Germany ... amended: 2017-06-08 GLP/GEP: Yes 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 10.2.1 / 03	Kuhl, K.	2016	Lemna gibba G3 - Growth inhibition test with AE F130619 (BCS-AU59648) under peak exposure conditions - Final Report - Report No.: EBFS0002, Edition Number: M-574191-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 10.2.1 / 04	Kuhl, K.	2016	Amendment no.1 - Lemna gibba G3 - Growth inhibition test with thiencarbazone-methyl tech. (BCS-AG17468) under peak exposure conditions - Final report - Report No.: EBGS0002, Edition Number: M-568404-02-1 Bayer CropScience AG, Monheim, Germany ... amended: 2016-12-07 GLP/GEP: Yes unpublished	No	Bayer
KCP 10.2.1 / 05	Bruns, E.	2013	Lemna gibba G3 - Growth inhibition test with BYH 18636 (thiencarbazone-methyl) under peak exposure conditions Report No.: EBGSN002, Edition Number: M-462568-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 10.2.1 / 06	Banman, C. S.; Moore, S.	2013	Toxicity of thiencarbazone-methyl technical to the aquatic macrophyte, myriophyllum spicatum under peak exposure conditions Report No.: EBGSN048, Edition Number: M-466233-01-1 SynTech Research Laboratory Services, LLC, Stilwell, KS, USA GLP/GEP: Yes unpublished	No	Bayer
KCP 10.2.1 / 07	Bruns, E.	2014	Lemna gibba G3 - Growth inhibition test with foramsulfuron + thiencarbazone-methyl OD 80 (50 + 30) G under static conditions Report No.: EBGSP149, Edition Number: M-477103-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes 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 10.2.3 / 01	Solga, A.; Heine, S.	2018	Justification for the use of time-weighted average concentrations in the chronic risk assessment for foramsulfuron and aquatic plants Report No.: M-615294-02-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: n.a. unpublished	No	Bayer
KCP 10.2.3 / 02	Schmitt, W.; Bruns, E.; Dollinger, M.; Sowig, P.	2013	Mechanistic TK/TD-model simulating the effect of growth inhibitors on Lemna populations Publisher: Elsevier B.V. Location: Amsterdam Journal: Ecological Modelling Volume: 255 Pages: 1-10 Year: 2013 Report No.: M-455483-01-1 GLP/GEP: n.a. published	No	published
KCP 10.2.3 / 03	Heine, S.	2017	Lemna TK/TD modelling - Compound-specific parameterization and validation for foramsulfuron and its metabolite AE F130619 Report No.: EnSa-17-0346, Edition Number: M-591817-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: No unpublished	No	Bayer
KCP 10.2.3 / 04	Heine, S.	2017	Lemna TK/TD modelling - Compound-specific parameterization and validation for thiencarbazone-methyl Report No.: EnSa-17-0347, Edition Number: M-591850-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: No unpublished	No	Bayer
KCP 10.2.3 / 05	Heine, S.	2019	Lemna TK/TD modelling: Assessing the impact of FSN+TCM OD 80 applications on Lemna in Europe (FOCUSsw) Report No.: EnSa-18-0891, Edition Number: M-665818-01-1 Bayer AG, Crop Science Division, 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 10.2.3 / 06	Heine, S.	2019	Lemna TK/TD modelling: Assessing the impact of FSN+TCM OD 80 applications on Lemna in Europe (FOCUSsw multiyear) Report No.: EnSa-18-0892, Edition Number: M-665817-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: No unpublished	No	Bayer
KCP 10.3.1 / 01	Maynard, S. K.; Albuquerque, R.; Weber, C.; von Merey, G.; Geiger, M. F.; Becker, R.; Keppler, J.; Maschke, J.; Brougham, K.; Couson, M.	2015	1.8 Weeds in the treated field - a realistic scenario for pollinator risk assessment ? Publisher: Julius-Kuehn Archiv Location: Ghent, Belgium Journal: 12th International Symposium of the ICP-PR Bee Protection Group Volume: 450 Pages: 56-62 Year: 2015 Report No.: M-542146-01-1 GLP/GEP: n.a. published	No	published
KCP 10.3.1.1.1 / 01 **... also filed: KCP 10.3.1.1.2 / 01**	Sekine, T.	2013	Effects of foramsulfuron + thiencarbazone-methyl OD 80 (50+30) G (acute contact and oral) on honey bees (Apis mellifera L.) in the laboratory Report No.: 81151035, Edition Number: M-461860-01-1 IBACON GmbH, Rossdorf, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 10.3.1.1.2 / 01 **... also filed: KCP 10.3.1.1.1 / 01**	Sekine, T.	2013	Effects of foramsulfuron + thiencarbazone-methyl OD 80 (50+30) G (acute contact and oral) on honey bees (Apis mellifera L.) in the laboratory Report No.: 81151035, Edition Number: M-461860-01-1 IBACON GmbH, Rossdorf, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 10.3.2.2 / 01	Waibel, J.	2013	Toxicity to the predatory mite Typhlodromus pyri (Acari: Phytoseiidae) using an extended laboratory test on apple Thiencarbazone-methyl + Foramsulfuron OD 80 (30+50 g/L) Report No.: CW13/014, Edition Number: M-457257-01-1 Bayer CropScience AG, Frankfurt am Main, Germany GLP/GEP: Yes 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 10.3.2.2 / 02	Waibel, J.	2013	Toxicity to the parasitoid wasp Aphidius rhopalosiphi (Hymenoptera: Braconidae) using an extended laboratory test on barley - Thiencarbazone-methyl + foramsulfuron OD 80 (30+50 g/L Report No.: CW13/013, Edition Number: M-469970-01-1 Bayer CropScience AG, Frankfurt am Main, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 10.3.2.2 / 03	Waibel, J.	2013	Toxicity to the green lacewing Chrysoperla carnea (Neuroptera: Chrysopidae) using an extended laboratory test on apple Thiencarbazone-methyl + Foramsulfuron OD 80 (30+50 g/L) Report No.: CW13/015, Edition Number: M-469943-01-1 Bayer CropScience AG, Frankfurt am Main, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 10.3.2.2 / 04	Schmitzer, S.	2013	Effects of thiencarbazone-methyl + foramsulfuron OD 80 (30+50 g/L) on the reproduction of rove beetles Aleochara bilineata - Extended laboratory study - Dose response test Report No.: 81291071, Edition Number: M-461869-01-1 IBACON GmbH, Rossdorf, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 10.3.2.2 / 05	Jans, D.	2014	Toxicity to the parasitoid wasp Aphidius rhopalosiphi (Hymenoptera: Braconidae) using an extended laboratory test on barley thiencarbazone-methyl + foramsulfuron OD 80 (30+50 g/L) Report No.: CW13/057, Edition Number: M-477760-01-1 Bayer CropScience AG, Frankfurt am Main, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 10.4.1.1 / 01	Kratz, M.	2013	Foramsulfuron + thiencarbazone-methyl OD 80 (50+30) G: Effects on survival, growth and reproduction of the earthworm Eisenia fetida tested in artificial soil Report No.: kra/Rg-R-144/13, Edition Number: M-468316-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes 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 10.4.2.1 / 01	Frommholz, U.	2013	Foramsulfuron + thiencarbazone-methyl OD 80 (50+30) G: Influence on the reproduction of the collembolan species Folsomia candida tested in artificial soil Report No.: FRM-Coll-155/13, Edition Number: M-459537-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 10.4.2.1 / 02	Kratz, M. A.	2013	Foramsulfuron + thiencarbazone-methyl OD 80 (50+30) G: Influence on mortality and reproduction of the soil mite species Hypoaspis aculeifer tested in artificial soil Report No.: kra-HR-86/13, Edition Number: M-462709-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 10.5 / 01	Schulz, L.	2013	Foramsulfuron + thiencarbazone-methyl OD 80 (50+30) G: Effects on the activity of soil microflora (nitrogen transformation test) Report No.: 13 10 48 045 N, Edition Number: M-460665-01-1 BioChem agrar, Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 10.6.2 / 01	Koehler, P.	2013	Thiencarbazone-methyl + Foramsulfuron OD 80 (30 + 50 g/L) - Effects on the seedling emergence and growth of ten species of non-target terrestrial plants (Tier 2) Report No.: SE13/007, Edition Number: M-467676-01-1 Bayer CropScience AG, Frankfurt am Main, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 10.6.2 / 02	Koehler, P.	2014	Thiencarbazone-methyl + foramsulfuron OD 80 (30 + 50 g/L) - Effects on the vegetative vigour of ten species of non-target terrestrial plants (Tier 2) Report No.: VV13/006, Edition Number: M-491267-01-1 Bayer CropScience AG, Frankfurt am Main, Germany GLP/GEP: Yes 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 10.6.2 / 03	Koehler, P.	2014	Thiencarbazone-methyl + foramsulfuron OD 80 (30 + 50 g/L) - Effects on the vegetative vigour of ten species of non-target terrestrial plants (Tier 2) Report No.: VV14/012, Edition Number: M-496996-01-1 Bayer CropScience AG, Frankfurt am Main, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 10.6.4 / 01	Koehler, P.	2014	Thiencarbazone-methyl + foramsulfuron OD 80 (30 + 50 g/L) -Effects on the vegetative vigour of seven species of non-target terrestrial plants under semi-field conditions (Higher Tier) Report No.: HT14/016, Edition Number: M-502816-01-1 Bayer CropScience AG, Frankfurt am Main, Germany GLP/GEP: No unpublished	No	Bayer
KCP 10.7 / 01	Gladbach, A.; Ebeling, M.; Weyers, A.	2017	Technical stand-alone combined toxicity assessment for the Central zone Report No.: M-571377-02-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: n.a. 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.**
Bayer is the owner of the data package peer-reviewed for the EU approval of the active substance **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).
Only the data related to the active ingredient (KCA studies) are listed.

Data Point	**Author(s)**	**Year**	**Title** **Compagny Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	**Vertebrate study Y/N**	**Owner**
KCA 8.2.1 /04	xxx	1993	Hoe 092944 - substance, technical (Hoe 092944 00 ZD99 0001) Effect to *Oncorhynchus mykiss* (Rainbow trout) in a Static-Acute Toxicity Test (method OECD) xxx Report No.: A50396, Edition Number: M-131422-01-1 Date: 1993-04-13 GLP/GEP: yes, unpublished	Y	Bayer CropScience

Data Point	**Author(s)**	**Year**	**Title** **Compagny Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	**Vertebrate study Y/N**	**Owner**
KCA 8.2.2.1 /02	xxx	2004	Early Life Stage Toxicity of Foramsulfuron (AE F130360) Technical to the Fathead Minnow (*Pimephales promelas*) Under Flow-Through Conditions xxx Report No.: B004606, Report includes Trial Nos.: EBFSX001 (A3841201) Edition Number: M-241508-01-1 Date: 2004-03-17 GLP/GEP: yes, unpublished	Y	Bayer CropScience
KCA 8.2.4.1 /02	Heusel, R.	1993	Hoe 092944 - substance, technical (Hoe 092944 00 ZD99 0001) Effect to *Daphnia magna* (waterflea) in a Static -Acute Toxicity Test (method OECD) Hoechst AG, Frankfurt am Main, Germany Bayer CropScience, Report No.: A50353, Edition Number: M-131382-01-1 Date: 1993-04-13 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCA 8.2.6.1 /02	Heusel, R.	1993	Hoe 092944 - substance, technical (Hoe 092944 00 ZD99 0001) Effect to *Scenedesmus subspicatus* (Green alga) in a Growth Inhibition Test (method OECD) Hoechst AG, Frankfurt am Main, Germany Bayer CropScience, Report No.: A50395, Edition Number: M-131421-01-1 Date: 1993-04-13 GLP/GEP: yes, unpublished	N	Bayer CropScience

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 8.2.6.1 /03	Dorgerloh, M.	2005	*Pseudokirchneriella subcapitata* - growth inhibition test with AE F099095 00 1B99 0001 Bayer CropScience, Report No.: EBMMX092, Edition Number: M-254084-01-1 Date: 2005-07-08 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCA 8.2.7 /05	Dorgerloh, M.	2005	*Lemna gibba* G3 Exposure and recovery test with Foramsulfuron (tech.) (code: AE F130360 00 1D97 0001) BCS, Report No.: EBFSX010, Edition Number: M-250268-01-1 Date: 2005-04-26 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCA 8.2.7 /06	Bruns, E.	2013	*Lemna gibba* G3 - Growth inhibition test with foramsulfuron (tech) (AE F 130360) under peak exposure conditions Bayer CropScience, Report No.: EBFSN003, Edition Number: M-462569-01-1 Date: 2013-08-13 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCA 8.2.7 /07	Kirkwood, A.	2012	Outdoor growth inhibition and recovery of aquatic plants exposed to foramsulfuron WG 50 percent Smithers Viscient, Wareham, MA, USA Bayer CropScience, Report No.: EBFSL012, Edition Number: M-429538-01-1 EPA MRID No.: 48869701 Date: 2012-04-13 GLP/GEP: yes, unpublished	N	Bayer CropScience

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 8.2.7 /08	Bruns, E.	2013	*Lemna gibba* G3 - Prolonged growth inhibition test with foramsulfuron (AE F130360) with stepwise decreasing concentrations over an 6 week test duration Bayer CropScience, Report No.: EBFSL014, Edition Number: M-464150-01-1 Date: 2013-09-10 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCA 8.2.7 /09	xxx	2012	Toxicity of foramsulfuron technical to the aquatic macrophyte, *Myriophyllum spicatum* xxx xxx, Report No.: EBFSL004, Edition Number: M-431270-01-1 Date: 2012-05-17 GLP/GEP: yes, unpublished	Y	Bayer CropScience
KCA 8.2.7 /10	Sowig, P.; Weller, O.	2000	Duckweed (*Lemna gibba* G3) growth inhibition test AE F092944 (metabolite of ethoxysulfuron and amidosulfuron) substance technical Code: AE F092944 00 1C99 0001 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: C003865, Edition Number: M-186916-01-1 Date: 2000-11-03 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCA 8.2.7 /11	Dorgerloh, M.	2005	*Lemna gibba* G3 - growth inhibition test with AE F099095 under static conditions (Code: AE F099095 00 1B99 0001) BCS, Report No.: EBMMX091, Edition Number: M-254496-01-1 Date: 2005-07-14 GLP/GEP: yes, unpublished	N	BCS

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 8.2.7 /12	Bruns, E.	2013	*Lemna gibba* G3 - Growth inhibition test with with AE F130619 (metabolite of foramsulfuron) under static conditions Bayer CropScience, Report No.: EBFSL011, Edition Number: M-452669-01-1 Date: 2013-04-15 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCA 8.2.7 /13	Bruns, E.	2013	*Lemna gibba* G3 - Growth inhibition test with BCS-CV29520 (metabolite of foramsulfuron) under static conditions Bayer CropScience, Report No.: EBFSN010, Edition Number: M-464163-01-1 Date: 2013-08-29 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCA 8.2.7 /14	Bruns, E.	2013	*Lemna gibba* G3 - Growth inhibition test with BCS-CW90756 (metabolite of foramsulfuron) under static conditions Bayer CropScience, Report No.: EBFSN011, Edition Number: M-464321-01-1 Date: 2013-08-29 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCA 8.2.7 /15	Hoffmann, K.	2013	*Lemna gibba* G3 - Growth inhibition test with BCS-AW41401 under static conditions Bayer CropScience, Report No.: EBFSN012, Edition Number: M-464386-01-1 Date: 2013-08-29 GLP/GEP: yes, unpublished	N	Bayer CropScience

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 8.3.1.1.2 /02	Schmitzer S.; Sekine T.	2012	Effects of foramsulfuron tech. (acute contact and oral) on honey bees (*Apis mellifera* L.) in the laboratory IBACON GmbH, Arheilger Weg 17, 64380 Rossdorf, Germany Report No. EBFSN009 GLP, unpublished Bayer File No: M-444765-01-1	N	Bayer Crop Science
KCA 8.3.1.2 /01	Kling A.	2013	Foramsulfuron WG 50 W - Assessment of chronic effects to the honeybee, *Apis mellifera* L., in a 10 days continuous laboratory feeding limit test EurofinsAgroscience Services, EcoChem GmbH, Eutinger Straße 24, 75223 Niefern-Öschelbronn, Germany Report No. EBFSN022 GLP, unpublished Bayer File No: M-470639-01-1	N	Bayer Crop Science
KCA 8.3.1.3 /01	Przygoda D.; Nikolakis A.	2013	Foramsulfuron WG 50 W: Effects of a single exposure to spiked diet on honey bee larvae (*Apis mellifera carnica*) in an in vitro laboratory testing design Bayer CropScience AG, BCS-AG-D-EnSa-Testing, 40789 Monheim, Germany Report No. EBFSN044 GLP, unpublished Bayer File No: M-470485-01-1	N	Bayer Crop Science
KCA 8.3.1.3/02	Jeker L.	2013	Foramsulfuron WG 50 W - honeybee brood feeding study to evaluate potential effects on brood development and mortality of the honeybee, *Apis mellifera* L. (Hymenoptera: Apidae) Innovative Environmental Services (IES) Ltd, Benkenstrasse 260, 4108 Witterswil, Switzerland Report No. EBFSL013 GLP, unpublished Bayer File No: M-465326-01-1	N	Bayer Crop Science

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 8.3.1.3 /03	Schmitzer S.	2013	Foramsulfuron + isoxadifen-ethyl OD 45 (22.5+22.5 g/L): Effects on honey bee brood (*Apis mellifera* L.) under semi-field conditions - Tunnel test – IBACON GmbH, Arheilger Weg 17, 64380 Rossdorf, Germany Report No. EBFSN034 GLP, unpublished Bayer File No: M-468794-01-1	N	Bayer Crop Science
KCA 8.3.2.2 /03	Roehlig U.	2013	Effects of foramsulfuron + isoxadifen-ethyl OD 45 (22.5+22.5 g/L) on the predatory mite *Typhlodromus pyri* SCHEUTEN in a laboratory test BioChem agrar, Labor für biologische und chemische Analytik GmbH Kupferstraße 604827 Gerichshain, Germany Report No. 13 10 48 031 A GLP, unpublished Bayer file No.: M-457360-01-1	N	Bayer Crop Science
KCA 8.3.2.1./03	Roehlig U.	2013	Effects of foramsulfuron + isoxadifen-ethyl OD 45 (22.5+22.5 g/L) on the parasitic wasp *Aphidius rhopalosiphi* (DESTEFANI-PEREZ) in a laboratory BioChem agrar, Labor für biologische und chemische Analytik GmbH Kupferstraße 604827 Gerichshain, Germany Report No. 131048030A GLP, unpublished Bayer file No.: M-461455-01- 1	N	Bayer Crop Science
KCA 8.4.1 /02	Kratz, M. A.	2013	AE F092944 (BCS-AA25052): Effects on survival, growth and reproduction of the earth-worm *Eisenia fetida* tested in artificial soil Bayer CropScience, Report No.: kra/Rg-R-147/13, Edition Number: M-461051-01-1 Date: 2013-07-31 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCA 8.4.1 /03	Kratz, M. A.	2013	AE F130619 (BCS-AU59648): Effects on survival, growth and reproduction of the earth-worm *Eisenia fetida* tested in artificial soil Bayer CropScience, Report No.: kra/Rg-R-138/13, Edition Number: M-461453-01-1 Date: 2013-08-14 GLP/GEP: yes, unpublished	N	Bayer CropScience

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 8.4.1 /04	Kratz, M. A.	2013	Foramsulfuron-AE F153745 (BCS-AU80017): Effects on survival, growth and reproduction on the earthworm *Eisenia fetida* tested in artificial soil Bayer CropScience, Report No.: kra/Rg-R-140/13, Edition Number: M-459518-01-1 Date: 2013-07-17 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCA 8.4.2.1 /01	Kratz, M. A.	2012	Foramsulfuron (AE F130360) a.s.: Influence on mortality and reproduction on the soil mite species *Hypoaspis aculeifer* tested in artificial soil Bayer CropScience, Report No.: KRA-HR-78/12, Edition Number: M-443308-01-1 Date: 2012-12-10 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCA 8.4.2.1 /02	Frommholz, U.	2012	Foramsulfuron (AE F130360) a.s.: Influence on the reproduction of the collembolan species *Folsomia candida* tested in artificial soil Bayer CropScience, Report No.: FRM-Coll-147/12, Edition Number: M-443369-01-1 Date: 2012-12-12 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCA 8.4.2.1 /03	Schulz, L.	2013	AE F092944 (BCS-AA25052): Effects on the reproduction of the predatory mite *Hypoaspis aculeifer* BioChem agrar, Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Bayer CropScience, Report No.: 13 10 48 044 S, Edition Number: M-454043-01-1 Date: 2013-05-02 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCA 8.4.2.1 /04	Friedrich, S.	2013	AE F092944 (BCS-AA25052): Effects on the reproduction of the collembolan *Folsomia candida* BioChem agrar, Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Bayer CropScience, Report No.: 13 10 48 045 S, Edition Number: M-451142-01-1 Date: 2013-03-28 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCA 8.4.2.1 /05	Schulz, L.	2013	Foramsulfuron-AE F130619 (BCS-AU59648): Effects on the reproduction of the predatory mite *Hypoaspis aculeifer* BioChem agrar, Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Bayer CropScience, Report No.: 13 10 48 046 S, Edition Number: M-454051-01-1 Date: 2013-05-02 GLP/GEP: yes, unpublished	N	Bayer CropScience

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 8.4.2.1 /06	Friedrich, S.	2013	Foramsulfuron-AE F130619 (BCS-AU59648): Effects on the reproduction of the collembolan *Folsomia candida* BioChem agrar, Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Bayer CropScience, Report No.: 13 10 48 047 S, Edition Number: M-450824-01-1 Date: 2013-03-28 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCA 8.4.2.1 /07	Schulz, L.	2013	Foramsulfuron-AE F153745 (BCS-AU80017): Effects on the reproduction of the predatory mite *Hypoaspis aculeifer* BioChem agrar GmbH, Gerichshain, Germany Bayer CropScience, Report No.: 13 10 48 048 S, Edition Number: M-447606-01-1 Date: 2013-02-22 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCA 8.4.2.1 /08	Friedrich, S.	2013	Foramsulfuron-AE F153745 (BCS-AU80017): Effects on the reproduction of the collembolan *Folsomia candida* BioChem agrar, Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Bayer CropScience, Report No.: 13 10 48 049 S, Edition Number: M-450830-01-1 Date: 2013-03-28 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCA 8.5 /05	Schulz, L.	2013	AE F092944 (BCS-AA25052): Effects on the activity of soil microflora (Nitrogen transformation test) BioChem Agrar GmbH, Gerichshain, Germany Bayer CropScience, Report No.: 13 10 48 018 N, GLP/GEP: yes, unpublished Bayer file No.: M-453511-01-1	N	Bayer Crop Science
KCA 8.5 /06	Schulz, L.	2013	Foramsulfuron-AE F130619 (BCS-AU59648): Effects on the activity of soil microflora (nitrogen transformation test) BioChem Agrar GmbH, Gerichshain, Germany Bayer CropScience, Report No.: 13 10 48 019 N GLP/GEP: yes, unpublished Bayer file No.: M-453568-01-1	N	Bayer Crop Science

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 8.5 /07	Schulz, L.	2013	Foramsulfuron-AE F153745 (BCS-AU80017): Effects on the activity of soil microflora (Nitrogen transformation test) BioChem Agrar GmbH, Gerichshain, Germany Bayer CropScience, Report No.: 1321048020N GLP/GEP: yes, unpublished Bayer file No.: M-453508-01-1	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).

Only the data related to the active ingredient (KCA studies) are listed.

Data Point	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant) Published or not	Vertebrate study Y/N	Owner
KIIA 8.1.1 /01	xxx	2005	Acute oral toxicity for bobwhite quail (Colinus virginianus) with BYH 18636 a.s. xxx Report No.: BAR/LD075, Edition Number: M-261212-01-2 Date: 21.11.2005 GLP, unpublished	Y	Bayer Crop Science
KIIA 8.1.2 /01	xxx	2006	Technical BYH 18636: A subacute dietary LC50 with northern bobwhite xxx xxx Report No.: EBGSM006, Edition Number: M-278496-01-1 Date: 06.08.2006 GLP, unpublished	Y	Bayer Crop Science
KIIA 8.1.3 /01	xxx	2006	Technical BYH 18636: A subacute dietary LC50 with mallards xxx Report No.: EBGSP009, Edition Number: M-278504-01-1 Date: 28.07.2006 GLP, unpublished	Y	Bayer Crop Science
KIIA 8.1.4 /01	xxx	2007	Effect of technical BYH 18636 on northern bobwhite reproduction xxx Report No.: EBGSP008, Edition Number: M-285465-01-1 Date: 15.03.2007 GLP, unpublished	Y	Bayer Crop Science

Data Point	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant) Published or not	Verte-brate study Y/N	Owner
KIIA 8.1.4 /02	xxx	2007	Effect of technical BYH 18636 on mallard reproduction xxx Report No.: EBGSP007, Edition Number: M-285456-01-1 Date: 15.03.2007 GLP, unpublished	Y	Bayer Crop Science

Data Point	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant) Published or not	Verte-brate study Y/N	Owner
KIIA 8.2.1.1 /01	xxx	2005	Acute toxicity of BYH 18636 technical to the rainbow trout (Oncorhynchus mykiss) under static conditions xxx Report No.: EBGSM014, Edition Number: M-252506-01-1 Date: 03.06.2005 GLP, unpublished	Y	Bayer Crop Science
KIIA 8.2.1.2 /01	xxx	2005	Acute toxicity of BYH 18636 technical to the bluegill (Lepomis macrochirus) under static conditions xxx Report No.: EBGSM013, Edition Number: M-257680-01-1 Date: 28.07.2005 GLP, unpublished	Y	Bayer Crop Science
KIIA 8.2.1.3 /01	xxx	2005	Acute toxicity of BYH 18636 sulfonamide to the rainbow trout (Oncorhynchus mykiss) under static conditions xxx Report No.: EBGSP001-1, Edition Number: M-262252-02-1 Date: 01.12.2005***, Amended: 04.01.2007*** GLP, unpublished	Y	Bayer Crop Science
KIIA 8.2.4 /01	xxx	2006	Early life stage toxicity of BYH 18636 technical to the fathead minnow (Pimephales promelas) under flow-through conditions xxx Report No.: EBGSP013, Edition Number: M-264063-01-1 Date: 12.01.2006 GLP, unpublished	Y	Bayer Crop Science
KIIA 8.3.1.1 /01	Banman, C. S.; Lam, C. V.	2005	Acute toxicity of BYH 18636 technical to the Daphnia magna under static conditions Bayer CropScience, Stilwell, Kansas, USA Bayer CropScience AG, Report No.: EBGSM007, Edition Number: M-251028-01-2 Date: 13.05.2005 GLP, unpublished	No	Bayer Crop Science

Data Point	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant) Published or not	Verte-brate study Y/N	Owner
KIIA 8.3.1.1 /02	Banman, C. S.; Lam, C. V.	2005	Acute toxicity of BYH 18636 sulfonamide to the Daphnia magna under static conditions Bayer Corporation, Stilwell, KS, USA Bayer CropScience AG, Report No.: EBGSP002-1, Edition Number: M-261931-02-1 Date: 05.12.2005***, Amended: 04.01.2007*** GLP, unpublished	No	Bayer Crop Science
KIIA 8.3.1.1 /03	Bruns, E.	2006	BYH 18636-sulfonamide (tech.): Comparative toxicity of two different batches of the test-item to the waterflea Daphnia magna in a static laboratory test system Bayer CropScience AG, Report No.: EBGSP081, Edition Number: M-271240-01-2 Date: 16.05.2006 Non GLP, unpublished	No	Bayer Crop Science
KIIA 8.3.1.1 /04	xxx.	2007	Acute toxicity of BYH 18636-sulfonamide to the waterflea Daphnia magna in a static laboratory test system - limit-test xxx Report No.: EBGSP087, Edition Number: M-282608-01-2 Date: 25.01.2007 GLP, unpublished	Yes	BCS
KIIA 8.3.2.1 /01	xxx	2006	Chronic toxicity of BYH 18636 technical to the Daphnia magna under static renewal conditions xxx Report No.: EBGSM008-1, Edition Number: M-264057-02-1 Date: 12.01.2006***, Amended: 09.02.2007*** GLP, unpublished	Yes	BCS
KIIA 8.4 /01	Dorgerloh, M.	2004	How to express growth effects on algae under 91/414/EEC? Bayer CropScience AG, Report No.: MO-04-005000, Edition Number: M-069427-01-1 Date: 18.04.2004 Non GLP, unpublished	No	Bayer Crop Science

Data Point	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant) Published or not	Verte-brate study Y/N	Owner
KIIA 8.4 /02	Kern, M. E.; Banman, C. S.; Lam, C. V.	2005	Toxicity of BYH 18636 technical to the green alga - Pseudokirchneriella subcapitata Bayer CropScience, Stilwell, KS, USA Bayer CropScience AG, Report No.: EBGSM001, Edition Number: M-256477-01-1 Date: 26.08.2005 GLP, unpublished	No	Bayer Crop Science
KIIA 8.4 /03	Banman, C. S.; Lam. C. V.	2005	Toxicity of BYH 18636 sulfonamide to the green alga Pseudokirchneriella subcapitata Bayer CropScience, Stilwell, KS, USA Bayer CropScience AG, Report No.: EBGSP003, Edition Number: M-262576-01-1 Date: 15.12.2005 GLP, unpublished	No	Bayer Crop Science
KIIA 8.4 /04	Kern, M. E.; Roberts, J. A.; Lam, C. K.	2005	Toxicity of BYH 18636 technical to the freshwater diatom Navicula pelliculosa Bayer CropScience, Stilwell, KS, USA Bayer CropScience AG, Report No.: EBGSM015, Edition Number: M-257683-01-1 Date: 19.08.2005 GLP, unpublished	No	Bayer Crop Science
KIIA 8.4 /05	Kern, M. E.; Lam, C. V.	2006	Toxicity of BYH 18636 technical to the blue-green alga Anabaena flos-aquae Bayer CropScience, Kansas City, MO, USA Bayer CropScience AG, Report No.: EBGSP012-1, Edition Number: M-264060-02-2 Date: 12.01.2006***, Amended: 09.02.2007*** GLP, unpublished	No	Bayer Crop Science
KIIA 8.5.1 /01	Bruns, E.	2006	Acute toxicity of BYH 18636 (tech.) to larvae of Chironomus riparius in a 48 h static laboratory test system (Limit-Test) Bayer CropScience AG, Report No.: EBGSP037, Edition Number: M-279507-01-2 Date: 30.10.2006 GLP, unpublished	No	Bayer Crop Science

Data Point	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant) Published or not	Verte-brate study Y/N	Owner
KIIA 8.5.1 /02	Bruns, E.	2006	Acute toxicity of BYH 18636-carboxylic acid to larvae of Chironomus riparius in a 48 h static laboratory test system (Limit-Test) Bayer CropScience AG, Report No.: EBGSP079, Edition Number: M-281173-01-2 Date: 06.12.2006 GLP, unpublished	No	Bayer Crop Science
KIIA 8.5.1 /03	Bruns, E.	2006	Acute toxicity of BYH 18636-sulfonamide-carboxylic acid to larvae of Chironomus riparius in a 48 h static laboratory test system (limit-test) Bayer CropScience AG, Report No.: EBGSP078, Edition Number: M-281523-01-2 Date: 13.12.2006 GLP, unpublished	No	Bayer Crop Science
KIIA 8.6 /01	Kern, M. E.; Lam, C. V.	2006	Toxicity of BYH 18636 technical to duckweed (Lemna gibba G3) under static-renewal conditions Bayer CropScience, Stilwell, KS, USA Bayer CropScience AG, Report No.: EBGSM016, Edition Number: M-269681-01-1 Date: 24.03.2006 GLP, unpublished	No	Bayer Crop Science
KIIA 8.6 /02	Christ, M. T.; Lam, C. V.	2007	Exposure and recovery with BYH 18636 technical to duckweed (Lemna gibba G3) Bayer CropScience, Stilwell, KS, USA Bayer CropScience AG, Report No.: EBGSP070, Edition Number: M-285458-01-1 Date: 15.03.2007 GLP, unpublished	No	Bayer Crop Science

Data Point	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant) Published or not	Verte-brate study Y/N	Owner
KIIA 8.6 /03	Christ, M. T.; Lam, C. V.	2007	Toxicity of BYH 18636 technical to the aquatic macrophyte Myriophyllum spicatum, during a 14-day exposure and 14-day recovery period Bayer CropScience, Stilwell, KS, USA Bayer CropScience AG, Report No.: EBGSP077, Edition Number: M-285462-01-1 Date: 15.03.2007 GLP, unpublished	No	Bayer Crop Science
KIIA 8.6 /04	Hoberg, J. R.	2007	BYH 18636 - comparative toxicity to three aquatic macrophytes during a 14-day exposure followed by a 14-day recovery period Springborn Laboratories, Inc., Wareham, MA, USA Bayer CropScience AG, Report No.: EBGSP086, Edition Number: M-284928-01-2 Date: 08.03.2007 GLP, unpublished	No	Bayer Crop Science
KIIA 8.6 /05	Banman, C. S.; Lam, C. V.	2005	Toxicity of BYH 18636 carboxylic acid to duckweed (Lemna gibba G3) under static-renewal conditions Bayer CropScience, Stilwell, KS, USA Bayer CropScience AG, Report No.: EBGSP019, Edition Number: M-258496-01-1 Date: 22.09.2005 GLP, unpublished	No	Bayer Crop Science
KIIA 8.6 /06	Dorgerloh, M.	2006	Lemna gibba G3 growth inhibition test with BYH 18636 -sulfonamide-carboxylic acid under static conditions Bayer CropScience AG, Report No.: EBGSP042, Edition Number: M-273657-02-2 Date: 27.06.2006***, Amended: 17.11.2006*** GLP, unpublished	No	Bayer Crop Science

Data Point	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant) Published or not	Verte-brate study Y/N	Owner
KIIA 8.6 /07	Christ, M. T; Lam, C. V.	2006	Toxicity of BYH 18636 sulfonamide (a metabolite of BYH 18636) to duckweed (Lemna gibba G3) under static-renewal conditions Bayer CropScience, Stilwell, KS, USA Bayer CropScience AG, Report No.: EBGSP029, Edition Number: M-284166-01-1 Date: 13.12.2006 GLP, unpublished	No	Bayer Crop Science
KIIA 8.6 /08	Christ, M. T; Lam, C. V.	2007	Toxicity of BYH 18636 MMT (a metabolite of BYH 18636) to duckweed (Lemna gibba G3) under static-renewal conditions Bayer CropScience, Stilwell, KS, USA Bayer CropScience AG, Report No.: EBGSP040, Edition Number: M-283972-01-1 Date: 17.01.2007 GLP, unpublished	No	Bayer Crop Science
KIIA 8.6 /09	Christ, M. T; Hoff-mann, J. M.; Lam, C. V.	2007	Toxicity of BYH 18636-dicarboxy-sulfonamide (a metabolite of BYH 18636) to duckweed (Lemna gibba G3) under static-renewal conditions Bayer CropScience, Stilwell, KS, USA Bayer CropScience AG, Report No.: EBGSP045, Edition Number: M-283800-01-1 Date: 08.01.2007 GLP, unpublished	No	Bayer Crop Science
KIIA 8.7.1 /01	Barth, M.	2005	Acute toxicity of BYH 18636 a.i. tech. to the honeybee Apis mellifera L. under laboraotry conditions BioChem agrar, Gerichshain, Germany Bayer CropScience AG, Report No.: 05 10 48 030, Edition Number: M-253914-01-2 Date: 27.06.2005 GLP, unpublished	No	Bayer Crop Science

Data Point	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant) Published or not	Verte-brate study Y/N	Owner
KIIA 8.8.1.1 /01	Waltersdor-fer, A.	2006	Toxicity to the parasitoid wasp Aphidius rhopalosiphi (DeStephani-Perez) (Hymenoptera: Braco-nidae) in the laboratory - BYH 18636 & AE 0001789 SC 225 + 225 g/l Bayer CropScience GmbH, Frankfurt am Main, Germany Bayer CropScience AG, Report No.: CW06/004, Edition Number: M-269942-01-2 Date: 27.04.2006 GLP, unpublished	No	Bayer Crop Science
KIIA 8.8.1.2 /01	Waltersdor-fer, A.	2006	Toxicity to the predatory mite Typhlodromus pyri Scheuten (Acari, Phytoseiidae) in the laboratory BYH 18636 & AE 0001789 SC 225 + 225 g/l Bayer CropScience GmbH, Frankfurt am Main, Germany Bayer CropScience AG, Report No.: CW06/006, Edition Number: M-270231-01-3 Date: 05.05.2006 GLP, unpublished	No	Bayer Crop Science
KIIA 8.9.1 /01	Heimbach, F.	2005	BYH 18636 (tech.): Acute toxicity to earthworms (Eisenia fetida) tested in artificial soil Bayer CropScience AG, Report No.: LKC/RG-A-59/05, Edition Number: M-262506-01-2 Date: 13.12.2005 GLP, unpublished	No	Bayer Crop Science
KIIA 8.9.1 /02	Friedrich, S.	2005	BYH 18636 carboxylic acid: Acute toxicity to the earthworm Eisenia fetida in artificial soil BioChem agrar, Gerichshain, Germany Bayer CropScience AG, Report No.: 05 10 48 058, Edition Number: M-259511-01-2 Date: 27.10.2005 GLP, unpublished	No	Bayer Crop Science

Data Point	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant) Published or not	Verte-brate study Y/N	Owner
KIIA 8.9.2 /01	Friedrich, S.	2006	BYH 18636 & AE 0001789 SC 450: Sublethal toxicity to the earthworm Eisenia fetida in artificial soil BioChem agrar, Gerichshain, Germany Bayer CropScience AG, Report No.: 06 10 48 099, Edition Number: M-277481-01-2 Date: 13.09.2006 GLP, unpublished	No	Bayer Crop Science
KIIA 8.9.2 /02	Lechelt-Kunze, C.	2005	BYH 18636-carboxylic acid (technical): Effects on survival, growth and reproduction on the earth-worm Eisenia fetida tested in artificial soil Bayer CropScience AG, Report No.: LKC-RG-R-17/05, Edition Number: M-260378-01-2 Date: 11.11.2005 GLP, unpublished	No	Bayer Crop Science
KIIA 8.9.2 /03	Friedrich, S.	2006	BYH 18636-sulfonamide: Sublethal toxicity to the earthworm Eisenia fetida in artificial soil BioChem agrar, Gerichshain, Germany Bayer CropScience AG, Report No.: 06 10 48 063, Edition Number: M-275605-01-2 Date: 01.08.2006 GLP, unpublished	No	Bayer Crop Science
KIIA 8.9.2 /04	Luehrs, U.	2006	BYH 18636-sulfonamide-carboxylic acid: effects on reproduction and growth of earthworms Eisenia fetida in artificial soil Ibacon GmbH, Rossdorf, Germany Bayer CropScience AG, Report No.: 28471022, Edition Number: M-269975-01-2 Date: 24.04.2006 GLP, unpublished	No	Bayer Crop Science

Data Point	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant) Published or not	Verte-brate study Y/N	Owner
KIIA 8.9.2 /05	Luehrs, U.	2006	BYH 18636-MMT: Effects on reproduction and growth of earthworms Eisenia fetida in artificial soil Ibacon GmbH, Rossdorf, Germany Bayer CropScience AG, Report No.: 28461022, Edition Number: M-269458-01-2 Date: 10.04.2006 GLP, unpublished	No	Bayer Crop Science
KIIA 8.10.1 /01	Lechelt-Kunze, C.	2005	BYH 18636 tech.: determination of effects on nitrogen transformation in soil Bayer CropScience AG, Report No.: LKC-N-55/05, Edition Number: M-259518-01-2 Date: 27.10.2005 GLP, unpublished	No	Bayer Crop Science
KIIA 8.10.1 /02	Lechelt-Kunze, C.	2005	Metabolite BYH 18636-carboxylic acid: Determination of effects on nitrogen transformation in soil Bayer CropScience AG, Report No.: LKC-N-56/05, Edition Number: M-259751-01-2 Date: 03.11.2005 GLP, unpublished	No	Bayer Crop Science
KIIA 8.10.1 /03	xxx	2006	Metabolite BYH 18636-sulfonamide: Determination of effects on nitrogen transformation in soil xxx Report No.: LKC-N-66/06, Edition Number: M-269346-01-2 Date: 10.04.2006 GLP, unpublished	Yes	BCS
KIIA 8.10.1 /04	Heimbach, F.	2006	Metabolite BYH 18636-sulfonamide-carboxylic acid: Determination of effects on nitrogen transformation in soil Bayer CropScience AG, Report No.: LKC-N-67/06, Edition Number: M-268712-01-2 Date: 31.03.2006 GLP, unpublished	No	Bayer Crop Science

Data Point	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant) Published or not	Verte-brate study Y/N	Owner
KIIA 8.10.1 /05	Heimbach, F.	2006	Metabolite BYH 18636-MMT: Determination of effects on nitrogen transformation in soil Bayer CropScience AG, Report No.: LKC-N-65/06, Edition Number: M-268710-01-2 Date: 31.03.2006 GLP, unpublished	No	Bayer Crop Science
KIIA 8.10.2 /01	Lechelt-Kunze, C.	2005	BYH 18636 tech: Determination of effects on carbon transformation in soil Bayer CropScience AG, Report No.: LKC-C-47/05, Edition Number: M-260127-01-2 Date: 08.11.2005 GLP, unpublished	No	Bayer Crop Science
KIIA 8.10.2 /02	Lechelt.Kunze, C.	2005	Metabolite BYH 18636-carboxylic acid: Determination of effects on carbon transformation in soil Bayer CropScience AG, Report No.: LKC-C-48/05, Edition Number: M-260363-01-2 Date: 14.11.2005 GLP, unpublished	No	Bayer Crop Science
KIIA 8.11.1 /01	Banman, C. S.; Lam, C. V.	2005	Acute toxicity of BYH 18636 technical to the sheepshead minnow (Cyprinodon variegatus) under static conditions Bayer CropScience, Stilwell, KS, USA Bayer CropScience AG, Report No.: EBGSM011, Edition Number: M-252017-01-1 Date: 27.05.2005 GLP, unpublished	No	Bayer Crop Science
KIIA 8.11.1 /02	Cafarella, M. A.	2006	BYI 08330 technical - Acute toxicity to eastern oysters (Crassostrea virginica) under flow-through conditions Springborn Smithers Laboratories, Wareham, MA, USA Bayer CropScience AG, Report No.: EBGSP010, Edition Number: M-281935-01-1 Date: 20.11.2006 GLP, unpublished	No	Bayer Crop Science

Data Point	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant) Published or not	Verte-brate study Y/N	Owner
KIIA 8.11.1 /03	Putt, A. E.	2006	BYH 18636 technical - Acute toxicity to mysids (Americamysis bahia) under flow-through conditions Springborn Smithers Laboratories, Wareham, MA, USA Bayer CropScience AG, Report No.: EBGSP011, Edition Number: M-281936-01-1 Date: 01.09.2006 GLP, unpublished	No	Bayer Crop Science
KIIA 8.11.1 /04	Putt, A. E.	2006	BYH 18636 technical - Life-cycle toxicity test with mysids (Americamysis bahia) Springborn Smithers Laboratories, Wareham, MA, USA Bayer CropScience AG, Report No.: EBGSP004, Edition Number: M-281198-01-2 Date: 22.11.2006 GLP, unpublished	No	Bayer Crop Science
KIIA 8.11.1 /05	Christ, M. T.; Lam, C. V.	2006	Toxicity of BYH 18636 technical to the saltwater diatom Skeletonema costatum Bayer CropScience, Stilwell, KS, USA Bayer CropScience AG, Report No.: EBGSM017, Edition Number: M-281203-01-1 Date: 12.07.2006 GLP, unpublished	No	Bayer Crop Science
KIIA 8.12 /01	Pallett, K.; Nguyen, D. H.; Gosch, H.; Bach, F.	2006	BYH 18636 + AE 0001789 SC 450 Effects on eleven species of non-target terrestrial plants: seedling emergence and seedling growth test (Tier 2) Bayer CropScience GmbH, Frankfurt am Main, Germany Bayer CropScience AG, Report No.: SE 06/001, Edition Number: M-281379-01-2 Date: 12.12.2006 GLP, unpublished	No	Bayer Crop Science

Data Point	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant) Published or not	Verte-brate study Y/N	Owner
KIIA 8.12 /02	Bach, F.; Pallett, K.	2007	Higher tier non target terrestrial plant study on the seedling emergence and growth of 4 plant species under semi-field conditions. The phytotoxic effects of TCM + CSA SC 225 + 225 G (thiencarba-zone-methyl + cyprosulfamide SC 225 + 225 G/L) Bayer CropScience GmbH, Frankfurt am Main, Germany Bayer CropScience AG, Report No.: HT06/041-A1, Edition Number: M-282887-02-2 Date: 26.01.2007***, Amended: 26.02.2007*** GLP, unpublished	No	Bayer Crop Science
KIIA 8.12 /03	Pallett, K.; Nguyen, D. H.; Gosch, H.	2006	BYH 18636 + AE 0001789 SC 450 effects on eleven species of non-target terrestrial plants: vegeta-tive vigour test (tier 2) Bayer CropScience GmbH, Frankfurt am Main, Germany Bayer CropScience AG, Report No.: VV 06/002, Edition Number: M-281425-01-2 Date: 13.12.2006 GLP, unpublished	No	Bayer Crop Science
KIIA 8.12 /04	Bach, F.; Pallett, K.	2006	Higher tier non target terrestrial plant study on the vegetative vigour test of 3 plant species deter-mined under semi-field conditions. The phytotoxic effects of BYH 18636 + AE 0001789 SC 225 + 225 (thiencarbazone-methyl + cyprosulfamide) Bayer CropScience GmbH, Frankfurt am Main, Germany Bayer CropScience AG, Report No.: HT06/040-A1, Edition Number: M-281484-02-2 Date: 14.12.2006***, Amended: 23.02.2007*** GLP, unpublished	No	Bayer Crop Science
KIIA 8.12 /05	Hess, M.	2006	Evaluation of the pre-emergence biological activity of AE 1394083, the carboxylic acid of thien-carbazone.methyl Bayer CropScience GmbH, Frankfurt am Main, Germany Bayer CropScience AG, Report No.: PP03067, Edition Number: M-274414-02-1 Date: 22.06.2006 Non GLP, unpublished	No	Bayer Crop Science

Data Point	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant) Published or not	Verte-brate study Y/N	Owner
KIIA 8.12 /06	Hess, M.	2006	Evaluation of the post-emergence biological activity of AE 1394083, the carboxylic acid of thien-carbazone-methyl Bayer CropScience GmbH, Frankfurt am Main, Germany Bayer CropScience AG, Report No.: PP04013, Edition Number: M-274413-02-1 Date: 22.06.2006 Non GLP, unpublished	No	Bayer Crop Science
KIIA 8.13 /01	xxx	2007	Comment on the extrapolation of LD50 values from acute oral toxicity tests in rodents xxx, Report No.: M-284766-01-1, Edition Number: M-284766-01-1 Date: 07.03.2007 Non GLP, unpublished	No	Bayer Crop Science
KIIA 8.15 /01	Weyers, A.	2005	BYH 18636 - Toxicity to bacteria Bayer Industry Services, Leverkusen, Germany Bayer CropScience AG, Report No.: 2005/0059/01, Edition Number: M-256617-01-2 Date: 23.08.2005 GLP, unpublished	No	Bayer Crop Science
KIIA 8.15 /02	Weyers, A.	2005	BYH 18636 carboxylic acid - Toxicity to bacteria Bayer Industry Services, Leverkusen, Germany Bayer CropScience AG, Report No.: 2005/0067/01, Edition Number: M-256620-01-2 Date: 22.08.2005 GLP, unpublished	No	Bayer Crop Science
KIIA 8.15 /03	Weyers, A.	2005	BYH 18636-Sulfonamide - Toxicity to bacteria Bayer Industry Services GmbH, Leverkusen, Germany Bayer CropScience AG, Report No.: 1354 N/05 B, Edition Number: M-253800-01-2 Date: 31.05.2005 GLP, unpublished	No	Bayer Crop Science

Data Point	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant) Published or not	Verte-brate study Y/N	Owner
KIIA 8.16.1 /01	Frommholz, U.	2006	BYH 18636 tech.: Influence on the reproduction of the collembola species Folsomia candida tested in artificial soil Bayer CropScience AG, Report No.: FRM-COLL-46/06, Edition Number: M-275211-01-2 Date: 31.07.2006 GLP, unpublished	No	Bayer Crop Science
KIIA 8.16.1 /02	Frommholz, U.	2005	BYH 18636-carboxylic acid: Influence on the reproduction of the collembola species Folsomia candida tested in artificial soil Bayer CropScience AG, Report No.: LKC-COLL-44/05, Edition Number: M-262498-01-2 Date: 13.12.2005 GLP, unpublished	No	Bayer Crop Science
KIIA 8.16.1 /03	Friedrich, S.	2006	BYH 18636-sulfonamide-carboxylic acid: Effects on the reproduction of the collembolans Folsomia candida BioChem agrar, Gerichshain, Germany Bayer CropScience AG, Report No.: 06 10 48 168, Edition Number: M-280689-01-2 Date: 28.11.2006 GLP, unpublished	No	Bayer Crop Science
KIIA 8.16.1 /04	Friedrich, S.	2006	BYH 18636-MMT: Effects on the reproduction of the collembolans Folsomia candida BioChem agrar, Gerichshain, Germany Bayer CropScience AG, Report No.: 06 10 48 167, Edition Number: M-280552-01-2 Date: 24.11.2006 GLP, unpublished	No	Bayer Crop Science

Data Point	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant) Published or not	Verte-brate study Y/N	Owner
KIIA 8.16.1 /05	Friedrich, S.	2006	BYH 18636-triazolinone-carboxamide: Effects on the reproduction of the collembolans Folsomia candida BioChem agrar, Gerichshain, Germany Bayer CropScience AG, Report No.: 06 10 48 169, Edition Number: M-280750-01-2 Date: 29.11.2006 GLP, unpublished	No	Bayer Crop Science
KIIA 8.16.2 /01	Leicher, T.	2006	BYH 18636-carboxylic acid: Effects on soil litter degradation Bayer CropScience AG, Report No.: LRT-SLD 30/06, Edition Number: M-280506-02-2 Date: 23.11.2006***, Amended: 13.02.2007*** GLP, unpublished	No	Bayer Crop Science
KIIA 8.16.2 /02	McMillan-Staff, S.; Thomas, J.	2006	Residues of thiencarbazone-methyl on corn - Proposal for a DT50 calculation Bayer CropScience SA, Lyon, France Bayer CropScience AG, Report No.: M-280632-02-1, Edition Number: M-280632-02-1 Date: 11.12.2006 Non GLP, unpublished	No	Bayer Crop Science

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	**Vertebrate study Y/N**	**Owner**
KCP XX	Author	YYYY	Title Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

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

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	**Vertebrate study Y/N**	**Owner**
KCP XX	Author	YYYY	Title Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

Appendix 2 Detailed evaluation of the new studies

A 2.1 KCP 10.1 Effects on birds and other terrestrial vertebrates

A 2.1.1 KCP 10.1.1 Effects on birds

A 2.1.1.1 KCP 10.1.1.1 Acute oral toxicity

A 2.1.1.2 KCP 10.1.1.2 Higher tier data on birds

A 2.1.2 KCP 10.1.2 Effects on terrestrial vertebrates other than birds

A 2.1.2.1 KCP 10.1.2.1 Acute oral toxicity to mammals

A 2.1.2.2 KCP 10.1.2.2 Higher tier data on mammals

A 2.1.3 KCP 10.1.3 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians)

A 2.2 KCP 10.2 Effects on aquatic organisms

Comments of zRMS:	Additional information.

Reference:	**KCP 10.2/01**
Title:	Predicting the environmental fate and ecotoxicological and toxicological effects of pesticide transformation products
Report:	Sinclair, C. J.; 2009; M-551653-01-1
Authority registration No:	
Guideline(s):	none
Deviations:	none
GLP/GEP:	no
Acceptability:	
Duplication (if vertebrate study):	

The overall aim of this work was to investigate and develop pragmatic approaches for assessing the fate and effects of pesticides transformation products in the absence of experimentally determined data. Specific objectives were:
1. To identify relationships that exist between parent pesticides and their transformation products in terms of the physico-chemical properties, ecotoxicology and toxicology;
2. To identify and evaluate methods by which the most important physico-chemical properties and effects of transformation products can be estimated;
3. To develop approaches for assessing the ecotoxicity, toxicity and pesticidal activity (e.g. fungicidal activity) of transformation products to non-target organisms;

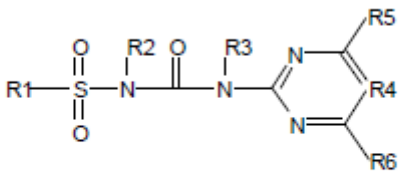
4. To develop methodologies for identifying and ranking those transformation products that could pose the greatest risk to the public through exposure via drinking water.

The summary below will not address all these objectives but only those related to the identification of toxophores in pesticide active substances.

Materials and Methods:
Information on the identity, physico-chemical properties, ecotoxicity, and fate and behaviour of both pesticides and their transformation products was gathered from multiple sources (open literature, databases, UK authority reports). Data quality was checked in the original citation according to the following rules: 1) when a large number of data points were available on a particular substance from a number of sources and where the values for one or more of the data points exhibited a large difference compared to the majority of the data points; and 2) when three or fewer data points were reported for a particular substance. If appropriate, the data were revised in light of the Results of the quality assessment.
The ecotoxicity data for transformation products and their parent compound were compared to determine whether the transformation products had similar ecotoxicity or were more or less toxic.
Toxophores for each of the major classes of pesticides were identified by looking for sub-structural similarities within a pesticide class. The structure of each transformation product for which ecotoxicity data were available was then examined to determine whether or not it contained a pesticide toxophore.

Results and Discussion:
Using the search strategy, information was obtained on the transformation pathways of 60 active substances and based on these pathways; the structures of 485 transformation products were identified. The active substances examined covered a range of pesticide classes and included 27 herbicides, 20 insecticides, 12 fungicides and one compound used as an herbicide, fungicide and insecticide. All the major classes of pesticides were represented by at least one active substance.
The final database only comprised property and ecotoxicity values for 89 transformation products arising from 37 parent compounds. Twenty-three parent compounds with identified transformation pathways had either no corresponding data or only unsuitable data for their respective transformation products.
Fifty-four toxophores associated with a wide range of pesticide classes were identified. It was not possible to identify a toxophore for all the active compounds considered in the study. Some pesticide classes contained too few members for reasonable toxophore identification, whilst some compounds had an undefined mode of action and/or were not a member of a defined pesticide class.

Conclusions:
For the substance foramsulfuron, the toxophore is:



sulfonylurea

A 2.2.1 KCP 10.2.1 Acute toxicity to fish, aquatic invertebrates, or effects on aquatic algae and macrophytes

A 2.2.1.1 Fish

Comments of zRMS:	The study is considered valid. **Agreed endpoint:** **$LC_{50\ geomean}$ = 169.2 mg/L**

Reference:	**KCP 10.2.1/01**
Title:	Re-evaluation of acute fish study with metabolite AE F092944 (M-131422-01-1) in context of mesosulfuron approval renewal (EFSA request, Point 33)
Report:	xxx.; 2016; M-549001-01-1
Authority registration No:	
Guideline(s):	none
Deviations:	none
GLP/GEP:	no
Acceptability:	
Duplication (if vertebrate study):	No

The study reports on a static acute toxicity test on rainbow trout with the metabolite amidosulfuron-ADMP. Signs of intoxication were observed at concentrations of 180 mg/L and higher. No fish died at concentrations up to 100 mg/L. 100 % mortality was observed at the test concentrations of 560 mg/L and 1000 mg/L within 24 hours. At the end of test 10 % and 80 % of fish were dead at concentrations of 180 and 320 mg/L. The 96 h LC_{50} value was calculated to be 254 mg metabolite/L. A 96 h NOEC = 100 mg metabolite/L was reported.

The study was evaluated in the EU review for the first inclusion of amidosulfuron on Annex I, a study review is found in the previous DAR (2006).

The oxygen concentration in one sample was lower than 60 % of air saturation. As all other measured values were higher, this single value can be classified as erroneous and does not invalidate the test. Therefore, the study was considered to be acceptable and was used for the risk assessment. An EU agreed endpoint of LC_{50} =254 mg/L was derived from this test.

As measured concentration below 80% were obtained at t=0 for some concentrations, the endpoint has been recalculated on the basis of geometric mean measured concentrations.
Only 3 concentrations out of 8 were analyzed in this study: the lowest (18 mg/L), the middle (100 mg/L) and the highest concentration (1000 mg/L). It is therefore not possible to perform the statistical analysis with each actual mean measured concentration to derive the LC_{50}. Then the concentrations expressed as % of nominal have to be used.
Solubility issues were observed between 56 and 1000 mg/L, with low recoveries at t=0 for 100 and 1000 mg/L. The "nominal" LC_{50} falls in this range (254 mg/L). So, as a worst case, the geometric mean % of nominal for 1000 mg/L is used to recalculate the "mean measured" LC_{50} (Table 1). The geometric mean is selected to follow the recommendations of the guidance document OECD 23 (OECD, 2000) for static tests.

Measured concentrations of AE F09 2944 (% of nominal)

Nominal concentrations	**18 mg/L**	**100 mg/L**	**1000 mg/L**
Day 0	101.1	49.3	49.9
Day 2	102.5	105.5	88.8
Day 4	100.6	103.5	Not analyzed
Geometric mean	**101.7**	**86.8**	**66.6**

In conclusion, the mean measured LC_{50} is 169.2 mg/L.

A 2.2.1.2 Aquatic invertebrates

A 2.2.1.3 Effects on aquatic algae

A 2.2.1.4 Effects on aquatic macrophytes

Comments of zRMS: The study is considered acceptable. All validity criteria were met.
The study was not used in the risk assessment.

Agreed endpoints:

	Effect on mean growth rate of frond number [µg a.s./L]	Effect on mean growth rate of total frond area of plants [µg a.s./L]
Endpoint (0-7 days) **Design 1**:		
E_rC_{50} (95% C.I.):	**18.3 (16.3 – 20.9)**	**9.60 (9.04 – 10.2)**
E_rC_{20} (95% C.I.):	< 1.30	< 1.30
E_rC_{10} (95% C.I.):	< 1.30	< 1.30
LOE_rC: lowest concentration with an effect	≤ 1.30	≤ 1.30
NOE_rC: highest concentration without adverse effects	< 1.30	< 1.30
Endpoint (0-7 days) **Design 2**:		
E_rC_{50} (95% C.I.):	**> 50.0**	**> 50.0**
E_rC_{20} (95% C.I.):	> 50.0	27.6 (23.00 – 34.0)
E_rC_{10} (95% C.I.):	7.32 (3.40 – 11.6)	4.38 (3.14 – 5.66)
LOE_rC: lowest concentration with an effect	8.06	≤ 1.30
NOE_rC: highest concentration without adverse effects	3.24	< 1.30
Endpoint (7-14 days) **Design 2:**		
E_rC_{50} (95% C.I.):	**> 50.0**	**> 50.0**
E_rC_{20} (95% C.I.):	26.6 (21.3 – 34.6)	34.7 (28.4 – 44.2)
E_rC_{10} (95% C.I.):	2.20 (1.39 – 3.10)	5.11 (3.71 – 6.55)
LOE_rC: lowest concentration with an effect	≤ 1.30	≤ 1.30
NOE_rC: highest concentration without adverse effects	< 1.30	< 1.30

Endpoints were based on nominal concentrations.
Design 1: two 24 hour peaks on day 0 and 3
Design 2: two 24 hour peaks on day 0 and 7

Reference:	**KCP 10.2.1/02**
Title:	Amendment no. 2: Lemna gibba G3 - Growth inhibition test with foramsulfuron tech. (BCS-AH47624) under peak exposure conditions
Report:	Kuhl, K.; 2017; EBFS0001; M-572386-03-1
Authority registration No:	
Guideline(s):	EU Directive 91/414/EEC Regulation (EC) Number 1107/2009 US EPA OCSPP 850.4400
Deviations:	none
GLP/GEP:	yes
Acceptability:	
Duplication (if vertebrate study):	

Material and methods:

Test material	Foramsulfuron tech., (BCS-AH47624) Batch No. AE F130360-01-6 Specification: 102000011654-02 98.6 % w/w
Guideline(s) adaptation	Guidelines were adapted to peak exposure conditions and a prolonged study duration (Design 2)
Test species	Duckweed (*Lemna gibba*) strain G3
Acclimation	inoculum pre-culture, preparation 7 – 10 days before the start of the main test cultivation under the same conditions as in main test
Culturing conditions	20X AAP medium 6500 – 7000 lux temperature of 23 - 26° C
Test solutions	Nominal concentrations: 1.30, 3.24, 8.06, 20.1 and 50.0 µg a.s./L Control: water Visual observations of test medium on days 0, 1, 3, 4, 7, 8 gave no evidence of undissolved material
Replication	No. of vessels per concentration (replicates): 3 No. of vessels per control (replicates): 3
Organisms per replicate	No. of fronds per vessel: 12 No. of fronds per plant: 3-4 For Design 2, only 12 fronds of each replicate (from week 1) were transferred into the exposure media before the second peak was set on day 7.
Exposure	Peak exposure following 2 different designs Total study duration: Design 1: 7 days (two 24 hours lasting peaks, day 0 and 3) Design 2: 14 days (two 24 hours lasting peaks on day 0 and 7)
Test conditions	Incubation chamber used: Multitron, Infors GmbH Temperature: 24.1 °C to 24.4 °C Photoperiod: permanent light Light quality: bank light containing fluorescent lamps Light intensity: 6.52 to 6.69 klux pH: 7.5- 7.9 (freshly prepared media), 8.1 – 9.1 (aged media) Growth medium: 20X AAP
Parameters Measured / Observations	Determination of frond number and total frond area on days 0, 2, 4, 7 (design 1 and 2) and on days 9, 11 and 14 (design 2) by computerized image analysis (LemnaTec Scanalyzer) Visual observations of sublethal effects on days 2, 4, 7 (design 1 and 2) and on days 9, 11 and 14 (design 2)

Sampling for chemical analysis	Day 0 (design 1+2), 3 (design 1) and 7 (design 2): fresh media samples were taken from the prepared volume of each test treatment level Day 1 (design 1+2), 4 (design 1) and 8 (design 2): after removing the plant material from the test vessels, all replicates of a treatment level were combined and an aged media sample was taken of the combined replicates. The water samples were analyzed with HPLC-MS/MS.
Data analysis	EC_x calculations were performed by probit analysis using linear max. likelihood regression. Effect thresholds (e.g. NOECs) were determined by Williams Multiple Sequential t-test Procedure following a trend analysis by contrasts. All statistical evaluations were done with ToxRatProfessional Version 3.2.1.

Results:

Validity criteria	**Required**		**Obtained**	
Doubling time	< 2.5 days		1.9 – 2.0 days	
Control CV for growth rate at test termination*	Design 1/ week 1	Design 2/ week 2	Design 1 / week 1	Design 2/ week 2
	< 20 %		4.3 / 3.6 %	2.9 / 0.8 %
Control CV for yield at test termination*	Design 1/ week 1	Design 2/ week 2	Design 1/ week 1	Design 2 / week 2
	< 20 %		11.9 / 10.8 %	7.9 / 8.6 %

* Validity element of OCSPP 850.4400; values are presented for frond number / total frond area

Analytical results:

In the control no test substance was detected. Since correct dosing was proven and since the test item was stable over the exposure periods, the study results are presented based on nominal peak concentrations.

The summarised results of the analytical measurements of foramsulfuron tech. are shown in the following table:

	Design 1 [% of nominal]	**Design 2 [% of nominal]**
Day 0 (freshly prepared)	109 – 112	
Day 1 (aged)	106 – 109	
Day 3 (freshly prepared)	113 – 207*	--
Day 4 (aged)	110 – 199 *	--
Day 7 (freshly prepared)	--	113 – 118
Day 8 (aged)	--	109 – 117

Design 1: two 24 hour peaks on day 0 and 3
Design 2: two 24 hour peaks on day 0 and 7
* The concentrations of 1.30 and 3.24 µg a.s./L were erroneously overdosed by 50 to 100 %. This is not regarded to reduce the reliability of the study for risk assessment purposes as the overdosing represents a worst-case situation.

The detailed results of the analytical measurements of foramsulfuron tech. (**Design 1 and 2, first peak**) are shown in the following table:

Nominal concentration [µg a.s./L]	Day 0 measured concentration* [µg a.s./L]	Day 0 % nominal	Day 1 measured concentration* [µg a.s./L]	Day 1 % nominal
control	< 1.30	--	< 1.30	-
1.30	1.44	111	1.40	108
3.24	3.56	110	3.44	108
8.06	8.76	109	8.60	107
20.1	22.5	112	21.6	107
50.0	55.9	112	54.3	109

* mean value of two measurements
Design 1: two 24 hour peaks on day 0 and 3
Design 2: two 24 hour peaks on day 0 and 7

The detailed results of the analytical measurements of foramsulfuron tech. (**Design 1, second peak**) are shown in the following table:

Nominal concentration [µg a.s./L]	Day 3 measured concentration* [µg a.s./L]	Day 3 % nominal	Day 4 measured concentration* [µg a.s./L]	Day 4 % nominal
control	< 1.30	--	< 1.30	-
1.30	2.69**	207	2.59**	199
3.24	4.54**	140	4.52**	140
8.06	9.07	113	8.90	110
20.1	23.9	119	23.7	118
50.0	56.8	114	56.6	113

* mean value of two measurements
** mean value of four measurements (A and B sample)
Design 1: two 24 hour peaks on day 0 and 3

The detailed results of the analytical measurements of foramsulfuron tech. (**Design 2, second peak**) are shown in the following table:

Nominal concentration [µg a.s./L]	Day 7 measured concentration* [µg a.s./L]	Day 7 % nominal	Day 8 measured concentration* [µg a.s./L]	Day 8 % nominal
control	< 1.30	--	< 1.30	-
1.30	1.52	117	1.48	114
3.24	3.66	113	3.54	109
8.06	9.49	118	9.41	117
20.1	23.3	116	22.9	114
50.0	57.6	115	56.3	113

* mean value of two measurements
Design 2: two 24 hour peaks on day 0 and 7

Biological results:

The following table summarizes the effects on growth rate observed in design 1 after 7 days:

Nominal test concentration [µg a.s./L]	Frond number (day 7) mean values from 3 replicates	Mean growth rate for frond number	Total frond area of plants (day 7) mean values from 3 replicates [mm^2]	Mean growth rate for total frond area of plants	% Inhibition	
					Mean growth rate for frond number	Mean growth rate for total frond area of plants
control	164	0.373	1371	0.374	--	--
1.30	101	0.305●	817	0.293●	18.3●	21.8●
3.24	67.0	0.244●	582	0.242●	34.5●	35.4●
8.06	52.3	0.210●	395	0.190●	43.7●	49.3●
20.1	44.7	0.188●	320	0.146●	49.7●	61.1●
50.0	34.3	0.149●	240	0.110●	60.0●	70.6●

● Results which were significantly different (based on Williams Multiple sequential t-test Procedure) from the control
Design 1: two 24 hour peaks on day 0 and 3

The following table summarizes the effects on growth rate observed in design 2 after 7 days (week 1):

Nominal test concentration [µg a.s./L]	Frond number (day 7) mean values from 3 replicates	Mean growth rate for frond number	Total frond area of plants (day 7) mean values from 3 replicates [mm^2]	Mean growth rate for total frond area of plants	% Inhibition	
					Mean growth rate for frond number	Mean growth rate for total frond area of plants
control	132	0.341	1088	0.334	--	--
1.30	114	0.320	921	0.308●	6.2	7.9●
3.24	120	0.328	982	0.309●	3.8	7.4●
8.06	102	0.305●	811	0.296●	10.7●	11.6●
20.1	88.3	0.284●	688	0.271●	16.7●	18.8●
50.0	85.3	0.280●	661	0.253●	17.9●	24.3●

● Results which were significantly different (based on Williams Multiple sequential t-test Procedure) from the control
Design 2: two 24 hour peaks on day 0 and 7

The following table summarizes the effects on growth rate observed in design 2 after 14 days (week 2):

Nominal test concentration [µg a.s./L]	Frond number (day 7) mean values from 3 replicates	Mean growth rate for frond number	Total frond area of plants (day 7) mean values from 3 replicates [mm^2]	Mean growth rate for total frond area of plants	% Inhibition	
					Mean growth rate for frond number	Mean growth rate for total frond area of plants
control	151	0.362	1266	0.345	--	--
1.30	118	0.326●	953	0.321●	9.8●	6.7●
3.24	116	0.324●	930	0.317●	10.5●	8.1●
8.06	109	0.315●	860	0.308●	12.9●	10.5●
20.1	91.0	0.289●	688	0.285●	20.1●	17.2●
50.0	84.3	0.278●	627	0.267●	23.1●	22.6●

● Results which were significantly different (based on Williams Multiple sequential t-test Procedure) from the control
Design 2: two 24 hour peaks on day 0 and 7

Within 7 days in design 1, sublethal effects in terms of small fronds were observed in each test concentration. In design 2, within the first week, smaller fronds were observed in the concentrations of 20.1and 50.0 µg a.s./L. In the second week smaller fronds were recorded in the test concentration 3.24 to 50.0 µg a.s./L.

