

FINAL REGISTRATION REPORT

Part B

Section 9

Ecotoxicology

Detailed summary of the risk assessment

Product code: **102000025743**

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

Central Zone

Zonal Rapporteur Member State: Poland

NATIONAL ASSESSMENT: Poland
(Re-Authorisation)

Applicant: **Bayer Crop Science Division**

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

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



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Version history

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

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9 Ecotoxicology (KCP 10)

This national addendum contains an aquatic risk assessment for foramsulfuron, AE F130619 and thien-carbazone-methyl for the most sensitive species *Lemna gibba* based on FOCUS Step 4 PEC_{sw} calculations considering VFSmod.

9.1 Critical GAP and overall conclusions

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. interval between applications (days)	L product/ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Birds	Mammals	Aquatic organisms	Bees	Non-target arthro- pods	Soil organisms	Non-target plants
Zonal uses (field or outdoor uses, certain types of protected crops)																				
22	POL	Sugar beet (BEAVA)	F	AETCY, ECHCG, VIOAR, STEME, LAMP, 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)	F	AETCY, ECHCG, VIOAR, STEME, LAMP, MATIN, CHEAL, GALAP, POLCO, POLAV, POLPE, BRSNN, VERAR, THLAR, POAAN, VERPE	spraying (broadcast, overall)	10-18 B1: 10-12 B2: 12-18	a) B1: 1 B2: 1 b) 2	B1: - B2: - 10 d after B1	a) B1: 0.5 B2: 0.5 b) 1	a) FSN 25 + TCM 15 b) FSN 50 + TCM 30	100-300	as per growth stage								

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

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

Explanation for column 15 – 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

9.1.1.1 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)

Please refer to the core dossier.

9.1.1.2 Effects on aquatic organisms (KCP 10.2)

Risk assessment for the individual substances considering VFSmod

At Tier 1, all FOCUS run-off scenarios are resolved considering PEC_{max} and following mitigation measures:

Use group B (1 × 1.0 L prod./ha)	Scenario R1	-
	Scenario R3	10 m VFSmod
Use group C (± 2 × 0.5 L prod./ha)	Scenario R1	-
	Scenario R3	20 m VFSmod

For further refinements (Tier 2 & 3) and for FOCUS drainage scenarios, please refer to the core dossier.

Combined risk assessment considering VFSmod

At Tier 1, all FOCUS run-off scenarios are resolved considering PEC_{max} and following mitigation measures:

Use group B (1 × 1.0 L prod./ha)	Scenario R1	10 m VFSmod or 5 m VFSmod + 50% drift reduction
	Scenario R3	20 m VFSmod
Use group C (± 2 × 0.5 L prod./ha)	Scenario R1	5 m VFSmod
	Scenario R3	20 m VFSmod

For further refinements (Tier 2 & 3) and for FOCUS drainage scenarios, please refer to the core dossier.

9.1.1.3 Effects on bees (KCP 10.3.1)

Please refer to the core dossier.

9.1.1.4 Effects on arthropods other than bees (KCP 10.3.2)

Please refer to the core dossier.

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

Please refer to the core dossier.

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

Please refer to the core dossier.

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

Please refer to the core dossier.

9.1.2 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 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
B *	Sugar beet, single application use no. 22 [POL]	Application rate: 1 × 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]	Application rate: 2 × 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

* Please note: For consistency reasons, the use groups are assigned to the same letters as in the core dossier. Use group A (as defined in the core dossier) is not relevant for this national addendum and is therefore omitted.

9.1.3 Consideration of metabolites

Please refer to the core dossier.

9.2 Effects on birds (KCP 10.1.1)

Please refer to the core dossier.

9.2.1 Toxicity data

9.2.1.1 Justification for new endpoints

9.2.2 Risk assessment for spray applications

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

9.2.2.2 Higher-tier risk assessment

9.2.2.3 Drinking water exposure

9.2.2.4 Effects of secondary poisoning

9.2.2.5 Biomagnification in terrestrial food chains

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

9.2.4 Overall conclusions

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

Please refer to the core dossier.

9.3.1 Toxicity data

9.3.1.1 Justification for new endpoints

9.3.2 Risk assessment for spray applications

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

9.3.2.2 Higher-tier risk assessment

9.3.2.3 Drinking water exposure

9.3.2.4 Effects of secondary poisoning

9.3.2.5 Biomagnification in terrestrial food chains

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

9.3.4 Overall conclusions

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

Please refer to the core dossier.

