

REGISTRATION REPORT

Part B

Section 9

Ecotoxicology

Detailed summary of the risk assessment

Product code: 102000028562

Product name(s): Deltamethrin + flupyradifurone

EC 85 (10+75 g/L)

Chemical active substance(s):

Deltamethrin, 10 g/L

Flupyradifurone, 75 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(Authorisation)

Applicant: Bayer Crop Science Division

Submission date: August 2019 (updated in 2020 and 2021)

MS Finalisation date: October 2021 (initial Core Assessment)

March 2022 (final Core Assessment)

Version history

When	What
01/08/2019	Original Bayer Crop Science Division submission
11/2020	<p>Updated further to the ZRMS Poland's request from 10/09/2020 for new environmental exposure calculations :</p> <ul style="list-style-type: none"> - New groundwater and surface water modelling for deltamethrin and its metabolites based on EU agreed parameters. - New groundwater and surface water modelling for flupyradifuron performed with consideration of PUF (TSCF) of 0. <p>For flupyradifuron metabolites only additional groundwater modelling is required.</p>
03/2021	Updated further to the ZRMS Poland's request from 08/02/2021 maintaining the demand for groundwater and surface water additional modelling for flupyradifuron performed with consideration of PUF (TSCF) of 0 (due to the non-acceptance of Bayer argumentation and proposal to perform only calculations with PUF (TSCF) of 0.5).
10/2021	<p>Initial zRMS assessment</p> <p>The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are struck through and shaded for transparency.</p>
03/2022	<p>Final report (Core Assessment updated following the commenting period)</p> <p>Additional information/assessments included by the zRMS in the report in response to comments recieved from the cMS and the Applicant are highlighted in yellow. Information no longer relevant is struck through and shaded.</p>

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9 Ecotoxicology (KCP 10)

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: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g saf- ener/ syner- gist per ha	Conclusion						
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product/ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Birds	Mammals	Aquatic organisms ***	Bees ****	Non-target arthropods	Soil organisms	Non-target plants
Zonal uses (field or outdoor uses, certain types of protected crops)																				
11	POL	Rape, winter (BRSNW)	F	CEUTNA, CEUTQU	spraying (foliar)	30-49 (spring)	a) 2 b) 2	14	a) 0.75 b) 1.5	a) DLT 7.5 + FPF 56.25 b) DLT 15 + FPF 112.5	200-600	as per growth stage	Autumn applications not covered by the aquatic risk assessment performed with Steps 3+4 PEC _{sw}	A	A	R	N	R	A	A
12	POL	Rape, spring (Canola) (BRSNS)	F	CEUTNA, CEUTQU	spraying (foliar)	30-49 (spring)	a) 2 b) 2	14	a) 0.75 b) 1.5	a) DLT 7.5 + FPF 56.25 b) DLT 15 + FPF 112.5	200-600	as per growth stage	Autumn applications not covered by the aquatic risk assessment performed with Steps 3+4 PEC _{sw}	A	A	R	N	R	A	A
13	POL	Rape, winter (BRSNW)	F	MELIAE	spraying (foliar)	50-57 50-59	a) 2 b) 2	14	a) 0.75 b) 1.5	a) DLT 7.5 + FPF 56.25 b) DLT 15 + FPF 112.5	200-600	as per growth stage	Application not later than 10 days before flowering	A	A	R	N	R	A	A
14	POL	Rape, spring (Canola) (BRSNS)	F	MELIAE	spraying (foliar)	50-57 50-59	a) 2 b) 2	14	a) 0.75 b) 1.5	a) DLT 7.5 + FPF 56.25 b) DLT 15 + FPF 112.5	200-600	as per growth stage	Application not later than 10 days before flowering	A	A	R	R	R	A	A

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
15	POL	Rape, winter (BRSNW)	F	CEUTAS, DASYBR	spraying (foliar)	70-79 65-79	a) 2 b) 2	14	a) 0.5 b) 1	a) DLT 5 + FPF 37.5 b) DLT 10 + FPF 75	200-600	45		A	A	R	R	R	A	A
16	POL	Rape, spring (Canola) (BRSNS)	F	CEUTAS, DASYBR	spraying (foliar)	70-79 65-79	a) 2 b) 2	14	a) 0.5 b) 1	a) DLT 5 + FPF 37.5 b) DLT 10 + FPF 75	200-600	45		A	A	R	R	R	A	A

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

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

*** Risk assessment finalised following the commenting period; risk mitigation measures required in order to protect aquatic organisms. The risk assessment for aquatic organisms could not be finalised at this stage and further calculations should be submitted by the Applicant during the commenting period (for details, see point 9.5 of this document)

**** Risk assessment finalised following the commenting period; risk mitigation measures required in order to protect bees must be decided at the CMS level. The risk assessment for bees could not be finalised at this stage and further information should be submitted by the Applicant during the commenting period (for details, see points 9.1.1.3 and 9.6 of this document)

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/m² 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

A summary of the conclusions and potential risk mitigation measures for the risk assessments conducted in this core assessment document is as follows.

zRMS comments:

Conclusions provided in points below were corrected by the zRMS accordingly depending on the outcome of the performed risk assessment.

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)

The risk assessment demonstrates that the use of formulation DLT+FPF EC 85 in OSR is unlikely to result in unacceptable risk to birds or other terrestrial vertebrates.

9.1.1.2 Effects on aquatic organisms (KCP 10.2)

zRMS comments:

As the risk assessment performed for DLT+FPF EC 85 was not entirely accepted by the zRMS and further calculations are deemed necessary, no final conclusion at this stage is possible.

The Applicant is kindly requested to provide following calculations during the commenting period:

- Risk assessment for aquatic invertebrates from deltamethrin based on the EAC of 3.2 ng a.s./L with an AF of 2.
- Combined risk assessment performed fully in line with EFSA (2013) on the basis of endpoints agreed by the zRMS.
- Additional explanations to justify selection of the substance for chemical verification in the studies performed with DLT+FPF EC 85 or data to confirm that deltamethrin was most stable during the study.

Respective data and calculations based on the listed above assumptions were provided by the Applicant during the commenting period. On the basis of the risk assessment provided in the initial dRR and additional evaluation performed following the commenting period acceptable risk to aquatic species may be concluded provided that respective risk mitigation measures are respected. Summary of risk mitigation measures for deltamethrin and flupyradifurone identified in respective surface water scenarios depending on the use pattern is presented in table below.

Use group	Intended uses	RMM relevant for winter OSR uses		RMM relevant for spring OSR uses	
		DLT	FPF	DLT	FPF
C	Winter and spring OSR (spring application) 2 × 0.75 L/ha, 14 d interval BBCH 30-49	D3 5 m + 90% DRN; 20 m + 75% DRN	D3 None	D3 5 m + 90% DRN; 20 m + 75% DRN	D3 None
		D4 5 m + 90% DRN; 20 m + 75% DRN	D4 None	D4 5 m + 90% DRN; 20 m + 75% DRN	D4 None
		D5 5 m + 90% DRN; 20 m + 75% DRN	D5 None	D5 5 m + 90% DRN; 20 m + 75% DRN	D5 None
		R1 5 m + 90% DRN; 10 m + 75% DRN	R1 20 m VFS	R1 5 m + 90% DRN; 10 m + 75% DRN	R1 10 m VFS

		R3 10 m + 90% DRN; 20 m + 75% DRN	R3 10 m VFS		
D	Winter and spring OSR (spring /summer application) 2 × 0.75 L/ha, 14 d interval BBCH 50-59	D3 5 m + 90% DRN; 20 m + 75% DRN D4 5 m + 90% DRN; 20 m + 75% DRN D5 5 m + 90% DRN; 20 m + 75% DRN R1 5 m + 90% DRN; 10 m + 75% DRN R3 10 m + 90% DRN; 20 m + 75% DRN	D3 None D4 None D5 None R1 10 m VFS R3 20 m VFS	D3 5 m + 90% DRN; 20 m + 75% DRN D4 5 m + 90% DRN; 20 m + 75% DRN D5 5 m + 90% DRN; 20 m + 75% DRN R1 5 m + 90% DRN; 10 m + 75% DRN	D3 None D4 None D5 None R1 10 m VFS
E	Winter and spring OSR (spring/summer application) 2 × 0.5 L/ha, 14 d interval BBCH 65-79	D3 5 m + 90% DRN; 10 m + 75% DRN; 20 m + 50% DRN D4 5 m + 90% DRN; 10 m + 75% DRN; 20 m + 50% DRN D5 5 m + 90% DRN; 10 m + 75% DRN; 20 m + 50% DRN R1 5 m + 90% DRN; 10 m + 75% DRN; 20 m + 50% DRN R3 5 m + 90% DRN; 10 m + 75% DRN; 20 m + 50% DRN	D3 None D4 None D5 None R1 10 m VFS R3 10 m VFS	D3 5 m + 90% DRN; 10 m + 75% DRN; 20 m + 50% DRN D4 5 m + 90% DRN; 10 m + 75% DRN; 20 m + 50% DRN D5 5 m + 90% DRN; 10 m + 75% DRN; 20 m + 50% DRN R1 5 m + 90% DRN; 10 m + 75% DRN; 20 m + 50% DRN	D3 None D4 None D5 None R1 10 m VFS
<p>From the above table the concerned Member States should select risk mitigation measures applicable in their countries.</p> <p>Additional calculations may be required by cMS that do not accept surface water exposure derived using FOCUS models.</p>					

The refined risk assessments for deltamethrin and flupyradifurone demonstrate a safe use of the formulation DLT+FPF EC 85 in winter and spring OSR considering the risk mitigation measures specified.

9.2 Effects on bees (KCP 10.3.1)

9.2.1.1 Effects on bees (KCP 10.3.1)

zRMS comments:

The acute risk assessment performed in line with current guidance document (SANCO/10329/2002 rev 2 final) demonstrated unacceptable acute oral and contact risk from deltamethrin for both application rates (2x0.75 L product/ha and 2x0.5 L product/ha). The contact toxicity from the formulated product was unacceptable from both rates, while the oral risk was unacceptable only from the higher rate. The acute oral and contact risk from flupyradifurone was acceptable from both application rates of DLT+FPF EC 85.

In order to resolve the risk the Applicant submitted higher tier studies: one tunnel study performed with DLT+FPF EC 85 and multiple semi-field as well as field studies performed with solo formulation of the individual active compounds. It is, however, noted that the combined risk resulting from the exposure to mixture of deltamethrin and flupyradifurone cannot be addressed based on semi-field and field studies performed with solo formulations of particular compounds and the semi-field and field studies should be performed with the formulation for which authorisation is sought, at least in case of products containing more than one active substances.

In the only tunnel study performed with DLT+FPF EC 85 the test item was applied 10 days before introduction of bees to the tunnels and for this reason its results are not relevant to address the risk resulting from direct overspray of the bees foraging on the flowering oilseed rape. However, results of the study may be used to confirm lack of residual toxicity after application outside of the flowering (i.e. for BBCH stages 30-59 and 70-79) ~~provided that more detailed evaluation of results obtained during colonies assessments is available (only limited information is provided in the study report).~~ Application after the flowering (BBCH 70-79) will not lead to exposure to residues of the product, since bees will no longer forage in the treated crop. However, application at BBCH 59 (i.e. just before the flowering) may not warrant the 10 day window between the last application and start of the flowering, which was included in the tunnel study by Taenzler (2017). In consultation with the efficacy specialising in agronomy of oilseed rape, the following restriction is proposed to be displayed on the label:

The last application must be performed not later than at BBCH 57, but not less than 10 days before beginning of the flowering (BBCH 60). Application date must be thus determined on the basis of the expected number of days to flowering, estimated with consideration of the expected weather conditions, variety, agricultural practices and the BBCH stage on the day when the decision is taken.

In addition to that the product cannot be applied when flowering weeds are present in the treated crop and the application must be performed in the evening in order to avoid accidental exposure to the spray drift of bees foraging on flowering weeds outside the field or in adjacent crops.

Since risk mitigation measures are country specific, provided above indications should be considered as proposal only. Each cMS must decide what risk mitigation measures will be applicable in their countries.

Please note that in case the application at BBCH 30-57 is not accepted in some countries, application after the flowering at BBCH 70-79 is still possible.

In order to support application of DLT+FPF EC 85 to flowering oilseed rape, more data must be generated. Study/studies should be performed in line with most up-to-date requirement (e.g. in case of field indications of EFSA bee guidance should be considered in order to assure sufficient statistical power of the study). Exposure regime should reflect the intended use pattern (including two applications of the product due to systemicity of flupyradifurone) and all parameters necessary to evaluate effects on the colony development should be investigated (in case of field studies it is highly recommended to investigate effects on the overwintering success). As the intended crop is highly attractive to bees, consideration of the surrogate attractive crop (i.e. *Phacelia tanacetifolia*) is not necessary and the study (studies) should be performed in the intended crop.

In conclusion, the zRMS is of the opinion that the available data are not sufficient to support application of DLT+FPF EC 85 during the flowering period of oilseed rape. Application outside the flowering is possible provided that **respective risk mitigation measures indicated above are respected.** ~~more detailed evaluation of results obtained during colonies assessments in the study by Taenzler (2017, M 598914 01 1) is submitted during the commenting period. At this stage no final conclusion may be taken and the risk remains unresolved.~~

Furthermore, studies on chronic and larvae toxicity of DLT+FPF EC 85 should be submitted in order to fulfil data requirements as set by the Commission Regulation (EU) No 284/2013. These studies may be waived provided that the Applicant will perform relevant semi-field and field studies including all relevant parameters.

~~The results of laboratory, semi field and field studies on bees and the corresponding first and higher tier risk assessment showed that the use of the formulated product will not pose any unacceptable risk to bees.~~

9.3 Effects on arthropods other than bees (KCP 10.3.2)

9.3.1.1 Effects on arthropods other than bees (KCP 10.3.2)

When considering the proposed risk mitigation measure no unacceptable effects on non-target arthropods are to be expected from the use of the formulation according to the GAP.

Group	Mitigation
OSR (use group A) 2 × 0.75 L/ha, 14 d interval	No-spray buffer zone of 10m
	No-spray buffer zone of 5 m with 50% drn
	90% drn without additional buffer
OSR (use group B) 2 × 0.5 L/ha, 14 d interval	No-spray buffer zone of 5m
	90% drn without additional buffer

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

As demonstrated by the risk assessment, no unacceptable effects on earthworms and other soil macro-organisms are to be expected from the application of the product according to the proposed use pattern.

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

The TER value for the risk envelope approach considering the highest application rate is above the trigger of. Accordingly, the use of the product as recommended is considered to be safe.

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

No further information is available or considered to be necessary.

9.3.2 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 0-1: Critical use pattern of DLT+FPF EC 85 grouped according to application rate

Grouping according to application rate			
Group	Intended uses	Relevant use parameters for grouping	Relevant parameter or value for sorting
A	OSR (spring/winter) 2 × 0.75 L/ha, 14 d interval BBCH 30-59	Application rate	Same application rate, number of applications and application interval
B	OSR (spring/winter) 2 × 0.5 L/ha, 14 d interval BBCH 65-79	Application rate	Same application rate, number of applications, application interval and growth stage
C	Winter and spring OSR (spring/autumn application) 2 × 0.75 L/ha, 14 d interval BBCH 30-49	Application rate	Relevant for aquatic risk assessment. Same application rate, number of applications, application interval.
D	Winter and spring OSR (spring/autumn/summer application) 2 × 0.75 L/ha, 14 d interval BBCH 50-59	Application rate	Relevant for aquatic risk assessment. Same application rate, number of applications, application interval.
E	Winter and spring OSR (spring/summer application) 2 × 0.5 L/ha, 14 d interval	Application rate	Relevant for aquatic risk assessment. Same application rate, number of applications, application

Grouping according to application rate			
Group	Intended uses	Relevant use parameters for grouping	Relevant parameter or value for sorting
	BBCH 65-79		interval.

zRMS comments:

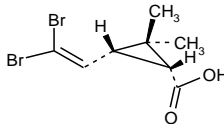
It is noted that for use groups C and D autumn applications to winter oilseed rape are indicated, while in surface water exposure assessment application dates relevant for autumn uses were considered only for Step 1+2 calculations. At Step 3+4 application dates were consistent with spring/summer applications and for this reason autumn uses of DLT+FPF EC 85 to winter OSR cannot be authorised.

Following the comment provided by the Applicant, Table 9.1-2 was further amended in order to make it more clear that autumn applications are not intended in the GAP for DLT+FPF EC 85. In addition to that also the application rate for uses in group E was corrected from 0.75 to 0.5 L/ha.

9.3.3 Consideration of metabolites

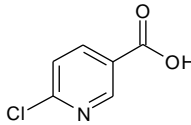
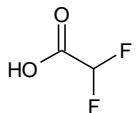
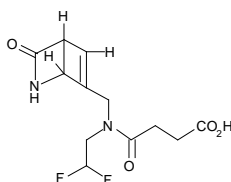
A list of metabolites found in environmental compartments is provided below. The need for conducting a metabolite-specific risk assessment in the context of the evaluation of DLT+FPF EC 85 is indicated in the table.

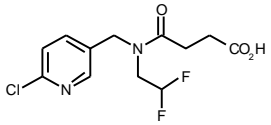
Table 0-2 Metabolites of deltamethrin

Metabolite	Chemical structure	Molar mass	Maximum occurrence in compartments	Risk assessment required?
Br ₂ Ca		298.0 g/mole	Soil: 23% (aerobic), 52% (anaerobic) Water/sediment: 13.3% *	Yes, aquatic organisms

* Value was stated in the DAR (max formed in the outdoor microcosm study) but not stated in the final LoEP.

Table 0-3 Metabolites of flupyradifurone

Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartment	Risk assessment required?
6-CNA 6-Chloronicotinic acid (IUPAC)	157.6 g/mole		Soil: 17.1%	Yes soil organisms aquatic organisms
DFA Difluoroacetic acid (IUPAC)	96.0 g/mole		Soil: 33.9% Water/Sediment: 6.9%	Yes soil organisms aquatic organisms
BYI 02960- azabicyclo- succinamide	288.3 g/mole		Water (plus light): 25.9%	Yes aquatic organisms

Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartment	Risk assessment required?
BYI 02960-succinamide	306.7 g/mole		Water (plus light): 39.6%	Yes aquatic organisms

zRMS comments:

Deltamethrin

Information regarding soil metabolites of deltamethrin is in line with the Review Report for deltamethrin 6504/VI/99-final of 2002, which is still valid LoEP.

With regard to maximum occurrence of metabolite Br₂CA in water it is noted that according to the LoEP its maximum formation in aquatic systems could not be determined due to position of ¹⁴C-labelling. No clear information may be also obtained from the DAR of 1998 or Addendum of 2002, since residues of metabolite Br₂CA are not expressed in terms of %AR, but as concentrations in water or sediment. In summary of the outdoor microcosm study by Schanné & van der Kolk (2001) and Schanné (2001a and 2001b) available in Addendum of 2002, the maximum occurrence of Br₂CA is reported as 20% AR, while in the LoEP prepared by the RMS (working document of 2002) it is indicated that in higher-tier studies (micro-mesocosms and natural ponds) metabolite Br₂CA was found at 23 and 53%. It should be, however, noted that none of these values was eventually reported in the Review Report of 2002 and metabolite was considered neither in exposure nor risk assessment.

It is noted that maximum occurrence of Br₂CA at 13.3% AR has been already agreed in the course of the zonal evaluations of at least two formulations of the same Applicant (Multirose, evaluated by AT as zRMS in 2016 and Decis 15 EW evaluated by BE as the zRMS in 2018) and for this reason this value is also agreed for DLT+FPF EC 85 for consistency.

Flupyradifurone

Information regarding metabolites of flupyradifurone is in line with EU agreed endpoints as reported in EFSA Journal 2015;13(2):4020.

9.4 Effects on birds (KCP 10.1.1)

9.4.1 Toxicity data

Avian toxicity studies have been carried out with deltamethrin and flupyradifurone. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on birds of DLT+FPF EC 85 were not evaluated as part of the EU assessment of deltamethrin. However, the provision of further data on DLT+FPF EC 85 is not considered essential, because studies done with mammals indicate that the formulation is not more toxic than expected based on its active substances (see 9.3.1.). Furthermore for DLT+FPF EC 85 there is no indication that there would be increased toxicity and the acute risk assessment shows a very high margin safety, clearly above the required triggers. For this reasons and also considering animal welfare, no acute oral toxicity study with the preparation was deemed necessary and the risk to birds from the formulation can be adequately assessed from risk assessment for the active substances.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

Table 9.4-1: Endpoints and effect values relevant for the risk assessment for birds

Species	Substance	Exposure System	Results	Reference
Bobwhite quail	Deltamethrin	Oral Acute	LD ₅₀ > 2250 mg a.s./kg bw	EC Review Report 6504/ VI/99- final (2002), 1-78 Monograph annex B Ecotoxicology
Bobwhite quail	Deltamethrin	Dietary Reproductive toxicity 22 w Long-term	NOEC ≥ 450 mg a.s./kg diet NOED ≥ 53.6 mg a.s./kg bw/d ^A	EU Review Report 6504/ VI/99- final (2002), 1-78 Monograph annex B Ecotoxicology
Bobwhite quail	Flupyradifurone	Oral Acute	LD ₅₀ = 232 mg a.s./kg bw	EFSA Journal 2015;13(2):4020
Bobwhite quail	Flupyradifurone	Dietary Reproductive toxicity 23 w feeding Long-term	NOEL = 14 mg a.s./kg bw/d	EFSA Journal 2015;13(2):4020

^A Calculation of endpoint according to Guidance Document on Risk Assessment for Birds and Mammals (SANCO/4145/ 2000-final (2002).

zRMS comments:

Avian toxicity data provided in Table 9.2-1 are in line with EU agreed endpoints reported in the Review Report for deltamethrin (6504/VI/99-final, 2002) and EFSA Journal 2015;13(2):4020 for flupyradifurone.

9.4.1.1 Justification for new endpoints

No deviation from EU agreed endpoints.

9.4.2 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 also covers the risk for birds from all other intended uses in group B (see 9.3.2).

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

The results of the acute and reproductive first-tier risk assessments are summarised in the following tables.

Table 9.4-2: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of DLT + FPF EC85 in OSR (use group A)

Intended use	OSR (use group A)				
Active substance/product	Deltamethrin				
Application rate (kg/ha)	2 × 0.0075, 14 days interval				
Acute toxicity (mg/kg bw)	>2250				
TER criterion	10				
Crop scenario Growth stage	Generic focal species	SV₉₀	MAF₉₀	DDD₉₀ (mg/kg bw/d)	TER_a
Oilseed rape Late - late (with seeds) (BBCH 30-99)	Small insectivorous bird “dunnoch”	7.4	1.2	0.0666	>33784
Oilseed rape BBCH 30–39	Small omnivorous bird “lark”	7.2	1.2	0.0648	>34722
Oilseed rape BBCH ≥ 40	Small omnivorous bird “lark”	6.0	1.2	0.054	>41667
Oilseed rape BBCH 30–39	Medium herbivorous/granivorous bird “pigeon”	2.4	1.2	0.0216	>104167
Oilseed rape BBCH ≥ 40	Medium herbivorous/granivorous bird “pigeon”	2.0	1.2	0.018	>125000
Reprod. toxicity (mg/kg bw/d)	≥53.6				
TER criterion	5				
Crop scenario Growth stage	Generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{it}
Oilseed rape Late - late (with seeds) (BBCH 30-99)	Small insectivorous bird “dunnoch”	2.7	1.4 × 0.53	0.015	≥3567
Oilseed rape BBCH 30–39	Small omnivorous bird “lark”	3.3	1.4 × 0.53	0.0184	≥2919
Oilseed rape BBCH ≥ 40	Small omnivorous bird “lark”	2.7	1.4 × 0.53	0.015	≥3567
Oilseed rape BBCH 30–39	Medium herbivorous/granivorous bird “pigeon”	1.1	1.4 × 0.53	0.00612	≥8756
Oilseed rape BBCH ≥ 40	Medium herbivorous/granivorous bird “pigeon”	0.9	1.4 × 0.53	0.00501	≥10702

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.

Table 9.4-3: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of DLT + FPF EC85 in OSR (use group A)

Intended use	OSR (use group A)				
Active substance/product	Flupyradifurone				
Application rate (kg/ha)	2 × 0.05625, 14 days interval				
Acute toxicity (mg/kg bw)	232				
TER criterion	10				
Crop scenario Growth stage	Generic focal species	SV₉₀	MAF₉₀	DDD₉₀ (mg/kg bw/d)	TER_a
Oilseed rape Late - late (with seeds) (BBCH 30-99)	Small insectivorous bird “dunnoch”	7.4	1.2	0.500	464
Oilseed rape BBCH 30–39	Small omnivorous bird “lark”	7.2	1.2	0.486	477
Oilseed rape BBCH ≥ 40	Small omnivorous bird “lark”	6.0	1.2	0.405	573
Oilseed rape BBCH 30–39	Medium herbivorous/granivorous bird “pigeon”	2.4	1.2	0.162	1432
Oilseed rape BBCH ≥ 40	Medium herbivorous/granivorous bird “pigeon”	2.0	1.2	0.135	1719
Reprod. toxicity (mg/kg bw/d)	14				
TER criterion	5				
Crop scenario Growth stage	Generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_t
Oilseed rape Late - late (with seeds) (BBCH 30-99)	Small insectivorous bird “dunnoch”	2.7	1.4 × 0.53	0.113	124
Oilseed rape BBCH 30–39	Small omnivorous bird “lark”	3.3	1.4 × 0.53	0.138	102
Oilseed rape BBCH ≥ 40	Small omnivorous bird “lark”	2.7	1.4 × 0.53	0.113	124
Oilseed rape BBCH 30–39	Medium herbivorous/granivorous bird “pigeon”	1.1	1.4 × 0.53	0.0459	305
Oilseed rape BBCH ≥ 40	Medium herbivorous/granivorous bird “pigeon”	0.9	1.4 × 0.53	0.0376	373

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.

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., 2016, [M-571377-02-1](#), Appendix 2 KCP 10.1). 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:

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

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} ≥ 10 (acute) or 5 (long-term)

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

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

Table 9.4-4: Combined toxicity assessment

Intended use	Oilseed rapese (spray application)				
Active substances	Flupyradifurone (FPF) + Deltamethrin (DLT)				
Application rate (L/ha)	2 × 0.75				
Scenario / Generic focal species	TER values ¹		1 st step	2 nd step	3 rd step
	FPF	DLT	all TER ≥ trigger × n	Rpfmax	TER _{MIX}
Acute / Small insectivorous bird “dunnock”	464	> 33784	Yes	Not needed	Not needed
Long-term / Small omnivorous bird “lark”	102	≥ 2919	Yes	Not needed	Not needed

¹ Differing TER values used for rpf calculations to fulfil the criterion of identical exposure levels are shown in brackets

zRMS comments:

Active compounds

The Tier 1 risk assessment performed for particular active substances presented in Tables 9.2-2 and 9.2-3 above is agreed by the zRMS.

Although use group A considered in evaluation includes uses up to BBCH 59, the generic focal species and BBCH stages taken into account in evaluation are relevant for uses at BBCH 30-79 and for this reason all intended uses of DLT+FPF EC 85 are covered by performed calculations.

Metabolites

No risk assessment for plant metabolites was performed during the first EU review of deltamethrin or during the ongoing renewal process. For this reason no specific evaluation of the dietary risk from plant metabolites is also deemed necessary for purposes of this zonal evaluation of DLT+FPF EC 85.

According to information available in the flupyradifurone DAR (December 2014), only metabolite DFA is considered to be relevant for dietary risk but it is considered to be covered by evaluation performed for the parent compound. The same conclusion is applicable for this zonal evaluation of DLT+FPF EC 85 and no specific risk assessment is deemed necessary.

Mixture

As the TER values for individual active compounds are considerably higher than the trigger multiplied by the number of active substances in the product it may be concluded that the dietary risk to birds is addressed with sufficient margin of safety and no detailed combined risk assessment is deemed necessary.

Overall, acceptable acute and long-term dietary risk to birds may be concluded from all intended uses of DLT+FPF EC 85.

9.4.2.2 Higher-tier risk assessment

Not needed.

9.4.2.3 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 DLT+FPF EC 85 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 ($K_{oc} < 500$ L/kg) or 3000 in the case of more sorptive substances ($K_{oc} \geq 500$ L/kg).

With a $K(f)_{oc}$ of 10240000, deltamethrin belongs to the group of more sorptive substances. With a $K(f)_{oc}$ of 98.4, flupyradifurone belongs to the group of less sorptive substances. To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group A also covers the risk for birds from all other intended uses in group B (see 9.3.2).

Deltamethrin

Effective application rate (g/ha) =	12.8 12.0 ¹		
Acute toxicity (mg/kg bw) =	> 2250	quotient =	< 0.006 <0.005
Reprod. toxicity (mg/kg bw/d) =	≥ 53.6	quotient =	≤ 0.24 ≤0.22

¹ $AR \times MAF_m = 7.5 \text{ g/ha} \times 1.71 \text{ }^{1.6} = 12.0 \text{ g/ha}$; MAF_m based on max $DT_{50, \text{soil}} = 28 \text{ d}$ ~~17.1 d~~ and 2 applications with a 14 day interval

Flupyradifurone

Effective application rate (g/ha) =	107 ¹		
Acute toxicity (mg/kg bw) =	232	quotient =	0.46
Reprod. toxicity (mg/kg bw/d) =	14	quotient =	7.64

¹ $AR \times MAF_m = 56.25 \text{ g/ha} \times 1.9 = 107 \text{ g/ha}$; MAF_m based on $DT_{50, \text{soil}} = 94.8 \text{ d}$ and 2 applications with a 14 day interval

zRMS comments:

Deltamethrin

Calculations performed for deltamethrin were based on the soil DT₅₀ not agreed in area of Section 8 and for this reason respective corrections were introduced by the zRMS above.

It is noted that the drinking water risk assessment should be also performed for pertinent soil metabolites. For deltamethrin one relevant soil metabolite (Br₂CA) was identified in the course of the EU review. Respective drinking water risk assessment performed by the zRMS is presented below.

Compound	Effective application rate [g/ha]	Endpoint	Quotient	Trigger
Br ₂ CA	1.7 ¹⁾	Acute: > 2250 ²⁾	< 0.0008	50 ³⁾
		Long-term: ≥ 53.6 ²⁾	≤ 0.032	

¹⁾ Based on molar ratio of 0.59, max occurrence of 23%, MAF of 1.63 (based on max soil DT₅₀ of 21 days and 2 applications with 14 days interval)

²⁾ In line with decisions taken by the RMS during the ongoing renewal process of deltamethrin, metabolite Br₂CA is not more toxic than the parent and for this reason deltamethrin endpoints may be used for the risk assessment purposes (although the renewal process is not finalised yet, the endpoints used by the RMS in the evaluation of the risk of secondary poisoning for Br₂CA have been already peer-reviewed and no changes were introduced following commenting period; the same endpoints are relevant for the drinking water risk assessment)

³⁾ Koc of Br₂CA = 26 mL/g

Based on the above calculations, acceptable risk from metabolite Br₂CA via drinking water is concluded.

Flupyradifurone

The evaluation of the risk from drinking water performed for flupyradifurone is agreed by the zRMS.

It is noted that the drinking water risk assessment should be also performed for pertinent soil metabolites. For flupyradifurone two relevant soil metabolite (6-CNA and DFA) were identified in the course of the EU review. Respective drinking water risk assessment performed by the zRMS is presented below.

Compound	Effective application rate [g/ha]	Endpoint	Quotient	Trigger
6-CNA	9.5 ¹⁾	Acute: 23.2 ³⁾	0.41	50 ³⁾
		Long-term: 1.4 ³⁾	6.79	
DFA	12.0 ²⁾	Acute: 23.2 ³⁾	0.52	
		Long-term: 1.4 ³⁾	8.57	

¹⁾ Based on molar ratio of 0.55, max occurrence of 17.1%, MAF of 1.8 (based on max soil DT₅₀ of 36.6 days and 2 applications with 14 days interval)

²⁾ Based on molar ratio of 0.33, max occurrence of 33.9%, MAF of 1.9 (based on max soil DT₅₀ of 73.6 days and 2 applications with 14 days interval)

³⁾ In absence of the toxicity data, 10 times toxicity of the parent was assumed as a worst case

⁴⁾ Koc of 6-CNA = 88 mL/g; Koc of DFA = 6.8 mL/g

Based on the above calculations, acceptable risk from both flupyradifurone metabolites via drinking water is concluded.

Overall, acceptable acute and long-term risk to birds via drinking water may be concluded from all intended uses of DLT+FPF EC 85.

9.4.2.4 Effects of secondary poisoning

The log P_{ow} of deltamethrin amounts to 4.6 and thus exceeds the trigger value of 3. The log P_{ow} of

flupyradifurone amounts to 1.2 and thus does not exceed the trigger value of 3. Furthermore the log P_{ow} values of flupyradifurone and deltamethrin metabolites are as well lower than 3. A risk assessment for effects due to secondary poisoning is therefore only required for deltamethrin.

Risk assessment for earthworm-eating birds via secondary poisoning

According to EFSA/2009/1438, the risk for vermivorous birds is assessed for a bird of 100 g body weight with a daily food consumption of 104.6 g. Bioaccumulation in earthworms is estimated based on predicted concentrations in soil.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group A also covers the risk for birds from all other intended uses in group B (see 9.3.2).

Table 9.4-5: Assessment of the risk for earthworm-eating birds due to exposure to deltamethrin via bioaccumulation in earthworms (secondary poisoning) for the intended use in OSR (use group A)

Parameter	Deltamethrin	Comments
PEC _{SOIL} (twa = 21 d) (mg/kg soil)	0.003	
log Pow / Pow	4.6 / 39811 23442.3	
Koc	10240000	Mean (n = 4)
foc	0.02	Default
BCF _{worm}	0.002 0.001	BCF _{worm/soil} = (PEC _{worm,ww} /PEC _{soil,dw}) = (0.84 + 0.012 × Pow) / foc × Koc
PEC _{worm}	0.000006 0.000004	PEC _{worm} = PEC _{soil} × BCF _{worm/soil}
Daily dietary dose (mg/kg bw/d)	0.000006 0.000004	DDD = PEC _{worm} × 1.05
NOEL (mg/kg bw/d)	≥ 53.6	
TER _{It}	≥ 8933333 ≥ 12351162	

Risk assessment for fish-eating birds via secondary poisoning

According to EFSA/2009/1438, the risk for piscivorous birds is assessed for a bird of 1000 g body weight with a daily food consumption of 159 g. Bioaccumulation in fish is estimated based on predicted concentrations in surface water of deltamethrin in water.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group A also covers the risk for birds from all other intended uses in group B (see 9.3.2).

Table 9.4-6: Assessment of the risk for fish-eating birds due to exposure to deltamethrin via bioaccumulation in fish (secondary poisoning) for the intended use in OSR (use group A)

Parameter	Deltamethrin	Comments
PEC _{sw} (twa = 21 d) (mg/L)	0.000005 0.0000036	Overall worst case TWA 21-d PEC _{sw}
BCF _{fish}	1400	
BMF	-	biomagnification factor (relevant for BCF ≥ 2000)
PEC _{fish}	0.007 0.00504	PEC _{fish} = PEC _{water} × BCF _{fish}
Daily dietary dose (mg/kg bw/d)	0.0011 0.00080	DDD = PEC _{fish} × 0.159
NOEL (mg/kg bw/d)	≥ 53.6	
TER _{It}	≥ 48727 ≥ 67000	

zRMS comments:

The evaluation of the risk of secondary poisoning was not triggered for flupyradifurone or its metabolites due to log Pow being all <3.

For deltamethrin the evaluation was triggered due to $\log Pow > 3$. Calculations performed by the Applicant in Tables 9.2-5 and 9.2-6 were amended accordingly with consideration of relevant input parameters.

With regard to metabolite Br₂CA it is noted that no respective information on $\log Pow$ of this compound is available from the first EU review of deltamethrin. According to the data available from the ongoing renewal process, $\log Pow$ of this compound is < 3 at pH 7 and 9. However, for pH 5 the $\log Pow$ of 3.1 was determined and for this reason respective evaluation is deemed necessary as acidic pH of soil or water under field conditions cannot be excluded. Evaluation performed by the zRMS is provided below.

Earthworm-eating birds

Parameter	Br ₂ CA	Comments
PEC _{soil} (twa = 21 d) (mg/kg soil)	0.001	
$\log Pow / Pow$	3.1 / 1259	
Koc	26.0	Mean (n = 4)
foc	0.02	Default
BCF _{worm}	30.6	$BCF_{worm/soil} = (PEC_{worm,ww} / PEC_{soil,dw}) = (0.84 + 0.012 \times Pow) / foc \times Koc$
PEC _{worm}	0.031	$PEC_{worm} = PEC_{soil} \times BCF_{worm/soil}$
Daily dietary dose (mg/kg bw/d)	0.033	$DDD = PEC_{worm} \times 1.05$
NOEL (mg/kg bw/d)	≥ 53.6	In line with decisions taken by the RMS during the ongoing renewal process of deltamethrin, metabolite Br ₂ CA is not more toxic than the parent and for this reason deltamethrin endpoints may be used for the risk assessment purposes (although the renewal process is not finalised yet, the endpoints used by the RMS in the evaluation of the risk of secondary poisoning for Br ₂ CA have been already peer-reviewed and no changes were introduced following commenting period)
TER _{lt}	≥ 1624	

Fish-eating birds

Parameter	Br ₂ CA	Comments
PEC _{sw} (twa = 21 d) (mg/L)	0.00104	Overall worst case TWA 21-d PEC _{sw}
BCF _{fish}	1400	Parent BCF
BMF	-	biomagnification factor (relevant for $BCF \geq 2000$)
PEC _{fish}	1.456	$PEC_{fish} = PEC_{water} \times BCF_{fish}$
Daily dietary dose (mg/kg bw/d)	0.232	$DDD = PEC_{fish} \times 0.159$
NOEL (mg/kg bw/d)	≥ 53.6	In line with decisions taken by the RMS during the ongoing renewal process of deltamethrin, metabolite Br ₂ CA is not more toxic than the parent and for this reason deltamethrin endpoints may be used for the risk assessment purposes (although the renewal process is not finalised yet, the endpoints used by the RMS in the evaluation of the risk of secondary poisoning for Br ₂ CA have been already peer-reviewed and no changes were introduced following commenting period; the same endpoints are relevant for the drinking water risk assessment)
TER _{lt}	≥ 231	

Overall, based on performed calculations, acceptable risk of secondary to earthworm- and fish-eating birds from deltamethrin and metabolite Br₂CA may be concluded.

9.4.2.5 Biomagnification in terrestrial food chains

Not relevant.

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

Not relevant.

9.4.4 Overall conclusions

All acute and long-term TER values are higher than the trigger values indicating an acceptable risk for birds after use of DLT+FPF EC85 for all intended uses.

The assessment on combined toxicity risk proved an acceptable risk for birds for the application rate of 0.75 L product/ha (use group A) after the use of DLT+FPF EC 85.

No risk to birds ~~resulted~~ from exposure via drinking water **is expected**.

The risk from secondary poisoning of birds via prey like fish and earthworms is considered to be low.

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

9.5.1 Toxicity data

Mammalian toxicity studies have been carried out with deltamethrin and flupyradifurone. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on mammals of DLT+FPF EC 85 were not evaluated as part of the EU assessment of deltamethrin and flupyradifurone. New data submitted with this application are listed in Appendix 1 and summarised in Section 6 (Mammalian Toxicology) of this report.

The selection of studies and endpoints for the risk assessment deviates from the results of the EU review process. Justifications are provided below.

Table 9.5-1: Endpoints and effect values relevant for the risk assessment for mammals

Species	Substance	Exposure System	Results	Reference
Rat	Deltamethrin a.s.	Oral Acute	LD ₅₀ = 87 mg/kg bw	EC Review Report 6504/VI/99- final (2002), 1-78 Monograph Annex B toxicology
Rat	Deltamethrin a.s.	Dietary 13 weeks Short-term	NOEL = 2.5 mg/kg bw/d	EC Review Report 6504/VI/99- final (2002), 1-78 Monograph Annex B toxicology See justification
Rat	Deltamethrin a.s.	Dietary Long-term (multi-generation)	NOEC = 80 mg a.s./kg diet NO(A)ED = 4.2 mg a.s./kg bw/d	EC Review Report 6504/VI/99- final (2002), 1-78 Monograph Annex B toxicology See justification
Rat	Flupyradifurone	Oral Acute Acute neurotoxicity Combined	LD ₅₀ = 1607 mg/kg bw	EFSA Journal 2015;13(2):4020
Rat	Flupyradifurone	Oral 2-generation reproduction toxicity study	NOAEL = 6.4 mg/kg bw/d (parental and offspring toxicity)	EFSA Journal 2015;13(2):4020

zRMS comments:

Mammalian toxicity data provided in Table 9.3-1 are in line with EU agreed endpoints reported in the Review Report for deltamethrin (6504/VI/99-final, 2002) and EFSA Journal 2015;13(2):4020 for flupyradifurone.

Acute oral toxicity of the preparation

Table 9.5-2: Mammalian toxicity data of the formulated product DLT + FPF EC 85

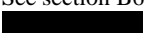
Species	Substance	Exposure System	Results	Reference
Rat	DLT + FPF EC 85	Oral Acute	550 < LD ₅₀ < 2000 mg prod./kg bw	See section B6  M-516318-01-1

Table 9.5-3: Calculation of the acute mixed toxicity of the formulation to mammals according to Finney (GIFAP, 1990)

	DLT	FPF
Content within the product (%) ¹	0.867	6.62
LD ₅₀ (mg a.s./kg bw)	87	1607
LD ₅₀ – mixed toxicity (mg product/kg bw)	7100	

¹ Based on a measured a.s. content

A comparison of the acute LD₅₀ valued derived for the formulation with the LD₅₀ value calculated from the toxicity data of the active substances indicates that the formulation is not more toxic than expected based on its active ingredient content. Therefore, the risk assessment performed below will be based on the active substances.

zRMS comments:

Although acute mixed toxicity provided in Table 9.3-3 seems to be correct, it is not clear if it was performed in line with EFSA (2009), indicating that in calculation of LD_{50mix} the sum of fractions of particular active compounds in the formulation must be 1. Therefore additional calculations were performed by the zRMS in line with EFSA (2009):

Substance	Fraction in DLT+FPF EC 85	LD ₅₀ [mg a.s./kg bw]	LD _{50mix} [mg a.s./kg bw]
Deltamethrin	0.12	87	519
Flupyradifurone	0.88	1607	

The Applicant stated that the formulation is not expected to be more toxic than the individual active compounds, however experimentally derived endpoint for the formulated product expressed in terms of the sum of active compounds would be greater than 40.4 mg a.s./kg bw and lower than 146.8 mg a.s./kg bw, which in comparison with estimated LD_{50mix} of 519 mg a.s./kg bw indicates that the formulated product may be more toxic than the particular substances. Taking this into account, respective acute risk assessment for the formulation has been performed by the zRMS in point 9.3.2.1 below.

9.5.1.1 Justification for new endpoints

Table 9.5-4: Active substance Deltamethrin

Species	Substance	Exposure System	Justification
Rat	Deltamethrin a.s.	Oral	<p>Since the mode of application of deltamethrin, and particularly the carrier, considerably influences the toxicity induced in the test animals, the endpoint for the wild mammal long-term and reproductive risk assessment should only be taken from studies including relevant exposure of the test animals. In the context of this exposure evaluation for a spray application of deltamethrin, wild mammals may be mainly exposed through uptake of residues on their natural diet consisting of plant or animal material.</p> <p>The endpoint for the long-term and reproductive risk assessment should therefore be selected only from studies with (i) dietary exposure and (ii) endpoints relevant to that risk assessment.</p> <p>Based on these criteria, the endpoint for the long-term and reproductive risk assessment can be best selected from the following two studies:</p> <ul style="list-style-type: none"> - The multigeneration study with deltamethrin (Hoberman, 1992) providing a NO(A)ED of 4.2 mg a.s./kg bw/d (NOEC = 80 ppm), this value was included in the List of end-points. - The developmental neurotox study with deltamethrin (Gilmore et al. 2006) providing a NO(A)ED of 6.78 mg a.s./kg bw/d (NOEC = 80 ppm)

Species	Substance	Exposure System	Justification
			<p>In these studies, the toxicological effect potential of deltamethrin on survival chances or the reproductive capacity for wild mammal populations is considered to be best and fully reflected.</p> <p>In the multigeneration study, deltamethrin did not affect the reproduction in rats. The NOAEL in adult male and female rats was 80 ppm (the average consumed dosages ranged from 4.2 to 12.4 mg/kg bw/day in the periods evaluated in this study) based on mortality, clinical signs, reduced body weight, reduced food consumption and gastric erosion noted in animals of the 320 ppm level. The NOAEL in offsprings was 80 ppm based on increased pup mortality, a reduced lactation index and reduced body weight noted in animals of the 320 ppm dose level.</p> <p>In the developmental neurotoxicity study (DNT) by Gilmore et al. (2006), deltamethrin did not affect the development and behavioural fitness of the offspring at the NOEC of 80 ppm. In this study a test design was employed (exposure of pregnant dams, giving birth to the pups which are then raised on diet until completion of a range of behavioural fitness tests) which is basically very similar to a standard developmental toxicity study, except that the administration in the DNT study is more relevant (via diet rather than per gavage), and that the behavioural fitness of the offspring was tested. No environmentally relevant adverse effects on endpoints for wild mammals were observed at the NOEC of 80 ppm (6.78 mg a.s./kg bw/d).</p> <p>Thus, no adverse effects were observed in, neither reproduction, nor the developmental neurotoxicity study with dietary exposure at 80 ppm.</p> <p>For deltamethrin it is therefore proposed to apply a NOAED of 80 ppm (4.2 mg/kg bw/d) from the reproduction study in rat (with dietary administration over a full life cycle) in the reproductive wild mammal risk assessment.</p>

Flupyradifurone:

No deviation from EU agreed endpoints.

zRMS comments:

In line with indications of SANCO/10328/2004 - rev. 8 (2012) and decisions taken during the Central Zone harmonisation meetings in area of ecotoxicology, the risk assessment should be based on the EU agreed endpoints and new active substance data should not be generated unless critical for the risk assessment. As the risk assessment for deltamethrin could be finalised on the basis of the EU agreed NOAEL of 2.5 mg a.s./kg bw/d, selection of the new, not peer-reviewed endpoint was not necessary and was thus not agreed by the zRMS.

It is further noted that in the course of the ongoing renewal process the long-term toxicity endpoint selected by the RMS was the same as this reported in the current LoEP.

The zRMS would also like to emphasise that although in the field situation mammals will be exposed to the active substance via the diet, in the hazard assessment the type of exposure is not taken into account.

Overall, the EU agreed NOAEL of 2.5 mg a.s./kg bw/d is considered relevant for the mammalian long-term risk assessment.

9.5.2 Risk assessment for spray applications

The risk assessment is based on the methods presented in the Guidance Document on Risk Assessment for Mammals 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 also covers the risk for mammals from all other intended uses in group B (see 9.3.2).

9.5.2.1 First-tier assessment (generic focal species)

The results of the acute and reproductive first-tier risk assessments are summarised in the following tables.

Table 9.5-5: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of DLT + FPF EC85 in OSR (use group A)

Intended use		OSR				
Active substance/product		Deltamethrin				
Application rate (kg/ha)		2 × 0.0075, 14 days interval				
Acute toxicity (mg/kg bw)		87				
TER criterion		10				
Crop scenario	Generic focal species	SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a	
Growth stage						
Oilseed rape BBCH ≥ 20	Small insectivorous mammal “shrew”	5.4	1.2	0.0486	1790	
Oilseed rape BBCH ≥ 40	Small herbivorous mammal "vole"	34.1	1.2	0.307	283	
Oilseed rape All season	Large herbivorous mammal “lagomorph”	35.1	1.2	0.316	275	
Oilseed rape BBCH 30 - 39	Small omnivorous mammal “mouse”	5.2	1.2	0.0468	1859	
Oilseed rape BBCH ≥ 40	Small omnivorous mammal “mouse”	4.3	1.2	0.0387	2248	
Reprod. toxicity (mg/kg bw/d)		2.5 4.2				
TER criterion		5				
Crop scenario	Generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{lt}	
Growth stage						
Oilseed rape BBCH ≥ 20	Small insectivorous mammal “shrew”	1.9	1.4 × 0.53	0.0106	236 397	
Oilseed rape BBCH ≥ 40	Small herbivorous mammal "vole"	18.1	1.4 × 0.53	0.101	24.8 41.7	
Oilseed rape All season	Large herbivorous mammal “lagomorph”	14.3	1.4 × 0.53	0.0796	31.4 52.8	
Oilseed rape BBCH 30 - 39	Small omnivorous mammal “mouse”	2.3	1.4 × 0.53	0.0128	195 328	
Oilseed rape BBCH ≥ 40	Small omnivorous mammal “mouse”	1.9	1.4 × 0.53	0.0106	236 397	

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.

Table 9.5-6: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of DLT + FPF EC85 in OSR (use group A)

Intended use	OSR				
Active substance/product	Flupyradifurone				
Application rate (kg/ha)	2 × 0.05625, 14 days interval				
Acute toxicity (mg/kg bw)	1607				
TER criterion	10				
Crop scenario Growth stage	Generic focal species	SV₉₀	MAF₉₀	DDD₉₀ (mg/kg bw/d)	TER_a
Oilseed rape BBCH ≥ 20	Small insectivorous mammal “shrew”	5.4	1.2	0.365	4409
Oilseed rape BBCH ≥ 40	Small herbivorous mammal "vole"	34.1	1.2	2.30	698
Oilseed rape All season	Large herbivorous mammal “lagomorph”	35.1	1.2	2.37	678
Oilseed rape BBCH 30 - 39	Small omnivorous mammal “mouse”	5.2	1.2	0.351	4578
Oilseed rape BBCH ≥ 40	Small omnivorous mammal “mouse”	4.3	1.2	0.290	5537
Reprod. toxicity (mg/kg bw/d)	6.4				
TER criterion	5				
Crop scenario Growth stage	Generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{lt}
Oilseed rape BBCH ≥ 20	Small insectivorous mammal “shrew”	1.9	1.4 × 0.53	0.0793	80.7
Oilseed rape BBCH ≥ 40	Small herbivorous mammal "vole"	18.1	1.4 × 0.53	0.755	8.47
Oilseed rape All season	Large herbivorous mammal “lagomorph”	14.3	1.4 × 0.53	0.597	10.7
Oilseed rape BBCH 30 - 39	Small omnivorous mammal “mouse”	2.3	1.4 × 0.53	0.096	66.7
Oilseed rape BBCH ≥ 40	Small omnivorous mammal “mouse”	1.9	1.4 × 0.53	0.0793	80.7

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.

Assessment of combined toxicity

For explanations please refer to chapter 9.4.2.

Table 9.5-7: Combined toxicity assessment

Intended use	Oilseed rapeseed (spray application)				
Active substances	Flupyradifurone (FPF) + Deltamethrin (DLT)				
Application rate (L/ha)	2 × 0.75				
Scenario / Generic focal species	TER values ¹		1 st step	2 nd step	3 rd step
	FPF	DLT	all TER ≥ trigger × n	Rpfmax	TER _{MIX}
Acute / Large herbivorous mammal “lagomorph”	678	275	Yes	Not needed	Not needed
Long-term / Small herbivorous mammal “vole”	8.47	24.8 41.7	No	0.83	6.3 7.0

¹ Differing TER values used for rpf calculations to fulfil the criterion of identical exposure levels are shown in brackets

zRMS comments:

Active compounds

The Tier 1 risk assessment performed for particular active substances presented in Tables 9.3-5 and 9.3-6 above is in general agreed by the zRMS with exception of the long-term risk assessment for deltamethrin due to not agreed endpoint proposed by the Applicant. Calculations performed in Table 9.3-5 were thus amended accordingly with consideration of the relevant EU agreed NOAEL.

Although use group A considered in evaluation includes uses up to BBCH 59, the generic focal species and BBCH stages taken into account in evaluation are relevant for uses at BBCH 30-79 and for this reason all intended uses of DLT+FPF EC 85 are covered by performed calculations.

Metabolites

No risk assessment for plant metabolites was performed during the first EU review of deltamethrin or during the ongoing renewal process. For this reason no specific evaluation of the dietary risk from plant metabolites is also deemed necessary for purposes of this zonal evaluation of DLT+FPF EC 85.

According to information available in the flupyradifurone DAR (December 2014), only metabolite DFA is considered to be relevant for dietary risk but it is considered to be covered by evaluation performed for the parent compound. The same conclusion is applicable for this zonal evaluation of DLT+FPF EC 85 and no specific risk assessment is deemed necessary.

Mixture

Although the acute TER values for individual active compounds were considerably higher than the trigger multiplied by the number of active substances in the product, available data indicate that the formulation may be acutely more toxic than the active substances. Taking this into account, respective acute risk assessment has been performed by the zRMS below with consideration of the generic focal species with highest SV, covering all other species. Since no definite endpoint was derived from the study performed with the formulated product, as a worst case the lowest value of the tested range is considered.

Intended use	OSR				
Active substance/product	DLT+FPF EC85				
Application rate (kg/ha)	2 × 0.87, 14 days interval (based on relative density of 1.158 g/mL and maximum application rate of 0.75 L/ha)				
Acute toxicity (mg/kg bw)	550				
TER criterion	10				
Crop scenario Growth stage	Generic focal species	SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a
Oilseed rape All season	Large herbivorous mammal “lagomorph”	35.1	1.2	36.6	15.0

Derived TER is above the trigger of 10 indicating acceptable acute risk from the formulation.

With regard to the combined long-term risk assessment, the calculation of Rpfmax is no longer correct since it was based on deltamethrin TER values calculated with consideration of not agreed endpoint. Taking this into account the toxic units were calculated by the zRMS and are presented below. It is noted that in case of the long-term toxicity, calculation of the TU is not fully certain since endpoints originate from studies not performed under comparable conditions and are based on effects observed on different parameters, however currently no better options are available.

Substance	Fraction in formulation	NOAEL [mg/kg bw/d]	Toxic Unit	% of total TU
Deltamethrin	0.12	2.5	0.048	25.9
Flupyradifurone	0.88	6.4	0.1375	74.1

Based on the above calculation it is evident that neither of the active compounds contributes to the overall toxicity at >90% and for this reason the TERmix approach, as calculated by the Applicant in Table 9.3-7 above, is relevant. Nevertheless, the TERmix was amended by the zRMS using long-term TER for deltamethrin calculated with consideration of the agreed NOAEL of 2.5 mg a.s./kg bw/d. The resulting TERmix of 6.3 is still greater than the trigger of 5.

Overall, acceptable acute and long-term dietary risk to mammals may be concluded from all intended uses of DLT+FPF EC 85.

9.5.2.2 Higher-tier risk assessment

Not relevant.

9.5.2.3 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).

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 ($K_{oc} < 500$ L/kg) or 3000 in the case of more sorptive substances ($K_{oc} \geq 500$ L/kg).

With a $K(f)_{oc}$ of 10240000, deltamethrin belongs to the group of more sorptive substances. With a $K(f)_{oc}$ of 98.4, flupyradifurone belongs to the group of less sorptive substances.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group A also covers the risk for mammals from all other intended uses in group B (see 9.3.2).

Deltamethrin

Effective application rate (g/ha) =	12.8 12.0 ¹		
Acute toxicity (mg/kg bw) =	87	quotient =	0.15 0.14
Reprod. toxicity (mg/kg bw/d) =	2.5 4.2	quotient =	5.12 2.68

¹ $AR \times MAF_m = 7.5 \text{ g/ha} \times 1.71 ~~1.6~~ = 12.0 \text{ g/ha}$; MAF_m based on $\max DT_{50, \text{soil}} = 28 \text{ d} ~~17.1 d~~$ and 2 applications with a 14 day interval

Flupyradifurone

Effective application rate (g/ha) =	107 ¹		
Acute toxicity (mg/kg bw) =	1607	quotient =	0.067
Reprod. toxicity (mg/kg bw/d) =	6.4	quotient =	16.7

¹ AR × MAF_m = 56.25 g/ha × 1.9 = 107 g/ha; MAF_m based on DT_{50, soil} = 94.8 d and 2 applications with a 14 day interval

zRMS comments:

Deltamethrin

Calculations performed for deltamethrin were based on the soil DT₅₀ not agreed in area of Section 8 and for this reason respective corrections were introduced by the zRMS above.

It is noted that the drinking water risk assessment should be also performed for pertinent soil metabolites. For deltamethrin one relevant soil metabolite (Br₂CA) was identified in the course of the EU review. Respective drinking water risk assessment performed by the zRMS is presented below.

Compound	Effective application rate [g/ha]	Endpoint	Quotient	Trigger
Br ₂ CA	1.7 ¹⁾	Acute: 87 ²⁾	0.02	50 ³⁾
		Long-term: 2.5 ²⁾	0.68	

¹⁾ Based on molar ratio of 0.59, max occurrence of 23%, MAF of 1.63 (based on max soil DT₅₀ of 21 days and 2 applications with 14 days interval)

²⁾ In line with decisions taken by the RMS during the ongoing renewal process of deltamethrin, metabolite Br₂CA is not more toxic than the parent and for this reason deltamethrin endpoints may be used for the risk assessment purposes (although the renewal process is not finalised yet, the endpoints used by the RMS in the evaluation of the risk of secondary poisoning for Br₂CA have been already peer-reviewed and no changes were introduced following commenting period; the same endpoints are relevant for the drinking water risk assessment)

³⁾ Koc of Br₂CA = 26 mL/g

Based on the above calculations, acceptable risk from metabolite Br₂CA via drinking water is concluded.

Flupyradifurone

The evaluation of the risk from drinking water performed for flupyradifurone is agreed by the zRMS.

It is noted that the drinking water risk assessment should be also performed for pertinent soil metabolites. For flupyradifurone two relevant soil metabolite (6-CNA and DFA) were identified in the course of the EU review. Respective drinking water risk assessment performed by the zRMS is presented below.

Compound	Effective application rate [g/ha]	Endpoint	Quotient	Trigger
6-CNA	9.5 ¹⁾	Acute: 160.7 ³⁾	0.06	50 ³⁾
		Long-term: 0.64 ³⁾	14.8	
DFA	12.0 ²⁾	Acute: 160.7 ³⁾	0.17	
		Long-term: 0.64 ³⁾	18.8	

¹⁾ Based on molar ratio of 0.55, max occurrence of 17.1%, MAF of 1.8 (based on max soil DT₅₀ of 36.6 days and 2 applications with 14 days interval)

²⁾ Based on molar ratio of 0.33, max occurrence of 33.9%, MAF of 1.9 (based on max soil DT₅₀ of 73.6 days and 2 applications with 14 days interval)

³⁾ In absence of the toxicity data, 10 times toxicity of the parent was assumed as a worst case

⁴⁾ Koc of 6-CNA = 88 mL/g; Koc of DFA = 6.8 mL/g

Based on the above calculations, acceptable risk from both flupyradifurone metabolites via drinking water is concluded.

Overall, acceptable acute and long-term risk to mammals via drinking water may be concluded from all intended uses of DLT+FPF EC 85.

9.5.2.4 Effects of secondary poisoning

The log P_{ow} of deltamethrin amounts to 4.6 and thus exceeds the trigger value of 3. The log P_{ow} of flupyradifurone amounts to 1.2 and thus does not exceed the trigger value of 3. Furthermore the log P_{ow} values of flupyradifurone metabolites are as well lower than 3. A risk assessment for effects due to secondary poisoning is therefore only required for deltamethrin.

Risk assessment for earthworm-eating mammals via secondary poisoning

According to EFSA/2009/1438, the risk for vermivorous mammals is assessed for a small mammal of 10 g body weight with a daily food consumption of 12.8 g. Bioaccumulation in earthworms is estimated based on predicted concentrations in soil.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group A also covers the risk for mammals from all other intended uses in group B (see 9.3.2).

Table 9.5-8: Assessment of the risk for earthworm-eating mammals due to exposure to deltamethrin via bioaccumulation in earthworms (secondary poisoning) for the intended use in OSR (use group A)

Parameter	Deltamethrin	comments
PECsoil (twa = 21 d) (mg/kg soil)	0.003	
log Pow / Pow	4.6 / 39811 23442.3	
Koc	10240000	Mean (n = 4)
foc	0.02	Default
BCFworm	0.001	$BCF_{worm/soil} = (PEC_{worm,ww} / PEC_{soil,dw}) = (0.84 + 0.012 \times Pow) / foc \times Koc$
PECworm	0.000006 0.000004	$PEC_{worm} = PEC_{soil} \times BCF_{worm/soil}$
Daily dietary dose (mg/kg bw/d)	0.000008 0.000005	$DDD = PEC_{worm} \times 1.28$
NOEL (mg/kg bw/d)	2.5 4.2	
TERlt	312500 793911	

TER values shown in bold fall below the relevant trigger.

Risk assessment for fish-eating mammals via secondary poisoning

According to EFSA/2009/1438, the risk for piscivorous mammals is assessed for a bird of 3000 g body weight with a daily food consumption of 425 g. Bioaccumulation in fish is estimated based on predicted concentrations in surface water of deltamethrin in water.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group A also covers the risk for mammals from all other intended uses in group B (see 9.3.2).

Table 9.5-9: Assessment of the risk for fish-eating mammals due to exposure to deltamethrin via bioaccumulation in fish (secondary poisoning) for the intended use in OSR (use group A)

Parameter	Deltamethrin	comments
PEC _{sw} (twa = 21 d) (mg/L)	0.000005 0.0000036	Overall worst case TWA 21-d PEC _{sw}
BCF _{fish}	1400	
BMF	-	biomagnification factor (relevant for BCF ≥ 2000)
PEC _{fish}	0.007 0.00504	PEC _{fish} = PEC _{water} × BCF _{fish}
Daily dietary dose (mg/kg bw/d)	0.001 0.00080	DDD = PEC _{fish} × 0.142
NOEL (mg/kg bw/d)	2.5 4.2	
TER _{lt}	2500 5241	

TER values shown in bold fall below the relevant trigger.

zRMS comments:

The evaluation of the risk of secondary poisoning was not triggered for flupyradifurone or its metabolites due to log Pow being all <3.

For deltamethrin the evaluation was triggered due to log Pow >3. Calculations performed by the Applicant in Tables 9.3-8 and 9.3-9 were amended accordingly with consideration of relevant input parameters.

With regard to metabolite Br₂CA it is noted that no respective information on log Pow of this compound is available from the first EU review of deltamethrin. According to the data available from the ongoing renewal process, log Pow of this compound is <3 at pH 7 and 9. However, for pH 5 the log Pow of 3.1 was determined and for this reason respective evaluation is deemed necessary as acidic pH of soil or water under field conditions cannot be excluded. Evaluation performed by the zRMS is provided below.

Earthworm-eating birds

Parameter	Br ₂ CA	Comments
PEC _{SOIL} (twa = 21 d) (mg/kg soil)	0.001	
log Pow / Pow	3.1 / 1259	
Koc	26.0	Mean (n = 4)
foc	0.02	Default
BCF _{worm}	30.6	BCF _{worm/soil} = (PEC _{worm,ww} /PEC _{soil,dw}) = (0.84 + 0.012 × Pow) / foc × Koc
PEC _{worm}	0.031	PEC _{worm} = PEC _{soil} × BCF _{worm/soil}
Daily dietary dose (mg/kg bw/d)	0.040	DDD = PEC _{worm} × 1.28
NOEL (mg/kg bw/d)	2.5	In line with decisions taken by the RMS during the ongoing renewal process of deltamethrin, metabolite Br ₂ CA is not more toxic than the parent and for this reason deltamethrin endpoints may be used for the risk assessment purposes (although the renewal process is not finalised yet, the endpoints used by the RMS in the evaluation of the risk of secondary poisoning for Br ₂ CA have been already peer-reviewed and no changes were introduced following commenting period)
TER _{lt}	62.5	

Fish-eating birds

Parameter	Br ₂ CA	Comments
PEC _{sw} (twa = 21 d) (mg/L)	0.00104	Overall worst case TWA 21-d PEC _{sw}
BCF _{fish}	1400	Parent BCF
BMF	-	biomagnification factor (relevant for BCF ≥ 2000)
PEC _{fish}	1.456	PEC _{fish} = PEC _{water} × BCF _{fish}
Daily dietary dose (mg/kg bw/d)	0.207	DDD = PEC _{fish} × 0.142
NOEL (mg/kg bw/d)	≥ 53.6	In line with decisions taken by the RMS during the ongoing renewal process of deltamethrin, metabolite Br ₂ CA is not more toxic than the parent and for this reason deltamethrin endpoints may be used for the risk assessment purposes (although the renewal process is not finalised yet, the endpoints used by the RMS in the evaluation of the risk of secondary poisoning for Br ₂ CA have been already peer-reviewed and no changes were introduced following commenting period; the same endpoints are relevant for the drinking water risk assessment)
TER _{lt}	12.1	

Overall, based on performed calculations, acceptable risk of secondary to earthworm- and fish-eating mammals from deltamethrin and metabolite Br₂CA may be concluded.

9.5.2.5 Biomagnification in terrestrial food chains

Not relevant.

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

Not relevant.

9.5.4 Overall conclusions

All acute and long-term TER values are higher than the trigger values indicating an acceptable risk for mammals after use of DLT+FPF EC85 for all intended uses.

The assessment on combined toxicity risk proved an acceptable risk for mammals for the application rate of 0.75 L product/ha (use group A) after the use of DLT+FPF EC 85.

No risk to mammals ~~resulted~~ from exposure via drinking water ~~is expected~~.

The risk from secondary poisoning of mammals via prey like fish and earthworms is considered to be low.

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

The available and relevant data covering potential effects of deltamethrin on terrestrial vertebrates are presented under point 9.2 for birds and 9.3 for mammals. Regarding assessment of potential effects on reptiles and amphibians neither guidance documents nor testing guidelines are available at present. Therefore, no additional data on terrestrial vertebrate wildlife is presented here for deltamethrin.

For flupyradifurone, a study on the African clawed frog (*Xenopus laevis*) is available and listed in the EFSA conclusion for flupyradifurone (p. 74). No effect on mortality or behaviour was observed in this acute limit test (48 h-LC₅₀ > 80 mg a.s./L; functional limit of solubility) indicating ~~very~~ low risk for amphibians. No further testing is deemed necessary.

zRMS comments:

As currently there are no agreed rules or criteria for evaluation of the risk to other terrestrial vertebrates like reptiles and amphibians, this issue should be addressed once respective guidance is available and EU agreed endpoints concluded.

9.7 Effects on aquatic organisms (KCP 10.2)

9.7.1 Toxicity data

Studies on the toxicity to aquatic organisms have been carried out with deltamethrin, as the active ingredient or representative formulations, and its relevant metabolite Br₂CA. 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).

Effects on aquatic organisms of DLT+FPF EC 85 were not evaluated as part of the EU assessment of deltamethrin or flupyradifurone. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

The selection of studies and endpoints for the risk assessment deviates from the results of the EU review process. Justifications are provided below.

Table 9.7-1: Endpoints and effect values relevant for the risk assessment for aquatic organisms – deltamethrin and relevant metabolites

Species	Substance	Exposure System	Results	Reference
Fish, acute, Rainbow trout (<i>Oncorhynchus mykiss</i>)	Decis EC 2.5	96 h, f	LC ₅₀ = 0.26 µg a.s./L _{mm}	EC Review Report 6504/ VI/99- final (2002), 1-78 Monograph Annex B Ecotoxicology
Fish, chronic, Rainbow trout (<i>Oncorhynchus mykiss</i>)	Deltamethrin a.s.	28 d, f	NOEC < 0.032 µg a.s./L _{mm}	EC Review Report 6504/ VI/99- final (2002), 1-78 Monograph Annex B Ecotoxicology
Invertebrate, acute <i>Daphnia magna</i>	Deltamethrin a.s.	48 h, f	EC ₅₀ = 0.56 µg a.s./L _{mm}	EC Review Report 6504/ VI/99- final (2002), 1-78 Addendum monograph Annex B Ecotox. 2002
Invertebrate, acute <i>Gammarus fasciatus</i>	Deltamethrin EC 25	96 h, f water only	LC ₅₀ = 0.00031 µg a.s./L _{mm}	EC Review Report 6504/ VI/99- final (2002), 1-78 Monograph Annex B Ecotox 2002
Invertebrate, acute <i>Asellus aquaticus</i>	Deltamethrin EC 25	96 h, ss water only	LC ₅₀ = 0.0051 µg a.s./L _{nom}	EC Review Report 6504/ VI/99- final (2002), 1-78 Monograph Annex B Ecotox 2002
Invertebrates, acute <i>Asellus aquaticus</i> , <i>Gammarus fasciatus</i>	Deltamethrin EC 25	96 h	LC _{50 geomean} = 0.00384 µg a.s./L	See justification
Invertebrate, chronic <i>Daphnia magna</i>	Deltamethrin a.s.	21 d, f	NOEC = 0.0041 µg a.s./L _{mm}	EC Review Report 6504/ VI/99- final (2002), 1-78 Monograph Annex B Ecotox
Invertebrate, chronic <i>Chironomus riparius</i>	Deltamethrin a.s.	28 d, s Water-sediment, spiked water	NOEC = 0.01 µg a.s./L _{nom}	EC Review Report 6504/ VI/99- final (2002), 1-78 Monograph Annex B Ecotox. 2002

Species	Substance	Exposure System	Results	Reference
Green algae, <i>Pseudokirchneriella subcapitata</i> Spiked water	Deltamethrin a.s.	96 h, s	ErC ₅₀ > 9100 µg a.s./L _{im} *	EC Review Report 6504/ VI/99- final (2002), 1-78. Monograph Annex B Ecotox.
Fish, acute Rainbow trout (<i>Oncorhynchus mykiss</i>)	Metabolite Br ₂ CA	96 h, s	LC ₅₀ > 42 370 µg p.m./L _{ini, meas} LC₅₀ > 100 000 µg p.m./L_{nom}	Appendix 2 [REDACTED] (2001) M-199816-01-1 See justification
Invertebrate, acute <i>Daphnia magna</i>	Metabolite Br ₂ CA	48 h, s	EC ₅₀ > 100 000 µg p.m./L _{mm}	Appendix 2 Sowig & Gosch (2001) M-199793-01-1 See justification
Higher-tier studies, including microcosm and mesocosm studies				
Outdoor full microcosm	Deltamethrin EC 25	3 appl. mixed into water, application interval 7 d	NOEAEC = 0.01 µg a.s./L _{nom} EAC = 0.0032 µg a.s./L	Addendum Monograph Annex B Ecotox. 2002
Outdoor full mesocosm	Deltamethrin EW 15	3 applications onto water surface, spray interval 7 d	NOEAEC = 0.051 µg a.s./L _{nom}	Appendix 2 Heimbach et al. (2005) M-246137-01-2
Species-focused outdoor mesocosm Rainbow trout (<i>Oncorhynchus mykiss</i>)	Deltamethrin EW 15	3 applications onto water surface, spray interval 7 d	EAC = 0.1 µg a.s./L _{nom}	Appendix 2 Deneer (2005) M-256605-01-1 See justification
Bioassay with mesocosm water <i>Gammarus pulex</i>	Deltamethrin EW 15	28 d water-only	NOEC = 0.023 µg a.s./L _{nom}	Appendix 2 Heimbach & Arnold (2005) M-246173-01-1
Life-stage study (acute + chronic) <i>Aelurus aquaticus</i>	Deltamethrin EW 15	21 d, s water-sediment	NOEC = 0.0234 µg a.s./L _{nom}	Appendix 2 Jergentz (2007) M-291885-02-1
Most sensitive aquatic invertebrates	Deltamethrin a.s. and EW 15	Combination of higher tier studies, expert statements and ecological modeling	EAC = 0.023 µg a.s./L _{nom}	“General refined risk assessment for aquatic invertebrates” Appendix 2

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

* Reported as “uncertain value, but probably only moderate toxicity” in EC Review Report for deltamethrin; 6504/VI/99-final.

Table 9.7-2: Endpoints and effect values relevant for the risk assessment for aquatic organisms – Flupyradifurone and relevant metabolites

Species	Substance	Exposure System	Results	Reference
<i>Pimephales promelas</i>	Flupyradifurone	96h, s	LC ₅₀ > 70.5 mg a.s./L _{mm}	EFSA Journal 2015;13(2):4020
<i>Pimephales promelas</i>	Flupyradifurone	ELS, 35d, f	NOEC = 4.41 mg a.s./L _{mm}	EFSA Journal 2015;13(2):4020
<i>Daphnia magna</i>	Flupyradifurone	48h, s	EC ₅₀ > 77.6 mg a.s./L _{mm}	EFSA Journal 2015;13(2):4020
<i>Daphnia magna</i>	Flupyradifurone	21d, ss	NOEC = 3.2 mg a.s./L _{nom}	EFSA Journal 2015;13(2):4020
<i>Americamysis bahia</i>	Flupyradifurone	96h, f	EC ₅₀ = 0.26 mg a.s./L _{mm}	EFSA Journal 2015;13(2):4020
<i>Americamysis bahia</i>	Flupyradifurone	28d, f	NOEC = 0.0132 mg a.s./L _{mm}	EFSA Journal 2015;13(2):4020
<i>Chironomus riparius</i>	Flupyradifurone	48h, s, spiked water	EC ₅₀ = 0.0617 mg a.s./L _{nom}	EFSA Journal 2015;13(2):4020
<i>Chironomus riparius</i>	Flupyradifurone	28d, s, spiked water	NOEC = 0.00681 mg a.s./L _{mm}	EFSA Journal 2015;13(2):4020
<i>Pseudokirchneriella subcapitata</i>	Flupyradifurone	72h, s	E _r C ₅₀ , E _y C ₅₀ , E _b C ₅₀ > 80 mg a.s./L _{nom}	EFSA Journal 2015;13(2):4020
<i>Lemna gibba</i>	Flupyradifurone	7d, s	E _r C ₅₀ , E _y C ₅₀ , E _b C ₅₀ > 67.7 mg a.s./L _{mm}	EFSA Journal 2015;13(2):4020
<i>Oncorhynchus mykiss</i>	BYI 02960-succinamide	96h, s	EC ₅₀ > 100 mg/L _{nom}	EFSA Journal 2015;13(2):4020
<i>Oncorhynchus mykiss</i>	DFA	96h, s	EC ₅₀ > 10 mg/L _{nom}	EFSA Journal 2015;13(2):4020
<i>Daphnia magna</i>	DFA	48h, s	EC ₅₀ > 10 mg/L _{nom}	EFSA Journal 2015;13(2):4020
<i>Daphnia magna</i>	6-CNA	48h, s	EC ₅₀ > 95.1 mg/L _{mm}	EFSA Journal 2015;13(2):4020
<i>Daphnia magna</i>	BYI 02960-succinamide	21d, ss	NOEC = 43.3 mg/L _{nom}	EFSA Journal 2015;13(2):4020
<i>Chironomus riparius</i>	BYI 02960-succinamide	48h, s, spiked water	EC ₅₀ > 100 mg/L _{nom}	EFSA Journal 2015;13(2):4020
<i>Chironomus riparius</i>	BYI 02960-azabicyclosuccinamide, sodium salt	48h, s, spiked water	EC ₅₀ > 100 mg/L _{nom}	EFSA Journal 2015;13(2):4020
<i>Chironomus tentans</i>	6-CNA	96h, s, spiked water	EC ₅₀ > 1 mg/L _{nom}	EFSA Journal 2015;13(2):4020
<i>Chironomus riparius</i>	6-CNA	28d, s, spiked water	NOEC = 100 mg/L _{nom}	EFSA Journal 2015;13(2):4020
<i>Chironomus riparius</i>	DFA	28d, s, spiked water	NOEC = 100 mg/L _{nom}	EFSA Journal 2015;13(2):4020
<i>Pseudokirchneriella subcapitata</i>	BYI 02960-succinamide	72h, s	E _r C ₅₀ , E _y C ₅₀ > 10 mg a.s./L _{nom}	EFSA Journal 2015;13(2):4020
<i>Pseudokirchneriella subcapitata</i>	6-CNA	72h, s	E _r C ₅₀ > 100 mg/L _{nom} E _y C ₅₀ = 85 mg a.s./L _{nom}	EFSA Journal 2015;13(2):4020
<i>Pseudokirchneriella subcapitata</i>	DFA	72h, s	E _r C ₅₀ , E _y C ₅₀ > 10 mg/L _{nom}	EFSA Journal 2015;13(2):4020

Species	Substance	Exposure System	Results	Reference
Endpoints used for metabolites risk assessment in case that no test data are available				
<i>Pimephales promelas</i>	Metabolites of flupyradifurone ¹⁾	96h, s	LC ₅₀ > 70.5 mg/L _{mm}	from parent compound (see justification)
<i>Pimephales promelas</i>	Metabolites of flupyradifurone ²⁾	ELS, 35d, f	NOEC = 4.41 mg/L _{mm}	from parent compound (see justification)
<i>Daphnia magna</i>	Metabolites of flupyradifurone ³⁾	48h, s	EC ₅₀ > 77.6 mg/L _{mm}	from parent compound (see justification)
<i>Daphnia magna</i>	Metabolites of flupyradifurone ⁴⁾	21d, ss	NOEC = 3.2 mg/L _{nom}	from parent compound (see justification)
<i>Chironomus riparius</i>	Metabolites of flupyradifurone ⁵⁾	48h, s, spiked water	EC ₅₀ > 100 mg/L _{nom}	Predicted based on available chronic study with <i>Chironomus riparius</i> (see justification)
<i>Chironomus riparius</i>	Metabolites of flupyradifurone ³⁾	28d, s, spiked water	NOEC = 10 mg/L _{nom}	Predicted based on ACR from parent compound (see justification)

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

¹⁾ applicable for 6-CNA and BYI 02960-azabicyclosuccinamide

²⁾ applicable for DFA, 6-CNA, BYI 02960-succinamide and BYI 02960-azabicyclosuccinamide

³⁾ applicable for BYI 02960-succinamide and BYI 02960-azabicyclosuccinamide

⁴⁾ applicable for DFA, 6-CNA and BYI 02960-azabicyclosuccinamide

⁵⁾ applicable for DFA

Table 9.7-3: Endpoints and effect values relevant for the risk assessment for aquatic organisms – formulation

Species	Substance	Exposure System	Results	Reference
<i>Oncorhynchus mykiss</i>	DLT + FPF EC 85	96 h, s	LC ₅₀ = 158.3 µg prod./L	Appendix 2 <u>Matlock, D.; Moore, S.; 2016; M 548840-01-1</u>
<i>Oncorhynchus mykiss</i>	DLT + FPF EC 85	96 h, semi-static	LC ₅₀ > 150 µg product/L (nom) (>10.496 µg sum of a.s./L (mm))	Appendix 2, KCP 10.2.1/07 Bebon & Sonntag (2020a) M-679497-01-1
<i>Daphnia magna</i>	DLT + FPF EC 85	48 h, s	EC ₅₀ = 1.63 µg prod./L	Appendix 2 <u>Matlock, D.; Moore, S.; 2016; M 553769-03-1</u>
<i>Daphnia magna</i>	DLT + FPF EC 85	48 h, semi-static	EC ₅₀ = 1.82 µg product/L (nom) (0.1235 µg sum of a.s./L (mm))	Appendix 2, KCP 10.2.1/08 Bebon & Sonntag (2020b) M-686370-01-1
<i>Chironomus riparius</i>	DLT + FPF EC 85	48 h, s	EC ₅₀ = 3.24 µg prod./L	Appendix 2 <u>Silke, G.; 2016; M-556348-01-1</u>
<i>Chironomus riparius</i>	DLT + FPF EC 85	48 h, semi-static	LC ₅₀ = 5.72 µg product/L (nom) (0.3496 µg sum of a.s./L (mm))	Appendix 2, KCP 10.2.1/09 Bebon & Sonntag (2020c) M-686369-01-1

Species	Substance	Exposure System	Results	Reference
<i>Pseudokirchneriella subcapitata</i>	DLT+FPF EC 85	72 h, s	E ₁ C ₅₀ =27.4 mg prod./L	Appendix 2 <u>Matlock, D.; Moore, S.; 2015; M-547460-01-1</u>

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

zRMS comments:

Active compounds (Tier 1 data)

Aquatic toxicity data provided in Table 9.5-1 and 9.5-2 for particular active substances are in line with EU agreed endpoints reported in the Review Report for deltamethrin (6504/VI/99-final, 2002) and EFSA Journal 2015;13(2):4020 for flupyradifurone.

It is noted that for flupyradifurone more species of fish and aquatic invertebrates were tested in acute toxicity studies, however the lowest values for each group of organisms were presented in Table 9.5-2 and for this reason remaining endpoints are not inserted by the zRMS as being not relevant for the risk assessment.

Deltamethrin (higher tier data)

Detailed discussion on the proposed endpoint of 23 ng a.s./L concluded by Heimbach & Koelzer, (2008, M-297157-01-1) is presented in Appendix 2 under KCP 10.2.2/01. In summary, proposed endpoint is not agreed by the zRMS since it was derived with consideration of indications of the outdated guidance document (SANCO/3268/2001 rev. 4, final) which was replaced by the EFSA aquatic guidance (2013), applicable for all applications submitted since 2015. Furthermore, conclusion on the endpoint of 23 ng a.s./L was based on recovery observed in some of the studies submitted, but in line with the Central Zone agreements and specific Polish requirements, recovery is no longer an option in derivation of the endpoints and higher tier studies must be evaluated with consideration of the ETO option. This is of specific importance for DLT+FPF EC 85, which contains two active substances of insecticidal mode of action (deltamethrin and flupyradifurone) and it is not known if the populations of aquatic invertebrates would recover after simultaneous exposure to both active compounds.

It was further noted that majority of the studies included in the data package on the basis of which Heimbach & Koelzer (2008) proposed an overall endpoint of 23 ng deltamethrin/L with no AF, has been also evaluated in the course of the ongoing EU renewal process of deltamethrin. Based on results of the same studies the endpoint was set by the RMS to 1.0 ng deltamethrin/L with and AF of 2, resulting with RAC of 0.5 mg deltamethrin/L. Since in the evaluation indications and criteria of EFSA (2013) were considered, this endpoint seems to be most reliable. Nevertheless, as the renewal process is not finalised yet and the endpoint to be used in the aquatic risk assessment will be most probably further discussed during the expert meeting the zRMS is of the opinion that at the current stage the EU agreed EAC of 3.2 ng deltamethrin/L should be used with AF of 2, resulting with RAC of 1.6 ng/L. **For further justification of the selected AF, please refer to Appendix 2, KCP 10.2.2/01.**

With regard to fish, the study by [REDACTED] (2005, M-256605-01-1) on effects of Deltamethrin EW 15 on rainbow trout in aquatic outdoor microcosm enclosures was considered. It was indicated by the RMS that no definite endpoint could be derived from the study due to the exposure regime, however the evidence available in the study was considered sufficient to conclude that the risk to fish is addressed by the risk assessment performed for aquatic invertebrates. The zRMS agrees with the RMS conclusion and considers it to be applicable also for this evaluation. It is noted that no definite endpoint could be derived from the study by Deneer (2005) due to the exposure regime, however rough estimations provided by the RMS indicated that the overall NOEC from the study would be at ~200 ng a.s./L, which is much higher comparing to 3.2 ng a.s./L derived for aquatic invertebrates.

Calculation of the geometric mean LC₅₀ from endpoints for *Asellus aquaticus* and *Gammarus fasciatus* is agreed by the zRMS as being in line with indications of EFSA (2013). It should be, however, noted that the acute as well as long-term risk to aquatic invertebrates are addressed considering the EU agreed endpoint from microcosm study.

Metabolites

Studies on acute toxicity of Br2CA to fish and *Daphnia magna* were not available in the course of the first EU

review of deltamethrin, but were evaluated and agreed by the RMS in the course of the ongoing EU renewal process. Although the renewal process is not finalised yet, change of the derived endpoints is not expected and values as reported in the LoEP of July 2019 are relevant for the risk assessment. Respective corrections were made in Table 9.5-1 in order to comply with most recent evaluation of the RMS.

Available data package for flupyradifurone clearly indicates that metabolites are not more toxic than the parent and in general evaluation performed for the active substance is considered to be protective also for metabolites. Nevertheless, the approach taken by the Applicant in order to derive missing endpoints for metabolites is agreed by the zRMS.

Formulation

Studies on acute toxicity of DLT+FPF EC 85 were evaluated by the zRMS and it was noted that only concentration of flupyradifurone was confirmed in respective chemical analyses while no measurements were performed for deltamethrin. It should be, however, noted that in line with requirements of the Central Zone the test concentrations of both substances should be verified in respective chemical analyses or, as a minimum, the least stable active compound should be analysed. Of the two substances present in DLT+FPF EC 85, deltamethrin seems to be less stable than flupyradifurone and this compound should have been analysed. No explanation or justification of the substance selected for the measurements was provided in the studies reports. Since stability of both active compounds throughout the study period could not be confirmed, the studies were considered not acceptable by the zRMS.

During the commenting period the Applicant may provide additional explanations to justify selection of the substance for chemical verification or data to confirm that deltamethrin was most stable during the study.

During the commenting period additional studies on acute toxicity of DLT+FPF EC 85 to fish, *Daphnia magna* and *Chironomus riparius* were submitted by the Applicant. Studies were evaluated and agreed by the zRMS (for summaries of the studies and details of zRMS evaluation, please refer to respective points of Appendix 2). In all studies the concentration of both active compounds was verified in respective chemical analyses. Flupyradifurone was stable in all new toxicity studies, but measured concentrations of deltamethrin were not maintained at 80-120% of nominal and for this reason the Applicant was requested to provide calculation of the endpoints in line with indications of Appendix J of EFSA Supporting publication 2019:EN-1673 (only endpoints based on nominal concentrations were presented in the study reports). The endpoints were recalculated by the Applicant using method described in point 4.1 of Appendix J of EFSA Supporting publication 2019:EN-1673 (the preferred Option A was selected as being more reliable comparing to Option 2). Obtained results are reported in Table 9.5-3 above and were used in the combined toxicity assessment presented in the next commenting box.

It is noted that the study with vertebrates (fish) was repeated. However, in opinion of the zRMS, it was justified since the previous study was not acceptable and fish are one of the group of aquatic species very sensitive to deltamethrin. Taking this into account, valid study should be available.

No additional study with algae was performed, nevertheless due to low toxicity of both active compounds to primary producers new study was deemed not necessary and the combined risk was addressed with toxicity endpoints derived using the concentration addition model (CA model). Respective risk assessment is presented in the zRMS commenting box point 9.5.3 below.

Not relevant or not agreed data were struck through in Tables 9.5-1 to 9.5-3 above.

~~In order to assess whether the formulation is more toxic than expected based on its containing active substances the following has been considered:~~

~~A calculation of acute mixture toxicity of the formulation DLT+FPF EC 85 according to Finney is not reasonable as the acute endpoints for fish, *Daphnia* and algae for flupyradifurone are “greater than” values.~~

~~Furthermore, when comparing the available acute *Daphnia* and fish endpoints for the two a.s. it is obvious that the endpoints for deltamethrin are at least 5 orders of magnitude lower than the endpoints for flupyradifurone. Thus it becomes clear that the toxicity of the formulation is clearly~~

driven by deltamethrin although present at a much lower content than flupyradifurone (DLT: 0.867 %; FPF: 6.62%). Therefore a calculation according to Finney would be of little relevance. As for these two insecticidal active substances there is no concern regarding algae toxicity, no mixture toxicity assessment for algae is considered necessary. The lowest measured endpoint for the formulation has been derived for *Daphnia* ($EC_{50} = 0.00163$ mg prod./L). Considering the information on *Daphnia* toxicity provided for deltamethrin in this dossier the following can be concluded:

From the chronic *Daphnia* study an acute EC_{50} of > 37 ng/L can be derived. As deltamethrin is driving the toxicity (as described above) the theoretical toxicity of the formulation can be calculated based on the EC_{50} of 37 ng/L as worst case approach in combination with the DLT content of 0.867%. This calculation ($37 \text{ ng/L} / 0.867 * 100$) results in a theoretical EC_{50} of 4.27 µg prod./L. The comparison of this calculated value with the actual measured endpoint for the formulation results in an MDR of 2.6 ($4.27 / 1.63$).

For the formulation a $LC_{50} = 158$ µg prod./L for fish acute has been experimentally derived. Considering the information on fish toxicity provided for deltamethrin in this dossier the following can be concluded:

The acute fish LC_{50} for deltamethrin is 0.26 µg a.s./L. As deltamethrin is driving the toxicity (as described above) the theoretical toxicity of the formulation can be calculated based on the LC_{50} of 0.26 µg/L in combination with the DLT content of 0.867%. This calculation ($0.26 \text{ µg/L} / 0.867 * 100$) results in a theoretical LC_{50} of 30.0 µg prod./L. The comparison of this calculated value with the actual measured endpoint for the formulation results in an MDR of 0.19 ($30.0 / 158.3$).

Thus it can be concluded that the formulation DLT+FPF EC85 is not more toxic than expected based on its containing active substances. Therefore the risk assessment can be based on the active substances.

zRMS comments:

Calculation of the theoretical endpoints for the formulation containing more than one active substance based on the endpoint and content of the single substance is not foreseen by EFSA (2013). In case for one substance endpoints greater than the maximum tested concentration are concluded, these unbound values should be used in respective calculations in order to calculate MDR values.

Furthermore, the Applicant states that deltamethrin drives toxicity of DLT+FPF EC 85 only comparing the endpoints. However, in line with EFSA (2013) also concentrations of particular active compounds should be considered and Toxic Units calculated in order to check if one active compound contributes to the toxicity of the mixture at >90%. In case not, the respective risk assessment for the formulated product must be performed based on measured or estimated toxicity of the mixture, depending on the outcome of MDR calculations.

The Applicant is thus requested to provide respective evaluation of the mixture toxicity performed in line with indications of EFSA (2013).

It should be also noted that none of the acute toxicity studies performed with the formulation were agreed by the zRMS since concentration of the least stable substance (deltamethrin) was not verified in the respective chemical analyses. During the commenting period the Applicant may provide additional explanations to justify selection of the substance for chemical verification or data to confirm that deltamethrin was most stable during the study. In case this will be confirmed, measured formulation endpoints will be relevant for the combitox assessment. Otherwise, the risk assessment for the mixture will have to be based on the theoretically estimated exposure.

During the commenting period additional studies on acute toxicity of DLT+FPF EC 85 to fish, *Daphnia magna* and *Chironomus riparius* were submitted by the Applicant. For endpoints and additional information on the studies, please refer to the commenting box under Table 9.5-3 above.

In addition to the new toxicity studies, also TU values were calculated by the Applicant. Results of the calculation are presented in table below.

Organism	Time scale	Toxicity endpoint [µg/L]			TU <i>i</i> ¹⁾		% TU <i>i</i> ²⁾		Trigger % TU <i>i</i> ≥ 90%?
		Endpoint	DLT	FPF	DLT	FPF	DLT	FPF	
Fish	acute	LC ₅₀	0.26	> 70500	38.462	0.001	100.00	0.00	yes
	chronic	NOEC	0.032	4410	312.50	0.017	99.99	0.01	yes
Aquatic invertebrates	acute	EC ₅₀	0.56	> 77600	17.857	0.001	99.99	0.01	yes
	chronic	NOEC	0.0041	3200	2439.0	0.023	100.00	0.00	yes
Sediment dweller	acute	NOEC*/EC ₅₀	0.01*	61.7	1000.0	1.216	99.96	0.04	yes
	chronic	NOEC	0.01	6.81	1000.0	11.013	98.91	1.09	yes

* There is no acute sed. dweller study performed for DLT. Therefore, the chronic NOEC is used as a worst case surrogate endpoint.

¹⁾ Based on the following equation: $TU_i = \frac{C_i}{EC_{X_i}}$

i index from 1...n mixture components

EC_X *i* concentration of component *i* provoking X % effect (or NOEC_{*i*})

TU *i* Toxic Unit; the concentration of the concentration of substance *i* in the product divided by its EC_X.

C *i* concentration of the *i*th a.s. at the ECxPPP (recalculated to the sum of a.s.)

²⁾ Based on the following equation: $\%TU_i = \frac{TU_i}{\sum_{i=1}^n TU_i}$

Calculations above were independently checked by the zRMS and obtained results were in good agreement with Applicants' values regardless if the concentrations of particular active substances in the formulation were considered (10 and 75 g/L for deltamethrin and flupyradifurone, respectively) or the fraction in the mixture was taken into account (0.12 and 0.88 for deltamethrin and flupyradifurone, respectively). Performed calculations demonstrate that deltamethrin contributes to >90% of the toxicity of the mixture.

No calculations for algae were provided by the Applicant and respective calculation was thus performed by the zRMS in table below

Organism	Time scale	Toxicity endpoint [µg/L]			TU <i>i</i>		% TU <i>i</i>		Trigger % TU <i>i</i> ≥ 90%?
		Endpoint	DLT	FPF	DLT	FPF	DLT	FPF	
Algae	chronic	E _r C ₅₀	> 9100	> 80000	0.001	0.0009	54.0	46.0	no

TU at approximately 50% for both active substances indicate that the toxicity to algae cannot be explained by presence of one active compound and for this reason separate risk assessment should be performed for this group of species. Due to lack of valid algae toxicity study with the formulated product, in opinion of the zRMS it is acceptable to perform respective evaluation based on estimated endpoint, since none of the active compounds is toxic to primary producers and the risk assessment is performed in order to fulfil formal requirements. Based on individual E_rC₅₀ values of >9100 and 80000 µg a.s./L and fraction in the mixture of 0.12 and 0.88 for deltamethrin and flupyradifurone, respectively, the surrogate E_rC₅₀ value of 41344.84 µg/L was calculated by the zRMS.

Although calculated above TU values indicate that deltamethrin drives the acute toxicity of the mixture to fish, aquatic invertebrates and sediment dwelling organisms, the combined toxicity assessment was also performed by the zRMS in order to check if the measured formulation toxicity data are in agreement with the estimated toxicity of the mixture of both active compounds. In MDR calculations presented in table below, results of the newly submitted acute toxicity studies were considered together with currently EU agreed endpoints for the same species.

Species	Fraction of a.s. in formulation		LC ₅₀ /EC ₅₀ [µg a.s./L]		EC _x [µg a.s./L]		MDR ^{c)}
	DLT	FPF	DLT	FPF	PPP ^{a)}	Mix-ca ^{b)}	
Fish	0.12	0.88	0.26	>70500	>10.496	2.167	0.21
<i>D. magna</i>			0.56	>77600	0.1235	4.666	37.8
<i>C. riparius</i>			0.01 ^{e)}	61.7	0.3496	0.083	0.24

DLT: deltamethrin FPF: flupyradifurone

^{a)} measured mixture toxicity, based on sum of active substances, see Table 9.5-3

^{b)} calculated mixture toxicity, EC_x_{mixture}-CA

^{d)} MDR = EC_x_{mixture}-CA/EC_x_{PPP}

^{e)} there is no acute sediment dweller study performed for DLT and the chronic NOEC is used as a worst case surrogate endpoint

The MDR values calculated for fish and *Chironomus riparius* are between 0.2-5 indicating that the measured and estimated mixture toxicity are in good agreement with no increased toxicity observed due to the simultaneous exposure of these species to both active compounds.

However, the MDR calculated for *Daphnia magna* is far above 5, showing that the measured acute toxicity of the mixture is much higher than expected on the basis of calculations performed with consideration of the toxicity of the individual substances.

Although the measured toxicity of the formulation is much higher than expected, the zRMS is of the opinion that on the basis of the available toxicity data and calculated TU values (nearly 100% mixture toxicity attributed to deltamethrin) it may be expected that this is rather due to increased toxicity of deltamethrin and not flupyradifurone, which with EC₅₀ of >77600 µg/L is practically not toxic to *Daphnia magna*, even comparing with substances with no insecticidal mode of action.

The zRMS decided therefore to analyse the toxicity data for *Daphnia magna* in more detail to find possible explanation for such an increased toxicity of deltamethrin in the mixture with flupyradifurone. However, due to the poor reporting no valuable information on the study resulting with EC₅₀ of 0.56 µg/L (Putt, 1999) could be obtained from the old monograph (Addendum of July 2002). Therefore, the Vol. 3CA, B.9 (July 2019) was consulted. Unfortunately, in this document also no detailed summary of the study by Putt (1999) has been presented by the RMS (UK) and the available summary was just copied from the Addendum of 2002, so no detailed results are available for analysis. However, in the renewal report more up-to-date study performed in the semi-static design was also available (Ribschlaeger, 2014), resulting with 48 h EC₅₀ of 0.01149 µg a.s./L, i.e. value considerably lower than the EC₅₀ of 0.56 µg/L derived from the old flow-through study by Putt (1999). The difference in obtained endpoints seems not to be caused entirely by the different test design. It is noted that the concentrations tested in the new study by Ribschlaeger (2014) were considerably lower (0.0065-0.0995 µg/L, mean measured) comparing to the old study (0.11-1.3 µg/L, mean measured) and yet, >50% immobilisation was observed already at 0.0129 µg/L, i.e. at concentration almost 10 times lower than the minimum concentration of 0.11 µg/L tested in the study by Putt (1999). In opinion of the zRMS this adds some uncertainty to the results of the old study and indicates that deltamethrin may be actually more toxic than expected on the basis on the old study results. The endpoint from the study by Ribschlaeger (2014) has been used for MDR calculation below.

Species	Fraction of a.s. in formulation		LC ₅₀ /EC ₅₀ [µg a.s./L]		EC _x [µg a.s./L]		MDR ^{c)}
	DLT	FPF	DLT	FPF	PPP ^{a)}	Mix-ca ^{b)}	
<i>D. magna</i>	0.12	0.88	0.01149	>77600	0.1235	0.09575	0.78

When the lower endpoint from the new study is used, the MDR value of 0.78 (i.e. between 0.2-5) shows that the measured and predicted toxicity of the mixture are in good agreement. In opinion of the zRMS this confirms the general pattern observed also for other species. This may also indicate that the endpoint currently agreed at the EU level is under-protective. Since the renewal process was not finalised yet and the expert meeting in area of ecotoxicology was not yet performed, the provided above calculations and discussion should be considered as illustrative. Nevertheless, the zRMS is of the opinion that they are sufficient to conclude that the measured and estimated toxicity of the mixture is comparable and that deltamethrin is definitely the toxicity driver in DLT+FPF EC 85.

Based on above, in line with indications of EFSA aquatic guidance (2013), no separate risk assessment for fish, *Daphnia magna* and *Chironomus riparius* exposed to the mixture is required and the risk to these aquatic species is considered to be sufficiently addressed by calculations performed for individual active compounds.

Higher tier options for refined risk assessment in fish and aquatic invertebrates

Refined Risk Assessment for fish

A comprehensive refined risk assessment for fish is provided by Heimbach and Koelzer (2008; [M-292027-02-1](#), Appendix 2). The main approaches and results presented in this report are summarized below.

For the refined endpoint for fish, a Species Sensitivity Distribution (SSD) was conducted to determine the HC₅. Data for acute fish studies used for the SSD approach are presented in Appendix 2 (see chapter ‘Higher tier options for refined risk assessment in fish and aquatic invertebrates’ in A 2.2, Appendix 2 **Table 9.15-1**

A median HC₅ value of 272 ng/L was obtained.

Following the recommendation of the 2013 EFSA Aquatic Guidance Document (p. 101 and Table 28), an Assessment Factor of 9 should be applied to a median acute HC₅ based on acute LC₅₀ data. Thus, the SSD-RAC for deltamethrin in fish is 30 ng/L.

All acute LC₅₀ values are derived from laboratory studies either under flow-through, semi-static or static test conditions. All these studies overemphasize the exposure, since deltamethrin dissipates much more rapidly in natural water bodies. Therefore, a study was conducted in outdoor enclosures to simulate reasonable worst-case conditions of actual field situations resulting in a NOEAEC \geq 1000 ng a.s./L (Deneer, J.W., 2005; [M-256605-01-1](#), Appendix 2)..

At the NOEAEC of this study, no adverse effects on the overall most sensitive endpoint (weight increase, according to the results of the laboratory ELS and full life-cycle studies) were observed. For these reasons, the use of the NOEAEC and the chronic assessment factor of 10 seems appropriate for the final risk assessment for fish, resulting in an ecologically acceptable concentration (EAC) of 100 ng a.s./L.

This conclusion is further supported by several semi-field and field studies, presented in chapter ‘Higher tier options for refined risk assessment in fish and aquatic invertebrates’ in A 2.2, Appendix 2.

Deltamethrin was shown to be highly acutely toxic to aquatic organisms when exposed under laboratory conditions. However, the outlined field studies demonstrate that deltamethrin has a very low toxicity or is even non-toxic to fish under field conditions and realistic uses.

Therefore, the use of a RAC derived from laboratory data represents a very conservative approach. The EAC of 100 ng a.s./L derived from the outdoor microcosm test is considered to be an appropriate endpoint for the acute and chronic risk assessment of deltamethrin for fish, that can be used without an additional assessment factor.

However, aquatic invertebrates are much more sensitive to deltamethrin exposure and therefore drive the aquatic risk assessment for this active substance. A comprehensive refined risk assessment for aquatic invertebrates is presented below, which also covers the risk assessment for fish.

General refined risk assessment of deltamethrin for aquatic invertebrates

In the following, a refined risk assessment is presented taking into account experimental studies, expert statements and metapopulation model calculations, which were performed after the Annex I inclusion of deltamethrin to address specific concerns raised during the past years. According to the EFSA Aquatic Guidance Document (2013), a combination of experimental data and modelling can be used to assess population- and/or community-level responses (e.g., recovery, indirect effects) at relevant spatio-temporal scale. For more details, please refer to chapter ‘Higher tier options for refined risk assessment in fish and aquatic invertebrates’ below in A 2.2, Appendix 2).

The zooplankton dynamics as evaluated in the mesocosm study of Heimbach et al. (2005, [M-246137-01-2](#), Appendix 2) have been interpreted considering direct effects from the deltamethrin applications

as well as secondary effects. Special emphasis was put on *Asellus aquaticus*, an isopod species, which was identified as the aquatic invertebrate most sensitive to deltamethrin exposure. Next to a sensitivity study on different life stages, studies on the drift of this species in a natural stream were performed to investigate drift rates to be used for the meta-population modelling. Expert statements and evaluations on the biology and ecology and on the occurrence of this species in water bodies in the agricultural landscape demonstrate that *A. aquaticus* is predominantly inhabiting lentic or slowly flowing water bodies. The meta-population model MASTEP demonstrates the recovery potential *via* reproduction and recolonization of a population which had been affected by deltamethrin,

All this information demonstrates that deltamethrin can be used in agriculture without unacceptable effects on aquatic ecosystems up to an environmental concentration of 30 ng a.s./L.

However, due to the more pronounced effects in flowing water bodies identified in the MASTEP modelling at a concentration of 30 ng a.s./L, the concentration of 23 ng a.s./L (which is also supported by the experimentally derived NOEC of 23.4 ng a.s./L for *A. aquaticus*) was determined as the regulatory relevant endpoint for deriving more conservative acute and chronic ETO-RAC_{sw}.

According to the EFSA Aquatic Guidance Document (2013) and considering the fact that the experiments and approaches presented below addressed worst-case conditions, the assessment factor to be applied to both the acute and chronic ETO-RAC_{sw} should not be greater than 2.

zRMS comments:

Conclusions of the zRMS regarding the endpoints to be used in the aquatic risk assessment are provided in the commenting box under Table 9.5-3 and are not repeated here.

9.7.1.1 Justification for new endpoints

Deltamethrin

Species	Substance	Exposure System	Justification
<i>G. fasciatus</i> / <i>A. aquaticus</i>	Deltamethrin EC 25	96 h	The EC Review Report for deltamethrin (6504/VI/99-final; 2002) provides four acute endpoint (96-h LC ₅₀) values for the two most sensitive invertebrate species, namely <i>Gammarus fasciatus</i> (0.00031, 0.032 and > 0.043 µg/L) and <i>Asellus aquaticus</i> (0.0051 µg/L). These values were derived from additional laboratory toxicity tests (<i>i.e.</i> , tier 2) with the same test item (EC formulation of deltamethrin). According to the EFSA Aquatic Guidance Document (2013), as the two species belong to the same taxonomic group (crustaceans), the four acute LC ₅₀ can be used to calculate a geomean LC ₅₀ to which an AF of 100 is applied to derive an acute tier-2 RAC. Using 0.043 µg/L as the most conservative LC ₅₀ for <i>G. fasciatus</i> , the geomean 96-h LC ₅₀ of deltamethrin for the most sensitive aquatic invertebrate species: LC₅₀ geomean = 0.00384 µg a.s./L.
Fish, acute Rainbow trout	Br ₂ CA	96 h, s	New study endpoint LC₅₀ > 100 000 µg p.m./L_{nom} To provide information on the toxicity of Br ₂ CA to fish
Invertebrate, acute <i>Daphnia magna</i>	Br ₂ CA	48 h, s	New study endpoint EC₅₀ > 100 000 µg p.m./L_{nom} To provide information on the toxicity of Br ₂ CA to daphnia

Species	Substance	Exposure System	Justification
Mesocosm rainbow trout	Deltamethrin EW 15	3 applications onto water surface; spray interval 7 d	Refined endpoint required for risk assessment. Regarding chronic laboratory data for fish, several studies are available for deltamethrin. However, the chronic risk assessment is based on a higher tier outdoor microcosm study, resulting in a NOEAEC of 0.1 µg a.s./L (Deneer, 2005, M 256605 01 1). For chronic exposure, the corresponding EAC values range from 1.7 to 2.2 ng a.s./L based on laboratory studies, to 100 ng a.s./L based on the microcosm enclosure study with rainbow trout (NOEAEC of ≥ 1000 ng a.s./L, Assessment Factor of 10). The 21d LC ₅₀ gained under flow through conditions in the laboratory is >> 19 times lower than the 21d LC ₅₀ of >> 1000 ng a.s./L in the outdoor enclosure study, indicating the overestimation of risks based on results from laboratory conditions. The NOEC of this outdoor study is based on short term behavioral symptoms (swimming behavior) as the most sensitive endpoint. A change in behavior is an expression of physiological effects, which is highly sensitive and may lead to a reduced growth over time, particularly because food intake will be hampered. Insofar, it is comparable to the integrative parameter of growth, which was determined as the most sensitive endpoint in the chronic ELS and FFLC studies on fathead minnow. In addition, the microcosm study was performed under realistic worst-case exposure conditions with the maximum number of three applications of deltamethrin in minimum of 7 day intervals. Thus, the NOEAEC and the chronic assessment factor of 10 seems the most appropriate endpoint for the final chronic risk assessment resulting in an ecologically acceptable concentration of 100 ng a.s./L for fish.
Higher tier data aquatic invertebrates	Deltamethrin/Deltamethrin EC 25/Deltamethrin EW 15	-	Refined endpoint required for risk assessment. Based on a weight of evidence approach taking into account experimental studies, expert statements and metapopulation model calculations (please refer to Annex 2 for details), an EAC of 23 ng a.s./L for aquatic invertebrates can be used for the refined risk assessment without any further assessment factor.

Flupyradifurone: No deviation from EU agreed endpoints.

Flupyradifurone metabolites

In the EFSA conclusion for flupyradifurone it is stated that for the metabolites DFA, 6-CNA, BYI 02960-succinamide and BYI 02960-azabicyclosuccinamide the risk to aquatic organisms was assessed as low (page 17 of EFSA Journal 2015;13(2):4020).

Nevertheless a risk assessment for the metabolites is presented based on part 10.2.4 decision scheme of the EFSA Aquatic Guidance Document (EFSA AGD, 2013). The decision scheme is followed step by step.

Step 1: Are the studies with the active substance adequate for assessing the potential effect of the metabolites? ⇒ No: Go to step 3.

Step 3: Is it clear that the toxophore has been lost from the molecule?
The answer is “No or unclear” ⇒ Go to step 4.

Step 4: Identify the species or taxonomic group determining the lowest tier 1 RAC_{sw,ac} for the parent compound. Is the acute metabolite L(E)C₅₀ > 10 times the a.s. L(E)C₅₀ (on a molar basis)?

For flupyradifurone, the lowest standard tier 1 RAC_{sw,ac} is determined by *Chironomus riparius*.

For the metabolites 6-CNA, BYI 02960-succinamide and BYI 02960-azabicyclosuccinamide acute

Chironomus endpoints are available. The comparison between the acute Chironomus endpoints of parent and metabolites (on a molar basis) reveals that these metabolites are more than 10× less toxic to *Chironomus riparius* than the parent. ⇒ Go to step 6

For the metabolite DFA no acute, but chronic Chironomus endpoint is available. Thus toxicity comparison (on molar basis) between parent and metabolite has been done based on the respective chronic Chironomus studies. This comparison reveals that DFA is more than 10× less toxic to *Chironomus riparius* than the parent. ⇒ Go to step 6

Step 6: Assume that the acute and chronic toxicity of the metabolite is equal to the toxicity of the a.s. for all first tier taxonomic groups. Is $RAC_{sw,ac} > PEC_{sw}$ and $RAC_{sw,ch} > PEC_{sw}$?

6-CNA: The acute and chronic tier I risk assessment is passed for all first tier taxonomic groups considering the parent endpoints as surrogate where no test data are available. ⇒ Low risk

DFA: The chronic tier I risk assessment is passed for all first tier taxonomic groups considering the parent endpoints as surrogate where no test data are available. The acute tier I risk assessment is not passed for *Chironomus riparius* when considering the parent endpoint as surrogate. ⇒ Go to step 7

BYI 02960-succinamide and BYI 02960-azabicyclosuccinamide: The acute tier I risk assessment is passed for all first tier taxonomic groups considering the parent endpoints as surrogate where no test data are available. The chronic tier I risk assessment is not passed for *Chironomus riparius* when considering the parent endpoint as surrogate. ⇒ Go to step 7

Step 7: Are reliable and adequate non-testing predictions of toxicity available for all first tier taxonomic groups (fish, plants and invertebrates) for which risks were identified in step 6? Are $RAC_{sw,ac} > PEC_{sw}$ and $RAC_{sw,ch} > PEC_{sw}$ using these predictions?

DFA: For DFA a chronic Chironomus study is available resulting in a NOEC of 100 mg/L after 28 days of exposure. Thus it can be predicted that when exposed for 48 hours, the resulting EC_{50} will be > 100 mg/L. Considering this endpoint, the acute risk assessment for *Chironomus riparius* is passed for DFA ⇒ Low risk

BYI 02960-succinamide and BYI 02960-azabicyclosuccinamide: For BYI 02960-succinamide and BYI 02960-azabicyclosuccinamide, acute Chironomus studies are available resulting in an EC_{50} of > 100 mg/L. The Acute-to-Chronic Ratio (ACR) of available *Chironomus riparius* endpoints for the parent is 10. Applying this ACR of 10 to the metabolites the chronic endpoint for *Chironomus riparius* can be predicted to be 10 mg/L for both, BYI 02960-succinamide and BYI 02960-azabicyclosuccinamide. Considering this endpoint the chronic risk assessment for *Chironomus riparius* is passed ⇒ Low risk.

zRMS comments:

Conclusions of the zRMS regarding the endpoints to be used in the aquatic risk assessment are provided in the commenting box under Table 9.5-3 and are not repeated here.

9.7.2 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).

The relevant global maximum FOCUS Step 1, 2 and 3 PEC_{sw} for risk assessments covering the proposed use pattern and the resulting PEC/RAC ratios are presented in the table below for scenarios relevant for

the central zone.

To achieve a concise risk assessment, the risk envelope approach is applied for all metabolites of deltamethrin and flupyradifurone. Here, the assessment for the use group C (winter OSR) also covers the risk for aquatic organisms from all other intended uses in groups C (spring OSR), D and E (both winter and spring OSR) (see 9.3.2). For both active substances, a risk assessment is presented for all use groups C, D and E for winter OSR as well as spring OSR.

In the following tables, the ratios between predicted environmental concentrations in surface water bodies (PEC_{SW} , PEC_{SED}) and regulatory acceptable concentrations (RAC) for aquatic organisms are given per intended use for each FOCUS scenario relevant in the Central Zone and each organism group. As a first step of the assessment a risk assessment considering exposure from spray drift of the formulated product is presented.

Table 9.7.4: Aquatic organisms: acceptability of risk ($PEC/RAC < 1$) for DLT+FPF EC 85 (7.5 + 56.25) for each organism group (drift exposure) for the use in OSR 0.75 L prod./ha (use group A)

Group		Fish acute	Inverteb. acute	Algae	Sediment dweller acute
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Pseudokirchneriella subcapitata</i>	<i>Chironomus riparius</i>
Endpoint ($\mu\text{g/L}$)		LC_{50} 158.3	EC_{50} 1.63	EC_{50} 27400	EC_{50} 3.24
AE		100	100	10	100
RAC ($\mu\text{g/L}$)		1.583	0.0163	2740	0.0324
Drift only	PEC_{gl-max} ($\mu\text{g/L}$)				
no buffer					
0 % drift reduction	13.768	8.697	844.663	0.005	424.938
50% drift reduction	6.884	4.349	422.331	-	212.469
75 % drift reduction	3.442	2.174	211.166	-	106.235
90% drift reduction	1.377	0.870	84.479	-	42.500
5-meters buffer					
0 % drift reduction	2.719	1.718	166.810	-	83.920
50% drift reduction	1.359	0.858	83.374	-	41.944
75 % drift reduction	0.680	0.430	41.718	-	20.988
90% drift reduction	0.272	0.172	16.687	-	8.395
10-meters buffer					
0 % drift reduction	1.388	0.877	85.153	-	42.840
50% drift reduction	0.694	0.438	42.577	-	21.420
75 % drift reduction	0.347	0.219	21.288	-	10.710
90% drift reduction	0.139	0.088	8.528	-	4.290
15-meters buffer					
0 % drift reduction	0.926	0.585	56.810	-	28.580
50% drift reduction	0.463	0.292	28.405	-	14.290
75 % drift reduction	0.231	0.146	14.172	-	7.130
90% drift reduction	0.093	0.059	5.706	-	2.870

Group		Fish-acute	Inverteb.-acute	Algae	Sediment dweller acute
20-meters-buffer					
0-% drift reduction	0.694	0.438	42.577	-	21.420
50%-drift reduction	0.347	0.219	21.288	-	10.710
75-% drift reduction	0.174	0.110	10.675	-	5.370
90%-drift reduction	0.069	0.044	4.233	-	2.130

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

Table 9.7-5: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for DLT+FPF EC 85 (7.5 + 56.25) for each organism-group (drift exposure) for the use in OSR—0.5 L prod./ha (use group-B)

Group		Fish-acute	Inverteb.-acute	Algae	Sediment dweller acute
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Pseudokirchneriella subcapitata</i>	<i>Chironomus riparius</i>
Endpoint (µg/L)		LC ₅₀	EC ₅₀	ErC ₅₀	EC ₅₀
AF		158.3	1.63	27400	3.24
RAC (µg/L)		100	100	10	100
		1.583	0.0163	2740	0.0324
Drift only	PEC _{gl-max} (µg/L)				
no-buffer					
0-% drift reduction	9.179	5.798	563.129	0.003	283.302
50%-drift reduction	4.589	2.899	281.534	-	141.636
75-% drift reduction	2.295	1.450	140.798	-	70.833
90%-drift reduction	0.918	0.580	56.319	-	28.333
5-meters-buffer					
0-% drift reduction	1.813	1.145	111.227	-	55.957
50%-drift reduction	0.906	0.572	55.583	-	27.963
75-% drift reduction	0.453	0.286	27.791	-	13.981
90%-drift reduction	0.181	0.114	11.104	-	5.586
10-meters-buffer					
0-% drift reduction	0.926	0.585	56.810	-	28.580
50%-drift reduction	0.463	0.292	28.405	-	14.290
75-% drift reduction	0.231	0.146	14.172	-	7.130
90%-drift reduction	0.093	0.059	5.706	-	2.870
15-meters-buffer					
0-% drift reduction	0.617	0.390	37.853	-	19.043
50%-drift reduction	0.309	0.195	18.957	-	9.537
75-% drift reduction	0.154	0.097	9.448	-	4.753
90%-drift reduction	0.062	0.039	3.804	-	1.914
20-meters-buffer					

Group		Fish-acute	Inverteb.-acute	Algae	Sediment-dweller-acute
0-% drift reduction	0.463	0.292	28.405	-	14.290
50% drift reduction	0.231	0.146	14.172	-	7.130
75 % drift reduction	0.116	0.073	7.117	-	3.580
90% drift reduction	0.046	0.029	2.822	-	1.420

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 the intended uses of the formulation the risk assessment for exposure via spray drift indicates an unacceptable risk for invertebrates and sediment dweller for the uses in winter and spring OSR of DLT+FPF EC 85. As it was be concluded that the formulation DLT+FPF EC 85 is not more toxic than expected based on its containing active substances further refinement can be based on the active substances.

zRMS comments:

As already indicated in the zRMS comments in point 9.6.1, the Applicant is requested to provide the respective evaluation of the combined risk performed in line with EFSA (2013).

Risk assessment performed with consideration of the formulation endpoints and formulation exposure based on the spray drift is not relevant anymore, as the risk assessment should be based on the PEC_{mix} calculated as the sum of active substances. In addition to that, before performing such a risk assessment it has to be checked if the mixture composition giving the measured toxicity is similar to the mixture composition at the PEC_{mix} in terms of the relative proportions of individual active substances.

It has to be also pointed out that in the studies performed with DLT+FPF EC 85 the concentration of the least stable active substance (deltamethrin) was not analytically verified and for this reason none of these studies was agreed by the zRMS as the actual exposure was not confirmed. During the commenting period the Applicant may provide additional explanations to justify selection of the substance for chemical verification or data to confirm that deltamethrin was most stable during the study.

During the commenting period additional studies on acute toxicity of DLT+FPF EC 85 to fish, *Daphnia magna* and *Chironomus riparius* were submitted by the Applicant. For endpoints and additional information on the studies, please refer to the commenting box under Table 9.5-3 in point 9.5.1 of this document.

In addition to the new toxicity studies, also TU values were calculated by the Applicant and demonstrated that deltamethrin contributes to >90% of the acute and chronic toxicity of the mixture to fish, aquatic invertebrates and sediment dwellers. Taking this into account, in line with indications of EFSA aquatic guidance (2013), no specific risk assessment for the mixture is deemed necessary and the risk to these groups of species is sufficiently addressed by calculations performed for individual active compounds.

None of the active substances contributes at >90% to toxicity of the mixture to algae and for this reason separate risk assessment is required and is performed below. In absence of the valid toxicity data for the formulated product, the endpoint estimated using CA model was considered in evaluation. Based on individual E_rC₅₀ values of >9100 and 80000 µg a.s./L and fraction in the mixture of 0.12 and 0.88 for deltamethrin and flupyradifurone, respectively, the surrogate E_rC₅₀ value of 41344.84 µg/L was calculated.