Conclusion:

	Effect on mean growth rate of frond number [µg a.s./L]	Effect on mean growth rate of total frond area of plants [µg a.s./L]
Endpoint (0-7 days) **Design 1**:		
E_rC_{50} (95% C.I.):	**18.3 (16.3 – 20.9)**	**9.60 (9.04 – 10.2)**
E_rC_{20} (95% C.I.):	< 1.30	< 1.30
E_rC_{10} (95% C.I.):	< 1.30	< 1.30
LOE_rC: lowest concentration with an effect	≤ 1.30	≤ 1.30
NOE_rC: highest concentration without adverse effects	< 1.30	< 1.30
Endpoint (0-7 days) **Design 2**:		
E_rC_{50} (95% C.I.):	**> 50.0**	**> 50.0**
E_rC_{20} (95% C.I.):	> 50.0	27.6 (23.00 – 34.0)
E_rC_{10} (95% C.I.):	7.32 (3.40 – 11.6)	4.38 (3.14 – 5.66)
LOE_rC: lowest concentration with an effect	8.06	≤ 1.30
NOE_rC: highest concentration without adverse effects	3.24	< 1.30
Endpoint (7-14 days) **Design 2:**		
E_rC_{50} (95% C.I.):	**> 50.0**	**> 50.0**
E_rC_{20} (95% C.I.):	26.6 (21.3 – 34.6)	34.7 (28.4 – 44.2)
E_rC_{10} (95% C.I.):	2.20 (1.39 – 3.10)	5.11 (3.71 – 6.55)
LOE_rC: lowest concentration with an effect	≤ 1.30	≤ 1.30
NOE_rC: highest concentration without adverse effects	< 1.30	< 1.30

Endpoints were based on nominal concentrations.
Design 1: two 24 hour peaks on day 0 and 3
Design 2: two 24 hour peaks on day 0 and 7

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Comments of zRMS: The study is considered acceptable. All validity criteria were met.
The study is not used in the risk assessment.

Agreed endpoints:

	Effect on mean growth rate of frond number [µg p.m./L]	Effect on mean growth rate of total frond area of plants [µg p.m./L]
Endpoint (0-7 days) **Design 1**:		
E_rC_{50} (95% C.I.):	**53.4 (45.3 – 64.5)**	**22.1 (20.6 – 23.9)**
E_rC_{20} (95% C.I.):	1.34 (1.02 – 1.70)	0.840 (0.712 – 0.976)

	E_rC_{10} (95% C.I.):	< 1.30	< 1.30
	LOE_rC: lowest concentration with an effect	≤ 1.30	≤ 1.30
	NOE_rC: highest concentration without adverse effects	< 1.30	< 1.30
	Endpoint (0-7 days) **Design 2**:		
	E_rC_{50} (95% C.I.):	**> 70.0**	**> 70.0**
	E_rC_{20} (95% C.I.):	25.0 (15.8 – 44.7	8.25 (4.64 – 13.0)
	E_rC_{10} (95% C.I.):	< 1.30	< 1.30
	LOE_rC: lowest concentration with an effect	≤ 1.30	≤ 1.30
	NOE_rC: highest concentration without adverse effects	< 1.30	< 1.30
	Endpoint (7-14 days) **Design 2:**		
	E_rC_{50} (95% C.I.):	**> 70.0**	**> 70.0**
	E_rC_{20} (95% C.I.):	> 70.0	> 70.0
	E_rC_{10} (95% C.I.):	1.39 (0.182 – 3.36)	4.69 (2.95 – 6.61)
	LOE_rC: lowest concentration with an effect	≤ 1.30	≤ 1.30
	NOE_rC: highest concentration without adverse effects	< 1.30	< 1.30
	Endpoints were based on nominal concentrations. Design 1: two 24 hour peaks on day 0 and 3 Design 2: two 24 hour peaks on day 0 and 7		

Reference:	**KCP 10.2.1/03**
Title:	Lemna gibba G3 - Growth inhibition test with AE F130619 (BCS-AU59648) under peak exposure conditions - Final Report -
Report:	Kuhl, K.; 2016; EBFS0002; M-574191-01-1
Authority registration No:	
Guideline(s):	OECD Guideline 221 (March 23, 2006), US EPA OCSPP 850.4400
Deviations:	During the period of test preparation on day 0 and 7, the pH had risen from initial 7.5 (as recommended in the guideline) before test start to a pH of 7.7 and 7.9, respectively, in the controls at start of the exposures. This pH had no negative effect on Lemna growth as shown in a doubling time clearly below the validity criterion of 2.5 days doubling time. The medium for day 0 and 7 was prepared 3 days before use instead of 1 to 2 days as defined in the OECD guideline. Since this recommendation in the guideline was made to allow the pH to stabilize, this deviation has no impact on the outcome of the study. In replicate 1, concentration 3.52 µg p.m./L, design 1, 14 instead of 12 fronds were introduced in the test at day 0 (instead of 12) as given in the guideline and study plan. This replicate was excluded from the statistical evaluation. Between day 4 and 7 the pH in the control of design 1 shifted by more than 1.5 units as recommended in the guideline. Since all validity criteria were met, this deviation has no impact in the validity of the study.
GLP/GEP:	yes
Acceptability:	
Duplication (if vertebrate study):	

Material and methods:

Test material	AE F130619, (BCS-AU59648) Batch No. AE F130619-01-01 Specification: not specified 94.2 % w/w
Guideline(s) adaptation	Guidelines were adapted to peak exposure conditions and a prolonged study duration (Design 2)
Test species	Duckweed (*Lemna gibba*) strain G3
Acclimation	inoculum pre-culture, preparation 7 – 10 days before the start of the main test cultivation under the same conditions as in main test
Culturing conditions	20X AAP medium 6500 – 7000 lux temperature of 23 - 26° C
Test solutions	Nominal concentrations: 1.30, 3.52, 9.54, 25.8 and 70.0 µg p.m./L Control: water Visual observations of test medium on days 0, 1, 3, 4, 7, 8 gave no evidence of undissolved material
Replication	No. of vessels per concentration (replicates): 3 No. of vessels per control (replicates): 3
Organisms per replicate	No. of fronds per vessel: 12 No. of fronds per plant: 3-4 For Design 2, only 12 fronds of each replicate (from week 1) were transferred into the exposure media before the second peak was set on day 7.
Exposure	Peak exposure following 2 different designs Total study duration: Design 1: 7 days (two 24 hours lasting peaks, day 0 and 3) Design 2: 14 days (two 24 hours lasting peaks on day 0 and 7)
Test conditions	Incubation chamber used: Multitron, Infors GmbH

	Temperature: 24.2 °C to 24.5 °C Photoperiod: permanent light Light quality: bank light containing fluorescent lamps Light intensity: 6.53 to 6.71 klux pH: 7.5- 8.1 (freshly prepared media), 8.1 – 9.1 (aged media) Growth medium: 20X AAP
Parameters Measured / Observations	Determination of frond number and total frond area on days 0, 2, 4, 7 (design 1 and 2) and on days 9, 11 and 14 (design 2) by computerized image analysis (LemnaTec Scanalyzer) Visual observations of sublethal effects on days 2, 4, 7 (design 1 and 2) and on days 9, 11 and 14 (design 2)
Sampling for chemical analysis	Day 0 (design 1+2), 3 (design 1) and 7 (design 2): fresh media samples were taken from the prepared volume of each test treatment level Day 1 (design 1+2), 4 (design 1) and 8 (design 2): after removing the plant material from the test vessels, all replicates of a treatment level were combined and an aged media sample was taken of the combined replicates. The water samples were analyzed with HPLC-MS/MS.
Data analysis	EC_x calculations were performed by probit analysis using linear max. likelihood regression. Effect thresholds (e.g. NOECs) were determined by Williams Multiple Sequential t-test Procedure following a trend analysis by contrasts. All statistical evaluations were done with ToxRatProfessional Version 3.2.1.

Results:

Validity criteria	**Required**		**Obtained**	
Doubling time	< 2.5 days		1.8 – 1.9 days	
Control CV for growth rate at test termination*	Design 1/ week 1	Design 2/ week 2	Design 1/ week 1	Design 2/ week 2
	< 20 %		4.5 / 4.6 %	3.4 / 3.2 %
Control CV for yield at test termination*	Design 1/ week 1	Design 2/ week 2	Design 1/ week 1	Design 2/ week 2
	< 20 %		13.3 / 13.6 %	9.7 / 9.8 %

* Validity element of OCSPP 850.4400; values are presented for frond number / total frond area

Analytical results:

In the control no test substance was detected. Since correct dosing was proven and since the test item was stable over the exposure periods, the study results are presented based on nominal peak concentrations.

The summarised results of the analytical measurements of AE F130619 are shown in the following table:

	Design 1 [% of nominal]	**Design 2 [% of nominal]**
Day 0 (freshly prepared)	89 – 100	
Day 1 (aged)	88 – 98	
Day 3 (freshly prepared)	88 – 99	--
Day 4 (aged)	74* – 97	--
Day 7 (freshly prepared)	--	90 – 99
Day 8 (aged)	--	90 – 97

Design 1: two 24 hour peaks on day 0 and 3
Design 2: two 24 hour peaks on day 0 and 7
* Only the aged medium of the treatment level 1.30 µg p.m./L showed a concentration below the range of 80-120% of nominal.

The detailed results of the analytical measurements of AE F130619 (**Design 1 and 2, first peak**) are shown in the following table:

Nominal concentration [µg p.m./L]	Day 0 measured concentration [µg p.m./L]	Day 0 % nominal	Day 1 measured concentration [µg p.m./L]	Day 1 % nominal
control	< 0.100	--	< 0.100	--
1.30	1.16	89	1.13	88
3.52	3.36	95	3.26	93
9.54	9.27	97	9.00	94
25.8	25.7	100	25.2	98
70.0	67.6	97	66.9	96

Design 1: two 24 hour peaks on day 0 and 3
Design 2: two 24 hour peaks on day 0 and 7

The detailed results of the analytical measurements of AE F130619 (**Design 1, second peak**) are shown in the following table:

Nominal concentration [µg p.m./L]	Day 3 measured concentration [µg p.m./L]	Day 3 % nominal	Day 4 measured concentration [µg p.m./L]	Day 4 % nominal
control	< 0.100	--	< 0.100	--
1.30	1.14	88	0.96	74*
3.52	3.35	95	2.88	82
9.54	9.09	95	8.76	92
25.8	25.4	99	24.8	96
70.0	68.7	98	67.8	97

* the only measured value below the nominal range
Design 1: two 24 hour peaks on day 0 and 3

The detailed results of the analytical measurements of AE F130619 (**Design 2, second peak**) are shown in the following table:

Nominal concentration [µg p.m./L]	Day 7 measured concentration [µg p.m./L]	Day 7 % nominal	Day 8 measured concentration [µg p.m./L]	Day 8 % nominal
control	< 0.100	--	< 0.100	--
1.30	1.22	94	1.17	90
3.52	3.39	96	3.25	92
9.54	8.56	90	9.11	96
25.8	25.5	99	25.0	97
70.0	68.4	98	67.5	96

Design 2: two 24 hour peaks on day 0 and 7

Biological results:

The following table summarizes the effects on growth rate observed in design 1 after 7 days:

Nominal test concentration [µg p.m./L]	Frond number (day 7) mean values from 3 replicates	Mean growth rate for frond number	Total frond area of plants (day 7) mean values from 3 replicates [mm^2]	Mean growth rate for total frond area of plants	% Inhibition	
					Mean growth rate for frond number	Mean growth rate for total frond area of plants
control	181	0.387	1591	0.376	--	--
1.30	112	0.318●	883	0.293●	17.6●	22.2●
3.52	76.5	0.265●	631	0.2487●	31.6●	34.2●
9.54	68.7	0.249●	534	0.219●	35.6●	41.8●
25.8	61.7	0.233●	432	0.188●	39.8●	49.9●
70.0	41.7	0.178●	296	0.142●	54.1●	62.3●

● Results which were significantly different (based on Williams Multiple sequential t-test Procedure) from the control
Design 1: two 24 hour peaks on day 0 and 3

The following table summarizes the effects on growth rate observed in design 2 after 7 days (week 1):

Nominal test concentration [µg p.m./L]	Frond number (day 7) mean values from 3 replicates	Mean growth rate for frond number	Total frond area of plants (day 7) mean values from 3 replicates [mm^2]	Mean growth rate for total frond area of plants	% Inhibition	
					Mean growth rate for frond number	Mean growth rate for total frond area of plants
control	158	0.368	1345	0.358	--	--
1.30	125	0.333●	1052	0.310●	9.6●	13.4●
3.52	111	0.316●	869	0.290●	14.1●	19.2●
9.54	102	0.305●	827	0.289●	17.1●	19.3●
25.8	91.0	0.289●	709	0.269●	21.5●	24.9●
70.0	88.0	0.284●	688	0.261●	22.8●	27.1●

● Results which were significantly different (based on Williams Multiple sequential t-test Procedure) from the control
Design 2: two 24 hour peaks on day 0 and 7

The following table summarizes the effects on growth rate observed in design 2 after 14 days (week 2):

Nominal test concentration [µg p.m./L]	Frond number (day 7) mean values from 3 replicates	Mean growth rate for frond number	Total frond area of plants (day 7) mean values from 3 replicates [mm^2]	Mean growth rate for total frond area of plants	% Inhibition	
					Mean growth rate for frond number	Mean growth rate for total frond area of plants
control	155	0.365	1353	0.348	--	--
1.30	124	0.332●	1059	0.324●	9.0●	7.2●
3.52	114	0.322●	978	0.317●	11.9●	9.1●
9.54	110	0.316●	927	0.309●	13.4●	11.4●
25.8	99.3	0.301●	793	0.292●	17.5●	16.1●
70.0	101	0.304●	780	0.289●	16.7●	17.2●

● Results which were significantly different (based on Williams Multiple sequential t-test Procedure) from the control
Design 2: two 24 hour peaks on day 0 and 7

Within 7 days in design 1 and 14 days in design 2 no visual effects of the plants were observed.

Conclusion:

	Effect on mean growth rate of frond number [µg p.m./L]	Effect on mean growth rate of total frond area of plants [µg p.m./L]
Endpoint (0-7 days) **Design 1**:		
E_rC_{50} (95% C.I.):	**53.4 (45.3 – 64.5)**	**22.1 (20.6 – 23.9)**
E_rC_{20} (95% C.I.):	1.34 (1.02 – 1.70)	0.840 (0.712 – 0.976)
E_rC_{10} (95% C.I.):	< 1.30	< 1.30
LOE_rC: lowest concentration with an effect	≤ 1.30	≤ 1.30
NOE_rC: highest concentration without adverse effects	< 1.30	< 1.30
Endpoint (0-7 days) **Design 2**:		
E_rC_{50} (95% C.I.):	**> 70.0**	**> 70.0**
E_rC_{20} (95% C.I.):	25.0 (15.8 – 44.7	8.25 (4.64 – 13.0)
E_rC_{10} (95% C.I.):	< 1.30	< 1.30
LOE_rC: lowest concentration with an effect	≤ 1.30	≤ 1.30
NOE_rC: highest concentration without adverse effects	< 1.30	< 1.30
Endpoint (7-14 days) **Design 2:**		
E_rC_{50} (95% C.I.):	**> 70.0**	**> 70.0**
E_rC_{20} (95% C.I.):	> 70.0	> 70.0
E_rC_{10} (95% C.I.):	1.39 (0.182 – 3.36)	4.69 (2.95 – 6.61)
LOE_rC: lowest concentration with an effect	≤ 1.30	≤ 1.30
NOE_rC: highest concentration without adverse effects	< 1.30	< 1.30

Endpoints were based on nominal concentrations.
Design 1: two 24 hour peaks on day 0 and 3
Design 2: two 24 hour peaks on day 0 and 7

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Comments of zRMS:	The study is not assessed in the context of the Art 43 renewal assessment of foramsulfuron

Reference:	**KCP 10.2.1/04**
Title:	Amendment no.1 - Lemna gibba G3 - Growth inhibition test with thiencarbazone-methyl tech. (BCS-AG17468) under peak exposure conditions - Final report -
Report:	Kuhl, K.; 2016; EBGS0002; M-568404-02-1
Authority registration No:	
Guideline(s):	OECD Guideline 221 (March 23, 2006); US EPA OCSPP 850.4400
Deviations:	The medium for day 0 and 7 was prepared 3 days before use instead of 1 to 2 days as defined in the OECD guideline. Since this recommendation was made to allow the pH to stabilise, this deviation has no impact on the outcome of the study
GLP/GEP:	yes
Acceptability:	
Duplication (if vertebrate study):	

Material and methods:

Test material	Thiencarbazone-methyl tech., (BCS-AG17468) Batch No. BYH 18636-04-05 Specification: 102000021722 97.5 % w/w
Guideline(s) adaptation	Guidelines were adapted to peak exposure conditions and a prolonged study duration (Design 2)
Test species	Duckweed (*Lemna gibba*) strain G3
Acclimation	inoculum pre-culture, preparation 7 – 10 days before the start of the main test cultivation under the same conditions as in main test
Culturing conditions	20X AAP medium 6500 – 7000 lux temperature of 23 - 26° C
Test solutions	Nominal concentrations: 2.00, 4.47, 10.0, 22.4, 50 µg a.s./L Control: water Solvent control: Dimethylformamid (DMF), 100 µl/L added to all concentration levels and the solvent control Evidence of undissolved material: visual observations of test medium on days 0, 1, 3, 4, 7, 8; no visual effects of the test substance were found
Replication	No. of vessels per concentration (replicates): 3 No. of vessels per control (replicates): 3 No. of vessels per solvent control (replicates): 3
Organisms per replicate	No. of fronds per vessel: 12 No. of fronds per plant: 3-4 For Design 2, only 12 fronds of each replicate (from week 1) were transferred into the exposure media before the second peak was set on day 7.
Exposure	Peak exposure following two different designs Total study duration: Design 1: 7 days (two 24 hours lasting peaks, day 0 and 3) Design 2: 14 days (two 24 hours lasting peaks on day 0 and 7)
Test conditions	Incubation chamber used: Multitron, Infors GmbH Temperature: 23.6 °C to 25.5 °C Photoperiod: permanent light Light quality: bank light containing fluorescent lamps

	Light intensity: 6.59 to 6.81 klux pH: 7.4- 7.8 (freshly prepared media), 8.0 – 9.1 (aged media) Growth medium: 20X AAP
Parameters Measured / Observations	Determination of frond number and total frond area on days 2, 4, 7 (design 1 and 2) and on days 9, 11 and 14 (design 2) by computerized image analysis (LemnaTec Scanalyzer) Visual observations of sublethal effects on days 2, 4, 7 (design 1 and 2) and on days 9, 11 and 14 (design 2)
Sampling for chemical analysis	Day 0, 3 and 7 (fresh): samples were taken from the prepared volume of each test treatment level Day 1, 4 and 8 (aged): after removing the plant material from the test vessels, all replicates of a treatment level were combined and a sample was taken of the combined replicates. The water samples were analyzed with HPLC-MS/MS
Data analysis	ECx calculations were performed by probit analysis using linear max. likelihood regression. Effect thresholds (e.g. NOECs) were determined by Williams Multiple Sequential t-test Procedure following a trend analysis by contrasts. Since there were no statistically significant differences between water and solvent controls, controls were pooled for all evaluations. All statistical evaluations were done with ToxRatProfessional Version 3.2.1.

Results:

Validity criteria	**Required**		**Obtained**	
Doubling time	< 2.5 days		1.8 – 1.9 days	
Control CV for growth rate at test termination*	Design 1/ week 1	Design 2/ week 2	Design 1 / week 1	Design 2/ week 2
	< 20 %		3.3 / 3.8 % (6.5 / 4.7 %)	3.5 / 4.6 % (3.0 / 2.2 %)
Control CV for yield at test termination*	Design 1/ week 1	Design 2/ week 2	Design 1/ week 1	Design 2/ week 2
	< 20 %		9.2 / 11.0 % (17.6 / 15.5 %)	9.9 / 7.1 % (8.4 / 8.9 %)

* Validity element of OCSPP 850.4400; values are presented for frond number / total frond area
CVs for solvent control are given in brackets

Analytical results:

In the controls no test substance was detected. Since correct dosing was proven and since the test item was stable over the exposure periods, the study results are presented based on nominal peak concentrations.

The summarised results of the analytical measurements of thiencarbazone-methyl are shown in the following table:

	Design 1 [% of nominal]	**Design 2 [% of nominal]**
Day 0 (freshly prepared)	108 – 114	
Day 1 (aged)	108 – 111	
Day 3 (freshly prepared)	98.4 – 103	--
Day 4 (aged)	97.7 – 103	--
Day 7 (freshly prepared)	--	105 – 112
Day 8 (aged)	--	105 – 112

Design 1: two 24 hour peaks on day 0 and 3
Design 2: two 24 hour peaks on day 0 and 7

The detailed results of the analytical measurements of thiencarbazone-methyl (**Design 1 and 2, first peak**) are shown in the following table:

Nominal concentration [µg a.s./L]	Day 0 measured concentration [µg a.s./L]	Day 0 % nominal	Day 1 measured concentration [µg a.s./L]	Day 1 % nominal
control	< 0.200	--	< 0.200	--
solvent control	< 0.200	--	< 0.200	--
2.00	2.23	112	2.19	109
4.47	4.94	111	4.87	109
10.0	10.8	108	10.8	108
22.4	25.1	112	24.9	111
50.0	56.9	114	55.4	111

Design 1: two 24 hour peaks on day 0 and 3
Design 2: two 24 hour peaks on day 0 and 7

The detailed results of the analytical measurements of thiencarbazone-methyl (**Design 1, second peak**) are shown in the following table:

Nominal concentration [µg a.s./L]	Day 3 measured concentration [µg a.s./L]	Day 3 % nominal	Day 4 measured concentration [µg a.s./L]	Day 4 % nominal
control	< 0.200	--	< 0.200	--
solvent control	< 0.200	--	< 0.200	--
2.00	2.04	102	2.06	103
4.47	4.47	100	4.37	97.7
10.0	9.87	98.4	9.81	98.1
22.4	22.4	100	24.4	109
50.0	51.7	103	51.4	103

Design 1: two 24 hour peaks on day 0 and 3

The detailed results of the analytical measurements of thiencarbazone-methyl (**Design 2, second peak**) are shown in the following table:

Nominal concentration [µg a.s./L]	Day 7 measured concentration [µg a.s./L]	Day 7 % nominal	Day 8 measured concentration [µg a.s./L]	Day 8 % nominal
control	< 0.200	--	< 0.200	--
solvent control	< 0.200	--	< 0.200	--
2.00	2.10	105	2.15	108
4.47	4.68	105	4.68	105
10.0	10.4	104	10.5	105
22.4	24.4	109	24.3	108
50.0	55.8	112	56.0	112

Design 2: two 24 hour peaks on day 0 and 7

Biological results:

The following table summarizes the effects on growth rate observed in design 1 after 7 days:

Nominal test concentration [µg a.s./L]	Frond number (day 7) mean values from 3 replicates	Mean growth rate for frond number	Total frond area of plants (day 7) mean values from 3 replicates [mm^2]	Mean growth rate for total frond area of plants	% Inhibition	
					Mean growth rate for frond number	Mean growth rate for total frond area of plants
control	171	0.379	1434	0.363	--	--
solvent control	158	0.367	1311	0.358	--	--
2.00	67.0	0.245●	607	0.233●	34.2 ●	35.5 ●
4.47	35.7	0.155●	265	0.134●	58.5 ●	62.8 ●
10.0	21.0	0.080●	176	0.075●	78.6 ●	79.1 ●
22.4	17.3	0.052●	149	0.047●	86.0 ●	86.9 ●
50.0	17.3	0.051●	154	0.042●	86.3 ●	88.3 ●

● Results which were significantly different (based on Williams Multiple sequential t-test Procedure) from the pooled controls
Design 1: two 24 hour peaks on day 0 and 3

The following table summarizes the effects on growth rate observed in design 2 after 7 days (week 1):

Nominal test concentration [µg a.s./L]	Frond number (day 7) mean values from 3 replicates	Mean growth rate for frond number	Total frond area of plants (day 7) mean values from 3 replicates [mm^2]	Mean growth rate for total frond area of plants	% Inhibition	
					Mean growth rate for frond number	Mean growth rate for total frond area of plants
control	158	0.367	1319	0.361	--	--
solvent control	165	0.375	1330	0.376	--	--
2.00	106	0.311●	873	0.301●	16.0 ●	18.3 ●
4.47	82.3	0.274●	647	0.246●	26.1 ●	33.2 ●
10.0	67.0	0.245●	540	0.228●	33.9 ●	38.2 ●
22.4	41.3	0.174●	333	0.163●	53.1 ●	55.6 ●
50.0	30.7	0.134●	233	0.107●	63.9 ●	70.8 ●

● Results which were significantly different (based on Williams Multiple sequential t-test Procedure) from the pooled controls
Design 2: two 24 hour peaks on day 0 and 7

The following table summarizes the effects on growth rate observed in design 2 after 14 days (week 2):

Nominal test concentration [µg a.s./L]	Frond number (day 7) mean values from 3 replicates	Mean growth rate for frond number	Total frond area of plants (day 7) mean values from 3 replicates [mm^2]	Mean growth rate for total frond area of plants	% Inhibition	
					Mean growth rate for frond number	Mean growth rate for total frond area of plants
control	164	0.373	1357	0.363	--	--
solvent control	177	0.384	1434	0.371	--	--
2.00	117	0.324●	963	0.316●	14.4 ●	13.9 ●
4.47	83.7	0.277●	644	0.272●	26.8 ●	26.0 ●
10.0	61.3	0.233●	463	0.226●	38.5 ●	38.5 ●
22.4	34.7	0.150●	212	0.128●	60.5 ●	65.1 ●
50.0	23.7	0.096●	130	0.057●	74.5 ●	84.5 ●

● Results which were significantly different (based on Williams Multiple sequential t-test Procedure) from the pooled controls
Design 2: two 24 hour peaks on day 0 and 7

Within 7 days in design 1 and 2, sublethal effects in terms of coalesced plants were observed in the two highest concentrations of 22.4 and 50.0 µg a.s./L. In design 2, within the second week, additionally smaller fronds were observed in the concentrations of 10.0 to 50.0 µg a.s./L.

Conclusion:

	Effect on mean growth rate of frond number	Effect on mean growth rate of total frond area of plants

	[µg a.s./L]	[µg a.s./L]
Endpoint (0-7 days) **Design 1**:		
E_rC_{50} (95% C.I.):	**3.39 (3.14 – 3.63)**	**3.10 (3.01 – 3.18)**
E_rC_{20} (95% C.I.):	< 2.00	< 2.00
E_rC_{10} (95% C.I.):	< 2.00	< 2.00
LOE_rC: lowest concentration with an effect	≤ 2.00	≤ 2.00
NOE_rC: highest concentration without adverse effects	< 2.00	< 2.00
Endpoint (0-7 days) **Design 2**:		
E_rC_{50} (95% C.I.):	**21.3 (18.4 – 25.3)**	**15.7 (14.6 – 17.0)**
E_rC_{20} (95% C.I.):	3.02 (2.26 – 3.80)	2.22 (1.92 – 2.53)
E_rC_{10} (95% C.I.):	< 2.00	< 2.00
LOE_rC: lowest concentration with an effect	≤ 2.00	≤ 2.00
NOE_rC: highest concentration without adverse effects	< 2.00	< 2.00
Endpoint (7-14 days) **Design 2:**		
E_rC_{50} (95% C.I.):	**14.9 (13.6 – 16.4)**	**12.8 (12.2 – 13.3)**
E_rC_{20} (95% C.I.):	3.17 (2.66 – 3.68)	3.59 (3.33 – 3.84)
E_rC_{10} (95% C.I.):	< 2.00	< 2.00
LOE_rC: lowest concentration with an effect	≤ 2.00	≤ 2.00
NOE_rC: highest concentration without adverse effects	< 2.00	< 2.00

Endpoints were based on nominal concentrations.
Design 1: two 24 hour peaks on day 0 and 3
Design 2: two 24 hour peaks on day 0 and 7

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Comments of zRMS:	The study is not assessed in the context of the Art 43 renewal assessment of foramsulfuron

Reference:	**KCP 10.2.1/05**
Title:	Lemna gibba G3 - Growth inhibition test with BYH 18636 (thiencarbazone-methyl) under peak exposure conditions
Report:	Bruns, E.; 2013; EBGSN002; M-462568-01-1
Authority registration No:	
Guideline(s):	Directive 91/414/EEC; Regulation (EC) No 1107/2009
Deviations:	none
GLP/GEP:	yes
Acceptability:	
Duplication (if vertebrate study):	

Material and methods:

Test material	BYH 18636 (thiencarbazone-methyl) Origin batch no: EFTC000017 Specification number 102000021722 Analyzed purity: 98.2 % w/w
Guideline(s) adaptation	Not specified
Test species	Duckweed (*Lemna gibba*) strain G3
Acclimation	inoculum pre-culture, preparation 7 – 10 days before the start of the main test cultivation under the same conditions as in main test
Culturing conditions	Nutrient medium 6500 – 1000 lux temperature of 24 ± 2° C
Test solutions	1st peak nominal concentrations: 0.5, 1.0 and 1.5 µg a.s./L 2nd peak nominal concentrations: 0.3 µg a.s./L (same in all treatment groups) Control and solvent control
Replication	No. of vessels per concentration (replicates): 3 No. of vessels per control (replicates): 3
Organisms per replicate	No. of fronds per vessel: 12
Exposure	Peak exposure conditions Total study duration: 21 days
Test conditions	Incubation chamber used: not specified Temperature: 24.3°C to 25.0 °C Photoperiod: permanent light Light intensity: 6,500-10,000 lux pH: 7.5 at day 0; 8.5 at day 1 (peak 1); 7.5 at day 9; 8.5 at day 10 (peak 2)
Parameters Measured / Observations	Counting of fronds and determination of total frond area was carried out by computerized image analysis (LemnaTec Scanalyzer) Visual observations were made on study days 0, 3, 7, 10, 13, 17 and 21.
Sampling for chemical analysis	Day 0 and day 9 (fresh): Quantitative amounts of BYH 18636 were measured in all freshly prepared test levels and the control Day 1 and day 10 (aged): Quantitative amounts of BYH 18636 were measured in all aged test levels and the control Samples were analyzed with HPLC-MS/MS
Data analysis	The LOE_rC and NOE_rC (using the ANOVA procedure (p = 0.05, one sided) and properly selected multiple t-tests) was directly determined from the raw data Basic calculations were carried out using Microsoft Excel®. All further statistical evaluations were done with ToxRatProfessional

Findings:

Validity criteria:

Validity criterion	Recommended	Obtained
Doubling time of frond number in the control group	< 2.5 days (60 hours)	phase 1: 1.6 days phase 2: 1.7 days

All biological validity criteria for this study were met, requested by the mentioned guidelines.

Analytical findings:

The analytical findings of BYH 18636 in all freshly prepared test levels on day 0 ranged between 95 and 100 % of nominal peak concentrations. For the second peak on day nine the analytical finding was 111 % of nominal peak concentration. No test item was found at any test level in the untreated fresh test media

on day 1 and 10 to which previously exposed plants had been transferred. Thus, no carry-over of the test item occurred.
All reported results are based on nominal initial peak concentrations.

The following table summarizes the analytical findings for the **first peak**

nominal concentrations of BYH 18636 of day 0 [µg a.s./L]	measured concentration of BYH 18636 [µg/L]		recoveries based on nominal test concentrations of day 0 [%]
	treated test medium	untreated test medium	treated test medium
	day 0	day 1	day 0
control	<0.0500	<0.0500	-
solvent control	<0.0500	<0.0500	-
0.50	0.50	<0.0500	100
1.00	0.953	<0.0500	95
1.50	1.48	<0.0500	99

The following table summarizes the analytical findings for the **second peak**

nominal concentrations of BYH 18636 of day 7 [µg a.s./L]	measured concentration of BYH 18636 [µg/L]		recoveries based on nominal test concentrations of day 9 [%]
	treated test medium	untreated test medium	treated test medium
	day 9	day 10	day 10
control	<0.0500	<0.0500	-
solvent control	<0.0500	<0.0500	-
0.30	0.333	<0.0500	111

Biological findings:

The growth inhibition test provided the following tabulated effects:

Nominal test concentration [µg a.s/L]	**0 -3 days**	**3 -7 days**	**7 -9 days**	**9 -10 days**	**10 -13 days**	**13 -17 days**	**17 -21 days**
% Inhibition of mean growth rate of frond number							
0.50	30.3*	-12.5	-3.7	- 8.6	6.8	- 5.9	- 10.7
1.00	24.0*	-7.2	-18.4	- 22.2	8.1	- 3.8	- 10.0
1.50	39.9*	-4.0	-19.0	- 39.5	0.2	- 1.2	6.2
% Inhibition of mean growth rate of frond area							
0.50	15.3*	- 3.2	2.5	16.2	- 1.0	- 3.9	- 18.5
1.00	30.2*	- 9.0	- 12.5	12.0	6.6	- 9.0	- 9.9
1.50	42.4*	- 6.2	- 5.5	4.5	- 2.2	- 5.7	9.5

* Significantly (α=0.05, one-sided smaller) reduced growth compared to the control, based on Williams multiple sequential t-test procedure
Negative values indicate higher growth rate in the test item groups compared to the control

No visual effects were observed.
Results are based on nominal concentrations of the test item.

NOE_rC [µg a.s/L]	**0 -3 days (peak 1)**	**3 -7 days (peak 1)**	**7 -9 days (peak 1)**	**9 -10 days (peak 2)**	**10 -13 days (peak 2)**	**13 -17 days (peak 2)**	**17 -21 days (peak 2)**

Frond number growth rate	<0.50	≥ 1.50	≥ 1.50	≥ 1.50	≥ 1.50	≥ 1.50	≥ 1.50
Frond area growth rate	<0.50	≥ 1.50	≥ 1.50	≥ 1.50	≥ 1.50	≥ 1.50	≥ 1.50

Conclusion:
No statistically significant effects on frond number and total frond area were found for the three concentrations for most of the investigated sections.
There were mainly increases of growth rates compared to the control (i.e. negative inhibitions) or inhibitions which did not exceed the 10% level. Only for the first section (0-3 days), statistically significant inhibitions of growth rates were found at all peak concentrations tested and for both measurement variables, frond number and total frond area.
Correspondingly, except for the first section (0-3 days) with some pronounced short-term effects, all NOE_rC values were calculated as ≥ 1.50 µg a.s./L.

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Comments of zRMS:	The study is not assessed in the context of the Art 43 renewal assessment of foramsulfuron.

Reference:	**KCP 10.2.1/06**
Title:	Toxicity of thiencarbazone-methyl technical to the aquatic macrophyte, myriophyllum spicatum under peak exposure conditions
Report:	Banman, C. S.; Moore, S.; 2013; EBGSN048; M-466233-01-1
Authority registration No:	
Guideline(s):	EU Directive 91/414/EEC Regulation (EC) No.1107/2009 US EPA OCSPP.SUPP
Deviations:	none
GLP/GEP:	yes
Acceptability:	
Duplication (if vertebrate study):	

Material and methods:

Test material	Thiencarbazone-methyl tech. (TCM), (BYH 18636) Batch Code BYH 18636-04-01 Batch number: EFTC000017 Specification No.: 102000021722 Purity: 98.2 % w/w
Guideline(s) adaptation	Not specified
Test species	*Myriophyllum spicatum*
Acclimation	7 days before the start of the main test
Culturing conditions	hard processed water photoperiod of 16 hours light: 8 hours dark temperature of 20 ± 5° C
Test solutions	Nominal concentrations: 1.0, 2.0, 4.0, 8.0 and 16 µg a.s./L Control: water Visual observations of the stock solutions clear and colorless with no visible precipitates
Replication	No. of vessels per concentration and control (replicates): 3

	No. of plants per replicate: 3
Exposure	7-day acclimation period followed by a 24 hour (peak) exposure period and an additional 13 day growth period in dilution water
Test conditions	Temperature: 19.68 to 20.62 °C (mean = 20.23 °C) Photoperiod: 16 hours light Light source: Cool white fluorescent lights Light intensity: 7680 to 8210 lux (mean = 7957 lux) pH: 8.1 (day -7) to 9.8 (day 14) Growth medium: 20X AAP
Parameters Measured / Observations	Growth rate and yield (NOEC, LOEC, EC_{20} and EC_{50}) of total shoot lengths, total plant wet weight and total plant dry weight Measurement technique for shoot length: measurement to the nearest mm using a ruler Measurement technique weights: Wet and dry weight measured to the nearest 0.1 mg on balance Visual observations were performed daily
Sampling for chemical analysis	Day 0, 1 (old and new) and 14 Samples were analyzed with HPLC-MS/MS.
Data analysis	EC_x values were estimated by linear interpolation. No Observed Effects Determinations (using the ANOVA procedure followed by Dunnett's tests ($p \leq 0.05$, one tailed)) was directly determined from the raw data

Findings:

Analytical findings:

Measured recoveries from day 0 and 1 (new and old solutions) ranged from 95 to 110% of the nominal test concentrations. The toxicity values were calculated based on nominal concentrations.
No precipitates were found during the exposure. The concentration of the test item was stable within the test vessels during the 24-hour exposure period (within 20% of initial measured concentrations). Following the exposure period, new (clean) solutions on day 1 and old solutions on day 14 had very minimal recoveries of the test item in a few of the samples and were roughly equal to the LOQ.

The following table summarizes the analytical findings

Nominal Concentration (µg a.i./L)	Day 0 Measured Concentration (µg a.i./L)	Day 0 % Nominal	Day 1 Measured Concentration (old) (µg a.i./L)	Day 1 (old) Percent Nominal	Mean Measured Concentration (µg a.i./L)	Mean Measured % Nominal	Day 1 Measured Concentration (clean) (µg a.i./L)	Day 14 Measured Concentration (clean) (µg a.i./L)
Control	<0.10	na	<0.10	na	<0.10	na	<0.10	<0.10
1.0	1.01	101%	0.98	98%	1.00	100%	<0.10	<0.10
2.0	2.10	105%	2.03	102%	2.07	103%	<0.10	<0.10
4.0	4.41	110%	4.34	109%	4.37	109%	<0.10	0.104
8.0	7.73	97%	7.61	95%	7.67	96%	<0.10	0.102
16	16.2	101%	16.0	100%	16.1	101%	0.104	0.175

Biological findings:

Active growth of the control plants was demonstrated by a total shoot length yield of 36.9 cm. Plants in the control vessels and all treatment groups appeared normal throughout the study. At study termination roots from plants in the three highest treatment levels were observed to have less development than roots in the control group.

The tables below show mean yields and growth rates and their inhibitions for shoot length, wet weight and dry weight.

Nominal Concentration (µg a.i./L)	Length Yield (cm)	Inhibition (%)		Wet Weight Yield (g)	Inhibition (%)		Dry Weight Yield (g)	Inhibition (%)
Control	36.9	NA		1.6002	NA		0.1402	NA
1.0	25.3	31.6	*	1.2543	21.6	*	0.1370	2.3
2.0	21.3	42.4	*	1.2251	23.4	*	0.1351	3.7
4.0	12.1	67.2	*	0.6438	59.8	*	0.1213	13.5
8.0	11.3	69.5	*	0.6967	56.5	*	0.1131	19.4
16	4.1	88.9	*	0.3815	76.2	*	0.1104	21.3

*Statistically significant difference from control (Dunnett's one-tailed test; $p \leq 0.05$).
% Inhibition=100-((Treatment group parameter mean / control parameter mean)*100). These calculations were done in Microsoft Excel, on the unrounded numbers. Manual calculations may vary slightly.

Nominal Concentration (µg a.i./L)	Length Growth Rate (cm^{-1})	Inhibition (%)		Wet Weight Growth Rate ($grams^{-1}$)	Inhibition (%)		Dry Weight Growth Rate ($grams^{-1}$)	Inhibition (%)
Control	0.1214	NA		0.0996	NA		0.0754	NA
1.0	0.1064	12.3	*	0.0870	12.6		0.0735	2.4
2.0	0.0985	18.9	*	0.0858	13.8	*	0.0734	2.6
4.0	0.0707	41.7	*	0.0554	44.3	*	0.0688	8.7
8.0	0.0659	45.7	*	0.0599	39.8	*	0.0655	13.1
16	0.0326	73.2	*	0.0382	61.6	*	0.0637	15.5

*Statistically significant difference from control (Dunnett's one-tailed test; $p \leq 0.05$).
% Inhibition=100-((Treatment group parameter mean / control parameter mean)*100). These calculations were done in Microsoft Excel, on the unrounded numbers. Manual calculations may vary slightly.

Results are based on nominal concentrations of the test item.

Test item	Thiencarbazone-methyl technical		
Test object	*Myriophyllum spicatum*		
Exposure	24 hour – Peak Exposure		
Endpoint Units	(µg a.s./L)		
Endpoint results	Day 14 Shoot Length Growth Rate	Day 14 Wet Weight Growth Rate	Day 14 Dry Weight Growth Rate
Highest Concentration Without an Effect (NOE_rC)	< 1.0	1.0	16
Lowest Concentration With an Effect (LOE_rC)	1.0	2.0	16
E_rC_{50} (95% C.I.)	9.2 (NA to 11.6)	11.3 (NA to 17.5)	16 (NA)

NA = Not applicable

Conclusion:
The lowest E_rC_{50} in this 24-hour peak exposure study performed with the rooted aquatic macrophyte *Myriophyllum spicatum* and Thiencarbazone-methyl technical was obtained for shoot length growth rate. The statistical NOE_rC, LOE_rC and E_rC_{50} for this endpoint were <1.0, 1.0 and 9.2 µg a.s./L, respectively.

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Comments of zRMS:	The study is considered acceptable. All validity criteria were met.

	Agreed endpoints: $E_rC_{50\ \text{frond growth rate}}$ = 13.4 µg/L nominal concentration NOE_rC = 0.00284 mg product/L nominal concentration

Reference:	**KCP 10.2.1/07**
Title:	Lemna gibba G3 - Growth inhibition test with foramsulfuron + thiencarbazone-methyl OD 80 (50 + 30) G under static conditions
Report:	Bruns, E.; 2014; EBGSP149; M-477103-01-1
Authority registration No:	
Guideline(s):	EU Directive 91/414/EEC Regulation (EC) No. 1107/2009 US EPA OCSPP 850.4400
Deviations:	none
GLP/GEP:	yes
Acceptability:	
Duplication (if vertebrate study):	

Objective:

The aim of the study was to determine the influence of the test item Foramsulfuron + Thiencarbazone-methyl OD 80 (50+30 g/L) on exponentially growing *Lemna gibba* G3 expressed as NOEC, LOEC and EC_x for growth rate of the response variables, frond number and total frond area of plants.

Material and methods:

Test item: Foramsulfuron + Thiencarbazone-methyl OD 80 (50+30 g/L) G; batch ID: 2012-005269; specification No.: 102000025743-01; content: 4.97 % w/w foramsulfuron, 2.97 % w/w thiencarbazone-methyl; TOX-No.: 09970-00; density: 1.028 g/mL.

3 x 12 fronds of *Lemna gibba* G3 per test concentration were exposed in a chronic multigeneration test for 7 days under static exposure conditions to the nominal concentrations of 0.101, 0.233, 0.535, 1.23, 2.84, 6.52 and 15.0 µg form./L in comparison to a control. The pH values ranged from 7.6 to 8.8 in the control and the incubation temperature ranged from 24.7 °C to 25.1 °C (measured in an additional incubated glass vessel) over the whole period of testing at a continuous illumination of 6817 lux (average of nine measurements).

Quantitative amounts of foramsulfuron were measured in all freshly prepared test levels on day 0 and additionally in all aged test levels on day 7 of the exposure period.

Dates of experimental work: April 22, 2013 to November 18, 2013

Results:

Validity criteria:
The doubling time of frond number in the control was 1.8 days, corresponding to a 13.8-fold increase. Therefore, the study met all validity criteria, requested by the mentioned guidelines.

Analytical findings:
The analytical findings of foramsulfuron found in all freshly prepared test levels on day 0 ranged between 86 and 103 % of nominal (average 94.9 %). In aged test levels on days 7 analytical findings ranged between 78 and 97 % of nominal (average 88.6 %).
Given that the toxicity cannot be attributed to any of the active substance compounds but to the formulation as a whole, all results are based on nominal test concentrations of the formulation.

Table: Analytical findings on day 0

day 0				
nominal concentration in µg form/L	actual concentration (µg foramsulfuron/L)			
	1. determination	2. determination	average	%
control	0.00242*	< 0.001005*1	-	-
0.101	0.00509	0.00525	0.00517	103
0.233	0.0112	0.0113	0.0113	97
0.535	0.0255	0.0260	0.0257	97
1.23	0.0591	0.0589	0.0590	97
2.84	0.132	0.134	0.133	94
6.52	0.291	0.289	0.290	90
15.0	0.645	0.634	0.639	86
			mean	94.9

*average sample A
*[1] average Sample B

Table: Analytical findings on day 7

day 7				
nominal concentration in µg form/L	actual concentration (µg foramsulfuron/L)			
	1. determination	2. determination	average	%
control	<0.001005	<0.001005	<0.001005	-
0.101	0.00463	0.00475	0.00469	93
0.233	0.0102	0.0102	0.0102	88
0.535	0.0261	0.0256	0.0258	97
1.23	0.0584	0.0576	0.0580	95
2.84	0.120	0.120	0.120	85
6.52	0.273	0.272	0.272	84
15.0	0.586	0.573	0.579	78
			mean	88.6

Biological findings:
Inhibitory effects during the exposure phase are summarised in the following table.

Table: Summary of the observed effects on *Lemna gibba* G3 in a static 7-day growth inhibition test

nominal test concentration [µg form./L]	final frond no. (replicate means, day 7)	final total frond area of plants (replicate means, day 7) [mm2]	% inhibition	
			mean growth rate for frond no.	mean growth rate for total frond area of plants
control	166	1198	--	--
0.101	156	1091	2.2	-0.3
0.233	162	1175	0.8	-0.1
0.535	157	1159	2.0	-3.3
1.23	156	1140	2.3	-3.0
2.84	187	1409	-4.5	-5.8
6.52	98.3	755	20.2	16.7*
15.0	39.3	291	55.0*	58.2*

-% inhibition: increase in growth relative to the control
* Results which were significantly different (based on Williams Multiple sequential t-test Procedure) from the control

No visual effects on *Lemna gibba* G3 were observed.

Table: Results based on mean growth rates

end point (0-7 day)	effect on mean growth rate of frond no. [µg form.]	effect on mean growth rate of total frond area of plants [µg form.]
E_rC_{50} (CI 95%)	**13.4** (12.2 – 15.1)	**21.0** (7.61 – 592)
LOE_rC	15.0	6.52
NOE_rC	6.52	2.84

The LOE_rC and NOE_rC determination is based on statistical data analysis.

Conclusions:

The most sensitive response variable in this study was total frond number resulting in a (0-7 day) - E_rC_{50} of 13.4 µg form./L.
The lowest NOE_rC was 2.84 µg form./L and was based on statistical data analysis of the total frond number.

A 2.2.2 KCP 10.2.2 Additional long-term and chronic toxicity studies on fish, aquatic invertebrates and sediment dwelling organisms

A 2.2.3 KCP 10.2.3 Further testing on aquatic organisms

A 2.3 KCP 10.3 Effects on arthropods

A 2.3.1 KCP 10.3.1 Effects on bees

Comments of zRMS:	Additional information.

Reference:	**KCP 10.3.1/01**
Title:	1.8 Weeds in the treated field - a realistic scenario for pollinator risk assessment ?
Report:	Maynard, S. K.; Albuquerque, R.; Weber, C.; von Merey, G.; Geiger, M. F.; Becker, R.; Keppler, J.; Maschke, J.; Brougham, K.; Couson, M.; 2015; M-542146-01-1
Authority registration No:	
Guideline(s):	--
Deviations:	--
GLP/GEP:	no
Acceptability:	
Duplication (if vertebrate study):	

Objective:
This project aims to answer the question posed by the EFSA bee guidance document regarding the relevance of the weeds in the treated field scenario: "*Is a significant fraction of the surface area of treated fields covered by attractive weeds for >10% of the area of use?*"

Material and Methods:
A cross-industry group (Syngenta, Bayer, BASF, Dow AgroSciences and Monsanto) collected herbicide efficacy trials data from the control plots of 9 different crop groups (wheat, oilseed rape, sugar beet, sunflower, potatoes, maize, peas, beans and permanent crops (orchards and vines)). The data collected includes crop type, crop growth stage, application date, trial location, tillage information, weed species, growth stage, and ground coverage.
A three-stage assessment process was used for analysing the data, to attempt to quantify the coverage of relevant attractive weeds in the in-field area of use:
1. The quantity of weeds recorded within the field at a flowering growth stage was defined as those observed with a growth stage of BBCH ≥ 60.
2. These weeds highlighted as being present and potentially attractive were then assessed for attractiveness to bees. No known definitive list is available for non-crop species and attractiveness to bees, so the species were categorised based on monocotyledonous as a surrogate for non-attractive plants, and dicotyledonous as a surrogate for attractive plants.
3. Finally the data on ground coverage can be combined with that of the above and used to establish the percentage coverage of attractive weeds throughout the area of use.

Results:

Percentage of weeds recorded at a flowering growth stage

Database size for each crop and the % of weed recordings which were above a flowering growth stage

Crop	**Total number of trials examined**	**Total number of weed recordings in all trials**	**% weeds recorded at BBCH ≥ 60**
Wheat	1024	9113	0.86%
Maize	7669	38421	1.94%
Oliseed Rape	1022	3587	1.28%
Sunflower	388	1435	1.11%
Potatoes	182	1159	1.04%
Sugar Beet	156	5006	0.12%
Peas	650	5780	0.48%
Beans	203	1807	1.49%
Permanent Crops	233	552	37.0%

For the arable crops studied, weeds at a flowering growth stage account for less than 2% of the weeds present in these trials. In permanent crops, likely due to the difference in agricultural practices, around 37% of the weeds present are at or above a flowering growth stage.

Percentage of weeds assessed to be attractive:

Data for permanent crops (orchards and vineyards) showing the number of mono- and dicotyledonous species and the respective percentages in terms of species diversity and abundance in the investigated trials.

Permanent crops (Vineyards/Orchards)	**Total weed species at BBCH ≥ 60**	**Monocotyledonous**	**Dicotyledonous**
Number of species	77	15	62
Number of recordings	204	47	157
Percentage of recordings (n = 552)	37%	8.5%	28.5%

Only 28.5% of weeds in permanent crops are attractive to bees. The classification of attractiveness of weeds in arable crops has not yet been conducted as the percentage of weeds has been shown to be low enough to be of little concern even if all weeds are attractive.

Percentage ground coverage of weeds:

Data for permanent crops (orchards and vineyards) showing the number of mono- and dicotyledonous species present at flowering growth stage and above 10% ground coverage and the respective percentages in terms of species diversity and abundance in the investigated trials.

Permanent crops (Vineyards/Orchards)	**Total weed species at BBCH ≥ 60 and ≥ 10% ground cover**	**Monocotyledonous**	**Dicotyledonous**
Number of species	12	5	7
Number of recordings	35	14	21
Percentage of recordings (n = 177)	20.5%	8.2%	12.3%

For permanent crops the authors can demonstrate that, considering weeds at a flowering growth stage and present at ≥ 10% ground cover, only 12.3% are also potentially attractive to bees.

Conclusion:
For the arable crops assessed in this study, the data analysis presented has demonstrated conclusively that the "weeds in the treated field scenario" is not applicable. For the arable crops: wheat, maize, oilseed rape, sunflower, potatoes, sugar beet, beans and peas, less than 2% of all weeds recorded were found to be at a flowering growth stage (BBCH ≥ 60), despite the data being recorded in control trial plots with no weed control measures. When further investigations into the ground coverage of such weeds are carried out, it is clear that the weeds in arable fields do not present a 90th%ile exposure scenario for bees.
For permanent crops a maximum percentage of 12.3% of the recorded weeds were potentially attractive (dicotyledonous) flowering weeds (BBCH ≥ 60) and present at greater than 10% ground coverage. This indicates potential concern for the flowering weeds in the treated field for this crop; although again it is noteworthy that the data examined here represent a very worst-case scenario. Due to current risk assessment schemes, extensive field and semi-field testing and precautionary risk mitigation measures available to risk managers, it is considered that the risk to bees is appropriately controlled using current practices for permanent crops.

A 2.3.1.1 KCP 10.3.1.1 Acute toxicity to bees

A 2.3.1.1.1 KCP 10.3.1.1.1 Acute oral toxicity to bees

Comments of zRMS: The study is considered acceptable. All validity criteria were met.

Agreed endpoints:

Test Item	Foramsulfuron + Thiencarbazone-methyl OD 80 (50+30 g/L) G
LD_{50} µg product/bee	> 215.6

Reference:	**KCP 10.3.1.1.1/01**
Title:	Effects of foramsulfuron + thiencarbazone-methyl OD 80 (50+30) G (acute contact and oral) on honey bees (Apis mellifera L.) in the laboratory
Report:	Sekine, T.; 2013; 81151035; M-461860-01-1
Authority registration No:	
Guideline(s):	OECD 213 and 214 (1998)
Deviations:	none
GLP/GEP:	yes
Acceptability:	
Duplication (if vertebrate study):	

Objective

The purpose of this study was to determine the acute contact and oral toxicity of Foramsulfuron + Thiencarbazone-methyl OD 80 (50+30 g/L) G to the honey bee (*A. mellifera* L.). Mortality of the bees was used as the toxic endpoint. Sublethal effects, such as changes in behaviour, were also assessed.

Material and methods

Test item: Foramsulfuron + Thiencarbazone-methyl OD 80 (50+30 g/L) G; analytical content of a.s.: foramsulfuron (AE F130360): 4.97 % w/w, 51.05 g/L, thiencarbazone-methyl (BYH 18636): 2.97 % w/w, 30.49 g/L; Batch ID.: 2012-005269; Sample description: TOX 09970-00; Material No.: 80979444; Specification No.: 102000025743-01; density: 1.028 g/mL (20° C).

Under laboratory conditions *Apis mellifera* 50 worker bees were exposed for 48 hours to a single dose of 200.0 µg product per bee by topical application (contact limit test) and 50 worker bees were exposed for 48 hours to a single dose of 215.6 µg product per bee by feeding (oral limit test, value based on the actual intake of the test item).
In addition to the oral limit toxicity test another dose response test with three dose levels was conducted. In this oral dose response test 30 worker bees per dose were exposed for 48 hours to 3 doses of 178.0, 143.5 and 103.3 µg product/bee for feeding (oral dose response toxicity test, values based on the actual intake of the test item) for the determination of a NOED.
The control used for both oral tests (limit test and dose response test) was 50 % (w/w) aqueous sugar syrup solution (50 % tap water, 50 % ready-to-use sugar syrup). For the contact limit test tap water with 0.5 % Adhäsit (applied after anesthetization with CO_2) was used as control.
As a toxic reference Perfekthion EC (active ingredient: dimethoate, 400.0 g/L nominal, 411.7 g/L analytical) was applied at nominal dose levels of 0.30, 0.20, 0.15 and 0.10 µg dimethoate/bee in the contact limit test and 0.30, 0.15, 0.08 and 0.05 µg dimethoate/bee in both oral tests (limit test and dose response test).

In the contact limit test the test item was applied as one 5 µL droplet of the test item, dissolved in tap water with 0.5 % Adhäsit, placed on the dorsal bee thorax using a Burkard – Applicator. The reference was applied as one 5 µL droplet of dimethoate, dissolved in tap water with 0.5% Adhäsit. For the control, one 5 µL droplet of tap water containing 0.5 % Adhäsit was used.
A 5 µL droplet was chosen in deviation to the guideline recommendation of a 1 µL droplet, since a higher volume ensured a more reliable dispersion of the test item.

In both oral tests (limit test and dose response test) aqueous stock solutions of the test item and reference item were prepared in order to give the target concentration of the test item and reference item after being mixed with ready-to-use sugar syrup (composition of the sugar component: 30 % sucrose, 31 % glucose, 39 % fructose). The final concentration of sugar syrup in the aqueous test and reference item solutions offered to the bees was 50 % (w/w). For the control, tap water and sugar syrup was used at the same ratio

50% (w/w) tap water, 50% (w/w) ready-to-use sugar syrup. The treated food was offered in syringes, which were weighed before and after introduction into the cages. After a maximum of 1 hour 25 minutes (limit test) or 45 minutes (dose response test), the uptake was complete and the syringes were removed, weighed and replaced by ones containing fresh, untreated food.

The number of dead bees was recorded after 4 (± 0.5 h) hours (first day); 24 and 48 (± 2 h) hours. Behavioural abnormalities (e.g. vomiting, apathy, intensive cleaning) were assessed after 4 (± 0.5 h) hours (first day); 24 and 48 (± 2 h) hours. The test was performed in incubators in completely darkness (except during observation) with a temperature range of 24 - 25 °C and a relative humidity range of 50 – 77 % in the contact test and the oral limit test and 59 – 79 % in the oral dose response test. The short-term deviation for a time period < 2 hours were not reported. Test conditions were recorded with suitable instruments and documented in the raw data.

Dates of work: May 14, 2013 to May 23, 2013 (contact and oral limit test)
July 09, 2013 to July 11, 2013 (oral dose response test)

Findings

Validity criteria

Validity criteria of the study

Validity Criteria		Recommended	Obtained
Control mortality	Contact Test		
	CO_2/water control	< 10%	0.0%
	Oral Test		
	water/sugar syrup control	< 10%	0.0% (limit and dose response test)
LD_{50} of reference item (24 h)	Contact Test		
		0.10 - 0.30 µg a.s./bee (24 h)	0.19 µg a.s./bee
	Oral Test		
		0.10 - 0.35 µg a.s./bee (24 h)	0.13 µg a.s./bee (limit test) 0.15 µg a.s./bee (dose response test)

All validity criteria for the study were met.

Biological findings:

Contact Test:
At the end of the contact toxicity test (48 hours after application), there was 2.0 % mortality at 200.0 µg product/bee. No mortality occurred in the control group (water + 0.5 % Adhäsit). There were no behavioural abnormalities of the bees during the entire trial at 200.0 µg product/bee.

Oral Test:
In the oral toxicity test, the maximum nominal test level of Foramsulfuron + Thiencarbazone-methyl OD 80 (50+30 g/L) G (i.e. 200 µg product/bee) corresponded to an actual intake of 215.6 µg product/bee. This dose level led to 10.0 % mortality after 48 hours. No mortality occurred in the control group (50 % aqueous sugar syrup solution). After 4 hours one bee showed discoordinated movements and five bees showed apathic symptoms. Apathy occurred also after 24 hours in two bees. No test item induced behavioural abnormalities occurred after 48 hours.

An additional oral dose response test with 166.6, 133.3 and 100.0 µg product/bee (nominal values) was performed in order to determine a NOED. The actual oral doses of 178.0, 143.5 and 103.3 µg product/bee resulted in 13.3, 10.0 and 0.0 % mortality at the end of the test (after 48 hours). No mortality occurred in the control group (50 % aqueous sugar syrup solution). After 4 hours a few bees in the 178.0 and 143.5 µg product/bee dose groups showed apathy or moving coordination problems. Thereafter no test item induced behavioural abnormalities occurred.

Acute toxicity of the test item to honey bees; contact and oral laboratory test

Test Item	Foramsulfuron + Thiencarbazone-methyl OD 80 (50+30 g/L) G	
Test Object	*Apis mellifera*	
Exposure	contact (solution in Adhäsit (0.5 %)/water)	oral (sugar syrup solution)
Application rate µg product/bee	200.0	215.6
LD_{50} µg product/bee	> 200.0	> 215.6
LD_{20} µg product/bee	> 200.0	> 215.6
LD_{10} µg product/bee	> 200.0	158.3
NOED µg product/bee*	≥ 200.0	178.0

* The NOED was estimated using Fisher Exact Test (pairwise comparison, one-sided greater, $\alpha = 0.05$).

The contact and oral LD_{50} (24 h) values of the reference item (dimethoate) were calculated to be 0.19 and 0.13 µg a.s./bee, respectively. In the additional oral dose response test the oral LD_{50} (24 h) value of the reference item (dimethoate) was 0.15 µg a.s./bee.

Conclusion

The toxicity of of Foramsulfuron + Thiencarbazone-methyl OD 80 (50+30 g/L) G was tested in both, an acute contact and an acute oral toxicity test on honey bees.
The contact LD_{50} (48 h) was > 200.0 µg product/bee. The oral LD_{50} (48 h) was > 215.6 µg product/bee.
The contact NOED was ≥ 200 µg product/bee. The oral NOED was estimated in an additional dose response toxicity test. The oral NOED was 178.0 µg product/bee.

A 2.3.1.1.2 KCP 10.3.1.1.2 Acute contact toxicity to bees

Comments of zRMS: The study is considered acceptable. All validity criteria were met.

Agreed endpoints:

Test Item	Foramsulfuron + Thiencarbazone-methyl OD 80 (50+30 g/L) G
LD_{50} µg product/bee	> 200.0

Reference:	**KCP 10.3.1.1.2/01**
Title:	Effects of foramsulfuron + thiencarbazone-methyl OD 80 (50+30) G (acute contact and oral) on honey bees (Apis mellifera L.) in the laboratory
Report:	Sekine, T.; 2013; 81151035; M-461860-01-1
Authority registration No:	
Guideline(s):	OECD 213 and 214 (1998)
Deviations:	none
GLP/GEP:	yes
Acceptability:	
Duplication (if vertebrate study):	

Please refer to summary above (point A 2.3.1.1.1).

A 2.3.1.2 KCP 10.3.1.2. Chronic toxicity to bees

Comments of zRMS:	The study was not considered by zRMS in the current dossier.

In order to complete the dataset and the knowledge on chronic toxicity to honey bees a further study has been performed with the formulated thiencarbazone-methyl in combination with the safener cyprosulfamide. This study has not yet been evaluated at EU level, however for transparency a detailed Tier 2 summary is provided below. The related study report can be made available to the zRMS upon request.

Reference:	**- Study report will be made available to the zRMS upon request -**
Title:	Thiencarbazone-methyl + cyprosulfamide SC 450 (225+225 g/L): Chronic Oral Toxicity Test on the Honey Bee (*Apis mellifera* L.) in the Laboratory
Report:	Gossmann, A.; 2016; 11321136; M-576217-01-1
Authority registration No:	
Guideline(s):	OECD (2016), Proposal for a New Guideline for the Testing of Chemicals. Honey Bee (*Apis mellifera* L.), Chronic Oral Toxicity Test. 10 Day Feeding Test in the Laboratory
Deviations:	None
GLP:	yes
Acceptability:	
Duplication (if vertebrate study):	

Objective:

The purpose of this study was to determine the chronic oral toxicity of Thiencarbazone-methyl + cyprosulfamide SC 450 (225+225 g/L) to the honey bee (*A. mellifera* L.) for a period of ten days. Mortality of the bees was used as the toxic endpoint. Sublethal effects, such as changes in behaviour, were also assessed.

Material and methods:

Test item: Thiencarbazone-methyl + cyprosulfamide SC 450 (225 + 225) G; short name: TCM+CSA SC 450 (225+225) G; Sample description: TOX20259-00; Sample ID: M16002877001; Specification no.: 102000013579; Batch ID: 2016-002466; Lot No.: 2016-002466-01; Analysed content of a.s: 230.9 g/L (19.6% w/w) thiencarbazone-methyl (BYH 18636), 230.0 g/L (19.6% w/w) cyprosulfamide (AE 0001789), Density (20 C): 1.174 g/mL.

Over a period of 10 days, 3 replicates per treatment level, each consisting of 10 bees per test cage were exposed to 29.7, 27.0, 23.5, 14.9 and 12.9µg a.s./bee/day by continuous and *ad libitum* feeding. Addition-

ally an untreated control and a reference item BAS 152 11 I (Perfekthion EC); 400 g/L dimethoate) were included in this study. The control group was exposed for the same period of time under identical exposure conditions to untreated 50 % (w/v) aqueous sucrose application solution. Mortality, sub-lethal effects and behavioural abnormalities were assessed every day throughout the 10 days continuous exposure period. The treated and untreated food was offered ad libitum to each cage in syringes. The syringes were weighed daily before introduction into the cages and after the feeding interval (before replacement with fresh food). The concentrations were calculated taking into account the analytical content of the a.s. In the final report, the concentrations are presented as both, concentration and dose per bee (taking into account the uptaken amount of treated or untreated feeding solution)

Number of dead bees was assessed daily (at the same time of the day) until test end, ten days following start of exposure. Behavioural abnormalities were assessed daily until test end (day 1 to day 10). Sub-lethal effects such as symptoms of poisoning or any abnormal behaviour in comparison to the control were recorded according to the categories: a = affected (bees still upright and attempting to walk but showing signs of reduced coordination), m = moribund (bees cannot walk and show only very feeble movements of legs and antennae, only weak response to stimulation; e.g. light or blowing; bumble bees may recover but usually die), c = cramps (bees contracting abdomen or entire body), ap = apathy (bees show only low or delayed reactions to stimulation e.g. light or puff of air; bees are sitting motionless in the unit) and v = vomiting. The test was performed in incubators in completely darkness (except during observation) with a temperature range of 32 - 33 °C and a relative humidity range of 46 – 78 %. The short-term deviation for a time period < 2 hours are not reported.

Dates of experimental work: July 26 to August 18, 2016

Results:

Validity criteria:
The validity criteria for the chronic oral test were fulfilled.

Validity criterion	Observed/ calculated	Recommended
Control mortality	0.0 %	≤ 15 %
Reference item mortality	100.0 %	≥ 50 %

Analytical results:
The actual concentrations of thiencarbazone-methyl in the feeding solutions were analysed. The actual concentrations of the feeding solutions were in a range of 70% - 81%.

Biological results:

10-Day Chronic Feeding of Thiencarbazone-methyl + cyprosulfamide SC 450 (225+225 g/L) to young honey bees; laboratory test

Test Object		*Apis mellifera carnica*	
Treatment Group	Concentration [mg a.s./kg]	Dose Level [1] [µg a.s./bee/day]	Mortality at day 10 [2,] [% Mean]
Thiencarbazone-methyl + cyprosulfamide SC 450 (225+225 g/L)	3333	29.7	100.0 *
Thiencarbazone-methyl + cyprosulfamide SC 450 (225+225 g/L)	2381	27.0	56.7 *
Thiencarbazone-methyl + cyprosulfamide SC 450 (225+225 g/L)	1701	23.5	10.0 (n.s.)
Thiencarbazone-methyl + cyprosulfamide SC 450	1215	14.9	13.3 (n.s.)

(225+225 g/L)			
Thiencarbazone-methyl + cyprosulfamide SC 450 (225+225 g/L)	868	12.9	3.3 (n.s.)
Water control	0.0	0.0	0.0
Reference Item	1.0	0.015	100.0
Endpoint at test termination (day 10)			
LC_{50}	LDD_{50}	NOEC	NOEDD
2101.2 mg a.s./kg	24.5 µg a.s./bee/day	1701 mg a.s./kg	23.5 µg a.s./bee/day
LC_{20}	LDD_{20}	LOEC	LOEDD
1548.2 mg product/kg	18.8 µg product/bee/day	2381 mg product/kg	27.5 µg product/bee/day
LC_{10}	LDD_{10}		
1319.7 mg product/kg	16.4 µg product/bee/day		

[1]mean dose per bee per day; dose measured based on consumed feeding solution
[2]Mortality at study termination 10 days after start of first feeding
Statistics:
LC_x/LDD_x: according to Probit Analysis (according to Finney 1971)
Mortality: Fisher`s Exact Test, pairwise comparison, one-sided greater, $\alpha = 0.05$
NOEC/NOEDD: was estimated using Fisher's Exact Test (pairwise comparison, one-sided greater, $\alpha = 0.05$).
LOEC/LOEDD: was estimated using Fisher's Exact Test (pairwise comparison, one-sided greater, $\alpha = 0.05$).
n.s. = no statistical significant difference compared to the control, * = statistically significant different compared to the control ($\alpha = 0.05$),

The test item was daily administered to the bees in a feeding solution at the following concentrations: 3333, 2381, 1701, 1215 and 868 mg a.s./kg feeding solution. These concentrations led to actual daily mean doses of 29.7, 27.0, 23.5, 14.9 and 12.9 µg a.s./bee/day after 10 days.