9.5 Effects on aquatic organisms (KCP 10.2)

The effectiveness of vegetated filter strips for mitigating entries into surface water via runoff can be modelled using the PRZM-SWAN-VFSMOD models (SETAC MAgPIE working group, 2013)¹. In addition to the Tier 1 risk assessment based on FOCUS Step 4 calculations provided in the core dossier, a risk assessment for R-scenarios based on FOCUS Step 4 calculations considering VFSmod is therefore provided in this national addendum for foramsulfuron, AE F130619 and thiencazone-methyl. Furthermore, a combined toxicity risk assessment considering VFSmod is provided.

9.5.1 Toxicity data

Please refer to the core dossier.

9.5.1.1 Justification for new endpoints

Please refer to the core dossier.

¹ SETAC, 2013: MAgPIE. Mitigating the Risks of Plant Protection Products in the Environment. Editors: Anne Alix, Colin Brown, Ettore Capri, Gerhard Goerlitz, Burkhard Golla, Katja Knauer, Volker Laabs, Neil Mackay, Alexandru Marchis, Elena Alonso Prados, Wolfgang Reinert, Martin Streloke, Véronique Poulsen. Proceedings of the two-part SETAC Workshop Mitigating the Risk of Plant Protection Products in the Environment. ISBN: 978-1-880611-99-9

9.5.2 Risk assessment

Foramsulfuron

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

Sugar beet, 1 × 50 g FSN/ha	Scenario	PECsw STEP 4 - foramsulfuron			PECsw / RAC RAC = 0.101 µg/L		
		PEC gl-max			RQ		
Nozzle red.	Vegetated strip (m)	VFSmod 5 m	VFSmod 10 m	VFSmod 20 m	VFSmod 5 m	VFSmod 10 m	VFSmod 20 m
	No spray buffer (m)	5 m	10 m	20 m	5 m	10 m	20 m
None	R1 Pond	0.0095	0.0068	0.0045	0.0941	0.0673	0.0446
50 %		0.0047	0.0034	0.0022	0.0465	0.0337	0.0218
75 %		0.0024	0.0017	0.0011	0.0238	0.0168	0.0109
90%		0.0011	0.0007	0.0004	0.0109	0.0069	0.0040
None	R1 Stream	0.0762	0.0404	0.0209	0.7545	0.4000	0.2069
50 %		0.0381	0.0202	0.0105	0.3772	0.2000	0.1040
75 %		0.0191	0.0101	0.0052	0.1891	0.1000	0.0515
90%		0.0135	0.0040	0.0021	0.1337	0.0396	0.0208
None	R3 Stream	0.1478	0.0942	0.0294	1.4634	0.9327	0.2911
50 %		0.1478	0.0942	0.0147	1.4634	0.9327	0.1455
75 %		0.1478	0.0942	0.0074	1.4634	0.9327	0.0733
90%		0.1478	0.0942	0.0029	1.4634	0.9327	0.0287

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

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

Sugar beet, 2 × 25 g FSN/ha	Scenario	PECsw STEP 4 - foramsulfuron			PECsw / RAC RAC = 0.101 µg/L		
		PEC gl-max			RQ		
Nozzle red.	Vegetated strip (m)	VFSmod 5 m	VFSmod 10 m	VFSmod 20 m	VFSmod 5 m	VFSmod 10 m	VFSmod 20 m
	No spray buffer (m)	5 m	10 m	20 m	5 m	10 m	20 m
None	R1 Pond	0.0069	0.0048	0.0032	0.0683	0.0475	0.0317
50 %		0.0039	0.0024	0.0016	0.0386	0.0238	0.0158
75 %		0.0026	0.0012	0.0008	0.0257	0.0119	0.0079
90%		0.0017	0.0005	0.0003	0.0168	0.0050	0.0030
None	R1 Stream	0.0319	0.0166	0.0085	0.3158	0.1644	0.0842
50 %		0.0309	0.0083	0.0043	0.3059	0.0822	0.0426
75 %		0.0309	0.0041	0.0021	0.3059	0.0406	0.0208
90%		0.0309	0.0017	0.0009	0.3059	0.0168	0.0089
None	R3 Stream	0.3451	0.2200	0.0120	3.4168	2.1782	0.1188
50 %		0.3451	0.2200	0.0060	3.4168	2.1782	0.0594
75 %		0.3451	0.2200	0.0030	3.4168	2.1782	0.0297
90%		0.3451	0.2200	0.0012	3.4168	2.1782	0.0119