Table 9.7-6: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for deltamethrin for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of FPF+DLT EC 85 in OSR (use group C; 2 x 0.75 L prod./ha, BBCH 30-49, winter OSR)

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Inverteb. most sensitive	Algae	Sed. dwell. prolonged	Higher-tier information	Higher-tier information	Higher-tier information
Test species		<i>Oncorhynchus mykiss</i>	<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>G. fasciatus</i> / <i>A. aquaticus</i>	<i>Pseudok. subcapitata</i>	<i>Chironomus riparius</i>	Mesocosm <i>O. mykiss</i>	Aquatic invert.	Aquatic invert.
Endpoint (µg/L)		LC ₅₀ = 0.26	NOEC ≥ 0.032	EC ₅₀ = 0.56	NOEC = 0.0041	LC _{50 geo} = 0.00384	ErC ₅₀ > 9100	NOEC = 0.010	NOEAEC = 1.0	NOEC = 0.023	NOEC = 0.0032
AF		100	10	100	10	100	10	10	10	1	2
RAC (µg/L)		= 0.0026	≥ 0.0032	= 0.0056	= 0.00041	= 0.0000384	> 910	= 0.001	= 0.1	= 0.023	= 0.0016
FOCUS Scenario	PEC _{gl-max} (µg/L)										
Step 1											
	0.1383	53	< 43	25	337	3602	< 0.001	138	1.4	6.0	86
Step 2											
N-Europe	0.0690	27	< 22	12	168	1797	< 0.001	69	0.69	3.0	43
Step 3											
D3 ditch	0.047	18	< 15	8.4	115	1224	< 0.001	47	0.47	2.0	29
D4 pond	0.002	0.77	< 0.63	0.36	4.9	52	< 0.001	2.0	0.02	0.09	1.3
D4 stream	0.038	15	< 12	6.8	93	990	< 0.001	38	0.38	1.7	24
D5 pond	0.002	0.77	< 0.63	0.36	4.9	52	< 0.001	2.0	0.02	0.09	1.3
D5 stream	0.038	15	< 12	6.8	93	990	< 0.001	38	0.38	1.7	24
R1 pond	0.002	0.77	< 0.63	0.36	4.9	52	< 0.001	2.0	0.02	0.09	1.3
R1 stream	0.031	12	< 10	5.5	76	807	< 0.001	31	0.31	1.3	19
R3 stream	0.044	17	< 14	7.9	107	1146	< 0.001	44	0.44	1.9	28

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

Table 9.7-7: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for deltamethrin for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of FPF+DLT EC 85 in OSR (use group C; 2 x 0.75 L prod./ha, BBCH 30-49, spring OSR)

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Inverteb. most sensitive	Algae	Sed. dwell. prolonged	Higher-tier information	Higher-tier information	Higher-tier information
Test species		<i>Oncorhynchus mykiss</i>	<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>G. fasciatus</i> / <i>A. aquaticus</i>	<i>Pseudok. subcapitata</i>	<i>Chironomus riparius</i>	Mesocosm <i>O. mykiss</i>	Aquatic invert.	Aquatic invert.
Endpoint (µg/L)		LC ₅₀ = 0.26	NOEC ≥ 0.032	EC ₅₀ = 0.56	NOEC = 0.0041	LC _{50 geo} = 0.00384	ErC ₅₀ > 9100	NOEC = 0.010	NOEAEC = 1.0	NOEC = 0.023	NOEC = 0.0032
AF		100	10	100	10	100	10	10	10	1	2
RAC (µg/L)		= 0.0026	≥ 0.0032	= 0.0056	= 0.00041	= 0.0000384	> 910	= 0.001	= 0.1	= 0.023	= 0.0016
FOCUS Scenario	PEC _{gl-max} (µg/L)										
Step 1											
	0.1383	53	< 43	25	337	3602	< 0.001	138	1.4	6.0	86
Step 2											
N-Europe	0.0690	27	< 22	12	168	1797	< 0.001	69	0.69	3.0	43
Step 3											
D3 ditch	0.048	18	< 15	8.6	117	1250	< 0.001	48	0.48	2.1	30
D4 pond	0.002	0.77	< 0.63	0.36	4.9	52	< 0.001	2.0	0.02	0.09	1.3
D4 stream	0.039	15	< 12	7.0	95	1016	< 0.001	39	0.39	1.7	24
D5 pond	0.002	0.77	< 0.63	0.36	4.9	52	< 0.001	2.0	0.02	0.09	1.3
D5 stream	0.041	16	< 13	7.3	100	1068	< 0.001	41	0.41	1.8	26
R1 pond	0.002	0.77	< 0.63	0.36	4.9	52	< 0.001	2.0	0.02	0.09	1.3
R1 stream	0.031	12	< 10	5.5	76	807	< 0.001	31	0.31	1.3	19

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

Table 9.7-8: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for deltamethrin metabolite Br2CA for each organism group based on FOCUS Steps 1 and 2 calculations for the use of FPF+DLT EC 85 in OSR (use group C; 2 x 0.75 L prod./ha, BBCH 30-49, winter OSR)

Group		Fish acute	Invertebrate acute
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>
Endpoint (µg/L)		LC ₅₀ > 100000	EC ₅₀ > 100000
AF		100	100
RAC (µg/L)		> 1000	> 1000
FOCUS Scenario	PEC _{gl-max} (µg/L)		
Step 1			
	1.05	< 0.001	< 0.001
Step 2			
N-Europe	0.124	< 0.001	< 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

Table 9.7.9: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for flupyradifurone for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of FPF+DLT EC 85 in OSR (use group C; 2 x 0.75 L prod/ha, BBCH 30-49, winter OSR)

Group		Fish-acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Inverteb. acute	Inverteb. prolonged	Sed. dwell. acute	Sed. dwell. prolonged	Aquatic macrophytes	Algae
Test species		<i>Pimephales promelas</i>	<i>Pimephales promelas</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Americamysis bahia</i>	<i>Americamysis bahia</i>	<i>Chironomus riparius</i>	<i>Chironomus riparius</i>	<i>Lemna gibba</i>	<i>Pseudokirchneriella subcapitata</i>
Endpoint (µg/L)		LC ₅₀ >70500	NOEC =4410	EC ₅₀ >77600	NOEC =3200	EC ₅₀ =260	NOEC =13.2	EC ₅₀ =61.7	NOEC =6.81	E _r C ₅₀ >67700	E _r C ₅₀ >80000
AF		100	10	100	10	100	10	100	10	10	10
RAC (µg/L)		>705	=441	>776	=320	=26	=1.32	=0.617	=0.681	>6770	>8000
FOCUS Scenario	PEC _{gl-max} (µg/L)										
Step 1											
	34.185	<0.048	0.078	<0.044	0.11	13	26	55	50	<0.005	<0.004
Step 2											
N-Europe	5.4076	<0.008	0.012	<0.007	0.017	2.1	4.1	8.8	7.9	<0.001	<0.001
Step 3											
D3-ditch	0.3586	<0.001	<0.001	<0.001	0.001	0.14	0.27	0.58	0.53	<0.001	<0.001
D4-pond	0.5162	<0.001	0.001	<0.001	0.002	0.20	0.39	0.84	0.76	<0.001	<0.001
D4-stream	0.4808	<0.001	0.001	<0.001	0.002	0.18	0.36	0.78	0.71	<0.001	<0.001
D5-pond	0.3156	<0.001	<0.001	<0.001	<0.001	0.12	0.24	0.51	0.46	<0.001	<0.001
D5-stream	0.3381	<0.001	<0.001	<0.001	0.001	0.13	0.26	0.55	0.50	<0.001	<0.001
R1-pond	0.0979	<0.001	<0.001	<0.001	<0.001	0.038	0.074	0.16	0.14	<0.001	<0.001
R1-stream	1.4350	<0.002	0.003	<0.002	0.004	0.55	1.1	2.3	2.1	<0.001	<0.001
R3-stream	1.0930	<0.002	0.002	<0.001	0.003	0.42	0.83	1.8	1.6	<0.001	<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

Table 9.7-9A: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for flupyradifurone for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of FPF+DLT EC 85 in OSR (use group C; 2 x 0.75 L prod/ha, BBCH 30-49, winter OSR) the plant uptake factor for the parent flupyradifurone was set to 0

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Inverteb. acute	Inverteb. prolonged	Sed. dwell. acute	Sed. dwell. prolonged	Aquatic macrophytes	Algae
Test species		<i>Pimephales promelas</i>	<i>Pimephales promelas</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Americamysis bahia</i>	<i>Americamysis bahia</i>	<i>Chironomus riparius</i>	<i>Chironomus riparius</i>	<i>Lemna gibba</i>	<i>Pseudokirchneriella subcapitata</i>
Endpoint (µg/L)		LC ₅₀ > 70500	NOEC = 4410	EC ₅₀ > 77600	NOEC = 3200	EC ₅₀ = 260	NOEC = 13.2	EC ₅₀ = 61.7	NOEC = 6.81	E _r C ₅₀ > 67700	E _r C ₅₀ > 80000
AF		100	10	100	10	100	10	100	10	10	10
RAC (µg/L)		> 705	= 441	> 776	= 320	= 2.6	= 1.32	= 0.617	= 0.681	> 6770	> 8000
FOCUS Scenario	PEC ^{gl-max} (µg/L)										
Step 3											
D3 ditch	0.3592	< 0.001	< 0.001	< 0.001	0.001	0.14	0.27	0.58	0.53	< 0.001	< 0.001
D4 pond	0.5931	< 0.001	0.001	< 0.001	0.002	0.23	0.45	0.96	0.87	< 0.001	< 0.001
D4 stream	0.5404	< 0.001	0.001	< 0.001	0.002	0.21	0.41	0.88	0.79	< 0.001	< 0.001
D5 pond	0.3373	< 0.001	< 0.001	< 0.001	0.001	0.13	0.26	0.55	0.50	< 0.001	< 0.001
D5 stream	0.344	< 0.001	< 0.001	< 0.001	0.001	0.13	0.26	0.56	0.51	< 0.001	< 0.001
R1 pond	0.0991	< 0.001	< 0.001	< 0.001	< 0.001	0.038	0.075	0.16	0.15	< 0.001	< 0.001
R1 stream	1.456	< 0.002	0.003	< 0.002	0.005	0.56	1.1	2.4	2.1	< 0.001	< 0.002
R3 stream	1.103	< 0.002	0.003	< 0.001	0.003	0.42	0.84	1.8	1.6	< 0.001	< 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

Table 9.7-10: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for flupyradifurone for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of FPF+DLT EC 85 in OSR (use group C; 2 x 0.75 L prod/ha, BBCH 30-49, spring OSR)

Group		Fish-acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Inverteb. acute	Inverteb. prolonged	Sed. dwell. acute	Sed. dwell. prolonged	Aquatic macrophytes	Algae
Test species		<i>Pimephales promelas</i>	<i>Pimephales promelas</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Americamysis bahia</i>	<i>Americamysis bahia</i>	<i>Chironomus riparius</i>	<i>Chironomus riparius</i>	<i>Lemna gibba</i>	<i>Pseudokirchneriella subcapitata</i>
Endpoint (µg/L)		LC ₅₀ >70500	NOEC =4410	EC ₅₀ >77600	NOEC =3200	EC ₅₀ =260	NOEC =13.2	EC ₅₀ =61.7	NOEC =6.81	E _r C ₅₀ >67700	E _r C ₅₀ >80000
AF		100	10	100	10	100	10	100	10	10	10
RAC (µg/L)		>705	=441	>776	=320	=2.6	=1.32	=0.617	=0.681	>6770	>8000
FOCUS Scenario	PEC _{gl-max} (µg/L)										
Step 1											
	34.185	<0.048	0.078	<0.044	0.11	13	26	55	50	<0.005	<0.004
Step 2											
N-Europe	2.6510	<0.004	0.006	<0.003	0.008	1.0	2.0	4.3	3.9	<0.001	<0.001
Step 3											
D3-ditch	0.3584	<0.001	<0.001	<0.001	0.001	0.14	0.27	0.58	0.53	<0.001	<0.001
D4-pond	0.4599	<0.001	0.001	<0.001	0.001	0.18	0.35	0.75	0.68	<0.001	<0.001
D4-stream	0.4534	<0.001	0.001	<0.001	0.001	0.17	0.34	0.73	0.67	<0.001	<0.001
D5-pond	0.3328	<0.001	<0.001	<0.001	0.001	0.13	0.25	0.54	0.49	<0.001	<0.001
D5-stream	0.3391	<0.001	<0.001	<0.001	0.001	0.13	0.26	0.55	0.50	<0.001	<0.001
R1-pond	0.1236	<0.001	<0.001	<0.001	<0.001	0.048	0.094	0.20	0.18	<0.001	<0.001
R1-stream	1.0080	<0.001	0.002	<0.001	0.003	0.39	0.76	1.6	1.5	<0.001	<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

Table 9.7-10A: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for flupyradifurone for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of FPF+DLT EC 85 in OSR (use group C; 2 x 0.75 L prod/ha, BBCH 30-49, spring OSR) the plant uptake factor for the parent flupyradifurone was set to 0

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Inverteb. acute	Inverteb. prolonged	Sed. dwell. acute	Sed. dwell. prolonged	Aquatic macrophytes	Algae
Test species		<i>Pimephales promelas</i>	<i>Pimephales promelas</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Americamysis bahia</i>	<i>Americamysis bahia</i>	<i>Chironomus riparius</i>	<i>Chironomus riparius</i>	<i>Lemna gibba</i>	<i>Pseudokirchneriella subcapitata</i>
Endpoint (µg/L)		LC ₅₀ > 70500	NOEC = 4410	EC ₅₀ > 77600	NOEC = 3200	EC ₅₀ = 260	NOEC = 13.2	EC ₅₀ = 61.7	NOEC = 6.81	E _r C ₅₀ > 67700	E _r C ₅₀ > 80000
AF		100	10	100	10	100	10	100	10	10	10
RAC (µg/L)		> 705	= 441	> 776	= 320	= 2.6	= 1.32	= 0.617	= 0.681	> 6770	> 8000
FOCUS Scenario	PEC ^{gl-max} (µg/L)										
Step 3											
D3 ditch	0.3587	< 0.001	< 0.001	< 0.001	0.001	0.14	0.27	0.58	0.53	< 0.001	< 0.001
D4 pond	0.4971	< 0.001	0.001	< 0.001	0.002	0.19	0.38	0.81	0.73	< 0.001	< 0.001
D4 stream	0.4837	< 0.001	0.001	< 0.001	0.002	0.19	0.37	0.78	0.71	< 0.001	< 0.001
D5 pond	0.3521	< 0.001	< 0.001	< 0.001	0.001	0.14	0.27	0.57	0.52	< 0.001	< 0.001
D5 stream	0.3408	< 0.001	< 0.001	< 0.001	0.001	0.13	0.26	0.55	0.50	< 0.001	< 0.001
R1 pond	0.1284	< 0.001	< 0.001	< 0.001	< 0.001	0.049	0.097	0.21	0.19	< 0.001	< 0.001
R1 stream	1.038	< 0.001	0.002	< 0.001	0.003	0.40	0.79	1.7	1.5	< 0.001	< 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

Table 9.7-11: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for flupyradifurone metabolite 6-chloronicotinic acid (6-CNA) for each organism group based on FOCUS Steps 1 and 2 calculations for the use of FPF+DLT EC 85 in OSR (use group C; 2 x 0.75 L prod/ha, BBCH 30-49, winter OSR)

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Sed. dwell. acute	Sed. dwell. prolonged	Algae
Test species		<i>Pimephales promelas</i>	<i>Pimephales promelas</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Chironomus tentans</i>	<i>Chironomus riparius</i>	<i>Pseudokirchn. subcapitata</i>
Endpoint (µg/L)		LC ₅₀ # > 70500	NOEC # = 4410	EC ₅₀ > 95100	NOEC # = 3200	EC ₅₀ > 1000	NOEC = 100000	ErC ₅₀ > 100000
AF		100	10	100	10	100	10	10
RAC (µg/L)		> 705	= 441	> 951	= 320	> 10	= 10000	> 10000
FOCUS Scenario	PEC _{gl-max} (µg/L)							
Step 1								
	3.133	< 0.004	0.007	< 0.003	0.010	< 0.31	< 0.001	< 0.001
Step 2								
N-Europe	0.1468	< 0.001	< 0.001	< 0.001	< 0.001	< 0.015	< 0.001	< 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

Endpoint from parent compound as surrogate according to decision scheme of the AGD (see justification for new endpoints)

Table 9.7-12: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for flupyradifurone metabolite difluoroacetic acid (DFA) for each organism group based on FOCUS Steps 1 and 2 calculations for the use of FPF+DLT EC 85 in OSR (use group C; 2 x 0.75 L prod/ha, BBCH 30-49, winter OSR)

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Sed. dwell. acute	Sed. dwell. prolonged	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Pimephales promelas</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Chironomus riparius</i>	<i>Chironomus riparius</i>	<i>Pseudokirchn. subcapitata</i>
Endpoint (µg/L)		LC ₅₀ > 10000	NOEC # = 4410	EC ₅₀ > 10000	NOEC # = 3200	EC ₅₀ * > 100000	NOEC = 100000	ErC ₅₀ > 10000
AF		100	10	100	10	100	10	10
RAC (µg/L)		> 100	= 441	> 100	= 320	> 1000	= 10000	> 1000
FOCUS Scenario	PEC _{gl-max} (µg/L)							
Step 1								
	5.0657	< 0.051	0.011	< 0.051	0.016	< 0.005	< 0.001	< 0.005
Step 2								
N-Europe	0.6714	< 0.007	0.002	< 0.007	0.002	< 0.001	< 0.001	< 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

Endpoint from parent compound as surrogate according to decision scheme of the AGD (see justification for new endpoints)

* Endpoint predicted based on available chronic study with *Chironomus riparius* according to decision scheme of the AGD (see justification for new endpoints)

Table 9.7-13: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for flupyradifurone metabolite BYI 02960-succinamide for each organism group based on FOCUS Steps 1 and 2 calculations for the use of FPF+DLT EC 85 in OSR (use group C; 2 x 0.75 L prod/ha, BBCH 30-49, winter OSR)

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Sed. dwell. acute	Sed. dwell. prolonged	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Pimephales promelas</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Chironomus riparius</i>	<i>Chironomus riparius</i>	<i>Pseudokirchn. subcapitata</i>
Endpoint (µg/L)		LC ₅₀ > 100000	NOEC # = 4410	EC ₅₀ # > 77600	NOEC = 43300	EC ₅₀ > 100000	NOEC * = 10000	ErC ₅₀ > 10000
AF		100	10	100	10	100	10	10
RAC (µg/L)		> 1000	= 441	> 776	= 4330	> 1000	= 1000	> 1000
FOCUS Scenario	PEC _{gl-max} (µg/L)							
Step 1								
	16.211	< 0.016	0.037	< 0.021	0.004	< 0.016	0.016	< 0.016
Step 2								
N-Europe	2.5681	< 0.003	0.006	< 0.003	< 0.001	< 0.003	0.003	< 0.003

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

Endpoint from parent compound as surrogate according to decision scheme of the AGD (see justification for new endpoints)

* Endpoint predicted based on ACR_{parent} according to decision scheme of the AGD (see justification for new endpoints)

Table 9.7-14: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for flupyradifurone metabolite BYI 02960-azabicyclo-succinamide for each organism group based on FOCUS Steps 1 and 2 calculations for the use of FPF+DLT EC 85 in OSR (use group C; 2 x 0.75 L prod/ha, BBCH 30-49, winter OSR)

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Sed. dwell. acute	Sed. dwell. prolonged	Algae
Test species		<i>Pimephales promelas</i>	<i>Pimephales promelas</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Chironomus riparius</i>	<i>Chironomus riparius</i>	<i>Pseudokirchn. subcapitata</i>
Endpoint (µg/L)		LC ₅₀ # > 70500	NOEC # = 4410	EC ₅₀ # > 77600	NOEC # = 3200	EC ₅₀ > 100000	NOEC * = 10000	E _r C ₅₀ # > 80000
AF		100	10	100	10	100	10	10
RAC (µg/L)		> 705	= 441	> 776	= 320	> 1000	= 1000	> 8000
FOCUS Scenario	PEC _{gl-max} (µg/L)							
Step 1								
	9.9666	< 0.014	0.023	< 0.013	0.031	< 0.010	0.010	< 0.001
Step 2								
N-Europe	1.5789	< 0.002	0.004	< 0.002	0.005	< 0.002	< 0.002	< 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

Endpoint from parent compound as surrogated according to decision scheme of the AGD (see justification for new endpoints)

* Endpoint predicted based on ACR_{parent} according to decision scheme of the AGD (see justification for new endpoints)

Table 9.7-15: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for deltamethrin for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of FPF+DLT EC 85 in OSR (use group D; 2 x 0.75 L prod./ha, BBCH 50-59, winter OSR)

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Inverteb. most sensitive	Algae	Sed. dwell. prolonged	Higher-tier information	Higher-tier information	Higher-tier information
Test species		<i>Oncorhynchus mykiss</i>	<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>G. fasciatus</i> / <i>A. aquaticus</i>	<i>Pseudok. subcapitata</i>	<i>Chironomus riparius</i>	<i>Mesocosm O. mykiss</i>	Aquatic invert.	Aquatic invert.
Endpoint (µg/L)		LC ₅₀ = 0.26	NOEC > 0.032	EC ₅₀ = 0.56	NOEC = 0.0041	LC _{50 geo} = 0.00384	ErC ₅₀ > 9100	NOEC = 0.010	NOEAEC = 1.0	NOEC = 0.023	NOEC = 0.0032
AF		100	10	100	10	100	10	10	10	1	2
RAC (µg/L)		= 0.0026	> 0.0032	= 0.0056	= 0.00041	= 0.0000384	> 910	= 0.001	= 0.1	= 0.023	= 0.0016
FOCUS Scenario	PEC _{gl-max} (µg/L)										
Step 1											
	0.1383	53	< 43	25	337	3,602	< 0.001	138	1.4	6.0	86
Step 2											
N-Europe	0.0690	27	< 22	12	168	1,797	< 0.001	69	0.69	3.0	43
Step 3											
D3 ditch	0.048	18	< 15	8.6	117	1250	< 0.001	48	0.48	2.1	30
D4 pond	0.002	0.77	< 0.63	0.36	4.9	52	< 0.001	2.0	0.02	0.09	1.3
D4 stream	0.037	14	< 12	6.6	90	964	< 0.001	37	0.37	1.6	23
D5 pond	0.002	0.77	< 0.63	0.36	4.9	52	< 0.001	2.0	0.02	0.09	1.3
D5 stream	0.039	15	< 12	7.0	95	1016	< 0.001	39	0.39	1.7	24
R1 pond	0.002	0.77	< 0.63	0.36	4.9	52	< 0.001	2.0	0.02	0.09	1.3
R1 stream	0.031	12	< 10	5.5	76	807	< 0.001	31	0.31	1.3	19
R3 stream	0.044	17	< 14	7.9	107	1146	< 0.001	44	0.44	1.9	28

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

Table 9.7-16: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for deltamethrin for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of FPF+DLT EC 85 in OSR (use group D; 2 x 0.75 L prod./ha, BBCH 50-59, spring OSR)

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Inverteb. most sensitive	Algae	Sed. dwell. prolonged	Higher-tier information	Higher-tier information	Higher-tier information
Test species		<i>Oncorhynchus mykiss</i>	<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>G. fasciatus</i> / <i>A. aquaticus</i>	<i>Pseudok. subcapitata</i>	<i>Chironomus riparius</i>	Mesocosm <i>O. mykiss</i>	Aquatic invert.	Aquatic invert.
Endpoint (µg/L)		LC ₅₀ = 0.26	NOEC > 0.032	EC ₅₀ = 0.56	NOEC = 0.0041	LC ₅₀ geo = 0.00384	ErC ₅₀ > 9100	NOEC = 0.010	NOEAEC = 1.0	NOEC = 0.023	NOEC = 0.0032
AF		100	10	100	10	100	10	10	10	1	2
RAC (µg/L)		= 0.0026	> 0.0032	= 0.0056	= 0.00041	= 0.0000384	> 910	= 0.001	= 0.1	= 0.023	= 0.0016
FOCUS Scenario	PEC _{gl-max} (µg/L)										
Step 1											
	0.1383	53	< 43	25	337	3,602	< 0.001	138	1.4	6.0	86
Step 2											
N-Europe	0.0690	27	< 22	12	168	1,797	< 0.001	69	0.69	3.0	43
Step 3											
D3 ditch	0.048	18	< 15	8.6	117	1250	< 0.001	48	0.48	2.1	30
D4 pond	0.002	0.77	< 0.63	0.36	4.9	52	< 0.001	2.0	0.02	0.09	1.3
D4 stream	0.041	16	< 13	7.3	100	1068	< 0.001	41	0.41	1.8	26
D5 pond	0.002	0.77	< 0.63	0.36	4.9	52	< 0.001	2.0	0.02	0.09	1.3
D5 stream	0.042	16	< 13	7.5	102	1094	< 0.001	42	0.42	1.8	26
R1 pond	0.002	0.77	< 0.63	0.36	4.9	52	< 0.001	2.0	0.02	0.09	1.3
R1 stream	0.031	12	< 10	5.5	76	807	< 0.001	31	0.31	1.3	19

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

Table 9.7-17: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for flupyradifurone for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of FPF+DLT EC 85 in OSR (use group D; 2 x 0.75 L prod/ha, BBCH 50-59, winter OSR)

Group		Fish-acute	Fish-prolonged	Inverteb. acute	Inverteb. prolonged	Inverteb. acute	Inverteb. prolonged	Sed. dwell. acute	Sed. dwell. prolonged	Aquatic macrophytes	Algae
Test species		<i>Pimephales promelas</i>	<i>Pimephales promelas</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Americamysis bahia</i>	<i>Americamysis bahia</i>	<i>Chironomus riparius</i>	<i>Chironomus riparius</i>	<i>Lemna gibba</i>	<i>Pseudokirchneriella subcapitata</i>
Endpoint (µg/L)		LC ₅₀ >70500	NOEC =4410	EC ₅₀ >77600	NOEC =3200	EC ₅₀ =260	NOEC =13.2	EC ₅₀ =61.7	NOEC =6.81	E _r C ₅₀ >67700	E _r C ₅₀ >80000
AF		100	10	100	10	100	10	100	10	10	10
RAC (µg/L)		>705	=441	>776	=320	=2.6	=1.32	=0.617	=0.681	>6770	>8000
FOCUS Scenario	PEC _{gl-max} (µg/L)										
Step 1											
	34.185	<0.048	0.078	<0.044	0.11	13	26	55	50	<0.005	<0.004
Step 2											
N-Europe	4.6419	<0.007	0.011	<0.006	0.015	1.8	3.5	7.5	6.8	<0.001	<0.001
Step 3											
D3-ditch	0.3577	<0.001	<0.001	<0.001	0.001	0.14	0.27	0.58	0.53	<0.001	<0.001
D4-pond	0.3757	<0.001	<0.001	<0.001	0.001	0.14	0.28	0.61	0.55	<0.001	<0.001
D4-stream	0.3677	<0.001	<0.001	<0.001	0.001	0.14	0.28	0.60	0.54	<0.001	<0.001
D5-pond	0.2985	<0.001	<0.001	<0.001	<0.001	0.11	0.23	0.48	0.44	<0.001	<0.001
D5-stream	0.3332	<0.001	<0.001	<0.001	0.001	0.13	0.25	0.54	0.49	<0.001	<0.001
R1-pond	0.1821	<0.001	<0.001	<0.001	<0.001	0.070	0.14	0.30	0.27	<0.001	<0.001
R1-stream	1.1330	<0.002	0.003	<0.001	0.004	0.44	0.86	1.8	1.7	<0.001	<0.001
R3-stream	2.0940	<0.003	0.005	<0.003	0.007	0.81	1.6	3.4	3.1	<0.001	<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

Table 9.7-17A: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for flupyradifurone for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of FPF+DLT EC 85 in OSR (use group D; 2 x 0.75 L prod/ha, BBCH 50-59, winter OSR) the plant uptake factor for the parent flupyradifurone was set to 0

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Inverteb. acute	Inverteb. prolonged	Sed. dwell. acute	Sed. dwell. prolonged	Aquatic macrophytes	Algae
Test species		<i>Pimephales promelas</i>	<i>Pimephales promelas</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Americamysis bahia</i>	<i>Americamysis bahia</i>	<i>Chironomus riparius</i>	<i>Chironomus riparius</i>	<i>Lemna gibba</i>	<i>Pseudokirchneriella subcapitata</i>
Endpoint (µg/L)		LC ₅₀ > 70500	NOEC = 4410	EC ₅₀ > 77600	NOEC = 3200	EC ₅₀ = 260	NOEC = 13.2	EC ₅₀ = 61.7	NOEC = 6.81	E _r C ₅₀ > 67700	E _r C ₅₀ > 80000
AF		100	10	100	10	100	10	100	10	10	10
RAC (µg/L)		> 705	= 441	> 776	= 320	= 2.6	= 1.32	= 0.617	= 0.681	> 6770	> 8000
FOCUS Scenario	PEC ^{gl-max} (µg/L)										
Step 3											
D3 ditch	0.358	< 0.001	< 0.001	< 0.001	0.001	0.14	0.27	0.58	0.53	< 0.001	< 0.001
D4 pond	0.4207	< 0.001	< 0.001	< 0.001	0.001	0.16	0.32	0.68	0.62	< 0.001	< 0.001
D4 stream	0.4031	< 0.001	< 0.001	< 0.001	0.001	0.16	0.31	0.65	0.59	< 0.001	< 0.001
D5 pond	0.3163	< 0.001	< 0.001	< 0.001	< 0.001	0.12	0.24	0.51	0.46	< 0.001	< 0.001
D5 stream	0.3366	< 0.001	< 0.001	< 0.001	0.001	0.13	0.26	0.55	0.49	< 0.001	< 0.001
R1 pond	0.1831	< 0.001	< 0.001	< 0.001	< 0.001	0.070	0.14	0.30	0.27	< 0.001	< 0.001
R1 stream	1.138	< 0.002	0.003	< 0.001	0.004	0.44	0.86	1.8	1.7	< 0.001	< 0.001
R3 stream	2.121	< 0.003	0.005	< 0.003	0.007	0.82	1.6	3.4	3.1	< 0.001	< 0.003

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

Table 9.7-18: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for flupyradifurone for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of FPF+DLT EC 85 in OSR (use group D; 2 x 0.75 L prod/ha, BBCH 50-59, spring OSR)

Group		Fish-acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Inverteb. acute	Inverteb. prolonged	Sed. dwell. acute	Sed. dwell. prolonged	Aquatic macrophytes	Algae
Test species		<i>Pimephales promelas</i>	<i>Pimephales promelas</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Americamysis bahia</i>	<i>Americamysis bahia</i>	<i>Chironomus riparius</i>	<i>Chironomus riparius</i>	<i>Lemna gibba</i>	<i>Pseudokirchneriella subcapitata</i>
Endpoint (µg/L)		LC ₅₀ ≥70500	NOEC =4410	EC ₅₀ ≥77600	NOEC =3200	EC ₅₀ =260	NOEC =13.2	EC ₅₀ =61.7	NOEC =6.81	E _r C ₅₀ ≥67700	E _r C ₅₀ ≥80000
AF		100	10	100	10	100	10	100	10	10	10
RAC (µg/L)		≥705	=441	≥776	=320	=2.6	=1.32	=0.617	=0.681	≥6770	≥8000
FOCUS Scenario	PEC _{gl-max} (µg/L)										
Step 1											
	34.185	<0.048	0.078	<0.044	0.11	13	26	55	50	<0.005	<0.004
Step 2											
N-Europe	2.3447	<0.003	0.005	<0.003	0.007	0.90	1.8	3.8	3.4	<0.001	<0.001
Step 3											
D3-ditch	0.3579	<0.001	<0.001	<0.001	0.001	0.14	0.27	0.58	0.53	<0.001	<0.001
D4-pond	0.4678	<0.001	0.001	<0.001	0.001	0.18	0.35	0.76	0.69	<0.001	<0.001
D4-stream	0.4839	<0.001	0.001	<0.001	0.002	0.19	0.37	0.78	0.71	<0.001	<0.001
D5-pond	0.3419	<0.001	<0.001	<0.001	0.001	0.13	0.26	0.55	0.50	<0.001	<0.001
D5-stream	0.3807	<0.001	<0.001	<0.001	0.001	0.15	0.29	0.62	0.56	<0.001	<0.001
R1-pond	0.1030	<0.001	<0.001	<0.001	<0.001	0.040	0.078	0.17	0.15	<0.001	<0.001
R1-stream	1.0830	<0.002	0.002	<0.001	0.003	0.42	0.82	1.8	1.6	<0.001	<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

Table 9.7-18A: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for flupyradifurone for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of FPF+DLT EC 85 in OSR (use group D; 2 x 0.75 L prod/ha, BBCH 50-59, spring OSR) the plant uptake factor for the parent flupyradifurone was set to 0

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Inverteb. acute	Inverteb. prolonged	Sed. dwell. acute	Sed. dwell. prolonged	Aquatic macrophytes	Algae
Test species		<i>Pimephales promelas</i>	<i>Pimephales promelas</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Americamysis bahia</i>	<i>Americamysis bahia</i>	<i>Chironomus riparius</i>	<i>Chironomus riparius</i>	<i>Lemna gibba</i>	<i>Pseudokirchneriella subcapitata</i>
Endpoint (µg/L)		LC ₅₀ > 70500	NOEC = 4410	EC ₅₀ > 77600	NOEC = 3200	EC ₅₀ = 260	NOEC = 13.2	EC ₅₀ = 61.7	NOEC = 6.81	E _r C ₅₀ > 67700	E _r C ₅₀ > 80000
AF		100	10	100	10	100	10	100	10	10	10
RAC (µg/L)		> 705	= 441	> 776	= 320	= 2.6	= 1.32	= 0.617	= 0.681	> 6770	> 8000
FOCUS Scenario	PEC ^{gl-max} (µg/L)										
Step 3											
D3 ditch	0.3581	< 0.001	< 0.001	< 0.001	0.001	0.14	0.27	0.58	0.53	< 0.001	< 0.001
D4 pond	0.4927	< 0.001	0.001	< 0.001	0.002	0.19	0.37	0.80	0.72	< 0.001	< 0.001
D4 stream	0.5035	< 0.001	0.001	< 0.001	0.002	0.19	0.38	0.82	0.74	< 0.001	< 0.001
D5 pond	0.3548	< 0.001	< 0.001	< 0.001	0.001	0.14	0.27	0.58	0.52	< 0.001	< 0.001
D5 stream	0.3827	< 0.001	< 0.001	< 0.001	0.001	0.15	0.29	0.62	0.56	< 0.001	< 0.001
R1 pond	0.1032	< 0.001	< 0.001	< 0.001	< 0.001	0.040	0.078	0.17	0.15	< 0.001	< 0.001
R1 stream	1.107	< 0.002	0.003	< 0.001	0.003	0.43	0.84	1.8	1.6	< 0.001	< 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

Table 9.7-19: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for deltamethrin for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of FPF+DLT EC 85 in OSR (use group E; 2 x 0.5 L prod./ha, BBCH 65-79, winter OSR)

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Inverteb. most sensitive	Algae	Sed. dwell. prolonged	Higher-tier information	Higher-tier information	Higher-tier information
Test species		<i>Oncorhynchus mykiss</i>	<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>G. fasciatus</i> / <i>A. aquaticus</i>	<i>Pseudok. subcapitata</i>	<i>Chironomus riparius</i>	Mesocosm <i>O. mykiss</i>	Aquatic invert.	Aquatic invert.
Endpoint (µg/L)		LC ₅₀ = 0.26	NOEC > 0.032	EC ₅₀ = 0.56	NOEC = 0.0041	LC _{50 geo} = 0.00384	E _r C ₅₀ > 9100	NOEC = 0.010	NOEABC = 1.0	NOEC = 0.023	NOEC = 0.0032
AF		100	10	100	10	100	10	10	10	1	2
RAC (µg/L)		= 0.0026	> 0.0032	= 0.0056	= 0.00041	= 0.0000384	> 910	= 0.001	= 0.1	= 0.023	= 0.0016
FOCUS Scenario	PEC _{gl-max} (µg/L)										
Step 1											
	0.0922	35	< 29	16	225	2,401	< 0.001	92	0.92	4.0	58
Step 2											
N-Europe	0.0460	18	< 14	8.2	112	1,198	< 0.001	46	0.46	2.0	29
Step 3											
D3 ditch	0.032	12	< 10	5.7	78	833	< 0.001	32	0.32	1.4	20
D4 pond	0.001	0.38	< 0.31	0.18	2.4	26	< 0.001	1.0	0.01	0.04	0.63
D4 stream	0.027	10	< 8.4	4.8	66	703	< 0.001	27	0.27	1.2	17
D5 pond	0.001	0.38	< 0.31	0.18	2.4	26	< 0.001	1.0	0.01	0.04	0.63
D5 stream	0.030	12	< 9.4	5.4	73	781	< 0.001	30	0.30	1.3	19
R1 pond	0.001	0.38	< 0.31	0.18	2.4	26	< 0.001	1.0	0.01	0.04	0.63
R1 stream	0.021	8.1	< 6.6	3.8	51	547	< 0.001	21	0.21	0.91	13
R3 stream	0.029	11	< 9.1	5.2	71	755	< 0.001	29	0.29	1.3	18

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

Table 9.7-20: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for deltamethrin for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of FPF+DLT EC 85 in OSR (use group E; 2 x 0.5 L prod./ha, BBCH 65-79, spring OSR)

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Inverteb. most sensitive	Algae	Sed. dwell. prolonged	Higher-tier information	Higher-tier information	Higher-tier information
Test species		<i>Oncorhynchus mykiss</i>	<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>G. fasciatus</i> / <i>A. aquaticus</i>	<i>Pseudok. subcapitata</i>	<i>Chironomus riparius</i>	<i>Mesocosm O. mykiss</i>	Aquatic invert.	Aquatic invert.
Endpoint (µg/L)		LC ₅₀ = 0.26	NOEC > 0.032	EC ₅₀ = 0.56	NOEC = 0.0041	LC ₅₀ geo = 0.00384	E _r C ₅₀ > 9100	NOEC = 0.010	NOE/AEC = 1.0	NOEC = 0.023	NOEC = 0.0032
AF		100	10	100	10	100	10	10	10	1	2
RAC (µg/L)		= 0.0026	> 0.0032	= 0.0056	= 0.00041	= 0.0000384	> 910	= 0.001	= 0.1	= 0.023	= 0.0016
FOCUS Scenario	PEC _{gl-max} (µg/L)										
Step 1											
	0.0922	35	< 29	16	225	2,401	< 0.001	92	0.92	4.0	58
Step 2											
N-Europe	0.0460	18	< 14	8.2	112	1,198	< 0.001	46	0.46	2.0	29
Step 3											
D3 ditch	0.032	12	< 10	5.7	78	833	< 0.001	32	0.32	1.4	20
D4 pond	0.001	0.38	< 0.31	0.18	2.4	26	< 0.001	1.0	0.01	0.04	0.63
D4 stream	0.027	10	< 8.4	4.8	66	703	< 0.001	27	0.27	1.2	17
D5 pond	0.001	0.38	< 0.31	0.18	2.4	26	< 0.001	1.0	0.01	0.04	0.63
D5 stream	0.030	12	< 9.4	5.4	73	781	< 0.001	30	0.30	1.3	19
R1 pond	0.001	0.38	< 0.31	0.18	2.4	26	< 0.001	1.0	0.01	0.04	0.63
R1 stream	0.021	8.1	< 6.6	3.8	51	547	< 0.001	21	0.21	0.91	13

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

Table 9.7-21: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for flupyradifurone for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of FPF+DLT EC 85 in OSR (use group E; 2 x 0.5 L prod./ha, BBCH 65-79, winter OSR)

Group		Fish-acute	Fish-prolonged	Inverteb. acute	Inverteb. prolonged	Inverteb. acute	Inverteb. prolonged	Sed. dwell. acute	Sed. dwell. prolonged	Aquatic macrophytes	Algae
Test species		<i>Pimephales promelas</i>	<i>Pimephales promelas</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Americamysis bahia</i>	<i>Americamysis bahia</i>	<i>Chironomus riparius</i>	<i>Chironomus riparius</i>	<i>Lemna gibba</i>	<i>Pseudokirchneriella subcapitata</i>
Endpoint (µg/L)		LC ₅₀ >70500	NOEC =4410	EC ₅₀ >77600	NOEC =3200	EC ₅₀ =260	NOEC =13.2	EC ₅₀ =61.7	NOEC =6.81	E _r C ₅₀ >67700	E _r C ₅₀ >80000
AF		100	10	100	10	100	10	100	10	10	10
RAC (µg/L)		>705	=441	>776	=320	=2.6	=1.32	=0.617	=0.681	>6770	>8000
FOCUS Scenario	PEC _{gl-max} (µg/L)										
Step 1											
	22.790	<0.032	0.052	<0.029	0.071	8.8	17	37	33	<0.003	<0.003
Step 2											
N-Europe	1.5631	<0.002	0.004	<0.002	0.005	0.60	1.2	2.5	2.3	<0.001	<0.001
Step 3											
D3-ditch	0.2389	<0.001	<0.001	<0.001	<0.001	0.092	0.18	0.39	0.35	<0.001	<0.001
D4-pond	0.2725	<0.001	<0.001	<0.001	<0.001	0.10	0.21	0.44	0.40	<0.001	<0.001
D4-stream	0.3007	<0.001	<0.001	<0.001	<0.001	0.12	0.23	0.49	0.44	<0.001	<0.001
D5-pond	0.2508	<0.001	<0.001	<0.001	<0.001	0.096	0.19	0.41	0.37	<0.001	<0.001
D5-stream	0.2216	<0.001	<0.001	<0.001	<0.001	0.085	0.17	0.36	0.33	<0.001	<0.001
R1-pond	0.1492	<0.001	<0.001	<0.001	<0.001	0.057	0.11	0.24	0.22	<0.001	<0.001
R1-stream	0.8361	<0.001	0.002	<0.001	0.003	0.32	0.63	1.4	1.2	<0.001	<0.001
R3-stream	0.9793	<0.001	0.002	<0.001	0.003	0.38	0.74	1.6	1.4	<0.001	<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

Table 9.7-21A: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for flupyradifurone for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of FPF+DLT EC 85 in OSR (use group E; 2 x 0.5 L prod./ha, BBCH 65-79, winter OSR) the plant uptake factor for the parent flupyradifurone was set to 0

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Inverteb. acute	Inverteb. prolonged	Sed. dwell. acute	Sed. dwell. prolonged	Aquatic macrophytes	Algae
Test species		<i>Pimephales promelas</i>	<i>Pimephales promelas</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Americamysis bahia</i>	<i>Americamysis bahia</i>	<i>Chironomus riparius</i>	<i>Chironomus riparius</i>	<i>Lemna gibba</i>	<i>Pseudokirchneriella subcapitata</i>
Endpoint (µg/L)		LC ₅₀ > 70500	NOEC = 4410	EC ₅₀ > 77600	NOEC = 3200	EC ₅₀ = 260	NOEC = 13.2	EC ₅₀ = 61.7	NOEC = 6.81	E _r C ₅₀ > 67700	E _r C ₅₀ > 80000
AF		100	10	100	10	100	10	100	10	10	10
RAC (µg/L)		> 705	= 441	> 776	= 320	= 2.6	= 1.32	= 0.617	= 0.681	> 6770	> 8000
FOCUS Scenario	PEC ^{gl-max} (µg/L)										
Step 3											
D3 ditch	0.2389	< 0.001	< 0.001	< 0.001	< 0.001	0.092	0.18	0.39	0.35	< 0.001	< 0.001
D4 pond	0.2854	< 0.001	< 0.001	< 0.001	< 0.001	0.11	0.22	0.46	0.42	< 0.001	< 0.001
D4 stream	0.3115	< 0.001	< 0.001	< 0.001	< 0.001	0.12	0.24	0.50	0.46	< 0.001	< 0.001
D5 pond	0.2542	< 0.001	< 0.001	< 0.001	< 0.001	0.098	0.19	0.41	0.37	< 0.001	< 0.001
D5 stream	0.2216	< 0.001	< 0.001	< 0.001	< 0.001	0.085	0.17	0.36	0.33	< 0.001	< 0.001
R1 pond	0.1505	< 0.001	< 0.001	< 0.001	< 0.001	0.058	0.11	0.24	0.22	< 0.001	< 0.001
R1 stream	0.8405	< 0.001	0.002	< 0.001	0.003	0.32	0.64	1.4	1.2	< 0.001	< 0.001
R3 stream	0.981	< 0.001	0.002	< 0.001	0.003	0.38	0.74	1.6	1.4	< 0.001	< 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

Table 9.7-22: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for flupyradifurone for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of FPF+DLT EC 85 in OSR (use group E; 2 x 0.5 L prod./ha, BBCH 65-79, spring OSR)

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Inverteb. acute	Inverteb. prolonged	Sed. dwell. acute	Sed. dwell. prolonged	Aquatic macrophytes	Algae
Test species		<i>Pimephales promelas</i>	<i>Pimephales promelas</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Americamysis bahia</i>	<i>Americamysis bahia</i>	<i>Chironomus riparius</i>	<i>Chironomus riparius</i>	<i>Lemna gibba</i>	<i>Pseudokirchneriella subcapitata</i>
Endpoint (µg/L)		LC ₅₀ >70500	NOEC =4410	EC ₅₀ >77600	NOEC =3200	EC ₅₀ =260	NOEC =13.2	EC ₅₀ =61.7	NOEC =6.81	E _r C ₅₀ >67700	E _r C ₅₀ >80000
AF		100	10	100	10	100	10	100	10	10	10
RAC (µg/L)		>705	=441	>776	=320	=2.6	=1.32	=0.617	=0.681	>6770	>8000
FOCUS Scenario	PEC _{gl-max} (µg/L)										
Step 1											
	22.790	<0.032	0.052	<0.029	0.071	8.8	17	37	33	<0.003	<0.003
Step 2											
N-Europe	1.5631	<0.002	0.004	<0.002	0.005	0.60	1.2	2.5	2.3	<0.001	<0.001
Step 3											
D3-ditch	0.2388	<0.001	<0.001	<0.001	<0.001	0.092	0.18	0.39	0.35	<0.001	<0.001
D4-pond	0.3273	<0.001	<0.001	<0.001	0.001	0.13	0.25	0.53	0.48	<0.001	<0.001
D4-stream	0.3368	<0.001	<0.001	<0.001	0.001	0.13	0.26	0.55	0.49	<0.001	<0.001
D5-pond	0.2077	<0.001	<0.001	<0.001	<0.001	0.080	0.16	0.34	0.30	<0.001	<0.001
D5-stream	0.2217	<0.001	<0.001	<0.001	<0.001	0.085	0.17	0.36	0.33	<0.001	<0.001
R1-pond	0.1296	<0.001	<0.001	<0.001	<0.001	0.050	0.098	0.21	0.19	<0.001	<0.001
R1-stream	1.0410	<0.001	0.002	<0.001	0.003	0.40	0.79	1.7	1.5	<0.001	<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

Table 9.7-22A: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for flupyradifurone for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of FPF+DLT EC 85 in OSR (use group E; 2 x 0.5 L prod./ha, BBCH 65-79, spring OSR) the plant uptake factor for the parent flupyradifurone was set to 0

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Inverteb. acute	Inverteb. prolonged	Sed. dwell. acute	Sed. dwell. prolonged	Aquatic macrophytes	Algae
Test species		<i>Pimephales promelas</i>	<i>Pimephales promelas</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Americamysis bahia</i>	<i>Americamysis bahia</i>	<i>Chironomus riparius</i>	<i>Chironomus riparius</i>	<i>Lemna gibba</i>	<i>Pseudokirchneriella subcapitata</i>
Endpoint (µg/L)		LC ₅₀ > 70500	NOEC = 4410	EC ₅₀ > 77600	NOEC = 3200	EC ₅₀ = 260	NOEC = 13.2	EC ₅₀ = 61.7	NOEC = 6.81	E _r C ₅₀ > 67700	E _r C ₅₀ > 80000
AF		100	10	100	10	100	10	100	10	10	10
RAC (µg/L)		> 705	= 441	> 776	= 320	= 2.6	= 1.32	= 0.617	= 0.681	> 6770	> 8000
Step 3											
D3 ditch	0.2388	< 0.001	< 0.001	< 0.001	< 0.001	0.092	0.18	0.39	0.35	< 0.001	< 0.001
D4 pond	0.3426	< 0.001	< 0.001	< 0.001	0.001	0.13	0.26	0.56	0.50	< 0.001	< 0.001
D4 stream	0.3494	< 0.001	< 0.001	< 0.001	0.001	0.13	0.26	0.57	0.51	< 0.001	< 0.001
D5 pond	0.2123	< 0.001	< 0.001	< 0.001	< 0.001	0.082	0.16	0.34	0.31	< 0.001	< 0.001
D5 stream	0.2217	< 0.001	< 0.001	< 0.001	< 0.001	0.085	0.17	0.36	0.33	< 0.001	< 0.001
R1 pond	0.1302	< 0.001	< 0.001	< 0.001	< 0.001	0.050	0.099	0.21	0.19	< 0.001	< 0.001
R1 stream	1.048	< 0.001	0.002	< 0.001	0.003	0.40	0.79	1.7	1.5	< 0.001	< 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

For the intended use in OSR (all use groups, winter and spring OSR), calculated PEC/RAC ratios for flupyradifurone did not indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for sediment dweller acute as characterised by an EC_{50} for *Chironomus riparius* of 61.7 $\mu\text{g/L}$ in connection with an assessment factor of 100) in several FOCUS Steps 1-3 scenarios.

Considering the active substance deltamethrin, calculated PEC/RAC ratios for all uses indicate an unacceptable risk for all organism groups except algae. ~~The most sensitive group of aquatic organisms are aquatic invertebrates as characterised by a NOEC of 0.023 $\mu\text{g/L}$ in connection with an assessment factor of 1 (higher tier information).~~

Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{sw} considering reduced exposure of surface water bodies based on most sensitive species group for deltamethrin and flupyradifurone.

All metabolites of both active substances demonstrated acceptable use at Step 2 calculations. No further risk assessment is required.

All metabolites of both active substances demonstrated acceptable use at Step 2 calculations. No further risk assessment is required.

Table 9.7-23: Aquatic organisms: PEC_{sw}^o calculation and acceptability of risk (PEC/RAC < 1) for deltamethrin based on FOCUS Step 4 calculations and toxicity data for aquatic invertebrates (higher tier information) with mitigation of spray drift and run-off for the use of DLT + FPF EC 85 in OSR winter, **BBCH 30-49** (use group C)

Intended use		spray application							
Active substance		deltamethrin							
Application rate (g/ha)		2 x 7.5 g/ha							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10 m	20 m		
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m		
None	D3 Ditch	0.0474	0.0129	0.0068	0.0035	0.0068	0.0035		
50 %		0.0237	0.0064	0.0034	0.0018	0.0034	0.0018		
75 %		0.0118	0.0032	0.0017	0.0009	0.0017	0.0009		
90 %		0.0048	0.0013	0.0007	0.0004	0.0007	0.0004		
None	D4 Pond	0.0017	0.0014	0.0010	0.0007	0.0010	0.0007		
50 %		0.0008	0.0007	0.0005	0.0003	0.0005	0.0003		
75 %		0.0004	0.0004	0.0003	0.0002	0.0003	0.0002		
90 %		0.0002	0.0001	0.0001	<0.0010	0.0001	<0.0010		
None	D4 Stream	0.0377	0.0138	0.0073	0.0038	0.0073	0.0038		
50 %		0.0189	0.0069	0.0037	0.0019	0.0037	0.0019		
75 %		0.0094	0.0035	0.0018	0.0009	0.0018	0.0009		
90 %		0.0038	0.0014	0.0007	0.0004	0.0007	0.0004		
None	D5 Pond	0.0016	0.0014	0.0010	0.0007	0.0010	0.0007		
50 %		0.0008	0.0007	0.0005	0.0003	0.0005	0.0003		
75 %		0.0004	0.0004	0.0003	0.0002	0.0003	0.0002		
90 %		0.0002	0.0001	0.0001	<0.0010	0.0001	<0.0010		
None	D5 Stream	0.0379	0.0138	0.0073	0.0038	0.0073	0.0038		
50 %		0.0190	0.0069	0.0037	0.0019	0.0037	0.0019		
75 %		0.0095	0.0035	0.0018	0.0009	0.0018	0.0009		
90 %		0.0038	0.0014	0.0007	0.0004	0.0007	0.0004		
None	R1 Pond	0.0017	0.0015	0.0010	0.0007	0.0010	0.0007		
50 %		0.0008	0.0007	0.0005	0.0003	0.0005	0.0003		

Intended use		spray application								
Active substance		deltamethrin								
Application rate (g/ha)		2 x 7.5 g/ha								
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10 m	20 m			
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m			
75 %		0.0004	0.0004	0.0003	0.0002	0.0003	0.0002			
90 %		0.0002	0.0002	0.0001	<0.0010	0.0001	<0.0010			
None		R1 Stream	0.0313	0.0114	0.0060	0.0032	0.0060	0.0032		
50 %			0.0156	0.0057	0.0030	0.0016	0.0030	0.0016		
75 %	0.0078		0.0029	0.0015	0.0008	0.0015	0.0008			
90 %	0.0031		0.0011	0.0006	0.0003	0.0006	0.0003			
None	R3 Stream	0.0439	0.0160	0.0085	0.0044	0.0085	0.0044			
50 %		0.0220	0.0080	0.0043	0.0022	0.0043	0.0022			
75 %		0.0110	0.0040	0.0021	0.0011	0.0021	0.0011			
90 %		0.0044	0.0016	0.0009	0.0004	0.0009	0.0004			
RAC (µg/L)		0.0016	PEC / RAC ratio							
None	D3 Ditch	29.6	8.1	4.3	2.2	4.3	2.2			
50 %		14.8	4.0	2.1	1.1	2.1	1.1			
75 %		7.4	2.0	1.1	0.563	1.1	0.563			
90 %		3.0	0.813	0.438	0.250	0.438	0.250			
None	D4 Pond	1.1	0.875	0.625	0.438	0.625	0.438			
50 %		0.500	0.438	0.313	0.188	0.313	0.188			
75 %		0.250	0.250	0.188	0.125	0.188	0.125			
90 %		0.125	0.063	0.063	0.625	0.063	0.625			
None	D4 Stream	23.6	8.6	4.6	2.4	4.6	2.4			
50 %		11.8	4.3	2.3	1.2	2.3	1.2			
75 %		5.9	2.2	1.1	0.563	1.1	0.563			
90 %		2.4	0.875	0.438	0.250	0.438	0.250			

Intended use		spray application							
Active substance		deltamethrin							
Application rate (g/ha)		2 x 7.5 g/ha							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10 m	20 m		
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m		
None	D5 Pond	1.0	0.875	0.625	0.438	0.625	0.438		
50 %		0.500	0.438	0.313	0.188	0.313	0.188		
75 %		0.250	0.250	0.188	0.125	0.188	0.125		
90 %		0.125	0.063	0.063	0.625	0.063	0.625		
None	D5 Stream	23.7	8.6	4.6	2.4	4.6	2.4		
50 %		11.9	4.3	2.3	1.2	2.3	1.2		
75 %		5.9	2.2	1.1	0.563	1.1	0.563		
90 %		2.4	0.875	0.438	0.250	0.438	0.250		
None	R1 Pond	1.1	0.938	0.625	0.438	0.625	0.438		
50 %		0.500	0.438	0.313	0.188	0.313	0.188		
75 %		0.250	0.250	0.188	0.125	0.188	0.125		
90 %		0.125	0.125	0.063	0.625	0.063	0.625		
None	R1 Stream	19.6	7.1	3.8	2.0	3.8	2.0		
50 %		9.8	3.6	1.9	1.0	1.9	1.0		
75 %		4.9	1.8	0.938	0.500	0.938	0.500		
90 %		1.9	0.688	0.375	0.188	0.375	0.188		
None	R3 Stream	27.4	10.0	5.3	2.8	5.3	2.8		
50 %		13.8	5.0	2.7	1.4	2.7	1.4		
75 %		6.9	2.5	1.3	0.688	1.3	0.688		
90 %		2.8	1.0	0.563	0.250	0.563	0.250		
RAC (µg/L)	0.023	PEC / RAC ratio							
None	D3 Ditch	2.06	0.5591	0.2967	0.1541	0.2967	0.1541		
50 %		1.03	0.2796	0.1483	0.0770	0.1483	0.0770		
75 %		0.5148	0.1398	0.0742	0.0385	0.0742	0.0385		

Intended use		spray application							
Active substance		deltamethrin							
Application rate (g/ha)		2 x 7.5 g/ha							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10 m	20 m		
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m		
90 %	D4 Pond	0.2069	0.0557	0.0300	0.0157	0.0300	0.0157		
None		0.0721	0.0624	0.0443	0.0295	0.0443	0.0295		
50 %		0.0360	0.0312	0.0221	0.0147	0.0221	0.0147		
75 %		0.0183	0.0156	0.0113	0.0074	0.0113	0.0074		
90 %		0.0070	0.0065	0.0043	<0.0010	0.0043	<0.0010		
None	D4 Stream	1.64	0.5978	0.3168	0.1654	0.3168	0.1654		
50 %		0.8196	0.2990	0.1590	0.0827	0.1590	0.0827		
75 %		0.4097	0.1501	0.0789	0.0407	0.0789	0.0407		
90 %		0.1641	0.0598	0.0318	0.0165	0.0318	0.0165		
None	D5 Pond	0.0712	0.0616	0.0443	0.0295	0.0443	0.0295		
50 %		0.0356	0.0308	0.0221	0.0147	0.0221	0.0147		
75 %		0.0178	0.0156	0.0113	0.0074	0.0113	0.0074		
90 %		0.0070	0.0061	0.0043	<0.0010	0.0043	<0.0010		
None	D5 Stream	1.65	0.6013	0.3185	0.1663	0.3185	0.1663		
50 %		0.8239	0.3006	0.1599	0.0831	0.1599	0.0831		
75 %		0.4119	0.1509	0.0793	0.0409	0.0793	0.0409		
90 %		0.1650	0.0601	0.0320	0.0166	0.0320	0.0166		
None	R1 Pond	0.0736	0.0637	0.0450	0.0297	0.0450	0.0297		
50 %		0.0368	0.0319	0.0225	0.0148	0.0225	0.0148		
75 %		0.0187	0.0159	0.0113	0.0074	0.0113	0.0074		
90 %		0.0071	0.0066	0.0044	<0.0010	0.0044	<0.0010		
None	R1 Stream	1.36	0.4965	0.2630	0.1373	0.2630	0.1373		
50 %		0.6800	0.2482	0.1320	0.0687	0.1320	0.0687		
75 %		0.3400	0.1246	0.0655	0.0338	0.0655	0.0338		
90 %		0.1362	0.0497	0.0264	0.0137	0.0264	0.0137		

Intended use		spray application							
Active substance		deltamethrin							
Application rate (g/ha)		2 x 7.5 g/ha							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10 m	20 m		
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m		
None	R3 Stream	1.91	0.6974	0.3696	0.1930	0.3696	0.1930		
50 %		0.9557	0.3488	0.1855	0.0965	0.1855	0.0965		
75 %		0.4778	0.1751	0.0920	0.0475	0.0920	0.0475		
90 %		0.1915	0.0697	0.0371	0.0193	0.0371	0.0193		

* Maximum values coming from multiple applications are marked in italics

° PEC_{sw} values including suspended solids are reported

PEC: predicted environmental concentration

RAC: regulatory acceptable concentration

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

Table 9.7-24: Aquatic organisms: PEC_{sw}^o calculation and acceptability of risk ($PEC/RAC < 1$) for deltamethrin based on FOCUS Step 4 calculations and toxicity data for aquatic invertebrates (higher tier information) with mitigation of spray drift and run-off for the use of DLT + FPF EC 85 in OSR spring, **BBCH 30-49 (use group C)**

Intended use		spray application							
Active substance		deltamethrin							
Application rate (g/ha)		2 x 7.5 g/ha							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10 m	20 m		
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m		
None	D3 Ditch	0.0476	0.0129	0.0069	0.0036	0.0069	0.0036		
50 %		0.0238	0.0065	0.0034	0.0018	0.0034	0.0018		
75 %		0.0119	0.0032	0.0017	0.0009	0.0017	0.0009		
90 %		0.0048	0.0013	0.0007	0.0004	0.0007	0.0004		
None	D4 Pond	0.0016	0.0014	0.0010	0.0007	0.0010	0.0007		
50 %		0.0008	0.0007	0.0005	0.0003	0.0005	0.0003		
75 %		0.0004	0.0004	0.0003	0.0002	0.0003	0.0002		
90 %		0.0002	0.0001	0.0001	<0.0010	0.0001	<0.0010		
None	D4 Stream	0.0390	0.0142	0.0075	0.0039	0.0075	0.0039		
50 %		0.0195	0.0071	0.0038	0.0020	0.0038	0.0020		
75 %		0.0097	0.0036	0.0019	0.0010	0.0019	0.0010		
90 %		0.0039	0.0014	0.0008	0.0004	0.0008	0.0004		
None	D5 Pond	0.0016	0.0014	0.0010	0.0007	0.0010	0.0007		
50 %		0.0008	0.0007	0.0005	0.0003	0.0005	0.0003		
75 %		0.0004	0.0004	0.0003	0.0002	0.0003	0.0002		
90 %		0.0002	0.0001	0.0001	<0.0010	0.0001	<0.0010		
None	D5 Stream	0.0414	0.0151	0.0080	0.0042	0.0080	0.0042		
50 %		0.0207	0.0076	0.0040	0.0021	0.0040	0.0021		
75 %		0.0104	0.0038	0.0020	0.0010	0.0020	0.0010		
90 %		0.0041	0.0015	0.0008	0.0004	0.0008	0.0004		
None	R1 Pond	0.0016	0.0014	0.0010	0.0007	0.0010	0.0007		
50 %		0.0008	0.0007	0.0005	0.0003	0.0005	0.0003		

Intended use		spray application							
Active substance		deltamethrin							
Application rate (g/ha)		2 x 7.5 g/ha							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10 m	20 m		
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m		
75 %	R1 Stream	0.0004	0.0004	0.0003	0.0002	0.0003	0.0002		
90 %		0.0002	0.0001	0.0001	<0.0010	0.0001	<0.0010		
None		0.0313	0.0114	0.0060	0.0032	0.0060	0.0032		
50 %		0.0156	0.0057	0.0030	0.0016	0.0030	0.0016		
75 %		0.0078	0.0029	0.0015	0.0008	0.0015	0.0008		
90 %		0.0031	0.0011	0.0006	0.0003	0.0006	0.0003		
RAC (µg/L) 0.0016		PEC / RAC ratio							
None	D3 Ditch	29.8	8.1	4.3	2.3	4.3	2.3		
50 %		14.9	4.1	2.1	1.1	2.1	1.1		
75 %		7.4	2.0	1.1	0.563	1.1	0.563		
90 %		3.0	0.813	0.438	0.250	0.438	0.250		
None	D4 Pond	1.0	0.875	0.625	0.438	0.625	0.438		
50 %		0.500	0.438	0.313	0.188	0.313	0.188		
75 %		0.250	0.250	0.188	0.125	0.188	0.125		
90 %		0.125	0.063	0.063	0.625	0.063	0.625		
None	D4 Stream	24.4	8.9	4.7	2.4	4.7	2.4		
50 %		12.2	4.4	2.4	1.3	2.4	1.3		
75 %		6.1	2.3	1.2	0.625	1.2	0.625		
90 %		2.4	0.875	0.500	0.250	0.500	0.250		
None	D5 Pond	1.0	0.875	0.625	0.438	0.625	0.438		
50 %		0.500	0.438	0.313	0.188	0.313	0.188		
75 %		0.250	0.250	0.188	0.125	0.188	0.125		
90 %		0.125	0.063	0.063	0.625	0.063	0.625		
None	D5 Stream	25.9	9.4	5.0	2.6	5.0	2.6		

Intended use		spray application							
Active substance		deltamethrin							
Application rate (g/ha)		2 x 7.5 g/ha							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10 m	20 m		
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m		
50 %		12.9	4.8	2.5	1.3	2.5	1.3		
75 %		6.5	2.4	1.3	0.625	1.3	0.625		
90 %		2.6	0.938	0.500	0.250	0.500	0.250		
None	R1 Pond	1.0	0.875	0.625	0.438	0.625	0.438		
50 %		0.500	0.438	0.313	0.188	0.313	0.188		
75 %		0.250	0.250	0.188	0.125	0.188	0.125		
90 %		0.125	0.063	0.063	0.625	0.063	0.625		
None	R1 Stream	19.6	7.1	3.8	2.0	3.8	2.0		
50 %		9.8	3.6	1.9	1.0	1.9	1.0		
75 %		4.9	1.8	0.938	0.500	0.938	0.500		
90 %		1.9	0.688	0.375	0.188	0.375	0.188		
RAC (µg/L)		PEC / RAC ratio							
0.023									
None	D3 Ditch	2.07	0.5613	0.2979	0.1547	0.2979	0.1547		
50 %		1.04	0.2807	0.1490	0.0773	0.1490	0.0773		
75 %		0.5170	0.1403	0.0745	0.0387	0.0745	0.0387		
90 %		0.2077	0.0559	0.0301	0.0157	0.0301	0.0157		
None	D4 Pond	0.0712	0.0617	0.0443	0.0295	0.0443	0.0295		
50 %		0.0356	0.0308	0.0221	0.0147	0.0221	0.0147		
75 %		0.0178	0.0156	0.0113	0.0074	0.0113	0.0074		
90 %		0.0070	0.0061	0.0043	<0.0010	0.0043	<0.0010		
None	D4 Stream	1.69	0.6187	0.3277	0.1711	0.3277	0.1711		
50 %		0.8474	0.3093	0.1645	0.0855	0.1645	0.0855		
75 %		0.4237	0.1553	0.0816	0.0421	0.0816	0.0421		
90 %		0.1697	0.0619	0.0329	0.0171	0.0329	0.0171		

Intended use		spray application							
Active substance		deltamethrin							
Application rate (g/ha)		2 x 7.5 g/ha							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10 m	20 m		
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m		
None	D5 Pond	0.0718	0.0622	0.0443	0.0295	0.0443	0.0295		
50 %		0.0359	0.0311	0.0221	0.0148	0.0221	0.0148		
75 %		0.0182	0.0157	0.0113	0.0074	0.0113	0.0074		
90 %		0.0070	0.0064	0.0043	<0.0010	0.0043	<0.0010		
None	D5 Stream	1.80	0.6574	0.3482	0.1818	0.3482	0.1818		
50 %		0.9004	0.3286	0.1748	0.0909	0.1748	0.0909		
75 %		0.4504	0.1650	0.0867	0.0447	0.0867	0.0447		
90 %		0.1804	0.0657	0.0350	0.0182	0.0350	0.0182		
None	R1 Pond	0.0712	0.0616	0.0443	0.0295	0.0443	0.0295		
50 %		0.0356	0.0308	0.0221	0.0147	0.0221	0.0147		
75 %		0.0181	0.0156	0.0113	0.0074	0.0113	0.0074		
90 %		0.0071	0.0065	0.0044	<0.0010	0.0043	<0.0010		
None	R1 Stream	1.36	0.4961	0.2628	0.1372	0.2628	0.1372		
50 %		0.6796	0.2480	0.1320	0.0686	0.1320	0.0686		
75 %		0.3399	0.1246	0.0654	0.0338	0.0654	0.0338		
90 %		0.1362	0.0496	0.0264	0.0137	0.0264	0.0137		

* Maximum values coming from multiple applications are marked in italics

° PEC_{sw} values including suspended solids are reported

PEC: predicted environmental concentration

RAC: regulatory acceptable concentration

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

Table 9.7.25: Aquatic organisms: PEC_{sw} calculation and acceptability of risk (PEC/RAC < 1) for flupyradifurone based on FOCUS Step 4 calculations and toxicity data for sediment dweller (worst case species) with mitigation of spray drift and run-off for the use of DLT + FPF EC 85 in OSR winter (use group C; modelling use PMT00)

Intended-use		spray application							
Active substance		flupyradifurone							
Application rate (g/ha)		2 x 56.3 g/ha							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10-m	20-m		
	No spray buffer (m)	0-m	5-m	10-m	20-m	10-m	20-m		
None	D3-Ditch	0.3586	0.0995	0.0556	0.0349	0.0556	0.0349		
50-%		0.1808	0.0540	0.0346	0.0271	0.0346	0.0271		
75-%		0.0919	0.0338	0.0271	0.0271	0.0271	0.0271		
90-%		0.0447	0.0271	0.0271	0.0271	0.0271	0.0271		
None	D4-Pond	0.5162	0.5158	0.5153	0.5148	0.5153	0.5148		
50-%		0.5150	0.5149	0.5146	0.5143	0.5146	0.5143		
75-%		0.5144	0.5144	0.5142	0.5141	0.5142	0.5141		
90-%		0.5141	0.5141	0.5140	0.5140	0.5140	0.5140		
None	D4-Stream	0.4808	0.4808	0.4808	0.4808	0.4808	0.4808		
50-%		0.4808	0.4808	0.4808	0.4808	0.4808	0.4808		
75-%		0.4808	0.4808	0.4808	0.4808	0.4808	0.4808		
90-%		0.4808	0.4808	0.4808	0.4808	0.4808	0.4808		
None	D5-Pond	0.3156	0.3153	0.3148	0.3144	0.3148	0.3144		
50-%		0.3146	0.3144	0.3142	0.3139	0.3142	0.3139		
75-%		0.3140	0.3140	0.3138	0.3137	0.3138	0.3137		
90-%		0.3137	0.3137	0.3136	0.3136	0.3136	0.3136		
None	D5-Stream	0.2197	0.2197	0.2197	0.2197	0.2197	0.2197		
50-%		0.2197	0.2197	0.2197	0.2197	0.2197	0.2197		
75-%		0.2197	0.2197	0.2197	0.2197	0.2197	0.2197		
90-%		0.2197	0.2197	0.2197	0.2197	0.2197	0.2197		
None	R1-Pond	0.0979	0.0959	0.0923	0.0891	0.0427	0.0227		
50-%		0.0906	0.0896	0.0878	0.0862	0.0382	0.0198		

Intended use		spray-application							
Active substance		flupyradifurone							
Application rate (g/ha)		2 x 56.3 g/ha							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10-m	20-m		
	No-spray buffer (m)	0-m	5-m	10-m	20-m	10-m	20-m		
75-%		0.0870	0.0864	0.0855	0.0847	0.0359	0.0183		
90-%		0.0848	0.0846	0.0842	0.0839	0.0345	0.0174		
None	R1-Stream	1.4350	1.4350	1.4350	1.4350	0.6512	0.3411		
50-%		1.4350	1.4350	1.4350	1.4350	0.6512	0.3411		
75-%		1.4350	1.4350	1.4350	1.4350	0.6512	0.3411		
90-%		1.4350	1.4350	1.4350	1.4350	0.6512	0.3411		
None	R3-Stream	1.0930	1.0930	1.0930	1.0930	0.4920	0.2572		
50-%		1.0930	1.0930	1.0930	1.0930	0.4920	0.2572		
75-%		1.0930	1.0930	1.0930	1.0930	0.4920	0.2572		
90-%		1.0930	1.0930	1.0930	1.0930	0.4920	0.2572		
RAC (µg/L)		0.617							
		PEC / RAC-ratio							
None	D3-Ditch	0.5812	0.1613	0.0901	0.0566	0.0901	0.0566		
50-%		0.2930	0.0875	0.0561	0.0439	0.0561	0.0439		
75-%		0.1489	0.0548	0.0439	0.0439	0.0439	0.0439		
90-%		0.0724	0.0439	0.0439	0.0439	0.0439	0.0439		
None	D4-Pond	0.8366	0.8360	0.8352	0.8344	0.8352	0.8344		
50-%		0.8347	0.8345	0.8340	0.8335	0.8340	0.8335		
75-%		0.8337	0.8337	0.8334	0.8332	0.8334	0.8332		
90-%		0.8332	0.8332	0.8331	0.8331	0.8331	0.8331		
None	D4-Stream	0.7793	0.7793	0.7793	0.7793	0.7793	0.7793		
50-%		0.7793	0.7793	0.7793	0.7793	0.7793	0.7793		
75-%		0.7793	0.7793	0.7793	0.7793	0.7793	0.7793		
90-%		0.7793	0.7793	0.7793	0.7793	0.7793	0.7793		
None	D5-Pond	0.5115	0.5110	0.5102	0.5096	0.5102	0.5096		

Intended-use		spray-application							
Active substance		flupyradifurone							
Application rate (g/ha)		2 x 56.3 g/ha							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10 m	20 m		
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m		
50 %		<i>0.5099</i>	<i>0.5096</i>	<i>0.5092</i>	<i>0.5088</i>	<i>0.5092</i>	<i>0.5088</i>		
75 %		<i>0.5089</i>	<i>0.5089</i>	<i>0.5086</i>	<i>0.5084</i>	<i>0.5086</i>	<i>0.5084</i>		
90 %		<i>0.5084</i>	<i>0.5084</i>	<i>0.5083</i>	<i>0.5083</i>	<i>0.5083</i>	<i>0.5083</i>		
None	D5 Stream	<i>0.5480</i>	<i>0.3561</i>	<i>0.3561</i>	<i>0.3561</i>	<i>0.3561</i>	<i>0.3561</i>		
50 %		<i>0.3561</i>	<i>0.3561</i>	<i>0.3561</i>	<i>0.3561</i>	<i>0.3561</i>	<i>0.3561</i>		
75 %		<i>0.3561</i>	<i>0.3561</i>	<i>0.3561</i>	<i>0.3561</i>	<i>0.3561</i>	<i>0.3561</i>		
90 %		<i>0.3561</i>	<i>0.3561</i>	<i>0.3561</i>	<i>0.3561</i>	<i>0.3561</i>	<i>0.3561</i>		
None	R1 Pond	<i>0.1587</i>	<i>0.1554</i>	<i>0.1496</i>	<i>0.1444</i>	<i>0.0692</i>	<i>0.0368</i>		
50 %		<i>0.1468</i>	<i>0.1452</i>	<i>0.1423</i>	<i>0.1397</i>	<i>0.0619</i>	<i>0.0321</i>		
75 %		<i>0.1410</i>	<i>0.1400</i>	<i>0.1386</i>	<i>0.1373</i>	<i>0.0582</i>	<i>0.0297</i>		
90 %		<i>0.1374</i>	<i>0.1371</i>	<i>0.1365</i>	<i>0.1360</i>	<i>0.0559</i>	<i>0.0282</i>		
None	R1 Stream	<i>2.3258</i>	<i>2.3258</i>	<i>2.3258</i>	<i>2.3258</i>	<i>1.0554</i>	<i>0.5528</i>		
50 %		<i>2.3258</i>	<i>2.3258</i>	<i>2.3258</i>	<i>2.3258</i>	<i>1.0554</i>	<i>0.5528</i>		
75 %		<i>2.3258</i>	<i>2.3258</i>	<i>2.3258</i>	<i>2.3258</i>	<i>1.0554</i>	<i>0.5528</i>		
90 %		<i>2.3258</i>	<i>2.3258</i>	<i>2.3258</i>	<i>2.3258</i>	<i>1.0554</i>	<i>0.5528</i>		
None	R3 Stream	<i>1.7715</i>	<i>1.7715</i>	<i>1.7715</i>	<i>1.7715</i>	0.7974	0.4169		
50 %		<i>1.7715</i>	<i>1.7715</i>	<i>1.7715</i>	<i>1.7715</i>	0.7974	0.4169		
75 %		<i>1.7715</i>	<i>1.7715</i>	<i>1.7715</i>	<i>1.7715</i>	0.7974	0.4169		
90 %		<i>1.7715</i>	<i>1.7715</i>	<i>1.7715</i>	<i>1.7715</i>	0.7974	0.4169		

* Maximum values coming from multiple applications are marked in italics

PEC: predicted environmental concentration

RAC: regulatory acceptable concentration

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

Table 9.7-25A: Aquatic organisms: PEC_{sw} calculation and acceptability of risk (PEC/RAC < 1) for flupyradifurone based on FOCUS Step 4 calculations and toxicity data for sediment dweller (worst case species) with mitigation of spray drift and run-off for the use of DLT + FPF EC 85 in OSR winter **BBCH 30-49** (use group C; modelling use PMT01) the plant uptake factor for the parent flupyradifurone was set to 0

Intended use		spray application							
Active substance		flupyradifurone							
Application rate (g/ha)		2 x 56.3 g/ha							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10 m	20 m		
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m		
None	D3 Ditch	0.3592	0.1001	0.0584	0.0378	0.0584	0.0378		
50 %		0.1814	0.0568	0.0375	0.0329	0.0375	0.0329		
75 %		0.0941	0.0366	0.0329	0.0329	0.0329	0.0329		
90 %		0.0475	0.0329	0.0329	0.0329	0.0329	0.0329		
None	D4 Pond	0.5931	0.5927	0.5922	0.5917	0.5922	0.5917		
50 %		0.5919	0.5918	0.5915	0.5912	0.5915	0.5912		
75 %		0.5914	0.5913	0.5911	0.591	0.5911	0.5910		
90 %		0.591	0.591	0.5909	0.5909	0.5909	0.5909		
None	D4 Stream	0.5404	0.5404	0.5404	0.5404	0.5404	0.5404		
50 %		0.5404	0.5404	0.5404	0.5404	0.5404	0.5404		
75 %		0.5404	0.5404	0.5404	0.5404	0.5404	0.5404		
90 %		0.5404	0.5404	0.5404	0.5404	0.5404	0.5404		
None	D5 Pond	0.3373	0.337	0.3365	0.336	0.3365	0.336		
50 %		0.3362	0.3361	0.3358	0.3356	0.3358	0.3356		
75 %		0.3357	0.3356	0.3355	0.3354	0.3355	0.3354		
90 %		0.3354	0.3354	0.3353	0.3353	0.3353	0.3353		
None	D5 Stream	0.344	0.2343	0.2343	0.2343	0.2343	0.2343		
50 %		0.2343	0.2343	0.2343	0.2343	0.2343	0.2343		
75 %		0.2343	0.2343	0.2343	0.2343	0.2343	0.2343		
90 %		0.2343	0.2343	0.2343	0.2343	0.2343	0.2343		
None	R1 Pond	0.0991	0.097	0.0934	0.0902	0.0432	0.0229		
50 %		0.0918	0.0907	0.0889	0.0873	0.0386	0.02		

Intended use		spray application							
Active substance		flupyradifurone							
Application rate (g/ha)		2 x 56.3 g/ha							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10 m	20 m		
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m		
75 %		0.0881	0.0876	0.0867	0.0859	0.0364	0.0185		
90 %		0.0859	0.0857	0.0854	0.085	0.035	0.0177		
None	R1 Stream	1.456	1.456	1.456	1.456	0.6604	0.3459		
50 %		1.456	1.456	1.456	1.456	0.6604	0.3459		
75 %		1.456	1.456	1.456	1.456	0.6604	0.3459		
90 %		1.456	1.456	1.456	1.456	0.6604	0.3459		
None	R3 Stream	1.103	1.103	1.103	1.103	0.4968	0.2597		
50 %		1.103	1.103	1.103	1.103	0.4968	0.2597		
75 %		1.103	1.103	1.103	1.103	0.4968	0.2597		
90 %		1.103	1.103	1.103	1.103	0.4968	0.2597		
RAC (µg/L)		0.617							
		PEC / RAC ratio							
None	D3 Ditch	0.58	0.16	0.095	0.061	0.095	0.061		
50 %		0.29	0.092	0.061	0.053	0.061	0.053		
75 %		0.15	0.059	0.053	0.053	0.053	0.053		
90 %		0.077	0.053	0.053	0.053	0.053	0.053		
None	D4 Pond	0.96	0.96	0.96	0.96	0.96	0.96		
50 %		0.96	0.96	0.96	0.96	0.96	0.96		
75 %		0.96	0.96	0.96	0.96	0.96	0.96		
90 %		0.96	0.96	0.96	0.96	0.96	0.96		
None	D4 Stream	0.88	0.88	0.88	0.88	0.88	0.88		
50 %		0.88	0.88	0.88	0.88	0.88	0.88		
75 %		0.88	0.88	0.88	0.88	0.88	0.88		
90 %		0.88	0.88	0.88	0.88	0.88	0.88		
None	D5 Pond	0.55	0.55	0.55	0.54	0.55	0.54		

Intended use		spray application							
Active substance		flupyradifurone							
Application rate (g/ha)		2 x 56.3 g/ha							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10 m	20 m		
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m		
50 %		0.54	0.54	0.54	0.54	0.54	0.54		
75 %		0.54	0.54	0.54	0.54	0.54	0.54		
90 %		0.54	0.54	0.54	0.54	0.54	0.54		
None	D5 Stream	0.56	0.38	0.38	0.38	0.38	0.38		
50 %		0.38	0.38	0.38	0.38	0.38	0.38		
75 %		0.38	0.38	0.38	0.38	0.38	0.38		
90 %		0.38	0.38	0.38	0.38	0.38	0.38		
None	R1 Pond	0.16	0.16	0.15	0.15	0.070	0.037		
50 %		0.15	0.15	0.14	0.14	0.063	0.032		
75 %		0.14	0.14	0.14	0.14	0.059	0.030		
90 %		0.14	0.14	0.14	0.14	0.057	0.029		
None	R1 Stream	2.4	2.4	2.4	2.4	1.1	0.56		
50 %		2.4	2.4	2.4	2.4	1.1	0.56		
75 %		2.4	2.4	2.4	2.4	1.1	0.56		
90 %		2.4	2.4	2.4	2.4	1.1	0.56		
None	R3 Stream	1.8	1.8	1.8	1.8	0.81	0.42		
50 %		1.8	1.8	1.8	1.8	0.81	0.42		
75 %		1.8	1.8	1.8	1.8	0.81	0.42		
90 %		1.8	1.8	1.8	1.8	0.81	0.42		

* Maximum values coming from multiple applications are marked in italics

PEC: predicted environmental concentration

RAC: regulatory acceptable concentration

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

Table 9.7-26: Aquatic organisms: PEC_{sw} calculation and acceptability of risk (PEC/RAC < 1) for flupyradifurone based on FOCUS Step 4 calculations and toxicity data for sediment dweller (worst case species) with mitigation of spray drift and run-off for the use of DLT + FPF EC 85 in OSR spring (use group C; modelling use PMT01)

Intended-use		spray application							
Active substance		flupyradifurone							
Application rate (g/ha)		2 x 56.3 g/ha							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10-m	20-m		
	No spray buffer (m)	0-m	5-m	10-m	20-m	10-m	20-m		
None	D3-Ditch	0.3584	0.0983	0.0528	0.0281	0.0528	0.0281		
50-%		0.1799	0.0499	0.0274	0.0170	0.0274	0.0170		
75-%		0.0907	0.0266	0.0169	0.0153	0.0169	0.0153		
90-%		0.0375	0.0153	0.0153	0.0153	0.0153	0.0153		
None	D4-Pond	0.4599	0.4593	0.4583	0.4575	0.4583	0.4575		
50-%		0.4579	0.4576	0.4571	0.4567	0.4571	0.4567		
75-%		0.4569	0.4567	0.4565	0.4563	0.4565	0.4563		
90-%		0.4563	0.4562	0.4561	0.4560	0.4561	0.4560		
None	D4-Stream	0.4534	0.4534	0.4534	0.4534	0.4534	0.4534		
50-%		0.4534	0.4534	0.4534	0.4534	0.4534	0.4534		
75-%		0.4534	0.4534	0.4534	0.4534	0.4534	0.4534		
90-%		0.4534	0.4534	0.4534	0.4534	0.4534	0.4534		
None	D5-Pond	0.3328	0.3324	0.3317	0.3311	0.3317	0.3311		
50-%		0.3314	0.3312	0.3309	0.3306	0.3309	0.3306		
75-%		0.3307	0.3306	0.3305	0.3303	0.3305	0.3303		
90-%		0.3303	0.3303	0.3302	0.3301	0.3302	0.3301		
None	D5-Stream	0.2627	0.2627	0.2627	0.2627	0.2627	0.2627		
50-%		0.2627	0.2627	0.2627	0.2627	0.2627	0.2627		
75-%		0.2627	0.2627	0.2627	0.2627	0.2627	0.2627		
90-%		0.2627	0.2627	0.2627	0.2627	0.2627	0.2627		
None	R1-Pond	0.1236	0.1217	0.1182	0.1152	0.0530	0.0278		
50-%		0.1166	0.1157	0.1139	0.1124	0.0486	0.0250		

Intended use		spray-application							
Active substance		flupyradifurone							
Application rate (g/ha)		2 x 56.3 g/ha							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10-m	20-m		
	No-spray buffer (m)	0-m	5-m	10-m	20-m	10-m	20-m		
75-%		0.1132	0.1127	0.1118	0.1111	0.0465	0.0236		
90-%		0.1111	0.1109	0.1105	0.1102	0.0452	0.0228		
None	R1-Stream	1.0080	1.0080	1.0080	1.0080	0.4579	0.2398		
50-%		1.0080	1.0080	1.0080	1.0080	0.4579	0.2398		
75-%		1.0080	1.0080	1.0080	1.0080	0.4579	0.2398		
90-%		1.0080	1.0080	1.0080	1.0080	0.4579	0.2398		
RAC (µg/L)		0.617							
		PEC / RAC-ratio							
None	D3-Ditch	0.5809	0.1593	0.0856	0.0455	0.0856	0.0455		
50-%		0.2916	0.0809	0.0444	0.0276	0.0444	0.0276		
75-%		0.1470	0.0431	0.0274	0.0248	0.0274	0.0248		
90-%		0.0608	0.0248	0.0248	0.0248	0.0248	0.0248		
None	D4-Pond	0.7454	0.7444	0.7428	0.7415	0.7428	0.7415		
50-%		0.7421	0.7417	0.7408	0.7402	0.7408	0.7402		
75-%		0.7405	0.7402	0.7399	0.7395	0.7399	0.7395		
90-%		0.7395	0.7394	0.7392	0.7391	0.7392	0.7391		
None	D4-Stream	0.7348	0.7348	0.7348	0.7348	0.7348	0.7348		
50-%		0.7348	0.7348	0.7348	0.7348	0.7348	0.7348		
75-%		0.7348	0.7348	0.7348	0.7348	0.7348	0.7348		
90-%		0.7348	0.7348	0.7348	0.7348	0.7348	0.7348		
None	D5-Pond	0.5394	0.5387	0.5376	0.5366	0.5376	0.5366		
50-%		0.5371	0.5368	0.5363	0.5358	0.5363	0.5358		
75-%		0.5360	0.5358	0.5357	0.5353	0.5357	0.5353		
90-%		0.5353	0.5353	0.5352	0.5350	0.5352	0.5350		
None	D5-Stream	0.5496	0.4258	0.4258	0.4258	0.4258	0.4258		

Intended-use		spray-application							
Active substance		flupyradifurone							
Application rate (g/ha)		2 x 56.3 g/ha							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10-m	20-m		
	No-spray buffer (m)	0-m	5-m	10-m	20-m	10-m	20-m		
50-%		0.4258	0.4258	0.4258	0.4258	0.4258	0.4258		
75-%		0.4258	0.4258	0.4258	0.4258	0.4258	0.4258		
90-%		0.4258	0.4258	0.4258	0.4258	0.4258	0.4258		
None	R1-Pond	0.2003	0.1972	0.1916	0.1867	0.0859	0.0451		
50-%		0.1890	0.1875	0.1846	0.1822	0.0788	0.0405		
75-%		0.1835	0.1827	0.1812	0.1801	0.0754	0.0382		
90-%		0.1801	0.1797	0.1791	0.1786	0.0733	0.0370		
None	R1-Stream	1.6337	1.6337	1.6337	1.6337	0.7421	0.3887		
50-%		1.6337	1.6337	1.6337	1.6337	0.7421	0.3887		
75-%		1.6337	1.6337	1.6337	1.6337	0.7421	0.3887		
90-%		1.6337	1.6337	1.6337	1.6337	0.7421	0.3887		

* Maximum values coming from multiple applications are marked in italics

PEC: predicted environmental concentration

RAC: regulatory acceptable concentration

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

Table 9.7-26A: Aquatic organisms: PEC_{sw} calculation and acceptability of risk (PEC/RAC < 1) for flupyradifurone based on FOCUS Step 4 calculations and toxicity data for sediment dweller (worst case species) with mitigation of spray drift and run-off for the use of DLT + FPF EC 85 in OSR spring **BBCH 30-49** (use group C; modelling use PMT02) the plant uptake factor for the parent flupyradifurone was set to 0

Intended use		spray application							
Active substance		flupyradifurone							
Application rate (g/ha)		2 x 56.3 g/ha							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10 m	20 m		
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m		
None	D3 Ditch	0.3587	0.0986	0.0531	0.0288	0.0531	0.0288		
50 %		0.1802	0.0502	0.0285	0.0181	0.0285	0.0181		
75 %		0.0910	0.0277	0.0180	0.0179	0.0180	0.0179		
90 %		0.0386	0.0179	0.0179	0.0179	0.0179	0.0179		
None	D4 Pond	0.4971	0.4966	0.4955	0.4947	0.4955	0.4947		
50 %		0.4951	0.4948	0.4943	0.4939	0.4943	0.4939		
75 %		0.4941	0.4940	0.4937	0.4935	0.4937	0.4935		
90 %		0.4935	0.4935	0.4933	0.4933	0.4933	0.4933		
None	D4 Stream	0.4837	0.4837	0.4837	0.4837	0.4837	0.4837		
50 %		0.4837	0.4837	0.4837	0.4837	0.4837	0.4837		
75 %		0.4837	0.4837	0.4837	0.4837	0.4837	0.4837		
90 %		0.4837	0.4837	0.4837	0.4837	0.4837	0.4837		
None	D5 Pond	0.3521	0.3518	0.3510	0.3505	0.3510	0.3505		
50 %		0.3508	0.3506	0.3502	0.3499	0.3502	0.3499		
75 %		0.3501	0.3500	0.3498	0.3497	0.3498	0.3497		
90 %		0.3497	0.3496	0.3496	0.3495	0.3496	0.3495		
None	D5 Stream	0.3408	0.2776	0.2776	0.2776	0.2776	0.2776		
50 %		0.2776	0.2776	0.2776	0.2776	0.2776	0.2776		
75 %		0.2776	0.2776	0.2776	0.2776	0.2776	0.2776		
90 %		0.2776	0.2776	0.2776	0.2776	0.2776	0.2776		
None	R1 Pond	0.1284	0.1264	0.1230	0.1200	0.0549	0.0288		
50 %		0.1214	0.1204	0.1187	0.1172	0.0506	0.0260		

Intended use		spray application							
Active substance		flupyradifurone							
Application rate (g/ha)		2 x 56.3 g/ha							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10 m	20 m		
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m		
75 %		0.1179	0.1174	0.1166	0.1158	0.0484	0.0246		
90 %		0.1158	0.1156	0.1153	0.1150	0.0471	0.0237		
None	R1 Stream	1.0380	1.0380	1.0380	1.0380	0.4712	0.2468		
50 %		1.0380	1.0380	1.0380	1.0380	0.4712	0.2468		
75 %		1.0380	1.0380	1.0380	1.0380	0.4712	0.2468		
90 %		1.0380	1.0380	1.0380	1.0380	0.4712	0.2468		
RAC (µg/L) 0.617		PEC / RAC ratio							
None	D3 Ditch	0.58	0.16	0.086	0.047	0.086	0.047		
50 %		0.29	0.081	0.046	0.029	0.046	0.029		
75 %		0.15	0.045	0.029	0.029	0.029	0.029		
90 %		0.063	0.029	0.029	0.029	0.029	0.029		
None	D4 Pond	0.81	0.80	0.80	0.80	0.80	0.80		
50 %		0.80	0.80	0.80	0.80	0.80	0.80		
75 %		0.80	0.80	0.80	0.80	0.80	0.80		
90 %		0.80	0.80	0.80	0.80	0.80	0.80		
None	D4 Stream	0.78	0.78	0.78	0.78	0.78	0.78		
50 %		0.78	0.78	0.78	0.78	0.78	0.78		
75 %		0.78	0.78	0.78	0.78	0.78	0.78		
90 %		0.78	0.78	0.78	0.78	0.78	0.78		
None	D5 Pond	0.57	0.57	0.57	0.57	0.57	0.57		
50 %		0.57	0.57	0.57	0.57	0.57	0.57		
75 %		0.57	0.57	0.57	0.57	0.57	0.57		
90 %		0.57	0.57	0.57	0.57	0.57	0.57		
None	D5 Stream	0.55	0.45	0.45	0.45	0.45	0.45		

Intended use		spray application							
Active substance		flupyradifurone							
Application rate (g/ha)		2 x 56.3 g/ha							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10 m	20 m		
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m		
50 %		0.45	0.45	0.45	0.45	0.45	0.45		
75 %		0.45	0.45	0.45	0.45	0.45	0.45		
90 %		0.45	0.45	0.45	0.45	0.45	0.45		
None	R1 Pond	0.21	0.20	0.20	0.19	0.089	0.047		
50 %		0.20	0.20	0.19	0.19	0.082	0.042		
75 %		0.19	0.19	0.19	0.19	0.078	0.040		
90 %		0.19	0.19	0.19	0.19	0.076	0.038		
None	R1 Stream	1.7	1.7	1.7	1.7	0.76	0.40		
50 %		1.7	1.7	1.7	1.7	0.76	0.40		
75 %		1.7	1.7	1.7	1.7	0.76	0.40		
90 %		1.7	1.7	1.7	1.7	0.76	0.40		

* Maximum values coming from multiple applications are marked in italics

PEC: predicted environmental concentration

RAC: regulatory acceptable concentration

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

Table 9.7-27: Aquatic organisms: PEC_{sw}^o calculation and acceptability of risk ($PEC/RAC < 1$) for deltamethrin based on FOCUS Step 4 calculations and toxicity data for aquatic invertebrates (higher tier information) with mitigation of spray drift and run-off for the use of DLT + FPF EC 85 in OSR winter **BBCH 50-59** (use group D; modelling use PMT00)

Intended use		spray application							
Active substance		deltamethrin							
Application rate (g/ha)		2 x 7.5 g/ha							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10 m	20 m		
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m		
None	D3 Ditch	0.0475	0.0129	0.0068	0.0036	0.0068	0.0036		
50 %		0.0238	0.0064	0.0034	0.0018	0.0034	0.0018		
75 %		0.0119	0.0032	0.0017	0.0009	0.0017	0.0009		
90 %		0.0048	0.0013	0.0007	0.0004	0.0007	0.0004		
None	D4 Pond	0.0016	0.0014	0.0010	0.0007	0.0010	0.0007		
50 %		0.0008	0.0007	0.0005	0.0003	0.0005	0.0003		
75 %		0.0004	0.0004	0.0003	0.0002	0.0003	0.0002		
90 %		0.0002	0.0001	0.0001	<0.0010	0.0001	<0.0010		
None	D4 Stream	0.0365	0.0133	0.0071	0.0037	0.0071	0.0037		
50 %		0.0183	0.0067	0.0035	0.0018	0.0035	0.0018		
75 %		0.0091	0.0033	0.0018	0.0009	0.0018	0.0009		
90 %		0.0037	0.0013	0.0007	0.0004	0.0007	0.0004		
None	D5 Pond	0.0016	0.0014	0.0010	0.0007	0.0010	0.0007		
50 %		0.0008	0.0007	0.0005	0.0003	0.0005	0.0003		
75 %		0.0004	0.0004	0.0003	0.0002	0.0003	0.0002		
90 %		0.0002	0.0001	0.0001	<0.0010	0.0001	<0.0010		
None	D5 Stream	0.0385	0.0141	0.0075	0.0039	0.0075	0.0039		
50 %		0.0193	0.0070	0.0037	0.0019	0.0037	0.0019		
75 %		0.0096	0.0035	0.0019	0.0010	0.0019	0.0010		
90 %		0.0039	0.0014	0.0007	0.0004	0.0007	0.0004		
None	R1 Pond	0.0016	0.0014	0.0010	0.0007	0.0010	0.0007		
50 %		0.0008	0.0007	0.0005	0.0003	0.0005	0.0003		

Intended use		spray application							
Active substance		deltamethrin							
Application rate (g/ha)		2 x 7.5 g/ha							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10 m	20 m		
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m		
75 %	R1 Stream	0.0004	0.0004	0.0003	0.0002	0.0003	0.0002		
90 %		0.0002	0.0001	0.0001	<0.0010	0.0001	<0.0010		
None		0.0311	0.0113	0.0060	0.0031	0.0060	0.0031		
50 %		0.0155	0.0057	0.0030	0.0016	0.0030	0.0016		
75 %	R3 Stream	0.0078	0.0028	0.0015	0.0008	0.0015	0.0008		
90 %		0.0031	0.0011	0.0006	0.0003	0.0006	0.0003		
None		0.0439	0.0160	0.0085	0.0044	0.0085	0.0044		
50 %		0.0220	0.0080	0.0043	0.0022	0.0043	0.0022		
75 %		0.0110	0.0040	0.0021	0.0011	0.0021	0.0011		
90 %		0.0044	0.0016	0.0009	0.0004	0.0009	0.0004		
RAC (µg/L)		0.0016	PEC / RAC ratio						
None	D3 Ditch	29.7	8.1	4.3	2.3	4.3	2.3		
50 %		14.9	4.0	2.1	1.1	2.1	1.1		
75 %		7.4	2.0	1.1	0.563	1.1	0.563		
90 %		3.0	0.813	0.438	0.250	0.438	0.250		
None	D4 Pond	1.0	0.875	0.625	0.438	0.625	0.438		
50 %		0.500	0.438	0.313	0.188	0.313	0.188		
75 %		0.250	0.250	0.188	0.125	0.188	0.125		
90 %		0.125	0.063	0.063	0.625	0.063	0.625		
None	D4 Stream	22.8	8.3	4.4	2.3	4.4	2.3		
50 %		11.4	4.2	2.2	1.1	2.2	1.1		
75 %		5.7	2.1	1.1	0.563	1.1	0.563		
90 %		2.3	0.813	0.438	0.250	0.438	0.250		
None	D5 Pond	1.0	0.875	0.625	0.438	0.625	0.438		

Intended use		spray application							
Active substance		deltamethrin							
Application rate (g/ha)		2 x 7.5 g/ha							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10 m	20 m		
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m		
50 %		0.500	0.438	0.313	0.188	0.313	0.188		
75 %		0.250	0.250	0.188	0.125	0.188	0.125		
90 %		0.125	0.063	0.063	0.625	0.063	0.625		
None	D5 Stream	24.1	8.8	4.7	2.4	4.7	2.4		
50 %		12.1	4.4	2.3	1.2	2.3	1.2		
75 %		6.0	2.2	1.2	0.625	1.2	0.625		
90 %		2.4	0.875	0.438	0.250	0.438	0.250		
None	R1 Pond	1.0	0.875	0.625	0.438	0.625	0.438		
50 %		0.500	0.438	0.313	0.188	0.313	0.188		
75 %		0.250	0.250	0.188	0.125	0.188	0.125		
90 %		0.125	0.063	0.063	0.625	0.063	0.625		
None	R1 Stream	19.4	7.1	3.8	1.9	3.8	1.9		
50 %		9.7	3.6	1.9	1.0	1.9	1.0		
75 %		4.9	1.8	0.938	0.500	0.938	0.500		
90 %		1.9	0.688	0.375	0.188	0.375	0.188		
None	R3 Stream	27.4	10.0	5.3	2.8	5.3	2.8		
50 %		13.8	5.0	2.7	1.4	2.7	1.4		
75 %		6.9	2.5	1.3	0.688	1.3	0.688		
90 %		2.8	1.0	0.563	0.250	0.563	0.250		
RAC (µg/L)		PEC / RAC ratio							
0.023									
None	D3 Ditch	2.07	0.5604	0.2974	0.1544	0.2974	0.1544		
50 %		1.03	0.2803	0.1487	0.0772	0.1487	0.0772		
75 %		0.5161	0.1401	0.0743	0.0386	0.0743	0.0386		
90 %		0.2073	0.0558	0.0300	0.0157	0.0300	0.0157		

Intended use		spray application							
Active substance		deltamethrin							
Application rate (g/ha)		2 x 7.5 g/ha							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10 m	20 m		
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m		
None	D4 Pond	0.0712	0.0616	0.0443	0.0295	0.0443	0.0295		
50 %		0.0356	0.0308	0.0221	0.0147	0.0221	0.0147		
75 %		0.0178	0.0156	0.0113	0.0074	0.0113	0.0074		
90 %		0.0070	0.0061	0.0043	<0.0010	0.0043	<0.0010		
None	D4 Stream	1.59	0.5796	0.3070	0.1603	0.3070	0.1603		
50 %		0.7939	0.2898	0.1541	0.0801	0.1541	0.0801		
75 %		0.3970	0.1455	0.0764	0.0395	0.0764	0.0395		
90 %		0.1590	0.0580	0.0308	0.0160	0.0308	0.0160		
None	D5 Pond	0.0740	0.0640	0.0453	0.0298	0.0453	0.0298		
50 %		0.0370	0.0320	0.0227	0.0149	0.0227	0.0149		
75 %		0.0188	0.0160	0.0113	0.0074	0.0113	0.0074		
90 %		0.0072	0.0066	0.0044	<0.0010	0.0044	<0.0010		
None	D5 Stream	1.67	0.6117	0.3240	0.1692	0.3240	0.1692		
50 %		0.8383	0.3058	0.1627	0.0846	0.1627	0.0846		
75 %		0.4190	0.1536	0.0807	0.0417	0.0807	0.0417		
90 %		0.1679	0.0612	0.0325	0.0169	0.0325	0.0169		
None	R1 Pond	0.0712	0.0616	0.0443	0.0295	0.0443	0.0295		
50 %		0.0356	0.0308	0.0221	0.0147	0.0221	0.0147		
75 %		0.0178	0.0156	0.0113	0.0074	0.0113	0.0074		
90 %		0.0070	0.0061	0.0043	<0.0010	0.0043	<0.0010		
None	R1 Stream	1.35	0.4930	0.2613	0.1364	0.2613	0.1364		
50 %		0.6757	0.2466	0.1312	0.0682	0.1312	0.0682		
75 %		0.3379	0.1238	0.0650	0.0336	0.0650	0.0336		
90 %		0.1353	0.0493	0.0262	0.0137	0.0262	0.0137		

Intended use		spray application							
Active substance		deltamethrin							
Application rate (g/ha)		2 x 7.5 g/ha							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10 m	20 m		
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m		
None	R3 Stream	1.91	0.6974	0.3696	0.1930	0.3696	0.1930		
50 %		0.9557	0.3488	0.1855	0.0965	0.1855	0.0965		
75 %		0.4778	0.1751	0.0920	0.0475	0.0920	0.0475		
90 %		0.1915	0.0697	0.0371	0.0193	0.0371	0.0193		

* Maximum values coming from multiple applications are marked in italics

° PEC_{sw} values including suspended solids are reported

PEC: predicted environmental concentration

RAC: regulatory acceptable concentration

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

Table 9.7-28: Aquatic organisms: PEC_{sw}^o calculation and acceptability of risk ($PEC/RAC < 1$) for deltamethrin based on FOCUS Step 4 calculations and toxicity data for aquatic invertebrates (higher tier information) with mitigation of spray drift and run-off for the use of DLT + FPF EC 85 in OSR spring **BBC**H 50-59 (use group D; modelling use PMT01)

Intended use		spray application							
Active substance		deltamethrin							
Application rate (g/ha)		2 x 7.5 g/ha							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10 m	20 m		
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m		
None	D3 Ditch	0.0476	0.0129	0.0069	0.0036	0.0069	0.0036		
50 %		0.0238	0.0065	0.0034	0.0018	0.0034	0.0018		
75 %		0.0119	0.0032	0.0017	0.0009	0.0017	0.0009		
90 %		0.0048	0.0013	0.0007	0.0004	0.0007	0.0004		
None	D4 Pond	0.0016	0.0014	0.0010	0.0007	0.0010	0.0007		
50 %		0.0008	0.0007	0.0005	0.0003	0.0005	0.0003		
75 %		0.0004	0.0004	0.0003	0.0002	0.0003	0.0002		
90 %		0.0002	0.0001	0.0001	<0.0010	0.0001	<0.0010		
None	D4 Stream	0.0411	0.0150	0.0080	0.0042	0.0080	0.0042		
50 %		0.0206	0.0075	0.0040	0.0021	0.0040	0.0021		
75 %		0.0103	0.0038	0.0020	0.0010	0.0020	0.0010		
90 %		0.0041	0.0015	0.0008	0.0004	0.0008	0.0004		
None	D5 Pond	0.0016	0.0014	0.0010	0.0007	0.0010	0.0007		
50 %		0.0008	0.0007	0.0005	0.0003	0.0005	0.0003		
75 %		0.0004	0.0004	0.0003	0.0002	0.0003	0.0002		
90 %		0.0002	0.0001	0.0001	<0.0010	0.0001	<0.0010		
None	D5 Stream	0.0415	0.0152	0.0080	0.0042	0.0080	0.0042		
50 %		0.0208	0.0076	0.0040	0.0021	0.0040	0.0021		
75 %		0.0104	0.0038	0.0020	0.0010	0.0020	0.0010		
90 %		0.0042	0.0015	0.0008	0.0004	0.0008	0.0004		
None	R1 Pond	0.0016	0.0014	0.0010	0.0007	0.0010	0.0007		
50 %		0.0008	0.0007	0.0005	0.0003	0.0005	0.0003		

Intended use		spray application							
Active substance		deltamethrin							
Application rate (g/ha)		2 x 7.5 g/ha							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10 m	20 m		
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m		
75 %	R1 Stream	0.0004	0.0004	0.0003	0.0002	0.0003	0.0002		
90 %		0.0002	0.0001	0.0001	<0.0010	0.0001	<0.0010		
None		0.0314	0.0115	0.0061	0.0032	0.0061	0.0032		
50 %		0.0157	0.0057	0.0031	0.0016	0.0031	0.0016		
75 %		0.0079	0.0029	0.0015	0.0008	0.0015	0.0008		
90 %		0.0031	0.0011	0.0006	0.0003	0.0006	0.0003		
RAC (µg/L) 0.0016		PEC / RAC ratio							
None	D3 Ditch	29.8	8.1	4.3	2.3	4.3	2.3		
50 %		14.9	4.1	2.1	1.1	2.1	1.1		
75 %		7.4	2.0	1.1	0.563	1.1	0.563		
90 %		3.0	0.813	0.438	0.250	0.438	0.250		
None	D4 Pond	1.0	0.875	0.625	0.438	0.625	0.438		
50 %		0.500	0.438	0.313	0.188	0.313	0.188		
75 %		0.250	0.250	0.188	0.125	0.188	0.125		
90 %		0.125	0.063	0.063	0.625	0.063	0.625		
None	D4 Stream	25.7	9.4	5.0	2.6	5.0	2.6		
50 %		12.9	4.7	2.5	1.3	2.5	1.3		
75 %		6.4	2.4	1.3	0.625	1.3	0.625		
90 %		2.6	0.938	0.500	0.250	0.500	0.250		
None	D5 Pond	1.0	0.875	0.625	0.438	0.625	0.438		
50 %		0.500	0.438	0.313	0.188	0.313	0.188		
75 %		0.250	0.250	0.188	0.125	0.188	0.125		
90 %		0.125	0.063	0.063	0.625	0.063	0.625		
None	D5 Stream	25.9	9.5	5.0	2.6	5.0	2.6		

Intended use		spray application							
Active substance		deltamethrin							
Application rate (g/ha)		2 x 7.5 g/ha							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10 m	20 m		
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m		
50 %		13.0	4.8	2.5	1.3	2.5	1.3		
75 %		6.5	2.4	1.3	0.625	1.3	0.625		
90 %		2.6	0.938	0.500	0.250	0.500	0.250		
None	R1 Pond	1.0	0.875	0.625	0.438	0.625	0.438		
50 %		0.500	0.438	0.313	0.188	0.313	0.188		
75 %		0.250	0.250	0.188	0.125	0.188	0.125		
90 %		0.125	0.063	0.063	0.625	0.063	0.625		
None	R1 Stream	19.6	7.2	3.8	2.0	3.8	2.0		
50 %		9.8	3.6	1.9	1.0	1.9	1.0		
75 %		4.9	1.8	0.938	0.500	0.938	0.500		
90 %		1.9	0.688	0.375	0.188	0.375	0.188		
RAC (µg/L)		PEC / RAC ratio							
0.023									
None	D3-Ditch	2.07	0.5617	0.2980	0.1547	0.2980	0.1547		
50 %		1.04	0.2808	0.1490	0.0773	0.1490	0.0773		
75 %		0.5174	0.1404	0.0745	0.0387	0.0745	0.0387		
90 %		0.2077	0.0559	0.0301	0.0157	0.0301	0.0157		
None	D4-Pond	0.0737	0.0638	0.0451	0.0297	0.0451	0.0297		
50 %		0.0369	0.0319	0.0226	0.0149	0.0226	0.0149		
75 %		0.0187	0.0160	0.0113	0.0074	0.0113	0.0074		
90 %		0.0072	0.0066	0.0044	<0.0010	0.0044	<0.0010		
None	D4-Stream	1.79	0.6530	0.3459	0.1806	0.3459	0.1806		
50 %		0.8943	0.3264	0.1736	0.0903	0.1736	0.0903		
75 %		0.4474	0.1639	0.0861	0.0444	0.0861	0.0444		
90 %		0.1792	0.0653	0.0347	0.0180	0.0347	0.0180		

Intended use		spray application							
Active substance		deltamethrin							
Application rate (g/ha)		2 x 7.5 g/ha							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10 m	20 m		
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m		
None	D5 Pond	0.0730	0.0632	0.0447	0.0295	0.0447	0.0295		
50 %		0.0365	0.0316	0.0223	0.0148	0.0223	0.0148		
75 %		0.0185	0.0158	0.0113	0.0074	0.0113	0.0074		
90 %		0.0071	0.0065	0.0043	<0.0010	0.0043	<0.0010		
None	D5 Stream	1.81	0.6596	0.3494	0.1824	0.3494	0.1824		
50 %		0.9039	0.3298	0.1754	0.0912	0.1754	0.0912		
75 %		0.4517	0.1656	0.0870	0.0449	0.0870	0.0449		
90 %		0.1810	0.0660	0.0351	0.0183	0.0351	0.0183		
None	R1 Pond	0.0712	0.0617	0.0443	0.0295	0.0443	0.0295		
50 %		0.0356	0.0308	0.0221	0.0148	0.0221	0.0147		
75 %		0.0179	0.0157	0.0113	0.0074	0.0113	0.0074		
90 %		0.0070	0.0063	0.0043	<0.0010	0.0043	<0.0010		
None	R1 Stream	1.37	0.4987	0.2643	0.1380	0.2643	0.1380		
50 %		0.6835	0.2494	0.1327	0.0690	0.1327	0.0690		
75 %		0.3418	0.1253	0.0658	0.0340	0.0658	0.0340		
90 %		0.1369	0.0499	0.0265	0.0138	0.0265	0.0138		

* Maximum values coming from multiple applications are marked in italics

° PEC_{sw} values including suspended solids are reported

PEC: predicted environmental concentration

RAC: regulatory acceptable concentration

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

Table 9.7.29: Aquatic organisms: PEC_{sw} calculation and acceptability of risk (PEC/RAC < 1) for flupyradifurone based on FOCUS Step 4 calculations and toxicity data for sediment dweller (worst case species) with mitigation of spray drift and run-off for the use of DLT + FPF EC 85 in OSR winter (use group D; modelling use PMT00)

Intended-use		spray application							
Active substance		flupyradifurone							
Application rate (g/ha)		2 x 56.3 g/ha							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10-m	20-m		
	No spray buffer (m)	0-m	5-m	10-m	20-m	10-m	20-m		
None	D3-Ditch	0.3577	0.0979	0.0525	0.0279	0.0525	0.0279		
50-%		0.1795	0.0496	0.0269	0.0159	0.0269	0.0159		
75-%		0.0904	0.0254	0.0157	0.0152	0.0157	0.0152		
90-%		0.0369	0.0152	0.0152	0.0152	0.0152	0.0152		
None	D4-Pond	0.3757	0.3752	0.3743	0.3736	0.3743	0.3736		
50-%		0.3740	0.3737	0.3733	0.3729	0.3733	0.3729		
75-%		0.3731	0.3730	0.3728	0.3726	0.3728	0.3726		
90-%		0.3726	0.3725	0.3725	0.3724	0.3725	0.3724		
None	D4-Stream	0.3677	0.3677	0.3677	0.3677	0.3677	0.3677		
50-%		0.3677	0.3677	0.3677	0.3677	0.3677	0.3677		
75-%		0.3677	0.3677	0.3677	0.3677	0.3677	0.3677		
90-%		0.3677	0.3677	0.3677	0.3677	0.3677	0.3677		
None	D5-Pond	0.2985	0.2981	0.2975	0.2970	0.2975	0.2970		
50-%		0.2973	0.2971	0.2968	0.2965	0.2968	0.2965		
75-%		0.2967	0.2966	0.2964	0.2963	0.2964	0.2963		
90-%		0.2963	0.2963	0.2962	0.2962	0.2962	0.2962		
None	D5-Stream	0.3332	0.2127	0.2127	0.2127	0.2127	0.2127		
50-%		0.2127	0.2127	0.2127	0.2127	0.2127	0.2127		
75-%		0.2127	0.2127	0.2127	0.2127	0.2127	0.2127		
90-%		0.2127	0.2127	0.2127	0.2127	0.2127	0.2127		
None	R1-Pond	0.1821	0.1800	0.1763	0.1731	0.0769	0.0399		
50-%		0.1746	0.1736	0.1718	0.1701	0.0723	0.0369		

Intended use		spray-application							
Active substance		flupyradifurone							
Application rate (g/ha)		2 x 56.3 g/ha							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10 m	20 m		
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m		
75 %		0.1709	0.1704	0.1695	0.1687	0.0699	0.0354		
90 %		0.1687	0.1685	0.1681	0.1678	0.0686	0.0345		
None	R1 Stream	1.1330	1.1330	1.1330	1.1330	0.5155	0.2701		
50 %		1.1330	1.1330	1.1330	1.1330	0.5155	0.2701		
75 %		1.1330	1.1330	1.1330	1.1330	0.5155	0.2701		
90 %		1.1330	1.1330	1.1330	1.1330	0.5155	0.2701		
None	R3 Stream	2.0940	2.0940	2.0940	2.0940	0.9558	0.5014		
50 %		2.0940	2.0940	2.0940	2.0940	0.9558	0.5014		
75 %		2.0940	2.0940	2.0940	2.0940	0.9558	0.5014		
90 %		2.0940	2.0940	2.0940	2.0940	0.9558	0.5014		
RAC (µg/L)		0.617							
		PEC / RAC ratio							
None	D3 Ditch	0.5797	0.1587	0.0851	0.0452	0.0851	0.0452		
50 %		0.2909	0.0804	0.0436	0.0258	0.0436	0.0258		
75 %		0.1465	0.0412	0.0254	0.0246	0.0254	0.0246		
90 %		0.0598	0.0246	0.0246	0.0246	0.0246	0.0246		
None	D4 Pond	0.6089	0.6081	0.6066	0.6055	0.6066	0.6055		
50 %		0.6062	0.6057	0.6050	0.6044	0.6050	0.6044		
75 %		0.6047	0.6045	0.6042	0.6039	0.6042	0.6039		
90 %		0.6039	0.6037	0.6037	0.6036	0.6037	0.6036		
None	D4 Stream	0.5959	0.5959	0.5959	0.5959	0.5959	0.5959		
50 %		0.5959	0.5959	0.5959	0.5959	0.5959	0.5959		
75 %		0.5959	0.5959	0.5959	0.5959	0.5959	0.5959		
90 %		0.5959	0.5959	0.5959	0.5959	0.5959	0.5959		
None	D5 Pond	0.4838	0.4831	0.4822	0.4814	0.4822	0.4814		

Intended-use		spray-application							
Active substance		flupyradifurone							
Application rate (g/ha)		2 x 56.3 g/ha							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10 m	20 m		
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m		
50 %		<i>0.4818</i>	<i>0.4815</i>	<i>0.4810</i>	<i>0.4806</i>	<i>0.4810</i>	<i>0.4806</i>		
75 %		<i>0.4809</i>	<i>0.4807</i>	<i>0.4804</i>	<i>0.4802</i>	<i>0.4804</i>	<i>0.4802</i>		
90 %		<i>0.4802</i>	<i>0.4802</i>	<i>0.4801</i>	<i>0.4801</i>	<i>0.4801</i>	<i>0.4801</i>		
None	D5 Stream	<i>0.5400</i>	<i>0.3447</i>	<i>0.3447</i>	<i>0.3447</i>	<i>0.3447</i>	<i>0.3447</i>		
50 %		<i>0.3447</i>	<i>0.3447</i>	<i>0.3447</i>	<i>0.3447</i>	<i>0.3447</i>	<i>0.3447</i>		
75 %		<i>0.3447</i>	<i>0.3447</i>	<i>0.3447</i>	<i>0.3447</i>	<i>0.3447</i>	<i>0.3447</i>		
90 %		<i>0.3447</i>	<i>0.3447</i>	<i>0.3447</i>	<i>0.3447</i>	<i>0.3447</i>	<i>0.3447</i>		
None	R1 Pond	<i>0.2951</i>	<i>0.2917</i>	<i>0.2857</i>	<i>0.2806</i>	<i>0.1246</i>	<i>0.0647</i>		
50 %		<i>0.2830</i>	<i>0.2814</i>	<i>0.2784</i>	<i>0.2757</i>	<i>0.1172</i>	<i>0.0598</i>		
75 %		<i>0.2770</i>	<i>0.2762</i>	<i>0.2747</i>	<i>0.2734</i>	<i>0.1133</i>	<i>0.0574</i>		
90 %		<i>0.2734</i>	<i>0.2731</i>	<i>0.2724</i>	<i>0.2720</i>	<i>0.1112</i>	<i>0.0559</i>		
None	R1 Stream	<i>1.8363</i>	<i>1.8363</i>	<i>1.8363</i>	<i>1.8363</i>	<i>0.8355</i>	<i>0.4378</i>		
50 %		<i>1.8363</i>	<i>1.8363</i>	<i>1.8363</i>	<i>1.8363</i>	<i>0.8355</i>	<i>0.4378</i>		
75 %		<i>1.8363</i>	<i>1.8363</i>	<i>1.8363</i>	<i>1.8363</i>	<i>0.8355</i>	<i>0.4378</i>		
90 %		<i>1.8363</i>	<i>1.8363</i>	<i>1.8363</i>	<i>1.8363</i>	<i>0.8355</i>	<i>0.4378</i>		
None	R3 Stream	<i>3.3938</i>	<i>3.3938</i>	<i>3.3938</i>	<i>3.3938</i>	<i>1.5491</i>	<i>0.8126</i>		
50 %		<i>3.3938</i>	<i>3.3938</i>	<i>3.3938</i>	<i>3.3938</i>	<i>1.5491</i>	<i>0.8126</i>		
75 %		<i>3.3938</i>	<i>3.3938</i>	<i>3.3938</i>	<i>3.3938</i>	<i>1.5491</i>	<i>0.8126</i>		
90 %		<i>3.3938</i>	<i>3.3938</i>	<i>3.3938</i>	<i>3.3938</i>	<i>1.5491</i>	<i>0.8126</i>		

* Maximum values coming from multiple applications are marked in italics

PEC: predicted environmental concentration

RAC: regulatory acceptable concentration

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

Table 9.7-29A: Aquatic organisms: PEC_{sw} calculation and acceptability of risk (PEC/RAC < 1) for flupyradifurone based on FOCUS Step 4 calculations and toxicity data for sediment dweller (worst case species) with mitigation of spray drift and run-off for the use of DLT + FPF EC 85 in OSR winter BBCH 50-59 (use group D; modelling use PMT01) the plant uptake factor for the parent flupyradifurone was set to 0

Intended use		spray application							
Active substance		flupyradifurone							
Application rate (g/ha)		2 x 56.3 g/ha							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10 m	20 m		
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m		
None	D3 Ditch	0.3580	0.0982	0.0528	0.0281	0.0528	0.0281		
50 %		0.1797	0.0498	0.0273	0.0182	0.0273	0.0182		
75 %		0.0906	0.0264	0.0182	0.0182	0.0182	0.0182		
90 %		0.0374	0.0182	0.0182	0.0182	0.0182	0.0182		
None	D4 Pond	0.4207	0.4203	0.4194	0.4186	0.4194	0.4186		
50 %		0.4190	0.4188	0.4183	0.4180	0.4183	0.4180		
75 %		0.4181	0.4180	0.4178	0.4176	0.4178	0.4176		
90 %		0.4176	0.4176	0.4175	0.4174	0.4175	0.4174		
None	D4 Stream	0.4031	0.4031	0.4031	0.4031	0.4031	0.4031		
50 %		0.4031	0.4031	0.4031	0.4031	0.4031	0.4031		
75 %		0.4031	0.4031	0.4031	0.4031	0.4031	0.4031		
90 %		0.4031	0.4031	0.4031	0.4031	0.4031	0.4031		
None	D5 Pond	0.3163	0.3159	0.3153	0.3148	0.3153	0.3148		
50 %		0.3150	0.3149	0.3146	0.3143	0.3146	0.3143		
75 %		0.3144	0.3144	0.3142	0.3141	0.3142	0.3141		
90 %		0.3141	0.3140	0.3140	0.3139	0.3140	0.3139		
None	D5 Stream	0.3366	0.2253	0.2253	0.2253	0.2253	0.2253		
50 %		0.2253	0.2253	0.2253	0.2253	0.2253	0.2253		
75 %		0.2253	0.2253	0.2253	0.2253	0.2253	0.2253		
90 %		0.2253	0.2253	0.2253	0.2253	0.2253	0.2253		
None	R1 Pond	0.1831	0.1810	0.1774	0.1741	0.0773	0.0401		
50 %		0.1757	0.1746	0.1728	0.1712	0.0727	0.0371		

Intended use		spray application							
Active substance		flupyradifurone							
Application rate (g/ha)		2 x 56.3 g/ha							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10 m	20 m		
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m		
50 %		0.51	0.51	0.51	0.51	0.51	0.51		
75 %		0.51	0.51	0.51	0.51	0.51	0.51		
90 %		0.51	0.51	0.51	0.51	0.51	0.51		
None	D5 Stream	0.55	0.37	0.37	0.37	0.37	0.37		
50 %		0.37	0.37	0.37	0.37	0.37	0.37		
75 %		0.37	0.37	0.37	0.37	0.37	0.37		
90 %		0.37	0.37	0.37	0.37	0.37	0.37		
None	R1 Pond	0.30	0.29	0.29	0.28	0.13	0.065		
50 %		0.28	0.28	0.28	0.28	0.12	0.060		
75 %		0.28	0.28	0.28	0.28	0.11	0.058		
90 %		0.28	0.27	0.27	0.27	0.11	0.056		
None	R1 Stream	1.8	1.8	1.8	1.8	0.84	0.44		
50 %		1.8	1.8	1.8	1.8	0.84	0.44		
75 %		1.8	1.8	1.8	1.8	0.84	0.44		
90 %		1.8	1.8	1.8	1.8	0.84	0.44		
None	R3 Stream	3.4	3.4	3.4	3.4	1.6	0.82		
50 %		3.4	3.4	3.4	3.4	1.6	0.82		
75 %		3.4	3.4	3.4	3.4	1.6	0.82		
90 %		3.4	3.4	3.4	3.4	1.6	0.82		

* Maximum values coming from multiple applications are marked in italics

PEC: predicted environmental concentration

RAC: regulatory acceptable concentration

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

Table 9.7.30: Aquatic organisms: PEC_{sw} calculation and acceptability of risk (PEC/RAC < 1) for flupyradifurone based on FOCUS Step 4 calculations and toxicity data for sediment dweller (worst case species) with mitigation of spray drift and run-off for the use of DLT + FPF EC 85 in OSR spring (use group D; modelling use PMT01)

Intended-use		spray application							
Active substance		flupyradifurone							
Application rate (g/ha)		2 x 56.3 g/ha							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10-m	20-m		
	No spray buffer (m)	0-m	5-m	10-m	20-m	10-m	20-m		
None	D3-Ditch	0.3579	0.0977	0.0522	0.0275	0.0522	0.0275		
50-%		0.1794	0.0492	0.0269	0.0165	0.0269	0.0165		
75-%		0.0901	0.0261	0.0164	0.0146	0.0164	0.0146		
90-%		0.0370	0.0146	0.0146	0.0146	0.0146	0.0146		
None	D4-Pond	0.4678	0.4672	0.4660	0.4651	0.4660	0.4651		
50-%		0.4655	0.4652	0.4646	0.4641	0.4646	0.4641		
75-%		0.4644	0.4642	0.4639	0.4637	0.4639	0.4637		
90-%		0.4637	0.4636	0.4635	0.4634	0.4635	0.4634		
None	D4-Stream	0.4839	0.4839	0.4839	0.4839	0.4839	0.4839		
50-%		0.4839	0.4839	0.4839	0.4839	0.4839	0.4839		
75-%		0.4839	0.4839	0.4839	0.4839	0.4839	0.4839		
90-%		0.4839	0.4839	0.4839	0.4839	0.4839	0.4839		
None	D5-Pond	0.3419	0.3415	0.3407	0.3401	0.3407	0.3401		
50-%		0.3404	0.3402	0.3398	0.3395	0.3398	0.3395		
75-%		0.3397	0.3396	0.3394	0.3392	0.3394	0.3392		
90-%		0.3392	0.3392	0.3391	0.3390	0.3391	0.3390		
None	D5-Stream	0.2273	0.2273	0.2273	0.2273	0.2273	0.2273		
50-%		0.2273	0.2273	0.2273	0.2273	0.2273	0.2273		
75-%		0.2273	0.2273	0.2273	0.2273	0.2273	0.2273		
90-%		0.2273	0.2273	0.2273	0.2273	0.2273	0.2273		
None	R1-Pond	0.1030	0.1016	0.0990	0.0967	0.0439	0.0231		
50-%		0.0976	0.0969	0.0956	0.0945	0.0405	0.0209		

Intended use		spray-application							
Active substance		flupyradifurone							
Application rate (g/ha)		2 x 56.3 g/ha							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10-m	20-m		
	No-spray buffer (m)	0-m	5-m	10-m	20-m	10-m	20-m		
75 %		0.0950	0.0946	0.0940	0.0934	0.0388	0.0197		
90 %		0.0934	0.0932	0.0930	0.0927	0.0378	0.0191		
None	R1-Stream	1.0830	1.0830	1.0830	1.0830	0.4861	0.2546		
50 %		1.0830	1.0830	1.0830	1.0830	0.4861	0.2546		
75 %		1.0830	1.0830	1.0830	1.0830	0.4861	0.2546		
90 %		1.0830	1.0830	1.0830	1.0830	0.4861	0.2546		
RAC (µg/L)		PEC / RAC-ratio							
0.617									
None	D3-Ditch	0.5801	0.1583	0.0846	0.0446	0.0846	0.0446		
50 %		0.2908	0.0797	0.0436	0.0267	0.0436	0.0267		
75 %		0.1460	0.0423	0.0266	0.0237	0.0266	0.0237		
90 %		0.0600	0.0237	0.0237	0.0237	0.0237	0.0237		
None	D4-Pond	0.7582	0.7572	0.7553	0.7538	0.7553	0.7538		
50 %		0.7545	0.7540	0.7530	0.7522	0.7530	0.7522		
75 %		0.7527	0.7524	0.7519	0.7515	0.7519	0.7515		
90 %		0.7515	0.7514	0.7512	0.7511	0.7512	0.7511		
None	D4-Stream	0.7843	0.7843	0.7843	0.7843	0.7843	0.7843		
50 %		0.7843	0.7843	0.7843	0.7843	0.7843	0.7843		
75 %		0.7843	0.7843	0.7843	0.7843	0.7843	0.7843		
90 %		0.7843	0.7843	0.7843	0.7843	0.7843	0.7843		
None	D5-Pond	0.5541	0.5535	0.5522	0.5512	0.5522	0.5512		
50 %		0.5517	0.5514	0.5507	0.5502	0.5507	0.5502		
75 %		0.5506	0.5504	0.5501	0.5498	0.5501	0.5498		
90 %		0.5498	0.5498	0.5496	0.5494	0.5496	0.5494		
None	D5-Stream	0.6170	0.3684	0.3684	0.3684	0.3684	0.3684		

Intended-use		spray-application							
Active substance		flupyradifurone							
Application rate (g/ha)		2 x 56.3 g/ha							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10-m	20-m		
	No-spray buffer (m)	0-m	5-m	10-m	20-m	10-m	20-m		
50-%		0.3987	0.3684	0.3684	0.3684	0.3684	0.3684		
75-%		0.3684	0.3684	0.3684	0.3684	0.3684	0.3684		
90-%		0.3684	0.3684	0.3684	0.3684	0.3684	0.3684		
None	R1-Pond	0.1669	0.1647	0.1605	0.1567	0.0712	0.0374		
50-%		0.1582	0.1571	0.1549	0.1532	0.0656	0.0339		
75-%		0.1540	0.1533	0.1524	0.1514	0.0629	0.0319		
90-%		0.1514	0.1511	0.1507	0.1502	0.0613	0.0310		
None	R1-Stream	1.7553	1.7553	1.7553	1.7553	0.7878	0.4126		
50-%		1.7553	1.7553	1.7553	1.7553	0.7878	0.4126		
75-%		1.7553	1.7553	1.7553	1.7553	0.7878	0.4126		
90-%		1.7553	1.7553	1.7553	1.7553	0.7878	0.4126		

* Maximum values coming from multiple applications are marked in italics

PEC: predicted environmental concentration

RAC: regulatory acceptable concentration

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

Table 9.7-30A: Aquatic organisms: PEC_{sw} calculation and acceptability of risk (PEC/RAC < 1) for flupyradifurone based on FOCUS Step 4 calculations and toxicity data for sediment dweller (worst case species) with mitigation of spray drift and run-off for the use of DLT + FPF EC 85 in OSR spring BBCH 50-59 (use group D; modelling use PMT02) the plant uptake factor for the parent flupyradifurone was set to 0

Intended use		spray application							
Active substance		flupyradifurone							
Application rate (g/ha)		2 x 56.3 g/ha							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10 m	20 m		
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m		
None	D3 Ditch	0.3581	0.0978	0.0524	0.0282	0.0524	0.0282		
50 %		0.1795	0.0494	0.0279	0.0175	0.0279	0.0175		
75 %		0.0903	0.0271	0.0173	0.017	0.0173	0.017		
90 %		0.038	0.017	0.017	0.017	0.017	0.017		
None	D4 Pond	0.4927	0.492	0.4908	0.4899	0.4908	0.4899		
50 %		0.4904	0.49	0.4894	0.489	0.4894	0.489		
75 %		0.4892	0.489	0.4887	0.4885	0.4887	0.4885		
90 %		0.4885	0.4884	0.4883	0.4882	0.4883	0.4882		
None	D4 Stream	0.5035	0.5035	0.5035	0.5035	0.5035	0.5035		
50 %		0.5035	0.5035	0.5035	0.5035	0.5035	0.5035		
75 %		0.5035	0.5035	0.5035	0.5035	0.5035	0.5035		
90 %		0.5035	0.5035	0.5035	0.5035	0.5035	0.5035		
None	D5 Pond	0.3548	0.3544	0.3537	0.353	0.3537	0.353		
50 %		0.3534	0.3531	0.3528	0.3525	0.3528	0.3525		
75 %		0.3526	0.3525	0.3523	0.3522	0.3523	0.3522		
90 %		0.3522	0.3521	0.352	0.352	0.352	0.352		
None	D5 Stream	0.3827	0.2369	0.2369	0.2369	0.2369	0.2369		
50 %		0.248	0.2369	0.2369	0.2369	0.2369	0.2369		
75 %		0.2369	0.2369	0.2369	0.2369	0.2369	0.2369		
90 %		0.2369	0.2369	0.2369	0.2369	0.2369	0.2369		
None	R1 Pond	0.1032	0.1018	0.0992	0.0969	0.044	0.0231		
50 %		0.0979	0.0972	0.0959	0.0947	0.0406	0.0209		

Intended use		spray application							
Active substance		flupyradifurone							
Application rate (g/ha)		2 x 56.3 g/ha							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10 m	20 m		
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m		
75 %		0.0952	0.0948	0.0942	0.0936	0.0389	0.0198		
90 %		0.0936	0.0935	0.0932	0.093	0.0379	0.0191		
None	R1 Stream	1.107	1.107	1.107	1.107	0.4873	0.2553		
50 %		1.107	1.107	1.107	1.107	0.4873	0.2553		
75 %		1.107	1.107	1.107	1.107	0.4873	0.2553		
90 %		1.107	1.107	1.107	1.107	0.4873	0.2553		
RAC (µg/L)		0.617	PEC / RAC ratio						
None	D3 Ditch	0.58	0.16	0.085	0.046	0.085	0.046		
50 %		0.29	0.080	0.045	0.028	0.045	0.028		
75 %		0.15	0.044	0.028	0.028	0.028	0.028		
90 %		0.062	0.028	0.028	0.028	0.028	0.028		
None	D4 Pond	0.80	0.80	0.80	0.79	0.80	0.79		
50 %		0.79	0.79	0.79	0.79	0.79	0.79		
75 %		0.79	0.79	0.79	0.79	0.79	0.79		
90 %		0.79	0.79	0.79	0.79	0.79	0.79		
None	D4 Stream	0.82	0.82	0.82	0.82	0.82	0.82		
50 %		0.82	0.82	0.82	0.82	0.82	0.82		
75 %		0.82	0.82	0.82	0.82	0.82	0.82		
90 %		0.82	0.82	0.82	0.82	0.82	0.82		
None	D5 Pond	0.58	0.57	0.57	0.57	0.57	0.57		
50 %		0.57	0.57	0.57	0.57	0.57	0.57		
75 %		0.57	0.57	0.57	0.57	0.57	0.57		
90 %		0.57	0.57	0.57	0.57	0.57	0.57		
None	D5 Stream	0.62	0.38	0.38	0.38	0.38	0.38		

Intended use		spray application							
Active substance		flupyradifurone							
Application rate (g/ha)		2 x 56.3 g/ha							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10 m	20 m		
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m		
50 %		0.40	0.38	0.38	0.38	0.38	0.38		
75 %		0.38	0.38	0.38	0.38	0.38	0.38		
90 %		0.38	0.38	0.38	0.38	0.38	0.38		
None	R1 Pond	0.17	0.16	0.16	0.16	0.071	0.037		
50 %		0.16	0.16	0.16	0.15	0.066	0.034		
75 %		0.15	0.15	0.15	0.15	0.063	0.032		
90 %		0.15	0.15	0.15	0.15	0.061	0.031		
None	R1 Stream	1.8	1.8	1.8	1.8	0.79	0.41		
50 %		1.8	1.8	1.8	1.8	0.79	0.41		
75 %		1.8	1.8	1.8	1.8	0.79	0.41		
90 %		1.8	1.8	1.8	1.8	0.79	0.41		

* Maximum values coming from multiple applications are marked in italics

PEC: predicted environmental concentration

RAC: regulatory acceptable concentration

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

Table 9.7-31: Aquatic organisms: PEC_{sw}^o calculation and acceptability of risk ($PEC/RAC < 1$) for deltamethrin based on FOCUS Step 4 calculations and toxicity data for aquatic invertebrates (higher tier information) with mitigation of spray drift and run-off for the use of DLT + FPF EC 85 in OSR winter, **BBCH 65-79** (use group E; modelling use PMT00)

Intended use		spray application							
Active substance		deltamethrin							
Application rate (g/ha)		2 x 5.0 g/ha							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10 m	20 m		
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m		
None	D3 Ditch	0.0319	0.0086	0.0046	0.0024	0.0046	0.0024		
50 %		0.0159	0.0043	0.0023	0.0012	0.0023	0.0012		
75 %		0.0080	0.0021	0.0012	0.0006	0.0012	0.0006		
90 %		0.0032	0.0009	0.0005	0.0002	0.0005	0.0002		
None	D4 Pond	0.0011	0.0009	0.0007	0.0005	0.0007	0.0005		
50 %		0.0005	0.0005	0.0003	0.0002	0.0003	0.0002		
75 %		0.0003	0.0002	0.0002	0.0001	0.0002	0.0001		
90 %		0.0001	0.0001	<0.0010	<0.0010	<0.0010	<0.0010		
None	D4 Stream	0.0274	0.0100	0.0053	0.0027	0.0053	0.0027		
50 %		0.0137	0.0050	0.0027	0.0014	0.0027	0.0014		
75 %		0.0069	0.0025	0.0013	0.0007	0.0013	0.0007		
90 %		0.0027	0.0010	0.0005	0.0003	0.0005	0.0003		
None	D5 Pond	0.0011	0.0009	0.0007	0.0005	0.0007	0.0005		
50 %		0.0006	0.0005	0.0003	0.0002	0.0003	0.0002		
75 %		0.0003	0.0002	0.0002	0.0001	0.0002	0.0001		
90 %		0.0001	0.0001	<0.0010	<0.0010	<0.0010	<0.0010		
None	D5 Stream	0.0296	0.0108	0.0057	0.0030	0.0057	0.0030		
50 %		0.0148	0.0054	0.0029	0.0015	0.0029	0.0015		
75 %		0.0074	0.0027	0.0014	0.0008	0.0014	0.0008		
90 %		0.0030	0.0011	0.0006	0.0003	0.0006	0.0003		
None	R1 Pond	0.0011	0.0009	0.0007	0.0005	0.0007	0.0005		
50 %		0.0005	0.0005	0.0003	0.0002	0.0003	0.0002		

Intended use		spray application							
Active substance		deltamethrin							
Application rate (g/ha)		2 x 5.0 g/ha							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10 m	20 m		
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m		
75 %	R1 Stream	0.0003	0.0002	0.0002	0.0001	0.0002	0.0001		
90 %		0.0001	<0.0010	<0.0010	<0.0010	<0.0010	<0.0010		
None		0.0210	0.0077	0.0041	0.0021	0.0041	0.0021		
50 %		0.0105	0.0038	0.0020	0.0011	0.0020	0.0011		
75 %	R3 Stream	0.0053	0.0019	0.0010	0.0005	0.0010	0.0005		
90 %		0.0021	0.0008	0.0004	0.0002	0.0004	0.0002		
None		0.0293	0.0107	0.0057	0.0029	0.0057	0.0029		
50 %		0.0147	0.0054	0.0028	0.0015	0.0028	0.0015		
75 %	R3 Stream	0.0073	0.0027	0.0014	0.0008	0.0014	0.0008		
90 %		0.0029	0.0011	0.0006	0.0003	0.0006	0.0003		
RAC (µg/L)	0.0016	PEC / RAC ratio							
None	D3 Ditch	19.9	5.4	2.9	1.5	2.9	1.5		
50 %		9.9	2.7	1.4	0.750	1.4	0.750		
75 %		5.0	1.3	0.750	0.375	0.750	0.375		
90 %		2.0	0.563	0.313	0.125	0.313	0.125		
None	D4 Pond	0.688	0.563	0.438	0.313	0.438	0.313		
50 %		0.313	0.313	0.188	0.125	0.188	0.125		
75 %		0.188	0.125	0.125	0.063	0.125	0.063		
90 %		0.063	0.063	0.625	0.625	0.625	0.625		
None	D4 Stream	17.1	6.3	3.3	1.7	3.3	1.7		
50 %		8.6	3.1	1.7	0.875	1.7	0.875		
75 %		4.3	1.6	0.813	0.438	0.813	0.438		
90 %		1.7	0.625	0.313	0.188	0.313	0.188		
None	D5 Pond	0.688	0.563	0.438	0.313	0.438	0.313		

Intended use		spray application							
Active substance		deltamethrin							
Application rate (g/ha)		2 x 5.0 g/ha							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10 m	20 m		
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m		
50 %		0.375	0.313	0.188	0.125	0.188	0.125		
75 %		0.188	0.125	0.125	0.063	0.125	0.063		
90 %		0.063	0.063	0.625	0.625	0.625	0.625		
None	D5 Stream	18.5	6.8	3.6	1.9	3.6	1.9		
50 %		9.3	3.4	1.8	0.938	1.8	0.938		
75 %		4.6	1.7	0.875	0.500	0.875	0.500		
90 %		1.9	0.688	0.375	0.188	0.375	0.188		
None	R1 Pond	0.688	0.563	0.438	0.313	0.438	0.313		
50 %		0.313	0.313	0.188	0.125	0.188	0.125		
75 %		0.188	0.125	0.125	0.063	0.125	0.063		
90 %		0.063	0.625	0.625	0.625	0.625	0.625		
None	R1 Stream	13.1	4.8	2.6	1.3	2.6	1.3		
50 %		6.6	2.4	1.3	0.688	1.3	0.688		
75 %		3.3	1.2	0.625	0.313	0.625	0.313		
90 %		1.3	0.500	0.250	0.125	0.250	0.125		
None	R3 Stream	18.3	6.7	3.6	1.8	3.6	1.8		
50 %		9.2	3.4	1.8	0.938	1.8	0.938		
75 %		4.6	1.7	0.875	0.500	0.875	0.500		
90 %		1.8	0.688	0.375	0.188	0.375	0.188		
RAC (µg/L)		PEC / RAC ratio							
None	D3 Ditch	1.39	0.3750	0.1997	0.1034	0.1997	0.1034		
50 %		0.6926	0.1882	0.0991	0.0517	0.0991	0.0517		
75 %		0.3463	0.0934	0.0503	0.0259	0.0503	0.0259		
90 %		0.1379	0.0373	0.0201	0.0100	0.0201	0.0100		

Intended use		spray application							
Active substance		deltamethrin							
Application rate (g/ha)		2 x 5.0 g/ha							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10 m	20 m		
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m		
None	D4 Pond	0.0495	0.0424	0.0303	0.0200	0.0303	0.0200		
50 %		0.0248	0.0215	0.0149	0.0100	0.0149	0.0100		
75 %		0.0121	0.0105	0.0077	0.0050	0.0077	0.0050		
90 %		0.0050	0.0044	<0.0010	<0.0010	<0.0010	<0.0010		
None	D4 Stream	1.19	0.4361	0.2306	0.1194	0.2306	0.1194		
50 %		0.5961	0.2181	0.1153	0.0597	0.1153	0.0597		
75 %		0.2987	0.1083	0.0583	0.0306	0.0583	0.0306		
90 %		0.1194	0.0430	0.0236	0.0125	0.0236	0.0125		
None	D5 Pond	0.0497	0.0425	0.0304	0.0200	0.0304	0.0200		
50 %		0.0249	0.0215	0.0149	0.0100	0.0149	0.0100		
75 %		0.0122	0.0105	0.0077	0.0050	0.0077	0.0050		
90 %		0.0050	0.0044	<0.0010	<0.0010	<0.0010	<0.0010		
None	D5 Stream	1.29	0.4704	0.2487	0.1289	0.2487	0.1289		
50 %		0.6430	0.2353	0.1244	0.0644	0.1244	0.0644		
75 %		0.3222	0.1169	0.0630	0.0330	0.0630	0.0330		
90 %		0.1289	0.0464	0.0255	0.0135	0.0255	0.0135		
None	R1 Pond	0.0477	0.0412	0.0295	0.0200	0.0295	0.0200		
50 %		0.0239	0.0204	0.0147	0.0100	0.0147	0.0100		
75 %		0.0117	0.0104	0.0074	0.0048	0.0074	0.0048		
90 %		0.0048	<0.0010	<0.0010	<0.0010	<0.0010	<0.0010		
None	R1 Stream	0.9117	0.3337	0.1764	0.0914	0.1764	0.0914		
50 %		0.4557	0.1668	0.0882	0.0457	0.0882	0.0457		
75 %		0.2284	0.0829	0.0446	0.0234	0.0446	0.0234		
90 %		0.0914	0.0330	0.0180	0.0096	0.0180	0.0096		

Intended use		spray application							
Active substance		deltamethrin							
Application rate (g/ha)		2 x 5.0 g/ha							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10 m	20 m		
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m		
None	R3 Stream	<i>1.27</i>	<i>0.4665</i>	<i>0.2466</i>	<i>0.1277</i>	<i>0.2466</i>	<i>0.1277</i>		
50 %		<i>0.6374</i>	<i>0.2332</i>	<i>0.1233</i>	<i>0.0639</i>	<i>0.1233</i>	<i>0.0639</i>		
75 %		<i>0.3193</i>	<i>0.1159</i>	<i>0.0624</i>	<i>0.0327</i>	<i>0.0624</i>	<i>0.0327</i>		
90 %		<i>0.1277</i>	<i>0.0460</i>	<i>0.0253</i>	<i>0.0133</i>	<i>0.0253</i>	<i>0.0133</i>		

* Maximum values coming from multiple applications are marked in italics

° PEC_{sw} values including suspended solids are reported

PEC: predicted environmental concentration

RAC: regulatory acceptable concentration

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

Table 9.7-32: Aquatic organisms: PEC_{sw}^o calculation and acceptability of risk ($PEC/RAC < 1$) for deltamethrin based on FOCUS Step 4 calculations and toxicity data for aquatic invertebrates (higher tier information) with mitigation of spray drift and run-off for the use of DLT + FPF EC 85 in OSR spring, **BBCH 65-79** (use group E; modelling use PMT01)

Intended use		spray application							
Active substance		deltamethrin							
Application rate (g/ha)		2 x 5.0 g/ha							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10 m	20 m		
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m		
None	D3 Ditch	0.0318	0.0086	0.0046	0.0024	0.0046	0.0024		
50 %		0.0159	0.0043	0.0023	0.0012	0.0023	0.0012		
75 %		0.0080	0.0021	0.0012	0.0006	0.0012	0.0006		
90 %		0.0032	0.0009	0.0005	0.0002	0.0005	0.0002		
None	D4 Pond	0.0011	0.0009	0.0007	0.0005	0.0007	0.0005		
50 %		0.0006	0.0005	0.0003	0.0002	0.0003	0.0002		
75 %		0.0003	0.0002	0.0002	0.0001	0.0002	0.0001		
90 %		0.0001	0.0001	<0.0010	<0.0010	<0.0010	<0.0010		
None	D4 Stream	0.0274	0.0100	0.0053	0.0027	0.0053	0.0027		
50 %		0.0137	0.0050	0.0027	0.0014	0.0027	0.0014		
75 %		0.0069	0.0025	0.0013	0.0007	0.0013	0.0007		
90 %		0.0027	0.0010	0.0005	0.0003	0.0005	0.0003		
None	D5 Pond	0.0011	0.0009	0.0007	0.0005	0.0007	0.0005		
50 %		0.0005	0.0005	0.0003	0.0002	0.0003	0.0002		
75 %		0.0003	0.0002	0.0002	0.0001	0.0002	0.0001		
90 %		0.0001	<0.0010	<0.0010	<0.0010	<0.0010	<0.0010		
None	D5 Stream	0.0296	0.0108	0.0057	0.0030	0.0057	0.0030		
50 %		0.0148	0.0054	0.0029	0.0015	0.0029	0.0015		
75 %		0.0074	0.0027	0.0014	0.0008	0.0014	0.0008		
90 %		0.0030	0.0011	0.0006	0.0003	0.0006	0.0003		

Intended use		spray application							
Active substance		deltamethrin							
Application rate (g/ha)		2 x 5.0 g/ha							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10 m	20 m		
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m		
None	R1 Pond	0.0011	0.0009	0.0007	0.0005	0.0007	0.0005		
50 %		0.0005	0.0005	0.0003	0.0002	0.0003	0.0002		
75 %		0.0003	0.0002	0.0002	0.0001	0.0002	0.0001		
90 %		0.0001	0.0001	<0.0010	<0.0010	<0.0010	<0.0010		
None	R1 Stream	0.0210	0.0077	0.0041	0.0021	0.0041	0.0021		
50 %		0.0105	0.0038	0.0020	0.0011	0.0020	0.0011		
75 %		0.0053	0.0019	0.0010	0.0005	0.0010	0.0005		
90 %		0.0021	0.0008	0.0004	0.0002	0.0004	0.0002		
RAC (µg/L) 0.0016		PEC / RAC ratio							
None	D3 Ditch	19.9	5.4	2.9	1.5	2.9	1.5		
50 %		9.9	2.7	1.4	0.750	1.4	0.750		
75 %		5.0	1.3	0.750	0.375	0.750	0.375		
90 %		2.0	0.563	0.313	0.125	0.313	0.125		
None	D4 Pond	0.688	0.563	0.438	0.313	0.438	0.313		
50 %		0.375	0.313	0.188	0.125	0.188	0.125		
75 %		0.188	0.125	0.125	0.063	0.125	0.063		
90 %		0.063	0.063	0.625	0.625	0.625	0.625		
None	D4 Stream	17.1	6.3	3.3	1.7	3.3	1.7		
50 %		8.6	3.1	1.7	0.875	1.7	0.875		
75 %		4.3	1.6	0.813	0.438	0.813	0.438		
90 %		1.7	0.625	0.313	0.188	0.313	0.188		
None	D5 Pond	0.688	0.563	0.438	0.313	0.438	0.313		
50 %		0.313	0.313	0.188	0.125	0.188	0.125		
75 %		0.188	0.125	0.125	0.063	0.125	0.063		

Intended use		spray application							
Active substance		deltamethrin							
Application rate (g/ha)		2 x 5.0 g/ha							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10 m	20 m		
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m		
90 %		0.063	0.625	0.625	0.625	0.625	0.625		
None	D5 Stream	18.5	6.8	3.6	1.9	3.6	1.9		
50 %		9.3	3.4	1.8	0.938	1.8	0.938		
75 %		4.6	1.7	0.875	0.500	0.875	0.500		
90 %		1.9	0.688	0.375	0.188	0.375	0.188		
None	R1 Pond	0.688	0.563	0.438	0.313	0.438	0.313		
50 %		0.313	0.313	0.188	0.125	0.188	0.125		
75 %		0.188	0.125	0.125	0.063	0.125	0.063		
90 %		0.063	0.063	0.625	0.625	0.625	0.625		
None	R1 Stream	13.1	4.8	2.6	1.3	2.6	1.3		
50 %		6.6	2.4	1.3	0.688	1.3	0.688		
75 %		3.3	1.2	0.625	0.313	0.625	0.313		
90 %		1.3	0.500	0.250	0.125	0.250	0.125		
RAC (µg/L)	0.023	PEC / RAC ratio							
None	D3 Ditch	1.38	0.3746	0.1995	0.1033	0.1995	0.1033		
50 %		0.6917	0.1880	0.0990	0.0517	0.0990	0.0517		
75 %		0.3459	0.0933	0.0502	0.0258	0.0502	0.0258		
90 %		0.1378	0.0373	0.0201	0.0100	0.0201	0.0100		
None	D4 Pond	0.0495	0.0424	0.0303	0.0200	0.0303	0.0200		
50 %		0.0248	0.0215	0.0149	0.0100	0.0149	0.0100		
75 %		0.0121	0.0105	0.0077	0.0050	0.0077	0.0050		
90 %		0.0050	0.0044	<0.0010	<0.0010	<0.0010	<0.0010		
None	D4 Stream	1.19	0.4361	0.2306	0.1194	0.2306	0.1194		
50 %		0.5961	0.2181	0.1153	0.0597	0.1153	0.0597		

Intended use		spray application							
Active substance		deltamethrin							
Application rate (g/ha)		2 x 5.0 g/ha							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10 m	20 m		
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m		
75 %	D5 Pond	0.2987	0.1083	0.0583	0.0306	0.0583	0.0306		
90 %		0.1194	0.0430	0.0236	0.0125	0.0236	0.0125		
None		0.0478	0.0413	0.0295	0.0200	0.0295	0.0200		
50 %		0.0239	0.0204	0.0148	0.0100	0.0148	0.0100		
75 %		0.0117	0.0104	0.0074	0.0048	0.0074	0.0048		
90 %		0.0048	<0.0010	<0.0010	<0.0010	<0.0010	<0.0010		
None	D5 Stream	1.29	0.4704	0.2487	0.1289	0.2487	0.1289		
50 %		0.6430	0.2353	0.1244	0.0644	0.1244	0.0644		
75 %		0.3222	0.1169	0.0630	0.0330	0.0630	0.0330		
90 %		0.1289	0.0464	0.0255	0.0135	0.0255	0.0135		
None		0.0493	0.0422	0.0302	0.0200	0.0301	0.0200		
50 %	R1 Pond	0.0248	0.0215	0.0150	0.0100	0.0148	0.0100		
75 %		0.0122	0.0106	0.0079	0.0051	0.0077	0.0050		
90 %		0.0051	0.0046	<0.0010	<0.0010	<0.0010	<0.0010		
None		0.9117	0.3337	0.1764	0.0914	0.1764	0.0914		
50 %		0.4557	0.1668	0.0882	0.0457	0.0882	0.0457		
75 %	R1 Stream	0.2284	0.0829	0.0446	0.0234	0.0446	0.0234		
90 %		0.0914	0.0330	0.0181	0.0096	0.0180	0.0096		

* Maximum values coming from multiple applications are marked in italics

° PEC_{sw} values including suspended solids are reported

PEC: predicted environmental concentration

RAC: regulatory acceptable concentration

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

Table 9.7.33: Aquatic organisms: PEC_{sw} calculation and acceptability of risk (PEC/RAC < 1) for flupyradifurone based on FOCUS Step 4 calculations and toxicity data for sediment dweller (worst case species) with mitigation of spray drift and run-off for the use of DLT + FPF EC 85 in OSR winter (use group E; modelling use PMT00)

Intended-use		spray application							
Active substance		flupyradifurone							
Application rate (g/ha)		2 x 37.5							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10-m	20-m		
	No spray buffer (m)	0-m	5-m	10-m	20-m	10-m	20-m		
None	D3-Ditch	0.2389	0.0648	0.0344	0.0179	0.0344	0.0179		
50-%		0.1195	0.0324	0.0172	0.0090	0.0172	0.0090		
75-%		0.0598	0.0162	0.0086	0.0045	0.0086	0.0045		
90-%		0.0239	0.0065	0.0035	0.0035	0.0035	0.0035		
None	D4-Pond	0.2725	0.2721	0.2713	0.2706	0.2713	0.2706		
50-%		0.2709	0.2707	0.2703	0.2699	0.2703	0.2699		
75-%		0.2701	0.2700	0.2698	0.2696	0.2698	0.2696		
90-%		0.2696	0.2695	0.2695	0.2694	0.2695	0.2694		
None	D4-Stream	0.3007	0.3007	0.3007	0.3007	0.3007	0.3007		
50-%		0.3007	0.3007	0.3007	0.3007	0.3007	0.3007		
75-%		0.3007	0.3007	0.3007	0.3007	0.3007	0.3007		
90-%		0.3007	0.3007	0.3007	0.3007	0.3007	0.3007		
None	D5-Pond	0.2508	0.2508	0.2508	0.2508	0.2508	0.2508		
50-%		0.2508	0.2508	0.2508	0.2508	0.2508	0.2508		
75-%		0.2508	0.2508	0.2508	0.2508	0.2508	0.2508		
90-%		0.2508	0.2508	0.2508	0.2508	0.2508	0.2508		
None	D5-Stream	0.14216	0.1425	0.1425	0.1425	0.1425	0.1425		
50-%		0.1425	0.1425	0.1425	0.1425	0.1425	0.1425		
75-%		0.1425	0.1425	0.1425	0.1425	0.1425	0.1425		
90-%		0.1425	0.1425	0.1425	0.1425	0.1425	0.1425		
None	R1-Pond	0.1492	0.1479	0.1454	0.1434	0.0631	0.0328		
50-%		0.1443	0.1437	0.1424	0.1414	0.0601	0.0307		

[illegible]

Intended-use Active substance Application rate (g/ha)		spray-application flupyradifurone 2 x 37.5							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10 m	20 m		
	No-spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m		
None	D5 Pond	<i>0.4065</i>	<i>0.4065</i>	<i>0.4065</i>	<i>0.4065</i>	<i>0.4065</i>	<i>0.4065</i>		
50 %		<i>0.4065</i>	<i>0.4065</i>	<i>0.4065</i>	<i>0.4065</i>	<i>0.4065</i>	<i>0.4065</i>		
75 %		<i>0.4065</i>	<i>0.4065</i>	<i>0.4065</i>	<i>0.4065</i>	<i>0.4065</i>	<i>0.4065</i>		
90 %		<i>0.4065</i>	<i>0.4065</i>	<i>0.4065</i>	<i>0.4065</i>	<i>0.4065</i>	<i>0.4065</i>		
None	D5 Stream	<i>0.3592</i>	<i>0.2310</i>	<i>0.2310</i>	<i>0.2310</i>	<i>0.2310</i>	<i>0.2310</i>		
50 %		<i>0.2310</i>	<i>0.2310</i>	<i>0.2310</i>	<i>0.2310</i>	<i>0.2310</i>	<i>0.2310</i>		
75 %		<i>0.2310</i>	<i>0.2310</i>	<i>0.2310</i>	<i>0.2310</i>	<i>0.2310</i>	<i>0.2310</i>		
90 %		<i>0.2310</i>	<i>0.2310</i>	<i>0.2310</i>	<i>0.2310</i>	<i>0.2310</i>	<i>0.2310</i>		
None	R1 Pond	<i>0.2418</i>	<i>0.2397</i>	<i>0.2357</i>	<i>0.2324</i>	<i>0.1023</i>	<i>0.0532</i>		
50 %		<i>0.2339</i>	<i>0.2329</i>	<i>0.2308</i>	<i>0.2292</i>	<i>0.0974</i>	<i>0.0498</i>		
75 %		<i>0.2300</i>	<i>0.2295</i>	<i>0.2285</i>	<i>0.2277</i>	<i>0.0950</i>	<i>0.0481</i>		
90 %		<i>0.2277</i>	<i>0.2274</i>	<i>0.2271</i>	<i>0.2267</i>	<i>0.0934</i>	<i>0.0472</i>		
None	R1 Stream	<i>1.3551</i>	<i>1.3551</i>	<i>1.3551</i>	<i>1.3551</i>	<i>0.6097</i>	<i>0.3182</i>		
50 %		<i>1.3551</i>	<i>1.3551</i>	<i>1.3551</i>	<i>1.3551</i>	<i>0.6097</i>	<i>0.3182</i>		
75 %		<i>1.3551</i>	<i>1.3551</i>	<i>1.3551</i>	<i>1.3551</i>	<i>0.6097</i>	<i>0.3182</i>		
90 %		<i>1.3551</i>	<i>1.3551</i>	<i>1.3551</i>	<i>1.3551</i>	<i>0.6097</i>	<i>0.3182</i>		
None	R3 Stream	<i>1.5872</i>	<i>1.5872</i>	<i>1.5872</i>	<i>1.5872</i>	<i>0.7198</i>	<i>0.3767</i>		
50 %		<i>1.5872</i>	<i>1.5872</i>	<i>1.5872</i>	<i>1.5872</i>	<i>0.7198</i>	<i>0.3767</i>		
75 %		<i>1.5872</i>	<i>1.5872</i>	<i>1.5872</i>	<i>1.5872</i>	<i>0.7198</i>	<i>0.3767</i>		
90 %		<i>1.5872</i>	<i>1.5872</i>	<i>1.5872</i>	<i>1.5872</i>	<i>0.7198</i>	<i>0.3767</i>		

* Maximum values coming from multiple applications are marked in italics

PEC: predicted environmental concentration

RAC: regulatory acceptable concentration

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

Table 9.7-33A: Aquatic organisms: PEC_{sw} calculation and acceptability of risk (PEC/RAC < 1) for flupyradifurone based on FOCUS Step 4 calculations and toxicity data for sediment dweller (worst case species) with mitigation of spray drift and run-off for the use of DLT + FPF EC 85 in OSR winter BBCH 65-79 (use group E; modelling use PMT01) the plant uptake factor for the parent flupyradifurone was set to 0

Intended use		spray application							
Active substance		flupyradifurone							
Application rate (g/ha)		2 x 37.5							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10 m	20 m		
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m		
None	D3 Ditch	0.2389	0.0648	0.0344	0.0179	0.0344	0.0179		
50 %		0.1195	0.0324	0.0172	0.0090	0.0172	0.0090		
75 %		0.0598	0.0162	0.0086	0.0045	0.0086	0.0045		
90 %		0.0239	0.0065	0.0039	0.0039	0.0039	0.0039		
None	D4 Pond	0.2854	0.2849	0.2841	0.2834	0.2841	0.2834		
50 %		0.2837	0.2835	0.2831	0.2827	0.2831	0.2827		
75 %		0.2829	0.2828	0.2826	0.2824	0.2826	0.2824		
90 %		0.2824	0.2824	0.2823	0.2822	0.2823	0.2822		
None	D4 Stream	0.3115	0.3115	0.3115	0.3115	0.3115	0.3115		
50 %		0.3115	0.3115	0.3115	0.3115	0.3115	0.3115		
75 %		0.3115	0.3115	0.3115	0.3115	0.3115	0.3115		
90 %		0.3115	0.3115	0.3115	0.3115	0.3115	0.3115		
None	D5 Pond	0.2542	0.2542	0.2542	0.2542	0.2542	0.2542		
50 %		0.2542	0.2542	0.2542	0.2542	0.2542	0.2542		
75 %		0.2542	0.2542	0.2542	0.2542	0.2542	0.2542		
90 %		0.2542	0.2542	0.2542	0.2542	0.2542	0.2542		
None	D5 Stream	0.2216	0.1440	0.1440	0.1440	0.1440	0.1440		
50 %		0.1440	0.1440	0.1440	0.1440	0.1440	0.1440		
75 %		0.1440	0.1440	0.1440	0.1440	0.1440	0.1440		
90 %		0.1440	0.1440	0.1440	0.1440	0.1440	0.1440		
None	R1 Pond	0.1505	0.1492	0.1468	0.1447	0.0637	0.0330		
50 %		0.1457	0.1450	0.1438	0.1428	0.0606	0.0310		

Intended use		spray application							
Active substance		flupyradifurone							
Application rate (g/ha)		2 x 37.5							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10 m	20 m		
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m		
None	D5 Pond	0.41	0.41	0.41	0.41	0.41	0.41		
50 %		0.41	0.41	0.41	0.41	0.41	0.41		
75 %		0.41	0.41	0.41	0.41	0.41	0.41		
90 %		0.41	0.41	0.41	0.41	0.41	0.41		
None	D5 Stream	0.36	0.23	0.23	0.23	0.23	0.23		
50 %		0.23	0.23	0.23	0.23	0.23	0.23		
75 %		0.23	0.23	0.23	0.23	0.23	0.23		
90 %		0.23	0.23	0.23	0.23	0.23	0.23		
None	R1 Pond	0.24	0.24	0.24	0.23	0.10	0.053		
50 %		0.24	0.24	0.23	0.23	0.098	0.050		
75 %		0.23	0.23	0.23	0.23	0.096	0.049		
90 %		0.23	0.23	0.23	0.23	0.094	0.048		
None	R1 Stream	1.4	1.4	1.4	1.4	0.61	0.32		
50 %		1.4	1.4	1.4	1.4	0.61	0.32		
75 %		1.4	1.4	1.4	1.4	0.61	0.32		
90 %		1.4	1.4	1.4	1.4	0.61	0.32		
None	R3 Stream	1.6	1.6	1.6	1.6	0.72	0.38		
50 %		1.6	1.6	1.6	1.6	0.72	0.38		
75 %		1.6	1.6	1.6	1.6	0.72	0.38		
90 %		1.6	1.6	1.6	1.6	0.72	0.38		

* Maximum values coming from multiple applications are marked in italics

PEC: predicted environmental concentration

RAC: regulatory acceptable concentration

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

Table 9.7.34: Aquatic organisms: PEC_{sw} calculation and acceptability of risk (PEC/RAC < 1) for flupyradifurone based on FOCUS Step 4 calculations and toxicity data for sediment dweller (worst case species) with mitigation of spray drift and run-off for the use of DLT + FPF EC 85 in OSR spring (use group E; modelling use PMT01)

Intended-use		spray application							
Active substance		flupyradifurone							
Application rate (g/ha)		2 x 37.5							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10-m	20-m		
	No spray buffer (m)	0-m	5-m	10-m	20-m	10-m	20-m		
None	D3-Ditch	0.2388	0.0649	0.0345	0.0180	0.0345	0.0180		
50-%		0.1195	0.0325	0.0174	0.0091	0.0174	0.0091		
75-%		0.0599	0.0164	0.0089	0.0054	0.0089	0.0054		
90-%		0.0241	0.0073	0.0052	0.0052	0.0052	0.0052		
None	D4-Pond	0.3273	0.3268	0.3261	0.3254	0.3261	0.3254		
50-%		0.3257	0.3255	0.3251	0.3248	0.3251	0.3248		
75-%		0.3250	0.3249	0.3247	0.3245	0.3247	0.3245		
90-%		0.3245	0.3245	0.3244	0.3243	0.3244	0.3243		
None	D4-Stream	0.3368	0.3368	0.3368	0.3368	0.3368	0.3368		
50-%		0.3368	0.3368	0.3368	0.3368	0.3368	0.3368		
75-%		0.3368	0.3368	0.3368	0.3368	0.3368	0.3368		
90-%		0.3368	0.3368	0.3368	0.3368	0.3368	0.3368		
None	D5-Pond	0.2077	0.2074	0.2068	0.2063	0.2068	0.2063		
50-%		0.2065	0.2064	0.2061	0.2058	0.2061	0.2058		
75-%		0.2059	0.2058	0.2057	0.2056	0.2057	0.2056		
90-%		0.2056	0.2055	0.2055	0.2054	0.2055	0.2054		
None	D5-Stream	0.2217	0.1410	0.1410	0.1410	0.1410	0.1410		
50-%		0.1410	0.1410	0.1410	0.1410	0.1410	0.1410		
75-%		0.1410	0.1410	0.1410	0.1410	0.1410	0.1410		
90-%		0.1410	0.1410	0.1410	0.1410	0.1410	0.1410		
None	R1-Pond	0.1296	0.1281	0.1253	0.1230	0.0549	0.0286		
50-%		0.1240	0.1233	0.1219	0.1207	0.0514	0.0264		

Intended use		spray-application							
Active substance		flupyradifurone							
Application rate (g/ha)		2 x 37.5							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10 m	20 m		
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m		
75 %		0.1213	0.1209	0.1202	0.1196	0.0497	0.0252		
90 %		0.1196	0.1194	0.1192	0.1189	0.0487	0.0245		
None	R1 Stream	1.0410	1.0410	1.0410	1.0410	0.4731	0.2477		
50 %		1.0410	1.0410	1.0410	1.0410	0.4731	0.2477		
75 %		1.0410	1.0410	1.0410	1.0410	0.4731	0.2477		
90 %		1.0410	1.0410	1.0410	1.0410	0.4731	0.2477		
RAC (µg/L) 0.617		PEC / RAC ratio							
None	D3 Ditch	0.3870	0.1052	0.0559	0.0292	0.0559	0.0292		
50 %		0.1937	0.0527	0.0282	0.0147	0.0282	0.0147		
75 %		0.0971	0.0266	0.0144	0.0088	0.0144	0.0088		
90 %		0.0391	0.0118	0.0084	0.0084	0.0084	0.0084		
None	D4 Pond	0.5305	0.5297	0.5285	0.5274	0.5285	0.5274		
50 %		0.5279	0.5276	0.5269	0.5264	0.5269	0.5264		
75 %		0.5267	0.5266	0.5263	0.5259	0.5263	0.5259		
90 %		0.5259	0.5259	0.5258	0.5256	0.5258	0.5256		
None	D4 Stream	0.5459	0.5459	0.5459	0.5459	0.5459	0.5459		
50 %		0.5459	0.5459	0.5459	0.5459	0.5459	0.5459		
75 %		0.5459	0.5459	0.5459	0.5459	0.5459	0.5459		
90 %		0.5459	0.5459	0.5459	0.5459	0.5459	0.5459		
None	D5 Pond	0.3366	0.3361	0.3352	0.3344	0.3352	0.3344		
50 %		0.3347	0.3345	0.3340	0.3335	0.3340	0.3335		
75 %		0.3337	0.3335	0.3334	0.3332	0.3334	0.3332		
90 %		0.3332	0.3331	0.3331	0.3329	0.3331	0.3329		
None	D5 Stream	0.3593	0.2285	0.2285	0.2285	0.2285	0.2285		

Intended-use		spray-application							
Active substance		flupyradifurone							
Application rate (g/ha)		2 x 37.5							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10-m	20-m		
	No-spray buffer (m)	0-m	5-m	10-m	20-m	10-m	20-m		
50-%		0.2285	0.2285	0.2285	0.2285	0.2285	0.2285		
75-%		0.2285	0.2285	0.2285	0.2285	0.2285	0.2285		
90-%		0.2285	0.2285	0.2285	0.2285	0.2285	0.2285		
None	R1-Pond	0.2100	0.2076	0.2031	0.1994	0.0890	0.0464		
50-%		0.2010	0.1998	0.1976	0.1956	0.0833	0.0428		
75-%		0.1966	0.1959	0.1948	0.1938	0.0806	0.0408		
90-%		0.1938	0.1935	0.1932	0.1927	0.0789	0.0397		
None	R1-Stream	1.6872	1.6872	1.6872	1.6872	0.7668	0.4015		
50-%		1.6872	1.6872	1.6872	1.6872	0.7668	0.4015		
75-%		1.6872	1.6872	1.6872	1.6872	0.7668	0.4015		
90-%		1.6872	1.6872	1.6872	1.6872	0.7668	0.4015		

* Maximum values coming from multiple applications are marked in italics

PEC: predicted environmental concentration

RAC: regulatory acceptable concentration

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

Table 9.7-34A: Aquatic organisms: PEC_{sw} calculation and acceptability of risk (PEC/RAC < 1) for flupyradifurone based on FOCUS Step 4 calculations and toxicity data for sediment dweller (worst case species) with mitigation of spray drift and run-off for the use of DLT + FPF EC 85 in OSR spring BBCH 65-79 (use group E; modelling use PMT02) the plant uptake factor for the parent flupyradifurone was set to 0

Intended use		spray application							
Active substance		flupyradifurone							
Application rate (g/ha)		2 x 37.5							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10 m	20 m		
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m		
None	D3 Ditch	0.2388	0.0649	0.0346	0.0181	0.0346	0.0181		
50 %		0.1195	0.0326	0.0174	0.0092	0.0174	0.0092		
75 %		0.0599	0.0164	0.0092	0.0059	0.0092	0.0059		
90 %		0.0241	0.0076	0.0059	0.0059	0.0059	0.0059		
None	D4 Pond	0.3426	0.3422	0.3414	0.3408	0.3414	0.3408		
50 %		0.3411	0.3409	0.3405	0.3402	0.3405	0.3402		
75 %		0.3403	0.3402	0.3400	0.3399	0.3400	0.3399		
90 %		0.3399	0.3398	0.3398	0.3397	0.3398	0.3397		
None	D4 Stream	0.3494	0.3494	0.3494	0.3494	0.3494	0.3494		
50 %		0.3494	0.3494	0.3494	0.3494	0.3494	0.3494		
75 %		0.3494	0.3494	0.3494	0.3494	0.3494	0.3494		
90 %		0.3494	0.3494	0.3494	0.3494	0.3494	0.3494		
None	D5 Pond	0.2123	0.2120	0.2114	0.2109	0.2114	0.2109		
50 %		0.2111	0.2110	0.2107	0.2104	0.2107	0.2104		
75 %		0.2105	0.2104	0.2103	0.2102	0.2103	0.2102		
90 %		0.2102	0.2101	0.2101	0.2100	0.2101	0.2100		
None	D5 Stream	0.2217	0.1439	0.1439	0.1439	0.1439	0.1439		
50 %		0.1439	0.1439	0.1439	0.1439	0.1439	0.1439		
75 %		0.1439	0.1439	0.1439	0.1439	0.1439	0.1439		
90 %		0.1439	0.1439	0.1439	0.1439	0.1439	0.1439		
None	R1 Pond	0.1302	0.1287	0.1259	0.1236	0.0552	0.0288		
50 %		0.1247	0.1239	0.1225	0.1214	0.0517	0.0265		

Intended use		spray application							
Active substance		flupyradifurone							
Application rate (g/ha)		2 x 37.5							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10 m	20 m		
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m		
75 %		0.1219	0.1215	0.1208	0.1202	0.0500	0.0254		
90 %		0.1202	0.1201	0.1198	0.1196	0.0489	0.0247		
None	R1 Stream	1.0480	1.0480	1.0480	1.0480	0.4761	0.2494		
50 %		1.0480	1.0480	1.0480	1.0480	0.4761	0.2494		
75 %		1.0480	1.0480	1.0480	1.0480	0.4761	0.2494		
90 %		1.0480	1.0480	1.0480	1.0480	0.4761	0.2494		
RAC (µg/L) 0.617		PEC / RAC ratio							
None	D3 Ditch	0.39	0.11	0.056	0.029	0.056	0.029		
50 %		0.19	0.053	0.028	0.015	0.028	0.015		
75 %		0.097	0.027	0.015	0.010	0.015	0.010		
90 %		0.039	0.012	0.010	0.010	0.010	0.010		
None	D4 Pond	0.56	0.55	0.55	0.55	0.55	0.55		
50 %		0.55	0.55	0.55	0.55	0.55	0.55		
75 %		0.55	0.55	0.55	0.55	0.55	0.55		
90 %		0.55	0.55	0.55	0.55	0.55	0.55		
None	D4 Stream	0.57	0.57	0.57	0.57	0.57	0.57		
50 %		0.57	0.57	0.57	0.57	0.57	0.57		
75 %		0.57	0.57	0.57	0.57	0.57	0.57		
90 %		0.57	0.57	0.57	0.57	0.57	0.57		
None	D5 Pond	0.34	0.34	0.34	0.34	0.34	0.34		
50 %		0.34	0.34	0.34	0.34	0.34	0.34		
75 %		0.34	0.34	0.34	0.34	0.34	0.34		
90 %		0.34	0.34	0.34	0.34	0.34	0.34		
None	D5 Stream	0.36	0.23	0.23	0.23	0.23	0.23		

Intended use		spray application							
Active substance		flupyradifurone							
Application rate (g/ha)		2 x 37.5							
Nozzle reduction	Vegetated strip (m)	None	None	None	None	10 m	20 m		
	No spray buffer (m)	0 m	5 m	10 m	20 m	10 m	20 m		
50 %		0.23	0.23	0.23	0.23	0.23	0.23		
75 %		0.23	0.23	0.23	0.23	0.23	0.23		
90 %		0.23	0.23	0.23	0.23	0.23	0.23		
None	R1 Pond	0.21	0.21	0.20	0.20	0.089	0.047		
50 %		0.20	0.20	0.20	0.20	0.084	0.043		
75 %		0.20	0.20	0.20	0.19	0.081	0.041		
90 %		0.19	0.19	0.19	0.19	0.079	0.040		
None	R1 Stream	1.7	1.7	1.7	1.7	0.77	0.40		
50 %		1.7	1.7	1.7	1.7	0.77	0.40		
75 %		1.7	1.7	1.7	1.7	0.77	0.40		
90 %		1.7	1.7	1.7	1.7	0.77	0.40		

* Maximum values coming from multiple applications are marked in italics

PEC: predicted environmental concentration

RAC: regulatory acceptable concentration

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

The use of the product is considered safe for all FOCUS scenarios that are relevant in the Central zone if mitigation measures listed in Table 9.7-48 are used.