At test end, 10 days following start of exposure, 0.0 % mortality occurred in the untreated water control (50 % w/v sucrose solution). At 3333 mg a.s./kg feeding solution (corresponding to 29.7 µg a.s./bee/day) 100 % mortality and at 2381 mg a.s./kg feeding solution (corresponding to 27.0 µg a.s./bee/day) 56.7 % mortality occurred. These mortalities were statistically significant different to the control (Fisher`s Exact Test, $\alpha = 0.05$).

In the test item treated groups at 1701, 1215 and 868 mg a.s./kg feeding solution the mortality was statistically not significant different compared to the control.

The reference item (dimethoate) at a concentration of 1 mg dimethoate/kg feeding solution corresponding to actual 0.015 µg a.s./bee/day caused 100 % mortality at day 4.

Conclusions:

The chronic oral toxicity of Thiencarbazone-methyl + cyprosulfamide SC 450 (225+225 g/L) was tested over 10 days.
The LC_{50} value (10 days) was 2101.2 mg a.s./kg feeding solution.
The LDD_{50} value (10 days) was 24.5 µg a.s./bee/day.
The NOEC and NOEDD values (10 days) were 1701 mg a.s./kg feeding solution and 23.5 µg a.s./bee/day, respectively.

A 2.3.1.3 KCP 10.3.1.3 Effects on honey bee development and other honey bee life stages

Comments of zRMS:	The study was not considered by zRMS in the current dossier. The applicant indicates that these new studies performed with the active substances are available upon request in order to investigate the effects on development of bees chronic toxicity of foramsulfuron on bees. zRMS considers that the risk posed by a formulation containing more than one

	active substance cannot be addressed with data on active substances alone. Therefore, those studies, even if submitted, would not change the outcome of the conclusion for the current dossier on a formulation containing more than one active substance. According to new requirements of Reg. No. 284/2013, data on chronic effects on adult bees and on development of bees for the formulation should have been submitted.

In order to complete the data set and the knowledge on effects on developmental stages of honey bees a further study has been performed with the active substance foramsulfuron. This study has not yet been evaluated at EU level, however for transparency a detailed Tier 2 summary is provided below. The related study report can be made available to the zRMS upon request.

Reference:	**- Study report will be made available to the zRMS upon request -**
Title:	Foramsulfuron technical - Honey Bee (*Apis mellifera* L.) 22 Day Larval Toxicity Test (Repeated Exposure)
Report:	Oberrauch, S.; 2017; M-604343-01-1
Authority registration No	
Guideline(s):	OECD Guidance Document 239 on Honey bee (*Apis mellifera*) Larval Toxicity Test, Repeated Exposure (2016)
Deviations:	Only mortality, but no other observations were assessed for the toxic reference item group(s). No emergence boxes were used as from Day 15 onwards to enable the assignment of each emerged bee to the respective replicate.
GLP:	yes
Acceptability:	
Duplication (if vertebrate study):	

Objective:
The objective of this study was to determine the effects of foramsulfuron tech. on the larval development and emergence of adult honey bees, *Apis mellifera* L., from repeated feeding exposure in a 22 day laboratory test and to determine the cumulative mortalities during the larval phase and the pupation phase as well as the adult emergence rate. The Lowest Observed Effect Concentration/Dose (LOEC/LOED), the No Observed Effect Concentration/Dose (NOEC/NOED) as well as the concentrations and doses causing 10, 20 and 50 % reduction of adult emergence (EC_{10}/ED_{10}, EC_{20}/ED_{20} and the EC_{50}/ED_{50}) were determined for day 22, where possible.

Material and methods:
Test item: Foramsulfuron tech.; Batch No.: ELIR004626, Sample description: TOX 20322-00, Specification No.: 102000011654-03, Analysed purity a.s.: 98.3 % w/w, Certificate No.: AZ 20830.
Test species: Honey bee (*Apis mellifera carnica* POLLMANN), synchronized first instar (L1) larvae originating from three adequately fed, healthy, as far as possible parasite-free and queen-right colonies. The test was conducted at Eurofins Agroscience Services Ecotox GmbH, Nordweg 10, 75245 Neulingen-Göbrichen, Germany.
Test design: Dose response test with a duration of 22 days from grafting on day 1 to the final assessment on day 22. From day 3 until day 6 of the test, five different concentrations of foramsulfuron tech. were fed to larvae of the test item groups and one single concentration of the reference item dimethoate was fed to the larvae of the reference item group with diet B or C. The analysed purity was considered for the calculation of the test item and reference item concentrations; the daily feeding volume increased from 20 µL to 50 µL diet per larva over the application period. The cumulative feeding volume from day 3 until day 6 of 140 µL diet per larva and the density of the diet (1.1 g/cm^3) were considered for the calculation of the cumulative doses per larva. A control group was included in the test and exposed for the same period of time under identical exposure conditions to the water treated artificial diet. Each treatment group consisted of 48 larvae from three different colonies (each colony representing a replicate). Assessment of larval mortality was performed during the larval phase from day 4 until day 8, assessment of mor-

tality during pupation phase was performed on day 15 and day 22. Assessment of adult emergence was performed on day 22. The presence of uneaten food was qualitatively recorded on day 8. Other observations and any other adverse effects were qualitatively recorded to aid in the interpretation of mortality in comparison to the control group.
Test concentrations: One control group; 5 test item groups with 6.96, 15.3, 33.7, 74.1 and 163 mg a.s./kg diet, equivalent to cumulative doses of 1.07, 2.36, 5.19, 11.4 and 25.1 µg a.s./larva per developmental period; One dimethoate reference item group with 48.0 mg dimethoate/kg diet, equivalent to a cumulative dose of 7.39 µg dimethoate/larva per developmental period.

Dates of work: May 18 to September 06, 2017

Results:
Analytical results:
In the control the concentration of foramsulfuron was below LOD (LOD = 0.003 mg/kg).
The analytical dose verification of the larval diet of the test item groups from day 3 until day 6 resulted in concentrations that are equivalent to mean recoveries between 94 % and 98 % of nominal.
Since the mean measured concentrations of the test item in the larval diet were within ± 20 % of nominal for each test item group the presented endpoints are based on nominal concentrations.

Biological results:
On day 8, larval mortality was 2.1 % in the control group and 97.9 % in the reference item group. The larval mortality was 8.3, 2.1, 2.1, 2.1 and 0.0 % in the test item groups of 6.96, 15.3, 33.7, 74.1 and 163 mg a.s./kg diet or 1.07, 2.36, 5.19, 11.4 and 25.1 µg a.s./larva per developmental period, respectively.
On day 22, the adult emergence rate in the control group was 77.1 %. The adult emergence rates were 70.8, 75.0, 75.0, 89.6 and 87.5 % in the test item groups of 6.96, 15.3, 33.7, 74.1 and 163 mg a.s./kg diet or 1.07, 2.36, 5.19, 11.4 and 25.1 µg a.s./larva per developmental period, respectively.
Compared to the control group the adult emergence rate on day 22 was not statistically significantly different in any test item group (Multiple Chi²-test with Bonferroni-Holm adjustment, one-sided greater, α = 0.05).
During the assessments of mortality and emergence no other test item related observations such as deviating sizes, appearances and malformations of the test organisms were made.
On day 8, uneaten food was observed in the highest test item group of 163 mg a.s./kg diet or 25.1 µg a.s./larva per developmental period.
Results for larval mortality until day 8, as well as for adult emergence on day 22, including the corresponding endpoints are presented in the following table.

The Effects of foramsulfuron technical on the Larval Mortality and on the Adult Emergence of the Honey Bee from Repeated Exposure and the Corresponding Endpoints

Treatment Group	**Concentration**		**Cumulative Dose**		**Larval Mortality on Day 8**		**Adult Emergence on Day 22** [a]
					[%]	Corrected [%]	[%]
Control	---	---	---	---	2.1	---	77.1
Test Item (foramsulfuron tech.)	6.96	[mg a.s./ kg diet] [b]	1.07	[µg a.s./larva per developmental period] [b c]	8.3	6.3	70.8
	15.3		2.36		2.1	0.0	75.0
	33.7		5.19		2.1	0.0	75.0
	74.1		11.4		2.1	0.0	89.6
	163		25.1		0.0	-2.1	87.5
Reference Item (Dimethoate)	48.0	[mg dimethoate/ kg diet] [b]	7.39	[µg dimethoate/ larva per developmental period] [b c]	97.9	97.9	---

Endpoints for Day 22				
LOEC	**NOEC**	**EC_{10} (95 % CL)**	**EC_{20} (95 % CL)**	**EC_{50} (95 % CL)**
[mg a.s./kg diet] [b]				
> 163 [d]	≥ 163	> 163 [e]	> 163 [e]	> 163 [e]
LOED	**NOED**	**ED_{10} (95 % CL)**	**ED_{20} (95 % CL)**	**ED_{50} (95 % CL)**
[µg a.s./larva per developmental period] [b c]				
> 25.1 [d]	≥ 25.1	> 25.1 [e]	> 25.1 [e]	> 25.1 [e]

[a] statistical evaluation for non-emergence
[b] Based on the analysed purity
[c] Based on the cumulative feeding volume from day 3 until day 6 of 140 µL diet/larva and a density of the diet of 1.1 g/cm^3
[d] The LOEC/LOED could not be determined due to the lack of statistically significant effects (Multiple Chi²-test with Bonferroni-Holm adjustment, one-sided greater, $\alpha = 0.05$), but can be regarded as above the highest concentration/dose tested
[e] The EC_{10}/ED_{10}, EC_{20}/ED_{20} and EC_{50}/ED_{50} could not be calculated due to the lack of inhibition in emergence > 10 %, but can be regarded as above the highest concentration/dose tested.

Validity criteria:
All validity criteria were met in this study.

Validity criteria according to OECD GD 239	**Obtained in this study**
Cumulative larval mortality from day 3 to 8 in control: ≤ 15%	2.1%
Mean adult emergence rate on day 22 in control: ≥ 70%	77.1 %
For reference item dimethoate larval mortality at day 8: ≥ 50%	97.9%

Conclusions
In a repeated exposure larval toxicity test with foramsulfuron tech. and a duration of 22 days the NOEC for adult emergence on day 22 was determined as ≥ 163 mg a.s./kg diet, equivalent to a NOED of ≥ 25.1 µg a.s./larva per developmental period.
The EC_{10}/ED_{10}, EC_{20}/ED_{20} and EC_{50}/ED_{50} could not be calculated, but can be regarded as > 163 mg a.s./kg diet, respectively > 25.1 µg a.s./larva per developmental period.

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Comments of zRMS:	The study was not considered by zRMS in the current dossier in the context of the Art 43 renewal assessment of foramsulfuron.

In order to complete the data set and the knowledge on effects on developmental stages of honey bees a further study has been performed with formulated thiencarbazone-methyl in combination with the safener cyprosulfamide. This study has not yet been evaluated at EU level, however for transparency a detailed Tier 2 summary is provided below. The related study report can be made available to the zRMS upon request.

Reference:	**- Study report will be made available to the zRMS upon request -**
Title:	Thiencarbazone-methyl + cyprosulfamide SC 450 (225+225) G: Honey Bee (*Apis mellifera* L.) Larval Toxicity Test, Repeated Exposure
Report:	Sekine, T.; 2018; M-615921-01-1
Authority registration No	
Guideline(s):	OECD Guidance Document 239 on Honey bee (*Apis mellifera*) Larval Toxicity Test, Repeated Exposure (2016)
Deviations:	No major: The relative humidity was not recorded from day 1 to day 15.

GLP:	yes
Acceptability:	
Duplication (if vertebrate study):	

Objective:

The objective of this study was to determine the effects of thiencarbazone-methyl + cyprosulfamide SC 450 (225+225) G on the larval development and emergence of adult honey bees, *Apis mellifera* L., from repeated feeding exposure in a 22 day laboratory test and to determine the cumulative mortalities during the larval phase and the adult emergence rate. The endpoints at test end (22 days) were the No Observed Effect Concentration/Dose (NOEC/NOED), the $LC_{50/20/10}$/$LD_{50/20/10}$ and the Emergence Rate of the honey bees on day 22.
The objective of the analytical part of this study was to determine the concentration of thiencarbazone-methyl in the control and spiked feeding solutions.

Material and methods:

Test Item: Thiencarbazone-methyl + cyprosulfamide SC 450 (225+225) G: Supplier Batch No.: 2016-002466, Specification No.: 102000013579, Sample Description: TOX20259-00; content: 1.) thiencarbazone-methyl (BYH 18636): 19.7 % w/w (230.9 g/L) (analytical), 2.) cyprosulfamide (AE 0001789): 19.6 % w/w (230.0 g/L) (analytical); density: 1.174 g/mL (20 °C).
Test species: Honey bee (*Apis mellifera carnica*), synchronized first instar larvae originating from three different disease-free and queen-right colonies. The test facility was ibacon Gmbh, Arheilger Weg 17, 64380 Rossdorf, Germany.
Test Design: dose response test with a duration of 22 days from grafting on day 1 to the final assessment on day 22. On day 3 up to day 6, five concentrations of thiencarbazone-methyl + cyprosulfamide SC 450 (225+225) G, one single concentration of the reference item dimethoate and one untreated control (untreated food solution) were administrated to the larvae. The daily feeding volume increased from 20 µL to 50 µL diet per larva over the application period. Considering the density of the diet (1.1 g/cm^3), the daily feeding volume increased from 22 mg to 55 mg diet per larva over the application period. The cumulative dose levels of the test item were based on the active substance thiencarbazone-methyl only. One cumulative dose level with 7.5 µg dimethoate per larva was used as reference item. A control group was included in the test and exposed for the same period of time under identical exposure conditions to untreated feeding solution (diet). Each treatment group consisted of 36 larvae from three different colonies (each colony representing a replicate). Cumulative mortality of larvae was assessed on days 4, 5, 6, 7 and 8 (corresponding to days 1, 2, 3, 4 and 5 after application); pupae mortality was assessed on day 15 and on day 22. The emergence rate of the adult honey bees was assessed on day 22. The presence of unconsumed food was recorded qualitatively on day 8.
Test concentrations: untreated water control; test item at 5 doses of 20.0, 8.33, 3.47, 1.45 and 0.60 µg thiencarbazone-methyl per larva (equivalent to 129.9, 54.1, 22.5, 9.4 and 3.9 mg thiencarbazone-methyl/kg diet); reference item group at one dose of 7.4 µg dimethoate/larva (equivalent to 48 mg dimethoate/kg diet).

Dates of work: May 31 to June 19, 2017 (biological phase)

Results:

Analytical results:
The analytical dose verification in the larval diet of the test item groups from day 3 until day 6 resulted in thiencarbazone-methyl concentrations that are equivalent to mean recoveries between 73 and 80 % of the nominal test concentration. The presented endpoints are based on nominal concentrations for each test item group.

Biological results:

Cumulative larval mortality on day 8 was 2.8, 8.3, 5.6, 0.0 and 5.6 % in the 20.0, 8.33, 3.47, 1.45 and 0.60 µg a.s./larva dose groups (corresponding to 129.9, 54.1, 22.5, 9.4 and 3.9 mg a.s./kg diet). In the untreated control group cumulative mortality on day 8 was 13.9 %.
The reference item (dimethoate) at a dose of 7.4 µg a.s./larva (equivalent to 48 mg a.s./kg diet) caused 94.4 % mortality on day 8.
On day 15 mortality in the 20.0, 8.33, 3.47, 1.45 and 0.60 µg a.s./larva dose groups was 8.3, 16.7, 13.9, 13.9 and 13.9 %, respectively. There was 22.2 % mortality in the untreated control group and 100.0 % mortality in the reference item group.
At test end (day 22) the emergence rates of adult bees were 86.1, 83.3, 86.1, 83.3 and 75.0 % in the test item treated dosing groups of 20.0, 8.33, 3.47, 1.45 and 0.60 µg a.s./larva (corresponding to 129.9, 54.1, 22.5, 9.4 and 3.9 mg a.s./kg diet). Emergence rate in the untreated control group was 77.8 % and no adult bee emerged in the reference item group at test end (day 22).
None of the doses of the test item treatment groups was not statistically different compared to the control group (Chi^2 2x2 Table Test with Bonferroni Correction (one-sided smaller, $\alpha = 0.05$)).

Toxicity of thiencarbazone-methyl + cyprosulfamide SC 450 (225+225) G to honey bee larvae; laboratory test, repeated exposure

Test Item	Thiencarbazone-methyl + cyprosulfamide SC 450 (225+225) G					
Test Species	Larvae of *Apis mellifera carnica*					
Exposure	repeated exposure *via* treated artificial diets					
Cumulative Dose [µg a.s.*/larva]	Untreated control	0.60	1.45	3.47	8.33	20.0
Concentration [mg a.s.*/kg diet]	-	3.9	9.4	22.5	54.1	129.9
Cumulative Mortality [%] (day 8)	13.9	5.6	0.0	5.6	8.3	2.8
Cumulative Mortality [%] (day 22)	22.2	25.0	16.7	13.9	16.7	13.9
Emergence Rates [%] (day 22)**	77.8	75.0 n.s.	83.3 n.s.	86.1 n.s.	83.3 n.s.	86.1 n.s.
LD_{50} (day 22)	> 20.0 µg a.s.*/larva					
LC_{50} (day 22)	> 129.9 mg a.s.*/kg diet					
NOED (day 22)	≥ 20.0 µg a.s.*/larva					
NOEC (day 22)	≥ 129.9 mg a.s.*/kg diet					

The NOED on day 22 was estimated using Chi^2 2x2 Table Test with Bonferroni Correction (one-sided smaller, $\alpha = 0.05$); n.s. = no statistical significant difference compared to the control
* Calculation of dose / concentration is based on the active ingredient thiencarbazone-methyl
** percentage of successfully hatched bees
$LD_{50+20+10}$/$LC_{50+20+10}$ were not determined by any statistical analysis since the corrected mortality was below 5 % in all treatment groups. Since the NOEC and NOED were ≥ 20.0 µg a.s./larva and ≥ 129.9 mg a.s./kg diet, $LD_{50+20+10}$ and $LC_{50+20+10}$ could be considered as > 20.0 µg a.s./larva and > 129.9 mg a.s./kg diet.

Validity criteria:
All validity criteria were met in this study.

Validity criteria according to OECD GD 239	**Obtained in this study**
Cumulative control mortality on day 8: ≤ 15%	13.9 %
Control emergence rate of the adult bee on day 22: ≥ 70%	77.8 %
Mortality of the reference item on day 8: ≥50%	94.4 %

Conclusions

The toxicity of thiencarbazone-methyl + cyprosulfamide SC 450 (225+225) G was investigated in a honey bee larval toxicity test, following repeated exposure (duration 22 days) and assessing the success of adult emergence.
The $LD_{50/20/10}$ value (day 22) were > 20.0 µg thiencarbazone-methyl/larva.
The $LC_{50/20/10}$ value (day 22) were > 129.9 mg thiencarbazone-methyl/kg diet.
The NOED (day 22) was ≥ 20.0 µg thiencarbazone-methyl/larva.

The NOEC (day 22) was ≥ 129.9 mg thiencarbazone-methyl/kg diet.

A 2.3.1.4 KCP 10.3.1.4 Sub-lethal effects

A 2.3.1.5 KCP 10.3.1.5 Cage and tunnel tests

A 2.3.1.6 KCP 10.3.1.6 Field tests with honeybees

Comments of zRMS:	The study was not considered by zRMS in the current dossier in the assessed in the context of the Art 43 renewal assessment of foramsulfuron.

In order to complete the data set and the knowledge on effects on developmental stages of honey bees a further study has been performed with formulated thiencarbazone-methyl in combination with the safener cyprosulfamide. This study has not yet been evaluated at EU level, however for transparency a detailed Tier 2 summary is provided below. The related study report can be made available to the zRMS upon request.

Reference:	**- Study report will be made available to the zRMS upon request -**
Title:	Thiencarbazone-methyl + cyprosulfamide SC 450 (225+225) G: Effects on Honey Bee Brood (*Apis mellifera* L.) under Semi-Field Conditions - Tunnel Test -
Report:	Schmitzer, S.; Ehmke, A., 2016; 113121033; M-571235-01-1
Authority registration No:	
Guideline(s):	OECD No. 75 (2007), OEPP/EPPO No. 170 (4) (2010)
Deviations:	The post-application exposure phase in the tunnel was reduced to 3.5 days (i.e. day 0 after application and day 1, 2 and 3 after application = 3.5 days) due to the herbicide mode of action of the test item against the *Phacelia*-crop; at the end of the 3rd day after application, the *Phacelia*-crop was no longer attractive to bees (faded crop) and did no longer support the confined colonies.
GLP:	yes
Acceptability:	
Duplication (if vertebrate study):	

Executive summary:

A honey bee brood test with *Apis mellifera* can be required if exposure to honey bee brood and effects on bee brood development cannot be excluded. Investigations under semi-field conditions serve as practical tests to assess the effect of thiencarbazone-methyl + cyprosulfamide SC 450 (225+225) G to honey bee brood in tunnels (confinement) under more realistic exposure field conditions than in the laboratory.
The method of investigating the development of the bee brood is based on the OECD Guidance Document No. 75 (2007) and current recommendations of the AG Bienenschutz (2011). After spray application of the product during bee flight, ontogenesis of honey bee eggs was observed. Mortality of the bees and foraging activity of the bees on the crop were also monitored. The results were compared to a water treated control and to a reference item (fenoxycarb).

Material and Methods

Test item: Thiencarbazone-methyl + cyprosulfamide SC 450 (225 + 225) G; short name: TCM+CSA SC 450 (225+225) G; Sample description: TOX20259-00; Sample ID: M16002877001; Specification no.: 102000013579; Batch ID: 2016-002466; Lot No.: 2016-002466-01; Analysed content of a.s: 230.9 g/L (19.7% w/w) thiencarbazone-methyl (BYH 18636), 230.0 g/L (19.6% w/w) cyprosulfamide (AE 0001789), Density (20 C): 1.174 g/mL.

Test Species:
Honey bees (*Apis mellifera carnica* L.); small bee colonies, maintained according to normal beekeeping practice, containing 11 combs with honey, pollen and brood. The preliminary brood check indicated healthy colonies with all brood stages present and a minimum reserve of food (uncontaminated nectar and pollen) to guarantee colony viability and brood status but also to ensure that enough space is available for exposure of the brood to new food sources. The mean strength of the colonies per treatment group, one day before the application, was similar and ranged between 7369 and 8179 adult bees per colony.

Test Design:
The test was conducted under forced/confined exposure conditions (tunnel), in order to assess potential effects of Thiencarbazone-methyl + cyprosulfamide SC 450 (225+225) G to honey bee colonies including brood development under semi-field conditions. Tunnels (20 m length x 5.5 m width x 2.5 m height) were set up on a ca. 75 m² plot of *Phacelia tanacetifolia* (2 x 36 m²). Small bee colonies were introduced to the tunnels 3 days before the application. One honey bee colony was used per tunnel.
The test item, water and a reference item were applied on the whole plot of plants in two operations, with foraging bees present. The trial was carried out using four tunnels (i.e. replicates) for the test item treatment, the control and the reference item treatment (Insegar, 250 g/kg fenoxycarb), respectively. The confined exposure phase of the honey bees inside the treated crop was 3.5 days following the test item application. At the end of the 3rd day after application, due to the herbicide mode of action of the test item, the *Phacelia*-crop was no longer attractive to bees (faded crop) and did not longer support the confined colonies. Thus, all bee colonies (i.e. the colonies from the test item, the control and the reference item group, respectively) were relocated after 3.5 days of confined exposure from their respective tunnels and placed in an area with no main flowering, bee attractive crops.
After foliar (spray) application of the water (control), test item and the reference item, ontogenesis of a defined number of honey bee eggs was observed for each group and colony. Mortality of adult bees and pupae/larvae as well as foraging activity of the adult bees was also assessed. The condition of the colonies was assessed in regular intervals until the end of the trial.
Ontogenesis of the bees from egg to adult workers was observed for a period of 22 days (i.e. one complete honey bee brood cycle). This was done one day before the application by taking out one or more brood combs and taking a digital picture of the brood comb(s). After saving the file on a computer, 250 eggs per colony were marked at this first brood area fixing day BFD0 (BFD = Brood Area Fixing Day). For each subsequent brood assessment (BFDn), again, the respective comb(s) was taken out of the hive and another digital photo was taken in order to investigate the progress of the brood development until day 21 following the application (BFD22 following BFD0).

Test Parameters:
Mortality of adult bees and pupae: 3 days before to 27 days after application;
Behavioural abnormalities: 3 days before to 27 days after application);
Foraging activity of the bees: 3 days before to 3 days after application;
Condition of the colonies (food stores, brood status and colony strength): 1 day before and 4, 10, 14, 21, 27, 34 and 41 days after application (= end of the trial);
Bee brood development (eggs): 1 day before (= BFD0) and 4 (= BFD 5), 10 (= BFD 11), 14 (= BFD 15), 21 (= BFD 22) days after the application.

Application Rates:
Control: 400 L tap water/ha,
Test Item: 40 g thiencarbazone-methyl via 400 L spray solution/ha; according to Certificate of Analysis. This corresponds to 203.0 g thiencarbazone-methyl + cyprosulfamide SC 450 (225+225) G in 400 L tap water/ha (corresponding to 0.51 g thiencarbazone-methyl + cyprosulfamide SC 450 (225+225) G/L tap water),
Reference Item: 300 g fenoxycarb a.s. (1200 g product)/ha in 400 L spray solution/ha (corresponding to nominally 3.00 g product/L),
all applied during full flowering of the crop when honey bees were actively foraging on the *Phacelia*-crop.

Test Conditions:
Natural field conditions. The period before application was characterized by unsettled weather. The weather stabilised and over the course of the application day, the weather improved and it was warm and sunny. Accordingly there was a high honeybee foraging activity on the crop within the tunnels. Mean temperature during the whole experiment (day -3 to day +3) was between 16.4 and 21.5°C. No rain occurred during the exposure phase of the bees to the treated crop in the tunnels. First precipitation (1 mm) occurred on day 4. Thereafter rain occurred on 6 occasions until day 6.

Statistics:
Statistical evaluation was done for mortality, foraging activity, colony strength, brood termination rate and brood indices using Shapiro-Wilk`s test (check for normal distribution), Levene`s test (check for homogeneity of variance), Student or Welch t- test (pairwise comparison); (software: TOX Rat Professional, Version 2.10.05, ® ToxRat Solutions GmbH).

Dates of experimental work: June 16, 2016 - September 15, 2016

Results:

Mortality of the adult bees (worker bees)

Pre-application phase (day- 3 to day 0 before application):

Mortality of the pre-application phase in the control, test item and reference item group was 93.4, 76.6 and 86.3 dead bees/colony/day, respectively. This was not statistically significantly different compared to the water control (Student t-test, pairwise comparison to the control, two-sided, $\alpha = 0.05$).

Exposure phase in the tunnels (day 0 after application to day 3):

Mortality of adult bees in the test item treatment was very slightly higher compared to the control group. The comparison of the daily mortality values between the test item treatment and the control group did not show any statistically significant difference to the control at any assessment day. A statistical evaluation of the mean mortality levels from the post application period from day 0 after application to day 3 resulted in no statistically significant difference when compared to the control group (Student t-test, pairwise comparison, one-sided greater, $\alpha = 0.05$). Average control mortality of adult bees during the exposure phase (day 0 to day 3 following the application) was 47.7 dead bees/colony/day. The average mortality in the test item group was 49.3 dead bees/colony/day. Reference Item mortality was 42.1 dead bees/colony/day.

Phase outside the tunnels (day 4 after application to day 27):

The number of dead bees in the test item treatment was low with a mean of 10.4 dead bees per day and colony during the period from day 4 to day 27 after treatment. This was lower and accordingly not statistically significant different to the control (11.3 dead bees/day/colony) (Student t-test, pairwise comparison, one-sided greater, $\alpha = 0.05$). The overall comparison from day 0 to day 27 showed that the number of dead bees found in the test item treatment (16.0 dead bees /day/tunnel) was not statistically significant compared to the number of dead bees found in the control group (16.5 dead bees/day/colony). The day wise comparison also did not indicate a statistically significant difference of the test item mortality and the control mortality (Student t-test, pairwise comparison, one-sided greater, $\alpha = 0.05$).
After treatment with the reference item to the adult bees, mortality was the same as in the control group (control and reference item: 16.5 dead bees/day/colony). This was not statistically significant different to the control value.

Mortality of pupae

Pre-application phase (day -3 to day 0 before application):

In the test item treatment 2 dead pupae were found over the pre-application period of 4 days in all 4 colonies (0.13 dead pupae/day/colony). In the control group over the same period 16 dead pupae were found, which resulted in one dead pupae/colony/day. The lower numbers of dead pupae found in the test item group were statistically significant lower compared to the control group (Welch t-test, pairwise comparison to the control, two-sided, $\alpha = 0.05$). In the foreseen reference item colonies 5 pupae were found in all 4 colonies over the pre-application period (0.31 dead pupae/day/colony). As the number of pupae in all treatment groups was negligible the starting situation must be seen as good.

Exposure phase in the tunnels (day 0 after application to day 3):

No dead pupae were found during exposure phase in the test item treated group and this was consequently not statistically significantly different to the control group (0.31 dead pupae/day/colony) (Welch t-test, pairwise comparison one-sided greater, $\alpha = 0.05$).
No dead pupae were found after the application of the reference item following the first 3 days after treatment.

Phase outside the tunnels (day 4 after application to day 27):

In the test item treatment group only 2 dead pupae were found during the period from day 4 to 27 in all 4 colonies (0.02 dead pupae/day/colony). 9 dead pupae were found in the control group for this period (0.09 dead pupae/day/colony). The mean number of dead pupae found in the test item treatment for the period from day 4 to 27 and 0 to 27 was not statistically significantly different to the control group.
Pupae mortality in the reference item group was distinctly increased with means of 16.19 and 13.88 dead pupae/day/colony for both post-application periods from day 4 to 27 and 0 to 27 and both were statistically significantly different to the control group (Welch t-test, pairwise comparison one-sided greater, $\alpha = 0.05$).

Foraging Activity

Pre-application phase (day -3 to day 0 before application):

The mean foraging activity in the intended test item and reference item groups was comparable to the control group, resulting in overall daily mean values of 16.2, 15.3 and 16.5 bees/m²/day in the control, test item group and reference item groups, respectively. As there was no flight activity on day -3 due to enduring rain, this day has been excluded from the calculation of the mean flight density value before application. No statistically significant differences were found between the control, the test and reference item treatment groups at the overall daily mean comparison of this period (Student`s t-test, $\alpha = 0.05$, two-sided).

Exposure phase in the tunnels (day 0 after application to day 3):

Over the two days following application (day 0 and day 1), foraging activity in the test item group was not reduced when compared to the control group or the situation before application. From day 2 onwards foraging activity was decreasing due to the fading attractiveness of the crop as the result of the herbicidal activity of the test item. On day 3 foraging activity in the test item treatment was distinctly decreased to the control group and the bees were removed from the tunnels in the evening of day 3. Accordingly, the overall daily mean foraging activity from day 0 to day 3 in the test item group was lower with 15.8 bees/m²/day compared to 23.3 bees/m²/day in the control group. Consequently, foraging activity over the post application period was statistically significant different to the control (Student t-test, pair-wise comparison to the control, one-sided smaller, $\alpha = 0.05$).
The reference item (Insegar) resulted in no reduction of the foraging activity.

Behavioural abnormalities

No test item related behavioural abnormalities occurred at any time during the whole assessment period (up to day 27). No behavioural abnormalities were observed in the control group and in the reference item group.

Condition of the Colonies

Condition of the colonies was assessed over two complete brood cycles of the honey bees (i.e. 42 days [2 x 21 days]).
At the beginning of the trial, all queens (or eggs) and all brood stages (eggs, larvae and closed brood) were found in all colonies as an indication of healthy colonies. The amount of food reserves (nectar and pollen) was sufficient to ensure colony viability and brood status but also allowed that enough space was available for exposure of the brood to new food sources.
All queens and/or a sufficient presence of eggs were found in the test item treated colonies during all brood checks indicating that the queens were alive and healthy.
After application, no indication of a test item related effect on the condition of the colonies was observed. Compared to the control, a similar amount of all single brood stages (i.e. eggs, larvae or closed brood (pupae) was found during the assessments with no indication of a test item related effect. On all colony assessment days (i.e. 1 day before and on days 4, 10, 14, 21, 27, 34 and 41 after application the total number of brood in the colonies exposed to test item treated crop followed the same pattern as the control colonies. All test item colonies remained vital with increasing bee numbers and healthy brood. There was no indication of any hazard of the test item on the condition of the bee colonies.

Colony Strength

The mean number of honey bees per colony in all treatment groups was similar one day before application and did not differ statistically significantly (mean of 7369 to 8179 per colony). The subsequent development of the colony strength among the colonies in the control and test item treatment groups followed the same pattern. Following re-movement of the colonies from the tunnels, (beside a short decrease within the confinement period) there was a continuous increase of colony strength observable, which was very similar or even higher in the test item group compared to the control group. No statistically significant difference in the colony strength between the test item treated colonies and the control colonies occurred at any assessment date (Welch t-test, pair-wise comparison to the control, one-sided smaller, α = 0.05). Overall, no adverse effects of the test item on colony strength and population development have been observed throughout the study. Development in the reference item group was distinctly decreased which was statistic significant different to the control.
Considering the initial mean number of bees per treatment group before the application as 100 %, the following relative mean numbers of bees were determined:

Treatment Group	Day[1] -1	Day +4	Day +10	Day +14	Day +21	Day +27	Day 34	Day 41
Control	100%	113%	121%	120%	111%	107%	107%	107%
Test Item	100%	95% (n.s.)	105% (n.s.)	110% (n.s.)	114% (n.s.)	111% (n.s.)	103% (n.s.)	102% (n.s.)
Reference Item	100%	82% (*)	102% (*)	87% (*)	72% (*)	71% (*)	55% (*)	62% (*)

[1] in relation to the application
n.s. = not statistically significant to the control, *. = statistically significant to the control; Welch t-test, α=0.05, pairwise; one-sided smaller.

Development of Bee Brood

Brood Termination Rate:

Following the assessment of single cells from the egg stage to the successfully hatched worker bee, the

mean termination rate at BFD (Brood Fixing Day) 22 in the test item group was with a mean of 25.8 % very similar compared to the control group (25.4 %). This Brood Termination Rate in the test item group was not statistically significantly different compared to the control group.
Treatment with the reference item Insegar (a.s.: fenoxycarb) caused a clear decrease of brood development of the marked eggs, resulting in a termination rate of 85.6 %. This decrease was statistically significantly different compared to the control group (Student t-test, pair-wise comparison to the control, one-sided greater, $\alpha = 0.05$).

Brood Compensation Index:

The Brood Compensation Index is an indication for recovery and shows the development of the brood at each assessment. A continuous brood development was observed in the test item as well as in the control group. The Brood Compensation Indices following the labelling of the egg stage up to day 21 after application (BFD+22) were only slightly lower in the test item group compared to the control. Differences in the Brood Compensation Index between test item and control were not statistically significant. The high brood termination rate of the marked cells after treatment with the reference item Insegar (a.s.: fenoxycarb) is also reflected by the statistically significantly lower Brood Compensation Indices in the reference item group when compared to the control.

Treatment Group	BFD +5	BFD +11	BFD +15	BFD +22
Control	2.5	3.1	3.0	4.1
Test Item	2.4 (n.s.)	3.0 (n.s.)	3.0 (n.s.)	4.0 (n.s.)
Reference Item	0.6 (*)	0.7 (*)	0.8 (*)	1.9 (*)

n.s. = not statistically significant to the control, * = statistically significant to the control, Student t-test, α=0.05, pairwise; one-sided smaller

Brood Index:

The Brood Index as an additional indicator for the bee brood development facilitates a comparison between the different treatments. Following the labelling of the egg stage, the Brood Indices of the test item group were as well only slightly lower compared to the control values. Differences in the Brood Index between test item and control were not statistically significant. After treatment with the reference item Insegar (a.s.: fenoxycarb), following the labelling of the eggs, the mean Brood Indices were statistically significant lower compared to the control indices.

Treatment Group	BFD +5	BFD +11	BFD +15	BFD +22
Control	2.5	3.1	3.0	3.7
Test Item	2.3 (n.s.)	3.0 (n.s.)	3.0 (n.s.)	3.7 (n.s.)
Reference Item	0.6 (*)	0.7 (*)	0.6 (*)	0.7 (*)

Accordingly, no adverse effects of the test item on brood development have been observed throughout the study, following the labelling of the egg stage up to day 21 after application (BFD+22).

Effects of Thiencarbazone-methyl + cyprosulfamide SC 450 (225 + 225) G on honey bee brood under semi-field conditions (Tunnel Test)

Parameter	Treatment group[1)]		
	Control	Thiencarbazone-methyl + cyprosulfamide SC 450 (225+225) G	Reference Item Insegar [0.3 kg a.i./ha]

Mean mortality of worker bees / colony / day [%] during			
pre-application phase [2)]	93.4 ± 81.8	76.6 ± 58.6 (n.s.)	86.3 ± 79.3 (n.s.)
exposure phase in the tunnels [2)]	47.7 ± 15.6	49.3 ± 17.0 (n.s.)	42.1 ± 15.6 (n.s.)
phase outside the tunnels [3)]	11.3 ± 8.0	10.4 ± 9.8 (n.s.)	12.3 ± 11.7 (n.s.)
overall after application	16.5 ± 15.8	16.0 ± 17.5 (n.s.)	16.5 ± 16.0 (n.s.)
Mean mortality of larvae and pupae [%] during			
pre-application phase [4)]	1.00 ± 0.46	0.13 ± 0.25 (**)	0.31 ± 0.31 (n.s.)
exposure phase in the tunnels [4)]	0.31 ± 0.47	0.00 ± 0.00 (n.s.)	0.00 ± 0.00 (n.s.)
phase outside the tunnels [5)]	0.09 ± 0.32	0.02 ± 0.10 (n.s.)	16.19 ± 27.19 (*)
overall after application	0.13 ± 0.34	0.02 ± 0.09 (n.s.)	13.88 ± 25.75 (*)
Mean foraging activity / m² / colony / day [n] during			
pre-application phase	16.2 ± 2.8	15.3 ± 4.1 (n.s.)	16.5 ± 3.8 (n.s.)
exposure phase in the tunnels	23.3 ± 3.9	15.8 ± 6.5 (*)	20.4 ± 2.0 (n.s.)
Mean brood termination rate [%] [6)]	25.4	25.8 (n.s.)	85.6 (*)

[1)] Each with four tunnels (replicate)
2) Mean number of dead honey bees per day and colony found in dead bee traps and on gauze strips in the tunnels
3) Mean number of dead honey bees per day and colony found in dead bee traps, only
4) Mean number of dead pupae/larvae per day and colony found in dead bee traps and on gauze strips in the tunnels
5) Mean number of dead pupae/larvae per day and colony found in dead bee traps, only
6) At BFD 22
Statistic: Student or Welch t-test, α=0.05, pairwise; before application: two-sided; after application one-sided greater (mortality and termination rate), one-sided smaller (foraging activity, colony strength)
n.s. = not statistically significant compared to the control; * = statistically significant compared to the control
** Statistical significant lower compared to the control

Conclusions:

To assess the potential effects of Thiencarbazone-methyl + cyprosulfamide SC 450 (225+225) G on honey bee colonies including brood development, 203.0 g product in 400 L tap water/ha (corresponding to 40 g thiencarbazone-methyl/ha), tap water for the control and a reference item were applied to a full-flowering and highly bee-attractive crop (i.e. *Phacelia tanacetifolia*) under semi-field (tunnel) conditions during bee-flight.
No biological relevant adverse effects on mortality of worker bees or pupae were observed. Foraging activity, behaviour, nectar- and pollen storage as well as queen survival was not affected.
No effects on colony development, colony strength or bee brood were observed.
Based on the results of this study, it can be concluded that Thiencarbazone-methyl + cyprosulfamide SC 450 (225+225) G does not adversely affect honey bees and honey bee brood when applied at a rate 203.0 g product in 400 L tap water/ha (corresponding to 40 g thiencarbazone-methyl/ha), during honey bees actively foraging on a bee-attractive, flowering crop.
The observed, characteristic brood effects of the reference item Insegar (a.s.: fenoxycarb) in terms of typicality, time of occurrence and extent, showed that the prevailing test conditions allowed for a profound detection of effects on immature honey bee life stages.

A 2.3.2 KCP 10.3.2. Effects on non-target arthropods other than bees

A 2.3.2.1 KCP 10.3.2.1. Standard laboratory testing for non-target arthropods

A 2.3.2.2 KCP 10.3.2.2. Extended laboratory testing, aged residue studies with non-target arthropods

Comments of zRMS:	The study is considered acceptable. All validity criteria were met. The following deviation is noted: -Mean number of juveniles per female was 5.3 in the control, but only 3.0 for the highest concentration tested. This effect is not significant since the standard deviation was quite high. **Agreed endpoints:** LR_{50} > 1000 mL product/ ha ER_{50} > 1000 mL product/ ha

Reference:	**KCP 10.3.2.2/01**
Title:	Toxicity to the predatory mite Typhlodromus pyri (Acari: Phytoseiidae) using an extended laboratory test on apple Thiencarbazone-methyl + Foramsulfuron OD 80 (30+50 g/L)
Report:	Waibel, J.; 2013; CW13/014; M-457257-01-1
Authority registration No:	
Guideline(s):	EU Directive 91/414/EEC Regulation (EC) No. 1107/2009 US EPA OCSPP not applicable
Deviations:	not applicable
GLP/GEP:	yes
Acceptability:	
Duplication (if vertebrate study):	

Objective:

The objective of this study was to investigate the lethal and sub lethal toxicity of Foramsulfuron + Thiencarbazone-methyl OD 80 (50+30 g/L) to the predatory mite *Typhlodromus pyri* when exposed to treated leaf surfaces. This species was chosen as it is currently one of the two standard species required for EU registration. The use of leaf surfaces rather than glass provides a more relevant test substrate for the dispersion of the test item and thus a more realistic exposure of non-target arthropods to the product.
The test system meets the requirements of the EU Directive 91/414/EEC and the Regulation (EC) No. 1107/2009.

Materials and Methods:

Test item: Foramsulfuron + Thiencarbazone-methyl OD 80 (50+30 g/L); sample description: TOX09970-00; specification no.: 102000025743-01; batch ID: 2012-005269; analysed content of active ingredients: foramsulfuron 51.05 g/L, thiencarbazone-methyl 30.49 g/L; density: 1.028 g/mL.

The test item was applied onto detached apple leaves (*Malus sylvestris)* at rates of 80, 150, 283, 532, and 1000 mL product/ha and the effects on the predatory mite *Typhlodromus pyri* were compared to those of a deionised water treated control. A toxic reference (active substance: Dimethoate) applied at 36.4 mL product/ha (15.0 g a.s./ha) was included to indicate the relative susceptibility of the test organisms and the test system.
Mortality of 100 predatory mites, protonymphs at study start (5 replicates with 20 individuals per test group), was assessed 1, 4, 7, 10, 12 and 14 days after exposure by counting the number of living and dead mites. The number of escaped mites was calculated as the difference from the total number exposed.
The reproduction rate of surviving mites was then evaluated from day 7 until day 14 after treatment by counting the total number of offspring (eggs and larvae) produced.
The climatic test conditions during the study were 23.5 - 25.5 °C temperature and 60 – 72 % relative humidity. The light / dark cycle was 16:8 h with a light intensity range of 655 - 1601 Lux.

Dates of experimental work: January 24, 2013 to February 7, 2013

Results and Discussion:

Validity criteria:
In the control group the mortality was ≤ 20 % and the toxic reference resulted in ≥ 50 % corrected mortality. The average number of eggs per female in the control was ≥ 4.
Therefore, the results of this study can be considered as valid, requested by the mentioned guideline (BLÜMEL ET AL., 2000).

Biological findings:
The mortality / escaping rate in the control exposure units up to day 7 after treatment was 12.0 %. The mean corrected mortality of the mites and the mean reproduction rate of the surviving females exposed to the test item and the toxic reference is given below:

Table: Effects of Foramsulfuron + Thiencarbazone-methyl OD 80 (50+30 g/L)

Test item:		**Foramsulfuron + Thiencarbazone-methyl OD 80 (50+30 g/L)**					
Test organism:		*Typhlodromus pyri*					
Exposure on:		Detached apple leaves					
		Mortality after 7 days [%]			Reproduction		
Treatment	mL product/ha	Uncorr.	Corr.	P-Value(*)	Rate (eggs per female)	Red. rel. to Control [%]	P-Value (#)
Control	0	12.0			5.3		
Test item	80	9.0	-3.4	1.000 n.sign.	4.8	10.0	0.259 n.sign.
Test item	150	9.0	-3.4	1.000 n.sign.	5.2	3.0	0.309 n.sign.
Test item	283	19.0	8.0	0.602 n.sign.	3.8	28.0	0.330 n.sign.
Test item	532	7.5	-5.1	1.000 n.sign.	5.2	2.9	0.358 n.sign.
Test item	1000	12.0	0.0	1.000 n.sign.	3.0	43.0	0.350 n.sign.
Reference item	36.4	100.0	100.0		n.a.	n.a.	

LR_{50}: > 1000 mL product/ ha
ER_{50}: > 1000 mL product/ ha

* Fisher`s Exact test, one-sided, p-values are adjusted according to Bonferroni-Holm
# one-way ANOVA, Williams test (one-sided)
n.a. not assessed
n.sign. not significant

Mortality:
The mortality / escaping rate in the control group up to day 7 after treatment was 12.0 %.
No statistically significant mortality occurred in all test item rates. At the rates of 80 and 150 mL product/ha, no corrected mortality (-3.4 %) was found. At the 283 mL product/ha rate, the corrected mortality was 8.0 %. No corrected mortality (-5.1 %) occurred at the 532 mL product/ha rate. At the highest rate of 1000 mL product/ha, no corrected mortality (0 %) was observed.

The LR_{50} was estimated to be > 1000 mL product/ha.

The NOER (no observed effect rate) for mortality was 1000 mL product/ha.

In the reference item group, all mites were dead on day 7 of the study.

Reproduction:
No statistically significant reduction in reproductive success occurred at all test item rates.
The mean number of offspring produced per female in the control group was 5.3. This compared to 4.8 eggs/female in the 80 mL product/ha rate of the test item, 5.2 eggs/female in the 150 mL product/ha rate, 3.8 eggs/female in the 283 mL product/ha rate, 5.2 eggs/female in the 532 mL product/ha rate and 3.0 eggs/female in the 1000 mL product/ha rate (all rates refer to Thiencarbazone-methyl + Foramsulfuron OD 80).

The ER_{50} was estimated to be > 1000 mL product/ha.

The NOER (no observed effect rate) for reproduction was 1000 mL product/ha.

Conclusions:

The corrected mortality at all test item rates was below 8 %.
The LR_{50} was estimated to be > 1000 mL product/ha.
Reproduction was assessed for all rates of Foramsulfuron + Thiencarbazone-methyl OD 80 (50+30 g/L). At the rates of 80, 150, 283, 532, and 1000 mL product/ha, the reproduction was reduced by 10.0 %, 3.0 %, 28.0 %, 2.9 % and 43.0 %, respectively.
The ER_{50} was estimated to be > 1000 mL product/ha.
The figures obtained fulfil the validity criteria of the laboratory method for exposure on glass plates.

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Comments of zRMS:	The study is considered acceptable. All validity criteria were met. **Agreed endpoints:** LR_{50} > 1000 mL product/ha ER_{50} > 1000 mL product/ha

Reference:	**KCP 10.3.2.2/02**
Title:	Toxicity to the parasitoid wasp Aphidius rhopalosiphi (Hymenoptera: Braconidae) using an extended laboratory test on barley - Thiencarbazone-methyl + foramsulfuron OD 80 (30+50 g/L
Report:	Waibel, J.; 2013; CW13/013; M-469970-01-1
Authority registration No:	
Guideline(s):	EU Directive 91/414/EEC MEAD-BRIGGS ET AL. (2000), MEAD-BRIGGS ET AL. (2009), CANDOLFI ET AL. (2001) Regulation (EC) No. 1107/2009 US EPA OCSPP not applicable
Deviations:	none
GLP/GEP:	yes
Acceptability:	
Duplication (if vertebrate study):	

Objective:

The objective of this extended laboratory study was to investigate the lethal and sublethal toxicity of Foramsulfuron + Thiencarbazone-methyl OD 80 (50+30 g/L) on the parasitoid wasp Aphidius rhopalosiphi when exposed on a plant surface. This species was chosen as it is currently one of the two standard species required for EU registration. The test system meets the requirements of the EU Directive 91/414/EEC and the Regulation (EC) No. 1107/2009.

Materials and Methods:

Test item: Foramsulfuron + Thiencarbazone-methyl OD 80 (50+30 g/L); sample description: TOX09970-00; specification no.: 102000025743-01; batch ID: 2012-005269; content of active ingredients: Foramsulfuron 51.05 g/L, Thiencarbazone-methyl 30.49 g/L; density: 1.028 g/mL.

The test item was applied on barley seedlings (*Hordeum vulgare*) at rates of 80, 150, 283, 532, and 1000 mL product/ha and the effects on the parasitoid wasp *Aphidius rhopalosiphi* were compared to those of a deionised water treated control. A toxic reference (active substance: Dimethoate) applied at 7.3 mL product/ha (3 g a.s./ha) was included to indicate the relative susceptibility of the test organisms and the test

system.
Mortality of 30 female wasps, not older than 48 h at study start (6 replicates with 5 wasps per test group), was assessed 2, 24 and 48 h after exposure.
Repellency of the test item was assessed during the initial 3 h after the release of the females. Five separate observations were made at 30-minute intervals starting 15 - 30 minutes after the introduction of all wasps. An additional repellency assessment for the control and the highest test item rate group was conducted 24 h and 48 h after the release of the wasps into the exposure units.
From the water control and all test item rates, 15 impartially chosen females per treatment were each transferred to a cylinder containing untreated barley seedlings infested with *Rhopalosiphum padi* for a period of 24 h. The number of mummies was assessed 12 days later.
The climatic test conditions during the study were 19.5 - 21.5 °C temperature and 60 – 85 % relative humidity. The light / dark cycle was 16:8 h with a light intensity range of 506 - 741 Lux in the mortality phase, 2550 - 5290 Lux in the parasitation phase and 11240 - 19610 Lux in the reproduction phase of the study.

Dates of experimental work: February 04, 2013 to February 19, 2013

Results and Discussion:

Validity criteria:

Table: Validity criteria of the study

	Validity criteria	Finding
Mortality in water control	≤ 10%	0%
Corrected mortality reference item	≥ 50%	70.0%
Mean reproduction per female in water control	≥ 5	29.5
Number of wasps in the water control producing zero values for reproduction	≤ 2	1

All validity criteria of the test according to the guideline for an extended laboratory test (MEAD-BRIGGS ET AL., 2009) were met. Therefore, the results of this study can be considered as valid.

Biological findings:
Mortality, reproduction and repellency in each of the treatments are summarised below.

Table: Effects of Foramsulfuron + Thiencarbazone-methyl OD 80 on mortality, reproduction and repellency

Test item:		**Foramsulfuron + Thiencarbazone-methyl OD 80 (50+30 g/L)**						
Test organism:		*Aphidius rhopalosiphi*						
Exposure on:		Barley seedlings						
		Mortality after 48 h [%]			Reproduction		Repellency (first 3 h)	
Treatment	mL prod./ha	Uncorr.	Corr.	P-Value(*)	Rate (mummies per female)	Red. rel. to Control [%] P-Value(#)	% Wasps on plant	Red. rel. to Control [%] P-Value(##)
Control	0	0.0			29.5		56.0	
Test item	80	0.0	0.0	1.000 n.sign.	32.2	-9.3 0.855 n.sign.	58.3	-4.2 0.586 n.sign.
Test item	150	6.7	6.7	1.000 n.sign.	27.7	6.1 0.983 n.sign.	43.7	22.0 0.002 sign.
Test item	283	0.0	0.0	1.000 n.sign.	21.0	28.7 0.531 n.sign.	50.0	10.7 0.134 n.sign.
Test item	532	6.7	6.7	1.000 n.sign.	29.8	-1.1 0.500 n.sign.	38.8	30.7 < 0.001sign.

Test item:		**Foramsulfuron + Thiencarbazone-methyl OD 80 (50+30 g/L)**						
Test organism:		*Aphidius rhopalosiphi*						
Exposure on:		Barley seedlings						
		Mortality after 48 h [%]			Reproduction		Repellency (first 3 h)	
Treatment	mL prod./ha	Uncorr.	Corr.	P-Value(*)	Rate (mummies per female)	Red. rel. to Control [%] P-Value(#)	% Wasps on plant	Red. rel. to Control [%] P-Value(##)
Test item	1000	6.7	6.7	1.000 n.sign.	36.3	-23.1 0.659 n.sign.	14.8	73.5 < 0.001sign.
Reference item	7.3	70.0	70.0		n.a.	n.a.	46.7	16.7

LR_{50}: > 1000 mL product/ha;
ER_{50}: > 1000 mL product/ha;

* Fisher`s Exact test, one-sided, p-values are adjusted according to Bonferroni-Holm
# Wilcoxon test (one-sided), p-values are adjusted according to Bonferroni-Holm
One-way ANOVA, Dunnett test (one-sided)
n.a. not assessed n.sign. not significant sign. significant

At the highest test item rate of 1000 mL product/ha, repellent effects (settling of the wasps on plants < 30 %) were observed in the first 3 h after the introduction of the wasps into the exposure units. A second repellent assessment after 24 h was initiated in which the highest test item rate still showed repellency with 23.3 % of the wasps settling on the plant compared to 50.8 % in the control group.
At the assessment 48 hours after the introduction of the wasps, no repellent effects were observed anymore at the 1000 mL product/ha rate. A mean of 35.8 % of the wasps were found on the plants in this test item group compared to 46.7 % in the control group.

Conclusions:

In this extended laboratory test the effects of Thiencarbazone-methyl + Foramsulfuron OD 80 (30+50 g/L) residues on the survival of *Aphidius rhopalosiphi* were determined at 80, 150, 283, 532, and 1000 mL product/ha, applied to barley seedlings (*Hordeum vulgare*).

The corrected mortality at all test item rates was below 7 %.
The LR_{50} was estimated to be > 1000 mL product/ha.

No repellent effect of the test item (settling of the wasps on plants < 30 %) was observed except in the highest test item rate of 1000 mL product/ha. This initially observed effect disappeared within 48 h after the introduction of the wasps into the test system.

Reproduction was assessed for all test item rates. No reduction in reproductive success relative to the control (-9.3 %) was detected at the 80 mL product/ha rate. At the rates of 150, and 283 mL product/ha, a reduction of 6.1 % and 28.7 %, respectively, occurred. No reduction in reproductive success (-1.1 % and -23.1 %, respectively) was found at the highest test item rates of 532, and 1000 mL product/ha.

The ER_{50} was estimated to be > 1000 mL product/ha.

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Comments of zRMS:	The study is considered acceptable. All validity criteria were met. **Agreed endpoint:** LR_{50} > 1000 mL product/ha

Reference:	**KCP 10.3.2.2/03**
Title:	Toxicity to the green lacewing Chrysoperla carnea (Neuroptera: Chrysopidae) using an extended laboratory test on apple Thiencarbazone-methyl + Foramsulfuron OD 80 (30+50 g/L)
Report:	Waibel, J.; 2013; CW13/015; M-469943-01-1
Authority registration No:	
Guideline(s):	EU Directive 91/414/EEC Regulation (EC) No. 1107/2009 US EPA OCSPP not applicable
Deviations:	none
GLP/GEP:	yes
Acceptability:	
Duplication (if vertebrate study):	

Objective:

The purpose of this study was to investigate the lethal and sublethal toxicity of Foramsulfuron + Thiencarbazone-methyl OD 80 (50+30 g/L) to the green lacewing Chrysoperla carnea when exposed to treated leaf surfaces. The use of leaf surfaces rather than glass provides a more relevant test substrate for the dispersion of the test item and thus a more realistic exposure of non-target arthropods to the product. The test system meets the requirements of the EU Directive 91/414/EEC and the Regulation (EC) No. 1107/2009.

Materials and Methods:

Test item: Foramsulfuron + Thiencarbazone-methyl OD 80 (50+30 g/L); sample description: TOX09970-00; specification no.: 102000025743-01; batch ID: 2012-005269; analysed content of active ingredients: Foramsulfuron 51.05 g/L, Thiencarbazone-methyl 30.49 g/L; density: 1.028 g/mL.

The test item was applied to detached apple leaves (Malus sylvestris) at rates of 80, 150, 283, 532, and 1000 mL product/ha and the effects on the green lacewing Chrysoperla carnea were compared to those of a deionised water treated control. A toxic reference (active substance: Dimethoate) applied at 29.2 mL product/ha (12 g a.s./ha) was included to indicate the relative susceptibility of the test organisms and the test system.
The preimaginal mortality of 40 larvae (per test group), 2 days old at study start, was assessed till the hatch of the imagines (up to 19 days). The fertility and fecundity of the surviving hatched adults were then evaluated over the period of one week.
The experiment was performed in a controlled environment room at a temperature range of 23.5 - 27.0 °C and a relative humidity range of 61 – 77 %. Short deviations of the test conditions (less than 2 h; e.g. due to handling of the test system) are considered being without consequence to the study outcome and were not reported. The light / dark cycle was 16:8 h with a light intensity range of 1232 - 3036 Lux during the mortality phase and of 1860 - 2660 Lux during the reproduction phase of the study.

Dates of experimental work: January 29, 2013 to March 05, 2013

Results and Discussion:

Validity criteria:

Table: Validity criteria of the study

	Validity criteria	Finding
Mortality in water control	≤ 20%	0%
Corrected mortality reference item	≥ 50%	97.5%
Mean number of eggs per female and day in water control	≥ 15	29.3
Mean hatching rate of the eggs (fertility)	≥ 70%	80.1%

in water control		

All validity criteria of the test based on those of the laboratory method with glass plates (VOGT ET AL., 2000) were met. Therefore, the results of this study can be considered as valid.

Biological findings:
Mortality and reproduction in each of the treatments are summarised below.

Table: Effects of Foramsulfuron + Thiencarbazone-methyl OD 80 on mortality and reproduction in each treatment.

Test item:		**Foramsulfuron + Thiencarbazone-methyl OD 80 (50+30 g/L)**				
Test organism:		*Chrysoperla carnea*				
Exposure on:		Detached apple leaves				
		Preimaginal mortality [%]			Reproduction	
Treatment	mL product/ha	Uncorr.	Corr.	P-Value(*)	Eggs per female and day	Fertility [hatching rate in %]
Control	0	0.0			29.3	80.1
Test item	80	5.0	5.0	0.987 n.sign.	24.4	71.7
Test item	150	5.0	5.0	0.987 n.sign.	30.0	80.2
Test item	283	0.0	0.0	1.000 n.sign.	24.3	77.7
Test item	532	5.0	5.0	0.987 n.sign.	30.2	78.0
Test item	1000	7.5	7.5	0.601 n.sign.	29.1	80.6
Reference item	29.2	97.5	97.5		n.a.	n.a.

LR_{50}: > 1000 mL product/ha;

* Fisher`s Exact test (one-sided), p-values are adjusted according to Bonferroni-Holm
n.a. not assessed
n.sign. not significant

Preimaginal Mortality:
In the control, 40 larvae pupated, and all developed successfully into adults. At the test item rates of 80, and 150 mL product/ha, 40 and 39 larvae pupated, respectively. From these pupae 38 each developed into adults. In the 283 mL product/ha rate, 40 larvae pupated, and all hatched successfully. In the highest test item rates of 532, and 1000 mL product/ha, 39 larvae pupated each and out of those 38 and 37, respectively, developed into adult lacewings. In the reference item one larva pupated and developed into an adult. The corrected preimaginal mortality from all rates of the test item was below 8 % which was not statistically significant. The NOER (no observed effect rate) for preimaginal mortality was 1000 mL product/ha. The LR_{50} was estimated to be > 1000 mL product/ha. For the reference item 97.5 % corrected preimaginal mortality occurred.

Reproduction:
The mean number of eggs per female and day for the control during the test period was 29.3. The hatching rate (= fertility) of the eggs was 80.1 %. The mean number of eggs per female and day for the 80 mL product/ha rate was 24.4 with a hatching rate of 71.7 %. In the rate of 150 mL product/ha, 30.0 eggs/female/day were laid with a hatching rate of 80.2 %. The mean number of eggs/female/day at the 283 and 532 mL product/ha rates were 24.3 and 30.2, respectively, with corresponding hatching rates of 77.7 % and 78.0 %. In the highest test item rate of 1000 mL product/ha, 29.1 eggs per female and day were laid with a hatching rate of 80.6 %.

Conclusions:

In this extended laboratory test the effects of Thiencarbazone-methyl + Foramsulfuron OD 80 (30+50 g/L) residues on the survival of the green lacewing Chrysoperla carnea were determined at the rates of 80, 150, 283, 532, and 1000 mL product/ha applied to detached apple leaves (Malus sylvestris).

The corrected preimaginal mortality at all test item rates was below 8 %.

The LR_{50} was estimated to be > 1000 mL product/ha.

Reproduction was assessed for all rates of Thiencarbazone-methyl + Foramsulfuron OD 80. There were no adverse effects of the test item on the reproductive performance. The mean number of eggs/female/day was above the lower limit given as validity criterion for the glass plate method (mean number of eggs/female/day: ≥ 15, mean hatching rate: ≥ 70 %) according to the historical database of the ring testing group (VOGT ET AL., 2000).

The figures obtained fulfil the validity criteria of the laboratory method for the exposure on glass plates.

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Comments of zRMS:	The study is considered acceptable. All validity criteria were met. **Agreed endpoints:** LR_{50} and ER_{50} > 1000 mL product/ha

Reference:	**KCP 10.3.2.2/04**
Title:	Effects of thiencarbazone-methyl + foramsulfuron OD 80 (30+50 g/L) on the reproduction of rove beetles Aleochara bilineata - Extended laboratory study - Dose response test
Report:	Schmitzer, S.; 2013; 81291071; M-461869-01-1
Authority registration No:	
Guideline(s):	Grimm et al. 2000
Deviations:	none
GLP/GEP:	yes
Acceptability:	
Duplication (if vertebrate study):	

Objective:

The aim of this study was to estimate the reproduction efficiency of *Aleochara bilineata* under the impact of residues of Foramsulfuron + Thiencarbazone-methyl OD 80 (50+30 g/L) on a worst-case natural soil (LUFA 2.1) in an extended laboratory experiment, compared to water treated control and a reference item group.

Materials and Methods:

Test item: Foramsulfuron + Thiencarbazone-methyl OD 80 (50+30 g/L); Batch ID: 2012-005269; Sample Description: TOX09970-00; Material No.: 80979444; Specification No.: 102000025743 – 01; content of a.s.: a) foramsulfuron (AE F130360): 4.97% w/w (51.05 g/L) and b) thiencarbazone-methyl (BYH 18636): 2.97% w/w (30.49 g/L); density: 1.028 g/mL (20 °C).

1 to 6 days old staphylinid beetles (*Aleochara bilineata*) were exposed to the test item at 5 concentrations (80, 150, 283, 532, and 1000 mL product/ha in 400 L water/ha) for 28 days. In addition, a water treated control and a reference item group (Perfekthion EC [400 g/L dimethoate], at a rate of 4.4 L/ha in 400 L deionised water/ha) were tested. The test item at 5 concentrations, control and reference item were sprayed via laboratory spray applicator on the soil surface at a water amount of 400 L water/ha. Exposure of the beetles was reached via treated natural soil LUFA 2.1. The results were compared to a deionised water treated control and a reference item group.
The beetles were introduced into the test units immediately after treatment. Each replicate contained 10 female and 10 male beetles and 4 replicates per treatment. On day 7, 14, and 21 approx. 500 pupae of

Delia antiqua were buried into the soil of each replicate to be parasitized by the larvae of the beetles. On day 28, the adults were separated from the soil and the soil with the pupae was allowed to dry for seven days. On day 35 the pupae were sieved out of the natural soil and transferred into an emergence container. The emergence of the F1-generation of beetles was observed from day 37 - 75 and the effect on reproduction of *Aleochara bilineata* was assessed.
During the test the temperature ranged between 18 °C and 22 °C, relative humidity was 60 - 83 % and the light intensity was 420 - 930 lux with a photoperiod of 16 h light: 8 h dark.

Dates of experimental work: March 13, 2013 to May 27, 2013

Results and Discussion:

Validity criteria:

Table: Validity criteria of the study

Validity criteria	Recommended	Obtained
Mean number of emerged beetles in the control group (beetles per replicate)	> 400	958
Reduction of reproduction in the reference item compared to the Control	≥ 50%	99.8%

All validity criteria of the test according to the guideline were met. Therefore, this study is valid.

Biological findings:
The reduction of reproduction capacity of the rove beetle *Aleochara bilineata* exposed to the test item at all test item rates was below 7 % as listed below.

Table: Effects on reproduction of *Aleochara bilineata* exposed to Foramsulfuron + Thiencarbazone-methyl OD 80 (50+30 g/L) in an extended laboratory dose response trial

	Rate [1] [mL product/ha]	Reproduction Efficiency [mean number of emerged beetles ± Standard Deviation]	Effect on Reproduction [2] [%]
Test Item	80	940 ± 62 (n.s.)	2.0
Test Item	150	896 ± 50 (n.s.)	6.5
Test Item	283	900 ± 33 (n.s.)	6.1
Test Item	532	893 ± 48 (n.s.)	6.8
Test Item	1000	898 ± 79 (n.s.)	6.3
ER_{50} Test Item	> 1000		
Control	-	958 ± 41	-
Reference Item	4400	2 ± 1 (*)	99.8

[1] Application rate in 400 L water/ha
[2] Effect on reproduction according to the following formula: (1-Rt/Rc)*100 % calculated on the exact raw data (positive values represent a decreased reproduction compared to the control)
* = statistically significantly difference compared to the control; n.s. = not statistically significantly difference compared to the control; Test Item: Dunnett`s multiple t-test; Reference Item: Student pairwise t-test, one-sided smaller, α = 0.05;

Conclusions:

The ER_{50} was estimated to be > 1000 mL product/ha.

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Comments of zRMS:	The study is considered acceptable. All validity criteria were met. **Agreed endpoints:** LR50 and ER_{50} > 1000 mL PPP/ha

Reference:	**KCP 10.3.2.2/05**
Title:	Toxicity to the parasitoid wasp Aphidius rhopalosiphi (Hymenoptera: Braconidae) using an extended laboratory test on barley thiencarbazone-methyl + foramsulfuron OD 80 (30+50 g/L)
Report:	Jans, D.; 2014; CW13/057; M-477760-01-1
Authority registration No:	
Guideline(s):	EU Directive 91/414/EEC; Regulation (EC) No. 1107/2009; US EPA OCSPP not applicable
Deviations:	none
GLP/GEP:	yes
Acceptability:	
Duplication (if vertebrate study):	

Objective:

The objective of this study was to investigate the lethal and sublethal toxicity of residues of Foramsulfuron + Thiencarbazone-methyl OD 80 (50+30 g/L) that are aged under controlled environmental conditions to the parasitoid wasp *Aphidius rhopalosiphi* when exposed to these residues on treated barley seedlings. This species was chosen as it is currently one of the two standard species required for EU registration. The test system meets the requirements of the EU Directive 91/414/EEC and the Regulation (EC) No. 1107/2009.

Materials and Methods:

Test item: Foramsulfuron + Thiencarbazone-methyl OD 80 (50+30 g/L); analysed content of active ingredients: foramsulfuron 51.05 g/L, thiencarbazone-methyl 30.49 g/L; density: 1.028 g/mL; sample description: TOX09970-00; specification no.: 102000025743-01; batch ID: 2012-005269.

The test item was applied with 1.0 L product/ha diluted in 400 L deionised water/ha on barley plants (Hordeum vulgare). The control was treated with deionised water in the same way as the test item. A toxic reference (active substance: Dimethoate) was applied on each exposure date at 0.0075 L product/ha (3 g a.s./ha) diluted in 400 L deionised water/ha on untreated barley plants as well. It was included to indicate the relative susceptibility of the test organisms and the test system.

Parasitoid wasps (Aphidius rhopalosiphi) were exposed to these residues on the treated plants. Three bioassays were performed, the first started on the application day of the test item (0DAT1), the second two days later (2DAT1) and the last bioassay one week after application (7DAT1).