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

AE F130619

Table 9.5-3: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for AE F130619 based on FOCUS Step 4 calculations and toxicity data for aquatic plants with mitigation of spray drift and run-off (based on VFSmod) for the use of FSN+TCM OD 80 in sugar beet – Use: sugar beet, 1 × 50 g foramsulfuron/ha (use group B)

Sugar beet, 1 × 50 g FSN/ha	Scenario	PEC _{sw} STEP 4 - AE F130619			PEC _{sw} / RAC RAC = 0.0889 µg/L		
		PEC gl-max			RQ		
Nozzle red.	Vegetated strip (m)	VFSmod 5 m	VFSmod 10 m	VFSmod 20 m	VFSmod 5 m	VFSmod 10 m	VFSmod 20 m
	No spray buffer (m)	5 m	10 m	20 m	5 m	10 m	20 m
None	R1 Pond	0.0002	0.0001	0.0001	0.0022	0.0011	0.0011
50 %		0.0001	0.0001	<0.0001	0.0011	0.0011	0.0011
75 %		0.0001	<0.0001	<0.0001	0.0011	0.0011	0.0011
90%		0.0001	<0.0001	<0.0001	0.0011	0.0011	0.0011
None	R1 Stream	0.0015	<0.0001	<0.0001	0.0169	0.0011	0.0011
50 %		0.0015	<0.0001	<0.0001	0.0169	0.0011	0.0011
75 %		0.0015	<0.0001	<0.0001	0.0169	0.0011	0.0011
90%		0.0015	<0.0001	<0.0001	0.0169	0.0011	0.0011
None	R3 Stream	0.0176	0.0113	0.0001	0.1980	0.1271	0.0011
50 %		0.0176	0.0113	<0.0001	0.1980	0.1271	0.0011
75 %		0.0176	0.0113	<0.0001	0.1980	0.1271	0.0011
90%		0.0176	0.0113	<0.0001	0.1980	0.1271	0.0011

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

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

Sugar beet, 2 × 25 g FSN/ha	Scenario	PEC _{sw} STEP 4 - AE F130619			PEC _{sw} / RAC RAC = 0.0889 µg/L		
		PEC gl-max			RQ		
Nozzle red.	Vegetated strip (m)	VFSmod 5 m	VFSmod 10 m	VFSmod 20 m	VFSmod 5 m	VFSmod 10 m	VFSmod 20 m
	No spray buffer (m)	5 m	10 m	20 m	5 m	10 m	20 m
None	R1 Pond	0.0002	0.0001	0.0001	0.0022	0.0011	0.0011
50 %		0.0002	0.0001	<0.0001	0.0022	0.0011	0.0011
75 %		0.0001	<0.0001	<0.0001	0.0011	0.0011	0.0011
90%		0.0001	<0.0001	<0.0001	0.0011	0.0011	0.0011
None	R1 Stream	0.0028	<0.0001	<0.0001	0.0315	0.0011	0.0011
50 %		0.0028	<0.0001	<0.0001	0.0315	0.0011	0.0011
75 %		0.0028	<0.0001	<0.0001	0.0315	0.0011	0.0011
90%		0.0028	<0.0001	<0.0001	0.0315	0.0011	0.0011
None	R3 Stream	0.0340	0.0218	<0.0001	0.3825	0.2452	0.0011
50 %		0.0340	0.0218	<0.0001	0.3825	0.2452	0.0011
75 %		0.0340	0.0218	<0.0001	0.3825	0.2452	0.0011
90%		0.0340	0.0218	<0.0001	0.3825	0.2452	0.0011

Thiencarbazone-methyl

Table 9.5-5: 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 (based on VFSmod) for the use of FSN+TCM OD 80 in sugar beet – Use: sugar beet, 1 × 30 g thiencarbazone-methyl/ha (use group B)