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., 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 $\geq 90\%$ 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:

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

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:

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

At the first step, the following combined toxicity assessment was done for the use of the product in winter OSR (use group C) and covers the use in spring OSR (use group C) and use groups D and E.

Table 9.7-35: Combined toxicity assessment – aquatic organisms (use group C, winter OSR)

	Fish-acute	Fish prolonged	Invertebrate acute	Invertebrate prolonged	Sediment dweller prolonged	Algae
Use group C (winter OSR)						
RQ^{1,2}-values						
Deltamethrin	0.69 ⁻³ (27)	0.69 ⁻³ (<22)	0.6974 ⁻⁴ (12)	0.6974 ⁻⁴ (168)	0.6974 ⁻⁴ (69)	<0.001
Flupyradifurone	<0.002 ⁻⁵ (<0.008)	0.003 ⁻⁵ (0.012)	<0.002 ⁻⁵ <0.007	0.004 ⁻⁵ 0.017	0.8344 ⁻⁶ (7.9)	<0.001
Trigger	+	+	+	+	+	+
1/n	0.5	0.5	0.5	0.5	0.5	0.5
1 st step: All RQ < 1/n	No	No	No	No	No	Yes
2 nd step: Rpfmax	1.0 (DLT)	1.0 (DLT)	1.0 (DLT)	1.0 (DLT)	0.90 (DLT)	Not needed
3 rd step: RQ _{MIX}	Not needed	Not needed	Not needed	Not needed	1.5	Not needed

¹ RQ (risk quotient) = PEC/RAC, PEC was calculated according to FOCUS Step 2 if not otherwise stated

² Differing RQ values used for rpf calculations to fulfil the criterion of identical exposure levels are shown in brackets

³ PEC/RAC results from higher tier information: outdoor mesocosm study with *O. mykiss*

⁴ PEC/RAC results from worst case scenario R3 (stream) considering drift mitigation measures (5 m drift buffer covering also 75% drift reduction), refined RAC results from higher tier data (combination of higher tier studies, expert statements and ecological modeling)

⁵ PEC/RAC results from FOCUS Step 3 worst case scenario R1 (stream)

⁶ Refined maximum PEC/RAC calculated for sediment dweller acute as risk envelope, D4 (pond) as worst case FOCUS scenario, 20 m VFS buffer as mitigation measure

As the RQ_{MIX} for sediment dweller exceeds the trigger, a scenario specific combined risk assessment is conducted based on FOCUS Step 3 calculations for use groups C, D and E separately considering spring and winter OSR:

Table 9.7-36: Scenario specific combined toxicity assessment – sediment dweller prolonged (use group C, winter OSR)

-	RQ values (Tier 1)		1 st step: All RQ < 1/n	2 nd step: Rp _f max	3 rd step: RQ _{MIX}
FOCUS scenario (step 3)	Deltamethrin	Flupyradifurone			
Sediment dweller prolonged					
D3 ditch	47	0.53	no	0.99	Not needed
D4 pond	2.0	0.76	no	0.73	2.76
D4 stream	38	0.71	no	0.98	Not needed
D5 pond	2.0	0.46	no	0.81	2.46
D5 stream	38	0.50	no	0.99	Not needed
R1 pond	2.0	0.14	no	0.93	Not needed
R1 stream	31	2.1	no	0.94	Not needed
R3 stream	44	1.6	no	0.96	Not needed

Table 9.7-37: Scenario specific combined toxicity assessment – sediment dweller prolonged (use group C, spring OSR)

Group C, Spring 05K7					
-	RQ values (Tier 1)		1 st step: All RQ < 1/n	2 nd step: Rpfmax	3 rd step: RQ _{MIX}
FOCUS scenario (step 3)	Deltamethrin	Flupyradifurone			
Sediment dweller prolonged					

D3-ditch	48	0.53	no		Not-needed
D4-pond	2.0	0.68	no	0.75	2.68
D4-stream	39	0.67	no	0.98	Not-needed
D5-pond	2.0	0.49	no	0.80	2.49
D5-stream	41	0.50	no	0.99	Not-needed
R1-pond	2.0	0.18	no	0.92	Not-needed
R1-stream	31	1.5	no	0.95	Not-needed

The combined toxicity assessment results in acceptable risk for most FOCUS scenarios, refinement for the scenarios not passing the risk assessment is presented below considering the individual active substance risk assessments (including risk mitigation) and the worst case organism (sediment dwellers prolonged).

Table 9.7-38: Scenario specific refined combined toxicity assessment – sediment dweller prolonged (use group C, winter OSR)

(use group C, winter 05x7)			
-	RQ-values		Refined-RQ _{MIX}
FOCUS scenario	Deltamethrin	Flupyradifurone	
Sediment dweller-prolonged			
D4-pond	0.072	0.76	0.83
D5-pond	0.071	0.46	0.53

Table 9.7-39: Scenario specific refined combined toxicity assessment – sediment dweller prolonged (use group C, spring OSR)

(a) group C, spring 2017			
-	RQ-values		Refined-RQ _{MIX}
FOCUS-scenario	Deltamethrin	Flupyradifurone	
Sediment dweller-prolonged			
D4-pond	0.071	0.68	0.75
D5-pond	0.072	0.49	0.56
R1-pond	0.071	0.18	0.25

Table 9.7-40: Scenario specific combined toxicity assessment – sediment dweller prolonged (use group D, winter OSR)

Group D: winter (53K)					
-	RQ-values (Tier 1)		1 st step: All RQ < 1/n	2 nd step: Rpfmax	3 rd step: RQ _{MIX}
FOCUS scenario (step 3)	Deltamethrin	Flupyradifurone			
Sediment dweller prolonged					
D3-ditch	48	0.53	no	0.99	Not-needed
D4-pond	2.0	0.55	no	0.78	2.55
D4-stream	37	0.54	no	0.99	Not-needed
D5-pond	2.0	0.44	no	0.82	2.44
D5-stream	39	0.49	no	0.99	Not-needed
R1-pond	2.0	0.27	no	0.88	2.27
R1-stream	31	1.7	no	0.95	Not-needed
R3-stream	44	3.1	no	0.93	Not-needed

Table 9.7-41: Scenario specific combined toxicity assessment – sediment dweller prolonged (use group D, spring OSR)

Group D: Spring 03/17					
-	RQ values (Tier 1)		1 st step: All RQ < 1/n	2 nd step: Rpfmax	3 rd step: RQ _{MIX}
FOCUS scenario (step 3)	Deltamethrin	Flupyradifurone			
Sediment dweller prolonged					
D3-ditch	48	0.53	no	0.99	Not-needed
D4-pond	2.0	0.69	no	0.74	2.69
D4-stream	41	0.71	no	0.98	Not-needed
D5-pond	2.0	0.50	no	0.80	2.50
D5-stream	42	0.56	no	0.99	Not-needed
R1-pond	2.0	0.15	no	0.93	Not-needed
R1-stream	31	1.6	no	0.95	Not-needed

The combined toxicity assessment results in acceptable risk for most FOCUS scenarios, refinement for the scenarios not passing the risk assessment is presented below considering the individual active substance risk assessments (including risk mitigation) and the worst case organism (sediment dwellers prolonged).

Table 9.7-42: Scenario specific refined combined toxicity assessment – sediment dweller prolonged (use group D, winter OSR)

(use group D; winter 05K)			
-	RQ values		Refined RQ _{MIX}
FOCUS scenario	Deltamethrin	Flupyradifurone	
Sediment dweller-prolonged			
D4-pond	0.071	0.55	0.62
D5-pond	0.074	0.44	0.51
R1-pond	0.071	0.27	0.34

Table 9.7-43: Scenario specific refined combined toxicity assessment – sediment dweller prolonged (use group D, spring OSR)

(Use Group D; Spring 2017)			
-	RQ values		Refined RQ _{MIX}
FOCUS scenario	Deltamethrin	Flupyradifurone	
Sediment dweller-prolonged			
D4-pond	0.074	0.69	0.76
D5-pond	0.073	0.50	0.57

Table 9.7-44: Scenario specific combined toxicity assessment – sediment dweller prolonged (use group E, winter OSR)

-	RQ values (Tier 1)		1 st step: All RQ < 1/n	2 nd step: Rpfmax	3 rd step: RQ _{MIX}
FOCUS scenario (step 3)	Deltamethrin	Flupyradifurone			
Sediment dweller prolonged					
D3-ditch	32	0.35	no	0.99	Not-needed
D4-pond	1.0	0.40	no	0.71	1.4
D4-stream	27	0.44	no	0.98	Not-needed
D5-pond	1.0	0.37	no	0.73	1.4
D5-stream	30	0.33	no	0.99	Not-needed
R1-pond	1.0	0.22	no	0.82	1.2
R1-stream	21	1.2	no	0.94	Not-needed
R3-stream	29	1.4	no	0.95	Not-needed

Table 9.7-45: Scenario specific combined toxicity assessment – sediment dweller prolonged (use group E, spring OSR)

-	RQ-values (Tier 1)		1 st -step: All RQ < 1/n	2 nd -step: Rpfmax	3 rd -step: RQ _{MIX}
FOCUS-scenario (step 3)	Deltamethrin	Flupyradifurone			
Sediment dweller prolonged					
D3-ditch	32	0.35	no	0.99	Not-needed
D4-pond	1.0	0.48	no	0.68	1.5
D4-stream	27	0.49	no	0.98	Not-needed
D5-pond	1.0	0.30	no	0.77	1.3
D5-stream	30	0.33	no	0.99	Not-needed
R1-pond	1.0	0.19	no	0.84	1.2
R1-stream	21	1.5	no	0.93	Not-needed

The combined toxicity assessment results in acceptable risk for most FOCUS scenarios, refinement for the scenarios not passing the risk assessment is presented below considering the individual active substance risk assessments (including risk mitigation) and the worst case organism (sediment dwellers prolonged).

Table 9.7-46: Scenario specific refined combined toxicity assessment – sediment dweller prolonged (use group E, winter OSR)

(a) group 1, winter 05K			
-	RQ values		Refined-RQ _{MIX}
FOCUS scenario	Deltamethrin	Flupyradifurone	
Sediment dweller-prolonged			
D4-pond	0.050	0.40	0.45
D5-pond	0.050	0.37	0.42
R1-pond	0.048	0.22	0.27

Table 9.7-47: Scenario specific refined combined toxicity assessment – sediment dweller prolonged (use group E, spring OSR)

(USE GROUP 2; SPIN ₁₀ GDR)			
-	RQ values		Refined RQ _{MIX}
FOCUS scenario	Deltamethrin	Flupyradifurone	
Sediment dweller prolonged			
D4-pond	0.050	0.48	0.53
D5-pond	0.048	0.30	0.35
R1-pond	0.049	0.19	0.24

Additional risk mitigation measures due to the combined toxicity assessment are not needed.

Assessment of combined toxicity using a plant uptake factor of 0 as requested by zRMS Poland

Table 9.7-47A: Combined toxicity assessment – aquatic organisms (use group C, winter OSR)

	Fish-acute	Fish prolonged	Invertebrate acute	Invertebrate prolonged	Sediment dweller prolonged	Algae
Use group C (winter OSR)						
RQ^{1,2} values						
Deltamethrin	0.69 ³ (27)	0.69 ³ (<22)	0.6974 ⁴ (12)	0.6974 ⁴ (168)	0.6974 ⁴ (69)	<0.001
Flupyradifurone	<0.002 ⁵ (<0.008)	0.003 ⁵ (0.012)	<0.002 ⁵ <0.007	0.005 ⁵ 0.017	0.96 ⁶ (7.9)	<0.001
Trigger	+	+	+	+	+	+
1/n	0.5	0.5	0.5	0.5	0.5	0.5
1 st step: All RQ < 1/n	No	No	No	No	No	Yes
2 nd step: Rpfmax	1.0 (DLT)	1.0 (DLT)	1.0 (DLT)	1.0 (DLT)	0.90 (DLT)	Not needed
3 rd step: RQ _{MIX}	Not needed	Not needed	Not needed	Not needed	1.6574	Not needed

¹ RQ (risk quotient) = PEC/RAC, PEC was calculated according to FOCUS Step 2 if not otherwise stated

² Differing RQ values used for rpf calculations to fulfil the criterion of identical exposure levels are shown in brackets

³ PEC/RAC results from higher tier information: outdoor mesocosm study with *O. mykiss*

⁴ PEC/RAC results from worst case scenario R3 (stream) considering drift mitigation measures (5 m drift buffer covering also 75% drift reduction), refined RAC results from higher tier data (combination of higher tier studies, expert statements and ecological modeling)

⁵ PEC/RAC results from FOCUS Step 3 worst case scenario R1 (stream)

⁶ Refined maximum PEC/RAC calculated for sediment dweller acute as risk envelope, D4 (pond) as worst case FOCUS scenario, 20 m VFS buffer as mitigation measure

As the RQ_{MIX} for sediment dweller exceeds the trigger, a scenario specific combined risk assessment is conducted based on FOCUS Step 3 calculations for use groups C, D and E separately considering spring and winter OSR.

Table 9.7-47B: Scenario specific combined toxicity assessment – sediment dweller prolonged (use group C, winter OSR)

-	RQ-values (Tier 1)		1 st step: All RQ < 1/n	2 nd step: Rpfmax	3 rd step: RQ _{MIX}
FOCUS scenario (step 3)	Deltamethrin	Flupyradifurone			
Sediment dweller prolonged					
D3 ditch	47	0.53	no	0.99	Not needed
D4 pond	2.0	0.87	no	0.70	2.87
D4 stream	38	0.79	no	0.98	Not needed
D5 pond	2.0	0.50	no	0.80	2.50
D5 stream	38	0.51	no	0.99	Not needed
R1 pond	2.0	0.15	no	0.93	Not needed
R1 stream	31	2.1	no	0.94	Not needed
R3 stream	44	1.6	no	0.96	Not needed

Table 9.7-47C: Scenario specific combined toxicity assessment – sediment dweller prolonged (use group C, spring OSR)

Group C: Spring 05/17					
-	RQ values (Tier 1)		1 st step: All RQ < 1/n	2 nd step: Rpfmax	3 rd step: RQ _{MIX}
FOCUS scenario (step 3)	Deltamethrin	Flupyradifurone			
Sediment dweller prolonged					
D3-ditch	48	0.53	no	0.99	Not needed
D4-pond	2.0	0.73	no	0.73	2.73
D4-stream	39	0.71	no	0.98	Not needed
D5-pond	2.0	0.52	no	0.79	2.5
D5-stream	41	0.50	no	0.99	Not needed
R1-pond	2.0	0.19	no	0.91	Not needed
R1-stream	31	1.5	no	0.95	Not needed

The combined toxicity assessment results in acceptable risk for most FOCUS scenarios, refinement for the scenarios not passing the risk assessment is presented below considering the individual active substance risk assessments (including risk mitigation) and the worst case organism (sediment dwellers prolonged).

Table 9.7-47D: Scenario specific refined combined toxicity assessment – sediment dweller prolonged (use group C, winter OSR)

(use group C, winter 05K)			
-	RQ values		Refined RQ _{MIX}
FOCUS scenario	Deltamethrin	Flupyradifurone	
Sediment dweller prolonged			
D4-pond	0.072	0.87	0.94
D5-pond	0.071	0.50	0.57

Table 9.7-47E: Scenario specific refined combined toxicity assessment – sediment dweller prolonged (use group C, spring OSR)

(use group C, spring only)			
-	RQ-values		Refined RQ _{MIX}
FOCUS scenario	Deltamethrin	Flupyradifurone	
Sediment dweller prolonged			
D4-pond	0.071	0.73	0.8
D5-pond	0.072	0.52	0.6
R1-pond	0.071	0.19	0.3

Table 9.7-47F: Scenario specific combined toxicity assessment – sediment dweller prolonged (use group D, winter OSR)

-	RQ values (Tier 1)		1 st step: All RQ < 1/n	2 nd step: Rpfmax	3 rd step: RQ _{MIX}
FOCUS scenario (step 3)	Deltamethrin	Flupyradifurone			
Sediment dweller prolonged					
D3 ditch	48	0.53	no	0.99	Not needed
D4 pond	2.0	0.62	no	0.76	2.6
D4 stream	37	0.59	no	0.98	Not needed
D5 pond	2.0	0.46	no	0.81	2.5
D5 stream	39	0.49	no	0.99	Not needed
R1 pond	2.0	0.27	no	0.88	2.3
R1 stream	31	1.7	no	0.95	Not needed
R3 stream	44	3.1	no	0.93	Not needed

Table 9.7-47G: Scenario specific combined toxicity assessment – sediment dweller prolonged (use group D, spring OSR)

Group D: Spring 2017					
-	RQ-values (Tier 1)		1 st -step: All RQ < 1/n	2 nd -step: Rpfmax	3 rd -step: RQ _{MIX}
FOCUS scenario (step 3)	Deltamethrin	Flupyradifurone			
Sediment dweller prolonged					
D3 ditch	48	0.53	no	0.99	Not-needed
D4 pond	2.0	0.72	no	0.74	2.7
D4 stream	41	0.74	no	0.98	Not-needed
D5 pond	2.0	0.52	no	0.79	2.50
D5 stream	42	0.56	no	0.99	Not-needed
R1 pond	2.0	0.15	no	0.93	Not-needed
R1 stream	31	1.6	no	0.95	Not-needed

The combined toxicity assessment results in acceptable risk for most FOCUS scenarios, refinement for the scenarios not passing the risk assessment is presented below considering the individual active substance risk assessments (including risk mitigation) and the worst case organism (sediment dwellers prolonged).

Table 9.7-47H: Scenario specific refined combined toxicity assessment – sediment dweller prolonged (use group D, winter OSR)

(use group D; winner OSR)			
-	RQ values		Refined RQ _{MIX}
FOCUS scenario	Deltamethrin	Flupyradifurone	
Sediment dweller prolonged			
D4 pond	0.071	0.62	0.7
D5 pond	0.07	0.46	0.5
R1 pond	0.071	0.27	0.3

Table 9.7-47I: Scenario specific refined combined toxicity assessment – sediment dweller prolonged (use group D, spring OSR)

(use group D, spring 2007)			
-	RQ values		Refined RQ _{MIX}
FOCUS scenario	Deltamethrin	Flupyradifurone	
Sediment dweller-prolonged			
D4-pond	0.074	0.72	0.8
D5-pond	0.073	0.52	0.6

Table 9.7-47J: Scenario specific combined toxicity assessment – sediment dweller prolonged (use group E, winter OSR)

-	RQ values (Tier 1)		1 st step: All RQ < 1/n	2 nd step: Rpfmax	3 rd step: RQ _{MIX}
FOCUS scenario (step 3)	Deltamethrin	Flupyradifurone			
Sediment dweller prolonged					
D3 ditch	32	0.35	no	0.99	Not needed
D4 pond	1.0	0.42	no	0.70	1.4
D4 stream	27	0.46	no	0.98	Not needed
D5 pond	1.0	0.37	no	0.73	1.4
D5 stream	30	0.33	no	0.99	Not needed
R1 pond	1.0	0.22	no	0.82	1.2
R1 stream	21	1.2	no	0.95	Not needed
R3 stream	29	1.4	no	0.95	Not needed

Table 9.7-47K: Scenario specific combined toxicity assessment – sediment dweller prolonged (use group E, spring OSR)

Group 1; spring 2017					
-	RQ-values (Tier 1)		1 st -step: All RQ < 1/n	2 nd -step: Rpfmax	3 rd -step: RQ _{MIX}
FOCUS scenario (step 3)	Deltamethrin	Flupyradifurone			
Sediment dweller prolonged					
D3 ditch	32	0.35	no	0.99	Not-needed
D4 pond	1.0	0.50	no	0.67	1.5
D4 stream	27	0.51	no	0.98	Not-needed
D5 pond	1.0	0.31	no	0.76	1.3
D5 stream	30	0.33	no	0.99	Not-needed
R1 pond	1.0	0.19	no	0.84	1.2
R1 stream	21	1.5	no	0.93	Not-needed

The combined toxicity assessment results in acceptable risk for most FOCUS scenarios, refinement for the scenarios not passing the risk assessment is presented below considering the individual active substance risk assessments (including risk mitigation) and the worst case organism (sediment dwellers prolonged).

Table 9.7-47L: ~~Scenario specific refined combined toxicity assessment – sediment dweller prolonged (use group E, winter OSR)~~

(use group 1, winter case)			
-	RQ-values		Refined RQ _{MIX}
FOCUS scenario	Deltamethrin	Flupyradifurone	
Sediment dweller-prolonged			
D4-pond	0.050	0.42	0.5
D5-pond	0.050	0.37	0.4
R1-pond	0.048	0.22	0.3

Table 9.7-47M: ~~Scenario specific refined combined toxicity assessment – sediment dweller prolonged (use group E, spring OSR)~~

(use group 2, spring 2007)			
-	RQ-values		Refined RQ _{MIX}
FOCUS scenario	Deltamethrin	Flupyradifurone	
Sediment dweller prolonged			
D4-pond	0.050	0.50	0.6
D5-pond	0.048	0.31	0.4
R1-pond	0.049	0.19	0.2

~~Additional risk mitigation measures due to the combined toxicity assessment are not needed.~~

zRMS comments:

Deltamethrin

The risk assessment for aquatic organisms from deltamethrin was partially agreed by the zRMS.

The endpoint of 23 ng a.s./L proposed by the Applicant for aquatic invertebrates was not accepted by the zRMS and it was concluded that EAC of 3.2 ng a.s./L with an AF of 2 should have been used. For rationale of the taken decision, please refer to the commenting box in point 9.5.1 9.6.1 and in Appendix 2 under KCP 10.2.2/01. The Applicant is thus requested to provide respective risk assessment for deltamethrin based on the agreed endpoint. As Poland is the only cMS for DLT+FPF EC 85, the risk assessment may be performed only for scenarios relevant for Poland (i.e, D3, D4 and R1).

During the commenting period the risk assessment for deltamethrin based on Step 4 PEC_{SW} and RAC of 0.0016 µg a.s./L (EAC of 0.0032 µg a.s./L with AF of 2) has been provided by the Applicant. However, the submitted calculations could not be reproduced and for this reason PEC/RAC recalculated by the zRMS are presented in Tables 9.5-23, 9.5-24, 9.5-27, 9.5-28, 9.5-31 and 9.5-32 above. The risk mitigation measures identified on the basis of this evaluation are summarised in the zRMS commenting box in point 9.5.3 below.

As indicated in the zRMS comments in point 9.5.1 9.6.1, in line with conclusions taken during the ongoing EU renewal process, no exact endpoint could be derived from the microcosm study with fish due to the exposure regime. However, available data indicate that the risk assessment for aquatic invertebrates performed with consideration of the agreed EU endpoint of 3.2 ng a.s./L with AF of 2 will cover the risk to fish and no further assessment in this area is required.

Risk assessment for other aquatic species from deltamethrin as well as risk assessment for metabolite Br₂CA is agreed by the zRMS

Flupyradifurone

The risk assessment for flupyradifurone based on exposure calculated with consideration of TSCF of 0 is agreed by the zRMS. Acceptable risk may be concluded provided that respective risk mitigation measures are respected.

The risk assessment for flupyradifurone metabolites is also agreed. Acceptable risk could be concluded with no need for risk mitigation measures.

Combined risk assessment

The combined risk assessment does not seem to follow recommendations of the EFSA (2013) guidance. First of all, the tox per fraction was calculated based on the PEC/RAC ratios, while in line with EFSA (2013) the toxicity data and fractions of particular active compounds in the mixture should be considered. However, Toxic Units were not calculated by the Applicant. Furthermore, the endpoints to be used in the combined risk assessment should be determined based on calculation of MDR values, however - as indicated by the zRMS in point 9.5.1 ~~9.6.1~~ this was not correctly done by the Applicant. In addition to that, in case measured toxicity data are used, it has to be checked if the mixture composition giving the measured toxicity is similar to the mixture composition at the PEC_{mix} in terms of the relative proportions of individual active substances.

It is also noted that no additional explanations of the values considered in the combined risk assessment may be found in the position paper by Gladbach et al. (2017, M-571377-02-1) which makes validation of the performed calculations nearly impossible.

Taking this into account, the Applicant is kindly requested to provide the combined risk assessment performed fully in line with EFSA (2013). Please note that endpoints as agreed by the zRMS should be used in calculations.

During the commenting period additional studies on acute toxicity of DLT+FPF EC 85 to fish, *Daphnia magna* and *Chironomus riparius* were submitted by the Applicant. For endpoints and additional information on the studies, please refer to the commenting box under Table 9.5-3 in point 9.5.1 of this document.

In addition to the new toxicity studies, also TU values were calculated by the Applicant and demonstrated that deltamethrin contributes to >90% of the acute and chronic toxicity of the mixture to fish, aquatic invertebrates and sediment dwellers. Taking this into account, in line with indications of EFSA aquatic guidance (2013) no specific risk assessment for the mixture is deemed necessary and the risk to these groups of species is sufficiently addressed by calculations performed for individual active compounds. For details of the combined toxicity assessment, please refer to zRMS commenting boxes in point 9.5.1 above.

Since none of the active substances contributes at >90% to toxicity of the mixture to algae and for this reason separate risk assessment is required and is performed below. In absence of the valid toxicity data for the formulated product, the endpoint estimated using CA model was considered in evaluation. Based on individual E_rC₅₀ values of >9100 and 80000 µg a.s./L and fraction in the mixture of 0.12 and 0.88 for deltamethrin and flupyradifurone, respectively, the surrogate E_rC₅₀ value of 41344.84 µg/L was calculated and is used in the risk assessment below. The PEC_{SW,MIX} was calculated using the maximum Step 1 PEC_{SW} values for particular compounds, covering all intended uses of DLT+FPF EC 85.

Species	Step 1 max PEC _{SW} [µg a.s./L]	Step 1 max PEC _{SW,MIX} [µg sum of a.s./L]	Estimated E _r C ₅₀ [µg a.s./L]	AF	RAC	PEC/RAC	Trigger
Algae	DLT: 0.1383 FPF: 34.185	34.323	41344.84	10	4134.5	0.008	1

The PEC/RAC calculated with consideration of surrogate E_rC₅₀ and Step 1 PEC_{SW,MIX} is far below the trigger of 1 indicating acceptable risk to algae exposed to the mixture of deltamethrin and flupyradifurone when DLT+FPF EC 85 is applied in line with the Central Zone GAP.

9.7.3 Overall conclusions

zRMS comments:

As the risk assessment performed for DLT+FPF EC 85 was not entirely accepted and further calculations are deemed necessary, no final conclusion at this stage is possible.

The Applicant is kindly requested to provide following calculations during the commenting period:

- Risk assessment for aquatic invertebrates from deltamethrin based on the EAC of 3.2 ng a.s./L with an AF of 2.
- Combined risk assessment performed fully in line with EFSA (2013) on the basis of endpoints agreed by the zRMS.
- Additional explanations to justify selection of the substance for chemical verification in the studies performed with DLT+FPF EC 85 or data to confirm that deltamethrin was most stable during the study.

Respective data and calculations based on the listed above assumptions were provided by the Applicant during the commenting period. On the basis of the risk assessment provided in the initial dRR and additional evaluation performed following the commenting period acceptable risk to aquatic species may be concluded provided that respective risk mitigation measures are respected. Summary if risk mitigation measures for deltamethrin and flupyradifurone identified in respective surface water scenarios depending on the use pattern is presented in table below.

Use group	Intended uses	RMM relevant for winter OSR uses		RMM relevant for spring OSR uses	
		DLT	FPF	DLT	FPF
C	Winter and spring OSR (spring application) 2 × 0.75 L/ha, 14 d interval BBCH 30-49	D3 5 m + 90% DRN; 20 m + 75% DRN	D3 None	D3 5 m + 90% DRN; 20 m + 75% DRN	D3 None
		D4 5 m + 90% DRN; 20 m + 75% DRN	D4 None	D4 5 m + 90% DRN; 20 m + 75% DRN	D4 None
		D5 5 m + 90% DRN; 20 m + 75% DRN	D5 None	D5 5 m + 90% DRN; 20 m + 75% DRN	D5 None
		R1 5 m + 90% DRN; 10 m + 75% DRN	R1 20 m VFS	R1 5 m + 90% DRN; 10 m + 75% DRN	R1 10 m VFS
		R3 10 m + 90% DRN; 20 m + 75% DRN	R3 10 m VFS		
D	Winter and spring OSR (spring /summer application) 2 × 0.75 L/ha, 14 d interval BBCH 50-59	D3 5 m + 90% DRN; 20 m + 75% DRN	D3 None	D3 5 m + 90% DRN; 20 m + 75% DRN	D3 None
		D4 5 m + 90% DRN; 20 m + 75% DRN	D4 None	D4 5 m + 90% DRN; 20 m + 75% DRN	D4 None
		D5 5 m + 90% DRN; 20 m + 75% DRN	D5 None	D5 5 m + 90% DRN; 20 m + 75% DRN	D5 None
		R1 5 m + 90% DRN; 10 m + 75% DRN	R1 10 m VFS	R1 5 m + 90% DRN; 10 m + 75% DRN	R1 10 m VFS
		R3 10 m + 90% DRN; 20 m + 75% DRN	R3 20 m VFS		
E	Winter and spring OSR (spring/summer application) 2 × 0.5 L/ha, 14 d interval BBCH 65-79	D3 5 m + 90% DRN; 10 m + 75% DRN; 20 m + 50% DRN	D3 None	D3 5 m + 90% DRN; 10 m + 75% DRN; 20 m + 50% DRN	D3 None
		D4 5 m + 90% DRN; 10 m + 75% DRN; 20 m + 50% DRN	D4 None	D4 5 m + 90% DRN; 10 m + 75% DRN; 20 m + 50% DRN	D4 None
		D5 5 m + 90% DRN; 10 m + 75% DRN; 20 m + 50% DRN	D5 None	D5 5 m + 90% DRN; 10 m + 75% DRN; 20 m + 50% DRN	D5 None

		R1 5 m + 90% DRN; 10 m + 75% DRN; 20 m + 50% DRN R3 5 m + 90% DRN; 10 m + 75% DRN; 20 m + 50% DRN	R1 10 m VFS R3 10 m VFS	R1 5 m + 90% DRN; 10 m + 75% DRN; 20 m + 50% DRN	R1 10 m VFS
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From the above table the concerned Member States should select risk mitigation measures applicable in their countries.

Additional calculations may be required by cMS that do not accept surface water exposure derived using FOCUS models.

The following text is added due to agreements during the Central Zone harmonisation meetings. It should be noted that this text has no impact on the outcome of zonal evaluation of formulation GLOB1809H, which was performed in line with the EU agreed methodology.

“The endpoint E_rC_{50} is selected in this Core Assessment but there are some uncertainties regarding the level of protection reached for primary producers. This is indicated for macrophytes in the aquatic Guidance Document (EFSA Journal 2013;11(7):3290) that recommends: “... a proper calibration between different tiers (higher and lower tier data) for macrophytes should be performed in the future”. Such calibration should be extended to algae. Until available relevant information on the level of protection reached is considered at EU level, it is recommended to address this uncertainty at each Member State level in the National Addendum if considered necessary, although it would be highly appreciated to have a harmonised approach in the Central zone.”

The refined risk assessments for the active substances considering the higher tier studies for deltamethrin and FOCUS Step 4 PEC_{sw} values including risk mitigation measures indicate an acceptable risk for the use of the product according to the GAP and the mitigation measures summarised below. Scenario specific risk mitigation measures may be applicable in different countries. For metabolites of both active substances an acceptable risk was concluded considering exposure using FOCUS Step 2.

Table 9.7-48: Overview of the mitigation measurements for the relevant FOCUS scenarios

Group	Mitigation	Scenario
OSR (winter) (use group C) 2 × 0.75 L/ha, 14 d interval, BBCH 30-49	no spray buffer zone of 5 m or 75% DRN	D3
	no spray buffer zone of 5 m or 50% DRN	D4, D5
	vegetated filter strip of 20 m	R1
	vegetated filter strip of 10 m	R3
Conclusion on mitigation	20m vegetated filter strip (incorporating spray buffer)	All scenarios
OSR (spring) (use group C) 2 × 0.75 L/ha, 14 d interval, BBCH 30-49	no spray buffer zone of 5 m or 75% DRN	D3
	no spray buffer zone of 5 m or 50% DRN	D4, D5
	vegetated filter strip of 10 m	R1
Conclusion on mitigation	40m vegetated filter strip (incorporating spray buffer)	All scenarios
OSR (winter) (use group D) 2 × 0.75 L/ha, 14 d interval, BBCH 50-59	no spray buffer zone of 5 m or 75% DRN	D3
	no spray buffer zone of 5 m or 50% DRN	D4, D5
	vegetated filter strip of 10 m	R1
	vegetated filter strip of 20 m	R3
Conclusion on mitigation	20m vegetated filter strip (incorporating spray buffer)	All scenarios
OSR (spring) (use group D) 2 × 0.75 L/ha, 14 d interval, BBCH 50-59	no spray buffer zone of 5 m or 75% DRN	D3
	no spray buffer zone of 5 m or 50% DRN	D4, D5
	vegetated filter strip of 10 m	R1
Conclusion on mitigation	10m vegetated filter strip (incorporating spray buffer)	All scenarios

Group	Mitigation	Scenario
OSR (winter) (use group E) 2 × 0.5 L/ha, 14 d interval, BBCH 65–79	no spray buffer zone of 5 m or 50% DRN	D3, D4, D5
	vegetated filter strip of 10 m	R1, R3
	Conclusion on mitigation	10m vegetated filter strip (incorporating spray buffer)
OSR (spring) (use group E) 2 × 0.5 L/ha, 14 d interval, BBCH 65–79	no spray buffer zone of 5 m or 50% DRN	D3, D4, D5
	vegetated filter strip of 10 m	R1
	Conclusion on mitigation	10m vegetated filter strip (incorporating spray buffer)

9.8 Effects on bees (KCP 10.3.1)

9.8.1 Toxicity data

Studies on the toxicity to bees have been carried out with deltamethrin and flupyradifurone. 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).

Effects on bees of DLT+FPF EC 85 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. Findings from laboratory studies conducted with the individual active substances compared to DLT+FPF EC 85 indicated the formulation was not more toxic. In chronic feeding tests on adult bees neither active substance was shown to be more chronically than acutely toxic.

The selection of studies and endpoints for the risk assessment deviates from the results of the EU review process. Justifications are provided below.

Table 9.8-1: Endpoints and effect values relevant for the risk assessment for bees

Species	Substance ^a	Exposure System	Results	Reference
Laboratory tests				
<i>Apis mellifera</i>	Deltamethrin a.s.	Acute oral	LD ₅₀ = 0.079 µg a.s./bee	EC Review Report 6504/VI/99- final (2002), 1-78 Monograph Annex B Ecotox
<i>Apis mellifera</i>	Deltamethrin a.s.	Acute contact	LD ₅₀ = 0.0015 µg a.s./bee	EC Review Report 6504/VI/99- final (2002), 1-78 Monograph Annex B Ecotox
<i>Apis mellifera</i>	Deltamethrin EW 15	Chronic oral 10 days	LC₅₀ = 15100 µg a.s./kg LDD₅₀ = 0.53 µg a.s./bee/day	Appendix 2 Kling (2014) M 477250-01-1 See justification
<i>Apis mellifera</i> (adult)	Flupyradifurone a.s.	Oral Acute	LD ₅₀ = 1.2 µg a.s./bee	EFSA Journal 2015;13(2):4020
<i>Apis mellifera</i> (adult)	Flupyradifurone a.s.	Contact Acute	LD ₅₀ = 122.8 µg a.s./bee	EFSA Journal 2015;13(2):4020
<i>Apis mellifera</i> (adult)	Flupyradifurone SL 200-G	Oral Acute	LD₅₀ = 3.2 µg a.s./bee	EFSA Journal 2015;13(2):4020
<i>Apis mellifera</i> (adult)	Flupyradifurone SL 200-G	Contact Acute	LD₅₀ = 15.7 µg a.s./bee	EFSA Journal 2015;13(2):4020
<i>Apis mellifera</i> (adult)	Flupyradifurone a.s.	Feeding Chronic	LC ₅₀ = 61100 µg/kg; 1.83 µg a.s./bee/d	EFSA Journal 2015;13(2):4020
<i>Apis mellifera</i> (larvae)	Flupyradifurone a.s.	Feeding Chronic	NOEC ≥ 10000 µg a.s./diet NOEC = 1.32 µg a.s./ larvae	EFSA Journal 2015;13(2):4020
Semi-field/tunnel studies (deltamethrin)				
Phacelia full flowering, 7.5 g a.s./ha, bees actively foraging Test item: Deltamethrin EW 15 Location: Germany Slight increase in mortality, slight decrease in foraging activity, no adverse effects on brood and colony development (digital imaging as well as overall brood assessment)				Appendix 2 Rentschler (2014) M 477316-01-1 See justification

Species	Substance ^a	Exposure System	Results	Reference
<i>Phacelia tanacetifolia</i> , 7.5 g a.s./ha Test item: Deltamethrin EW 50 Location: Germany			The test item Deltamethrin EW 50 (7.5 g a.s. (156.9 g product) in 400 L water/ha), water (400 L water/ha) and a reference item (1.5 L Perfekthion EC (dimethoate) in 400 L water/ha) were applied on the whole plot of plants in two operations, with foraging bees present. The trial was performed using three tunnels for the test item treatment, the control and the reference item treatment (dimethoate 400 g/L), respectively. One bee hive was used per tunnel. The total duration of the test was 7 days following the application. The test substance had no ecologically relevant effects on mortality, flight intensity, behaviour or brood of the honey bees were observed after direct application of the test item.	Appendix 2 Schmitzer (2006) M_274120_01_1 See justification
<i>Phacelia tanacetifolia</i> , 7.5 g a.s./ha Test item: Deltamethrin EC 15 G (AE F032640 00 EC02 A804) Location: Germany			The test substance Deltamethrin EC 15 (AE F032640 00 EC02 A804) was applied at an application rate of 7.5 g a.i./ha in 300 L water/ha. Plots treated with tap water served as control. As toxic standard, Hostathion 40 EC was applied at a concentration of 0.6 L/ha in 300 L water/ha. The effect of the test substance was examined on small bee colonies in cages placed over plots with flowering <i>Phacelia tanacetifolia</i> Benth. The application of the test substance resulted in an increase of the mortality restricted to the day of application DAA 0aa, which was determined to be not significantly different to the control. An obvious repellent effect occurred directly after application assumed by the behaviour of the bees and confirmed due to the flight intensity on this day, which remained significantly below the level of the control group. The significantly reduced flight intensity lasted until evaluation day DAA1. Compared with the pre-application period the average daily post-application level of flight intensity was lower in the test substance treatment group. Regarding the colonies strength and the bee brood development no abnormal differences attributable to the influence of the test substance were observed between the test substance and control group.	Appendix 2 Schur (2001) M_200402_01_1 See justification
<i>Phacelia tanacetifolia</i> , 7.5 g a.s./ha Test item: Deltamethrin EC 100 Location: Germany			A moderate increase of mortality was observed after the application during bee flight, indicating a slight immediate contact toxicity of the test item to the exposed bees. When the application was performed with closed hives, no increase of mortality was observed. No effects on colony strength were observed. A slight repellent effect of the product was observed during 2 to 3 days following the application and in a greater extent in the tunnel where bees were directly exposed to the treatment. Foraging activity returned to a normal level after 4 days in both treatment groups. Similarly, other endpoints were not negatively affected by the treatment which could pose a risk to the viability of bee colonies.	Appendix 2 Maus et al. (2005) M_262389_02_1 See justification
Field studies (deltamethrin)				
Mustard, 7.5 g a.s./ha, 10 g a.s./ha, 12.5 g a.s./ha and 17.5 g a.s./ha Test item: Deltamethrin EC 30 Location: France			After application of 17.5 g deltamethrin/ha reduced flight activity and short-term repellency were observed. Directly after the application slight behavioural effects were noticed. Only insignificantly or slightly increased mortality was found throughout the trial.	Monograph Annex B Ecotox

Species	Substance ^a	Exposure System	Results	Reference
<i>Phacelia tanacetifolia</i> , 2 x 12.5 g a.s./ha, Spray interval 13 d Test item: Deltamethrin EW 15 Location: France			No test item related adverse effects were observed on mortality and flight intensity in the test field. No test item related adverse effects were observed on honeybee health, colony development (including colony strength, colony health, brood and food development of the colonies) as well as on overall colony vitality throughout the entire field exposure period and throughout the entire monitoring period until the end of overwintering in spring. Behavioural observations indicated a possible short term correlation between the application of the test item during bee flight activity and an intensive cleaning behaviour in a larger number of exposed honeybees as well as motionless bees and intoxication symptoms in a smaller number of exposed honeybees.	Appendix 2 Rexer (2013) M 452717-01-1 See justification
<i>Phacelia tanacetifolia</i> , 2 x 12.5 g a.s./ha, Spray interval 13 d Deltamethrin EW 15 B-G Location: France			No test item related adverse effects were observed on mortality and flight intensity in the test field. No test item related adverse effects were observed on honeybee health, colony development (including colony strength, colony health, brood and food development of the colonies) as well as on overall colony vitality throughout the entire field exposure period and throughout the entire monitoring period until the end of overwintering in spring. Behavioural observations indicated a possible short term correlation between the application of the test item during bee flight activity and an intensive cleaning behaviour in a larger number of exposed honeybees as well as motionless bees and intoxication symptoms in a smaller number of exposed honeybees.	Appendix 2 Rexer (2013) M 452723-01-1 See justification
<i>Phacelia tanacetifolia</i> , 7.5 g a.s./ha Test item: Deltamethrin EG 6.25 W (AE F032640 00 EG06 A106) Location: Germany			No acute intoxication of adult bees was observed. An increase of mortality was detected during the post application period in the test substance and control variant. A slight decrease of flight intensity occurred directly after application of AE F032640 00 EG06 A106 and the flight intensity dropped below the level of the control variant. During the post application period evaluations showed flight intensities at levels which were in the range of results in the control variant. Regarding the colonies strength and the bee brood development no abnormal difference which could be attributed to the influence of the test substance were observed between the Deltamethrin EG 6.25 W (AE F032640 00 EG06 A106) variant and control.	EC Review Report 6504/ VI/99 final (2002), 1 78
<i>Phacelia tanacetifolia</i> , 7.5 g a.s./ha Test item: Deltamethrin EC 25 (AE F032640 00 EC03 B003) Location: Germany			The spray treatment of Deltamethrin EC 25 (AE F032640 00 EC03 B003) caused a slight increase in honey bee mortality for 1–2 days. Flight intensity decreased after treatment and returned to control values within 24 hours. No adverse effects on honey bee brood were observed.	Monograph Annex B Ecotox
<i>Phacelia tanacetifolia</i> , 7.5 g a.s./ha Test item: Deltamethrin EC 25 Location: Germany			Decrease of the flight intensity on the day of application after the treatment. After the application, the mortality was not elevated and remained below the pre-application level up to DAA +2, increased slightly between DAA +3 and DAA +5 and then returned below the pre-application level. Some bees showed symptoms of affected behaviour at the hive entrance (only in front of the hives) mainly on the day of application after the treatment. The condition of the colonies, size of the brood nest and the development of the honey bee brood in the test item treatment group was not different compared to the control during the observation period.	Appendix 2 Pistorius (2007) M 286584-01-1 See justification

Species	Substance ^a	Exposure System	Results	Reference
<i>Brassica napus</i> , 7.5 g a.s./ha Test item: Deltamethrin EC 25 Location: Germany			Slight decrease of the flight intensity on the day of application after the treatment. Mortality was not increased in any of the trials. The observations of bee behaviour of individually Opalith-marked and paint marked bees did not indicate any disturbance of the homing behaviour. Only a few bees in the observation hives or at the hive entrances showed symptoms of abnormal behaviour after application of the test item. The condition of the colonies, size of the brood nest and the development of the honey-bee brood in the test item treatment group was not different compared to the control during the observation period and not affected by any of the treatments.	Appendix 2 Pistorius (2007) M-295800-01-1 See justification
Field or semi-field tests (flupyradifurone) (EFSA Journal 2015;13(2):4020)				
<p>Five acceptable semi-field (gauze tunnel) studies are available, where BYI 02960 formulations were applied to <i>Phacelia tanacetifolia</i> with honey bees actively foraging on the crop (i.e. during bee flight) with different application regimes (ranging from 1x 75 g a.s. foliar spray to 1x 300 g a.s./ha soil application + 2x 200 g a.s./ha. Furthermore, two field studies are available in oil seed rape where BYI 02960 formulations were applied with honey bees actively foraging on the crop (i.e. during bee flight) at 2x 200 g a.s./ha with preceding 1x 300 g a.s./ha soil application and 10 g a.s./kg seed seed treatment.</p> <p>In the semi field and field studies, the only clearly treatment related effects seen were short term reduced flight intensity (one to at most seven days after application) and behaviour anomalies in some bees (one day after application) after the foliar application during full flowering. Furthermore some slight, transient, potential effects were observed on other parameters. However this did not lead to reduced colony performance or survival.</p> <p>Also, a large residue package is available with residues measured in pollen and nectar taken both from foragers and from hives, from studies in <i>Phacelia</i> and oil seed rape.</p> <p>Lastly, a long term feeding study was submitted in which colonies were forced to feed on up to 10 mg/kg diet for six weeks. This did not lead to collapse of the colonies, including overwintering.</p> <p>The overall data package shows that the spraying of 2x 200 g a.s./ha on a bee attractive crop during full flowering and active foraging of honey bees may have caused some slight transient treatment related effects, but does not result in adverse acute or long term (including overwintering) effects on honey bee colonies.</p>				

^a For simplification and as they are not used in the risk assessment endpoints for the flupyradifurone metabolites have been omitted from the table, the endpoints demonstrate that the metabolites are of low toxicity to bee by acute or chronic exposure

Table 9.8-2: Endpoints for bees – DLT + FPF EC 85

Species	Substance	Exposure System	Results	Reference
<i>Apis mellifera</i>	DLT + FPF EC 85	Semi-field honey bee study (forced exposure conditions) in <i>Phacelia</i> ; application before full-flowering and without bees present	No adverse effects on behaviour, colony strength, queen survival at 990 mL product/ha (equivalent to 1.14 kg product/ha).	Appendix 2 Taenzler, V.: 2017; M-598914-01-1
<i>Apis mellifera</i>	DLT + FPF EC 85	Acute, contact	LD ₅₀ = 9.1 µg prod./bee (24 h) LD ₅₀ = 7.1 µg prod./bee (48 h)	Appendix 2 Schmitzer, S.: 2015; M-542907-01-1
<i>Apis mellifera</i>	DLT + FPF EC 85	Acute, oral	LD ₅₀ = 13.2 µg prod./bee (24 h) LD ₅₀ = 13.0 µg prod./bee (48 h)	Appendix 2 Schmitzer, S.: 2015; M-542907-01-1

zRMS comments:

Bee toxicity data for particular active compounds provided in Table 9.6-1 are in line with EU agreed endpoints reported in the Review Report for deltamethrin (6504/VI/99-final, 2002) and EFSA Journal 2015;13(2):4020 for flupyradifurone. Although not provided in table above, the acute and chronic toxicity studies with adult bees were performed during the EU review with relevant flupyradifurone metabolites demonstrating that these

compounds are not more toxic to bees comparing to the parent and for this reason risk assessment performed for flupyradifurone covers the risk from its metabolites.

No toxicity data were available from the EU review for deltamethrin metabolites and it is noted that no studies were also provided during the EU renewal process.

The study on acute toxicity of DLT+FPF EC 85 was evaluated and agreed by the zRMS. Details of the evaluation and study summary may be found in Appendix 2.

It is noted that no chronic and larvae toxicity studies were performed with DLT+FPF EC 85, although in line with the Commission Regulation (EU) No 284/2013, such studies are mandatory for formulations containing more than one active compound. These studies could be potentially replaced by respective field or semi-field studies, but for DLT+FPF EC 85 only single tunnel test with application carried out 10 days before bees introduction is available and colony parameters investigated not corresponding with these determined in bee brood feeding test or field studies. Since the data requirements are not fulfilled, a data gap for respective chronic and larvae study with DLT+FPF EC 85 is identified.

The tunnel study with DLT+FPF EC 85 was evaluated by the zRMS and partially agreed. However, in order to incorporate the study results into the risk assessment, the Applicant is kindly requested to provide more detailed assessment of the colony data in order to aid comparison between test groups at particular observation intervals (e.g. mean number of brood cells at particular colony assessments, showing evolving of the bee brood in time). Details of the evaluation and study summary may be found in Appendix 2.

During the commenting period the Applicant submitted the detailed statistical analysis of the tunnel study by Taenzler (2017, M-598914-01-1) performed using advanced statistical method GLMM which was agreed by the zRMS. Details of the statistical analysis by Miles & Murakami (2021, M-781941-01-1) may be found in Appendix 2 under KCP 10.3.1.5/08.

Obtained results confirmed that application of DLT+FPF EC 85 at 0.99 L/ha before the full flowering of *Phacelia tanacetifolia* (BBCH 60-61) 10 days before introduction of bees had no significant effect on colony strength (defined as number of bees counted on the comb sides) or the total brood (defined as the sum of the numbers of closed brood cells, eggs and maggots).

It is noted that the brood indices, compensation indices and brood termination rates were not calculated, although in the comments to the study by Taenzler (2017) it was indicated that these parameters are most suitable to analyse effects of the test item on the bee colonies. Nevertheless, these parameters are calculated rather in the field studies and are only rarely available in the tunnel tests.

Overall, the zRMS is of the opinion that results of the study by Taenzler (2017) may be used in support of authorisation of DLT+FPF EC 85.

Studies on chronic toxicity of solo deltamethrin formulation to adult bees were not validated by the zRMS as being not relevant for risk assessment performed for DLT+FPF EC 85 since studies with the target formulation should have been provided. In order to compare chronic and larvae toxicity of deltamethrin and flupyradifurone as active substances and within the formulated product, studies performed with the individual compounds and the target formulation should be available as prediction of the toxicity of the formulation containing multiple substances from toxicity data derived for solo formulations of particular compounds is not appropriate due to potential impact of co-formulants leading to increased or decreased toxicity.

In support of evaluation performed for DLT+FPF EC 85 the Applicant provided multiple semi-field and field studies performed with various solo formulations of deltamethrin. These studies were, however, not evaluated by the zRMS since field studies must be performed with the target formulation applied in line with the intended use pattern. This is particularly important for formulations containing multiple active compounds with supplementary mode of action and prediction of the effects of the mixture under field conditions is not possible based on results of field trials performed with solo formulations. Further discussion regarding this issue is provided in point 9.6.2.2 below.

9.8.1.1 Justification for new endpoints

For the active substances deltamethrin and flupyradifurone there are no deviations to EU agreed endpoints.

New studies presented to fulfil current data requirements and refine the risk assessment are submitted as described below.

Table 9.8-3: Justification for new endpoints for honey bees

Species	Substance	Exposure system	Justification
Laboratory tests			
<i>Apis mellifera</i>	Deltamethrin EW 15	Chronic 10 days	To provide information on the chronic toxicity to adult bees according to new data requirements- (Kling (2014), Appendix 2)
Semi-field/tunnel studies			
<i>Apis mellifera</i>	Deltamethrin EW 15	Semi-field study in tunnels on <i>Phacelia</i>	To refine risk assessment, providing information on the effects of deltamethrin on honey bee colonies (Rentschler (2014), Appendix 2)
<i>Apis mellifera</i>	Deltamethrin EW 50	Semi-field study in tunnels on <i>Phacelia</i>	To refine risk assessment, providing information on the effects of deltamethrin on honey bee colonies (Schmitzer (2006), Appendix 2)
<i>Apis mellifera</i>	Deltamethrin EC 15-G	Semi-field study in tunnels on <i>Phacelia</i>	To refine risk assessment, providing information on the effects of deltamethrin on honey bee colonies (Schur (2001), Appendix 2)
<i>Apis mellifera</i>	Deltamethrin EC 100	Semi-field study in tunnels on <i>Phacelia</i>	To refine risk assessment, providing information on the effects of deltamethrin on honey bee colonies (Maus et al. (2005), Appendix 2)
Field studies			
<i>Apis mellifera</i>	Deltamethrin EW 15	Field study on <i>Phacelia</i>	To refine risk assessment, providing information on the effects of deltamethrin on honey-bee colonies (Rexer (2013), Appendix 2)
<i>Apis mellifera</i>	Deltamethrin EW 15 BG	Field study on <i>Phacelia</i>	To refine risk assessment, providing information on the effects of deltamethrin on honey-bee colonies (Rexer (2013), Appendix 2)
<i>Apis mellifera</i>	Deltamethrin EC 25	Field study on <i>Phacelia</i>	To refine risk assessment, providing information on the effects of deltamethrin on honey-bee colonies (Pistorius (2007), Appendix 2)
<i>Apis mellifera</i>	Deltamethrin EC 25	Field study on rape <i>Brassica napus</i>	To refine risk assessment, providing information on the effects of deltamethrin on honey-bee colonies (Pistorius (2007), Appendix 2)

zRMS comments:

As already indicated in point 9.6.1 above, studies performed with solo formulations of particular active compounds are not sufficient to address data requirement of the formulation containing multiple substances. For this reason respective chronic and larvae toxicity studies performed with DLT+FPF EC 85 must be provided in order to fulfil the data requirements.

For comments regarding consideration of field trials performed with deltamethrin solo formulations in the risk assessment performed for DLT+FPF EC 85, please refer to point 9.6.1 above and 9.6.2.2 below. In general, the field effects of the formulation containing more than one active substance cannot be addressed based on results of field studies performed with solo formulations of particular compounds. Field studies must be performed with the formulation for which authorisation is sought and extrapolation is possible only from one solo to another solo formulation, provided that their toxicity is comparable or the formulation tested represents worst case.

9.8.2 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).

9.8.2.1 Hazard quotients for bees

Table 9.8-4: First-tier assessment of the risk for bees due to the use of DLT+FPF EC 85 in OSR (use group A) (pre-flowering applications BBCH 30 - 59)

Intended use		OSR (use group A), 2 × 0.75 L/ha	
Active substance		Deltamethrin	
Application rate (g/ha)		2 × 7.5	
Test design	LD₅₀ (lab.) (µg/bee)	Single application rate (g/ha)	Q_{HO}, Q_{HC} criterion: Q_H ≤ 50
Oral toxicity	0.079	7.5	95
Contact toxicity	0.0015		5000
Active substance		Flupyradifurone	
Application rate (g/ha)		2 × 56.3	
Test design	LD₅₀ (lab.) (µg/bee)	Single application rate (g/ha)	Q_{HO}, Q_{HC} criterion: Q_H ≤ 50
Oral toxicity	1.2	56.3	47
Contact toxicity	122.8		<1
Product		DLT+FPF EC 85	
Application rate (g/ha)		2 × 868	
Test design	LD₅₀ (lab.) (µg/bee)	Single application rate (g/ha)	Q_{HO}, Q_{HC} criterion: Q_H ≤ 50
Oral toxicity	13	868	67
Contact toxicity	7.1		122

Q_{HO}, Q_{HC}: Hazard quotients for oral and contact exposure. Q_H values shown in bold breach the relevant trigger.
Product density = 1.157 kg/L.

Table 9.8-5: First-tier assessment of the risk for bees due to the use of DLT+FPF EC 85 in OSR (use group B) (flowering and post-flowering applications BBCH 65 – 79)

Intended use		OSR (use group B), 2 × 0.5 L/ha	
Active substance		Deltamethrin	
Application rate (g/ha)		2 × 5	
Test design	LD₅₀ (lab.) (µg/bee)	Single application rate (g/ha)	Q_{HO}, Q_{HC} criterion: Q_H ≤ 50
Oral toxicity	0.079	5	63
Contact toxicity	0.0015		3333
Active substance		Flupyradifurone	
Application rate (g/ha)		2 × 37.5	
Test design	LD₅₀ (lab.) (µg/bee)	Single application rate (g/ha)	Q_{HO}, Q_{HC} criterion: Q_H ≤ 50
Oral toxicity	1.2	37.5	31
Contact toxicity	122.8		<1
Product		DLT+FPF EC 85	
Application rate (g/ha)		2 × 579	
Test design	LD₅₀ (lab.) (µg/bee)	Single application rate (g/ha)	Q_{HO}, Q_{HC} criterion: Q_H ≤ 50
Oral toxicity	13	579	45
Contact toxicity	7.1		82

Q_{HO}, Q_{HC}: Hazard quotients for oral and contact exposure. Q_H values shown in bold breach the relevant trigger.
Product density = 1.157 kg/L.

For both use groups (A and B) for the use of DLT+FPF EC 85 in OSR the calculated HQ-values based on deltamethrin endpoints exceeded the trigger of 50 for both acute and contact exposure. However the risk assessment based on flupyradifurone endpoints indicated low risk (HQ-values below the trigger).

A potential risk was indicated in the risk assessment when DLT+FPF EC 85 endpoints were used for use pattern A, whereas only a contact risk was indicated for use pattern B. Overall it is clear that the risk to bees is driven by the high laboratory of deltamethrin in the formulation.

A refined risk assessment is presented below considering tunnel and field tests for deltamethrin and flupyradifurone.

Chronic toxicity to adult honey bees

In the chronic toxicity study for deltamethrin by Kling (2014, [M-477250-01-1](#)) bees were fed continuously for 10 days and ad libitum with a 50 % (w/v) aqueous sucrose solution, containing the test item Deltamethrin EW 15B G at the nominal concentration levels of 2, 6, 18, 54 and 162 mg a.s./kg resulting in a LD₅₀ of 0.53 µg a.s./bee/day. As this is higher than the observed acute toxicity values there is no evidence for increased toxicity due to chronic exposure compared to acute exposure.

The chronic toxicity study for flupyradifurone (EFSA journal) resulted in a LC₅₀ of 1.83 µg a.s./bee which is in line with the acute endpoint (LD₅₀ oral = 1.2 µg a.s./bee).

Consequently, there is no evidence for increased toxicity or delayed effects due to chronic exposure compared to acute exposure.

zRMS comments:

The acute risk assessment presented in Tables 9.6-4 and 9.6-5 above is agreed by the zRMS. Based on the performed calculations unacceptable acute oral and contact risk from deltamethrin was concluded for both application rates. The contact risk from the formulated product was unacceptable from both rates, while the oral risk was unacceptable from the higher rate. The acute oral and contact risk from flupyradifurone was acceptable from both application rates of DLT+FPF EC 85.

As already indicated in the zRMS comments in point 9.6.1 above, studies on chronic or larvae toxicity of solo formulations of particular active compounds are not sufficient to fulfil the data requirements for products containing multiple active substance, since according to the Commission Regulation (EU) No 284/2013, in such respective studies with the formulation in question must be performed. As no chronic and larvae toxicity studies were performed with DLT+FPF EC 85, a data gap in this area has been identified. Submission of these laboratory studies may be waived provided that respective semi-field or field data with DLT+FPF EC 85 are available with all necessary parameters enabling evaluation of long-term effects on adult bees, bee brood and entire colonies measured.

Since the chronic effects of DLT+FPF EC 85 cannot be reliably estimated from the data available for the solo formulations of particular active compounds, the study on chronic toxicity of Deltamethrin EW 15B G was not validated by the zRMS.

The approach taken by the Applicant to conclude on lack of chronic effects is also not agreed by the zRMS. It has to be noted that potential long-term effects are not evaluated by simple comparison of endpoints derived from acute and chronic studies as even with similar endpoints the outcome of the acute and chronic risk assessment may be different due to different evaluation scheme and criteria. Furthermore, in absence of the chronic toxicity endpoints for DLT+FPF EC 85 it is not possible to conclude if the chronic toxicity of the formulated product to bees is higher or comparable to its acute toxicity.

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

Refined Risk Assessment

Based on the tier I risk assessment the risk to bees is primarily driven by effects due to deltamethrin. Relatively low LD₅₀ values have been determined under laboratory conditions which drive the tier I risk assessment based on HQ-values. However, higher tier studies (semi-field and field tests) have been carried out with deltamethrin containing products throughout the years in order to investigate whether deltamethrin containing products do actually pose an unacceptable risk for foraging honey bees and their honey bee colonies under more realistic conditions. When originally considered by the EU, the review report for the active substance for Deltamethrin (Deltamethrin 6504/VI/99-rev. 3, 2002) concluded:

“For the protection of bees, risk mitigation measures must be prescribed where appropriate.”

The conclusion in the DAR addendum 2002 stated the following:

“With reference to field crops only, it is suggested that single applications to flowering field crops can be carried out without unacceptable effects on bees at rates below 10 g/ha. In case multiple applications are performed in flowering field crops, it is suggested that the rate which can be regarded as “safe” be reduced to 6.25 g/ha, since no adverse effects have been shown at this rate. ECCO 81 proposed that restrictions in use must be applied at application rates higher than these”.

A range of studies conducted with deltamethrin at relevant test rates under flowering crop conditions have been conducted. These support that the pre-, during, and post-flowering uses (use groups A and B) will not pose an unacceptable risk to honey bees. At test rates of 6.25 and 7.5 g a.s./ha tested under semi-field conditions applied to highly bee attractive flowering crops only minor, transient effects were noted on honey bees. Under more realistic field conditions (less severe than semi-field tests) no test item related effects were noted on mortality with only minor and short lived effects on foraging rates which did not lead to adverse colony level effects at test rates of 7.5 g a.s./ha which exceeds the use pattern for DLT+FPF EC 85. In two modern state-of the-art field studies (see Appendix 2, Rexer (2013), [M-452717-01-1](#); Rexer (2013), [M-452723-01-1](#)), where in addition to the usual assessments, potential side-effects on long-term colony vitality, long-term honey bee health and over-wintering performance were evaluated, after two sequential applications of 12.5 g a.s./ha to the highly bee-attractive crop *Phacelia tanacetifolia* during full-bloom. The data obtained from these studies revealed that two sequential applications of 12.5 g a.s./ha did neither cause acute, short-term nor long-term adverse effects on mortality, flight intensity, colony strength, colony health and vitality, brood- and food development, honey bee health as well as on the over-wintering performance of the exposed colonies.

Overall, the findings of the semi-field and field tests indicated that for proposed uses for DLT+FPF EC 85 in OSR there was no unacceptable risk to bees due to deltamethrin.

Flupyradifurone is a new insecticide, for this active substance a recent EFSA conclusion published in the EFSA Journal 2015;13(2):4020 states:

“However, as an overall conclusion, the experts agreed that the data set indicated no adverse acute or long-term effects to honey bee colonies including assessments for over-wintering. Therefore the risk to honey bees was considered as low for the representative uses of flupyradifurone”.

The proposed uses for DLT+FPF EC 85 in OSR are for up to 2 x 56.25 g FPF/ha which is covered by the representative uses (up to 200 g FPF/ha). In addition the tier I risk assessment for DLT+FPF EC 85 in OSR based on flupyradifurone endpoints and semi-field and field studies conducted which included test rates up to 2 x 200 g a.s./ha indicated no unacceptable effects on honey bee colonies (including overwintering).

Tier 1 toxicity tests with DLT+FPF EC 85 do not indicate that the formulation is more toxic than would be predicted by the individual active substances and there two act independently. The toxicity is clearly driven by the deltamethrin content. Furthermore a semi-field test (tunnel test) conducted at 0.99 L/ha which is equivalent to 1.32x use group A and 1.98x use group B applied at the start of flowering in a highly attractive crop in the absence of bees did not indicate any adverse effects on behaviour, colony strength as well as on queen survival were observed for the honey bee colonies.

Overall it can be concluded that based on a wide range of evidence of high tier testing with the active substances and the product, that DLT+FPF EC 85 does not pose an unacceptable risk to honey bee colonies when used according to the GAP in OSR applications.

zRMS comments:

As already mentioned in the zRMS comment in point 9.6.1 above, semi-field and field studies must be performed with the target formulation applied in line with the intended use pattern, which is particularly

important for formulations containing more than one active substance. The concentration addition approach is applicable only for results of the laboratory studies, but not the semi-field or field studies, which are designed to evaluate effects of the formulated product under the practical conditions of use and due to the test design, no actual endpoints are derived from such studies. It should be also noted that according to the Commission Regulation (EU) No 284/2013, acute, chronic and larvae studies with bees are a data requirement for formulations containing more than one active substance, even when laboratory data for individual substance are available enabling concentration addition approach. This means that toxicity of formulations containing multiple substances cannot be reliably predicted based on active substance data. Taking this into account, effects seen in semi-field or field studies performed with the solo formulations cannot be extrapolated to the simultaneous exposure to both (or more) active substances.

However, with exception of one tunnel test, all other semi-field and field studies provided by the Applicant were performed with solo formulations of deltamethrin and flupyradifurone. The Applicant points out that this is sufficient as the performed risk assessment indicates that the risk to bees from DLT+FPF EC 85 is driven by deltamethrin. It should be, however, noted that only acute risk assessment has been performed and results of the acute risk assessment cannot be automatically translated into the chronic risk, as even with similar endpoints the outcome of the acute and chronic risk assessment may be different due to different evaluation schemes and criteria applied. Furthermore, in absence of the respective chronic toxicity study with DLT+FPF EC 85 it cannot be excluded that simultaneous exposure of bees to deltamethrin and flupyradifurone would result with more severe long-term effects. In addition to that, no larvae toxicity data are available for deltamethrin and DLT+FPF EC 85 and for this reason no conclusions regarding the impact on larvae may be taken based on results of the laboratory studies.

In evaluation of the deltamethrin semi-field and field studies the Applicant points out that no unacceptable effects on mortality, foraging activity, behaviour and bee colonies were observed. Although the studies were not validated by the zRMS as being not relevant to address the risk from DLT+FPF EC 85, it should be noted that they were considered in the course of the ongoing EU renewal process of deltamethrin based on their results the RMS concluded the following (updated Vol. 3CP, B.9 for Decis EW 15 of July 2019):

In conclusion, on the basis of all the information submitted, the RMS considers that a risk to honeybees cannot be excluded. To protect bees and pollinating insects, Deltamethrin should not be applied when crop plants are in flower, where bees are actively foraging and when flowering weeds are present.

Taking into account evaluation performed by the RMS it may be concluded that some effects in semi-field and field studies with deltamethrin described as negligible by the Applicant, were actually considered significant.

With regard to flupyradifurone it should be noted that the semi-field and field studies available during the EU review process were discussed during the Pesticides Peer Review 124 in the context of the representative uses evaluated, i.e. lettuce and hops, crops not attractive to bees. It cannot be excluded that due to some effects observed in these studies the conclusion of the experts would be different (or at least modified) when bee attractive crops were considered.

Evaluation performed at the EU level clearly indicates that some effects on bees were observed in the semi-field and field studies with deltamethrin and flupyradifurone, even if they were transient. It is, however not known what would be the effects from simultaneous exposure of bees under the semi-field or field conditions to both, deltamethrin and flupyradifurone, and this cannot be reliably predicted based on studies performed with solo formulations, even when these studies were performed at rates exceeding these intended for DLT+FPF EC 85. It has to be pointed out that both substances have supplementary mode of action acting through different pathways: deltamethrin is a non-systemic “knock-out” insecticide extremely disturbing the nervous system by blocking the sodium channel and flupyradifurone is a systemic insecticide interacting with insect nicotinic acetylcholine receptors, similar to neonicotinoids. Taking this into account it cannot be excluded that the impact of the mixture on bees may be enhanced comparing to individual compounds. It is also not known if the second application of the product would not lead to more severe effects due to limited time for recovery after the exposure following first application.

The zRMS is aware that according to indications of EPPO 170¹, testing of the maximum single application rate of the product during the flowering should be sufficient in most cases, but multiple applications may be more appropriate in case of sprayed compounds that have the potential to move to the flowers via foliar uptake, which may be the case for flupyradifurone, being a systemic insecticide.

¹ OEPP/EPPO Bulletin 40, 313-319 (2010); PP 1/170 (4)

The potential simultaneous exposure to both active compounds in DLT+FPF EC 85 was investigated in a single tunnel study. No unacceptable effects of the test item were observed and the mortality, foraging activity and colony strength (measured as the number of bees in the hive) in the test item groups were at the level comparable with control groups. It is, however, noted that in this study DLT+FPF EC 85 was applied at the beginning of the flowering (BBCH 60-61), 10 days before introduction of bees. During that time the residue level of both active compounds could decline considerably to the level at which the residual toxicity was low. This, however, cannot be confirmed since residues of particular active compounds in flowers, nectar and pollen were not measured in the study and it is thus not known if lack of effects was due to negligible exposure of bees or low toxicity of DLT+FPF EC 85.

It is further noted that with regard to the colony assessments the raw data are available in the study report, but no detailed analysis of the brood parameters was carried out and the only parameter evaluated quantitatively was the colony strength, measured as the number of bees in the hive. Taking this into account the Applicant is kindly requested to provide during the commenting period the respective numerical summary of the effects on colony development (e.g. mean number of brood cells at particular colony assessments) in order to aid comparison between test groups and particular observation intervals.

During the commenting period the Applicant submitted the detailed statistical analysis of the tunnel study by Taenzler (2017, M-598914-01-1) performed using advanced statistical method GLMM which was agreed by the zRMS. Details of the statistical analysis by Miles & Murakami (2021, M-781941-01-1) may be found in Appendix 2 under KCP 10.3.1.5/08.

Obtained results confirmed that application of DLT+FPF EC 85 at 0.99 L/ha before the full flowering of *Phacelia tanacetifolia* (BBCH 60-61) 10 days before introduction of bees had no significant effect on colony strength (defined as number of bees counted on the comb sides) or the total brood (defined as the sum of the numbers of closed brood cells, eggs and maggots).

It is noted that the brood indices, compensation indices and brood termination rates were not calculated, although in the comments to the study by Taenzler (2017) it was indicated that these parameters are most suitable to analyse effects of the test item on the bee colonies. Nevertheless, these parameters are calculated rather in the field studies and are only rarely available in the tunnel tests.

Although due to the exposure regime the study is not sufficient to support application of DLT+FPF EC 85 during the flowering period of oilseed rape, it may be used to confirm lack of residual toxicity after application outside the flowering, since the additional statistical analyses confirmed that the test item had no effects on the colony strength and the total brood. ~~provided that more detailed evaluation of results obtained during colonies assessments is available.~~ It should be noted that in the test item was not applied in line with the intended use pattern (i.e. two applications at 2x0.75 or 2x0.5 L product/ha). However, in opinion of the zRMS single application at exaggerated rate (0.99 L/ha used vs. intended max rate of 0.75 L/ha) is sufficient to address the risk for application outside the flowering period.

The BBCH stages outside the flowering at which the product is intended to be applied are BBCH 30-59 and BBCH 70-79. Application after the flowering will not lead to exposure to residues of the product, since bees will no longer forage in the treated crop. However, application at BBCH 59 (i.e. just before the flowering) may not warrant the 10 day window between the last application and start of the flowering, which was included in the tunnel study by Taenzler (2017). In order to determine the latest stage at which the product could be applied, the zRMS ecotox expert consulted the efficacy expert specialising in agronomy of oilseed rape. It was indicated by the expert that indication of the latest stage at which application of the product is not sufficient, since the time to flowering will depend on multiple factors (such as e.g. variety, weather conditions, agricultural practices etc.) and the last BBCH stage together with minimum interval between the last application and the flowering should be indicated non the label. For this reason the following information to be displayed on the label has been proposed:

The last application must be performed not later than at BBCH 57, but not less than 10 days before beginning of the flowering (BBCH 60). Application date must be thus determined on the basis of the expected number of days to flowering, estimated with consideration of the expected weather conditions, variety, agricultural practices and the BBCH stage on the day when the decision is taken.

In addition to that the product cannot be applied when flowering weeds are present in the treated crop and the application must be performed in the evening in order to avoid accidental exposure to the spray drift of bees foraging on flowering weeds outside the field or in adjacent crops.

Since risk mitigation measures are country specific, provided above indications should be considered as proposal only. Each cMS must decide what risk mitigation measures will be applicable in their countries.

Please note that in case the application at BBCH 30-57 is not accepted, application after the flowering at BBCH 70-79 is still possible.

More data must be generated in order to support application of DLT+FPF EC 85 to flowering oilseed rape. Study/studies should be performed in line with most up-to-date requirement (e.g. in case of field studies indications of EFSA bee guidance should be considered in order to assure sufficient statistical power of the study). Exposure regime should reflect the intended use pattern (including two applications of the product due to systemicity of flupyradifurone) and all parameters necessary to evaluate effects on the colony development should be investigated (in case of field studies it is highly recommended to investigate effects on the overwintering success). As the intended crop is highly attractive to bees, consideration of the surrogate attractive crop (i.e. *Phacelia tanacetifolia*) is not necessary and the study (studies) should be performed in the intended crop.

In general, it is not clear to the zRMS why such a limited and insufficient data for a product being an insecticide and containing two active compounds were generated. It is also not clear why in the only higher tier study with DLT+FPF EC 85 the application was carried out 10 days before introduction of bees, especially the intended use pattern includes application to highly bee attractive crop during the flowering period. As the Applicant argues that the product will not have any adverse effects even when applied during flowering, this study could confirm this conclusion. Yet, for unknown reasons it was decided to avoid direct exposure of bees to the product.

In conclusion, the zRMS is of the opinion that the available data are not sufficient to support application of DLT+FPF EC 85 during the flowering period of oilseed rape. Application outside the flowering is possible provided that **respective risk mitigation measures indicated above are respected**. ~~more detailed evaluation of results obtained during colonies assessments in the study by Taenzler (2017, M 598914 01 1) is submitted during the commenting period. At this stage no final conclusion may be taken and the risk remains unresolved.~~

Furthermore, studies on chronic and larvae toxicity of DLT+FPF EC 85 should be submitted in order to fulfil data requirements as set by the Commission Regulation (EU) No 284/2013. These studies may be waived provided that the Applicant will perform relevant semi-field and field studies including all relevant parameters.

9.8.3 Effects on bumble bees

~~Studies on the toxicity to bees have been carried out the active substances (formulated as Flupyradifurone SL 200 G, Deltamethrin EW 15 G and Deltamethrin EG 6.25 W). Full details of these studies are provided in the following table.~~

Table 9.8-6: Endpoints and effect values relevant for the risk assessment for bumble bees

Species	Substance	Exposure System	Results	Reference
<i>Bombus terrestris</i>	Deltamethrin EW 15 G	Semi-field (Tunnel)	Temporary decrease in foraging and no impact on daily mortality at an application rate of 12.5 g a.s./ha (during foraging activity)	Appendix 2 Giffard (2000) <u>M 200040 01 1</u>
<i>Bombus terrestris</i>	Deltamethrin EG 6.25 W	Semi-field (Tunnel)	Temporary decrease in foraging and no impact on mortality at an application rate of 200 g a.s./ha (during foraging activity)	Appendix 2 Giffard (2000) <u>M 200043 01 1</u>
<i>Bumble bees (adult)</i>	Flupyradifurone (tested as Flupyradifurone SL200 G)	Contact Acute	LD ₅₀ > 100 µg a.s./bumble bee	EFSA Journal 2015;13(2):4020

The effects of Deltamethrin EW 15 and Deltamethrin EG 6.25 were evaluated under confined semi-field conditions in tunnels with *phacelia tanacetifolia* as a bee attractive crop. Product applications were carried out during intense foraging activity with application rates of 12.5 and 200 g a.s./ha. Mortality was observed 5 days before treatment (5DBT) to 7 days after treatment (7DAT) and only showed a temporary decrease in foraging but no impact on daily mortality.

No unacceptable risk has to be expected from the use of DLT + FPF EC 85 to bumblebees.

zRMS comments:

The data for bumblebees provided by the Applicant are relevant to address the risk from deltamethrin or flupyradifurone, but not from simultaneous exposure to both these substances. Taking this into account the Applicants' text above has been struck through since derived conclusions are not substantiated by the relevant data for DLT+FPF EC 85.

Nevertheless, it is noted that data and risk assessment for bumblebees are currently not mandatory and for this reason no specific data for DLT+FPF EC 85 are required.

9.8.4 Effects on solitary bees

No data is available.

9.8.5 Overall conclusions

zRMS comments:

The acute risk assessment performed in line with current guidance document (SANCO/10329/2002 rev 2 final) demonstrated unacceptable acute oral and contact risk from deltamethrin for both application rates (2x0.75 L product/ha and 2x0.5 L product/ha). The contact toxicity from the formulated product was unacceptable from both rates, while the oral risk was unacceptable only from the higher rate. The acute oral and contact risk from flupyradifurone was acceptable from both application rates of DLT+FPF EC 85.

In order to resolve the risk the Applicant submitted higher tier studies: one tunnel study performed with DLT+FPF EC 85 and multiple semi-field as well as field studies performed with solo formulation of the individual active compounds. It is, however, noted that the combined risk resulting from the exposure to mixture of deltamethrin and flupyradifurone cannot be addressed based on semi-field and field studies performed with solo formulations of particular compounds and the semi-field and field studies should be performed with the formulation for which authorisation is sought, at least in case of products containing more than one active substances.

In the only tunnel study performed with DLT+FPF EC 85 the test item was applied 10 days before introduction of bees to the tunnels and for this reason its results are not relevant to address the risk resulting from direct overspray of the bees foraging on the flowering oilseed rape. However, results of the study may be used to confirm lack of residual toxicity after application outside of the flowering (i.e. for BBCH stages 30-59 and 70-79) provided that more detailed evaluation of results obtained during colonies assessments is available (only limited information is provided in the study report). Application after the flowering (BBCH 70-79) will not lead to exposure to residues of the product, since bees will no longer forage in the treated crop. However, application at BBCH 59 (i.e. just before the flowering) may not warrant the 10 day window between the last application and start of the flowering, which was included in the tunnel study by Taenzler (2017). In consultation with the efficacy specialising in agronomy of oilseed rape the following restriction is proposed to be displayed on the label:

The last application must be performed not later than at BBCH 57, but not less than 10 days before beginning of the flowering (BBCH 60). Application date must be thus determined on the basis of the expected number of days to flowering, estimated with consideration of the expected weather conditions, variety, agricultural practices and the BBCH stage on the day when the decision is taken.

In addition to that the product cannot be applied when flowering weeds are present in the treated crop and the application must be performed in the evening in order to avoid accidental exposure to the spray drift of bees foraging on flowering weeds outside the field or in adjacent crops.

Since risk mitigation measures are country specific, provided above indications should be considered as proposal only. Each cMS must decide what risk mitigation measures will be applicable in their countries.

Please note that in case the application at BBCH 30-57 is not accepted in some countries, application after the flowering at BBCH 70-79 is still possible.

In order to support application of DLT+FPF EC 85 to flowering oilseed rape, more data must be generated. Study/studies should be performed in line with most up-to-date requirement (e.g. in case of field indications of EFSA bee guidance should be considered in order to assure sufficient statistical power of the study). Exposure regime should reflect the intended use pattern (including two applications of the product due to systemicity of flupyradifurone) and all parameters necessary to evaluate effects on the colony development should be investigated (in case of field studies it is highly recommended to investigate effects on the overwintering success). As the intended crop is highly attractive to bees, consideration of the surrogate attractive crop (i.e. *Phacelia tanacetifolia*) is not necessary and the study (studies) should be performed in the intended crop.

In conclusion, the zRMS is of the opinion that the available data are not sufficient to support application of DLT+FPF EC 85 during the flowering period of oilseed rape. Application outside the flowering is possible provided that **respective risk mitigation measures indicated above are respected**. ~~more detailed evaluation of results obtained during colonies assessments in the study by Taenzler (2017, M 598914 01 1) is submitted during the commenting period. At this stage no final conclusion may be taken and the risk remains unresolved.~~

Furthermore, studies on chronic and larvae toxicity of DLT+FPF EC 85 should be submitted in order to fulfil data requirements as set by the Commission Regulation (EU) No 284/2013. These studies may be waived provided that the Applicant will perform relevant semi-field and field studies including all relevant parameters.

~~The results of laboratory, semi field and field studies on bees and the corresponding first and higher tier risk assessment showed that the use of the formulated product will not pose any unacceptable risk to bees.~~

9.9 Effects on arthropods other than bees (KCP 10.3.2)

9.9.1 Toxicity data

Studies on the toxicity to non-target arthropods have been carried out with the formulation deltamethrin + flupyradifurone EC 85. Full details of these studies are provided in Appendix 2 of this document (new studies).

Table 9.9-1: Endpoints and effect values relevant for the risk assessment for non-target arthropods

Species	Substance	Exposure System	Results	Reference
<i>Coccinella septempunctata</i>	DLT + FPF EC 85	Aged residue spray deposits on potted apple plants	No effect on mortality and reproduction at 1250 mL prod./ha after aging period of 42 and 56 d	Appendix 2 Waibel, J.; 2018; M-614308-01-1
<i>Chrysoperla carnea</i>	DLT + FPF EC 85	Extended laboratory study, exposure on detached bean leaves	LR ₅₀ = 207.2 mL prod./ha ER ₅₀ > 125 mL prod./ha	Appendix 2 Mueller, R. U.; 2015; M-539469-01-1
<i>Coccinella septempunctata</i>	DLT + FPF EC 85	Extended laboratory study, exposure on detached bean leaves	LR ₅₀ = 4.70 mL prod./ha ER ₅₀ > 3.9 mL prod./ha	Appendix 2 Moll, M.; 2015; M-530897-01-1
<i>Aphidius rhopalosiphi</i>	DLT + FPF EC 85	Extended laboratory study, exposure on potted barley seedlings	LR ₅₀ = 42.1 mL prod./ha ER ₅₀ = 26.1 mL prod./ha	Appendix 2 Mueller, R. U.; 2015; M-539457-01-1
<i>Typhlodromus pyri</i>	DLT + FPF EC 85	Extended laboratory study, exposure on detached bean leaves	LR ₅₀ = 9.5 mL prod./ha ER ₅₀ > 9 mL prod./ha	Appendix 2 Mueller, R. U.; 2015; M-539453-01-1
Natural grassland community (Southern France)	DLT EW 15	Off-crop field study; spray application on grassland	NOER = 0.6 g a.s./ha NOEAER = 3 g a.s./ha	Appendix 2 Aldershof, S.; Bakker, F.; 2012; M-430827-01-1
Natural grassland community (Netherlands)	DLT EW 15	Off-crop field study; spray application on grassland	NOER = 0.23 g a.s./ha NOEAER = 3 g a.s./ha	Appendix 2 Aldershof, S.; Bakker, F.; 2012; M-430876-03-1
Natural grassland community (Southern France)	FPF SL 200	Off-crop field study; spray application on grassland	NOER = 1.7 g a.s./ha NOEAER = 21 g a.s./ha	EFSA Journal 2015;13(2):4020
Natural grassland community (Netherlands)	FPF SL 200	Off-crop field study; spray application on grassland	NOER = 5.1 g a.s./ha NOEAER = 21 g a.s./ha	EFSA Journal 2015;13(2):4020
Natural grassland community (Netherlands)	DLT + FPF EC 85	Off-crop field study; spray application on grassland	NOER = 4 mL/ha NOEAER = 17 mL/ha	Appendix 2 Aldershof, S.; Bakker, F.; 2019; M-661092-01-1
Natural grassland community (Southern France)	DLT + FPF EC 85	Off-crop field study; spray application on grassland	NOER = 9 mL/ha NOEAER = 17 mL/ha (endpoints could not be confirmed due to incomplete presentation of results and weather data in the study report)	Appendix 2 Aldershof, S.; Bakker, F.; 2019; M-661091-01-1

zRMS comments:

Extended laboratory and aged residue studies performed with DLT+FPF EC 85 were evaluated and agreed by the zRMS.

Field study on effects of spray drift deposits of DLT+FPF EC 85 on grassland community of non-target arthropods in The Netherlands was evaluated by the zRMS and agreed. Derived endpoints are confirmed.

The field study on effects of spray drift deposits of DLT+FPF EC 85 on grassland community of non-target arthropods in the Southern France was evaluated by the zRMS, but derived endpoints could not be confirmed due to incomplete reporting of the study results.

Since field studies should be performed with the formulation in question, studies on effects of spray deposits of solo formulations of deltamethrin and flupyradifurone on grassland community of non-target arthropods were not validated by the zRMS as they do not account for combined effects of both active compounds .

For details of the evaluation and summaries of the submitted studies, please refer to Appendix 2.

9.9.1.1 Justification for new endpoints

New studies with the product DLT+FPF EC 85 were conducted which were not part of an EU approval process. The studies were performed to characterize the toxicity of the product to non-target arthropods. Off-crop field studies with DLT EW 15 were conducted which characterize the intrinsic toxicity of deltamethrin to off-crop non-target arthropod populations in natural grassland habitats and are used in the refined risk assessment.

9.9.2 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.

9.9.2.1 Risk assessment for in-field exposure

Table 9.9-2: First- and higher-tier assessment of the in-field risk for non-target arthropods due to the use of DLT+FPF EC 85 in OSR (use group A)

Intended use	OSR (use group A), 2 × 0.75 L prod./ha		
Active substance/product	DLT+FPF EC 85		
Application rate	2 × 0.75 L prod./ha		
MAF	1.7		
Test species Tier 1	LR₅₀ (lab.) (mL/ha)	PER_{in-field} (mL/ha)	HQ_{in-field} criterion: HQ ≤ 2
<i>Typhlodromus pyri</i> ¹⁾	-	-	-
<i>Aphidius rhopalosiphi</i> ¹⁾	-		-
Test species Higher-tier	Rate with ≤ 50% effect* (mL/ha)	PER_{in-field} (mL/ha)	PER_{in-field} below rate with ≤ 50 % effect?
<i>Typhlodromus pyri</i>	>9	1275	no
<i>Aphidius rhopalosiphi</i>	26.1	1275	no
<i>Chrysoperla carnea</i>	>125	1275	no
<i>Coccinella septempunctata</i>	>3.9	1275	no
Test species Higher-tier	Rate with ≤ 50% effect (mL/ha) at 42 DALT	PER_{in-field} (mL/ha)	PER_{in-field} below rate with ≤ 50 % effect?
<i>Coccinella septempunctata</i>	1 x 1250 mL/ha	1275	yes**

MAF: multiple application factor; PER: predicted environmental rate; HQ: hazard quotient; DALT: days after last treatment. Criteria values shown in bold breach the relevant trigger.

* If an LR₅₀ or ER₅₀ from a relevant extended laboratory test is available, it is considered in place of the rate with ≤ 50 % effect.

1) Tier 2 data is available for 4 species, the Tier 1 risk assessment has therefore been omitted.

** see explanation below

For the indicator species the risk assessment does not lead to an acceptable risk as the in-field PER is higher than the rates at which effects were <50%. *Coccinella septempunctata* is considered the most sensitive species (see Table 9.7-1). Hence, an aged residue study was run in order to demonstrate that potential for recovery is given for the in-field non-target arthropod community.

The application rate tested in the aged residue study with *Coccinella septempunctata* was 1250 mL/ha and does not fully cover the predicted environmental rate (application rate of 0.75 L/ha multiplied by MAF of 1.7) for the use group A; the tested rate is by 2% lower. However, the in-field risk can be considered acceptable following the application of 2 x 0.75 L/ha. The observed effect magnitudes in the aged residue study with *Coccinella septempunctata* after aging period of 42 and 56 d were low: a mortality of 5%, 7.2 eggs/female/day, and a hatching rate of 92.3% were observed at 1250 mL/ha after aging for 56 days. A 2% higher application rate of 1275 mL/ha would most likely not have caused unacceptable effects (>50% effects) in the aged residue study. Thus, the in-field risk can be considered acceptable following 2 x 0.75 L/ha in OSR (use group A).

Table 9.9-3: First- and higher-tier assessment of the in-field risk for non-target arthropods due to the use of DLT+FPF EC 85 in OSR (use group B)

Intended use	OSR (use group B), 2 × 0.5 L prod./ha		
Active substance/product	DLT+FPF EC 85		
Application rate	2 × 0.5 L prod./ha		
MAF	1.7		
Test species Tier 1	LR₅₀ (lab.) (mL/ha)	PER_{in-field} (mL/ha)	HQ_{in-field} criterion: HQ ≤ 2
<i>Typhlodromus pyri</i> ¹⁾	-	-	-
<i>Aphidius rhopalosiphi</i> ¹⁾	-		-
Test species Higher-tier	Rate with ≤ 50% effect* (mL/ha)	PER_{in-field} (mL/ha)	PER_{in-field} below rate with ≤ 50 % effect?
<i>Typhlodromus pyri</i>	>9	850	no
<i>Aphidius rhopalosiphi</i>	26.1	850	no
<i>Chrysoperla carnea</i>	>125	850	no
<i>Coccinella septempunctata</i>	>3.9	850	no
Test species Higher-tier	Rate with ≤ 50% effect (mL/ha) at 42 DALT	PER_{in-field} (mL/ha)	PER_{in-field} below rate with ≤ 50 % effect?
<i>Coccinella septempunctata</i>	1 x 1250 mL/ha	850	yes

MAF: multiple application factor; PER: predicted environmental rate; HQ: hazard quotient; DALT: days after last treatment. Criteria values shown in bold breach the relevant trigger.

* If an LR₅₀ or ER₅₀ from a relevant extended laboratory test is available, it is considered in place of the rate with ≤ 50 % effect.

1) Tier 2 data is available for 4 species, the Tier 1 risk assessment has therefore been omitted.

For all indicator species tested the tier 2 risk assessment does not lead to an acceptable risk as the in-field PER is higher than the rates at which effects were <50%. *Coccinella septempunctata* is considered the most sensitive species. Hence, an aged residue study was run in order to demonstrate that potential for recovery is given for the in-field non-target arthropod community. In the aged residue study no effects were seen at 1250 mL/ha which is higher than the PER for the use group B (2 x 0.5 L/ha in OSR). Therefore, the risk for the in-field non-target arthropod community can be considered acceptable.

zRMS comments:

The in-field risk assessment provided in Tables 9.7-2 and 9.7-3 above is in general agreed by the zRMS. No Tier I data were generated and evaluation was based on results of Tier II studies performed with 4 species (two standard and two additional) and results of the aged residue study performed with *Coccinella septempunctata*.

The zRMS agrees that although the rate of 1250 mL/ha tested in the aged residue study was slightly lower than the effective application rate of 1275 mL/ha for use group A (single rate of 750 mL/ha multiplied by MAF of 1.7), it is not expected that rate 2% higher would lead to effects >50% after 42 or 56 days of aging, given that at 1250 mL/ha and 56 days of aging the corrected mortality was lower than in control groups and effects on reproduction were at 15% while after 42 days of aging reproductive performance in the test item groups was better than in controls.

The Applicant argued that *C. septempunctata* was the most sensitive species in Tier II studies and for this reason aged residue study performed only with this species is sufficient to demonstrate potential for recolonisation of the treated field and address the in-field risk to non-target arthropods. The zRMS does not fully agree with this statement. Of course, the endpoint for *C. septempunctata* was the lowest, but endpoints for *T. pyri* were in the same order of magnitude and in opinion of the zRMS this indicates similar sensitivity of both species to DLT+FPF EC 85. Taking this into account, aged residue study should have been also performed for *T. pyri*. In absence of the respective data, data available from the EU review of both active compounds were checked. It is noted that no relevant data for deltamethrin are available in the Review Report (6504/VI/99-final of 2002) and for this reason studies submitted for purposes of the ongoing EU renewal process were consulted. It is noted that the renewal process is not finalised yet, but the studies performed with non-target arthropods were already

peer-reviewed during the commenting period and no corrections in this area were made in the LoEP of July 2019. For flupyradifurone data reported in the EFSA Journal 2015;13(2):4020 were checked.

In case of deltamethrin, aged residue studies were performed with *T. pyri*, *A. rhopalosiphi* and *C. carnea*. No unacceptable effects of rates exceeding the maximum in-field rate of deltamethrin in DLT+FPF EC 85 (i.e. 12.75 g a.s./ha resulting from multiplication of single application rate of 7.5 g a.s./ha by MAF of 1.7) were observed after aging for 14 to 56 days.

In case of flupyradifurone aged residue studies were performed with *A. rhopalosiphi* and *O. laevigatus* at application rate of 2x250 g a.s./ha with 10 days interval, clearly exceeding maximum effective in-field rate of flupyradifurone (95.6 g a.s./ha). No unacceptable effects were observed after 42 and 56 days of aging, depending on the species. It is noted that no aged residue study was performed with *T. pyri*, which turned out to be not particularly sensitive to flupyradifurone. It is, however, noted that residue decline studies performed with flupyradifurone in order to refine the long-term risk to wild mammals resulted with maximum DT₅₀ on vegetation (monocots and dicots) not exceeding 12 days. On this basis it may be expected that the residual toxicity of flupyradifurone to *T. pyri* would be also acceptable after 56 days of aging.

Overall, based on results of aged residue studies available for individual substances and rapid dissipation of both compounds from the plant matrix the zRMS is of the opinion that the residual toxicity of DLT+FPF EC 85 for other species (and especially *T. pyri*) will not be longer than this observed in the study performed with *C. septempunctata*. On this basis it is concluded that the in-field risk from the intended uses of DLT-FPF EC 85 is sufficiently addressed.

9.9.2.2 Risk assessment for off-field exposure

Table 9.9-4: First- and higher-tier assessment of the off-field risk for non-target arthropods due to the use of DLT+FPF EC 85 in OSR (use group A)

Intended use	OSR (use group A), 2 × 0.75 L prod./ha				
Active substance/product	DLT+FPF EC 85				
Application rate	2 × 0.75 L prod./ha				
MAF	1.7				
VDF	10 (2D) / 1 (3D)				
Test species Tier 1	LR₅₀ (lab.) (mL/ha)	Drift rate (%)	PER_{off-field} (mL/ha)	CF	HQ_{off-field} criterion: HQ ≤ 2
<i>Typhlodromus pyri</i> ¹⁾	-	-	-	-	-
<i>Aphidius rhopalosiphi</i> ¹⁾	-				-
Test species Higher-tier	Rate with ≤ 50% effect* (mL/ha)	Drift rate (%)	PER_{off-field} (mL/ha)	CF	corr. PER_{off-field} with ≤ 50 % effect?
<i>Typhlodromus pyri</i>	>9.0	2.38	3.035	5	no
<i>Aphidius rhopalosiphi</i>	26.1	2.38	30.35	5	no
<i>Chrysoperla carnea</i>	>125	2.38	3.035	5	yes
<i>Coccinella septempunctata</i>	>3.9	2.38	3.035	5	no
Off-crop field studies					
Test substance	Lowest NOER	Drift rate (%)	PER_{off-field}	CF, VDF	PER_{off-field} < NOER (off-crop field studies)
Flupyradifurone SL 200	NOER = 1.7 g a.s./ha	2.38	2.27 g a.s./ha	-	no
Deltamethrin EW 15	NOER = 0.23 g a.s./ha	2.38	0.303 g a.s./ha	-	no
DLT+FPF EC 85	NOER = 4 mL/ha	2.38	30.35 mL/ha	-	no

MAF: multiple application factor; VDF: vegetation distribution factor; (corr.) PER: (corrected) predicted environmental rate; CF: conversion factor; HQ: hazard quotient. Criteria values shown in bold breach the relevant trigger.

* If an LR₅₀ or ER₅₀ from a relevant extended laboratory test is available, it is considered in place of the rate with ≤ 50 % effect.

1) Tier 2 data is available for 4 species, the Tier 1 risk assessment has therefore been omitted.

Table 9.9-5: First- and higher-tier assessment of the off-field risk for non-target arthropods due to the use of DLT+FPF EC 85 in OSR (use group B)

Intended use	OSR (use group B), 2 × 0.5 L prod./ha				
Active substance/product	DLT+FPF EC 85				
Application rate	2 × 0.5 L prod./ha				
MAF	1.7				
VDF	10 (2D) / 1 (3D)				
Test species Tier 1	LR₅₀ (lab.) (mL/ha)	Drift rate (%)	PER_{off-field} (mL/ha)	CF	HQ_{off-field} criterion: HQ ≤ 2
<i>Typhlodromus pyri</i> ¹⁾	-	-	-	-	-
<i>Aphidius rhopalosiphi</i> ¹⁾	-				-
Test species Higher-tier	Rate with ≤ 50% effect* (mL/ha)	Drift rate (%)	PER_{off-field} (mL/ha)	CF	corr. PER_{off-field} with ≤ 50 % effect?
<i>Typhlodromus pyri</i>	>9.0	2.38	2.024	5	no
<i>Aphidius rhopalosiphi</i>	26.1	2.38	20.24	5	no
<i>Chrysoperla carnea</i>	>125	2.38	2.024	5	yes
<i>Coccinella septempunctata</i>	>3.9	2.38	2.024	5	no
Off-crop field studies					
Test substance	Lowest NOER	Drift rate (%)	PER_{off-field}	CF, VDF	PER_{off-field} < NOER (off-crop field studies)
Flupyradifurone SL 200	NOER = 1.7 g a.s./ha	2.38	1.52 g a.s./ha	-	yes
Deltamethrin EW 15	NOER = 0.23 g a.s./ha	2.38	0.202 g a.s./ha	-	yes
DLT+FPF EC 85	NOER = 4 mL/ha	2.38	20.23 mL/ha	-	no

MAF: multiple application factor; VDF: vegetation distribution factor; (corr.) PER: (corrected) predicted environmental rate; CF: conversion factor; HQ: hazard quotient. Criteria values shown in bold breach the relevant trigger.

* If an LR₅₀ or ER₅₀ from a relevant extended laboratory test is available, it is considered in place of the rate with ≤ 50 % effect.

1) Tier 2 data is available for 4 species, the Tier 1 risk assessment has therefore been omitted.

For both application rates (2 x 0.75 L/ha and 2 x 0.5 L/ha; use group A and B) an acceptable risk for off-crop non-target arthropod populations could not be concluded without mitigation measures. Possible mitigation options are presented below.

zRMS comments:

The off-field risk assessment provided in Tables 9.7-4 and 9.7-5 above is in general agreed by the zRMS. No Tier I data were generated and evaluation was based on results of Tier II studies performed with 4 species (two standard and two additional), justifying consideration of correction factor of 5.

Acceptable risk could be concluded neither for higher (2x0.75 L/ha) nor lower (2x0.5 L/ha) application rates based on extended laboratory and field studies simulating the spray drift of DLT+FPF EC 85.

As already indicated in the zRMS comments in point 9.7.1 above, off-crop field studies performed with the solo formulations of deltamethrin and flupyradifurone were considered not relevant for the risk assessment performed for DLT+FPF EC 85, since field studies should be performed with the formulation in question, which is particularly important in case of formulation containing several active compounds which may have synergistic effects. Taking this into account, evaluation based on results of studies available for individual compounds was struck through in tables above.

Refinement based on risk mitigation measures is presented in point 9.7.2.4 below.

During the commenting period it was pointed out that the VDF of 5 was agreed during the CZHW in Brno in 2019 and that this value should have been used for purposes of the off-field exposure calculation. It should be, however, noted that in line with implementation schedule indicated in the Bullet points in area of ecotoxicology agreed by the CZSC in November 2021, VDF of 5 should be considered since 1st of July 2022. Furthermore, Bullet point 4 presented in this document indicates that:

The majority of MSs agreed to be in line with the EFSA Technical Report (2019) and use a VDF of 5

It should be pointed out that the EFSA Technical Report (EFSA Supporting publication 2019:EN-1673) does not indicate that currently VDF of 5 must be used in evaluations, but that VDF of 5 should be considered as an interim solution that will be reflected in the SANCO/10329/2002-rev.2 guidance document with its implementation considered further. However, the SANCO guidance document was not amended yet and this is acknowledged in the most recent version of the Working document on Risk Assessment of Plant Protection Products in the Central Zone (May 2021):

The CZSC will make an urgent request to the Commission to adjust this issue in the guidance document as soon as possible.

Therefore, from the formal point of view, VDF of 10 is still applicable and may be used for purposes of calculation of the off-field exposure.

It is also uncertain if consideration of VDF of 5 will be possible after 1st of July 2022 in case it will not be reflected in the terrestrial GD as an interim solution.

9.9.2.3 Additional higher-tier risk assessment

Not needed.

9.9.2.4 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 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 table.

Table 9.9-6: Assessment of the off-field risk for non-target arthropods due to the use of DLT+FPF EC 85 in OSR (use group A) considering risk mitigation (in-field no-spray buffer zones, and drift-reducing nozzles)

Intended use		OSR (use group A), 2 × 0.75 L prod./ha			
Active substance/product		DLT+FPF EC 85			
Application rate (L/ha)		2 × 0.75 L prod./ha (equivalent to 2 × 56.25 g FPF/ha and 2 × 7.5 g DLT/ha)			
MAF		1.7			
vdf		-			
Buffer strip (m)	Drift rate (%)	PER_{off-field} (mL/ha) (g FPF/ha) (g DLT/ha)	PER_{off-field} 50 % drift red. (mL/ha) (g FPF/ha) (g DLT/ha)	PER_{off-field} 75 % drift red. (mL/ha) (g FPF/ha) (g DLT/ha)	PER_{off-field} 90 % drift red. (mL/ha) (g FPF/ha) (g DLT/ha)
1	2.38	30.35 mL/ha 2.27 g FPF/ha 0.303 g DLT/ha	15.17 mL/ha 1.14 g FPF/ha 0.1515 g DLT/ha	7.59 mL/ha 0.568 g FPF/ha 0.0758 g DLT/ha	3.04 mL/ha 0.227 g FPF/ha 0.0303 g DLT/ha
5	0.47	5.99 mL/ha 0.449 g FPF/ha 0.060 g DLT/ha	3.00 mL/ha 0.225 g FPF/ha 0.030 g DLT/ha	1.50 mL/ha 0.113 g FPF/ha 0.015 g DLT/ha	0.599 mL/ha 0.045 g FPF/ha 0.006 g DLT/ha
10	0.24	3.06 mL/ha 0.230 g FPF/ha 0.031 g DLT/ha	1.53 mL/ha 0.115 g FPF/ha 0.015 g DLT/ha	0.765 mL/ha 0.057 g FPF/ha 0.0077 g DLT/ha	0.306 mL/ha 0.023 g FPF/ha 0.0031 g DLT/ha
Higher-tier toxicity value NOER = 4 mL product/ha NOER = 1.7 g FPF/ha NOER = 0.23 g DLT/ha		PER_{off-field} below NOER (off-crop field study)			
1		no	no	no	yes
5		no	yes	yes	yes
10		yes	yes	yes	yes

MAF: Multiple application factor; PER: Predicted environmental rates; HQ: Hazard quotient; Criteria values shown in bold breach the relevant trigger.

Values in bold indicate exceedances of the PER compared to the lowest NOER from off-crop field studies for DLT+FPF EC 85, flupyradifurone (a.s.), or deltamethrin (a.s.)

No unacceptable risk can be concluded for off-field non-target arthropod populations if 90% drift reducing nozzles or a 5 m buffer zone with 50% drift reducing nozzles or a 10 m buffer zone is considered for use group A.

Table 9.9-7: Assessment of the off-field risk for non-target arthropods due to the use of DLT+FPF EC 85 in OSR (use group B) considering risk mitigation (in-field no-spray buffer zones, and drift-reducing nozzles)

Intended use		OSR (use group B), 2 × 0.50 L prod./ha			
Active substance/product		DLT+FPF EC 85			
Application rate (L/ha)		2 × 0.50 L prod./ha (equivalent to 2 × 37.5 g FPF/ha and 2 × 5.0 g DLT/ha)			
MAF		1.7			
vdf		-			
Buffer strip (m)	Drift rate (%)	PER_{off-field} (mL/ha) (g FPF/ha) (g DLT/ha)	PER_{off-field} 50 % drift red. (mL/ha) (g FPF/ha) (g DLT/ha)	PER_{off-field} 75 % drift red. (mL/ha) (g FPF/ha) (g DLT/ha)	PER_{off-field} 90 % drift red. (mL/ha) (g FPF/ha) (g DLT/ha)
1	2.38	20.23 mL/ha 1.52 g FPF/ha 0.202 g DLT/ha	10.12 mL/ha 0.76 g FPF/ha 0.101 g DLT/ha	5.06 mL/ha 0.38 g FPF/ha 0.051 g DLT/ha	2.02 mL/ha 0.15 g FPF/ha 0.020 g DLT/ha
5	0.47	3.995 mL/ha 0.30 g FPF/ha 0.040 g DLT/ha	1.997 mL/ha 0.15 g FPF/ha 0.020 g DLT/ha	0.999 mL/ha 0.075 g FPF/ha 0.010 g DLT/ha	0.40 mL/ha 0.030 g FPF/ha 0.004 g DLT/ha
Higher-tier toxicity value NOER = 4 mL product/ha NOER = 1.7 g FPF/ha NOER = 0.23 g DLT/ha		PER_{off-field} below NOER (off-crop field study)			
1		no	no	no	yes
5		yes	yes	yes	yes

MAF: Multiple application factor; PER: Predicted environmental rates; HQ: Hazard quotient; Criteria values shown in bold breach the relevant trigger.

Values in bold indicate exceedances of the PER compared to the lowest NOER from off-crop field studies for DLT+FPF EC 85, flupyradifurone (a.s.), or deltamethrin (a.s.)

No unacceptable risk can be concluded for off-field non-target arthropod populations if 90% drift reducing nozzles or a 5 m buffer zone is considered for use group B.

zRMS comments:

The zRMS agrees with calculations presented in Tables 9.7-6 and 9.7-7 above and performed with consideration of results of off-crop field study performed with DLT+FPF EC 85 in the Central Zone and various mitigation options (buffer zones, drift reduction and combination of both).

Based on the performed evaluation following risk mitigation measures must be respected in order to protect the off-crop population of non-target arthropods following uses of DLT+FPF EC 85:

- For application to oilseed rape (winter and spring) at BBCH 30-79 at 2x0.75 L/ha with 14 days interval:
 - 90% drift reduction, or
 - 5 m unsprayed buffer zone to non-agricultural land combined with 50% drift reduction, or
 - 10 m unsprayed buffer zone to non-agricultural land.
- For application to oilseed rape (winter and spring) at BBCH 30-79 at 2x0.50 L/ha with 14 days interval:
 - 90% drift reduction, or
 - 5 m unsprayed buffer zone to non-agricultural land.

Evaluation based on off-crop field studies performed with solo formulation of individual substances was not taken into account as not relevant for risk assessment for DLT+FPF EC 85 and was thus struck through in tables above for clarity.

9.9.3 Overall conclusions

No unacceptable risk can be concluded from the in-field risk assessment for use group A and B following application of up to 2 x 0.75 L/ha in OSR.

An acceptable off-crop risk can be concluded following the application of drift reducing measures as outlined below.

Group	Mitigation
OSR (use group A) 2 × 0.75 L/ha, 14 d interval	No-spray buffer zone of 10m
	No-spray buffer zone of 5 m with 50% drn
	90% drn without additional buffer
OSR (use group B) 2 × 0.5 L/ha, 14 d interval	No-spray buffer zone of 5m
	90% drn without additional buffer

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

9.10.1 Toxicity data

Studies on the toxicity to earthworms and other non-target soil organisms (meso- and macrofauna) have been carried out with the active substances and 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).

Effects on earthworms and other non-target soil organisms (meso- and macrofauna) of 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 9.10-1: Endpoints and effect values relevant for the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna)

Species	Substance	Exposure System	Results	Reference
<i>Eisenia fetida</i>	Deltamethrin a.s.	Acute 14 d 10 % peat	LC ₅₀ > 1290 mg a.s./kg dw	EC Review Report 6504/VI/99-final (2002), 1-78 Monograph Annex B Ecotox
<i>Eisenia fetida</i>	Deltamethrin (tested as Deltamethrin EC 100)	Mixed into substrate 56 d, chronic 10 % peat content	NOEC = 18 mg prod./kg dw equivalent to 1.89 mg a.s./kg dw ^a NOEC _{corr} = 0.945 mg a.s./kg dw ^a	Appendix 2 Friedrich, S.; 2014; M-494315-01-1
<i>Folsomia candida</i>	Deltamethrin (tested as Deltamethrin EC 100)	Mixed into substrate 28 d, chronic 5 % peat content	NOEC _{Repro} = 444 mg prod./kg dw equivalent to 46.62 mg a.s./kg dw ^a NOEC _{Repro,corr} = 23.31 mg a.s./kg dw ^a	Appendix 2 Friedrich, S.; 2014; M-494027-01-1
<i>Hypoaspis aculeifer</i>	Deltamethrin (tested as Deltamethrin EC 100)	Mixed into substrate 14 d, chronic 5 % peat content	NOEC = 18 mg prod./kg dw equivalent to 1.89 mg a.s./kg dw ^a NOEC _{corr} = 0.945 mg a.s./kg dw ^a	Appendix 2 Schulz, L.; 2014; M-495034-01-1
<i>Eisenia fetida</i>	Flupyradifurone	Mixed into substrate 14 d, acute 10% organic content	LC ₅₀ = 185.6 mg a.s./kg dw	EFSA Journal 2015;13(2):4020
<i>Eisenia fetida</i>	Flupyradifurone (tested as BYI 02960 SL 200)	Mixed into substrate 14 d, acute 5% organic content	LC ₅₀ = 121 mg a.s./kg dw	EFSA Journal 2015;13(2):4020
<i>Eisenia fetida</i>	Flupyradifurone (tested as BYI 02960 SL 200)	Mixed into substrate 56 d, chronic 10% organic content	NOEC = 1.5 mg a.s./kg dw	EFSA Journal 2015;13(2):4020
<i>Eisenia fetida</i>	Difluoroacetic acid	Mixed into substrate 14 d, acute 10% organic content	LC ₅₀ > 958 mg/kg dw	EFSA Journal 2015;13(2):4020
<i>Eisenia fetida</i>	Difluoroacetic acid	Mixed into substrate 56 d, chronic 10% organic content	NOEC = 59 mg/kg dw	EFSA Journal 2015;13(2):4020
<i>Eisenia fetida</i>	6-CNA	Mixed into substrate 14 d, acute 10% organic content	LC ₅₀ > 1000 mg/kg dw	EFSA Journal 2015;13(2):4020
<i>Eisenia fetida</i>	6-CNA	Mixed into substrate 56 d, chronic 10% organic content	NOEC = 95 mg/kg dw	EFSA Journal 2015;13(2):4020

Species	Substance	Exposure System	Results	Reference
<i>Hypoaspis aculeifer</i>	Flupyradifurone (tested as BYI 02960 SL 200)	Mixed into substrate 28 d, chronic 5% organic content	NOEC ≥ 170 mg a.s./kg dw	EFSA Journal 2015;13(2):4020
<i>Hypoaspis aculeifer</i>	Difluoroacetic acid	Mixed into substrate 14 d, chronic 5% organic content	NOEC ≥ 958 mg/kg dw	EFSA Journal 2015;13(2):4020
<i>Hypoaspis aculeifer</i>	6-CNA	Mixed into substrate 14 d, chronic 5% organic content	NOEC ≥ 100 mg/kg dw	EFSA Journal 2015;13(2):4020
<i>Folsomia candida</i>	Flupyradifurone (tested as BYI 02960 SL 200)	Mixed into substrate 28 d, chronic 5% organic content	NOEC = 1.44 mg a.s./kg dw	EFSA Journal 2015;13(2):4020
<i>Folsomia candida</i>	Difluoroacetic acid	Mixed into substrate 28 14 d, chronic 5% organic content	NOEC ≥ 95.8 mg/kg dw	EFSA Journal 2015;13(2):4020
<i>Folsomia candida</i>	6-CNA	Mixed into substrate 28 14 d, chronic 5% organic content	NOEC = 90 mg/kg dw	EFSA Journal 2015;13(2):4020
<i>Eisenia fetida</i>	DLT + FPF EC 85	Mixed into substrate, 56 d, chronic 10 % peat content	NOEC = 14.1 mg prod./kg dw (1.06 mg a.s./kg dw) EC ₁₀ = 10.7 mg prod./kg dw (0.803 mg a.s./kg dw) LOEC = 25 mg prod./kg dw	Appendix 2 Friedrich, S.; 2015; M-528187-01-1
<i>Folsomia candida</i>	DLT + FPF EC 85	Mixed into substrate, 28 d, chronic 5 % peat content	NOEC= 14.1 mg prod./kg dws (1.06 mg a.s./kg dw) EC ₁₀ = 15.7 mg prod./kg dw (1.18 mg a.s./kg dw) LOEC = 25 mg prod./kg dw	Appendix 2 Friedrich, S.; 2015; M-515381-01-1
<i>Hypoaspis aculeifer</i>	DLT + FPF EC 85	Mixed into substrate, 14 d, chronic 5 % peat content	NOEC _{Reproduction} = 198 mg prod./kg soil dw (14.83 mg a.s./kg dw) EC ₁₀ = 253.4 10.7 mg prod./kg dw (18.97 mg a.s./kg dw) LOEC _{Reproduction} = 296 mg prod./kg soil dw	Appendix 2 Schulz, L.; 2015; M-519953-01-1

Litter bag test

Litter bag study (overspray): Soil treated with 150 g a.s./ha for plateau concentration (incorporated) + the annual rate of 300 g a.s./ha (oversprayed), both with product BYI 02960 SL 200 G 3. At a measured initial concentration of 237 µg a.s./kg dry soil no statistically significant effects were found on soil litter degradation 217 d after treatment.
Litter bag study (seed treatment): Soil treated with 150 g a.s./ha for plateau concentration (incorporated, product BYI 02960 SL 200 G 3) + the annual rate of 265 g a.s./ha (by sowing of treated wheat seed, product BYI 02960 FS 480 G). At a measured initial concentration of 243 µg a.s./kg dry soil no statistically significant effects were found on soil litter degradation 217 d after treatment.

* Corrected value derived by dividing the endpoint by a factor of 2 in accordance with the EPPO earthworm scheme 2002.

^a Based on an analysed content of 10.5% (w/w) a.s. within the product

zRMS comments:

Toxicity data for particular active compounds and their metabolites reported in Table 9.8-1 are in line with EU agreed endpoints reported in the Review Report for deltamethrin (6504/VI/99-final, 2002) and EFSA Journal 2015;13(2):4020 for flupyradifurone. It is, however, noted that part of the chronic toxicity data was derived from studies performed with the representative solo formulations of both active substances and is thus not relevant for the risk assessment performed for DLT+FPF EC 85, containing two active compounds. Furthermore, acute toxicity studies with earthworms and litter bag studies are no longer a data requirement.

Taking this into account, endpoints not relevant for the risk assessment for DLT+FPF EC 85 were struck through in the table above.

Since no long-term toxicity data for soil macro- and meso-fauna were available from the first EU review of deltamethrin, the Applicant submitted studies performed with a solo formulation. However, as already mentioned, results of studies performed with a solo formulation are not relevant for the risk assessment for the formulated product containing 2 active compounds and results of studies performed with the formulation in question should be considered in calculation of TER values.

The studies on effects of DLT+FPF EC 85 to earthworms, springtails and soil mite were evaluated by the zRMS and considered acceptable. For details of evaluation and zRMS comments on the studies, please refer to Appendix 2.

Since all required studies for DLT+FPF EC 85 are available, they are considered more relevant for the risk assessment than studies performed with solo formulations of individual active substances, as they cover the combined toxicity of the product.

No toxicity data for deltamethrin soil metabolite Br₂CA were available. It is, however, noted that in the course of the ongoing EU renewal process of deltamethrin studies on toxicity of Br₂CA to soil macro- and meso-fauna were available and resulted with following endpoints:

- Earthworms NOEC_{corr} = 5 mg pm/kg dws
- *Folsomia candida* NOEC_{corr} = 50 mg pm/kg dws
- *Hypoaspis aculeifer* NOEC_{corr} = 50 mg pm/kg dws

Although the renewal process was not finalised yet, changes in mentioned above endpoints are not expected since they were obviously agreed during the commenting phase. Taking this into account they may be used in the risk assessment performed for DLT+FPF EC 85.

In line with EFSA Supporting publication 2015:EN-924, the endpoints must be corrected when log Pow is greater than 2, irrespective of the peat content in soil used in the study. In consequence, corrected endpoints obtained from all studies performed with the formulated product should be used in the risk assessment due to deltamethrin log Pow >2.

9.10.1.1 Justification for new endpoints

For flupyradifurone no deviation from the EU agreed endpoints.

For deltamethrin studies with the formulation Deltamethrin EC 100 were performed and are submitted with this application to fulfil current data requirements, the endpoints from these studies were used for risk assessment.

zRMS comments:

It has to be noted that the data requirements for the active substance should be fulfilled during the EU review process, while at the level of the product authorisation data requirements for the formulation must be fulfilled which was done by submission of respective studies performed with DLT+FPF EC 85.

Since in line with the Commission Regulation (EU) No 283/2013, to address the risk to soil organisms studies performed with the formulated products are more relevant, no specific data for the active compounds (also tested as solo formulations) are deemed necessary. For this reason additional studies with the solo formulation of deltamethrin were not validated by the zRMS as being not necessary for the risk assessment for DLT+FPF EC 85, which was based on endpoints derived from studies performed with the formulation in question.

9.10.2 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).

9.10.2.1 First-tier risk assessment

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group A also covers the risk for earthworms and other non-target soil organisms (meso- and macrofauna) from all other intended uses in group B (see 9.3.2).

Table 9.10-2: First-tier assessment of the acute and chronic risk for earthworms and other non-target soil organisms (meso- and macrofauna) due to the use of DLT+FPF EC 85 in OSR (use group A)

Intended use		Spray application-OSR	
Acute effects on earthworms			
Product/active substance	LC ₅₀ (mg/kg-dw)	PEC _{soil} (mg/kg-dw)	TER _{crit} (criterion TER ≥ 10)
Chronic effects on earthworms			
Product/active substance	NOEC (mg/kg-dw)	PEC _{soil} (mg/kg-dw)	TER _{crit} (criterion TER ≥ 5)
Deltamethrin	0.945 ^A	0.003	315
Flupyradifurone	1.5	0.034	44.1
DFA	59	0.003	19667
6-CNA	95	0.002	47500
DLT+FPF EC 58	14.1	0.463	30.5
Chronic effects on other soil macro- and mesofauna			
Product/active substance	NOEC (mg/kg-dw)	PEC _{soil} (mg/kg-dw)	TER _{crit} (criterion TER ≥ 5)
Deltamethrin (<i>F. candida</i>)	23.31 ^A	0.003	7770
Deltamethrin (<i>H. aculeifer</i>)	0.945 ^A	0.003	315
Flupyradifurone (<i>H. aculeifer</i>)	≥ 170	0.034	5000
DFA (<i>H. aculeifer</i>)	≥ 958	0.003	319333
6-CNA (<i>H. aculeifer</i>)	≥ 100	0.002	50000
Flupyradifurone (<i>F. candida</i>)	1.44	0.034	42.4
DFA (<i>F. candida</i>)	≥ 95.8	0.003	31933
6-CNA (<i>F. candida</i>)	90	0.002	54000
DLT+FPF EC 58 (<i>F. candida</i>)	14.1	0.463	30.5
DLT+FPF EC 58 (<i>H. aculeifer</i>)	198	0.463	428

^ACorrected value derived by dividing the endpoint by factor of 2 in accordance with EPPO earthworm scheme 2002.

All TER exceed the critical trigger value of 5. Thus, an acceptable risk can be concluded for non-target soil meso- and macrofauna following the application of up to 2 x 0.75 L product/ha in OSR.

zRMS comments:

The risk assessment for deltamethrin and flupyradifurone provided in Table 9.8-2 above was based on endpoints derived from studies performed with the solo formulations of particular active compounds, not necessary for evaluation performed for DLT+FPF EC 85. Furthermore, for DLT+FPF EC 85 not corrected endpoints were used and deltamethrin metabolite Br₂CA was not considered. In addition to that, the soil exposure for some compounds agreed in area of Section 8 is different than this used by the Applicant. Since multiple corrections

resulting from difference between agreed and used data would make Table 9.8-2 not transparent, the table was struck through and the relevant risk assessment is performed by the zRMS in table below.

Please note that the initial PEC_{SOIL} for the formulation does not account for potential accumulation of flupyradifurone in soil. For this reason the risk assessment for DLT+FPF EC 85 should be performed with consideration of PEC_{SOIL,MIX}, calculated as the sum of initial PEC_{SOIL} for deltamethrin and accumulation PEC_{SOIL} for flupyradifurone. In order to aid calculation of TER values, formulation endpoints were expressed in terms of the sum of active substances, calculated with consideration of the analysed content of particular compounds in formulation used for testing. In calculations either NOEC or EC₁₀ values were used, whichever was lower.

For metabolite Br₂CA endpoints derived in the course of the ongoing renewal process were used, as indicated in the zRMS comments in point 9.8.1 above.

Intended use	Spray application OSR, BBCH 30-79, 2x0.75 L/ha, 14 days interval (risk envelope)		
Product/active substance	NOEC / EC₁₀ (mg/kg dw)	PEC_{soil} (mg/kg dw)	TER_{it} (criterion TER ≥ 5)
Risk assessment for earthworms			
Br ₂ CA (DLT metabolite)	5.0 *	<0.001	>5000
DFA (FPF metabolite)	59	0.003	19667
6-CNA (FPF metabolite)	95	0.0025	38000
DLT+FPF EC 58	0.402 *	0.0432	9.3
Risk assessment for <i>Folsomia candida</i>			
Br ₂ CA (<i>F. candida</i>) (DLT metabolite)	50.0 *	<0.001	>50000
DFA (<i>F. candida</i>)	≥ 95.8	0.003	31933
6-CNA (<i>F. candida</i>)	90	0.0025	36000
DLT+FPF EC 58 (<i>F. candida</i>)	0.53 *	0.0432	12.3
Risk assessment for <i>Hypoaspis aculeifer</i>			
Br ₂ CA (<i>H. aculeifer</i>) (DLT metabolite)	50.0 *	<0.001	>50000
DFA (<i>H. aculeifer</i>) (FPF metabolite)	≥ 958	0.003	319333
6-CNA (<i>H. aculeifer</i>) (FPF metabolite)	≥ 100	0.0025	40000
DLT+FPF EC 58 (<i>H. aculeifer</i>)	7.415 *	0.0432	171.6

* Corrected value derived by dividing the endpoint by factor of 2 in accordance with EFSA Supporting publication 2015:EN-924

Based on the above calculations, acceptable risk to soil macro- and meso-fauna may be concluded from all intended uses of DLT+FPF EC 85.

9.10.2.2 Higher-tier risk assessment

Not relevant.

9.10.3 Overall conclusions

Based on the performed risk assessment, ~~As demonstrated by chronic studies,~~ no unacceptable effects on earthworms and other soil macro-organisms are to be expected from the application of the product according to the proposed use pattern.

9.11 Effects on soil microbial activity (KCP 10.5)

9.11.1 Toxicity data

Studies on effects soil microorganisms have been carried out with the active substances and relevant metabolites and the formulation deltamethrin + flupyradifurone EC 85. Full details of this studies are provided in the respective EU DAR and related documents as well as in Appendix 2 of this document (new studies). All PECsoil values are given in Section 8 of the core assessment.