Mortality of 30 female wasps, not older than 48 h at study start (6 replicates with 5 wasps per test group), was assessed 2, 24 and 48 h after exposure in all bioassays.
Repellency of the test item was assessed during the initial 3 h after the release of the females. Five separate observations were made at 30-minute intervals starting 15 - 30 minutes after the introduction of all wasps.
The reproductive performance was assessed in all bioassays. For this 15 impartially chosen females from the water control and the test item group were each transferred to a cylinder containing untreated barley seedlings infested with Rhopalosiphum padi for a period of 24 h. The number of mummies was assessed 12 days later in the first bioassay, 10 days in the second and 11 days in the third bioassay.

Aging of the spray residues on the potted barley plants took place under controlled environmental conditions. The climatic conditions (temperature and relative humidity) were continuously recorded using a

data logger. The temperature ranged from 19.5 to 20.5 °C and the relative humidity from 68 to 79 % during the aging time of the barely plants. The light intensity was measured once per phase for each bioassay using a Luxmeter. The light intensity range was 998 - 1522 Lux with a light / dark cycle of 16:8 hours. The laboratory phase for each exposure date was performed in a controlled environment room (target range 20 ± 2 °C and 60 – 90 % relative humidity). Temperature and relative humidity were continuously recorded with a data logger. The light intensity was measured once per phase for each bioassay using a Luxmeter.

Dates of experimental work: November 11, 2013 to December 02, 2013

Results and Discussion:

Validity criteria:
In all bioassays no control mortality occurred, and the corrected mortality of the reference item group was ≥ 50 %. The mean reproduction per female in the control was ≥ 5 mummies per female with zero wasps producing no mummies in all bioassays.
Therefore, the results of this study can be considered as valid (The validity criteria are based on the guideline for an extended laboratory test (MEAD-BRIGGS ET AL., 2010)).

Biological findings:
The effects of Foramsulfuron + Thiencarbazone-methyl OD 80 (50+30 g/L) applied at a rate of 1.0 L product/ha in 400 L deionised water/ha were tested after exposure of the parasitic wasps to freshly applied and aged spray residues on potted barley plants.

Table: Effects of Foramsulfuron + Thiencarbazone-methyl OD 80 (50+30 g/L)

Test item:	**Foramsulfuron + Thiencarbazone-methyl OD 80 (50+30 g/L)**		
Application rate:	1.0 L product/ha		
Test organism:	*Aphidius rhopalosiphi*		
Exposure on:	Dried spray deposits on barley plants		
Start bioassay:	0DAT1[a]	2DAT1[a]	7DAT1[a]
	Mortality (%) after 48 h		
Control:	0.0	0.0	0.0
Test item:	0.0	0.0	0.0
Reference item:	70.0	96.7	96.7
	Corrected Mortality (%)		
Test item:	**0.0** (p-value 1.000, not significant[b])	**0.0** (p-value 1.000, not significant[b])	**0.0** (p-value 1.000, not significant[b])
Reference item:	70.0	96.7	96.7
	Repellency (mean values)		
	% Wasps on plant		
Control:	44.0	72.7	73.2
Test item:	25.8	58.3	59.2
Reference item:	41.7	67.8	69.8
	Reduction rel. to control (%)		
Test item	**41.3** (p-value 0.002, significant[c])	**19.7** (p-value 0.056, not significant[c])	**19.1** (p-value 0.038, significant[c])
Reference item:	5.3	6.7	4.6
	Reproduction		
	Number of mummies per female		
Control:	54.0	49.2	35.8
Test item:	40.9	45.0	37.4
	Reduction rel. to control (%)		
Test item:	**24.2**	**8.5**	**-4.4**

	(p-value 0.152, not significant[c])	(p-value 0.347, not significant[c])	(p-value 0.419, not significant[c])

[a] Days after treatment
[b] Fisher´s Exact test (one-sided, α = 0.05)
[c] one-way ANOVA, Williams test (one-sided, α = 0.05)

Mortality:
In all three bioassays, no mortality was found in the control as well as in the test item groups.
In the first bioassay the exposure to the reference item resulted in 70.0 % mortality of the test organisms after 48 h of exposure. In the second and third bioassay, 96.7 % mortality was detected.

Repellency:
During the observations in the initial 3 h of each bioassay, repellent effects could be observed in the first bioassay with only 25.8 % of the wasps settling on the plants in the test item group compared to 44.0 % of the wasps found on the plants in the control group. In the second bioassay no repellent effects were found anymore with 58.3 % of the wasps sitting on the plants in the test item group compared to 72.7 % of the wasps found on the plants in the control group. No repellent effects occurred in the third bioassay as well with 59.2 % of the wasps settling on the plants in the test item group compared to 73.7 % of the wasps found on the plants in the control group.

Reproduction:
No statistically significant reduction in reproductive success relative to the control was found in all bioassays. In the first bioassay the reduction was 24.2 %. In the second bioassay the reduction was 8.5 %. No reduction (-4.4 %) occurred in the third bioassay.

Conclusions:

No mortality was found in all bioassays.

The reduction in reproductive success relative to the control in the first bioassay started on the application day was 24.2 %. The reduction decreased to 8.5 % in the second bioassay started 2 days after the application. In the last bioassay started 7 days after the application no reduction in reproduction (-4.4 %) was found anymore.

A repellent effect of the test item was observed only in the first bioassay. This repellent effect disappeared after 2 days of aging of the treated plants.

A 2.3.2.3 KCP 10.3.2.3. Semi-field studies with non-target arthropods

A 2.3.2.4 KCP 10.3.2.4. Field studies with non-target arthropods

A 2.3.2.5 KCP 10.3.2.5. Other routes of exposure for non-target arthropods

A 2.4 KCP 10.4 Effects on non-target soil meso- and macrofauna

A 2.4.1 KCP 10.4.1 Earthworms

A 2.4.1.1 KCP 10.4.1.1 Earthworms - sub-lethal effects

Comments of	The study is considered acceptable. All validity criteria were met.

zRMS:	**Agreed endpoints:** $NOEC_{rep.}$ = 178 mg PPP/ kg dws LOEC = 316 mg PPP/ kg dws EC_{10}=209 mg PPP/ kg dws $NOEC_{growth}$=56 mg test item/kg dry weight artificial soil

Reference:	**KCP 10.4.1.1/01**
Title:	Foramsulfuron + thiencarbazone-methyl OD 80 (50+30) G: Effects on survival, growth and reproduction of the earthworm Eisenia fetida tested in artificial soil
Report:	Kratz, M.; 2013; kra/Rg-R-144/13; M-468316-01-1
Authority registration No:	
Guideline(s):	EU Directive 91/414/EEC Regulation (EC) No. 1107/2009 US EPA OCSPP not applicable
Deviations:	not applicable
GLP/GEP:	yes
Acceptability:	
Duplication (if vertebrate study):	

Objective:

The purpose of this study was to assess the effect of Foramsulfuron + Thiencarbazone-methyl OD 80 (50+30 g/L) G on survival, growth, and reproduction of the earthworm *Eisenia fetida* during an exposure in an artificial soil with 5 different test concentrations. The method of application and the test species are recommended by the international test guidelines (ISO 11268-2: 1998 (E) and OECD 222: April 13, 2004).

Materials and Methods:

Test item: Foramsulfuron + Thiencarbazone-methyl OD 80 (50+30 g/L) G; Sample description: TOX09970-00; Batch ID: 2012-005269; Material No.: 80979444; Specification No. 102000025743-01; content: 51.05 g foramsulfuron/L and 30.49 g thiencarbazone-methyl/L; density: 1.028 g/mL.

Adult *Eisenia fetida* (approx. six months old, 8 x 10 animals for the control group and 4 x 10 animals per test concentration of the treatment group) were exposed in an artificial soil (containing 69 % industrial quartz sand, 20 % kaolin clay, 10 % sphagnum peat, 1 % food and $CaCO_3$ for the adjustment to pH 6.0 ± 0.5) to the nominal test concentrations of 56, 100, 178, 316 and 562 mg test item/kg dry weight artificial soil. The test item was mixed into the soil. After 28 days the number of surviving animals and their weight alteration was determined. They were then removed from the artificial soil. After further 28 days, the number of offspring was determined.

During the test period, the temperature was in the range of 18 to 22 °C. The test vessels were kept under under a 16-hour light to 8-hour darkness photoperiod. The measured mean light intensity was 575 Lux at day 0, 518 Lux at day 28 and 511 Lux at day 56 of the study.

Toxic standard: Carbendazim (Carbendazim EC 360 G): 1.25, 2.50 and 5.00 mg a.s./kg dry weight artificial soil, control: artificial soil moistened with deionised water, solvent control: none.

Dates of experimental work: April 25, 2013 to July 03, 2013

Results and Discussion:

Validity criteria:

Table: Validity criteria of the study

Validity criteria	Recommended	Obtained
Mortality of the adults in the control	≤ 10 %	0 %
Rate of reproduction of juveniles (earthworms per control vessel)	≥ 30	179, 285, 230, 191, 211, 212, 262, 181
Coefficient of variance of reproduction in the control	≤ 30 %	17.5 %

The validity criteria of the test according to the guideline were fulfilled.

Reference test:
The most recent toxic standard reference test, with the reference test item mixed into the artificial soil, was performed from September 21 to November 28, 2012 (Study No.: Rg-R-Ref 19/12; Report No. kra-Rg-R-Ref 19/12; NON-GLP). No mortality of the adult earthworms was observed 28 days after application. The change of body weight of the adult earthworms of the test concentration of 5.0 mg a.s./kg dry weight soil was statistically significant reduced in comparison to the control. The number of juveniles per test vessel of the two highest test concentrations of 2.50 and 5.00 mg a.s./kg dry weight artificial soil were statistically significant reduced in comparison to the control. EC_{10}, EC_{20} and EC_{50} for reproduction were calculated to be 3.06, 3.22 and 3.54 mg a.s./kg dry weight artificial soil, respectively. Confidence limits (95 %) could not be calculated.
The results of the reference test indicated that the test system was sensitive to the reference test item.

Biological findings:
Effects on mortality and changes in body weight of the adults after an exposure period of 28 days and the number of offspring per test vessel after 56 days are shown in the following table.

Table: Effects on mortality and changes in body weight of the adults after an exposure period of 28 days and the number of offspring per test vessel after 56 days.

Test object	*Eisenia fetida*					
Test item	Control	FSN+TCM OD 80 (50+30) G				
mg test item/kg dry weight artificial soil	---	56	100	178	316	562
Mortality of adult earthworms [%] after 28 days	0	0	0	0	40	100
Mean change of body weight of the adults from day 0 to day 28 [%]	41.80	38.79	52.08*	63.19*	80.14*	n. d.
Standard Deviation	6.86	3.74	3.07	7.41	11.34	n. d.
Mean number of offspring per test vessel after 56 days	218.9	222.0	212.0	215.0	46.3**	0.3**
Standard Deviation	38.3	4.8	29.3	24.1	4.7	0.5
Coefficient of variance (%)	17.5	2.2	13.8	11.2	10.2	200
% of control	---	101.4	96.9	98.2	21.1	0.1
						Reproduction
EC_{10} (mg test item/kg dry weight soil [1)]) (95% confidence limits)						**209** (149 - 38)
EC_{20} (mg test item/kg dry weight soil [1)]) (95% confidence limits)						**228** (175 - 253)
EC_{50} (mg test item/kg dry weight soil [1)]) (95% confidence limits)						**270** (236 - 285)

* statistical significance compared to the control (Williams Multiple Sequential t-test, two-sided, α = 0.05)
**statistical significance compared to the control (Williams Multiple Sequential t-test, one-sided smaller, α = 0.05)
1) Probit analysis
n. d. not determined due to mathematical reasons

Mortality
After 28 days of exposure, no worms died in the control group and no mortality was observed at the test item concentrations up to and including 178 mg test item/kg dry weight soil. In the test item concentration of 316 mg test item/kg dry weight soil, 40 % died and in the highest test item concentration no adult worm survived. The results of the probit analysis of the mortality data shows that the LC_{50} is given at 326 mg test item /kg dry weight artificial soil. The 95 %-confidence limits could not be calculated.

Effects on growth
Statistically significant different values for the growth relative to the control were observed at the test concentrations of 100, 178 and 316 mg test item/kg dry weight artificial soil. Since the weight increase in the treatment groups was higher than in the control, this is not considered as an adverse effect. For the highest test item concentration, no calculation was possible since no worms survived. Based on statistical evaluation, the NOEC related to growth is:
NOEC related to growth: 56 mg test item/kg dry weight artificial soil.
LOEC related to growth: 100 mg test item/kg dry weight artificial soil.

Effects on reproduction
No statistically significant different values for the number of juveniles per test vessel relative to the control were observed at the test concentrations of 56, 100 and 178 mg test item/kg dry weight artificial soil. Statistically significant different values for the number of juveniles per test vessel relative to the control were observed at the two highest test concentration of 316 and 562 mg test item/kg dry weight artificial soil.
Therefore, based on biological and statistical significance:
NOEC related to reproduction: 178 mg test item/kg dry weight artificial soil
LOEC related to reproduction: 316 mg test item/kg dry weight artificial soil

Conclusions:

Based on biological relevance and statistical significance of the effects, the overall NOEC for this study is 178 mg test item/kg dry weight artificial soil. The overall LOEC is determined to be 316 mg test item/kg dry weight artificial soil.

A 2.4.1.2 KCP 10.4.1.2 Earthworms - field studies

A 2.4.2 KCP 10.4.2 Effects on non-target soil meso- and macrofauna (other than earthworms)

A 2.4.2.1 KCP 10.4.2.1 Species level testing

Comments of zRMS:	The study is considered acceptable. All validity criteria were met. **Agreed endpoints:** NOEC = 31 mg PPP/kg dws LOEC = 47 mg PPP/ kg dws EC_{10}=39.9 mg PPP/kg dws

Reference:	**KCP 10.4.2.1/01**
Title:	Foramsulfuron + thiencarbazone-methyl OD 80 (50+30) G: Influence on the reproduction of the collembolan species Folsomia candida tested in artificial soil
Report:	Frommholz, U.; 2013; FRM-Coll-155/13; M-459537-01-1
Authority registration No:	
Guideline(s):	OECD 232 adopted, September 07, 2009: OECD Guidelines for Testing Chemicals - Collembolan Reproduction Test in Soil; US EPA OCSPP: None
Deviations:	not specified
GLP/GEP:	yes
Acceptability:	
Duplication (if vertebrate study):	

Objective:

The purpose of this study was to assess the effect of Foramsulfuron + Thiencarbazone-methyl OD 80 (50+30 g/L) G on survival and reproduction of the collembolan species *Folsomia candida* during an exposure of 28 days in an artificial soil comparing control and treatment.

Materials and Methods:

Test item: Foramsulfuron + Thiencarbazone-methyl OD 80 (50+30 g/L) G; analytical findings: 4.97 % w/w foramsulfuron (AE F130360) equivalent to 51.05 g/L, 2.97 % w/w thiencarbazone-methyl (BYH 18636) equivalent to 30.49 g/L; density: 1.028 g/mL (20°C), batch ID: 2012-005269, sample description.: TOX09970-00, specification no.: 102000025743-01, master recipe ID: 0108526-001.

10 collembolans (10-11 days old) per replicate (8 replicates for the control group and 4 replicates for each treatment group) were exposed to control (water treated), 9.3, 14, 21, 31, 47, 71, 106 and 159 mg test item/kg artificial soil dry weight at 20 ± 2 °C, 400-800 lux, 16 h light : 8 h dark. During the study, the collembolans were fed with granulated dry yeast. The artificial soil was prepared according to the guideline with the following constituents (percentage distribution on dry weight basis): 75 % fine quartz sand, 5 % Sphagnum peat, air dried and finely ground, 20 % Kaolin clay, Calcium carbonate (CaCO3) for adjustment to pH to 6.0 ± 0.5.
The assessment of adult mortality and reproduction (number of juveniles) were determined after 28 days.

Dates of experimental work: April 16, 2013 to May 24, 2013

Results and Discussion:

Validity criteria:

Table: Validity criteria of the study

Validity criteria	Recommended by the guideline	Obtained in this study
Mean adult mortality	≤ 20 %	3.8 %
Mean number of juveniles per replicate (with 10 collembolans introduced)	≥ 100	1648.1
Coefficient of variation calculated for the number of juveniles per replicate	≤ 30 %	13.1 %

All validity criteria were met. Therefore, this study is valid.

Reference test:
The most recent non-GLP-test (FRM-Coll-Ref-21/13, U. Frommholz, March 26, 2013) with the reference item Boric acid was performed at test concentrations 44 – 67 – 100 – 150 and 225 mg Boric acid/kg artificial soil dry weight. Boric acid showed an EC_{50} of 108 mg test item/kg artificial soil dry weight (95 % confidence limits from 98 mg to 120 mg Boric acid/kg artificial soil dry weight) for reproduction according Probit analysis using maximum likelihood regression. The result is in the recommended range of the guideline (about 100 mg Boric acid/kg artificial soil dry weight).

The $NOEC_{reproduction}$ was calculated to be 67 mg Boric acid/kg artificial soil dry weight and accordingly the $LOEC_{reproduction}$ is 100 mg Boric acid/kg artificial soil dry weight according Williams multiple t-test procedure, $\alpha = 0.05$, one-sided smaller. This shows that the test organisms are sufficiently sensitive.

Biological findings:
Effects on mortality of the adults and the number of offspring per test vessel after an exposure period of 28 days are shown in the following table.

Table: Effect of the test item on the mortality and reproduction of *Folsomia candida*.

Test item	Foramsulfuron + thiencarbazone-methyl OD 80 (50+30) G

Test object Exposure	*Folsomia candida* Artificial soil			
mg test item/kg soil dry weight nominal concentration	Adult mortality (%)	Mean number of juveniles per test vessel ± standard deviation	Reproduction (% of control)	Significance (*)
Control	3.8	1648.1 ± 215.7	-	
9.3	2.5	1601.0 ± 45.5	97.1	-
14	10.0	1493.8 ± 139.8	90.6	-
21	2.5	1516.3 ± 159.4	92.0	-
31	2.5	1562.5 ± 100.9	94.8	-
47	5.0	1329.3 ± 161.8	80.7	+
71	52.5	730.8 237.5	44.3	+
106	82.5	158.3 27.0	9.6	+
159	100.0	0.3 0.5	0.0	+

		Reproduction	
$NOEC_{reproduction}$ (mg test item/kg soil dry weight)		31	
$LOEC_{reproduction}$ (mg test item/kg soil dry weight)		47	
		Reproduction	
EC_{10} (mg test item/kg soil dry weight) [1)]		39.9	
95% confidence limits		(29.4 – 46.7)	
EC_{20} (mg test item/kg soil dry weight) [1)]		47.4	
95% confidence limits		(38.1 – 53.7)	
EC_{50} (mg test item/kg soil dry weight) [1)]		66.1	
95% confidence limits		(59.4 – 73.4)	

The calculations were performed with un-rounded values
[1)] Probit analysis
(*) = (William's-t test one-sided-smaller, $\alpha = 0.05$, + = significant, - = not siginficant)

Mortality:
In the control group 3.8 % of the adult *Folsomia candida* died which is below the allowed maximum of ≤ 20 % mortality.

Reproduction:
Concerning the number of juveniles, statistical analysis (William's-t test, one-sided smaller, $\alpha = 0.05$) revealed statistically significant difference between control and the treatment groups with 47, 71, 106 and 159 mg test item/kg artificial soil dry weight. Therefore, the No-Observed-Effect-Concentration (NOEC) for reproduction is 31 mg test item/kg artificial soil dry weight. The Lowest-Observed-Effect-Concentration (LOEC) for reproduction is 47 mg test item/kg artificial soil dry weight.

Conclusions:

$NOEC_{reproduction}$: 31 mg test item/kg artificial soil dry weight.
$LOEC_{reproduction}$: 47 mg test item/kg artificial soil dry weight.

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Comments of zRMS:	The study is considered acceptable. All validity criteria were met. **Agreed endpoints:** $NOEC_{reproduction}$: 178 mg PPP/kg dws EC_{10}=220 mg PPP/kg dws

Reference:	**KCP 10.4.2.1/02**
Title:	Foramsulfuron + thiencarbazone-methyl OD 80 (50+30) G: Influence on mortality and reproduction of the soil mite species Hypoaspis aculeifer tested in artificial soil
Report:	Kratz, M. A.; 2013; kra-HR-86/13; M-462709-01-1
Authority registration No:	
Guideline(s):	OECD 226 from October 03, 2008: OECD guideline for the Testing of Chemicals; Predatory mite (Hypoaspis (Geolaelaps) aculeifer) reproduction test in soil; US EPA OCSPP: None
Deviations:	none
GLP/GEP:	yes
Acceptability:	
Duplication (if vertebrate study):	

Objective:

The purpose of this study was to assess the effect of Foramsulfuron + Thiencarbazone-methyl OD 80 (50+30 g/L) G on mortality and reproduction of the soil mite species *Hypoaspis aculeifer* tested during an exposure of 14 days in artificial soil comparing control and treatment.

Materials and Methods:

Test item: Foramsulfuron + Thiencarbazone-methyl OD 80 (50+30 g/L) G; analytical findings: 4.97 % w/w foramsulfuron (AE F130360) equivalent to 51.05 g/L; 2.97 % w/w thiencarbazone-methyl (BYH 18636) equivalent to 30.49 g/L; density: 1.028 g/mL (20°C); batch ID: 2012-005269; sample description: TOX09970-00; specification no.: 102000025743-01; master recipe ID: 0108526-001.

Ten adults, fertilized, female *Hypoaspis aculeife*r per replicate (8 replicates for the control group and 4 replicates for each treatment group) were exposed to untreated control and to concentrations of 56, 100, 178, 316 and 562 mg test item/kg artificial soil dry weight. During the test, the *Hypoaspis aculeife*r were fed with cheese mites bred on brewer's yeast. During the study a temperature of 20 ± 2 °C and light regime of 400 – 800 Lux, 16 h light: 8 h dark was applied. The artificial soil was prepared according to the guideline with the following constituents (percentage distribution on dry weight basis): 75 % fine quartz sand, 5 % Sphagnum peat, air dried and finely ground, 20 % Kaolin clay, Calcium carbonate ($CaCO_3$) for adjustment to pH to 6.0 ± 0.5.
After a period of 14 days, the surviving adults and the living juveniles were extracted by applying a temperature gradient using a McFadyen-apparatus. Extracted mites were collected in a fixing solution (20 % ethylene glycol, 80 % deionised water; 2 g detergent/L fixing solution were added). All *Hypoaspis aculeifer* were counted under a binocular.

Dates of experimental work: March 28, 2013 to April 23, 2013

Results and Discussion:

Validity criteria:
Validity criteria for the untreated control of the study according OECD 232 from September 07, 2009 are listed below.

Table: Validity criteria of the study

Validity criteria	Recommended by the guideline	Obtained in this study
Mean adult mortality	≤ 20 %	0 %

Mean number of juveniles per replicate (with 10 mites introduced)	≥ 50	323.3
Coefficient of variation calculated for the number of juveniles per replicate	≤ 30 %	8.5

All validity criteria were met. Therefore, this study is valid.

Reference test:
The most recent non-GLP-test (Marie-Agnes Kratz, kra/HR-O-12/13, April 08, 2013) with the reference item dimethoate was performed at test concentrations 1.0, 1.8, 3.2, 5.6 and 10.0 mg dimethoate/kg dry weight artificial soil.
Dimethoate showed a LC50 of 4.32 mg a.s./kg (95 % confidence limits from 4.31 mg a. s./kg to 4.32 mg a. s./kg) for mortality of the adult mites according Probit analysis using maximum likelihood regression.
The reproduction of the soil mites was not significantly reduced in comparison to the control up to 3.2 mg a.s./kg dry weight artificial soil. Therefore, the NOEC is calculated to be 3.2 mg a.s./kg and accordingly the LOEC is 5.6 mg a.s./kg. Since variances of the data were homogenous, Williams-t test $\alpha = 0.05$, one-sided smaller was used. Dimethoate EC 400E G showed a EC50 of 5.67 mg a. s./kg (95 % confidence limits from 5.58 mg a. s./kg to 5.79 mg a. s./kg) for reproduction according Probit analysis using maximum likelihood regression.
This is in the recommended range of the guideline for the EC_{50} based on the number of juveniles of 3.0 – 7.0 mg a. s./kg dry weight artificial soil and shows that the test organisms are sufficiently sensitive.

Biological findings:
Adult mortality and results of the reproduction performance were observed as listed below.

Table: Effect of Foramsulfuron + Thiencarbazone-methyl OD 80 (50+30 g/L) G on the predatory mite *Hypoaspis aculeifer* in a 14-day reproduction study

Test item / Test object / Exposure	Foramsulfuron + Thiencarbazone-methyl OD 80 (50+30 g/L) G / Hypoaspis aculeifer / Artificial Soil					
mg test item/Kg dry weight artificial soil	% mortality (Adults)	Mean number of juveniles per test vessel ± standard dev.			Reproduction (% of control)	Significance (*)
Control	0.0	323.3	±	27.6	-	-
56	17.5	332.5	±	43.5	102.9	n.s.
100	5.0	333.8	±	8.4	103.2	n.s.
178	5.0	318.3	±	37.3	98.5	n.s.
316	35.0	134.3	±	91.0	41.5	+
562	97.5	1.3	±	1.3	0.4	+
NOECreproduction mg test item/kg dry weight artificial soil:					**178**	
LOECreproduction mg test item/kg dry weight artificial soil:					**316**	
Reproduction						
EC_{10} mg t.i./kg dry weight artificial soil1) (95% confidence limits)					220 (219 – 221)	
EC_{20} mg t.i./kg dry weight artificial soil1) (95% confidence limits)					245 (244 – 246)	
EC_{50} mg t.i./kg dry weight artificial soil1) (95% confidence limits)					300 (300 – 300)	

(*)=Bonferroni-Holm-t.-test one sided smaller; α=0.05
n.s.= not significant; + = significant
1) Probit analysis
t.i.: test item

Mortality:
In the control group 0 % of the adult Hypoaspis aculeifer died which is below the allowed maximum of ≤ 20 % mortality.

Reproduction:

Concerning the number of juveniles statistical revealed a statistically significant difference between control and the treatment groups with 316 and 512 mg test item/kg artificial soil dry weight.
Therefore, the No-Observed-Effect-Concentration (NOEC) for reproduction is 178 mg test item/kg artificial soil dry weight. The Lowest-Observed-Effect-Concentration (LOEC) for reproduction is 316 mg test item/kg artificial soil dry weight.

Conclusions:

$NOEC_{reproduction}$: 178 mg test item/kg artificial soil dry weight
$LOEC_{reproduction}$: 316 mg test item/kg artificial soil dry weight

A 2.4.2.2 KCP 10.4.2.2 Higher tier testing

A 2.5 KCP 10.5 Effects on soil nitrogen transformation

Comments of zRMS:	The study is considered acceptable. All validity criteria were met. **Agreed endpoints:** <25% effects on nitrogen transformation were observed at day 28 at both tested rates 1.37 and 6.85 mg product/kg soil dws

Reference:	**KCP 10.5/01**
Title:	Foramsulfuron + thiencarbazone-methyl OD 80 (50+30) G: Effects on the activity of soil microflora (nitrogen transformation test)
Report:	Schulz, L.; 2013; 13 10 48 045 N; M-460665-01-1
Authority registration No:	
Guideline(s):	OECD 216; adopted January 21, 2000, OECD Guideline for the Testing of Chemicals, Soil Microorganisms: Nitrogen Transformation
Deviations:	none
GLP/GEP:	yes
Acceptability:	
Duplication (if vertebrate study):	

Objective:

The purpose of this study was to determine the effects of the test item Foramsulfuron + Thiencarbazone-methyl OD 80 (50+30 g/L) on the activity of soil microflora with regard to nitrogen transformation in a laboratory test. The test was performed in accordance with OECD guideline 216 (2000) by measuring the nitrogen turnover.

Material and Methods:

Test item: Foramsulfuron + Thiencarbazone-methyl OD 80 (50+30 g/L) G; short name: FSN+TCM OD 80 (50+30) G; BCS-codes: Foramsulfuron: BCS-AH47626, Thiencarbazone-methyl: BCS-AG17468; Sample description: TOX09970-00; Specification No.: 102000025743-01; Batch ID: 2012-005269; Master recipe ID: 0108526-001; analytical findings: 4.97 % w/w foramsulfuron (AE F130360); 2.97 % w/w thiencarbazone-methyl (BYH 18636); water solubility: dispersible.

A loamy sand soil (DIN 4220) was exposed for 28 days to 1.37 and 6.85 mg test item/kg soil dry weight. Application rates were equivalent to 1 and 5 L test item/ha. The nitrogen transformation was determined in soil enriched with lucerne meal (concentration in soil 0.5 %). NH_4-nitrogen, NO_3- and NO_2-nitrogen were determined by an Autoanalyzer at different sampling intervals (0, 7, 14 and 28 days after treatment).

The control was prepared with deionised water. As reference item Dinoterb is tested routinely in a separate study to verify the sensitivity of the test system.
The study was performed in a climatic room at 19.4 – 21.5°C under an illumination in complete darkness and a water content of soil of 15.64 - 16.60 g/100 g soil d.w. (equivalent to 42.72 - 45.34 % of WHC).

Dates of experimental work: May 27, 2013 to June 25, 2013

Results and Discussion:

Validity criteria:
The coefficients of variation in the control (NO_3-N) were maximum 1.5 % and thus fulfilled the demanded range (≤15 %).

Reference test:
In a separate study (conducted from 04.01.2013 to 01.02.2013) the reference item Dinoterb caused a stimulation of nitrogen transformation of +33.7 % and +42.6 % (required ≥ 25 %) at 16.00 mg and 27.00 mg Dinoterb per kg soil dry weight, respectively, 28 days after application and thus demonstrates the sensitivity of the test system.

Biological findings:
Foramsulfuron + Thiencarbazone-methyl OD 80 (50+30 g/L) G caused a temporary stimulation of the daily nitrate rate at the tested concentration of 6.85 mg/kg dry soil at time interval 7-14 days after application.
However, no adverse effects of Foramsulfuron + Thiencarbazone-methyl OD 80 (50+30 g/L) G on nitrogen transformation in soil could be observed at both test concentrations (1.37 mg and 6.85 mg test item/kg dry soil) at the end of the test, 28 days after application (time interval 14-28). Differences from the control of +4.7 % (test concentration 1.37 mg/kg dry soil) and +8.2 % (test concentration 6.85 mg/kg dry soil) were measured at the end of the 28-day incubation period (time interval 14-28).

Table: Effects on nitrogen transformation in soil after treatment with Foramsulfuron + Thiencarbazone-methyl OD 80 (50+30 g/L) G

Time Interval (days)	Control			1.37 mg test item/kg soil dry weight equivalent to 1 L test item/ha				6.85 mg test item/kg soil dry weight equivalent to 5 L test item/ha			
	Nitrate-N[1)]			Nitrate-N[1)]			% difference to control	Nitrate-N[1)]			% difference to control
0-7	3.79	±	0.06	3.97	±	0.30	**+4.6** n.s.	4.01	±	0.46	**+5.9** n.w.
7-14	1.49	±	0.10	1.40	±	0.26	**-6.1** n.s.	1.95	±	0.79	**+30.7** n.w.
14-28	0.96	±	0.08	1.00	±	0.04	**+4.7** n.s.	1.04	±	0.04	**+8.2** n.s.

The calculations were performed with unrounded values
1) Rate: Nitrate-N in mg/kg soil dry weight/time interval/day, mean of 3 replicates and standard deviation
n.s. = No statistically significant difference to the control (Student-t-test for homogeneous variances, 2-sided, $p \leq 0.05$)
n.w. = No statistically significant difference to the control (Welch-t-test for inhomogeneous variances, 2-sided, $p \leq 0.05$)

Conclusions:

Foramsulfuron + Thiencarbazone-methyl OD 80 (50+30 g/L) G caused no adverse effects (difference to control < 25 %, OECD 216) on the soil nitrogen transformation (measured as NO_3-N production) at the end of the 28- day incubation period. The study was performed in a field soil at concentrations up to 6.85 mg test item/kg soil, which are equivalent to application rates up to 5 L test item/ha.

A 2.6 KCP 10.6 Effects on terrestrial non-target higher plants

A 2.6.1 KCP 10.6.1 Summary of screening data

A 2.6.2 KCP 10.6.2 Testing on non-target plants

Comments of zRMS:	The study is considered acceptable. All validity criteria were met. **Agreed endpoint:**	The lowest endpoint -**ER_{50} = 16.91 mL PPP/ha** for *Sorghum vulgaris*

Beta vulgaris d [1)]	[1)] ER_{50} shoot dry weight = 31.36 mL product/ha
Brassica napus d [2)]	[2)] ER_{50} shoot dry weight = 54.74 mL product/ha
Cucumis sativus d [3)]	[3)] ER_{50} shoot dry weight = 75.53 mL product/ha
Fagopyrum esculentum d [4)]	[4)] ER_{50} shoot dry weight = 91.79 mL product/ha
Glycine max d [5)]	[5)] ER_{50} shoot dry weight = 221.48 mL product/ha
Helianthus annuus d [6)]	[6)] ER_{50} shoot dry weight = 62.14 mL product/ha
Lycopersicon esculentum d [7)]	[7)] ER_{50} shoot dry weight = 21.45 mL product/ha
Allium cepa m [8)]	[8)] ER_{50} shoot dry weight = 26.35 mL product/ha
Avena sativa m [9)]	[9)] ER_{50} shoot dry weight = 22.12 mL product/ha
Sorghum vulgare m [10)]	**[10)] ER_{50} shoot dry weight = 16.91 mL product/ha**

Reference:	**KCP 10.6.2/01**
Title:	Thiencarbazone-methyl + Foramsulfuron OD 80 (30 + 50 g/L) - Effects on the seedling emergence and growth of ten species of non-target terrestrial plants (Tier 2)
Report:	Koehler, P.; 2013; SE13/007; M-467676-01-1
Authority registration No:	
Guideline(s):	EU Directive 91/414/EEC; Regulation (EC) No. 1107/2009; US EPA OCSPP 850.4100
Deviations:	none
GLP/GEP:	yes
Acceptability:	
Duplication (if vertebrate study):	

Objective:

The purpose of this specific study was to evaluate the effect of Foramsulfuron + Thiencarbazone-methyl OD 80 (50+30 g/L) on the seedling emergence and growth of ten non-target terrestrial plant species following a pre-emergence application of the product onto the soil surface.

Material and Methods:

Test item: Foramsulfuron + Thiencarbazone-methyl OD 80 (50+30 g/L), analyzed content of active substance: foramsulfuron (AE F130360): 4.97 % (51.05 g/L); thiencarbazone-methyl (BYH 18636): 2.97 % (30.49 g/L); Batch ID: 2012-005269, Material No.: 80979444; Specification number: 102000025743 - 01, TOX no.: 09970-00; density: 1.028 g/mL.

Test species: 7 dicotyledonous and 3 monocotyledonous species representing 9 different plant families (EPPO code): *Beta vulgaris* (BEAVA), *Brassica napus* (BRSNW), *Cucumis sativus* (CUMSA), *Fagopyrum esculentum* (FAGES), *Glycine max* (GLXMA), *Helianthus annuus* (HELAN), *Lycopersicum esculentum* (LYPES), *Allium cepa* (ALLCE), *Avena sativa* (AVESA), *Sorghum vulgaris* (SORVU).

Ten non-target terrestrial plant species sugar beet (*Beta vulgaris*), oilseed rape (*Brassica napus*), cucumber (*Cucumis sativus*), buckwheat (*Fagopyrum esculentum*), soybean (*Glycine max*), sunflower (*Helianthus annuus*), tomato (*Lycopersicum esculentum*), onion (*Allium cepa*), oat (*Avena sativa*) and sorghum (*Sorghum vulgaris*) were sown in a mixture of 90 % sandy-silt loam + 10% washed sand prior to application of Foramsulfuron + Thiencarbazone-methyl OD 80 (50+30 g/L) to the soil surface.
Five seeds per pot were sown in 10.5 cm pots in the greenhouse. There were 8 replicate pots per treatment, giving a total of 40 seeds per treatment level. The plant species were treated with 9 application rates (i.e. 1.96, 3.91, 7.81, 15.63, 31.25, 62.5, 125, 250, and 500 mL product/ha in 200 L deionised water) and a water control (200 L/ha deionised water).
Serial dilutions of Foramsulfuron + Thiencarbazone-methyl OD 80 (50+30 g/L) were sprayed onto the soil surface using a laboratory track sprayer.

Details of the range of application rates are summarised in the following table.

Table: Application rates during the study

Test item rate in mL product/ha		**1.96**	**3.91**	**7.81**	**15.63**	**31.25**	**62.5**	**125**	**250**	**500**
BEAVA	*Beta vulgaris*		x	x	x	x	x	x		
BRSNW	*Brassica napus*	x	x	x	x	x	x			
CUMSA	*Cucumis sativus*		x	x	x	x	x	x		
FAGES	*Fagopyrum esculentum*			x	x	x	x	x	x	
GLXMA	*Glycine max*				x	x	x	x	x	x
HELAN	*Helianthus annuus*		x	x	x	x	x	x		
LYPES	*Lycopersicon esculentum*	x	x	x	x	x	x			
AVESA	*Avena sativa*		x	x	x	x	x	x		
ALLCE	*Allium cepa*		x	x	x	x	x	x		
SORVU	*Sorghum vulgaris*		x	x	x	x	x	x		

Following application, the pots with seeds were maintained under greenhouse conditions with a temperature regulation at 23-24 ºC during day and 18 ºC at night with a 16/8 h light/dark cycle and relative humidity of 70 %.

Control pots of each species were observed daily for number of seedlings emerged until 50 % of the seedlings had emerged. Assessments were made on this day (= day 0) and 7, 14, and 21 days post emergence of 50 % of the control seedlings.
Final assessments were made for emergence, plant survival, visual phytotoxicity, plant growth stage and shoot dry weight.
Statistical analysis of data was performed to obtain NOER (No observed effect rate), LOER (Lowest ob-

served effect rate), ER/LR_{25} (rate producing 25 % effect) and ER/LR_{50} (rate producing 50 % effect) values for emergence, survival and shoot dry weight, using ToxRat statistical software.

Dates of experimental work: February 19, 2013 to May 14, 2013

Results and Discussion:

Validity criteria:
All species in this study met the validity criteria for seedling emergence, and survival according to the OECD guideline (OECD 208) and US EPA guideline (OCSPP 850.4100).

Analytical findings:
The analysis of foramsulfuron content in the highest tested application rate revealed measured concentrations of 95.6 % to 101.3 % of nominal.

Biological findings:
Typical symptoms observed at the final assessment in this study (on day 21 after 50 % emergence of the control seedlings) were chlorosis, reddening, necrosis, leaf deformation and stunting. The severity and occurrence differed between species and application rates.
The no observed effect rate (NOER), ER/LR_{25} and ER/LR_{50} values expressed in mL product/ha are summarised for each of the plant species in the following table for the final assessment (21 days after 50% emergence of the control seedlings).

Table: Effects of the test item on emergence, survival and shoot dry weight

Species	mL product / ha								
	Emergence			Survival			Shoot dry weight		
	NOER	ER_{25}	ER_{50}	NOER	LR_{25}	LR_{50}	NOER	ER_{25}	ER_{50}
Beta vulgaris	125	>125[#]	>125[#]	62.5	123.5	>125[a]	7.81	16.71	31.36
Brassica napus	15.63	36.96	>62.5[a]	62.5	>62.5[a]	>62.5[a]	15.63	31.77	54.74
Cucumis sativus	125	>125[a]	>125[a]	125[b]	>125[b]	>125[b]	7.81	22.49	75.53
Fagopyrum esculentum	125	>250[#]	>250[#]	250	>250[a]	>250[a]	15.63	44.92	91.79
Glycine max	500	>500[a]	>500[a]	500	>500[a]	>500[a]	62.5	121.26	221.48
Helianthus annuus	125	>125[a]	>125[a]	125	>125[a]	>125[a]	31.25	44.17	62.14
Lycopersicon esculentum	62.5	>62.5[a]	>62.5[a]	62.5	>62.5[a]	>62.5[a]	7.81	13.53	21.45
Allium cepa	125	>125[#]	>125[#]	7.81	16.10	39.61	7.81	12.08	26.35
Avena sativa	125	>125[a]	>125[a]	31.25	60.83	83.67	3.91	11.07	22.12
Sorghum vulgaris	125	>125[#]	>125[#]	62.5	84.49	>125[a]	7.81	11.30	**16.91**

[a] Calculated values were outside the range tested.
[b] Because no change in %Mortality was to be observed, no further computations have been performed for 21d
[#] Only weak rate-response relation (p(F) >0.05; i.e. slope of the relationship is not significant different from zero). Not determined due to the lacking rate-response relation.

Table: Growth stage of the non-target terrestrial plant species at application rates at the final assessment

Growth stage (BBCH) Min-Max at application rates (in mL product/ha) at the final assessment										
Species	**control**	**1.96**	**3.91**	**7.81**	**15.63**	**31.25**	**62.5**	**125**	**250**	**500**
Beta vulgaris	13-16		14-16	10[a]-16	13-16	12[b]-16	12-16 [c]	12-14		
Brassica napus	14[d]-31	14[r]-31	14[r]-31	14-31	10[e]-31	13-31	10[f]-31			
Cucumis sativus	13-15		13-15	12[b]-15	12[b]-15	11[g]-15	12-15	10-15		
Fagopyrum esculentum	55[h]-62			55[h]-62	55[h]-62	12[i]-62	12[j]-62	12-62[k]	10-61	
Glycine max	14-22[m]				14[n]-21	13[n]-21	13-21	13-21	10[o]-21	10-21
Helianthus annuus	16-32		16-32	16-32	14[p]-32	14-32	10-32	10-31		
Lycopersicon esculentum	14-16	14-15	13[a]-16	12[a]-16	10-17[z]	10-18[*]	10-17[*]			
Allium cepa	11-13		11-13	12-13	11-13	11-13	11-13	11		
Avena sativa	15-22		15-22	15-22	14-22	14-22	13-22	13-21		
Sorghum vulgaris	14-21		14-21	14-21	14-21	12-21	11-14	11-12		

[a] Only one plant was affected, the majority of the plants were BBCH 14-16
[b] Only one replicate was affected, the majority of the plants were BBCH 13-15
[c] Only one plant was BBCH 16, the majority of the plants were BBCH 12-15
[d] Only one replicate was affected, the majority of the plants were BBCH 31
[e] Only one replicate was affected, the majority of the plants were BBCH 14-31
[f] Only two replicates were affected, the majority of the plants were BBCH 13-31.
[g] Only one plant was BBCH 16, the majority of the plants were BBCH 12-15
[h] Only one,two replicates were affected, the majority of the plants were BBCH 59-62
[I] Only one plant was BBCH 12, the majority of the plants were BBCH 51-62
[j] Only two replicates were affected, the majority of the plants were BBCH 51-62
[k] Only one replicate was affected, the majority of the plants were BBCH 12-60
[m] Only one replicate was BBCH 21-22, the majority of the plants were BBCH 14-21.
[n] Only few replicates were affected, the majority of the plants were BBCH 21.
[o] Only two replicates were BBCH 10 and 12, the majority of the plants were BBCH 13-21
[p] Only one replicate was affected, the majority of the plants were BBCH 16-32
[r] Only two replicates were affected, the majority of the plants were BBCH 31
[z] Only two replicates were affected, the majority of the plants were BBCH 15-16.
* Identification of BBCH not always clear because of strong plant and leaf deformations.

Table: Phytotoxicity summary at application rates at the final assessment

Phytotoxicity summary (min-max) at application rates (in mL product/ha) at the final assessment										
Species	**Control**	**1.96**	**3.91**	**7.81**	**15.63**	**31.25**	**62.5**	**125**	**250**	**500**
Beta vulgaris	0		0	0-Ade	0-Ade	A-Cade	B-Cade	D-Eabe		
Brassica napus	0	0-Ade	0-Aade	0-Bade	Aade	B-Cade	B-Dade			
Cucumis sativus	0		0	0-Bade	0-Bae	A-Bade	A-Bade	C-Dade		
Fagopyrum esculentum	0			0-Ae	0-Aade	0-Cade	A-Cade	C-Dade	C-Dade	
Glycine max	0				0	0-Ae	Aabde	B-Cabde	C-Dabde	Dabde
Helianthus annuus	0		0	0	0	0-Cabe	B-Dade	C-Eade		
Lycopersicon esculentum	0	0-Ae	0	0-Aabde	A-Cade	C-Dade	Dade			
Allium cepa	0		0	0-Ae	0-Be	0-Cbe	0-Eabe	C-Eabe		
Avena sativa	0		0	0-Aae	A-Babde	A-Cabde	C-Dabde	Dabde		
Sorghum vulgaris	0		0	0-Aaef	0-Daef	C-Eabdef	D-Eabef	Eabef		

Key:
0 no injury or effect
A: slight symptom (s)
B: moderate symptom (s)
C: severe symptom (s)
D: total-plant symptom (s)
E: moribund
Any plant considered as being dead was not rated for phytotoxicity.
Phytotoxicity codes: Symptoms:
a : chlorosis (yellowing of green shoot tissue)
b : necrosis (brown shoot tissue)
c : bleaching (shoot tissue without pigmentation)
d : leaf deformation (leaf curl, abnormal leaf shape)
e : stunting (plant height reduced with shorter internode length)
f: reddening (reddening of green shoot tissue)

Conclusions:

Based on the results of this Tier 2 seedling emergence and growth study in which the effect of Foramsulfuron + Thiencarbazone-methyl OD 80 (50+30 g/L) on ten species of non-target terrestrial plants was tested under greenhouse conditions, the most sensitive species was *Sorghum vulgaris* with the lowest ER_{50} of 16.91 mL product/ha for shoot dry weight.

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Comments of zRMS:	The study is considered acceptable. All validity criteria were met.		
	Beta vulgaris $_d$ [1)]	[1)] ER_{50} shoot dry weight = 14.44 mL product/ha	**Agreed endpoint:** **Lowest endpoint - ER_{50} = 6.92 ml PPP/ ha for Cucumis sativus**
	Brassica napus $_d$ [2)]	[2)] ER_{50} shoot dry weight = 22.90 mL product/ha	
	Cucumis sativus $_d$ [3)]	**[3)] ER_{50} shoot dry weight = 6.92 mL product/ha**	
	Fagopyrum esculentum $_d$ [4)]	[4)] ER_{50} shoot dry weight = 7.92 mL product/ha	
	Glycine max $_d$ [5)]	[5)] ER_{50} shoot dry weight = 62.94 mL product/ha	
	Helianthus annuus $_d$ [6)]	[6)] ER_{50} shoot dry weight = 31.46 mL product/ha	
	Lycopersicon esculentum $_d$ [7)]	[7)] ER_{50} shoot dry weight = 20.49 mL product/ha	
	Allium cepa $_m$ [8)]	[8)] ER_{50} shoot dry weight = 339.82 mL product/ha	
	Avena sativa $_m$ [9)]	[9)] ER_{50} shoot dry weight = 57.44 mL product/ha	
	Sorghum vulgare $_m$ [10)]	[10)] ER_{50} shoot dry weight = 47.88 mL product/ha	

Reference:	**KCP 10.6.2/02**
Title:	Thiencarbazone-methyl + foramsulfuron OD 80 (30 + 50 g/L) - Effects on the vegetative vigour of ten species of non-target terrestrial plants (Tier 2)
Report:	Koehler, P.; 2014; VV13/006; M-491267-01-1
Authority registration No:	
Guideline(s):	EU Directive 91/414/EEC Regulation (EC) No. 1107/2009 US EPA OCSPP 850.4150
Deviations:	not applicable
GLP/GEP:	yes
Acceptability:	
Duplication (if vertebrate study):	

Objective:

The purpose of this specific study was to evaluate the effect of Foramsulfuron + Thiencarbazone-methyl OD 80 (50+30 g/L) on the vegetative vigour of ten non-target terrestrial plant species following a post-emergence application of the test item onto the foliage of plants at the 2-4 leaf stage.

Material and Methods:

Test item: Foramsulfuron + Thiencarbazone-methyl OD 80 (50+30 g/L); analysed content of active ingredient: foramsulfuron (AE F130360): 4.97% w/w (51.05 g/L), thiencarbazone-methyl (BYH 18636):

2.97% w/w (30.49 g/L); Batch ID: 2012-005269; Material No.: 80979444; Specification number: 102000025743-01; TOX No.: TOX09970-00; density: 1.028 g/mL.

Test species: 7 dicotyledonous species and 3 monocotyledonous species representing 9 different plant families (EPPO code): *Beta vulgaris* (BEAVA), *Brassica napus* (BRSNW), *Cucumis sativus* (CUMSA), *Fagopyrum esculentum* (FAGES), *Glycine max* (GLXMA), *Helianthus annuus* (HELAN), *Lycopersicon esculentum* (LYPES), *Allium cepa* (ALLCE), *Avena sativa* (AVESA), *Sorghum vulgaris* (SORVU).

The plants were grown in a greenhouse in 13 cm pots and were treated at the 2-4 leaf stage. The used soil was a sandy-silt loam. There were 4 plants per pot and 8 replicate pots, giving a total of 32 plants per treatment level. The plant species were treated with 5 to 6 different application rates ranging from 0.98 to 500 mL product/ha (see table below). Control plants were only treated with 200 L/ha deionised water (200 L/ha).
The test item was dissolved in deionized water for the preparation of the initial test item stock solution with the rate of 5000 mL product/ha. The initial test item stock solution was only used for the analytical part and to set up the application rates. The test item application rates were prepared by dilution with de-ionized water. Serial dilutions of Foramsulfuron + Thiencarbazone-methyl OD 80 (50+30 g/L) were sprayed onto the foliage of plants using a laboratory track sprayer.

Table: Application rates during the study

Test item rate in mL product/ha		**0.98**	**1.96**	**3.91**	**7.81**	**15.63**	**31.25**	**62.5**	**125**	**250**	**500**
BEAVA	*Beta vulgaris*	x	x	x	x	x	x				
BRSNW	*Brassica napus*		x	x	x	x	x	x			
CUMSA	*Cucumis sativus*		x	x	x	x	x				
FAGES	*Fagopyrum esculentum*	x	x	x	x	x	x				
GLXMA	*Glycine max*				x	x	x	x	x	x	
HELAN	*Helianthus annuus*		x	x	x	x	x	x			
LYPES	*Lycopersicon esculentum*		x	x	x	x	x	x			
AVESA	*Avena sativa*			x	x	x	x	x	x		
ALLCE	*Allium cepa*						x	x	x	x	x
SORVU	*Sorghum vulgaris*		x	x	x	x	x	x			

Following application, the plants were maintained under greenhouse conditions with a temperature regulation at 23 °C during day and 18 °C at night with a 16 h photoperiod and relative humidity of 70 %.
Assessments were made 7, 14 and 21 days after application. Final assessments were made for plant survival, visual phytotoxicity, plant growth stage (BBCH) and shoot dry weight.
Statistical analysis of data was performed to obtain NOER (No observed effect rate), LOER (Lowest observed effect rate), ER/LR_{25} (rate producing 25% effect) and ER/LR_{50} (rate producing 50% effect) values for survival and shoot dry weight, using ToxRat statistical software.

Dates of experimental work: February 20, 2013 to August 09, 2013

Results and Discussion:

Validity criteria:
The validity criterion of at least 90 % survival of the plants during the study period was achieved for the untreated controls of all ten species tested.

Analytical findings:
The analysis of foramsulfuron content in the initial tested item stock solution revealed measured concentrations of 96.0 % to 101.3 % of nominal.

Biological findings:
Typical symptoms of phytotoxicity observed at the final assessment in this study (on day 21 after application) were chlorosis, reddening, necrosis, leaf deformation and stunting. The severity and occurrence differed between species and application rates.
The no observed effect rate (NOER), ER/LR_{25} and ER/LR_{50} values expressed in mL product/ha are summarised for each of the plant species in the following table for the final assessment (21 days after application).

Table: Effects of the test item on survival and shoot dry weight

	mL product / ha					
	Survival			**Shoot dry weight**		
Species	**NOER**	**LR_{25}**	**LR_{50}**	**NOER**	**ER_{25}**	**ER_{50}**
Beta vulgaris	31.25	>31.25[c]	>31.25[c]	0.98	2.78	14.44
Brassica napus	62.5	>62.5[c]	>62.5[c]	7.81	11.68	22.9
Cucumis sativus	7.81	16.66	31.65[a]	<1.96[a]	2.40	**6.92**
Fagopyrum esculentum	15.63	26.10	>31.25a	3.91	4.16	7.92
Glycine max	250	>250[c]	>250[c]	<7.81[a]	21.17	62.94
Helianthus annuus	31.25	>62.5[c]	>62.5 [c]	7.81	15.9	31.46
Lycopersicon esculentum	62.5	>62.5[b]	>62.5[b]	3.91	8.85	20.49
Allium cepa	500	>500[c]	>500[c]	62.50	167.14	339.82
Avena sativa	62.5	107.5	117.33	31.25	40.93	57.44
Sorghum vulgaris	62.5	>62.5[b]	>62.5[b]	31.25	36.24	47.88

[a] Calculated values were outside the range tested.
[b] Because no effect was observed, no further computations were performed for 21d
[c] Not determined (outside the range tested)

Table: Growth stage of the non-target terrestrial plant species at application rates at the final assessment

Growth stage (BBCH) Min-Max at application rates (in mL product/ha) at the final assessment											
Species	**Control**	**0.98**	**1.96**	**3.91**	**7.81**	**15.63**	**31.25**	**62.5**	**125**	**250**	**500**
Beta vulgaris	16-17	16-17	15a-17	15-19[b]	14-17	14-17	14-16[c]				
Brassica napus	15-18		15-18	16-17	15-18	14[d]-21	14[e]-25	12-21			
Cucumis sativus	57-66		55[f]-64	53-63	16-56[g]	14-56[g]	14-18				
Fagopyrum esculentum	65	65	65	65	59-65	51-64	51-59,64[h]				
Glycine max	59				55-59	51-59	51-55	51	51	21	
Helianthus annuus	32-33		18[i]-33	19[j]-33	32-33	19[j] - 33	15-33	14-19			
Lycopersicon esculenttum	51-61		51-61	51-61	51-54	51-53	14-51	14-51			
Avena sativa	31-33			31-32	31-32	31-32	31-32	13-32	14-22		
Allium cepa	14-16						14-16	13-16	13-15	12-16	12-14

Sorghum vulgaris	15-22[k]		15-21	15-21	15-22	16-21	15-22	14-23[l]			

[a]: Only one replicate was affected, the majority of the plants were BBCH 16-17.
[b]: Only one replicate was affected, the majority of the plants were BBCH 15-17.
[c]: Only one replicate was affected, the majority of the plants were BBCH 14.
[d]: Only one replicate was affected, the majority of the plants were BBCH 16-21.
[e]: Only two replicate were affected, the majority of the plants were BBCH 21-23.
[f]: Only one replicate affected, the rest of the plants were BBCH 56-64.
[g]: Due to leaf deformation and stunting, the growth stage (BBCH) was not clearly to define and should be taken with caution.
[h]: Only two replicates were affected, the majority of the plants were BBCH 51.
[i]: Only two replicates were affected, the majority of the plants were BBCH 32-33.
[j]: Only one replicates was affected, the majority of the plants were BBCH 32-33.
[k]: Only one replicate was affected, the majority of the plants were BBCH 15-21.
[l]: Only one replicate was affected, the majority of the plants were BBCH 21-22.

Table: Phytotoxicity summary at application rates at the final assessment

Phytotoxicity summary (minimum to maximum damage) at application rates (in mL product/ha) at the final assessment											
Species	**Con-trol**	**0.98**	**1.96**	**3.91**	**7.81**	**15.63**	**31.25**	**62.5**	**125**	**250**	**500**
Beta vulgaris	0	0-Aae	A-Bade	B-Cabde	D-Eabde	D-Eabde	Eabde				
Brassica napus	0x		0-B*1aex	0-Aaex	0-C*2aex	A-Badex	C-Eabdex	D-Eabdex			
Cucumis sativus	0		0-Bae	A-Bade	C-Dabde	C-E#1abde	D-Eabde				
Fagopyrum esculentum	0	0-Aa	Aa	A-Cabde	B-Cabde	C-Dabde	D-Eabde				
Glycine max	0				0-Aae	0-Bae	A-Cae	C-Daef	Dabef	Eabef	
Helianthus annuus	0		0-Abe	0-Ab	0-Aab	A-Babe	B-Cabe	C-Eabe			
Lycopersicon esculenttum	0		0-Aa	A-C~1ade	B-Cade	C-Dabde	Dabde	D-Eabde			
Avena sativa	0			0	Aabde	Aabe	A-Babde	Cabde	D-Eabde		
Allium cepa	0						0	0	0-Ae	A-Babe	B-Cabe
Sorghum vulgaris	0		0-Aae*4	0-Aae`1	0-Babe*3	0-Aaef*4	A-Babef	C-Dabdef			

[*1]: Only one replicate was affected (B), all other replicates showed none to slight phytotoxic effects.
[x]: Aphid infestation.
[*2]: Only one replicate was affected (C), the majority f the plants showed slight to moderate phytotoxic effects.
[#1]: Only one replicate contained partly moribund plants.
[~1]: Only one replicate showed severe phytotoxic symptoms, the majority of the plants showed slight effects.
[*4]: Only four replicates were affected, all other replicates showed no phytotoxic effects.
[`1]: Only one replicate was affected, the rest of the plants showed no phytotoxic symptoms.
[*3]: Only three replicates were affected, all other replicates showed no phytotoxic effects.

Key:
0 no injury or effect
A: slight symptom (s)
B: moderate symptom (s)
C: severe symptom (s)
D: total-plant symptom (s)

E: moribund
Any plant considered as being dead was not rated for phytotoxicity.
Phytotoxicity codes: Symptoms:
a : chlorosis (yellowing of green shoot tissue)
b : necrosis (brown shoot tissue)
c : bleaching (shoot tissue without pigmentation)
d : leaf deformation (leaf curl, abnormal leaf shape)
e : stunting (plant height reduced with shorter internode length)
f: reddening of green shoot tissue

Conclusions:

In a Tier 2 vegetative vigour and growth study, Foramsulfuron + Thiencarbazone-methyl OD 80 (50+30 g/L) was tested under greenhouse conditions for effects on the survival, growth and shoot dry weight of ten non-target terrestrial plant species, following a post-emergence application of the test item the foliage of plants at the 2-4 leaf stage. The most sensitive species was found to be *Cucumis sativus* with the lowest ER_{50} of 6.92 mL product/ha for shoot dry weight.

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Comments of zRMS: The study is acceptable. The all validity criteria were met.

Agreed endpoints:

Beta vulgaris d 1)	1) ER_{50} shoot dry weight = 6.97 mL product/ha	**Lowest ER_{50} = 6.92 mLprod./ha (shoot dry weight for *Cucumis sativus*)**
Brassica napus d 2)	2) ER_{50} shoot dry weight = 25.33 mL product/ha	
Cucumis sativus d 3)	**3) ER_{50} shoot dry weight = 6.92 mL product/ha**	
Fagopyrum esculentum d 4)	4) ER_{50} shoot dry weight = 11.33 mL product/ha	
Glycine max d 5)	5) ER_{50} shoot dry weight = 38.36 mL product/ha	
Helianthus annuus d 6)	6) ER_{50} shoot dry weight = 28.75 mL product/ha	
Lycopersicon esculentum d 7)	7) ER_{50} shoot dry weight = 10.53 mL product/ha	
Allium cepa m 8)	8) ER_{50} shoot dry weight = 138.72 mL product/ha	
Avena sativa m 9)	9) ER_{50} shoot dry weight = > 62.5 mL product/ha	
Sorghum vulgare m 10)	10) ER_{50} shoot dry weight = = 33.48 mL product/ha	

Reference:	**KCP 10.6.2/03**
Title:	Thiencarbazone-methyl + foramsulfuron OD 80 (30 + 50 g/L) - Effects on the vegetative vigour of ten species of non-target terrestrial plants (Tier 2)
Report:	Koehler, P.; 2014; VV14/012; M-496996-01-1
Authority registration No:	
Guideline(s):	EU Directive 91/414/EEC; Regulation (EC) No. 1107/2009; US EPA OCSPP 850.4150; The study was conducted according to OECD 227 guideline for the testing of chemicals, Terrestrial Plant Test: Vegetative vigour (July 2006) and considers the recommendations of US EPA Ecological Effects Test Guideline OCSPP 850.4150
Deviations:	none
GLP/GEP:	yes
Acceptability:	
Duplication (if vertebrate study):	

Objective:

The purpose of this specific study was to evaluate the effect of Foramsulfuron + Thiencarbazone-methyl OD 80 (50+30 g/L) on the vegetative vigour of ten non-target terrestrial plant species following a post-emergence application of the test item onto the foliage of plants at the 2-4 leaf stage.

Material and Methods:

Test item: Foramsulfuron + Thiencarbazone-methyl OD 80 (50+30 g/L); analysed content of active ingredient: foramsulfuron (AE F130360): 4.97 % w/w (51.05 g/L), thiencarbazone-methyl (BYH 18636): 2.97% w/w (30.49 g/L); Batch ID: 2012-005269; Material No.: 80979444; Specification number: 102000025743-01; TOX No.: TOX09970-00; density: 1.028 g/mL.

Test species: 7 dicotyledonous species and 3 monocotyledonous species representing 9 different plant families (EPPO code): *Beta vulgaris* (BEAVA), *Brassica napus* (BRSNW), *Cucumis sativus* (CUMSA), *Fagopyrum esculentum* (FAGES), *Glycine max* (GLXMA), *Helianthus annuus* (HELAN), *Lycopersicon esculentum* (LYPES), *Allium cepa* (ALLCE), *Avena sativa* (AVESA), *Sorghum vulgaris* (SORVU).

The plants were grown in a greenhouse in 15 cm pots and were treated at the 2-4 leaf stage. The used soil was a sandy-silt loam. There were 2 or 4 plants per pot and 10 or 5 replicate pots, giving a total of 20 plants per treatment level. The plant species were treated with 5 to 6 different application rates ranging from 0.49 to 500 mL product/ha (see table below). Control plants were only treated with 200 L/ha deionised water (200 L/ha).
The test item was dissolved in deionized water for the preparation of the initial test item stock solution with the rate of 5000 mL product/ha. The initial test item stock solution was only used for the analytical part and to set up the application rates. The test item application rates were prepared by dilution with deionized water. Serial dilutions of Foramsulfuron + Thiencarbazone-methyl OD 80 (50+30 g/L) were sprayed onto the foliage of plants at the 2 – 4 leaf stage using a laboratory track sprayer at a volume rate of 200 L/ha.

Table: Application rates during the study

Test item rate in mL product/ha		**0.49**	**0.98**	**1.96**	**3.91**	**7.81**	**15.6**	**31.3**	**62.5**	**125**	**250**	**500**
BEAVA	*Beta vulgaris*	x	x	x	x	x	x					
BRSNW	*Brassica napus*		x	x	x	x	x	x				
CUMSA	*Cucumis sativus*	x	x	x	x	x						
FAGES	*Fagopyrum esculentum*		x	x	x	x	x					
GLXMA	*Glycine max*			x	x	x	x	x	x			
HELAN	*Helianthus annuus*			x	x	x	x	x	x			
LYPES	*Lycopersicon esculentum*		x	x	x	x	x	x				

ALLCE	*Allium cepa*							x	x	x	x	x
AVESA	*Avena sativa*				x	x	x	x	x			
SORVU	*Sorghum vulgaris*				x	x	x	x	x			

Following application, the plants were maintained under greenhouse conditions with a temperature regulation at 23 °C during day and 18 °C at night with a 16 h photoperiod and relative humidity of 70 %.
Assessments were made 7, 14 and 21 days after application.
Final assessments were made for plant survival, visual phytotoxicity, plant growth stage (BBCH) and shoot dry weight.
Statistical analysis of data was performed to obtain NOER (No observed effect rate), LOER (Lowest observed effect rate), ER_{25} (rate producing 25% effect) and ER_{50} (rate producing 50% effect) values for emergence, survival and shoot dry weight, using ToxRat statistical software.

Dates of experimental work: April 29, 2014 to June 04, 2014

Results and Discussion:

Validity criteria:
The validity criterion of at least 90 % survival of the plants during the study period was achieved for the untreated controls of all ten species tested. In accordance with OECD guideline (OECD 227) and US EPA guideline (OCSPP 850.4150), there was no visible phytotoxicity and a normal growth in the controls of the 10 species tested. The control plants of each species represented a normal variation in growth, plant development and morphology. The environmental conditions during the test time were identical within one species. The pots used for all species of this study were filled in equal manner with the same soil.

Analytical findings:
The analysis of foramsulfuron content in the initial tested item stock solution revealed measured concentrations of 94.2 % to 96.0 % of nominal for foramsulfuron.

Biological findings:
Typical symptoms observed at the final assessment in this study (on day 21 after application) were chlorosis, necrosis, deformation, stunting and reddening. The severity and occurrence differed between species and application rates.

The no observed effect rate (NOER), ER_{25} and ER_{50} values expressed in mL product/ha are summarised for each of the plant species in the following table for the final assessment (21 days after application).

Table: Effects of the test item on survival and shoot dry weight

	mL product / ha					
	Survival			**Shoot dry weight**		
Species	**NOER**	**ER_{25}**	**ER_{50}**	**NOER**	**ER_{25}**	**ER_{50}**
Beta vulgaris	15.6	>15.6°	>15.6°	1.96	3.99	6.97
Brassica napus	31.3	>31.3•	>31.3•	7.81	16.83	25.33
Cucumis sativus	7.81	>7.81•	>7.81•	1.96	4.84	**6.92**
Fagopyrum esculentum	15.6	>15.6•	>15.6•	3.91	6.50	11.33
Glycine max	62.5	>62.5•	>62.5•	3.91	20.79	38.36
Helianthus annuus	31.3	59.84	>62.5◊	3.91	19.98	28.75
Lycopersicon esculentum	31.3	>31.3•	>31.3•	1.96	4.71	10.53
Allium cepa	500	>500°	>500°	31.3▪	48.81▪	138.72▪
Avena sativa	62.5	>62.5•	>62.5•	31.3	49.73▪	>62.5◊
Sorghum vulgaris	62.5	>62.5•	>62.5•	15.6	21.08	33.48

◊: Calculated values were outside the range tested.
°: Not calculated (outside the range tested).

•: Because no effect was observed, no further computations were performed for 21 d.
⁃: Probit analysis: Replicates used while fitting.
◙: Calculated value 125 mL product/ha (NOER) > ER_{25}.

Table: Growth stage of the non-target terrestrial plant species at application rates at the final assessment

Growth stage (BBCH) Min-Max at application rates (in mL product/ha) at the final assessment												
Species	**Control**	**0.49**	**0.98**	**1.96**	**3.91**	**7.81**	**15.6**	**31.3**	**62.5**	**125**	**250**	**500**
Beta vulgaris	16-19	16-19	17-19	17-19	18-19	18-19	14-19					
Brassica napus	19		19	19	19	19	19-23	21-29				
Cucumis sativus	56-69	61-69	61-69	61-69	53-69♦	51-63						
Fagopyrum esculentum	63-65		63-65	63-65	63-65	63-64	59-63					
Glycine max	59			59	59	59	59	51	51			
Helianthus annuus	19			19	19	19	19	19	12-17			
Lycopersicon esculenttum	52-62		61-62	52-62	52-61▫	51-54	16-51	14-16				
Allium cepa	11-41▼							12-17	12-15	13-17	13-16	11-13
Avena sativa	32-33				32-33	32-33	32-33	31-33	31-33□			
Sorghum vulgaris	21-22				21-22	21-22	17-22`	17-24§	21-25			

♦: Only one plant was BBCH 53, all other plants were BBCH 61 – 69
▫: Only one plant was BBCH 61, the majority of the plants were BBCH 53-54
§: Only one replicate was BBCH 17-22 and one was BBCH 21-24, all other plants were BBCH 21 – 22.
`: Only one replicate was BBCH 17-22, all other plants were BBCH 21 – 22.
▼: Only one replicate was BBCH 15-41, the majority of the plants was BBCH 11-17.
□: Only one replicate was BBCH 31-33, all other plants were BBCH 31- 32.