Sugar beet, 1 × 30 g TCM/ha	Scenario	PECsw STEP 4 - Thiencarbazone-methyl			PECsw / RAC RAC = 0.131 µg/L		
		PEC gl-max			RQ		
Nozzle red.	Vegetated strip (m)	VFSmod 5 m	VFSmod 10 m	VFSmod 20 m	VFSmod 5 m	VFSmod 10 m	VFSmod 20 m
	No spray buffer (m)	5 m	10 m	20 m	5 m	10 m	20 m
None	R1 Pond	0.0057	0.0041	0.0027	0.0435	0.0313	0.0206
50 %		0.0028	0.0020	0.0013	0.0214	0.0153	0.0099
75 %		0.0014	0.0010	0.0007	0.0107	0.0076	0.0053
90%		0.0006	0.0004	0.0003	0.0046	0.0031	0.0023
None	R1 Stream	0.0458	0.0243	0.0127	0.3496	0.1855	0.0969
50 %		0.0229	0.0122	0.0063	0.1748	0.0931	0.0481
75 %		0.0114	0.0061	0.0032	0.0870	0.0466	0.0244
90%		0.0072	0.0024	0.0013	0.0550	0.0183	0.0099
None	R3 Stream	0.0821	0.0519	0.0178	0.6267	0.3962	0.1359
50 %		0.0821	0.0519	0.0089	0.6267	0.3962	0.0679
75 %		0.0821	0.0519	0.0045	0.6267	0.3962	0.0344
90%		0.0821	0.0519	0.0018	0.6267	0.3962	0.0137

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

Table 9.5-6: 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 (based on VFSmod) for the use of FSN+TCM OD 80 in sugar beet – Use: sugar beet, 2 × 15 g thiencarbazone-methyl/ha (use group C)

Sugar beet, 2 × 15 g TCM/ha	Scenario	PECsw STEP 4 - Thiencarbazone-methyl			PECsw / RAC RAC = 0.131 µg/L		
		PEC gl-max			RQ		
Nozzle red.	Vegetated strip (m)	VFSmod 5 m	VFSmod 10 m	VFSmod 20 m	VFSmod 5 m	VFSmod 10 m	VFSmod 20 m
	No spray buffer (m)	5 m	10 m	20 m	5 m	10 m	20 m
None	R1 Pond	0.0040	0.0028	0.0019	0.0305	0.0214	0.0145
50 %		0.0022	0.0014	0.0009	0.0168	0.0107	0.0069
75 %		0.0015	0.0007	0.0005	0.0115	0.0053	0.0038
90%		0.0010	0.0003	0.0002	0.0076	0.0023	0.0015
None	R1 Stream	0.0192	0.0100	0.0051	0.1466	0.0763	0.0389
50 %		0.0168	0.0050	0.0026	0.1282	0.0382	0.0198
75 %		0.0168	0.0027	0.0013	0.1282	0.0206	0.0099
90%		0.0168	0.0010	0.0005	0.1282	0.0076	0.0038
None	R3 Stream	0.1907	0.1205	0.0072	1.4557	0.9198	0.0550
50 %		0.1907	0.1205	0.0036	1.4557	0.9198	0.0275
75 %		0.1907	0.1205	0.0018	1.4557	0.9198	0.0137
90%		0.1907	0.1205	0.0007	1.4557	0.9198	0.0053

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

Combined toxicity assessment

Table 9.5-7: Combined toxicity assessment – aquatic macrophytes, Tier 1

	RQ values based on EU endpoints			RQ _{MIX}
Aquatic macrophytes	FSN	AE F130619	TCM	
use group B – FOCUS Step 3/4 use on sugarbeet / rate = 1 × 50 g/ha FSN + 1 × 30 g/ha TCM ≡ 1 × 1.0 L prod./ha				
Without mitigation (results based on EU endpoints, taken from point 9.5.2.4 in the core dossier)				
R1/Pond	0.1495	0.0112	0.0656	0.2263
R1/Stream	1.7950	0.2171	0.8305	2.8426
R3/Stream	3.6079	0.4859	1.5634	5.6572
Mitigation: 5 m VFSmod + 50% drift reducing nozzles				
R1/Stream	0.3772	0.0169	0.1748	0.5689
Mitigation: 10 m VFSmod				
R1/Stream	0.4000	0.0011	0.1855	0.5866
Mitigation: 20 m VFSmod				
R3/Stream	0.2911	0.0011	0.1359	0.4281
use group C – FOCUS Step 3/4 use on sugarbeet / rate = 2 × 25 g/ha FSN + 2 × 15 g/ha TCM ≡ 2 × 0.5 L prod./ha				
Without mitigation (results based on EU endpoints, taken from point 9.5.2.4 in the core dossier)				
R1/Pond	0.2446	0.0191	0.1099	0.3736
R1/Stream	4.0653	0.4094	1.8229	6.2976
R3/Stream	8.4248	0.9370	3.6313	12.9931
Mitigation: 5 m VFSmod				
R1/Stream	0.3158	0.0315	0.1466	0.4939
Mitigation: 20 m VFSmod				
R3/Stream	0.1188	0.0011	0.055	0.1749