Table 9.11-1: Endpoints and effect values relevant for the risk assessment for soil microorganisms

Endpoint	Substance	Exposure System	Results	Reference
N-mineralisation	Deltamethrin tech.	28 d, loamy sand soil and silty loam soil	No unacceptable effects on N-transformation at 375 g a.s./ha (0.5 mg a.s./kg dw)	EC Review Report 6504/ VI/99- final (2002), 1-78 Monograph Annex B Ecotox.
C-mineralisation	Deltamethrin tech.	28 d and 56 d, loamy sand	No unacceptable effects on C-transformation at 375 g a.s./ha (0.50 mg a.s./dw)	EC Review Report 6504/ VI/99- final (2002), 1-78 Monograph Annex B Ecotox.
N-mineralisation	Flupyradifurone	28 d, aerobic, loamy sand	< 25% effect at day 28 at 3.8 mg a.s./kg soil	EFSA Journal 2015;13(2):4020
C-mineralisation	Flupyradifurone	28 d, aerobic, loamy sand	< 25% effect at day 28 at 3.8 mg a.s./kg soil	EFSA Journal 2015;13(2):4020
N-mineralisation	6-CNA	28 d, aerobic, loamy sand	< 25% effect at day 28 at 1.33 mg/kg soil	EFSA Journal 2015;13(2):4020
N-mineralisation	DLT + FPF EC 85	28 d	No effects > 25% at 9.64 mg prod./kg dw (= 6.25 L prod./ha) (0.722 mg a.s./kg dw) no adverse effects	Appendix 2 Schulz, L.: 2015; M-515385-01-1

zRMS comments:

Information regarding effects of particular active compounds and metabolites on nitrogen mineralisation is in line with EU agreed data reported in the Review Report for deltamethrin (6504/VI/99-final, 2002) and EFSA Journal 2015;13(2):4020 for flupyradifurone.

No toxicity data for deltamethrin soil metabolite Br₂CA were available. It is, however, noted that in the EU agreed soil metabolism studies maximum occurrence of this compound was observed at 14 d of the study and it may be expected that sufficient amount of Br₂CA was formed in the 28 d study. Therefore results of the study performed with DLT+FPF EC 85 cover also effects resulting from exposure to metabolite. In addition to that, in the course of the ongoing EU renewal process of deltamethrin studies on toxicity of Br₂CA to soil microorganisms were available and no effects on soil nitrogen transformation were observed up to 0.24 mg pm/kg dw.

No endpoint for flupyradifurone soil metabolite DFA is available in EFSA Journal 2015;13(2):4020, most probably due to availability of litter bag studies which covered effects from the active substance and its metabolites. However, litter bag studies are no longer considered in the risk assessment for soil microorganisms.

As no information on the time of maximum formation of DFA is available in the LoEP, the DAR for flupyradifurone (December 2014) was consulted. In all soils the peak occurrence of DFA was observed at 45-48 days of incubation and for this reason the study with DLT+FPF EC 85 was too short to assure sufficient exposure to this compound. In absence of any relevant data the risk from DFA has been addressed with consideration of 10 times toxicity of the parent.

Study on effects of the formulated product on soil nitrogen transformation was evaluated and agreed by the zRMS. For details of the evaluation, please refer to Appendix 2.

Information regarding effects on carbon mineralisation is no longer a data requirement and for this reason is struck through in Table 9.9-1.

9.11.1.1 Justification for new endpoints

No deviation from the EU agreed endpoints.

9.11.2 Risk assessment

The evaluation of the risk for soil microorganisms 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. Here, the assessment for the use group A also covers the risk for the soil microorganisms from all other intended uses in group B (see 9.3.2).

Table 9.11-2: Assessment of the risk for effects on soil micro-organisms due to the use of DLT+FPF EC 85 in OSR (use group A)

DLT+FPF EC 85 in OSR (use group A)			
Intended use	Spray application OSR		
N-mineralisation			
Product/active substance	Max. conc. with effects ≤ 25 % (mg/kg dw)	PEC _{soil} (mg/kg dw)	Risk acceptable?
Deltamethrin	0.5 (at 28 d)	0.0034 0.003	yes
Br ₂ CA	0.24 (at 28 d)	<0.001	yes
Flupyradifurone	3.8 (at 28 d)	0.0398 0.034	yes
6-CNA	1.33 (at 28 d)	0.0025 0.002	yes
DFA	0.133 *	0.003	yes
DLT + FPF EC 85	0.722 (at 28 d) ** 9.64 (at 28 d)	0.0432 ** 0.463	yes
C-mineralisation			
not required			

* 10 times toxicity of the parent assumed as a worst case

** Formulation endpoint and exposure expressed in terms of the sum of active compounds

zRMS comments:

The risk assessment provided in Table 9.9-2 above was amended accordingly with consideration of the soil exposure agreed in area of Section 8. Furthermore, the risk assessment for metabolites Br₂CA and DFA has been added.

It was also noted that the initial PEC_{SOIL} for the formulation does not account for potential accumulation of flupyradifurone in soil. For this reason the risk assessment for DLT+FPF EC 85 should be performed with consideration of PEC_{SOIL,MIX}, calculated as the sum of initial PEC_{SOIL} for deltamethrin and accumulation PEC_{SOIL} for flupyradifurone and endpoint expressed in terms of sum of active substances. Respective corrections were introduced in Table 9.9-2 above.

Overall, performed evaluation demonstrated that no adverse effects on soil microbial activity are expected from all intended uses of DLT+FPF EC 85.

9.11.3 Overall conclusions

The risk assessment indicates that no adverse effects on soil micro-organisms are to be expected when the product is applied according to the proposed use pattern.

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

9.12.1 Toxicity data

Studies on the toxicity to non-target terrestrial plants have been carried out with the active substances and the formulation. 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).

Table 9.12-1: Endpoints and effect values relevant for the risk assessment for non-target terrestrial plants

Species	Substance	Exposure System	Results	Reference
<i>Beta vulgaris</i> _d (sugar beet) ^A , <i>Brassica napus</i> _d (rape) ^B , <i>Cucumis sativus</i> _d (cucumber) ^C , <i>Glycine max</i> _d (soybean) ^D , <i>Helianthus annuus</i> _d (sunflower) ^E , <i>Lycopersicon esculentum</i> _d (tomato) ^F , <i>Allium cepa</i> _m (onion) ^G , <i>Hordeum vulgare</i> _m (barley) ^H , <i>Triticum aestivum</i> _m (wheat) ^I , <i>Zea mays</i> _m (corn) ^J	DLT + FPF EC 85	21 d, Vegetative vigour	A,B, F statistically significant inhibition of shoot dry weight at 1250 mL prod./ha (<50%) Other plants: No statistically significant effects ER ₅₀ >1250 mL product/ha	Appendix 2 Ripperger, D.; 2016; M-554604-01-1
<i>Beta vulgaris</i> _d (sugarbeet) ^A , <i>Brassica napus</i> _d (rape) ^B , <i>Cucumis sativus</i> _d (cucumber) ^C , <i>Glycine max</i> _d (soybean) ^D , <i>Helianthus annuus</i> _d (sunflower) ^E , <i>Lycopersicon esculentum</i> _d (tomato) ^F <i>Allium cepa</i> _m (onion) ^G , <i>Hordeum vulgare</i> _m (barley) ^H , <i>Triticum aestivum</i> _m (wheat) ^I , <i>Zea mays</i> _m (maize) ^J	DLT + FPF EC 85	21 d, Seedling emergence	C,F inhibition of shoot dry weight at 1250 mL prod./ha (<50%) Other plants: No statistically significant effects A-J No statistically significant effects on seedling emergence at 1250 mL prod./ha A-J No mortality occurred at 1250 mL prod./ha A-J No symptoms of phytotoxicity at 1250 mL prod./ha ER ₅₀ >1250 mL product/ha	Appendix 2 Ripperger, D.; 2016; M-554592-01-1

m: monocotyledonous; d: dicotyledonous

zRMS comments:

Studies on toxicity of DLT+FPF EC 85 to non-target terrestrial plants were evaluated and agreed by the zRMS. For details of the evaluation, please refer to Appendix 2. Table above was amended to provide clear information on the derived endpoints.

9.12.1.1 Justification for new endpoints

Studies with the formulation DLT+FPF EC 85 were performed and are submitted with this application.

9.12.2 Risk assessment

9.12.2.1 Tier-1 risk assessment (based screening data)

Not relevant.

9.12.2.2 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.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group A also covers the risk for non-target terrestrial plants from all other intended uses in group B (see 9.3.2).

Table 9.12-2: Assessment of the risk for non-target plants due to the use of DLT+FPF EC 85 in OSR (use group A)

Intended use		Spray application in OSR		
Active substance/product		DLT + FPF EC 85		
Application rate (mL/ha)		2 × 750		
MAF		1.0 Justification: At the recent Pesticide Peer Review Meeting 133 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	ER₅₀ (mL/ha)	Drift rate	PER_{off-field} (g/ha)	TER criterion: TER ≥ 5
All species tested	1250	2.77 2.38	20.8 17.85	60.1 70.0

MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

zRMS comments:

zRMS agrees with the Applicant that currently consideration of MAF value in the risk assessment for NTTP is not required. However, as only single use is considered, the spray drift of 2.77% for single use should be taken into account. The risk assessment in Table 9.10-2 has been amended accordingly.

Overall, acceptable risk to non-target terrestrial plants may be concluded from all intended uses of DLT+FPF EC 85 with no need for risk mitigation measures.

9.12.2.3 Higher-tier risk assessment

Not relevant.

9.12.2.4 Risk mitigation measures

No risk mitigation needed.

9.12.3 Overall conclusions

The TER values for the risk envelope approach considering the highest application rate (2 x 0.75 L prod./ha) and the highest drift rate for OSR is above the trigger of 5 for the Tier 2 risk assessment. Accordingly, acceptable risk from the recommended uses is concluded. ~~use of the product as recommended is considered to be safe.~~

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

No further information is available or considered to be necessary.

9.14 Monitoring data (KCP 10.8)

No data available.


9.15 Classification and Labelling

Reference:	KCP Section 10/01
Title:	DLT+FPF EC 10+75 G
Report:	Anon.; 2019; M-567053-03-1
Guideline(s):	--
Deviations:	--
GLP/GEP:	no
Acceptability:	Acceptable
Duplication (if vertebrate study):	

CLASSIFICATION

Hazard class(es), categories:	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
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LABELLING

Signal Word :	Danger 
Hazard statement	H 410: Very toxic to aquatic life with long lasting effects EUH401: To avoid risks to human health and the environment, comply with the instruction for use
Precautionary statement	P501 Dispose of contents/container in accordance with local regulation P391: Collect spillage

zRMS comments:

Classification provided above is agreed by the zRMS. The precautionary statement P391 has been added as being mandatory for mixtures classified as H410.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Owner
KCP Section 10 / 01 ... also filed: KCP Section 12 / 01	Anon.	2019	DLT+FPF EC 10+75 G Report No.: M-567053-03-1 Bayer AG, Leverkusen, Germany GLP/GEP: n.a. unpublished	No	Bayer
KCP 10.1.1 / 01 ... also filed: KCP 10.1.2 / 01 KCP 10.2 / 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
KCP 10.1.2 / 01 ... also filed: KCP 10.1.1 / 01 KCP 10.2 / 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
KCP 10.2 / 01 ... also filed: KCP 10.1.1 / 01 KCP 10.1.2 / 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
KCP 10.2 / 02	[REDACTED]	2008	Refined risk assessment for effects of Deltamethrin to fish Report No.: RA07-046-2a, Edition Number: M-292027-02-1 [REDACTED] GLP/GEP: n.a. unpublished	Yes	Bayer
KCP 10.2.1 / 01 ... also filed: KCP 5.1.2.6 / 01	[REDACTED]	2001	Acute toxicity to Oncorhynchus mykiss (rainbow trout) AE F108565 (metabolite of deltamethrin) substance, pure Code: AE F108565 00 1B99 0001 Report No.: C010902, Edition Number: M-199816-01-1 [REDACTED] GLP/GEP: Yes unpublished	Yes	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 / 02 ... also filed: KCP 5.1.2.6 / 06	Sowig, P.; Gosch, H.	2001	Acute toxicity to Daphnia magna (Waterflea) AE F108565 (Metabolite of deltamethrin) substance, pure Code: AE F108565 00 1B99 0001 Report No.: C010889, Edition Number: M-199793-01-1 Aventis CropScience GmbH, Frankfurt am Main, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 10.2.1 / 07	[REDACTED]	2020a	Deltamethrin + flupyradifurone EC85 (10+75 g/L): Acute toxicity to rainbow trout (Oncorhynchus mykiss) in a 96-hour semi-static test Report No.: EBRV0196, Edition Number: M-679497-01-1 [REDACTED] GLP/GEP: Yes unpublished	Yes	Bayer
KCP 10.2.1 / 08	Bebon, R.; Sonntag, F.	2020b	Deltamethrin + flupyradifurone EC85 (10+75 g/L): Acute toxicity to Daphnia magna in a semi-static 48-hour immobilisation test Report No.: EBRV0195, Edition Number: M-686370-01-1 ibacon GmbH, Rossdorf, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 10.2.1 / 09	Bebon, R.; Sonntag, F.	2020c	Deltamethrin + flupyradifurone EC85 (10+75 g/L): Acute toxicity to larvae of Chironomus riparius in a semi-static 48-hour immobilisation test Report No.: EBRV0194, Edition Number: M-686369-01-1 ibacon GmbH, Rossdorf, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 10.3.1.1 / 01	Schmitzer, S.	2015	Deltamethrin + flupyradifurone EC 85 (10+75) G: Effects (acute contact and oral) on honey bees (Apis mellifera L.) in the laboratory - Final report Report No.: 99811035, Edition Number: M-542907-01-1 IBACON GmbH, Rossdorf, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 10.3.1.5 / 05	Taenzler, V.	2017	Assessment of side effects of deltamethrin + flupyradifurone EC085 on honey bees (Apis mellifera L.) under semi-field conditions - Tunnel test - Report No.: 113331037, Edition Number: M-598914-01-1 IBACON GmbH, Rossdorf, 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 10.3.1.5 / 08	Miles, M., Murakami, L.	2021	Sivanto Energy: A detailed evaluation of results obtained during colony assessments in the study by Taenzler (2017, M-598914-01-1) Report No.: BEES-211206, Edition Number: M-781941-01-1 Bayer AG, Crop Science Division, Environmental Safety GLP/GEP: No, calculation unpublished	No	Bayer
KCP 10.3.2.2 / 01	Waibel, J.	2018	Toxicity to the ladybird beetle <i>Coccinella septempunctata</i> (Coleoptera: Coccinellidae) using an extended laboratory test with aged residues on apple - flupyradifurone + deltamethrin EC 85 (75+10 g/L) Report No.: CW16/016, Edition Number: M-614308-01-1 Bayer AG, Crop Science Division, Frankfurt am Main, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 10.3.2.2 / 02	Mueller, R. U.	2015	Toxicity to the green lacewing <i>Chrysoperla carnea</i> (Neuroptera: Chrysopidae) using an extended laboratory test on bean flupyradifurone + deltamethrin EC 85 (75+10 g/L) Report No.: CW15/008, Edition Number: M-539469-01-1 Bayer CropScience AG, Frankfurt am Main, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 10.3.2.2 / 03	Moll, M.	2015	Flupyradifurone + deltamethrin EC 85 (75 + 10 g/L): Effects on the ladybird beetle - <i>Coccinella septempunctata</i> , extended laboratory study - Dose response test - Report No.: 101151012, Edition Number: M-530897-01-1 IBACON GmbH, Rossdorf, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 10.3.2.2 / 04	Mueller, R. U.	2015	Toxicity to the parasitoid wasp <i>Aphidius rhopalosiphi</i> (Hymenoptera: Braconidae) using an extended laboratory test on barley flupyradifurone + deltamethrin EC 85 (75+10 g/L) Report No.: CW15/006, Edition Number: M-539457-01-1 Bayer CropScience AG, Frankfurt am Main, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 10.3.2.2 / 05	Mueller, R. U.	2015	Toxicity to the predatory mite <i>Typhlodromus pyri</i> (Acari: Phytoseiidae) using an extended laboratory test on bean flupyradifurone + deltamethrin EC 85 (75+10 g/L) Report No.: CW15/005, Edition Number: M-539453-01-1 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 10.3.2.4 / 03	Aldershof, S.; Bakker, F.	2019	A field study to assess the effects of deltamethrin + flupyradifurone EC 85 (10+75 g/L) on the non-target, surface- and plant-dwelling, arthropod fauna of a grassland habitat (off-crop) in The Netherlands during spring/summer Report No.: B168FFN, Edition Number: M-661092-01-1 Eurofins MITOX, Amsterdam, Netherlands GLP/GEP: Yes unpublished	No	Bayer
KCP 10.3.2.4 / 04	Aldershof, S.; Bakker, F.	2019	A field study to assess the effects of deltamethrin + flupyradifurone EC 85 (10+75 g/L) on the non-target, surface- and plant-dwelling, arthropod fauna of a grassland habitat (off-crop) in SW France during spring/summer Report No.: B169FFN, Edition Number: M-661091-01-1 Eurofins MITOX, Amsterdam, Netherlands GLP/GEP: Yes unpublished	No	Bayer
KCP 10.4.1.1 / 02	Friedrich, S.	2015	Deltamethrin + flupyradifurone EC 85 (10+75) G: Sublethal toxicity to the earthworm Eisenia fetida in artificial soil Report No.: 15 10 48 071 S, Edition Number: M-528187-01-1 BioChem agrar GmbH, Gerichshain, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 10.4.2.1 / 03	Friedrich, S.	2015	Deltamethrin + flupyradifurone EC 85 (10+75) G: Effects on the reproduction of the collembolan Folsomia candida Report No.: 15 10 48 069 S, Edition Number: M-515381-01-1 BioChem agrar GmbH, Gerichshain, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 10.4.2.1 / 04	Schulz, L.	2015	Deltamethrin + flupyradifurone EC 85 (10+75) G: Effects on the reproduction of the predatory mite Hypoaspis aculeifer Report No.: 15 10 48 070 S, Edition Number: M-519953-01-1 BioChem agrar GmbH, Gerichshain, 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 10.5 / 01	Schulz, L.	2015	Deltamethrin + flupyradifurone EC 85 (10+75) G: Effects on the activity of soil microflora (Nitrogen transformation test) Report No.: 15 10 48 025 N, Edition Number: M-515385-01-1 BioChem agrar GmbH, Gerichshain, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 10.6.2 / 01 ... also filed: KCP 6.4 / 04 KCP 6.5.2 / 01	Ripperger, D.	2016	Deltamethrin + flupyradifurone EC 85 (10+75 g/L): Effects on the vegetative vigour of non-target terrestrial plant species under greenhouse conditions Report No.: S15-01671, Edition Number: M-554604-01-1 Eurofins Agrosience Services EcoChem GmbH, Niefern-Oeschelbronn, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 10.6.2 / 02 ... also filed: KCP 6.4 / 05 KCP 6.5.1 / 01	Ripperger, D.	2016	Deltamethrin + flupyradifurone EC 85 (10+75 g/L): Effects on the seedling emergence of non-target terrestrial plant species under greenhouse conditions Report No.: S15-01670, Edition Number: M-554592-01-1 Eurofins Agrosience Services EcoChem GmbH, Niefern-Oeschelbronn, Germany GLP/GEP: Yes 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 on.

zRMS comments:

The list below was not validated by the zRMS. For details of active substance studies evaluated at the EU level, please refer to the respective EU documents.

Deltamethrin


Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 8.1 / 01	Ebert, E.; Romijn, K.	2000	Response to ECCO 81 overview meeting Point 3.1 refinement of long-term risk for wild mammals Deltamethrin Code: AE F032640 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer Report No.: C007762 Edition Number: M-196600-01-1 Date: 2000-03-27 GLP/GEP: n.a., unpublished	No	Bayer
KCA 8.1 / 02		1973	Factors to be considered in the evaluation of the toxicity of pesticides to birds in their environment. Journal: Environmental Quality and Safety Volume: 2 Pages: 166-181 Year: 1973 Report No.: A32849 Edition Number: M-112797-01-1 GLP/GEP: n.a., published	Yes	published
KCA 8.1 / 03	Nagy, K. A.	1987	Field metabolic rate and food requirement scaling in mammals and birds Journal: Ecological Monographs Volume: 57 Issue: 2 Pages: 111-128 Year: 1987 Report No.: A74185 Edition Number: M-152436-01-1 GLP/GEP: n.a., published	No	published

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 8.1.1 / 01	Martens, R.; Schaefer, D.	1999	Estimation of half-life of residues on leafy crops Deltamethrin Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer Report No.: C005514 Edition Number: M-192201-01-1 Date: 1999-10-04 GLP/GEP: No, unpublished	No	Bayer
KCA 8.1.1 / 02	Schaefer, D.; Ellerich, C.	2019	Deltamethrin (DLT): Kinetic evaluation of residue dissipation after application in or on lettuce and spinach Bayer Report No.: EnSa-18-1107 Edition Number: M-642794-02-1 Date: 2018-11-30 ... amended: 2019-01-15 GLP/GEP: No, unpublished	No	Bayer
KCA 8.1.1 / 03	[REDACTED]	2019	Bayer response to EFSA request for additional information related to birds and mammals - Foliage residue DT50 for herbivorous mammal long-term risk refinement - Kinetic evaluation of lettuce and spinach residue decline trials - Weight-of-evidence evaluation of foliage residue decline of deltamethrin Bayer Report No.: M-646806-01-1 Date: 2019-01-17 GLP/GEP: n.a., unpublished	Yes	Bayer
KCA 8.1.1.1 / 01	[REDACTED]	1977	Acute Oral LD50 - Mallard Duck. Technical Decis. Final Report - unknown - Bayer Report No.: A20231 Edition Number: M-093403-01-1 Date: 1977-06-06 GLP/GEP: No, unpublished	Yes	Bayer
KCA 8.1.1.1 / 02	[REDACTED]	1986	Deltamethrin: An acute oral toxicity study with the bobwhite - final report [REDACTED] Report No.: A41913 Edition Number: M-124976-01-1 Date: 1986-02-17 GLP/GEP: Yes, unpublished	Yes	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 8.1.1.1 / 03	[REDACTED]	2013	Toxicity of deltamethrin technical during an acute oral LD50 with the canary (<i>Serinus canaria</i>) [REDACTED] Report No.: EBDAL083 Edition Number: M-444452-01-1 Date: 2013-01-10 GLP/GEP: Yes, unpublished	Yes	Bayer
KCA 8.1.1.2 / 01	[REDACTED]	1986	Deltamethrin: A dietary LC50 study with the Bobwhite. Final report. [REDACTED] Report No.: A41915 Edition Number: M-124978-01-1 Date: 1986-05-02 GLP/GEP: Yes, unpublished	Yes	Bayer
KCA 8.1.1.2 / 02	[REDACTED]	1986	Deltamethrin: A dietary LC50 study with the mallard Final report [REDACTED] Report No.: A41870 Edition Number: M-124933-01-1 Date: 1986-07-22 GLP/GEP: Yes, unpublished	Yes	Bayer
KCA 8.1.1.3 / 01	[REDACTED]	1991	Deltamethrin: A one generation reproduction study with the Northern bobwhite (<i>Colinus virginianus</i>). [REDACTED] Report No.: A70913 Edition Number: M-149397-01-1 Date: 1991-09-13 GLP/GEP: Yes, unpublished	Yes	Bayer
KCA 8.1.1.3 / 02	[REDACTED]	1991	Deltamethrin: A one generation reproduction study with the mallard (<i>Anas platyrhynchos</i>). [REDACTED] Report No.: A70914 Edition Number: M-149398-01-1 Date: 1991-09-13 GLP/GEP: Yes, unpublished	Yes	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 8.1.2.2 / 01	[REDACTED]	2011	A developmental neurotoxicity screening study with technical grade deltamethrin in Wistar rats Bayer Report No.: 201469-2 Edition Number: M-270180-03-1 Date: 2006-04-03 ... amended: 2011-12-12 GLP/GEP: Yes, unpublished ... also filed: KCA 5.7.1 / 02	Yes	Bayer
KCA 8.2 / 01	Kennedy, J. H.; Rodgers, J. H.; Johnson, P. C.	1989	Evaluation of the ecological/biological effects of tralomethrin utilizing an experimental pond system. University of Texas, Houston, TX, USA Bayer Report No.: A47958 Edition Number: M-136731-01-1 Date: 1989-10-16 GLP/GEP: Yes, unpublished	No	Bayer
KCA 8.2 / 02	[REDACTED]	1989	Supplement to: Evaluation of the ecological, biological effects of tralomethrin utilizing an experimental pond system. [REDACTED] Report No.: A73939 Edition Number: M-152210-01-1 Date: 1989-10-16 GLP/GEP: n.a., unpublished	Yes	Bayer
KCA 8.2 / 03	[REDACTED]	2000	Ecological risks of pesticides in freshwater ecosystems - Part 2: Insecticides Publisher: Alterra Location: The Netherlands Journal: Ecological risks of pesticides in freshwater ecosystems (Part 2) Volume: 2 Pages: 1-142 Year: 2000 Report No.: Lit. 9324 Edition Number: M-201559-01-1 GLP/GEP: n.a., published	Yes	published

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 8.2 / 04	Giddings, J. M.	1999	A review of field studies on the fate and effects of deltamethrin and tralomethrin in aquatic ecosystems Springborn Laboratories, Inc. (SLS), USA Bayer Report No.: C002977 Edition Number: M-185344-01-1 Date: 1999-03-12 GLP/GEP: n.a., unpublished ... also filed: KCA 7.2.1 / 01	No	Bayer
KCA 8.2 / 05	Heusel, R.	1999	Comments to the ECCO groups on the draft monograph for deltamethrin. Section B-8 ecotoxicology Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer Report No.: C003084 Edition Number: M-185587-01-1 Date: 1999-03-19 GLP/GEP: n.a., unpublished ... also filed: KCA 7.2.1 / 02	No	Bayer
KCA 8.2 / 06	Schanne, C.; van der Kolk, J.	2001	(14C)-deltamethrin formulated as emulsifiable concentrate (25 g/L deltamethrin): outdoor aquatic microcosm study of the ecological effects and environmental fate Springborn Laboratories (Europe) AG, Horn, Switzerland Bayer Report No.: C015510 Edition Number: M-200619-03-1 Date: 2001-09-21 ... amended: 2001-12-12 GLP/GEP: Yes, unpublished ... also filed: KCA 8.2.5 / 01	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 8.2 / 07	Suess, A.; Schmidt, H.; Schmidt, K.	2000	Investigation of the effects of Decis Fluessig (R) (deltamethrin) on the aquatic macrofauna, and of the dissipation over time and distance of the active substance in a small stream Journal: Mitteilungen aus der Biologischen Bundesanstalt fuer Land- und Forstwirtschaft Volume: 376 Pages: 442;443 Year: 2000 Report No.: C016963 Edition Number: M-200323-01-2 GLP/GEP: n.a., published ... also filed: KCA 8.2.5 / 05	No	published
KCA 8.2 / 08	Feyerabend, M.; Romijn, K.; Schaefer, D.; Sowig, P.	2001	Aquatic risk assessment for the active ingredient deltamethrin with special reference for aquatic invertebrates Code: AE F032640 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer Report No.: C016021 Edition Number: M-201581-01-1 Date: 2001-09-27 GLP/GEP: n.a., unpublished ... also filed: KCA 8.2.5 / 02	No	Bayer
KCA 8.2 / 09		2001	Probabilistic risk assessment of cotton pyrethroids: I. Distributional analyses of laboratory aquatic toxicity data Journal: Environmental Toxicology and Chemistry Volume: 20 Issue: 3 Pages: 652-659 Year: 2001 Report No.: C013417 Edition Number: M-204574-01-1 GLP/GEP: n.a., published ... also filed: KCA 8.2.5 / 03	Yes	published

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 8.2 / 10	[REDACTED]	2000	Statement on the potential risk of bioaccumulation of deltamethrin from the aquatic to the terrestrial food chain with special consideration of aquatic plants (response to ECCO 81 and the Overview Meeting / Point 3.3) Code: AE F032640 [REDACTED] Report No.: C009548 Edition Number: M-198780-01-1 Date: 2000-09-08 GLP/GEP: n.a., unpublished ... also filed: KCA 8.2.2.3 / 02	Yes	Bayer
KCA 8.2 / 11	Anon.	2016	Bayer Deltamethrin - CRD Ecotox request 27-01-2016 Bayer Report No.: M-583896-01-1 Date: 2016-01-27 GLP/GEP: n.a., unpublished	No	Bayer
KCA 8.2 / 12	Lagadic, L.	2018	ECx value calculation for aquatic chronic studies with deltamethrin (submitted for AIR3 of deltamethrin) Bayer Report No.: M-644600-01-1 Date: 2018-12-14 GLP/GEP: No, unpublished	No	Bayer
KCA 8.2.1 / 01	[REDACTED]	1986	Acute toxicity of deltamethrin to Bluegill Sunfish (<i>Lepomis macrochirus</i>). [REDACTED] Report No.: A70934 Edition Number: M-149416-01-1 Date: 1986-01-23 GLP/GEP: No, unpublished	Yes	Bayer
KCA 8.2.1 / 02	[REDACTED]	1986	Acute toxicity of deltamethrin to rainbow trout (<i>Salmo gairdneri</i>). [REDACTED] Report No.: A70935 Edition Number: M-149417-01-1 Date: 1986-01-06 GLP/GEP: No, unpublished	Yes	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 8.2.1 / 03	[REDACTED]	1990	(LX 165-08, deltamethrin technical) - Acute (28-Day) toxicity to rainbow trout (<i>Oncorhynchus mykiss</i>) under flow-through conditions. [REDACTED] Report No.: A47111 Edition Number: M-135553-01-1 Date: 1990-04-11 GLP/GEP: Yes, unpublished ... also filed: KCA 4.1.2 / 45 KCA 8.2.2.1 / 01	Yes	Bayer
KCA 8.2.1 / 04	[REDACTED]	1990	(Deltamethrin) - Acute toxicity to sheepshead minnow (<i>Cyprinodon variegatus</i>) under flow-through conditions [REDACTED] Report No.: A47094 Edition Number: M-135536-01-1 Date: 1990-06-19 GLP/GEP: Yes, unpublished	Yes	Bayer
KCA 8.2.1 / 05	[REDACTED]	2014	Acute toxicity of alpha-R isomer of deltamethrin (tech.) to fish (<i>Oncorhynchus mykiss</i>) under static-renewal conditions Bayer Report No.: EBDAL021 Edition Number: M-473954-01-1 Date: 2014-01-08 GLP/GEP: Yes, unpublished	Yes	Bayer
KCA 8.2.1 / 06	[REDACTED]	2013	Acute toxicity of trans-isomer of deltamethrin (tech.) to fish (<i>Oncorhynchus mykiss</i>) under static conditions Bayer Report No.: EBDAL029 Edition Number: M-473731-01-1 Date: 2013-12-23 GLP/GEP: Yes, unpublished	Yes	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 8.2.1 / 07		2013	BCS-BY84407 (tech.) - Acute toxicity to fish (Oncorhynchus mykiss) under static-renewal conditions Bayer Report No.: EBDAL030 Edition Number: M-473195-01-1 Date: 2013-12-03 GLP/GEP: Yes, unpublished	Yes	Bayer
KCA 8.2.1 / 08		2001	Acute toxicity to Oncorhynchus mykiss (rainbow trout) AE F108565 (metabolite of deltamethrin) substance, pure Code: AE F108565 00 1B99 0001 Report No.: CE00/074 Edition Number: M-199816-01-2 Date: 2001-04-19 GLP/GEP: Yes, unpublished	Yes	Bayer
KCA 8.2.1 / 09	Buser, H. P.	2014	Letter of access to the benefit of Bayer CropScience AG - Deltamethrin Syngenta Crop Protection AG, Basel, Switzerland Bayer Report No.: M-479954-01-1 Date: 2014-03-11 GLP/GEP: n.a., unpublished ... also filed: KCA 8.2.4.1 / 10	No	Bayer
KCA 8.2.1 / 10	Koepruecue, S. S.; Koepruecue, K.; Ural, M. S.	2006	Acute toxicity of the synthetic pyrethroid deltamethrin to fingerling European catfish, Silurus glanis L. Journal: Bull. Environ. Contam. Toxicol., Volume 76, Issue 1, Page 59-65, Publication Year 2006 Year: 2006 Report No.: M-460890-01-1 GLP/GEP: n.a., published	No	published
KCA 8.2.1 / 11	Chen, H. H.; Qin, J. H.; Liu, H. C.; Zhang, X. M.; Ma, X. F.	2011	Acute toxicity of representative heavy metals, polycyclic aromatic hydrocarbons (PAHs) and pyrethroid pesticides to Tanichthys albonubes Journal: Huazhong Nongye Daxue Xuebao Volume: 30 Issue: 4 Pages: 511-515 Year: 2011 Report No.: M-462645-01-1 GLP/GEP: n.a., published	No	published

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 8.2.2 / 01	[REDACTED]	1991	Deltamethrin: Toxicity test with Fathead minnow (Pimephales promelas) embryos and larvae. [REDACTED] Report No.: A70931 Edition Number: M-149413-01-1 Date: 1991-07-18 GLP/GEP: Yes, unpublished	Yes	Bayer
KCA 8.2.2.1 / 01	[REDACTED]	1990	(LX 165-08, deltamethrin technical) - Acute (28-Day) toxicity to rainbow trout (Oncorhynchus mykiss) under flow-through conditions. [REDACTED] Report No.: A47111 Edition Number: M-135553-01-1 Date: 1990-04-11 GLP/GEP: Yes, unpublished ... also filed: KCA 4.1.2 / 45 KCA 8.2.1 / 03	Yes	Bayer
KCA 8.2.2.1 / 02	[REDACTED]	2012	Early life stage toxicity of deltamethrin technical to the sheepshead minnow (Cyprinodon variegatus) under flow-through conditions Bayer Report No.: EBDAL085 Edition Number: M-439783-01-1 Date: 2012-10-19 GLP/GEP: Yes, unpublished	Yes	Bayer
KCA 8.2.2.2 / 01	[REDACTED]	1993	Deltamethrin: The chronic toxicity to the fathead minnow (Pimephales promelas) during a full life-cycle exposure. [REDACTED] Report No.: A70972 Edition Number: M-149454-01-1 Date: 1993-05-20 GLP/GEP: Yes, unpublished	Yes	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 8.2.2.3 / 01	[REDACTED]	1992	Supplemental information to the study "(Deltamethrin) - bioconcentration and elimination of (14)C-residues by Bluegill (LEPOMIS MACROCHIRUS)" (EPA MRID No. 41651040) [REDACTED] Report No.: A97600 Edition Number: M-174973-01-1 Date: 1992-09-03 GLP/GEP: No, unpublished	Yes	Bayer
KCA 8.2.2.3 / 02	[REDACTED]	2000	Statement on the potential risk of bioaccumulation of deltamethrin from the aquatic to the terrestrial food chain with special consideration of aquatic plants (response to ECCO 81 and the Overview Meeting / Point 3.3) Code: AE F032640 [REDACTED] Report No.: C009548 Edition Number: M-198780-01-1 Date: 2000-09-08 GLP/GEP: n.a., unpublished ... also filed: KCA 8.2 / 10	Yes	Bayer
KCA 8.2.2.3 / 03	[REDACTED]	1985	Fate of the Pyrethroid Insecticide Deltamethrin in Small Ponds: A Mass Balance Study Publisher: American Chemical Society Journal: Journal of Agricultural and Food Chemistry Volume: 33 Pages: 603-609 Year: 1985 Report No.: A33111 Edition Number: M-113322-01-1 GLP/GEP: n.a., published ... also filed: KCA 8.2.8 / 02	Yes	published
KCA 8.2.2.3 / 04	[REDACTED]	1990	(Deltamethrin) - Bioconcentration and elimination of 14C-residues by bluegill (Lepomis macrochirus). [REDACTED] Report No.: A47117 Edition Number: M-135559-01-1 Date: 1990-07-05 GLP/GEP: Yes, unpublished	Yes	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 8.2.3 / 01	De Assis, H.; Tramujas, F.; Favaro, L.; Assis, H.; Pauka, L.	2011	Reproductive aspects of zebrafish, Danio rerio, exposed to sublethal doses of deltamethrin . Aspectos reprodutivos do peixe-zebra, Danio rerio, exposto a doses subletais de deltametrina. Journal: Archives of Veterinary Science (2006) Volume 11, Number 1, pp. 48-53, 18 refs. ISSN: 1517-784X Published by: Universidade Federal do Parana, Curitiba Year: 2006 Report No.: M-460900-01-2 GLP/GEP: n.a., published	No	published
KCA 8.2.4 / 01	Gries, T.; van der Kolk, J.	2001	Acute toxicity test with fresh water isopods (Asellus aquaticus) under semi-static conditions (14C)-deltamethrin formulated as emusifiable concentrate (25 g/L deltamethrin) Code: AE F032640 Springborn Laboratories (Europe) AG, Horn, Switzerland Bayer Report No.: C015003 Edition Number: M-199681-01-1 Date: 2001-07-30 GLP/GEP: Yes, unpublished	No	Bayer
KCA 8.2.4 / 02	Thybaud, E.; Le Bras, S.; Cosson, R. P.	1987	Etude comparée de la sensibilité d'Asellus aquaticus L. (Crustace, Isopode) vis-a-vis de quelques insecticides et de divers métaux lourds Journal: Acta Oecologica Volume: 8 Issue: 4 Pages: 355-361 Year: 1987 Report No.: C016962 Edition Number: M-201338-01-1 GLP/GEP: n.a., published	No	published
KCA 8.2.4 / 03	Putt, A. E.	2000	Acute toxicity to gammarids (Gammarus fasciatus) under flow-through conditions Decis EC 25 g/L Springborn Laboratories, Inc., Wareham, MA, USA Bayer Report No.: C006608 Edition Number: M-194285-01-1 Date: 2000-01-07 GLP/GEP: Yes, unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 8.2.4 / 04	Putt, A. E.	2000	Acute toxicity to gammarids (Gammarus fasciatus) in a sediment-water system Decis EC 25 g/L Code: AE F032640 00 EC03 B003 Springborn Laboratories, Inc., Wareham, MA, USA Bayer Report No.: C009363 Edition Number: M-198400-01-1 Date: 2000-08-14 GLP/GEP: Yes, unpublished	No	Bayer
KCA 8.2.4 / 05	Presing, M.	1989	Data to toxic effect of K-othrine on crustaceans Journal: Arch. Hydrobiol. Volume: 114 Issue: 4 Pages: 621-629 Year: 1989 Report No.: C015982 Edition Number: M-201511-01-1 GLP/GEP: n.a., published	No	published
KCA 8.2.4 / 06	Sowig, P.	2001	Acute toxicity to non-target aquatic invertebrates - literature review Code: AE F032640 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer Report No.: C015761 Edition Number: M-201135-01-1 Date: 2001-09-11 GLP/GEP: n.a., unpublished ... also filed: KCA 8.2.5 / 04	No	Bayer
KCA 8.2.4.1 / 01	Forbis, A. D.; Frazier, S.	1986	Acute toxicity of deltamethrin to Daphnia magna. ABC Laboratories, Inc., California, Madera, CA, USA Bayer Report No.: A70998 Edition Number: M-149479-01-1 Date: 1986-01-29 GLP/GEP: Yes, unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 8.2.4.1 / 02	Putt, A. E.	1999	Acute toxicity to Daphnids (Daphnia magna) under flow-through conditions Deltamethrin (14C-labelled) Springborn Laboratories, Inc., Wareham, MA, USA Bayer Report No.: C003959 Edition Number: M-187113-01-1 Date: 1999-05-13 GLP/GEP: Yes, unpublished	No	Bayer
KCA 8.2.4.1 / 03	Riebschlaeger, T.	2014	Acute toxicity of deltamethrin (tech.) to the waterflea Daphnia magna in a static renewal laboratory test system Bayer Report No.: EBDAN150 Edition Number: M-474111-01-1 Date: 2014-01-10 GLP/GEP: Yes, unpublished	No	Bayer
KCA 8.2.4.1 / 04	Bruns, E.	2014	Acute toxicity of alpha-R isomer of deltamethrin (tech.) to the waterflea Daphnia magna in a static-renewal laboratory test system Bayer Report No.: EBDAL022 Edition Number: M-474118-01-1 Date: 2014-01-10 GLP/GEP: Yes, unpublished	No	Bayer
KCA 8.2.4.1 / 05	Bruns, E.	2014	Acute toxicity of trans-isomer of deltamethrin (tech.) to the waterflea Daphnia magna in a static renewal laboratory test system Bayer Report No.: EBDAL028 Edition Number: M-473835-01-1 Date: 2014-01-08 GLP/GEP: Yes, unpublished	No	Bayer
KCA 8.2.4.1 / 06	Riebschlaeger, T.	2013	Acute toxicity of BCS-BY84407 to the waterflea Daphnia magna in a static renewal laboratory test system Bayer Report No.: EBDAL031 Edition Number: M-465317-01-1 Date: 2013-09-11 GLP/GEP: Yes, unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 8.2.4.1 / 07	Sowig, P.; Gosch, H.	2001	Acute toxicity to Daphnia magna (Waterflea) AE F108565 (Metabolite of deltamethrin) substance, pure Code: AE F108565 00 1B99 0001 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer Report No.: CE99/158 Edition Number: M-199793-01-2 Date: 2001-04-18 GLP/GEP: Yes, unpublished	No	Bayer
KCA 8.2.4.1 / 08	Riebschlaeger, T.	2013	Acute toxicity of BCS-CW57835 to the waterflea Daphnia magna in a static renewal laboratory test system Bayer Report No.: EBDAN001 Edition Number: M-465372-01-1 Date: 2013-09-06 GLP/GEP: Yes, unpublished	No	Bayer
KCA 8.2.4.1 / 09	Caspers, N.	2010	Daphnia sp., acute immobilisation test with Cyfluthrin-m- phenoxybenzaldehyde (AE F114152) Currenta GmbH & Co. OHG, Leverkusen, Germany Bayer Report No.: 2010/0064/01 Edition Number: M-386854-01-1 Date: 2010-07-26 GLP/GEP: Yes, unpublished	No	Bayer
KCA 8.2.4.1 / 10	Buser, H. P.	2014	Letter of access to the benefit of Bayer CropScience AG - Deltamethrin Syngenta Crop Protection AG, Basel, Switzerland Bayer Report No.: M-479954-01-1 Date: 2014-03-11 GLP/GEP: n.a., unpublished ... also filed: KCA 8.2.1 / 09	No	Bayer
KCA 8.2.4.1 / 11	Sadler, T.	2019	Validation data for method used in study report 2010/0064/01 Bayer Report No.: M-646878-01-1 Date: 2019-01-18 GLP/GEP: n.a., unpublished ... also filed: KCA 4.1.2 / 59	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 8.2.4.2 / 01	Bradley, M. J.	2013	Deltamethrin - Acute toxicity to freshwater amphipods (<i>Hyalella azteca</i>) under flow-through conditions Smithers Viscient, Wareham, MA, USA Pyrethroid Working Group Report No.: 13656.6170 Edition Number: M-461147-01-1 Date: 2013-07-25 GLP/GEP: Yes, unpublished	No	Pyrethroid Working Group
KCA 8.2.4.2 / 02	Lelievre, M. K.	1991	(Deltamethrin) - Acute toxicity to Mysid shrimp (<i>Mysidopsis bahia</i>) under static renewal conditions. Springborn Laboratories, Inc. (SLS), USA Bayer Report No.: A70997 Report includes Trial Nos.: 1719.0889.6120.510 Edition Number: M-149478-01-1 Date: 1991-08-06 GLP/GEP: Yes, unpublished	No	Bayer
KCA 8.2.4.2 / 03	Wu, N.; Wei, H.; Shen, H.; Wu, T. T.; Guo, M.	2012	Acute toxic effects of deltamethrin on red swamp crayfish, <i>Procambarus clarkii</i> (Decapoda, Cambaridae) Publisher: Koninklijke Brill NV Journal: Crustaceana (Leiden), (JUL 2012) Vol. 85, No. 8, pp. 993-1005. http://www.ingentaconnect.com/content/vsp . Year: 2012 Report No.: M-462626-01-1 GLP/GEP: n.a., published	No	published
KCA 8.2.4.2 / 04	Shen, M. F.; Kumar, A.; Ding, S. Y.; Grocke, S.	2011	Comparative study on the toxicity of pyrethroids, -cypermethrin and deltamethrin to <i>Ceriodaphnia dubia</i> Journal: Ecotoxicol. Environ. Saf., Volume 78, Page 9-13, Publication Year 2012 Year: 2012 Report No.: M-462170-01-1 GLP/GEP: n.a., published ... also filed: KCA 8.2.5.2 / 02	No	published


Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 8.2.4.2 / 05	Key, P.; Chung, K.; Sapozhnikova, Y.; Fulton, M.; De Lorenzo, M.	2013	Comparative toxicity of pyrethroid insecticides to two estuarine crustacean species, Americamysis bahia and Palaemonetes pugio Publisher: Wiley Periodicals, Inc. Journal: Environmental Toxicology Ahead of Print Year: 2013 Report No.: M-462328-01-1 GLP/GEP: n.a., published	No	published
KCA 8.2.5 / 01	Schanne, C.; van der Kolk, J.	2001	(14C)-deltamethrin formulated as emulsifiable concentrate (25 g/L deltamethrin): outdoor aquatic microcosm study of the ecological effects and environmental fate Springborn Laboratories (Europe) AG, Horn, Switzerland Bayer Report No.: C015510 Edition Number: M-200619-03-1 Date: 2001-09-21 ... amended: 2001-12-12 GLP/GEP: Yes, unpublished ... also filed: KCA 8.2 / 06	No	Bayer
KCA 8.2.5 / 02	Feyerabend, M.; Romijn, K.; Schaefer, D.; Sowig, P.	2001	Aquatic risk assessment for the active ingredient deltamethrin with special reference for aquatic invertebrates Code: AE F032640 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer Report No.: C016021 Edition Number: M-201581-01-1 Date: 2001-09-27 GLP/GEP: n.a., unpublished ... also filed: KCA 8.2 / 08	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 8.2.5 / 03		2001	Probabilistic risk assessment of cotton pyrethroids: I. Distributional analyses of laboratory aquatic toxicity data Journal: Environmental Toxicology and Chemistry Volume: 20 Issue: 3 Pages: 652-659 Year: 2001 Report No.: C013417 Edition Number: M-204574-01-1 GLP/GEP: n.a., published ... also filed: KCA 8.2 / 09	Yes	published
KCA 8.2.5 / 04	Sowig, P.	2001	Acute toxicity to non-target aquatic invertebrates - literature review Code: AE F032640 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer Report No.: C015761 Edition Number: M-201135-01-1 Date: 2001-09-11 GLP/GEP: n.a., unpublished ... also filed: KCA 8.2.4 / 06	No	Bayer
KCA 8.2.5 / 05	Suess, A.; Schmidt, H.; Schmidt, K.	2000	Investigation of the effects of Decis Fluessig (R) (deltamethrin) on the aquatic macrofauna, and of the dissipation over time and distance of the active substance in a small stream Journal: Mitteilungen aus der Biologischen Bundesanstalt fuer Land- und Forstwirtschaft Volume: 376 Pages: 442;443 Year: 2000 Report No.: C016963 Edition Number: M-200323-01-2 GLP/GEP: n.a., published ... also filed: KCA 8.2 / 07	No	published

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 8.2.5.1 / 01	McNamara, P. C.	1990	Deltamethrin - the chronic toxicity to Daphnia magna under flow-through conditions Springborn Laboratories, Inc. (SLS), USA Bayer Report No.: A97601 Edition Number: M-174975-01-1 Date: 1990-11-19 GLP/GEP: No, unpublished	No	Bayer
KCA 8.2.5.1 / 02	Boumaiza, M.; Felten, V.; Ferard, J. F.; Fouque, C.; Millet, M.; Radetski, C. M.; Toumi, H.	2013	Effects of deltamethrin (pyrethroid insecticide) on growth, reproduction, embryonic development and sex differentiation in two strains of Daphnia magna (Crustacea, Cladocera). Publisher: Elsevier Journal: Science of the Total Environment Volume: 458-460 Pages: 47-53 Year: 2013 Report No.: M-462220-01-1 GLP/GEP: n.a., published	No	published
KCA 8.2.5.2 / 01	Claude, M. B.; Kendall, T. Z.; Gallagher, S. P.; Krueger, H. O.	2012	Deltamethrin: A flow-through life-cycle toxicity test with the saltwater mysid (Americamysis bahia) Wildlife International, Ltd., Easton, MD, USA Bayer Report No.: 149A-245A Edition Number: M-437923-01-1 Date: 2012-08-28 GLP/GEP: Yes, unpublished	No	Bayer
KCA 8.2.5.2 / 02	Shen, M. F.; Kumar, A.; Ding, S. Y.; Grocke, S.	2011	Comparative study on the toxicity of pyrethroids, -cypermethrin and deltamethrin to Ceriodaphnia dubia Journal: Ecotoxicol. Environ. Saf., Volume 78, Page 9-13, Publication Year 2012 Year: 2012 Report No.: M-462170-01-1 GLP/GEP: n.a., published ... also filed: KCA 8.2.4.2 / 04	No	published

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 8.2.5.3 / 01	Heusel, R.; Gildemeister, H.; Gosch H.	1998	Chronic toxicity to the sediment dwelling chironomid larvae Chironomus riparius Deltamethrin 14C- labelled Code: AE F032640 Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer Report No.: A74315 Edition Number: M-152560-01-1 Date: 1998-04-06 GLP/GEP: Yes, unpublished ... also filed: KCA 8.2.8 / 03	No	Bayer
KCA 8.2.5.4 / 01	Bruns, E.	2012	Chironomus riparius 28-day chronic toxicity test with deltamethrin (tech.) in a water-sediment system using spiked sediment Bayer Report No.: EBDAL036 Edition Number: M-425202-01-1 Date: 2012-02-08 GLP/GEP: Yes, unpublished	No	Bayer
KCA 8.2.5.4 / 02	Picard, C. R.	2013	Life-cycle toxicity test exposing midges (Chironomus dilutus) to deltamethrin applied to sediment under static-renewal conditions following EPA test methods Smithers Viscient, Wareham, MA, USA Bayer Report No.: 13798.6301 Edition Number: M-466314-01-1 Date: 2013-09-26 GLP/GEP: Yes, unpublished	No	Bayer
KCA 8.2.6 / 01	Giddings, J. M.	1990	LX165-08 (deltamethrin technical): Toxicity to the freshwater green alga (Selenastrum capricornutum). Springborn Laboratories, Inc. (SLS), USA Bayer Report No.: A70904 Edition Number: M-149388-01-1 Date: 1990-04-11 GLP/GEP: Yes, unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 8.2.6.2 / 01	Banman, C. S.; Shepherd, D. W.; Moore, S.	2013	Toxicity of deltamethrin technical to the freshwater diatom <i>Navicula pelliculosa</i> during a 96 hour exposure SynTech Research Laboratory Services, LLC, Stilwell, KS, USA Bayer Report No.: 7SRLS13C7 Edition Number: M-468384-01-1 Date: 2013-10-29 GLP/GEP: Yes, unpublished	No	Bayer
KCA 8.2.6.2 / 02	Banman, C. S.; Shepherd, D. W.; Moore, S.	2013	Toxicity of deltamethrin technical to the Cyanobacterium <i>Anabeana flos-aquae</i> during a 96 hour exposure SynTech Research Laboratory Services, LLC, Stilwell, KS, USA Bayer Report No.: 7SRLS13C38 Edition Number: M-468386-01-1 Date: 2013-10-29 GLP/GEP: Yes, unpublished	No	Bayer
KCA 8.2.6.2 / 03	Banman, C. S.; Shepherd, D. W.; Moore, S.	2013	Toxicity of deltamethrin technical to the saltwater diatom <i>Skeletonema costatum</i> during a 96 hour exposure SynTech Research Laboratory Services, LLC, Stilwell, KS, USA Bayer Report No.: 7SRLS13C39 Edition Number: M-468465-01-1 Date: 2013-10-29 GLP/GEP: Yes, unpublished	No	Bayer
KCA 8.2.7 / 01	Banman, C. S.; Howerton, J. H.; Moore, S.	2012	Toxicity of deltamethrin technical to duckweed (<i>Lemna gibba</i> G3) under static-renewal conditions Bayer Report No.: EBDAL089 Edition Number: M-439085-01-1 Date: 2012-10-03 GLP/GEP: Yes, unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 8.2.8 / 01	Muir, D. C. G.; Rawn, G. P.; Townsend, B. E.; Lockhart, W. L.; Greenhalgh, R.	1985	Bioconcentration of cypermethrin, deltamethrin, fenvalerate and permethrin by Chironomus tentans in sediment and water Journal: Environmental Toxicology and Chemistry Volume: 4 Pages: 51-61 Year: 1985 Report No.: A41920 Edition Number: M-124982-01-1 GLP/GEP: n.a., published ... also filed: KCA 7.2.2.3 / 02	No	published
KCA 8.2.8 / 02		1985	Fate of the Pyrethroid Insecticide Deltamethrin in Small Ponds: A Mass Balance Study Publisher: American Chemical Society Journal: Journal of Agricultural and Food Chemistry Volume: 33 Pages: 603-609 Year: 1985 Report No.: A33111 Edition Number: M-113322-01-1 GLP/GEP: n.a., published ... also filed: KCA 8.2.2.3 / 03	Yes	published
KCA 8.2.8 / 03	Heusel, R.; Gildemeister, H.; Gosch H.	1998	Chronic toxicity to the sediment dwelling chironomid larvae Chironomus riparius Deltamethrin 14C-labelled Code: AE F032640 Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer Report No.: A74315 Edition Number: M-152560-01-1 Date: 1998-04-06 GLP/GEP: Yes, unpublished ... also filed: KCA 8.2.5.3 / 01	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 8.2.8 / 04	[REDACTED]	2007	Influence of isolation on the recovery of pond mesocosms from the application of an insecticide I. Study design and planktonic community responses Publisher: SETAC Press Journal: Environ. Toxicol. Chem., Volume 26, Issue 6, Page 1265-1279, Publication Year 2007 Year: 2007 Report No.: Lit. 8832 Edition Number: M-294182-01-1 GLP/GEP: n.a., published	Yes	published
KCA 8.2.8 / 05	[REDACTED]	2007	Influence of isolation on the recovery of pond mesocosms from the application of an insecticide II. Benthic macroinvertebrate responses Publisher: SETAC Press Journal: Environ. Toxicol. Chem., Volume 26, Issue 6, Page 1280-1290, Publication Year 2007 Year: 2007 Report No.: Lit. 8833 Edition Number: M-294188-01-1 GLP/GEP: n.a., published	Yes	published
KCA 8.2.8 / 06	[REDACTED]	2019	Assessment of the potential risk to amphibians and reptiles after application of deltamethrin as plant protection product Bayer Report No.: M-646792-01-1 Date: 2019-01-18 GLP/GEP: n.a., unpublished	Yes	Bayer
KCA 8.2.8 / 07	[REDACTED]	2017	An interspecies correlation model to predict acute dermal toxicity of plant protection products to terrestrial life stages of amphibians using fish acute toxicity and bioconcentration data Publisher: Elsevier Journal: Chemosphere Volume: 189 Pages: 619-626 Year: 2017 Report No.: M-645423-01-1 Date: 2017-09-12 GLP/GEP: n.a., published	Yes	published

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 8.2.8 / 08	[REDACTED]	2018	Risk assessment considerations for plant protection products and terrestrial life-stages of amphibians Publisher: Elsevier Journal: Science of the Total Environment Volume: 636 Pages: 500-511 Year: 2018 Report No.: M-645427-01-1 GLP/GEP: n.a., published	Yes	published
KCA 8.2.8 / 09	[REDACTED]	2002	Strategies for maintain pond-breeding amphibians on golf courses Publisher: USGA Journal: Turfgrass and Environmental Research Online Volume: 1 Issue: 20 Pages: 1-7 Year: 2002 Report No.: M-646165-01-1 GLP/GEP: n.a., published	Yes	published
KCA 8.2.8 / 10	[REDACTED]	2018	An independent assessment of two microcosm studies conducted with deltamethrin, with ecological and practical context [REDACTED] Report No.: M-645035-01-1 Date: 2018-12-20 GLP/GEP: n.a., unpublished	Yes	Bayer
KCA 8.2.8 / 11	[REDACTED]	2019	Expert statement on the bioavailability of deltamethrin in two mesocosm studies [REDACTED] Report No.: M-646880-01-1 Date: 2019-01-17 GLP/GEP: n.a., unpublished	Yes	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 8.3.1 / 01	Nengel, S.	1998	Assessment of side effects of AE F032640 00 EC03 B003 on the honey bee (<i>Apis mellifera</i> L.) in the field following application during bee-flight Arbeitsgemeinschaft GAB GmbH & IFU GmbH, Germany Bayer Report No.: C002768 Edition Number: M-185038-01-1 Date: 1998-11-16 GLP/GEP: Yes, unpublished ... also filed: KCA 8.3.1.1 / 03	No	Bayer
KCA 8.3.1.1 / 01	Stevenson, J. H.	1978	The acute toxicity of unformulated pesticides to worker honey bees (<i>Apis mellifera</i> L.). Journal: Plant Pathology Volume: 27 Pages: 38-40 Year: 1978 Report No.: Lit. 4463 Edition Number: M-098831-01-1 GLP/GEP: n.a., published	No	published
KCA 8.3.1.1 / 02	Hoxter, K. A.; Lynn, S. P.	1991	Deltamethrin technical: An acute contact toxicity study with the honey bee Wildlife International, Ltd., Easton, MD, USA Bayer Report No.: A70896 Edition Number: M-149380-01-1 Date: 1991-08-06 GLP/GEP: Yes, unpublished	No	Bayer
KCA 8.3.1.1 / 03	Nengel, S.	1998	Assessment of side effects of AE F032640 00 EC03 B003 on the honey bee (<i>Apis mellifera</i> L.) in the field following application during bee-flight Arbeitsgemeinschaft GAB GmbH & IFU GmbH, Germany Bayer Report No.: C002768 Edition Number: M-185038-01-1 Date: 1998-11-16 GLP/GEP: Yes, unpublished ... also filed: KCA 8.3.1 / 01	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 8.3.1.1.1 / 01	Anon.	1977	Acute toxicity of decamethrine to honey bees. Procida Roussel Uclaf, France Bayer Report No.: A72154 Edition Number: M-150494-01-2 Date: 1977-01-01 GLP/GEP: No, unpublished	No	Bayer
KCA 8.3.1.1.1 / 02	Schmitzer, S.	2013	Effects of deltamethrin tech. (acute contact and oral) on honey bees (<i>Apis mellifera</i> L.) in the laboratory IBACON GmbH, Rossdorf, Germany Bayer Report No.: 73581035 Edition Number: M-444971-01-1 Date: 2013-01-16 GLP/GEP: Yes, unpublished ... also filed: KCA 8.3.1.1.2 / 01	No	Bayer
KCA 8.3.1.1.1 / 03	Waltersdorfer, A.	1996	Deltamethrin; Code: RU 22974 - Oral toxicity (LD 50) to honey bees (<i>Apis mellifera</i> L.) Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer Report No.: A56794 Edition Number: M-140579-01-1 Date: 1996-05-08 GLP/GEP: Yes, unpublished	No	Bayer
KCA 8.3.1.1.2 / 01	Schmitzer, S.	2013	Effects of deltamethrin tech. (acute contact and oral) on honey bees (<i>Apis mellifera</i> L.) in the laboratory IBACON GmbH, Rossdorf, Germany Bayer Report No.: 73581035 Edition Number: M-444971-01-1 Date: 2013-01-16 GLP/GEP: Yes, unpublished ... also filed: KCA 8.3.1.1.1 / 02	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 8.3.1.1.2 / 02	Waltersdorfer, A.	1996	Deltamethrin (Code: RU 22974): Contact toxicity (LD 50) to honey bees (<i>Apis mellifera</i> L.). Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer Report No.: A71137 Edition Number: M-149608-01-1 Date: 1996-04-22 GLP/GEP: Yes, unpublished	No	Bayer
KCA 8.3.1.1.2 / 03	Kling, A.	2014	Deltamethrin (tech.): Acute contact toxicity to the bumble bee, <i>Bombus terrestris</i> L. under laboratory conditions Eurofins-GAB GmbH, Niefern-Oeschelbronn, Germany Bayer Report No.: S13-04467 Edition Number: M-477381-01-1 Date: 2014-02-03 GLP/GEP: Yes, unpublished	No	Bayer
KCA 8.3.1.2 / 01	Kling, A.	2014	Deltamethrin EW 15B G - Assessment of chronic effects to the honeybee, <i>Apis mellifera</i> L., in a 10 days continuous laboratory feeding test Eurofins-GAB GmbH, Niefern-Oeschelbronn, Germany Bayer Report No.: S13-00151 Edition Number: M-477250-01-1 Date: 2014-01-27 GLP/GEP: Yes, unpublished	No	Bayer
KCA 8.3.2 / 01	Brown, K. C.; Selby, K. A.	2000	An evaluation of the effects of field and drift rates of a 6 percent EG (emulsifiable granule) formulation of deltamethrin (AE F032640 00 EG06 A) on the epigeal non-target arthropod fauna in a cereal field in England Ecotox Limited, Tavistock, Devon, United Kingdom Bayer Report No.: C008877 Report includes Trial Nos.: KCB114 Edition Number: M-197880-01-1 Date: 2000-06-30 GLP/GEP: Yes, unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 8.3.2 / 02	Aldershof, S.A.	2001	Evaluation effects of AE F032640 00 EC03 B007 applications on predatory mites (Acari: Phytoseiidae) and other non-target arthropods species in the field (apple orchards, Portugal) MITOX BV, Amsterdam, Netherlands Bayer Report No.: C014857 Edition Number: M-207424-01-1 Date: 2001-06-27 GLP/GEP: Yes, unpublished	No	Bayer
KCA 8.3.2 / 03	Romijn, K.; Waltersdorfer, A.	2001	Evaluation and risks assessment on non-target arthropod species (including predatory mites) based on a field study in apple orchards Deltamethrin Code: AE F032640 00 EC03 B007 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer Report No.: C015965 Edition Number: M-201483-01-1 Date: 2001-09-17 GLP/GEP: n.a., unpublished	No	Bayer
KCA 8.3.2 / 04	██████████	1976	Toxicity of DECAMETHRINE or Decis by Single Ingestion in Grey Partridge, <i>Perdix perdix</i> L. and Red Partridge, <i>Alectoris rufa</i> L. ██ Report No.: A20234 Edition Number: M-149392-01-2 Date: 1976-09-28 GLP/GEP: No, unpublished	Yes	Bayer
KCA 8.3.2 / 05	Soubrier, G.	1995	Production of deltamethrin: Industrial measures to protect the environment. Roussel Uclaf Agrovet; Bayer Report No.: A72157 Edition Number: M-150497-01-1 Date: 1995-03-13 GLP/GEP: n.a., unpublished confidential	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 8.3.2.1 / 01	Wientjes, J. C.	2000	A laboratory dose-response study to evaluate the effects of AE F032640 00 EW01 B103 on survival and reproduction of the parasitoid wasp <i>Aphidius rhopalosiphi</i> (DeStephani-Perez) (Hymenoptera: Braconidae) MITOX Stichting Bevordering Duurzame Plagbestrijding, Amsterdam, Netherlands Bayer Report No.: C009444 Edition Number: M-198587-01-1 Date: 2000-07-31 GLP/GEP: Yes, unpublished	No	Bayer
KCA 8.3.2.1 / 02	Bardon, C.; Delpuech, J.; Bouletreau, M.	2005	Increase of the behavioral response to kairomones by the parasitoid wasp <i>Leptopilina heterotoma</i> surviving insecticides Journal: Arch. Environ. Contam. Toxicol., Volume 49, Issue 2, Page 186-191, Publication Year 2005 Year: 2005 Report No.: M-460858-01-1 GLP/GEP: n.a., published	No	published
KCA 8.3.2.1 / 03	Delpuech, J.; Delahaye, M.	2013	The sublethal effects of deltamethrin on <i>Trichogramma</i> behaviors during the exploitation of host patches. Journal: Sci. Total Environ., Volume 447, Page 274-279, Publication Year 2013 Year: 2013 Report No.: M-462302-01-1 GLP/GEP: n.a., published	No	published
KCA 8.3.2.1 / 04	Meilin, A.; Trisyono, Y. A.; Martono, E.; Buchori, D.	2012	The effects of deltamethrin applied at sublethal concentrations on the adults of <i>Anagrus nilaparvatae</i> (Hymenoptera: Mymaridae) Publisher: Asian Research Publishing Network Journal: Journal of Agricultural and Biological Science (2012) Volume 7, Number 12, pp. 1032-1037, 34 refs. ISSN: 1990-6145 Published by: Asian Research Publishing Network - ARPN, Islamabad URL: http://www.arpnjournals.com/jabs/research_papers/rp_2012/jabs_1212_5 Year: 2012 Report No.: M-462184-01-1 GLP/GEP: n.a., published	No	published
KCA 8.3.2.1 / 05	Desneux, N.; Denoyelle, R.; Kaiser, L.	2006	A multi-step bioassay to assess the effect of the deltamethrin on the parasitic wasp <i>Aphidius ervi</i> Journal: Chemosphere, Volume 65, Issue 10, Page 1697-1706, Publication Year 2006 Year: 2006 Report No.: M-460882-01-1 GLP/GEP: n.a., published	No	published

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 8.3.2.1 / 06	Desneux, N.; Ramirez-Romero, R.; Kaiser, L.	2006	Multistep bioassay to predict recolonization potential of emerging parasitoids after a pesticide treatment Journal: Environ. Toxicol. Chem., Volume 25, Issue 10, Page 2675-2682, Publication Year 2006 Year: 2006 Report No.: M-460881-01-1 GLP/GEP: n.a., published	No	published
KCA 8.3.2.1 / 07	Desneux, N.; Wajnberg, E.; Fauvergue, X.; Privet, S.; Kaiser, L.	2004	Oviposition behaviour and patch-time allocation in two aphid parasitoids exposed to deltamethrin residues Journal: Entomol. Exp. Appl., Volume 112, Issue 3, Page 227-235, Publication Year 2004 Year: 2004 Report No.: M-460857-01-1 GLP/GEP: n.a., published	No	published
KCA 8.3.2.2 / 01	Aldershof, S.	2010	A laboratory dose-response study to evaluate the effects of Deltamethrin EW 15 g/L on survival of the predaceous mite Typhlodromus pyri Scheuten (Acari: Phytoseiidae) on glass MITOX Consultants, Amsterdam, Netherlands Bayer Report No.: B156TPL Edition Number: M-387027-01-1 Date: 2010-07-26 GLP/GEP: Yes, unpublished	No	Bayer
KCA 8.4 / 01	Hoxter, K. A.; Smith, G. J.	1993	Deltamethrin technical: An acute toxicity study with the earthworm in an artificial soil substrate. Final report Wildlife International, Ltd., Easton, MD, USA Bayer Report No.: A50956 Edition Number: M-131941-01-1 Date: 1993-05-17 GLP/GEP: Yes, unpublished	No	Bayer
KCA 8.4 / 02	Frings, H.; Bock, K. D.	1994	Deltamethrin; technical substance (Hoe 032640 00 ZD99 0001): Investigating the effect on the microbial activity in soil (short-term effects on aerobic soil respiration in accordance with BBA, VI, 1-1, 2nd edition) Hoechst AG, Frankfurt am Main, Germany Bayer Report No.: A52240 Edition Number: M-133032-01-2 Date: 1994-02-18 GLP/GEP: Yes, unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 8.4 / 03	Hackenberger, B.; Velki, M.	2013	Different Sensitivities of Biomarker Responses in Two Epigeic Earthworm Species After Exposure to Pyrethroid and Organophosphate Insecticides Publisher: Springer Science+Business Media Journal: Archives of Environmental Contamination and Toxicology Ahead of Print Year: 2013 Report No.: M-466808-01-1 GLP/GEP: n.a., published	No	published
KCA 8.4.1 / 01	Friedrich, S.	2011	Br2CA (Metabolite of deltamethrin, AE F108565): Sublethal toxicity to the earthworm Eisenia fetida in artificial soil with 5 percent peat BioChem agrar GmbH, Gerichshain, Germany Bayer Report No.: 10 10 48 102 S Edition Number: M-403733-01-1 Date: 2011-03-15 GLP/GEP: Yes, unpublished	No	Bayer
KCA 8.4.1 / 02	Friedrich, S.	2011	mPBacid (Metabolite of deltamethrin, AE F109036): sublethal toxicity to the earthworm Eisenia fetida in artificial soil with 5 percent peat BioChem agrar GmbH, Gerichshain, Germany Bayer Report No.: 10 10 48 099 S Edition Number: M-402952-01-1 Date: 2011-02-28 GLP/GEP: Yes, unpublished	No	Bayer
KCA 8.4.1 / 03	Kratz, M. A.	2012	Deltamethrin EW 15A G: Effects on survival, growth and reproduction on the earthworm Eisenia fetida tested in artificial soil with 5 % peat Bayer Report No.: KRA-RG-R-108/11 Edition Number: M-426439-01-1 Date: 2012-03-05 GLP/GEP: Yes, unpublished	No	Bayer
KCA 8.4.1 / 04	Oberdoerster, S.; Frommholz, U.	2018	Statistical re-evaluation (non-glp) of several soil studies with deltamethrin and the metabolite Br2CA using the probit analysis Bayer Report No.: M-643924-01-1 Date: 2018-11-19 GLP/GEP: n.a., unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 8.4.2 / 01	Schulz, L.	2011	Br2CA (Metabolite of deltamethrin, AE F108565): Effects on the reproduction of the predatory mite Hypoaspis aculeifer BioChem agrar GmbH, Gerichshain, Germany Bayer Report No.: 10 10 48 104 S Edition Number: M-400275-01-1 Date: 2011-01-19 GLP/GEP: Yes, unpublished	No	Bayer
KCA 8.4.2 / 02	Schulz, L.	2011	mPBacid (Metabolite of deltamethrin, AE F109036): Effects on the reproduction of the predatory mite Hypoaspis aculeifer BioChem agrar GmbH, Gerichshain, Germany Bayer Report No.: 10 10 48 101 S Edition Number: M-400270-01-1 Date: 2011-01-19 GLP/GEP: Yes, unpublished	No	Bayer
KCA 8.4.2 / 03	Friedrich, S.	2010	Br2CA (Metabolite of deltamethrin, AE F108565): Effects on the reproduction of the collembolans Folsomia candida BioChem agrar GmbH, Gerichshain, Germany Bayer Report No.: 10 10 48 103 S Edition Number: M-398826-01-1 Date: 2010-12-20 GLP/GEP: Yes, unpublished	No	Bayer
KCA 8.4.2 / 04	Friedrich, S.	2010	mPBacid (Metabolite of deltamethrin, AE F109036): Effects on the reproduction of the collembolans Folsomia candida BioChem agrar GmbH, Gerichshain, Germany Bayer Report No.: 10 10 48 100 S Edition Number: M-398820-01-1 Date: 2010-12-20 GLP/GEP: Yes, unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 8.4.2 / 05	Kratz, M. A.	2010	Deltamethrin EW 15A G: Influence on mortality and reproduction on the soil mite species Hypoaspis aculeifer tested in artificial soil with 5 percent peat Bayer Report No.: KRA-HR-39/10 Edition Number: M-393654-01-1 Date: 2010-10-26 GLP/GEP: Yes, unpublished	No	Bayer
KCA 8.4.2 / 06	Frommholz, U.	2010	Deltamethrin EW 15A G: Influence on the reproduction of the collembolan species Folsomia candida tested in artificial soil. Bayer Report No.: FRM-COLL-102/10 Edition Number: M-397993-01-1 Date: 2010-12-16 GLP/GEP: Yes, unpublished	No	Bayer
KCA 8.4.2 / 07	Griffiths, B. S.; Caul, S.; Thompson, J.; Birch, A. N. E.; Scrimgeour, C.; Cortet, J.; Foggo, A.; Hackett, C. A.; Krogh, P. H.	2006	Soil microbial and faunal community responses to Bt maize and insecticide in two soils Journal: J. Environ. Qual., Volume 35, Issue 3, Page 734-741, Publication Year 2006 Year: 2006 Report No.: M-460894-01-1 GLP/GEP: n.a., published	No	published
KCA 8.4.2 / 08	Negrisoni, A. S.; Garcia, M. S.; Barbosa Negrisoni, C. R. C.	2010	Compatibility of entomopathogenic nematodes (Nematoda: Rhabditida) with registered insecticides for Spodoptera frugiperda (Smith, 1797) (Lepidoptera: Noctuidae) under laboratory conditions Publisher: Elsevier Ltd. Journal: Crop protection, 2010 June Vol. 29, no. 6 p. 545-549 Year: 2010 Report No.: M-461809-01-1 GLP/GEP: n.a., published	No	published
KCA 8.4.2 / 09	Mochi, D. A.; Monteiro, A. C.; Barbosa, J. C.	2005	Action of pesticides to Metarhizium anisopliae in soil Journal: Neotrop. Entomol., Volume 34, Issue 6, Page 961-971, Publication Year 2005 Year: 2005 Report No.: M-460907-01-1 GLP/GEP: n.a., published	No	published

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 8.4.2 / 10	Shi, Y.; Shi, Y.; Wang, X.; Lu, Y.; Yan, S.	2007	Comparative effects of lindane and deltamethrin on mortality, growth, and cellulase activity in earthworms (<i>Eisenia fetida</i>) Journal: Pestic. Biochem. Physiol., Volume 89, Issue 1, Page 31-38, Publication Year 2007 Year: 2007 Report No.: M-460908-01-1 GLP/GEP: n.a., published	No	published
KCA 8.4.2 / 11	Owojore, O.; Roembke, J.; Waszak, K .	2013	Avoidance and reproduction tests with the predatory mite <i>Hypoaspis aculeifer</i> : Effects of different chemical substances Publisher: SETAC Journal: Environmental Toxicology and Chemistry / SETAC, (2013 Oct 9) . Electronic Publication Date: 9 Oct 2013 Year: 2013 Report No.: M-469671-01-1 GLP/GEP: n.a., published	No	published
KCA 8.5 / 01	Frings, H.; Bock, K. D.	1994	Deltamethrin; technical substance (Hoe 032640 00 ZD99 0001) - Investigating the effect on the nitrogen cycle in soil (in accordance with BBA, VI, 1-1 2nd edition) Hoechst AG, Frankfurt am Main, Germany Bayer Report No.: A52241 Edition Number: M-133031-01-2 Date: 1994-02-21 GLP/GEP: Yes, unpublished	No	Bayer
KCA 8.5 / 02	Schulz, L.	2011	Br2CA (Metabolite of deltamethrin, AE F108565): Effects on the activity of soil microflora (nitrogen transformation test) BioChem agrar GmbH, Gerichshain, Germany Bayer Report No.: 10 10 48 077 N Edition Number: M-400292-01-1 Date: 2011-01-21 GLP/GEP: Yes, unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 8.5 / 03	Schulz, L.	2011	mPBacid (Metabolite of deltamethrin, AE F109036): Effects on the activity of soil microflora (nitrogen transformation test) BioChem agrar GmbH, Gerichshain, Germany Bayer Report No.: 10 10 48 076 N Edition Number: M-400287-01-1 Date: 2011-01-21 GLP/GEP: Yes, unpublished	No	Bayer
KCA 8.5 / 04	Kolesnikov, S.; Kazeev, K.; Borovikova, L.; Loseva, E.	2011	Effect of contamination with currently used pesticides on the biological activity ordinary in chernozem. Journal: Agrokhimiya, Issue 11, Page 39-44, Publication Year 2010 Year: 2010 Report No.: M-462161-01-2 GLP/GEP: n.a., published	No	published
KCA 8.5 / 05	Munoz-Leoz, B.; Garbisu, C.; Antiguedad, I.; Alonso, M. L.; Alonso, R. M.; Ruiz-Romera, E.	2009	Deltamethrin degradation and soil microbial activity in a riparian wetland soil Journal: Soil Sci., Volume 174, Issue 4, Page 220-228, Publication Year 2009 Year: 2009 Report No.: M-460927-01-1 GLP/GEP: n.a., published	No	published
KCA 8.5 / 06	Madakka, M.; Rangaswamy, V.	2009	Effect of pesticides and insecticide combinations on Azospirillum sp. in groundnut soils Journal: Pollut. Res., Volume 28, Issue 1, Page 105-109, Publication Year 2009 Year: 2009 Report No.: M-461209-01-1 GLP/GEP: n.a., published	No	published
KCA 8.5 / 07	Zayed, S.; Farghaly, M.; Soliman, S.	2013	Deltamethrin degradation and effects on soil microbial activity. Journal: J. Environ. Sci. Health, Part B, Volume 48, Issue 7, Page 575-581, Publication Year 2013 Year: 2013 Report No.: M-462470-01-1 GLP/GEP: n.a., published	No	published

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 8.5 / 08	Mohiddin, G.; Srinivasulu, M.; Madakka, M.; Rangaswamy, V.; Madari, B.	2011	Effect of pesticides on microbial diversity and urease in groundnut (Arachis hypogaea L.) soil. Publisher: Global Science Books Location: http://www.globalsciencebooks.info Journal: Dynamic Soil, Dynamic Plant; Special Issue: Soil organic matter: Brazilian perspectives. Volume: 5 Issue: 1 Pages: 75-82 Year: 2011 Report No.: M-476820-01-1 GLP/GEP: n.a., published	No	published
KCA 8.5 / 09	Ruiz-Romera, E.; Munoz-Leoz, B.; Garbisu, C.; Antiguedad, I.	2012	Fertilization can modify the non-target effects of pesticides on soil microbial communities. Journal: Soil Biol. Biochem., Volume 48, Page 125-134, Publication Year 2012 Year: 2012 Report No.: M-458656-01-1 GLP/GEP: n.a., published	No	published
KCA 8.5 / 10	Madakka, M.; Mohiddin, G. J.; Srinivasulu, M.; Rangaswamy, V.	2011	Influence of pesticides, alone and in combination, on phosphatase activity in soils of groundnut (Arachis hypogaea L.) fields Publisher: Global Science Book Journal: Dynamic soil, dynamic plant Volume: 5 Issue: 1 Pages: 70-74 Year: 2011 Report No.: M-463427-01-1 GLP/GEP: n.a., published	No	published
KCA 8.5 / 11	Fatu, C.; Sorin, S.; Fatu, V.; Andrei, A. M.	2011	Laboratory study of biological interaction between entomopathogenic fungi Beauveria bassiana (Bals.) Vuill. and some pesticides used in integrated plant protection systems Publisher: Faculty of Agriculture, University of Craiova, Craiova Journal: Annals of the University of Craiova - Agriculture, Montanology, Cadastre Volume: 41 Issue: 2 Pages: 154-161 Year: 2011 Report No.: M-462287-01-1 GLP/GEP: n.a., published	No	published

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 8.5 / 12	Ruiz-Romera, E.; Antiguedad, I.; Garbisu, C.; Munoz- Leoz, B.; Charcosset, J.; Sanchez-Perez, J.	2013	Non-target effects of three formulated pesticides on microbially-mediated processes in a clay-loam soil. Journal: Sci. Total Environ., Volume 449, Page 345-354, Publication Year 2013 Year: 2013 Report No.: M-462303-01-1 GLP/GEP: n.a., published	No	published
KCA 8.6.2 / 01	Peterek, S.	2011	Deltamethrin EW 15A G: Vegetative vigour limit test for non target plants on eleven plant species Eurofins Agroscience Services GmbH, Niefern-Oeschelbronn, Germany Bayer Report No.: S10-02921 Report includes Trial Nos.: S10-02921-L1 Edition Number: M-402931-01-1 Date: 2011-02-17 GLP/GEP: Yes, unpublished	No	Bayer
KCA 8.6.2 / 02	Peterek, S.	2011	Deltamethrin EW 15A G: Seedling emergence test for non target plants on eleven plant species Eurofins Agroscience Services GmbH, Niefern-Oeschelbronn, Germany Bayer Report No.: S10-02920 Report includes Trial Nos.: S10-02920-L1 Edition Number: M-403202-01-1 Date: 2011-02-17 GLP/GEP: Yes, unpublished	No	Bayer
KCA 8.8 / 01	Hertl, J.	2001	Toxicity of AE F032640 deltamethrin, substance technical Code: AE F032640 00 1D99 0007 to activated sludge in a respiration test IBACON GmbH, Rossdorf, Germany Bayer Report No.: C012186 Edition Number: M-202236-01-1 Date: 2001-03-26 GLP/GEP: Yes, unpublished	No	Bayer

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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
KIIA 8.1.1 /01	[REDACTED]	2010	Toxicity of BYI 02960 technical during an acute oral LD50 with the northern bobwhite quail (Colinus virginianus) [REDACTED] Report No.: EBRVP022, Edition Number: M-386036-01-1 EPA MRID No.: 48843715 Date: 2010-07-14 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 8.1.1 /02	[REDACTED]	2011	Toxicity of BYI 02960 technical during an acute oral LD50 with the canary (Serinus canaria) [REDACTED] Report No.: EBRVP036, Edition Number: M-408514-01-1 EPA MRID No.: 48843716 Date: 2011-05-25 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 8.1.1 /03	[REDACTED]	2011	Acute oral toxicity of chicken (Gallus gallus domesticus) with BYI 2960 (tech.), according to OECD 223 - limit test- [REDACTED] Report No.: BAR/LD 141, Edition Number: M-420519-01-2 Date: 2011-12-19 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 8.1.2 /01	[REDACTED]	2010	Toxicity of BYI 02960 technical during an acute dietary LC50 with the mallard duck (Anas platyrhynchos) [REDACTED] Report No.: EBRVP020, Edition Number: M-388718-01-1 EPA MRID No.: 48843719 Date: 2010-08-26 GLP/GEP: yes, unpublished	Y	Bayer

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
KIIA 8.1.2 /02	[REDACTED]	2010	Toxicity of BYI 02960 technical during an acute dietary LC50 with the northern bobwhite quail (<i>Colinus virginianus</i>) [REDACTED] Report No.: EBRVP021, Edition Number: M-394535-01-1 EPA MRID No.: 48843718 Date: 2010-11-10 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 8.1.4 /01	[REDACTED]	2011	Toxicity of BYI 02960 technical on reproduction to the mallard duck (<i>Anas platyrhynchos</i>) [REDACTED] Report No.: EBRVP018-1, Edition Number: M-412917-02-1 EPA MRID No.: 48843721 Date: 2011-08-25 ...Amended: 2012-03-19 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 8.1.4 /02	[REDACTED]	2012	Toxicity of BYI 02960 technical on reproduction to the northern bobwhite quail (<i>Colinus virginianus</i>) [REDACTED] Report No.: EBRVP019, Edition Number: M-424704-01-2 EPA MRID No.: 48843720 Date: 2012-02-09 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 8.2.1.1 /01	[REDACTED]	2010	Acute toxicity of BYI 02960 technical to the rainbow trout (<i>Oncorhynchus mykiss</i>) under static conditions [REDACTED] Report No.: EBRVP041, Edition Number: M-390611-01-1 EPA MRID No.: 48843705 Date: 2010-09-27 GLP/GEP: yes, unpublished	Y	Bayer

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
KIIA 8.2.1.1 /02	[REDACTED]	2011	Acute toxicity of BYI 02960 to <i>Xenopus laevis</i> under flow-through conditions [REDACTED] Report No.: EBRVP187, Edition Number: M-417822-01-1 EPA MRID No.: 48843737 Date: 2011-11-18 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 8.2.1.2 /01	[REDACTED]	2010	Acute toxicity of BYI 02960 technical to the fathead minnow (<i>Pimephales promelas</i>) under static conditions [REDACTED] Report No.: EBRVP035, Edition Number: M-392560-01-1 EPA MRID No.: 48843706 Date: 2010-10-21 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 8.2.1.2 /02	[REDACTED]	2011	Acute toxicity of BYI 02960 (tech.) to fish (<i>Cyprinus carpio</i>) under static conditions (limit test) [REDACTED] Report No.: EBRVP186, Edition Number: M-420407-01-2 Date: 2011-12-19 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 8.2.1.3 /01	[REDACTED]	2011	Acute toxicity of BYI 02960 succinamide (tech.) to fish (<i>Oncorhynchus mykiss</i>) under static conditions (limit test) [REDACTED] Report No.: EBRVP203, Edition Number: M-414293-01-2 Date: 2011-09-21 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 8.2.1.3 /02	[REDACTED]	2011	Acute toxicity of sodium difluoro acetate (BCS AB60481, tech.) to fish (<i>Oncorhynchus mykiss</i>) under static conditions (limit test) [REDACTED] Report No.: EBRVP080, Edition Number: M-413889-01-2 Date: 2011-09-12 GLP/GEP: yes, unpublished	Y	Bayer

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
KIIA 8.2.4 /01	[REDACTED]	2011	Early life stage toxicity of BYI 02960 technical to the Fathead minnow (Pimephales promelas) under flow-through conditions [REDACTED] Report No.: EBRVP033, Edition Number: M-409339-01-1 EPA MRID No.: 48843714 Date: 2011-06-14 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 8.3.1.1 /01	Banman, C. S.; Lam, C. V.	2009	Acute toxicity of BYI 02960 to Daphnia magna under static conditions Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: EBRVP032, Edition Number: M-357476-01-1 EPA MRID No.: 48843701 Date: 2009-10-14 GLP/GEP: yes, unpublished	N	Bayer
KIIA 8.3.1.1 /02	Bruns, E.	2011	Acute toxicity of BCS-AB60481 to the waterflea Daphnia magna in a static laboratory test system - limit test- Bayer CropScience, Report No.: EBRVP079, Edition Number: M-409326-01-2 Date: 2011-06-10 GLP/GEP: yes, unpublished	N	Bayer
KIIA 8.3.1.1 /03	McElligott, A.	1997	Acute toxicity (48 hours) to Daphnids (Daphnia magna) under semi-static conditions IC-0 Rhone-Poulenc Agro, Sophia Antipolis, France Bayer CropScience, Report No.: SA97045, Edition Number: M-196569-01-1 Date: 1997-05-20 GLP/GEP: yes, unpublished	N	Bayer
KIIA 8.3.1.2 /01	Bruns, E.	2011	Acute toxicity of BYI 02960 (tech.) to larvae of Chironomus riparius in a 48 h static laboratory test system Bayer CropScience, Report No.: EBRVP026, Edition Number: M-414739-01-2 Date: 2011-09-26 GLP/GEP: yes, unpublished ...also filed: KIIA 8.5.1 /01	N	Bayer

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
KIIA 8.3.1.2 /02	Bruns, E.	2011	Acute toxicity of BYI 02960-succinamide to larvae of Chironomus riparius in a 48 h static laboratory test system Bayer CropScience, Report No.: EBRVP202, Edition Number: M-417386-01-2 Date: 2011-11-17 GLP/GEP: yes, unpublished	N	Bayer
KIIA 8.3.1.2 /03	Bruns, E.	2012	Acute toxicity of BYI 02960-azabicyclosuccinamide (BCS-CS64875) to larvae of Chironomus riparius in a 48 h static laboratory test system Bayer CropScience, Report No.: EBRVP207, Edition Number: M-424404-01-1 Date: 2012-02-02 GLP/GEP: yes, unpublished	N	Bayer
KIIA 8.3.1.2 /04	Bowers, L. M.; Lam, C. V.	1998	Acute toxicity of 6-chloronicotinic acid (a metabolite of imidacloprid) to Chironomus tentans under static renewal conditions Bayer Corporation, Stilwell, KS, USA Bayer CropScience, Report No.: 108127, Edition Number: M-048448-01-1 EPA MRID No.: 44558901 Date: 1998-04-23 GLP/GEP: yes, unpublished	N	Bayer
KIIA 8.3.2.1 /01	Riebschlaeger, T.	2011	Effects of BYI 02960 (techn.) on development and reproductive output of the waterflea Daphnia magna in a static-renewal laboratory test system Bayer CropScience, Report No.: EBRVP209, Edition Number: M-414066-01-2 EPA MRID No.: 48843711 Date: 2011-09-15 GLP/GEP: yes, unpublished	N	Bayer

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
KIIA 8.3.2.1 /02	Riebschlaeger, T.	2012	Influence of BYI02960-succinamide (tech.) on development and reproductive output of the waterflea Daphnia magna in a static-renewal laboratory test system Bayer CropScience, Report No.: EBRVP185, Edition Number: M-424700-01-2 EPA MRID No.: 48843712 Date: 2012-02-10 GLP/GEP: yes, unpublished	N	Bayer
KIIA 8.3.2.2 /01	Bruns, E.	2011	Chironomus riparius 28-day chronic toxicity test with BYI 02960 (tech.) in a water-sediment system using spiked water Bayer CropScience, Report No.: EBRVP025, Edition Number: M-401792-01-2 Date: 2011-02-14 GLP/GEP: yes, unpublished ...also filed: KIIA 8.5.2 /01	N	Bayer
KIIA 8.3.2.2 /02	Bruns, E.	2011	Chironomus riparius 28-day chronic toxicity test with Sodium difluoroacetate in a water-sediment system using spiked water - limit test Bayer CropScience, Report No.: EBRVP181, Edition Number: M-415913-01-2 Date: 2011-10-06 GLP/GEP: yes, unpublished	N	Bayer
KIIA 8.3.2.2 /03	Bruns, E.	2011	Chironomus riparius 28-day chronic toxicity test with 6-Chloronicotinic acid in a water-sediment system using spiked water - limit test Bayer CropScience, Report No.: EBRVP183, Edition Number: M-416604-02-2 Date: 2011-10-18 ...Amended: 2011-12-20 GLP/GEP: yes, unpublished	N	Bayer

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KIIA 8.4 /01	Banman, C. S.; Lam, C. V.	2010	Toxicity of BYI 02960 technical to the green alga <i>Pseudokirchneriella subcapitata</i> Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: EBRVP030, Edition Number: M-397552-01-1 EPA MRID No.: 48843732 Date: 2010-12-10 GLP/GEP: yes, unpublished	N	Bayer
KIIA 8.4 /02	Bruns, E.	2011	<i>Pseudokirchneriella subcapitata</i> growth inhibition test with BCS-AB60481 - limit test Bayer CropScience, Report No.: EBRVP077, Edition Number: M-409118-01-2 Date: 2011-06-10 GLP/GEP: yes, unpublished	N	Bayer
KIIA 8.4 /03	Sobczyk, H.	2011	<i>Pseudokirchneriella subcapitata</i> growth inhibition test with BYI 02960 - succinamide - limit test Bayer CropScience, Report No.: EBRVP184, Edition Number: M-414090-01-2 Date: 2011-09-23 GLP/GEP: yes, unpublished	N	Bayer
KIIA 8.4 /04	Bruns, E.	2012	<i>Pseudokirchneriella subcapitata</i> growth inhibition test with 6 - chloronicotinic acid Bayer CropScience, Report No.: EBRVP242, Edition Number: M-424145-01-2 Date: 2012-02-01 GLP/GEP: yes, unpublished	N	Bayer
KIIA 8.5.1 /01	Bruns, E.	2011	Acute toxicity of BYI 02960 (tech.) to larvae of <i>Chironomus riparius</i> in a 48 h static laboratory test system Bayer CropScience, Report No.: EBRVP026, Edition Number: M-414739-01-2 Date: 2011-09-26 GLP/GEP: yes, unpublished ...also filed: KIIA 8.3.1.2 /01	N	Bayer

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
KIIA 8.5.2 /01	Bruns, E.	2011	Chironomus riparius 28-day chronic toxicity test with BYI 02960 (tech.) in a water-sediment system using spiked water Bayer CropScience, Report No.: EBRVP025, Edition Number: M-401792-01-2 Date: 2011-02-14 GLP/GEP: yes, unpublished ...also filed: KIIA 8.3.2.2 /01	N	Bayer
KIIA 8.6 /01	Banman, C. S.; Alexander, T. M.; Lam, C. V.	2010	Toxicity of BYI 02960 technical to duckweed (Lemna gibba G3) under static-renewal conditions Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: EBRVP043, Edition Number: M-398376-01-1 EPA MRID No.: 48843731 Date: 2010-12-21 GLP/GEP: yes, unpublished	N	Bayer
KIIA 8.7.1 /01	Schmitzer, S.	2008	Revised final report no.: 1 - Effects of BYI 02960 (acute contact and oral) on honey bees (Apis mellifera L.) in the laboratory IBACON GmbH, Rossdorf, Germany Bayer CropScience, Report No.: 41121035, Edition Number: M-308904-02-1 Date: 2008-08-20 ...Amended: 2012-03-22 GLP/GEP: yes, unpublished	N	Bayer
KIIA 8.7.1 /02	Schmitzer, S.	2010	Effects of BYI02960 - difluoroethyl - amino - furanone (acute contact and oral) on honey bees (Apis mellifera L.) in the laboratory IBACON GmbH, Rossdorf, Germany Bayer CropScience, Report No.: 60291035, Edition Number: M-398557-01-3 EPA MRID No.: 48843723 Date: 2010-12-21 GLP/GEP: yes, unpublished	N	Bayer

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
KIIA 8.7.1 /03	Schmitzer, S.	2011	Effects of BYI 02960 - hydroxy (acute contact and oral) on honey bees (<i>Apis mellifera</i> L.) in the laboratory IBACON GmbH, Rossdorf, Germany Bayer CropScience, Report No.: 63901035, Edition Number: M-409606-01-2 Date: 2011-06-15 GLP/GEP: yes, unpublished	N	Bayer
KIIA 8.7.1 /04	Schmitzer, S.	2010	Effects of difluoroacetic acid (acute contact and oral) on honey bees (<i>Apis mellifera</i> L.) in the laboratory IBACON GmbH, Rossdorf, Germany Bayer CropScience, Report No.: 56331035, Edition Number: M-367915-01-2 Date: 2010-04-29 GLP/GEP: yes, unpublished	N	Bayer
KIIA 8.7.1 /05	Schmitzer, S.	2010	Effects of 6-chloronicotinic acid (acute contact and oral) on honey bees (<i>Apis mellifera</i> L.) in the laboratory IBACON GmbH, Rossdorf, Germany Bayer CropScience, Report No.: 60281035, Edition Number: M-395279-01-2 Date: 2010-11-19 GLP/GEP: yes, unpublished	N	Bayer
KIIA 8.7.1 /06	Schmitzer, S.	2010	Effects of 6-chloro-picolylalcohol (acute contact and oral) on honey bees (<i>Apis mellifera</i> L.) in the laboratory IBACON GmbH, Rossdorf, Germany Bayer CropScience, Report No.: 50911035, Edition Number: M-361234-01-2 Date: 2010-01-11 GLP/GEP: yes, unpublished	N	Bayer
KIIA 8.7.1 /07	Vergé, E.	2012	Flupyradifurone SL 200 G: Acute contact toxicity to the bumblebee <i>Bombus terrestris</i> L.(Hymenoptera, Apidae) under laboratory conditions (multi doses test) Eurofins-GAB GmbH, Niefern-Oeschelbronn, Germany Bayer CropScience, Report No.: S12-03216, Edition Number: M-443696-01-1 Date: 2012-12-13 GLP/GEP: yes, unpublished	N	Bayer

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KIIA 8.8.1.1 /01	Jans, D.	2010	Toxicity to the parasitoid wasp <i>Aphidius rhopalosiphi</i> (DESTEPHANI-PEREZ) (Hymenoptera: Braconidae) using a laboratory test; BYI 02960 SL 200 g/L Bayer CropScience, Report No.: CW09/079, Edition Number: M-366965-01-3 EPA MRID No.: 48843744 Date: 2010-04-15 GLP/GEP: yes, unpublished	N	Bayer
KIIA 8.8.1.2 /01	Jans, D.	2010	Toxicity to the predatory mite <i>Typhlodromus pyri</i> SCHEUTEN (Acari, Phytoseiidae) using a laboratory test; BYI 02960 SL 200 g/L Bayer CropScience, Report No.: CW09/073, Edition Number: M-366957-01-2 EPA MRID No.: 48843745 Date: 2010-04-15 GLP/GEP: yes, unpublished	N	Bayer
KIIA 8.9.1 /01	Leicher, T.	2010	BYI 02960 (tech.): Acute toxicity to earthworms (<i>Eisenia fetida</i>) tested in artificial soil Bayer CropScience, Report No.: LRT/RG-A-131/09, Edition Number: M-363742-01-2 EPA MRID No.: 48843746 Date: 2010-02-18 GLP/GEP: yes, unpublished	N	Bayer
KIIA 8.9.1 /02	Leicher, T.	2010	BYI 02960-difluoroacetic acid: acute toxicity to earthworms (<i>Eisenia fetida</i>) tested in artificial soil Bayer CropScience, Report No.: LRT/RG-A-135/10, Edition Number: M-368835-01-2 EPA MRID No.: 48843747 Date: 2010-04-12 GLP/GEP: yes, unpublished	N	Bayer
KIIA 8.9.1 /03	Wetton, P. M.	1999	Acute toxicity to earthworms (<i>Eisenia foetida</i>) IC-0 Safepharma Lab. Ltd., Derby, United Kingdom Bayer CropScience, Report No.: C007758, Edition Number: M-196591-01-1 Date: 1999-08-25 GLP/GEP: yes, unpublished	N	Bayer

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KIIA 8.9.2 /01	Leicher, T.	2010	BYI 02960 SL 200 G: Effects on survival, growth and reproduction on the earthworm Eisenia fetida tested in artificial soil Bayer CropScience, Report No.: LRT-RG-R-76/09, Edition Number: M-392964-01-2 Date: 2010-10-21 GLP/GEP: yes, unpublished	N	Bayer
KIIA 8.9.2 /02	Leicher, T.	2010	BYI 02960 Difluoroacetic acid: Effects on survival, growth and reproduction on the earthworm Eisenia fetida tested in artificial soil with 10 % peat Bayer CropScience, Report No.: LRT-RG-R-81/10, Edition Number: M-398061-01-3 EPA MRID No.: 48843750 Date: 2010-12-16 GLP/GEP: yes, unpublished	N	Bayer
KIIA 8.9.2 /03	Leicher, T.; Kratz, M. A.	2011	6-chloronicotinic acid (AE F161089): Effects on survival, growth and reproduction on the earthworm Eisenia fetida tested in artificial soil with 5 percent peat Bayer CropScience, Report No.: M-413562-02-3 , Edition Number: M-413562-02-3 EPA MRID No.: 48843751 Date: 2011-09-05 ...Amended: 2012-02-23 GLP/GEP: yes, unpublished	N	Bayer
KIIA 8.10.1 /01	Frommholz, U.	2009	BYI 02960 a.s.: Determination of effects on nitrogen transformation in soil Bayer CropScience, Report No.: FRM-N-130/09, Edition Number: M-359803-01-2 Date: 2009-12-03 GLP/GEP: yes, unpublished	N	Bayer
KIIA 8.10.1 /02	Frommholz, U.	2011	6-chloronicotinic acid (AE F161089): Determination of effects on nitrogen transformation in soil Bayer CropScience, Report No.: FRM-N-156/11, Edition Number: M-408028-01-2 Date: 2011-05-20 GLP/GEP: yes, unpublished	N	Bayer

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
KIIA 8.10.2 /01	Schulz, L.	2011	BYI 02960 a.s.: Effects on the activity of soil microflora (carbon transformation test) BioChem agrar GmbH, Gerichshain, Germany Bayer CropScience, Report No.: 11 10 48 058 C, Edition Number: M-417194-01-2 EPA MRID No.: 48843754 Date: 2011-11-11 GLP/GEP: yes, unpublished	N	Bayer
KIIA 8.11.1 /01	[REDACTED]	2009	Acute toxicity of BYI 02960 technical to the sheepshead minnow (<i>Cyprinodon variegatus</i>) under static conditions [REDACTED] Report No.: EBRVP034, Edition Number: M-357479-01-1 EPA MRID No.: 48843710 Date: 2009-10-14 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 8.11.1 /02	Gallagher, S. P.; Kendall, T. Z.; Krueger, H. O.	2009	BYI 02960: A 96-hour shell deposition test with the eastern oyster (<i>Crassostrea virginica</i>) Wildlife International, Ltd., Easton, MD, USA Bayer CropScience, Report No.: EBRVP023, Edition Number: M-361668-01-1 EPA MRID No.: 48843703 Date: 2009-12-01 GLP/GEP: yes, unpublished	N	Bayer
KIIA 8.11.1 /03	Gallagher, S. P.; Kendall, T. Z.; Krueger, H.O.	2009	BYI 02960: A 96-hour static acute toxicity test with the saltwater mysid (<i>Americamysis bahia</i>) Wildlife International, Ltd., Easton, MD, USA Bayer CropScience, Report No.: 149A-236, Edition Number: M-364620-01-1 EPA MRID No.: 48843704 Date: 2009-12-08 GLP/GEP: yes, unpublished	N	Bayer

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KIIA 8.11.1 /04	Claude, M. B.; Kendall, T. Z.; Krueger, H. O.	2011	BYI 02960: A flow-through life-cycle toxicity test with the saltwater mysid (<i>Americanysis bahia</i>) Wildlife International, Ltd., Easton, MD, USA Bayer CropScience, Report No.: EBRVP038, Edition Number: M-420783-01-1 Date: 2011-09-08 GLP/GEP: yes, unpublished	N	Bayer
KIIA 8.12 /01	Gosch, H.	2010	BYI 02960 SL 200 g/L - Effects on the vegetative vigour of eleven species of non-target terrestrial plants (Tier 1) Bayer CropScience, Report No.: VV 10/002, Edition Number: M-397734-01-2 EPA MRID No.: 48843730 Date: 2010-12-14 GLP/GEP: yes, unpublished	N	Bayer
KIIA 8.12 /02	Gosch, H.	2010	BYI 02960 SL 200 g/L - Effects on the seedling emergence and growth of eleven species of non-target terrestrial plants (Tier 1) Bayer CropScience, Report No.: SE10/001, Edition Number: M-397727-01-2 EPA MRID No.: 48843729 Date: 2010-12-14 GLP/GEP: yes, unpublished	N	Bayer
KIIA 8.14 /01	Frommholz, U.	2009	BYI 02960 SL 200 G: Influence on the reproduction of the collembola species <i>Folsomia candida</i> tested in artificial soil with 5 % peat Bayer CropScience, Report No.: FRM-COLL-75/09, Edition Number: M-359728-01-2 EPA MRID No.: 48843755 Date: 2009-12-02 GLP/GEP: yes, unpublished	N	Bayer

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
KIIA 8.14 /02	Frommholz, U.	2010	Metabolite BYI 02960-difluoroacetic acid: Influence on the reproduction of the collembolan species Folsomia candida tested in artificial soil Bayer CropScience, Report No.: FRM-COLL-85/10, Edition Number: M-368675-01-3 EPA MRID No.: 48843756 Date: 2010-05-12 GLP/GEP: yes, unpublished	N	Bayer
KIIA 8.14 /03	Frommholz, U.	2011	6-chloronicotinic acid (AE F161089): Influence on the reproduction of the collembolan species Folsomia candida tested in artificial soil Bayer CropScience, Report No.: FRM-COLL-111/11, Edition Number: M-407861-01-2 Date: 2011-05-18 GLP/GEP: yes, unpublished	N	Bayer
KIIA 8.14 /04	Kratz, M.-A.	2009	BYI 02960 SL 200 G: Influence on mortality and reproduction on the soil mite species Hypoaspis aculeifer tested in artificial soil with 5 % peat Bayer CropScience, Report No.: KRA-HR-19/09, Edition Number: M-358752-01-2 EPA MRID No.: 48843758 Date: 2009-11-10 GLP/GEP: yes, unpublished	N	Bayer
KIIA 8.14 /05	Kratz, M.-A.	2010	BYI 02960-DFA (BCS-AA56716): Influence on mortality and reproduction on the soil mite species Hypoaspis aculeifer tested in artificial soil with 5 % peat Bayer CropScience, Report No.: KRA-HR-27/10, Edition Number: M-390091-01-2 Date: 2010-09-15 GLP/GEP: yes, unpublished	N	Bayer
KIIA 8.14 /06	Kratz, M.-A.	2011	6-chloronicotinic acid (AE F161089): Influence on mortality and reproduction on the soil mite species Hypoaspis aculeifer tested in artificial soil Bayer CropScience, Report No.: KRA-HR-44/11, Edition Number: M-404434-01-2 EPA MRID No.: 48843760 Date: 2011-03-24 GLP/GEP: yes, unpublished	N	Bayer

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KIIA 8.15 /01	Caspers, N.	2010	Activated sludge, respiration inhibition test with BYI 02960 (tech.) Currenta GmbH & Co. OHG, Leverkusen, Germany Bayer CropScience, Report No.: 2010/0089/01, Edition Number: M-377311-01-1 Date: 2010-06-21 GLP/GEP: yes, unpublished	N	Bayer
KIIA 8.16.1 /01	Kling, A.	2011	BYI 02960 - Assessment of chronic effects to the honey bee, Apis mellifera L., in a 10 days laboratory feeding test Eurofins Agrosience Services GmbH, Niefern-Oeschelbronn, Germany Bayer CropScience, Report No.: S10-02924, Report includes Trial Nos.: S10-02924-L1_BLEU Edition Number: M-400539-01-2 Date: 2011-01-13 GLP/GEP: yes, unpublished	N	Bayer
KIIA 8.16.1 /02	Kling, A.	2012	BYI 02960-difluoroethyl-amino-furanone (BYI 02960-DFEAF) - Assessment of chronic effects to the honey bee, Apis mellifera L., in a 10 days continuous laboratory feeding limit test Eurofins Agrosience Services EcoChem GmbH, Niefern-Oeschelbronn, Germany Bayer CropScience, Report No.: S11-01959, Report includes Trial Nos.: S11-01959-L1_BLCF Edition Number: M-425174-01-2 EPA MRID No.: 48843763 Date: 2012-02-14 GLP/GEP: yes, unpublished	N	Bayer

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
KIIA 8.16.1 /03	Kling, A.	2012	BYI 02960-hydroxy - Assessment of chronic effects to the honey bee, Apis mellifera L., in a 10 days continuous laboratory feeding limit test Eurofins Agrosience Services EcoChem GmbH, Niefern-Oeschelbronn, Germany Bayer CropScience, Report No.: S11-01960, Report includes Trial Nos.: S11-01960-L1_BLCF Edition Number: M-425212-01-2 EPA MRID No.: 48843764 Date: 2012-02-15 GLP/GEP: yes, unpublished	N	Bayer
KIIA 8.16.1 /04	Kling, A.	2012	Difluoroacetic acid - Assessment of chronic effects to the honey bee, Apis mellifera L., in a 10 days continuous laboratory feeding limit test Eurofins Agrosience Services EcoChem GmbH, Niefern-Oeschelbronn, Germany Bayer CropScience, Report No.: S11-01939, Report includes Trial Nos.: S11-01939-L1_BLCF Edition Number: M-425105-01-1 Date: 2012-02-13 GLP/GEP: yes, unpublished	N	Bayer
KIIA 8.16.1 /05	Kling, A.	2012	6-chloronicotinic acid - Assessment of chronic effects to the honey bee, Apis mellifera L., in a 10 days continuous laboratory feeding limit test Eurofins Agrosience Services EcoChem GmbH, Niefern-Oeschelbronn, Germany Bayer CropScience, Report No.: S11-01957, Report includes Trial Nos.: S11-01957-L1_BLCF Edition Number: M-425155-01-2 EPA MRID No.: 48843766 Date: 2012-02-13 GLP/GEP: yes, unpublished	N	Bayer

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
KIIA 8.16.1 /06	Kling, A.	2012	6-chloropicolyl alcohol - Assessment of chronic effects to the honey bee, Apis mellifera L., in a 10 days continuous laboratory feeding limit test Eurofins Agrosience Services EcoChem GmbH, Niefern-Oeschelbronn, Germany Bayer CropScience, Report No.: S11-01958, Report includes Trial Nos.: S11-01958-L1_BLCF Edition Number: M-425159-01-2 EPA MRID No.: 48843767 Date: 2012-02-13 GLP/GEP: yes, unpublished	N	Bayer
KIIA 8.16.1 /07	Nikolakis, A.; Theis, M.; Przygoda, D.	2011	BYI 02960 tech.: Effects of exposure to spiked diet on honeybee larvae (Apis mellifera carnica) in an in vitro laboratory testing design Bayer CropScience, Report No.: E 318 3897-9, Edition Number: M-406645-01-3 EPA MRID No.: 48843768 Date: 2011-05-02 GLP/GEP: yes, unpublished	N	Bayer
KIIA 8.16.1 /09	Gladbach, D.; Theis, M.; Przygoda, D.; Nikolakis, A.	2013	Assessment of chronic effects of BYI 02960 tech. to the honey bee, Apis mellifera L., in a 10 days continuous laboratory feeding test Bayer CropScience, Report No.: E 318 4561-8, Edition Number: M-462475-01-1 Date: 2013-08-26 GLP/GEP: yes, unpublished	N	Bayer
KIIA 8.16.2 /01	Leicher, T.	2011	BYI 02960: Effects on soil litter degradation after spray application Bayer CropScience, Report No.: LRT-SLD-45/11, Edition Number: M-413408-01-2 Date: 2011-09-06 GLP/GEP: yes, unpublished	N	Bayer
KIIA 8.16.2 /02	Leicher, T.	2011	BYI 02960: Effects on soil litter degradation if applied as seed treatment Bayer CropScience, Report No.: LRT-SLD-46/11, Edition Number: M-413416-01-2 Date: 2011-09-06 GLP/GEP: yes, unpublished	N	Bayer

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
KIIA 8.16.2 /03	Nikolakis, A.; Krieg, V.; Aumeier, P.; Gladbach, D.	2012	Honey bee colony feeding study, evaluating the effects of BYI 02960-fortified sugar- and pollen diet on the development of honey bee colonies under confined semi-field conditions, followed by a post-exposure field observation period Bayer CropScience, Report No.: E 319 4111-0, Edition Number: M-438748-01-1 EPA MRID No.: 48843771 Date: 2012-09-24 GLP/GEP: yes, unpublished	N	Bayer
KIIA 8.16.2 /04	Rexer, H. U.	2012	Assessment of side effects on the honeybee (<i>Apis mellifera</i> L.), exposed to winter oil-seed rape, grown from seeds treated with BYI 02960 FS 480 G and sequentially sprayed with BYI 02960 SL 200 G during immediate pre- and full flowering in a long-term field study in Northern Germany Eurofins Agrosience Services EcoChem GmbH, Niefern-Oeschelbronn, Germany Bayer CropScience, Report No.: S10-03261, Report includes Trial Nos.: 2012-09-27 S10-03261-L2 S10-03261-L3 Edition Number: M-438818-01-1 Date: 2012-09-27 GLP/GEP: yes, unpublished	N	Bayer
KIIA 8.16.2 /05	Rexer, H. U.	2012	Assessment of side effects on the honeybee (<i>Apis mellifera</i> L.), exposed to winter oil-seed rape, grown from seeds treated with BYI 02960 FS 480 G and sequentially sprayed with BYI 02960 SL 200 G during immediate pre- and full flowering in a long-term field study in France Eurofins Agrosience Services GmbH, Niefern-Oeschelbronn, Germany Bayer CropScience, Report No.: S10-03262, Report includes Trial Nos.: S10-03262-01 S10-03262-02 Edition Number: M-438819-01-1 Date: 2012-07-24 GLP/GEP: yes, unpublished	N	Bayer

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
KIIA 8.16.2 /06	Gould, T. J.; Lawrence, J.; Harbin, A. M.	2012	Determination of residues of BYI 02960 in blossoms, nectar, and pollen when applied via soil drench and Foliar Spray to melon under semi-field Conditions in North Carolina Eurofins Agrosience Services, Inc., Mebane, NC, USA Bayer CropScience, Report No.: RARVP019, Edition Number: M-435037-01-1 EPA MRID No.: 48844525 Date: 2012-07-24 GLP/GEP: yes, unpublished	N	Bayer
KIIA 8.16.2 /07	Bocksch, S.	2012	Determination of residues of BYI 02960 applied via drench application in watermelon in the semi-field Eurofins Agrosience Services EcoChem GmbH, Niefern-Oeschelbronn, Germany Bayer CropScience, Report No.: S09-01391, Report includes Trial Nos.: S09-01391-01_BZEU Edition Number: M-424666-01-2 EPA MRID No.: 48844522 Date: 2012-02-09 GLP/GEP: yes, unpublished	N	Bayer
KIIA 8.16.2 /08	Bocksch, S.	2012	Determination of residues of BYI 02960 applied via drench application in tomato in the semi-field Eurofins Agrosience Services EcoChem GmbH, Niefern-Oeschelbronn, Germany Bayer CropScience, Report No.: S10-03818, Report includes Trial Nos.: S10-03818-01 Edition Number: M-424683-01-2 EPA MRID No.: 48844521 Date: 2012-02-10 GLP/GEP: yes, unpublished	N	Bayer

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
KIIA 8.16.2 /09	Bocksch, S.	2012	Determination of residues of BYI 02960 applied via drench application in watermelon in the semi-field Eurofins Agrosience Services EcoChem GmbH, Niefern-Oeschelbronn, Germany Bayer CropScience, Report No.: S10-03825, Report includes Trial Nos.: S10-03825-01 Edition Number: M-424675-01-2 EPA MRID No.: 48844523 Date: 2012-02-08 GLP/GEP: yes, unpublished	N	Bayer
KIIA 8.16.2 /10	Rexer, H. U.	2013	Determination of residues of BYI 02960 after application of BYI 02960 SL 200 G once before and once during flowering in a semi-field honeybee (Apis mellifera L.) study in Phacelia tanacetifolia in 2012 Eurofins-GAB GmbH, Niefern-Oeschelbronn, Germany Bayer CropScience, Report No.: S12-00038, Report includes Trial Nos.: S12-00038-L1 S12-00038-L2 Edition Number: M-457246-01-1 Date: 2013-05-31 GLP/GEP: yes, unpublished	N	Bayer
KIIA 8.16.2 /11	Rexer, H. U.	2012	A field study to determine residues of BYI 02960 in guttation liquid from winter oil-seed rape (OSR) plants in Northern Germany in 2010/2011 Eurofins Agrosience Services GmbH, Niefern-Oeschelbronn, Germany Bayer CropScience, Report No.: S10-03312, Report includes Trial Nos.: S10-03312-01 Edition Number: M-438826-01-1 Date: 2012-09-27 GLP/GEP: yes, unpublished	N	Bayer

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
KIIA 8.16.2 /12	Rexer, H. U.	2012	A field study to determine residues of BYI 02960 in guttation liquid from winter oil-seed rape (OSR) plants in France in 2010/2011 Eurofins Agrosience Services GmbH, Niefern-Oeschelbronn, Germany Bayer CropScience, Report No.: S10-03313, Report includes Trial Nos.: S10-03313-01 Edition Number: M-438829-01-1 Date: 2012-09-27 GLP/GEP: yes, unpublished	N	Bayer

List of data submitted by the applicant and not relied on

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Owner
KCP 10.2.1 / 03	[REDACTED]	2016	Acute toxicity of deltamethrin + flupyradifurone EC 85 (10+75 g/L) to the rainbow trout (Oncorhynchus mykiss) under static conditions Report No.: 007SRLS15C08, Edition Number: <u>M-548840-01-1</u> [REDACTED] GLP/GEP: Yes unpublished	Yes	Bayer
KCP 10.2.1 / 04	Matlock, D.; Moore, S.	2016	Amendment no. 2 - Acute toxicity of deltamethrin + flupyradifurone EC 85 to Daphnia magna under static conditions - Final report - Report No.: EBRVR015, Edition Number: <u>M-553769-03-1</u> SynTech Research Laboratory Services, LLC, Stilwell, KS, USA ... amended: 2016-10-19 GLP/GEP: Yes unpublished	No	Bayer
KCP 10.2.1 / 05	Silke, G.	2016	Acute toxicity of deltamethrin + flupyradifurone EC 85 (10+75) G to larvae of Chironomus riparius in a 48 h static laboratory test system Report No.: EBRVN060, Edition Number: <u>M-556348-01-1</u> Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 10.2.1 / 06	Matlock, D.; Moore, S.	2015	Toxicity of deltamethrin + flupyradifurone EC 85 to the green algae Pseudokirchneriella subcapitata during a 72 hour exposure Report No.: EBRVR016, Edition Number: <u>M-547460-01-1</u> SynTech Research Laboratory Services, LLC, Stilwell, KS, USA GLP/GEP: Yes unpublished	No	Bayer
KCP 10.2.2 / 01	[REDACTED]	2008	Refined risk assessment for aquatic effects of Deltamethrin based on recent higher tier studies, expert statements and population models Report No.: RA08-022, Edition Number: <u>M-297157-01-1</u> [REDACTED] GLP/GEP: n.a. unpublished	Yes	Bayer

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Owner
KCP 10.2.2 / 02	[REDACTED]	2007	Analysis and interpretation of the zooplankton dynamics after application of Deltamethrin EW 015 to aquatic mesocosms with special focus on the Chaoborus crystallinus population Report No.: <u>M-291864-01-1</u> [REDACTED] GLP/GEP: n.a. unpublished	Yes	Bayer
KCP 10.2.2 / 03	Heimbach, F.; Arnold, M.	2005	Bioassay on the effects of Deltamethrin EW 015 on Gammarus pulex in mesocosm water Report No.: HBF/BT 08, Edition Number: <u>M-246173-01-1</u> Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 10.2.2 / 04	Schulz, R.; Bruehl, C.	2007	Biology and distribution of selected waterlice and freshwater shrimps of Central Europe - a literature review Report No.: <u>M-291865-01-1</u> ecoco GBR, Karlsruhe, Germany GLP/GEP: n.a. unpublished	No	Bayer
KCP 10.2.2 / 05	Schulz, R.; Bruehl, C.	2007	Drift of the freshwater isopod Asellus aquaticus in a stream in an agricultural landscape - a case study Report No.: <u>M-291925-01-1</u> ecoco GBR, Karlsruhe, Germany GLP/GEP: No unpublished	No	Bayer
KCP 10.2.2 / 06	Bruehl, C.; Schulz, R.	2009	Freshwater isopods in water bodies of the agricultural landscape in Southern Europe Report No.: <u>M-329195-01-1</u> ecoco GBR, Karlsruhe, Germany GLP/GEP: n.a. unpublished	No	Bayer
KCP 10.2.2 / 07	[REDACTED]	2007	Re-evaluation of the impact of Deltamethrin on Asellus aquaticus in a mesocosm study (biological effects and fate of Deltamethrin EW 015 in outdoor mesocosm ponds, HBF/Bt 07) Report No.: RA07-046, Edition Number: <u>M-291862-01-1</u> [REDACTED] GLP/GEP: n.a. unpublished	Yes	Bayer

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Owner
KCP 10.2.2 / 08	[REDACTED]	2007	Deltamethrin EW 15 G: Acute and chronic effects to different life stages of the isopod Assellus aquaticus L in a natural water-sediment-system Report No.: P1MA, Edition Number: <u>M-291885-02-1</u> [REDACTED] ... amended: 2007-08-29 GLP/GEP: Yes unpublished	Yes	Bayer
KCP 10.2.2 / 09	[REDACTED]	2007	Brief summary of methods and first results (non-GLP) of the cancelled microcosm study on chronic effects of deltamethrin EW 15 G on population dynamics of the isopod Assellus aquaticus L in a natural water-sediment-system Report No.: P2MA, Edition Number: <u>M-291879-01-1</u> [REDACTED] GLP/GEP: No unpublished	Yes	Bayer
KCP 10.2.2 / 10	Schaefer, D.	2008	Modelling studies on the recovery of populations of assellus aquaticus from effects of deltamethrin in natural water bodies of agricultural landscapes Summary and conclusions Report No.: MEF-08/027, Edition Number: <u>M-296752-01-1</u> Bayer CropScience AG, Monheim, Germany GLP/GEP: n.a. unpublished	No	Bayer
KCP 10.2.2 / 11	Verboom, J.; Baveco, J. M. H.; van den Brink, P. J.	2005	A simulation model for spatial population dynamics of Asellus aquaticus after a spray drift event of deltamethrin in aquatic ecosystems. Report No.: MO-05-004734, Edition Number: <u>M-246365-01-1</u> Alterra, Wageningen, Netherlands GLP/GEP: No unpublished	No	Bayer
KCP 10.2.2 / 12	[REDACTED]	2007	Sensitivity analysis of the MASTEP population model: influence of life-cycle characteristics, drift and recovery of immobilisation of assellus aquaticus and time of application of the pesticide on their recovery Report No.: <u>M-290838-02-1</u> [REDACTED] ... amended: 2007-08-14 GLP/GEP: No unpublished	Yes	Bayer

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Owner
KCP 10.2.2 / 13	[REDACTED]	2007	Influence of drift of individuals and time of application on the recovery of Asellus aquaticus following deltamethrin exposure. Report No.: <u>M-292035-01-1</u> [REDACTED] GLP/GEP: No unpublished	Yes	Bayer
KCP 10.2.3 / 01	[REDACTED]	2005	Effects of Deltamethrin EW 15 on rainbow trout in aquatic outdoor microcosm enclosures Report No.: ALT.JD.2005.1, Edition Number: <u>M-256605-01-1</u> [REDACTED] GLP/GEP: Yes unpublished	Yes	Bayer
KCP 10.2.3 / 02 ... also filed: KCP 5.1.2.6 / 09	[REDACTED]	2005	Biological effects and fate of deltamethrin EW 015 in outdoor mesocosm ponds Report No.: HBF/BT 07, Edition Number: <u>M-246137-01-2</u> [REDACTED] GLP/GEP: Yes unpublished	Yes	Bayer
KCP 10.3.1.2 / 01	Kling, A.	2014	Deltamethrin EW 15B G - Assessment of chronic effects to the honeybee, Apis mellifera L., in a 10 days continuous laboratory feeding test Report No.: S13-00151, Edition Number: <u>M-477250-01-1</u> Eurofins-GAB GmbH, Niefern-Oeschelbronn, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 10.3.1.5 / 01	Rentschler, S.	2014	Determination of side-effects of Deltamethrin EW 15B G on honey bee (Apis mellifera L.) brood under confined semi-field conditions Report No.: S12-00041, Edition Number: <u>M-477316-01-1</u> Eurofins Agrosience Services EcoChem GmbH, Niefern-Oeschelbronn, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 10.3.1.5 / 02	Schmitzer, S.	2006	Toxicity testing of Deltamethrin EW 50 on honey bees (Apis mellifera L.) under semi-field conditions - tunnel test Report No.: 29011037, Edition Number: <u>M-274120-01-1</u> IBACON GmbH, Rossdorf, 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 10.3.1.5 / 03	Schur, A.	2001	Assessment of side effects of AE F032640 00 EC02 A804 on the honey bee (<i>Apis mellifera</i> L.) in the semi-field Report No.: C011205, Edition Number: <u>M-200402-01-1</u> Arbeitsgemeinschaft GAB Biotechnologie GmbH & IFU Umweltanalytik GmbH, Niefern-Oeschelbronn, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 10.3.1.5 / 04	Maus, C.; Curé, G.; Doering, J.	2006	Assessment of the short-term effects of Deltamethrin EC 100 on behaviour, foraging activity and mortality of honeybees (<i>Apis mellifera</i>) under semifield conditions (tunnel test) in Phacelia. Report No.: MAUS/AM 037, Edition Number: <u>M-262389-02-1</u> Bayer CropScience AG, Monheim, Germany ... amended: 2006-04-26 GLP/GEP: Yes unpublished	No	Bayer
KCP 10.3.1.5 / 06	Giffard, H.	2000	Impact on bumblebees (insectproof tunnels on phacelia crop) Code: AE F032640 00 EW01 B106 Report No.: C011021, Edition Number: <u>M-200040-01-1</u> Testapi, Sarre, Gennes, France GLP/GEP: Yes unpublished	No	Bayer
KCP 10.3.1.5 / 07	Giffard, H.	2000	Impact on bumblebees (<i>Bombus terrestris</i>) (insectproof tunnels on phacelia crop) Code: AE F032640 00 EG0G06 A107 Report No.: C011023, Edition Number: <u>M-200043-01-1</u> Testapi, Sarre, Gennes, France GLP/GEP: Yes unpublished	No	Bayer
KCP 10.3.1.6 / 01	Rexer, H. U.	2013	Assessment of side effects on the honeybee (<i>Apis mellifera</i> L.), exposed to <i>Phacelia tanacetifolia</i> , sprayed sequentially with deltamethrin during flowering in a long-term field study in North Alsace, France Report No.: S10-03820, Edition Number: <u>M-452717-01-1</u> Eurofins Agrosience Services GmbH, Niefern-Oeschelbronn, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 10.3.1.6 / 02	Rexer, H. U.	2013	Assessment of side effects on the honeybee (<i>Apis mellifera</i> L.), exposed to <i>Phacelia tanacetifolia</i> , sprayed sequentially with deltamethrin during flowering in a long-term field study in Mid Alsace, France Report No.: S10-03824, Edition Number: <u>M-452723-01-1</u> Eurofins Agrosience Services GmbH, Niefern-Oeschelbronn, 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 10.3.1.6 / 03	Pistorius, J.	2007	Assessment of side effects of Deltamethrin EC 25 on the honey bee (<i>Apis mellifera</i> L.) in the field Report No.: 20061298/G1-BFEU, Edition Number: <u>M-286584-01-1</u> Eurofins-GAB GmbH, Niefern-Oeschelbronn, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 10.3.1.6 / 04	Pistorius, J.	2007	Assessment of side effects of Deltamethrin EC 25 on the honey bee (<i>Apis mellifera</i> L.) in the field Report No.: 20071100/G1-BFEU, Edition Number: <u>M-295800-01-1</u> Eurofins-GAB GmbH, Niefern-Oeschelbronn, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 10.3.2.4 / 01	Aldershof, S.; Bakker, F.	2012	A field study to assess the effects of deltamethrin EW 15 (g/L) on the non-target, surface- and plant-dwelling, arthropod fauna of a grassland habitat (off-crop) in SW France during spring/summer Report No.: B157FFN, Edition Number: <u>M-430827-01-1</u> MITOX Consultants, Amsterdam, Netherlands GLP/GEP: Yes unpublished	No	Bayer
KCP 10.3.2.4 / 02	Aldershof, S.; Bakker, F.	2012	A field study to assess the effects of deltamethrin EW 15 (g/L) on the non-target, surface- and plant-dwelling, arthropod fauna of a grassland habitat (off-crop) in the Netherlands during spring/summer (Amendment 1) Report No.: B158FFN, Edition Number: <u>M-430876-03-1</u> MITOX Consultants, Amsterdam, Netherlands ... amended: 2012-10-12 GLP/GEP: Yes unpublished	No	Bayer
KCP 10.3.2.4 / 03	Aldershof, S.; Bakker, F.	2019	A field study to assess the effects of deltamethrin + flupyradifurone EC 85 (10+75 g/L) on the non-target, surface- and plant-dwelling, arthropod fauna of a grassland habitat (off-crop) in The Netherlands during spring/summer Report No.: B168FFN, Edition Number: <u>M-661092-01-1</u> Eurofins MITOX, Amsterdam, Netherlands 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 10.3.2.4 / 04	Aldershof, S.; Bakker, F.	2019	A field study to assess the effects of deltamethrin + flupyradifurone EC 85 (10+75 g/L) on the non-target, surface- and plant-dwelling, arthropod fauna of a grassland habitat (off-crop) in SW France during spring/summer Report No.: B169FFN, Edition Number: <u>M-661091-01-1</u> Eurofins MITOX, Amsterdam, Netherlands GLP/GEP: Yes unpublished	No	Bayer
KCP 10.4.1.1 / 01	Friedrich, S.	2014	Deltamethrin EC 100 G: Sublethal toxicity to the earthworm Eisenia fetida in artificial soil Report No.: 14 10 48 127 S, Edition Number: <u>M-494315-01-1</u> BioChem agrar GmbH, Gerichshain, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 10.4.2.1 / 01	Friedrich, S.	2014	Deltamethrin EC 100 G: effects on the reproduction of the collembolan Folsomia candida Report No.: 14 10 48 125 S, Edition Number: <u>M-494027-01-1</u> BioChem agrar GmbH, Gerichshain, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 10.4.2.1 / 02	Schulz, L.	2014	Deltamethrin EC 100 G: Effects on the reproduction of the predatory mite Hypoaspis aculeifer Report No.: 14 10 48 126 S, Edition Number: <u>M-495034-01-1</u> BioChem agrar GmbH, Gerichshain, Germany GLP/GEP: Yes unpublished	No	Bayer

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

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

Appendix 2 Detailed evaluation of the new 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

Comments of zRMS:	Please, refer to point 9.2 and 9.3 for the combined risk assessment.
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Reference:	KCP 10.1.1/01
Title:	Technical stand-alone combined toxicity assessment for the Central zone
Report:	Gladbach, A.; Ebeling, M.; Weyers, A.; 2017; M-571377-02-1
Guideline(s):	none
Deviations:	--
GLP/GEP:	no
Acceptability:	Refer to points 9.2 and 9.3
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.

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).

The second step, in case the first step is not satisfied, investigates whether the combined risk is significantly dominated (>90%) by one substance.

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 2.1.1.1 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

Comments of zRMS:	Please, refer to point 9.2 and 9.3 for the combined risk assessment.
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Reference:	KCP 10.1.2/01
Title:	Technical stand-alone combined toxicity assessment for the Central zone
Report:	Gladbach, A.; Ebeling, M.; Weyers, A.; 2017; M-571377-02-1
Guideline(s):	none
Deviations:	--
GLP/GEP:	no
Acceptability:	Refer to points 9.2 and 9.3
Duplication (if vertebrate study):	

Please refer to chapter A 2.1.1.

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:	<p>No actual combined risk assessment for aquatic organisms was performed by the Applicant and the conclusions that deltamethrin drives the toxicity was based on qualitative assessment of the endpoints with concentration of the particular substances in DLT+FPF EC 85 not taken into account.</p> <p>The Applicant is thus requested to provide respective evaluation of the mixture toxicity performed in line with indications of EFSA (2013).</p> <p>It should be also noted that none of the acute toxicity studies performed with the formulation were agreed by the zRMS since concentration of the least stable substance (deltamethrin) was not verified in the respective chemical analyses. During the commenting period the Applicant may provide additional explanations to justify selection of the substance for chemical verification or data to confirm that deltamethrin was most stable during the study. In case this will be confirmed, measured formulation endpoints will be relevant for the combitox assessment. Otherwise, the risk assessment for the mixture will have to be based on the theoretically estimated exposure.</p>
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Reference:	KCP 10.2/01
Title:	Technical stand-alone combined toxicity assessment for the Central zone
Report:	Gladbach, A.; Ebeling, M.; Weyers, A.; 2017; M-571377-02-1
Guideline(s):	none
Deviations:	--
GLP/GEP:	no
Acceptability:	
Duplication (if vertebrate study):	

Please refer to chapter A 2.1.1.

Comments of zRMS:	<p><u>Fish</u></p> <p>The study by Feyerabend et al. (2001) was not provided in support of this evaluation and its summary was also not presented in Deltamethrin Addendum of July 2002. Taking this into account, it is not possible to verify endpoints listed by the Applicant in Table 9.13-1, especially they were also not provided in the Addendum of July 2002 or reported in the Review Report for deltamethrin (6504/VI/99-final, 2002). It is thus not known if available endpoints are fully reliable and may be actually used for the higher tier risk assessment for fish. It is, however, noted that according to conclusions taken by the RMS in the course of the ongoing EU renewal process of deltamethrin, based on the whole data package for aquatic organisms (including the higher tier microcosm study by Deneer, 2005, M-256605-01-1), the endpoint derived for aquatic invertebrates will cover also risk to fish. The zRMS fully agrees with this conclusion and is of the opinion that it is also applicable for evaluation of DLT+FPF EC 85. It is noted that no definite endpoint could be derived from the study by Deneer (2005) due to the exposure regime, however rough estimations provided by the RMS indicated that the overall NOEC from the study would be at ~200 ng a.s./L, which is much higher comparing to 3.2 ng a.s./L derived for aquatic invertebrates. Taking this into account, the endpoints for fish based on data that could not be validated were not considered further.</p>
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Higher tier options for refined risk assessment in fish and aquatic invertebrates

Refined Risk Assessment for fish

A comprehensive refined risk assessment for fish is provided by [REDACTED] (2008; [M-292027-02-1](#)). The main approaches and results presented in this report are summarized below.

- *Fish Species Sensitivity Distribution (SSD)*

As recommended in the EFSA Aquatic Guidance Document (2013), constructing a separate SSD for fish may be necessary if the risks of a PPP to populations of invertebrates and primary producers have been assessed by means of appropriate microcosm or mesocosm experiments without fish. The micro- and mesocosm studies that are presented below did not include fish, thus meeting the requirements of the EFSA Aquatic Guidance Document (2013). Therefore, a specific SSD for fish was constructed.

An SSD that addresses the sensitivity of fish should be based on a minimum of 5 toxicity data points for different fish species (Campbell et al., 1999²). Feyerabend et al. (Feyerabend, Romijn, Schaefer, Sowig, 2001; [M-201581-01-1](#); IIA, Addendum (C016021)) reported acute LC₅₀ values for 13 different fish species (see Table 9.15-1). Additional data were retrieved from the U.S. EPA literature database ECOTOX³. For three of the species, the studies delivered LC₅₀ values which were higher than the solubility limit of deltamethrin in water (< 5000 ng a.s./L). These endpoints were excluded from the HC₅ calculation.

Table 9.15-1: Acute LC₅₀ values of deltamethrin for fish species (from Feyerabend *et al.*, 2001)

Species	Common name	Species mean LC ₅₀ [ng/L]
<i>Oncorhynchus mykiss</i>	Rainbow trout	260*
<i>Lepomis gibbosus</i>	Pumpkinseed	580
<i>Cyprinodon macularius</i>	Desert pupfish	600
<i>Ictalurus punctatus</i>	Channel catfish	630
<i>Lepomis macrochirus</i>	Bluegill sunfish	780
<i>Gambusia affinis</i>	Mosquitofish	1342
<i>Cyprinus carpio</i>	Common carp	1890
<i>Salmo salar</i>	Atlantic salmon	1970
<i>Brachydanio rerio</i>	Zebrafish	2000
<i>Sarotherodon mossambicus</i>	Java tilapia	3500
<i>Tilapia nilotica</i>	Nile tilapia	14500
<i>Esox lucius</i>	Northern pike	23000
<i>Ctenopharyngodon idella</i>	Grass carp	91000

*Acute endpoint for deltamethrin, as listed in the List of Endpoints (European Commission (2002). Review report for the active substance deltamethrin, 6504/VI/99-final, 17 October 2002), derived from a study with the representative formulation for Annex I listing, Deltamethrin EC25.

The HC₅ was calculated by Brock (2005, [M-254687-01-1](#), Appendix 2) according to the method of Aldenberg & Jaworska (2000). Considering the 10 most sensitive fish species, a median HC₅ value of 272 ng/L was obtained.

- *Refinement of the Assessment Factor (AF) to be used with the SSD*

Following the recommendation of the 2013 EFSA Aquatic Guidance Document (p. 101 and Table 28), in order to derive an SSD-RAC for fish, an Assessment Factor of 9 should be applied to a median acute HC₅ based on acute LC₅₀ data. Thus, **the SSD-RAC for deltamethrin in fish is 30 ng/L.**

All acute LC₅₀ values presented and discussed above are derived from laboratory studies either under flow-through, semi-static or static test conditions. All these studies overemphasize the exposure and thus are prone to lead to an overestimation of the toxicity to fish, since deltamethrin dissipates much

² Campbell, P.J., Arnold, D.J.S., Brock, T.C.M., Grandy, N.J., Heger, W., Heimbach, F., Maund, S.J., Streloke, M. 1999. Guidance Document on Higher-tier Aquatic Risk Assessment for Pesticides (HARAP). SETAC-Europe publication, 179 pp

³ ECOTOX is a literature database maintained by the U.S. Environmental Protection Agency and is available for public access through a search interface at www.epa.gov/ecotox.

more rapidly in natural water bodies, mainly due to the very low solubility in water and the adsorption to particulate matter, sediment or macrophytes. For these reasons, a study was conducted in outdoor enclosures to simulate reasonable worst-case conditions of actual field situations.

- *Effect of deltamethrin on rainbow trout in outdoor microcosm enclosures (Deneer, J.W., 2005; [M-256605-01-1](#), see Appendix 2, section A 2.2.3)*

In order to obtain data on potential effects of deltamethrin on fish under more realistic exposure conditions and to consider multiple applications of deltamethrin, a species-focused microcosm study was performed under actual semi-field conditions. The most sensitive fish species, *Oncorhynchus mykiss*, was exposed under realistic worst-case conditions in outdoor oligo-mesotrophic enclosures with a water depth of 0.5 m. Deltamethrin was applied as Deltamethrin EW15 three times at 7-day intervals. Nominal initial concentrations were 125, 250, 500 and 1000 ng a.s./L.

No treatment-related effects on length, wet and dry weights, length and weight increases, or survival were observed at all treatment levels including the highest one of 1000 ng a.s./L. However, slight symptoms (swimming behaviour, coughing) occurred within a few hours on day 1 after the first application at 500 ng a.s./L, the overall NOEC of this study on rainbow trout has therefore been set as 500 ng a.s./L. Considering the fast recovery of the initially observed symptoms, the NOEAEC was set as ≥ 1000 ng a.s./L.

The outdoor microcosm study was performed:

- under realistic exposure conditions of a natural freshwater community,
- with three applications of deltamethrin at 7-day intervals,
- with the most sensitive fish species, *Oncorhynchus mykiss*.

At the NOEAEC of this study, no adverse effects on the overall most sensitive endpoint (weight increase, according to the results of the laboratory ELS and full life-cycle studies) were observed. **For these reasons, the use of the NOEAEC and the chronic assessment factor of 10 seems appropriate for the final risk assessment for fish, resulting in an ecologically acceptable concentration (EAC) of 100 ng a.s./L.**

This conclusion is further supported by several semi-field and field studies, presented below as supporting data.

- *Further experimental pond, microcosm and mesocosm studies on deltamethrin with fish (Deltamethrin Monograph and Addendum Annex B Ecotoxicology)*

Supporting data from several higher tier studies with fish are summarised below. They conclusively demonstrate that the risk assessment based on laboratory data by far over-estimates the effect levels that can be expected under field conditions.

Experimental ponds (Deltamethrin Monograph Annex B Ecotox / Tooby, T. E.; Thompson, A. N.; Rycroft, R. J.; Black, I. A.; Hewson, R. T.; 1981;): No mortality was observed in roach (*Rutilus rutilus*) and crucian carp (*Carassius carassius*) at a nominal concentration of 1000 ng a.s./L from overspray at 10 g a.s./ha to 1 m deep water (≈ 3 g a.s./ha to a standard 0.3 m deep water). Severe mortality was observed in fish at a nominal concentration of 5000 ng/L from overspray at 50 g a.s./ha to 1 m deep water (≈ 15 g a.s./ha to a 0.3 m deep water). Observations were made at 14 d.

Microcosms (Deltamethrin Monograph Annex B Ecotox / [REDACTED]; 1991): No adverse effects were observed in fathead minnow (*Pimephales promelas*) at a nominal concentration of 2200 ng a.s./L from overspray at 20 g a.s./ha to 0.9 m deep water (≈ 6.7 g a.s./ha to a 0.3 m deep water). Observations were made at 7 d.

Mesocosms (Deltamethrin Monograph Annex B Ecotox / [REDACTED] 1985): No mortality was observed in fathead minnow at a nominal concentration of 3200 ng a.s./L from application of 10 g a.s./ha below the surface of 0.5 m deep water (\approx 6 g a.s./ha to a 0.3 m deep water). Frequent samplings were performed during the first week, and then twice a week until 112 days post-treatment.