Table: Phytotoxicity summary at application rates at the final assessment

Phytotoxicity summary (minimum to maximum damage) and symptom(s) at application rates (in mL product/ha) at the final assessment												
Species	**Control**	**0.49**	**0.98**	**1.96**	**3.91**	**7.81**	**15.6**	**31.3**	**62.5**	**125**	**250**	**500**
Beta vulgaris	0	0-C be▌	0-A abφ	0-A ae	A-B ae	C-D abde	E abde					
Brassica napus	0		0	0	0	0-A abe	A-C adei	C-D abde♪				
Cucumis sativus	0	0	A ab	A-B abe&	A-B abe	C-D abe						
Fagopyrum esculentum	0		0-A abde	0-B abdef∞	0-B adef∞	A-B ade	C-D abdef					
Glycine max	0			0	0-A abφ	0	A abe	B-C abde	C-D adefΩ			

Helianthus annuus	0			0	0-A ae	0-A ab	A-B abe[&]	C abde	E abde			
Lycopersicon esculenttum	0		0	0-A ade	A-B ade[∂]	C ade	C-D abde	D abde				
Allium cepa	0							0	0-A ae	A ae	B abe	D abe
Avena sativa	0				0	0-A e	0-A e	0-B ade[∨]	A-B abde			
Sorghum vulgaris	0				0	0	A ade	A-C abdef	C-D abdef[♪]			

[ǁ]: Only one replicate was C, all other plants were 0.
[φ]: Only one replicate was A, all other replicates were 0.
[ɨ]: One replicate was A, one replicate was C, all other replicates were B.
[♪]: Only one replicate was C, all other replicates were D.
[&]: Only one replicate was B, all other replicates were A.
[∞]: Only one replicate was B, the majority of the replicates were A.
[Ω]: Only two replicates were C, all other replicates were D.
[∂]: Only two replicates were A, all other replicates were B.
[∨]: Only one replicate showed no phytotoxic symptoms. The other replicates were A to B.

Key:
0: no injury or effect
A: slight symptom (s)
B: moderate symptom (s)
C: severe symptom (s)
D: total-plant symptom (s)
E: moribund
Any plant considered as being dead was not rated for phytotoxicity.

Phytotoxicity symptoms:
a: chlorosis (yellowing of green shoot tissue)
b: necrosis (brown shoot tissue)
c: bleaching (shoot tissue without pigmentation)
d: deformation (leaf curl. abnormal leaf shape)
e: stunting (plant height reduced with shorter internode length)
f: reddening of green shoot tissue

Conclusions:

In a Tier 2 vegetative vigour and growth study, Foramsulfuron + Thiencarbazone-methyl OD 80 (50+30 g/L) was tested under greenhouse conditions for effects on the survival, growth and shoot dry weight of ten non-target terrestrial plant species, following a post-emergence application of the test item onto the foliage of plants at the 2-4 leaf stage. The most sensitive species was found to be *Cucumis sativus* with the lowest ER_{50} of 6.92 mL product/ha for shoot dry weight.

A 2.6.3 KCP 10.6.3 Extended laboratory studies on non-target plants

A 2.6.4 KCP 10.6.4. Semi-field and field tests on non-target plants

Comments of zRMS:

The study is acceptable. The all validity criteria were met.

Agreed endpoints:
Vegetative vigour ER_{50} shoot dry weight (most sensitive parameter)

Species	ER_{50} mL product / ha
Beta vulgaris d	37.30
Brassica napus d	53.20
Cucumis sativus d	8.90
Fagopyrum esculentum d	63.79
Helianthus annuus d	63.39
Lycopersicon esculentum d	62.50
Sorghum vulgare m	26.27

The lowest ER_{50} = 8.90 mLprod./ha (shoot dry weight for *Cucumis sativus*)

Reference:	**KCP 10.6.4/01**
Title:	Thiencarbazone-methyl + foramsulfuron OD 80 (30 + 50 g/L) -Effects on the vegetative vigour of seven species of non-target terrestrial plants under semi-field conditions (Higher Tier)
Report:	Koehler, P.; 2014; HT14/016; M-502816-01-1
Authority registration No:	
Guideline(s):	EU Directive 91/414/EEC Regulation (EC) No. 1107/2009 US EPA OCSPP 850.4150
Deviations:	not applicable
GLP/GEP:	no
Acceptability:	
Duplication (if vertebrate study):	

Objective:

The purpose of this specific higher tier study was to evaluate the effect of Foramsulfuron + Thiencarbazone-methyl OD 80 (50+30 g/L) on the vegetative vigour of seven non-target terrestrial plant species following a post-emergence application of the test item onto the foliage of plants at the 4 to 6 leaf stage grown under semi-field conditions.

Material and Methods:

Test item: Foramsulfuron + Thiencarbazone-methyl OD 80 (50+30 g/L); analysed content of active ingredient: foramsulfuron (AE F130360): 4.97% w/w (51.05 g/L), thiencarbazone-methyl (BYH 18636): 2.97% w/w (30.49 g/L); Batch ID: 2012-005269; Material No.: 80979444; Specification number: 102000025743-01; TOX No.: TOX09970-00; density: 1.028 g/mL.

Test species: 6 dicotyledonous species and 1 monocotyledonous species representing 7 different plant families (EPPO code): *Beta vulgaris* (BEAVA), *Brassica napus* (BRSNW), *Cucumis sativus* (CUMSA), *Fagopyrum esculentum* (FAGES), *Helianthus annuus* (HELAN), *Lycopersicon esculentum* (LYPES), *Sorghum vulgaris* (SORVU).

The plants were grown in a canopied test area with UV permeable roof as rain protection, in commercial 40 L polyethylene containers and were treated at the 4-6 leaf stage. The used soil was a natural silt loam. There were 16 plants per container and 3 replicate containers, giving a total of 48 plants per treatment level. The plant species were treated with 4 application rates ranging from 3.91 to 250 mL product/ha (see table below). Control containers were sprayed with 400 L/ha of deionised water.
The test item was dissolved in deionized water for the preparation of the test item stock solution (5000 mL product/ha, volume rate equivalent to 400 L/ha). The test item stock solution was only used for the analytical part and to set up the application rates. The test item application solutions were prepared by dilution of the stock solution with deionized water. The applications of the test item and the water control were done under semi-field conditions. Serial dilutions of Foramsulfuron + Thiencarbazone-methyl OD 80 (50+30 g/L) were sprayed onto the foliage of plants using a plot sprayer at a volume rate of 400 L/ha. The actually applied spray volume was determined by re-measuring the residual volume found in the sprayer after application.

Table: Application rates during the study

Test item rate in mL product/ha		**3.91**	**7.81**	**15.63**	**31.25**	**62.5**	**125**	**250**
BEAVA	*Beta vulgaris*			x	x	x	x	
BRSNW	*Brassica napus*			x	x	x	x	
CUMSA	*Cucumis sativus*	x	x	x	x			
FAGES	*Fagopyrum esculentum*		x	x	x	x		
HELAN	*Helianthus annuus*			x	x	x	x	
LYPES	*Lycopersicon esculentum*			x	x	x	x	
SORVU	*Sorghum vulgaris*				x	x	x	x

Immediately after application, the containers, placed on pallets, were transferred to the canopied test area to ensure full penetration of the test item into the foliage of the plants and to avoid any wash-off by natural precipitation. One to two days after application, the containers were transferred to an outdoor area enclosed within a cage but without protection by a roof. In this outdoor area, the test plants were fully exposed to environmental conditions including natural precipitation.
After application, bottom watering was performed according to the need of the plants in order to have an optimal water supply for plant growth. This was checked daily. Water was given directly onto the soil without wetting the leaves until the containers were transferred to the outdoor area. Natural rainfall was supplemented if it was not sufficient to water the plants, during the test time in the outdoor area. Additional water was given directly onto the soil as described above.
Assessments were made 7, 14 and 21 days after application.
Final assessments were made for plant survival, visual phytotoxicity, plant growth stage (BBCH, see Appendix 5) and shoot dry weight.
Statistical analysis of data was performed to obtain NOER (No observed effect rate), LOER (Lowest observed effect rate), ER_{25} (rate producing 25% effect) and ER_{50} (rate producing 50% effect) values for survival and shoot dry weight, using ToxRat statistical software.

Dates of experimental work: May 26, 2014 to September 30, 2014

Results and Discussion:

Validity criteria:
All species in this study met the validity criterion for survival (at least 90%). In accordance with OECD guideline (OECD 227) and US EPA guideline (OCSPP 850.4150), there was no visible phytotoxicity and a normal growth in the controls of the 7 species tested. The control plants of each species showed normal variation in growth, plant development and morphology. The environmental conditions during the test time were identical within one species (see point 3.3). The containers used for all species of this study were filled in equal manner with the same soil.

Analytical findings:
The analysis of foramsulfuron content in the initial test item stock solution revealed measured concentrations of 91 % to 93 % of nominal for foramsulfuron.

Biological findings:
Typical symptoms observed at the final assessment in this study (on day 21 after application) were chlorosis, necrosis, deformation and stunting. The severity and occurrence differed between species and application rates.
The no observed effect rate (NOER), ER_{25} and ER_{50} values expressed in mL product/ha are summarised for each of the plant species in the following table for the final assessment (21 days after application).

Table: Effects of the test item on survival and shoot dry weight

	mL product / ha					
	Survival			Shoot dry weight		
Species	**NOER**	**ER_{25}**	**ER_{50}**	**NOER**	**ER_{25}**	**ER_{50}**
Beta vulgaris	<15.63	23.51	44.20	<15.63	<15.63°▪	37.30▪
Brassica napus	31.25	71.70	94.31	15.63	19.51▪	53.20▪
Cucumis sativus	15.63	>31.25◊	>31.25◊	<3.91	<3.91	**8.90**
Fagopyrum esculentum	>62.5	>62.5°	>62.5°	7.81	22.87	63.79♦
Helianthus annuus	62.5	118.33	131.30♦	15.63	21.23▪	63.39▪
Lycopersicon esculentum	125	>125•	>125•	<15.63	<15.63○	62.5§
Sorghum vulgaris	125	225.44	>250◊	<31.25	<31.25°	26.27▪♦

•: No effect was observed; hence numeric statistical effect assessment was dispensable for the data of '21 d'.
°: Not calculated (outside the range tested).
◊: Calculated values were outside the range tested
▪: Probit analysis: Replicates used while fitting.
♦: Extrapolated value
§: Not calculated (values proposed by expert judgement)

Table: Growth stage of the non-target terrestrial plant species at application rates at the final assessment

Growth stage (BBCH) Min-Max at application rates (in mL product/ha) at the final assessment								
Species	**Control**	**3.91**	**7.81**	**15.63**	**31.25**	**62.5**	**125**	**250**
Beta vulgaris	17-19			17-19	16-19	16-19	16-17	
Brassica napus	17-31			18-31	21-29	13-21	14-16	
Cucumis sativus	56-66	53-64	52-65	52-63	14-62			
Fagopyrum esculentum	64-65		64-65	63-65	62-65	61-64		
Helianthus annuus	51-55			19-53	18-51	16-51	14-19	
Lycopersicon esculenttum	61-64			18-61	18-61	16-52	16-52	
Sorghum vulgaris	21-31				22-31•	15-24	14-21	14-16

•: The majority of the plants were BBCH 22-24; only two plants were BBCH 31.

Table: Phytotoxicity summary at application rates at the final assessment

Phytotoxicity summary (minimum to maximum damage) at application rates (in mL product/ha) at the final assessment								
Species	**Con-trol**	**3.91**	**7.81**	**15.6**	**31.3**	**62.5**	**125**	**250**
Beta vulgaris	0			C-D abde	D-E abde	E abde	E abde	
Brassica napus	0			B abde	B-C abdef	D abdef	E abdef	
Cucumis sativus	0	A-B abe	A-B abe	C-D abde	D-E bde			
Fagopyrum esculentum	0		A ade	B abde	C abde	C-D abde		
Helianthus annuus	0			A abe	B-C abde	C-D abde	D-E abe	
Lycopersicon esculenttum	0			B ade	B-C abde	C abde	C-D abde	
Sorghum vulgaris	0				B-C abde	C-D abef	D-E abef	D-E bef

Key:
0: no injury or effect
A: slight symptom (s)
B: moderate symptom (s)
C: severe symptom (s)
D: total-plant symptom (s)
E: moribund
Any plant considered as being dead was not rated for phytotoxicity.

Phytotoxicity symptoms:
a: chlorosis (yellowing of green shoot tissue)
b: necrosis (brown shoot tissue)
c: bleaching (shoot tissue without pigmentation)
d: deformation (e.g. leaf curl, abnormal leaf shape, abnormal plant habitus)
e: stunting (plant height reduced with shorter internode length)
f: reddening of green shoot tissue

Conclusions:

In a higher tier vegetative vigour and growth study, Foramsulfuron + Thiencarbazone-methyl OD 80 (50+30 g/L) was tested under semi-field conditions for effects on the survival, growth and shoot dry weight of seven non-target terrestrial plant species, following a post-emergence application of the test item onto the foliage of plants at the 4-6 leaf stage. The most sensitive species was found to be *Cucumis sativus* with the lowest ER_{50} of 8.90 mL product/ha for shoot dry weight.

A 2.7 KCP 10.7 Effects on other terrestrial organisms (flora and fauna)

Comments of zRMS:	Accepted.

Reference:	**KCP 10.7/01**
Title:	Technical stand-alone combined toxicity assessment for the Central zone
Report:	Gladbach, A.; Ebeling, M.; Weyers, A.; 2017; M-571377-02-1
Authority registration No:	
Guideline(s):	none
Deviations:	--
GLP/GEP:	no
Acceptability:	
Duplication (if vertebrate study):	

This document summarises the tiered approach to assess the risk due to the combined toxicity of active substances. The approach is based on the conservative assumption of concentration-additive combination toxicity. Where necessary, a more detailed and realistic evaluation (e.g, information on mode of action) may be conducted as a further refinement of the tiered approach presented in this document.

1. The first step proceeds as a screening to check whether the margin of safety based on the single substance assessments is large enough.
   The margin of safety is large enough if:
   TER assessments: The TER for each single a.s. exceed the regulatory trigger multiplied by the number of a.s. (trigger × n).
   RQ assessments: The RQ ('risk quotient' = PEC/RAC) for each single a.s. is lower than the regulatory trigger divided by the number of a.s. (1/n).
2. The second step, in case the first step is not satisfied, investigates whether the combined risk is significantly dominated (>90%) by one substance.
3. As the third step, in case the first two steps would not be satisfied, TER_{mix} or RQ_{mix} calculations are performed. These TER_{mix} and RQ_{mix} calculations may include refinement when necessary.

A 2.8 KCP 10.8 Monitoring data

Appendix 3 Additional information provided by the applicant

zRMS comments:'

A 3.1 Detailed information to Section 9.5.2.4: Analysis of applicability of the TWA approach for Tier 1 risk assessment

(a) TWA justification for foramsulfuron

Reference:	**KCP 10.2.3/01**
Title:	Justification for the use of time-weighted average concentrations in the chronic risk assessment for foramsulfuron and aquatic plants
Report:	Solga, A.; Heine, S.; 2018; M-615294-02-1
Authority registration No:	
Guideline(s):	none
Deviations:	--
GLP/GEP:	no
Acceptability:	
Duplication (if vertebrate study):	

For the references cited in this summary and for the appendix of the document, please go back to the original report (see Appendix 1 – List of data submitted by the applicant).

Summary

The EFSA Aquatic Guidance Document (EFSA, 2013[14]) proposes the use of a time weighted average (TWA) concentration in the risk assessment of aquatic organisms in order to address a possible discrepancy between the duration of an exposure event and the exposure period in the corresponding effect study. Specific prerequisites have to be fulfilled before the use of a TWA approach can be justified. In the present document, it is discussed for the active substance foramsulfuron and the test organism *Lemna gibba* whether the $PEC_{sw,twa}$ can be compared to the $RAC_{sw,ch}$ in the risk assessment using the TWA approach by (i) showing reciprocity for this species compound combination, (ii) using a decision scheme as presented in the EFSA AGD and (iii) direct proof of conservatism of the TWA approach itself. All lines of evidence are supported by biological data derived of static exposure or peak exposure studies and/or by simulations (*in silico* experiments) using a mechanistic *Lemna* model (see Table A 1). As a crucial first step, it is shown that linear reciprocity can be ascertained for the combination of *Lemna* and foramsulfuron, forming the basis of the TWA approach. Furthermore, the EFSA AGD decision scheme clearly allows for the use of TWA in the case presented here, putting a special focus on the evaluation of onset of effects and potential delayed effects. An additional alternative direct test presented by the applicant also confirms that the TWA approach in the case of *Lemna* and foramsulfuron can be regarded as conservative and therefore protective.

[14] In the following abbreviated as 'EFSA AGD'

Table A 1: Overview on methodologies used in the present document:

Criteria addressed / methodology		Analysis of biological data	*In silico* experiment
Reciprocity		X	-
Decision scheme	Generic parts	X	-
	Early onset of effects	X	X
	Delayed effects	X	X
Direct proof of conservatism		Graphical data comparison between constant exposure and pulse exposure studies.	

As an overall conclusion, it is considered justified to base the risk assessment for *Lemna gibba* and foramsulfuron on 7d time-weighted average concentrations ($PEC_{sw,\ 7d\text{-}twa}$).

Introduction

In standard studies with macrophytes aiming to derive a Regulatory Acceptable Concentration for surface water bodies ($RAC_{sw,ch}$) the plants are constantly exposed to a test compound over several days. For *Lemna*, the duration of this exposure period is normally seven days (OECD TG 221, 2016). According to the EFSA Aquatic Guidance Document (EFSA, 2013[15]), as initial step in Tier 1 risk assessment, the $RAC_{sw,ch}$ derived from this long-term exposure is compared to the maximum concentration of complex exposure scenarios ($PEC_{sw,max}$). Depending on the actual product use situation, exposure scenario and the characteristics of the compound under assessment, the exposure event which defines the $PEC_{sw,max}$ can however be significantly shorter (e.g. < 1 day) than the exposure period in the effect study. This may lead into an overly conservative Tier 1 assessment in some cases.
A possible technique to address this discrepancy is a risk assessment based on time weighted average (TWA) concentration. It should be noted that the TWA approach is still Tier 1 and does not belong to higher tier (Tier 2) refinement options like the geomean approach (Tier 2A), the SSD approach (Tier 2B) or the refined exposure approach (Tier 2C).
According to the EFSA AGD, the TWA approach may be applied if certain criteria are fulfilled. These criteria are included in a decision scheme presented in the EFSA AGD. The scheme has to be successfully passed before it is justified to compare $PEC_{sw,twa}$ to $RAC_{sw,ch}$ in the risk assessment.
This document presents a detailed analysis of the applicability of the time-weighted average approach in the risk assessment for foramsulfuron and aquatic plants. The analysis comprises of two fundamentally different methodologies:

1. Analysis according to the EFSA AGD, addressing all criteria requested for TWA
2. Direct proof of conservatism of TWA by considering results from refined exposure experiments

The straightforward method 2 which was recently developed by the applicant is explained in more detail under point "Alternative approach for proving conservatism of TWA".

General principle and prerequisites for applying the time-weighted average concept

The use of a TWA concentration approach in the aquatic risk assessment of plant protection products is based on the observation that effects on aquatic organisms may be similar when exposed for a short time to a higher concentration or for a longer time to a lower concentration, a phenomenon referred to as reciprocity (Giesy and Graney, 1989). Reciprocity relates to Haber's law, which assumes that toxicity depends on the product of concentration and time. Linear reciprocity is the basis of the TWA approach, where exposure concentration is integrated over time (= area under the curve, AUC) and then divided by a default of 7 days (or – if differing – the duration of the toxicity test). An example visualizing this as-

[15] In the following abbreviated as 'EFSA AGD'

sumption is given in Figure A 1. When this approach is applied, different exposure patterns with the same AUC are assumed to have the same effects.

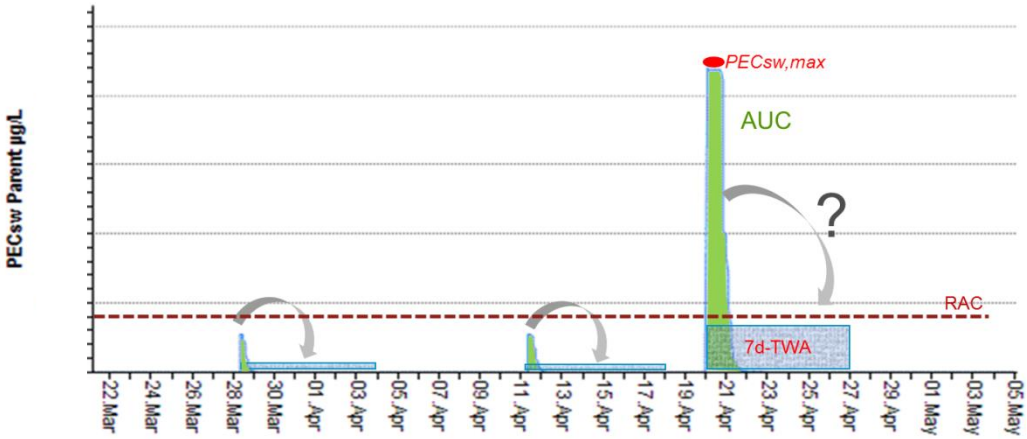


Figure A 1: **Theoretical example of FOCUS exposure pattern with two peaks below the Regulatory Acceptable Concentration (RAC) and one prominent peak exceeding this RAC. The blue boxes represent calculated 7d-twa values for the individual peaks, none of them exceeding the RAC.**

Due to its importance for the application of the TWA approach, the demonstration of linear reciprocity for a certain compound/species combination is the crucial first step. The analysis of linear reciprocity is usually based on standard study data (e.g. *Lemna* 7d constant exposure study).
Further aspects to be addressed in context of the TWA approach according to the EFSA AGD are the time to onset of effects and (non-)latency of effects. With macrophytes, the time to onset of effects is investigated to reveal how rapidly a compound affects the plants. This is done to exclude that short exposure to high concentrations as it may occur under realistic outdoor conditions (e.g. runoff events) produces effects that are 'overlooked' when comparing the Tier 1 $RAC_{sw,ch}$ to averaged (and by this lowered) $PEC_{sw,twa}$. Analysis of time to onset of effects can be based on standard study data (e.g. *Lemna* 7d constant exposure study); however, TK/TD modelling approaches may be used in addition.
Investigating (non-)latency of effects is done to prove that delayed effects in the post-exposure phase caused by damage during exposure are not to be expected. A possible way to address this point is considering available recovery studies or to perform TK/TD modelling.
Criteria and an evaluation scheme dedicated to this purpose have been set up in the EFSA AGD, chapters 4.5.1 '*When and how (not) to use the $PEC_{sw;twa}$ in chronic risk assessments*' and 4.5.2 '*Decision scheme to use the $PEC_{sw;max}$ or $PEC_{sw;twa}$ in the risk assessment'*. Under points "Analysis of reciprocity" and "The EFSA decision scheme for $PEC_{sw;twa}$ in chronic risk assessment" below a detailed step-by-step assessment will be presented, providing analysis and supportive explanation on each evaluation point.

Alternative approach for proving conservatism of TWA:

When using TWA in the aquatic risk assessment, predicted concentrations are averaged over time ($PEC_{sw;twa}$) and these averaged concentrations are compared to an effect endpoint from a constant exposure study. Recently, a number of procedural questions around the demonstration of applicability of the TWA concept with regard to a specific substance have been raised which is reflected in complex and in part controversial discussions on how to practically handle certain elements of the EFSA AGD decision scheme for TWA. As final clarification on these matters is not yet available at the authoring time of the present document, the applicant wishes to provide in addition to the AGD science-based approach a further confirming element, i.e. a novel and practicable screening test for TWA applicability based on simple phenomenological considerations. The procedure is laying focus exclusively on the question whether or not a risk assessment based on averaged concentrations is conservative and protective, irrespective of scientific or mechanistic backgrounds. For the intended purpose of risk assessment, ultimately, it has to

be ensured that also exceptional exposure events (e.g. runoff peaks, drift peaks) are covered when using $PEC_{sw;twa}$ values.
To demonstrate the conservatism of TWA for specific species-compound-exposure combinations, the applicant recently developed a new approach that was also presented at the SETAC Europe Conference in Brussels 2017 (Preuss et al. 2017). The idea behind this new approach is to provide direct proof, instead of an implicit justification, that the assumption shown in Figure A 1 above is conservative. The approach basically requires two datasets for the same compound and species: 1. A constant exposure study (e.g. *Lemna* 7-days standard laboratory test); 2. A refined exposure study (*Lemna* 1-day pulsed exposure + 6 days in clean medium).
The general procedure of this new approach includes the following steps:

1. Calculate twa-values for the different test levels of the refined exposure study; the time window of the TWA can be set to different values, e.g. the default 7 days as recommended by ELINK (Brock et al. 2010) and adopted in the EFSA AGD.
2. Insert the obtained twa-values in the dose-response curve of the standard constant exposure study to derive inhibition percentages; this calculates the effects which would be predicted by the twa-concentration.
3. Compare these predicted inhibition percentages with inhibition percentages as observed in the refined exposure study.
4. If the predicted inhibition is > the observed inhibition, then TWA is conservative and can be applied (see example in Figure A 2 below).

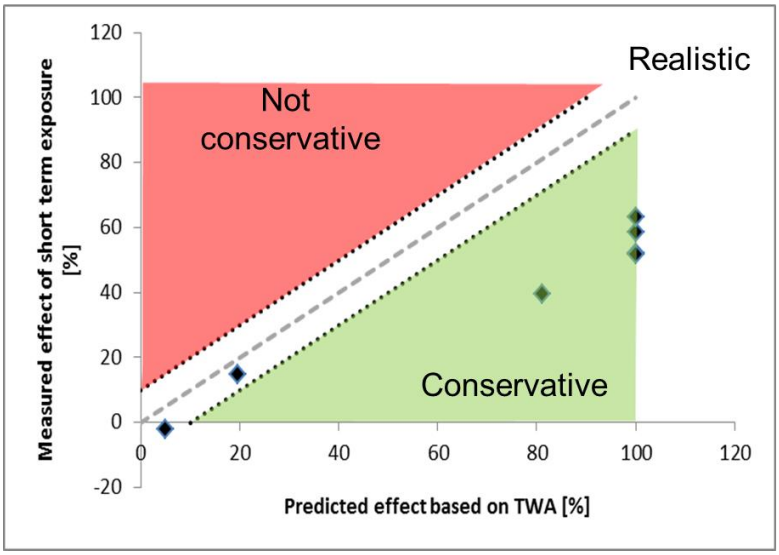


Figure A 2: **Predicted effects based on TWA vs. measured effects of a short-term exposure event.** The predicted effects from the concentration response relationship of the standard test using the twa-concentration of the refined exposure study are plotted against the measured effect at the respective concentration in the refined exposure test. If Haber's law would apply for this species-compound combination, all data points would be on the dashed 1:1 line ± 10% (white area). In general, data points below the 1:1 line (green area) indicate that TWA over-predicts the effects (TWA is conservative), whereas data points above the 1:1 line (red area) indicate that TWA under-predicts the effects of short-term exposure events. In the latter case, TWA would not be protective and should thus not be applied.

As for reciprocity this approach can theoretically not work in the lower non-linear part of the concentration-response relationship (inhibitions <17.6%, cf. point "Analysis of reciprocity"). However, since macrophyte risk assessment is based on the EC_{50} (EFSA AGD, p. 17) and the TWA is thus applied to 50% effect, this lower effect range is not relevant for the actual risk assessment question.
A further advantage of this new approach is that the time window for TWA can be modified to either achieve a higher level of conservatism (e.g. 5 instead of standard 7 days for *Lemna*), or to justify longer

time windows, as recommended in the EFSA AGD (p. 49). An example for the increase of conservatism is given in Figure A 3 below.

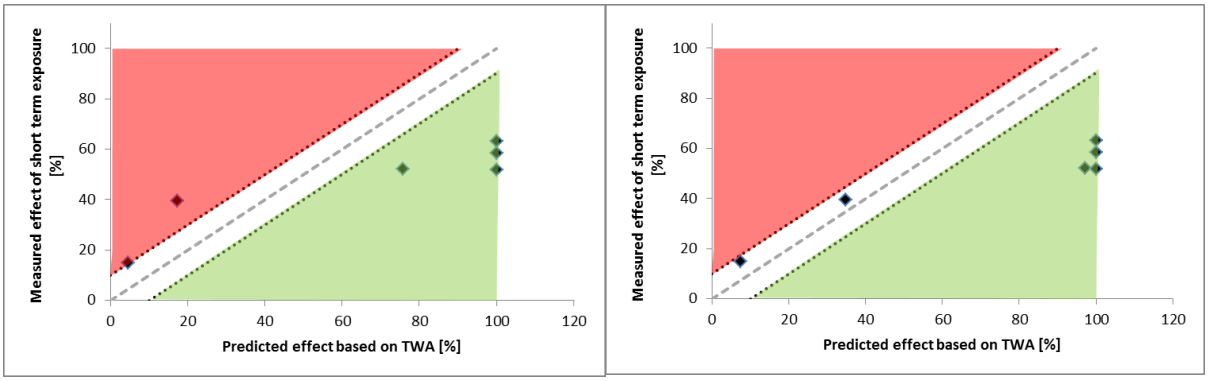


Figure A 3: **Theoretical example of the impact of the time window on conservatism of the TWA approach.** Left: For the time window of 7 days TWA is not conservative (data points in red area, some predicted effects < observed effects); Right: For the shortened time window of 5 days TWA is conservative (all data points in white or green area, predicted effects always > observed effects). Hence, TWA could be used with 5-day time window.

For foramsulfuron and aquatic plants the direct proof of conservatism of TWA is provided under "Direct proof of conservatism of TWA for foramsulfuron" in this summary.

Analysis of reciprocity:

A prerequisite for applying the EFSA AGD decision scheme is the demonstration of linear reciprocity for a certain species/compound combination. Reciprocity relates to Haber's law which states that the toxicity depends on the product of concentration and exposure duration. As an example, the same effect is expected to occur if the exposure duration is halved while the concentration is doubled (EFSA AGD, point 4.5). A straightforward way to demonstrate reciprocity is to prove the linear relationship between the effect and the product of exposure duration and test concentration (EFSA, 2015, point 3.3.2). In this context, it is important that the underlying study includes several measurement time points to avoid 'inevitable linearity': if all measurements originate from the same time interval, the generated line just mirrors the dose response curve but does not provide information about reciprocity.
Moreover, linear reciprocity can only be demonstrated for the linear part of a dose-response relationship. As shown by Sebaugh & McGray (2003), the range of this linear part is independent of EC_{50} and slope. For a logistic model, the authors derived an effect range of 17.6% to 82.4% for which linearity is given. Even though the dose-response curve for foramsulfuron was calculated with probit, a similar range can be assumed as the models differ mainly towards their curve tails.
Accordingly, an effect range of 15-85% for the investigation of linear reciprocity was used.
In the case of foramsulfuron the check for linear reciprocity was based on the Lemna tier-1 study of Christ & Ruff (1998, M-147891-02-1) which also delivers the endpoint to be used in the Tier 1 risk assessment for aquatic plants ($E_rC_{50\ \text{frond no.}}$ = 1.01 µg a.s./L) as listed in the EFSA Conclusion on foramsulfuron (EFSA, 2016a). By basing the analysis on the measurement variable frond number of this study, the applicant follows the suggestion made in the Minutes of the Consultation for the corrigendum of the Aquatic Guidance Document (EFSA, 2016b): '*The reciprocity has to be demonstrated for the endpoint that is used for the risk assessment*'.
Inhibitions of the area under the curve (AUC) for frond number were considered for the intervals 0-2, 0-4 and 0-7 days, as originally reported by the study authors (see Christ & Ruff, 1998, p. 27, Table 4). It should be noted that a reciprocity analysis can only be done with 'biomass'-related' endpoints (e.g. AUC, yield); basing the analysis on the response variable growth rate is not meaningful. For an example, see Appendix 10.3 of the full report.
The relationship between %-inhibitions and time x concentration is shown in Figure A 4 below. An R^2 of 0.9389 was obtained, indicating a clear linear correlation.

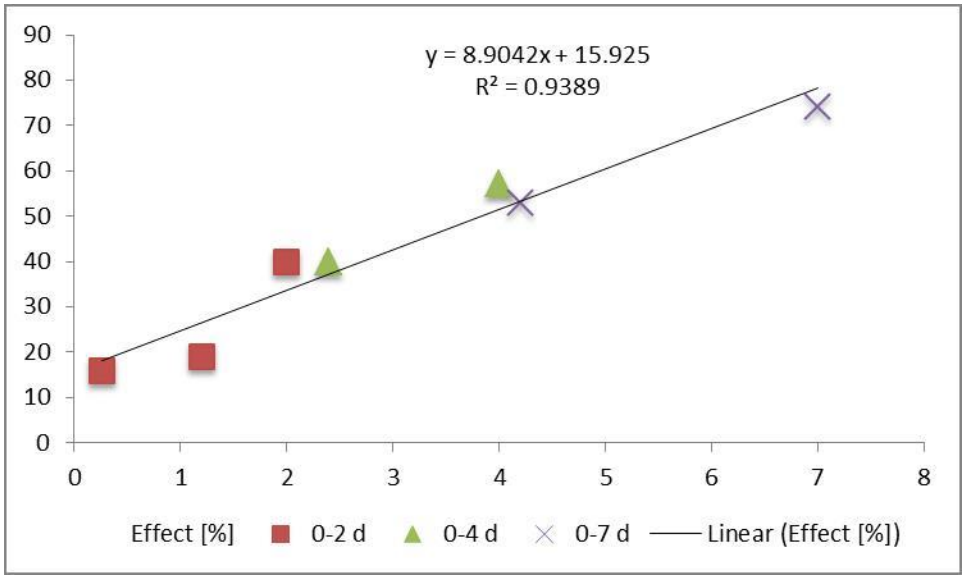


Figure A 4: **Relationship between %-inhibitions of frond number AUC and time x concentration for foramsulfuron.** An effect range of 15% to 85% was chosen to show linearity (8 data points excluded which were mainly < 10% effect values).

To conclude, reciprocity can be assumed, and Haber's law can be applied to this compound species combination, indicating that a longer exposure of aquatic plants to a lower concentration of foramsulfuron (a.s.) leads to similar effects as a shorter exposure to a higher concentration. The decision scheme as provided in the EFSA AGD (point 4.5.2) thus can be applied.
It should be noted that the RAC (Regulatory Acceptable Concentration) mentioned in the decision scheme is based on the Tier 1 endpoint (here: E_rC_{50} = 1.01 µg a.s./L) which is divided by the standard assessment factor of 10 for aquatic plants, leading to a Tier 1 RAC of 0.101 µg a.s./L.

The EFSA decision scheme for $PEC_{sw;twa}$ in chronic risk assessment:

In the following paragraphs the individual steps of the EFSA decision scheme for $PEC_{sw;twa}$ in chronic risk assessment as provided in the EFSA AGD (2013, pp. 49) are addressed:

1. *Chronic Assessment*. Is $PEC_{sw;max}$ (of highest available tier) > $RAC_{sw;ch}$ (of highest available tier)?

   Yes: Go to 2

   No: Low chronic risk

Answer for foramsulfuron & *Lemna*: Yes; the aquatic risk assessment for foramsulfuron is characterised by short-term exposure events which may result in $PEC_{sw;max}$ exceeding $RAC_{sw;ch}$ in scenarios relevant to the zonal or country evaluation of the product. For a detailed numeric assessment on the specific product GAP, reference is made to the corresponding product dRR.
The present document exclusively aims at investigating on the question whether the TWA approach can in principle be used for foramsulfuron and *Lemna*, from the general science perspective.
Moreover, it should be noted that – according to the Aquatic Guidance Document (EFSA, 2013, p. 15; Decision scheme B of Section 2.1.2) – the use of TWA concentrations in combination with Tier-1 endpoints is by definition no 'refinement' but still Tier-1 within the tiered approach. Accordingly, in the base case the "highest available tier" refers to Tier-1 data without any further refinements, but the approach may also be applied to any following higher tier level, as a secondary step.

→ Go to 2

2. Is the $RAC_{sw;ch}$ derived from a test with algae, or from a long-term (≥ 7 days) test with another water organism and the following conditions apply: (i) loss of the a.s. from water is more than 20% of nominal at the end of the exposure period and (ii) the toxicity estimate (e.g. EC_{10} or NOEC) is expressed in terms of nominal/initially measured concentration of the a.s.?

   Yes: $PEC_{sw;twa}$ not appropriate (low risk not demonstrated)

   No: Go to 3

Answer for foramsulfuron & *Lemna*: No. The RACsw;ch of 0.101 µg a.s./L is derived from a 7-day test with Lemna gibba (Christ & Ruff; 1998; M-147891-02-1). Measured concentrations at the end of the exposure period ranged between 87-152% of nominal, respectively. Thus, there was no indication for a compound decline, and it was justified to express the endpoints in terms of nominal concentrations of foramsulfuron.

→ Go to 3

3. Is the $RAC_{sw;ch}$ based on treatment-related responses of the relevant test species early in the chronic test (e.g. during the initial 96-hours observed mortality/immobility in tests with animals, or 50% reduction in growth rate in tests with macrophytes, in the treatment level above the one from which the $RAC_{sw;ch}$ is derived) or is the acute to chronic ratio (acute $L(E)C_{50}$/chronic NOEC or acute $L(E)C_{50}$/chronic EC_{10}) based on immobility or mortality < 10?

   Yes: $PEC_{sw;twa}$ not appropriate (low risk not demonstrated)

   No: Go to 4

Answer for foramsulfuron & *Lemna*: No. It has to be made clear that question 3 which deals with the onset of effects should be answered based on 'biomass' rather than on growth rate data. Under constant exposure conditions which are intended for *Lemna* standard (Tier 1) studies, effects on growth rate are expected to be stable over time. As a consequence, if question 3 is on the concentration above the one delivering the 7d-E_rC_{50}, it is almost inevitable to find a 50% growth rate reduction also for the early phase of the study (i.e. day 0-2 or 0-3).
Therefore, question 3 will be answered based on data for frond number area under the curve (AUC). Consequently, the concentration above the E_bC_{50} needs to be considered for the analysis. In the study of Christ & Ruff (1998; M-147891-02-1), the E_bC_{50} is 0.65 µg a.s./L and the concentration above this value is 1.00 µg a.s./L. At this test level, the reduction of frond number AUC was observed to be 40% on day 2 which is less than the 50 % threshold.
With regard to the question on acute to chronic ratio, it should be mentioned that this point does not apply to macrophytes for which no acute studies are performed.

To further explore time to onset of effects, simulations (*in silico* experiments) were performed using a mechanistic *Lemna* model parameterized for foramsulfuron (Heine 2017a, M-591817-01-1). The development of this mechanistic model has been published in an international peer reviewed journal (Schmitt et al. 2013, M-455483-01-1). The entire results of the model-based analysis, including a detailed description of the modelling tasks, are presented in a separate report (Heine 2017b, M-593677-01-1). The calibration and validation of the model can be found in the Appendix of the full document.
The *Lemna* model uses an EC_{50} that is based on internal concentration of foramsulfuron. This value is

used as a reference to define the treatment level above the one from which the $RAC_{sw;ch}$ has been derived. Therefore, for modelling the onset of effects a treatment of 1.1 µg a.s./L was selected. This slightly differs from the treatment that is used to evaluate the onset of effects on an experimental basis (1.0 µg/L, see above).

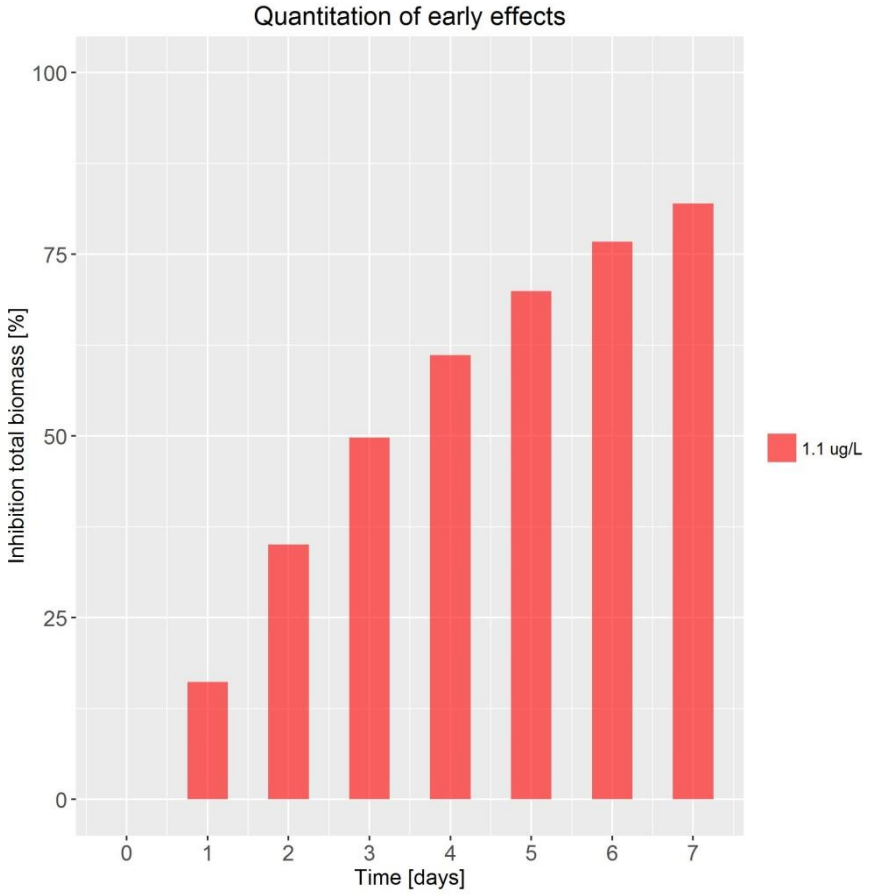


Figure A 5: Simulated effect on biomass during exposure to foramsulfuron using the mechanistic *Lemna* effect model.

As shown in Figure A 5 above, predicted effects on biomass at a concentration of 1.1 µg a.s./L during the initial 2 days of the simulation / *in silico* experiment are clearly less than 50% and thus support the conclusions from the biological study above.

→ Go to 4

4. Is it demonstrated by the notifier that, for the organisms and the PPP under evaluation and/or PPP with a similar toxic mode of action (read-across information), the following phenomena are not likely: (i) latency of effects due to short-term exposure; (ii) the co-occurrence of exposure and specific sensitive life stages that last a short time only?

   Yes: Go to 5

   No: $PEC_{sw;twa}$ not appropriate (low risk not demonstrated)

Answer for foramsulfuron & *Lemna*: Yes. In a first *Lemna* peak exposure study (Bruns, 2013a, M-462569-03-1) normal growth was observed already four days after a 24h pulse of up to 56.7 µg a.s./L.

This is reflected in the parallel growth lines from day 5 to day 7 in Figure 1 of the study report. Also, no visual signs of phytotoxicity were observed in this study which allows concluding that the compound temporarily inhibited growth but did not produce irreversible damage, even at unrealistically high short-term exposure concentrations. These results were confirmed by a second, more recent pulsed exposure study (Kuhl, 2016, M-572386-03-1) which included different exposure designs. Also in this study, normal growth was observed soon after the peaks (see Fig. 2 and Fig. 3 of the original study report: parallel growth lines from day 4 to day 7).
The findings of the refined exposure studies are in line with the results of the 21 day *Lemna* recovery study of Dorgerloh (2005, M-250268-01-1) in which *Lemna gibba* was exposed to concentrations up to 20 µg a.s./L for seven days. During the subsequent 14-d recovery phase effects on frond number, frond area and phytotoxicity decreased over time with no indication for any delayed effects as a result of initial high exposure.
Delayed effects are generally not known for sulfonyl-urea herbicides and aquatic plants and further evidence for this can be found in public literature. Mohammad et al. (2006) tested eight different SUs and came to the following conclusion: '*When Lemna sp. was transferred to fresh medium after exposure, development of new fronds was observed for all [8 tested] SU even at 1000 ppb'.*
Moreover, according to the outcome of a consultation for the corrigendum of the Aquatic Guidance Document (EFSA, 2016), the criterion only needs to be addressed in the specific case of rooted macrophytes and thus not for *Lemna*.
To further explore potential latency of effects, simulations (*in silico* experiments) were performed with the *Lemna* model parameterized and validated for foramsulfuron (as explained above). As shown in Figure A 6, the *in silico* experiments did not give any indication for delayed effects on *Lemna* growth: already two days after simulated exposure (day 9 in graph below), growth rates were not inhibited anymore and had reached again control level.

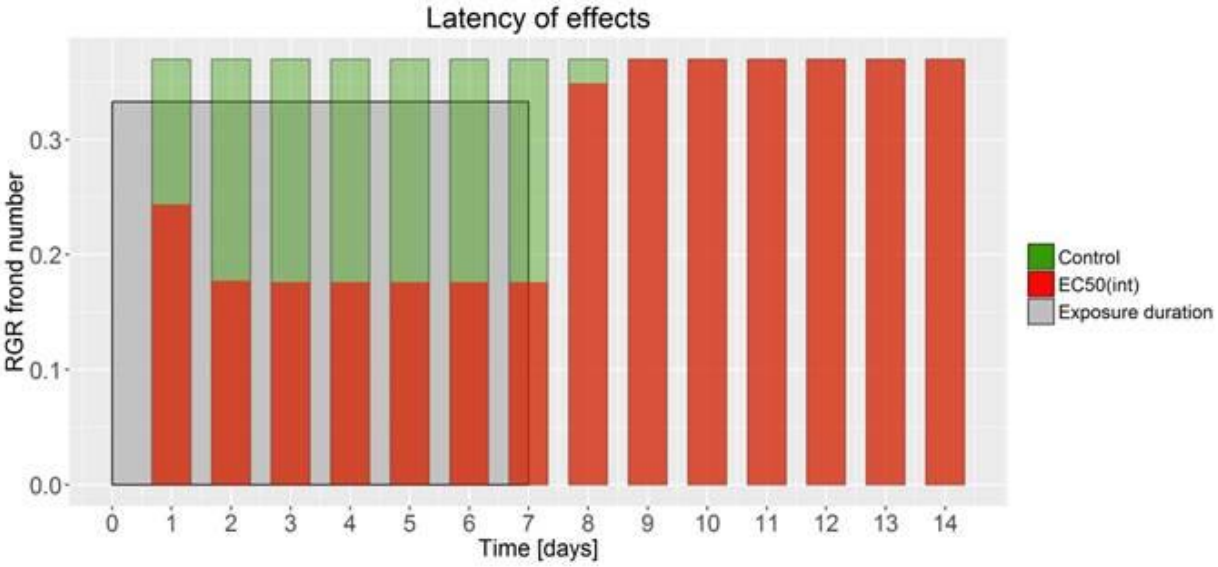


Figure A 6: Simulated effect on growth rate during and after exposure to foramsulfuron using the mechanistic *Lemna* effect model.

With regard to the second part (ii) of question 4, the EFSA AGD (p. 48) gives examples for specific sensitive life stages: '*e.g. malformations during metamorphosis, effects caused by endocrine disruption'*. This point is not related to macrophytes for which coincidence of exposure and a specific sensitive life stage is not an issue, but rather refers to other aquatic organisms, e.g. fish. *Lemna* propagates by vegetative multiplication. Due to the exponential growth, a *Lemna* study covers several life cycles of that species and derived endpoints integrate any potential differences in sensitivity (e.g. young vs. older fronds).

→ Go to 5

5. Is $PEC_{sw;7d\text{-}twa}$ (of highest available tier) > $RAC_{sw;ch}$ (of highest available tier)?

Yes: Go to 6

No: Low risk demonstrated

Answer for foramsulfuron & *Lemna*: No. Please refer to the corresponding product dRR document for a detailed risk assessment based on $PEC_{sw;7d\text{-}twa}$ and *Lemna*.

Direct proof of conservatism of TWA for foramsulfuron:

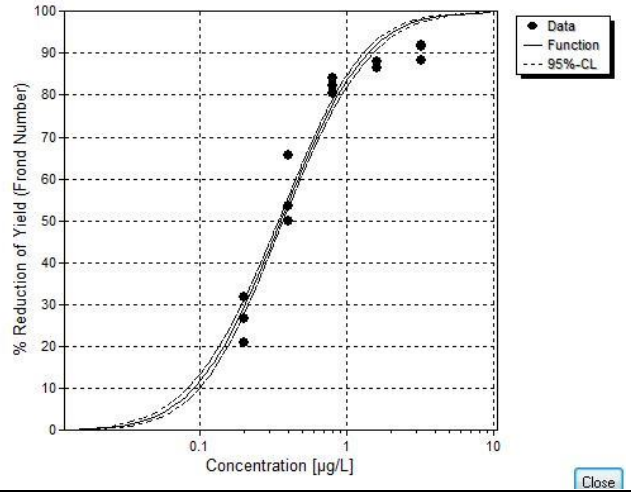
The following studies were considered in the evaluation of conservatism of TWA for foramsulfuron:

- 6 weeks *Lemna* bioassay with stepwise decreasing concentrations, first 7 days are considered as standard test: Bruns, 2013b (M-464150-01-1)
- 1+6-day pulsed exposure test: Bruns, 2013a (M-462569-01-1)
- 2+5-day pulsed exposure test (first week of design 1): Kuhl, 2016 (M-572386-03-1)

Note that for the derivation of the probit function from the constant exposure study which is needed to predict effects of short-term exposure, not the 7d standard study of Christ & Ruff (1998, M-147891-02-1) was used, but the first seven days of the 42d bioassay by Bruns (2013b, M-464150-01-1). The reason for this is that the dose-response curve of Christ & Ruff showed a poor fit at lower concentrations and under-estimated effects in this range (see Appendix 10.4 of this full report). The underlying function was therefore not considered robust enough for further predictions. In contrast, the curve derived by Bruns showed an overall better fit with narrow confidence limits (see graph in Table A 2 below); the underlying function can therefore be considered as robust.
In the following table data of the 7d standard test is given, including observed inhibitions of 7d frond number yield and effects as predicted by probit. The table also includes the dose-response curve for the variable 7d frond number yield derived from Toxrat and basic parameters like EC_{50} and slope.

Table A 2: Observed and probit calculated inhibitions of frond number yield for the constant exposure study (1st week of 6 weeks bioassay) of Bruns (2013b, M-464150-01-1)

7d-exposure concentration [µg/L]	Inhibition of yield [%]	
	observed	calculated according to probit function*
Control	-	-
0.20	26.4	36.9
0.40	56.3	53.8
0.80	82.2	83.1
1.60	87.4	99.6
3.20	90.7	100

*Parameters for predictions: Model: probit E_yC_{50} = 0.3554 µg/L Slope= 2.15596	

In Tables A 3 and A 4 data of the pulsed exposure studies are summarized including 7d twa-values calculated for each test level, inhibitions of frond number yield observed in the study and effects predicted based on the dose-response curve from the constant exposure study.

Table A 3: **Observed inhibitions of frond number yield in the pulsed exposure study of Bruns (2013a; M-462569-01-1) vs. results of a prediction based on 7d-twa concentrations and probit function from the 7d constant exposure study of Bruns (2003b, M-464150-01-1).**

Tested 1-day peak concentration [µg/L]	Calculated equivalent 7d-twa concentration* [µg/L]	Inhibition of yield [%]	
		as experimentally observed in the peak-exposure study	as predicted for an equivalent 7d-twa concentration based on probit function of the 7 day constant exposure study data
Control	-	-	-
0.5	0.071	-2.2	6.7
1.1	0.157	14.8	22.2
2.42	0.346	39.6	49.0
5.32	0.760	52.1	76.2
11.7	1.671	51.8	92.6
25.8	3.686	58.5	98.6
56.7	8.100	63.2	99.8

* as evaluation can be based on nominal values for the present study, 7 day TWA = 1 day peak concentration / 7.

Table A 4: **Observed inhibitions of frond number yield in the pulsed exposure study of Kuhl (2016; M-572386-03-1) vs. results of a prediction based on 7d-twa concentrations and probit function from the 7d constant exposure study of Bruns (2003b, M-464150-01-1).**

Tested 2-day peak concentration* [µg/L]	Calculated equivalent 7d-twa concentration** [µg/L]	Inhibition of yield [%]	
		as experimentally observed in the peak-exposure study	as predicted for an equivalent 7d-twa concentration based on probit function of the 7 day constant exposure study data
Control	-	-	-
1.3	0.371	41.2	51.6
3.24	0.926	63.8	81.5
8.06	2.303	73.5	96.0

20.1	5.743	78.5	99.5
50.0	14.286	85.3	100.0

* exposure to two peaks on day 0 and day 3 combined here to one 2d peak
** as evaluation can be based on nominal values for the present study, 7 day TWA = 2 day peak concentration / 3.5

Figures A 7 and A 8 display the comparison of measured effects of pulsed exposure vs. effects predicted for these pulses based on 7d-twa values (see explanations under point "Alternative approach for proving conservatism of TWA"). As can be seen the effects directly observed in the pulsed exposure experiments are all smaller than those predicted from the constant exposure study (data points right to the dashed line). Accordingly, the use of TWA is conservative and protective for effects of foramsulfuron on *Lemna*.

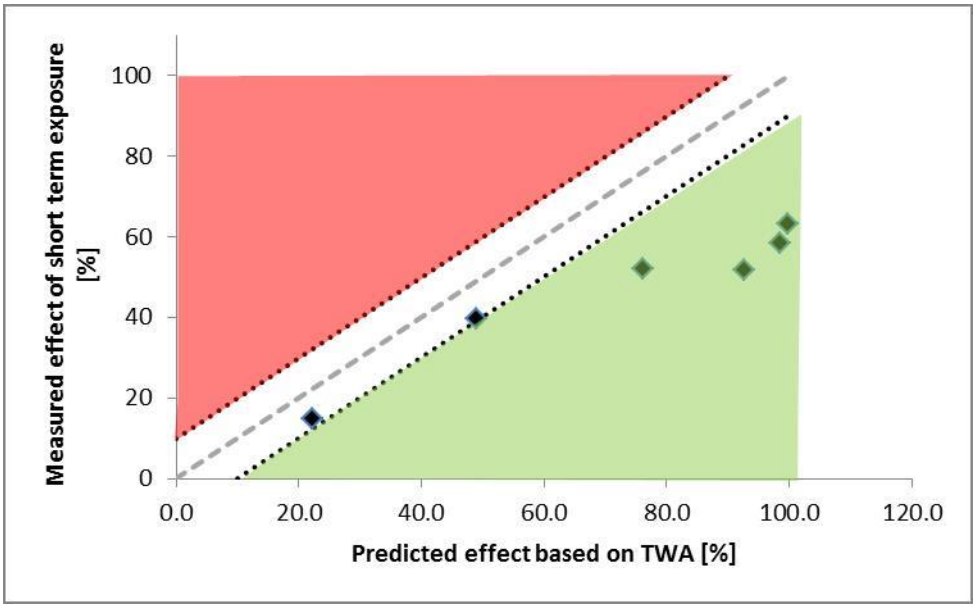


Figure A 7: **Comparison of predicted and observed inhibitions for foramsulfuron based on 7d-twa values; <u>1d peak results</u>**

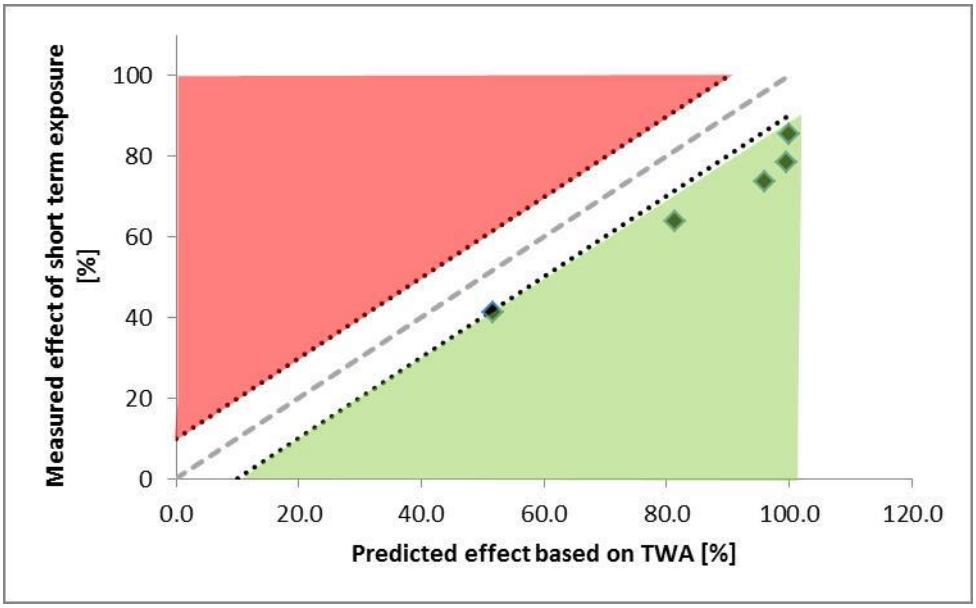


Figure A 8: **Comparison of predicted and observed inhibitions for foramsulfuron based on 7d-twa values; <u>2d peak results</u>**

Conclusions:

The applicability of $PEC_{sw,twa}$ in the chronic risk assessment for *Lemna gibba* and foramsulfuron was investigated by using two different approaches: the analysis according to the EFSA AGD and the direct proof of conservatism of TWA. As an overall conclusion, it is considered justified to base the risk assessment for *Lemna gibba* and foramsulfuron on 7d time-weighted average concentrations ($PEC_{sw, 7d\text{-}twa}$).

A 3.2 Detailed information to Section 9.5.2.5: Tier 2C: Higher-tier assessment based on refined exposure testing combined with exposure pattern analysis

Additional information on extraction and characterisation of exposure patterns from the FOCUSsw simulations:

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.

A 3.3 Detailed information to Section 9.5.2.6: Tier 2C: Higher-tier assessment based on refined exposure testing combined with exposure pattern analysis - considering multi-year exposure simulations

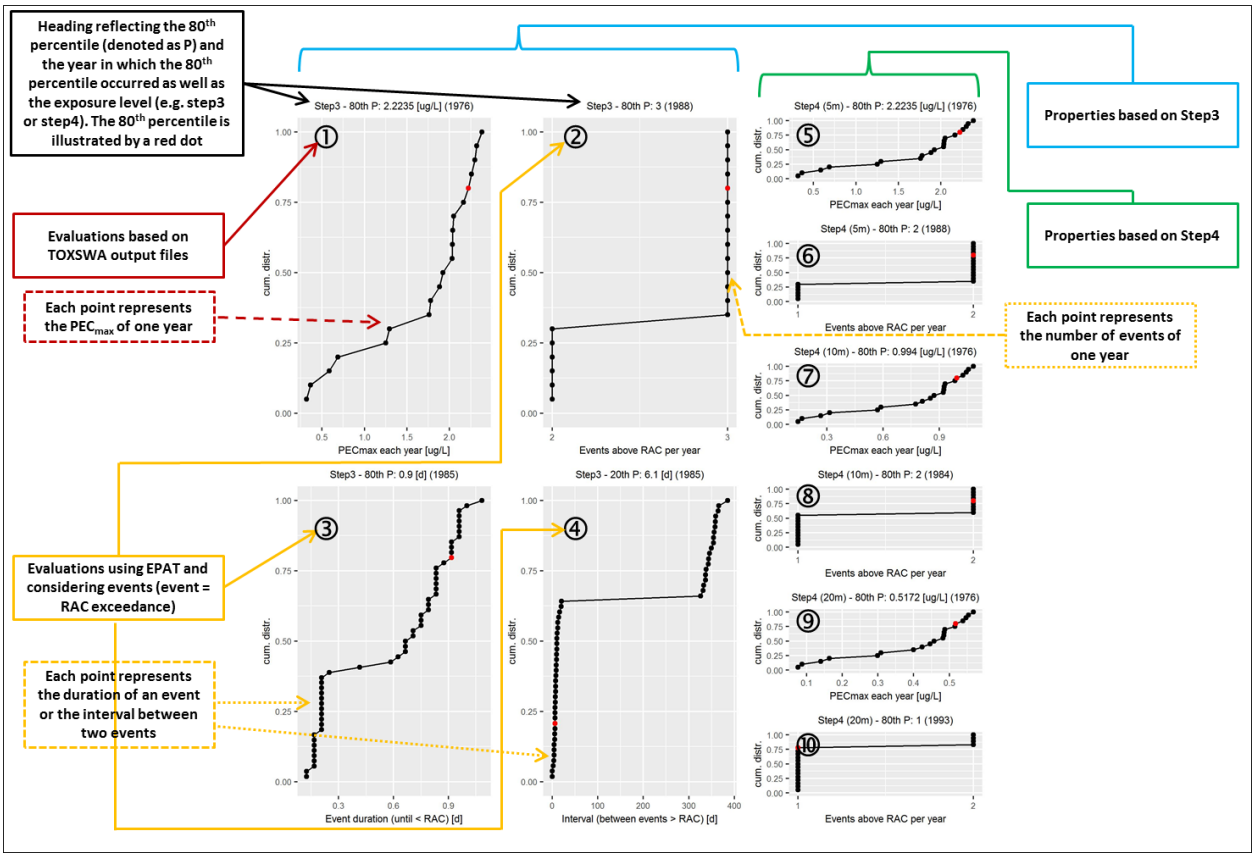
In response to concerns over the representativeness of the FOCUS model's inherent single weather year in the context of refined exposure assessment, additional FOCUS exposure simulations have been conducted for an extended period of 20 years (multi-year calculations). For information on the methodology applied, reference is made to the PEC_{sw} FOCUS Multiyear methodology and application reports (Bolekhan A., 2017; M-602115-01-1, Heine et al., 2017; M-592861-02-1 for foramsulfuron and its metabolite AE F130619, and Heine et al., 2017; M-592862- 01-1 for thiencarbazone-methyl), and their corresponding summaries in the E-fate section to this dRR.

As it is not possible to easily judge which of the resulting twenty annual exposure patterns per scenario water body should be considered the relevant one for macrophyte risk assessment, the characterizing properties (i.e. PEC_{max}, number of peak events, duration of peaks events, and interval between events) of each simulated year have been assessed separately: For each FOCUS scenario ten cumulative distribution figures were generated (explained example see Figure A 9 below), illustrating the statistic of properties of the multiyear simulated exposure patterns. These were then used to synthesize a single surrogate exposure pattern for ecotoxicological risk assessment that describes a realistic worst-case annual exposure situation, by combining the 80th percentile $PEC_{sw,max}$, the 80th percentile number of events and the 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 into a single representative 90th percentile worst case exposure pattern usable for conservative risk assessment. This is in accordance with the current concepts of EFSA for groundwater (EFSA, 2013) and soil risk assessment (EFSA, 2016). Since however there exists no EU agreed analysis of percentiles for multi-year FOCUS PECsw calculations so far, a detailed rationale for the above percentile selections, and including vulnerability analysis, is provided in the original modelling report (sections 4.3.1 and 4.3.2).

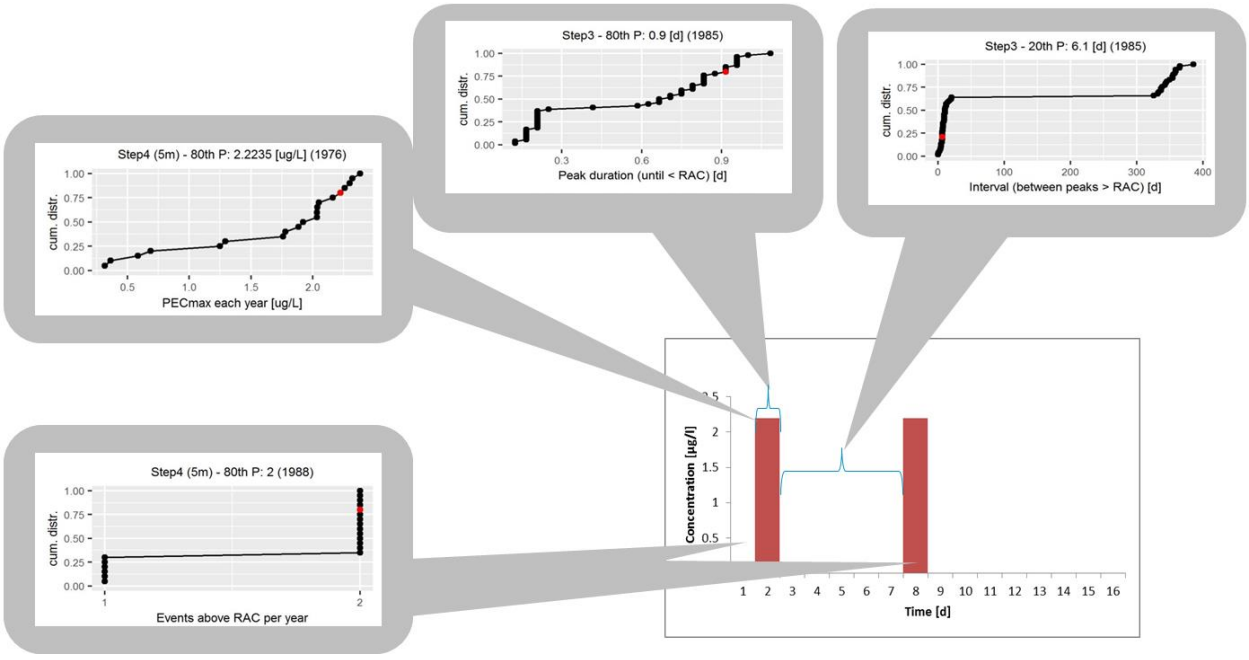
For risk assessment, the so generated conservative surrogate exposure pattern is then compared to the experimental results of a refined exposure study (2 peaks test, with 2 different time intervals, see A 2.2.1.4), in analogy to the Tier 2C risk assessment presented before for the standard FOCUS year.

Where necessary to pass a risk assessment, PEC_{max} and the number of peak events (i.e. concentrations above the RAC) can also be analysed at Step 4 (with 5 m, 10 m and 20 m buffer): In the illustrated example (Figure A 9), 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.
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.

Figure A 9: 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 9 – Step 3	2.2235	3 peaks	0.9	6.1
Example from Figure A 9 – 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.

A 3.3.1 Foramsulfuron

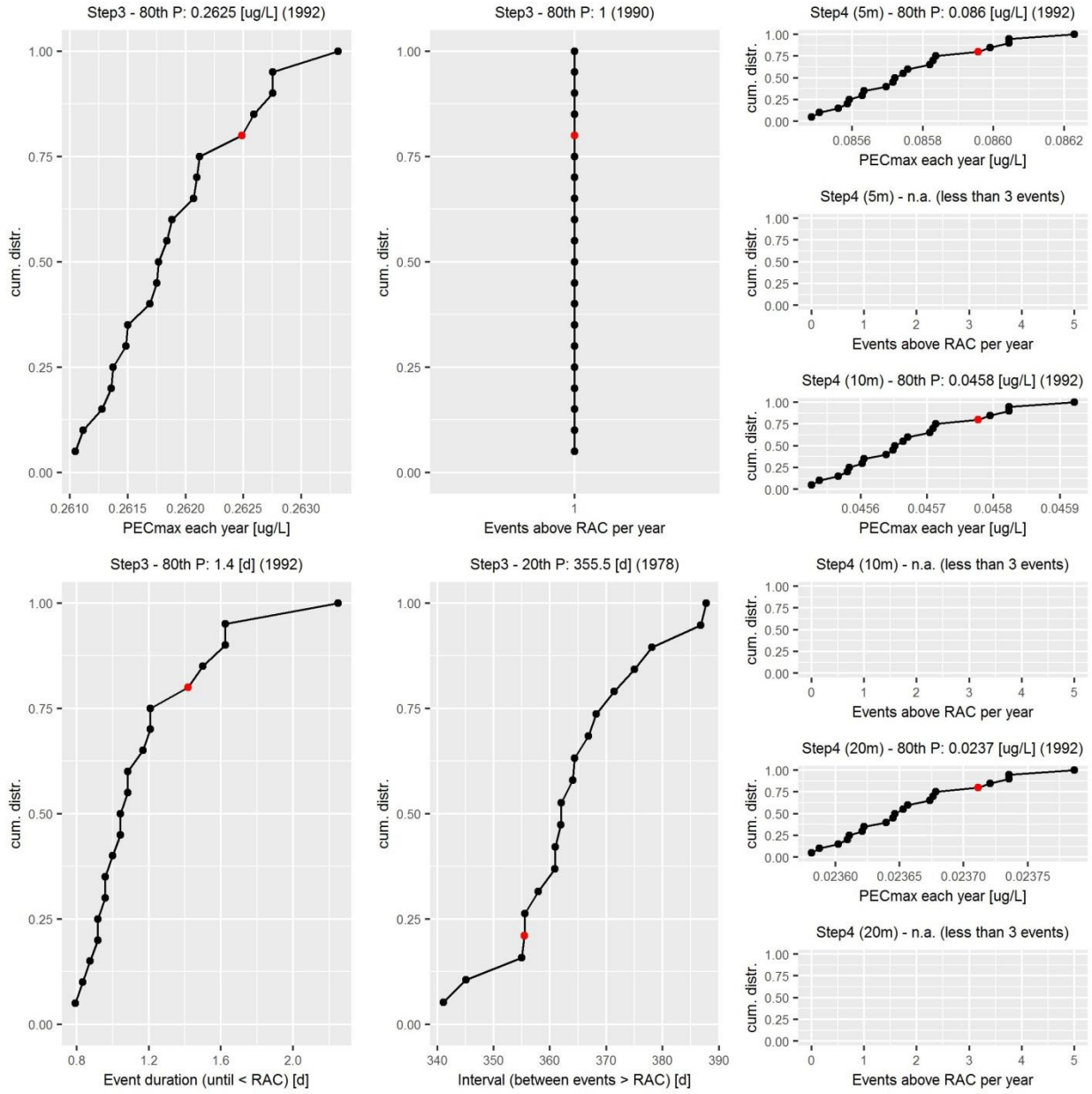
Detailed explanations on the design and the results of the refined exposure study with foramsulfuron and *Lemna gibba* are given under point 9.5.2.5 (Tier 2C risk assessment for the FOCUS year). The following table again summarizes the results of the study as they are needed for comparison with the FOCUS multi-year simulations below.