PEC/RAC ratios above the relevant trigger of 1 are shown in **bold**

Overall conclusion from Tier 1 combined toxicity risk assessment:

The following table shows the conclusions of the Tier 1 combined risk assessment as presented under point 9.5.2.4 of the core dossier (grey font colour) and additionally the conclusions of the Tier 1 risk assessment considering VFSmod as presented in this national addendum (black font colour). Note that VFSmod is only calculated for run-off scenarios.

Table 9.5-8: 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 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
	FOCUS Step 4 based on PEC _{max} and VFSmod	See conclusions without VFSmod #	See conclusions without VFSmod #	See conclusions without VFSmod #	No mitigation needed	Resolved 10 m VFSmod or 5 m VFSmod + 50% drift reduction	Resolved 20 m VFSmod

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

VFSmod is only calculated for run-off scenarios

Table 9.5-9: 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 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
	FOCUS Step 4 based on PEC _{max} and VFSmod	See conclusions without VFSmod #	See conclusions without VFSmod #	See conclusions without VFSmod #	No mitigation needed	Resolved 5 m VFSmod	Resolved 20 m VFSmod

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

VFSmod is only calculated for run-off scenarios

9.5.3 Overall conclusions

Risk assessment for the individual substances considering VFSmod

At Tier 1, all FOCUS run-off scenarios are resolved considering PEC_{max} and following mitigation measures:

Use group B (1 × 1.0 L prod./ha)	Scenario R1	-
	Scenario R3	10 m VFSmod
Use group C (1 × 0.5 L prod./ha)	Scenario R1	-
	Scenario R3	20 m VFSmod

For further refinements (Tier 2 & 3) and for FOCUS drainage scenarios, please refer to the core dossier.

Combined risk assessment considering VFSmod

At Tier 1, all FOCUS run-off scenarios are resolved considering PEC_{max} and following mitigation measures:

Use group B (1 × 1.0 L prod./ha)	Scenario R1	10 m VFSmod or 5 m VFSmod + 50% drift reduction
	Scenario R3	20 m VFSmod
Use group C (1 × 0.5 L prod./ha)	Scenario R1	5 m VFSmod
	Scenario R3	20 m VFSmod

For further refinements (Tier 2 & 3) and for FOCUS drainage scenarios, please refer to the core dossier.

zRMS comments:

The conclusion of risk assessment for both active substances and metabolite of AE F130619 for aquatic organism included in the Core Dossier, B9 was as follows:

Forasulfuron- Tier 1

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
Tier 1	FOCUS Step 4, based on PEC_{max}	resolved 5 m buffer	resolved 5 m buffer	resolved 10 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
Tier 1	FOCUS Step 4, based on PEC_{max}	resolved 5 m buffer	resolved 5 m buffer	resolved 20 m buffer

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

Thiencarbazone-methyl- Tier 1

The PEC/RAC ratio is below <1 for thiencarbazone-methyl when following risk mitigation 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

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

Combined risk assessment:

Summary table of the aquatic risk assessment for combined toxicity included in the Core Dossier, B9.

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
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

* 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 (Section reference)	Approach	D3 ditch	D4 pond	D4 stream	R1 pond	R1 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

Therefore, further refinement for R1 scenario for use in Group C was needed.

In the same time for R1 scenario for use in group B the 20 meter buffer zone resolve the risk

In addition, to the Tier 1 risk assessment based on FOCUS Step 4 calculations provided in the core dossier, a risk assessment for R-scenarios based on FOCUS Step 4 calculations considering VFSmod were provided in this national addendum for Poland for foramsulfuron, AE F130619 and thiencarbazone-methyl.

Conclusion from the risk assessment for active substance - Foramsulfuron-methyl considering VFS_{mod} is preseted below:

At Tier 1, FOCUS run-off R1 scenario is resolved considering PEC_{max} without needs using buffer zone.

Use group B (1×1.0 L prod./ha)	Scenario R1	-no buffer zone
Use group C (2×0.5 L prod./ha)	Scenario R1	-no buffer zone

Risk assessment for the individual substance - Thiencarbazon-methyl considering VFS_{mod} is presented below:

At Tier 1, FOCUS run-off R1 scenario is resolved considering PEC_{max} without needs using buffer zone.