Mesocosm study with tralomethrin (Deltamethrin Monograph Annex B Ecotox / Kennedy, J. H.; Rodgers, J. H.; Johnson, P. C.; 1989): Tralomethrin, which is very similar to deltamethrin in terms of mode of action and toxicity, is rapidly transformed into deltamethrin. No adverse effects were observed in bluegill sunfish (*Lepomis macrochirus*) at nominal concentrations of up to 10 x 270 ng a.s./L (spray) plus 5 x 870 ng a.s./L (slurry) from applications of up to 10 x 4.5 g a.s./ha (as spray) plus 5 x 7.2 g a.s./ha (as slurry) (\approx up to 10 x 0.8 g a.s./ha as spray plus 5 x 1.2 g a.s./ha as slurry to a 0.3 m deep water). Observations were made weekly/bi-weekly for 4-5 months.

- ***Semi-field and field studies on deltamethrin with fish***

The conclusion drawn in the refined risk assessment of deltamethrin is further supported by different semi-field and field studies carried out with Decis EC 2.5. All studies showed that fish are less sensitive under natural conditions than under laboratory conditions.

In a study conducted by Bayer Indonesia (2004; Anon.; 2004), randomized rice field plots were sprayed with 125, 250 and 500 mL/ha Decis EC 2.5 (corresponding to 3.125, 6.25 and 12.5 g deltamethrin/ha), respectively. The study investigated (i) the decline of bioactivity of deltamethrin in rice field water and (ii) fish fingerlings survival and growth by introducing 25 common carp (*Cyprinus carpio*) and 25 Nile tilapia (*Oreochromis niloticus*) fingerlings in rice field plots 4 days prior application and reared for the following 20 days. Results of the field biotest revealed rapid loss of the bioactivity of the tested insecticide dose rates (less than 1 day), suggesting that Decis EC 2.5 readily dissipated from rice field water. In the fish culture experiment, neither the common carp, nor the Nile tilapia showed significant differences in plots receiving 125, 250 and 500 mL/ha Decis EC2.5 compared to the control regarding mean survival rates and biomass gain.

Similar results were obtained in field studies performed in 1987 in irrigated rice fields in Taiwan, where effects of Decis 2.5 % spray (5 and 10 g a.s./ha) on fish culture in rice fields were investigated (Yeh, 1988a). Decis 2.5% spray was not toxic to the common carp (*Cyprinus carpio*) and did not affect growth, survival rate and productivity compared to the control. The author also investigated multiple applications of Decis 2.5% on eel ponds at distinct concentrations (6.5, 12.5 and 25 g a.s./ha deltamethrin). Paddy fields were sprayed once a week for 4 weeks; paddy water was then pumped into eel ponds after each application. Total eel mortality after 4 applications was 2% at 6.25 g a.s./ha (daily application of 1 g a.s./ha for 3 weeks) and increased from 20% to 65% with increasing concentration (Yeh, 1988b).

The low to non-toxic properties of deltamethrin formulations applied to fish culture in irrigated rice fields were confirmed in many other field and semi-field studies. Decis 0.42 Flow (a.s. deltamethrin) was tested for toxicity and effects on reproduction on the common carp *Cyprinus carpio*. At concentration rates of 3.15, 6.25 and 12.5 g a.s./ha, neither any significant mortality, nor decreases in productivity caused by deltamethrin were observed (Koesoemadinata, 1986).

Fish toxicity of Decis 2.5% WP to *Cyprinus carpio*, *Tilapia mosambica*, and *Gambusia patruelis* investigated by Han and Yeh (1986a) in rice fields in Taiwan was found to be extremely low (mortality rate < 5% at 12.5 g a.s./ha).

In Indonesia, Han and Yeh (1986b; [M-125139-01-1](#) (A42102)) investigated the effect of Decis 2.5% FP at 6.25 g a.s./ha in rice fields. They revealed deltamethrin as non-toxic to common carp fingerlings in terms of mortality and productivity of fish biomass.

Field studies carried out by Santosa *et al.* (1986; [M-125138-01-1](#) (A42101)) investigated the effects of the application of Decis 0.42 Flow to rice on common carp and Java tilapia in irrigated rice fields. At application rates of 3.15, 6.3 and 12.6 g a.s./ha, neither mortality, nor the fish biomass production was significantly different from the control.

Mulla *et al.* (1981; [M-095419-01-1](#) (A22298)) investigated the impact of repeated spray applications of deltamethrin on reproduction of the mosquito fish *Gambusia affinis* and the desert pupfish *Cyprinodon macularius*. Deltamethrin was applied weekly for 6 successive weeks at application rates of 1.1 and 5.5 g a.s./ha (4 replicates per concentration; 20 fish per test pond). Assessment was performed 1 week after the last application. It was shown that under the weekly deltamethrin treatment regime, the number of fish increased more than in the control ponds.

In semi-field studies, Dejoux *et al.* (1977; [M-149399-01-2](#) (A70915)) and Dejoux (1983; [M-150823-01-1](#) (A72508)) investigated the effect of deltamethrin on non-target organisms in a flow-through water basin. Deltamethrin was directly injected into the water, using a syringe placed at the outfall of the pouring system, at a single rate of 100 000 ng/L (0.1 mg a.s./L). Deltamethrin showed a repellent effect on fish but no toxic effects on fish were observed. When deltamethrin was sprayed to a stagnant water basin at an application rate of 18.75 g a.s./ha, again no toxic effects on fish were observed.

Fixed wing application of deltamethrin and its effects on aquatic organisms was investigated in the Upper Volta following spraying the fringing riverine forestry in the Komoe Valley (the track was about 15 m from the river banks). Aerial application was performed twice within a month at a rate of 12.5 g a.s./ha and assessments after spraying were focused on aquatic organisms. Fish were not affected by this treatment (Baldry *et al.* 1981; [M-094580-01-1](#) (A21408)).

- **Conclusion on the risk of deltamethrin to fish**

Deltamethrin was shown to be highly acutely toxic to aquatic organisms when exposed under laboratory conditions. However, the outlined field studies demonstrate that deltamethrin has a very low toxicity or is even non-toxic to fish under field conditions and realistic uses.

Therefore, the use of a RAC derived from laboratory data represents a very conservative approach. The EAC of 100 ng a.s./L derived from the outdoor microcosm test on fish (see KCA 10.2.3/01) is considered to be an appropriate endpoint for the acute and chronic risk assessment of deltamethrin for fish, that can be used without an additional assessment factor.

However, aquatic invertebrates are much more sensitive to deltamethrin exposure and therefore drive the aquatic risk assessment for this active substance. A comprehensive refined risk assessment for aquatic invertebrates is presented below, which also covers the risk assessment for fish.

Comments of zRMS:	<p><u><i>Aquatic invertebrates</i></u></p> <p>It is noted that the study by Feyerabend et al. (2001) was not provided in support of this evaluation and its summary was also not presented in Deltamethrin Addendum of July 2002. Taking this into account, it is not possible to verify endpoints listed by the Applicant in Table 9.13-2, especially they were also not provided in the Addendum of July 2002 or reported in the Review Report for deltamethrin (6504/VI/99-final, 2002). It is thus not known if available endpoints are fully reliable and may be actually used for the higher tier risk assessment for fish.</p> <p>Detailed discussion on the proposed endpoint of 23 ng a.s./L for aquatic invertebrates concluded by Heimbach & Koelzer, (2008, M-297157-01-1) is presented below under KCP 10.2.2/01. In summary proposed endpoint is not agreed by the zRMS since it was</p>
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	<p>derived with consideration of indications of the outdated guidance document (SANCO/3268/2001 rev. 4, final) which was replaced by the EFSA aquatic guidance (2013), applicable for all applications submitted since 2015. Furthermore, conclusion on the endpoint of 23 ng a.s./L was based on recovery observed in some of the studies submitted, but in line with the Central Zone agreements and specific Polish requirements, recovery is no longer an option in derivation of the endpoints and higher tier studies must be evaluated with consideration of the ETO option. This is of specific importance for DLT+FPF EC 85, which contains two active substances of insecticidal mode of action (deltamethrin and flupyradifurone) and it is not known if the populations of aquatic invertebrates would recover after simultaneous exposure to both active compounds.</p> <p>It was further noted that majority of the studies included in the data package on the basis of which Heimbach & Koelzer (2008) proposed an overall endpoint of 23 ng deltamethrin/L with no AF, has been also evaluated in the course of the ongoing EU renewal process of deltamethrin. Based on results of the same studies the endpoint was set by the RMS to 1.0 ng deltamethrin/L with and AF of 2, resulting with RAC of 0.5 mg deltamethrin/L. Since in the evaluation indications and criteria of EFSA (2013) were considered, this endpoint seems to be most reliable. Nevertheless, as the renewal process is not finalised yet and the endpoint to be used in the aquatic risk assessment will be most probably further discussed during the expert meeting the zRMS is of the opinion that at the current stage the EU agreed EAC of 3.2 ng deltamethrin/L should be used with AF of 2, resulting with RAC of 1.6 ng/L.</p>
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General refined risk assessment of deltamethrin for aquatic invertebrates

In the following, a refined risk assessment is presented taking into account experimental studies, expert statements and metapopulation model calculations, which were performed after the Annex I inclusion of deltamethrin to address specific concerns raised during the past years. According to the EFSA Aquatic Guidance Document (2013), a combination of experimental data and modelling can be used to assess population- and/or community-level responses (e.g., recovery, indirect effects) at relevant spatio-temporal scale. This was therefore applied to deltamethrin, as described below. The risk assessment is in general agreement with the expert report by Heimbach & Koelzer (Heimbach, F.; Koelzer, U.; 2008; [M-297157-01-1](#); Appendix 2, section 2.2.2).

The refined risk assessment for aquatic invertebrates includes the following documents:

- Schanné, C. & van der Kolk, J. (2001): (¹⁴C)-deltamethrin formulated as emulsifiable concentrate (25 g/L deltamethrin): outdoor aquatic microcosm study of the ecological effects and environmental fate (Monograph Addendum Annex B Ectotoxicology)
- Heimbach, F. *et al.* (2005): Biological effects and fate of Deltamethrin EW 015 in outdoor mesocosm ponds ([M-246137-01-2](#), Appendix 2, section 2.2.3)
- [REDACTED] (2007): Effects on zooplankton in the mesocosm study: Analysis and interpretation of the zooplankton dynamics after application of Deltamethrin EW 015 to aquatic mesocosms with special focus on the *Chaoborus crystallinus* population ([M-291864-01-1](#), Appendix 2, section 2.2.2)
- Heimbach, F. & Arnold, M. (2005): Bioassay on the effect of Deltamethrin EW 15 on *Gammarus pulex* in mesocosm water ([M-246173-01-1](#), Appendix 2, section 2.2.2)
- Bruehl, C. & Schulz, R. (2007a): Biology and distribution of selected waterlice and freshwater shrimps of Central Europe – a literature review ([M-291865-01-1](#), Appendix 2, section 2.2.2)
- Bruehl, C. & Schulz, R. (2007b): Drift of the freshwater isopod *Asellus aquaticus* in a stream in an agricultural landscape – a case study ([M-291925-01-1](#), Appendix 2, section 2.2.2)
- Bruehl, C. & Schulz, R. (2009): Freshwater isopods in water bodies of the agricultural landscape in Southern Europe ([M-329195-01-1](#), Appendix 2, section 2.2.2)
- Heimbach, F. & Koelzer, U. (2007a): Re-evaluation of the impact of deltamethrin on *Asellus*

aquaticus in a mesocosm study (“Biological Effects and Fate of Deltamethrin EW 015 in Outdoor Mesocosm Ponds”, HBF/Bt 07) ([M-291862-01-1](#), Appendix 2, section 2.2.2)

- [REDACTED] (2007): Deltamethrin EW 15 G: Acute and chronic Effects to Different Life Stages of the Isopod *Asellus aquaticus* L. in a Natural Water-Sediment System ([M-291885-02-1](#), Appendix 2, section 2.2.2)
- [REDACTED] (2007): Brief summary of methods and first results (non GLP) of the cancelled microcosm study on chronic effects of Deltamethrin EW 15 G on population dynamics of the isopod *Asellus aquaticus* L. in a natural water-sediment. system ([M-291879-01-1](#), Appendix 2, section 2.2.2)
- Schaefer, D. (2008): Modeling studies on the recovery of populations of *Asellus aquaticus* from effects of deltamethrin on natural water bodies of agricultural landscapes ([M-296752-01-1](#), Appendix 2, section 2.2.2); including:
 - A simulation model for spatial population dynamics of *Asellus aquaticus* after a spray drift event of Deltamethrin in aquatic ecosystems ([Verboom, J.; Baveco, J. M. H.; van den Brink, P. J.; 2005; M-246365-01-1](#), Appendix 2, section 2.2.2)
 - Sensitivity analysis of the MASTEP population model: influence of life-cycle characteristics, drift and recovery of immobilisation of *Asellus aquaticus* and time of application of the pesticide on their recovery ([REDACTED] 2007; [M-290838-02-1](#), Appendix 2, section 2.2.2)
 - Influence of drift of individuals and time of application on the recovery of *Asellus aquaticus* following deltamethrin exposure ([REDACTED] 2007; [M-292035-01-1](#), Appendix 2, section 2.2.2)

- ***Additional data on acute toxicity of deltamethrin to aquatic invertebrates***

Feyerabend *et al.* (Feyerabend, M.; Romijn, K.; Schaefer, D.; Sowig, P.; 2001; Monograph Addendum Annex B Ectotoxicology) reported acute endpoints for 28 aquatic freshwater arthropod species derived from the EPA literature database as listed in Table 9.15-2. The ECOTOX database was searched for toxicity data on deltamethrin. ECOTOX is maintained by the U.S. Environmental Protection Agency (US EPA) and is available for public access through a search interface at www.epa.gov/ecotox.

The test endpoints were mortality or immobilisation after 24 to 96 h. Results are mainly expressed as nominal concentrations. When more than one result was available for a species, only results from flow-through or static-renewal tests were used, to maintain comparability among tests within different species (although these conservative continuous exposure regimes are less relevant to natural conditions than static exposures). For each species, the geometric mean of LC₅₀ or EC₅₀ values was calculated from all flow-through or static-renewal studies with measured concentrations. An exception to the use of geometric means was made for *Daphnia magna*. For *D. magna*, the EC₅₀ value from the definitive study officially accepted by the EU (110 ng/L) was used rather than the geometric mean (91 ng/L; n = 10).

Table 9.15-2: Acute LC₅₀ values of aquatic arthropod species exposed to deltamethrin (from Feyerabend *et al.*, 2001)*

Species	Common name	Species Mean LC ₅₀ [ng/L]
<i>Gammarus fasciatus</i>	Amphipod	0.31
<i>Asellus aquaticus</i>	Isopod	5.1
<i>Culex pipiens quinquefasciata</i>	Mosquito	20.0
<i>Culex quinquefasciatus</i>	Mosquito	21.9
<i>Daphnia hyaline</i>	Water flea	30.0
<i>Gammarus pulex</i>	Amphipod	30.0
<i>Eudiaptomus gracilis</i>	Copepod	50.0
<i>Procladius</i>	Midge	67.0
<i>Crocothemis</i>	Odonate	82.5
<i>Daphnia magna</i>	Water flea	110
<i>Tanytus nubifer</i>	Midge	110
<i>Cricotopus</i>	Midge	129
<i>Gammarus roeseli</i>	Amphipod	130
<i>Aedes aegypti</i>	Mosquito	150
<i>Pseudagrion</i> sp.	Odonate	188
<i>Chironomus utahensis</i>	Midge	290
<i>Baetis parvulus</i>	Mayfly	400
<i>Hydropsyche californica</i>	Caddisfly	400
<i>Chironomus decorus</i>	Midge	545
<i>Chironomus salinarius</i>	Midge	710
<i>Daphnia similis</i>	Water flea	870
<i>Brachythemis contaminata</i>	Odonate	890
<i>Dicrotendipes californicus</i>	Midge	1715
<i>Anisops bouvieri</i>	Hemipteran	2250
<i>Ranatra elengata</i>	Hemipteran	2300
<i>Ranatra filiformis</i>	Hemipteran	2300
<i>Diplonychus indicus</i>	Hemipteran	26500
<i>Chironomus</i> sp.	Midge	39000

* Including additional data derived from ECOTOX database (<http://www.epa.gov/ecotox>)

These acute laboratory studies indicate a high intrinsic toxicity of deltamethrin for many freshwater arthropod species when tested in clean water under flow-through or semi-static test conditions. Some insect species and the macrocrustaceans *Gammarus* spp. and *Asellus aquaticus* are the most sensitive species under these test conditions.

- Outdoor full micro- and mesocosm studies

Two higher tier outdoor mesocosm studies investigating the effects of deltamethrin on aquatic invertebrate communities are available and summarized below:

- Outdoor microcosm study with artificial exposure conditions

(Schanne, C.; van der Kolk, J.; 2001; Monograph Addendum Annex B Ectotoxicology).

To study the effects of deltamethrin under more realistic conditions on a natural freshwater community, an outdoor microcosm study with 1 m³ enclosures was used as test model. Decis EC 25 was applied under the water surface to static systems of 1 m depth and artificially mixed into the water body immediately thereafter. Deltamethrin was applied three times at 7 day intervals, at nominal concentrations of 1.0, 3.2, 10, 18, 32, 56, 100 and 180 ng a.s./L.

The results of this study show that 27 of 51 taxa - *i.e.* 53% - were neither directly, nor indirectly affected by the test item, even at the highest test concentration of 180 ng a.s./L. These include Gastropoda, Hirudinea, Oligochaeta, sediment dwelling organisms, Insecta and several zooplankton organisms. The taxonomic richness of the aquatic communities was not affected at concentrations of 1.0, 3.2, 10 and 18 ng a.s./L. At higher levels, effects on taxonomic richness lasted for maximum 71 days, depending on the concentration and the organism.

The effects found at the three lowest test levels 1.0, 3.2 and 10 ng a.s./L were similar. In total, 4 groups

of organisms were affected: the larvae and emergent adults of Chaoborids at all these three levels, Ephemeroptera larvae at 3.2 and 10 ng a.s./L, the crustacean zooplankton species *Daphnia* spec. at 10 ng/L, and the Isopod species *Asellus aquaticus* at all three levels. However, the effects on Chaoborids, Ephemeroptera and *Daphnia* sp. were only short-term effects lasting between 8 and 13 days after the first application. The effects on *A. aquaticus* lasted longer, i.e. for 65 days, until recovery was observed. All groups affected at ≤ 10 ng a.s./L recovered from the impact of the test item between 21 and 85 days after the first treatment.

In the conditions of this microcosm study where mixing of the test item in the water column resulted in exaggerated exposure conditions, especially for benthic organisms, the final conclusion by regulatory authorities resulted in an aquatic NOAEC of 10 ng a.s./L (EAC of 3.2 ng a.s./L) for deltamethrin in the EU List of Endpoints⁴. However, the application method in this study overestimated exposure and bioavailability of deltamethrin to aquatic organisms. Therefore, the exposure of aquatic invertebrates to deltamethrin in this study cannot be considered as representative of spray drift, which is the only relevant entry route into water bodies for this insecticide. The results of this microcosm study are therefore considered to show the intrinsic properties of deltamethrin only and should not be used to derive a higher-tier RAC.

- Outdoor mesocosm study simulating the relevant route of entry
(XXXXXXXXXX; 2005; [M-246137-01-2](#); **Appendix 2**, section 2.2.3)

To simulate drift as the relevant entry for deltamethrin under field conditions, an outdoor mesocosm study was conducted as a “higher tier” study. Outdoor tanks with 6 m³ of water (1.0 m deep) and 15 cm natural sediment taken from an uncontaminated pond nearby were used for this study. The application rates were 4.8, 10.5, 23, 51 and 111 ng a.s./L, and three applications were done at 7 day intervals. The study evaluated all freshwater pelagic and benthic invertebrate species. This mesocosm study with Deltamethrin EW 15 was conducted in order to simulate spray drift as the actual entry route. However, the exposure was increased since all biological, physicochemical and analytical sampling that occurred within the first hours after application resulted in an exaggerated artificial mixing of the pond water as compared to undisturbed natural waters.

Shredders (gammarids and aselids) were tested in parallel bioassays, using the mesocosm water. Since most Gammarids clearly prefer running waters, this taxon was not tested in this static pond system. *Asellus aquaticus* was artificially introduced into the test systems since populations did not appropriately develop in the ponds. Because it was unclear whether the inserted populations could be maintained throughout the study, bioassays were also performed with water and food samples taken from the ponds throughout the study. The bioassays also allowed the demonstration of potential recovery of affected populations.

In the mesocosm study, deltamethrin concentrations followed a steady and fast decline, with a mean DT₅₀ of 22.4 hours in the water and a mean DT₅₀ of 31.6 hours for the whole test system (water plus sediment).

Chaoborus crystallinus was identified as the most sensitive taxon with consistent effects even at 4.8 ng a.s./L. These occurred immediately after application until about a very few weeks after the last application when a full recovery was observed even at the highest test level. At 10.5 ng a.s./L, short-term effects were also observed for one Rotatoria species (*Keratella quadrata*) and Copepod Nauplii. *A. aquaticus* showed a reduced activity at this test level for very few days after application without any sign of mortality or affected reproduction. At 23 and 51 ng a.s./L, effects on one to three more individual species were observed, but these effects were also short-term only, a full recovery having occurred within the first weeks after the last application. The abundance of *Asellus* was clearly reduced after application at these concentrations but returned mostly to the level of controls until study termination. The differences between control and treatment levels were small and population abundance clearly

⁴ European Commission (2002). Review report for the active substance deltamethrin, 6504/VI/99-final, 17 October 2002

increased in these ponds during the study, as additionally demonstrated by the increasing number of juvenile organisms. The bioassay findings confirmed that water and food samples, taken from the mesocosms at the latest one week after the applications, did not have any negative effects on *A. aquaticus*. At 111 ng a.s./L, the number of affected zooplankton and insect species was distinctly higher, and the effects on *A. aquaticus* even more developed as compared to lower treatment levels.

Based on the observed effects on several invertebrate species at 51 ng a.s./L and the observed fast recovery of affected populations at 4.8 to 51 ng a.s./L, a NOEAEC (“no observed ecological adverse effect concentration”) of 51 ng a.s./L can be derived from this study. (Because of the missing replication at the highest treatment level of 111 ng a.s./L, this concentration was not considered for the NOEAEC deduction.)

A recovery of affected populations was clearly demonstrated for all pelagic or benthic invertebrate species at test concentrations up to and including 51 ng a.s./L. Nevertheless, the demonstration of an *in situ* recovery of the *Asellus* population remains partly unclear at 23, 51 and 111 ng a.s./L because of the isolation of the individual test ponds and the resulting missing inoculation potential of this species during the study. However, the bioassays on *A. aquaticus* demonstrate the potential for recovery within a few days after application.

Overall, the effects observed in this study raised some open questions for the aquatic risk assessment. Therefore, additional studies, expert statements and population model calculations were initiated to evaluate the risks in more detail. Several of these initiatives focused on specific focal species, *i.e.* *Chaoborus crystallinus* and *Asellus aquaticus*, and are summarized and discussed below.

- ***Analysis and interpretation of the zooplankton dynamics after application of Deltamethrin EW 015 to aquatic mesocosms with special focus on the Chaoborus crystallinus population*** ([REDACTED] [2007; M-291864-01-1](#); **Appendix 2**, section 2.2.2)

This expert statement provides an analysis and interpretation of the zooplankton dynamics after the application of deltamethrin to aquatic pond mesocosms in the study of Heimbach *et al.* (2005, see KIIIA 10.2.3/01, core document) with special focus on the *Chaoborus crystallinus* population. *Chaoborus* was overall the intrinsically most sensitive species within the mesocosm study, showing strong initial effects followed by a fast recovery of the affected population shortly after application.

Ratte concluded: “Exemplary life-cycle calculations, observations and considerations on the population densities and emergence of *Chaoborus crystallinus* in the mesocosm revealed that this population probably recovered by means of external sources *via* egg masses laid on the water surface of treated ponds soon after the last application. Larvae which hatched from egg masses about 6 to 7 days onwards after the last application of 4.8 ng a.s./L (7 to 8 days at 111 ng a.s./L; egg deposition about 4 days earlier) survived and got trapped as emerged midges later on during the study”.

Following the food web evaluation, it is seen as very unlikely that the test item had any effects on rotifers. On the contrary, the population growth of rotifers was promoted due to an indirect effect *via* the toxicant-induced loss of effective predators (*Chaoborus*) and of competing *Cladocerans* (*Daphnia longispina*, *Chydorus sphaericus*), until the predators came into play again. *Asplanchna* and new young *chaoborid* larvae repopulating the mesocosms probably caused the sharp decline in rotifers soon after the applications. Thus, it can be confirmed that all observed effects on the population dynamics of rotifers are to be considered as secondary effects of the treatment with deltamethrin.

The increase in the population densities of *Daphnia longispina* at higher test concentrations some weeks after the applications probably does not depend on exposure to the test item. Taking into consideration the rapid dissipation of deltamethrin from the water phase and the short generation cycles (< 10 d) of this species, the start of recovery appears rather delayed. Since the daphnid densities did not reach control densities until the first emergence of chaoborids, most probably the growing population of 3rd- and 4th-instar larvae substantially contributed to the delayed recovery by predation.

With respect to the copepod populations, the expert statement concurs to the description and interpretation of Heimbach *et al.* (2005). However, the effects on the nauplii are seen to be also caused by the decline of the copepods themselves, since their decline caused less production of eggs and thus nauplii.

Overall, *Chaoborus crystallinus* was found as the most sensitive species in this mesocosm study with deltamethrin, demonstrating a distinct reduction in abundance of larvae and emerging midges immediately after the application at all treatment levels. However, larvae hatching from egg masses in the pond treated at the highest test level (111 ng a.s./L) already survived 7 to 8 days after the last application and emerged later on. In addition the abundance of *Daphnia longispina* and copepods (mainly nauplii) was affected by deltamethrin at the highest test levels. Although the recovery for *D. longispina* was delayed by the predation of a growing population of *Chaoborus* larvae, the populations of both *Daphnia longispina* and copepods (mainly nauplii) recovered even up to the highest test level within some weeks after the last application at the latest. The population dynamics of *Chaoborus crystallinus* also caused some short-term indirect food web effects (as on rotifers and phytoplankton).

Thus, the treatment with deltamethrin caused distinct short-term effects on a few zooplankton species, which also induced fluctuations on other zooplankton and phytoplankton species within the food web for some weeks only, because of the short half-life of deltamethrin ($DT_{50} < 1$ day) in the water phase. The results gained from this mesocosm study even enable to detect secondary effects caused by the population growth of a predator like *Chaoborus*, or food competition between Cladocera/Copepoda and Rotatoria. These relationships cause delayed fluctuations and oscillating population dynamics for some time until a population density is reached permanently, which cannot be differentiated from control findings. These secondary effects are restricted to higher test concentrations, and the impacts on population densities are not very strong as compared to fluctuations of natural populations in control mesocosms. All observed direct and indirect effects recovered within some weeks after the application: the latest full recovery was observed for the rotifer *Kerratella quadrata* and the cladoceran *Daphnia longispina* seven weeks after application. However, the generation time of these species is a few days only and, thus, the potential for the growth of an affected population is high. This period of seven weeks is shorter than the recovery period of eight weeks, which had been defined as an acceptability criterium for observed effects in the EFSA Aquatic Guidance Document (2013).

- ***Additional studies on invertebrate species***

Other species with distinctly longer life cycles or even univoltine species did not show adverse effects in the mesocosm study with deltamethrin (*Asellus aquaticus* is discussed separately – see below).

- Based on the U.S. EPA's ECOTOX database, Feyerabend *et al.* (Feyerabend, M.; Romijn, K.; Schaefer, D.; Sowig, P.; 2001; [M-201581-01-1](#); IIA, Addendum (C016021)) reported sensitivities for 28 freshwater invertebrates (see Table 9.15-2). The most sensitive species, *Gammarus fasciatus*, is a North American species, which does not occur in Central Europe ([Schulz, R.; Bruehl, C.; 2007; M-291865-01-1](#); see **Appendix 2**, section 2.2.2). The second most sensitive species, *Asellus aquaticus*, was included in the mesocosm study and tested in additional bioassays. The further most sensitive species are insects (mosquitos) which are covered by several other insect species with similar life cycles evaluated in the mesocosm study. Other sensitive organisms are water fleas, *Gammarus pulex*, copepods and a midge species. With the exception of *Gammarus*, these species represent groups with short life cycles. The sensitivity of *Gammarus pulex* to deltamethrin is clearly lower than the sensitivity of *Asellus*, as also demonstrated by the bioassay on *Gammarus pulex* performed in parallel to the mesocosm study (Heimbach, F.; Arnold, M.; 2005; [M-246173-01-1](#), see **Appendix 2**, section 2.2.2). The most sensitive organism group concerning univoltine species is represented by the odonata *Crocothemis*. However, this species is 16-times less sensitive than *Asellus aquaticus* and unacceptable effects on these organisms are not to be expected at environmental concentrations of deltamethrin, which do not have adverse effects even on the most sensitive species.

Because it was identified as the most sensitive species relevant for Central Europe, *Asellus aquaticus* was selected as test species in the mesocosm study (██████; 2005; [M-246137-01-2](#); **Appendix 2**, section 2.2.3) and in parallel bioassays. As *Gammarus fasciatus* is a North American species mainly inhabiting upstream brooks with clear and fast flowing water, and is not considered relevant for European agricultural areas ([Schulz, R.; Bruehl, C.; 2007; M-291865-01-1](#); see **Appendix 2**, section 2.2.2), this species was not selected as a second test species for bioassays. *Gammarus pulex*, which is known to be sensitive to deltamethrin and other pyrethroids, was preferred. This species is the most common *Gammarus* species in streams in agricultural landscapes in Europe (Meijering 1991⁵, Geldhill *et al.* 1993⁶, Liess and Schulz 1995⁷), and the most relevant *Gammarus* species for agricultural areas in Europe.

Two bioassays, one with *Asellus aquaticus* and one with *Gammarus pulex* were performed in parallel to and reported within the mesocosm study of Heimbach *et al.* (██████; 2005; [M-246137-01-2](#); **Appendix 2**, section 2.2.3). For both studies, water from the mesocosms was used as test water. Leaf litter, which serves as habitat and food for both species, was also taken from the mesocosm (██████; 2005; [M-246137-01-2](#); see **Appendix 2**, section 2.2.3, [Heimbach, F.; Arnold, M.; 2005; M-246173-01-1](#); see **Appendix 2**, section 2.2.2).

Both bioassays showed mortality of test organisms only shortly after each application. *Asellus aquaticus* was more sensitive in these bioassays (NOEC 10.5 ng a.s./L) than *Gammarus pulex* (NOEC 23 ng a.s./L), confirming the ECOTOX data base information for these two species. Therefore, the aquatic risk assessment of deltamethrin further focuses on *Asellus aquaticus*.

- ***Re-evaluation of the impact of deltamethrin on Asellus aquaticus in a mesocosm study (“Biological Effects and Fate of Deltamethrin EW 15 in Outdoor Mesocosm Ponds”, HBF/Bt 07)*** (██████ 2007; [M-291862-01-1](#); see **Appendix 2**, section 2.2.2)

Based on the results of the mesocosm study and parallel bioassays, Heimbach & Koelzer (2007a) concluded the following regarding the effects of deltamethrin to *Asellus aquaticus*:

- *Asellus aquaticus* was among the most sensitive species of the mesocosm study on deltamethrin.
- Both sampling devices for *A. aquaticus* (Artificial Substrate Sampler (ASS), leaf cages) are activity measures of this species only (“activity traps”). The efficiency of these methods is influenced by other competing factors such as availability of food in the mesocosm ponds (macrophytes). Thus, numbers of trapped individuals cannot be directly used for the interpretation of population dynamics or mortalities.
- Since macrophytes are the preferred habitat for *A. aquaticus* in this mesocosm study, it can be assumed that organisms tend to stay on macrophytes and do not move very far over the open sediment surface. Thus, the probability of an individual to find and invade a leaf cage or ASS will also depend on the distance it has to move from a macrophyte to the sampling device. The increasing number of *A. aquaticus* in the control samples during the study proves this relationship between macrophyte densities and the number of organisms in the sampling devices.
- Three applications of 4.8 and 10.5 ng a.s./ L deltamethrin at a 7-day interval did not cause relevant effects on the activity or mortalities of exposed adult and juvenile *A. aquaticus*, resulting in an in situ-NOEC and bioassay-NOEC of 10.5 ng a.s./L.
- However, at 10.5 ng a.s./L, a slight reduction in the activity of adult and juvenile *A. aquaticus*

⁵ Meijering, M.P.D. 1991 Lack of oxygen and low pH as limiting factors for *Gammarus* on Hessian brooks and rivers. *Hydrobiologia* 223,159-169

⁶ Geldhill, T., Scutcliffe, D.W. & Williams, W.D. (1993): British Freshwater Crustacea Malacostraca: A Key With Ecological Notes. Freshwater Biological Association Scientific Publication 52, 173 S.

⁷ Liess, M. & Schulz, R. (1995): Ökotoxikologische Bewertung von Pflanzenschutzmittel-Einträgen aus landwirtschaftlich genutzten Flächen in Fließgewässern, V-3.3.5 / 1-44. In: C. Steinberg, H. Bernhardt and H. Klapper (1995): Handbuch angewandte Limnologie, ecomed Verlagsgesellschaft, Landsberg am Lech, Germany

was observed for very few days after the first application only, due to the well-known effect of pyrethroids to cause short-term paralysis of invertebrates at low exposure concentrations. The later findings clearly indicate no mortality at this test concentration, since the abundance of “trapped” individuals was the same as in control ponds at the following sampling days.

- In the three highest test concentrations of 23, 51 and 111 ng a.s./L, the mobility of *A. aquaticus* during the treatment period was clearly reduced in all ponds. However, one to two weeks after the third application, the number of mobile (*i.e.* trapped) individuals clearly increased in one pond of each of the 23 and 51 ng a.s./L treatments, and the abundance reached the control level by the end of the study at the latest in both treatment groups.
- The number of mobile *A. aquaticus* was low 7 days after the third application in all ponds of the three highest test concentrations. Hence, the study performers decided to introduce further individuals of *A. aquaticus* from the culture to one replicate of each of these test concentrations as well as to the highest test concentration of 111 ng a.s./L in order to simulate immigration:
- At 23 ng a.s./L, the numbers of mobile *Asellus* slowly increased after the introduction of new individuals in the inoculated ponds and reached the same abundance as in control ponds 8 weeks after the last application – although control ponds can no longer be considered as fully valid controls for these ponds. At the two highest test concentrations, the number of sampled mobile *Asellus* fluctuated and remained nearly constant for the rest of the study. At the end of the study, the abundance of *Asellus* was clearly within the range of the control, even at 111 ng a.s./L. However, a full recovery to the control level within 8 weeks after the last application could not be demonstrated without doubt for 23, 51 and 111 ng a.s./L. Nevertheless, the differences between control and treatment levels are small and population abundances clearly increased in these ponds, as also demonstrated by the increasing number of juvenile organisms and the corresponding reproduction *in situ*. Since *Asellus* has a long generation time of several weeks under the conditions of this study, it cannot be expected that this species could have built up the same population density as in control ponds within a few weeks only. The bioassays performed in parallel demonstrate that three weeks after the first application (one week after last application) survival of immigrating *Asellus* would no longer be affected by the water and leaves from treated ponds even at the highest test concentration, indicating the recovery potential of impacted *A. aquaticus* population.
- However, since control ponds cannot be used for a direct comparison after the inoculation of treated ponds only, and since the interpretation of the numbers of trapped *Asellus* does not allow a final persuasive conclusion, these additionally inoculated mesocosm replicates cannot be considered as fully valid and have to be interpreted with care.
- The bioassays demonstrated effects on survival of adults at all test concentrations above 10.5 ng a.s./L only shortly after each application, indicating a recovery potential for all test concentrations including the highest one (111 ng a.s./L) as early as about one week after application.
- The bioassays also indicate no differences in sensitivities between juveniles and adults in samples taken 6.5 to 8 weeks after the last application.
- Overall, the findings justify to judge the detected effects on *Asellus aquaticus* at 23 – 51 ng a.s./L as “class 3” effects (according to the 2013 EFSA Aquatic Guidance Document and de Jong *et al.*, 2008⁸), summarising all results gained from the mesocosm study and parallel bioassays. Thus, a NOEAEC of 51 ng a.s./L can be derived.
- However, since the final NOEAEC for the potential impacts of deltamethrin on *A. aquaticus* populations must also consider recovery from the immigration potential of this species, the final NOEAEC should not be derived from this mesocosm study in isolation.
- ***Acute and chronic effects of deltamethrin to different life stages of *Asellus aquaticus**** (██████████ 2007; [M-291885-02-1](#); see Appendix 2, section 2.2.2)

⁸ de Jong, F.M.W., Brock, T.C.M., Foekema, E.M. & Leeuwangh, P. (2008). Guidance for summarizing and evaluating aquatic micro- and mesocosm studies. RIVM Report 601506009/2008.

To gain additional information on the toxicity of deltamethrin to *Asellus aquaticus*, a study was performed to determine the acute toxicity (EC₅₀ and LC₅₀) of deltamethrin towards different life stages under realistic spray exposure conditions in the laboratory. Since the test organisms were exposed to different concentrations (simulated spray drift) in a natural water-sediment system for a period of 21 days, a conclusion on chronic effects was possible.

The observed toxicity of deltamethrin to *Asellus aquaticus* after 24 hours in this study was in the same range as after 48 hours and up to 21 days after application. Since it was not possible to find all introduced individuals at the interim sampling dates due to technical reasons, the final evaluation on day 21 is considered the most relevant for the risk assessment. After 21 days, an LC₅₀ value of 43.9 ng a.s./L (with a lower limit of 34.8 ng a.s./L and an upper limit of 55.3 ng a.s./L, corrected for control mortality) for adult *A. aquaticus* and an LC₅₀ value of 44.8 ng a.s./L (with a lower limit of 36.7 ng a.s./L and an upper limit of 54.8 ng a.s./L, corrected for control mortality) for the juvenile *A. aquaticus* were found. These results indicate that the sensitivity of juvenile *A. aquaticus* to deltamethrin was the same as for adults. Based on mortality, the 21-day NOEC value for adult and juvenile *A. aquaticus* was determined to be 23.4 ng a.s./L.

In the vessels where adults had been introduced, newborn *A. aquaticus* were already observed four days after application up to a concentration of 23.4 ng a.s./L. At 51.5 ng a.s./L, newborns were only observed 14 days after application.

The findings of this life stage study are confirmed by the results of a laboratory population study with *Asellus aquaticus* (Jergentz 2007b). The study aimed to determine the chronic effects (on *e.g.* population dynamics and potential recovery) of deltamethrin towards a population of different age (size) classes of *A. aquaticus* in a water-sediment system under realistic spray exposure conditions. However, since the life stage study provided reliable results and the interpretation of results from a population study with different age classes is difficult, the microcosm study was terminated already five weeks after study implementation. Nevertheless, the results obtained (Jergentz 2007) confirm the results of the life stage study as discussed above.

The results of these laboratory studies on *Asellus aquaticus* are also in agreement with those from the mesocosm study (Heimbach *et al.*, 2005). Since deltamethrin had been sprayed three times at 7 day intervals in the mesocosm study, the biological effects are slightly more pronounced as compared to the laboratory studies with a single application only.

- ***Modelling studies on the recovery of populations of *Asellus aquaticus* from effects of deltamethrin on natural water bodies of agricultural landscapes* (Schaefer, D.; 2008; [M-296752-01-1](#); see Appendix 2, section 2.2.2)**

Different model simulations to determine the recovery potential of *Asellus aquaticus* from effects of deltamethrin in natural water bodies of agricultural landscapes have been performed. These studies have been summarized by Schaefer (Schaefer, D.; 2008; [M-296752-01-1](#); see Appendix 2, section 2.2.2):

The sensitivity of *Asellus aquaticus* populations to deltamethrin cannot be fully investigated in mesocosm studies. The limited size of the pond mesocosms compared to natural water bodies, and their isolation artificially impedes, or for species like *Asellus* even prevents, recovery by re-colonization (from external sources). In natural water bodies, *Asellus* may re-colonize affected sections of a water body from internal refuges or from neighbouring unaffected sections. This recovery potential is particularly high for deltamethrin, because of its rapid dissipation from water (DT₅₀ of 1 day or less).

Such re-colonization processes were investigated for *Asellus* and deltamethrin with the population model MASTEP in a four-step approach:

- preliminary modelling (Verboom, J.; Baveco, J. M. H.; van den Brink, P. J.; 2005; [M-246365-01-1](#); see Appendix 2, section 2.2.2) with best available parameter estimates

- sensitivity analysis of the model ([REDACTED] 2007; [M-290838-02-1](#))
- gathering of additional data on key model parameters
- second modelling exercise ([REDACTED] 2007; [M-292035-01-1](#); see Appendix 2, section 2.2.2), using a revised parameterization and considering the results of the sensitivity analysis

The objective of the MASTEP modeling was to quantify the recovery of an *Asellus* population from effects of deltamethrin in natural water bodies of agricultural landscapes.

The preliminary metapopulation model (Verboom, J.; Baveco, J. M. H.; van den Brink, P. J.; 2005; [M-246365-01-1](#), see Appendix 2, section 2.2.2) describes the effects and recovery of a local *A. aquaticus* population (one annual cycle) after the exposure to deltamethrin as a result of spray drift, using the pond, ditch and stream FOCUS scenarios.

The dose-response curve was based on the data obtained in the mesocosm study ([REDACTED]; 2005; [M-246137-01-2](#); Appendix 2, section 2.2.3), although overall the mesocosm results do not allow the calculation of a proper dose-response relationship. Due to the sampling method (“activity traps”), the EC₅₀ of 16 ng a.s./L included mortality and short-term transient immobility of *Asellus*. Because of the design of the study, the dose-response curve refers to three applications of deltamethrin at 7-day intervals. The use patterns resulting in nominal concentrations of 16, 23, 30 and 43 ng a.s./L were evaluated in this model against an untreated control simulation.

The preliminary modelling indicated significant potential for recovery of affected *Asellus* populations by re-colonization and reproduction. Recovery was least pronounced in the ditch scenario, which can be attributed to the assumed absence of *Asellus* drift.

- *The sensitivity analysis of MASTEP* ([REDACTED] 2007; [M-290838-02-1](#); Appendix 2, section 2.2.2) focussed on the number of model runs per scenario, the timing of the deltamethrin spray drift event, and the *Asellus* drift parameters.

From the results of the sensitivity analysis, the following was concluded for the second modeling exercise:

- to do 20 model runs for each scenario
- to run the model separately for different realistic application dates of deltamethrin
- to broaden the data base for the *Asellus* drift parameters

New experimental studies were conducted on the sensitivity of *Asellus* to deltamethrin ([REDACTED] 2007; [M-291885-01-1](#); Appendix 2, section 2.2.2) and on drift of *Asellus* in natural water bodies ([Schulz, R.; Bruehl, C.; 2007; M-291925-01-1](#), Appendix 2, section 2.2.2).

The sensitivity of *Asellus* to deltamethrin was tested in a water/sediment system under laboratory conditions, with a single deltamethrin treatment (Jergentz, 2007). The study provided an experimental NOEC of 23.4 ng a.s./L and a dose-response curve with an LC₅₀ of 46 ng a.s./L (re-calculated by van den Brink & Baveco, 2007, from the experimental data, using a logistic regression). There was no difference in the sensitivity of adult and juvenile *Asellus* to deltamethrin.

These results show that the sensitivity of *Asellus* was overestimated in the preliminary MASTEP modelling with an EC₅₀ of 16 ng a.s./L. That EC₅₀ had been based on mesocosm data that did not differentiate between transient immobilisation and mortality of *Asellus* (and did not include some further results of the mesocosm study). The laboratory dose-response curve more reliably refers to mortality of *Asellus*.

The second refined model ([REDACTED] 2007; [M-292035-01-1](#); Appendix 2, section 2.2.2) was set up in the same way as for the preliminary modelling, except for the refinements and modifications described below:

- the dose-response curve was taken from the water/sediment laboratory study (Jergentz, 2007)
- drift parameters for *Asellus* were taken from a field drift study (Bruehl and Schulz, 2007b)
- the sensitivity analysis of MASTEP (van den Brink et al., 2007a) took into account the fact that:
 - 20 number of runs per scenario are necessary to receive reliable result with sufficiently narrow confidence intervals
 - the application time influences the recovery chance of *Asellus*
 - drift chance has a greater influence on recovery than drift distance
- the ditch and stream FOCUS scenario were merged (due to the results of the field drift study, the drift of *Asellus* was shown as independent of water flow; significant movement occurred even at very low flow rate, i.e. 0.01 m/s)
- Due to its short water DT₅₀ of < 2 days, a continued exposure of aquatic organisms can be excluded. However, since deltamethrin is applied twice up to a maximum of three times per season, a repeated exposure cannot be ruled out. It was assumed in the simulation that a third application will normally only be performed many weeks after the first two (e.g. two applications in spring and the third in autumn). In case repeated exposure is considered relevant at all (with a dissipation time of deltamethrin of < 2 days and a minimum spray interval of 7 days), it will usually only occur within the two initial applications. Therefore, the application scenario in the meta-population model was limited to scenarios with two applications with an interval of 7 days.

The effects of deltamethrin were described by the dose-response curve from the laboratory study (water-sediment system), with an LC₅₀ of 46 ng a.s./L (Jergentz, 2007a). There was no difference in the sensitivity of adult and juvenile *Asellus*. Since that dose-response relationship is based on data for a single application, the same effects on *Asellus* were assumed for each deltamethrin spray drift event. Note that the laboratory study gave a statistical no-effect concentration (NOEC) of 23.4 ng a.s./L.

The results for the recovery criterion of reaching 90% of the control were selected. Recovery times for the criterion of 95% are generally higher but do not differ substantially.

In the ditch/stream scenarios, the results for the directly affected 100 m stretch were always selected, since effects are less pronounced if the population in the full 600 m of the water body is considered.

The MASTEP modelling showed that for exposure of *Asellus* to 23 ng/L of deltamethrin, the effects in ponds and ditches/streams are minimal, without ecological relevance for *Asellus* populations. *Asellus* populations recover quickly (within less than 5 days) and reliably (probability 87.5% or more) from the small and insignificant effects at this treatment level by reproduction and re-colonisation.

At 30 ng a.s./L, effects are still minimal in the pond, but more pronounced in the ditch/stream. For spring and summer applications (April to July), the *Asellus* populations in the ditch/stream still recover quickly (within less than 40 days) and reliably (probability more than 90%) from initial effects. For application in August or later, the recovery is less reliable (probability 85% to 60%) and takes slightly longer (30 to 86 days). The weaker recovery in autumn, however, must be seen in the context that deltamethrin affects an already naturally declining population. In addition (although this could not be investigated with the model), it can be assumed that the population fully recovers until the start of the next season. The slightly increased effects from late applications at 30 ng a.s./L may therefore be less ecologically relevant.

At 43 ng a.s./L, there were clear and long-lasting effects of deltamethrin on the *Asellus* population in the pond and in the ditch/stream for all application dates. Recovery generally took longer and was less reliable compared to lower exposure, in particular for autumn applications.

In conclusion, the MASTEP model allowed a detailed analysis of the effects of deltamethrin on populations of *Asellus aquaticus* in water bodies of agricultural landscapes. Extensive experimental and literature studies were conducted to get the most reliable information on:

- biology and ecology of *Asellus*, in particular with regard to its movement
- effects of deltamethrin on *Asellus*
- use patterns of deltamethrin

The collected information was implemented in the MASTEP model, and for a range of scenarios (different water bodies, exposure concentrations, application dates), the dynamics of *Asellus* populations and their potential for recovery from initial effects (expressed as recovery probability and recovery time) were calculated.

The model predicts negligible effects at population level for exposure to 23 ng a.s./L of deltamethrin, which is the experimental NOEC. Effects are more pronounced at 30 ng/L, but populations quickly and reliably recover from exposure in spring and early summer (up to July). The recovery from later exposure at 30 ng a.s./L (in August to November) is slightly slower and less reliable; however, as the effects occur in an already naturally declining *Asellus* population, they are still considered acceptable. Effects at 43 ng a.s./L are clearly more pronounced.

Considering the results of the MASTEP modelling, it is concluded that exposure of *Asellus* populations to deltamethrin at up to 30 ng a.s./L is ecologically acceptable.

- **General conclusion on *Asellus aquaticus***

- No differences in sensitivities between adult and juvenile life stages of *A. aquaticus* have been found: 21 days-LC₅₀ values obtained from laboratory study in a water-sediment system were 43.9 ng a.s./L for adults and 44.8 ng a.s./L for juveniles. The NOEC in this study was 23 ng a.s./L.
- The effects on *A. aquaticus* obtained in the mesocosm study are slightly more pronounced since deltamethrin had been applied three times at 7-day intervals in the mesocosm study as compared to a single application in the laboratory study.
- *A. aquaticus* is predominately found in lentic and slowly flowing water bodies. Due to their proximity to crops, ditches are the most vulnerable water bodies. Non-permanent ditches are not assumed as a suitable habitat for *A. aquaticus*, since it is not possible for *A. aquaticus* to build up stable populations under these conditions.
- The drift rate of *A. aquaticus* seems not to be influenced by the flow velocity in the range of typical flow velocities of ditches and streams in agricultural landscapes (between 0.01 and 0.2 m/s).
- The drift rate obtained in several studies in an agricultural stream in Germany is relatively high with 2.7% (0.5% to 8.6%) of the total population per 24 h.
- The observed drift patterns suggested that drift distances of 14 m or even of 25 m is of relevance for *A. aquaticus*. The results thus confirm the assumption of a drift distance of at least 10.7 m as reported by McLay (1970)⁹.
- Even if it is not conclusively possible to distinguish between active or passive components or between drift and locomotion, the data from the study reported here still suggest a rather high spatial dynamic for the isopod species *A. aquaticus*.
- The MASTEP population model, using the best available data on *Asellus* ecology, predicts negligible effects of deltamethrin to an *A. aquaticus* population level at an environmental concentration of 23 ng a.s./L. Effects at 30 ng a.s./L are more pronounced, but populations quickly and reliably recover from exposure in spring and early summer (up to July). Recovery from later exposure at 30 ng a.s./L (August to November) is slower and less reliable; however, as the effects occur in an already naturally declining population, they still are considered acceptable. Though this could not be demonstrated with the model, it can be assumed that the population fully recovers until the start of the next season. Effects at 43 ng a.s./L are clearly more pronounced and not considered acceptable.

⁹ McLay, C., 1970. A theory concerning the distance travelled by animals entering the drift of a stream. Journal of Research Board Canada 27, pp. 359-370

- Considering the results of the MASTEP modeling, it is concluded that exposure of *Asellus* at up to 30 ng/L of deltamethrin is ecologically acceptable.

Overall assessment of the presented higher tier studies – Derivation of an endpoint for the aquatic risk assessment of deltamethrin

Several aspects of the aquatic risk assessment for the use of deltamethrin in agriculture have been discussed in detail, based on specific laboratory and field studies, expert evaluations and meta-population modelling approaches.

A refined highest tier risk assessment has been presented for fish (see page 29 ff. of this dossier). The zooplankton dynamics as evaluated in the mesocosm study of Heimbach et al. (2005) have been interpreted considering direct effects from the deltamethrin applications as well as secondary effects. Special emphasis was put on *Asellus aquaticus*, an isopod species, which was identified as the aquatic invertebrate most sensitive to deltamethrin exposure. Next to a sensitivity study on different life stages, studies on the drift of this species in a natural stream were performed to investigate drift rates to be used for the meta-population modelling. Expert statements and evaluations on the biology and ecology and on the occurrence of this species in water bodies in the agricultural landscape demonstrate that *A. aquaticus* is predominantly inhabiting lentic or slowly flowing water bodies. The meta-population model MASTEP demonstrates the recovery potential *via* reproduction and recolonization of a population which had been affected by deltamethrin,

All this information demonstrates that deltamethrin can be used in agriculture without unacceptable effects on aquatic ecosystems up to an environmental concentration of 30 ng a.s./L.

However, due to the more pronounced effects in flowing water bodies identified in the MASTEP modelling at a concentration of 30 ng a.s./L, **the concentration of 23 ng a.s./L (which is also supported by the experimentally derived NOEC of 23.4 ng a.s./L for *A. aquaticus*) was determined as the regulatory relevant endpoint for deriving more conservative acute and chronic ETO-RAC_{sw}.**

According to the EFSA Aquatic Guidance Document (2013) and considering the fact that the experiments and approaches presented below addressed worst-case conditions, the assessment factor to be applied to both the acute and chronic ETO-RAC_{sw} should not be greater than 2.

Comments of zRMS:	Please refer to zRMS comments on fish endpoints above.
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Reference:	KCP 10.2/02
Title:	Refined risk assessment for effects of Deltamethrin to fish
Report:	2008; RA07-046-2a; M-292027-02-1
Guideline(s):	--
Deviations:	--
GLP/GEP:	no
Acceptability:	See above
Duplication (if vertebrate study):	No

Summary

This document presents a refined risk assessment of potential effects of deltamethrin to fish considering the current state-of-the-art, particularly the so-called “EFSA (2005a) opinion” on the relevance of sediment in aquatic studies and the extrapolation of results to other fish species, as well as the “EFSA (2005b) opinion” on the risk evaluation for species sensitivity.

The first tier acceptable concentration for short-term exposure to deltamethrin is 2.6 ng a.s./L. The

acceptable environmental concentration obtained by applying the “EFSA method 2” ranges from 6.0 to 6.3 ng a.s./L. Since this method is designed to be as protective as current practice based on the sensitivity of two fish species, there is no significant increase in the acceptable concentration compared to the 2.6 ng a.s./L. However, “EFSA method 3” is based on a protection level of 95% and results in a range from 23 to 25 ng a.s./L since this method considers the variation between species to a greater extent, as well as details of the sensitivity distribution. These endpoints are well in accordance with the acceptable concentrations derived from the SSD analysis of 27 to 29 ng a.s./L.

A chronic risk assessment is required for “continued or repeated” exposure conditions only. Based on the short DT₅₀ of deltamethrin of < 2 days in water, a continued exposure of fish can be excluded. However, deltamethrin is applied twice up to a maximum of three times per season. Thus, a repeated exposure cannot be excluded completely, even though a third application will normally only be performed many weeks after the first two. In case repeated exposure is considered relevant at all, it will usually only occur within the two initial applications.

For chronic exposure, the corresponding EAC values range from 1.7 to 2.2 based on laboratory studies, to 100 ng a.s./L based on the microcosm enclosure study with rainbow trout (NOEAEC of > 1000 ng a.s./L / Assessment Factor of 10). The 21d-LC₅₀ of 52 ng a.s./L gained under flow-through conditions in the laboratory is >> 19 times lower than the 21d-LC₅₀ of >>1000 ng a.s./L in the outdoor enclosure study, indicating the overestimation of risks based on results determined under laboratory conditions. The NOEC of this outdoor study is based on short-term behavioural symptoms (swimming behaviour) as the most sensitive endpoint. A change in behaviour is an expression of physiological effects which is highly sensitive and may lead to a reduced growth over time, particularly because food intake will be hampered. Insofar, it is comparable to the integrative parameter of growth, which was determined as the most sensitive endpoint in the chronic ELS and FLC studies on fathead minnow. In addition, the microcosm study was performed under realistic exposure conditions with the maximum number of three applications of deltamethrin in seven-day intervals. Thus, the NOEAEC and the chronic Assessment Factor of 10 seem the most appropriate endpoints for the final chronic risk assessment resulting in an acceptable environmental concentration of 100 ng a.s./L for fish.

The microcosm enclosure study with fish was performed under reasonable worst-case conditions as compared to water bodies in the agricultural landscape, particularly since the outdoor microcosms represent an oligo-mesotrophic aquatic system, which is known to yield relatively unbiased, exact results due to its relatively low amount of organic matter as compared to water bodies in agricultural landscapes.

Comments of zRMS:	Please refer to zRMS comments on aquatic invertebrates endpoints above.
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Reference:	KCP 10.2/03
Title:	Evaluation report on higher-tier tests to assess the ecological risks of the insecticide deltamethrin to freshwater organisms
Report:	Brock, T. C. M.; 2005; M-254687-01-1
Guideline(s):	--
Deviations:	--
GLP/GEP:	no
Acceptability:	See above
Duplication (if vertebrate study):	No

The evaluation report considered the available higher tier studies to conclude on the appropriate risk to aquatic organisms considering previously evaluated report, a copy of the conclusion is provided below.

Taking into account the two mesocosm studies and related bioassays, the author comes to the following conclusions:

The two outdoor semi-field tests reported by Schanné & Van der Kolk (2001) and Heimbach et al. (2005) can be used to evaluate the effects of short-term pulsed (3x, interval 7 d) deltamethrin exposure on freshwater communities.

The study of Schanné & Van der Kolk (2001) used test systems that had a relatively high diversity of freshwater arthropods. In this study relatively worst case exposure conditions were simulated, due to mixing of the test compound in the water column immediately after deltamethrin application.

The study of Heimbach et al. (2005) is characterised by test systems with a lower (but not exceptional for such model ecosystem studies) diversity of freshwater arthropods. However, several very sensitive arthropod populations (e.g. *Chaoborus*, *Asellus*) were present and additional bioassays with the sensitive macro-crustaceans *A. aquaticus* and *G. pulex* were performed. In addition, the study of Heimbach et al. (2005) more realistically simulated the risks due to spray drift and described the stratification and dynamics in exposure concentrations in the course of the experiment in great detail.

On basis of the most sensitive endpoints studied a NOEC_{community} of approximately 1 ng deltamethrin/L can be derived from the study of Schanné & Van der Kolk (2001).

Under the assumption that short-term (class 3) effects on a few populations of sensitive arthropods are acceptable a NOEAEC of approximately 10 ng deltamethrin/L (based on nominal initial concentration) can be derived from the semi-field experiment reported by Schanné & Van der Kolk (2001), and of 10 – 23 ng deltamethrin/L for the study reported by Heimbach et al. (2005).

Publications on the ecological effects of other pyrethroids in aquatic micro/mesocosms suggest that the NOEAEC of approximately 10 - 23 ng deltamethrin/L as observed in the studies reported by Schanné & Van der Kolk (2001) and Heimbach et al. (2005) can be used as an Environmentally Acceptable Concentration of deltamethrin in freshwater ecosystems (without applying an extra Uncertainty Factor), at least if short term effects on a few insects and crustaceans are considered acceptable.

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 was not available in the course of the first EU review of deltamethrin, but it was evaluated and agreed by the RMS in the course of the ongoing EU renewal process with LC ₅₀ of >42.37 mg pm/L based on initial measured concentrations. Although the renewal process is not finalised yet, no changes regarding the derived endpoint are expected.
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Reference:	KCP 10.2.1/01
Title:	Acute toxicity to <i>Oncorhynchus mykiss</i> (rainbow trout) AE F108565 (metabolite of deltamethrin) substance, pure Code: AE F108565 00 1B99 0001
Report:	; 2001; C010902; M-199816-01-1
Guideline(s):	OECD No. 203; US-EPA E § 72-1; EUC.1 US EPA OPPTS 850.1075
Deviations:	not specified
GLP/GEP:	yes
Acceptability:	Already evaluated in the course of the ongoing EU renewal process thus additional validation at the zonal level deemed not necessary
Duplication (if vertebrate study):	No

Materials and methods

A study on the acute toxicity to the rainbow trout (*Oncorhynchus mykiss*) was performed with AE F108565 (pure substance; code: AE F108565 00 1B99 0001) under static conditions. Six month old trout were exposed to the nominal concentrations of 10, 18, 32, 56 and 100 mg test substance/L together with an untreated control and a solvent control (0.1 mL acetone/L) at 13 ± 1 °C for 96 hours. The test water was not aerated.

Chemical analysis of the freshly prepared and aged (96 hours old) test solutions was performed for the active ingredient AE F108565 using HPLC/UV. The concentrations were analysed prior dilution.

Results and discussion

Observations:

Mortality, lethargy, surfacing, ceased swimming and/or loss of equilibrium were observed as intoxication symptoms at the treatment levels of and above 32 mg/L. Therefore the concentration without mortality and without any intoxication symptoms (NOEC) was 18 mg test item/L

Analytics:

Analyses of freshly prepared water for AE F108565 resulted in test item concentrations ranging from 39.7% to 61.7% of nominal values due to a limited solubility during the first two test days. Analyses of aged water (96 h) for AE F108565 at experimental termination resulted in test item concentrations from 93.7% to 102.7% of nominal values. Mean concentrations over the test duration ranged from 69.9% to 79.4% of nominal. Despite the obviously retarded solution of the test substance all effect concentrations were based on nominal initial test concentrations.

	LC ₅₀ 24 h	48 h	72 h	96 h	NOEC (96 h)
Nominal concentration of [mg/L]	>100	100	100	100	18
95% confidence limits	—	>56	>56	>18	

Conclusion

The 96-hour LC₅₀ (95% confidence limits) based on nominal concentrations was >100 (>56) mg/L. The

No Observed Effect Concentration (NOEC) through 96 hours was 18 mg/L.

Comments of zRMS:	The study was not available in the course of the first EU review of deltamethrin, but it was evaluated and agreed by the RMS in the course of the ongoing EU renewal process with EC ₅₀ of >100.0 mg pm/L based on nominal concentrations. Although the renewal process is not finalised yet, no changes regarding the derived endpoint are expected.
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Reference:	KCP 10.2.1/02
Title:	Acute toxicity to <i>Daphnia magna</i> (Waterflea) AE F108565 (Metabolite of deltamethrin) substance, pure Code: AE F108565 00 1B99 0001
Report:	Sowig, P.; Gosch, H.; 2001; C010889; M-199793-01-1
Guideline(s):	OECD No. 202; US-EPA E § 72-2 EUC.2; US EPA OPPTS 850.1010
Deviations:	not specified
GLP/GEP:	yes
Acceptability:	Already evaluated in the course of the ongoing EU renewal process thus additional validation at the zonal level deemed not necessary
Duplication (if vertebrate study):	

Materials and methods

Twenty *Daphnia magna* (10 per replicate) were exposed in two replicate test vessels to nine concentrations of AE F108565 and a dilution untreated control for 48 hours under static conditions. During the test, nominal concentrations of 1.0, 1.8, 3.2, 5.6, 10, 18, 32, 56 and 100 mg a.s./L were tested.

Chemical analysis of the freshly prepared and aged (48 hours old) test solutions was performed for the active ingredient AE F108565 using HPLC/UV. The concentrations were analysed prior dilution.

Results and discussion

Observations:

No mortality and no intoxication symptoms were observed in any treatment levels or the untreated control.

Analytatics:

Analyses of freshly prepared water for AE F108565 resulted in test item concentrations ranging from 81.1% to 114.1% of nominal values. Analyses of aged water (48 h) for AE F108565 at experimental termination resulted in test substance concentrations ranging from 68.6% to 136.9% of nominal values. The mean measured values over the time of exposure ranged from 75.1% to 115.7%. With the exception of the 48 h analyses from 1.0 and 1.8 mg/L all analysed concentrations of AE F108565 were within ± 20% of nominal at the start and the end of the study, all effect concentrations were based on nominal initial test concentrations.

	EC ₅₀		NOEC (48 h)
	24 h	48 h	
Nominal concentration of [mg/L]	>100	>100	100

Conclusion

The 48 hours EC₅₀, based on nominal concentrations, was > 100 mg/L. The NOEC over 48 hours was 100 mg test substance/L.

Comments of zRMS:	The study was performed in line with OECD 203 with no major deviations.
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	<p>It is noted that the temperature range was between 12.2°C and 12.8°C which was slightly below the minimum of 13°C recommended by the guideline (applicable at the time of conducting the study). Nevertheless, this deviation is considered to have no impact on the results since all validity criteria were met:</p> <ul style="list-style-type: none"> the mortality in the control(s) did not exceed 10 % at the end of the test (actually all fish survived); dissolved oxygen concentrations remained > 60 % of the air saturation value throughout the exposure (observed 74 to 93% saturation). <p>It is noted that DLT+FPF EC 85 contains two active substances and in line with requirements of the Central Zone the test concentrations of both substances should be verified in respective chemical analyses or, as a minimum, the least stable active compound should be analysed. However, in the study only concentration of flupyradifurone were measured and no analyses were performed for deltamethrin, which seems to be less stable than flupyradifurone. No explanation or justification of the substance selected for the measurements was provided in the study report. Since stability of both active compounds throughout the study period cannot be confirmed, the study is considered not acceptable.</p> <p>During the commenting period the Applicant may provide additional explanations to justify selection of the substance for chemical verification or data to confirm that deltamethrin was most stable during the study.</p>
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Reference:	KCP 10.2.1/03
Title:	Acute toxicity of deltamethrin + flupyradifurone EC 85 (10+75 g/L) to the rainbow trout (<i>Oncorhynchus mykiss</i>) under static conditions
Report:	2016; 007SRLS15C08; M-548840-01-1
Guideline(s):	OCSPP Guideline 850.1075, OECD Guideline 203. The afore mentioned guidelines were harmonized for various test parameters (i.e. temperature, light, etc.) to achieve optimal environmental conditions for the test organisms. Scientific discretion was implemented where guideline parameters do not fully converge.
Deviations:	not applicable
GLP/GEP:	yes
Acceptability:	Unacceptable (chemical analyses performed only with flupyradifurone and concentration of deltamethrin not confirmed)
Duplication (if vertebrate study):	No

Materials and Methods

Deltamethrin + flupyradifurone EC 85 (10+75 g/L), a.s.-content: deltamethrin 0.867 % w/w & flupyradifurone 6.62 % w/w was tested, specified by batch no 2014-012629-01 and specification no.: 102000028562.

Juvenile Rainbow Trout (organism length (mean ± S.D.) 51.0 ± 2.77 mm; length range 47.5 mm to 56.5 mm) were exposed under static conditions to determine the 96-hour LC₅₀. There was a single replicate of 10 fish each (organism weight (mean ± S.D.) 1.0075 ± 0.1869 g, weight range 0.8007 g to 1.3183 g, loading 0.336 g/L (grams of fish per liter test solution)) in the control and each treatment level. Nominal test concentrations were control, 15.0, 30.0, 60.0, 120 and 240 µg formulation/L. Nominal Flupyradifurone concentrations were control <LOQ, 0.993, 1.99, 3.97, 7.94, and 15.9 µg Flupyradifurone/L. Initial measured concentrations of Flupyradifurone ranged from 89 to 106% of nominal concentrations. 96 Hour Measured Test Concentrations of Flupyradifurone ranged from 92 to 105% of nominal concentrations. Mean measured recoveries analyzed for content of Flupyradifurone ranged from 91 to 106% of nominal concentrations. Results are based on nominal formulation concentrations.

Test Vessel Size: 38-L (49.5 x 25.4 x 30.5 cm)
Test Vessel Material: All glass aquaria
Test Vessel Fill Volume: 30-L (49.5 x 25.4 x 23.8 cm)
Photoperiod: 16 hours light, 8 hours dark
Light Intensity: 640 - 840 lux (mean: 760 lux)
Temperature Range (Min/Max Thermometer; exposure period): 12.2°C – 12.8°C
D.O. Range: 7.8 to 9.8 mg/L (74 to 93% saturation)
pH Range: 7.0 to 7.7
Hardness Range: 44 to 46 mg/L
Conductivity Range: 143.0 to 178.5 µmhos/cm
During exposure: no aeration, no feeding

Results and discussions

Acute toxicity to Rainbow Trout

Test Substance	Deltamethrin + Flupryadifurone EC 85 (10+75 g/L)
Test Object	Rainbow Trout
Exposure	96-Hour, Static
96 Hour LC ₅₀ (95% Confidence Interval)	158.3 (138.8 to 180.6) µg formulation/L
Lowest Concentration With an Effect (LOEC)	60.0 µg formulation/L
Highest Concentration Without Toxic Effect (NOEC)	30.0 µg formulation/L
Highest Concentration Causing No Mortality (NOLEC)	60.0 µg formulation/L

Observations

Nominal Conc. (µg form./L)	Hour 4		24 Hour		48 Hour		72 Hour		96 Hour	
	D	Obs	D	Obs	D	Obs	D	Obs	D	Obs
Control	0	10 N	0	10 N	0	10 N	0	10 N	0	10 N
15.0	0	10 N	0	10 N	0	10 N	0	10 N	0	10 N
30.0	0	10 N	0	10 N	0	10 N	0	10 N	0	10 N
60.0	0	10 LE, E	0	1 Q, OB; 9 LR, LE	0	1 Q; 9 LR, LE	0	6 Q, AS, E, LE; 4 Q, E	0	10 Q, LE, E
120	0	5 LE, AS; 1 LE, E; 4 LE, Q	1	4 LE, AS, LR; 4 LE, OB, LR, Q; 1 LE, E, LR	1	6 OB, LR, E, LE; 3 AS, LE, LR, E	1	3 OB, Q, LE; 6 E, LE, LR, AS	1	2 Q, OB, LE; 7 LE, LR, E
240	0	8 OB, LR, E, LE; 2 LE, E, LR	10	-----	10	-----	10	-----	10	-----

D = Dead
Obs = Observations (number of individuals observed plus observation)
N = Normal
OB = On Bottom
E = Erratic Behavior
LR = Labored Respiration
AS = At Surface
Q = Quiescent
LE = Loss of Equilibrium

Conclusion

Based on mortalities and sublethal effects:

96 Hour NOEC	30.0 µg formulation/L
96 Hour NOLEC	60.0 µg formulation/L
96 Hour LOEC	60.0 µg formulation/L
96 Hour LC ₅₀ (95% C.I.)	158.3 (138.8 to 180.6) µg formulation/L

Comments of zRMS:	<p>The study was performed in line with OECD 203 with no major deviations.</p> <p>It is noted that the range of fish length is not given in the study report, but with the mean length of 4.63 cm and SD of 0.3 cm the size of all fish taken for the study is in line with recommendations of OECD 203.</p> <p>Since the test was performed in a semi-static design with daily renewal, the measured concentrations of both active compounds were determined at each renewal interval in fresh and aged test solutions. The mean measured concentrations of flupyradifurone in fresh and aged solutions were maintained at 80-120% of nominal throughout the study period. The measured concentrations of deltamethrin dropped below 80% in all aged test solutions and in fresh solutions at 3 lower test concentrations. Measured concentrations <80% of nominal in fresh test solutions could be due to adhesion of the test item to the walls of test vessels, despite their pre-conditioning. Nevertheless, deltamethrin is known for its sorptive properties and all available chemical analyses were sufficient to determine the actual exposure of test organisms to this compound via the water column and derive reliable endpoints.</p> <p>All validity criteria were met and the study is considered acceptable with following endpoint:</p> <p>LC₅₀ >150 µg product/L (nominal)</p> <p>Since the concentration of deltamethrin was <80%, the Applicant was requested to recalculate the endpoints as mean measured concentrations of the active substances, in line with indications of Appendix J of EFSA Supporting publication 2019:EN-1673. Respective calculations were submitted during the commenting period. Option A of point 4.1 was followed (preferred option because associated with fewer uncertainties):</p> <ol style="list-style-type: none">For both active substances deltamethrin and flupyradifurone, the geometric mean concentrations between the start and end of the test for each tested concentration were calculated; the recovery rates at each tested concentration (geomean compared with nominal or initial measured) were calculated (see table below).The new calculated geomean concentration levels for the active substances were summed up to derive the ‘sum of active substances’ per concentration level to calculate the endpoint in the following step (see table below).The endpoints (mean and confidence interval) were calculated based on the ‘sum of active substances’ geomean concentration levels using an appropriate statistical tool (see table below). <table><tr><th>Fish</th><th>M-679497-01-1</th><th></th><th></th><th></th><th></th><th></th></tr><tr><td rowspan="3">FPF</td><td>nominal (µg/L)</td><td>0.406</td><td>0.895</td><td>1.969</td><td>4.331</td><td>9.525</td></tr><tr><td>geomean (µg/L)</td><td>0.449</td><td>0.942</td><td>1.992</td><td>4.366</td><td>9.634</td></tr><tr><td>% of nominal</td><td>110</td><td>105</td><td>101</td><td>101</td><td>101</td></tr><tr><td rowspan="3">DLT</td><td>nominal (µg/L)</td><td>0.059</td><td>0.131</td><td>0.287</td><td>0.632</td><td>1.389</td></tr><tr><td>geomean (µg/L)</td><td>0.029</td><td>0.054</td><td>0.12</td><td>0.427</td><td>0.862</td></tr><tr><td>% of nominal</td><td>48</td><td>41</td><td>42</td><td>68</td><td>62</td></tr><tr><td>FPF+DLT</td><td>geomean (µg/L)</td><td>0.478</td><td>0.996</td><td>2.112</td><td>4.793</td><td>10.496</td></tr></table> <p>Based on above assumptions, the following endpoint based on mean measured concentrations of both active compounds was calculated:</p> <p>LC₅₀ >10.496 µg DLT+FPF/L</p>	Fish	M-679497-01-1						FPF	nominal (µg/L)	0.406	0.895	1.969	4.331	9.525	geomean (µg/L)	0.449	0.942	1.992	4.366	9.634	% of nominal	110	105	101	101	101	DLT	nominal (µg/L)	0.059	0.131	0.287	0.632	1.389	geomean (µg/L)	0.029	0.054	0.12	0.427	0.862	% of nominal	48	41	42	68	62	FPF+DLT	geomean (µg/L)	0.478	0.996	2.112	4.793	10.496
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FPF+DLT	geomean (µg/L)	0.478	0.996	2.112	4.793	10.496																																															

Reference:	KCP 10.2.1/07
Title:	Deltamethrin + flupyradifurone EC85 (10+75 g/L): Acute toxicity to rainbow trout (<i>Oncorhynchus mykiss</i>) in a 96-hour semi-static test
Report:	2020a; EBRV0196; M-679497-01-1
Guideline(s):	OECD Guideline for Testing of Chemicals, Section 2, No. 203, "Fish, Acute Toxicity Test", June 18, 2019 OECD Series on Testing and Assessment, No. 23, "Guidance Document on Aqueous-phase Aquatic Toxicity Testing of Difficult Test Chemicals", 2nd Ed., February 08, 2019 EPA Guideline 712-C-16-007: OCSPP 850.1075, "Freshwater and Saltwater Fish Acute Toxicity Test", October 2016 SANCO/3029/99 rev.4 11/07/00: Residues: Guidance for generating and reporting methods of analysis in support of pre-registration data requirements for Annex II (part A; Section 4) and Annex III (part A; Section 5) of directive 91/414
Deviations:	None
GLP/GEP:	Yes
Acceptability:	Acceptable
Duplication (if vertebrate study):	Yes, new study necessary to address the combined toxicity of DLT+FPF EC 85, since the study performed in 2016 could not be accepted due to lack of determination of the measured concentrations of the least stable substance (deltamethrin) in test solutions.

Materials and methods

Test material	Deltamethrin + Flupyradifurone EC 85 batch No.: EQ10000696 active ingredients content: 10.71 g/L Deltamethrin (0.926 % w/w) and 73.46 g/L Flupyradifurone (6.35% w/w), analysed
Guideline(s) adaptation	None specified
Test species	Rainbow trout (<i>Oncorhynchus mykiss</i>)
Acclimation	The fish were held for 12 days prior to study initiation daily. The holding area was maintained on a 12-hour daylight photoperiod. The fish were healthy and no treatments for disease were administered. During the 7 days immediately prior to initiation of the 96-hour exposure period, the fish were held under test conditions at 12 ± 2 °C. During the last 7 days prior to the start of the test two fish (1.8 %) died in the test fish batch. Therefore, the mortalities in the fish batch were below 5 % and the fish batch was accepted. The fish were not fed 48-hours prior to test initiation.
Organism age/size at study initiation	Life stage: Juvenile The mean body length of the fish* in the test was $4.63 \text{ cm} \pm 0.3 \text{ cm}$ (Mean \pm SD), the mean body wet weight $0.94 \text{ g} \pm 0.1 \text{ g}$ (Mean \pm SD). The longest fish was not twice the length of the shortest fish. The weight of the fish was $< 3.0 \text{ g}$. * 10 fish from the test fish batch were measured 3 days before the start of the test
Test solutions	Nominal concentrations: 6.40, 14.1, 31.0, 68.2, 150 µg formulation/L. Controls: Reconstituted water. Evidence of undissolved material: none observed
Replication	No. of vessels per concentration (replicates):1 No. of vessels per control (replicates): 1
Organisms per replicate	No. of organisms per vessel: 7 to 8. In the highest test concentration of 150 µg test item/L, by mistake 8 fish were introduced at test start (this had no impact on the integrity or validity of the study and derived endpoints).
Exposure	Test type: semi static Total exposure duration: 96 hours
Test Vessel Loading	0.8 g fish tissue/ L test water.
Feeding during test	None

Test conditions	<p>Temperature: 12.5 – 14.0°C Photoperiod: 12 hours light/ 12 hours dark Light intensity: 540 – 610 lux pH: 7.0 – 7.8 Water hardness: 1.78 mmol/L (= 178.4 mg/L) as CaCO₃ Alkalinity: 0.55 mmol/L Dissolved oxygen: 88 to 100 % of the air saturation value</p> <p>Before test start and at each test medium renewal, the test vessels were preconditioned for at least 1 hour with the test item using the test concentrations chosen for the exposure phase of the fish. The test concentrations and media used for the preconditioning were discarded before the start of the test and each water renewal. The test concentrations and control were freshly prepared just before introduction of the fish (= start of the test) and before each test medium renewal.</p>
Parameters Measured / Observations	<p>Daily observations were made for mortality and sublethal effects. The fish were observed at test start and at least twice within the first 24 hours (at least 3 hours between observations). From Day 2 to Day 4, fish were inspected twice per day for sub-lethal effects and mortality. Dead fish will be removed directly after observation. The water temperature, pH-values and the dissolved oxygen concentrations were determined daily in the freshly prepared and aged test media of each treatment group.</p>
Sampling for chemical analysis	<p>The analytical method for the determination of flupyradifurone is based on HPLC with MS/MS detection. Liquid/Liquid Extraction with Dichlormethane followed by analysis via GC-MS/MS was the method used to determine Deltamethrin. The samples were taken from the biological phase of the study. One sample from the freshly prepared stock solution was taken at the start of the test and at day 1 and day 2. Six samples from the freshly prepared test media of all test concentrations and the controls were taken at the start of the test and at day 1, day 2 and day 3. For the determination of the stability of the test item and the maintenance of the test item concentrations under the test conditions, respectively, six samples from the aged test media of all treatment groups were taken at the end of all renewal periods (day 1, 2, 3 and 4) from the approximate centre of the aquaria. The concentrations of the active ingredient Flupyradifurone of the test item Deltamethrin + Flupyradifurone EC85 (10+75 g/L) were measured in the entire taken diluted test medium and control samples. The concentrations of the active ingredient Deltamethrin of the test item Deltamethrin + Flupyradifurone EC85 (10+75 g/L) were measured in two of the four taken undiluted test medium and control samples after extraction. The additional samples of the untreated control and the dilution solvent acetonitrile as well as of the stock solution were not analysed.</p>
Data analysis	<p>As test item related mortality occurred only in the highest test concentration, no statistical calculations were conducted. The NOEC, LOEC and LC50 were empirically determined based upon observation data including lethal and sublethal effects.</p>

Results and discussions

Validity criteria (according to OECD 203, rev. 2019)	Required	Obtained
Mortality in control during test	≤ 10 %	0 %
Dissolved oxygen saturation	≥ 60 %	88-100 %
Analytical measurement of test concentrations is compulsory	Preferably concentrations should be at least 80% of the nominal concentration throughout the test.	To maintain constant conditions as good as possible a semi-static design was chosen. Both active substances were analyzed.

Analytical results

Measured concentrations of the test substances in test solutions are presented in tables below. Please note that they represent mean concentrations/recoveries in all fresh and 24-h aged solutions taken at each renewal.

Summary of Analytical Results for Deltamethrin

Nominal concentration [µg test item/L]	fresh			24h aged			time weighted arithmetic mean value ²		time weighted arithmetic mean concentration
	% of nominal ¹	RSD [%]	n	% of nominal ¹	RSD [%]	n	[%]	n	
									[µg Deltamethrin/L] ³
Control	n.a.	n.a.	8	n.a.	n.a.	8	n.a.	16	n.a.
6.4	79	31	8	31	12	8	51	16	0.0303
14.1	56	10	8	31	20	8	42	16	0.0548
31.0	66	18	8	27	21	8	44	16	0.125
68.2	118	24	8	41	29	8	72	16	0.456
150	107	22	8	37	20	8	65	16	0.909

¹ The tabulated results represent rounded results calculated on the exact raw data

² Calculated according to OECD Guidance Document No. 23 (2019), Annex 2

³ The tabulated results represent results rounded to three significant digits

n.a.: not applicable; RSD: Relative Standard Deviation; n: number of analysed samples

The recoveries below 80% determined for Deltamethrin at test start are likely related to adhesion effects of the very unipolar substance which probably occurred despite the conducted pre-conditioning of the sampling vessels.

The data presented in B5 demonstrates that the analytical method complies with all guideline criteria according to SANCO/3029/99 rev. 4 and is suitable for the determination of deltamethrin in test water samples via GC-MS/MS.

Summary of Analytical Results for Flupyradifurone

Nominal concentration [µg test item/L]	fresh			24h aged			overall mean		
	% of nominal ¹	RSD [%]	n	% of nominal ¹	RSD [%]	n	% of nominal ¹	RSD [%]	n
Control	n.a.	n.a.	8	n.a.	n.a.	8	n.a.	n.a.	16
6.4	110	7	8	111	10	8	111	8	16
14.1	107	6	8	104	6	8	105	6	16
31.0	102	7	8	101	7	8	101	7	16
68.2	101	4	8	101	5	8	101	4	16
150	104	4	8	98	13	7	101	9	15

¹ mean value of all measured samples per treatment group

RSD: relative standard deviation per treatment group

n: number of analysed samples; n.a.: not applicable; RSD: Relative Standard Deviation

Since nominal recoveries were determined for Flupyradifurone, correct dosage is confirmed. All reported results refer to nominal concentrations of the test item.

The data presented in B5 demonstrates that the analytical method complies with all guideline criteria according to SANCO/3029/99 rev. 4 and is suitable for the determination of Flupyradifurone in test water samples via HPLC-MS/MS.

Biological results

Observations

In the control and at the concentrations up to 68.2 µg test item/L, all fish survived until the end of the experiment, except at the test concentration of 31.0 µg test item/L where one fish was killed due to handling during water renewal on day 1. At the highest test concentration of 150 µg test item/L, three fish were dead at test end. At test end, sub-lethal effects were observed at 68.2 and 150 µg/L, such as

loss of equilibrium, abnormal swimming behaviour, abnormal ventilation function and abnormal skin pigmentations. The fish was located in the surrounding water bath and appeared to be normal.

Observed Mortality of unfed Rainbow trout (*Oncorhynchus mykiss*) exposed to Deltamethrin + Flupyradifurone EC85 (10+75 g/L) for 96 hours

Nominal Concentration (µg form./L)	0 hour # mort	2 hour # mort	24 hour # mort	48 hour # mort	72 hour # mort	96 hour # mort
Control	0	0	0	0	0	0
6.40	0	0	0	0	0	0
14.1	0	0	0	0	0	0
31.0	0	0	1	1	1	1
68.2	0	0	0	0	0	0
150	0	0	0	0	0	3

mort: Number of dead fish; form. = formulation

At a test concentration of 31.0 µg test item/L, one fish was killed due to handling during water renewal.

Conclusion

The study meets the validity criteria and the endpoints based on nominal concentrations are represented in the table below:

LC₅₀ 96 hours (95% C.I.):	>150 µg formulation / L (n.d.)
LOEC: lowest concentration with an effect	68.2 µg formulation / L
NOEC: highest concentration without adverse effects	31.0 µg formulation / L

A 2.2.1.2 Aquatic invertebrates

Comments of zRMS:	<p>The study was performed in line with OECD 202 with no major deviations.</p> <p>All validity criteria were met and the study is considered acceptable:</p> <ul style="list-style-type: none"> in the control, not more than 10% of the daphnids showed immobilization or other signs of disease or stress, dissolved oxygen concentrations at the end of the test were ≥ 3 mg/L in control and test vessels. <p>It is noted that DLT+FPF EC 85 contains two active substances and in line with requirements of the Central Zone the test concentrations of both substances should be verified in respective chemical analyses or, as a minimum, the least stable active compound should be analysed. However, in the study only concentration of flupyradifurone were measured and no analyses were performed for deltamethrin, which seems to be less stable than flupyradifurone. No explanation or justification of the substance selected for the measurements was provided in the study report. Since stability of both active compounds throughout the study period cannot be confirmed, the study is considered not acceptable.</p> <p>During the commenting period the Applicant may provide additional explanations to justify selection of the substance for chemical verification or data to confirm that deltamethrin was most stable during the study.</p>
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Reference:	KCP 10.2.1/04
Title:	Amendment no. 2 - Acute toxicity of deltamethrin + flupyradifurone EC 85 to <i>Daphnia magna</i> under static conditions - Final report -
Report:	Matlock, D.; Moore, S.; 2016; EBRVR015; M-553769-03-1
Guideline(s):	OCSPP Guideline 850.1010 [10], OECD Guideline 202 [3]. The afore- mentioned guidelines were harmonized for various test parameters (i.e. temperature, light, etc.) to achieve optimal environmental conditions for the test organism. Scientific discretion was implemented where guideline parameters do not fully converge EU Directive 91/414/EEC Regulation (EC) No. 1107/2009 US EPA OCSPP 850.1010
Deviations:	none
GLP/GEP:	yes
Acceptability:	Unacceptable (chemical analyses performed only with flupyradifurone and concentration of deltamethrin not confirmed)

Materials and methods

Daphnia magna were exposed under static conditions to determine the 24-hour and the 48-hour EC50. There were four replicates of five daphnia each in the control and the toxicant levels. Nominal concentrations were control, 0.194, 0.427, 0.939, 2.07, 4.55, and 10.0 µg formulation/L. Nominal Flupyradifurone concentrations were control, 0.0128, 0.283, 0.0622, 0.137, 0.301, and 0.662 µg Flupyradifurone/L. Initial measured concentrations of Flupyradifurone ranged from 96 to 145% of nominal concentrations. Mean measured recoveries analyzed for content of Flupyradifurone ranged from 95 to 151% of nominal concentrations. Results are based on nominal formulation concentrations.

Results and discussions

Temperature during exposure: 20.0°C -20.3°C
Conductivity range = 328 to 334 µmhos/cm
Hardness Range = 162 to 170 mg/L
Alkalinity Range = 149 to 155 mg/L
Maximum D.O. saturation at 20°C = 9.092
Dissolved Oxygen Range = 8.0 to 8.4 mg/L (88% to 92%)
pH Range = 8.1 to 8.3

Acute toxicity to *Daphnia magna*

Test Substance	Deltamethrin + Flupyradifurone EC 85
Test Object	<i>Daphnia magna</i>
Exposure	48-Hour, Static
48 Hour EC ₅₀ (95% C.I.)	1.634 µg formulation/L (0.856 to 2.33)
Lowest Concentration With an Effect (LOEC)	0.939 µg formulation/L
Highest Concentration Without Toxic Effect (NOEC)	0.427 µg formulation/L

Observations

Nominal Concentration (µg form./L)	Hour 4		24 Hour		48 Hour	
	I	Obs.	I	Obs.	I	Obs.
Control	0	20 N	0	20 N	0	20 N
0.194	0	20 N	1	19 N	2	18 N
0.427	0	20 N	0	19 N; 1 DC	0	19 N; 1 DC
0.939	0	20 N	1	19 N	3	2 N; 12 OB, Q; 3 LE, OB
2.07	0	20 N	0	11 N; 6 OB, Q; 2 AS, LE; 1 OB, Q, LE	14	4 OB, Q; 2 AS, LE

4.55	0	19 N; 1 Q, OB	2	7 N; 7 OB, Q; 1 LE,E; 3 AS, LE	13	6 OB, Q; 1 AS, LE, Q
10.0	0	20 N	1	1 OB, Q; 18 LE, OB, Q	17	3 OB, Q

Note: There were 20 organisms present in each test concentration at the start of the test.

I = Cumulative number of organisms immobilized, not able to swim after 15 seconds of gentle agitation of the test solution.

Obs = Observations (number of individuals observed alive plus observation)

N = Normal

Q = Quiescent

LE = Loss of equilibrium

OB = On the bottom

DC = Dark coloration

E = Erratic

AS = At the surface

Conclusion

Based on mortalities and sublethal effects:

48 Hour NOEC	0.427 µg formulation/L
48 Hour LOEC	0.939 µg formulation/L
48 Hour EC ₅₀ (95% C.I.)	1.634 µg formulation/L (0.856 to 2.33)

Comments of zRMS:	<p>The study was performed in line with OECD 202 with no major deviations.</p> <p>Since the test was performed in a semi-static design with daily renewal, the measured concentrations of both active compounds were determined at each renewal interval in fresh and aged test solutions. The mean measured concentrations of flupyradifurone in fresh and aged solutions were maintained at 80-120% of nominal throughout the study period. The measured concentrations of deltamethrin dropped below 80% in all fresh and aged test solutions. Measured concentrations <80% of nominal in fresh test solutions could be due to adhesion of the test item to the walls of test vessels, despite their pre-conditioning. Nevertheless, deltamethrin is known for its sorptive properties and all available chemical analyses were sufficient to determine the actual exposure of test organisms to this compound via the water column and derive reliable endpoints.</p> <p>All validity criteria were met and the study is considered acceptable with following endpoint:</p> <p>EC₅₀ = 1.82 µg product/L (nominal)</p> <p>Since the concentration of deltamethrin was <80%, the Applicant was requested to recalculate the endpoints as mean measured concentrations of the active substances, in line with indications of Appendix J of EFSA Supporting publication 2019:EN-1673. Respective calculations were submitted during the commenting period. Option A of point 4.1 was followed (preferred option because associated with fewer uncertainties):</p> <ol style="list-style-type: none"> For both active substances deltamethrin and flupyradifurone, the geometric mean concentrations between the start and end of the test for each tested concentration were calculated; the recovery rates at each tested concentration (geomean compared with nominal or initial measured) were calculated (see table below). The new calculated geomean concentration levels for the active substances were summed up to derive the 'sum of active substances' per concentration level to calculate the endpoint in the following step (see table below).
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3. The endpoints (mean and confidence interval) were calculated based on the ‘sum of active substances’ geomean concentration levels using an appropriate statistical tool (see table below).

Daphnia	M-686370-01-1					
FPF	nominal (µg/L)	0.064	0.114	0.206	0.37	0.667
	geomean (µg/L)	0.0598	0.1155	0.2104	0.3779	0.6772
	% of nominal	93	101	102	102	102
DLT	nominal (µg/L)	0.0093	0.0167	0.03	0.054	0.097
	geomean (µg/L)	0.0041	0.0067	0.0146	0.0249	0.0457
	% of nominal	44	40	49	46	47
FPF+DLT	geomean (µg/L)	0.0639	0.1222	0.225	0.4028	0.7229

Based on above assumptions, the following endpoint based on mean measured concentrations of both active compounds was calculated:

EC₅₀ = 0.1235 µg DLT+FPF/L (CI: 0.1090-0.1437 µg DLT+FPF/L)

Reference:	KCP 10.2.1/08
Title:	Deltamethrin + flupyradifurone EC85 (10+75 g/L): Acute toxicity to <i>Daphnia magna</i> in a semi-static 48-hour immobilisation test
Report:	Bebon, R.; Sonntag, F.; 2020b; EBRV0195; M-686370-01-1
Guideline(s):	EPA Guideline 712-C-16-013: OCSPP 850.1010, "Aquatic Invertebrate Acute Toxicity Test, Freshwater Daphnids" October 2016 OECD Guideline for Testing of Chemicals No. 202: "Daphnia sp., Acute Immobilisation Test" adopted April 13, 2004 OECD Series on Testing and Assessment, No. 23, "Guidance Document on Aqueous-phase Aquatic Toxicity Testing of Difficult Test Chemicals", 2nd Ed., February 08, 2019 Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009, Official Journal of the European Union No. L 309: 1 – 50 SANCO/3029/99 rev.4 11/07/00: Residues: Guidance for generating and reporting methods of analysis in support of pre-registration data requirements for Annex II (part A; Section 4) and Annex III (part A; Section 5) of directive 91/414
Deviations:	None
GLP/GEP:	Yes
Acceptability:	Acceptable
Duplication (if vertebrate study):	Not relevant

Material and methods

Test material	Deltamethrin + Flupyradifurone EC85 (10+75 g/L) batch no.: EQ10000696 active ingredients content: Deltamethrin (AE F032640): 0.926 % w/w (10.71 g/L); Flupyradifurone (BYI 02960): 6.35 % w/w (73.46 g/L) Purity: Deltamethrin; 99.73 %, Flupyradifurone; 99.8 %
Guideline(s) adaptation	none
Test species	<i>Daphnia magna</i> (Straus)
Culturing conditions	Similar environmental conditions as used in the test. The parental daphnids were cultured in Elendt M4 Medium
Organism age/size at study initiation	Neonates (< 24 hours old) Age at study initiation: 2.25 to 19.50 hours old
Test solutions	Nominal concentrations: 10.5, 5.83, 3.24, 1.80, 1.00 µg test item/L and a control Control: Reconstituted water.

	There were no remarkable observations in the appearance of the test item in test medium.
Replication	No. of vessels per concentration (replicates): 4 No. of vessels per control (replicates): 4
Organisms per replicate	No. of organisms per vessel: 5
Exposure	Semi-static conditions Total exposure duration: 48 h
Feeding during test	None
Test conditions	<p>Temperature during test: 19.0 to 19.4 °C in fresh media, 19.2 to 19.7 °C in aged media Photoperiod: 24 h darkness Light intensity: The test was exposed in the dark. pH: 7.6 to 7.8 Water hardness: the batch of test water was measured to be 231.4 mg CaCO₃/L Conductivity: not determined Dissolved oxygen: 8.4 to 9.0 mg/L (94 to 101 %) Aeration: none</p> <p>Before test start and before the test medium renewal, the test vessels were preconditioned for approximately 1 hour with the test item using the test concentrations chosen for the exposure phase of the daphnids. The test concentrations and media used for the preconditioning were discarded before the start of the test and before the water renewal.</p>
Parameters Measured / Observations	<p>The numbers of immobile organisms were visually determined at test start and after 24 h and 48 h. Immobility was determined according to the OECD guideline 202. Specimens which were not able to swim within 15 seconds after gentle agitation of the test vessel were considered to be immobilized (even if they could still move their antennae).</p> <p>Any signs of disease or stress or unusual behaviour were documented in the raw data.</p> <p>The pH was measured in new and old medium at 0, 24 and 48 h of the test.</p>
Sampling for chemical analysis	<p>Samples of test item solutions were taken for quantification of the test item concentrations in the freshly prepared test samples, and in 24h aged test media samples (all test concentrations considered).</p> <p>The quantification of the active ingredient Deltamethrin of the test item Deltamethrin + Flupyradifurone EC85 (10+75 g/L) in the test samples was performed using Liquid/Liquid Extraction with Dichlormethane followed by analysis via GC-MS/MS; the quantification of the active ingredient Flupyradifurone was done using liquid chromatography with MS/MS detection.</p>
Data analysis	<p>The 24-hour EC₅₀ could not be quantified due to the absence of toxicity of the test item. No statistical analysis was performed.</p> <p>The 48-hour EC₅₀, EC₂₀ and EC₁₀ and the 95% confidence limits were calculated by Weibull analysis.</p> <p>The NOEC and LOEC after 24 and 48 hours were determined directly from the raw data.</p> <p>The software used to perform the statistical analysis was ToxRat Professional, Version 3.3.0, ToxRat® Solutions GmbH.</p>

Results and discussions

Validity criteria of OECD guideline 202 (2004)	Required	Obtained
Immobilisation in control	≤ 10%	0%
Signs of disease or stress or unusual behavior in control	≤ 10%	0%
Dissolved O ₂ concentration in test media	≥ 3 mg/L	≥ 8.4 mg/L

Analytical results

Measured concentrations of the test substances in test solutions are presented in tables below. Please note that they represent mean concentrations/recoveries in all fresh and 24-h aged solutions taken at each renewal.

Summary of Analytical Results for Deltamethrin

Nominal concentration [µg test item/L]	fresh (0h)			aged (24h)			time weighted arithmetic mean value ² [%]	n	time weighted arithmetic mean concentration [µg Deltamethrin/L] ³
	% of nominal ¹	RSD [%]	n	% of nominal ¹	RSD [%]	n			
Control	n.a.	n.a.	4	n.a.	n.a.	4	n.a.	8	n.a.
1.00	71	5	4	28	17	4	46	8	0.00423
1.80	64	22	4	26	8	4	42	8	0.00699
3.24	72	25	4	35	25	4	51	8	0.0153
5.83	68	22	4	32	6	4	47	8	0.0255
10.5	74	11	4	30	8	4	49	8	0.0474

¹ The tabulated results represent rounded results calculated on the exact raw data

² Calculated according to OECD Guidance Document No. 23 (2019), Annex 2

³ The tabulated results represent results rounded to three significant digits

n.a.: not applicable; RSD: Relative Standard Deviation; n: number of analysed samples

The recoveries of <80% analysed for Deltamethrin in the freshly prepared samples are likely related to the extreme hydrophobicity of this compound (log Kow = 6.2) in combination with the very low tested concentrations in the range of nominal 9.3 – 97 ng/L. Although the test vessels for the daphnia were pre-conditioned as well as the sampling vessels, adhesion of Deltamethrin to the glass surface of the test and sampling vessels seem to be unavoidable to a certain extent in the used low ng/L scale and likely led to unextractable parts of the nominal concentrations. These adhesion effects might have also occurred during pipetting from test vessels to the sampling vessels at the pipette tips although the tips were pre-saturated several times before pipetting.

The data presented in B5 demonstrates that the analytical method complies with all guideline criteria according to SANCO/3029/99 rev. 4 and is suitable for the determination of deltamethrin in test water samples via GC-MS/MS.

Summary of Analytical Results for Flupyradifurone

Nominal concentration [µg test item/L]	fresh (0h)			aged (24h)			overall mean		
	% of nominal ¹	RSD [%]	n	% of nominal ¹	RSD [%]	n	% of nominal ¹	RSD [%]	n
Control	n.a.	n.a.	4	n.a.	n.a.	4	n.a.	n.a.	8
1.00	95	5	4	93	4	3	94	5	7
1.80	101	3	4	101	4	4	101	3	8
3.24	102	10	4	103	6	4	103	8	8
5.83	103	3	4	102	3	4	102	3	8
10.5	100	2	4	103	2	4	102	3	8

¹ mean value of all measured samples per treatment group

RSD: relative standard deviation per treatment group

n: number of analysed samples; n.a.: not applicable; RSD: Relative Standard Deviation

Due to the nominal recoveries determined for Flupyradifurone, a correct dosage of the test item is confirmed. All reported results refer to nominal concentrations of the test item.

The data presented in B5 demonstrates that the analytical method complies with all guideline criteria according to SANCO/3029/99 rev. 4 and is suitable for the determination of Flupyradifurone in test water samples via HPLC-MS/MS.

Biological results

Observations

After 48 hours of exposure no immobilisation of the test animals was observed in the control and up to and including the test item concentration of 1.00 µg test item/L. At the concentration of 1.80 µg test item/L, ten animals (50 %) were immobile and all animals (100%) were immobile at the concentration of 3.24 µg test item/L and above.

At the concentration of 3.24 µg test item/L and above the Daphnia showed signs of agitation (hectic movements) during the 24h assessment.

Nominal test concentrations [µg test item/L]	% of immobilized daphnids	
	24 h	48 h
Control	0	0
1.00	0	0
1.80	0	50
3.24	0	100
5.83	0	100
10.5	0	100

Conclusion

The endpoints are expressed in terms of nominal test concentrations:

EC ₅₀ 48 hours (95% C.I.):	1.82 µg test item/L (1.63 – 2.03 µg test item/L)
EC ₂₀ 48 hours (95% C.I.):	1.50 µg test item/L (1.31 – 1.72 µg test item/L)
EC ₁₀ 48 hours (95% C.I.):	1.32 µg test item/L (1.09 – 1.59 µg test item/L)
NOEC [µg test item/L] (48 h):	1.00
LOEC [µg test item/L] (48 h):	1.80

Comments of zRMS:	<p>The study was performed in line with OECD 235 with no deviations.</p> <p>All validity criteria were met:</p> <ul style="list-style-type: none"> in the control not more than 15% of the larvae showed immobilisation or other signs of disease or other stress (e.g. abnormal appearance or unusual behaviour, such as trapping at the water surface) at the end of the test (actually 10% immobilisation), the dissolved oxygen concentration at the end of the test was ≥ 3 mg/L in control and test vessels (actually 8.4 to 8.5 mg O₂/L (8.5 mg O₂/L = 95 % O₂ - saturation). <p>It is noted that DLT+FPF EC 85 contains two active substances and in line with requirements of the Central Zone the test concentrations of both substances should be verified in respective chemical analyses or, as a minimum, the least stable active compound should be analysed. However, in the study only concentration of flupyradifurone were measured and no analyses were performed for deltamethrin, which seems to be less stable than flupyradifurone. No explanation or justification of the substance selected for the measurements was provided in the study report. Since stability of both active compounds throughout the study period cannot be confirmed, the study is considered not acceptable.</p> <p>During the commenting period the Applicant may provide additional explanations to justify selection of the substance for chemical verification or data to confirm that deltamethrin was most stable during the study.</p>
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Reference:	KCP 10.2.1/05
Title:	Acute toxicity of deltamethrin + flupyradifurone EC 85 (10+75) G to larvae of <i>Chironomus riparius</i> in a 48 h static laboratory test system
Report:	Silke, G.; 2016; EBRVN060; M-556348-01-1
Guideline(s):	OECD Guideline No. 235 (Guideline for Testing of Chemicals, <i>Chironomus</i> sp., Acute Immobilisation Test, adopted July 28, 2011) US EPA OCSPP 850.SUPP
Deviations:	none
GLP/GEP:	yes
Acceptability:	Unacceptable (chemical analyses performed only with flupyradifurone and concentration of deltamethrin not confirmed)

Materials and methods

Deltamethrin + flupyradifurone EC 85 (10+75) G, a.s.-content: deltamethrin 0.867 % w/w & flupyradifurone 6.62 % w/w was tested, specified by batch-ID.: 2014-012629, TOX-no 10717-00 and specification no.: 102000028562. Larvae of *Chironomus riparius* (1st instars < 2-3 days old, 6 beakers per test concentration and control(s), with 5 animals each) were exposed for 48 hours in a static test system (water only) to concentrations of 0 (control), 0.50, 1.10, 2.42, 5.32, 11.7 and 25.8 µg formulation (form.)/ L.

Measurements of the water temperature were done continuously in one negative control vessel and recorded hourly by a data logger. Additionally water parameters (temperature, pH and oxygen) were measured in the freshly prepared test solutions of each test concentration on day 0 and on day 2 in the combined test solutions of each test concentration.

For verification of the aspired exposure concentrations, the content of the active substance flupyradifurone was chosen to be analytically determined. The other active ingredient (deltamethrin) was not analysed, since it is present in the formulated product in a fixed ratio to the analysed component. Quantitative amounts of flupyradifurone were measured in all freshly prepared test levels on day 0, and control(s). On day 2, at the end of exposure, additionally all aged test levels including control(s) were measured.

Results and discussions

Test system

Dissolved oxygen concentrations ranged from 8.4 to 8.5 mg O₂/L (8.5 mg O₂/L = 95 % O₂-saturation), the water pH values ranged from 7.7 to 7.9 and the water temperature ranged from 20.0°C to 20.4°C over the whole period of testing, fulfilling the guideline requirements.

Analytical findings

The analysed a.s. flupyradifurone was found in all freshly prepared test levels on day 0 in reference to nominal concentrations ranged between 94 and 100 % (average 98 %). In aged test levels on day 2 there were analytical findings between 93 and 99 % (average 97 %) of nominal. Due to the high recoveries at the beginning of the exposure and the analytical findings after 2 days, all results are based on nominal concentrations.

As the toxicity has to be attributed to the test formulation as a whole, all results submitted by this report are related to nominal test concentrations of the formulated product.

Biological findings

Acute toxicity of test item to first instar-larvae of *Chironomus riparius* after 48 hours (based on nominal concentrations):

Test concentration DLT+FPF EC 85 (10+75) G [µg form./L]	Exposed chironomids (=100%)	Immobility			
		24 h		48 h	
		n	%	n	%
control	30	0	0.0	3	10.0
0.50	30	1	3.3	3	10.0
1.10	30	3	10.0	9	30.0
2.42	30	6	20.0	18	60.0*
5.32	30	6	20.0	21	70.0*
11.7	30	13	43.3*	23	76.7*
25.8	30	20	66.7*	29	96.7*

* statistical significant ($\alpha = 0.05$)

Other observations:

After 24 of incubation larvae were observed showing reduced mobility at test concentrations from 2.42 to 25.8 µg form./L with increasing tendency and some larvae which got trapped at the water surface from the control (2 larvae) to 5.32 µg form./L. After 48 hours of incubation the prevailing part of the surviving larvae showed reduced mobility at test concentrations from 2.42 to 25.8 µg form./L and one larvae which got trapped at the water surface were observed at test concentration of 0.50 and four larvae at 1.10 µg form./L.

Conclusions

The immobility and other observations (larvae trapping at the water surface) in the control did not exceed 15 % and measured dissolved oxygen concentrations in the control and all test concentrations did not fall below 3 mg/L during exposure, fulfilling the guideline requirements.

Statistical results of probit analysis conducted for determination of EC₅₀ values (based on nominal concentrations):

Probit analysis for data obtained after	NOEC µg form./L (nominal)	EC ₅₀ µg form./L (nominal)	lower 95% ci µg form./L (nominal)	upper 95% ci µg form./L (nominal)
24 hours	5.32	14.8	9.57	29.1
48 hours	1.10	3.24	2.42	4.31

Due to the results of the statistical analysis a 24 h-NOEC (No Observed Effect Concentration) of 5.32 µg form./L was evaluated (Williams multiple sequential t-test procedure, $\alpha = 0.05$) and at 48 h a NOEC of 1.10 µg form./L was found (Welch-t test for Inhomogeneous Variances with Bonferroni-Holm Adjustment, $\alpha = 0.05$).

Comments of zRMS:	<p>The study was performed in line with OECD 223503 with no major deviations.</p> <p>Since the test was performed in a semi-static design with daily renewal, the measured concentrations of both active compounds were determined at each renewal interval in fresh and aged test solutions. The mean measured concentrations of flupyradifurone in fresh and aged solutions were maintained at 80-120% of nominal throughout the study period. The measured concentrations of deltamethrin dropped below 80% in all fresh and aged test solutions. Measured concentrations <80% of nominal in fresh test solutions could be due to adhesion of the test item to the walls of test vessels, despite their pre-conditioning. Nevertheless, deltamethrin is known for its sorptive properties and all available chemical analyses were sufficient to determine the actual exposure of test organisms to this compound via the water column and derive reliable endpoints.</p>
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All validity criteria were met and the study is considered acceptable with following endpoint:

$EC_{50} = 5.72 \text{ }\mu\text{g product/L (nominal)}$

Since the concentration of deltamethrin was <80%, the Applicant was requested to recalculate the endpoints as mean measured concentrations of the active substances, in line with indications of Appendix J of EFSA Supporting publication 2019:EN-1673. Respective calculations were submitted during the commenting period. Option A of point 4.1 was followed (preferred option because associated with fewer uncertainties):

- For both active substances deltamethrin and flupyradifurone, the geometric mean concentrations between the start and end of the test for each tested concentration were calculated; the recovery rates at each tested concentration (geomean compared with nominal or initial measured) were calculated (see table below).
- The new calculated geomean concentration levels for the active substances were summed up to derive the ‘sum of active substances’ per concentration level to calculate the endpoint in the following step (see table below).
- The endpoints (mean and confidence interval) were calculated based on the ‘sum of active substances’ geomean concentration levels using an appropriate statistical tool (see table below).

Chironomus	M-686369-01-1					
FPF	nominal ($\mu\text{g/L}$)	0.064	0.14	0.307	0.676	1.486
	geomean ($\mu\text{g/L}$)	0.0622	0.1275	0.2797	0.6091	1.3505
	% of nominal	97	91	91	90	91
DLT	nominal ($\mu\text{g/L}$)	0.0093	0.0204	0.0448	0.0986	0.217
	geomean ($\mu\text{g/L}$)	0.0037	0.0075	0.0167	0.0331	0.0803
	% of nominal	39	37	37	34	37
FPF+DLT	geomean ($\mu\text{g/L}$)	0.0659	0.135	0.2964	0.6422	1.4308

Based on above assumptions, the following endpoint based on mean measured concentrations of both active compounds was calculated:

$EC_{50} = 0.3496 \text{ }\mu\text{g DLT+FPF/L (CI: 0.2677-0.4599 }\mu\text{g DLT+FPF/L)}$

Reference:	KCP 10.2.1/09
Title:	Deltamethrin + flupyradifurone EC85 (10+75 g/L): Acute toxicity to larvae of Chironomus riparius in a semi-static 48-hour immobilisation test
Report:	Bebon, R.; Sonntag, F.; 2020c; EBRV0194; M-686369-01-1
Guideline(s):	OECD Guideline for Testing of Chemicals 235: "Chironomus sp., Acute Immobilisation Test" adopted July 28, 2011 OECD Series on Testing and Assessment, No. 23, "Guidance Document on Aqueous-phase Aquatic Toxicity Testing of Difficult Test Chemicals", 2nd Ed., February 08, 2019 SANCO/3029/99 rev.4 11/07/00: Residues: Guidance for generating and reporting methods of analysis in support of pre-registration data requirements for Annex II (part A; Section 4) and Annex III (part A; Section 5) of directive 91/414
Deviations:	None
GLP/GEP:	Yes
Acceptability:	Acceptable
Duplication (if vertebrate study):	Not relevant

Materials and methods

Test material	Name of substance: Deltamethrin + Flupyradifurone EC85 (10+75 g/L) lot/batch: EQ10000696 Specifications: 102000028562 active ingredients content: Deltamethrin (AE F032640): 0.926 % w/w (10.71 g/L); Flupyradifurone (BYI 02960): 6.35 % w/w (73.46 g/L), analysed purity: Deltamethrin; 99.73 %, Flupyradifurone; 99.8 %
Guideline(s) adaptation	none specified
Test species	<i>Chironomus riparius</i>
Acclimation	Was not necessary, since the test was performed in the same medium as the culturing.
Organism age/size at study initiation	- Age at study initiation: First instar larvae, 2 to 3 days old - Length at study initiation (range): not specified - Weight at study initiation (range): not specified
Test solutions	Nominal concentrations: 1.00, 2.20, 4.84, 10.65 and 23.4 µg test item/L Control: Reconstituted water (Elendt "M4"). Evidence of undissolved material (e.g. precipitate, surface film, etc.): not observed.
Replication:	No. of vessels per concentration (replicates): 4 No. of vessels per control (replicates):4
Organisms per replicate	No. of organisms per vessel: 5
Exposure	Test type: semi static, test medium renewed on Day 1 Total exposure duration: 48 hours
Feeding during test	None
Test conditions	Temperature: 19.3 to 19.6 °C in fresh media, 19.2 to 20.5 °C in aged media Photoperiod: 24 h darkness Light intensity: The test was performed in the dark. pH: 7.9 to 8.0 Water hardness: 2.5 mmol/L (= 250 mg/L) as CaCO ₃ . To avoid trapping of the larvae at the water surface 2 µL Tween 80/L were added. The dispersant reduces the surface tension of the medium. Dissolved oxygen: 9.0 to 9.7 mg/L Before test start and before the test medium renewal, the test vessels were preconditioned for 1 hour with the test item using the test concentrations chosen for the exposure phase of the chironomid larvae. The test concentrations and media used for the preconditioning were discarded before the start of the test and before the water renewal.
Parameters Measured / Observations	The mobility of <i>Chironomus riparius</i> larvae was determined by visual observation after 24 and 48 hours. Those animals not able to change their position within 15 seconds after gentle agitation of the test beaker were considered to be immobile. Any signs of disease or stress or unusual behaviour were documented in the raw data.
Sampling for chemical analysis	One sample from the freshly prepared stock solution and six samples (before Tween 80 addition) from the freshly prepared test media of all test concentrations and the controls were taken on day 0 and day 1 of exposure. For the determination of the stability of the test item and the maintenance of the test item concentrations under the test conditions, respectively, six samples from the aged test media of all treatment groups were taken at the end of all renewal periods (day 1 and 2) from the additional vessels prepared for analytical samplings that did not contain Tween 80.

	<p>Two of the six taken samples per sampling time were diluted by a factor of 1.25 with acetonitrile (for Flupyradifurone analysis). The other 4 samples remained undiluted (for Deltamethrin analysis).</p> <p>Additional samples of the untreated control and the dilution solvent acetonitrile were taken at each sampling date without any sample treatment.</p> <p>Samples were taken without Tween 80 since it interferes with the liquid/liquid extraction performed with Dichloromethane for the sample preparation of Deltamethrin.</p> <p>Method for Deltamethrin Determination: Liquid/Liquid Extraction with Dichloromethane followed by analysis via GC-MS/MS.</p> <p>Method for Flupyradifurone Determination: Direct analysis via LC-MS/MS.</p>
Data analysis	<p>The 24-hour and 48-hour EC₅₀, EC₂₀ and EC₁₀ and the 95% confidence limits were calculated by probit analysis corrected by the control response using Abbott's formula.</p> <p>The NOEC and LOEC after 24 and 48 hours were determined directly from the raw data.</p> <p>The software used to perform the statistical analysis was ToxRat Professional, Version 3.3.0, ToxRat® Solutions GmbH.</p>

Results and discussions

Validity criteria of OECD guideline 235 (2011)	Required	Obtained
Immobilisation in control	≤ 15%	15%
Signs of disease or stress or unusual behavior in control	≤ 10%	0%
Dissolved O ₂ concentration	≥ 3 mg/L	≥ 9.1 mg/L

Analytical results

Measured concentrations of the test substances in test solutions are presented in tables below. Please note that they represent mean concentrations/recoveries in all fresh and 24-h aged solutions taken at each renewal.

Summary of Analytical Results for Deltamethrin

Nominal concentration [µg test item/L]	fresh (0h)			aged (24h)			time weighted arithmetic mean value ² [%]	n	time weighted arithmetic mean concentration [µg Deltamethrin/L] ³
	% of nominal ¹	RSD [%]	n	% of nominal ¹	RSD [%]	n			
Control	n.a.	n.a.	4	n.a.	n.a.	4	n.a.	8	n.a.
1.00	49	10	4	32	12	4	40	8	0.00368
2.20	45	10	4	31	19	4	37	8	0.00760
4.84	45	9	4	31	10	4	37	8	0.0168
10.65	45	9	4	25	3	4	34	8	0.0336
23.4	44	20	4	32	11	4	37	8	0.0808

¹ The tabulated results represent rounded results calculated on the exact raw data

² Calculated according to OECD Guidance Document No. 23 (2019), Annex 2

³ The tabulated results represent results rounded to three significant digits

n.a.: not applicable; RSD: Relative Standard Deviation; n: number of analysed samples

The lower recoveries analysed for Deltamethrin are likely related to the extreme hydrophobicity of this compound (log K_{ow} = 6.2) in combination with the very low concentrations in the range of nominal 9.3 – 217 ng/L. Although the test vessels for the chironomids were pre-conditioned, the sampling vessels were not. Therefore, adhesion of Deltamethrin to the glass surface of the sampling vessels likely led to unextractable parts of the nominal concentrations. These adhesion effects might have also occurred during pipetting from test vessels to the sampling vessels at the pipette tips and even at the test vessels in case performed pre-conditioning was not 100% sufficient.

The data presented in B5 demonstrates that the analytical method complies with all guideline criteria according to SANCO/3029/99 rev. 4 and is suitable for the determination of deltamethrin in test water

samples via GC-MS/MS.

Summary of Analytical Results for Flupyradifurone

Nominal concentration [µg test item/L]	fresh (0h)			aged (24h)			overall mean		
	% of nominal ¹	RSD [%]	n	% of nominal ¹	RSD [%]	n	% of nominal ¹	RSD [%]	n
Control	n.a.	n.a.	4	n.a.	n.a.	4	n.a.	n.a.	8
1.00	99	6	4	97	5	3	98	5	7
2.20	92	1	4	91	2	4	91	2	8
4.84	91	3	4	91	4	4	91	3	8
10.65	90	2	4	90	1	4	90	2	8
23.4	90	3	4	91	3	4	91	3	8

¹ mean value of all measured samples per treatment group

RSD: relative standard deviation per treatment group

n: number of analysed samples; n.a.: not applicable; RSD: Relative Standard Deviation

Due to the nominal recoveries determined for Flupyradifurone, a correct dosage of the test item is confirmed. All reported results refer to nominal concentrations of the test item.

The data presented in B5 demonstrates that the analytical method complies with all guideline criteria according to SANCO/3029/99 rev. 4 and is suitable for the determination of Flupyradifurone in test water samples via HPLC-MS/MS.

Biological results

Observations

After 48 hours of exposure, 15% of the larvae were immobile in the control. This is acceptable according to the guideline. At concentrations of 1.00, 2.20, 4.84, 10.65 and 23.4 µg test item/L, immobilities of 10, 25, 60, 70 and 100 % were observed at test end.

Nominal test concentrations [µg test item/L]	% of immobilized chironomids	
	24 h	48 h
Control	0	15
1.00	0	10
2.20	5	25
4.84	0	60
10.65	10	70
23.4	80	100

Conclusion

The study meets the validity criteria and the endpoints based on nominal concentrations are represented in the table below:

EC ₅₀ 48 hours (95% C.I.):	5.72 µg test item / L (4.35 – 7.54 µg test item / L)
EC ₂₀ 48 hours (95% C.I.):	2.93 µg test item / L (1.91 – 3.90 µg test item / L)
EC ₁₀ 48 hours (95% C.I.):	2.07 µg test item / L (1.19 – 2.89 µg test item / L)
LOEC (48 h): lowest concentration with an effect	2.20 µg test item / L
NOEC (48 h): highest concentration without adverse effects	1.00 µg test item / L

A 2.2.1.3 Effects on aquatic algae

Comments of zRMS:	<p>The study was performed fully in line with OECD 201 with no deviations.</p> <p>All the validity criteria were met.</p> <p>It is noted that DLT+FPF EC 85 contains two active substances and in line with requirements of the Central Zone the test concentrations of both substances should be verified in respective chemical analyses or, as a minimum, the least stable active compound should be analysed. However, in the study only concentration of flupyradifurone were measured and no analyses were performed for deltamethrin, which seems to be less stable than flupyradifurone. No explanation or justification of the substance selected for the measurements was provided in the study report. Since stability of both active compounds throughout the study period cannot be confirmed, the study is considered not acceptable.</p> <p>During the commenting period the Applicant may provide additional explanations to justify selection of the substance for chemical verification or data to confirm that deltamethrin was most stable during the study.</p>
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Reference:	KCP 10.2.1/06
Title:	Toxicity of deltamethrin + flupyradifurone EC 85 to the green algae <i>Pseudokirchneriella subcapitata</i> during a 72 hour exposure
Report:	Matlock, D.; Moore, S.; 2015; EBRVR016; M-547460-01-1
Authority registration No:	
Guideline(s):	OCSPP Guideline 850.4500, OECD Guideline 201. The afore- mentioned guidelines were harmonized for various test parameters (i.e. temperature, light, etc.) to achieve optimal environmental conditions for the test organism. Scientific discretion was implemented where guideline parameters do not fully converge.
Deviations:	not applicable
GLP/GEP:	yes
Acceptability:	Unacceptable (chemical analyses performed only with flupyradifurone and concentration of deltamethrin not confirmed)

Materials and methods

Deltamethrin + flupyradifurone EC 85 (10+75 g/L), a.s.-content: deltamethrin 0.867 % w/w & flupyradifurone 6.62 % w/w was tested, specified by batch no 2014-012629 and specification no.: 102000028562.

The green algae *Pseudokirchneriella subcapitata* were exposed under static (shaken cultures) conditions for 72-hours. Nominal concentrations were Control, 0.477, 1.53, 4.88, 15.6 and 50.0 µg formulation/L. Nominal test concentrations of flupyradifurone were control, 0.0316, 0.101, 0.323, 1.03 and 3.31 µg flupyradifurone/L. Initial measured test concentrations of flupyradifurone ranged from 88 to 97% of nominal test concentrations. Day 3 (72h) measured test concentrations of flupyradifurone ranged from 93 to 99% of nominal test concentrations. Mean measured recoveries analyzed for content of Flupyradifurone ranged from 91 to 98% of nominal concentrations. Results are based on the nominal test concentrations in mg formulation/L.

Initial cell density: 1.0 x 10⁴ cells/mL
Number of replicates: 4 for control and test levels
Photoperiod: 24 hour light
Light intensity: 4510 to 4860 lux (mean: 4633 lux)
Test/Culture media: 1x AAP
Temperature range (Min/Max thermometer): 24.4 to 24.6°C
pH Range: 7.3 to 9.0

Parameters measured (based on cell density): 72 hour: growth rate (NOEC, LOEC, EC₁₀, EC₂₀, EC₅₀)
Cell density measurement technique: manual count by hemocytometer (daily measurement)

Results and discussions

72 hour mean growth rate during the exposure of *Pseudokirchneriella subcapitata* to Deltamethrin + Flupyradifurone EC 85:

Nominal Concentration (µg form./L)	Mean Growth Rate ^a	%Inhibition ^b
Control	0.067567	NA
0.477	0.068160	-0.88
1.53	0.067547	0.03
4.88	0.067295	0.40
15.6	0.049361	26.9*
50.0	0.004282	93.7*

* Statistically significant from control (Dunnett's test; $p \leq 0.05$).

^a Growth rate [1/h] is calculated from the cell density data.

^b % Inhibition=100-((Treatment group parameter mean/control parameter mean)*100).

Toxicity to algae

Test substance	Deltamethrin + Flupyradifurone EC 85
Test object	<i>Pseudokirchneriella subcapitata</i>
Exposure	72 hour, static
Growth Rate 0-72 h E _r C ₁₀ (95% confidence interval)	8.60 (7.58 to 11.2) µg form./L
Growth Rate 0-72 h E _r C ₂₀ (95% confidence interval)	12.7 (10.7 to 18.0) µg form./L
Growth Rate 0-72 h E _r C ₅₀ (95% confidence interval)	27.4 (24.5 to 31.4) µg form./L

0 to 72 Hour Control Growth Validity Criteria:	
Control Biomass Increase (minimum recommended multiplication factor is 16):	128
Mean coefficient of variation for section-by-section specific growth rates (days 0-1, 1-2, 2-3) in the controls (criterion is ≤ 35%)	26%
Coefficient of variation for average specific growth rates during the 0 to 72 hour test period in replicate control cultures (criterion is ≤ 7%)	0.59%

No abnormalities were observed in the control and any treatment groups.

Conclusion

The 72-hour growth rate was calculated based on nominal test concentrations. The 72-hour EC₅₀ value for growth rate (E_rC₅₀) was 27.4 µg formulation/L with NOEC and LOEC values of 4.88 and 15.6 µg formulation/L, respectively.

A 2.2.2 KCP 10.2.2 Additional long-term and chronic toxicity studies on fish, aquatic invertebrates and sediment dwelling organisms

Comments of zRMS:	<p>The summarised below position paper and underlying studies (summarised below) have been already agreed by the zRMS (BE) in the course of the zonal evaluation of formulation Decis 15 EW, belonging to the same Applicant (see Core Assessment, Part B, Section 6, finalised in May 2018) and EAC of 23.0 ng deltamethrin/L was concluded with no additional assessment factor.</p> <p>It is, however, noted that during the commenting period conclusion of the RMS (BE) was questioned by the cMS (NL) who indicated that for other deltamethrin formulation NOEAEC of 3.2 ng/L has been derived based on the results of the two mesocosm studies and which were also considered in the position paper by Heimbach & Koelzer, (2008). Unfortunately, the name of the product has been not recalled by the NL, but in the zonal evaluation of formulation Multirose by the zRMS (AT) in 2016, the EU agreed EAC of 3.2 ng deltamethrin/L with an AF of 2 has been considered relevant. In the zonal report it was noted that during the EU review of deltamethrin the AF of 1-3 was recommended, but due to uncertainties in the microcosm studies the zRMS (AT) considered AF of 2 to be most relevant. This AF has been agreed by the concerned Member States.</p> <p>The zRMS for the current assessment of DLT+FPF EC 85 was able to find only three finalised zonal reports for Bayer deltamethrin spray formulations with Core Assessment in area of ecotox included. Two of them are described above (Decis 15 EW and Multirose). The third evaluation was performed by DE for Decis Forte (finalised in October 2018) and the respective assessment was available only in a form of National Addendum, where EAC of 3.2 ng a.s./L was used with AF of 5. However, no justification for selected AF was given and since this was an National Addendum, its outcome is not necessarily applicable for the Central Zone, especially AF of 1-3 has been recommended at the EU level.</p> <p>With regard to the position paper by Heimbach & Koelzer (2008) the zRMS for DLT+FPF EC 85 would like to point out that it has been prepared before EFSA aquatic guidance (2013) came into force and in their evaluation the authors refer to an old guidance document (SANCO/3268/2001 rev. 4, final), which is no longer valid. For all applications submitted since 2015 the criteria as set by the EFSA (2013) are applicable, which may have significant impact on the derived endpoints.</p> <p>Furthermore, in evaluation of results of multiple studies on effects of deltamethrin formulations on aquatic invertebrates and fish (summarised below) the authors of the position paper refer sometimes to NOEC values, but analysis of the provided information indicate that actually for multiple species endpoints based on recovery were considered in derivation of the overall endpoint relevant for the risk assessment. It has to be, however, pointed out that according to the Central Zone agreements and specific Polish requirements, recovery is no longer an option in derivation of the endpoints and higher tier studies must be evaluated with consideration of the ETO option. This is of specific importance for DLT+FPF EC 85, which contains two active substances of insecticidal mode of action (deltamethrin and flupyradifurone) and it is not known if the populations of aquatic invertebrates would recover after simultaneous exposure to both active compounds.</p> <p>In the position paper also modelling studies on the recovery of populations of <i>Asellus aquaticus</i> from deltamethrin were considered (Schäfer, 2007). It should be, however, noted that first of all (as mentioned above) recovery is not an option in derivation of an endpoint based on results of higher tier studies. Furthermore, the model was not validated for the use in the regulatory risk assessment and the modelling exercise was performed in 2007, i.e. before the EFSA PPR Panel opinion on good modelling practice was issued (EFSA Journal 2014;12(3):3589). It has to be also noted that in Poland the population modelling is used only in case the standard risk assessment is only slightly</p>
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	<p>below the trigger values.</p> <p>It should be also noted that majority of the studies included in the data package on the basis of which Heimbach & Koelzer (2008) proposed an overall endpoint of 23 ng deltamethrin/L with no AF, has been also evaluated in the course of the ongoing EU renewal process of deltamethrin. Based on results of the same studies the endpoint was set by the RMS to 1.0 ng deltamethrin/L with and AF of 2, resulting with RAC of 0.5 mg deltamethrin/L. Since in the evaluation indications and criteria of EFSA (2013) were considered, this endpoint seems to be most reliable. Nevertheless, as the renewal process is not finalised yet and the endpoint to be used in the aquatic risk assessment will be most probably further discussed during the expert meeting the zRMS is of the opinion that in order to maintain consistent approach in evaluation of deltamethrin formulations in the Central Zone, at the current stage the EU agreed EAC of 3.2 ng deltamethrin/L should be used with AF of 2, resulting with RAC of 1.6 ng/L.</p> <p>In the course of the renewal process also the study by Deneer (2005, M-256605-01-1) on effects of Deltamethrin EW 15 on rainbow trout in aquatic outdoor microcosm enclosures was considered. It was indicated by the RMS that no definite endpoint could be derived from the study due to the exposure regime, however the evidence available in the study was considered sufficient to conclude that the risk to fish is addressed by the risk assessment performed for aquatic invertebrates. The zRMS agrees with the RMS conclusion and considers it to be applicable also for this evaluation. It is noted that no definite endpoint could be derived from the study by Deneer (2005) due to the exposure regime, however rough estimations provided by the RMS indicated that the overall NOEC from the study would be at ~200 ng a.s./L, which is much higher comparing to 3.2 ng a.s./L agreed by the zRMS for aquatic invertebrates.</p>
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Reference:	KCP 10.2.2/01
Title:	Refined risk assessment for aquatic effects of Deltamethrin based on recent higher tier studies, expert statements and population models
Report:	: 2008; RA08-022; M-297157-01-1
Authority registration No:	
Guideline(s):	--
Deviations:	--
GLP/GEP:	no
Acceptability:	
Duplication (if vertebrate study):	no

Summary

Several aspects of the aquatic risk assessment for the use of deltamethrin in agriculture have been discussed in detail, based on special laboratory and field studies as performed within the last years, expert statements and meta-population modelling.

A refined highest tier risk assessment has been presented for fish. The zooplankton dynamics as evaluated in a new mesocosm study have been interpreted considering direct effects from the deltamethrin applications as well as the resulting secondary effects. Special emphasis was put on *Asellus aquaticus*, an isopod species, which is amongst the most sensitive aquatic invertebrates for deltamethrin. Next to a sensitivity study on different life stages, studies on the drift of this species in a natural stream have been performed to investigate drift rates to be used for the meta-population modelling. Expert statements on the biology and ecology and on the occurrence of this species in water bodies in the agricultural landscape demonstrate that *A. aquaticus* is predominantly inhabiting lentic or slowly flowing water bodies. The meta-population model demonstrates the recovery potential of a population by reproduction and recolonisation, which had been affected by deltamethrin. All this information demonstrates that deltamethrin can be used in agriculture without unacceptable

effects on aquatic ecosystems up to an environmental concentration of 30 ng a.s./L. The application of an assessment factor greater than one does not seem necessary because of the broad and intensive information on all detailed concerns provided. The applicant thus recommends an EAC of 30 ng a.s./L for deltamethrin.

Comments of zRMS:	Please, refer to zRMS discussion presented under KCP 10.2.2/01.
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Reference:	KCP 10.2.2/02
Title:	Analysis and interpretation of the zooplankton dynamics after application of Deltamethrin EW 015 to aquatic mesocosms with special focus on the <i>Chaoborus crystallinus</i> population
Report:	2007; M-291864-01-1
Guideline(s):	--
Deviations:	--
GLP/GEP:	no
Acceptability:	Please, refer to zRMS comments under KCP 10.2.2/01
Duplication (if vertebrate study):	No

Summary

Based on the results of the mesocosm study with Deltamethrin EW 15 ([2005; M-246137-01-2](#); see Appendix 2, section 2.2.3, KCP 10.2.3/02) a food web evaluation of the mesocosm zooplankton community has been used to analyse direct and indirect effects on the zooplankton composition observed in the above mentioned mesocosm study. Exemplary life-cycle calculations, observations and considerations on the population densities and emergence of *Chaoborus crystallinus* in the mesocosm revealed that this population probably recovered by means of external sources via egg masses laid on the water surface of treated ponds soon after the last application. Larvae which hatched from egg masses about 6 to 7 days onwards after the last application of 4.8 ng a.s./L (7 to 8 days at 111 ng a.s./L; egg deposition about 4 days earlier) survived and got trapped as emerged midges later on during the study.

Following the food web evaluation it is seen as highly improbable that the test item had any effects on rotifers. On the contrary, the population growth of rotifers was promoted due to an indirect effect via the toxicant-induced loss of effective predators (*Chaoborus*) and of competing Cladocerans (*Daphnia longispina*, *Chydorus sphaericus*), until the predators came into play again. *Asplanchna* and new young chaoborid larvae repopulating the mesocosms probably caused the sharp decline in rotifers soon after the applications. Thus, it can be confirmed that all observed effects on the population dynamics of rotifers are to be considered as secondary effects of the treatment with Deltamethrin.

The increase in the population densities of *Daphnia longispina* at higher test concentrations some weeks after the applications does probably also not depend on the test item concentrations. Taking into consideration the rapid dissipation of the test item from the water phase and the short generation cycles (< 10 d) of this species, the start of recovery appears rather delayed. Since the daphnid densities did not reach control densities until the first Analysis and Interpretation of Deltamethrin effects 3 emergence of the chaoborids, most probably the growing population of 3rd- and 4th-instar larvae substantially contributed to the delayed recovery by predation. With respect to the copepod populations the author shares the description and interpretation of Heimbach et al. ([2005; M-246137-01-2](#); see Appendix 2, section 2.2.3) that the toxic effect of the test item on the cyclopoid copepods (juvenile copepodids plus adult copepods) was slightly lower than on the nauplii (only at test concentration of 23 to 111 ng a.s./L), but the population density reached the control level not before day 29. However, the effects on the nauplii are seen by the present author to be also caused by the decline of the copepods themselves, since their decline caused less production of eggs and thus nauplii.

Overall, *Chaoborus crystallinus* was found as the most sensitive species in this mesocosm study with

Deltamethrin, demonstrating a distinct reduction in abundance of larvae and emerging midges immediately after the application at all treatment levels. However, larvae hatching from egg masses in the treated pond of the highest test level (111 ng a.s./L) already survived 7 to 8 days after the last application and emerged later on. In addition the abundance of *Daphnia longispina* and copepodps (mainly nauplii) was affected by Deltamethrin at the highest test levels. Although the recovery for *D. longispina* was delayed by the predation of a growing population of *Chaoborus* larvae, the populations of both, *Daphnia longispina* and copepodps (mainly nauplii) recovered even up the highest test level within some weeks after the last application at the latest. The population dynamics of *Chaoborus crystallinus* also caused some short-term indirect food web effects (as on rotifers and phytoplankton). Thus, the treatment with deltamethrin caused distinct short-term effects on a few zooplankton species, which also induced fluctuations on other zooplankton and phytoplankton species within the food web for some weeks only.

Comments of zRMS:	Please, refer to zRMS discussion presented under KCP 10.2.2/01.
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Reference:	KCP 10.2.2/03
Title:	Bioassay on the effects of Deltamethrin EW 015 on Gammarus pulex in mesocosm water
Report:	Heimbach, F.; Arnold, M.; 2005; HBF/BT 08; M-246173-01-1
Guideline(s):	OECD Guidance Doc. "Freshwater Lentic Field Tests", 2004 (Draft); Guidance Doc. on Testing Procedures for Pesticides in Freshwater Microcosms (SETAC 1991); Community-Level Aquatic System Studies Interpretation Criteria (SETAC 2002)
Deviations:	none
GLP/GEP:	yes
Acceptability:	Please, refer to zRMS comments under KCP 10.2.2/01
Duplication (if vertebrate study):	

Material and methods

In this study the ecological effects of Deltamethrin EW 15 (Batch.-No. AAIM00846, TOX-No. AZ 10459) were studied on the aquatic invertebrate *Gammarus pulex*. The investigation was performed within several consecutive bioassays running parallel to the mesocosm study (Project ID.: E 413 2623 – 1, Report ID.: HBF/Bt 07). The bioassay test water and food for the Gammarids (*Populus* leaves) originated from the mesocosm study with deltamethrin, the test organisms from a laboratory culture.

The test regime enabled the investigation of the toxicity of deltamethrin to *Gammarus pulex* and demonstration of the possibility of a population recovery by immigration of new individuals into an affected system.

The 12 test tanks (6 m³ water, 1 m water depth) used in the mesocosm are especially designed systems which allow the establishment of almost identical conditions at the start of a study. The bottoms of the artificial tanks were covered with natural sediment (approximately 15 cm in height) 7 months prior to beginning of the study. The water was composed of local ground water and water from an uncontaminated pond nearby, which was inoculated several times with zooplankton also from a natural pond nearby. Natural communities developed spontaneously from seeds and roots of aquatic plants as well as from airborne and naturally transferred stages of planktonic, benthic and filamentous algae organisms during the months before the beginning of the study. In general, the artificial ponds were representative of a small stagnant mesotrophic water body.

The test substance was applied during the early growing season in May 2004, three times at an interval of 7 days onto the water surface of 9 test ponds. The treatment levels were 4.8, 10.5, 23, 51 and 111 ng a.s./L per application (two replicates 4.8 to 51 ng a.s./L, one replicate for 111 ng a.s./L). Three further tanks were used as untreated controls.

The test organisms (*Gammarus pulex*) were derived from ditches of the research institute ALTErrA in Wageningen (The Netherlands). They were cultured in the laboratory at about 12-15 °C, LD 16:8 hours in aerated tanks and fed by leaves of *Populus spec.*

Two and 7 days after each application (and 4 hours after the 2nd and 3rd application), and on days 15, 21 and 28 after the last application of the mesocosms, pond water samples were taken from the mesocosms, together with some of the exposed leaves (*Populus spec.*). The bottles were exposed in a climatized room (same climatic conditions as the culture) and slightly aerated. After adaptation of the water samples to room temperature within a few hours, ten *Gammarus pulex* of similar size were transferred from the culture into each bottle. The experimental time for each bioassay was 3 weeks with 1 to 2 evaluations weekly. Surviving and dead animals were counted to calculate the survival rate. Water and living animals were refilled into the test bottles each time.

Univariate analyses were performed to calculate NOEC values.

Results and discussion

A response from *Gammarus pulex* could only be observed at the highest treatment levels of 51 ng a.s./L and 111 ng a.s./L. A reduction of the numbers of surviving Gammarids was noted at these concentrations in the bioassay water and food samples taken 4 hours to 2 days after application. Nevertheless, no effects were found at any of the test concentrations, even the highest one, in bioassays established seven or more days after applications.

Calculated NOEC values after each application:

Time after application	NOEC (ng a.s./L) after		
	1 st application	2 nd application	3 rd application
4 hours	not tested	23	23
2 days	23	23	≥ 111
7 days	≥ 111	≥ 111	≥ 111
15 days	see 2 nd application	see 3 rd application	≥ 111
21 days			≥ 111
28 days			≥ 111

Conclusion

A NOEC of 23 ng a.s./L can be derived from this bioassay study. At higher test concentrations, mortality was observed only in samples taken during the first 2 days after application. Samples taken thereafter did not indicate any toxic effects, even at the highest test concentration of 111 ng a.s./L.

Comments of zRMS:	Please, refer to zRMS discussion presented under KCP 10.2.2/01.
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Reference:	KCP 10.2.2/04
Title:	Biology and distribution of selected waterlice and freshwater shrimps of Central Europe - a literature review
Report:	Schulz, R.; Bruehl, C.; 2007; M-291865-01-1
Guideline(s):	--
Deviations:	--
GLP/GEP:	no
Acceptability:	Please, refer to zRMS comments under KCP 10.2.2/01
Duplication (if vertebrate study):	

Summary

In that literature review current knowledge on the biology and distribution of selected waterlice and freshwater shrimps of Central Europe is summarized. Information for the both Crustacean groups on reproduction and life cycle, preferred habitat of the different species is given. In addition, the variation of occurrence, the geographic distribution pattern in Central Europe, food preferences and interactions with other species focussing on other species in the same group is described. Scarce information on the recolonisation potential of the selected species or quantitative data on drift rates in small streams and ditches is given in the literature survey.