Table A 5: Derivation of peak-RACs from the *Lemna* 2-peak study with foramsulfuron

Test species	Test system	Test duration	Endpoint [µg as/L]		Peak-RAC [µg as/L]	Reference
Lemna gibba (duck weed)	growth inhibition, 2-peak exposure	Design 1: 7 d , peaks on d0 & d3	E_rC_{50} (days 0-7)	9.60 µg/L	0.96 µg/L	Kuhl, 2016 EBFS0001 M-572386-03-1
		Design 2: 14 d , peaks on d0 & d7	E_rC_{50} (days 0-7)	> 50.0 µg/L	> 5.0 µg/L	
			E_rC_{50} (days 7-14)	> 50.0 µg/L	> 5.0 µg/L	

Risk assessment:

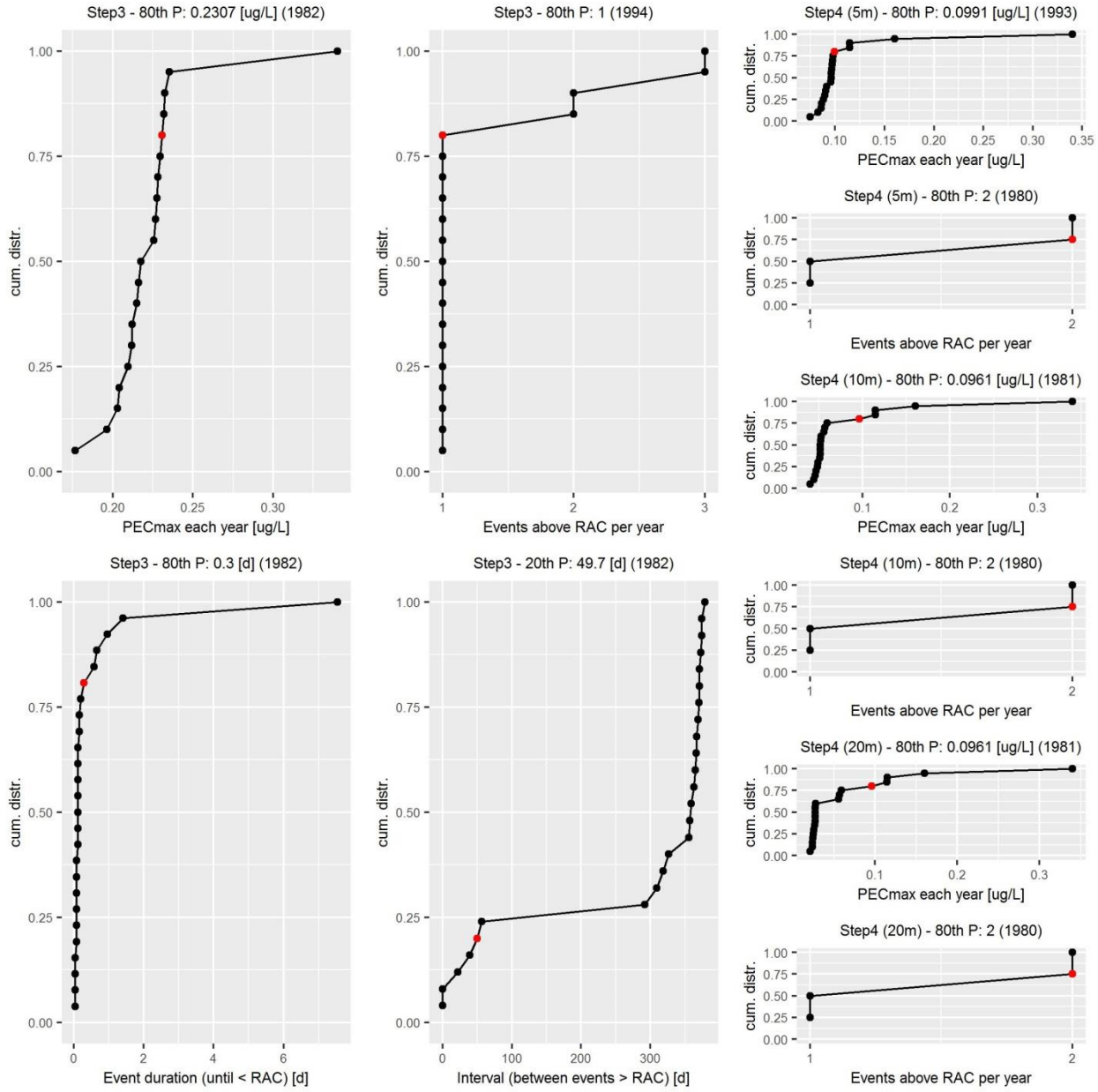
use group B – FOCUS multiyear Scenario D3 ditch:
(use on sugar beet / **rate = 1 × 50 g/ha FSN)**



The 80th percentiles of the peak height, duration and number of peaks at step 3 show that 1 peak is expected at a maximum of 0.2625 µg/L for a duration of 1.4 days. These results have to be compared to the peak-RAC of > 5.0 µg/L for a single peak. Since the PEC is much lower than the RAC, the slightly longer predicted exposure (1.4 days) compared to the exposure in the underlying Lemna study (1.0 days) should be covered. Thus, it can be concluded that the risk is acceptable in these conservative conditions of a 20 years FOCUS simulation.

Consequently, the risk to aquatic macrophytes arising from this multiyear pattern is considered to be low, with a resulting RQ of < 0.053.

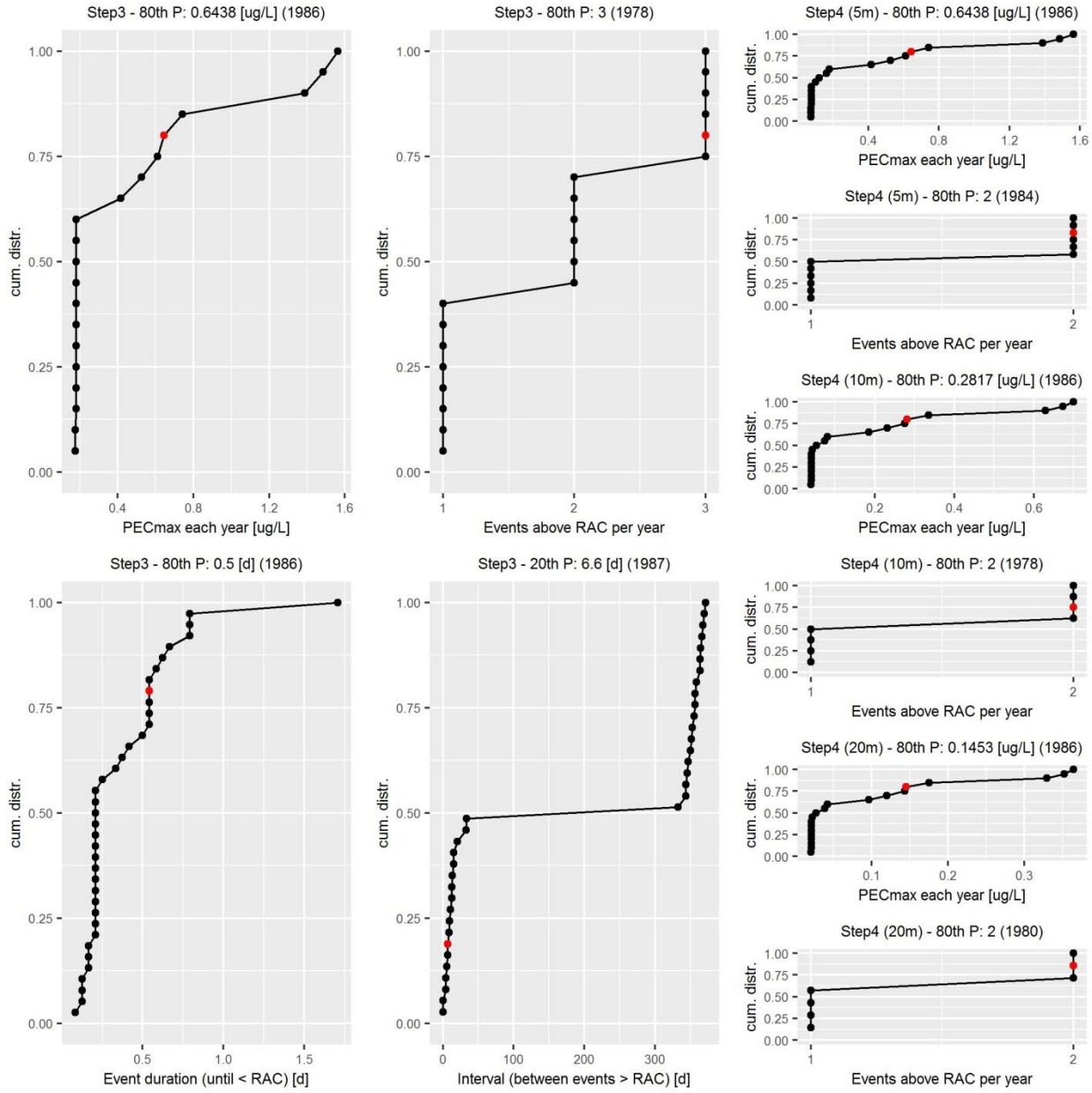
use group B – FOCUS multiyear Scenario D4 stream:
(use on sugar beet / **rate = 1 × 50 g/ha FSN)**



The 80th percentiles of the peak height, duration and number of peaks at step 3 show that 1 peak is expected at a maximum of 0.2307 µg/L for a duration of 0.3 days. These results have to be compared to the peak-RAC of > 5.0 µg/L for a single peak. The PEC is lower than the RAC so it can be concluded that the risk is considered acceptable in these conservative conditions of a 20 years FOCUS simulation.

Consequently, the risk to aquatic macrophytes arising from this multiyear pattern is considered to be low, with a resulting RQ of < 0.046.

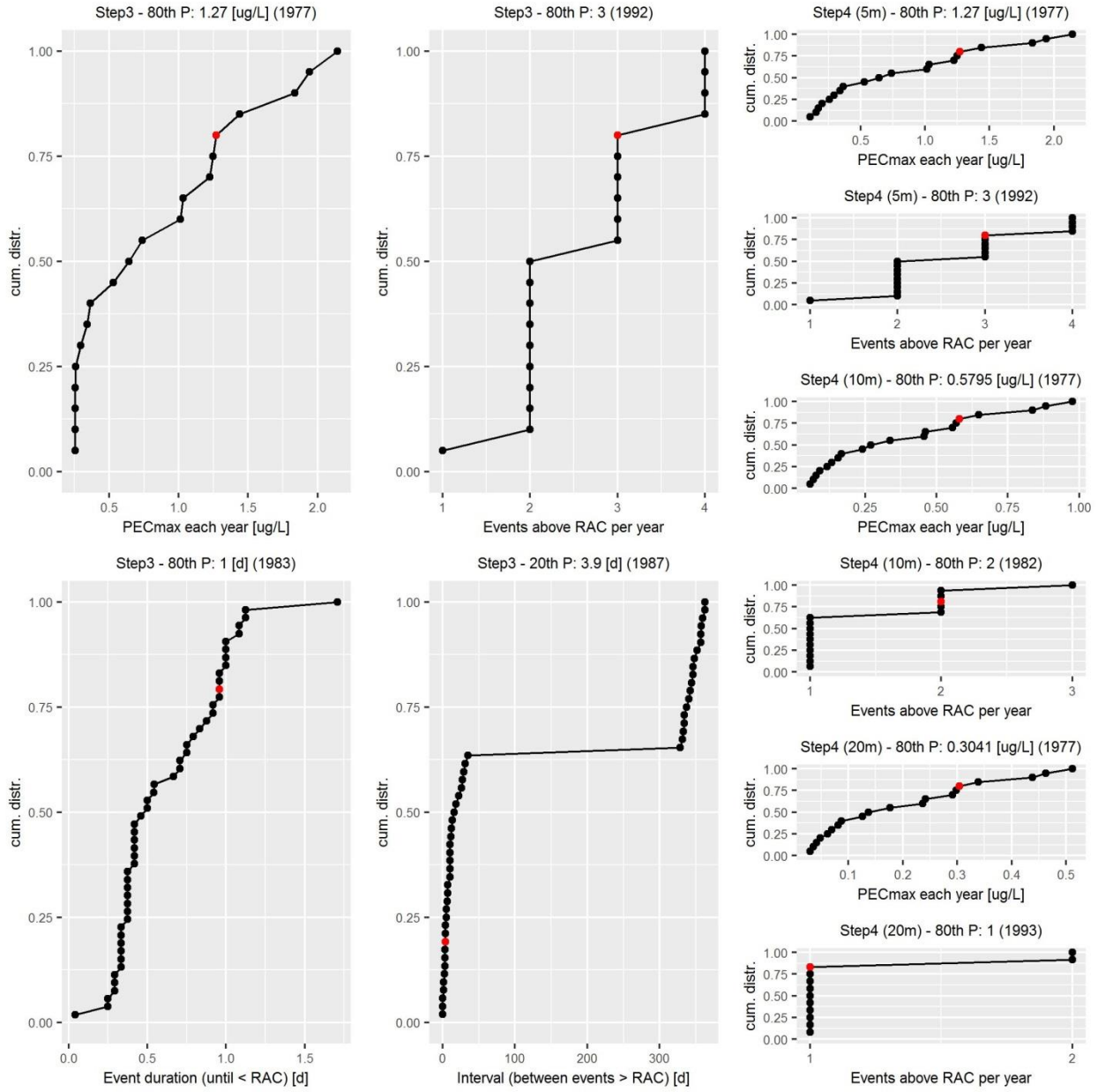
use group B – FOCUS multiyear Scenario R1 stream:
(use on sugar beet / **rate = 1 × 50 g/ha FSN)**



The 80th percentiles of the peak height, duration and number of peaks and the 20th percentile of the interval between peaks at step 3 show that 3 peaks are expected at a maximum of 0.6438 µg/L for a duration of 0.5 days and an interval of 6.6 days between the peaks. Since the interval between the peaks is close to 7 days, this result has to be compared to the peak-RAC of > 5.0 µg/L for independent peak events. The PEC is lower than the RAC so it can be concluded that the risk is considered acceptable in these conservative conditions of a 20 years FOCUS simulation.

Consequently, the risk to aquatic macrophytes arising from this multiyear pattern is considered to be low, with a resulting RQ of < 0.13.

use group B – FOCUS multiyear Scenario R3 stream:
(use on sugar beet / **rate = 1 × 50 g/ha FSN)**

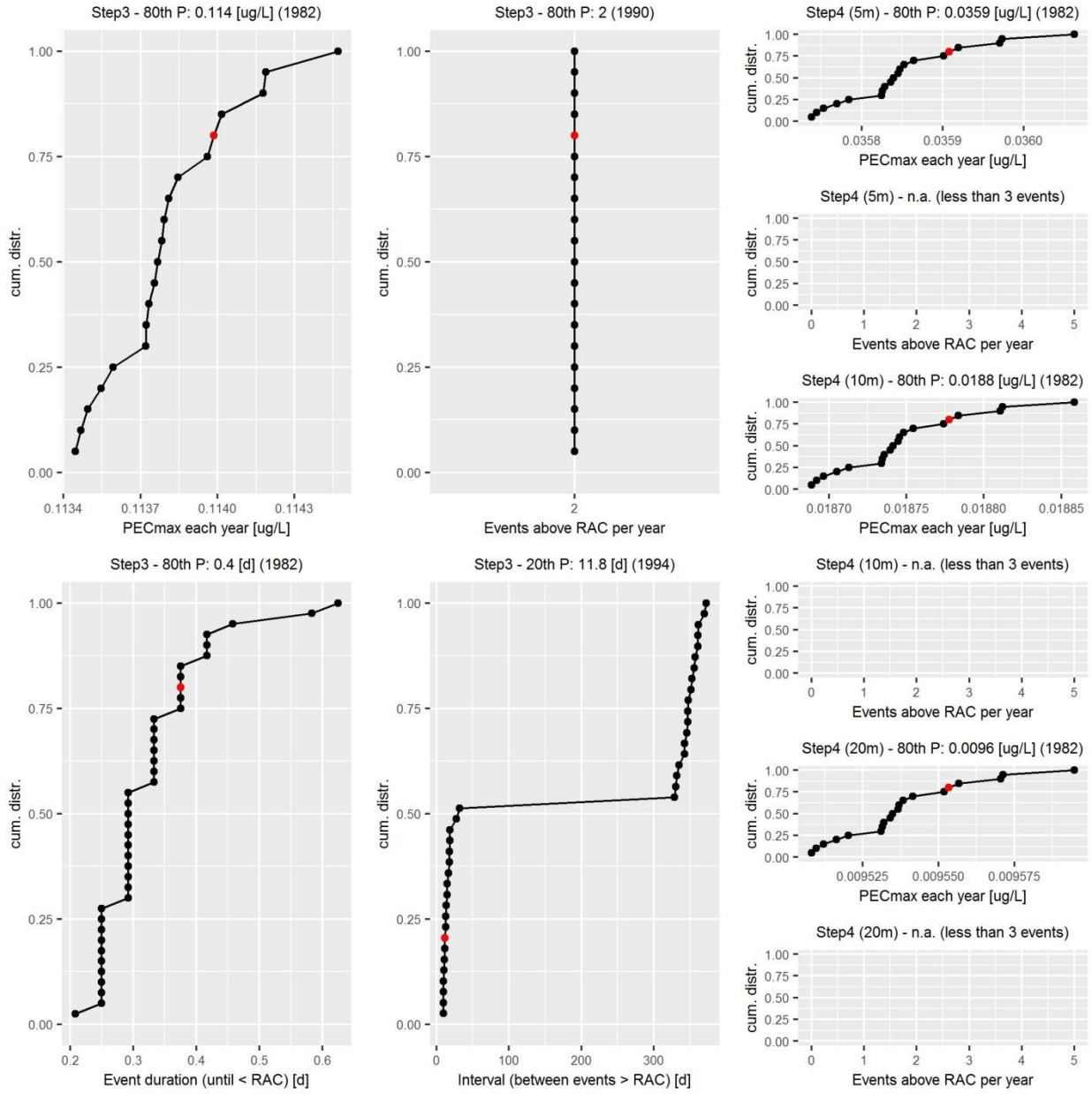


The 80th percentiles of the peak height, duration and number of peaks and the 20th percentile of the interval between peaks at step 3 show that 3 peaks are expected at a maximum of 1.27 µg/L for a duration of 1.0 days and an interval of 3.9 days between the peaks. Since 3 dependent peaks were not directly tested in the underlying refined exposure experiment, 10 m buffer have to be considered which reduces the number of peaks to 2 (see small graphs above). This result has to be compared to the peak-RAC of 0.96 µg/L for two peak events with short interval. The PEC is lower than the RAC so it can be concluded that the risk is considered acceptable in these conservative conditions of a 20 years FOCUS simulation.

Consequently, the risk to aquatic macrophytes arising from this multiyear pattern is considered to be low, with a resulting RQ of 0.60.

*****

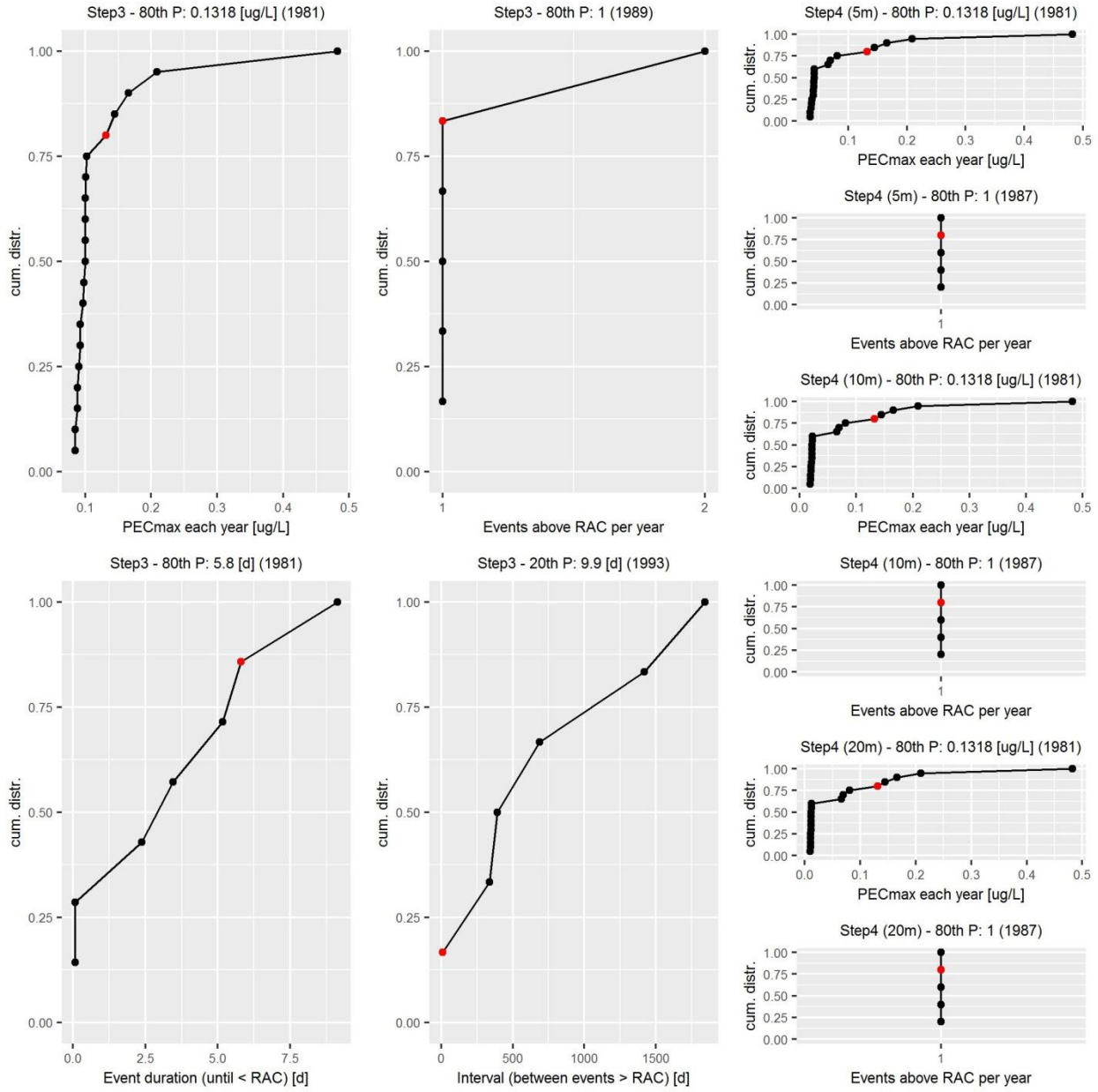
use group C – FOCUS multiyear Scenario D3 ditch:
(use on sugar beet **/ rate = 2 × 25 g/ha FSN)**



The 80th percentiles of the peak height, duration and number of peaks and the 20th percentile of the interval between the peaks at step 3 show that 2 peaks are expected at a maximum of 0.1140 µg/L for a duration of 0.4 days and an interval of 11.8 days between the peaks. These results have to be compared to the peak-RAC of > 5.0 µg/L for two peak events with longer interval. The PEC is lower than the RAC so it can be concluded that the risk is considered acceptable in these conservative conditions of a 20 years FOCUS simulation.

Consequently, the risk to aquatic macrophytes arising from this multiyear pattern is considered to be low, with a resulting RQ of < 0.023.

use group C – FOCUS multiyear Scenario D4 stream:
(use on sugar beet / **rate = 2 × 25 g/ha FSN)**



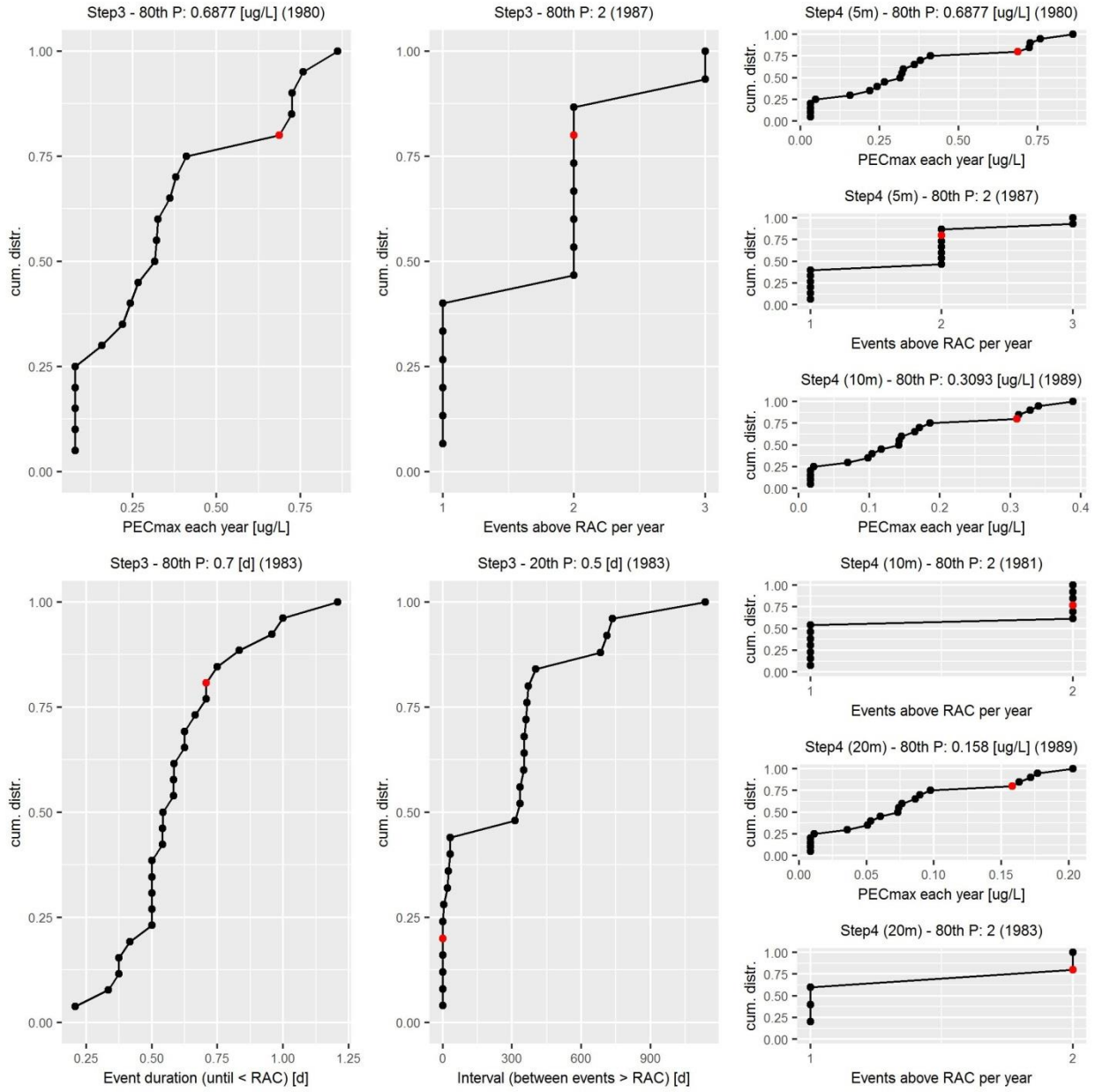
At Step 3 and at Step 4 level, the representative worst-case pattern (i.e. combination of 80th/20th percentiles) of the FOCUS multi-year calculations for D4 (stream) consists of 1 single peak per year that has a concentration of 0.1318 µg a.s./L irrespective of the buffer width applied. The peak duration is calculated to be 5.8 days which makes it impossible to address the multi-year pattern by either of the peak studies where the peak exposure did not last longer than 1 day.

However, the PEC_{max} of 0.1318 µg a.s./L is only slightly above the tier-1 RAC = 0.101 µg a.s./L which is derived from the standard Lemna study conducted under constant exposure conditions for 7 days. It is therefore reasonable to assume that the risk to aquatic macrophytes arising from a peak with a slightly higher concentration, but a shorter duration is covered by the Lemna tier-1 study. Additional information should be considered that supports this conclusion:

a) Lemna is the most sensitive species based on the evaluation of a large dataset for foramsulfuron containing 12 different aquatic plant species in total (cf. EFSA Conclusion and Justification for the reduction of the Assessment Factor).

b) in the *Lemna* tier-1 study (Christ & Ruff, 1998; M-147891-02-1) the LOEC for growth rate inhibition of frond number was 0.6 µg a.s./L. In all concentrations lower than 0.6 µg a.s./L (including the test concentration 0.13 µg a.s./L which equals the PEC_{max} of the representative worst-case pattern) effects on growth rate ranged between 2 and 4% and no sign of phytotoxicity was observed.
c) in a recovery study that was evaluated in the AIR process (Dorgerloh, 2005; M-250268-01-1) *Lemna* was exposed to foramsulfuron (a.s.) for 7 days followed by a 14-day period in clean medium. After the exposure to the test item had ended on d7, the growth rates for frond number and total frond area fully recovered for all test levels (up to the highest test concentration of 20 µg a.s./L) within the first phase of the recovery period (study day 7-14).
Applying an assessment factor of 10 to this study the RAC of 2.0 µg a.s./L could be used in risk assessments that allows stronger effects than 50% (up to 85.1% effect on growth rate at 20 µg a.s./L on d7 of the exposure period) which are able to recover within a week after the exposure has ended.
The PEC_{max} of 0.1318 µg a.s./L is considerably lower than this recovery-RAC of 2.0 µg a.s./L.
In conclusion, no unacceptable risk to aquatic macrophytes is expected and no buffer zones are considered to be necessary.

use group C – FOCUS multiyear Scenario R1 stream:
(use on sugar beet / **rate = 2 × 25 g/ha FSN)**



Detailed results of the exposure pattern analysis for scenario R1 (stream), 2 x 25 g/ha and the properties duration of and interval between peak events at Step 3 level

	Originally reported events		Combined events	
Year of the event	**Duration [days]**	**Interval [days]**	**Combined Duration [days]**	**Adapted Interval [days]**
1975	0.542	-	0.542	
1976a	0.75	313.417		
1976b	0.625	0.25	1.625	313.417
1978a	0.541	735.375		
1978b	0.5	0.459	1.5	735.375
1978c	1	19.5	1	19.5
1980a	0.583	711	0.583	711

1980b	0.5	4.417	0.5	4.417
1981a	0.958	352.5		
1981b	0.666	0.042	1.666	352.5
1982a	0.708	371.334	0.708	371.334
1982b	0.584	32.333	0.584	32.333
1983a	0.541	350.375		
1983b	0.708	0.459		
1983c	0.625	0.292	2.625	350.375
1984	0.583	360.375	0.583	360.375
1985	0.417	365.5	0.417	365.5
1986a	0.5	353.541	0.5	353.541
1986b	0.5	23.459	0.5	23.459
1987a	0.334	335.541	0.334	335.541
1987b	0.208	32.708	0.208	32.708
1989a	0.375	683.75		
1989b	0.375	0.625	1.375	683.75
1992	1.208	1137.584	1.208	1137.584
1993	0.5	335.833	0.5	335.833
1994	0.833	403.459	0.833	403.459
80th percentile	0.708		**1.375**	
20th percentile		0.459		**32.333**

At Step 3 level, the representative worst-case pattern (i.e. combination of 80th/20th percentiles) of the FOCUS multi-year calculations for R1 (stream) consists of 2 peaks per year with a concentration of 0.6877 µg a.s./L. The calculated 80th percentile for the peak duration is 0.7 days and the analysis for the 20th percentile of all multi-year values gave an interval of 0.5 days. This very short interval cannot be covered by any of the peak study designs available. Moreover, it would neither be feasible nor advisable to simulate such a pattern with regard to the number of transfers of *Lemna* fronds from treated to untreated medium and vice versa that would be necessary within a very short time period.

To address this issue through further refinement, all peak events that were derived from the exposure pattern analysis have been copied into the detailed table above (see left column "originally reported events") to allow for a case-by-case analysis. If a specific year is only given once (i.e. without a and b), not more than a single event occurred in that year. The figures in the columns with 'interval' always refer to the time span before an event with certain duration, e.g. 1982b: interval of 32.333 days between event with duration of 0.584 days (1982b) and earlier event with duration of 0.708 days (1982a).

It is obvious that some of the events have an extremely small interval, e.g. 0.042 days between the two peaks in 1981, and these could also be regarded as one large instead of two separate events. In order to establish a "Combined duration", events having a short interval in-between were merged with each other by summing up the duration of the single events and adding the interval on top.

With respect to the influence on the expected effect on aquatic plants this approach can be regarded as being on the worst-case side. The merging of events including their interval results in a calculated longer "constant exposure" and thereby eliminates the possibility of recovery that might have taken place in the "break" between the two or three peaks whereas the interval is now counted as additional exposure time.

After all events from the multi-year calculation had been combined (where appropriate), a revised 80th percentile duration and a revised 20th percentile interval have been calculated (see right column "Combined events") and are used in the following refined exposure assessment.

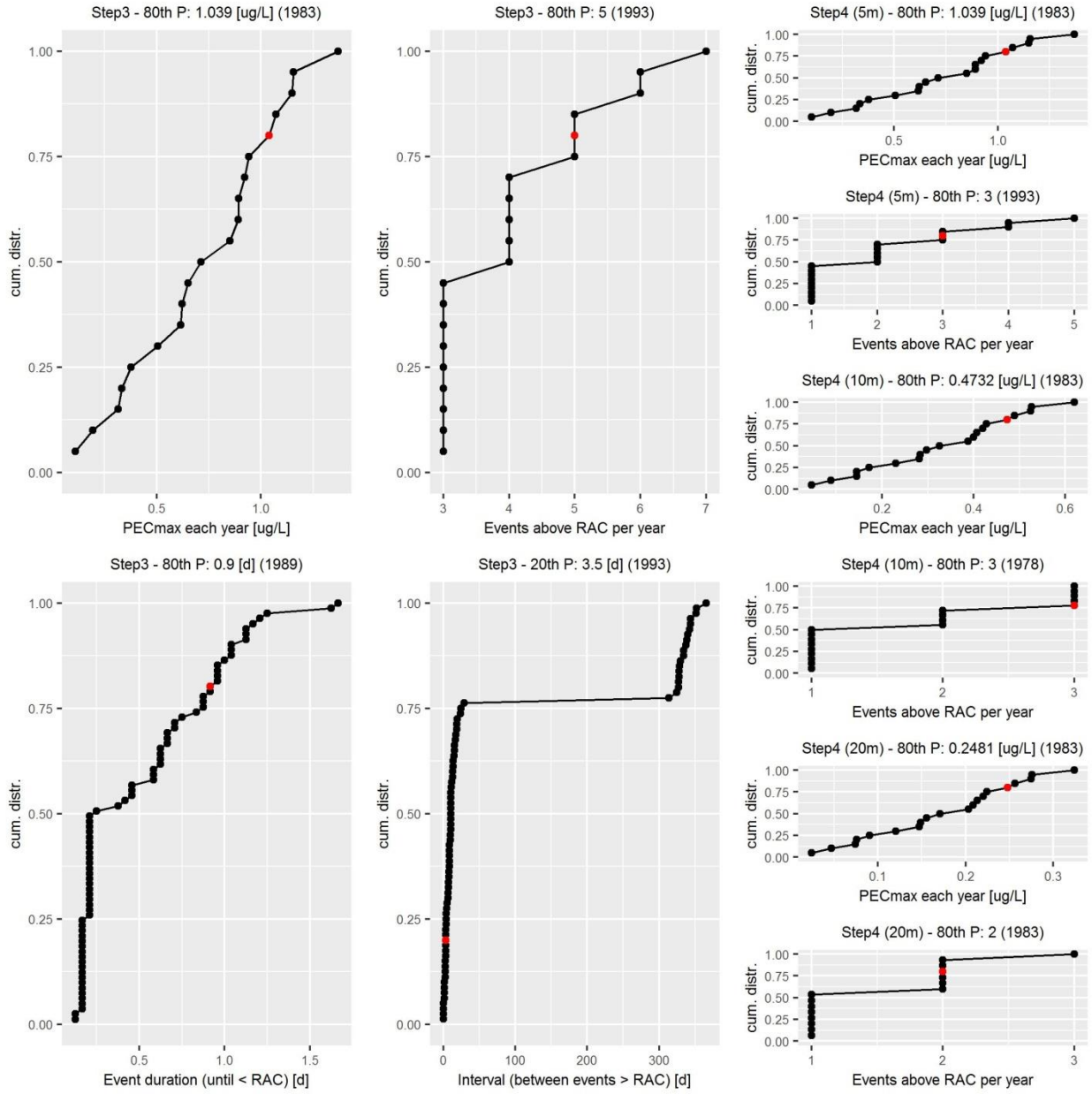
The further refined representative worst-case pattern of the FOCUS multi-year calculations for R1

(stream) at Step 3 level has an adapted interval of 32.333 days which allows for the use of peak study Design 2 (RAC > 5.0 µg a.s./L) for independent peaks that have in this case partly been merged. The combined duration of the peaks is 1.375 days which is slightly longer than the exposure of 1 day in the peak study. However, there is a margin of safety of a factor 7.3 between the RAC (already taking into account the assessment factor of 10) and the PEC_{max} value of 0.6877 µg a.s./L.

As an additional supporting element, it should be considered that in the *Lemna* recovery study (Dorgerloh, 2005; M-250268-01-1) the growth rates for frond number and total frond area fully recovered up to the highest test concentration of 20 µg a.s./L within the first week after the exposure to foramsulfuron had ended. Applying an assessment factor of 10 to this study the RAC of 2.0 µg a.s./L could be used in a refined risk assessment that includes recovery but is also built on worst-case conditions, i.e. an exposure period of 7 days (recovery study) vs. 1.375 days (multi-year exposure calculation) and an interval needed for *Lemna* recovery of 7 days (recovery study) vs. an interval available of 32.333 days between peaks (multi-year exposure calculation).

In conclusion, the risk to aquatic macrophytes is considered to be low and no risk mitigation measures have to be applied.

use group C – FOCUS multiyear Scenario R3 stream:
(use on sugar beet / **rate = 2 × 25 g/ha FSN)**



The 80th percentiles of the peak height, duration and number of peaks and the 20th percentile of the interval between peaks at step 3 show that 5 peaks are expected at a maximum of 1.039 µg/L for a duration of 0.9 days and an interval of 3.5 days between the peaks. Since 5 dependent peaks were not directly tested in the underlying refined exposure experiment, 20 m buffer have to be considered which reduces the number of peaks to 2 and also reduces the PEC to 0.2481 µg/L (see small graphs above). This result has to be compared to the peak-RAC of 0.96 µg/L for two peak events with short interval. The PEC is lower than the RAC so it can be concluded that the risk is considered acceptable in these conservative conditions of a 20 years FOCUS simulation.

Consequently, the risk to aquatic macrophytes arising from this multiyear pattern is considered to be low, with a resulting RQ of 0.26.

A 3.3.2 Thiencarbazone-methyl

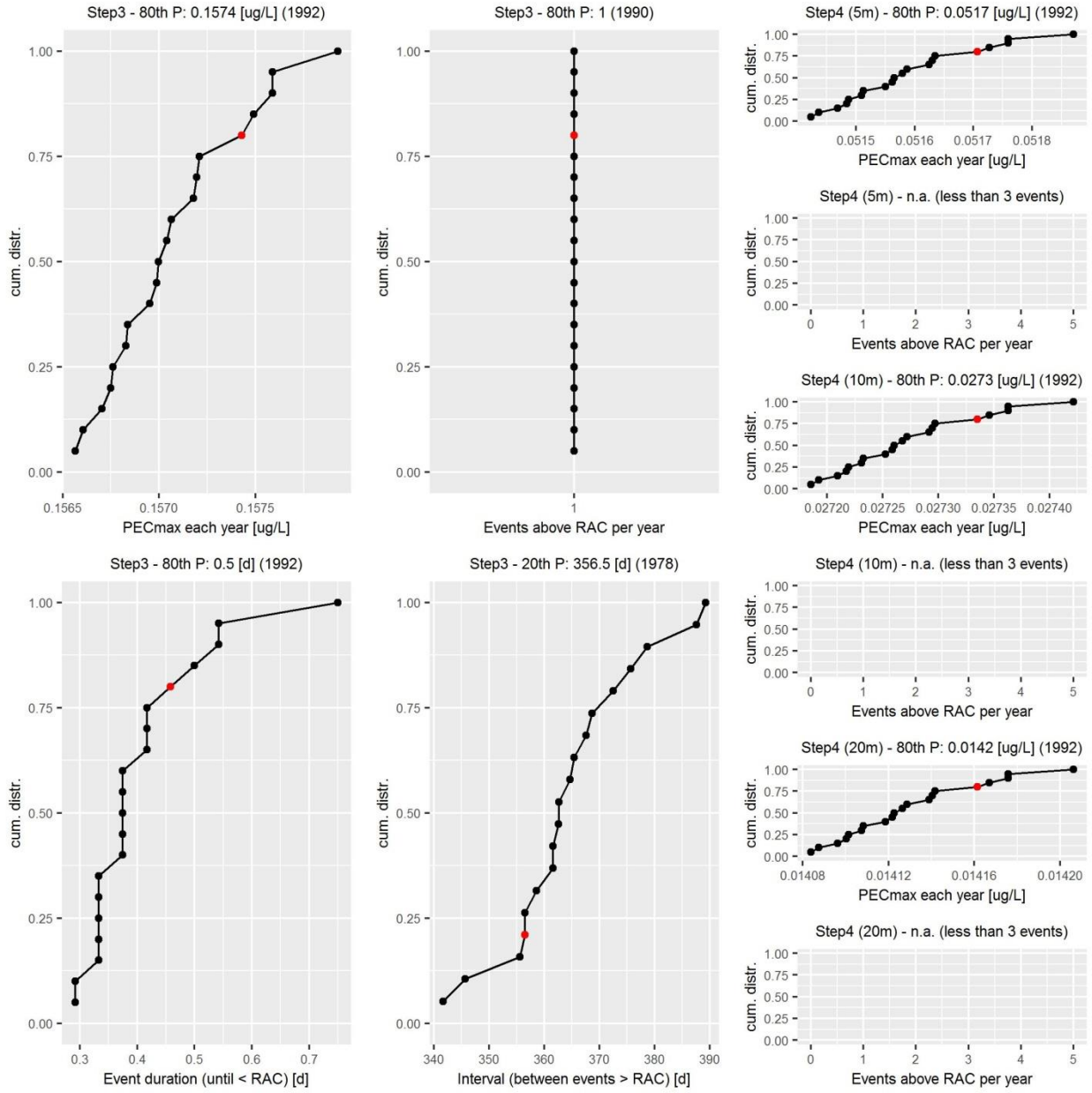
Detailed explanations on the design and the results of the refined exposure study with thiencarbazone-methyl and *Lemna gibba* are given under point 9.5.2.5 (Tier 2C risk assessment for the FOCUS year). The following table again summarizes the results of the study as they are needed for comparison with the FOCUS multi-year simulations below.

Table A 6: Derivation of peak-RACs from the *Lemna* 2-peak study with thiencarbazone-methyl

Test species	Test system	Test duration	Endpoint [µg as/L]		Peak-RAC [µg as/L]	Reference
Lemna gibba (duck weed)	growth inhibition, 2-peak exposure	Design 1: 7 d , peaks on d0 & d3	E_rC_{50} (days 0-7)	3.10 µg/L	0.31 µg/L	Kuhl, 2016 EBGS0002 M-568404-02-1
		Design 2: 14 d , peaks on d0 & d7	E_rC_{50} (days 0-7)	15.7 µg/L	1.57 µg/L	
			E_rC_{50} (days 7-14)	12.8 µg/L	1.28 µg/L	

Risk assessment:

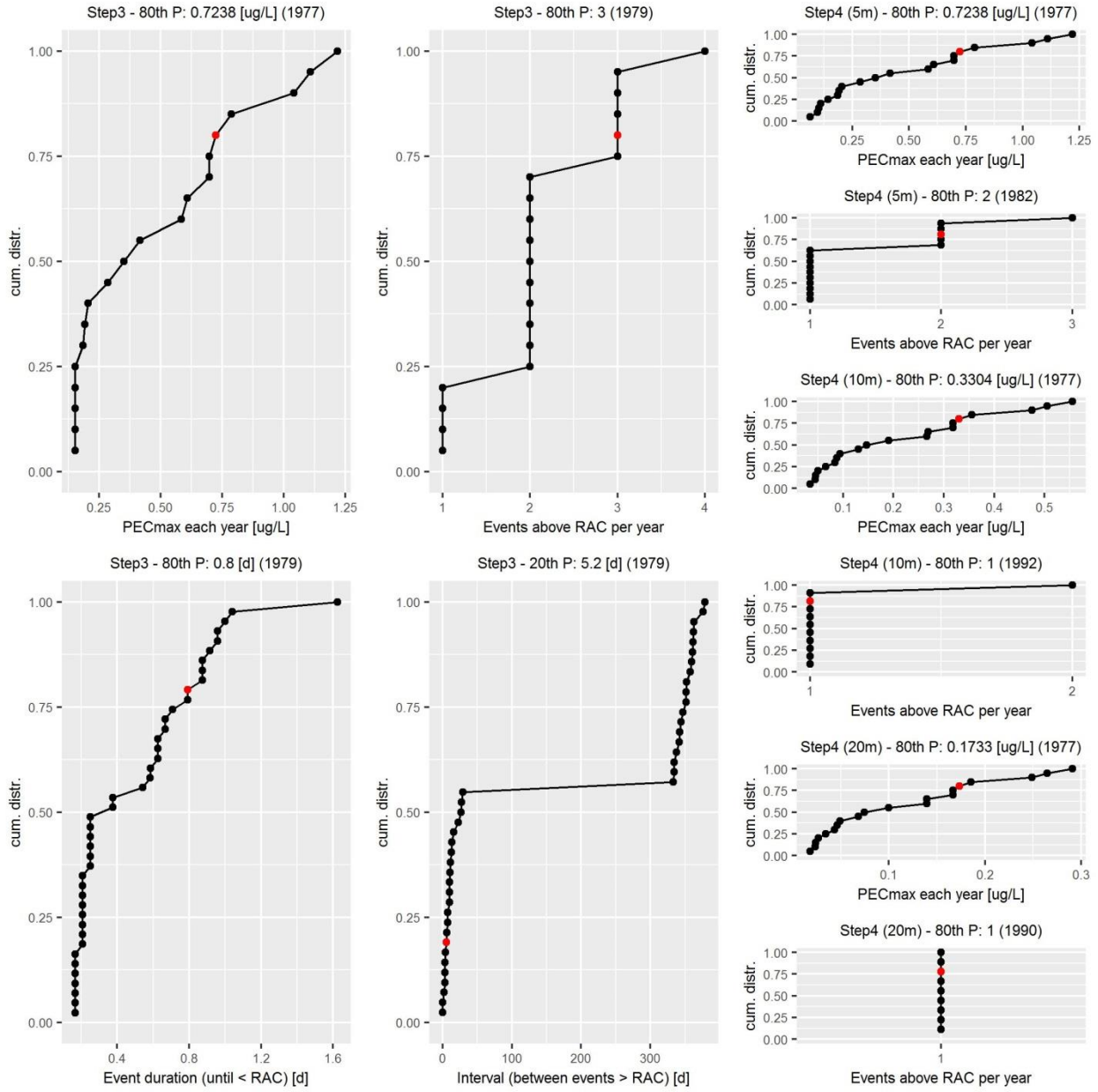
use group B – FOCUS multiyear Scenario D3 ditch:
(use on sugar beet / **rate = 1 × 30 g/ha TCM)**



The 80th percentiles of the peak height, duration and number of peaks at step 3 show that 1 peak is expected at a maximum of 0.1574 µg/L for a duration of 0.5 days. These results have to be compared to the peak-RAC of 1.57 µg/L for a single peak. The PEC is lower than the RAC so it can be concluded that the risk is considered acceptable in these conservative conditions of a 20 years FOCUS simulation.

Consequently, the risk to aquatic macrophytes arising from this multiyear pattern is considered to be low, with a resulting RQ of 0.1.

use group B – FOCUS multiyear Scenario R3 stream:
(use on sugar beet / **rate = 1 × 30 g/ha TCM)**

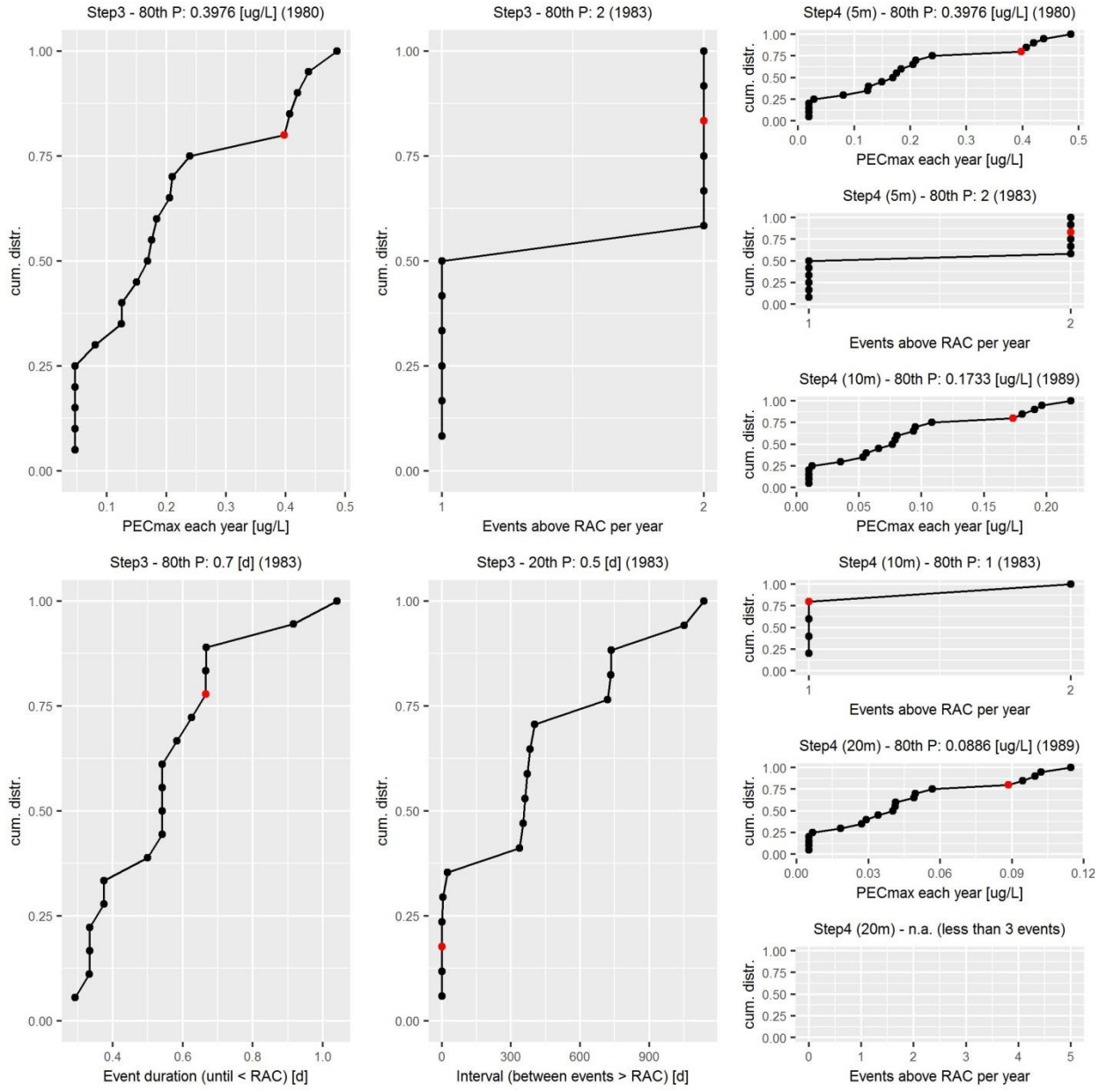


The 80th percentiles of the peak height, duration and number of peaks and the 20th percentile of the interval between peaks at step 3 show that 3 peaks are expected at a maximum of 0.7238 µg/L for a duration of 0.8 days and an interval of 5.2 days between the peaks. Since 3 dependent peaks were not tested in the underlying refined exposure experiment, 10 m buffer have to be considered which reduces the number of peaks to 1 and also lowers the PEC (see small graphs above). These results have to be compared to the peak-RAC of 1.57 µg/L for a single peak. The PEC is lower than the RAC so it can be concluded that the risk is considered acceptable in these conservative conditions of a 20 years FOCUS simulation.

Consequently, the risk to aquatic macrophytes arising from this multiyear pattern is considered to be low, with a resulting RQ of 0.21.

*****

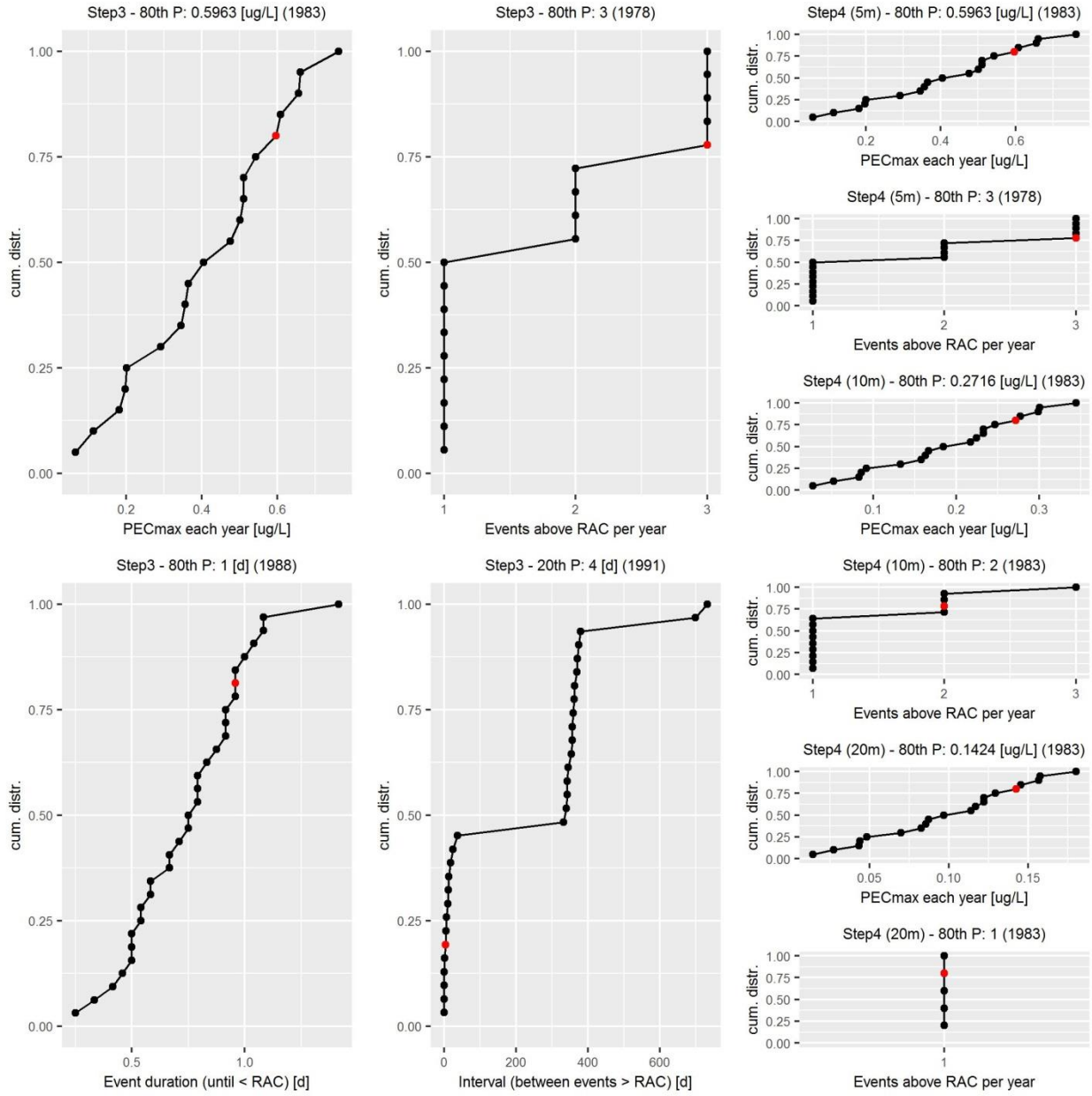
use group C – FOCUS multiyear Scenario R1 stream:
(use on sugar beet / **rate = 2 × 15 g/ha TCM)**



The 80th percentiles of the peak height, duration and number of peaks and the 20th percentile of the interval between the peaks at step 3 show that 2 peaks are expected at a maximum of 0.3976 µg/L for a duration of 0.7 days and an interval of 0.5 days between the peaks. Since this short interval is not covered by the underlying refined exposure study (minimum of 3 days between tested peaks), a 10 m buffer has to be considered which reduces the number of peaks to 1 and also lowers the PEC. These results have to be compared to the peak-RAC of 1.57 µg/L for a single peak. The PEC is lower than the RAC so it can be concluded that the risk is considered acceptable in these conservative conditions of a 20 years FOCUS simulation.

Consequently, the risk to aquatic macrophytes arising from this multiyear pattern is considered to be low, with a resulting RQ of 0.11.

use group C – FOCUS multiyear Scenario R3 stream:
(use on sugar beet / **rate = 2 × 15 g/ha TCM)**



The 80th percentiles of the peak height, duration and number of peaks and the 20th percentile of the interval between peaks at step 3 show that 3 peaks are expected at a maximum of 0.5963 µg/L for a duration of 1.0 days and an interval of 4.0 days between the peaks. Since 3 dependent peaks were not directly tested in the underlying refined exposure experiment, 10 m buffer have to be considered which reduces the number of peaks to 2 (see small graphs above). This result has to be compared to the peak-RAC of 0.31 µg/L for two peak events with short interval. The PEC is lower than the RAC so it can be concluded that the risk is considered acceptable in these conservative conditions of a 20 years FOCUS simulation.

Consequently, the risk to aquatic macrophytes arising from this multiyear pattern is considered to be low, with a resulting RQ of 0.88.

Overall conclusion:
The above assessments based on multiyear simulations confirmed the conclusion of acceptable risk for macrophytes previously made for the standard FOCUS year.

A 3.4 Detailed information to Section 9.5.2.7: Ecological modelling approaches, and their use in higher-tier risk assessment for the present product

(a) Lemna TK/TD population model - General description

The classical tier 1 macrophyte risk assessment tends to overestimate the impact of time variable and in particular short-term exposure patterns, since only the PECmax and the EC_{50} from toxicological tests with constant concentration over long periods are used for the risk characterization. To increase the realism of risk characterization, different approaches are available (Figure A 10) in the Aquatic Guidance Document. One of the recommendations by EFSA is the use of TK/TD models. For Lemna, as the Tier-1 data is already determined on population level, it is reasonable that all higher Tiers are also addressing the population level.

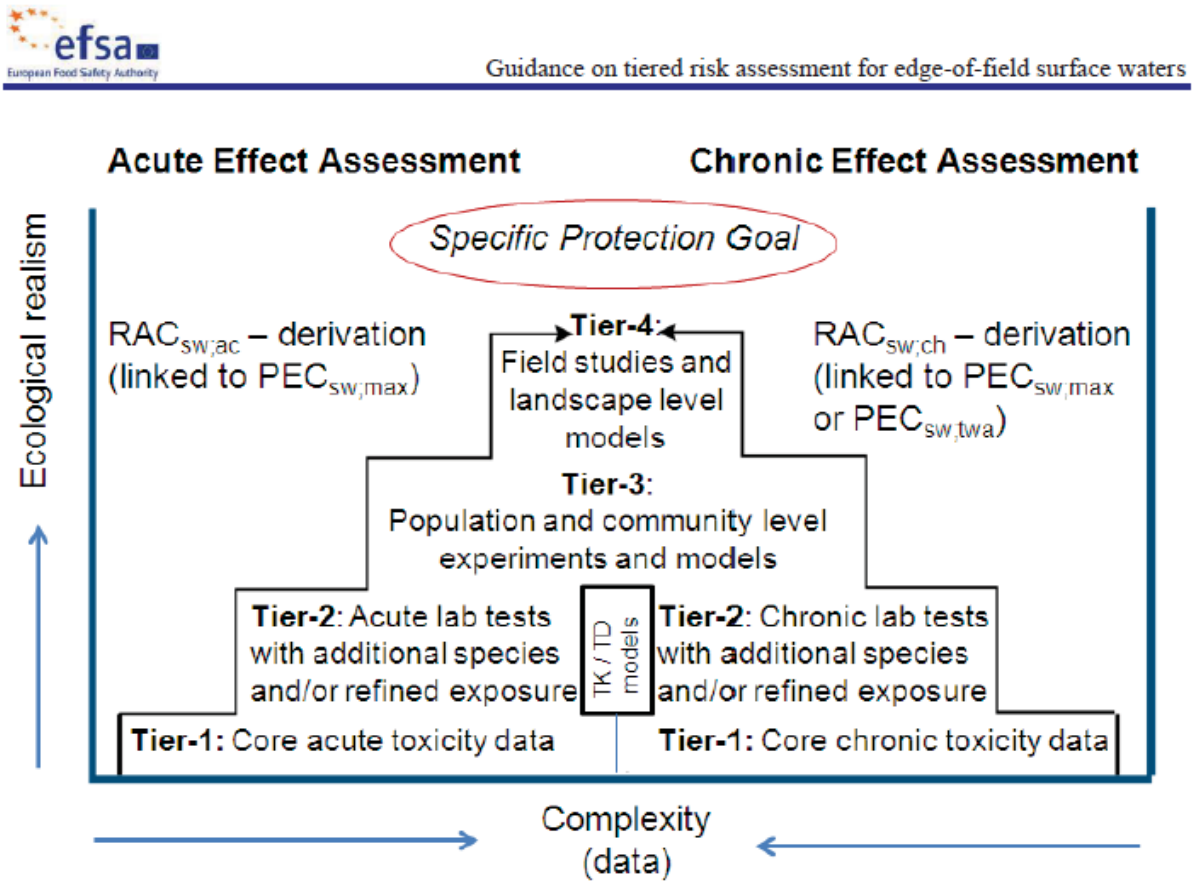


Figure A 10: Schematic presentation of the tiered effect assessment approach for plant protection products taken from EFSA aquatic guidance document (EFSA, 2013)

The here presented approach is based on a TK/TD population model of *Lemna* published by Schmitt et al (2013), which addresses the issue of time variable exposure by enabling a realistic link of exposure to effects at the population level. As the population level is considered, this approach is in accordance with the specific protection goal for macrophytes.

Reference:	**KCP 10.2.3/02**
Title:	Mechanistic TK/TD-model simulating the effect of growth inhibitors on Lemna populations
Report:	Schmitt, W.; Bruns, E.; Dollinger, M.; Sowig, P.; 2013; M-455483-01-1
Authority registration No:	
Guideline(s):	not applicable
Deviations:	not applicable
GLP/GEP:	no
Acceptability:	
Duplication (if vertebrate study):	

The primary objective of the model is the extrapolation of effects determined using standardised exposure patterns in laboratory studies to realistic - i.e. temporally varying - exposures as they occur in small water bodies at the edge of fields treated with plant protection products. A key component of the model is thus a toxicokinetic sub-model translating external concentrations into internal concentrations. The model should additionally allow the prediction of effects on *Lemna* populations under realistic, temporally varying environmental conditions, i.e., temperature and light, based on observations derived under standard laboratory conditions. For use of the model in risk assessments, pure extrapolation of exposure patterns and additional consideration of realistic environmental conditions are considered as two separate steps. The primary endpoint that is derived from the simulation results is the reduction of biomass compared to an unaffected control. As a secondary endpoint, the duration of such effects can also be determined.

The concept of the *Lemna* TK/TD-population model is visualised in Figure A 19: Three main components, a toxicokinetic (TK), a toxicodynamic (TD) and a growth model can be identified.

Generally, the model is a combination of a one compartment TK model and a differential equation model describing the dynamic development of biomass based on photosynthesis rate and respiration rate. The TK model translates the substance concentration in the water body (external exposure) into a *Lemna* internal concentration of this substance. Based on the internal concentration the parameter photosynthesis rate is reduced via the TD model, thus reflecting the growth inhibiting effect of the toxicant for the subsequent growth model. Apart from the influence of the toxicant, photosynthesis rate and respiration rate may also be modulated by other external factors such as temperature, radiation, nutrition and biomass density. This allows for an extrapolation of the biomass growth behaviour to realistic environmental conditions. In the present context of providing a regulatory risk assessment based on FOCUSsw procedures (see following sections), the growth model can e.g. be parameterised for the constant conditions of a virtual laboratory, or for the variable environmental and climatic conditions of the FOCUS water bodies associated with the crop relevant FOCUSsw scenarios.

For a detailed description of all model relevant variables and their derivation, reference is made to the original publication; indepth specific information on these matters is also found provided in the model application report cited later under point (c) in the present section.

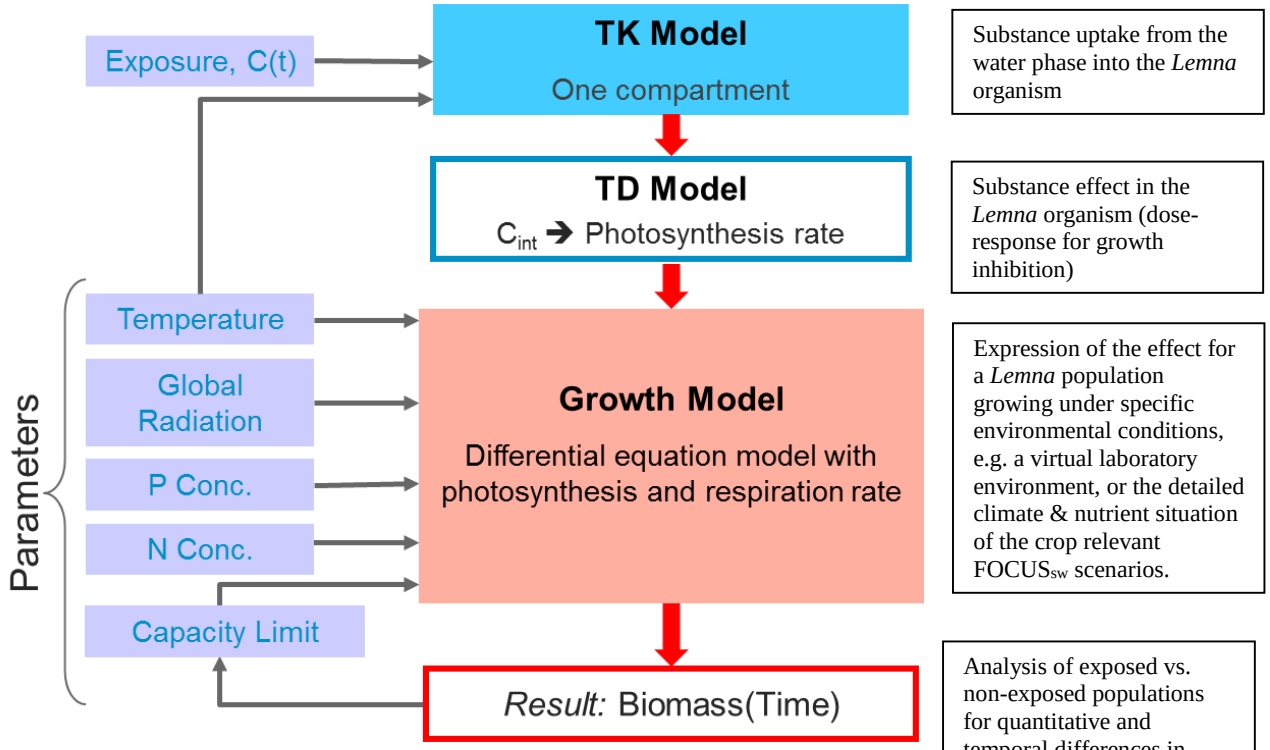


Figure A 11: Concept of the *Lemna* TKTD-model

(b) Model calibration and validation

The practical use of the model includes 3 major steps:

- Model Calibration - to adjust the model to compound specific TK/TD parameters.
- Model Validation - to check and demonstrate the prediction power and accuracy of the calibrated model.
- Model Application - i.e. use of the model for the intended risk assessment purpose.