Use group B (1 × 1.0 L prod./ha)	Scenario R1	-no buffer zone
Use group C (2× 0.5 L prod./ha)	Scenario R1	-no buffer zone

Combined risk assessment considering VFS_{mod}

The combined toxicity risk assessment considering VFS_{mod} was also provided by the applicant to refined risk for R1 scenario, relevant for Poland

At Tier 1, all FOCUS run-off scenarios are resolved considering PEC_{max} and following mitigation measures:

Use group B (1 × 1.0 L prod./ha)	Scenario R1	10 m VFS _{mod} or 5 m VFS _{mod} + 50% drift reduction
Use group C (2× 0.5 L prod./ha)	Scenario R1	5 m VFS _{mod}

In conclusion:

The risk is considered acceptable when the following risk mitigation measures to surface water bodies are applied:

-10 m VFS_{mod} or 5 m VFS_{mod} + 50% drift reduction for use in group B (1 × 1.0 L prod./ha)

- 5 m VFS_{mod} for use in group C (2 × 0.5 L prod./ha)

9.6 Effects on bees (KCP 10.3.1)

Please refer to the core dossier.

9.6.1 Toxicity data

zRMS comment:

According to Reg. 284/2009 the chronic tests for adult and larvae bees should be provided by the applicant when GD for Bees will be implemented at EU level.

9.6.1.1 Justification for new endpoints

9.6.2 Risk assessment

9.6.2.1 Hazard quotients for bees

9.6.2.2 Higher-tier risk assessment for bees (tunnel test, field studies)

9.6.3 Effects on bumble bees

9.6.4 Effects on solitary bees

9.6.5 Overall conclusions

9.7 Effects on arthropods other than bees (KCP 10.3.2)

Please refer to the core dossier.

9.7.1 Toxicity data

9.7.1.1 Justification for new endpoints

9.7.2 Risk assessment

9.7.2.1 Risk assessment for in-field exposure

9.7.2.2 Risk assessment for off-field exposure

9.7.2.3 Additional higher-tier risk assessment

9.7.2.4 Risk mitigation measures

9.7.3 Overall conclusions

9.8 Effects on non-target soil meso- and macrofauna (KCP 10.4)

Please refer to the core dossier.

9.8.1 Toxicity data

9.8.1.1 Justification for new endpoints

9.8.2 Risk assessment

9.8.2.1 First-tier risk assessment

9.8.2.2 Higher-tier risk assessment

9.8.3 Overall conclusions

9.9 Effects on soil microbial activity (KCP 10.5)

Please refer to the core dossier.

9.9.1 Toxicity data

9.9.1.1 Justification for new endpoints

9.9.2 Risk assessment

9.9.3 Overall conclusions

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

Please refer to the core dossier.

zRMS comment:

According to the results provided in the Core assessment based on the **propabilistic** approach 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 $HR_{50} = 3.949$ ml/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**

9.10.1 Toxicity data

9.10.1.1 Justification for new endpoints

9.10.2 Risk assessment

9.10.2.1 Tier-1 risk assessment (based screening data)

9.10.2.2 Tier-2 risk assessment (based on dose-response data)

9.10.2.3 Higher-tier risk assessment

9.10.2.4 Risk mitigation measures

9.10.3 Overall conclusions

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

Please refer to the core dossier.

9.12 Monitoring data (KCP 10.8)

Please refer to the core dossier.

9.13 Classification and Labelling

Please refer to the core dossier.

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

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

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
-	-				

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

Refer to Core section

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
-	-				

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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

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

A 2.2.1.2 Aquatic invertebrates

A 2.2.1.3 Effects on aquatic algae

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
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
A 2.3.1.1.2	KCP 10.3.1.1.2	Acute contact toxicity to bees
A 2.3.1.2	KCP 10.3.1.2.	Chronic toxicity to bees
A 2.3.1.3	KCP 10.3.1.3	Effects on honey bee development and other honey bee life stages
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
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	
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

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
A 2.4.2.2	KCP 10.4.2.2	Higher tier testing
A 2.5	KCP 10.5	Effects on soil nitrogen transformation
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
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
A 2.7	KCP 10.7	Effects on other terrestrial organisms (flora and fauna)
A 2.8	KCP 10.8	Monitoring data