Comments of zRMS:	Please, refer to zRMS discussion presented under KCP 10.2.2/01.
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Reference:	KCP 10.2.2/05
Title:	Drift of the freshwater isopod <i>Asellus aquaticus</i> in a stream in an agricultural landscape - a case study
Report:	Schulz, R.; Bruehl, C.; 2007; M-291925-01-1
Guideline(s):	no guideline available
Deviations:	none
GLP/GEP:	no
Acceptability:	Please, refer to zRMS comments under KCP 10.2.2/01
Duplication (if vertebrate study):	

Summary

There is rarely any published scientific information available on the drift and foraging behavior of the freshwater isopod *Asellus aquaticus* L. Therefore, field studies were conducted in the Birnbach, a third order stream (width: about 1.2 m, depth: about 20 cm, flow velocity: between 0.01 and 0.2 m/s) discharging agricultural land (mainly vineyards) close to Landau, South Western Germany. The stream itself is considered to belong to the category “Ditch” when applying a scheme on FOCUS scenarios in the UK landscape context. It may be furthermore classified to be comparable to the „Till landscapes“ with level to gently sloping till plains (defined by Brown et al. 2006¹⁰).

Drift and abundance measurements were conducted in the Birnbach in order to derive an estimate for a proportion of the present population entering the drift. The estimated mean population density of 2223 ± 1040 ind/m² (n = 15) and the estimated mean drift rate of 675 ± 467 ind/24 h (n = 45) are well comparable with other published studies conducted in the UK and elsewhere. A drift distance of 10.7 m was assumed (McLay 1970¹¹), as this is supported by literature data on aquatic macroinvertebrates in

¹⁰ Brown, C.D., Turner, N., Hollis, J., Bellamy, P., Biggs, J., Williams, P., Arnold, D., Pepper, T. & Maund, S. (2006): Morphological and physico-chemical properties of British aquatic habitats potentially exposed to pesticides. – Agriculture Ecosystems and Environment 113:307-319.

¹¹ McLay, C. (1970): A theory concerning the distance travelled by animals entering the drift of a stream. – Journal of Research Board Canada 27:359-370.

general and by the blocking experiments also conducted as part of this study and outlined below. Using this assumption and the monitoring results of this case study concerning the drift and the abundances of *A. aquaticus*, an average drift rate of 2.7% (0.5% to 8.6%) per 24 h was estimated.

Two blocking experiments were conducted in order to derive an estimate for the drift distance of *A. aquaticus*. These experiments were designed to determine the effect of blocking the total drift on drift rates of *A. aquaticus* at various stations downstream of the mesh barrier used for blocking the drift. In both blocking experiments a reduced drift during the later time intervals due to a reduced population density resulting from the lack of isopod recruitment from upstream was observed as a result of the presence of the mesh barrier. Furthermore, the observed drift patterns suggested that drift distances of 14 m (1st experiment) or even of 25 m (2nd experiment) are of relevance for *A. aquaticus*, as the drift was reduced even at these distances downstream of the mesh barrier. The results from the blocking experiments thus confirm the assumption of a drift distance of at least 10.7 m.

Over a range of flow velocities between 0.01 and 0.2 m/s measured during the study reported here (n = 40), drift rate was not correlated with flow velocity. Even if it is not conclusively possible to distinguish between active or passive components or between drift and locomotion, the data from the study reported here still suggest a rather high spatial dynamic for the isopod species *A. aquaticus*.

Comments of zRMS:	Study not evaluated as being not relevant for the Central Zone conditions
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Reference:	KCP 10.2.2/06
Title:	Freshwater isopods in water bodies of the agricultural landscape in Southern Europe
Report:	Bruehl, C.; Schulz, R.; 2009; M-329195-01-1
Authority registration No:	
Guideline(s):	--
Deviations:	--
GLP/GEP:	no
Acceptability:	Not validated (not relevant for the Central Zone conditions)
Duplication (if vertebrate study):	

Summary

This review summarises the current knowledge on the distribution and biology of waterlice (Crustacea, Isopoda, Asellidae) of Southern Europe occurring in freshwater bodies such as small streams, brooks and ditches typical for the agricultural landscape.

After an intensive search of various databases 158 species of the Asellidae were identified having their type location or reported occurrences in Southern Europe. The majority of these species is belonging to the stygobiont fauna which is not in direct contact with surface waters.

With the help of literature and communication with leading experts in the field of asellid research and taxonomy, sixteen asellid species were identified that live in surface freshwaters in Southern Europe. When analysing their distribution pattern and habitat descriptions, eleven of these species were either endemics to lakes or islands where they were often restricted to specific mountain systems or they showed a restricted distribution in continental mountain or karst waterbodies. Since agriculture in these areas is limited to small olive groves or vineyards, and grazing of sheep and goats is common we did not consider these species as being present in water bodies typical of an intensively managed agricultural landscape.

Unfortunately information on the distribution pattern of these species is scarce since in most taxonomic records only a few locations of the type specimens are mentioned. Even these records are sometimes buried in obscure literature or are not accurate. In most cases habitat information is therefore not of a quantitative manner since ecological research carried out with a standardised methodology is lacking.

The information on asellid species of surface waters was of highest quality for species occurring in Italy, since researchers there had set up a database that includes location records for many species. Species distribution data and ecological information was especially scarce for species occurring in Spain, the Balkans and Greece. Therefore although widely distributed, not much details on the habitat of *P. ibericus* and *P. banyulensis* were available.

Nevertheless, we obtained better information on the distribution and ecology of the three most widely distributed species *A. aquaticus*, *P. coxalis* and *P. meridianus*. These three species show a wide ecological amplitude and are present in habitats from small brooks in intensively managed agricultural areas without structural features, with a silty bottom and low water quality to stagnant water bodies, that can be perennial or even temporal, at least in the case of *Proasellus coxalis*. It seems that *A. aquaticus* has the broadest ecological amplitude of the three species towards pollution since it can thrive in water bodies of high salinities and organic or metal concentrations and low pH and oxygen concentrations.

We therefore would expect to find *A. aquaticus* as the dominant species in water bodies of the agricultural landscape throughout its range which includes France, Italy, the Balkans, Greece, Turkey and Crete in Southern Europe.

Comments of zRMS:	Please, refer to zRMS discussion presented under KCP 10.2.2/01.
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Reference:	KCP 10.2.2/07
Title:	Re-evaluation of the impact of Deltamethrin on <i>Asellus aquaticus</i> in a mesocosm study (biological effects and fate of Deltamethrin EW 015 in outdoor mesocosm ponds, HBF/Bt 07)
Report:	[REDACTED]: 2007; RA07-046; M-291862-01-1
Guideline(s):	--
Deviations:	--
GLP/GEP:	no
Acceptability:	Please, refer to zRMS comments under KCP 10.2.2/01
Duplication (if vertebrate study):	no

Summary

The results of the mesocosm study allow the following conclusions on the effects of deltamethrin to *Asellus aquaticus*:

- *aquaticus* was among the most sensitive species of the mesocosm study on deltamethrin.
- The concentration of deltamethrin in pond water decreased with a mean DT₅₀ for water only of 22.4 hours.
- Both sampling devices for *A. aquaticus* (Artificial Substrate Sampler (ASS), leaf cages) are activity measures of this species only ("activity traps"). The efficiency of these methods is influenced by other competing factors such as availability of food in the mesocosm ponds (macrophytes). Thus, numbers of trapped individuals cannot be directly used for the interpretation of population dynamics or mortalities.
- Since macrophytes are the preferred habitat for *A. aquaticus* in this mesocosm study, it can be assumed that organisms tend to stay on macrophytes and do not move very far over the open sediment surface. Thus, the probability of an individual to find and invade a leaf cage or ASS will also depend on the distance it has to move from a macrophyte to the sampling device. The increasing number of *A. aquaticus* in the control samples during the study proves this relationship between macrophyte densities and the number of organisms in the sampling devices.
- Three applications of 4.8 and 10.5 ng a.s./ L deltamethrin in a 7-day interval did not cause relevant effects on the activity or short- and long-term mortalities on exposed adult and juvenile *A. aquaticus*, resulting in an in situ-NOEC and bioassay-NOEC of 10.5 ng a.s./L.

- However, at 10.5 ng a.s./L a slight reduction in the activity of adult and juvenile *A. aquaticus* was observed for very few days after the first application only, due to the well-known effect of pyrethroids of causing only short-term paralysis of invertebrates at low exposure concentrations. The later findings clearly indicate no mortality at this test concentration since the abundance of “trapped” individuals was the same as in control ponds at the following sampling days.
- The macrophyte biomass at the day of the first application was very low: macrophyte growth started just a few days earlier. The sediment coverage increased steadily thereafter, already reaching a maximum coverage of about 83% seven weeks later. However, the macrophyte biomass increased even further thereafter because of the ongoing growth of macrophytes in length. (Quantitative data on the development of macrophyte biomass in this study are not available).
- The bioassays demonstrated effects on survival of adults at all test concentrations above 10.5 ng a.s./L only shortly after each application, indicating a recovery potential for all test concentrations including the highest one (111 ng a.s./L) as early as about one week after application.
- The bioassays also indicate no differences in sensitivities between juveniles and adults in samples taken 6.5 to 8 weeks after the last application. (No results on juveniles were available from earlier bioassays.)
- In the three highest test concentrations of 23, 51 and 111 ng a.s./L the mobility of *Asellus* during the treatment period was clearly reduced in all ponds. However, one to two weeks after the third application the number of mobile (i.e. trapped) *Asellus* clearly increased in one pond of each of the 23 and 51 ng a.s./L treatments, and the abundance reached the control level by the end of the study at the latest in both treatment groups.
- The number of mobile *A. aquaticus* was low 7 days after the third application in all ponds of the three highest test concentrations. Hence, the study performers decided to introduce further individuals of *A. aquaticus* from the culture to one replicate of each of these test concentrations as well as to the highest test concentration of 111 ng a.s./L in order to simulate immigration: At 23 ng a.s./L the numbers of mobile *Asellus* slowly increased after the introduction of new *Asellus* in these additionally inoculated ponds and reached the same abundance as in control ponds 8 weeks after the last application – although control ponds can no longer be considered as fully valid controls for these ponds. At the two highest test concentrations, the number of sampled mobile *Asellus* fluctuated and remained nearly constant for the rest of the study. At the end of the study the abundance even at 111 ng a.s./L was clearly within the range of the control. After day 70, the proportion of juveniles at these test levels also reached the level of control ponds. However, a full recovery to control level within 8 weeks after the last application could not be demonstrated without doubt for 23, 51 and 111 ng a.s./L. Nevertheless, the differences between control and treatment levels are small and population abundances clearly increased in these ponds, as also demonstrated by the increasing number of juvenile organisms and the corresponding reproduction in situ. Since *Asellus* has a long generation time of several weeks under the conditions of this study, it cannot be expected that this species could have build up the same population density as in control ponds within a few weeks only. The bioassays performed in parallel demonstrate that three weeks after the first application (one week after last application) survival of immigrating *Asellus* would no longer be affected by treated pond water and exposed leaves even at the highest test concentration, indicating the recovery potential of an impacted *A. aquaticus* population.

However, since control ponds cannot be used for a direct comparison after the inoculation of treated ponds only and the interpretation of the numbers of trapped *Asellus* does not allow a final persuasive conclusion, these additionally inoculated mesocosm replicates cannot be considered as fully valid and have to be interpreted with care.

Overall, the findings justify to judge the detected effects on *Asellus aquaticus* at 23 – 51 ng/L as “class 3” effects (following the common European procedure according to the Guidance Document on Aquatic Ecotoxicology (SANCO/3268/2001 rev. 4 (final) 2002) as shown in Table 7, summarising all results gained from the mesocosm study and the bioassays which had been performed in parallel. Thus, a

NOEAEC of 51 ng a.s./L can be concluded.

However, since the final NOEAEC for the potential impacts of deltamethrin on *A. aquaticus* populations must also consider recovery from the immigration potential of this species, the final NOEAEC should not be derived from this mesocosm study in isolation.

Summarizing classification of the effects of deltamethrin on *Asellus aquaticus*

	Test concentration [ng a.s./L]				
	4.8	10.5	23	51	111
<i>Asellus aquaticus</i>					
<i>Asellus</i> in mesocosms					
Leaf cages	1	1	3	3	3 (?)
ASS	1	1	3	3	3 (?)
Leaf cages and ASS	1	1	3	3	3 (?)
<i>Asellus</i> bioassay					
Bioassay 1 (Day 2)	1	1	1	2	3
Bioassay 2 (Day 7)	1	1	1	1	2
Bioassay 3 (Day 9)	1	1	2	3	3
Bioassay 4 (Day 14)	1	1	1	1	1
Bioassay 5 (Day 16)	1	1	1	2*	2
Bioassay 6-13 (Day21 to Day 70)	1	1	1	1	1
Lowest <i>In situ</i> -NOEC		x			
Lowest bioassay-NOEC		x			
NOEAEC				x	

- Statistically not significant

Classified according to the following effect categories:

1	effect could not be demonstrated	<ul style="list-style-type: none"> - no (statistically significant) effects observed as result of the treatment, and - observed differences between treatment and controls show no causal relationship
2	slight effect	<ul style="list-style-type: none"> - effects reported in terms of "slight" or "transient" and/or other similar descriptions, and - short-term and/or quantitatively restricted response of sensitive endpoints, and - effects only observed at individual samplings
3	pronounced short-term effect	<ul style="list-style-type: none"> - clear response of sensitive endpoints, but total recovery within 8 weeks after the last application, and - effects reported as "temporary effects on less sensitive species/endpoints" and/or other similar descriptions, and - effects observed at some subsequent sampling instances
4	pronounced effect in short-term study (not relevant in this study)	<ul style="list-style-type: none"> - clear effects (such as strong reductions in densities of sensitive species) observed, but the study is too short to demonstrate complete recovery within 8 weeks after the (last) application
5	pronounced long-term effect	<ul style="list-style-type: none"> - clear response of sensitive endpoints and recovery time of sensitive endpoints is longer than 8 weeks after the last application, and - effects reported as "long-term effects on many sensitive species/endpoints" and/or other similar descriptions, and - effects observed at various subsequent samplings.

Comments of zRMS:	Please, refer to zRMS discussion presented under KCP 10.2.2/01.
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Reference:	KCP 10.2.2/08
Title:	Deltamethrin EW 15 G: Acute and chronic effects to different life stages of the isopod <i>Asellus aquaticus</i> L in a natural water-sediment-system
Report:	2007; PIMA; M-291885-02-1
Guideline(s):	no guideline available
Deviations:	--
GLP/GEP:	yes
Acceptability:	Please, refer to zRMS comments under KCP 10.2.2/01
Duplication (if vertebrate study):	No

Material and methods

In this study the ecological effects of Deltamethrin EW 15 (batch: OP240778; content of a.s.: 15.4 g/L) were studied on the aquatic invertebrate *Asellus aquaticus* L. Different life stages of *A. aquaticus* were tested in two approaches, one with juveniles and one with adults. The animals were collected in natural ditches in Wageningen (The Netherlands), from where the natural water and sediment was collected and transferred to the test facility.

The following biological parameters were monitored: Mortality, sublethal effects (such as reduced activity) and the time taken for recovery if effects occur. The endpoints of the study were: LC₅₀, NOEC mortality and sublethal effects.

Test concentrations were 0, 1.0, 2.2, 4.8, 10.6, 23.4 and 51.5 ng a.s./L (number of replicates: 3 for each life stage). 10 test organisms of each life stage were introduced randomly into corresponding test vessels 8 days before application. Exposure period was 21 days; the system has been equilibrated and conditioned for approximately 12 days before the application of the test item.

The test conditions were: temperature: 18.3 – 20.3 °C, light regime: 16 light:8 dark, light intensity: 100 – 500 lux, aeration of test chambers: gentle aeration, feeding: 10 leaves of pre-conditioned *Populus canadensis* per replicate; the leaves were introduced into the test vessels 11 days before the test item application.

For each test item concentration three additional replicated without test species were prepared for analytical purposes. These replicates were treated in the same way as the test systems with test species. Samples for analytical purposes were taken from the overlying water column of all additional test vessels 2 – 4 hours after application and at each observation point for each concentration level. Sediment samples were taken for the three highest concentrations on day 7, 14 and 21 of the test period. The chemical analysis was performed by Bayer CropScience AG.

Results and discussion

Observations

The analysed concentrations of the stock solutions and the test water confirm the nominal test concentrations. After application the concentration of deltamethrin in test water decreased rapidly. The total recovery of all introduced individuals was not possible at the interim sampling dates (e.g. due to turbidity in the test vessels). At the end of the test period (21 days after application) a final inventory was performed by emptying the test vessels and searching through the sediment for surviving test organism. Therefore, the final evaluation is the most relevant one.

In the test vessels with initially introduced adults of *A. aquaticus*, newborns were observed for the first time 4 days after application up to a concentration of 23.4 ng a.s./L. In the highest concentration (51.5 ng deltamethrin/L) the first newborns appeared only in one replicate 14 days after application.

During the 21-day test period no newborns of *A. aquaticus* were observed in the vessels with initially introduced juveniles. To gain additional information on the life-cycle of *A. aquaticus*, the control vessels with initially introduced juveniles were kept until newborns appeared for the first time. This was observed 35 days after the application of the test item. Since the juveniles were introduced 8 days prior to application with an age of approximately 46 days, the time for an individual from hatching until becoming a reproducing adult was determined to be approximately 6 – 7 weeks at test conditions (20 ± 2 °C).

Biological findings

Survival: For the adult individuals the survival in the controls and up to a concentration level of 10.6 ng/L was equal or above 80% 21 days after exposure. For the juveniles the survival in the control was above 75% and equal or above 90% in the two lowest concentration levels (1.0 and 2.2 ng a.s./L) at the end of the study. The survival in the concentration levels 4.8 ng a.s./L and 10.6 ng a.s./L were below the survival rate above 85%. The highest concentration level (51.5 ng a.s./L) had the lowest survival rate for the adult as well as for the juvenile individuals, resulting in 30% and 26.7% survival, respectively.

If the survival in the controls is set to 100%, the survival in the first five concentration levels is above 85% for the adult and the juveniles of *A. aquaticus*. The survival rate of the highest concentration level is in a similar range for adults and juveniles with 34.8% and 36.0%, respectively.

Percentage of survival as mean of 3 replicates at day 21 (survival in the control is set to 100%)

Treatment	Survival at day 21 [%]	
	Juveniles	Adults
Control	100	100
1.0 ng a.s./L	100	100
2.2 ng a.s./L	100	96
4.8 ng a.s./L	95.7	100
10.6 ng a.s./L	87.0	100
23.4 ng a.s./L	100	92.0
51.5 ng a.s./L	34.8	36.0

LC₅₀, LOEC and NOEC:

A clear concentration-reponse relationship was observed in the test. Therefore, the following LC_x-values were calculated for juveniles and adults of *A. aquaticus*.

Estimated LC_x mortality LOEC and NOEC in ng a.s./L for adult *Asellus aquaticus* based on statistical evaluation of biological results and nominal (initial) concentrations for day 21. Control mortality was compensated using Abbott's formula

	Endpoint [ng a.s./L]	0 – 21 d	
		Lower 95% confidence interval	Upper 95% confidence interval
LC ₁₀	24.7	14.7	41.7
LC ₂₀	30.1	20.4	44.5
LC ₅₀	43.9	34.8	55.3
LOEC	51.5		
NOEC	23.4		

Estimated LC_x mortality LOEC and NOEC in ng a.s./L for juvenile *Asellus aquaticus* based on statistical evaluation of biological results and nominal (initial) concentrations for day 21. Control mortality was compensated using Abbott's formula

	Endpoint [ng a.s./L]	0 – 21 d	
		Lower 95% confidence interval	Upper 95% confidence interval
LC ₁₀	28.2	19.6	40.5
LC ₂₀	33.1	25.0	43.8
LC ₅₀	44.8	36.7	54.8
LOEC	51.5		
NOEC	23.4		

Conclusion

The LC₅₀-values observed 21 days after application was 43.9 ng a.s./L for adults and 44.8 ng a.s./L for juveniles of *Asellus aquaticus*. The NOEC was 23.4 ng a.s./L for juveniles and adults.

Comments of zRMS:	Please, refer to zRMS discussion presented under KCP 10.2.2/01.
Reference:	KCP 10.2.2/09
Title:	Brief summary of methods and first results (non-GLP) of the cancelled microcosm study on chronic effects of deltamethrin EW 15 G on population dynamics of the isopod <i>Asellus aquaticus</i> L in a natural water-sediment-system
Report:	2007; P2MA; M-291879-01-1
Guideline(s):	--
Deviations:	--
GLP/GEP:	no
Acceptability:	Please, refer to zRMS comments under KCP 10.2.2/01
Duplication (if vertebrate study):	No

Summary

The water-sediment system was composed of natural sediment, natural overlying water and the isopod *Asellus aquaticus* L. as an aquatic indoor microcosm. The test was performed under static conditions, i. e. no water exchange was undertaken during exposure. All natural materials used in the test, i. e. animals, natural water, natural sediment were provided by ALTERRA Green World Research Institute, Wageningen, The Netherlands. The taxonomic identification of the test species *Asellus aquaticus* L. was done by the provider. The ditches from where water, sediment and animals were sampled are located at the biological research station in Wageningen (The Netherlands). Dried *Populus*-leaves were obtained from Bayer CropScience, Monheim, Germany.

On the day of application, each of the test vessels contained 50 individuals of the species *Asellus aquaticus* L. representing the distribution of life stages in the laboratory stock culture. Ten females with juveniles in the marsupium were introduced in each microcosm to study potential recovery of the population. Care was taken to achieved a population structure as similar as practical possible between the different replicates.

The individual results of the counting of the test organisms 48 hours and 7, 14, 21. 28 and 35 days after test initiation were reported in the study.

The study was terminated at day 35 in agreement with the sponsor. Even though the study was started under GLP no full GLP report was presented in compliance with the sponsor since the results of the study on the sensitivity of different life-stages of *Asellus* to deltamethrin performed in parallel were well in line with the results of the population study indicating that the population study does not need to be continued. Thus methods and results are summarized only briefly in the report.

Comments of zRMS:	Please, refer to zRMS discussion presented under KCP 10.2.2/01.
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Reference:	KCP 10.2.2/10
Title:	Modelling studies on the recovery of populations of <i>Asellus aquaticus</i> from effects of deltamethrin in natural water bodies of agricultural landscapes Summary and conclusions
Report:	Schaefer, D.; 2008; MEF-08/027; M-296752-01-1
Guideline(s):	not specified
Deviations:	not specified
GLP/GEP:	no
Acceptability:	Please, refer to zRMS comments under KCP 10.2.2/01
Duplication (if vertebrate study):	

Summary

The MASTEP model allowed a detailed analysis of the effects of deltamethrin on populations of *Asellus aquaticus* in water bodies of agricultural landscapes. Extensive experimental and literature studies were conducted to get the most reliable information on

- biology and ecology of *Asellus*, in particular with regard to its movement
- effects of deltamethrin on *Asellus*
- use patterns of deltamethrin

The collected information was implemented in the MASTEP model, and for a range of scenarios (different water bodies, exposure concentrations, application dates) the dynamics of *Asellus* populations and their potential for recovery from initial effects (expressed as recovery probability and recovery time) were calculated. The model predicts negligible effects at population level for exposure to 23 ng a.s./L of deltamethrin, which is the experimental NOEC. Effects at 30 ng a.s./L are more pronounced, but populations quickly and reliably recover from exposure in spring and early summer (up to July). The recovery from later exposure at 30 ng a.s./L (in August to November) is slightly slower and less reliable; however, as the effects occur in an already naturally declining *Asellus* population, they are still considered acceptable. Effects at 43 ng a.s./L are clearly more pronounced.

Considering the results of the MASTEP modelling, it is concluded that exposure of *Asellus* populations to deltamethrin at up to 30 ng a.s./L is ecologically acceptable.

Comments of zRMS:	Please, refer to zRMS discussion presented under KCP 10.2.2/01.
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Reference:	KCP 10.2.2/11
Title:	A simulation model for spatial population dynamics of <i>Asellus aquaticus</i> after a spray drift event of deltamethrin in aquatic ecosystems.
Report:	Verboom, J.; Baveco, J. M. H.; van den Brink, P. J.; 2005; MO-05-004734; M-246365-01-1
Guideline(s):	--
Deviations:	--
GLP/GEP:	no
Acceptability:	Please, refer to zRMS comments under KCP 10.2.2/01
Duplication (if vertebrate study):	

Summary

A metapopulation model was used to describe the effects and recovery of the waterlouse *Asellus aquaticus* after exposure to the pyrethroid insecticide deltamethrin as a result of spray drift. Effects on and recovery of the species were evaluated using the pond, ditch and stream FOCUS scenario. The exposure modelling was done using the use patterns of deltamethrin, the FOCUS spray drift data and the fate model TOXSWA 1.2. Use patterns resulting in nominal concentrations of 16, 23, 30 and 43 ng/L were evaluated against an untreated control simulation. The linking of exposure and effects was provided using the results of a mesocosm study evaluating the effects of three applications of deltamethrin on *A. aquaticus*. In this way the relation between the nominal doses applied and the resulting effects of three applications with a weekly interval on the abundance values on day 21 after the first application could be established. The modelled landscape is represented as a lattice of connected cells, which have a dimension of 1 by 1 meter. The structure of the landscapes is defined according to the FOCUS scenarios for pond, ditch and stream. The pond consisted of 30 by 30 cells with an in- and outflow. The pond and ditch scenarios were 600 cells long, of which a stretch of 100 cells were treated. The model includes processes of mortality of *A. aquaticus*, life history, random walk between cells, density dependence of population regulation and, in case of the stream scenario, medium-distance drift of *A. aquaticus* due to flow velocity. All parameter estimates were based on expert judgment and the results of a thorough literature review on published information on the ecology of *A. aquaticus* covering the last 50 years.

When looking at the total numbers in the pond scenario and the numbers in the treated 100 meter stretch for the ditch and stream scenario, the results show small effects of the 16 ng/L treatment for all three scenarios on the numbers found during the summer peak, which occurred two months after the spraying event. At higher concentrations effects were the largest for the ditch scenario followed by the pond and stream scenario. The differences in peak height between the higher treatment levels were small for the ditch and stream scenario, while the pond scenario resulted in a clear dose-response relation. The ditch scenario proved to be worst-case because the whole 100 meter stretch was treated and no drift of *A. aquaticus* due to wind influence or stream velocity was included. Effects for the pond scenario were smaller because the pond was exposed from one side, so migration from the less contaminated other side was possible. Moreover, in a two-dimensional system such as a pond, recolonisation is easier than in a one-dimensional system such as a ditch. The results of the stream scenario show the importance of the inclusion of drift on the height of the summer peak observed in the treated 100 meter of the stream. It should be noted, however, that the inclusion of drift only had a small influence when the numbers were evaluated for the whole modeled 600 meter stretch.

In the light of the assumptions and uncertainties discussed in the report, the results of this study seem robust for most factors, but more research is needed to establish the effects of especially density dependence and dispersal (including drift). However, the overall outcome of this study is considered to represent a reasonable worst-case situation for the recovery of a local *A. aquaticus* population when affected by a local use of deltamethrin.

Comments of zRMS:	Please, refer to zRMS discussion presented under KCP 10.2.2/01.
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Reference:	KCP 10.2.2/12
Title:	Sensitivity analysis of the MASTEP population model: influence of life-cycle characteristics, drift and recovery of immobilisation of <i>Asellus aquaticus</i> and time of application of the pesticide on their recovery
Report:	2007; M-290838-02-1
Guideline(s):	not specified
Deviations:	not specified
GLP/GEP:	no
Acceptability:	Please, refer to zRMS comments under KCP 10.2.2/01
Duplication (if vertebrate study):	No

Summary

When pesticide-induced effects are observed in microcosms or mesocosms on species that have no resistant or terrestrial life stages, recovery is often not observed (Van den Brink et al. 1996¹²). For species with such a life cycle, the isolated nature of microcosms and mesocosms preclude recovery through immigration as it may occur in a more natural environment. Also the duration of the experiments is often too short to achieve recovery by reproduction. Simulation models can be used to extrapolate the results of microcosm and mesocosm to the landscape level, herewith providing more ecological realism to the results of microcosm and mesocosm experiments. In 2004 and 2005 Alterra conducted a modelling exercise for Bayer CropScience to estimate the recovery of the waterlouse *Asellus aquaticus* after exposure to different concentrations of deltamethrin (Verboom et al., 2005; see KIIIA 10.2.6/12). The individual-based MASTEP meta-population model was used for this purpose (Van den Brink et al., 2007). Parameter estimates of life cycle characteristics and the moving pattern of *Asellus aquaticus* were based on a thorough literature review and expert judgement, leaving however quite some uncertainty on their real values and their dependence on environmental factors and geography. In this report we have investigated:

1. How the number of runs (now 5) affects the confidence interval of the output and the model output (time to recovery as defined by the time needed for the predicted numbers for the impacted scenario to reach 50, 90, 95 or 99% of the numbers of the control run).
2. How model-output (observables) depend on the values of drift parameters (probability of a drift event and drift distance) and time of application in the year. This is to identify the most sensitive parameters, to enable a focussed improvement of parameter estimation in the future.
3. Because we envisage that drift will be a very important variable for the model output, a literature research on the relation between flow velocity and drift of *A. aquaticus* is executed.
4. The effect of including immobilisation into the dose-effect relationship describing the relation between the concentration of deltamethrin and its effects on individuals of *A. aquaticus* on the population-level effects of deltamethrin is investigated.

¹² Van den Brink, P. J., Van Wijngaarden, R. P. A., et al. (1996). "Effects of the insecticide Dursban 4E (active ingredient chlorpyrifos) in outdoor experimental ditches: II. Invertebrate community responses and recovery." *Environmental Toxicology and Chemistry* **15**(7): 1143-1153.

Comments of zRMS:	Please, refer to zRMS discussion presented under KCP 10.2.2/01.
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Reference:	KCP 10.2.2/13
Title:	Influence of drift of individuals and time of application on the recovery of <i>Asellus aquaticus</i> following deltamethrin exposure.
Report:	2007; M-292035-01-1
Guideline(s):	--
Deviations:	--
GLP/GEP:	no
Acceptability:	Please, refer to zRMS comments under KCP 10.2.2/01
Duplication (if vertebrate study):	No

Model parameterisation

The model was set up in the same way as for the preliminary modelling (see Verboom et al., 2005, [M-246365-01-1](#)), except for the refinements and modifications described below:

Dose-response curve

The effects of deltamethrin were described by the dose-response curve from a laboratory study, with an LC₅₀ of 46 ng/L (Jergentz, 2007a; see KIIIA 10.2.6/02, core dossier). Since that dose-response relationship is based on data for a single application, the same effects on *Asellus* were assumed for each deltamethrin spray drift event. Note that the laboratory study gave a statistical no-effect concentration (NOEC) of 23.4 ng/L.

Asellus drift parameters

Based on the results of the field monitoring study (Bruehl & Schulz, 2007b; see KIIIA 10.2.6/04), the drift of *Asellus* was described by two alternative sets of drift parameters:

- a mean drift distance of 10 m, with 2 % of the population drifting per day (equivalent to a drift chance of 0.071% per individual and per movement in MASTEP)
- a mean drift distance of 10 m, with 6 % of the population drifting per day (equivalent to a drift chance of 0.2% per individual and per movement in MASTEP)

The two values for the extent of *Asellus* drift (2% and 6% of the population drifting per day) are meant to cover the range of 0.5% to 8.6% that was observed in the field study. Note that the extent of *Asellus* drift is expressed differently in the MASTEP model, not as percentage of the population drifting per day, but as the drift chance per individual and per movement. The two expressions can be converted, however, when the number of movements of an individual *Asellus* per day is considered.

Water bodies

In the preliminary MASTEP modelling two types of flowing water bodies had been used, a FOCUS ditch and a FOCUS stream. According to FOCUS (2001) the two water bodies are identical with regard to their geometry but have different flow dynamics (the flow is generally faster in the stream).

For the second MASTEP calculations, the ditch and the stream were merged into one type of water body, "ditch/stream". The only difference between ditch and stream with regard to *Asellus* had been the assumed absence of *Asellus* drift in the ditch because of its lower flow rate. However, the field drift study by Schulz & Bruehl (2007b) showed that *Asellus* drift is independent of water flow in the relevant range of flow velocities and that significant movement occurs even at very low flow (0.01 m/s). Therefore it is not reasonable to consider a flowing water body without *Asellus* drift. A static ditch (in which there may indeed be no drift of *Asellus*) on the other hand will most likely dry up in summer and is therefore not a suitable habitat for *Asellus*.

The MASTEP calculations were thus limited to ditch/stream (a small, permanent and flowing water body in which recovery of *Asellus* can occur via reproduction, active locomotion and/or passive drift)

and pond (a larger, permanent, but isolated water body in which recovery of *Asellus* can only occur via reproduction and/or active locomotion, starting from internal refuges).

The exposure (deltamethrin profiles in time and space) in the ditch/stream scenario was set to the calculated exposure in the FOCUS stream representing a worst-case scenario.

Application scenarios

Based on the actual use patterns of deltamethrin, the calculations were limited to sequences of two applications at a 7-day interval. To address the range of possible uses, six typical application scenarios between April 12th and November 4th were defined.

Number of model runs

Based on the results of the MASTEP sensitivity analysis it was decided to conduct 20 model runs per scenario.

Definition of recovery

The following approach was selected as the most statistically sound: Recovery is assumed to be complete when the treated population reaches 90% of the control population (for comparison also an alternative, more conservative trigger of 95% of the control was used).

Results and discussions

The key modelling results are summarised in the following table. The recovery time is quantified by the median, which is a more robust measure than the arithmetic mean. The results for the recovery criterion of reaching 90% of the control were selected. In the ditch/stream scenarios always the results for the directly affected 100 m stretch were selected, since effects are less pronounced if the population in the full 600 m of the water body is considered. The results for the two alternative sets of drift parameters in the ditch/stream did not differ substantially; here, in all cases the more critical of the two numbers was selected.

Results for the pond scenario

23 ng/L and 30 ng/L: Independent of the application date deltamethrin had no substantial effects on the *Asellus* population in the pond at 23 or 30 ng/L. Recovery time was always minimal (1 day), and recovery probability was always high (above 94%)

43 ng/L: At 43 ng/L the effects on the *Asellus* population were small, but clear and longer-lasting. The extent of the effects and the recovery times increased from application in April (day 102; recovery time 1 day) to July (day 178; recovery time 72 days). Later applications had smaller effects (measured as deviation from the control) but the recovery probability decreased to less than 50%. On the other hand, even at this exposure no elimination of the *Asellus* population was observed in any case.

Results for the ditch/stream scenario

In the ditch/stream scenario the effects were larger than in the pond scenario. This confirms the worst case character of the ditch/stream scenario. The extent and duration of effects increased with increasing exposure. Nevertheless, even at the highest treatment level (43 ng/L, approximately equal to the LC₅₀), no elimination of the *Asellus* population was observed in any scenario.

Recovery probabilities were generally higher and recovery times were generally lower, when higher drift of *Asellus* was assumed. Overall, however, the calculations with a drift chance of 0.071% and with a drift chance of 0.2% gave similar results.

23 ng/L: At 23 ng/L effects of deltamethrin on the *Asellus* population were minimal (recovery time 1 day). Only in the ditch/stream scenario with higher drift, there were small, short-term effects (recovery times up to 4 days). It may be surprising to see any effects at all, since 23 ng/L was the experimental NOEC in the laboratory life-stage study (Jergentz, 2007). But according to the dose-response curve that was fitted to the experimental data, there are small effects (2%) even at 23 ng/L which was considered

in the modelling.

The *Asellus* populations always recovered quickly from any small initial effects; the median recovery time at 23 ng/L was always less than 5 days. The recovery probability was always above 93.5%, except for the last application date (November), where it dropped to 87.5%. This drop is certainly influenced by the fact that for the late applications the remaining simulation time is often just not sufficient to explicitly show full recovery.

30 ng/L: At 30 ng/L effects of deltamethrin on the *Asellus* population were clearly visible for spring and early summer applications (days 102, 132 and 178), but with quick and reliable recovery: The median recovery times were 12, 19 and 40 days, respectively, and the recovery probability was always greater than 92.5%.

For late summer and autumn applications (days 224, 255 and 301) the effects appear less pronounced, but last longer and the recovery probability declines from 84.75% to 60%. The median recovery times were 86, 56 and 25 days, respectively, for higher drift of *Asellus*, and 33, 68, and 30 days, respectively, for lower drift of *Asellus*. The maximum deviation of the treatment from the control is always less than 50% and the weaker recovery for the later applications must be seen in the context that deltamethrin affects an already naturally declining population.

43 ng/L: At 43 ng/L the effects of deltamethrin on the *Asellus* population in the ditch/stream were pronounced for all application dates. Median recovery times were up to 185 days, and the recovery probability was as low as 9% (for late autumn applications).

Results of the MASTEP population modelling: Median recovery time (in days) and probability of recovery (% of comparisons with recovery within the simulation period) for *Asellus* populations in ponds or ditches/streams, for exposure to 23, 30 or 43 ng/L of deltamethrin at different dates.

exposure to 23 ng/L							
	<i>Julian date</i>	<i>102</i>	<i>132</i>	<i>178</i>	<i>224</i>	<i>255</i>	<i>301</i>
pond	median time [d]	1	1	1	1	1	1
	probability [%]	100	100	100	99.5	96.5	97.75
ditch / stream	median time [d]	3	2	1	2	4	2
	probability [%]	99.75	98.5	99.25	95.25	93.5	87.5
exposure to 30 ng/L							
	<i>Julian date</i>	<i>102</i>	<i>132</i>	<i>178</i>	<i>224</i>	<i>255</i>	<i>301</i>
pond	median time [d]	1	1	1	1	1	1
	probability [%]	100	100	100	96.75	96.75	94.25
ditch / stream	median time [d]	12	19	40	86	68	30
	probability [%]	99	99	92.5	84.75	63.5	60
exposure to 43 ng/L							
	<i>Julian date</i>	<i>102</i>	<i>132</i>	<i>178</i>	<i>224</i>	<i>255</i>	<i>301</i>
pond	median time [d]	1	27	72	*	*	63
	probability [%]	98.5	93.5	80	41	37.5	52
ditch / stream	median time [d]	115	182	(135) **	(115) **	(108) **	*
	probability [%]	88.25	74.75	47.75	25.75	13.5	9

* no median, as more than 50 % of the comparisons showed no recovery within the simulation period

** less than 50 % of the comparisons showed recovery within the simulation period for the model runs with low drift of *Asellus*; the recovery times given in brackets are those from the parallel runs with higher drift of *Asellus* (recovery probabilities > 50 %)

Note: All values in Table 1 are based on the recovery criterion of reaching 90% of the control. The results for the ditch/stream scenario refer to the directly affected 100 m stretch; each result is the worst case (higher median recovery time, the lower recovery probability) of the two values from the parallel simulations with the different *Asellus* drift parameters.

Summary of the results

The MASTEP modelling showed that for exposure of *Asellus* to 23 ng/L of deltamethrin the effects in ponds and in ditches/streams are minimal, without ecological relevance for *Asellus* populations. *Asellus* populations recover quickly (within less than 5 days) and reliably (probability 87.5% or more) from the small and insignificant effects at this treatment level by reproduction and re-colonisation.

At 30 ng/L effects are still minimal in the pond, but more pronounced in the ditch/stream. For spring and summer applications (April to July) the *Asellus* populations in the ditch/ stream still recover quickly (within less than 40 days) and reliably (probability more than 90%) from initial effects. For application in August or later, the recovery is less reliable (probability 85% to 60%) and takes slightly longer (30 to 86 days). The weaker recovery in autumn, however, must be seen in the context that deltamethrin affects an already naturally declining population. In addition (although this could not be investigated with the model), it can be assumed that the population fully recovers until the start of the next season. The slightly increased effects from late applications at 30 ng/L may therefore be less ecologically relevant.

At 43 ng/L there were clear and long-lasting effects of deltamethrin on the *Asellus* population in the pond and in the ditch/stream for all application dates. Recovery generally took longer and was less reliable compared to lower exposure, in particular for autumn applications.

Conclusion

The model predicts negligible effects at population level for exposure to 23 ng/L of deltamethrin, which is the experimental NOEC. Effects at 30 ng/L are more pronounced, but populations quickly and reliably recover from exposure in spring and early summer (up to July). The recovery from later exposure at 30 ng/L (in August to November) is slightly slower and less reliable; however, as the effects occur in an already naturally declining *Asellus* population, they are still considered acceptable. Effects at 43 ng/L are clearly more pronounced.

Considering the results of the MASTEP modelling, it is concluded that exposure of *Asellus* populations to deltamethrin at up to 30 ng/L is ecologically acceptable.

A 2.2.3 KCP 10.2.3 Further testing on aquatic organisms

Comments of zRMS:	Please, refer to zRMS discussion presented under KCP 10.2.2/01.
Reference:	KCP 10.2.3/01
Title:	Effects of Deltamethrin EW 15 on rainbow trout in aquatic outdoor microcosm enclosures
Report:	2005; ALT.JD.2005.1; M-256605-01-1
Authority registration No:	
Guideline(s):	OECD Guidance Document "Freshwater Lentic Tests", 2004 (Draft); Guidance Document on Testing Procedures for Pesticides in Freshwater Mesocosm (SEATC-Europe Workshop, July 1991)
Deviations:	none
GLP/GEP:	yes
Acceptability:	Please, refer to zRMS comments under KCP 10.2.2/01
Duplication (if vertebrate study):	No

Materials and methods

Test item: Deltamethrin EW 15 (= Decis Protech EW015), purity: 16.24 g deltamethrin/L (1.58% w/w), batch no.: AAIM00846

The study was carried out using 10 enclosures in an experimental ditch at Renkum, the Netherlands. All enclosures contained approx. 433 dm³ of water, some macrophytes and had a bottom layer of sediment.

The treatment consisted of 3 applications of Deltamethrin EW 15 at one week intervals, simulating spray drift. Nominal treatment levels were 125 ng a.s./L, 250 ng a.s./L, 500 ng a.s./L and 1000 ng a.s./L. Treatments were duplicated, using 2 enclosures per treatment level and 2 controls. The test lasted for 21 days after the first application of the test substance on 11 April 2005. The concentrations of the active ingredient in the water phase were followed over time. The weight and length of the fish were determined 4 days prior to the first application of the test substance (day -4), when they were transferred to the enclosures, and at the end of the experiment (day 21). Dynamics in chlorophyll-a content of phytoplankton, macrophyte species composition and cover and community metabolism (temperature, pH and dissolved oxygen content) were followed over time in all enclosures.

Results and discussions

Analytics

The measured concentrations in the spray solutions were $85 \pm 14\%$ of intended concentrations, indicating that the initial concentrations in the enclosures would have been close to nominal target concentrations.

The water concentrations measured in the enclosures 4 h after application were on average $88 \pm 17\%$ of the nominal target concentrations. The concentration of the test compound decreased steadily after the application with a DT50 in water of 0.9 ± 0.2 day (average value over all treatment levels and all applications).

For the nominal treatment levels of 125, 250, 500 and 1000 ng a.s./L, the average peak concentrations were 90, 215, 447 and 1013 ng a.s./L resp., whereas the highest peak concentrations were 109, 224, 478 and 1063 ng a.s./L resp. Time-weighted average exposure levels over the 21-day treatment period were 16, 37, 96 and 231 ng a.s./L.

Biological findings

No treatment-related effects on macrophytes species composition and cover were observed, nor could any treatment-related effects be demonstrated on the measurement endpoints temperature, oxygen content pH and chlorophyll-a content of phytoplankton.

During the 21-day period of exposure to the test substance, 9 out of 100 fish had died and 7 fish were missing at the end of the study. There was no apparent relationship between mortality and the treatment with the test substance.

Dead and missing fish after 21 days of exposure

Nominal treatment level [ng a.s./L]	Dead fish recovered [% of inserted]	Fish missing on day 21 [% of inserted]	Sum of dead and missing fish [% of inserted]
0	0 %	21 %	21 %
125	20 %	10 %	30 %
250	15 %	0 %	15 %
500	0 %	6 %	6 %
1000	10 %	5 %	15 %

There were no significant differences in mean length, weight, growth of length and growth of weight of the fish in the various treatment levels.

In the enclosures treated at the highest level (1000 ng a.s./L) several of the fish showed slightly erratic swimming without losing balance. The fish also appeared to be coughing. These symptoms occurred within a few hours after the first and third applications, and were no longer apparent on the next day. Similar behavior was observed in the enclosures treated with 500 ng a.s./L, but only after the first application and not after the second and third application. In view of the fast recovery of the fish within a day after the application these symptoms are considered to be of less biological relevance.

Conclusion

At all treatment levels up to and including 1000 ng a.s./L no treatment-related effects were observed on length, weight, growth of length and survival of juvenile rainbow trout. In addition, no consistent

treatment-related effects on chlorophyll-a or community metabolism endpoints could be observed after 3 applications of the test substance in a weekly interval. The NOEC is 500 ng a.s./L since the symptoms observed at this test concentration were only short term and were only observed after the first application. Considering the fast recovery of observed symptoms after each application, the No Observed Ecological Adverse Effect Concentration (NOEAEC) can be set as ≥ 1000 ng a.s./L.

Comments of zRMS:	Please, refer to zRMS discussion presented under KCP 10.2.2/01.
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Reference:	KCP 10.2.3/02
Title:	Biological effects and fate of deltamethrin EW 015 in outdoor mesocosm ponds
Report:	2005; HBF/BT 07; M-246137-01-2
Guideline(s):	OECD Guidance Doc. "Freshwater Lentic Field Tests", 2004 (Draft) ; Guidance Doc. on Testing Procedures for Pesticides in Freshwater Microcosms (SETAC 1991) Community-Level Aquatic System Studies Interpretation Criteria (SETAC 2002)
Deviations:	none
GLP/GEP:	yes
Acceptability:	Please, refer to zRMS comments under KCP 10.2.2/01
Duplication (if vertebrate study):	No

Materials and methods

Twelve test tanks (6 m³ water, 1 m water depth) which were used in this study are especially designed systems which allow the establishment of almost identical conditions at the start of a study. The bottoms of the artificial tanks were covered with natural sediment (approximately 15 cm in height) 7 months prior to the study start. The water was composed of local ground water and water from a nearby uncontaminated pond, which was inoculated several times with zooplankton from a natural pond nearby. Natural communities developed spontaneously from seeds and roots of aquatic plants as well as from air borne and naturally transferred stages of planktonic, benthic and filamentous algae organisms during the months before study start. Some weeks before the first application 300 *Asellus aquaticus* were artificially inserted in each pond to establish a stable population of this isopoda. Since the populations could not be maintained in a few ponds during the study, new *Asellus aquaticus* were added to these ponds. In general, the artificial ponds are representative of a small stagnant water body.

The test substance Deltamethrin EW 015 (Batch.-No.AAIM00846, AZ No.10459) was applied during the early growing season in May 2004 three times at an interval of 7 days onto the water surface of nine test ponds. The treatment levels were 4.8, 10.5, 23, 51 and 111 ng a.s./L per application (two replicates of 4.8 to 51 ng a.s./L, one replicate for 111 ng a.s./L). Three further tanks were used as untreated controls. The mesocosms were investigated for a period of 14 days before and 105 days after the first treatment (= 91 days after the last treatment). Several times during the study period water and sediment samples were taken and analysed to investigate the concentration of the test substance in water and sediment. Further parameters studied were the taxonomic composition of zooplankton, phytoplankton, macroinvertebrates and emergence of insects at different days before and after the applications. Since *Asellus aquaticus* was assumed to be one of the most sensitive species in this study, this species was studied intensively in situ on Artificial Substrate Samplers (ASS) and in small cages with leaves which function as traps for these organisms. In addition, bioassays were performed with this species to investigate the potential recovery of a population by immigration of organisms from adjacent water bodies. The physico-chemical water parameters and the content of chlorophyll-a of phytoplankton were also evaluated, as well as the coverage of the sediment with macrophytes and filamentous algae. One diurnal cycle of oxygen concentration, water temperature and pH was recorded during the study.

Results and discussion

Analytics

The analytical results of water samples taken four hours after each of the three applications show that an average of 94.1% of the nominal concentrations could be found in the mesocosm water confirming

nominal concentrations very well. The a.s. disappeared after all applications quickly and steadily with an average half-life in the water column of 22.4 hours. At some sampling dates the percentage of adsorbed a.s. in the water was determined, the results revealed that about 2/3 of the total applied amount was bioavailable (solubilized in water) in the pond water, whereas 1/3 was adsorbed to particles as algae or particulate matter.

In the sediment of the 2 lowest test levels (4.8 and 10.5 ng/L) the test substance could be found only once shortly after the first application (limit of detection = 0.03 µg/kg dry weight). The results of the higher test levels (23 to 111 ng/L) show a slight increase of sediment concentrations during about 7 weeks after application resulting up to 20% of total applied amount in the sediment, and a slow decrease during the later part of the study to less than 6% of total applied amount. The DT50 for whole system (water plus sediment) is 31.6 hours.

Biological findings

Direct and indirect effects of the application of deltamethrin to the chemical and physical parameters of the pond water have not been observed at any test concentration. Also no effects on the coverage of the ponds and the biomass of macrophytes and filamentous algae were observed at any treatment level.

The biological data showed some minor and major effects on some groups of organisms, as indicated in the following Tables. In these Tables, the effects were classified according to the following effect categories according to “Guidance Document on Aquatic Ecotoxicology” in the context of the Directive 91/414/EEC (SANCO 3268/2001 rev.4 (final) of 17 October 2002:

Classification of effects		
1	effect could not be demonstrated	no (statistically significant) effects observed as result of the treatment, and observed differences between treatment and controls show no causal relationship
2	slight effect	effects reported in terms of “slight” or “transient” and/or other similar descriptions, and short-term and/or quantitatively restricted response of sensitive endpoints, and effects only observed at individual samplings
3	pronounced short-term effect	clear response of sensitive endpoints, but total recovery within 8 weeks after the last application, and effects reported as “temporary effects on less sensitive species/endpoints” and/or other similar descriptions, and effects observed at some subsequent sampling instances
4	pronounced effect in short-term study (not relevant in this study)	clear effects (such as strong reductions in densities of sensitive species) observed, but the study is too short to demonstrate complete recovery within 8 weeks after the (last) application
5	pronounced long-term effect	clear response of sensitive endpoints and recovery time of sensitive endpoints is longer than 8 weeks after the last application, and effects reported as “long-term effects on many sensitive species/endpoints” and/or other similar descriptions, and effects observed at various subsequent samplings.

Effects on species						
		Test concentration [ng a.s./L]				
		4.8	10.5	23	51	111
Zooplankton						
Phyllopoda						
	Daphnia longispina	1	1	3	3	3
	Simocephalus vetulus	1	1	1	1	2
	Chydorus sphaericus	1	1	1*	2*	2*
	Acroperus harpae	1	1	1	1	2*
	Eurycercus lamellatus	1	1	1	1	1
	Graptoleberis testudinella	1	1	1	1	1
Ostracoda						
	Ostracodes (not det.)	1	1	1	1	1
Copepoda						
	Cyclopoid Copepods	1	1	2	3	3
	Copepod Nauplii	1	2	3	3	3
Rotatoria						
	Keratella quadrata	1	3	3	3	3
	Lecane lunaris	1	1	1	1	2
	Polyarthra spec.	1	1	+	+	+
	Lepadella patella	1	1	1	+	+
	Asplanchna spec.	1	1	1	+	+
	Trichotria pocillum	1	1	1	1	+
	Synchaeta spec.	1	1	1	1	+
	Testudinella patella	1	1	1	1	1
	Cephalodella spec.	1	1	1	1	1
	Euchlanis deflexa	1	1	1	1	1
Diptera						
	Chaoborus crystallinus larvae	3	3	3	3	3
Taxa richness		1	1	1	1	1
Diversity (Shannon Index)		1	1	2	3	3
Evenness		1	1	1	2	2
Similarity (Steinhaus Index)		1	1	3	3	3
Similarity (Stander's Index)		1	1	3	3	3
Principal Response Curves (PRC)		1	2	3	3	3
Community-NOEC		x				
Lowest population-NOEC		<4.8				
NOEAEC					x*)	

+ Increase in numbers

* Statistically not significant

*) The NOEAEC was set to 51 ng/L due to the missing replication at 111 ng/L.

Effects on species					
	Test concentration [ng a.s./L]				
Macroinvertebrates (benthic, ASS)	4.8	10.5	23	51	111
Turbellaria					
Dugesia spec.	1	1	1	1	1
Oligochaeta					
Tubificidae	1	1	1	1	1
Stylaria lacustris	1	1	1	1	1
Hirudineae					
Helobdella stagnalis	1	1	1	1	1
Diptera					
Chaoborus crystallinus larvae	see zooplankton evaluation				
Sum of Chironomid larvae	1	1	1	1	2
Ephemeroptera					
Cloeon dipterum	1	1	1	1	1
Odonata					
Ischnura elegans	1	1	1	1	1
Pulmonata					
Gyraulus albus	1	1	1	1	1
Radix ovata	1	1	1	1	1
Taxa richness	1	1	1	1	1
Diversity (Shannon Index)	1	1	1	1	1
Evenness	1	1	1	1	2
Similarity (Steinhaus Index)	1	1	1	1	1
Similarity (Stander's Index)	1	1	1	1	1
Principal Response Curves (PRC)	1	1	1	2	2
Community-NOEC			x		
Lowest population-NOEC **)				x	
NOEAEC				x*)	

	Test concentration [ng a.s./L]				
Macroinvertebrates (benthic)	4.8	10.5	23	51	111
Oligochaeta					
Tubificidae	1	1	1	1	1
Diptera					
Chironomidae larvae	1	1	1	1	1
Ceratopogonidae larvae	1	1	1	1	1
Pulmonata					
Gyraulus albus	1	1	1	1	1
Bivalvia					
Pisidium spec.	1	1	1	1	1
Taxa richness	1	1	1	1	1
Diversity (Shannon Index)	1	1	1	1	1
Evenness	1	1	1	1	1
Similarity (Steinhaus Index)	1	1	1	1	1
Similarity (Stander's Index)	1	1	1	1	1
Principal Response Curves (PRC)	1	1	1	1	1
Community-NOEC				x*)	
Lowest population-NOEC				x*)	
NOEAEC				x*)	

Effects on species					
	Test concentration [ng a.s./L]				
Emergence	4.8	10.5	23	51	111
Chironomidae					
Sum of Chironominae	1	1	1	1	2
Chironominae (female)	1	1	1	1	2
Chironomus spec. (male)	1	1	1	1	3
Dicortendipes spec. (male)	1	1	1	1	1
Paratanytarsus spec. (male)	1	1	1	1	1
Einfeldia spec. (male)	1	1	1	1	1
Micropsectra spec. (male)	1	1	1	1	1
Cryptotendipes spec. (male)	1	1	1	1	1
Polypedilum spec. (male)	1	1	1	1	1
Sum of Orthocladiinae	1	1	1	1	1
Orthocladiinae (female)	1	1	1	1	2
Orthocladiinae (male) cf. Dratnalia sp.	1	1	1	1	1
Cricotopus spec. (male)	1	1	1	1	1
Psectrocladius spec. (male)	1	1	1	1	1
Limnophyes spec. (male)	1	1	1	1	1
Corynoneura spec. (male)	1	1	1	1	1
Acricotopus spec. (male)	1	1	1	1	1
Sum of Tanypodinae	1	1	1	1	1
Tanypodinae (female)	1	1	1	1	2
Tanypus spec. (male)	1	1	1	1	1
Ablabesmyia spec. (male)	1	1	1	1	1
Holotanypus spec. (male)	1	1	1	1	1
Psectrotanypus spec. (male)	1	1	1	2	2
Monopelopia spec. (male)	1	1	1	1	1
Culicidae					
Anopheles spec.	1	1	1	1	1
Chaoboridae					
Chaoborus crystallinus	2	2	2	2	2
Ephydridae					
Clanoneurum spec.	1	1	1	1	1
Ephemeroptera					
Cloeon spec.	1	1	1	1	1
Taxa richness	1	1	1	1	2
Diversity (Shannon Index)	1	1	1	1	2
Evenness	1	1	1	1	1
Similarity (Steinhaus Index)	1	1	1	1	1
Similarity (Stander's Index)	1	1	1	1	1
Principal Response Curves (PRC)	1	1	1	2	2
Community-NOEC			x		
Lowest population-NOEC	< 4.8				
NOEAEC				x*)	

*) The NOEAEC was set at 51 ng/L due to the missing replication at 111 ng/L.

Effects on species						
		Test concentration [ng a.s./L]				
		4.8	10.5	23	51	111
Diatomeae		1	1	1	1	2
	Nitzschia spec.	1	1	1	1	2
Cryptophyceae		1	1	1	1	2
	Chroomonas spec. <10 µm	1	1	2	2	2
	Cryptomonas spec. 10-20 µm	1	1	1	1	2
	Cryptomonas spec. 30-40 µm	1	1	1	1	1
Englenophyta		1	1	1	1	1
Conjugatophyceae		1	1	1	1	1
	Cosmarium spec.	1	1	1	1	1
Cyanobacteria (Merismopedia spec.)		1	1	1	1	+
Sum of filamentous algae		1	1	1	1	1
Taxa richness		1	1	1	1	1
Diversity (Shannon Index)		1	1	1	1	1
Evenness		1	1	1	1	1
Similarity (Steinhaus Index)		1	1	1	1	2
Similarity (Stander's Index)		1	1	1	1	1
Principal Response Curves (PRC)		1	1	1	1	1
Community-NOEC				x		
Lowest population-NOEC			x			
NOEAEC					x*)	

		Test concentration [ng a.s./L]				
		4.8	10.5	23	51	111
Asellus aquaticus						
Asellus in mesocosms						
	Leaf cages	1	1	3	3	3
	ASS	1	1	3	3	3
	Leaf cages and ASS	1	1	3	3	3
Asellus bioassay						
	Bioassay 1 (Day 2)	1	1	1	2	3
	Bioassay 2 (Day 7)	1	1	1	1	2
	Bioassay 3 (Day 9)	1	1	2	3	3
	Bioassay 4 (Day 14)	1	1	1	1	1
	Bioassay 5 (Day 16)	1	1	1	2**	2
	Bioassay 6-13 (Day21 to Day 70)	1	1	1	1	1
Lowest In situ-NOEC			x			
Lowest bioassay-NOEC			x			
NOEAEC					x*)	
		Test concentration [ng a.s./L]				
		4.8	10.5	23	51	111
Phytoplankton		1	1	1	1	1
Chlorophyceae		1	1	1	1	1
Scenedesmus spec.		1	1	1	1	+
Schroederia spec.		1	1	1	1	1

+ Increase in numbers

*) The NOEAEC was set at 51 ng/L due to the missing replication at 111 ng/L.

** Statistically not significant

At the end of the study, no zooplankton taxon showed significant differences in abundance compared to controls, demonstrating the recovery of the zooplankton after the third application within 7 weeks. Chaoborus crystallinus was identified as the most sensitive zooplankton taxon with consistent effects even at 4.8 ng a.s./L immediately after application until about 2 weeks after the last application when a full recovery of the Chaoborus population was observed. The crustaceans, especially the copepods and Daphnia longispina, proved to be the next most sensitive zooplankton group exhibiting a consistent NOEC of 4.8 ng a.s./L and 10.5 ng a.s./L, respectively. The rotifers were either suppressed (especially Keratella quadrata, consistent NOEC of 4.8 ng a.s./L) or promoted (e.g. Polyarthra spec., consistent

NOEC of 10.5 ng a.s./L) obviously by secondary effects. The PRC (Principal Response Curve) and to some degree Similarity and Shannon Diversity Indices reflected these effects on the zooplankton with a community NOEC of 4.8 ng a.s./L. However, all effected populations recovered shortly after the last application and reached control abundances within some weeks only at all treatment levels including the highest one. Seven weeks after the last application, no taxon showed significant differences in abundance compared to controls, demonstrating the full recovery of the zooplankton community. Due to the missing replication at 111 ng a.s./L the results of this study yield a NOEAEC (no observed ecological adverse effect concentration) of 51 ng a.s./L for the zooplankton.

In sediment, significant impacts on the identified species in the ASS (Artificial Substrate Samplers) were only obtained for chironomid larvae at the highest test concentration, resulting in a NOEC of 51 ng a.s./L for the evenness and 23 ng a.s./L for the PRC, whereas all other community parameters did not indicate any effect up to the highest test concentration. Observed effects were even short-term only: no long-lasting effects could be detected. In the sediment samples, no effects even up to the highest treatment level could be detected (NOEC 111 ng a.s./L).

Direct effects of the test item on the emergence of some insects were detected for five taxonomic groups: *Chironomus spec.*, *Orthocladinae*, *Psectrotanypus spec.*, *Tanypodinae* (females) and *Chaoborus crystallinus*. Except of *Chaoborus* (same NOEC as in zooplankton), all other groups were affected only at the highest treatment level (*Psectrotanypus spec.* also at 51 ng a.s./L), with a full recovery within 8 weeks after last application for the latest for all species. Thus, the community indices yielded a community NOEC of 23 ng a.s./L. Because of the fast and full recovery in emergence (which even included the full aquatic life cycle of the emerged insects) within the first weeks after application on the one hand and the missing replication of the highest treatment level of 111 ng a.s./L on the other hand, the NOEAEC for emergence can also be set as 51 ng a.s./L.

In the mesocosms clear effects on *Asellus aquaticus* were demonstrated for the 3 highest test concentrations both in leaf cages and ASS. At 10.5 ng a.s./L *Asellus* was only short-term affected after the first application indicating only a decrease in mobility but no mortality. (Both sampling methods indicate a reduction in activity of individuals, which does not necessarily mean mortality). Thus, a consistent NOEC of 10.5 ng a.s./L can be derived from this study for *Asellus* in the mesocosms. In the 3 highest test concentrations the abundance of *Asellus* reached mostly the level of controls until study termination. After day 70 the proportion of juveniles in the higher treated ponds reached the level of controls. A full recovery to control level within 8 weeks after last application could not be demonstrated for 23, 51 and 111 ng a.s./L. However, the differences between control and treatment levels are small and population abundances clearly increased in these ponds, as demonstrated by the increasing number of juvenile organisms and the corresponding reproduction in situ. The bioassay findings confirm that water and food samples from the mesocosms taken at the latest 1 week after the applications did not have any negative effects on *Asellus aquaticus*. Overall, the NOEAEC for *Asellus* was 51 ng/L due to the missing replication at 111 ng a.s./L.

No direct toxic effects were observed on the phytoplankton. During the application period cell densities of some species, as e.g. the dominant *Chroomonas spec.*, were slightly lower at higher treatment levels for a short time than in the controls caused by indirect food web effects, probably by toxic effects of the test item treatments on the copepod populations, which enhanced the rotifer population density by decreased competition. The community NOEC for phytoplankton was 23 ng a.s./L and the NOEAEC 51 ng a.s./L because of the missing replication at the highest treatment level.

Conclusion

The fate of deltamethrin demonstrates a steady and fast decline of deltamethrin in the mesocosm water with a mean DT50 of 22.4 hours, and a mean DT50 of 31.6 hours for the whole test system (water plus sediment). In the sediment of the 2 lowest test concentrations (4.8 and 10.5 ng a.s./L) the active substance was only detected once shortly after application. The results of the higher test concentrations (23 to 111 ng a.s./L) show a slight increase of the amount of the test substance in the sediment for about the first 7 weeks after application and a slow but constant decrease thereafter.

Chaoborus crystallinus was identified as the most sensitive taxon with consistent effects even at 4.8 ng a.s./L immediately after application until about a very few weeks after the last application when a full recovery had been observed even at the highest test level. At 10.5 ng a.s./L also short-term effects for one Rotatoria species (*Keratella quadrata*) and Copepod Nauplii had been observed. *Asellus aquaticus* showed just a reduced activity at this test level for a very few days after application without any sign of mortality or affected reproduction. At 23 and 56 ng a.s./L effects on 1 to 3 individual more species had been observed, but also these effects were short-term only with a full recovery within the first weeks after the last application. The abundance of *Asellus* was clearly reduced after application at this test levels but reached mostly the level of controls until study termination. The differences between control and treatment levels were small and population abundances clearly increased in these ponds during the study, as also demonstrated by the increasing number of juvenile organisms. The bioassay findings confirm that water and food samples from the mesocosms taken at the latest 1 week after the applications did not have any negative effects on *Asellus aquaticus*. At 111 ng a.s./L the number of affected zooplankton and insect species was distinctly higher, and the effects on *Asellus aquaticus* even more developed as compared to lower treatment levels.

Based on these findings and because of the missing replication at the highest test level, 51 ng a.s./L can be concluded as the overall NOEAEC (no observed ecological adverse effect concentration) of this study.

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

Comments of zRMS:	<p>The study was performed fully in line with OECD 213 and 214 with no major deviations.</p> <p>It was noted that the relative humidity during the test was outside of the recommended range of around 50-70 % (actually recorded 42-73 %). However, this deviation is considered to have no effect on the study since all validity criteria were met:</p> <ul style="list-style-type: none"> the average mortality for the total number of controls must not exceed 10 % at the end of the test (48h) (observed: oral 6.7%, contact 10.0%), the oral 24h LD₅₀ of the toxic standard is in the range 0.10-0.35 µg a.i./bee (observed 0.11 µg a.i./bee), the contact 24h LD₅₀ of the toxic standard is in the range 0.10-0.30 µg a.i./bee (observed 0.21 µg a.i./bee). <p>Overall, the study is considered acceptable with the following endpoints relevant for the risk assessment:</p> <p>48h oral LD₅₀ = 13.0 µg product/bee (corresponding to 0.113 µg deltamethrin + 0.861 µg flupyradifurone/bee) 48h contact LD₅₀ = 7.1 µg product/bee (corresponding to 0.062 µg deltamethrin + 0.470 µg flupyradifurone/bee)</p>
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Reference:	KCP 10.3.1.1/01
Title:	Deltamethrin + flupyradifurone EC 85 (10+75) G: Effects (acute contact and oral) on honey bees (<i>Apis mellifera</i> L.) in the laboratory - Final report
Report:	Schmitzer, S.: 2015; 99811035; M-542907-01-1
Guideline(s):	Regulation (EC) No. 1107/2009 Directive 2003-01 (Canada/PMRA) US EPA OCSPP 850.3020, 850.supp. OECD 213 and 214 (1998)
Deviations:	none
GLP/GEP:	yes
Acceptability:	Acceptable

Materials and methods

Deltamethrin + flupyradifurone EC 85 (10+75) G: deltamethrin (AE F032640): 0.867 % w/w (10.03 g/L), flupyradifurone (BYI 02960): 6.62 % w/w (76.59 g/L) (all analytical values); Supplier Batch No.: 2014-012629; Sample Description: TOX10717-00; Specification No.: 102000028562; density: 1.157 g/mL (20 °C).

Under laboratory conditions *Apis mellifera* 30 worker bees per treatment level (10 individuals per replicate, 3 replicates per treatment level) were exposed for 48 hours to doses of 50.0, 25.0, 12.5, 6.3 and 3.1 µg product per bee (nominal dose levels) by topical application (contact dose response test) and 30 worker bees per treatment level (10 individuals per replicate, 3 replicates per treatment level) were exposed for 48 hours to doses of 28.7, 14.4, 6.5, 3.1, 1.4 and 0.65 µg product per bee by feeding (oral dose response test, value based on the actual intake of the test item).

Mortality of the bees was used as the toxic endpoint. Number of dead bees was assessed after 4 (± 0.5 h) hours (first day); 24 and 48 (± 2 h) hours (contact and oral tests).

Sublethal effects, such as changes in behaviour (e.g. vomiting, apathy, intensive cleaning), were also assessed after 4 (± 0.5 h) hours (first day); 24 and 48 (± 2 h) hours (contact and oral tests).

The reference item in the contact test was applied as one 5 µL droplet of dimethoate, dissolved in tap water with 0.5 % Adhäsit. In the oral test the reference item was applied in 50 % w/v sucrose solution. Nominal dose levels of the reference item in the contact and oral test were:
0.30, 0.20, 0.15 and 0.10 µg dimethoate per bee (contact test)
0.30, 0.15, 0.08 and 0.05 µg dimethoate per bee (oral test)
Actual dose levels of the reference item in the oral test: 0.35, 0.17, 0.09 and 0.06 µg dimethoate per bee.

Test conditions:

Temperature: 25 °C; short-term deviations (< 2 hours) were not reported

Relative Humidity: 42 - 73 %; short-term deviations (< 2 hours) were not reported

Light: Darkness (except during observation)

Results and discussions

Table 9-3: Toxicity to Honey Bees; laboratory tests

Test Item	Deltamethrin + flupyradifurone EC 85 (10+75) G	
Test Species	<i>Apis mellifera</i> L.	
Exposure	contact (solution in Adhäsit (0.5 %)/water)	oral (50 % w/v sucrose solution)
Dose rate µg product/bee	50.0, 25.0, 12.5, 6.3 and 3.1	28.7, 14.4, 6.5, 3.1, 1.4 and 0.65
LD ₅₀ µg product/bee	24 hours: 9.1 (equivalent to 0.079 µg deltamethrin + 0.602 µg flupyradifurone) lower – upper 95% CI: 1.7 – 26.4 48 hours: 7.1 (equivalent to 0.062 µg deltamethrin + 0.470 µg flupyradifurone) lower – upper 95% CI: 5.9 – 8.4	24 hours: 13.2 (equivalent to 0.114 µg deltamethrin + 0.874 µg flupyradifurone) lower – upper 95% CI: 4.4 – 98.1 48 hours: 13.0 (equivalent to 0.113 µg deltamethrin + 0.861 µg flupyradifurone) lower – upper 95% CI: 4.5 – 55.3
LD ₂₀ µg product/bee	24 hours: 4.2 (equivalent to 0.036 µg deltamethrin + 0.278 µg flupyradifurone) 48 hours: 4.5 (equivalent to 0.039 µg deltamethrin + 0.298 µg flupyradifurone)	24 hours: 7.1 (equivalent to 0.062 µg deltamethrin + 0.470 µg flupyradifurone) 48 hours: 7.5 (equivalent to 0.065 µg deltamethrin + 0.497 µg flupyradifurone)
LD ₁₀ µg product/bee	24 hours: 2.8 (equivalent to 0.024 µg deltamethrin + 0.185 µg flupyradifurone) 48 hours: 3.6 (equivalent to 0.031 µg deltamethrin + 0.238 µg flupyradifurone)	24 hours: 5.2 (equivalent to 0.045 µg deltamethrin + 0.344 µg flupyradifurone) 48 hours: 5.6 (equivalent to 0.049 µg deltamethrin + 0.371 µg flupyradifurone)
NOED µg product/bee*	24 hours: 3.1 (equivalent to 0.027 µg deltamethrin + 0.205 µg flupyradifurone) 48 hours: 3.1 (equivalent to 0.027 µg deltamethrin + 0.205 µg flupyradifurone)	24 hours: 3.1 (equivalent to 0.027 µg deltamethrin + 0.205 µg flupyradifurone) 48 hours: 3.1 (equivalent to 0.027 µg deltamethrin + 0.205 µg flupyradifurone)

* The NOED was estimated using Fisher's Exact Test (pairwise comparison, one-sided greater, $\alpha = 0.05$).

The contact and oral LD₅₀ (24 h) values of the reference item (dimethoate) were calculated to be 0.21 µg a.i./bee (lower – upper 95% CI: 0.18 – 0.28 µg a.i./bee) and 0.11 µg a.i./bee (lower – upper 95% CI: 0.10 – 0.13 µg a.i./bee), respectively.

Contact Test:

Dose levels of 50.0, 25.0, 12.5, 6.3 and 3.1 µg product/bee led to dose dependent mortality levels of 100.0, 100.0, 90.0, 36.7 and 20.0 % at test termination (48 hours). 10.0 % mortality occurred in the control group (water + 0.5 % Adhäsit).

During the first 24 hours behavioural abnormalities (e.g. affected, apathetic and/or moribund bees) were observed in all test item dose level groups. 48 hours following the application a few bees were behaving abnormal in the 6.3 and 3.1 µg product/bee dose level. No further behavioural impairments occurred

during the 48 hrs-assessment anymore.

Oral Test:

Actual oral doses of 28.7, 14.4, 6.5, 3.1, 1.4 and 0.65 µg product/bee resulted in mortality ranging from 100.0 % to 3.3 % at the end of the test (48 hours after application). There was 6.7 % mortality in the control group (50 % w/v sucrose solution = 500 g sucrose/L tap water). During the 4 hours assessment, moribund and affected bees were observed in the 28.7, 14.4 and 6.5 µg product/bee dose groups. A few bees behaved abnormal in the 28.7 and 14.4 dose group during the 24 hours assessment. All other surviving bees appeared normal.

Conclusion

The toxicity of deltamethrin + flupyradifurone EC 85 (10+75) G was tested in both, an acute contact and an acute oral toxicity test on honey bees. The contact LD₅₀ values (24 and 48 h) of deltamethrin + flupyradifurone EC 85 (10+75) G were determined to be 9.1 and 7.1 µg product/bee (equivalent to 0.079 µg deltamethrin + 0.602 µg flupyradifurone/bee and 0.062 µg deltamethrin + 0.470 µg flupyradifurone/bee), respectively. The oral LD₅₀ value (24 and 48 h) was 13.2 and 13.0 µg product/bee (equivalent to 0.114 deltamethrin + 0.874 µg flupyradifurone/bee and 0.113 µg deltamethrin + 0.861 µg flupyradifurone/bee), respectively.

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

Comments of zRMS:	In order to fulfil the data requirements for bees as set by the Commission Regulation (EU) No 284/2013, in case of products containing more than one active substance the study with the formulation for which authorisation is sought must be submitted and cannot be replaced by studies performed with solo formulations of particular active substances. Taking this into account, the study below was not validated as being not relevant for the risk assessment for DLT+FPF EC 85 and its summary is struck through below.
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Reference:	KCP 10.3.1.2/01
Title:	Deltamethrin EW 15B G - Assessment of chronic effects to the honeybee, <i>Apis mellifera</i> L., in a 10 days continuous laboratory feeding test
Report:	Kling, A.; 2014; S13-00151; M-477250-01-1
Guideline(s):	not applicable
Deviations:	not applicable
GLP/GEP:	yes
Acceptability:	Not validated, not relevant for the risk assessment for DLT+FPF EC 85
Duplication (if vertebrate study):	

Materials and methods

Test item: Deltamethrin EW 15B G (batch no.: 2012 000065; density: 1.024 g/mL, content of active substance analysed (a.s.): 16.14 g/L, 1.58 % w/w (15 g/L nominal)).

The chronic effects of the test item Deltamethrin EW 15B G on the honey bee, *Apis mellifera* L., were assessed in a 10 days continuous feeding test in the laboratory. Over a period of 10 days, honey bees were exposed to 50 % (w/v) aqueous sucrose application (feeding) solution, containing nominally 2, 6, 18, 54 and 162 mg a.s./kg of the test item Deltamethrin EW 15B G by continuous and *ad libitum* feeding. The control group was exposed for the same period of time under identical exposure conditions to untreated 50 % (w/v) aqueous sucrose application (feeding) solution. Mortality, sub-lethal effects and

behavioural observations were assessed every day throughout the 10 days continuous exposure period. Furthermore, the daily food uptake was determined.

Samples of the application (feeding) solutions prepared freshly every day throughout the 10 days continuous feeding period were taken daily for subsequent chemical analysis in order to reveal the actual concentration of the test item.

Dates of experimental work: 16 August 2013 to 11 September 2013

Results and discussions

After 10 days of continuous exposure, mortality at all test item treatment levels of 2, 18, 54 and 162 mg a.s./kg of Deltamethrin EW 15B-G were statistically significantly different when compared to the control group. Up to and including 6 mg a.s./kg, mortality after 10 days of continuous exposure was max. 10 %, and as such below the control mortality threshold level for study validity.

The cumulative control mortality was 1.0 %, as determined at the final evaluation after 10 days. The cumulative mortality at the treatment levels of 2, 6, 18, 54 and 162 mg a.s./kg Deltamethrin EW 15B-G was 10.0, 0.0, 50.0, 100 and 100 %, (corrected 9.1, 1.0, 49.5, 100 and 100 %), respectively, at the final evaluation.

From the first assessment throughout the entire observation period of 10 days, at all treatment levels of Deltamethrin EW 15B-G, sub-lethal effects or behavioural abnormalities were observed, showing a strong dose response dependency.

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 levels of 2, 6, 18, 54 and 162 mg a.s./kg was 0.73, 1.77, 6.48, 12.48 and 8.10 µg a.s./bee, the corresponding average daily dose was therefore 0.07, 0.18, 0.65, 1.25 and 0.81 µg a.s./bee (nominal), respectively.

The overall mean daily consumption of the aqueous sucrose application (feeding) solution (i.e. the average value over 10 days per replicate) in the test item treatment groups of 6, 18 and 162 mg a.s./kg was statistically significantly different when compared to the untreated control group (29.3, 36.0 and 24.9 mg/bee at 6, 18 and 162 mg a.s./bee, respectively, compared to 44.4 mg/bee in the control group). The mean daily consumption of the aqueous sucrose application (feeding) solution was often statistically significantly different (lower) between the control group and the test item treatment group throughout the entire testing period (day by day comparison).

Mean consumption of application (feeding) solution, mean nominal intake of test item accumulated over all test days, average daily dose, cumulative mortality after ten days of continuous exposure (test end) as well as the LC₅₀ and LDD₅₀

Treatment Level	Control ¹	Deltamethrin EW 15B-G [mg a.s./kg] ²				
		2	6	18	54	162
Cumulative mortality after ten days of continuous exposure [%]	1.0	10.0*	0.0	50.0*	100*	100*
Corrected cumulative mortality after ten days of continuous exposure [%]	-	9.1	1.0	49.5	100	100
Overall mean daily consumption of application (feeding) solution [mg/bee] ³	44.4	36.9	29.3**	36.0**	41.5	24.9**
Mean nominal intake accumulated over ten test days [µg a.s./bee/10d]	-	0.73	1.77	6.48	12.48	8.10
Average daily dose (nominal) throughout ten days of continuous exposure [µg a.s./bee/d]	-	0.07	0.18	0.65	1.25	0.81
LC ₅₀ (95 % confidence limits)	15.1 mg a.s./kg (nominal) (11.9 to 19.3 mg a.s./kg)					
LDD ₅₀ (95 % confidence limits)	0.53 µg a.s./bee/day (nominal) (0.41 to 0.70 µg a.s./bee/day)					

¹— Application (feeding) solution: 50 % (w/v) aqueous sucrose solution

²— Application (feeding) solution: 50 % (w/v) aqueous sucrose solution containing Deltamethrin EW 15B-G

³— The mean values per replicate over the test period (non rounded values) were used as basis for the calculation of the overall mean daily consumption of application (feeding) solution

*— Statistically significantly different compared to the control; Fisher's Exact Test (Bonferroni-Holms corrected, right-sided, $p \leq 0.05$)

**— Statistically significantly lower compared to the control group; Dunnett's t-Test (left sided, $p \leq 0.05$)

a.s.— active substance; LDD₍₅₀₎: Lethal Dietary Dose₍₅₀₎

Analytical results

The actual concentration of deltamethrin in the application (feeding) solutions, determined for each preparation day, was in the range from 63 to 94 % of the nominal concentration. The average actual concentration of deltamethrin over a period of 10 consecutive days per individual test item treatment level was within the range of 84—90 % of the nominal concentration, the overall average actual concentration of deltamethrin (over 10 consecutive days, over all treatment levels) accounted to 88 % of the nominal concentration. No residues of deltamethrin above the LOQ (10 µg/kg) were found in any of the control samples.

Conclusion

It can be concluded that the continuous *ad libitum* feeding of honey bees in the laboratory over a period of 10 consecutive days with the test item Deltamethrin EW 15B-G at the treatment levels of 2, 6, 18, 54 and 162 mg a.s./kg resulted in dose dependent effects on mortality, sub-lethal effects and behaviour. The cumulative control mortality was 1.0 %, as determined at the final evaluation after 10 days. The cumulative mortality at the treatment levels of 2, 6, 18, 54 and 162 mg a.s./kg Deltamethrin EW 15B-G was 10.0, 0.0, 50.0, 100 and 100 %, (corrected 9.1, 1.0, 49.5, 100 and 100%) at the final evaluation, respectively. Up to and including 6 mg a.s./kg, mortality after 10 days of continuous exposure was max. 10 %, and as such below the control mortality threshold level for study validity.

The overall mean daily consumption of the aqueous sucrose application (feeding) solution (i.e. the average value over 10 days) was lower at each test item treatment level when compared to the untreated control group, for some test item treatment levels the difference was statistically significant. The same holds true for the daily mean food consumption, which was in a day by day comparison often statistically significantly lower in the test item treatment groups when compared to control. This indicates that there was a repellent effect of the test item at all treatment levels.

The LC₅₀ after 10 days of continuous exposure was determined to be 15.1 mg a.s./kg (nominal). The

corresponding LDD₅₀ (Lethal Dietary Dose), based on the actual consumption of the respective feeding solutions, was calculated to be 0.53 µg a.s./bee/day (nominal).

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

Comments of zRMS:	<p>In general, the field and semi-field studies should be performed with the formulation in question with application regime being in line with the intended use pattern. This is particularly important in case of formulations containing more than one active compound due to possibility for synergistic effects.</p> <p>Since the study summarised below was performed with the solo formulation of deltamethrin, it is considered not relevant for the risk assessment performed for DLT+FPF EC 85, which contains two substances with supplementary mode of action: deltamethrin and flupyradifurone, which act through different pathways: deltamethrin is a non-systemic “knock-out” insecticide extremely disturbing the nervous system by blocking the sodium channel and flupyradifurone is a systemic insecticide interacting with insect nicotinic acetylcholine receptors, similar to neonicotinoids. Taking this into account it cannot be excluded that the impact of the mixture on bees may be enhanced comparing to individual compounds and it is thus not possible to predict effects of simultaneous exposure of bees to both active compounds based on semi-field/field studies performed with single active compounds, even when applied at higher rates. For this reason the semi-field and field tests should be performed with formulation under evaluation in order to account for effects resulting from simultaneous exposure to both active compounds.</p> <p>The study below was not validated by the zRMS as being not relevant for the risk assessment and its summary is struck through below.</p>
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Reference:	KCP 10.3.1.5/01
Title:	Determination of side-effects of Deltamethrin EW 15B G on honey bee (<i>Apis mellifera</i> L.) brood under confined semi-field conditions
Report:	Rentschler, S.; 2014; S12-00041; M-477316-01-1
Guideline(s):	OECD Guidance Document No. 75 (2007)
Deviations:	not applicable
GLP/GEP:	yes
Acceptability:	Not validated, not relevant for the risk assessment for DLT+FPF EC 85
Duplication (if vertebrate study):	

Materials and methods

Test item: Deltamethrin EW 15B G; Sample description: TOX09629-00; Batch ID: 2012-000065; content of a.s. (analysed): deltamethrin: 16.14 g/L, 1.58 % w/w (15.0 g/L nominal).

The effects of Deltamethrin EW 15B G were tested on the honeybee (*Apis mellifera* L.) under confined semi-field conditions by following the OECD guidance document No. 75 (2007), with modifications. The aim of the study was to evaluate potential side effects of a spray application of Deltamethrin EW 15B G on the honeybee, *Apis mellifera* L. under forced exposure conditions. The crop used for this semi-field study was *Phacelia tanacetifolia*, the study was conducted in Niefern-Öschelbronn, federal state of Baden-Württemberg, Germany.

This study included three exposure groups with three replicates (tunnels) each: one tap water treated control group (C), one test item group (T) and one reference item group (R). In all exposure groups, the

crop was sprayed 4 days after set up of the hives in the tunnels at BBCH 65 (full flowering), during honeybees actively foraging on the crop under confined conditions. The target application rate of the test item Deltamethrin EW 15B-G corresponded to 7.5 g a.s./ha, tap water was applied in the control group and Insegar 25 WG was applied at a target rate of 600 g product/ha in the reference item group (corresponding to 150 g fenoxycarb per ha). The spray volume was 400 L/ha in all treatment groups. The colony size at set up was in the range of 6188–9188 bees. The honeybees remained 10 days in the tunnels.

The first colony assessment was performed 3 days before set up of the colonies in the tunnel tents. Subsequently, six further colony assessments were conducted.

The colonies were assessed once before, twice during and four times after the end of the confined exposure phase. The development of the bee brood was assessed in parallel in individual marked brood cells. One assessment before application (Brood Area Fixing Day = BFD0) and four further assessments took place. Mortality, flight intensity and behaviour assessments were conducted daily, starting 3 days before the test item application and continued for seven days after the test item application under confined conditions. Further mortality assessments (in bee traps only) and behaviour assessments were conducted at the monitoring site, after the end of the confinement period until DAA26.

The influence of the test item was evaluated by comparing the results obtained in the test item treatment group to those of the control and the reference item group.

The following endpoints were assessed:

- Total and mean number of dead bees on the linen sheets in tunnel tents and in the dead bee traps before as well as after the application in T, C and R, respectively.
- Flight intensity (mean number of forager bees/m² and treatment group on *P. tanacetifolia* before as well as after the applications in T, C and R, respectively.
- Behaviour of the bees in the crop and around the hive.
- Condition of the colonies and development of the bee brood (number of bees (strength) and area of the different brood stages and food storage per colony and assessment date).
- Development of the bee brood assessed in individual brood cells.

Dates of Work: 15 June 2012 to 18 July 2012

Results and discussions

Mortality and Flight Intensity of Honey Bees, Semi-Field Test under Confined Exposure Conditions

Test item	Deltamethrin EW 15B-G		
Test object	<i>Apis mellifera</i>		
Treatment group	Control (C)	Deltamethrin EW 15B-G (T)	Reference item Insegar 25 WG (R)
Application rate	—	1 × 7.5 g Deltamethrin a.s./ha at BBCH 65	1 × 150 g Fenoxycarb/ha at BBCH 65
Mean mortality DAA-3 to 0ba [dead bees/day]	15.1	17.3	15.3
Mean mortality DAA0ba [dead bees/day]	36.3	33.7	32.3
Mean mortality DAA0aa [dead bees/day]	22.0	30.3	19.3
Mean mortality DAA0aa to 7 [dead bees/day]	19.2	29.9*	27.5
Mean mortality DAA0aa to 26 [dead bees/day]	15.6	18.4	72.7*
Sum of dead pupae and larvae DAA0aa to DAA26	16 Pu/2La	15 Pu	4574 Pu
Q _M (DAA0aa)	1.4	1.8	1.3
Q _M (DAA0aa to 7)	1.3	1.7	1.8
Daily mean flight intensity DAA-3 to 0ba [bees/m ²]	7.6	9.3	10.5
Daily mean flight intensity DAA0aa [bees/m ²]	17.3	6.0*	16.8
Daily mean flight intensity DAA1 [bees/m ²]	28.5	24.4	24.7
Daily mean flight intensity DAA0aa to 7 [bees/m ²]	22.6	17.0*	19.5

DAA = Days after application

ba = before application

aa = after application

* = statistically significant compared to the control

Pu = pupae

La = larvae

Observations:

Honey Bee Mortality:

After set up of the colonies inside the tunnels until the day of the test item application (DAA-3 to 0ba), the mean mortality value was 15.1, 17.3, and 15.3 dead bees/day for the treatment group C, T, and R, respectively. There are no statistically significant results between the treatment groups concerning mortality during this period (t test, method pooled, one sided, $\alpha = 0.05$).

On the day of the application, immediately before the test item application in T and the concurrent application in C and R, respectively (DAA0ba), the mean mortality value was 36.3, 33.7 and 32.3 dead bees/day for the treatment group C, T and R, respectively.

On the day of application, after the application (DAA0aa), the mean mortality value in the treatment group C, T, and R accounted to 22.0, 30.3 and 19.3 dead bees/day, respectively.

One day after application (DAA1) the mean mortality in T (34.7 dead bees/day) was slightly, but statistically significantly higher than the corresponding value in the control group C (15.0 dead bees/day) (t test, method pooled, one sided, $\alpha = 0.05$). Also statistically significantly higher than the corresponding value in the control group C (13.7 dead bees/day) (t test, method pooled, one sided, $\alpha = 0.05$) were the mean mortality values of T and R on DAA7 with 35.7 dead bees/day in T and 36.3 in R, respectively.

The mean daily mortality value during the confined exposure period after the application (DAA0aa to DAA7) of the test item treatment was slightly increased with a mean value of 29.8 dead bees/day and statistically significantly higher than the corresponding value in the control group C with 19.2 dead bees/day (t test, method pooled, one-sided, $\alpha = 0.05$).

During the further monitoring of the colonies outside the tunnels at the remote monitoring location (DAA8 to DAA26), daily mean mortality was in a range from 6.0 to 25.0 dead bees in C, 6.0 to 35.0 dead bees in T and 5.7 to 277.7 dead bees in R. A statistically significantly higher mortality value occurred only on DAA8 during this period of time in the test item treatment group T when compared to the control group C (t test, method pooled, one-sided, $\alpha = 0.05$). The mortality values of the reference item treatment group were statistically higher throughout DAA10 to DAA15.

During the total time period after the application (DAA0aa to 26), the mean daily mortality was recorded to be 15.6, 18.4 and 72.7 for C, T, and R, respectively. The mean mortality values in the test item treatment group T before (DAA 3 to 0ba) as well as after test item application (DAA0aa to 26) were not statistically significantly different, when compared to the control group C (t test, method pooled, one-sided, $\alpha = 0.05$).

Additionally, from DAA10 onwards (i.e. the typical point in time to detect the effect of the reference item), dead bees, dead pupae and dead larvae on the bottom board of each hive were counted and added to the dead bees found in the dead bee trap and were included in the calculation. The values from the bottom board of DAA10 are as such the sum of dead bee life stages until that day.

During the daily assessments of mortality (DAA0aa to 26), the sum of dead pupae and larvae, found inside the dead bee traps and on the bottom board (from DAA10 onwards) of the test item group and control group stayed on the same level with 18 and 15 dead pupae and larvae for C and T, respectively. In contrast, 4574 dead pupae were found in the reference item group during this period.

When comparing the mean mortality before application (DAA 3 to DAA0ba) until the day of the test item application, the $Q_{M(DAA0aa)}$ values were 1.5, 1.8 and 1.3 for the treatment groups C, T and R, respectively. The $Q_{M(DAA0aa \text{ to } 7)}$ values were 1.3, 1.7 and 1.8 for C, T and R, respectively.

Although the mean mortality in the test item treatment group was compared to control statistically significantly increased one day after test item application (C: 15.0 vs. T: 34.7 dead bees/day) as well as during the confined exposure period after the application (DAA0aa to DAA7, C: 19.2 vs. T: 29.9 dead bees/day), mortality was in absolute terms still on a low, biologically not adverse level.

Therefore, it can be concluded that Deltamethrin EW 15B G, even when applied under forced (confined) exposure conditions at a rate corresponding to 7.5 g a.s./ha during full flowering of a highly bee-attractive crop (*Phacelia tanacetifolia*) with honey bees actively foraging on the crop during application, does not result in biologically adverse effects on mortality.

Honey Bee Flight Intensity:

After set up of the colonies inside the tunnels until the day of the test item application and the concurrent application in C and R, respectively (DAA 3 to 0ba), the mean daily flight intensity was 7.6, 9.3 and 10.5 bees/m² in C, T and R, respectively. The daily mean flight intensity during this period was in a range from 1.8 to 15.1 forager bees/m² in C, 0.8 to 15.4 in T and 1.9 to 17.7 in R, respectively.

On the day of the test item application after application (DAA0aa), the mean daily flight intensity across 7 assessments within a period of about 6 hours was 17.3, 6.0, and 16.8 honeybees/m², for C, T, and R, respectively, and was statistically significantly reduced in T, when compared to C (t test, method pooled, one-sided, $\alpha = 0.05$).

One day after the test item application and the concurrent application in C and R, respectively (DAA1), the mean flight intensity was nearly on the same level in all treatment groups with 28.5, 24.4 and 24.7 forager bees/m² in the C, T and R, respectively and there were no statistically significant differences in the test item treatment group T when compared to the control group C, but statistically significant differences were observed in the reference item group (t test, method pooled, one-sided, $\alpha = 0.05$).

During the confined exposure period, after test item application and the concurrent application in C and R, respectively (DAA0aa to DAA7), the flight intensity in the test item treatment group T was statistically significantly lower on DAA2 (23.8 forager bees/m²) and DAA3 (10.6 forager bees/m²) when

compared to the control group C (DAA2: 28.8 and DAA3: 17.7 forager bees/m²) (t test, method pooled, one-sided, $\alpha = 0.05$). The mean daily flight intensity during DAA0aa–DAA7 was in a range from 17.3–28.8 forager bees/m² in C, 6.0–24.4 in T and 13.1–27.5 in R, respectively. The corresponding mean daily flight intensity during DAA0aa–DAA7 was 22.6, 17.0 and 19.5 for C, T and R, respectively. The flight activity was statistically significantly lower in T when compared to C (Mann Whitney Exact, one-sided, $\alpha = 0.05$) during this period.

Overall, a slight repellent effect of the test item was indicated in comparison to control by a statistically significantly reduced flight intensity on DAA0 (day of application, after application), during the 2nd and 3rd day after application as well when considering the overall mean value during confinement. The reduction in flight intensity was most apparent immediately after application, but recovered shortly and distinctly thereafter. Overall, flight intensity was in absolute terms on a sufficiently high level, and as such biologically not adversely reduced.

Behaviour of the Bees

No abnormal behaviour was recorded in the control, in the test item and in the reference item treatment group before application (DAA-3 to DAA0ba). The few cramping, inactive / motionless and clustering bees observed during this period are considered as not unusual and did not impair the interpretation of the study. Bees sitting on the linen sheet and motionless wet bees were considered as normal.

In the test item treatment T, shortly after the application on DAA0aa, across 7 observation time points, 22 cramping bees, 27 bees with locomotion / coordination problems and 6 inactive / motionless bees were observed. Furthermore, many bees intensively cleaning themselves were noticed in the test item treatment group at these 7 observation time points. On DAA1, on the first out of three assessments that day, 28 cramping bees, 81 motionless bees and 6 bees with locomotion problems were observed in the three replicates of test item treatment. In the following two assessments, only one motionless bee but mainly normal behaviour of the bees was observed. From DAA2 to DAA26 only occasionally cramping bees, motionless bees, bees with locomotion problems and fighting bees were observed in T.

In the reference item treatment group, shortly after application on DAA0aa across 7 observation time points, 26 intensive cleaning bees, 13 trembling bees, 6 intensive cleaning bees with locomotion problems, 2 motionless bees and one bee trembling with locomotion problems, one bee flying without landing on the crop, one cramping bee and one bee with locomotion problems. One day after application (DAA1), mainly normal behaviour of the bees was observed in the three assessment times per replicate (Ra, Rb, Rc). Only 1 cramping and 3 motionless bees were recorded in this time period. On the following days during confined exposure (DAA2 to DAA7) mainly normal behaviour was noticed. One cramping bee, one bee with locomotion problems and 1 bee intensively controlled by a guarding bee were observed in this time period in the reference item tents. Additionally, 44 inactive / motionless bees could also be observed, which is probably due to adverse weather conditions.

During the observations from DAA0aa to DAA26, abnormal behaviour was observed in the control group C only on very few occasions, which is considered biologically normal under confined conditions.

Overall, sub-lethal/behavioural effects in the test item treatment group occurred mainly on the day of application, with a clear decline during the following day, and thereafter only occasionally, showing the transient nature of the effect.

Development of Honey Bee Brood in Individual Cells (Digital Image Analysis)

According to the development time of a worker honey bee from egg to adult bee (imago), which normally averages to 21±1 days, it can be expected that young bees will have hatched until the assessment date BFD+21 (i.e. 21 days after the Brood Area Fixing Day BFD0).

For this particular assessment, about 250 individually marked cells per hive were selected in C, T and R, respectively.

The control (C) and test item treatment colonies Tb and Tc showed a successful development, with rising brood indices throughout the entire assessment period, except for the assessment on BFD+15, where stable values (due to the long development time of the sealed brood) compared to the previous

assessment on BFD+11 were observed in all C colonies and in the colonies Tb and Tc. The development of the colony Ta was interrupted in the observed cells between the assessments BFD0 and BFD+6 and the brood indices were 0 from BFD+6 up to BFD+21.

Maybe this development occurred due to unknown mechanical reasons at the assessment on BFD0 or due to individual characteristics of this bee hive (e.g. the marked, small number of eggs had no priority for the colony at this point in time). Considering (i) the equivalent performance of the colonies Tb and Tc when compared to control, (ii) the overall low termination rates in Tb and Tc, (iii) the absence of any difference between T and C in terms of dead larvae and dead pupae as determined in the bee traps and on the bottom boards of each hive in combination with (iv) the overall comparable performance of brood development in all hives in the test item treatment group when compared to the control group—as assessed in a series of six subsequent colony assessments, involving both sides of each comb per hive—a direct, test item related effect appears unlikely.

The brood development of the reference item colonies Ra and Rb was interrupted and the indices decreased to 0 at the first assessment after application (on BFD+6). The colony Rc showed a successful development of the observed cells, with rising brood indices which is rather untypical for colonies treated with the reference item Insegar. Even with this positive development of the marked cells in this particular R colony, the effect of the reference item treatment became obvious in Rc by the high number of dead pupae (partially with sickle eyes) in the bee traps, by the high number of dead brood in the cells of the individual combs as well as by the high number of dead pupae on the bottom board, in all of the three R replicates—Ra, Rb and Rc, respectively.

In total, the brood indices were 1.00 in each treatment group at the first BFD assessment and reached mean values of 3.79, 2.68 and 1.53 in C, T and R at the last assessment on BFD+21.

The compensation index is an indicator for the recovery of the brood in those cells which had been emptied before successful hatch. The mean compensation indices of the control were 2.64, 3.06, 3.11 and 4.28 on BFD+6 to BFD+21 and 1.93, 2.36, 2.75 and 3.79 in the test item treatment. In the only replicate in the test item treatment group (Ta) which showed a total loss of the brood in the marked cells at BFD+6, the determined increasing compensation indices of 0.54, 0.57, 1.74 and 2.87 on BFD+6, +11, +15 and +21, indicate recovery from this event and show new egg laying activity and successful brood development.

In the reference item treatment R, the mean compensation index increased only to 1.11 at BFD+6 and thereafter on BFD+21 to a value of 2.39.

At the last assessment (BFD+21), the mean termination rate was 24.37 % in the control and 46.58 % in T, compared to a mean value of 69.51 % in the reference item treatment R.

Over the entire assessment period, no statistically significant differences of the brood and compensation indices and the termination rate of the test item treatment group compared to the control was recorded (t test, method pooled, one-sided, $\alpha = 0.05$). Similarly, also no statistically significant difference of the reference item group compared to the control group was noticed, due to the good development of the individual cells of the replicate Rc. However, the high number of dead pupae (partially with sickle eyes) in the bee traps, the high number of dead brood in the cells of the individual combs as well as the high number of dead pupae on the bottom boards show a clear effect of the reference item treatment.

Overall, the quantitative assessments of brood development in individually marked cells revealed that Deltamethrin EW 15B G, when applied under forced (confined) exposure conditions in gauze tunnels at a rate corresponding to 7.5 g a.s./ha during full flowering of a highly bee attractive crop (*Phacelia tanacetifolia*) with honey bees actively foraging on the crop during application, does not cause treatment related adverse effects on honey bee brood development.

This conclusion is in line with the other brood related parameters as measured during the course of the study (i.e. the absence of any difference between T and C in terms of dead larvae and dead pupae as determined in the bee traps and on the bottom boards of each hive and the overall performance of brood development within all hives in the test item treatment group, when compared to the control group, as assessed in a series of six subsequent colony assessment and by considering all combs per hive).

Summary of the brood and compensation indices and termination rates

Replicate	Brood / Compensation indices at x days after brood area fixing day (BFD)					Termination rate (BFD+21)
	0	+6	+11	+15	+21	[%]
Ca	1.00 / 1.00	3.12 / 3.13	3.92 / 3.93	3.90 / 3.92	4.87 / 4.91	3.20
Cb	1.00 / 1.00	2.81 / 2.81	2.93 / 2.95	2.93 / 2.99	3.67 / 4.00	26.70
Ce	1.00 / 1.00	1.97 / 1.97	2.27 / 2.29	2.27 / 2.42	2.84 / 3.93	43.22
Mean-C	1.00 / 1.00	2.63 / 2.64	3.04 / 3.06	3.03 / 3.11	3.79 / 4.28	24.37
STD	0.00 / 0.00	0.60 / 0.60	0.83 / 0.83	0.82 / 0.76	1.02 / 0.55	20.11
Ta	1.00 / 1.00	0.00 / 0.54	0.00 / 0.57	0.00 / 1.74	0.00 / 2.87	100.00
Tb	1.00 / 1.00	2.64 / 2.66	3.31 / 3.33	3.31 / 3.34	4.13 / 4.32	17.65
Te	1.00 / 1.00	2.58 / 2.58	3.17 / 3.18	3.13 / 3.16	3.91 / 4.27	22.08
Mean-T	1.00 / 1.00	1.74 / 1.93	2.16 / 2.36	2.15 / 2.75	2.68 / 3.84	46.58
STD	0.00 / 0.00	1.51 / 1.20	1.87 / 1.55	1.86 / 0.88	2.32 / 0.85	46.32
Ra	1.00 / 1.00	0.00 / 0.45	0.00 / 0.18	0.00 / 0.27	0.00 / 0.71	100.00
Rb	1.00 / 1.00	0.00 / 0.07	0.00 / 0.00	0.00 / 0.38	0.00 / 1.78	100.00
Re	1.00 / 1.00	2.79 / 2.81	3.67 / 3.68	3.67 / 3.69	4.59 / 4.67	8.54
Mean-R	1.00 / 1.00	0.93 / 1.11	1.22 / 1.29	1.22 / 1.45	1.53 / 2.39	69.51
STD	0.00 / 0.00	1.61 / 1.48	2.12 / 2.07	2.12 / 1.94	2.65 / 2.05	52.80

DAA = Days after application

ba = before application

aa = after application

* = statistically significant compared to the control

Strength of the Colonies

The mean number of bees assessed before set-up of the hives (first colony assessment, DAA-7) in the tunnels revealed a mean colony strength with an average of 6875 bees/hive in C [range: 6188–7625], 6875 bees/hive in T [range: 6688–7125], and 8459 bees/hive in R [range: 8000–9188].

At the second colony assessment on DAA-1, the mean colony strength was 6771 bees/hive in C [range: 6063–7563], 5875 bees/hive in T [range: 5500–6375] and 7709 bees/hive in R [range: 6688 to 8813].

At the third colony assessments (DAA5), during the confined exposure period, an increase of the mean number of bees was observed in both C and T (C: 8500 bees/hive, T: 7313 bees/hive), whereas the mean number of bees in R was almost on the same level as on the first assessment with 8605 bees/hive.

At the subsequent colony assessments, after the end of the confined exposure period outside the tunnels, on the remote monitoring location the mean number of bees increased continuously in the C and T colonies up to the sixth colony assessment (DAA20) to 15000 bees in C and 10875 bees in T. On the last colony assessment (DAA26) the number of bees was comparable in both, C and T, with 11708 and 10271 bees, respectively.

On DAA10 and 14, the mean number of bees in the R colonies was nearly on the same level with 11813 and 11771 bees, respectively. On DAA20 the number of bees increased to 12750 and decrease to 8917 bees on DAA26.

The increase of the mean number of bees from the first to the last colony assessment in the C and T was comparable and accounted to +70.3 % and +49.4 %, respectively, whereas the increase in R colonies accounted only to +5.4 %.

The overall development of colony strength of all treatment groups showed fluctuations which are typical for this type of study. The colony strength values at the last assessment in the C and T colonies were higher compared to the first assessment and showed comparable absolute numbers (C: 11708, T: 10271 bees). Also the relative increase in colony strength until the end of the study was comparable in C and T (C: +70.3 %, T: +49.4 %). As such, no test item related adverse effects on colony strength were observed.

Development of Brood Area

The mean abundance of brood (sum of cells containing eggs, larvae, and pupae) assessed before set-up (confinement) of the hives (first colony assessment, DAA 7) was 20600 cells/hive for C, 20133 cells/hive for T and 22800 cells/hive for R. At the second colony assessment (DAA 1 / BFD0), before start of exposure, the mean abundance of brood in C, T and R had increased to 23133 cells/hive for C, 20533 cells/hive for T and 24267 cells/hive for R.

At the third colony assessment, during the confined exposure period, on DAA5, the mean abundance of brood in C, T and R was nearly on the same level with 22333, 20933 and 21933 cells/hive in C, T and R, respectively.

On the fourth colony assessment (end of confined exposure, at the monitoring site) on DAA10, the mean abundance of brood in C and T had decreased slightly and in parallel to almost identical 20267 cells/hive for C and 20400 cells/hive for T, whereas the mean abundance of brood decreased noticeably to 15933 cells/hive in the R colonies.

On the fifth colony assessment (DAA14), the mean abundance of brood in C and T had increased in parallel and was again almost on an identical level with 24000 cells/hive for C and 24533 cells/hive for T, whereas in R, with 13533 cells/hive, the mean abundance of brood had further and noticeably decreased. This refers to a clearly detectable effect of the reference item, which is typical for this point in time.

On the following assessments, the mean abundance of brood in C increased to 29200 cells/hive on DAA20 and 29867 cells/hive on DAA26. In the T colonies on DAA20, the mean abundance of brood increased to 28400 cells/hive and on the last colony assessment (DAA26) 26800 cells/hive was recorded. Brood of all stages (eggs, larvae, capped brood) was present in all colonies at all assessments during the study, with the exception of colony Ra, where no larvae were recorded on the third colony assessment at DAA5. The fluctuations of all brood stages were within the range of natural variation and typical for this kind of study.

Overall, honey bee brood development and colony conditions in the test item treatment T were comparable to control during the entire assessment period. No test item related adverse effect on brood development was observed.

Development of the Food Storage Area

The mean extent of food stores in the colonies (sum of cells containing nectar and pollen) assessed before set-up (confinement) of the hives (first colony assessment, DAA 7) was 18467 cells/hive for C, 14533 cells/hive for T and 11467 cells/hive for R. At the second colony assessment (DAA 1, before start of exposure), the mean extent of food stores decrease slightly in C and increased in T and R (C: 18200 cells/hive, T: 17333 cells/hive, R: 15733 cells/hive). At the third colony assessment, during the confined exposure period, on DAA5, the mean extent of food stores in the colonies C, T and R had decreased to almost identical levels, i.e. 15867 cells/hive in C, 15333 cells/hive in T and 15533 cells/hive in R).

At the subsequent colony assessments on the remote monitoring location, after the confined exposure period, the mean extent of food stores in C, T and R decreased from DAA10 to DAA26 to finally 8867 cells/hive in C, 6267 cells/hive in T and 8333 cells/hive in R.

The observed decrease and increase in food stores in both, treatment and control, during confinement and thereafter can be considered as typical for this type of study. The colonies were well provided during the course of the study. No test item related adverse effects on the development of the food storage area were observed.

Conclusion

Deltamethrin EW 15B G was applied at a rate corresponding to 7.5 g a.s./ha during full flowering to the highly bee attractive crop *Phacelia tanacetifolia* with honey bees actively foraging on the crop during application. The effects on bee hives under confined exposure conditions considering mortality, flight intensity, behaviour, colony strength and brood development were evaluated.

The tested Deltamethrin EW 15B G application rate has not caused adverse effects on the survival of marked eggs (brood termination rate), on brood development from eggs into adult bees (brood index) as well as on the brood compensation ability (brood compensation index).

Overall, the employed application scenario did not result in test item related adverse effects on brood development, on colony development and on overall colony vitality under forced exposure conditions. A repellent effect of the test item was indicated by reduced flight intensity on the day of the test item application as well as on two further days during the confined exposure period, but the observed repellent effect was not biologically adverse.

The mortality values in the test item treatment group during the post application phase were slightly increased on three days compared to the control, but were never on a biologically adverse level.

Bees intensively cleaning themselves, cramping bees and bees showing locomotion problems were observed particularly on the day of test item application.

The application of the reference item showed clear effects on the brood development, resulting in low brood indices, low compensation indices and high termination rates in two of the three replicates and high mortality values concerning pupae and larvae in all replicates of R.

Overall, based on the results of this study, Deltamethrin EW 15B G applied at a rate corresponding to 7.5 g a.s./ha does not adversely affect honey bee brood and colony development.

Comments of zRMS:	<p>In general, the field and semi-field studies should be performed with the formulation in question with application regime being in line with the intended use pattern. This is particularly important in case of formulations containing more than one active compound due to possibility for synergistic effects.</p> <p>Since the study summarised below was performed with the solo formulation of deltamethrin, it is considered not relevant for the risk assessment performed for DLT+FPF EC 85, which contains two substances with supplementary mode of action: deltamethrin and flupyradifurone, which act through different pathways: deltamethrin is a non-systemic “knock-out” insecticide extremely disturbing the nervous system by blocking the sodium channel and flupyradifurone is a systemic insecticide interacting with insect nicotinic acetylcholine receptors, similar to neonicotinoids. Taking this into account it cannot be excluded that the impact of the mixture on bees may be enhanced comparing to individual compounds and it is thus not possible to predict effects of simultaneous exposure of bees to both active compounds based on semi-field/field studies performed with single active compounds, even when applied at higher rates. For this reason the semi-field and field tests should be performed with formulation under evaluation in order to account for effects resulting from simultaneous exposure to both active compounds.</p> <p>The study below was not validated by the zRMS as being not relevant for the risk assessment and its summary is struck through below.</p>
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Reference:	KCP 10.3.1.5/02
Title:	Toxicity testing of Deltamethrin EW 50 on honey bees (<i>Apis mellifera</i> L.) under semi-field conditions - tunnel test
Report:	Schmitzer, S.; 2006; 29011037; M-274120-01-1
Guideline(s):	"The OECD Principles of Good Laboratory Practice (as revised in 1997) ENV/MC/CHEM(98)17 "Chemikaliengesetz ('Chemicals Act') der Bundesrepublik Deutschland (ChemG), "OEPP/EPPO (2001): Guideline for the efficacy evaluation of plant protection products - Side effects on honeybees. OEPP/EPPO, PP 1/170(3) update 2000 "Revision (updated with ICPBR -recommendations) approved in 2000
Deviations:	--
GLP/GEP:	yes
Acceptability:	Not validated, not relevant for the risk assessment for DLT+FPF EC 85
Duplication (if vertebrate study):	

Materials and methods

Test item: Deltamethrin EW 50, Batch ID: 2005-004004, Sample Description: TOX07463-00, analysed content of AE F032640 (= deltamethrin): 49.7 g/L (4.78 % w/w) (nominal: 50 g/L).

A tunnel test was conducted, in order to assess the effect of Deltamethrin EW 50 on honey bees under semi-field conditions. Cages (14 m length x 5.5 m width x 2.5 m height) were set up on a 40 m² plot of flowering *Phacelia tanacetifolia* (2 x 20 m²) and small bee colonies were introduced 6 days before the application. One bee hive was used per tunnel. The test item (7.5 g a.s. (156.9 g product) in 400 L water/ha), water (400 L water/ha) and a reference item (1.5 L Perfekthion EC (dimethoate) in 400 L water/ha) were applied on the whole plot of plants in two operations, with foraging bees present. The trial was performed using three tunnels for the test item treatment, the control and the reference item treatment (dimethoate 400 g/L), respectively. The total duration of the test was 7 days following the application.

Mortality and foraging activity (flight density) of the bees were assessed before and after application. Sublethal effects, such as changes in behaviour, were also monitored. Colony assessments (food stores, brood status and hive populations) were made twice, 2 days before the applications and at the end of the study (day + 7). Weather conditions were good during application. The sky was a little cloudy but warm with no precipitation. No rain occurred during the treatment day and the following 3 days. The weather was variable but warm for the remainder of the trial.

Results and discussions

Effect on honey bee mortality:

Starting conditions of the experiment were ideal, indicating similar natural mortality levels among the different treatment groups before application (no statistical significant difference of the hives, Dunnett's t-test, multiple comparison to the control, two-sided, $\alpha = 0.05$).

On the day of the test item application a short lasting and slight increase of bee mortality occurred, when a mean of 171.0 dead bees per colony were found in the test item treatment compared to 31.0 in the controls but this was not statistically significant compared to the control (Student t test, one-sided greater, $\alpha = 0.05$). However, this level of mortality will not affect colony vitality or pollination activity of the colony.

The following day (day +1) mortality levels in the test item treatment remained slightly higher compared to the control, but this was not statistical significant anymore.

From day 2 onwards until the end of the assessment period on day 7, mortality levels of the bees after treatment with Deltamethrin EW 50 were comparable to the levels of the control treatments. At any day the number of dead bees per tunnel in the test item group did not differ from the control (Student t test, pairwise comparison, $\alpha = 0.05$, one-sided greater). An overall comparison of the mean dead bees found in the traps and on the gauze did not show a statistical difference between the control and the test item

treatment (Student t test, pair-wise comparison to the control, one-sided greater, $\alpha = 0.05$).

After treatment with the reference item (dimethoate) a distinct increase of bee mortality was observed for the first five days. From day 1 to day 3 following the application the number of dead bees found in the reference item treatment was approximately 6 to 15 times higher compared to the control values, indicating the sensibility of the test system. An overall comparison of the mortality data indicates a statistically significant difference compared to the control (Student t test, pairwise comparison to the control, one-sided greater, $\alpha = 0.05$).

Effects on honey bee flight intensity:

After application of Deltamethrin EW 50 flight intensity was reduced on the day of application (statistically significant differences, Welch t test, pairwise comparison to the control, one-sided smaller, $\alpha = 0.05$). From day 1 onwards until the end of the trial the foraging activity of the bees were comparable or even higher in the test item treated tunnels compared to the controls. An overall comparison of the mean flight activity did not show a statistical difference between the control and the test item treatment (Welch t test, pair-wise comparison to the control, one-sided smaller, $\alpha = 0.05$).

The foraging activity after application of the reference item (dimethoate) led to a clear decrease of flight intensity until the end of the experiment (7 days), which was statistically significant compared to the control on each single day (Welch t test, pairwise comparison, one-sided smaller, $\alpha = 0.05$).

Effects on honey bee behaviour

Behavioural abnormalities e.g. poisoning symptoms such as discoordinated movement, apathy or an intensive cleaning behaviour were observed following the application after Deltamethrin EW 50 treatment on day 0 for ca. 4 hours. Up to a maximum of 65 bees per tunnel were observed with such symptoms. 6 hours following the application, these behavioural abnormalities had gone. On the next days until the end of the experiment no more behavioural impairments were noted at any time until test end in the test item treatment. No behavioural abnormalities could be observed in the control group. The reference item treatment caused behavioural abnormalities (moving coordination problems, abnormal cleaning) at least until the first day following the application of dimethoate.

Effects on honey bee brood development:

No adverse effect of the test item on the brood was observable. After the applications, all colonies showed a sufficient amount of all brood stages without any indication of a test item related effect. During the brood assessment 7 days following the application, all queens were found in the colonies.

Conclusion

No ecologically relevant effects on mortality, flight intensity, behaviour or brood of the honey bees were observed after direct application of Deltamethrin EW 50 (7.5 g a.s./ha) in 400 L water/ha into a bee-attractive, flowering crop and during bee flight in a semi-field (tunnel) study. According to the results of this study Deltamethrin EW 50 does not adversely affect honeybee colonies.

Comments of zRMS:	<p>In general, the field and semi-field studies should be performed with the formulation in question with application regime being in line with the intended use pattern. This is particularly important in case of formulations containing more than one active compound due to possibility for synergistic effects.</p> <p>Since the study summarised below was performed with the solo formulation of deltamethrin, it is considered not relevant for the risk assessment performed for DLT+FPF EC 85, which contains two substances with supplementary mode of action: deltamethrin and flupyradifurone, which act through different pathways: deltamethrin is a non-systemic “knock-out” insecticide extremely disturbing the nervous system by blocking the sodium channel and flupyradifurone is a systemic insecticide interacting with insect nicotinic acetylcholine receptors, similar to neonicotinoids. Taking this into account it cannot be excluded that the impact of the mixture on bees may be enhanced comparing to individual compounds and it is thus not possible to predict effects of simultaneous exposure of bees to both active compounds based on semi-field/field studies performed with single active compounds, even when applied at higher rates. For this reason the semi-field and field tests should be performed with formulation under evaluation in order to account for effects resulting from simultaneous exposure to both active compounds.</p> <p>The study below was not validated by the zRMS as being not relevant for the risk assessment and its summary is struck through below.</p>
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Reference:	KCP 10.3.1.5/03
Title:	Assessment of side effects of AE F032640 00 EC02 A804 on the honey bee (<i>Apis mellifera</i> L.) in the semi-field
Report:	Schur, A.; 2001; C011205; M-200402-01-1
Guideline(s):	EPPO: 170
Deviations:	--
GLP/GEP:	yes
Acceptability:	Not validated, not relevant for the risk assessment for DLT+FPF EC 85
Duplication (if vertebrate study):	

Materials and methods

The side effects of the test substance AE F032640 00 EC02 A804 were tested on the honey bee (*Apis mellifera* L.) under semi field conditions according to the guideline of the European and Mediterranean Plant Protection Organization No. 170 (EPPO, 1992). The test substance AE F032640 00 EC02 A804 was applied at an application rate of 7.5 g a.i./ha in 300 L water/ha. Plots treated with tap water served as control. As toxic standard, Hostathion 40 EC was applied at a concentration of 0.6 L/ha in 300 L water/ha. The effect of the test substance was examined on small bee colonies in cages placed over plots with flowering *Phacelia tanacetifolia* Benth.

The influence of AE F032640 00 EC02 A804 was evaluated by comparing the effect of the test substance treatment group to the effect of the control group and toxic standard group regarding the following observations:

- Mortality at the edge of the treated area and in the bee traps
- Foraging activity (number of forager bees/m² flowering *Phacelia* crop)
- Behaviour of the bees on the crop and around the hive
- Development of the bee brood

Results and conclusion

Effect on honey bee mortality:

The application of the test substance AE F032640 00 EC02 A804 resulted in an increase of the mortality restricted to the day of application DAA 0aa (133.7 dead bees/colony) which was determined to be not

significantly different to the control (74.3 dead bees/colony). A drastically increase of mortality was observed after application of the toxic standard with an average of 533.7 dead bees/colony. The effect of the toxic standard demonstrated the sensitivity of the method in detecting the toxic effects of a pesticide. When comparing the average pre-application mortality and the average post application mortality utilising $Q_{M(average)}$ (average post application mortality divided by the average pre application mortality) no increase of mortality occurred after application of the test substance AE F032640 00 EC02 A804. The values for $Q_{M(average)}$ were calculated as 1.0 in the test substance treatment group and 0.7 in the control group. The value for $Q_{M(average)}$ in the toxic standard treatment was determined as 4.6.

Effects on honey bee flight intensity:

In the AE F032640 00 EC02 A804 treatment group an obvious repellent effect occurred directly after application assumed by the behaviour of the bees and confirmed due to the flight intensity (9.2 bees/m²) on this day which remained significantly below the level of the control group (23.2 bees/m²). The significantly reduced flight intensity in the AE F032640 00 EC02 A804 treatment group and in the toxic standard treatment lasted until evaluation day DAA1. Compared with the pre-application period the average daily post application level of flight intensity was lower in the test substance treatment group AE F032640 00 EC02 A804 and in the toxic standard treatment but higher in the control group.

Effects on honey bee brood development:

Regarding the colonies strength and the bee brood development no abnormal differences attributable to the influence of the test substance were observed between the test substance groups and control.

Comments of zRMS:	<p>In general, the field and semi-field studies should be performed with the formulation in question with application regime being in line with the intended use pattern. This is particularly important in case of formulations containing more than one active compound due to possibility for synergistic effects.</p> <p>Since the study summarised below was performed with the solo formulation of deltamethrin, it is considered not relevant for the risk assessment performed for DLT+FPF EC 85, which contains two substances with supplementary mode of action: deltamethrin and flupyradifurone, which act through different pathways: deltamethrin is a non-systemic “knock-out” insecticide extremely disturbing the nervous system by blocking the sodium channel and flupyradifurone is a systemic insecticide interacting with insect nicotinic acetylcholine receptors, similar to neonicotinoids. Taking this into account it cannot be excluded that the impact of the mixture on bees may be enhanced comparing to individual compounds and it is thus not possible to predict effects of simultaneous exposure of bees to both active compounds based on semi-field/field studies performed with single active compounds, even when applied at higher rates. For this reason the semi-field and field tests should be performed with formulation under evaluation in order to account for effects resulting from simultaneous exposure to both active compounds.</p> <p>The study below was not validated by the zRMS as being not relevant for the risk assessment and its summary is struck through below.</p>
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Reference:	KCP 10.3.1.5/04
Title:	Assessment of the short-term effects of Deltamethrin EC 100 on behaviour, foraging activity and mortality of honeybees (<i>Apis mellifera</i>) under semifield conditions (tunnel test) in Phacelia.
Report:	Maus, C.; Curé, G.; Doering, J.; 2006; MAUS/AM 037; M-262389-02-1
Guideline(s):	French official method CEB 230
Deviations:	Yes, but acceptable
GLP/GEP:	yes
Acceptability:	Not validated, not relevant for the risk assessment for DLT+FPF EC 85
Duplication (if vertebrate study):	

Materials and methods

Test item: Deltamethrin EC 100 (development No.: 30-00308466, article No.: 00-05943388, batch No.: OP240841, TOX No.: 07099-00, content of a.s. analysed: deltamethrin: 102.08 g/L), applied in treatment groups 3 and 4 at 0.075 L/ha (7.5 g a.s./ha) at a water volume of 250 L/ha. Toxic reference item: Dimethoate EC 400 (batch No.: 37M20919, content of a.s. analysed: dimethoate: 378.05 g/L), applied at 1 L product/ha at a water volume of 250 L/ha in treatment group 2. Treatment group 1 served as tap water treated control. In treatment group 3 the application was carried out during foraging activity of the bees, while the application in treatment group 4 was carried out in the evening, with no foraging activity.

In this semifield study one replicate, represented by one tunnel (160 m²) with one bee colony (approx. 10,000 honeybees) was set up for each treatment group. Each tunnel was divided into 4 subplots (T1 to T4) of *Phacelia tanacetifolia* (size of each sub-plot: 16 m² each). In all treatment groups the subplots T1 to T4 received application.

The applications were performed in all 4 treatment groups after 3 days with a stable level of daily mortality. Mortality was assessed every day during 9 days (from day 3 before until day 5 after application). Foraging activity and bee behaviour were assessed every day during 8 days (from day 2 before until day 5 after application). Two evaluation checks on the weight of the colonies, the development of food stores, and brood and egg laying activity of the colonies were done, one carried out at the beginning of the study (3 days before the application) and one at the end of study (6 days after the application). Additionally the number of adult bees on the combs was estimated 3 days before and 6 days after the application.

~~Dates of biological work: 2005-05-30 to 2005-06-08~~

Results and discussions

For all applications performed during the activity of bees on the crop (groups 1, 2 and 3), a high number of bees was present on the crop and was exposed to the application (between 22 and 29 bees/m²). In treatment group 3 (with bees active during the application), an increase in mortality was observed at the day of treatment (study day T: 1013 bees), but in a much lower range than in the toxic reference treatment group (study day T: 3137 bees). The mortality level in treatment group 3 returned to normal at the following day. In treatment group 4, where bees were not exposed to the treatment, no noticeable increase in mortality was observed. The progression of mortality level remained in the same range than in the control group during the whole study duration.

Foraging activity in both treatment groups 3 and 4, with and without bees active during the application, decreased slightly after the application compared to the control, indicating a moderate repellent effect of the test item.

Hive weight development was within the same order of magnitude in all treatment groups, although there was a recognisable difference concerning the toxic reference group, which had very low foraging activity during the second part of the study. The estimated number of adult bees on the combs was variable, as typical for this endpoint. However, a treatment-related development was not observed in this endpoint.

Bee brood development and food stores were not affected by the application in the treatment groups 3 and 4.

Conclusion

A moderate increase of mortality was observed after the application in the tunnel where bees were directly exposed during application (treatment group 3), indicating a slight immediate contact toxicity of the test item to the bees exposed, but in a much lower extent compared to the toxic reference. When the application was performed without bees active on the crop (treatment group 4), no increase of mortality was observed. Even in treatment group 3, the mortality remained at a level where no adverse effects to the colony could arise. No effect on colony strength was found.

A slight repellent effect of the product was observed during 2 to 3 days following the application, in a greater extent in the tunnel where bees were directly exposed to the treatment. Foraging activity returned to a normal level after 4 days in both treatment groups.

Likewise, other endpoints were not negatively affected by the treatment which could pose a risk to the viability of bee colonies.

The application of Deltamethrin EC 100 to crops visited by bees at a rate of 0.075 L/ha (= 7.5 g a.s./ha) does not pose a risk to honeybees foraging during the application of the product.

Comments of zRMS:	<p>The summarised below semi-field study was performed in order to investigate effects of DLT+FPF EC 85 on bees following single application of the test item at 0.99 L product/ha application to bee-attractive crop <i>Phacelia tanacetifolia</i> at BBCH 60-61 (i.e. before the full flowering) without presence of bees, which were introduced to tunnels 10 days after application of the test item and 3 days before application of water control and reference item.</p> <p>The exposure period in the test item groups lasted 10 days, while bees in water control and reference item groups were exposed for 7 days.</p> <p>Observation of bee colonies included 2 brood cycles and was in line with current requirements.</p> <p>It is noted that the study was performed rather late in the season (application of the test item was carried out on 26th of July) resulting with the last brood assessment performed in the middle of September, i.e. at the time of the natural decline of the bee colony before wintering. This may add some uncertainty in the brood parameters investigated at the end of the test.</p> <p>It is noted that the test item was not applied in line with the intended use pattern (i.e. two applications at 2x0.75 or 2x0.5 L product/ha). However, in line with EPPO 170 indications, single application of the maximum label rate is deemed sufficient. Due to systemicity of flupyradifurone and potential migration of this compound from leaves to flowers, multiple applications would be more relevant for application during flowering and in bee presence, but in case of application 10 days before introduction of bees single application at exaggerated rate (0.99 L/ha used vs. intended max rate of 0.75 L/ha) is considered acceptable by the zRMS.</p> <p>The weather conditions were rather favourable during the study with some showers at 0.2-0.6 mm at 2, 3, 5, 6, 7, 8, 9 and 10 days after application of the test item.</p>
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	<p>Nevertheless, precipitation was very low and is not expected to significantly reduce the exposure. No precipitation was observed on the day of introduction of bees to test item tunnels and during the next 4 days. First significant rainfall at 12 mm was observed 4 days after application of water control and reference item (17 days after the test item application).</p> <p>The investigated parameters included bee mortality, foraging activity, behavioural abnormalities and condition of the colonies.</p> <p>It is noted that the first colony assessment in all test groups was performed on the day of application of the water control and toxic standard (no colony assessments in the test item groups directly after introduction of bees).</p> <p>Test item had no effects on mortality or foraging activity of the worker bees, which were at the level comparable with control groups. In contrast, significant effects on these both parameters were observed in the toxic reference groups.</p> <p>No effects of the test item were observed on colony strength measured as the number of bees in hives.</p> <p>Ideally, brood indices, compensation indices and brood termination rates should be calculated to provide objective quantitative data enabling evaluation of the effects on bee colonies and colony development. In the study report only information on coverage of combs with eggs, capped brood, supplies and maggots was available, but no numerical summary regarding these parameters was provided in order to aid comparison between test groups at particular observation intervals (e.g. mean number of brood cells at particular colony assessments). Therefore the Applicant is kindly requested to provide during the commenting period the respective numerical summary of the effects on colony development.</p> <p>Additional statistical analysis of effects on bee colonies in the below summarised tunnel test (Miles & Murakami, 2021, M-781941-01-1) has been provided by the Applicant during the commenting period and is summarised below under KCP 10.3.1.5/08.</p>
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Reference:	KCP 10.3.1.5/05
Title:	Assessment of side effects of deltamethrin + flupyradifurone EC085 on honey bees (<i>Apis mellifera</i> L.) under semi-field conditions - Tunnel test -
Report:	Taenzler, V.; 2017; 113331037; M-598914-01-1
Guideline(s):	OEPP/EPPO No. 170 (4)(2010) Regulation (EC) No. 1107/2009 Directive 2003-01 (Canada/PMRA) US EPA OCSPP Not Applicable
Deviations:	None
GLP/GEP:	yes
Acceptability:	The study as such is considered acceptable, but more detailed evaluation of results regarding bee colonies is required in order to aid derivation of the final conclusion. The additional statistical analyses were submitted by the Applicant and are presented below the summary of the tunnel study.
Duplication (if vertebrate study):	

Materials and methods

Test item

Deltamethrin + Flupyradifurone EC085: deltamethrin (AE F032640) 0.878 % w/w (10.15 g/L) (analytical); flupyradifurone (BYI 02960) 6.45 % w/w (74.53 g/L) (analytical); Supplier Batch No.: 2016-000815; Sample Description: FAR30066-00; Specification No.: 102000028562, density: 1.156 g/cm³.

Test Species

Honey bees (*Apis mellifera carnica* L.); small bee colonies, maintained according to normal beekeeping practice, containing 4-5 combs with honey, pollen and brood. The preliminary brood check indicated healthy colonies, with all brood stages present and a sufficient amount of pollen and honey to guarantee colony viability. The mean strength of the colonies per treatment group, one day before the application, was similar and ranged between 4444 and 5108 adult bees per colony.

Test Design

The test was conducted under forced/confined exposure conditions (tunnel), in order to assess potential effects of Deltamethrin + Flupyradifurone EC085 on honey bees and honey bee colonies under semi-field conditions. Four tunnels for each treatment group (14 m length × 5.0 m width × 2.5 m height) were set up on a ca. 40 m² plot of *Phacelia tanacetifolia* (2 × 20 m²).

Application scheme:

Four tunnels were treated with the test item at 0.99 L product/ha before full flowering of the crop (BBCH 60-61) and without honey bees present; four tunnels were treated with tap water (serving as controls) during full flowering of the crop (BBCH 65) and honey bees actively foraging on the crop;

four tunnels were treated with a reference item (Perfekthion EC (BAS 152 11 I), nominal 400 g/L dimethoate) during full flowering of the crop (BBCH 65) and honey bees actively foraging on the crop. One small bee colony was introduced to each tunnel, in the morning, at BBCH 65, three days before the application of the control (water) and the reference item. This corresponded to 10 days after the test item application before full flowering of the crop (BBCH 60-61) and honey bees actively foraging.

The confined exposure phase of the honey bees to the control (water) and reference item treated crop inside the tunnels was 7 days following the application day DA0* (during full flowering (BBCH 65) and honey bees actively foraging on the crop). The confined exposure phase of the honey bees to the test item-treated crop inside the tunnels started on the day when the honey bees were placed inside the tunnels (DA-3). Thus, exposure phase of the honey bees to the test item-treated crop was 10 days.

In the following, the point in time refers to the control and reference item application during full flowering (BBCH 65) and honey bees actively foraging on the crop (= DA0*).

Seven days after exposure following DA0, all honey bee colonies were removed from the tunnels to an area with no main flowering crops in the surroundings. The condition of the colonies were examined until day 42 following DA0.

*From now on DA0 (Day of Application 0)

For details see the following scheme.

Weather recordings	Start																												End
Application	A														B														
Colony assessments															x*														
Mortality, behav. abnormalities and foraging activity																													
Bees set-up																													
Bees removed																													
Experimental days	-13	-12																											
Date [2016]	26-Jul	27-Jul																											

A = test item application (BBCH 60-61), before full flowering and honey bees foraging on the crop

B = application of the control and reference item (BBCH 65)

* = first colony assessment performed before the application of the control and reference item

Test Parameters

Mortality of adult bees: 3 days before to 7 days after DA0;

Behavioural abnormalities: 3 days before to 7 days after DA0;

Foraging activity of the bees: 3 days before to 7 days after DA0;

Colony assessments including assessment of brood status (food stores, colony strength and hive populations): once before application of the control and reference item on DA0 and DA7, DA14, DA21,

DA28, DA35 and DA42 (= end of the trial).

Application Rates

Control: 400 L tap water/ha;

Test Item: 0.99 L product in 400 L water/ha corresponding to 1.14 kg product/ha and to 2.86 g product/L, considering a density of 1.156 g/mL according to Certificate of Analysis;

Reference Item: nominally 1.0 L Perfekthion EC in 400 L water/ha (corresponding to 2.50 mL/L or 2.68 g).

Test Conditions

Natural field conditions. On the day of the test item application (DA-13), the weather conditions were good and no rain occurred. First rain occurred 2 days after this application (0.4 mm) and afterwards, on day DA-10 and days DA-8 to DA-4.

On the day of the control and reference item application, the sky was cloudy but it was warm without precipitation. No rain occurred until day 2 (0.5 mm) following DA0. Afterwards, rain was recorded on days DA3 and DA4 (2.0 and 12.0 mm, respectively). During the exposure inside the tunnels, the mean temperature was between 12.0 and 20.0°C.

Results and discussions

Mortality of the adult bees (worker bees)

Pre-application phase (DA-3 to DA0):

After placing the honey bee hives inside the tunnels, bees in the test item treatment group were exposed to residues of the test item application. Following this exposure, mean mortality from DA-3 to DA-1 was not statistically significantly different compared to the water control (mean of 8.8 dead bees/colony/day in the test item group vs. mean of 7.7 dead bees/colony/day in the control group) (Student t-test, pairwise comparison to the control, one-sided greater, $\alpha = 0.05$).

Mean mortality during the pre-application phase in the reference item group was 5.8 dead bees/colony/day and not statistically significantly different to the control group (Student t-test, pairwise, two-sided, $\alpha = 0.05$).

Exposure phase (DA0 to DA7):

After the application of the control and reference item (DA0), mean mortality of adult bees in the test item treatment group was comparable to the control group (7.8 and 8.0 dead bees/colony/day in the control and the test item group, respectively). This was not statistically significantly different compared to the control (Student t-test, pairwise, one-sided greater, $\alpha = 0.05$).

An overall evaluation of the mean mortality levels of the exposure days from DA0 to DA7, resulted in no statistical significant differences 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 (DA0 to DA7) was 22.8 dead bees/colony/day whilst the average mortality in the test item group was 27.0 dead bees/colony/day, respectively.

In contrast, application of the reference item (dimethoate at a rate of 400 g/ha) resulted in a markedly increased number of dead bees found in the traps and on the gauze strips during the assessments performed after DA0 until DA7. Following the application, mortality in the reference item group increased up to ca. 27 × the mortality levels of the control group on day DA0. The average mortality during the exposure phase (DA0 to DA7) in the reference item group was statistically significantly increased, with a mean mortality of 94.9 dead bees/colony/day (Student t-test, pairwise comparison to the control, one-sided greater, $\alpha = 0.05$).

Foraging Activity

Pre-application phase (DA-3 to DA0):

The mean foraging activities from days DA-3 to DA-1 were comparable in all three treatment groups with 17.9, 18.9 and 17.6 bees/m²/day in the control, test item and reference item group, respectively. Therefore, no statistical differences were found between the test item compared to the control (Student t-test, pairwise, one-sided smaller, $\alpha = 0.05$) and between the reference item compared to the control (Student t-test, pairwise, two-sided, $\alpha = 0.05$).

Exposure phase (DA0 to DA7):

Overall, from DA0 to DA7, mean foraging activities in the test item group were comparable to the control values (16.5 bees/m²/day and 16.8 bees/m²/day, respectively), and thus not statistically significantly different (Student t-test, pairwise, one-sided smaller, $\alpha = 0.05$).

After application of the reference item (dimethoate), the foraging activity was statistically significantly reduced compared to the control group (Student t-test, pairwise, one-sided smaller, $\alpha = 0.05$). The overall daily mean foraging activity from DA0 to DA7 in the reference item group was 0.7 bees/m²/day.

Behavioural abnormalities

No behavioural abnormalities occurred in the test item treated group and in the control group at any assessment day. The reference item caused behavioural abnormalities (cramps, moribund and affected bees) for two days following the DA0.

Condition of the Colonies

The first brood check was performed on DA0, shortly before application of the control and the reference item. The assessment indicated healthy colonies, with all brood stages present, and a sufficient supply of nectar and pollen. The assessment period comprised two brood cycles until day 42 following DA0. During this period the proportions of the different brood stages (eggs, larvae, pupae) fluctuated according to a normal development pattern in both, the control and test item group, respectively. All queens in the colonies of the control and test item group were either directly observed or noticed as present (presence of eggs) during all colony assessments, as a clear sign of a healthy queen. Overall, no adverse effect of the test item on honey bee brood was observed throughout the study.

Colony Strength

The mean number of honey bees per colony in the control, test item and reference item group during the first colony strength assessment (DA0) was 4534 bees/colony in the control group, 5108 bees/colony in the test item group and 4444 bees/colony in the reference item group, respectively.

The colony strength in the test item group at the end of the assessment period (day 42) was not statistically significant different to the control colonies (Student t-test, pair-wise comparison to the control, one-sided smaller, $\alpha = 0.05$).

Table 9-4: Summarised mortality and foraging activity data of the honey bees

time ^a	Foraging activity						Mortality								
	water treated control	Test Item			Reference Item		water treated control		Test Item			Reference Item			
	mean number of bees per m ² ^b	mean number of bees per m ² ^b	statistics	mean number of bees per m ² ^b	statistics	total dead bees ^b	SD	total dead bees ^b	SD	statistics	total dead bees ^b	SD	statistics		
DA-3	10.9 ± 4.4	13.3 ± 4.7	-	13.6 ± 3.0	-	3.5 ± 2.9		2.3 ± 1.7	-		1.8 ± 1.0	-			
DA-2	21.3 ± 5.5	23.2 ± 6.8	-	20.3 ± 2.7	-	10.8 ± 4.8		11.8 ± 6.6	-		6.5 ± 3.3	-			
DA-1	21.4 ± 3.2	20.3 ± 10.5	-	19.0 ± 4.9	-	8.8 ± 6.9		12.5 ± 9.0	-		9.3 ± 4.1	-			
daily mean DA-3 to DA-1	17.9 ± 6.0	18.9 ± 5.1	n.s.	17.6 ± 3.5	n.s.	7.7 ± 3.7		8.8 ± 5.7	n.s.		5.8 ± 3.8	n.s.			
DA0 ha.	14.3 ± 1.5	14.8 ± 0.2	n.s.	14.3 ± 1.2	n.s.	9.3 ± 6.6		9.8 ± 6.4	n.s.		4.3 ± 3.6	n.s.			
mean DA0	12.1 ± 9.4	11.9 ± 8.0	n.s.	1.4 ± 0.8	*	7.8 ± 4.9		8.0 ± 6.2	n.s.		211.0 ± 49.1	*			
DA1	16.9 ± 4.6	15.6 ± 4.3	n.s.	0.0 ± 0.0	*	4.0 ± 1.4		6.5 ± 4.0	n.s.		227.0 ± 64.7	*			
DA2	4.5 ± 3.2	6.9 ± 4.8	n.s.	0.0 ± 0.0	*	9.3 ± 4.7		12.8 ± 6.4	n.s.		147.5 ± 55.6	*			
DA3	0.3 ± 0.5	1.0 ± 0.7	n.s.	0.0 ± 0.0	n.s.	9.3 ± 4.5		12.8 ± 13.1	n.s.		45.8 ± 22.1	*			
DA4	18.9 ± 1.2	18.1 ± 5.5	n.s.	0.3 ± 0.5	*	30.5 ± 16.6		41.3 ± 20.7	n.s.		26.8 ± 11.3	n.s.			
DA5	21.8 ± 4.4	22.3 ± 3.9	n.s.	0.8 ± 0.6	*	37.0 ± 16.5		36.8 ± 25.9	n.s.		17.3 ± 6.7	n.s.			
DA6	25.5 ± 3.2	25.2 ± 1.0	n.s.	1.8 ± 1.0	*	33.0 ± 20.6		43.5 ± 35.5	n.s.		58.3 ± 18.6	n.s.			
DA7	31.8 ± 1.7	33.1 ± 5.0	n.s.	1.4 ± 1.0	*	52.0 ± 22.9		54.3 ± 26.7	n.s.		25.5 ± 6.0	n.s.			
daily mean DA0 to DA7 a.a.	16.5 ± 10.5	16.8 ± 10.3	n.s.	0.7 ± 0.8	*	22.8 ± 17.6		27.0 ± 18.9	n.s.		94.9 ± 87.0	*			

Day of test item application (BBCH 60-61): July 26, 2016

Day of application of control and reference item group (BBCH 65): August 08, 2016 = DA0

^a DA-3 to DA-1 = days before application DA0; DA0 to DA7 = days after application DA0

^b mean values (rounded) of four tunnels per treatment group

b.a. = before application of control and reference item group

a.a. = after application of control and reference item group

n.s. = not statistically significant compared to the control; * = statistically significant compared to the control; "-" = no statistics were performed

statistics (foraging activity): Student t-test; pairwise; α = 0.05; before DA0: two-sided (control, reference item), one-sided smaller (test item); after DA0: one-sided smaller (control, test item),

statistics (mortality): Student t-test; pairwise; α = 0.05; before DA0: two-sided (control, reference item), one-sided greater (test item); after DA0: one-sided greater (control, test item, reference item)

Conclusion

In order to assess the potential risk of Deltamethrin + Flupyradifurone EC085 to honey bee colonies, honey bees were exposed under realistic but severe (forced) exposure conditions in a semi-field test (confinement in tunnels). The test item was applied at 0.99 L product in 400 L/ha (corresponding to 1.14 kg product/ha) once before full flowering (BBCH 60-61) of the surrogate crop *Phacelia tanacetifolia* and without honey bees present.