The calibration and validation of the model is reported in detail in Heine, 2017a. (M-591817-01-1) for foramsulfuron and its metabolite AE F130619, and in Heine, 2017b; M-591850-01-1 for thiencarbazone-methyl. Summaries of these activities are provided here below:

Reference:	**KCP 10.2.3/03**
Title:	Lemna TK/TD modelling - Compound-specific parameterization and validation for foramsulfuron and its metabolite AE F130619
Report:	Heine, S.; 2017; EnSa-17-0346; M-591817-01-1
Authority registration No:	
Guideline(s):	not applicable
Deviations:	not applicable
GLP/GEP:	no
Acceptability:	
Duplication (if vertebrate study):	

Materials and Methods:

This report describes the compound specific preparation of the generic toxicokinetic and toxicodynamic (TK/TD) *Lemna* model to be used for foramsulfuron and its metabolite AE F130619.

In a first step, toxicokinetic and toxicodynamic parameters of the model are calibrated on selected datasets in terms of adjusting them so that the model can describe the measured effects over time in all concentrations of the dataset. Toxicokinetic and toxicodynamic parameters are the uptake rate (P_up) and the internal concentration-response relationship that is based on an $EC(int)_{50}$ and a value defining the slope of the curve (b).

In a second step, the fully parameterized model is validated by testing the predictive power of the model with an independent (different from the datasets used for model calibration) dataset having a different exposure situation. If the calibration and validation are successful it is proven that the model can be used to extrapolate to untested exposure situations for foramsulfuron and its metabolite AE F130619 with their specific mechanism of action in *Lemna*.

Results and Discussion:

Model calibration:
Model calibration is the process of adjusting model parameters until optimal fit to the dataset is obtained.

The plant growths parts of the model were calibrated using the rates of exponential growth measured for the untreated control groups of all studies.

The TK and TD parts of the model for **foramsulfuron** were calibrated with the *Lemna* standard study of Christ & Ruff, 1999 (M-147891-02-1; EU reviewed, see DRAR KCA 8.2.7/01) with constant exposure and with the *Lemna* peak exposure study of Bruns (2013, M-462569-03-1; EU reviewed, see DRAR KCA 8.2.7/06). In this peak exposure study with a total duration of seven days, the effect of one peak of 24h on the growth of *Lemna* had been tested. The calibration results are shown in Figure A 12 and Figure A 13.

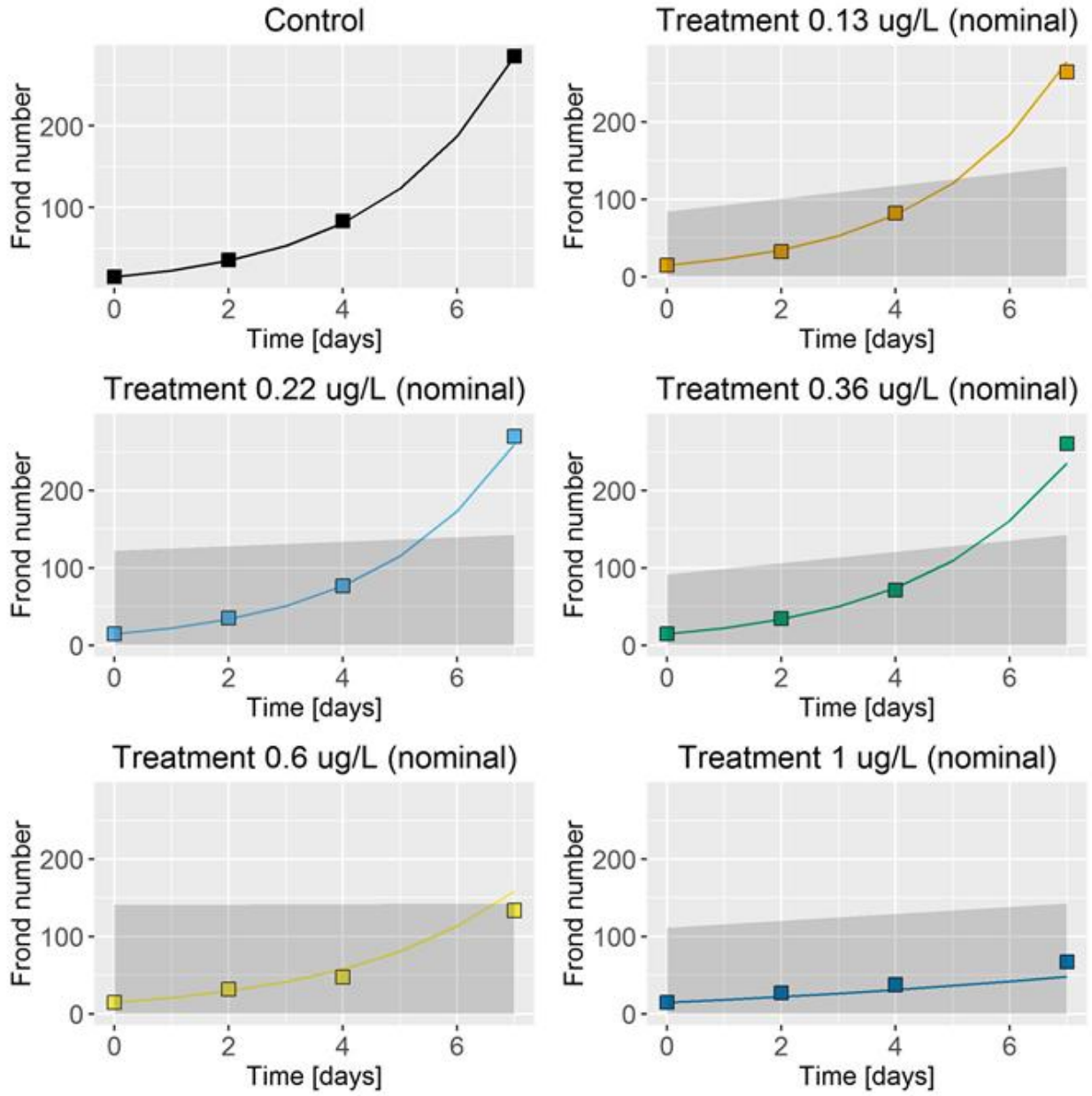


Figure A 12: **Results of the toxicodynamic calibration for foramsulfuron with lines representing model output and symbols representing experimental data (the grey shaded area illustrates the concentration of foramsulfuron in water) 7 days constant exposure situation, based on data from study KCA 8.2.7/01, Christ & Ruff, 1999, M-147891-02-1.**

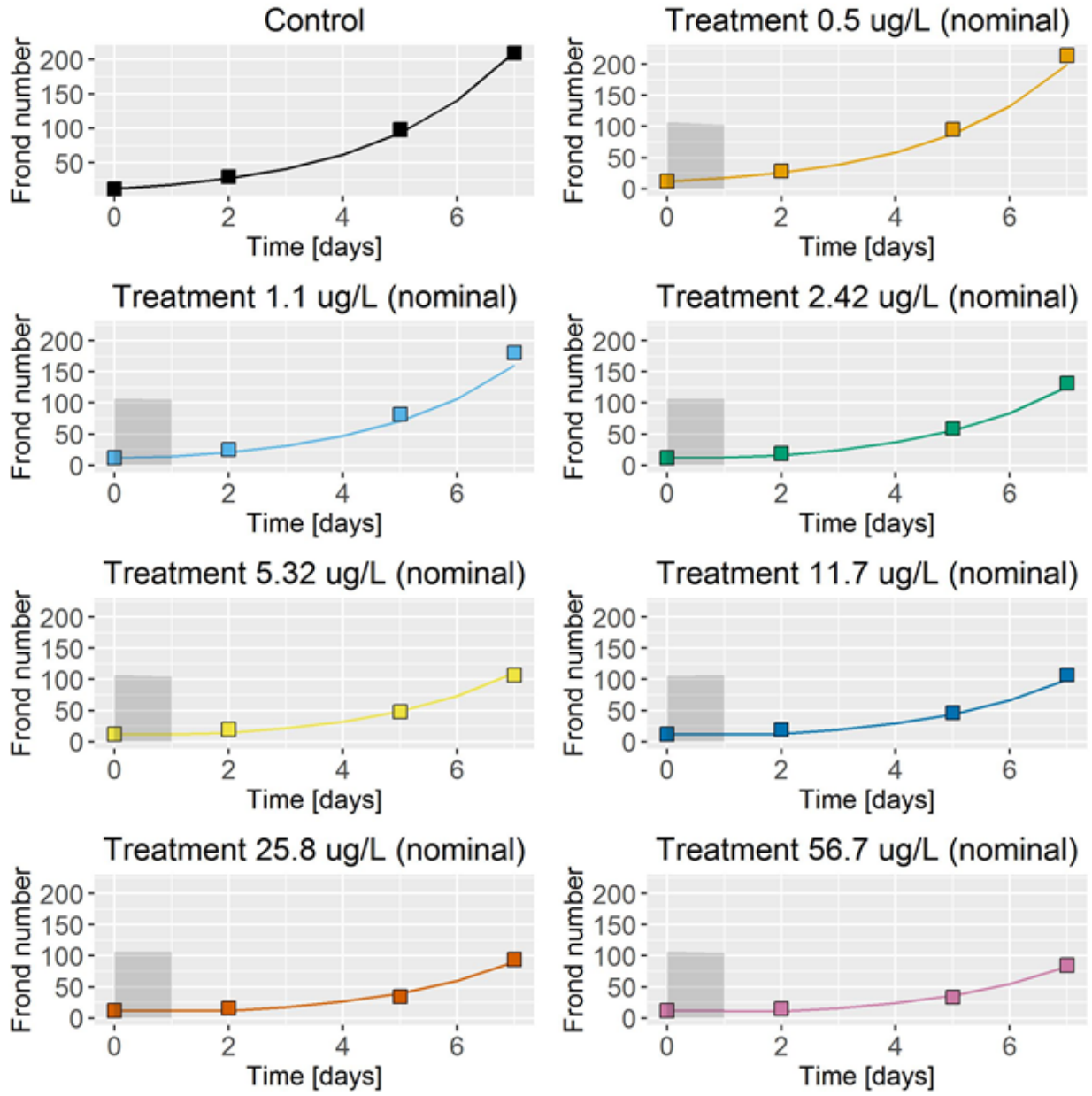


Figure A 13: **Results of the model calibration for foramsulfuron with symbols representing experimental data and lines showing model results (grey areas illustrate the exposure situation): peak exposure with a 24 hours peak event at day 0 of a 7 days observation period, based on data from study KCA 8.2.7/06, Bruns, 2013, M-462569-03-1.**

The TK and TD parts of the model for **metabolite AE F130619** of foramsulfuron were calibrated with the *Lemna* standard study of Bruns, 2013 (M-452669-01-1; EU reviewed, see DRAR KCA 8.2.7/12) with constant exposure and with the *Lemna* peak exposure study (design 1) study of Kuhl (2016, M-574191-01-1; new study, see Appendix A 2.2.1 of this dRR). In this peak exposure study with a total duration of seven days, the effect of two peaks of 24h each on the growth of *Lemna* had been tested. The calibration results are shown in Figure A 14 and Figure A 15.

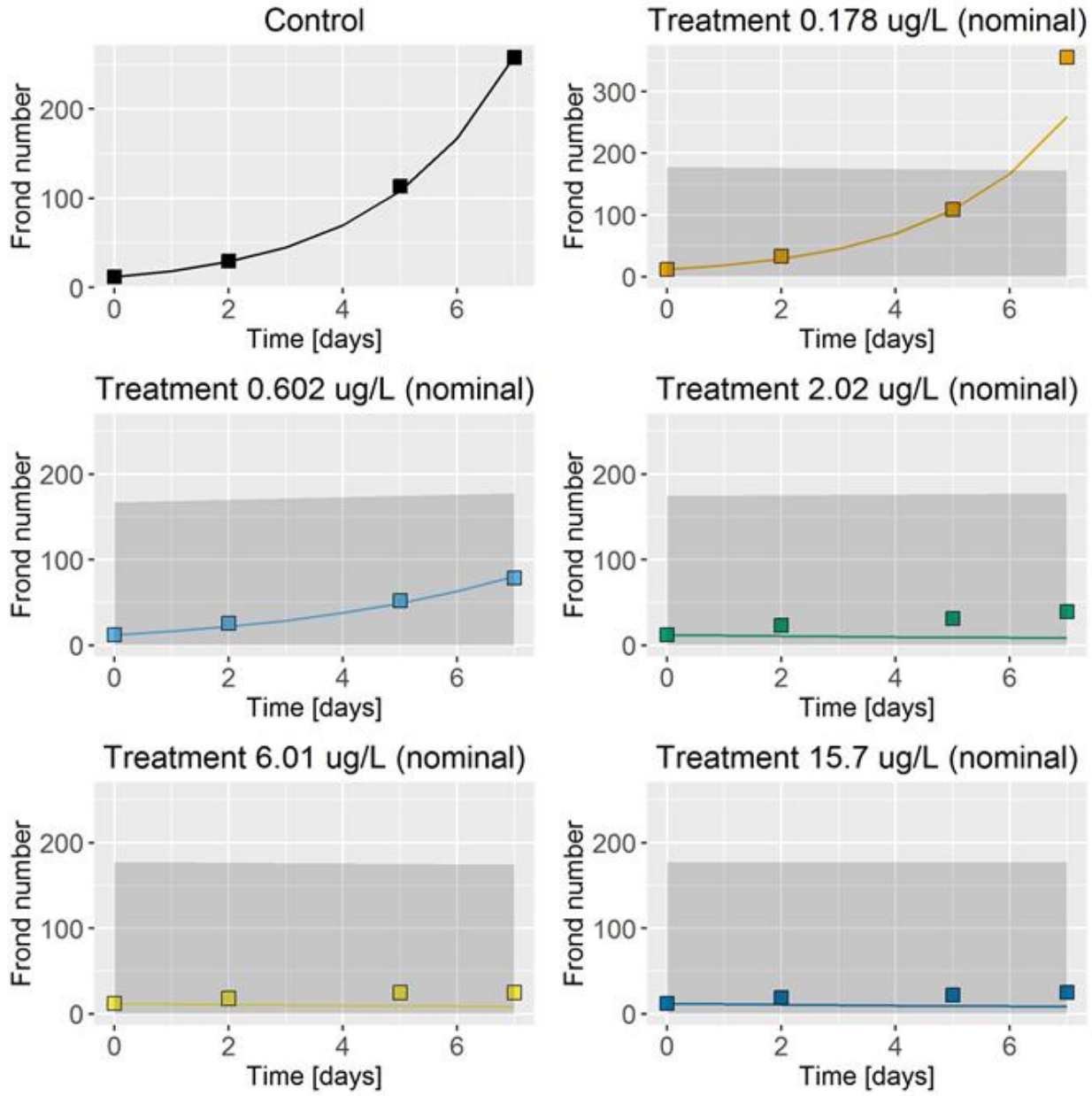


Figure A 14: **Results of the toxicodynamic calibration for metabolite AE F130619 with lines representing model output and symbols representing experimental data (the grey shaded area illustrates the concentration of AE F130619 in water) 7 days constant exposure situation, based on data from study KCA 8.2.7/12 Bruns, 2013, M-452669-01-1.**

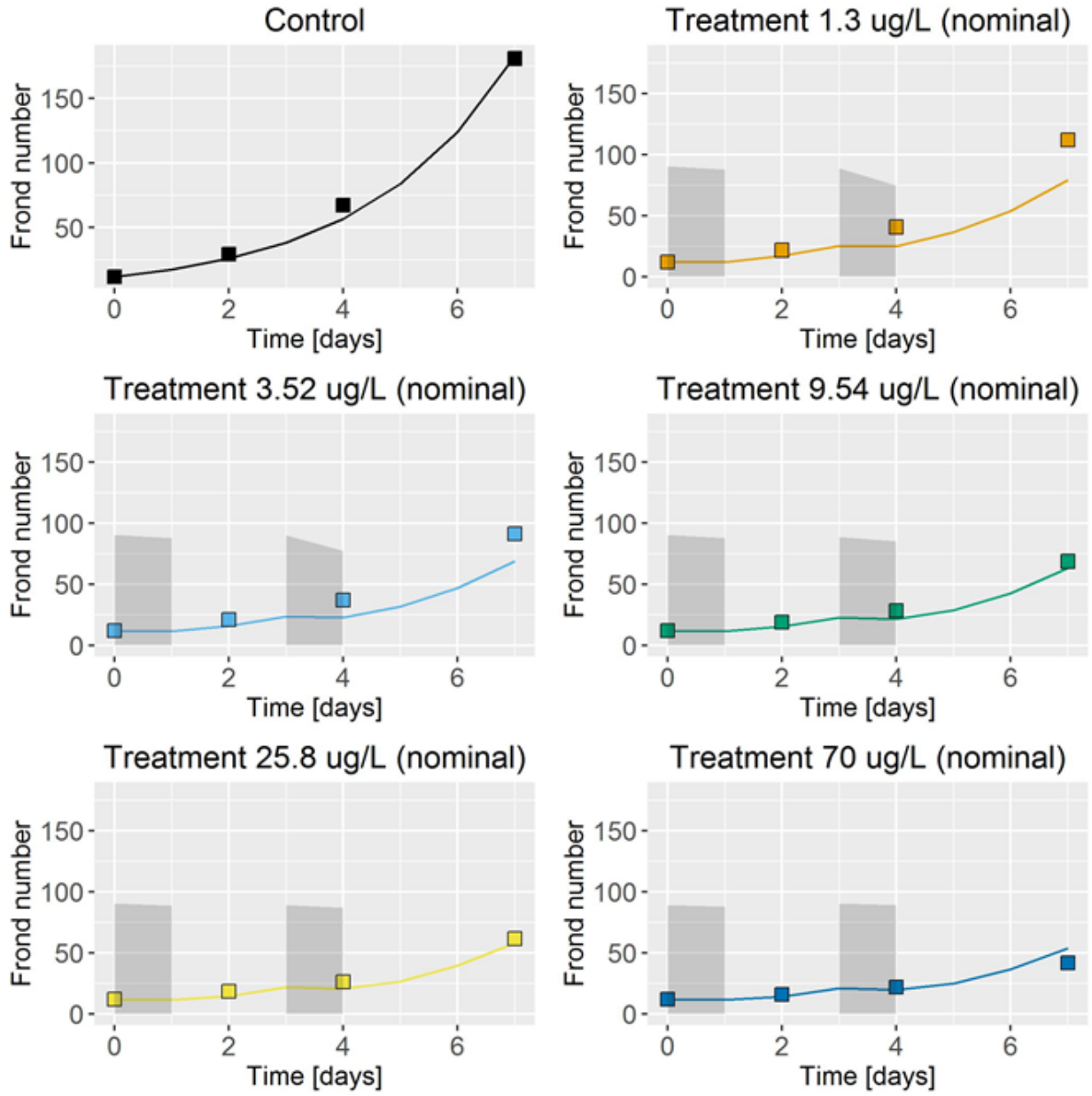


Figure A 15: **Results of the model calibration for metabolite AE F130619 with symbols representing experimental data and lines showing model results (grey areas illustrate the exposure situation): pulsed exposure with two 24 hours peak events at days 0 and 3 of a 7 days observation period, based on data from study Kuhl, 2016, M-574191-01-1; test series of 'design 1' study part**

Due to the number of available *Lemna* studies, the following robust model calibration could be generated:

Table A 7: Compound specific parameterization for foramsulfuron

Parameter	Description	Value	Unit	Remark
$EC_{(int)50}$	Effective internal concentration at which 50% response is observed	0.9	µg/L	Calibrated
b	Value defining the slope of the concentration-response	2.8	-	Calibrated

	function			
E_{max}	Maximum effect	1	-	Set to 1 to enables effect of up to100%
P_up	Cuticular permeability	0.055	cm/d	Calibrated
Kbm	Plant/water partition coefficient	0.83	-	Estimated

Table A 8: Compound specific parameterization for metabolite AE F130619 of foramsulfuron

Parameter	Description	Value	Unit	Remark
$EC_{(int)50}$	Effective internal concentration at which 50% response is observed	0.66	µg/L	Calibrated
b	Value defining the slope of the concentration-response function	10.3	-	Calibrated
E_{max}	Maximum effect	1	-	Set to 1 to enables effect of up to100%
P_up	Cuticular permeability	0.83	cm/d	Calibrated
Kbm	Plant/water partition coefficient	4.2	-	Estimated

Model validation:

Exposure situations that were considered for the validation were nearly constant exposure for seven days with a subsequent recovery phase of fourteen days (Figure A 16 for foramsulfuron), as well as short-term peaks (Figure A 17 and Figure A 18 for foramsulfuron, Figure A 19 for metabolite AE F130619). Overall, the model parameterization for both foramsulfuron and its metabolite AE F130619 can be deemed acceptable considering the excellent visual fit of the validation as shown in the figures below. Besides the visual assessment, the model efficiency (EF) was calculated according FOCUS kinetics (2006) report procedures. EF ranges from minus infinity to +1 with larger values indicating better agreement. EF compares the sum of squared differences between calculated and observed data. For EF > 0, the value gives an indication of the fraction of the dataset that can be explained by the model.

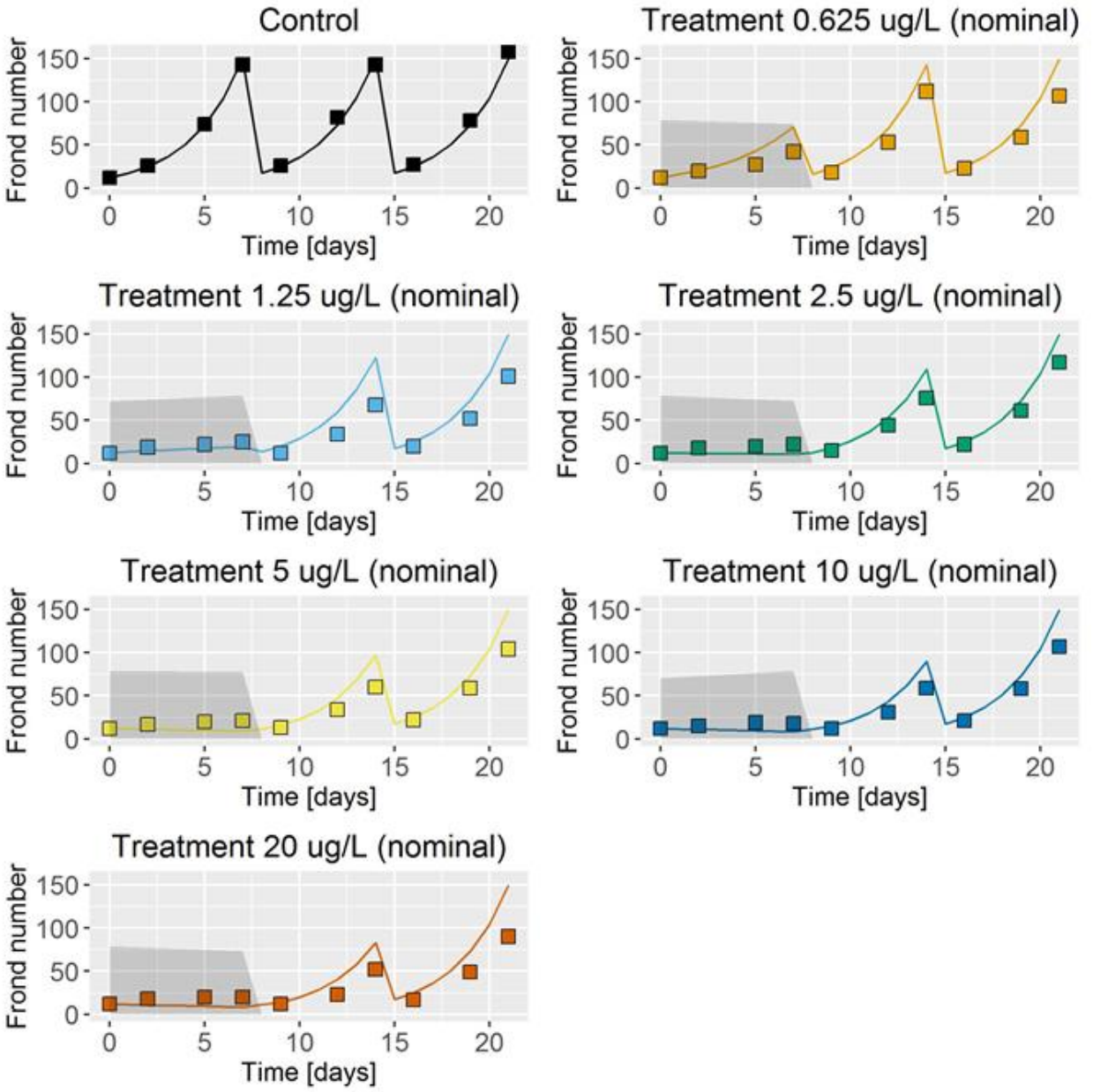


Figure A 16: **Validation of the calibrated *Lemna* model for foramsulfuron with symbols representing experimental data and lines showing predictions of the model (grey areas illustrate the exposure situation): 7 days constant exposure + 14 days recovery period situation, based on data from study KCA 8.2.7 /05, Dorgerloh, M.; 2005; M-250268-01-1**

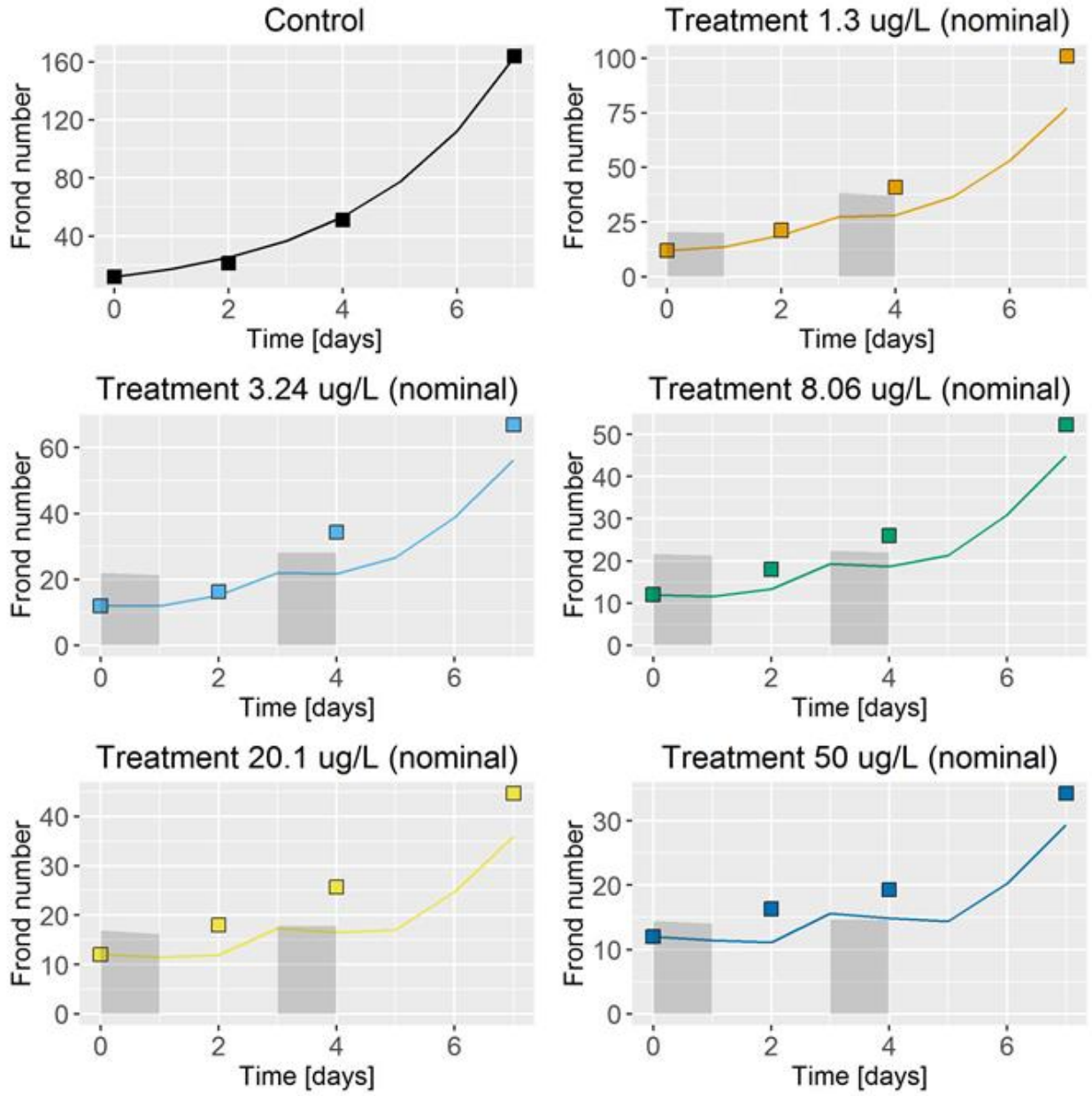


Figure A 17: **Validation of the calibrated *Lemna* model for foramsulfuron with symbols representing experimental data and lines showing predictions of the model (grey areas illustrate the exposure situation): pulsed exposure with two 24 hours peak events at days 0 and 3 of a 7 days observation period, based on data from study Kuhl, 2016, M-572386-03-1; test series of 'design 1' study part**

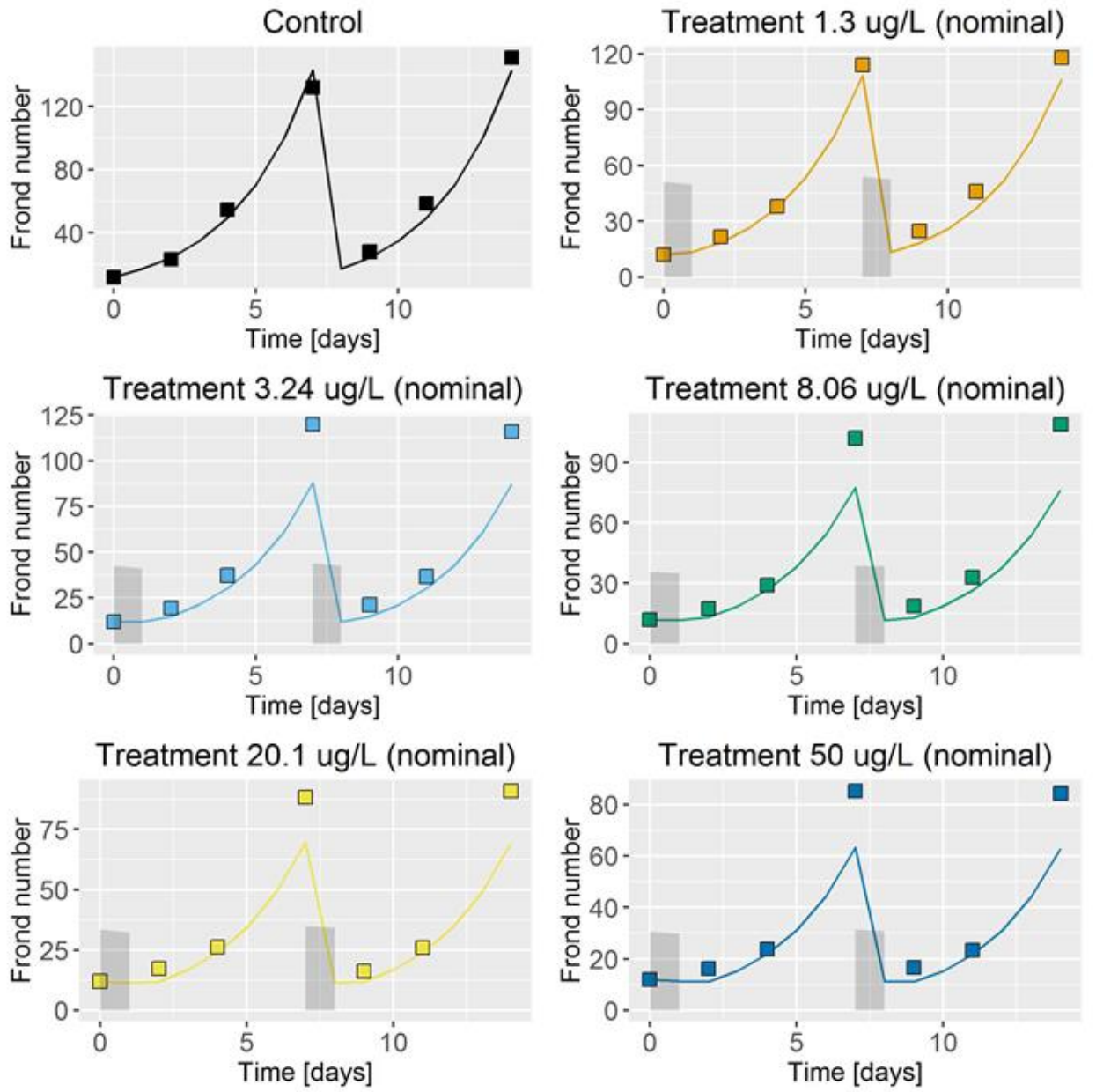


Figure A 18: **Validation of the calibrated *Lemna* model for foramsulfuron with symbols representing experimental data and lines showing predictions of the model (grey areas illustrate the exposure situation): pulsed exposure with two 24 hours peak events at days 0 and 7 of a 14 days observation period, based on data from study Kuhl, 2016, M-572386-03-1; test series of 'design 2' study part**

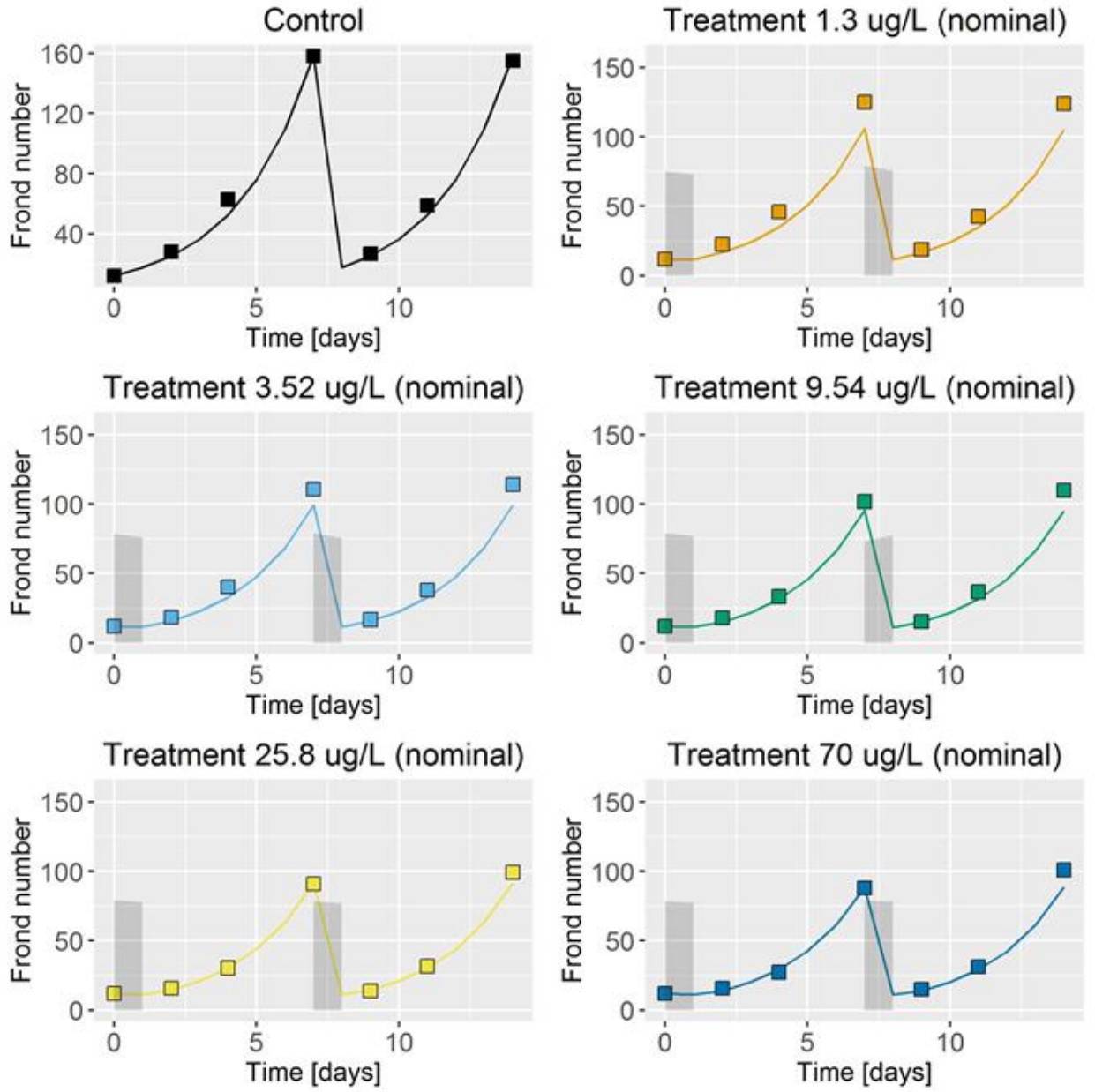


Figure A 19: **Validation of the calibrated *Lemna* model for metabolite AE F130619 with symbols representing experimental data and lines showing predictions of the model (grey areas illustrate the exposure situation): pulsed exposure with two 24 hours peak events at days 0 and 7 of a 14 days observation period, based on data from study Kuhl, 2016, M-574191-01-1; test series of 'design 2' study part**

Table A 9: Numeric description of validation of the compound specific parameterization with EF being the model efficiency and RSS being the residual sum of squares.

Study No.	EF	RSS
Foramsulfuron		
M-250268-01-1	0.71	27131
M-572386-03-1 (Design 1)	0.95	1435
M-572386-03-1 (Design 2)	0.91	6291

metabolite AE F130619		
M-574191-01-1 (Design 2)	0.97	2036

According to a visual inspection of the model validation tests (Figure A 16 to Figure A 19), as well as the numeric evaluation for model efficiency (Table A 9), the calibrated model reliably predicted the effect of time-variable exposures to foramsulfuron and metabolite AE F130619 on *Lemna*. Hence, the model is considered valid and robust, and can be furtheron applied for the purpose of risk assessment to simulate effects of any time-variable exposure to both active components.

Reference:	**KCP 10.2.3/04**
Title:	Lemna TK/TD modelling - Compound-specific parameterization and validation for thiencarbazone-methyl
Report:	Heine, S.; 2017; EnSa-17-0347; M-591850-01-1
Authority registration No:	
Guideline(s):	not applicable
Deviations:	not applicable
GLP/GEP:	no
Acceptability:	
Duplication (if vertebrate study):	

Materials and Methods:

This report describes the compound specific preparation of the generic toxicokinetic and toxicodynamic (TK/TD*)* *Lemna* model to be used for thiencarbazone-methyl.

In a first step, toxicokinetic and toxicodynamic parameters of the model are calibrated on selected datasets in terms of adjusting them so that the model can describe the measured effects over time in all concentrations of the dataset. Toxicokinetic and toxicodynamic parameters are the uptake rate (P_up) and the internal concentration-response relationship that is based on an $EC(int)_{50}$ and a value defining the slope of the curve (b).

In a second step, the fully parameterized model is validated by testing the predictive power of the model with an independent (different from the datasets used for model calibration) dataset having a different exposure situation. If the calibration and validation are successful it is proven that the model can be used to extrapolate to untested exposure situations for thiencarbazone-methyl with its specific mechanism of action in *Lemna*.

Results and Discussion:

Model calibration:
Model calibration is the process of adjusting model parameters until optimal fit to the dataset is obtained.

The plant growths parts of the model were calibrated using the rates of exponential growth measured for the untreated control groups of all studies.

The TD and TK parts of the model were calibrated with the *Lemna* standard study Kern & Lam, 2006 (M-269681-01-1, EU reviewed, see DAR KIIA 8.6 /01) with seven days constant exposure, and with the *Lemna* recovery study of Christ & Lam, 2007 (M-285458-01-1; EU reviewed, see DAR KIIA 8.6 /02) with seven days constant exposure and seven days recovery. In this recovery study with a total duration of 21 days, the effect of seven days constant exposure and a recovery phase consisted of two 7-day intervals on the growth of *Lemna* had been tested.

The calibration results are shown in Figure A 20 and Figure A 21.

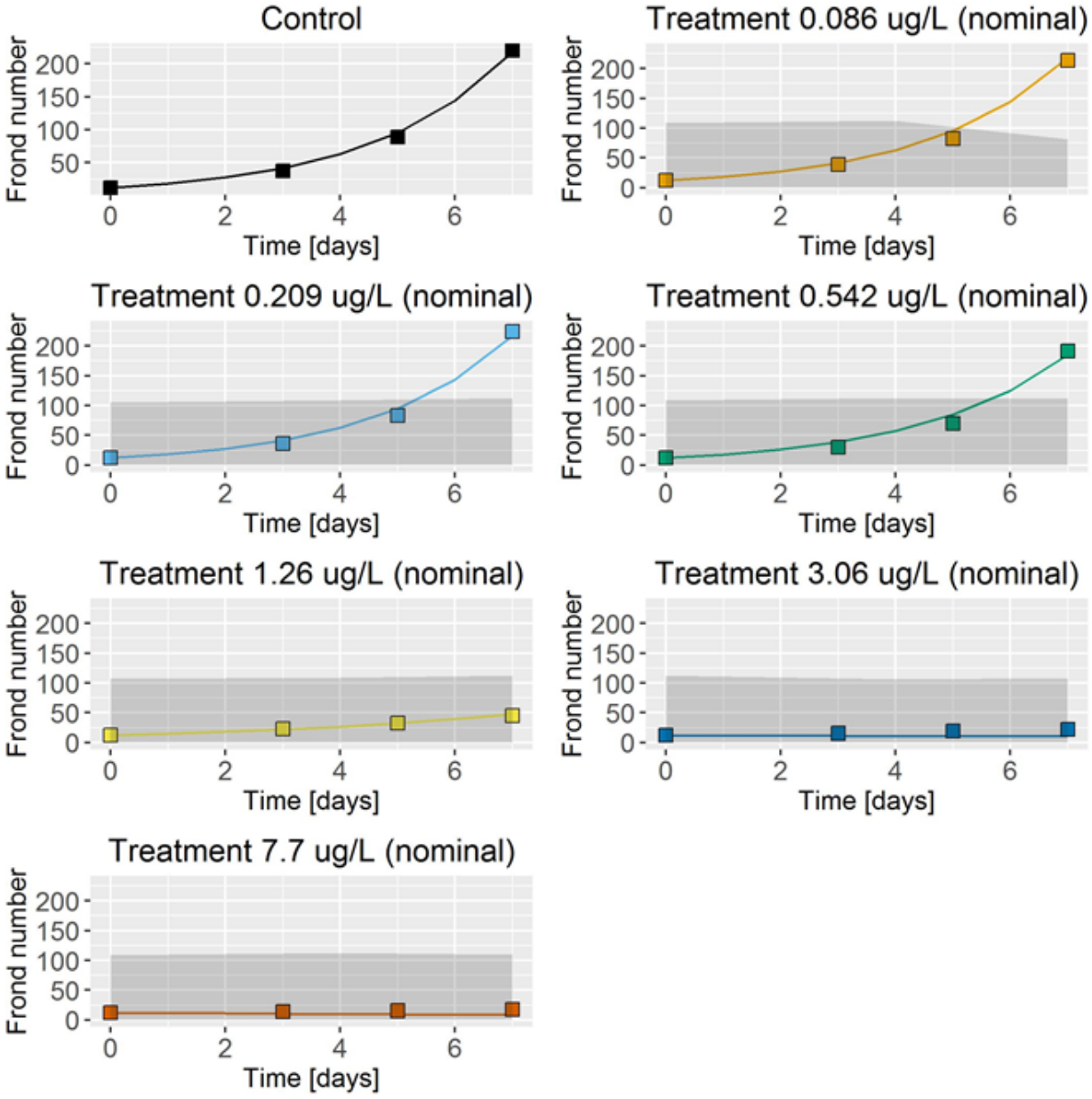


Figure A 20: **Results of the model calibration for thiencarbazone-methyl with symbols representing experimental data and lines showing model results (grey areas illustrate the exposure situation): 7 days constant exposure situation, based on data from study KIIA 8.6 /01, Kern & Lam, 2006; M-269681-01-1**

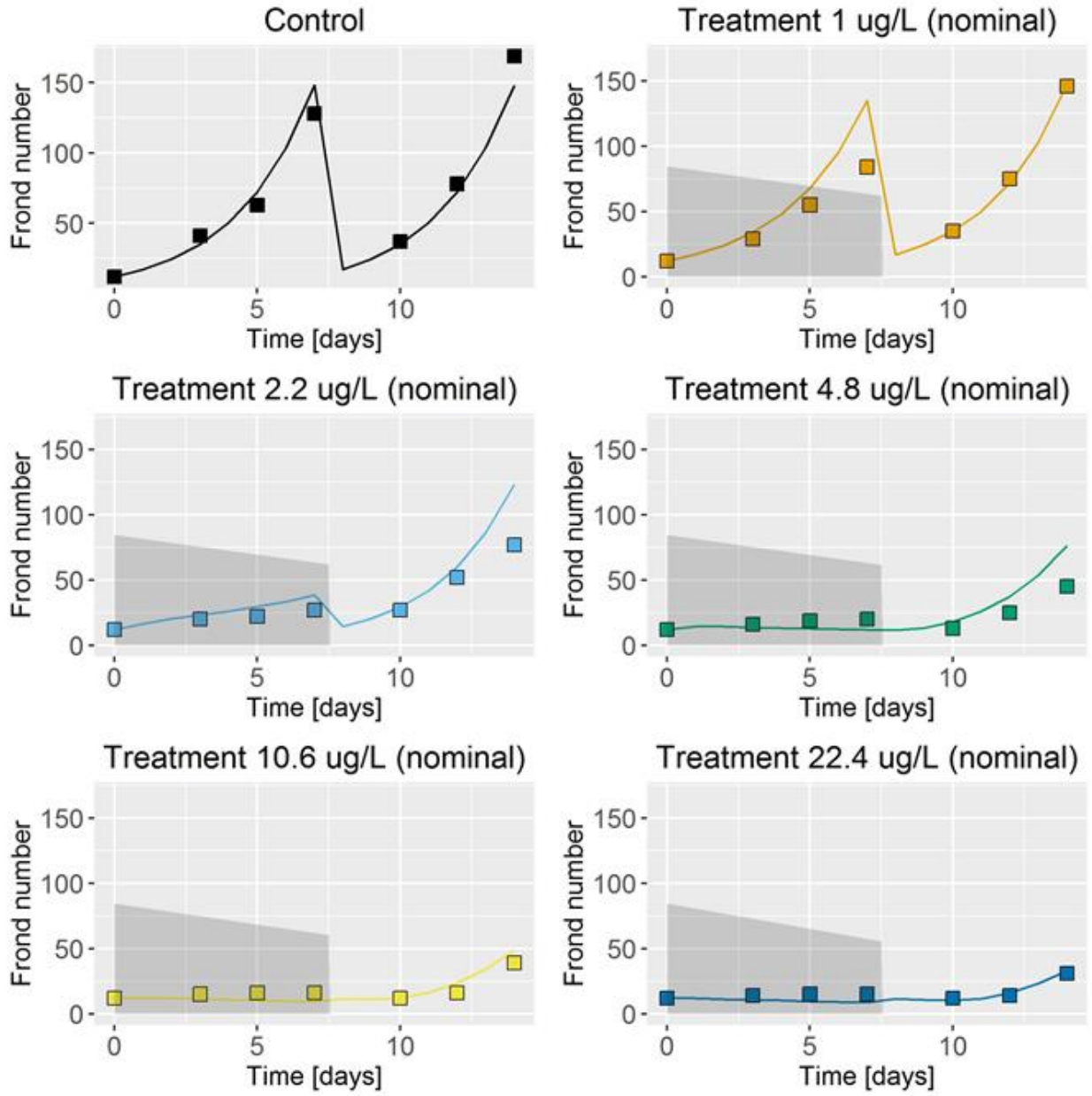


Figure A 21: **Results of the model calibration for thiencarbazone-methyl with symbols representing experimental data and lines showing model results (grey areas illustrate the exposure situation): 7 days constant exposure situation with 7 days recovery, based on data from study KIIA 8.6 /02, Christ & Lam, 2007; M-285458-01-1**

Due to the number of available Lemna studies, the following robust model calibration could be generated:

Table A 10: Compound specific parameterization for thiencarbazone-methyl

Parameter	Description	Value	Unit	Remark
$EC_{(int)50}$	Effective internal concentration at which 50% response is observed	1.3	µg/L	Calibrated
b	Value defining the slope of the concentration-response function	3.4	-	Calibrated
E_{max}	Maximum effect	1	-	Set to 1 to enables effect of up to100%
P_up	Cuticular permeability	0.0088	cm/d	Calibrated
Kbm	Plant/water partition coefficient	0.71	-	Estimated

Model validation:

Exposure situations that were considered for the validation were short-term peaks (Figure A 22 to Figure A 24). Overall, the model parameterization for thiencarbazone-methyl can be deemed acceptable considering the excellent visual fit of the validation as shown in the figures below. Besides the visual assessment, the model efficiency (EF) was calculated according FOCUS kinetics (2006) report procedures. EF ranges from minus infinity to +1 with larger values indicating better agreement. EF compares the sum of squared differences between calculated and observed data. For EF > 0, the value gives an indication of the fraction of the dataset that can be explained by the model.

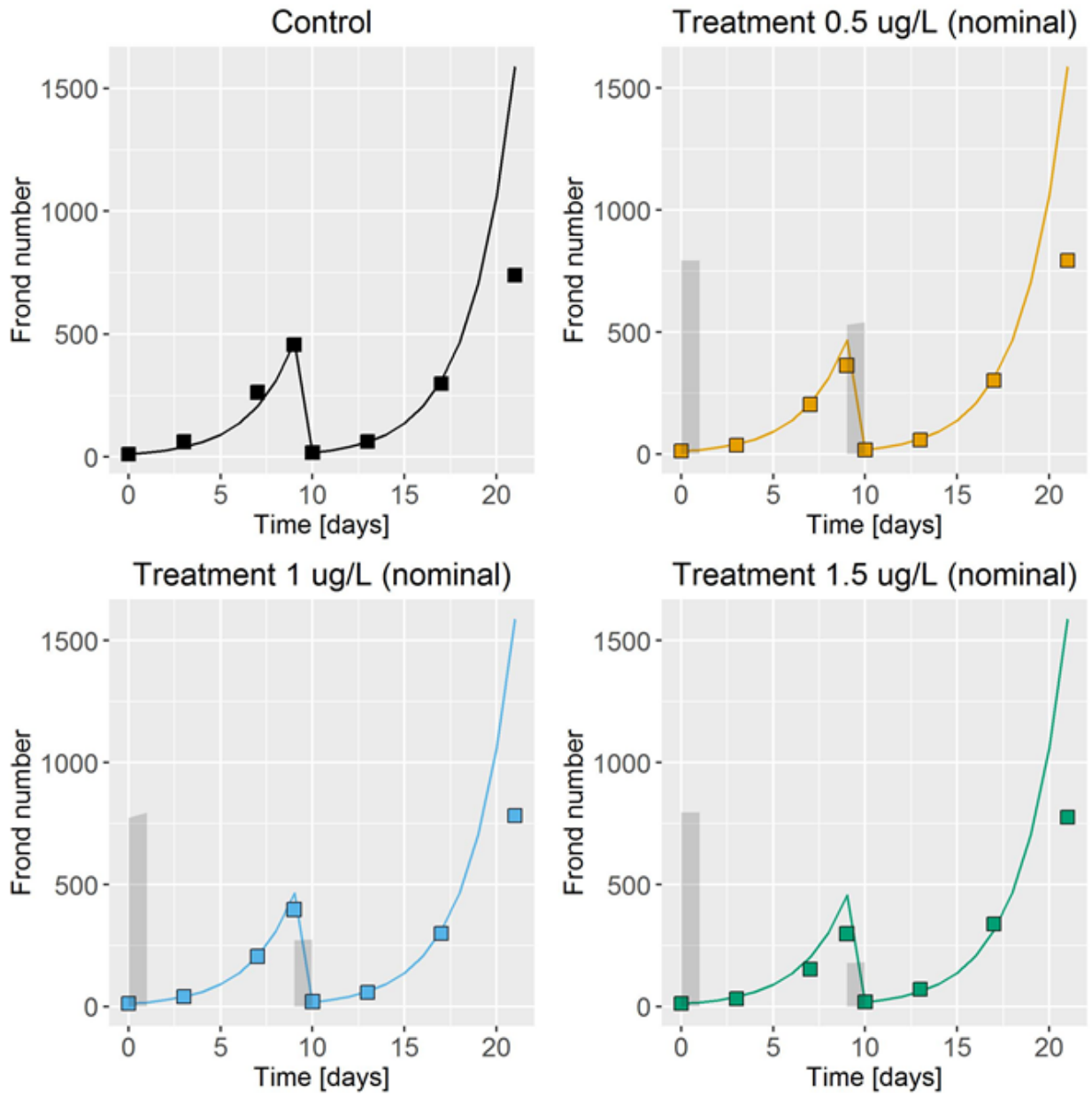


Figure A 22: **Validation of the calibrated *Lemna* model for thiencarbazone-methyl with symbols representing experimental data and lines showing predictions of the model (grey areas illustrate the exposure situation): pulsed exposure with two 24 hours peak events at days 0 and 9 of a 21 days observation period, based on data from *Lemna* peak exposure study of Bruns (2013; M-462568-01-1)**

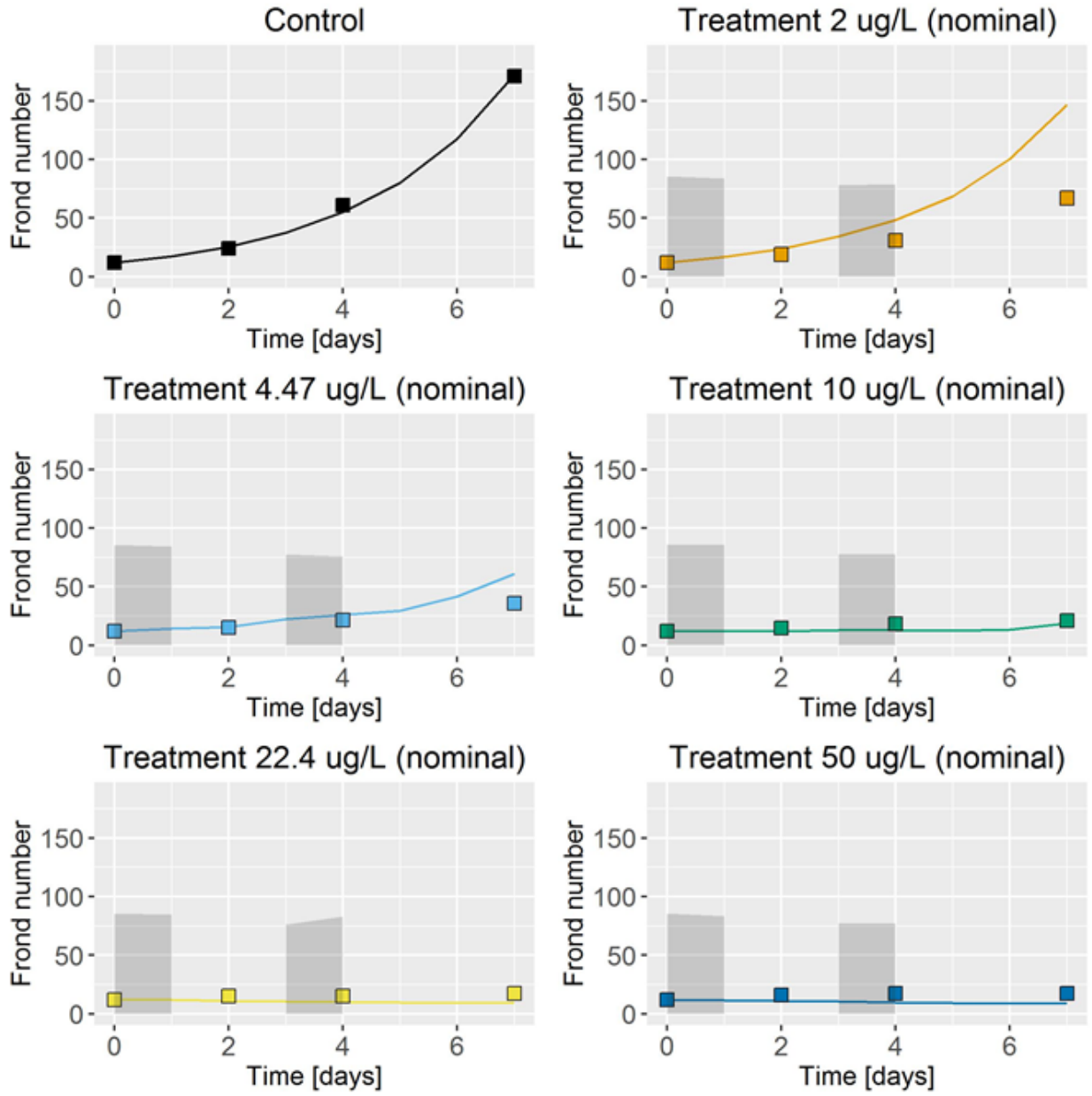


Figure A 23: **Validation of the calibrated *Lemna* model for thiencarbazone-methyl with symbols representing experimental data and lines showing predictions of the model (grey areas illustrate the exposure situation): pulsed exposure with two 24 hours peak events at days 0 and 3 of a 7 days observation period, based on data from study Kuhl, 2016, M-568404-02-1; test series of 'design 1' study part**

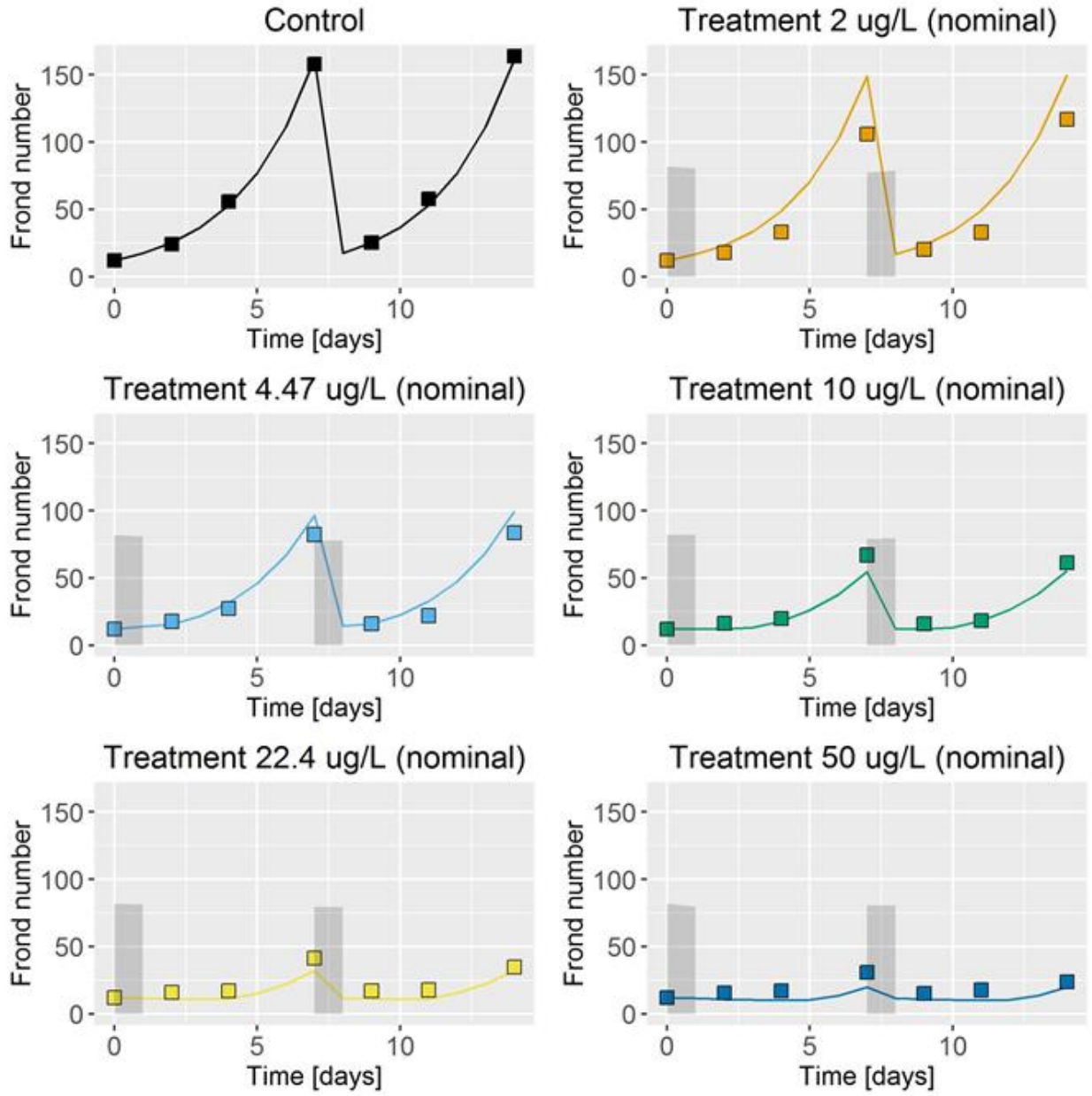


Figure A 24: **Validation of the calibrated *Lemna* model for thiencarbazone-methyl with symbols representing experimental data and lines showing predictions of the model (grey areas illustrate the exposure situation): pulsed exposure with two 24 hours peak events at days 0 and 7 of a 14 days observation period, based on data from study Kuhl, 2016, M-568404-02-1; test series of 'design 2' study part**

Table A 11: Numeric description of validation of the compound specific parameterization with EF being the model efficiency and RSS being the residual sum of squares.

Study No.	EF	RSS
M-462568-01-1	0.91	48657
M-568404-02-1 (Design 1)	0.71	7661
M-568404-02-1 (Design 2)	0.92	4880

According to a visual inspection of the model validation tests (Figure A 22 to Figure A 24), as well as the numeric evaluation for model efficiency (Table A 11), the calibrated model reliably predicted the effect of time-variable exposures to thiencarbazone-methyl on *Lemna*. Hence, the model is considered valid and robust, and can be furtheron applied for the purpose of risk assessment to simulate effects of any time-variable exposure to thiencarbazone-methyl.

(c) Model application for risk assessment of the product

For risk assessment of the present product, the successfully calibrated and validated *Lemna* models were applied in two ways, referring to AGD levels Tier 2C, and Tier 3:

In-silico time-variable exposure testing of *Lemna, for derivation of $RAC_{pattern}$ of FOCUSsw scenarios*: 'Virtual laboratory tests' on *Lemna* were simulated to address $FOCUS_{sw}$ exposure patterns of particular interest for the risk assessment, applying the model confirmatory to the assessments made before at Tier 2C (Section 9.5.2.5). Starting from the condensed exposure pattern representations previously derived via EPAT tool analysis of the FOCUSsw output (number, duration, maximum concentration, and interval of events exceeding the Tier 1 RAC), the biological effect of such patterns was simulated for a *Lemna* population assumed to grow under constant environmental conditions representing an 'in-silico laboratory'. To investigate on the dose-response relationship, the simulation was repeated multiple times with arbitrarily scaled concentration dimension of the exposure pattern, while keeping constant all further parameters. Based on the so generated data set, an $EC_{50pattern}$ could be derived in analogy to the procedures of a standard laboratory experiment. This $EC_{50pattern}$ is a descriptor which specifically reflects macrophyte sensitivity for the exposure timecourse experienced in the regarded FOCUSsw scenario of interest, and can be compared to the $PEC_{sw,max}$ predicted for this scenario.

Population effect modelling for outdoor FOCUSsw water bodies: Dynamics of a *Lemna* population growing outdoors in an edge-of-field surface water body were simulated for each of the crop relevant $FOCUS_{sw}$ exposure scenarios, for the critical GAP situations of the present product. To realistically simulate the biological impact of the predicted exposure patterns, the model environmental scenarios were constructed to reflect the properties of each associated FOCUS surface water body[16]. Additionally, to generate information on the margin of safety, *Lemna* population dynamics were simulated as well for exaggerated exposure situations, generated via a multiplication of the concentration dimension of the exposure patterns with exemplary scaling factors of either 10 or 100. Scaling the exposure supports the assessment and is intended to demonstrate that the model is able to predict considerable inhibitions of population dynamics. Following the standard concept of concentration addition, the population modelling approach can consider and combine the effect contributions by all biologically active components relevant to a product, i.e. can directly provide a combined risk assessment for the detailed and potentially complex exposure situation of macrophytes in surface water bodies.

A detailed description of both approaches and their results is provided in the following report:

Reference:	**KCP 10.2.3/05**
Title:	Lemna TK/TD modelling: Assessing the impact of FSN+TCM OD 80 applications on Lemna in Europe (FOCUSsw)
Report:	Heine, S.; 2019; EnSa-18-0891; M-665818-01-1
Authority registration No:	
Guideline(s):	none
Deviations:	none
GLP/GEP:	no
Acceptability:	
Duplication (if vertebrate study):	

The before described, calibrated and validated, *Lemna* TK/TD-population model was applied to establish higher tier risk assessments for the product FSN+TCM OD 80 (50+30). Two critical use patterns (use

[16] To account for the uncertainty resp. natural variation in some model relevant parameters, e.g. waterbody's nutrient concentration, a stochastic simulation was performed varying those parameters in a Monte-Carlo approach. Therefore, actually 100 model runs were made per scenario, yielding output ranges.

groups B and C) were addressed and are presented in the table below.

Table A 12: GAP translation for *Lemna* population effect modelling purposes

Use group	GAP No. (in report)	Crop	Growth stage & use timing	Max. apps	Interval (days)	Rate (kg a.s./ha)
B	I	Sugar beets	BBCH 10-18	1	-	FSN: 0.050 TCM: 0.030
C	II	Sugar beets	BBCH 10-18	2	10	FSN: 0.025 TCM: 0.015

Aquatic exposure for these use patterns was described based on standard FOCUSsw exposure simulations, see summaries in the E-Fate section to this dRR (for foramsulfuron and its metabolite AE F130619: Heine et al. 2016; [M-582622-01-1]; for thiencarbazone-methyl: Bolekhan et al. 2016; [M-582854-01-1]).

For the assessment at **Tier 2C (*in-silico* time-variable exposure testing of *Lemna*)** $RAC_{pattern}$ determinations were conducted with the active substances foramsulfuron and thiencarbazone-methyl and the foramsulfuron metabolite AE F130619 in combination. The determinations were done for all six FOCUS scenarios at FOCUS Step 3 level and can be found in the original report. In this section, simulation results are presented only for those scenarios that failed at Tier 1 level or required mitigation measures and were therefore also evaluated under point 9.5.2.5 (Tier 2C: Higher-tier assessment based on refined exposure testing combined with exposure pattern analysis). An overview of the addressed scenarios for the different use groups is given below:

- Use group B: D3 ditch, D4 stream, R1 stream, R3 stream
- Use group C: D3 ditch, D4 stream, R1 stream, R3 stream

Exposure patterns as provided by FOCUSsw are used for all biologically active components of relevance to the product. To account for the duration of ecotoxicological *Lemna* tests, not the entire annual FOCUSsw patterns are assessed but the pattern from a 4-week (4x7 days) period, starting with the seven days before the week having the maximum concentration of all components. In case the selection results in periods that exceed the beginning or the end of the FOCUSsw exposure pattern, the first or the last 4 weeks of the FOCUSsw exposure pattern are assessed.