The control (tap water) and reference item applications (dimethoate) were conducted on the full flowering *Phacelia* crop (BBCH 65) and with honey bees actively foraging on the crop.

After exposure of the honey bee colonies to the test item-treated crop, overall no statistical significant difference in mortality compared to the control group was observed. Foraging activities of the bees in the test item-treated tunnels were comparable to the control group throughout the entire exposure time inside the tunnels.

No adverse effects on behaviour, colony strength as well as on queen survival were observed for the honey bee colonies exposed to the test-item treated surrogate crop. Based on the results of this study, it can be concluded that Deltamethrin + Flupyradifurone EC085 does not adversely affect honey bee behaviour, colony strength and queen survival when applied at a rate of 0.99 L product in 400 L/ha (corresponding to 1.14 kg product/ha) under the above described conditions.

Comments of zRMS:	<p>The detailed statistical analysis of the tunnel study by Taenzler (2017, M-598914-01-1) was performed using advanced statistical method GLMM and is agreed by the zRMS.</p> <p>Obtained results confirmed that application of DLT+FPF EC 85 at 0.99 L/ha before the full flowering of <i>Phacelia tanacetifolia</i> (BBCH 60-61) 10 days before introduction of bees had no significant effect on colony strength (defined as number of bees counted on the comb sides) or the total brood (defined as the sum of the numbers of closed brood cells, eggs and maggots).</p>
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	<p>It is noted that the brood indices, compensation indices and brood termination rates were not calculated, although in the comments to the study by Taenzler (2017) it was indicated that these parameters are most suitable to analyse effects of the test item on the bee colonies. Nevertheless, these parameters are calculated rather in the field studies and are only rarely available in the tunnel tests.</p> <p>Overall, the zRMS is of the opinion that results of the study by Taenzler (2017) may be used in support of authorisation of DLT+FPF EC 85. Conclusions from the risk assessment are presented in point 9.6 above.</p>
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Reference:	KCP 10.3.1.5/08
Title:	Sivanto Energy: A detailed evaluation of results obtained during colony assessments in the study by Taenzler (2017, M-598914-01-1)
Report:	Miles, M.; Murakami, L. 2021; BEES-211206; M-781941-01-1
Guideline(s):	None; statistical evaluation
Deviations:	None
GLP/GEP:	Not applicable
Acceptability:	Acceptable
Duplication (if vertebrate study):	Not applicable

Materials and methods

This study provides a detailed evaluation of the results obtained during colonies assessments in the study by Taenzler (2017, M-598914-01-1), i.e. colony strength (as presented by total number of bees) and total brood using advanced statistical methods.

Generalized Linear Mixed Models (GLMM) approach was selected as the most appropriate and powerful statistical method as they are able to incorporate multiple variables to explain the response in another variable. A full copy of the report (Hotopp, 2021) is included in the appendix.

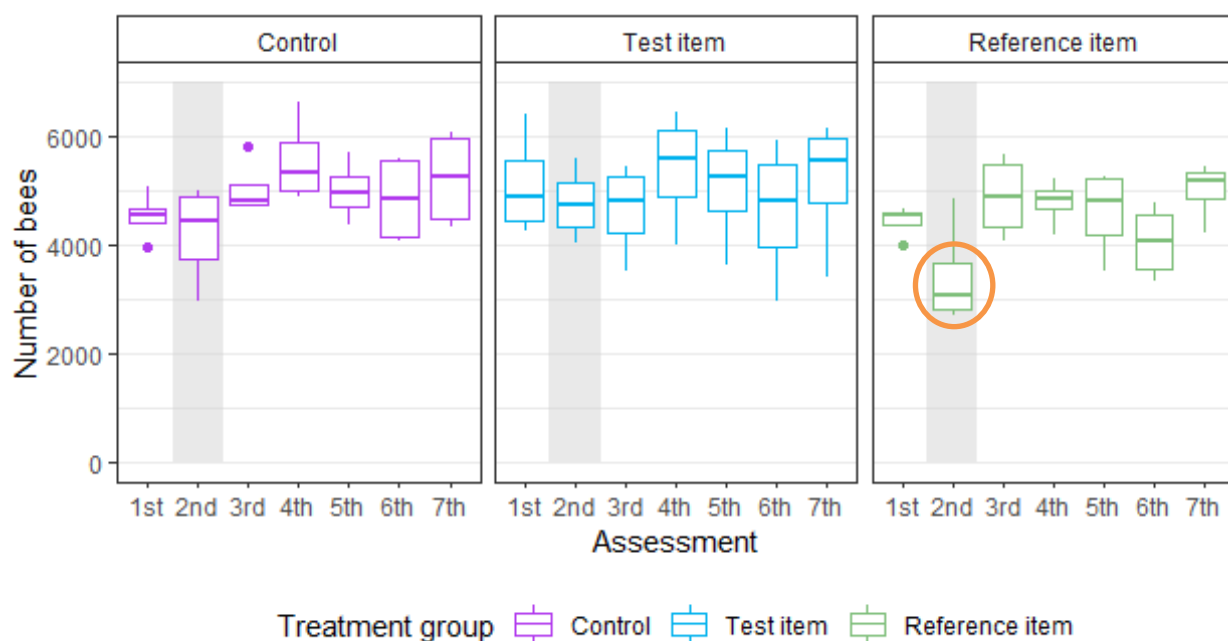
The raw data was evaluated GLMMs which is able to incorporate multiple variables to explain the response in another variable. The data analysis was carried out in R using the function `glmmTMB()` of the R package `glmmTMB` (see appendix). The analysis focused on colony strength and total brood.

Colony strength is defined as number of bees counted on the comb sides whereas total brood was calculated as the sum of the numbers of closed brood cells, eggs, and maggots (i.e. uncapped honey bee larva). The numbers of brood cells, eggs and uncapped larvae were calculated by multiplying the percentage of covered area per comb by nine and summing up the numbers per colony and assessment. The total brood was chosen for the analysis, as it is a better overall reflection of the colonies as they naturally go through different cycles of eggs, uncapped larvae and capped brood. The colony strength data is count data (non-negative integer numbers). The data was analysed using statistical models with a negative binomial family. This family was used to account for overdispersion in the data.

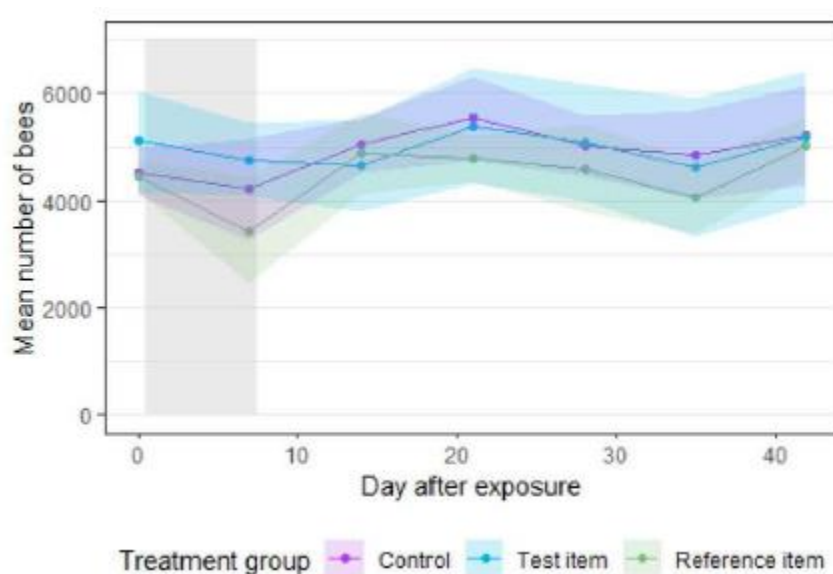
Results and discussions

Colony strength

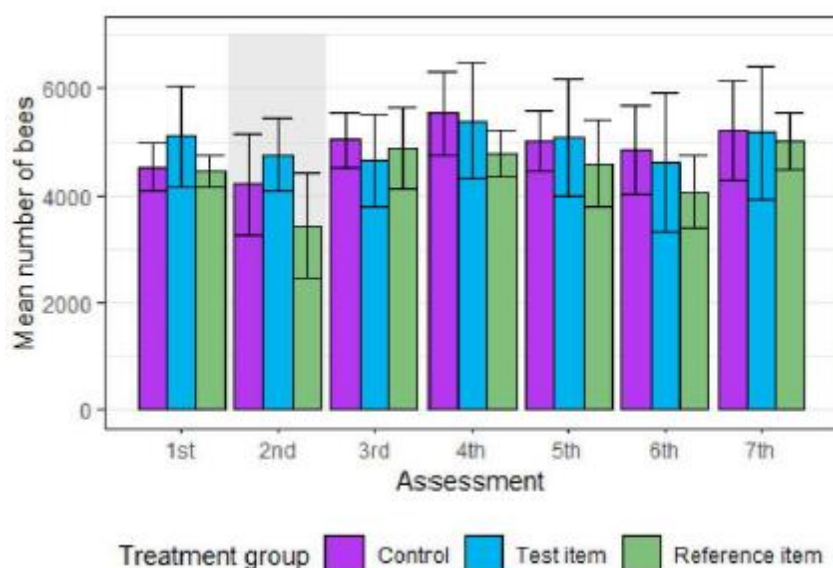
The visual inspection of the colony strength data of the individual colonies showed a normal variability of the colonies. In the statistical analysis a total of nine models were investigated to look at both random and fixed effects. The model output of the chosen model showed no significant differences (at the 0.05 level) of the test item and reference item groups compared to the control group on any of the assessment days. In the reference colonies on the second Assessment (DAE 7), a lower colony strength was observed compared to the controls with three of the four colonies showing a visible decrease following exposure to dimethoate (see circled data in figure below). However, this difference was not significant ($p = 0.06$).



Colony strength: Boxplot of the number of bees per assessment. The grey box indicates the exposure phase



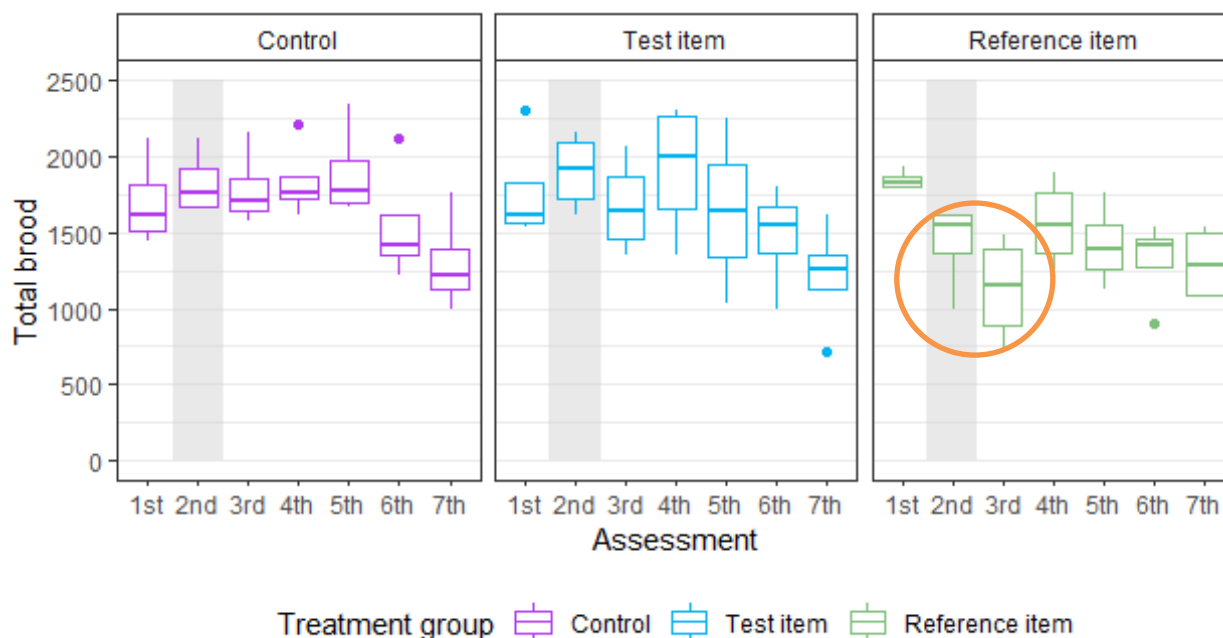
Colony strength: Mean number of bees per treatment over time. Coloured area indicates the standard deviation from the mean. The grey box indicates the exposure phase



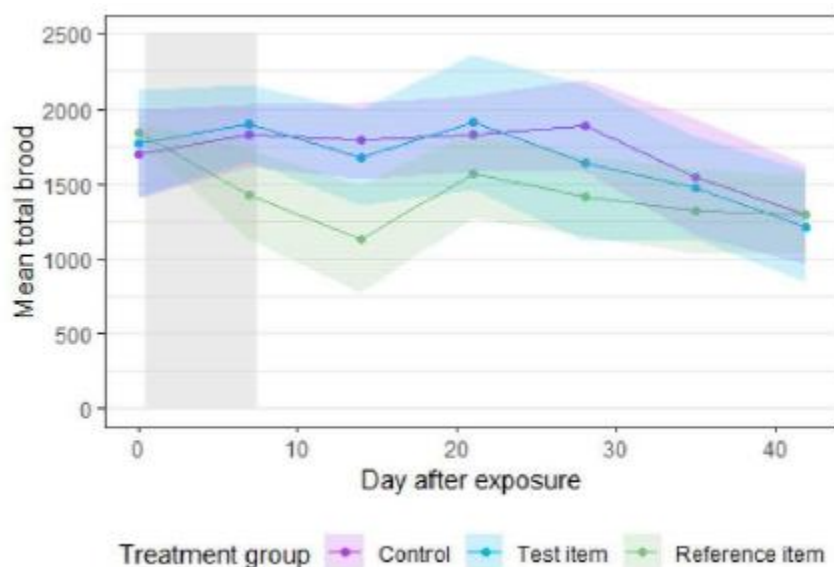
Colony strength: Mean number of bees per treatment at each assessment. Error bars indicate the standard deviation from the mean. The grey box indicates the exposure phase

Total brood

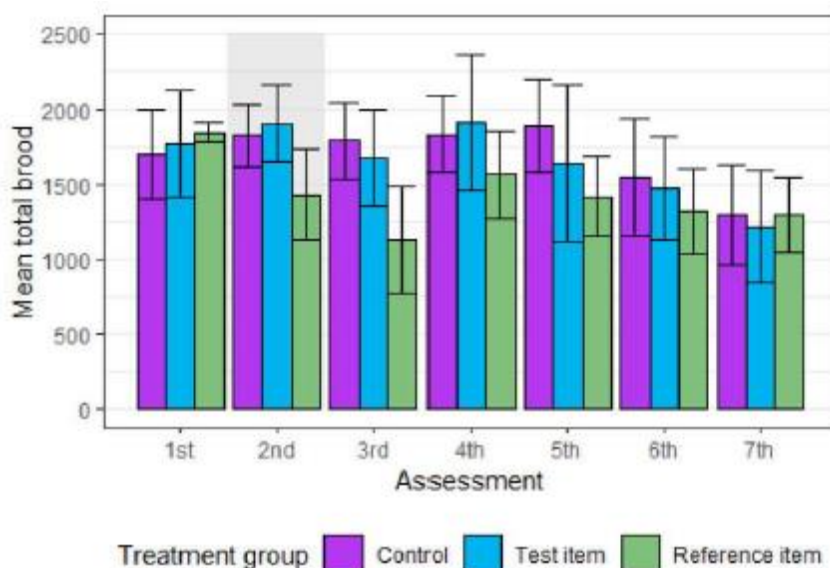
Brood development showed a similar development in test item and control group. Reference item colonies developed on a lower level after first exposure. In the statistical analysis a total of eight models were investigated to look at both random and fixed effects. The model output of the chosen model indicated no significant difference (at the 0.05 level) of the development of the total brood in the test item group compared to the control group. For the reference item group exposed to dimethoate, the development of the total brood over time differed significantly from the development in the control groups. Effects of dimethoate on total brood were particularly noticeable at the 2nd and 3rd assessment points (see circled data in figure below).



Total brood: Boxplot of the total brood per assessment. The grey box indicates the exposure phase



Total brood: Mean total brood per treatment over time. Coloured area indicates the standard deviation from the mean. The grey box indicates the exposure phase



Total brood: Mean total brood per treatment at each assessment. Error bars indicate the standard deviation from the mean. The grey box indicates the exposure phase

This detailed analysis shows that colony strength follows the same pattern as bee morality observed in the tunnels for the three treatments. No statistically significant treatment related effects were found for test item (DLT+FPF, EC85) and reference item (dimethoate) for colony strength. In the reference item treated colonies a lower colony strength was observed at the second assessment when compared to the controls with three of the four colonies showing a visible decrease, however, this difference was not significant ($p = 0.06$). Colonies exposed to dimethoate exhibited a marked increase in the number of dead bees found in the traps and on the gauze strips during the assessments performed after DA0 until DA7 which was statistically significant. Whereas the average control mortality of adult bees during the exposure phase (DA0 to DA7) was 22.8 dead bees/colony/day whilst the average mortality in the test item group was 27.0 dead bees/colony/day, respectively (not statistically significant). A similar pattern was noted for foraging activity with no difference between the foraging rate of bees in control and test item colonies but a strong reduction in foraging was noted in the dimethoate treated tunnels. For total brood data no treatment related effect was found for the test item, however the reference item

colonies differed significantly from the control colonies. The pattern of no effects on the colonies exposed in the test item treated tunnel is also reflected in the number of dead bees found in bee traps and on the gauze strips during the assessments and the observations made on foraging behaviour.

Conclusion

Using advanced statistical methods (GLMM) no statistically significant treatment related effects were found for test item (DLT+FPF, EC85) or reference item (dimethoate) for colony strength. In the reference item treated colonies a lower colony strength was observed at the second assessment when compared to the controls with three of the four colonies showing a visible decrease, however, this difference was not significant ($p = 0.06$). For total brood data no treatment related effect was found for the test item, however the reference item colonies differed significantly from the control colonies. The pattern of no effects on the colonies exposed in the test item treated tunnel is also reflected in the number of dead bees found in bee traps and on the gauze strips during the assessments and the observations made on foraging behaviour.

In conclusion, no treatment related effect of the test item was indicated for colony strength and total brood based on a detailed evaluation of results obtained in the study by Taenzler (2017, M-598914-01-1).

Comments of zRMS:	<p>In general, the field and semi-field studies should be performed with the formulation in question with application regime being in line with the intended use pattern. This is particularly important in case of formulations containing more than one active compound due to possibility for synergistic effects.</p> <p>Since the study summarised below was performed with the solo formulation of deltamethrin, it is considered not relevant for the risk assessment performed for DLT+FPF EC 85, which contains two substances with supplementary mode of action: deltamethrin and flupyradifurone, which act through different pathways: deltamethrin is a non-systemic “knock-out” insecticide extremely disturbing the nervous system by blocking the sodium channel and flupyradifurone is a systemic insecticide interacting with insect nicotinic acetylcholine receptors, similar to neonicotinoids. Taking this into account it cannot be excluded that the impact of the mixture on bees may be enhanced comparing to individual compounds and it is thus not possible to predict effects of simultaneous exposure of bees to both active compounds based on semi-field/field studies performed with single active compounds, even when applied at higher rates. For this reason the semi-field and field tests should be performed with formulation under evaluation in order to account for effects resulting from simultaneous exposure to both active compounds.</p> <p>The study below was not validated by the zRMS as being not relevant for the risk assessment and its summary is struck through below.</p>
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Reference:	KCP 10.3.1.5/03
Title:	Assessment of side effects of AE F032640 00 EC02 A804 on the honey bee (<i>Apis mellifera</i> L.) in the semi-field
Report:	Schur, A.; 2001; C011205; M-200402-01-1
Guideline(s):	EPPO: 170
Deviations:	--
GLP/GEP:	yes
Acceptability:	Not validated, not relevant for the risk assessment for DLT+FPF EC 85
Duplication (if vertebrate study):	

Materials and methods

The side effects of the test substance AE F032640 00 EC02 A804 were tested on the honey bee (*Apis mellifera* L.) under semi field conditions according to the guideline of the European and Mediterranean Plant Protection Organization No. 170 (EPPO, 1992). The test substance AE F032640 00 EC02 A804 was applied at an application rate of 7.5 g a.i./ha in 300 L water/ha. Plots treated with tap water served as control. As toxic standard, Hostathion 40 EC was applied at a concentration of 0.6 L/ha in 300 L water/ha. The effect of the test substance was examined on small bee colonies in cages placed over plots with flowering *Phacelia tanacetifolia* Benth.

The influence of AE F032640 00 EC02 A804 was evaluated by comparing the effect of the test substance treatment group to the effect of the control group and toxic standard group regarding the following observations:

- Mortality at the edge of the treated area and in the bee traps
- Foraging activity (number of forager bees/m²-flowering *Phacelia* crop)
- Behaviour of the bees on the crop and around the hive
- Development of the bee brood

Results and Conclusion

Effect on honey bee mortality:

The application of the test substance AE F032640 00 EC02 A804 resulted in an increase of the mortality restricted to the day of application DAA 0aa (133.7 dead bees/colony) which was determined to be not significantly different to the control (74.3 dead bees/colony). A drastically increase of mortality was observed after application of the toxic standard with an average of 533.7 dead bees/colony. The effect of the toxic standard demonstrated the sensitivity of the method in detecting the toxic effects of a pesticide. When comparing the average pre application mortality and the average postapplication mortality utilising $Q_{M(average)}$ (average post application mortality divided by the average pre application mortality) no increase of mortality occurred after application of the test substance AE F032640 00 EC02 A804. The values for $Q_{M(average)}$ were calculated as 1.0 in the test substance treatment group and 0.7 in the control group. The value for $Q_{M(average)}$ in the toxic standard treatment was determined as 4.6.

Effects on honey bee flight intensity:

In the AE F032640 00 EC02 A804 treatment group an obvious repellent effect occurred directly after application assumed by the behaviour of the bees and confirmed due to the flight intensity (9.2 bees/m²) on this day which remained significantly below the level of the control group (23.2 bees/m²). The significantly reduced flight intensity in the AE F032640 00 EC02 A804 treatment group and in the toxic standard treatment lasted until evaluation day DAA1. Compared with the pre application period the average daily post application level of flight intensity was lower in the test substance treatment group AE F032640 00 EC02 A804 and in the toxic standard treatment but higher in the control group.

Effects on honey bee brood development:

Regarding the colonies strength and the bee brood development no abnormal differences attributable to the influence of the test substance were observed between the test substance groups and control.

Comments of zRMS:	<p>In general, the field and semi-field studies should be performed with the formulation in question with application regime being in line with the intended use pattern. This is particularly important in case of formulations containing more than one active compound due to possibility for synergistic effects.</p> <p>Since the study summarised below was performed with the solo formulation of deltamethrin, it is considered not relevant for the risk assessment performed for</p>
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	<p>DLT+FPF EC 85, which contains two substances with supplementary mode of action: deltamethrin and flupyradifurone, which act through different pathways: deltamethrin is a non-systemic “knock-out” insecticide extremely disturbing the nervous system by blocking the sodium channel and flupyradifurone is a systemic insecticide interacting with insect nicotinic acetylcholine receptors, similar to neonicotinoids. Taking this into account it cannot be excluded that the impact of the mixture on bumblebees may be enhanced comparing to individual compounds and it is thus not possible to predict effects of simultaneous exposure of bumblebees to both active compounds based on semi-field/field studies performed with single active compounds, even when applied at higher rates. For this reason the semi-field and field tests should be performed with formulation under evaluation in order to account for effects resulting from simultaneous exposure to both active compounds.</p> <p>The study below was not validated by the zRMS as being not relevant for the risk assessment and its summary is struck through below.</p> <p>Please note also that currently evaluation of effects on bumblebees is not mandatory.</p>
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Reference:	KCP 10.3.1.5/06
Title:	Impact on bumblebees (insectproof tunnels on phacelia crop) Code: AE F032640 00 EW01 B106
Report:	Giffard, H.; 2000; C011021; M-200040-01-1
Guideline(s):	--
Deviations:	--
GLP/GEP:	yes
Acceptability:	Not validated, not relevant for the risk assessment for DLT+FPF EC 85. In addition to that, evaluation of effects on bumblebees is currently not mandatory.
Duplication (if vertebrate study):	

Materials and methods

Test item: Deltamethrin EW 15 G (AE F032640 00 EG06 A107), content of a.s.: deltamethrin: 1.51 % w/w (15.0 g a.s./L nominal), density: 1.023 g/ml.

Test design: The aim of the study was to evaluate potential side effects of a spray application of Deltamethrin EW 15 G on the bumblebees (*Bombus terrestris*) under forced exposure conditions. The study included three exposure groups (tunnels) with one replicate (tunnel) each: one water treated control group, one test item group and one reference item group. Two bumblebee boxhives were introduced into each elementary unit 6 days before product applications in order to enable the colonies to adapt to their environment. Bumblebee colonies were submitted to test substances while foraging on sprayed crops.

Mortality in each tunnel unit was recorded on a daily basis for all areas covered with plastic film, from days 5DBT to 7DAT. Moreover, the day on which product application was carried out (day 0) additional counts were done at the end of the day (0DAT) in order to establish possible brutal intoxication of foraging bumblebees. The total mortality rate recorded in a tunnel unit for a given day results from adding up mortality rates observed in each of the plastic rows in the unit.

Foraging was observed from 2DBT to 3DAT, on all treated and sheltered areas. It was possible to adapt the time of counting to the environment of the trial and to active foraging periods. Counts could be shifted if activity was not considered satisfying (late activity due to morning mist or disturbed by rainfall...etc.) This parameter was also taken into account for an additional count on the day of treatment, during the hour following product application.

Observations on behaviour were carried out during the trial in order to better understand the incidence of pesticide application on bumblebee behaviour. But these observations appeared especially important

on the day the products were applied. On this time and during the thirty minutes following product application, bumblebee reactions and behaviour in each of the tunnels were observed (intense flying, clusters on the net or at the entrance of the box hive, aggressiveness, beginning of an intoxication etc.). In general, this observation phase continued all over the day, between counts, and results were compared to usual activities before product application.

Results and discussions

Mortality:

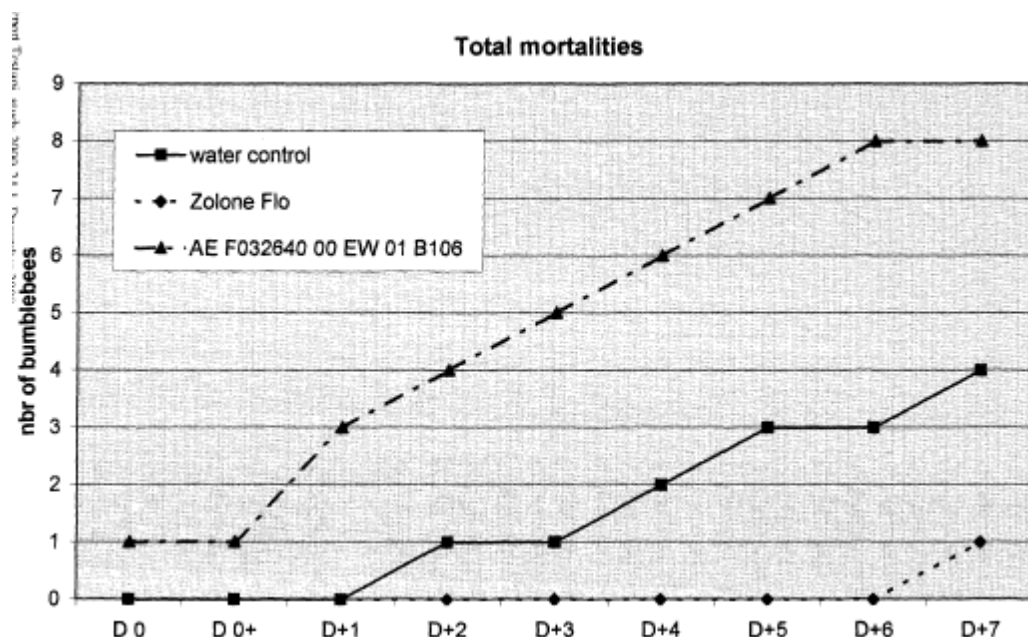
A summary of the daily mortality and total mortality results are shown in the following tables.

Daily mortality data

Total	Deltamethrin EW 15 at 12.5 g a.s./ha	Zolone Flo	Water control
5DBT 23 th August	1	0	0
4DBT 24 th August	1	1	0
3DBT 25 th August	0	2	0
2DBT 26 th August	1	0	0
1DBT 27 th August	0	0	2
0DBT 28 th August	1	0	0
0DAT 28 th August	0	0	0
1DAT 29 th August	2	0	0
2DAT 30 th August	1	0	1
3DAT 31 st August	1	0	0
4DAT 1 st September	1	0	1
5DAT 2 nd September	1	0	1
6DAT 3 rd September	1	0	0
7DAT 4 th September	0	1	1

DBT: days before treatment

DAT: days after treatment



Total mortalities for the reference group (Zolone Flo), Deltamethrin EW 15 (AEF032640 00 EW01 B106) at 12.5 g a.s./ha and for the water-control group

D0: 0 days before treatment

D0+: 0 days after treatment

D+1 to D+7: 1 to 7 days after treatment

Daily mortality did not increase in any modality after treatment. Only one or two individuals were collected a day in Deltamethrin EW 15 G modality. However the difference occurred while there was absolutely no mortality in the reference modality. In the control tunnel (treated with water) the colony

was no more disturbed by the treatment. Mortality rates recorded varied very few along the week.

Only total mortalities seemed dissimilar after seven days post treatment as the graph shows. In this graph curves were therefore all increasing, records were taken into account from days of application (day 0) in order to understand the impact of product applications.

Foraging:

In the morning of the product application day, foraging was already quite active in the 3 modalities and quite similar one another. The level of this foraging activity was again 3 to 6 bumblebees per m². During the three counts that followed product application, mean foraging trends were a bit different between modalities. In fact, foraging activity remained stable in the reference modality where spraying did not disturb the foragers' activity. However, in the unit where Deltamethrin EW 15 formulation was applied the activity decreases a few but didn't stop and the average level in the afternoon was therefore over 5 bumblebees per metre square. The bumblebee colony in the water control modality seemed indifferent to water application and foraging increased during the day over pre-treatment phase level.

Colony behaviour:

In such a test, with homogeneous bumblebee colonies, behaviour was also comparable between modalities, as foraging was quite regular on phacelia plots. Bumblebee foragers only showed little reaction to treatments in the different modalities. The volume of a unit modality represented sufficient flight space but it was nevertheless confined and colonies adapt to this environment after the first recordings.

From the beginning of this experimental phase, plots were very attractive for foragers and this triggers activity of bumblebees within box hives. During spraying, the bumblebees present on the experimental plot when the boom passes flight away over treated plot. Generally they come back again a little further away. Experimentators did not notice neither any particular aggressiveness nor any frenetic bumblng.

Conclusion

Overall conditions for conducting this experimental phase of the scheme were favourable to bumblebee activity. Climatic and crop conditions were satisfactory. The different parameters observed agree with the results obtained.

Experimental conditions of the study were quite strict, including confinement and product application carried out during intense foraging activity, on attractive plots.

The use of any phyto-pharmaceutical substance did not give any high mortality stage.

The effects of the test substance Deltamethrin EW 15 in the case of this trial on a phacelia crop, only showed a temporary decrease in foraging, and no impact on daily mortality.

Comments of zRMS:	<p>In general, the field and semi-field studies should be performed with the formulation in question with application regime being in line with the intended use pattern. This is particularly important in case of formulations containing more than one active compound due to possibility for synergistic effects.</p> <p>Since the study summarised below was performed with the solo formulation of deltamethrin, it is considered not relevant for the risk assessment performed for DLT+FPF EC 85, which contains two substances with supplementary mode of action: deltamethrin and flupyradifurone, which act through different pathways: deltamethrin is a non-systemic “knock-out” insecticide extremely disturbing the nervous system by blocking the sodium channel and flupyradifurone is a systemic insecticide interacting with insect nicotinic acetylcholine receptors, similar to neonicotinoids. Taking this into account it cannot be excluded that the impact of the mixture on bumblebees may be enhanced comparing to individual compounds and it is thus not possible to predict</p>
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	<p>effects of simultaneous exposure of bumblebees to both active compounds based on semi-field/field studies performed with single active compounds, even when applied at higher rates. For this reason the semi-field and field tests should be performed with formulation under evaluation in order to account for effects resulting from simultaneous exposure to both active compounds.</p> <p>The study below was not validated by the zRMS as being not relevant for the risk assessment and its summary is struck through below.</p> <p>Please note also that currently evaluation of effects on bumblebees is not mandatory.</p>
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Reference:	KCP 10.3.1.5/07
Title:	Impact on bumblebees (<i>Bombus terrestris</i>) (insectproof tunnels on phacelia crop) Code: AE F032640 00 EG0G06 A107
Report:	Giffard, H.; 2000; C011023; M-200043-01-1
Guideline(s):	--
Deviations:	--
GLP/GEP:	yes
Acceptability:	Not validated, not relevant for the risk assessment for DLT+FPF EC 85. In addition to that, evaluation of effects on bumblebees is currently not mandatory.
Duplication (if vertebrate study):	

Materials and methods

Test item: Deltamethrin EG-6.25 W (AE F032640-00 EG06 A107), 6.14 % w/w (62.5 g a.s./kg nominal).

Test design: The effects of Deltamethrin EG-6.25 W were tested on the bumblebees (*Bombus terrestris*) under confined semi-field conditions by following the guidance document C.E.B. method no. 129. The aim of the study was to evaluate potential side effects of a spray application of Deltamethrin EG-6.25 W on the bumblebees (*Bombus terrestris*) under forced exposure conditions. This study included three exposure groups (tunnels) each: one water treated control group, one test item group and one reference item group. Bumblebee colonies were submitted to test substances while foraging on sprayed crops. The bee colonies were confined in tunnel parts. Two bumblebee boxhives were introduced into each elementary unit 6 days before product applications in order to enable the colonies to adapt to their environment.

Mortality in each tunnel unit was recorded on a daily basis for all areas covered with plastic film, from 5 days before treatment (5DBT) to 7 days after treatment (7DAT). Moreover, the day on which product application was carried out (day 0) additional counts were done at the end of the day (0DAT) in order to establish possible brutal intoxication of foraging bumblebees. The total mortality rate recorded in a tunnel unit for a given day resulted from adding up mortality rates observed in each of the plastic rows in the unit.

Foraging was observed from 2DBT to 3DAT, on all treated and sheltered (untreated) areas. It was possible to adapt the time of counting to the environment of the trial and to active foraging periods. Counts could be shifted if activity was not considered satisfying (late activity due to morning mist or disturbed by rainfall...etc.). This parameter was also taken into account for an additional count on 0DAT, during the hour following product application.

Observations on behaviour were carried out during the trial in order to better understand the incidence of pesticide application on bumblebee behaviour. But these observations appeared especially important on the day the products were applied. On this time and during the thirty minutes following product application, bumblebee reactions and behaviour in each of the tunnels were observed (intense flying, clusters on the net or at the entrance of the box hive, aggressiveness, beginning of intoxication...). In general, this observation phase continued all over the day, between counts, and results were compared to usual activities before product application.

The influence of the test item was evaluated by comparing the results obtained in the test item treatment

group to those of the control and the reference item group.

Results and discussions

Mortality

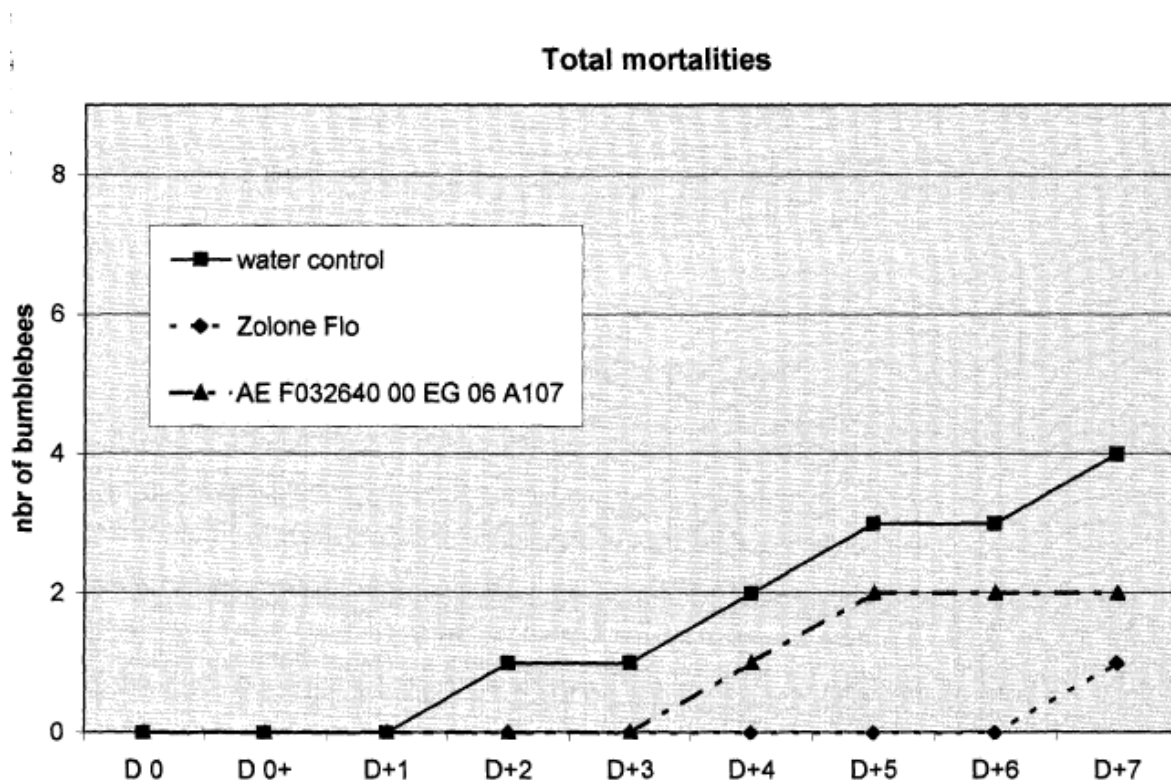
A summary of the daily mortality and total mortality results are shown in the following table.

Daily mortality data

Total	Deltamethrin-EG 6.25 at 0.2 kg a.s./ha	Zolone Flo	Water control
5DBT—23 th August	0	0	0
4DBT—24 th August	0	+	0
3DBT—25 th August	+	±	0
2DBT—26 th August	0	0	0
1DBT—27 th August	+	0	±
0DBT—28 th August	0	0	0
0DAT—28 th August	0	0	0
1DAT—29 th August	0	0	0
2DAT—30 th August	0	0	±
3DAT—31 st August	0	0	0
4DAT—1 st September	±	0	±
5DAT—2 nd September	±	0	±
6DAT—3 rd September	0	0	0
7DAT—4 th September	0	±	±

DBT: days before treatment

DAT: days after treatment



Total mortalities: Deltamethrin EG 6.25 W (AE F032640 00 EG06 A107) at 0.2 kg a.s./ha, reference item (Zolone flo) and the water control

D0: 0 days before treatment

D0+: 0 days after treatment

D+1 to D+6: 1 to 7 days after treatment

Daily mortality did not increase in any tunnel after treatment. Only one individual was collected per day

in the Deltamethrin EG 6.25 tunnel at 4DAT and 5DAT. It was the same as in the reference tunnel where there was no higher mortality. In the control unit (treated with water) the colony was not more disturbed than the Deltamethrin EG 6.25 treatment. Mortality rates recorded varied very few along the week. Looking to total mortalities, curves were similar seven days after treatment (7DAT) in both study item and water control as the graph showed. After a week total mortalities contained between 1 and 4 individuals that meant no impact.

Therefore all the graph curves of the mortalities were increasing: Records were taken into account from the day of application (0DAT) in order to understand the impact of product applications.

There was no toxic reference which might have provided an eventual higher mortality, so Deltamethrin EG 6.25 as well as Zolone Flo was considered as neutral on bumblebees, with data closed to the untreated water control.

Foraging activity

On day of the product application (day 0), in the morning before treatment (ODBT), foraging was already quite active in the 3 treatment groups and quite similar. The level of this foraging activity was about 3 to 5 bumblebees per m² again.

During the three counts that followed product application, mean foraging trends were a bit different between treatment groups. In fact, foraging activity remained stable in the reference treatment groups where spraying did not disturb the foragers' activity. However, in the unit where Deltamethrin EG 6.25 formulation was applied the activity remained stable as in the untreated treatment groups, and the average level in the afternoon was therefore above 5 bumblebees per metre square. On the same way, the bumblebee colony in the water control treatment groups seemed indifferent to water application and foraging increased during the day over pre-treatment phase level.

On the following day (1DAT) foragers' activity decreased in the Deltamethrin EG 6.25 treatment, between 3 and 4 bumblebees per m², a medium level between the water control and the standard. Foraging activity decreased too, but slowly in the water control modality, staying over the pre application activity level for the next 2 days. In the modality where the reference item was used this activity did not move and stayed at approximately the same level the day before.

Shortly after product application (0DAT, during the thirty minutes following product application), a repulsive effect was observed in the Deltamethrin EG 6.25 tunnel. The decrease in foraging activity affected both treated and non-treated areas. This confirmed the short term impact of Deltamethrin EG 6.25 on foraging activity on average on the treatment day. On the contrary, the water control modality showed increasing activity on both sheltered and treated areas, this explained the level over 100 %, while foraging remained stable shortly after treatment in the standard phosalone treatment.

Colony behaviour

In such a test, with homogeneous bumblebee colonies, behaviour was also comparable between the treatment groups, as foraging was quite regular on phacelia plots. Bumblebee foragers only showed little reaction to treatments in the different treatment groups. The volume of a unit treatment group represented sufficient flight space but it was nevertheless confined and colonies adapted to this environment after the first recordings.

From the beginning of this experimental phase, plots were very attractive for foragers and this triggers activity of bumblebees within box hives. During spraying, the bumblebees presented on the experimental plot when the boom passed flew away over treated plot. Generally they came back again a little further away. Experimentators noticed neither any particular aggressiveness nor any frenetic bumbling.

Conclusion

Overall conditions for conducting this experimental phase of the scheme were favourable to bumblebee activity. Climatic and crop conditions were satisfactory. The different parameters observed agreed with obtained data.

~~Experimental conditions of the study were quite strict, including confinement and product application carried out during intense foraging activity, on attractive plots.~~

~~The use of any phyto-pharmaceutical substance did not give any high mortality stage.
The effects of the test substance Deltamethrin EG 6.25 in the case of this trial on a phacelia crop, only showed a temporary decrease in foraging, but no impact on mortality.~~

A 2.3.1.6 KCP 10.3.1.6 Field tests with honeybees

Comments of zRMS:	<p>In general, the field and semi-field studies should be performed with the formulation in question with application regime being in line with the intended use pattern. This is particularly important in case of formulations containing more than one active compound due to possibility for synergistic effects.</p> <p>Since the study summarised below was performed with the solo formulation of deltamethrin, it is considered not relevant for the risk assessment performed for DLT+FPF EC 85, which contains two substances with supplementary mode of action: deltamethrin and flupyradifurone, which act through different pathways: deltamethrin is a non-systemic “knock-out” insecticide extremely disturbing the nervous system by blocking the sodium channel and flupyradifurone is a systemic insecticide interacting with insect nicotinic acetylcholine receptors, similar to neonicotinoids. Taking this into account it cannot be excluded that the impact of the mixture on bees may be enhanced comparing to individual compounds and it is thus not possible to predict effects of simultaneous exposure of bees to both active compounds based on semi-field/field studies performed with single active compounds, even when applied at higher rates. For this reason the semi-field and field tests should be performed with formulation under evaluation in order to account for effects resulting from simultaneous exposure to both active compounds.</p> <p>The study below was not validated by the zRMS as being not relevant for the risk assessment and its summary is struck through below.</p>
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Reference:	KCP 10.3.1.6/01
Title:	Assessment of side effects on the honeybee (<i>Apis mellifera</i> L.), exposed to <i>Phacelia tanacetifolia</i> , sprayed sequentially with deltamethrin during flowering in a long-term field study in North Alsace, France
Report:	Rexer, H. U.; 2013; S10-03820; M-452717-01-1
Guideline(s):	OEPP/EPPO Guideline No. 170 (4) (2010), SANCO/3029/99 rev. 4
Deviations:	not specified
GLP/GEP:	yes
Acceptability:	Not validated, not relevant for the risk assessment for DLT+FPF EC 85
Duplication (if vertebrate study):	

Materials and methods

Test item: Deltamethrin EW 15B-G (spray application product, Batch ID: 2011-002948)

Test organism: *Apis mellifera* L. (Hymenoptera, Apidae), provided by EAS EcoChem GmbH, Niefern, Germany

Crop used for field study: *Phacelia tanacetifolia*

Study dates / location: June 2011 – March 2012, near Quatzenheim and Osthoffen, France (region: Alsace)

Description field plots: The size of the field plots were approx. 2.11 ha (test item treatment field) and approx. 2.23 ha (control field). The field plots were separated by 4.28 km in order to minimise the chance of the bees from T visiting the field plot of C or vice versa.

The colonies were placed at the field sites early in the morning on 15 Jun 2011 at early to full flowering of *P. tanacetifolia* (C: BBCH 63-64, T: BBCH 64).

Treatments:

- Test item group T: Two applications of test item Deltamethrin EW 15B-G (target application rate: 2 x 12.5 g a.s./ha, spray interval 13 days). The applications were performed during flowering of *P. tanacetifolia*. The first application was carried out after set up of the honeybee colonies at the test fields during flowering of *P. tanacetifolia* on 21 Jun 2011 (BBCH 65). The 2nd application was performed on flowering *P. tanacetifolia* on 04 Jul 2011 (BBCH 65-67). The applications were carried out during honeybee flight. The actual application rate was 13.5 g

a.s./ha (1st application) and 13.4 g a.s./ha (2nd application) in the test item group.

- Untreated control C: No application was performed on the corresponding control field plot (C).

Assessments

The effects of honeybee exposure to Deltamethrin EW 15B-G treated *Phacelia tanacetifolia* flowers were examined on six commercial honeybee colonies placed at each test field.

The influence of Deltamethrin EW 15B-G was evaluated by comparing the results of the test item group to the data of the control regarding the following observations:

- Total and mean number of dead honeybees
- Flight intensity
- Behaviour of bees in the crop and around hives
- Condition of colonies (number of bees (colony strength), mean values of the different brood stages per colony and assessment date)
- Colony health (bee diseases, bee viruses)
- Residue analysis

Seven days before the first application, the first colony assessment was performed, which included an assessment of the colony strength and the brood and food status. Pollen, nectar and wax from combs, honeybees (for disease and virus analysis), as well as nectar for AFB analysis were sampled on the same day.

At the end of the flowering period at BBCH 69, the honeybee colonies were relocated to a monitoring site without extensive agricultural crops attractive to bees. Here colony health and strength were assessed. Pollen, nectar and bee wax from combs were collected for residue analysis until 22 Mar 2012. Samplings of honeybees for disease and virus analysis and nectar for AFB analysis were performed twice after relocation of the colonies to the monitoring site.

Results and discussions

Mortality and Flight Intensity

Summary of Effects on Honeybees during the Exposure Phase of the Study

Treatment group		Control (C)	Test item treatment (T)
Daily mean mortality (dead bees/colony) ±STD	Pre application 1 (5DBA1 to 0DBA1)	24.1 ± 12.8	29.5 ± 31.0
	Post application 1 (0DAA1 to 0DBA2)	18.9 ± 32.3	10.1 ± 16.2
	Post application 2 (0DAA2 to 17DAA2)	8.4 ± 9.6	7.7 ± 10.0
	Post application total (5DBA1 to 17DAA2)	13.0 ± 23.1	8.7 ± 13.1
Daily mean flight intensity (bees/m ²) ±STD	Pre application 1 (5DBA1 to 0DBA1)	3.1 ± 3.1	6.0 ± 5.8
	Post application 1 (0DAA1 to 0DBA2)	4.1 ± 2.8	7.6 ± 4.2
	Post application 2 (0DAA2 to 17DAA2)	2.1 ± 2.0	2.5 ± 2.7
	Post application total (5DBA1 to 17DAA2)	3.0 ± 2.6	4.8 ± 4.2

DBAn: days before application (number n); DAAAn: days after application (number n)

Mortality of Honeybees

Pre application phase (5DBA1 to 0DBA1): mortality in test item group slightly higher (mean value: 29.5 dead bees/colony/day) than in control (mean value: 24.1 dead bees/colony/day), but still in the same range for both treatment groups.

After first application of test item:

0DAA1: mean mortality in T (26.2 dead bees/colony/day) moderately higher than in control (8.8 dead bees/colony/day) but still below the mean pre application mortality in T.

1DAA1: mean mortality in T (11.8 dead bees/colony/day) declined to about the mortality level of control (7.0 dead bees/colony/day).

Entire post application phase after the 1st application and before the 2nd application (0DAA1 to 0DBA2): mean number of dead bees slightly lower in test item group (10.1 dead bees/colony/day) than in control (18.9 dead bees/colony/day). Mean mortality levels in both treatment groups during this period below the pre application mortalities.

Calculated mortality quotients during this period: 0.8 in C and 0.3 in T.

After second application of test item:

0DAA2: mean mortality in T (28.3 dead bees/colony/day) was higher than in control (10.0 dead bees/colony/day) but still below mean pre application mortality in T.

1DAA1: mean mortality in T (9.0 dead bees/colony/day) declined to mortality level of control (9.2 dead bees/colony/day).

Entire post application phase after the 2nd application (0DDA2 to 17DAA2):

mean number of dead bees slightly lower in test item group (7.7 dead bees/colony/day) than in control (8.4 dead bees/colony/day). Mean mortality levels in both treatment groups during this period were below the pre application mortalities.

Calculated mortality quotients during this period: 0.4 in C and 0.3 in T.

Entire post application phase (0DAA1 to 17DAA2): mortality 13.0 dead bees/colony/day in control and 8.7 dead bees/colony/day in test item group. Calculated mortality quotients for this period: 0.5 in C and 0.3 in T.

Mortality assessment within the crop area:

On linen sheets spread out within the crop area in the test fields, 1.8 dead bees/day were found in the test item field compared to 1.7 dead bees/day in the control during the entire post application phase (0DAA1 to 17DAA2). No notable differences between control and test item group were observed. Thus, no test item related adverse effects on mortality were observed.

Flight Intensity

Pre application phase (5DBA1 to 0DBA1): mean flight intensity in the test fields lower in control than in treatment (3.1 bees/m²/day in C compared to 6.0 bees/m²/day in T).

After first application of test item:

0DAA1: mean flight intensity amounted to 6.4 bees/m²/day in C compared to 4.8 bees/m²/day in T.

1DAA1: mean flight intensity 3.6 bees/m²/day in C compared to 7.5 bees/m²/day in T.

Entire post application phase after the 1st application and before the 2nd application (0DAA1 to 0DBA2): mean flight intensity 4.1 bees/m²/day in C compared to 7.6 bees/m²/day in T. No notable differences between control and test item treatment group observed during this period.

After second application of test item:

0DAA2: mean flight intensity amounted to 5.5 bees/m²/day in C compared to 3.0 bees/m²/day in T.

1DAA2: mean flight intensity was 4.3 bees/m²/day in C compared to 8.2 bees/m²/day in T.

Entire exposure phase at the field sites after the 2nd application (0DAA2 to 17DAA2): mean flight intensity 2.1 bees/m²/day in C compared to 2.5 bees/m²/day in T. No notable differences between control and test item treatment group observed during this period.

~~Entire post application phase (0DAA1 to 17DAA2): Total daily mean flight calculated to be 3.0 bees/m²/day in control and 4.8 bees/colony/day in T, respectively.
Thus, no test item related adverse effects on flight intensity were observed.~~

Behaviour of the Honeybees

~~Notable differences in behaviour in the test item group compared to the control group occurred on the day of the first (0DAA1) and the second application (0DAA2). On 0DAA1, up to approx. 700 bees exhibiting intensive cleaning behaviour and up to approx. 80 motionless bees were observed in T. Further observed behavioural differences compared to the control group were observed only in a few bees of the test item group. A slightly elevated number of bees showing intensive cleaning behaviour in T were still present on 1DAA1. On 0DAA2, up to 69 bees were observed in T which exhibited intoxication symptoms (cramping). Further observed behavioural differences affected only a few bees of the test item group.~~

~~On all other days during the exposure period, no notable difference in behaviour was observed in the test item treatment group compared to the control group.~~

Condition of the Colonies

Colony Strength

~~On the first assessment at 7DBA1 (14 Jun 2011), one day before set up of the colonies at the test fields, the mean numbers of bees per colony in C and T were 18740 and 13884, respectively. All bee colonies were strong and healthy. The control colonies were slightly stronger than the test item group colonies at the first brood assessment.~~

~~On the second assessment on 8DAA1 (29 Jun 2011), the mean number of bees per colony amounted to 16354 bees in C and 13574 bees in T, respectively.~~

~~The 3rd colony assessment was performed on the last day of exposure (21 Jul 2011), 17 days after the 2nd application (= EOE). The mean number of bees per colony in C and T was 19824 and 19977, respectively.~~

~~From the 3rd to the 5th colony assessment, the colony assessments were on a rather stable level with only slight fluctuations in colony size.~~

~~In both groups (C and T), a noticeable decline of the colony size occurred from end of July (mean value of bees per colony: 18154 in C and 21476 bees in T; 28 Jul 2011) until start of overwintering by middle of October 2011 (mean value of bees per colony: 10488 in C and 13159 bees in T; 13 Oct 2011). This decline of the colony size at the end of summer followed the natural course of colony strength development, with a decreasing tendency from late summer to autumn and spring of the following year. At the end of overwintering on 22 Mar 2012, the mean colony strength was 5361 bees per colony in C and 7185 bees per colony in T.~~

~~No test item related adverse effects on colony strength were observed during the course of the study.~~

Brood Stages and Overwintering Success

~~At the first assessment at 7DBA1 (14 Jun 2011), all colonies of the control and the test item treatment group contained brood of all stages. Brood of all stages was also present in all colonies at all further assessments with a few exceptions on single occasions. However, test item group and control were equally affected regarding the sporadic occurrence of missing brood stages.~~

~~At the end of overwintering on 22 March 2012, all colonies of the test item group and the control had successfully survived the winter. All brood stages were present in all colonies except for the absence of eggs in the colonies Ce and Cf. However, since the queens were noticed in both colonies, so it was assumed that this was only a temporary gap of egg laying activity, probably due to low temperatures. In colony Tf, the number of brood cells was slightly lower than in the colonies Ta to Te. This could be attributed to the presence of frost damaged brood in this colony.~~

~~No notable differences between the test item treatment group and the control were observed. Overall, no test item related adverse effect on colony vitality and brood development was observed, which includes queen survival and overwintering performance.~~

Food Storage

~~In the colonies of the control group C and the test item treatment group T, respectively, the natural and~~

typical changes and fluctuations in the relative amount of nectar and pollen storage cells occurred during the observation period. All colonies of the study showed approximately equal numbers of pollen and nectar storage cells in C and T throughout the entire observation period, respectively. Thus, no test item related adverse effects on the food storage behaviour of the exposed colonies were observed.

Bee Diseases Analysis, AFB Assessment

The objective of the bee disease analysis phase was to determine the presence of different pathogens (*Nosema* sp., *Malpighamoeba mellificae*, *Varroa destructor*, *Paenibacillus larvae*) in bee samples taken at different time points during the study period.

Nosema sp. spores

Three control colonies (Ca, Cc, Cd) were free of analysable *Nosema* sp. spores at each of the four sampling dates.

In the bee samples taken from the control colonies at start of exposure, only in colony Cf *Nosema* sp. spores were analysed (high infestation level). All other colonies were free of analysable spores.

In the bee samples taken from control colonies at end of exposure the colony Cb had a high infestation level and the colony Ce had a medium infestation level with *Nosema* sp. spores. In the bee samples of the other control colonies no *Nosema* sp. spores were analysed.

In the bee samples taken at start overwintering, no *Nosema* sp. spores were found in any colony except in colony Cf (high infestation level).

In the control bee samples taken at end of overwintering, no *Nosema* sp. spores were analysed in any colony.

In the test item treatment colony Td no *Nosema* sp. spores were analysed in any of the samples taken in 2011 and 2012.

In the bee samples taken at start of exposure from test item treatment colonies, no *Nosema* sp. spores were found.

In the bee samples taken at end of exposure, one test item treatment colony had a low infestation level (Tf) and two test item treatment colonies had a medium infestation level with *Nosema* sp. spores (Tb and Te).

In the samples taken at start of overwintering, no *Nosema* sp. spores were found in any of the test item treatment colonies.

In the samples taken at end of overwintering, test item treatment colony Ta had a low infestation level and test item treatment colony Tc had a high infestation level. In all other colonies no infestation with *Nosema* sp. spores was analysed.

Varroa mites

The highest infestation rate with *Varroa* mites was 10 % in one bee sample taken at end of exposure of the control colonies (colony Cb). In all other bee samples examined the *Varroa* infestation rate was between 0.0 % and 4.4 % in all samples taken from control colonies.

The *Varroa* mite infestation rate never exceeded the 7 % level in the bee samples taken from the test item treatment colonies. The infestation rate varied between 0.0 % and 5.4 % in all samples analysed.

Malpighamoeba mellificae and spores of *Paenibacillus larvae*

No *Malpighamoeba mellificae* and no spores of *Paenibacillus larvae* were found in any of the samples taken in 2011 and 2012 neither in the control nor in the test item treatment colonies.

Overall, no differences in health could be observed between the control and the test item treatment colonies. Thus, no test item related adverse effects on colony health in terms of bee diseases were observed.

Pollen Source Identification

The pollen from the pollen traps was collected once before the first application (1DBA1), twice before (3DAA1, 6DAA1) and twice after the 2nd application (1DAA2, 3DAA2) in C and T, respectively.

In the control colonies Ca–Cf, the percentage of *Phacelia* pollen collected per colony was 67–97 % on 1DBA1, 97–100 % on 3DAA1, 94–100 % on 6DAA1, 49–96 % on 1DAA2 and 35–95 % on 3DAA2. In the test item treatment colonies Ta–Tf, the percentage of *Phacelia* pollen collected per colony was 89–99 % on 1DBA1, 88–99 % on 3DAA1, 63–89 % on 6DAA1, 2–17 % on 1DAA2 and 2–31 % on 3DAA2.

Thus, it can be concluded that *Phacelia tanacetifolia* crop under investigation was a significant foraging area of the exposed colonies.

Bee Virus Analysis

The objective of the bee virus analysis was to determine the following bee viruses in bee samples collected at different time points of the year: DWV (deformed wing virus), SBV (sacbrood virus), ABPV (acute bee paralysis virus), CBPV (chronic bee paralysis virus), KBV (Kashmir bee virus), IAPV (Israeli acute paralysis virus), BQCV (black queen cell virus).

The bee viruses ABPV, CBPV, KBV and IAPV were not detected in any of the samples taken at any time point.

DWV was detected in sample Ce of the control group taken at the time point ‘start of exposure phase’, in samples Cc and Cd of the control group taken at the time point ‘end of exposure phase’, and in samples Ca, Cc, Cd, and Ce of the control group, and in samples Ta, Td, and Tf of the test item group taken at the time point ‘start of overwintering’ in 2011, and in sample Tf of the test item group taken at the time point ‘end of overwintering in 2012’.

SBV was detected in all samples of the control group (Ca–Cf) and in all samples of the test item group (Ta–Tf) taken at the time point ‘start of exposure phase’, and in sample Te of the test item group taken at the time point ‘end of exposure phase’ in 2011.

BQCV was detected in samples Ca, Cb, Cc, Ce, and Cf of the control group, and in samples Tb–Tf of the test item group taken at the time point ‘start of exposure phase’, and in all samples of the control group (Ca–Cf), and as well as in all samples of the test item group (Ta–Tf) taken at the time point ‘end of exposure phase’ in 2011.

Thus, no test item related adverse effects on colony health in terms of virus infestation were observed.

Residue Analysis

Samples of *Phacelia* flowers as well as nectar/honey, pollen/bee bread and bee wax collected from hives were analysed. In pollen, nectar, beewax residues of deltamethrin were below the limit of quantitation (LOQ = 10 µg/kg). The measured residues in flowers/blossoms were 158–468 µg/kg.

Conclusion

No test item related adverse effects were observed on mortality and flight intensity in the test field.

No test item related adverse effects were observed on honeybee health, colony development (including colony strength, colony health, brood and food development of the colonies) as well as on overall colony vitality throughout the entire field exposure period and throughout the entire monitoring period until the end of overwintering in spring 2012.

Moreover, the overwintering performance of the colonies in the test item treatment group was not adversely affected when compared to control performance.

Overall, it can be concluded that exposure of honeybee colonies to *Phacelia tanacetifolia*, sequentially sprayed with Deltamethrin EW 15B G at a target rate of 12.5 g a.s./ha on two occasions during flowering, did neither cause acute, short term nor long term adverse effects on mortality, flight intensity, colony strength, colony health and vitality, brood and food development and overwintering performance in the exposed colonies.

Behavioural observations indicated a possible short term correlation between the application of the test item during bee flight activity and an intensive cleaning behaviour in a larger number of exposed honeybees as well as motionless bees and intoxication symptoms in a smaller number of exposed honeybees.

Comments of zRMS:	<p>In general, the field and semi-field studies should be performed with the formulation in question with application regime being in line with the intended use pattern. This is particularly important in case of formulations containing more than one active compound due to possibility for synergistic effects.</p> <p>Since the study summarised below was performed with the solo formulation of deltamethrin, it is considered not relevant for the risk assessment performed for DLT+FPF EC 85, which contains two substances with supplementary mode of action: deltamethrin and flupyradifurone, which act through different pathways: deltamethrin is a non-systemic “knock-out” insecticide extremely disturbing the nervous system by blocking the sodium channel and flupyradifurone is a systemic insecticide interacting with insect nicotinic acetylcholine receptors, similar to neonicotinoids. Taking this into account it cannot be excluded that the impact of the mixture on bees may be enhanced comparing to individual compounds and it is thus not possible to predict effects of simultaneous exposure of bees to both active compounds based on semi-field/field studies performed with single active compounds, even when applied at higher rates. For this reason the semi-field and field tests should be performed with formulation under evaluation in order to account for effects resulting from simultaneous exposure to both active compounds.</p> <p>The study below was not validated by the zRMS as being not relevant for the risk assessment and its summary is struck through below.</p>
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Reference:	KCP 10.3.1.6/02
Title:	Assessment of side effects on the honeybee (<i>Apis mellifera</i> L.), exposed to <i>Phacelia tanacetifolia</i> , sprayed sequentially with deltamethrin during flowering in a long-term field study in Mid Alsace, France
Report:	Rexer, H. U.; 2013; S10-03824; M-452723-01-1
Guideline(s):	OEPP/EPPO Guideline No. 170 (4) (2010), SANCO/3029/99 rev. 4
Deviations:	not specified
GLP/GEP:	yes
Acceptability:	Not validated, not relevant for the risk assessment for DLT+FPF EC 85
Duplication (if vertebrate study):	

Materials and methods

Test item: Deltamethrin EW 15B-G (spray application product, Batch ID: 2011-002948)

Test organism: *Apis mellifera* L. (Hymenoptera, Apidae), provided by EAS EcoChem GmbH, Niefern, Germany

Crop used for field study: *Phacelia tanacetifolia*

Study dates / location: June 2011– March 2012, near Saint Pierre and Stotzheim, France (region: Alsace)

Description field plots: The size of the field plots were approx. 2.35 ha (test item treatment field) and approximately 2.25 ha (control field). The field plots were separated by 4.0 km in order to minimise the chance of the bees from T visiting the field plot of C or vice versa.

The colonies were placed at the field sites early in the morning on 10 Jun 2011 at early flowering of *P. tanacetifolia* (BBCH 63).

Treatments:

Test item group T: Two applications of test item Deltamethrin EW 15B-G (target application rate: 2 x 12.5 g a.s./ha, spray interval 13 days). The applications were performed during flowering of *P. tanacetifolia*. The first application was carried out after set up of the honeybee colonies at the test fields during flowering of *P. tanacetifolia* on 15 Jun 2011 (BBCH 64–65). The 2nd application was performed on flowering *P. tanacetifolia* on 28 Jun 2011 (BBCH 65–67). The applications were carried out during honeybee flight. The actual application rate was 16.6 g a.s./ha (1st application) and 12.8 g a.s./ha (2nd

application) in the test item group.

Untreated control C: No application was performed on the corresponding control field plot (C).

Assessments

The effects of honeybee exposure to Deltamethrin EW 15B-G treated *Phacelia tanacetifolia* flowers were examined on six commercial honeybee colonies placed at each test field.

The influence of Deltamethrin EW 15B-G was evaluated by comparing the results of the test item group to the data of the control regarding the following observations:

- Total and mean number of dead honeybees
- Flight intensity
- Behaviour of bees in the crop and around hives
- Condition of colonies (number of bees (colony strength), mean values of the different brood stages per colony and assessment date)
- Colony health (bee diseases, bee viruses)
- Residue analysis

Six days before the first application, the first colony assessment was performed, which included an assessment of the colony strength and the brood and food status. Pollen, nectar and wax from combs, honeybees (for disease and virus analysis), as well as nectar for AFB analysis were sampled on the same day.

At the end of the flowering period at BBCH 67–69, the honeybee colonies were relocated to a monitoring site without extensive agricultural crops attractive to bees. Here colony health and strength were assessed. Pollen, nectar and bee wax from combs were collected for residue analysis until 23 Mar 2012.

Samplings of honeybees for disease and virus analysis and nectar for AFB analysis were performed twice after relocation of the colonies to the monitoring site.

Findings and discussions

Mortality and Flight Intensity

Summary of Effects on Honeybees during the Exposure Phase of the Study

Treatment group		Control (C)	Test item treatment (T)
Daily mean mortality (dead bees/colony) ±STD	Pre-application 1 (5DBA1 to 0DBA1)	15.3 ± 8.3	22.9 ± 13.5
	Post application 1 (0DAA1 to 0DBA2)	11.0 ± 8.5	19.2 ± 27.2
	Post application 2 (0DAA2 to 16DAA2)	18.7 ± 32.4	11.8 ± 8.0
	Post application total (5DBA1 to 16DAA2)	15.2 ± 24.9	15.2 ± 19.5
Daily mean flight intensity (bees/m ²) ±STD	Pre-application 1 (5DBA1 to 0DBA1)	4.0 ± 2.5	4.8 ± 2.8
	Post application 1 (0DAA1 to 0DBA2)	3.4 ± 2.0	5.9 ± 4.1
	Post application 2 (0DAA2 to 16DAA2)	1.4 ± 1.4	2.6 ± 2.2
	Post application total (5DBA1 to 16DAA2)	2.3 ± 2.0	4.1 ± 3.6

DBAn: days before application (number n); DAAAn: days after application (number n)

Mortality of honeybees

Pre application phase (5DBA1 to 0DBA1): mortality in test item group slightly higher (mean value: 22.9 dead bees/colony/day) than in control (mean value: 15.3 dead bees/colony/day), but still in the same range in both treatment groups.

After first application of test item:

0DAA1: mortality in T (14.5 dead bees/colony/day) was on the same level as in control (11.8 dead bees/colony/day) and below the mean pre-application mortality in T.

1DAA1: mean mortalities were low and amounted to 3.3 dead bees/colony/day in C and to 7.0 dead bees/colony/day in T, and showed no notable differences between the test item treatment colonies and the control colonies.

Entire post application phase after the 1st application and before the 2nd application (0DAA1 to 0DBA2): mean number of dead bees slightly higher in the test item group (19.3 dead bees/colony/day) than in control (11.0 dead bees/colony/day), but still below the mean pre-application mortality in T. Calculated mortality quotients during this period: 0.7 in C and 0.8 in T.

After second application of test item:

0DAA2: mean mortality in T (15.2 dead bees/colony/day) slightly higher than in control (4.3 dead bees/colony/day) but still on a normal level and below the mean pre-application mortality in T.

1DAA1: mean mortality in T (12.7 dead bees/colony/day) declined to the mortality level of the control (9.5 dead bees/colony/day).

Entire post application phase after the 2nd application (0DDA2 to 16DAA2):

mean number of dead bees was slightly lower in the test item group (11.8 dead bees/colony/day) than in control (18.7 dead bees/colony/day). The mean mortality levels in the test item group during this period were below the mean pre-application mortality in T. Calculated mortality quotients during this period: 1.2 in C and 0.5 in T.

Entire post application phase (0DAA1 to 16DAA2): mean daily mortality per colony 15.2 dead bees/colony/day in control as well as in test item group. Calculated mortality quotients for this period: 1.0 in C and 0.7 in T.

Mortality assessment within the crop area:

On linen sheets spread out within the crop area in the test fields, 1 dead bees/day were found in the test item field compared to 0.6 dead bees/day in the control during the entire post application phase (0DAA1 to 16DAA2). No notable differences between control and test item group were observed.

Thus, no test item-related adverse effects on mortality were observed.

Flight Intensity

Pre application phase (5DBA1 to 0DBA1): mean flight intensity on the same level in test fields and in control (4.0 bees/m²/day in C compared to 4.8 bees/m²/day in T).

After first application of test item:

0DAA1: mean flight intensity amounted to 6.0 bees/m²/day in C compared to 1.9 bees/m²/day in T.

1DAA1: mean flight intensity 2.9 bees/m²/day in C compared to 1.6 bees/m²/day in T.

Entire post application phase after the 1st application and before the 2nd application (0DAA1 to 0DBA2): mean flight intensity 3.4 bees/m²/day in C compared to 5.9 bees/m²/day in T. Besides a slight reduction of flight intensity immediately after the application of the test item on 0DAA1, no notable differences between control and test item treatment group observed during this period.

After second application of test item:

0DAA2: mean flight intensity amounted to 3.8 bees/m²/day in both, C and T.

Entire exposure phase at the field sites after the 2nd application (0DAA2 to 16DAA2): mean flight intensity 1.4 bees/m²/day in C compared to 2.6 bees/m²/day in T. No notable differences between control and test item treatment group were observed during this period.

Entire post application phase (0DAA1 to 16DAA2): Total daily mean flight calculated to be 2.3 bees/m²/day in control and 4.1 bees/colony/day in T, respectively.

Thus, no test item related adverse effects on flight intensity were observed.

Behaviour of the Honeybees

Notable differences in behaviour in the test item group compared to the control group occurred on the day of the first (0DAA1) and the second application (0DAA2). On 0DAA1, up to approx. 360 bees in total exhibiting intensive cleaning behaviour, up to approx. 20 motionless bees per colony and up to approx. 20 bees in total with intoxication symptoms were observed in T. A slightly elevated number of bees showing intensive cleaning behaviour in T were still present on 1DAA1. Further observed behavioural differences compared to the control group were observed on 6DAA1, 8DAA1, 9DAA1 and 11DAA1, but only a few bees of the test item group were involved. On 0DAA2, up to approx. 300 bees per colony in T exhibited intensive cleaning behaviour and up to 50 motionless bees per colony were observed. Further observed behavioural differences compared to the control group were observed only in a few bees of the test item group. From 1DAA2 until the end of exposure, no notable difference in behaviour was observed in the test item treatment group compared to the control group.

Condition of the Colonies

Colony Strength

On the first assessment on 6DBA1 (09 Jun 2011), one day before set-up of the colonies at the test fields, the mean numbers of bees per colony in C and T were 18365 and 16970, respectively, and were therefore on the same level. On the second assessment on 7DAA1 (22 Jun 2011), the mean number of bees per colony had increased in both treatment groups and amounted to 19237 in C and 19414 in T, respectively. The 3rd colony assessment (last assessment at the field sites) was performed on 16DAA2 (14 Jul 2011). The mean number of bees per colony in C and T was 23012 and 18112, respectively. The lower mean number of bees in T compared to C was most likely due to swarming activity of colony Tf. The number of bees of all other test item group colonies increased or remained stable during the period from the 2nd to the 3rd colony assessment.

From the 3rd to the 5th colony assessment, the colony assessments were on a rather stable level with only slight fluctuations in colony size.

In both groups (C and T), a noticeable decline of the colony size occurred from beginning of August (mean value of bees per colony: 21913 in C and 19173 bees in T; 04 Aug 2011) until start of overwintering by middle of October 2011 (mean value of bees per colony: 10375 in C and 7841 bees in T; 07 Oct 2011). This decline of the colony size at the end of summer followed the natural course of colony strength development, with a decreasing tendency from late summer to autumn and spring of the following year.

At the end of overwintering on 23 Mar 2012, the mean colony strength was 5050 bees per colony in C and 3068 bees per colony in T.

No test item related adverse effects on colony strength were observed during the course of the study

Brood Stages and Overwintering Success

At the first assessment at 6DBA1 (09 Jun 2011), all colonies of the control and the test item treatment group contained brood of all stages. Brood of all stages was also present in all colonies at all further assessments with a few exceptions on single occasions. However, test item group and control were equally affected regarding the sporadic occurrence of missing brood stages.

At the end of overwintering on 23 March 2012, all colonies of the test item group and the control had successfully survived the winter. All brood stages were present in all colonies, with the exception of colony Te, which contained larvae and pupae but no eggs. However, since the queen was noticed in this colony, it was assumed that this was only a temporary gap of egg laying activity, probably due to low temperatures. In colony Te, the number of brood cells was slightly lower than in the other colonies of the test item group. This could be attributed to the presence of frozen brood in this colony.

No notable differences between the test item treatment group and the control were observed. Overall, no test item related adverse effect on colony vitality and brood development was observed, which includes queen survival and overwintering performance.

Food Storage

In the colonies of the control group C and the test item treatment group T, respectively, the natural and

typical changes and fluctuations in the relative amount of nectar and pollen storage cells occurred during the observation period. All colonies of the study showed approximately equal numbers of pollen and nectar storage cells in C and T throughout the entire observation period, respectively. Thus, no test item related adverse effects on the food storage behaviour of the exposed colonies were observed.

Bee Diseases Analysis, AFB Assessment

The objective of the bee disease analysis phase was to determine the presence of different pathogens (*Nosema* sp., *Malphigamoeba mellificae*, *Varroa destructor*, *Paenibacillus larvae*) in bee samples taken at different time points during the study period.

Nosema sp. spores

From the bee samples taken from the control colonies, only in the colonies Cc and Cd *Nosema* spec. spores were analysed. Control colony Cd showed a low infestation level with *Nosema* spec. spores in the bee sample taken at start of exposure and control colony Cc showed a high infestation level in the bee sample taken at end of overwintering. After overwintering, no samples could be analysed for colonies Cc and Cf.

In the bee samples taken at start of exposure in the test item treatment colonies, no *Nosema* spec. spores were found.

The amount of infestations with *Nosema* spec. spores increased moderately in the bee samples of the test item treatment colonies taken at end of exposure. In these samples, test item treatment colony Tb had a low infestation level with *Nosema* spec. spores and test item treatment colonies Ta, Te, Td and Te had a medium infestation rate, whereas colony Tf was free of analysable *Nosema* spec. spores.

In the bee samples taken at start of overwintering, only test item treatment colony Te had an infestation with *Nosema* spec. spores (medium level).

In the bee samples taken at end of overwintering, *Nosema* spec. spores were found in the test item treatment colonies Tb (medium infestation level) and Te (high infestation level). No samples were available from end of overwintering for test item treatment colonies Td and Te. In the summer samples, the amount of positive *Nosema* spec. spore findings in the test item treatment colony group was slightly higher than in the control colony group, but the infestation level was not higher than medium. For the health status evaluation, the more distinctive high infestation level occurred once in the control and in the test item treatment group, respectively.

Varroa mites

In three out of 22 bee samples taken from control colonies, *Varroa* mites were found. The infestation rates with *Varroa* mites of these three findings were between 0.4 % and 0.5 % in all samples taken from control colonies. The *Varroa* mite infestation varied between 0.0 % and 4.3 % in all samples analysed.

Malphigamoeba mellificae and spores of *Paenibacillus larvae*

No *Malphigamoeba mellificae* and no spores of *Paenibacillus larvae* were found in any of the samples taken in 2011 and 2012 neither in the control nor in the test item treatment colonies.

Overall, no differences in health could be observed between the control and the test item treatment colonies. Thus, no test item related adverse effects on colony health in terms of bee diseases were observed.

Pollen Source Identification

The pollen from the pollen traps was collected once before the first application (1DBA1), twice before (1DAA1, 5DAA1) and twice after (7DAA2, 8DAA2) the 2nd application in C and T, respectively.

In the control field, the percentage of *Phacelia* pollen collected per colony was 1-10 % on 1DBA1, 1-7 % on 1DAA1, 72-91 % on 5DAA1, <1-30 % on 7DAA2 and <1-47 % on 8DAA2 in the colonies Ca-Cf.

In the test item treatment field, the percentage of *Phacelia* pollen collected per colony was 10-91 % on 1DBA1, 21-71 % on 1DAA1, 94-100 % on 5DAA1, 18-60 % on 7DAA2 and 4-56 % on 8DAA2 in the colonies Ta-Tf.

Thus, it can be concluded that the *Phacelia tanacetifolia* crop under investigation was a significant foraging area of the exposed colonies.

Bee Virus Analysis

The objective of the bee virus analysis was to determine the following bee viruses in bee samples collected at different time points of the year: DWV (deformed wing virus), SBV (sacbrood virus), ABPV (acute bee paralysis virus), CBPV (chronic bee paralysis virus), KBV (Kashmir bee virus), IAPV (Israeli acute paralysis virus), BQCV (black queen cell virus).

The bee viruses ABPV, CBPV, KBV and IAPV were not detected in any of the samples taken at any time point.

DWV was detected in sample Te of the test item group taken at the time point 'start of exposure phase', in sample Cf of the control group, and in samples Ta and Te Tf of the test item group taken at the time point 'end of exposure phase', in samples Ce and Cf of the control group, and in samples Ta, Tb, Td, and Te of the test item group taken at the time point 'start of overwintering' in 2011, and in samples Ta and Te of the test item group taken at the time point 'end of overwintering' in 2012.

SBV was detected in Ce and Cd of the control group, and in samples Ta, Tb, Td, and Tf of the test item group taken at the time point 'start of exposure phase', in samples Ca-Ce of the control group, and in samples Ta and Td of the test item group taken at the time point 'end of exposure phase' taken in 2011.

BQCV was detected in samples Cb-Cf of the control group, and in all samples of the test item group (Ta-Tf) taken at the time point 'start of exposure phase', and in samples Ca, Ce, and Cd of the control group, and in samples Ta, Tb, Te, and Tf of the test item group taken at the time point 'end of exposure phase' in 2011.

Since the bee viruses DWV, SBV and BQCV were detected in both C and T, respectively, no test item-related adverse effects on colony health in terms of virus infestation were observed.

Residue Analysis

Samples of *Phacelia* flowers as well as nectar/honey, pollen/bee bread and bee wax collected from hives were analysed. In pollen and nectar, residues of deltamethrin were below the limit of quantitation (LOQ = 10 µg/kg). In beewax the measured residues of the test substance ranged between the LOQ and 22. The measured residues in floweres/blossoms were 68–417 µg/kg.

Conclusion

No test item-related adverse effects were observed on mortality and flight intensity in the test field.

No test item-related adverse effects were observed on honeybee health, colony development (including colony strength, colony health, brood and food development of the colonies) as well as on overall colony vitality throughout the entire field exposure period and throughout the entire monitoring period until the end of overwintering in spring 2012.

Moreover, the overwintering performance of the colonies in the test item treatment group was not adversely affected when compared to control performance.

Overall, it can be concluded that exposure of honeybee colonies to *Phacelia tanacetifolia*, sequentially sprayed with Deltamethrin EW 15B G at a target rate of 12.5 g a.s./ha on two occasions during flowering, did neither cause acute, short-term nor long-term adverse effects on mortality, flight intensity, colony strength, colony health and vitality, brood and food development and overwintering performance in the exposed colonies.

Behavioural observations indicated a possible short-term correlation between the application of the test item during bee flight activity and an intensive cleaning behaviour in a larger number of exposed honeybees as well as motionless bees and intoxication symptoms in a smaller number of exposed honeybees.

Comments of zRMS:	In general, the field and semi-field studies should be performed with the formulation in question with application regime being in line with the intended use pattern. This is particularly important in case of formulations containing more than one active
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	<p>compound due to possibility for synergistic effects.</p> <p>Since the study summarised below was performed with the solo formulation of deltamethrin, it is considered not relevant for the risk assessment performed for DLT+FPF EC 85, which contains two substances with supplementary mode of action: deltamethrin and flupyradifurone, which act through different pathways: deltamethrin is a non-systemic “knock-out” insecticide extremely disturbing the nervous system by blocking the sodium channel and flupyradifurone is a systemic insecticide interacting with insect nicotinic acetylcholine receptors, similar to neonicotinoids. Taking this into account it cannot be excluded that the impact of the mixture on bees may be enhanced comparing to individual compounds and it is thus not possible to predict effects of simultaneous exposure of bees to both active compounds based on semi-field/field studies performed with single active compounds, even when applied at higher rates. For this reason the semi-field and field tests should be performed with formulation under evaluation in order to account for effects resulting from simultaneous exposure to both active compounds.</p> <p>The study below was not validated by the zRMS as being not relevant for the risk assessment and its summary is struck through below.</p>
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Reference:	KCP 10.3.1.6/03
Title:	Assessment of side effects of Deltamethrin EC 25 on the honey bee (<i>Apis mellifera</i> L.) in the field
Report:	Pistorius, J.; 2007; 20061298/G1-BFEU; M-286584-01-1
Guideline(s):	OEPP/EPPO No. 170 (3), 2001
Deviations:	none
GLP/GEP:	yes
Acceptability:	Not validated, not relevant for the risk assessment for DLT+FPF EC 85
Duplication (if vertebrate study):	

Material and Methods:

The effects of the test substance Deltamethrin EC 25 were tested on the honey bee (*Apis mellifera* L.) under field conditions following the OEPP/EPPO Guideline No. 170 (3). The study comprised one trial which was carried out in Germany. As crop *Phacelia tanacetifolia* was used. In total there were three test fields per trial: one test item field with application of Deltamethrin EC 25, one test item field with application of the reference item Fastac SC and the untreated control field. The distance between the control field (size: 5832 m²) and the reference item field (size: 5229 m²) was 2.0 km, the distance between the control and the test item fields T1 (2 smaller fields, separated by approximately 100 m, sizes: 2592 m² and 2898 m² = total field size 5490 m²) was >10 km. The distance between the reference item field R1 and the test item field was 12.8 km, respectively. At the each field 4 honey bee colonies were set up. In the test item field (code: T1) Deltamethrin EC 25 was applied once at an application rate of 7.5 g a.i./ha (nominal). In the reference item field (code: R1) Fastac SC was applied once at a rate of 10 g a.i./ha (nominal). All applications were carried out with a rate of 300 L water/ha on the flowering crop with foraging activity of the bees on the test fields. The control field remained untreated, no application of water was carried out in the control field.

Mortality, flight intensity, and the condition of the colonies and development of the bee brood were assessed before and after application. Homing behaviour was assessed twice before application by marking foraging bees in the crop. As only a small amount of the marked bees were recovered at the hive entrances in an appropriate time span in all control and treatment groups, detailed observations of the foraging activity in the field and at the hive entrances were conducted instead.

The treatment groups T1 and R1 are individually compared to the flight activity at the control field at the corresponding time of the day. Therefore, two subsequent assessments were conducted on the control field (C for T1 and C for R1). This was necessary as the time lag between the 2 applications was about

90 minutes due to the distance between the test fields. For the evaluation assessments were made at the control field at the same time as the assessments at the reference item or test item field. For the evaluation only data assessed at about the same time for the test item treatment and the control treatment respectively for the reference item treatment and the control treatment were used.

The influence of the test item was evaluated by comparing the results of the test item treatment to the control and reference item data and by comparing the pre and post application results of the observations. The following points were assessed:

- Condition of the colonies (strength) and development of the bee brood
- Mortality in the field and in the bee traps in front of the hives
- Foraging activity (number of forager bees/m²-flowering crop)
- Behaviour of the bees on the crop and around the hive

Results and discussions

Effects of Deltamethrin EC 25 on the honey bee (*Apis mellifera* L.) in the field

Test item		Deltamethrin EC 25			
Test species		Apis mellifera L., carnica			
Exposure		T1 and R1 : spray treatment during foraging activity at full flowering of the crop under field conditions			
Treatment group		Control for T1	Control for R1	T1	R1
Application rate g a.i./ha nominal		-	-	7.5	10.0
Spray volume pro ha [L water/ha]		-	-	300	300
Mean mortality {deadbees/colony/day}	Pre-application [DAA -4 to 0ba]	24.0		38.3	4.7
	DAA 0ba	18.0		24.5	4.8
	DAA 0aa	9.5		14.5	16.8
	DAA +1	4.3		22.8	5.0
	Post-application [DAA 0aa to +7]	17.4		36.7	9.1
	QM(average):	0.7		1.0	1.9
Daily mean flight intensity {foraging bees/m2}	Pre-application [DAA -4 to 0ba]	2.0	2.3	4.2	7.9
	DAA 0ba	4.2	5.8	6.2	9.4
	DAA 0aa	5.2	5.1	4.1	4.1
	DAA +1	5.0	5.0	5.7	8.1
	Post-application [DAA 0aa to +7]	6.4	6.4	7.8	6.0

DAA = ——— Days after application

ba = ——— before application

aa = ——— after application

QM(average) = — 0 Post application mortality / 0 pre-application mortality

Observations

Honey bee mortality:

The daily mean bee mortality (number of dead bees in the dead bee traps and in front of the hives) before the application was 38.3 dead bees/colony in the test item group T1, 4.7 dead bees/colony in the test item treatment R1 and 24.0 dead bees in control colonies. In the morning before application on DAA 0 the mean mortality was 24.5 dead bees/colony in the test item group T1, 6.0 dead bees/colony in the test item treatment R1 and 18.0 dead bees per hive in control. In the evening of the application day (DAA 0aa) a mean number of 14.5 dead bees per colony was recorded in the test item group T1, 2.0 dead bees/colony in the reference item treatment R1 and 9.5 dead bees in control colonies. Before the application the natural mortality in the test item treatment and the control was on a higher level than in

the reference item treatment. Considering the results before and after application of each treatment group, the mortality in the test item treatment was on the same level during the post application period as during the preapplication period. The mortality of the reference item treatment was slightly increased after the application. The control mortality remained on about the same level in the pre and post application period, but showed a slight increase of mortality between DAA +3 and DAA +5. The value for $Q_{M(average)}$ was calculated as 1.0 in the test item treatment group T1 compared to 0.7 in the control group, indicating that the treatment had no effect on honey bee mortality. In the reference item treatment the mortality was on a low level during the entire postapplication period and the $Q_{M(average)}$ value was 1.9, indicating that the bees were well exposed and the test system was sensitive and adequate for detection of effects by plant protection product on honeybee.

Honey bee flight intensity:

Shortly before application on DAA 0 the mean flight intensity (foraging bees/m²) was 6.2 bees/m² in the test item treatment group T1 and 4.2 bees/m² in the control treatment group for T1. In the reference item treatment group R1 the mean flight intensity was 9.4 bees/m² and 5.8 bees/m² in the corresponding control group for R1. The mean flight intensity pre application was 4.2 bees/m² in the test item treatment group T1 and 2.0 bees/m² in the control treatment group for T1. The mean flight intensity pre application in the reference item treatment group R1 was 7.9 bees/m² and 2.3 bees/m² in the control treatment group for R1. During the assessments on DAA 0 after application a decreased flight activity was observed in the test item field as well as in the reference item field and resulted in a mean number of 1.1 foraging bees/m² in the test item treatment group T1 and 1.1 foraging bees/m² in the reference item treatment group R1. In the control group for T1 and in the control group for R1 the mean flight intensity on DAA 0 was 5.2 and 5.1 foraging bees/m² after application respectively.

On the following assessment dates no treatment related difference regarding the flight intensity was observed between the treatment groups. The daily mean flight intensity after the application was 7.4 foraging bees/m² in the treatment group T1, 6.0 foraging bees/m² in the treatment group R1 and 6.4 foraging bees/m² in the control group for T1 and 6.4 foraging bees/m² in the control group for R1. The observation of intense flight and foraging activity of the bees on the test fields was also supported by the fact that the amount of *P. tanacetifolia* pollen in the combs of the colonies of all treatment groups was on a high level (see following chapter).

Condition of the colonies:

Assessments of the colony strength as judged by number of bee ways between combs filled with bees and the brood nest size (number of brood combs per colony) did not indicate significant differences between treatment groups T1, R1 and the corresponding control groups. The colonies of the treatment groups T1 and R1 and control showed all brood stages at the assessment dates during the experimental phase of the study. The colonies of both groups treated with Deltamethrin EC 25 were in good condition throughout the entire observation period, except one colony (2T1) which died due to Varroosis. Although the colonies were checked for Varroa mites before the trial and showed no symptoms of a high infestation, a rapid increase of the mite population is possible to occur in autumn between July and October. The increase can show strong differences between different individual colonies and varies between locations.

Most of the colonies in the treatment groups of the trials showed a high percentage of *P. tanacetifolia* pollen from the total amount of pollen per colony. In the trial the percentage of *P. tanacetifolia* pollen on combs in most of the colonies of the treatments ranged from approximately 20% up to 70% during time of exposure at the test fields. The results of the pollen assessments in the colonies confirms the fact that the bees were actively foraging on the test fields. A quantitative comparison between the results of the treatments is not possible, because the foraging and storage of pollen in a bee colony depends on outside conditions as well as on the individual need of pollen in the bee colony.

Behaviour of the bees during foraging activity:

During the detailed observations of the foraging activity of the bees in the field, symptoms of affected foraging behaviour of the bees, like trembling, shaking or cramping bees, bees showing erratic foraging behaviour, bees hanging or dropping from flowers or green parts of the plant, excessive cleaning or

showing other visible impact on behaviour were assessed. In both the test item treatment and the reference item treatment only a small percentage bees showed symptoms of affected foraging behaviour, and only on the day of application after the application. The fraction and absolute number of honey bees showing affected behaviour was slightly higher in the reference item field compared to the fraction and absolute number of bees foraging in the test item field. On the days following the application no further affected foraging behaviour was observed. No abnormal behaviour was observed in the control during the entire observation period.

Behaviour of the bees at the hive entrance:

During the observations at the hive entrance, symptoms of affected bee behaviour, like shaking, trembling or cramping bees, bees showing impaired movements, excessive cleaning behaviour, or fighting bees were observed in the test item treatment and the reference item treatment. After the application on DAA0 the fraction and absolute number of honey bees showing affected behaviour at the hive entrance was higher in the reference item field compared to the fraction and absolute number of bees at the entrance of hives in the test item field. Before the application, in T1 and also in R1 a very small proportion of bees was assessed which were already showing symptoms which are categorized as affected behaviour. Also in the control group some bees showing abnormal behaviour were noticed in the entire observation period, before and after application of the test item and reference item up to DAA+3. For the evaluation it has to be taken into account that the behaviour of some bees may have been categorized as affected, although abnormal bee behaviour is not always due to the use of pesticides, and may likewise be triggered by natural or other factors to some extent. A higher degree of affected behaviour in comparison to the control was observed in the entire observation period up to DAA+3 in the test item treatment and in the reference item treatment, was highest on the day of application and showed a decrease on the following days.

Conclusion

An application of Deltamethrin EC 25 to flowering *Phacelia tanacetifolia* at a rate of 7.5 g a.i./ha (nominal) led to a decrease of the flight intensity on the day of application after the treatment. After the application, the mortality was not elevated and remained below the pre-application level up to DAA+2, increased slightly between DAA+3 and DAA+5 and then returned below the pre-application level. Before the application the mortality was already slightly higher in the test item T1 treatment group and in the reference item group R1 compared to the mortality of the control colony group. In the Deltamethrin EC 25 treatment some bees showed symptoms of affected behaviour at the hive entrance (only in front of the hives) mainly on the day of application after the treatment. In the reference item treatment the fraction of bees showing symptoms of affected behaviour was higher than in the test item treatment and higher than in the control treatment. Symptoms observed and evaluated as affected behaviour at the hive entrance were: bees that were trembling or shaking, bees showing impaired movements, showing intense cleaning behaviour, also bees showing aggressive behaviour and fighting with other bees at the hive entrance. The condition of the colonies, size of the brood nest and the development of the honey bee brood in the test item treatment group was not different compared to the control during the observation period.

Comments of zRMS:	<p>In general, the field and semi-field studies should be performed with the formulation in question with application regime being in line with the intended use pattern. This is particularly important in case of formulations containing more than one active compound due to possibility for synergistic effects.</p> <p>Since the study summarised below was performed with the solo formulation of deltamethrin, it is considered not relevant for the risk assessment performed for DLT+FPF EC 85, which contains two substances with supplementary mode of action: deltamethrin and flupyradifurone, which act through different pathways: deltamethrin is a non-systemic “knock-out” insecticide extremely disturbing the nervous system by blocking the sodium channel and flupyradifurone is a systemic insecticide interacting</p>
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	<p>with insect nicotinic acetylcholine receptors, similar to neonicotinoids. Taking this into account it cannot be excluded that the impact of the mixture on bees may be enhanced comparing to individual compounds and it is thus not possible to predict effects of simultaneous exposure of bees to both active compounds based on semi-field/field studies performed with single active compounds, even when applied at higher rates. For this reason the semi-field and field tests should be performed with formulation under evaluation in order to account for effects resulting from simultaneous exposure to both active compounds.</p> <p>The study below was not validated by the zRMS as being not relevant for the risk assessment and its summary is struck through below.</p>
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Reference:	KCP 10.3.1.6/04
Title:	Assessment of side effects of Deltamethrin EC 25 on the honey bee (<i>Apis mellifera</i> L.) in the field
Report:	Pistorius, J.; 2007; 20071100/G1-BFEU; M-295800-01-1
Guideline(s):	OEPP/EPPO No. 170 (3), 2001
Deviations:	none
GLP/GEP:	yes
Acceptability:	Not validated, not relevant for the risk assessment for DLT+FPF EC 85
Duplication (if vertebrate study):	

Materials and methods

The effects of Deltamethrin EC 25 were tested on the honey bee (*Apis mellifera* L.) under field conditions following the OEPP/EPPO Guideline No. 170 (3): Guideline on test methods for evaluation the side effects of plant protection products on honey bees (OEPP/EPPO, 2001).

The study comprised three trials and was carried out in Germany. Trial G07N001B was carried out in Southern Germany, near Tübingen, trial G07N002B was carried out in Eastern Germany, near Gerichshain, trial G07N003B was carried out in Northern Germany, near Celle. As crop *Brassica napus* var. *napus* was used. In total there were three test fields per trial: one test item field with application of Deltamethrin EC 25, one test item field with application of the reference item Fastac SC and the untreated control field.

For trial G07N001B, the distance between the control field (size: 8,076 m²) and the reference item field (size: 7,800 m²) was 8.4 km, the distance between the control and the test item field (size: 7,600 m²) was 9.3 km. The distance between the reference item field and the test item field the was 2.1 km.

For trial G07N002B, the distance between the control field (size: 111,006 m²) and the reference item field (size: 59,747 m²) was 5.0 km, the distance between the control and the test item field (size: 64,741 m²) was 23.5 km. The distance between the reference item field and the test item field was 28.5 km.

For trial G07N003B, the distance between the reference item field (size: 22,500 m²) and the control field (size: 18,200 m²) was about 13 km, between the test item field (size: 23,040 m²) and the control field the distance was about 9 km. The distance between the test item field and the reference item field was about 8 km.

At each field 4 honey bee colonies were set up. In the test item fields (code: T) Deltamethrin EC 25 was applied once at an application rate of 7.5 g a.i./ha (nominal). In the reference item fields (code: R) Fastac SC was applied once at a rate of 10 g a.i./ha (nominal). All applications were carried out with a rate of 300 L water/ha on the flowering crop with foraging activity of the bees on the test fields. The control field remained untreated, no application of water was carried out in the control field.

Mortality, flight intensity, and the condition of the colonies and development of the bee brood were assessed before and after application. The homing behaviour of forager bees was evaluated by

individually marking 10 bees with numbered Opalith plates and by additionally marking 40 bees with paint once before and three times after application. For each marking date, the behaviour and recovery of 10 Opalith marked bees and the recovery of 40 paint marked forager bees were monitored using a special observation hive which allows a quick inspection of the whole colony inside the hive without disturbing the bees. The marked forager bees leaving the hive and returning to the hive were counted once before and three times after application.

The treatment groups T and R are individually compared to the flight activity at the control field at the corresponding time of the day. Therefore, two subsequent assessments had to be conducted on the control field (C for T and C for R) in trial G07N001B. This was necessary in this trial as the time lag between the 2 applications was here about 75 minutes due to the distance between the test fields and the duration of the application. In the other two trials, one control assessment was sufficient. For the evaluation, assessments were made at the control field at the same time as the assessments at the reference item or test item field. For the evaluation only data assessed at about the same time for the test item treatment and the control treatment respectively for the reference item treatment and the control treatment were used.

The influence of the test item was evaluated by comparing the results of the test item treatment to the control and reference item data and by comparing the pre and post application results of the observations. The following points were assessed:

Condition of the colonies (strength) and development of the bee brood
Mortality in the field and in the bee traps in front of the hives
Foraging activity (number of forager bees/m² flowering crop)
Behaviour of the bees in the crop and around the hive
Homing behaviour of forager bees

Results and discussions

Toxicity to Honey Bees, Field Test

Test item (T)		Deltamethrin EC 25			
Reference item (R)		Fastac SC			
Test object		Apis mellifera L. carnica			
Exposure		T and R: spray treatment during foraging activity at full flowering of the crop under field conditions			
Trial code/Location		G07N001B / Near Tübingen			
Treatment group		Control for Ta	Control for Ra	Test item	Reference item
Application rate g a.i./ha (nominal)		-	-	7.5	10.0
Spray volume pro ha [L water/ha]		-	-	300	300
Mean mortality [dead bees/ colony/day]	Pre-application {DAA 2 to 0ba}:	16.0		18.5	24.3
	DAA0ba:	15.5		13.0	29.5
	DAA0aa:	9.0		8.3	10.3
	DAA+I:	10.0		6.5	6.5
	Post-application DAA0aa to +7}:	12.2		10.4	9.8
	QM(average):	0.8		0.6	0.4
Daily mean flight intensity [forager bees/m ²]	Pre-application {DAA 2 to 0ba}:	3.3	2.9	2.2	2.4
	DAA0ba:	4.2	3.0	3.8	2.8
	DAA0aa:	2.9	3.4	0.9	0.6
	DAA+I:	3.0	3.0	2.2	1.3

	Post application {DAA0aa to +7}:	3.0	3.1	2.2	2.7
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a — = Two separate sets of assessments were conducted on the control field of trial G07N001B (C for T and C for R) on DAA0aa due to a time lag between the applications of T and R of more than 60 minutes. For the evaluation, only control group data assessed at about the same time as in the test item treatment and the reference item treatment, respectively, were used.

Toxicity to Honey Bees, Field Test (continued)

Trial code/Location		G07N002B / Near Gerichshain		
Treatment group		Control	Test item	Reference item
Application rate g a.i./ha (nominal)		-	7.5	10.0
Spray volume pro ha [L water/ha]		-	300	300
Mean mortality [dead bees/ colony/day]	Pre application {DAA3 to 0ba}:	41.9	25.2	22.7
	DAA0ba:	17.0	19.8	7.0
	DAA0aa:	15.5	14.0	6.8
	DAA+1:	33.8	21.0	19.0
	Post application DAA0aa to +7}:	20.3	16.2	17.9
	QM(average):	0.5	0.6	0.8
Daily mean flight intensity [forager bees/m2]	Pre application {DAA 3 to 0ba}:	1.5	1.6	1.5
	DAA0ba:	1.8	2.2	2.0
	DAA0aa:	1.6	1.1	0.0
	DAA+1:	2.5	1.7	1.7
	Post application {DAA0aa to +7}:	2.4	1.7	1.6
Trial code/Location		G07N003B / Near Celle		
Treatment group		Control	Test item	Reference item
Application rate g a.i./ha (nominal)		-	7.5	10.0
Spray volume pro ha [L water/ha]		-	300	300
Mean mortality [dead bees/ colony/ day]	Pre application {DAA 3 to 0ba}:	24.7	18.2	28.0
	DAA0ba	11.5	8.8	17.0
	DAA0aa	6.3	12.8	9.8
	DAA+1	3.3	4.0	6.8
	Post application DAA0aa to +7}:	5.2	7.6	9.7
	QM(average):	0.2	0.4	0.3
Daily mean flight intensity [forager bees/m2]	Pre application {DAA 3 to 0ba}:	1.3	1.2	1.8
	DAA0ba	1.8	1.0	2.6
	DAA0aa	2.4	0.2	0.6
	DAA+1	0.5	0.3	0.1
	Post application {DAA0aa to +7}:	1.8	1.1	1.0

DAA = Days after application

QM(average) — = Ø Post application mortality + Ø pre application mortality

ba — = before application

aa — = after application

Observations Trial G07N001B

Honey bee mortality (Trial G07N001B)

The daily mean bee mortality (number of dead bees in the dead bee traps and in front of the hives) before the application was 18.5 dead bees/colony in the test item group, 24.3 dead bees/colony in the reference item treatment and 16.0 dead bees in control colonies. In the morning before application on DAA0 the

mean mortality was 13.0 dead bees/colony in the test item group, 29.5 dead bees/colony in the reference item treatment and 15.5 dead bees per hive in control. A mean number of 8.3 dead bees per colony was recorded in the test item group, 10.3 dead bees/colony in the reference item treatment and 9.0 dead bees in control colonies was found on the application day after application (DAA0aa).

Before the application the natural mortality in the reference item treatment and the test item treatment was on a slightly higher level than in the control treatment. Considering the results before and after application of each treatment group, the mortality in the test item treatment was on a lower level during the post application period as during the pre application period. The mortality of the reference item treatment was also slightly lower after the application. The control mortality remained on about the same low level in the pre and post application period.

The value for QM(average) was calculated as 0.6 in the test item treatment group compared to 0.8 in the control group, indicating that the treatment had no effect on honey bee mortality. In the reference item treatment the mortality was on a low level during the entire post application period and the QM(average) value was 0.4.

Honey bee flight intensity (Trial G07N001B)

Shortly before application on DAA0 the mean flight intensity (forager bees/m²) was 3.8 bees/m² in the test item treatment group and 4.2 bees/m² in the control treatment group for T. In the reference item treatment group the mean flight intensity was 2.8 bees/m² and 3.0 bees/m² in the corresponding control group for R. The mean flight intensity pre application was 2.2 bees/m² in the test item treatment group and 3.3 bees/m² in the control treatment group for T. The mean flight intensity pre application in the reference item treatment group was 2.4 bees/m² and 2.9 bees/m² in the control treatment group for R. During the assessments on DAA0 after application a decreased flight activity was observed in the test item field as well as in the reference item field and resulted in a mean number of 0.9 forager bees/m² in the test item treatment group and 0.6 forager bees/m² in the reference item treatment group. In the control group for T and in the control group for R the mean flight intensity on DAA0 was 2.9 and 3.4 forager bees/m² after application respectively. On DAA+1 the flight intensity was 3.0 forager bees/m² in the control treatment group, the flight intensity observed in the treatment groups T and R was slightly lower, 2.2 in the test item treatment group and 1.3 forager bees/m² in the reference item treatment group.

On the assessment dates following DAA+2 no treatment related difference regarding the flight intensity was observed between the treatment groups.

The daily mean flight intensity after the application in the entire post application period was 2.2 forager bees/m² in the treatment group, 2.7 forager bees/m² in the treatment group R and 3.0 forager bees/m² in the control group for T and 3.1 forager bees/m² in the control group for R.

After the application on DAA0 the amount of bees foraging in the test item and reference item field was reduced for several hours after application, slightly reduced on DAA+1 and returned to normal foraging activity on DAA+2. Slightly lower flight intensities in the test item treatment after DAA+1 are presumably due to natural reasons and the condition of the test item fields, as the flight intensity in the test item treatment was already lower than the flight intensity in the reference item treatment and the control treatment before application.

Homing behaviour – marking of forager bees (Trial G07N001B)

During the observation of bee behaviour of 10 Opalith marked bees in the trial on DAA-1 few bees were observed showing affected behaviour in the observation hive in the control and in the reference item treatment group, whereas no affected behaviour was observed in the test item treatment group. On DAA0 after the application few bees with affected behaviour were observed in the test and reference item treatment groups, and slightly more in the reference item treatment group compared to the test item treatment group. On DAA+1 no affected behaviour was observed in the reference item treatment and in the control group, only in the test item treatment group few bees were showing symptoms of affected behaviour.

No clear effect on the recovery of 10 Opalith marked and 40 paint marked bees was observed after the application. During Marking II on DAA0 and Marking III on DAA+2 a lower number of Opalith marked

bees of the reference group compared to the control and the test item treatment was noticed returning to the hive, also the recovery of paint marked bees of the reference item treatment group on DAA0 was slightly lower than the control but not on DAA+2. On Marking IV on DAA+3 the recovery of Opalith-marked bees in the test item treatment group was lower compared to the control treatment group and compared to the reference item treatment group. The recovery of paint marked bees was slightly lower in the reference item treatment before the application on marking I on DAA-1 compared to the control and test item treatment group. After the application the recovery of bees marked at Marking II in the test item treatment group, the reference item treatment group and the control treatment group was on a similar level. On DAA+2, Marking III, a slightly lower number of bees was recovered in the test item treatment group compared to the reference item and the control treatment group. On Marking IV the recovery of the paint marked bees in test item treatment and in the reference item treatment group were lower compared to the control but in the range of natural variability. The observation of the paint marked bees of Marking I from DAA-1 up to DAA+2 did not indicate any impact on the recovery of the forager bees. The amounts of bees recovered in the test item treatment group were on the same level as the amount of bees observed before the application as well as on the same level with the amount of bees counted in the control treatment and the reference item treatment.

Condition of the colonies (Trial G07N001B)

Assessments of the colony strength as judged by number of bee ways between combs filled with bees and the brood nest size (number of brood combs per colony) did not indicate significant differences between treatment groups T, R and the control. The colonies of the treatment groups T and R and control showed all brood stages at any time at the assessment dates and increased colony size during the experimental phase of the study. The colonies of all treatment groups were in good condition throughout the entire observation period.

Behaviour of the bees at the hive entrance and during foraging activity in the crop (Trial G07N001B)

During the observations of the foraging activity no symptoms of affected behaviour were observed in the control treatment. In the test item treatment on DAA0 a slightly reduced foraging activity was observed. Half an hour after the application of the reference item on DAA0 it was observed that the bees would not land on the flowers, at the hive entrance cleaning bees were seen. One hour after application no further symptoms of affected bee behaviour were observed. On DAA+1 the colonies of all treatment groups were slightly nervous at the hive entrance which was presumably due to natural reasons as it occurred in all treatment groups. On the following assessment dates no further symptoms of affected bee behaviour, like shaking, trembling or cramping bees, bees showing impaired movements, excessive cleaning behaviour, or fighting bees were observed in any of the treatments.

Observations Trial G07N002B

Honey bee mortality (Trial G07N002B)

The daily mean bee mortality (number of dead bees in the dead bee traps and in front of the hives) before the application was 25.2 dead bees/colony in the test item group, 22.7 dead bees/colony in the reference item treatment and 41.9 dead bees in control colonies. In the morning before application on DAA0 the mean mortality was 19.8 dead bees/colony in the test item group, 7.0 dead bees/colony in the reference item treatment and 17.0 dead bees per hive in control. After application on the application day (DAA0aa) a mean number of 14.0 dead bees per colony was recorded in the test item group, 6.8 dead bees/colony in the reference item treatment and 15.5 dead bees in control colonies.

Before the application the natural mortality in the reference item treatment and the test item treatment was on a lower level than in the control treatment. Considering the results before and after application of each treatment group, the mortality in the test item treatment was on a lower level during the post-application period as during the pre-application period. The mortality of the reference item treatment was also on slightly lower level after the application. The post application control mortality decreased compared to the pre-application level and was on about the same low level as observed in the reference and test item treatment group in the pre- and post application period. The Mortality in the test and reference item treatment group were not increased after application.

The value for QM(average) was calculated as 0.6 in the test item treatment group compared to 0.5 in the

control group, indicating that the treatment had not affected honey bee mortality. In the reference item treatment the mortality was on a low level during the entire post application period and the QM(average) value was 0.8.

Honey bee flight intensity (Trial G07N002B)

Shortly before application on DAA0 the mean flight intensity (forager bees/m²) was 2.2 bees/m² in the test item treatment group, in the reference item treatment group the mean flight intensity was 2.0 bees/m² and 1.8 bees/m² in the control treatment group. The mean flight intensity pre application was 1.6 bees/m² in the test item treatment group. The mean flight intensity pre application in the reference item treatment group was 1.5 bees/m² and 1.5 bees/m² in the control treatment group. During the assessments on DAA0aa after application a slightly decreased flight activity was observed in the test item field, a mean number of 1.1 forager bees/m² in the test item treatment group was observed. In the reference item treatment group flight activity was discontinued, a mean flight intensity of 0.0 forager bees/m² was observed. In the control group the mean flight intensity on DAA0aa was 1.6 forager bees/m². On DAA+1 the mean flight intensity was 2.5 in the control, 1.7 in the test item treatment and 1.7 forager bees/m² in the reference item treatment.

On the following assessment dates no treatment related difference regarding the flight intensity was observed between the treatment groups. The flight intensity of the control treatment group increased slightly during the post application period, the mean flight intensity of the test item and reference item groups was on the same level in the entire pre and post application period. The daily mean flight intensity in the post application period was 1.7 forager bees/m² in the treatment group T, 1.6 forager bees/m² in the treatment group R and 2.4 forager bees/m² in the control group.

Homing behaviour – marking of forager bees (Trial G07N002B)

During the observations of behaviour and recovery of 10 Opalith marked bees and the recovery of 40 paint marked forager bees using a special observation hive, no symptoms of affected behaviour were detected in the entire observation period.

The results do not indicate any differences in the behaviour or in the recovery of Opalith marked bees between the different treatment groups and the control. The recovery of the paint marked bees was on a similar level in the control, test item and reference item treatment group.

During four days of observation of paint marked bees, no differences between the treatment groups control, test item and reference item were perceived.

Condition of the colonies (Trial G07N002B)

Assessments of the colony strength as judged by number of bee ways between combs filled with bees and the brood nest size (number of brood combs per colony) did not indicate differences between treatment groups T, R and the control. On the first and second brood assessment the colonies of the treatment groups T and R and control showed all brood stages at any time and increased colony size. After the second brood assessment no further swarm prevention was conducted, 3 colonies of the control treatment, 2 of the test item treatment and 1 colony of the reference item treatment had swarmed. In these colonies the colony strength as judged by number of bee ways covered with bees decreased, and a reduction of the brood nest size was observed. The lack of eggs and larvae at the third brood assessment date is due to the natural process and the biological procedure of swarming. Summing up, the colonies of all treatment groups were in good condition throughout the entire observation period. No treatment-related effects were observed.

Behaviour of the bees at the hive entrance and during foraging activity in the crop (Trial G07N002B)

On DAA0 during the first two hours after application of the test item many bees cleaning themselves were observed at the hive entrance. In the reference item treatment, bees cleaning themselves were observed at the hive entrance during the first half hour after the application, the foraging activity was discontinued after the application until the next Day, DAA+1. The behaviour of foraging bees and around the hive entrance was normal in the control treatment during the entire observation period.

Observations Trial G07N003B

Honey bee mortality (Trial G07N003B)

The daily mean bee mortality (number of dead bees in the dead bee traps and in front of the hives) before the application was 18.2 dead bees/colony in the test item group, 28.0 dead bees/colony in the reference item group and 24.7 dead bees in control colonies. In the morning before application on DAA0 the mean mortality was 8.8 dead bees/colony in the test item group, 17.0 dead bees/colony in the reference item treatment and 11.5 dead bees per hive in control. After application on the application day (DAA0aa) a mean number of 12.8 dead bees per colony was recorded in the test item group, 9.8 dead bees/colony in the reference item treatment and 6.3 dead bees in control colonies.

On DAA 3 the natural mortality in the reference item treatment was about the level of the control mortality and on a slightly higher level than in the test item treatment. All treatment groups were about the same level of natural mortality before application. Considering the results before and after application of each treatment group, the mortality in all treatment groups was on a lower level during the post-application period as during the pre-application period and on the level of natural mortality. The mortality was not increased by any of the treatments. Only on DAA+3 a slightly higher but still normal range of mortality in the reference treatment compared to the control and test item treatments was observed.

The value for QM(average) was calculated as 0.4 in the test item treatment group compared to 0.2 in the control group and 0.3 in the reference item group, indicating that the treatment had no effect on honey bee mortality.

Honey bee flight intensity (Trial G07N003B)

Shortly before application on DAA0 the mean flight intensity (forager bees/m²) was 1.0 bees/m² in the test item treatment group and 1.8 bees/m² in the control treatment group. In the reference item treatment group the mean flight intensity was 2.6 bees/m². The mean flight intensity in the pre-application period was 1.2 bees/m² in the test item treatment group and 1.3 bees/m² in the control treatment group, the mean flight intensity pre-application in the reference item treatment group was 1.8 bees/m².

During the assessments on DAA0 after application a decreased flight activity was observed in the test item field as well as in the reference item field and resulted in a mean number of 0.2 forager bees/m² in the test item treatment group and 0.6 forager bees/m² in the reference item treatment group, in the control group the mean flight intensity on DAA 0 was 2.4 forager bees/m² after application.

On DAA+1 and on DAA+2 the flight intensity was only reduced in the reference item treatment, the flight intensity of the test item treatment and of the control treatment were on a similar level. The flight intensities of all treatments recovered to a similar level on DAA+3, the differences in the flight intensity on DAA+4 and DAA+5 were presumably due to natural reasons and the weather conditions at the field sites.

On the following assessment dates no treatment related difference regarding the flight intensity was observed between the treatment groups.

The daily mean flight intensity after the application was 1.1 forager bees/m² in the treatment group T, 1.0 forager bees/m² in the treatment group R and 1.8 forager bees/m² in the control group.

Homing behaviour – marking of forager bees (Trial G07N003B)

The observation of behaviour and recovery of 10 Opalith-marked bees and the recovery of 40 paint-marked forager bees using a special observation hive did not indicate any behavioural differences between the different treatment groups. No bees with symptoms of affected behaviour were observed in any of the treatment groups.

No difference in behaviour of Opalith-marked bees of the test item treatment group, the reference item treatment group and the control group was observed. The recovery of Opalith-marked bees was slightly higher in the test item and the reference item treatment group compared to the control. Only on DAA0 on Marking II the recovery of Paint-marked bees was slightly higher in the control treatment compared to the test item treatment and the reference item treatment, and slightly lower on Marking III and Marking IV on DAA+1 and DAA+2. The results show that the recovery of bees marked on Marking I (DAA-1) was not reduced after the application of the test item or the reference item up to the last

~~observation on DAA+2.~~

Condition of the colonies (Trial G07N003B)

~~Assessments of the colony strength as judged by number of bee ways between combs filled with bees and the brood nest size (number of brood combs per colony) did not indicate apparent differences between treatment groups T, R and the control. The colonies of the treatment groups T and control showed all brood stages at any time at the assessment dates and increased or maintained colony size during the experimental phase of the study. The colonies of the reference item treatment increased size slightly as judged by the number of bee ways covered but showed a slight reduction of the brood nest size on the last brood assessment. On the last brood assessment 2 of the colonies had no more eggs and a small brood nest size, which indicates that the colonies had swarmed.~~

~~Behaviour of the bees at the hive entrance and during foraging activity in the crop (Trial G07N003B). During the observations at the hive entrance no symptoms of affected bee behaviour, like shaking, trembling or cramping bees, bees showing impaired movements, excessive cleaning behaviour, or fighting bees were observed in the control treatment. In the test item treatment one hour after the application individual bees (numbers not exactly quantified) with shaking, spinning and cramping movements were observed around the hive entrance. In the reference item treatment it was observed 45 minutes after the application that single bees did not land on flowers, if they did, they remained sitting on the flowers. Other bees showed normal foraging behaviour. After one hour the foraging behaviour was normal, an intense flight intensity was observed at the hive entrance but almost no foraging activity in the crop.~~

Conclusions

~~An application of Deltamethrin EC 25 to flowering *Brassica napus* at a rate of 7.5 g a.i./ha (nominal) led to a mostly slight decrease of the flight intensity on the day of application after the treatment in all trials. After application of the test item, the mortality was not increased in any of the trials. The observations of bee behaviour of individually Opalith marked and paint marked bees did not indicate any disturbance of the homing behaviour. Only a few bees in the observation hives or at the hive entrances showed symptoms of abnormal behavior after application of the test item. In the reference item treatment the fraction of bees showing symptoms of affected behaviour was slightly higher than in the test item treatment and higher than in the control treatment.~~

~~The condition of the colonies, size of the brood nest and the development of the honey bee brood in the test item treatment group was not different compared to the control during the observation period and not affected by any of the treatments.~~

~~The application of Deltamethrin EC 25 did not result in adverse effects on the honeybees in the trials reported here.~~

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:	<p>The study was performed in line with the respective guideline with no deviations.</p> <p>All validity criteria were met and the study is considered acceptable with the following endpoints relevant for the risk assessment:</p> <p>42DAT and 56DAT LR₅₀ > 1.25 L product/ha 42DAT and 56DAT ER₅₀ > 1.25 L product/ha</p> <p>(DAT – day after treatment)</p>
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Reference:	KCP 10.3.2.2/01
Title:	Toxicity to the ladybird beetle <i>Coccinella septempunctata</i> (Coleoptera: Coccinellidae) using an extended laboratory test with aged residues on apple - flupyradifurone + deltamethrin EC 85 (75+10 g/L)
Report:	Waibel, J.; 2018; CW16/016; M-614308-01-1
Guideline(s):	<p>EU Directive 91/414/EEC Regulation (EC) No. 1107/2009 US EPA OCSPP Not Applicable SCHMUCK ET AL. (2000) modified CANDOLFI ET AL. (2001)</p>
Deviations:	None
GLP/GEP:	yes
Acceptability:	Acceptable

Materials and methods

Test item:	flupyradifurone + deltamethrin EC 85 (75+10 g/L)
Type of formulation:	EC (emulsifiable concentrate)
Sample description:	TOX 10717-00
Active substances (analysed content):	flupyradifurone: 76.59 g/L deltamethrin: 10.03 g/L
Specification no.:	102000028562
Supplier batch no.:	2014-012629
Density:	1.157 g/mL

The test item was applied once with 1.25 L product/ha diluted in 1500 L deionised water/ha on potted apple trees (*Malus sylvestris*), with 600 mL spray solution per tree using a backpack sprayer. The control plants were treated with deionised water in the same way as the test item.

The reference item (active substance: dimethoate EC 400) was applied at 0.0476 L product/ha (20 g a.s./ha) diluted in 200 L deionised water/ha on each exposure date directly on detached apple leaves.

Aging of the spray deposits of the test item on the potted apple trees took place under semi-field conditions with UV permeable rain protection during the first four weeks of the study. Four bioassays were performed, the first started on the application day (0DAT1 = 0 days after treatment), the second one three weeks later (21DAT1), the third one started six weeks after application (42DAT1) and the last one eight weeks after application (56DAT1). Larvae of the ladybird beetle (*Coccinella septempunctata*) were exposed to these residues on the treated leaf surfaces.

The preimaginal mortality of 40 larvae (per test group), 4 days old at each bioassay start, was assessed only 1 and 2 days in the first and second bioassay and till the hatch of the imagines up to 14 days in the third and fourth bioassay (food = *Acyrtosiphon pisum*).

The reproduction assessment of the surviving hatched adults was done for the third and fourth bioassay and started one week after the first eggs in the control could be observed. The number of fertile eggs laid per viable female was recorded over a period of two weeks in both bioassays. The eggs were counted daily and hatch success of the eggs was determined.

The effects of the test item on the test organisms were compared to those of the control with suitable statistical procedures using the statistical software program SAS (Version 9.4).

Climatic conditions during laboratory phase of study

Start of bioassay	Temperature (°C)	Rel. humidity (%)	Light intensity (Lux)
0DAT1	24.5 - 25.5	69 - 72	1270 - 1720
21DAT1	24.0 - 26.0	68 - 75	1015 - 3337
42DAT1	24.0 - 25.5	63 - 74	1049 - 3042
56DAT1	24.0 - 25.5	63 - 74	1437 - 3715

DAT = Days after treatment

Results and discussions

In this extended laboratory study the effects of flupyradifurone + deltamethrin EC 85 (75+10 g/L) residues (fresh and aged under semi-field conditions, with rain protection during the first four weeks of the study) on the survival of the ladybird beetle *Coccinella septempunctata* were determined after one application of 1.25 L product/ha onto apple trees (*Malus sylvestris*).

The first bioassay was started on the application day of the test item (0DAT1) and the second bioassay started three weeks later (21DAT1). A statistically significant mortality occurred (Fisher`s Exact test, one-sided, $\alpha = 0.05$) in both bioassays, the corrected mortality was 100.0%.

The third bioassay started six weeks after application (42DAT1). In this bioassay no statistically significant mortality was found anymore (Fisher`s Exact test, one-sided, $\alpha = 0.05$). The corrected mortality was 10.3%.

The fourth bioassay started eight weeks after application (56DAT1). In this bioassay no corrected mortality was found (-15.2%).

The exposure to the reference item resulted in 95.0% corrected mortality in the first and 100.0% in the second, third and fourth bioassay.

Reproduction was assessed in the third and fourth bioassay. In the third bioassay started six weeks after application, the mean number of fertile eggs per female and day was 7.3 in the control treatment and 9.6 in the test item treatment. In the fourth bioassay started eight weeks after application, the mean number of fertile eggs per female and day was 8.4 in the control treatment and 7.2 for the test item treatment. Since the reproductive performance was within the range of the historical data base for control beetles (≥ 2 fertile eggs per female and day, SCHMUCK ET AL. 2000) this parameter is considered as not affected in both bioassays.

A summary of the effects observed in this study is given below.

Test item:	flupyradifurone + deltamethrin EC 85 (75+10 g/L)			
Application:	1.25 L product/ha			
Test organism:	<i>Coccinella septempunctata</i>			
Exposure on:	Dried spray deposits on apple leaves (from treated apple trees)			
Start bioassay:	0DAT1 ^a	21DAT1 ^a	42DAT1 ^a	56DAT1 ^a
	Preimaginal mortality (%)			
Control:	0.0	0.0	27.5	17.5
Test item:	100.0	100.0	35.0	5.0
Reference item:	95.0	100.0	100.0	100.0
	Corrected preimaginal mortality (%)			
Test item:	100.0 (p-value <0.001, significant ^b)	100.0 (p-value <0.001, significant ^b)	10.3 (p-value 0.315, not significant ^b)	-15.2 (p-value 0.986, not significant ^b)
Reference item:	95.0	100.0	100.0	100.0
	Reproduction			
	Fertile eggs per female and day			
Control:	n.a.	n.a.	7.3	8.4
Test item:	n.a.	n.a.	9.6	7.2

^a DAT = days after treatment

^b Fisher's Exact test, one-sided ($\alpha = 0.05$), p-values adjusted according to Bonferroni-Holm

n.a. = not assessed

	Validity criteria	Finding Start of bioassay			
		0DAT1^a	21DAT1^a	42DAT1^a	56DAT1^a
Preimaginal mortality in water control	≤ 30%	0.0%	0.0%	27.5	17.5%
Preimaginal mortality reference item	≥ 40%	95.0%	100.0%	100.0%	100.0%
Mean number of fertile eggs per female and day in water control	≥ 2	n.a.	n.a.	7.3	8.4

^a DAT = days after treatment

n.a. = not assessed

Conclusion

The third and fourth bioassay (started on 42DAT1 and 56DAT1) resulted in a corrected mortality of <50%. The reproductive performance was not affected in both bioassays.

The figures obtained fulfil the validity criteria of the laboratory method for exposure on glass plates (SCHMUCK ET AL., 2000).

Comments of zRMS:	<p>The study was performed in line with the respective guideline with no deviations.</p> <p>All validity criteria were met:</p> <ul style="list-style-type: none"> mortality in the control group was ≤ 20 % (observed 15 %), mortality in the reference item group was ≥ 50 % (observed 71 %), fecundity in the control (mean number of eggs per female per day) was ≥ 15 (observed 29), fertility in the control (mean hatching rate) was ≥ 70 % (observed 70 %). <p>Overall, the study is considered acceptable with the following endpoints relevant for the risk assessment:</p> <p>LR₅₀ = 207.2 mL product/ha ER₅₀ > 125 mL product/ha</p>
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Reference:	KCP 10.3.2.2/02
Title:	Toxicity to the green lacewing <i>Chrysoperla carnea</i> (Neuroptera: Chrysopidae) using an extended laboratory test on bean flupyradifurone + deltamethrin EC 85 (75+10 g/L)
Report:	Mueller, R. U.; 2015; CW15/008; M-539469-01-1
Guideline(s):	EU Directive 91/414/EEC; Regulation (EC) No. 1107/2009; US EPA OCSPP not applicable; VOGT ET AL. (2000) modified: Use of natural substrate (bean leaves) instead of glass plate; CANDOLFI ET AL. (2001)
Deviations:	none
GLP/GEP:	yes
Acceptability:	Acceptable

Materials and methods

The emulsion concentrate formulation flupyradifurone + deltamethrin EC 85 (75+10 g/L) was tested, specified by sample description: TOX10717-00; specification no.: 102000028562; batch ID: 2014-012629 [analysed content of active substance: flupyradifurone 76.59 g/L; deltamethrin 10.03 g/L; density: 1.157 g/mL.

The test item was applied to detached bean leaves (*Phaseolus vulgaris*) at rates of 125, 222, 395, 703 and 1250 mL product/ha in 200 L deionised water 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 EC 400) applied at 89.8 mL product/ha (36 g a.s./ha) in 200 L deionised water 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 22 days). The fertility (the hatching rate of eggs) and fecundity (the number of eggs laid per female per day) of the surviving hatched adults were then evaluated over the period of one week.

The climatic test conditions during the study were 23.0 - 25.0 °C temperature and 60 - 75% relative humidity. The light / dark cycle was 16:8 h with a light intensity range of 1536 - 4037 Lux during the mortality phase and of 2829 - 3010 Lux during the reproduction phase of the study.

Results and discussions

In this extended laboratory test the effects of flupyradifurone + deltamethrin EC 85 (75+10 g/L) residues on the survival of the green lacewing *Chrysoperla carnea* were determined at the rates of 125, 222, 395, 703 and 1250 mL product/ha applied to detached bean leaves (*Phaseolus vulgaris*).

All test item rates showed statistically significant influence on preimaginal mortality. At the test item rates of 125, 222 and 395 mL product/ha, a corrected preimaginal mortality of 26.5%, 67.6%, and 58.8% has been observed, respectively. In the test item rates of 703 and 1250 mL product/ha, a corrected preimaginal mortality of 85.3% and 88.2% occurred, respectively. For the reference item 70.6% corrected preimaginal mortality occurred.

Reproduction was assessed only for the lowest rate of flupyradifurone + deltamethrin EC 85 (75+10 g/L), 125 mL product/ha. There were no adverse effects of this test item rate on the reproductive performance. The mean number of eggs per female and day for the control during the test period was 28.6. The hatching rate (= fertility) of the eggs was 70 %. The mean number of eggs per female and day for the 125 mL product/ha rate was 30.3 with a hatching rate of 74%.

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: $\geq 70\%$) according to the historical database of the ring testing group (VOGT ET AL., 2000).

A summary of the effects observed in this study is given below.

Test item:		flupyradifurone + deltamethrin EC 85 (75+10 g/L)				
Test organism:		<i>Chrysoperla carnea</i>				
Exposure on:		Detached bean leaves				
		Preimaginal mortality [%]			Reproduction	
Treatment	mL product/ha	Uncorr.	Corr.	P-Value(*)	Eggs per female and day	Fertility [hatching rate in %]
Control	0	15.0			29	70
Test item	125	37.5	26.5	0.020 sign.	30	74
Test item	222	72.5	67.6	<0.001 sign.	n.a.	n.a.
Test item	395	65.0	58.8	<0.001 sign.	n.a.	n.a.
Test item	703	87.5	85.3	<0.001 sign.	n.a.	n.a.
Test item	1250	90.0	88.2	<0.001 sign.	n.a.	n.a.
Reference item	89.8	75.0	70.6		n.a.	n.a.
LR₅₀: 207.2 mL product/ha; 95 % Confidence Interval: (113.5 - 298.3); calculated with Probit analysis						
* Fisher's Exact test (one-sided, $\alpha = 0.05$), p-values are adjusted according to Bonferroni-Holm						
n.a. not assessed sign. significant						

Conclusion

The LR₅₀ was calculated to be 207.2 mL product/ha. The NOER for mortality was estimated to be < 125 mL product/ha.

The reproductive performance was not affected up to and including the test item rate of 125 mL product/ha.

The figures obtained fulfil the validity criteria of the laboratory method for the exposure on glass plates.

Comments of zRMS:	<p>The study was performed in line with the respective guideline with no deviations from the guideline but with the following deviation to the study plan.</p> <p>According to the study plan aphids should be replaced or added each day until larvae have entered the pupal stage. However, since there were not enough aphids in the rearing left, on day 3 no aphids have been replaced in test unit 7.0 mL product/ha and on day 4 no aphids have been replaced in all treatments (control, 0.7 – 7.0 mL product/ha). Nevertheless, sufficient aphids were left in all test units from the feeding on the previous days, thus the above deviation is considered to have no impact on the study. Furthermore, the guideline requires a daily feeding only during the week. Feeding is not mandatory on weekends (day 3 and day 4 of this study).</p> <p>All validity criteria were met:</p> <ul style="list-style-type: none"> • pre-imaginal mortality in the control was ≤ 30 % (observed 7.5 %), • number of eggs per female per day in the control was > 2 (observed 6.7), • pre-imaginal mortality in the reference treatment was > 40 % (observed 100%). <p>Overall, the study is considered acceptable with the following endpoints relevant for the risk assessment:</p> <p>LR₅₀ = 4.70 mL product/ha ER₅₀ > 3.9 mL product/ha</p>
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Reference:	KCP 10.3.2.2/03
Title:	Flupyradifurone + deltamethrin EC 85 (75 + 10 g/L): Effects on the ladybird beetle - <i>Coccinella septempunctata</i> , extended laboratory study - Dose response test -
Report:	Moll, M.; 2015; 101151012; M-530897-01-1
Guideline(s):	EU Directive 91/414/EEC Regulation (EC) No. 1107/2009 US EPA OCSPP not applicable Schmuck <i>et al.</i> 2000. Modified for exposure of <i>C. septempunctata</i> on natural substrate.
Deviations:	None to the guideline, minor to the study plan (see the table above for details) not specified
GLP/GEP:	yes
Acceptability:	Acceptable

Materials and methods

Flupyradifurone + deltamethrin EC 85 (75 + 10 g/L): Sample Description: TOX10717-00, Specification No.: 102000028562, Supplier Batch No.: 2014-012629, content of a.s.: 0.867% w/w (10.03 g/L) deltamethrin (AE F032640) and 6.62% w/w (76.59 g/L) flupyradifurone (BYI 02960); density: 1.157 g/mL.

Under extended laboratory conditions 4 - 5 day old larvae of the ladybird beetle *Coccinella septempunctata* were exposed to dried spray deposits of 0.7, 1.2, 2.2, 3.9 and 7.0 mL product/ha (diluted in 200 L deionised water/ha) on treated bean leaves (40 replicates, each containing 1 larva per treatment group). Deionised water was used as a control treatment and dimethoate (50 mL product/ha diluted in 200 L deionised water/ha) as a reference treatment. Exposure time lasted until the hatching of the adults. Mortality checks were carried out regularly until eclosion of adult ladybird beetles (up to 16 days after test start). In addition, for the control and the test item treatment groups where the corrected mortality was < 50%, the reproduction performance, *i.e.* egg deposition and larval hatching rate, was determined over two weeks.

Test Conditions: Temperature: 24 - 26 °C; relative humidity: 61 - 90%; photoperiod: 16 h light : 8 h dark; light intensity: 1010 - 1480 lux.

Results and discussions

Table: Pre-imaginal mortality and reproduction of *Coccinella septempunctata*

	Rate ¹⁾ [mL/ha]	Mortality ²⁾ [%]		Mortality corr. ³⁾ [%]	Reproduction [fertile eggs per female per day]
Control	0	7.5		--	6.7
flupyradifurone + deltamethrin EC 85 (75 + 10 g/L)	0.7	22.5	n.s.	16.2	7.6
flupyradifurone + deltamethrin EC 85 (75 + 10 g/L)	1.2	22.5	n.s.	16.2	9.1
flupyradifurone + deltamethrin EC 85 (75 + 10 g/L)	2.2	40.0	*	35.1	9.5
flupyradifurone + deltamethrin EC 85 (75 + 10 g/L)	3.9	42.5	*	37.8	8.6
flupyradifurone + deltamethrin EC 85 (75 + 10 g/L)	7.0	67.5	*	64.9	-
Reference item	50.0	100.0	*	100.0	-
Endpoint ⁴⁾					
LR ₅₀ (95 % CL): 4.70 mL product/ha (3.37 - 8.33 mL product/ha)					

1) Application rate in 200 L water/ha

2) Fisher's Exact Test, $\alpha = 0.05$: n.s. = not significant, * = significant

3) Corrected pre-imaginal mortality according to Abbott and improvements by Schneider-Orelli

4) LR₅₀ was calculated with Probit-Analysis; CL = confidence limits

In this extended laboratory study the effects of flupyradifurone + deltamethrin EC 85 (75 + 10 g/L) residues to larvae of the ladybird beetle *Coccinella septempunctata* were determined at 0.7, 1.2, 2.2, 3.9 and 7.0 mL product/ha. The application was done onto bean leaves (*Phaseolus vulgaris*).

The pre-imaginal mortality was 7.5% in the control, 22.5% at 0.7 and 1.2 mL product/ha, 40.0% at 2.2 mL product/ha, 42.5% at 3.9 mL product/ha and 67.5% at 7.0 mL product/ha, respectively. This resulted in corrected mortalities of 16.2% at 0.7 and 1.2 mL product/ha, 35.1% at 2.2 mL product/ha, 37.8% at 3.9 mL product/ha and 64.9% at 7.0 mL product/ha, respectively. Mortality in the reference item was 100%.

The reproductive capacity of *C. septempunctata* was tested at 0.7, 1.2, 2.2 and 3.9 mL product/ha. The number of fertile eggs per female per day was 6.7 in the control, 7.6 at 0.7 mL product/ha, 9.1 at 1.2 mL product/ha, 9.5 at 2.2 mL product/ha and 8.6 at 3.9 mL product/ha, respectively. Therefore reproduction was > 2 fertile eggs per viable female per day at all tested test item rates, so the reproductive output is within the historical data base for control beetles and therefore this parameter is considered as not impacted by the treatment (Schmuck *et al.* 2000) up to and including 3.9 mL product/ha.

Conclusion

The LR₅₀ was calculated to be 4.70 mL product/ha (95 % confidence limits: 3.37 - 8.33 mL product/ha) in 200 L water/ha. The NOER (no observed effect rate) for mortality was 1.2 mL product/ha.

The reproductive capacity is within the range of the historical data base for control beetles and therefore this parameter is considered as not impacted by the treatment (Schmuck *et al.* 2000) up to and including 3.9 mL product/ha.

The figures obtained fulfil the validity criteria of the laboratory method for the exposure on glass plates.

Comments of zRMS:	The study was performed in line with the respective guideline with no deviations.
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	<p>All validity criteria were met:</p> <ul style="list-style-type: none"> mortality in the control was $\leq 10\%$ (actually 0%), the corrected mortality in the reference item was $\geq 50\%$ (actually 90.0%), mean reproduction per female in the control was ≥ 5 mummies per female (actually 38.7), number of surviving wasps in the control producing zero values for reproduction was ≤ 2 (actually 0). <p>Overall, the study is considered acceptable with the following endpoints relevant for the risk assessment:</p> <p>LR₅₀ = 42.1 mL product/ha ER₅₀ = 26.1 mL product/ha</p>
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Reference:	KCP 10.3.2.2/04
Title:	Toxicity to the parasitoid wasp <i>Aphidius rhopalosiphi</i> (Hymenoptera: Braconidae) using an extended laboratory test on barley flupyradifurone + deltamethrin EC 85 (75+10 g/L)
Report:	Mueller, R. U.; 2015; CW15/006; M-539457-01-1
Guideline(s):	EU Directive 91/414/EEC; Regulation (EC) No. 1107/2009; US EPA OCSPP not applicable; MEAD-BRIGGS ET AL. (2010), CANDOLFI ET AL. (2001)
Deviations:	none
GLP/GEP:	yes
Acceptability:	Acceptable

Materials and methods

The emulsion concentrate formulation flupyradifurone + deltamethrin EC 85 (75+10 g/L) was tested, specified by sample description: TOX10717-00; specification no.: 102000028562; batch ID: 2014-012629 [analysed content of active substance: flupyradifurone 76.59 g/L; deltamethrin 10.03 g/L; density: 1.157 g/mL.

The test item was applied on barley seedlings (*Hordeum vulgare*) at rates of 10, 18, 32, 56 and 100 mL product/ha in 400 L deionised water 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 EC 400) applied at 10 mL product/ha (4 g a.s./ha) in 400 L deionised water 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.

For the mortality assessments the following condition of the test animals was observed:

- Live (alive and apparently unaffected)
- Affected (showing reduced co-ordination or any abnormal behaviour)
- Moribund (unable to walk, but still moving legs or antennae)
- Dead (no longer moving)

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 test item rate of 100 mL product/ha was conducted 24 h after the release of the wasps into the exposure units.

For the reproduction assessment from the water control and the test item rates 10 and 18 mL product/ha 20 impartially chosen from the surviving females per treatment were each transferred to a cylinder containing untreated barley seedlings infested with *Rhopalosiphum padi* for a period of 24 h.

From the test item rate 32 mL product/ha only 17 females were left after the mortality phase, they also

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 11 days later.

The climatic test conditions during the study were 18.5 - 21.5 °C temperature and 60 - 83% relative humidity. The light / dark cycle was 16:8 h with a light intensity range of 677 - 826 Lux in the mortality phase, 3230 - 4340 Lux in the parasitism phase and 12560 - 15980 Lux in the reproduction phase of the study.

Results and discussions

In this extended laboratory test the effects of flupyradifurone + deltamethrin EC 85 residues on the survival of *Aphidius rhopalosiphii* were determined at 10, 18, 32, 56 and 100 mL product/ha, applied to barley seedlings (*Hordeum vulgare*).

After 48 h of the study all wasps survived in the control group. At the rate of 10 mL product/ha no mortality was detected. In the test item rate of 18 mL product/ha, a corrected mortality of 13.3% occurred which was not statistically significant different compared to the control. A statistically significant corrected mortality was found in the 32, 56 and 100 mL product/ha rates with 43.3%, 70.0% and 80.0%, respectively. In the test item rates of 18 and 32 mL product/ha a corrected mortality of 13.3% and 43.3% was observed and at the rates of 56 and 100 mL product/ha a corrected mortality of 70.0% and 80.0% occurred, respectively.

During the observations in the initial 3 h of the test a mean of 48.0% of the wasps settled on the plants in the control group. In the groups treated with 10, 18, 32, 56 and 100 mL product/ha a mean, of 42.0%, 46.2%, 36.0%, 37.7% and 16.9% of the wasps settled on the plants, respectively. In the toxic reference group 62.0% of the wasps were found on the plants.

Repellent effects of the test item (settling of the wasps on plants <30%) were observed in the first 3 hours after the introduction of the wasps into the exposure units only at the highest test item rate of 100 mL product/ha. This effect was found again in a second repellent assessment which was initiated 24 h later. In this assessment 78.3% of the wasps were found on the plants in the control group compared to 6.7% in the test item group treated with 100 mL product/ha. A further repellent assessment was not possible due to high mortality.

Reproduction was assessed for the three lowest rates of 10, 18 and 32 mL product/ha of flupyradifurone + deltamethrin EC 85. No statistically significance occurred for the reduction in reproductive success relative to the control. The reduction in reproductive success relative to the control was 14.4%, 50.6% and 19.5%, respectively.

A summary of the effects observed in this study is presented in the table below given on the next page.

Test item:		flupyradifurone + deltamethrin EC 85 (75+10 g/L)						
Test organism:		<i>Aphidius rhopalosiphi</i>						
Exposure on:		Barley seedlings						
		Mortality after 48 h [%]			Reproduction		Repellency (first 3 h)	
Treatment	mL product/ha	Uncorr.	Corr.	P-Value(*)	Rate (mummies per female)	Reduction relative to control [%] P-Value(#)	% Wasps on plant	Reduction relative to control [%] P-Value(#)
Control	0	0.0			38.7		48.0	
Test item	10	0.0	0.0	1.000 n.sign.	33.1	14.4 0.075 n.sign.	42.0	12.5 0.072 n.sign.
Test item	18	13.3	13.3	0.112 n.sign.	19.1	50.6 0.092 n.sign.	46.2	3.8 0.085 n.sign.
Test item	32	43.3	43.3	<0.001 sign.	31.1	19.5 0.233 n.sign.	36.0	25.0 0.090 n.sign.
Test item	56	70.0	70.0	<0.001 sign.	n.a.	n.a.	37.7	21.5 0.093 n.sign.
Test item	100	80.0	80.0	<0.001 sign.	n.a.	n.a.	16.9	64.8 0.094 n.sign.
Reference item	10	90.0	90.0		n.a.	n.a.	62.0	-29.2

LR₅₀: 42.1 mL product/ha; 95% Confidence Interval: (34.8 - 51.6); calculated with Probit analysis
ER₅₀: 26.1mL product/ha; 95% Confidence Interval: (21.1 - 32.3); calculated with Spearman-Kärber
* Fisher's Exact test (one-sided, $\alpha = 0.05$), p-values are adjusted according to Bonferroni-Holm
one-way ANOVA, Williams test (one-sided)
n.a. not assessed n.sign. not significant sign. significant

Conclusion

The LR₅₀ was calculated to be 42.1 mL product/ha. The NOER for mortality was 18 mL product/ha. In the reference item group 90% of the wasps were dead after 48 h of exposure. The ER₅₀ was calculated to be 26.1 mL product/ha. The NOER for reproduction was ≥ 32 mL product/ha. The figures obtained fulfil the validity criteria of the extended laboratory method (MEAD-BRIGGS ET AL., 2010).

Comments of zRMS:	<p>The study was performed in line with the respective guideline with a minor deviation.</p> <p>It was noted that the study was performed with 10 predator protonymphs in 10 replicates per treatment group instead of 20 individuals in 5 replicates per treatment. This deviation is considered to have no impact on the test results, since relevant number of individuals was tested.</p> <p>All validity criteria of the study were met:</p> <ul style="list-style-type: none"> the arithmetic mean mortality rate (dead and escaped mites) in the control was $\leq 20\%$ on day 7 after treatment application (actually 7.0%), the cumulative mean number of eggs per female (reproduction) in the control (from day 7 to day 14) was ≥ 4 eggs/female (actually 7.0 eggs/female), the cumulative mean mortality (control corrected) of protonymphs on day 7 exposed to the toxic reference item was between 50 and 100% (actually 63.4%). <p>Overall, the study is considered acceptable with the following endpoints relevant for the</p>
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	risk assessment: LR ₅₀ = 9.5 mL product/ha ER ₅₀ > 9 mL product/ha
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Reference:	KCP 10.3.2.2/05
Title:	Toxicity to the predatory mite <i>Typhlodromus pyri</i> (Acari: Phytoseiidae) using an extended laboratory test on bean flupyradifurone + deltamethrin EC 85 (75+10 g/L)
Report:	Mueller, R. U.; 2015; CW15/005; M-539453-01-1
Guideline(s):	EU Directive 91/414/EEC; Regulation (EC) No. 1107/2009; US EPA OCSP not applicable; BLUEMEL ET AL. (2000) modified: Instead of glass plates use of natural substrate (detached bean leaves) enclosed in ventilated cells (Munger cages) for the first 7 days of the study; CANDOLFI ET AL. (2001)
Deviations:	Minor deviations (see the table above for details) none
GLP/GEP:	yes
Acceptability:	Acceptable

Materials and methods

The emulsion concentrate formulation flupyradifurone + deltamethrin EC 85 (75+10 g/L) was tested, specified by sample description: TOX10717-00; specification no.: 102000028562; batch ID: 2014-012629 [analysed content of active substance: flupyradifurone 76.59 g/L; deltamethrin 10.03 g/L; density: 1.157 g/mL.

The test item was applied onto detached bean leaves (*Phaseolus vulgaris*) at rates of 5, 9, 16, 28 and 50 mL product/ha in 200 L deionised water 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 EC 400) applied at 74.8 mL product/ha in 200 L deionised water (30 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 (10 replicates with 10 individuals per test group), was assessed 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.

Due to the known repellent effects of the test item the mortality part of this study was performed in closed but actively ventilated cells (Munger cages). On day 7 after application the surviving mites were transferred on untreated open exposure units (glass plates) and 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 24.5 - 25.5 °C temperature and 69 - 76% relative humidity. The light / dark cycle was 16:8 h with a light intensity range of 1767 - 2971 Lux.

Results and discussions

In this extended laboratory test the effects of flupyradifurone + deltamethrin EC 85 residues on the survival of the predatory mite *Typhlodromus pyri* were determined at the rates of 5, 9, 16, 28 and 50 mL product/ha applied to detached bean leaves (*Phaseolus vulgaris*).

The mortality / escaping rate in the control exposure units up to day 7 after treatment was 7.0%.

At the lower test item rates of 5 and 9 mL product/ha, a corrected mortality of 24.7% and 47.3% has been observed, respectively. At the higher rates of 16, 28 and 50 mL product/ha, the corrected mortality was 67.7%, 94.6% and 97.8%, respectively. In the reference item group a corrected mortality of 63.4% was found on day 7 of the study.

Reproduction was assessed for the two lowest rates of flupyradifurone + deltamethrin EC 85. The mean number of offspring produced per female in the control group was 7.0. This compared to 5.7 eggs/female in the 5 mL product/ha rate of the test item and 4.2 eggs/female in the 9 mL product/ha rate (all rates refer to flupyradifurone + deltamethrin EC 85).

The reproduction was reduced by 17.5% at the rate of 5 mL product/ha and by 40.2% at the rate of 9 mL product/ha.

A summary of the effects observed in this study is given below.

Test item:		flupyradifurone + deltamethrin EC 85 (75+10 g/L)					
Test organism:		<i>Typhlodromus pyri</i>					
Exposure on:		Detached bean leaves (day 0 to day 7 after application)					
		Mortality after 7 days [%]			Reproduction		
Treatment	mL product/ha	Uncorr.	Corr.	P-Value(*)	Rate (eggs per female)	Reduction relative to control [%]	P-Value (#)
Control	0	7.0			7.0		
Test item	5	30.0	24.7	<0.001 sign.	5.7	17.5	0.028 sign.
Test item	9	51.0	47.3	<0.001 sign.	4.2	40.2	0.035 sign.
Test item	16	70.0	67.7	<0.001 sign.	n.a.	n.a.	
Test item	28	95.0	94.6	<0.001 sign.	n.a.	n.a.	
Test item	50	98.0	97.8	<0.001 sign.	n.a.	n.a.	
Reference item	74.8	66.0	63.4		n.a.	n.a.	
LR ₅₀ : 9.5 mL product/ ha; 95 % Confidence Interval: (7.5 – 11.3); calculated with Probit analysis							
ER ₅₀ : > 9 mL product/ha							
* Fisher's Exact test (one-sided, $\alpha = 0.05$), p-values are adjusted according to Bonferroni-Holm							
# one-way ANOVA, Williams test (one-sided)							
n.a. not assessed sign. significant							

Conclusion

The LR₅₀ was calculated to be 9.5 mL product/ha. The NOER for mortality was < 5 mL product/ha. The ER₅₀ was estimated to be > 9 mL product/ha. The NOER for reproduction was < 5 mL product/ha. The figures obtained fulfil the validity criteria of the laboratory method for exposure on glass plates.

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

Comments of zRMS:	<p>In general, the field studies should be performed with the formulation in question with application regime being in line with the intended use pattern.</p> <p>This is particularly important in case of formulations containing more than one active compound due to possibility for synergistic effects.</p> <p>Since the study summarised below was performed with the solo formulation of deltamethrin, it is considered not relevant for the risk assessment performed for DLT+FPF EC 85, which contains two substances of insecticidal mode of action: deltamethrin and flupyradifurone. For this reason the field studies should be performed with formulation under evaluation in order to account for effects resulting from simultaneous exposure to both active compounds.</p> <p>The study below was not validated by the zRMS as being not relevant for the risk assessment and its summary is struck through below.</p>
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Reference:	KCP 10.3.2.4/01
Title:	A field study to assess the effects of deltamethrin EW 15 (g/L) on the non-target, surface- and plant-dwelling, arthropod fauna of a grassland habitat (off-crop) in SW France during spring/summer
Report:	Aldershof, S.; Bakker, F.; 2012; B157FFN; M-430827-01-1
Guideline(s):	IOBC (Hassan, 1992), Anonymous (1992), Brown (1998), IOBC, BART and EPPO Joint Initiative (Candolfi et al., 2000, 2001), De Jong et al., 2010
Deviations:	not applicable
GLP/GEP:	yes
Acceptability:	Not validated by the zRMS, not relevant for the risk assessment for DLT+FPF EC 85
Duplication (if vertebrate study):	

Materials and methods

Deltamethrin EW 15 was applied once to a grassland meadow on 2 June 2011 at nominal rates of 0.1, 0.23, 0.6, 1.3 and 3.0 g a.s./ha, equivalent to typical drift values for different use patterns of the test item. Average application rates per treatment deviated 2.6% or less from intended rates. A water control treatment and a toxic reference treatment (lambda-cyhalothrin at a rate of 0.4 L product/ha) were run in parallel. Nominal application volumes were 200 L/ha.

The soil surface and plant dwelling arthropod communities were monitored shortly before, one, two, four and eight weeks after application. A broad spectrum of arthropods was sampled with different sampling methods, viz. pitfall trapping, Berlese Tullgren extraction from weed samples and suction sampling.

The trial had a randomized complete block design with 4 replicates/treatment. Each block had seven treatment plots of 24 x 24 m. To minimize interference among plots, the trial was laid out in a checkerboard design.

The effects of Deltamethrin EW 15 were expressed in terms of population and community changes relative to the water control. The No Observed Effect Rate (NOER) was defined at the community level and at the population level as the rate at which adverse responses were not significantly different from the water control at any time point. The No Observed Ecologically Adverse Effect Rate (NOEAER) was defined at the community level and at the population level as the rate at which statistically significant adverse responses were observed, but recovery was demonstrated within two months after applications. By analogy the LOEAER (for community and population responses) was defined as the lowest test rate at which adverse effects were significantly different from the water control without recovery occurring. Statistical significances were in principal considered at an alpha level of 5%. Statistical significances at an alpha level of 10% were also indicated as additional information to evaluate potential trends.

Results and discussions

Biological system

The arthropod community sampled in this study was diverse and typical for grassland vegetation, and representative for an off-crop non-target arthropod community. The timing of the experiment was such that a high number of abundant taxa were present during the sampling period. In addition timing coincided with typical use patterns for the test item. The entire dataset was appropriate for community analyses using ordination techniques. In addition, a total of 80 taxa were sufficiently abundant to be subjected to population level evaluations. A number of evaluations were performed at the family level, but several taxa occurred at sufficiently high numbers to allow for an evaluation at genus or species level.

The taxonomical analysis was performed in great detail. Despite the restrictions caused by the inevitable categorization of specimens at different taxonomic levels, it was felt that the number of taxa together with the choice of taxonomic level used for analysis did provide a sufficiently detailed and valid ecological analysis.

Sampling strategy

The entire arthropod community occurring in the off-crop habitat was monitored using pitfall-, weed/Berlese and suction sampling techniques. There was some overlap of taxa sampled with the different trapping techniques. Because of taxonomic differences (different species in the same higher level taxon), biological differences (e.g. life stages with different susceptibility in different traps) or behavioural differences (e.g. different exposure in different sub-habitats sampled), taxa sampled with different techniques were considered different taxa for the overall community analyses (based on a pooled dataset with all sampling methods included).

Test performance (insecticidal reference treatment)

At the family level there were no fundamental differences in the composition of the off-crop arthropod fauna in comparison to agricultural sites. The number of taxa occurring at sufficiently high numbers to allow for a population level analysis was higher than the number of taxa usually evaluated in studies performed in commercial agricultural settings.

By using three different collecting methods (weed/Berlese sampling, pitfall, suction) the arthropod community occurring in grasslands was comprehensively sampled (ground- and plant dwelling arthropods).

Application of the insecticidal toxic reference lambda-cyhalothrin resulted in clear responses at both the arthropod community level and the population level. This was true for taxa and communities collected with all three sample types.

The overall PRC obtained from community analyses of all sample types combined was statistically significant for the toxic reference treatment. On individual sampling moments the response was statistically significant in comparison to the control on all post application moments. At the population level many taxa appeared adversely and statistically significantly affected. Indirect effects were also observed: numbers of the collembolan taxa Entomobryidae, Sminthuridae and Symphypleona were significantly increased compared to the control, probably due to reduced predation by spiders which were adversely affected by the toxic reference.

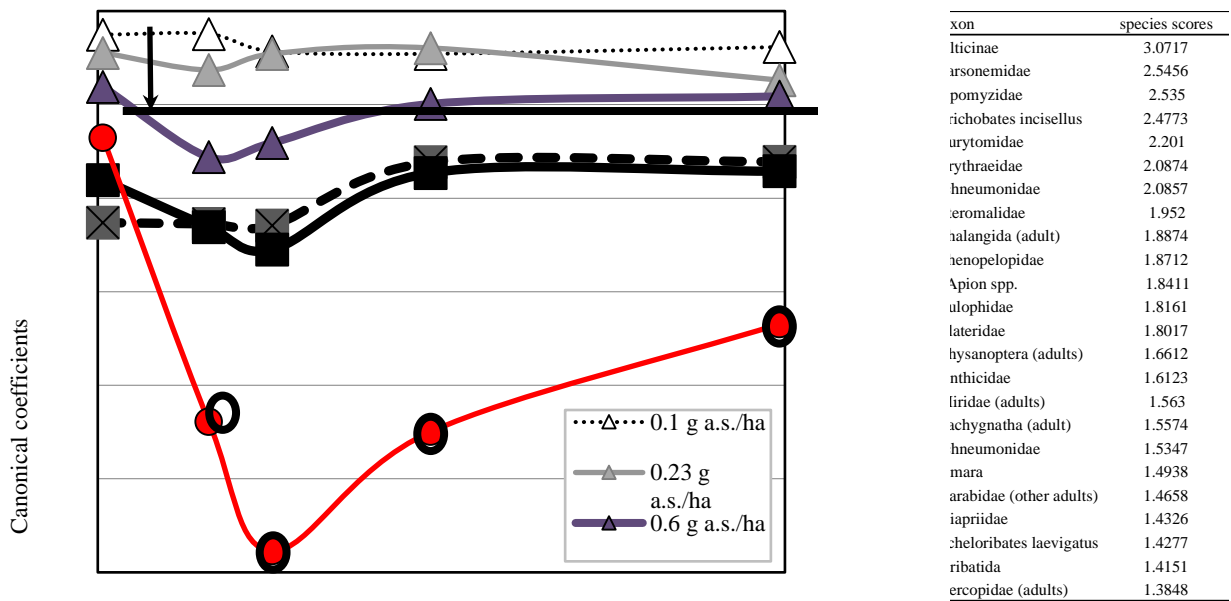
For several taxa no recovery was seen in the toxic reference treatment within the two-month sampling period, indicating that the experimental period and plot size chosen were adequate to demonstrate persistent treatment related effects. Abbott values in the toxic reference treatment were above 50% for at least 40% of all taxa examined one and two weeks after application. Consequently validity criteria according to De Jong *et al.* (2010) were met.

It is concluded that the test method presented in this study accurately examined potential risks for NTA fauna in true and representative off-crop habitats under a realistic worst-case test scenario.

Results

Treatment with the insecticide Deltamethrin EW 15 in an off-field grassland habitat in South West France did not lead to statistically significant effects on prevailing arthropod communities for any of the rates tested up to 3 g a.s./ha. Visual inspection of the PRC graph confirmed that at the community level no treatment-related response could be observed.

Summary community level effects



Principle Response Curve (first ordination axis)

Test and toxic references were analyzed separately but for comparison plotted in one graph. PRC analyses comprised data from weed (W), pitfall (P) and suction (S) samples. Encircled data points are statistically significant (Monte Carlo Permutation test, $\alpha = 0.05$). The 25 largest species scores of the test item treatments are presented (i.e. these species had the largest influence on the shape of the PRC curves).

treatments included in analysis	% Variance accounted for by		% Variance explained by treatment captured by		P-value ax1	P-value ax2
	time	treatment	ax1	ax2		
all	38.7	16.2	31.8	9.3	0.001	0.803
test item rates	41.1	11.8	18.1	9.3	0.621	0.998
0.1 g a.s./ha	47.2	6.5	44.7	17.8	0.645	0.971
0.23 g a.s./ha	44.4	5.6	38.2	20.6	0.943	0.932
0.6 g a.s./ha	44.5	6.2	38	20.3	0.893	0.956
1.3 g a.s./ha	47.2	6.8	40.1	22.5	0.515	0.844
3 g a.s./ha	43.6	7.2	43.3	19.8	0.606	0.648
Reference	40.9	16.5	69.8	10.7	0.033	0.373

P-values at individual sampling moments (Monte Carlo Permutation Test)							
All data	sample	0.1 g a.s./ha	0.23 g a.s./ha	0.6 g a.s./ha	1.3 g a.s./ha	3 g a.s./ha	Reference
30-May-11	1	0.760	0.943	0.914	0.401	0.804	0.929
09-Jun-11	2	0.548	0.790	0.742	0.318	0.498	0.021
15-Jun-11	3	0.669	0.944	0.864	0.642	0.471	0.029
30-Jun-11	4	0.789	0.828	0.837	0.914	0.942	0.027
02-Aug-11	5	0.849	0.943	0.908	0.869	0.643	0.035
Weed data	sample	0.1 g a.s./ha	0.23 g a.s./ha	0.6 g a.s./ha	1.3 g a.s./ha	3 g a.s./ha	Reference
26-May-11	1	0.389	0.892	0.785	0.466	0.779	0.791
09-Jun-11	2	0.846	0.440	0.426	0.142	0.160	0.037
16-Jun-11	3	0.318	0.706	0.524	0.820	0.368	0.044
30-Jun-11	4	0.608	0.749	0.896	0.497	0.915	0.048
30-Jul-11	5	0.434	1.000	0.850	0.745	0.648	0.354
Pitfall data	sample	0.1 g a.s./ha	0.23 g a.s./ha	0.6 g a.s./ha	1.3 g a.s./ha	3 g a.s./ha	Reference
01-Jun-11	1	0.471	0.612	0.621	0.343	0.730	0.526
09-Jun-11	2	0.633	0.973	1.000	0.655	0.638	0.034
16-Jun-11	3	1.000	1.000	0.977	0.325	0.378	0.024
30-Jun-11	4	0.759	0.872	0.465	0.839	0.898	0.026
02-Aug-11	5	0.828	0.941	0.672	0.509	0.136	0.410
Suction data	sample	0.1 g a.s./ha	0.23 g a.s./ha	0.6 g a.s./ha	1.3 g a.s./ha	3 g a.s./ha	Reference
30-May-11	1	0.851	1.000	0.878	0.525	0.664	0.942
09-Jun-11	2	0.405	0.674	0.370	0.284	0.598	0.027
15-Jun-11	3	0.692	0.829	0.899	0.655	0.629	0.019
30-Jun-11	4	0.891	0.671	0.863	0.800	0.815	0.028
02-Aug-11	5	0.819	0.672	0.693	0.903	0.714	0.035

At the population level three taxa showed statistically significant adverse response patterns that were considered related to the test item treatment (based on magnitude and duration in relation to dose, timing). These were Poduromorpha (Collembola, 3 g a.s./ha), adult Coccinellidae (Coleoptera, 3 g a.s./ha) and adult Thysanoptera (1.3 g and 3 g a.s./ha).

For few other taxa reductions compared to the control occurred incidentally, but no consistent trend in time or relation to the dose rate was found.

Summary table effect classifications Deltamethrin EW 15 rates

Community level effects (PRC/Monte-Carlo; 5% alpha level)	0.1 g a.s./ha	0.23 g a.s./ha	0.6 g a.s./ha	1.3 g a.s./ha	3 g a.s./ha
<i>Effect class</i>					
Weed/Berlese dataset	1	1	1	1	1
Pitfall dataset	1	1	1	1	1
Suction dataset	1	1	1	1	1
Conclusion	Community NOER				
Population level effects (Mann-Whitney U test; 5% alpha level)	0.1 g a.s./ha	0.23 g a.s./ha	0.6 g a.s./ha	1.3 g a.s./ha	3 g a.s./ha
<i>Effect class</i>					
Poduromorpha (Arthropodea, Collembola)	1	1	1	1	2
Adult Coccinellidae (Coleoptera)	1	1	1	1	2
Adult Thysanoptera	1	1	1	2	2
Conclusion			Population NOER	Population NOEAER	

NOER: No Observed Effect Rate (no statistically significant differences compared to control)

NOEAER: No Observed Ecologically Adverse Effect Rate (at least 1 taxon with effect class 2 or 3, i.e. clear response to treatment but with recovery within 2 months after application)

Effect classification:	Effect class:
no effect	No consistent treatment related statistically significant differences compared to the control
one occasion	Clear adverse treatment related effect but observed only on one occasion
< 2 months (a)	Adverse effect no longer statistically significant on the last two sampling moments
< 2 months (b)	Adverse effect no longer statistically significant on the last sampling moment
> 2 months	No recovery from adverse effect within the study period (= 2 months)

Conclusion

It is concluded that Deltamethrin EW 15 applied at a rate of 3 g a.s./ha in an off-crop grassland in South-West France is the community NOER (No Observed Effect Rate).

At the population level, three taxa were adversely affected by treatment with Deltamethrin EW 15 applied at a rate of 3 g a.s./ha and one taxon by treatment with 1.3 g a.s./ha. They all recovered within one month which is considered to be the ecologically acceptable. Deltamethrin EW 15 applied at 3 g a.s./ha is therefore classified as the population NOEAER (No Observed Ecologically Adverse Effect Rate), and 0.6 g a.s./ha as the population NOER.

Comments of zRMS:	<p>In general, the field studies should be performed with the formulation in question with application regime being in line with the intended use pattern.</p> <p>This is particularly important in case of formulations containing more than one active compound due to possibility for synergistic effects.</p> <p>Since the study summarised below was performed with the solo formulation of deltamethrin, it is considered not relevant for the risk assessment performed for DLT+FPF EC 85, which contains two substances of insecticidal mode of action: deltamethrin and flupyradifurone. For this reason the field studies should be performed with formulation under evaluation in order to account for effects resulting from simultaneous exposure to both active compounds.</p> <p>The study below was not validated by the zRMS as being not relevant for the risk assessment and its summary is struck through below.</p>
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Reference:	KCP 10.3.2.4/02
Title:	A field study to assess the effects of deltamethrin EW 15 (g/L) on the non-target, surface- and plant-dwelling, arthropod fauna of a grassland habitat (off-crop) in the Netherlands during spring/summer (Amendment 1)
Report:	Aldershof, S.; Bakker, F.; 2012; B158FFN; M-430876-03-1
Guideline(s):	IOBC (Hassan, 1992), Anonymous (1992), Brown (1998), IOBC, BART and EPPO Joint Initiative (Candolfi et al., 2000, 2001), De Jong et al., 2010
Deviations:	not applicable
GLP/GEP:	yes
Acceptability:	Not validated by the zRMS, not relevant for the risk assessment for DLT+FPF EC 85
Duplication (if vertebrate study):	

Materials and methods

Deltamethrin EW 15 was applied once to a grassland meadow on 1 July 2011 at nominal rates of 0.1, 0.23, 0.6, 1.3 and 3.0 g a.s./ha, equivalent to typical drift values for different use patterns of the test item. Average application rates per treatment deviated 7% or less from intended rates. A water control treatment and a toxic reference treatment (lambda-cyhalothrin at a rate of 0.4 L product/ha) were run in parallel. Nominal application volumes were 200 L/ha.

The soil surface and plant dwelling arthropod communities were monitored shortly before, one, two, four and eight weeks after application. A broad spectrum of arthropods was sampled with different sampling methods, viz. pitfall trapping, Berlese Tullgren extraction from weed samples and suction sampling.

The trial had a randomized complete block design with 4 replicates/treatment. Each block had seven treatment plots of 24 x 24 m. To minimize interference among plots, the trial was laid out in a checkerboard design.

The effects of Deltamethrin EW 15 were expressed in terms of population and community changes relative to the water control. The No Observed Effect Rate (NOER) was defined at the community level and at the population level as the rate at which adverse responses were not significantly different from the water control at any time point. The No Observed Ecologically Adverse Effect Rate (NOEAER) was defined at the community level and at the population level as the rate at which statistically significant adverse responses were observed, but recovery was demonstrated within two months after applications. By analogy the LOEAER (for community and population responses) was defined as the lowest test rate at which adverse effects were significantly different from the water control without recovery occurring. Statistical significances were in principal considered at an alpha level of 5%. Statistical significances at an alpha level of 10% were also indicated as additional information to evaluate potential trends.

Results and discussions

Biological system

The arthropod community sampled in this study was diverse and typical for grassland vegetation, and representative for an off-crop non-target arthropod community. The timing of the experiment was such that a high number of abundant taxa were present during the sampling period. In addition, timing coincided with typical use patterns for the test item. The entire dataset was appropriate for community analyses using ordination techniques. In addition, a total of 62 taxa were sufficiently abundant to be subjected to population-level evaluations. A number of evaluations were performed at the family level, but several taxa occurred at sufficiently high numbers to allow for an evaluation at genus or species level.

The taxonomical analysis was performed in great detail. Despite the restrictions caused by the inevitable categorization of specimens at different taxonomic levels, it was felt that the number of taxa together with the choice of taxonomic level used for analysis did provide a sufficiently detailed and valid ecological analysis.

Sampling strategy

The entire arthropod community occurring in the off-crop habitat was monitored using pitfall-, weed/Berlese and suction sampling techniques. There was some overlap of taxa sampled with the different trapping techniques. Because of taxonomic differences (different species in the same higher level taxon), biological differences (e.g. life stages with different susceptibility in different traps) or behavioural differences (e.g. different exposure in different sub-habitats sampled), taxa sampled with different techniques were considered different taxa for the overall community analyses (based on a pooled dataset with all sampling methods included).

Test performance (insecticidal reference treatment)

At the family level there were no fundamental differences in the composition of the off-crop arthropod fauna in comparison to agricultural sites. The number of taxa occurring at sufficiently high numbers to allow for a population-level analysis was higher than the number of taxa usually evaluated in studies performed in commercial agricultural settings.

By using three different collecting methods (weed/Berlese sampling, pitfall, suction) the arthropod community occurring in grasslands was comprehensively sampled (ground- and plant-dwelling arthropods).

Application of the insecticidal toxic reference item lambda-cyhalothrin resulted in clear responses at both the arthropod community level and the population level. This was true for taxa and communities collected with all three sample types.

The overall PRC obtained from community analyses of all sample types combined was statistically significant for the toxic reference treatment. On individual sampling moments the response was statistically significant in comparison to the control on all post-application moments. At the population level many taxa appeared adversely and statistically significantly affected. Indirect effects were also observed: numbers of some Collembola taxa were significantly increased compared to the control, probably due to reduced predation by spiders which were adversely affected by the toxic reference item. For several taxa no recovery was seen in the toxic reference treatment within the two-month sampling period, indicating that the experimental period and plot size chosen were adequate to demonstrate persistent treatment-related effects. Abbott values in the toxic reference treatment were above 50% for approximately half of all taxa examined during the entire post-treatment period. Consequently, validity criteria according to De Jong *et al.* (2010) were met.

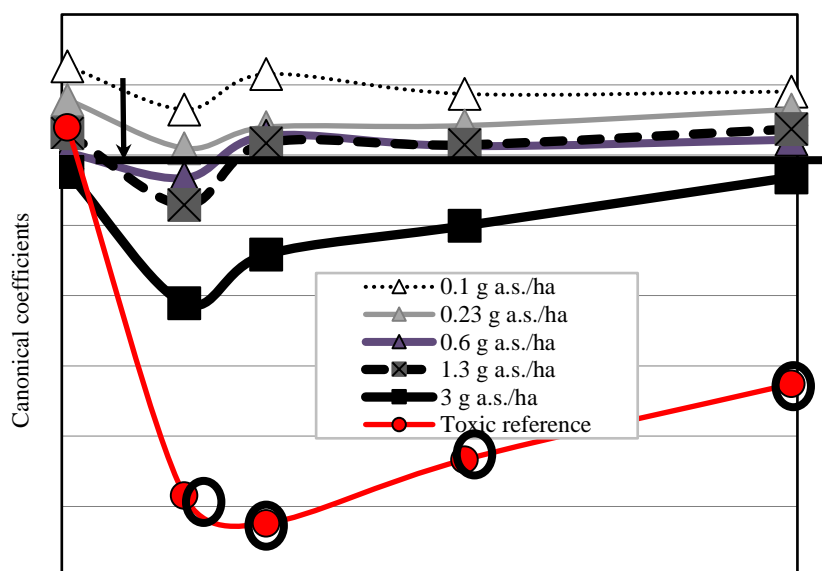
It is concluded that the test method presented in this study accurately examined potential risks for NTA fauna in true and representative off-crop habitats under a realistic worst-case test scenario.

Conclusion

Treatment with the insecticide Deltamethrin EW 15 in an off-field grassland habitat in The Netherlands

led to a statistically significant adverse effect on prevailing arthropod communities only for the highest test rate of 3 g a.s./ha, on only one sampling occasion one week after application, and only in the suction and the pitfall dataset. Visual inspection of the PRC graph confirmed that at the community level a moderate and transient treatment related response could be observed. With all sampling methods analyzed together differences compared to the control were not statistically significant.

Summary community level effects





sample	taxon	species scores
P	Poduromorpha	4.528
P	Alticinae	2.1044
S	Chloropidae	1.9324
P	Lathridiidae	1.9215
P	<i>Amara</i>	1.8322
S	Lepidoptera (adults)	1.7777
P	Phalangida (adult)	1.7725
P	Coccinellidae (adults)	1.769
S	Miridae (juveniles)	1.7249
P	Curculionidae	1.7072
P	Aleocharinae	1.4922
S	Cecidomyiidae	1.4748
S	Mymaridae	1.4395
S	Cynipoidea	1.4027
P	Entomobryidae	1.3823
W	Phytoseiidae (female)	1.3776
S	Cicadellidae (juveniles)	1.3638
S	Eurytomidae	1.1952
S	Agromyzidae	1.1952
S	<i>Pachygnatha</i> (juvenile)	1.1873
P	<i>Pardosa</i> (adult)	1.1454
P	Carabidae (juveniles)	1.1366
P	Scelionidae	-1.2576
W	Pygmephoroidae	-1.3201

Principal Response Curve (first ordination axis)

Test and toxic reference items were analyzed separately but for comparison plotted in one graph. PRC analyses comprised data from weed (W), pitfall (P) and suction (S) samples. Encircled data points are statistically significant (Monte Carlo Permutation test, $\alpha = 0.05$). The 25 largest species scores of the test item treatments are presented (i.e. these species had the largest influence on the shape of the PRC curves). The arrow indicates the application day.

Treatments in analysis	% Variance accounted for by		% Variance explained by treatment captured by		P-value ax1	P-value ax2	
	time	treatment	ax1	ax2			
Test item rates	30.5	12.3	17.7	10.4	0.928	1.000	
Reference	26.4	23.4	73.3	13.4	0.027	0.054	
P-values at individual sampling moments (Monte Carlo Permutation Test)							
All data	sample	0.1 g a.s./ha	0.23 g a.s./ha	0.6 g a.s./ha	1.3 g a.s./ha	3 g a.s./ha	Reference
28-Jun-11	1	0.366	0.942	0.977	0.900	0.743	0.862
08-Jul-11	2	0.910	0.887	0.910	0.509	0.131	0.029
15-Jul-11	3	0.452	0.869	0.813	0.660	0.495	0.025
01-Aug-11	4	0.761	1.000	0.963	0.919	0.638	0.032
29-Aug-11	5	0.818	1.000	1.000	0.917	1.000	0.027
Weed data	sample	0.1 g a.s./ha	0.23 g a.s./ha	0.6 g a.s./ha	1.3 g a.s./ha	3 g a.s./ha	Reference
28-Jun-11	1	0.321	0.790	0.856	0.703	0.392	0.971
08-Jul-11	2	0.937	0.841	0.975	0.732	0.886	0.235
15-Jul-11	3	0.838	0.910	0.858	0.570	0.756	0.035
01-Aug-11	4	1.000	0.946	0.837	0.608	0.975	0.023
30-Aug-11	5	0.829	0.823	0.882	1.000	0.797	0.026
Pitfall data	sample	0.1 g a.s./ha	0.23 g a.s./ha	0.6 g a.s./ha	1.3 g a.s./ha	3 g a.s./ha	Reference
01-Jul-11	1	0.276	0.947	0.895	0.930	0.719	0.719
08-Jul-11	2	0.742	0.866	0.825	0.223	0.045	0.028
15-Jul-11	3	0.234	0.302	0.571	0.304	0.176	0.031
05-Aug-11	4	0.634	1.000	1.000	0.894	0.664	0.029
26-Aug-11	5	0.583	0.864	0.971	0.812	0.793	0.097
Suction data	sample	0.1 g a.s./ha	0.23 g a.s./ha	0.6 g a.s./ha	1.3 g a.s./ha	3 g a.s./ha	Reference
28-Jun-11	1	0.362	0.862	0.857	0.762	0.941	0.830
08-Jul-11	2	0.632	0.869	0.830	0.617	0.050	0.031
15-Jul-11	3	0.446	0.906	0.909	1.000	0.606	0.037
01-Aug-11	4	0.389	1.000	0.884	0.920	0.441	0.032
29-Aug-11	5	0.406	1.000	1.000	0.841	1.000	0.045

 Statistically significant at alpha = 0.1 
 Statistically significant at alpha = 0.05 

At the population level nine taxa showed statistically significant adverse response patterns that were considered related to the test item treatment (based on magnitude and duration in relation to dose and timing). These were two Coleoptera taxa (Alticinae, Chrysomelidae; 1.3 g and 3 g a.s./ha, and adult Coccinellidae; 3 g a.s./ha), one spider taxon (adult *Pardosa*, Lycosidae; 0.6 g, 1.3 g and 3 g a.s./ha), Thysanoptera (3 g a.s./ha), juvenile and adult Cicadellidae (Homoptera; 3 g a.s./ha), and three dipteran taxa (Cecidomyiidae; 0.6 g, 1.3 g and 3 g a.s./ha, Agromyzidae and Chloropidae; 3 g a.s./ha).

For few other taxa reductions compared to the control occurred incidentally, but no consistent trend in time or relation to the dose rate was found.

Summary table effect classifications Deltamethrin EW 15 rates

Community level effects	0.1 g a.s./ha	0.23 g a.s./ha	0.6 g a.s./ha	1.3 g a.s./ha	3 g a.s./ha
(PRC/Monte-Carlo; 5% alpha level)					
Effect class					
Weed/Berlese dataset	1	1	1	1	1
Pitfall dataset	1	1	1	1	2
Suction dataset	1	1	1	1	2
Conclusion				Community NOER	Community NOE AER
Population level effects	0.1 g a.s./ha	0.23 g a.s./ha	0.6 g a.s./ha	1.3 g a.s./ha	3 g a.s./ha
(Mann-Whitney U test; 5% alpha level)					
Effect class					
Alticinae (Chrysomelidae, Coleoptera)	1	1	1	2	2
adult Coccinellidae (Coleoptera)	1	1	1	1	2
adult <i>Pardosa</i> (Lycosidae, Araneae)	1	1	2	3a	3a
Thysanoptera	1	1	1	1	2
juvenile Cicadellidae (Homoptera)	1	1	1	1	3b
adult Cicadellidae (Homoptera)	1	1	1	1	3b
Cecidomyiidae (Nematocera, Diptera)	1	1	2	2	2
Agromyzidae (Acalyptrata, Diptera)	1	1	1	1	2
Chloropidae (Acalyptrata, Diptera)	1	1	1	1	3a
Conclusion	Population NOER			Population NOE AER	
NOER: No Observed Effect Rate (no statistically significant differences compared to control)					
NOE AER: No Observed Ecologically Adverse Effect Rate (at least 1 taxon with effect class 2 or 3, i.e. clear response to treatment but with recovery within 2 months after application)					

Effect classification:	Effect class:
no effect	No consistent treatment related statistically significant differences compared to the control
one occasion	Clear adverse treatment related effect but observed only on one occasion
< 2 months (a)	Adverse effect no longer statistically significant on the last two sampling moments
< 2 months (b)	Adverse effect no longer statistically significant on the last sampling moment
> 2 months	No recovery from adverse effect within the study period (= 2 months)

Conclusion

It is concluded that Deltamethrin EW 15 applied at a rate of 3 g a.s./ha in an off-crop grassland in The Netherlands is the community NOE AER (No Observed Ecologically Adverse Effect Rate). No statistically significant adverse effects were found in the 1.3 g a.s./ha rate. This rate is classified as the community NOER (No Observed Effect Rate).

~~At the population level nine taxa were considered adversely affected by treatment with Deltamethrin EW 15 applied at a rate of 3 g a.s./ha, three taxa by treatment with 1.3 g a.s./ha and two taxa by treatment with 0.6 g a.s./ha. These taxa all recovered within two to eight weeks after application. Deltamethrin EW 15 applied at 3 g a.s./ha is therefore classified as population NOEAER, and 0.23 g a.s./ha as the population NOER.~~

Comments of zRMS:	<p>The study was performed in line with the most up-to-date guidelines describing methods for field testing of effects on non-target arthropods. The evaluation of the study was performed by the zRMS in line with the criteria given in de Jong et al. (2010).</p> <p>The study was performed in period between May and July, at the time of the highest abundance of non-target arthropods.</p> <p>The test site was selected in order to mimic the off-crop ecosystem in which the non-target arthropods will be exposed to the spray drift deposits following application of DLT+FPF EC 85. It is noted that the product is intended to be applied twice, while in the study single application regime was selected. Nevertheless, as the study was performed in dose-response design, this is acceptable for derivation of the NOER value.</p> <p>The spraying equipment was calibrated before the application and the concentration of the test item in the spraying solutions was verified in chemical analyses. It is, however, noted that only concentration of flupyradifurone was determined while no analyses were performed for deltamethrin. Nevertheless, the zRMS is of the opinion that this is sufficient, since under practical conditions of use the formulated product will be used and behaviour of particular active compounds will be the same as in the performed study.</p> <p>The sampling intervals were sufficient to investigate effects of application of the test item shortly after the application and in the longer period of time in order to determine potential for recovery of affected populations. Additional sampling was performed one week before the treatment in order to determine the general structure of arthropods community in the treated fields. It is, however, noted that no sampling was performed directly after the application and for this reason the direct effect of the test item is not known. Nevertheless, the zRMS is of the opinion that effects occurring at 0DAT would be also visible 3DAT, the first sampling point after the application.</p> <p>Sampling techniques used were sufficient to collect the insects inhabiting various compartments (arthropods on soil surface, dwelling in soil and on vegetation).</p> <p>Relevant statistical methods were used for evaluation of obtained results.</p> <p>High number of taxa was identified (489) and the number of taxa relevant for further statistical analyses (86) was higher than recommended by de Jong, 2010 (50-80).</p> <p>Significant effects with no recovery of some species observed in the toxic reference group confirmed sufficient sensitivity of the test system.</p> <p>No rainfall occurred on the day of application. Precipitation at <2 mm was observed was observed between 2-3, 3-4 and 4-5DAT. First significant rainfall (at ~8 mm) was observed at 10DAT and 15DAT. High number of days with precipitation was observed in July with rainfall >8 mm. Due to high number of days with rain it may be questioned if the exposure of the non-target arthropods was sufficient. On the other hand, the same conditions were observed on the toxic standard plots, where clear, long-lasting effects were detected, demonstrating that the exposure was sufficient to lead to significant effects. The zRMS is thus of the opinion that in case the test item had effects on insects, these would be detected in the study.</p> <p>Analysis of the Abbott values showed statistically significant effects on <i>Aleocharinae</i>,</p>
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	<p>other <i>Braconidae</i> and <i>Ichneumonidae</i> at consecutive samplings (including the last sampling) in the 4 mL/ha test group, however effects on these taxa were not observed at higher and lower test levels and for this reason effects observed at 4 mL/ha are considered to be not treatment related.</p> <p>Due to significant effects on particular taxa (i.e. <i>Lepidosyrus cyaneus</i>, <i>Cecidomyiidae</i>, <i>Psychodidae</i>, <i>Agromysidae</i>, <i>Sphaeroceridae</i>, <i>Aphidiinae</i>, <i>Platygastridae</i> and <i>Cynipoidea</i>) at single sampling points at 4 mL/ha were also observed, it was checked by the zRMS if these species were also affected at 9 and 17 mL/ha in order to exclude potential dose-response. Analysis demonstrated that majority of species affected at single samplings at 4 mL/ha was not affected at higher test rates showing that effects were not treatment related. However, in case of other <i>Braconidae</i> effects were no seen in two lower test groups, but were observed at 4, 9 and 17 mL/ha treatment levels. It is, however, noted that effects were seen only at the last sampling occasion so it is highly unlikely that they were treatment related, especially in the toxic standard group effects on this taxon were observed at the first and third sampling, but not at the two last samplings. Graphs also have not indicated any drop in the abundance of this taxon after the application and the trends in controls and all treatment groups were actually the same with slightly lower numbers at test termination observed in the treatment groups mentioned. Overall, available data does not indicate that effects on other <i>Braconidae</i> would be treatment related.</p> <p>Analysis of the graphs for abundance available in the study report confirms conclusions derived by the study authors. It is, however, noted that range of controls should be marked on the graphs to illustrate the variation within control plots.</p> <p>Overall, the zRMS agrees that the NOER of 4 mL/ha may be derived from the study and used for the risk assessment purposes.</p> <p>Evaluation of the study by the zRMS was performed based on information available in the study report. Although the study summary provides rather limited information, it sufficiently reflects obtained results.</p>
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Reference:	KCP 10.3.2.4/03
Title:	A field study to assess the effects of deltamethrin + flupyradifurone EC 85 (10+75 g/L) on the non-target, surface- and plant-dwelling, arthropod fauna of a grassland habitat (off-crop) in The Netherlands during spring/summer
Report:	Aldershof, S.; Bakker, F.; 2019; B168FFN; M-661092-01-1
Guideline(s):	EU Directive 91/414/EEC Regulation (EC) no. 1107/2009 IOBC (Hassan, 1992), Anonymous (1992), Brown (1998), IOBC, BART and EPPO Joint Initiative (Candolfi et al., 2000, 2001), De Jong et al. (2010) US EPA OCSPP Not Applicable
Deviations:	none
GLP/GEP:	yes
Acceptability:	Acceptable
Duplication (if vertebrate study):	

Materials and methods

The emulsion concentrate formulation DLT+FPF EC 85 (10+75) G was tested, specified by sample description: TOX10717-00; specification no.: 102000028562; LOT no: 2014-012629 [analysed content of active substance: deltamethrin 10.03 g/L (0.867% w/w), flupyradifurone 76.59 g/L (6.62% w/w)]; density: 1.157 g/mL.

DLT+FPF EC 85 (10+75) G was applied once to a grassland meadow in The Netherlands on 21 May

2015 at nominal rates of 1, 2.1, 4, 9 and 17 mL product/ha, equivalent to typical drift values for various use patterns of the test item. A water control treatment and a toxic reference treatment (lambda-cyhalothrin at a rate of 40 g a.s./ha) were run in parallel. Nominal application volumes were 200 L/ha. The soil-surface- and plant-dwelling arthropod communities were monitored shortly before application and three days, one, two, four and eight weeks after application. A broad spectrum of arthropods was sampled with a combination of sampling methods, viz. pitfall trapping, Berlese-Tullgren extraction from weed samples and suction sampling.

The trial had a randomized complete block design with 4 replicates/treatment. Each block had seven treatment plots of 30 x 30 m. Each plot was surrounded by untreated areas of at least 15 m wide.

The effects of DLT+FPF EC 85 (10+75) G were expressed in terms of population and community changes relative to the water control. The No Observed Effect Rate (NOER) was defined at the community level and at the population level as the rate at which adverse responses were not significantly different from the water control at any time point. The No Observed Ecologically Adverse Effect Rate (NOEAER) was defined at the community level and at the population level as the highest rate at which statistically significant adverse responses were observed, but recovery was demonstrated within two months after application. By analogy the LOEAER (for community and population responses) was defined as the lowest test rate at which adverse effects were statistically significantly different from the water control without recovery occurring.

Results and discussions

Test performance application

The average deviation from the intended application volume was 0.1%. Average deviation from intended application volume per treatment group did not exceed 10%.

The flupyradifurone content of the test item solutions were determined by analysis of the test solution samples by HPLC-PDA in the analytical phase (S15-04454-L1) of the study. The analytical method for the determination of flupyradifurone was validated with regard to recovery (97-98%), linearity of detector response ($R^2 > 0.999$), repeatability, specificity, limit of quantification (0.0397 mg flupyradifurone/L) and limit of detection (0.012 mg flupyradifurone/L). The analytical method fulfills the requirements of SANCO/3029/99 rev. 4, 11/07/2000.

The analytical chemistry showed that the water used was uncontaminated and that the measured content of the active ingredients ranged from 76% to 87% of the nominal concentration (mean recovery 84%). See the table below.

Test item rate	Nominal application rate (L product/ha)	Analytical recovery (% of nominal)
T1	0.0010	76
T2	0.0021	84
T3	0.0040	86
T4	0.0090	86
T5	0.0170	87

Test performance biological system

The experimental field was a grassland with high coverage and moderate plant species diversity. There were no structures potentially causing irregular microclimates. At the onset of the study, vegetation height (non flowering parts) was approximately 10-15 cm. Common plant species were *Lolium perenne* (perennial rye-grass) and *Rumex* (sorrel).

The arthropod community sampled in this study was diverse and typical for grassland vegetation, and representative for an off-crop non-target arthropod community. The timing of the experiment was such that a high number of abundant taxa were present during the sampling period. In addition, timing coincided with typical use patterns for the test item. The entire dataset was appropriate for community analyses using ordination techniques. In addition, a large number of taxa were sufficiently abundant to

be subjected to population level evaluations, depending on abundance, generally at the family-, genus- or species level.

More than 5.5 million specimens from 489 taxa were identified; 86 of which were included in population analyses. Highly abundant taxa were springtails, mosquitoes, aphids and the mite family Tarsonemidae. Collembola were largely dominating the arthropod community (ca 90% from all specimens).

The sampling results were sufficiently precise to allow for a valid and robust evaluation of potential treatment effects at the community level and at the population level. However, the mite abundance dataset was not appropriate for statistical hypothesis testing as a consequence of high density variability between plots. However, graphical analysis was still possible due to low intra-block variability.

Both univariate and multivariate analyses of suction- and pitfall datasets demonstrated acute and persistent statistically significant adverse effects in plots treated with the reference item, indicating that the test system was sufficiently sensitive and adequate to detect statistically significant and distinctly different responses. No effects of the reference item was found for mites from weed samples in community evaluations or population level examinations.

For some taxa, no recovery was seen in the reference treatment within the time frame of the study, indicating that test design parameters, such as plot size, were adequate to demonstrate persistent adverse treatment related effects.

Results test item

Based on statistical analyses and considerations described in the previous chapter, effects of DLT+FPF EC 85 (10+75) G applied to an off-crop grassland arthropod fauna in The Netherlands are classified as follows:

No statistically significant adverse community effects were found at a rate of 17 mL product/ha. This rate is classified as the community NOER (No Observed Effect Rate).

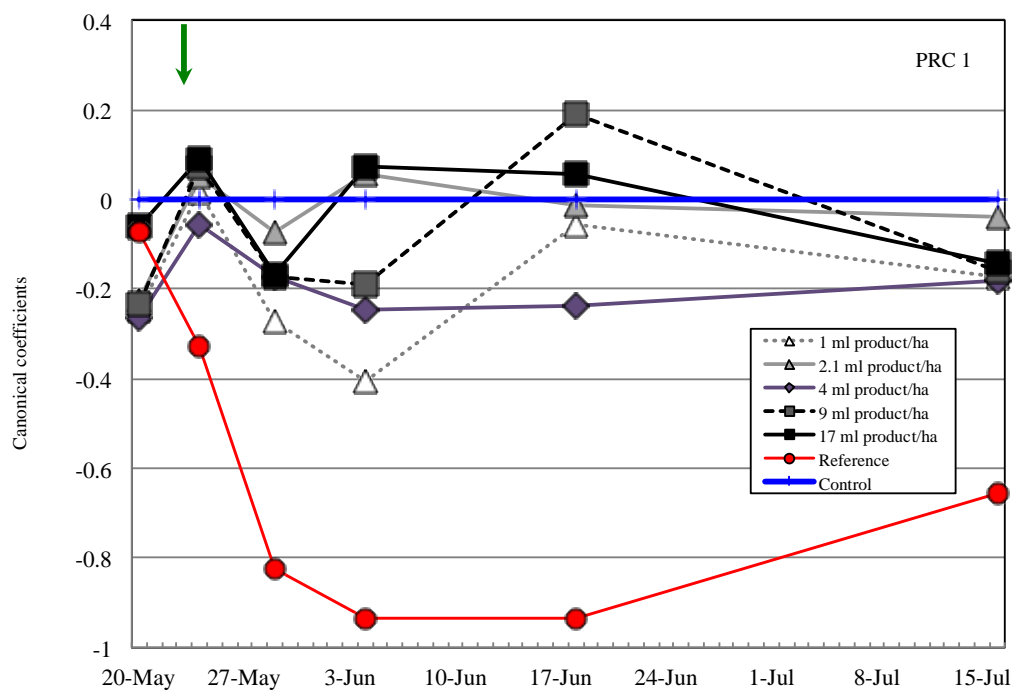
DLT+FPF EC 85 (10+75) G applied at the rate of 17 mL product/ha is the population NOEAER (No Observed Ecologically Adverse Effect Rate). Adverse effects were observed for few taxa, they lasted at maximum one month, and all populations had recovered within two months after treatment. Affected taxa were adult *Pardosa palustris* (Lycosidae, Araneae), adult *Erigone dentipalpis* (Linyphiidae, Araneae), Alticinae (Chrysomelidae, Coleoptera), *Deuterosminthurus pallipes* (Bourletiellidae, Collembola), and Chironomidae (Nematocera, Diptera).

At a test rate of 9 mL product/ha statistically significant adverse population effects occurred for two taxa (adult *Erigone dentipalpis* and Alticinae), which recovered within one month after treatment or earlier.

DLT+FPF EC 85 (10+75) G applied at the rate of 4 mL product/ha is the population NOER (No Observed Effect Rate). At this rate no adverse treatment related effects were detected for any of the 86 taxa examined at the population level.

The community and population LOER and LOEAER are higher than 17 mL product/ha, the highest rate tested in this study.

Summary community level effects:



Principal Response Curves suction dataset

Summary population effect classifications:

Fig	Method	Class/Order	Taxon	1 mL	2.1 mL	4 mL	9 mL	17 mL	Ref
5	Wd	ACARI	Gamasina						
6	Wd	ACARI	Oribatida						
7	Wd	ACARI	Tarsonemidae						
8	Pt	ARANEAE	Pardosa agrestis adult					3b	
9	Pt	ARANEAE	Pardosa palustris adult					3a	3b
10	Su	ARANEAE	Pardosa juvenile					3b	
11	Pt	ARANEAE	Other Lycosidae					8	
12 a	Pt	ARANEAE	Erigone atra adult					8	
12 b	Su	ARANEAE	Erigone atra adult					3a	
13 a	Pt	ARANEAE	Erigone dentipalpis adult			3a	3a	8	
13 b	Su	ARANEAE	Erigone dentipalpis adult					3b	
14 a	Pt	ARANEAE	Oedothorax fuscus adult					8	
14 b	Su	ARANEAE	Oedothorax fuscus adult					8	
15	Pt	ARANEAE	Other adult Erigoninae					8	
16 a	Pt	ARANEAE	Erigoninae juvenile					8	
16 b	Su	ARANEAE	Erigoninae juvenile					8	
17 a	Pt	ARANEAE	Bathypantes gracilis adult					3b	
17 b	Su	ARANEAE	Bathypantes gracilis adult					8	
18	Su	ARANEAE	Lepthyphantes tenuis adult						
19	Su	ARANEAE	Linyphiinae juvenile					8	
20	Pt	ARANEAE	Pachygnatha degeeri adult					3b	
21	Pt	COLEOPTERA	Bembidion					3a	
22	Pt	COLEOPTERA	Poecilus cupreus					3b	
23	Pt	COLEOPTERA	Pterostichus melanarius						
24	Pt	COLEOPTERA	Pterostichus strenuus					3a	
25	Pt	COLEOPTERA	Pterostichus vernalis					3a	
26	Pt	COLEOPTERA	Other Carabidae					3a	
27	Su	COLEOPTERA	Carabidae					3a	
28	Pt	COLEOPTERA	Juvenile Carabidae						
29 a	Pt	COLEOPTERA	Aleocharinae						
29 b	Su	COLEOPTERA	Aleocharinae						
30	Pt	COLEOPTERA	Gabrius						
31	Pt	COLEOPTERA	Xantholinus longiventris						
32	Pt	COLEOPTERA	Philonthus fuscipennis					3a	
33	Pt	COLEOPTERA	Philonthus varius					3a	
34	Su	COLEOPTERA	Other Staphylinidae					3b	
35	Pt	COLEOPTERA	Staphylininae juvenile						
36 a	Pt	COLEOPTERA	Hydrophilidae					8	
36 b	Su	COLEOPTERA	Hydrophilidae						
37	Pt	COLEOPTERA	Alticinae			2	2	3b	
38	Pt	COLEOPTERA	Curculionidae						
39	Su	COLEOPTERA	Juvenile Coleoptera					3a	
40	Su	COLLEMBOLA	Lepidocyrtus cyaneus						
41	Su	COLLEMBOLA	Lepidocyrtus lanuginosus						
42	Su	COLLEMBOLA	Isotomurus palustris						
43	Su	COLLEMBOLA	Isotomurus prasinus						
44	Su	COLLEMBOLA	Parisotoma notabilis						
45	Su	COLLEMBOLA	Isotoma viridis - group						
46	Su	COLLEMBOLA	Deuterosminthurus pallipes					3a	
47	Su	COLLEMBOLA	Sminthurinus elegans						
48	Su	COLLEMBOLA	Sminthurus viridis						
49	Su	COLLEMBOLA	Sphaeridia pumilis						
50	Su	DIPTERA	Cecidomyiidae					3b	
51	Su	DIPTERA	Sciaridae					3b	
52	Su	DIPTERA	Chironomidae				2	3b	
53	Su	DIPTERA	Psychodidae					8	
54	Su	DIPTERA	Dolichopodidae					3b	
55	Su	DIPTERA	Lonchopteridae					3b	
56	Su	DIPTERA	Phoridae						
57	Su	DIPTERA	Chloropidae					3b	
58	Su	DIPTERA	Drosophilidae						
59	Su	DIPTERA	Agromyzidae					8	
60	Su	DIPTERA	Sepsidae					2	
61	Su	DIPTERA	Sphaeroceridae					3a	
62	Su	DIPTERA	Other Acalyptrata					2	
63	Su	DIPTERA	Juvenile Diptera						
64	Su	HEMIPTERA	Cicadellidae					8	
65	Su	HEMIPTERA	Delphacidae					8	
66	Su	HEMIPTERA	Aphidoidea					8	
67	Su	HEMIPTERA	Heteroptera					3b	
68	Su	HYMENOPTERA	Alysiinae					3b	
69	Su	HYMENOPTERA	Aphidiinae					3a	
70	Su	HYMENOPTERA	Other Braconidae					3a	
71	Pt	HYMENOPTERA	Braconidae brachypterous					2	
72	Su	HYMENOPTERA	Ichneumonidae					8	
73	Su	HYMENOPTERA	Eulophidae					8	
74	Su	HYMENOPTERA	Mymaridae					3b	
75	Su	HYMENOPTERA	Pteromalidae					8	
76	Su	HYMENOPTERA	Platygastridae					3b	
77	Su	HYMENOPTERA	Scelioninae					8	
78	Pt	HYMENOPTERA	Scelioninae brachypterous					3a	
79	Su	HYMENOPTERA	Ceraphronoidea						
80	Su	HYMENOPTERA	Cynipoidea					8	
81	Su	HYMENOPTERA	Juvenile Symphyta					3b	
82	Pt	CHILOPODA	Chilopoda						
83	Su	THYSANOPTERA	Thysanoptera					8	

** Or on two occasions, but with recovery within two weeks after treatment

Conclusion

Final conclusions community- and population level effects:

Effect classification (Based on De Jong <i>et al.</i> , 2010):			Effect class:				
one occasion	Clear adverse treatment related effect but observed on one occasion only**		2				
<1 month	Adverse effects no longer apparent on the last two sampling moments		3a				
<2 months	Adverse effect no longer apparent on the last sampling moment		3b				
>2 months	No recovery from adverse effect within the study period (= 2 months)		8				
3a	Based on graphical trends (P>0.1 but effect >70% on two or more occasions)						
3a	Based on graphical trends and P<0.1 (one or more occasions)						
3a	Based on graphical trends and P<0.05 (one or more occasions)						
-	No effect						
Community level effects (multivariate analyses)			1 mL	2.1 mL	4 mL	9 mL	17 mL
(PRC/Monte-Carlo; 5% and 10% alpha level and trends)							
Suction all data			-	-	-	-	-
Suction excluding Collembola			-	-	-	-	-
Weed			-	-	-	-	-
Pitfall			-	-	-	-	-
Conclusion			Community NOER				
Population level effects (univariate analyses)			1 mL	2.1 mL	4 mL	9 mL	17 mL
(Mann-Whitney U test; 5% and 10% alpha level and trends)							
Class/Order	Taxon						
Pt	ARANEAE	Pardosa palustris adult	-	-	-	-	3a
Pt	ARANEAE	Erigone dentipalpis adult	-	-	-	3a	3a
Pt	COLEOPTERA	Alticinae	-	-	-	2	2
Su	COLLEMBOLA	Deuterosminthurus pallipes	-	-	-	-	3a
Su	DIPTERA	Chironomidae	-	-	-	-	2
Conclusion			Population NOER	Population LOER	Population NOEER		

Su=suction; Pt=pitfall; Wd=weed

Rates are in mL product/ha

** Or on two occasions, but with recovery within two weeks after treatment

Comments of zRMS:	<p>The study was performed in line with the most up-to-date guidelines describing methods for field testing of effects on non-target arthropods. The evaluation of the study was performed by the zRMS in line with the criteria given in de Jong et al. (2010).</p> <p>The study was performed in period between May and July, at the time of the highest abundance of non-target arthropods.</p> <p>It is noted that the test site was located in the Southern France and for this reason it may be questioned if obtained results are representative for the Central Zone. Nevertheless, the zRMS is of the opinion that since one field study was performed in the Central Zone, the additional study performed in another zone may serve as additional source of information on potential effects of DLT+FPF EC 85 on NTA populations and community.</p> <p>The test site was selected in order to mimic the off-crop ecosystem in which the non-target arthropods will be exposed to the spray drift deposits following application of DLT+FPF EC 85. It is noted that the product is intended to be applied twice, while in the study single application regime was selected. Nevertheless, as the study was performed in dose-response design, this is acceptable for derivation of the NOER value.</p>
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	<p>The spraying equipment was calibrated before the application and the concentration of the test item in the spraying solutions was verified in chemical analyses. It is, however, noted that only concentration of flupyradifurone was determined while no analyses were performed for deltamethrin. Nevertheless, the zRMS is of the opinion that this is sufficient, since under practical conditions of use the formulated product will be used and behaviour of particular active compounds will be the same as in the performed study.</p> <p>The sampling intervals were sufficient to investigate effects of application of the test item shortly after the application and in the longer period of time in order to determine potential for recovery of affected populations. Additional sampling was performed one week before the treatment in order to determine the general structure of arthropods community in the treated fields. It is, however, noted that no sampling was performed directly after the application and for this reason the direct effect of the test item is not known. Nevertheless, the zRMS is of the opinion that effects occurring at 0DAT would be also visible 3DAT, the first sampling point after the application.</p> <p>Sampling techniques used were sufficient to collect the insects inhabiting various compartments (arthropods on soil surface, dwelling in soil and on vegetation).</p> <p>Relevant statistical methods were used for evaluation of obtained results.</p> <p>High number of taxa was identified (682) and the number of taxa relevant for further statistical analyses (85) was higher than recommended by de Jong, 2010 (50-80).</p> <p>Significant effects with no recovery of some species observed in the toxic reference group confirmed sufficient sensitivity of the test system.</p> <p>The weather data were incomplete and detailed analysis of the rainfall events was thus not possible. However, from the limited data presented it seems that significant rainfall at >5 mm occurred 2 or 3DAT, potentially reducing exposure.</p> <p>Analysis of the Abbott values showed statistically significant effects on some individual taxa in the 9 mL/ha test group at single sampling occasions, however in absence of effects at higher test level they seem to be not treatment related.</p> <p>Analysis of the graphs for abundance available in the study report was not possible since the graphs were incomplete (x and y axis were missing, trend lines were drawn only for two treatment levels, the range of controls was not marked). The same was observed for multivariate analyses.</p> <p>Due to incomplete presentation of the study results, full and detailed validation of the derived endpoints was not possible. It seems, however, that results of this study were in good agreement with results of the study performed in The Netherlands. However, due to potentially significant precipitation shortly after treatment it cannot be excluded that the exposure was reduced (this cannot be confirmed since incomplete weather data are provided in the study report).</p> <p>Overall, confirmation of the endpoints derived by the study authors is not possible due to technical drawbacks listed above.</p>
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Reference:	KCP 10.3.2.4/04
Title:	A field study to assess the effects of deltamethrin + flupyradifurone EC 85 (10+75 g/L) on the non-target, surface- and plant-dwelling, arthropod fauna of a grassland habitat (off-crop) in SW France during spring/summer
Report:	Aldershof, S.; Bakker, F.; 2019; B169FFN; M-661091-01-1
Guideline(s):	EU Directive 91/414/EEC Regulation (EC) no. 1107/2009 IOBC (Hassan, 1992), Anonymous (1992), Brown (1998), IOBC, BART and EPPO Joint Initiative (Candolfi et al., 2000, 2001), De Jong et al. (2010) US EPA OCSPP Not Applicable
Deviations:	--
GLP/GEP:	yes
Acceptability:	In general acceptable, but confirmation of results not possible due to not complete presentation of the study results and weather data in the study report.
Duplication (if vertebrate study):	

Materials and methods

The emulsion concentrate formulation DLT+FPF EC 85 (10+75) was tested, specified by sample description: TOX10717-00; specification no.: 102000028562; LOT no: 2014-012629-01 [analysed content of active substance: deltamethrin 10.03 g/L (0.867% w/w), flupyradifurone 76.59 g/L (6.62% w/w)]; density: 1.157 g/mL.

DLT+FPF EC 85 (10+75) G was applied once to a grassland meadow in South-West France on 16 May 2015 at nominal rates of 1, 2.1, 4, 9 and 17 mL product/ha, equivalent to typical drift values for different use patterns of the test item. A water control treatment and a toxic reference treatment (lambda-cyhalothrin at a rate of 40 g a.s./ha) were run in parallel. Nominal application volumes were 200 L/ha.

The soil-surface- and plant-dwelling arthropod communities were monitored shortly before and three days after application, and one, two, four and eight weeks after application. A broad spectrum of arthropods was sampled with a combination of sampling methods, viz. pitfall trapping, Berlese-Tullgren extraction from weed samples and suction sampling.

The trial had a randomized complete block design with 4 replicates/treatment. Each block had seven treatment plots of 30 x 30 m. Plots were surrounded by untreated areas of 8 m wide.

The effects of DLT+FPF EC 85 (10+75) G were expressed in terms of population and community changes relative to the water control. The No Observed Effect Rate (NOER) was defined at the community level and at the population level as the rate at which adverse responses were not significantly different from the water control at any time point. The No Observed Ecologically Adverse Effect Rate (NOEAER) was defined at the community level and at the population level as the highest rate at which statistically significant adverse responses were observed, but recovery was demonstrated within two months after application. By analogy the LOEAER (for community and population responses) was defined as the lowest test rate at which adverse effects were statistically significantly different from the water control without recovery occurring.

Results and discussions

Test performance application

The average deviation from intended application rates was 3.3%. Average deviations from intended rates per treatment did not exceed 10%.

The flupyradifurone content of the test item solutions were determined by analysis of the test solution

samples by HPLC-PDA in the analytical phase (S15-04453-L1) of the study. The analytical method for the determination of flupyradifurone was validated with regard to recovery (97-98%), linearity of detector response ($R^2 > 0.999$), repeatability, specificity, limit of quantification (0.0397 mg flupyradifurone/L) and limit of detection (0.012 mg flupyradifurone/L). The analytical method fulfills the requirements of SANCO/3029/99 rev. 4, 11/07/2000.

The analytical chemistry showed that the water used was uncontaminated and that the measured content of the active ingredients ranged from 88% to 112% of the nominal concentration (mean recovery 101%). See the table below.

Test item rate	Nominal application rate (L product/ha)	Analytical recovery (% of nominal)
T1	0.0010	101
T2	0.0021	99
T3	0.0040	112
T4	0.0090	104
T5	0.0170	88

Test performance biological system

The experimental field was a humid, moderately nutrient rich grassland with high coverage and moderate plant species diversity. There was a homogeneous vegetation and soil constitution, without structures potentially causing irregular microclimates. *Holcus lanatus* (common velvet grass), *Dactylis glomerata* (Cocks foot), and *Festuca pratensis* (Meadow Fescue) were dominant grass species. Birdsfoot trefoil (*Lotus corniculatus*), white clover (*Trifolium repens*) and field bindweed (*Convolvulus arvensis*) were common dicotyledonous plant species. At the onset of the study vegetation height (non-flowering parts) was approximately 15-20 cm.

The arthropod community sampled in this study was diverse and typical for grassland vegetation, and representative for an off-crop non-target arthropod community. The timing of the experiment was such that a high number of abundant taxa were present during the sampling period. In addition, timing coincided with typical use patterns for the test item. The entire dataset was appropriate for community analyses using ordination techniques. In addition, a large number of taxa were sufficiently abundant to be subjected to population level evaluations, depending on abundance, generally at the family-, genus- or species level.

In total almost six hundred thousand specimens from 682 taxa were identified; 85 of which were included in population analyses. Most abundant taxa were several Collembola and oribatid mites.

A thorough survey of the entire arthropod community prevailing in the vegetation and on the ground of the grassland habitat was established with pitfall-, suction- and weed sampling methods, which yielded a comprehensive faunistic inventory of the test site.

The sampling results of the pitfall- and suction datasets were sufficiently precise to allow for a valid and robust evaluation of potential treatment effects at the community level and at the population level. Mite abundance showed a high variability between plots, but statistical hypothesis testing and graphical analysis was still feasible.

Both univariate and multivariate analyses of all datasets demonstrated acute and persistent (statistically significant) adverse effects in plots treated with the reference item, indicating that the test system was sufficiently sensitive and adequate to detect distinctly different responses.

For many taxa, no recovery was seen in the reference treatment within the time frame of the study, indicating that test design parameters, such as plot size, were adequate to demonstrate persistent adverse treatment related effects.

Results test item

No statistically significant adverse community effects were found at a rate of 17 mL product/ha or lower in any of the datasets analyzed. This rate is classified as the community NOER (No Observed Effect Rate).

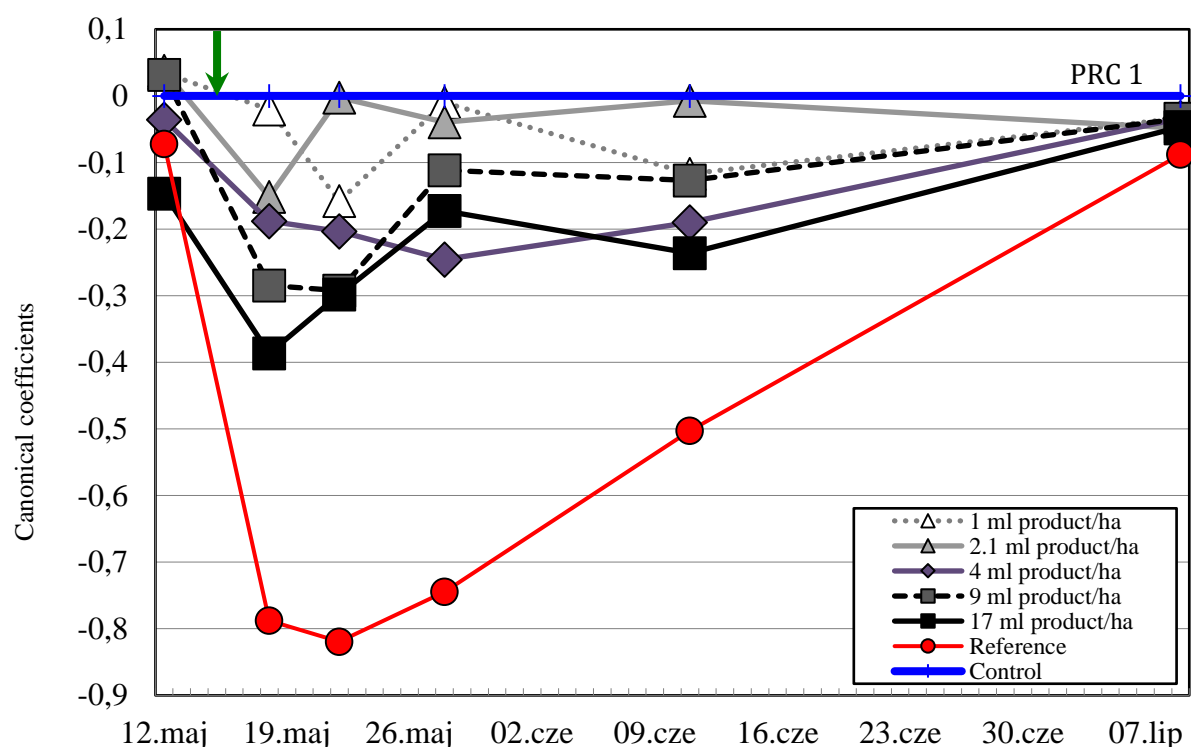
DLT+FPF EC 85 (10+75) G applied at the rate of 17 mL product/ha is the population NOEAER (No Observed Ecologically Adverse Effect Rate). Adverse population effects were observed, but recovery of all populations occurred within one month after treatment. Affected taxa were Alticinae (Chrysomelidae, Coleoptera) and Fulgoromorpha (Auchenorrhyncha, Hemiptera).

Additional small and short-lived adverse effects were observed in the highest test rate of 17 mL product/ha for a few other taxa, but in these cases deviations from the control were below the statistical detection level, or interpretation was ambiguous due to unequal starting densities or high within treatment variability. These taxa were: *Pardosa prativaga* (Lycosidae, Araneae), Thomisidae (Araneae), *Pachygnatha degeeri* (Tetragnathidae, Araneae), Histeridae (Coleoptera), Cecidomyiidae (Diptera) and Chloropidae (Diptera).

DLT+FPF EC 85 (10+75) G applied at the rate of 9 mL product/ha is the population NOER (No Observed Effect Rate). At this rate, no adverse treatment related effects were detected for any of the 85 taxa examined at the population level.

The community and population LOER and LOEAER are higher than 17 mL product/ha, the highest rate tested in this study.

Summary community level effects:



Principal Response Curves suction dataset

Summary population effect classifications:

Fig	Method	Class/Order	Taxon	1 mL	2.1 mL	4 mL	9 mL	17 mL	Ref
5	Wd	ACARI	Phytoseiidae Female						8
6	Wd	ACARI	Gamasina other Female						8
7	Wd	ACARI	Gamasina Male, Nymph						8
8	Wd	ACARI	Acaridae						
9	Wd	ACARI	Oribatulidae Zygobatulata						
10	Wd	ACARI	Other adult Oribatida						
11	Wd	ACARI	Oribatida juvenile						
12	Wd	ACARI	Tydeoidea						3b
13	Wd	ACARI	Pygmephoroidae						
14	Wd	ACARI	Tarsonemidae						
15	Wd	ACARI	Erythraeoidea						
16	Wd	ACARI	Tetranychidae						
17	Pt	ARANEAE	Alopecosa cuneata adult						3a
18	Pt	ARANEAE	Trochosa robusta adult						8
19	Pt	ARANEAE	Pardosa palustris adult						8
20	Pt	ARANEAE	Pardosa pratigava adult						3b
21	Pt	ARANEAE	Pardosa proxima adult						3b
22	Pt	ARANEAE	Other adult Pardosa						3b
23	Pt	ARANEAE	Other adult Lycosidae						2
24	Pt	ARANEAE	Lycosidae juvenile						3b
25	Pt	ARANEAE	Thomisidae						8
26	Pt	ARANEAE	Haplodrassus signifer adult						3a
27	Pt	ARANEAE	Zelotes pusillus adult						2
28	Pt	ARANEAE	Other adult Zelotes						
29	Pt	ARANEAE	Hahnina nava adult						
30	Pt	ARANEAE	Linyphiidae						3b
31 a	Su	ARANEAE	Pachygnatha degeeri juvenile						3b
31 b	Pt	ARANEAE	Pachygnatha degeeri						8
32	Pt	COLEOPTERA	Harpalus						3a
33	Pt	COLEOPTERA	Other Carabidae						
34 a	Pt	COLEOPTERA	Drusilla canaliculata juvenile						2
34 b	Pt	COLEOPTERA	Drusilla canaliculata						3a
35	Pt	COLEOPTERA	Other Aleocharinae						
36	Pt	COLEOPTERA	Other Staphylinidae						
37 a	Pt	COLEOPTERA	Lathridiidae juvenile						2
37 b	Pt	COLEOPTERA	Lathridiidae						3b
38	Pt	COLEOPTERA	Nitidulidae						
39	Pt	COLEOPTERA	Histeridae						3b
40	Pt	COLEOPTERA	Hydrophilidae						
41	Pt	COLEOPTERA	Elaeteridae						3b
42	Pt	COLEOPTERA	Alticinae					2	3b
43	Pt	COLEOPTERA	Chrysomelidae juvenile						2
44 *	Pt	COLEOPTERA	Dermestidae juvenile						2
45	Pt	COLEOPTERA	Other juvenile Coleoptera						3b
46	Su	COLEOPTERA	Juvenile Coleoptera						2
47	Su	COLLEMBOLA	Entomobrya lanuginosa						
48	Su	COLLEMBOLA	Entomobrya schoetti						
49 *	Su	COLLEMBOLA	Other Entomobryidae						
50	Su	COLLEMBOLA	Isotomurus prasinus						
51	Su	COLLEMBOLA	Deuterosminthurus pallipes						
52	Su	COLLEMBOLA	Sminthurinus elegans						
53	Su	COLLEMBOLA	Sminthurus viridis						
54	Su	COLLEMBOLA	Sphaeridia pumilis						
55	Su	DIPTERA	Cecidomyiidae						3b
56	Su	DIPTERA	Sciaridae						
57	Su	DIPTERA	Hybotidae						2
58	Su	DIPTERA	Phoridae						3b
59	Su	DIPTERA	Chloropidae						3b
60	Su	DIPTERA	Acalyptata other						8
61 a	Su	HEMIPTERA	Cicadellidae juvenile						3a
61 b	Su	HEMIPTERA	Cicadellidae adult						8
61 c	Pt	HEMIPTERA	Cicadellidae						3a
62	Su	HEMIPTERA	Delphacidae						8
63	Pt	HEMIPTERA	Fulgoromorpha					3a	8
64	Su	HEMIPTERA	Aphidoidea						8
65	Pt	HEMIPTERA	Tingidae adult						3a
66	Pt	HEMIPTERA	Other adult Heteroptera						2
67 a	Su	HEMIPTERA	Juvenile Heteroptera						8
67 b	Pt	HEMIPTERA	Juvenile Heteroptera						3b
68	Su	HYMENOPTERA	Formicidae						2
69	Su	HYMENOPTERA	Braconidae						8
70	Su	HYMENOPTERA	Aphelinidae						3b
71	Su	HYMENOPTERA	Eulophidae						3b
72	Su	HYMENOPTERA	Mymaridae						3b
73	Su	HYMENOPTERA	Trichogrammatidae						
74	Su	HYMENOPTERA	Scelioninae						3a
75	Su	HYMENOPTERA	Other Proctotrupoidea						2
76	Su	HYMENOPTERA	Ceraphronidae						2
77	Pt	HYMENOPTERA	Brachypterous Hymenoptera (ex. ants)						2
78	Pt	DIPLOPODA	Diplopoda						2
79	Pt	CHILOPODA	Chilopoda						2
80	Pt	ISOPODA	Oniscidea roller						3b
81	Pt	HOMOPTERA	Gryllidae						8
82 *	Pt	LEPIDOPTERA	Lepidoptera juvenile						2
83	Su	THYSANOPTERA	Thysanoptera						3b

** Or on two occasions, but with recovery within two weeks after treatment

Conclusion

Final conclusions community- and population level effects:

Effect classification (Based on De Jong <i>et al.</i> , 2010):		Effect class:
one occasion	Clear adverse treatment related effect but observed on one occasion only**	2
<1 month	Adverse effects no longer apparent on the last two sampling moments	3a
<2 months	Adverse effect no longer apparent on the last sampling moment	3b
>2 months	No recovery from adverse effect within the study period (= 2 months)	8
3a	Based on graphical trends (P>0.1 but effect >70% on two or more occasions)	
3a	Based on graphical trends and P<0.1 (one or more occasions)	
3a	Based on graphical trends and P<0.05 (one or more occasions)	
-	No effect	

Community level effects (multivariate analyses) (PRC/Monte-Carlo; 5% and 10% alpha level and trends)	1 mL	2.1 mL	4 mL	9 mL	17 mL
Suction all data	-	-	-	-	-
Suction excluding Collembola	-	-	-	-	-
Weed	-	-	-	-	-
Pitfall	-	-	-	-	-

Conclusion	Community NOER
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Population level effects (univariate analyses) (Mann-Whitney U test; 5% and 10% alpha level and trends)		1 mL	2.1 mL	4 mL	9 mL	17 mL
Class/Order	Taxon					
Pt COLEOPTERA	Alticinae	-	-	-	-	2
Pt HEMIPTERA	Fulgoromorpha	-	-	-	-	3a

Conclusion	Population NOER	Population NOEAER
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Su=suction; Pt=pitfall; Wd=weed

Rates are in mL product/ha

** Or on two occasions, but with recovery within two weeks after treatment

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 zRMS:	The study was performed with a solo formulation of deltamethrin and is not relevant for the risk assessment of DLT+FPF ED 85 since studies with the formulation in question are available and will be used for the risk assessment purposes. The study was thus not validated by the zRMS and its summary is struck through.
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Reference:	KCP 10.4.1.1/01
Title:	Deltamethrin EC 100 G: Sublethal toxicity to the earthworm <i>Eisenia fetida</i> in artificial soil
Report:	Friedrich, S.; 2014; 14 10 48 127 S; M-494315-01-1
Guideline(s):	OECD 222 (2004), ISO 11268-2 (1998)
Deviations:	not specified
GLP/GEP:	yes
Acceptability:	Not validated, not relevant for the risk assessment for DLT+FPF EC 85
Duplication (if vertebrate study):	

Materials and methods

Test item: Deltamethrin EC 100 G, Short name: DLT EC 100 G, BCS code: BCS-AU56293, Sample description: TOX10325-00, Specification No.: 102000002876, Batch ID: EV63000636, Material No.: 05943388, active ingredient (analysed content): 10.5 % w/w (100.2 g/L) deltamethrin (AE F032640), Density (20 °C): 0.953 g/mL, water solubility: dispersible.

Adult earthworms (*Eisenia fetida*, about 3 months old) were exposed to 1.8—3.2—5.6—10—18—32—56—100 mg test item/kg dry weight (d.w.) of soil containing 69.5 % quartz sand, 20 % kaolin clay, 10 % sphagnum peat and 0.5 % CaCO₃, at 18.4—21.5 °C and a photoperiod: light : dark = 16 h : 8 h (630 lx) and were fed with horse manure. Mortality and biomass change were determined after 4 weeks and reproduction was determined after 8 weeks.

Toxic standard: 5 and 10 mg Nutdazim 50 FLOW/kg soil d.w.; control: untreated, solvent control: none.

Dates of work: April 25, 2014—June 20, 2014

Results and discussions

Effects on mortality, growth and reproduction of the earthworms

Effects on mortality, growth and reproduction of the earthworms

Test item	Deltamethrin EC 100 G		
Test object	<i>Eisenia fetida</i>		
Exposure	Artificial soil		
	Mortality	Biomass change	Reproduction
	[mg test item/kg d.w.]		
NOEC	≥ 100	56	18
LOEC	> 100	100	32
EC ₁₀ ^{†)}	—	—	20
(95% confidence limits)	—	—	(13—29)
EC ₂₀ ^{†)}	—	—	31
(95% confidence limits)	—	—	(24—41)

^{†)} based on Probit analysis

Deltamethrin EC 100 G [mg test item/kg d.w.]									
	Control	1.8	3.2	5.6	10	18	32	56	100
<i>Mortality of adult worms after 4 weeks</i>									
Mortality (%)	3.8	2.5	2.5	0.0	5.0	0.0	5.0	0.0	17.5
<i>Biomass change (change in fresh weight after 4 weeks relative to initial fresh weight)</i>									
Mean (mg)	138.4	135.3	150.1	134.8	136.3	139.3	142.4	116.9	51.9*
Mean (%)	38.0	37.0	41.0	36.7	37.3	38.1	38.9	32.1	14.1
<i>Number of juveniles per surviving adult worm after 8 weeks</i>									
Mean	13.3	13.7	14.9	13.7	13.0	11.2	10.4	9.0	5.3
<i>Number of juveniles per replicate after 8 weeks</i>									
Mean	128.4	133.3	144.8	137.3	125.0	111.8	99.0*	90.0*	45.0*
<i>Reproduction compared to control (%)</i>									
% to control	100	103.8	112.8	106.9	97.4	87.0	77.1	70.1	35.1

No statistically significant differences between the control and test item were calculated for mortality (Fisher's Exact Binomial Test with Bonferroni Correction, $\alpha = 0.05$, one-sided greater)

* statistically significantly different compared to control for biomass and reproduction
(Williams t test, $\alpha = 0.05$, one-sided smaller)

Validity criteria (for control group)

Adult mortality:	$\leq 10\%$ (being 3.8 % after 4 weeks)
Number of juveniles per replicate:	≥ 30 (being 147, 112, 136, 165, 103, 121, 129 and 114 for replicate 1, 2, 3, 4, 5, 6, 7 and 8)
Coefficient of variation of reproduction:	$\leq 30\%$ (being 15.9 %)

In a reference test, the number of juveniles was reduced by 39 and 100 % by the toxic standard Nutdazim 50 FLOW (Carbendazim, SC 500) in comparison to the control. Therefore, the observed effects assure a high sensitivity of the test system.

Conclusion

Deltamethrin EC 100 G showed no statistically significantly adverse effects on mortality of the earthworm *Eisenia fetida* in artificial soil up to and including 100 mg test item/kg soil dry weight, i.e. the highest concentration tested. The test item caused a significant reduction in adult biomass change of the earthworm *Eisenia fetida* at 100 mg test item/kg soil d.w. The test item showed statistically significantly adverse effects on reproduction at 32, 56 and 100 mg test item/kg soil d.w. Therefore, the overall No Observed Effect Concentration (NOEC) was determined to be 18 mg test item/kg soil d.w., and the overall Lowest Observed Effect Concentration (LOEC) was determined to be 32 mg test item/kg soil d.w.

Comments of zRMS:	<p>The study was performed in line with OECD 222 with minor deviations.</p> <p>It was noted that the minimum weight of individual animals used in the test was 257 mg/worm which is lower than the recommended minimum of 300 mg/worm. This deviation is, however, considered to have no impact on the study results since all validity criteria were met.</p> <p>Reliability of the EC₁₀ value was evaluated in line with recommendations of EFSA Supporting publication 2019:EN-1673:</p> <ul style="list-style-type: none"> NW (normalised width) of 0.8 was calculated, which results in rating “fair” in line with Table E9 in EFSA Supporting publication 2019:EN-1673, median EC₁₀ (10.7 mg/kg soil dw) is lower than EC_{20,low} (14.0 mg/kg dw), the dose-response curve could not be calculated because EC₅₀ value was not determined in the study.
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	<p>Taking the above results into account, the calculated EC₁₀ is considered to be sufficiently reliable.</p> <p>The following endpoints are relevant for the risk assessment:</p> <p>NOEC (reproduction) = 14.1 mg product/kg soil dw (corresponding to 1.06 mg sum of a.s./kg dw, based on analysed content of active substances)</p> <p>EC₁₀ (reproduction) = 10.7 mg product/kg soil dw (corresponding to 0.803 mg sum of a.s./kg dw, based on analysed content of active substances)</p>
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Reference:	KCP 10.4.1.1/02
Title:	Deltamethrin + flupyradifurone EC 85 (10+75) G: Sublethal toxicity to the earthworm <i>Eisenia fetida</i> in artificial soil
Report:	Friedrich, S.; 2015; 15 10 48 071 S; M-528187-01-1
Guideline(s):	OECD 222 (2004), ISO 11268-2 (1998)
Deviations:	Minor deviations (see table above for details) none
GLP/GEP:	yes
Acceptability:	Acceptable

Materials and methods

Test item: Deltamethrin + flupyradifurone EC 85 (10+75) G, Short name: DLT+FPF EC 85 (10+75) G, Supplier batch No.: 2014-012629, Sample description: TOX10717-00, Specification No.: 102000028562, active ingredients (analysed content): 0.867 % w/w (10.03 g/L) deltamethrin (AE F032640), 6.62 % w/w (76.59 g/L) flupyradifurone (BYI 02960), Density (20 °C): 1.157 g/mL, water solubility: dispersible.

Adult earthworms (*Eisenia fetida*, about 3 months old with clitellum) were exposed to 2.5 - 4.4 - 7.9 - 14.1 - 25.0 - 44.4 - 79.0 - 140.5 mg test item/kg dry weight (d.w.) of soil containing 69.5 % quartz sand, 20 % kaolin clay, 10 % sphagnum peat and 0.5 % CaCO₃, at 19.2 – 22.0 °C and a photoperiod: light : dark = 16 h : 8 h (520 lx) and were fed with horse manure. Test item was mixed into soil. Mortality and biomass change were determined after 4 weeks and reproduction was determined after 8 weeks.

Toxic standard: 5 and 10 mg Nutdazim 50 FLOW/kg soil d.w.; control: untreated, solvent control: none.

Weight of individual animals used in the test: 257 – 449 mg/worm

Number of animals/vessel (= replicate): 10

Number of replicates/ control group: 8

Number of replicates/ treated group: 4

Number of animals/ treatment group: 40 (control group: 80)

Amount of soil/test vessel: 675 g wet weight corresponding to 500 g dry weight of artificial soil with a water content corresponding to 40-60 % of WHC

Water content (g/100 g soil d.w.):* guideline requirement: 40-60 % of WHC (difference between start and end of the test: ≤ 10 %)

test start: 34.9 - 35.1 (equivalent to 54.7 – 55.0 % of WHC)

test end: 34.3 – 34.9 (equivalent to 53.8 – 54.7 % of WHC)

Difference between start and end of the test: max. 2.3 %

pH-value:* guideline requirement: 6.0 ± 0.5

test start: 6.06 – 6.12

test end: 5.73 – 5.81

* pooled replicates per treatment group

Temperature: 19.2 – 22.0 °C

Light conditions: intensity: 520 lx ; duration: light : dark = 16 h : 8 h

Results and discussions

Effects on mortality, growth and reproduction of the earthworms

Test item	Deltamethrin + flupyradifurone EC 85 (10+75) G		
Test object	<i>Eisenia fetida</i>		
Exposure	Artificial soil		
	Mortality	Biomass change	Reproduction
	[mg test item/kg d.w.]		
NOEC	≥ 140.5	≥ 140.5	14.1
LOEC	> 140.5	> 140.5	25.0
EC ₁₀ ¹⁾	-	-	10.7
(95% confidence limits)			(7.2 – 15.8)
EC ₂₀ ¹⁾	-	-	18.6
(95% confidence limits)			(14.0 – 24.7)

¹⁾ based on Probit analysis

Deltamethrin + flupyradifurone EC 85 (10+75) G									
[mg test item/kg d.w.]									
	Control	2.5	4.4	7.9	14.1	25.0	44.4	79.0	140.5
Mortality of adult worms after 4 weeks									
Mortality (%)	2.5	0.0	0.0	2.5	5.0	0.0	0.0	0.0	2.5
Biomass change (change in fresh weight after 4 weeks relative to initial fresh weight)									
Mean (mg)	110.8	116.6	114.0	107.0	106.2	112.8	109.8	113.4	95.4
Mean (%)	34.6	36.4	35.5	33.4	33.2	35.0	34.2	35.4	29.9
Number of juveniles per surviving adult worm after 8 weeks									
Mean	17.7	16.5	19.0	17.1	16.7	11.8	8.9	6.8	4.5
Number of juveniles per replicate after 8 weeks									
Mean	172.5	164.5	189.8	166.5	158.0	118.3*	88.5*	67.5*	44.3*
Reproduction compared to control (%)									
% to control	100	95.4	110.0	96.5	91.6	68.6	51.3	39.1	25.7

* statistically significantly different compared to control for reproduction (Williams-t-test, $\alpha = 0.05$, one-sided smaller)

The mortality of adult worms was 0 – 5.0 % in the treated groups and 2.5 % in the control group.

No statistically significant differences between the control and test item were calculated for mortality (Fisher's Exact Binomial Test with Bonferroni Correction, $\alpha = 0.05$, one-sided greater) and biomass (Williams-t-test, $\alpha = 0.05$, one-sided smaller).

No pathological symptoms and no effects on behaviour (including feeding activity) of the worms were observed during the test.

The weight change of adult worms ranged between 29.9 and 36.4 % in the treated groups and was 34.6 % in the control group. The test item caused no statistically significant change in biomass (change in fresh weight after 4 weeks relative to initial fresh weight) compared to the control group at any concentration tested (Williams-t-test, $\alpha = 0.05$, one-sided smaller).

Statistically significant effects (Williams-t-test, $\alpha = 0.05$, one-sided smaller) on number of juveniles compared to the control group were recorded at concentrations of 25.0, 44.4, 79.0 and 140.5 mg test item/kg d.w.

Validity criteria (for control group)

- Adult mortality: $\leq 10\%$ (being 2.5 % after 4 weeks)
- Number of juveniles per replicate: ≥ 30 (being 195, 154, 203, 182, 128, 189, 172 and 157 for replicate 1, 2, 3, 4, 5, 6, 7 and 8)
- Coefficient of variation of reproduction: $\leq 30\%$ (being 14.5 %)

In a reference test, the number of juveniles was reduced by 46 and 100 % by the toxic standard Nutdazim 50 FLOW (Carbendazim, SC 500) at concentrations of 5 and 10 mg/kg d.w. (mean number of juveniles = 74 and 0) after 8 weeks of test duration in comparison to the control (mean number of juveniles = 138). Therefore, the observed effects assure a high sensitivity of the test system.

Conclusion

Deltamethrin + flupyradifurone EC 85 (10+75) G showed no statistically significantly adverse effects on mortality and biomass of the earthworm *Eisenia fetida* in artificial soil up to and including 140.5 mg test item/kg soil dry weight, i.e. the highest concentration tested. The test item showed statistically significantly adverse effects on reproduction at 25.0, 44.4, 79.0 and 140.5 mg test item/kg soil d.w. Therefore, the overall No-Observed-Effect-Concentration (NOEC) was determined to be 14.1 mg test item/kg soil d.w., and the overall Lowest-Observed-Effect-Concentration (LOEC) was determined to be 25.0 mg test item/kg soil d.w.

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 was performed with a solo formulation of deltamethrin and is not relevant for the risk assessment of DLT+FPF ED 85 since studies with the formulation in question are available and will be used for the risk assessment purposes. The study was thus not validated by the zRMS and its summary is struck through.
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Reference:	KCP 10.4.2.1/01
Title:	Deltamethrin EC 100 G: effects on the reproduction of the collembolan <i>Folsomia candida</i>
Report:	Friedrich, S.; 2014; 14 10 48 125 S; M-494027-01-1
Guideline(s):	OECD 232 (2009); ISO 11267 (1999)
Deviations:	none
GLP/GEP:	yes
Acceptability:	Not validated, not relevant for the risk assessment for DLT+FPF EC 85
Duplication (if vertebrate study):	

Materials and methods

Test item: Deltamethrin EC 100 G, Short name: DLT EC 100 G, BCS-code: BCS-AU56293, Sample description: TOX10325-00, Specification No.: 102000002876, Batch ID: EV63000636, Material No.: 05943388, active ingredient (analysed content): 10.5 % w/w (100.2 g/L) deltamethrin (AE F032640), Density (20 °C): 0.953 g/mL, water solubility: dispersible.

10 Collembola (9-12 days old) were exposed to 59-88-132-198-296-444-667-1000 mg test item/kg dry weight of soil containing 74.7 % quartz sand, 20 % kaolin clay, 5 % sphagnum peat and 0.3 % CaCO₃, at 18.0-21.8 °C and a photoperiod: light : dark = 16 h : 8 h (540 lx) and were fed weekly with granulated dry yeast. Mortality and reproduction were determined after 28 days.

Toxic standard: 44-67-100-150-225 mg boric acid/kg soil d.w.; control: untreated, solvent control: none.

Dates of work: May 21, 2014 – June 18, 2014

Results and discussions

Test item	Deltamethrin EC 100-G			
Test object	<i>Folsomia candida</i>			
Exposure	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	2.5	595 ± 11	-	
59	2.5	602 ± 20	101	-
88	2.5	629 ± 11	106	-
132	2.5	642 ± 16	108	-
198	2.5	615 ± 9	103	-
296	5.0	607 ± 12	102	-
444	10.0	585 ± 17	98	-
667	15.0	438 ± 20	74	*
1000	80.0	182 ± 28	31	*
			Reproduction	
NOEC _{reproduction} (mg test item/kg soil dry weight)			444	
LOEC _{reproduction} (mg test item/kg soil dry weight)			667	
			Reproduction	
EC ₁₀ (mg test item/kg soil dry weight) ¹⁾			531	
95% confidence limits			(509-594)	
EC ₂₀ (mg test item/kg soil dry weight) ¹⁾			621	
95% confidence limits			(602-640)	

The calculations were performed with unrounded values

¹⁾ Probit analysis

(*) = (Williams t test one-sided smaller, $\alpha = 0.05$, + = significant, - = not significant)

Percent reproduction: $(R_t / R_c) * 100 \%$

R_t = mean number of juveniles observed in the treated groups

R_c = mean number of juveniles observed in the control group

In a separate study (Bio-Chem project No. R 13 10 48 004 S, dated July 16, 2013), the EC₅₀ (reproduction) of the reference item boric acid was calculated to be 108 mg/kg soil dry weight. The results of the reference test demonstrate the sensitivity of the test system.

Validity criteria (for the control group):

	Recommended	Obtained
Mean adult mortality	≤ 20 %	2.5 %
Mean number of juvenile per replicate	≥ 100	595
Coefficient of variation (mean number of juveniles per replicate)	< 30 %	10.5 %

Conclusion

The test item Deltamethrin EC 100-G showed statistically significantly adverse effects on adult mortality of the collembolans *Folsomia candida* in artificial soil at 1000 mg test item/kg soil d.w.

The test item caused a significant reduction of reproduction of the collembolan *Folsomia candida* in artificial soil at 667 and 1000 mg test item/kg soil dry weight. Therefore, the No Observed Effect Concentration (NOEC) was determined to be 444 mg test item/kg soil d.w., and the Lowest Observed-Effect Concentration (LOEC) was determined to be 667 mg test item/kg soil d.w.

Comments of zRMS:	The study was performed with a solo formulation of deltamethrin and is not relevant for
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	the risk assessment of DLT+FPF ED 85 since studies with the formulation in question are available and will be used for the risk assessment purposes. The study was thus not validated by the zRMS and its summary is struck through.
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Reference:	KCP 10.4.2.1/02
Title:	Deltamethrin EC 100 G: Effects on the reproduction of the predatory mite <i>Hypoaspis aculeifer</i>
Report:	Schulz, L.; 2014; 14 10 48 126 S; M-495034-01-1
Guideline(s):	OECD 226 (2008)
Deviations:	none
GLP/GEP:	yes
Acceptability:	Not validated, not relevant for the risk assessment for DLT+FPF EC 85
Duplication (if vertebrate study):	

Materials and methods

Test item: Deltamethrin EC 100 G [short name: DLT EC 100 G], BCS-code: BCS AU56293, Batch ID: EV63000636, Sample description: TOX10325-00, Material No.: 05943388, Specification No.: 102000002876, analytical findings: 10.5 % w/w (100.2 g/L) deltamethrin (AE F032640), density (20 °C): 0.953 g/mL.

10 adult soil mites (females) were exposed to 1.8 – 3.2 – 5.6 – 10 – 18 – 32 – 56 – 100 mg test item/kg dry weight (d.w.) of soil containing 74.8 % quartz sand, 20 % kaolin clay, 5 % sphagnum peat and 0.2 % CaCO₃, at 19.7 – 20.8 °C and a photoperiod: light : dark = 16 h : 8 h (511 lx) and were fed every 2 – 3 days with *Tyrophagus putrescentiae* (SCHRANK). Mortality and reproduction were determined after 14 days of exposure.

The reference item (Dimethoate): 1.00 – 1.60 – 2.56 – 4.10 – 6.55 – 10.5 mg/kg soil d.w.; control: untreated, solvent control: none.

Dates of work: ——— June 20, 2014 – July 09, 2014

Results and discussions

Effects on mortality and reproduction of *Hypoaspis aculeifer*

Test item Test object Exposure	DLT EC 100 G <i>Hypoaspis aculeifer</i> Artificial soil	
	Adult mortality	Reproduction
	(mg test item/kg soil d.w.)	
NOEC	≥ 100	18
LOEC	≥ 100	32
EC ₁₀	≥ 100	30.6
(95 % confidence limits)		(14.4 – 65.1)
EC ₂₀	≥ 100	74.7
(95 % confidence limits)		(41.6 – 134.2)

Observations:

Endpoint		Treatment group (mg test item/kg soil d.w.)							
	Control	1.8	3.2	5.6	10	18	32	56	100
Mortality of soil mites after 14 days (%)	3.8	2.5	0.0	5.0	2.5	5.0	0.0	2.5	2.5
Mean number of juveniles after 14 days	155.4	170.0	166.8	154.0	157.5	157.5	123.8 *	130.3 *	121.3 *
CV (%)	12.8	13.0	14.4	8.6	4.1	10.1	15.7	12.7	13.5
Reproduction (% of control)	100	109	107	99	101	101	80	84	78

No statistically significant differences compared to the control (Fisher's Exact Binomial with Bonferroni Correction for mortality;

$\alpha = 0.05$, one-sided greater)

* statistically significant differences compared to the control (Williams t test for reproduction, $\alpha = 0.05$, one-sided smaller)

Calculations were done using unrounded values

Percent reproduction: $(R_t / R_c) * 100 \%$

R_t = mean number of juvenile mites in the treated group(s)

R_c = mean number of juvenile mites in the control group

CV (%) = Coefficient of variation

In a separate study (BioChem project No. R 14 10 48 001 S, dated June 10, 2014), the EC_{50} (reproduction) of the reference item Dimethoate was calculated to be 6.2 mg/kg soil d.w. The results of the reference test demonstrate the sensitivity of the test system.

Validity criteria (for the control group)

	Recommended	Obtained
Mean mortality of adult females	$\leq 20 \%$	3.8 %
Mean number of juvenile per replicate	≥ 50	155.4
Coefficient of variation (mean number of juveniles per replicate)	$\leq 30 \%$	12.8 %

Conclusion

The test item Deltamethrin EC 100 G showed no statistically significantly adverse effects on adult mortality of the predatory mite *Hypoaspis aculeifer* in artificial soil at all tested concentrations.

Furthermore, the test item showed no statistically significantly adverse effects on reproduction of *Hypoaspis aculeifer* up to and including a test concentration of 18 mg test item/kg soil dry weight. However, at test concentrations of 32, 56 and 100 mg test item/kg soil dry weight statistically significant effects on reproduction (Williams t test, $\alpha = 0.05$) could be observed.

Therefore, the No Observed Effect Concentration (NOEC) and Lowest Observed Effect Concentration (LOEC) for mortality were determined to be ≥ 100 mg and > 100 mg test item/kg soil d.w., respectively. The No Observed Effect Concentration (NOEC) and Lowest Observed Effect Concentration (LOEC) for reproduction were determined to be 18 and 32 mg test item/kg soil dry weight, respectively.

Comments of zRMS:	<p>The study was performed fully in line with OECD 232 with no deviations. All validity criteria were met.</p> <p>Reliability of the EC_{10} value was evaluated in line with recommendations of EFSA Supporting publication 2019:EN-1673:</p> <ul style="list-style-type: none"> NW (normalised width) of 0.7 was calculated, which results in rating “fair” in line with Table E9 in EFSA Supporting publication 2019:EN-1673, median EC_{10} (15.7 mg/kg soil dw) is lower than $EC_{20,low}$ (20.9 mg/kg dw), the dose-response curve could not be calculated because EC_{50} value was not
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	<p>determined in the study.</p> <p>Taking the above results into account, the calculated EC₁₀ is considered to be sufficiently reliable.</p> <p>Overall, the study is considered acceptable with the following endpoints relevant for the risk assessment:</p> <p>NOEC (reproduction) = 14.1 mg product/kg soil dw (corresponding to 1.06 mg sum of a.s./kg dw, based on analysed content of active substances)</p> <p>EC₁₀ (reproduction) = 15.7 mg product/kg soil dw (corresponding to 1.18 mg sum of a.s./kg dw, based on analysed content of active substances)</p>
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Reference:	KCP 10.4.2.1/03
Title:	Deltamethrin + flupyradifurone EC 85 (10+75) G: Effects on the reproduction of the collembolan <i>Folsomia candida</i>
Report:	Friedrich, S.: 2015; 15 10 48 069 S; M-515381-01-1
Guideline(s):	OECD 232 (2009): OECD Guideline for testing of chemicals No. 232 (adopted 7 September 2009): Collembolan reproduction test in soil ISO 11267 (1999): Soil quality – Inhibition of reproduction of <i>Collembola</i> (<i>Folsomia candida</i>) by soil pollutants
Deviations:	none
GLP/GEP:	yes
Acceptability:	Acceptable

Materials and methods

Test item: Deltamethrin + flupyradifurone EC 85 (10+75) G, Short name: DLT+FPF EC 85 (10+75) G, Supplier batch No.: 2014-012629, Sample description: TOX10717-00, Specification No.: 102000028562, active ingredients (analysed content): 0.867 % w/w (10.03 g/L) deltamethrin (AE F032640), 6.62 % w/w (76.59 g/L) flupyradifurone (BYI 02960), Density (20 °C): 1.157 g/mL, water solubility: dispersible.

10 *Collembola* (9-12 days old) were exposed to 2.5 - 4.4 - 7.9 - 14.1 - 25.0 - 44.4 - 79.0 - 140.5 mg test item/kg dry weight of soil containing 74.7 % quartz sand, 20 % kaolin clay, 5 % sphagnum peat and 0.3 % CaCO₃, at 19.2 – 22.0 °C and a photoperiod: light : dark = 16 h : 8 h (540 lux) and were fed at the start of the test and after 14 days weekly with 2 mg granulated dry yeast. Mortality and reproduction were determined after 28 days.

Number of collembolans/ test vessel (= replicate): 10

Number of replicates/ control group: 8 (+ 2 replicates not loaded with collembolans for measurement purposes)

Number of replicates/ treated group: 4 (+ 2 replicates not loaded with collembolans for measurement purposes)

Number of collembolans/ control group: 80

Number of collembolans/ treated group: 40

Water content (g/100 g soil d.w.): guideline requirement: 40-60 % of WHC

test start: 24.9 – 25.1 (equivalent to 57.9 – 58.4 % of WHC)

test end: 24.3 – 24.7 (equivalent to 56.5 – 57.4 % of WHC)

pH-value: guideline requirement: 6.0 ± 0.5

test start: 6.07 – 6.13

test end: 5.71 – 5.80

Toxic standard: 44 – 67 – 100 - 150 - 225 mg boric acid/kg soil d.w; control: untreated, solvent control: none.

Results and discussions

Test item	Deltamethrin + flupyradifurone EC 85 (10+75) G				
Test object	<i>Folsomia candida</i>				
Exposure	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	1.3	615	± 73	-	
2.5	0.0	641	± 84	104	-
4.4	2.5	599	± 45	97	-
7.9	2.5	581	± 51	95	-
14.1	2.5	597	± 151	97	-
25.0	20.0	514	± 28	84	+
44.4	27.5	387	± 74	63	+
79.0	30.0	326	± 64	53	+
140.5	42.5	224	± 70	36	+
				Reproduction	
NOEC _{reproduction} (mg test item/kg soil dry weight)				14.1	
LOEC _{reproduction} (mg test item/kg soil dry weight)				25.0	
				Reproduction	
EC ₁₀ (mg test item/kg soil dry weight) ¹⁾				15.7	
95% confidence limits				(10.2 – 21.1)	
EC ₂₀ (mg test item/kg soil dry weight) ¹⁾				28.0	
95% confidence limits				(20.9 – 34.5)	

The calculations were performed with unrounded values

¹⁾ Probit analysis

(*) = (Williams-t-test one-sided-smaller, $\alpha = 0.05$, + = significant, - = not significant)

Percent reproduction: $(R_t / R_c) * 100 \%$

R_t = mean number of juveniles observed in the treated groups

R_c = mean number of juveniles observed in the control group

In a separate study (BioChem project No. R 14 10 48 003 S, dated July 30, 2014), the EC₅₀ (reproduction) of the reference item boric acid was calculated to be 104 mg/kg soil dry weight. The results of the reference test demonstrate the sensitivity of the test system.

Validity criteria (for the control group)

	Recommended	Obtained
Mean adult mortality	≤ 20 %	1.3 %
Mean number of juveniles per replicate	≥ 100	615
Coefficient of variation (mean number of juveniles per replicate)	< 30 %	11.8 %

Conclusion

The test item deltamethrin + flupyradifurone EC 85 (10+75) G showed statistically significantly adverse effects on adult mortality of the collembolan *Folsomia candida* in artificial soil at 25.0, 44.4, 79.0 and 140.5 mg test item/kg soil d.w.

The test item caused a significant reduction of reproduction of the collembolan *Folsomia candida* in artificial soil at 25.0, 44.4, 79.0 and 140.5 mg test item/kg soil dry weight. Therefore, the overall No-Observed-Effect-Concentration (NOEC) was determined to be 14.1 mg test item/kg soil d.w. and the overall Lowest-Observed-Effect-Concentration (LOEC) was determined to be 25.0 mg test item/kg soil d.w.

Comments of zRMS:	<p>The study was performed fully in line with OECD 226 with no deviations. All validity criteria were met.</p> <p>Reliability of the EC₁₀ value was evaluated in line with recommendations of EFSA Supporting publication 2019:EN-1673:</p> <ul style="list-style-type: none"> NW (normalised width) of 0.98 was calculated, which results in rating “fair” in line with Table E9 in EFSA Supporting publication 2019:EN-1673, median EC₁₀ (253.4 mg/kg soil dw) is lower than EC_{20,low} (272.2 mg/kg dw), the dose-response curve is shallow with steepness of 0.32 (i.e. <0.33). <p>Taking the above results into account and in line with Table E10 in EFSA Supporting publication 2019:EN-1673, the calculated EC₁₀ is considered to be sufficiently reliable.</p> <p>Overall, the study is considered acceptable with the following endpoints relevant for the risk assessment:</p> <p>NOEC = 198 mg/kg soil dw (corresponding to 14.83 mg sum of a.s./kg dw, based on analysed content of active substances) EC₁₀ = 253.4 mg/kg soil dw (corresponding to 18.97 mg sum of a.s./kg dw, based on analysed content of active substances)</p>
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Reference:	KCP 10.4.2.1/04
Title:	Deltamethrin + flupyradifurone EC 85 (10+75) G: Effects on the reproduction of the predatory mite <i>Hypoaspis aculeifer</i>
Report:	Schulz, L.; 2015; 15 10 48 070 S; M-519953-01-1
Guideline(s):	OECD 226 (2008)
Deviations:	none
GLP/GEP:	yes
Acceptability:	Acceptable

Materials and methods

Test item: Deltamethrin + flupyradifurone EC 85 (10+75) G [short name: DLT+FPF EC 85 (10+75) G], Supplier batch No.: 2014-012629, Sample description: TOX10717-00, Specification No.: 102000028562, analytical findings: 0.867 % w/w (10.03 g/L) deltamethrin (AE F032640); 6.62 % w/w (76.59 g/L) flupyradifurone (BYI 02960), density (20 °C): 1.157 g/mL.

10 adult soil mites (females) *Hypoaspis aculeifer* (CANESTRINI) were exposed to 59 - 88 - 132 - 198 - 296 - 444 - 667 – 1000 mg test item/kg dry weight (d.w.) of soil containing 74.8 % quartz sand, 20 % kaolin clay, 5 % sphagnum peat and 0.2 % CaCO₃, at 19.7 - 20.2 °C and a photoperiod: light: dark = 16 h : 8 h (513 lux) and were fed every 2 - 3 days with *Tyrophagus putrescentiae* (SCHRANK). Mortality and reproduction were determined after 14 days of exposure.

Reference item (Dimethoate): 1.00 – 1.60 – 2.56 – 4.10 – 6.55 – 10.5 mg/kg soil d.w.; control: untreated, solvent control: none.

Number of predatory mites/test vessel (= replicate): 10

Number of replicates in the control group: 8 (+2 replicates for determination of water content and pH-value; not loaded with predatory mites)

Number of replicates in test item treated group: 4 (+ 2 replicates for determination of water content and pH-value; not loaded with predatory mites)

Number of predatory mites in the control group: 80

Number of predatory mites in the test item treated group: 40

Amount of soil/test vessel: 20 g soil dry weight (height of soil approximately 1.6 cm)

Water content (g/100 g soil d.w.): guideline requirement: 40 - 60 % of WHC (determination according to DIN ISO 11465 (1996))

test initiation: 16.18 - 18.15 (equivalent to 43.90 - 49.24 % of WHC)

test termination: 15.81 - 17.59 (equivalent to 42.88 - 47.70 % of WHC)

pH-value: guideline requirement at test start: 6.0 ± 0.5 (determination according to DIN ISO 10390 (2005))

test start: 6.1 - 6.4

test termination: 5.7 - 5.9

Temperature: guideline requirement: 20 ± 2 °C, measured: 19.7 - 20.2 °C

Results and discussions

Effects on mortality and reproduction of *Hypoaspis aculeifer*

Test item Test object Exposure	DLT+FPF EC 85 (10+75) G <i>Hypoaspis aculeifer</i> Artificial soil	
	Adult mortality	Reproduction
	(mg test item/kg soil d.w.)	
NOEC	≥ 1000	198
LOEC	> 1000	296
EC ₁₀	-	253.4
(95 % confidence limits)		(158.1 - 406.1)
EC ₂₀	-	374.2
(95 % confidence limits)		(272.2 - 514.6)
EC ₅₀	-	789.1
(95 % confidence limits)		(614.3 - 1013.7)

Endpoint	Control	Treatment group (mg test item/kg soil d.w.)							
		59	88	132	198	296	444	667	1000
Mortality of soil mites after 14 days (%)	2.5	2.5	2.5	2.5	2.5	7.5	10.0	0.0	5.0
Mean number of juveniles after 14 days	199.5	215.0	191.0	194.0	193.8	156.8 *	170.8 *	99.0 *	83.3 *
CV (%)	14.8	20.5	18.0	9.0	15.1	13.9	14.1	13.8	27.1
Reproduction (% of control)	100	108	96	97	97	79	86	50	42

Not statistically significantly different compared to the control (Fisher's Exact Binomial with Bonferroni Correction for mortality,

$\alpha = 0.05$, one-sided greater)

* statistically significantly different compared to the control (Williams-t-test for reproduction, $\alpha = 0.05$, one-sided smaller)

Calculations were done using unrounded values

Percent reproduction: $(R_t / R_c) * 100$ %

R_t = mean number of juvenile mites in the treated group(s)

R_c = mean number of juvenile mites in the control group

CV (%) = Coefficient of variation

In a separate study (BioChem project No. R 14 10 48 001 S, dated June 10, 2014), the EC₅₀ (reproduction) of the reference item Dimethoate was calculated to be 6.2 mg/kg soil d.w. (tested concentrations: 1.00, 1.60, 2.56, 4.10, 6.55 and 10.5 mg/kg soil dry weight).

The results of the reference test demonstrate the sensitivity of the test system.

Validity criteria (for the control group)

	Recommended		Obtained	
Mean mortality of adult females		≤ 20 %		2.5 %
Mean number of juveniles per replicate		≥ 50		199.5
Coefficient of variation (mean number of juveniles per replicate)		≤ 30 %		14.8 %

Conclusion

The test item Deltamethrin + flupyradifurone EC 85 (10+75) G showed no statistically significantly adverse effects on adult mortality of the predatory mite *Hypoaspis aculeifer* in artificial soil at all tested concentrations. Furthermore, the test item showed no statistically significantly adverse effects on reproduction of *Hypoaspis aculeifer* up to and including a test concentration 198 mg test item/kg soil dry weight. However, at test concentrations of 296, 444, 667 and 1000 mg test item/kg soil dry weight statistically significant effects on reproduction (Williams-t-test, $\alpha = 0.05$, one-sided smaller) could be observed.

Therefore, the No-Observed-Effect-Concentration (NOEC) and Lowest-Observed-Effect-Concentration (LOEC) for mortality were determined to be ≥ 1000 and > 1000 mg test item/kg soil d.w., respectively. The NOEC and LOEC for reproduction were determined to be 198 and 296 mg test item/kg soil d.w., respectively.

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:	<p>The study was performed fully in line with OECD 216 with no deviations.</p> <p>It was noted that there were small errors in the calculations of differences of NO₃-N transformation rates to control (values were corrected in the text and the corresponding table below). Further statistical analyses on the corrected values were not conducted by the zRMS since the overall values were well below 25% and no actual endpoint is required for the risk assessment.</p> <p>Nevertheless, all validity criteria were met and the study is considered acceptable.</p> <p>It may be concluded that the effects of the test item on soil nitrogen formation rates were < 25% at the end of the study period (28 days) up to 9.64 mg product/kg soil dw (corresponding to 0.722 mg sum of a.s./kg dw, based on analysed content of active substances)</p>
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Reference:	KCP 10.5/01
Title:	Deltamethrin + flupyradifurone EC 85 (10+75) G: Effects on the activity of soil microflora (Nitrogen transformation test)
Report:	Schulz, L.; 2015; 15 10 48 025 N; M-515385-01-1
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:	Acceptable

Materials and methods

Deltamethrin + flupyradifurone EC 85 (10+75) G [short name: DLT+FPF EC 85 (10+75) G], Supplier batch No.: 2014-012629, Specification No.: 102000028562, Sample description: TOX10717-00, analytical findings: 0.867 % w/w (10.03 g/L) deltamethrin (AE F032640); 6.62 % w/w (76.59 g/L) flupyradifurone (BYI 02960), Density (20 °C): 1.157 g/mL, water solubility: dispersible.

A loamy sand soil (DIN 4220): pH 6.2, 1.34% Corg, WHC: 39.02 g/100 g soil d.w., was exposed for 28 days to 1.93 mg test item/kg soil dry weight and 9.64 mg test item/kg soil dry weight. Application rates were equivalent to 1.25 L test item/ha and 6.25 L test item/ha. The nitrogen transformation was determined in soil enriched with lucerne meal (concentration in soil 0.5 %). NH₄-nitrogen, NO₃- and NO₂-nitrogen were determined by an Autoanalyzer at different sampling intervals (0, 7, 14 and 28 days after treatment).

Test conditions: water content of the soil 16.83-17.55 g/100 g soil d.w. (equivalent to 42.56-44.39 % of WHC), pH 5.9-6.1, soil samples incubated at 19.2-20.8°C in the dark.

The coefficients of variation in the control (NO₃-N) were maximum 4.8 % and thus fulfilled the demanded range (≤ 15 %).

Dates of work: February 06, 2015 - March 06, 2015

Results and discussions

The findings are summarised in the table below. Values are given as mg NO₃-N/kg soil d.w.

The test item deltamethrin + flupyradifurone EC 85 (10+75) G caused a temporary inhibition of the daily nitrate rate at the tested concentrations of 1.93 mg test item/kg dry soil and 9.64 mg test item/kg dry soil at time interval 7-14 days after application.

However, no adverse effects of deltamethrin + flupyradifurone EC 85 (10+75) G on nitrogen transformation in soil could be observed at both tested concentrations at the end of the test, 28 days after application (time interval 14-28). Differences from the control of +3.3% +3.1% (test concentration

1.93 mg test item/kg dry soil) and +15.8 % (test concentration 9.64 mg test item/kg dry soil) were measured at the end of the 28-day incubation period (time interval 14-28). For details Table below.

Effects on nitrogen transformation in soil after treatment with deltamethrin + flupyradifurone EC 85 (10+75) G

Time Interval (days)	Control			1.93 mg test item/kg soil dry weight equivalent to 1.25 L test item/ha				9.64 mg test item/kg soil dry weight equivalent to 6.25 L test item/ha			
	Nitrate-N ¹⁾			Nitrate-N ¹⁾		% difference to control		Nitrate-N ¹⁾		% difference to control	
0-7	4.48	±	0.65	4.86	±	0.37	+8.5 n.s.	4.87	±	0.60	+8.7 n.s.
7-14	2.35	±	0.94	1.71	±	0.62	-27.2 n.s.	1.52	±	0.49	-35.3 n.s.
14-28	1.52	±	0.17	1.57	±	0.39	+3.3 n.s.	1.76	±	0.25	+15.8 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, $p \leq 0.05$)

In a separate study the reference item Dinoterb caused a stimulation of nitrogen transformation of +39.1 %, +62.5 % and +112.0 % at 6.80 mg, 16.00 mg and 27.00 mg Dinoterb per kg soil dry weight, respectively, determined 28 days after application (time interval 14-28).

Validity criteria

The coefficients of variation in the control for NO₃-N were maximum 4.8 % and thus fulfilled the demanded range (≤ 15 %).

In the most recent test with the toxic standard (conducted from 06.01.2015 to 03.02.2015), Dinoterb caused an effect of +39.1 %, +62.5 % and +112.0 % (required ≥ 25 %) on the nitrogen transformation in a field soil at the tested concentrations of 6.80 mg, 16.00 mg and 27.00 mg Dinoterb per kg soil dry weight, respectively, 28 days after application (time interval 14-28) and thus demonstrates the sensitivity of the test system.

Conclusion

Deltamethrin + flupyradifurone EC 85 (10+75) G caused no adverse effects (difference to control < 25 %, OECD 216) on the soil nitrogen transformation (expressed as NO₃-N-production) at the end of the 28-day incubation period. The study was performed in a field soil at concentrations up to 9.64 mg test item/kg dry soil, which are equivalent to application rates up to 6.25 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:	<p>The study was performed in line with OECD 227 with a minor deviation in the test conditions.</p> <p>It was noted that on some days the air temperature and air humidity were outside the recommended ranges:</p> <ul style="list-style-type: none"> target air temperature 12°C to 32 °C and target air humidity 45 % to 95 %, actual air temperature 18.8°C to 41.5°C and actual air humidity 22.8 % to 84.1 %. <p>However, these deviations are considered to have no impact on the test results since all plants were kept in one greenhouse with the same growth conditions and no mortality in the control was observed. Furthermore, all validity criteria of the test were met:</p> <ul style="list-style-type: none"> the seedling emergence was $\geq 70\%$ (actually between 90% and 98 %), the control seedlings of each species did not exhibit visible phytotoxic effects (e.g. chlorosis, necrosis, wilting, leaf and stem deformations) and control plants exhibited only normal variation in growth and morphology for that particular species, the mean survival of emerged control seedlings was $\geq 90\%$ (actually 100 %), the environmental conditions for each particular species were identical and growing media contained the same amount of soil matrix, support media, or substrate from the same source. <p>During the study growth promotion at >50% was observed on maize. However, in opinion of the zRMS, effects on NTTPs growing outside the field should be evaluated in relation to potential of the given product to damage the shelter and food sources for off-crop species (such as arthropods, small wild mammals, birds) and some growth promotion observed on intensively growing species as maize should not be considered to be adverse in these terms.</p> <p>Overall, the study is considered acceptable with the following endpoint relevant for the risk assessment:</p> <p>ER₅₀ > 1.25 L product/ha</p>
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Reference:	KCP 10.6.2/01
Title:	Deltamethrin + flupyradifurone EC 85 (10+75 g/L): Effects on the vegetative vigour of non-target terrestrial plant species under greenhouse conditions
Report:	Ripperger, D.: 2016; S15-01671; M-554604-01-1
Guideline(s):	EU Directive 91/414/EEC Regulation (EC) No. 1107/2009 OCSPP 850.4150 (2012) OECD 227 (2006)
Deviations:	Deviations with no major impact occurred regarding the test conditions (see zRMS comment above for details)
GLP/GEP:	yes
Acceptability:	Acceptable

Materials and methods

Test item

Deltamethrin + flupyradifurone EC 85 (10+75 g/L)
Batch No.: 2014-012629

Specification number: 102000028562

Active ingredients (a.i.): 1) deltamethrin
2) flupyradifurone
Content of a.i. (analysed): 1) 10.03 g/L (0.867 % w/w)
2) 76.59 g/L (6.62 % w/w)
Density 1.157 g/mL

Plant species

Dicotyledonous species: *Beta vulgaris* (sugar beet), *Brassica napus* (rape), *Cucumis sativus* (cucumber), *Glycine max* (soybean), *Helianthus annuus* (sunflower), *Lycopersicon esculentum* (tomato)

Monocotyledonous species: *Allium cepa* (onion), *Hordeum vulgare* (barley), *Triticum aestivum* (wheat), *Zea mays* (corn)

Test design

The experimental phase was performed in a controlled environment greenhouse in 75245 Neulingen-Göbrichen, Germany.

Six dicotyledonous and four monocotyledonous species were cultivated in soil. Deltamethrin + flupyradifurone EC 85 (10+75 g/L) was applied at 1250 mL product/ha for all plant species. Results were compared to the deionised water treated control. In each treatment group a total number of 20 plants in the 2-4 leaf stage (BBCH growth stage 12-14) were applied. The test duration was 21 days following application. During this period, plants were assessed for mortality and phytotoxicity symptoms on day 7, 14 and 21. Additionally the BBCH growth stage was determined for all treatment groups on day 21. The effects on plant shoot dry weight were determined for day 21.

Endpoints

Mortality, phytotoxicity and shoot dry weight

Test rate

0 (control),
1250 mL product/ha

Analytical rate verification

Analysis of the test item solution and the control solution by HPLC / PDA

Soil characterization

Sand composed of 88.5 % sand, 8.4 % silt and 3.3 % clay, with a pH of 7.6, a total organic carbon content of 0.75 % and an electronic conductivity of 333 μ S/cm.

Test conditions

Air temperature (min/max) [°C]: 18.8/41.5
Relative humidity (min/max) [%]: 22.8/84.1
Photoperiod (light /dark) [h]: 16/8
Light intensity (min) [lux]: 13701

Since all plants were kept in one greenhouse, they had the same growth conditions. As no control mortality was observed, the deviations from the recommended test conditions had no influence on the outcome of the study.

Statistics

Since no mortality could be observed in the control and test item group, no further statistical computations were performed.

The data of shoot dry weight were tested for normality and homoscedasticity using Shapiro-Wilk's Test and Levene-Test. In case both requirements were fulfilled, Student t-test was conducted. If Levene's Test indicated variance heterogeneity, Welch t-test was used. The significance level was set to $\alpha = 0.05$ for all tests.

Validity criteria

Validity criteria were fulfilled for all ten species tested.

Results and discussions

Mortality:

No mortality occurred for any species tested.

Phytotoxicity:

Slight symptoms of phytotoxicity (up to median 2) could be observed for *Beta vulgaris* and *Brassica napus* at the test item rate of 1250 mL product/ha. The observed symptom was stunted growth on day 21 for these species.

Growth Stage:

On day 21 no differences in the BBCH growth stages was observed between test item and the control group for any species tested, except *Beta vulgaris*. The BBCH growth stage of test item treated plants of this species was 15 and the BBCH growth stage of control plants was 16.

Shoot Dry Weight:

An application of deltamethrin + flupyradifurone EC 85 (10+75 g/L) resulted in statistically significant effects on shoot dry weight for the plant species *Beta vulgaris*, *Brassica napus* and *Lycopersicon esculentum* (Student t-test, one-sided smaller, $p \leq 0.05$). The highest inhibition of shoot dry weight compared to the control was observed for *Brassica napus* with 48.4 %, followed by *Beta vulgaris* with 32.0 % and *Lycopersicon esculentum* with an inhibition of 25.3 % at the test item rate of 1250 mL product/ha, respectively.

Analytical Rate Verification:

The analysed concentration of deltamethrin and flupyradifurone in the test item solution corresponded to 100 % and 97 % of the target concentration, respectively.

Summary of the effects of deltamethrin + flupyradifurone EC 85 for day 21 after application

Plant species	Cumulative mortality [%]	Phytotoxicity ¹ (Median)	BBCH growth stage		Inhibition of shoot dry weight [%]
			C	T	
Dicotyledonous Species					
<i>Beta vulgaris</i>	0.0	2	16	15	32.0 ^a
<i>Brassica napus</i>	0.0	2	16	16	48.4 ^a
<i>Cucumis sativus</i>	0.0	1	61	61	2.6
<i>Glycine max</i>	0.0	1	79	79	0.8
<i>Helianthus annuus</i>	0.0	1	51	51	22.1
<i>Lycopersicon esculentum</i>	0.0	1	17	17	25.3 ^a
Monocotyledonous Species					
<i>Allium cepa</i>	0.0	1	15	15	-1.3 #
<i>Hordeum vulgare</i>	0.0	1	23	23	-44.6 #
<i>Triticum aestivum</i>	0.0	1	23	23	4.2
<i>Zea mays</i>	0.0	1	17	17	-67.2 #

C: Control, T: Test item

¹ Phytotoxicity grades: 1 = normal plant appearance; 2 = slight symptoms; 3 = moderate symptoms; 4 = strong symptoms; 5 = plants being totally affected

^a Statistically significantly different compared to the control (Student t-test for homogenous variances one-sided smaller, $p \leq 0.05$)

Negative values indicate that there was an increase compared to the control

Conclusions

An application of deltamethrin + flupyradifurone EC 85 (10+75 g/L) with a test item rate of 1250 mL product/ha, resulted in a statistically significant inhibition of shoot dry weight for the plant species *Beta vulgaris*, *Brassica napus* and *Lycopersicon esculentum*. Furthermore, the species *Beta vulgaris* and *Brassica napus* showed slight symptoms of phytotoxicity in the treated group. On day 21 after

application, the BBCH growth stage of *Beta vulgaris* was slightly lower in the test item group than in the control group.

Comments of zRMS:	<p>The study was performed in line with OECD 208 with a minor deviation in the test conditions.</p> <p>It was noted that on some days the air temperature and air humidity were outside the recommended ranges:</p> <ul style="list-style-type: none"> target air temperature 12°C to 32 °C and target air humidity 45 % to 95 %, actual air temperature 18.1 to 46.4°C and actual air humidity 24.0 % to 95.0 %. <p>However, these deviations are considered to have no impact on the test results as all the validity criteria were met:</p> <ul style="list-style-type: none"> the control seedling emergence was ≥ 70 % (actually between 90 and 100 %), the control seedlings of each species did not exhibit visible phytotoxic effects (e.g. chlorosis, necrosis, wilting, leaf and stem deformations) and control plants exhibited only normal variation in growth and morphology for that particular species, the mean survival of emerged control seedlings was ≥ 90 % (actually 100 %), the environmental conditions for each particular species were identical and growing media contained the same amount of soil matrix, support media, or substrate from the same source. <p>Overall, the study is considered acceptable with the following endpoint relevant for the risk assessment: ER₅₀ > 1.25 L product/ha</p>
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Reference:	KCP 10.6.2/02
Title:	Deltamethrin + flupyradifurone EC 85 (10+75 g/L): Effects on the seedling emergence of non-target terrestrial plant species under greenhouse conditions
Report:	Ripperger, D.: 2016; S15-01670; M-554592-01-1
Guideline(s):	EU Directive 91/414/EEC Regulation (EC) No. 1107/2009 OCSPP 850.4100 (2012) OECD 208 (2006)
Deviations:	Minor deviations (see the table above for details) not specified
GLP/GEP:	yes
Acceptability:	Acceptable

Materials and methods

Test item

Deltamethrin + flupyradifurone EC 85 (10+75 g/L)

Batch No.: 2014-012629

Specification number: 102000028562

Active ingredients (a.i.):
1) deltamethrin
2) flupyradifurone

Content of a.i. (analysed):
1) 10.03 g/L (0.867 % w/w)
2) 76.59 g/L (6.62 % w/w)
Density: 1.157 g/mL

Plant species

Dicotyledonous species: *Beta vulgaris* (sugarbeet), *Brassica napus* (rape), *Cucumis sativus* (cucumber), *Glycine max* (soybean), *Helianthus annuus* (sunflower), *Lycopersicon esculentum* (tomato)

Monocotyledonous species: *Allium cepa* (onion), *Hordeum vulgare* (barley), *Triticum aestivum* (wheat), *Zea mays* (maize)

Test design

The experimental phase was performed in a controlled environment greenhouse in 75245 Neulingen-Göbbrichen, Germany.

Six dicotyledonous and four monocotyledonous species were cultivated in soil. Deltamethrin + flupyradifurone EC 85 (10+75 g/L) was applied at 1250 mL product/ha to the soil surface by spray application. Results were compared to the deionised water treated control. In each treatment group a total of 20 seeds were sown (2 or 4 seeds per replicate (pot) depending on the plant species, 5 or 10 replicates per treatment group depending on the plant species, 2 treatment groups: 1 test item treatment group and 1 control group). The test duration was from seeding until 21 days after 50 % of the seedlings in the control had emerged in each species. During this period, plants were assessed for seedling emergence, mortality and phytotoxicity symptoms 7, 14 and 21 days after 50 % of the seedlings in the control group had emerged. Additionally the BBCH growth stage was determined for all treatment groups on day 21. The effects on plant shoot dry weight were determined for day 21.

Endpoints

Seedling emergence, mortality, phytotoxicity and shoot dry weight

Test rate

0 (control),
1250 mL product/ha

Analytical rate verification

Analysis of the test item solution and the control solution by HPLC / PDA

Soil characterisation

Sand composed of 88.5 % sand, 8.4 % silt and 3.3 % clay, with a pH of 7.6, a total organic carbon content of 0.75 % and an electronic conductivity of 333 µS/cm.

Test conditions

Air temperature (min/max) [°C]: 18.1/46.4
Relative air humidity (min/max) [%]: 24.0/95.0
Photoperiod (light /dark) [h]: 16/8
Light intensity (min) [lux]: 13765

Since all plants were kept in one greenhouse, they had the same growth conditions. As no control mortality was observed, the deviations from the recommended test conditions had no influence on the outcome of the study.

Statistics

For the data of seedling emergence and mortality the Fisher`s Exact Binomial Test with Bonferroni Correction was used.

For the parameter shoot dry weight normality of data distribution was tested using Shapiro-Wilk`s Test. The variance homogeneity was tested with Levene`s Test. Student t-test was conducted in case that both requirements were fulfilled or if normal distribution were poor but the variance homogeneity requirements were seen as fulfilled

Validity criteria

Validity criteria were fulfilled for all ten species tested.

Results and discussions

Seedling Emergence:

No statistically significant effects on seedling emergence compared to the control was observed for any of the plant species tested on all assessment days.

The most sensitive species was *Allium cepa* with an inhibition of 10.5 % at the application rate of 1250 mL product/ha on day 21.

Mortality:

No mortality occurred for any of the plant species tested except *Allium cepa*. For this species a mortality of 5.9 % was determined in the treatment group.

Phytotoxicity:

No symptoms of phytotoxicity were observed for any of the plant species tested on all assessment days.

Growth Stage:

No differences in BBCH growth stages between treatment and control groups were observed for any of the plant species tested on the last assessment day.

Shoot Dry Weight:

An application of deltamethrin + flupyradifurone EC 85 (10+75 g/L) resulted in statistically significant effects on shoot dry weight for the plant species *Cucumis sativus* and *Lycopersicon esculentum* (Student t-test, one-sided smaller, $p \leq 0.05$). The most sensitive species was *Allium cepa* with an inhibition of 29.2 %, followed by *Helianthus annuus* with 24.6 % inhibition, compared to the control group.

Analytical Dose Verification:

The analysed concentration of deltamethrin and flupyradifurone in the test item solution corresponded to 104 % and 94 % of the target concentration, respectively.

Summary of the effects of deltamethrin + flupyradifurone EC 85 for day 21 after 50 % seedling emergence in the control

in the control						
Plant species	Inhibition of seedling emergence [%]	Cumulative mortality [%]	Phyto-toxicity ¹ [Median]	BBCH growth stage		Inhibition of shoot dry weight [%]
				C	T	
Dicotyledonous Species						
<i>Beta vulgaris</i>	0.0	0.0	1	14	14	6.0
<i>Brassica napus</i>	5.0	0.0	1	15	15	-21.1 #
<i>Cucumis sativus</i>	5.3	0.0	1	13	13	20.1 ^a
<i>Glycine max</i>	0.0	0.0	1	14	14	4.7
<i>Helianthus annuus</i>	5.6	0.0	1	16	16	24.6
<i>Lycopersicon esculentum</i>	0.0	0.0	1	14	14	17.6 ^a
Monocotyledonous Species						
<i>Allium cepa</i>	10.5	5.9	1	12	12	29.2
<i>Hordeum vulgare</i>	0.0	0.0	1	14	14	-16.2 #
<i>Triticum aestivum</i>	5.3	0.0	1	14	14	1.3
<i>Zea mays</i>	-5.3	0.0	1	15	15	-19.9 #

C: Control, T: Test item

¹ Phytotoxicity grades: 1 = normal plant appearance; 2 = slight symptoms; 3 = moderate symptoms; 4 = strong symptoms; 5 = plants being totally affected

^a Statistically significantly different compared to control (Student t-test for homogenous variances, one-sided smaller, $p \leq 0.05$)

Negative values indicate that there was an increase compared to the control

Conclusions

No statistically significant inhibition of seedling emergence was observed for any of the species tested. The highest inhibition was observed for the species *Allium cepa*, 10.5 % compared to the control.

No effects on mortality and phytotoxicity were observed for any of the plant species tested.

No differences on the BBCH growth stages were observed for any of the test item treated plants compared to the control group on the last assessment day.

No statistically significant inhibition on shoot dry weight was observed for all plant species tested except *Cucumis sativus* and *Lycopersicon esculentum* at the test item rate of 1250 mL product/ha.

The highest inhibition on shoot dry weight was observed for the species *Allium cepa* with 29.2 %, followed by *Helianthus annuus* with 24.6 % compared to the control group.

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