For the assessment at **Tier 3** (**population effect modelling for outdoor FOCUSsw water bodies)** all three biologically active components of relevance to the product were considered in a combined toxicity approach based on concentration addition, for all crop relevant FOCUSsw scenarios:

Table A 13: FOCUS scenarios and compounds that are evaluated by *Lemna* population modelling

Use group	FOCUS scenario	Effect modelling based on:
B	D3 (ditch)	foramsulfuron & AE F130619 & thiencarbazone-methyl
	D4 (pond)	foramsulfuron & AE F130619 & thiencarbazone-methyl
	D4 (stream)	foramsulfuron & AE F130619 & thiencarbazone-methyl
	R1 (pond)	foramsulfuron & AE F130619 & thiencarbazone-methyl
	R1 (stream)	foramsulfuron & AE F130619 & thiencarbazone-methyl
	R3 (stream)	foramsulfuron & AE F130619 & thiencarbazone-methyl

C	D3 (ditch)	foramsulfuron & AE F130619 & thiencarbazone-methyl
	D4 (pond)	foramsulfuron & AE F130619 & thiencarbazone-methyl
	D4 (stream)	foramsulfuron & AE F130619 & thiencarbazone-methyl
	R1 (pond)	foramsulfuron & AE F130619 & thiencarbazone-methyl
	R1 (stream)	foramsulfuron & AE F130619 & thiencarbazone-methyl
	R3 (stream)	foramsulfuron & AE F130619 & thiencarbazone-methyl

Methods & Results:

(d) *In-silico* time-variable exposure testing of *Lemna*, for derivation of RACpattern to FOCUSsw scenarios:

Virtual laboratory test simulations are used to derive $RAC_{pattern}$(s) for specific exposure patterns. To be able to establish a dose-response relationship for the $RAC_{pattern}$ determination several virtual laboratory tests are conducted for the same exposure pattern. For each simulation the concentration is increased by factors (scaling) while all other exposure pattern characteristics such as the duration and the interval between peaks are not changed. By this the exposure pattern that causes 50% effect ($EC50_{pattern}$) is determined. The $RAC_{pattern}$ is then calculated with the $EC50_{pattern(mix)}$ and a standard assessment factor of 10.

The virtual laboratory tests are conducted for 4x7 days simulating the transfer of 12 fronds after seven days in accordance to standard *Lemna* tests. Effects are based on the relative growth rate at the end of a seven days period by selecting the week with the strongest effects. The time frame of the FOCUS exposure patterns that is considered ranges from seven days before the week having the maximum concentration (seven days area under the curve) to 14 days after the week having the maximum concentration covering a period of 28 days in total. The settings of the virtual laboratory simulation are designed in accordance to standard *Lemna* studies. Due to optimum growth conditions in standard *Lemna* studies, a maximum growth rate is considered and the other parameters that influence growth (e.g. nutrition and temperature) are neglected. An initial biomass of 0.0012 g corresponding to a frond number of 12 and the compound specific parameters of foramsulfuron, its metabolite AE F130619 and thiencarbazone-methyl are used.

The virtual Lemna laboratory tests presented in the following are based on FOCUS Step 3. In case the assessment at Step 3 level provided RQ values > 1, the tests were additionally based on FOCUS Step 4.

Sum of foramsulfuron, thiencarbazone-methyl and metabolite AE F130619

*$EC_{50pattern}$ determination and risk assessment for **use group B (≡GAP I) – FOCUS Step 3:***

In virtual laboratory tests based on FOCUS Step 3, to achieve an inhibition of the relative growth rate by 50% ($EC_{50pattern}$), the concentrations had to be increased to 13.73 µg/L for the scenario D3 ditch, to 241 µg/L for the scenario D4 stream, to 34.97 µg/l for the scenario R1 stream and to 27.09 µg/L for the scenario R3 stream. This corresponds to scaling factors of 32.7 for the scenario D3 ditch, of 701.4 for the scenario D4 stream, of 115.9 for the scenario R1 stream and of 44.2 for the scenario R3 stream. In agreement with an assessment factor of 10 the $RAC_{pattern}$ were therefore 1.37 µg/L, 24.1 µg/L, 3.5 µg/L and 2.71 µg/L for the specific exposure situation predicted for the sum of biologically active compounds in the scenarios D3 ditch, D4 stream, R1 stream and R3 stream, for the application to sugar beet.

For risk assessment, these $RAC_{pattern}$ were compared to the sum of the $PEC_{sw,max}$ concentrations of all biologically active compounds of 0.42 µg/L for the scenario D3 ditch, 0.3436 µg/L for the scenario D4 stream, 0.3017 µg/L for the scenario R1 stream or 0.6124 µg/L for the scenario R3 stream. This resulted in RQ_{mix} values of < 1 for all scenarios at FOCUS Step 3 level and no further risk assessment based on $RAC_{pattern}$ is needed.

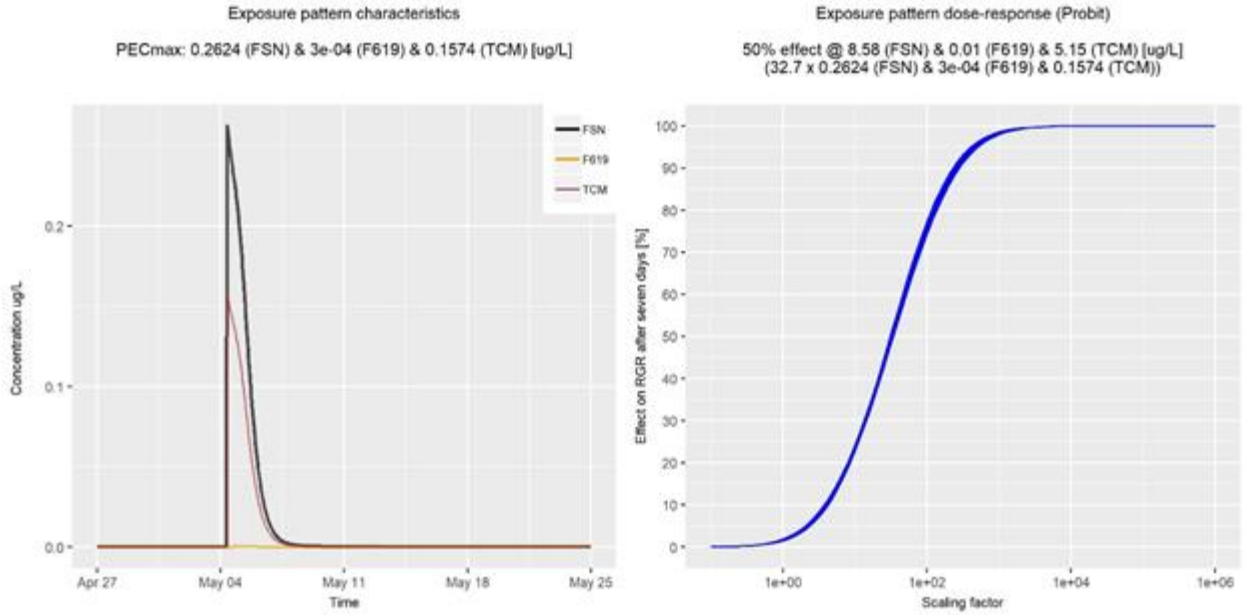


Figure A 25: Illustration of the evaluated exposure pattern and the corresponding dose-response relationship for scenario D3 ditch based on FOCUS Step 3, for use group B

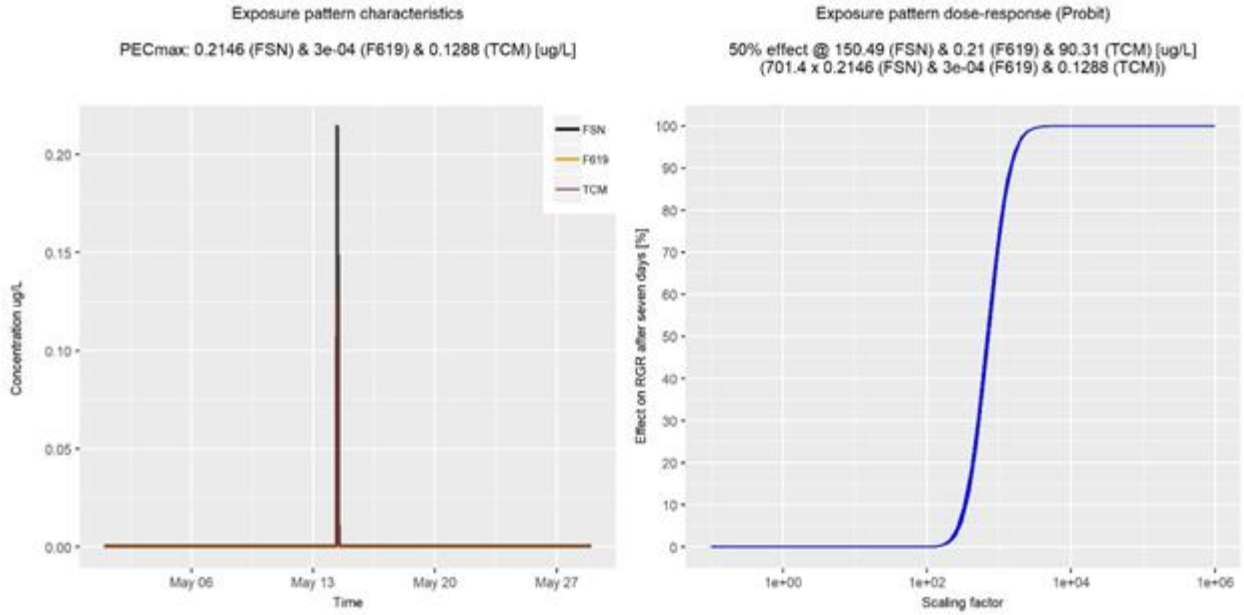


Figure A 26: Illustration of the evaluated exposure pattern and the corresponding dose-response relationship for scenario D4 stream based on FOCUS Step 3, for use group B

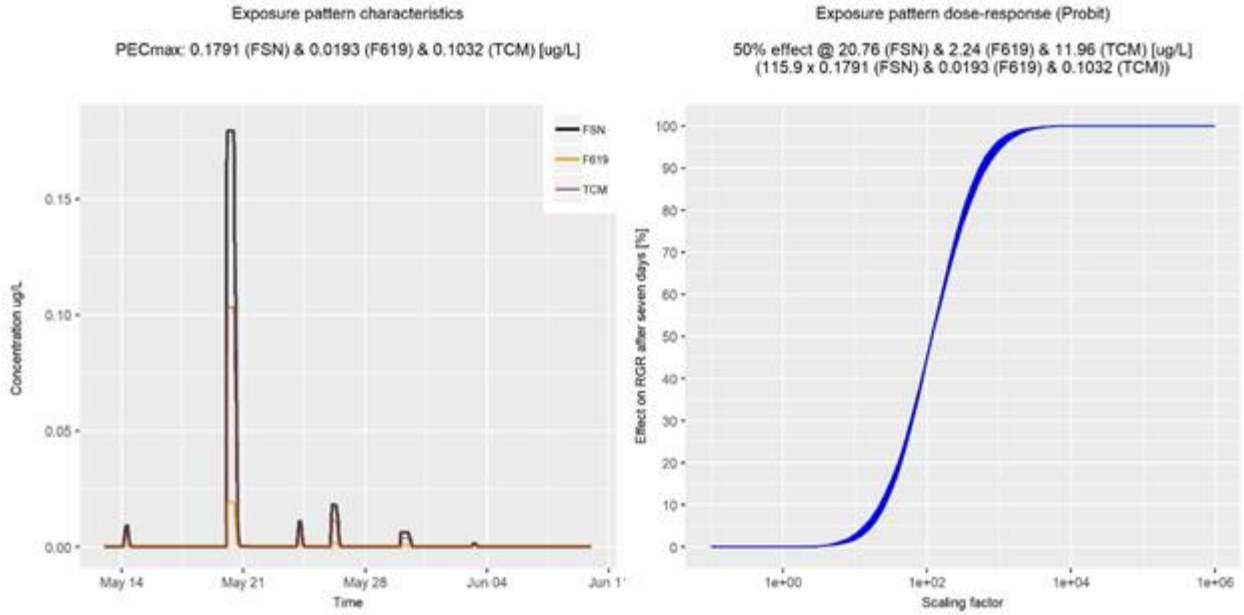


Figure A 27: Illustration of the evaluated exposure pattern and the corresponding dose-response relationship for scenario R1 stream based on FOCUS Step 3, for use group B

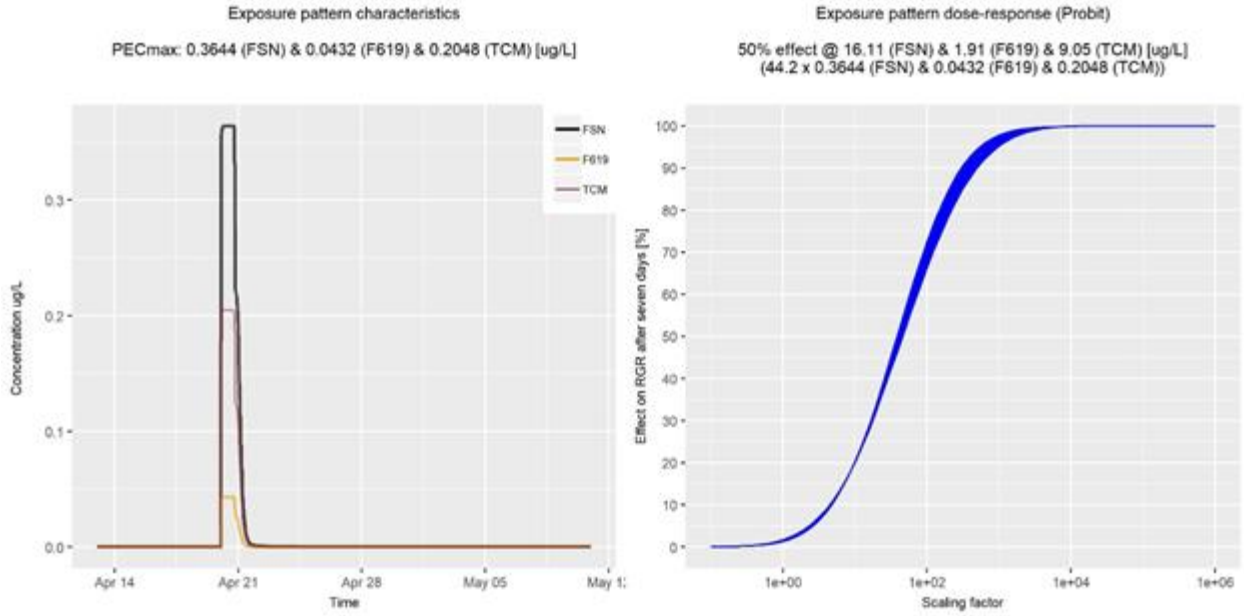


Figure A 28: Illustration of the evaluated exposure pattern and the corresponding dose-response relationship for scenario R3 stream based on FOCUS Step 3, for use group B

Table A 14: Assessing exposure patterns derived from $FOCUS_{sw}$ calculation based on FOCUS Step 3 to determine the corresponding exposure pattern that causes 50% effect by increasing the concentration and keeping all other pattern characteristics - <u>for use group B</u>

Scenario	Pattern mixture toxicity				
	PEC_{max} [µg/L] <u>FSN</u>	**PEC_{max} [µg/L] <u>F619</u>**	**PEC_{max} [µg/L] <u>TCM</u>**	**PEC_{max} (sum) [µg/L]**	**Seven-day period with highest sum of all concentrations (the assessed exposure pattern range is seven days before and 14 days after this period covering 28 days)**
D3 (Ditch)	0.2624	3.00E-04	0.1574	0.42	1992-05-04 - 1992-05-11
D4 (Stream)	0.2146	3.00E-04	0.1288	0.3436	1985-05-08 - 1985-05-15
R1 (Stream)	0.1791	0.0193	0.1032	0.3017	1984-05-20 - 1984-05-27
R3 (Stream)	0.3644	0.0432	0.2048	0.6124	1980-04-20 - 1980-04-27

	Scaling factor (used to multiply the entire mixture pattern)	**$EC50_{pattern}$<u>mix</u>**	**$RAC_{pattern}$<u>mix</u>**	**RQ_{mix} = PEC_{max} (sum)/ $RAC_{pattern}$mix**
D3 (Ditch)	32.7	13.73	1.37	0.306
D4 (Stream)	701.4	241	24.1	0.014
R1 (Stream)	115.9	34.97	3.5	0.086
R3 (Stream)	44.2	27.09	2.71	0.226

*<u>$EC_{50pattern}$ determination and risk assessment for **use group C (≡GAP II) – FOCUS Step 3:**</u>*

In virtual laboratory tests based on FOCUS Step 3, to achieve an inhibition of the relative growth rate by 50% ($EC_{50pattern}$), the concentrations had to be increased to 13.36 µg/L for the scenario D3 ditch, to 82.53 µg/L for the scenario D4 stream, to 32.52 µg/l for the scenario R1 stream and to 27.01 µg/L for the scenario R3 stream. This corresponds to scaling factors of 73.3 for the scenario D3 ditch, of 537.3 for the scenario D4 stream, of 47.4 for the scenario R1 stream and of 19.2 for the scenario R3 stream. In agreement with an assessment factor of 10 the $RAC_{pattern}$ were therefore 1.34 µg/L, 8.25 µg/L, 3.25 µg/L and 2.70 µg/L for the specific exposure situation predicted for the sum of biologically active compounds in the scenarios D3 ditch, D4 stream, R1 stream and R3 stream, for the application to sugar beet.

For risk assessment, these $RAC_{pattern}$ were compared to the sum of the $PEC_{sw,max}$ concentrations of all biologically active compounds of 0.1823 µg/L for the scenario D3 ditch, 0.1536 µg/L for the scenario D4 stream, 0.6859 µg/L for the scenario R1 stream or 1.41 µg/L for the scenario R3 stream. This resulted in RQ_{mix} values of < 1 for all scenarios at FOCUS Step 3 level and no further risk assessment based on $RAC_{pattern}$ is needed.

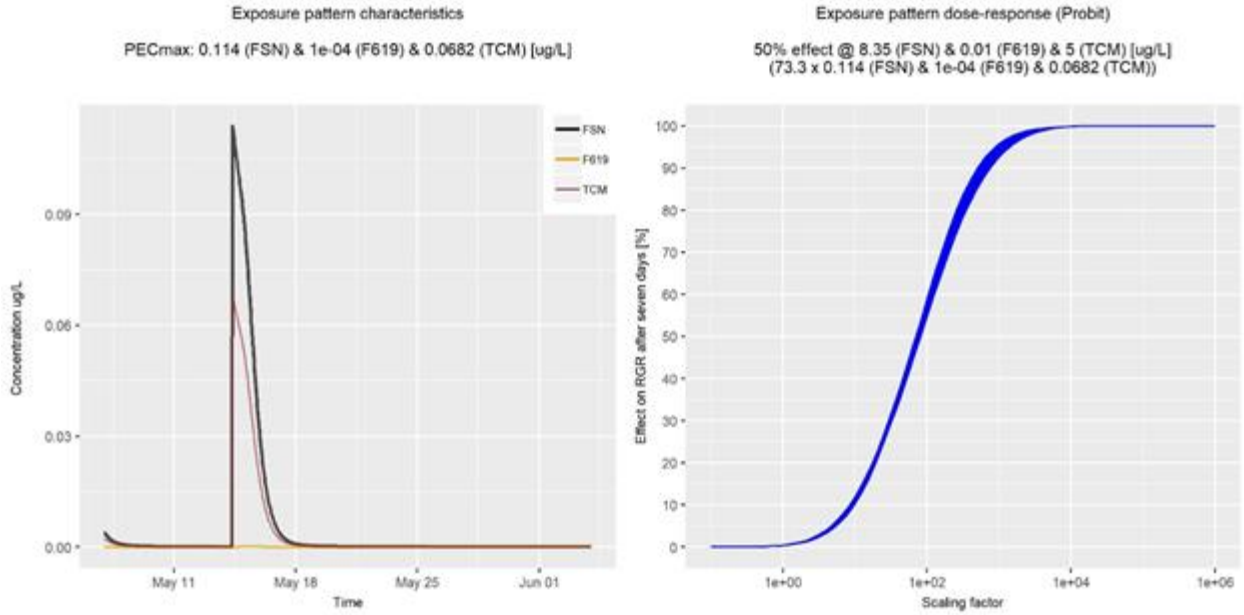


Figure A 29: Illustration of the evaluated exposure pattern and the corresponding dose-response relationship for scenario D3 ditch based on FOCUS Step 3, for use group C

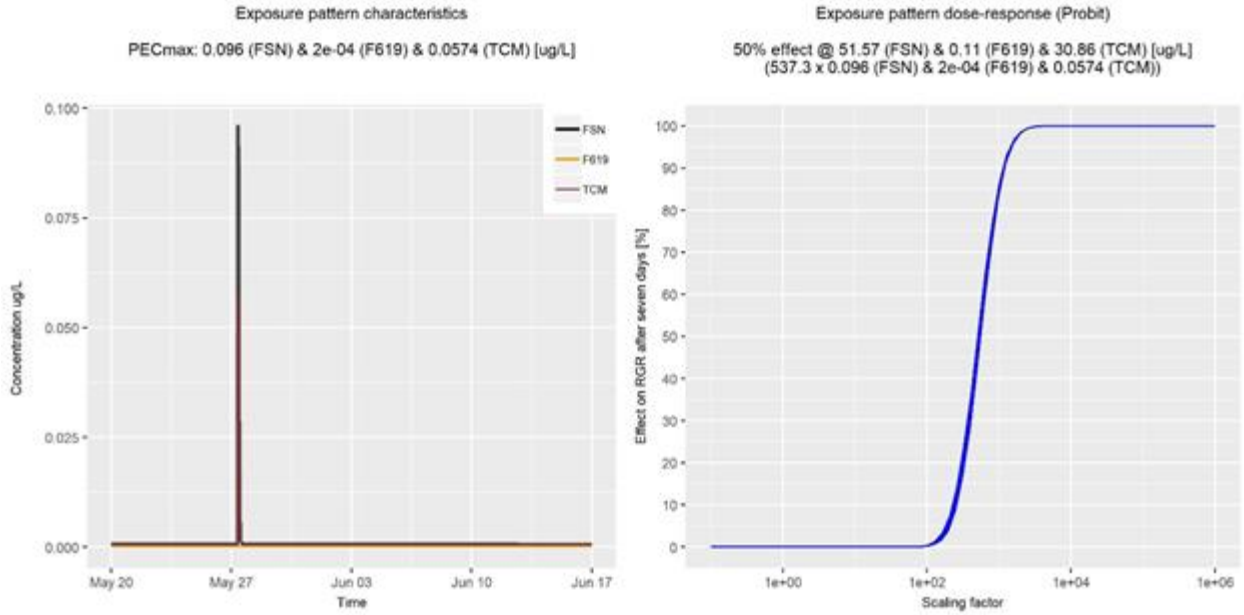


Figure A 30: Illustration of the evaluated exposure pattern and the corresponding dose-response relationship for scenario D4 stream based on FOCUS Step 3, for use group C

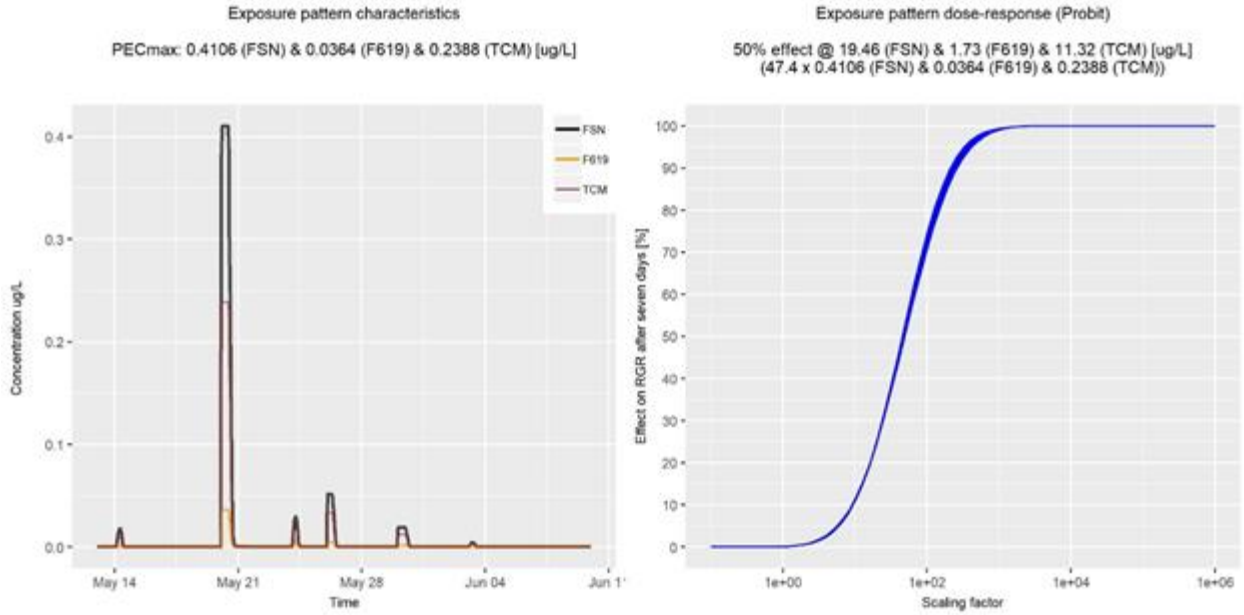


Figure A 31: Illustration of the evaluated exposure pattern and the corresponding dose-response relationship for scenario R1 stream based on FOCUS Step 3, for use group C

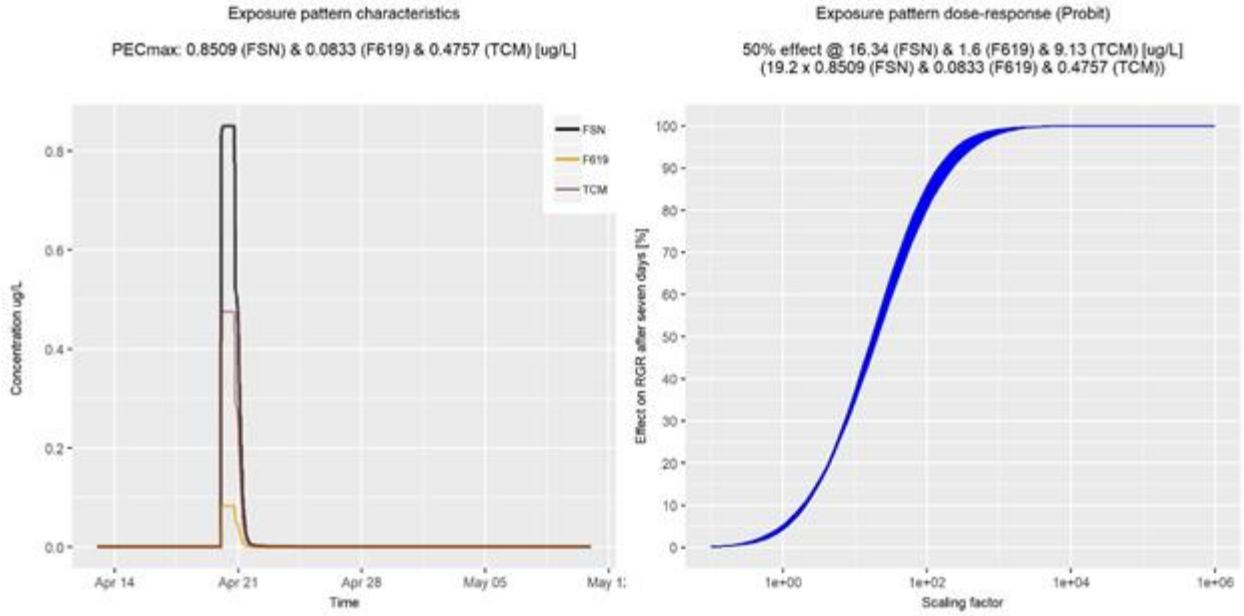


Figure A 32: Illustration of the evaluated exposure pattern and the corresponding dose-response relationship for scenario R3 stream based on FOCUS Step 3, for use group C

Table A 15: Assessing exposure patterns derived from $FOCUS_{sw}$ calculation based on FOCUS Step 3 to determine the corresponding exposure pattern that causes 50% effect by increasing the concentration and keeping all other pattern characteristics - <u>for use group C</u>

Scenario	Pattern mixture toxicity				
	PEC_{max} [µg/L] <u>FSN</u>	**PEC_{max} [µg/L] <u>F619</u>**	**PEC_{max} [µg/L] <u>TCM</u>**	**PEC_{max} (sum) [µg/L]**	**Seven-day period with highest sum of all concentrations (the assessed exposure pattern range is seven days before and 14 days after this period covering 28 days)**
D3 (Ditch)	0.114	1.00E-04	0.0682	0.1823	1992-05-14 - 1992-05-21
D4 (Stream)	0.096	2.00E-04	0.0574	0.1536	1985-05-27 - 1985-06-03
R1 (Stream)	0.4106	0.0364	0.2388	0.6859	1984-05-20 - 1984-05-27
R3 (Stream)	0.8509	0.0833	0.4757	1.41	1980-04-20 - 1980-04-27

	Scaling factor (used to multiply the entire mixture pattern)	**$EC50_{pattern}$<u>mix</u>**	**$RAC_{pattern}$<u>mix</u>**	**RQ_{mix} = PEC_{max} (sum)/ $RAC_{pattern}$mix**
D3 (Ditch)	73.3	13.36	1.34	0.136
D4 (Stream)	537.3	82.53	8.25	0.019
R1 (Stream)	47.4	32.52	3.25	0.211
R3 (Stream)	19.2	27.01	2.7	0.522

Overall conclusion: For overall conclusions, please refer to the dRR main part.

(e) Population effect modelling for FOCUSsw water bodies

The impact of FOCUS predicted exposure pattern on *Lemna* population dynamics is assessed by calculating the inhibition of the total biomass for each day of a year, considering all biologically active components of relevance to the product. This provides a realistic estimation of the impact over the entire year covering typical growing phases in spring and phases with low or no growth in winter. As the simulation should also account for uncertainty, the confidence intervals of some parameters have been considered. For each FOCUS scenario 100 simulations were conducted, each having randomly chosen parameters in the specified ranges as shown in the table below. For the initial biomass a variability of ± 20% was assumed as the data is derived from measurements in summer. For the density dependence a variability of only ± 10% was assumed due to the high reliability of the data source.

Table A 16: Uncertainty of model parameters and their range that is considered during simulations.

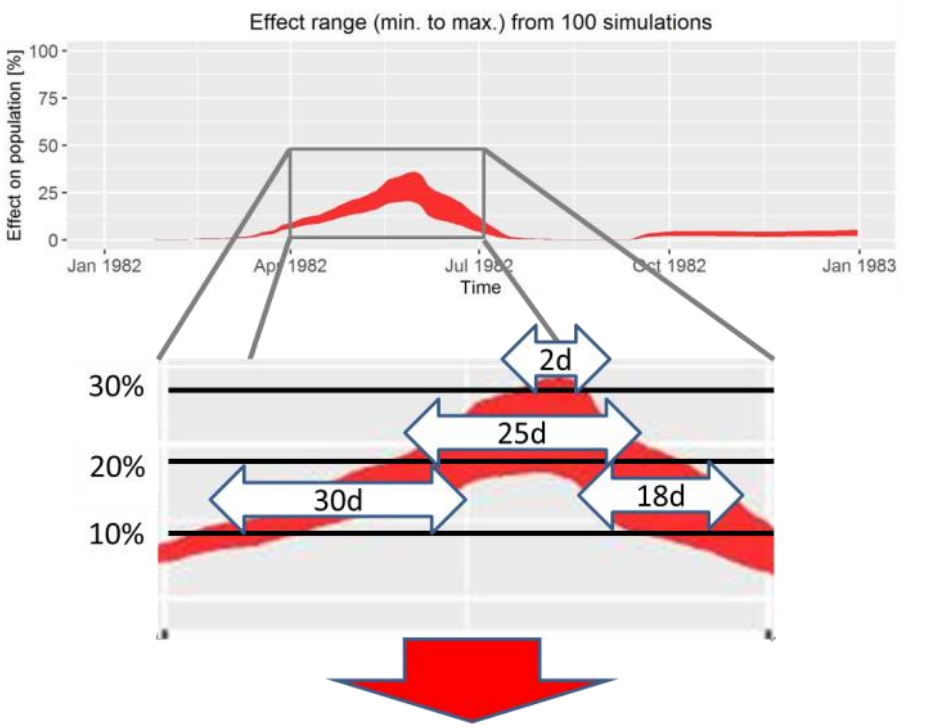
General Parameter	Description	Value	Unit	SE	CI
BM	Initial biomass	60	g/m²	-	28-141
Density	Maximum biomass density	176	g/m²	-	158-194
k_phot_max	Maximum growth rate	0.42	1/d	0.0060[1)]	0.41-0.43
Compound specific parameter (foramsulfuron)					
EC50(int)	Effective internal concentration at which 50% response is observed	0.9	µg/L	0.037	0.8-1.0
b	Value defining the slope of the dose-response function	2.8	-	0.14	2.5-3.1
P_up	Cuticular permeability	0.055	cm/d	0.0034	0.048-0.061
Compound specific parameter (AE F130619)					
EC50(int)	Effective internal concentration at which 50% response is observed	0.66	µg/L	0.015	0.63-0.69
b	Value defining the slope of the dose-response function	10.3	-	0.050	10.2-10.4
P_up	Cuticular permeability	0.83	cm/d	0.086	0.66-0.99
Compound specific parameter (thiencarbazone-methyl)					
EC50(int)	Effective internal concentration at which 50% response is observed	1.3	µg/L	0.032	1.2-1.4
b	Value defining the slope of the dose-response function	3.4	-	0.065	3.2-3.5
P_up	Cuticular permeability	0.0088	cm/d	0.0008	0.0072-0.01

[1)] Largest value during the model preparation for foramsulfuron, its metabolite AE F130619 and thiencarbazone-methyl

The impact was quantified as effects on standing crop (total biomass) per day. To provoke effects and gain information about exposure patterns that would have an impact on *Lemna* population two additional simulations were conducted for each GAP. In these simulations the Step 3 FOCUSsw exposure patterns were multiplied by a factor of either 10 or 100.

To link the model outcome to the specific protection goals the following criteria were applied. According to EFSA Aquatic Guidance Document (2013) the NOEC is equivalent to the EC_{10}. Therefore, negligible

effects were defined as effects < 10%. For small and medium effects, no clear thresholds are given in the EFSA AGD. Nevertheless, in Table 31 (page 118) for the MDD calculations small effects are defined < 50% and medium effects <70%. According to the EFSA Opinion on the development of specific protection goal options (EFSA, 2010) the effect levels should be linked to ecological relevance. This is missing for macrophytes at the moment. Due to the lack of guidance a pragmatic and conservative approach was taken in this study to define small and medium effects by means of 20 % increment steps. Since negligible effects are defined by EFSA as <10%, we defined small effect as <30% and medium effects as <50%. To compare model output to the specific protection goals, effects over time were summarized into tables as demonstrated in Figure A 33.



Year	0-10 %	10-20 %	20-30 %	30-40 %	40-50 %	> 50 %
D1 (Ditch)	290 (274 - 308)	48 (36 - 52)	25 (8 - 35)	2 (0 - 20)	0 (0 - 0)	0 (0 - 0)

Figure A 33: Summary of effects over time into effect table.

The effects were calculated daily as the deviation between treatment and control expressed in percent. Effects were investigated in bands with a resolution of 10%. All days within one effect band are added up and the respective sum of days within this effect class is entered in the respective column.

As the simulation should also account for uncertainty, the confidence intervals of some model parameters have been considered. For each FOCUS scenario 100 simulations were conducted, each having randomly chosen parameters only limited by pre-defined boundaries. Due to this the results of the population modelling are given in ranges.

Simulation results and discussion:

Original exposure patterns of product FSN+TCM OD 80 (50+30) FOCUS Step 3 results - no scaling factor

The detailed simulation results are summarised in tabular form below, showing number of days with biomass deviations (mean (minimum - maximum)) divided into effect classes and years based on 100 simulations and FOCUS exposure patterns.

The original (non-scaled) use patterns (use group B and C) are not expected to have adverse effects on macrophytes in any of the considered FOCUSsw scenario at all. Simulations did not show any days where the inhibition of population dynamics was above 10%.

Table A 17: Detailed simulation results for use group B (application in sugar beet) - original exposure situation: 1 × 50 g/ha FSN + 1 × 30 g/ha TCM

Scenario	<10 %	≥ 10 < 20 %	≥ 20 < 30 %	≥ 30 < 40 %	≥ 40 < 50 %	≥ 50 %
D3 (Ditch)	366 (366 - 366)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
D4 (Pond)	365 (365 - 365)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
D4 (Stream)	365 (365 - 365)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
R1 (Pond)	366 (366 - 366)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
R1 (Stream)	366 (366 - 366)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
R3 (Stream)	366 (366 - 366)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

Table A 18: Detailed simulation results for use group C (application in sugar beet) - original exposure situation: 2 × 25 g/ha FSN + 2 × 15 g/ha TCM

Scenario	<10 %	≥ 10 < 20 %	≥ 20 < 30 %	≥ 30 < 40 %	≥ 40 < 50 %	≥ 50 %
D3 (Ditch)	366 (366 - 366)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
D4 (Pond)	365 (365 - 365)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
D4 (Stream)	365 (365 - 365)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
R1 (Pond)	366 (366 - 366)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
R1 (Stream)	366 (366 - 366)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
R3 (Stream)	366 (366 - 366)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

Exaggerated exposure patterns – concentration scaled by factor 10

The original use patterns (use group B and C) multiplied by a factor of 10 are not expected to have adverse effects on macrophytes in any of the considered FOCUSsw scenario even when the exposure patterns are multiplied by ten. Simulations did not show any days where the inhibition of population dynamics was above 10%.

Table A 19: Detailed simulation results for use group B (application in sugar beet) - Exaggerated exposure situation, concentration scaled by factor 10: 1 × 50 g/ha FSN + 1 × 30 g/ha TCM

Scenario	<10 %	≥ 10 < 20 %	≥ 20 < 30 %	≥ 30 < 40 %	≥ 40 < 50 %	≥ 50 %
D3 (Ditch)	366 (366 - 366)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
D4 (Pond)	365 (365 - 365)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
D4 (Stream)	365 (365 - 365)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
R1 (Pond)	366 (366 - 366)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
R1 (Stream)	366 (366 - 366)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
R3 (Stream)	366 (366 - 366)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

Table A 20: Detailed simulation results for use group C (application in sugar beet) - Exaggerated exposure situation, concentration scaled by factor 10: 2 × 25 g/ha FSN + 2 × 15 g/ha TCM

Scenario	<10 %	≥ 10 < 20 %	≥ 20 < 30 %	≥ 30 < 40 %	≥ 40 < 50 %	≥ 50 %
D3 (Ditch)	366 (366 - 366)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
D4 (Pond)	365 (365 - 365)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
D4 (Stream)	365 (365 - 365)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
R1 (Pond)	366 (366 - 366)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
R1 (Stream)	366 (366 - 366)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
R3 (Stream)	366 (366 - 366)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

Exaggerated exposure patterns – concentration scaled by factor 100

Increasing the FOCUSsw exposure patterns by a factor of 100 causes in several of the FOCUSsw scenarios inhibitions of population dynamics. While D4 (Pond) and R1 (Pond) show strong effects >50% the effects in all other scenarios are small and do not exceed 30%.

Table A 21: Detailed simulation results for use group B (application in sugar beet) - Exaggerated exposure situation, concentration scaled by factor 100: 1 × 50 g/ha FSN + 1 × 30 g/ha TCM

Scenario	<10 %	≥ 10 < 20 %	≥ 20 < 30 %	≥ 30 < 40 %	≥ 40 < 50 %	> 50 %
D3 (Ditch)	**357 (357 - 358)**	**9 (8 - 9)**	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
D4 (Pond)	**304 (300 - 308)**	**8 (7 - 9)**	**7 (5 - 8)**	**7 (5 - 9)**	**8 (5 - 10)**	**31 (12 - 64)**
D4 (Stream)	**365 (365 - 365)**	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
R1 (Pond)	**278 (274 - 282)**	**9 (8 - 12)**	**8 (6 - 10)**	**12 (10 - 15)**	**10 (8 - 13)**	**48 (24 - 86)**
R1 (Stream)	**361 (355 - 366)**	**5 (0 - 11)**	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
R3 (Stream)	**359 (355 - 363)**	**7 (3 - 11)**	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

Table A 22: Detailed simulation results for use group C (application in sugar beet) - Exaggerated exposure situation, concentration scaled by factor 100: 2 × 25 g/ha FSN + 2 × 15 g/ha TCM

Scenario	<10 %	≥ 10 < 20 %	≥ 20 < 30 %	≥ 30 < 40 %	≥ 40 < 50 %	> 50 %
D3 (Ditch)	**350 (348 - 351)**	**12 (11 - 13)**	**4 (3 - 5)**	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
D4 (Pond)	**313 (307 - 318)**	**13 (11 - 15)**	**9 (7 - 11)**	**10 (7 - 22)**	**16 (0 - 23)**	**4 (0 - 20)**
D4 (Stream)	**365 (365 - 365)**	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
R1 (Pond)	**268 (261 - 273)**	**12 (11 - 14)**	**9 (8 - 10)**	**8 (6 - 9)**	**9 (8 - 10)**	**61 (41 - 88)**
R1 (Stream)	**351 (348 - 353)**	**15 (13 - 17)**	0 (0 - 3)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)
R3 (Stream)	**355 (352 - 357)**	**11 (9 - 14)**	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)	0 (0 - 0)

Overall conclusion: For overall conclusions, please refer to the dRR main part.

A 3.5 Detailed information to Section 9.5.2.8: Ecological modelling approaches, and their use in higher-tier risk assessment for the present product –considering multiyear exposure simulations

In response to concerns over the representativeness of the FOCUS model inherent weather year in the context of refined exposure assessment, additional FOCUS exposure simulations have been conducted for an extended period of 20 years (multi-year calculations). The present summary details the use of this multi-year exposure information in the context of *Lemna* population modelling, based on the general methodology outlined before.

For information on the methodology applied and results for exposure modelling, reference is made to the corresponding PEC_{sw} FOCUS Multiyear reports found presented in the E-fate section to this dRR.

Reference:	**KCP 10.2.3/06**
Title:	Lemna TK/TD modelling: Assessing the impact of FSN+TCM OD 80 applications on Lemna in Europe (FOCUSsw multiyear)
Report:	Heine, S.; 2019; EnSa-18-0892; M-665817-01-1
Authority registration No:	
Guideline(s):	none
Deviations:	none
GLP/GEP:	no
Acceptability:	
Duplication (if vertebrate study):	

For general information about the ecological modelling approaches, as well as model calibration, validation, and use in risk assessment, please refer to the description provided in Appendix A 3.4 (a)-(c) before. For the product FSN+TCM OD 80 (50+30) two critical use patterns (use groups B and C) were addressed and presented in the table below.

Table A 23: GAP translation for *Lemna* population effect modelling purposes

Use group (in dRR)	GAP No. (in report)	Crop	Growth stage & use timing	Max. apps	Interval (days)	Rate (kg a.s./ha)
B	I	Sugar beet	BBCH 10-18	1	-	FSN: 0.050 TCM: 0.030
C	II	Sugar beet	BBCH 10-18	2	10	FSN: 0.025 TCM: 0.015

In contrast to the procedures for the standard FOCUS year, aquatic exposure assessment for deriving exposure patterns for these use patterns that can be assessed with *Lemna* modelling was based on FOCUS multiyear calculations, see summaries in the E-Fate section to this dRR (for foramsulfuron and its metabolite AE F130619: Heine et al. 2017 a; [M-592861-02-1]; for thiencarbazone-methyl: Heine et al. 2017 b; [M-592862-01-1]).

In analogy to the procedures for the standard FOCUS year, the successfully calibrated and validated *Lemna* models were applied in two ways, referring to AGD levels Tier 2C, and Tier 3:

(a) *In-silico* time-variable exposure testing of *Lemna*, for derivation of $RAC_{pattern}$ to FOCUSsw scenarios:

'Virtual laboratory tests' on *Lemna* were simulated for the combination of foramsulfuron, its metabolite AE F130619 and thiencarbazone-methyl to address specific exposure patterns as provided by $FOCUS_{sw}$ multiyear calculations at Tier 2C (Section 9.5.2.6 / Appendix A3.3). Starting from the condensed realistic worst-case exposure pattern representations previously derived via percentile analysis of the FOCUSsw-multiyear output (80th percentile number, duration, maximum concentration, and 20th percentile interval of events exceeding the Tier 1 RAC; cf. A 3.3), the biological effect of such patterns was simulated for a *Lemna* population assumed to grow under constant environmental conditions representing an 'in-silico laboratory'. This was done for each of the 20 years that are provided by $FOCUS_{sw}$ multiyear calculations and for each scenario. The virtual laboratory tests were conducted for 4x7 days simulating the transfer of 12 fronds after seven days in accordance to standard *Lemna* tests and to be able to cover the most relevant exposures. To investigate the dose-response relationship, the simulation was repeated multiple times with arbitrarily scaled concentration dimension of the exposure pattern, while keeping constant all further parameters. Based on the so generated data set, an $EC_{50pattern}$ could be derived in analogy to the procedures of a standard laboratory experiment. This $EC_{50pattern}$ is a descriptor which specifically reflects macrophyte sensitivity for the exposure timecourse experienced in the regarded FOCUSsw scenario of interest, and can be compared to the $PEC_{sw,max}$ predicted for this scenario. The $RAC_{pattern}$ was calculated with the $EC50_{pattern(mix)}$ and a standard assessment factor of 10.

For defining the exposure characteristics of the combination of foramsulfuron, its metabolite AE F130619 and thiencarbazone-methyl, the exposure patterns of each component as provided by FOCUSsw multiyear calculations were used. Each year of the FOCUSsw multiyear calculations was assessed separately. To account for the duration of ecotoxicological *Lemna* tests, not the entire annual FOCUSsw patterns but the pattern from a 4-week (4x7 days) period starting with the seven days before the week having the maximum concentration (seven days area under the curve) of all mixture components were used. The RQ values were derived for each scenario and for each year by dividing the sum of all PEC_{max} through the $RAC_{pattern}$ of the combination. Afterwards, the 80th percentile RQ value for each scenario was selected and presented for the risk assessment.

For the assessment at Tier 2C, $RAC_{pattern}$ determinations were conducted with the active substances foramsulfuron and thiencarbazone-methyl and the foramsulfuron metabolite AE F130619 in combination. The determinations were done for all six FOCUS scenarios on FOCUS Step 3 and Step 4 level and can be found in the original report. In this section, simulation results are presented only for those scenarios that failed at Tier 1 level or required mitigation measures and were therefore also evaluated under point 9.5.2.6 (Tier 2C: Higher-tier assessment based on refined exposure testing combined with exposure pattern analysis – considering multi-year exposure simulations). An overview of the addressed scenarios for the different use groups is given below:

- Use group B: D3 ditch, D4 stream, R1 stream, R3 stream
- Use group C: D3 ditch, D4 stream, R1 stream, R3 stream

Sum of foramsulfuron, thiencarbazone-methyl and metabolite AE F130619

*$EC_{50pattern}$ determination and risk assessment for **use group B (≡GAP I) – FOCUS Step 3:***

In virtual laboratory tests based on FOCUS Step 3, simulations for each year were conducted and ranked by the RQ value that they provide. The values presented in the following belong to the FOCUS multi-year that caused the 80th percentile RQ value: To achieve an inhibition of the relative growth rate by 50% ($EC_{50pattern}$), the concentrations had to be increased to 12.56 µg/L for the scenario D3 ditch, to 1.67 µg/L for the scenario D4 stream, to 36.03 µg/L for the scenario R1 stream and to 23.87 µg/L for the scenario R3 stream. This corresponds to scaling factors of 29.9 for the scenario D3 ditch, of 8.4 for the scenario D4 stream, of 40.8 for the scenario R1 stream and of 10 for the scenario R3 stream. In agreement with an assessment factor of 10 the $RAC_{pattern}$ were therefore 1.26 µg/L, 0.17 µg/L, 3.6 µg/L and 2.39 µg/L for the

specific exposure situation predicted for the sum of biologically active compounds in the scenarios D3 ditch, D4 stream, R1 stream and R3 stream, for the application to sugar beet.

For risk assessment, these $RAC_{pattern}$ were compared to the sum of the $PEC_{sw,max}$ concentrations of all biologically active compounds of 0.4202 µg/L for the scenario D3 ditch, 0.1981 µg/L for the scenario D4 stream, 0.8827 µg/L for the scenario R1 stream or 2.3783 µg/L for the scenario R3 stream. This resulted in RQ_{mix} values (multiyear 80th percentile) of < 1 for all scenarios at FOCUS Step 3 level except for scenario D4 stream. The pattern characteristics of the scenario D4 stream inhibit growth the strongest in terms of having the smallest scaling factor to achieve a growth inhibition of 50%. The scenario D4 stream remains unresolved when risk assessment is based on $RAC_{pattern}$ and FOCUS Step 3.

As the drainage entry is driving the environmental concentrations in the scenarios that caused RQ_{mix} values > 1 step 4 concentrations were not considered for refinements.

Table A 24: Assessing exposure patterns derived from $FOCUS_{sw}$ multiyear calculation to determine the corresponding exposure pattern that causes 50% effect by increasing the even concentration and keeping all other pattern characteristics - Use group B

Scenario	Pattern mixture toxicity				
	PEC_{max} [µg/L] FSN	**PEC_{max} [µg/L] F619**	**PEC_{max} [µg/L] TCM**	**$PEC_{max\ (sum)}$ [µg/L]**	**Seven day period with highest sum of all concentrations (the assessed exposure pattern range is seven days before and 14 days after this period covering 28 days)**
D3 (Ditch)	0.2625	3.00E-04	0.1574	0.4202	1992-05-04 - 1992-05-11
D4 (Stream)	0.1147	0.0192	0.0642	0.1981	1987-07-20 - 1987-07-27
R1 (Stream)	0.5267	0.0583	0.2977	0.8827	1993-05-06 - 1993-05-13
R3 (Stream)	1.4385	0.1519	0.7879	2.3783	1979-04-05 - 1979-04-12

	Scaling factor (used to multiply the entire mixture pattern)	**$EC50_{patternmix}$**	**$RAC_{patternmix}$**	**80th percentile RQ_{mix} = $PEC_{max\ (sum)}$/ $RAC_{patternmix}$**
D3 (Ditch)	29.9	12.56	1.26	0.335
D4 (Stream)	8.4	1.67	0.17	**1.186**
R1 (Stream)	40.8	36.03	3.6	0.245
R3 (Stream)	10	23.87	2.39	0.997

*$EC_{50pattern}$ determination and risk assessment for **use group C (≡GAP II) – FOCUS Step 3:***

In virtual laboratory tests based on FOCUS Step 3, simulations for each year were conducted and ranked by the RQ value that they provide. The values presented in the following belong to the FOCUS multi-year that caused the 80th percentile RQ value: To achieve an inhibition of the relative growth rate by 50% ($EC_{50pattern}$), the concentrations had to be increased to 10.96 µg/L for the scenario D3 ditch, to 1.63 µg/L for the scenario D4 stream, to 37.83 µg/L for the scenario R1 stream and to 27.96 µg/L for the scenario R3 stream. This corresponds to scaling factors of 40.4 for the scenario D3 ditch, of 7 for the scenario D4 stream, of 45.5 for the scenario R1 stream and of 13.1 for the scenario R3 stream. In agreement with an assessment factor of 10 the $RAC_{pattern}$ were therefore 1.1 µg/L, 0.16 µg/L, 3.78 µg/L and 2.8 µg/L for the specific exposure situation predicted for the sum of biologically active compounds in the scenarios D3 ditch, D4 stream, R1 stream and R3 stream, for the application to sugar beet.

For risk assessment, these $RAC_{pattern}$ were compared to the sum of the $PEC_{sw,max}$ concentrations of all bio-

logically active compounds of 0.2715 µg/L for the scenario D3 ditch, 0.2322 µg/L for the scenario D4 stream, 0.832 µg/L for the scenario R1 stream or 2.1288 µg/L for the scenario R3 stream. This resulted in RQ_{mix} values (multiyear 80th percentile) of < 1 for all scenarios at FOCUS Step 3 level except for the scenario D4 stream. The pattern characteristics of scenario D4 stream inhibit growth the strongest in terms of having the smallest scaling factor to achieve a growth inhibition of 50%. The scenario D4 stream remains unresolved when risk assessment is based on $RAC_{pattern}$ and FOCUS Step 3.

As the drainage entry is driving the environmental concentrations in the scenarios that caused RQ_{mix} values > 1 step 4 concentrations were not considered for refinements.

Table A 25: Assessing exposure patterns derived from $FOCUS_{sw}$ multiyear calculation to determine the corresponding exposure pattern that causes 50% effect by increasing the even concentration and keeping all other pattern characteristics - Use group B

Scenario	Pattern mixture toxicity				
	PEC_{max} [µg/L] FSN	**PEC_{max} [µg/L] F619**	**PEC_{max} [µg/L] TCM**	**$PEC_{max\ (sum)}$ [µg/L]**	**Seven day period with highest sum of all concentrations (the assessed exposure pattern range is seven days before and 14 days after this period covering 28 days)**
D3 (Ditch)	0.114	1.00E-04	0.1574	0.2715	1992-05-04 - 1992-05-11
D4 (Stream)	0.1445	0.0236	0.0642	0.2322	1987-07-20 - 1987-07-27
R1 (Stream)	0.3787	0.0397	0.4136	0.832	1982-05-04 - 1982-05-11
R3 (Stream)	0.9414	0.0779	1.1095	2.1288	1990-03-21 - 1990-03-28

	Scaling factor (used to multiply the entire mixture pattern)	**$EC50_{patternmix}$**	**$RAC_{patternmix}$**	**80th percentile RQ_{mix} = $PEC_{max\ (sum)}$/ $RAC_{patternmix}$**
D3 (Ditch)	40.4	10.96	1.1	0.248
D4 (Stream)	7	1.63	0.16	**1.426**
R1 (Stream)	45.5	37.83	3.78	0.22
R3 (Stream)	13.1	27.96	2.8	0.761

(b) Population effect modelling for FOCUSsw water bodies

Dynamics of a *Lemna* population growing outdoors in an edge-of-field surface water body were simulated for each of the crop relevant $FOCUS_{sw}$ exposure scenarios, for the critical GAP situations of the present product. The simulations and data interpretations were held identical to those previously reported for the standard FOCUS year, however were extended in the time dimension to consider the hourly prediction of exposure over a 20 years period of scenario weather data, resulting from the multiyear PECsw simulation (cf. summary in dRR E-Fate section).

Again, to generate supportive information on the margin of safety, *Lemna* population dynamics were simulated as well for exaggerated exposure situations, generated via a multiplication of the concentration dimension of the exposure patterns with exemplary scaling factors of either 10 or 100.

A discussion of the results for the different use groups presented in the tables below is provided at the end of this section, i.e. after use group C.

Results for use group B (single spring application in sugar beet, 1 x 1.0 L prod./ha):

Only a condensed results overview is provided here for the sake of dRR length. For the full detailed simulation results reference is made to the original modelling report provided with this submission.

Table A 26: Effect magnitude and duration caused by FOCUS multiyear exposure patterns from use group B (1 x 50 g/ha foramsulfuron & 1 x 30 g/ha thiencarbazone-methyl). No scaling of exposure concentrations.

Level ►	Step3					
Scaling factor ►	1					
Year ▼	GAP I = use group B (use on maize: 1 x 50 g/ha FSN with consideration of metabolite AE F130619 & 1 x 30 g/ha TCM)					
Scenario ►	D3d	D4p	D4s	R1p	R1s	R3s
1975	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
1976	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
1977	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
1978	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
1979	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
1980	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
1981	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
1982	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
1983	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
1984	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
1985	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
1986	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
1987	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
1988	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
1989	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
1990	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
1991	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
1992	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
1993	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
1994	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.

Neg. = negligible; d = days

Table (contd.): Effect magnitude and duration caused by FOCUS multiyear exposure patterns from use group B (1 x 50 g/ha foramsulfuron & 1 x 30 g/ha thiencarbazone-methyl). Exposure concentrations scaled by factor 10.

Level ►	**Step3**					
Scaling factor ►	**10**					
Year ▼	**GAP I = use group B** (spring use on maize: 1 x 50 g/ha FSN with consideration of metabolite AE F130619 & 1 x 30 g/ha TCM)					
Scenario ►	**D3d**	**D4p**	**D4s**	**R1p**	**R1s**	**R3s**
1975	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
1976	Neg.	Neg.	Neg.	>30%<40% (35d)	Neg.	>10%<20% (5d)
1977	>10%<20% (1d)	Neg.	Neg.	Neg.	Neg.	Neg.
1978	Neg.	Neg.	Neg.	>10%<20% (12d)	Neg.	Neg.
1979	Neg.	Neg.	Neg.	Neg.	Neg.	>10%<20% (7d)
1980	Neg.	>10%<20% (5d)	>10%<20% (6d)	>20%<30% (27d)	Neg.	Neg.
1981	Neg.	Neg.	>20%<30% (15d)	>60%<70% (70d)	Neg.	Neg.
1982	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
1983	Neg.	Neg.	Neg.	Neg.	Neg.	>10%<20% (19d)
1984	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
1985	>10%<20% (8d)	Neg.	Neg.	Neg.	Neg.	Neg.
1986	>10%<20% (4d)	Neg.	Neg.	Neg.	Neg.	Neg.
1987	>10%<20% (18d)	Neg.	Neg.	Neg.	Neg.	>10%<20% (15d)
1988	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
1989	Neg.	>30%<40% (45d)	>20%<30% (12d)	Neg.	Neg.	Neg.
1990	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
1991	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
1992	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
1993	>10%<20% (3d)	Neg.	Neg.	Neg.	Neg.	>10%<20% (9d)
1994	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.

Neg. = negligible; d = days

Table (contd.): Effect magnitude and duration caused by FOCUS multiyear exposure patterns from use group B (1 x 50 g/ha foramsulfuron & 1 x 30 g/ha thiencarbazone-methyl). Exposure concentrations scaled by factor 100.

Level ►	Step3					
Scaling factor ►	100					
Year ▼	GAP I = use group B (spring use on maize: 1 x 50 g/ha FSN with consideration of metabolite AE F130619 & 1 x 30 g/ha TCM)					
Scenario ►	D3d	D4p	D4s	R1p	R1s	R3s
1975	>20%<30% (19d)	>60%<70% (62d)	Neg.	>50%<60% (59d)	Neg.	Neg.
1976	>20%<30% (11d)	>70%<80% (95d)	>40%<50% (36d)	>90% (140d)	>10%<20% (11d)	>20%<30% (28d)
1977	>20%<30% (14d)	>80%<90% (107d)	>50%<60% (34d)	>50%<60% (56d)	Neg.	>10%<20% (22d)
1978	>10%<20% (10d)	>70%<80% (67d)	Neg.	>90% (124d)	>20%<30% (24d)	>20%<30% (25d)
1979	>10%<20% (9d)	>70%<80% (66d)	Neg.	>50%<60% (43d)	Neg.	>40%<50% (39d)
1980	>10%<20% (17d)	>90% (233d)	>30%<40% (32d)	>90% (136d)	>20%<30% (23d)	>10%<20% (8d)
1981	Neg.	>90% (240d)	>50%<60% (51d)	>90% (247d)	Neg.	Neg.
1982	>10%<20% (1d)	>90% (238d)	>40%<50% (29d)	>90% (105d)	>10%<20% (12d)	>20%<30% (34d)
1983	Neg.	>70%<80% (135d)	Neg.	>50%<60% (62d)	Neg.	>30%<40% (34d)
1984	>10%<20% (21d)	>80%<90% (234d)	>20%<30% (27d)	>70%<80% (89d)	>10%<20% (7d)	>20%<30% (20d)
1985	>20%<30% (16d)	>70%<80% (70d)	Neg.	>50%<60% (70d)	Neg.	>10%<20% (22d)
1986	>30%<40% (23d)	>60%<70% (212d)	>20%<30% (19d)	>60%<70% (56d)	>20%<30% (8d)	>20%<30% (20d)
1987	>30%<40% (33d)	>90% (220d)	>30%<40% (31d)	>70%<80% (75d)	>10%<20% (2d)	>40%<50% (35d)
1988	Neg.	>80%<90% (174d)	Neg.	>40%<50% (44d)	Neg.	>10%<20% (6d)
1989	>10%<20% (2d)	>90% (227d)	>50%<60% (55d)	>30%<40% (42d)	Neg.	Neg.
1990	>20%<30% (7d)	>60%<70% (182d)	Neg.	>30%<40% (41d)	Neg.	>20%<30% (28d)
1991	Neg.	>80%<90% (222d)	>30%<40% (22d)	>40%<50% (56d)	Neg.	>10%<20% (7d)
1992	>10%<20% (9d)	>60%<70% (55d)	Neg.	>50%<60% (85d)	Neg.	>10%<20% (9d)
1993	>20%<30% (13d)	>60%<70% (69d)	Neg.	>50%<60% (60d)	>10%<20% (3d)	>30%<40% (25d)
1994	>20%<30% (15d)	>60%<70% (67d)	Neg.	>50%<60% (72d)	Neg.	>10%<20% (15d)

Neg. = negligible; d = days

Results for use group C (multiple applications in sugar beet, 2 x 0.5 L prod./ha):

Only a condensed results overview is provided here for the sake of dRR length. For the full detailed simulation results reference is made to the original modelling report provided with this submission.

Table A 27: Effect magnitude and duration caused by FOCUS multiyear exposure patterns from use group C (2 x 25 g/ha foramsulfuron & 2 x 15 g/ha thiencarbazone-methyl). No scaling of exposure concentrations.

Level ►	Step3					
Scaling factor ►	1					
Year ▼	GAP II = use group C (spring use on maize: 2 x 25 g/ha FSN with consideration of metabolite AE F130619 & 2 x 15 g/ha TCM)					
Scenario ►	D3d	D4p	D4s	R1p	R1s	R3s
1975	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
1976	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
1977	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
1978	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
1979	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
1980	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
1981	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
1982	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
1983	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
1984	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
1985	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
1986	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
1987	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
1988	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
1989	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
1990	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
1991	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
1992	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
1993	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
1994	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.

Neg. = negligible; d = days

Table (contd.): Effect magnitude and duration caused by FOCUS multiyear exposure patterns from use group C (2 x 25 g/ha foramsulfuron & 2 x 15 g/ha thiencarbazone-methyl). Exposure concentrations scaled by factor 10.

Level ►	**Step3**					
Scaling factor ►	**10**					
Year ▼	**GAP II = use group C** (spring use on maize: 1 x 45 g/ha FSN with consideration of metabolite AE F130619 & 1 x 15 g/ha TCM)					
Scenario ►	**D3d**	**D4p**	**D4s**	**R1p**	**R1s**	**R3s**
1975	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
1976	Neg.	Neg.	Neg.	>10%<20% (11d)	Neg.	>10%<20% (4d)
1977	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
1978	Neg.	Neg.	Neg.	>50%<60% (66d)	Neg.	>10%<20% (2d)
1979	Neg.	Neg.	Neg.	Neg.	Neg.	>10%<20% (10d)
1980	Neg.	>10%<20% (26d)	>10%<20% (9d)	Neg.	Neg.	Neg.
1981	Neg.	Neg.	>20%<30% (19d)	>40%<50% (53d)	Neg.	Neg.
1982	Neg.	>10%<20% (13d)	>10%<20% (7d)	Neg.	Neg.	Neg.
1983	Neg.	Neg.	Neg.	>20%<30% (28d)	Neg.	>10%<20% (15d)
1984	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
1985	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
1986	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
1987	Neg.	Neg.	>10%<20% (3d)	Neg.	Neg.	>10%<20% (12d)
1988	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
1989	Neg.	>40%<50% (60d)	>20%<30% (14d)	Neg.	Neg.	Neg.
1990	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
1991	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
1992	Neg.	Neg.	Neg.	>10%<20% (18d)	Neg.	>10%<20% (3d)
1993	Neg.	Neg.	Neg.	Neg.	Neg.	>10%<20% (8d)
1994	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.

Neg. = negligible; d = days

Table (contd.): Effect magnitude and duration caused by FOCUS multiyear exposure patterns from use group C (2 x 25 g/ha foramsulfuron & 2 x 15 g/ha thiencarbazone-methyl). Exposure concentrations scaled by factor 100.

Level ►	Step3					
Scaling factor ►	100					
Year ▼	GAP II = use group C (spring use on maize: 2 x 25 g/ha FSN with consideration of metabolite AE F130619 & 2 x 15 g/ha TCM)					
Scenario ►	D3d	D4p	D4s	R1p	R1s	R3s
1975	>20%<30% (29d)	>40%<50% (56d)	Neg.	>30%<40% (73d)	Neg.	Neg.
1976	>20%<30% (30d)	>40%<50% (72d)	>20%<30% (26d)	>90% (115d)	>10%<20% (11d)	>20%<30% (34d)
1977	>20%<30% (18d)	>60%<70% (76d)	>30%<40% (23d)	>30%<40% (49d)	Neg.	>10%<20% (24d)
1978	>10%<20% (14d)	>60%<70% (53d)	Neg.	>90% (250d)	>20%<30% (29d)	>20%<30% (26d)
1979	>10%<20% (13d)	>40%<50% (55d)	Neg.	>40%<50% (44d)	Neg.	>40%<50% (41d)
1980	>20%<30% (26d)	>90% (231d)	>30%<40% (32d)	>90% (112d)	>20%<30% (25d)	>10%<20% (10d)
1981	Neg.	>90% (242d)	>50%<60% (56d)	>90% (245d)	>10%<20% (1d)	Neg.
1982	>30%<40% (16d)	>90% (265d)	>40%<50% (33d)	>90% (109d)	>10%<20% (15d)	>30%<40% (37d)
1983	>10%<20% (2d)	>70%<80% (178d)	Neg.	>90% (224d)	Neg.	>30%<40% (41d)
1984	>10%<20% (30d)	>80%<90% (234d)	>30%<40% (33d)	>80%<90% (104d)	>10%<20% (13d)	>20%<30% (23d)
1985	>20%<30% (21d)	>70%<80% (68d)	Neg.	>40%<50% (80d)	Neg.	>10%<20% (29d)
1986	>30%<40% (26d)	>70%<80% (208d)	>20%<30% (21d)	>50%<60% (84d)	>20%<30% (10d)	>20%<30% (20d)
1987	>20%<30% (38d)	>90% (218d)	>30%<40% (33d)	>50%<60% (71d)	Neg.	>40%<50% (38d)
1988	>10%<20% (3d)	>70%<80% (180d)	Neg.	>20%<30% (35d)	Neg.	>10%<20% (8d)
1989	>10%<20% (3d)	>90% (225d)	>60%<70% (79d)	>50%<60% (56d)	Neg.	Neg.
1990	>20%<30% (7d)	>70%<80% (190d)	>10%<20% (1d)	>20%<30% (29d)	Neg.	>20%<30% (34d)
1991	>10%<20% (10d)	>80%<90% (222d)	>30%<40% (24d)	>30%<40% (46d)	Neg.	>10%<20% (10d)
1992	>20%<30% (16d)	>50%<60% (75d)	Neg.	>90% (218d)	Neg.	>20%<30% (44d)
1993	>20%<30% (20d)	>50%<60% (63d)	Neg.	>20%<30% (52d)	>10%<20% (1d)	>30%<40% (28d)
1994	>20%<30% (18d)	>50%<60% (65d)	Neg.	>60%<70% (70d)	Neg.	>10%<20% (20d)

Neg. = negligible; d = days

Overall, the simulations showed that no adverse effects on *Lemna* populations are to be expected from all FOCUS multiyear exposure scenarios for the two investigated uses (use groups B and C). Without artificial scaling of exposure concentrations, negligible effects were found for all run-off and drainage scenarios and all investigated years.
Assuming a 10-fold exaggerated exposure situation for use group B, only small (>10%/<20% and >20%/<30%) effects were predicted for five years in scenario D3 ditch, for one year in scenario D4 pond, for three years in D4 stream, for two years in scenario R1 pond and for five years in scenario R3 stream. Medium (>30%/<40%) effects were predicted for one year in scenario D4 pond and for one year in scenario R1 pond. Maximum effects of >60/<70% were predicted for a single year in scenario R1 pond. For use group C, only small (>10%/<20% and >20%/<30%) effects were predicted for two years in scenario D4 pond, for five years in scenario D4 stream, for three years in R1 pond and for seven years in scenario R3 stream. Medium (>40%/<50%) effects were predicted for one year in scenario D4 pond and for one year in scenario R1 pond. Maximum effects of >50%/<60% were predicted for a single year in scenario R1 pond. For all other run-off and drainage scenarios, effects were negligible for the 10-fold exaggerated exposure patterns.
A 100-fold increase of the exposure patterns resulted in a significant expression of effects in D4 pond and R1 pond water bodies in most of the simulation years. This applies to all two assessed uses (use groups B and C). For the scenario D4 stream of use group B, maximum effects (>50%) were predicted for three years, medium effects (≤50%) were predicted for five years and small effects (≤30%) were predicted for two years. For the scenario D4 stream of use group C, maximum effects (>50%) were predicted for two years, medium effects (≤50%) were predicted for six years and small effects (≤30%) were predicted for three years. For all other scenarios, only small (≤30%) to medium (≤50%) effects were predicted in some or most of the simulation years for the 100-fold exaggerated exposure patterns representing the critical uses assessed.